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About the E-Bulletin

The OHTAC E-Bulletin is issued on a regular basis to provide you with the latest updates on the committee's recommendations.

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

The complete Health Technology and Policy Assessment (HTPA) reports for each technology review conducted by OHTAC, together with the accompanying recommendations, can be downloaded from the OHTAC website located [here](#).



Gastric Electrical Stimulation

A summary of the Health Technology Policy Assessment by the Medical Advisory Secretariat and the OHTAC Recommendation

Background

Gastroparesis (GP) refers to impaired gastric emptying in the absence of obstruction and may occur in association with diabetes, as a complication of gastric surgery or for unknown reasons. Symptoms consist of early satiety, nausea, vomiting, abdominal pain and malnutrition. Treatment consists of optimal blood glucose control in patients with diabetes, dietary modifications, and drugs to stimulate gastric movement or relieve nausea. For patients who are refractory to drug treatment, surgical options may include enteral tube feeding, partial or full gastric resection, or total parenteral nutrition. The incidence of severe refractory GP in Ontario is estimated to be about 20 to 150 cases per year.

Morbid obesity is defined as a body mass index of at least 40 kg/m² or at least 35 kg/m² with comorbid conditions (e.g., diabetes, hypertension, dyslipidemias, obstructive sleep apnea, and weight-related arthropathies). An expert estimated that about 160,000 to 180,000 people are morbidly obese in Ontario. Bariatric surgery is considered an intervention of last resort for patients who have attempted first-line forms of medical management, such as diet, physical activity, behavioural modification, and drugs.

GES is an implanted system for the treatment of GP and morbid obesity. The system consists of a neurostimulator and 2 leads. The potential advantages of GES for the treatment of GP and morbid obesity include reversibility of the procedure and that it is less invasive compared to gastric surgery.

Findings

Severe Treatment-Resistant Gastroparesis

The randomized controlled trial (RCT) reviewed for GES in the treatment of nausea and vomiting due to treatment-resistant gastroparesis was of low quality due to several factors including:

- Short term duration.
- Confounding factors for diabetes patients such as status of glucose control, renal insufficiency, and use of antidiabetes medication.
- Small sample size due to early termination of enrolment.
- Placebo effect.
- Retrospective subgroup analyses.
- Attrition of patients.
- Use of concurrent medical therapy.

About OHTAC

OHTAC is envisaged as the first step in creating a single portal for providing 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](#).



Your Input Helps

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Morbid Obesity

The quality of the RCT of GES for the treatment of morbid obesity is very low. There was no statistically significant difference in excess weight loss between the study and control groups at the end of the 6 months (1.3% for active stimulation compared to 2.4% for placebo). The percent of excess weight loss at 12 months after implantation was 2.5%. (Of note, other bariatric procedures such as gastric bypass can produce an excess weight loss of up to 80%).

OHTAC Recommendations

Based on the above, OHTAC recommends the following with regard to GES:

At this time, the quality of evidence is insufficient to make a recommendation in favour of the use of gastric electrical stimulation (GES) for people with severe, treatment-resistant gastroparesis.

OHTAC does not recommend GES for the treatment of morbid obesity as evidence of its effectiveness does not currently exist.

Implications

There is no Schedule of Benefits code for GES. In 2005, there were less than 5 out-of-country requests (for either consultation or surgery to treat GP). The GES device is approximately CDN \$10,700; the estimated budget impact for the treatment of 20-150 patients in Ontario with severe drug-refractory GP would be approximately CDN \$107,000 to \$1.6M per year for the device cost alone. The degree of uptake of GES for morbid obesity is unknown in relation to other types of bariatric surgery which have been shown to be more effective.

The full downloadable version of the February OHTAC recommendation for this technology can be found [here](#)

The full downloadable version of this February Health Technology Policy Analysis by the Medical Advisory Secretariat can be found [here](#).

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).

Subscription Information

The OHTAC E-Bulletin is published by the Medical Advisory Secretariat of the Ontario Ministry of Health and Long-Term Care.

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Energy Delivery Systems for Treatment of Benign Prostatic Hyperplasia

A summary of the Health Technology Policy Assessment by the Medical Advisory Secretariat and the OHTAC Recommendation

Issue

BPH is a non-cancerous enlargement of the prostate. Patients with BPH normally present with lower urinary tract symptoms. About a quarter of men over the age of 50 have symptoms of BPH. The incidence of BPH increases with increasing age to the point that more than 80% of 80 years old men have enlarged prostate.

