



International Journal of Orthopaedics Sciences

ISSN: 2395-1958
IJOS 2018; 4(2): 501-504
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www.orthopaper.com
Received: 17-02-2018
Accepted: 18-03-2018

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Prospective randomised control study of bipolar versus unipolar prosthesis in the management of fracture neck of femur in elderly patients

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DOI: <https://doi.org/10.22271/ortho.2018.v4.i2h.77>

Abstract

Introduction: In elderly patients suffering from a displaced femoral neck fracture, a cemented hip arthroplasty (HA) has been shown to reduce the reoperation rate and give better hip function. When using an HA two types of prosthesis exists- unipolar or bipolar. It is hypothesized that bipolar prostheses lead to better long-term functional outcomes with less complications. Aim of this study is to compare the results of unipolar (Austin Moore's Prosthesis) and bipolar hemiarthroplasty done at our institution.

Materials & Methods: This is a randomized control trial including 100 patients with fracture neck of femur, equally divided into 2 groups of 50 each. Patients in Group-A were treated using unipolar Austin Moore's Prosthesis (AMP) and in Group-B were treated using Bipolar prosthesis. Patients were assessed clinically based on Harris hip score, and radiologically for acetabular erosion according to the method described by Baker.

Results: 66% of patients with bipolar prosthesis reported minimal or no pain at follow-up compared to 65% of patients with Moore's prosthesis. Hip function according to the HHS was similar at both follow-ups. Acetabular erosion was observed in 2 patients belonging to the Moore's group but not in the bipolar group. Other complications were similar in both groups.

Discussion: Hemiarthroplasty, as an effective technique for displaced femoral neck fractures. Controversy has persisted for a long time regarding the use of bipolar versus unipolar prosthesis. The results of our study did not demonstrate any differences between the two groups. However, at a mean follow up of one year signs of acetabular erosion were more frequent after the unipolar HA, but this difference was not statistically significant.

Conclusion: This study suggests that Bipolar HA is associated with similar improvement in hip functionality, hip pain, and quality of life compared with Unipolar HA and that there are no significant differences between Bipolar HA and Unipolar HA at 1year follow up.

Keywords: Unipolar, bipolar, prosthesis, femur, elderly

Introduction

Fracture neck of the femur is a common injury presenting to the orthopaedic department. With increasing life expectancy worldwide, the number of elderly individuals is increasing, and it is estimated that the incidence of hip fracture will rise from 1.66 million in 1990 to 6.26 million by 2050^[1]. The surgical treatment of patients with a femoral neck fracture should be based on the patient's age, walking ability, comorbidities and life expectancy^[2]. Internal fixation (IF) or different types of hip arthroplasties are the available treatment modalities. In patients with undisplaced fractures (Garden I-II)^[3], IF is uncontroversial with an acceptable rate of fracture healing complications and a good outcome regarding function and the health-related quality of life^[4]. Internal fixation is also considered to be the treatment of choice in young patients with displaced fractures (Garden III-IV)^[5]. In elderly patients suffering from a displaced femoral neck fracture, a cemented hip arthroplasty, compared to IF, has been shown to reduce the reoperation rate and give better hip function^[6-8].

Hip hemiarthroplasties (HA) are commonly performed for displaced femoral neck fractures. The advantages of hemiarthroplasty over internal fixation include earlier mobility, less reoperations and better functional outcome at 1 year^[9, 10].

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When using an HA there are two types of articulations of the prosthesis and the patient's acetabulum—unipolar or bipolar. Where the unipolar head has a single articulation between the prosthesis and the acetabulum, the bipolar head offers a second articulation between an inner smaller head and the polyethylene liner of the larger outer head. In theory this reduces stress on the acetabular surface and thereby acetabular erosion. Acetabular erosion is believed to cause pain and impaired hip function. Other proposed benefits are less risk for dislocation and better range of motion [11]. It is thus hypothesized that bipolar prostheses lead to better long-term functional outcomes with less complications. However, evidence from the literature so far has not been supportive of this theory [12-16]. All studies so far have found that bipolar implants have a significantly higher cost compared to unipolar implants [13-17]. In our price-sensitive population, we wonder whether the higher costs associated with the use of bipolar implants are justified.

Although several randomized controlled trials (RCTs) on this topic have been published, these studies showed inconclusive and controversial results [11, 12, 18-20]. The purpose of this study is to compare the results of unipolar (Austin Moore's Prosthesis) and bipolar hemiarthroplasty done at our institution.

