

Health Technology Update

CADTH

A newsletter on new and emerging health care technologies in Canada

ISSUE 20 | JUNE 2018



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Informing Decision-Makers About Emerging Medical Technologies

This issue of *Health Technology Update* features brief summaries of information on a broad range of medical technologies – from nature-assisted therapy to emerging obstructive sleep apnea devices. These technologies were identified through CADTH's Horizon Scanning Service as topics potentially of interest to health care decision-makers in Canada.

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FEEDBACK

Have you heard of a new health technology you think will have an impact on health care in Canada?

Please let us know!

Email: HorizonScanning@cadth.ca.

Acknowledgements: The authors would like to acknowledge Lorna Adcock and Carolyn Spry for their assistance with the literature searching and referencing for the report. CADTH thanks the external reviewers who kindly provided comments on earlier article drafts.

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Funding: CADTH receives funding from Canada's federal, provincial, and territorial governments, with the exception of Quebec.

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ISSN: 1715-555X

Contained Power Morcellation for the Removal of Uterine Fibroids

Uterine fibroids are benign growths that originate in the uterus.¹ Uterine fibroids may be common, but not all cause symptoms or need treatment interventions.² The most common symptoms include heavy menstrual bleeding, pressure symptoms, and infertility.² While medical options do exist for the treatment and management of fibroids, surgery is often required.¹

Uterine fibroids represent the most common reason for hysterectomy.¹ Other less-invasive uterine-preserving alternatives include myomectomy (an alternative surgical procedure which involves removing only the fibroids and preserving the uterus), uterine artery embolization or occlusion, myolysis, and endometrial ablation.¹

Surgery for uterine fibroids may be done through a traditional approach (laparotomy) or large incision.¹ However, there are proven benefits of the laparoscopic approach (key hole surgery) including less pain, reduced length of stay, and overall fewer complications.³ In order to remove masses such as uterine fibroids through laparoscopic incisions, it is necessary to debulk, or reduce the size, of the tumours in order to extract them. This is referred to as “morcellation” and may be done using a scalpel or a power morcellator — a device that assists in tissue extraction.⁴ As tissue is removed, inadvertent tissue spread is a major concern if the specimen was an unexpected malignancy. This may result in the spreading of a cancer that was otherwise contained until it was removed.³

RECENT CONTROVERSY

Both the US FDA and Health Canada issued safety warnings in 2014 discouraging the use of power morcellators. Their concern was that the power morcellation process might spread uterine tissue containing undiagnosed

cancer to other parts of the body.³ The FDA subsequently recommended against the use of laparoscopic power morcellators in most women with uterine fibroids;⁵ however, the procedure is still performed in Canada.³

The FDA’s recommendation has been challenged by some gynecologists who argue that, as an alternative to open surgery, the benefits of laparoscopic myomectomy with power morcellation outweigh the risks.⁶ It is suggested that it may be more prudent to screen patients for risk factors associated with spreading undiagnosed cancer than to eliminate power morcellation itself. Compared with open surgery, minimally invasive gynecologic surgery with power morcellation is associated with improved surgical outcomes — including decreased pain, decreased post-operative infection, decreased blood loss, fewer transfusions, reduced cost and hospital length of stay, and accelerated return to work and normal activities.^{6,7}

Technical innovation in morcellation, prompted by the FDA’s safety warnings, has given rise to new strategies to mitigate risk, including the development of contained tissue extraction often using an in-bag technique. The container bag is intended to collect the tissue for removal from the uterus and minimize spillage of uterine tissue or cells. Gynecologic professional societies have indicated that the container bag presents a promising solution that minimizes the



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risk of spreading undetected cancer and circumvents the need for open surgery.⁸ The Society of Gynecologic Oncology advises “caution when using any morcellation technique” and is not supportive of any overt restriction of power morcellation. Currently, there is no sufficiently accurate means of preoperatively determining malignant tumours from benign fibroids.⁹

HOW IT WORKS

Tissue morcellation is part of a minimally invasive surgical procedure for hysterectomy or myomectomy that facilitates tissue extraction.¹⁰ The tissue is removed laparoscopically from the abdominal cavity in pieces through small incisions, rather than via a large incision as used in a conventional hysterectomy.¹⁰

Containment morcellation works by fragmenting pieces of tissue within a containment bag or system.¹¹ The PneumoLiner (Olympus America) is a containment system designed for use with certain laparoscopic morcellators. It is intended to isolate uterine tissue not suspected to contain cancer.¹² The system consists of a containment bag and an introducer shaft and plunger. Its design allows a camera, laparoscopic instrument, and bag to enter the body through a single opening. Tissue to be removed from the body is placed in the bag, which is sealed and inflated. Inflation of the bag promotes visualization, creates a working space, and helps prevent puncturing of the bag by the

morcellator. The PneumoLiner is the first containment device to receive FDA market clearance for fibroid morcellation.¹² Other containment bags in use and development that can be used with power morcellators include the EcoSac 230 specimen bag (Espiner Medical), the Steri-Drape Isolation Bag (3M), the LapSac Surgical Tissue Pouch (Cook Medical), the Anchor Tissue Retrieval System TRS-200 (ConMed), and the Endo Catch (Medtronic).¹³

WHO MIGHT BENEFIT?

