A comparative study between osteosynthesis by proximal femoral nail (PFN) and Coxafemoral bypass with bipolar hemiarthroplasty Incomminuted inter- trochanteric fractures of femur in elderly patients

Dr Ameya Y Nandanwar
Senior Resident, Department: Orthopaedics MIMER Medical College Talegaon Dabhade, Contact number- 9699463686
Corresponding author email: ameya_nandanwar@yahoo.com

Dr. Shivraj Konde
Associate Professor, MIMER Medical College, Talegaon Dabhade

Dr. Abhishek G Patil
Junior Resident, MIMER Medical College, Talegaon Dabhade
Email: drabhishekpatil@gmail.com

Dr. Santosh Borkar
Professor, MIMER Medical College, Talegaon Dabhade.

Dr. Sunil R Yadav
Junior Resident, MIMER Medical College, Talegaon Dabhade
Email: sunily501@gmail.com

Dr. P. S Kamath
Professor, MIMER Medical College, Talegaon Dabhade and MIMER Medical College
and BhausahebSardesai Talegaon Rural Hospital, Talegaon, Maval, Pune-410507
Email: Pskamath1407@gmail.com

Abstract---This study was done to compare osteosynthesis by Proximal Femoral Nail And coxa femoral bypass by Bipolar Hemiarthroplasty in Comminuted/ Unstable Inter- Trochanteric Fractures of Femur in Elderly patients. The study was Interventional, prospective study. The study was conducted at department of Orthopaedics at tertiary care centre. Sample size 60. Fractures included in this study were restricted to comminuted and unstable inter-trochanteric fractures. Evans classification type 3,4,5. patients...
were divided in 2 groups- Group A which was Operated by Proximal femoral nail (PFN) and Group B which was Operated by Bipolar Hemiarthroplasty. Pre-operative workup was done followed by Operation and post operatively physiotherapy was given. Follow up was taken at regular intervals. At each follow up Harris hip score was evaluated. The study concludes that, Coxa femoral bypass by bipolar hemiarthroplasty is a better option than proximal femoral nail in the treatment of unstable IT fractures in the elderly.

**Keywords**---Bipolar hemiarthroplasty, Coxa-femoral bypass, intertrochanteric fractures, Proximal femoral nail.

**Introduction**

Intertrochanteric fractures are a major cause of morbidity and mortality in elderly population. The incidence of all hip fractures is approximately 80 per 1,00,000 persons. Inter-trochanteric fracture makes up 45% of all hip fractures. Isolated subtrochanteric fractures, or intertrochanteric fractures with subtrochanteric extension, are generally considered to be unstable fractures. Subtrochanteric fractures are complicated by the multiple strong muscular forces acting across the site of the fracture. Biomechanical studies have found the region one to three inches below the lesser trochanter, a small bony knob on the upper and inner portion of the femur, to be the most highly stressed region of the body, which increases the possibility of implant failure and malunion of the fracture. The comminuted intertrochanteric fractures are in cancellous area and so the fixation of all fragments is difficult. The posteromedial void is generally present which makes the fracture very unstable. Device options include similar internal fixation devices that are used for isolated intertrochanteric fractures. Intramedullary nails may be indicated for certain subtypes of fractures that are particularly unstable. Sliding hip screw devices are not well suited for subtrochanteric and reverse oblique intertrochanteric fractures as they may allow unacceptable displacement of the femur shaft. Again, as for all surgical decisions, surgeon experience and familiarity with the devices must also be considered. The 4th generation of intramedullary nails like the proximal femoral nails is a popular modality of treatment of such fractures. But with these implants immobilization is required for few days. If in such cases primary Hemiarthroplasty is done it will help in early mobilization and avoid most of the complications.

For stable fracture patterns, the literature suggests that the sliding plate/screw devices remain the treatment of choice, although surgeon practice varies widely. As the literature is not clear on this topic, the present study was undertaken to compare osteosynthesis by Proximal Femoral Nail and coxa femoral bypass by Bipolar Hemiarthroplasty in Comminuted/ unstable intertrochanteric fractures of femur in elderly patients.

