Internal fixation *versus* hemiarthroplasty for displaced fractures of the femoral neck in elderly patients with severe cognitive impairment

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We studied 60 patients with an acute displaced fracture of the femoral neck and with a mean age of 84 years. They were randomly allocated to treatment by either internal fixation with cannulated screws or hemiarthroplasty using an uncemented Austin Moore prosthesis. All patients had severe cognitive impairment, but all were able to walk independently before the fracture. They were reviewed at four, 12 and 24 months after surgery. Outcome assessments included complications, revision surgery, the status of activities of daily living (ADL), hip function according to the Charnley score and the health-related quality of life (HRQOL) according to the Euroqol (EQ-5D) (proxy report).

General complications and the rate of mortality at two years (42%) did not differ between the groups. The rate of hip complications was 30% in the internal fixation group and 23% in the hemiarthroplasty group; this was not significant. There was a trend towards an increased number of re-operated patients in the internal fixation group compared with the hemiarthroplasty group, 33% and 13%, respectively (p = 0.067), but the total number of surgical procedures which were required did not differ between the groups. Of the survivors at two years, 54% were totally dependent in ADL functions and 60% were bedridden or wheelchair-bound regardless of the surgical procedure. There was a trend towards decreased mobility in the hemiarthroplasty group (p = 0.066). All patients had a very low HRQOL even before the fracture. The EQ-5D index score was significantly worse in the hemiarthroplasty group compared with the internal fixation group at the final follow-up (p < 0.001).

In our opinion, there is little to recommend hemiarthroplasty with an uncemented Austin Moore prosthesis compared with internal fixation, in patients with severe cognitive dysfunction.

The treatment of elderly patients with an undisplaced (Garden I and II) fracture of the femoral neck is hardly controversial and good results regarding healing, function and the health-related quality of life (HRQOL) can be expected after internal fixation. This is also the method of choice in young patients with displaced fractures (Garden III and IV) and patients not medically fit for an arthroplasty. However, there is still debate about the treatment of displaced fractures of the femoral neck in the elderly patient. The results after internal fixation are disappointing with a rate of complications in most studies with a follow-up for two years in the range of 35% to 50%, and a significant decline in the HRQOL in lucid patients, even when the fracture heals uneventfully.

The population of elderly patients with such fractures comprises several subpopulations, ranging from the lucid, healthy, active and independent patient with a substantial life expectancy, to the institutionalised, cognitively impaired and bedridden patient. There is a growing opinion that the outcome would be improved by a more patient-related, rather than diagnosis-related, approach. Consequently, the treatment should be based on the patient's age, functional demands and individual risk profile. This opinion is supported by the recommendation regarding future research in the most recent issue from the Cochrane Library stating that future trials should be undertaken to screen groups of patients who would be better treated by specific surgical methods namely internal fixation, hemiarthroplasty or total hip replacement (THR).

A number of recent randomised, controlled trials have shown that, for the relatively healthy, active and lucid patient, a primary THR is superior to internal fixation in regard to the need for secondary surgery, hip function...
and the HRQOL.\textsuperscript{6-9} However, for the cognitively-impaired patient, the rate of dislocation after THR is unacceptably high, as shown by the study by Johansson et al\textsuperscript{6} in which the rate of dislocation was 32\% in cognitively-impaired patients operated upon using the posterior approach.

Besides the increased risk of dislocation, patients with severe cognitive dysfunction pose significant challenges to the treating surgeon in several respects, for example the lack of compliance, problems in assimilating rehabilitation regimens and frequent comorbidities. This is a demanding group of patients for the health-care system. About 10\% of patients with a fracture of the hip who have independent living conditions\textsuperscript{10} and about 35\% of patients admitted from institutions (unpublished data, Stockholm Hip Fracture Group) have a score of less than 3 on the short portable mental status questionnaire (SPMSQ).\textsuperscript{11}

Our aim was to compare the outcome in patients with severe cognitive impairment and a displaced fracture of the femoral neck, who were randomly allocated to receive either internal fixation or hemiarthroplasty. We also describe the HRQOL within this defined group of patients.

