

E-Bulletin

April 2006, Issue #11

The OHTAC E-bulletin is issued on a regular basis to provide you with updates on the latest committee recommendations. OHTAC has reviewed several health technologies and all its recommendations are available on the OHTAC Web site at http://www.health.gov.on.ca/english/providers/program/mas/ohtac_recomm.html.

Should you have additional information about any of these technologies, please submit it to the Medical Advisory Secretariat (MAS) at the contact information found at the end of this bulletin.

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**INTEGRATED HEALTH TECHNOLOGY REPORT:
OSTEOARTHRITIS OF THE KNEE**

Osteoarthritis (OA) is a chronic degenerative disease that results in pain, joint deformity and disability. It affects one in ten Ontario adults. More than 40% of Ontario adults over the age of 60 have osteoarthritis and suffer with pain and disability.

Between February and June 2005, OHTAC received applications to review the evidence on the effectiveness of three individual technologies to treat OA of the knee – hylan (i.e. viscosupplementation), lavage and debridement and total knee replacement.

This e-bulletin will first describe each OA technology separately. The e-bulletin will conclude with the OA expert panel findings and OHTAC's recommendations on osteoarthritis technologies for the knee.

INTRA-ARTICULAR VISCOSUPPLEMENTATION WITH HYLAN G-F 20

JUNE 2005

Issue

Hylan G-F 20 (brand name Synvisc) is a high molecular weight derivative of hyaluronan, a component of synovial fluid, which is found in the joints and acts as a lubricant and shock absorber. It is administered by injection into the joint space to treat pain associated with osteoarthritis (OA) of the knee. Health Canada classifies it as a device. Although the injection procedure is an insured service in Ontario, the device, Hylan G-F 20, is not.

Key Findings

Many of the studies of Hylan G-F 20 have significant methodological limitations that result in uncertainty about the magnitude of effect.

- There is moderate evidence that Hylan G-F 20 is no more clinically effective than non-steroidal anti-inflammatories (NSAIDs).
- The evidence that Hylan G-F 20 may be an appropriate option for individuals with osteoarthritis of the knee who can not tolerate NSAIDs is indirect. The possible benefit of a reduced incidence of NSAID-induced gastropathy in this population must be weighed against the level of uncertainty around the likelihood of a severe inflammatory adverse reaction to Hylan G-F 20.
- There is moderate evidence that Hylan G-F 20 is no more clinically effective than intra-articular (IA) corticosteroids. The lower cost of intra-articular corticosteroids makes IA corticosteroids the preferred treatment option.

- There is moderate evidence that Hylan G-F 20 is effective as an adjunct to conventional care, delivering a small magnitude of temporary relief at 4-26 weeks post-treatment.
- There is moderate evidence that Hylan G-F 20 is not effective in individuals with advanced osteoarthritis for whom total knee replacement is indicated.

**OHTAC
Recommendations
(June 2005)**

- That Hylan G-F 20 not be funded at this time
- That the risk benefit ratio of funding Hylan G-F 20 be compared to the risk/benefit ratio of investing resources in other, perhaps more definitive, technologies for treating osteoarthritis of the knee (i.e. arthroscopic procedures and total knee replacement)
- That an Osteoarthritis Advisory Panel review the evidence and advise OHTAC about the appropriate indications for and clinical utility of the MAS-reviewed technologies for OA of the knee
- That OHTAC revisit these recommendations once the Osteoarthritis Advisory Panel has reported to OHTAC

Implications

The magnitude and duration of clinical benefit produced by Hylan G-F 20 must be weighed against the uncertainty and potential magnitude of budget impact (circa \$35M-105M/year) of funding this device given the high burden of osteoarthritis in the Ontario adult population.

The **OHTAC recommendation** for this technology can be found at the following link:

http://www.health.gov.on.ca/english/providers/program/mas/tech/recommend/rec_hylan_061705.pdf

The full downloadable version of the **health technology literature review** by the Medical Advisory Secretariat can be found at:

http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_hylan_061705.pdf

TOTAL KNEE REPLACEMENT

JUNE 2005

Issue

Total knee replacement (TKR) is an end-of-line treatment for patients with severe pain and functional limitations. More women than men undergo knee replacement, and most patients are between 55 and 84 years old.

