

Bone and Arthroscopy Science

Editors-in-Chief

Kenneth M.C. Cheung

The University of Hong Kong, Hong Kong SAR, China

Biao Wang

Honghui Hospital Affiliated to Xi'an Jiaotong University, China

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Bone and Arthroscopy Science

Focus and Scope

Bone and Arthroscopy Science is a peer-reviewed articles across a wide spectrum of clinical treatise, basic research, review, frontier of orthopedics, case analysis and comment. This journal is aimed at professionals at all levels engaged in the basic and clinical work of orthopedics. Each issue is guest-edited by an acknowledged expert and focuses on a single topic or controversy.

It mainly reports new viewpoints, new achievements and new technologies in basic and clinical research of bone and joint surgery. The covered topics include, but are not limited to: sports medicine and arthroscopy, prosthetic design, biomechanics, biomaterials, metallurgy, biologic response to arthroplasty materials *in vivo* and *in vitro*.

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Clinical Guidelines for the Use of Platelet-Rich Plasma (PRP) for Osteoarthritis

Ying Zhang, Feng Shuang, Dongfa Liao, Xiaohui Li

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Preface

This document is drafted in accordance with the provisions of GB/T 1.1-2020 “Directives for Standardization – Part 1: Rules for the Structure and Drafting of Standardization Documents.”

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Medicine (The Third Affiliated Hospital of Yunnan University of Chinese Medicine) / Pharmacy Department, Rongjun Welfare Hospital of Heze City, Shandong Province / Department of Orthopedics, The First People's Hospital of Guangyuan / Jintang County Maternity and Child Health Hospital / The Second Affiliated Hospital of Liaoning University of Traditional Chinese Medicine Department of Orthopedics VII.

Main drafters of this document: Ying Zhang, Feng Shuang, Dongfa Liao, Xiaohui Li

List of Authors for the English Version of the Guidelines for PRP Therapy for OA.

All authors have no conflict of interest and have made corresponding contributions.

1. Ying Zhang, National PRP Group, Department of Orthopedics, 920th Hospital of the Joint Logistics Support Force of the PLA&Yunnan Pain Disease Hospital, Yunnan, China (First Author+Corresponding Author)
2. Feng Shuang, Department of Orthopedics, the 908th Hospital of the Joint Logistics Support Force of the Chinese PLA, Nanchang, China(Co-first author)
3. Dongfa Liao, Department of Orthopedics, General Hospital of the PLA Western Theater Command, Cheng Du, China(Co-first author)
4. Xiaohui Li, Department of Orthopedics II, Shenyang Sixth People's Hospital.(Co-first author)
5. Hongbo Tan, Department of Orthopedics, 920th Hospital of the Joint Logistics Support Force of the PLA, Yunnan, China
6. Zhian Chen, Department of Orthopedics, 920th Hospital of the Joint Logistics Support Force of the PLA, Yunnan, China
7. Xiaoli Wei, The First People's Hospital of Kunming, Yunnan, China
8. Xihua Zhang, Ward 3 of the Department of Orthopedics and Traumatology, Yunnan Provincial Hospital of Traditional Chinese Medicine (The First Affiliated Hospital of Yunnan University of Traditional Chinese Medicine), China
9. Xiaoming Chen, Guidong People's Hospital of Guangxi Zhuang Autonomous Region, China
10. Yifan Hao, Department of Orthopedics II, Shenyang Sixth People's Hospital, China
11. Guoyin Liu, Department of Orthopedics, Nanjing Jinling Hospital, Affiliated Hospital of Medical School, Nanjing University, Nanjing, 210093, China
12. Jun Zhou, Sichuan Gem-flower Hospital Affiliated to North Sichuan Medical College, China
13. Yongguo Ding, Ningxia integrated Chinese and western medicine hospital, China
14. Zheng Ding, Department of Rehabilitation Medicine, The Central Hospital of Xiangtan, Hunan, China
15. Jimin Pei, Department of Orthopedics, Affiliated People's Hospital of Xinxiang Medical University, Henan, China.
16. Qiangjin Ruan, Third People's Hospital of Yunnan Province, China
17. Xiaoyan Li, Department of Rehabilitation Medicine Beijing Anzhen Nanchong Hospital of Capital Medical University & Nanchong Central Hospital
18. Fang Feng, Department of Rehabilitation Medicine, Beijing Anzhen Nanchong Hospital of Capital Medical University & Nanchong Central Hospital, Sichuan, China
19. Liren Ma, Department of Peripheral Vascular Diseases, Pingdingshan Hospital of Traditional Chinese Medicine, China
20. Yanmei Wang, people's Hospital of Jinning District, Kunming City, China
21. Hongying Ren, Department of Rehabilitation Medicine, Beijing Anzhen Nanchong Hospital of Capital

- Medical University & Nanchong Central Hospital, Sichuan, China
22. Hui Xiao, Department of Orthopedics, Xinxiang First People's Hospital, Henan, China
 23. Jun Zhang, Dazhou Integrated TCM & Western Medicine Hospital, Sichuan, China
 24. Weiguo Li, Tongliang Traditional Chinese Medicine Hospital, Chongqing, China.
 25. Ming Shuai, Chongyi County People's Hospital, Ganzhou, China.
 26. Zehui Song, Department of Orthopedics, First People's Hospital of Yuhang District, Hangzhou, Zhejiang, China
 27. Guang Yang, Shuguang Anhui Hospital Affiliated to Shanghai University of Traditional Chinese Medicine(The First Affiliated Hospital West District of Anhui University of Chinese Medicine), China
 28. Huan Yu, the Fifth Hospital of Harbin, Heilongjiang, China
 29. Guoliang Chen, Harbin Huayi Hospital/Heilongjiang Chen Yisheng Medical Hair Transplant, China
 30. Ying Zhao, Department of Orthopedics, Guiqian International Hospital , Guizhou, China
 31. Hua Song, Department of Orthopaedics, Tengzhou Central People's Hospital, Tengzhou, Shandong Province, China
 32. Dongfa, Liao, Department of Orthopedics, General Hospital of the PLA Western Theater Command, China
 33. Li Li, Department of Orthopedics and Traumatology, Kunming Municipal Hospital of Traditional Chinese Medicine (The Third Affiliated Hospital of Yunnan University of Chinese Medicine), Yunnan , China.
 34. Chunmei Li, Pharmacy Department, Rongjun Welfare Hospital of Heze City, Shandong Province , China
 35. Gang Li, Dept of Orthopedics , The First People's Hospital of Guangyuan, Sichuan, China
 36. Hua Wang , Jintang County Maternity And Child Health Hospital, China
 37. Fang Li, The Second Affiliated Hospital of Liaoning University of Traditional Chinese Medicine Department of Orthopedics VII.Shenyang, China

1. Scope

This document specifies the requirements for institutions and personnel involved in the treatment of osteoarthritis with platelet-rich plasma (PRP), including the acquisition of PRP, the process of local injection therapy, and post-treatment patient examination and follow-up. This document is applicable to the treatment of osteoarthritis patients caused by degenerative diseases in orthopedic and joint surgery departments of general hospitals using PRP.

2. Normative references

The following documents contain provisions that, through normative references in the text, constitute essential clauses of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- (1) GB/T 14396 Classification and Codes of Diseases
- (2) Good Manufacturing Practice for Pharmaceutical Products
- (3) Expert Consensus on the Clinical Application of Platelet-Rich Plasma in Orthopedic Surgery (2018 Edition)
- (4) Expert Consensus on the Preparation Technique of Autologous Platelet-Rich Plasma (PRP) (2021 Edition)

3. Terms and definitions

The following terms and definitions are applicable to this document.

- (1) Platelet-rich plasma (PRP): A platelet concentrate extracted from autologous blood through centrifugation.
- (2) Osteoarthritis (OA): Also known as osteoarthrosis, degenerative joint disease, hypertrophic arthritis, or senile arthritis, is a chronic joint disease characterized by degenerative changes in articular cartilage and secondary osteoproliferation, with an uncertain etiology.

4. Clinical classification

4.1. Basic requirements

Classification should comply with the provisions of GB/T 14396.

4.2. Classification based on the presence of a clear etiology

It can be divided into primary and secondary OA, specifically as follows:

- (1) Primary: The cause of primary osteoarthritis is unknown, without clear systemic or local predisposing factors, and may be related to genetic and constitutional factors. It is mostly seen in middle-aged and elderly people over 50 years old.
- (2) Secondary: It refers to osteoarthritis that occurs on the basis of preexisting lesions in the joint, caused by congenital deformities such as developmental hip dislocation; trauma such as intra-articular fractures; acquired joint surface irregularities such as collapse and degeneration of the joint surface due to avascular necrosis of the bone; joint instability such as laxity of the joint capsule or ligaments; and joint malalignment causing poor articular surface apposition, such as genu varus or genu valgus.

4.3. Classification based on joint distribution

It can be divided into systemic OA, hand OA, knee OA, hip OA, etc.

4.4. Classification based on the presence of symptoms

It can be divided into symptomatic and asymptomatic (radiographic) OA.

5. Symptoms

5.1. Overview

Osteoarthritis symptoms often start as mild dull pain, which gradually worsens, and may be accompanied by temporary stiffness after rest, joint crepitus, and occasional joint locking. In later stages, it is often associated with joint pain, swelling, and effusion.

5.2. Typical symptoms

5.2.1. Joint pain

Initially, it presents as mild or moderate intermittent dull pain that improves with rest and worsens with activity. The pain is often related to changes in weather. Persistent pain or nocturnal pain may occur in later stages.

5.2.2. Joint stiffness

There is morning stiffness that improves with activity. Joint stiffness worsens when air pressure drops or humidity increases, and the duration is usually short, ranging from a few minutes to ten minutes, rarely exceeding 30 minutes.

5.2.3. Joint swelling

Swelling and deformation of hand joints are obvious, and Heberden's nodes and Bouchard's nodes may appear. Some knee joints may also swell due to osteophyte formation or joint effusion.

5.2.4. Crepitus (sensation)

Due to articular cartilage damage and irregular joint surfaces, crepitus (sensation) may occur during joint movement, which is most common in the knee joint.

5.2.5. Joint weakness and dysfunction

Joint pain, decreased range of motion, muscle atrophy, and soft tissue contracture can cause joint weakness, buckling during walking or joint locking, incomplete extension, or dysfunction.

5.2.6. Complications

Osteoarthritis can be complicated by periostitis, joint damage, or joint deformity.

6. Screening

6.1. Examination

6.1.1. Expected examinations

When patients experience joint pain and stiffness, they should seek medical attention promptly. Doctors typically perform a physical examination first and may request blood tests, synovial fluid analysis, and X-rays for further diagnosis and treatment.

6.1.2. Physical examination

6.1.2.1. Inspection and palpation

The affected joint may show no swelling or mild swelling, and some may present with joint deformities and varying degrees of muscle atrophy. There is mild tenderness, and the range of motion may be unrestricted or partially restricted. Crepitus or a grating sensation may be felt during movement.

6.1.2.2. Floating patella test

When the knee joint is accompanied by synovitis, swelling may increase, and joint effusion may occur. The patient straightens the affected leg's knee joint and relaxes the quadriceps muscle. The doctor presses on the suprapatellar bursa with one hand, causing synovial fluid to accumulate behind the patella. With the other hand, the doctor gently presses on the patella with the index finger, feeling a floating sensation and a clicking sound as the patella collides with the femoral condyle. When the pressure is released, the patella floats back up, indicating a positive floating patella test (+).

6.1.2.3. Thomas Sign and “4” test

- (1) When there is a hip joint pathology, internal rotation of the affected side can exacerbate pain. The doctor instructs the patient to lie flat on the examination bed, hold one knee with both hands, and try to flex the hip and knee joints to make the thigh close to the abdominal wall and the waist stick to the bed surface. If the patient cannot straighten the other lower limb, this is a positive Thomas Sign (+).
- (2) The doctor asks the patient to curl up their affected limb and place the outer ankle on top of the patella of the healthy lower limb. Then, the doctor presses down on the patient’s affected knee. If the patient experiences pain in the affected hip and the knee cannot touch the bed surface, this is a positive “4” test.

6.1.3. Laboratory tests

6.1.3.1. Blood tests

Including but not limited to the following aspects:

- (1) Indicators such as blood routine, protein electrophoresis, immune complexes, and serum complement are generally within the normal range.
- (2) In the presence of synovitis, C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR) may be slightly elevated.

6.1.3.2. Joint fluid examination

A slight increase in white blood cells may be seen, occasionally with red blood cells, cartilage fragments, and collagen fiber fragments.

6.1.4. Imaging examinations

Including but not limited to the following:

- (1) X-ray examination may show narrowed joint spaces, subchondral bone sclerosis, or cystic changes, and the formation of osteophytes on the joint edges.
- (2) In later stages, the joint space disappears, and there may be varus or valgus deformities of the joints.
- (3) Sometimes, loose bodies can be seen, which may be accompanied by osteoporosis and soft tissue swelling.

6.1.5. Other examinations

Including but not limited to the following:

- (1) Arthroscopy may show significant hyperplasia, swelling, and congestion of synovial villi, as well as yellowing, roughness, erosion, and loss of articular cartilage.
- (2) There may be exposed bone and bone deformation.
- (3) The meniscus may be damaged to varying degrees.

