

Comparative Analysis of Results of Primary Bipolar Arthroplasty versus Proximal Femoral Nail Antirotation: A Prospective Study

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Abstract

Introduction: Comminuted peritrochanteric fracture commonly occurs in older age group. Commonly used methods are dynamic hip screw and proximal femoral nail. However, they are associated with complication and chance of failure is high. Primary bipolar arthroplasty is now emerging as a new modality of treatment. Our study compares the result of internal fixation with primary bipolar arthroplasty in the unstable trochanteric fracture.

Materials and Methods: This institution-based, prospective longitudinal study was conducted in our institution between January 2011 and March 2016. The inclusion criteria were: Unstable intertrochanteric severe osteoporosis. The exclusion criteria were: Suspected pathological fracture, significant senile dementia, and osteoarthritis or rheumatoid arthritis in the fractured hip and polytrauma. The final results were evaluated Parker and Postel Merle d'Aubigné (PMA) scores.

Results: A total 130 patients were included in the study. The differences between the two groups in operation time, blood loss, and transfusion volume were significant ($P < 0.05$). We found clinical results were significantly in favor of arthroplasty in terms of final Parker score, overall PMA score, and all three PMA items. Our observation that mortality was independent of surgical technique (21.7% nailing and 21.4% arthroplasty), time to surgery, and fracture type.

Discussion: Overall; the incidence of fixation failure in osteoporotic hip fractures is 5% in peritrochanteric fractures. In general, failed internal fixation leads to prolonged hospital stay, a doubling of healthcare costs, increase in social dependency. Our study underlined that arthroplasty was not associated with greater post-operative mortality than osteosynthesis and that the general complications rate was similar between the two groups (21.7% in nailing versus 21.4% in arthroplasty).

Conclusion: Primary bipolar arthroplasty is a good alternative to fixation. Overall, rigorously conducted prospective random clinical trials with larger population and long-term follow-up are needed.

Key words: Arthroplasty, Nail, Trochanteric fracture

INTRODUCTION

Proximal femoral fractures constitute 30% of all fractures referred to hospitals for treatment. Among them, the intertrochanteric fracture was seen in the extreme of ages. As the life expectancy of the population is increasing, the proportion of patients with postmenopausal or senile

osteoporosis is increasing simultaneously. Therefore, the number of proximal femoral fractures requiring urgent treatment is growing accordingly. In the age category of 50 years and older, the incidence of these fractures has increased exponentially.

The standard treatment, commonly accepted, is osteosynthesis. Its objective is to have a stable fixation and early mobilization. The prognosis of this fracture is poor, due to the presence of numerous comorbidities, prolonged immobilization, and noncompliance to rehabilitation therapy. The indication for prosthetic replacement in this type of fractures already exists in the literature as rescue intervention in failed osteosynthesis.

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The principal of treatment is based on whether the fracture is stable or unstable. This can change the therapeutic approach to surgery. The two main classifications are used worldwide to determine whether a fracture can be considered stable or not: AO/ASIF classification and Evans classification. According to the AO classification, Type 31-A1 and Evans classifications Types I and II are considered stable as they are two-part fracture. These types of fractures already have an absolute indication of osteosynthesis in the form of a dynamic hip screw or intramedullary nail that is accepted by all surgeons.

The AO/ASIF considers unstable fractures the multifragmentary intertrochanteric fractures or 31-A2 and the intertrochanteric ones or 31-A3 - type, while the Evans classification, which assesses the lack of medial and posterolateral support, or both, considers unstable fractures the III, IV, and V types. The treatment of unstable intertrochanteric fractures in the elderly patient is still controversial because often this type of fractures are comminuted, patients are elderly with marked osteoporosis, and it is very difficult to obtain a stable synthesis and a good reduction of the fracture.¹

