



Protocol of a Thesis for partial fulfillment of M.D. degree of Orthopedic Surgery

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Title of the protocol: Functional outcome after Dual mobility cups total hip replacement versus Bipolar hemiarthroplasty in fracture neck of femur in active elderly patients.

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What is already known about this subject?

What does this study add?

The decision to perform arthroplasty in patients with a femoral neck fracture is currently not well standardized. The choice between performing total hip arthroplasty or hemiarthroplasty is not straightforward in older patients with femoral neck fracture, particularly when co-morbidities are factored in.⁽¹⁾ This led us to carry out this comparative study between Dual mobility cups total hip replacement and bipolar hemiarthroplasty to reveal the functional and mechanical outcome of each.

1.Introduction/Review

Femoral neck fractures in the elderly are frequent, represent a great health care problem, and have a significant impact on health insurance costs.⁽²⁾ A typical patient with fracture neck of femur is characterized by old age, severe osteoporosis and significant co-morbid diseases. Fracture neck of femur has always been a great challenge to the orthopedic surgeon.⁽³⁾

The primary aim of treatment should be to perform a surgery that provides the patient with the greatest opportunity for early ambulation. This requirement is fulfilled to a great extent by the use of a primary prosthetic replacement.

Reconstruction options using hip arthroplasty include bipolar hemiarthroplasty (HA), and total hip arthroplasty (THA) & Dual mobility cups total hip replacement (DMTHA).⁽⁴⁾

Bipolar hemiarthroplasty (HA) has long been the preferred treatment, and is performed in 75% of cases. It is justified by the reasonable operating time, low blood loss and acceptable functional outcomes. In the 2000s, total hip arthroplasty (THA) emerged as a relevant alternative to HA. Since then, there is an on-going debate on the best implant to use. Age, co-morbidities, patient independence and potential surgical complications must be taken into account when deciding between implants.⁽⁵⁾ The risk of dislocation is a key deciding factor because of its well-described consequences. Up to the early 2010s, the THA procedures described in the studies used a fixed cup. In some cases, this

resulted in the dislocation rate being higher than with HA. The emergence of dual mobility (DM) cups has reduced the dislocation rate.⁽⁶⁾ However, the relative role of DMTHA and HA is not well defined in the context of co-morbidities and functional outcome.⁽⁷⁾

2.Aim/Objectives

The aim of the work is to compare the results of the functional outcome, mechanical outcome and the possible complications of bipolar hemiarthroplasty versus dual mobility cups total hip replacement in fracture neck of femur in active elderly patients.

3.Methodology

- **Type of the study:** randomized control clinical trial
- **Study setting:** Ain Shams University hospitals
- **Study period:** 24 months
- **Study population:** active elderly patients with fracture neck of femur
 - Inclusion criteria:**
 - Sex: both sexes
 - Age: 60-80 years old
 - Lesion: displaced fracture neck of femur
 - Exclusion criteria:**
 - Acetabular grade 3 arthritis
 - Acetabular dysplasia
 - Previous hip surgeries
- **Sampling method:** convenient sample
- **Sample size:** 30 patients will be randomly divided by a computer generated sequence in to 2 groups:
 - Group A: will undergo bipolar hemiarthroplasty
 - Group B: will undergo dual mobility cups total hip replacement.

- **Ethical considerations:** will be followed by obtaining the hospital research/ethics committee approval and written informed consents from the patients.
- **Study tools:**
 - **Preoperative diagnosis and evaluation:**
 - **Clinical Evaluation:**
 - **History:** Katz index of independence in activity of daily living (ADL) will be used to estimate the independence of patients immediately before their fracture occurred.
 - **General examination**
 - **Local examination**
 - **Radiological Evaluation:**
 - Plain X-ray Pelvis showing both hips (antero-posterior)
 - Plain X-ray of the fractured hip showing the femur (antero-posterior & lateral).
 - **Laboratory investigations:** CBC & routine preoperative lab investigations
 - **Operative technique:**

All the patients will be operated through the standard posterior approach, intra-osseous repair of the capsule and the lateral rotators will be done in all cases.

Blood loss, the need for blood transfusion and the operative time will be recorded.
 - **Post-operative management:**
 - Proper antibiotic and analgesics will be given post-operative.
 - Prophylaxis against DVT
 - Post-operative x-rays will be done, plain X-ray pelvis showing both hips (antero-posterior view) & plain X-ray of the operated hip showing femur (antero-posterior view).
 - **Follow up strategy:**

Patients will be reviewed after 2 weeks to check their wounds and for sutures removal, then the follow up will be every month in the first 6 months then every 3 months till the end of the study (2 years). The follow up will include:

➤ **Clinical and functional assessment:**

- Harris hip score to assess the function.
- Visual analogue scale (VAS) to assess pain.
- Emotional acceptance.
- Walking ability and the use of walking aids.
- Gait.

➤ **Radiological assessment:**

Plain X-ray as described before at every follow up visit.

- **Statistical Analysis:** Statistical package for social science (SPSS 15.0.1 for windows; SPSS Inc., Chicago, IL, 2001). Data will be presented as Mean and Standard deviation (+/-SD) for quantitative parametric data, and Median and Interquartile range for quantitative non parametric data. Frequency and percentage will be used for presenting qualitative data. Suitable analysis will be done according to the type of data obtained. $P < 0.05$ will be considered significant.
- **Statistical package:** data entry and statistical analysis of the collected data will be performed using a reliable software program.

4. References

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