In Canada, by the age of 50, 70% to 80% of women will have uterine fibroids.¹⁴ Most uterine fibroids are asymptomatic and do not require medical management. Treatment is necessary in 15% to 30% of these women.¹⁵ While fibroids are benign, they can cause menstrual abnormalities, iron deficiency anemia, bulk symptoms (caused by the pressure of individual fibroids or the enlarged uterus on adjacent structures), and fertility issues. As well, they can impact quality of life and productivity.¹⁴

While there is currently no preoperative way of accurately distinguishing between a uterine sarcoma and a fibroid, according to the Society of Obstetricians and Gynaecologists of Canada (SOGC), endometrial biopsy should be considered prior to any procedure involving uncontained uterine morcellation.^{16,17} Improved patient selection may help to reduce the incidence of spreading unsuspected cancer via power morcellation. Known risk factors for uterine cancer include age — specifically in postmenopausal women. Other risk factors include history of treatments with tamoxifen or pelvic radiation, and hereditary conditions such as Lynch syndrome, hereditary leiomyomatosis, and renal cell carcinoma.¹⁷

AVAILABILITY IN CANADA

The PneumoLiner is not currently available in Canada. The FDA approved it in 2016, with the requirement that patients are counselled by a physician that the device has not been proven to reduce the risk of tissue dissemination.¹¹

WHAT DOES IT COST?

The cost of the various container bags previously mentioned in this article is reported to range from US\$90 to US\$160, although there is one that costs between US\$25 to \$35.¹³ The cost of the PneumoLiner was not included in these cost estimates.¹³ One study assessed the cost-effectiveness of hysterectomy via open surgery compared to hysterectomy with morcellation, but it did not discuss contained morcellation.¹⁸

CURRENT PRACTICE

Guidance from the SOGC indicates that treatment for fibroids should be personalized and take into consideration symptoms, the size and location of the fibroids, the patient's age, and preservation of fertility or the uterus. In Canada, uterine fibroids account for 30% of all hysterectomies, which is associated with significant morbidity, mortality, and economic burden to the health care system.¹⁴

To date, the management and treatment of fibroids with drugs has been limited because of concerns around their efficacy and adverse events. However, pharmacologic alternatives are available for the reduction in volume of fibroids and/or a reduction in bleeding.

For women who have completed childbearing, the SOGC considers hysterectomy to be a definitive treatment option for uterine fibroids.¹⁴ A hysterectomy can be performed via the abdominal, laparoscopic, or vaginal route. For women who want to keep the uterus intact irrespective of whether they intend to bear children or not, myomectomy — the surgical removal of fibroids from the uterus — or alternative options (medical, interventional) are recommended. However, myomectomies are associated with a 15% recurrence of fibroids, and 1 in 10 women who have a myomectomy will require a hysterectomy within ten years. A myomectomy can be performed by

laparotomy, mini-laparotomy, hysteroscopy, or a combination of each approach.¹⁴

If a laparoscopic approach is used, it will often involve tissue morcellation, for which the SOGC suggests careful patient preoperative assessment and the use of a contained technique.¹⁴ Alternative conservative treatments for those who wish to preserve their uterus include uterine artery embolization, focused energy devices based on radiofrequency electricity, supercooled cryoprobes, magnetic resonance-focused ultrasound, and high-frequency ultrasound-guided transcatheter focused ultrasound ablation.¹⁴

WHAT IS THE EVIDENCE?

Two unblinded randomized controlled trials (RCTs) comparing contained morcellation with uncontained morcellation for the removal of fibroids from the uterus have been published.^{9,18,19} The RCTs evaluated the feasibility and safety of containment bags, and reported on morcellation operative time (MOT) and other outcomes including total operative time (TOT), rate of intraoperative complications, and post-operative outcomes.¹⁹ Neither study performed an evaluation of occult tissue leakage.^{9,18,19}

One RCT, involving 72 women between the ages of 18 years and 50 years with at least one fibroid measuring between 4 cm and 10 cm in diameter, reported that mean MOT and TOT were longer in the contained bag group than in the non-contained bag group.^{9,18} Intraoperative complications and cases of bag disruption or laparotomic conversion (the need for open surgery) were not reported in either group.^{9,18} As well, no significant difference in hemoglobin drop, hospital stay, and post-operative outcomes were observed.⁹

The second RCT involving 104 premenopausal women eligible for fibroid removal reported that MOT was similar in both study groups and the size of the fibroid was identified as the main factor influencing

morcellation time.¹⁹ No significant difference in TOT, simplicity of morcellation, post-operative pain, and post-operative outcomes between groups was observed.¹⁹

Safety

While there is limited data available on the safety of containment bags,^{7,11} and the aforementioned trials reported no adverse events, spillage of morcellation tissue, bag rupture, injury to neighbouring tissues and organs, and infection are risks that have been linked to them.¹² Long-term safety outcomes, including the impact on risk for cancer dissemination, were not investigated.

