

Randomized Trial of Hemiarthroplasty versus Internal Fixation for Femoral Neck Fractures: No Differences at 6 Years

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Abstract

Background Hemiarthroplasty has been shown superior to internal fixation for displaced femoral neck fractures (FNF) in the first 2 years. However, there are unanswered questions about the performance of hemiarthroplasty over the longer term compared with internal fixation.

Questions/purposes We sought to compare hemiarthroplasty with internal fixation in terms of (1) outcomes scores for pain, hip function, and quality of life at a minimum of 5 years after surgery in a randomized trial. A secondary

purpose was to compare (2) patient survival and (3) frequency of reoperation in the two groups.

Methods A total of 222 consecutive patients older than 60 years, including those cognitively impaired, with FNF were randomized to either internal fixation with two parallel screws or bipolar hemiarthroplasty. At a minimum followup of 4.9 years (mean, 5.9 years; range, 4.9–7.2 years), 68 of the 70 surviving patients were examined by a study nurse and study physiotherapist blinded to initial treatment. Questionnaires on hip function (Harris hip score), quality of life (Eq5D), and activity of daily living function (Barthel ADL) were administered. The Barthel ADL index score was split into good function (score 95 or 100) and reduced function (score below 95).

Results The mean survival of the groups was similar with 66.4% (73 of 110) of the patients undergoing hemiarthroplasty and 70.5% (79 of 112) of the patients undergoing internal fixation having died since surgery ($p = 0.51$). Only 12 of 31 living patients in the internal fixation group had retained their native hips at a mean of 6 years. Between 2 and 6 years, there were two new major reoperations (both in the internal fixation group, for avascular necrosis and deep wound infection). The mean Harris hip score was 66 (SD 19) and 67 (SD 20) in the internal fixation and hemiarthroplasty groups, respectively ($p = 0.96$). The mean Eq5D index was 0.50 (SD 0.40) in the

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Data collection was performed at Oslo University Hospital, Ullevål, Norway.

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internal fixation group and 0.34 (SD 0.36) in the hemiarthroplasty group ($p = 0.10$). Function in terms of ADLs was comparable between the groups; of the patients in the internal fixation group, 42% reported good function on the Barthel ADL index, and the corresponding number in the hemiarthroplasty group was 51% ($p = 0.44$).

Conclusions Hemiarthroplasty has predictable and good long-term results after FNF and is the treatment of choice compared with internal fixation. Further studies will evaluate if total hip arthroplasty has advantages over hemiarthroplasty in patients with fracture with long life expectancy.

Level of Evidence Level II, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

Introduction

Among orthopaedic injuries, none accounts for more morbidity, mortality, and healthcare costs than hip fracture [3, 25, 35]. Cooper et al. [6] have estimated that as a result of an increasing proportion of elderly people in the world, the number of hip fractures will approximate four million in 2025. A hip fracture changes the patient's life; 20% to 25% of patients die after 1 year [10], 40% are still unable to walk independently, 60% have difficulty with at least one essential activity of daily living, and 80% are restricted in other activities such as grocery shopping or driving [5]. Hip fractures are classified as either intracapsular femoral neck fractures or extracapsular fractures, which are either trochanteric or subtrochanteric fractures. Femoral neck fractures constitute approximately half of all hip fractures [36].

Treatment of displaced intracapsular femoral neck fractures has been controversial since the early 20th century [12, 18], although increasing evidence has been presented supporting arthroplasty as superior to internal fixation in these fractures [17, 27]. Data from followup longer than 1 or 2 years are sparse, however. Studies with bipolar hemiarthroplasty indicate that acetabular wear is less of a problem than previously thought [8, 31]. Several reports show, however, high rates of pain, migration, and the need for revision to THA in middle- and long-term followup [24, 38].

We sought to compare hemiarthroplasty with internal fixation in terms of (1) outcome scores for pain, hip function, and quality of life at a minimum of 5 years after surgery in a randomized trial. A secondary purpose was to compare (2) patient survival and (3) frequency of reoperation between the two groups.

