A systematic review of the clinical effectiveness and cost-effectiveness and economic modelling of minimal incision total hip replacement approaches in the management of arthritic disease of the hip

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Executive summary

Health Technology Assessment 2008; Vol. 12: No. 26

Health Technology Assessment
NHS R&D HTA Programme
www.hta.ac.uk
Description of proposed service

Minimal incision total hip replacement (THR) is performed with significant variations between surgeons but approaches fall into two main groups. Of these, the ‘double-incision’ or ‘two-incision’ approach is novel and specific to minimally invasive hip surgery, whereas the single mini-incision approach is a development of traditional anterolateral and posterior approaches. Minimal incision techniques can be used for all the main categories of hip prostheses. Although shorter incisions may result in less muscle dissection, they may also reduce visualisation at operation, leading to potential risks that the placement of the prosthesis will be sub-optimal and may, therefore, lead to a higher rate of revisions than might be expected with standard THR.

Epidemiology and background

Osteoarthritis was the primary diagnosis in 94% of THR operations in England and Wales in 2005. Its incidence increases with age, and consequently THR is most common in older people (the average age of patients is 68 years). With improvements in implant design and longevity, younger patients are also now considered for THR. Over 55,000 primary THRs are recorded annually in the National Joint Registry, of which 6–14% are reported to be mini-incision THR. Minimally invasive surgery (MIS) is thought to be less suitable for patients who are obese, very muscular or with severe osteoporosis.

Objective

This review aimed to assess the clinical effectiveness and cost-effectiveness of minimal incision approaches to THR for arthritis of the hip.

Methods

The search strategy included electronic databases (covering 1966–2007) and relevant websites, contact with experts in the field and scrutiny of retrieved papers to identify reports of published and ongoing studies. Systematic reviews and selected conference proceedings were also searched.

Studies of minimal (one or two) incision THR compared with standard THR were assessed for inclusion for the review of clinical effectiveness. Studies of two-incision THR compared with one mini-incision THR were also eligible. Randomised controlled trials (RCTs), quasi-RCTs, prospective non-randomised studies with concurrent comparisons and matched-pair studies, and retrospective comparative studies with prospective design or total population recruitment were included. Additional long-term data were sought from national registries, and also single-surgeon case series with a minimum follow-up of 3 years and multiple-surgeon case series with a minimum follow-up of 1 year. Pre-specified subgroups were based on age, gender, deformity, muscularity and body mass index (BMI), and also operative approach (i.e. posterior, anterior).

Two reviewers independently extracted data and assessed methodological quality. Meta-analyses were performed with the RCT data; dichotomous data were combined using the Peto odds ratios and continuous data were combined using the inverse variance weighted mean differences.

A systematic review of economic evaluations comparing a minimal incision approach to standard THR was performed and the estimates from the systematic review of clinical effectiveness were incorporated into an economic model. This model estimated the cost–utility of single mini-incision THR for time horizons of 1 and 40 years (although few long-term data relevant to the 40-year time horizon were available). Many of the outcomes produced by the meta-analysis were implausible and it was not possible to incorporate them into the model. Data were suggestive of equal outcomes following standard and mini-incision THR, hence the risks of revision, postoperative dislocation and infection, deep vein thrombosis (DVT) and pulmonary embolism (PE) were assumed to be equal but with wide confidence intervals (CIs) [relative risk (RR) 1, 95% CI 0.1 to 1.89]. The key costs included in the model were operative costs in terms of hospital costs, equipment and staffing for the two procedures.
and hospital stay. Differences in hospital stay (weighted mean difference (WMD) –0.5 days, \( p \leq 0.01 \)) and operation duration (WMD –3.70 minutes, \( p \leq 0.01 \)) both favoured single mini-incision THR and were taken directly from the meta-analysis conducted as part of the review of effectiveness. The management costs of postoperative complications were also included, such as the cost of a revision surgery (£7858) after a subsequent failure, the cost of reoperations, due to both dislocations (£1925) and infections (£3365) and the cost associated with managing DVT (which varied depending on severity) and non-fatal pulmonary embolisms (£1326). Long-term costs of care included the follow-up of patients in consultant-led outpatient visits (£103 per visit) and the management costs of those patients whose surgeries have failed and who, therefore, are treated non-operatively for the remainder of their lives (annual cost £743). Utilities data were sourced to estimate quality-adjusted life-years (QALYs) and therefore utilities were also assigned to the main quality of life outcomes included in the model, such as success (0.75), failure (0.33) and the utility associated with various complications. Due to lack of data, no economic analysis was conducted for the two mini-incision surgical method.

