Efficacy of femoral nail anti-rotation of helical blade in unstable intertrochanteric fracture

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Abstract. – OBJECTIVE: We analyzed the comparative efficacy and long-term prognosis with proximal femoral nail anti-rotation (PFNA) and dynamic hip screw (DHS) for the treatment of unstable intertrochanteric fractures, retrospectively. We determined the independent risk factors to guide subsequent surgery and improve the long-term quality of life.

PATIENTS AND METHODS: We selected 165 patients suffering from unstable intertrochanteric fracture from January 2010 to January 2015 in our hospital, including 89 treated with PFNA and 76 with DHS surgery. The duration of follow-up lasted from 10 months to 56 months (34.7 ± 8.5) on average. The patient demographics included gender, age, reasons for fracture, fracture type (Evans-Jensen), fracture time, comorbidities, surgical procedures (PFNA and DHS), the number of internal fixations, length, surgical time, blood loss, postoperative drug therapy, time for auxiliary external fixation and postoperative weight duration. The final indicators included adverse effects associated with implants; postoperative complications, clinical healing or bone healing time and functional score (Harris hip joint function scale, fine/excellent rate).

RESULTS: The differences in gender, age, fracture reasons, fracture type, fracture time and comorbidities were not statistically significant between the groups (p>0.05). However, the number of internal fixations, length, surgical time and blood loss, postoperative drug combination, time for auxiliary external fixation and postoperative weight duration were statistically significant (p<0.05). The effect of PFNA was more significant than that of DHS group. The prevalence of complications was reduced significantly. The patients treated with PF-NA scored significantly higher on the Harris hip joint function scale than the DHS group (p<0.05). The independent risk factors affecting healing after surgery included fracture type, fracture time, different surgical procedures, the number of internal fixations and length. The independent risk factors affecting the follow-up Harris hip score included age, fracture type, comorbidities, different surgical procedures, postoperative drug combination, auxiliary external fixation, application time and postoperative weight duration.

CONCLUSIONS: Compared with DHS, PFNA resulted in better clinical outcomes and long-term prognosis of unstable intertrochanteric fractures.

Key Words

Proximal femoral nail anti-rotation, Dynamic hip screw, Unstable fracture in femoral intertrochanter, Independent risk factors.

Introduction

Intertrochanteric fractures usually involve parts below the intracapsular fracture of the femoral neck (IFFN) and the margin of the lesser trochanter. Unstable fractures such as comminuted fractures and wedge fracture, often occur in elderly individuals with osteoporosis with a prevalence of about 12.4-23.1%. The prevalence of fractures in young adults due to accidents and injuries caused by falls is approximately 5.6%^{1,2}. Organ dysfunction in the elderly complicates the clinical outcome. Studies³ suggested that external fixation in patients afflicted with intertrochanteric fractures led to limb shortening in 56.4%, wound infection in 60.2%, knee stiffness in 64.2% and hip varus deformity in 48.8% of the patients within 6 months post-surgery. Dynamic hip screw (DHS) is a popular extra medullary fixation device and is considered as the "gold standard" for the treatment of stable intertrochanteric fracture⁴. However, the limitations in its design include the inability to address unstable intertrochanteric fracture due to the DHS steel located lateral to the weight-bearing line. The stress is not effectively conducted through the calcar due to a missing femoral intertrochanteric cortex. The varus stress is focused on the outside plate, resulting in nail plate fracture, screw skipping, caput femoris rotation and other issues. The surgical failure rate is about 16.5 to 23.1%⁵. The advantages of proximal femoral nail anti-rotation (PFNA) in clinical bone healing, surgical complications and quality of life are as follows: 1- spiral blade and bone closely fit to enhance stability, prevent rotation and varus deformity⁶; 2- the large flank of the hip screw terminal compresses the surrounding bone, especially in osteoporosis resulting in a better grip force⁷; 3- nails with 6°

