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Arthroscopic Lavage and Debridement for Osteoarthritis of the Knee

An Evidence-Based Analysis

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The Medical Advisory Secretariat also provides a secretariat function and evidence-based health technology policy analysis for review by the Ontario Health Technology Advisory Committee (OHTAC).

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Executive Summary

Objective

The purpose of this review was to determine the effectiveness and adverse effects of arthroscopic lavage and debridement, with or without lavage, in the treatment of symptoms of osteoarthritis (OA) of the knee, and to conduct an economic analysis if evidence for effectiveness can be established.

Questions Asked

- Does arthroscopic lavage improve motor function and pain associated with OA of the knee?
- Does arthroscopic debridement improve motor function and pain associated with OA of the knee?
- If evidence for effectiveness can be established, what is the duration of effect?
- What are the adverse effects of these procedures?
- What are the economic considerations if evidence for effectiveness can be established?

Clinical Need

Osteoarthritis, the most common rheumatologic musculoskeletal disorder, affects about 10% of the Canadian adult population. Although the natural history of OA is not known, it is a degenerative condition that affects the bone cartilage in the joint. It can be diagnosed at earlier ages, particularly within the sports injuries population, though the prevalence of non-injury-related OA increases with increasing age and varies with gender, with women being twice as likely as men to be diagnosed with this condition. Thus, with an aging population, the impact of OA on the health care system is expected to be considerable.

Treatments for OA of the knee include conservative or nonpharmacological therapy, like physiotherapy, weight management and exercise; and more generally, intra-articular injections, arthroscopic surgery and knee replacement surgery. Whereas knee replacement surgery is considered an end-of-line intervention, the less invasive surgical procedures of lavage or debridement may be recommended for earlier and more severe disease. Both arthroscopic lavage and debridement are generally indicated in patients with knee joint pain, with or without mechanical problems, that are refractory to medical therapy. The clinical utility of these procedures is unclear, hence, the assessment of their effectiveness in this review.

Lavage and Debridement

Arthroscopic lavage involves the visually guided introduction of saline solution into the knee joint and removal of fluid, with the intent of extracting any excess fluids and loose bodies that may be in the knee joint. Debridement, in comparison, may include the introduction of saline into the joint, in addition to the smoothening of bone surface without any further intervention (less invasive forms of debridement), or the addition of more invasive procedures such as abrasion, partial or full meniscectomy, synovectomy, or osteotomy (referred to as debridement in combination with meniscectomy or other procedures). The focus of this health technology assessment is on the effectiveness of lavage, and debridement (with or without meniscal tear resection).

Review Strategy

The Medical Advisory Secretariat followed its standard procedures and searched these electronic

databases: Ovid MEDLINE, EMBASE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews and The International Network of Agencies for Health Technology Assessment.

The keywords searched were: arthroscopy, debridement, lavage, wound irrigation, or curettage; arthritis, rheumatoid, osteoarthritis; osteoarthritis, knee; knee or knee joint.

Time frame: Only 2 previous health technology assessments were identified, one of which was an update of the other, and included 3 of 4 randomized controlled trials (RCTs) from the first report. Therefore, the search period for inclusion of studies in this assessment was January 1, 1995 to April 24, 2005.

Excluded were: case reports, comments, editorials, and letters. Identified were 335 references, including previously published health technology assessments, and 5 articles located through a manual search of references from published articles and health technology assessments. These were examined against the criteria, as described below, which resulted in the inclusion of 1 health technology assessment and its corresponding update, and 4 articles (2 RCTs and 2 level 4 studies) for arthroscopic lavage and 8 papers (2 RCTs and 6 level 4 studies) for arthroscopic debridement.

Inclusion Criteria

- English-language articles from PubMed, EMBASE, Cochrane Systematic Reviews, and health technology assessments from January 1, 1995 onward
- Studies on OA of the knee with a focus on the outcomes of motor function and pain
- Studies of arthroscopic procedures only
- Studies in which meniscal tear resection/meniscectomy (partial or full) has been conducted in conjunction with lavage or debridement.

Exclusion Criteria

- Studies that focus on inflammatory OA, joint tuberculosis, septic joints, psoriatic joints (e.g., psoriatic knee joint synovitis), synovitis, chondropathy of the knee and gonarthrosis (which includes varotic gonarthrosis)
- Studies that focus on rheumatoid arthritis
- Studies that focus on meniscal tears from an acute injury (e.g., sports injury)
- Studies that are based on lavage or debridement for microfracture of the knee
- Studies in which other surgical procedures (e.g., high tibial osteotomy, synovectomy, have been conducted in addition to lavage/debridement)
- Studies based on malalignment of the knee (e.g., varus/valgus arthritic conditions).
- Studies that compare lavage to lavage plus drug therapy
- Studies on procedures that are not arthroscopic (i.e., visually guided) (e.g., nonarthroscopic lavage)
- Studies of OA in children.

Intervention

- Arthroscopic lavage or debridement, with or without meniscectomy, for the treatment of motor function symptoms and pain associated with OA of the knee.

Comparators

- Studies in which there was a comparison group of either diseased or healthy subjects or one in which

subjects were their own control were included. Comparisons to other treatments included placebo (or sham) arthroscopy. Sham arthroscopy involved making small incisions and manipulating the knee, without the insertion of instruments.

Summary of Findings

In early OA of the knee with pain refractory to medical treatment, there is level 1b evidence that:

Arthroscopic lavage gives rise to a statistically significant, but not clinically meaningful effect in improving pain (WOMAC pain and VAS pain) up to 12 months following surgery. The effect on joint function (WOMAC function) and the primary outcome (WOMAC aggregate) was neither statistically nor clinically significant.

In moderate or severe OA of the knee with pain refractory to medical treatment, there is:

Level 1b evidence that the effect on pain and function of arthroscopic lavage (10 L saline) and debridement (with 10 L saline lavage) is not statistically significant up to 24 months following surgery.

Level 2 evidence that arthroscopic debridement (with 3 L saline lavage) is effective in the control of pain in severe OA of the medial femoral condyle for up to 5 years.

For debridement in combination with meniscectomy, there is level 4 evidence that the procedure, as appropriate, might be effective in earlier stages, unicompartmental disease, shorter symptom duration, sudden onset of mechanical symptoms, and preoperative full range of motion. However, as these findings are derived from very poor quality evidence, the identification of subsets of patients that may benefit from this procedure requires further testing.

In patients with pain due to a meniscal tear, of the medial compartment in particular, repair of the meniscus results in better pain control at 2 years following surgery than if the pain is attributable to other causes. There is insufficient evidence to comment on the effectiveness of lateral meniscus repair on pain control.

Conclusions

Arthroscopic debridement of the knee has thus far only been found to be effective for medial compartmental OA. All other indications should be reviewed with a view to reducing arthroscopic debridement as an effective therapy.

Arthroscopic lavage of the knee is not indicated for any stage of OA.

There is very poor quality evidence on the effectiveness of debridement with partial meniscectomy in the case of meniscal tears in OA of the knee.

Abbreviations

CI Confidence interval
OA Osteoarthritis
RCT Randomized controlled trial
SD Standard deviation
TKR Total knee replacement

Self-reported pain and function scales reported in this review

AIMS2: Arthritis Impact Measurement Scales
AIMS2-WB: 5-item walking-bending subscale of the AIMS2; transformed to range 0–100, higher score = worse function

KSPS: Knee Specific Pain Scale; range 0–100; higher score = more severe pain

Lysholm: Modified Lysholm for pain; range 0–70, higher score = better pain

VAS pain: Transformed to range 0–100; higher score = worse pain

WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index:

- Aggregate score: summation of pain, function and stiffness subscales, range 0–96; higher scores = worse overall pain and function
- Pain score: subscale, range 0–20; higher score = worse pain
- Function score: subscale, range 0–68; higher score = worse function

Objective

The purpose of this systematic review was to determine the effectiveness and adverse effects of arthroscopic lavage and debridement, with or without lavage, to treat symptoms of osteoarthritis (OA) of the knee, and to conduct an economic analysis if evidence for effectiveness can be established.

Background

Clinical Need: Target Population and Condition

Osteoarthritis, the most common rheumatologic musculoskeletal disorder, affects about 10% of the Canadian adult population. (1) The natural history of this disease, which is a degenerative condition that affects the bone cartilage in the joint, is unknown. It can be diagnosed at earlier ages, particularly within the sports injuries population, but the non-injury-related prevalence increases with increasing age and varies with gender, with women twice as likely as men to be diagnosed with OA. Thus, with an aging population, its impact on the health care system will be considerable.

Although OA can affect all joints, the focus of this health technology assessment is on OA of the knee. The American College of Rheumatology's diagnostic criteria includes pain in the knee and otherwise varies with the type of findings. For patients that have their medical history taken and a physical exam only, 3 of the following conditions must also exist: age over 50 years, less than 30 minutes of morning stiffness, crepitus on active motion, bony tenderness, bony enlargement, or no palpable warmth of synovium. When radiographic findings are available in addition to findings from the history taking and physical exam, the presence of only one of these additional conditions may result in a diagnosis of OA of the knee. For patients with laboratory findings in addition to findings from the history taking and physical exam, the diagnostic criteria include pain and at least 5 of the following: age over 50 years, less than 30 minutes of morning stiffness, crepitus on active motion, bony tenderness, bony enlargement, no palpable warmth of synovium, eosinophil sedimentation rate (ESR) < 40mm/hr, rheumatoid factor < 1:40 or synovial fluid signs of OA. (2)

The natural history of OA of the knee is unclear, yet it is known that the disease process produces various pathological changes, such as the development of meniscal tears; chondral damage, including the development of cartilage flaps and loose bodies; osteophyte (i.e., bone spur) formation; mechanical malalignment, and soft-tissue contraction. (3) Different arthroscopic procedures exist for different aspects of OA. The presenting pathology determines which surgical procedure is needed.

