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Original article

Treatment of osteoporotic intertrochanteric fractures by zoledronic acid injection combined with proximal femoral nail anti-rotation

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ABSTRACT

Objective: To observe the clinical results of proximal femoral nail anti-rotation (PFNA) combined with zoledronic acid injection in the treatment of osteoporotic intertrochanteric fractures in the elderly.
Methods: 60 elderly patients with osteoporotic intertrochanteric fractures were diagnosed using a dual energy X-ray bone density instrument. Patients were randomly divided into treatment or control groups (30 cases in each group). Patients in both groups were treated by closed/open reduction and internal fixation using PFNA. In the treatment group, patients received one zoledronic phosphonic acid injection of 5 mg/100 ml via intravenous drip, in addition to 600 mg of Caltrate D (qd) and 0.25 μg of alpha ossification alcohol (qd). The control group received 600 mg of Caltrate D (qd) and 0.25 μg of alpha ossification alcohol (qd). The oral drugs were administered for 12 months. Bone pain relief was observed, and changes in the bone mineral density (BMD) of the lumbar and health-side hip were recorded. Clinical results were evaluated using the Visual Analogue Scale (VAS), Harris joint function score, and Osteoporosis Quality of Life Scale (OQOLS).
Results: Compared with the control group, bone pain symptoms were significantly alleviated ($p < 0.05$) in the treatment group. In the treatment and control groups, both between-group and within-group differences in BMD were significantly increased in L_{1-4}, femoral neck and trochanter ($p < 0.05$). No significant differences were found between the two groups in regard to the involved hip or the total rate of improvement at the end of the follow-up period, although cases in the treatment group had higher OQOLS scores than those of the controls ($p = 0.04$). Cases in the treatment group healed more quickly than those in the control group [(13 ± 3.2) weeks *vs* (15 ± 4.6) weeks, $p = 0.02$]. During the follow-up period, cases in the treatment group had no new fractures, whereas 2 new cases of hip fracture and 2 cases of distal radial fractures were observed among the controls.
Conclusion: Zoledronic acid injection combined with PFNA is a favorable treatment option for the elderly patients with osteoporotic intertrochanteric fracture. It can effectively relieve bone pain, increase bone density, improve quality of life, reduce the occurrence of new fractures and promote fracture healing.

Introduction

Given the accelerated aging of the Chinese population, osteoporosis, being an age-related disease, has shown a corresponding yearly growth in the incidence among the elderly.[1] The characteristics of osteoporosis include decreased bone mass and microstructure damage to bone tissue, which leads to a decrease in bone strength and accompanying increase in bone fragility, along with an increased risk of fracture. Osteoporotic fracture often occurs at the hip, the distal radius or the spinal column. The most serious fracture is an osteoporotic hip fracture, especially an intertrochanteric fracture, which features in high morbidity, mortality, and disability rates. At present, surgical intervention is the primary treatment for intertrochanteric fractures; however, more and more studies have shown that anti-osteoporosis therapy for patients in the perioperative period may be better for postoperative rehabilitation and long-term survival.[2] The purpose of the present

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study was to observe the clinical results of the treatment of senile osteoporotic intertrochanteric fractures using a combination of zoledronic acid injection and proximal femoral nail antirotation (PFNA).

Patients and methods

Patients

This study was undertaken at the Department of Orthopedic Surgery of West China Hospital, Sichuan University, from January 2011 to December 2011. The research administration department and the ethical committee of West China Hospital approved the study protocol and procedures.

Study inclusion criteria included: (1) a diagnosis of osteoporosis (Chinese Diagnosis Standards of Osteoporosis[3]); (2) the presence of a hip fracture caused by low energy trauma; and (3) age ≥65 years. Exclusion criteria included: (1) a history of treatment for osteoporosis prior to hip fracture; (2) a history of administration of calcium, heparin, glucocorticoid or other medicines affecting bone metabolism within 6 months prior to hip injury; (3) a history of gastrointestinal surgery; (4) a history of illness related to the liver, kidney, thyroid or parathyroid glands; and (5) a history of organic psychosis or negative habits such as smoking. Based on the different treatment methods, the included patients were divided into a treatment group and a control group, each containing 30 cases. The bone mineral density (BMD) of all cases was determined using dual energy X-ray absorption (DEXA), and the BMD values reached the diagnostic criteria of osteoporosis according to the WHO standard. The Evans-Jensen system was used in the classification of fractures.[4]

