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Retrospective Study

Effects of alendronate sodium combined with InterTan on osteoporotic femoral intertrochanteric fractures and fracture recurrence

Abstract

BACKGROUND

Osteoporosis is a global disease affecting 6.6% of the total population. Osteoporosis complications include fractures, increased bone fragility, and reduced bone strength. The most commonly affected parts are the vertebral body, hip, and wrist.

AIM

To examine the effect of alendronate sodium combined with InterTan for osteoporotic femoral intertrochanteric fractures on bone and fracture recurrence

METHODS

In total, 126 cases of osteoporotic femoral intertrochanteric fractures were selected and divided into two groups according to the 1:1 principle by the simple random method. They were admitted to the Department of Orthopedics, First Affiliated Hospital of Xingtai Medical College, from January 2018 to September 2020. The control group was treated with InterTan fixation combined with placebo, and the observation group with alendronate sodium based on InterTan fixation. Operation-related indicators, complications, and recurrent fractures were compared between the groups. Changes in bone metabolism markers, *t* value for hip bone mineral density, and Harris Hip Score were observed.

RESULTS

Operation time, intraoperative blood loss, postoperative ambulation time, and complications were compared between the groups, and no significant difference was found. The fracture healing time was significantly shorter in the observation group than in the control group. β-Collagen-specific sequence (β-CTX) and total aminoterminal propeptide of type I procollagen (T-PINP) in the control group at 3 mo after operation were compared with those before operation, and the difference was not significant. Six months after the operation, the β-CTX level decreased and T-PINP level increased. β-CTX level at 3 and 6 mo in the observation group after operation was lower, and T-PINP level was higher, than that before operation. Compared with the control group, T-PINP level of the observation group was significantly higher and β-CTX level was significantly lower at 3 and 6 mo after operation. The *t* value of hip bone mineral density was compared in the control group before and 1 mo after operation, and significant difference was not found. Compared with the control group, the *t* value of hip bone mineral density in the observation group was significantly higher at 1, 3, 6, and 12 mo after operation. Compared with the control group, the Harris score of the observation group was significantly higher at 1, 3, 6, and 12 mo after operation. The recurrence rate of fractures in the observation group within 12 mo was 0.00%, which was significantly lower than 6.35% in the control group.

CONCLUSION

Alendronate sodium combined with InterTan in the treatment of osteoporotic femoral intertrochanteric fractures can increase bone mineral density, improve hip joint function, promote fracture healing, and reduce fracture recurrence.

INTRODUCTION

InterTan is an intramedullary fixation, short lever arm force-based, anti-rotation, and stable clinical treatment of intertrochanteric fractures commonly used[1]. However, for patients with osteoporotic intertrochanteric fractures, osteoporosis can affect the healing rate of fracture ends, with slow fracture healing and reduced exercise possibly aggravating osteoporosis and thereby leading to a vicious circle[2]. Therefore, the treatment of osteoporosis should be strengthened during the treatment of osteoporotic intertrochanteric fractures.

Alendronate sodium is a third-generation diphosphonate drug of the amino-bisphosphonate bone metabolic regulator family, which can inhibit osteoclast activity and the bone resorption process and reduce bone destruction. It is often used in the treatment of osteoporosis and the prevention of compression fractures of the hip and vertebral body in clinical practice[3]. However, there are only few studies on its impact on long-term recurrence of fractures. In this study, we observed the effect of alendronate sodium combined with InterTan on osteoporosis and fracture recurrence in the treatment of osteoporotic femoral intertrochanteric fractures and discussed its mechanism.

MATERIALS AND METHODS

General information

A total of 126 patients with osteoporotic intertrochanteric fractures admitted to the Department of Orthopedics, the First Affiliated Hospital of Xingtai Medical College, from January 2018 to September 2020 were selected. The patients were divided into two groups according to the principle of 1:1 using the simple random method. The general characteristics of the two groups was not comparable ($P > 0.05$) (Table 1).