The severity of disease may be an important determinant of treatment outcome. The most commonly used method of determining OA severity of the knee is the Outerbridge scale; this method accounts for articular degeneration by knee compartment with each of the 5 Outerbridge grades of degeneration described below: (4)

- Grade 0: Normal articular cartilage
- Grade I: Softening or blistering of joint cartilage
- Grade II: Cartilage fragmentation or fissuring on the surface, < 1 cm in diameter
- Grade III: Cartilage fragmentation or fissuring > 1 cm in diameter
- Grade IV: Cartilage erosion down to subchondral bone

With grade 0, there is no observed damage to the articular cartilage, whereas with grades I and II,

moderate degeneration is seen. Grade III indicates damage to a greater area (> 1 cm diameter), and grade IV is the most severe form of degeneration.

Treatments for OA of the knee include conservative or nonpharmacological therapy, like physiotherapy, weight management and exercise; and more generally, intra-articular injections, arthroscopic surgery and knee replacement surgery. Whereas knee replacement surgery is considered an end-of-line intervention, the less invasive surgical procedures of lavage or debridement have been recommended in the literature for earlier disease, and knee joint pain, with or without mechanical problems, that is refractory to medical therapy. For these patients, however, the use of intra-articular injections remains a nonsurgical option.

Existing Treatments Other Than Technology Being Reviewed

Treatments for OA of the knee that is refractory to drug treatment, other than arthroscopic lavage or debridement, include intra-articular injections, other surgical interventions such as cartilage repair techniques, osteotomy, and total knee replacement. (3) Progression through the clinical pathway, however, is not linear, with treatment dependent on factors such as disease severity, patient preference, and even the medical specialty of the physician the patient sees. For example, if a rheumatologist sees a patient, than the patient is more likely to receive intra-articular injections, while an orthopedic surgeon will likely recommend surgical procedures. In addition, some patients prefer not to have invasive surgery such as knee replacement; instead, they would prefer the less invasive injections and/or arthroscopic procedures.

In this health technology assessment, only the effectiveness of arthroscopic lavage and debridement are addressed. The effectiveness of intra-articular injections of Hyalgan, a hyaluronic therapy to treat OA knee pain, and the effectiveness of unicompartmental knee replacement or total knee replacement are examined in other health technology assessments of the Medical Advisory Secretariat.

Technology Being Reviewed: Arthroscopic Lavage and Debridement

History of Arthroscopic Procedures

Arthroscopic surgery for degenerative disease of the knee was first introduced in 1934 by Burman, Finkelstein, and Mayer. (3) However, early debridement techniques such as those by Magnuson and Haggart were based on open (nonarthroscopic) procedures, and their use was limited due to unacceptable levels of morbidity and prolonged recovery time. Improvement of arthroscopic techniques in the 1970s gave rise to procedures associated with less morbidity and quicker recovery times; hence, the re-emergence of interest in these less invasive forms of knee surgery. (3)

Lavage and Debridement

Arthroscopic lavage involves the visually guided introduction of saline solution into the knee joint and the removal of fluid, in effect, to “wash out” by removing any excess fluid and loose bodies that might be in the knee joint.

In comparison, debridement may include the introduction of saline into the joint, in addition to the smoothening of bone surface without any further intervention, or debridement in combination with other procedures such as abrasion, partial or full meniscectomy, synovectomy, or osteotomy. The focus of this health technology assessment is on lavage and debridement (with or without meniscal tear resection, also

referred to as a meniscectomy).

Literature Review on Effectiveness

Objective

The aim of this review was to determine the effectiveness and adverse effects of arthroscopic lavage and debridement (with and without meniscectomy) to treat symptoms of OA of the knee, and to conduct an economic analysis if evidence for effectiveness can be established.

Questions Asked

- Does arthroscopic lavage improve motor function and pain associated with OA of the knee?
- Does arthroscopic debridement, with or without meniscectomy, improve motor function and pain associated with OA of the knee?
- If evidence for effectiveness can be established, what is the duration of effect?
- What are the adverse effects of these procedures?
- What are the economic considerations if evidence for effectiveness can be established?

Methods

The Medical Advisory Secretariat followed its standard search procedures and searched these electronic databases: Ovid MEDLINE, EMBASE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews and The International Network of Agencies for Health Technology Assessment.

The keywords searched were: arthroscopy, debridement, lavage, wound irrigation, or curettage; arthritis, rheumatoid, osteoarthritis; osteoarthritis, knee; knee or knee joint.

Only 2 previous health technology assessments were identified, one of which was a 2005 update (5) of a 2003 report (6), and included 3 of 4 randomized controlled trials (RCTs) from the earlier report. Therefore, the search period for inclusion of studies in this assessment was January 1, 1995 to April 24, 2005.

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- Studies that focus on rheumatoid arthritis
- Studies that focus on meniscal tears from an acute injury (e.g., sports injury)
- Studies that are based on lavage or debridement for microfracture of the knee
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- Studies that compare lavage to lavage plus drug therapy.
- Studies on procedures that are not arthroscopic (i.e., visually guided) (e.g., nonarthroscopic lavage)
- Studies of OA in children.

Intervention

- Arthroscopic lavage or debridement, with or without meniscectomy, for the treatment of motor function symptoms and pain associated with OA of the knee.

Comparators

- Studies in which there was a comparison group of either diseased or healthy people, or one in which subjects were their own controls were included. Comparisons to other treatments included placebo (or sham) arthroscopy. Sham arthroscopy involves making small incisions and manipulating the knee without inserting any instruments. (6)

Outcomes of Interest

- Motor function, disability
- Pain
- Quality of life.

Results of Literature Review

Included in this review are 2 RCTs (7;8) on the effectiveness of arthroscopic lavage and 2 RCTs on the effectiveness of arthroscopic debridement. (7;9) The Moseley trial (7) examined the effectiveness of lavage and debridement (with lavage) relative to placebo, and has been included in the lavage and debridement sections of this review.

Level 4 studies, which include descriptive analyses of cohorts or case series, whether derived from a clinical sample or a population-based database, were also identified. Two pertain to arthroscopic lavage, (10;11) and 6 level 4 studies are specific to arthroscopic debridement. (12-16)

Summary of Existing Health Technology Assessments

The Medical Advisory Secretariat found 2 English-language health technology assessments. These were specific to arthroscopic lavage and conducted by the Wessex Institute in the United Kingdom. The initial

report was published in 2003, (6) and the recent update was published in June 2005 (5). One additional review, a collaborative effort between the Agency for Healthcare Research and Quality (AHRQ) and the Centers for Medicare & Medicaid Services (CMS) in the Unites States intended for Medicare coverage funding recommendations, was based on an evaluation of the evidence for both lavage and debridement.

A Cochrane Collaboration protocol was also identified, (17) for which a report is not yet available.

One English-language summary of a health technology assessment published in 1994 by l'Agence Nationale d'Accréditation et d'Evaluation en Santé in France (ANAES) predates the search period for the Medical Advisory Secretariat review; therefore, it was not included.

The authors and focus of the health technology assessments for arthroscopic procedures for OA of the knee are outlined in Table 1.

Table 1: Summary and Focus of Previous Health Technology Assessments and Ongoing Assessments of Arthroscopic Procedures in Osteoarthritis of the Knee

Year	Author	Focus of Assessment
2005	The Cochrane Collaboration protocol	Appropriate use of arthroscopic debridement on knee OA*
2005	The Wessex Institute, update of 2003 report	Effects of arthroscopic lavage, with or without debridement, in people with OA of the knee
2004	Centers for Medicare & Medicaid Services	Impact of arthroscopic lavage alone, or debridement (used alone or not otherwise stated), on reduction of pain and improvement of function

*OA indicates osteoarthritis.

Summary of Findings on Effectiveness

The findings and conclusions on the effectiveness of arthroscopic lavage/debridement from the health technology assessments and CMS review are summarized below, followed by the analysis of the Medical Advisory Secretariat.

The Wessex Institute, United Kingdom, 2005 (Update of 2003 Report) (5)

Arthroscopic lavage for osteoarthritis of the knee

Objective: To determine the effects of arthroscopic lavage, with or without debridement, in people with OA of the knee

Search Date: December 2002 to December 2004

Studies Included	Comments	Conclusions

4 RCTs* (3 of which were in 2003 report)	➢ Arthroscopic lavage involves washing out joint space with saline solution. ➢ Debridement involves lavage and removal of debris and trimming or shaving of rough surfaces.	➢ Findings in the direction of no effect, though quality of studies are generally poor, with all RCTs lacking in power. ➢ (Note: Hubbard and Kalunian trials have not been included.)

*RCT indicates randomized controlled trial.

The Wessex Institute, United Kingdom, 2003 (6)

Arthroscopic lavage for knee osteoarthritis

Objective: To determine the effects of arthroscopic lavage, with or without debridement, in people with OA of the knee

Search Date: 1966 to December 2002

Studies Included	Comments	Conclusions
5 RCTs* 2 non-RCTs	➢ Arthroscopic lavage involves washing out joint space with saline solution. ➢ Debridement involves lavage and removal of debris and trimming or shaving of rough surfaces.	➢ One good-quality RCT that arthroscopic debridement or lavage did not improve patient-reported pain and function at 2 years compared with sham arthroscopy in men.

*RCT indicates randomized controlled trial.

Three of the 4 RCTs in the 2005 update were in the previous report from 2003. These were the RCTs by Moseley et al. (7), Chang et al. (18) and Ward et al. (19) The Moseley trial will be described in detail in this review. The 2003 report, however, refers to it as a good-quality study, whereas in the 2005 update the authors suggest it may be underpowered.

The trial by Chang et al., which was published in 1993, found no difference in pain or function at 1 year for arthroscopic lavage with debridement compared to nonarthroscopic lavage. However, the sample size for this trial was 32 patients; therefore, the non-significant differences could have been owing to low study power.

The RCT by Ward et al. similarly reported no significant difference in pain or function at 1 year in 51 patients randomized to either arthroscopic or non-arthroscopic lavage. However, the sample size of this study also was also small, and their conclusion is published in abstract form only, with minimal data with which to assess the quality of the study.

