Bone and Arthrosurgery Science, 2025, Volume 3, I Special
http://ojs.bbwpublisher.com/index.php/BAS
Online ISSN: 2981-8222

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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Drafting units of this document: PRP Study Group of Orthopedic Branch, National Health Industry Enterprise Management Association / The 920th Hospital of the Chinese People's Liberation Army Joint Logistics Support Force / The 908th Hospital of the Chinese People's Liberation Army Joint Logistics Support Force / The General Hospital of the Western Theater Command of the Chinese People's Liberation Army / The Sixth People's Hospital of Shenyang, Liaoning Provincial Hospital for Infectious Diseases / The First People's Hospital of Kunming / Guidong People's Hospital of Guangxi Zhuang Autonomous Region / Department of Orthopedics, Nanjing Jinling Hospital, Affiliated Hospital of Medical School, Nanjing University / Sichuan Gem-flower Hospital Affiliated to North Sichuan Medical College / Department of Rehabilitation Medicine, The Central Hospital of Xiangtan, Hunan / Department of Orthopedics, Affiliated People's Hospital of Xinxiang Medical University, Henan / Department of Peripheral Vascular Diseases, Pingdingshan Hospital of Traditional Chinese Medicine / People's Hospital of Jinning District, Kunming City / Department of Orthopedics, Xinxiang First People's Hospital, Henan / Dazhou Integrated TCM & Western Medicine Hospital, Sichuan / Tongliang Traditional Chinese Medicine Hospital, Chongqing / Chongyi County People's Hospital, Ganzhou / Department of Orthopedics, First People's Hospital of Yuhang District, Hangzhou, Zhejiang / Shuguang Anhui Hospital Affiliated to Shanghai University of Traditional Chinese Medicine (The First Affiliated Hospital West District of Anhui University of Chinese Medicine) / the Fifth Hospital of Harbin, Heilongjiang / Harbin Huayi Hospital / Heilongjiang Chen Yisheng Medical Hair Transplant / Department of Orthopedics, Guiqian International Hospital, Guizhou/Department of Orthopedics, Tengzhou Central People's Hospital, Tengzhou, Shandong Province / Department of Orthopedics and Traumatology, Kunming Municipal Hospital of Traditional Chinese

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 Matemity 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℃ and thawed at 37℃ 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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