Clinical effectiveness and cost-effectiveness of 2 management strategies for infected total hip arthroplasty in the elderly
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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
Two techniques for the management of infected total hip arthroplasty (THA) were considered in the study: two-stage exchange arthroplasty, and open debridement of the hip with prosthesis retention. The former is considered the standard approach and is based on the surgical removal of prosthesis and 6 weeks of subsequent antibiotic therapy. A period of six weeks to one year is necessary before a new prosthesis can be reimplanted. The latter technology represents a less aggressive approach and the debridement is followed by 6 weeks of antibiotic therapy.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised hypothetical cohorts of male and female patients, with an established diagnosis of infected THA, aged over 65 years, with American Society of Anesthesiologist (ASA) score of 2 (i.e., mild systemic disease), and aged 80 years with ASA score = 3 (i.e., more severe systemic disease).

Setting
The setting was hospital. The economic study was carried out in Boston, USA.

Dates to which data relate
The effectiveness evidence and resource use data were gathered between 1979 and 1999. The price year was 1999.

Source of effectiveness data
The effectiveness evidence was derived from a review of the literature.

Modelling
A Markov model was used to simulate the initial management, clinical course, and later complications of an infected THA. The model had five general, mutually exclusive, health states with a cycle length of 1 month.

Outcomes assessed in the review
The outcomes used as model inputs were the annual relapse rate after debridement, after 2-stage exchange, and while taking suppressive antibiotics; the probability of loosened prosthesis; the median time to reimplantation; the state utilities after total hip arthroplasty with good function and after resection arthroplasty; and the baseline surgical
mortality rate (BSM) for 65 year old patients and frail 80 year old patients after debridement, resection arthroplasty, and reimplantation arthroplasty.

Study designs and other criteria for inclusion in the review
The study designs of the primary studies were not reported. However, preference was given to studies that used accepted clinical, pathological, and microbiological criteria and reported either the outcomes (separately) or follow-up time.

Sources searched to identify primary studies
The MEDLINE database was searched from January 1980 to June 1999. The keywords "prosthesis-related infections" and "hip" were used when searching MEDLINE. Manual searches of references and abstracts from major conferences were also used to identify relevant primary studies.

Criteria used to ensure the validity of primary studies
Not reported.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
Twenty-five primary studies were used as sources of effectiveness evidence.

Methods of combining primary studies
The method of combination of primary studies was not reported. However, the best estimate within a plausible range of values obtained from the literature was selected.

Investigation of differences between primary studies
Not reported.

Results of the review
The results of the review were as follows:

The annual relapse rate was 30% (range: 15% - 80%) after debridement, 3.5% (range: 0.6% - 10%) after 2-stage exchange, and 30% (range: 15% - 65%) while taking suppressive antibiotics.

The probability of loosened prosthesis was 70% (range: 35% - 90%).

The median time to reimplantation was 2 months (range: 1 - 12 months).

The state utility was 0.93 (range: 0.70 - 1) after total hip arthroplasty with good function and 0.60 (range: 0.5 - 0.75) after resection arthroplasty.

The male and female BSM rates were:

For 65 year old patients: 0.5% (range: 0.3% - 1%) and 0.4% (range: 0.2% - 0.8%) after debridement, 1.2% (range: 0.6% - 4%) and 1% (range: 0.7% - 4%) after resection arthroplasty, 0.9% (range: 0.5% - 2%) and 0.7% (range: 0.5% - 3%) after reimplantation arthroplasty; and
For frail 80 year old patients: 3% (range: 1% - 4%) and 2% (range: 1% - 3%) after debridement, 7% (range: 4% - 9%) and 6% (range: 3% - 9%) after resection arthroplasty, and 6% (range: 4% - 7%) and 4% (range: 3% - 6%) after reimplantation arthroplasty.

Measure of benefits used in the economic analysis
The benefit measures used in the economic analysis were life expectancy and quality-adjusted life years (QALYs). Valuation of health states was derived from published data and from some experts' opinions. Staff orthopaedic surgeons, reported to be familiar with THA management, were asked to rate by pain, mobility and self-care. These results were then transformed using the Health Utilisation Index, mark 2. Intermediate outcomes, important to decision-makers, were also considered: the average number of operative procedures (obtained through a Monte Carlo simulation) and mean duration of relapse-free survival (time form first operative procedures to relapse infection or death).

Direct costs
A 3% discount rate was used. Quantities and unit costs were not reported separately. The costs included resection arthroplasty, reimplantation arthroplasty, debridement and retention, 6-week course of parenteral antibiotic therapy, oral suppressive antibiotics, and rehabilitation. The estimation of costs was based both on published data and on Medicare reimbursement charges. The total expected costs were calculated through the decision model. The price year was 1999.

Statistical analysis of costs
No statistical analysis of costs was reported.

Indirect Costs
Indirect costs (patient time) were calculated on the basis of the assumption that a patient could not work when immobilised. The 1999 wage rates for a person aged over 65 years were used. However, indirect costs were not included in the base case but only in the sensitivity analysis.

Currency
US dollars ($).

Sensitivity analysis
One-way and multi-way sensitivity analyses were conducted to determine the robustness of the model results in the face of reasonable variations in the data assumptions. Both cost and effectiveness data were varied.