Traditional treatment of BPH includes watchful waiting, pharmacotherapy, and surgical procedures. Surgical techniques include open prostatectomy, transurethral resection of the prostate (TURP), and transurethral incision of the prostate (TUIP). TURP has been considered the gold standard and continues to be the operation most commonly performed in the treatment of BPH in Ontario. TURP produces significant changes of all subjective and objective outcome parameters. However, the procedure is associated with intra-operative and post-operative complications including hemorrhage during or after the procedure, which often necessitates blood transfusion, transurethral resection (TUR) syndrome, urinary incontinence, bladder neck stricture, and development of sexual dysfunction.

During the last decade, a number of treatment modalities using different sources of energy have been developed

as alternatives to TURP. These techniques include the use of laser, radiofrequency, microwave, and ultrasound, to heat prostate tissue and cause coagulation or vaporization. In addition, new electrosurgical techniques that use higher amounts of energy to cut, coagulate, and vaporize prostatic tissue have entered the market as competitors to TURP. The driving force behind these new treatment modalities is the potential of producing good haemostasis and therefore, reducing catheterization time and length of hospital stay.

Laser treatment of BPH encompasses a variety of techniques using different laser wavelengths (Nd:YAG, Diode, Holmium:YAG, and Potassium Titanyl Phosphate). The procedures using Nd:YAG laser include visual laser ablation of the prostate (VLAP) and contact laser vaporization (CLV), while interstitial laser coagulation (ILC) uses diode laser. One of the proposed benefits of PVP is the ability to successfully discharge patients on the day of surgery without a catheter.

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

Findings

A review of these methods showed that:

- Although patients undergoing VLAP were kept in hospital for shorter period of time, they had to be catheterized for significantly longer time to allow tissue sloughing off. In addition, a MAS meta-analysis on the rate of reoperation in VLAP studies showed that the difference between VLAP and TURP was significant in favour of TURP.
- Patients undergoing ILC also needed to be catheterized for longer period of time compared to TURP. An important complication of ILC procedure was a significantly higher rate of urinary tract infection (UTI) associated with longer catheterization time.
- A MAS meta-analysis of published RCTs on CLV with long-term follow-up showed that the improvement in urinary symptom scores was significantly better in patients undergoing TURP compared to CLV.
- HoLEP procedure creates significant vaporization of the prostatic tissue while maintaining hemostasis and preventing TUR syndrome. HoLEP demonstrated superior outcomes compared to TURP since this technique allows true anatomic enucleation of the prostate. A MAS meta-analysis of 4 RCTs on HoLEP which provided one year follow-up showed that this technique reduced urinary symptom scores and improved urinary flow significantly better than TURP.
- No randomized controlled trial has been published to compare the efficacy and safety of the PVP technique with TURP. A prospective cohort study published in 2005 has shown that outcomes are similar to TURP. However, the length of follow-up (6 months) is not sufficient to draw any definite conclusion.
- Transurethral microwave thermotherapy (TUMT) uses microwaves to deliver heat through a special catheter to selected portions of prostatic gland. The procedure can be performed with local anaesthesia in an outpatient setting. Three RCTs which provided follow-up of one year or more have demonstrated significant difference between TUMT and TURP in improving subjective and objective outcomes in favour of TURP. In addition, patients required longer duration of catheterization.
- Transurethral needle ablation of prostate (TUNA) uses radiofrequency waves to heat the prostatic tissue. Two small needles are placed inside the prostatic tissue under endoscopic control and energy is applied to the tissue to cause coagulative necrosis. RCTs showed that TUNA technique is significantly less effective in reducing urinary symptom score and improving urinary flow compared to TURP. A MAS meta-analysis on the reoperation rates reported by RCTs showed that significantly more patients undergo reoperation following TUNA than TURP.
- The application of HIFU in BPH has not been demonstrated in any RCTs.

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.

OHTAC Recommendations

OHTAC makes the following recommendations regarding the above technologies:

- Based on effectiveness, economic analysis and complication rates, it is appropriate to offer TURP, HoLEP, bipolar, or monopolar electrovaporization to patients for the treatment of BPH.
- Informed consent for patients should include the fact that for HoLEP and bipolar electrovaporization, only 1-year follow-up is currently available, there is a slightly higher blood transfusion requirements for TURP and that TURP is associated with a small risk (0.5%) of TUR syndrome. Therefore, the choice of technique should be tailored around patient's characteristics and preferences, surgeon's experience and skills, and the availability of the technique.
- OHTAC recommends that facilities providing VLAP, CLV, ILC, TUMT, and TUNA consider alternatives mentioned above.
- OHTAC recommends that a registry study be conducted to establish longer term effectiveness and complication rates for PVP given the likelihood of increasing diffusion of this technology.

