OHTAC

Ontario Health Technology Advisory Committee

E-Bulletin

Issue 24 August 2007

Seeking the best health technologies for Ontario

In This Issue:

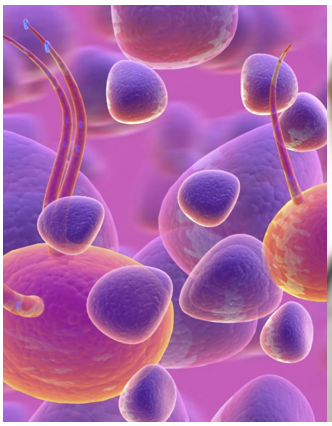
Focus on

Programs for Assessment of Health Technologies (PATH)

Introduction

The following E-Bulletin highlights studies conducted by the Program for Assessment of Technology in Health (PATH) on behalf of the Ontario Health Technology Advisory Committee.

PATH constitutes a new research program in economic evaluation and HTA associated with the Centre for Evaluation of Medicines (CEM) at St Joseph's Healthcare Hamilton and the Department of Clinical Epidemiology & Biostatistics (CE&B), Faculty of Health Sciences, McMaster University.



Drug Eluting Stents Compared to Bare Metal Stents for the Percutaneous Coronary Interventions in Ontario

Background

In 2002, the Ontario Ministry of Health and Long-term Care (MOHLTC) completed a review of the evidence regarding drug eluting stents (DES). The DES technology, through the prolonged release of drugs from a polymer matrix (Cypher™ Sirolimus-eluting stent and Taxus® Express Paclitaxel-eluting coronary stent), was believed to reduce the need for repeat revascularization procedures due to subsequent narrowing of the coronary arteries at the site of the stent. As a result, The MOHLTC felt that further Ontario-specific evaluation of the technology was warranted.

Therefore, in collaboration with the MOHLTC and the 12 Ontario Regional Interventional Cardiac Care Centres and the Cardiac Care Network of Ontario (CCN); the Institute for Clinical & Evaluative Sciences (ICES) and the Program for Assessment and Technology in Health (PATH) Research Institute at McMaster University designed and conducted an observational study or "field evaluation" to support the evaluation of the effectiveness and cost-effectiveness DES compared to BMS in Ontario through modifications to the CARDIACCESS database in early 2004.

An interim evaluation of the information from 9,103 patients with at least 9 months of follow-up was presented to OHTAC in 2005. Based on these results OHTAC recommended that DES be offered to patients who had any 2 of the following: diabetes, long lesions (greater than 20 mm) or narrow lesions (less than 2.75 mm). Continued data collection was warranted from the field evaluation to better resolve the effectiveness of DES in patients following an acute myocardial infarction (MI) as well as to evaluate longer-term outcomes.

continued

Ontario

OHTAC

The Ontario Health Technology Advisory Committee (OHTAC) provides advice to the Ontario Ministry of Health and Long-Term Care regarding the uptake, diffusion, and distribution of new health technologies.

Find out more about OHTAC, its application process, and its recommendations here.

Partners in Research

PATH

The Program for Assessment of Technology in Health (PATH) is a research program in economic evaluation and health technology assessment (HTA) that primarily supports government reimbursement decisions in the province of Ontario.

PATH constitutes a new research program in economic evaluation and HTA associated with the Centre for Evaluation of Medicines (CEM) at St Joseph's Healthcare Hamilton and the Department of Clinical Epidemiology & Biostatistics (CE&B), Faculty of Health Sciences, McMaster University.

Find out more about PATH, its projects, and its publications here.

Background continued

In the spring of 2007, the final analysis of the field evaluation was presented to OHTAC and provided results from 16,498 patients that received either a DES or BMS only and with a least 1 year of follow-up information. The primary objective of the study was to compare the rate of revascularization procedures (both target vessel and non-target vessel) in patients receiving a PCI intervention with either a DES or a BMS. The analysis evaluated patient outcomes according to their history of a recent MI, diabetes status and lesion characteristics (length and diameter).

Findings

The field evaluation analysis provided details regarding the predicted 2 year revascularization rates for those individuals undergoing a PCI with stent placement between December 2003 and March 2005. A summary of the key findings are as follows:

Among patients with diabetes, DES are effective in reducing the need for revascularization, especially in patients with long and/or narrow lesions, regardless of recent MI status.

