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Cemented Bipolar Prosthesis Versus Proximal Femoral Nail in the Management of Unstable Intertrochanteric Fractures in Elderly – A Prospective Observational Study

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Abstract

Background: In elderly patients, unstable intertrochanteric fractures (ITFs) pose significant challenges in orthopedic management; however, the treatment strategies for optimal functional outcomes remain uncertain. Thus, this study aimed to compare the functional outcomes of cemented bipolar prosthesis and proximal femoral nailing (PFN) using the Harris Hip Score (HHS).

Materials and Methods: This prospective observational study was conducted at the Department of Orthopedics over 24 months (September 2022 to August 2024). Based on the treatment received, total 60 patients with unstable ITF were assigned equally into two groups: cemented bipolar prosthesis group (n = 30) or PFN group (n = 30). Functional outcomes were assessed using the HHS and were measured at 6-, 12- and 24-weeks post-surgery.

Results: The bipolar prosthesis group experienced longer surgery durations, increased intraoperative blood loss, and extended hospitalization compared to the PFN group. Both surgical groups demonstrated significant increase in HHS at 12- and 24-weeks compared to 6-weeks (all $p < 0.05$). Notably, the HHS were significantly higher in the bipolar prosthesis group at 6-, 12- and 24-weeks compared to the PFN group (all $p < 0.05$).

Conclusions: Both cemented bipolar prosthesis and PFN result in significant improvement in functional outcomes. However, the improvement in functional outcomes is significantly greater with cemented bipolar prosthesis than PFN.

Keywords: bipolar prosthesis, intertrochanteric, functional outcomes, Harris Hip score, proximal femoral nailing

INTRODUCTION

Hip fractures represent a significant health concern, particularly among the elderly, with intertrochanteric fractures (ITFs) being highly

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prevalent and associated with a one-year mortality rate of up to 20%.[1] Owing to increased life expectancy and sedentary lifestyles, the incidence of ITF is expected to rise from 1.66 million in 1990 to an estimated 6.26 million by 2050.[2] Surgical intervention is commonly recommended, as conservative treatment is limited to high-risk patients or those with minimal pain and non-ambulatory status emphasizing the need for effective treatment strategies to optimize the outcomes.[3]

Proximal femoral nailing (PFN) is valued for its minimally invasive nature and potential for early mobilization, especially in the elderly.[4] However, it poses challenges such as unstable fracture geometry, varus collapse, and screw cut-out, which may lead to a poor prognosis.[5] While PFN may be a viable choice for unstable ITFs, complex fractures can compromise fixation, resulting in lower functional outcome.[6] Consequently, some prefer artificial hip replacement as a potentially better option for treating ITFs in elderly patients.[7]

Hemiarthroplasty is reported to permit early full-weight bearing, and reduce complications from prolonged bed rest.[8] Among its variants, cemented bipolar hemiarthroplasty is notable for bypassing bone healing, facilitating early mobilization, shorter hospital stays, and better initial functional outcomes.[9] Although early outcomes are often superior with cemented bipolar hemiarthroplasty, patients treated with PFN tend to reach comparable activity levels sooner, ultimately displaying better long-term activity.[10]

Some authors found that bipolar hemiarthroplasty allows early weight-bearing with significantly better HHS scores at 3-months, but outcomes were similar at 6-months, while PFN showed significantly better long-term results with fewer implant-related complications.[11,12] Moreover, others have concluded that PFN had significant advantages in reduced surgical time, blood loss, and superior HHS over time, despite hemiarthroplasty's benefit of earlier weight bearing.[13,14] Despite the short- and long-term benefits of hemiarthroplasty,[15] and PFN,[16] there remains a lack of consensus regarding the comparable functional outcomes between these techniques, necessitating a more individualized treatment approach.[17] To address this discrepancy, we compared the functional outcomes in elderly patients with unstable ITFs managed with either PFN or cemented bipolar prostheses.

MATERIALS AND METHODS

Study Design and Ethics

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This prospective observational study was conducted over 24 months (September 2022 to August 2024) in the Department of Orthopedics of a tertiary care institute. Institutional Ethics Committee approval was obtained (IEC/2022/114, Dated 26 August 2022), and all patients provided written informed consent.