Results

Number and quality of studies, and direction of evidence
Fifty-five reports describing 42 studies were identified. Of these, 32 studies (nine RCTs, 17 non-randomised comparative studies and six case series and one registry) were useful for the comparison of single mini-incision THR with standard THR. One RCT compared two mini-incision THR with standard THR and nine studies (two RCTs, five non-randomised comparative studies and two case series) compared two mini-incision with single mini-incision THR. The RCTs were of moderate quality. The majority had fewer than 200 patients (range 20–219). The majority of comparative studies comparing single mini-incision with standard THR (four RCTs, 12 non-randomised) and those comparing the two mini-incision THR with single mini- or standard THR (one RCT, three non-randomised) had a follow-up period of less than 1 year.

Summary of benefits
The single mini-incision THR may have some perioperative advantages, namely less blood loss (WMD –57.71 ml, \( p \leq 0.01 \)) and shorter operative time, of uncertain practical significance. The mini-incision approach may also offer a shorter recovery period and greater patient satisfaction with the operation and scar appearance. Evidence on long-term outcomes (especially revision) is too limited to be useful. Subgroup analysis was not possible due to lack of suitable data.

With respect to the two-incision approach, data were suggestive of shorter recovery compared with single-incision THR, although the data were not in a form amenable to meta-analysis. As data were sparse, conclusions must be treated with caution.

Costs
The costs to the health service, per patient, of single mini-incision THR depends on the assumptions made, but are similar (£7060) to standard THR, which costs the NHS, on average, £7350 per patient. In the base-case analysis, the cost difference between standard and single mini-incision THR for a 1-year time horizon was approximately £300 less per patient than standard THR (for the 40-year time horizon the costs were £11,618 for mini-incision and £11,899 for standard THR).

Cost-effectiveness
Two existing economic evaluations were identified, but they added little, if any, value to the current evidence base owing to their limited quality. In the economic model, mini-incision THR was less costly and provided slightly more QALYs and therefore dominated standard THR, in both the 1- and 40-year analyses. The mean QALYs at 1 year were 0.677 for standard THR and 0.695 for mini-incision THR. At 40 years, the mean QALYs were 8.463 for standard THR and 8.480 for mini-incision. The probabilistic sensitivity analyses conducted indicate that mini-incision THR has a 95% probability of being cost-effective at threshold values of up to £50,000 for society’s willingness to pay for a QALY. This probability is reduced to approximately 55% for the 40-year analyses. The cost-effectiveness results were driven by the assumption of a 1-month earlier return to usual activities and a decreased hospital length of stay and operation duration following mini-incision THR.

Sensitivity analyses
Although it appeared that mini-incision THR was associated with a shorter recovery, the precise reduction could not be estimated, so a threshold analysis was performed around time to return to usual activities following mini-incision THR. This analysis was conducted for the base-case
model and a model assuming more intensive use of resources for mini-incision patients. In terms of the base-case model, as mini-incision THR is less costly than standard THR, mini-incision continued to dominate standard THR. When increased resource use was assumed for mini-incision compared with standard THR (mini-incision THR is approximately £200 more expensive than standard THR in this analysis), then provided that recovery was 1.5 weeks faster, the incremental cost-effectiveness per QALY would be £30,000 or less.

One major area of uncertainty is in risk of revision. Initially it was assumed that revision rates in the long-term would be equal (with wide CIs). A threshold analysis around risk of revision showed that if society would be willing to pay £30,000 for a QALY, mini-incision THR would have to be associated with a 7.5% increase in revisions compared with standard THR for it to be no longer considered cost-effective (one more revision for every 200 procedures performed).

Further sensitivity analysis involved relaxing assumptions of equal long-term outcomes where possible. Data produced by the meta-analysis in relation to postoperative dislocation [odds ratio (OR) 1.72, 95% CI 0.43 to 6.92] favouring standard THR, and DVT (OR 0.39, 95% CI 0.12 to 1.30), favouring mini-incision THR, were utilised in this sensitivity analysis. Broadly similar results to the base-case analysis were found in this and further sensitivity analyses.

