Scanning the Horizon
Informing Decision Makers About Emerging Medical Technologies

In April 2006, the **Canadian Coordinating Office for Health Technology Assessment (CCOHTA)** was renamed the **Canadian Agency for Drugs and Technologies in Health (CADTH)**.

At the same time, all of our publications received a new “look,” including this newsletter. However, the goal of the **Health Technology Update** remains the same: to provide brief, informative articles about new and emerging health technologies.

This issue brings you information about diagnostic, biologic, surgical, and radiology-based health technologies that have been newly introduced or that are expected to emerge shortly in Canada. We hope that you will find the **Health Technology Update** informative and useful.

In this Issue

2 **HearTwave®**: a non-invasive test may help predict which patients with chronic heart disease might benefit from an implanted cardiac defibrillator.

3 **Medicinal leeches**: an age-old treatment is being prescribed to remove pools of congested blood after tissue grafting and limb re-attachment surgery.

4 **SuturTek 360° Fascia Closure Device**: a reusable device enclosing a disposable suture cartridge and needle is designed to reduce needlestick injuries in the operating room.

5 **Balloon Sinuplasty™ System**: an outpatient sinusitis treatment uses a minimally invasive technique to open blocked sinus passages with a flexible balloon-tipped wire.

6 **Laser-induced interstitial thermotheraphy**: a laser procedure is being used to destroy liver tumours and improve survival in patients who are ineligible for traditional surgery.

7 **PET-MRI scanners**: machines that combine the capability of positron emission tomography (PET) with magnetic resonance imaging (MRI) are now under development.

8 **New and emerging health technology reports**: a listing of recent publications from CADTH and other health technology assessment agencies.

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**Inukshuk at Clyde River, Nunavut.**

Photo composition by Paul Ting and Vera Saltzman.
A test that measures tiny changes in the electrical activity of the heart may identify which patients with heart disease are at negligible risk of sudden cardiac death due to ventricular arrhythmia and therefore may not benefit from an implantable cardioverter defibrillator (ICD). The ICD is a device that terminates arrhythmias with a high-energy shock.

**How the Test Works**

High-resolution electrodes are placed on the patient’s chest before controlled exercise. Voltage changes are measured and the results are interpreted by a cardiologist.

The HearTwave® II System (Cambridge Heart, Bedford, MA) is a commercial MTWA test that uses spectral analysis. Another MTWA system, the Marquette (GE Healthcare) uses an algorithm, but not spectral analysis, to detect fluctuations in the T-wave.

**Regulatory Status**

The HearTwave® II System received approval from the US Food and Drug Administration (FDA) in April 2005 for use as an adjunct therapy to clinical history and other diagnostic tests. A licensing application for the HeartTwave® II System was submitted to Health Canada in March 2006.

**Selecting Patients for ICDs**

ICDs effectively prevent death from ventricular arrhythmias in patients with impaired left ventricular ejection fraction.¹

Using MTWA testing as a risk stratification tool could potentially identify which heart patients are at a negligible risk of sudden death and could therefore avoid costly ICD therapy and its attendant risks.² Other than measuring left ventricular ejection fraction (commonly measured by echocardiography), there are no alternative non-invasive tests.³

**Evidence**

A meta-analysis evaluating the predictive value of MTWA testing in 2,608 patients with various types of heart disease found that 97.2% of those with a negative MTWA test had no ventricular arrhythmias during an average follow-up of 21 months. However, of the patients who had a positive MTWA test, ventricular arrhythmias occurred in only 19.3%.⁴

A multicentre US study found that among patients with heart disease and a left ventricular ejection fraction of less than 40%, MTWA testing could identify patients at high risk for sudden cardiac death, and patients at low risk who are unlikely to benefit from ICDs.¹

**Cost**


**US Policy Decisions**

Blue Cross Blue Shield recently concluded that there was insufficient evidence to reimburse for MTWA testing.³ However, in March 2006, the US Centers for Medicare and Medicaid Services decided to reimburse for MTWA testing because of the higher risk of sudden cardiac death due to ventricular arrhythmia and an increased likelihood of potential harms caused by ICD placement in the older Medicare population.²

**References**

Leeches are being prescribed by Canadian surgeons to remove pools of congested blood after operations to re-attach severed fingers, ears and other body parts. Pooled blood interferes with circulation and can cause tissue death.¹

The Benefit of the Bite

A leech bite in the grafted or replanted area removes about 5 mL of congested blood. However, the major therapeutic benefit is linked to natural anticoagulants and vasodilators in the leech saliva that cause the bite wound to ooze blood (up to 50 mL) for six or more hours following detachment.²

New leeches are applied several times daily for three to seven days until new blood vessels grow and restore regular blood flow in the affected tissue.¹

Cost

Leeches cost US$9.45 each. Same-day delivery can add significantly to the cost. Toronto-based Canada World Wide is the distributor for Leeches U.S.A. Ltd. (Westbury, NY), which imports the leeches from Ricarimpex SAS, in France.