**Method**

The present study was Interventional, prospective study to compare two surgeries: Osteosynthesis by proximal femoral nail (group A) and coxa femoral bypass by bipolar hemiarthroplasty (group B) in comminuted/ unstable inter-
trochanteric fractures of femur in elderly patients at tertiary care center. The study period was July 2019 to June 2020. The study population was selected patients diagnosed as comminuted/ unstable inter- trochanteric fractures of femur during the study period.

The sample size was 60 eligible patients, both male and female with comminuted/ unstable inter- trochanteric fractures of femur during study period. A total of 60 patients was recruited for the study and randomized into two equal groups using computer generated simple random allocation tables. Hence, a minimum sample size of approximately 30 cases in each group during study period was randomly selected and included in present study. Written informed consents were taken.

The sample size was calculated using the formula. Estimation done using G power™software. The proportion of functional restoration at first follow up was assumed to be 0.7 in group B and 0.3 in group A thus yielding a moderate effect size of 0.4. Assuming an alpha of 0.05 and beta of 0.2 with the ratio of cases in group B to group A kept as 1, a minimum sample size of 29 was calculated for each group. Therefore, we intend to include 30 patients per group.

Fractures included in this study were restricted to comminuted and unstable inter-trochanteric fractures. Evan’s classification type 3,4,5. All patients were from age group 60 years and above, both male and female. All fractures were acute. Only closed fractures were included in the study.

Evans type 1 and 2 are excluded. Patients below the age of 60 years were excluded. All open fractures were excluded. Pathological fractures were excluded. Old fractures were excluded. Group A was Operated by Proximal femoral nail (PFN) and Group B was Operated by Bipolar Hemiarthroplasty. The study was approved by the Ethical Committee of the institute. A written and informed consent was obtained in the language that the patient understands. Under all aseptic precautions and with appropriate Anaesthesia, open reduction and internal fixation using proximal femoral nail or bipolar hemiarthroplasty was done. Drain to be removed on day 2 or 3. Appropriate Post Op. X-Ray - AP, Lateral view was taken.

Physiotherapy was started form the second or third day of the surgery. Sutures were removed on day 14 or depending on the conditions of wound. Prophylactic antibiotics were given. Mobility with Weight bearing/ non weight bearing on operated side to be assessed. Patient was followed up after 3 weeks, 6 weeks, 3 months, 6 months and 9 months of surgery and X-Rays was taken. Also mobility was assessed. The final outcome of study analysed only after 9-12 months of follow up. HARRIS HIP SCORE was assessed at each visit. Single blinding was done to avoid bias. All the expenses of operative procedures were covered up in MJPYAY scheme.
For statistical analysis, Categorical variables were summarized as frequency and percentages and numerical variables were summarized as mean, median, mode, standard deviation and Interquartile range. Analysis of pre- and post-treatment data for each group was done using paired t test. Comparison between groups was done using unpaired t test and significance of post treatment improvement throughout the different stages was assessed by one way ANOVA test. Analysis was done using SPSS version 21 and Microsoft excel 2010 for graphical representation. p value less than or equal to 0.05 was considered statistically significant. Reference citation was done By Vancouver style.

**Results**

It was observed that majority of patients in Group A (63.3%) and Group B (66.67%) was in age group 71-80 years. The mean age in group A was 72.20 ±7.55 years and group B was 71.63 ±6.28 years. There was no significant difference in age distribution in two groups. (p>0.05). Out of total 60 patients, 38 were females while 22 patients were male. There was female dominance with 18 (60%) and 20 (66.67%) patients among Group A and Group B respectively. There was no gender difference when two groups were compared statistically. (p>0.05). According to distribution of patients the mode of injury, it was observed that majority of patients in Group A (70%) and Group B (66.67%) had history of fall with no difference when two groups were compared statistically. (p>0.05).