Hemiarthroplasty has been used for unstable intertrochanteric fractures since 1971,² however, less frequently as compared to femoral neck fractures.³ Its initial use was as a salvage procedure for failed pinning or other complications.⁴ Grimsrud *et al.* performed 39 consecutive cemented bipolar hip arthroplasty in unstable intertrochanteric fractures. He used a standard femoral stem and reconstructed the trochanter by cerclage cabling. This technique allowed safe and early weight bearing on the injured hip and had a relatively low rate of complications.⁵ Rodop *et al.* performed primary bipolar hemiprosthesis for unstable intertrochanteric fractures in 37 elderly patients. According to Harris hip-scoring system, 17 excellent (45%) and 14 good (37%) results were found after 12 months.⁶

In this prospective study, we compare the results of primary bipolar arthroplasty and proximal femoral nail antirotation (PFNA) in unstable trochanteric fractures.

MATERIALS AND METHODS

This was an institution-based, prospective longitudinal study. The study was conducted in our institution after getting ethical permission. All the patients with intertrochanteric fractures admitted to the hospital between January 2011 and March 2016 were evaluated. All the patients were counseled about the advantages, disadvantages, and complications of the procedure. After getting written consent from patients, they were

selected for the study. We used Singh's classification of the trabecular bone structure in the proximal femur as a measure of osteoporosis based on the anteroposterior (AP) radiograph of the contralateral hip. The inclusion criteria were: Unstable intertrochanteric fractures (three or more part intertrochanteric fractures with a loss of posteromedial cortical buttress and reverse obliquity fractures, AO/ASIF classification 31-A2 and - A3), age over 70 years, severe osteoporosis (Singh index ≤ 3), no contraindication to anesthesia (American Society of Anesthesiologists [ASA] score of 1-4), and pre-injury independent walking with or without aids. The exclusion criteria were: Suspected pathological fracture, significant senile dementia, and osteoarthritis or rheumatoid arthritis in the fractured hip poor ambulation before the trauma, polytrauma, and severe concomitant medical conditions (ASA-5). The patients underwent surgery 4-10 days (mean, 6 days) after admission.

All cases of bipolar arthroplasty were operated using a standard posterior approach in lateral decubitus position. The principal was to the removal of femoral head, reconstruction of calcar and greater trochanter with the femoral shaft. Removal of femoral head is really difficult in trochanteric fracture as the capsule was attached to proximal fragment. In general, two methods were used according to fracture pattern. A proximal neck cut at the subcapital level was done and removed the head like in fracture neck femur or by releasing the whole capsule by rotating the proximal fragment with the help of corkscrew (Figure 1). With the removal of the head, the fracture now had three main fragments, namely, the greater trochanter, the lesser trochanter, and the shaft. Reconstruction of calcar was done by fixing lesser trochanter with the shaft. If lesser trochanter was comminuted, it was reconstructed with wedge shape graft taken from the head fragment. In case of the greater trochanter was the fracture en masse, it was reattached to the main shaft using steel wires. In cases where the greater trochanter was coronally split a tension band was applied beneath the gluteus medius and attached to the shaft. If the greater trochanter was found to be severely comminuted; ethibond sutures were used to suture together the trochanter pieces and the soft tissue to make a stable construct. Thus, at the end of reconstruction, the greater trochanter, the lesser trochanter, and the shaft were wired together using steel wires. The femoral canal was broached with appropriate anteversion (Figure 2). Trail reduction was done with the broach *in situ* and neck size was measured second-generation cementing technique and cement restrictor were used in all cases. Once the prosthesis was fixed, the broken trochanter and calcar were again retightened by tensioning the wire cables (Figures 3 and 4).

