Short-term Effects of Sacral Nerve Stimulation for Idiopathic Slow Transit Constipation

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Published Online: December 4, 2001

Abstract. This study assessed the short-term clinical and physiological effect of continuous sacral nerve stimulation in patients with slow transit constipation. Some patients with idiopathic slow transit constipation are unresponsive to conservative treatments, while colectomy has a variable and poorly predictable outcome. Sacral nerve stimulation is a less invasive and reversible procedure that enables direct neuromodulation of the pelvic floor and hindgut. It has been used successfully in the treatment of urologic disorders and fecal incontinence, and some of these patients with concurrent constipation have also noted improved stool frequency and rectal evacuation. Eight women (median age 47 years, median symptom duration 31 years, median stool frequency once per 6 days) were implanted with a temporary percutaneous stimulating S3 electrode for 3 weeks, attached to an external stimulator (Medtronic, Minneapolis, USA). A bowel symptom diary card, anorectal physiological studies, and a radiopaque marker transit study were completed before and during stimulation. Two patients had cessation or marked diminution of symptoms, including normalization of bowel frequency. Colonic transit did not return to normal in any patient. Rectal sensory threshold to distension was decreased during stimulation. Percutaneous temporary sacral nerve stimulation symptomatically improved a minority of patients with resistant idiopathic slow transit constipation. Sensory function was altered by stimulation. Further studies are required to identify patients who may benefit and to assess a range of stimulation parameters.

Patients with idiopathic slow transit constipation have reduced stool frequency but a morphologically normal colon and rectum [1]. Abdominal pain and bloating are common and cause considerable disability. The primary colonic motility disturbance is reduced frequency and duration of mass movements [2].

Treatment of idiopathic slow transit constipation is difficult. Dietary manipulation is often insufficient to resolve symptoms. Laxatives are often ineffective and have side effects of bloating, fecal urgency, and urge fecal incontinence [3]. Some patients respond to behavioral retraining (biofeedback) [4]. There remains a significant group of patients, however, with intractable and incapacitating symptoms despite conservative measures. Traditionally, the worst of these patients come to surgery, with colectomy and ileorectal anastomosis having been the most commonly performed procedure. This may improve up to half of patients, but has significant associated morbidity. Up to a third develop chronic diarrhea, 10% remain constipated, and 10% ultimately require a permanent ileostomy for relief of symptoms [5]. Other options such as the antegrade continence enema procedure [6] and colonic conduit irrigation [7] have not been widely accepted, partly because of long-term problems, associated morbidity, and the need to continue irrigating. Fecal diversion with a colostomy or ileostomy has body image consequences, particularly in the young female population in which slow transit constipation primarily occurs, and often fails to resolve other functional symptoms such as abdominal pain and bloating [8]. There remains a large gap between the treatment and the invasiveness of resectional or other colonic surgery for this condition.

An alternative approach may be to stimulate the extrinsic nerve supply to the large bowel, or to modulate reflexes that may be inhibiting large bowel function. Direct anterior sacral nerve root stimulation has been employed in patients with spinal cord injury to stimulate bowel peristalsis [9–11]. Much lower level electrical stimulation has been used in the treatment of nonobstructive urinary retention and detrusor instability [12, 13], by use of electrodes implanted into sacral foramina, thereby stimulating mixed sacral nerves. As part of the latter treatment, some patients treated by sacral nerve stimulation for urinary voiding dysfunction have experienced improvement in both bowel continence and evacuation, suggesting that stimulation also affects pelvic floor and possibly hindgut function. More recently sacral nerve stimulation has been successfully used to treat patients with fecal incontinence [14, 15].

For such an approach to be successful in patients with slow transit constipation, the intrinsic nerve plexuses in the bowel would need to be intact, and the bowel would need to be capable of responding with a normal pattern of coordinated peristalsis. In patients with idiopathic slow transit constipation such conditions would appear to exist. Direct stimulation of the colonic mucosa with strong contact laxatives results in coordinated peristalsis associated with transport of colonic contents [16].

This pilot study aimed, therefore, to assess whether sacral nerve stimulation might benefit patients with severe idiopathic slow transit constipation who had been unresponsive to traditional conservative treatments. Patients with slow transit constipation
were chosen because they have an objective abnormality that can be quantitatively and serially assessed.

### Materials and Methods

Eight women, median age 47 years (range 35–68 years) were studied. All had longstanding constipation as defined by the Rome criteria [17] and slow gut transit as documented on radiopaque marker studies within the last 12 months [18]. All patients had failed traditional conservative treatments including bulk-forming agents, oral laxatives, bowel cleansing solutions, enemas, or suppositories. All patients had also failed a full course of biofeedback treatment [19]. No patient had undergone surgery for constipation.

All were considered psychologically suitable for temporary sacral nerve stimulation and study evaluation, without any past psychiatric history and on no current psychiatric medications.

Patients had experienced symptoms of constipation for a median of 31 years (range 9–47 years). Their average stated stool frequency was once per 6 days (range every other day to every 3 weeks). All patients also complained of abdominal pain and bloating, 6 complained of the need to strain excessively at stool, and 4 analy digitized to aid rectal emptying.