Patients and Methods

A total of 222 consecutive patients from September 2002 to March 2004 were included in the study (Fig. 1). Results up

to 2 years have been published previously [10]. The resident on call included patients when they presented in the emergency department at Ullevål University Hospital (now Oslo University Hospital), Oslo, Norway, with a displaced intracapsular femoral neck fracture judged by angular displacement in either radiographic plane. The patients were not eligible for inclusion if they were not ambulant before the fracture, were unfit for arthroplasty according to the anesthesiologist, had previous symptomatic hip pathology, had a pathological fracture, if there was delay of more than 96 hours from injury to treatment, or if they lived outside the hospital's area.

The randomization was performed by placing 115 notes with the word "hemi" and 115 notes with the word "screws" in opaque envelopes, which were sealed and mixed before numbering. After inclusion, the resident on call opened the envelope with the lowest number in the emergency department. At the end of inclusion, there were eight remaining envelopes that were collected. All envelopes for randomization were accounted for at the end of the study.

During the inclusion period, 445 consecutive patients with femoral neck fracture presented to the department. Of them, 185 did not meet the inclusion criteria and 38 were not included, mainly because of refusal of consent ($n = 31$). The 222 included patients were randomized to internal fixation ($n = 112$) or hemiarthroplasty ($n = 110$). In the internal fixation group, 102 were treated according to the protocol, nine with hemiarthroplasty because of irreducible fracture ($n = 8$) or poor screw purchase ($n = 1$), and one died before surgery. In the hemiarthroplasty group, 105 patients were treated according to the protocol, three were operated on with internal fixation, one with a sliding hip plate because of a new ipsilateral fracture before surgery, and one patient died before surgery.

Of the 222 patients included in the study, 70 patients were alive and 68 patients continued participation in the study after a minimum of 5 years, of whom 37 were in the hemiarthroplasty group and 31 were in the internal fixation group (Fig. 1). The 68 patients (52 females, 16 males) were examined after 5 to 7 years (mean, 71 months; range, 59–86 months). The patients who did not come to the outpatient clinic were visited at their place of residence ($n = 26$ [39%]) or contacted by phone ($n = 1$). More than half of the patients lived independently ($n = 38$ [56%]) (Table 1).

Intervention

Surgery was performed by the doctors on call. For hemiarthroplasty, a cemented Charnley-Hastings bipolar hemiprostheses (DePuy/Johnson and Johnson, Leeds, UK)

Fig. 1 Flowchart is shown of included patients in the study, their survival, and randomization group. IF = internal fixation; HA = hemiarthroplasty.