The fourth RCT, published in 2003 by Forster et al., (20) was included in the 2005 update but had not been in the 2003 report. This RCT compared 38 patients randomized to receive either arthroscopic lavage (with debridement, if necessary) or 5 intra-articular injections with Hyalgan. No significant difference was detected between the 2 groups for pain or function at 1 year, although the study was underpowered. The exclusion of patients with mechanical symptoms further restricts the generalizability of the findings to the OA population.

In summary, the Wessex Institute reported there was insufficient evidence to determine the effectiveness of arthroscopic lavage or debridement in the treatment of OA of the knee.

Centers for Medicare & Medicaid Services (CMS), United States, 2004 (21)
Arthroscopic lavage and arthroscopic debridement for the osteoarthritic knee

Objective: To determine the effects of arthroscopic lavage, with or without debridement, in people with OA of the knee

Search Date: December 2002 to December 2004

This report was based on a review of the evidence to develop insurability guidelines for the 2 procedures. Their recommendations are presented in the table below.

Studies Included	Comments	Conclusions
4 RCTs* (3 of which were in previous report)	➢ Arthroscopic lavage involves washing out joint space with saline solution. ➢ Debridement involves lavage and removal of debris and trimming or shaving of rough surfaces.	➢ Evidence adequate to conclude that lavage alone is not reasonable or necessary for OA* of the knee. ➢ Evidence adequate to conclude that debridement is not reasonable or necessary for patients with knee pain only or severe OA (Outerbridge grade III or IV). All other indications of debridement for OA of the knee remain at contractor discretion.

*RCT indicates randomized controlled trial; OA, osteoarthritis.

Cochrane Collaboration protocol, 2005 (17)

Arthroscopic debridement for knee osteoarthritis (Protocol)

Objective: To estimate the effectiveness of arthroscopic debridement in OA of the knee with respect to pain reduction (reduced use of relevant medications) and/or functional improvement. Secondary objectives were to observe the type or stage of severity of the OA in which arthroscopic debridement is most effective, and the expected length of effectiveness until patients need further intervention.

The final report has not yet been published.

Summary of Medical Advisory Secretariat Review

The evidence for arthroscopic lavage is presented first, followed by that for arthroscopic debridement. Table 2 outlines the quality of the evidence for the effectiveness of arthroscopic lavage, as defined by the Medical Advisory Secretariat, for arthroscopic lavage alone.

Table 2: Quality of Evidence of Studies for Lavage in Osteoarthritis of the Knee

Study Design	Level of Evidence	Number of Eligible Studies
Systematic reviews of RCT*	1a	0
Large RCT	1b	2

Large RCT unpublished but reported to an international scientific meeting	1(g)†	0
Small RCT	2	0
Small RCT unpublished but reported to an international scientific meeting	2(g)	0
Non-RCT with contemporaneous controls	3a	0
Non-RCT with historical controls	3b	0
Non-RCT presented at international conference	3(g)	0
Surveillance (database or register)	4a	0
Case series (multisite)	4b	0
Case series (single site)	4c	2
Retrospective review, modeling	4d	0
Case series presented at international conference	4(g)	0

*RCT refers to randomized controlled trial.
†g indicates grey literature.

Randomized Clinical Trials – Arthroscopic Lavage

Two RCTs (both level 1b) were identified for the assessment of the effectiveness of arthroscopic lavage. In general, patients were eligible for arthroscopic intervention if they were refractory to medical management. Inclusion and exclusion criteria for patient selection were as shown in Table 3.

Table 3: Methods, Including Inclusion and Exclusion Criteria, for 2 Included Randomized Controlled Trials

Author, Year	Study Design, Follow-up Period	Inclusion Criteria	Exclusion Criteria
Kalunian et al., 2000 (8)	Multicentre RCT*, 12 mos	Early disease: symptom duration ≤ 5 yrs and normal/minimally abnormal radiographs; age > 40 yrs; knee pain ≤ 10 yrs; unsatisfactory pain relief despite ≥ 6 wks physical therapy and ≥ 6 wks drug therapy. Willingness to attend follow-up visits; informed consent.	Significant back/hip, ankle/ foot disease to confuse assessment of knee pain; ICI* within 1 month of enrollment; significant degeneration (Kellgren/Lawrence grades 3–4); BMI* > 35 kg/m^2; sensitivity to amide anesthetics; serious medical illness; recent history of substance abuse.
Moseley et al., 2002 (7)	Single-centre RCT, 24 months	Age ≤ 75 yrs; at least moderate knee pain despite maximal medical treatment for > 6 mos; no knee arthroscopy in previous 2 yrs; informed consent.	Severity ≥ 9 (on scale of 0–12) based on radiographic findings of 3 knee compartments; severe deformity; serious medical problems.

*RCT indicates randomized controlled trial; ICI, intra-articular corticosteroid injection; BMI, body mass index.

A double-blinded (where neither the patients nor the assessors of outcomes knew which subjects received the treatment) multicentre RCT by Kalunian et al. in 2000 (8) assessed the effects on pain and function of arthroscopic irrigation with 3,000 ml of saline solution (treatment) compared with minimal irrigation (250

ml saline) in the control arm. This study was based on 90 patients with early OA, who were defined as having had symptoms for less than or equal to 5 years, with normal or minimally abnormal radiographs. Patients were recruited from 4 centres in the United States. All had pain that was refractory to standard therapy (inclusion criteria detailed in Table 3 above).

The primary outcome of interest was the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) aggregate score at 12 months, a combination of the subscales of pain, stiffness, and function. Secondary outcomes included the WOMAC subscales of pain (range 0–20), stiffness, (range 0–8) and function (range 0–68), in addition to an assessment of pain using the visual analogue scale (VAS). All pain measurements were based on self-reports.

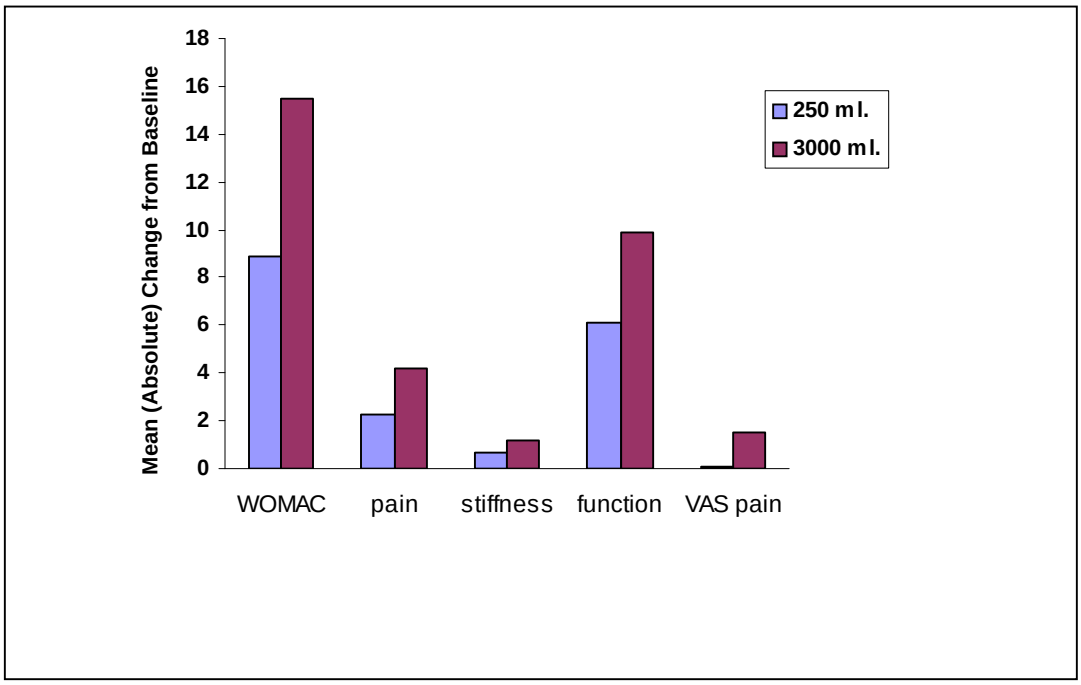
The intervention in this study was irrigation with 3 L of a saline solution. The control group received irrigation with 250 ml saline, the least amount of solution to enable arthroscopy. Although referred to as a placebo, 250 ml saline irrigation is considered to have some therapeutic benefit. Therefore, the comparison of relative effectiveness between the 2 arms should take into account the potential therapeutic effect of the saline irrigation on patients in the control group, and thus the likely underestimation of relative improvement in outcome.

The mean age of participants was 58.3 years (range, 40–85 years) in the treatment arm and 60.9 years (range, 41–88 years) in the control arm. Baseline characteristics were similar between groups, except that those in the treatment group had significantly higher physician ratings of knee swelling ($P = .01$). Baseline aggregate WOMAC scores were 41.09 and 40.67 for the treatment and control groups, respectively ($P = .64$).

At 12 months, there was no statistically significant (absolute) change from baseline in the aggregate WOMAC score ($P = .10$), WOMAC stiffness ($P = .22$) and WOMAC function ($P = .15$). However, the WOMAC pain ($P = .04$) and VAS pain scores ($P = .02$) were significantly improved at 12 months from baseline in the treatment group. (However, please see MAS analysis on a clinically meaningful difference on page 20).