The inclusion criteria were as follows: compliance with the standards of osteoporotic femoral intertrochanteric fractures [unilateral femoral intertrochanteric fractures were diagnosed based on medical history, signs, and imaging findings and bone mineral density (BMD) showed femoral neck fracture ($T \leq -2.50$ SD)]; $18 \leq$ age ≤ 80 years; initial

fracture developed < 2 wk; closed fracture; and patients provided informed consent. This study was conducted in line with the principles of the Declaration of Helsinki.

Conversely, the exclusion criteria were as follows: fractures caused by bone tumors and bone tuberculosis; combined fractures in other parts; allergic constitution; presence of other diseases affecting bone metabolism or use of drugs affecting bone metabolism; presence of cardiovascular and cerebrovascular, liver, kidney, and other serious diseases; uncontrollable hypertension and diabetes; and presence of mental illness.

Method

The control group was treated with InterTan fixation. In brief, after successful anesthesia, the patient was placed in the supine position, and the affected limb was pulled and reset. Routine disinfection and towel laying were performed. A long incision of approximately 5 cm was made along the proximal end of the femoral greater trochanter. The deep fascia was opened, and the top of the femoral greater trochanter was bluntly separated and exposed. Then, a 2.5-mm S-wire was placed within the top exposed region. The S-wire was confirmed to be located in the medullary cavity using the C-arm X-ray machine. The sleeve was used to protect the proximal opening, remove the S-wire, place the guide needle, and place the intramedullary nail after marrow enlargement. The depth of intramedullary nailing was adjusted, and the anteversion angle was modified under C-arm fluoroscopy. Afterward, the guide length was measured, the lower anti-rotation blade was inserted, and guide length was re-measured. Tension screws were placed in the fracture space, followed by the distal locking screws, and the tail cap was twisted after determining the internal fixation position was proper. At the same time, placebo treatment, placebo appearance, administration time, and alendronate sodium administration were combined.

The observation group was treated with alendronate sodium based on the InterTan fixation: oral alendronate sodium tablets (Shiyao Group Ouyi Pharmaceutical Co., Ltd., specification: 70 mg, H20061303) 70 mg/wk.

Observation indicators and detection methods

Operation-related indexes (operation time, intraoperative blood loss, postoperative ambulation time, and fracture healing time), complications (bedsore, urinary tract infection, pulmonary infection, incision infection, *etc.*), and recurrent fractures were compared between the two groups. The changes in bone metabolism marker levels, hip BMD *t* value, and Harris Hip Score (Harris) score were observed, with Harris scores of ≥ 90, 80–89, 70–79, and < 70 points considered excellent, good, fair, and poor, respectively[4].

Fasting peripheral venous blood samples of the patients were collected in an EDTA-K2 anticoagulant tube before operation, 3 mo after operation, and 6 mo after operation. The blood samples were centrifuged for 1 h at 4000 r/min for 10 min. The separated serum was used to detect β-collagen-specific sequence (β-CTX) and total type I procollagen amino-terminal propeptide (T-PINP) by an enzyme-linked immunosorbent assay kit (Shanghai Enzyme-linked Biotechnology Co., Ltd.). The detection instrument used was RT-96 (Shenzhen Mindray Medical Electronics Co., Ltd.).

Dual-energy X-ray absorptiometry was performed to detect the *t* value of BMD for the affected hip before operation and 1, 3, 6, and 12 mo after operation.

Statistical analysis

The data were processed using SPSS19.0. The measurement indexes are described as mean ± SD, and the *t* test was performed for comparison. The enumeration data are expressed as the number of cases (percentage), and the χ^2 test was performed for comparison. The statistical test level was set at 0.05.

RESULTS

Comparison of operation-related indicators between the two groups

The operation time, blood loss, and postoperative ambulation time were compared between the two groups, and the difference was not statistically significant ($P > 0.05$).

Fracture healing time in the observation group was shorter than that in the control group; the difference was statistically significant ($P < 0.05$, Table 2).

Comparison between the two groups

The complications such as bedsore, urinary tract infection, pulmonary infection, and incision infection were compared between the two groups, and the difference was not statistically significant ($P > 0.05$, Table 3).