It was observed that majority of patients in Group A (83.3%) and Group B (73.3%) had quality of bone ≤3 by Singh index with no difference when two groups were compared statistically. (p>0.05). It was observed that majority of patients in Group A (73.3%) and Group B (63.3%) had shortening ≤1cm with no difference when two groups were compared statistically (p>0.05). The surgery time in Group A and Group B was 51.29 ±6.29 and 73.70 ±8.23 minutes respectively. This difference in mean surgery time in patients was more in Group B with statistically significant difference. (P<0.05). The average blood loss in Group A and Group B was 163.70 ±12.47 and 518.56 ±34.33 ml respectively. The average blood loss in Group B patients was more compared to Group A which was statistically significant (P<0.05). The hospital stay in Group A and Group B was 6.30 ±1.42 and 6.12 ±1.19 days respectively. There was no difference in mean hospital stay in patients among both groups. (P>0.05). The Harris score in Group A and Group B was 73.01 ±8.92 and 77.8 ±7.81 respectively. This difference in mean Harris score in patients was more in Group B with statistically significant difference. (P<0.05) Similarly, at 3 months patients in Group B showed better outcome compared to Group A with statistically significant difference. (P<0.05). But, at 6 and 9 months both groups shows better outcome with no statistical significance. (P>0.05).
Distribution of patients according to intraoperative variables

<table>
<thead>
<tr>
<th>Intraoperative variables</th>
<th>Group A</th>
<th>Group B</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of surgery (min)</td>
<td>51.29±6.29</td>
<td>73.70±8.23</td>
<td>&lt;0.001 (S)</td>
</tr>
<tr>
<td>Blood loss (ml)</td>
<td>163.70±12.47</td>
<td>518.56±34.33</td>
<td>&lt;0.001 (S)</td>
</tr>
<tr>
<td>Hospital stay (days)</td>
<td>6.30±1.42</td>
<td>6.12±1.19</td>
<td>0.13 (NS)</td>
</tr>
</tbody>
</table>

(Table number 1).

Chart of intraoperative variables
Distribution of patients according to Outcome (Harris Hip score)

<table>
<thead>
<tr>
<th>Harris score</th>
<th>Group A</th>
<th>Group B</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 weeks</td>
<td>73.01 ±8.92</td>
<td>77.8 ±7.81</td>
<td>0.03 (S)</td>
</tr>
<tr>
<td>3 months</td>
<td>78.22±6.29</td>
<td>81.83 ±6.52</td>
<td>0.04 (S)</td>
</tr>
<tr>
<td>6 months</td>
<td>81.21±5.27</td>
<td>83.31 ±6.21</td>
<td>0.09 (NS)</td>
</tr>
<tr>
<td>9 months</td>
<td>84.20 ±5.92</td>
<td>86.52±5.28</td>
<td>0.31 (NS)</td>
</tr>
</tbody>
</table>

Table number 2

It was observed that majority of patients in Group A (60%) had good outcome followed by excellent outcome (20%). In group B, 9 (30%) patients had excellent outcome. The difference among outcome at one year in both groups showed no statistical significance by chi square test. (P>0.05). It was observed that majority of patients in Group A (10%) had implant removal followed by surgical site infection (10%). In group B, 2 (6.67%) patients had infection. The difference among complications in both groups showed no statistical significance.(P>0.05)

**Discussion**

Hip fracture has been recognized as the most serious consequence of osteoporosis because of its complications, which include chronic pain, disability, diminished quality of life, and premature death. The comminuted inter-trochanteric fractures are in cancellous area and so the fixation of all fragments is difficult. The treatment for undisplaced or minimally displaced fractures is osteosynthesis with DHS plate and screws or PPN. However, for displaced unstable fractures the treatment is controversial. The present study was conducted to compare osteosynthesis by Proximal Femoral Nail and coxafemoral bypass by bipolar hemiarthroplasty in Comminuted/ Unstable Inter-Trochanteric fractures of femur in elderly patients at Tertiary Care Centre.
Fig no 10. 80 years old female with unstable left intertrochanteric femur fracture managed operatively with bipolar hemiarthroplasty.

Figure no. 11. 75 years old male with unstable left intertrochanteric femur fracture operated with PFNA2

In the present study, the distribution of patients according to age showed that majority of patients in Group A (63.3%) and Group B (66.67%) was in age group 71-80 years. The mean age in group A was 72.20 ±7.55 years and group B was 71.63 ±6.28 years. There was no significant difference in age distribution in two groups. (p>0.05). Narendra Reddy Medagam et al studied effectiveness of coxofemoral bypass in comparison to proximal femoral nail in the treatment of unstable intertrochanteric fractures in the elderly observed no difference among study population with respect to age. This finding was similar to present study. Parth Vinod Agrawal et al in a study on functional outcome of primary cemented bipolar hemiarthroplasty observed mean age of 72.8 years among patients. Out of total 60 patients, 38 were females while 22 patients were male. There was female dominance with 18 (60%) and 20 (66.67%) patients among Group A and Group B respectively. There was no gender difference when two groups were compared statistically. (p>0.05). Narendra Reddy Medagam et al studied effectiveness of coxofemoral bypass in comparison to proximal femoral nail in the treatment of unstable intertrochanteric fractures in the elderly observed among study
population included, 30 (71.4%) were females and 12 (28.6%) males. This finding was similar to present study.