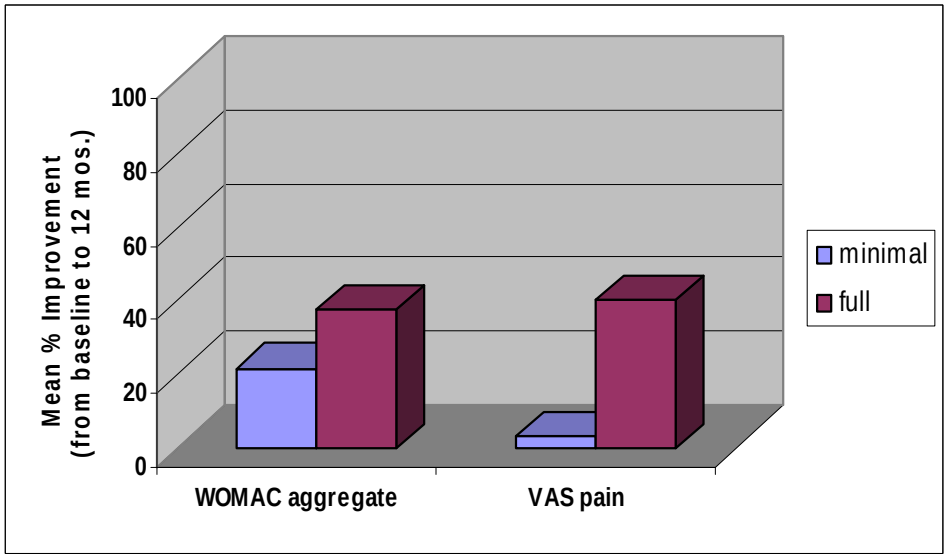
Figure 1 shows the mean absolute improvement in the treatment (full irrigation) and control (minimal irrigation) groups for each of the outcome measures. It is important to note that the range of the y-axis in Figure 1 (from 0–16) was selected to reflect the magnitude of change in the different measures; it is not a reflection of the actual range of possible values for the different measures along the x-axis. The actual range for the aggregate WOMAC score is 0 to 96, whereas the range of values for the subscales of WOMAC pain is 0 to 20; for WOMAC function, it is 0 to 68.

Figure 1: Mean Absolute Improvement in Pain and Function at 12 Months



Another measure of effectiveness is the percent change from baseline, which requires a baseline score. In this study, baseline scores were reported for the aggregate WOMAC and VAS pain scores only, and the percent change at 12 months was calculated as a proportion of the baseline value: [(baseline - value at 12 months) / baseline value x 100]. As shown in Figure 2, the percent improvement at 12 months in the aggregate WOMAC score was 37.7% [or (41.1-25.6) / 41.1] for the treatment (full irrigation) arm and 21.9% [or (40.7-31.8) / 40.7] for the control (minimal irrigation) arm. The percent improvement in VAS pain was 45.5% [or (3.7-2.2) / 3.7] and 2.8% [or (3.6-3.5) / 3.6] for the treatment and control arms, respectively.

Figure 2: Mean Percent Improvement in Aggregate WOMAC and VAS Pain at 12 Months



For this health technology assessment, the Medical Advisory Secretariat imposed an additional criterion for significance of the findings. This was based on a clinically meaningful difference in absolute change from baseline. The literature on values for clinical significance (or cut-offs) varies with the measurement tool, and there is much uncertainty in the field regarding the application of these cut-offs. That is, the uncertainty pertains to whether the 'clinically meaningful' change from baseline be examined within the one arm of the RCT (as a pre-post assessment), or as the difference between the 2 arms. The answers to these questions may differ with the comparison groups in each trial. For example, in trials of arthroscopic surgery where the placebo effect is known to be large, (e.g., a 20%–30% improvement from baseline [Personal communication, clinical expert, June 2005]), a comparison between the treatment and placebo arms may lead to an underestimation of clinical effect. After all, if there were no clinically meaningful difference between the arms, one would not offer the patient a placebo or sham surgery. Perhaps, then, clinical effectiveness of the procedure is best described relative to another intervention, such as total knee replacement.

For these reasons, the assessment of a clinically meaningful difference will be conducted on the absolute change at 12 months from baseline within each arm separately. This is the recommended assessment for the WOMAC subscales of pain and function [Personal communication, clinical expert, June 2005], with the minimal clinically important difference (MCID) of 1.6/20 points for improvement in pain, and 2.2/20 points for worsening of pain. The criterion for function is 5.44/68 points for improvement and 9.04/68 for worsening. In addition to these specific cut-offs, however, interpretation of a clinically significant difference in this report also took into account the uncertainty about these cut-offs, that is, in terms of a confidence interval. An MCID for the WOMAC aggregate score does not exist (Personal communication, clinical expert, June 2005).

Based on these criteria for the WOMAC pain subscale and a mean absolute improvement of 4.2 (95% confidence interval [CI], - 0.9–9.4) in the treatment group (scale range from 0–20), there was a clinically meaningful improvement in pain for lavage. The mean improvement of 2.3 (95% CI, -0.1–4.7) in the control group (250 ml saline) arm was also clinically meaningful. However, when the cut-offs were applied to the difference between the two arms, the value of 1.9 (difference between 4.2 and 2.3) was considered not clinically meaningful, as this value was within the 95%CI for the specific cut-off of 1.6/20 points.

On the WOMAC function subscale, the mean absolute improvement from baseline was 9.9 (95% CI, 4.9–13.0) for the lavage group, and 6.1 (95% CI, 2.8–9.4) for the control group. The difference from baseline within each arm achieved the minimal clinically important effect, although the difference of 3.8 between the two arms was not clinically significant.

The second RCT (level 1b evidence), also double-blinded (patients and assessors of outcomes), was published by Moseley et al. in 2002. (7) Unlike the Kalunian trial, (8) this was a single-centre study with all interventions conducted by one orthopedic surgeon. Included in the Moseley trial were 180 patients with severe OA that had failed standard medical therapy. Participants were recruited from the Houston Veterans Affairs Medical Center from October 1995 through September 1998. They were eligible if they were aged younger than 75 years, had OA of the knee, reported at least moderate knee pain despite at least 6 months of medical treatment, and had not undergone arthroscopy of the knee in the previous 2 years. Patients were excluded if they had a severe deformity and serious medical problems. Patients known to have meniscal tears were also excluded (Personal communication with clinical expert, September, 2005).

The severity of OA was determined radiographically, as opposed to that derived from the aggregate WOMAC score in the Kalunian trial, and graded on a scale of 0 to 4 for each of the 3 knee quadrants, the

sum of which ranged from 0 to 12. Patients with a disease severity score of 9 or higher were excluded. The remaining patients were stratified into 3 groups according to disease severity (group 1: severity score of 1, 2 or 3; group 2: score of 4, 5, or 6; and group 3: score of 7 or 8), with randomization to debridement and lavage, lavage alone, or placebo, in a stratified randomization process with block sizes of 6. Allocation was sealed in envelopes that were numbered and opened in sequential order.

The 2 intervention arms were diagnostic arthroscopy and either lavage (lavage arm), or lavage plus debridement (debridement arm). The volume of saline lavage in both arms was 10 L. To maintain patient blinding, those in the placebo arm were prepped and draped, and kept in the operating room for as long as a debridement procedure, and 3 1-cm incisions were made in the skin. No saline was introduced into their joints, although saline was splashed to simulate the sounds of lavage.

Patients in the debridement arm underwent shaving of rough articular cartilage and/or removal of loose debris. For meniscal tears detected with arthroscopy, in either the lavage or debridement arms, this was treated with trimming of all torn or degenerated meniscal tears. As no arthroscopy was performed in the placebo arm, it was not possible to determine if meniscal tears existed in this group. Nevertheless, as randomization results in the distribution of all factors similarly in the 3 trial arms, it can be assumed that meniscal tears were present in the placebo group, but were not treated. There was no reporting of the percentage of patients with meniscal tears, nor whether the measures of pain or function were factors in these cases; therefore, it was not possible to determine the effect of this subgroup of patients on results.

All patients in the study had an overnight stay in hospital and were cared for by nurses that were also blinded to their treatment assignment.

Outcomes of interest in this study were pain and physical function. The primary end point was pain in the knee under study at 24 months, as assessed by a 12-item self-reported Knee Specific Pain Scale (KSPS) developed for this study. Score ranged from 0 to 100, with higher scores indicating more severe pain. To ensure the ability to detect any benefit, the authors used 5 secondary endpoints: 2 self-reported measures of pain and function each, and one objective function measure. One pain measure was the 4-item pain subscale of the Arthritis Impact Measurement Scale (or AIMS2-P), with higher scores indicating more pain. The second measure was of body pain, and not necessarily from arthritis or the knee, which was assessed as a 2-item pain subscale of the Medical Outcomes Study 36-item Short-Form General Health Survey (SF-36-P), with higher scores indicating less severe pain. AIMS2-P and SF-36-P scores were transformed into scores from 0 to 100.

Two self-reported measures of function include (i) the 5-item walking-bending subscale of the AIMS2 (AIMS2-WB), transformed into scores of 0 to 100, with higher scores indicating more limited function, and (ii) the 10-item physical function subscale from the SF-36 (SF-36-PF), transformed into scores from 0 to 100, with higher scores indicating more function. The one objective measure of function was the Physical Functioning Scale (PFS) to record amount of time in seconds required to walk 30 m (100 ft) and to climb up and down a flight of stairs as quickly as possible; longer times indicate poorer function.

With respect to pain as an outcome, the baseline KSPS measures for the placebo and the lavage arms were 49.4 and 50.2, respectively. The statistical comparisons in this study, however, were based on the difference between the 2 arms at 12 and 24 months. There was no significant difference in knee pain between the placebo and lavage groups at 12 months or at 24 months: mean absolute scores ±SD for placebo and lavage arms, respectively, were 48.9±21.9 and 54.8±19.8 (difference, $P = .14$) at 12 months, and 51.6∀23.7 and 53.7∀23.7 (difference, $P = .64$) at 24 months. Figure 3 shows the mean absolute change in KSPS scores for all 3 arms. Figure 4 shows the mean percent change in pain [(baseline - follow-up) / baseline]. The focus in both figures is on the placebo and lavage arms.

