Total Hip Arthroplasty versus Bipolar Hemiarthroplasty for Treatment of Intracapsular Displaced Fracture Neck Femur in Elderly Active Patients; single-center randomized controlled trial.

NCT Number: Not yet registered

Study Date: January 2024-January 2026

Introduction

Femoral neck fracture (FNF) is a worldwide health problem that can cause significant morbidity and mortality. Most femoral neck fractures are associated with a fall, and the risk factors include osteoporosis, chronic medication use, and reduced level of activity (LeBlanc et al., 2014).

Femoral neck fractures are among the most common injuries in the elderly, and their number continues to increase with a more aged population(Baidwan & Naranje, 2017).

In the elderly, femoral neck fractures may lead to significant mortality and morbidity, with impaired mobility and loss of independence. Given their high incidence and associated detrimental effects on patient lives (Chow et al., 2018; Pillai et al., 2011).

The femoral neck fracture is a major type of hip fracture, whose treatment includes internal fixation, hemiarthroplasty (HA), or total hip arthroplasty (THA). The decision depends on multiple variables, including fracture pattern, surgeon comfort, and the patient's age, health, and ambulatory status. Internal fixation is a preferred management option for young people or the elderly who are intolerant of prosthesis surgery. THA and HA are widely used in displaced femoral neck fractures in the elderly (Bhandari & Swiontkowski, 2017). Surgery in these patients is undertaken to facilitate nursing and provide timely pain relief, rapid mobilization, and accelerated rehabilitation (Lowe et al., 2010).

In general, HA has the advantages of shorter operation time, less blood loss, less technical demand, less economic burden, and a lower dislocation rate. However, some patients treated with HA require conversion to THA due to complications such as acetabular erosion (Bhandari et al., 2019).

THA, on the other hand, has been associated with superior patient satisfaction and better hip function, less acetabular erosion, and a lower revision rate. However, increased surgical complexity, operation time, and blood loss, as well as higher dislocation rates in THA for FNFs, remain a concern (Liodakis et al., 2016).

With the increase in longevity and activity level, today's elderly have a higher demand for adequate hip function and a higher risk of acetabular erosion after hemiarthroplasty than before, which seems to favor the THA procedure. However, in choosing surgical treatment of displaced femoral neck fractures, orthopedic surgeons should keep in mind patient age, life expectancy, preexisting disease, quality-of-life demands, anticipated functional demands, psychological-mental status, as well as bone and joint quality (Sköldenberg et al., 2015). However, for active, mentally alert, and relatively healthy elderly patients with displaced intracapsular femoral neck fractures, the decision regarding whether to select bipolar HA or THA is controversial(Kyle, 2009) . This study aimed to compare the functional hip outcomes of Bipolar HA and THA for the treatment of intracapsular displaced femoral neck fractures in elderly active patients. We also aimed to assess the complications of both procedures and their associated risk factors.

Methodology

Study Design and Setting

This prospective Randomized comparative study will conducted at the Orthopedic Surgery Department, Al-Zahraa University Hospital, Faculty of Medicine for Girls – Al-Azhar University, between January 2024 and January 2026.

Ethical Considerations

The study protocol was reviewed and approved by the Institutional Review Board (IRB) of the Faculty of Medicine for Girls – Al-Azhar University (Approval No: **2221/2/1/2024**)

Written informed consent will be obtained from all patients or their legally authorized representatives prior to participation. Confidentiality and patient anonymity were strictly maintained according to the principles of the Declaration of Helsinki (2013 revision).

Patients will be divided into two equal groups: Group A, managed by Cemented Total Hip Arthroplasty (THA), and Group B, managed by Cemented Bipolar Hemiarthroplasty (BHA).

Sample Size and Randomization

The sample size was determined based on previous studies comparing total hip and bipolar hemiarthroplasty outcomes, using GPower version 3.1*, assuming an effect size of 0.8, $\alpha = 0.05$, and power $(1-\beta) = 0.80$. The number of patients required was 20 per group

Patients will be randomly allocated to either group using a computer-generated randomization list to minimize selection bias.

Eligibility Criteria

Patients will be included if they are aged ≥ 65 years with a displaced intracapsular fracture of the femoral neck (Garden type III, IV). On the other hand, patients with an extracapsular fracture of the femoral neck, with pathological fractures, open fractures, or active infection at or near the hip joints will be excluded. Additional exclusion criteria will be bedridden, immobile, or cognitively impaired patients or patients with associated pelvic or acetabular fractures.

Preoperative Assessment

All patients will undergo a comprehensive preoperative evaluation via clinical, radiological, and laboratory evaluation. The radiological evaluation was performed using a pelvic X-ray (AP view) and a fractured hip and femur X-ray for fracture classification and preoperative planning. All patients received a preoperative prophylactic dose of intravenous antibiotics for 30 minutes before skin incision. Finally, Preoperative planning included assessment of bone quality, estimation of prosthesis size, and ensuring the availability of appropriate implants and instruments.

Surgical Technique

Anesthesia and Position

All procedures will be performed under spinal anesthesia. The patient will be placed in the lateral decubitus position on the unaffected side, with proper padding of pressure points and pelvic stabilization using posterior and anterior supports

Approach: A direct lateral hip approach (Modified Hardinge) will be utilized for all patients.