Estimated benefits used in the economic analysis
The expected duration of relapse-free survival after exchange arthroplasty and debridement and retention were 10.74 years and 2.51 years for 65-year-old men, 12.90 years and 2.60 years for 65-year-old women, 5.29 years and 2.07 years for frail 80-year-old men, and 6.79 years and 2.25 years for frail 80-year-old women, respectively.

The average numbers of operative procedures with exchange arthroplasty and debridement were 2.43 (+/-0.71) and 3.21 (+/-0.96) for 65-year-old men, 2.55 (+/-0.34) and 3.39 (+/-0.89) for 65-year-old women, 2.08 (+/-0.66) and 2.56 (+/-1.04) for frail 80-year-old men, and 2.19 (+/-0.69) and 2.73 (+/-1.04) for frail 80-year-old women.

The discounted life expectancy with exchange arthroplasty and debridement was 11.03 years and 11.04 years for 65-year-old men, 13.36 years and 13.35 years for 65-year-old women, 5.27 years and 5.39 years for frail 80-year-old men, and 6.81 years and 6.89 years for frail 80-year-old women.

The discounted QALYs with exchange arthroplasty and debridement were 9.20 and 9.38 for 65-year-old men, 11.04
and 11.26 for 65-year-old women, 4.46 and 4.66 for frail 80-year-old men, and 5.76 and 5.94 for frail 80-year-old women.

Cost results
The expected total direct costs with exchange arthroplasty and debridement were $53,600 and $57,200 for 65-year-old men, $54,200 and $58,900 for 65-year-old women, $47,800 and $47,900 for frail 80-year-old men, and $49,600 and $51,100 for frail 80-year-old women.

Synthesis of costs and benefits
Costs and benefits were combined by performing an incremental cost-effectiveness analysis. With respect to life expectancy, the incremental cost-effectiveness ratio of debridement over exchange arthroplasty was equal to $432,500 per life year in the group of 65-year-old men, $900 per life year in the group of frail 80-year-old men, and $19,250 per life year in the group of frail 80-year-old women. Debridement was dominated (more costly and less effective) by exchange arthroplasty in the group of women aged 65 years. The incremental cost per QALY of exchange arthroplasty over debridement was $19,700 for 65-year-old men, $21,800 for 65-year-old women, $500 for frail 80-year-old men, and $8,170 for frail 80-year-old women. By one way sensitivity analysis, the cost-effectiveness of debridement was stated to be most sensitive to the initial age of the cohort, annual rate of relapse after debridement and retention, and annual rate of relapse after exchange arthroplasty. Results were given for the 65-year-old man. With the inclusion of indirect costs, debridement became a cost-saving intervention. A 3-way analysis showed the annual rate of relapse after debridement versus age necessary to achieve an incremental cost-effectiveness ratio (ICER), from dominated to 'cost-saving'.

Authors' conclusions
'Initial debridement and retention increased life-expectancy 2.2 - 2.6 quality adjusted life months and had a favourable cost-effectiveness ratio on all cohorts'.

CRD COMMENTARY - Selection of comparators
The reason for the selection of comparators was clear. Exchange arthroplasty and debridement were chosen because they represented the gold standard and a less aggressive approach, respectively, for the management of THA. You should consider whether they are commonly used technologies in your own setting.

Validity of estimate of measure of effectiveness
A review of the literature was conducted to derive the effectiveness measures, and the search methods were stated. However, criteria to ensure the validity of primary studies were not reported and the authors did not state how they selected the best estimate within the range of values obtained or how they managed to account for differences among the primary studies.

Validity of estimate of measure of benefit
The estimation of benefit was modelled through a Markov model, which was appropriate to simulate the natural history of the disease and the clinical decision making. The authors covered the standard and available range of measures and clearly stated how utility weights were obtained. They also stated that they followed a reference case method including a societal perspective. It is arguable to what extent the valuation of their expert group represented that of society.

Validity of estimate of costs
The cost estimates used in the study were quite specific to the Medicare reimbursement system, and unit costs and resource quantities were not given. Although the authors stated that a societal perspective was adopted, indirect costs were included only in the sensitivity analysis and results were only given for the 65-year-old male cohort. Although a sensitivity analysis was conducted, and it is difficult to present all results for all possible variations in all parameters, the
authors have been selective in their choice of ranges and presentation. Without access to the model, it is difficult to test the generalisability or robustness of the authors' findings.

Other issues
The authors made appropriate comparisons of their findings with those from other studies. The issue of the generalisability of the results to other settings was addressed by performing sensitivity analyses on the model parameters. Some limitations of the study were reported, mainly related to model assumptions and sources of data.

Implications of the study
According to the authors, the analysis has indicated that debridement and retention was a reasonable strategy for the treatment of older people with THA. They also note that some caution should be necessary when the results are applied to patients with S. aureus prosthetic joint infection in whom diagnosis and treatment are delayed. Although the results are reasonably clearly set out, they are, as the authors acknowledge, selective, and there is wide variability in the cost-effectiveness ratios, indicating that there is a significant risk of debridement and retention not being cost-effective.

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