The aim of this review was to assess the effectiveness, in terms of pain reduction and functional improvement, and costing of TKR for people with osteoarthritis for whom less invasive treatments have failed.

Key Findings

There is substantial evidence to indicate that TKR effectively reduces pain and improves function:

- Overall, patients who undergo TKR surgery for osteoarthritis have substantial improvements in terms of reduction of pain and improvement of function. The revision rates ranged from 0% to 13% in the studies that reported at least 5 years of follow-up.
- In terms of the timing of TKR surgery, 2 studies found that the severity of osteoarthritis does not predict outcome, but 1 study was found that higher functioning patients had significantly less pain and better function up to 2 years after surgery compared with lower functioning patients.

**OHTAC
Recommendations
(June 2005)**

OHTAC will make recommendations regarding the management of osteoarthritis of the knee once they have received a response from the expert panel.

Implications

Almost 18,000 knee replacement procedures (primary TKR and revisions) will be performed in Ontario in 2005/2006. The cost per TKR is approximately \$10,375 (including the costs associated with the 5 day hospital stay and the cost of the device). Thus, approximately \$186 million will be spent on knee replacements in Ontario in 2005/2006.

The **OHTAC recommendation** for this technology can be found at the following link:

http://www.health.gov.on.ca/english/providers/program/mas/tech/recommend/rec_tkr_061705.pdf

The full downloadable version of the **health technology literature review** by the Medical Advisory Secretariat can be found at:

http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_tkr_061705.pdf

ARTHROSCOPIC LAVAGE AND DEBRIDEMENT

SEPTEMBER 2005

Issue

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. Debridement can be categorized into two main groups: the less invasive and the more invasive procedures. The less invasive procedures includes the removal of debris and smoothing of cartilage surfaces, whereas the more invasive debridement procedures may include abrasion, and additional surgical interventions such as meniscectomy, osteotomy, and synovectomy.

What is the effectiveness and cost-effectiveness of arthroscopic lavage and debridement, with or without lavage, in the treatment of symptoms of OA of the knee? Are there any adverse effects of these procedures?

Key Findings

Evidence on lavage and debridement is sparse and of poor quality. It was found that:

- 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.

**OHTAC
Recommendations
(September 2005)**

- Arthroscopic debridement of the knee has thus far only been found to be effective for medial compartmental osteoarthritis. All other indications should be reviewed with a view to reducing arthroscopic debridement as an effective therapy.
- Arthroscopic lavage of the knee alone (without debridement) is not recommended for any stage of OA.

However, OHTAC agreed that all recommendations be reviewed upon presentation of the report of its expert panel on osteoarthritis.

Implications

Based on a volume of 1,994 debridement procedures (some with lavage) conducted in Ontario for fiscal year 2003, and 28 lavage procedures (lavage only) in fiscal year 2003, the approximate hospital costs and OHIP costs combined are \$3.3 million annually. Downstream cost savings per procedure were not estimated. At issue is if total knee replacement is simply being delayed.

The **OHTAC recommendation** for this technology can be found at the following link:

http://www.health.gov.on.ca/english/providers/program/mas/tech/recommend/rec_lavdeb_061705.pdf

The full downloadable version of the **health technology literature review** by the Medical Advisory Secretariat can be found at:

http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_lavdeb_090105.pdf

**INTEGRATED HEALTH TECHNOLOGY REPORT:
OSTEOARTHRITIS OF THE KNEE**

Based on the evidence, OHTAC concluded that the utility of hylan (see above) and of lavage and debridement (see above) for treatment of OA of the knee was questionable; yet use of these technologies was diffused in Ontario. In contrast, the evidence to support total knee replacement was good. Given the current system strains, indicated by the demand and long waiting list for total knee replacement, the advisability of supporting technologies for OA with uncertain utility was questionable. Acknowledging the ambiguities in the evidence, OHTAC subsequently requested that a multidisciplinary advisory panel of clinical experts with experience in using these technologies adopt a systems perspective to integrate the evidence and advise OHTAC on the appropriate recommendation.