\textbf{Patients and Methods}

We recruited 60 patients (54 women, 90\%), with a mean age of 84 years (70 to 96) who had a displaced fracture of the femoral neck (Garden III and IV)\textsuperscript{1} after a simple fall. The study was carried out according to the Helsinki Declaration and the protocol was approved by the local Ethics Committee. Informed consent was given for all patients by a close relative or a guardian, before inclusion. The inclusion criteria were age \(\geq 70\) years, diagnosed dementia and/or severe cognitive dysfunction, according to the SPMSQ\textsuperscript{11} and independent walking capability with or without a walking aid. The results of the SPMSQ were categorised as follows: 8 to 10 correct answers, cognitive function intact; 6 to 7 correct answers, cognitive function mildly impaired; 3 to 5 correct answers, cognitive function moderately impaired and 0 to 2 correct answers, cognitive function severely impaired. Patients with fractures not suitable for internal fixation, such as pathological fractures or displaced fractures of duration more than 24 hours and those with rheumatoid arthritis or osteoarthritis were not included. After acceptance by an anaesthetist, the patients were randomised (sealed-envelope technique) to either internal fixation or hemiarthroplasty. We also describe the HRQOL within this defined group of patients.

\textbf{Operative technique.} All the primary operations in both groups were performed by either one of two surgeons (JT or HT), both of whom were experienced in both procedures.

Internal fixation was carried out with the patient lying supine on a fracture table. With the aid of an image intensifier the fractures were reduced by closed methods to neutral or slight valgus impaction and internally fixed by means of two cannulated screws (DePuy/Johnson-Johnson, Solle-tuna, Sweden). The goals for positioning of the screw were slightly modified from the recommendations of Lindqvist and Törnkvist.\textsuperscript{12} The reduction was categorised as good (displacement < 2 mm, Garden angle 160\’ to 175\’, posterior angulation < 10\’), fair (displacement < 5 mm, Garden angle 160\’ to 175\’, posterior angulation < 20\’) or poor (displacement > 5 mm, Garden angle < 160\’ or > 175\’, posterior angulation > 20\’). The position of the screws was categorised as good if the screw tips were less than 5 mm from the subchondral bone. In the anteroposterior projection, the distal screw was introduced at the level of the lesser trochanter to lie on the calcar femorale. The proximal screw was introduced at least 2 cm apart from and parallel to the distal screw (the angle being less than 10\’). In the lateral projection, the screws were parallel and positioned in the central or posterior third of the femoral head and neck. All patients were given low-molecular-weight heparin (Fragmin; Pharmacia, Töby, Sweden) pre-operatively and for approximately ten days post-operatively. No antibiotic prophylaxis was administered.

Hemiarthroplasty was carried out using an anterolateral modified Hardinge approach,\textsuperscript{13} with the patient in the lateral decubitus position. An uncemented Austin Moore implant was used (DePuy/Johnson-Johnson). All patients were given low-molecular-weight heparin (Fragmin) pre-operatively and for approximately 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.

Both groups of patients were mobilised to bear weight as tolerated. Two patients from the internal fixation group were treated by primary hemiarthroplasty when their fracture proved to be irreducible; they were excluded.

\textbf{Primary assessment and follow-up.} The primary assessment included determination of the type of fracture,\textsuperscript{3} cognitive function according to the Short Portable Mental Status Questionnaire (SPMSQ)\textsuperscript{11} and comorbidities according to Ceder, Thorngren and Wallden.\textsuperscript{14} A close relative or caregiver (proxy) was interviewed about the patient’s living status, walking capability, status of activities of daily living (ADL) index A and B, continence and feeding. ADL index A indicated partial dependence of patients, in bathing, dressing, going to the toilet, transferring, continence and feeding. ADL index A indicated full dependence of patients. The primary assessment was made on the day before admission (T0), at four months (mean 12.5, SD 1.1) and 24 months (mean 24.9, SD 1.3). General complications, hip complications, healing of the fracture, re-operations, function of the hip according to Charnley’s numerical classification\textsuperscript{17} and the HRQOL according to the EuroQol (EQ-5D)\textsuperscript{16} during the last week before the fracture, as a baseline measure.

