Canadian Journal of Health Technologies

CADTH

August 2021 Volume 1 Issue 8

CADTH Horizon Scan

The Portable Neuromodulation Stimulator: Targeting Neuroplasticity for Balance or Gait Deficit

Health Technology Update

CADTH

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ISSN: 2563-6596

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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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Key Messages

- CADTH's Horizon Scanning Service identifies new and emerging technologies that may be of interest to health care decision-makers in Canada
- *Health Technology Update* articles generally focus on a single technology or intervention.
- This Horizon Scan presents a brief summary of information relevant to the Portable Neuromodulation Stimulator, designed to be used in conjunction with physical therapy to improve balance or gait impairments associated with mild-to-moderate symptoms of multiple sclerosis or mild-to-moderate traumatic brain injury.

The Portable Neuromodulation Stimulator

Individuals who are living with multiple sclerosis (MS) or have experienced traumatic brain injury (TBI) often have difficulty with walking and balance, causing challenges with mobility and affecting quality of life.[1,2] Physical therapy and other interventions can help people with these disorders, including a new device, the Portable Neuromodulation Stimulator (PoNS) (Figure 1), designed to supplement physical therapy and improve chronic balance and/or gait impairment for patients with mild-to-moderate symptoms of MS or a mild-to-moderate TBI.[3,4]

How It Works

The PoNS device uses translingual neurostimulation (TLNS) — a type of cranial nerve, non-invasive neuromodulation (CN-NINM) — to deliver electrical signals that are painlessly transmitted from the tongue through cranial nerves to the brain.[3] It is believed that TLNS using the PoNS can support the brain's neuroplastic capacity for restructuring and relearning motor and other skills following trauma or injury.[5,6] The PoNS uses a mouthpiece connected to a battery-powered controller[7] and is intended for short-term use during sessions of approximately 20 minutes in length, in conjunction with physical therapy, over a 14-week course of treatment.[6]

Who Might Benefit?

The PoNS is intended for use in patients living with MS or those who have experienced mild-to-moderate TBI and are experiencing difficulty with walking and/or mobility; i.e., gait deficit or chronic balance deficit. Based on data collected in 2015 to 2016, the Public Health Agency of Canada reported that more than 77,000 people in Canada were living with MS[8] and that annual incident cases per 100,000 are estimated to rise from 4,051 in 2011 to 4,794 by 2031.[9] And in 2017, it was estimated there were 447 new cases of TBI per 100,000 people in Canada, with an estimated national prevalence of 442,623 cases. Many of these people are affected by chronic balance and/or gait disorders, which can significantly reduce their mobility and have a negative effect on their quality of life.[1,2,10]

Given the burden of illness in Canada caused by MS, TBI, and other conditions that impair walking, movement, or mobility, as well as the potential importance of neuro-rehabilitation for improving outcomes in affected people,[6] emerging technologies like the PoNS could benefit thousands of people in Canada if demonstrated to be effective.

Availability in Canada

The PoNS is currently authorized by Health Canada for the short-term use (14 weeks) for treatment of gait deficit in patients living with MS as well as those with chronic balance deficit from mild-to-moderate TBI and is to be used in conjunction with physical therapy (Emma Grenon, Director of Business Development, Helius Canada, Vancouver, BC: personal communication, Jul 13, 2021). Physical therapy with the PoNS device is available in more than 30 clinics across the country, including those in British Columbia, Alberta, Ontario,

Figure 1: Neurostimulation Device Ready to Be Used

Source: Reproduced with permission from Helius Medical Technologies, Inc.

Quebec, New Brunswick, and Nova Scotia.[11] Clinics are selected for their use of the PoNS based on their experience treating patients with neurologic disorders such as MS and TBI (Emma Grenon: personal communication, Jul 13, 2021).

What Does It Cost?

The manufacturer of the PoNS confirms that the cost of the 14-week PoNS treatment program ranges from $10,000 to 15,000, depending on the particular clinic at which the treatment is provided (Emma Grenon: personal communication, Jul 13, 2021). The cost of therapy using the PoNS is not currently covered by provincial health jurisdictions in Canada, with some people paying out of pocket and others seeking support from other sources.[12,13] Several patients have achieved full or partial reimbursement via personal health insurance plans (Emma Grenon: personal communication, Jul 13, 2021).