Figure 3: Mean Absolute Change in Knee Pain at 12 and 24 Months

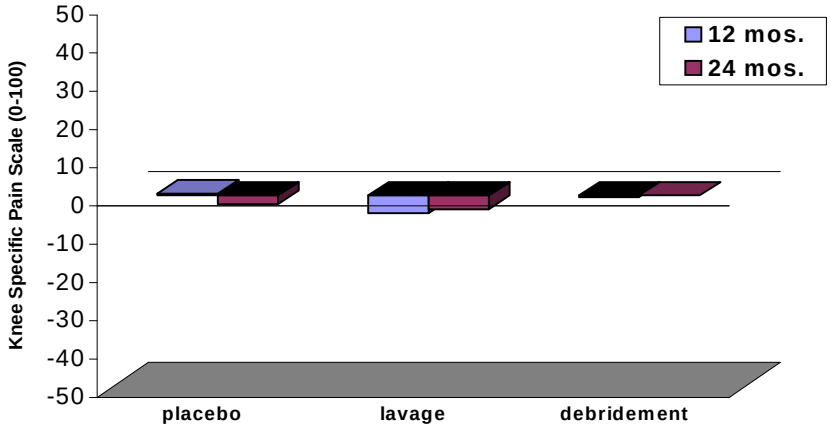
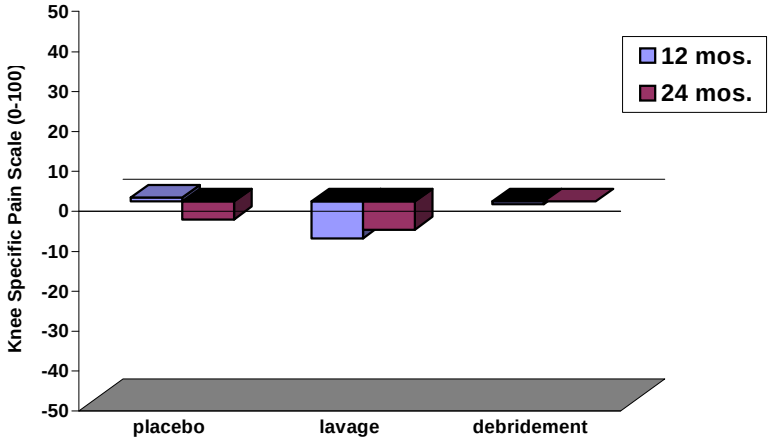


Figure 4: Mean Percent Change in Knee Pain From Baseline to 12 and 24 Months



Similarly, there was no significant effect observed for function, as measured by the AIMS2-WB scale, at both time points. For placebo and lavage, respectively, the mean ±SD AIMS2-WB function scores were 49.4∀25.5 and 49.6∀29.1 (difference, *P* = .98) at 12 months, and 53.8∀27.5 and 51.1∀28.3 (difference, *P* = .61) at 24 months. Figures 5 and 6 show the mean absolute change and percent change from baseline for function; the focus is on placebo and lavage.

Figure 5: Mean Absolute Change in Function at 12 and 24 Months

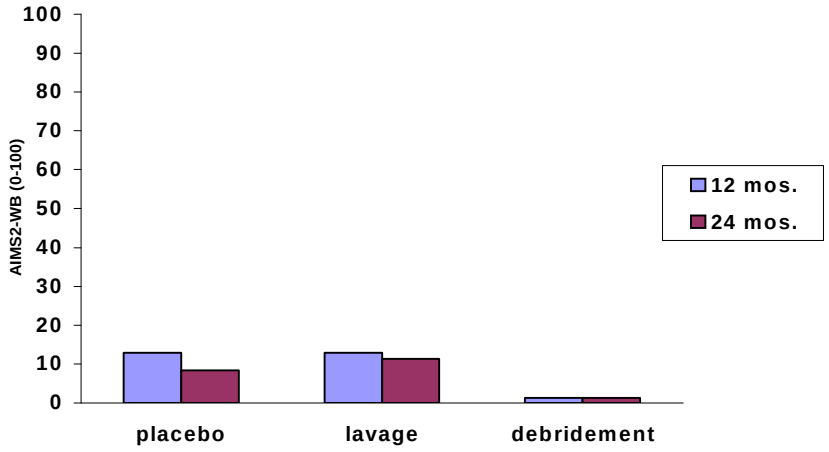
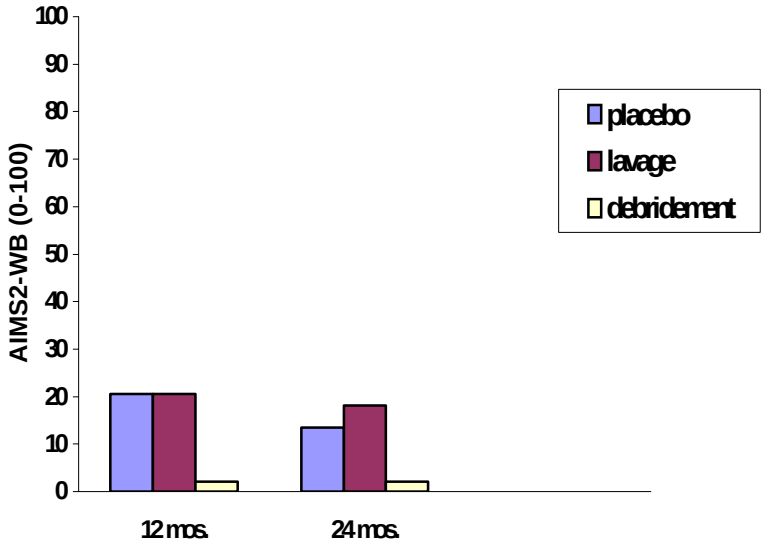


Figure 6: Mean Percent Change in Function From Baseline to 12 and 24 Months



The study was designed to have 90% power to detect an effect size of 0.55 (on pain) between the placebo arm and the combined arthroscopic treatment groups as measured by the SF-36-P at 2 years, with a 2-sided type I error of 0.04. Nevertheless, the primary outcome of interest was pain as measured by the

KSPS. Thus, the potential lack of study power has been a major criticism of this study.

A further point of discussion has been the volume of saline utilized in both the lavage and debridement arms of the study. A volume of 10 L, much larger than that used in the Kalunian trial (3 L), has been criticized as excessive and potentially resulting in hemarthrosis (bleeding in the joint), a condition that may interfere with the effectiveness of the procedure. (22)

Non-Randomized Clinical Studies

Two level 4c studies, both conducted in severe OA (Outerbridge grades III or IV), were identified. The case series by Bernard et al. (11) was based on 99 patients that had undergone arthroscopic lavage in the United Kingdom, with a follow-up of 5 years. They reported that within 5 years, 18% (n = 18) required further surgery which included total knee replacement (n=11, or 11%), a high tibial osteotomy (n=4, or 4%), and a unicondylar knee arthroplasty (n=3, or 3%).

The likelihood of a total knee replacement increased with age; among those aged 60 years or older, 32% required further surgery, while the rate was significantly lower (11%, $P = .02$) in those younger than 60 years.

The second case series was by Bohnsack et al. (10) in Germany. They reported on 104 patients with severe OA that had undergone arthroscopic lavage. The mean period of follow-up was 33.1 months (range 5–98 months), and 20% (n = 21) required further surgery within this period. Eight percent (n = 8) of the 104 patients underwent total knee replacement, 3% (n = 3) had a monocondylar knee arthroscopy, 2% (n = 2) had a high tibial osteotomy, and 4% (n = 4) had another arthroscopy.

Evidence for the Effectiveness of Arthroscopic Debridement

Table 4 outlines the quality of the evidence, as defined by the Medical Advisory Secretariat, for arthroscopic debridement.

Table 4: Quality of Evidence of Studies for Debridement in Osteoarthritis of the Knee

Study Design	Level of Evidence	Number of Eligible Studies
Systematic reviews of RCT*	1a	0
Large RCT	1b	1
Large RCT unpublished but reported to an international scientific meeting	1(g)†	0
Small RCT	2	1
Small RCT unpublished but reported to an international scientific meeting	2(g)	0
Non-RCT with contemporaneous controls	3a	0
Non-RCT with historical controls	3b	0
Non-RCT presented at international conference	3(g)	0
Surveillance (database or register)	4a	1
Case series (multisite)	4b	0
Case series (single site)	4c	5
Retrospective review, modeling	4d	0
Case series presented at international conference	4(g)	0

*RCT refers to randomized controlled trial.
†g indicates grey literature.

Randomized Clinical Trials

Two RCTs (one level 1b and one level 2 evidence) on arthroscopic debridement (7;9) met the inclusion and exclusion criteria for this assessment. The design and randomization process for the Moseley trial have been described above in the section on lavage. The results presented here are for the comparison of debridement with lavage to placebo. Inclusion and exclusion criteria have been included for both RCTs on debridement.

In the Moseley trial (level 1b evidence), there was no significant difference between the debridement and placebo arms at either 12 or 24 months. Baseline KSPS measures were 49.4 and 51.4 for the placebo and debridement arms, respectively. The statistical comparisons based on the difference between the arms at 12 and 24 months were as follows: absolute mean scores ∀SD at 12 months were 48.9∀21.9 and 51.7∀22.4 (difference, *P*=.51), and at 24 months they were 51.6∀23.7 and 51.4∀23.2 for placebo and debridement, respectively (difference, *P* = .96). Figure 3 shows the mean absolute change in KSPS scores for all 3 arms. Figure 4 shows the mean percent change in pain [(baseline – follow-up) / baseline]. The focus in both figures for this section is between the placebo and debridement arms.

Similarly, there was no significant effect observed for function, as measured by the AIMS2-WB scale, at both time points. For placebo and debridement, respectively, the mean AIMS2-WB function scores ±SD were 49.4∀25.5 and 56.4∀28.4 (difference, *P* = .19) at 12 months, and 53.8∀27.5 and 56.4∀29.4 (difference, *P* = .64) at 24 months. Figures 5 and 6 show the mean absolute change and percent change from baseline for function; the focus in this figure should be on placebo and debridement.