The mean operating time, the intra-operative blood loss and the need for blood transfusion were recorded. Clinical and radiological examination was performed at four (mean 4.1, SD 0.4), 12 (mean 12.5, SD 1.1) and 24 months (mean 24.9, SD 1.3). General complications, hip complications, healing of the fracture, re-operations, function of the hip according to Charnley’s numerical classification\textsuperscript{17} and the HRQOL according to the EQ-5D\textsuperscript{16} were recorded. Since all the patients were severely cognitively impaired, all clinical variables except movement of the hip and cognitive function according to the SPMSQ, were assessed by way of a proxy report.

The status of the ADL index according to Katz et al\textsuperscript{15} is based on an evaluation of the functional independence or dependence of patients, in bathing, dressing, going to the toilet, transferring, continence and feeding. ADL index A indi-
cates independence in all six functions and index B independence in all but one. Indices C to G indicate dependence in bathing and, additionally, in one to five other functions. In order to be able to display the outcome in this group of highly dependent patients, the ADL index is also presented as an ordinal scale from 0 (independent) to 6 (dependent in all functions). Comorbidity was graded as A, full health; B, another illness not affecting rehabilitation; and C, another illness which affected rehabilitation. Living conditions were categorised as independent (i.e. own home, old people’s home or block of service flats) or as institutionalised (i.e. care homes for demented patients or nursing homes).

Complications of the hip in the hemiarthroplasty group included dislocation of the prosthesis, periprosthetic fracture and a deep wound complication (infection or haematoma) requiring re-operation. In the internal fixation group complications included failure to unite, avascular necrosis, refracture round the implant and a wound complication requiring re-operation. The fracture was defined as healed if there were visible trabeculations crossing the line of fracture. Nonunion was defined as an absence of radiologically visible trabeculations across the line of fracture. Such cases often showed early or progressive re-displacement.

Deep wound infection (defined as an established infection beneath the fascia requiring surgical intervention), superficial wound infection (defined as cutaneous/subcutaneous infection requiring antibiotic therapy) and severe general complications (cardiac, pulmonary, thromboembolic or cerebrovascular) were noted. We also recorded new fractures in either lower limb during the period of study.

Charnley’s numerical classification defines the clinical state of the affected hip according to pain in the hip, movement of the hip and walking ability. Each was graded from 1 to 6 (1, total disability and 6, normal state). The questions were modified to suit the proxy approach.

The HRQOL was rated by using the EQ-5D. We used the preference scores (EQ-5D scores) generated from a large UK population (UK EQ-5D Index Tariff) when calculating the scores for our study population. An EQ-5D score of 0 indicated the worst possible health state and a score of 1 indicated full health.

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

There were no significant differences between the internal fixation and hemiarthroplasty groups regarding baseline data as shown in Table I.

### Statistical analysis

The statistical software used was SPSS 11.5 for Windows (SPSS, Cary, North Carolina). The Mann-Whitney U-test was used for scale variables and ordinal variables in independent groups. Nominal variables were tested by the chi-squared test or Fisher’s exact test. A Wilcoxon signed-rank test was used to compare scores between the baseline and follow-up. All tests were two-sided. The results were considered to be significant at $p < 0.05$. Trend values, $0.05 \leq p < 0.1$ were displayed, all other values were reported as not significant.

### Results

The mean operating time in the internal fixation group, including reduction but excluding the two primary hemiarthroplasties, was 19 minutes (10 to 40). The intra-operative blood loss was 10 ml (0 to 100) and post-operative blood transfusions were required in only three patients. The reduction and position of the screws were assessed after the termination of the study and the primary post-operative radiographs were retrieved in 22 of 28 patients. The reduction was considered to be good in 19 patients (86%) and the position of the screw was good in 20 (91%).