RELATED DEVELOPMENTS

Some alternative treatments for fibroids include focused energy delivery systems, magnetic resonance-guided focused ultrasound, and the use of radiofrequency energy.¹⁴

LOOKING AHEAD

It is suggested, by some members of the gynecologic community,^{17,20} that more research on the risk of occult sarcoma is needed before there is certainty on the extent of the risk. To ensure the success of contained power morcellation, new approaches are required to communicate the preoperative risks with patients. As well, appropriate education on the risks and training on techniques is required for physicians.¹⁶

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Localized Thermal Therapy for Fibromyalgia

Fibromyalgia is a poorly understood condition, characterized by chronic widespread pain throughout the body that negatively impacts the lives of the people affected by this condition.^{1,2} Unfortunately, there is currently no cure for fibromyalgia.¹

Available therapies aim to control the pain and other symptoms associated with the condition but are reported to be moderately effective, at best.¹ While the mechanism of action is not fully understood, applying heat to the body may contribute to the reduction of pain in patients with fibromyalgia, according to some reports.³⁻⁵ The AVACEN 100 is a localized warming device used in the treatment of fibromyalgia.

TECHNOLOGY OVERVIEW

The AVACEN 100 was developed to dispense thermal therapy with the aim of providing relief from pain caused by muscular and joint problems, arthritis – and fibromyalgia.⁶ Conventional, whole-body thermal therapy approaches, such as saunas and warm water baths, expose the entire body to the heat source to target broad pain relief. The AVACEN 100, in contrast, relies on the localized application of heat, but the approach also seeks to achieve a widespread effect on the body.⁶ To undertake a therapy session with the AVACEN 100, the user must wear a specially designed mitt on one hand and place that hand inside a vacuum chamber located on top of the device. Dry heat is applied to the palm of the hand while an amount of negative pressure is maintained inside the vacuum chamber. The manufacturer explains that the negative pressure helps to increase blood flow through the hand, thereby causing more blood to be exposed to the heat being delivered to the surface of the palm.⁷ This heat is said to rapidly diffuse throughout the body as the blood circulates from the warmed hand to other parts of the body.⁷

The treatment is self-administered by the user and can be performed at home or in other convenient settings. The length of a therapy session can be set to last between 10 and 30 minutes. The product's user guide recommends a standard treatment regimen consisting of two 15-minute sessions, one in the morning and one at bedtime, on a daily basis.⁸

WHO MIGHT BENEFIT?

In 2010, about 1.5% of Canadians aged 12 years and older reported having been diagnosed with fibromyalgia.⁹ The prevalence of this condition is higher among women than men.^{1,9} There is a lack of information regarding the specific target patient group for the AVACEN 100, but it appears to be targeting people with fibromyalgia, in general.

AVAILABILITY IN CANADA

In September 2017, the manufacturer of the AVACEN 100 announced that the device had received Health Canada approval for the treatment of widespread pain associated with fibromyalgia.¹⁰ Canadians can order the AVACEN 100, and its accessories and replacement parts, directly from the manufacturer's website.¹¹

WHAT DOES IT COST?

The purchase price listed on the manufacturer's website is US\$2,995 for the consumer-grade device and US\$3,995 for the variant designated for commercial use. A lease-to-own option is also available to non-commercial buyers at 24 payments of US\$149.50 per month, with a US\$499 down payment. Beyond this, users may occasionally need to purchase

a new supply of the special mitts that are required to use the device. According to the manufacturer, the device is expected to last five to 10 years.¹²

CURRENT PRACTICE

Evidence-based guidelines for the diagnosis and management of fibromyalgia developed by a panel of Canadian experts (the National Fibromyalgia Guideline Advisory Panel) were published in 2012.^{1,13} The guidelines recommend a patient-tailored, multimodal approach that favours the use of non-pharmacological strategies to address the physical and psychological care needs of fibromyalgia patients.¹ Thermal therapy is not expressly mentioned in the guidelines.¹

WHAT IS THE EVIDENCE?

The published evidence on the AVACEN 100 is currently limited to one study⁷ conducted by the manufacturer. This small randomized study included 22 patients with fibromyalgia who treated themselves with the AVACEN 100 for 28 days. A first group of five patients were told to perform one 10-minute session per day. The second group of 17 patients, which included 15 women, were told to follow the manufacturer-recommended treatment regimen of two 15-minute sessions per day, one in the morning and one at bedtime. The study reported on 10 outcomes, such as widespread pain index, tender point count, and symptom severity. At present, there is a lack of evidence comparing the AVACEN 100 with currently available proven treatments or with other whole-body, thermal therapy approaches for fibromyalgia.

Safety

In the aforementioned trial conducted by the manufacturer, no adverse events were reported by any of the patients.⁷ In that trial, patients were contacted “several times” throughout the four-week treatment period to “record adverse events;” however, no details are provided in the study report about specifically what questions were asked about adverse events. No other information related to the safety of the AVACEN 100 was found in the published literature.

RELATED DEVELOPMENTS

Health Canada first approved the AVACEN 100 in April 2017¹⁴ as a Class II medical device for the temporary relief of minor muscle and joint pain, and stiffness; joint pain associated with arthritis; muscle spasms, and minor strains and sprains; and the temporary increase of local circulation, where applied (Renelle Briand, Media Relations Officer, Health Canada and the Public Health Agency of Canada, Ottawa, ON: personal communication, 2017 Oct 27). The device is approved for a similar indication in the US.¹⁵ In the context of fibromyalgia treatment, other thermal therapy methods have been investigated, including conventional sauna therapy, warm baths in mineral waters, and Waon therapy (a type of whole-body thermal therapy).^{3,16-18}

LOOKING AHEAD

The AVACEN 100 may offer a non-pharmacological alternative to address pain related to fibromyalgia, but the evidence on its effectiveness and safety is currently limited. Given the broad range of therapies targeting fibromyalgia, it is also important to determine how this device performs compared with other treatment options. Additional evidence would be required for a thorough assessment of this product in managing chronic pain associated with fibromyalgia.

