CADTH

Health Technology Update

Issue 14 • May 2013

A newsletter on new and emerging health care technologies in Canada

Scanning the Horizon

Informing Decision-Makers About Emerging Medical Technologies

Welcome to the 14th edition of the *Health Technology Update* newsletter. This, the first newsletter of 2013, brings you information about health technologies that could significantly impact the health of patients and lead to high-quality, efficient, and sustainable health care in Canada.

The focus of this issue of the newsletter is on new and emerging medical devices and procedures for the treatment of diabetes, arthritis, glaucoma, gastroesophageal reflux disease, and peripheral artery disease.

In This Issue

We want your feedback... tell us what you think

Health Technology Update is a source of information for those involved in planning and providing health care in Canada. Did we hit the mark in our efforts to bring you information on medical technologies and issues in practice and policy? Has the information we've provided on HTA research been useful in helping to make decisions? Tell us what you think.

Send your comments to Andra Morrison at andram@cadth.ca.

Bariatric Surgery for the Reversal of Type 2 Diabetes in Obese Patients

Bariatric surgery (BS) was originally designed to promote weight loss in morbidly obese patients. Emerging evidence suggests that BS may also be the most effective treatment for type 2 diabetes mellitus, leading to its remission or cure.

How It Works

Gastric bypass (GB) is the most commonly practised form of BS. It is usually performed laparoscopically and involves the rerouting of the small intestine to a pocket at the top of the stomach. The pocket is sealed off from the rest of the stomach, allowing food to bypass most of the stomach and the upper part of the small intestine. The new smaller stomach prevents overeating and the bypassing of the small intestine substantially reduces calorie absorption.

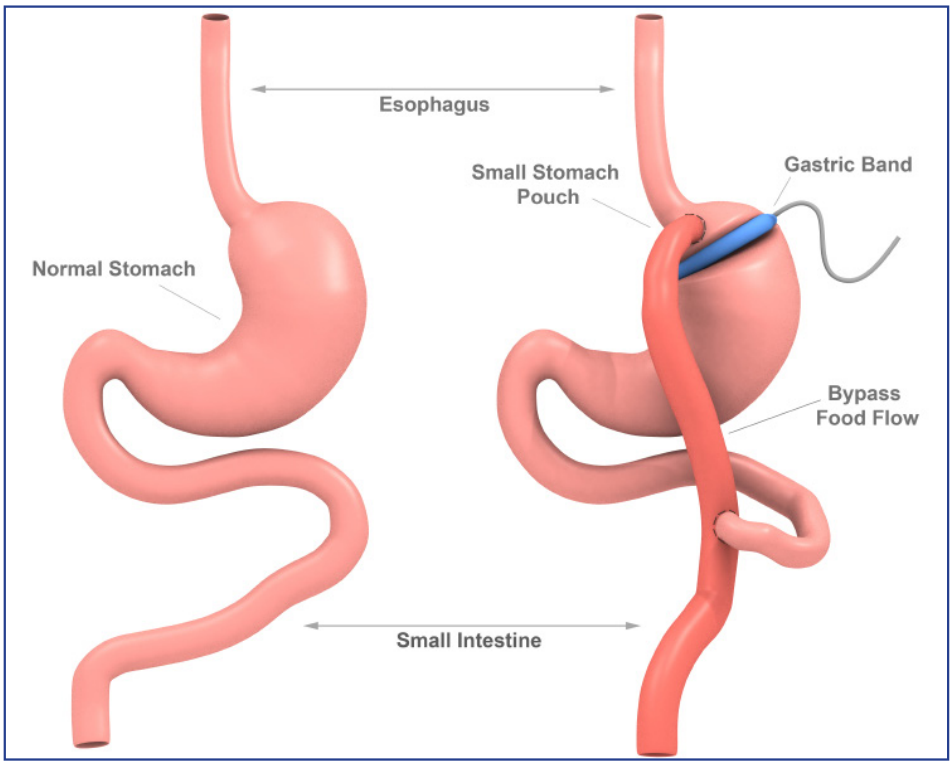
Other common types of bariatric surgeries include: biliopancreatic diversion (BD), gastric banding, banded gastroplasty, and gastric sleeve.