6.2. Diagnosis

6.2.1. Diagnostic principles

Osteoarthritis can be diagnosed based on medical history, symptoms, physical signs, X-rays, and laboratory test results, while excluding other inflammatory joint diseases.

6.2.2. Diagnostic basis

6.2.2.1. Clinical criteria for hand OA

Hand pain, soreness, morning stiffness, and meeting at least 3 of the following 4 criteria can diagnose hand OA:

- (1) Hard tissue hypertrophy in at least 2 of the 10 specified joints.
- (2) Hard tissue hypertrophy in at least 2 interphalangeal joints of the fingertips.
- (3) Swelling of the metacarpophalangeal joints in fewer than 3 joints.
- (4) Joint deformity in at least 1 of the 10 specified finger joints.

Note: The 10 specified joints refer to the bilateral second and third distal and proximal interphalangeal joints and the first carpometacarpal joint.

6.2.2.2. Clinical criteria for knee OA

Knee pain and meeting at least 3 of the following 6 criteria can diagnose knee OA:

- (1) Age ≥ 50 years old.
- (2) Morning stiffness for less than 30 minutes.
- (3) Bone friction sensation.
- (4) Bone tenderness.
- (5) Bone hypertrophy.
- (6) The knee is not hot to the touch.

6.2.2.3. Clinical and radiological criteria for knee OA

Knee pain, osteophytes, and meeting at least 1 of the following 3 criteria can diagnose knee OA:

- (1) Age ≥ 40 years old.
- (2) Morning stiffness for less than 30 minutes.
- (3) Bone friction sensation.

6.2.2.4. Clinical and radiological criteria for hip OA

Hip pain and meeting at least 2 of the following 3 criteria can diagnose hip OA:

- (1) Erythrocyte sedimentation rate ≤ 20 mm/h.
- (2) X-ray shows osteophytes on the femoral head and/or acetabulum.
- (3) X-ray shows narrow hip joint space (superior, axial, and/or medial).

6.2.3. Differential diagnosis

6.2.3.1. Rheumatoid arthritis

The most commonly affected joints are the lumbar spine and finger (toe) joints, often accompanied by an increased rheumatoid factor titer, and the characteristics of bone destruction are also different.

6.2.3.2. Crystal sediment

If a patient with osteoarthritis experiences acute pain and unilateral joint swelling, joint fluid examination should be performed to rule out other possibilities, such as crystal arthritis or septic arthritis.

7. Indications and contraindications

7.1. Indications

- (1) Fractures, non-unions, and bone defects.
- (2) Acute and chronic muscle and ligament injuries.
- (3) Acute and chronic wounds.
- (4) Intra-articular cartilage injuries.
- (5) Osteoarthritis, especially symptomatic osteoarthritis with mild to moderate degenerative changes on X-ray or MRI.
- (6) Additionally, it can be used as an adjuvant therapy for osteomyelitis and osteonecrosis of the femoral head.

7.2. Contraindications

- (1) Patients with skin diseases around the injection site, skin ulceration around the joint puncture site, or those who cannot rule out significant joint swelling and effusion caused by other diseases.
- (2) Abnormal coagulation function, such as platelet dysfunction syndrome or severe thrombocytopenia.
- (3) Sepsis.

8. Institutional and personnel requirements

8.1. Institutional requirements

Legal qualification and license: The institution should have a legal qualification and a license to operate in the medical field, complying with local laws and regulations.

Adequate medical equipment and facilities: The institution should have relevant medical equipment and advanced laboratory facilities suitable for platelet-rich plasma (PRP) therapy, meeting the requirements of Good Manufacturing Practices for Pharmaceutical Products.

Professional medical team: The team should include orthopedic surgeons, PRP experts, nursing staff, etc., with relevant expertise and clinical experience to effectively perform PRP therapy.

Rigorous patient screening and evaluation: The institution should have a comprehensive patient screening and evaluation mechanism to ensure that the treatment is suitable for patients who meet the corresponding criteria, while excluding cases with contraindications. Patients should meet at least one of the following conditions:

- (1) Mild to moderate osteoarthritis patients with meniscal degeneration, not accompanied by loose bodies or meniscal locking;
- (2) Poor response to conservative drug therapy;
- (3) No liver cirrhosis, coagulation dysfunction, hemophilia, etc.;
- (4) General condition allows for injection surgery.

Clear treatment plan: The institution should develop a clear and specific PRP treatment plan, including but not limited to the following aspects:

- (1) Source of PRP
- (2) Processing method
- (3) Treatment dose
- (4) Administration route, to ensure the safety and effectiveness of the treatment.

Detailed treatment process and follow-up plan: The institution should establish a complete treatment

process and follow-up plan to ensure that patients receive timely medical care and follow-up after treatment.

Compliance with ethical principles and regulations: The institution should follow medical ethical principles and relevant regulations during PRP therapy, protecting patients' rights and safety.

Comprehensive medical record and data management system: The institution should establish a sound medical record and data management system to ensure the traceability of the treatment process and the integrity of the data.

8.2. Personnel requirements

Medical background and professional qualification: Medical personnel should have a relevant medical background, typically a medical degree or other medical professionals, such as orthopedic surgeons.

Professional knowledge and skills: Medical personnel should possess professional knowledge and skills in the relevant field, especially in osteoarthritis treatment and PRP therapy, as well as aseptic techniques and joint injection techniques.

Familiarity with PRP therapy principles and techniques: Medical personnel should be familiar with the principles, methods, and techniques of PRP therapy, including PRP extraction, culture, identification, and infusion processes.

Familiarity with clinical practice guidelines: Medical personnel should be familiar with clinical practice guidelines and the latest research related to PRP therapy for osteoarthritis to ensure scientific and reliable treatment.

Rigorous patient screening and evaluation capabilities: Medical personnel should have the ability to rigorously screen and evaluate patients, ensuring that the treatment is suitable for those who meet the corresponding criteria while excluding cases with contraindications.

Communication skills and doctor-patient relationship maintenance: Medical personnel should have good communication skills, be able to establish trust and cooperation with patients, and fully explain the treatment process, potential effects, and risks.

Compliance with medical ethical principles: Medical personnel should adhere to medical ethical principles during PRP therapy, protecting patients' rights and safety.

Continuous education and training: Medical personnel should participate in continuous education and training, staying up-to-date with the latest medical research and clinical practices to maintain professional standards in the field.

Emergency response capabilities: Medical personnel should have the ability to respond to unexpected situations and complications that may occur during the treatment process, making quick and correct emergency responses.

9. Treatment process

9.1. Initial evaluation and screening

The medical team will conduct an initial evaluation of the patient, including inquiry of medical history and physical examination, to assess whether PRP therapy is necessary based on the patient's actual condition, while excluding cases with contraindications.

For patients who require PRP therapy, pre-treatment communication will be conducted, and the PRP treatment informed consent form will be signed. The physician will order tests including blood routine,

coagulation function, liver and kidney function, blood glucose, blood lipids, and pre-operative eight items (qualitative detection of infection markers such as hepatitis B, hepatitis C, syphilis, and HIV).

9.2. Preoperative preparation (preoperative evaluation)

9.2.1. Required examination items

The following items should be included at a minimum:

- (1) Blood routine, blood type, urine routine, stool routine;
- (2) Blood glucose, rheumatoid factor, erythrocyte sedimentation rate, C-reactive protein, liver and kidney function (blood uric acid), coagulation function tests, screening for infectious diseases (hepatitis B, hepatitis C, syphilis, AIDS);
- (3) Chest X-ray, electrocardiogram;
- (4) Joint X-ray examination.

9.2.2. Optional examination items based on patient condition

Such as joint MRI examination, procalcitonin, tuberculosis antibody, and immune antibody spectrum, etc.

9.2.3. Other preparations

After confirming the treatment plan, the medical team will make pre-treatment preparations for the patient, including pre-guidance, dietary, and medication considerations.

9.3. Platelet-rich plasma (PRP) extraction and preparation

9.3.1. Blood collection

For those who pass the examination items, the clinician will issue a PRP collection and clinical transfusion (PRP treatment) application form. The patient will go to the transfusion department to collect blood or to the affiliated laboratory of the institution for collection.

9.3.2. Platelet-rich plasma (PRP) extraction

The preparation technique should comply with the *Expert Consensus on the Preparation Technique of Autologous Platelet-Rich Plasma PRP* (2021 edition).

9.3.3. Quality requirements

The PRP products used must comply with the regulations of the China Food and Drug Administration (CFDA) for Class III medical device management, ensuring their safety and effectiveness in clinical treatment.

9.3.4. Cryopreservation and storage

The collected PRP should be stored at -20°C and thawed at 37°C before patient treatment.

9.4. Pre-treatment preparation

During stem cell treatment, the medical team will prepare the cryopreserved PRP based on the specific disease and treatment plan for subsequent treatment.

9.5. Treatment process (injection therapy as an example)

9.5.1. Method

Choice of injection time point: It is recommended to use PRP immediately after preparation.

Choice of injection method: The following requirements should be met:

- (1) PRP can be injected directly under direct vision during surgery for fractures, non-unions, bone defects, osteomyelitis, wounds, tendon and ligament injuries, etc. PRP and thrombin can also be injected into the implantation area through a double-barrel syringe, or PRP can be directly injected into the lesion area during arthroscopy.
- (2) For PRP injection treatment of tendinopathy, it is recommended to inject into the lesion area under ultrasound guidance. Local anesthesia is recommended before injection.
- (3) The method of PRP treatment for osteoarthritis is intra-articular injection; it cannot be injected into soft tissues. If there is joint effusion before injection, it should be removed first.

9.5.2. Dosage

The following requirements should be met:

- (1) The user can adjust the injection volume, frequency, and dosage based on the patient's specific conditions (such as the size of the bone defect, the size and depth of the wound, whether there is bone exposure in the wound, etc.);
- (2) For intra-articular PRP injection treatment of osteoarthritis, the injection volume can be 3–5 mL each time. The interval is generally 1–3 weeks, and 2–3 injections constitute one course of treatment.

9.5.3. Post-injection observation

After the injection, the patient will be observed for a period of time to ensure there are no abnormal reactions or discomfort. The patient is required to rest for a period of time to ensure the medication takes effect within the joint.

9.5.4. Adverse event management

9.5.4.1. Local injection reactions

During PRP injection treatment for tendinopathy or osteoarthritis, some patients may experience mild or moderate pain and swelling, which are generally tolerable and do not require special treatment. Symptomatic treatment can also be provided, and symptoms usually disappear within 1–3 days.

9.5.4.2. Post-injection joint purulent infection

If joint infection is confirmed, it should be treated promptly as an infectious arthritis.

9.6. Postoperative hospital recovery period (1–2 days)

9.6.1. Items to be reviewed if necessary

Blood routine, and review of erythrocyte sedimentation rate and C-reactive protein if necessary.

9.6.2. Postoperative medication

Use of antimicrobial agents: Follow the *Guiding Principles for the Clinical Application of Antimicrobial Agents* (Wei Yi Fa [2017] No. 285), and there is no need to use antimicrobial agents.

Postoperative analgesia: Celecoxib capsules, etc.

Special complications: Intra-articular heat sensation, local heavy pressure sensation, adopt cold compress, local immobilization, plaster fixation if necessary, plus celecoxib capsules or dexamethasone 2–5 mg intra-articular injection.

Treatment of osteoarthritis: Refer to the *Guidelines for the Diagnosis and Treatment of Osteoarthritis*.

Other medications: Swelling reduction medications, etc.

9.7. Discharge criteria

- (1) Normal body temperature and local joint skin temperature.
- (2) No signs of infection at the surgical puncture site (or wound condition that can be managed in the outpatient clinic).
- (3) No complications and/or comorbidities that require inpatient treatment.

9.8. Post-treatment observation and follow-up

After the treatment is completed, the medical team will closely observe the patient and conduct regular follow-ups to monitor changes in the patient's condition and the effectiveness of stem cell treatment.

9.9. Rehabilitation and life guidance

The medical team will provide patients with corresponding rehabilitation guidance, including post-operative exercise, diet, and lifestyle recommendations, to help restore and improve joint function.

10. Follow-up and adverse reaction monitoring

10.1. Follow-up plan

10.1.1. First week after treatment

Conduct an initial post-operative follow-up during the first week after treatment. The medical team will examine the knee joint, evaluate post-treatment recovery, observe for post-operative pain, swelling, etc., and assess the active and passive range of joint movement.

10.1.2. First month after surgery

Conduct a follow-up during the first month after treatment to continue evaluating the recovery of the joint. Observe for post-treatment pain, functional improvement, etc., and assess the active and passive range of joint movement.

10.1.3. Sixth month after surgery

Conduct a follow-up during the sixth month after treatment to evaluate the long-term effects of the treatment. Observe the recovery of joint function and check for possible complications.

10.1.4. One year after surgery and beyond

After one year of treatment, patients can continue with regular follow-ups to continuously monitor treatment effectiveness and joint status. The frequency of follow-ups can be adjusted based on the patient's condition and the medical team's recommendations.

10.2. Adverse reaction monitoring

10.2.1. Pain and swelling

Patients should regularly report post-treatment pain and swelling, and the medical team will evaluate and manage accordingly.

10.2.2. Infection

Regularly check the treated area and observe for signs of infection, such as redness, swelling, or drainage.

10.2.3. Allergic reactions

Observe whether patients develop any allergic symptoms, such as rash, urticaria, difficulty breathing, etc.