Implications

Recent laser treatment methods including Holmium laser and PVP are emerging techniques that challenge the standard TURP. The Holmium laser provides several applications in urology including the management of stone diseases, urinary tumors, and urinary tract stenoses. On the other hand, the wavelength of PVP does not allow the laser to be used for conditions other than BPH. The older generation of the holmium laser generators is low power (20 W) and cannot be used for the treatment of BPH. However, only a few hospitals in Ontario have purchased a high-power (80-W) holmium laser generator, which has the capability of being used for the treatment of BPH as well as other applications. HoLEP procedure requires a short duration of catheterization and 2 days hospital stay.

PVP technique promises several notable advantages provided it can pass the test of time. Like HoLEP, PVP requires a short duration of catheterization but can also be performed in an outpatient setting; therefore, it has the potential to reduce health care cost. If all TURP procedures were to be replaced by PVP, the potential cost savings to the provincial health system could be as high as \$13.5 million (not including capital costs). This advantage has resulted in rapid diffusion of the technology in the United States even before rigorous evaluation could be applied as occurred with the other surgical technologies.

The full downloadable version of the February OHTAC recommendation for this technology can be found [here](#)

The full downloadable version of this February Health Technology Policy Analysis by the Medical Advisory Secretariat can be found [here](#).

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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.

Routine Eye Examinations for Ontarians 20-64 years of age

A summary of the Health Technology Policy Assessment by the Medical Advisory Secretariat and the OHTAC Recommendation

Background

Glaucoma and macular degeneration are leading causes of visual impairment in Canada and world wide.

Glaucoma is a progressive degenerative disease of the optic nerve, which causes gradual loss of peripheral (side) vision, and in advanced disease states loss of central vision. Blindness may result if glaucoma is not diagnosed and managed. The prevalence of primary open angle glaucoma (POAG) ranges from 1.1% to 3.0% in Western populations, and from 4.2% to 8.8% in populations of African descent. In Canada, glaucoma disease is the second leading cause of blindness in people aged 50 years and older.

Age-related maculopathy (ARM) is a degenerative disease of the macula, which is a part of the retina. Damage to the macula causes loss of central vision affecting the ability to read, recognize faces and to move about freely. AMD is the leading cause of blindness in developed countries. It is estimated that 1% of people 55 years of age, 5% aged 75 to 84 years and 15% 80 years of age and older have AMD.

In each case, knowledge of existing disease may not be apparent until symptoms appear at which time irreparable damage to vision may have occurred. Neither eye disease has either a prevention or cure. However, evidence exists to support the effectiveness of early treatment to delay the progression of disease.

Findings

A systematic review of the scientific literature was completed by the Medical Advisory Secretariat to determine the association between five possible non-modifiable risk factors including age, gender, refractive error, ethnicity and family history of disease, and the risk of having open angle glaucoma (OAG) or macular degeneration (MD).

Open Angle Glaucoma

The prevalence of OAG increases with age for all populations and is greater in

populations of African descent.

- The prevalence of OAG in Caucasian and South Asian populations ranges from 1.2%-2.4% of the population.
- The prevalence of OAG in an African American and African Caribbean populations is 4.2% and 7.0% of the population respectively.

It is estimated that 50% of people with OAG are undiagnosed and therefore unaware that they have the disease.

Continued

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Risk Factors:

- Studies examined by this review indicate that South Asian population, persons 50 years of age and older are two to four times more likely to have OAG than persons 40-49 years of age in the same population.
- Persons with a family history of OAG (any first degree relative with OAG) are 2 to 3.9 times more likely to have OAG than persons without a family history of OAG.
- African Americans 50 years of age and older are 4 times more likely to have OAG compared to Caucasian Americans 50 years of age and older.
- Persons with a refractive error of -1.00 Diopters (D) or worse have a 1.6 to 2.0 times greater chance of OAG than persons with a refractive error better than -1.00 D.

Macular Degeneration

The incidence of early and late stage MD increases with age. The incidence of early and late stage MD begins to increase at 55 years of age.

Risk Factors:

- Persons with a family history of late stage MD are 2 to 3 times more likely to have early or late stage MD compared to persons without a family history.

OHTAC Recommendations

Following review of these findings, OHTAC recommends that:

- Eye examinations which include tonometry and inspection of the optic disc are recommended for all persons 50 years of age and older.

OHTAC notes from the evidence that persons with a family history of OAG and people of African descent are at an increased risk of having OAG and persons with a family history of MD are at an increased risk of having MD.

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2006

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January	<u>Coil Embolization for Intracranial Aneurysms (Updated)</u>

2005

December	<u>Advanced Electrophysiologic Mapping and Catheter Ablation for the treatment of complex cardiac arrhythmias</u>
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2005 continued

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March	Deep Brain Stimulation in Parkinson's Disease and Other Movement Disorders
January	Bariatric Surgery

2004

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)