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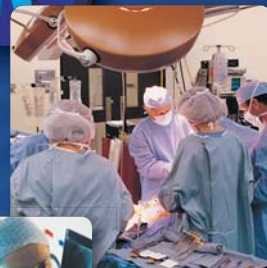


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Systematic Review and Economic
Evaluation of Minimally Invasive
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Supporting Informed Decisions

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Publications can be requested from:

CADTH
600-865 Carling Avenue
Ottawa ON Canada K1S 5S8
Tel. 613-226-2553
Fax. 613-226-5392
E-mail: pubs@cadth.ca

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Systematic Review and Economic Evaluation of Minimally Invasive Techniques for Total Hip Replacement

February 2008

We thank Suzanne Morphet for her assistance in creating this overview from a longer report authored by Coyle *et al.*

This overview is based on the Technology Report commissioned by CADTH: Coyle D, Coyle K, Vale L, de Verteuil R, Imamura M, Glazener C, Zhu S. *Minimally Invasive Arthroplasty in Management of Hip Arthritic Disease: Systematic Review and Economic Evaluation* [Technology Report 102]. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2008.

CADTH takes sole responsibility for the final form and content.

Minimally Invasive Arthroplasty in the Management of Hip Arthritic Disease: Systematic Review and Economic Evaluation

Technology

Minimally invasive total hip replacement (MI THR) procedures that involve single- and double- incision techniques.

Condition

Patients who are eligible for THR due to degenerative, rheumatoid, or other arthritic diseases of the hip.

Issue

Emerging minimally invasive surgical techniques for hip replacement require specialized equipment. There is uncertainty regarding the clinical and economic arguments about the adoption of these techniques.

Methods and Results

Fifty-five articles describing 42 studies [12 randomized controlled trials (RCTs), 22 non-randomized comparative studies, and eight case series (including registry data)] were identified through a systematic literature review. Thirty-two compared single mini-incision with standard incision, including nine RCTs. One RCT compared double incision to single mini-incision. A cost-utility analysis of single incision procedures from the perspective of the Canadian public health care system and a 40-year time horizon was conducted. A value of information analysis was also conducted.

Implications for Decision Making

- **Differences between minimally invasive and standard techniques exist, but the clinical significance is unknown.** MI THR techniques may have some peri-operative advantages (less blood loss and shorter operative time), although these may be of limited clinical significance. Of particular concern is the absence of evidence on the rates of revision after a primary procedure.
- **Single-incision MI THR is unlikely to be cost-effective.** Single-incision techniques are associated with higher costs (C\$20,400 versus C\$19,100) and quality-adjusted life-years (7.48 versus 7.47) compared to standard THR resulting in an incremental cost per QALY gained of \$148,300. The probability that MI THR is more cost-effective than standard THR for a decision maker willing to pay \$50,000 for a QALY is 47%. These results are most sensitive to the cost of initial hospitalization and patient utility values in the first year post-treatment.
- **Collecting long-term comparative information may be of value.** Compared to expanding funding for single-incision MI THR, it would be cost-effective to spend up to C\$480M on gathering additional data through field evaluation, to remove uncertainty regarding the effect of MI THRs on revision rates.

This summary is based on a comprehensive health technology assessment available from CADTH's web site (www.cadth.ca): Coyle D, Coyle K, Vale L, de Verteuil R, Imamura M, Glazener C, Zhu S. *Minimally Invasive Arthroplasty in the Management of Hip Arthritic Disease: Systematic Review and Economic Evaluation*.

1 Introduction

Hip arthroplasty, also known as total hip replacement (THR), is most commonly required by patients with degenerative arthritis (osteoarthritis). In 2002 in Canada, there were 19,977 THRs, of which an estimated 86.9% were primary and 13.1% were revisions.¹ Osteoarthritis was the indication for 81% of the primary THRs. Two-thirds of patients, both male and female, were older than 65 years and needed a hospital stay ranging from 8.2 days in Ontario to 14.2 days in Newfoundland and Labrador.¹

Minimally invasive (MI) THR is increasingly popular, accounting for 9% of all THRs in 1992,¹ but whether there is enough clinical and economic evidence to support its widespread adoption in the Canadian health system is questionable.

In standard THR, the surgeon makes an incision that is large enough to remove the hip ball and socket and replace them with an artificial joint, without using additional instruments or computer guidance. With MI THR, one or two smaller incisions are made, and specially designed instruments may be used.