10.2.4. Other complications

Including thrombosis, bleeding, nerve injury, etc., which require regular examination and observation.

10.2.5. Imaging examination

Conduct imaging examinations such as X-rays and MRIs as needed to evaluate changes in joint structure and disease condition.

Disclosure statement

The authors declare no conflict of interest.

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Analysis of the Efficacy of Arthroscopy-Assisted Treatment for Tibial Plateau Fractures

Jun Ge

Taizhou Hospital of Integrated Traditional Chinese and Western Medicine, Taizhou 225300, Jiangsu, China

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Abstract: *Objective:* To explore the efficacy of arthroscopy-assisted treatment for patients with tibial plateau fractures. *Methods:* A total of 80 patients with tibial plateau fractures in our hospital from January 2024 to January 2025 were selected as the research subjects. The patients were divided into an observation group and a control group based on their admission numbers, with 40 patients in each group. Relevant treatment indicators were compared between the two groups. *Results:* The total effective rate of the observation group was higher than that of the control group, and the incidence of complications was lower than that of the control group ($P < 0.05$). The surgical indicators (incision length, time to ambulate, fracture healing time, hospital stay) of the observation group were all better than those of the control group ($P < 0.05$). After treatment, the HSS score and modified Lysholm score of the observation group were higher than those of the control group ($P < 0.05$). The maximum angles of knee extension and flexion in the observation group were greater than those in the control group after treatment ($P < 0.05$). The GQOL-74 scores (material living status, physical, psychological, and social) of the observation group were significantly higher than those of the control group ($P < 0.05$). *Conclusion:* Arthroscopy-assisted minimally invasive surgery is effective in the treatment of tibial plateau fractures. It can not only optimize surgical indicators but also improve knee function and range of motion, which is beneficial for improving patients' postoperative quality of life. The promotion of this treatment is feasible.

Keywords: Arthroscopy; Tibial plateau fracture; Knee function; Efficacy

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1. Introduction

Clinically, tibial plateau fractures are a type of traumatic fracture of the knee joint with a high risk of clinical onset. External injuries such as car accidents or falls from heights are the main causes of the condition^[1]. For the human body, the knee joint plays a key role in weight-bearing, and tibial plateau fractures can directly affect its function and stability. Surgical treatment is the main approach for such patients. The application of open reduction and internal fixation can ensure the treatment effect, but patients need to bear large trauma, and many complications may occur after surgery, resulting in slow fracture healing^[2]. In recent years, arthroscopy technology has achieved significant development results, with small trauma and fast postoperative recovery, and is gradually being used in

the clinical treatment of fractures. Therefore, it is of certain practical significance to conduct in-depth research and analyze the value of arthroscopic minimally invasive surgery for patients with tibial plateau fractures.

2. Materials and methods

2.1. Clinical data

Eighty patients with tibial plateau fractures treated in our hospital from January 2024 to January 2025 were selected. The patients were divided into an observation group ($n = 40$) and a control group ($n = 40$) based on their admission numbers. In the control group, there were 22 male and 18 female patients, with an age range of 18–67 years and an average age of 50.62 ± 10.14 years. The fracture side was evenly distributed, with 20 cases on the left and 20 cases on the right. In the observation group, the male-to-female ratio was 21:19, with a maximum age of 76 and a minimum age of 27, and a median age of 50.64 ± 10.16 years. There were 23 left-sided fractures and 17 right-sided fractures. Comparison of the two groups' data showed $P > 0.05$, indicating significant comparability.

Inclusion criteria: Patients diagnosed with tibial plateau fractures by X-ray; patients with normal physical indicators; patients with complete clinical data.

Exclusion criteria: Pathological fractures; patients with malignant tumors; patients with cognitive dysfunction.

2.2. Methods

Patients in the control group underwent conventional surgery. Examination was completed with the assistance of CT or X-ray. An arcuate incision was made at the distal extension of the tibia, the fracture site, and beside the patella. After these operations, 1–3 screws were used for fixation. The fixation and reduction were confirmed by X-ray, and a drainage tube was placed after confirmation, followed by suturing the incision.

The observation group underwent minimally invasive surgery assisted by arthroscopy. After admission, patients underwent CT/X-ray examination. A standard-sized incision was made on the anterior position of the knee joint of the affected limb to explore the joint cavity and perform irrigation. With the help of arthroscopy, the morphology of the fracture site, as well as the specific direction and degree of displacement, could be systematically understood. Reduction was achieved through a probe trench by prying and lifting the fracture site. Subsequently, Kirschner wires were temporarily used to fix the fracture blocks. The accuracy of anatomy and the precision of fracture block reduction were explored based on X-ray conditions. Screws were screwed in along the direction of the Kirschner wires for fixation. To ensure the smoothness of the articular surface, appropriate pressure was applied to the screws to prevent fracture block fragmentation. After the operation, negative pressure drainage was performed on the patients. The reduction was confirmed under X-ray fluoroscopy. After ensuring the accuracy of the above operations, pressure could be applied with a bandage, and the negative pressure drainage device was removed two days later.

2.3. Evaluation indicators

- (1) Systematic evaluation of patient treatment effects and complications.
- (2) Comparison of surgical indicators, changes in HSS score and modified Lysholm score, knee joint range of motion, and postoperative GQOL-74 score between groups.

2.4. Statistical analysis

Statistical software SPSS 23.0 was used to analyze the data, and $P < 0.05$ indicated a significant difference.

3. Results

3.1. Comparison of the therapeutic effect between the two groups

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

Table 1. Treatment effect in the two groups of patients [n (%)]

Group	n	Markedly effective	Effective	Ineffective	Total effective rate
Observation group	40	24 (60.0)	15 (37.5)	1 (2.5)	39 (97.5)
Control group	40	20 (50.0)	12 (30.0)	8 (20.0)	32 (80.0)
χ^2					6.1346
P					0.0132

3.2. Comparison of complication rates between the two groups

The overall complication rate in the observation group was lower than that in the control group, with $P < 0.05$ (Table 2).

Table 2. Complication rates in the two groups of patients [n (%)]

Group	n	Incision infection	Knee joint adhesion	Joint stiffness	Total incidence rate
Observation group	40	1 (2.5)	1 (2.5)	0 (0.0)	2 (5.0)
Control group	40	3 (7.5)	3 (7.5)	3 (7.5)	9 (22.5)
χ^2					5.1647
P					0.0230

3.3. Comparison of surgical indicators between the two groups

The surgical indicators of the observation group were better than those of the control group, with $P < 0.05$ (Table 3).

Table 3. Surgical indicators in the two groups of patients (mean \pm standard deviation)

Group	n	Incision length (cm)	Time to ambulation (d)	Fracture healing time (w)	Hospital stay (d)
Observation group	40	6.04 \pm 0.24	3.02 \pm 0.83	11.02 \pm 2.01	14.53 \pm 3.09
Control group	40	14.43 \pm 3.22	6.03 \pm 1.46	13.76 \pm 2.26	19.44 \pm 3.32
t		16.4336	11.3353	5.7296	6.8468
P		0.0000	0.0000	0.0000	0.0000

3.4. Analysis of HSS scores and modified Lysholm scores before and after treatment in the two groups

Before treatment, there was no significant difference in scores between the groups, with $P > 0.05$. After treatment, all scores in the observation group were better than those in the control group, with $P < 0.05$ (Table 4).

Table 4. Comparison of changes in HSS and modified Lysholm scores between the two groups (mean \pm standard deviation)

Group	<i>n</i>	HSS score (points)		Modified Lysholm score (points)	
		Before treatment	After treatment	Before treatment	After treatment
Observation group	40	54.47 \pm 6.18	80.98 \pm 6.42	53.53 \pm 5.16	84.02 \pm 7.14
Control group	40	54.52 \pm 6.14	62.29 \pm 5.53	53.57 \pm 5.13	64.13 \pm 6.05
<i>t</i>		0.0363	13.9504	0.0348	13.4418
<i>P</i>		0.9711	0.0000	0.9724	0.0000

3.5. Analysis of knee joint range of motion in the two groups

The maximum knee extension and flexion angles in the observation group were better compared with those in the control group, with $P < 0.05$ (Table 5).

Table 5. Knee joint range of motion before and after treatment in the two groups (mean \pm standard deviation)

Group	<i>n</i>	Maximum knee extension angle (°)	Maximum knee flexion angle (°)
Observation group	40	-0.74 \pm 0.11	135.24 \pm 5.23
Control group	40	-0.42 \pm 0.24	120.04 \pm 5.35
<i>t</i>		7.6659	12.8492
<i>P</i>		0.0000	0.0000

3.6. Comparison of postoperative GQOL-74 scores between the two groups

All indicator scores in the observation group were higher than those in the control group, with $P < 0.05$ (Table 6).

Table 6. Analysis of postoperative GQOL-74 scores in the two groups (mean \pm standard deviation)

Group	<i>n</i>	Material life status score (points)	Physical function score (points)	Psychological function score (points)	Social function score (points)
Observation group	40	85.64 \pm 5.21	84.28 \pm 5.11	84.29 \pm 5.33	83.57 \pm 4.55
Control group	40	77.69 \pm 4.29	75.96 \pm 4.82	73.58 \pm 4.25	75.39 \pm 3.79
<i>t</i>		7.4501	7.4909	9.9363	8.7365
<i>P</i>		0.0000	0.0000	0.0000	0.0000

4. Discussion

Tibial plateau fractures are influenced by factors such as car accidents, trauma, and strenuous activities, and their clinical incidence is increasing year by year. A fracture directly affects joint function, significantly increasing the risk of blood vessel rupture and soft tissue damage^[3]. This type of fracture has a significant impact on patients, and due to the complex anatomical structure of the surrounding tissue, it is necessary to attach great importance to clinical treatment^[4]. At the same time, attention should also be paid to soft tissue damage. Surgical treatment is the preferred method for clinical treatment of tibial plateau fractures, and the most common surgical method is open reduction and internal fixation. During treatment, patients' ligamentous soft tissue and meniscus are subjected to

traction, which can lead to damage to cartilage tissue and articular surfaces^[5]. Moreover, this surgical method is more traumatic for patients, slowing down their postoperative recovery and making it difficult to detect other knee joint injuries in a timely manner. As a result, patients undergoing this surgical method have a higher incidence of postoperative complications, which adversely affects the treatment effect^[6].

In recent years, modern medical technology has achieved promising developments, and minimally invasive arthroscopic surgery has been widely used in clinical practice^[7]. This surgical approach does not severely damage the body's soft tissues and local nerves. With the assistance of arthroscopy, the anatomical structure of the tissues surrounding the patient's fracture can be displayed, providing a clear surgical field for the surgeon^[8]. Clinically, arthroscopic minimally invasive surgery allows for detailed observation of the scope, size, and surrounding involvement of the patient's fracture, preserving the function of the meniscus as much as possible^[9]. Additionally, patients treated with this surgical approach can enhance the reduction effect, and effectively control the direction of screw insertion and the degree of compression. The use of arthroscopy provides a more intuitive observation of the damage to the cruciate ligaments and meniscus in patients with tibial plateau fractures, allowing for targeted treatment measures^[10]. Based on this, arthroscopy can be used to repeatedly clean the joint cavity, enabling the removal of bone fragments and blood clots without opening the joint capsule, thereby significantly reducing the risk of infection^[11–13].

Based on the above research data, it is understood that the observation group had significantly better HSS scores, modified Lysholm scores, and knee joint range of motion compared to the control group ($P < 0.05$). This confirms that arthroscopy-assisted minimally invasive surgery significantly improves knee joint function in patients with tibial plateau fractures. The surgical indicators of the observation group were significantly better than those of the control group ($P < 0.05$). The reason for this is that this surgical approach can avoid further trauma to the patient, does not severely damage their body, and accelerates their postoperative recovery^[14]. The treatment effect, GQOL-74 score, and complications in the observation group were significantly better than those in the control group ($P < 0.05$). This indicates that arthroscopy-assisted treatment allows for systematic observation of fracture conditions, effective removal of bone fragments and blood clots, ensures precise reduction, significantly promotes postoperative recovery, and benefits the optimization of quality of life^[15].

5. Conclusion

Overall, during surgical treatment of tibial plateau patients, the use of arthroscopy for minimally invasive surgery significantly improves knee joint function and postoperative quality of life, with fewer complications and high clinical value for promotion and application.

Disclosure statement

The author declares no conflict of interest.

