

efficacy <sup>[7]</sup>. Another set of data indicates that the uric acid, blood urea nitrogen, serum creatinine, and 24-hour urinary protein levels in Group A are lower than those in Group B, and the symptom score is also lower than that of Group B, with  $P < 0.05$ .

During dialectical administration, Mannitol disinfectant treats dampness-heat obstruction type patients. Radix of *Scutellaria baicalensis* (Radix Scutellariae), *Artemisia scoparia*, *Hedyotis diffusa*, and *Talcum* can eliminate stones, promote urination, remove dampness, and clear heat. *Belamcanda chinensis*, *Patrinia*, and *Lonicera japonica* can relieve pain, reduce swelling, dissipate stagnation, and detoxify. The roots of *Clematis chinensis* and *Angelica sinensis* can eliminate stagnation, promote blood circulation, and relieve pain. *Agastache rugosa*, *Stephania tetrandra*, *Fritillaria thunbergii*, and *Poria cocos* can dissipate stagnation, eliminate phlegm, and strengthen the spleen. *Anemarrhena* can harmonize Yin and Yang <sup>[8]</sup>. The medicines in the prescription can work together to benefit the kidneys, strengthen the spleen, eliminate phlegm, and remove dampness.

Zhibai Dihuang Decoction treats patients with liver and kidney Yin deficiency. The bark of *Phellodendron chinense* (Phellodendron Bark) and *Anemarrhena* can clear heat, reduce fire, and nourish Yin. *Smilax glabra* and *Alismatis rhizoma* can promote urination and drain heat. Rhizome of *Ligusticum chuanxiong* (Chuanxiong Rhizoma), Radix Paeoniae Rubra, and Cortex Moutan can relieve pain, dredge meridians, eliminate stagnation, and promote blood circulation. The dried fruit of *Ligustrum lucidum* (Fructus Ligustri Lucidi), *Dioscoreae rhizoma*, and *Cornus officinalis* can nourish the roots, nourish the liver, and nourish the kidneys. Nidus Vespae, *Scutellariae barbatae*, and Cortex Lycii can detoxify, clear heat, and eliminate stagnation. The medicines in the prescription can work together to eliminate stagnation, promote blood circulation, reduce fire, and nourish Yin.

Shen Tong Zhu Yu Tang treats patients with stagnation and turbidity obstruction. The root of *Gentianae macrophyllae* and *Notopterygium incisum* can relieve pain, dredge meridians, eliminate dampness, and dispel wind. The root of *Angelica sinensis*, *Persicae Semen*, *Carthamus tinctorius* (Flos Carthami) and the rhizome of *Ligusticum chuanxiong* can dissipate stagnation, eliminate stagnation, and promote blood circulation. *Eupolyphaga steleophaga* and *Commiphora myrrha* (Myrrha) can promote tissue regeneration, reduce swelling, relieve pain, and promote blood circulation. *Curcuma zedoaria* and *Sparganium stoloniferum* can promote Qi circulation and break blood stagnation. *Scutellaria barbata*, *Patrinia*, *Lonicera japonica*, and *Taraxacum mongolicum* can reduce swelling, resist inflammation, detoxify, and clear heat. The medicines in the prescription can work together to detoxify, clear heat, eliminate stagnation, and promote blood circulation.

Ermiao Powder combined with Shiwei Powder treats patients with kidney deficiency and stone stranguria. *Pyrrosiae Folium*, *Atractylodis Rhizoma*, and the bark of *Phellodendron chinense* (Phellodendron Bark) can promote urination, detoxify, and dry dampness. The seeds of *Malva verticillata* (Malvae Semen), *Alismatis Rhizoma*, and *Poria cocos* can reduce swelling, promote urination, benefit water, and strengthen the spleen. The seeds of *Vaccaria segetalis* (Vaccariae Semen), Radix Paeoniae Alba, and the root of *Angelica sinensis* can relieve pain, dissipate stagnation, and dredge meridians. *Dianthus superbus* can repair the stomach meridian, promote urination, and eliminate stones. *Glycyrrhiza uralensis* (Glycyrrhizae Radix et Rhizoma) can benefit Qi and harmonize the overall efficacy of the prescription <sup>[9]</sup>. The medicines in the prescription can work together to benefit water, strengthen the spleen, dry dampness, clear heat, dredge meridians, and promote blood circulation.

The final set of data indicates that the adverse reactions of gouty nephropathy in Group A are lower than those in Group B, with  $P < 0.05$ . According to the analysis, traditional Chinese medicine dialectical treatment often chooses Chinese herbal medicines or animal medicines, which are natural ingredients and have mild side effects in the treatment of patients with gouty nephropathy. In addition, traditional Chinese medicine emphasizes the concept

of “preventive treatment of disease,” and dialectical treatment of gouty nephropathy can dialectically regulate the patient’s physical condition, strengthen their resistance, and reduce adverse reactions<sup>[10]</sup>.

## 5. Conclusion

In summary, the dialectical treatment of gouty nephropathy using Traditional Chinese Medicine (TCM) demonstrates significant clinical benefits by alleviating patient discomfort and preserving renal function. Given its efficacy and patient-centered methodology, the integration of TCM into standard care protocols for gouty nephropathy should be further promoted and researched to optimize long-term outcomes for affected individuals.

## Disclosure statement

The authors declare no conflict of interest.

## References

- [1] Sun Y, Liu H, Long M, et al., 2024, Discussion on the Differentiation and Treatment of Gouty Nephropathy Based on the Theory of “Spleen and Kidney Dampness and Stasis”. *Journal of Traditional Chinese Medical Books and Information*, 48(1): 215–218.
- [2] Sun F, Li L, Yang Y, 2024, Clinical Efficacy of Traditional Chinese Medicine Syndrome Differentiation and Treatment of Gouty Nephropathy. *Inner Mongolia Journal of Traditional Chinese Medicine*, 43(5): 16–18.
- [3] Li H, Liu D, Jiang L, et al., 2024, Study on the Renal Protective Mechanism of Traditional Chinese Medicine Regulating Uric Acid Transporter in Gouty Nephropathy. *Information on Traditional Chinese Medicine*, 41(5): 7–12, 18.
- [4] Qiao T, Yin C, Huo M, et al., 2024, Liu Shaowu’s Experience in Treating Gouty Nephropathy by Staging Differentiation and Treatment Based on “Spleen Deficiency Causing Wind”. *International Journal of Traditional Chinese Medicine*, 46(5): 665–668.
- [5] Zhang J, Liu Y, Huang C, et al., 2024, Li Jianmin’s Experience in Treating Gouty Nephropathy Based on “Syndrome as the Point and Disease as the Line”. *Guiding Journal of Traditional Chinese Medicine and Pharmacology*, 30(5): 173–176.
- [6] Lu W, Niu X, 2021, Clinical Observation on the Treatment of Gouty Nephropathy with Modified Si Jun Zi He Wen Dan Tang. *Journal of Guangzhou University of Traditional Chinese Medicine*, 38(4): 690–696.
- [7] Chen S, Yu H, Fang Z, et al., 2020, Overview of the Progress of Traditional Chinese Medicine in the Treatment of Gouty Nephropathy. *Journal of Emergency in Traditional Chinese Medicine*, 29(10): 1877–1880.
- [8] Wang W, Chen Z, Han L, et al., 2024, National Medical Master Zou Yanqian’s Treatment of Gouty Nephropathy from Deficiency, Dampness, and Stasis. *Journal of Traditional Chinese Medicine*, 39(2): 349–353.
- [9] Ren T, Zhu P, Ji Y, et al., 2020, Summary of Professor Huang Wenzheng’s Experience in the Clinical Treatment of Gouty Nephropathy. *Tianjin Journal of Traditional Chinese Medicine*, 37(6): 645–648.
- [10] Jiang W, Wei S, Zhang J, et al., 2023, Wang Yaoxian’s Experience in Treating Gouty Nephropathy Based on Syndrome Differentiation. *Shandong Journal of Traditional Chinese Medicine*, 42(9): 987–990.

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# Clinical Study of Autologous Skull Transplantation for the Treatment of Skull Defects

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**Abstract:** *Objective:* To explore the clinical value of autologous skull transplantation in the treatment of skull defects. *Methods:* Sixty-six patients who underwent skull defect reconstruction treatment in our hospital from January 2022 to March 2024 were selected and divided into an autologous skull transplantation group ( $n=31$ ) and an artificial bone transplantation material group ( $n=35$ ) based on different bone transplantation materials. The two groups of patients were followed up for 12 months to observe the bone healing and the incidence of postoperative complications. *Results:* After 9 months of treatment, the bone healing performance of the autologous skull transplantation group was better than that of the artificial bone transplantation material group ( $P < 0.05$ ). By the end of the last follow-up, the incidence of bony postoperative complications in the autologous skull transplantation group was lower than that in the artificial bone transplantation material group ( $P < 0.05$ ). *Conclusion:* Autologous skull repair for skull defects has good biocompatibility, can promote bone healing, and reduce the incidence of postoperative complications.

**Keywords:** Bone transplantation; Skull defect reconstruction; Autologous bone transplantation; Biomaterials

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## 1. Introduction

Skull defects disrupt the integrity of the cranial cavity, and the loss of bony protection for brain tissue and the imbalance of intracranial pressure due to changes in external atmospheric pressure and natural temperature can lead to symptoms such as dizziness and headache, which have a severe impact on patients' physiology and psychology. Large defects can also cause changes in local blood flow and intracranial pressure, which can result in local brain atrophy and exacerbate the patient's brain function deficits<sup>[1]</sup>. Cranioplasty is the main treatment method for skull defects, which can restore the early closed state of the cranial cavity, maintain normal intracranial

pressure, promote the recovery of brain physiological functions, reduce the occurrence of skull defect syndrome, and avoid cerebrospinal fluid circulation disorders caused by ectopic brain tissue <sup>[2]</sup>. Although cranioplasty is effective, there is currently no unified conclusion on the choice of repair materials. Autologous skull flaps meet physiological requirements, have the same tissue source, have good tissue compatibility, are not easily deformed, and have perfect shaping. They are not only safe and reliable but also inexpensive, making them the preferred material for cranioplasty. Based on this, sixty-six patients who underwent skull defect reconstruction treatment in our hospital from January 2022 to March 2024 were selected as the research subjects to explore the clinical value of autologous skull transplantation in the treatment of skull defects, as follows.

## 2. Materials and methods

### 2.1. General information

Sixty-six patients who underwent skull defect reconstruction treatment in the hospital from January 2022 to March 2024 are selected. The patients are divided into two groups based on different bone transplantation materials: an autologous skull transplantation group with 31 patients and an artificial bone transplantation material group with 35 patients. The general information of the two groups is comparable ( $P > 0.05$ ), as shown in **Table 1**. The study is approved by the ethics committee of the hospital.

**Table 1.** Comparison of general data between the two groups

Group	Number of cases	Gender		Age (years)	Defect area(cm <sup>2</sup> )	BIMindex (kg/m <sup>2</sup> )	Time from craniotomy to repair surgery (days) (d)
		Male (%)	Female (%)				
Artificial bone graft material group	35	18 (51.43)	17 (48.57)	54.34 ± 11.32	115.43 ± 21.18	25.66 ± 3.51	119.45 ± 23.42
Autologous skull transplantation group	31	16 (54.84)	15 (45.16)	54.12 ± 11.61	117.41 ± 23.35	25.75 ± 3.62	120.11 ± 21.32
X <sup>2</sup> /t		0.077		0.078	0.361	0.102	0.119
P		0.782		0.938	0.719	0.919	0.906

### 2.2. Inclusion and exclusion criteria

The inclusion criteria of the study are: (1) clinically examined and diagnosed; (2) skull defect area larger than 3cm; (3) no history of intracranial infection, coagulation dysfunction, or intracranial hypertension after decompressive craniotomy; (4) agreed to surgery and signed the informed consent form.

Meanwhile, the exclusion criteria are: (1) presence of severe systemic diseases such as general malnutrition, severe abnormal liver and kidney function, and malignant tumors; (2) presence of infections such as pneumonia and severe mental system diseases; (3) loss of follow-up after surgery; (4) incomplete clinical data.

### 2.3. Methods

After anesthesia, routine disinfection and draping are performed. The scalp is incised along the original surgical incision, and scalp clips are used for hemostasis. Sharp separation is performed along the dura mater and temporal muscle fascia or galea aponeurotica. For patients with severe adhesions, normal saline is first injected epidurally, taking care to protect the blood supply at the base of the skin flap. During scalp separation, damage to the deep

dura mater is avoided to prevent postoperative effusion. To avoid cerebrospinal fluid leakage after surgery, the scalp separation should not be too thin. The skull defect area is fully exposed, and hemostasis is strictly performed.

- (1) Artificial bone graft material group: Domestic ordinary plexiglass with polymethyl methacrylate as the main component is used. The material is cut according to the size of the patient's skull defect before surgery, placed in a fumigation box for strict disinfection after cutting to the appropriate size, and shaped by steaming and baking on an alcohol burner during surgery to ensure it matched the physiological curvature of the skull. The overlay method is used for repair.
- (2) Autologous skull transplantation group: The skull bone flap is soaked in alcohol for 30 minutes for disinfection, placed back into the defect site, and repaired using the mosaic method. When the defect area is large and the marginal area did not match well, small metal titanium plates are used for fixation to prevent the bone flap from floating.

## **2.4. Observation indicators**

### **2.4.1. Comparison of bone healing between the two groups after 9 months of repair**

Criteria for bony healing: Examination shows continuous bone callus passing through the fracture line, and the fracture line is nearly invisible or completely disappears.

### **2.4.2. Comparison of complications between the two groups**

Patients were followed up for 12 months after surgery, and complications such as headache, infection, epidural hematoma, and subcutaneous effusion are recorded.

## **2.5. Statistical methods**

Data are analyzed using SPSS 22.0 statistical software package. Count data are expressed as relative numbers, and comparisons between the two groups were performed using the  $\chi^2$  test.  $P < 0.05$  is considered statistically significant.

## **3. Results**

### **3.1. Comparison of bone healing between the two groups after 9 months of repair**

In the autologous skull transplantation group, 30 cases achieved bony healing after 9 months, with a bony healing rate of 96.77%. In the artificial bone graft material group, 25 cases achieved bony healing after 9 months, with a bony healing rate of 71.43%. The bony healing rate in the autologous skull transplantation group was significantly higher than that in the artificial bone graft material group ( $\chi^2=7.604$ ,  $P=0.006$ ).

### **3.2. Comparison of complications between the two groups**

The incidence of complications in the autologous skull transplantation group was significantly lower than that in the artificial bone graft material group ( $P < 0.05$ ), as shown in **Table 2**.

**Table 2.** Comparison of complications between the two groups [n, (%)]

Group	Number of cases	Headache	Infection	Epidural hematoma	Subcutaneous effusion	Total occurrence
Artificial bone graft material group	35	2(5.71)	3(8.57)	1(2.86)	4(11.42)	10(28.57)
Autologous skull transplantation group	31	1(3.23)	0(0)	1(3.23)	0(0)	2(6.45)
$\chi^2$						5.407
$P$						0.020

## 4. Discussion

Performing cranioplasty as soon as conditions allow after a skull defect can reduce the psychological burden caused by the skull defect and prevent secondary brain tissue damage caused by the defect [3]. Research has shown that skull defects can affect cerebral blood flow, and cranioplasty can improve the hemodynamics of local brain tissue, increasing local cerebral blood flow by 15% to 30% [4]. For cranioplasty, the ideal repair material should have stable chemical properties and sufficient mechanical strength, can fuse bone windows and transmit radiation, and have a small tissue reaction, non-carcinogenic, non-toxic, and not easy to age [5]. Various synthetic biomaterials have emerged with the development of medical and tissue engineering technology. Although they can be used to repair skull defects, they may cause rejection reactions and cannot integrate with the host bone. The main component of plexiglass is polymethyl methacrylate, which has the advantages of being convenient, non-conductive of heat and electricity, heat-moldable, good quality, and not affected by radioactivity. It was once the preferred material for cranioplasty.

However, it is prone to aging, poor impact resistance, easy to stab brain tissue, and easy to form subgaleal effusion. At the same time, it has poor application effects on areas with high plastic requirements, such as the orbital region [6]. Studies have shown that the incidence of subgaleal effusion can be as high as 65.6% when plexiglass is used for repair [7]. Studies have pointed out that polyetheretherketone (PEEK) is used in skull defect repair with subcutaneous effusion in the surgical area [8]. Yang *et al.* pointed out that the use of autologous bone in cranioplasty patients can reduce hospital stay [9]. Although there are currently many types of materials used for cranioplasty, there is no material that can completely replace autologous skull in terms of heat insulation, cold resistance, plasticity, compression resistance, impact resistance, and biocompatibility.

In selecting skull defect repair materials, promoting bone formation should be the selection strategy. During the healing process after skull defect repair, the survival of implanted bone cells, osteoconduction, and osteoinduction play decisive roles. Autologous skull bone, used for skull defect repair, shares a consistent embryonic origin and tissue structure with the patient. The transplanted bone volume and shape can be maintained for a long time after surgery. It has biological activity and osteoinductive effects, making it easier to integrate with recipient bone tissue and having a low resorption rate. This study shows that the bony healing rate in the autologous skull transplantation group is significantly higher than that in the artificial bone graft material group ( $P < 0.05$ ). The autologous skull tissue has a consistent source, meets physiological requirements, has sufficient strength, can avoid rejection, and can also induce bone formation. It promotes bone growth by utilizing the periosteum on the bone flap and the surrounding normal bone, resulting in better bone healing. Skull repair surgery

has a complication rate of about 10%–40%, and the repair material is one of the important influencing factors for postoperative complications.

The tissue reactivity of the repair material during skull repair surgery is the main cause of infection and subcutaneous effusion<sup>[10]</sup>. The autologous skull flap avoids immune rejection, eliminates the need for additional material sourcing and shaping, has a good scalp reactive edema, is less prone to subcutaneous effusion, and may even eliminate subcutaneous effusion. The results of this study show that the incidence of complications in the autologous skull transplantation group is significantly lower than that in the artificial bone transplantation material group ( $P < 0.05$ ). The autologous skull retains the skull shape and structure, has good anatomical reduction, eliminates the need for additional material sourcing and shaping, reduces operation complexity and the risk of infection, and has good tissue compatibility, reducing subcutaneous effusion and postoperative complications.

## 5. Conclusion

In summary, the autologous skull meets physiological requirements, has good tissue compatibility, avoids rejection reactions, promotes bone healing as a skull repair material, and reduces postoperative complications, demonstrating clinical value.

## Disclosure statement

The author declares no conflict of interest.

## References

- [1] Guo P, Li T, Peng Y, et al., 2024, Clinical Effect Analysis of Three-Dimensional Printed Intracranial Pressure Balancing Device in Preventing Postoperative Complications of Supratentorial Decompressive Craniectomy. *Chinese Journal of Surgery*, 62(12): 1120–1127.
- [2] Yadav R, Chaudhary A, Gupta D, et al., 2024, Use of Autologous Leukocyte-Platelet Rich Fibrin (L-PRF) in Endoscopic Anterior Skull Base Defect Repair – A Newer Graft Material. *Indian Journal of Otolaryngology Head and Neck Surgery*, 76(6): 5618–5622.
- [3] Gutierrez JA, Soler Z, Larrew T, et al., 2024, Utilization of Polydioxanone Plate for Endoscopic Anterior Skull Base Repair: Operative Technique and Long-Term Cohort Outcomes. *Journal of Neurological Surgery Part B: Skull Base*, 86(2): 129–137.
- [4] Starup-Hansen J, Williams S, Valetopoulou A, et al., 2024, Skull Base Repair Following Resection of Vestibular Schwannoma: A Systematic Review (Part 2: The Translabyrinthine Approach). *Journal of Neurological Surgery Part B: Skull Base*, 85(Suppl 2): e131–e144.
- [5] Zhan Y, Yang K, Zhao J, et al., 2024, Injectable and In Situ Formed Dual-Network Hydrogel Reinforced by Mesoporous Silica Nanoparticles and Loaded with BMP-4 for the Closure and Repair of Skull Defects. *ACS Biomaterials Science and Engineering*, 10(4): 2414–2425.
- [6] Fei X, Jiang D, Shen L, et al., 2023, Clinical Application of Polyetheretherketone Materials in Skull Repair after Large Bone Flap Removal. *Journal of Clinical Neurosurgery*, 20(4): 448–452.
- [7] Yang Z, Lin Y, Zhang Y, et al., 2023, Progress in the Application of Synthetic Polymer Materials and Natural Polymer Materials in Dura Mater Repair. *International Journal of Biomedical Engineering*, 46(2): 156–162.

- [8] Liao J, Cai Z, Li Y, et al., 2024, Clinical Analysis of Different Materials Used for Large Area Skull Defect Repair in Frontotemporal Region. *Journal of Clinical Surgery*, 32(8): 811–813.
- [9] Yang Y, Huang Z, Liu Y, 2023, Efficacy and Prognosis of Autologous Bone, Customized Titanium Mesh, and Polyetheretherketone in Patients with Skull Repair after Traumatic Brain Injury. *Journal of North Sichuan Medical College*, 38(8): 1098–1101.
- [10] Shen H, Chu W, Chu Z, et al., 2024, Analysis of Etiological Characteristics and Risk Factors of Incision Infection after Skull Repair Surgery. *Zhejiang Medical Journal*, 46(19): 2066–2069.

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# Application Analysis of Perioperative Comprehensive Nursing Management Intervention in Patients Undergoing Breast Surgery in Oncology Surgery

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**Abstract:** *Objective:* To analyze the effect of perioperative comprehensive nursing intervention on patients undergoing breast surgery in oncology surgery. *Methods:* A total of 100 patients undergoing breast surgery were selected as the study subjects and divided into a control group and a study group. The control group received routine nursing, while the study group received perioperative comprehensive nursing. The effects were observed. *Results:* The study group had lower negative emotion scores and complication rates than the control group, and higher range of motion of the affected shoulder joint and quality of life than the control group ( $P < 0.05$ ). *Conclusion:* Oncology breast surgery is often accompanied by adverse psychological emotions during the perioperative period. To ensure surgical efficacy and postoperative recovery, comprehensive perioperative nursing measures can effectively prevent and develop complications, improve shoulder joint range of motion, and promote recovery.

**Keywords:** Perioperative comprehensive nursing; Oncology surgery; Breast surgery; Nursing effect

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## 1. Introduction

With the current socio-economic development, significant changes have occurred in people's living habits, leading to a gradual increase in the incidence of breast diseases among women, which is showing a trend of younger age. Currently, common breast diseases in clinical practice include breast tumors and severe breast conditions. The majority of patients admitted to oncology surgery departments are those with breast tumor diseases. Due to the relatively severe nature of the disease, it can have a significant impact on patients' physical and mental health, and the pathogenesis is complex. To ensure disease control, early breast surgery is often performed to ensure clinical effectiveness. As patients undergoing breast surgery are susceptible to multiple factors, perioperative nursing

measures play an important role. Routine nursing content is relatively simple, focusing only on the implementation of basic nursing tasks, and lacks comprehensiveness and targeted nursing, resulting in unsatisfactory nursing effects.

In recent years, perioperative comprehensive nursing has been gradually applied in clinical practice. This method provides patients with comprehensive nursing guidance, requires strict professional literacy and standards from nursing staff, and achieves high-quality guidance for patient care. Perioperative nursing is based on surgical treatment, with the entire nursing process integrated into surgical treatment <sup>[1]</sup>. Nursing staff play a vital role in supporting patients by offering comprehensive care and guidance. They should clearly explain essential ward information, treatment procedures, recovery expectations, and necessary precautions. By actively listening to patients' concerns and maintaining open, empathetic communication, nurses can build trust and address individual questions effectively. Understanding each patient's daily habits and personality helps in meeting their psychological needs. Additionally, by providing thorough preoperative, intraoperative, and postoperative care, nurses contribute significantly to the success of breast surgery and promote a smooth, healthy recovery, ultimately enhancing the overall quality of modern nursing care. In this regard, this study takes patients undergoing breast surgery in oncology surgery as an example to analyze the implementation effect of perioperative comprehensive nursing.

## 2. Materials and methods

### 2.1. Basic information

A total of 100 patients undergoing breast surgery in the oncology surgery department of the hospital from January to December 2024 are selected as the study subjects. The details are shown in **Table 1**.

**Table 1.** Patient clinical data

Group	n(cases)	Average age (years)	Average disease duration (months)	Tumor diameter (cm)	Body Mass Index (kg/m <sup>2</sup> )
Control group	50	33.41 ± 2.45	5.87± 0.97	2.08 ± 0.35	23.74 ± 1.22
Study group	50	33.36 ± 2.51	5.92 ± 0.85	2.11 ± 0.38	23.68 ± 1.18
X2/t		0.1008	0.2741	0.4106	0.2500
P		0.9199	0.7846	0.6823	0.8031

### 2.2. Methods

In the control group, routine nursing care is provided. Before surgery, patients are helped to understand the basic knowledge of the disease, including the causes of the disease, nursing care during treatment, precautions in life, and related health care content. Patients are assisted to understand their own conditions, complete relevant examination items, and effectively monitor their vital signs. Patients are also guided on how to choose safe foods and how to have a nutritious diet.

In the study group, perioperative comprehensive nursing is implemented, including:

(1) Preoperative nursing

After the patient is admitted to the hospital during treatment, their overall health status is assessed, and patients are guided to perform necessary preparations, such as blood draws. At the same time, the

hospital environment and department equipment information are explained to alleviate anxiety about the unknown. Patients are given a clear explanation of the surgical content, expected effects, and other relevant information. Before surgery, it is ensured that the patient fully understood this content and is well-prepared. Finally, patients are encouraged to communicate and interact with each other to reduce their anxiety. Surgical facilities and instruments are inspected and cleaned, and the operating room temperature and humidity are maintained at appropriate levels before surgery. If patients had poor physiological conditions, large tumor diameters, large wound areas, or long expected surgical times, postoperative catheters and other auxiliary measures are prepared after admission. Before surgery, patients and their families are informed to prepare them psychologically and reduce doctor-patient conflicts. Additionally, patients are taught the skill of abdominal breathing and made to master it before surgery to facilitate postoperative recovery.

## (2) Intraoperative nursing

Before the start of surgery, the indoor temperature is adjusted to 21–25°C, and the humidity should be controlled at 50–60%. A warming blanket is placed on the operating table ahead of time, with the temperature adjusted to 37–39°C. When the patient enters the operating room, nursing staff interacts with them, using friendly eye contact and comforting language to encourage them, and even using some words to provide psychological comfort. At the same time, various measures are taken to protect the patient's privacy, covering areas that do not require surgery. Before anesthesia, the patient is instructed to lie on their back with their head slightly raised, their arm on the same side as the surgery straight and placed on the armrest, a suitable knee pillow placed under their thigh, and a heel pad under their feet. The patient's knee is securely fixed 5cm above the knee to improve comfort.

Operating room nurses are familiar with the entire process and coordination methods of breast surgery, as well as the personal habits and requirements of each senior surgeon, to avoid wasting unnecessary time due to unfamiliarity with the operation. All necessary items are prepared ahead of time, and surgical instruments should be passed quickly and accurately to reduce useless time and unnecessary consumption caused by poor coordination. If the patient cannot close their eyes under anesthesia, their eyes should be protected. Cleaning solution and injection fluid is prepared before surgery and placed in a thermostat to adjust the temperature, typically set to close to 37°C. The nurses assist the anesthesiologist in administering heated intravenous fluids or blood transfusions to the patient, adjusting the temperature of the fluids to match the patient's body temperature. The circulating nursing staff provides warmth to the patient's body parts other than the surgical area, using blankets or warm fabrics to protect the patient.

During the entire surgical process, all relevant physiological parameters of the patient are observed and recorded. If any problems occur during the surgery, they are addressed promptly with the doctor. The cleanliness of the entire operating room is maintained, and the number of visitors are strictly controlled to prevent infections and other diseases.

## 2.3. Observation indicators

The perioperative psychological status is evaluated using the Self-Rating Anxiety Scale (SAS) and Self-Rating Depression Scale (SDS). The lower the score, the lower the emotional level.

Complications are recorded, and the activity of the affected shoulder joint is evaluated after surgery. The quality of life after surgery is assessed using a quality of life scale, with a higher score indicating a higher quality of life.

## 2.4. Statistical analysis

Data was processed and analyzed using SPSS 23.0, with chi-square ( $\chi^2$ ) and t-tests applied. Values are expressed as (n/%) or ( $\bar{x} \pm s$ ). A  $P$ -value  $< 0.05$  is considered statistically significant.

## 3. Results

### 3.1. Perioperative psychological status

The perioperative SAS and SDS scores in the study group were lower than those in the control group, with  $P < 0.05$ , as shown in Table 2.

**Table 2.** Comparison of SAS and SDS scores between the two groups ( $\bar{x} \pm s$ )

Group	n(cases)	SAS Score		SDS Score	
		Before nursing	After nursing	Before nursing	After nursing
Control group	50	53.58 $\pm$ 3.78	49.54 $\pm$ 2.81	54.13 $\pm$ 3.65	48.54 $\pm$ 2.74
Study group	50	53.62 $\pm$ 3.81	47.22 $\pm$ 2.52	54.37 $\pm$ 3.59	45.08 $\pm$ 2.96
$t$		0.0527	4.3463	0.3315	6.0657
$P$		0.9581	0.0000	0.7410	0.0000

### 3.2. Incidence of complications

The incidence of complications in the study group was lower than that in the control group, with  $P < 0.05$ .

**Table 3.** Comparison of the incidence of complications between the two groups (n/%)

Group	N (cases)	Infection	Pressure sore	Thrombus	Total incidence rate
Control group	50	4(7.50)	2(4.00)	2(4.00)	8(16.00)
Study group	50	1(2.00)	1(2.00)	0	2(4.00)
$\chi^2$					4.0000
$P$					0.0455

### 3.3. Improvement in shoulder joint mobility

The range of motion of the affected shoulder joint in the study group was higher than that in the control group after surgery, with  $P < 0.05$ .

**Table 4.** Comparison of the range of motion of the affected shoulder joint between the two groups after surgery ( $\bar{x} \pm s$ )

Group	n(cases)	Adduction	Abduction	Flexion	Extension
Control group	40	31.24 $\pm$ 1.26	94.25 $\pm$ 3.78	112.34 $\pm$ 5.47	43.52 $\pm$ 0.98
Study group	40	41.08 $\pm$ 2.85	125.34 $\pm$ 8.74	135.25 $\pm$ 6.85	46.34 $\pm$ 1.13
$\chi^2/t$		22.3289	23.0866	18.4802	13.3313
$P$		0.0000	0.0000	0.0000	0.0000

### 3.4. Quality of life

The quality of life scores in the study group were higher than those in the control group,  $P < 0.05$ .

**Table 5.** Comparison of the quality of life scores between the two groups ( $\bar{x} \pm s$ )

Group	N (cases)	Physical functioning	Role-physical	Social functioning	General health
Control group	40	62.34 $\pm$ 3.74	62.48 $\pm$ 3.89	62.37 $\pm$ 3.91	62.48 $\pm$ 3.88
Study group	40	65.48 $\pm$ 4.13	65.37 $\pm$ 4.12	65.48 $\pm$ 3.65	65.37 $\pm$ 3.74
$X^2/t$		3.9849	3.6065	4.1113	3.7920
$P$		0.0001	0.0005	0.0001	0.0003

## 4. Discussion

Breast surgery departments typically treat patients with breast tumors, often requiring surgical intervention to remove the lesion. However, traditional surgical methods offer limited control over incision location and size, resulting in large scars that can increase patient trauma. As people's demands for breast surgery have gradually increased, and with advancements in medical technology, minimally invasive surgical techniques have been increasingly applied. These techniques allow for more precise control of surgical incisions, reducing trauma and improving surgical safety<sup>[2-4]</sup>. However, most patients have limited understanding of their condition and may experience fear and anxiety about disease progression during treatment. Additionally, the loss of important female organs can lead to feelings of self-doubt, uncertainty, and resistance, reducing patients' enthusiasm for participating in clinical treatment and affecting treatment outcomes<sup>[5-9]</sup>.

For patients undergoing breast surgery, the procedure often involves the removal of one breast, axillary vein branches, pectoral muscles, and ribs, and sometimes even the removal of lymph nodes in the affected axilla. This can cause significant physical trauma, especially in women, as breast removal can also lead to a decrease in social interaction abilities. While surgical techniques are crucial for improving patient outcomes, postoperative care is equally important. A good postoperative quality of life not only depends on the application of clinical techniques but is also influenced by perioperative nursing care. Patients' self-management plays a significant role in perioperative recovery, and a thorough understanding of their condition and treatment options is essential for active participation. To build patients' confidence in recovery, it is necessary to provide adequate psychological preparation and educate them about their condition, enabling them to develop appropriate disease awareness and mental preparedness<sup>[10-14]</sup>.

As a comprehensive nursing approach, perioperative integrated nursing involves personalized nursing guidance for patients before, during, and after surgery. By strengthening preoperative nursing and visits, this method allows timely attention to patients' physical and mental conditions, provides health education and psychological comfort, encourages patients to establish a positive attitude, and lays a solid foundation for surgery. During the operation, vital signs are closely monitored, and the surgical environment is optimized to provide a comfortable setting, reduce physical discomfort, and maintain good physiological conditions<sup>[15]</sup>. Operating room nurses need to have a thorough understanding of all aspects of the surgery, closely coordinate with doctors in instrument delivery, minimize surgical time, prevent unexpected situations during the procedure, and ensure the smooth completion of the surgery. Postoperatively, patients receive enhanced basic nursing, sleep nursing, and incision care to prevent infection, improve sleep quality, and provide rehabilitation guidance as their physical

condition gradually recovers. This ensures the gradual restoration of physical function and improvement in quality of life.

## 5. Conclusion

Breast cancer surgery patients frequently experience negative emotional states, including anxiety and distress, throughout the surgical journey. Implementing holistic perioperative care strategies plays a vital role in optimizing surgical outcomes and enhancing recovery. These comprehensive nursing interventions serve to both prevent potential complications and facilitate rehabilitation, particularly in restoring upper limb mobility and shoulder function.

## Disclosure statement

The authors declare no conflict of interest.

## References

- [1] Chen K, Lv P, 2024, Current Application Status and Development Trend of Robot-Assisted Breast Surgery. *Chinese Journal of Practical Surgery*, 44(11): 1317–1320.
- [2] Cao X, 2024, Disputes and Future of Endoscope Application in Breast Surgery. *Journal of Surgical Concepts & Practice*, 29(5): 371–375.
- [3] Lyu S, Zhang X, You J, 2024, Application Effect of Humanized Nursing in Patients Undergoing Breast Surgery. *Women's and Children's Health Guide*, 3(8): 124–127.
- [4] Li T, Chen L, 2024, Dilemmas and Challenges of Robots in Breast Surgery. *Journal of Clinical Surgery*, 32(3): 228–230.
- [5] Huang T, Wang L, Jiang Y, et al., 2024, The Influence of Modified Position on the Process and Effect of Breast Surgery. *Hebei Medical Journal*, 46(4): 585–587, 591.
- [6] Gao J, Zhou Y, Cui L, 2024, The Effect of Clinical Nursing Pathway on Postural Syndrome in Breast Surgery. *Marriage, Fertility & Health*, 30(1): 115–117.
- [7] Chang J, Wang C, 2023, Effect Analysis of Breast-Preserving Surgery for Early Breast Cancer. *Chinese Community Doctors*, 39(32): 16–18.
- [8] Li S, Zhu L, Chen K, et al., 2023, Key Operational Details and Standards for Breast Surgery: Expert Consensus of Guangdong Medical Industry Association. *Journal of Southern Medical University*, 43(10): 1827–1833.
- [9] Tang X, 2023, Clinical Value of Breast-Preserving Surgery for Early Breast Cancer. *China Practical Medicine*, 18(15): 64–66.
- [10] Xiao P, Gong F, Xu Q, 2023, The Influence of Perioperative Nursing Intervention on Patients Undergoing Minimally Invasive Breast Surgery. *Qilu Nursing Journal*, 29(14): 124–127.
- [11] Zhao M, Zhu Q, Wang W, et al., 2023, Influencing Factors and Infection Control Effects of Surgical Site Infections in Breast Surgery. *Chinese Journal of Medicine*, 58(6): 634–638.
- [12] Zhang Y, Kong Y, Zhu B, et al., 2023, The Effect of Ultrasound-Guided Serratus Anterior Plane Block Combined with Music Therapy on Analgesia and Anxiety in Patients Undergoing Daytime Breast Surgery. *Chongqing Medicine*, 52(10): 1520–1524.
- [13] Wang S, Ye Y, Meng Z, et al., 2023, Application Progress of Ultrasound-Guided Serratus Anterior Plane Block in Breast

Surgery. Qingdao Medical and Health, 55(2): 148–156.

- [14] Wang Y, 2023, Clinical Effect Analysis of Breast-Preserving Surgery for Early Breast Cancer. Chinese Journal of Modern Drug Application, 17(1): 51–53.
- [15] Su C, Gao J, Liu Y, et al., 2022, Application Analysis of Ultra-High-Definition Video Follow-Up for Thyroid and Breast Surgery Patients Based on 5G Technology. Journal of Harbin Medical University, 56(5): 512–515.

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# Analysis of the Therapeutic Effect of ZhenGan XiFeng Decoction in the Acute Phase of Hypertensive Intracerebral Hemorrhage

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**Abstract:** *Objective:* To analyze the therapeutic effect of ZhenGan XiFeng Decoction in patients with hypertensive intracerebral hemorrhage (HICH) in the acute phase. *Methods:* Fifty-seven patients with HICH in the acute phase who visited the hospital from April 2024 to March 2025 were selected as samples and randomly divided into two groups. Group A received combined therapy with ZhenGan XiFeng Decoction, while Group B received conventional treatment. The efficacy, blood pressure, and symptom scores were compared between the two groups. *Results:* The effective rate of HICH patients in Group A was higher than that in Group B ( $P < 0.05$ ). The SBP and DBP indicators of HICH patients in Group A were lower than those in Group B ( $P < 0.05$ ). The symptom scores of HICH patients in Group A were lower than those in Group B ( $P < 0.05$ ). *Conclusion:* The use of ZhenGan XiFeng Decoction in the treatment of acute HICH can enhance the effect of HICH management, stabilize blood pressure, and also relieve HICH-related symptoms.

**Keywords:** Hypertensive intracerebral hemorrhage; ZhenGan XiFeng Decoction; Therapeutic effect

**Online publication:** June 3, 2025

## 1. Introduction

HICH refers to a series of pathological changes caused by long-term abnormal elevation of blood pressure, which leads to degeneration, necrosis, or the formation of micro-aneurysms in intracranial small arteries. If the blood pressure rises abnormally, it can cause intracranial small vessel rupture and bleeding, which is a parenchymal lesion of the brain. Western medicine often treats HICH with symptomatic drug therapy, which can adjust intracranial pressure and correct water-electrolyte imbalance. However, if the indications for hematoma removal surgery are met, a surgical plan is needed to completely remove the hematoma. According to dialectical analysis of traditional Chinese medicine, HICH patients mostly belong to the type of liver yang hyperactivity, and need to be treated with prescriptions for removing blood stasis, promoting blood circulation, detoxifying, resolving phlegm, and calming the wind. The commonly used prescription is ZhenGan XiFeng Decoction<sup>[1]</sup>. Based on this, this study analyzes the therapeutic effect of ZhenGan XiFeng Decoction using 57 patients with HICH who visited the

hospital from April 2024 to March 2025 as samples.

## 2. Materials and methods

### 2.1. Materials

Fifty-seven patients with acute HICH who visited the hospital from April 2024 to March 2025 are selected as samples and randomly divided into two groups. There is no statistically significant difference in the baseline data of acute HICH between Group A and Group B ( $P > 0.05$ ), as shown in **Table 1**.

**Table 1.** Baseline data analysis of acute HICH

Group	n	Gender(%)		Age (years)		Hematoma volume(ml)		BMI(kg/m <sup>2</sup> )	
		Male	Female	Range	Mean	Range	Mean	Range	Mean
Group A	29	15(51.72)	14(48.28)	45–82	68.21 ± 1.25	3–30	22.09 ± 1.81	19–27	23.81 ± 1.82
Group B	28	14(50.00)	14(50.00)	46–79	68.19 ± 1.31	3–30	22.11 ± 1.79	19–28	23.79 ± 1.79
X <sup>2</sup> /t	-	0.0169		0.0590		0.0419		0.0418	
P	-	0.8964		0.9532		0.9667		0.9668	

### 2.2. Inclusion and exclusion criteria

The inclusion criteria of the study are: (1) Consistent with cerebral hemorrhage in the “Key Points for the Diagnosis of Various Cerebrovascular Diseases”<sup>[2]</sup>, and dialectical analysis in traditional Chinese medicine indicates liver yang hyperactivity syndrome; (2) CT suggests cerebral hemorrhage; (3) Presence of hypertension; (4) Hematoma volume less than 30ml and GCS (Glasgow Coma Scale) score greater than 8.

Meanwhile, the exclusion criteria are: (1) Intracranial hemorrhage caused by trauma; (2) Drug-induced intracranial hemorrhage; (3) Non-liver yang hyperactivity syndrome; (4) Hematoma volume greater than 30ml and GCS score less than or equal to 8.

### 2.3. Treatment methods

Group A received conventional treatment, including blood pressure control, reduction of cerebral edema, stabilization of the internal environment, combined with ZhenGan XiFeng Decoction. The prescription is as follow: 30g each of raw oyster shell, raw keel, and Huai Niu Xi; 15g each of Tian Dong, Xuan Shen, Bai Shao, raw tortoise shell, and raw Dai Zhe stone; 10g of Yin Chen; 5g each of raw malt, Chuan Lian Zi, and licorice. The prescription can be adjusted according to the patient’s other symptoms. All herbs are decocted in water to obtain 300ml of juice, taken once a day, warm, in the morning, afternoon, and evening. The medication is administered for 1 week.

Group B received conventional treatment, including blood pressure control, reduction of cerebral edema, and stabilization of the internal environment.

### 2.4. Observation indicators

- (1) Efficacy: Stable blood pressure and blood sugar, no expansion of the hematoma, no psychiatric symptoms, no reversal of sleep, no aggravation of neurological damage symptoms, recorded as effective; BI index decreased, hematoma expanded, neurological damage symptoms aggravated, recorded as ineffective.

- (2) Blood pressure: Monitor SBP and DBP using an arm-type blood pressure monitor.
- (3) Symptom score: Score symptoms such as hyperglycemia, psychiatric symptoms, sleep disorders, independent eating, deepened consciousness, and decreased muscle strength based on the criteria of none, mild, moderate, and severe, with scores ranging from 0–3.

## 2.5. Statistical analysis

SPSS 23.0 is used to process the data. The  $\chi^2$  test and % are used to record count data, while the t-test and  $\bar{x} \pm s$  are used to record measurement data. Statistical differences exist when  $P < 0.05$ .

## 3. Results

### 3.1. Efficacy of HICH patients

The effective rate of HICH patients in Group A was higher than that in Group B, with  $P < 0.05$ . The results are shown in **Table 2**.

**Table 2.** Comparison of therapeutic effects (n,%)

Group	Effective rate	Ineffective rate
Group A ( $n=29$ )	28(96.55)	1(3.45)
Group B ( $n=28$ )	22(78.57)	6(21.43)
$\chi^2$	4.2752	
$P$	0.0387	

### 3.2. Blood pressure of HICH patients

After medication, the SBP and DBP indicators of HICH patients in Group A were lower than those in Group B, with  $P < 0.05$ . The results are illustrated in **Table 3**.

**Table 3.** Comparison of blood pressure ( $\bar{x} \pm s$ )

Group	SBP(mmHg)	DBP(mmHg)
Group A ( $n=29$ )	136.42 $\pm$ 1.82	84.44 $\pm$ 1.06
Group B ( $n=28$ )	145.11 $\pm$ 1.96	97.06 $\pm$ 1.19
$t$	17.3537	42.3135
$P$	0.0000	0.0000

### 3.3. Symptom scores of HICH patients

After medication, the symptom scores of HICH patients in Group A were lower than those in Group B, with  $P < 0.05$ . Refer **Table 4** for the details.

**Table 4.** Comparison of symptom scores ( $\bar{x} \pm s$ )

Group	Hyperglycemia (score)	Psychiatric symptoms (score)	Sleep disorder (score)	Independent eating (score)	Deepening of consciousness (score)	Muscle strength decline (score)
Group A (n=29)	0.49 ± 0.11	0.52 ± 0.14	0.44 ± 0.15	0.51 ± 0.16	0.42 ± 0.12	0.47 ± 0.14
Group B (n=28)	1.31 ± 0.28	1.36 ± 0.31	1.35 ± 0.32	1.35 ± 0.29	1.33 ± 0.27	1.36 ± 0.28
<i>t</i>	14.6473	13.2616	13.8247	13.6034	16.5406	15.2586
<i>P</i>	0.0000	0.0000	0.0000	0.0000	0.0000	0.0000

## 4. Discussion

HICH is a disease with high incidence in middle-aged and elderly populations, characterized by acute onset and high disability rate, and most patients have poor prognosis. Cerebral edema after HICH can alter the physiological and anatomical structure of craniocerebral tissues, increasing the risk of patient fatality, so active treatment should be provided. Scholars of traditional Chinese medicine believe that HICH belongs to the category of stroke and is related to the poor flow of Qi in the six hollow organs. The internal obstruction of wind, yang, phlegm, and fire leads to the disturbance of Qi movement. Over time, pathogenic Qi rises and attacks the brain, causing the disease. There are many inducements of HICH, and patients often experience attacks during emotional excitement, overexertion, excessive anxiety, and heavy lifting. These influencing factors cause Yin-Yang imbalance and Qi-blood disturbance, leading to the onset of the disease<sup>[3]</sup>.

Additionally, under the influence of various underlying diseases such as vascular diseases, atherosclerosis, and hypertension, blood pressure can suddenly rise, causing blood vessels to rupture and inducing cerebral hemorrhage. This generates intracranial edema, which increases pressure on craniocerebral tissues, leading to displacement, softening, necrosis of healthy intracranial tissues, and ultimately inducing HICH. Scholars of traditional Chinese medicine have found that patients with acute HICH experience blood stasis. During treatment, it is necessary to quickly resolve the state of edema and reduce local intracranial tissue compression, with a focus on removing blood stasis rather than stopping bleeding. Therefore, dialectical selection of traditional Chinese medicines should be made to regulate blood viscosity, reduce the degree of cerebral edema, improve cerebral blood circulation, and reduce the degree of nerve fiber bundle damage in HICH patients<sup>[4]</sup>. The HICH patients included in this study all presented with hyperactivity of liver yang syndrome, and were treated with Zhen Gan Xi Feng Decoction. The combined use of the herbs in the formula can guide qi and blood downward, alleviating HICH-related symptoms.

Based on the data analysis in this study, the effective rate of HICH patients in Group A is higher than that in Group B, with  $P < 0.05$ . Analyzing the reasons, in the Zhen Gan Xi Feng decoction, Radix Cyathulae is the monarch drug that can nourish the liver and kidneys, stabilize Qi and blood turbulence, and guide blood downward. Raw haematite is also a minister drug that can calm the liver and suppress yang, reducing the liver yang rising and causing adverse Qi of liver and stomach; further studying the etiology of HICH, using raw oyster with other drugs such as white peony root, tortoise plastron, raw dragon bone, etc., to calm the wind, soften the liver, descend the adverse Qi, and suppress yang, all of which are minister drugs. *Asparagus cochinchinensis*

is paired with figwort root to nourish water, clear heat, and nourish yin; the liver has characteristics of hating depression and liking harmony. If only heavy sedative drugs are selected, it can inhibit its harmonious nature. When paired with malt sprout, sichuan chinaberry fruit, and *capillaris*, it can regulate Qi, disperse the liver, and also reduce liver heat and suppress liver Yang. The above drugs are all adjuvant drugs <sup>[5]</sup>.

Licorice can adjust the medicinal properties of various medicines in Zhen Gan Xi Feng decoction. When paired with malt sprout, it can regulate the middle burner and harmonize the stomach, and can inhibit the disadvantages of stone drugs. It is a guiding drug <sup>[6]</sup>. Zhen Gan Xi Feng decoction focuses on the treatment of symptoms with sedative drugs, and at the same time selects nourishing Yin products to treat the root cause, which can achieve the effect of taking care of both the symptoms and the root cause. In addition, the combination of various medicines in Zhen Gan Xi Feng decoction can achieve the effect of nourishing Yin and suppressing Yang, calming the liver and extinguishing wind. Another set of data shows that the SBP and DBP indicators of HICH patients in Group A are lower than those in Group B, with  $P < 0.05$ . Based on modern pharmacological analysis, raw dragon bone, raw oyster, etc. in Zhen Gan Xi Feng decoction are rich in magnesium, calcium, and other elements, which can regulate the membrane potential of vascular smooth muscle cells, block calcium ion influx, and reduce vascular tension. Moreover, oyster extracts can inhibit the RAAS system and lower SBP; *Radix Cyathulae* is rich in polysaccharides and triterpenoid saponins, which can stimulate the expansion of peripheral blood vessels, improve vascular compliance, and thus lower blood pressure; raw haematite is rich in magnesium, iron and other elements, which can regulate calcium ion channels, block sympathetic excitation, and help maintain stable blood pressure and heart rate <sup>[7]</sup>.

Another set of data indicates that the symptom scores of HICH patients in Group A were lower than those in Group B, with  $P < 0.05$ . Upon analysis, the reason for this difference is related to hyperglycemia and the impairment of central nervous system function in HICH patients, which causes the body to enter a stress state. At this time, the secretion of cortisol and epinephrine increases in the patients' bodies, which can antagonize the effects of insulin and accelerate the decomposition of glycogen in the liver. Additionally, under severe stress response conditions, the body's tissues become less sensitive to insulin, leading to elevated blood glucose levels. Psychiatric symptoms are related to the signs of brain edema compression. In HICH patients, increased intracranial pressure and impaired cranial function can induce psychotic symptoms such as delusion, hallucinations, and irritability. Coupled with the influence of cranial neurotransmitter release and metabolic disorders, these psychiatric symptoms can be further exacerbated.

Sleep disorders are related to damage to the brain's sleep regulation center, leading to abnormalities in the sleep-wake rhythm, manifesting as dreaminess, easy waking, and difficulty entering deep sleep. Autonomous eating disorders are associated with brain edema damaging swallowing nerve function, causing patients to fear eating due to choking, and a few severely ill patients may be in a coma and unable to eat independently. Deepened consciousness is related to the continuous increase in intracranial pressure, which further impairs cranial function, manifesting as delirium, agitation, and coma. Muscle weakness is related to brain edema damaging nerve conduction pathways and neurons <sup>[8]</sup>. In addition, severely ill HICH patients who are bedridden for long periods and have reduced physical activity may experience muscular atrophy due to disuse, leading to decreased muscle strength.

In this study, Zhen Gan Xi Feng decoction is chosen for treatment. Drugs such as *Radix Scrophulariae* and *Radix Asparagi* are rich in polysaccharides and saponins, which can resist platelet accumulation and lower blood pressure. Additionally, the extract of *Radix Asparagi* can prolong PT and APTT times, which is beneficial for

restoring blood circulation. The total glycosides of white peony root can block the proliferation of smooth muscle cells, delay atherosclerosis, and reduce cerebral vascular reperfusion injury, thereby reducing the volume of brain edema and relieving HICH-related symptoms. The capillarisin in Yin Chen can promote cerebral blood circulation, accelerate cerebrovascular expansion, and correct insufficient cerebral perfusion. Therefore, HICH patients have a good prognosis, and various symptoms quickly resolve. In addition, the raw tortoise shell in Zhen Gan Xi Feng Decoction contains amino acids and collagen, which can stimulate the repair of damaged nerve cells.

Moreover, extracts from the tortoise shell can inhibit neuronal apoptosis and reduce damage to craniocerebral nerve tissues. Raw malt contains vitamins of the B group and maltase, which can regulate neurotransmitter metabolic pathways and accelerate the repair of damaged nerve cells. Extracts from Sichuan chinaberry can protect craniocerebral neurons and inhibit intracranial calcium overload. Extracts from licorice can block the release of inflammatory factors in the body, reduce the stress response in patients with acute HICH, and help patients recover their self-care ability. Herbs such as Yin Chen and raw ochre can reduce oxidative stress damage in the body, and the chlorogenic acid in Yin Chen can block the process of platelet activation, inhibit the generation of blood clots in the body, and further reduce patient discomfort <sup>[9]</sup>.

However, patients with acute HICH should avoid taking tetracycline drugs during treatment with Zhen Gan Xi Feng Decoction, as it may adversely affect the absorption of mineral medicines such as raw oysters and raw ochre. The dosage of each medicine should be adjusted dynamically based on the patient's physical condition. During medication, blood pressure should be monitored to avoid the effects of hypotension on cerebral perfusion, and neurological function recovery, including language, consciousness, and limb movements, should be evaluated. If unequal pupils or severe consciousness disturbances occur, medication should be immediately suspended and re-examined. If dizziness, headache, nausea, and vomiting occur, the drug dosage should be adjusted dialectically <sup>[10]</sup>.

## 5. Conclusion

In summary, treatment with Zhen Gan Xi Feng Decoction for patients with acute HICH can enhance the efficacy of acute HICH management, maintain stable blood pressure, and reduce HICH-related symptoms, making it worthy of promotion. However, due to the small sample size of acute HICH included in this study, there may be some randomness in the data on the effectiveness of Zhen Gan Xi Feng Decoction. Future studies should increase the sample size of acute HICH and conduct multi-center investigations to further explore the therapeutic effects of Zhen Gan Xi Feng Decoction.

## Disclosure statement

The author declares no conflict of interest.

## References

- [1] Zhao B, Zhang J, Fu W, et al., 2021, Therapeutic Effect of Modified Zhen Gan Xi Feng Decoction Combined with Acupuncture on Stroke of Yin Deficiency and Wind Movement Type and Its Influence on Immune Balance. *Traditional Chinese Drug Research and Clinical Pharmacology*, 32(10): 1537–1542.
- [2] Chinese Neurological Society, 1996, Main points for diagnosis of various cerebrovascular diseases. *Chinese Journal of Neurology*, 29(6): 379–380.

- [3] Su H, 2022, Application of Modified Zhen Gan Xi Feng Decoction in Perioperative Period of Subarachnoid Hemorrhage. *Practical Clinical Medicine Combined with Traditional Chinese Medicine*, 22(3): 67–69.
- [4] Wang X, Guo W, Huang L, 2022, Clinical Observation on the Treatment of Liver Yang Hyperactivity Cerebral Hemorrhage with Zhen Gan Xi Feng Decoction Plus Some Hemostatic and Removing Blood Stasis Drugs. *Xinjiang Journal of Traditional Chinese Medicine*, 40(2): 17–19.
- [5] Yao L, Zhu Y, Chen F, 2021, Effects of Xingnao Tongluo Decoction on Cerebral Edema Volume, Neurological Function and Quality of Life of Patients with Wind-Phlegm Obstructing Collaterals Type Hypertensive Cerebral Hemorrhage After Minimally Invasive Hematoma Removal. *Journal of Practical Cardio-Cerebral-Pulmonary Vascular Disease*, 29(4): 105–110.
- [6] Zhang T, Zhi J, Yan Y, 2024, Therapeutic Effect of Modified Zhen Gan Xi Feng Decoction Combined with Cobamamide on Tinnitus with Liver Yang Hyperactivity Syndrome and Its Influence on Hemorheology and Oxidative Stress Level. *Shaanxi Journal of Traditional Chinese Medicine*, 45(8): 1065–1069.
- [7] Li L, Chen Y, Zhao Y, et al., 2023, Analysis of the Effect of Modified Zhen Gan Xi Feng Decoction Combined with Acupuncture at Sihua Points on Neurological Deficits and Prognosis of Ischemic Stroke with Yin Deficiency and Wind Movement Type. *Chinese Archives of Traditional Chinese Medicine*, 41(6): 147–150.
- [8] Hu B, 2024, Clinical Observation on the Treatment of Yin Deficiency and Wind Movement Type Stroke Patients with Meridian Involvement by Modified Zhen Gan Xi Feng Decoction. *Practical Clinical Medicine Combined with Traditional Chinese Medicine*, 24(10): 52–54, 82.
- [9] He H, 2023, Study on the Clinical Effect of Modified Zhen Gan Xi Feng Decoction in Treating Hypertension and Its Influence on Patients' Blood Pressure Level. *Database of Chinese Scientific and Technological Periodicals (Abstract Edition) Medicine and Health*, 2023(11): 52–54.
- [10] Wei M, Zheng M, 2023, Observation on the Effect and Adverse Reactions of Modified Zhen Gan Xi Feng Decoction in Treating Hypertension. *Northern Pharmacology*, 20(8): 182–184.

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# Evaluating the Application of the PDCA Cycle Model in Nursing Management of the Hospital Disinfection Supply Room

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**Abstract:** *Objective:* To study the effectiveness of the PDCA cycle model in the nursing management of the disinfection supply room. *Method:* From March 2022 to February 2024, the hospital adopted the PDCA cycle model to manage the related work of the disinfection supply room. In this study, 40 nursing staff were selected as the research subjects. Sixty-five sets of data generated during the implementation of the PDCA model were selected, and 65 sets of similar data before the implementation were also selected. The relevant data information was compared and evaluated to understand the changes in work before and after the implementation of the PDCA cycle model management. Meanwhile, twenty departments in the hospital were selected to investigate the satisfaction before and after the implementation of the PDCA cycle model management. *Result:* After the implementation of the PDCA cycle model, the completion rates of various tasks were improved, and there was a significant difference compared with those before the implementation ( $P < 0.05$ ). The work quality of each working link has also been improved since the implementation. Compared with that before the implementation of the PDCA cycle model, there are significant changes ( $P < 0.05$ ). It can be learned from the comparison of satisfaction among various departments that the satisfaction of departments has improved after the implementation of PDCA, and there is a significant difference compared with that before the implementation ( $P < 0.05$ ). *Conclusion:* The application of the PDCA cycle model in the nursing management of the disinfection supply room can effectively improve the working conditions of the disinfection supply room and provide a basic guarantee for hospital treatment. Therefore, the PDCA cycle management model can be actively adopted in the actual work management.

**Keywords:** PDCA cycle model; Disinfection supply room; Nursing management

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## 1. Introduction

The disinfection supply room is an indispensable department in a hospital, specifically responsible for the recovery of various medical devices within the hospital and the disinfection of cleaning agents. It supplies various sterile medical items and equipment to the entire hospital. The task is arduous and the workload is large. Although it does

not directly participate in treatment, it affects the final treatment outcome. The quality of work in the disinfection supply room is the guarantee of patients' safety during illness <sup>[1]</sup>. With the development of medical technology, the requirements for various departments have gradually increased. For the disinfection supply room, the previous management measures cannot meet the medical rescue needs. Effective management methods should be actively adopted, and a systematic and comprehensive management model should be formulated. The PDCA cycle model was proposed by the American quality management expert Walter Armand Shehart and is also known as the Deming cycle <sup>[2]</sup>. Comprehensive supervision and management of quality, which can only be carried out according to the plan and the implementation of the plan is inspected and handled, is a complete and systematic management model, often used in enterprise management <sup>[3, 4]</sup>. In this experimental study, the PDCA management model is applied to the management of the disinfection supply room to investigate its effectiveness in the management of the disinfection supply room.

## **2. Data and methods**

### **2.1. Clinical data**

From March 2022 to February 2024, the hospital adopted the PDCA cycle model to manage the related work of the disinfection supply room. This study selected 40 nursing staff as the research subjects, including 2 males and 38 females. Their ages ranged from 23 to 45 years old, with an average age of  $(34.25 \pm 2.21)$  years old and working years ranging from 1 to 22 years. Sixty-five sets of data generated during the implementation of the PDCA model are selected, and 65 similar data before the implementation are also selected. The relevant data information is compared and evaluated to understand the changes in the work before and after the implementation of the PDCA cycle model management. Meanwhile, twenty departments in the hospital are selected to investigate the satisfaction before and after the implementation of the PDCA cycle model management.

### **2.2. Research method**

#### **(1) Planning stage**

During the planning stage, a quality control team needs to be established as required to supervise and inspect the disinfection supply room and identify any hidden problems. Investigate and analyze the unreasonable work arrangements and systems in the workflow of the disinfection supply room, identify the root causes of the problems, and adjust and optimize them according to actual needs. Operate strictly in accordance with the "Technical Specifications for Disinfection in Medical Institutions" and the "Management Specifications for Hospital Disinfection Supply Centers". In the disinfection supply room, the work content is simple and mechanical, and the comprehensive quality of the operators varies greatly. Due to cognitive differences and a lack of safety awareness, the disinfection of medical devices is not thorough, failing to meet the disinfection supply requirements and posing a huge hidden danger to the lives and health of patients. Improper operation procedures can cause harm to the operators themselves, and situations such as iatrogenic infections or high-temperature scalds occur frequently. Therefore, it is particularly important to formulate a sound and standardized disinfection operation system to promote the standardization, rationalization, and scientification of the operation process.

#### **(2) Implementation stage**

During the implementation stage, it is necessary to put the plan into actual work, and more emphasis

should be placed on the importance of “doing”<sup>[5]</sup>. To comprehensively enhance the technical proficiency and safety awareness of the staff in the disinfection supply room, training measures should be taken for the relevant personnel. Safety protection measures should be implemented in every link of the disinfection management work. Disinfection and cleaning work should be carried out in accordance with the norms. Various medical devices should be cleaned as required and thoroughly disinfected. The quality should be strictly controlled. When disinfection is completed, all kinds of medical devices should be placed separately. In the course of work, monitoring and sampling inspections should be carried out on each link to prevent any omissions and provide guarantees for the cleaning, disinfection and placement of medical devices. Clarifying job responsibilities enables the allocation of work responsibilities to individuals. Each staff member adheres to quality standards, records work content, and optimizes each management link based on feedback from departments. Work is completed to the highest standards to ensure the normal supply of clean and sterile medical devices to all departments.

During the entire implementation process, personnel from relevant departments should do a good job in their own safety protection, keep their hands clean, and collect and organize relevant data. Separate the positions again to prevent the tools for cleaning and disinfection from causing secondary contamination during circulation, which may affect the completion of the final disinfection work. Therefore, after the medical devices are recycled, the person in charge of the contaminated ones should conduct a classified inventory of the medical devices and recheck them after cleaning. Due to the different ways of cleaning medical devices, it is necessary to select devices suitable for machine cleaning and those that require manual cleaning to avoid incomplete cleaning. After the disinfection of medical devices is completed, the corresponding labels should be affixed to the outer packaging of the devices as required to clearly distinguish them. In disinfection work, the concentration of disinfectant is a factor that directly affects the disinfection effect. Therefore, it is also necessary to conduct regular checks to prevent incomplete disinfection when the concentration is too low, leaving an opportunity for the retention of bacteria and viruses. Air can also be a medium for the spread of bacteria and viruses. In the disinfection supply room, the surfaces of items and the air should be disinfected regularly to provide a qualified environment for the disposal of medical devices.

### (3) Inspection stage

The inspection stage mainly involves verifying the cleaning, disinfection, and placement work, conducting sampling checks on medical devices to understand whether the disinfection work on that day is carried out following the standards, whether the disinfection effect meets the set requirements, and whether they can be supplied to various departments. Based on daily spot checks, monthly inspection targets should also be set. At the end of each month, a comprehensive inventory of medical devices should be conducted, and the quality of disinfection should be inspected. At the same time, the inspection results should be made public in accordance with the open and fair quality inspection standards. By adopting a combination of work quality and reward and punishment mechanisms, the aim is to change the lax and irresponsible attitude of staff members, encourage them to actively engage in their work, voluntarily abide by all regulations, and complete relevant tasks with both quality and quantity guaranteed. Those with poor work quality should be punished, while those with outstanding performance should be rewarded. This can make the relevant personnel realize the importance of their work attitude, establish the determination to follow the standards, and lay a foundation for the smooth implementation of the work. In addition, relevant staff members working on the front line can offer suggestions based on the actual situation. During the meeting, the

rationality of the personnel's opinions can be discussed and valuable suggestions adopted to optimize the current management status of the disinfection supply room and enhance the management effect.

#### (4) Processing stage

The quality control team inspects the quality of disinfection work in accordance with relevant regulations, evaluates and summarizes the related work, verifies and discusses the existing problems, formulates corresponding solutions based on the actual situation, widely listens to the opinions of department members, finds effective solutions, optimizes the management process, promotes further reform of management work, and pushes management to a new level.

### 2.3. Observation index

Compare the completion of disinfection supply room tasks before and after the implementation of the PDCA cycle in the hospital, focusing on work rate and work quality. Work quality is evaluated across five specific aspects, with higher assessment scores indicating better performance. Additionally, assess the satisfaction levels of nursing staff and conduct a departmental survey to collect and analyze satisfaction data.

### 2.4. Statistical method

This study utilized the software SPSS 25.0 for analysis and processing. When  $P < 0.05$ , there was a significant difference and it was statistically significant.

## 3. Result

### 3.1. Comparison of work completion rates before and after the implementation of the PDCA cycle model

After the implementation of the PDCA cycle model, the completion rates of various tasks were improved, and there was a significant difference compared with those before the implementation ( $P < 0.05$ ). The results can be seen in **Table 1**.

**Table 1.** Comparison of work completion rates before and after implementing the PDCA cycle model [n (%)]

Group	n	Hand hygiene	Concentration of disinfectant for sterilized items	Rust removal	Breathing tube cleaning and disinfection	Surgical instruments cleaning and disinfection
Before implementation	65	55(84.62)	56(86.15)	54(83.08)	53(81.54)	56(86.15)
After implementation	65	65(100%)	62(95.38)	63(96.92)	64(98.46)	63(96.92)
<i>p</i>		$< 0.05$	$< 0.05$	$< 0.05$	$< 0.05$	$< 0.05$

### 3.2. Comparison of work quality scores before and after the implementation of the PDCA cycle

After the implementation of the PDCA cycle model, the work quality of each working link has been improved. Compared with before the implementation of the PDCA cycle model, there are significant changes ( $P < 0.05$ ), as shown in **Table 2**.

**Table 2.** Comparison of work quality scores before and after the implementation of PDCA cycle ( $\bar{x} \pm s$ , points)

Group	The quality of instrument disassembly and assembly	Cleaning process	Cleaning quality	Environmental management	Packaging quality
Before implementation	85.83 $\pm$ 3.12	86.95 $\pm$ 1.43	86.57 $\pm$ 1.48	88.72 $\pm$ 3.54	91.13 $\pm$ 2.88
After implementation	97.96 $\pm$ 4.15	97.52 $\pm$ 1.36	98.68 $\pm$ 2.32	98.61 $\pm$ 2.26	99.72 $\pm$ 1.37
<i>p</i>	< 0.05	< 0.05	< 0.05	< 0.05	< 0.05

### 3.3. Comparison of departmental satisfaction before and after the implementation of the PDCA cycle model

It can be learned from the comparison of satisfaction among various departments that the satisfaction of departments has improved after the implementation of PDCA, and there is a significant difference compared with that before the implementation ( $P < 0.05$ ). The results are shown in **Table 3**.

**Table 3.** Comparison of department satisfaction before and after the implementation of the PDCA cycle model [n (%)]

Time	n	Very satisfied	Generally satisfied	Not satisfied	Overall satisfaction
Before implementation	20	10(50.00)	7(35.00)	3(15.00)	17 (85.00)
After implementation	20	12(60.00)	8(40.00)	0	20 ( 100.0)
<i>P</i>					< 0.05

## 4. Discussion

Infection is an important reason for the reduced treatment effect in hospitals, posing a threat to the life and health of patients. The recovery time of patients is prolonged. For patients, they have to endure physical pain as well as the psychological torment brought by infection to themselves<sup>[6]</sup>. Therefore, infection is not beneficial to the treatment effect of hospitals or the recovery of patients, and it may even increase the conflict between doctors and patients. It can be seen from this that it is of great significance for doctors to use clean and sterile medical devices to treat patients. The corresponding disinfection and supply work should keep up with the treatment demands, adopt standardized management, improve management effectiveness, meet the supply and demand requirements of various departments in the hospital, enhance the treatment effect of patients, and reduce doctor-patient conflicts caused by infections<sup>[7]</sup>.

This study examines and discusses the effectiveness of the PDCA cycle model applied in the disinfection supply room, providing a new management approach for improving the working effectiveness of the disinfection supply room and perfecting the working management process of the disinfection supply room<sup>[8, 9]</sup>. Through the PDCA cycle model, deficiencies in the work can be identified and optimized and improved, thereby enhancing the working level of nursing staff and significantly improving the work completion rate<sup>[10, 11]</sup>. For instance, in terms of hand hygiene, it has increased from 84.62% before implementation to 100%, and the inspection of disinfectant concentration in sterilized items has received attention, rising from 86.15% to 95.38%. After medical equipment

rusts, it not only affects its use but also carries various bacteria and may remain in the patient's body, causing infection. After the implementation of PDCA, the situation has been effectively improved, rising from the original 83.08% to 96.92%. Clearly, the cleaning and disinfection effect has been enhanced, and more attention has been paid to the cleanliness of medical devices. After the awareness of the nursing staff was enhanced, the quality of work in each link was also improved, and the difference was significant compared with the previous management ( $P < 0.05$ ). Therefore, it can be affirmed that the PDCA cycle model has indeed improved each process of disinfection management. The survey on the satisfaction of 20 departments is also sufficient to confirm that the work of the disinfection supply department has been improved, the satisfaction of the department has increased, and the incidence of adverse events has been effectively controlled<sup>[12, 13]</sup>.