The mean operating time in the hemiarthroplasty group was 43 minutes (29 to 60). The intra-operative blood loss was 250 ml (50 to 650) and 13 of 30 patients (43%) were given post-operative blood transfusions (mean 340 ml; range 0 to 1800).

The differences between the internal fixation and the hemiarthroplasty groups in mean operating time, intra-operative blood loss and the need for peri-operative transfusion were all highly significant ($p < 0.005$).

### Complications

There were no peri-operative deaths. Before the follow-up at four months, five patients in the hemiarthroplasty group developed severe general medical complications. One had pneumonia and four died. In the internal fixation group, five patients died before the follow-up.
up at four months. Twenty-five patients (42%) died during the two-year observation period, 13 (43%) in the internal fixation group and 12 (40%) in the hemiarthroplasty group (not significant). The patients who died had a significantly greater need for walking-aids before their fracture compared with survivors (p < 0.005), but there were no significant differences in other baseline data such as the SPMSQ score, gender, ADL and the HRQOL.

In total, eight patients sustained new fractures affecting a lower limb apart from the re-fractures or periprosthetic fractures of the studied hip. They included three in the internal fixation group (two with a fracture of the contralateral femoral neck and one with an ipsilateral tibial fracture) and five in the hemiarthroplasty group (three with a fracture of the femoral neck, one with a subtrochanteric fracture and one with a fracture of the ankle, all affecting the contralateral side).

**Surgical outcome** (Fig. 1). In the internal fixation group nine patients (30%) had complications and ten (33%) had re-operations. Eight developed nonunion. Of these seven required conversion to hemiarthroplasty and one to a Girdlestone arthroplasty. One patient sustained a trochanteric fracture after a new fall two months after the primary procedure and was treated by removal of the cannulated screws and internal fixation by a sliding hip screw and a derotation screw. One patient had her screws removed for local pain, 18 months after the fracture. There were seven cases (41%) of complications of fracture healing (all nonunions), among the 17 survivors at two years.

There were complications in the hip in seven patients (23%) in the hemiarthroplasty group and re-operations in four (13%). One patient sustained a rupture of the wound after a fall one month after primary surgery; there was no sign of infection and the wound healed after lavage and closure. Four patients sustained periprosthetic fractures after a further fall. Three of these were proximal, type I according to Whittaker, Sotos and Ralston, which is a fracture proximal to the tip of the prosthesis at the intertrochanteric level, with the stem extending across the site of the fracture providing sufficient stability. All were successfully treated conservatively without restriction of mobilisation. One patient had a type-II fracture, which is a fracture distal to the intertrochanteric line but proximal to the tip of the prosthesis causing some instability and requiring revision to a cemented bipolar arthroplasty. Two patients had deep infection. One required four drainage procedures one month after the primary procedure. The infection, however, healed without removal of the prosthesis. The other was treated primarily by wound debridement and lavage but a further operation was required to remove the prosthesis following which the infection healed. There were no dislocations in the hemiarthroplasty group.

The total number of hip complications, nine in the internal fixation group and seven in the hemiarthroplasty group, did not differ significantly between the groups. There was a trend towards an increased number of further operations in the internal fixation group compared with the hemiarthroplasty group, ten and four respectively (p = 0.067), but the total number of required surgical procedures, ten and eight respectively, did not differ significantly.

**Functional outcome, HRQOL and living status.** The outcome regarding ADL status is shown in Table II. There was a
The main finding of our study was the high rate of mortality and the marked deterioration in ADL function, mobility and the HRQL in this strictly selected group of patients, regardless of the surgical procedure. The effect of the selection criterion, severe cognitive dysfunction, profoundly influenced and partly overshadowed the effect of the randomisation procedure. However, the randomisation resulted in a better outcome regarding the HRQL and a trend towards better ADL function in the internal fixation group at follow-up at four months. The deterioration in ADL function between pre-fracture and the follow-up at 24 months was highly significant in both groups (p < 0.005) with 54% of the patients being totally dependent at the final follow-up.