All cases of PFNA were operated in supine position on the fracture table. Traction was applied first in the direction



Figure 1: Removal of femoral head

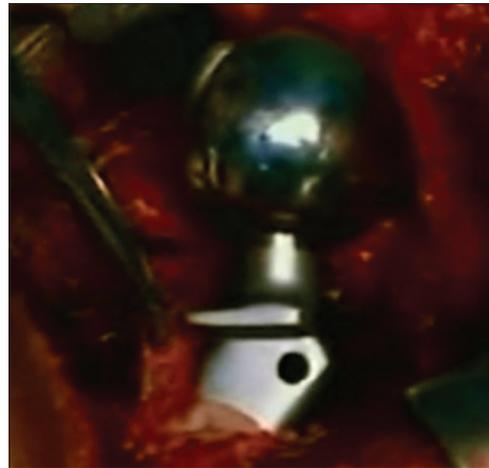


Figure 3: Prosthesis *in situ*



Figure 2: Broaching of femoral canal in proper anteversion



Figure 4: (a) Pre-operative X-ray, (b) post-operative X-ray

of the length of the extremity to reduce the fracture. This would distract the fragments and restore length. The second step was internal rotation. Each step was checked with the image intensifier. The entry point was usually on the lateral aspect of the greater trochanter. Skin incision was given in line with the femoral shaft axis and about 5 cm proximal to the tip of the trochanter. Guidewire was inserted into the femoral shaft, and its position was checked using the image intensifier. In most patients, the nail was inserted manually over the guidewire. The nail was inserted to such a depth that it would allow the column screw to be placed through the middle of the femoral neck. Insert the femoral neck screw over the guide wire under image intensification that the femoral neck screw protrudes slightly over the lateral cortex. The neck screw had to be locked and was verified intraoperatively. The distal screws were inserted thereafter (Figure 5).

Patients were examined postoperatively at 6 weeks, 3 months, 6 months, 1 year, and thereafter annually. At each follow-up visit, a clinicoradiological examination was done, and the patient was evaluated using Parker and Postel Merle d'Aubigné (PMA) scores. AP radiographs of the hip were analyzed at each follow-up to note evidence

of loosening or screw cut out. Quantitative data were analyzed by Wilcoxon/Kruskal-Wallis test to compare means and Levene test to compare scatter; qualitative data were analyzed by Chi-square test. The significance threshold was set at 0.05.

RESULTS

A total 130 patients were included in the study from January 2011 to March 2016. Bipolar arthroplasty was done in 70 patients, and internal fixation in the form of the proximal femoral nail was done in 60 cases.

The demographic characteristics of the 130 patients are summarized in (Table 1). The bipolar arthroplasty group included 38 males and 32 females with a mean age of 77.02 ± 7.58 years (range 70-80 years), and the internal fixation group included 29 males and 31 females with a mean age of 72.05 ± 5.8 years (range 71-85 years). Most patients had comorbidities that could adversely affect the functional outcomes, such as cardiovascular problems,



Figure 5: (a) Pre-operative X-ray, (b) post-operative X-ray of proximal femoral nail antirotation

diabetes mellitus, pulmonary diseases, and other associated diseases, but there was no significant difference in the number of comorbidities between the two groups. The data including age, sex, body mass index, fracture type, and Singh index of patients in the two groups also showed no significant difference.

The detailed surgery information of the patients is given in (Table 2). The mean operation time in the bipolar arthroplasty group was 74.5 min, much longer than 53.4 min in the internal fixation group. The average blood loss of the bipolar arthroplasty patients was 475.3 ml in comparison to two times of the blood loss of 252.8 ml of the internal fixation patients, and the average blood transfusion volume in the arthroplasty group was even more than two times that in the other groups. The differences between the two groups in operation time, blood loss, and transfusion volume were significant ($P < 0.05$). It can be also seen that although the patients stayed in the hospital for the similar length of duration.

At 12 months follow-up, we found that 13 of the 60 osteosynthesis patients had died (21.7%). Among the rest 47 patients, general complications were noted in 10 patients (21.3%). These include one thromboembolism, three cardiorespiratory, four neurological complications, and two infections. Surgical complications were found in eight patients (13.3%). These patients required revision surgery. Among them, six patients were managed by revision arthroplasty. At 1 year follow-up, the mean Parker score was 4.3 points range 0-9, mean PMA score 11.6 range 3-18, mean pain score 4.4, motion 4.46, and gait score 2.7, respectively. The average time of allowing weight-bearing was 13.8 days, and the mean time of effective weight bearing was at 28.6 days. The average time of recovery of walking distance at 46 days; and free gait without cane was at a mean 96 days (median 90 days).