Population

The study included patients aged over 60 years, of either sex, presenting with acute closed unstable ITFs classified as Boyd and Griffin types 2, 3, or 4, and who were independently ambulant prior to the ITFs. While the patients aged under 60 years, medically unfit, had neurovascular deficits in the affected limb, sustained polytrauma, and required ambulatory support or were non-ambulant before the ITFs were excluded from the study.

Data collection

Upon arrival, patients' hemodynamic status and vital signs were assessed. A history was taken, focusing on the injury mechanism, comorbidities (e.g., diabetes, hypertension, COPD), and presence of history of smoking, previous fractures, and osteoporosis. A local examination was performed to evaluate skin condition, swelling, and neurovascular compromise. X-rays of the injured limb and pelvis (both hip views and lateral) were obtained, with fractures classified using AO and Evans systems. Temporary immobilization with a slab was applied. The patients were transferred to the ward, placed in ankle traction, and given analgesics. Preoperative blood tests and anesthesiology consultations were conducted, and x-rays were reviewed by senior faculty to select eligible patients for the study.

The patients were divided equally into two groups—bipolar prosthesis and PFN—based on the surgeon’s discretion. Once considered fit for surgery, they underwent the assigned procedure under spinal or general anesthesia. Post-operative pelvic x-rays (both hip and lateral views) were attained. In both the groups, the patients were instructed to elevate their legs and perform toe movements. Antibiotics were administered for five days intravenously, followed by oral third-generation cephalosporins for another ten days after discharge.

Investigations

Digital x-rays (anteroposterior and lateral views) and routine pre-operative examinations, including complete blood count, random blood sugar, blood grouping, Rh-typing, serology, serum creatinine, and blood urea, were conducted. Further evaluations included electrocardiogram, 2D echocardiography, and

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hip imaging *via* computed tomography and/or magnetic resonance imaging scans. Digital radiography was used for imaging, while measuring tape was used for physical measurements. An intra-operative image intensifier was used for real-time visualization during surgery.

Post-operative follow-up

Post-operatively, anti-inflammatory analgesics and antibiotics were administered, and the negative suction drain was removed 48 hours later. Quadriceps strengthening exercises were initiated on the first day post-surgery. The patients were encouraged to sit up on day two, stand with a walker on day three, and based on pain tolerance, bear full weight and walk with a walker by day four. Walking was encouraged, while sitting cross-legged and squatting were restricted. Sutures were removed on day 14, with follow-up evaluations at 14-15 days for fresh x-rays and at 6-, 12-, and 24-weeks.

The functional outcome was evaluated using the HHS, with scores <70 as poor, 70-79 fair, 80-89 good, and 90-100 excellent.[18] The post-operative complications were monitored at each follow-up, with standard x-rays to check for prosthesis loosening, stem malposition, or sinking.

Sample size estimation

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 (\sigma_1^2 + \sigma_2^2)}{(\mu_1 - \mu_2)^2}$$

A sample size of 60 subjects, 30 in each group, was sufficient to detect the difference between the groups, assuming standard deviation of 13.1 and 18.7 and mean HHS of 86.7 and 70.3 in cemented bipolar prosthesis group and PFN group, respectively, using a one-tailed Z-test of difference between means with 90% power and a 1% (two-tailed) level of significance. Considering a dropout rate of 5%, the required sample size per group was 28.839 approximating to 30 per group.

Statistical analyses

The data analyses were conducted using Epi Info version-6. The qualitative data was presented as frequencies and percentages, and the quantitative data was presented as mean (standard deviation). An independent sample t-test was used as a test of significance for quantitative data. Repeated measure ANOVA was used to perform within group analysis of HHS at various intervals. Statistical significance was determined at a p-value < 0.05.

RESULTS

The patients were slightly female predominant (55.00%) and the mean age was 68.35 ± 9.33 years. The majority of the patients had left sided

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injury (56.67%) with BG Type 3 (58.33%) fracture and trivial trauma (70.00%) being the most common mechanism of injury. Equal proportion of patients received bipolar prosthesis and proximal femoral nail (each 50.00%) (Table 1).