Parth Vinod Agrawal et al in a study on functional outcome of primary cemented bipolar hemiarthroplasty observed out of 25 cases, there were 14 male and 11 female patients. This was contrast to present study. In the present study, it was observed that majority of patients in Group A (70%) and Group B (66.67%) had history of fall with no difference when two groups were compared statistically. (p>0.05). Similarly, Narendra Reddy Medagam et al observed most of the fractures (88.1%) were the result of trivial fall. This finding was similar to present study. Parth Vinod Agrawal et al in a study on functional outcome of primary cemented bipolar hemiarthroplasty observed 80% of the cases admitted were due to trivial trauma, 20% due to RTA. It was observed that majority of patients in Group A (83.3%) and Group B (73.3%) had quality of bone ≤3 by Singh index with no difference when two groups were compared statistically. (p>0.05) The majority of patients in Group A (73.3%) and Group B (63.3%) had shortening ≤1cm with no difference when two groups were compared statistically. (p>0.05). Parth Vinod Agrawal et al in a study on functional outcome of primary cemented bipolar hemiarthroplasty observed post operatively 4 patients (16%), had a shortening of less than 2 cms and 2 patients (8%), had a shortening of more than 2 cms. 4 patients had lengthening of less than 2 cms (16%). The surgery time in Group A and Group B was 51.29 ±6.29 and 73.70 ±8.23 minutes respectively. This difference in mean surgery time in patients was more in Group B with statistically significant difference. (P<0.05). The average blood loss in Group A and Group B was 163.70 ±12.47 and 518.56 ±34.33 ml respectively. The average blood loss in Group B patients was more compared to Group A with statistical significant. (P<0.05) The hospital stay in Group A and Group B was 6.30 ±1.42 and 6.12 ±1.19 days respectively. There was no difference in mean hospital stay in patients among both groups. (P>0.05).

Narendra Reddy Medagam et al studied effectiveness of coxofemoral bypass in comparison to proximal femoral nail in the treatment of unstable intertrochanteric fractures in the elderly observed mean duration of surgery in proximal femoral nail group was 49.5 min whereas in coxofemoral bypass group was 71 min. The mean intraoperative blood loss in proximal femoral nail group was 147 ml and in coxofemoral bypass group was 508 ml. The difference between the two groups regarding duration of procedure, and blood loss was statistically significant. This finding was similar to present study.

Parth Vinod Agrawal et al in a study on functional outcome of primary cemented bipolar hemiarthroplasty observed mean duration of hospital stay was 13.2 days. In the present study, the Harris score in Group A and Group B was 73.01 ±8.92 and 77.8 ±7.81 respectively. This difference in mean Harris score in patients was more in Group B with statistically significant difference. (P<0.05) Similarly, at 3 months patients in Group B showed better outcome compared to Group A with statistically significant difference. (P<0.05) But, at 6 and 9 months both groups shows better outcome with no statistical significant difference. (P>0.05).
Narendra Reddy Medagam et al observed the mean HHS at the end of 6 weeks in proximal femoral nails (PFN) group was 73.09 and in coxofemoral bypass group was 77.8. At the end of 6 months, the mean HHS in PFN was 77.38 and in coxofemoral bypass group was 79.85. The study shows statistically significant difference in HHS at the end of 6 weeks ($P = 0.048$) between two groups, but the difference between two groups at the end of 6 months was not significant statistically ($P = 0.357$). This finding was similar to present study.