Table 1: Comparison of demographic characteristics of patients

Parameters	Bipolar arthroplasty (70)	Internal fixation (60)	P value
Gender: Male/female	38/32	29/31	0.46
Age (years): Mean (range)	77.02±7.58	72.05±5.8	<0.05
Side: Right/left	32/38	28/32	0.95
Mechanism of injury			
Simple fall at home	57	44	0.39
Traffic accident	13	16	
BMI	22.3±4.7	25.1±5.2	<0.001
Singh index	2.9±0.7	25.1±5.2	<0.001
Associated comorbidities	38	37	0.67
Cardiac	21	20	
Vascular	20	19	
Pneumological	6	7	
Renal	6	6	
Neurological	10	9	
Associated contralateral osteoarthritis of the hip	6	5	
Associated osteoarthritis of the knee (s)	14		
AO fracture classification			
A2	38	34	0.85
A3	32	26	
Mean pre-operative Parker score	5.5	5.9	<0.05

Table 2: Comparison surgical details of both groups

Parameters	Bipolar arthroplasty (70)	Internal fixation (60)	P value
Operation time (minute)	74.5±15.2	53.4±12.5	<0.001
Blood loss (ml)	482.3±132.4	262.8±92.6	<0.001
Blood transfusion volume (unit)	3.7±1.3	1.8±0.9	<0.001
Hospitalization (days)	18.6±4.7	18.3±5.3	0.615

At 12 months follow-up, we found that 15 of the 70 arthroplasty patients had died (21.4%). Among the rest 55, there were seven general complications. These include three neurological, three cardiorespiratory, and one venous thrombosis. The local complications included one dislocation (2.2%) and one sepsis for total 4.4% cases of surgical revision (Table 3). At 1 year follow-up, the mean Parker score was 5.1 points range 0-9, mean PMA score 13.9 points range 4-18, mean pain score 5.2, motion 5, and gait score 3.6, respectively. The average time of mean effective weight-bearing was at 11.1 days and recovery of walking distance at 21 days. The recovery of free gait without cane was at a mean 117 days (median, 90 days).

Thus, we found that clinical results were significantly in favor of arthroplasty in terms of final Parker score, overall PMA score, and all three PMA items (Table 4).

At 12 months follow-up, 28 patients in all had died. Two patients died within 10 days postoperatively, 15 between

Table 3: Comparison of complications of both groups

Parameters(%)	Arthroplasty (70)	Nail (60)	P
Complications	9 (22.5)	16 (22.2)	0.973
Dislocation	3 (7.5)	0 (0)	0.018
Revision operation	2 (5.0)	3 (4.2)	0.838
Mortality	11 (27.5)	19 (26.3)	0.899

Table 4: Comparison of final results of both groups

Parameters	Nail (60)	Arthroplasty (70)	Wilcoxon test	Levene test
Mean postop Parker	4.3	5.10	0.02570	0.0632
Mean postel Merle	11.6	13.9	<0.0010	0.006
Pain score	4.4	5.2	<0.0001	<0.0001
Motion score	4.46	5	<0.0049	<0.001
Gait score	2.7	3.6	0.00050	0.092

days 10 and 90, and 11 later than day 90. We found that deceased patients had significantly greater mean age (87.4 vs. 85.3 years; $P = 0.002$), lower pre-operative Parker score (4.7 vs. 6; $P = 0.0005$), and a higher rate of renal comorbidity. Our observation that mortality was independent of surgical technique (21.7% nailing and 21.4% arthroplasty), time to surgery and fracture type, but correlated with general complication rate ($P = 0.03$) and post-operative sepsis ($P = 0.05$).

