Medtronic News

Newly Published Data Show Medtronic InterStim(R) Therapy Decreases Episodes of Chronic Fecal Incontinence and Positively Impacts Quality of Life

InterStim Therapy for Bowel Control Currently Under Review by the U.S. FDA

MINNEAPOLIS, Mar 29, 2010 (BUSINESS WIRE) --Data published in the March issue of the Annals of Surgery show that investigational use of sacral nerve stimulation with Medtronic InterStim(R) Therapy reduces fecal incontinent episodes and increases quality of life in patients with the condition. The 120-patient, multi-center study - the largest trial of its kind in the world and the first such trial in North America - examined the efficacy of InterStim Therapy in patients with chronic fecal incontinence who had failed or were not candidates for more conservative treatments. InterStim Therapy for bowel control in this patient population is currently under review by the U.S. Food and Drug Administration (FDA).

"Fecal incontinence is a debilitating and distressing condition, and current treatment options are limited," said Steven Wexner, M.D., professor and chair, Department of Colorectal Surgery at Cleveland Clinic Florida, first author of the published manuscript and lead investigator of the clinical trial. "The results of this study are promising and may provide a new treatment option for patients with fecal incontinence." Dr. Wexner is a paid consultant assisting Medtronic in the development of educational materials relating to this therapy. He assumed this role after the clinical study was completed.

Study participants were implanted with a Medtronic InterStim system to deliver mild electrical stimulation to the sacral nerves that control the bladder, sphincter and pelvic floor muscles. At 12 months of follow-up, 83 percent of patients experienced therapeutic success, defined as a greater than 50 percent reduction in the number of fecal incontinent episodes per week. Furthermore, perfect continence (100 percent improvement) was achieved in approximately 40 percent of the patients. Improvement remained stable over time, with 87 percent therapeutic success rate in patients who had passed three years of therapy (n=30 patients who had completed the diary requirements in the study).

Additionally, patients receiving InterStim Therapy experienced an increase in overall quality of life at 12 months post-implant, as defined by the Fecal Incontinence Quality of Life (FIQOL) scale, a questionnaire composed of 29 questions, grouped into four domains: lifestyle, coping/behavior, depression/self-perception and embarrassment.

"InterStim Therapy has become an important treatment option for patients with overactive bladder who do not have success with more conservative therapies and a similar unmet clinical need exists for people living with fecal incontinence," said Tom Tefft, president of the Neuromodulation business and senior vice president at Medtronic. "Medtronic has been the pioneer and long-time leader in neuromodulation technologies, including pursuing a high level of clinical evidence for our therapies. InterStim Therapy has been used to treat fecal incontinence in Europe since 1994 and this clinical study shows InterStim Therapy has a significant impact on quality of life when few other treatment options exist."

About the Study

The study collected data from 2002 to 2008 from 120 patients at 16 centers, including 14 U.S. centers, one in Canada and one in Australia, who were candidates for sacral nerve stimulation for fecal incontinence. Patients were asked to record total incontinent episodes per week, total urgent incontinent episodes per week and total

incontinent days per week. Data were recorded at 3 months, 6 months, 12 months, and annually thereafter, with an average total follow-up period of 28 months. At the time of thispublication, 76 patients have reached two years and 34 have reached three years on therapy. The study was sponsored by Medtronic, Inc.

In the study, the most common device or therapy-related adverse events that occurred during the implant phase included implant site pain (25.8 percent), paraesthesia, or a sensation of tingling, pricking, or numbness of the skin, (12.5 percent) and implant site infection (10.8 percent). The majority of the events were successfully handled by minimal interventions. There were no reported unanticipated adverse device effects associated with InterStim Therapy.

About InterStim Therapy

InterStim Therapy is currently approved by the FDA to treat the symptoms of overactive bladder and urinary retention when more conservative treatments have failed. The therapy utilizes an implantable system, consisting of a lead (a thin wire), neurostimulator, or pacemaker-like device, as well as external clinician and patient programmers, to send mild electrical impulses to the sacral nerves. Physicians and patients can assess the effectiveness of the therapy during a test stimulation phase before moving forward with long-term InterStim Therapy. The therapy was originally approved by the U.S. Food and Drug Administration (FDA) in 1997 for urinary urge incontinence and received CE Mark in 1994 for dysfunctions of the lower urinary and intestinal tract. To date, more than 75,000 people have received InterStim Therapy worldwide. InterStim Therapy for fecal incontinence remains under review by the FDA for marketing in the United States.

About Fecal Incontinence

Fecal incontinence is the inability to control the bowels and is a debilitating condition that is often underreported and stigmatized. According to the National Institutes of Health (NIH), more than 5.5 million Americans have fecal incontinence. It is more common in adults, predominately women, but it is not a normal part of aging. Fecal incontinence can be caused by a variety of factors, including damage to the nerves or muscles in the rectum (from trauma such as childbirth), diabetes, or other pelvic health disorders. Greater than 50 percent of patients with severe fecal incontinence report a significant impact on quality of life, including impact on their ability to work or engage in social activities.

About Medtronic

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