The four stages of the PDCA cycle model are progressive. Through these four stages, the deficiencies and root causes in previous management can be identified, and improvements can be made based on the actual situation<sup>[14]</sup>. Scientific and reasonable management systems can be formulated to enhance management effectiveness and gradually improve the work management system<sup>[15]</sup>. Therefore, PDCA is a continuously improving management model. Identifying problems and solving them ensures that management is implemented effectively. As a result, management is in a virtuous cycle, which plays a positive role in the smooth progress of the nursing work in the disinfection supply room.

## 5. Conclusion

In conclusion, in the nursing management of hospital disinfection supply rooms, the PDCA cycle model should be adopted and promoted to the management of disinfection supply rooms in more hospitals. This is conducive to enhancing the hospital's reputation, improving its social benefits, and providing medical and health security for more patients.

## Disclosure statement

The author declares no conflict of interest.

## References

- [1] Feng H, Zhou S, Zhou Q, et al., 2023, The Effect of the Quality Cycle (PDCA Cycle) Model in the Nursing Management Work of the Disinfection Supply Center. *Wisdom and Health*, 9(1): 221–224.
- [2] Xu Y, 2022, Application of PDCA Cycle in Improving the Qualification Rate of Surgical Instrument Cleaning. *Shanghai Nursing Association Abstract Compilation of the 5th Shanghai International Nursing Congress (Part 1)*, Shanghai Nursing Association: 583.
- [3] Qi Y, Wei J, Xu M, et al., 2022, The Application Effect of PDCA Cycle Mode in the Cleaning, Disinfection and Sterilization of Rigid Endoscopic Instruments in the Disinfection Supply Center. *Contemporary Nurses (Mid-month Edition)*, 29(9): 109–112.
- [4] Ding F, 2020, Research on the Impact Value of Applying PDCA Cycle in the Nursing Management of Disinfection Supply Centers on the Quality of Cleaning, Disinfection and Sterilization. *Medical Food Therapy and Health*, 18(23): 153–154.
- [5] Li S, Ma L, 2019, Observation on the Application of PDCA Cycle in the Nursing Management of the Disinfection

- Supply Center and Its Impact on Reducing the Infection Rate of Surgical Instruments. *World Latest Medical Information Abstracts*, 19(54): 314+318.
- [6] Feng H, 2019, Observation on the Application of PDCA Cycle in the Nursing Management of Disinfection Supply Room and Its Impact on Reducing the Infection Rate of Surgical Instruments. *World Latest Medical Information Abstracts*, 19(48): 269+272.
  - [7] Su Y, Jin D, Zhang A, et al., 2018, Analysis of the Impact of PDCA Management Cycle Mode on the Incidence of Wet Packages After Pressure Steam Sterilization in the Disinfection Supply Center. *Biomedical Engineering and Clinical Practice*, 22(02): 196–199.
  - [8] Li X, Wang W, Zou M, 2021, The Influence of PDCA Cycle Management on the Nursing Quality of Hospital Disinfection Supply Rooms and Hospital Infections. *Heilongjiang Medical Sciences*, 44(06): 30–31.
  - [9] Liang J, Xiong W, Huang Y, et al., 2021, Research on the Quality Management of Centralized Disinfection Supply of Reusable Medical Devices Using the FOCUS-PDCA Model. *Chinese Medical Innovation*, 18(08): 96–100.
  - [10] Xiong G, Du Y, 2020, Research on the Application Effect of PDCA Cycle in the Nursing Management of Disinfection Supply Room. *Chinese Journal of Materia Medica and Clinical Medicine*, 20(23): 4032–4033.
  - [11] Chen Z, You P, Lai X, 2020, Analysis of the Impact of PDCA Cycle Nursing Model on the Sterilization and Disinfection Quality of the Disinfection Supply Room. *Jilin Medical Journal*, 41(11): 2774–2776.
  - [12] Mu Y, Ding Y, 2020, Research on the Application of PDCA Cycle in the Nursing Management of the Disinfection Supply Room and Its Effect on Reducing the Infection Rate of Surgical Instruments. *Jilin Medical Journal*, 41(07): 1727–1729.
  - [13] Pan X, 2023, The Impact of PDCA Cycle on the Qualification Rate of Cleaning and Sterilization in the Nursing Management of Disinfection Supply Rooms. *Famous Doctor*, 2023(18): 183–185.
  - [14] Sun X, 2020, The Effect of PDCA Cycle Method Applied in the Nursing Management of Disinfection Supply Room. *Electronic Journal of Integrated Traditional Chinese and Western Medicine on Cardiovascular Diseases*, 8(36): 140.
  - [15] Yang M, Xu J, Zhang D, 2022, The Influence of the Nursing Management Model Based on the PDCA Cycle on the Quality of Equipment Management and the Incidence of Infection in the Disinfection Supply Center. *Baotou Medical Journal*, 46(03): 47–49.

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# The Application Effect of Operating Room Nursing for Cerebral Hemangioma Combined with Preventive Measures for Moderate and Hypothermia

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**Abstract:** *Objective:* To explore the application of moderate and hypothermia control in patients undergoing cerebral hemangioma surgery. By adjusting the precise body temperature of the patients and controlling the changes, the intraoperative and postoperative risks can be reduced, thereby better promoting postoperative recovery. *Methods:* Thirty patients undergoing cerebral hemangioma surgery were randomly selected as the subjects. All the patients were inpatients in the neurology department between May 2023 and May 2024. The control group received traditional routine nursing management. For the patients in the experimental group, in addition to traditional nursing management, there was also moderate and hypothermia intervention. The body temperature was monitored at three points: the tympanic membrane, esophagus, and rectum. The body temperature was effectively monitored to make it fluctuate within a relatively ideal range. The postoperative recovery was paid attention to and monitored. Key monitoring will be conducted on the intraoperative body temperature changes, hemodynamic indicators of the patients, as well as the postoperative awakening time and neurological function recovery indicators of the patients. *Results:* Compared with the control group, the patients in the experimental group with moderate to low body temperature had relatively gentle body temperature curves and little fluctuation in body temperature. In terms of hemodynamics, patients in the experimental group were more stable than those in the control group. Meanwhile, they recovered faster after the operation, the time required for patients to regain consciousness was shortened, and the incidence of postoperative complications was lower, especially infection, cerebral edema, and electrolyte abnormalities were more prominent. The comfort level and satisfaction of patients were relatively higher compared with those in the control group. Therefore, it can play a very good promoting role for the patient in the postoperative recovery. *Conclusion:* The application of moderate and low body temperature in cerebral hemangioma surgery can better stabilize the patient's condition, reduce the occurrence of complications, and is conducive to the recovery of the patient's neurological function. This method has changed the deficiency of body temperature management in traditional nursing and created a more ideal surgical environment for patients.

**Keywords:** Cerebral hemangioma; Moderate to low body temperature; Operating room nursing; Neural protection

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# 1. Introduction

Cerebral hemangioma surgery is one of the difficult surgeries in neurosurgery. Factors such as intraoperative temperature, hemodynamics, and neurological functional status can all have a significant impact on the postoperative recovery of patients. Temperature factors, especially the control of body temperature, have always been a key point in nursing work. In the past, it was often difficult to effectively control moderate and low body temperatures in nursing work, which led to a series of complications during the postoperative recovery period of patients, such as cerebral edema and infection. With the gradual development of science, innovative means of nursing work are constantly increasing. The intervention technology for moderate and low body temperature has gradually become a new research direction. The application of temperature control technology can help control moderate and low body temperature during postoperative treatment, reduce temperature fluctuations, improve intraoperative conditions and postoperative management, achieve the improvement of patients' recovery quality, and reduce complications. This approach aims to improve patients' recovery quality and reduce complications, ultimately enhancing patient prognosis <sup>[1]</sup>. In clinical research, the application of moderate and mild hypothermia interventions during cerebral hemangioma surgery will be explored at an appropriate time.

## 2. Data and methods

### 2.1. General information

Thirty patients who underwent cerebral hemangioma resection in the Neurosurgery department of the hospital from May 2023 to May 2024 are selected as the research subjects. The inclusion and exclusion criteria are detailed in the patients' explicit acceptance conditions, examination methods, and severity. It was confirmed that all patients are diagnosed with cerebral hemangioma through imaging examinations (CT, magnetic resonance or angiography), and are aged 18 to 65 years old, meeting ASA grades I to III. Meanwhile, the patients voluntarily accepted and cooperated with this study. Patients with severe cardiopulmonary insufficiency, coagulation dysfunction, preoperative infection, etc., are excluded, as well as those who had undergone brain surgery and radiotherapy, and pregnant or lactating women.

The patients are randomly divided into a control group and an experimental group, with 15 cases in each group. The control group consisted of 8 males and 7 females, with ages ranging from 26 to 64 years. The tumor diameter ranged from 2.1 to 5.8 cm. The experimental group included 7 males and 8 females, with ages ranging from 24 to 63 years, and the tumor diameter ranged from 2.0 to 5.9 cm. There was no significant difference in the general data (gender, age, tumor diameter, etc.) between the two groups ( $P > 0.05$ ), indicating that the groups were comparable <sup>[2]</sup>.

### 2.2. Method

#### 2.2.1. Control group

The management of the operating room temperature in the nursing of the control group is relatively simple. With the adoption of conventional vital sign monitoring and intraoperative cooperation, the temperature in the operating room remained basically stable. Before the operation, the vital signs, identity, and other information of the patients are confirmed, and during the operation, the smooth operation is ensured through methods such as tracheal intubation and position adjustment. However, the monitoring of the patient's body temperature during the operation is limited to two measurements before anesthesia induction and the end of the operation, and there is no continuous and accurate method for temperature regulation. Room temperature and cotton quilts can ensure

a certain degree of temperature control, but they cannot regulate the slight changes in the body temperature of surgical patients during the operation <sup>[3]</sup>.

### **2.2.2. Experimental group**

The control group is only given a further detailed and precise body temperature management plan on the basis of routine care. This included preoperative body temperature sensitivity assessment, which could formulate a body temperature management plan based on the patient's physical signs. Temperature monitoring during the operation and effective cooling plans could avoid body temperature fluctuations. Intensive cooling of key indicators during the operation could bring more guarantees for the neuroprotection of patients. The mild rewarming plan after the operation can ensure that the patient's body temperature rises steadily during the rewarming process and avoid the occurrence of complications caused by a relatively fast rewarming speed. The postoperative body temperature monitoring and hemodynamic monitoring can enable the nursing staff to adjust the nursing plan based on the results of various indicators during the operation and precisely adjust the increase in body temperature <sup>[4]</sup>.

### **2.3. Observation indicators**

The observation indicators of this study include body temperature control, hemodynamics, neurological function recovery, and postoperative complication observation indicators, which reflect the surgical and recovery conditions of patients in detail and comprehensively <sup>[5]</sup>.

Stabilizing body temperature is the first step. Measuring the range of body temperature changes and the percentage fluctuation of the target temperature is used to evaluate the effect of temperature regulation during the operation, and also serves as the basis for analyzing postoperative care strategies. The amplitudes of MA and HR can reflect the stability of the patient's circulation, and at the same time, the impact of body temperature changes on the cardiovascular system can also be observed. The influence of body temperature regulation on hemodynamic indicators is observed through these two indicators <sup>[6]</sup>. The recovery of neurological function, the recovery time of patients combined with the GCS score further reflects the recovery of patients' consciousness. The neurological deficit score further reflects the comprehensive functional impairment of the nervous system.

In terms of complication monitoring, the focus is on factors such as incision infection, cerebral edema, and electrolyte imbalance that might affect the recovery of patients <sup>[7]</sup>.

### **2.4. Statistical analysis**

This study used statistical software SPSS 25.0 for data analysis to ensure the reliability and validity of the research results. Measurement data are expressed as  $\bar{x} \pm s$ , and t-tests are used for comparison between groups. Count data are expressed as cases or rates (%) and  $\chi^2$  tests are used. All data are double-entered and checked by both parties to ensure the accuracy of the data <sup>[8]</sup>. Due to the missing data, the mean method is adopted for processing to reduce the impact of the data missing rate on the results.

## **3. Result**

### **3.1. Comparison of intraoperative body temperature control and hemodynamic parameters between the two groups of patients**

**Table 1** illustrates the precise control of intraoperative body temperature and the stability of hemodynamics are the

key factors for the success of cerebral hemangioma surgery. By comparing and analyzing the amplitude of body temperature fluctuation, the proportion of target temperature maintenance time and hemodynamic indicators of the two groups of patients, it is found that the intraoperative body temperature of the patients in the experimental group was more stable and the hemodynamic parameters fluctuated less. Precise control of moderate and low body temperature can provide a better protective environment for brain tissue and reduce the risk of ischemia-reperfusion injury. The following table presents in detail the comparison results of intraoperative body temperature control and hemodynamic parameters between the two groups of patients. The data show that the experimental group is superior to the control group in all indicators.

**Table 1.** Comparison of intraoperative body temperature control and hemodynamic parameters between two groups of patients ( $\bar{x} \pm s$ )

Indicator	Control group ( $n=15$ )	Experimental group ( $n=15$ )	$t$	$P$
Amplitude of body temperature fluctuation ( $^{\circ}\text{C}$ )	$1.83 \pm 0.46$	$0.76 \pm 0.29$	7.624	0.003
The proportion of the target temperature maintenance time (%)	$58.41 \pm 9.27$	$91.63 \pm 5.18$	12.304	0.006
Fluctuation range of mean arterial pressure (mmHg)	$26.47 \pm 6.85$	$12.36 \pm 3.94$	6.853	0.005
Heart rate fluctuation range (bpm)	$21.69 \pm 5.93$	$10.28 \pm 3.17$	6.759	0.003

### 3.2. Comparison of postoperative recovery and incidence of complications between the two groups of patients

**Table 2** shows that the rapid recovery of neurological function and the reduction of complications after surgery are important criteria for evaluating the quality of surgery and nursing. Detailed records and analyses of the indicators, such as the postoperative awakening time, neurological function score, complication rate, and patient satisfaction of the two groups of patients were made. The results showed that the patients in the experimental group who received moderate and hypothermia intervention recovered faster after the operation, had better neurological function, a significantly lower incidence of complications, and higher patient satisfaction. This further confirms the positive role and clinical application value of moderate and hypothermia intervention in the surgery of cerebral hemangioma.

**Table 2.** Comparison of postoperative recovery and incidence of complications between the two groups of patients

Indicator	Control group ( $n=15$ )	Experimental group ( $n=15$ )	$t/\chi^2$	$P$
Postoperative awakening time (min)	$62.47 \pm 13.26$	$38.94 \pm 9.57$	5.763	0.002
After the operation 24h GCSScore (points)	$12.67 \pm 1.94$	$14.33 \pm 0.82$	3.136	0.004
Postoperative NIHSS score (points)	$8.21 \pm 2.47$	$4.53 \pm 1.68$	4.927	0.003
Complication rate (%)	33.33(5/15)	6.67(1/15)	3.968	0.046
Patient satisfaction (points)	$83.27 \pm 6.35$	$92.64 \pm 4.18$	4.802	0.008

## 4. Discussion

In this study, regarding body temperature and postoperative recovery, the conclusion on the relationship between body temperature control and intraoperative hemodynamic stability was drawn<sup>[9]</sup>. Starting from the actual clinical

situation, the research results can be understood at a deeper level, providing a basis for the improvement of future treatment strategies. The two indicators of temperature fluctuation amplitude and the time to maintain the target temperature in this subject can indicate the influence of the stability of intraoperative temperature on the circulatory system. Frequent fluctuations in body temperature after surgery can lead to vasoconstriction or dilation of the body's blood vessels, thereby causing hemodynamic instability. Good body temperature control can provide a more ideal condition for the circulatory system and reduce the occurrence of postoperative complications<sup>[10]</sup>.

Secondly, this study points out the significance of postoperative neurological function recovery. The changes in items such as postoperative awakening time, Glasgow Coma Scale score (GCS), and NIHSS score indicate the metabolic rate of anesthetic drugs and the process of nerve recovery. The metabolism of anesthetic drugs and the postoperative recovery largely depend on the quality of the patient's recovery, such as the recovery of neurological function<sup>[11]</sup>. The postoperative recovery speed of patients in the experimental group was relatively fast. It can be seen that body temperature control and neuroprotection have an impact on postoperative recovery. The metabolism of anesthetic drugs in the body is affected by many aspects. The stability of body temperature may indirectly assist the metabolism of anesthetic drugs, reduce the awakening period of anesthesia for patients, and help patients recover faster<sup>[13]</sup>.

In addition, the incidence of complications and the satisfaction of patients are also notable results in this study. The reduction in the incidence of postoperative complications is closely related to the control of body temperature during the operation<sup>[12]</sup>. Both higher and lower temperatures may induce the occurrence of various complications. This is particularly important for brain surgeries. During the operation, a certain body temperature needs to be maintained. If the body temperature is not properly controlled, it will cause various complications for the patient, thereby affecting the quality of postoperative recovery. In this study, the incidence of complications in the experimental group was not high, and the postoperative satisfaction of the patients was also relatively high. This might be closely related to various factors such as meticulous intraoperative management and postoperative care methods. The psychological needs of patients themselves will be inseparably related to their treatment effects. Providing patients with a good treatment experience can improve their overall satisfaction<sup>[14, 15]</sup>.

## 5. Conclusion

In conclusion, this study has demonstrated the significance of maintaining the patient's body temperature during surgery for the stability of circulatory circulation during the operation and the early recovery of patients after the operation.

## Disclosure statement

The author declares no conflict of interest.

## References

- [1] Yang Z, Ni Y, Jiang B, 2024, The Application Effect of High-Quality Nursing Combined with Humanized Guidance in Interventional Operating Room in Cerebral Angiography. *Chinese Clinical Research*, 37(08): 1304–1308.
- [2] Hu J, 2022, Preventive Analysis of Unsafe Factors in Operating Room Nursing for Elderly Patients with Cardiovascular Diseases by Humanistic Care Nursing Model. *Electronic Journal of Integrated Traditional Chinese and Western*

Medicine on Cardiovascular Diseases, 10(33): 96–99.

- [3] Sun B, 2025, Nursing and Prevention of Intraoperative Hypothermia. *Health Must-Read*, 2025(2): 118.
- [4] An W, 2024, Research on the Preventive Effect of Quality Control Circle Management on Intraoperative Hypothermia in Elderly Patients. *Continuing Medical Education*, 38(12): 189–192.
- [5] Hu F, Li R, Zhong L, 2024, Analysis of the Preventive Effect of Early Heat Preservation Nursing on Hypothermia During Blood Purification in ICU Patients. *Chinese and Foreign Medical Research*, 22(36): 95–98.
- [6] Xia J, Zhao Y, 2024, The Application of Nursing Intervention Based on Strategy Optimization Management Model in Preventing Hypothermia in Elderly Patients During Surgical Operations. *General Practice Nursing*, 22(22): 4289–4292.
- [7] Hao B, Yan J, Zhu F, 2024, The Preventive Effect of External Application of Hot Compress Packs of Traditional Chinese Medicine on Intraoperative Hypothermia in Surgical Patients. *Modern Health Preservation*, 24(22): 1705–1708.
- [8] Wang S, Hu Y, Liu J, 2024, The Application Effect of Hypothermia Nursing in Laparoscopic Radical Resection of Rectal Cancer. *Chinese and Foreign Medical Research*, 3(25): 99–101.
- [9] Yang S, 2024, The Effect of Refined Insulation Measures on Preventing Hypothermia During Transurethral Resection of the Prostate in Elderly Patients. *Heilongjiang Journal of Traditional Chinese Medicine*, 53(04): 126–128.
- [10] Li H, He Y, Yan L, 2024, The Application of Modular Nursing for Preventing Hypothermia in Elderly Patients Undergoing Prostate Surgery. *China Medical Review*, 21(18): 125–128.
- [11] Xu J, Zou J, Hou Z, et al., 2024, Progress in Influencing Factors and Preventive Measures of Intraoperative Hypothermia in Laparoscopic Colorectal Cancer Surgery. *Jilin Medical Sciences*, 45(6): 1464–1468.
- [12] Zhou B, Tao C, 2024, Observation on the Application Effect of Hypothermia Prevention Nursing in Total Hip Arthroplasty. *Clinical Medical Engineering*, 31(6): 741–742.
- [13] Zhou Y, Zhu L, Liu L, et al., 2024, Construction of the Quality Index System for Intraoperative Hypothermia Nursing. *Chinese Journal of Nursing Management*, 24(4): 571–576.
- [14] Wang W, Qian J, Qian W, et al., 2024, The Evaluation Index System for the Prevention and Management of Perioperative Hypothermia in the Operating Room Was Constructed Based on the Delphi Method. *Shanghai Nursing*, 24(3): 26–30.
- [15] Qiu Y, Lan X, Zhang Y, et al., 2024, The Influence of Multimodal Insulation Combined with Cluster-Based Intervention Measures on Intraoperative Hypothermia, Stress Response and Rehabilitation in Patients Undergoing Laparoscopic Surgery. *Contemporary Chinese Medicine*, 31(18): 155–158.

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# Clinical Value of Quantitative Scoring Nursing Intervention for Adverse Reactions in PD-1 Monoclonal Antibody Treatment

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**Abstract:** *Objective:* To monitor the incidence of immune-related adverse events (irAEs) in patients treated with immune checkpoint inhibitors (ICIs) and programmed cell death protein-1 (PD-1), and to evaluate the effectiveness of nursing interventions using a quantitative scoring system. *Methods:* A retrospective analysis was performed on 65 cancer patients who received PD-1 therapy at the Oncology Department of Baotou Cancer Hospital from December 2023 to December 2024. The study examined the clinical features and blood test results related to irAEs. The National Cancer Institute's Common Terminology Criteria for Adverse Events (NCI-CTCAE) was used to grade the severity of these events, which were classified into five levels. Based on the NCI-CTCAE scores, appropriate nursing measures were implemented, and a comprehensive risk assessment framework was developed. *Results:* The study group showed lower complication rates, overall incidence, and average hospital stay compared to the control group ( $P < 0.05$ ). Among the 65 patients, twenty-eight (43.07%) experienced a total of 35 irAEs, with 2 (5.71%) being grade 3 or 4. The most frequent irAEs were dermatological conditions (34.29%), particularly rash with itching. The occurrence of irAEs did not correlate with patient gender, age, blood parameters (hemoglobin, white blood cell count, platelet count, etc.), or liver function ( $P > 0.05$ ), but it was associated with tumor type ( $P < 0.05$ ). *Conclusion:* PD-1 treatment is generally safe, with a low incidence of severe (grade 3 or higher) irAEs. Close monitoring is essential to ensure early detection, intervention, and management of irAEs, thereby maintaining a low level of adverse events and enhancing the safety and efficacy of PD-1 therapy. Implementing a quantitative risk scoring system for nursing care can decrease the rate of complications, enhance patient safety, and potentially reduce hospital stays and medical costs.

**Keywords:** Programmed cell death protein-1; Tumor; Adverse reactions; Quantitative rating; Nursing intervention; Clinical value research

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# 1. Introduction

Immune checkpoint inhibitors (ICIs), by inhibiting the suppressive regulatory molecules (i.e., checkpoints) of T-cell function on the surface of immune cells and tumor cells, can ensure the normal functioning of antigen-presenting cells (APCs), thereby stimulating the immune potential of T-cells and strengthening the immune response against tumors. Among the many T-cell checkpoints that may respond to this strategy, two specific target proteins, cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) and programmed death receptor-1 (PD-1), have been widely adopted and validated in clinical practice <sup>[1]</sup>. PD-1 immune checkpoint blockers are known as “broad-spectrum anticancer drugs” because they achieve antitumor effects by regulating the activity of the host immune system. They have demonstrated significant efficacy in the treatment of various tumors such as head and neck cancer, gastric cancer, melanoma, lymphoma, non-small cell lung cancer, liver cancer, renal cell carcinoma, colorectal cancer, squamous cell lung cancer, and urothelial carcinoma, and are being expanded into clinical trials for other tumor types. However, this approach is also associated with immune-related adverse events (irAEs) specific to tumor immunotherapy. The occurrence of irAEs stems from the activation of the body’s immune system by immune checkpoint inhibitors, which can cause nonspecific damage to normal cells, tissues, and organs while treating tumors, inducing a series of adverse consequences <sup>[2]</sup>. The scope of irAEs covers almost all organ systems and may occur at any time during immunotherapy <sup>[3]</sup>. Asmar *et al.* revealed that anti-PD-1 antibodies can significantly improve the short-term efficacy and survival rate of patients with advanced cancer <sup>[4]</sup>.

According to the NCI-CTCAE (National Cancer Institute - Common Terminology Criteria for Adverse Events) grading system, the severity of adverse events is subdivided into five levels. By carefully monitoring changes in the patient’s condition, implementing appropriate nursing strategies, and enhancing understanding of irAEs symptoms, it can boost patients’ belief in fighting the disease and promote their active cooperation with treatment. Quality nursing can not only improve treatment effects but also effectively reduce adverse events. Through targeted monitoring of the patient’s condition, deepening understanding of irAEs symptoms, and improving patients’ tolerance, medical staff should proactively provide professional knowledge guidance, psychological comfort, social assistance, and continuous nursing services to fully meet patients’ nursing needs. This will optimize nursing quality, promote good cooperation between patients and treatment plans, and enhance their confidence in overcoming the disease. In clinical practice, programmed death receptor-1 (PD-1) inhibitors among immune checkpoint inhibitors (ICIs) have been widely used in the treatment of various malignancies. Therefore, in-depth exploration of adverse events (irAEs) associated with their treatment is of great significance for optimizing clinical strategies and improving the quality of life of patients with malignancies. This study is a retrospective exploration focusing on the occurrence of irAEs in 65 patients with different types of malignancies who received PD-1 treatment for a total of 200 times in the oncology department of Baotou Cancer Hospital from December 2023 to December 2024, and conducted a detailed clinical analysis.

## 2. Clinical data

### 2.1. General information

The study included 65 patients with malignant tumors who received PD-1 immunotherapy at Baotou Cancer Hospital from the end of 2023 to the end of 2024. The patients ranged in age from 34 to 88 years old, with 47 males and 18 females. The types of diseases are diverse, including 14 cases of liver cancer, 17 cases of lung cancer, 9 cases of colon cancer, 6 cases of kidney cancer, 4 cases of malignant melanoma, 3 cases each of cervical

cancer and gastric cancer, 2 cases each of ovarian cancer and esophageal cancer, and 1 case each of bladder cancer, Hodgkin's lymphoma, throat cancer, and tongue cancer. Each patient received an average of 3.08 PD-1 treatments, totaling 200 treatments. It is worth noting that this study strictly excluded patients with liver and kidney dysfunction. For a deeper analysis, the study also selected another 65 patients who are hospitalized in the palliative oncology department of Baotou Cancer Hospital during the same period as the control group.

The National Cancer Institute-Common Terminology Criteria for Adverse Events (NCI-CTCAE) scoring system is used for quantitative evaluation. Based on the severity of adverse reactions, the system classifies them into five levels, allowing for personalized nursing plans to be developed. Through timely adjustment and optimization of the scoring criteria, a comprehensive nursing risk assessment framework is been established. This framework aims to improve treatment effectiveness and reduce the occurrence of immune-related adverse events (irAEs) through high-quality nursing services. By carefully monitoring patients' conditions and enhancing understanding of immune-related adverse reactions, patients' tolerance can be improved. During this process, medical staff actively provide professional knowledge, psychological counseling, social resource integration, and continuous nursing services to fully meet patients' nursing needs. This aims to improve the quality of care, promote patients' treatment compliance, and enhance their confidence in fighting the disease.

## **2.2. Methods**

### **2.2.1. Treatment**

In this study, an immune checkpoint inhibitor (ICI) that is approved by the US Food and Drug Administration (FDA) is adopted, specifically nivolumab targeting programmed death receptor-1 (PD-1). The drug is administered intravenously at a dose of 3 mg per kilogram of body weight, once every two weeks. Treatment continued until disease progression is observed or unmanageable side effects occurred, at which point treatment is terminated.

Before initiating treatment, the research team provided comprehensive information about PD-1 targeted therapy to the patients and their families, including potential benefits, possible risks, and expected adverse reactions. All participating patients signed informed consent forms based on their full understanding. During the treatment phase, drug dosages strictly followed the product instructions, and dosing intervals are flexibly adjusted based on the recommendations in the instructions or the patients' actual follow-up treatment schedules. Adverse reactions are evaluated according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0. Additionally, the implementation of this research project is formally approved by the Ethics Review Committee of Baotou Cancer Hospital.

### **2.2.2. Nursing care**

According to the NCI-CTCAE grading system, targeted nursing plans are implemented based on the severity of adverse reactions, which are subdivided into five levels:

#### **(1) Drug administration and nursing procedures**

Use 0.9% sodium chloride solution as a diluting medium, gently stir the drug until it is completely dissolved, and avoid vigorous shaking to ensure drug stability. The preparation process should follow the principle of immediate use, and the time span from preparation to the start of infusion should not exceed four hours. During the infusion process, a sterile filtered infusion device should be used, and the infusion rate should be precisely controlled with an infusion pump. A single drug infusion strategy should be implemented, and mixing with other drugs is strictly prohibited. The entire infusion duration should be

maintained between thirty to sixty minutes. After the infusion is completed, use 0.9% sodium chloride solution to flush the tubing, and simultaneously implement ECG monitoring to comprehensively monitor the patient's vital signs.

(2) Nursing strategies for immune-mediated adverse reactions

Anti-PD-1 monoclonal antibody therapy may induce a wide range of immune-related adverse reactions that can affect almost all organ systems in the body, including but not limited to the skin system, gastrointestinal system, liver, kidney, visual organs, endocrine glands, and even the central and peripheral nervous systems.

(3) Nursing practices for thyroid dysfunction

Among patients receiving anti-PD-1 monoclonal antibody therapy, approximately 10% experience varying degrees of immune-mediated adverse reactions in the endocrine system, with hypothyroidism being particularly prominent, occurring in up to 11% of patients with a median onset period of approximately 2.9 months <sup>[5]</sup>. In the patient samples included in this study, five cases are diagnosed with hypothyroidism. Their blood test results revealed that free triiodothyronine (FT3) concentrations are generally below the normal range, fluctuating between 2.90 and 3.60 pmol/L, while thyroid-stimulating hormone (TSH) concentrations are significantly elevated, ranging from 5.16 to 81.99 mIU/L. These patients presented with symptoms such as chills, fatigue, lethargy, loss of appetite, hypoglycemia, nausea, and vomiting. Physicians recommended that patients take Euthyrox (levothyroxine sodium) and emphasized that patients should not change the medication dosage without consultation. Additionally, physicians explained the potential adverse reactions of the medication and the pathogenesis of hypothyroidism to patients and their families to alleviate their anxiety. After discharge, patients need to regularly monitor blood electrolytes and thyroid function indicators, and pay close attention to changes in their behavior and mental state. In case of symptoms related to hypothyroidism, they should seek medical attention and take corresponding treatment measures immediately. After effective treatment, the serum FT3 levels of these five patients returned to the normal range, fluctuating between 4.51 and 5.92 pmol/L, and their serum TSH levels also dropped to the normal range, ranging from 1.30 to 4.8 mIU/L.

(4) Nursing strategies for skin side effects

Among the various adverse reactions caused by immunotherapy, skin toxicity effects are particularly significant, tending to emerge around the fifth week of treatment <sup>[6]</sup>. Specifically, minor skin side effects are most common, with the incidence of rash fluctuating between 28% and 37%. In contrast, more severe skin reactions such as psoriasis and erythema multiforme are rare, typically affecting the limbs and trunk areas of patients. The root cause of symptoms such as rash and itching induced by anti-PD-1 monoclonal antibody therapy lies in the antibody's blockage of the interaction between tumor tissue and shared antigens in the skin <sup>[7]</sup>. On the eve of drug infusion, nursing staff need to fully explain the specific manifestations and symptoms of potential skin side effects to patients, so that they can be psychologically prepared and remain calm when the rash appears. Following medical advice, nursing staff should continuously administer anti-allergic agents such as dexamethasone and cimetidine via intravenous pumps. After administration, patients' skin conditions should be closely monitored, and nursing staff should listen patiently to patients' subjective feelings and feedback. Once a rash appears on the patient's skin, nursing staff should guide them to apply urea cream externally and record the initial time point, exact location, and symptom details of the skin side effects.

Additionally, nursing staff should advise patients to avoid squeezing blisters or pimples in the rash area to prevent skin breakage and infection. At the same time, patients are recommended to trim their nails to reduce the risk of infection due to scratching. It is crucial to maintain cleanliness and hygiene of the surrounding skin, which can be cleaned with neutral soap, but avoid using hot water for soaking. Choose soft and loosely fitted cotton clothing, and ensure that the bedding is clean and dry. When patients are engaged in outdoor activities, they should be careful to avoid direct sunlight exposure, as this may exacerbate skin side effects. For patients with allergic constitutions, nursing staff should remind them to moderately reduce their intake of beef, mutton, and seafood during medication to lower the risk of potential allergic reactions. At the same time, patients should be clearly informed that when local skin is affected by a rash, it usually does not leave lasting scar marks. Skin adverse reactions induced by anti-PD-1 monoclonal antibodies often exhibit a self-limiting characteristic.

Nursing staff should assume the responsibility of comforting patients' emotions, ensuring that they can receive treatment without worries, thereby effectively relieving their inner anxiety and unease. In the case population included in this study, a total of 4 individuals were observed to have skin adverse reactions. Specifically, two patients suffered from skin hemangioma, and no special intervention measures were taken. The symptoms gradually resolved spontaneously with the discontinuation of the drug. Another patient developed a rash accompanied by itching in the lower extremity area after receiving medication for the first time, but fortunately, it did not progress to ulceration or suppuration. The symptoms are significantly relieved after a week of external treatment with urea ointment. In addition, a patient encountered a recurrence of psoriasis after receiving the fourth medication and is subsequently transferred to another hospital for targeted treatment. After several treatments, the symptoms showed a trend of improvement.

#### (5) Nursing strategies for pulmonary diseases

When discussing nursing measures for immunotherapy-related pneumonia, it must be mentioned that the immune-related pneumonia that may be induced by the use of anti-PD1 monoclonal antibodies, whose main clinical manifestation is nonspecific interstitial pneumonia <sup>[8]</sup>. The onset time of such adverse reactions varies widely, typically ranging from 0.5 to 24.3 months after medication, with a median onset time concentrated between 2 to 2.6 months <sup>[9, 10]</sup>. Given this, nursing staff must maintain a high level of vigilance during the entire cycle of patients receiving drug treatment and closely monitor patients' vital signs. Once patients develop new cough symptoms or clinical manifestations such as dyspnea that may be related to impaired lung function, the nursing staff should immediately notify the attending physician and quickly arrange for the patient to undergo a chest CT scan to comprehensively evaluate and analyze the lung condition.

Among the patient population, one patient unfortunately developed interstitial lung disease after the second drug treatment, with clinical manifestations including worsened cough and shortness of breath induced by physical activity. With the help of computed tomography (CT) technology, the medical team observed areas of ground-glass opacity in the lungs. As a result, the doctor quickly discontinued the patient's medication and initiated high-dose glucocorticoid therapy. After two weeks of careful treatment, the patient's symptoms gradually improved. Additionally, another patient developed a complex condition of interstitial lung disease accompanied by heart failure after the fourth drug administration. He reported a strong feeling of chest compression, difficulty breathing, and could only breathe with difficulty while

sitting upright. CT scan results showed reticular and nodular images in the lungs, accompanied by fluid retention in the pleural and pericardial cavities. In response to this situation, the doctor performed thoracentesis to reduce the pressure of the fluid accumulation, provided comprehensive treatment measures including strengthening the heart, promoting diuresis, and fighting infection, and supplemented with adequate glucocorticoids. After three weeks of systematic treatment, the patient's condition also showed a gradual improvement.

#### (6) Nursing strategies for fever symptoms

Fever is a common immune-related adverse event, and its pathogenesis involves the release of cytokines and nonspecific activation of immune responses. Before treatment with programmed death receptor-1 (PD-1) monoclonal antibodies, standard procedures require temperature monitoring, and continuous monitoring of dynamic changes in body temperature during and after drug infusion. In case of high fever symptoms, physical methods should be prioritized for cooling treatment, and drug cooling such as antipyretic and analgesic tablets, indomethacin suppositories, and compound aminopyrine injections can be implemented when necessary.

Simultaneously, patients should be encouraged to increase water intake and provided with a nutritious diet rich in calories, protein, and vitamins. Additionally, it is necessary to ensure good air circulation, a fresh and pleasant environment in the ward, and appropriate temperature control to prevent patients from getting chilled again. In this group of cases, one patient developed transient fever during the drug infusion process, with a temperature rise to 38 °C. The medical staff quickly guided the patient to increase hot water intake and assisted with warm water sponging care, and the patient's temperature gradually returned to the normal range.

## 2.3. Statistical analysis

The collected data is analyzed using the SPSS statistical software package (version 22.0). For categorical variables, percentages is used for description. To compare differences between groups, chi-square ( $\chi^2$ ) test is performed. The level of statistical significance is set at a P-value less than 0.05, which is used as the criterion to determine whether the differences between groups are statistically significant.

## 3. Results

### 3.1. Occurrence of irAEs

Among a total of 65 cases (accounting for 43.08% of the patients), the occurrence of 75 immune-related adverse events (irAEs) was observed. Among these, two cases (accounting for 5.71%) were classified as severe irAEs of grade 3 or 4. The most frequent type of irAEs was skin system disorders (accounting for 34.29%), and most of them manifested as rash phenomena accompanied by itching symptoms (see Table 1 for details). Based on the consensus guidelines published by the American Society of Clinical Oncology, the recommended management for low-grade irAEs is to suspend treatment with immune checkpoint inhibitors (ICIs) and implement continuous disease monitoring <sup>[11]</sup>. For grade 2 or more severe irAEs, the use of steroid hormones is recommended as a treatment approach. The results are shown in **Table 1**.

**Table 1.** Occurrence of 35 adverse reactions in 28 patients

Class	Total number of times	Percentage %	Level 1–2 / times	Level 3 > / times
Skin	12	34.29	11	1
Erythra	6			
Pruritus	4			
Spiloplaxia	1			
Acute posterior ganglionitis	1			
Gastrointestinal reaction	4	11.43	4	0
Diarrhoea	2			
Stomatitis	2			
Renal inadequacy	2	5.71	2	0
Pneumonia	2	5.71	2	0
Pneumonia	2	5.71	2	0
Hepatobiliary reaction	9	25.71	8	1
Other	6	17.14	6	0
Cerebritis	1			
Diabetes mellitus	2			
Initis	2			
Neuroinflammation	1			

### 3.2. Exploration of the association between patient baseline characteristics and irAEs

In statistical analysis, we found that the occurrence of irAEs did not show a significant correlation with patient gender ratio, age level, blood routine indicators (including hemoglobin level, white blood cell count, platelet count, etc.), and liver function status (all  $P$ -values > 0.05). However, it is worth noting that there was a statistically significant difference between tumor classification and the occurrence of irAEs ( $P$ -value < 0.05). The results are shown in **Table 2**.

**Table 2.** Comparison of other clinical characteristics between patients with and without irAEs

Baseline data	Happen irAEs (N = 28) / case	No irAEs have occurred (N. = 28) / case	$\chi^2$	$P$
Sex			0.710	0.40
Man	22	32		
Woman	6	5		
Age / year			0.288	0.60
> 60	22	31		
< 60	6	6		
Hemoglobin			1.837	0.40
Lower than normal	13	12		
Normal value	6	13		

**Table 2 (Continued)**

Baseline data	Happen irAEs (N = 28) / case	No irAEs have occurred (N. = 28) / case	$\chi^2$	P
Higher than normal	9	12	1.030	0.59
Leucocyte count				
Lower than normal	6	12		
Normal value	14	15	0.274	0.87
Higher than normal	8	10		
Platelet count				
Lower than normal	6	10	1.403	0.24
Normal value	12	15		
Higher than normal	10	12		
Absolute values of the lymphocytes			0.371	0.54
Normal value	11	19		
Lower than normal	17	16		
Absolute values of the monocytes			0.010	0.92
Normal value	15	17		
Lower than normal	13	20		
Albumin			0.014	0.91
Normal value	11	15		
Lower than normal	17	22		
Lactate dehydrogenase			14.15	0.03
Normal value	17	23		
Lower than normal	11	14		
Tumor type			14.15	0.03
Gastric cancer	4	2		
Carcinoma of the lungs	15	6		
Renal cell carcinoma, and the urinary tract	4	12	14.15	0.03
Skin and bladder cancer	2	6		
Malignant mela noma	1	3		
Head and Neck Cancers	1	4	14.15	0.03
Malignant pleural mesothelioma	1	4		

## 4. Discussion

Immune checkpoint blockade therapy has opened up broad prospects in the field of oncology treatment. However, along with its significant efficacy, it also induces a series of side effects mediated by non-specific immune overactivation, which are often referred to as immune-related adverse events (irAEs) in medical literature <sup>[12]</sup>.

Although cases of severe irAEs are relatively rare, without timely and appropriate intervention measures, such events can pose a potential threat to life. Studies have shown that among patients treated with PD-1/PD-L1 and CTLA-4 inhibitors, 15% and 20% experienced  $\geq 3$  grade irAEs during immunotherapy, respectively <sup>[13]</sup>. The timing of irAEs is uncertain, as they can occur during treatment or at any time after treatment discontinuation.

Most cases occur within a 3-to-6-month window after the initial administration, but recurrence within one year of treatment is not uncommon <sup>[14]</sup>. irAEs can affect any tissue or organ in the body, with common sites reported in the literature including the lungs (5% to 53%), skin (34% to 45%), gastrointestinal tract (less than 19%), endocrine system (5% to 10%), liver (5%), as well as rheumatic/skeletal muscle lesions (15%) and infusion-related reactions (10%). Comparatively, involvement of the heart (less than 1%), nervous system (6.1%), eyes (less than 1%), blood system, and kidneys (less than 5%) is less common <sup>[15]</sup>.

In this study, the overall incidence of irAEs was recorded as 43.08%, which is similar to previously reported values <sup>[16]</sup>. Among the study samples, skin diseases were the most common irAEs, especially rashes with dry skin and itching symptoms. Only one patient experienced grade 3 or higher skin lesions. In terms of severity, most skin disease patients can be effectively managed through topical moisturizers, oral antihistamines, and topical steroid hormones. In clinical practice, reducing the dose of immune checkpoint inhibitors (ICIs) or discontinuing treatment to prevent irAEs should be done with caution. Healthcare professionals need to maintain high vigilance to identify and scientifically manage irAEs early, thus ensuring the safety and effectiveness of treatment.

In the treatment of malignant tumors, compared to traditional chemotherapy, the use of anti-PD-1/PD-L1 therapy induces adverse events with a lower incidence, better patient tolerance, and rare fatal cases. Studies by Zhang *et al.* have revealed a significant positive correlation between the frequency of immune-related adverse events (irAEs) and tumor treatment efficacy and patient survival time <sup>[17]</sup>. Given the rapid onset of irAEs, timely medical intervention and care are particularly important, especially for elderly patient populations, who require meticulous monitoring of these potential toxic reactions to effectively prevent potential irAEs. Xu *et al.*, through a comprehensive review of recent advances in PD-1 inhibitor-related immune adverse reactions, concluded that PD-1-related irAEs are characterized by randomness, widespread involvement, and difficulty in control <sup>[16]</sup>. Therefore, it is essential to strengthen real-time detection mechanisms, take early intervention measures, and thoroughly explain relevant risks to patients before medication, ensuring their informed consent.

In summary, when applying immune checkpoint inhibitors (ICIs) in clinical practice, physicians should maintain high vigilance regarding adverse reactions while striving to improve anti-tumor efficacy. Clinicians should be proficient in diagnosing various irAEs and implementing the most effective treatment strategies, aiming for early detection, intervention, and treatment. This approach can control the severity of irAEs, ensuring the safety of ICIs in clinical applications, thereby extending the survival of cancer patients and enhancing treatment effectiveness.

## 5. Conclusion

Anti-programmed death receptor-1 (PD-1) monoclonal antibodies have demonstrated remarkable therapeutic efficacy for patients with advanced lung cancer, offering a new ray of hope for this patient population <sup>[18]</sup>. However, while enjoying the benefits of this treatment, a series of immune-mediated adverse reactions have also emerged, highlighting the importance of effective nursing strategies. Professional nursing intervention can help patients identify and avoid potential adverse reactions, teach self-monitoring skills, and ensure that once symptoms

appear, patients can closely collaborate with the medical team to quickly implement appropriate intervention measures, thereby optimizing the management of adverse reactions.

The core of nursing work focuses on the following aspects: Before treatment, nursing staff need to provide detailed education and guidance to patients and their families, provide necessary psychological comfort, enhance their understanding of the treatment process, and reduce unnecessary psychological burden. During the drug preparation stage, nursing staff must follow strict operating procedures, precisely control the infusion time and rate, and ensure the safety of the medication process. During treatment, patients' vital signs are continuously monitored using electrocardiographic monitoring equipment to capture any abnormal signs as early as possible. Additionally, nursing staff need to listen carefully to every complaint from patients, immediately notify doctors and handle any adverse reaction signs properly, and keep detailed records to lay a solid foundation for subsequent clinical decisions. It is worth noting that due to the limited sample size of this study, it may not cover all possible immune-related adverse reactions caused by PD-1 monoclonal antibodies.

Therefore, nursing staff should continue to pay attention to new trends in immune adverse reactions in clinical practice, continuously accumulate nursing wisdom, deepen the practice of detailed nursing, and gradually optimize nursing plans. Currently, the influence of anti-PD-1 monoclonal antibodies is expanding in clinical practice. While celebrating their efficacy, equal emphasis needs to be placed on medication safety, avoiding interference from severe adverse reactions during the treatment journey. Only in this way can it be ensured that patients obtain maximum benefits from treatment.

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## Disclosure statement

The authors declare no conflict of interest.

## References

- [1] Friedman CF, Proverbs-Singh TA, Postow MA, 2016, Treatment of the Immune-Related Adverse Effects of Immune Checkpoint Inhibitors: A Review. *JAMA Oncol*, 2(10): 1346–1353.
- [2] Tang S, Li L, Hou L, 2021, Research Progress on Immune-Related Adverse Reactions of PD-1 Inhibitors. *Journal of Clinical and Pathological Research*, 41(3): 720–725.
- [3] Wang PF, Chen Y, Song SY, et al., 2017, Immune-Related Adverse Events Associated with Anti-PD-1/PD-L1 Treatment for Malignancies: A Meta-Analysis. *Front Pharmacol*, 8: 730.
- [4] Schneider BJ, Naidoo J, Santomasso BD, et al., 2021, Management of Immune-Related Adverse Events in Patients Treated with Immune Checkpoint Inhibitor Therapy: ASCO Guideline Update. *J Clin Oncol*, 39(36): 4073–4126.
- [5] Lv H, Zhuang W, Huang Y, et al., 2020, Observation on the Efficacy and Prognosis of PD-1/PD-L1 Inhibitors in the Treatment of NSCLC. *Oncology Progress*, 18(3): 279–281.
- [6] Martins F, Sofiya L, Sykietis GP, et al., 2019, Adverse Effects of Immune-Checkpoint Inhibitors: Epidemiology, Management and Surveillance. *Nat Rev Clin Oncol*, 16(9): 563–580.
- [7] Wright JJ, Powers AC, Johnson DB, 2021, Endocrine Toxicities of Immune Checkpoint Inhibitors. *Nat Rev Endocrinol*,

17(7): 389–399.

- [8] Wang Z, Song Y, 2020, Immunotherapy with Checkpoint Inhibitors for Lung Cancer: From Clinical Research to Clinical Practice. *Chinese Journal of Tuberculosis and Respiratory Diseases*, 43(2): 95–99.
- [9] Baxi S, Yang A, Gennarelli RL, et al., 2018, Immune-Related Adverse Events for Anti-PD-1 and Anti-PD-L1 Drugs: Systematic Review and Meta-Analysis. *BMJ*, 360: 793.
- [10] Qin Shukui, Guo Jun, Li Jin. Guidelines for the Management of Immune Qin S, Guo J, Li J, 2019, Guidelines for the Management of Immune Checkpoint Inhibitor-Related Toxicities by the Chinese Society of Clinical Oncology (CSCO). People's Medical Publishing House, China.
- [11] Thompson JA, Schneider BJ, Brahmer J, et al., 2019, Management of Immunotherapy-Related Toxicities, Version 1.2019. *J Natl Compr Canc Netw*, 17(3): 255–289.
- [12] Wei S, 2020, Current Status and Progress of Neoadjuvant Immunotherapy for Resectable NSCLC. *Cancer*, 39(3): 95–103.
- [13] Zhou J, Wang H, Guo X, et al., 2020, Management of Immune Checkpoint Inhibitor-Related Rheumatic Adverse Events. *Thorac Cancer*, 11(1): 198–202.
- [14] Zhang S, Yang L, Gu K, 2022, Prognostic Value of Immune-Related Adverse Events in Patients with Advanced Cancer Treated with PD-1/PD-L1 Inhibitors. *Journal of Clinical Oncology*, 27(2): 109–115.
- [15] Su C, Wang H, Liu Y, et al., 2020, Adverse Effects of Anti-PD-1/PD-L1 Therapy in Non-Small Cell Lung Cancer. *Front Oncol*, 10: 554313.
- [16] Xu Y, Liu Y, 2020, Research Progress on Immune-Related Adverse Reactions of PD-1/PD-L1 Inhibitors. *Journal of Practical Oncology*, 35(6): 491–494.
- [17] Ge C, 2022, Clinical Observation of Adverse Reactions During the Treatment of Tumor Immune Checkpoint Inhibitor PD-1. *Journal of Clinical and Pathological Research*, 42(7): 1601–1606.
- [18] Liu T, Hu Y, 2018, Review of Immune-Related Adverse Reactions and Their Management of PD-1/PD-L1 Inhibitors. *Academic Journal of Chinese PLA Medical School*, 39(3): 251–252.

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# Observation on the Effect of Internal Limiting Membrane Flipping and Covering Technique in the Treatment of High Myopic Macular Hole

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**Abstract:** *Objective:* To evaluate the effectiveness of the internal limiting membrane (ILM) flipping and covering technique in the treatment of patients with high myopic macular hole (HMMH). *Methods:* One hundred and two patients with HMMH who were admitted to the hospital from June 2019 to June 2024 were selected. The minimum diameter of the macular hole (MH) in all patients was  $\leq 500\mu\text{m}$ . The patients were randomly divided into two groups. The experimental group received 25G pars plana vitrectomy (PPV) combined with ILM flipping and covering technique, while the reference group received PPV combined with ILM peeling. The efficacy indicators and best corrected visual acuity levels were compared between the two groups. *Results:* The MH closure rate and retinal reattachment rate were higher in the experimental group than in the reference group at 3 and 6 months postoperatively ( $P < 0.05$ ). The best corrected visual acuity level was higher in the experimental group than in the reference group at 3 and 6 months postoperatively ( $P < 0.05$ ). The Chinese version of the Visual Function-Related Quality of Life Questionnaire-25 (CVRQOL-25) score was higher in the experimental group than in the reference group at 3 and 6 months postoperatively ( $P < 0.05$ ). No serious complications were observed in both groups postoperatively, and there was no difference between the two groups ( $P > 0.05$ ). *Conclusion:* The ILM flipping and covering technique can improve the MH closure rate and retinal reattachment rate in patients with HMMH (diameter  $\leq 500\mu\text{m}$ ), enhance the best corrected visual acuity level, and improve the quality of life related to visual function, with fewer postoperative complications.

**Keywords:** Internal limiting membrane flipping; Internal limiting membrane peeling; High myopic macular hole

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## 1. Introduction

HMMH is a common comorbidity for patients with high myopia, and its pathogenesis is complex, involving various factors such as vitreous traction, thinning of the macular retinal area, and axial length extension. Symptoms can include decreased vision, floaters, or distorted vision, which can long-term affect patients' daily lives<sup>[1]</sup>. PPV combined with internal limiting membrane peeling is a commonly used surgical method for this disease, which can

significantly relieve disease symptoms, but it is difficult to improve patients' visual function, and the MH closure rate is limited. Comparatively, the internal limiting membrane flap technique is suitable for patients with large-diameter macular holes, which can maximize hole closure and improve surgical effectiveness<sup>[2]</sup>. Therefore, this study selected 102 patients with HMMH (diameter  $\leq 500\mu\text{m}$ ) to evaluate the implementation effect of the internal limiting membrane flap technique.

## 2. Materials and methods

### 2.1. General information

One hundred and two patients with HMMH (diameter  $\leq 500\mu\text{m}$ ) admitted to the hospital from October 2019 to October 2024 are included and randomly divided into two groups. The experimental group consisted of 51 patients, including 31 males and 20 females, aged between 40–79 years old, with a mean age of  $(55.18 \pm 4.16)$  years. The course of disease ranged from 3–15 months, with a mean duration of  $(9.15 \pm 1.75)$  months. The axial length ranged from 26–31mm, with a mean of  $(28.97 \pm 1.48)\text{mm}$ . The minimum diameter of MH ranged from 400–410 $\mu\text{m}$ , with a mean of  $(404.53 \pm 14.26)\mu\text{m}$ . The control group consisted of 51 patients, including 29 males and 22 females, aged between 41–78 years old, with a mean age of  $(55.20 \pm 4.24)$  years. The course of disease ranged from 4–14 months, with a mean duration of  $(9.09 \pm 1.71)$  months. The axial length ranged from 27–33mm, with a mean of  $(28.88 \pm 1.45)\text{mm}$ . The minimum diameter of MH ranged from 401–411 $\mu\text{m}$ , with a mean of  $(404.72 \pm 14.48)\mu\text{m}$ . There was no statistically significant difference between the two groups ( $P > 0.05$ ).

Inclusion criteria: Patients are confirmed as having high myopia through fundus examination, with an axial length between 26–33mm. A comprehensive diagnosis of MH was made based on optical coherence tomography (OCT) and fundus angiography. Patients were adults, had normal communication skills and consciousness, complete clinical data, and were highly informed about the study. Exclusion criteria: Patients with a history of ocular trauma or surgery, other ocular diseases, coagulation or immune system abnormalities, malignancies, organ dysfunction, or mental illnesses are excluded.

### 2.2. Methods

All patients underwent ophthalmic examinations such as best-corrected visual acuity, non-contact intraocular pressure, and OCT before surgery to ensure that they met the surgical indications. The same surgeon performed the operation, using a minimally invasive three-channel (25G) vitrectomy at the pars plana and precise excision with a wide-angle lens. Triamcinolone acetonide is selected as the staining agent, and indocyanine green is used to stain the internal limiting membrane at a concentration of 5g/L.

The experimental group is combined with the internal limiting membrane flap technique. The internal limiting membrane is torn along the MH using a circular tearing method, with a diameter of about two times the diameter of the optic disc. The vitrectomy probe is used to moderately preserve the internal limiting membrane at the edge of the MH, ensuring it is not disconnected. The residual tissue of the internal limiting membrane is flipped to cover the MH. Subsequently, gas-liquid exchange treatment is performed to smoothly discharge the fluid under the retina, and the internal limiting membrane flap was flipped into the macular hole to fill the area.

The control group is treated with internal limiting membrane peeling, completely peeling off the internal limiting membrane within the range of the vascular arch. Gas-liquid exchange is performed, and the incision is sutured with an 8-0 suture after confirming no leakage at the puncture site and the presence of bubbles under

the conjunctiva. After surgery, patients in both groups are instructed to keep their faces downward for 3 days to promote MH closure.

## 2.3. Observation indicators

### (1) Therapeutic effect indicators

(a) MH closure rate: OCT examination is performed. If the two sides of the fissure are tightly fitted and connected, it is considered as completely closed; if there are pores at the broken end of the fissure that are in contact with the retinal pigment epithelium, it is considered as an exposed closure; if the broken end of the fissure is raised and the retina is detached, it is considered as unclosed. The completely closed state is recorded as the closure rate.

(b) Retinal reposition: If the retinal pigment epithelium in the macular area is tightly fitted to the neuroepithelium, it is considered as successfully repositioned.

### (2) Best corrected visual acuity level

Preoperatively and postoperatively at 1, 3, and 6 months, the best corrected visual acuity level is evaluated using the international standard logarithmic visual acuity chart and converted to the logarithm of the minimum angle of resolution (Log MAR) value.

### (3) Complication rate

Observe the probabilities of intraocular infection, visual field defects, elevated intraocular pressure, and poor incision closure.

### (4) Quality of life score

The Chinese version of the Vision-Related Quality of Life Questionnaire-25 (CVRQOL-25) is used, which contains 25 questions in 12 categories, all related to visual function, specifically including near activities, overall health, distance activities, social functioning, peripheral vision, mental health, dependence, and color vision. Each question is scored from 0 to 100, with intervals of 25 corresponding to grades A to E. The average score for each category is recorded, and the total score of the questionnaire is converted to a scale of 0 to 100, with higher scores indicating better quality of life.

## 2.4. Statistical analysis

Data processing is done using SPSS 28.0 software. Measurement values are compared and tested using t-values, while count values are compared and tested using chi-square values. The criterion for statistical significance is a  $P$ -value  $< 0.05$ .

## 3. Results

### 3.1. Comparison of therapeutic effect indicators between the two groups

At 3 and 6 months postoperatively, the MH closure rate and retinal reposition rate in the experimental group were higher than those in the reference group ( $P < 0.05$ ). The results are shown in **Table 1** and **Table 2**.

**Table 1.** Comparison of therapeutic effect indicators between the two groups at 3 months postoperatively [n/%]

Group	Number of cases	MH closure rate			Retinal reattachment rate
		Complete closure	Exposed closure	Not closed	
Experimental group	51	43(84.31)	6(11.76)	2(3.92)	50(98.04)
Control group	51	34(66.67)	10(19.61)	7(13.73)	44(86.27)
$\chi^2$	-	4.292	1.186	3.047	4.883
<i>P</i>	-	0.038	0.276	0.081	0.027

**Table 2.** Comparison of therapeutic effect indicators between the two groups at 6 months postoperatively [n/%]

Group	Number of cases	MH closure rate			Retinal reattachment rate
		Complete closure	Exposed closure	Not closed	
Experimental group	51	49(96.08)	2(3.92)	0	51(100.00)
Control group	51	41(80.39)	6(11.76)	4(7.84)	46(90.20)
$\chi^2$	-	6.044	2.170	4.163	5.258
<i>P</i>	-	0.014	0.141	0.041	0.022

### 3.2. Comparison of best corrected visual acuity between the two groups

There was no difference in the best corrected visual acuity between the two groups before surgery and at 1 month postoperatively ( $P > 0.05$ ). However, at 3 and 6 months postoperatively, the best corrected visual acuity in the experimental group was higher than that in the reference group ( $P < 0.05$ ). The results are shown in **Table 3**.

**Table 3.** Comparison of best corrected visual acuity between the two groups [ $\bar{x} \pm s$ , Log MAR]

Group	Number of Cases	Pre-operation	1 Month Post-operation	3 Months Post-operation	6 Months Post-operation
Experimental group	51	0.14 $\pm$ 0.05	0.31 $\pm$ 0.12	0.40 $\pm$ 0.10	0.47 $\pm$ 0.11
Control group	51	0.12 $\pm$ 0.07	0.30 $\pm$ 0.14	0.35 $\pm$ 0.08	0.42 $\pm$ 0.08
<i>t</i>	-	1.660	0.387	2.788	2.625
<i>P</i>	-	0.100	0.699	0.006	0.010

### 3.3. Comparison of complication rates between the two groups

The complication rate in the experimental group was similar to that in the reference group ( $P > 0.05$ ). The results are shown in **Table 4**.

**Table 4.** Comparison of complication rates between the two groups [n/%]

Group	Number of cases	Intraocular infection	Visual field defect	Increased intraocular pressure	Poor incision closure	Incidence rate
Experimental group	51	1(1.96)	0	1(1.96)	0	3.92(2/51)
Control group	51	1(1.96)	1(1.96)	1(1.96)	1(1.96)	7.84(4/51)
$\chi^2$	-	-	-	-	-	0.708
<i>P</i>	-	-	-	-	-	0.400

### 3.4. Comparison of quality of life scores between the two groups

Before surgery and at 1 month postoperatively, the quality of life scores in the experimental group were similar to those in the reference group ( $P < 0.05$ ). However, at 3 and 6 months postoperatively, the quality of life scores in the experimental group were higher than those in the reference group ( $P < 0.05$ ), as shown in **Table 5**.

**Table 5.** Comparison of quality of life scores between the two groups [ $\bar{x} \pm s$ , points]

Group	Number of cases	Pre-operation	1 Month post-operation	3 Months post-operation	6 Months post-operation
Experimental Group		50.17 $\pm$ 3.53	59.19 $\pm$ 3.14	68.14 $\pm$ 3.41	72.65 $\pm$ 4.18
Control Group	51	50.22 $\pm$ 3.49	55.09 $\pm$ 3.21	64.02 $\pm$ 3.17	66.48 $\pm$ 4.32
<i>t</i>	-	0.072	6.521	6.319	7.330
<i>P</i>	-	0.943	< 0.001	< 0.001	< 0.001

## 4. Discussion

High myopia is a risk factor for macular hole (MH), and the two often coexist<sup>[3, 4]</sup>. The pathogenic factors of high myopia macular hole (HMMH) include persistent traction on the macular area by the epiretinal membrane or posterior cortical vitreous, as well as vitreous degeneration and posterior scleral staphyloma. After the appearance of a hole in the macular area, surrounding glia continuously release cytokines, exacerbating inflammatory reactions, which leads to the generation of a large amount of collagen fibers. This can further increase traction forces, causing the hole to gradually expand. Common surgical procedures for this disease include posterior scleral buckling or pars plana vitrectomy (PPV), which can quickly reposition the retina and improve symptoms such as metamorphopsia. However, these procedures have limited effectiveness in healing MH and improving visual function, resulting in general long-term treatment effects and a high risk of recurrence<sup>[5]</sup>.

Internal limiting membrane (ILM) peeling is a commonly used adjunctive procedure in PPV. It involves the removal of a large area of the ILM, which can rapidly relieve the traction forces exerted by the ILM, thereby improving the MH closure rate. Additionally, peeling treatment can prevent hole recurrence, stabilize surgical efficacy, and prevent adverse events such as vision loss due to hole reopening<sup>[6]</sup>. However, this surgical procedure carries a high risk and can easily lead to complications such as intraocular infection. More importantly, ILM peeling can alter the retinal structure, potentially affecting its function. This can result in significant thinning of the retinal nerve fiber layer, which may induce retinal pathology and negatively impact disease prognosis. ILM flap technique can repair glial cells and act as a scaffold for proliferative tissue in MH. This improves photoreceptor cell function, allowing these cells to accumulate in the center of the hole, thereby filling the hole, extending the length of the retina, and ultimately repairing the hole. As a result, the macular morphology of HMMH patients can be significantly improved, and their best-corrected visual acuity (BCVA) can be enhanced<sup>[7, 8]</sup>.

The results showed that the MH closure rate and retinal reposition rate at 3 and 6 months postoperatively were higher in the experimental group than in the reference group ( $P < 0.05$ ). At 3 and 6 months postoperatively, the BCVA and quality of life scores were also higher in the experimental group than in the reference group ( $P < 0.05$ ). The reason for this may be that after ILM flap technique treatment, gas absorption may cause slight drift of the flap, leading to closure failure in a few patients. Overall, however, the ILM flap technique is highly feasible. The use of a circular peeling technique during surgery allows for appropriate removal of the ILM, thereby eliminating

various factors that pull on the macular area. This can relax the retina, restore RT levels, and promote effective hole closure<sup>[9]</sup>. Additionally, the flap technique adequately preserves the hole edges and flips the ILM to the MH site, functioning as a biological scaffold. This promotes effective proliferation of neuroepithelial cells, enabling the retina to grow towards the center of the hole, closing the hole and repositioning the retina<sup>[10]</sup>.

The complication rate in the experimental group was similar to that in the reference group ( $P > 0.05$ ). This may be due to the mature surgical techniques used in the combined procedures, which can provide nutritional support to the whole area while relieving traction. These procedures also enhance the adhesion between cells and the extracellular matrix, ensuring that the ILM closely adheres to the retina and preventing conditions such as visual field defects<sup>[11]</sup>. Furthermore, the use of a minimally invasive three-channel approach for vitrectomy in these procedures allows for smaller incisions, reducing the risk of bleeding and infection. Coupled with reasonable handling of the ILM to prevent excessive peeling, these techniques minimize retinal damage and postoperative complications<sup>[12]</sup>.

## 5. Conclusion

In conclusion, the ILM flap technique can enhance the clinical efficacy of HMMH patients (with a diameter  $\leq 500\mu\text{m}$ ). It not only restores vision but also reduces complications and significantly improves patients' quality of life. The surgical feasibility of this technique is high.

## Disclosure statement

The author declares no conflict of interest.

## References

- [1] Hao Z, 2020, Clinical Efficacy of Vitrectomy Combined with Internal Limiting Membrane Peeling in the Treatment of Macular Hole in High Myopia. *Journal of Practical Medicine*, 37(2): 114–116.
- [2] Fu Z, Wang R, Xu Y, et al., 2022, Observation on the Curative Effect of Vitrectomy Combined with Internal Limiting Membrane Peeling in the Treatment of Macular Hole in High Myopia. *Practical Blindness Prevention Technology*, 17(1): 17–19.
- [3] Li N, Xiao L, 2020, Analysis of the Efficacy of Vitrectomy with Internal Limiting Membrane Peeling in the Treatment of Retinal Detachment Caused by Macular Hole in High Myopia. *Capital Food and Medicine*, 27(21): 17–18.
- [4] Li W, Wang R, Tang W, 2025, Effect of Vitrectomy Combined with Internal Limiting Membrane Inversion and Tamponade in the Treatment of Retinal Detachment Caused by Macular Hole in Patients with High Myopia. *Kangmin Medical Journal of China*, 37(4): 47–50.
- [5] Zhu W, Li W, Xu P, 2023, PPV Combined with Internal Limiting Membrane Inversion and Tamponade in the Treatment of Retinal Detachment Caused by Macular Hole in High Myopia. *International Journal of Ophthalmology*, 23(4): 640–643.
- [6] Wang C, Zhou J, Yao T, et al., 2024, Comparison of the Efficacy of Human Amniotic Membrane Tamponade and Internal Limiting Membrane Inversion Tamponade in the Treatment of Retinal Detachment Caused by Macular Hole in High Myopia. *Chinese Journal of Experimental Ophthalmology*, 42(1): 47–52.
- [7] Pan Y, Yang J, Yi B, et al., 2023, Comparative Observation on the Efficacy of Internal Limiting Membrane Inversion

- Coverage and Multilayer Tamponade in the Treatment of Retinal Detachment Caused by Macular Hole in High Myopia. *Chinese Journal of Fundus Diseases*, 39(12): 964–968.
- [8] Sun Y, 2023, Application of Internal Limiting Membrane Inversion Tamponade and Internal Limiting Membrane Peeling in Retinal Detachment Caused by Macular Hole in High Myopia. *Journal of Shandong Medical College*, 45(1): 9–12.
- [9] Guo J, Gao Y, 2022, Evaluation of the Efficacy of Internal Limiting Membrane Peeling and Inversion Tamponade in the Adjuvant Treatment of Patients with Retinal Detachment Caused by Macular Hole in High Myopia. *Practical Blindness Prevention Technology*, 17(1): 7–9.
- [10] Li Q, Hong M, Xie Y, et al., 2023, Clinical Comparative Study of Vitrectomy Combined with Internal Limiting Membrane Peeling and Vitrectomy in the Treatment of Retinal Detachment Caused by Macular Hole in High Myopia. *Henan Journal of Surgery*, 29(3): 164–166.
- [11] Liu J, Zheng Y, Yang X, 2024, Comparison of the Effects of Vitrectomy Combined with Internal Limiting Membrane Peeling and Internal Limiting Membrane Coverage in the Treatment of Retinal Detachment Caused by Macular Hole in High Myopia. *Clinical Medicine*, 44(12): 29–31.
- [12] Hou Y, Liu L, Wang G, et al., 2020, Comparison of the Efficacy of Vitrectomy Combined with Internal Limiting Membrane Coverage and Peeling Surgery in the Treatment of Retinal Detachment Caused by Macular Hole in High Myopia. *Chinese Journal of Fundus Diseases*, 36(12): 943–947.