Who Might Benefit

Approximately 2.4 million Canadians have diabetes. Current guidance from the Canadian Diabetes Association recommends BS in severely obese patients who have type 2 diabetes mellitus, when other interventions fail to achieve weight goals.[1] Less than half of patients with moderate to severe type 2 diabetes mellitus achieve and maintain glycemic control using standard medical therapy (SMT).[2]

Evidence

A two-year follow-up, single-centred, non-blinded, randomized controlled trial (RCT) evaluated the efficacy of two types of BS, GB and BD, compared with SMT in 60 patients with type 2 diabetes mellitus who were severe obese. At two years, the authors reported that none of the patients receiving SMT experienced remission in diabetes compared with 75% of patients receiving GB, and 95% of patients receiving BD.[3]



A 12-month follow-up, single-centred, non-blinded RCT compared the effectiveness of SMT with SMT plus GB or sleeve gastrectomy as a means of improving glycemic control in 150 obese patients with type 2 diabetes mellitus. The authors reported that at 12-months, glycated hemoglobin levels of 6% were achieved in 12% of the SMT group versus 42% in the GB group, and 37% in the sleeve gastrectomy group. With the continued use of drugs to lower glucose, lipid and blood pressure levels decreased significantly in the BS groups but increased in patients receiving SMT alone.[2]

A Canadian multivariate cost-effectiveness analysis, based on data from more than 2,000 patients, compared type 2 diabetes mellitus patients who underwent BS with patients with type 2 diabetes mellitus who were treated with SMT. The authors reported BS to be clinically more effective and ultimately less expensive than SMT. Cost savings accrued to third-party payers at three months post surgery; and, for laparoscopic surgeries, surgical costs were fully recovered at 47 months.[4]

A United Kingdom cost-effectiveness evaluation compared laparoscopic adjustable gastric banding with SMT in obese type 2 diabetes mellitus patients. The authors reported that from the health-payers perspective, the surgical route was highly cost-effective compared with SMT.[5]

Cost

The cost of BS ranges between $15,000 and $25,000, depending on the specific procedure used.

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iStent: A Micro-Invasive Treatment for Open-Angle Glaucoma

The Trabecular Micro Bypass Stent System (iStent) is a heparin-coated titanium bypass stent implant. It is intended to reduce intraocular pressure (IOP), which slows the progression of open-angle glaucoma (OAG). OAG is an eye disease that can lead to permanent blindness. The iStent is implanted into the eye during cataract surgery in adults with mild to moderate OAG who are being treated with ocular hypotensive drugs.

How It Works

The iStent is L-shaped and measures 1 mm in length and 0.33 mm in height. It is implanted through a small corneal incision under gonioscopic guidance. The implant is preloaded into an applicator that facilitates its placement into Schlemm's canal, where it is released at the lower nasal quadrant. The device bypasses the trabecular meshwork and reroutes aqueous humour from the anterior chamber directly to Schlemm's canal.

Regulatory Status

The iStent is manufactured by Glaukos Corp. It was licensed by Health Canada in 2009 and by the US Food and Drug Administration (FDA) in 2012.

Who Might Benefit

Almost 250,000 Canadians have OAG; half are unaware that they have the disease. The number of people blind as a result of this disease will double by 2031, reaching nearly 20, 000.[1]

Evidence

A 2011 technology assessment[2] evaluated a variety of novel glaucoma procedures, including the iStent. The authors found that although all the new approaches showed potential for the treatment of OAG, there were no RCTs of appropriate power to determine their efficacy.

A 12-month follow-up RCT[3] involving 239 patients with mild to moderate OAG assessed the safety and efficacy of the iStent. The study compared patients receiving cataract surgery in combination with the iStent versus patients receiving cataract surgery alone. The authors reported that the patients who had the iStent implant experienced statistically and clinically significant benefits in reducing IOP with less medication. The safety profile for the two patient groups was similarly favourable. Follow-up at two years found significantly better IOP control in the iStent treatment group compared with the control group in patients not taking any medication for OAG.

A double-blinded RCT compared the IOP-lowering efficacy of phacoemulsification alone and in combination with the iStent in 36 patients.[5] Results showed that the iStent-treated patients experienced significantly lower IOP and a significant reduction in the use of ocular hypotensive drugs, with 67% of patients being medication free 15-months post-operatively compared with the control group. No adverse events were reported in the study group.

A 12-month follow-up RCT[6] of 33 patients with OAG or ocular hypertension evaluated the changes in aqueous humour dynamics, and the efficacy and safety of the iStent. The study population consisted of patients who received two iStents in combination with cataract surgery and patients who underwent cataract surgery alone. At one year, the authors indicated that the iStent group (n = 17) showed a clinically significant increase in trabecular outflow facility, significant IOP reduction, and a reduction in reliance on ocular medications compared with the control group (n = 16).

Cost

The cost of the iStent is unknown.