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Analysis of the Therapeutic Effect and Influencing Factors of PFNA Internal Fixation Using Improved Needle Insertion Method in Treating Intertrochanteric Fractures of the Femur

Lei Wang¹, Junxing Ye^{2*}, Zheng Feng^{1*}

¹Jiangyin Second People's Hospital, Jiangyin 214400, Jiangsu, China

²Jiangnan University Affiliated Hospital, Wuxi 214000, Jiangsu, China

**Authors to whom correspondence should be addressed.*

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Abstract: *Objective:* Exploring the therapeutic effect of implementing an improved needle insertion method in the treatment of proximal femoral nail anti-rotation (PFNA) internal fixation in patients with intertrochanteric fractures of the femur, and exploring the influencing factors of postoperative efficacy. *Method:* 100 patients with intertrochanteric fractures of the femur admitted to our hospital from January 2020 to December 2023 were randomly divided into two groups, both receiving PFNA internal fixation treatment. The control group received conventional method of inserting guide pins during surgery, while the study group received improved method of inserting guide pins. The efficacy, clinical indicators, and complications were compared between the two groups. Then, those with excellent and poor postoperative efficacy were included in the excellent group and the poor group, respectively. Univariate and multivariate logistic regression analyses were conducted on the factors that affect postoperative efficacy. *Results:* The proportion of age in the excellent group was generally younger than that in the poor group. The proportions of preoperative and postoperative complications and anemia in the excellent group were lower than those in the poor group. The proportion of early postoperative functional exercise in the excellent group was higher than that in the poor group. The proportion of improved needle insertion method in the excellent group was higher than that in the poor group ($P < 0.05$). After multiple logistic regression analysis, age, postoperative complications, preoperative complications, anemia, and intraoperative needle insertion method were risk factors affecting postoperative efficacy ($P < 0.05$). *Conclusion:* The implementation of improved needle insertion method in PFNA internal fixation treatment for patients with intertrochanteric fractures of the femur has a definite therapeutic effect and high safety. Age, preoperative complications and postoperative complications, anemia, and intraoperative needle insertion methods are risk factors that affect the therapeutic effect.

Keywords: PFNA internal fixation; Intertrochanteric fracture of femur; Improved needle insertion method; Therapeutic effect; Influencing factor

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1. Introduction

Intertrochanteric hip fractures are a common type of fracture, particularly prevalent among the elderly population ^[1]. These fractures are often caused by indirect external forces, such as external impacts, adduction and abduction during falls, or sudden twisting of the lower limbs, and most patients experience comminuted fractures ^[2,3]. Non-surgical treatment often requires long-term bed rest, which can lead to complications such as urinary tract infections and deep vein thrombosis, as well as hip varus, causing significant negative impacts on the patient's recovery. Internal fixation surgery is a commonly used surgical treatment for such fractures, and among them, proximal femoral nail anti-rotation (PFNA) internal fixation is widely used in clinical practice due to its low operational difficulty and minimal trauma to the patient ^[4,5]. However, there are certain technical difficulties in the needle insertion process during PFNA surgery, especially because the fractured end of the intertrochanteric region has no support, making it difficult to insert the guide pin ^[6]. To improve the efficacy of PFNA surgery and reduce the incidence of complications, this study implemented a modified method of inserting the guide pin for patients with intertrochanteric hip fractures treated in our hospital. By adjusting parameters such as the angle, position, or depth of the needle insertion, the goal is to better adapt to the anatomical characteristics of the fracture, improve the stability and fixation effect of the internal fixation device, and explore factors that may affect the efficacy. Through the analysis of these factors, clinical practice can be better guided, improving the success rate of surgical treatment, reducing complications, and providing a basis for clinical treatment.

2. Materials and methods

2.1. General information

100 patients with intertrochanteric hip fractures treated in our hospital from January 2020 to December 2023 were selected. The control group (50 patients) consisted of 34 males and 16 females, with ages distributed as follows: <65 years old (25 patients), 65–75 years old (18 patients), and >75 years old (7 patients). The causes of injury were car accidents (9 patients), falls (27 patients), heavy object injuries (10 patients), and other reasons (4 patients). The study group (50 patients) consisted of 33 males and 17 females, with age distributions of <65 years old (27 patients), 65–75 years old (15 patients), and >75 years old (8 patients). The causes of injury were car accidents (8 patients), falls (32 patients), heavy object injuries (7 patients), and other reasons (3 patients). Inclusion criteria were: age ≥ 60 years old; diagnosis of intertrochanteric hip fracture confirmed by X-ray and CT; receipt of PFNA internal fixation treatment; unilateral fracture; and informed consent. Exclusion criteria were: coagulation dysfunction; limited mobility of the affected limb before the fracture; pathological fracture; fracture of other parts; severe organ damage; and intolerance to surgery. There was no statistically significant difference in general information between the two groups ($P > 0.05$).

2.2. Methods

The control group underwent conventional guide pin insertion. The patients were positioned in a supine position, with the healthy lower limb in hip and knee flexion, fixed in an abducted position on the operating table, and the trunk adducted towards the healthy side. Under C-arm X-ray fluoroscopy, the affected limb was tractioned in an abducted position, adducted, and internally rotated until the fracture was satisfactorily reduced. A Kirschner wire guide pin was used to locate the insertion point, and after confirming the satisfactory position of the insertion point under fluoroscopy, an opener was used to open along the guide pin and insert the guide pin. Subsequently, reaming was performed, and the main pin was inserted. The study group underwent modified guide pin insertion. The surgeon used their fingers to touch the patient's greater trochanter from behind and find the apex of the

greater trochanter. The intersection of the intertrochanteric crest and the apex of the greater trochanter, extended approximately 1.5 cm forward from the apex, was used as the insertion point for the main pin. The remaining operation steps were the same as those in the control group.

2.3. Observation indicators

(1) Efficacy: Excellent: The fracture is completely healed, and normal walking is possible; Good: The fracture is basically healed, and walking is possible; Acceptable: There is slight hip varus, and hip joint movement is slightly restricted; Poor: The fracture site is healed with deformity, and hip joint movement is severely restricted. Excellent and good efficacy rates were calculated as the sum of excellent and good cases, while poor efficacy rates were calculated as the sum of acceptable and poor cases. (2) Various clinical indicators were recorded for the two groups. (3) The occurrence of complications was analyzed for the two groups.

2.4. Statistical analysis

SPSS 22.0 was used for statistical analysis. Clinical indicators such as guide pin insertion time and fracture healing time, which followed a normal distribution and had homogeneous variances, were expressed as mean \pm standard deviation (SD) and analyzed using the *t*-test. Count data such as efficacy and complications were expressed as [*n* (%)] and analyzed using the chi-square test. Multivariate analysis was performed using logistic regression analysis. $P < 0.05$ was considered statistically significant.

3. Results

3.1. Efficacy

The overall excellent and good rate in the study group was 76.00% (38/50), which was higher than the 92.00% (46/50) in the control group ($\chi^2 = 4.762$, $P < 0.05$).

3.2. Typical case

Patient Zhou Xiaojun, female, 73 years old, was admitted to the hospital due to pain and limited mobility in the left hip caused by a fall one hour prior. The diagnosis at admission was a left intertrochanteric hip fracture. The patient underwent closed reduction and PFNA internal fixation of the left intertrochanteric hip fracture and recovered well after surgery. See **Figure 1**.

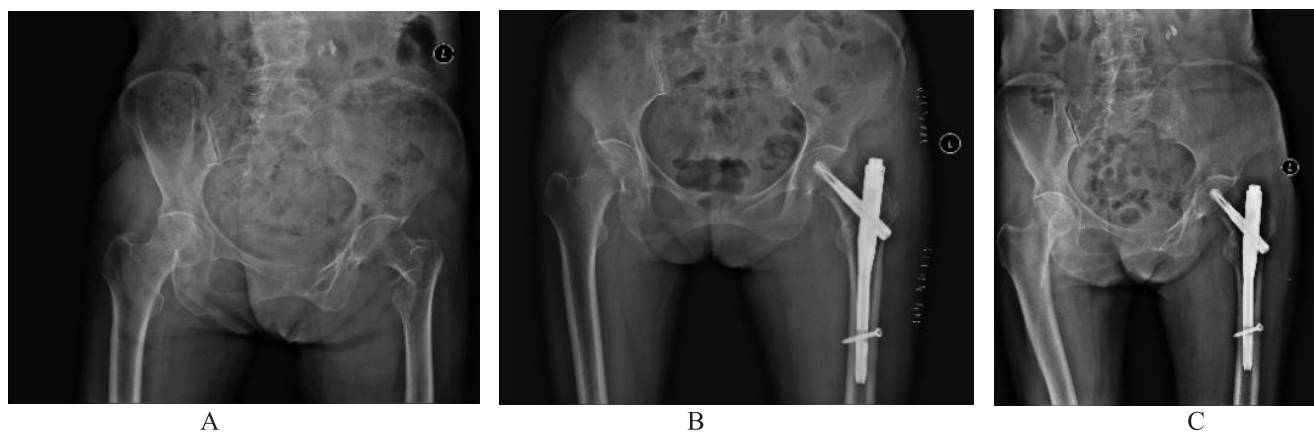


Figure 1. A shows the preoperative X-ray of the patient, B shows the postoperative X-ray, and C shows the follow-up X-ray 3 months after surgery

3.3. Clinical indicators

The clinical indicators of the study group were superior to those of the control group ($P < 0.05$). See **Table 1**.

Table 1. Comparison of clinical indicators between the two groups (mean \pm SD)

Group	Guide pin insertion time (min)	Bleeding volume during guide pin insertion (ml)	Fluoroscopy frequency (times)	Operation time (min)	Fracture healing time (weeks)	Hospital stay (days)	Time to weight-bearing (weeks)
Control group ($n = 50$)	35.27 \pm 8.94	189.78 \pm 30.16	17.13 \pm 1.48	74.38 \pm 6.27	13.52 \pm 1.74	10.84 \pm 1.35	4.77 \pm 0.96
Study group ($n = 50$)	25.17 \pm 7.58	133.29 \pm 26.47	5.14 \pm 1.06	55.63 \pm 5.19	11.08 \pm 1.48	9.01 \pm 1.29	3.57 \pm 0.92
<i>t</i>	6.093	9.954	46.572	16.289	7.553	6.930	6.382
<i>P</i>	0.000	0.000	0.000	0.000	0.000	0.000	0.000

3.4. Complications

The overall incidence of complications in the study group was lower than that in the control group ($P < 0.05$). See **Table 2**.

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

Group	Hip varus	Delayed fracture union	Internal fixation loosening	Lower extremity deep vein thrombosis (DVT)	Total
Control group ($n = 50$)	2	5	3	1	11 (22.00)
Study group ($n = 50$)	0	1	2	0	3 (6.00)
χ^2	-	-	-	-	5.316
<i>P</i>	-	-	-	-	0.021*

3.5. Univariate analysis of factors affecting postoperative efficacy

84 patients with excellent postoperative efficacy were included in the excellent group, and 16 patients with poor postoperative efficacy were included in the poor group. Compared with the poor group, the excellent group had a younger overall age distribution, a lower proportion of preoperative comorbidities, postoperative complications, and anemia, and a higher proportion of early postoperative functional exercise and the modified needle insertion method during surgery ($P < 0.05$). See **Table 3**.

Table 3. Univariate analysis of factors affecting postoperative efficacy

Item	Excellent group ($n = 84$)	Poor group ($n = 16$)	χ^2	<i>P</i>
Gender	Male	56	0.026	0.871
	Female	28		
Age (years)	<65	49	26.026	0.000
	65–75	29		
	>75	6		

Table 3 (Continued)

Item		Excellent group (<i>n</i> = 84)	Poor group (<i>n</i> = 16)	χ^2	<i>P</i>
Cause of injury	Traffic accident	13	4	2.325	0.508
	Fall	52	7		
	Heavy object injury	14	3		
	Other	5	2		
Postoperative complications	Yes	5	9	24.217	0.000
	No	79	7		
Preoperative comorbidities	Yes	31	12	7.958	0.005
	No	53	4		
Anemia	Yes	38	13	6.975	0.008
	No	46	3		
Early postoperative functional exercise	Yes	70	5	16.766	0.000
	No	14	11		
Preoperative long-term bed rest	Yes	14	5	1.031	0.310
	No	70	11		
Intraoperative needle insertion method	Conventional method	36	14	10.714	0.001
	Modified method	48	2		

3.6. Multivariate logistic regression analysis of factors affecting postoperative efficacy

Age, preoperative comorbidities, postoperative complications, intraoperative needle insertion method, and anemia were identified as risk factors affecting postoperative efficacy ($P < 0.05$). See **Table 4**.

Table 4. Multivariate logistic regression analysis of factors affecting postoperative efficacy

Factor	B	S.E.	Wald χ^2	<i>P</i>	OR	95% CI
Age	3.052	0.716	16.113	0.001	0.902	0.081–0.763
Postoperative complications	-2.937	1.024	7.085	0.009	1.026	0.108–0.924
Preoperative comorbidities	-1.897	0.926	9.242	0.005	1.084	0.091–1.975
Anemia	-1.852	0.706	7.295	0.013	0.602	0.195–1.042
Early postoperative functional exercise	0.831	0.054	1.276	0.094	0.483	0.093–0.905
Intraoperative needle method (modified)	5.082	1.704	14.039	0.001	0.891	0.102–1.226

4. Discussion

Intertrochanteric hip fracture is one of the common types of fractures among the elderly, usually caused by osteoporosis, falls, or other traumatic factors ^[7,8]. Due to the deepening trend of population aging, the incidence of intertrochanteric hip fractures is also rising continuously ^[9]. In this context, it is crucial to find a safe and effective treatment method ^[10]. Internal fixation surgery, as one of the main methods to treat intertrochanteric hip fractures,

has been widely used in clinical practice. Among internal fixation surgeries, PFNA is favored because of its good stability at the fracture site and support for early patient mobilization^[11]. However, traditional PFNA surgery poses certain challenges in terms of surgeon experience and operational skills, especially during the needle insertion process^[12]. In traditional PFNA surgery, the surgeon needs to reasonably determine the needle insertion angle and position based on the patient's fracture situation, to ensure the correct placement and stability of the internal fixation device^[13,14]. However, in actual clinical practice, difficulties often arise in the smooth insertion of the guide pin, and in this study, better results were achieved by adopting a modified needle insertion method^[15].