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# Pharmacokinetics and Safety of Chiglitazar in Patients with Renal Impairment: A Multicenter, Open-label, Parallel-controlled Phase I Clinical Trial

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**Abstract:** Background: Chiglitazar is a novel pan-agonist that can activate all three subtypes of peroxisome proliferator-activated receptor. It was approved for the treatment of type 2 diabetes mellitus as monotherapy on October 19, 2021, and as combination therapy with metformin when using metformin alone failed in blood glucose control on July 16, 2024, by the National Medical Products Administration (NMPA) in China. However, pharmacokinetic (PK) study of this product in patients with renal impairment have not yet been conducted. The purpose of this study is to evaluate the effects of renal impairment on the PK and safety after a single oral dose of Chiglitazar. *Methods:* This multicenter, open-label, parallel-controlled, single-dose Phase I clinical trial (NCT 05515458) enrolled 24 participants (12/group) with severe renal impairment (SRI) or normal renal function (NRF). All participants received a single oral dose of 48 mg chiglitazar after breakfast and the PK and safety was evaluated. *Results:* The median  $T_{max}$  was similar in both SRI and NRF groups (5.01 vs. 5.02 hours). The geometric mean ratios (GMR) for  $C_{max}$ ,  $AUC_{0-12}$ , and  $AUC_{0-\infty}$  were 0.807 (90% confidence interval [CI]: 0.697–0.935), 0.853 (90% CI: 0.713–1.02), and 0.855 (90% CI: 0.716–1.02), respectively, indicating that SRI did not significantly affect the exposure of chiglitazar. The  $C_{max}$  was weakly positively correlated with eGFR ( $r = 0.4798$ ,  $P = 0.0177$ ) and creatinine clearance rate ( $r = 0.4667$ ,  $P = 0.0215$ ). Urinary excretion of chiglitazar was negligible in the SRI group, with average values of  $Ae_{0-12} = 2,900$  ng,  $Fe_{0-12} = 0.0060\%$ , and  $CL_R = 0.323$  mL/h within 0–72 hours post-dose. The treatment-

emergent adverse event (TEAE) incidence in the SRI group (16.7%, 2/12) was comparable to that in the NRF group (25%, 3/12). All TEAEs were of mild severity and were adjudicated by the investigators to be unrelated to chiglitazar. No serious AE were reported. Chiglitazar exhibits a favorable safety profile. *Conclusion:* Severe renal impairment does not significantly affect the PK and safety of chiglitazar, and no dose adjustment for mild, moderate, and severe renal impairments is required.

**Keywords:** Chiglitazar; Pharmacokinetics; Renal impairment; Safety

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## 1. Introduction

Diabetic nephropathy is the predominant cause of end-stage kidney disease within developed nations, responsible for nearly 40% of new cases that necessitate kidney replacement therapy <sup>[1, 2]</sup>. In patients with Diabetic nephropathy, the use of antidiabetic medications may require dosage adjustments due to reduced renal function to prevent drug accumulation and potential safety issues. Accordingly, PK studies of antidiabetic agents in patients with renal impairment are warranted to clarify appropriate dosing regimens for this patient population.

Chiglitazar, a pan-agonist for all three subtypes of peroxisome proliferator-activated receptor (PPAR), can fully activate PPAR $\gamma$  with minimal reverse effect due to its strong and specific binding affinity <sup>[3–5]</sup>. Chiglitazar preferentially regulates the gene expressions of angiopoietin-like 4 (ANGPTL4) and pyruvate dehydrogenase kinase 4 (PDK4), which are involved in glucose and lipid metabolism, through conformational restricted binding and phosphorylation inhibition of PPAR $\gamma$  <sup>[6]</sup>. Clinical trials have confirmed that chiglitazar improves blood glucose control, reverse insulin resistance, regulates lipid metabolism and alleviates liver injury while maintaining a favorable safety profile in patients with type 2 diabetes mellitus (T2DM) and metabolic dysfunction-associated steatohepatitis (MASH) <sup>[7]</sup>.

To date, there is a paucity of research investigating the use of chiglitazar in the context of renal impairment. The pharmacokinetics (PK) properties of chiglitazar in vitro and in vivo indicated that the relatively high distribution of the drug is in the liver, pancreas, and skeletal muscles, with minimal excretion through the kidneys <sup>[4]</sup>. The plasma exposure and peak levels of chiglitazar after repeated doses were comparable between elderly ( $\geq 65$  years old) and younger patients <sup>[8]</sup>. It is recommended to evaluate the PK for the drugs that may be used in patients with renal impairment to provide reasonable usage and dose regimen <sup>[9, 10]</sup>. The purpose of this study is to evaluate effects of renal impairment on the PK and safety after a single oral dose of chiglitazar.

## 2. Materials and results

### 2.1. Study design

This multicenter, open-label, parallel-controlled, single-dose Phase I clinical trial is conducted from November 17, 2022 to July 19, 2023, including four centers: the First Affiliated Hospital of Soochow University, the First Affiliated Hospital of Zhengzhou University, the Second People's Hospital of Hefei, and the Second Affiliated Hospital of Soochow University. The screening phase spanned from day -14 to day -2. Subsequently, the baseline is established on day -1. The observation period, comprising day 1 to day 4, allowed for detailed data collection. Finally, on day 7, a telephone follow-up is implemented to gather additional information. A simplified PK study

design is employed. Initially, the study cohort comprises 12 subjects exhibiting severe renal impairment, followed by the recruitment of 12-14 subjects with NRF. The study would not proceed with further PK investigation in subjects with mild to moderate renal dysfunction if it was confirmed that severe renal impairment resulted in a less than 1.5-fold increase (The 1.5-fold exposure was based on the previous clinical study results that a single dose of 96 mg chiglitazar are safe and well-tolerated) in chiglitazar exposure. Conversely, a comprehensive PK study would be initiated, encompassing subjects across various renal function classifications. The mean weight, age, and gender distribution of the NRF group are matched with the renal impairment cohort within  $\pm 10$  kg,  $\pm 10$  years, and  $\pm 1$  subject per gender, respectively. The institutional review board or independent ethics committee of each participating research center approved the study protocol and all participants provided written informed consent. The study has been registered in the ClinicalTrials.gov database (NCT 05515458) and is conducted complying with the Declaration of Helsinki.

## 2.2. Participants

Subjects in the renal impairment group should meet the following criteria:

- (1) Aged 18–79 years old
- (2) Males having a body weight of no less than 50 kg and females of no less than 45 kg, with a body mass index (BMI) ranging from 18 to 30 kg/m<sup>2</sup>
- (3) Not having taken any drugs within 2 weeks before screening or having had a stable medication for at least 4 weeks for the treatment of renal impairment and/or other comorbidities
- (4) The absolute estimated glomerular filtration rate (eGFR) meets the standard of 15–29 mL/min for severe renal impairment
- (5) Subjects (including their partners) are willing to voluntarily take effective contraceptive measures from the screening period until 6 months after the administration of the study drug. The inclusion criteria for subjects in the NRF group are as follows: body weight, age, and gender were matched with those in the renal impairment group; the absolute eGFR was  $\geq 90$  mL/min and  $< 130$  mL/min.

Participants with the following conditions should be excluded:

- (1) Allergic constitution, or allergic to PPAR agonist drugs, or allergic to any component of chiglitazar tablets
- (2) Having taken PPAR agonist drugs within 2 weeks before the start of the trial
- (3) Having undergone or planning to receive surgery that might affect the absorption, distribution, metabolism, and excretion of drugs
- (4) Acute hepatitis, chronic liver disease, or any one of alanine aminotransferase (ALT), aspartate aminotransferase (AST), and total bilirubin greater than 2 times the upper limit of the normal value
- (5) Female subjects who are pregnant, lactating, or have a positive serum pregnancy test result during the screening period or the trial process

## 2.3. Intervention

Chiglitazar tablets, manufactured by Chengdu Chipscreen Pharmaceutical Co., Ltd, were utilized for oral administration. In the Phase I, II, and III clinical trials conducted in China, the results have demonstrated that 48 mg exhibits favorable efficacy and safety. Even at a dose of 96 mg, it remains safe and well-tolerated in the healthy population. Additionally, since the PK characteristics after multiple dosing were consistent with those observed after the first administration. A single oral dose of 48 mg was selected as the trial dosage. Moreover, food intake

had no significant effect on the PK of the drug. Consequently, the dosing is scheduled to be taken after meals. On the morning of day 1, subjects received a single 48 mg dose of chiglitazar after breakfast. Extra consumption of water is prohibited within a 1-hour window prior to and following drug intake, while food intake is permitted 4 hours after administration. The participants are dismissed following sample collection and a safety assessment on day 4, with a follow-up telephone call conducted on the 7<sup>th</sup> day.

## 2.4. Outcomes

The primary outcomes of the study focused on the pharmacokinetic (PK) profile of a single oral dose of chiglitazar in subjects with either impaired or normal renal function. Key PK parameters assessed in plasma included the maximum plasma concentration ( $C_{max}$ ), area under the concentration-time curve from time zero to the last measurable concentration ( $AUC_{0-t}$ ), area under the concentration-time curve extrapolated to infinity ( $AUC_{0-\infty}$ ), time to reach maximum plasma concentration ( $T_{max}$ ), apparent volume of distribution ( $V_z/F$ ), apparent clearance ( $CL/F$ ), terminal elimination half-life ( $t_{1/2}$ ), mean residence time from time zero to the last measurable concentration ( $MRT_{0-t}$ ), mean residence time extrapolated to infinity ( $MRT_{0-\infty}$ ), and the unbound fraction ( $f_u$ ). Additionally, the study investigated the correlations between plasma PK parameters ( $C_{max}$ ,  $AUC_{0-t}$ , and  $AUC_{0-\infty}$ ) and renal function indices, including estimated glomerular filtration rate (eGFR) and creatinine clearance rate (CCR).

Urinary PK parameters included the cumulative amount of drug excreted from time zero to the last measurable concentration ( $Ae_{0-t}$ ), fraction of dose excreted unchanged in urine ( $f_e$ ), and  $CL_R$ . Secondary outcomes comprised the evaluation of treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs), alongside safety assessments including complete blood count, serum biochemistry, urinalysis, coagulation profile, 12-lead electrocardiogram (ECG), vital signs, and physical examination. The severity of all adverse events was classified according to the Adverse Event and Serious Adverse Event Guidelines (2018) issued by the National Institute on Aging<sup>[11]</sup>.

## 2.5. Pharmacokinetic sampling

For PK blood sampling, the time points are as follow: before drug administration (-60 min to 0 h) and 0.5 h  $\pm$  3 min, 1 h  $\pm$  3 min, 2 h  $\pm$  3 min, 3 h  $\pm$  5 min, 4 h  $\pm$  5 min, 5 h  $\pm$  5 min, 6 h  $\pm$  5 min, 8 h  $\pm$  5 min, 12 h  $\pm$  5 min, 24 h  $\pm$  10 min, 36 h  $\pm$  10 min, 48 h  $\pm$  10 min, and 72 h  $\pm$  10 min after drug administration. When there was a conflict between PK blood sampling points and other examinations, priority is given to ensuring blood sampling time. For PK urine sample collection, urine specimens are collected respectively before drug administration (-24 h to 0 h, random urine) and in the periods of 0–4 h, 4–8 h, 8–12 h, 12–24 h, 24–48 h, and 48–72 h after drug administration.

## 2.6. Statistics

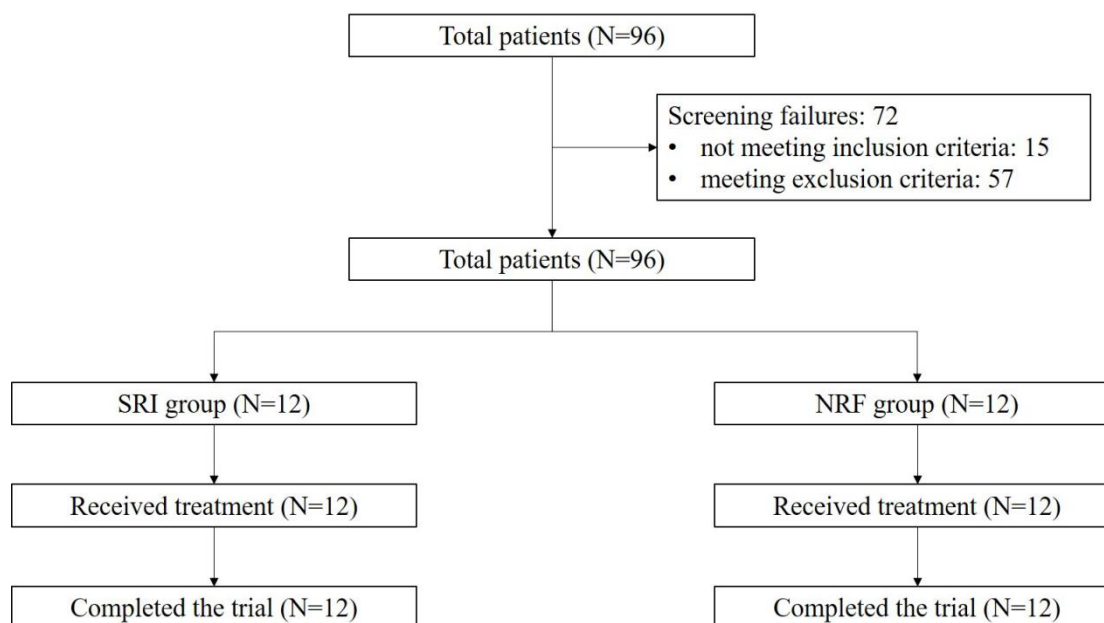
Descriptive statistics for quantitative data are expressed as the mean  $\pm$  the standard deviation or median (minimum, maximum), while count data are described using frequency and proportion. The 90% confidence interval (CI) is calculated for the observed indicators. The full analysis set (FAS) included all subjects who received at least one dose of the study drug and was used for demographic and baseline characteristic analysis. The PK parameter analysis set (PKPS) included subjects who received at least one correct dose of the study drug and had at least one evaluable PK parameter. The PK concentration analysis set (PKCS) included subjects who received at least one correct dose of the study drug, had at least one evaluable drug concentration data, and are not affected by related factors that influenced the PK concentration data. The safety analysis set (SS) included all subjects who received at

least one dose of the study drug. Based on PKPS, an equivalence test method is adopted to evaluate comparison of the main PK parameters ( $C_{\max}$ ,  $AUC_{0-t}$ ,  $AUC_{0-\infty}$ ) of chiglitazar after natural logarithm transformation among severe renal impairment (SRI) and normal renal function (NRF) groups, and calculate the geometric mean ratio (GMR) of the PK parameters and the corresponding 90% CI. Also based on PKPS, the formula  $\log(y) = \beta_0 + \beta_1 * \log(x)$  is adopted to evaluate the quantitative relationship between each PK parameter and each renal function index (where  $y$  represents the PK parameter and  $x$  refers to the renal function index) with  $\log(x)$  as the fixed effect term.  $P < 0.05$  (two-sides) is set as a significant difference. Phoenix WinNonlin 8.3 software is used for PK analysis, and the statistical software is SAS 9.4.

### 3. Results

#### 3.1. Demographic and baseline characteristics

A total of 96 subjects were screened in the trial, out of which 72 failed the screening. Eventually, 24 subjects were enrolled, including 12 subjects in the SRI group and 12 subjects in the NRF group, and all these subjects completed the trial (**Figure 1**).



**Figure 1.** Flowgraph of NRF and SRI group

The mean age was  $55.9 \pm 6.93$  years old; the average height was  $162.42 \pm 6.58$  cm; the average weight was  $66.00 \pm 8.53$  kg; and the average BMI was  $24.95 \pm 2.22$  kg/m<sup>2</sup>. There were 17 males (70.8%) and 7 females (29.2%). All 24 subjects were of Han ethnicity. The average ages in the SRI group and NRF group were  $57.8 \pm 9.15$  years old and  $54.0 \pm 2.95$  years old respectively; the average body weights were  $66.33 \pm 11.27$  kg and  $65.67 \pm 4.98$  kg respectively; and the proportions of male subjects were 75.0% (9/12) and 66.7% (8/12) respectively. The demographic information, such as age, body weight, and gender composition of the two groups was comparable (**Table 1**).

Concomitant medications were presented in Supplementary **Table 1**, and none of the prohibited drugs per the protocol were involved.

**Table 1.** Demographic and baseline characteristics

Group		SRI (N = 12)	NRF (N = 12)	Total (N = 24)
Gender	Male n (%)	9 (75.0)	8 (66.7)	17 (70.8)
	Female n (%)	3 (25.0)	4 (33.3)	7 (29.2)
Ethnicity	Han n (%)	12 (100)	12 (100)	24 (100)
	Others n (%)	0	0	0
Age (years)	n (Missing)	12 (0)	12 (0)	24 (0)
	Mean (SD)	57.8 (9.15)	54.0 (2.95)	55.9 (6.93)
Height (cm)	n (Missing)	12 (0)	12 (0)	24 (0)
	Mean (SD)	161.88 (7.453)	162.96 (5.852)	162.42 (6.577)
Weight (kg)	n (Missing)	12 (0)	12 (0)	24 (0)
	Mean (SD)	66.33 (11.269)	65.67 (4.980)	66.00 (8.527)
BMI (kg/m <sup>2</sup> )	n (Missing)	12 (0)	12 (0)	24 (0)
	Mean (SD)	25.15 (2.716)	24.74 (1.671)	24.95 (2.215)
Smoking status	Never smoked n (%)	9 (75.0)	11 (91.7)	20 (83.3)
	Used to smoke n (%)	2 (16.7)	1 (8.3)	3 (12.5)
	Still smoking currently n (%)	1 (8.3)	0	1 (4.2)
Drinking status	Never drank n (%)	7 (58.3)	9 (75.0)	16 (66.7)
	Used to drink n (%)	5 (41.7)	1 (8.3)	6 (25.0)
	Still drinking currently n (%)	0	2 (16.7)	2 (8.3)

\*BMI: Body mass index; NRF: Normal renal function group; SRI: Severe renal impairment group.

### 3.2. Pharmacokinetics in plasma

Following a single oral administration of 48 mg chiglitazar, the median  $T_{\max}$  was documented at 5.01 and 5.02 hours for two groups, respectively, with the average  $C_{\max}$  of 1010 ng/mL and 1240 ng/mL. Moreover, the mean  $AUC_{0-t}$  was 8110 ng\*h/mL and 9240 ng\*h/mL, while the average  $AUC_{0-\infty}$  was 8230 ng\*h/mL and 9360 ng\*h/mL, respectively (**Table 2**).

It indicates that although there is a difference in  $C_{\max}$  between the two cohorts, the reduction amplitude is relatively modest. Upon comparison between the two groups, no significant variations were observed in  $T_{\max}$  and  $t_{1/2}$  in the SRI group. Notably, the plasma  $f_u$  in the SRI group (3.76%) exhibited a slight increase relative to that in the NRF group (1.45%). Furthermore, the  $V_z/F$  and  $CL/F$  in the SRI group were elevated by approximately 22.0% and 19.6%, respectively, when compared to those in the NRF group (**Table 2**).

The average  $C_{\max}$  was recorded as 1,010 ng/mL and 1,240 ng/mL, while the average  $AUC_{0-t}$  was 8,110 ng\*h/mL and 9,240 ng\*h/mL, and the average  $AUC_{0-\infty}$  was 8,230 ng\*h/mL and 9,360 ng\*h/mL, respectively. The GMR for the exposure parameters of chiglitazar ( $C_{\max}$ ,  $AUC_{0-t}$ , and  $AUC_{0-\infty}$ ) were 0.807 (90% CI 0.697–0.935), 0.853 (90% CI 0.713–1.02), and 0.855 (90% CI 0.716–1.02), respectively. Compared with NRF group, the  $C_{\max}$  was reduced by approximately 19.3%, the  $AUC_{0-t}$  by approximately 14.7%, and the  $AUC_{0-\infty}$  by approximately 14.5% in the SRI group, indicating that SRI did not markedly impact the PK profile of chiglitazar (**Table 3, Figure 2**).

**Table 2.** The PK parameters after a single oral administration of 48 mg of chiglitazar (PKPS)

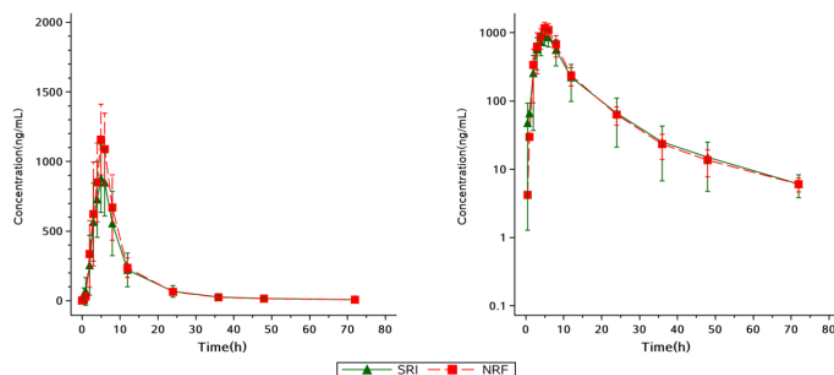
PK	SRI(N=12)	NRF(N=12)
	Plasma PK parameters <sup>#</sup>	
T <sub>max</sub> (h)	5.01 (3.00, 6.02)	5.02 (3.00, 6.00)
C <sub>max</sub> (ng/mL)	1010 ± 222 (22.0)	1240 ± 231 (18.7)
AUC <sub>0-t</sub> (ng*h/mL)	8110 ± 2670 (32.9)	9240 ± 1710 (18.5)
AUC <sub>0-∞</sub> (ng*h/mL)	8230 ± 2680 (32.5)	9360 ± 1720 (18.4)
t <sub>1/2</sub> (h)	12.3 ± 3.98 (32.5)	12.4 ± 3.72 (30.1)
V <sub>z</sub> /F (mL)	111000 ± 49400 (44.3)	91000 ± 18900 (20.7)
CL/F (mL/h)	6340 ± 1740 (27.5)	5300 ± 1040 (19.6)
f <sub>u</sub> (%)	3.76 ± 1.10 (29.3)	1.45 ± 0.58 (40.0)
MRT <sub>0-t</sub> (h)	11.0 ± 2.36 (21.4)	10.5 ± 1.66 (15.8)
MRT <sub>0-∞</sub> (h)	12.1 ± 2.42 (20.0)	11.4 ± 1.79 (15.6)
Urinary PK Parameters <sup>*</sup>		
Ae <sub>0-t</sub> (ng) #	2900 ± 1500 (51.9)	/
Fe (%)#	0.0060 ± 0.0031 (51.9)	/
CL <sub>R</sub> (mL/h) #	0.323 ± 0.166 (51.5)	/

<sup>#</sup>Except that T<sub>max</sub> is presented as Median (Min, Max), all the other parameters are expressed as Mean ± SD (CV%). <sup>\*</sup>All the indicators are expressed as Mean ± SD (CV%). <sup>#</sup>N = 6. Only the urinary drug concentration values of 6 subjects in the severe renal impairment group can be evaluated. The urinary drug concentrations of the remaining subjects in all periods are all below the lower limit of quantification (4.00 ng/mL), and their urinary drug parameters cannot be calculated. Ae<sub>0-t</sub>: Amount excreted from time 0 to the last measurable concentration; AUC<sub>0-∞</sub>: Area under the curve from time 0 to infinity; AUC<sub>0-t</sub>: Area under the curve from time 0 to the last measurable concentration; CL<sub>R</sub>: Renal clearance; CL/F: Apparent clearance; C<sub>max</sub>: Maximum concentration; CV: Coefficient of variation; Fe: Fraction excreted; fu: Fraction unbound; MRT<sub>0-∞</sub>: Mean residence time from time 0 to infinity; MRT<sub>0-t</sub>: Mean residence time from time 0 to the last measurable concentration; NRF: Normal renal function; PK: pharmacokinetic; PKPS: PK parameter analysis set; SRI: Severe renal impairment; t<sub>1/2</sub>: Terminal half-life; T<sub>max</sub>: Time to maximum concentration; V<sub>z</sub>/F: Apparent volume of distribution.

**Table 3.** Comparison of the main PK parameters(PKPS)

PK	Group	GM	GMR (90% CI)
C <sub>max</sub> (ng/mL)	SRI	985	0.807(0.697, 0.935)
	NRF	1220	
AUC <sub>0-t</sub> (ng*h/mL)	SRI	7750	0.853(0.713, 1.02)
	NRF	9090	
AUC <sub>0-∞</sub> (ng*h/mL)	SRI	7880	0.855(0.716, 1.02)
	NRF	9210	

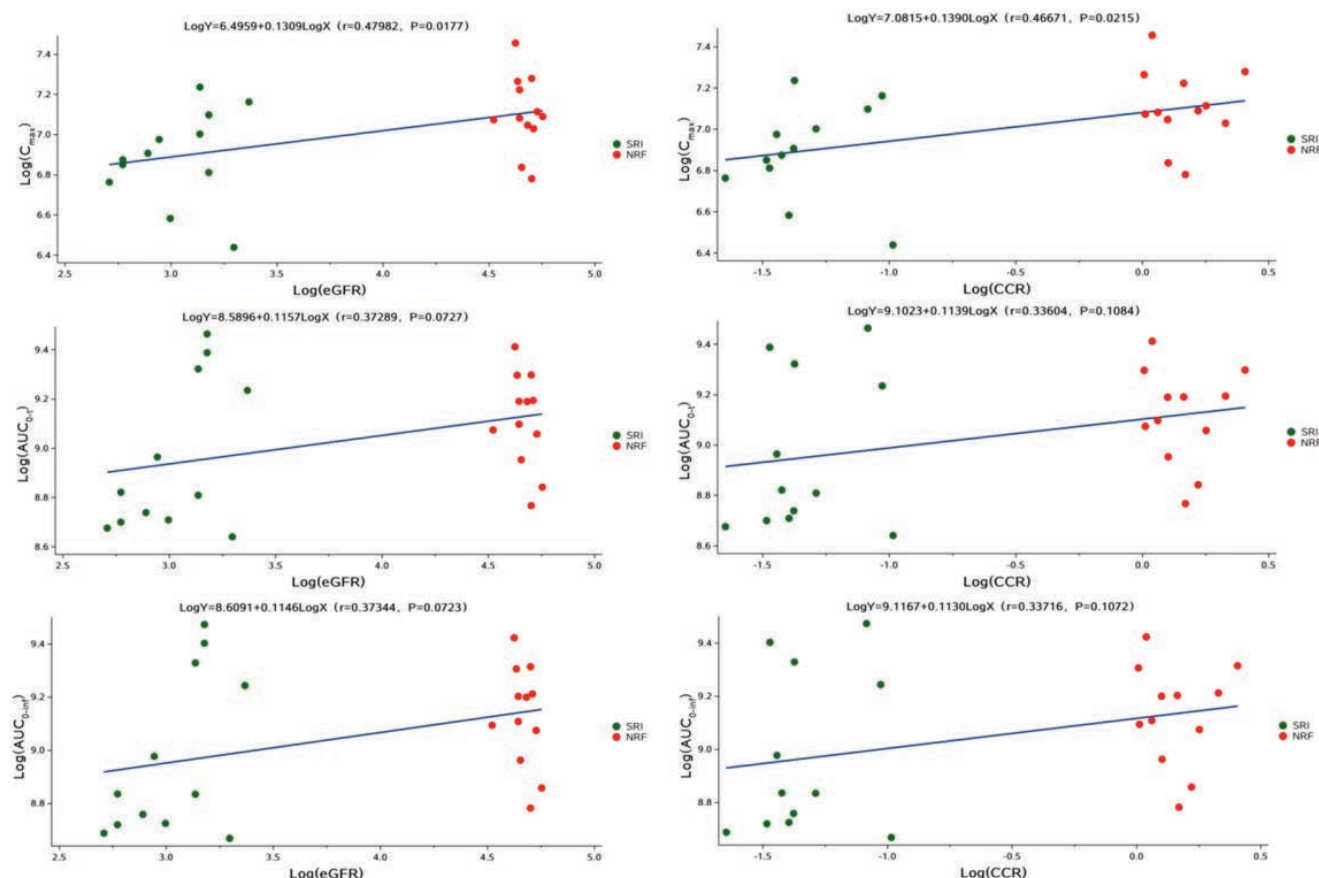
<sup>\*</sup>AUC<sub>0-∞</sub>: Area under the curve from time 0 to infinity; AUC<sub>0-t</sub>: Area under the curve from time 0 to the last measurable concentration; C<sub>max</sub>: Maximum concentration; GM: Geometric mean; GMR: Geometric mean ratio; NRF: Normal renal function; PK: Pharmacokinetics; PKPS: Pharmacokinetic parameter analysis set; SRI: Severe renal impairment.



**Figure 2.** The average concentration-time curves of the drug in plasma for the SRI and NRF groups (linear and semi-logarithmic, PKCS).

\*NRF: Normal renal function group; PKCS: Pharmacokinetic concentration analysis set; SRI: Severe renal impairment group.

The  $C_{max}$  exhibited a significant weakly positive correlation with eGFR ( $r = 0.4798$ ,  $P = 0.0177$ ) and creatinine clearance rate ( $r = 0.4667$ ,  $P = 0.0215$ ). Regarding the AUC, it presented a weakly positive correlation without significance with both eGFR and creatinine clearance rate. A lower  $C_{max}$  and AUC were observed in the SRI group. Collectively, these findings suggest that SRI does not lead to an elevation in peak plasma drug concentration and drug accumulation (**Figure 3**).



**Figure 3.** The correlation regression fitting line graphs between the exposure of chiglitazar and renal function indicators.

\*AUC: Area under the curve; CCR: creatinine clearance rate;  $C_{max}$ : Maximum concentration; eGFR: Estimated glomerular filtration rate; NRF: Normal renal function group; SRI: Severe renal impairment group.

### 3.3. Pharmacokinetics in urine

The urinary drug concentrations in six subjects from the SRI group and in all participants from the NRF group remained below the lower limit of quantification ( $< 4.00$  ng/mL) throughout the urine collection periods, precluding the calculation of their urinary PK. For the remaining six subjects in the SRI group, within 0–72 hours after administration of chiglitazar, the average values of the  $Ae_{0-72}$ ,  $Fe_{0-72}$ , and CCR of chiglitazar were 2,900 ng, 0.0060%, and 0.323 mL/h, respectively, indicating that the fractional excretion of chiglitazar via urine was negligible in the SRI patients (Table 2).

### 3.4. Safety assessment

Mild TEAEs occurred in 5 of 24 subjects (20.8%), with the investigator determining no causal relationship to chiglitazar. The TEAE incidences were comparable between the SRI (16.7%, 2/12) and the NRF groups (25%, 3/12). All TEAEs resolved spontaneously, without requiring therapeutic intervention (Table 4). Chiglitazar demonstrated good safety among subjects with SRI.

**Table 4.** Summary of adverse events(SS)

Adverse events	SRI (N=12),n (%)	NRF (N=12),n (%)	Total(N=24)
TEAE	2(16.7)	3(25)	5(20.8)
TEAE related to chiglitazar	0	0	0
SAE	0	0	0
TEAE leading to withdrawal	0	0	0
Count the TEAE according to SOC and PT			
Various examinations	1(8.3)	3(25)	4(16.7)
Elevated C-reactive protein	0(0)	2(16.7)	2(8.3)
Abnormal T-wave	1(8.3)	0(0)	1(4.2)
Elevated blood triglycerides	0(0)	1(8.3)	1(4.2)
Cardiac organ diseases	1(8.3)	0(0)	1(4.2)
Ventricular extrasystoles	1(8.3)	0(0)	1(4.2)

\*The judgment results of clinical significance after treatment are statistically analyzed based on the worst result after treatment. TEAE: treatment-emergent adverse event; SAE: serious adverse event; SRI: severe renal impairment; NRF: normal renal function; SOC: system organ class; PT: preferred term; SS: safety analysis set.

## 4. Discussion

This study revealed that individuals with SRI exhibited lower GM of  $C_{max}$  and AUC compared to those with NRF, indicating that severe renal status has no obvious impact on the chiglitazar exposure. Urinary PK data indicated trivial amounts are excreted in the urine even in patients with SRI. All TEAEs were mild, and no SAEs were reported. The findings suggest that metabolism and excretion of chiglitazar are not significantly compromised by renal impairment, thus no dose adjustment is necessary for patients with mild, moderate, and severe renal impairment.

The  $C_{max}$ ,  $AUC_{0-72}$ , and  $AUC_{0-\infty}$  in the SRI group were relatively lower than NRF group, as well as the minimal

excretion of unchanged chiglitazar in the urine, indicating that renal function status has little impact on the PK. The results of this trial also aligned with the data from the previous study: The phase I study in healthy Chinese subjects showed that when a single oral dose of 8–72 mg was administered, the  $C_{max}$  and AUC increased proportionally with low inter-subject variability, and there was no significant change in  $t_{1/2}$ . After multiple administrations of 16 mg for 9 days, a steady state was achieved on the 6 th day with no significant accumulation <sup>[12]</sup>. The PK outcomes from a 7-day consecutive chiglitazar in T2DM patients revealed no significant age-related disparities in AUC,  $T_{max}$ , and  $t_{1/2}$  parameters. Even after continuous medication, the AUC increment in subjects aged 65 and older was only marginal. Both cohorts exhibited commendable tolerability towards chiglitazar <sup>[8]</sup>.

According to the prescribing information, approximately  $92.69\% \pm 4.29\%$  of chiglitazar is excreted via feces, while only  $4.03\% \pm 0.66\%$  is excreted through the kidneys. The amount of unchanged drug in the urine is minimal (0.01%) <sup>[13]</sup>. The results of previous in vitro studies showed that the free rate of chiglitazar in human plasma was approximately 0.5%. In this study, the free rates of chiglitazar in plasma samples at 5 hours after a single dose in subjects with SRI and NRF were  $3.76 \pm 1.10\%$  and  $1.45 \pm 0.58\%$ , respectively. The free rate in the SRI group was slightly increased compared with that in the NRF group. The observed discrepancies in free fraction may lack clinical significance, attributable to methodological limitations. This study used ultracentrifugation to determine free fraction; however, extreme centrifugal forces may disrupt drug-protein equilibrium and introduce sampling bias, thereby compromising the accuracy of free fraction. Differences between this study and prior in vitro data probably due to the methodological variations. Additionally, a pharmacokinetic study in hepatic subjects using the same ultracentrifugation method reported a 5-hour free fraction of  $2.81 \pm 0.81\%$  in normal hepatic function subjects, which is similar to the free fraction of chiglitazar in severe renal impairment subjects. Thus, the differences of free fraction may not translate to clinical meaningful differences in drug efficacy and safety. As chiglitazar's PK are not significantly altered by renal impairment, PK studies are not required in mild or moderate cases per guidelines <sup>[9, 10]</sup>.

Enzymes and transporters at the sites of drug distribution and absorption influence the PK parameters of the drug <sup>[14]</sup>. PPAR agonists are typically involved in a variety of physiological processes, including enhancing insulin sensitivity, regulating lipid metabolism, as well as exerting anti-inflammatory and antioxidant effects <sup>[5, 15–17]</sup>. Therefore, this extensive distribution may represent a significant factor influencing the non-renal excretion of chiglitazar. The liver is the primary organ for drug metabolism, where the majority of drugs are metabolized into active or inactive forms and subsequently excreted into the intestines via bile, ultimately being eliminated through feces. Chiglitazar is also predominantly metabolized in the liver and excreted via feces, therefore, the liver plays a significant role in the non-renal metabolism of chiglitazar <sup>[4, 13]</sup>. Concurrently, PPAR agonists suggested its potential protective role in renal diseases including acute kidney injury, DN, and chronic kidney disease (CKD) <sup>[18]</sup>. Son *et al.* also revealed that pan PPAR agonist effectively prevented the progression of renal fibrosis in in vitro and in vivo fibrotic kidney models, by mitigating inflammatory responses and inhibiting fibroblast activation <sup>[19]</sup>. This study also validated that SRI limitedly affects the PK of chiglitazar.

In terms of AEs, previous study has also confirmed the good tolerability of chiglitazar in the elderly diabetic population <sup>[8]</sup>. This study further confirmed the safety profile in patients with SRI. There was no significant difference in the incidence of AE between the NRF group and the SRI group. Most AEs were mild or moderate, and no severe AE occurred. This indicates that chiglitazar has good tolerance in patients with different renal functions. Renal impairment does not increase the risk of drug-related AEs. Chiglitazar has demonstrated promising therapeutic effects in various conditions such as T2DM, dyslipidemia, and MASH <sup>[7, 17]</sup>. This research further confirms the safety profile in patients with SRI, expands the potential patient population for chiglitazar

treatment, and holds significant value for the management of DN.

## 5. Conclusion

The plasma and urinary PK profiles of chiglitazar were minimally affected in subjects with severe renal impairment. The occurrence of AEs in subjects with severe renal impairment was comparable to the normal population. It is safe and no dose adjustment is required for the population with mild to severe renal impairment.

## Disclosure statement

The authors declare no conflict of interest.

## References

- [1] Varghese RT, Jialal I, 2024, Diabetic Nephropathy [Updated 2023 Jul 24], in StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing.
- [2] Chowdhury TA, Mukuba D, Casabar M, et al., 2024, Management of Diabetes in People with Advanced Chronic Kidney Disease. *Diabetic Medicine*, 2024: e15402.
- [3] Sullivan HJ, Wang X, Nogle S, et al., 2020, To Probe Full and Partial Activation of Human Peroxisome Proliferator-Activated Receptors by Pan-Agonist Chiglitazar Using Molecular Dynamics Simulations. *PPAR Research*, 2020: 5314187.
- [4] He BK, Ning ZQ, Shan S, et al., 2012, In Vitro and In Vivo Characterizations of Chiglitazar, a Newly Identified PPAR Pan-Agonist. *PPAR Research*, 2012: 546548.
- [5] Ji L, Song W, Fang H, et al., 2021, Efficacy and Safety of Chiglitazar, a Novel Peroxisome Proliferator-Activated Receptor Pan-Agonist, in Patients with Type 2 Diabetes: A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial (CMAP). *Science Bulletin*, 66(15): 1571–1580.
- [6] Pan DS, Wang W, Liu NS, et al., 2017, Chiglitazar Preferentially Regulates Gene Expression via Configuration-Restricted Binding and Phosphorylation Inhibition of PPAR $\gamma$ . *PPAR Research*, 2017: 4313561.
- [7] You H, Sun Y, Wu C, et al., 2024, A Randomized, Double-Blind, Placebo-Controlled Phase 2 Trial to Evaluate the Efficacy and Safety of Chiglitazar in NASH Patients. *Hepatology*, 80(S1): S1–S2011.
- [8] Li X, Yu J, Wu M, et al., 2021, Pharmacokinetics and Safety of Chiglitazar, a Peroxisome Proliferator-Activated Receptor Pan-Agonist, in Patients < 65 and  $\geq$  65 Years with Type 2 Diabetes. *Clinical Pharmacology in Drug Development*, 10(7): 789–796.
- [9] U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), 2024, Pharmacokinetics in Patients with Impaired Renal Function – Study Design, Data Analysis, and Impact on Dosing Guidance for Industry, viewed on March 4, 2025 <https://www.fda.gov/media/78573/download>
- [10] National Medical Products Administration (NMPA), 2021, Technical Guidelines for Pharmacokinetic Studies in Patients with Renal Impairment, viewed on March 13, 2025. <https://www.cde.org.cn/main/att/download/48d48e401e673dda2c4b8ded0d9f45fc>
- [11] National Institute on Aging, National Institutes of Health (NIH), 2018, NIA Adverse Event and Serious Adverse Event Guidelines, viewed on March 24, 2025. <https://www.nia.nih.gov/sites/default/files/2018-09/nia-ae-and-sae-guidelines-2018.pdf>

- [12] Xu HR, Zhang JW, Chen WL, et al., 2019, Pharmacokinetics, Safety and Tolerability of Chiglitazar, a Novel Peroxisome Proliferator-Activated Receptor (PPAR) Pan-Agonist, in Healthy Chinese Volunteers: A Phase I Study. *Clinical Drug Investigation*, 39(6): 553–563.
- [13] Deeks ED, 2022, Chiglitazar: First Approval. *Drugs*, 82(1): 87–92. doi: 10.1007/s40265-021-01648-1. PMID: 34846697.
- [14] Urquhart BL, Tirona RG, Kim RB, 2007, Nuclear Receptors and the Regulation of Drug-Metabolizing Enzymes and Drug Transporters: Implications for Interindividual Variability in Response to Drugs. *Journal of Clinical Pharmacology*, 47(5): 566–578.
- [15] Jia W, Ma J, Miao H, et al., 2021, Chiglitazar Monotherapy with Sitagliptin as an Active Comparator in Patients with Type 2 Diabetes: A Randomized, Double-Blind, Phase 3 Trial (CMAS). *Science Bulletin*, 66(15): 1581–1590.
- [16] Cooreman MP, Vonghia L, Francque SM, 2024, MASLD/MASH and Type 2 Diabetes: Two Sides of the Same Coin? From Single PPAR to Pan-PPAR Agonists. *Diabetes Research and Clinical Practice*, 212: 111688.
- [17] Cheng HS, Tan WR, Low ZS, et al., 2019, Exploration and Development of PPAR Modulators in Health and Disease: An Update of Clinical Evidence. *International Journal of Molecular Sciences*, 20(20): 5055.
- [18] Gao J, Gu Z, 2022, The Role of Peroxisome Proliferator-Activated Receptors in Kidney Diseases. *Frontiers in Pharmacology*, 13: 832732.
- [19] Son M, Kim GY, Yang Y, et al., 2023, PPAR Pan Agonist MHY2013 Alleviates Renal Fibrosis in a Mouse Model by Reducing Fibroblast Activation and Epithelial Inflammation. *International Journal of Molecular Sciences*, 24(5): 4882.

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# Analysis of the Application Effect of Systematic Nursing Intervention in Patients with Knee Osteoarthritis

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**Abstract:** *Objective:* To analyze the value of systematic nursing care received by patients with knee osteoarthritis (OA). *Methods:* Eighty-two OA patients who visited the hospital from August 2023 to August 2024 were selected as samples and divided into groups by drawing. Group A received systematic nursing, while Group B received routine nursing. Emotional scores, pain scores, knee joint assessments, quality of life scores, and adverse reactions were compared. *Results:* After 3 weeks of nursing, Group A had lower scores for anxiety (SAS), depression (SDS), and visual analog scale (VAS) compared to Group B, with  $P < 0.05$ . At 1 week, 2 weeks, and 3 weeks of nursing, Group A had higher scores on the American Hospital for Special Surgery (HHS) scale compared to Group B, with  $P < 0.05$ . After 3 weeks of nursing, Group A had higher scores for quality of life (SF-36) compared to Group B, with  $P < 0.05$ . The adverse reaction rate in Group A was lower than that in Group B, with  $P < 0.05$ . *Conclusion:* Systematic nursing care for OA patients results in improved knee function, pain relief, emotional stability, and improved quality of life, making it highly effective and feasible.

**Keywords:** Knee osteoarthritis; Systematic nursing; Nursing value

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## 1. Introduction

OA is a high-incidence joint disease among middle-aged and elderly people, which progresses slowly and can cause swelling, pain, and stiffness of the knee joint. In severe cases, it can lead to changes in joint morphology and even secondary joint deformities, which have a significant impact on daily life. Comprehensive treatment should be started as early as possible. Both local administration of medications to the joint and oral non-steroidal anti-inflammatory drugs can inhibit the progression of OA. Based on this, nursing intervention can shorten the course of OA and relieve joint pain. Routine OA management focuses on disease control, and the overall control effect is poor. Systematic nursing, which integrates individualized service concepts and rapid recovery concepts, can relieve OA symptoms and optimize the quality of life of OA patients. It is a targeted intervention strategy<sup>[1]</sup>. This study explores the value of systematic nursing using 82 OA patients who visited the hospital from August 2023 to

August 2024 as samples.

2. Materials and methods

2.1. Materials

Eighty-two OA patients who visited the hospital from August 2023 to August 2024 are selected as samples and divided into groups by drawing. The baseline data of OA patients in Group A are compared with those in Group B, with  $P > 0.05$ , as shown in Table 1.

Table 1. Baseline data of OA patients

Group	n	Gender(%)		Age (years)		BMI(kg/m <sup>2</sup> )	
		Male	Female	Range	Mean	Left	Right
Group A	41	21(51.22)	20(48.78)	61–79	67.58 ± 2.11	20–29	26.11 ± 1.24
Group B	41	22(53.66)	19(46.34)	61–80	67.61 ± 2.13	20–28	26.08 ± 1.26
X <sup>2</sup> /t	-	0.0489		0.0641		0.1087	
P	-	0.8250		0.9491		0.9137	

2.2. Inclusion and exclusion criteria

Inclusion criteria: (1) Consistent with OA in the “Expert Consensus on TCM Diagnosis and Treatment of Knee Osteoarthritis”<sup>[2]</sup>; (2) Joint stiffness and swelling occurred;(3) Signed informed consent; (4) Complete information provided.

Exclusion criteria: (1) Ligament damage; (2) Meniscus damage;(3)Organ lesions; (4) History of major surgery.

2.3. Methods

2.3.1. Group A

(1) Psychological counseling

OA patients tend to experience depression and anxiety due to the pain and discomfort caused by joint pain. Therefore, it is important to actively communicate with OA patients, find topics to distract their attention, and patiently answer their questions about OA knowledge and nursing knowledge, while respecting the patients. During nursing, potential complications of OA should be explained, and the nursing process and the value of following medical advice should be clarified. Family members of OA patients should be advised to provide comfort and companionship, and to stabilize their emotions through various means such as chatting and listening to soft music.

(2) Education

Strengthen OA patients’ understanding of the disease through multiple forms such as WeChat videos and manuals, and urge them to cooperate with medical operations. Provide targeted education based on the age, inflammatory state, degree of joint damage, and muscle weakness of OA patients, and use pictures to deepen their understanding.

(3) Pain management

OA patients may experience pain during rehabilitation exercises. To reduce swelling and pain, analgesics

such as paracetamol can be used as prescribed by a doctor. Attention should be paid to regulating the dosage and timing of medication to avoid overdose of analgesics. Additionally, some OA patients may experience severe muscle tension due to pain in the affected area. Muscle relaxants can be administered to relieve muscle spasms, restore normal joint movement, and cold compresses can be used to stimulate blood circulation, promote the absorption of edema in the affected limb, and inhibit the progression of inflammation.

(4) Diet

Guide OA patients to plan their diet, ensuring balanced nutrition in three meals a day, increasing intake of fruits, vegetables, and high-protein foods, and avoiding stimulating and cold foods, which can optimize nutritional status.

(5) Rehabilitation exercises

- (a) Passive joint exercises: Nurses and family members assist OA patients to complete joint flexion and extension exercises, gradually increasing the range of motion, while avoiding violent activities that may cause pain.
- (b) Muscle strength exercises: Targeted exercises for the hamstring, quadriceps, and soleus muscles, such as preparing a chair with armrests and guiding patients to stand up and sit down for exercise; encouraging patients to walk backwards to strengthen muscle strength using ground resistance; and lifting the toes while sitting in a chair.
- (c) Balance exercises: Once the patient's condition stabilizes, start static balance exercises in a standing position, such as standing on one leg, climbing stairs, etc., to improve muscle coordination and flexibility.
- (d) Life skill exercises: Use walking aids and canes to walk correctly, slowly moving the healthy leg to reduce pressure on the affected knee; follow the principle of "good foot first, bad foot later" when climbing stairs to reduce pressure on the affected knee and prevent falls.
- (e) Herbal wet and hot compress: Take 30g each of Chuanxiong, Niuxi, Honghua, Ruxiang, Chuanwu, Caowu, Moyao, and Weilingxian. Boil the above herbs to obtain 100ml of juice, prepare a wet compress package, soak it in the medicinal juice, heat it to 60°C, and apply it externally to the knee joint. Each wet and hot compress should last for 15–20 minutes, 2–3 times a day.

### 2.3.2. Group B

Guide OA patients to take medication correctly, inform them of the medication plan, precautions, and potential risks, monitor various physiological indicators, including blood routine, respiration, blood pressure, and heart rate, and follow medical advice to complete knee joint physiotherapy.

## 2.4. Observation indicators

- (1) Emotion and pain: SAS and SDS are positively correlated with anxiety and depression in OA patients, with critical values of 50 and 53, respectively. VAS is positively correlated with pain sensation in OA patients, ranging from 0–10.
- (2) Joint function: The HHS score is positively correlated with joint function, ranging from 0–100.
- (3) Quality of life: The SF-36 score is positively correlated with the quality of life of OA patients, with each dimension ranging from 0–100.
- (4) Adverse reactions: Record the number of cases of edema and infection.

## 2.5. Statistical analysis

Data is processed using SPSS 23.0. Count data (%) is tested using the  $\chi^2$  test, and measurement data ( $\bar{x} \pm s$ ) is tested using the t-test. There is a statistically significant difference with  $P < 0.05$ .

## 3. Results

### 3.1. Emotion and pain

After 3 weeks of nursing, the scores of SAS, SDS, and VAS in Group A were lower than those in Group B, with  $P < 0.05$ . The results are shown in **Table 2**.

**Table 2.** Comparison of emotion and pain scores ( $\bar{x} \pm s$ )

Group	SAS(score)		SDS(score)		VAS(score)	
	Before nursing	3 weeks of nursing	Before nursing	3 weeks of nursing	Before nursing	3 weeks of nursing
Group A ( $n=41$ )	$55.19 \pm 2.61$	$34.21 \pm 1.26$	$54.28 \pm 2.57$	$34.17 \pm 1.29$	$6.59 \pm 1.25$	$1.66 \pm 0.36$
Group B ( $n=41$ )	$55.21 \pm 2.58$	$42.62 \pm 1.96$	$54.32 \pm 2.59$	$43.06 \pm 1.88$	$6.61 \pm 1.27$	$2.91 \pm 0.43$
$t$	0.0349	23.1111	0.0702	24.9663	0.0719	14.2722
$P$	0.9723	0.0000	0.9442	0.0000	0.9429	0.0000

### 3.2. Joint function

After 1, 2, and 3 weeks of nursing, the HHS scores of Group A were higher than those of Group B, with  $P < 0.05$ , as shown in **Table 3**.

**Table 3.** Comparison of HHS scores ( $\bar{x} \pm s$ )

Group	1 week of nursing	2 weeks of nursing	3 weeks of nursing
Group A ( $n=41$ )	$83.11 \pm 1.25$	$91.44 \pm 1.81$	$97.43 \pm 2.12$
Group B ( $n=41$ )	$80.13 \pm 1.31$	$86.21 \pm 1.62$	$88.36 \pm 1.96$
$t$	10.5381	13.7863	20.1150
$P$	0.0000	0.0000	0.0000

### 3.3. Quality of life

After 3 weeks of nursing, the SF-36 score of Group A was higher than that of Group B, with  $P < 0.05$ , as shown in **Table 4**.

**Table 4.** SF-36 scores ( $\bar{x} \pm s$ )

Group	Physical health (score)		Mental health (score)		Social functioning (score)		Physiological functioning (score)	
	Before nursing	3 weeks of nursing	Before nursing	3 weeks of nursing	Before nursing	3 weeks of nursing	Before nursing	3 weeks of nursing
Group A (n=41)	68.19 $\pm$ 2.11	87.43 $\pm$ 3.85	67.44 $\pm$ 2.06	87.48 $\pm$ 3.82	66.44 $\pm$ 2.08	86.43 $\pm$ 3.79	65.42 $\pm$ 2.11	86.69 $\pm$ 3.82
Group B (n=41)	68.21 $\pm$ 2.08	76.11 $\pm$ 3.16	67.41 $\pm$ 2.09	76.21 $\pm$ 3.11	66.42 $\pm$ 2.06	75.16 $\pm$ 3.06	65.39 $\pm$ 2.14	76.11 $\pm$ 3.14
<i>t</i>	0.0432	14.5526	0.0655	14.6497	0.0437	14.8145	0.0639	13.7000
<i>P</i>	0.9656	0.0000	0.9480	0.0000	0.9652	0.0000	0.9492	0.0000

### 3.4. Adverse reactions

The adverse reaction rate in Group A was lower than that in Group B, with  $P < 0.05$ , as shown in **Table 5**.

**Table 5.** Adverse reactions (n,%)

Group	Edema	Infection	Incidence rate
Group A (n=41)	0(0.00)	1(2.44)	1(2.44)
Group B (n=41)	3(7.32)	3(7.32)	6(14.63)
$\chi^2$	-	-	-
<i>P</i>	-	-	-

## 4. Discussion

OA is a highly prevalent disease among middle-aged and elderly populations, particularly affecting joints with high weight-bearing and activity levels. Long-term joint overloading or excessive use can lead to joint degeneration, inducing symptoms such as joint swelling, stiffness, and pain, which may even restrict joint movement<sup>[3, 4]</sup>. OA is associated with the degeneration of systemic organs. If the patella is affected, patients may experience increased pain when squatting, climbing mountains, or stairs. In severe cases, joint popping and bent stretching difficulties may occur. If the tibial or femoral bones are affected, patients may experience pain during daily walking or rest<sup>[5]</sup>. Additionally, as OA progresses, the continuous thinning of the cartilage layer and damage to the meniscus in the affected limb can lead to local bone spur formation, inducing joint deformity and swelling. The continuous reduction of joint cartilage results in an uneven joint surface, producing a bone rubbing sound. In late-stage patients, limited joint movement and intensified pain can lead to difficulties in straightening the joints or leg weakness during daily walking, significantly impacting their daily lives. There are numerous treatment options for OA, requiring the control of joint inflammation accompanied by nursing intervention. Conventional OA nursing, which is passive and non-targeted, cannot rapidly improve knee joint function and is not conducive to patients' later rehabilitation exercises. Systematic nursing, centered on the rehabilitation of OA patients and considering their psychological and physiological needs, provides services from multiple aspects and can correct patients' joint dysfunction<sup>[6]</sup>.

Based on the data analysis in this study, the SAS, SDS, and VAS scores of Group A were lower than those

of Group B, while the HHS scores were higher, with  $P < 0.05$ . The reason for this is that systematic nursing emphasizes psychological intervention and education intervention, patiently guiding OA patients to alleviate their negative emotions, improve their comfort level, optimize their mental health, and reduce psychological stress. Additionally, utilizing diversified methods for education assists OA patients in understanding their disease knowledge and nursing process knowledge, strengthening their confidence in rehabilitation. Furthermore, nurses assess the level of pain in OA patients and provide pain relief through various forms such as analgesics, cold compresses, and muscle relaxants, which can alleviate joint pain, facilitate patients' subsequent functional exercises, and stabilize OA conditions <sup>[7]</sup>.

Another set of data indicates that the HHS scores of Group A were higher than those of Group B, with  $P < 0.05$ . This is because systematic nursing can alleviate patients' joint pain, improve their prognosis, and encourage them to actively participate in rehabilitation exercises, thereby optimizing knee joint physiology and improving their quality of life. During actual systematic nursing, passive joint exercises are performed to assist OA patients in flexing and extending their joints, enhancing joint movement range. Muscle strength exercises are conducted to improve lower limb muscle strength, laying the foundation for patients to restore walking ability. Balance exercises and life skill training are introduced to help patients relearn life skills, reduce the pressure on the affected limb, and ultimately resolve joint limitations <sup>[8]</sup>.

Additionally, this article introduces the intervention of traditional Chinese medicine damp heat compress during systematic nursing. Applying damp heat compresses with medication at specific locations in the patient's area can increase local blood drug concentration and achieve systemic therapeutic effects. Traditional Chinese medicine damp heat compress is a characteristic technique that is efficient and safe. It can exert effects such as relaxing muscles, promoting blood circulation, removing dampness, and dispelling cold. Through transdermal absorption of medicinal components, it can block inflammation progression, optimize the body's microcirculation, and reduce local inflammatory exudation, resulting in excellent improvement of knee joint function. Another set of data shows that the SF-36 score of Group A was higher than that of Group B, with  $P < 0.05$ . This is because systematic nursing emphasizes rehabilitation exercises and psychological intervention, which can change patients' perceptions of OA disease, encourage them to actively cooperate with nursing interventions, thereby enhancing the effectiveness of rehabilitation exercises, alleviating joint pain in the affected limb, and improving the quality of life for OA patients <sup>[9]</sup>.

The final set of data indicates that the adverse reaction rate in Group A was lower than that in Group B, with  $P < 0.05$ . This is due to the dynamic assessment of OA patients' conditions during systematic nursing services, the improvement of efficient and feasible nursing strategies, the transition from local exercises to mastering self-care skills, and the adjustment of nursing plans and rehabilitation exercise difficulty based on OA patients' adaptability, which can meet patient needs and reduce adverse reactions in OA <sup>[10]</sup>.

## 5. Conclusion

In summary, systematic nursing for OA patients optimizes their quality of life, provides emotional comfort, reduces pain, and decreases adverse reactions, making it worthy of promotion.

## Disclosure statement

The author declares no conflict of interest.

## References

- [1] Chen J, Zhang K, Lu M, et al., 2023, The Impact of Refined Nursing Under the Guidance of Accelerated Rehabilitation Theory on Patients Undergoing Unicompartmental Knee Replacement for Osteoarthritis. *Qilu Nursing Journal*, 29(6): 121–124.
- [2] Orthopedic Professional Committee of China Association for the Promotion of Chinese Medicine Research, Joint Working Committee of Orthopedics and Traumatology Professional Committee of China Association of Integrative Medicine, 2015, Expert Consensus on TCM Diagnosis and Treatment of Knee Osteoarthritis (2015 Edition). *Chinese Journal of Orthopedics and Traumatology*, 27(7): 4–5.
- [3] Mou J, Jiang K, 2022, Application Effect of Nursing Intervention Based on Evidence in the Treatment of Knee Osteoarthritis with Sodium Hyaluronate Injection into Knee Joint Cavity. *Guide of China Medicine*, 20(25): 148–151.
- [4] Zhou Y, 2024, Application Effect of BiosocialPsychological Integrated Nursing in Patients with Knee Osteoarthritis Treated by Acupotomy. *Chinese Journal of Rehabilitation Medicine*, 36(18): 177–180.
- [5] Cui J, 2024, Study on the Application of Perioperative Holistic Nursing and Standardized Pain Intervention in Patients Undergoing Total Knee Replacement. *Heilongjiang Medical Journal*, 48(8): 996–998.
- [6] Zhang F, Huang M, Zhang M, 2024, Effect of Full Psychological Care Combined with Continuous Passive Motion Intervention on Knee Function in Postoperative Knee Patients. *Guide of China Medicine*, 22(13): 180–182.
- [7] Zhao X, Li A, Wang S, Shang W, 2023, Analysis of the Application Effect of Systematic Nursing Intervention in Patients with Knee Osteoarthritis. *Medical Research and War Trauma Treatment*, 36(7): 768–770.
- [8] Li J, 2023, Influence of Accelerated Rehabilitation Surgical Nursing on Joint Function and Mental State of Patients with Knee Osteoarthritis. *Chinese Journal of Disabled Medicine*, 31(8): 81–84.
- [9] Wen H, Gao Q, Wang A, 2023, Effects of Accelerated Rehabilitation Surgical Nursing on Joint Function, Mental State, and Treatment Compliance of Patients with Cervical Spondylosis. *Guizhou Medical Journal*, 47(11): 1838–1839.
- [10] Hui J, Huang T, Cai L, 2021, Effects of Accelerated Rehabilitation Surgical Nursing on Joint Function, Mental State, and Treatment Compliance of Patients with Knee Osteoarthritis. *Chinese Journal of Modern Nursing*, 27(14): 1914–1917.

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# Application of Lung Ultrasound Combined with Multi-organ Evaluation in Assessing the Risk of Weaning from Mechanical Ventilation in Severe Patients

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**Abstract:** *Objective:* To explore the role of lung ultrasound combined with multi-organ evaluation in assessing the risk of weaning from mechanical ventilation (MV) in severe patients. *Methods:* A retrospective analysis was conducted on 60 severe patients admitted to the hospital from December 2022 to December 2024, all of whom underwent MV treatment. Based on weaning status, thirty-eight patients were successfully weaned (success group), and 22 patients failed weaning (failure group). All patients underwent lung ultrasound and multi-organ evaluation. The parameter differences between the two groups were compared, risk factors for weaning risk were evaluated, and a receiver operating characteristic curve (ROC) was drawn to assess the predictive value of lung ultrasound combined with multi-organ evaluation for weaning risk. *Results:* The lung ultrasound score (LUS) of the success group was lower than that of the failure group, the left ventricular ejection fraction (LVEF) was higher than that of the failure group, and the diaphragmatic excursion (DE) and diaphragmatic thickening fraction (DTF) were higher than those of the failure group ( $P < 0.05$ ). Multifactor analysis showed that LUS was a risk factor for weaning risk, while LVEF, DE, and DTF were protective factors ( $P < 0.05$ ). The ROC showed that the area under the curve (AUC) of a single parameter for weaning risk was smaller than that of the combined parameters ( $P < 0.05$ ). *Conclusion:* Lung ultrasound combined with multi-organ evaluation can predict the weaning risk of severe patients undergoing MV treatment, and the diagnostic efficiency of multiple parameters combined evaluation is higher.

**Keywords:** Lung ultrasound; Multi-organ evaluation; Severe patients; Mechanical ventilation; Weaning risk

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## 1. Introduction

MV is a commonly used treatment technique for severe patients, which can maintain patients' lung ventilation function and stabilize their vital signs. MV treatment involves multiple complex processes, such as intubation and weaning, and weaning is the final step. When the patient's condition improves and vital signs stabilize, timely

weaning is necessary to prevent complications such as ventilator-associated pneumonia <sup>[1]</sup>. The spontaneous breathing test (SBT) is a common weaning assessment method with high assessment accuracy, but it has a certain degree of subjectivity, which may lead to weaning failure. Currently, ultrasound technology has become a practical assessment method for severe patients. Among them, lung ultrasound can evaluate lung function status, and multi-organ ultrasound can visually evaluate diaphragmatic movement and thickness levels under noninvasive conditions, understand patients' cardiac function parameters, and thus comprehensively evaluate weaning risk and reasonably determine the weaning timing. However, previous studies have lacked systematic and mature ultrasound evaluation criteria, which have limited guiding significance for the weaning process <sup>[2]</sup>. Therefore, this study selected 60 severe MV-treated patients to explore the predictive effect of lung ultrasound combined with multi-organ evaluation on weaning risk.

## 2. Methods and materials

### 2.1. General information

A retrospective analysis is conducted on the clinical data of 60 patients with severe illness undergoing MV treatment who are admitted to the hospital between December 2022 and December 2024. The patients are grouped based on their weaning status. The successful group consisted of 38 patients, including 21 males and 17 females, aged between 26 and 78 years, with a mean age of  $(49.53 \pm 4.15)$  years. The disease types included 11 cases of acute respiratory failure, 22 cases of severe pneumonia, and 5 other cases. The failure group consisted of 22 patients, including 13 males and 9 females, aged between 24 and 76 years, with a mean age of  $(49.61 \pm 4.24)$  years. The disease types included 10 cases of acute respiratory failure, 9 cases of severe pneumonia, and 3 other cases. There was no significant difference between the two groups ( $P > 0.05$ ).

The criteria for weaning failure are as follows: respiratory rate not less than 35 breaths per minute, or an increase of not less than 50%; blood oxygen saturation not less than 90%, or arterial oxygen partial pressure less than 60 mmHg; pH value less than 7.35; heart rate not less than 145 beats per minute or an increase of not less than 20%; severe arrhythmia; anxiety, profuse sweating; systolic blood pressure less than 90 mmHg, heart rate higher than 145 beats per minute, or an increase of not less than 20%. If none of the above situations occurred, the weaning is considered successful.

The inclusion criteria of the study are: admitted to the intensive care unit; meeting the indications for MV treatment; hemodynamically stable; complete clinical data; informed and consenting to participate in the study. Meanwhile, the exclusion criteria included: history of trauma; abnormal signs such as fever or hypothermia; comorbid pneumothorax; abnormal communication ability; intolerance to MV treatment; mental illness; comorbid malignant tumor; withdrawal from the study.

### 2.2. Methods

Color Doppler ultrasonography (portable) is used for all ultrasound examinations.

- (1) Lung ultrasonography: Patients are positioned in a supine position, and a 12-zone method is adopted. The ultrasound probe is placed on areas such as the patient's anterior axillary line and paravertebral line, which served as the longitudinal axis, while the transverse axis is the nipple level area. The unilateral chest wall is divided into six zones: upper and lower zones of the lateral chest wall, anterior chest wall, and posterior chest wall. A convex array probe with a frequency of 1–5 MHz or a linear array probe with a frequency of

4–12 MHz is used for scanning. Various regions are observed for A/B lines and pleural lines to evaluate pathological manifestations such as lung consolidation or fluid accumulation, and the LUS score was assessed.

- (2) Multi-organ ultrasonography: Echocardiography is performed on the patient's chest. The patient is positioned in a supine position, and a phased array probe with a frequency of 1–5 MHz is used. The probe is placed in areas such as the subxiphoid region, suprasternal notch, and apical region for multi-slice scanning, including parasternal short-axis view, five-chamber view, and apical four-chamber view. Cardiac function parameters are recorded. A convex or linear array probe is placed in the ZOA area, which is the circular lateral area of the diaphragm connected to the lower chest wall. The probe is positioned perpendicular to the chest wall to measure indicators such as diaphragmatic thickness at the end of exhalation and inhalation.

Two senior imaging physicians are responsible for analyzing the ultrasound images using a double-blind method. If there are disagreements, a consensus is reached through discussion to provide the final results. All ultrasound parameters are continuously evaluated three times, and the average value is taken.

## **2.3. Observation indicators**

### **2.3.1. Ultrasonic parameters**

- (1) LUS score: Zero points indicate fewer than 3 A/B lines; 1 point indicates at least 3 well-spaced B lines; 2 points indicate diffuse fusion of B lines; 3 points indicate concomitant lung consolidation. The total score is the sum of the scores in 12 regions, with a maximum of 36 points. Lung lesions are positively correlated with the score.
- (2) Cardiac function parameters: Record values such as LVEF, right/left ventricular end-diastolic diameter ratio (RV/LV), cardiac output [CO, calculated as blood flow velocity-time integral (VTI) in the left ventricular outflow tract \*  $\pi r^2$  \* heart rate], and tricuspid annular plane systolic excursion (TAPSE).
- (3) Diaphragmatic function parameters: diaphragmatic thickness, DE, and DTF (the difference in diaphragmatic thickness between end-inspiration and end-exhalation divided by diaphragmatic thickness at end-exhalation).

### **2.3.2. Risk factors for weaning**

Use multifactor analysis to evaluate protective and risk factors for weaning.

### **2.3.3. Predictive value of ultrasonic parameters for weaning risk**

Use ROC curves to evaluate various parameters' AUC values, cut-off values, sensitivity, and specificity for weaning risk.

## **2.4. Statistical analysis**

Data processing is performed using SPSS 28.0 software. Measurement data are expressed as  $\bar{x} \pm s$  and compared using the t-test. Count data are expressed as [n/%] and compared using the  $\chi^2$  test. Logistic multifactor regression analysis is used to identify independent influencing factors, ROC analysis is used to assess predictive value, and the AUC is compared using the Z-test. Statistical significance is set at  $P < 0.05$ .

### 3. Results

#### 3.1. Comparison of ultrasonic parameters between the two groups

The successful group had a lower LUS score, higher LVEF, and higher DE and DTF than the failure group ( $P < 0.05$ ). There were no differences in other ultrasonic parameters between the two groups ( $P > 0.05$ ). The results are shown in **Table 1**.

**Table 1.** Comparison of ultrasonic parameters between the two groups [ $\bar{x} \pm s$ ]

Group	Number of cases	LUS score (points)	Cardiac function parameters				Diaphragmatic function parameters		
			LVEF (%)	RV/LV	CO (L/min)	TAPSE (cm)	Diaphragm thickness (cm)	DE(cm)	DTF(%)
Success group	38	15.14 $\pm$ 2.08	56.04 $\pm$ 4.38	0.92 $\pm$ 0.24	5.91 $\pm$ 0.44	2.11 $\pm$ 0.22	0.18 $\pm$ 0.27	1.79 $\pm$ 0.43	32.48 $\pm$ 4.12
Success group	22	21.48 $\pm$ 2.91	44.05 $\pm$ 4.31	0.88 $\pm$ 0.27	5.87 $\pm$ 0.49	2.08 $\pm$ 0.25	0.17 $\pm$ 0.25	1.42 $\pm$ 0.40	26.15 $\pm$ 4.03
<i>t</i>	-	9.805	10.277	0.594	0.325	0.484	0.142	3.293	5.780
<i>P</i>	-	< 0.001	< 0.001	0.555	0.746	0.630	0.888	0.002	< 0.001

#### 3.2. Multifactor analysis of weaning risk

Using weaning status as the dependent variable, with a value of 1 assigned to successful weaning and 0 assigned to failed weaning, and using the ultrasonic parameters from **Table 1** with  $P < 0.05$  as independent variables. Logistic analysis showed that LUS was a risk factor for weaning, while LVEF, DE, and DTF were protective factors ( $P < 0.05$ ). The results are shown in **Table 2**.

**Table 2.** Multifactor analysis of weaning risk

Variables	Standard error	Regression coefficient	Wald $\chi^2$ value	OR value	95%CI	<i>P</i> value
LUS	0.214	0.699	10.715	2.010	1.320–3.051	0.001
LVEF	0.105	-0.271	6.968	0.768	0.621–0.936	0.009
DE	0.095	-0.211	8.710	0.764	0.630–0.915	0.004
DTF	0.084	-0.210	6.692	0.814	0.690–0.955	0.008

#### 3.3. Predictive value of ultrasonic parameters for weaning risk

ROC analysis showed that the AUC values of single parameters for predicting weaning risk were all lower than that of combined detection ( $P < 0.05$ ), as shown in **Table 3**.

