A randomised controlled trial comparing bipolar hemiarthroplasty with total hip replacement for displaced intracapsular fractures of the femoral neck in elderly patients

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The best treatment for the active and lucid elderly patient with a displaced intracapsular fracture of the femoral neck is still controversial. Randomised controlled trials have shown that a primary total hip replacement is superior to internal fixation as regards the need for secondary surgery, hip function and health-related quality of life. Despite good results achieved with total hip replacement in this group, most orthopaedic surgeons still advocate hemiarthroplasty for this injury. We studied 120 patients with a mean age of 81 years (70 to 90) with an acute displaced intracapsular fracture of the femoral neck. They were randomly allocated to be treated with either a bipolar hemiarthroplasty or total hip replacement.

Outcome measurements included peri-operative data, general and hip-specific complications, hip function and health-related quality of life. The patients were reviewed at four and 12 months.

The duration of surgery was longer in the total hip replacement group (102 minutes (70 to 151)) versus 78 minutes (43 to 131) (p < 0.001), and the intra-operative blood loss was increased 460 ml (100 to 1100) versus 320 ml (50 to 850) (p < 0.001), but there were no differences between the groups regarding any complications or mortality. There were no dislocations in either group. Hip function measured by the Harris hip score was significantly better in the total hip replacement group at both follow-up periods (p = 0.011 and p < 0.001, respectively). The health-related quality of life measure was in favour of the total hip replacement group but did not reach statistical significance (p = 0.818 at four months and p = 0.636 at 12 months).

These results indicate that a total hip replacement provides better function than a bipolar hemiarthroplasty as soon as one year post-operatively, without increasing the complication rate. We recommend total hip replacement as the primary treatment for this group of patients.

Whether fractures of the femoral neck in elderly patients are treated with internal fixation, hemiarthroplasty, or total hip replacement (THR), should be determined by the degree of fracture displacement, the patient’s age, functional demands and risk profile, such as level of cognitive function and degree of physical fitness. Internal fixation is not a controversial treatment for undisplaced intracapsular fractures of the femoral neck, with good results expected in terms of fracture healing, function, and the health-related quality of life. Internal fixation is also the method of choice in young patients with displaced intracapsular fractures and in very frail elderly patients not medically fit for arthroplasty surgery. There appears to be a consensus among orthopaedic surgeons that unipolar or bipolar hemiarthroplasty is the preferred treatment for displaced intracapsular fractures in elderly patients with low functional demands. However, for the relatively healthy, active and mentally alert elderly patient, treatment is still controversial.

Randomised controlled trials (RCTs) have shown that a primary THR provides superior results to internal fixation in relation to the need for secondary surgery, hip function, and health-related quality of life for the active alert patient. Nevertheless, most orthopaedic surgeons prefer hemiarthroplasty to THR in the management of this injury.
are two meta-analyses\textsuperscript{15,16} and only a limited number of studies\textsuperscript{13,17} which have evaluated the optimal type of arthroplasty in properly designed RCTs. The overall conclusion is that there is inadequate evidence to support the choice between different types of arthroplasty.

A recent multicentre RCT comparing internal fixation, bipolar hemiarthroplasty and THR concluded that THR was clearly superior to internal fixation and should be regarded as the treatment of choice for the elderly patient in good health with a displaced intracapsular fracture of the femoral neck.\textsuperscript{18} There also seemed to be an advantage for THR over bipolar hemiarthroplasty, especially at longer follow-up, but the authors recommended further trials to verify this.\textsuperscript{18}

The aim of this study was to analyse outcome, with hip function as the primary end-point, and health-related quality of life, after a displaced intracapsular fracture of the femoral neck in a relatively healthy, active and alert elderly patient randomised to receive either a bipolar hemiarthroplasty or a THR. Our null hypothesis was that there were no differences in these respects between the two treatments.

**Patients and Methods**

The study included 120 patients (101 females; 84\%) with a mean age of 81 years (70 to 90) with an acute displaced intracapsular fracture of the femoral neck following a fall. The inclusion criteria were age 70 to 90 years, absence of severe cognitive dysfunction demonstrated by three or more correct answers on the ten-item Short Portable Mental Status Questionnaire,\textsuperscript{19} non-institutionalised independent living status, and pre-injury independent walking capability with or without aids. Patients with pathological fractures and displaced fractures present for more than 48 hours before presentation, and patients with rheumatoid arthritis or osteoarthritis, were not included. After assessment by an anaesthetist for fitness for operation, the patient randomised to receive either a bipolar hemiarthroplasty or a THR. Consequently, there were 60 patients randomised to receive a bipolar hemiarthroplasty and 60 to receive a THR.