Table 1: Demographic and clinical characteristics

Characteristics	n = 60
Age, years, mean ± SD	68.35 ± 9.33
Gender, n (%)	
Female	33 (55.00%)
Male	27 (45.00%)
Side of injury, n (%)	
Right	26 (43.33%)
Left	34 (56.67%)
Mechanism of injury, n (%)	
Trivial trauma	42 (70.00%)
RTA	18 (30.00%)
Type of fracture	
BG Type 2	24 (40.00%)
BG Type 3	35 (58.33%)
BG Type 4	1 (1.67%)
Treatment group	
Bipolar prosthesis	30 (50.00%)
Proximal Femoral Nail	30 (50.00%)

BG: Baumgaertner classification system

The bipolar prosthesis group had significantly longer surgery time ($p < 0.0001$) and higher blood loss ($p < 0.0001$) than the PFN group. Moreover, the length of hospital stay was significantly longer in the bipolar prosthesis group than the PFN group ($p = 0.025$). Though the limb length discrepancy was greater in the bipolar group than the PFN group, the difference did not reach a statistically significant level ($p = 0.156$) (Table 2).

Table 2: Intra- and post-operative characteristics

Characteristics	Treatment group		p
	Bipolar prosthesis (n=30)	PFN (n=30)	
Surgery time, min	91.93 (8.62)	68.80 (9.67)	< 0.0001
Blood loss, ml	294.33 (55.50)	125.50 (23.21)	< 0.0001
Hospital stay, days	5.63 (1.29)	5.07 (0.37)	0.025
LLD, mm	0.38 (0.58)	0.20 (0.39)	0.156

LLD: Limb length discrepancy

In both the bipolar prosthesis and the PFN groups, HHS score increased significantly at 12- and 24-weeks compared to 6-weeks (all p <

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0.0001). However, at 6-, 12-, and 24-weeks, the HHS score was significantly greater in the bipolar prosthesis group than the PFN group (all $p < 0.0001$) (Table 3).

Table 3: Functional outcomes (HHS)

HHS	Treatment group		p
	Bipolar prosthesis (n=30)	PFN (n=30)	
6-weeks	62.77 (3.77)	53.57 (3.27)	< 0.0001
12-weeks	74.27 (3.32)	65.67 (2.66)	< 0.0001
24-weeks	87.07 (1.39)	82.80 (1.92)	< 0.0001
p	< 0.0001	< 0.0001	

HHS: Harris hip score, PFN: Proximal femoral nail

In both the groups, none of the patients had intra- and post-operative complications, except one (3.33%) patient in the PFN group developed surgical site infection.

DISCUSSION

The principal findings of the study revealed that both bipolar prosthesis and PFN led to significant improvement in the functional outcomes. However, the functional outcomes were significantly better with bipolar prosthesis than PFN, though at the cost of significantly longer duration of surgery and length of hospital stay as well as higher intra-operative blood loss. Moreover, both the procedures were comparable in terms of safety.

The significant intra-operative observations, including average blood loss and mean surgery duration, showed that PFN group had upper hand compared to bipolar prosthesis group. This is supported by the findings of Zhou et al., who reported a longer surgical time with bipolar hemiarthroplasty, and Özkayın et al. reported that shorter internal fixation time with PFN.[10,19] Compared to PFN, the bipolar prosthesis procedure is more complex, requiring precise prosthesis placement and handling of surrounding tissues. This added complexity leads to longer operative durations as surgeons navigate the intricacies of implanting a modular system that ensures both joint stability and mobility.[20] The meticulous nature of the bipolar hemiarthroplasty, which involves careful alignment and fixation of the prosthesis, contributes to the increased duration of surgery. Furthermore, the cementing process used in bipolar hemiarthroplasty may also lead to higher bleeding, as it requires femoral canal manipulation and surrounding structures, which can disrupt vascular integrity.[19] In contrast, PFN procedures are typically less invasive, leading to reduced blood loss.[14] This is in consensus with the Roy et al. study which

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highlighted that intra-operative blood loss was significantly higher in cemented bipolar prosthesis group as compared to PFN group.[11]