Surgeons can choose one of three approaches for MI THR: a “double incision”, a posterior incision, or an anterolateral incision. X-ray fluoroscopy is used throughout the double incision procedure.² A short incision is made anterior to the femoral neck, and a second incision is made laterally above the greater trochanter, through which the femoral instrument is inserted.

With the posterior (or posterolateral) approach, an incision is made along the posterior edge of the greater trochanter. With the anterolateral (or anterior) approach, the surgeon makes one incision over the anterior part of the greater trochanter.

MI THR and standard THR require similar staff, and the single-incision approaches can be performed using the same equipment, although specialized equipment is often used at a one-time cost of approximately \$6,000.

2 Objective

The aim of this health technology assessment was to examine the impact of adopting MI THR on the Canadian health system by answering the following questions:

- What are the known clinical effects of MI THR compared with standard THR for patients undergoing primary THR?
- What is the cost-effectiveness of MI THR compared with that of standard THR?
- What is the potential financial impact of increased adoption of MI THR?

3 Clinical Review

Methods

This systematic review was initially done concurrently with a UK National Institute for Health Research Health Technology Assessment study, which used the same initial methods and reporting procedure. The final versions of the two reports differ because of different editorial processes, including peer review.

Literature Search Strategy

The following databases were searched for published and ongoing studies on the effectiveness of MI THR: Medline, Medline In-Process, Embase, Biosis, Science Citation Index, and Cochrane Central Register of Controlled Trials as well as current research registers (National Research Register, Current Controlled Trials, and Clinical Trials). A search was also conducted for systematic reviews and background information on the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effectiveness, the Health Technology Assessment Database, and the Health Management Information Consortium.

Also searched were full texts in key surgical journals: American and British editions of *Journal of Bone & Joint Surgery*, *Journal of Arthroplasty*, and *Clinical Orthopaedics & Related Research*. Conference proceedings were examined for potential studies, and the web sites of relevant organizations, such as national orthopedic registries, professional organizations, and manufacturers of artificial joints, were searched.

Selection criteria for inclusion

- Studies could be randomized controlled trials (RCTs), quasi-RCTs, prospective non-randomized studies with concurrent comparisons and matched-pair studies, retrospective comparative studies, case series or single cohort studies with two or more surgeons and at least one year of follow-up, single-surgeon case series with at least three years of follow-up and full text availability, or data from national registries if they provided long-term outcomes such as revision rates.
- Study populations were adults who were eligible for standard THR for arthritis.
- Studies comparing single mini-incision primary THR with standard primary THR were included. Studies comparing two-incision primary THR with standard primary THR or with single mini-incision primary THR were considered.
- Outcomes were categorized under clinical performance, harm, resource utilization, and patient-relevant measures.

Two reviewers independently assessed titles and abstracts for inclusion in the review using these criteria. Any disagreements were resolved by discussion.

Data Abstraction Strategy

Two reviewers independently reviewed the full-text articles, applied the selection criteria, and extracted data from selected studies. A third reviewer helped resolve discrepancies when necessary.

Strategy for Quality Assessment

Two reviewers working independently rated the quality of RCTs, quasi-RCTs, and other comparative studies using the Delphi criteria list.³

Data analysis methods

Quantitative data were synthesized from the RCTs, but not from the comparative studies, to avoid introducing any inherent systematic bias.⁴ To measure effect on outcomes, dichotomous outcome data were combined using the Peto odds ratio (OR), a method of estimating ORs when trials have no or few events in one or both arms.⁵ Continuous outcomes were combined using weighted mean difference (WMD) and 95% confidence intervals (CI); p values were calculated for ORs and WMDs. Results were reported using a fixed effects model. To explore statistical heterogeneity across studies, chi-squared tests and I-squared quantities were used. When heterogeneity appeared, random effects models for continuous outcomes were used, and further analysis was conducted under different conditions.

Many studies lacked uniform data, so a qualitative review was performed. For continuous variables, this was supplemented by two additional analyses. In the first, standard deviations (SDs) were calculated (if they were not reported by the authors) based on p values, and it was assumed that they were the same in both arms of a trial. In the second analysis, where p values were also unavailable, SDs were estimated based on the weighted means of SDs in other studies.

Results

Of the 887 reports that were identified, 186 were selected for full assessment. Of the 186 reports, 55 reports describing 42 studies met the inclusion criteria. There were 12 RCTs, 22 non-randomized comparative studies, and eight case series (including one report from a registry). Thirty-two studies compared single mini-incision with standard incision, including nine RCTs⁶⁻¹⁴ and 17 comparative studies.^{2,15-30} One study compared double incisions with standard THR,³¹ and nine studies, including two RCTs^{32,33} and five comparative studies,³⁴⁻³⁸ looked at double incisions versus single mini-incisions. The trials were of moderate quality and ranged in size from 20 to 219 participants. Trials and comparative studies were conducted in the UK, Canada, the US, Australia, Czech Republic, Korea, Austria, China, Hungary, Japan, the Netherlands, Spain, and Thailand. The case series and registries data came from Germany, Italy, France, the US, and Norway; or they were multi-centered and conducted in the US.