Patient Population

The frequency of leech use following reconstructive and plastic surgery in Canada is unknown. According to Rudy Rosenberg, co-owner of Leeches U.S.A. Ltd., approximately 8,000 leeches were shipped to Canadian hospitals in 2005, a number that has been steadily increasing during the last 20 years.

Regulatory Status

The US Food and Drug Administration approved Hirudo medicinalis as a medical device in June 2004.¹ Medicinal leeches are regulated as biologic products by Health Canada’s Biologics and Genetic Therapies Directorate.

Evidence

A meta-analysis of 36 reports of medicinal leech use after tissue grafting in 108 patients showed that tissue that would have otherwise required debridement or amputation was successfully salvaged in 70% to 80% of cases.³

Patient Care Implications

Applying and monitoring leech therapy requires significant nursing staff time to ensure that leeches do not feed on healthy tissue or migrate during treatment. Bite wounds require close monitoring after the leech detaches. Patient acceptance of leech therapy depends largely on thorough pre-treatment counselling.

Treatment Risk

The risks associated with leech therapy include infection, excessive blood loss requiring transfusion, migration of leeches into body orifices and allergic reactions to leech saliva. Leeches have the potential to transmit blood-borne viruses such as hepatitis and HIV. They are intended for single use only and must be handled as biohazardous waste.² Prophylactic intravenous antibiotics are recommended to protect patients against leech bacteria.²

Hospital Policies

Hospital staff must be familiar with procedures for the safe acquisition, storage, dispensing and disposal of these live parasites. A standardized protocol will help meet the challenges of using this therapy.

References

Most needlestick injuries in the OR occur during fascia closure. The fascia is the tough band of fibrous connective tissue between the skin and underlying muscles and organs that must be closed at the end of most major surgical procedures.

How it Works

The SuturTek 360° Fascia Closure Device is a reusable unit that encloses a pre-loaded, single-use suture cartridge and curved fascia closure needle. When the suturing is complete, the cartridge and needle are disposed of in standard hospital sharps containers.

Prevalence of Needlestick Injuries

Needlestick injuries are a major occupational health concern for hospital staff as these “sharps” injuries can spread infectious diseases, particularly blood-borne viruses, such as hepatitis B, hepatitis C and HIV.

The Canadian Institute for Health Information estimates that approximately 180 Canadian health care workers experience needlestick injuries each day, or about 66,000 per year. According to the Canadian Needle Stick Surveillance Network, five categories of devices are responsible for 62% of sharps injuries. Of these, 12% are caused by suture needles.

Regulatory Status

The SuturTek 360° Fascia Closure Device was developed by SuturTek Inc. (North Chelmsford, MA). SuturTek was commercially launched in the US at the end of 2005, following US Food and Drug Administration (FDA) approval. The SuturTek device is not yet licensed by Health Canada.

Cost

According to the manufacturer, the SuturTek 360° Fascia Closure Device is often supplied at no charge to hospitals that purchase the disposable suture cartridges. The cartridges cost approximately US$300 per box of 12.

Evidence

Many sharps injury prevention programs recommend the introduction of safety engineered devices that are evaluated by the health care workers who use them.

SuturTek Inc. provided the FDA with simulated use testing data, demonstrating zero needlestick injuries with the device. Further clinical studies of the device are underway, though published results are not yet available.

References

New Sinusitis Treatment May Be a Breath of Fresh Air

How it Works

Performed through the nostrils, a flexible balloon-tipped wire is threaded through the delicate twists and turns of the sinus passages under fluoroscopic guidance. An ear, nose and throat (ENT) surgeon or rhinologist inflates the balloon slightly to gently restructure and widen the sinus walls to restore normal drainage and function.