Parth Vinod Agrawal et al. in a study on functional outcome of primary cemented bipolar hemiarthroplasty observed excellent outcome in 24% cases, Fair to Good results were seen in 72% of cases according to Harris Hip Score. In the present study, it was observed that majority of patients in Group A (60%) had good outcome followed by excellent outcome (20%). In group B, 9 (30%) patients had excellent outcome. The difference among outcome at one year in both groups showed no statistical significance by chi square test. ($P > 0.05$). Green et al., in a series of 20 cases, performed bipolar hemiarthroplasty for elderly patients with unstable trochanteric fractures with a mean time to ambulation of 5.5 days, and a mean follow up of 13.2 months. Amongst the 20 cases, 7 patients had excellent results, 11 patients had good results, 7 patients had fair results, 5 patients had poor results and 3 patients died. They concluded that with technical considerations in mind head neck replacement hip arthroplasty for unstable intertrochanteric fractures in forgetful, elderly patients was a suitable alternative to internal fixation because the prosthesis provided for early full weight bearing and rapid rehabilitation.

Haentjens et al., in a series of 37 cases, with a mean age of 82 years who sustained unstable intertrochanteric fractures were treated with immediate bipolar hemiarthroplasty. Amongst the 37 cases, who were rated according to criteria of Merle d’Aubigne, 7 patients had excellent results, 11 patients had good results, 7 patients had fair results, 5 patients had poor results and reported death of 3 cases. They concluded that immediate bipolar hemiarthroplasty for independently mobile patients older than 70 years having unstable intertrochanteric fractures, allowed early walking with full weight bearing and helped the patients to return to prefracture level of activity rapidly, preventing complications such as pressure sores, pneumonia, and atelectasis and pseudoarthrosis. They observed bone callus radiologically 4 weeks post operatively on the medial aspect of the femur and sometimes completely surrounding the prosthesis.

Rosenfeld et al., in a series of 72 elderly patients with unstable trochanteric fractures treated using head neck replacement prosthesis. The series showed excellent results in 33 patients, good results in 21 patients, fair results in 11 patients, poor results in 2 patients and reported death of 5 patients. They concluded that in elderly, frail and confused patients who had intertrochanteric fractures, hemiarthroplasty helped in faster ambulation and reduced the complications.

The results were in agreement with Kim et al. who concluded that in elderly patients with an unstable ITfemoral fracture, a proximal femoral nail had no
advantage with regard to functional outcome when compared with a prosthetic replacement arthroplasty.\textsuperscript{12}

Rodop et al. observed good-to-excellent results in 80\% of patients with unstable IT femur fractures, using HHS, who had been treated with bipolar Leinbach hemiprostheses. The distribution of patients according to complications showed that majority of patients in Group A (10\%) had implant removal followed by surgical site infection (10\%). In Group B, 2 (6.67\%) patients had infection. The difference among complications in both groups showed no statistical significance (P>0.05).\textsuperscript{13}

Narendra Reddy Medagam et al study the complications encountered in proximal femoral nail group were bedsore, malunion, pulmonary infection, wound dehiscence, implant failure, and shortening of operated limb in 3, 2, 1, 1, and 1 patient, respectively. Whereas, complications noted in coxofemoral bypass group were wound dehiscence, bedsore, shortening of operated limb, retroverted placement of prosthesis in 2, 1, 1, and 1 patient, respectively. Liang et al., in their study, concluded that hemiarthroplasty is an effective method for the unstable IT fractures in elderly patients as it can decrease the complications, reduce the mortality, and improve the patient’s living quality. Earlier similar study done by Haentjens et al. also had similar results, which showed a significant reduction in the incidence of pneumonia and pressure sores in those undergoing prosthetic replacement.

In another comparative study by Kayali et al., patients treated with prosthetic replacement were allowed full weight bearing significantly earlier than the internal fixation patients. Bipolar hemiarthroplasty reduced the complications of prolonged immobilization, prolonged rehabilitation, marked residual deformities and need for revision surgeries. The procedure offered, faster mobilization, rapid return to pre injury level, improved the quality of life and gave a long term solution in elderly patients with intertrochanteric fractures of the femur.\textsuperscript{14} These study findings are similar to our study which shows similar results.

\textbf{Conclusion}

The present study concludes that, Coxofemoral bypass by bipolar hemiarthroplasty is a better option than proximal femoral nail in the treatment of unstable IT fractures in the elderly. The procedure offered, better HARRIS Hip score and rapid return to pre injury level, improved the quality of life and gave a long-term solution in elderly patients with intertrochanteric fractures of the femur.

\textbf{References}