Current Practice

Most patients living with MS develop gait disability over time, which is diagnosed using clinical and patient-reported measures.[14] Current treatment focuses on physical therapy,[15] but other therapies include medication and/or other forms of neuromodulation, including invasive approaches such as deep brain stimulation (DBS)[3] and other therapies such as functional electrical stimulation, which provide a limited and non-progressive benefit to patients.[10]

For patients who have experienced mild-to-moderate TBI, balance deficit may or may not be present but is also assessed using clinical measures and is often treated using physical therapy.[16] Nonetheless, new technologies — including those using TLNS — are being investigated for their effects on improving outcomes for those affected.[5,17]

What Is the Evidence?

Multiple studies have been conducted assessing the effectiveness of the PoNS device for gait and/or balance deficit in people with MS or mild-to-moderate TBI, several of which are also highlighted by the manufacturer.[18] Of these, 1 randomized study of 14 participants with MS compared physical therapy with and without the PoNS device, reporting significant improvement in gait among the group receiving physical therapy with the PoNS device.[10] Similarly, another randomized study of 20 MS patients reported a significant improvement in gait among participants receiving physical therapy with the PoNS device, as compared to those receiving physical therapy with a non-functioning PoNS device (to maintain blinding).[19] For people who had experienced mild-to-moderate TBI, another randomized trial reports data on 43 participants who received physical therapy with either high- or low-dose frequency using the PoNS device. Whereas no difference in a measure of postural stability was reported between the 2 groups, improvement following treatment from baseline was reported for both groups.[5,18]

A 2020 review of available evidence describing TLNS identified, summarized, and assessed the quality of several studies evaluating the clinical effectiveness of interventions using the technology (including the PoNS).[3] Authors of the review reported that most of the studies to-date are of variable and/or low quality, making the available evidence less useful for informing decisions about the overall effectiveness of interventions that use TLNS — including the PoNS.[3] Nonetheless, the authors did indicate that the feasibility and safety of TLNS using the PoNS and other technologies has been clearly demonstrated by the available evidence and that additional research will be able to more definitively demonstrate the efficacy of this technology.[3]

Safety

Developers of the PoNS report that no overstimulation or other adverse effects have been observed across multiple studies and case evaluations.[7] The 2020 review assessing the clinical effectiveness of TLNS (including the PoNS) reported that, while the evidence remains too premature to sufficiently assess efficacy, safety has been demonstrated.[3]

Related Developments

PoNS is a new and innovative approach to neurorehabilitation and is currently authorized in Canada for use with patients experiencing balance or gait disorder caused by either MS or TBI. However, there may be additional applications for the PoNS that could benefit patients with a variety of neurologic conditions, including those affected by balance and/or gait deficit, such as cerebral palsy and stroke,[12] spinal cord injury,[20,21] Parkinson disease,[22] and acoustic neuroma.[23]

Other, broader indications have also been proposed as possible targets for the PoNS technology, including eye movement disorders,[24] as well as cognitive function, self-reported bladder function, and tremor.[4]

Looking Ahead

The need for more evidence is an important theme that emerges from the current literature describing the PoNS device[4] — particularly sufficiently powered, randomized controlled trials that can adequately assess its efficacy (i.e., while feasibility and safety have been demonstrated, the extent to which the PoNS provides a benefit to patients remains uncertain). Notably, developers of the PoNS concede that producing such evidence will be challenging, not least because the development of a suitable placebo to allow for blinded assessment of the technology will be particularly challenging given the features of the intervention.[4]

The cost of the therapy and the current lack of coverage for Canadians also represent important barriers to access for patients who might benefit; nonetheless, these patients have expressed enthusiasm and a desire for access to this emerging technology.[12,25] Likewise,

developers, clinicians, and others remain optimistic that the innovative, non-invasive neurorehabilitation the PoNS may support is likely to have increased uptake and additional applications in the future.

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