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Drug-Eluting Stents for Peripheral Artery Disease

The Zilver PTX is a minimally invasive endovascular revascularization treatment for patients with above-the-knee femoropopliteal peripheral artery disease (PAD). PAD is characterized by the progressive narrowing of the arteries in the legs, reducing the flow of blood from the heart to the legs.

The Zilver PTX includes a self-expanding nitinol stent that remains in the artery to keep it open. The stent is coated with paclitaxel, an anti-restenotic drug that is gradually eluted to the artery wall.

Who Might Benefit

Approximately 800,000 Canadians have PAD.[1] At least 25% of this population will require endovascular or surgical revascularization.

Regulatory Status

The Zilver PTX drug-eluting stent is manufactured by Cook Medical. It received US FDA approval in November 2012. A condition of the FDA approval requires the manufacturer to conduct a five-year, post-approval safety and efficacy study involving 900 participants. The stent is not yet licensed in Canada.

Evidence

An industry-sponsored, multinational RCT involving 479 patients with above-the-knee femoropopliteal PAD compared the Zilver PTX with balloon angioplasty.[2] The primary safety end point was met, with an event-free survival rate at 12 months of 90.5% for patients in the Zilver PTX treatment group and 83.9% for patients in the angioplasty control group. Primary patency rate at 12 months was 82.7% in the Zilver PTX group and 32.7% in the angioplasty group.

A second phase of the study included patients who experienced suboptimal percutaneous transluminal angioplasty (PTA). These patients underwent a second randomization to either the Zilver PTX or a bare metal stent (BMS) to evaluate the paclitaxel drug effect. The primary patency rate at 12 months was 89.9% for the Zilver PTX compared with 73.0% for the BMS.

The authors concluded that the Zilver PTX is safe and is associated with superior 12-month patency compared with angioplasty and the provisional BMS placement. Year two data reported a 50% reduction in restenosis rates with the Zilver PTX compared with BMS.[3]

An international single-arm registry[4] involving 1,000 patients with above-the-knee femoropopliteal PAD evaluated the safety and performance of the Zilver PTX. Event-free survival at 12 months was 89% and the primary patency rate was 83%. The authors concluded that treatment with the Zilver PTX is safe and effective in the above-the-knee femoropopliteal PAD population.

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A French budget impact analysis[5] of a progressive five-year transition from BMS to the Zilver PTX estimated that the adoption of Zilver PTX is cost saving from one year onward and is sustained over five years. The model calculated a five-year budget reduction of €6,807,202 for a projected patient population of 83,316, of which 21,361 (26%) received the Zilver PTX. The authors concluded that, although initially more costly, the Zilver PTX resulted in health care savings.

Cost

According to the manufacturer, the cost of the Zilver PTX has not been determined for the Canadian market at this time.

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RegJoint — A Biodegradable Joint Implant That Helps Restore Normal Mobility

The RegJoint implant is a biodegradable joint scaffold that reconstructs damaged joints. The implant stimulates new tissue growth and creates a flexible and durable new joint. It consists of a porous biodegradable polylactide copolymer implant (BPI) that is round and disc-like in shape, with a diameter that varies from 8.0 mm to 18.0 mm and thickness from 3.6 mm to 4.5 mm. It is intended for damaged small joints in the fingers and toes caused by osteoarthritis (OA) and rheumatoid arthritis (RA). OA and RA are the leading causes of disability in Canada. More than 6% of total hospitalizations in Canada are associated with arthritis.

The RegJoint implant offers an alternative to conventional surgical options that include joint replacement with silicone implants or the induction of joint ossification between two bones.

How It Works

The implant is inserted into the space between the two bones of a joint. It functions as a cushioning spacer, relieving pain caused by friction from the two bones rubbing together. The implant provides temporary support, while allowing a progressive substitution of the implant with the patient's own fibrous connective tissue, to provide a new natural joint between the bone ends. The new joint fuses the bone heads in a way that enables normal mobility. The implant gradually disintegrates and is assimilated into the bloodstream.[1]

Who Might Benefit

Arthritis is a chronic disease. OA, the most common form of arthritis, affects 4.4 million Canadians; while RA affects approximately 0.9% of the Canadian adult population. The most commonly affected joints include the hands and feet, hips, knees, and spine.[2]

Surgery plays a major role in the management of arthritis. In Ontario alone, approximately 44,000 arthritis-related surgical procedures are carried out annually. Less than 2% of these are for the hands and feet.[3]

Regulatory Status

The RegJoint implant has not been licensed by Health Canada or the US FDA. It was granted the European Union CE (conformité européenne) Mark in 2011.