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Nature-Assisted Therapy for Post-Traumatic Stress Disorder

People who have experienced a traumatic event may continue to relive the trauma through recurrent nightmares, flashbacks, and mental distress that prevent them from returning to their everyday lives. Examples of traumatic events include near-death experiences such as experienced in serious accidents or in war zones, life-threatening illness, sexual assault, or the unexpected death of a loved one.^{1,2}

Individuals with post-traumatic stress disorder (PTSD) are at higher risk for depression, cardiovascular disease, substance abuse disorders, and suicide.^{1,2} Substantial personal and societal costs are also involved because of stress-related work leave and unemployment, and the increased use of disability and health care services.^{1,3}

The healing aspects of natural environments have been recognized throughout human history.⁴ Nature-assisted therapy — also called nature-based rehabilitation or horticultural therapy — was first used for veterans suffering from trauma during World War I.⁵⁻⁸ Recent research indicates it may still be a useful treatment option for some people with PTSD.

HOW IT WORKS

Nature-assisted therapy has been described as an “intervention...with the fundamental principle that the therapy involves plants, natural materials, and/or outdoor environment, without any therapeutic involvement of extra human mammals or other living creatures.”⁷ Although definitions vary,^{7,9} nature-assisted therapy generally combines conventional medical care with therapeutic activities in a natural setting, such as a garden or farm.^{5,6,9} Nature-assisted therapy is distinct from outdoor adventure, wilderness, sports-based, or animal-assisted therapies — which may also fall under the broader umbrella of green care or ecotherapy.^{7,9-11} These interventions aim to improve

“psychological, intellectual, social, or physiological or physical outcomes...”⁷

Much of the recent work in this area has been done by Scandinavian researchers, who define the following components of nature-based therapy programs:

- mindfulness-based cognitive activities
- nature-based activities, such as horticultural therapy through gardening or farm work
- individual “conversation” therapy, with or without group therapy sessions.^{5,10,12}

Nature-based therapy involves multidisciplinary teams with expertise in psychotherapy or psychology, physiotherapy or occupational therapy, and horticultural or nature-based therapy.³ The conventional therapy components of the program are similar to other psychosocial therapy programs (for example, education about stress management, and physical and mindfulness exercises).³ The programs may last from eight weeks up to a year, occurring one to four days per week, for two to four hours each day.^{3,6} Group therapy sessions may involve small groups of up to eight participants.³

WHO MIGHT BENEFIT?

Stress-related disorders, which include PTSD, are common.² The lifetime prevalence of PTSD in Canada, based on a 2008 study, was estimated to be 9.2% in the general population. The prevalence

of PTSD is higher in Canadian Forces personnel, with rates of 11% reported after one deployment in Afghanistan, and 15% after two deployments.^{1,11} Approximately 73% of Canadian veterans who receive disability benefits for mental health reasons suffer from PTSD.¹³ Although it is associated with veterans suffering from war trauma, PTSD affects more civilians than soldiers and is more common in women than in men.^{1,14}

People with PTSD may experience all or some of the following symptoms: recurring thoughts of the traumatic event, avoidance of or hypersensitivity to certain stimuli, feelings of guilt or shame, attention deficit, numbness, and dissociation or detachment.^{1,15-17} The symptoms may last for more than a year, and it becomes a chronic condition in about 10% of those affected.¹

Nature-assisted therapies are also used for other mental health conditions, and for children and adults with physical disabilities.⁸

AVAILABILITY IN CANADA

Nature-assisted therapy is not regulated by Health Canada. Private therapy services that offer some types of nature-assisted therapy are available in Canada. The Canadian Horticultural Therapy Association offers professional training in horticultural therapy, and voluntary professional registration, but does not currently offer

accreditation.¹⁸ Information on where nature-assisted therapy programs are available in Canada is needed.

In Sweden, nature-assisted therapy is offered in at least 25 centres and has been used for more than ten years in rehabilitation for stress-related illnesses.³ Denmark has several therapy gardens in place¹⁹ and several Danish municipal health authorities are planning to provide this treatment.¹⁹ In the UK, more than 1,000 nature-assisted programs are in operation, of which about 40% provide support to people with mental health conditions.^{8,9} In the US, several Department of Veterans Affairs hospitals offer horticultural therapy within the Compensated Work Therapy clinical vocational rehabilitation program.¹⁷

WHAT DOES IT COST?

No Canadian information on the costs of nature-assisted therapy programs was available.

CURRENT PRACTICE

Treatments for PTSD include various types of psychotherapy.^{10,20} In the US, the Department of Veterans Affairs guidelines recommend individualized “trauma-focused psychotherapy” as an initial treatment rather than the use of drug therapies.²¹ These guidelines note that group therapy or Internet-based cognitive behavioural therapy with a trained provider are preferable to no treatment.^{15,21} Drug therapies are sometimes used, including many drugs that are not specifically indicated for PTSD.^{21,22}

WHAT IS THE EVIDENCE?