The study observed that the study group had better efficacy than the control group, and the overall complication rate was lower than that of the control group ($P < 0.05$). This suggests that the modified needle insertion technique has a significant effect on improving efficacy and can reduce the incidence of complications. This may be due to the different fracture characteristics of patients with femoral intertrochanteric fractures, traditional needle insertion methods may not fully meet clinical needs, resulting in poor surgical outcomes or increased incidence of complications^[16,17]. To overcome such problems, the modified needle insertion method adjusts parameters such as needle insertion angle, position, or depth to better adapt to the patient's individual anatomical structure and fracture characteristics, improving the stability and treatment effect of the internal fixation device. This helps prevent post-surgical displacement and instability during early activity, thereby reducing complications such as fracture nonunion or loosening of internal fixation^[18,19]. Additionally, once surgeons become proficient in the modified needle insertion technique, it can effectively reduce surgery time, which not only helps reduce the risk of surgery-related complications but also benefits patients by lightening their post-surgical burden and improving surgical efficiency^[20,21]. The study observed that multivariable logistic regression analysis identified several risk factors that can affect treatment efficacy, including age, preoperative comorbidities, postoperative complications, intraoperative needle insertion method, and anemia. The reasons for these factors are analyzed as follows: (1) Age: Older patients have different bone density, physiological conditions, and fracture types compared to younger patients. Additionally, elderly patients may have more complex fractures due to osteoporosis and comorbidities, affecting the difficulty and complexity of surgical operations^[22,23]. (2) Preoperative comorbidities and postoperative complications: Patients with comorbidities before surgery may have involvement of other organs, significantly increasing the risk of postoperative complications and affecting surgical treatment efficacy. Moreover, preoperative comorbidities such as diabetes and cardiovascular diseases can affect the patient's overall condition and fracture healing ability, increasing surgical risk. Postoperative complications can directly impact fracture healing^[24]. (3) Anemia: Anemia can affect postoperative tissue oxygen supply, thus delaying the fracture healing process. (4) Intraoperative needle insertion method: The choice and skill level of the intraoperative needle insertion method directly relate to the position and stability of the internal fixation device^[25]. The modified needle insertion technique requires a higher level of skill and more precise operation from the surgeon; otherwise, it may lead to inaccurate or unstable needle insertion and affect surgical efficacy.

5. Conclusion

In summary, the application of the modified needle insertion technique in PFNA internal fixation treatment demonstrates better efficacy and higher safety. Meanwhile, age, preoperative comorbidities, postoperative complications, anemia, and intraoperative needle insertion method are risk factors that can affect treatment efficacy.

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Study on the Application of Refined Management of Foreign Medical Devices and Implants in Infection Control of Orthopedic Implant Surgery

Chen Chen, Zifeng Li*

Shaanxi Provincial People's Hospital, Xi'an 710068, Shaanxi, China

**Author to whom correspondence should be addressed.*

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Abstract: *Objective:* To analyze the application effect of refined management of foreign medical devices and implants in infection control of orthopedic implant surgery. *Methods:* 252 patients who underwent orthopedic implant surgery in a hospital from May 2023 to April 2024 were selected and grouped according to the time node of the introduction of the refined management method. 126 patients before the introduction of the refined management method were included in the control group, and the surgical operation was completed by 20 doctors, with a total of 1,204 pieces of medical devices and implants. The 126 patients after the introduction of the refined management method were included in the observation group, and the surgical operations were performed by 21 doctors, using a total of 1,207 medical devices and implants. The two groups were compared in terms of the qualification rate of foreign medical devices and implants, satisfaction with their use, and the rate of infection of surgical incisions in the hospital. *Results:* The qualified rate of foreign medical devices and implants in the observation group was 96.93%, which was significantly higher than that of 83.97% in the control group ($P < 0.05$). Satisfaction scores for the observation group in the dimensions of the quality of foreign medical device and implant items, device distribution, timeliness of supply, and improvement of the problem were respectively 85.27 ± 6.78 , 86.69 ± 6.73 , 85.92 ± 6.47 , 86.79 ± 5.83 , which were significantly higher than the control group's 80.42 ± 6.26 , 82.24 ± 6.29 , 81.19 ± 5.83 , 82.14 ± 5.72 , and the difference was statistically significant ($P < 0.05$); the rate of nosocomial surgical incision infection in the observation group was 0.79%, which was significantly lower than that of the control group (6.34%) ($P < 0.05$). *Conclusion:* The application of refined management in the infection control of orthopedic implant surgery can obtain ideal results, significantly reducing the risk of nosocomial incision infection and further improving the qualification rate of foreign medical devices and implants, and ultimately, obtaining a higher degree of satisfaction with the use.

Keywords: Foreign medical devices; Implants; Refined management; Orthopedic implant surgery; Incision infection

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1. Introduction

With the increasing number of traffic injuries, fall injuries, and other emergency surgeries in recent years, the use

of artificial prostheses, internal fixation materials, and other foreign medical devices and implants has gradually increased. Although it can significantly improve the therapeutic effect of the skeletal system diseases, due to the supplier-led flow, complex structure, and frequent turnover, there are significant hidden dangers in the cleaning and sterilization, quality traceability, and other aspects, which easily cause surgical incision infections—a serious threat to patients’ prognosis ^[1]. Clinical studies have shown that the incidence of orthopedic implant-related infections can be up to 2.1–5.8%, and because of its tendency to form biofilms that lead to antibiotic resistance, the rate of secondary surgery for infected patients is as high as 34%, and the cost of healthcare is increased by nearly three times. Notably, about 40% of infections are directly related to defective management of foreign medical devices and implants ^[2]. A domestic multicenter study pointed out that the first sterilization failure rate of orthopedic foreign devices exceeded 30%, and the functional defect rate of devices reached 8.6%, exposing the systemic risk of traditional rough management. Firstly, multi-departmental collaboration in the flow of instruments is faulty, and delayed pretreatment leads to bioburden overload; secondly, the sterilization protocol is not sufficiently adapted to the material of the instruments, such as porous titanium alloy implants with residual contaminants due to inappropriate sterilization parameters; and furthermore, the informationization traceability system is missing, and it is difficult to trace the correlation between infection cases and instrument batches. Although the international guidelines emphasize the implementation of the full life-cycle management of devices, the domestic practice still focuses on the optimization of a single link, and lacks an integrated strategy covering “access-processing-use-monitoring” ^[3]. After the revision of the Medical Device Supervision and Management Regulations in 2023, how to build a refined management program to fit the local healthcare system has become a clinical proposition that needs to be solved urgently ^[4]. Based on the closed-loop quality theory, this study innovatively establishes a refined management system that includes standardized pretreatment, dynamic sterilization monitoring, RFID intelligent traceability, and multidisciplinary quality control. By comparing and analyzing the changes in the qualification rate, clinical satisfaction, and infection rate of the instruments before and after refined interventions, the study aims to validate the practical value of the systematic management of infection control and provide empirical evidence for the standardization of orthopedic surgical instrument management.

2. Information and methods

2.1. General information

Two hundred and fifty-two patients who underwent implant surgery in the orthopedic department of a hospital from May 2023 to April 2024 were selected as study subjects and grouped according to the time point of the implementation of the refined management system. The 126 patients before the introduction of the refined management method (May to October 2023) were included in the control group, of which 68 were male and 58 were female, aged 25–78 years, with an average of 56.3 ± 12.7 years; disease types: 61 traumatic fractures, 39 arthroplasties, and 26 internal spinal fixations; the surgeries were performed by 20 attending surgeons, and a total of 1,204 implants (824 titanium alloy instruments, 256 cobalt-chromium-molybdenum alloys, and 124 polymer polyethylene liners) were used. One hundred and twenty-six patients after the introduction of the refined management method (November 2023 to April 2024) were included in the observation group. Among them, there were 71 males and 55 females, aged 22–81 years, with a mean of 57.1 ± 13.2 years; the distribution of disease types: 59 cases of traumatic fracture, 42 cases of arthroplasty, and 25 cases of internal spinal fixation; the surgeries were performed by 21 attending surgeons, and a total of 1,207 pieces of foreign medical devices and implants were

used (831 pieces of titanium instruments, 259 pieces of cobalt-chromium-molybdenum alloys, and 117 pieces of polymer polyethylene liner). Comparing the baseline data of the two groups, the differences were not statistically significant and were comparable.

Inclusion criteria: (1) aged 22–81 years old, requiring open orthopedic surgery and application of foreign medical devices and implants; (1) preoperative imaging and laboratory tests confirming no signs of active infections (CRP < 10 mg/L, leukocyte count $\leq 10 \times 10^9/L$); (3) having complete preoperative assessment data and standardized 3-month postoperative follow-up compliance; (4) approved by the hospital ethics committee and signed a written informed consent.

Exclusion criteria: (1) preoperative presence of a clear source of infection such as osteomyelitis, septic arthritis, or abnormal inflammatory indexes (CRP ≥ 10 mg/L, PCT ≥ 0.5 ng/mL); (2) comorbidity with immune system diseases or long-term use of immunosuppressants (prednisone > 10 mg/d for more than 1 month); (3) comorbidity with severe organ insufficiency (cardiac function NYHA classification III-IV, eGFR < 30 mL/min/1.73m²); (4) participation in other clinical trials within 3 months or presence of study interfering factors such as risk of loss of visits, language communication disorders.

2.2. Methodology

The control group implemented routine management. Suppliers were notified to send foreign medical devices and implants directly to the sterilizing supply center according to the surgical demand, and the standard process of mechanical cleaning, pressure steam sterilization, and biomonitoring was qualified and then issued to the operating room. Post-operative instruments were recovered by the Sterilization and Supply Center, and the manual brushing-ultrasonic cleaning-lubrication and maintenance process was implemented, and they were returned to the suppliers after sterilization. Waste implants removed during surgery were contained in closed containers by the operating room and incinerated at high temperatures in accordance with medical waste management regulations. Personalized adjustment of sterilization parameters and application of the electronic traceability system were not implemented during the entire surgical process.

The observation group implemented refined management, with the following specific management measures: (1) Constructing a refined management team: A special management group for orthopedic implants was set up, headed by the director of the Hospital Infection Management Department, with members covering the director of the orthopedic department, the head nurse of the disinfection and supply center, the engineer of the device department, and the commissioner of the information department. The group has implemented a monthly joint meeting system and formulated the “Specification for Full Process Management of Foreign Devices (Version 2.0),” specifying 18 operational standards for device access, pretreatment, sterilization monitoring, and so on. (2) Closed-loop management of supply chain: Establish a black and white list system for suppliers, require ISO13485 quality system certification, FDA/CE registration certificates and biocompatibility test reports, and update the qualification files quarterly; develop orthopedic surgical instrument demand prediction system, automatically generate instrument specification recommendations (error $\leq \pm 5\%$) by retrieving patient image data through HIS, and generate an electronic purchase order after confirmation by the surgeon-in-charge, and the system automatically verifies the inventory and instrument validity period. The system automatically verifies the inventory and the validity period of the instruments; when the implants are delivered, a two-person verification process of “clinical engineer + surgical nurse” is implemented to verify the registration certificate, sterilization validity period, and traceability information by scanning the UDI code of the instruments, and then uploading

them to the hospital's SPD system after confirming that they are free from errors. (3) Sterilization process reengineering: The sterilization program is customized according to the physical characteristics of the implant, titanium alloy instruments are sterilized at 132°C pre-vacuum (exposure time 10 min), and polymer materials are sterilized by low-temperature hydrogen peroxide plasma; temperature-pressure sensor arrays are deployed inside the sterilization chamber, and the real-time data is transmitted to the central monitoring platform, which triggers the audible and visual alarms and suspends the cycle automatically in the case of deviation from the parameters; a gradient decompression is implemented for the cooling zone (200 kPa → 50 kPa/15min) in the cooling area and equipped with condensate adsorption device, so that the wet pack rate from 12.6% to 2.3%. (4) Full-cycle traceability system: Applying RFID chip implantation technology, temperature-resistant electronic tags are embedded in instrument packages, and the operating room automatically checks the matching degree between the instrument list and the surgical program through the read-write; the surface of implants is coated with antimicrobial coatings containing nano-silver ions (in accordance with YY/T1293 standard), and the number of colonies is dynamically monitored through the irrigation fluid of the surgical field (the threshold value is ≤ 50 CFU/mL); after the operation, the establishment of an instrument-patient-infection ternary correlation database can be used to track the infection rate through machine learning algorithms to identify the characteristics of high-risk devices (such as the number of reuse > 20 times, structural porosity > 30% of the implant), to achieve the risk of infection early warning. (5) Establishment of three-level quality control nodes: Pre-operative device function testing (e.g. power tool speed deviation $\leq 5\%$) is performed by CSSD, intra-operative 20-item verification checklist is performed by roving nurses, and post-operative data on device usage is collected via IOT terminals, including surgical duration-sterilization cycle matching degree, physician operation standard score, etc.), and ultimately, a device full life-cycle quality report is generated, which serves as the core basis for supplier performance evaluation.

2.3. Observation indicators

Qualified status of foreign medical devices and implants: Evaluate the qualification status of foreign medical devices and implants used in the operation before and after management according to the qualification criteria in the Regulations on Supervision and Administration of Medical Devices.