Prior to implantation all patients were prospectively assessed over a 3-week period using a detailed bowel symptom diary card (Table 1). This recorded details of stool frequency and consistency, and the presence and degree of the symptoms of abdominal pain, bloating, and straining, on a daily basis. Patients were asked to cease taking all oral laxatives and to cease using suppositories and enemas during this 3-week period. Medication of 2 mg tablets of oral bisacodyl (Dulcolax, Boehringer Ingelheim, UK) was permitted if patients had disabling symptoms after a minimum period of 3 days without opening their bowels. The use of bisacodyl was also prospectively recorded.

A transit study was obtained prior to implantation, using radiopaque markers which were ingested over consecutive days, followed by a plain abdominal radiograph taken 120 hours after ingestion of the first set of markers [18]. Retention of an excessive proportion of any one of the sets of markers (more than 80%) was regarded as diagnostic for slow transit constipation.

Table 1. Questions asked on bowel symptom diary card.

<table>
<thead>
<tr>
<th>Number of bowel movements</th>
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<tbody>
<tr>
<td>Straining at stool (nil, some, moderate, marked)</td>
</tr>
<tr>
<td>Stool consistency (loose, normal, hard/pellets)</td>
</tr>
<tr>
<td>Abdominal bloating (present, absent)</td>
</tr>
<tr>
<td>Abdominal pain or discomfort (present, absent)</td>
</tr>
<tr>
<td>Other symptoms (details—mild, moderate, severe)</td>
</tr>
<tr>
<td>Rescue medication (number of tablets)</td>
</tr>
<tr>
<td>Other medications (details)</td>
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Anorectal physiological testing was undertaken before implantation. Anal manometry was undertaken using a station pull-through technique with an eight-channel water perfused system, to determine the maximum resting and squeeze anal pressures. The maximum squeeze pressure was measured as the mean incremental rise above resting pressure. The rectal sensory threshold, sensation of urgency, and maximum tolerated rectal volume to balloon distension with air were determined [20]. Anal and rectal mucosal electrosensitivity were assessed using a bipolar ring electrode (Dantec 21L10, Dantec Electronics, Ltd, UK) [21]. The ability to expel a 50 ml water-filled rectal balloon and the presence or absence of paradoxical contraction of the pelvic floor muscles during straining were noted [22].

Patients were implanted with a percutaneously placed stimulating sacral electrode as outpatients. The procedure and equipment used for temporary percutaneous sacral stimulation have been described previously (Model 3065U PNE Kit, Medtronic, Minneapolis, USA) [14, 15, 23]. Xylocaine 1% plain local anesthetic was infiltrated into the skin and subcutaneous tissues at the site of each needle insertion. Sacral nerve roots were tested with a needle connected to a stimulating device to determine which root produced the maximal clinical anal response to stimulation. The S3 root was tested initially as it is the root which most commonly results in effective stimulation [14, 15, 24]. Optimal placement was confirmed by observing anal contractions and perineal elevation on stimulation, combined with the patient reporting a perineal sensation. A flexible stimulating wire electrode was then placed adjacent to the sacral nerve trunks using a Seldinger technique through the stimulating electrode. The wire electrode was secured in place with tape. The electrode was then attached to an external stimulator (Medtronic Screener Model 3625, Medtronic, Minneapolis, USA).

All patients underwent a 3-week period of stimulation. Stimulation was performed continuously at a level just above the perineal sensory threshold for each patient, to ensure the device was operating throughout the whole of the period of the study. Patients experienced a slight “bubbling” or pulsing sensation within the perineum, and often also intravaginally and/or intraanally. The level of stimulation varied between 3 and 10 volts. Pulse frequency (15 Hz) and pulse width (210 microseconds) were the same for all patients and kept constant throughout the period of stimulation.

During the stimulation phase all patients were contacted weekly to exclude problems, and to ensure that patients were continuing to experience a sensation indicative of ongoing stimulation. During the 3-week stimulation period patients completed a further identical daily diary.

At the end of each 3-week diary period, patients were asked to rate on a visual analog scale their overall bowel function over the previous 3 weeks from “very poor” (0 mm) to “very good” (100 mm). Also at this time patients were asked to rate on a scale from absent to severe their constipation, the need to strain at stool, the presence of abdominal bloating or pain, the need for anal digitation, and the sensation of incomplete rectal evacuation after defeation.

During the last day of stimulation, patients had repeat anorectal physiological studies and a further transit study.

As this study aimed to assess the short-term effects of sacral nerve stimulation, the stimulating leads were removed after 3 weeks for all patients, as agreed by patients and approved by the local ethics committee. Patients who felt subjectively clinically improved then completed a further 3-week bowel symptom diary card.

In view of the small number of patients in this study only limited statistical analysis has been performed.

The study was approved by the Harrow research ethics committee and all patients gave written informed consent.

### Results

All patients had successful unilateral lead implantation into the S3 foramen, on the left side in 6 patients. There were no procedural complications, and no side effects of continuous stimulation. All leads were removed after 3 weeks with no subsequent problems.