OHTAC Recommendation

Sacral Nerve Stimulation for the Management of Urge Incontinence, Urgency-Frequency, Urinary Retention and Fecal Incontinence

March 2, 2005
Sacral Nerve Stimulation

The Ontario Health Technology Advisory Committee (OHTAC) met on March 2, 2005 and reviewed the use of sacral nerve stimulation for the management of urge incontinence, urgency-frequency, urinary retention and fecal incontinence, following a request from OHTAC to review the technology.

Based on a review of sacral nerve stimulation presented by the Medical Advisory Secretariat (MAS), OHTAC offers the following advice to the Ministry of Health and Long-term Care (MOHLTC) for its consideration. This advice is provided according to the OHTAC terms of reference.

Several studies have attempted to estimate the number of people who suffer from urge incontinence, urgency-frequency, urinary retention or fecal incontinence. Urge incontinence is the most prevalent of these conditions. A 2004 Canadian study (Corcos 2004) reported that the prevalence of urge incontinence was 4.5% (2.3% for men and 6.5% for women). Based on the prevalence estimates, approximately 558,176 people suffer from at least one of these conditions in Ontario.

Sacral nerve stimulation is designed for people who have not responded to drug and behaviour therapy. The alternative for sacral nerve stimulation is surgery. Current surgical interventions include implanting artificial urinary or anal sphincters, or increasing the size of the bladder.

Sacral nerve stimulation involves implanting a small generator device in the lower abdomen that is attached to a lead with electrodes at the end.
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Prior to the implantation of the device, the patient undergoes a ‘test stimulation phase’, to see if the patient will respond to stimulation. The test stimulation involves inserting a lead into the lower back, and placing the lead next to the sacral nerve. The lead is attached to an external generator which can be attached to the patient’s waistband. The test stimulation phase lasts between 3 and 7 days. If a patient has a greater than 50% improvement in his or her symptoms, then the patient is considered for the implant.

In the implantation itself, a lead is placed next to the sacral nerve (at the base of the spinal cord), and electric pulses stimulate the sacral nerve, which in turn, stimulates bladder and bowel function. The patient has a control to turn the device on and off. The physician also has a control which is used to set the amplitude, pulse rate and pulse width.

Sacral nerve stimulation is currently being used in Ontario at one hospital. An urologist (or gastroenterologist for patients with fecal incontinence) performs the procedure. The hospital is currently performing 12 sacral nerve stimulations per year. There are 47 people on the waiting list for the procedure (as of January 2005).

Since 2000, 5 international health technology assessments (HTA) have been conducted to evaluate sacral nerve stimulation. All 5 HTAs reported that sacral nerve stimulation was effective.
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The HTAs also reported that there are several complications associated with the device. Approximately 33% of the patients required additional surgery to manage the complications associated with the device. Most of the complications were related to pain at the implant site or lead migration (inappropriate movement of the lead attached to the device). There were no permanent injuries or deaths associated with sacral nerve stimulation.

MAS evaluated the most recent literature to determine if sacral nerve stimulation is effective in patients who do not respond to drug or behaviour therapy. The conclusion of this review was that sacral nerve stimulation is effective in treating patients with urge incontinence, urgency-frequency, urinary retention or fecal incontinence. However, there are several people who are not eligible to use the device, including:

- Children (<16 years)
- Neurogenic conditions (including multiple sclerosis, Parkinson’s disease, spinal cord lesions)
- Inability to operate patient programmer (i.e. cognitive impairments, mobility limitations)
- Other stimulation devices (i.e. pacemaker)
- Urinary retention due to obstruction
- Pregnancy
- Stress or mixed incontinence
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Based on an estimate of 100 procedures per year, the global cost (including the device, hospitalization costs and professional costs) would be approximately $1.4-1.8 million. These costs do not include the cost of surgical revision or replacement of the device. The first year after implant there may be additional costs for adjustments. However, once the device is in place and calibrated appropriately, the cost associated with managing the voiding conditions will decrease.

Based on the published literature and discussions with clinical experts, OHTAC concluded that:

- There is evidence indicating that sacral nerve stimulation is effective in patients with urge incontinence (level 2), urgency-frequency (level 2), urinary retention (level 2) and fecal incontinence (level 4).

- While the long-term data is limited, there is data indicating the device is effective up to 5 years (level 4).

- There is a high surgical revision rate (33%) and explantation rate (devices removed) (13%)--but no permanent injuries or deaths reported.
As a result of its review, OHTAC recommends:

Increased access to sacral nerve stimulation for people with urinary urge incontinence, urgency-frequency, urinary retention and fecal incontinence who have failed drug and behaviour therapy.

Guidelines for sacral nerve stimulation should be developed by the Program in Evidence-Based Care (PEBC). The guideline panel should include urologists, gastroenterologists and general practitioners.