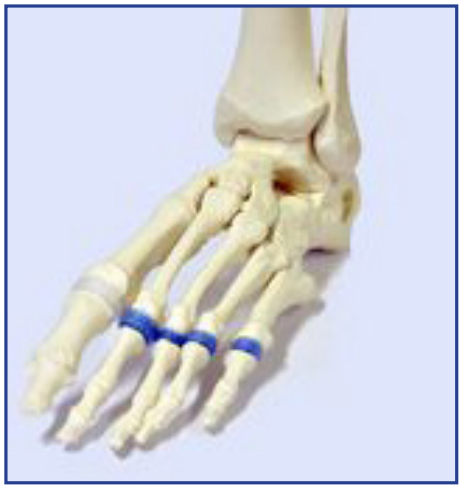
Evidence

A two-year follow-up RCT involving 52 patients with RA compared a BPI with a silicone implant. Clinically relevant outcomes were similar between the two groups. However, recurrent palmar subluxation was more prevalent in the BPI group. Implant fractures, cortical perforations, and osteolysis were more common in the silicone implant group. The surgical technique used for BPI arthroplasty was described by the study authors as somewhat laborious because of the need to fix the implant both to the metacarpal bone and the palmar plate.[4]

An RCT involving 35 patients with rheumatoid forefoot deformities compared a BPI with a conventional metatarsal head resection group. Clinical performance and complication rates, at 3 and 12 months, were comparable between the BPI and the control group.[5]

Cost

According to the manufacturer of RegJoint, the device costs between $400.00 and $470.00 per implant in hospitals.



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The SRS Endoscopic Stapling System: A Non-Surgical Treatment for Gastroesophageal Reflux Disease

The SRS is an endoscopic treatment for gastroesophageal reflux disease (GERD). The device performs an anterior fundoplication without requiring abdominal incisions.

GERD is a chronic condition that occurs when the lower esophageal sphincter relaxes, allowing the contents of the stomach to flow back into the esophagus. Common symptoms of GERD include heart burn, regurgitation, and chest pain. Proton pump inhibitors (PPIs) are the primary treatment for GERD. However, for patients who are poorly controlled with PPIs or who wish to discontinue medical therapy, surgical intervention with laparoscopic fundoplication is the conventional alternative.[1]

GERD has a significant impact on health care resources and is associated with considerable productivity loss. Patients with GERD are absent from work 16% of each year due to their symptoms. In Canada, this represents a workforce productivity loss of 1.7 billion hours, amounting to $21 billion every year.[2]

How It Works

The SRS system consists of a flexible endoscope with an integrated miniature video camera, ultrasound sensor, and surgical stapler. The endoscope is inserted into the esophagus through the mouth. A partial fundoplication is performed above the gastroesophageal junction by stapling the fundus to the esophagus. The procedure is performed under general anesthesia, in approximately 45 to 60 minutes, by a physician in a hospital setting.[3]

Who Might Benefit

GERD is a common condition that effects between 10% and 20% of adults in Western populations. The SRS is indicated for patients who require and respond to pharmacological therapy.[4] It is not recommended to patients with hiatal hernia > 3 cm.

Regulatory Status

The SRS Endoscopic Stapling System is manufactured by Medigus Ltd. It was licensed by Health Canada and the US FDA in 2012.

Evidence

There are no published trials of SRS in peer-reviewed literature. Numerous abstracts of studies are posted on the manufacturer's website. It should be noted that data contained in abstracts may not always accurately reflect data contained within the full article.

An abstract describing a multicentred, international, industry-sponsored safety and efficacy study involving 72 patients with GERD found acceptable safety (9%) rates. As well, high efficacy (75%) rates were reported with a 50% reduction in GERD health-related quality of life scores (reflecting improvement).[5]

Three additional abstracts of single-centre safety and effectiveness studies are posted on the manufacturer's website. The combined population of these studies includes 50 patients with GERD. Overall, the authors of these studies found the device to be relatively safe and effective, with some patients experiencing significant improvements in GERD symptoms and satisfaction with the procedure. Two-year follow-up data in one study showed that 50% of patients remained off daily PPIs.[6-8]

Cost

According to the manufacturer, the cost of the SRS has not yet been determined for the North American market.