The study was conducted in accordance with the Helsinki Declaration;\textsuperscript{20} all patients gave their informed consent to participate and the protocol was approved by the local Ethics Committee.

**Surgical intervention.** All the operations in both groups were performed by one of nine consultants experienced in both procedures using a modified Hardinge anterolateral approach,\textsuperscript{21} with the patient in the lateral decubitus position. The modular Exeter femoral component (Howmedica, Malmö, Sweden) with a 28 mm head was used in all cases, with either a bipolar head (Bicentric, Howmedica or Universal Head Replacement (UHR) Howmedica) or with an OGEE (DePuy/Johnson & Johnson, Sollentuna, Sweden) acetabular component. The same cementing technique was used in both groups. The cement bed was cleaned with repeated high-pressure pulsatile lavage. We used a vacuum-mixed low-viscosity cement with gentamicin (Palacos with gentamicin; Schering-Plough, Stockholm, Sweden) in all cases. A distal restrictor and a proximal seal were used when cementing the femoral component and a cement pressuriser was used when cementing the acetabular component. All patients were given low-molecular-weight heparin (Fragmin; Pfizer, Täby, Sweden) pre-operatively and for at least ten days post-operatively. Cefuroxime (Zinacef; GlaxoSmithKline, Mölndal, Sweden), 1.5 g, was given pre-operatively, followed by two additional doses during the first 24 hours.

Patients in both groups were mobilised bearing full weight with the aid of two crutches as tolerated. The patients were instructed in precautions to take in order to avoid dislocation of the prosthesis and were allowed to sit on a high chair immediately after surgery, and to abandon crutches at their own convenience. After six weeks they were permitted to mobilise without further restriction.

**Primary assessment and follow-up.** The primary assessment established that the patient fulfilled the inclusion/exclusion criteria and identified any comorbidity.\textsuperscript{22} The patients were interviewed about their mobility, activities of daily living (ADL) status\textsuperscript{23} and health-related quality of life according to the EQ-5D\textsuperscript{24} during the last week before the fracture as a baseline. Peri-operative data, including intra-operative blood loss, need for blood transfusion and duration of surgery, were recorded.

The patients were reviewed at four and 12 months with a clinical and radiological examination. Two patients, randomised to hemiarthroplasty, declined to attend for the final follow-up examination (1.7\%) but reported satisfactory outcomes and had not experienced any complication. Three others had died, leaving 55 patients available for the 12-month review in the bipolar hemiarthroplasty group. For those who received a THR none was lost to follow-up but four died, leaving 56 patients available for the 12-month review in this group. Patients were assessed by a research nurse who had not been involved in the surgery or clinical decision-making, but who was aware of the type of treatment undertaken.

Complications relating to the hip, general complications, new fractures of the lower extremity, ADL status, living conditions, hip function as demonstrated by the Harris hip score (HHS)\textsuperscript{25} and EQ-5D were all recorded. An EQ-5D\textsubscript{index} score of 0 indicated the worst possible health state, and a value of 1 indicated the best possible health state.

Comorbidities graded according to Ceder et al\textsuperscript{22} were A, full health; B, another illness not affecting rehabilitation; and C, another illness that affected rehabilitation.

The Katz ADL\textsuperscript{23} was applied where status was based on an evaluation of the functional independence or dependence of patients in bathing, dressing, using the lavatory, transferring, continence and feeding. Grade A indicates independence in all six functions and grade B independence in all but one of the six. Grades C to G indi-
cate assistance being required with bathing and at least one additional function.

Living conditions were categorised as either independent, if the patient resided in their own home or in housing for the elderly, or as institutional, when the patient lived in a nursing home.

The following complications were recorded: dislocation, peri-prosthetic fracture, radiological signs of loosening of the femoral component, radiological signs of erosion in the acetabulum with a hemiarthroplasty, or loosening of the acetabular component in a THR. Deep wound infection was defined as an established infection beneath the fascia requiring surgical revision, and superficial wound infection was defined as cutaneous/subcutaneous infection requiring antibiotic therapy. General complications, including pressure sores, cardiac, pulmonary, thromboembolic or cerebrovascular complications, arising before the four-month follow-up, and any new fracture of the lower limb during the follow-up were recorded.

All patients included in the outcome analysis remained in their primary randomisation group regardless of secondary procedures according to an intention-to-treat principle.