The procedure dilates the sinus passages by 3 mm to 7 mm, depending on the size of the sinus balloon catheter used.\(^1\)

The one-time outpatient procedure is done under general anesthesia or conscious sedation and takes 30 to 120 minutes, depending on the number of sinus passages to be treated. The same catheter can be used on several sinuses in one patient. Patients can return to normal activities within a day.\(^1\)

Prevalence and Symptoms

Six to seven per cent of Canadians report symptoms of chronic sinusitis,\(^2\) which include:

- nasal congestion, obstruction and postnasal drainage
- facial pressure and pain
- headache
- fatigue
- loss of smell and taste

Limitations

People are not candidates for balloon sinuplasty if they have extensive scarring from previous sinus surgery; cystic fibrosis; nasal polyps; sinonasal tumours or obstruction; or ciliary dysfunction.\(^3\)

Regulatory Status

The Balloon Sinuplasty™ System, manufactured by Acclarent Inc. (Menlo Park, CA), is not yet licensed for use in Canada. The US Food and Drug Administration granted approval in August 2005 for its use in diagnostic and therapeutic procedures of the sinus cavities.

Evidence

In a small feasibility pilot study, no adverse events occurred among 10 patients.\(^3\) Evidence of long-term patency (openness) of the sinus passages is lacking. A multicentre registry (CLEAR) is prospectively collecting data on sinus passageway patency, adverse event rates and quality of life outcomes six months after balloon sinuplasty surgery in 115 patients.\(^4\)

Other Sinus Surgeries

Functional endoscopic sinus surgery (FESS) to remove bone and tissue is the most common surgery for patients with sinusitis who do not respond to medical treatment. Tissue trauma and bleeding with balloon sinuplasty may be less than what is encountered during FESS.\(^1,3\) Balloon sinuplasty may be combined with other sinus surgery techniques.

Cost

The disposable components of the Balloon Sinuplasty System cost approximately US$1,200 per procedure. The System includes the Relieva™ sinus balloon catheter, guide catheter, guidewire, lavage catheter, exchange catheter and the sinus balloon inflation device.

References


A flexible balloon catheter is inserted (Step 1), then inflated (Step 2), to widen the sinus passages.

Photo courtesy of Acclarent Inc.
Using Lasers to Destroy Liver Tumours

Laser energy can destroy liver tumours in patients who are ineligible for surgery, resulting in survival outcomes similar to patients who undergo traditional surgery.

A New Treatment Option

The standard treatment for patients with metastatic liver cancer is surgical resection to remove part of the liver; however, 70% to 90% of patients are ineligible for resection due to the number, size or position of the tumours. A new option for these patients is to destroy the liver tumour(s) using magnetic resonance-guided laser-induced interstitial thermotherapy (MR-guided LITT).

The Technology

MR-guided LITT is performed with the Medilas™ Fibertom 5100 laser (Dornier, Germany) and a laser application kit (Somatex, Germany). The laser applicator is compatible with MR imaging, which provides the visualization necessary to precisely position the laser probe in the tumour.

The Procedure

An interventional radiologist performs MR-guided LITT in an outpatient setting where patients receive local anesthesia. The laser procedure takes approximately 20 minutes. Larger or multiple tumours can be treated simultaneously using multiple laser applicators.

Patient Group

Unlike liver resection, MR-guided LITT is a suitable treatment for multiple liver tumours, tumours in both lobes of the liver and tumour recurrence. However, the treatment is generally limited to patients with five or fewer tumours that each measure less than 5 cm.

Regulatory Status

The Medilas Fibertom 5100 laser is not licensed in Canada. It received US Food and Drug Administration approval in February 1997.

Evidence

In a 12-year prospective case series, 646 patients with five or fewer liver metastases who underwent MR-guided LITT demonstrated an average survival time of 48 months from the first treatment. This compares with an average survival time of 25 to 35 months for patients who undergo liver resection.

Low rates of major complications following 2,132 MR-guided LITT procedures were reported in one study, including pleural effusion requiring thoracentesis (0.8%), liver abscess (0.7%), bile duct injury (0.2%), segmental infarction (0.1%) and hemorrhage requiring blood transfusion (0.05%). The death rate was 0.1%. By comparison, the mortality rate following surgical resection of liver tumours is approximately 5.0%.

MR-guided LITT has not been used in randomized studies. Dr. Martin Mack, a LITT researcher (Institute of Diagnostics and Interventional Radiology, Frankfurt) said that efforts to conduct a randomized study have been unsuccessful because most patients refused open surgery over the less invasive MR-guided LITT.