Among non-diabetic patients, the benefit of DES is far more limited across all lesion types, primarily limited to those with the adverse lesion characteristics of length and small vessel size where both adverse features co-exist.

DES revascularization rates observed in this study, as found in the interim report, appear to be similar to those reported within the clinical literature however; the revascularization rates for BMS are significantly lower than those reported from randomized controlled trials.

OHTAC Recommendations

Based on the above field evaluation study, on March 30, 2007 OHTAC recommended the following with regard to DES for PCI interventions in Ontario:

1. That DES be offered to those patients considered for stent placement and who have:

- Diabetes, and
- Long lesions (greater than 20 mm) and/or narrow lesions (less than or equal to 2.75 mm)

2. That the current support of DES not be increased at this time.

3. That these recommendations be provided to hospitals and cardiologists as soon as possible.

4. That these recommendations be provided to hospitals and cardiologists as soon as

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In each E-Bulletin issue you will find brief summaries of technology reviews conducted on behalf of OHTAC by the Medical Advisory Secretariat.

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Implications

This evaluation provided a unique analysis of the comparative effectiveness of DES and BMS by lesion characteristics and MI and diabetes status providing evidence to support allocation to targeted patient groups receiving PCI with stents. As previously, OHTAC made its recommendations based on effectiveness, but it is also noteworthy that the field evaluation found that DES was not cost-effective with the cost per quality adjusted life years (QALY) gained greater than $200,000 per QALY in all evaluated cohorts except one (patients with diabetes, no recent MI having very-long (>30 mm) lesions in a small vessel). The high cost-effectiveness was primarily due to the higher costs associated with DES as compared to BMS.

The full downloadable version of this Health Technology Policy Analysis by the Programs for Assessment of Health Technologies can be found here.

The full downloadable version of the OHTAC recommendation for this technology can be found here

Elective Endovascular Repair Compared to Open Surgical Repair of Abdominal Aortic Aneurysms

Background

In 2003, the Ministry of Health and Long Term Care (MOHLTC) conducted a review of primary studies on endovascular repair (EVAR) for abdominal aortic aneurysms (AAA) as well as a review of previous international and Canadian Health Technology Assessments (HTA). Due to the informational uncertainty associated with the long-term effectiveness of EVAR, the MOHLTC recommended that an Ontario-specific evaluation of the technology be undertaken.

AAAs (a pathologic dilatation of a segment of the aorta) represent a significant health problem in Ontario. It is estimated that the prevalence of AAA ranges from 4.1% to 14.2% in men and between 0.35% and 6.2% in women. The prevalence of AAA is greater in men, increases with age and also is more common to occur in smokers and patients with a history of myocardial infarction, peripheral vascular disease or a family history of AAA.

Subscription Information

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OHTAC Mandate

Examine proposed health technologies in the context of existing clinical practice.

- Provide advice and recommendations to MOHLTC, practitioners and the broader health care system based on a systematic, objective, evidence-based technology assessment and taking into account economic, human resource, regulatory and ethical considerations
- Create a forum to maximize opportunities and prioritize the uptake and diffusion of new / emerging health technologies deemed to significantly improve patient outcomes and/or systems efficiencies relative to other existing or competing interventions.
- Outline implications for implementing OHTAC recommendations including the impact on the public, society, health care sectors and professions
- Provide advice regarding the field evaluation of technologies deemed to be potentially useful but for which there is inadequate existing quality evidence to support multi-million dollar, multi-year investments.
- Provide transparency regarding its recommendations and the analyses upon which these recommendations are made to Ontario's health care system

The primary risk with AAA is rupture which is associated with significant mortality rates. Current treatment options for AAA include OSR, EVAR and best medical treatment (BMT). The choice of treatment depends on the health of the patient, their ability to undergo surgery, whether the patient is symptomatic and the size, progression rate and morphology of the aneurysm.

Briefly, the EVAR procedure can be done with the patient under general anaesthesia, regional anaesthesia, or local anaesthesia. This is due to the fact that the procedure involves incisions in the groins to expose the femoral arteries through which the sheathed endograft is inserted at the top and bottom of the aneurysmal segment of the aorta. The endograft allows blood to pass through it and not through the aneurysm and thus alleviates pressure from the diseased aortic wall.