outer angle are easily inserted into the top of the greater trochanter8; 4- the distal locking hole leads to static or dynamic locking⁹. PFNA-II is designed for Asians based on anatomical characteristics of the proximal femur and is better than PFNA-I in terms of stability¹⁰. The prevalence of spiral blade shift in patients receiving PFNA for the treatment of unstable fracture in osteoporosis rotor is rare within 6 months after surgery, and 62.4% of patients recovered pre-fracture functional status¹¹. Â comparative meta-analysis of PFNA and DHS12 showed that PFNA minimized blood loss in surgery, operative time, fixation failure rate and complications. The two randomized controlled studies indicated that intramedullary fixation was more suitable for unstable intertrochanteric fractures than extra medullary fixation^{13,14}. However, fewer clinical studies of intertrochanteric fracture mostly focused on single site and clinical observations with small samples or retrospective analysis of differences between the two procedures. Therefore, the conclusions were not robust enough for clinical application. Large randomized controlled and double-blind clinical trials were more difficult. The differences in baseline data of patients and biological characteristics of fractures increased the cost due to a large sample size. Therefore, we analyzed the efficacy, complications and long-term prognosis of proximal femoral nail anti-rotation (PFNA) and dynamic hip screw (DHS) for the treatment of unstable intertrochanteric fractures to reduce the clinical risk and improve the long-term patient outcomes and quality of life.

Patients and Methods

Patients

We selected 165 patients suffering from an unstable intertrochanteric fracture from January 2010 to January 2015 in our hospital, including 89 with PFNA surgery and 76 with DHS surgery. We excluded 12 patients due to inadequate follow-up data or death from other diseases (such as cerebrovascular diseases, traffic accidents, or other chronic diseases). Finally, 82 were treated with PFNA and 71 with DHS. The PFNA group included 50 males and 32 females, aged between 25 and 78 years (average, 56.8 years). We included 52 patients afflicted with osteoporotic fractures and 30 with traumatic fractures lasting from 1 d to 5 d (average, $2.3 \pm$ 0.6 d). There were 12 patients with hypertension, 6 with diabetes mellitus and 3 diagnosed with other diseases. The follow-up visit lasted from 11 months to 53 months (average, 35.4 ± 9.2 months). The DHS surgery group included 43 men and 33 women, aged from 22 to 77 (average, 57.4 years). Further, there were 42 patients with osteoporotic fractures, 34 with traumatic fracture, 25 with Evans-Jensen type II, 28 with Evans-Jensen type III, 13 with Evans-Jensen type IV and 10 Evans-Jensen type V fractures. The fracture lasted from 1.5 d to 4 d (average, 2.2 ± 0.5 d). Also, the study included 8 patients with hypertension, 4 with diabetes mellitus and 2 patients suffering from other diseases. The follow-up visit lasted from 10 months to 56 months (average, 34.7 ± 7.5 months). The study was approved by the Ethics Committee of our hospital. The baseline data of the two groups were comparable.

Inclusion and Exclusion Criteria

The diagnostic criteria for intertrochanteric unstable fracture were: patients aged more than 1.18 years and less than 75 years; a history of trauma; hip pain associated with walking difficulty and limb hip tenderness, shortening of lower limbs, external rotation deformity generally more than 60 degrees; X-ray, CT and MRI evidence. Exclusion criteria were: pregnancy; severe cardiovascular disease, liver and kidney dysfunction, blood coagulation disorders, cancer and autoimmune diseases; previous trauma and hip surgery; other orthopedic surgeries, which may affect the outcome and prognostic evaluation; patients who failed to provide informed consent. Diagnostic criteria for osteoporosis were based on the "primary osteoporosis treatment guideline 2011": 1 brittle fracture; 2 bone mineral density (BMD) with a T-Score \leq -2.5SD.

Research Methods and Indices

Clinical demographics included: gender, age, fractures (low-energy fractures caused by osteoporosis and high-energy fractures due to direct violence), fracture type, fracture time to surgery, history of similar surgery, including conservative treatment and single external fixation, complications (hypertension, diabetes mellitus, coronary heart disease, cerebral infarction, previous orthopedic trauma and osteoporosis), surgical procedures (PFNA and DHS), number of internal fixations, length, operative time, blood loss in surgery, postoperative drug combination (such as traditional Chinese medicine and Western medicine for the treatment of osteoporosis), use of auxiliary external fixation and postoperative weight-bearing time. Indices were as follows: 1- adverse reactions after implantation included local reactions (inflammation, irritation, allergic reactions, tissue hyperblastosis and material corrosion, wear, bio-degradation) and systemic reactions (systemic inflammation, allergy, cell toxicity, coagulation changes, complement activation, carcinogenesis, and immune response,); 2- postoperative complications (including hip varus deformity, proximal femur fracture, avascular necrosis, broken nails, infection, fracture dislocation, loose hip screws, dislodging or skipping, plate fracture and unhealed fracture); intraoperative intramedullary device-related complications such as fractures of upper femur and shaft of femur; postoperative device-related complications such as femoral cut, varus, shortening and loosening and fracture of internal fixation probability; 3- clinical healing or bone healing time and function score (Harris hip joint function scale, fine/excellent rate).