The outcome according to the Charnley hip score is shown in Table III. There was a trend towards more pain in the internal fixation group at the follow-up at four months, but this levelled out at the subsequent follow-up reviews. There was also a trend towards poorer walking capability in the hemiarthroplasty group at the final follow-up. The deterioration in mobility between pre-fracture and follow-up at 24 months was considerable and highly significant in both groups (p < 0.001) with 60% of the patients being bedridden or wheelchair-bound at the final follow-up.

There was an increasing difference in the HRQL according to the EQ-5D (EQ-5D_index score) in favour of the internal fixation group from the follow-up at 12 months, and the difference became highly significant at follow-up at 24 months (Fig. 2). The decline in the mean EQ-5D_index score for the 35 survivors at 24 months comparing the pre-fracture status with that at follow-up at 24 months, was 0.07 (not significant) in the internal fixation group, compared with 0.20 (p < 0.001) in the hemiarthroplasty group. At the final follow-up, only six of 17 (35%) in the internal fixation group and two of 18 (11%) in the hemiarthroplasty group had retained independent living status (not significant).

Discussion

The continuing controversy regarding the optimal treatment for elderly patients with displaced fractures of the femoral neck may be partly due to the determination to find a universal surgical treatment for all patients with a displaced fracture, regardless of physical demands and comorbidities. In our opinion, future research should be focused instead on finding the optimal treatment for well-defined subgroups within this population. We, in agreement with other researchers in this field,7 believe that the selection
should be based primarily on age, cognitive function and mobility. The anaesthetists assessment will exclude the oldest and most fragile patients who are not medically fit for an arthroplasty; in other words, the approach considers biological age rather than chronological age. To be able to apply the results of these studies to clinical practice, we need robust criteria for selecting patients for the different surgical interventions. It was reasonable to assume that the outcome of the treatment of the fracture would have a major impact on the future living situation of these already vulnerable patients. For a reliable assessment of cognitive function, a validated instrument is needed. We used the SPMSQ in this and our previous trials of patients with fracture of the hip.\textsuperscript{2,6}

The mortality rate at two years of 42\% is significantly higher than that reported for previous studies, in which patients have been unselected regarding cognitive function. In a review of studies on internal fixation in patients with fracture of the femoral neck with follow-up for at least two years, the median rate of mortality was 28\%.\textsuperscript{3} For comparison, in a recent randomised, controlled trial\textsuperscript{19} of patients with a displaced fracture of the femoral neck, the rate of mortality at two years was 15\%. The only differences in the inclusion criteria between that study and ours was the level of cognitive function according to the SPMSQ and the fact that our study also allowed inclusion of patients from institutions. Severe cognitive dysfunction is probably a good predictor of mortality as well as of the outcome in general.\textsuperscript{20}

Of the survivors at two years, 54\% were totally dependent in ADL function and 60\% were bedridden or wheelchair-bound regardless of the surgical procedure. This finding probably reflects the natural course of the dementia and cognitive impairment and the difficulty for these patients to assimilate rehabilitation regimens, and could also indicate inadequate rehabilitation resources for this specific group of patients. The deterioration in mobility was gradual between all follow-up reviews. The results of the study by van Dortmont et al\textsuperscript{21} agree with our findings. Their general conclusion was that the chance of successful rehabilitation was small regardless of the surgical procedure and that internal fixation was the treatment of choice because it is a minor surgical procedure with less morbidity.

In our study, the overall rate of healing of complications of 41\% in the internal fixation group in survivors at two years is comparable with that of most other studies.\textsuperscript{3,4} We noted that all patients with such complications were reoperated on during the period of study. This implied that a scheduled follow-up after internal fixation is indicated even, perhaps especially, for patients with cognitive dysfunction.

