Randomized comparison of reduction and fixation, bipolar hemiarthroplasty, and total hip arthroplasty: treatment of displaced intracapsular hip fractures in healthy older patients

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Three different types of surgical procedure for the treatment of hip fractures were examined. These were reduction and fixation, bipolar hemiarthroplasty with cement, and total hip replacement (THR) with cement.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with a displaced intracapsular hip fracture. Patients with an undisplaced or valgus impacted intracapsular fracture were not included. The inclusion criteria were normal cognitive function (a mini-mental test score of > 6), an ability to be mobile independent of another person prior to fracture, and no serious concomitant disease. There were no formal age criteria for eligibility, but it was expected that those recruited would be aged 60 years or older.

Setting
The setting was a hospital. The economic study was carried out in Scotland, UK.

Dates to which data relate
The patients included in the analysis were recruited between 1996 and 2000. The effectiveness and resource use data were estimated over 24 months from the date of recruitment. The costs were estimated using prices from the 2000/01 financial year.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness analysis.

Study sample
Power calculations were performed in the preliminary phase of the study. These suggested that a sample of 150 participants in each group would provide a 90% power to detect a 7-point difference in the main outcome measure (i.e. the hip rating score). However, owing to the slow recruitment rate, a projected total recruitment of 272 individuals
(which would have given an 80% power) was considered reasonable. Recruitment started in June 1996 and ended in May 2000. An overall sample of 299 patients was selected, but one patient withdrew on the way to surgery. Of these 298 individuals, 207 were randomised to the comparison between the three procedures (69 patients in each group) and 91 to the comparison between reduction and fixation versus bipolar hemiarthroplasty with cement. This led to a total of 118 patients for reduction and fixation versus 111 for bipolar hemiarthroplasty. An analysis of the data showed that only 13% of patients with a displaced intracapsular hip fracture were judged to be eligible for the study, and 69% of them agreed to participate. Typical reasons for ineligibility were failure of the mental test (30%), poor pre-fracture mobility (28%), a judgement that the patient was too elderly (9%), and a judgement that the patient was too young (4%).

In the triple comparison, the mean age of the patients was 74.3 (+/- 7) years with reduction and fixation, 75.0 (+/- 6) years with hemiarthroplasty, and 75.2 (+/- 6) years with THR. The proportions of women were 74% (reduction and fixation), 78% (hemiarthroplasty) and 78% (THR), respectively. In the double comparison, the mean age of the patients was 74.9 (+/- 7) years with reduction and fixation and 75.4 (+/- 7) years with hemiarthroplasty, and the proportions of women were 75% and 83%, respectively.

**Study design**

This was a prospective, multi-centre, randomised, clinical trial that was carried out in Scotland, UK. Forty-six surgeons in 11 Scottish orthopaedic units participated in the study. The participating surgeons elected to randomise patients to be treated either with one of the three surgical procedures or with either fixation or hemiarthroplasty. Randomisation was based on a centralised fully automated computer-based telephone service, and assignment was stratified by the consultant surgeon with minimisation on gender and age category. The length of follow-up was 2 years. The data were collected during admission and at 4, 12 and 24 months post-surgery. No patient was lost to follow-up. No blinding was performed.

**Analysis of effectiveness**

The analysis of the clinical study was conducted on an intention to treat basis. The primary outcome measure was hip function. This was assessed using a hip-rating questionnaire, based on a 100-point scale with four domains (global, pain, walking and function). The secondary outcome measures were:

- general health (based on the EuroQol questionnaire),
- mortality,
- readmission to the hospital,
- re-operations,
- fixation failure,
- nonunion,
- osteonecrosis,
- prosthetic dislocation, and
- postoperative complications (proven wound infection, septicaemia, deep venous thrombosis, pulmonary embolism, stroke and myocardial infarction).

The authors stated that the study groups were (statistically) comparable at study entry. An analysis was also performed adjusted by age, gender, and whether randomisation was two- or three-way.