The longer hospital stay for patients in the bipolar prosthesis group may be a direct consequence of the increased surgical complexity and blood loss compared to the PFN group. The patients undergoing more extensive surgeries often require closer monitoring and a longer recovery period to manage potential complications, such as infection or delayed healing.[21] Furthermore, the rehabilitation process for patients with bipolar prostheses may necessitate additional physical therapy sessions to ensure proper recovery and mobility, thereby extending the duration of hospitalization in the bipolar prosthesis group.[22] This aligns with the findings of a meta-analysis by Kumar et al., who reported significantly shorter duration of hospital stay, reduced surgical time, and less blood loss with the PFN compared to the bipolar prosthesis. Moreover, PFN was associated with significantly lower risk of mortality, and the incidence of implant-related complications, including fractures and subsidence, was greater with bipolar prosthesis, though not statistically significant.[23]

Though the LLD was higher in the bipolar prosthesis group than the PFN group, this difference did not reach statistical significance. This suggests that while bipolar prosthesis may represent a greater risk of discrepancies post-operatively, this risk is not uniformly distributed across all the patients. In the context of bipolar prosthesis, the increased LLD can be attributed to the complexity of surgical technique involved in prosthesis implantation which may lead to alterations in the positioning of prosthetic head relative to femoral neck, thereby affecting limb length.[24] In contrast, the less invasive nature of PFN technique allows for more controlled fracture reduction, which may contribute to a more consistent restoration of limb length. Moreover, minimal invasive nature of PFN often results in reduced soft tissue disruption subsequent to more alignment of femur which can help mitigate risk of LLD.[25]

In the present study, the patients in both groups had a significant increase in the functional outcomes. However, at 6-, 12-, and 24-week post-surgery, the cemented bipolar prosthesis group compared to the PFN group had significantly better functional outcomes in terms of higher HHS. The superior functional outcomes observed in the bipolar prosthesis group can be attributed to its full weight-bearing capacity and stability, which can lead to enhanced mobility and quicker recovery post-

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surgery.[20] The design of the bipolar prosthesis including a mobile bearing surface, may contribute to better joint function and reduced pain levels, facilitating earlier rehabilitation and improved HHS scores.[11] In contrast, while PFN is associated with a minimally invasive technique and shorter operative times, it may not provide the same level of stability and pain relief as bipolar prosthesis, particularly in the context of unstable ITF.[23] The findings of the present study are in consensus with the study by Jin et al. who reported statistically significant HHS outcomes at the 6-month follow-up in the patients of cemented hemiarthroplasty group, in terms of better walking support mobility and hip joint mobility, and better pain scores.[26] Contrarily, Tang et al. observed that total HHS did not vary between hemiarthroplasty and PFN groups, the latter group had better scores in most of the sub-parameters, suggesting that PFN ultimately allowed more social functionality.[27] The PFN surgery demands strong pre-operative traction and reduction, and quality of reduction directly impacts post-operative recovery. In contrast, bipolar cemented hemiarthroplasty relies on secure prosthesis fixation, which involves dividing the hip muscles and resulting in weakening the lateral hip muscles and reducing hip joint stability post-operatively.[28]

Limitations

The study's prospective design and use of HHS as a standardized measure allowed for a clear assessment of functional recovery over time, facilitating meaningful comparisons between the two groups. The significant improvements in HHS scores at follow-ups highlighted the effectiveness of both surgical methods in enhancing mobility and quality of life.

However, there were few limitations. The relatively small sample size may limit the generalizability of the findings. A larger cohort could yield more robust data and reveal further insights into functional outcomes. The patients were not randomized, and the assignment of surgical procedure was based on the surgeon preference. Additionally, variations in patient comorbidities, or fracture types were not accounted for, potentially affecting recovery and HHS. The absence of follow-up beyond 24 weeks limits the evaluation of the long-term durability of improvements. Uncontrolled factors like differences in rehabilitation or postoperative care may also have influenced outcomes.

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CONCLUSIONS

To conclude, internal fixation with both PFN and cemented bipolar prosthesis results in significantly improved functional outcomes. However, the improvement in functional outcomes was significantly better with cemented bipolar prosthesis than PFN at 6-, 12-, and 24-weeks. Thus, cemented bipolar prosthesis offers a stable, and early mobile joint with an improved early recovery.

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