Metal-on-metal hip resurfacing arthroplasty

A systematic review of the effectiveness and cost-effectiveness of metal-on-metal hip resurfacing arthroplasty for treatment of hip disease

L Vale[1,2*]
L Wyness[2]
K McCormack[1]
L McKenzie[2]
M Brazzelli[1]
SC Stearns[2]

[1] Health Services Research Unit, Institute of Applied Health Sciences, University of Aberdeen, UK
[2] Health Economics Research Unit, Institute of Applied Health Sciences, University of Aberdeen, UK

[*] Corresponding author

Executive summary

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Executive summary

Background

Disease affecting the hip joint is mainly caused by osteoarthritis, which may be primary or secondary, and the inflammatory arthropathies, of which rheumatoid arthritis is the archetype. Other conditions that cause arthritis and which could be treated by metal-on-metal hip resurfacing arthroplasty are avascular necrosis, congenital dislocation, Paget's disease, ankylosing spondylitis and traumatic arthritis.

The prevalence of osteoarthritis affecting the hip is difficult to estimate. A survey of 28,080 residents of Avon and Somerset (UK), aged 35 years and over, showed that 107 men per 1000 and 173 women per 1000 suffered from hip pain and that 15.2 people per 1000, aged between 35 and 85 years, had hip disease severe enough for surgery. There are fewer data on the incidence and prevalence of hip involvement in rheumatoid arthritis than for osteoarthritis. Hip involvement was found in 20% of patients with rheumatoid arthritis in a Swedish study, 3% of whom were found to have severe hip destruction. Other studies have reported the incidence of hip involvement in rheumatoid arthritis to be between 10% and 40%.

The predominant surgical intervention for the treatment of hip disease in use in England and Wales is total hip replacement (THR) with nearly 50,000 procedures performed annually, of which possibly as many as 7000 are revisions of primary THR. Swedish data suggest that moderate to severe osteoarthritis accounts for over 75% of the indications for THR, trauma for 11.3% and rheumatoid arthritis for 6%.

Aim

To assess the effectiveness and cost-effectiveness of metal-on-metal hip resurfacing arthroplasty compared with watchful waiting, THR, osteotomy, arthrodesis and arthroscopy of the hip joint. Suitable participants were those who would:

- be likely to outlive the life of a THR (i.e. those aged under 65 years)
- not be expected to outlive their prosthesis because of age (i.e. those aged 65 years and over) but who participate in activities predicted to shorten the life of a THR and who would thus outlive its life
- not be suitable for consideration for THR for reasons other than expected survival or activity.

Methods

A structured search of electronic databases, websites and relevant audit databases between 1990 and 2001 was conducted, using free text terms to identify potentially relevant papers evaluating metal-on-metal hip arthroplasty, osteotomy, arthrodesis and arthroscopy. A search was also carried out for randomised controlled trials (RCTs) of THR and systematic reviews of RCTs for THR.

Studies in languages other than English were identified from their abstracts but were not included in the review. Inclusion criteria for metal-on-metal hip arthroplasty studies were: any RCT comparing metal-on-metal hip arthroplasty with any other comparator that reported patient outcome data, and any comparative observational study comparing metal-on-metal hip arthroplasty with any other comparator that had concurrent controls and provided revision rates, clinical assessment or patient-based outcomes. There was no restriction on the length of follow-up. Single prosthesis observational studies of metal-on-metal hip arthroplasty were limited to those that provided revision rates, clinical assessment or patient-based outcomes, with a minimum follow-up of 2 years. For watchful waiting, arthrodesis, arthroscopy and osteotomy, inclusion was restricted to studies that made a relevant comparison or contained any observational data on the specified outcomes, with a minimum follow-up of 5 years (10 years for osteotomy). For THR, inclusion was restricted to RCTs with a minimum follow-up of 5 years and systematic reviews of such trials.

Details of study design, participants, setting and timing, interventions, patient characteristics and outcomes were recorded on a data abstraction form. Included studies were assessed using a quality assessment form based on a checklist

used to assess the quality of studies in orthopaedic research journals. The three systematic reviews included were quality assessed using a form specific to the assessment of the methodology of systematic reviews.

A systematic review of existing economic evaluations comparing metal-on-metal hip resurfacing arthroplasty with any of the comparators was conducted. Identified studies were critically appraised and their results summarised.

A Markov model comparing the comparators was developed, using the results of the review of effectiveness data together with data on costs from previous studies. This model was use to estimate costs and quality-adjusted life-years (QALYs) for up to 20 years following commencement of treatment. Subgroup analysis was conducted to reflect the costs and outcomes of those who would not be expected to outlive the life of a THR.

Results

Number and quality of studies

No studies were found that compared metal-on-metal hip resurfacing arthroplasty with any of the comparators. Data from case series were used as the basis of estimates of effectiveness for metal-on-metal hip resurfacing arthroplasty (five studies), watchful waiting (one study), osteotomy (12 studies), arthrodesis (one study) and arthroscopy (one study). Evidence for THR came from three systematic reviews and one RCT not previously identified by the systematic reviews. Substantial differences between studies were identified for the different interventions in terms of preoperative diagnosis, length of follow-up and outcome measures reported.