We found several studies related to nature-assisted therapy for individuals with PTSD or studies of chronic stress-related disorders that have included people with PTSD.

A 2015 Danish systematic review of nature-assisted therapies for veterans with PTSD identified two randomized controlled studies and one non-randomized study of wilderness-based programs, rather than horticultural therapy programs, along with a number of literature reviews and

qualitative studies.⁶ The level of evidence for all included studies was reported to be low, and the interventions and methods that were used varied; but, overall, nature-assisted therapy was associated with improved PTSD symptoms and other psychosocial measures of well-being.⁶

Other studies on patients with PTSD include one Danish qualitative study⁵ and one Danish narrative review,¹⁰ a 2009 UK qualitative evaluation of a Gardening Leave project,²³ and a 2016 UK narrative review⁹ that included two small studies with PTSD patients.^{24,25}

A 2017 Danish narrative review of nature-assisted therapy for veterans with PTSD noted that most of the available evidence was from qualitative studies, which used various interventions and health outcome measures.¹⁰ Despite this, the literature suggests that benefits include improved work skills, better physical health, and the sense of belonging to a group, rather than feelings of stigma and isolation.¹⁰

A 2016 qualitative study of eight Danish veterans with PTSD in a ten-week, nature-assisted therapy program found that, for most participants, the program reduced symptoms of PTSD and helped them better cope with stress.⁵ At one year follow-up, the participants generally saw their experiences of nature as “restorative,” and most were still using nature and nature-based activities; however, PTSD was still incapacitating for at least one of the participants.⁵

A 2009 UK evaluation of the Gardening Leave project at Hollybush House interviewed 44 veterans with PTSD and other mental health issues, who had participated in the program.²³ The main themes from the interviews with veterans were that helping in the garden provided a “sense of purpose” to their lives and was something they looked forward to. The walled garden provided a safe environment, and the physical exercise and being outdoors was reported to improve sleep and the ability to relax.²³

A 2016 Swedish health technology assessment,³ and several other recent Danish^{12,19,26} and Swedish²⁷ studies, have also focused on nature-assisted therapy for severe stress-related illness but did not include people with PTSD.

Safety

No adverse effects have been reported in reviews of nature-based therapy.^{6,10}

ISSUES TO CONSIDER

Regardless of the type of therapy offered, barriers to PTSD treatment include avoiding seeking help because of the fear of the stigma associated with a diagnosis of mental illness, and high dropout rates from treatment programs.^{8,10,28}

Although they may be offered within facilities, such as hospitals and mental health clinics, horticultural therapy programs are often run by private services or charity-based organizations that may lack stable long-term funding to ensure the continuity of treatment services.^{8,23} In addition, physicians may not be aware of how to refer patients to receive this type of therapy.¹⁶

RELATED DEVELOPMENTS

Evidence-based health design is an emerging area of landscape architecture that uses the best evidence on landscape, garden, and environmental design to improve health outcomes and well-being.¹⁹

Although the available evidence is limited, complementary and alternative therapies, such as meditation relaxation training and yoga, have also been proposed as possible alternative therapies for PTSD, including for patients who do not want to undergo standard therapies.^{22,29}

Virtual reality exposure therapy is another emerging area of PTSD treatment.³⁰ The aim of the controlled exposure is to desensitize the person to the event — first in the virtual world, and eventually in everyday life.^{31,32}

LOOKING AHEAD

Nature-assisted therapy involves other

therapeutic interventions, such as writing narratives (journaling) and mindfulness training.^{12,19} The rehabilitative value of the work (such as gardening), exercise, and being outdoors, and the companionship of others who share similar experiences (such as other veterans with PTSD) may also contribute to the overall impact of this therapy.^{6,8,23} It has been suggested that more evidence is needed from large, well-designed studies of nature-assisted therapy for people with PTSD and that these studies should include validated patient outcomes measures, cost analyses, and long-term follow-up.^{3,6-8,10}

In 2017, Veterans Affairs Canada announced plans for a centre of excellence in mental health care for veterans, which will focus on evidence-based prevention and treatments for PTSD.¹³

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Prostatic Artery Embolization for Benign Prostatic Hyperplasia

Benign prostatic hyperplasia (BPH) is an enlargement of the prostate gland that occurs when prostate cells increase in number.¹ As the prostate grows larger, it can put pressure on the urethra and bladder, narrowing the urethra and causing symptoms such as difficulty passing urine, an urgency to urinate, or the inability to completely empty the bladder.¹ A new intervention for BPH, prostatic artery embolization, is emerging as a treatment option for some patients and has been the subject of two horizon scans by Australia and New Zealand's HealthPACT.^{2,3}

HOW IT WORKS

Prostatic artery embolization is a procedure by which microparticles are released into the arteries supplying the prostate gland.² The goal of the procedure is to block blood and oxygen flow, leading to cell death and ultimately reducing the size of the prostate.² To deliver the microparticles, an interventional radiologist inserts microcatheters into the left or right femoral artery, guiding them to the small prostatic arteries.² Planning and executing the procedure involves several specialized imaging procedures (pelvic angiography, selective arteriography, and fluoroscopy) and specialized knowledge.⁴ The procedure is minimally invasive and can be performed under local anesthesia and sedation.²

HealthPACT identified three types of embolization agents² used for prostatic artery embolization, marketed by three companies:³

- Merit Medical Systems Inc. (South Jordan, Utah) – Embosphere Microspheres⁵
- Cook Medical LLC (Bloomington, Indiana) – PVA (or polyvinyl alcohol) Foam Embolization Particles⁶
- Boston Scientific – Embosphere Microspheres⁷ and Embosphere TANDEM Microspheres.⁸

WHO MIGHT BENEFIT?