Satisfaction scores for the use of foreign medical devices and implants: Satisfaction scores were given by the attending surgeons of each group on the quality of foreign medical devices and implant items used during surgery, device delivery, supply timeliness and problem improvement, etc., and the total score for each dimension was 100, with a higher score representing a higher degree of satisfaction.

Nosocomial surgical incision infection: Observe and record the occurrence of incision infection during hospitalization in the two groups, infection rate = number of infected cases/total number of cases $\times 100\%$.

2.4. Statistical treatment

SPSS 24.0 statistical software was used to process the data, and the measurement information was expressed as mean \pm standard deviation (SD), and the *t*-test was implemented between the groups, and the count information was expressed as [*n* (%)], and the χ^2 test was used, and the difference was considered to be statistically significant at $P < 0.05$.

3. Results

3.1. Comparison of the qualification rate of foreign medical devices and implants between the two groups

The qualification rate of foreign medical devices and implants in the observation group was 96.93%, which was significantly higher than that of 83.97% in the control group, and the difference was statistically significant ($P < 0.05$), as shown in **Table 1**.

Table 1. Comparison of the qualification rate of foreign medical devices and implants in the two groups (pieces, %)

Groups	Medical devices and implants (pieces)	Qualified pieces	Satisfactory rate
Control group	1204	1011	83.97
Observation group	1207	1170	96.93
χ^2			117.397
P			< 0.001

3.2. Comparison of satisfaction scores in the use of foreign medical devices and implants between the two groups

In the observation group, the satisfaction scores for the dimensions of external medical device and implant item quality, device distribution, supply timeliness, and problem improvement were significantly higher than those of the control group, with statistically significant differences ($P < 0.05$), as shown in **Table 2**.

Table 2. Comparison of satisfaction scores for the use of foreign medical devices and implants between the two groups (mean \pm SD, points)

Groups	Surgeons (cases)	Quality of device	Instrument distribution	Timeliness of supply	Issue improvement
Control group	20	80.42 \pm 6.26	82.24 \pm 6.29	81.19 \pm 5.83	82.14 \pm 5.72
Observation group	21	85.27 \pm 6.78	86.69 \pm 6.73	85.92 \pm 6.47	86.79 \pm 5.83
t		2.377	2.185	2.455	2.576
P		0.023	0.035	0.018	0.014

3.3. Comparison of nosocomial surgical incision infections between the two groups

The rate of nosocomial surgical incision infection in patients of the observation group was 0.79%, which was significantly lower than that of the control group (6.34%), and the difference was statistically significant ($P < 0.05$), see **Table 3**.

Table 3. Comparison of nosocomial surgical incision infection rates between the two groups [n (%)]

Groups	Patients (cases)	Infections	Rate of infection (%)
Control group	126	8	6.34
Observation group	126	1	0.79
χ^2			4.148
P			0.042

4. Discussion

In orthopedic surgery, foreign medical devices such as locking plates and pedicle screw systems can accurately match the anatomical structure of bones and improve surgical precision due to their highly specialized design; at the same time, titanium alloys and cobalt-chromium-molybdenum alloys are biocompatible and mechanically stable implantable materials that can maintain bone stability over time, which can provide technological protection to improve the prognosis of patients undergoing complex orthopedic surgery^[5,6]. However, in the management of sterilization supply centers, the traditional management model has systematic defects, leading to the coexistence of infection risk and service quality problems^[7]. First, a sloppy instrument sterilization process and an insufficient biofilm removal rate have resulted in high rates of postoperative incision infections. Secondly, the supplier qualification audit is a mere formality, with a high rate of functional defects of instruments, and intraoperative problems such as screw slippage and power tool jamming are likely to occur. Furthermore, instrument delivery relies on manual coordination, and surgical delays occur frequently due to information disconnection, which directly affects surgical efficiency^[8]. Finally, due to the lack of feedback mechanism in traditional management, only a small portion of the abnormal events of instruments can be traced back to the suppliers, coupled with the fact that the rate of wet packs and reuse of orthopedic instruments under traditional management is much higher than the standard of refined management, which further exacerbates the risk of infection, and the implementation of systematic reforms is urgently needed. Refined management is a systematic management model with risk control at its core, which makes use of a multi-departmental collaborative quality control network, material-appropriate sterilization strategy, RFID/UDI information traceability technology and continuous quality improvement (CQI) mechanism to achieve full life-cycle control of devices through standardized processes, intelligent monitoring, and closed-loop traceability, with the aim of eliminating management blind zones and raising the threshold of medical safety.

The results of this study show that the qualification rate of foreign medical devices and implants in the observation group is higher than that of the control group, the satisfaction scores in the dimensions of quality of items of foreign medical devices and implants, distribution of devices, timeliness of supply, and improvement of problems are significantly higher than that of the control group, and the rate of infection of nosocomial surgical incisions of patients in the observation group is significantly lower than that of the control group, and the differences are all statistically significant ($P < 0.05$). The reasons for this are attributed to the significant advantages of the refined management model: (1) material grading sterilization combined with real-time sensor monitoring effectively reduces the bioburden, improves the qualification rate of instruments, and blocks the possibility of infection from the source. (2) The application of an electronic demand prediction system effectively improves the error rate of instrument delivery and guarantees the smoothness of surgery^[9]. (3) The RFID traceability system realizes the data linkage of “instrument-patient-operator,” and combined with the dynamic monitoring of bacterial colonies in postoperative irrigation fluid, the risk of incisional infection is minimized. (4) Through the three-level quality control nodes of preoperative functional testing, intraoperative verification checklist, and postoperative data analysis, the response time for improvement of device problems has been shortened^[10,11].

5. Conclusion

In summary, the refined management has innovatively constructed a closed-loop system of “demand-supply-use-monitoring,” and systematically solved the core pain points of orthopedic foreign device management through the

dynamic review of qualification, optimization of sterilizing parameters, and intelligent traceability technology. It not only significantly improves the qualification rate of instruments and reduces the risk of infection rate of patients, but also provides a replicable management paradigm for orthopedic infection control.

Disclosure statement

The authors declare no conflict of interest.

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Effects of Goal-Directed Fluid Therapy on MAP, NT-proBNP, and hs-CRP in Elderly Patients with Lower Extremity Fractures Undergoing Open Reduction and Internal Fixation

Hongquan Ren, Yabo Hao*

Shaanxi Provincial People's Hospital, Xi'an 710068, Shaanxi, China

**Author to whom correspondence should be addressed.*

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Abstract: *Objective:* To investigate the effects of goal-directed fluid therapy on mean arterial pressure (MAP), N-terminal pro-brain natriuretic peptide (NT-proBNP), and high-sensitivity C-reactive protein (hs-CRP) levels in elderly patients with lower limb fracture undergoing open reduction and internal fixation surgery 24 hours after surgery. *Methods:* Sixty elderly patients admitted to our hospital from June 2022 to February 2023 for open reduction and internal fixation of lower limb fractures were randomly divided into two groups: 30 cases in the observation group and 30 cases in the control group. The patients in the control group were treated with conventional fluid therapy, and the observation group received goal-directed fluid therapy on the basis of the control group. The patients in the two groups were observed to monitor the changes of mean arterial pressure (MAP) and heart rate (HR), as well as the preoperative and 24-hour postoperative levels of NT-proBNP and hs-CRP. *Results:* The NT-proBNP level in the control group was 608.37 ± 180.46 ng/ml and the hs-CRP level was 510.09 ± 190.21 pg/ml during the operation, and the NT-proBNP and hs-CRP levels in the observation group were 608.74 ± 180.26 ng/ml and 514.12 ± 180.63 pg/ml, respectively, and the difference between the two groups was not statistically significant ($P > 0.05$). The levels of NT-proBNP and hs-CRP in the control group were 369.74 ± 77.11 ng/ml and 298.41 ± 72.14 pg/ml respectively at 24-hour postoperatively, and those in the observation group were 324.74 ± 71.26 ng/ml and 245.12 ± 77.63 pg/ml, the difference between the two groups was statistically significant ($P < 0.05$). In the control group, the preoperative MAP and heart rate were 14.12 ± 3.92 mmHg and 47.18 ± 15.42 beats/min respectively; in the intraoperative period, the MAP and heart rate were 54.81 ± 14.41 mmHg and 60.65 ± 14.11 beats/min. In the observation group, the preoperative MAP and heart rate were 15.12 ± 3.48 mmHg and 48.21 ± 15.36 beats/min, and the intraoperative MAP and heart rate were 50.16 ± 14.03 mmHg and 57.65 ± 14.10 beats/min, the difference was statistically significant ($P < 0.05$). *Conclusion:* Compared with traditional fluid therapy, goal-directed fluid therapy can reduce MAP, NT-proBNP, and hs-CRP levels in elderly patients with lower limb fractures undergoing open reduction and internal fixation surgery, and reduce the incidence of postoperative complications.

Keywords: Goal-directed fluid therapy; Fracture; Open reduction and internal fixation surgery; MAP; NT-proBNP; hs-CRP

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1. Introduction

With the development of population aging, the morbidity rate of elderly patients is increasing year by year. According to statistics, among the elderly over 60 years of age in China, about 13.7 million falls occur each year, of which lower limb fractures account for 60% to 80%. Since most elderly people have osteoporosis and reduced bone mass, they are prone to fractures due to falls. Therefore, early surgical treatment is the best option for elderly patients with fractures combined with osteoporosis. Traumatic shock is one of the common complications in elderly patients during fracture surgery. Its pathogenesis is still unclear, and it is currently believed to be related to systemic vasodilatory dysfunction and insufficient tissue perfusion. In actual clinical work, some studies have found that the condition of patients with acute traumatic shock can be rapidly improved after receiving a blood transfusion. In addition, acute traumatic shock patients can improve their survival rate and quality of life through rational fluid therapy. Goal-directed fluid therapy (GDFT) is a goal-oriented approach to fluid therapy that aims to minimize dehydration and avoid over- or under-rehydration to achieve the clinically required fluid target concentration. Most previous studies on GDFT therapy have focused on general adult patients, and fewer have addressed geriatric patients undergoing orthopedic surgery. The relevant literature reports are also relatively rare, it has been shown that on the basis of conventional treatment, increasing the amount of rehydration can shorten the ICU hospitalization time by 19.5 days and reduce the mortality rate by 17.5% ^[1]; one study used GDFT treatment on 80 patients, and the results showed that the average hospitalization time and the mortality rate were significantly reduced compared with the conventional treatment ^[2]. In addition, some scholars have pointed out that if GDFT treatment is applied to postoperative orthopedic patients, it is expected to obtain better efficacy ^[3]. However, there are fewer reports on GDFT treatment in China, and there is still a lack of uniform standards, so it cannot be promoted to medical institutions across the country. Therefore, in this study, we chose elderly patients with lower limb fractures undergoing open reduction and internal fixation as research subjects, and observed the effects of GDFT treatment and conventional fluid therapy on mean arterial pressure (MAP), N-terminal pro-brain natriuretic peptide (NT-proBNP), and high-sensitivity C-reactive protein (hs-CRP), to investigate the therapeutic effect of GDFT on these patients. The results of the study are reported as follows.

2. Information and methods

2.1. General information selection

Sixty cases of open reduction and internal fixation of lower limb fractures in the elderly admitted to our hospital from June 2022 to February 2023 were selected, of which 33 cases were male and 27 cases were female; their ages ranged from 67 to 85 years old, with an average age of 74.22 ± 3.15 years old; they were randomly divided into two groups, the observation group consisted of 30 cases, of which 17 cases were male and 13 cases were female, with an average age of 71.17 ± 7.53 years old. Inclusion criteria: (1) age ≥ 60 years; (2) need to perform open reduction and internal fixation surgery; (3) no other underlying diseases or complications before surgery; (4) no abnormal coagulation function, electrolyte disorders, or drug allergies; (5) no other underlying diseases or complications before surgery; (6) No preoperative use of anticoagulant, antiplatelet, lipid-lowering, and hepatoprotective drugs; (7) Informed consent of the patients and signing of the informed consent form. Exclusion criteria: (1) those who cannot provide valid information before surgery; (2) those who have serious infections, multiple organ insufficiency, and abnormal coagulation function; (3) patients with serious heart disease and cerebrovascular disease.

2.2. Methodology

The patients in the control group were treated with conventional fluid therapy, combined with lumbar and epidural anesthesia, applying Nussis anesthesia induction pump made in the United States to maintain the blood pressure and heart rate, and intravenously injecting midazolam 0.03–0.06 mg/kg before induction, and additional amounts were added according to the hemodynamic status of the patients during the operation. In the observation group, goal-directed fluid therapy was applied in addition to the treatment used in the control group. Specifically, 20 ml/kg of crystalloid fluid and 20 ml/kg of colloid fluid were given to patients on the basis of baseline blood pressure, and the total amount of fluid was appropriately adjusted according to the blood pressure.

2.3. Observation indicators

The patients in the two groups were observed to monitor the changes in mean arterial pressure and heart rate, as well as the levels of NT-proBNP and hs-CRP preoperatively and 24 hours postoperatively.

2.4. Statistical methods

Statistical processing was performed using SPSS 19.0 software for data analysis, and the measurement data were expressed as mean \pm standard deviation (SD) by *t*-test; the count data were expressed as rate (%) by χ^2 test.