Materials and Methods

This is a randomized control trial conducted between June 2016 to June 2017 at the Govt McGann hospital, SIMS, Shivamogga. After obtaining ethical clearance from the institutional ethical committee, 100 cases with post traumatic fracture neck of femur in elderly patients above the age of 65 years who were posted for an elective hemiarthroplasty were included for the study. Inclusion criteria were age more than or equal to 65 years; displaced femoral neck fracture of non-pathologic origin; normal cognitive function; ambulatory with or without assistive devices prior to the fracture; and treated with a primary prosthetic replacement. Patients with a pre-existing hip abnormality requiring total hip replacement or a pathological fracture secondary to malignant disease were excluded. An informed consent was obtained from all the participants of the study.

Patient characteristics examined included age, gender, prefracture ambulatory status, and number of associated comorbidities. Prefracture ambulatory status was classified into the following categories: independent community ambulatory; community ambulant with assistive devices; and home ambulant. The patients were divided into two demographically identical groups of 50 patients each. The patients were randomly divided into the 2 groups based on the computer generated random numbers. The patients in Group-A were surgically treated with unipolar Austin Moore's Prosthesis (AMP) and the patients in Group-B were surgically treated with a Bipolar prosthesis.

All patients were operated through a southern approach, and received antibiotics and venous thromboembolism prophylaxis. Postoperatively, full weight bearing was allowed with the help of physiotherapists as per their compliance. The patients were assessed preoperatively and post operatively based on Harris hip score at intervals of six weeks, three months, six months and one year. Sequential radiographs were compared to assess diminishing joint space, acetabular erosion, proximal migration and protrusion of the acetabulum. Loosening, subsidence and angular shift of the femoral stem were also assessed on these radiographs. The HHS contains four parameters: pain, function, absence of deformity and

range of motion. Higher score means better hip function and the maximum score is 100. Acetabular erosion was evaluated and graded according to the method described by Baker [21]. The system is a four-step grading system: grade 0 (no erosion), grade 1 (narrowing of the joint space), grade 2 (acetabular bone erosion) and grade 3 (protrusion acetabuli). The final scores were compared between the two groups at the end of 1 year. The mean follow up was 9 months with the minimum follow up duration being 6 months and the maximum being 1 year. No external funding was taken for the present study and there is no conflict of interest with respect to this study.

Results

The study included 100 elderly patients of displaced fracture neck of femur divided into two groups. Both the groups were equal, identical and demographically matched. The overall mean age was 76.8 (range 66–85) years with 56% of the patients being female and 44% males. 86% of the patients were either independent community ambulatory or community ambulant and the rest 14% of the patients were home ambulant or used assistive devices for ambulation prior to the fracture neck of the femur. There were no differences in the duration of surgery, intraoperative blood loss or need for blood transfusions between the two groups.

Sixty-six percent of patients who had a bipolar prosthesis reported minimal or no pain at follow-up compared to 65% of patients who had a Moore's prosthesis. This is however not statistically significant. Hip function according to the HHS was similar at both follow-ups (Table-1).

Table 1: Harris Hip Score

Harris Hip Score	Unipolar Group	Bipolar Group
Excellent (90-100)	44%	45%
Good (80-89)	48%	47%
Fair (70-79)	6%	5%
Poor (>70)	2%	3%

To determine whether the results were influenced by age, gender and prefracture ambulatory status, we had matched the two groups for these potential confounding factors. After adjustment for these factors, there were still no significant differences between the 2 groups for pain, satisfaction, Harris hip score.

Acetabular erosion was observed in 2 patients belonging to the Moore's group but not in the bipolar group. Of these 2 patients, neither of them underwent revision arthroplasty as they showed no significant clinical symptoms and hence deferred surgery. The Moore's group showed a mean cranialisation of 2.0 mm (range, 0 to 3.5) and mean medialisation of 1.6 mm (range, 0 to 3) of the prosthesis head compared to a mean cranialisation of 1.2 mm (range, 0 to 2) and a mean medialisation of 1.2 mm (range, 0 to 2) for the bipolar group. No cases of femoral stem loosening were noted in both groups. There were no significant differences with respect to acetabular erosion, component migration and revision rates between the 2 groups. Postoperative complications and length of stay were identical as well.