Table 5: Methods of Randomized Controlled Trials on Arthroscopic Debridement

Author, Year	Study Design, Follow-up Period	Inclusion Criteria	Exclusion Criteria
Hubbard et al., 1996 (9)	Single-centre RCT*, 5 yrs	On initial diagnostic arthroscopy: isolated degenerative lesions on medial femoral condyle of grade III or IV (Outerbridge classification); symptoms > 1 year; no previous knee surgery on same knee (surgery in contralateral knee permitted), laxity, deformity, other intra-articular pathology; normal plain radiograph, modified Lysholm score < 38/70. Subchondral sclerosis of grades I to III of medial femoral condyle accepted.	Knees with degenerative lesion other than medial femoral condyle, or any other intra-articular pathology; knees in which radiographs showed loss of joint space, had previous surgery or steroid injection for any reason.
Moseley et al., 2002 (7)	Single-centre RCT, 24 mos	Age ≤ 75yrs.; at least moderate knee pain despite maximal medical treatment for > 6 mos; no knee arthroscopy in previous 2 yrs; informed consent.	Severity ≥ 9 (on scale of 0–12) based on radiographic findings of 3 compartments of knee; severe deformity; serious medical problems.

*RCT indicates randomized controlled trial.

In the second RCT, considered level 2 evidence for its research design, but otherwise of poor quality, Hubbard et al. (9) reported on 76 patients with severe OA (Outerbridge grade III or IV) of the medial

femoral condyle that had suffered unremitting symptoms of the knee for 1 year before arthroscopy. The comparison in this study was between 2 intervention arms: debridement with lavage (3 L saline), and lavage alone (3 L saline). Physical examination at each review (at 3 and 12 months, and annually for 5 years postoperatively) included calculation of a modified Lysholm score, with a maximum of 70 points (excluding the usual 30 of 100 points for stability). The study's author evaluated all outcomes, as they report not being able to use blinded observers.

On entry to the trial, all patients had some tenderness over the medial joint line or medial femoral condyle, and all had an effusion. Full range of motion was from 0 to 140 degrees, and no patient had any obvious deformity.

At 1 year, there was no loss to follow-up, and the mean absolute improvement in symptoms from baseline, as measured by a modified Lysholm scale (range: 0–70, with higher scores representing less pain), was 28 points for the debridement arm and 5 points for the lavage arm. These changes were similar to those at 5 years (21 and 4 for debridement and lavage, respectively), though the loss to follow-up was about 25% at this second point.

The percentage of patients estimated to be pain-free (not defined in the report) at 1 year was 80% and 14% for the debridement and the lavage arms, respectively (difference, $P = .05$). At 5 years, the percentages were 59% and 10% for the debridement and lavage arms, respectively.

Overall, this study was of very poor quality, with no reporting or adjustment for procedures or other potential confounders over the 5-year period. As the loss to follow-up was about 25% at 5 years, results at 1 year might be more generalizable.

Non-Randomized Clinical Studies

One (level 4a) study by Wai et al. (23) described the utilization patterns of arthroscopic debridement (which includes debridement procedures with or without tibial osteotomy) from administrative files (OHIP database) for 1992 to 1996, inclusive. In those aged 50 years or over, 14,391 unilateral elective arthroscopic procedures were identified in this 5-year period, with about 3,000 being conducted annually (though fewer if tibial osteotomy procedures are excluded). Within 1 year of the procedure, 1,330 of all patients (9.2%) had had a total knee replacement, although patients aged 70 or older were 4.7 times more likely to have had this procedure than those under 60 years of age (19.0% vs. 4.0%, respectively, $P < .05$). A smaller proportion had had a second debridement (n = 399 or 2.8%) or high tibial osteotomy (n = 169 or 1.2%).

Within 3 years of surgery, 1,146 of the 6,212 patients (18.4%) with a minimum follow-up of 3 years had had a total knee replacement; 478 (7.7%) had a repeat debridement; and 178 (2.9%) had a high tibial osteotomy. A multivariate Cox proportional hazards model revealed a significant trend for higher rates of total knee replacement with increasing age in an unadjusted model and a model adjusted for gender and comorbid conditions ($P = .02$).

The authors concluded that arthroscopic debridement of the knee is effective and safe, and they recommended that the rates of subsequent surgeries be discussed with patients preoperatively. The limitations of this analysis include not having data (and therefore not adjusting) for other factors such as analgesic use and intra-articular injections, which may have an influence the timing of subsequent surgeries.

The 5 remaining studies (12-16) were considered level 4c evidence. Based on inclusion and exclusion

criteria for patient selection and the description of arthroscopic procedures reported in the methods section of each article, these studies were separated into 2 groups according to the invasiveness of the debridement. The more invasive debridement included resection of the meniscus (or meniscectomy), whereas the less invasive surgery did not.

In reviewing the evidence from these level 4 studies, it is important to recognize the limitations of these studies. Inherent in the case series included here are issues of information bias (reporting of effectiveness years after the procedure), selection bias, generalizability of results to other clinics/centres, inclusion of patients that are available years after the procedure only, lack of control of potential confounding bias, and inadequate information about additional treatments that may occur following the index arthroscopic procedure. Nevertheless, a review of these studies follows.

The study by McGinley et al. (12) evaluated the efficacy of arthroscopic debridement regarding patient satisfaction, return to function, and delaying or avoiding total knee replacement. Of 191 knees in patients older than 55 years of age identified as having undergone arthroscopic debridement as a temporizing procedure from 1981 to 1987, 77 patients (91 knees, or 48% of 191 knees) responded to a telephone interview conducted 10 or more years after arthroscopic debridement. Therefore, the potential for selection bias in this case series exits, and results should be interpreted with caution.

Symptoms included pain-limiting function and radiographic findings showed joint space narrowing. Each of the knees was deemed to have Outerbridge grade IV articular cartilage changes in at least one compartment of the knee, and was considered a potential candidate for osteotomy or total knee replacement. The authors describe the surgical procedure as nonaggressive arthroscopic debridement, which includes meniscal tear resection and nonaggressive shaving of frayed articular cartilage. Nevertheless, it has been included here as a more invasive form of debridement, as some patients had debridement with meniscectomy.

Thirty of the 91 knees, or 21 of 77 patients, had a total knee replacement within a mean of 6.7 years after arthroscopic debridement. The mean age of these 21 patients was 63.5 years (range, 57–72 years). Twenty-one patients (30 knees) had total knee arthroplasty at a mean of 6.7 years, whereas 7 patients had total knee arthroplasty within 2 years of arthroscopic debridement. Of the 7 knees replaced within 2 years of arthroscopy, 6 were found to have grade IV articular cartilage changes in more than 80% of the knee and had clinically significant meniscal tears, and 5 knees had a varus deformity as seen on radiographs. Relative to all patients who underwent a total knee replacement (n = 21), 8 (39%) had grade IV articular cartilage changes in at least 80% of one compartment. These data suggest that the severity of the degeneration (as defined by the extent of knee degeneration) may have an impact on the effectiveness of debridement, as well as the timing of the total knee replacement, with more severe disease resulting in a replacement earlier than less severe disease. Nevertheless, this analysis was based on a case series of OA patients reporting on surgical outcomes 10 or more years after the intervention, with a response rate of approximately 50% (i.e., there is a potential for selection bias).

In a prospective study, Krystallis et al. (14) compared the efficacy of arthroscopic debridement in osteoarthritic knees under local, general, or peridural anesthesia across 201 procedures (173 partial meniscectomy, 192 articular trimming, 119 microfractures, 201 lavage) done in 193 patients who had failed standard conservative nonoperative treatment. Surgical intervention included 3 L saline solution and removal of all intra-articular debris and free osteochondral or articular cartilage fragments.

Meniscal lesions were treated by conservative partial meniscectomy, preserving as much meniscal tissue as possible. Grade III and IV articular cartilage defects were debrided with mechanical shavers and basket forceps, and unstable flaps at the periphery of the lesion were removed. Abrasion arthroscopy was not done. Isolated chondral defects greater than 1 cm in diameter were microfractured.

For this review, the data on patients having undergone local anesthesia only were extracted (n = 67 patients; 71 knees) and included here as a case series (level 4c evidence). The mean age of this group was 60.8 years (range 31–71 years) with 63 patients having primary OA of the knee. The mean follow-up was 30.9 months (range, 24–72 months). Disease severity according to the Outerbridge classification was as follows: 12.7% (9/71 knees) were grades I and II; 28.2% (20/71 knees) were grade III; and 59.1% (42/71 knees) were grade IV. Damage location was unicompartmental in 50.7% of knees, bicompartmental in 40.9%, and tricompartmental in 8.4% of knees.

Descriptive results show that patients were more likely to report "excellent" results if they had less degeneration, unicompartmental disease, sudden onset of mechanical problems and full range of motion at baseline, as shown in the table below.

Table 6: Descriptive Results, Krystallis et al. (14)

Parameter	Variable	Knees (No.)	% (No.) Knees With Excellent Results
Symptoms	Mechanical (sudden onset)	26	65.4 (17)
	Loading (gradual onset)	45	28.9 (13)
Motion	Full range	28	64.3 (18)
	Limited range	43	27.9 (12)
Outerbridge classification	Grades I and II	9	77.7 (7)
	Grade III	20	50.0 (10)
	Grade IV	42	31.0 (13)
Damage location	Unicompartmental	36	50.0 (18)
	Bicompartmental	29	38.0 (11)
	Tricompartmental	6	16.6 (1)

The study by Fond et al. (16) was a retrospective chart review of a series of 36 patients with OA of the knee, with arthritic symptoms refractory to conservative treatment; the majority of patients had been recommended total knee replacement by other surgeons. Excluded were patients with an inflammatory disorder (e.g., rheumatoid or septic arthritis), and those with more severe malalignment (defined as valgus greater than 8 and less than 3 degrees). Treatment included debridement of meniscal tears, debridement and limited thermal stabilization of chondral defects, removal of impinging tibial, notch, or subpatellar osteophytes, partial synovectomy, and lateral retinacular release.