Despite the number of included studies, data were unavailable, or surrogates for longer-term outcomes were insufficient to judge any long-term differences between approaches. The single mini-incision approach seems to offer some advantages compared with standard THR, including less blood loss, shorter surgery, shorter hospital stay and faster return to usual activities, but these advantages may not be clinically significant. Table 1 shows data for single mini-incision versus standard THR.

The two-incision approach may offer earlier hospital discharge and better quality of life compared with the single-incision approach, but there were more cases of nerve injuries. There was an absence of data on the rates of revision after primary THRs with either technique.

Table 1: Effect size from meta-analysis of trial data for single mini-incision THR versus standard THR

Outcome (WMD and Peto OR based on trials)	Number of trials (number of comparative studies)
Favours mini-incision	
Blood loss (mL)* WMD -56.59 [-71.63, -41.55], p<0.00001	7 (11)
Duration of operation (minutes)* WMD -3.70 [-5.67, -1.74], p=0.0002	9 (15)
Length of hospital stay (days)* WMD -0.50 [-0.83, -0.18], p=0.002	6 (12)
Return to usual activities after operation • Time to return to normal activities: no trial data • Use of walking aids (days): WMD -3.40 [-5.23, -1.57], p=0.0003 • Use of walking aids (number of patients): Peto OR 0.55 [0.20, 1.53], p=0.25 • Limp (number of patients): Peto OR 0.31 [0.11, 0.91], p=0.03	0 (1) 1 (0) 1 (1) 1 (1)
Patient satisfaction WMD not estimable	1 (3)
No evidence of difference or insufficient information	
Revision rates Peto OR 7.96 [0.16, 402.02], p=0.30	3 (6)
Post-operative dislocation rates Peto OR 1.72 [0.43, 6.92], p=0.45	6 (11)
Surrogates for long-term outcomes • Implant position (cup): Peto OR 0.93 [0.50, 1.74], p=0.83 • Implant position (stem): Peto OR 0.70 [0.35, 1.40], p=0.31 • Implant migration: Peto OR not estimable • Heterotopic ossification: no trial data • Cement quality: Peto OR 1.26 [0.70, 2.27], p=0.45	3 (6) 5 (9) 1 (1) 0 (2) 3 (4)
Limb length inequality (number of patients with unequal length) No trial data	0 (1)
Intra-operative fractures Peto OR 0.14 [0.01, 2.18], p=0.16	2 (3)
Post-operative fractures Peto OR not estimable	2 (3)
Infections Peto OR 7.48 [0.78, 72.16], p=0.08	7 (9)
Nerve injury Peto OR 1.95 [0.20, 18.89], p=0.56	6 (9)
Vascular injuries Peto OR not estimable	1 (0)
Deep venous thrombosis Peto OR 0.39 [0.12, 1.30], p=0.12	5 (6)
Pulmonary embolism Peto OR not estimable	1 (2)
30-day mortality Peto OR 0.14 [0.01, 2.18], p=0.16	1 (2)
Long-term mortality Peto OR 0.15 [0.01, 2.45], p=0.18	1 (2)
Analgesic use • Narcotic (days): WMD not estimable	1 (0)

Table 1: Effect size from meta-analysis of trial data for single mini-incision THR versus standard THR

Outcome (WMD and Peto OR based on trials)	Number of trials (number of comparative studies)
• Patient-controlled anesthesia (mg): WMD -4.41 [-29.18, 20.36], p=0.73 • Total narcotic received (mg): no trial data	3 (0) 0 (3)
Short-term pain Pain (number of patients): no trial data Pain score: WMD -0.06 [-0.56, 0.44], p=0.81	0 (3) 4 (2)
Long-term pain Pain score: WMD not estimable	1 (0)
Long-term difference in usual activities Limp: Peto OR not estimable	1 (0)
Short-term condition-specific quality of life • Harris hip score:* WMD -1.25 [-3.75, 1.24], p=0.33 • WOMAC: WMD 0.45 [-3.13, 4.03], p=0.81 • Oxford Hip Score: WMD -0.91 [-2.74, 0.92], p=0.33 • Merle d'Aubigné-Charnley score: WMD not estimable	2 (3) 2 (0) 1 (1) 1 (0)
Long-term condition specific quality of life • Harris Hip Score:* WMD 0.35 [-0.13, 0.83], p=0.15 • Merle d'Aubigné-Charnley score: WMD not estimable	4 (6) 1 (0)
Short-term general quality of life • SF-12 physical component: WMD -0.75 [-3.38, 1.88], p=0.58 • SF-12 mental component: WMD 0.50 [-2.39, 3.39], p=0.73 • SF-36 physical function: WMD not estimable	1 (0) 1 (0) 1 (0)
Long-term general quality of life • SF-36 physical function: no trial data • SF-36 mental function: no trial data	0 (1) 0 (1)
Favours standard incision	
No outcomes	