The 8 person panel consisted of orthopedic surgeons, general practitioners, rheumatologists, physiotherapists and an epidemiologist, who was the director of the

Arthritis Community Research Education Unit (ACREU) at University of Toronto.

**QUESTIONS ASKED TO THE
OSTEOARTHRITIS EXPERT PANEL**

1. What is the level of evidence on the clinical utility of the individual technologies?
2. For what set of indications are the technologies recommended, not recommended?
3. For what set of indications might the technologies, if not recommended, be offered?
4. What is the appropriate placement of the technologies in the sequence of treatments for osteoarthritis of the knee in Ontario?
5. To what extent are the individual technologies underused and overused in Ontario?
6. What suggestions do you have to improve the use of the technologies to optimize the management of OA in Ontario?

INTEGRATED REPORT: OSTEOARTHRITIS TECHNOLOGIES

October 2005

Issue

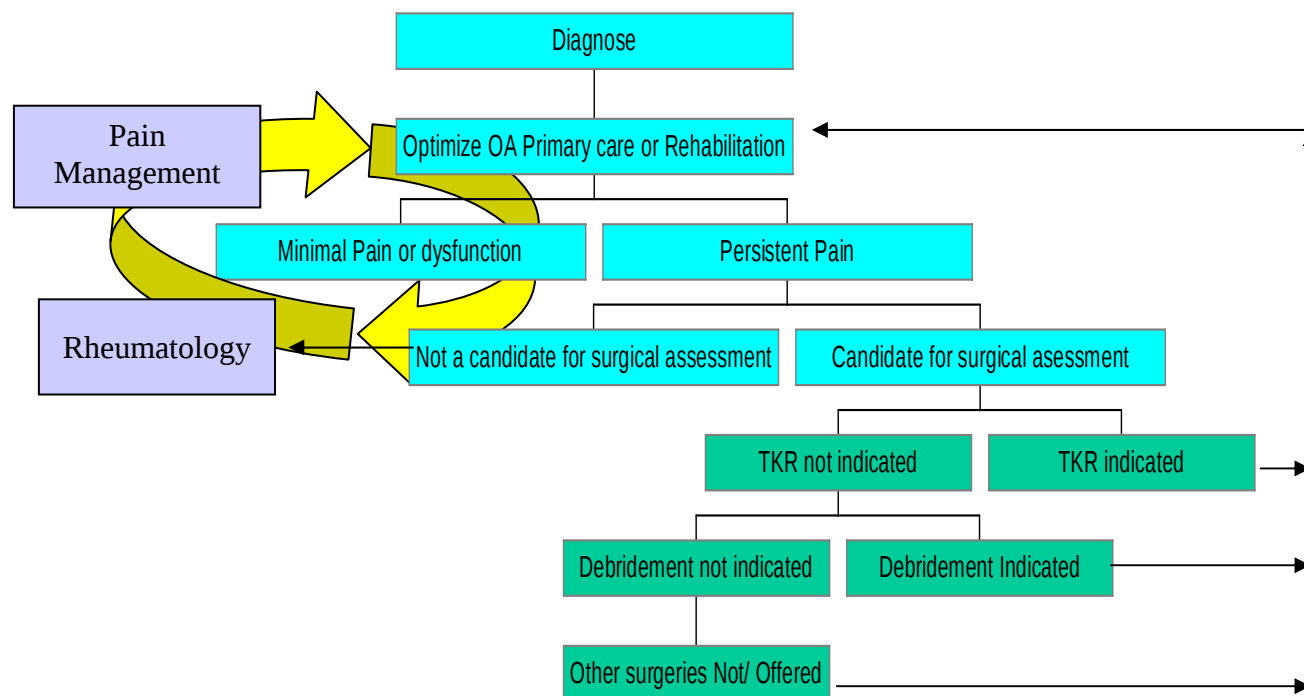
An expert panel was convened by the Medical Advisory Secretariat to advise OHTAC on the optimal integrated approach to the use of a variety of technologies available to treat osteoarthritis of the knee for patients who fail conventional drug treatment. The osteoarthritis expert panel membership consisted of rheumatologists, orthopedic surgeons, physiotherapists and family physicians and its report represents the first attempt by OHTAC to make recommendations based in the integration of technologies around a single disease state through the involvement of experts.