The mean age was 64.8 years (range, 50–82 years); 11 patients had unicompartmental disease, whereas 9 and 16 patients had bicompartmental and tricompartmental disease, respectively. The senior author conducted all procedures. Preoperative and postoperative measures were based on the modified Hospital for Special Surgery (HSS) scoring scale and the objective measure of patient satisfaction.

The mean preoperative HSS score was 29.2. At 2 and 5 years postoperatively it was 48.0 and 43.2, respectively. At 2 years following debridement, 88.9% (32/36) patients reported being satisfied with their relief of symptoms (good to excellent results). The proportion reporting this level of satisfaction at 5 years was 69.4% (25/36). The 8 patients that reported failures subsequently underwent another surgery.

Stratified analyses showed an association between level of satisfaction and duration of symptoms, number of compartments involved, preoperative range of motion. Significantly worse results ($P < .05$) were associated with having symptoms longer than 5 years, presence of tricompartmental disease, and preoperative contractures greater than 10 degrees. Patients identified to have benefitted from arthroscopic debridement were those with preoperative contractures of less than 10 degrees and preoperative HSS scores greater than 22.

Menetrey et al. (15) conducted a follow-up study of medial meniscectomy in 53 patients over the age of 50 (mean, 60 years; range, 51–74 years), with mean follow-up of 6 years (range, 3–7 years). All patients had evidence of an internal derangement of the knee, had failed a course of nonoperative treatment, and had no previous knee surgery. Excluded were patients with a history of rheumatoid arthritis, gout, ochronosis, ankylosing spondylitis, hemophilia, osteonecrosis, post-traumatic arthritis, or post-infectious arthritis. Tears were treated by partial meniscectomy that preserved as much tissue as possible. There was no abrasion arthroplasty or drilling of chondral defects in this series. Synovectomy was performed for significant peripatellar hypertrophic reactive synovitis.

Degenerative changes were based on arthroscopic findings, and patients were categorized into 2 groups: degenerative (multiple fibrillations, fissures, or horizontal cleavage tears) meniscal tears (n = 20), and non-degenerative meniscal tears (n = 12). Important to note is that results are based on the 32 of 53 patients for whom data was available at follow-up (proportion of 60.4% of baseline sample).

Outcomes in this study included the HSS score, a subjective measure of patient satisfaction, which was integrated into grades of excellent, good, fair, and poor results. An excellent result was based on no symptoms with activity, no limitation in sports- or work-related activity, a satisfaction score higher than 8, and an HSS score over 90. A good result was based on the patient having minimal symptoms (e.g., occasional aching with stair climbing or physical activity, weakness with strenuous exertion, no major disability, a satisfaction score between 6 and 8, and an HSS score over 85). A fair result was given if the patient had frequent pain or aching with activity, difficulty climbing stairs, occasional swelling or weakness with strenuous exertion, a satisfaction score between 3 and 6, and an HSS score between 70 and 85; patients generally thought their symptoms were disabling. A poor result was based on severe symptoms with pain present at rest, limitation in walking, a satisfaction score less than 3, and an HSS score less than 70.

Analyses stratified by degenerative versus nondegenerative meniscal tears revealed a significant difference in excellent and good results in these 2 groups ($P = .001$). Arthroscopic meniscectomy provided about 90% (11/12) satisfactory results (patients improved by arthroscopy) in the nondegenerative group, but only 20% (4/20) in the degenerative meniscal tear group. The authors concluded that older patients with traumatic tears do better with arthroscopic partial meniscectomy than do those with degenerative tears.

The largest of these case series was a study conducted by Dervin et al. (13) at the Ottawa General Hospital in Ontario. Patients (n = 156) with symptomatic primary OA of the knee that remained symptomatic despite physical therapy and comprehensive medical management (e.g., analgesics, NSAIDS, hyaluronate and/or cortisone injections) were identified between 1995 and 1997. Excluded were those with traumatic or inflammatory OA. Arthroscopy was conducted under general or spinal anesthesia. A diagnostic arthroscopy was performed, after which debridement included resection of loose chondral flaps and unstable meniscal tears and synovectomy. Abrasion arthroplasty or drilling was not performed. Outcomes were assessed by 2 self-administered quality of life instruments: the SF-36 and the WOMAC scales. The SF-36 assesses functional status, general well being, and overall health. The WOMAC is a disease-specific scale and includes measures of pain, stiffness, and physical function.

Data at 2 years after surgery were available for about 80% (126/156) of patients. There was no evidence of selection bias, as those unavailable at 2 years (n = 30) did not differ from the others significantly on demographic data, baseline symptomatology, or arthroscopic findings. The mean age was 61.7 years (range, 43 to 75 years). The mean baseline WOMAC pain score was 23.85 cm, and the prevalence of obesity was high (66% had BMI > 27). The medial compartment was more frequently and severely involved (proportion unspecified), with 57% of knees showing grade III or IV disease. Seventy-nine

patients (63%) had an unstable meniscal tear, all uniformly degenerative, none thought to be reparable: 57 (72%) and 14 (18%) were in the medial and lateral meniscus, respectively, while 8 (10%) were combined.

At 2 years, a clinically important improvement was observed in 56 (44%) patients for WOMAC pain, 55 (44%) patients for WOMAC stiffness, and 49 (39%) patients for WOMAC function. However, only 20 patients reached an SF-36 level consistent with the referenced norm (51.4; SD, 8.5) for asymptomatic adults. (24)

Another component of the analysis of this report was the accuracy of predicting which patients would have a clinically significant improvement in the pain score. Such a prediction had been attempted by physicians involved in these cases, giving rise to an accuracy of only 54% and 59% for fellows and staff, respectively. These estimates were only slightly better than chance (kappa = 0.27; 95% CI, 0.09–0.45).

To identify predictors of which patients were likely to experience most pain relief (categorized into those with and without a clinically important reduction in WOMAC pain), a prediction model was tested. Three variables were found to be univariately associated with the outcome: presence of an unstable meniscal tear at arthroscopy (P = .01), medial joint-line tenderness (P = .04), and a positive Steinman test (P = .01). The significance of these factors was not reported for a logistic model in which all 3 factors where included. However, combining these factors gave rise to an area under the receiver operating characteristic curve of 0.73 (95% CI, 0.63–0.82). The authors indicated that this is a small improvement over the surgeons' preoperative predictive accuracy and that these variables were only partially helpful for predicting a successful outcome.

In attempting to identify a subset of patients that may benefit from this procedure, any interpretation of results on the presence of an unstable meniscal tear at arthroscopy should be made cautiously. It is important to note that the referent group for this variable was comprised of patients that had no tear (and not a comparison of the effectiveness of meniscectomy in those with a tear). The Medical Advisory Secretariat's conclusion, therefore, is as follows:

In patients with pain due to a meniscal tear, of the medial compartment in particular, repair of the meniscus results in better pain control at 2 years following surgery than if the pain is attributable to other causes. (13) However, to determine the effectiveness of meniscal repair (relative to no repair), this question can only be answered in an RCT.

Table 7: Overview of Non-Randomized Controlled Trials Included in Review

Study, Follow-Up Period	Subjects	Surgery	Results	Conclusions
Krystallis et al., 2004 (14) 2–6 yrs	197 OA* knee patients, 201 procedures Aged 31–71 yrs	Lavage (3 L) and: 173 meniscectomy; 192 articular trimming ; 119 microfractures; 201 lavage.	Local anesthesia: Excellent response: Gr. I & II: 7/9 (78%) Gr. III: 10/20 (50%) Gr. IV: 13/42 (31%)	Patients with earlier disease, sudden onset mechanical symptoms, unicompartmental disease had better outcomes.
Dervin et al., 2003 (13) 2 yrs	156 OA knee patients Aged 43–75 yrs 57% gr. III or IV	Debridement + resection chondral flaps, meniscal tears. Baseline: WOMAC pain 3-49.	Success: Pain: 44% (56/126); Stiff: 44% (55/126); Function: 39% (49/126)	Medial compartment more frequently and severely involved. 63% (n = 79) w/ meniscal tears, 57/79 in medial meniscus. Clinical predictors of success only partially helpful.
McGinley et al.,	191 OA TKR*/	Debridement: meniscal	33% knees TKR at	Patients with unilateral

1999 (12) 10 yrs	osteotomy knee candidates; only 91 knees at 10 yrs (77 patients) Aged 55–82 yrs	tear resection and non-aggressive shaving of frayed articular cartilage.	average 6.7 yrs; 67% knees (21/77 patients) without TKR at mean 13.2 yrs: 7/21 patients TKR within 2 yrs (6/7Outerbridge grade IV with significant meniscal tears).	radiographic changes, pain limiting function good candidates, bilateral disease, and limited range of motion poor candidates for debridement.
Fond et al., 2002 (16) 2–5 yrs	36 OA knee patients, symptoms 6–140 mos Aged 50–82 yrs	Debridement of meniscal tears, debridement and limited thermal stabilization of chondral defects, removal of impinging tibial, notch, subpatellar osteophytes, partial synovectomy, and lateral retinacular release.	Excellent/good results: 2 yrs: 32/36 patients. 5 yrs: 25/36 patients.	Predictors of poor outcome: Disease duration > 5 yrs, tricompartmental OA.
Menetrey et al., 2002 (15) 3–7 yrs	32 OA knee patients Aged 51–74 yrs	Lavage + partial meniscectomy	Good results at 6 yrs: Degenerative: 20%; Non-degenerative: 90%	Older patients with degenerative disease (compared to traumatic meniscal tears) less likely to do well with partial meniscectomy: lavage better option?

*OA indicates osteoarthritis; TKR, total knee replacement.

In summary, these studies suggest that debridement with partial meniscectomy as appropriate might be effective in patients with earlier stages of degeneration, unicompartmental disease, shorter duration of symptoms, sudden onset of mechanical symptoms, and full range of motion preoperatively. However, given that these findings are derived from level 4 evidence (case series), the identification of subsets of patients that may benefit from this procedure requires further research.