Comparison of bone metabolism markers between the two groups

Before surgery, the bone metabolic markers were compared between the two groups, and the difference was not statistically significant ($P > 0.05$). The β-CTX and T-PINP were compared between before and 3 mo after operation in the control group, and the difference was not statistically significant ($P > 0.05$). Six months after operation, β-CTX decreased and T-PINP increased compared with those before operation ($P < 0.05$). The β-CTX at 3 and 6 mo after operation in the observation group was lower than that before operation, and the T-PINP was higher than that before operation ($P < 0.05$). Compared with the control group, T-PINP was significantly higher and β-CTX was significantly lower in the observation group at 3 and 6 mo after operation ($P < 0.05$, Table 4).

Comparison of hip bone mineral density t value between the two groups

Before operation, the t value of hip bone mineral density was compared between the two groups, and the difference was not statistically significant ($P > 0.05$). The t value of hip bone mineral density was compared between 1 mo after operation and before operation in the control group, and the difference was not statistically significant ($P > 0.05$). The t values of hip bone mineral density at 3, 6, and 12 mo after operation were higher than those before operation ($P < 0.05$). The t values of hip bone mineral density in the observation group at 1, 3, 6, and 12 mo after operation were higher than those before operation ($P < 0.05$). Compared with the control group, the t value of hip bone

mineral density in the observation group was significantly higher at 1, 3, 6, and 12 mo after operation ($P < 0.05$, Table 5).

Comparison of Harris scores between the two groups

Before operation, the Harris score was compared between the two groups, and the difference was not statistically significant ($P > 0.05$). The Harris scores of the two groups at 1, 3, 6, and 12 mo after operation were higher than those before operation ($P < 0.05$). Compared with that of the control group, the Harris score of the observation group was significantly higher at 1, 3, 6, and 12 mo after operation ($P < 0.05$, Table 6).

Comparison of recurrence of fractures in the two groups within 12 mo

The recurrence rate of fracture within 12 mo in the observation group was 0.00%, which was significantly lower than 6.35% in the control group, and the difference was statistically significant ($P < 0.05$, Table 7).

DISCUSSION

In recent years, with the advent of the aging society, the incidence of osteoporosis and osteoporotic femoral intertrochanteric fracture has been increasing. It is expected that by 2050, the incidence of osteoporotic femoral intertrochanteric fractures may be as high as 6 million, which poses a certain burden on social medical resources[5]. Intertrochanteric fractures of the femur can cause severe pain and restrict lower extremity activities. For example, conservative treatment has problems such as long treatment times, several bedridden complications, serious infectious complications, lower extremity deep vein thrombosis, *etc.*, and even threatens the life safety of patients[6]. Therefore, it is suggested that surgical internal fixation should be the first choice of treatment for patients with intertrochanteric fractures to obtain a solid internal fixation effect, promote fracture healing, and accelerate rehabilitation. However, when osteoporosis is severe, the risk of nail withdrawal and breakage after internal fixation

increases, leading to surgical failure[7]. Therefore, the treatment of osteoporotic femoral intertrochanteric fractures is more difficult.

InterTan is a new type of proximal femoral nail material specifically used for intertrochanteric fractures. The cross-section of the main nail is trapezoidal, which has stronger anti-rotation ability. The valgus angle of the main nail is 4°, which is more in line with the physiological and anatomical characteristics of the Asian femur. The head and neck screws are designed as tension screws and compression screws, which interlock and play a good compression effect on the fracture end and increase its anti-rotation ability and stability. The good matching of the medullary cavity increases the anatomical compatibility of the main nail with the mechanical requirements to obtain optimal stability, reduce the risk of internal fixation fracture, and help patients step out of bed early and perform rehabilitation training, which is conducive to fracture healing[8]. Hiragami *et al*[9] used Intertan static fixation assisted by Calqi D in the treatment of osteoporotic femoral intertrochanteric fractures, and found that it can promote fracture healing and improve the functional recovery of lower extremities. Polat *et al*[10] found that the internal fixation effect of InterTan in the treatment of elderly femoral intertrochanteric fractures is stronger than that of PFNA-II, which is conducive to maintaining a suitable fracture-to-apex distance, and has better anti-cutting and subsidence effects. It has been found that the internal fixation effect of InterTan in the treatment of intertrochanteric femoral fractures in the elderly is stronger than that of PFNA-II, which is beneficial for maintaining the appropriate fracture to the apex distance, with better anti-cutting and settlement effects.