**Effectiveness results**
The operative time was shortest in the fixation group and longest in the THR group.

Fixation failure within 2 years occurred in 37% of patients in the double comparison.

For the other outcomes, only statistically significant results will be reported in this abstract.

The proportion of patients undergoing further hip surgery was 39% with fixation and 5% with hemiarthroplasty (odds ratio, OR=8.59, 95% confidence interval, CI: 3.66 to 20.17) in the double comparison, and 39% with fixation and 9% with THR (OR 5.09, 95% CI: 2.09 to 12.40) in the triple comparison.

The rate of blood transfusions was 16% with hemiarthroplasty and 33% with THR (OR 0.38, 95% CI: 0.17 to 0.86) in the triple comparison.

In the comparison between fixation and hemiarthroplasty, fixation led to statistically significantly worse functional outcomes and EuroQol scores only in the short-term, but the differences disappeared at 24 months.

In the comparison between fixation and THR, fixation led to statistically significantly worse functional outcomes and EuroQol scores at 4 and 12 months, but the differences were not significant at 24 months.

In the comparison between hemiarthroplasty and THR, at 24 months the functional score was significantly worse in the hemiarthroplasty group than in the THR group (73.8 +/- 16 versus 79.9 +/- 17; adjusted difference -6.45, 95% CI: -12.53 to -0.37; p=0.04).

Similarly, the EuroQol score was significantly worse in the hemiarthroplasty group than in the THR group (0.53 +/- 0.36 versus 0.69 +/- 0.32; adjusted difference -0.16, 95% CI: -0.28 to -0.04; p=0.008).

**Clinical conclusions**

The effectiveness analysis showed that reduction and fixation was associated with poor outcomes. Thus, arthroplasty was more effective than reduction and fixation. THR was slightly more effective than bipolar hemiarthroplasty.

**Measure of benefits used in the economic analysis**

The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was undertaken.

**Direct costs**

The analysis of the costs appears to have been conducted from the perspective of the third-party payer. It included the costs related to hospital events and visits to outpatient clinics. The costs were grouped into three macro-categories (initial hospital episode, hip-related admission and non-hip-related admission). The unit costs were not presented separately from the quantities of resources used. Resource consumption was estimated using prospectively gathered data obtained from the sample of patients included in the effectiveness analysis. The costs were estimated using data from 4 Scottish university orthopaedic centres participating in the study. Discounting was not relevant since 2-year costs were incurred and, appropriately, was not performed. However, the authors stated that the impact of conventional discounting of costs incurred in the second year was negligible since the costs were mainly incurred during initial hospital admission. The costs were estimated using prices from the 2000/01 financial year.

**Statistical analysis of costs**

Statistical analyses of the costs were performed. Bootstrapped CIs were calculated for estimated untransformed arithmetic mean costs.

**Indirect Costs**

The indirect costs were not included.
Currency
UK pounds sterling ( ).

Sensitivity analysis
A univariate sensitivity analysis was carried out to assess the robustness of cost estimates to variations of -50% to +100% in the total cost of hip-related admissions and cost of prosthesis.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
In the comparison between fixation and hemiarthroplasty, the total costs per patient were 16,846 (95% CI: 13,712 - 19,979) with fixation and 13,863 (95% CI: 11,046 - 16,681) with hemiarthroplasty (difference 2,983, 95% CI: -1,277 to 7,192). The slightly higher costs of initial episodes with hemiarthroplasty were more than offset by the higher long-term costs of fixation.

In the comparison between fixation and THR, the total costs per patient were 14,882 (95% CI: 10,799 to 18,964) with fixation and 12,253 (95% CI: 10,227 to 14,278) with THR (difference 2,629, 95% CI: -1,888 to 7,146). Similarly, the slightly higher costs of initial episodes with THR were more than offset by the higher long-term costs of fixation.