Men with BPH may never develop symptoms.¹ For those who do, symptoms of BPH are most likely to appear in those over the age of 50.¹ Most men over the age of 70 will have some degree of prostate enlargement.¹

Most cases of BPH in Canada are managed conservatively (e.g., through watchful waiting).⁹ Men with moderate to severe BPH who are bothered by their symptoms may be recommended for minimally invasive surgery – typically transurethral resection of the prostate (TURP).⁹ If implemented, prostatic artery embolization may be an alternative to TURP.²

AVAILABILITY IN CANADA

The availability and use of prostatic artery embolization in Canada is unclear. HealthPACT's 2017 report indicates that trials are currently underway or completed in Canada,³ and at least two facilities in the Toronto area offer the treatment.^{10,11} According to one clinician, some Canadian sites have decided not to implement the procedure (or cannot implement it) because of the time and resources required (Dr. Mark Baerlocher, Interventional Radiologist, Royal Victoria Regional Health Centre, Barrie, ON: personal communication, 2018 Mar 13).

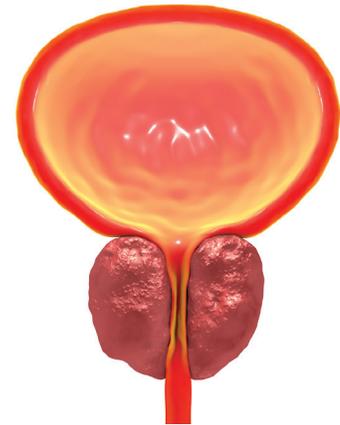


Photo: iStock/Dr_Microbe

WHAT DOES IT COST?

HealthPACT found limited economic and cost evidence for the use of prostatic artery embolization.^{2,3}

When considering the implementation of prostatic artery implementation in Australia, HealthPACT identified the following areas as key resource costs:³

- clinician consultations (primary care, urology, interventional radiology)
- imaging (pelvic angiography, arteriography, fluoroscopy)
- the procedure (peripheral artery or venous embolization, embolization agent).

CURRENT PRACTICE

Canadian guidelines recommend the conservative management of BPH, such as watchful waiting.⁹ Men who are bothered by their symptoms may be prescribed medications such as alpha-blockers and 5-alpha-reductase inhibitors, whereas those with moderate or severe BPH may be recommended for minimally invasive surgery – typically TURP, a procedure that involves making a small incision inside the urethra and removing pieces of the prostate gland from the inside.⁹ While TURP is considered the standard surgical intervention for BPH, Canadian researchers have observed an increased use of minimally invasive laser treatments such as holmium laser enucleation of the prostate and photoselective vaporization of the prostate.¹²

WHAT IS THE EVIDENCE?

HealthPACT reviewed and summarized the available evidence for prostatic artery embolization in 2014,² and updated their conclusions in 2017.² Both reports found limited high-quality evidence for the use of prostatic artery embolization.^{2,3} Outcomes explored by researchers included efficacy compared with TURP, efficacy compared with open prostatectomy, and safety.^{2,3}

Safety

Both HealthPACT and the Society of Interventional Radiology reported on the safety of prostatic artery embolization.^{2,4} Because of the complexity of the procedure and the anatomy of the prostatic arteries, prostatic artery embolization exposes patients and health care providers to a larger dose of radiation from fluoroscopy compared with other pelvic embolization procedures.² Although the risk of radiation exposure is less for older than younger patients, concern remains about skin burns, hair loss, or skin necrosis, but the studies identified by HealthPACT did not see these types of events.² Contrast materials used to visualize the arteries may cause allergic reactions or kidney damage in some patients.⁴

Compared with TURP, HealthPACT found that acute urinary retention occurred significantly more often in men receiving prostatic artery embolization.³ Conversely, men who undergo TURP are more likely to experience abnormal ejaculation.³

ISSUES TO CONSIDER

Treatment Failure

The Society of Interventional Radiology has commented on the rate of failure observed in prostatic artery embolization studies.⁴ The Society noted that, while success is often defined as the achievement of embolization on one side of the prostate, embolization on both sides may be a better definition and may only occur in 75% of patients.⁴ HealthPACT identified a lack of long-term outcomes data, finding only one retrospective study published since their 2014 report.³

Treatment Duration

HealthPACT notes the average procedure times reported for prostatic artery embolization ranges from 77 to 158 minutes compared with 83.5 minutes for TURP and 57 minutes for open prostatectomy.³