The purpose of this research was threefold. First, to provide an evaluation of the scientific literature related to EVAR. Second, to collect Ontario-specific clinical, resource utilization and quality-of-life data related to the use of EVAR and OSR. And finally, to evaluate the cost-effectiveness of endovascular repair compared to open surgical repair for the management of non-ruptured AAA in Ontario.

Methods

This non-randomized, prospective, observational study was conducted at LHSC on patients requiring elective repair of an AAA (AAA > 5.5 cm) between August 11, 2003 and April 3, 2005. Patients were followed for a period of one-year post-treatment.

The choice of intervention regarding the AAA repair method was determined as per usual LHSC clinical assessment and with discussion with the patient.

For patients accepting surgical options, surgical risk and suitability were assessed based on cardiac history and risk factors, the classifications of the SVS and the ASA, as well as the presence of pulmonary and renal diseases, hostile abdomen, technical challenges and thoracic aortic pathology and classified as low or high surgical risk patients.

Demographic, medical, health care resource utilization, cost and quality of life information (SF-36, EQ-5D) were collected from participating patients over a period of 1 year following their elective AAA repair.

Findings

The study enrolled 342 patients with a total of 351 individuals being approached.

All of the patients allocated to EVAR (n = 140) were all considered to be high surgical risk. Of the 195 patients allocated to OSR, 52 (26.6%) were considered to be high risk patients and were not suitable for EVAR. Results for patients refusing surgical treatments and who received BMT (n=7) are not discussed in the report.

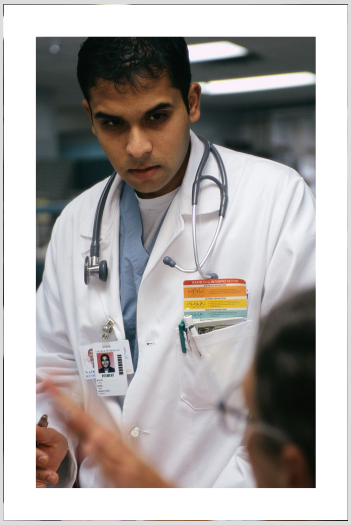
- The primary technical success rate (PTSR) was 100% for EVAR and 100% for OSR patients, respectively.
- EVAR patients spent less time in the hospital (7.7 days) than OSR low risk patients(9.36 days) or OSR high risk (16.13 days) patients ($P<0.05$).
- The mean procedural time in minutes was statistically significantly lower for EVAR patients (162.4 minutes) than for OSR low risk patients (181 minutes) ($P<.01$) as well as when EVAR patients are compared with OSR high risk patients (195.8 minutes) ($p<0.01$).

About the Medical Advisory Secretariat

The mandate of the Medical Advisory Secretariat is to provide evidence-based policy advice on the coordinated uptake of new health technologies and health services in Ontario to the ministry and other government agencies.

Through systematic reviews of scientific evidence and consultation with experts in the medical community, the Medical Advisory Secretariat provides up-to-date evidence-based assessment and advice to government health care decision-makers about emerging health technologies and health services. The aim is to ensure that residents of Ontario have access to the best available new health technologies that will improve patient outcomes.

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).



Findings continued

- Mid-term mortality (1 year) between the EVAR and the OSR high risk were statistically significantly different (7.1% vs. 17.3%, P=.04). Over the one-year period 12 (8.63%) EVAR treated patients developed a new type II endoleak with no other endoleaks, graft migrations, or re-interventions being required.
- The initial mean cost of hospitalization for EVAR was $28,139, for OSR low risk patients $15,494 and for OSR high risk $31,181
- A higher number of medical resources consumed during the one-year follow-up in the EVAR patients resulted in a statistically significantly higher cost of follow-up $5,181 compared to OSR low risk $1,899 and OSR high risk ($2,171) (P<.05).
- There was virtually no difference in the mean overall one year cost of EVAR and OSR high risk groupsand the difference in life years was 0.111 (0.959 vs. 0.848), respectively.
- The difference in adjusted quality adjusted life years (QALYs) between EVAR and OSR was 0.025 (0.848, vs 0.713).
- In patients with high surgical risk, OSR is dominated by EVAR, costing more and providing less QALY benefit.

Conclusions

For patients at a high risk of surgical mortality and complications, EVAR is a safe effective and cost-effective procedure with lower in-hospital costs, fewer complications and mortality occurring in EVAR patients compared to OSR patients with similar baseline risk. Re-intervention for the management of endoleaks or endograft failure was not required. The total hospitalization costs associated with EVAR compared to OSR HIGH RISK are similar and differences in the mean total annual 1 year costs are negligible.