Operative Steps

- Skin Incision: A longitudinal incision 10-15 cm will be made centered over the greater trochanter, extending proximally toward the iliac crest and distally along the femoral shaft
- Fascial Exposure: The iliotibial band will be incised to expose the underlying musculature
- Bursa Removal: The trochanteric bursa will be excised to improve visualization and minimize postoperative irritation and bursitis.

- Muscular Dissection: The anterior one-third of the gluteus medius will be incised and reflected anteriorly, exposing the gluteus minimus, which will be elevated to expose the hip capsule.
- Capsulectomy: A T-shaped capsulectomy will be performed to fully expose the femoral head and neck.
- Excision of the Femoral Head: The femoral head will be excised using a corkscrew extractor

Acetabular Preparation (for THA group):

- The acetabulum will be exposed using Hohmann retractors for full visualization.
- Sequential reaming of the acetabulum will be performed until healthy cancellous bone is reached.
- A trial acetabular cup will be inserted to verify fit and orientation (approximately 40–45° abduction and 15–20° anteversion)
- The final acetabular component will then be implanted (cemented cup).

Femoral Preparation:

- The femoral canal will be opened using a box chisel, and the medulla will be opened by reamer, then sequentially reamed and broached to the appropriate size.
- A trial femoral stem and head will be inserted to assess stability, leg length, and range of motion.
- The final femoral component will be implanted (cemented stem).

- “In the Bipolar Hemiarthroplasty group, after femoral head excision, the acetabulum will be inspected but not reamed. A bipolar prosthesis will be inserted after standard femoral canal preparation.”

Reduction and Stability Check: The hip joint will be reduced, and stability, limb length, and offset will be assessed through a full range of motion.

Irrigation and Hemostasis: The wound will be thoroughly irrigated with normal saline, and meticulous hemostasis will be achieved.

Closure:

The gluteus minimus and medius will be sutured, a suction drain will be placed and removed after 48 hours, the iliotibial band and fascia lata will be closed, and Subcutaneous tissue and skin will be sutured in layers.

Postoperative Management

- Antibiotic prophylaxis will continue for 5 days postoperatively.
- DVT prophylaxis: Low molecular weight heparin will be administered for 7 days, followed by oral anticoagulants for 30 days.
- Early mobilization: Patients will be encouraged to sit on the first postoperative day and begin static quadriceps and ankle exercises on the second day.
- Weight bearing: Allowed as tolerated with a walker.
- Suture removal: Performed at 14 days postoperatively.
- Follow-up schedule: Patients will be reviewed at 2 weeks, 1 month, 3 months, 6 months, and 12 months postoperatively.

Outcome Measures

The primary outcome will be patients' functional improvement assessed via the Modified Harris Hip Score (mHHS). The score was first introduced via Harris et al. 1969 (Harris, 1969), and then modified via Nilsdotter et al. 2010 (Nilsdotter et al., 2003), Chahal et al. 2012 (Chahal et al., 2015) to address both functional activity and pain. The score is calculated based on four parameters: Pain (0-44 points), function (0-47 points), absence of deformity (0-4 points), and range of motion (0-5 points). Patients receive an excellent score if their cumulative score is 90-100, while they receive good, fair, and poor scores if their cumulative score is 80-89, 70-79, and <70, respectively.

Secondary outcomes will be pain assessment via the Visual Analogue Scale (VAS) (Shafshak & Elnemr, 2021) and patient satisfaction using a subjective numeric scale ranging from 0 to 10. The scale assesses the satisfaction according to patients' relief of pain, ability to walk independently, return to pre-fracture level, and cosmetic and psychological appearance. These outcomes were assessed at 3, 6, and 12 months postoperatively.

Postoperative Complications

All postoperative complications will be documented and classified as early (<3 months) or late (>3 months) complications. The complications recorded included: Dislocation, Superficial or deep infection, Periprosthetic fracture (confirmed radiologically and classified according to the Vancouver classification), DVT, and Aseptic loosening (defined radiographically by progressive radiolucent lines >2 mm around the prosthesis interface or component migration during follow-up)

Radiological Outcome

Radiographic assessment will be performed at immediate postoperative, 3 months, 6 months, and 12 months using a standard anteroposterior pelvic hip view. The following parameters were evaluated:

- Component position and alignment (cup inclination, stem alignment) for the THA group.
- Signs of prosthetic loosening (radiolucent lines or migration).
- Heterotopic ossification, graded according to Brooker's classification.
- Leg length discrepancy, measured in pelvis A.P view from the interteardrop line to the lesser trochanter.

Statistical Analysis

Data will be analyzed using IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables will be expressed as mean ± standard deviation (SD) or median (IQR), and categorical variables as frequencies and percentages. The Shapiro–Wilk test will be used to assess data normality. Between-group comparisons (THA vs. BHA) were performed using the independent-samples t-test or Mann–Whitney U test for continuous data and the Chi-square or Fisher's exact test for categorical data. Changes in mHHS and VAS over time (3, 6, and 12 months) will be analyzed using repeated-measures ANOVA or the Friedman test, as appropriate. A p-value < 0.05 will be considered statistically significant. Pearson Correlation will be performed between the continuous variables, while multiple linear regression will be performed to assess the association of mHHS score and patients' risk factors.

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