Sample size. A power analysis based on a previous study with the same inclusion criteria indicated that a sample size of 120 patients would provide a power of 90% to identify a five-point difference in the HHS.

Statistical methods. SPSS 13.0 for Windows statistical software (SPSS Inc., Chicago, Illinois) was used. The Mann-Whitney U test was used for non-parametric data and for ordinal variables in independent groups. Nominal variables were tested by the chi-squared test or Fisher’s exact test. Wilcoxon’s signed-rank test was used when comparing data at the four- and 12-month follow-ups. All tests were two-sided. The results were considered significant at p < 0.05.

Results

There were no significant differences between the hemiarthroplasty and THR groups regarding baseline data, as shown in Table I. Of 120 patients 20 (17%) used some type of walking aid before fracture.

Peri-operative data and surgical outcome. The duration of the operation was longer in the THR group, 102 minutes (70 to 151) versus 78 minutes (43 to 131) (p < 0.001) and the intra-operative blood loss was increased, 460 ml (100 to 1100) versus 320 ml (50 to 850) (p < 0.001), although this was not reflected in an increased need for transfusion (Table II).

There were no differences between the two groups regarding complications specific to the hip. There were no dislocations in either group. Superficial infection that resolved after antibiotic therapy occurred in two patients from each group. In the THR group one patient had a wound dehiscence and, subsequently developed a deep infection requiring wound revision followed by two soft-tissue debridements before definitive wound closure. This particular patient was treated with antibiotics for four months, showed no signs of infection, and had a good clinical result at the 12-month follow-up (HHS 96). Another patient in the THR group sustained a peri-prosthetic fracture after a fall four months after the THR procedure which was successfully fixed internally with a plate.

In total, five patients sustained additional fractures involving the opposite lower limb before the 12-month follow-up. One patient in the hemiarthroplasty group had a subtrochanteric fracture which was treated with a long intramedullary hip screw (Stryker Howmedica, Malmo, Sweden), and two patients sustained undisplaced femoral neck fractures treated with internal fixation. One patient in the THR group had a displaced femoral neck fracture which was treated with a THR, and one had a patellar fracture treated with internal fixation.

There were no signs of acetabular erosion in any of the patients in the hemiarthroplasty group, and no signs of radiological loosening of the prosthetic components in any of the groups during the one-year follow-up.

General complications. The number of general complications before the four-month follow-up did not differ between the groups. In the hemiarthroplasty group five patients developed general medical complications: deep venous thrombosis in one, atrial fibrillation in one, myocardial infarction in one and two patients died. In the THR group six patients developed general complications: pneumonia in one, congestive heart failure in one, myocardial infarction in one, decubitus ulcer in one and two patients died. The overall one-year mortality rate was 5.8% (7 of 120) and for the hemiarthroplasty and THR groups individually the one-year mortality rates were 5% (three patients) and 6.7% (four patients), respectively. There was no statistical difference in the one-year mortality rates between the groups (p = 0.697).

Functional outcome and health-related quality of life. There were no differences regarding ADL or living conditions between the groups at either follow-up. At four months, 47 (2 missing values; 84%) in the hemiarthroplasty group and 51 (88%) in the THR group were category A or B, and at 12 months 51 (93%) and 50 (89%), respectively. There was no statistical difference in these results at four or 12 months (p = 0.539, chi-squared test and p = 0.742 Fisher’s exact test), respectively. At four months, 56 (97%) in the hemiarthroplasty group and 54 (93%) in the THR group were still living independently, and at 12 months this was 96% in both groups (53 of 55 in the hemiarthroplasty group and 54 of 56 in the THR group). There was no statistical difference in these outcomes at either follow-up (p = 0.679; p = 1.000; Fisher’s exact test), respectively.

Hip function was significantly better in the THR group at both follow-ups (Table III). There was a trend toward an increasing difference in the HHS score between the four- and 12-month reviews in favour of the THR group (p = 0.069, Mann Whitney U test). This finding was supported by a significant improvement in the HHS in the THR group between the four- and 12-month assessment (p = 0.001,
Wilcoxon’s signed-ranks test), but there was no significant improvement in the hemiarthroplasty group (p = 0.601, Wilcoxon’s signed-ranks test).

The health-related quality of life (EQ-5D index score) is shown in Figure 1. The values at both follow-ups were in favour of the THR group, although they were not statistically significant.

Discussion

This study indicates that in the treatment of relatively active, independent and lucid elderly patients with a displaced intracapsular fracture of the femoral neck, a THR provides better hip function than bipolar hemiarthroplasty with no increase in the complication rate.