Key Findings

The panel agreed that:

- there is some evidence that hylan has some utility as an adjunctive therapy to patients with persistent pain and mild disease, despite optimal primary care. However, the magnitude of effect is relatively small, producing pain relief for 13-26 weeks on a magnitude equivalent to intra-articular steroids and NSAIDS.
- there was good, consistent evidence that TKR is effective for patients with moderate-severe OA of the knee, and found that this technology is underused in Ontario
- there is no evidence to support the utility of lavage alone for the treatment of OA, although it may have utility for indications other than OA.
- the evidence on debridement was sparse and inconsistent. Debridement may have some clinical utility in patients with mild-moderate disease and mechanical symptoms, but this evidence is indirect and of low quality. The panel found that this technology is over used in Ontario.

The panel also developed the following treatment pathway for OA of the Knee:



**OHTAC
Recommendations
(October 2005)**

- That TKR be recommended as an appropriate treatment for osteoarthritis of the knee for patients with progressive disease despite the use of optimal drug therapy.
- Access to TKR be improved by the more efficient utilization of orthopedic surgical time, public education to better inform individuals about the benefits of TKR, clinical practice guidelines to guide physicians on the eligibility criteria for TKR, appropriate primary care for these patients and criteria for appropriate referrals to orthopedic surgeons.
- The report of the expert advisory Panel be used as the foundation for the initial draft of the guideline, which will subsequently be circulated for input from the field in the participatory and transparent manner consistent with the existing Health Technology Utilization Guidelines of Ontario (Health TUGO) guideline development process.

Implications

These recommendations may impact on wait times for total knee replacements.

The **OHTAC recommendation** for this technology can be found at the following link:

http://www.health.gov.on.ca/english/providers/program/mas/tech/recommend/rec_ostknee_102105.pdf

The full downloadable version of the **health technology literature review** by the Medical Advisory Secretariat can be found at:

http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_ostknee_100105.pdf

TECHNOLOGIES CURRENTLY UNDER REVIEW

• Cardiac positron emission tomography	• Bladder Ultrasound
• Endovascular repair for thoracic aortic aneurysm	• Breast Cancer Screening for Women 40-49 years of age--Mammography
• Electroanatomic cardiac mapping and ablative techniques	• Optimum Imaging Breast Technologies for Women 40-49 years of age—Modalities other than Mammography
• Intravascular coronary ultrasound	• Vascular ultrasound screening for abdominal aortic aneurysm
• Metal-on-metal Hip Resurfacing	• Hydrophilic Catheters
• Implantable Cardioverter defibrillator	• Routine Eye Exams
• Photopheresis	• Sleep Disorder Clinics
• Negative Pressure Wound Therapy	• Bone Densitometry
• Gastric Electrical Stimulation	• Energy based interventions for Benign Prostatic Hyperplasia (BPH)
Integrated Health Technology Literature Reviews	
• Heart failure	

OHTAC is envisaged as the first step in creating a single portal for providing advice to the Ministry of Health and Long-Term Care regarding the uptake, diffusion, and distribution for new health technologies. Find more about OHTAC, its application process, and its recommendations at the following Web site:

http://www.health.gov.on.ca/english/providers/program/mas/ohatc_about.html.