Specialist Capacity and Access

The complexity of the anatomy involved means that prostatic artery embolization requires a skilled interventional radiologist with specialized knowledge to perform the procedure.^{3,4} Organizations thinking about implementing the procedure would need to consider the capacity of these specialists to perform the procedure, as well as availability of access to patients living in rural or remote areas.³

ONGOING RESEARCH

HealthPACT identified an additional 12 studies (including five randomized controlled trials and two studies taking place in Canada) of prostatic artery embolization currently underway as of 2017.³ A CADTH search of ClinicalTrials.gov in March 2018 identified another 12 studies in progress including one underway in Edmonton (NCT02509975).¹³

RELATED DEVELOPMENTS

A device designed to mechanically move the prostate gland away from the bladder and urethra has also been developed and may be another minimally invasive option for some men.^{14,15}

LOOKING AHEAD

Prostatic artery embolization was considered by HealthPACT to be appropriate for investigational use, only, in both its reports.^{2,3} Both HealthPACT and the Society of Interventional Radiology comment that higher-quality evidence and more information on long-term outcomes are needed.^{3,4} In April 2018, the UK's National Institute for Health and Care Excellence produced updated guidance supporting the use of prostatic artery embolization.¹⁶

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Focus On: New Devices to Diagnose and Treat Obstructive Sleep Apnea

WHAT IS OBSTRUCTIVE SLEEP APNEA?

Obstructive sleep apnea (OSA) is a sleep disorder that affects as many as one in four adults in Canada.^{1,2} When someone with OSA falls asleep, the muscles in their throat relax, causing their upper airways to collapse.³ As a result, their breathing stops and restarts throughout the night.³

Symptoms of OSA include excessive daytime sleepiness, fatigue, and impaired memory.^{3,4} Anyone can develop OSA, but some risk factors include obesity, being male, and aging.³ Untreated OSA is associated with motor vehicle accidents, diabetes, hypertension, stroke, heart failure, and all-cause mortality.^{1,2,5-7}

HOW IS OBSTRUCTIVE SLEEP APNEA DIAGNOSED?

The presence and severity of OSA is usually determined by polysomnography, a test conducted in sleep laboratories under the supervision of a technician.³ During polysomnography, respiratory sensors detect apneas (cessations of airflow) and hypopneas (reductions in airflow). The number of both events occurring per hour of sleep — known as the apnea-hypopnea index (AHI), a commonly used metric for sleep-disordered breathing — is then calculated.³ The American Academy of Sleep Medicine³ and the Canadian Thoracic Society⁸ recommend the following AHI cut-offs for determining the severity of OSA:

- **mild:** AHI equal to or greater than five events per hour but fewer than 15 events per hour
- **moderate:** AHI equal to or greater than 15 events per hour but fewer than 30 events per hour
- **severe:** AHI equal to or greater than 30 events per hour.

HOW IS OBSTRUCTIVE SLEEP APNEA TREATED?

Many options are available for the treatment of OSA.^{7,9} The most commonly used intervention,

considered the gold standard, is continuous positive airway pressure (CPAP) therapy, which forces air into the upper airway to prevent the soft tissues from collapsing.⁷ Oral appliances adjust the position of the jaw or tongue to open up the airway.⁷ Surgical options permanently pull forward the lower jaw or base of the tongue to create more airway space.⁷ Other interventions include positional therapy, which discourages sleeping on the back, and lifestyle modifications, such as weight loss programs.⁷

WHAT NEW DEVICES ARE AVAILABLE FOR OBSTRUCTIVE SLEEP APNEA?

Figure 1: BresDx Portable Device for the In-Home Diagnosis of Sleep Apnea



Reproduced with permission from BresTec.

Transition From Laboratory to In-Home Diagnosis

High costs, long wait times, and the inconvenience associated with polysomnography have led to a growing interest in the in-home diagnosis of OSA using portable monitors.^{4,10,11} In 2011, it was reported that there were more than 40 different commercially available portable monitors in the US alone.¹² Transitioning OSA diagnosis from sleep laboratories to the home may increase patient access⁴ and address the challenge of underdiagnosis.^{13,14}

BresDX

BresDX¹⁵ is a portable device for the in-home diagnosis of sleep apnea.^{11,13} This wireless acoustic

device consists of an open, lightweight face frame, with an embedded microphone in front of the nose and mouth that detects breath sounds (see Figure 1).^{11,13} It is self-contained and battery-operated, with no need for an external power source.^{11,13} Breath sound data are recorded overnight, stored on a microSD card, and analyzed, using acoustic analysis algorithms, to determine the AHI.^{11,13}

The developers of BresDX compared their device with in-laboratory polysomnography in 135 adults with symptoms suggestive of OSA and reported that the portable device, when used in-laboratory, was comparable to in-laboratory polysomnography in diagnostic performance.¹³ AHI measurements made in-home with BresDX did not significantly differ from those made with in-laboratory polysomnography.¹³

The developers also compared the device with in-laboratory polysomnography in 23 post-stroke, in-hospital patients and reported that the portable device, when used in-hospital, was comparable to in-laboratory polysomnography in diagnostic performance.¹¹ AHI measurements made in the patients' own beds in the stroke rehabilitation unit with BresDX were similar to those made with in-laboratory polysomnography.¹¹

BresDX was authorized in 2014 for marketing in Canada. In 2016, the Ontario Ministry of Health and Long-Term Care announced the launch of a demonstration project using BresDX for select sleep clinics in the province.¹⁶

Other Portable Monitors

In addition to BresDX, many other portable monitors with wireless and easy-to-use features have been recently developed or approved for use in Canada.