Summary of benefits

The evidence with which to assess the benefits of metal-on-metal hip resurfacing arthroplasty compared with the other interventions was very limited. In terms of revisions, over a 3-year follow-up period 0–14% of patients who received metal-on-metal hip resurfacing arthroplasty required a revision. The available data came from a comparatively small number of surgeons. In comparison, those managed by watchful waiting avoided an immediate operation but had a 30% chance of an operation over 3 years. THR (depending on the prostheses used) was associated with revision rates of 10% or less over a 10-year follow-up period, while revision rates for osteotomy were, with one exception, between 2.9% and 29% over a period of 10–17 years. The estimated revision rates for patients receiving arthroscopy were slightly higher than those for metal-on-metal hip resurfacing arthroplasty. No data were available on revision rates following arthrodesis.

Patients who underwent metal-on-metal hip resurfacing arthroplasty experienced less pain than those who were managed by watchful waiting, with data from one study suggesting that 91% of patients were pain free at 4 years. This compares with an estimate of 84% at 11 years for THR, 22% for arthrodesis at 8 years, and fewer patients pain free following arthroscopy. Similar data for osteotomy were not available.

Costs

All costs were estimated from an NHS perspective for the year 2000. The direct healthcare costs of each alternative treatment were estimated using information from a variety of sources, published and unpublished. The cost of metal-on-metal hip resurfacing arthroplasty for a patient aged under 65 years was estimated to be £5515. Other estimated intervention costs were: £4195 for THR, £6027 for revision THR, £951 for arthroscopy, and £2731 for osteotomy. The annual cost per patient for the watchful waiting alternative was estimated at £642.

Cost-effectiveness

Benefits in the economic model were measured in QALYs. Quality-of-life scores were based on assumptions about levels of pain associated with the treatment alternatives and published quality-of-life scores for mild, moderate and severe osteoarthritis of the hip. In the modelling process, these were combined with revision rates and mortality rates to generate QALYs.

For each intervention, the costs, probabilities and quality-of-life data were synthesised using a Markov model run over a 20-year period from initial intervention. Costs were discounted at 6% per annum and quality of life at 1.5%. The resulting present values of cost and quality of life for each intervention were then compared across interventions to calculate the incremental cost per QALY. Results for patients under 65 years at the time of treatment showed that metal-on-metal hip resurfacing arthroplasty was dominated (i.e. was more costly with the same or less benefits) by THR, owing to the assumptions about metal-on-metal revision rates and the lower cost of THR. Metal-on-metal hip resurfacing arthroplasty dominated (i.e. generated cost savings and the same or more benefits) the watchful waiting alternative within a 20-year follow-up period. Incremental cost per QALY ▶

values of £3039 and £366 were estimated for metal-on-metal hip resurfacing arthroplasty relative to osteotomy and arthroscopy, respectively. For patients aged over 65 years, THR dominated metal-on-metal hip resurfacing. Sensitivity analysis revealed that metal-on-metal hip resurfacing arthroplasty was no longer dominated by THR once revision rates were less than 80–88% of THR revision rates. Sensitivity analysis was also performed using different metal-on-metal hip resurfacing arthroplasty operation times and different watchful waiting costs and quality-of-life values.

The economic modelling provided in this analysis was constrained substantially by the lack of data on key parameters for the economic models. The most severe problem was the limited information available for metal-on-metal hip resurfacing arthroplasty revision rates. For example, the alternative methods of metal-on-metal hip arthroplasty were considered as if they were a homogeneous set of procedures. In reality this is unlikely but there is very little evidence to suggest whether or not outcomes for different prostheses are similar. Another critical absence of data was on health outcomes for revision THR following metal-on-metal hip resurfacing arthroplasty.

Conclusions

The incremental cost-effectiveness ratios provided in the analysis illustrate several key points. First, the low quality of life experienced by young people with hip disease who have been advised to delay undertaking THR means that if metal-on-metal hip resurfacing arthroplasty can be proven (i) to have lower revision rates than THR over an extended period and (ii) to result in better outcomes from subsequent THR, then such a procedure could possibly be considered cost-effective or even dominant. Second, if metal-on-metal revision rates are below those for primary THR by a sufficient amount, then metal-on-metal hip resurfacing arthroplasty could possibly be judged cost-effective for older people who are more active and may outlive a primary THR.

The few data available on metal-on-metal hip resurfacing arthroplasty came from a very small number of clinicians. It is not clear whether their results could be replicated in practice. In particular, the available studies describe an evolution of the prostheses over time and also, presumably, surgical technique. To achieve the promising low revision rates indicated by recent unpublished data may require substantial training in the procedure as well as provision of the procedure on a high-volume basis to ensure skills are maintained. Potential increases in the surgical procedure rate as the threshold for treatment changes may require training of additional clinicians in order to avoid increases in waiting lists for orthopaedic procedures.

Information was not available on the quality of life of family and carers. An increase in quality of life for those with hip disease would reduce the burden on family members and carers.

Recommendations for research

All the limited data available and results obtained by modelling these data indicate that metal-on-metal hip resurfacing arthroplasty merits further investigation. The lack of any controlled studies comparing it with any of the comparators (but principally watchful waiting and THR) should be addressed in trials with long-term follow-up. Any comparison with watchful waiting is hampered by the absence of long-term data on metal-on-metal hip resurfacing arthroplasty, health outcome data following revision, and virtually any data on watchful waiting. Research is required to define more clearly what watchful waiting entails and how its outcomes compare with the other comparators, especially metal-on-metal hip resurfacing arthroplasty.

Publication

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