Evaluation Criteria

Clinical healing criteria: 1- no local tenderness; 2- no local vertical percussion pain; 3- no local anomaly; 4- X-ray showing blurred fracture line and continuous callus through the fracture line; 5- after removal of external fixation, stretching of upper limbs and ability to hold 1 kg for 1 min; ability to walk no less than 30 steps within 30 min without crutches; 6- no deformity of fracture within two weeks. Bone healing criteria: 1- clinical healing; 2- X-ray showing the callus through the fracture line, loss of fracture lines; Harris hip score including pain, function, deformity, range of motion: excellent (score ≥ 90), better (80-89), good (70 to 79), and poor (<70).

Surgical Procedures

PFNA

The patient was prostrate on the orthopedic traction bed with lower limbs in traction and fixation. The pelvis was tilted at a 30° angle between the trunk and the contralateral side after general anesthesia. The affected part was elevated so that the C-arm fluoroscopy and nails avoid coverage of the ilium. The C-arm in fluoroscopy was reset in closed reduction. Next, a 5 cm longitudinal

incision from the greater trochanter to the proximal separated the gluteus medius along the mesophragma to expose the greater trochanter apex. The needle was inserted into the interface between the lateral surface of the greater trochanter apex and the femoral shaft medullary cavity. Later, the prismatic cone was used to drill into the medullary cavity through the cortical bone to insert the guide pin. A 17-mm hollow drill was used to manually guide the pin reamed in the sleeve until the hollow drill stop-line touched the sleeve edge. Further, the PFNA nail with an appropriate diameter and length was pushed into the canal with the handle connector. Simultaneously, the guide pin was inserted through the aiming device to ensure proper depth and the guide pin entered the lower half of the femoral neck in the femoral head.

DHS

An incision of about 8-12 cm was made from the lateral proximal femur along the greater trochanter to expose the lateral cortex of the proximal femur. The specific length of incision was determined in accordance with the internal fixation length. Later, the guide pin was inserted towards the apex of the femoral head: the intersection between the center of the femoral neck and the straight line parallel to it and the femoral head subchondral bone. The lateral guide pin was also in the center to avoid any lateralization of the guide pin. The lag screw was screwed 10 mm from the lower position of the joint surface safely without any risk of penetration only when the guide pin was located in the center of the positive and the lateral position. After the position and depth of the guide pin was fixed, the length of DHS triple drill was adjusted to drill the guide pin slowly. After the reamer, a tap was used with a good lag screw at a suitable depth (about 1-1.5 cm from the femoral cortex) to fix the DHS plate by the cortical bone screws at an appropriate length to ensure coherence between the plate and the bone cortex.

Table I. Comparison of surgical indicators.

Groups	Internal fixation	Length (mm)		Blood loss in surgery (mL)			Postoper- tive weight- bearing time (d)
PFNA	2.4±0.5	20.7±4.3	78.4±12.3	257.8±40.6	2.9±0.8	8.5±2.2	7.4±1.3
DHS	3.3 ± 0.8	25.6 ± 4.6	95.6±14.8	356.4±43.5	4.6 ± 1.0	14.6 ± 3.5	12.5±2.8
t	5.632	5.127	5.857	4.857	5.634	6.234	6.457
p	0.037	0.040	0.034	0.042	0.037	0.028	0.024

Statistical Analysis

SPSS 19.0 software (SPSS Inc., Chicago, IL, USA) was used for all statistical analysis. The measurement data were expressed as mean \pm standard deviation. The groups were compared using the *t*-test or Fisher's exact test. The count data were expressed as case numbers or percentages. The two groups were compared with χ^2 -test. Multivariate logistic regression analysis was based on a stepwise backward iterative analysis. A *p*-value less than 0.05 indicated statistical significance.

Results

Comparison of Surgical Indicators

The fixation numbers, length, operative time, blood loss, postoperative medication, time for auxiliary external fixation and postoperative weight-bearing time, were all statistically significant (p<0.05) as shown in Table I.

Comparative Efficacy

The efficacy of PFNA was more significant than that of DHS, and the prevalence of complications was reduced significantly. The follow-up Harris hip score was significantly higher than that of DHS as well. The difference was statistically significant (p<0.05) as shown in Table II.