**Table 3.** Predictive value of ultrasonic parameters for weaning risk

Parameters	AUC	Cut-off value	Sensitivity	Specificity	<i>P</i> -value
LUS	0.818	19.55	72.65%	85.01%	< 0.001
LVEF	0.770	49.75%	71.25%	70.90%	< 0.001
DE	0.779	1.71cm	86.60%	63.05%	< 0.001
DTF	0.815	28.20%	71.25%	75.64%	< 0.001
Combined parameters	0.904	-	69.90%	95.31%	< 0.001

## 4. Discussion

Critically ill patients require respiratory support and other means to maintain normal physiological functions due to their severe condition. Mechanical ventilation (MV) is the primary treatment modality for these patients, providing noninvasive respiratory support based on their respiratory function and allowing for the rational selection of treatment plans <sup>[3]</sup>. However, these patients often experience prolonged coma, complex illnesses, and extended treatment cycles, leading to elevated risks of weaning failure during MV, which can result in complications such as hypostatic pneumonia or respiratory failure, ultimately affecting treatment outcomes. To prevent weaning failure, clinical practice commonly employs spontaneous breathing trials (SBT) to assess weaning risk and determine appropriate weaning opportunities. Nevertheless, critically ill patients may exhibit significant ventilator dependency, decreased physiological function, and considerable difficulty in weaning <sup>[4]</sup>. While SBT can predict weaning opportunities, it still has a failure rate of over 10%, limiting its applicability in severe cases.

Tissue damage is often severe in critically ill patients, and even if lung function indicators suggest readiness for weaning, conditions such as inadequate cardiac function may exist, increasing the likelihood of weaning failure <sup>[5, 6]</sup>. Therefore, actively incorporating indicators such as cardiac and diaphragmatic function into weaning risk assessment projects, adopting lung ultrasound combined with multi-organ evaluation techniques, can help clinicians grasp patients' respiratory status and cardiac health, enabling timely weaning and improving weaning success rates.

Results indicate that the Lung Ultrasound Score (LUS) was lower in the successful weaning group compared to the failure group, while Left Ventricular Ejection Fraction (LVEF), Diaphragmatic Excursion (DE), and Diaphragmatic Thickening Fraction (DTF) were higher in the successful group ( $P < 0.05$ ). Logistic analysis revealed that LUS is a risk factor for weaning, whereas LVEF, DE, and DTF serve as protective factors ( $P < 0.05$ ). Evidently, patients who successfully wean exhibit less severe lung pathology, better gas exchange function in lung tissue, and good lung compliance, reducing the likelihood of abnormalities such as hypoxemia or shortness of breath after weaning and lowering the difficulty of the weaning process <sup>[7]</sup>. If a patient's LUS score is high, they may require continued MV treatment with dynamic assessment of LUS score changes to adjust treatment plans and determine appropriate weaning opportunities<sup>[8]</sup>.

Echocardiography, with its noninvasive advantages and good repeatability, can adequately assess the positional relationship between cardiac tissue and surrounding large blood vessels, comprehensively capture cardiac function information, understand patients' cardiac structural characteristics, and grasp their cardiac preload and afterload, as well as systolic and diastolic functions. This allows for accurate assessment of patients' hemodynamic characteristics and determination of weaning opportunities. A high LVEF parameter in successfully weaned patients indicates good cardiac function and a high tolerance for weaning procedures, reducing adverse events such as weaning failure <sup>[9]</sup>. Diaphragmatic ultrasound assesses diaphragmatic thickness and activity, predicting diaphragmatic excursion. High DE and DTF parameters in the successful weaning group suggest strong diaphragmatic contractility and endurance, enhancing patients' tolerance to the weaning process. Their respiratory and diaphragmatic functions are better, and they are less likely to experience symptoms such as dyspnea after weaning <sup>[10]</sup>.

Under the ROC curve, the AUC values of single parameters for weaning risk are all less than those of combined detection ( $P < 0.05$ ). This suggests that combined parameters can scientifically guide weaning decisions, providing comprehensive and accurate assessments of critically ill patients' physical conditions. This approach enables clinicians to control weaning opportunities, prevent weaning failures, and achieve better disease prognosis.

## 5. Conclusion

In summary, implementing lung ultrasound combined with multi-organ evaluation for critically ill patients undergoing MV treatment can predict their weaning risk, screen for protective and risk factors during the weaning process, and obtain better diagnostic performance using a combined parameter evaluation method. This approach offers high predictive value.

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## References

- [1] Chen D, Shi J, Han J, et al., 2021, Predictive Value of Lung Ultrasound B-Line Score for Weaning Results of Mechanically Ventilated Patients. *Journal of Medical Research*, 50(8): 55–60.
- [2] Wang F, He J, Huang X, et al., 2024, Predictive Value of Diaphragmatic Rapid Shallow Breathing Index Combined with Lung Ultrasound Score for Poor Weaning Outcomes of ICU Mechanically Ventilated Patients. *International Journal of Respiration*, 44(1): 53–58.
- [3] Cheng L, Xiao W, Zhuo R, et al., 2023, Exploring the Predictive Value of Lung Ultrasound B-Line Integration for Weaning Results of Mechanically Ventilated Patients. *World Latest Medicine Information (Electronic Version)*, 23(94): 52–57.
- [4] Liu Z, Zeng J, Liu L, et al., 2022, Application Value of Bedside Multi-Organ Ultrasound in Assessing the Risk of Weaning from Mechanical Ventilation in Severe Patients. *Chinese and Foreign Medical Research*, 1(18): 120–122.
- [5] Wu Y, Huang Y, Zhou Z, et al., 2023, Analysis of the Application Value of Lung Ultrasound Combined with Diaphragmatic Function in Weaning Severe Patients. *Xinjiang Medical Journal*, 53(7): 825–827, 862.
- [6] Qin H, Xia L, 2023, Construction and Verification of a Risk Assessment Model for Difficult Weaning in Critically Ill Patients with Invasive Mechanical Ventilation. *Modern Nurse*, 30(25): 86–90.
- [7] Liu X, Zhang J, Wang T, et al., 2024, Clinical Value of Bedside Multi-Organ Ultrasound in Predicting the Risk of Weaning from Mechanical Ventilation in Severe Patients. *Journal of Clinical Ultrasound in Medicine*, 26(9): 773–777.
- [8] Qian Z, Zheng L, Jin M, 2022, Study on the Predictive Value of Multi-Organ Combined Ultrasound for Weaning from Mechanical Ventilation. *Medical and Health Equipment*, 43(1): 58–62.
- [9] Wang X, Jia Y, 2021, Analysis of the Value of Applying Invasive Mechanical Ventilation in the Treatment of Severe Heart Failure to Reduce Adverse Reactions in Patients. *Chinese Remedies & Clinics*, 21(4): 633–635.
- [10] Zhang W, Yu P, Yu M, et al., 2024, A Qualitative Study on the Assessment Obstacles of ICU Nurses to Ambulation of Patients with Invasive Mechanical Ventilation. *Military Nursing*, 41(3): 39–42.

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# A Qualitative Study on the Influencing Factors of Training Transfer for Oral Specialist Nurses

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**Abstract:** *Objective:* Through interviews with oral specialist nurses, to explore the influencing factors of training transfer for oral specialist nurses, and provide references for scientifically improving the effect of specialist nurse training transfer. *Methods:* Using purposive sampling and descriptive qualitative research, 15 oral specialist nurses from two tertiary hospitals in Guangdong Province were selected for semi-structured interviews, and data analysis was performed. *Results:* After collating and analyzing the interview data, three types of factors affecting the training transfer of oral specialist nurses were proposed, including personal characteristics, training management, and training transfer atmosphere. *Conclusion:* Managers should formulate a comprehensive and systematic plan based on the influencing factors of oral specialist nurse training transfer to effectively promote training transfer behavior and enhance training transfer effects.

**Keywords:** Oral specialist nurses; Training transfer; Qualitative research

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## 1. Introduction

The “Healthy Oral Action Plan (2019–2025)” developed by the National Health Commission proposes to give full play to the role of specialized nursing and cultivate compound talents capable of oral health education, nursing, and prevention <sup>[1]</sup>. Studies have shown that some oral specialist nurses only stay at the stage of learning theoretical knowledge and operational skills, lacking the ability to translate what they have learned into actual nursing behavior, resulting in difficulties in sustaining the training effect in their work <sup>[2]</sup>. Training transfer, which effectively translates the professional knowledge and skills acquired during training into work practices, is a core aspect of ensuring the quality of oral nursing <sup>[3]</sup>. Baldwin and Ford proposed a model for the training transfer process that includes trainer personal traits, training design, and work environment, which they believe affect training transfer effect indicators <sup>[4]</sup>. This study intends to analyze interview results based on the Baldwin and Ford model, summarizing relevant influencing factors of oral specialist nurse training transfer as a strategic basis for

improving training effectiveness.

## 2. Objects and methods

### 2.1. Determination of research team

The team consists of 5 members, including 1 chief nursing officer, 1 deputy chief nursing officer, 3 nursing supervisors, and other team members who collaborate and divide the work.

### 2.2. Interview subjects

From April 2023 to November 2023, 15 oral specialist nurses from two tertiary hospitals in Guangdong Province were selected as samples using purposive sampling. Inclusion criteria: (1) Working experience in oral nursing  $\geq 1$  year; (2) Informed consent for the interview; (3) Obtained training certificate and practice qualification certificate. Based on the actual needs of the interview, the final sample size is determined based on the principle of no new themes and saturation of information. The number of interviewees included was 15 (**Table 1**).

**Table 1.** General information of interview subjects ( $n = 15$ )

Interviewee serial number	Age (years old)	Education	Title	Position	Years of oral nursing work (years)
N1	52	Bachelor's degree	Associate chief nursing officer	Head nurse	33
N2	35	Master's degree	Nurse-in-charge	Clinic nurse	6
N3	35	Bachelor's degree	Nurse-in-charge	Clinic nurse	8
N4	29	Master's degree	Nurse	Clinic nurse	3
N5	39	Bachelor's degree	Nurse-in-charge	Head nurse	9
N6	41	Bachelor's degree	Associate chief nursing officer	Head nurse	16
N7	43	Bachelor's degree	Nurse-in-charge	Clinic nurse	10
N8	35	Bachelor's degree	Nurse-in-charge	Clinic nurse	12
N9	46	Bachelor's degree	Nurse-in-charge	Clinic nurse	24
N10	36	Bachelor's degree	Nurse-in-charge	Head nurse	5
N11	30	Bachelor's degree	Nurse	Clinic nurse	4
N12	45	Bachelor's degree	Nurse-in-charge	Clinic nurse	18
N13	33	Bachelor's degree	Nurse-in-charge	Clinic nurse	3
N14	44	Bachelor's degree	Nurse-in-charge	Head nurse	22
N15	44	Bachelor's degree	Nurse-in-charge	Clinic nurse	20

### 2.3. Perfecting the interview outline

Based on grounded theory <sup>[5]</sup>, an interview outline was designed, and relevant literature was retrospectively analyzed. Team members were guided to conduct a preliminary analysis of the interview outline. Subsequently, two oral specialty nurses were selected to conduct a pre-interview. The results of the pre-interview were analyzed, the interview outline was adjusted, and the final version of the interview outline was clarified (**Table 2**).

**Table 2.** Interview outline

Serial number	Interview topic
1	What are your thoughts and feelings about your experience with oral specialty nurse training?
2	Are you able to proficiently apply the nursing knowledge and skills learned during training in your actual work?
3	What difficulties have you encountered when applying training knowledge during actual work?
4	What factors influence your ability to apply training knowledge during actual work?
5	What kind of assistance do you need when applying the knowledge learned during training in your actual work?

## 2.4. Data collection

One-on-one in-depth interviews were conducted using a semi-structured approach. The interview outline was used as the main thread for the interviews, and the questioning method was flexibly adjusted according to the on-site situation to ensure the rigor of the interviews. Each interview was limited to 30 minutes, and the interviewees were informed beforehand that the interview content would be recorded. Recording equipment was activated after the interviewee agreed.

## 2.5. Data analysis and quality control

The data management and analysis software Nvivo 11.0 was selected. Interview subject coding was completed according to the actual interview order, and independent archiving services were provided for each interview subject. Relevant data related to research questions were organized, and themes were extracted using the Colaizzi 7-step analysis method <sup>[6]</sup>. The interviewer maintained a neutral state throughout the interview process. Two interview staff transcribed the interview content within 24 hours and organized it into textual data.

## 3. Results

### 3.1. Personal factors

#### 3.1.1. Personal ability

Personal ability refers not only to the learning ability of specialized training content but also to the ability to effectively transform and apply learned content to work after specialized learning. Interview results showed that 10 interview subjects indicated that oral specialty nurse training could improve their professional abilities. N3 stated, “Through this specialized nurse training, I have improved my mastery of professional knowledge and technical operations.” N13 said, “I have gained a lot from the specialized nurse training. I completed a nursing case and participated in an oral health education competition.” N11 explained changes in nursing work methods after receiving specialized nurse training using the example of health education for patients with removable dentures. N14 mentioned, “After the training, when I encounter problems in my work, I will search for literature to conduct evidence-based practice.”

#### 3.1.2. Training transfer motivation

Interview results showed that the main motivations for training transfer among the interview subjects were to absorb new knowledge, improve personal abilities, and achieve self-worth through training; a few interviewees were motivated by meeting leadership expectations or accompanying nurses at the same level. N5 stated, “I like learning, and through training, I can learn a lot of new knowledge, not just four-handed operation but also

management, infection control, etc., which gives me a lot of satisfaction.” N10 said, “I want to learn some new knowledge and apply it in clinical work.” N9 mentioned, “It’s a work requirement, and I’m learning with my colleagues.”

### **3.2. Training management**

#### **3.2.1. Training content and methods**

All 15 interviewees indicated that the content and methods of training can affect the effectiveness of specialized nurse training, which in turn affects the effectiveness of training transfer. N2 stated, “The training method combines theory with practice, but for me personally, the practical part accounts for a relatively small proportion, which affects my application after the study is finished.” N8 said, “The systematization of theoretical training is particularly important for the training of specialized nurses.” N6 added, “I believe that scientific research knowledge is also important in specialized nurse training, but there is too little relevant content in actual training.”

#### **3.2.2. Teacher management**

The interview results showed that the level of instructors can affect the learning experience of specialized nurses, and the impact on training effectiveness cannot be ignored. This also has a certain impact on training transfer. N9 commented, “Most of the training content and practical operations are very practical, but some teachers speak very fast, and I haven’t absorbed this part of the knowledge before they start the next part.” N11 said, “There are differences in the teaching levels of different training classrooms, which leads to differences in my mastery of the training content.” N13 added, “The teaching ability of the instructor actually has a great impact on the degree of knowledge received by the students.”

### **3.3. Training transfer atmosphere**

#### **3.3.1. Organizational support**

Fifteen interviewees stated that support from management is a decisive factor affecting the effectiveness of specialized nurses’ work. N2 said, “The department leaders attach great importance to my specialized nurse studies. After the studies are finished, they arrange for me to report, and everyone is very enthusiastic.” N4 added, “Without the support of the department, it would be difficult to carry out the work.” N11 stated, “After the training, some of my ideas were adopted by the leaders, and implementation can be considered as smooth as if assisted by divine intervention.” N1 commented, “I am mainly responsible for management in the department, and compared with nurses who received the same batch of training, I have indeed had a smoother time carrying out the work.” N15 said, “When feeding back new ideas for department improvement to my superiors, they didn’t quite understand, which led to difficulties in implementation.”

#### **3.3.2. Department learning atmosphere**

Thirteen interviewees indicated that a good learning atmosphere is particularly important for training transfer effectiveness. N3 stated, “It’s not enough for just me to have this knowledge. If it’s the entire department, a team, then the effect can be optimized.” N4 added, “The department needs to have a good learning atmosphere where I can share and everyone can discuss.” N7 said, “Some department members lack the motivation to learn and receive new knowledge and skills.” N15 concluded, “Someone must be willing to learn, and everyone must make progress together to improve the professional technical ability of the entire department.”

### **3.3.3. Application opportunities**

Eleven interviewees indicated that although they had learned a lot of knowledge during the specialized nurse training, they had no opportunity to apply it to practical work. They maintained their pre-training work status in areas such as clinical patient care and health education. N14 stated, “I am too busy with my daily work, and my schedule is fully packed with routine tasks.” N8 said, “After returning to my department, there was no difference in my work content compared to before the training. I was too busy to follow the learned standards for health education.” N12 expressed, “When applying training knowledge to clinical work, I always encounter difficulties, such as the need for doctors’ cooperation with new techniques and skills, but some doctors are resistant to accepting new knowledge.”

## **4. Discussion**

### **4.1. Stimulating transfer motivation and cultivating job competency**

The results of this study show that the transfer motivation of oral specialized nurses has a significant positive effect on training transfer effectiveness, which is consistent with the findings of Wang *et al.* <sup>[7]</sup>. It is suggested that managers strengthen the personal capacity building of oral specialized nurses during training, invite specialized nurses with rich transfer experience to share methods and techniques, and help learners better integrate their knowledge into practice. Most interviewed nurses believe that training not only improves their professional level but also provides opportunities for their career development. This motivation promotes training transfer effectiveness. To fully stimulate this transfer motivation, it is recommended to establish a scientific reward and punishment system, conduct regular evaluations of specialized nurses’ work effectiveness, and provide appropriate recognition and rewards. Simultaneously, a clear career development path should be provided for specialized nurses to stimulate their professional enthusiasm and pride, enhance their work engagement, and ultimately improve training transfer effectiveness.

### **4.2. Optimizing training methods and standardizing teacher management**

The interview results indicate that training content, methods, and teachers significantly affect the training transfer effectiveness of oral specialized nurses after returning to their jobs. Ju *et al.* also proposed that appropriate training content and a good training environment can improve training transfer effectiveness <sup>[8]</sup>. Lv *et al.* validated the importance of training teachers in their study on stroke specialized nurses <sup>[9]</sup>. Regarding training methods, diverse and interactive innovative teaching approaches can be adopted to enhance learners’ participation and learning effectiveness. Simultaneously, emphasis should be placed on the practicality of training, providing sufficient practical opportunities and simulated environments. In terms of training content, a unified training outline should be established to ensure that the training content closely matches the actual work needs of oral specialized nurses, emphasizing practicality and operability. The training content can be set in stages, gradually deepening, and should be updated to ensure its cutting-edge and effectiveness. Regarding training teachers, it is essential to ensure that they can provide authoritative and professional guidance to learners, possess excellent teaching skills and communication abilities, and stimulate learners’ enthusiasm and motivation.

### **4.3. Create a transfer climate and enhance the work autonomy of specialized nurses**

The interview results indicate that the post-training transfer environment has a significant impact on training

transfer effectiveness. Studies have shown that managers providing a positive organizational climate can enhance employees' proactive behavior <sup>[10,11]</sup>. Zhang *et al.*'s research also suggests that China currently lacks a comprehensive management system for specialized nurses and urgently needs to establish a climate that promotes positive training transfer for specialized nurses <sup>[12]</sup>. Therefore, hospital administrators should provide platforms for specialized nurses to improve their knowledge level, encourage re-training and scientific research innovation for oral specialized nurses, establish a learning organization culture, set up reward mechanisms, and encourage specialized nurses to teach what they have learned to other nurses in the department. At the same time, it is necessary to regularly evaluate and provide feedback on the training outcomes of oral specialized nurses, promptly identify problems, and make adjustments and improvements to maintain the effectiveness and sustainability of the training.

## 5. Conclusion

This study found that individual characteristics, training management, and training transfer climate are the main factors that affect training transfer effectiveness. There are certain limitations in this study. The interview subjects were all from tertiary hospitals in Guangdong Province. In the future, different levels and regions of hospitals should be selected for further exploration, and the influencing factors of training transfer effectiveness for oral specialized nurses should be analyzed from multiple perspectives. Comprehensive programs should be developed by drawing on the experience of foreign oral specialized nurses and domestic nurses to enhance the quality of training transfer.

## Disclosure statement

The authors declare no conflict of interest

## References

- [1] National Health Commission of the People's Republic of China, 2019, Action Plan for Healthy Mouth (2019–2025). Chinese Journal of Practical Rural Doctor, 26(4): 3.
- [2] Nie S, Zhao J, Sun H, 2019, Investigation on the Utilization of Specialized Nurses in 226 Secondary and Tertiary Hospitals in China. Chinese Journal of Nursing, 54(11): 6.
- [3] London PA, Flannery DD, 2004, Social Factors That Impact Women's Practice of Breast Self-Examination: A Challenge to the Transfer of Training Literature. Journal of European Industrial Training, 28(7): 538–549.
- [4] Song H, Wang H, 2019, Research on the Transformation Promotion Mechanism of Teacher School-Based Training – A Moderated Mediation Model. Journal of East China Normal University: Educational Science Edition, 2019(2): 8.
- [5] Fei X, 2008, Research Methodology of Grounded Theory: Elements, Research Procedures, and Evaluation Criteria. Public Administration Review, 2008(3): 22.
- [6] Liu M, 2019, Application of Colaizzi's Seven Steps in the Analysis of Phenomenological Research Data. Journal of Nursing Science, 34(11): 3.
- [7] Wang Y, Xiong L, Guo X, Li X, Wang Y, Xu C, 2023, A Qualitative Study on the Development Process and Influencing Factors of Specialized Nurse Training Transfer. Journal of Nursing Science, 38(18): 72–75.
- [8] Ju S, Qu W, Xue H, et al., 2023, Application of Semi-Structured Interviews in Investigating the Current Status of

Community Wound Specialized Nurse Training Transfer. *Shanghai Pharmaceuticals*, 44(10): 11–14.

- [9] Lv F, Zhang Y, 2022, Analysis of the Current Situation and Influencing Factors of Stroke Specialized Nurse Training Transfer. *Modern Nurse: Comprehensive Edition*, 2022(001): 29.
- [10] Wu C, Parker SK, 2017, The Role of Leader Support in Facilitating Proactive Work Behavior. *Journal of Management*, 43(4): 1025–1049.
- [11] Westman J, Daleiden E, Chorpita B, 2019, The Agency Supervisor Model: Developing Supervisors Who Facilitate Therapist Transfer of Training in Community Behavioral Health Service Organizations. *The Clinical Supervisor*, 2019: 1–21.
- [12] Zhang Y, Lv F, Chen Q, et al., 2022, Research Progress of Training Transfer and Its Enlightenment to Specialized Nurse Training. *Chinese Journal of Nursing*, 57(11): 5.

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# Application of Transcranial Magnetic Stimulation Technology in the Management of Motor Symptoms of Parkinson's Disease

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**Abstract:** *Objective:* To study the effect of transcranial magnetic stimulation (TMS) on improving motor symptoms in patients with Parkinson's disease (PD). *Methods:* 60 PD patients who visited the hospital from September 2023 to August 2024 were selected as samples and randomly divided into two groups. Group A received conventional medication plus TMS treatment, while Group B received medication only. The efficacy of motor function improvement, neurological symptoms, mental state, sleep quality, quality of life, and adverse reactions was compared between the two groups. *Results:* The efficacy of Group A was higher than that of Group B ( $P < 0.05$ ). The scores of the Scales for Outcomes in Parkinson's Disease-Autonomic (SCOPA-AUT), Mini-Mental State Examination (MMSE), and Pittsburgh Sleep Quality Index (PSQI) in Group A were lower than those in Group B ( $P < 0.05$ ). The quality of life scale (SF-36) score in Group A was higher than that in Group B ( $P < 0.05$ ). The adverse reaction rate in Group A was lower than that in Group B ( $P < 0.05$ ). *Conclusion:* TMS used in the treatment of PD patients can improve patients' mental state and motor function, optimize sleep quality and quality of life, and is safe and efficient.

**Keywords:** Parkinson's disease; Transcranial magnetic stimulation technology; Motor symptom management

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## 1. Introduction

PD is a neurodegenerative disease related to dopamine and acetylcholine level disorders, which can cause a series of motor symptoms, including muscle rigidity, tremor, and bradykinesia. Clinically, anti-PD drugs are often used to reduce PD motor symptoms and delay disease progression. However, the cure rate is low, and long-term use of anti-PD drugs can easily cause side effects, increase the risk of drug dependence and dyskinesia, and even worsen patients' negative emotions and impair their cognitive function. Therefore, it is extremely important to explore efficient adjuvant treatment options for PD <sup>[1]</sup>. TMS refers to the stimulation of the central nervous system by pulsed magnetic fields, which continuously act on cortical nerve cells, causing changes in membrane potential

and generating induced currents. This can affect patients' neurological electrical activity and craniocerebral metabolism, inducing a series of physiological changes. It is suitable for the treatment of psychiatric and neurological diseases<sup>[2]</sup>. Based on this, this article explores the efficacy of TMS control using 60 PD patients who visited the hospital from September 2023 to August 2024 as samples.

## 2. Materials and methods

### 2.1. Materials

60 PD patients who visited the hospital from September 2023 to August 2024 were selected as samples and randomly divided into two groups using a lottery method. There was no difference in baseline data between Group A and Group B ( $P > 0.05$ ). As shown in Table 1.

**Table 1.** Analysis of the baseline data of PD patients

Group	n	Gender (%)		Age (years)		Course of disease (years)	
		Male	Female	Range	Mean	Range	Mean
Group A	30	17 (56.67)	13 (43.33)	41–72	66.26 ± 2.11	2–6	4.81 ± 0.26
Group B	30	18 (60.00)	12 (40.00)	41–73	66.31 ± 2.13	2–7	4.79 ± 0.29
$\chi^2/t$	-	0.0686		0.0913		0.2813	
$P$	-	0.7934		0.9275		0.7795	

### 2.2. Inclusion and exclusion criteria

Inclusion criteria: (1) Unilateral resting tremor with asymmetrical symptoms; (2) Signed informed consent; (3) Symptoms such as inability to maintain balance and muscular rigidity. Exclusion criteria: (1) History of craniocerebral injury; (2) Persistent gaze paralysis; (3) Malignant Parkinson's disease.

### 2.3. Treatment methods

Group A combined with TMS treatment: Treatment was completed with a YRDCCY-I magnetic field stimulator, using a 9 cm droplet-shaped coil with a frequency adjusted to 1 Hz. The stimulation position was determined, selecting the bilateral dorsolateral prefrontal cortex, with coil positions F3 and F4 on both sides, and the motor threshold was controlled at 80%. The threshold measurement position was selected 0.5–1.0 cm anterior to C3, with an initial intensity of 50%, and gradually increased until twitching of the upper limbs and fingers was observed. It is recommended that each treatment session last 20 minutes, with a frequency of 40 times per minute, stimulating for 2 weeks, for a total of 8000 stimulations.

Group B received oral administration of Dopamine Hydrochloride and Benserazide Hydrochloride Tablets (produced by Zhejiang Huayuan Pharmaceutical Co., Ltd., containing 600 mg of levodopa and 150 mg of benserazide). The initial single dose was 125 mg, taken 3 times daily, adjusted based on the patient's condition, with a maximum daily dose of 500–1000 mg. Administered for 2 weeks.

### 2.4. Observation indices

- (1) Efficacy: Evaluated based on the "Parkinson's Disease Treatment Guidelines"<sup>[3]</sup> and the Unified Parkinson's Disease Rating Scale Part III (UPDRS III). The total score of UPDRS III is 56, and the

severity of movement disorders is directly proportional to the score. Significant efficacy was noted when muscle tone was restored, movement disorders significantly improved, and UPDRS III decreased by  $\geq 50\%$ . Improvement was noted when muscle tone improved, movement disorders ameliorated, and UPDRS III decreased by  $\geq 20\%$ . No effect was recorded when UPDRS III decreased by  $< 20\%$ .

(2) Neurological symptoms, mental state, and sleep quality: SCOPA-AUT is directly proportional to the degree of autonomic nerve damage in PD, ranging from 0–69; MMSE is directly proportional to cognitive function in PD, ranging from 0–30; PSQI is directly proportional to sleep disorders in PD, ranging from 0–21.

(3) Quality of life: SF-36 is directly proportional to the quality of life in PD, ranging from 0–100.

(4) Adverse reactions: Nausea, insomnia, dizziness, and lethargy were recorded.

## 2.5. Statistical analysis

Data were processed using SPSS 23.0, with PD count data (%) analyzed using the  $\chi^2$  test and PD measurement data (mean  $\pm$  SD) analyzed using the *t*-test. Comparisons were considered statistically significant at  $P < 0.05$ .

## 3. Results

### 3.1. Efficacy

The efficacy of Group A was higher than that of Group B, with  $P < 0.05$ . See **Table 2**.

**Table 2.** Comparison of efficacy (*n*,%)

Group	Marked effect	Effective	Ineffective	Effective rate
Group A ( <i>n</i> = 30)	18 (60.00)	11 (36.67)	1 (3.33)	29 (96.67)
Group B ( <i>n</i> = 30)	10 (33.33)	13 (43.33)	7 (23.33)	23 (76.67)
$\chi^2$	-	-	-	5.1923
<i>P</i>	-	-	-	0.0227

### 3.2. Neurological symptoms, mental state, and sleep quality

After treatment, Group A had better SCOPA-AUT, MMSE, and PSQI scores compared to Group B, with  $P < 0.05$ . See **Table 3**.

**Table 3.** Comparison of neurological symptoms, mental state, and sleep quality (mean  $\pm$  SD)

Group	SCOPA-AUT (score)		MMSE (score)		PSQI (score)	
	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Group A ( <i>n</i> = 30)	21.23 $\pm$ 2.11	10.31 $\pm$ 1.26	21.58 $\pm$ 1.36	26.71 $\pm$ 2.29	13.15 $\pm$ 1.43	8.79 $\pm$ 1.06
Group B ( <i>n</i> = 30)	21.24 $\pm$ 2.13	13.72 $\pm$ 1.89	21.61 $\pm$ 1.39	25.13 $\pm$ 2.15	13.19 $\pm$ 1.48	9.62 $\pm$ 1.18
<i>t</i>	0.0183	8.2225	0.0845	2.7551	0.1065	2.8660
<i>P</i>	0.9855	0.0000	0.9330	0.0078	0.9156	0.0058

### 3.3. Quality of life

After treatment, Group A had a higher SF-36 score than Group B, with  $P < 0.05$ . See **Table 4**.

**Table 4.** Quality of life (mean  $\pm$  SD)

Group	Physical Health (score)		Mental Health (score)		Physiological Function (score)		Social Function (score)	
	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Group A ( $n = 30$ )	62.19 $\pm$ 2.43	87.11 $\pm$ 3.81	63.18 $\pm$ 2.51	86.43 $\pm$ 3.72	63.22 $\pm$ 2.61	87.16 $\pm$ 3.79	64.01 $\pm$ 2.38	86.43 $\pm$ 3.81
Group B ( $n = 30$ )	62.21 $\pm$ 2.39	76.26 $\pm$ 2.69	63.23 $\pm$ 2.54	75.43 $\pm$ 3.16	63.18 $\pm$ 2.63	75.43 $\pm$ 3.12	64.03 $\pm$ 2.37	74.25 $\pm$ 3.26
$t$	0.0321	12.7420	0.0767	12.3437	0.0591	13.0877	0.0326	13.3043
$P$	0.9745	0.0000	0.9391	0.0000	0.9531	0.0000	0.9741	0.0000

### 3.4. Adverse reactions

The adverse reaction rate in Group A was lower than that in Group B, with  $P < 0.05$ . See **Table 5**.

**Table 5.** Adverse reactions ( $n$ , %)

Group	Nausea	Insomnia	Dizziness	Lethargy	Incidence rate
Group A ( $n = 30$ )	0 (0.00)	0 (0.00)	1 (3.33)	0 (0.00)	1 (3.33)
Group B ( $n = 30$ )	1 (3.33)	2 (6.67)	3 (10.00)	1 (3.33)	7 (23.33)
$\chi^2$	-	-	-	-	5.1923
$P$	-	-	-	-	0.0227

## 4. Discussion

Parkinson's Disease (PD) belongs to the category of central nervous system disorders and is a chronic disease that commonly affects middle-aged and elderly people. It can cause abnormalities in speech expression and mobility. The pathogenesis of PD is still unclear, but it is widely believed to be related to abnormal function of cranial basal ganglia neurons and degeneration of substantia nigra brain cells. This leads to dysfunction of the neurons that produce dopamine in the body, resulting in a decrease in dopamine secretion. Dopamine is involved in cranial life activities and regulates muscle function. Therefore, excessively low dopamine levels in PD patients can induce and exacerbate physical movement disorders, and there are currently no effective anti-PD drugs to inhibit disease progression. As PD progresses, when dopamine neurons in patients' bodies die by 50% or more, and striatal dopamine (DA) levels drop by 80% or more, typical PD motor symptoms may appear, making it more difficult to reverse PD. Thus, early medical intervention is crucial<sup>[4]</sup>. However, some PD patients still have doubts about the side effects of anti-PD drugs and the efficacy of surgery. Long-term use of anti-PD drugs can stimulate the body, inducing dyskinesia and other complications. Therefore, exploring new management options is extremely important. Physical therapy provides a new treatment alternative for PD patients. TMS (Transcranial Magnetic Stimulation) is a non-invasive, safe, and drug-free management solution. TMS is easy to operate, does not increase patient discomfort, and allows for non-invasive neuromodulation based on neuropathophysiological characteristics

by adjusting the stimulation intensity during actual treatment. This can improve brain cortical function, thereby relieving PD-related discomfort <sup>[5]</sup>.

Based on the data analysis in this paper, the efficacy of Group A is higher than that of Group B, with  $P < 0.05$ . The reason for this is that TMS treatment for PD patients can relieve muscular rigidity and bradykinesia. TMS stimulates the cranial motor cortex, which can excite the cerebral cortex and activate dopamine neurons, thereby reducing bradykinesia. Continuous TMS treatment can also increase step speed and step length, reduce the degree of muscular rigidity, and alleviate muscle stiffness, thereby enhancing patients' turning and walking smoothness. TMS stimulates the thalamus and basal nuclei, which can inhibit abnormal neuronal discharges and reduce tremor amplitude, thus enhancing the stability of fine movements such as grasping objects and writing for PD patients. TMS stimulation of the supplementary motor area can improve the stability of the corticospinal tract and enhance gait stability, thereby reducing the risk of frozen gait and falls during turning, which is beneficial for PD patients to safely complete outdoor activities <sup>[6]</sup>.

Additionally, PD patients who comply with TMS treatment can stimulate the striatum, increase the amount of dopamine released by the body, and enhance the sensitivity of dopamine receptors in the brain to dopamine, thereby compensating for the degeneration of dopamine neurons in PD patients and restoring dopamine regulatory function. TMS regulates the cortico-basal nuclei circuit, rebuilds damaged neural network connections in the brain, and restores the function of brain regions that regulate body movements, further improving the brain's ability to control limb movements. TMS can optimize synaptic plasticity and accelerate the efficiency of information transmission between neurons, thereby optimizing brain executive function and improving motor function, resulting in superior efficacy <sup>[7]</sup>.

Another set of data shows that Group A has better SCOPA-AUT, MMSE, and PSQI scores than Group B, with  $P < 0.05$ . The reason for this is that TMS is characterized by being painless and non-invasive. It stimulates the cerebral cortex through the skull, regulating the metabolism of catecholamines in the brain of PD patients, stimulating the synthesis of ipsilateral endogenous dopamine, and increasing dopamine levels in tissues adjacent to the contralateral caudate nucleus. Continuous TMS stimulation can reduce the rate of dopamine breakdown in the intracranial nervous system and excite the striatal circuitry on the affected side of the brain, effectively controlling motor symptoms in PD patients. Additionally, during TMS treatment, endogenous currents are generated under the action of pulsed magnetic fields, which play a role in brain tissue, causing depolarization changes in nerve cells and generating potentials, leading to disordered excitation and inhibition between cortical layers. TMS directly stimulates the intracranial C3 point, affecting cortical occipital brain electrical activity, which indirectly improves cranial cortical function, facilitating the induction of new conduction pathways in the brain, resulting in recovery of damaged neural function, improvement of cognitive function, and sleep quality <sup>[8]</sup>.

Another set of data indicates that Group A has a higher SF-36 score than Group B, with  $P < 0.05$ . The reason for this is that TMS treatment for PD patients stimulates the left dorsolateral prefrontal cortex, which can increase the level of neurotransmitters in the body, thereby alleviating depressive emotions. Maintaining stable emotions in PD patients can enhance their willingness to socialize. Improved motor symptoms during continuous TMS treatment can restore patients' ability to perform activities such as eating, washing, and dressing, improving their self-care ability, further stabilizing their emotions, and improving motor function, making them more willing to return to society. With continuous TMS treatment, patients' limb motor function improves, reducing their dependence on family members and enabling them to maintain a long-term independent living status. This enhances patients' sense of dignity and improves their quality of life <sup>[9]</sup>.

The final set of data shows that the adverse reaction rate in Group A is lower than that in Group B, with  $P < 0.05$ . The reason for this is that TMS treatment for PD patients is a non-invasive procedure that does not require anesthesia. Only a few patients experience mild scalp discomfort, and adverse reactions that are difficult to tolerate are rare, indicating excellent safety and tolerability for most PD patients<sup>[10]</sup>. However, it is important to note that during actual TMS treatment, patients should be guided to correctly cooperate with the coil to ensure comfort and accuracy of the wearing position. Patients should also be instructed to maintain a quiet state to avoid coil displacement affecting the efficacy. During treatment, patients should be asked if they experience any discomfort, and treatment instrument parameters should be adjusted based on the physiological state of the PD patient.

## 5. Conclusion

In summary, conventional medication combined with TMS treatment for PD patients can improve cognitive function, sleep quality, and quality of life, while also reducing neurological symptoms and restoring motor function. This treatment approach has promotional value.

## Disclosure statement

The author declares no conflict of interest.

## References

- [1] Ma Y, Guo L, Liu C, et al., 2024, Intervention Value and Non-Motor Symptoms Observation of rTMS Combined With Resistance Training for Elderly Patients With Parkinson's Disease. *Ningxia Medical Journal*, 46(8): 676–679.
- [2] Wang X, Huang Z, Qian H, et al., 2022, Effects of High-Frequency Repetitive Transcranial Magnetic Stimulation of Bilateral M1 Areas Combined With Articulation Training on Hypokinetic Dysarthria in Parkinson's Disease Patients. *Practical Geriatrics*, 36(5): 508–511.
- [3] Chen S, 2006, Guidelines for the Treatment of Parkinson's Disease. *Chinese Journal of Neurology*, 39(6): 409–412.
- [4] Zhu Y, Xi C, 2023, Application of Different Stimulation Targets in Transcranial Direct Current Stimulation-Mediated Rehabilitation of Parkinson's Disease. *Journal of Rehabilitation*, 33(2): 180–185.
- [5] Li Y, Li L, 2023, Application of Transcranial Magnetic Stimulation and Transcranial Direct Current Stimulation in Regulating Brain Empathy Function. *Progress in Biochemistry and Biophysics*, 50(10): 2420–2436.
- [6] Yang Y, Li Y, Zhang J, et al., 2023, Study on the Evaluation of Cortical Excitability Changes in Patients With Postherpetic Neuralgia Using Transcranial Magnetic Stimulation. *Chinese Journal of General Practice*, 21(7): 1113–1116.
- [7] Ren H, Ma J, He S, et al., 2023, Therapeutic Effect of Repetitive Transcranial Magnetic Stimulation Combined With Virtual Reality Technology on Parkinson's Disease Patients With Cognitive Impairment. *Chinese Journal of Experimental Surgery*, 40(11): 2343–2346.
- [8] Sun H, Jin Q, 2022, Analysis of the Effects of Repetitive Transcranial Magnetic Stimulation on Motor and Non-Motor Symptoms of Parkinson's Disease in High-Altitude Areas. *Journal of Highland Medicine*, 32(3): 29–32.
- [9] Gong S, Liu J, Li J, et al., 2022, Meta-Analysis of High-Frequency and Low-Frequency Repetitive Transcranial Magnetic Stimulation for Improving Motor and Depressive Symptoms in Patients With Parkinson's Disease. *Evidence-Based Nursing*, 8(19): 2583–2589.

- [10] Ren W, He Y, 2022, Observation on the Curative Effect of Repetitive Transcranial Magnetic Stimulation Combined With Rehabilitation Training in the Treatment of Parkinson's Disease. *Ningxia Medical Journal*, 44(2): 147–149.

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# The Effectiveness of Mirena Intrauterine Device in the Treatment of Adenomyosis

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**Abstract:** *Objective:* To explore the efficacy of the Mirena intrauterine device (IUD) in the treatment of patients with adenomyosis. *Methods:* Forty patients with adenomyosis treated in our hospital from January 2021 to December 2024 were randomly divided into an observation group and a control group, with 20 cases in each group. The observation group received Mirena IUD treatment, while the control group received drug treatment. The treatment indicators were compared between the two groups. *Results:* The total effective rate in the observation group was higher than that in the control group ( $P < 0.05$ ). After treatment, the levels of sex hormone indicators in the observation group were better than those in the control group ( $P < 0.05$ ). Compared with the control group, the observation group had significant improvements in menstrual pain score, menstrual volume score, uterine volume, and endometrial thickness ( $P < 0.05$ ). The incidence of adverse reactions in the observation group was significantly lower than that in the control group ( $P < 0.05$ ). *Conclusion:* The treatment of adenomyosis patients with Mirena IUD is significantly effective, which can effectively improve menstrual volume and reduce the degree of menstrual pain. With fewer adverse reactions, the treatment is safer and feasible for promotion.

**Keywords:** Mirena intrauterine device; Adenomyosis; Sex hormones; Menstrual volume

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## 1. Introduction

Adenomyosis is a gynecological disease that mainly affects women of reproductive age. Patients typically present with increased menstrual volume and menstrual disorders, accompanied by progressive menstrual pain. If not treated promptly, the risk of infertility increases with the progression of the disease, directly affecting their quality of life and physical and mental health <sup>[1]</sup>. Clinical treatment for such patients mainly includes surgery and medication. Surgery can achieve a radical cure but may cause significant trauma and even loss of fertility <sup>[2]</sup>. Medication, on the other hand, has a relatively slow onset time and may not provide satisfactory results. Currently, the Mirena intrauterine device (IUD) is gradually gaining recognition in the clinical treatment of adenomyosis. As a type of intrauterine device, it contains levonorgestrel, which can inhibit endometrial hyperplasia and cause few serious adverse reactions <sup>[3]</sup>. Therefore, further investigation of the clinical application value of this treatment option is of practical significance.

## 2. Materials and methods

### 2.1. Clinical data

The subject selected patients with adenomyosis ( $n = 40$ ) who were treated in our hospital from January 2021 to December 2024 as the research objects, and the grouping was done based on a random number table. There were 20 patients in the control group, with a maximum of 4 pregnancies and a minimum of 1 pregnancy, averaging  $(2.58 \pm 0.46)$  pregnancies. The age range was from 22 to 47 years old, with an average age of  $(34.79 \pm 4.07)$  years old. In the observation group, the range of pregnancies was between 2 and 4, averaging  $(2.62 \pm 0.42)$  pregnancies. The maximum age was 48 years old, and the minimum age was 23 years old, with a median age of  $(34.83 \pm 4.04)$  years old. The basic information of the two groups of patients showed no difference, with  $P > 0.05$ .

Inclusion criteria: Patients who meet the diagnostic criteria for adenomyosis; patients with complete clinical data; patients without cardiac dysfunction. Exclusion criteria: Patients with contraindications to Mirena intrauterine device (IUD); patients with immune dysfunction; patients who withdrew from the study.

### 2.2. Methods

Patients in the control group were treated with mifepristone. The treatment began on the first day of menstruation, once a day, with a dose of 12.5 mg each time. The observation group received Mirena intrauterine contraceptive device (IUD) treatment. Before the treatment, basic clinical information such as menstrual cycle, menstrual flow, anemia status, and reproductive history was checked and confirmed with the patients. The patients were also informed about the significance, advantages, key points to note, and possible adverse effects of this treatment method. Routine gynecological examinations, including liver and kidney function, blood, urine, breast, and vaginal discharge, were performed. The Mirena IUD was placed in the uterine cavity between the 3<sup>rd</sup> and 7<sup>th</sup> day of menstruation, with a tail string (2 cm) left at the cervix to facilitate later removal. The position of the IUD was confirmed by B-ultrasound examination. If adverse reactions occurred during the treatment, prompt improvement measures or discontinuation of treatment were taken. After the insertion of the IUD, patients received antibiotic therapy for three days. Both groups of patients received treatment for half a year.

### 2.3. Evaluation indicators

- (1) The treatment effect and incidence of adverse reactions were evaluated.
- (2) Changes in sex hormone levels, menstrual pain scores before and after treatment, menstrual flow scores, uterine volume, and endometrial thickness were compared between the two groups.

### 2.4. Statistical analysis

Statistical software SPSS 21.0 was used to analyze the data from both groups, with  $P < 0.05$  considered statistically significant.

## 3. Results

### 3.1. Study on treatment effects in the observation group and control group

The total effective rate in the observation group was higher than that in the control group ( $P < 0.05$ ). (Table 1).

**Table 1.** Comparison of treatment effects between the two groups (*n*/ %)

Group	n	Significant Effect	Effective	Ineffective	Total Effective Rate
Observation group	20	11 (55)	8 (40)	1 (5)	19 (95)
Control group	20	8 (40)	4 (20)	8 (40)	12 (60)
$\chi^2$					7.0251
<i>P</i>					0.0080

### 3.2. Comparison of sex hormone indices

Before and after treatment in both groups: Before treatment, there were no significant differences in the indices between the groups ( $P > 0.05$ ); After treatment, the sex hormone indices in the observation group were significantly different from those in the control group ( $P < 0.05$ ) (Table 2).

**Table 2.** Analysis of changes in sex hormone indices in the observation group and control group (mean  $\pm$  SD)

Group	n	E <sub>2</sub> (nmol/L)		LH (IU/L)		FSH (IU/L)		T (nmol/L)		PRL ( $\mu$ IU/L)		TSH (mol/L)	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Observation Group	20	98.13 $\pm$ 7.79	97.79 $\pm$ 7.55	11.88 $\pm$ 2.29	9.98 $\pm$ 1.11	11.89 $\pm$ 3.32	10.75 $\pm$ 2.13	3.92 $\pm$ 0.42	3.64 $\pm$ 0.35	214.39 $\pm$ 21.85	210.09 $\pm$ 20.24	8.77 $\pm$ 2.36	7.69 $\pm$ 2.05
Control Group	20	98.15 $\pm$ 7.75	79.98 $\pm$ 7.33	11.85 $\pm$ 2.32	7.02 $\pm$ 1.28	11.86 $\pm$ 3.35	8.21 $\pm$ 2.09	3.95 $\pm$ 0.45	2.39 $\pm$ 0.31	214.43 $\pm$ 21.89	191.28 $\pm$ 22.23	8.79 $\pm$ 2.33	6.29 $\pm$ 1.44
T Value		0.0081	7.5691	0.0412	7.8132	0.0284	3.8066	0.2180	11.9564	0.0058	2.7981	0.0270	2.4992
P Value		0.9935	0.0000	0.9674	0.0000	0.9775	0.0000	0.8286	0.0000	0.9954	0.0080	0.9786	0.0169

### 3.3. Comparison of dysmenorrhea scores, menstrual volume scores, uterine volume, and endometrial thickness changes in the observation group and control group

Before treatment, there were no significant differences in the relevant indices between the two groups ( $P > 0.05$ ). After treatment, there were significant differences in the indices between the groups ( $P < 0.05$ ) (Table 3).

**Table 3.** Study of dysmenorrhea scores, menstrual volume scores, uterine volume, and endometrial thickness before and after treatment in both groups (mean  $\pm$  SD)

Group	n	Dysmenorrhea Score (points)		Menstrual Volume Score (points)		Uterine Volume (cm3)		Endometrial Thickness (mm)	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Observation group	20	6.11 $\pm$ 1.09	2.02 $\pm$ 0.78	167.90 $\pm$ 15.48	61.15 $\pm$ 15.03	159.87 $\pm$ 29.98	110.32 $\pm$ 11.27	11.77 $\pm$ 3.48	6.63 $\pm$ 2.09
Control group	20	6.13 $\pm$ 1.11	3.42 $\pm$ 0.96	167.87 $\pm$ 15.43	82.29 $\pm$ 15.47	159.92 $\pm$ 29.96	130.58 $\pm$ 17.53	11.79 $\pm$ 3.44	8.95 $\pm$ 2.99
T Value		0.0575	5.0617	0.0061	4.3832	0.0053	4.3476	0.0183	2.8441
P Value		0.9545	0.0000	0.9951	0.0001	0.9958	0.0001	0.9855	0.0071

### 3.4. Analysis of the incidence of adverse reactions in both groups

The total incidence rate in the observation group was lower than that in the control group ( $P < 0.05$ ) (Table 4).

**Table 4.** Comparison of the incidence of adverse reactions in the observation group and control group (n/%)

Group	n	Digestive tract injury	Breast pain	Impaired liver and kidney function	Total incidence rate
Observation group	20	1 (5)	0 (0)	1 (5)	2 (10)
Control group	20	2 (10)	2 (10)	4 (20)	8 (40)
$\chi^2$					4.8000
P					0.0284

## 4. Discussion

Clinically, adenomyosis is categorized as endometriosis. Patients with this condition experience regular shedding and bleeding in the myometrium due to the invasion of endometrial tissue and stroma, which leads to the hyperplasia of surrounding muscle tissue in the myometrium<sup>[4]</sup>. In recent years, changes in daily habits and increased work pressure have contributed to a year-by-year increase in the risk of adenomyosis among women<sup>[5]</sup>. Clinically, the causes of adenomyosis are believed to be concentrated in the following aspects:

- (1) Age factor. There is a certain relationship between the occurrence of the disease and age. As age increases, the severity of the disease also increases<sup>[6]</sup>.
- (2) The endometrium grows downward from the basal layer and invades the interior of the myometrium. The main reason is that patients have suffered severe trauma to the endometrial basal layer due to surgical treatments such as curettage or childbirth, or chronic inflammation in the body affects the boundary between the endometrium and myometrium, which leads to downward growth of the endometrium<sup>[7]</sup>.
- (3) The expression level of oxytocin receptors in patients with adenomyosis is relatively high. Based on the binding with receptors, many calcium ion signals play a synergistic role, causing the uterine smooth muscle to be in a contractile state<sup>[8]</sup>.
- (4) Reproductive status. Adenomyosis is commonly seen in women with a history of childbirth. The cause is damage to the inner wall of the uterus during pregnancy and childbirth<sup>[9]</sup>.
- (5) Neural mediators. During the release of substances such as nerve growth factor and TNF- $\alpha$  in adenomyosis lesions, nerve fibers show a trend of retrograde growth, which leads to dysmenorrhea<sup>[10]</sup>.

In the clinical treatment of such patients, surgical procedures have significant effects but can greatly impact their fertility, and may even cause endocrine abnormalities, increasing the psychological stress on patients. If patients have a strong desire for fertility, surgical treatment is not recommended<sup>[11]</sup>. Non-surgical treatment options are diverse, but there is still no clear and unified treatment standard, so it is still necessary to actively explore more effective and safer treatment methods<sup>[12]</sup>. Among many therapeutic drugs, mifepristone is commonly used. It can bind to receptors such as progesterone and glucocorticoids, directly inhibiting the release of progesterone receptors in the uterine muscle layer and endometrium, thereby achieving the therapeutic goal of preventing glandular hyperplasia. This is more conducive to the atrophy of the endometrium and ultimately achieves the goal of reducing uterine volume<sup>[13]</sup>. At the same time, after medication, the patient's endometrium will undergo static changes, and menstrual flow will decrease with regular cycles, which is beneficial for improving disease symptoms. However, drug treatment cannot fundamentally cure adenomyosis. Once the medication is stopped, the disease is more likely to recur. Long-term medication can also induce a series of adverse reactions, which can adversely affect the efficacy.

The Mirena intrauterine device (IUD) is a T-shaped device that contains levonorgestrel and can slowly release a small amount of the drug into the uterine cavity after placement <sup>[14]</sup>. Levonorgestrel is a highly effective progesterone that can specifically improve the progesterone and estrogen receptors of the endometrium, also achieving the goal of inhibiting endometrial vascular hyperplasia. As a result, the efficiency of clinical repair of the patient's endometrium will increase, reducing menstrual flow and achieving menstrual regularity. Furthermore, the Mirena IUD can directly affect the interstitial and glandular cells of the lesion, further optimizing the patient's endometrial microenvironment and keeping the endometrial tissue in an atrophic state. This can achieve the effect of reducing uterine volume and significantly improve the degree of dysmenorrhea <sup>[15]</sup>. On this basis, placing a Mirena IUD in the uterus can help reduce the concentration of drug released, avoiding unnecessary impact on ovarian function.

## 5. Conclusion

In the study, the observation group had better treatment efficacy, fewer adverse reactions, and better sex hormone profiles compared to the control group ( $P < 0.05$ ). This indicates that in the clinical treatment of patients with adenomyosis, the Mirena IUD has prominent efficacy and does not affect the patient's ovarian function, making it a safer treatment option.

## Disclosure statement

The authors declare no conflict of interest.

## References

- [1] Zhang Q, Zhang Y, Xu F, 2021, Effects of Mirena Combined with Leuprolide on Endometrial Indicators, Uterine Recovery, and Side Effects in Patients with Adenomyosis. *Pharmaceutical Biotechnology*, 28(3): 280–283.
- [2] He Y, Wang X, 2024, Analysis of the Effect of Mirena Combined with Low-Dose Dydrogesterone Tablets in the Treatment of Adenomyosis. *Chinese Journal of Obstetrics and Gynecology*, 25(3): 271–273.
- [3] Guo M, Deng Z, Xu H, 2020, Clinical Study of Mirena Combined with Gonadotropin-Releasing Hormone Agonist in the Treatment of Adenomyosis. *Journal of Guangxi Medical University*, 37(3): 4.
- [4] Yang X, Li J, 2022, Clinical Efficacy Analysis of Mirena Ring in the Treatment of Adenomyosis. *Chinese Maternal and Child Health Care*, 37(2): 4.
- [5] Tian Y, Ran L, Gu X, et al., 2020, Evaluation of the Clinical Effect of Mirena Combined with Leuprolide in the Treatment of Adenomyosis with Ovarian Endometriotic Cysts. *Modern Digestion & Intervention*, 2020(S01): 0294–0294.
- [6] Chu H, He Q, Yang L, 2023, Effects of Mirena Combined with GnRH-a on Postoperative Uterine Volume, Serum HE4 Level, and Menstrual Blood Volume in Patients with Adenomyosis. *Chinese Journal of Family Planning*, 31(1): 32–36.
- [7] Wang L, Fan A, 2023, Efficacy of Goserelin Acetate Combined with Mirena in the Treatment of Adenomyosis and Its Effects on Endometrial Receptivity and Serum CA125, CA199, and HE4. *Pharmaceutical Biotechnology*, 30(5): 498–502.
- [8] Wang N, Yang S, Li X, et al., 2023, Clinical Observation on the Efficacy of Intrauterine Placement of Mirena IUD in the Treatment of Adenomyosis. *Database of Chinese Scientific and Technological Periodicals (Abstract Version) Medicine*

and Health, 2023(2): 64-66.

- [9] Yuan Y, Zhang Y, Guo Y, 2023, To Investigate the Effects of Levonorgestrel Intrauterine System on Endometrial Receptivity and Hemodynamics in Patients with Adenomyosis. *Sichuan Journal of Physiological Sciences*, 45(8): 1385–1387.
- [10] Lin Y, 2023, Application of Levonorgestrel Intrauterine System Combined with Desogestrel and Ethinylestradiol Tablets in the Drug Treatment of Adenomyosis. *Northern Pharmacology*, 20(11): 104–106.
- [11] Li R, Zhen W, Guo P, et al., 2023, Clinical Observation on the Efficacy of Leuprolide Combined with Levonorgestrel Intrauterine Sustained-Release System (Mirena) in the Treatment of Adenomyosis. *The 6th National Rehabilitation and Clinical Pharmacy Academic Exchange Conference*, Xindu Central Hospital, Xingtai City, Hebei Province, 7.
- [12] Liu F, Zhang J, 2024, Effects of Leuprolide Acetate Combined with Mirena on Endometrial Receptivity and Serum CA125, CA199, and HE4 Levels in Patients with Adenomyosis. *Aerospace Medicine*, 2024(12): 1453–1455.
- [13] Li M, 2023, Effects of Mirena Combined with Leuprolide on Estrogen/Progesterone Levels and Endometrial Thickness in Patients with Adenomyosis. *Special Health*, 2023: 37–39.
- [14] You X, 2023, Effect of Goserelin Combined with Mirena in the Treatment of Adenomyosis and Its Influence on Endometrial Thickness and Sex Hormone Levels. *Primary Medical Forum*, 27(19): 85–87.
- [15] Shi C, Zhang J, 2024, Clinical Value Analysis of Mirena Combined with Gonadotropin-Releasing Hormone Agonist in the Treatment of Adenomyosis. *Marriage and Child Health Care*, 2024(19): 34–36.

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# Application of Bundle Nursing Strategy in the Maintenance of Difficult Blood Vessels for Long-term Hemodialysis Patients

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**Abstract:** *Objective:* To study the application effect of bundle nursing strategy in the maintenance of difficult blood vessels for long-term hemodialysis patients. *Methods:* A prospective study was conducted on 40 long-term hemodialysis patients admitted from January 2024 to January 2025. The patients were randomly divided into a control group (20 cases) and an observation group (20 cases) using computer random sampling. The control group received routine nursing for difficult blood vessels, while the observation group received a bundle nursing strategy for difficult blood vessels. The self-care ability, complication rate, and nursing satisfaction were compared between the two groups. *Results:* After nursing, the self-care ability score of the observation group was higher than that of the control group ( $P < 0.05$ ). The complication rate in the observation group was lower than that in the control group ( $P < 0.05$ ). The nursing satisfaction in the observation group was higher than that in the control group ( $P < 0.05$ ). *Conclusion:* The application of the bundle nursing strategy in the maintenance of difficult blood vessels for long-term hemodialysis patients is beneficial for improving self-care ability, reducing complications, and increasing patient satisfaction with nursing services.

**Keywords:** Long-term hemodialysis; Difficult blood vessels; Routine nursing; Bundle nursing strategy

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## 1. Introduction

Artificial vascular graft fistula, arteriovenous fistula, and long-term catheterization are commonly used vascular access for hemodialysis<sup>[1]</sup>. However, long-term hemodialysis is easily affected by various factors, and patients with weak constitutions are prone to various complications, affecting the normal use of vascular access<sup>[2]</sup>. Some patients lack the initiative to maintain awareness and do not recognize the necessity of protecting vascular access, or do not possess the skills to maintain vascular access, making it impossible to effectively prevent and treat vascular access complications<sup>[3]</sup>. To improve the service life and safety of vascular access, good nursing care is essential. Previous implementation of routine nursing can ensure hemodialysis treatment, but there are certain

deficiencies in maintaining vascular access, and it cannot effectively prevent and treat various complications, so its application value is limited. The bundle nursing strategy is based on evidence-based medical nursing to develop specific intervention plans to address clinical problems. The nursing measures are all evidence-based, clinically proven effective, and can solve many clinical problems when combined. This article selects 40 patients with long-term hemodialysis and difficult vascular maintenance as subjects to analyze the value of the bundle nursing strategy.

## 2. Materials and methods

### 2.1. General information

A prospective study was conducted on 40 patients with difficult vascular access for long-term hemodialysis admitted from January 2020 to January 2025. The patients were randomly divided into a control group (20 cases) and an observation group (20 cases) using a computer-based random sampling method. The data for both groups are presented in **Table 1**, showing no significant differences ( $P > 0.05$ ). The study was approved by the medical ethics committee, and informed consent was signed by the patients and their families.

**Table 1.** General information for both groups [ $n = 20$  cases,  $n/(mean \pm SD)$ ]

Group	Male/Female (cases)	Age (years)	Weight (kg)	Vascular access type (Long-term catheterization/ High fistula/Artificial blood vessels, cases)
Observation group	12/8	55.98 $\pm$ 5.62	61.98 $\pm$ 5.42	10/6/4
Control group	11/9	55.17 $\pm$ 5.46	62.67 $\pm$ 5.78	11/5/4
$t/\chi^2$ value	0.102	0.462	0.389	0.139
$P$ value	0.749	0.647	0.699	0.933

Inclusion criteria: (1) Met the criteria for vascular access creation in the “Chinese Expert Consensus on the Nursing of Arteriovenous Fistulas in Hemodialysis Grafts (1st Edition)”<sup>[4]</sup>; (2) Underwent maintenance hemodialysis 3-4 times per week, with each session lasting 3-4 hours; (3) Were able to cooperate with dialysis treatment, clinical nursing, and follow-up visits.

Exclusion criteria: (1) Abnormal coagulation function; (2) Puncture site not located on the graft; (3) Abnormal communication ability; (4) Transferred to another hospital for treatment during the study.

### 2.2. Methods

The control group received routine nursing care: After the creation of the vascular access, its function was evaluated, and once it was determined to be mature, it was used as the vascular access for hemodialysis. The patency of the vascular access was evaluated daily before use, and symptoms such as local swelling, fluid leakage, and moderate to severe pain were observed. Based on the condition of the vascular access and the requirements of dialysis, a scientifically appropriate puncture method was selected. Patient health education was strengthened, urging patients to actively protect their vascular access by avoiding heavy lifting or carrying with the dialysis-side limb, and prohibiting infusion, blood pressure measurement, etc., on the vascular access side. After dialysis, pressure bandaging was strictly applied, and long-term compression of the vascular access was prohibited to prevent its dysfunction.

The observation group implemented a bundled nursing strategy:

(1) Evidence-based process

Based on the evidence-based pyramid model, the responsible nurses searched authoritative databases such as CNKI and Wanfang for keywords such as “maintenance hemodialysis, difficult blood vessels (artificial blood vessels, long-term catheterization, high fistulas), nursing.” They conducted evidence-based summaries on comprehensive evaluation before puncture, puncture and needle removal, post-puncture care, and self-care. Based on the characteristics of the department’s work, they developed standardized, scientific, and reasonable bundled nursing strategies.

(2) Comprehensive evaluation before puncture

The maturity of difficult blood vessels should be evaluated before creation, and they should be used after confirmation of maturity. Before puncture, comprehensively evaluate the vascular access, analyze the surgical method, vascular anastomosis, and the depth of the subcutaneous tunnel. Use palpation, auscultation, and visual examination to evaluate the function and blood flow direction of the vascular access, determine the puncturable length, specific vascular shape, and depth from the skin. Record and draw diagrams in detail to develop a complete puncture plan.

(3) Puncture and application

Before dialysis, urge patients to carefully clean the blood vessel side of the limb, provide a clean and sterile mask, and require them to wear it during dialysis. Comprehensively analyze the patency of blood vessels before puncture and observe whether aneurysms or infections occur. Based on the anatomical location of blood vessels and vascular access maps, comprehensively evaluate the puncture site. Set up a sufficient number of puncture points through the rope ladder puncture method to facilitate later puncture applications. Implement sterile operation, then perform a puncture. The direction of venous puncture is the same as the blood flow direction, while arterial puncture can be in the reverse direction or in the blood flow direction. The distance between venous and arterial puncture needles should be  $\geq 5$  cm. Puncture on the same plane is prohibited to avoid affecting the fixation of the puncture needles and pressing to stop bleeding after needle removal. During puncture, the bevel of the needle should always face upwards, forming a  $30^{\circ}$ – $45^{\circ}$  angle with the skin to avoid vascular injury and intimal injury. After puncturing the blood vessel, rotation is prohibited to prevent damage to the blood vessel wall. If the location of the vascular access is deep, implement a three-point fixation method to make the blood vessels engorged, tighten the distal end of the puncture site, and then perform the puncture. Rubbing and disinfection should be performed before puncture, with spiral disinfection centered on the puncture site. The diameter of disinfection should be  $\geq 10$  cm, and disinfection should be performed twice. Use heparin-filled wet needles for puncture, select appropriate-sized puncture needles based on dialysis requirements, ensure that the puncture needles meet the blood flow requirements for hemodialysis, ensure uniform and reasonable puncture, prohibit repeated puncture at the same site, promote healing of puncture sites, and reduce blood vessel damage.

(4) Needle withdrawal care

Before removing the puncture needle, check blood pressure to prevent embolism caused by hypotension. Use the two-point finger pressing method to remove the needle, with two fingers pressing directly and gently on the skin and blood vessel puncture site. Loosen the puncture needle and pull it out. Immediately press the puncture site after removing the needle, controlling the pressure so that blood vessel noise can be heard, blood vessel tremor can be felt, and there is no bleeding at the puncture site. The use of a tourniquet for pressure hemostasis is prohibited. For non-immediate puncture sites, continuous pressure should be

applied for 20 minutes, with pressure released every 5 minutes; for immediate puncture sites, continuous pressure should be applied for 10 minutes, with pressure released every 2 minutes. Clean the local skin 24 hours after puncture, pay attention to the hygiene of the puncture site, and avoid pressing or lifting heavy objects with the punctured limb.

(5) Self-care

Provide free manuals, introduce common vascular access complications and discomfort symptoms through manuals and multimedia, list evaluation methods and complication prevention measures, and improve self-care ability. Keep the dialysis side limbs dry and clean during non-dialysis hours, and use soap to clean the puncture side limbs during dialysis, drying them with a dry towel. If a hematoma appears in the puncture area, immediately apply an ice pack, followed by a hot water bag for 24 hours, or perform compression hemostasis while controlling the compression force to avoid flattening the vascular access. If there is swelling or induration at the puncture site, apply Hirudoid ointment externally as prescribed. If there is redness, swelling, seepage, or moderate to severe pain at the puncture site, seek immediate medical attention. Patients are required to perform daily self-evaluation of vascular access through palpation, auscultation, and other comprehensive evaluations. If there is no noise in the vascular access and the tremor is significantly reduced, medical attention should be sought immediately. Dialysis patients should postpone taking antihypertensive drugs during dialysis, adjust medication dosages and frequencies under the guidance of a doctor, and flexibly use medications. Increasing or decreasing medication dosages is prohibited. If blood pressure is less than 120/70 mmHg during dialysis or less than 130/80 mmHg after dialysis, inform the doctor immediately and follow the doctor's advice to increase blood pressure. Patients are urged to strictly control their weight, with a weight gain of less than 2–3 kg. For young adults, weight gain should be less than 5% of dry weight, and for the elderly, weight gain should be less than 4% of dry weight, to prevent hypotension and internal fistula embolism caused by insufficient blood volume.

(6) Multi-channel education

Provide verbal introductions to puncture knowledge and precautions before puncture, and introduce common complications and discomfort symptoms after needle withdrawal. Continuously update self-awareness through picture albums, regularly updated top files and videos in WeChat groups, improve self-care ability, master self-care skills after dialysis and during non-dialysis, and actively prevent complications. Guide patients to learn and master rehabilitation measures such as fistula exercise, squeezing rubber balls, and aerobic exercise, do a good job in exercise care, and enhance immunity. If the vascular access heals well and there are no abnormalities, the intensity of rehabilitation exercise can be appropriately increased, and the grip strength ball can be squeezed to moderately expand and fully fill the blood vessels, improve the quality of vascular access, reduce the risk of complications, and extend the application time. Both groups received continuous nursing care for 3 months.

## 2.3. Observation indicators

- (1) Self-care ability: Evaluated using the Self-Care Behavior Scale<sup>[5]</sup> before and after nursing, focusing on two dimensions: complication prevention and symptom management. The total score is 40, with higher scores indicating better self-care ability.
- (2) Incidence of complications: This includes infection, pseudoaneurysm, and vascular stenosis.
- (3) Nursing satisfaction: Measured using a self-designed satisfaction survey scale with a total score of 20.

Scores of 0–10 indicate dissatisfaction, 10–16 indicate relative satisfaction, and 16–20 indicate high satisfaction. Patients evaluate their satisfaction, and nursing satisfaction is calculated as [(very satisfied + relatively satisfied) / total number of cases \* 100%].

## 2.4. Statistical methods

SPSS 26.0 software was used to process the data. Count data were expressed as percentages (%) and tested using  $\chi^2$ . Measurement data conforming to a normal distribution were tested using  $t$  (or  $F$ ).  $P < 0.05$  indicated that the difference in data was statistically significant.

## 3. Results

### 3.1. Comparison of self-care abilities between the two groups (see Table 2)

**Table 2.** Self-care abilities of two groups ( $n = 20$  cases, mean  $\pm$  SD, score)

Group	Complication prevention		Symptom and sign management	
	Pre-nursing	Post-nursing	Pre-nursing	Post-nursing
Observation group	20.31 $\pm$ 4.56	30.76 $\pm$ 5.26	18.43 $\pm$ 4.21	30.18 $\pm$ 4.78
Control group	21.07 $\pm$ 4.69	26.00 $\pm$ 4.91	19.32 $\pm$ 4.37	25.43 $\pm$ 4.52
$t$ value	0.520	2.958	0.656	3.229
$P$ value	0.606	0.005	0.516	0.003

Note: Compared with before nursing in the same group, <sup>a</sup> $P < 0.05$ .