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New and Emerging Health Technology Reports

Recent Reports from CADTH and Other Canadian Health Technology Assessment Producers Relating to Medical Devices and Procedures

Canadian Agency for Drugs and Technologies in Health (CADTH)

📖 Shilla and MAGEC Systems for Growing Children with Scoliosis: Clinical Benefits and Cost-Effectiveness. Available: http://www.cadth.ca/media/pdf/htis/jan-2013/RC0421%20Shilla%20and%20MAGEC%20for%20scoliosis%20Final.pdf

📖 Repetitive Transcranial Magnetic Stimulation for Specific Patient Populations: Clinical and Cost-Effectiveness and Safety. Available: http://www.cadth.ca/media/pdf/htis/jan-2013/RC0417%20rTMS-Final.pdf

📖 CT Colonography Versus Colonoscopy and/or Sigmoidoscopy for the Diagnosis and Treatment Planning of Colorectal Cancer: A Review of the Comparative Clinical and Cost-Effectiveness and Guidelines for Use. Available: http://www.cadth.ca/media/pdf/htis/dec-2012/RC0416%20CT%20Colography%20Final.pdf

📖 Alternative Energy Devices for Adults Undergoing General Surgery: A Review of Clinical Effectiveness and Evidence-Based Guidelines. Available: http://www.cadth.ca/media/pdf/htis/dec-2012/RC0413%20Alternate%20energy%20devices%20for%20surgery%20Final.pdf

📖 Dermoscopy for Patients with Skin Lesions: Clinical Effectiveness, Cost-Effectiveness, and Evidence-Based Guidelines. Available: http://www.cadth.ca/media/pdf/htis/nov-2012/RC0415%20dermoscopy%20Final.pdf

📖 Robot-Assisted Surgery for Partial Nephrectomy and Cardiac Surgery: A Review of the Clinical and Cost-Effectiveness — An Update. Available: http://www.cadth.ca/media/pdf/htis/nov-2012/RC0401%20-%20Robot-Assisted%20Nephrectomy%20and%20Cardiac%20Surgery%20Final.pdf

Health Quality Ontario

📖 Internet-Based, Device-Assisted Remote Monitoring of Cardiovascular Implantable Electronic Devices: An Evidence-Based Analysis. Available: http://www.hqontario.ca/en/mas/pdfs/RCM-Review-January2012.pdf

📖 OHTAC Recommendation: Twenty-Four-Hour Ambulatory Blood Pressure Monitoring in Hypertension. Available: http://www.hqontario.ca/en/eds/tech/pdfs/2012/rec_abpm_may2012.pdf

📖 OHTAC Recommendation: Transcatheter Aortic Valve Implantation for Treatment of Aortic Valve Stenosis. Available: http://www.hqontario.ca/en/eds/tech/pdfs/2012/rec_tavi_may2012.pdf

Institute of Health Economics

📖 The Safety and Efficacy/Effectiveness of Using Automated Testing Devices for Universal Newborn Hearing Screening: An Update. Available: http://www.ihe.ca/documents/Newborn%20Hearing%20Screening.pdf

Institut national d'excellence en santé et en services sociaux

📖 Microsurgical replantation and revascularization following the accidental amputation of an upper extremity (Report in French). Available: http://www.inesss.qc.ca/fileadmin/doc/INESSS/Rapports/Chirurgie/INESSS_r%C3%A9implantation_amputation_accidentelle.pdf

📖 Low-intensity Pulsed Ultrasound for the Treatment of Fractures (Report in French). Available: http://www.inesss.qc.ca/fileadmin/doc/INESSS/Rapports/Technologies/INESSS_Noteinformationve_ultrasonspulses_traitementfractures.pdf

📖 Diagnosis and Treatment of Chronic Cerebrospinal Venous Insufficiency (CCSVI) in People with Multiple Sclerosis (MS) (English summary, full report in French). Available: http://www.inesss.qc.ca/fileadmin/doc/INESSS/Rapports/Traitement/INESSS_Summary_MS_EN.pdf

📖 Sentinel Lymph Node Biopsy in Breast Cancer Treatment: Indications and Contraindications (English summary, full report in French). Available: http://www.inesss.qc.ca/fileadmin/doc/INESSS/Rapports/Oncologie/INESSS_Summary_BGSII_EN.pdf

Cite as: Morrison A., *Health Technology Update*, Issue 14. Ottawa: CADTH, 2013.

Production Notes

Health Technology Update is published by:
Canadian Agency for Drugs and Technologies in Health (CADTH)
600-865 Carling Ave.
Ottawa, ON Canada K1S 5S8
Tel.: 613-226-2553
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ISSN: 1715-5541 (print)
ISSN: 1715-555X (online)
Printed in English