In the unipolar HA group there were four hip complications: one prosthetic dislocations, one periprosthetic fracture, one contra-lateral hip fracture (after 9 months) and one deep infection. In the bipolar HA group there were five hip complications: two prosthetic dislocations, one deep infection, one contra-lateral hip fracture (after 9 months) and one periprosthetic fracture. All hip complications necessitated

reoperations. Deeper infections were treated with thorough debridement and excision arthroplasty. All patients showed subsidence of infection and did not warrant another surgical procedure for prosthesis implantation as they were pain free and managed to walk with a limp. Both the peri-prosthetic fractures were Vancouver type-C and hence were treated with retaining the prosthesis and LCP fixation. Contra-lateral hip fractures were surgically treated accordingly. The cases of hip dislocations were treated in the operation theater by closed reduction following which the patients were put on abduction brace for 8 wks. The differences in complication and reoperation rate between the groups were not significant ($p=0.30$). The number of general complications apart from mortality did not differ between groups. The overall 9 month mortality rate was 8% (4/50) in the unipolar group and 6% (3/50) in the bipolar group ($p=0.14$).

Discussion

Hemiarthroplasty, as an effective technique for displaced femoral neck fractures, could help early ambulation and satisfied function recovery and is increasingly performed by the surgeons [5, 22, 23]. However, controversy has persisted for a long time regarding the use of bipolar versus unipolar prosthesis. This study suggests that Bipolar HA is associated with similar improvement in hip functionality, hip pain, and quality of life compared with Unipolar HA and that there are no significant differences between Bioplar HA and Unipolar HA with regard to operation time, blood loss, blood transfusion, hospital stay, mortality, reoperation, dislocation, and complications.

The results of our study did not demonstrate any differences regarding complications, hip function as per the Harris hip score in elderly patients with a displaced fracture of the femoral neck randomised to either a unipolar HA or a bipolar HA. However, at a mean follow up of 9 months signs of acetabular erosion were more frequent after the unipolar HA than the bipolar HA. But this difference was not statistically significant at a mean follow up of 9 months.

Cornell *et al.* [24] reported no differences in functional outcome in a small study including 48 patients with a six-month follow-up. Calder *et al.* [12] in his study including 250 patients, all aged 80 years or more, with a 1.5–2-year follow-up found a higher proportion of patients returning to their preinjury condition was found in the unipolar HA group, but no other differences were found. Davison *et al.* [18] in their study of 187 elderly patients with a minimum two-year follow-up also found no differences between the two randomisation groups. Raia *et al.* [25] also reported no significant differences between the groups in terms of surgical complications, functional outcome according to the SF-36 in his study of 115 patients at one-year assessment. Another systematic review on this topic published in 2010 demonstrated that there was no significant difference in clinical outcomes between Bipolar HA and Unipolar HA [26].

Compared with unipolar prosthesis, bipolar prosthesis with an additional inner articulation has the theoretical advantages of less acetabular erosion and less dislocation [27, 28]. This study demonstrates that the incidence of acetabular erosion in bipolar HA is less than that in the unipolar HA group at the follow-ups. These findings are consistent with other previous studies [29, 30]. However, statistical difference was only noted at 1 year follow-up and the acetabular erosion rate increased at the later follow-ups with no significance observed. This may be because the bipolar articulation loses mobility with time and functions as a unipolar prosthesis [11, 31]. In addition,

it should be recognized that this result should be interpreted with caution until confirmed by future studies, because the number of the pooled studies is small and the studies are of small sample size.

However our study failed to show a statistical significance with respect to acetabular erosion in both the groups. Regarding to dislocation, it is not proved to be less comparing bipolar HA with unipolar HA in this study. Other studies have also failed to find this benefit [23, 32]. However, the closed reduction of bipolar head is more difficult than the unipolar prosthesis, and bipolar HA typically requires open reduction [33, 34]. Moreover, BH could not increase the risk of operation in terms of surgical and postoperative results, including operation time, blood loss, blood transfusion, hospital stay, mortality, reoperation, dislocation, and complications. It may be demonstrated that BH is an alternative treatment as safe as UH.

The main limitation of our study was the duration of follow up. As the maximum follow up was one year, the long term results comparing the 2 groups cannot be inferred by the results of this study. Also, as this was not a blinded study, there is a possibility of the observer bias in this study. Thirdly, the cost comparison between the two prosthesis was not considered in the study and hence the cost-benefit ratio could not be assessed.

Conclusion

The results of our study show that the unipolar and bipolar HA have similar short term postoperative results, including operation time, blood loss, blood transfusion, hospital stay, mortality, reoperation, dislocation, and complications. Bipolar HA may achieve better results with respect to acetabular erosion when compared with Unipolar HA but the difference was statistically insignificant in our study. In view of the increasing life expectancy of the local population, further studies are required to determine long-term outcomes.

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