In the comparison between hemiarthroplasty and THR, the total costs per patient were 15,263 (95% CI: 11,300 to 19,225) with hemiarthroplasty and 12,253 (95% CI: 10,227 to 14,278) with THR (difference 3,010, 95% CI: -1,400 to 7,420).

Hip-related costs were significantly higher in the fixation group in comparison with either hemiarthroplasty or THR, and in the hemiarthroplasty group compared with THR. However, the differences in total costs were not statistically significant. The variation in total cost of hip-related admissions and cost of prosthesis did not have an impact on the cost results.

Synthesis of costs and benefits
A synthesis of the costs and benefits was not relevant as a cost-consequences analysis was carried out.

Authors' conclusions
In otherwise healthy older patients with a displaced intracapsular fracture of the hip, arthroplasty was more clinically effective and cost-effective than reduction and fixation. The analysis suggested that total hip replacement (THR) may be better than bipolar hemiarthroplasty. The authors pointed out that despite THR being associated with the best clinical outcomes, it has not been a popular method because of the risk of prosthetic dislocation, although this was acceptable in the current series.

CRD COMMENTARY - Selection of comparators
The authors stated that reduction and fixation, hemiarthroplasty and THR were the usual alternatives for patients with a displaced intracapsular fracture of the hip. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from a clinical trial, which was appropriate for the study question. The method of randomisation was described and should have reduced the impact of selection bias. Details of the method of sample selection were provided, along with the proportions of patients who were excluded from the initial study sample or who
refused to participate. The study groups appear to have been well balanced at baseline with respect not only to demographics, but also in terms of their clinical characteristics. The length of follow-up was appropriate and a justification was provided for the size of the sample. The evidence came from several centres, which enhanced the representativeness of the patient sample. The use of an adjusted analysis further improved the robustness of the effectiveness analysis. The authors stated that some characteristics of the study design improved the internal validity of the study, which was high. Such characteristics included the use of intention to treat, unusual complete follow-up data, centralised randomisation, and exclusion of participating surgeons from data collection and analysis. However, the authors highlighted limitations associated with the wide CIs and with the fact that some surgeons did not randomise their patients to THR, which was considered inappropriate for some individuals. Thus, the double comparison was required in the analysis. The difficulties in recruiting some patients (i.e. those admitted to the emergency department and those deemed to be ineligible for all three procedures) were also pointed out.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

Validity of estimate of costs
The perspective selected for the study was unclear, although it appears that costs relevant to the third-party payer were included in the analysis. A detailed breakdown of the cost items was not provided, and information on the unit costs and resource quantities was not presented. Thus, it would be difficult to replicate the analysis in other settings. The costs were derived directly from the hospitals participating in the study and reflected Scottish rates. The impact of varying some cost estimates was investigated in the sensitivity analysis. Further, statistical analyses of the costs were used. The wide CIs around the mean costs reflected the small number of patients in some treatment groups. The price year was reported, thus enhancing the possibility of reflating costs in other time periods. Discounting was not applied, but the authors stated that the impact of discounting would not have been substantial.

Other issues
The authors stated that their clinical trial had several advantages over previous studies which often did not focus on patients who were previously capable of independent mobility, or did not incorporate measures of functional disability and economic estimates. However, the findings of the current study were quite similar to those from other studies with respect to specific outcomes of the analysis (i.e. mortality and failure rates). In terms of the generalisability of the study results to other settings, the authors stated that caution would be required when extrapolating the current findings to other settings, especially cost estimates, since data specific to the Scottish context were used. Further, the availability of new surgical approaches could change the results of the current comparative analysis.

Implications of the study
The authors stated that reduction and fixation could not be further recommended for the treatment of patients with a displaced intracapsular fracture of the hip. Arthroplasty with cement remains the preferred surgical approach at the authors’ institution. Long-term follow-up studies should be carried out in order to reach a definitive decision on the cost-effectiveness of THR versus hemiarthroplasty.

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Bibliographic details
Other publications of related interest


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