OR=odds ratio; SD=standard deviation; THR=total hip replacement; WMD=weighted mean difference; WOMAC=Western Ontario and McMaster Universities Index of Osteoarthritis. *Based on published data supplemented with calculated SDs. All other values (WMD and Peto OR) are based on published data.

Economic Analysis

A literature search for economic studies comparing MI THR with standard THR produced two studies, including an unpublished cost-utility analysis.^{39,40} Both studies, which used some of the same data, concluded that MI techniques would likely reduce health care costs and provide better short-term outcomes, but the studies incorporated assumptions by the authors and used techniques that are likely to have produced biased and unreliable results.

Primary Economic Evaluation Methods

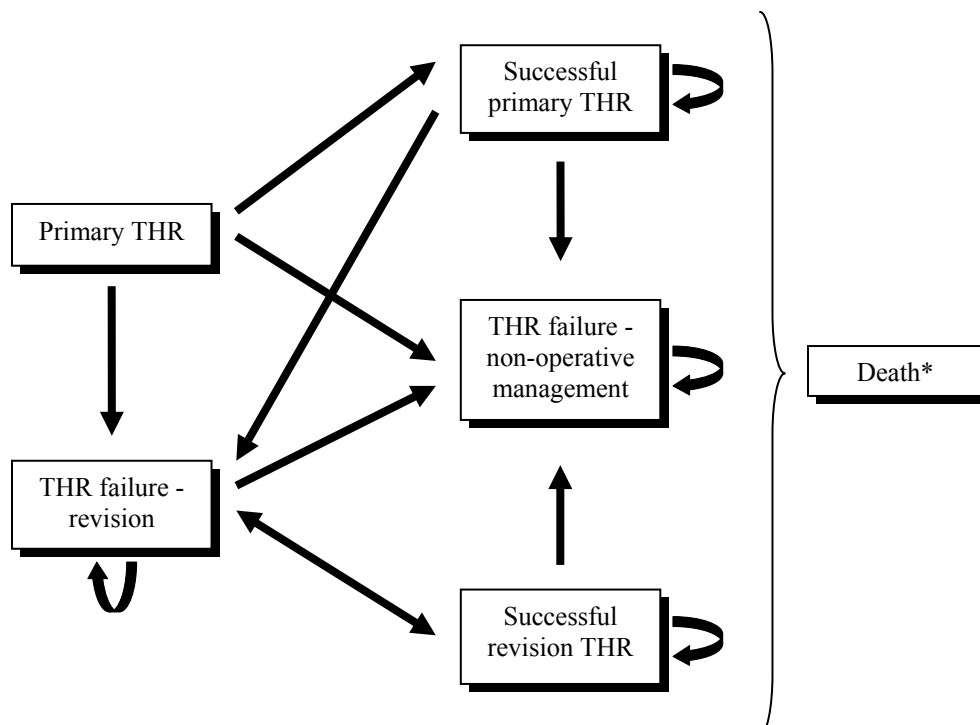
A cost-utility analysis was conducted to compare the cost-effectiveness of single mini-incision THR and standard THR. (Double-incision MI THR was not considered because evidence was lacking.) The perspective of a provincial ministry of health was adopted. Outcomes were measured in terms of quality-adjusted life years (QALYs) during a time horizon of 40 years with costs and benefits discounted at 5% per annum.⁴¹

A Markov model with a cycle length of one year (Figure 1) was developed to predict the outcomes of both surgical procedures. The transition probabilities and treatment effects were derived from the

literature. The short-term costs and utilities associated with each procedure were derived from a randomized Canadian clinical trial that compared MI THR with standard THR.¹² The long-term costs, including costs associated with complications, were derived from the literature.