Summary of Findings of Literature Review

In early OA of the knee with pain refractory to medical treatment, there is level 1b evidence that arthroscopic lavage gives rise to a statistically significant, but not a clinically meaningful effect in improving pain (WOMAC pain and VAS pain) up to 12 months following surgery. The effect on joint function (WOMAC function) and the primary outcome (WOMAC aggregate score) was neither statistically nor clinically significant. (8)

In moderate or severe OA of the knee with pain refractory to medical treatment, there is level 1b evidence that the effect on pain and function of arthroscopic lavage (10 L saline) and debridement (with 10 L saline lavage) is not statistically significant up to 24 months following surgery. (7) There is level 2 evidence that arthroscopic debridement (with 3 L saline lavage) is effective in the control of pain in severe OA of the medial femoral condyle for up to 5 years. (9)

For debridement with meniscectomy, there is level 4 evidence that the procedure, as appropriate, might be effective in earlier stages, unicompartmental disease, shorter symptom duration, sudden onset of mechanical symptoms, and preoperative full range of motion. However, as these findings derive from very poor quality evidence, the identification of subsets of patients that may benefit from this procedure requires further testing.

In patients with pain due to a meniscal tear, of the medial compartment in particular, repair of the meniscus results in better pain control at 2 years following surgery than if the pain is attributable to other

causes. (13) There is insufficient evidence to comment on the effectiveness of lateral meniscus repair on pain control.

Economic Analysis

Notes & Disclaimer

The Medical Advisory Secretariat uses a standardized costing methodology for all of its economic analysis of technologies. The main cost categories and the associated methodology from the province's perspective are as follows:

Hospital: Ontario Case Costing Initiative (OCCI) cost data is used for all program costs when there are ten or more hospital separations or one-third or more of hospital separations in the ministry's data warehouse are for the designated ICD-10 diagnosis and CCI procedure codes. Where appropriate, costs are adjusted for both hospital specific or peer-specific effects. In cases where the technology under review falls outside the hospitals that report to the OCCI, PAC-10 weights converted into monetary units are utilized. Adjustments may need to be made to ensure that the relevant Case Mix Group is reflective of the diagnosis and procedures under consideration. Due to the difficulties of estimating indirect costs in hospitals associated with a particular diagnosis/procedure, the MAS normally defaults to considering direct treatment costs only. Historical costs have been adjusted upward by 3% per annum representing a 5% inflation rate assumption less a 2% implicit expectation of efficiency gains by hospitals. Non-Hospital: These include physician services costs obtained from the Provider Services Branch of the Ontario Ministry of Health and Long Term Care, device costs from the perspective of local health care institutions and pharmaceutical costs from the Ontario Drug Benefit formulary list price. Discounting: For all cost-effective analysis, discount rates of 5% and 3% are used as per the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) and the Washington Panel of Cost-Effectiveness, respectively. Downstream cost savings: All cost avoidance and cost savings are based on assumptions of utilization, care patterns, funding and other factors. These may or may not be realized by the system or individual institutions.

In cases where a deviation from this standard is used, an explanation has been given as to the reasons, the assumptions and the revised approach.

The economic analysis represents an estimate only, based on assumptions and costing methodologies that have been explicitly stated above. These estimates will change if different assumptions and costing methodologies are applied for the purpose of developing implementation plans for the technology.

Budget Impact Analysis

The hospital cost for one debridement procedure based on a PAC-10 weight for fiscal year (FY) 2002 of 0.2539, based on a dollar value of $4,539 per 1.0 PAC-10 weight (Personal communication, Ministry of Health and Long-Term Care, May 2005) is about $1,153 Canadian. This estimate is for an outpatient surgical procedure (i.e., it includes operating room costs) and assumes there is no overnight hospital stay.

The professional costs per treated patient are based on the following:

- $251.53 = FSC R204 (debridement of 1 compartment)
- $326.55 = FSC R205 (debridement of > 1 compartment)
- ~$200 for anesthetist and surgical assistant billings
- $490 = weighted average OHIP costs per case (78.5% are R205)

Therefore, based on a volume of 1,994 debridement procedures (some with lavage) conducted in Ontario for FY 2003, and 28 lavage procedures (lavage only) in FY 2003, the approximate hospital costs and OHIP (physician billing) costs combined are $3.3 million annually. This excludes costs associated with pathology, radiology, and microbiology.

Downstream cost savings per procedure were not estimated. At issue is if total knee replacement is simply being delayed.
With respect to cost effectiveness, if the results of the Moseley trial (7) are replicated, then cost-effectiveness is likely to be unfavourable.

The estimated incidence of OA of the knee in Ontario is about 16,000 (130 per 100,000 people aged 45–64), whereas the prevalence is 125,000. Therefore, there is a potential backlog of 125,000 people that need one or another kind of treatment for OA of the knee (injections, arthroscopic procedures, drugs). Based on rates of utilization in the United States (240 procedures per 100,000), which are higher than in Ontario (130 procedures per 100,000), 3,600 procedures per year would be performed in Ontario, resulting in an 80% increase, for an annual cost of $6 million.

Please note, it is important to emphasize that these costs are overestimates for the less invasive debridement procedures being assessed in this review. As it was not possible to distinguish costing of the less invasive from the more invasive procedures, all have been included here. Therefore, the volume of procedures is an overestimate; accordingly, the cost per procedure may be overestimated.

Existing Guidelines for Use of These Procedures

The 2005 health technology assessment on arthroscopic lavage by the Wessex Institute in the United Kingdom (5) concluded that the evidence is insufficient (due to low study power in the RCTs reviewed) to compare the clinical effects of lavage and other treatments for OA of the knee. In the absence of sufficient evidence, however, the Wessex authors suggest that policy decisions may be based on the following clinical options:

- Withhold procedure.
- Offer less invasive treatments first, then arthroscopy.
- For severe OA, use arthroscopy as bridging procedure for symptom management while awaiting osteotomy or joint replacement.

Whereas no clinical guidelines specific to arthroscopic procedures were identified, 3 sets of insurability guidelines were identified. All 3 reports were from the United States and were based on a review of the literature for both lavage and debridement. They are presented in chronological order.

The Centers for Medicare & Medicaid Services (CMS) published their decision in 2004. (21) It states that the evidence is adequate to conclude that the 2 procedures are neither reasonable nor necessary for patients with OA of the knee. Their specific funding recommendations are as follows:

- No coverage of lavage alone for patients with OA of the knee.
- No coverage of debridement for patients with knee pain only or with severe OA.
- All other indications of debridement for patients with OA of the knee will remain at contractor discretion.

Aetna published their clinical policy bulletin in 2004 (25) and concluded the following:

- Arthroscopic lavage is considered experimental and investigational because its effectiveness is not established.
- Arthroscopic debridement is considered experimental and investigational for persons with knee pain only or with severe OA.

However, in contrast to the CMS decision (as noted above), Aetna concluded that arthroscopic debridement may be considered medically necessary in people with mild to moderate disease with pain plus mechanical problems such as those due to loose bodies and meniscal tears.

The CIGNA Health Care Coverage Position, (4) with an effective date of April 15, 2004, stated the following:

It does not cover any of the following treatments for OA as they are considered experimental, investigational, or unproven:

- Lavage alone
- Debridement for patients with knee pain only
- Debridement for patients with severe OA

It does cover arthroscopic debridement (with or without lavage) for OA of the knee as medically necessary in the presence of all of the following:

- Normal limb alignment or minimal malalignment of the joint is present
- X-ray confirmation of no or minimal degenerative arthritis
- Recent onset of symptoms or within one year of presentation
- Documentation of at least one of the following conditions:

    mechanical symptoms (e.g., locking of the limb, giving way or catching), loose bodies, unstable flaps of articular cartilage, disruption of the meniscus, or impinging osteophytes.

Policy Development

Diffusion – Provincial

To assess the potential pressure for further diffusion of these procedures in Ontario, information on the annual number of lavage, debridement, and total knee replacement procedures for the past 3 years were requested from other jurisdictions in Canada. Quebec and Saskatchewan provided information in time for the publication of this review and is included here.

For the 3-year period, Quebec reported a decline in the number of minor arthroscopic procedures from 10,224 to 9,541 to 8,891 for 2002 to 2003 to 2004. However, these figures must be interpreted with caution as the code on which these data are based (2724) includes debridement, as well as other minor arthroscopic surgeries. The number of lavage procedures (code 2577) also decreased over time, with 693 performed in 2002, 570 in 2003, and 412 in 2004. In contrast, the number of total knee replacement surgeries increased over time, with 3,612 conducted in 2002, 4,563 in 2003, and 4,550 in 2004.

Saskatchewan indicated there was no specific billing code for lavage; therefore, it might be billed as debridement. Two billing codes were reported for debridement: code 365M for less invasive debridement and code 841M for the more invasive form. There was an overall decline in the number of less invasive debridement procedures and an increase in the number of more invasive ones. Less invasive procedures decreased from 336 in 2002, to 237 in 2003, to 170 in 2004. In contrast to the utilization patterns in Quebec, though, the number of more extensive debridement procedures increased from 820 in 2002, to 1,138 in 2003, to 1,175 in 2004. The number of total knee replacements (code 444M) also increased from 1,142 procedures in 2002, to 1,334 in 2003, to 1,488 in 2004.

Whereas the overall pattern of utilization in these 2 provinces were similar, with a general decrease in the number of arthroscopic procedures and an increase in total knee replacements, the volume of procedures was much higher in Quebec than Saskatchewan. Thus, based on the limitations of these data as outlined above, comparisons between provinces must be made with caution.

Conclusions

Arthroscopic debridement of the knee has thus far only been found to be effective for medial compartmental OA. All other indications should be reviewed with a view to reducing arthroscopic debridement as an effective therapy.

Arthroscopic lavage of the knee is not indicated for any stage of OA.

There is very poor quality evidence on the effectiveness of debridement with partial meniscectomy in the case of meniscal tears in OA of the knee.

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