Sacral Nerve Stimulation Cut Fecal Incontinence

VITALS

Major Finding: Sacral nerve stimulation reduced the number of weekly episodes of fecal incontinence by at least half for 86% of 77 patients at 3 years.

Data Source: A prospective study of 133 patients with at least two episodes of fecal incontinence per week.

Disclosures: The study was funded entirely by Medtronic Inc., which makes the InterStim device. Three of the study's authors reported receiving research support from and acting as consultants to Medtronic. One of the authors reported being an employee of Medtronic.

BY KERRI WACHTER

FROM THE AMERICAN SOCIETY OF COLON AND RECTAL SURGEONS ANNUAL MEETING

MINNEAPOLIS — Improvements in fecal incontinence achieved with sacral nerve stimulation appear to persist at least 3 years, based on the results of a study involving 133 patients.

Among 77 patients who were implanted with the InterStim device and followed for at least 3 years, therapeutic success—defined as at least a 50% reduction in the number of incontinent episodes per week—was 86%, Dr. Anders Mellgren reported at the meeting.

The study was supported entirely by Medtronic Inc., which makes the InterStim device.

The researchers included 133 patients who were experiencing chronic fecal incontinence of at least two episodes per week and who had an external anal sphincter defect of less than 60 degrees. In addition, these patients either were not candidates for more conservative treatments or had experienced failure with such attempts.

The sacral nerve stimulation procedure is a two-step process. The patient is first implanted with a test lead for a 1- to 2-week trial. If the number of incontinent episodes is reduced by at least 50% during the trial, the stimulation device is implanted. In this study, following the initial test period, a total of 120 patients were implanted with the InterStim device.

The device delivers mild electrical stimulation to the sacral nerves that control the bladder, sphincter, and pelvic floor muscles.

Patients were asked to record their total number of incontinent episodes per week, total urgent incontinent episodes per week, and total incontinent days per week. Data were recorded at 3 months, 6 months, and 12 months, and annually thereafter. The average total follow-up period was 28 months, said Dr. Mellgren of colon and rectal surgery at the University of Minnesota in Minneapolis.

Depending on the type of analysis that was performed, the success rate ranged from 59% to 86%, Dr. Mellgren said.

A total of 77 patients completed treatment and had a 3-year follow-up period. Success in these patients was 86%. However, when all the implanted patients were included and the last observation was carried forward, the success rate was 79%.

And in a modified worst-case analysis, all patients who did not complete the follow-up period were considered failures, so the success rate dropped to 59%.

The average number of incontinent episodes per week decreased from almost 10 at baseline to about 2 at the end of 3 years (77 patients).

In addition, perfect continence (100% improvement) was achieved in about 40% of the patients, while 20%-30% of patients had a 75% improvement in symptoms.

The most common device- or therapy-related adverse events that occurred during the implant phase of the study were implant site pain (28% of patients), paresthesia (15%), change in sensation of stimulation (12%), and implant site infection (10%). Half of the patients with infection had to be reoperated, and five had the device removed, Dr. Mellgren noted. Most events were successfully handled by minimal interventions. ■