DISCUSSION

Fracture of proximal femur with their well-documented impact on morbidity and mortality, probably represent the most devastating outcome of osteoporosis in the elderly. As our population becomes increasingly older and the incidence of hip fractures continues to rise, even low failure rates will constitute a major challenge to health care systems. Internal fixation has drastically reduced the mortality associated with intertrochanteric fractures.⁷ However, early mobilization is still avoided in cases with comminution, osteoporosis, or poor screw fixation.^{8,9} Overall, the incidence of fixation failure in osteoporotic hip fractures is 5% in peritrochanteric fractures. In general, failed internal fixation leads to prolonged hospital stay, a doubling of healthcare costs, increase in social dependency. Furthermore, the marked disability and reduction in quality of life evident before salvage procedures may persist at long-term follow-up. Despite this, however, no clear link between revision surgery and an increase in mortality has been demonstrated in the literature. In view of these findings, of particular relevance then is the discussion between IF and arthroplasty in the management of osteoporotic fractures of the hip.

The earliest comparison of internal fixation and hemiarthroplasty was done by Haentjens showing a significant reduction in the incidence of pneumonia and pressure sores in those undergoing prosthetic replacement.¹⁰ In a comparative study of hemiarthroplasty versus internal fixation, Kayali reached the conclusion that clinical results of both groups were similar. Hemiarthroplasty patients were allowed full weight bearing significantly earlier than the internal fixation patients.¹¹ Broos *et al.*³⁶ concluded that the operative time, blood loss, and mortality rates were comparable between the two groups, with a slightly higher percentage (73% vs. 63%) of those receiving prosthesis.¹² The functional outcome was comparable between both groups. Stappaerts found no difference between two groups except a higher transfusion need in the replacement group.¹³ In our series, the average blood loss was 475.3 ml in comparison to 252.8 ml in fixation group. There was no incidence of dislocation. The present study showed better results with arthroplasty than with nailing in unstable trochanteric fracture in over 75 year olds, in terms both of associated complications (2.8% vs. 12.5%) and of Parker and PMA functional scores (Table 4).

Conflicting reports about post-operative mortality in cases with primary hemiarthroplasty are cited in the literature. Kesmezacar *et al.* reported post-operative mortality in 34.2% after a mean of 13 months and in 48.8% after a mean of 6 months in patients treated with internal fixation and endoprosthesis, respectively.¹⁴ Our study underlined that arthroplasty was not associated with greater post-operative mortality than osteosynthesis and that the general complications rate was similar between the two groups (21.7% in nailing vs. 21.4% in arthroplasty).

One major technical problem in trochanteric fracture arthroplasty is to restore lower-limb length.⁶ In unstable and therefore, complex fracture (31 A2.2 and 3, and 31 A3.3), the usual anatomic landmarks are disturbed (fracture of the lesser trochanter, pulled forward by the psoas tendon; fracture of the greater trochanter, pulled forward by the medial gluteal tendon) so that rigorous pre- and per-operative planning is mandatory to avoid discrepancy, which is badly accepted by active subjects (Parker 8 or 9).

Another problem is the primary stability of the prosthetic stem, lacking metaphyseal support in case of fracture, and possibly also lacking diaphyseal support in case of osteoporosis or of the uncemented implant. In the present series, all the implants were cemented. There was no varus collapse and dislocation in our study.

The Cochrane database analysis of relevant studies concluded that there is insufficient evidence to prove that primary arthroplasty has any advantage over internal

fixation.³ However, they also mentioned that there were only two randomized trials studied and both had methodological limitations, including an inadequate assessment of the longer term outcome. Delay in surgery is an important predictor for mortality in patients with proximal femur fracture and also of the post-operative morbidity.^{15,16} We in our study, however, could not comment on these points because of small sample size. Further, inhomogeneous population in terms of existing co-morbidity and retrospective nature of our study are the other limitations.

CONCLUSION

Thus, in conclusion, primary hemiarthroplasty does provide a stable, pain-free, and mobile joint with acceptable complication rate as seen in our study; however, a larger prospective randomized study comparing the use of intramedullary devices against primary hemiarthroplasty for unstable osteoporotic fractures will be needed.

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