As this is a non-randomized observational study, as with the majority of the literature comparing EVAR to OSR, the results are susceptible to selection bias and should be considered when examining the results. In addition, the study was conducted at a single center with comparisons limited to high risk patients. Therefore, the generalizability of the results to other patient groups in with EVAR is used to manage AAAsis unclear.

OHTAC Recommendations

The findings of this field evaluation study support the recommendations made by OHTAC on November 16, 2005 which state the following:

•Hospitals with the required expertise increase access to endovascular repair for abdominal aortic aneurysms in patients who are at high-risk of perioperative morbidity or death from co-morbidities from open surgical repair. Surgical expertise is critical and a surgeon should do a minimum of 50 EVAR procedures to prepare for this surgery and at least one procedure every two weeks to maintain his/her expertise in performing EVAR.

•A recommendation as to the provision of endovascular repair for abdominal aortic aneurysms in low or moderate risk patients requires additional long-term outcome studies. The use of EVAR in these patients is not recommended at this time.

•Based on the LHSC's protocol, endovascular repair is considered to be the most suitable treatment for patients falling into one or more of the following 'high-risk' categories:

(i) High-risk/comorbid diseases

Cardiac

- •class II-III angina
- •significant myocardium at risk
- •left ventricular ejection fraction < 30%
- •recent congestive heart failure

Pulmonary

- •chronic obstructive pulmonary disease or emphysema
- •severe pulmonary dysfunction
- •home oxygen or forced expiratory flow 25-75 of < 20% predicted

Renal

- creatinine > 250 µmol/L
- dialysis dependent

(ii) Hostile abdomen

(iii) Technical challenges

- inflammatory aneurysm
- renal anomalies (e.g., horseshoe kidney, renal allograft)
- anastomotic aneurysm

Implications

This field evaluation provides valuable insights into both the effectiveness and cost effectiveness of EVAR in Ontario. The assessment is based on an Ontario specific EVAR program, making the results particularly relevant for health policy decision makers in the province. The analysis of efficacy and cost outcomes from similar high surgical risk patients treated with EVAR or OSR allows for a comparison of the two interventions following 1 year of follow-up.

Health Technologies

Technology encompasses interventions at all stages of health care, from primary prevention and early detection of disease and risk factors, to diagnosis, treatment, rehabilitation and palliative care.

Health technologies may include new and existing diagnostic and treatment-related medical devices and services, equipment and supplies; laboratory tests and clinical procedures used in any health services delivery settings.

Health technologies examined do not include pharmaceuticals or information technology systems.

The full downloadable version of this Health Technology Policy Analysis by the Programs for Assessment of Health Technologies can be found here.

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Your Input Helps

Website Survey – We are conducting a brief survey to find out more about who is accessing the MAS and/or OHTAC web-sites. We would greatly appreciate if you would take a moment to complete the survey.

Rosiglitazone and Pioglitazone for the Treatment of Type 2 Diabetes Mellitus in Adults

Background

Rosiglitazone and pioglitazone belong to a class of oral anti-diabetic agents, the thiazolidinediones (TZDs), which act to improve insulin sensitivity of peripheral tissues in patients with type 2 diabetes. In Canada, TZDs are approved for use both as monotherapy and in combination with metformin or a sulfonylurea. These new agents are substantially more expensive than established oral antidiabetic medications. As a result, the overall aim of this report is to evaluate the clinical efficacy and incremental cost-effectiveness of pioglitazone and rosiglitazone in the treatment of adults with type 2 diabetes. The use of pioglitazone and rosiglitazone as monotherapy and in combination with metformin, sulfonylurea, or insulin as compared with established treatments were all considered in this study.

Search Methods

Mean changes from baseline to end of study on five key risk factors (i.e. HbA1c, blood pressure, total cholesterol, HDL cholesterol, smoking status) were abstracted from identified studies where available and combined. Unit costs for each of the drugs used in the treatment scenarios were obtained from the Ontario Drug Benefit Formulary. These data were used as inputs in the ODEM to estimate the cumulative first event rates for 7 DM-related complications, the mean difference in cost, and expected quality-adjusted life-years (QALYs). Incremental cost-effectiveness ratios (ICER) were calculated based on the net cost of health-care resources associated with the treatment and on effectiveness estimated over a patient's lifetime.