Actively correcting the osteoporosis status of patients promotes the postoperative rehabilitation of patients with osteoporotic intertrochanteric fractures. Alendronate sodium is a commonly used anti-osteoporosis drug. It is widely used in the treatment of osteoporosis in postmenopausal women. Zhao *et al*[11] applied sodium alendronate in the treatment of diabetic osteoporosis patients and found that it effectively relieved osteoporosis symptoms and improved bone metabolism. Sodium alendronate has a strong affinity for hydroxyapatite, which can inhibit osteoclast activity and bone

resorption, without an inhibitory effect on bone mineralization[12,13]. Some scholars used alendronate tablets combined with calcitonin for postoperative bone pain in patients with osteoporotic fracture and reported a good mitigation effect[14,15]. The present study found that alendronate sodium combined with InterTan in the treatment of osteoporotic femoral intertrochanteric fractures can shorten the fracture healing time and improve postoperative 1-, 3-, 6-, and 12-mo hip BMD *t* value and Harris score. The findings suggest that alendronate sodium combined with InterTan in the treatment of osteoporotic femoral intertrochanteric fractures can improve BMD, improve hip function, and promote fracture healing and has a good curative effect. However, there was no significant effect on operation time, intraoperative blood loss, postoperative ambulation time, and complications. Alendronate sodium can inhibit fracture processes, improve the degree of bone mineralization, increase the thickness of the bone cortex and BMD, promote fracture healing and early ambulation, and improve hip function.

Abnormal bone metabolism and a bone formation rate lower than the bone destruction rate are crucial mechanisms for osteoporosis; thus, fractures are associated with difficult healing[16]. T-PINP is a type I collagen deposition indicator related to bone tissue and a commonly used bone formation marker in the clinical setting[17]. β-CTX is the C-terminal peptide fragment of the decomposition product of type I collagen in the bone matrix during bone metabolism, and its serum level can reflect the degree of bone decomposition to a certain extent[18-20]. In this study, the levels of T-PINP and β-CTX were detected before operation and 3 and 6 mo after operation. It was found that alendronate sodium combined with InterTan in the treatment of osteoporotic intertrochanteric fractures could increase T-PINP level, reduce β-CTX level, and improve bone metabolism. Alendronate has a strong affinity with intraosseous hydroxyapatite, which can inhibit osteoclast activity, resist bone resorption, and has no inhibitory effect on bone mineralization, which is one of its important mechanisms for promoting postoperative healing of fractures.

It was also found that alendronate sodium combined with InterTan in the treatment of osteoporotic intertrochanteric fractures can reduce the risk of recurrent fractures:

some additionl within 12 mo after operation, with good long-term efficacy. This is related to the fact that alendronate sodium can better correct osteoporosis in patients.

CONCLUSION

Alendronate sodium combined with InterTan in the treatment of osteoporotic intertrochanteric fractures can improve BMD, improve hip function, promote fracture healing, and reduce fracture recurrence.

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Table 1 Comparison of general information between the two groups, *n* (%)

Material	Control group (*n* = 63)	Observation group (*n* = 63)	χ^2	*P* value
Gender			0.519	0.471
Male	38 (60.32)	34 (53.97)		
Female	25 (39.68)	29 (46.03)		
Age (yr)			0.037	0.847
< 60	19 (30.16)	20 (31.75)		
≥ 60	44 (69.84)	43 (68.25)		
Affected side			0.286	0.593
Left	34 (53.97)	31 (49.21)		
Right	29 (46.03)	32 (50.79)		
AO typing			0.140	0.710
A2 type	42 (66.67)	40 (63.49)		
A3 type	21 (33.33)	23 (36.51)		
Cause of injury			1.685	0.640
Fall	21 (33.33)	26 (41.27)		
Traffic accident	23 (36.51)	18 (28.57)		
Fall from height	15 (23.81)	13 (20.63)		
Other	4 (6.35)	6 (9.52)		
Combined diseases				
Coronary heart disease	14 (22.22)	12 (19.05)	0.194	0.660
Diabetes	11 (17.46)	9 (14.29)	0.238	0.626
Hypertension	15 (23.81)	18 (28.57)	0.370	0.543
Hyperlipidemia	8 (12.70)	11 (17.46)	0.558	0.455