The base-case analysis was for 68-year-old patients who needed THR, but were otherwise healthy. The analysis compared outcomes for these patients assuming that they underwent hip arthroplasty using the MI or standard THR technique. One year after surgery, patients were assumed to have experienced successful THR, failed THR requiring revision, failed THR to be treated by non-operative management, or death. In subsequent years, another health state of successful revision is incorporated into the model.

Figure 1: Simplified Markov model



*All states in the model may lead to death.
THR=total hip replacement.

In determining transition probabilities, four possible complications with THR surgery were taken into account: deep venous thrombosis (DVT), pulmonary embolism, dislocation, and deep infection. Because of a lack of data from the systematic review on the effects of the surgical techniques, however, it was assumed that there were no differences between procedures in terms of long-term outcomes in the base-case analysis.

The base-case analysis was a deterministic analysis with point estimates for each parameter entered into the model for expected costs and QALYs. This was followed by a sensitivity analysis to determine the robustness of the primary results when certain assumptions were changed. A Monte Carlo simulation (MCS) involving 5,000 estimates of incremental costs and QALYs was done to determine the uncertainty around the incremental cost-effectiveness ratio.⁴² A value of information

analysis was conducted to identify those parameters that contribute most to uncertainty and to indicate where more research would be beneficial.⁴³

Results

The base-case results appear in Table 2. The economic evaluation found that a single-incision MI THR technique was associated with higher costs than the standard technique (\$20,400 versus \$19,100) and higher QALYs (7.48 versus 7.47). The incremental cost per QALY gained was \$148,300. The sensitivity analysis found that the results were sensitive to changes in the costs of initial hospitalizations and utility values during the first year after treatment, but relatively insensitive to the effect of the two types of surgery with respect to DVT and dislocations.

Technique	Costs	QALYs	Incremental cost per QALY
Standard THR	\$19,100	7.47	
MI THR	\$20,400	7.48	\$148,000

MI=minimally invasive; QALY=quality-adjusted life year; THR=total hip replacement.

The MCS showed that if the common Canadian economic threshold of \$50,000 per QALY is adopted, the probability that MI THR would be more cost-effective than standard THR is 47%, which confirms the uncertainty about the cost-effectiveness of this procedure. The value of information analysis found that most of the uncertainty stems from the relative effectiveness of the procedures. The analysis found that it would be cost-effective to spend up to \$480 million on research to eliminate this uncertainty, while focusing on short-term costs and utilities, and long-term revision rates.

4 Limitations

The conclusions from the clinical review were limited by the lack of data, particularly on the long-term differences between MI and standard THR. The conclusions from the economic analysis were similarly limited because of uncertainty about the estimates of costs and utilities, and the small number of patients in the Canadian RCT that supplied the estimates. In addition, the absence of data on the long-term differences between the two surgical techniques led to the assumption that there are no differences between them, which was tested in the MCS. When no Canadian data were available, data from other countries were sometimes incorporated into the Markov model and assumed to be relevant. Furthermore, the limited quantity of data did not allow for subgroup analysis.

5 Health Services Impact

Between 1995 and 2002, the number of THRs increased in Canada by 1% per annum. Given the same annual increase and the fact that there were 19,997 THRs in 2002, of which 86.9% were primary, it can be forecasted that there would be 18,246 primary THRs in 2007. In 2002, 9% of all THRs were MI procedures.¹ If, in 2007, 25% of procedures were MI, and the incremental cost for initial hospitalization for MI THR compared with standard THR was \$1,316, the increased cost

would be \$3.8 million. This budget impact would be higher or lower, depending on the percentage of MI THRs.

6 Conclusions

Despite the number of studies identified, there was little evidence of any longer-term differences between MI THR and standard THR. This is mainly because of the lack of data available. In addition, surrogates for longer-term outcomes provided insufficient information with which to make judgements about longer-term performance. Overall, it seems likely that the MI approach offers some peri-operative advantages regarding blood loss and operative time, although these may be of limited clinical significance. The MI approach may also offer a shorter recovery period, as identified by the shorter length of hospital stay and time to return to usual activities.

Two economic evaluations of MI THR were identified. Both were of poor quality and did not provide useful information.

The economic analysis found little difference between therapies in costs and QALYs. Single-incision MI THR was more expensive with more QALYs. The incremental cost per QALY gained was \$148,000. The results were sensitive to changes in parameters, and value of information analysis confirms the benefit from conducting more research.

In conclusion, given the level of clinical evidence available and the results of the economic evaluation, greater value seems to be gained from conducting a larger definitive RCT focusing on long-term revision rates rather than providing funding for the expansion of MI THR.

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