3. Results

3.1. Comparison of intraoperative indicators

There was no statistically significant difference in intraoperative NT-proBNP and hs-CRP in the observation group compared with the control group ($P > 0.05$), and postoperative NT-proBNP and hs-CRP were significantly reduced ($P < 0.05$), and the difference was statistically significant (**Table 1**).

Table 1. Comparison of intraoperative indicators

Groups		Control group ($n = 30$)	Observation group ($n = 30$)	<i>t</i>	<i>P</i>
Intraoperative	NT-proBNP (ng/ml)	608.37 \pm 180.46	608.74 \pm 180.26	0.008	> 0.05
	hs-CRP (pg/ml)	510.09 \pm 190.21	514.12 \pm 180.63	0.084	> 0.05
Postoperative	NT-proBNP (ng/ml)	369.74 \pm 77.11	324.74 \pm 71.26	2.348	0.022
	hs-CRP (pg/ml)	298.41 \pm 72.14	245.12 \pm 77.63	2.754	0.008

3.2. Comparison of hemodynamic indices

The mean intraoperative arterial pressure in the control group was 54.81 \pm 14.41 mmHg and the heart rate was 60.65 \pm 14.11 beats/min, while in the observation group, the mean intraoperative arterial pressure was 50.16 \pm 14.03 mmHg and the heart rate was 57.65 \pm 14.10 beats/min, with a statistically significant difference ($P < 0.05$). In the patients of the control group, the postoperative mean arterial pressure was 14.12 \pm 3.92 mmHg and heart rate was 77.18 \pm 15.42 beats/min, and the mean arterial pressure in the patients of the observation group after surgery was 15.12 \pm 3.48 mmHg and heart rate was 78.21 \pm 15.36 beats/min, and the difference was not statistically significant ($P > 0.05$), as shown in **Table 2**.

Table 2. Comparison of hemodynamic indices

Groups	Intraoperative		Postoperative	
	Mean arterial pressure (mmHg)	Heart rate (beats/min)	Mean arterial pressure (mmHg)	Heart rate (beats/min)
Control group (<i>n</i> = 30)	54.81 ± 4.41	60.65 ± 4.11	14.12 ± 3.92	77.18 ± 15.42
Observation group (<i>n</i> = 30)	50.16 ± 4.03	57.65 ± 4.10	15.12 ± 3.48	78.21 ± 15.36
<i>t</i>	4.263	2.830	1.045	0.259
<i>P</i>	0.000	0.006	> 0.05	> 0.05

4. Discussion

With the aging of the population, the number of elderly fracture patients is increasing year by year. These patients often experience varying degrees of functional decline in multiple organs, such as the heart, brain, and kidneys, and frequently exhibit abnormalities in intraoperative bleeding and coagulation functions ^[4]. Goal-directed fluid therapy is an individualized fluid therapy that takes into account the patient's hemodynamic status and goals, and allows for appropriate fluid adjustments according to the patient's condition, thereby improving surgical safety and reducing postoperative complications ^[5,6]. However, whether GDFT is superior to conventional fluid therapy in elderly patients with fractures remains controversial. Currently, most of the elderly patients with fractures are in a state of incapacitation, and intraoperative problems such as abnormal coagulation function and excessive bleeding often exist, so their perioperative fluid therapy is particularly important ^[7]. Some studies have shown that MAP and NT-proBNP values before, during, and after surgery in the elderly are positively correlated with intraoperative bleeding, while hs-CRP values are negatively correlated with intraoperative bleeding ^[8]. Therefore, the type and amount of fluid should be rationally adjusted according to the patient's condition to reduce intraoperative bleeding during fracture surgery in the elderly. However, there are few studies on GDFT in elderly patients with fractures. Therefore, intraoperative fluid management in these patients should be emphasized to avoid problems such as high intraoperative bleeding and postoperative complications.

Elderly patients with weaker resistance to trauma and multiple co-morbidities are more likely to develop systemic inflammatory response syndrome (SIRS) and multiple organ dysfunction syndrome (MODS). Studies have shown that hypovolemia is one of the main factors leading to the development of SIRS and MODS in the postoperative period in the elderly ^[9]. Therefore, reducing fluid levels in patients can effectively prevent SIRS and MODS while ensuring hemodynamic stability.

GDFT, i.e., fluid therapy based on changes in fluid balance before and after surgery, enables patients to achieve fluid levels within the target range during surgery in order to reduce fluid loss due to traumatic stress in patients and to maintain tissue perfusion pressure in the body.

The results of this study showed that MAP and NT-proBNP of patients in the observation group were significantly lower than those of the control group (*P* < 0.05); hs-CRP of patients in the observation group was significantly lower than that of the control group (*P* < 0.05). This may be related to the fact that GDFT can be appropriately adjusted according to the patients' coagulation mechanism and hemodynamic status, and that the GDFT treatment improves the anti-inflammatory capacity of the organism. GDFT can adjust the fluid volume and rate of patients according to their coagulation mechanism and hemodynamic status by means of fluid resuscitation therapy and drug therapy.

In addition, the results of this study showed that the intraoperative mean arterial pressure and heart rate of patients in the GDFT group were significantly lower than those in the conventional fluid therapy group, and the

difference was statistically significant ($P < 0.05$). It has been shown that intraoperative mean arterial pressure and heart rate are positively correlated with 24-hour postoperative NT-proBNP levels ^[10]. In addition, the incidence of heart failure increases with age as cardiac reserve function decreases, and insufficient intravascular volume causes hypercapnia, which exacerbates heart failure.

5. Conclusion

In conclusion, goal-directed fluid therapy reduces MAP, NT-proBNP, and hs-CRP levels and decreases the incidence of postoperative complications in elderly patients with lower extremity fractures undergoing open reduction and internal fixation compared with traditional fluid therapy.

Disclosure statement

The authors declare no conflict of interest.

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Clinical Application of “Three-in-One” Bone Repair Strategy in the Perioperative Period of Elderly Intertrochanteric Femoral Fractures

Xihua Zhang^{1,2}, Zhongyu Peng^{1,2}, Hongchi Yi^{1,2}, Zhuoqian Dong^{1,2}, Huzhen Liu^{1,2}, Chengzheng Zhou^{1,2}, Wentao Zhao^{1,2}, Tao Chen^{1,2*}

¹Yunnan University of Traditional Chinese Medicine First Affiliated Hospital/Yunnan Provincial Hospital of Traditional Chinese Medicine Bone Injury Center Third Ward, Kunming 650021, Yunnan, China

²Yunnan University of Traditional Chinese Medicine, Kunming 650500, Yunnan, China

*Corresponding author: Tao Chen, henpao@126.com

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Abstract: *Objective:* To investigate the clinical value of the “three-in-one” bone repair strategy (perioperative anti-osteoporosis therapy, optimization of minimally invasive intramedullary fixation technology, and postoperative intervention of Shenqi Hexue Decoction) in the treatment of elderly intertrochanteric femoral fractures. *Methods:* We retrospectively analyzed the elderly patients with intertrochanteric femoral fracture and intramedullary nail fixation admitted from January 2022 to December 2024, and divided the patients into two groups according to the method of this study: control group (63 cases, routine intramedullary fixation and basic anti-osteoporosis therapy) and trinity group (63 cases, using the “three-in-one” strategy). The perioperative indexes, bone metabolism indexes (BALP, BGP, PICP, PINP), Harris hip score, complications, and 1-year survival rate were compared between the two groups. *Results:* The intraoperative blood loss (95.3 ± 15.2 mL) and hospital stay (9.8 ± 2.1 days) in the trinity group were significantly lower than those in the control group (128.7 ± 20.1 mL and 14.5 ± 3.6 days, respectively) ($P < 0.01$). Six weeks after surgery, the levels of bone formation markers BALP (25.1 ± 3.8 U/L) and PICP (125.6 ± 18.3 µg/L) in the trinity group were significantly higher than those in the control group ($P < 0.05$). At 12 weeks after operation, the Harris score (86.7 ± 6.4) was significantly better than that of the control group (78.2 ± 7.1) ($P < 0.01$). Compared with the control group (14.7 ± 2.3 weeks), the fracture healing time in the trinity group (11.2 ± 1.8 weeks) was shortened by 23.8%, and the incidence of deep vein thrombosis (4.8% vs 15.9%) was significantly reduced ($P < 0.05$). *Conclusion:* The “three-in-one” strategy optimizes perioperative management, promotes bone metabolism and fracture healing, rapidly improves hip joint function, and reduces complications through multi-target intervention. It is a safe and effective solution for intertrochanteric fractures in the elderly, and is worthy of clinical application.

Keywords: Three-in-one; Bone repair strategies; Intertrochanteric fractures; Perioperative; Shenqi Hexue Decoction

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1. Introduction

Intertrochanteric femoral fracture (IFF) is a common trauma among elderly patients with osteoporosis, accounting for 45–50% of hip fractures ^[1]. With the intensifying aging of the population, there are over 200,000 new cases in China every year, with a disability rate of 30% and a mortality rate of 15–30% within one year, earning it the nickname “the last fracture of life” ^[2]. Traditional treatment faces three major difficulties: (1) Deteriorating bone metabolism environment: Osteoporosis leads to a high failure rate of internal fixation, reaching 10–15%, and increases the risk of postoperative refracture by three times ^[3]; (2) Surgical technique limitations: Even with minimally invasive intramedullary nail fixation (such as PFNA), there are still risks of loss of reduction and cutting for comminuted fractures above Evans-Jensen type III ^[4,5]; (3) Delayed recovery process: Long-term bed rest can lead to complications such as hypostatic pneumonia and deep vein thrombosis, with 30% of patients suffering from permanent dysfunction ^[6].

The “three-in-one” bone repair strategy, first proposed by Chen *et al.*, focuses on integrating anti-osteoporosis treatment, reasonable bone implant technology, and accelerated bone healing measures ^[7]. The innovations of this study lie in: (1) Incorporating preoperative anti-osteoporosis pretreatment into the ERAS process; (2) Refining the technical operation specifications of intramedullary nails based on fracture classification; (3) Introducing Shenqi Hexue Decoction to replace traditional prescriptions for promoting blood circulation and removing blood stasis. Shenqi Hexue Decoction, originating from the Yao’s gynecology school, has proven effective in improving microcirculation and promoting callus formation in postoperative orthopedic recovery ^[8]. This study aims to verify the clinical application value of this strategy in the perioperative period of intertrochanteric femoral fractures.

2. Materials and methods

A retrospective analysis was conducted on elderly patients with intertrochanteric femoral fractures treated with intramedullary fixation from January 2022 to December 2024. Patients were divided into a control group and a trinity group based on the study methodology and inclusion criteria. The control group received conventional intramedullary fixation and basic anti-osteoporosis treatment, while the trinity group underwent a comprehensive intervention program incorporating preoperative anti-osteoporosis pretreatment, refined intramedullary nail techniques based on fracture typing, and the introduction of Shenqi Hexue Decoction.

2.1. Subjects

A retrospective analysis was conducted on elderly patients with intertrochanteric femoral fractures who underwent intramedullary fixation from January 2022 to December 2024. Based on the study methodology and inclusion criteria, the patients were divided into two groups after retrieving their medical records: the control group (63 cases) and the trinity group (63 cases). The control group consisted of 29 males and 34 females, aged between 70 and 94 years, with a mean age of 78.4 ± 6.2 years. According to the Evans-Jensen classification of fractures, there were 38 cases of Type III and 25 cases of Type IV. The mean bone mineral density T-score was -3.1 ± 0.4 . The trinity group comprised 27 males and 36 females, aged from 72 to 96 years old, with an average age of 79.2 ± 6.8 years. There were 36 cases of Type III and 27 cases of Type IV fractures based on the Evans-Jensen classification. The mean bone mineral density T-score was -3.0 ± 0.5 . Inclusion criteria for the study were: (1) age ≥ 70 years old, (2) bone mineral density T-score ≤ -2.5 , (3) fresh closed fracture (time from injury to surgery < 72 hours), and (4) surgical treatment required for Evans-Jensen Type III-IV fractures. Exclusion criteria included: (1) pathological fractures, (2) severe cardiac insufficiency (NYHA Class III-IV), (3) cognitive impairment preventing cooperation

with rehabilitation, and (4) coagulation disorders. There were no statistically significant differences in baseline characteristics between the two groups ($P > 0.05$), indicating comparability. This study followed the relevant guidelines of the hospital's ethics committee, and the patient and medical record data were objective, authentic, and complete.

2.2. Treatment methods

2.2.1. Control group

Adopting conventional intramedullary fixation + basic anti-osteoporosis regimen:

- (1) Surgical treatment: Patients underwent proximal femoral nail anti-rotation (PFNA) fixation under anesthesia.
- (2) Postoperative management: Included prophylactic antibiotics, anticoagulation, and a gradual rehabilitation program.
- (3) Anti-osteoporosis therapy: Oral administration of calcium carbonate D3 tablets and alendronate sodium.

2.2.2. Trinity group

The trinity group received a perioperative comprehensive intervention program (**Table 1**), which integrated anti-osteoporosis therapy, refined surgical techniques based on fracture typing, and the introduction of Shenqi Hexue Decoction.