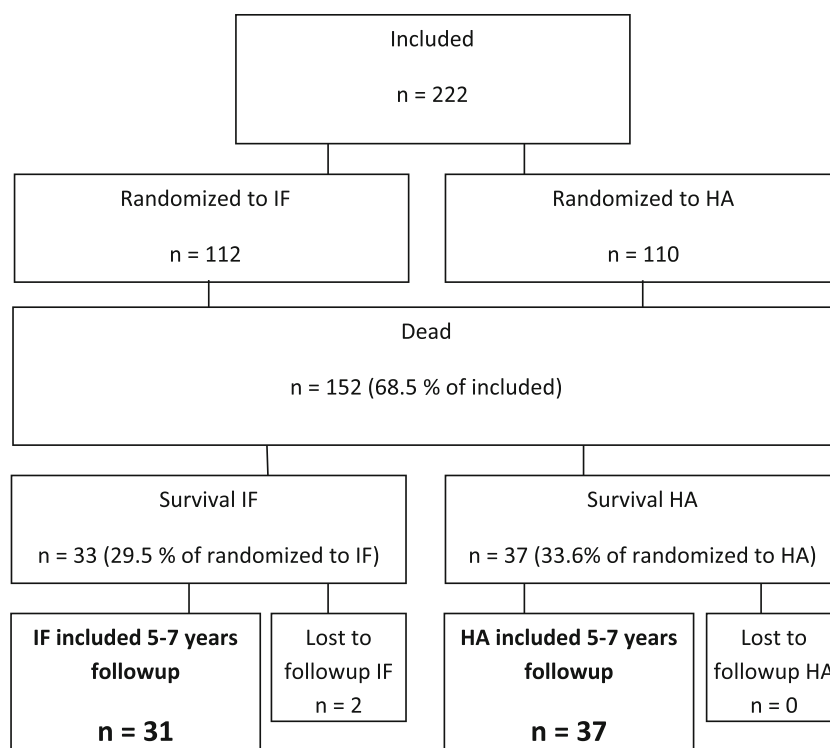


Table 1. Characteristics of all included patients and patients followed at 5 to 7 years (all data for both groups at baseline)

Factor for analysis	All included patients (n = 222) Median (95% CI for median)	Included at 5 to 7 years (n = 68) Median (95% CI for median)	p value
Age at inclusion (years), females	83.9 (82.7–85.1)	81.6 (78.2–84.2)	< 0.001
Age at inclusion (years), males	82.0 (80.1–83.9)	76.8 (66.6–82.7)	0.004
ASA females	2 (2–2)	2 (2–2)	0.25
ASA males	3	2	0.06
	Number	Number	
Females	165 (74%)	52 (76%)	0.62
Living at home at inclusion	163 (73%)	63 (92%)	< 0.001
Dementia	68 (31%)	6 (9%)	< 0.001
Walking without any aid	127 (58%)	48 (71%)	0.17

CI = confidence interval; ASA = American Society of Anesthesiologists.

was used through a direct lateral approach. Internal fixation was performed with two parallel cannulated screws (Olmed; DePuy/Johnson and Johnson, Uppsala, Sweden) after closed reduction. Both procedures were routine operations in the department before the study started. Spinal anesthesia was preferred in both groups. The hemiarthroplasty group was intravenously given 2 g cephalotin preoperatively with another three doses the first 24 hours after surgery. Both groups received 5000 IE low-molecular-weight heparin subcutaneously daily until they were well mobilized. Early mobilization with full weightbearing was encouraged regardless of treatment group.

Followup

Patients were seen in the outpatient clinic after 4, 12, and 24 months and at a mean of 6 years (range, 5–7 years). At inclusion, the surgeon filled in data on retrospective pre-fracture Harris hip score (HHS) as well as ability to walk independently, place of residence, and comorbidity, including dementia. At later visits, these data were also recorded.

At every scheduled visit, hip function, activities of daily living, and quality of life were assessed with questionnaires [11]. The patients were asked to fill in the Eq5D

questionnaire, a patient-reported measure of health-related quality of life [7, 37]. The Barthel Activities of Daily Living (ADL) questionnaire [23] was filled out by a study nurse blinded to the initial treatment. The Barthel ADL index score was split into good function (score 95 or 100) and reduced function (score below 95) for the analysis.

HHS [15] was examined by a study physiotherapist blinded to the initial treatment. The last part of the HHS (ROM) was not filled in as a result of difficulties with precise assessment. The maximum HHS was therefore 95 in this study. The patients were asked not to inform the nurse and physiotherapist about their treatment and kept their clothes on to obtain a blinded examination. A chart review was performed of all originally included patients before the last followup to record reoperations or other problems. Radiographs were obtained of all patients who visited the outpatient clinic. In addition, some of the patients had films obtained where they lived by a mobile xray unit. The films were analyzed by two of the authors (FF, RØS) together and consensus was reached on any new findings.

Statistics

All analyses were conducted with IBM® SPSS® Statistics Version 19 (SPSS Inc, Chicago, IL, USA). All comparisons

were made according to randomization group as defined by the intention-to-treat principle. The Mann-Whitney U test was used for comparison between groups and median and 95% confidence intervals for median were used unless otherwise stated. The t-test was used for comparison of mean values and Pearson chi-square was used for comparison of the dichotomous variable Barthel index score $\geq 95\%$ and mortality.