In the base case, the ICER was calculated assuming the effect of the intervention continued for 5 years using a discount rate of 3% and a time horizon of 40 years. Sensitivity analyses were conducted by varying the duration of the program and treatment effect.

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Systematic review and meta-analysis of the efficacy of rosiglitazone and pioglitazone on glycemic control

Search Results

The search produced 3,854 unique citations with 26 rosiglitazone and 25 pioglitazone trials which met inclusion criteria. Both rosiglitazone and pioglitazone showed the greatest decreases in HbA1c (up to 1.90%) and FPG (up to 4.55 mmol/L) when they were added to failed monotherapy compared with placebo. Combined results indicated that initiating TZD monotherapy in treatment-naïve patients was associated with a smaller decrease from baseline in HbA1c compared with other regimens.

Adding a TZD to failed dual therapy was not as effective at reducing HbA1c (-1.90% vs. -2.30%, respectively) and FPG (-2.90 mmol/L vs. -4.30 mmol/L) as adding insulin to the failed therapy. No study directly compared the addition of a TDZ to failed dual therapy with switching patients to insulin.

Summary

Overall there were a limited number of studies providing efficacy data for specific populations to determine the best place in therapy for TDZ. However, the systematic review of available data revealed that both rosiglitazone and pioglitazone were effective in reducing HbA1c and FPG levels in patients with type 2 diabetes, both as monotherapy (versus placebo and active comparator) and in combination with metformin, a sulfonylurea, or insulin when compared with placebo. Adding insulin to failed dual therapy resulted in greater decreases in both HbA1c and FPG compared with the addition of a TZD; however, the differences were not statistically significant.

Application of the Ontario Diabetes Economic Model (ODEM) to rosiglitazone and pioglitazone in the treatment of type 2 diabetes

Methods

Mean changes from baseline to end of study on five key risk factors (i.e. HbA1c, blood pressure, total cholesterol, HDL cholesterol, smoking status) were abstracted from identified studies where available and combined. Unit costs for each of the drugs used in the treatment scenarios were obtained from the Ontario Drug Benefit Formulary. These data were used as inputs in the ODEM to estimate the cumulative first event rates for 7 DM-related complications, the mean difference in cost, and expected quality-adjusted life-years (QALYs). Incremental cost-effectiveness ratios (ICER) were calculated based on the net cost of health-care resources associated with the treatment and on effectiveness estimated over a patient's lifetime. In the base case, the ICER was calculated assuming the effect of the intervention continued for 5 years using a discount rate of 3% and a time horizon of 40 years. Sensitivity analyses were conducted by varying the duration of the program and treatment effect.

Findings

In the base case analysis, the strategy of adding rosiglitazone to failed sulfonylurea was dominated by the strategy of adding metformin to failed sulfonylurea. Similarly, adding insulin to failed dual therapy of metformin and sulfonylurea dominated adding rosiglitazone to the same treatment. Adding rosiglitazone to failed insulin monotherapy compared with a 'do nothing' strategy was estimated to be less than $50,000 per QALY. Adding rosiglitazone to failed dual therapy (i.e. sulfonylurea plus metformin) compared with placebo had a $54,001 per QALY and adding rosiglitazone or sulfonylurea to failed metformin produced an incremental cost per QALY of $59,485.

Adding metformin to failed sulfonylurea or adding insulin to failed dual therapy (i.e. sulfonylurea plus metformin) were dominant treatment strategies compared with adding pioglitazone to these failed regimens. Adding pioglitazone to failed metformin resulted in an incremental increase in both costs and QALYs relative to adding sulfonylurea to give an incremental cost-effectiveness ratio of $122,480 per QALY. Pioglitazone add-on to failed insulin was associated with an incremental cost-effectiveness ratio of $55,072 compared with simply continuing insulin monotherapy.