**Limitations of the calculations (assumptions made)**

Much of the information available was reported in a form unsuitable for meta-analysis. Few data were available for many outcomes, including revision rates. Lack of standardisation in outcome measures was also evident and some outcomes were assessed in only one or two reports. The extent of the imprecision surrounding estimates was such that many of the meta-analysis results were not included in the base-case model (risk of revision, postoperative dislocation, DVT and PE). Consequently, these outcomes in relation to mini-incision are assumed to have, on average, equal relative effect sizes compared with standard THR (but with wide CIs). This represents an analyst assumption and is a limitation of the data inputs used by the model. Further limitations related to the estimates of costs and the impact that minimal incision THR had on QALYs in both the short and long term. In terms of utility, very few comparative and short-term data were available. Cost data would be greatly enhanced if they were collected within a full economic evaluation, alongside a clinical trial, for example.

**Other important issues regarding implications**

If the use of MIS were increased from its current level of 6% of all THRs to 25% of all THRs, then NHS costs may reduce by £4.1 million per year. These savings depend on judgements made about the relevance in reality of reductions in operation time, length of stay, the need for little extra specialised equipment and whether differences exist in longer term outcomes.

The increased adoption of mini-incision techniques may allow an earlier return to usual activities, which, in turn, reduces loss of income or need for informal care by family and friends. However, few patients currently have access to minimal incision THR and more surgeons would need training in this approach, which would be costly and take time to achieve. Furthermore, not all patients are clinically suitable.

**Notes on the generalisability of the findings**

Only two of the nine trials were conducted in the UK. No data were available to conduct any worthwhile subgroup analysis. No UK economic studies were identified.

**Conclusions**

Compared with standard THR, minimal incision THR has small perioperative advantages in terms of blood loss and operation time. It may offer a shorter hospital stay and quicker recovery. It appears to have a similar procedure cost to standard THR, but evidence on its longer term performance is very limited.

Further data are needed to assess long-term outcomes of single mini-incision or two mini-incision THR before robust decisions can be made. Further long-term follow-up data are also required on costs and outcomes.

**Recommendations for further research**

No useful data on long-term outcomes of single mini-incision or two mini-incision THR were available. Such data are required before robust decisions can be made. The sparse effectiveness data limit subsequent economic analysis. Further long-term follow-up data on costs and outcomes including analysis of subgroups of interest to the
NHS (e.g., obese or muscular patients, patients with significant bone deformity or severe osteoporosis and patients who present as emergency cases) would strengthen the current economic evaluation. The economic evaluation would also be strengthened by the collection of costs on long-term events and management, such as failure. In relation to utilities, short-term differences in recovery are required, in addition to long-term differences in outcomes which depend on both subsequent failures and differences in quality of life, caused by long-term implications of different degrees of dissection. If a large RCT addressing long-term effectiveness is conducted in the future, it is strongly recommended that a full economic evaluation be incorporated as an integral part of the study from design to dissemination. Further careful work would be required to explore the value of such a large RCT more formally.

**Publication**

The Health Technology Assessment (HTA) Programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. ‘Health technologies’ are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The research findings from the HTA Programme directly influence decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC). HTA findings also help to improve the quality of clinical practice in the NHS indirectly in that they form a key component of the ‘National Knowledge Service’.

The HTA Programme is needs-led in that it fills gaps in the evidence needed by the NHS. There are three routes to the start of projects.

First is the commissioned route. Suggestions for research are actively sought from people working in the NHS, the public and consumer groups and professional bodies such as royal colleges and NHS trusts. These suggestions are carefully prioritised by panels of independent experts (including NHS service users). The HTA Programme then commissions the research by competitive tender.

Secondly, the HTA Programme provides grants for clinical trials for researchers who identify research questions. These are assessed for importance to patients and the NHS, and scientific rigour.

Thirdly, through its Technology Assessment Report (TAR) call-off contract, the HTA Programme commissions bespoke reports, principally for NICE, but also for other policy-makers. TARs bring together evidence on the value of specific technologies.

Some HTA research projects, including TARs, may take only months, others need several years. They can cost from as little as £40,000 to over £1 million, and may involve synthesising existing evidence, undertaking a trial, or other research collecting new data to answer a research problem.

The final reports from HTA projects are peer-reviewed by a number of independent expert referees before publication in the widely read journal series *Health Technology Assessment*.

**Criteria for inclusion in the HTA journal series**
Reports are published in the HTA journal series if (1) they have resulted from work for the HTA Programme, and (2) they are of a sufficiently high scientific quality as assessed by the referees and editors.

Reviews in *Health Technology Assessment* are termed ‘systematic’ when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this issue of the journal was commissioned by the HTA Programme as project number 06/46/01. The contractual start date was in November 2006. The draft report began editorial review in May 2007 and was accepted for publication in February 2008. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors’ report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme or the Department of Health.

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