Ethics

The study was approved by the Regional Committee for Medical and Health Research Ethics Committee. All patients who were able signed an informed consent. Patients with permanent or temporary cognitive impairment were included after acceptance from their family.

Results

The registered data on hip function, ADL, or quality of life showed no difference between the randomization groups. Per-protocol analyses did not change this. The participants after 5 to 7 years were younger at inclusion than the initial patient group, more of them lived independently, less had diagnosed dementia, and more walked without any aid. The distribution between the sexes was, however, unchanged (Table 2).

Table 2. Hip function, activities of daily living, and quality of life in patients randomized to internal fixation compared with hemiarthroplasty

Followup	Internal fixation	Hemiarthroplasty	p value
Mean (SD) Harris hip score			
At 4 months	59 (19.5) (n = 89)	67 (15.8) (n = 84)	0.003*
At 12 months	65 (15.9) (n = 87)	72 (17.5) (n = 74)	0.01*
At 24 months	67 (15.5) (n = 71)	70 (19.1) (n = 68)	0.26
At 6 years	66 (18.9) (n = 30)	66 (19.9) (n = 37)	0.96
Mean (SD) Eq-5D index score and visual analog scale			
Index score			
At 4 months	0.53 (0.29) (n = 79)	0.61 (0.30) (n = 70)	0.06
At 12 months	0.56 (0.33) (n = 70)	0.65 (0.30) (n = 62)	0.07
At 24 months	0.61 (0.31) (n = 52)	0.72 (0.23) (n = 52)	0.03*
At 6 years	0.50 (0.40) (n = 31)	0.34 (0.36) (n = 37)	0.10
Visual analog scale			
At 4 months	53 (18.5) (n = 69)	62 (21.0) (n = 60)	0.01*
At 12 months	57 (21.6) (n = 59)	63 (24.3) (n = 54)	0.16
At 24 months	60 (18.0) (n = 45)	60 (21.0) (n = 43)	0.84
At 6 years	56 (24) (n = 23)	52 (22) (n = 22)	0.61
Number (%) of patients with Barthel index score of 95 or 100			
At 4 months	41 (47 %) (n = 88)	40 (50 %) (n = 80)	0.66
At 12 months	31 (36 %) (n = 87)	39 (53 %) (n = 73)	0.02*
At 24 months	24 (35 %) (n = 69)	36 (53 %) (n = 68)	0.02*
At 6 years	13 (42 %) (n = 31)	19 (51 %) (n = 37)	0.44

* Statistically significant differences ($p \leq 0.05$).

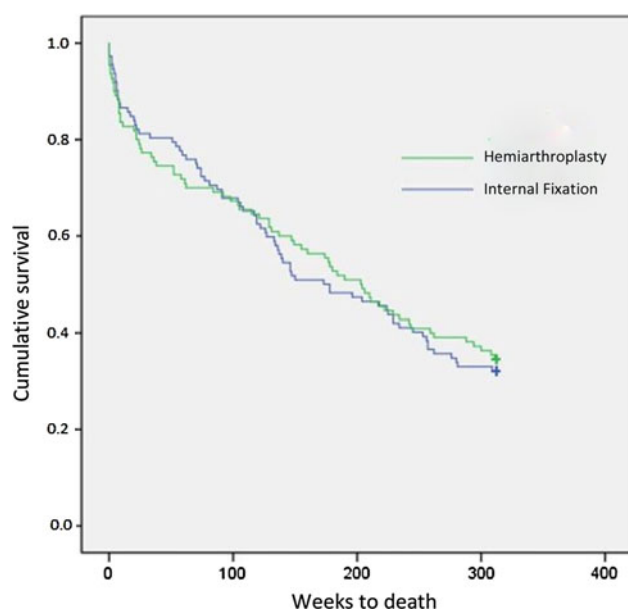


Fig. 2 Survival of patients (Kaplan-Meier) up to 6 years for hemiarthroplasty and internal fixation groups is shown.

There was no difference in patient survival between the groups with 33.6% (37 of 110) of the patients undergoing hemiarthroplasty and 29.5% (33 of 112) of the patients undergoing internal fixation still alive after a mean of 6 years ($p = 0.51$) (Fig. 2).