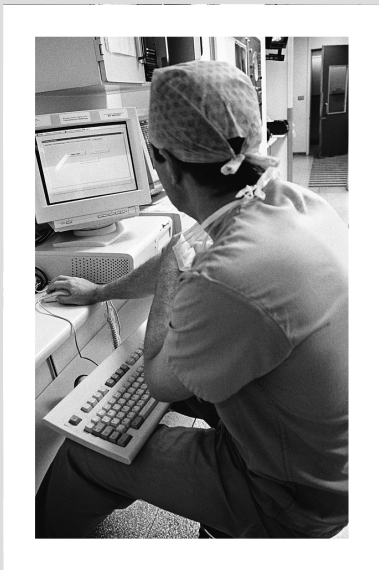
Summary

Half of the pioglitazone treatment scenarios were dominated by other treatment strategies and other regimens were more than $50,000 per QALY. Two of the five rosiglitazone treatments evaluated were dominated; however, the strategies that were not dominated were all less than $60,000 per QALY. Adding a TZD to failed insulin compared with continuing on insulin alone had the best ICER and appears to represent reasonable value for money.

The full downloadable version of this Health Technology Policy Analysis by the Programs for Assessment of Health Technologies can be found here.

From Science to Policy

Information concerning the health benefits; economic and human resources; and ethical, regulatory, social and legal issues relating to the technology assist policy makers to make timely and relevant decisions to maximize patient outcomes.



On The Cutting Edge

Field Evaluations

The Medical Advisory Secretariat may initiate field evaluation research of promising health technologies for which there is insufficient evidence of effectiveness or of how the technology will function within the Ontario health care system. Ontario, like Australia, is using field evaluation research projects to confirm the effectiveness of health technologies for patients. Field evaluations are designed to obtain evidence while meeting the care needs of informed, consenting patients, who may benefit.

CURRENT EVALUATION OF HYPERBARIC OXYGEN THERAPY (HBOT) FOR CHRONIC DIABETIC FOOT ULCERS

Background

Non-healing foot ulcers and their sequelae are a major source of morbidity and resource use for patients with diabetes mellitus (DM). Peripheral neuropathy, peripheral vascular disease, and poor glycemic control in conjunction with minor foot trauma increases the likelihood that patients with diabetes will develop foot ulcers. Because of the neuropathy, a foot injury and subsequent infection cannot be felt and since circulation is also affected, wound healing is compromised and causes the original ulcer to become chronic and may eventually require amputation.

The standard of care for treating diabetic foot ulcers includes the maintenance of optimal blood glucose levels; use of debridement, antibacterials, and dressings; administration of antibiotics to control infection; adequate nutrition; pressure relief in the areas of the foot that are most subject to weight bearing; and amputation. There has also been increasing interest in the use of hyperbaric oxygen therapy (HBOT) as an adjunctive treatment for diabetic foot ulcers. It has been suggested that the use of adjunctive HBOT will improve the healing of diabetic foot ulcer, and decrease the risk of LEA.

Overview of the Technology

HBOT is an established technology that has been in use for about 40 years. For wound healing treatment, a person is placed in a compression chamber under pressure greater than one atmosphere absolute (ATA) of 100% oxygen. The increased pressure increases the level of oxygen dissolved in the blood plasma affecting the immune system, wound healing, and vascular tone. Treatment regimens vary from 90-120 minutes once or twice daily for approximately 30 sessions.

There is evidence to support that adjunctive HBOT is more effective in the treatment of chronic diabetic foot ulcers than standard care alone. However, this evidence of efficacy for chronic diabetic foot ulcers is limited. In particular, only three, very small, prospective, randomized, controlled trials can be identified in the published literature to date. The first trial randomized 30 patients, the second randomized 68 patients while the most recent trial conducted in 2003 randomized just 16 patients. All three trials demonstrated that more wounds healed in HBOT-treated patients compared to the control group. Two of the three studies demonstrated a reduction of major LEA in the HBOT group, while the final study showed no difference between the groups. In addition, successes of adjunct HBOT for the treatment of diabetic foot ulcers have been reported in a few small case series and retrospective or prospective cohorts. However, many of these originated from one clinical centre.

Using this limited evidence, several health technology assessments and systematic literature reviews have been previously conducted.