Literature Reviews Being Updated

- | | |
|---|--|
| <ul style="list-style-type: none"> • Mid-Urethral Slings (February 2004) • Enhanced External Counterpulsation (February 2003) | <ul style="list-style-type: none"> • Artificial discs (March 2004) • Negative Pressure Wound Therapy (December 2004) |
|---|--|

PREVIOUS OHTAC RECOMMENDATIONS

- | | |
|--|----------------|
| • Coil Embolization for Intracranial Aneurysms (Update)
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_coil_010106.pdf | January 2006 |
| • Automated External Defibrillators
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_aed_120105.pdf | December 2005 |
| • Interim Report on Drug Eluting Stents
http://www.path-hta.ca/DESreport.pdf | December 2005 |
| • Air Cleaning Technologies
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_act_110105.pdf | November 2005 |
| • Biventricular Pacing (Cardiac Resynchronization Therapy)
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_biv_090105.pdf | September 2005 |
| • Athroscopic Lavage and Debridement
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_lavdeb_090105.pdf | September 2005 |
| • Hyperbaric Oxygen Therapy for Non-Healing Ulcers in Diabetes Mellitus
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_hypox_081105.pdf | August 2005 |
| • Interim Report on Endovascular Repair of Abdominal Aortic Aneurysm (EVAR)
http://www.path-hta.ca/EVAR%20Interim%20Report%20Jul%202005.pdf | July 2005 |
| • Intra-Articular Viscosupplementation With Hylan G-F 20 To Treat Osteoarthritis of the Knee
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_hylan_061705.pdf | June 2005 |
| • Total Knee Replacement
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_tkr_061705.pdf | June 2005 |
| • Intrathecal Baclofen Pump for Spasticity
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_pump_081605.pdf | May 2005 |
| • Osteogenic Protein-1
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_osteo_070105.pdf | April 2005 |
| • Multi-detector Computed Tomography Angiography for Coronary Artery Disease
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_multi_050105.pdf | April 2005 |
| • Spinal Cord Stimulation for Neuropathic Pain
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_scs_030105.pdf | March 2005 |
| • Sacral Nerve Stimulation for Urinary Incontinence, Urgency-Frequency, Urinary Retention, and Fecal Incontinence
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_sns_030105.pdf | March 2005 |
| • Deep Brain Stimulation in Parkinson's Disease and Other Movement Disorders
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_dbs_030105.pdf | March 2005 |
| • Bariatric Surgery
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_baria_010105.pdf | January 2005 |
| • Vacuum Assisted Closure Therapy for Chronic Wounds
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_vac_120104.pdf | December 2004 |
| • Balloon Kyphoplasty
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_kypho_120104.pdf | December 2004 |
| • Thermal Balloon Endometrial Ablation for Dysfunctional Uterine Bleeding
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_tbea_090104.pdf | October 2004 |
| • Primary Angioplasty
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_bis_060104.pdf | September 2004 |
| • Bispectral Index Monitor
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_bis_060104.pdf | August 2004 |

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- Radio Frequency Ablation for Primary Liver Cancer June 2004
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_rfa_060104.pdf
- Repetitive Transcranial Magnetic Stimulation for Major Depressive Disorder June 2004
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_rtms_060104.pdf
- Coil Embolization For Intracranial Aneurysms March 2004
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_coil_030104.pdf
- Pyrocarbon Finger Joint Implant March 2004
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_pyrocarb_030104.pdf
- Video Laryngoscopy for Tracheal Intubation March 2004
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_vidlaryng_030104.pdf
- Bone Morphogenetic Proteins and Spinal Surgery for Degenerative Disc Disease March 2004
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_bmp_030104.pdf
- Artificial Discs for Cervical and Lumbar Spinal Surgery for Degenerative Disease March 2004
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_artdisc_030104.pdf
- Computer-Assisted Hip and Knee Arthroplasty: Navigation and Robotic Systems March 2004
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_arthro_020104.pdf
- Computer-Assisted Surgery Using Telemanipulators March 2004
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_teleman_020104.pdf
- Tension-free Vaginal Tape for Stress Urinary Incontinence February 2004
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_tvt_020104.pdf
- Patient Monitoring System for MRI February 2004
http://www.health.gov.on.ca/english/providers/program/mas/tech/reviews/pdf/rev_patmri_120103.pdf

For any comments related to this E-bulletin, please contact the Medical Advisory Secretariat at:

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Web: http://www.health.gov.on.ca/english/providers/program/mas/mas_mn.html