### 3.2. Comparison of complication rates between the two groups (see Table 3)

**Table 3.** Incidence rate of complications in two groups ( $n = 20$  cases,  $n/\%$ )

Group	Infection ( $n$ )	Pseudoaneurysm ( $n$ )	Vascular stenosis ( $n$ )	Incidence rate of complications (%)
Observation group	0	0	0	0.00
Control group	1	1	2	20.00
$t$ value	-	-	-	4.444
$P$ value	-	-	-	0.035

### 3.3. Comparison of nursing satisfaction between the two groups (see Table 4)

**Table 4.** Nursing satisfaction in two groups ( $n = 20$ ,  $n/\%$ )

Group	Very satisfied ( $n$ )	Quite satisfied ( $n$ )	Dissatisfied ( $n$ )	Nursing satisfaction (%)
Observation group	15	5	0	100.00
Control group	8	8	4	80.00
$t$ value	-	-	-	4.444
$P$ value	-	-	-	0.035

## 4. Discussion

A good vascular access is the key to ensuring continuous and high-quality hemodialysis <sup>[6]</sup>. Vascular access maintenance is a common challenge in hemodialysis, especially for difficult vessels. Difficult vessels in patients undergoing long-term hemodialysis include three types: long-term catheterization, high fistulas, and artificial blood vessels. Various complications are prone to occur during the application of difficult vessels <sup>[7]</sup>. These complications can increase physical discomfort, affect the normal use of blood vessels, and even lead to the failure of vascular access <sup>[8]</sup>. Good puncture and maintenance during the application of vascular access, improving the patency rate of vascular access, and proactive prevention of complications can undoubtedly prolong the application time and improve the quality of application. The bundled nursing strategy is based on evidence-based nursing, to improve the quality of clinical nursing, optimize clinical nursing services, and satisfy patients with nursing care, and has significant application value.

In this study, the self-care ability score of the observation group after nursing was higher than that of the control group ( $P < 0.05$ ). Maintenance hemodialysis requires lifelong treatment, and the disease course is long. Patients need to be admitted to the hospital for hemodialysis regularly. During hospitalization, high-quality services are provided by nurses, but it is difficult to ensure the value of care during home stays <sup>[9]</sup>. Implementing a bundled nursing strategy can enrich patients' accurate knowledge of puncture and maintenance, help patients master prevention and treatment measures for various complications, and enable patients to provide high-quality services for internal fistulas during home stays, thereby significantly improving self-care ability. The incidence of complications in the observation group was lower than that in the control group ( $P < 0.05$ ), and nursing satisfaction was higher than that in the control group ( $P < 0.05$ ). Complications are the main reasons that induce physical and psychological discomfort, affect dialysis compliance, and reduce patients' nursing experience. Implementing a bundled nursing strategy allows patients to actively participate in the prevention and treatment of complications, familiarize themselves with various complications' inducements and effective response measures, prepare patients ahead of time, maintain vascular access during dialysis and non-dialysis periods, improve dialysis quality, effectiveness, and safety, reduce the risk of complications, enhance patients' dialysis experience, and increase their satisfaction with nursing care <sup>[10]</sup>.

## 5. Conclusion

In summary, the bundled nursing strategy can play a significant role in the maintenance of difficult vessels for patients undergoing long-term hemodialysis. It can improve patients' self-care ability, reduce the incidence of complications, and increase patients' satisfaction with nursing care, with significant application value.

## Disclosure statement

The authors declare no conflict of interest.

## References

- [1] Luo L, Yu J, Ling L, et al., 2022, Application of a Nursing Model Based on Multidisciplinary Collaboration for Internal Fistula Special Team in Patients With Arteriovenous Internal Fistula Pseudoaneurysm. *Chinese Journal of Modern Nursing*, 28(4): 521–525.

- [2] Zhao C, Li S, Bai Y, 2022, The Impact of Integrated Medical and Nursing Management on Postoperative Nursing Quality and Satisfaction of Hemodialysis Patients With Arteriovenous Internal Fistulas. *China Medical Herald*, 19(6): 175–178.
- [3] Huang J, Zhao R, Weng X, 2022, Application of Micro-Lecture Combined With Workshop Health Education Model in Arteriovenous Internal Fistula Nursing for Maintenance Hemodialysis Patients. *Qilu Nursing Journal*, 28(17): 147–149.
- [4] Hemodialysis Graft Arteriovenous Internal Fistula Nursing Chinese Expert Consensus Working Group, Xiao G, 2025, Chinese Expert Consensus on Hemodialysis Graft Arteriovenous Internal Fistula Nursing (1st Edition). *Chinese Blood Purification*, 24(2): 89–107.
- [5] Mai J, Gui P, Fang K, et al., 2023, The Impact of Cross-Departmental Continuous Quality Nursing on Postoperative Complications, Nutrition, Psychology, and Quality of Life of Initial Hemodialysis Patients With Arteriovenous Internal Fistulas. *Western Journal of Traditional Chinese Medicine*, 36(3): 147–150.
- [6] Cheng D, Tang K, Zeng W, et al., 2024, Research on the Effect of an Integrated Hospital-Community-Family Chinese and Western Nursing Model Based on “Internet+” to Promote the Maturation of Autologous Arteriovenous Internal Fistulas. *Sichuan Journal of Traditional Chinese Medicine*, 42(7): 213–217.
- [7] Shao Z, Tong H, Yan J, et al., 2024, Summary of Best Evidence for Infection Prevention and Management of Graft Arteriovenous Internal Fistulas in Hemodialysis Patients. *Journal of Nursing Science*, 39(23): 105–110.
- [8] Cao M, Jia R, 2023, The Impact of Nursing Intervention Based on Timing Theory on Self-Management Ability of Internal Fistulas in Patients Undergoing Autologous Arteriovenous Internal Fistula Plasty. *International Journal of Nursing*, 42(3): 559–564.
- [9] Lin P, Wu X, Chen S, 2024, Observation on the Effect of Combining Micro-Video Breakthrough Education and Special Workshops in the Nursing of Internal Fistulas for Maintenance Hemodialysis Patients. *Chinese Journal of Practical Nursing*, 40(8): 612–618.
- [10] Lv L, Ma J, Tong H, et al., 2023, Construction of a Cluster Intervention Strategy for Puncture and Maintenance of Artificial Blood Vessel Graft Internal Fistulas Based on Multi-Criteria Decision Analysis. *General Nursing*, 21(3): 390–392.

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# Effect of Surgical Combination with Traditional Chinese Medicine Dialectical Therapy in Three Phases on Intertrochanteric Fracture of the Femur and Its Impact on Fracture Healing Time

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**Abstract:** *Objective:* To evaluate the effectiveness of surgical combination with traditional Chinese medicine dialectical therapy in three phases for the treatment of intertrochanteric fracture of the femur (IFF). *Methods:* 84 patients with IFF admitted to the hospital from December 2022 to December 2024 were selected and randomly divided into two groups using a random number table. The combined group received surgery and traditional Chinese medicine dialectical therapy in three phases, while the control group received surgery alone. The total effective rate, fracture healing time, hip function score, and lower extremity function score were compared between the two groups. *Results:* The total effective rate was higher in the combined group than in the control group ( $P < 0.05$ ). After treatment, the fracture healing time was shorter in the combined group than in the control group, and the hip function and lower extremity function scores were higher in the combined group than in the control group ( $P < 0.05$ ). *Conclusion:* Surgical combination with traditional Chinese medicine dialectical therapy in three phases can shorten the fracture healing time of IFF patients and restore their hip and lower extremity function, demonstrating significant efficacy.

**Keywords:** Surgery; Traditional Chinese medicine dialectical therapy in three phases; Intertrochanteric fracture of the femur; Fracture healing time

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## 1. Introduction

Intertrochanteric fracture of the femur (IFF) has an incidence rate of 1.4% among all fractures in the body, with elderly people being the high-risk group. Symptoms include hip pain, joint swelling, and limited mobility. Long-term development can lead to complications such as deep vein thrombosis or hypostatic pneumonia<sup>[1]</sup>. Surgery is a commonly used treatment that can fix the fracture end, promote fracture healing, and reduce the long-term harm of the disease. Proximal femoral nail antirotation (PFNA) is the main surgical procedure for this disease, providing

stable and durable internal fixation support, allowing patients to get out of bed early after surgery, thus achieving better surgical results. At the same time, combined with traditional Chinese medicine dialectical therapy in three phases, patients can receive staged and dialectical treatment based on their postoperative recovery stage, fully considering individual differences among patients. This treatment plays a role in promoting blood circulation and removing blood stasis, strengthening muscles and bones, nourishing the liver and kidneys, nourishing blood, and relieving pain <sup>[2]</sup>. Based on this, this study selected 84 IFF patients to evaluate the clinical advantages of surgical combination with traditional Chinese medicine dialectical therapy in three phases.

## **2. Materials and methods**

### **2.1. General information**

84 IFF patients admitted to the hospital from December 2022 to December 2024 were selected and randomly divided into two groups using a random number table. The combined group consisted of 42 patients, including 26 males and 16 females, aged between 40 and 81 years old, with a mean age of  $(54.68 \pm 4.19)$  years old. The causes of fractures were violent blows in 25 cases and falls from heights in 17 cases. The Evans fracture classification was type IA in 4 cases, type IB in 13 cases, type IIA in 20 cases, and type IIB in 5 cases. The control group consisted of 42 patients, including 27 males and 15 females, aged between 41 and 84 years old, with a mean age of  $(54.77 \pm 4.25)$  years old. The causes of fractures were violent blows in 24 cases and falls from heights in 18 cases. The Evans fracture classification was type IA in 7 cases, type IB in 13 cases, type IIA in 17 cases, and type IIB in 5 cases. There was no significant difference in baseline characteristics between the two groups ( $P > 0.05$ ).

Inclusion criteria: diagnosed with IFF after imaging examinations such as X-rays; closed fracture; new fracture; normal cognitive and mental state; relatively complete clinical data; fully informed about the study. Exclusion criteria: presence of surgical contraindications; suffering from malignant tumors; abnormal liver and kidney function or immune system; accompanied by organic lesions; comorbidities such as infectious diseases; withdrawal from the study.

### **2.2. Methods**

The control group underwent surgical treatment alone, specifically PFNA surgery. Preoperatively, the affected tibia was moderately tractioned, and targeted treatments such as anticoagulation or analgesia were administered. Patients were assisted to complete preoperative examinations such as lower extremity arteriovenous ultrasonography and echocardiography to ensure they met surgical indications. 30 minutes before surgery, patients were intravenously administered cefuroxime sodium at a dose of 1.5 g combined with tranexamic acid treatment, with an intravenous dose of 0.5 g. General anesthesia was performed, and patients were positioned supine on a traction table. After C-arm fluoroscopy, traction reduction was performed on the fracture end. The needle insertion site was at the apex of the greater trochanter of the femur, where a guide needle was inserted. The rationality of the guide needle's position was evaluated using fluoroscopy, and the marrow cavity was reamed. A PFNA main nail of appropriate diameter and length was selected and placed into the marrow cavity along the guide needle, which was then removed. With the help of an external bracket, the guide needle was placed inside the femoral neck, and fluoroscopy was performed again to ensure satisfactory angles of the guide needle and femoral neck anteversion. A spiral blade was then placed along the drilled hole. A locking screw (1 piece) was placed at the distal end of

the intramedullary nail, and the proximal end cap was tightened. The surgical field was repeatedly rinsed, and hemostasis was performed; a drainage tube was placed, and sutures were made. Postoperatively, cefuroxime sodium was intravenously administered every 12 hours at the same dose as before surgery, for a total of 2 infusions. Low molecular weight heparin sodium treatment was initiated 12 hours after surgery, and the drainage tube was removed 24 hours postoperatively. Small-scale functional training began 2 weeks after surgery, gradually increasing training intensity to allow patients to get out of bed and move as soon as possible.

The surgical therapy for the combined group was the same as above, with the addition of traditional Chinese medicine dialectical treatment in three phases: From 3 days to 2 weeks postoperatively, or early stage, Taohong Siwu Decoction was selected, consisting of prepared rehmannia root (15 g), angelica (15 g), white peony root (10 g), chuanxiong (8 g), peach kernel (9 g), and safflower (6 g). From 2 to 4 weeks postoperatively, or mid-stage, Shujin Huoxue Decoction was chosen, comprising cyathula root (9 g), dipsacus root (12 g), *Fineleaf schizonepeta* herb (9 g), *Mulberry mistletoe* (9 g), green tangerine peel (5 g), *Drynaria rhizome* (9 g), safflower (9 g), angelica (12 g), bitter orange (9 g), notopterygium root (9 g), five-leaved akebia root bark (9 g), eucommia bark (9 g), *Divaricate saposhnikovia* root (9 g), and *Doubleteeth pubescent angelica* root (9 g). From 4 weeks postoperatively until fracture healing, or late stage, Zhuangjin Yangxue Decoction was administered, including white peony root (9 g), angelica (9 g), chuanxiong (6 g), dipsacus root slice (12 g), safflower (6 g), rehmannia root (12 g), cyathula root (9 g), moutan bark (9 g), and eucommia bark (6 g). All medicinal herbs were taken once a day, divided into morning and evening doses.

### 2.3. Observation indicators

- (1) Fracture healing time: The fracture healing time of the two groups was recorded.
- (2) Hip function score: Before treatment and 3 months after treatment, the Harris scoring system was selected, including pain (44 points), function (47 points), range of motion (5 points), and deformity (4 points), totaling 100 points. The hip function was scored positively.
- (3) Lower extremity function score: During the same time period, the Oswestry Lower Extremity Dysfunction Assessment Criteria (version 2.0) was chosen, consisting of 10 items including lumbar pain, personal daily care, and walking ability, with each item scoring 0–5 points, totaling 50 points. Lower extremity function was scored negatively.

### 2.4. Curative effect evaluation criteria

- (1) Significant efficacy: Fracture symptoms disappeared, patients could take care of themselves, and there was no limping or pain.
- (2) Initial efficacy: Fracture symptoms basically disappeared, patients could basically take care of themselves, joint movement was slightly restricted, and walking required the assistance of a cane.
- (3) No efficacy: Fracture symptoms did not improve, patients had difficulty taking care of themselves, joint movement was severely restricted, and walking was not possible.

### 2.5. Statistical analysis

Data processing software was SPSS 28.0. Measurement data were expressed as mean  $\pm$  SD (standard deviation), compared and tested using *t*-values. Count data were expressed as [*n*/%) and compared and tested using chi-square values. Statistical significance was defined as  $P < 0.05$ .

### 3. Results

#### 3.1. Comparison of total effective rate between the two groups

The total effective rate of the combined group was higher than that of the control group ( $P < 0.050$ ) (Table 1).

**Table 1.** Comparison of total effective rate between the two groups [n/%]

Group	Number of cases	Significant effect	Initial effect	No effect	Percentage
Combined group	42	22 (52.38)	19 (45.24)	1 (2.38)	97.62 (41/42)
Control group	42	16 (38.10)	18 (42.86)	8 (19.05)	80.95 (34/42)
$\chi^2$					6.010
$P$					0.014

#### 3.2. Comparison of fracture healing time between the two groups

The fracture healing time in the combined group was ( $11.05 \pm 2.64$ ) weeks, while in the control group it was ( $14.19 \pm 2.74$ ) weeks, with  $t = 5.348$  and  $P = 0.000$ .

#### 3.3. Comparison of hip function scores between the two groups

Before treatment, there was no difference in hip function scores between the two groups ( $P > 0.05$ ). After 3 months of treatment, the hip function score in the combined group was higher than that in the control group ( $P < 0.05$ ) (Table 2).

**Table 2.** Comparison of hip function scores between the two groups (mean  $\pm$  SD, points)

Group	Number of cases	Pain		Function		Range of motion		Deformity	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Combined group	42	21.29 $\pm$ 3.12	35.16 $\pm$ 4.72	25.18 $\pm$ 3.97	38.95 $\pm$ 4.81	2.05 $\pm$ 0.46	4.10 $\pm$ 0.32	1.14 $\pm$ 0.28	3.01 $\pm$ 0.42
Control group	42	21.25 $\pm$ 3.10	31.09 $\pm$ 4.53	25.22 $\pm$ 3.91	34.02 $\pm$ 4.73	2.07 $\pm$ 0.49	3.88 $\pm$ 0.27	1.12 $\pm$ 0.28	2.81 $\pm$ 0.34
$t$		0.059	4.032	0.047	4.736	0.193	3.405	0.327	2.399
$P$		0.953	< 0.001	0.963	< 0.001	0.848	0.001	0.744	0.019

#### 3.4. Comparison of lower limb function scores between the two groups

Before treatment, there was no difference in lower limb function scores between the two groups ( $P > 0.05$ ). After 3 months of treatment, the lower limb function score in the combined group was higher than that in the control group ( $P < 0.05$ ).

**Table 3.** Comparison of lower limb function scores between the two groups (mean  $\pm$  SD, points)

Group	Number of cases	Before treatment	After treatment
Combined group	42	21.95 $\pm$ 4.18	41.98 $\pm$ 5.35
Control group	42	22.03 $\pm$ 4.14	37.18 $\pm$ 5.79
$t$		0.088	3.946
$P$		0.930	< 0.001

## 4. Discussion

IFF is a common comorbidity of osteoporosis, with a high incidence rate in hip fractures. Its inducements are mostly high-altitude falls or violent blows, which can severely affect the hip joint function of patients and lead to lower limb dysfunction<sup>[3]</sup>. The conservative treatment for patients with this disease is bone traction therapy, which can reset the fracture end, but requires long-term bed rest, which may lead to complications such as hip varus deformity or deep venous thrombosis of the lower extremities<sup>[4]</sup>. Therefore, surgical treatment is necessary for patients with this disease to improve long-term effectiveness.

PFNA is a commonly used intramedullary fixation surgery for IFF patients. The surgical incision is 5 cm long, and only a small range of soft tissue needs to be processed, which can prevent large-scale tissue dissection, thereby protecting the nerves and blood supply around the fracture end and reducing periosteal or soft tissue damage<sup>[5]</sup>. The use of spiral blades during the operation can play a role in anti-rotation and anti-bending, thereby improving the stability of internal fixation. In addition, this surgical method can reduce shear force, prevent slight movement of the cancellous bone interface, and prevent postoperative complications. Implanting spiral blades into the femoral neck can expand the area of contact between the blade and the cancellous bone and enhance the anchoring force generated by the blade, thereby reducing adverse events such as femoral head separation<sup>[6]</sup>. At the same time, combined with traditional Chinese medicine, three-phase dialectical treatment can promote postoperative recovery. Among them, the principles of early treatment are analgesia, promoting blood circulation, reducing swelling, and removing blood stasis; the principles of mid-term treatment are nourishing blood, activating collaterals, and relaxing muscles; the principles of later treatment are strengthening muscles and bones, and nourishing the liver and kidneys. Staged treatment can implement individualized and dialectical treatment according to the treatment needs of patients at different stages after surgery, thereby reducing postoperative symptoms such as pain, shortening the time for patients to get out of bed, and accelerating fracture healing<sup>[7]</sup>.

The results showed that the total effective rate of the combined group was higher than that of the control group, the fracture healing time was shorter than that of the control group, and the hip joint function and lower limb function scores after treatment were higher than those of the control group ( $P < 0.05$ ). The reason is that the combined use of traditional Chinese medicine three-phase dialectical treatment after PFNA surgery can ensure the efficacy of the surgery. Among them, in the prescription of Taohong Siwu Decoction, *Angelicae sinensis radix* has the effects of regulating menstruation, nourishing Yin, nourishing liver and nourishing blood; *Chuanxiong rhizoma* can regulate Qi and blood circulation, and has the effects of nourishing Qi and promoting blood circulation; Taoren and Honghua have the effects of promoting blood circulation and removing blood stasis<sup>[8]</sup>. The combination of these medicines can eliminate blood stasis, promote the generation of new blood, improve blood circulation in the fracture site, and exert therapeutic effects such as promoting qi and relieving pain. In the prescription of Shujin Huoxue Decoction, *Notopterygium rhizoma radix* combined can relieve pain, eliminate dampness, activate collaterals and dispel wind; *Angelicae sinensis radix* combined with Honghua can smooth joints, remove blood stasis and promote blood circulation; *Saposhnikovia radix* combined with *Schizonepetae Herba* can relieve muscle spasms, relieve pain and eliminate dampness; *Pericarpium citri reticulatae viride* combined with *Eucommiae cortex* can widen the middle and promote Qi circulation. The combination of these medicines can nourish liver and kidney, relieve joint pain, and strengthen muscles and bones<sup>[9]</sup>. In the prescription of Zhuangjin Yangxue Decoction, *Paeoniae radix alba* can nourish blood and Yin; *Angelicae sinensis radix* can promote blood circulation and remove blood stasis; *Chuanxiong rhizoma* can nourish blood and benefit blood and remove blood stasis; *Dipsaci radix* can strengthen muscles and bones; *Dioscoreae rhizoma* can nourish Qi and Yin; *Corni fructus*

can nourish liver and kidney; *Atractylodis macrocephalae rhizoma* can nourish Qi and strengthen spleen; *Alismatis rhizoma* can promote urination and eliminate dampness; *Angelicae dahuricae radix* can dispel wind and relieve pain, reduce swelling and drain pus; Poria can nourish spleen and tranquilize mind; *Cyathulae radix* can eliminate blood stasis and regulate menstruation; *Rehmanniae radix* can nourish essence and marrow, nourish Yin and tonify blood; *Moutan* cortex can cool blood and clear heat; *Eucommiae cortex* can strengthen muscles and bones, nourish liver and kidney. The combination of these medicines can strengthen muscles and bones, relieve pain and eliminate blood stasis<sup>[10]</sup>. After adopting the above-mentioned traditional Chinese medicine dialectical treatment plan, the synergistic mechanism can be utilized to accelerate fracture recovery and effectively restore the joint function of patients.

## 5. Conclusion

In summary, the combined use of surgery and traditional Chinese medicine three-phase dialectical treatment for IFF patients has a better effect, which can shorten the fracture healing cycle and enhance their joint activity function, with excellent clinical efficacy. However, during the dialectical treatment of traditional Chinese medicine, it is necessary to dynamically observe the patient's fracture recovery and adjust the medication plan in a timely manner to ensure treatment timeliness.

## Disclosure statement

The authors declare no conflict of interest.

## References

- [1] Jing Y, Chen K, Xu J, et al., 2025, Comparison of the Effects of Two Different Surgical Methods for the Treatment of Intertrochanteric Hip Fractures in the Elderly. *Chinese Journal of Experimental Surgery*, 42(2): 363–366.
- [2] Li J, Pei H, Huang G, et al., 2024, Construction of a Nomogram Model for Individualized Prediction of Perioperative Occult Blood Loss Risk in Patients With Intertrochanteric Hip Fractures. *Sichuan Medical Journal*, 45(7): 760–765.
- [3] He T, Hou S, Wang J, et al., 2024, Comparison of the Efficacy of Two Surgical Methods for the Treatment of Intertrochanteric Hip Fractures in the Elderly. *Journal of Clinical Orthopaedics*, 27(3): 409–413.
- [4] Tan Z, Li K, Lan H, 2019, Comparison Between Orthopedic Surgical Robot-Assisted Navigation and Traditional Intramedullary Nail Fixation for the Treatment of Intertrochanteric Hip Fractures. *Chinese Journal of Tissue Engineering Research*, 23(24): 3792–3797.
- [5] Xie F, Zhang M, 2022, The Value of Multi-Slice Spiral CT Three-Dimensional Reconstruction in the Diagnosis and Surgical Guidance of Intertrochanteric Hip Fractures. *Chinese Journal of CT and MRI*, 20(5): 172–174.
- [6] Hu J, Wu X, Lin Q, et al., 2022, Effects of Ultrasound-Guided Lumbar Plexus Block on Anesthetic Efficacy and Hemodynamics in Elderly Patients Undergoing Surgery for Intertrochanteric Hip Fractures. *Shanxi Medical Journal*, 51(2): 128–131.
- [7] Chen Q, Fan K, Tian K, et al., 2023, Efficacy and Safety of Traditional Chinese Medicine Administered Orally and Externally Based on the “Qi and Blood Balance Theory” of Pingle Orthopedics in the Treatment of Intertrochanteric Hip Fractures in the Elderly. *Modern Journal of Integrated Traditional Chinese and Western Medicine*, 32(9): 1210–1216 + 1221.

- [8] Tan C, Yang D, Pan X, et al., 2024, Clinical Application of Bushen Huoxue Decoction Combined With Bazhen Decoction in the Treatment of Intertrochanteric Hip Fractures. *Journal of Traditional Chinese Medicine Clinical Medicine*, 36(9): 1802–1806.
- [9] Liao S, Li W, 2024, Observation on the Efficacy of Proximal Femoral Nail Antirotation Combined With Traditional Chinese Medicine in the Treatment of Intertrochanteric Hip Fractures in the Elderly. *Journal of Traditional Chinese Medicine Clinical Medicine*, 36(11): 2200–2203.
- [10] Wu X, Deng J, 2022, Clinical Study on the Adjuvant Treatment of PFN-A Minimally Invasive Internal Fixation With Traditional Chinese Medicine Decoction for Senile Closed Intertrochanteric Hip Fractures. *Modern Diagnosis and Treatment*, 33(19): 2867–2869.

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# Observation on the Clinical Efficacy of Moist Burn Ointment Combined with Rotating Moxibustion in the Treatment of Pressure Ulcers with Deficiency of Qi and Blood

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**Abstract:** *Objective:* To observe the therapeutic effect of Moist Burn Ointment combined with rotating moxibustion on patients with pressure ulcers and deficiency of both Qi and blood. *Methods:* 40 patients with pressure ulcers and deficiency of both Qi and blood were randomly divided into two groups from July 2024 to November 2025. Group A received Moist Burn Ointment combined with rotating moxibustion, while Group B received Moist Burn Ointment only. *Results:* Group A showed better efficacy, wound healing time, dressing change frequency, satisfaction, PUSH score, and adverse reaction indicators compared to Group B ( $P < 0.05$ ). *Conclusion:* The combination of Moist Burn Ointment and rotating moxibustion in the treatment of patients with pressure ulcers and deficiency of both Qi and blood can shorten wound healing time, reduce dressing change frequency, and alleviate the degree of pressure ulcers, which is safe and efficient.

**Keywords:** Pressure ulcer; Deficiency of both Qi and blood; Rotating moxibustion; Moist Burn Ointment; Efficacy

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## 1. Introduction

Pressure ulcers are related to excessive local pressure that blocks blood circulation, causing degeneration of the compressed skin due to insufficient blood oxygen and gradual ulceration. They are commonly seen in people who have been bedridden for a long time. Pressure ulcers are characterized by a long course of disease and a high infection rate, requiring early treatment to prevent severe conditions such as septic shock, sepsis, and even life-threatening situations. Due to factors such as car accidents, high blood sugar, hemiplegia, stroke, and falls from heights, the number of bedridden patients has increased. Currently, Western medicine treats pressure ulcers with various regimens such as negative pressure wound therapy, topical dressings, cytokines, and stem cell therapy. Although these treatments can delay the progression of pressure ulcers, their control effects are limited. Based on

dialectical analysis of pressure ulcer patients in traditional Chinese medicine, it is found that most cases belong to the deficiency of both Qi and blood syndrome. Treatment should focus on nourishing Qi, replenishing blood, and promoting tissue regeneration, such as using Moist Burn Ointment and moxibustion <sup>[1]</sup>. Based on this, this article explores the efficacy of Moist Burn Ointment combined with rotating moxibustion using 40 patients with pressure ulcers and deficiency of both Qi and blood who were treated between July 2024 and November 2025 as samples.

## 2. Materials and methods

### 2.1. Materials

40 patients with pressure ulcers and deficiency of both Qi and blood were randomly divided into two groups from July 2024 to November 2025. There was no significant difference in patient characteristics between Group A and Group B ( $P > 0.05$ ). See Table 1 for details.

**Table 1.** Analysis of patient data for pressure ulcers of qi and blood deficiency type

Group	n	Gender (%)		Age (years)		Wound Area (cm <sup>2</sup> )		Wound Location(%)	
		Male	Female	Range	Mean	Range	Mean	Trunk	Limbs
Group A	20	13 (65.00)	7 (35.00)	62–78	67.29 ± 2.41	30–90	72.26 ± 2.43	15 (75.00)	5 (25.00)
Group B	20	14 (70.00)	6 (30.00)	63–77	67.31 ± 2.39	30–89	72.31 ± 2.41	16 (80.00)	4 (20.00)
$\chi^2/t$	-	0.1140		0.0264		0.0653		0.1434	
$P$	-	0.7357		0.9791		0.9482		0.7050	

### 2.2. Inclusion and exclusion criteria

Inclusion criteria: (1) Diagnosed as Qi and blood deficiency type in traditional Chinese medicine, presenting with symptoms of difficult-to-remove necrotic tissue on the wound surface, poor appetite, poor nutrition intake, dull complexion, and fatigue; (2) Informed consent; (3) Refusal of surgical debridement treatment. Exclusion criteria: (1) Albumin level less than 28 g/L; (2) Terminal cancer patients; (3) Combined with severe complications.

### 2.3. Treatment methods

All patients with pressure ulcers received regulation of blood sugar and blood pressure, anti-infective drugs, and correction of microcirculation and hypoproteinemia. Group A received Meibo burn ointment treatment. The wound was routinely disinfected, draped, and debrided to completely remove necrotic tissue in the wound area. The wound was repeatedly rinsed with normal saline or hydrogen peroxide and wiped with a sterile cotton ball. Then, an appropriate amount of Meibo burn ointment was evenly applied to the wound, followed by covering with a gauze strip or gauze. After dressing change, moxibustion with rotating technique was performed. The operator ignited the moxa stick and repeatedly rotated and roasted it over the wound for 15 minutes until the local skin felt warm. However, it should be noted that some patients with pressure ulcers have reduced skin sensation, so the operator can use the middle finger and index finger to sense the temperature of moxibustion. Dressing changes and moxibustion treatments were performed once a day until the wound healed. Group B received Meibo burn ointment treatment only, with the same operation as Group A, until the wound healed.

## 2.4. Statistical analysis

SPSS 21.0 was used to process the data of patients with qi and blood deficiency type pressure ulcers. The count data of Qi and blood deficiency type pressure ulcers were described by percentage (%), and the measurement data were described by mean  $\pm$  standard deviation (SD). The chi-square test ( $\chi^2$  test) and *t*-test were used for statistical analysis. Statistical differences were considered significant at  $P < 0.05$ .

## 3. Results

### 3.1. Efficacy

The efficacy rate of Qi and blood deficiency type pressure ulcers in Group A was 95.00%, which was higher than that in Group B (70.00%). The difference was statistically significant ( $P < 0.05$ ). See **Table 2** for details.

**Table 2.** Comparison of the efficacy of treatment for pressure ulcers of qi and blood deficiency type (n, %)

Group	Marked effect	Effective	Ineffective	Effective rate
Group A ( $n = 20$ )	14 (70.00)	5 (25.00)	1 (5.00)	19 (95.00)
Group B ( $n = 20$ )	10 (50.00)	4 (20.00)	6 (30.00)	14 (70.00)
$\chi^2$	-	-	-	4.3290
<i>P</i>	-	-	-	0.0375

### 3.2. Wound healing time and dressing change frequency

The wound healing time of qi and blood deficiency type pressure ulcers in Group A was shorter than that in Group B, and the frequency of dressing changes was less than that in Group B. The differences were statistically significant ( $P < 0.05$ ). See **Table 3** for details.

**Table 3.** Comparison of wound healing time and dressing change frequency for pressure ulcers of Qi and blood deficiency type (mean  $\pm$  SD)

Group	Wound healing time (days)	Dressing change frequency (times)
Group A ( $n = 20$ )	45.25 $\pm$ 1.26	42.26 $\pm$ 1.06
Group B ( $n = 20$ )	48.95 $\pm$ 1.85	47.25 $\pm$ 1.42
<i>t</i>	7.3925	12.5936
<i>P</i>	0.0000	0.0000

### 3.3. PUSH score

At 7, 14, 21, and 28 days of treatment, the PUSH scores of Qi and blood deficiency type pressure ulcers in Group A were lower than those in Group B. The differences were statistically significant ( $P < 0.05$ ). Before treatment, there was no significant difference in PUSH scores between the two groups ( $P > 0.05$ ). See **Table 4** for details.

**Table 4.** Comparison of PUSH scores for pressure ulcers of Qi and blood deficiency type (scores, mean  $\pm$  SD)

Group	Before treatment	7 days of treatment	14 days of treatment	21 days of treatment	28 days of treatment
Group A ( $n = 20$ )	15.61 $\pm$ 2.15	11.02 $\pm$ 1.26	4.16 $\pm$ 0.58	2.39 $\pm$ 0.36	2.01 $\pm$ 0.21
Group B ( $n = 20$ )	15.63 $\pm$ 2.13	13.05 $\pm$ 1.37	9.58 $\pm$ 0.69	4.11 $\pm$ 0.57	2.53 $\pm$ 0.35
$t$	0.0296	4.8774	26.8907	11.4098	5.6975
$P$	0.9766	0.0000	0.0000	0.0000	0.0000

### 3.4. Satisfaction

The satisfaction rate of qi and blood deficiency type pressure ulcers in Group A was 95.00%, which was higher than that in Group B (70.00%). The difference was statistically significant ( $P < 0.05$ ). See **Table 5** for details.

**Table 5.** Comparison of satisfaction for pressure ulcers of Qi and blood deficiency type ( $n$ , %)

Group	Satisfied	Basically satisfied	Dissatisfied	Satisfaction rate
Group A ( $n = 20$ )	13 (75.00)	6 (30.00)	1 (5.00)	19 (95.00)
Group B ( $n = 20$ )	7 (35.00)	7 (35.00)	6 (30.00)	14 (70.00)
$\chi^2$	-	-	-	4.3290
$P$	-	-	-	0.0375

### 3.5. Adverse reactions

The adverse reaction rate of Qi and blood deficiency type pressure ulcers in Group A was 5.00%, which was lower than that in Group B (35.00%). The difference was statistically significant ( $P < 0.05$ ). See **Table 6** for details.

**Table 6.** Comparison of adverse reactions for pressure ulcers of Qi and blood deficiency type ( $n$ , %)

Group	Neck and shoulder pain	Limb numbness	Low back pain	Incidence rate
Group A ( $n = 20$ )	0 (0.00)	1 (5.00)	0 (0.00)	1 (5.00)
Group B ( $n = 20$ )	2 (10.00)	3 (15.00)	2 (10.00)	7 (35.00)
$\chi^2$	-	-	-	5.6250
$P$	-	-	-	0.0177

## 4. Discussion

The increasing number of long-term bedridden patients in the context of population aging is characterized by digestive system disorders, abnormal organ function, poor immunity, and multiple underlying diseases. Most bedridden individuals also suffer from malnutrition, blood circulation disorders, and other issues, which significantly impact their daily lives. Western medicine primarily treats pressure ulcers by reducing inflammation, sterilizing, and accelerating wound healing, without deeply analyzing the pathogenic characteristics of patients with Qi and blood deficiency type pressure ulcers. Therefore, treatment plans lack specificity and cannot address pressure ulcers from their root causes. Additionally, long-term western medicine treatment can have adverse effects such as hepatorenal toxicity, allergies, and drug dependence in a few patients, with the condition rebounding after

drug withdrawal, which is not conducive to the prognosis of patients with Qi and blood deficiency. Scholars of traditional Chinese medicine believe that pressure ulcers are related to long-term Qi and blood weakness and organ dysfunction. Over time, the lack of Yang Qi leads to Qi dysregulation and an inability to nourish the skin. As the duration of bed rest increases, continuous pressure and friction on local skin areas can worsen skin damage. The pathogenesis of Qi and blood deficiency type pressure ulcers is analyzed to be related to factors such as insufficient vital Qi, obstruction of pathogenic Qi, and externally contracted pathogenic factors, leading to skin necrosis and damage. These factors interact with each other, resulting in the onset of the disease. The dialectical analysis of Qi and blood deficiency type pressure ulcers in traditional Chinese medicine includes syndromes such as Qi and blood deficiency, toxin accumulation and ulceration, and Qi and blood stagnation.

The patients with pressure ulcers selected in this study primarily exhibited the Qi and blood deficiency type, manifesting as difficulty in removing necrotic tissue from the wound surface. In a few patients, new tissue did not grow after the necrotic tissue fell off, or the newly formed muscle had a pale color and was difficult to heal. Additionally, as the course of pressure ulcers progressed, patients gradually developed symptoms such as reduced appetite, poor nutrition, fatigue, and a lack of luster in their complexion. In this study, MEBO (Moist Exposing Burn Ointment) was chosen to treat Qi and blood deficiency type pressure ulcers. It is composed of multiple Chinese herbal medicines such as *Angelica sinensis*, *Astragalus membranaceus*, and *Scutellaria baicalensis*, making it a pure traditional Chinese medicine preparation. Among these herbs, *Scutellaria baicalensis* combined with *Phellodendron chinense* and *Coptis chinensis* can produce a cooling blood and detoxifying effect. *Lumbricus* can dredge meridians and stimulate blood circulation in the wound area. *Pericarpium papaveris* can relieve pain. *Angelica sinensis* combined with *Astragalus membranaceus* can promote the removal of necrotic tissue, stimulate tissue regeneration, nourish Qi, and enrich blood. The combined use of these Chinese herbal medicines aligns with the principles of “supporting,” “debridement,” and “healing” in the dialectical treatment of sore and ulcer diseases in traditional Chinese medicine. Therefore, patients with Qi and blood deficiency type pressure ulcers respond well to MEBO treatment, which promotes wet wound healing. Based on this, the application of revolving moxibustion therapy can dredge meridians and promote Qi and blood circulation. As early as the “Su Wen: Pathogenesis, Qi and Yi, and Life Protection Collections,” there are relevant records suggesting that patients with pressure ulcer-like diseases should receive acupuncture and moxibustion treatment to expel pathogenic Qi from their bodies, thereby promoting wound healing<sup>[2]</sup>. Additionally, persistent revolving moxibustion therapy can increase levels of IgM, IgA, CD3+, and other immune markers in patients with pressure ulcers, inhibit inflammatory reactions, and optimize immune function.

Based on the data analysis presented in this article, the efficacy rate of Group A’s treatment for pressure ulcers with Qi and blood deficiency was 95.00%, which was higher than Group B’s 70.00%, with  $P < 0.05$ . The analysis suggests that the use of Moist Exposing Burn Ointment (MEBO) in the treatment of pressure ulcer patients allows for the synergistic effect of various traditional Chinese medicine ingredients, which can reduce inflammation, promote healing, maintain wound moisture, accelerate local tissue repair, generate collagen, and enhance cell adhesion, thereby facilitating the repair of damaged skin. Additionally, consistent treatment with MEBO provides nutrients to the wound tissue, accelerates capillary blood circulation, corrects insufficient blood oxygen supply to cells, stimulates epithelial cell proliferation, and inhibits the growth of local pathogens. Combined with rotary moxibustion, which involves rotating a burning moxa stick clockwise over the wound area to generate warm stimulation, it can alleviate burning pain, accelerate blood circulation, and achieve the effects of removing blood stasis and promoting blood circulation<sup>[3]</sup>. Another set of data indicates that Group A’s Qi and blood deficiency type

pressure ulcer patients had a shorter wound healing time ( $45.25 \pm 1.26$  days) compared to Group B ( $48.95 \pm 1.85$  days), and fewer dressing changes ( $42.26 \pm 1.06$  times) compared to Group B ( $47.25 \pm 1.42$  times), with  $P < 0.05$ . The analysis suggests that MEBO can enhance the analgesic effect, relieve pain and discomfort in pressure ulcer wounds, and the drug administration scheme is simple and convenient, as operators only need to apply a suitable amount of ointment evenly. The warm stimulation generated by rotary moxibustion can relieve patient pain, promote wound healing, and is more easily accepted by medical staff and pressure ulcer patients. Moreover, rotary moxibustion accelerates local blood circulation, reducing the frequency of MEBO administration<sup>[4]</sup>.

Another set of data shows that at treatment intervals of 7, 14, 21, and 28 days, Group A's Qi and blood deficiency type pressure ulcer patients had lower PUSH scores than Group B, with  $P < 0.05$ . The analysis indicates that the PUSH score objectively reflects the healing status of pressure ulcers, including tissue type, amount of exudate, and wound size, which is beneficial for physicians to quantitatively analyze patient prognosis. In this article, the combination of MEBO and rotary moxibustion treatment was chosen, which can reduce the PUSH score in the following ways:

- (1) Shortening wound healing time: MEBO, composed of traditional Chinese medicines, can enhance the effects of promoting muscle growth, pain relief, detoxification, and heat clearance, thereby shortening wound healing time. Combined with rotary moxibustion to regulate qi and blood in the wound area, the synergistic effect can further shorten the healing time of pressure ulcers.
- (2) Inhibiting wound exudate: Regular application of MEBO maintains the moist state of pressure ulcer wounds, stimulates cell regeneration, reduces wound exudate, optimizes the wound environment, and inhibits local bacterial growth, thereby suppressing local infection. Additionally, rotary moxibustion stimulates the body to absorb and expel exudate when regulating local blood circulation, further optimizing the wound environment and lowering the PUSH score.
- (3) Accelerating epithelization: The active ingredients in MEBO can stimulate the body to generate collagen and enhance cell adhesion. Combined with rotary moxibustion, it can dredge meridians, accelerate Qi and blood circulation, stimulate the growth of new granulation tissue in the wound, and accelerate the epithelization process, which is beneficial for improving the PUSH score<sup>[5]</sup>.

Another set of data demonstrates that Group A's satisfaction rate of 95.00% for Qi and blood deficiency type pressure ulcer patients was higher than Group B's 70.00%, with  $P < 0.05$ . The analysis suggests that the combined treatment of MEBO and rotary moxibustion can alleviate patients' pain, improve their experience, and reduce psychological stress, thereby increasing patient satisfaction with treatment<sup>[6]</sup>. The final set of data indicates that Group A's adverse reaction rate of 5.00% for Qi and blood deficiency type pressure ulcer patients was lower than Group B's 35.00%, with  $P < 0.05$ . The analysis reveals that MEBO can reduce inflammation and prevent post-pressure ulcer infection. Combined with rotary moxibustion, it can further enhance the antibacterial effect. Moreover, the combined treatment accelerates pressure ulcer recovery, facilitating patients' later rehabilitation exercises and reducing the adverse reaction rate<sup>[7]</sup>. However, it is important to note the following considerations during the treatment of Qi and blood deficiency type pressure ulcer patients with MEBO and rotary moxibustion:

- (1) Strict control of contraindications: Evaluate whether the patient's wound conditions are suitable for topical administration, and exercise caution when administering the medication to breastfeeding women, elderly individuals, and children.
- (2) Adjustment of drug dosage: Adjust the dosage of MEBO according to the doctor's instructions, ensure proper wound cleaning before application, and completely cover the wound with the medication. Maintain

an appropriate distance between the moxa stick and the wound during rotary moxibustion treatment, ensuring that the patient feels warmth without burning pain. Determine the frequency of moxibustion and dressing changes based on the patient's wound condition, and discontinue medication once the wound has healed.

- (3) Management of adverse reactions: A few pressure ulcer patients may experience complications such as itching and skin rashes after applying MEBO. If these reactions occur, immediately stop the medication and seek medical treatment. Additionally, closely monitor the wound for signs of exudate or redness, and promptly initiate anti-infective treatment if abnormalities are detected.
- (4) Dietary adjustments: Advise Qi and blood deficiency type pressure ulcer patients to maintain a bland diet, increase intake of fresh fruits and vegetables, and easily digestible foods, while avoiding greasy, cold, and spicy foods, as these can affect drug absorption and potentially prolong wound healing time.
- (5) Daily care and management: Prevent friction and pressure on the wound, promote adequate sleep and maintain a positive attitude. Pay attention to drug interactions, and consult a doctor before using other medications to evaluate potential effects on drug efficacy. Store MEBO properly in a dry and cool environment, avoiding high temperatures or direct exposure to UV light to prevent drug deterioration. Inform pressure ulcer patients of follow-up appointments, and adjust treatment plans based on the assessment of wound healing status to enhance management effectiveness.

## 5. Conclusion

In summary, the combination of MEBO and rotary moxibustion treatment for Qi and blood deficiency type pressure ulcer patients can reduce wound healing time, alleviate pressure ulcer symptoms, increase patient satisfaction, and decrease adverse reactions, making it a viable treatment option.

## Disclosure statement

The authors declare no conflict of interest.

## References

- [1] Min Z, Zhang Y, 2023, Analysis of the Efficacy of Debridement and Suturing Combined With Moist Burn Ointment in the Treatment of Stage IV Pressure Ulcers on the Buttocks. *Chinese Journal of Burns and Wounds*, 35(5): 340–344.
- [2] Cui P, Hu J, Li P, et al., 2023, Analysis of the Efficacy of Negative Pressure Wound Therapy Combined With Sequential Treatment of Moist Burn Ointment for Stage III Pressure Ulcers. *Chinese Journal of Burns and Wounds*, 35(1): 9–12.
- [3] Luo X, Hu Z, Chen H, et al., 2023, Analysis of the Efficacy of Medical Bactericidal Liquid Dressing Combined With Moist Burn Ointment in the Treatment of Stage II–IV Pressure Ulcers. *Chinese Journal of Burns and Wounds*, 35(6): 425–428 + 435.
- [4] Liu W, Ning W, 2022, Analysis of the Efficacy of Moist Burn Ointment Combined With Autologous Platelet-Rich Gel Sequential Therapy for Stage III–IV Infectious Pressure Ulcers. *Chinese Journal of Burns and Wounds*, 34(5): 322–324 + 329.
- [5] Wang S, Liu J, Liu D, et al., 2021, Comparative Study on the Evaluation of Different Treatment Methods for Stage III–IV Sacral Pressure Ulcers. *Jilin Medical Journal*, 42(4): 835–838.

- [6] Guo X, Li H, Xie G, 2020, Clinical Efficacy of Heat-Sensitive Moxibustion Combined With Moist Burn Ointment in the Treatment of Stage II–IV Pressure Ulcers. *Journal of Clinical Rational Drug Use*, 13(15): 135–136.
- [7] Zheng J, Yang S, Zheng J, et al., 2020, Clinical Efficacy of External Application of Modified Qufu Shengji Ointment Combined With Rotating Moxibustion With Mugwort Sticks in the Treatment of Stage III and IV Pressure Ulcers and Its Effect on Healing Time. *International Journal of Nursing*, 39(7): 1245–1248.

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# Application and Challenges of Artificial Intelligence in the Care of Stroke Patients

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**Abstract:** Driven by the combined forces of social aging and digital transformation, the application of artificial intelligence (AI) in the care of stroke patients has become an inevitable trend. AI can serve patients through intelligent health monitoring, rehabilitation training assistance, and daily care, providing targeted and intelligent support that significantly improves patients' quality of life and the efficiency of caregivers. This article provides an overview of the application of AI in stroke care, explores the challenges encountered in technical bottlenecks, privacy data protection, and ethical considerations, and lays a theoretical foundation for the integration of AI into the care of stroke patients. In the future, AI will rely on technological updates, policy support, and ethical guidelines to promote sustainable development in the nursing industry.

**Keywords:** Artificial intelligence; Stroke; Intelligent health monitoring; Technical bottlenecks; Data privacy

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## 1. Introduction

Stroke, commonly known as a “brain attack,” is a major global public health issue and a serious acute cerebrovascular disease that threatens the health of Chinese citizens <sup>[1]</sup>. The “China Stroke Center Report 2022” indicates that stroke is characterized by high incidence, high prevalence, high mortality, and high recurrence rates <sup>[2]</sup>. Patients often experience impairments in movement, sensation, cognition, speech, urination, and defecation, as well as a decline in self-care ability <sup>[3]</sup>. In recent years, China has made some achievements in the care of stroke patients, but there are still challenges such as the lack of continuity in patient care services, poor rehabilitation effects, and the absence of psychological care. The application of AI technology has brought new solutions to these difficulties. This article aims to summarize the current status of AI application in stroke care, analyze the difficulties encountered, and provide an outlook on future development trends.

## 2. Artificial Intelligence

The term “Artificial Intelligence” (AI) was first proposed by McCarthy at a conference proposal held at Dartmouth

College in 1955, and its concept was defined as a new discipline <sup>[4]</sup>. AI refers to the simulation, extension, and expansion of human intelligence through computers to achieve abilities similar to human thinking, decision-making, language understanding, etc., exhibiting behaviors similar to humans <sup>[5]</sup>. In recent years, AI technology has continuously developed, integrating knowledge and disciplines from multiple fields, including medicine, computer science, statistics, mathematics, and others. It not only meets humans' needs for improved quality of life but also replaces or assists humans in completing complex tasks and solving problems faced by humanity. Currently, AI has penetrated into every aspect of human life, significantly changing lifestyles, improving quality of life, and ushering in an era of intelligence.

### **3. Application and background of AI in medicine**

With changing lifestyles and the intensifying aging population, there has been an explosive growth in the number of disabled or semi-disabled elderly, rehabilitation, disabled, and chronic disease groups, leading to an upward trend in medical demand. China has elevated AI to a national strategy. In 2021, the State Council issued the "Opinions on Promoting the High-Quality Development of Public Hospitals," which clearly proposes promoting the construction of a "three-in-one" smart hospital integrating electronic health records, smart services, and smart management, elevating the integration of AI and healthcare to the national level <sup>[6,7]</sup>. In recent years, AI has developed rapidly in the medical industry, with applications in intelligent health monitoring, intelligent rehabilitation training and assistance, and daily care. This has significantly improved medical efficiency, reduced the workload of caregivers, and brought transformative and innovative changes to the nursing model. Through big data analysis, AI utilizes machine learning and intelligent rehabilitation monitoring equipment, significantly improving patients' rehabilitation effects. This fully demonstrates the potential and broad development prospects of AI application in the field of stroke care.

### **4. Current status of AI application in stroke patient care**

#### **4.1. Intelligent health monitoring**

##### **4.1.1. Vital data collection**

Traditional vital data collection relies on pulse diagnosis methods, relying on the experience and knowledge of caregivers, which can easily lead to misjudgment. However, intelligent devices such as smart bracelets and watches, supported by high-precision sensors and advanced detection technology, can monitor patients' heart rate, blood pressure, blood sugar, blood oxygen saturation, and pulse at any time, efficiently and accurately collecting vital data <sup>[8,9]</sup>. Previously, vital data was primarily recorded through manual paper documentation by caregivers, which was then entered into a computer and transmitted to the hospital information system. This process was time-consuming and prone to errors <sup>[10]</sup>. Currently, an artificial intelligence voice recording system is applied to input vital signs data from hospitalized patients into the hospital information system, reducing the time required for data entry <sup>[11]</sup>. The reduction in time spent on vital data collection benefits patient safety. Additionally, the application of AI has significantly improved the accuracy of data collection and reduced the workload of caregivers <sup>[12]</sup>.

##### **4.1.2. Disease risk warning**

Utilizing deep learning and machine learning algorithms, AI technology can automatically extract features from

medical images such as Computed Tomography (CT) and Magnetic Resonance Imaging (MRI). This enables quantitative analysis of lesion size and location, aids in predicting disease progression trends, and facilitates early detection and intervention <sup>[13]</sup>. Post-surgical patients wearing smart devices can promptly predict bleeding conditions and infection risks, informing caregivers to take intervention measures and avoid the risk of secondary stroke. Stroke patients often experience confusion and weakened sensory function, leading to local tissue compression. Monitoring patient turning frequency and compression situations using smart beds can effectively prevent pressure injuries.

#### **4.1.3. Health status evaluation**

Previously, patient health assessments relied heavily on subjective observations by medical staff. Nowadays, AI motion capture technology allows for comprehensive evaluations of patients' gait, movement trajectories, strength, and other aspects, providing scientific guidance for their rehabilitation training <sup>[14]</sup>. Many patients experience language dysfunction, such as aphasia, after onset. AI's speech analysis tools can analyze various dimensions of patient speech, including vocabulary and speaking rate, to accurately assess the degree of language impairment and assist caregivers in developing more reasonable care plans <sup>[15]</sup>. Stroke patients often experience anxiety and depression due to impaired physical function and psychological stress. AI's facial recognition technology can detect patients' emotional fluctuations, facilitating timely psychological counseling by caregivers and helping patients maintain a positive attitude during rehabilitation <sup>[16]</sup>. AI's motion capture, language analysis, and facial recognition technologies have ushered in a new era of health assessment for stroke patients.

### **4.2. Intelligent rehabilitation training and assistance**

#### **4.2.1. Personalized rehabilitation**

By analyzing patients' psychological changes, physiological conditions, and behaviors, AI creates assistive technologies such as Brain-Computer Interfaces (BMI), Virtual Reality (VR), and rehabilitation robots to achieve personalized rehabilitation programs and training plans for patients <sup>[17]</sup>. Through digital model algorithms, AI comprehensively evaluates patients' individual basic conditions and then uses BMI technology, VR motion-sensing games, and other methods to recognize patients' movement intentions and formulate personalized plans <sup>[18]</sup>. This not only completes rehabilitation training for stroke patients but also adds fun, promotes the recovery of limb movement function, and improves the effectiveness of rehabilitation treatment <sup>[19,20]</sup>.

#### **4.2.2. Cognitive impairment training**

Stroke can cause neurological deficits, leading to cognitive dysfunction such as agnosia, apraxia, memory impairment, and visuospatial disorders, which have a significant impact on patients' lives <sup>[21]</sup>. Healthcare workers utilize AI-assisted cognitive training, remote rehabilitation systems, and companion robots as new methods to help patients with cognitive rehabilitation training and improve their quality of life <sup>[22-24]</sup>.

#### **4.2.3. Smart health education**

Through AI video information technology, mobile applications, and virtual classrooms, disease-related health knowledge can be conveyed intuitively and vividly, thereby enhancing patients' awareness of the disease <sup>[25]</sup>. Smart health education technology imaginatively elucidates key knowledge points, which not only improves patients' cognitive level of stroke but also enhances the work quality of nursing staff <sup>[26]</sup>.

### **4.3. Smart daily care**

Relying on smart devices and precise algorithms, AI can provide prompts and guidelines tailored to patients' exercise levels, excretion patterns, and nutritional intake after comprehensively considering their self-care abilities and physical parameters. Currently, the probability of malnutrition among acute stroke patients reaches 36%, which increases the risk of complications and subsequently leads to a rise in mortality rates <sup>[27,28]</sup>. Therefore, it becomes crucial to provide care for patients in their daily lives. AI-dynamically adjusted dietary plans for patients can prevent malnutrition and related complications <sup>[29]</sup>. Additionally, smart assistive technologies can help stroke patients complete daily activities such as moving from bed to chair, dressing, and eating, effectively reducing the workload of family members and caregivers <sup>[30]</sup>.

## **5. Challenges faced by artificial intelligence in stroke care**

### **5.1. Technical bottlenecks**

Currently, intelligent rehabilitation robots lack flexibility and precision in complex environments, making it difficult to meet diverse care needs. Life support equipment, on the other hand, needs improvement in force control to avoid causing secondary harm to patients <sup>[31]</sup>. Therefore, AI systems for stroke patients should have diverse functionalities to enhance their comprehensive capabilities.

### **5.2. Data privacy and security issues**

During the nursing process, AI collects a large amount of sensitive data related to patients. If there are loopholes in the data storage process, data leakage, alteration, or misuse will likely occur, leading to serious security incidents. Therefore, to avoid the risk of patient privacy leakage, medical staff should carefully store health data to prevent data leakage and misuse <sup>[32]</sup>. Moreover, AI developers should develop robots in accordance with legal regulations and should not embed their own biases or values into robot algorithms to avoid unexpected data situations that could lead to adverse consequences for patient care decisions, infringe on patient rights, and delay treatment progress <sup>[33]</sup>.

### **5.3. Ethical dilemmas**

Overreliance on AI by humans may weaken the emotional connection between patients and their family members, leading to ethical controversies. Although some nursing robots can provide continuous companionship and care for patients, they cannot fully understand patients' emotional needs and psychological states like nursing staff, and cannot provide emotional support to meet patients' emotional needs <sup>[34,35]</sup>.

## **6. Conclusion**

The application of artificial intelligence in stroke care has significantly improved nursing efficiency and quality, providing patients with precise and personalized nursing experiences. However, challenges in technology, privacy, and ethics still need to be further addressed. In the future, collaboration between researchers, healthcare teams, and policymakers is needed to overcome the technical bottlenecks of AI and provide comprehensive, high-quality nursing services to patients, improving their prognosis and quality of life.

## Disclosure statement

The authors declare no conflict of interest.

## References

- [1] Expert Committee of the National Health Commission on Strengthening Stroke Prevention and Treatment to Reduce One Million New Disabilities Project, Ji X, 2025, Promoting the National Health Commission's Project on Strengthening Stroke Prevention and Treatment to Reduce One Million New Disabilities: Current Status and Strategy of Stroke Prevention and Treatment in China. *Journal of Capital Medical University*, 46(1): 11–14.
- [2] Writing Group of “China Stroke Center Report 2022”, Wang L, 2024, Summary of “China Stroke Center Report 2022”. *Chinese Journal of Cerebrovascular Diseases*, 21(8): 565–576.
- [3] Tian P, Fan R, Wang H, et al., 2024, Pathogen Distribution, Clinical Characteristics, and Risk Factors of Urinary Tract Infections in Patients with Ischemic Stroke. *Chinese Journal of Rehabilitation Theory and Practice*, 30(10): 1179–1186.
- [4] Cui F, Li Z, He X, et al., 2025, Ethical Considerations of the Clinical Application of Medical Artificial Intelligence. *Chinese Medical Ethics*, 38(2): 159–165.
- [5] Wang Q, Ding X, Luo Z, et al., 2024, Progress in the Application of Artificial Intelligence in Nursing Quality Management. *Chinese Journal of Nursing*, 59(23): 2933–2939.
- [6] Meng L, Li Y, Sun Y, et al., 2025, Ethical Review of the Research and Application of Artificial Intelligence in the Field of Rehabilitation. *Chinese Medical Ethics*, 38(2): 166–172.
- [7] Yingshan County People's Hospital, 2024, How to Carry Out Informatization Construction in Hospitals Under the Background of Big Data. *China Science and Technology Information*, 2024, [missing journal info].
- [8] Yang M, Hu Z, Li L, Zhong S, Yao T, Li X, 2019, The Origin and Development of Pulse Diagnosis in Traditional Chinese Medicine. *Henan Journal of Traditional Chinese Medicine*, 39(6): 829–832.
- [9] Manar O, Abdelhamied A, Ateya M, et al., 2023, Internet of Medical Things and Healthcare 4.0: Trends, Requirements, Challenges, and Research Directions. *Sensors (Basel, Switzerland)*, 23(17): 7435.
- [10] Mohamed AB, Victor C, Nada A, Nabeeh, 2021, An Intelligent Framework Using Disruptive Technologies for COVID-19 Analysis. *Technological Forecasting and Social Change*, 163: 120431.
- [11] Du W, Li X, Ma J, Zhou J, Feng Z, 2024, Design and Implementation of a Pathology Report Writing System Based on AI Smart Voice Input. *Yunnan Medical Journal*, 45(4): 71–74.
- [12] Hou X, Sui W, Han F, Zhu J, Zhao H, Wang J, Li Q, Lu P, 2022, Construction and Application of an AI Voice-Based Clinical Nursing Data Collection System for Infectious Diseases. *Journal of Nursing*, 29(19): 20–24.
- [13] Hyunna L, Eun-Jae L, Sungwon H, Han-Bin L, Ji Sung L, Sun U L, Jong S K, Namkug K, Dong-Wha K, Kang, 2020, Machine Learning Approach to Identify Stroke Within 4.5 Hours. *Stroke*, 51(3): 860–866.
- [14] Wang S, Yu J, Tan Y, Wang T, 2015, Construction of a Stroke Rehabilitation Training System Based on Unity3D. *Electronics World*, 2015(17): 183–185.
- [15] Gao N, Yang Y, Zhai W, Gao F, Wang Y, 2018, A Voice Care System for Stroke Patients Based on Brain-Computer Interface. *Journal of Biomedical Engineering Research*, 37(4): 465–469.
- [16] Jarvis T, Thornburg D, Rebecca AM, Teven CM. Artificial Intelligence in Plastic Surgery: Current Applications, Future Directions, and Ethical Implications. [J]. *Plastic and reconstructive surgery. Global open*, 2020, 8(10): e3200. DOI:10.1097/GOX.0000000000003200.
- [17] Kang X, Liu L, 2022, Progress in the Application of Intelligent Technology in Stroke Rehabilitation. *Chinese Journal of Stroke*, 17(6): 658–663.

- [18] Hu Y, Xiao Y, Hua Y, Lu A, Lu H, Huang Y, Song X, 2022, The Effect of Virtual Reality Technology Combined with Upper Limb Rehabilitation Robots on the Recovery of Upper Limb Function in Stroke Patients. *Zhejiang Journal of Integrated Traditional Chinese and Western Medicine*, 32(6): 537–539.
- [19] Shao X, Zhang Y, Zhang D, Men Y, Wang Z, Chen X, Xie P. A Multi-sensory Stimulation Integrated Virtual Reality-Brain Computer Interface System for Hand Function Enhancement and Rehabilitation [J]. *Journal of Biomedical Engineering*, 2024, 41(4): 656–663. DOI: 10.7507/1001-5515.202312055.
- [20] Yu H, Dong Z, Song J, Feng W, Hua J, 2019, Meta-analysis of the Effect of Somatosensory Interactive Games on Lower Limb Functional Rehabilitation in Stroke Patients. *Chinese Journal of Rehabilitation Theory and Practice*, 25(11): 1320–1326.
- [21] Jiang M, Liu B, 2010, Research Progress on Cognitive Impairment in Stroke Patients. *Chinese Journal of Rehabilitation Medicine*, 25(3): 289–292.
- [22] Xia Y, Li Q, Fan K, 2022, Study on the Effect of Computer-Aided Cognitive Training on the Recovery of Cognitive Function and Neurological Function of Patients With Ischemic Stroke. *Journal of Clinical Nursing*, 21(2): 67–70.
- [23] Wang T, Qu Y, 2020, Current Status of Cloud-Based Rehabilitation for Stroke in China. *West China Medical Journal*, 35(6): 652–657.
- [24] Li S, Zhao Y, Zhang Y, 2019, Application of Artificial Intelligence in the Evaluation and Rehabilitation of Cognitive Impairment After Stroke. *Chinese Medical Journal*, 54(10): 1066–1070.
- [25] Bao L, Zhang C, Wang Y, 2021, The Influence of Virtual Classroom on Cognitive Bias and Health Behavior of Stroke Patients During Recovery. *Chinese Journal of Practical Nervous Diseases*, 24(9): 800–806.
- [26] Gui S, Wan C, Jiang T, 2022, Application of Intelligent Health Education System in Health Education of Neurosurgery. *Chinese Journal of Geriatric Care*, 20(2): 148–150.
- [27] Zhang Y, Qin Y, Ren X, 2011, Clinical Analysis of Stroke and Malnutrition. *Chinese Journal of Practical Medicine*, 6(25): 231–232.
- [28] Wang R, Wang L, Li H, Zeng X, 2023, Study on Influencing Factors of Nutritional Status at Different Time Points in Stroke Patients. *Chinese General Practice*, 26(6): 665–671.
- [29] Li H, He F, Li X, Kang L, Huang C, 2024, Construction of an Artificial Intelligence Continuing Care Platform and Its Application in Stroke Patients. *Evidence-Based Nursing*, 10(13): 2412–2415.
- [30] Zhang Y, Huang Y, Ma J, Zhou D, Wu X, Huang S, 2018, Effects of Upper Limb Intelligent Feedback Robot Training on Upper Limb Function and Activities of Daily Living in Stroke Patients. *Jiangsu Medical Journal*, 44(10): 1206–1208.
- [31] Yang Y, Liu Z. Analysis of Ethical Issues in the Application of Artificial Intelligence Medical Equipment [J]. *China Medical Equipment*, 2024, 39(04): 137–141.
- [32] Zeng Y, Zeng L, 2023, Application Status, Challenges, and Countermeasures of Smart Health and Wellness Metaverse From the Perspective of Healthy Aging. *Journal of Nursing*, 30(14): 70–73.
- [33] Li H, Xu Z, 2024, Research on the Generation Logic and Legal Regulation Path of Medical Artificial Intelligence Algorithm Discrimination. *China Digital Medicine*, 19(12): 11–19.
- [34] Ibuki T, Ibuki A, Nakazawa E. Possibilities and ethical issues of entrusting nursing tasks to robots and artificial intelligence. [J]. *Nursing ethics*, 2024, 31(6): 1010–1020. DOI: 10.1177/09697330221149094.
- [35] Chen J, Ding X, Yu F, 2023, Ethical Dilemmas of Nursing Robots Assisting Home-Based Elderly Care. *Chinese Medical Ethics*, 36(12): 1350–1357.

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# Study on the Application and Value of Multi-slice Spiral CT in Acute Appendicitis

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**Abstract:** *Objective:* To investigate the diagnostic value of multi-slice spiral CT (MSCT) for patients with acute appendicitis (AA). *Methods:* Fifty patients with suspected AA who visited the hospital from January 2023 to January 2025 were selected as samples. All patients underwent MSCT and ultrasound diagnosis, and the diagnostic efficacy of MSCT was analyzed in comparison with pathology. *Results:* Pathology indicated 40 positive and 10 negative cases, ultrasound indicated 30 positive and 20 negative cases, and MSCT indicated 39 positive and 11 negative cases. The diagnostic efficacy of MSCT was higher than that of ultrasound ( $P < 0.05$ ). The accuracy of pathological classification of MSCT was higher than that of ultrasound ( $P < 0.05$ ). The detection rate of MSCT imaging indicators in AA patients was higher than that in non-AA patients ( $P < 0.05$ ). *Conclusion:* MSCT has high diagnostic efficacy in AA patients and can assist physicians in determining pathological classification.

**Keywords:** Acute appendicitis; Multi-slice spiral CT; Diagnostic efficacy

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## 1. Introduction

AA is a common acute abdominal disease in general surgery, mostly caused by pathogenic bacteria infection and appendiceal duct blockage. The symptoms include fever, tenderness, and lower abdominal pain, which are mostly treated by surgical removal of the diseased appendix. However, before surgical treatment, it is necessary to determine the location of the diseased appendix in AA patients, evaluate the degree of appendiceal suppuration and necrosis, and provide a basis for physicians to choose the type of surgery. Ultrasound is a commonly used diagnostic technique for AA, but its diagnostic accuracy is affected by intestinal gas, which may lead to unnecessary appendectomy or delayed treatment. Therefore, it is necessary to explore other imaging techniques for the diagnosis of AA. Based on single-slice spiral CT technology, MSCT acquires volumetric parameters of the appendix in the detection area and analyzes the correlation between diseased and healthy tissues from multiple angles and links<sup>[1]</sup>. However, MSCT has certain radiation, so repeated examinations require attention to prevention and control. Based on this, this study explores the diagnostic efficacy of MSCT using 50 patients with suspected

AA who visited the hospital from January 2023 to January 2025 as samples.

## 2. Materials and methods

### 2.1. Materials

A sample of 50 patients with suspected acute appendicitis (AA) who visited the hospital from January 2023 to January 2025 is selected. There were 29 males and 21 females, with ages ranging from 19 to 73 years old, and a mean age of  $(43.19 \pm 2.44)$ . The course of the disease ranged from 1 to 4 days, with a mean of  $(2.18 \pm 0.43)$  days. Inclusion criteria are: Presence of tenderness in a fixed area of the right lower abdomen; Signed informed consent; Elevated white blood cell count. Meanwhile, the exclusion criteria are: Organ lesions; History of immunosuppressive drug use; History of hormone drug use; Psychiatric disorders.

### 2.2. Methods

- (1) Ultrasound: The ultrasound probe is adjusted to 3.5–4.0MHz and placed on the point of tenderness in the right lower abdomen of the patient, gradually applying pressure during scanning to reduce interference from ascending colon and cecum gases, and to obtain clear imaging of the appendiceal lesion. Based on this center point, a wide range of scanning is performed to obtain information on the size, shape, echo, and adjacent tissues of the appendix, as well as blood flow signals in the appendiceal region using color Doppler imaging technology. AA is confirmed if the ultrasound indicated an appendiceal diameter  $\geq 6\text{mm}$ , wall thickening  $\geq 2\text{mm}$ , enhanced serosal echo, cessation of appendiceal peristalsis, increased blood flow in the appendiceal lesion, or detection of fluid in the appendiceal cavity.
- (2) MSCT: Scanning is performed using a 64-slice multi-spiral CT scanner. Parameters are adjusted to acquire images from the second lumbar vertebra to the pubic symphysis region. For patients with a high suspicion of AA, 80ml of iohexol is injected at a rate of 3ml/s to obtain enhanced scan data. The data is then transmitted to a post-processing workstation for multi-planar reconstruction. AA is confirmed if MSCT indicated appendiceal wall thickening, appendiceal diameter  $> 6\text{mm}$ , visible exudate adjacent to the appendix, or thickening of the terminal ileum wall.

### 2.3. Statistical analysis

Data is processed using SPSS 21.0. Count data is recorded as percentages (%) and analyzed using the chi-square test ( $X^2$  test). Measurement data is recorded as mean  $\pm$  standard deviation ( $\bar{x} \pm s$ ) and analyzed using the t-test. Statistical differences are considered significant at  $P < 0.05$ .

## 3. Results

### 3.1. Detection indicators

Pathology indicated 40 positive and 10 negative cases. Ultrasound indicated 30 positive and 20 negative cases, as shown in **Table 1**. MSCT indicated 39 positive and 11 negative cases, as shown in **Table 2**.