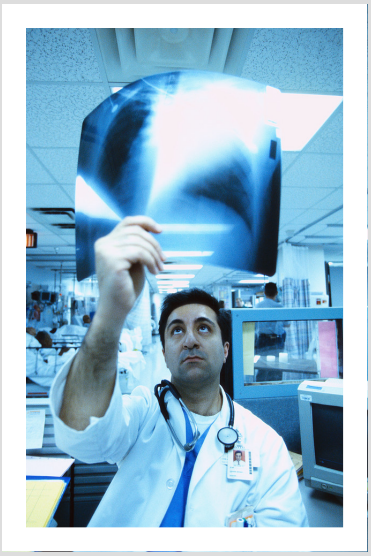
continued

Our Research Partners

Through a research framework, field evaluation projects are being conducted in partnership with the following organizations :

- Program for the Assessment of Technologies in Health (PATH)
- Human Factors Laboratory of the University Health Network
- The Toronto Rehab Institute
- Hamilton Health Sciences Centre
- Ottawa Heart Institute
- Toronto Health Economics and Technology Assessment Collaboration (THETA Collaboration)
- Li Ka Shing Knowledge Institute
- The Ontario Clinical Oncology Group

The Medical Advisory Secretariat coordinates its activities with other jurisdictions within the National Health Technology Strategy.



Overview continued

All of these reports recommend that good quality studies are required to confirm the comparative benefits of the technology for chronic diabetic foot ulcers in order to help clinicians and policy-makers decide whether HBOT should be more widely utilized.

Status of HBOT in Ontario

Currently in Ontario, HBOT is an accepted treatment of chronic diabetic ulcers and physicians who provide this service are reimbursed under the current Ontario Health Insurance Plan (OHIP) payment schedule. However there are only a few facilities which can provide proper wound care and adjunctive HBOT.

OHTAC Recommendations

Following the evidence-based review of the HBOT literature by the Medical Advisory Secretariat, Ontario Ministry of Health and Long-term Care (MOHLTC), the Ontario Health Technology Advisory Committee (OHTAC) recommended:

- That efforts be made to prevent chronic diabetic foot ulcers through diabetic care and education;
- That existing Ontario clinical guidelines on the prevention and management of diabetic foot ulcers be disseminated;
- That a well designed, adequately powered, clinical trial be undertaken to provide evidence on which to make a definitive decision on the effectiveness of HBOT in the treatment of non-healing diabetic foot ulcer. Given that a well conducted study may change the currently published estimates of effectiveness for wound healing and prevention of amputation for HBOT in the treatment of non-healing diabetic foot ulcers, the ministry should facilitate a field evaluation for this potentially important indication;
- That access to HBOT as an insured service be maintained until the results of the trial are available. Further expansion of this service for the treatment of non-healing diabetic foot ulcers should be predicated on better quality evidence of effectiveness. This does not apply to access to HBOT for other indications.

Based on these recommendations, the Program for Assessment of Technology in Health (PATH) was asked to conduct a field evaluation to determine the effectiveness and cost-effectiveness of HBOT in the treatment of non-healing ulcers in diabetic patients.

As a result, the goal of the current study is to conduct a well-designed, triple blind randomized controlled trial that would provide quality efficacy data on the use of adjunctive HBOT in the treatment of chronic foot ulcers for people with diabetes.

STUDY OVERVIEW

This study is being conducted at the Judy Dan Wound Care and Research Centre located at the North York General Hospital, Branson Site, Toronto, Ontario. Patients with non-healing diabetic foot ulcers will be enrolled. The Centre operates three monoplace hyperbaric chambers.

The primary objective of this prospective single-centre, triple-blind, randomized, placebo controlled clinical trial is to assess the efficacy of HBOT plus standard wound care compared with standard wound care alone in preventing the need for major amputation in patients with diabetes mellitus and chronic ulcers of the lower limb. Secondary objectives include, wound healing, safety, health care resource utilization, quality of life, and cost-effectiveness.

Contact Information

Medical Advisory Secretariat
Ontario Ministry of Health and Long-Term Care

20 Dundas Street West, 10th Floor,
Toronto, ON, Canada,
M5G 2N6

Tel: 416-314-1092
Fax: 416-325-2364
Email: MASinfo.moh@ontario.ca

Overview continued

Study participants will receive treatment 5 days per week for 6 weeks for a total of 30 treatments. During the 6-week treatment period dressing changes will be done at the Judy Dan Wound Care Centre as required based on the characteristics of the wound (at a minimum of 2 dressing changes per week). At the end of week 6, patients will enter a 12-week follow-up phase. Long-term follow-up of major amputation and quality of life will occur at weeks 26 and 52 after initiation of HBOT treatment.

It is anticipated that this study will commence recruiting patient by the fall of 2007 and will take two years to complete.