Table 2 Comparison of surgical indicators between the two groups (mean ± SD)

Groups	Operation time (min)	Intraoperative bleeding (mL)	Postoperative landing time (d)	Fracture healing time (mo)
Control group (n = 63)	75.25 ± 5.96	52.36 ± 11.47	7.06 ± 1.85	3.35 ± 0.29
Observation group (n = 63)	73.89 ± 6.08	51.74 ± 13.36	6.98 ± 1.91	3.04 ± 0.23
t value	1.268	0.279	0.239	6.648
P value	0.207	0.780	0.817	0.000

Table 3 Comparison of co-occurrence between the two groups, n (%)

Groups	Bedsore	Urinary tract infection	Pulmonary infection	Incision infection	Total complications
Control group (n = 63)	1 (1.59)	1 (1.59)	2 (3.17)	1 (1.59)	5 (7.94)
Observation group (n = 63)	1 (1.59)	1 (1.59)	1 (1.59)	0 (0.00)	3 (1.76)
t value					0.534
P value					0.465

Table 4 Comparison of bone metabolism markers between the two groups (mean ± SD)

Groups	β-CTX (ng/L)			T-PINP (μg/L)		
	Preoperative	3 mo after operation	12 mo after operation	Preoperative	3 mo after operation	12 mo after operation
Control group (n = 63)	345.85 ± 85.23	321.25 ± 71.36	304.58 ± 68.45[a]	21.45 ± 5.26	22.58 ± 6.04	25.89 ± 5.12[a]
Observation group (n = 63)	351.14 ± 79.92	261.25 ± 64.74[a]	162.25 ± 51.33[a]	21.37 ± 5.08	26.14 ± 4.86[a]	29.85 ± 4.75[a]
t value	0.359	4.943	13.204	0.087	3.645	4.500
P value	0.720	0.000	0.000	0.931	0.000	0.000

[a]$P < 0.05$ *vs* before operation.

β-CTX: β-Collagen-specific sequence; T-PINP: Total aminoterminal propeptide of type I procollagen.

Table 5 Comparison of *t*-values of hip bone mineral density between the two groups (mean ± SD)

Groups	Preoperative	After operation			
		1 mo	3 mo	6 mo	12 mo
Control group (n = 63)	-2.61 ± 0.18	-2.55 ± 0.19	-2.53 ± 0.17[a]	-2.34 ± 0.16[a]	-2.08 ± 0.13[a]
Observation group (n = 63)	-2.60 ± 0.15	-2.21 ± 0.22[a]	-2.02 ± 0.15[a]	-1.61 ± 0.11[a]	-1.37 ± 0.10[a]
t value	0.339	9.284	17.855	29.842	34.360
P value	0.735	0.000	0.000	0.000	0.000

[a]$P < 0.05$ *vs* before operation.

Table 6 Comparison of Harris scores between the two groups (mean ± SD)

Groups	Preoperative	After operation			
		1 mo	3 mo	6 mo	12 mo
Control group (n = 63)	34.25 ± 3.05	71.14 ± 4.06[a]	78.65 ± 3.58[a]	81.05 ± 4.06[a]	83.36 ± 3.64[a]
Observation group (n = 63)	34.18 ± 3.21	79.53 ± 4.51[a]	86.54 ± 4.12[a]	88.96 ± 4.11[a]	91.23 ± 4.52[a]
t value	0.125	10.974	11.474	10.868	10.764
P value	0.900	0.000	0.000	0.000	0.000

[a]$P < 0.05$ *vs* before operation.

Table 7 Comparison of recurrence of fractures in the two groups within 12 mo, n (%)

Groups	Recurrent fracture
Control group (n = 63)	4 (6.35)
Observation group (n = 63)	0 (0.00)
χ^2	4.131
P value	0.042

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