**Table 1.** Comparison between ultrasonic and pathological results (n,%)

Ultrasound	Pathological Positive	Pathological Negative	Total
Positive	23	7	30
Negative	17	3	20
Total	40	10	50

**Table 2.** Comparison between MSCT and pathological results (n,%)

Ultrasound	Pathological positive	Pathological negative	Total
Positive	38	1	39
Negative	2	9	11
Total	40	10	50

### 3.2. Diagnostic efficiency indicators

The diagnostic efficiency of MSCT is higher than that of ultrasound,  $P < 0.05$ , as shown in **Table 3**.

**Table 3.** Diagnostic efficiency indicators (n,%)

Diagnostic method	Sensitivity	Specificity	Accuracy	Positive predictive value	Negative predictive value
Ultrasound	57.50(23/40)	30.00(3/10)	52.00(26/50)	76.67(23/30)	15.00(3/20)
MSCT	95.00(38/40)	90.00(9/10)	94.44(47/50)	97.44(38/39)	81.82(9/11)
$X^2$	15.5306	7.5000	22.3744	7.1360	13.3548
$P$	0.0000	0.0062	0.0000	0.0076	0.0003

### 3.3. Pathological classification indicators

The accuracy of MSCT pathological classification is higher than that of ultrasound,  $P < 0.05$ , as shown in **Table 4**.

**Table 4.** Pathological classification indicators (n,%)

Diagnostic Method	Suppurative appendicitis	Simple appendicitis	Gangrenous appendicitis	Periappendiceal abscess	Accuracy rate
Ultrasound	42.11(8/19)	83.33(5/6)	40.00(6/10)	80.00(4/5)	72.97(23/40)
MSCT	94.74(18/19)	100.00(6/6)	90.00(9/10)	100.00(5/5)	97.30(38/40)
$X^2$	-	-	-	-	15.5306
$P$	-	-	-	-	0.0000

### 3.4. Imaging sign indicators

The detection rate of MSCT imaging indicators in AA patients is higher than that in non-AA patients,  $P < 0.05$ . The results are shown in **Table 5**.

**Table 5.** Imaging sign indicators (n,%)

Group	Periappendiceal effusion	Thickening of cecum wall	Appendicolith	Ileocecal lymph node enlargement	Intestinal congestion
AA ( <i>n</i> =40)	35(87.50)	38(95.00)	34(85.00)	35(87.50)	12(30.00)
Non-AA ( <i>n</i> =10)	5(50.00)	5(50.00)	4(40.00)	4(40.00)	0(0.00)
X <sup>2</sup>	7.0313	13.4551	8.8816	13.7730	3.9474
<i>P</i>	0.0080	0.0002	0.0029	0.0002	0.0469

## 4. Discussion

AA has a high incidence rate among acute abdominal diseases in general surgery. The typical symptom is tenderness at McBurney's point, while a few patients have non-specific manifestations, which can be easily confused with urinary calculi and gastroenteritis. Ultrasonic technology is commonly used in the diagnosis of appendicitis and other related diseases. It has the advantage of being non-radiative and can provide dynamic feedback on the location, morphology, structure, and echo of the appendix. This information can serve as a basis for physicians to evaluate appendiceal lesions. Additionally, ultrasonography is affordable and tolerable for most patients <sup>[2]</sup>. However, it is important to note that when AA patients undergo ultrasonography, the presence of excessive gas in the intestinal cavity or excessive abdominal wall fat can obstruct ultrasonic waves, reducing the detection rate of deep-seated diseases. Furthermore, ultrasonic results may be influenced by the subjectivity of the doctor, and the imaging quality can be affected by factors such as the scanning technique, intestinal gas accumulation, and abdominal pain, leading to missed diagnoses. MSCT, on the other hand, is a modern imaging diagnostic technique that offers advantages such as multi-level scanning and high-resolution imaging. It can clearly display the location and morphology of the appendix, and also observe changes in adjacent tissues, lymph nodes, fatty spaces, and fascia, facilitating accurate evaluation of AA pathological changes by physicians.

Based on the data analysis in this study, pathology indicated 40 positive cases and 10 negative cases, ultrasound indicated 30 positive cases and 20 negative cases, and MSCT indicated 39 positive cases and 11 negative cases. For patients with appendicitis (AA) undergoing MSCT diagnosis, there are several advantages: Firstly, MSCT technology provides high-resolution imaging, allowing for clear local images to be obtained. It enables multi-planar and multi-dimensional observation of local lesions. After collecting information, it can be transmitted back to the post-processing workstation for three-dimensional imaging, providing intuitive data for physicians to differentiate and diagnose AA. By observing the structure of the appendix and adjacent tissues, it can assist doctors in evaluating the scope of appendicitis lesions and the degree of inflammatory lesions <sup>[3]</sup>. Secondly, MSCT technology offers fast imaging speed and short scan time. The use of rapid reconstruction technology and multi-slice volume scanning technology to acquire abdominal imaging information can reduce scan time, improve abdominal comfort, and reduce the pain of abdominal examination for patients.

Shortening the scan time can also alleviate discomfort induced by the examination. In addition, MSCT technology's thin-slice scanning can enhance imaging clarity, facilitating the identification of early-stage AA patients by physicians. Finally, MSCT technology can assist doctors in completing preoperative evaluation and guiding the formulation of surgical plans. Another set of data shows that the diagnostic efficacy of MSCT is higher than that of ultrasound ( $P < 0.05$ ). The reason for this is that MSCT technology utilizes the different absorption and attenuation of X-rays by different human tissues to generate images. It can complete a full abdominal scan

in just 16–19 seconds, resulting in images without motion artifacts. Furthermore, the use of post-processing techniques for three-dimensional reconstruction of the affected area allows for observation of the appendiceal lumen from different angles, providing continuous and complete images of the appendix. Precise evaluation through observation of indicators such as appendiceal shape, thickness, length, location, and extravasation results in high diagnostic efficacy, compensating for the limitations of two-dimensional imaging <sup>[4]</sup>.

Additionally, during MSCT scanning, the thinnest multi-planar reconstruction image has a thickness of 0.5mm, which aids doctors in evaluating the appendiceal lumen and adjacent fine anatomical structures, facilitating the differential diagnosis of different AA types. Obtaining curved planar reconstruction images of the appendix can better reflect the relationship between the appendix and adjacent structures, thereby providing preoperative spatial conformation for the treating physician. Another set of data indicates that the accuracy of MSCT in pathological typing is higher than that of ultrasound ( $P < 0.05$ ). The reason for this is that ultrasound technology, when used for the differential diagnosis of suspected AA patients, offers non-invasive and convenient features. It relies on differences in sound impedance between different tissues to generate images. By analyzing changes in imaging signs and hemodynamics, it can improve the accuracy of pathological typing diagnosis <sup>[5]</sup>. However, it is important to note that ultrasound alone, indicating hemodynamic changes, cannot accurately evaluate AA. Furthermore, ultrasound imaging can be easily influenced by various subjective factors, potentially leading to missed diagnoses or misdiagnoses <sup>[6]</sup>.

MSCT technology combines the advantages of data acquisition and three-dimensional imaging, enabling the acquisition of three-dimensional and comprehensive imaging of the appendiceal region. By utilizing rotational scanning to obtain multi-layer imaging data, which is then transmitted back to a computer for three-dimensional reconstruction processing, it can generate three-dimensional images. This allows for the clear identification of the size, shape, location, and other data of the appendix, thereby assisting doctors in evaluating the pathological type of appendicitis <sup>[7]</sup>. The final set of data shows that the detection rate of MSCT imaging indicators is higher in AA patients compared to non-AA patients ( $P < 0.05$ ). The reason for this is that in AA patients, inflammatory infiltration and edema can increase vascular permeability, causing plasma components to leak into tissues adjacent to the appendix. If the leakage is excessive, it can lead to the formation of local abscesses, aggravating appendicitis. Additionally, widespread leakage can worsen abdominal pain. Under the influence of fecal stone compression and inflammatory stimulation, inflammatory factors can spread to the cecum, stimulating edema and hyperemia of the cecal mucosa, promoting local tissue proliferation, and even blocking intestinal contents, leading to increased intestinal distension.

Due to factors such as intestinal secretions, bacteria, and food residues, a large amount of calcified fecal stones can deposit in the appendiceal lumen, increasing intra-appendiceal pressure and blocking appendiceal blood flow. This results in worsened appendiceal inflammation and increased difficulty in treatment. Continuous stimulation of inflammatory factors on the ileocecal lymph nodes can lead to their enlargement. If adjacent tissues are compressed, it can aggravate local pain and even cause systemic infection. The influence of fecal stones and inflammation can also worsen adhesions in tissues adjacent to the appendix, leading to intestinal obstruction and stenosis, blocking the passage of intestinal contents. This can induce intestinal distension, causing symptoms such as nausea, vomiting, abdominal pain, and abdominal distension, and may even lead to perforation and intestinal necrosis <sup>[8]</sup>.

When performing MSCT diagnosis, observing increased density in the fat surrounding the appendix, appearing as cord-like or cloud-like structures with unclear boundaries, suggests the presence of diffuse or

localized extravasation signs. Observing high-density shadows in a cloud-like pattern indicates the spread of inflammatory factors to adjacent tissues. MSCT showing a cecal wall thickness greater than 3mm suggests diffuse or localized thickening of the cecal wall, and enhanced scan images can reveal local lesion enhancement. MSCT indicating high-density shadows in the appendiceal lumen, appearing as block-like or punctate structures with a diameter limited to approximately 3–10mm, suggests the presence of appendicoliths, which can block the lumen and worsen appendicitis. MSCT showing lymph nodes with a diameter greater than 8mm, and enhanced scan images revealing local lesion enhancement, indicates enlargement of ileocecal lymph nodes, which is associated with multiple factors such as inflammatory stimulation, immune response, and infection spread. MSCT indicating cecal dilation or terminal ileum dilation, and observing slowed intestinal motility and the presence of air-fluid levels within the intestinal lumen, suggests the presence of intestinal distension <sup>[9]</sup>.

To ensure diagnostic accuracy during MSCT examination, patients should fast for 4-6 hours before the examination to avoid the influence of intestinal fluids and food on MSCT imaging. If a patient's condition is critical, they can inform the radiologist and proceed with the examination directly. Before the examination, patients should remove any metal objects they are wearing, including phones, keys, and belts, to avoid the generation of artifacts under MSCT <sup>[10]</sup>. Additionally, due to the small number of suspected AA samples included in this study, there may be some coincidence in the MSCT diagnostic efficacy data. Further analysis of MSCT's diagnostic value should be conducted with an increased number of suspected AA samples in the future.

## 5. Conclusion

In summary, MSCT diagnosis of AA offers high diagnostic efficacy, can assist doctors in the classification of AA, and reveals distinct imaging features between AA and non-AA patients, making it a valuable tool for clinical application.

## Disclosure statement

The author declares no conflict of interest.

## References

- [1] Jia X, 2024, Application Value of Multi-Slice Spiral CT in the Pathological Classification Diagnosis of Acute Appendicitis. *China Minkang Medicine*, 36(19): 128–130.
- [2] Li S, 2024, The Application Value of Multi-Slice Spiral CT in the Diagnosis of Acute Appendicitis. *Chinese and Foreign Medical Research*, 3(5): 141–143.
- [3] Zhou Z, 2024, Application of Multi-Slice Spiral CT in the Diagnosis of Acute Appendicitis. *Modern Medical Imaging*, 33(5): 899–901.
- [4] Xu Y, Ma N, Xiao X, et al., 2024, The Value of Multi-Slice Spiral CT Combined with Ultrasonography in the Diagnosis of Acute Appendicitis. *Journal of Translational Medicine*, 13(10): 1559–1563.
- [5] Wang J, 2024, Analysis of the Diagnostic Value of Multi-Slice Spiral CT for Acute Appendicitis. *Modern Medical Imaging*, 33(11): 2075–207.
- [6] Shen J, Tang J, 2022, Clinical Value Analysis of Multi-Slice Spiral CT in the Diagnosis of Acute Appendicitis. *Journal of Medical Imaging*, 32(8): 1430–1432.

- [7] Zang W, Wang J, Zhang J, et al., 2020, Application of Multi-Slice Spiral CT Plain Scan and Reconstruction Technique in the Diagnosis of Acute Appendicitis. *Chinese Journal of Laboratory Diagnosis*, 24(4): 605–606.
- [8] Wang Q, 2021, Application of Multi-Slice Spiral CT Plain Scan and Reconstruction Technique in the Diagnosis of Acute Appendicitis. *Imaging Research and Medical Applications*, 5(6): 140–141.
- [9] Liu Z, 2022, Research on the Application Value of Multi-Slice Spiral CT Plain Scan Combined with Reconstruction Technique in the Diagnosis of Acute Appendicitis and Its Complications. *Imaging Research and Medical Applications*, 6(20): 50–52.
- [10] Peng L, Hu B, Mei L, et al., 2024, Diagnostic Application Value of MSCT in Acute Appendicitis. *Journal of Medical Imaging*, 34(9): 155–157.

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# Nursing Care after Cardiac Surgery for Termination of Pregnancy in Five Pregnant Women with Co-morbid Cardiac Disease

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**Abstract:** *Objective:* To summarize the clinical data and nursing experience of 5 cases of pregnant women with combined heart disease in pregnancy after cesarean section, followed by termination of pregnancy and then cardiac surgery in the postoperative period, to provide clinical experience for the care of such patients in the future. *Methods:* Retrospective analysis of the treatment and nursing process of 5 cases of pregnant women with pregnancy-related heart disease admitted to the hospital's department from May 16, 2023, to September 19, 2024, after cesarean section for termination of pregnancy, followed by cardiac surgery. For postoperative patients after cesarean section, using the "waist bag" type sandbag hemostasis method to prevent intra-abdominal pressure poly drop caused by heart rate, blood pressure abnormal treatment, and hemostatic effect, reduces the frequency of hemostatic drugs [1]. Strict monitoring of vital signs and hemodynamic monitoring, to maintain access and stability of the internal environment, digestive system care. *Result:* Five pregnant women with heart disease who underwent surgery all recovered and were discharged after appropriate nursing measures were taken. The average length of hospital stay for the five patients was  $(20 \pm 14.3)$  days. *Conclusion:* For pregnant women with complicated heart disease who undergo cesarean section to terminate pregnancy followed by cardiac surgery, it is essential to strengthen specialized monitoring and clearly define key observation points. Focused treatment and nursing care can help reduce postoperative complications, support patient recovery and self-care, and shorten hospital stays. This approach provides valuable clinical guidance for managing similar cases in the future. It is of clinical significance for future cardiac surgery after cesarean section in pregnant women with complicated heart disease.

**Keywords:** Combined heart disease of pregnancy; Pregnant women; Cardiac surgery; Nursing care; "Waist pack" type sandbag hemostasis

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## 1. Introduction

Heart disease in pregnancy has a certain incidence rate in the maternal population, and the prevalence rate is reported to be 1–4 % in various countries, which is one of the most important factors leading to maternal

mortality<sup>[2]</sup>. The main causes of maternal death in cardiac disease are postpartum hemorrhage, heart failure, and severe infections. Therefore, dynamic observation of cardiac function changes, timely management of various cardiac problems, and timely and appropriate termination of labor and delivery are crucial to reduce maternal and perinatal mortality in patients with confirmed cardiac disease. However, there is a relative lack of experience in the current nursing care of pregnant women with complicated heart disease undergoing cesarean section, followed by termination of pregnancy, and then cardiac surgery. In-depth investigation of the nursing measures for these patients is of great clinical significance in ensuring the recovery and prognosis of the patients.

## **2. Clinical data and surgical methods**

### **2.1. General information**

Five cases of pregnant women with combined heart disease in pregnancy admitted during May 2022–September 2024 are selected for this study. All patients are female, in the middle and late stages of pregnancy, with gestational weeks of 28–37 weeks, with a mean gestational week of  $(32.6 \pm 3.1)$  weeks; their ages ranged from 18–63 years, with a mean age of  $(34.6 \pm 3.4)$  years. Among them, there were 2 cases of combined hypertension, 1 case of combined diabetes mellitus, 3 cases of class III–VI cardiac function, 3 cases of type A aortic coarctation, and 2 cases of valvular lesions.

### **2.2. Surgical method**

Fetal heart auscultation is performed after anesthesia is completed and before the start of surgery. Cardiac surgery is performed first to open the chest, free the vessels, and prepare for extracardiac surgery, but extracorporeal circulation is withheld for the time being. Subsequently, a cesarean section is carried out, and a longitudinal incision is chosen for the abdominal wall incision, which is 12 cm long, to remove the fetus. Then, cardiac surgery is performed under general anesthesia. The specific surgical procedures are as follows: aortic valvuloplasty + aortic sinus repair + partial resection of the ascending aorta with prosthetic vascular replacement + total aortic arch prosthetic vascular replacement + stenting elephant trunk surgery in 2 cases; aortic valve mechanical valve replacement with ascending aortic replacement in 1 case; aortic valve replacement + mitral valve replacement + tricuspid valvuloplasty in 1 case; and aortic and ascending aortic replacement and coronary artery grafting in 1 case.

## **3. Surgical results**

All patients completed the operation and the operation time was  $(155 \pm 24.9)$  minutes under general anesthesia with extracorporeal circulation. They safely returned to the cardiac intensive care unit after the operation. The volume of pleural fluid was  $(258 \pm 97.7)$  ml at 48 hours after surgery. Two patients had sudden supraventricular tachycardia, which was improved after potassium and magnesium supplementation; Three patients with celiac disease were transferred to the ward and discharged successfully after chest tube removal.

## **4. Postoperative nursing measures**

### **4.1. Vital signs and hemodynamic monitoring**

Patients underwent cesarean section followed by cardiac surgery, which involved chest and abdominal incision, complex operation, and high risk of bleeding, with intraoperative bleeding of  $(260 \pm 90.3)$  ml. Post-operative blood pressure changes were the focus of nursing care, and all the patients returning to the intensive care unit

after surgery had large fluctuations in blood pressure <sup>[3]</sup>. Through early and continuous hemodynamic monitoring, circulating blood volume was effectively supplemented, and central venous pressure was maintained at 6–12 mmHg. Cardiac output was measured once a day via a floating catheter in the pulmonary artery to dynamically reflect changes in cardiac blood flow and pulmonary artery wedge pressure. The use of the “double-pump method” as a substitute for vasoactive drugs can help reduce blood pressure fluctuations caused by changes in vascular tone. This method allows for timely administration of fluids and blood products, correction of hypovolemia, and stabilization of vascular tone, thereby maintaining stable invasive arterial blood pressure. The maximum dose of dobutamine used was 8 µg/(kg·min). This approach was associated with reduced postoperative chest drainage and a decrease in the number of patients requiring further intervention. This reduced the amount of bleeding from postoperative chest drainage fluid <sup>[4]</sup>.

For two patients with symptoms of cold extremities and polyuria, they were given volume expansion therapy. Two patients with high blood pressure were given intravenous nitroglycerin vasodilator drugs, and the effect of blood pressure lowering was satisfactory. Another two patients with supraventricular tachycardia were improved by potassium and magnesium supplementation, and were maintained on oral amiodarone to prevent episodes, and the patient’s QTc intervals were closely monitored during the administration of the drug, to avoid the low-potassium and magnesium situation, and synchronized electrical cardioversion abortions could be considered in the event of an episode. In 2 patients with poor cardiac function, cardiac function was improved after pumping Levosimendan 0.1 µg/(kg·min), and urine output and blood pressure were improved.

## **4.2. Stabilization of the volume and internal environment**

Due to extensive surgical trauma, multiple vascular anastomoses, and the preoperative use of anticoagulant therapy (including anticoagulant needles and medications), controlling bleeding remained difficult despite the intraoperative administration of a large number of hemostatic agents during chest closure. Additionally, the use of heparin and other anticoagulants for extracorporeal circulation was insufficient in some cases. As a result, a significant amount of pleural effusion was observed in several patients during the early postoperative period. Intraoperatively, two patients had pleural fluid volumes exceeding 300 mL, with a corresponding hemodynamic mean pressure product of blood and gas around 23 mm Hg <sup>[5]</sup>.

Early transfusion of autologous blood is very important for the maintenance of stable circulation. Importantly, 200 ml of fresh frozen plasma and 2U of erythrocyte suspension were infused simultaneously, and the infusion rate was adjusted as needed. The volume of pleural fluid was closely observed, and blood gases were retested. A total of 600 IU of zymogen complex, 2000mg of fibrinogen, and 400 IU of coagulation factor VIII were given in time to stop bleeding, and finally the volume of pleural fluid was gradually reduced, and the active bleeding was controlled. Two patients experienced disturbances in their internal environment during the postoperative period. Blood gas analysis revealed hypokalemia (potassium < 3.6 mmol/L) and hypocalcemia (calcium < 1 mmol/L). Both patients had elevated heart rates exceeding 120 beats per minute and presented with supraventricular tachycardia. Supraventricular tachycardia improved after potassium, magnesium, and calcium supplementation.

## **4.3. Medication care**

Four patients had high blood counts after surgery, with a high risk of infection. They were treated with cefotaxime sodium sulbactam sodium injection 3g intravenous drip every 8 hours, combined with metronidazole 500mg intravenous drip twice a day to prevent infection. One pregnant woman had high fever and multiple invasive tubes

after heart surgery, and was considered to have aggravated infection. After replacing the deep venous catheter, the bacterial culture of the deep venous catheter showed carbapenem-resistant *Acinetobacter baumannii*. Therefore, meropenem injection 1000mg was administered intravenously every 6 hours (the first dose was 2000mg intravenous drip once) for anti-infection treatment. Vancomycin 1000mg was given as a loading dose intravenously, followed by 500mg intravenous drip. Fluconazole sodium injection (Diflucan) 800mg was given as a loading dose intravenously, followed by 400mg intravenous drip once a day. Polymyxin E mesylate injection 75mg was given by nebulization every 12 hours. Eventually, the patient's infection was controlled and she was discharged. When all patients had fibrinogen levels below the normal range, albumin was infused to correct hypoproteinemia, and respiratory exercises and ventilator-assisted treatment were continued. Blood gas, lactate, and blood glucose results were closely monitored. All patients were prescribed medications upon discharge after valve replacement surgery, including anticoagulant warfarin sodium tablets (taken once a day in the evening according to coagulation indicators), cardiac stimulant digoxin tablets (0.25mg once a day, with heart rate monitoring; stop taking if heart rate is below 60 beats per minute or if obvious nausea, vomiting or other discomfort occurs), diuretic spironolactone (20mg once a day), furosemide tablets (20mg once a day), lactation suppressant bromocriptine tablets (Bromocriptine) (2.5mg once a day), and blood tonic and menstrual regulator Leonurus japonicus granules (1 bag twice a day).

#### **4.4. Chest drainage and malodor care**

Postpartum mothers with a history of cardiac surgery should be closely monitored for vital signs, uterine contractions, abnormal discharge, abdominal incision status, IV access, and any complaints of discomfort. Any concerns should be promptly reported to the obstetrician, who will coordinate further care with the cardiac team <sup>[6]</sup>. In all patients, if vaginal bleeding and uterine drainage remain minimal for three days following the postoperative reduction of saline (125 ml or 250 ml) from the intrauterine balloon, the device is removed after an additional 24 hours of observation <sup>[7]</sup>.

All patients used a "waist bag" type sandbag to control bleeding after cesarean section. This method helps reduce wound pain, promotes hemostasis by applying pressure to the abdominal incision, minimizes blood and fluid seepage, stimulates uterine contractions, reduces uterine bleeding, and helps prevent shock caused by a sudden drop in abdominal pressure after delivery <sup>[8]</sup>. After cesarean section, abdominal compression with sandbags is typically maintained for 6 hours. Following this period, as the effects of anesthetic drugs gradually diminish through absorption and metabolism, patients are encouraged to turn from side to side to promote intestinal peristalsis. Close monitoring of anal gas passage and bowel movements is essential to assess gastrointestinal recovery. In three cases where patients had pleural effusion exceeding 300 ml, a blood salvage device was used to filter impurities from the pleural fluid. The concentrated red blood cells were then reinfused into the patients. Antiemetic medications were administered in a timely manner to manage potential side effects. Following the drainage of pleural fluid, patients also received transfusions of red blood cells, cryoprecipitate, and plasma as needed. The amount of pleural fluid gradually decreased, while the oral warfarin was stopped on the same day as prescribed by the doctor.

Three patients with positive celiac test were given a fat-free semi-fluid diet, and when the subsequent pleural fluid was still high, they were fasted, and the patients were closely monitored for their nutrition, electrolytes, and wounds, and continued to be observed. Eventually, the incision healed well without redness, swelling, and oozing. In obstetric postoperative care, when uterine balloon drainage was minimal, all saline was withdrawn from the uterine balloon. After confirming the absence of significant bleeding, the uterine balloon and the tailed gauze extending from the vagina were removed. A subsequent vaginal examination revealed no abnormalities.

Remaining patients continued with treatment protocols including lactation suppression, promotion of uterine contractions, and regular dressing changes at the incision site.

#### **4.5. Digestive system care**

All women undergoing cesarean section with abdominal incision and removal of the fetus will affect the mesentery to varying degrees<sup>[9]</sup>. Therefore, all patients were required to fast after surgery and could not eat until the abdomen was deflated. Two patients with healed cesarean section wounds, who reported lower abdominal pain and distension without pressure pain in the uterine area, underwent gastrointestinal decompression as per medical advice. The color and volume of gastric aspirate were monitored closely, and bowel sounds were auscultated during each shift. Abdominal circumference was measured as needed, with attention to signs of abdominal distension and peritoneal irritation. Blood and urinary amylase levels were closely monitored, and a fecal occult blood test was considered to assess for gastrointestinal flatulence. When the patient continued to experience abdominal distension, symptomatic treatment with a Pfizer enema was administered. A consultation with the Chinese Medicine Department was requested, and the patient was given treatment based on their medical advice. As a result, the patient's abdominal pain was relieved, and the abdomen became softer.

One patient experienced delayed chest closure following surgery, had been intubated for several days, and remained on fasting. No bowel sounds were detected, and a laxative was administered using an enema solution containing sodium phosphate. Another patient had postoperative blood gas analysis showing lactic acid levels between 4 and 5 mmol/L with abdominal distension, prompting concern for gastrointestinal flatulence. To rule out intestinal ischemia, a CT scan was immediately arranged. One patient's stool tested weakly positive, and treatment included growth inhibitors (250 µg/h) and continuous infusion of esomeprazole (8 mg/h), leading to the recovery of intestinal function. The other patients were able to ventilate and eat normally

#### **4.6. Rehabilitation and psychological care**

Absolute bed rest after surgery in all patients increases the risk of physical and psychological complications, such as pressure ulcers, deep vein thrombosis, ICU-acquired debility, ICU delirium, and so on. Two of the five postoperative patients had D-dimer levels > 10,000 ug/L, and all had a venous thromboembolism assessment score of > 5. They were at high risk for deep vein thrombosis. The patients were instructed to perform ankle exercises, including clockwise and counterclockwise encircling movements, dorsiflexion, inversion, plantarflexion, eversion, slowly, forcefully, and at the maximum angle possible to hold for 5 seconds, and the above movements were performed for 5 minutes per hour each time, and 5–8 times per day. One patient had delirium symptoms after surgery, and was given psychological counseling and ineffective comforting, and then was given olanzapine orally, and medetomidine was micro-pumped to keep her quiet and sleepy.

Postoperatively, all 5 patients had different degrees of coughing and thick sputum, and oxygen saturation was reduced to about 95% in 3 of them. The patients were instructed to adopt a standing or sitting position during abdominal breathing. When inhaling, the abdomen slowly rises, inhale deeply through the nose more slowly, the mouth is tightly closed, the lungs do not move, the whole body is relaxed, the shoulders do not lift, to ensure that the air is inhaled into the abdomen, can be used to press the hand to the position of one inch below the navel. When exhaling, contract the abdomen as far as possible inward, keep the chest still, and exhale the gas from the mouth, and do not inhale. Encourage the patient to do more deep breathing and coughing maneuvers. Deep breathing and coughing exercises are 2–3 times/day, 10–20 minutes/time.

## 5. Conclusion

In this study, a comprehensive and systematic nursing program was summarized by retrospectively analyzing the clinical data and nursing experience of five pregnant women with combined heart disease in pregnancy who had terminated pregnancy after cesarean section and then underwent cardiac surgery. During the nursing process, the patients' nursing problems were effectively solved by proposing the first-, middle-, and second-best nursing problems, formulating and implementing targeted, multidisciplinary, and collaborative nursing measures, and following up on the regression of the nursing problems promptly and repeatedly evaluating them. After careful nursing care, all patients were discharged successfully with improved cardiac function, stable vital signs, satisfactory oxygenation, confidence in disease recovery, and decreased BNP index and inflammatory index.

## Disclosure statement

The author declares no conflict of interest.

## References

- [1] Ao S, 2013, The Effect of Sandbag Pressurization of the Uterine Fundus on Women After Cesarean Section. *Medical Aesthetics and Cosmetology: A Middle-aged Journal*, 22(4): 1.
- [2] Lu Z, Qi H, 2020, Interpretation of "Management Guidelines for Pregnancy Complicated with Heart Disease (2019)" by the American College of Obstetricians and Gynecologists. *Chinese Journal of Obstetric Emergency Care Electronic Edition*, 9(3): 9.
- [3] Liu Z, Dai Q, Wang M, et al., 2014, Correlation Between Ultrasound Parameters of Cesarean Section Scar Pregnancy and Intraoperative Blood Loss. *Chinese Journal of Hua Liang*, 5(1): 7.
- [4] Shi H, Ge Y, Bao H, et al., 2009, A Comparative Study of Three Methods of Measuring Cardiac Volume Load and Hemodynamics. *Biomedical Engineering and Clinics*, 13(6): 8.
- [5] Chen X, 2011, Common Causes and Management Measures of Heparin Resistance During Cardiac Extracorporeal Circulation Surgery. *Chinese Practical Journal of Medicine*, 38(22): 2.
- [6] Zeng W, 2000, Modern Concept of Indication for Cesarean Section. *Chinese Journal of Practical Gynecology and Obstetrics*, 16(5): 3.
- [7] Ma Q, Zhou G, Cheng H, 2011, Observation on the Therapeutic Effect of Uterine Cavity Water Bag Compression in Treating Uterine Contraction Insufficiency-Induced Postpartum Hemorrhage in 56 Cases. *Journal of Jilin Medicine*, 32(28): 3.
- [8] Zhang XQ, 2007, The Efficacy of Sandbags Placed Under Pressure in Abdominal Incision on Wound Healing of the Abdominal Wall in Cesarean Delivery. *Journal of Xiangnan College: Medical Edition*, 9(3): 2.
- [9] Yang YF, 2016, Nursing Care of Patients With Mesenteric Vein Thrombosis Complicating Cesarean Delivery. *China Medical Guide*, 14(35): 1.

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# Dental Caries Among Preschool Children and the Impact of Behavioral Intervention on Caries Rate

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**Abstract:** *Objective:* To statistically analyze the prevalence of dental caries among preschool children and explore the application effect of behavioral intervention. *Methods:* The study period was from May 2024 to May 2025. Preschool children with dental caries ( $n=114$ ) admitted during this period were selected as the research subjects. They were divided into observation and control groups based on their admission number, with 57 cases in each group. Intervention indicators were compared between the groups. *Results:* Among all the children, the prevalence of dental caries at different age stages of preschool age (3–6 years old) showed that the caries rate increased with age, and there were significant differences in caries rates among different age groups ( $P < 0.05$ ). The total treatment compliance rate in the observation group was higher than that in the control group ( $P < 0.05$ ), and the new caries rate in the observation group was lower than that in the control group ( $P < 0.05$ ). After intervention, all indicators of the SESS in the observation group were better than those in the control group ( $P < 0.05$ ). *Conclusion:* The caries rate among preschool children is relatively high and increases with age. Active behavioral intervention facilitates better cooperation with clinical treatment among children with caries, significantly enhances self-efficacy, and significantly reduces the caries rate.

**Keywords:** Preschool children; Dental caries; Behavioral intervention; Caries rate

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## 1. Introduction

Dental caries is a common oral disease that mostly occurs in preschool children, causing damage to the hard tissue structure of their teeth due to bacterial corrosion<sup>[1]</sup>. As the disease progresses, children are prone to a series of complications such as pulpitis and swollen lymph nodes, which seriously affect their diet and quality of life<sup>[2]</sup>. During the clinical treatment of such children, root canal treatment can completely remove the damaged dental pulp. However, the role of self-care health behaviors still needs to be emphasized during nursing. Active behavioral intervention can enhance children's self-care efficacy and reduce the caries rate<sup>[3]</sup>. The following will focus on analyzing the prevalence of dental caries among preschool children and reducing the caries rate of children through behavioral intervention.

## 2. Materials and methods

### 2.1. Basic information

The subject included 114 preschool children with dental caries. They are divided into observation and control groups based on their admission number. The study started in May 2024 and is completed in May 2025. Among the 57 children in the control group, 35 are male and 22 are female, with an average age of  $(4.24 \pm 1.13)$  years. In the observation group ( $n=57$ ), the male to female ratio is 33:24, with a median age of  $(4.21 \pm 1.11)$  years. The basic conditions of the two groups are similar, and there was no statistical significance ( $P > 0.05$ ).

The inclusion criteria are: those who are not in the mixed dentition period; those aged between 3 and 6 years old; those who actively cooperate with the study. Meanwhile, the exclusion criteria include: those with incomplete clinical data; those who withdraw midway; those with a resistant attitude towards participation.

### 2.2. Methods

The control group received routine intervention, which involved organizing parents to participate in lectures on oral health education for young children. The lectures focused on promoting oral health among preschool children and their families, informing them of the key points and techniques of routine oral care, and raising awareness of the importance of oral health. The lectures are typically held every three months.

The observation group received behavioral intervention which includes:

#### (1) Strengthening health awareness

Nursing workers should focus on collecting and organizing information on the causes, manifestations, treatment plans, and nursing points of dental caries. Based on the data information base and expert guidance from the oral department, they should further optimize and improve the organized health education knowledge. The children need to receive explanations with their families, and the nursing workers can use pictures, videos, or cartoon animations to explain relevant health knowledge to the children in a graphic and textual form, attracting their attention. During the explanation, they can give demonic images to bacteria such as *Actinomyces* and *Streptococcus mutans*, vividly demonstrating their process of invading and damaging teeth, so that children can more clearly understand the process of tooth decay and the formation of caries. When teeth are being attacked, tense music can be selected to make children feel empathy, which is conducive to their systematic understanding of the causes of dental caries, treatment methods, and self-protection effects. At the same time, it can also stimulate their interest in learning and deepen their understanding and mastery of knowledge about dental caries.

#### (2) Standardizing oral health behaviors

To further standardize the oral care and health behaviors of children and their families, nursing workers should focus on the correct methods, time, and intensity of tooth brushing during knowledge education. They can also conduct on-site demonstrations through the use of tooth models to ensure that children and their families perceive this behavior effectively. In this process, it is important to emphasize the importance of cleaning teeth and interdental spaces, so that children can focus on cleaning these areas during brushing to avoid the growth of more bacteria. During the actual explanation, nursing workers should actively organize the children and complete the situational demonstration work through the use of tooth models. Additionally, based on the children's oral condition, a dental care plan should be developed, requiring a brushing time of no less than 3 minutes each time. After brushing teeth in the evening, dental floss should be used to remove residual substances from the interdental spaces, and it is generally required

to brush teeth 2–3 times a day to ensure a clean and fresh mouth.

(3) Optimizing dietary structure

To avoid teeth being eroded by external factors, nursing workers need to ensure the rationality of dietary planning based on the children's dietary preferences. In terms of choosing food properties, it is recommended to reduce the intake of hard foods as much as possible, reduce the frequency of using affected teeth during chewing, and also reduce the degree of wear and tear to avoid problems such as tooth splitting. Additionally, the intake of high-sugar foods should be controlled, especially watermelons, milk candies, and fruit candies, and it is required to rinse the mouth immediately after eating to better wash away the sugar attached to the tooth surface. More foods rich in crude fiber can be consumed, and fruits and yogurt are not allowed before bedtime. Foods rich in protein and vitamins can also be consumed to enhance children's immunity and resistance.

## 2.3. Evaluation indicators

- (1) Evaluate the caries rate, treatment compliance, and new caries rate among children of different age groups.
- (2) Compare the changes in SESS indicator scores between the two groups.

## 2.4. Statistical analysis

Data processing: SPSS 21.0 statistical software; Data description: Count data is expressed as (n%), and measurement data is expressed as ( $\bar{x} \pm s$ ); Difference test: Count data uses  $\chi^2$ , and measurement data uses  $t$ ;  $P < 0.05$  is the basis for expressing statistical differences.

## 3. Results

### 3.1. Analysis of caries rates among children of different age groups

The ages of preschool children with dental caries are 3, 4, 5, and 6 years old. The difference in caries rates among different age groups is statistically significant ( $P < 0.05$ ). The lowest caries rate is at 3 years old, and the highest is at 6 years old. There is a positive correlation between the caries rate and age growth (Table 1).

**Table 1.** Study on the caries rate of preschool children with dental caries (n/%)

Age	n	Dental caries rate
3 years old	16	5(31.25)
4 years old	30	16(53.33)
5 years old	32	18(56.25)
6 years old	36	24(66.67)

### 3.2. Comparison of treatment compliance between the observation group and the control group

The total compliance rate of the observation group was higher than that of the control group,  $P < 0.05$  (Table 2).

**Table 2.** Comparison of treatment compliance between the two groups of children (n/%)

Group	n	Complete compliance	Partial compliance	Non-compliance	Total compliance rate
Observation Group	57	28(49.12)	28(49.12)	1(1.75)	56(98.25)
Control Group	57	22(38.60)	27(47.37)	8(14.04)	49(85.96)
X <sup>2</sup>					5.9111
P					0.0150

### 3.3. Study on the incidence of new dental caries in two groups of children

The incidence of new dental caries in the observation group was lower than that in the control group,  $P < 0.05$  (Table 3).

**Table 3.** Analysis of the incidence of new dental caries in the observation group and the control group (n/%)

Group	n	New dental caries rate
Observation Group	57	2(3.51)
Control Group	57	9(15.79)
X <sup>2</sup>		4.9303
P		0.0263

### 3.4. Comparison of SESS scores before and after intervention between the observation group and the control group

Before the intervention, there was no significant difference in the scores of each index between the groups, i.e.,  $P > 0.05$ . After the intervention, the relevant indicators of the observation group were compared with the control group,  $P < 0.05$  (Table 4).

**Table 4.** Comparison of changes in SESS scores between the two groups of children( $\bar{x} \pm s$ )

Group	n	SE-B score (points)		SE-DC score (points)	
		Before intervention	After intervention	Before intervention	After intervention
Observation group	57	17.48 $\pm$ 1.22	24.43 $\pm$ 1.18	15.89 $\pm$ 1.42	23.32 $\pm$ 1.33
Control group	57	17.51 $\pm$ 1.25	19.70 $\pm$ 1.42	15.86 $\pm$ 1.45	19.78 $\pm$ 1.29
T value		0.1297	19.3418	0.1116	14.4246
P value		0.8971	0.0000	0.9113	0.0000

Group	n	SE-DH score (points)		SESS total score (points)	
		Before intervention	After intervention	Before intervention	After intervention
Observation group	57	17.02 $\pm$ 1.13	24.42 $\pm$ 1.42	50.27 $\pm$ 1.42	68.85 $\pm$ 1.21
Control group	57	17.05 $\pm$ 1.11	20.08 $\pm$ 1.12	50.23 $\pm$ 1.46	59.98 $\pm$ 1.52
T value		0.1430	18.1176	0.1483	34.4692
P value		0.8866	0.0000	0.8824	0.0000

## 4. Discussion

In recent years, based on the accelerated pace of modern social and economic development, medical diagnosis and treatment technology, as well as information technology, have achieved ideal development results. More knowledge about medical professionals has been popularized to social production and life, which has greatly helped improve people's material quality of life, but it has also changed people's dietary structure<sup>[4]</sup>. Dental caries is currently a common oral disease with a high incidence in pediatrics. If treatment intervention is not timely, children will suffer from toothache for a long time, making it difficult to fully chew food. This not only affects digestion and absorption but also indirectly restricts children's growth and development. It can even cause many complications, seriously affecting their physical health<sup>[5]</sup>. Root canal filling and restoration surgery is an effective method for treating dental caries. After cleaning and removing the decayed tissue, it can better restore the function and shape of the affected tooth, so that the decayed area of the tooth will not expand, and the symptoms will be significantly improved<sup>[6]</sup>. However, the recovery effect after treatment is still difficult to match the expected standard. The reason is that children and their families lack systematic oral self-care knowledge, and their health awareness is weak. The impact of dental caries on oral aesthetics can even increase the psychological pressure on children<sup>[7]</sup>. Therefore, it is necessary to implement necessary nursing intervention for children with dental caries<sup>[8]</sup>.

In the study, preschool children (aged 3–6) with dental caries were selected as the main subjects. Based on the analysis of caries rates among different age groups, it was found that the older the children were, the higher their caries rates were. The specific reason for this is that as children grow older, their dental arches expand and form physiological gaps, which cause the contact points between teeth to disappear, increasing the possibility of food impaction and making it easier for plaque to form<sup>[9]</sup>. The total compliance rate of the observation group was higher than that of the control group, while the incidence of new caries was lower than that of the control group ( $P < 0.05$ ). This confirms that behavioral interventions implemented through information and communication technologies such as the internet can enable children and their families to gain a deeper understanding and mastery of disease-related knowledge, oral self-care practices, and other relevant information, thereby enhancing their awareness of the disease<sup>[10]</sup>. Additionally, to ensure that children and their families pay more attention to oral hygiene and healthcare, various forms such as pictures, videos, and animations are used to showcase disease-related knowledge and self-care essentials to children. This helps attract their attention, stimulates their interest in learning, further enhances their level of self-care awareness, and encourages them to actively cooperate with clinical treatment<sup>[11]</sup>. Based on the actual conditions of the children, nursing workers develop oral hygiene plans to provide necessary assistance to the children and help them develop good oral hygiene habits, which positively impacts the maintenance of affected teeth and significantly reduces the incidence of new caries<sup>[12]</sup>. Compared to the control group, the SESS scores of the observation group were significantly different ( $P < 0.05$ ). This indicates that during the development of dietary plans, nursing staff comprehensively considered the causes of caries and prevention measures to ensure that children receive balanced nutrition while minimizing incorrect dietary behaviors that could corrode affected teeth<sup>[13, 14]</sup>.

## 5. Conclusion

Overall, for preschool children with dental caries, the caries rate increases with age. To effectively reduce the incidence of new caries, behavioral interventions should be actively implemented to encourage children's active cooperation in treatment. By enhancing their oral self-efficacy levels, the goal of reducing caries incidence can be achieved.

## Disclosure statement

The author declares no conflict of interest.

## References

- [1] Ding H, Xue L, Xue Q, 2023, Analysis of Caries Activity, Caries Rate, and Mean Caries Index Among 698 Preschool Children in Xinwu District of Wuxi City. *Shandong Medical Journal*, 63(6): 64–66.
- [2] Zhou R, Yang M, Ding Q, et al., 2024, Analysis of the Survey Results of Dental Fluorosis and Caries Among Children in Endemic Fluorosis Areas of Drinking Water in Shaanxi Province in 2023. *Journal of Environment and Health*, 41(9): 783–787.
- [3] Liu Y, Hou X, 2024, Study on the Correlation Between Gingival Crevicular Fluid IL6, TNF $\alpha$ , MCP1 and CAT Grading in Preschool Children With Caries, and Their Predictive Value for Chronic Apical Periodontitis. *Clinical Misdiagnosis & Mistherapy*, 37(2): 94–99.
- [4] Chen L, 2024, The Influence of Psychological Induction and Interactive Behavioral Intervention on the Treatment Effect and Cooperation Degree of Deciduous Tooth Caries in Children. *Maternal and Child Health Care of China*, 39(17): 3335–3338.
- [5] Xue W, Yang Y, Bao Z, et al., 2024, Investigation and Analysis of the Incidence of Caries Among Children Aged 3 to 6 in Wuhan and Parents' Intervention Measures for Children's Caries. *Maternal and Child Health Care of China*, 2024(10): 1840–1843.
- [6] Liu Y, Song P, 2023, Analysis of Influencing Factors of Recurrence After Treatment of Caries in Children Aged 3–10 and the Predictive Value of a Simple Scoring Tool for Recurrence. *Clinical Misdiagnosis and Mistherapy*, 36(2): 103–107.
- [7] Wang Y, Li S, Liu B, et al., 2023, Economic Evaluation of the Comprehensive Oral Health Intervention Project for Preventing Caries of the First Permanent Molars in Children in Harbin. *Chinese Health Economics*, 42(7): 13–16.
- [8] Jiang Y, 2023, Investigation of Caries Status and Evaluation of Caries Classification Management Effect Among Preschool Children in Shunqing District, Nanchong City, thesis, North Sichuan Medical College, 2023.
- [9] Zhang J, Wang Y, 2023, Meta-Analysis of Caries Prevalence and Filling Rate Among Preschool Children in China. *Journal of West China School of Stomatology*, 41(5): 573–581.
- [10] Long L, Tao R, 2023, Application Effect of Psychological Induction Combined With Behavioral Nursing Intervention in the Treatment of Caries in Preschool Children. *Medical Aesthetics and Cosmetology*, 32(22): 157–160.
- [11] Yan J, Xi R, 2024, The Influence of Childlike Induced Nursing Intervention on the Psychology and Behavior of Preschool Children During Caries Treatment. *Modern Nurses (Mid-Month Magazine)*, 31(3): 86–89.
- [12] Zhai L, Yao N, Kong J, et al., 2024, Latent Class and Heterogeneous Correlation Analysis of Oral Health Behaviors Related to Caries in Preschool Children. *Shanghai Journal of Stomatology*, 33(4): 415–420.
- [13] Chen N, Zhai L, Zhao Y, 2023, Correlation Analysis Between Deciduous Tooth Caries in Preschool Children and Parents' Cognition of Oral Hygiene. *Nursing of Integrated Traditional Chinese and Western Medicine (Chinese and English)*, 9(1): 133–135.
- [14] Ding Z, 2023, Analysis of Oral Health Status of Preschool Children in Shaoxing City and Their Parents' Cognition of Oral Health Knowledge, Attitudes, and Behaviors. *Chinese Journal of Public Health Management*, 2023(5): 703–705.

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# Effects of Nebulized $\alpha$ -Interferon on Immune Function in Elderly Patients with Respiratory Tract Infection

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**Abstract:** *Objective:* To investigate the effects of nebulized  $\alpha$ -interferon on immune function in elderly patients with respiratory tract infection. *Methods:* A total of 120 elderly patients with respiratory tract infection admitted to our hospital from June 2023 to June 2024 were selected and randomly divided into an observation group ( $n=60$ ) and a control group ( $n=60$ ) using the envelope method. The control group received conventional treatment, while the observation group received additional nebulized  $\alpha$ -interferon therapy based on conventional treatment. After the same treatment period, changes in immune function indicators (immunoglobulins IgG, IgA, IgM) were compared between the two groups. Patients were also followed up for 3 months to observe the frequency of respiratory tract infection recurrences. *Results:* After treatment, IgA and IgM levels decreased significantly, while IgG levels increased significantly in both groups. The improvement in each indicator was more pronounced in the observation group than in the control group ( $P < 0.05$ ). By the end of the follow-up period, all 120 patients had successfully completed the follow-up, and no patients were lost to follow-up. The frequency of respiratory tract infection recurrences was lower in the observation group than in the control group ( $P < 0.05$ ). *Conclusion:* Nebulized  $\alpha$ -interferon can improve immune function and reduce the frequency of recurrences in elderly patients with respiratory tract infection.

**Keywords:** Respiratory tract infection; Elderly patients;  $\alpha$ -Interferon; Immune function

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## 1. Introduction

Respiratory tract infection is one of the most common infectious diseases among the elderly population, with its incidence and mortality rates increasing significantly with age. Epidemiological data show that the incidence of respiratory tract infection among the elderly is approximately 10–20% per year, with a high proportion of severe infections and recurrent episodes. This phenomenon is closely related to the decline in immune function among the elderly, characterized by immune senescence features such as thymic atrophy, decreased T-cell function, and reduced B-cell antibody production, leading to a weakened ability to clear pathogens<sup>[1,2]</sup>. Additionally, the elderly

often have comorbid chronic diseases, further increasing their susceptibility to respiratory tract infections and the difficulty of treatment. Currently, clinical treatment for respiratory tract infections in the elderly mainly focuses on antibiotics and symptomatic support. Although antibiotics can effectively control bacterial infections, their efficacy against viral infections is limited, and long-term use can induce drug resistance. Symptomatic treatment can alleviate symptoms but does not improve immune function or prevent recurrences [3].

Therefore, exploring therapeutic approaches that can enhance immune function and reduce the risk of recurrence has become a focus of clinical research.  $\alpha$ -Interferon, as a broad-spectrum antiviral cytokine, exerts its therapeutic effects by inhibiting viral replication and activating immune cells [4]. However, traditional systemic administration routes may be associated with side effects such as fever and fatigue, limiting their use in elderly patients. Nebulization, as a local administration route, can directly target the respiratory mucosa, increasing drug concentration and reducing systemic adverse reactions, thus providing a new approach for the treatment of respiratory tract infections in the elderly. This study aims to investigate the effects of nebulized  $\alpha$ -interferon on immune function and infection recurrence in elderly patients, aiming to provide evidence for optimizing clinical treatment regimens.

## 2. Materials and methods

### 2.1. General information

A total of 120 elderly patients with respiratory infections treated in the hospital from June 2023 to June 2024 are selected and randomly divided into an observation group ( $n=60$ ) and a control group ( $n=60$ ) using the envelope method. There was no statistically significant difference in basic data between the two groups ( $P > 0.05$ ), as shown in **Table 1**. This study is approved by the hospital ethics committee and complies with the relevant ethical principles of the Declaration of Helsinki.

**Table 1.** Comparison of general information between the two groups (/n)

General information	Observation group( $n=60$ )	Control group( $n=60$ )	$t/x^2$	$P$
Male/Female	39/21	41/19	0.150	0.699
Age (years)	61–89	63–87	0.041	0.967
	79.11 $\pm$ 3.87	79.08 $\pm$ 4.11		
Disease duration (d)	5–19	5–22	0.260	0.795
	16.42 $\pm$ 2.44	16.53 $\pm$ 2.19		

### 2.2. Inclusion and exclusion criteria

The inclusion criteria of the study are: (1) Age  $\geq 60$  years; (2) Clinically diagnosed with respiratory infection and presenting clear symptoms of respiratory infection; (3) Disease duration not exceeding 1 month; (4) Able to cooperate and complete the detection of immune function indicators; (5) Able to ensure compliance during the study and follow-up periods, completing various examinations and follow-ups on time; (6) Patients or their families signed informed consent and voluntarily participated in this study.

The exclusion criteria includes: (1) Suffering from malignant tumors, autoimmune diseases, etc.; (2) Allergic to  $\alpha$ -interferon; (3) Unable to complete follow-up during the study period; (4) Presence of severe respiratory failure, heart failure, and other complications; (5) Recent use of immunosuppressants or immunomodulators; (6)

Presence of cognitive impairment or mental illness affecting informed consent or study compliance; (7) Pregnant or breastfeeding women; (8) Comorbid with other severe infectious diseases such as AIDS and tuberculosis.

## 2.3. Methods

The control group received conventional treatment, including the selection of appropriate antibiotics based on the type of pathogen. For bacterial infections, broad-spectrum antibiotics are usually chosen, and their use is individualized based on the severity of the patient's condition, the site of infection, and the sensitivity of the pathogen. Symptomatic supportive treatment, including antipyretics, antitussives, and expectorants, is also provided.

The observation group received  $\alpha$ -interferon nebulization therapy based on conventional treatment. Patients in the observation group are treated with a dedicated nebulizer using  $\alpha$ -interferon. The dose of  $\alpha$ -interferon is 1 million units per time, twice a day for 14 consecutive days.

## 2.4. Observation indicators

### 2.4.1. Immune function

The serum immunoglobulins (IgG, IgA, IgM) of the two groups are observed and compared before and after treatment. Immunoglobulins are measured using the immunoturbidimetric method. A total of 5 mL of fasting venous blood is collected from patients in the morning, placed in a coagulation-promoting tube, centrifuged at 3000 r/min for 10 minutes to separate the serum, and then quantitatively analyzed using an automatic biochemical analyzer (model: AU5800) strictly following the instructions of the kit (purchased from Shanghai Kehua Biotech Co., Ltd.).

### 2.4.2. Number of respiratory infection recurrences

The number of respiratory infection recurrences in the two groups is observed and compared. Recurrences are recorded through outpatient visits or telephone follow-ups. The follow-up period is 3 months after treatment, and recurrences are confirmed based on patients' complaints combined with clinical examinations.

## 2.5. Statistical methods

Statistical analysis is performed using SPSS 21.0 software package in the hospital. Measurement data are expressed as  $(\bar{x} \pm s)$ , which followed a normal distribution. The t-test is used for comparisons between groups. Count data are expressed as relative numbers, and the chi-square test ( $\chi^2$  test) is used for comparisons between groups. The rank sum test is used to compare clinical efficacy. A  $P$ -value  $< 0.05$  was considered statistically significant.

## 3. Results

### 3.1. Comparison of immune function levels between the two groups

Before treatment, there was no significant difference in immune function levels between the two groups ( $P > 0.05$ ). After treatment, the levels of IgA and IgM decreased significantly, while the level of IgG increased significantly in both groups. Moreover, the improvement in each index level in the observation group was better than that in the control group ( $P < 0.05$ ). The results are shown in **Table 2**.

**Table 2.** Comparison of immune function levels before and after treatment between the two groups ( $\bar{x} \pm s$ , g/L)

Group	Number of cases(n)	IgG		IgA		IgM	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Observation group	60	7.26 $\pm$ 1.09	13.44 $\pm$ 1.26*	3.84 $\pm$ 0.69	1.19 $\pm$ 0.41*	2.19 $\pm$ 0.71	1.31 $\pm$ 0.36*
Control group	60	7.19 $\pm$ 1.14	10.46 $\pm$ 1.08*	3.77 $\pm$ 0.76	1.47 $\pm$ 0.64*	2.26 $\pm$ 0.79	1.84 $\pm$ 0.41*
<i>t</i>	-	0.344	13.909	0.368	2.854	0.510	7.524
<i>P</i>	-	0.732	< 0.001	0.713	0.005	0.611	< 0.001

\*Note: Compared with the same group before treatment, \* $P < 0.05$

### 3.2. Comparison of respiratory infection recurrence between the two groups

By the end of the last follow-up, all 120 patients had successfully completed the follow-up, and no one was lost to follow-up. The number of respiratory infection recurrences in the observation group was lower than that in the control group ( $P < 0.05$ ), as seen in **Table 3**.

**Table 3.** Comparison of the recurrence times of respiratory tract infection between the two groups ( $\bar{x} \pm s$ )

Group	Number of cases(n)	Number of recurrences of respiratory tract infection	
Observation group	60	0–2	0.63 $\pm$ 0.19
Control group	60	0–5	1.44 $\pm$ 0.36
<i>t</i>	-	-	15.413
<i>P</i>	-	-	< 0.001

## 4. Discussion

The high incidence of respiratory infections in the elderly population is associated with multiple factors. Firstly, immunosenescence leads to a decline in both innate and adaptive immune responses, manifested by reduced neutrophil chemotaxis, decreased natural killer cell activity, and delayed antibody production. Secondly, the degradation of respiratory mucosal barrier function and reduced secretory IgA make it easier for pathogens to adhere to and invade the submucosal layer. Additionally, elderly patients often suffer from chronic diseases (such as COPD and heart failure), which not only exacerbate local inflammatory responses but also further inhibit immune function through systemic metabolic disorders [5]. In terms of pathological mechanisms, pathogens damage the mucosal epithelium, triggering an excessive inflammatory response that elevates inflammatory factors such as IL-6 and TNF- $\alpha$ , ultimately exacerbating tissue damage [6]. If the infection is not controlled in a timely manner, chronic inflammation may induce complications such as pulmonary fibrosis and bronchiectasis, forming a vicious cycle.

In this study, the control group received conventional treatment with antibiotics combined with symptomatic therapy. Antibiotics can specifically kill bacteria, but they are ineffective against viral infections. Respiratory infections in elderly patients are often caused by viruses or mixed infections, limiting the effectiveness of monotherapy with antibiotics. Furthermore, long-term use of broad-spectrum antibiotics can disrupt the balance

of respiratory flora, increasing the risk of secondary infections. Symptomatic treatments (such as antipyretics and expectorants) can provide short-term relief of symptoms, but they cannot reverse immune defects or repair mucosal barriers. More importantly, conventional treatment lacks interventions targeting immune regulation, leading to persistent immune dysfunction in some patients despite resolution of acute infection. This immune dysfunction becomes an important predisposing factor for recurrence<sup>[7]</sup>.

The application of  $\alpha$ -interferon nebulization is based on its dual mechanism of action: direct antiviral activity by activating the JAK-STAT signaling pathway to inhibit viral RNA replication, and immune modulation by stimulating the activity of macrophages, NK cells, and promoting the production of neutralizing antibodies such as IgG<sup>[8]</sup>. Nebulization allows the drug to be directly distributed to the respiratory mucosa, forming a high concentration locally, rapidly inhibiting viral proliferation while avoiding side effects caused by systemic administration. In this study, the significant increase in IgG levels in the observation group may be related to the enhancement of B cell differentiation into plasma cells and the promotion of antibody synthesis by  $\alpha$ -interferon. The decrease in IgA and IgM levels suggests a weakening of the acute phase response and a trend towards inflammation resolution after infection control<sup>[9]</sup>. Additionally, the strengthening effect of  $\alpha$ -interferon on mucosal immunity may not be fully reflected by serum detection and requires further validation through respiratory secretion analysis.

This study confirms that nebulized  $\alpha$ -interferon can improve humoral immune function in elderly patients and reduce the recurrence rate of infections. This result has important implications for clinical practice. Firstly, this therapy provides a specific intervention for viral respiratory infections, complementing the limitations of antibiotic treatment. Secondly, by enhancing local immunity, it may reduce the occurrence of severe infections and complications. Finally, the convenience and safety of nebulization make it particularly suitable for elderly patients with multiple comorbidities. Future research should further explore the optimal dosage, duration of treatment, and differences in efficacy against different pathogens of  $\alpha$ -interferon, as well as evaluate its long-term effects on mucosal and cellular immunity<sup>[10]</sup>. In addition, combining  $\alpha$ -interferon with other immunomodulators or anti-inflammatory drugs may produce synergistic effects, which deserves further investigation.

## 5. Conclusion

In summary, nebulized  $\alpha$ -interferon can significantly improve immune function and reduce the recurrence of respiratory infections in elderly patients. This result provides new ideas and methods for clinical treatment, potentially improving the prognosis of elderly patients with respiratory infections.

## Disclosure statement

The author declares no conflict of interest.

## References

- [1] Yan C, Shan H, Pei X, et al., 2022, Analysis of the Efficacy and Safety of Shufeng Jiedu Capsule Combined With  $\alpha$ -Interferon and Abidol in the Treatment of Common Type Coronavirus Disease 2019. *Journal of Guangzhou University of Chinese Medicine*, 39(3): 475–480.
- [2] Liu Y, 2021, Effect of Abidol Combined With  $\alpha$ -Interferon Atomization Inhalation in the Treatment of COVID-19

and Its Influence on Nucleic Acid and IgM Antibody Negative Conversion Rate. *The Journal of Medical Theory and Practice*, 34(9): 1499–1501.

- [3] Tian C, Xiang M, 2020, Feasibility Analysis of Remdesivir Combined With  $\alpha$ -Interferon in the Treatment of Coronavirus Disease 2019. *Herald of Medicine*, 39(4): 477–482.
- [4] Yu S, Zhang Y, Wang N, et al., 2024, Study on the Etiological Characteristics of Lower Respiratory Tract Infection in Elderly Patients With AECOPD and Its Relationship With Inflammatory Immune Balance. *Progress in Modern Biomedicine*, 24(14): 2650–2655+2671.
- [5] Klouda T, Hao Y, Kim H, et al., 2022, Interferon-Alpha or -Beta Facilitates SARS-CoV-2 Pulmonary Vascular Infection by Inducing ACE2. *Angiogenesis*, 25(2): 225–240.
- [6] Zhao C, Li R, Huang H, 2021, Clinical Study on the Efficacy and Safety of Moxifloxacin Combined With Pidotimod in the Treatment of Respiratory Infections in the Elderly. *Chinese and Foreign Medical Research*, 40(14): 83–86.
- [7] Hadjadj J, Yatim N, Barnabei L, et al., 2020, Impaired Type I Interferon Activity and Inflammatory Responses in Severe COVID-19 Patients. *Science*, 369(6504): 718–724.
- [8] Kong Y, Wang X, Li X, et al., 2019, Evaluation of the Efficacy and Cellular Immune Indicators of Moxifloxacin Combined With Pidotimod in the Treatment of Respiratory Infections in Elderly Patients. *Chinese Journal of Clinical Healthcare*, 22(6): 814–817.
- [9] Yang L, Wang J, Hui P, et al., 2021, Potential Role of IFN- $\alpha$  in COVID-19 Patients and Its Underlying Treatment Options. *Applied Microbiology and Biotechnology*, 105(10): 4005–4015.
- [10] Yin H, Liu H, 2019, Observation of Tanreqing Application and Evaluation of Cellular Immune Indicators in Elderly Patients With Respiratory Tract Infection. *Journal of Clinical Medical Literature (Electronic Edition)*, 6(18): 161.

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# Effects of Acupoint Catgut Embedding Combined with Auricular Point Pressing with Beans on Self-Efficacy of Symptom Management and Quality of Life of Patients with Nonalcoholic Steatohepatitis of Liver Depression and Spleen Deficiency Type

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**Abstract:** *Objective:* To explore the effects of acupoint catgut embedding combined with auricular point pressing with beans on symptom management self-efficacy and quality of life in patients with nonalcoholic steatohepatitis (NASH) of liver depression and spleen deficiency type. *Methods:* Sixty patients with NASH of liver depression and spleen deficiency type admitted to our hospital from January 2021 to December 2023 were selected and divided into an acupoint catgut embedding group ( $n=30$ ) and a combined group ( $n=30$ ) using the envelope lottery method. The acupoint catgut embedding group received acupoint catgut embedding intervention, while the combined group received auricular point pressing with beans on the basis of the acupoint catgut embedding group. The two groups were compared in terms of TCM syndrome scores, symptom management self-efficacy [Chronic Disease Self-Efficacy Scale (CDSSES)], and quality of life [Chronic Liver Disease Questionnaire (CLDQ)]. *Results:* After intervention, the combined group had lower TCM syndrome scores for both primary and secondary symptoms compared to the acupoint catgut embedding group ( $P < 0.05$ ). The combined group also had higher scores in all dimensions and total score of the CDSSES compared to the acupoint catgut embedding group ( $P < 0.05$ ). Similarly, the combined group had higher scores in all dimensions and total score of the CLDQ compared to the acupoint catgut embedding group ( $P < 0.05$ ). *Conclusion:* Acupoint catgut embedding combined with auricular point pressing with beans can effectively improve TCM symptoms, enhance symptom management self-efficacy, and improve quality of life in patients with NASH of liver depression and spleen deficiency type.

**Keywords:** Nonalcoholic steatohepatitis; Liver depression and spleen deficiency; Acupoint catgut embedding; Auricular point pressing with beans; Symptom management; Self-efficacy; Quality of life

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# 1. Introduction

Nonalcoholic steatohepatitis (NASH) is a metabolic disorder primarily characterized by fatty degeneration of liver parenchymal cells, with a higher incidence among obese populations <sup>[1]</sup>. In traditional Chinese medicine (TCM), NASH is categorized as “liver addiction,” “fullness,” and “hypochondriac pain,” with pathogenesis including liver Qi stagnation, spleen dysfunction, Qi and blood stagnation, and liver blood stasis. The phrase “all diseases arise from Qi” and the emotions’ effects on organs (anger hurts the liver, joy hurts the heart, excessive thinking hurts the spleen, grief hurts the lungs, and fear hurts the kidneys) suggest that NASH is associated with negative emotions such as irritability and anxiety <sup>[2]</sup>. Therapeutic interventions can focus on dredging meridians, soothing the liver and relieving depression, and promoting Qi and blood circulation. Acupoint catgut embedding is an extension and development of acupuncture therapy. It stimulates meridians at specific acupoints using needles and medicinal threads to harmonize Qi and blood and balance Yin and Yang. This therapy offers advantages such as painlessness, long-lasting effects, relaxing muscles and dredging meridians, and strengthening the body’s resistance to eliminate pathogens <sup>[3]</sup>. Auricular point pressing with beans is a TCM therapy that involves applying appropriate pressure, such as pressing, pinching, rubbing, and massaging, to auricular acupoints with seeds of *Vaccaria segetalis* or other seeds attached using adhesive tape. This therapy can connect meridians and promote Qi and blood perfusion. Currently, it has been applied to intervene in diseases such as diabetes and insomnia, with promising results <sup>[4]</sup>. However, there are still limited reports on whether this therapy can be used as an adjuvant intervention for NASH. This study explores the effects of acupoint catgut embedding combined with auricular point pressing with beans on symptom management, self-efficacy, and quality of life in patients with NASH of liver depression and spleen deficiency type.

## 2. Objects and methods

### 2.1. Study objects

Sixty patients with NASH of liver depression and spleen deficiency type admitted to the hospital from January 2021 to December 2023 are selected. According to the “Expert Consensus on the Diagnosis and Treatment of Nonalcoholic Fatty Liver Disease with Traditional Chinese Medicine (2017),” the primary symptoms associated with liver depression and spleen deficiency include fullness or wandering pain in the right hypochondrium, often induced by emotional distress such as irritability or anger, dull pain in the liver region, and abdominal distension <sup>[5]</sup>. Secondary symptoms include abdominal distension, fatigue, chest tightness, loose stools, abdominal pain with a desire to defecate, and frequent sighing. Tongue and pulse manifestations typical of liver depression and spleen deficiency include a pale tongue with tooth marks on the edges, a thin white or greasy tongue coating, and a taut or taut and thin pulse. For Western medicine, diagnostic criteria refer to the Guidelines for the Prevention and Treatment of Nonalcoholic Fatty Liver Disease (2018 Updated Edition). Inclusion criteria were as follows: meeting both the TCM and Western medicine diagnostic standards; liver-to-spleen CT attenuation ratio  $\leq 1$ ; no history of alcohol consumption or alcohol intake less than 140 g per week for males and less than 70 g per week for females; histopathological confirmation of diagnosis; and provision of informed consent. Exclusion criteria included patients with viral or drug-induced hepatitis, those receiving total parenteral nutrition, individuals with hepatolenticular degeneration, pregnant or breastfeeding women, and those with inflammatory skin diseases, diabetes, or other conditions affecting subcutaneous tissue absorption and repair, rendering catgut embedding inappropriate.

## 2.2. Methods

The acupoint catgut embedding group received acupoint catgut embedding intervention. The selected acupoints included Tianshu (ST25), Zhongwan (CV12), Fenglong (ST40), Qihai (CV6), Ganshu (BL18), Taichong (LR3), Zusanli (ST36), and Sanyinjiao (SP6). Specific intervention steps: routinely disinfect the acupoints with 75% alcohol, evaluate the thickness of the acupoints, select a 2cm sheep intestine thread, insert the thread into the acupoints using a disposable 7-gauge catgut embedding needle, slowly withdraw the needle after embedding into the corresponding acupoints, and disinfect the surrounding skin. If accompanied by diarrhea, add Juxu (ST37). If accompanied by rib distension, add Taichong (LR3). Catgut embedding frequency is once per week for a total of 12 weeks.

The combined group received auricular point pressing with beans based on the acupoint catgut embedding group. Selected auricular acupoints included Shenmen, Liver, Gallbladder, Stomach, Spleen, Kidney, Endocrine, and Large Intestine. *Vaccaria segetalis* seeds are attached to the corresponding auricular acupoints, pressed in a spiral manner until the patients felt sourness, distension, numbness, or slight pain accompanied by a sensation of Qi. Each pressing session lasted 2–5 minutes. The *Vaccaria segetalis* seeds are replaced every 2 days, with interventions performed 3 times per week for a total of 6 weeks.

## 2.3. Observation indicators

### (1) Scores of traditional Chinese medicine (TCM) syndromes

Referring to the relevant standards in the expert consensus on the diagnosis and treatment of nonalcoholic fatty liver disease with TCM, the scores of TCM syndromes for NASH patients in the two groups are evaluated before and after 12 weeks of intervention<sup>[5]</sup>. The primary symptoms included distension and pain in the right hypochondrium, while the secondary symptoms included loose stools, fatigue, and thin or greasy tongue coating. Scoring principles are conducted according to normal, mild, moderate, and severe levels. the primary symptoms are scored as 0, 2, 4, and 6 points, respectively, and the secondary symptoms are scored as 0, 1, 2, and 3 points, respectively.

### (2) Self-efficacy in symptom management

The Chronic Disease Self-Efficacy Scale (CDESES) is used to evaluate the self-efficacy in symptom management of NASH patients in the two groups before and after 12 weeks of intervention<sup>[7]</sup>. The evaluation mainly focused on six items which are: medication compliance, self-care, emotional control, reasonable rest, management of health problems, and pain and discomfort control. Each item could be scored from 0 to 10, and the score was directly proportional to self-efficacy, meaning that a lower score indicated poorer self-efficacy.