Table 1. Perioperative comprehensive intervention program in the trinity group

Phase	Core intervention	Implementation details
Preoperative	Antiresorptive pretreatment	Initiated upon admission: - Correct hypocalcemia - Menatetrenone Soft Capsules 15 mg TID PO - Elcatonin Injection 20 U QD SC (1 week total)
	Multidisciplinary risk assessment	Consultations with Anesthesiology, Cardiology & Endocrinology: - Maintain blood glucose <8.3 mmol/L - Control systolic BP <160 mmHg
Intraoperative	Optimized intramedullary fixation	1. Tip-Apex Distance (TAD) control: <20 mm on AP/lateral views 2. Blade fixation + Bone cement augmentation 3. Arthrocentesis to prevent myositis ossificans
Postoperative	Shenqi Hexue Decoction	Initiated 8h post-op: -Composition: Astragalus 30 g, Ginseng 15 g, Angelica 15 g, Atractylodes 30 g, Poria 30 g, Chuanxiong 15 g, Peach Kernel 10 g, Dipsacus 15 g, Amomum 10 g, Honey-fried Licorice 10 g - Decoction: 300 mL BID $\times 8$ weeks
	Phased rehabilitation protocol	- 8h post-op: Ankle pumps & lower extremity exercises - 24h post-op: Bedside sitting - 72h post-op: Standing with walker - 2 weeks: 50% weight-bearing ambulation
	Maintenance antiresorptive therapy	- Calcium Carbonate + D3 Tablets (600 mg/d) + sequential Calcitriol - Zoledronic Acid 5 mg IV infusion (within 1–3 days post-op; repeated annually $\times 5$ years)

Strategy description:

- (1) Pre-treatment for osteoporosis resistance: Tetrahydroxymenadione promotes bone formation; Elcatonin

inhibits acute bone loss, reduces inflammation, and alleviates pain caused by osteoporosis and fractures^[9]; Postoperative zoledronic acid rapidly inhibits osteoclast activity, sequential basic calcium and vitamin D supplementation promote bone metabolism and improve bone healing.

- (2) Optimization of intramedullary fixation technique: For Evans-IV type fractures, a spiral blade and bone cement reinforcement technique (bone cement injection volume ≤ 3 mL) is used to enhance the holding force; intraoperative C-arm monitoring ensures that the tip-apex distance is less than 20 mm in both planes.
- (3) Application of Shenqi Hexue Decoction: In the prescription, *Astragalus* and Ginseng tonify qi and consolidate the constitution; *Angelica* and Chuanxiong promote blood circulation and remove blood stasis; *Dipsacus* root strengthens muscles and bones; *Amomum villosum* regulates qi and harmonizes the stomach, reducing gastrointestinal reactions^[8].

2.3. Observation indicators

- (1) Perioperative indicators: Operation time, intraoperative blood loss, hospital stay, and complications (deep vein thrombosis, lung infection, incision infection, etc.).
- (2) Bone metabolism indicators: Serum bone alkaline phosphatase (BALP), osteocalcin (BGP), procollagen type I carboxy-terminal propeptide (PICP), and procollagen type I amino-terminal propeptide (PINP) were measured before surgery and at 6 weeks postoperatively.
- (3) Imaging evaluation: Hip joint X-rays were taken at 1, 6, and 12 weeks postoperatively to observe fracture healing (criterion: continuous callus passing through the fracture line), internal fixation position, and tip-apex distance changes.
- (4) Functional score: Harris hip score (including pain, function, range of motion, and deformity, with a total score of 100) was used to evaluate the function at 12 weeks postoperatively.
- (5) Quality of life: SF-36 score at 6 months postoperatively and 1-year survival rate were recorded.

2.4. Statistical methods

Data were analyzed using SPSS 25.0. Measurement data were expressed as mean \pm standard deviation (SD) and compared between groups using the *t*-test. Count data were expressed as a rate (%) and compared using the χ^2 test. Survival analysis was performed using the Kaplan-Meier curve. $P < 0.05$ was considered statistically significant.

3. Results

3.1. Comparison of perioperative indicators

The trinity group significantly outperformed the control group in terms of intraoperative blood loss, time to weight-bearing, and hospital stay ($P < 0.01$). Regarding complications, the trinity group had significantly lower rates of deep vein thrombosis (4.8% vs 15.9%) and lung infection (6.3% vs 15.9%) ($P < 0.05$). See **Table 2** for details.

Table 2. Comparison of perioperative indicators between the two groups (mean \pm SD)

Indicator	Control group (<i>n</i> = 63)	Trinity group (<i>n</i> = 63)	Statistic	<i>P</i>
Operation time (min)	68.5 \pm 12.3	65.2 \pm 11.6	<i>t</i> = 1.612	> 0.05
Intraoperative blood loss (mL)	128.7 \pm 20.1	95.3 \pm 15.2*	<i>t</i> = 10.387	< 0.01
Time to weight-bearing (d)	6.2 \pm 1.5	3.1 \pm 0.8*	<i>t</i> = 15.239	< 0.01
Hospital stay (d)	14.5 \pm 3.6	9.8 \pm 2.1*	<i>t</i> = 9.213	< 0.01
Complications [<i>n</i> (%)]			χ^2 = 6.714	< 0.05
Deep vein thrombosis	10 (15.9%)	3 (4.8%)*		
Pulmonary infection	10 (15.9%)	4 (6.3%)*		
Surgical site infection	3 (4.8%)	2 (3.2%)		

Note: Compared with the control group, **P* < 0.05

3.2. Changes in bone metabolism indicators

At 6 weeks postoperatively, bone metabolism indicators improved in both groups, but the trinity group showed a more significant increase in bone formation markers: BALP (25.1 \pm 3.8 U/L vs 19.3 \pm 3.1 U/L) and PICP (125.6 \pm 18.3 μ g/L vs 98.7 \pm 15.2 μ g/L) (*P* < 0.05). PINP levels in the trinity group reached 58.9 \pm 7.8 μ g/L, which was 38.6% higher than the control group (42.5 \pm 6.3 μ g/L) (*P* < 0.01).

3.3. Fracture healing and functional recovery

The fracture healing time in the trinity group (11.2 \pm 1.8 weeks) was 23.8% shorter than that in the control group (14.7 \pm 2.3 weeks) (*P* < 0.01). At 12 weeks postoperatively, the Harris score showed that the trinity group had significant advantages in pain relief (38.5 \pm 3.2 vs 32.1 \pm 4.1) and walking ability (24.3 \pm 2.8 vs 20.1 \pm 3.2) (*P* < 0.01), and the overall excellent and good rate (88.9% vs 73.0%) was significantly improved (*P* < 0.05). At 6 months postoperatively, the SF-36 score indicated that the trinity group performed better in physiological function (75.6 \pm 8.3 vs 68.2 \pm 9.1) and mental health (72.4 \pm 7.5 vs 65.3 \pm 8.2) dimensions compared to the control group (*P* < 0.05).

3.4. Survival analysis

After 1 year of follow-up, the survival rate of the trinity group (93.7%) was higher than that of the control group (85.7%), but the difference was not statistically significant (*P* > 0.05). The deaths were mainly due to cardiopulmonary failure (5 cases in the control group and 2 cases in the trinity group).

4. Discussion

4.1. Theoretical basis and innovation of the “three-in-one” strategy

There are many difficulties in the treatment of osteoporotic fractures, such as complex fracture comminution, a vicious cycle of bone loss, and delayed fracture healing. There are also misconceptions in diagnosis and treatment processes, including cognitive, conceptual, and technical misunderstandings. Within 1 year after hip fracture, 21–30% of patients die from various complications, up to 50% of survivors have disabilities, and only about 30% of patients can return to their pre-injury status^[10].

This study is the first to integrate “anti-osteoporosis pretreatment–intramedullary fixation optimization–accelerated healing with traditional Chinese medicine” into the perioperative management of intertrochanteric hip fractures in the elderly. The main innovations include the following.

4.1.1. Rapid bone metabolism regulation starting before surgery

Dual-channel bone metabolism regulation is achieved through the combination of tetracycline (activates osteocalcin, promotes bone formation; inhibits osteoclast release) and zoledronic acid (inhibits osteoclast activity; induces osteoclast apoptosis). Upon admission, patients are administered elcatonin injection (a calcium homeostasis agent) to inhibit acute bone loss caused by immobilization and bed rest after fracture, and to reduce inflammation and relieve pain caused by fractures and osteoporosis^[9]. Data from this study showed that the PICP level in the trinity group increased by 27.3% at 6 weeks postoperatively, verifying the bone formation effect of this protocol.

4.1.2. Standardization of intramedullary nailing technique

For unstable Evans-IV fractures, a dual-plane control method for tip-apex distance (both anteroposterior and lateral views are <20 mm) and a bone cement augmentation technique are proposed. Biomechanical studies have confirmed that bone cement can increase the holding force of spiral blades by 30–50%, especially suitable for patients with severe osteoporosis with a Singh index \leq III. No cases of cutting or loss of reduction occurred in this group, confirming the reliability of this technique.

4.1.3. Multi-target regulation of Shenqi Hexue Decoction

Based on traditional qi-invigorating and blood-activating herbs, this prescription adds *Dipsacus asper* to strengthen tendons and bones, and *Amomum villosum* to invigorate the spleen and stomach, which not only promotes bone healing but also reduces gastrointestinal reactions to medications^[8]. Modern pharmacology has confirmed that *Astragalus* polysaccharides can increase serum TGF- β 1 levels and promote osteoblastic differentiation^[11,12]; *Angelica sinensis* ferulic acid inhibits the release of TNF- α and reduces inflammatory responses^[13]; *Dipsacus* saponin VII increases callus calcium salt deposition. In this study, the average healing time of the integrated treatment group was reduced to 11.2 weeks, and the Harris score increased by 11.1%, reflecting the synergistic advantages of integrated Chinese and Western medicine.

4.2. Optimization of perioperative management and prevention and control of complications

Surgery within 48 hours for hip fractures in the elderly can significantly reduce mortality^[14,15]. Through a multidisciplinary team (MDT) approach, this study achieved a reduction in the average time from admission to surgery to 28.5 hours and a decrease in the incidence of deep vein thrombosis to 4.8% in the integrated treatment group. This was mainly attributed to: (1) advance anticoagulation: initiating low molecular weight heparin 12 hours before surgery combined with postoperative pneumatic compression therapy, coupled with the blood rheology improvement effect of Shenqi Hexue Decoction (reducing whole blood viscosity and fibrinogen); (2) graded rehabilitation: starting ankle pump exercises 6 hours postoperatively and seated training at 24 hours, significantly reducing the risk of hypostatic pneumonia; (3) nutritional support: the postoperative serum albumin level in the integrated treatment group (35.2 ± 3.1 g/L) was higher than that in the control group (32.5 ± 2.8 g/L) (P

< 0.05), benefiting from the gastrointestinal function regulation of Shenqi Hexue Decoction and high-protein diet guidance.

4.3. Mechanism of Shenqi Hexue Decoction in bone repair

Osteoporotic fractures have a high incidence and are harmful, being a significant cause of disability and death in the elderly population^[16,17]. The integrated treatment of Chinese and Western medicine highlights its advantages in China. This study reveals that Shenqi Hexue Decoction accelerates fracture healing through a triple predictive mechanism:

(1) Improving microcirculation: The ligustrazine in Chuanxiong and polysaccharides in *Angelica sinensis* dilate microvessels, increase local blood flow to the fracture site, and alleviate ischemia-reperfusion injury.

(2) Regulating bone metabolism: Ginsenoside Rg1 upregulates the BMP-2/Runx2 pathway^[18], promotes osteoblast differentiation, and synergistically enhances BALP and PINP levels with zoledronic acid^[19].

(3) Inhibiting inflammatory response: *Astragalus* flavonoids reduce IL-6 and TNF- α expression^[20], alleviate pain, and create conditions for early functional exercise.

Compared to anti-osteoporosis drugs alone, the multi-target characteristics of Chinese medicine intervention are more aligned with the pathogenesis of “qi and blood deficiency, blood stasis blocking meridians” in elderly fractures. The results of this study are consistent with reports on the treatment of hip fractures with Shenqi Bushen Huoxue Decoction^[8], but Shenqi Hexue Decoction has more advantages in improving gastrointestinal tolerance.

4.4. Research limitations and prospects

This study has the following limitations: (1) No control subgroup using different Chinese medicine prescriptions was set up; (2) The medication costs in the integrated treatment group are relatively high, requiring pharmacoeconomic evaluation; (3) There is a lack of dynamic monitoring data on postoperative bone density. Future research directions include: (1) Developing formula granules of Shenqi Hexue Decoction to improve medication compliance; (2) Exploring individualized responses to bone metabolism interventions based on gene polymorphism; (3) Extending the follow-up period to 2 years to evaluate the prevention effect of secondary fractures.

5. Conclusion

The “three-in-one” bone repair strategy significantly optimizes perioperative management for intertrochanteric hip fractures in the elderly: preoperative anti-osteoporosis pretreatment improves the basis of bone metabolism; individualized intramedullary fixation techniques ensure mechanical stability; Shenqi Hexue Decoction intervention synergistically promotes bone healing. This strategy reduces fracture healing time to 11.2 ± 1.8 weeks, achieves a Harris score of 86.7 ± 6.4 , and lowers the incidence of deep vein thrombosis to 4.8%, effectively promoting rapid patient recovery. It is a safe and effective comprehensive treatment plan worthy of clinical promotion.

Disclosure statement

The authors declare no conflict of interest.

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