ApneaStrip¹⁷ is applied to the upper lip.¹⁸ It has an embedded temperature sensor that detects nasal and oral airflow.¹⁸ Patients activate it before bedtime by pressing once on a button located on the device and get the results by pressing twice on the same button upon awakening.¹⁸ Results are presented as positive (i.e., AHI equal to or greater than 15 events per hour), negative (i.e., AHI fewer than 15 events per hour), or inconclusive.¹⁸ ApneaStrip was authorized in 2015 for marketing in Canada.¹⁷

Nox T3¹⁹ is a Bluetooth-based sleep monitor with a few different parts that are designed to be easily and quickly assembled by patients.¹⁹ It records nasal pressure, snoring, rib cage and abdominal movement, pulse oximetry, and body position.²⁰ Nox T3 was authorized in 2015 for marketing in Canada.²⁰

Implications for Practice

Unlike in-laboratory polysomnography,⁴ portable monitors may lack the ability to differentiate sleep from wakefulness, are incapable of measuring actual sleep time,¹³ and may underestimate OSA severity,⁴ especially in patients with severe OSA.¹³ Additionally, to initiate positive airway pressure treatment, in-home diagnosis with a portable monitor requires an auto-adjusting, positive airway pressure device for several nights, which can add to the cost — unlike in-laboratory diagnosis

Figure 2: aerSleep Negative Pressure System for Obstructive Sleep Apnea



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with polysomnography, which can be used for CPAP titration to an effective setting in a single night.²¹ Further, portable monitors may not be capable of distinguishing between OSA and central sleep apnea¹³ (abnormal breathing caused by improper signals from the brain to the muscles that control breathing, rather than by upper airway

obstruction).²² Accordingly, the guidelines published by the American Academy of Sleep Medicine,^{23,24} the Canadian Sleep Society, and the Canadian Thoracic Society²⁵ suggest that portable monitors are appropriate diagnostic modalities, and non-inferior to in-laboratory polysomnography for patients at high risk of having moderate to severe OSA, without significant medical comorbidities⁴ — such as cardiopulmonary diseases, neuromuscular conditions, or severe insomnia — that can complicate the acquisition and interpretation of data from portable monitors.²⁴

Nevertheless, there is emerging literature evaluating the utility of portable monitoring in a wider array of patients than initially recommended by the existing guidelines.⁴ Further, several portable monitors, including the Apnea Risk Evaluation System or ARES²⁶ and the WatchPAT device,²⁷ more closely approximate total sleep time, as opposed to total bed time spent in both sleep and wakefulness, by using surrogates for sleep.⁴

Developments in Treatment

Nerve Stimulation

While CPAP is the gold standard treatment for OSA, many patients are unable to tolerate it long-term because of discomfort with breathing, drying of the oral cavity, and the cosmetic disadvantages associated with the device.⁷ Companies are now marketing implants, such as Inspire²⁸ and Targeted Hypoglossal Neurostimulation (THN) Sleep Therapy,²⁹ which stimulate nerves on the tongue and throat to open airway muscles.³⁰

A 2017 study sponsored by the manufacturer of Inspire reported that 56 patients with moderate to severe OSA and non-adherence to CPAP experienced significant reductions in AHI and excessive daytime sleepiness after 12 months of device implantation.³¹ One patient requested the removal of the device for personal reasons; no other adverse events, including surgical complications, were reported.³¹

Negative Pressure

Another new alternative to CPAP is aerSleep,³² which applies continuous negative external pressure to the airway (see Figure 2).³³ This system consists of a soft silicone collar and an integrated vacuum pump module, which is fitted over the

neck.³³ By applying negative pressure, the device pulls on the outside of the neck and helps keep the airway open during sleep.³³ Because the collar does not intrude on the face or force air into the airway, it may be easier for patients to get used to the device, potentially improving long-term adherence.³³

A 2017 pilot study sponsored by the manufacturer of aerSleep reported that, of the 15 patients with OSA who underwent overnight titration with the device, nine patients had a strong response (i.e., final AHI fewer than five events per hour) and four patients had a partial response (i.e., final AHI fewer than 15 events per hour and less than 50% of baseline AHI).³³ Adverse events were reported in three patients, all related to contact pressure between the collar of the device and the underlying skin.³³ aerSleep was authorized in 2017 for marketing in Canada and is accessible through AvantSleep clinics across Canada.³⁴

FINAL THOUGHTS

There is growing interest in personalized and more accessible approaches to the diagnosis and treatment of OSA.¹⁴ Individualized approaches might address the complex biological mechanisms underlying OSA and each patient's physiology and preference.¹⁴ As such, new devices are constantly being developed for OSA to address patients' needs in accessing portable, wireless, and easy-to-use monitors at home for its diagnosis, as well as effective and less cumbersome options for its treatment. In the interest of improving the care of patients with OSA, it will be important to consider the effectiveness and safety of these devices, and patient preference for them.

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