Independent Risk Factors

The independent risk factors affecting healing include fracture type, fracture time, the procedures, the internal fixation and length. Independent risk factors affecting the follow-up Harris hip score include age, fracture type, comorbidities, different procedures, postoperative drug combination, time for auxiliary external fixation and postoperative weight-bearing time as listed in Tables III-IV.

Discussion

The intertrochanteric anatomy is closely associated with clinical treatment. The rich vascular supply contributes to clinical healing. The two major blood vessels including lateral femoral and internal arteries and the four branch arteries provide nutrition to intertrochanteric and femoral neck. A conservative approach and surgery were used to treat intertrochanteric fractures. Surgical intervention utilized a dynamic condylar screws, PCP, distal femur without invasive stabilization plate and proximal femoral intertrochanteric fractures with a locking plate. Gamma nails, proximal femoral nails (PFN) and PFNA, expandable and proximal femoral nails, united pulling interlocking intramedullary nails, InterTAN bone nails, Asia proximal femoral nail anti-rotation (PFNA-II), Russell-Tayler reconstruction nails and joint replacement¹⁵. The surgical procedures target different indications with varying clinical effect. They have been used clinically with much difficulty suggesting the absence of a perfect surgery for unstable intertrochanteric fracture. PFNA outscored DHS in terms of number of internal fixations, length, operative time, blood loss, postoperative drug combination, duration of auxiliary external fixations and postoperative weight-bearing time. It improved postoperative clinical results and contributed to excellent Harris hip scores and

excellence 77 (93.9) 59 (83.1) 4.497 0.034 Poor 36 (43.9) 27 (38.0) Cases 25 (30.5) 22 (31.0) **Excellent Group** 16 (19.5) 10 (14.1) 8 (9.8) 16 (22.5) 4.699 0.030 Table II. Summary of Non-overlapped Cases of Acute Fibrinous and Organizing Pneumonia and the Present Case. compli-cations related 1 (1.2) 3 (4.2) medullary compli-cations 2 (2.4) 4 (5.6) operative compli-cations 3 (3.7) 6 (8.5) reactions reactions Systemic 1 (1.2) 2 (2.8) Clinical Bone healing 82 $\begin{array}{c} \text{PFNA} \\ \text{DHS} \\ \chi^2 \\ p \end{array}$

Table III. Analysis of independent risk factors in postoperative healing.

Risk factor	β	Wald	Р	OR	95% CI
Fracture type	0.123	4.213	0.042	1.005	0.423-3.528
Fracture time	0.065	3.267	0.044	1.214	0.826-2.568
Different procedures	0.524	5.458	0.028	1.867	1.102-2.534
Number of internal fixations	0.411	5.102	0.031	1.224	0.724-2.125
Length	0.329	5.322	0.030	1.325	0.236-3.201

Table IV. Analysis of independent risk factors on Harris score.

Risk factor	β	Wald	Р	OR	95% CI
Age	0.201	4.102	0.043	1.125	0.421-3.527
Fracture type	0.328	3.625	0.045	1.157	0.632-3.120
Comorbidities	0.124	3.231	0.044	1.230	0.854-2.629
Different procedures	0.052	5.754	0.026	2.034	1.234-3.235
Postoperative drug combination	0.063	4.265	0.035	1.427	0.857-2.869
External fixation time	0.133	4.538	0.032	1.628	1.023-3.524
Postoperative weight- bearing time	0.258	4.629	0.030	1.865	1.231-4.257

reduced the prevalence of complications. Multivariate regression analysis revealed independent risk factors affecting the postoperative healing. They include fracture type, fracture time, different procedures, internal fixation and length. The independent risk factors for follow-up Harris hip score include age, fracture type, comorbidities, different procedures, postoperative drug combination, duration of external auxiliary fixture and postoperative weight-bearing time.

Conclusions

PFNA yielded better clinical results and longterm prognosis than DHS in the treatment of unstable intertrochanteric fractures. Although the theoretical basis for the clinical treatment of intertrochanteric fractures has undergone continuous improvement, the surgical procedures have increased, and clinical results and long-term prognosis have improved. However, evidence supporting clinical application is insufficient due to different or even contradictory conclusions. The retrospective study of the clinical factors based on univariate and multivariate logistic regression analysis has clinical implications based on comparative analysis. However, the study has several limitations inherent to the retrospective design relate to statistical bias and surgical intervention. Nonetheless, the biomechanical applications of different surgical procedures and mechanical properties of internal fixation provide new ideas for the development of bioengineering and biomaterial science.

Conflict of Interests:

The authors declare that they have no conflict of interests.

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