Surgical treatment

Each patient underwent an internal fixation operation performed by the same surgical team using PFNA within three days of hospitalization. Under general or epidural anesthesia, the patient laid on his/her back on the traction table, with the uninjured extremity fixed on the bracket as far as possible to allow for C-arm fluoroscopic imaging during the operation. To expose the greater trochanter and the femoral medullary cavity, a 15-degree angle should be maintained between the affected extremity and trunk of the body. The operation should proceed with the C-arm fluoroscopy on. After traction and fracture reduction, a minor longitudinal incision of 4–6 cm in length was made approximately 5–10 cm proximal from the tip of the greater trochanter. Make a parallel incision of the fascia of the gluteus medius and split the gluteus medius in line with the fibers. In the AP view, the PFNA entry point was usually on the tip or slightly lateral to the tip of the greater trochanter in the 5° curved extension of the medullary cavity, as the medial-lateral angle of the PFNA was 5°. The tip, or slightly lateral to the tip, of the greater trochanter is a good option as the entry point for PFNA nailing. The guide pin was then burrowed into the distal medullary cavity under the monitoring of the C-arm. After proximal reaming, the PFNA is manually inserted with care as far as possible into the femoral opening. A slight twisting of the hand would facilitate insertion. If the PFNA cannot be inserted, select a PFNA with a smaller diameter or ream the medullary cavity to a diameter that is at least 1 mm larger than that of the selected nail. If necessary, light blows with the hammer on the protection shield of the insertion handle can support PFNA insertion. Fix the screw at the distal end after fixing the helical-faced blades at the proximal end. Use fluoroscopy again after fixing the PFNA to decide its position. An open reduction should be performed if the close reduction was difficult.

The patient should engage in joint motion and muscle strength exercise in bed on the first day after surgery. One day later, walking-assistance should be recommended. Weight-bearing exercise depends on the fracture type and the stability after reduction. In our study, all rehabilitation in the hospital was performed by the same therapist. Clinical healing of the fracture was standardized as follows: no pain in the affected extremity during weight-bearing walking; no percussion pain at the fracture area; no longitudinal percussion pain at the affected extremity; a fuzzy facture line observed on X-ray; and trabecular bone growth observed in the fractured zone.

Zoledronic acid injection

Given a creatinine clearance ≥35 ml/min and normal blood calcium levels, the patients in the treatment group were injected with zoledronic acid on postoperative day 3. The patients took one Tylenol tablet (q6h) continuing into the next day after the infusion. A 1000 mL balanced salt solution was given before the zoledronic acid injection (5 mg/100 mL, infusion time ≥15 min); next, a 500 mL balanced salt injection was also given. Patients in both groups continuously took 600 mg of Caltrate D and 0.25 μg of Calcitriol (qd) for 12 months after surgery.

Observation index

Bone pain evaluation: Hip pain was measured by the four-grade bone pain score: 0, no pain; 1, obvious pain while not affecting daily life; 2, bearable pain or partially affecting daily life and work; and 3, unbearable pain or unable to work. General pain was measured using the Visual Analogue Scale/Score (VAS), with scores ranging from 0 (no pain) to 10 (greatest pain).

Hip joint function score: The Harris joint function score was used to measure the function at the hip joint. Standard scores of ≥90, 80–90, 70–79, and ≤70 were indicative of excellent, good, acceptable, and poor function, respectively.

Quality of life score: The life quality was evaluated using the Osteoporosis Quality of Life Scale (OQOLS).[5]

Bone density examination: The American lunar prodigy dual-energy X-ray absorptiometry (DEXA) was used to examine the pretreatment and posttreatment bone density of the lumbar (L_{1-4}) and hip (femoral neck, Ward's triangle area, and greater trochanter) of the uninjured side.

Safety evaluation: Influenza-like symptoms, such as fever, myalgia, and arthralgia were observed and recorded, in addition to the occurrence of any new fractures.

Statistical methods

SPSS version 17.0 statistical software was used. Data are represented as the mean ± standard deviation, and Student's *t*-test was used to conduct between-group comparisons. The Chi-square test was used to examine differences between categorical variables. Any result with a *p*-value below 0.05 was deemed statistically significant.

Results

Comparison of the pretreatment baseline and relative operation data are shown in Table 1.

In general, patients were followed up two weeks after surgery and every four to six weeks thereafter. All the patients in the two groups received a 12-month follow-up.

The bone pain symptoms of the two groups was greatly alleviated after 12 months of treatment ($p = 0.000$, Table 2). There were no significant differences between the two groups in terms of VAS

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