It is well known that an uncemented hemiarthroplasty gives inferior results compared with THR in active patients with a long life expectancy. In a follow-up over 13 years of patients randomised to internal fixation, hemiarthroplasty (uncemented Austin Moore) and THR, the rate of revision was 33\%, 24\% and 7\%, respectively.\textsuperscript{22} Hip function according to the Harris hip score\textsuperscript{23} was best in the THR group and worst in the hemiarthroplasty group. In a recent randomised, controlled study, internal fixation and the uncemented Austin Moore hemiarthroplasty were compared in patients with displaced fractures of the femoral neck aged over 70 years, but unselected with regard to walking ability, living conditions and cognitive function. The conclusion was that elderly patients should generally be treated by hemiarthroplasty because of a lower rate of re-operation.\textsuperscript{24} The outcome regarding pain and walking ability, however, was similar in both groups and clearly worse than that expected after THR in an active, lucid elderly patient.\textsuperscript{6} However, THR cannot be recommended for patients with severe cognitive impairment because of the high rates of dislocation.\textsuperscript{4,9} This is lower after hemiarthroplasty.\textsuperscript{4} In spite of our patients’ severe cognitive dysfunction, there were no dislocations, indicating that this risk is limited in hemiarthroplasty when using the anterolateral approach, a finding also supported by previous studies.\textsuperscript{21,25}

Five of the seven hip complications in the hemiarthroplasty group were due to a new fall, resulting in a rupture of the wound in one patient and periprosthetic fractures in four. This propensity for falling was further displayed by the large number of new fractures in the lower limb in both groups. In total, 12 (20\%) patients sustained a new fracture of the lower limb, including periprosthetic fracture, during the period of study. Deep infection in two patients (6.7\%) was the reason for six of eight re-operations in the hemiarthroplasty group. This is more than twice the rate of deep infections reported by Parker et al\textsuperscript{24} and probably reflects the inclusion of older, more fragile and possibly malnourished patients.\textsuperscript{26}

The pre-fracture HRQOL (EQ-5D index score) for all patients in our study was 0.26, which is extremely low when compared with the value of 0.74 in a Swedish reference population\textsuperscript{27} and with a value of 0.78 to 0.83 in patients with fractures of the femoral neck but without severe cognitive function.\textsuperscript{2,6} The EQ-5D index score was significantly worse in the hemiarthroplasty group than in the internal fixation group at the final follow-up and there was also a significant decline in the mean EQ-5D index score, comparing the pre-fracture status with that at follow-up at 24 months in the hemiarthroplasty group.

In contrast to our previous studies, because of the severely impaired cognitive function, it was necessary to collect data by proxy, namely, from someone who knows the patient well. There is generally good proxy-patient agreement for concrete, observable variables, for example mobility or ADL, but not so good for less observable variables such as pain or anxiety and depression. However, in patients with dementia and severe cognitive dysfunction, this is the only way to assess the outcome, not only regarding the HRQOL but also for variables such as living status, ADL status and the pain and walking sections of the Charn-
ley hip score.17 This approach has also been used previously for the EQ-5D in patients with dementia.28,29

The limited number of patients in our study is a weakness regarding statistical power. On the other hand, it is a strictly selected group of patients with a follow-up at two years and only one patient was ‘lost’ by the follow-up at 12 months. We believe our findings are amenable to generalisation, not only regarding the reported differences between randomisation groups, but also regarding the general outcome for this selected group of patients.

In summary, patients with severe cognitive impairment and an associated displaced fracture of the femoral neck, randomly allocated to receive either internal fixation or Austin Moore implant, show an extremely high rate of mortality and a pronounced deterioration of ADL function, mobility and the HRQOL regardless of the surgical procedure. There does not seem to be any obvious advantage in performing hemiarthroplasty with an uncemented Austin Moore implant as compared with internal fixation, in patients with severe cognitive dysfunction.

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