### (3) Quality of life

The Chronic Liver Disease Questionnaire (CLDQ) is used to assess the quality of life of NASH patients in the two groups before and after 12 weeks of intervention<sup>[8]</sup>. The CLDQ is a specialized scale for quantifying the stages of liver disease, specifically evaluating six items: abdominal symptoms, fatigue, systemic symptoms, activity, emotions, and anxiety, with a total of 29 entries. The score for each evaluation item is inversely proportional to severity and directly proportional to quality of life.

## 2.4. Statistical methods

The study used SPSS 25.0 to analyze the data. Normally distributed measurement data are expressed as  $(\bar{x} \pm s)$ ,

and independent sample t-tests are used for intergroup difference analysis. Count data are expressed as [number (%)], and chi-square tests were used for difference analysis. A  $P$ -value  $< 0.05$  is considered statistically significant.

### 3. Results

#### 3.1. Comparison of general information between the two groups

There were no significant differences in general information between the two groups, indicating comparability ( $P > 0.05$ ), as shown in **Table 1**.

**Table 1.** Comparison of general information between the two groups [cases (%),  $\bar{x} \pm s$ ]

Group	Number of cases	Age (years)	Gender (cases)		Duration of illness (years)	BMI (kg/m <sup>2</sup> )	Classification of fatty liver disease		
			Male	Female			Mild	Moderate	Severe
Combined group	30	44.62 $\pm$ 5.73	21 (70.00)	9 (30.00)	3.40 $\pm$ 0.81	26.60 $\pm$ 2.89	11 (36.67)	17 (56.67)	2 (6.67)
Acupoint catgut Embedding group	30	43.98 $\pm$ 6.03	22 (73.33)	8 (26.67)	3.55 $\pm$ 0.93	26.67 $\pm$ 2.73	13 (43.33)	15 (50.00)	2 (6.67)
$t/c^2$		0.421		0.082	0.666	0.096		0.292	
$P$		0.675		0.774	0.508	0.924		0.864	

\*BMI: Body Mass Index

#### 3.2. Comparison of TCM syndrome scores between the two groups

The TCM syndrome scores of the combined group after intervention were lower than those of the acupoint catgut embedding group ( $P < 0.05$ ), as shown in **Table 2**.

**Table 2.** Comparison of TCM syndrome scores before and after intervention between the two groups (scores,  $\bar{x} \pm s$ )

Group	Number of cases	Right hypochondriac distension		Wandering pain		Loose stool	
		Before intervention	After 12 weeks of intervention	Before intervention	After 12 weeks of intervention	Before intervention	After 12 weeks of intervention
Combined group	30	3.93 $\pm$ 0.61	1.88 $\pm$ 0.46*	3.34 $\pm$ 0.57	1.36 $\pm$ 0.39*	2.28 $\pm$ 0.31	1.05 $\pm$ 0.26*
Acupoint catgut embedding group	30	3.89 $\pm$ 0.58	2.37 $\pm$ 0.50*	3.32 $\pm$ 0.59	2.05 $\pm$ 0.43*	2.24 $\pm$ 0.29	1.53 $\pm$ 0.32*
$t$		0.260	3.950	0.134	6.510	0.516	6.376
$P$		0.796	$< 0.001$	0.894	$< 0.001$	0.608	$< 0.001$

Group	Number of cases	Fatigue		Thin white or greasy tongue coating	
		Before intervention	After 12 weeks of intervention	Before intervention	After 12 weeks of intervention
Combined group	30	2.17 $\pm$ 0.32	0.98 $\pm$ 0.25*	2.09 $\pm$ 0.30	1.16 $\pm$ 0.22*
Acupoint catgut embedding group	30	2.13 $\pm$ 0.27	1.34 $\pm$ 0.28*	2.01 $\pm$ 0.26	1.41 $\pm$ 0.27*
$t$		0.523	5.253	1.104	3.932
$P$		0.603	$< 0.001$	0.274	$< 0.001$

\*Note: Compared with the acupoint catgut embedding group, \* $P < 0.05$ .

### 3.3. Comparison of self-efficacy between the two groups

The scores of each dimension and total score of CDESES in the combined group after intervention were higher than those in the acupoint catgut embedding group ( $P < 0.05$ ), as shown in **Table 3**.

**Table 3.** Comparison of CDESES scores before and after intervention between the two groups (scores,  $\bar{x} \pm s$ )

Group	Number of cases	Compliance with Medication		Self-care		Emotional control	
		Before intervention	After 12 weeks of intervention	Before intervention	After 12 weeks of intervention	Before intervention	After 12 weeks of intervention
Combined group	30	3.85 $\pm$ 0.54	5.97 $\pm$ 0.64*	3.67 $\pm$ 0.45	6.29 $\pm$ 0.66*	3.24 $\pm$ 0.70	5.89 $\pm$ 1.02*
Acupoint catgut embedding group	30	3.87 $\pm$ 0.59	5.16 $\pm$ 0.62*	3.75 $\pm$ 0.49	5.32 $\pm$ 0.60*	3.51 $\pm$ 0.68	5.05 $\pm$ 0.86*
<i>t</i>		0.137	4.979	0.659	5.956	1.515	3.448
<i>P</i>		0.892	< 0.001	0.513	< 0.001	0.135	0.001

Group	Number of cases	Reasonable rest		Managing health issues		Pain and discomfort control	
		Before intervention	After 12 weeks of intervention	Before intervention	After 12 weeks of intervention	Before intervention	After 12 weeks of intervention
Combined group	30	3.91 $\pm$ 0.71	7.82 $\pm$ 0.88*	4.03 $\pm$ 0.63	8.12 $\pm$ 0.7*8	3.01 $\pm$ 0.46	7.58 $\pm$ 0.75*
Acupoint catgut embedding group	30	3.96 $\pm$ 0.73	6.74 $\pm$ 0.79*	4.11 $\pm$ 0.60	7.09 $\pm$ 0.66*	3.13 $\pm$ 0.42	6.65 $\pm$ 0.69*
<i>t</i>		0.269	5.002	0.504	5.521	1.055	4.998
<i>P</i>		0.789	< 0.001	0.616	< 0.001	0.296	< 0.001

Group	Number of cases	Total score	
		Before intervention	After 12 weeks of intervention
Combined group	30	21.71 $\pm$ 6.72	41.67 $\pm$ 8.35*
Acupoint catgut embedding group	30	22.33 $\pm$ 6.48	36.01 $\pm$ 8.07*
<i>t</i>		0.364	2.670
<i>P</i>		0.717	0.010

\*Note: Compared with the acupoint catgut embedding group, \* $P < 0.05$ .

### 3.4. Comparison of quality of life between the two groups

The scores of each dimension and total score of CLDQ in the combined group after intervention were higher than those in the acupoint catgut embedding group ( $P < 0.05$ ), as shown in **Table 4**.

**Table 4.** Comparison of CLDQ scores before and after intervention between the two groups (scores,  $\bar{x} \pm s$ )

Group	Number of cases	Abdominal symptoms		Fatigue		Systemic symptoms	
		Before intervention	After 12 weeks of intervention	Before intervention	After 12 weeks of intervention	Before intervention	After 12 weeks of intervention
Combined group	30	3.14 ± 0.56	5.08 ± 0.61*	3.07 ± 0.55	4.62 ± 0.49*	2.88 ± 0.73	4.39 ± 0.58*
Acupoint catgut embedding group	30	3.17 ± 0.52	4.50 ± 0.57*	3.11 ± 0.43	4.20 ± 0.47*	2.94 ± 0.69	3.92 ± 0.61*
<i>t</i>		0.215	3.805	0.314	3.388	0.327	3.058
<i>P</i>		0.831	< 0.001	0.755	0.001	0.745	0.003

Group	Number of cases	Activity		Emotion		Anxiety	
		Before intervention	After 12 weeks of intervention	Before intervention	After 12 weeks of intervention	Before intervention	After 12 weeks of intervention
Combined group	30	3.82 ± 0.66	5.19 ± 0.52*	3.43 ± 0.50	5.57 ± 0.48*	2.99 ± 0.43	5.07 ± 0.54*
Acupoint catgut embedding group	30	3.85 ± 0.63	4.73 ± 0.58*	3.45 ± 0.53	5.05 ± 0.51*	3.06 ± 0.47	4.42 ± 0.49*
<i>t</i>		0.180	3.234	0.150	4.067	0.602	4.882
<i>P</i>		0.858	0.002	0.881	< 0.001	0.550	< 0.001

Group	Number of cases	Total score	
		Before intervention	After 12 weeks of intervention
Combined group	30	19.33 ± 3.15	29.92 ± 3.78*
Acupoint catgut embedding group	30	19.58 ± 3.23	26.82 ± 3.52*
<i>t</i>		0.304	3.287
<i>P</i>		0.763	0.002

\*Note: Compared with the acupoint catgut embedding group, \* $P < 0.05$ .

## 4. Discussion

Auricular point pressing with beans is a traditional Chinese medicine therapy based on the holographic theory of traditional Chinese medicine and modern anatomical knowledge. It works by stimulating positive response points on the auricle using small round objects, such as cowherb seeds, to unblock meridians and enhance the function of internal organs. It can exert effects such as promoting blood circulation to remove blood stasis, promoting Qi and blood circulation, clearing heat and detoxifying, and improving spleen and stomach weakness. It has advantages such as low cost, convenience and comfort, wide range of effects, and strong operability<sup>[9]</sup>. However, whether it can effectively intervene in NASH remains to be verified. Acupoint catgut embedding is a special acupuncture therapy that has been proven to promote the improvement of lipid metabolism disorders<sup>[10]</sup>. However, whether

acupoint catgut embedding combined with auricular point pressing with beans can further improve the symptoms of NASH patients and enhance patients' self-efficacy and quality of life in symptom management still needs to be further studied.

The research results showed that the scores of traditional Chinese medicine (TCM) syndromes such as right hypochondriac distension, loose stool, and fatigue were lower in the combined group after intervention compared to the acupoint catgut embedding group, indicating that acupoint catgut embedding combined with auricular point pressing with beans can effectively improve TCM symptoms in patients with NASH. The analysis of the reasons is as follows: The TCM pathogenesis of NASH is liver depression and spleen deficiency, with adverse emotions stagnating internally and Qi and blood congestion. Acupoint catgut embedding includes acupoints such as Tianshu, Ganshu, Taichong, and Sanyinjiao. Tianshu belongs to the Foot Yangming Stomach Meridian. Stimulating Tianshu can regulate the spleen and stomach, relax muscles, and activate meridians, effectively relieving "liver depression and spleen deficiency." Ganshu belongs to the Bladder Meridian of the Sun. Stimulating Ganshu can relieve liver depression, regulate liver and kidney, clear heat and disperse wind, and clear dampness and heat, which can be targeted at "hypochondriac distension."

Stimulating Taichong has the effects of soothing liver and regulating Qi, clearing heat and purging fire, and clearing liver and gallbladder, which can effectively improve the symptoms of "Qi and blood congestion." Sanyinjiao is the intersecting point of the liver, spleen, and kidney meridians. Stimulating Sanyinjiao can also improve "chest and hypochondriac fullness and pain." In auricular point pressing with beans, Wangbuliu seeds are the dry and mature seeds of *Vaccaria segetalis*, which belong to the liver and stomach meridians and have the effects of promoting blood circulation and dredging meridians, and facilitating blood circulation. Using Wangbuliu seeds to spirally press on the acupoints of liver, gallbladder, stomach, spleen, kidney, endocrine, and large intestine on the auricle is beneficial for activating meridians and promoting the improvement of TCM symptoms in patients with NASH.

The results also showed that the scores of each dimension and the total score of CDESES in the combined group were higher than those in the acupoint catgut embedding group after intervention, suggesting that acupoint catgut embedding combined with auricular point pressing with beans can effectively improve the self-efficacy of symptom management in patients with NASH. The long-term accumulation of adverse emotions causes poor circulation of Qi and blood and spleen and stomach disorders, which are important pathogeneses of NASH.

Acupoint catgut embedding includes acupoints such as Qihai and Zusanli. Qihai is a major acupoint on the Ren meridian, where "Qi" refers to zongqi and the Qi of water and grains. It can convert the essence of water and grains into zongqi through regulating respiration, which gathers at Qihai. Stimulating Qihai can invigorate Qi and tonify the spleen, promote urination and drenching, promote blood circulation and remove blood stasis, and regulate the lower Jiao, which helps improve the mood of patients with NASH and resolve stagnation. The superficial layer of Zusanli has cutaneous nerves passing through, and the deep layer has anterior tibial arteries and veins. "When pathogens are in the spleen and stomach, there is excess of both Yin and Yang, or deficiency of both, which leads to cold or heat symptoms. All these can be regulated by Zusanli," indicating that Zusanli is associated with the spleen and stomach. Stimulating Zusanli can tonify the spleen and stomach, promote Qi circulation and reduce distension, digest food and resolve accumulation, tonify Qi and warm the middle to dispel cold, which is beneficial for patients with NASH to resolve Qi and blood stagnation caused by adverse emotions and improve self-efficacy. Auricular point pressing with beans is easy to operate and can be performed under the guidance of a doctor, which is conducive to improving self-efficacy in symptom management.

The results also showed that the scores of each dimension and the total score of CLDQ in the combined group were higher than those in the acupoint catgut embedding group after intervention, indicating that acupoint catgut embedding combined with auricular point pressing with beans can effectively improve the quality of life of patients with NASH. Acupoint catgut embedding also includes acupoints such as Zhongwan and Fenglong. Zhongwan is an important acupoint on the Ren meridian. Stimulating Zhongwan can harmonize the stomach and tonify the spleen, regulate stomach Qi, regulate emotions, improve sleep, and descend adverse Qi, and promote diuresis. Fenglong is a connecting point of the Stomach Meridian of Foot-Yangming, which connects the spleen and stomach meridians. Stimulating Fenglong can tonify the spleen and stomach and improve the abnormal circulation of Qi and blood. Auricular point pressing with beans includes not only liver and spleen acupoints but also endocrine and large intestine acupoints. The auricular points have high sensitivity, and the auricular holographic acupoints have strong correspondence with related organs and tissues of the body. Auricular point pressing with beans can tonify the spleen and eliminate diseases, which is conducive to improving the quality of life.

## 5. Conclusion

In summary, acupoint catgut embedding combined with auricular point pressing with beans can effectively alleviate the TCM symptoms of patients with liver depression and spleen deficiency type NASH, and improve self-efficacy in symptom management and quality of life.

## Disclosure statement

The author declares no conflict of interest.

## References

- [1] Zhang W, Sun D, Wang P, 2020, The Role and Mechanism of Inflammasome-Mediated Pyroptosis in Nonalcoholic Fatty Liver Disease. *Journal of Pharmaceutical Practice*, 38(1): 9–13, 41.
- [2] Zhang M, Zhang Y, Liu L, et al., 2021, Discussion on the Function of the Six-Character Formula Based on the Theory of “All Diseases Originate From Qi”. *World Journal of Integrated Traditional and Western Medicine*, 16(11): 2140–2143.
- [3] Liu E, Li Y, Huang Y, 2022, Effects of Liver-Soothing and Spleen-Strengthening Therapy Combined With Acupoint Catgut Embedding on Lipid Metabolism and Inflammatory Factors in Adolescents With Nonalcoholic Fatty Liver Disease (Liver Stagnation and Spleen Deficiency Type). *Sichuan Journal of Traditional Chinese Medicine*, 40(1): 114–116.
- [4] Wang Y, Bao J, Hu J, et al., 2021, Application Effect of Stress Inoculation Training Combined With Auricular Point Pressing With Beans in Elderly Patients With Diabetes and Insomnia. *Chinese Journal of Geriatrics*, 41(5): 955–958.
- [5] Splenogastric Disease Branch of China Association of Chinese Medicine, 2017, Expert Consensus on the Diagnosis and Treatment of Nonalcoholic Fatty Liver Disease With Traditional Chinese Medicine. *Journal of Traditional Chinese Medicine*, 58(19): 1706–1710.
- [6] Fatty Liver and Alcoholic Liver Disease Group of Chinese Liver Disease Association, Fatty Liver Expert Committee of Chinese Medical Doctor Association, 2018, Guidelines for the Prevention and Treatment of Nonalcoholic Fatty Liver Disease (2018 Updated Version). *Chinese Journal of Hepatology*, 26(3): 195–203.

- [7] Zhu F, Qian Q, Zhu L, 2023, Application of Nursing Based on Self-Efficacy Theory in Early Functional Exercise of Affected Limbs After Permanent Pacemaker Implantation. *Chinese Journal of Practical Nursing*, 39(15): 1144–1150.
- [8] Tao J, Li X, Gao X, et al., 2019, Study on the Influencing Factors of Quality of Life in Patients With Chronic Hepatitis B Treated With Antiviral Therapy. *Chinese General Practice*, 22(23): 2798–2804.
- [9] Ma X, Xue G, Wang D, et al., 2024, Clinical Effect of Tongxinbi Plaster Acupoint Application Combined With Auricular Point Pressing With Beans in the Treatment of Stable Angina Pectoris. *World Chinese Medicine*, 19(3): 393–397.
- [10] Jin Y, Zhang S, Hai Y, 2019, Study on the Effect and Mechanism of Acupoint Catgut Embedding on Lipid Metabolism in Perimenopausal Rats. *Chinese Archives of Traditional Chinese Medicine*, 37(3): 593–596.

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# Subchronic and Chronic Toxicity Tests of Fuyanxiao Capsules

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**Abstract:** To evaluate the subchronic and chronic toxicity of Fuyanxiao capsules, Sprague-Dawley (SD) rats were used in toxicity studies. In the subchronic toxicity study, 50 female rats were randomly divided into a high-dose group (5.4g/kg/day) and a control group, with 15 rats in each, and medium (2.7g/kg/day) and low (1.35g/kg/day) dose groups, with 10 rats in each. The test substance was administered orally (mixed with feed, twice daily) for 90 consecutive days. In the chronic toxicity study, 40 female rats were randomly divided into high, medium, and low dose groups and a control group, with 10 rats in each. The test substance was administered orally in the same manner for 180 consecutive days. Clinical signs, body weight, and food consumption were observed and recorded daily. At the end of the terminal phase (the first 10 rats from each group, 1 day after the last dose) and the recovery phase (the last 5 rats from the control group and the high-dose group, observed for an additional 28 days after the last dose), blood and urine samples, as well as organs, were collected. Organ coefficients were calculated, and various hematological and urinary indicators were detected, followed by pathological analysis. The results showed that there were no significant differences in body weight, food consumption, or organ coefficients between any of the dose groups and the control group in both subchronic and chronic toxicity studies ( $P > 0.05$ ). Histopathological examination revealed no lesions, suggesting no tissue or organ damage in any of the dose groups. The rats exhibited good mental status, and hematological and urinary physiological indicators were within normal ranges, indicating stable liver and kidney function, hematopoietic system of the bone marrow, and internal environment in all dose groups. Therefore, Fuyanxiao capsule has no obvious subchronic or chronic toxicity in SD rats, and it is safe and reliable to use at reasonable dosage in clinical practice.

**Keywords:** Fuyanxiao capsule; SD rats; Subchronic toxicity; Chronic toxicity; Body weight; Organ coefficient; Blood routine; Liver function biochemical indexes; Urine routine

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## 1. Introduction

Fuyanxiao capsule is a pharmaceutical preparation derived from a classic Miao medicine prescription

(Manufacturer: Guizhou Yibai Women's Pharmaceutical Factory, Approval number: National Medicine Zhunzi Z20025333). Its main ingredients include *Oxalis corniculata*, *Patrinia scabiosifolia*, *Trichosanthes kirilowii*, *Rheum palmatum*, Tree peony bark, *Atractylodes lancea*, and Combined spicebush root, etc. The capsule is formulated to clear heat and detoxify, promote Qi circulation, resolve blood stasis, and eliminate dampness to alleviate leukorrhea. Clinical studies have shown that Fuyanxiao capsule has a certain therapeutic effect on gynecological inflammation such as endometritis and cervicitis when used in the female reproductive system<sup>[1-6]</sup>. To further verify the safety of Fuyanxiao capsule, this study conducted subchronic and chronic toxicity tests in rats based on the "Technical guidelines for long-term toxicity testing of traditional Chinese medicine and natural medicine", aiming to provide a basis for the toxicological evaluation and clinical safety of Fuyanxiao capsule.

## **2. Materials and methods**

### **2.1. Materials**

#### **2.1.1. Experimental animals**

Female Sprague-Dawley (SD) rats, aged 6–8 weeks and weighing approximately 150g, are purchased from SPF (Beijing) Biotechnology Co., Ltd. [Production License: SCXK (Beijing) 2019-0010]. The animals are housed at Beijing Weishang Lituo Technology Co., Ltd., with barrier facilities [Production License: SYXK (Beijing) 2016-0039]. They are maintained according to the SPF-grade control standards of the animal facility, with a temperature of 22–24°C and a relative humidity of 50%–60%. The rats are acclimated for 7 days before the experiment, with free access to food and water.

#### **2.1.2. Preparation of test drugs**

Fuyanxiao capsule, provided by Guizhou Yibai Women's Pharmaceutical Factory Co., Ltd., has a specification of 0.45g per capsule. The test drug is prepared by mixing with feed at low-dose (1.35g/kg/day, 20 times the clinical dosage), medium-dose (2.7g/kg/day, 40 times the clinical dosage), and high-dose (5.4g/kg/day, 80 times the clinical dosage) levels for standby use.

#### **2.1.3. Equipment**

Clean bench (Suzhou Antai Airtech Co., Ltd., SW-CJ-1FD), electronic balance (Haining Shengbo Weighing Apparatus Co., Ltd., SB5002), and rat metabolic cages (Shanghai Yuyan Scientific Instrument Co., Ltd.).

## **2.2. Grouping and treatment**

### **2.2.1. Subchronic toxicity test**

Fifty female SD rats are randomly divided into four groups: a blank control group with 15 rats, a high-dose test group with 15 rats, and medium- and low-dose test groups, each with 10 rats. On the day of grouping, dosing is initiated orally (administered with feed, twice daily) according to the medium-dose level of the test substance for a consecutive period of 90 days.

### **2.2.2. Chronic toxicity test**

Forty female SD rats are randomly divided into four groups: a blank control group, high-, medium-, and low-dose test groups, with 10 rats in each. On the day of grouping, dosing was initiated orally (administered with feed, twice

daily) according to the medium-dose level of the test substance for a consecutive period of 180 days.

### **2.3. Sample collection**

- (1) Subchronic toxicity test: The observation period for toxicity exposure is at least 90 days. Blood and urine samples are collected from the first 10 rats in all groups at the terminal stage (1 day after the final dose), followed by euthanasia and systematic anatomy. The satellite group (the last 5 rats in the blank control group and the high-dose test group) entered a recovery period (continued observation for 28 days after the final dose), during which the incidence of clinical signs and mortality are recorded. Blood and urine samples are collected at the end of the recovery period, the animals are euthanized for dissection, and tissues are collected and weighed according to the protocol.
- (2) Chronic toxicity test: The observation period for toxicity exposure is at least 180 days. At the end of the observation period, all rats are euthanized and dissected. The observation and recording procedures for the rats adhered to the methods described above.

### **2.4. Observation indicators**

#### **2.4.1. Body weight**

Body weight was measured once a week to observe changes.

#### **2.4.2. Hematological examination**

After the final dose administration, blood samples are collected after 12 hours of fasting with anticoagulants. Whole blood samples are used for routine hematological tests (including but not limited to: red blood cell count, hemoglobin, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, reticulocyte count, white blood cell count and its classification, platelet count, etc.) and coagulation tests (coagulation time). Plasma samples are used for biochemical analysis (including but not limited to: aspartate aminotransferase, alanine aminotransferase, alkaline phosphatase, creatine phosphokinase, urea nitrogen, creatinine, total protein, albumin, blood glucose, total bilirubin, total cholesterol, triglycerides, etc.).

#### **2.4.3. Urinalysis**

After the final dose administration, 24-hour urine samples are collected in metabolic cages. The appearance and volume are recorded. Urine samples are tested for routine indicators, including but not limited to: density or specific gravity, pH, protein, glucose, and occult blood, and blood cells.

#### **2.4.4. Gross anatomy**

At the end of the experiment, all animals underwent complete and detailed necropsy. The external surface, orifices, cranial cavity, chest cavity, abdominal cavity, and the color, hardness, and morphology of their organs were visually inspected for abnormalities.

#### **2.4.5. Organ index measurement and histopathological examination**

- (1) Organ index measurement: The rats are weighed before necropsy. Following necropsy, the main organs of the rats are promptly isolated, weighed, and the relative masses of each organ are calculated <sup>[7, 8]</sup>.
- (2) Histopathological examination: Fixed organs and tissues are processed through dehydration, paraffin

embedding, paraffin sectioning, and hematoxylin and eosin (HE) staining, then observed under a microscope. Lesions are graded according to a 5-point grading system (minimal, mild, moderate, severe, very severe), and some lesions are not graded. Any tissue or part of the tissue that was missing in this study did not affect the integrity of the pathological data and the conclusions drawn from it.

## 2.5. Data analysis

The experimental data are analyzed using the t-test in SPSS 20.0, with the results presented as “mean  $\pm$  standard error”.  $P < 0.01$  indicated that the difference is extremely significant,  $P < 0.05$  indicated that the difference was significant, and  $P > 0.05$  denoted no statistically significant difference.

## 3. Results

The experimental animals underwent regular clinical observations from post-drug administration until D90 and D180, including (but not limited to) changes in skin, hair, eyes, and mucosa, secretions and excretions, as well as spontaneous activities such as tearing, piloerection, pupil size changes, and abnormal respiration. Observations also included changes in gait, posture, and response to handling, as well as clonic or tonic movements, restricted and repetitive behaviors (such as excessive grooming behavior, repetitive circling), or other abnormal behaviors. The observation results revealed that the condition of the experimental animals was good, with no abnormalities observed in their general behavior, respiration, gross morphology, diet, and feces. No animal deaths or near-death situations were observed throughout the entire duration of the experiment.

### 3.1. Subchronic toxicity test

#### 3.1.1. Measurement of body weight changes

The SD rats in all groups exhibited a certain degree of weight increase over the feeding period, with consistent growth rates and no statistically significant differences ( $P > 0.05$ ). This indicates that the various doses of Fuyanxiao capsule used in this experiment had no obvious effect on the body weight of the rats, and the rats were able to grow normally and stably. Detailed information on the body weight changes of rats in each group is shown in **Table 1**.

**Table 1.** Changes in body weight of SD rats in each group during the subchronic toxicity test

Group	SD rats/n		Body weight /g		Changes/g
	D1	D90	D1	D90	
Control	10	10	151.3 $\pm$ 5.2	319.0 $\pm$ 28.9	+167.7
Low-dose	10	10	150.5 $\pm$ 6.8	308.9 $\pm$ 21.4	+158.4
Medium-dose	10	10	152.6 $\pm$ 6.0	319.5 $\pm$ 35.5	+166.9
High-dose	10	10	148.4 $\pm$ 2.7	309.2 $\pm$ 15.8	+160.8

\*Note: D1 refers to the day of drug administration, and D90 refers to the end of the drug administration period; Data without superscript letters in the same row indicate no significant difference ( $P > 0.05$ ).

#### 3.1.2. Detection of blood routine, liver function biochemistry, and coagulation indexes

After the end of drug administration (D90), there were no statistical differences in blood routine, serum

biochemical indexes, and coagulation time between the various dose groups of female SD rats and the normal control group ( $P > 0.05$ ). This indicates that Fuyanxiao capsule has no significant adverse effects on the bone marrow hematopoietic system, liver and kidney function and immune system of the experimental rats. Detailed information is presented in **Tables 2** and **Table 3**.

**Table 2.** Blood routine test for SD rats in each group during subchronic toxicity test

Index	Unit	Control group	Low-dose group	Medium-dose group	High-dose group
White blood cell count (WBC)	$10^9/L$	$7.38 \pm 2.34$	$6.20 \pm 1.89$	$6.72 \pm 2.11$	$9.30 \pm 3.34$
Absolute lymphocyte count (LYM#)	$10^9/L$	$5.56 \pm 1.86$	$4.23 \pm 1.22$	$5.00 \pm 1.70$	$5.87 \pm 1.53$
Mid-cell absolute count (MID#)	$10^9/L$	$0.69 \pm 0.23$	$0.93 \pm 0.32$	$0.83 \pm 0.28$	$1.41 \pm 0.70$
Absolute granulocyte count (GRA#)	$10^9/L$	$1.12 \pm 0.46$	$1.04 \pm 0.50$	$0.89 \pm 0.23$	$2.02 \pm 1.42$
Lymphocyte percentage (LYM%)	%	$75.4 \pm 6.0$	$68.6 \pm 4.3$	$73.8 \pm 4.8$	$65.7 \pm 10.6$
Mid-cell percentage (MID%)	%	$9.5 \pm 2.4$	$15 \pm 1.3$	$12.4 \pm 2.0$	$14.6 \pm 2.9$
Granulocyte percentage (GRA%)	%	$15.1 \pm 4.7$	$16.5 \pm 3.6$	$13.8 \pm 3.3$	$19.8 \pm 8.0$
Red blood cell count (RBC)	$10^{12}/L$	$5.73 \pm 0.29$	$6.13 \pm 0.58$	$5.22 \pm 0.65$	$5.4 \pm 0.26$
Hemoglobin (HGB)	g/L	$153 \pm 8$	$161 \pm 5$	$147 \pm 18$	$152 \pm 5$
Hematocrit (HCT)	L/L	$0.255 \pm 0.014$	$0.274 \pm 0.024$	$0.224 \pm 0.029$	$0.231 \pm 0.012$
Mean corpuscular volume (MCV)	fL	$44.4 \pm 1.5$	$43.2 \pm 1.2$	$43 \pm 1.4$	$42.8 \pm 0.9$
Mean corpuscular hemoglobin (MCH)	pg	$26.5 \pm 0.9$	$25.4 \pm 1.8$	$28 \pm 1.0$	$28.1 \pm 0.7$
Mean corpuscular hemoglobin concentration (MCHC)	g/L	$568 \pm 14$	$559 \pm 49$	$619 \pm 21$	$623 \pm 13$
Red cell distribution width-SD (RDW-SD)	fL	$21 \pm 0$	$13 \pm 1$	$19 \pm 4$	$19 \pm 4$
Red cell distribution width-CV (RDW-CV)	%	$25 \pm 1$	$24 \pm 2$	$23 \pm 2$	$24 \pm 1$
Platelet count (PLT)	$10^9/L$	$692 \pm 116$	$488 \pm 91$	$439 \pm 175$	$481 \pm 73$
Platelet crit (PCT)	L/L	$0.521 \pm 0.086$	$0.359 \pm 0.061$	$0.322 \pm 0.127$	$0.353 \pm 0.053$
Mean platelet volume (MPV)	fL	$7.5 \pm 0.2$	$7.3 \pm 0.2$	$7.3 \pm 0.2$	$7.3 \pm 0.1$
Platelet distribution width (PDW)	%	$20.5 \pm 2.6$	$21.1 \pm 2.8$	$27.5 \pm 11.8$	$24.5 \pm 1.9$

\*Note: SD: Standard deviation; CV: Coefficient of variation; Data without superscript letters in the same row indicate no significant difference ( $P > 0.05$ ).

**Table 3.** Liver function biochemistry and coagulation tests for SD rats in each group during subchronic toxicity test

Index	Unit	Control group	Low-dose group	Medium-dose group	High-dose group
Aspartate aminotransferase (AST)	U/L	$181.34 \pm 51.52$	$192.14 \pm 69.97$	$347.36 \pm 231.77$	$184.52 \pm 102.98$
Alanine Aminotransferase (ALT)	U/L	$123.66 \pm 18.62$	$147.65 \pm 20.82$	$178.67 \pm 51.71$	$134.48 \pm 38.87$
Alkaline phosphatase (ALP)	Activity unit	$7.94 \pm 2.48$	$6.69 \pm 2.99$	$12.04 \pm 4.67$	$14.49 \pm 5.88$
Creatine kinase (CK)	U/ml	$0.84 \pm 0.43$	$0.52 \pm 0.35$	$1.12 \pm 0.47$	$0.59 \pm 0.47$
Urea	mg/100ml	$22.88 \pm 5.27$	$18.91 \pm 3.41$	$15.38 \pm 3.20$	$20.61 \pm 5.27$
Creatinine (Cr)	umol/L	$29.25 \pm 11.94$	$20.7 \pm 11.45$	$21.45 \pm 8.70$	$24.39 \pm 15.59$
Total protein (TP)	g/L	$117.47 \pm 28.51$	$122.53 \pm 14.57$	$123.16 \pm 34.62$	$117.92 \pm 60.15$

**Table 3 (Continued)**

Index	Unit	Control group	Low-dose group	Medium-dose group	High-dose group
Albumin(ALB)	g/L	227.63 ± 40.23	309.41 ± 37.45	276.97 ± 63.66	244.83 ± 43.59
Glucose(GLU)	mmol/L	7.55 ± 2.99	7.2 ± 3.04	6.58 ± 3.25	7.44 ± 2.21
Total bilirubin(TBIL)	umol/L	5.73 ± 5.22	4.51 ± 2.57	5.32 ± 3.16	4.19 ± 2.59
Total cholesterol CHO/TC)	mmol/L	1.83 ± 0.71	1.8 ± 0.61	2.01 ± 0.57	1.9 ± 0.48
Triglycerides(TG)	mg/dl	108.56 ± 39.94	79.48 ± 46.36	90.38 ± 48.61	114.20 ± 68.18
Prothrombin time(PT)	S	14.3 ± 1.2	14.7 ± 1.2	14.3 ± 1.4	14.1 ± 1.5

Note: Data without superscript letters in the same row indicate no significant difference ( $P > 0.05$ ).

### 3.1.3. Urinalysis

After the end of drug administration (D90), two animals in the high-dose group (852# and 857#) and 2 animals in the medium-dose group (864# and 865#) were weakly positive (“+/-”) for urine occult blood (BLD). Furthermore, 2 animals in the high-dose group (856# and 859#) and 2 animals in the medium-dose group (863# and 866#) showed weak positive (“+/-”) urine protein (PRO). These results were considered as non-adverse reactions. During the recovery period (D118), no changes in urinalysis parameters related to the test substances were observed.

### 3.1.4. Gross anatomical and histopathological observations

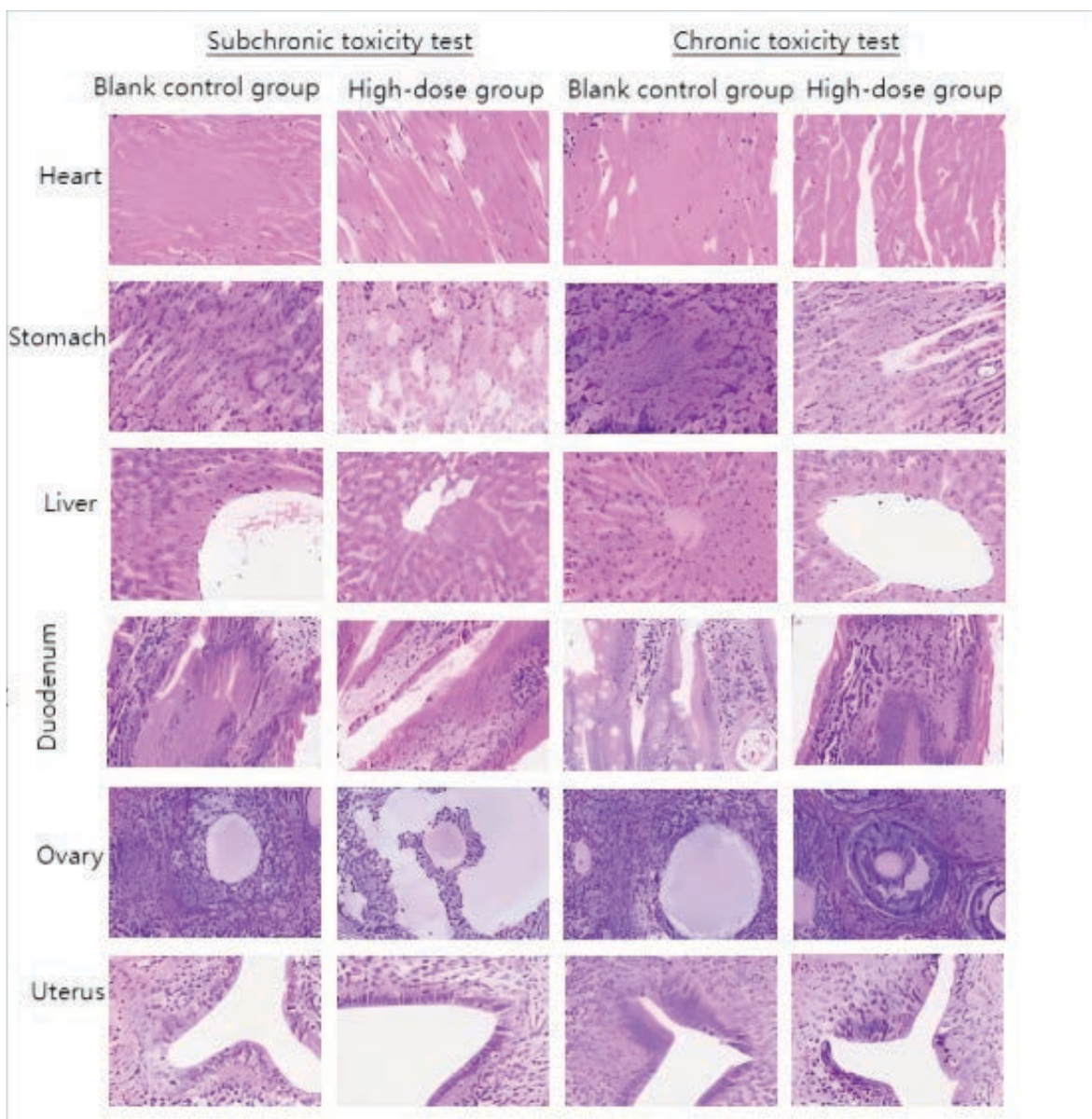
After the end of drug administration (D90), there were no significant differences in the changes of organ weights among SD rats in various dose groups related to the test substance ( $P > 0.05$ ). During the recovery period (D118), no changes in organ weights associated with the test substance were observed either ( $P > 0.05$ ). Therefore, the concentrations of Fuyanxiao capsule used in this experiment did not cause changes in organ weights or damage to the organs of rats, as shown in **Table 4**.

**Table 4.** Summary of organ weight data for SD rats in each group during subchronic toxicity test

Organ/unit	Control group	Low-dose group	Medium-dose group	High-dose group
Body weight/g	306.7 ± 25.9	295.5 ± 18.7	322.8 ± 33.0	299.4 ± 19.6
Brian/g	1.9 ± 0.1	1.9 ± 0.1	1.9 ± 0.1	1.9 ± 0.1
Heart/g	0.9 ± 0.1	1.0 ± 0.1	1.0 ± 0.1	1.0 ± 0.1
Liver/g	11.0 ± 1.1	8.8 ± 0.8	11.1 ± 1.5	10.9 ± 1.1
Kidney/g	1.9 ± 0.2	1.8 ± 0.1	2.0 ± 0.2	2.0 ± 0.1
Adrenal gland/g	0.1 ± 0.0	0.1 ± 0.0	0.1 ± 0.0	0.1 ± 0.0
Thymus/g	0.3 ± 0.1	0.4 ± 0.1	0.4 ± 0.1	0.4 ± 0.1
Spleen/g	0.6 ± 0.1	0.6 ± 0.1	0.7 ± 0.1	0.7 ± 0.1
Ovary/g	0.3 ± 0.3	0.1 ± 0.0	0.1 ± 0.0	0.1 ± 0.0
Uterus/g	1.0 ± 0.6	0.6 ± 0.2	0.8 ± 0.2	0.6 ± 0.1
Lung/g	1.2 ± 0.1	1.2 ± 0.1	1.4 ± 0.1	1.2 ± 0.1

\*Note: Data without superscript letters in the same row indicate no significant difference ( $P > 0.05$ ).

After the completion of the subchronic toxicity test, no obvious pathological changes were observed in the organ tissues of each group. Histological examination revealed no degeneration of myocardial fibers. The gastric mucosa, submucosa, and muscularis layers exhibited normal architecture with orderly cellular arrangement. The central veins of the liver were distinct, hepatic cords were well-organized, and no pathological changes such as fatty degeneration were observed. Duodenal columnar epithelial cells were neatly aligned. Ovarian follicles at various developmental stages were visible, with intact and well-defined tissue structures. The endometrial lining appeared uniform, and myometrial cells were regularly arranged. These observations indicate that the concentrations of Fuyanxiao capsule used in this experiment did not cause substantial damage to the heart, liver, stomach, duodenum, ovary, and uterus of rats, as shown in **Figure 1**.



**Figure 1.** Histopathological observations of SD rats (400×)

## 3.2. Chronic toxicity test

### 3.2.1. Measurement of body weight changes

At the end of dosing (D180), the body weights of SD rats in all groups showed a certain degree of increase over time, with consistent growth rates and no significant differences ( $P > 0.05$ ). This indicates that the various doses of Fuyanxiao capsule used in the chronic toxicity test had no obvious effect on the body weights of the rats, and the rats were able to grow normally and stably. The results are shown in **Table 5**.

**Table 5.** Summary of body weight of SD rats in each group in the chronic toxicity test

Group	SD Rats/n		Body weight /g		Changes/g
	D1	D180	D1	D180	
Control	10	10	152.3 ± 6.1	377.4 ± 43.3	+225.1
Low-dose	10	10	154.9 ± 4.3	372.6 ± 49.5	+217.7
Medium-dose	10	10	150.4 ± 5.2	370.0 ± 34.8	+219.6
High-dose	10	10	152.4 ± 6.4	350.6 ± 53.8	+198.2

\*Note: D1 refers to the day of drug administration, and D180 refers to the end of the drug administration period; Data without superscript letters in the same row indicate no significant difference ( $P > 0.05$ ).

### 3.2.2. Detection of blood routine and serum biochemical indicators

After the end of dosing (D180), there were no significant differences ( $P > 0.05$ ) in blood routine, serum biochemistry, and coagulation time indexes between female SD rats in each dose group and those in the normal control group. This indicates that Fuyanxiao capsule had no obvious impact on the hematopoietic system of the bone marrow, liver and kidney functions, and immune system of rats. The results are shown in **Tables 6** and **Table 7**.

**Table 6.** Blood routine test for SD rats in each group during chronic toxicity test

Index	Unit	Control group	Low-dose group	Medium-dose group	High-dose group
White blood cell count (WBC)	10 <sup>9</sup> /L	5.48 ± 2.11	3.63 ± 1.55	3.33 ± 1.60	4.40 ± 2.05
Neutrophil count(NEU#)	10 <sup>9</sup> /L	0.91 ± 0.28	0.88 ± 0.52	0.59 ± 0.33	1.16 ± 0.74
Absolute lymphocyte count (LYM#)	10 <sup>9</sup> /L	3.93 ± 1.71	234 ± 110	236 ± 1.29	272 ± 1.36
Eosinophil count(EOS#)	10 <sup>9</sup> /L	0.24 ± 0.29	0.09 ± 0.06	0.07 ± 0.4	0.10 ± 0.05
Basophil count(BAS#)	10 <sup>9</sup> /L	0.08 ± 0.05	0.05 ± 0.03	0.03 ± 0.02	0.08 ± 0.05
Monocyte count (MON#)	10 <sup>9</sup> /L	0.30 ± 0.16	0.29 ± 0.13	0.28 ± 0.14	0.36 ± 0.16
Neutrophil percentage(NEU%)	%	18.4 ± 5.5	23.5 ± 9.4	18.3 ± 7.4	26.0 ± 9.7
Lymphocyte percentage(LYM% )	%	70.4 ± 5.8	65.0 ± 10.6	70.1 ± 9.8	61.9 ± 11.2
Eosinophil percentage(EOS%)	%	4.0 ± 3.4	2.4 ± 0.7	2.4 ± 0.8	2.3 ± 0.8
Basophil percentage (BAS%)	%	1.5 ± 0.5	1.3 ± 0.4	0.9 ± 0.6	1.6 ± 0.5
Monocyte percentage(MON%)	%	6.2 ± 4.0	8.0 ± 2.4	8.8 ± 3.0	8.5 ± 1.7
Red blood cell count(RBC)	10 <sup>12</sup> /L	8.02 ± 4.35	7.64 ± 0.78	5.91 ± 2.05	9.82 ± 1.51
Hemoglobin (HGB)	g/L	192 ± 38	146 ± 14	121 ± 42	191 ± 31
Hematocrit(HCT)	%	44.690 ± 24.192	40.890 ± 4.133	33.480 ± 11.454	54.030 ± 9.032

**Table 6 (Continued)**

Index	Unit	Control group	Low-dose group	Medium-dose group	High-dose group
Mean orpuscular volume (MCV)	fL	57.1 ± 3.2	54.1 ± 2.8	56.6 ± 1.6	55.0 ± 2.5
Mean corpuscular hemoglobin(MCH)	pg	103.9 ± 177.3	19.2 ± 1.3	20.3 ± 0.6	19.4 ± 0.8
Mean corpuscular hemoglobin concentration(MCHC)	g/L	1681 ± 2791	354 ± 7	359 ± 6	353 ± 7
Red cell distribution width-SD (RDW-SD)	fL	49 ± 45	26 ± 1	26 ± 1	27 ± 2
Red cell distribution width-CV (RDW-CV)	%	20 ± 17	12 ± 0	11 ± 0	12 ± 1
Platelet count  (PLT)	109/L	790 ± 234	702 ± 357	563 ± 424	630 ± 257
Platelet crit(PCT)	%	0.587 ± 0.204	0.442 ± 0.229	0.37 ± 0.275	0.421 ± 0.165
Mean platelet volume (MPV)	fL	7.0 ± 0.6	6.3 ± 0.4	6.5 ± 0.3	6.7 ± 0.4
Platelet distribution width (PDW)	fL	16.3 ± 1.2	15.5 ± 0.6	15.8 ± 1.0	15.5 ± 0.1

\*Note: SD: Standard deviation; CV: Coefficient of variation; Data without superscript letters in the same row indicate no significant difference ( $P > 0.05$ ).

**Table 7.** Liver function biochemistry and coagulation tests for SD rats in each group during chronic toxicity test

Index	Unit	Control group	Low-dose group	Medium-dose group	High-dose group
Aspartate aminotransferase(AST)	U/L	114.8 ± 49.43	92.81 ± 113.12	110.08 ± 62.28	141.38 ± 67.23
Alanine Aminotransferase(ALT)	U/L	91.88 ± 42.97	43.66 ± 41.19	65.64 ± 30.90	99.71 ± 46.97
Alkaline phosphatase(ALP)	Activity unit	76.12 ± 22.08	35.29 ± 32.46	81.76 ± 57.23	90.09 ± 37.70
Creatine kinase(CK)	U/ml	355.87 ± 257.63	377.81 ± 457.32	378.36 ± 217.52	306.35 ± 192.66
Urea	mg/100ml	7.6 ± 1.53	5.24 ± 2.77	6.82 ± 2.47	7.68 ± 3.06
Creatinine(Cr)	umol/L	15.37 ± 2.85	10.06 ± 3.41	10.72 ± 4.24	10.5 ± 3.58
Total protein(TP)	g/L	91.43 ± 7.23	49.27 ± 26.46	64.43 ± 17.63	74.4 ± 26.84
Albumin(ALB)	g/L	28.16 ± 1.89	15.59 ± 6.98	20.23 ± 4.91	23.42 ± 7.34
Glucose(GLU)	mmol/L	4.3 ± 0.3	4.3 ± 0.5	4.2 ± 0.6	4.9 ± 0.6
Total bilirubin(TBIL)	umol/L	1.48 ± 0.58	0.82 ± 0.58	0.64 ± 0.73	1.33 ± 0.50
Total cholesterol CHO/TC)	mmol/L	3.47 ± 0.94	2.3 ± 1.32	2.41 ± 0.64	2.37 ± 1.22
Triglycerides(TG)	mg/dl	3.47 ± 2.28	0.99 ± 0.86	1.77 ± 0.56	1.71 ± 0.89
Prothrombin time(PT)		14.3 ± 0.7	15.6 ± 1.8	15.9 ± 1.6	15.0 ± 1.0

\*Note: Data without superscript letters in the same row indicate no significant difference ( $P > 0.05$ ).

### 3.2.3. Urinalysis

No changes in urine parameters related to the test substance were observed ( $P > 0.05$ ). Across the groups, varying degrees of positive were noted in urine PRO protein tests. These were considered to be due to instrumental detection issues and were classified as non-adverse reactions.

### 3.2.4. Gross anatomical and histopathological observations

After the end of drug administration (D180), there were no significant differences in organ weight changes among

SD rats in various dose groups related to the test substance ( $P > 0.05$ ). All statistically significant variations in organ weights were attributed to individual differences, due to the absence of microscopic correlations and the lack of a dose-response relationship. This indicates that the concentrations of Fuyanxiao capsule used in this experiment did not cause changes in organ weights or damage to the organs of the rats, as shown in **Table 9**.

**Table 9.** Summary of organ weight data for SD rats in each group during chronic toxicity test

Organ/unit	Control group	Low-dose group	Medium-dose group	High-dose group
Body weight/g	371.5 ± 38.6	358 ± 50.9	362.6 ± 36.7	351 ± 54.5
Brian/g	1.9943 ± 0.1088	2.0922 ± 0.0923	2.0323 ± 0.1333	2.0147 ± 0.0915
Heart/g	1.1406 ± 0.1132	1.2196 ± 0.1916	1.1694 ± 0.1665	1.1856 ± 0.1685
Liver/g	11.1665 ± 1.8382	9.8646 ± 1.9761	11.5285 ± 2.0180	10.9644 ± 1.6466
Kidney/g	2.3432 ± 0.4347	2.2863 ± 0.3828	2.3037 ± 0.3280	2.3273 ± 0.3710
Adrenal gland/g	0.08 ± 0.0151	0.0697 ± 0.0097	0.0682 ± 0.0117	0.0681 ± 0.0116
Thymus/g	0.2231 ± 0.0573	0.2139 ± 0.0672	0.2152 ± 0.0275	0.2188 ± 0.0627
Spleen/g	0.6793 ± 0.1065	0.6644 ± 0.0986	0.6362 ± 0.0801	0.6683 ± 0.1210
Ovary/g	0.1278 ± 0.0308	0.1404 ± 0.0313	0.1058 ± 0.0199	0.1257 ± 0.0275
Uterus/g	0.9698 ± 0.1570	1.1094 ± 0.6825	0.8719 ± 0.2271	0.9707 ± 0.3565
Lung/g	1.6161 ± 0.1187	1.5352 ± 0.1557	1.5781 ± 0.1866	1.5151 ± 0.2209

\*Note: Data without superscript letters in the same row indicate no significant difference ( $P > 0.05$ ).

After the completion of the chronic toxicity test, no obvious pathological changes were observed in the organ tissues of each group. The histopathological manifestations of each organ were generally consistent with those observed in the subchronic toxicity test. The results indicated that the concentration of Fuyanxiao capsule used in this test did not cause substantial damage to the heart, liver, stomach, duodenum, ovary and uterus of rats, as shown in **Figure 1**.

## 4. Discussion

In this study, after continuous oral administration of Fuyanxiao capsule granules to SD rats for 90 and 180 days, the experimental and control groups exhibited good survival status. There were no significant differences in general behavior, diet, defecation, body weight, and organ coefficients among the experimental and control groups. No animal deaths or near-death situations were observed, indicating that the appetite, behavior, and growth of the rats were not affected by Fuyanxiao capsule. Blood maintains the homeostasis of the internal environment of the body, and routine blood test is crucial for assessing the health status of an individual <sup>[9]</sup>. Liver and kidney function tests serve as important clinical indicators for assessing whether liver and kidney functions are impaired <sup>[10]</sup>. Routine coagulation test directly reflects bone marrow coagulation function <sup>[11, 12]</sup>. The subchronic and chronic toxicity tests showed no significant differences in blood routine, liver function biochemistry, and routine coagulation among rats in various dose groups.

After the end of dosing (D180), no changes in organ weights related to the test substance were observed. No gross pathological changes related to the test substance were found in appearance and body surface examination

and body cavity examination at the end of dosing (D90). No gross pathological changes related to the test substance were observed during the recovery period (D118). Some altered values in the urinalysis results after the end of dosing (D90 and D180) were close to the historical background range and showed no microscopic correlation, so they were considered non-adverse reactions. Statistically significant changes in organ weights were also attributed to individual variations, with no microscopic correlation and a lack of dose-response relationship.

The results revealed that Fuyanxiao capsule had no adverse effects on the general behavior, liver and kidney functions, and bone marrow hematopoiesis of rats. No animal deaths or near-death situations were observed. No clinically pathological parameters, organ weight changes, or histopathological alterations related to the test substance were found. Additionally, no observed adverse effect level (NOAEL) of the test substance was identified. These findings suggest that there are no subchronic and chronic toxic effects from the medium- to long-term repeated application of Fuyanxiao capsule in rats, providing a basis for the safety evaluation of Fuyanxiao capsule and also serving as a reference for subsequent clinical medication use.

## Disclosure statement

The authors declare no conflict of interest.

## References

- [1] Cui YT, 2019, Clinical Study on Treatment of Bacterial Vaginitis With Fuyanxiao Capsule Combined With Nifuratel. *J Med Inf*, 32(11): 154–155.
- [2] Huang XM, 2019, Clinical Efficacy of Fuyanxiao Capsule Combined With Nifuratel in the Treatment of Bacterial Vaginosis. *Smart Healthcare*, 5(3): 135–136.
- [3] Zhu J, 2021, Fuyanxiao Capsule Combined With Western Medicine in Treatment of Acute Pelvic Inflammatory in 73 Cases. *Fujian J Tradit Chin Med*, 52(12): 7–9.
- [4] Zhang Y, 2019, Clinical Study of Hongteng Decoction Combined With Fuyanxiao Capsule in the Treatment of Chronic Pelvic Inflammatory Disease. *New Tradit Chin Med*, 51(04): 192–195.
- [5] Zhang QD, Yin HZ, Wang P, et al., 2018, Effect of Fuyanxiao Capsule Combined With Nifuratel Nysfungin Vaginal Soft Capsule in the Treatment of Bacterial Vaginitis. *Drugs & Clinic*, 33(12): 3298–3301.
- [6] Yao DQ, 2018, Clinical Study of Fuyanxiao Capsules Combined With Nifuratel Nysfungin in Treatment of Bacterial Vaginitis. *Drugs & Clinic*, 33(09): 2321–2325.
- [7] Shen J, 2002, *Animal Toxicology*. Beijing: China Agriculture Press, Beijing.
- [8] Chen Q, 2011, *Chinese Medicine Pharmacology Research Methodology*. 3rd edition. Beijing: People's Health Press, Beijing.
- [9] Yu S, Gan M, Zuo Z, et al., 2014, Effects of Traditional Chinese Medicine Compound on Cytokines, Immunoglobulins and Immune Adhesion Function of Red Blood Cells in Immunosuppressed Mice. *J Northwest A and F Univ (Nat Sci Ed)*, 42(4): 27–32.
- [10] Deng X, Lu Y, Qin L, et al., 2018, Acute and Subchronic Toxicity Tests of Compound Ku Xuan Shen Granules. *J South Agriculture*, 49(9): 1873–1879.
- [11] Miao M, Cheng B, Guo L, et al., 2015, Effects of Fuzheng Paidu Tablet on Peripheral Blood T Lymphocytes, Intestinal Mucosa T Lymphocytes, and Immune Organs in Cyclophosphamide-Induced Immunosuppressed Mice. *Hum Vaccin*

Immunother, 11(11): 2659–2663.

- [12] Zhang HX, Guan J, Tian YH, et al., 2019, Acute and Sub-Chronic 90-Day Oral Toxicity Study of Perilla Seed Oil in Rodents and Beagle Dogs. Regul Toxicol Pharmacol, 103: 229–236.

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# Advances in Prevention and Treatment of Alzheimer's Disease among Community-Dwelling Elderly from the Perspective of Traditional Chinese Medicine (TCM)

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**Abstract:** This article examines the progress in the prevention and treatment of Alzheimer's disease among elderly individuals in communities from the perspective of traditional Chinese medicine (TCM). Through a systematic review of recent related studies, it analyzes new insights into the etiology and pathogenesis of Alzheimer's disease within TCM and summarizes novel methods and achievements in the prevention and treatment of the disease using TCM. Based on the TCM principles of "preventive treatment" and holistic health, innovative intervention models with Chinese characteristics, such as the "brain-heart-kidney axis" and "brain-gut connection," have shown new breakthroughs in improving cognitive function and slowing disease progression. The article also explores the benefits of shifting preventive and therapeutic measures to earlier stages, contributing to the establishment of an integrated community prevention model of "prevention-intervention-rehabilitation."

**Keywords:** Traditional Chinese medicine; Community; Elderly; Alzheimer's disease; Prevention and treatment

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## 1. Introduction

Alzheimer's disease (AD) stands as one of the primary neurodegenerative disorders seriously threatening the health of elderly populations. With the intensification of global population aging, the prevention and treatment of AD have emerged as a critical public health challenge worldwide, while effective and definitive diagnostic or therapeutic solutions remain elusive. Traditional Chinese Medicine (TCM) demonstrates unique advantages in managing age-related diseases and has achieved remarkable progress in AD prevention and treatment in recent years<sup>[1]</sup>. This study aims to systematically summarize novel theories, innovative approaches, and emerging models

in community-based AD prevention and management for elderly populations from the TCM perspective. The research seeks to provide new insights and evidence for enhancing therapeutic outcomes, improving quality of life in aging populations, reducing disease burden, enriching treatment modalities, elevating health awareness in ecological communities, and fostering collective health benefits. These efforts may potentially pioneer new possibilities for AD prevention and treatment strategies.

## **2. New understandings of Alzheimer's disease pathogenesis from the perspective of traditional Chinese medicine (TCM)**

This syndrome has been documented in classical literature under terms such as “forgetfulness” and “dementia.” In traditional Chinese medicine (TCM) theory, it is understood to originate in the brain and involve dysfunction among the five viscera, primarily caused by deficiency of marrow sea (essence of the brain), obstruction of cerebral orifices by phlegm and stasis, and dysfunction of the spirit mechanism. Recent advances in TCM research have expanded understanding of Alzheimer's disease pathogenesis by integrating the brain-gut axis dysregulation theory. Building upon the traditional framework of “kidney essence deficiency, phlegm turbidity obstructing orifices, and blood stasis blocking channels,” contemporary TCM scholars have proposed the concept of brain-gut axis imbalance. This innovative theory highlights the interconnected regulatory mechanisms between cerebral and intestinal functions, reflecting TCM's holistic perspective of visceral interdependence. Modern medicine has also termed the gastrointestinal tract the ‘second brain’ in research, reflecting its sophisticated neural networks and regulatory capacities comparable to those of the central nervous system <sup>[2]</sup>.

Modern biomedical research has identified a bidirectional communication network comprising the gut microbiota, autonomic nervous system, central nervous system, and enteric nervous system <sup>[3]</sup>. This sophisticated system connects the brain and gastrointestinal tract through neuroendocrine, immunological, and metabolic pathways, collectively termed the microbiome-brain-gut axis. Within TCM's holistic framework, the concept of “gut” extends beyond anatomical intestines to encompass the functional spleen-stomach system (Pi Wei). Emphasizing that “the spleen-stomach are the postnatal foundation”, TCM theory posits that robust spleen-stomach function serves as the basis for Qi and blood generation. “Classical Canon of Medicine (Leijing): Section” on Zangxiang states: “The small intestine is located below the stomach, receiving and containing the stomach's ingested grains. It differentiates clear and turbid essences: clear fluids seep forward (to distribute throughout the body), while turbid residues flow backward (to the large intestine).

Spleen Qi ascends while small intestine Qi descends, thereby enabling the transformation and transportation of substances, hence it is called “the organ of differentiation and transformation.” After food intake, the spleen-stomach system transforms dietary grains into essence and Qi. The small intestine further segregates clear nutrients from turbid waste, while the large intestine transmits residual matter and absorbs remaining body fluids. These organs collaborate in maintaining physiological homeostasis through their interconnected functions. Additionally, “Suwen: Yin-Yang Correspondence and Manifestations” observes: “Anger injures the liver, joy affects the heart, overthinking harms the spleen, sorrow damages the lung, and fear weakens the kidney.” As elaborated in “Jingyue Quanshu: Miscellaneous Diseases”, dementia may arise from emotional blockages, excessive worry, unfulfilled desires, skepticism, or fright, gradually progressing to cognitive decline. Chronic emotional stress (e.g., prolonged anxiety) disrupts spleen function, leading to digestive disorders. Conversely, spleen-stomach dysfunction may impair cerebral function through Qi-blood deficiency or Qi stagnation, creating a

vicious cycle.

From TCM's holistic perspective, the brain-gut axis embodies multidimensional connections between the brain and intestines via Qi-blood circulation, Qi movement, and emotional regulation. By modulating spleen-stomach function, smoothing liver and Qi, and nourishing kidney essence, TCM interventions aim to restore brain-gut axis homeostasis, thereby preventing disease and promoting health. This integrative approach converges with modern research on the microbiome-brain-gut axis, offering innovative directions for Alzheimer's disease prevention and treatment.

### **3. Integrative traditional Chinese medicine (TCM) approaches to Alzheimer's disease**

#### **3.1. Therapeutic strategies and clinical efficacy**

From the perspective of TCM syndrome differentiation, the development of Alzheimer's disease is closely associated with dysfunctions of the brain, kidneys, and heart <sup>[4]</sup>. The brain is regarded as the "residence of primordial spirit" (Yuan Shen Zhi Fu), the kidneys govern essence (Shen), and the heart presides over mental activities (Shen Ming). These three organs interact dynamically to maintain cognitive function.

According to Qianjin Yifang ("Supplement to the Thousand Ducal Prescriptions"): "After age fifty, Yang Qi declines progressively... leading to forgetfulness of past events." And Yifang Jijie ("Collected Explanations of Medical Formulas") states: "Both essence (Jing) and willpower (Zhi) reside in the kidneys. Deficiency of kidney essence leads to weakened willpower, failing to ascend to the heart, resulting in confusion and forgetfulness." The kidneys are considered the "foundation of prenatal constitution." They regulate growth, development, and aging through the waxing and waning of kidney and Qi.

Adequate kidney essence ensures abundant physical energy, vigorous brain function, and sharp mental acuity. Conversely, aging-related depletion of kidney essence, combined with spleen Qi deficiency, impairs Qi-blood generation. Deficient essence fails to nourish the marrow, leading to brain malnutrition, sensory orifices dysfunction, intellectual decline, and emotional disturbances. This TCM perspective aligns with modern gerontological understanding: age-related physiological memory decline and cognitive slowing are associated with neuronal loss, reduced brain weight, cortical atrophy, and narrowing gyri <sup>[5,6]</sup>. These structural changes correspond to the TCM mechanisms of marrow sea deficiency, heart fire hyperactivity, and brain orifice dysfunction in elderly patients.

In recent years, traditional Chinese medicine (TCM) has made significant advances in the prevention and treatment of Alzheimer's disease. In terms of herbal interventions, multiple novel compound formulations have been developed, including Naoxintong capsules (NXTC), Yizhi Jiannao pills, Jiannao Yishen pills, Xingnao Yizhi capsules, Tianma Xingnao capsules, Haima Yizhi powder, and Compound Congrong Yizhi capsules <sup>[7-13]</sup>. These formulae are designed based on TCM theoretical principles combined with modern pharmacological research, demonstrating multi-target and multi-pathway mechanisms. Clinical studies confirm their significant efficacy in improving cognitive function and delaying disease progression. Notably, recent research has focused on modulating the gut microbiota environment to suppress excessive activation of intestinal glial cells and astrocytes, thereby preventing the progression of neuroinflammation. This approach aims to reduce peripheral immune cell infiltration into the brain and inhibit microglial inflammation in the central nervous system, ultimately lowering the incidence of late-stage AD-associated neuroinflammation and improving patients' cognitive function <sup>[14-17]</sup>.

Extracts from *Magnolia officinalis* (Houpo), *Polygala tenuifolia* (Yuanzhi), *Nardostachys jatamansi* (Gansong), and algae (Sodium Oligomannate, extracted from algae) have been specifically reported for these effects.

In traditional non-pharmacological treatments, acupuncture and moxibustion have been shown to regulate cerebrovascular function, improve cerebral blood supply, inhibit neuroinflammation, reduce oxidative stress, promote neuroregeneration, protect neurons, and regulate neurotransmitters, thereby enhancing cognitive function. In recent years, various innovative techniques have been developed, such as electroacupuncture, laser acupuncture, and abdominal acupuncture<sup>[18–21]</sup>. These new techniques combine traditional acupuncture and modern theories with modern scientific technologies, enhancing therapeutic effects. Studies have indicated that electroacupuncture stimulation of specific acupuncture points can regulate gastrointestinal function<sup>[22, 23]</sup>. Acupuncture at Tianshu and Zusanli points not only increases the abundance of beneficial gut probiotics but also effectively alleviates gut microbiota dysbiosis. These interventions help maintain the integrity of neural networks and gastrointestinal cellular structures, thereby modulating the gut microbiota and improving cognitive function and quality of life in Alzheimer's disease patients. Furthermore, traditional Chinese medicine (TCM)-based therapies such as music therapy and aromatherapy have also been applied in the prevention and treatment of Alzheimer's disease, with certain achievements reported<sup>[24–28]</sup>.

#### **4. Community-based prevention and treatment model integrating traditional Chinese medicine theory**

Traditional Chinese medicine (TCM) is an important component of excellent traditional Chinese culture. With the advent of the “health-centered” medical model, community-level disease prevention and treatment has increasingly demonstrated its cornerstone role. According to the data from the Seventh National Population Census, the population aged 65 and above in China has reached 13.50%, marking the country's entry into a deeply aging society. In the early stages of Alzheimer's disease among the elderly, symptoms are limited to memory impairment and inattention, which are easily overlooked as normal aging or stress-related and thus neglected. Furthermore, the lack of specific biomarkers and effective auxiliary diagnostic tools, coupled with the challenges in accurately diagnosing the disease through existing imaging and neuropeptide tests, makes early detection of Alzheimer's disease extremely difficult. Given this context, it is imperative to emphasize TCM's holistic concept and preventive healthcare principles (“treating before disease occurs”). Community-based interventions should prioritize identifying high-risk groups through analysis of TCM constitutional characteristics rather than relying solely on individualized syndrome differentiation. Population-oriented treatment models must integrate both symptom differentiation and TCM constitutional assessment to enhance preventive care effectiveness.

Traditional Chinese medicine (TCM) emphasizes individualized treatment through syndrome differentiation, where prevention and therapeutic strategies are tailored to patients' specific conditions. The holistic concept focuses on comprehensively assessing overall health status, prioritizing systemic functional regulation over isolated disease manifestations to enhance disease resistance. Through syndrome differentiation and treatment, early identification of disease risk factors and signs is possible. Through the holistic perspective, comprehensive regulation of the body's functional state and enhancement of immunity can be achieved, thereby preventing diseases.

Extracting traditional medications and treatment methods proven effective in clinical practice, advancing the treatment intervention to the preventive window period, leveraging modern technology and medicine-centered

multidisciplinary collaboration and integration, adopting the TCM concept of “preventive treatment of disease” to view the entire susceptible population, and combining modern community medical resources to provide dialectical solutions can enrich the new integrated community prevention and treatment model of “prevention-intervention-rehabilitation,” potentially becoming a new breakthrough in Alzheimer’s treatment and intervention with Chinese characteristics to improve cognitive function and delay disease progression.

In the prevention phase, high-risk individuals are identified through TCM constitution identification and risk assessment, and personalized prevention plans are developed. These plans include TCM health guidance, emotional regulation, and exercise therapy, aiming to delay cognitive decline and prevent the occurrence of Alzheimer’s disease. In the intervention phase, an integrated traditional Chinese and Western medicine approach is adopted to develop individualized treatment plans for patients at different stages. These plans include Chinese herbal medicine treatment, acupuncture therapy, cognitive training, etc., aiming to improve cognitive function and delay disease progression. In the rehabilitation phase, emphasis is placed on functional recovery and improved quality of life. With the help of TCM rehabilitation techniques such as Tui Na (Chinese massage) and Qigong (breathing exercises), combined with community support services, patients are assisted in maintaining daily living abilities and reducing the burden on families and society.

## **5. Conclusion**

Alzheimer’s disease in the elderly is a complex pathological process characterized by multifactorial etiology, multisystemic involvement, and progressive, fulminant, and severely debilitating clinical trajectories. This study systematically reviews recent advances in community-based prevention and treatment of Alzheimer’s disease from the perspective of traditional Chinese medicine (TCM). Modern TCM research has deepened understanding of the disease’s pathogenesis through integrative studies combining classical theories with modern physiological and pharmacological mechanisms. Notably, innovative theories such as brain-gut axis dysregulation have emerged, alongside novel therapeutic approaches and empirical evidence that revitalize classical formulas through scientific exploration. Future research should focus on elucidating the precise mechanisms of TCM interventions, optimizing community-based prevention models, and providing more robust scientific evidence to enhance treatment efficacy and improve the quality of life for elderly patients.