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Technologies Currently Under Review

- Optimal Design for Screening Programs
- Anal Dysplasia Screening
- Coronary Artery Screening [formerly : Electron Beam Computed Tomography (EBCT) and CT Screening for Asymptomatic Coronary Heart Disease]
- LDL Column Apheresis

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Previous OHTAC Recommendations

2007

January	Functional Brain Imaging
February	Screening Mammography

2006

October	In Vitro Fertilization and Multiple Pregnancies
August	Energy Delivery Systems for Treatment of Benign Prostatic Hyperplasia
August	Gastric Electrical Stimulation
July	Negative Pressure Wound Therapy - Updated
June	Computed Tomography Radiation Safety Issues in Ontario
June	Polysomnography in Patients with Obstructive Sleep Apnea
April	Intravascular Ultrasound to Guide Percutaneous Coronary Interventions
April	Portable Bladder Ultrasound
April	Artificial Disc Replacement for Lumbar and Cervical Degenerative Disc Disease - Updated
April	Magnetic Resonance Imaging (MRI) Environment Safety in Ontario
March	Hydrophilic Intermittent Catheters
March	Extracorporeal Photopheresis (ECP)
February	Metal-on-Metal Total Hip Resurfacing Arthroplasty
February	Midurethral Slings for Women with Stress Urinary Incontinence - Updated
January	Ultrasound Screening for Abdominal Aortic Aneurysm
January	Coil Embolization for Intracranial Aneurysms (Updated)

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December	Advanced Electrophysiologic Mapping and Catheter Ablation for the treatment of complex cardiac arrhythmias
December	Positron Emission Tomography for the Assessment of Myocardial Viability
December	Automated External Defibrillators
November	Endovascular Repair of Descending Thoracic Aortic Aneurysm
November	Air Cleaning Technologies
October	Appropriate Utilization of Integrated Health Technologies to treat Osteoarthritis of the Knee
October	Drug Eluting Stents (DES)
June	Total Knee Replacement
September	Biventricular Pacemakers (Cardiac Resynchronization Therapy)
August	Hyperbaric Oxygen Therapy for Non-Healing Ulcers in Diabetes Mellitus
June	Arthroscopic Lavage and Debridement for Osteoarthritis of the Knee

Previous OHTAC Recommendations

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June	Intra-Articular Viscosupplementation With Hylan G-F 20 for Treatment of Osteoarthritis Knee Pain
June	Physiotherapy Rehabilitation after Total Knee or Hip Replacement
May	Intrathecal Pumps for Baclofen Infusion for Spasticity
May	Interim Report on Endovascular Repair of Abdominal Aortic Aneurysms (EVAR)
April	Osteogenic Protein-1 for Long Bone Nonunion
April	Multi-Detector Computed Tomography Angiography for Coronary Artery Disease
March	Spinal Cord Stimulation for the Management of Neuropathic Pain
March	Sacral Nerve Stimulation for the Management of Urge Incontinence, Urgency-Frequency, Urinary Retention and Fecal Incontinence
March	Deep Brain Stimulation in Parkinson's Disease and Other Movement Disorders
January	Bariatric Surgery

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December	Balloon Kyphoplasty
December	Vacuum-assisted closure (V.A.C. therapy) for chronic wounds (Updated : please see July 2006 Recommendation)
October	Thermal Balloon Endometrial Ablation for Dysfunctional Uterine Bleeding (TBEA)
September	Primary Angioplasty
August	Bispectral Index Monitor
June	Repetitive Transcranial Magnetic Stimulation (rTMS) for the Treatment of Major Depressive Disorder
June	Radiofrequency Ablation for hepatocellular carcinoma or primary liver cancer
May	Indication for Positron Emission Tomography Imaging of a Single Pulmonary Nodule
March	Pyrocarbon Finger Joint Implants
March	Endovascular Coil Embolization for the Treatment of Intracranial Aneurysm (Updated : please see January 2006 Recommendation)
March	Computer assisted Surgery using Telemanipulators
March	Computer assisted Hip and Knee Arthroplasty : Navigation and Robotic Systems
March	Video-assisted Laryngoscopy for Tracheal Intubation
February	Bone Morphogenetic Proteins and Artificial Disc use in spinal surgery for degenerative disc disease
February	Patient Monitoring System for Magnetic Resonance Imaging (MRI)
February	Tension-free Vaginal Tape for Stress Urinary Incontinence in Women (Updated : please see February 2006 Recommendation)