Of patients alive after 5 to 7 years, only 39 % (12 of 31) in the group randomized to internal fixation had their native hips, whereas 95% (35 of 37) patients initially receiving hemiarthroplasty still had the hemiarthroplasty ($p < 0.001$). The total percentage of reoperations for all patients originally included in the study was 43% (48 of 112) in the internal fixation group and 10% (11 of 110) in the hemiarthroplasty group ($p < 0.001$) after 5 to 7 years. From 2 to 6 years, two patients, both in the internal fixation group, were reoperated on, none in the hemiarthroplasty group (Fig. 3). One had a deep infection around the screws and was revised several times and the screws removed; the other had avascular necrosis and received THA. The chart review revealed no new surgical complications or reoperations in the patients who died between the followup at 24 months and the last followup. Radiographs were obtained of 56 of the patients. Changes from previous films were seen in three patients, one avascular necrosis of the femoral head, one loosening of the femoral stem (fractured cement and movement of the stem), and one acetabular wear (obliterated medial joint space). These patients were clinically doing well and no revision surgeries were planned.

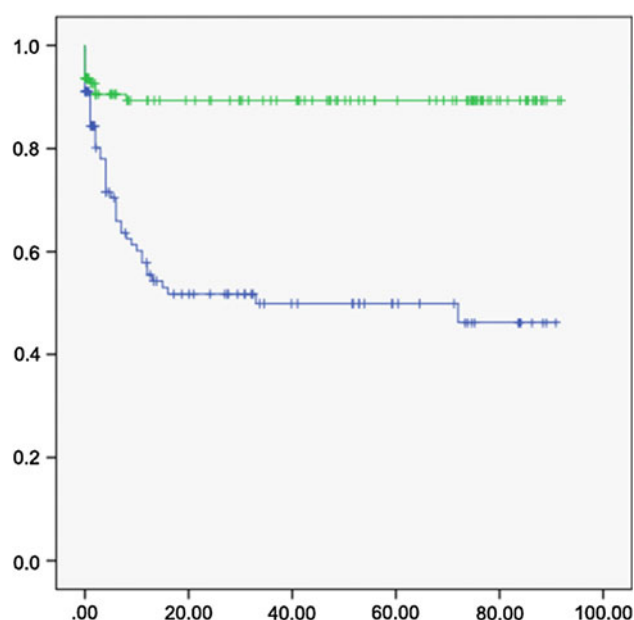


Fig. 3 Kaplan-Meier plot is shown of patients without any reoperation up to 6 years for hemiarthroplasty and internal fixation groups.

Discussion

As the population is getting older, the number of hip fractures will increase all over the world. Hip fracture leads to morbidity, mortality, and healthcare costs. Femoral neck fractures are treated with hemiarthroplasty or internal fixation; each of these treatments has different complications. Internal fixation has a high reoperation rate the first year after surgery compared with hemiarthroplasty [27], but concerns have been raised that hemiarthroplasty will lead to long-term complications because of loosening and acetabular wear [21]. Our study demonstrates that patient survival, hip function, quality of life, and ADL were similar at a mean 6 years after fracture regardless of randomization group. Reoperations were, however, more frequent in the internal fixation group. The short life expectancy in this group of patients was again demonstrated [14].

The present study has several limitations, among which lack of power resulting from the high mortality rate is the most important. The very low number of patients lost to followup is, however, an important advantage of this study compared with other studies comparing internal fixation and hemiarthroplasty. Furthermore, the unselected patient material and inclusion of demented patients make the results valid for the entire population of patients with displaced femoral neck fractures.