The difference in the HHS was in favour of the THR group at both reviews, and increased with time. At one year the difference was equally distributed between the pain and function dimensions of the HHS. The explanation for the generally lower values in the function dimension of the HHS in our study, compared with studies on patients who received THR for degenerative joint disease, probably reflects the older age and the more frequent comorbidities in our patient population. Even before the fracture, 20 (17%) of our patients used walking aids, and 5 (4%) of them sustained a new fracture of the lower limb during the follow-up. Our findings of increased pain and reduced walking ability after hemiarthroplasty compared with THR confirm the results of Keating et al18 and are in agreement with a previous review of the literature on outcomes and cost-effectiveness after surgical treatment of displaced femoral neck fractures.28

The finding of better hip function in the THR group as early as at four months post-operatively may be somewhat surprising, as Bhandari et al4 found that many orthopaedic surgeons felt that the short-term outcome following a bipolar hemiarthroplasty was comparable with that after a THR. However, reports have shown that bipolar hemiarthroplasty functions as a unipolar device within three to 12 months after surgery.29,30 Early wear on the acetabular cartilage may be one explanation of the difference in hip function between THR and hemiarthroplasty in our own and previous studies.18

Considering the previously demonstrated good long-term outcome for THR in patients with osteoarthritis and
patients and in those with the longest life expectancy. The risk for deteriorating hip function, especially in the most active elderly patients will survive their remaining lifespan provided there are no early complications. This is in contrast to matches previous reports from our institution using the same registry. All patients before fracture. NS, not significant.

Fig. 1

Health-related quality of life (EQ-5Dindex score) before fracture and for all patients available at each follow-up (before fracture, n = 120; 4 months, n = 116; 12 months, n = 111). * One value missing in each group. † Two values missing in the hemiarthroplasty group, and one in the total hip replacement group. NS, not significant.

In conclusion, previous RCTs have shown that THR is superior to internal fixation, while the present study clearly indicates that THR yields better hip function than bipolar hemiarthroplasty without increasing the complication rate.

The increased blood loss and longer operating time associated with THR did not increase the number of general complications or the mortality rate. The low overall incidence of complications and the overall good functional outcome in both groups imply that both these methods of treatment are safe in this patient cohort, and for elderly patients with lower functional demands and a shorter life expectancy a bipolar hemiarthroplasty may be sufficient.

The strict inclusion criteria are one of the cornerstones of the study, clearly defining the population to whom the results can be generalised. The study also has some limitations. All clinical variables except hip movement were assessed by an independent observer who was not blinded to the type of surgical intervention. This may have introduced a risk of bias. Furthermore, a one-year follow-up may be considered too short. However, in previous studies on arthroplasty after femoral neck fractures, hip function seemed to reach its peak after one year. With the passage of time there is a gradual deterioration in function and health-related quality of life probably reflecting the natural course of ageing, the increased frequency of comorbidities and new fractures of the lower limb in this patient cohort. Therefore, our finding of an improved outcome as early as one year post-operatively without an increased complication rate in the THR group is important information to convey to orthopaedic surgeons.

In conclusion, previous RCTs have shown that THR is superior to internal fixation, while the present study clearly indicates that THR yields better hip function than bipolar hemiarthroplasty without increasing the complication rate.

The risk of dislocation may be one reason why orthopaedic surgeons generally hesitate to recommend THR even in active elderly patients. Alternatively, in some healthcare systems THR is performed by surgeons specially trained in hip arthroplasty and not routinely involved in treating patients with acute fractures of the femoral neck. However, the present study and other recent reports imply that adequately-trained general orthopaedic surgeons using an anterolateral approach in carefully selected patients can achieve good results and low dislocation rates with a primary THR.

The failure to show a statistical difference in the higher EQ-5Dindex scores in the THR group could be because the health-related quality of life is influenced by several other factors besides hip function, such as comorbidities, resulting in a higher variability in the EQ-5Dindex score. Finally, it may be that the study was insufficiently powered to reveal any difference.

Our findings of a low dislocation rate after the anterolateral approach in this and earlier studies are supported by a multicentre RCT comparing internal fixation, bipolar hemiarthroplasty, and THR, in which the dislocation rate in patients who had their arthroplasty via a lateral approach was 1%, compared with 29% in those who were operated upon using a posterior approach, and also by a recent meta-analysis examining the stability of the hip after hemiarthroplasty.

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References