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## **Disclosure statement**

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## References

- [1] Bai S, 2007, Understanding and Syndromal Differentiation of Alzheimer's Disease in Traditional Chinese Medicine (TCM). *China Medical Guidelines*, 5(12): 706–707. DOI: 10.3969/j.issn.1671-8194.2007.12.158.
- [2] Track NS, 1980, The Gastrointestinal Endocrine System. *Canadian Medical Association Journal*, 122(3): 287–292.
- [3] Goyal D, Ali SA, Singh RK, 2021, Emerging Role of Gut Microbiota in Modulation of Neuroinflammation and Neurodegeneration with Emphasis on Alzheimer's Disease. *Progress in Neuropsychopharmacology & Biological Psychiatry*, 106: 110112. DOI: 10.1016/j.pnpbp.2021.110112.
- [4] Bai Shuyu. Understanding and Syndromal Differentiation of Alzheimer's Disease in Traditional Chinese Medicine (TCM) [J]. *China Medical Guidelines*, 2007, 5(12): 706-707.
- [5] Dong J, 2015, Cerebral Atrophy and Cognitive Impairment. *Practical Geriatric Medicine*, 29(4): 277–279. DOI: 10.3969/j.issn.1003-9198.2015.04.004.
- [6] Sun N, Mormino EC, Chen J, et al., 2019, Multi-modal Latent Factor Exploration of Atrophy, Cognitive and Tau Heterogeneity in Alzheimer's Disease. *NeuroImage*, 201: 116043.
- [7] Jiao H, 2023, Systematic Evaluation of the Efficacy and Safety of Chinese Patent Medicines for Vascular Cognitive Impairment, thesis, Shaanxi University of Chinese Medicine, 2023.
- [8] Chongqing Institute of Chinese Materia Medica, 2023, A Traditional Chinese Medicine Compound for Enhancing Brain Function and Intelligence: Composition and Preparation Method. Patent No. CN202211494430.4.
- [9] Liu S, Miao L, Mou L, et al., 2019, Quality Standard Research of Jiannao Yishen Pills. *China Medical Herald*, 16(1): 24–27, 32.
- [10] Zhang X, Yin J, Ji Y, et al., 2023, Combined Effects of Xingnao Guanchang Liquid and Jianpi Yizhi Capsules on TrkB Expression, Motor Function, and Notch1 Signaling in Stroke-induced Rats. *Chinese Journal of Gerontology*, 43(14): 3511–3515. DOI: 10.3969/j.issn.1005-9202.2023.14.045.
- [11] Chen W, Hu L, Lin Y, 2021, Randomized, Double-Blind, Parallel-Controlled, Multicenter Clinical Study of Tianma Xingnao Capsules in Patients with Mild-to-Moderate Vascular Dementia (Kidney-Yin Deficiency, Liver-Wind Disturbance Pattern). *Journal of Anhui University of Chinese Medicine*, 40(1): 30–34. DOI: 10.3969/j.issn.2095-7246.2021.01.009.
- [12] Zhang R, Wang M, Chen H, 2017, Clinical Observation of Haima Yizhi San Combined with Acupuncture in 48 Cases of Vascular Dementia. *New Chinese Medicine*, 49(12): 142–145. DOI: 10.13457/j.cnki.jncm.2017.12.047.
- [13] Wang H, Zhang X, Zhang X, 2024, Study on Compound Congrong Yizhi Capsules for Mild-to-Moderate Vascular Dementia. *Jilin Journal of Chinese Medicine*, 44(9): 1055–1059. DOI: 10.13463/j.cnki.jlzyy.2024.09.015.
- [14] Zhang J, 2022, A Study on the Effects of Houpu on Functional Dyspepsia Rats and Its Metabolic Markers via the Gut-Brain Axis, thesis, China Academy of Chinese Medical Sciences, 2022.
- [15] Chen Q, Yu L, Zhao W, et al., 2021, Study on the Effects of Farzhi Extract on Intestinal Microbiota in Depressive Rats. *Chinese Materia Medica*, 52(8): 2313–2323. DOI: 10.7501/j.issn.0253-2670.2021.08.014.
- [16] Xue J, Wan G, Li J, et al., 2023, Mechanistic Study of Gan Song on Motor Dysfunction and Parkinson's Disease Pathogenesis via the Gut-Brain Axis. *Chinese Materia Medica*, 54(9): 2822–2831. DOI: 10.7501/j.issn.0253-2670.2023.09.015.
- [17] Zhang Y, Yu X, Lu F, et al., 2024, Combined Effects of Sodium Glutamate Capsules and Donepezil on Cognition and Gut Microbiota in Mild-to-Moderate Alzheimer's Disease. *Modern Biomedical Progress*, 24(20): 3870–3872. DOI: 10.13241/j.cnki.pmb.2024.20.016.
- [18] Wan F, Zhu P, 2023, Exploring Acupuncture's Role in Modulating Gut Microbiota for Alzheimer's Disease Prevention

via the Brain-Gut Axis. *Hebei Journal of Traditional Chinese Medicine*, 38(3): 29–34.

- [19] Yuan F, Hong X, Duan Y, et al., 2021, Effects of Electroacupuncture at ST36 on Pancreatic and Hippocampal Tau Phosphorylation in Diabetic Rats. *Acupuncture Research*, 46(11): 901–906, 947. DOI: 10.13702/j.1000-0607.200921.
- [20] Yu G, Yin R, Guan Y, et al., 2024, Simulated Transcranial Scalp Acupuncture Manipulation on Learning-Memory and Cerebral Microcirculation in Vascular Dementia Rats. *Acupuncture Research*, 49(9): 917–923. DOI: 10.13702/j.1000-0607.20230474.
- [21] Jiang S, Zheng M, Wang Z, et al., 2024, Exploring Abdominal Acupuncture Therapy for Dementia Based on the “Heaven-Earth-Human” Multilayer Regulation Theory. *Chinese Health Preservation Journal*, 42(3): 77–81.
- [22] Ben D, Liu Q, Chen Y, et al., 2016, Clinical Observation of Electroacupuncture at ST36 and Fenglong for Senile Dementia. *Acupuncture and Moxibustion Medicine*, 14(6): 386–390.
- [23] Chen D, Zhang H, Xie J, et al., 2022, Effects of Electroacupuncture on Intestinal Microbiota and Serum IL-1 $\beta$ /IL-18 in Vascular Dementia Rats. *Acupuncture Research*, 47(3): 216–223.
- [24] Hong M, Li X, Hu W, 2023, Combined Effects of Music Therapy and Transcranial Magnetic Stimulation on Cognitive Function and Activities of Daily Living in Stroke Patients with Cognitive Impairment. *Chinese Journal of Rehabilitation Medicine*, 38(12): 1745–1748. DOI: 10.3969/j.issn.1001-1242.2023.12.019.
- [25] Muddasani SR, 2023, Cost-effective Treatment of Alzheimer’s Disease: Music Therapy. *Medical Forum*, 5(22): 3–5. DOI: 10.12417/2705-098X.23.22.002.
- [26] Liu B, Ma N, Shi J, et al., 2020, Applications of Aromatherapy in Cognitive Disorder Management. *Life Chemistry*, 40(7): 1079–1085. DOI: 10.13488/j.smhx.20190446.
- [27] He J, Liu Y, Shi Y, et al., 2023, Non-pharmacological Therapies for Alzheimer’s Disease: Advances in Research on the Entorhinal Cortex. *Chinese Journal of Traditional Chinese Medicine*, 38(10): 4847–4850.
- [28] Duan R, Lin L, 2023, Meta-analysis of Aromatherapy on Agitation Behavior in Elderly Patients with Dementia. *Modern Medicine*, 51(5): 643–648.

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# Research on the Integration of Traditional Chinese Medicine Theory into Medical Students' Clinical Internship

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**Abstract:** The integration of traditional Chinese medicine (TCM) into clinical education presents an opportunity to enhance medical training by providing students with a more holistic approach to patient care. This study explores the methods and challenges of integrating TCM theory into clinical internships for medical students at the First Affiliated Hospital of Guizhou University of Traditional Chinese Medicine. A mixed-methods approach was employed, combining quantitative surveys and qualitative interviews with medical students, clinical instructors, and TCM practitioners. The results indicate that while students generally recognize the relevance and benefits of TCM in enhancing diagnostic skills and promoting a holistic understanding of health, several challenges remain. These include the lack of standardized TCM training, limited practical exposure to TCM diagnostic methods, and resistance from some clinical instructors. Despite these challenges, students expressed a strong desire for more structured TCM training and greater support from instructors. Based on the findings, the study recommends the standardization of TCM curricula, enhanced professional development for instructors, and increased collaboration between Western and TCM practitioners. The study concludes that the integration of TCM into medical education can significantly improve student clinical skills and patient care outcomes if appropriately structured and supported.

**Keywords:** Traditional Chinese medicine; Clinical education; Medical internships; TCM integration; Medical curriculum; Holistic approach; Student training; Healthcare education; Interdisciplinary collaboration

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## 1. Introduction

Traditional Chinese medicine (TCM) has a profound history, with roots extending over two millennia, offering a unique and holistic approach to healthcare. It focuses on the balance of the body's vital forces, often referred

to as Qi, and the relationship between the human body and its environment, emphasizing the interconnectedness of physical, mental, and spiritual health. In recent decades, TCM has gained increasing recognition worldwide, not only for its efficacy in treating a variety of health conditions but also for its potential to complement modern medical practices. Despite its long-standing existence, the integration of TCM into contemporary medical curricula remains a challenge, especially in clinical training environments where Western medicine predominantly shapes the educational framework.

The application of TCM theory in clinical practice offers significant benefits, particularly in promoting a more holistic understanding of patient care. TCM's core principles, such as Yin-Yang, the Five Elements, and the Zang-Fu organ theory, provide a comprehensive view of health, which contrasts with the more reductionist approaches of Western medicine. These traditional concepts can deepen students' understanding of disease pathogenesis, diagnosis, and treatment by encouraging them to consider the broader context of a patient's condition, something that may be underemphasized in conventional medical training. However, despite this potential, medical students often face challenges in fully incorporating TCM principles into their clinical practice during internships due to the dominant focus on Western methodologies<sup>[1-3]</sup>.

The First Affiliated Hospital of Guizhou University of Traditional Chinese Medicine plays a pivotal role in medical education, offering a distinctive environment for the training of both undergraduate and graduate students in TCM. This hospital, with its integration of both traditional and modern medical practices, provides a unique opportunity to examine how TCM theory can be effectively integrated into clinical internships. The purpose of this study is to investigate the methods of integrating TCM theory into the clinical internships of medical students, focusing on how these methods can enrich the students' clinical skills and improve their diagnostic and treatment abilities.

This research aims to achieve the following objectives: first, to identify the strategies and methods used to incorporate TCM principles into medical student training; second, to evaluate the effectiveness of these integration methods from the perspectives of both students and clinical instructors; and third, to explore the challenges and barriers faced by students and faculty in incorporating TCM theory into clinical practice. Furthermore, this study seeks to provide actionable recommendations for enhancing the integration of TCM into the clinical education system.

By investigating the integration of TCM into clinical internships, this paper will offer insights into how medical students can benefit from a more holistic approach to patient care, one that encompasses both Western and Eastern medical traditions. Ultimately, the findings of this research could contribute to the development of an educational framework that fosters greater understanding and application of TCM principles, enhancing the overall quality of medical education and patient care.

## **2. Literature review**

### **2.1. Overview of traditional Chinese medicine education in medical curricula**

Traditional Chinese medicine (TCM) has a long and rich history, offering a holistic approach to healthcare that emphasizes the balance of physical, mental, and spiritual well-being. Despite its profound influence, TCM has faced challenges in gaining widespread integration into mainstream medical education, particularly in clinical internships where Western medicine tends to dominate. In many regions, TCM is treated as a complementary or alternative approach rather than being fully integrated into the core curriculum of medical schools.

The integration of TCM into medical curricula has been approached differently across educational systems. In countries where TCM has a long-standing tradition, such as China, its principles are often embedded within the medical curriculum. However, in other parts of the world, TCM is largely excluded from the mainstream medical training, and students are exposed to it in a limited, often theoretical manner. This divergence in educational practices highlights the challenges faced by medical schools in effectively incorporating TCM principles into their clinical training programs<sup>[4, 5]</sup>.

Although some medical schools offer courses in TCM, these courses are typically not included as part of clinical internships, where hands-on experience and direct patient care are emphasized. This discrepancy between classroom learning and clinical practice can hinder medical students from fully understanding how TCM concepts can be applied in real-world healthcare settings.

## **2.2. The role of TCM theory in clinical practice**

TCM is founded on several key theoretical principles, such as Yin-Yang, Qi, the Five Elements, and Zang-Fu organ theory. These theories provide a framework for understanding the body's health and its interactions with the environment. While Western medicine often focuses on the biological and mechanical aspects of disease, TCM emphasizes balance, harmony, and the interconnectedness of bodily systems. By considering these broader factors, TCM offers an alternative perspective that can complement conventional medical practices.

In clinical practice, TCM theory serves as a guide for diagnosing and treating a wide range of conditions, particularly chronic and complex diseases. TCM encourages a more personalized approach to care, where the practitioner takes into account not only the physical symptoms but also the emotional and environmental factors that may contribute to the patient's condition. This holistic perspective can help medical students gain a deeper understanding of the complexities of patient health and expand their diagnostic and therapeutic skills<sup>[4-7]</sup>.

Despite its potential benefits, the integration of TCM into clinical practice faces challenges. Many medical students, especially those trained in Western medicine, may find it difficult to apply TCM principles alongside the evidence-based practices they have learned. TCM's emphasis on qualitative assessment methods, such as pulse diagnosis and pattern identification, contrasts with the more quantitative and standardized diagnostic techniques of Western medicine. This difference can lead to confusion and difficulty in integrating both approaches during clinical internships.

## **2.3. Challenges in integrating TCM into clinical education**

Several obstacles hinder the effective integration of TCM into clinical education. One major challenge is the resistance to change from both medical students and clinical instructors who may have limited exposure to TCM or may not fully understand its principles. For many students, especially those primarily trained in Western medicine, TCM can seem foreign and disconnected from the evidence-based approaches they are accustomed to. This resistance is often compounded by the lack of a clear, standardized framework for teaching and applying TCM in clinical settings.

Another challenge is the shortage of qualified instructors who are proficient in both Western and TCM practices. The integration of TCM into clinical internships requires instructors who are not only experts in Western medical techniques but also well-versed in the application of TCM principles in patient care. Without such dual expertise, students may struggle to understand how to effectively apply both paradigms in their clinical practice.

Additionally, TCM's reliance on more subjective, individualized methods of diagnosis and treatment presents

a challenge in a clinical internship setting where standardization and objectivity are often prioritized. TCM's holistic approach, which involves a detailed examination of a patient's emotional, physical, and environmental states, does not always align with the more reductionist approach of Western medicine. As a result, students may find it challenging to reconcile these two approaches when making clinical decisions <sup>[8]</sup>.

## **2.4. Benefits of integrating TCM in medical education**

Despite these challenges, there are significant benefits to integrating TCM into clinical education. One of the most notable advantages is the development of a more holistic understanding of health. TCM encourages students to consider the interconnectedness of the body's systems, the role of environmental factors, and the importance of prevention and lifestyle modification. This approach can be particularly valuable when addressing complex and chronic health conditions that require long-term management, rather than just acute intervention.

Furthermore, TCM's emphasis on patient-centered care aligns well with the growing emphasis on personalized medicine in modern healthcare. By incorporating TCM principles into their training, medical students can develop a more comprehensive approach to patient care that considers the whole person, rather than focusing solely on specific diseases or symptoms. This approach can foster a deeper empathy for patients and improve the overall quality of care.

The integration of TCM can also enhance students' diagnostic skills by encouraging them to look beyond the immediate physical symptoms and consider the broader context of a patient's health. This can be particularly useful in cases where conventional treatments may not be sufficient or when the patient presents with symptoms that do not fit neatly into Western diagnostic categories.

## **2.5. Conclusion of the literature review**

The literature highlights the ongoing challenges and barriers to integrating TCM into clinical education. Resistance to change, the lack of qualified instructors, and the absence of standardized teaching frameworks are significant obstacles that need to be addressed. However, there is also considerable evidence supporting the benefits of TCM integration, particularly in enhancing diagnostic skills and fostering a holistic approach to patient care.

In order to effectively integrate TCM into medical curricula, it is essential to develop standardized guidelines and teaching strategies that clearly define how TCM can be applied in clinical settings. By doing so, medical schools can ensure that students gain a comprehensive understanding of both Western and Eastern medical practices, which will ultimately contribute to better patient outcomes and a more holistic approach to healthcare.

## **3. Theoretical framework**

### **3.1. Core principles of traditional Chinese medicine**

Traditional Chinese medicine (TCM) is built upon a set of foundational theories that explain the dynamics of health and disease. These principles are rooted in a holistic understanding of the human body, where the physical, mental, and environmental aspects are seen as interconnected and interdependent. The primary concepts of TCM that influence its clinical practice include Yin-Yang, Qi, the Five elements, and Zang-Fu organ theory. These theories provide a framework that guides diagnosis, treatment, and prevention <sup>[9]</sup>.

- (1) Yin-Yang theory: One of the most fundamental concepts in TCM, Yin-Yang represents the dualistic nature of existence. Yin and Yang are opposite but complementary forces that are in a constant state of dynamic

balance. In TCM, health is viewed as the harmonious interaction between Yin and Yang within the body. An imbalance in this relationship leads to disease. For instance, a deficiency in Yin (cool, passive energy) or an excess of Yang (hot, active energy) can manifest as various clinical conditions such as fever or cold sensations.

- (2) Qi: Qi, often translated as “vital energy” or “life force,” is another core concept in TCM. It is considered the vital substance that flows through the body, sustaining all physiological functions. Qi is believed to circulate through pathways called meridians, and any disruption in its flow can lead to illness. Qi deficiency, stagnation, or blockage is commonly identified as a cause of many ailments. Treatment in TCM aims to restore the smooth flow of Qi and reestablish balance in the body <sup>[10–12]</sup>.
- (3) Five elements theory: The five elements—wood, fire, earth, metal, and water—are used in TCM to explain the relationships and interactions between the body’s organs and systems. Each element is associated with specific organs, emotions, and physiological functions. For example, the liver is associated with wood, the heart with fire, and the kidney with water. These elements are in constant interaction, and imbalances among them can result in physical and emotional disorders. The five elements theory is essential for understanding the underlying causes of disease and creating individualized treatment plans.
- (4) Zang-Fu organ theory: This theory categorizes the organs in TCM into two groups: Zang (solid organs) and Fu (hollow organs). The Zang organs, including the heart, liver, spleen, lung, and kidney, are responsible for the production and storage of vital substances such as Qi, blood, and fluids. The Fu organs, such as the stomach, large intestine, and bladder, primarily function to transform, transport, and excrete substances. The interaction between Zang and Fu organs governs the body’s overall health. Disruptions in their function can manifest as various diseases, which are treated by restoring balance between these organs <sup>[13, 14]</sup>.

### 3.2. Integration of TCM theories into clinical practice

In clinical practice, TCM’s core theories are applied to diagnose and treat diseases based on a holistic approach. Unlike Western medicine, which often focuses on isolated symptoms and specific organs, TCM emphasizes the interconnectedness of the entire body. Diagnosis in TCM involves a thorough assessment of the patient’s physical, emotional, and environmental states through various methods, such as pulse-taking, tongue examination, and inquiry into lifestyle and habits.

- (1) Diagnosis: In TCM, diagnosis is not limited to laboratory tests or imaging but includes a comprehensive understanding of the patient’s symptoms, lifestyle, and constitutional factors. The four diagnostic methods—observation, auscultation and olfaction, inquiry, and palpation—are used to gather information and form a diagnosis. For example, a TCM practitioner may examine the tongue and pulse to determine the state of Qi and blood, identify any imbalances in Yin and Yang, and understand the underlying root cause of the condition.
- (2) Treatment: The treatment in TCM is aimed at restoring balance within the body using methods such as acupuncture, herbal medicine, and Qi Gong. Acupuncture stimulates specific points on the body to regulate the flow of Qi and restore balance in the Yin-Yang relationship. Herbal medicine uses a wide variety of plants and natural substances to treat imbalances, often targeting specific organs or systems to promote healing. Dietary therapy, which aligns with the principles of the five elements, is also commonly employed to support the body’s natural healing processes.

### 3.3. The role of TCM theory in enhancing clinical education

The integration of TCM theory into clinical education offers a valuable opportunity to expand medical students' perspectives on health and disease. While Western medicine emphasizes the scientific and evidence-based treatment of diseases, TCM offers an alternative approach by encouraging students to view health through a more holistic lens. This broader perspective can deepen students' understanding of patient care, particularly in treating chronic conditions, multifactorial diseases, and patients with complex health profiles.

- (1) Holistic approach to patient care: The holistic nature of TCM encourages students to consider not only the physical symptoms of a patient but also the emotional, psychological, and environmental factors that contribute to the patient's overall health. This aligns with the growing emphasis on patient-centered care in modern medicine, where treatment is tailored to the individual rather than being based solely on disease-specific protocols.
- (2) Preventive medicine: TCM places a strong emphasis on prevention, which is increasingly important in contemporary medical practice. By incorporating TCM theory, students can learn the importance of preventing disease before it manifests, rather than focusing only on the treatment of existing conditions. Prevention in TCM includes dietary adjustments, lifestyle changes, and the use of herbs and acupuncture to maintain balance and strengthen the body's resistance to illness.
- (3) Complementary role in modern medicine: TCM theory also complements modern Western medical practices. By integrating both approaches, medical students can develop a more comprehensive and flexible approach to patient care. For instance, TCM's focus on individualized treatment can be beneficial in addressing conditions that are less well-understood or poorly managed by Western medicine alone, such as chronic pain, gastrointestinal disorders, and stress-related conditions <sup>[15]</sup>.

### 3.4. Bridging Eastern and Western medical practices

The integration of TCM theory into clinical internships allows medical students to experience firsthand how these two approaches can work together to enhance patient care. While Western medicine is rooted in scientific research and evidence-based practices, TCM offers a different perspective that focuses on the balance of energies and the prevention of illness. By blending these approaches, students can learn to recognize the strengths and limitations of both systems and apply them effectively in clinical settings.

This theoretical framework highlights the value of integrating TCM theories into medical education. By understanding and applying TCM principles, students can develop a more nuanced approach to patient care, enhancing their ability to treat a wide range of conditions and improving patient outcomes. Furthermore, the incorporation of TCM theory can foster a deeper understanding of health as an interconnected system, promoting more effective, individualized, and preventive care.

## 4. Methodology

### 4.1. Study design

This mixed-methods study explores the integration of Traditional Chinese Medicine (TCM) theory into clinical internships at the First Affiliated Hospital of Guizhou University of traditional Chinese medicine. Quantitative data are collected through structured surveys, while qualitative insights coming from in-depth interviews and participant observations. This approach enabled a comprehensive analysis of the benefits and challenges of

integrating TCM into clinical education.

## **4.2. Participants**

Participants included 150 final-year medical students, 30 clinical instructors (from both TCM and Western medicine), and 15 experienced TCM practitioners. Purposive sampling ensured relevant experience with TCM education and clinical practice. Twenty students, along with all instructors and practitioners, also participated in interviews.

## **4.3. Data collection**

Quantitative data are gathered via a 30-item electronic survey assessing attitudes and experiences with TCM integration. Semi-structured interviews explored the relevance of TCM theory, integration challenges, and suggestions for improvement. Participant observations documented clinical interactions, including diagnostic methods and TCM treatments in practice.

## **4.4. Data analysis**

Survey responses are analyzed using descriptive and inferential statistics. Interview transcripts underwent thematic analysis using both inductive and deductive coding. Triangulation of survey, interview, and observation data enhanced validity and ensured robust findings.

## **4.5. Ethical considerations**

The study is approved by the hospital's IRB. All participants gave informed consent, with assurances of confidentiality and the right to withdraw at any time.

## **4.6. Limitations**

Findings are limited by the single-site design and reliance on self-reported data. Broader studies using objective measures across institutions are recommended.

# **5. Results**

## **5.1. Overview of participants**

A total of 150 medical students completed the survey (80% response rate), alongside interviews with 20 students, 30 clinical instructors, and 15 TCM practitioners. The student group was 60% female with an average age of 24. Most students (70%) had prior exposure to TCM. Instructors included both Western-trained doctors (60%) and TCM practitioners (40%), averaging 10 and 15 years of experience, respectively.

## **5.2. Quantitative results**

Survey results indicated that 75% of students saw TCM as relevant to clinical practice, though 25% found integration difficult. Sixty percent felt confident combining TCM and Western medicine, while 40% lacked confidence. Seventy percent believed TCM improved diagnostic skills, and 65% reported using TCM methods like pulse-taking. Satisfaction was high, with 80% valuing TCM exposure and 70% desiring more structured training.

### 5.3. Qualitative results

Interview data highlighted perceived benefits of TCM's holistic view, particularly for chronic conditions. However, students faced challenges applying TCM in settings dominated by Western diagnostic methods. Instructor support varied, with some lacking TCM expertise. Many students called for more structured, hands-on TCM training during internships.

### 5.4. Instructor and TCM practitioner feedback

Clinical instructors generally supported TCM integration but noted limited capacity to teach it effectively. TCM practitioners emphasized the need for collaboration with Western-trained staff and expressed willingness to mentor students.

## 6. Conclusion

Overall, students viewed TCM integration positively, citing enhanced diagnostic skills and patient understanding. However, they also identified barriers such as limited training opportunities and inconsistent instructor support. Expanding structured, practical TCM training and fostering interdisciplinary collaboration are key to improving integration in clinical education.

## Disclosure statement

The authors declare no conflict of interest.

## References

- [1] Zhou Y, 2022, Research on the Quality Monitoring System of Clinical Internship in Traditional Chinese Medicine. *Science and Technology Information*, 20(9): 203–206. DOI: 10.16661/j.cnki. 1672-3791.2201-5042-7782
- [2] Zhao S, Sun W, Li X, 2019, Reform of Formative Evaluation System Based on Networked PBL+CBL in Clinical Internship Teaching of Traditional Chinese Medicine. *Modern Distance Education of Traditional Chinese Medicine in China*, 17(24): 7–9. DOI: 10.3969/j.issn.1672-2779.2019.24.003
- [3] Wei X, 2020, A Preliminary Analysis of Teaching Issues and Countermeasures for Interns Majoring in Traditional Chinese Medicine Entering the Clinical Internship Stage. *Clinical Medical Literature Electronic Journal*, 7(51): 190–191.
- [4] Zheng Z, Liang F, Zhang X, et al., 2024, The Role of Famous Chinese Medicine Studios in Undergraduate Practice of Acupuncture and Moxibustion and Massage. *Modern Distance Education of Chinese Medicine*, 22(13): 4–7. DOI: 10.3969/j.issn.1672-2779.2024.13.002
- [5] Chen W, Peng D, 2024, Application of “Three Rings and Three Stages” Mixed Teaching Method Based on OBE Concept in Internship Teaching of Traditional Chinese Medicine Pulmonary Disease Department. *Journal of Guangxi University of Chinese Medicine*, 27(6): 107–111. DOI: 10.3969/j.issn.2095-4441.2024.06.26
- [6] Yang R, Jiao N, Huo H, et al., 2024, Research on Satisfaction Evaluation of Clinical Graduation Internship for Undergraduate Students Majoring in Traditional Chinese Medicine. *Traditional Chinese Medicine Education*, 43(4): 126–131. DOI: 10.3969/j.issn.1003-305X. 2024.04.798
- [7] Zheng Y, Wang Y, 2024, Application of Modular Teaching in the Training of Interns in Traditional Chinese

- Medicine. *Modern Distance Education of Traditional Chinese Medicine in China*, 22(7): 21–23. DOI: 10.3969/j.issn.1672-2779.2024.07.007
- [8] Wang F, Lin Z, Yang X, et al., 2024, Chinese Medicine Clinical Thinking Training for Nursing Interns Based on Internet Plus. *Modern Distance Education of Chinese Medicine*, 22(18): 203–206. DOI: 10.3969/j.issn.1672-2779.2024.18.064
- [9] Han J, Pang X, Wang X, et al., 2024, A New Model for Undergraduate Internship and Training in Traditional Chinese Medicine Based on Ideological and Political Education Courses. *Modern Distance Education of Traditional Chinese Medicine in China*, 22(3): 4–6. DOI: 10.3969/j.issn.1672-2779.2024.03.002
- [10] Lai C, Wu Y, 2024, Research on the Clinical Thinking Effect of Undergraduate Interns in Traditional Chinese Medicine Based on the Kirkpatrick Evaluation Model. *Modern Distance Education of Traditional Chinese Medicine in China*, 22(14): 1–3. DOI: 10.3969/j.issn.1672-2779.2024.14.001
- [11] Yang S, Xu Q, 2024, Analysis of the Application Effect of PBL Teaching Mode in Clinical Practice Teaching of Traditional Chinese Medicine. *China Health Industry*, 21(18): 158–160. DOI: 10.16659/j.cnki.1672-5654.2024.18.158
- [12] Qiu J, Zhu Y, Yuan S, 2023, Preliminary Exploration of Clinical Teaching Difficulties for Undergraduate Interns in Traditional Chinese Medicine. *Guangming Traditional Chinese Medicine*, 38(3): 564–567. DOI: 10.3969/j.issn.1003-8914.2023.052
- [13] Wang D, Zhang W, Lv S, 2023, Evaluation of the Application Effect of PBL Teaching Method in Clinical Practice of Traditional Chinese Medicine. *Xinjiang Traditional Chinese Medicine*, 41(5): 62–64.
- [14] Wang Q, 2023, Teaching Reform Ideas for Clinical Internship in Traditional Chinese Medicine Internal Medicine. *Science and Education Guide (Electronic Edition)*, 2023(24): 234–236.
- [15] Feng J, 2023, A Study on the Status Quo and Influencing Factors of Self-Cognition of Traditional Chinese Medicine Clinical Thinking Among Medical Interns. *China Higher Medical Education*, 2023(9): 48–49. DOI: 10.3969/j.issn.1002-1701.2023.09.018

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# A Bibliometric Analysis of Research Trends in Neck Pain from 2000 to 2025

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**Abstract:** *Objective:* This paper conducts a bibliometric analysis of the literature on neck pain research from 2000 to 2025, aiming to comprehensively and systematically understand the research landscape, hotspots, and frontier trends in this field, providing a reference for future research directions. *Methods:* Data were sourced from the Web of Science Core Collection, with the search term TI = “neck pain,” covering the time span from 2000 to 2025, resulting in 2746 articles. Software such as CiteSpace V6.3.R1 and VOSviewer 1.6.20 was used to analyze publication volume, countries, authors, institutions, keywords, and co-citation networks. *Results:* The number of publications in neck pain research has been increasing year by year, indicating a rising level of research activity. Authors like Falla, D, Jull, G, and institutions such as Univ Queensland and Univ Toronto have significant influence in this field. Co-occurrence analysis of keywords shows that “neck pain,” “low back pain,” and “disability index” are high-frequency keywords, reflecting research hotspots such as the characteristics and treatment of neck pain and its interrelation with pain in other regions. Timeline analysis and keyword emergence analysis reveal the frontiers and development trends in this field, such as the growing attention on emerging therapeutic methods like “exercise therapy” and “dry needling,” while keywords like “intensity,” “individuals,” and “quality” indicate an increasing emphasis on personalization, precision, and quality control in the treatment process. *Conclusion:* The field of neck pain research is continuously expanding and deepening. Future research should further investigate the pathogenesis of neck pain, its associations with other conditions, the refinement of assessment methods, and the development of innovative rehabilitation strategies. Emphasis should also be placed on interdisciplinary collaboration to provide more robust theoretical foundations and practical guidance for the clinical treatment and rehabilitation management of neck pain.

**Keywords:** Neck pain; CiteSpace; VOSviewer; Bibliometrics; Research Trends

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## 1. Introduction

Neck pain, as one of the common pain conditions in clinical practice, severely affects the quality of life and

work efficiency of modern people and brings a heavy burden to society <sup>[1]</sup>. With the increasing demand for health and the rapid development of medical technology, research on neck pain has attracted widespread attention. Relevant studies cover multiple aspects, including pathogenesis, diagnostic methods, therapeutic strategies, and rehabilitation management, and have achieved many results <sup>[2]</sup>. However, research on neck pain still faces some challenges, such as insufficient understanding of the pathogenesis, the need to optimize evaluation methods, and significant individual differences in therapeutic effects <sup>[3]</sup>. Against this background, this paper uses bibliometric methods to conduct a quantitative analysis of the relevant literature in the field of neck pain research from 2000 to 2025, aiming to comprehensively and systematically understand the research trends, hotspots, and cutting-edge trends in this field, provide references for future research directions, promote further development of neck pain research, and provide more scientific and effective theoretical support and technical guidance for clinical practice.

## 2. Methods

### 2.1. Data source and search strategy

The data in this paper are from the Web of Science Core Collection. The citation index selected is “Science Citation Index Expanded (SCI-EXPANDED)–1900 to present”. The search formula is: TI = “neck pain”, time span: 2000–2025, and the search date is March 13, 2025. The document type is limited to articles and review articles, excluding conference proceedings papers, online publications, letters, review materials, etc. At the same time, to ensure the quality and representativeness of the source data, two members of the research group screened the literature based on the titles and abstracts, excluded completely irrelevant literature, checked and compared it, and removed duplicates. Finally, 2746 articles are retained.

### 2.2. Data analysis tools

Bibliometric analysis software, such as CiteSpace V6.3.R and VOSviewer1.6.20, are used to conduct bibliometric analysis on the number of publications, countries, authors, institutions, keywords, and co-citation networks.

## 3. Results

### 3.1. Top 10 authors by publication output

**Table 1** shows the relevant data of the top 10 authors by publication output in the field of neck pain research.

**Table 1.** Top 10 authors by publication output

Author name	Total number of articles	Total citations	Average citations	First author citations	First author average citations	Corresponding author count	Corresponding author citations
Falla, D	56	953	17.02	566	37.73	32	602
Jull, G	50	1078	21.56	94	31.33	3	94
Côté, P	50	1013	20.26	326	46.57	9	267
Treleaven, J	42	420	10	154	19.25	15	228
Carroll, LJ	36	835	23.19	240	34.29	7	240
Fernández-de-las-Peñas, C	32	321	10.03	24	12	16	262

**Table 1 (Continued)**

Author name	Total number of articles	Total citations	Average citations	First author citations	First author average citations	Corresponding author count	Corresponding author citations
Cleland, JA	31	822	26.52	391	48.88	7	337
Cassidy, JD	31	764	24.65	4	4	1	4
Holm, LW	31	594	19.16	1	0.33	2	0
Cagnie, B	30	334	11.13	122	24.4	5	122

In terms of publication output, Falla ranks first with 56 publications, indicating the richest research output and high research activity in this field. Jull and Côté both published 50 articles, following closely behind, showing their continuous investment and contribution to neck pain research. Regarding citation situations, Jull has the highest total citation count, reaching 1,078 times, with an average citation count of 21.56 times, which means that her research findings have been widely concerned and cited in the academic community and have high academic influence. Cleland's average citation count is 26.52 times, and his corresponding author's articles have been cited 337 times, indicating that his research work as a corresponding author has high quality and influence. Fernández-de-las-Peñas's first-author average citation is 12 times, and his corresponding author's articles have been cited 262 times, showing his influence in different research roles. These authors have high publication output and citation counts in the field of neck pain research and have played an important role in promoting the development of this field. Their research findings provide important theoretical basis and practical guidance for the prevention, diagnosis, and treatment of neck pain and offer rich reference resources for relevant researchers.

### 3.2. Top 10 institutions by publication output

**Table 2** shows the relevant data of the top 10 institutions by publication output in the field of neck pain research.

**Table 2.** Top 10 institutions by publication output

Institution name	Total number of articles	Total citations	Average citations	Total first author articles	First author citations	First author average citations
Univ Queensland	161	2746	17.06	75	1607	21.43
Univ Toronto	112	2003	17.88	10	74	7.4
Univ Rey Juan Carlos	100	950	9.5	27	327	12.11
Vrije Univ Amsterdam	99	872	8.81	18	102	5.67
Univ Alberta	95	2075	21.84	12	365	30.42
Karolinska Inst	84	874	10.4	35	181	5.17
NYU	74	1366	18.46	6	47	7.83
McMaster Univ	66	1249	18.92	21	472	22.48
Univ Sydney	64	1242	19.41	21	286	13.62
Canadian Mem Chiropract Coll	60	781	13.02	10	117	11.7

In terms of publication output, Univ Queensland ranks first with 161 articles, indicating the richest research output and high research activity in this field. Institutions such as Univ Toronto and Univ Rey Juan Carlos also have relatively high publication outputs, showing their continuous investment and contribution to neck pain research. Regarding citation situations, Univ Alberta has the highest average citation count, reaching 21.84 times, with a first-author average citation count of 30.42 times, which means that its research findings have been widely cited and highly recognized in the academic community and have high academic influence. McMaster Univ has an average citation count of 18.92 times, with a first-author average citation count of 22.48 times, showing the high quality and influence of its research. Although Univ Rey Juan Carlos has a relatively low average citation count of 9.5 times, its first-author average citation count is 12.11 times, indicating that it has a certain influence in some specific research areas.

### 3.3. Top 10 journals by publication output

**Table 3** shows the relevant quantitative indicators of the top 10 journals by publication output in the field of neck pain research.

**Table 3.** Top 10 journals by publication output

Journal name	Total number of articles	Total citations	Average citations
Journal of Manipulative and Physiological Therapeutics	121	781	6.45
Spine	114	2226	19.53
Manual Therapy	91	1683	18.49
European Spine Journal	81	904	11.16
BMC Musculoskeletal Disorders	80	586	7.33
Musculoskeletal Science and Practice	61	167	2.74
Journal of Orthopaedic & Sports Physical Therapy	49	1025	20.92
Journal of Back and Musculoskeletal Rehabilitation	43	144	3.35
Physical Therapy	40	495	12.38
Pain Medicine	39	151	3.87

In terms of the number of publications, the journal “Spine” ranks first with 114 articles, reflecting its high output rate in the field of neck pain research and its status as an important platform for publishing relevant academic achievements. Journals such as “Manual Therapy” and “European Spine Journal” are also significant. Focusing on the key indicator of citation situations, “Spine” has a total of 2,226 citations, with an average citation count of 19.53 times, which fully demonstrates the wide influence and high recognition of the articles published in this journal in the academic community, meaning that its published research findings have become important references for many subsequent studies. The average citation count of “Journal of Orthopaedic & Sports Physical Therapy” has reached 20.92 times, indicating that it also has an undeniable influence and academic value in the professional field. Overall, these 10 journals, with their high publication and citation counts, constitute important academic carriers in the field of neck pain research and have played a key role in promoting the continuous development of this field, as well as in promoting the accumulation and innovation of knowledge.

The co-occurrence network of keywords helps to discover the knowledge network relationships in research content, mine the core knowledge points in the research field, and also displays the current knowledge structure, research themes, and hotspots in the field (**Figure 1**).

**Table 4.** Top 10 keywords by co-occurrence frequency

Rank	Frequency	Centrality	Time	Keyword
1	1325	0.05	2000	neck pain
2	523	0.06	2000	low back pain
3	489	0.08	2000	reliability
4	394	0.09	2000	disability
5	363	0.08	2000	prevalence
6	317	0.08	2004	disability index
7	281	0.08	2000	disorders
8	277	0.07	2001	risk factors
9	273	0.08	2000	cervical spine
10	250	0.02	2009	2000 2010 task force

The hotspots in the field of neck pain are mainly focused on the following aspects. First, the characteristics and treatment of neck pain are the core themes of this field. The high-frequency appearance of keywords such as “neck pain,” “low back pain,” and “disability index” indicates that researchers are highly concerned with the characteristics, treatment methods, and rehabilitation effects of these pain conditions, understanding their manifestations and impacts in clinical medicine, including symptoms, pathogenesis, and therapeutic approaches. They study how these conditions recover and regain function under different treatment conditions and the impact of such treatments on patients’ quality of life and functional recovery. Second, the interrelationship between neck pain and other types of pain is one of the current research hotspots. The frequent occurrence of keywords such as “back pain,” “musculoskeletal pain,” and “chronic neck pain” shows that the field is committed to studying the interactions between neck pain and other body pains, such as how back pain affects the treatment outcomes and rehabilitation process of neck pain and how neck pain, in turn, impacts patients’ overall musculoskeletal health.

In addition, the integration of diagnostic and assessment methods is a key research direction in this field. The frequent appearance of keywords, such as “questionnaire” and “disability index”, indicates that research not only focuses on traditional clinical examination methods but also combines modern assessment tools, such as questionnaires and disability index evaluations, to more accurately study the severity and functional impairment of neck pain. In addition, the occurrence of keywords such as “randomized controlled trial” and “management” also reflects researchers’ efforts in the treatment and management of neck pain, understanding the effectiveness of different therapeutic approaches to develop more effective treatment and management strategies. Finally, the impact of rehabilitation therapy on neck pain is an emerging research hotspot in this field. The appearance of keywords, such as “physical therapy” and “reliability”, indicates that researchers are beginning to focus on the reliability and effectiveness of rehabilitation therapies, such as the actual effects of physical therapy in relieving neck pain and restoring function, and how to improve the reliability and stability of rehabilitation therapies to better promote patient recovery and enhance quality of life.

### 3.5. Timeline analysis

The research frontiers in the field of neck pain can reflect the innovations and future research trends in this area. The timeline view focuses on depicting the relationships between clusters and the historical span of a cluster’s literature. The timeline map of keyword clusters has the cluster name labels on the vertical axis and the publication years of the literature on the horizontal axis. The time zone where a node appears is the time when the keyword first emerged. By clustering the keywords and controlling the number of clusters to be 7, the top 7 frontier timeline threads can be obtained. Moreover, the top 7 keywords in terms of research are subjected to burst analysis to explore the development history and research frontiers of this field.

Based on the keyword timeline map show in **Figure 2**, the research on neck pain can be divided into three time periods for analysis: The first stage is basic theory and core concepts. In this stage, the research mainly focuses on the basic theory and core concepts of neck pain. Keywords such as “neck pain,” “low back pain,” and “disability index” frequently appear, indicating that researchers are exploring the basic principles and mechanisms of neck pain, emphasizing the causes of pain, symptoms, and their impact on patients’ quality of life. The second stage is technological application and deepening. Over time, more technological means and treatment methods, such as “questionnaire” and “randomized controlled trial,” are introduced to more accurately assess and treat neck pain. Keywords in this period also include “physical therapy” and “manual

therapy,” showing that researchers are paying more attention to the effects and applications of different treatment methods. The third stage is comprehensive management and emerging therapies. Recent research trends show that comprehensive management and emerging therapies for neck pain have become new focal points. Keywords, such as “acupuncture,” “exercise therapy,” and “central sensitization”, reflect the attention to multidimensional treatment and management strategies for neck pain and how to improve treatment outcomes and patient recovery quality through comprehensive intervention measures.

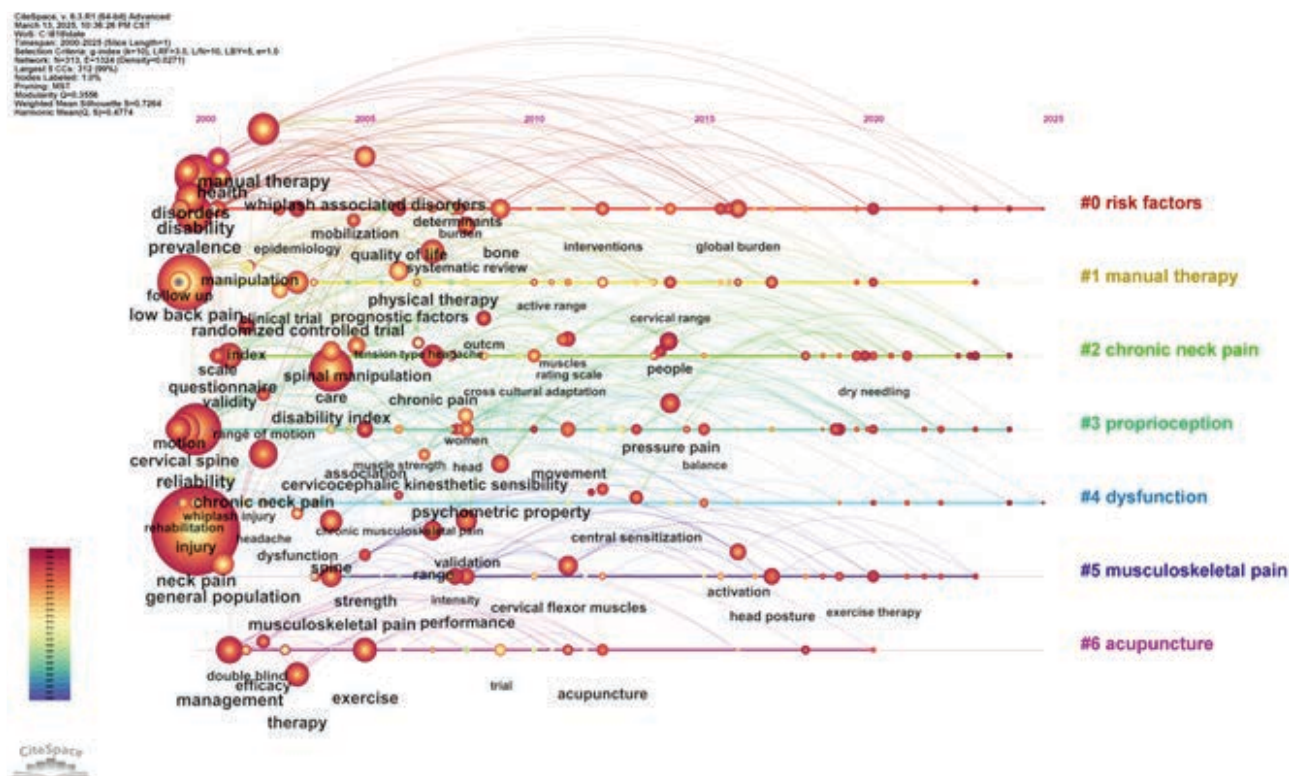


Figure 2. Keyword timeline

### 3.6. Keyword burst analysis

Figure 3 shows the keyword burst map. Keyword burstiness is considered an indicator of highly active research areas in visualized research. It refers to keywords that have a rapid increase in growth or high frequency of use within a short period of time. This dynamic feature can be used to explore research hotspots and emerging trends in a research field.

Trend analysis in recent years has shown that the keyword “exercise therapy” first emerged in 2020 and reached its peak between 2020 and 2025. This indicates a significant increase in researchers’ attention to exercise therapy for neck pain. This trend reflects the emphasis on conservative treatment methods in the field of neck pain treatment, as well as the focus on cultivating patients’ self-recovery abilities.

The keyword “dry needling” first emerged in 2020 and reached its peak between 2020 and 2022. This shows that researchers have paid more attention to the application of this emerging physical treatment method in neck pain treatment. This trend reflects the diversification of neck pain treatment techniques and the exploration of precise and efficient treatment methods. The keyword “intensity” first emerged in 2021 and maintained a high citation intensity between 2021 and 2025. This reflects an increased focus by researchers on

the control and optimization of treatment intensity in neck pain treatment. It indicates a greater emphasis on personalization and scientific approach in the formulation of treatment plans. The keyword “individuals” first emerged in 2022 and reached its peak between 2022 and 2025. This further highlights the in-depth development of patient-centered treatment concepts in neck pain research.

## Top 25 Keywords with the Strongest Citation Bursts

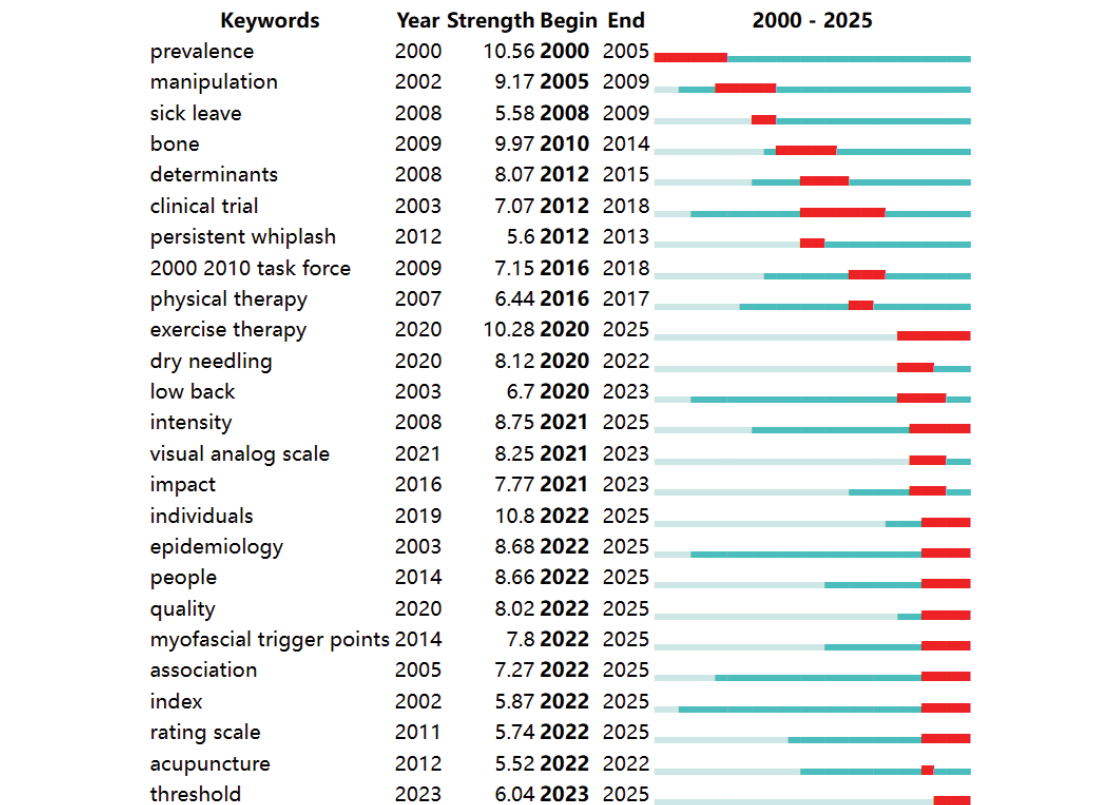


Figure 3. Keyword burst map

Researchers are paying more attention to the impact of individual differences on treatment outcomes, providing a basis for formulating more precise treatment plans. The keyword “quality” first emerged in 2022 and reached its peak between 2022 and 2025. This indicates an increased focus by researchers on the overall quality control and effectiveness evaluation of neck pain treatment. It reflects a shift from the exploration of treatment methods alone to the optimization of the entire treatment process quality.

## 4. Discussion

Based on an in-depth bibliometric analysis, this study systematically combs through and analyzes various aspects of the neck pain research field from 2000 to 2025, including publication output, authors, institutions, and keywords. The aim is to fully grasp the research trends and development directions in this field, providing references and directions for future research.

In terms of publication output, the research output in this field has increased year by year, indicating that neck pain, as a common clinical disease, has attracted widespread attention and importance in research <sup>[4]</sup>.

Authors and institutions with high publication output have a high influence and research strength in this field. Their research results provide an important basis for the clinical diagnosis, treatment, and rehabilitation of neck pain. For example, the high publication output and citation counts of authors such as Falla and Jull indicate their profound academic achievements and practical experience in neck pain research. Their research may cover multiple aspects of neck pain, including pathogenesis, assessment methods, and treatment strategies, playing a key role in promoting the development of this field. Institutions like the University of Queensland and the University of Toronto, with their strong research teams and rich resources, hold important positions in neck pain research. Their research results are not only of great academic value but may also have a positive impact on clinical practice <sup>[5]</sup>.

The co-occurrence analysis of keywords reveals the core themes and hotspots in neck pain research. High-frequency keywords such as “neck pain,” “low back pain,” and “disability index” reflect researchers’ high attention to the characteristics of neck pain, treatment methods, and rehabilitation outcomes <sup>[6]</sup>. The relationship between neck pain and other types of pain, in particular, suggests that in clinical practice, neck pain often coexists with other pain conditions. It is necessary to consider their mutual influence comprehensively and develop a holistic treatment and rehabilitation plan. In addition, the frequent appearance of keywords, such as “questionnaire” and “disability index”, indicates that modern assessment methods are becoming increasingly important in neck pain research. Through multidimensional assessment methods, a more accurate understanding of the patient’s pain level, functional impairment, and quality of life can be obtained, providing a basis for precise treatment.

Timeline analysis and keyword burst analysis further demonstrate the evolution and frontier trends in neck pain research. From basic theoretical research to technological application, and then to comprehensive management and the exploration of emerging therapies, this evolution reflects the continuous deepening and expansion of research in this field. In recent years, the emergence of keywords, such as “exercise therapy” and “dry needling”, indicates that conservative treatments and emerging physical therapy methods are gaining increasing attention in neck pain treatment. This not only enriches the treatment options but also provides more choices for patients. At the same time, the emergence of keywords such as “intensity,” “individuals,” and “quality” reflects the growing emphasis by researchers on personalization, precision, and quality control in the treatment process, which will help improve treatment outcomes and patient satisfaction.

Future research can be carried out in the following aspects: First, further deepen the understanding of the pathogenesis of neck pain, especially through in-depth research at the molecular and neurobiological levels, to provide a theoretical basis for the development of new treatment methods and drugs. Second, strengthen the research on the relationship between neck pain and other diseases, exploring their mechanisms of interaction and influence, to provide a theoretical basis for comprehensive treatment. In addition, optimize assessment methods by combining more advanced technological means, such as biosensors and artificial intelligence, to improve the accuracy and efficiency of assessments. Furthermore, explore more effective rehabilitation treatment methods and strategies, focusing on personalization and precision, to improve patients’ rehabilitation and quality of life <sup>[7]</sup>. Finally, enhance interdisciplinary collaboration, integrating knowledge and technologies from multiple disciplines such as medicine, biology, and psychology, to jointly promote the in-depth development of neck pain research <sup>[8]</sup>.

## 5. Conclusion

In summary, bibliometric analysis of research trends in neck pain offers a clear understanding of the current status and key focus areas in the field. It also provides valuable insights and guidance for future research directions, with the goal of supporting more scientific and effective approaches to the clinical treatment and rehabilitation management of neck pain.

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## Disclosure statement

The authors declare no conflict of interest.

## References:

- [1] Krebs EE, Goldsmith ES, 2022, Conservative Therapy for Acute and Subacute Back or Neck Pain. *JAMA*, 328(23): 2307–2309. doi: 10.1001/jama.2022.21833.
- [2] O’Leary K, 2023, Opioids Unhelpful for Acute Low-Back and Neck Pain. *Nature Medicine*. *Nat Med*, 2023: 37550403.
- [3] Shahi P, Vaishnav A, Lee R, et al., 2022, Outcomes of Cervical Disc Replacement in Patients with Neck Pain Greater Than Arm Pain. *Spine Journal*, 22(9): 1481–1489.
- [4] Haider N, Gargya A, 2023, Management of Osteoarthritic Axial Neck Pain With Cervical Neuromodulation. *Cureus*, 15(10): e46890.
- [5] Peng B, DePalma M, 2018, Cervical Disc Degeneration and Neck Pain. *Journal of Pain Research*, 11: 2853–2857.
- [6] Gidaszewski B, Khajehei M, McGee T, 2018, Outpatient Cervical Ripening: Discomfort/Pain During Speculum and Foley Catheter Insertion. *Midwifery*, 67: 57–63.
- [7] Aoyama R, Anazawa U, Hotta H, et al., 2022, Cervical Implant Allergy With Chronic Neck Pain: A Case Report. *Cureus*, 14(8): e28293.
- [8] Naja A, Madi N, Tfayli Y, et al., 2021, Deep Cervical Plexus Block for Neck and Shoulder Pain Due to Myofascial Pain: A Randomized Clinical Trial. *Clinical Journal of Pain*, 37(2): 133–139.

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# Patient Journey Map In Chronic Disease Management: Theory, Practice And Future

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**Abstract:** This review aims to comprehensively discuss the application status, theoretical basis, practical methods, empirical research, challenges, and future development direction of patient journey map in chronic disease management. By integrating current advances in academia and practice, this paper suggests that the patient journey map is an effective tool that can significantly improve the efficiency and quality of care delivery, increase patient engagement, and optimize the allocation of health care resources in chronic disease management. Nevertheless, the popularization and deepening application of patient journey map also faces a series of problems, such as difficulties in data collection, challenges in technology integration, and resistance to organizational change. In the future, with the progress of technology and policy support, the patient journey map is expected to become a key force to promote the innovation of chronic disease management model. Through in-depth analysis of these problems and opportunities, this paper provides valuable reference and enlightenment for healthcare providers, policy makers and relevant stakeholders.

**Keywords:** Patient journey map; Chronic disease; Chronic disease management

**Online publication:** June 4, 2025

## 1. Introduction

Chronic disease is an abbreviation for chronic non-communicable diseases (NCDs). It does not refer to a specific illness, but rather serves as a general term encompassing a group of non-communicable diseases characterized by prolonged onset periods and the absence of curative treatment once the disease manifests <sup>[1, 2]</sup>. Common chronic diseases encompass coronary heart disease, stroke, hypertension, malignant tumors, diabetes, and chronic respiratory diseases. According to the WHO report, 7 of the 10 leading causes of death in 2019 were chronic non-communicable diseases (chronic diseases), with the number of deaths reaching 33.2 million, accounting for 73.6% of the total global deaths, an increase of 28% over 2000 <sup>[3]</sup>. Facing the increasingly complex and severe situation of prevention and control for chronic diseases, chronic disease management is facing great challenges. The patient journey map represents a relatively novel approach to gaining insights into

the patient experience, and it is increasingly being adopted <sup>[4]</sup>. It aims to improve the overall quality of chronic disease management by visualizing patients' experience throughout the medical process, helping medical service providers identify service breakpoints, optimize resource allocation, and improve patient satisfaction.

## **2. Theoretical basis of patient journey map**

### **2.1. Definition and origin**

The patient journey is a journey that begins with the discovery of one's discomfort or symptoms, through diagnosis, treatment, recovery, and management of the disease <sup>[5]</sup>. The patient journey map is a tool that visually presents the path followed by the patient at all stages of the medical care trajectory and the emotional experience of the patient during this process. This tool first appeared in the commercial field, and then gradually penetrated into the medical service industry, especially in chronic disease management, showing great potential. The patient journey map was initially conceived as a market research tool, designed to assist business enterprises in comprehending consumers' motivations and behaviors <sup>[6]</sup>.

### **2.2. Core values**

#### **2.2.1. Patient centered**

- (1) Enhanced patient engagement: Patient journey map enable patients to better understand and participate in their own treatment by documenting and analyzing their entire medical process, improving treatment compliance and satisfaction.
- (2) Improved doctor-patient communication: With patient journey map, clearer communication can be achieved between doctors and patients, reducing misunderstandings and information asymmetry, and enhancing trust relationships <sup>[7]</sup>.

#### **2.2.2. Systemic perspective**

Comprehensive understanding of patients: Patient journey map comprehensively records the medical experience of patients from multiple perspectives and links, helping healthcare providers to have a more comprehensive understanding of patients' conditions, to formulate more scientific and reasonable treatment plans <sup>[8, 9]</sup>.

#### **2.2.3. Personalized treatment**

According to the specific needs and experiences of patients, more personalized treatment plans are formulated to improve the treatment effect.

Enhanced patient education: Through the patient journey map, it is possible to identify patient deficiencies in knowledge and skills and provide targeted educational materials and training courses to help patients better manage their disease.

#### **2.2.4. Optimizing the medical service process**

- (1) Streamline processes: Identify and eliminate unnecessary steps to reduce patient waiting time and inconvenience.
- (2) Improve efficiency: By optimizing the process, improve the efficiency of medical services, reduce medical costs, and improve patient satisfaction.

### **2.2.5. Promoting the long-term management of chronic diseases**

- (1) Continuous monitoring and support: Patient journey map can help healthcare providers to continuously monitor changes in a patient's condition and provide necessary support and interventions.
- (2) Multidisciplinary cooperation: By setting up a team of multidisciplinary experts including doctors, nurses, dietitians and psychological counselors to provide a full range of services and ensure that patients receive comprehensive care <sup>[10]</sup>.

## **3. Application of patient journey map in chronic disease management**

### **3.1. Design principle**

#### **3.1.1. Patient-centered**

- (1) Focus on patients experience: The design process is always to the patient's needs and experience as the core, to ensure that the map can reflect the patient's feelings and needs.
- (2) Respect for patient privacy: When collecting and processing patient data, privacy protection regulations are strictly followed to ensure the safety of patient information.

#### **3.1.2. Data driven**

- (1) Multi-source data collection: Use a combination of qualitative data (e.g., in-depth interviews, focus group discussions) and quantitative data (e.g., electronic health records, medical expense data) to get a comprehensive picture of the patient <sup>[11]</sup>.
- (2) Data validation and update: Verify and update data regularly to ensure the accuracy and timeliness of the map.

#### **3.1.3. Systemic perspective**

- (1) Comprehensive coverage: Covers the entire process of the patient from the onset of symptoms to treatment to recovery or long-term management, ensuring the integrity of the map.
- (2) Multi-link analysis: From registration, consultation, examination, treatment to follow-up and other links to conduct detailed analysis, identify the problems and opportunities in each link.

#### **3.1.4. User friendly**

- (1) Visual presentation: Charts, flow charts, and other forms are used to make the map easy to understand and use.
- (2) Concise and clear: Avoid redundant information and highlight key nodes and main activities.

#### **3.1.5. Flexibility and extensibility**

- (1) Adapt to different requirements: Design and considering the specific requirements of the patients with different groups, the map has a certain flexibility.
- (2) Continuous improvement: According to the practical application of the feedback, and constantly optimize and improve map and make it more in line with the actual demand.

#### **3.1.6. Multidisciplinary cooperation**

- (1) Interdisciplinary team: Establish by doctors, nurses, dieticians, psychological consultants, and other

multi-disciplinary team of experts, jointly participate in the design and implementation of the map.

- (2) Collaborative: Associated with patients, families, communities, and institutions closely to ensure the practicability and validity of the map.

### **3.1.7. Technical support**

- (1) Using modern technology: Combining big data, artificial intelligence, telemedicine and other technologies to improve the intelligent level and application range of maps.
- (2) Platform integration: Integrate the patient journey map into the existing medical information system to achieve data interconnection.

### **3.1.8. Policy and ethics**

- (1) Compliance with laws and regulations: Strictly abide by relevant laws and regulations in the design and use process to ensure compliance.
- (2) Ethical considerations: Ethical issues are fully considered in the design and implementation process to ensure that patients' rights are not infringed.

## **3.2. Production process**

First, identify the target group and research purpose; Secondly, qualitative and quantitative methods are used to collect data, such as questionnaire survey, in-depth interview, data analysis, etc; Then, organize and analyze the data to extract the key contacts and service breakpoints; Finally, visualize the results using charts and other forms, and share them with stakeholders to discuss improvement measures.

## **4. Empirical study and case study**

### **4.1. Review of research at home and abroad**

Currently, the patient journey map has been extensively utilized in the management of chronic conditions such as diabetes, hypertension, heart disease, cancer, and others. Previous studies have shown that patient journey map can significantly improve patient satisfaction, reduce rehospitalization rate and reduce unnecessary medical expenditure in chronic disease management. For example, a U.S. study showed significant improvements in glycemic control with the use of patient journey maps to optimize diabetes care <sup>[12]</sup>.

### **4.2. Successful case sharing**

By mapping the journeys of patients with cardiovascular disease, a British health care organization found that patients often experience delays in referrals, resulting in missed opportunities for treatment. As a result, they have simplified the referral process, reduced waiting times, and greatly improved patient satisfaction and treatment outcomes <sup>[13]</sup>.

## **5. Challenges and countermeasures**

### **5.1. Data Collection Challenges**

Collecting high-quality data is the basis for making a patient journey map, but in practice, there may be problems such as data dispersion, inconsistent format, and sensitive information protection. To solve this

problem, the data collection process can be standardized and the data security measures can be strengthened.

## **5.2. Technology integration issues**

Patient journey map with the existing information system seamless docking, is the prerequisite to realize the automatic data collection and analysis. This requires strong technical support, including the development of specialized software platforms, the establishment of data exchange standards, etc.

## **5.3. Organizational resistance to change**

Changing existing work processes and cultural atmosphere often meets employee resistance and management hesitation. Therefore, it is necessary to gradually eliminate the resistance to change through education and training, incentive mechanism, demonstration effect and other means.

# **6. Future prospects**

## **6.1. Technology-driven Innovation**

With advancements in cutting-edge technologies like artificial intelligence and machine learning, the future patient journey map will become even more intelligent and personalized. For example, algorithms can automatically analyze large amounts of patient data to predict potential risk factors and intervene in advance to achieve true preventive medicine.

## **6.2. Policy and System guarantee**

The government and health management departments should give sufficient attention and support to patient journey map at the policy level, such as setting up special funds, formulating guidelines, and encouraging pilot projects, to pave the way for its large-scale application.

# **7. Conclusion**

The application of patient journey map in chronic disease management reflects the transformation of modern medical service to “people-oriented” concept. Through continuous exploration and practice, it is believed that this tool will enhance the efficiency of the medical service, to improve the harmonious doctor-patient relationship and promoting the health welfare aspects make an even bigger impact.

## **Disclosure statement**

The authors declare no conflict of interest.

## **References**

- [1] Boteanu RM, Suica VI, Uyy E, et al., 2017, Alarmins in Chronic Noncommunicable Diseases: Atherosclerosis, Diabetes and Cancer. *J Proteomics*, 153: 21–29.
- [2] Huo GY, Xu FX, Wang C, 2022, Application Progress of Family Empowerment Nursing in the Nursing of Children With Chronic Diseases in China. *Chin J Mod Nurs*, 28(7): 848–851.

- [3] World Health Organization, 2022, World Health Statistics 2022: Monitoring Health for the SDGs, Sustainable Development Goals
- [4] Davies EL, Bulto LN, Walsh A, et al., 2023, Reporting and Conducting Patient Journey Map Research in Healthcare: A Scoping Review. *J Adv Nurs*, 79: 83–100
- [5] Chu HL, Li N, Zhao YM, 2024, Application of Longitudinal Mixed Methods Research in Patient Journey Research. *Chin J Pediatrics*, 62(07): 642. doi:10.3760/cma.j.cn112140-20240518-00341
- [6] Crosier A, Handford A, 2012, Customer Journey Map as an Advocacy Tool for Disabled People. *Soc Mark Q*, 18(1): 67–76. doi: 10.1177/1524500411435483
- [7] Smith L, Phillipson L, 2022, Using Journey Mapping to Support Staff, Family Members and Allies of People With Dementia to Think and Act Differently During a Care Transition: The Benefits and Limits of Care Imagination. *Dementia-London*, 21(6): 1873–1889. doi: 10.1177/14713012221097237
- [8] Fennelly O, Blake C, FitzGerald O, et al., 2019, Advanced Musculoskeletal Physiotherapy Practice: The Patient Journey and Experience. *Musculoskelet Sci Pract*, 45: 102077. doi: 10.1016/j.msksp.2019.102077
- [9] De Ridder E, Dekkers T, Porsius J, et al., 2018, The Perioperative Patient Experience of Hand and Wrist Surgical Patients: An Exploratory Study Using Patient Journey Mapping. *Patient Exp J*, 5(3): 97–107. doi: 10.35680/2372-0247.1273
- [10] McCarthy S, O’Raghallaigh P, Woodworth S, et al., 2020, Embedding the Pillars of Quality in Health Information Technology Solutions Using “Integrated Patient Journey Mapping” (IPJM): Case Study. *JMIR Hum Factors*, 7(3): e17416. doi: 10.2196/17416
- [11] Lamprell K, Braithwaite J, 2016, Patients as Story-Tellers of Healthcare Journeys. *Med Humanit*, 42(3): 207–209. doi: 10.1136/medhum-2016-010885
- [12] Solh Dost L, Gastaldi G, Dos Santos Mamed M, et al., 2023, Navigating Outpatient Care of Patients With Type 2 Diabetes After Hospital Discharge – A Qualitative Longitudinal Study. *BMC Health Serv Res*, 24(1): 476. doi: 10.1186/s12913-024-10959-4
- [13] Van Schalkwijk DL, Widdershoven JWMG, Elias-Smale S, et al., 2023, ShareHeart: A Patient Journey Map of Patients With Ischemia and Non-Obstructive Coronary Artery Disease Based on Qualitative Research. *J Clin Nurs*, 32(13–14): 3434–3444. doi: 10.1111/jocn.16409

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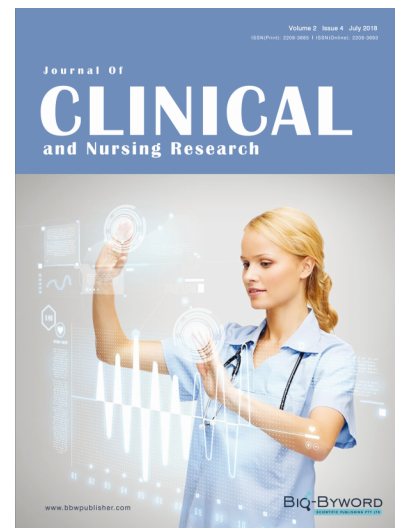
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