The present study was not statistically powered to detect differences in functional outcomes after a mean of 6 years. Thus, the present results do not necessarily imply that the

outcomes are equal. The results of the predefined main end point of the study, HHS, was, however, very similar after 6 years. A chart review was performed for all originally included patients, and no new reoperations or complications were discovered. Some patients may, however, have been reoperated on elsewhere, although the organization of the healthcare system in Oslo is that each hospital is responsible for a defined part of the city population, so this number is probably low. The concern that the treatment with hemiarthroplasty for femoral neck fractures leads to long-term problems such as acetabular wear and loosening with corresponding pain, loss of function, and the need for revision surgeries could not be verified in the present work at intermediate-term followup. Leonardsson et al. [22] published in 2010 similar results with no differences in functional outcome but a higher reoperation rate in the group of hemiarthroplasty. A study by Parker et al. [30] did not show any differences in clinical outcomes either.

The Kaplan-Meier curves did not identify any differences in the two groups in patient survival either early on or in the present report at a minimum followup of 5 years. This has also been documented in registry studies [13]. Hemiarthroplasty may represent a heavier surgical burden for the patient compared with internal fixation, which may lead to increased early mortality. If there is a difference in mortality between the methods, it would be an important factor in decision-making, even when including the functional benefits of treatment with hemiarthroplasty. No randomized study has reported a higher mortality rate after hemiarthroplasty [2, 28], and it would require a very large study to conclude on this matter; Bhandari et al. [2] estimated that demonstrating a 5% increased mortality rate would require a study sample size of 26,641 patients. Regarding mortality in this patient group overall, it is high the first year after fracture [20]. Later on, however, the mortality rate approaches the mortality rate of persons of the same age and sex [9], which makes it important to differentiate the treatment between patients with short and long life expectancies.

Hemiarthroplasty has in later years been established as the treatment of choice for displaced femoral neck fractures [30, 34]. However, hemiarthroplasty has also been shown to have an unacceptably high risk of pain and revision compared with THA when used to treat degenerative osteoarthritis or osteonecrosis of the femoral neck [19, 27, 32]. This has led to a concern that the long-term survivors after hip fracture may experience late problems with their hemiarthroplasty. The present study gave no indication that this is true. On the contrary, only patients in the internal fixation group were reoperated on between 2 and 6 years. This is similar to results reported by Leonardsson et al. [22], in which 89 patients randomized to hemiarthroplasty had no reoperations between 2 and 10 years. Hemiarthroplasty may thus provide

adequate function for this patient group. One study has even shown that hemiarthroplasty has better results than THA in this unsorted total patient population with hip fracture, mainly because of problems with hip prosthesis dislocation in fragile patients with THA [39].

Despite hemiarthroplasty being the treatment of choice in an unsorted population, the healthiest patients with long life expectancy might have a better result with THA [1]. This is the conclusion in a Cochrane review in which THA in a majority of relatively young and healthy patients had significantly less residual pain and better function at 1, 2, and 4 years after fracture at the cost of increased risk of dislocation and increased surgical time [28], also shown by Hedbeck et al. [16]. A cost-effectiveness analysis concluded that it is likely that THA is associated with increased costs in the initial 2-year period, but the longer-term costs favor THA as a result of lower revision rates [4]. Regarding cost of hemiarthroplasty versus internal fixation, hemiarthroplasty has been reported to be favorable [40].

As expected, there were demographic differences between patients who died within the first 6 years after fracture and the one-third who still were alive after 6 years. The patients who died were older at inclusion, more of them were cognitively impaired, and fewer lived home at inclusion [26].

The overall short life expectancy and the superior short-term function in the hemiarthroplasty group reinforce bipolar hemiarthroplasty as the treatment of choice in elderly patients with a displaced intracapsular hip fracture [10, 13, 29, 33]. The excess mortality compared with the background population is well demonstrated for the first year after fracture [20]. One-third of the patients are dead after 2 years, and they have been demonstrated to do best with hemiarthroplasty compared with both internal fixation and THA [39]. However, there is a small patient group that will live for 5 years or more; approximately 31% were still alive at that time point in the present report, and it is important to consider this group as decisions are made about treatment approaches. Further studies should focus on the subgroup of the relatively youngest and fittest patients with displaced femoral neck fractures to elucidate whether internal fixation, hemiarthroplasty, or THA might be the preferred treatment for them.

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