Cost

According to the manufacturer, the Medilas Fibertom 5100 laser costs approximately US$65,000. Dr. Mack estimates that MR-guided LITT costs approximately C$7,000 per patient procedure depending on the size of tumours. This cost includes all required materials and diagnostics.

References

PET-MRI Scanners: A Further Evolution in Diagnostic Imaging

Scanners that combine the capability of positron emission tomography (PET) with magnetic resonance imaging (MRI) are now being developed. PET evaluates metabolic aspects of disease, while MRI provides high-resolution anatomical information. The PET-MRI scanner is a further evolution of an earlier hybrid, PET–CT, which combines PET with computed tomography (CT) imaging.

There are technical difficulties in engineering a hybrid that has PET and MRI scanners in a single unit.

A process known as image fusion has been used for some time, where a composite picture is produced by overlaying images obtained after patients are scanned in separate PET and MRI machines. The composite image is then used to help guide diagnosis, treatment planning and follow-up.

A hybrid PET–MRI scanner would reduce imaging time and potentially increase patient throughput. A combined unit might also avoid errors due to a partial mismatch of images caused by variations in patient position in the separate scanners.

**Clinical Applications of PET–MRI Image Fusion**

PET–MRI fusion has been used for the initial evaluation of brain tumours, as well as treatment planning and follow-up after therapy. Diagnosis with PET–MRI fusion has been associated with increased survival times for patients with recurrent high grade gliomas treated by radiotherapy, and with more specific diagnoses of brain tumours in children.

PET–MRI fusion has been used to manage the treatment of patients with some types of brain tumours and those with intractable epilepsy, sometimes with the use of additional images from CT or single photon emission computed tomography (SPECT). The combined images provide additional information on the volume of the brain to be treated, permitting more complete destruction of the target lesion and potentially reducing adverse events associated with the treatment (surgery or radiotherapy).

The use of PET–MRI has improved the detection of epileptogenic regions in children with a genetic disorder who are being evaluated for epilepsy surgery. PET–MRI fusion has also been used with a frameless surgical guidance system to permit more precise excision of epileptogenic tissue and minimize damage to normal tissue.

**Cost**

The cost of a PET–MRI machine is unknown, but it is likely to be higher than the US$2.5 to US$3 million for a hybrid PET–CT scanner. A cost-effectiveness evaluation of the technology would need to take into account the cost offsets gained through faster imaging.

**Future Directions**

Comparative clinical benefits for existing PET-MRI or PET-CT approaches need to be established, as well as the caseload and casemix required for effective utilization of a hybrid PET-MRI scanner.

**References**

New and Emerging Health Technology Reports

Recent Reports from CADTH and Other HTA Agencies

These reports are available without cost at the web sites shown below:

Agence d'évaluation des technologies et des modes d'intervention en santé (AÉTMIS)

- Contribution of BRCA1/2 Mutation Testing to Risk Assessment for Susceptibility to Breast and Ovarian Cancer

- The 13C-Urea Breath Test for Detection of Helicobacter Pylori: Potential Applications in Québec

Telehealth: Clinical Guidelines and Technological Standards for Telepsychiatry (English summary)

- Available: http://www.aetmis.gouv.qc.ca/site/download.php?e084149977c6efcd9858098e343a87

Alberta Heritage Foundation for Medical Research (AHFMR)

- Gastric Electrical Stimulation (Enterra™ Therapy system) for the Treatment of Gastroparesis
  Available: http://www.ahfmr.ab.ca/download.php?747f6e4af4860313de92b2b2fd872e3d

Canadian Agency for Drugs and Technologies in Health (CADTH)

- CYP450 Genotyping for Determining Drug Metabolizer Status
  Available: http://www.cadth.ca/media/pdf/375_armpliciph_cetap_e.pdf


- Radiofrequency Ablation in the Treatment of Kidney Cancer
  Available: http://www.cadth.ca/media/pdf/376_radiofrequency_cetap_e_2006feb2.pdf

- Intragastric Balloons: A Temporary Treatment for Obesity
  Available: http://www.cadth.ca/media/pdf/401_balloons_cetap_e.pdf

Ontario Medical Advisory Secretariat (MAS)

- Coil Embolization for Intracranial Aneurysms: Update

- Air Cleaning Technologies

UK National Institute for Health and Clinical Excellence (NICE)

- Image-guided Vacuum-assisted Excision Biopsy of Benign Breast Lesions [Guidance]

- Mosaicplasty for Knee Cartilage Defects [Guidance]