



## Functional Urology

## A case of lead migration after sacral neuromodulation with erosion into the rectum

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## ABSTRACT

We present a case of a 73-year-old female with medication refractory overactive bladder treated with the InterStim® sacral neuromodulation device. Five months post implantation she developed drainage over the lead site and rectal bleeding. Evaluation identified lead migration with rectal perforation requiring surgical removal of the battery and lead. Post removal, the patient returned to baseline urinary symptoms with the development of de novo fecal incontinence. This is the third reported case of sacral neuromodulation lead migration causing rectal perforation in the literature, and the only case managed with endoscopic closure of the rectal defect.

## 1. Introduction

Sacral neuromodulation (SNM) can reduce overactive bladder (OAB) symptoms in patients who are refractory to pharmacotherapy. A randomized trial studying SNM with Medtronic's InterStim® sacral neuromodulation device revealed that at 5 years post implantation, 68 % of patients with urge incontinence, 56 % of patients with urinary urgency and 71 % with retention had 50 % or greater improvement of symptoms.<sup>1</sup> A review from 1998 to March of 2020 revealed similar results, with a 66.2 % pooled success rate of SNM.<sup>2</sup> In this analysis, adverse events were found in less than 25 % of cases, with loss of effectiveness in 4.7 %, infection in 3.6 %, pain at implant site and lead migration in 3.2 % in each case.<sup>2</sup> A multicenter prospective cohort trial listed the most frequent adverse events as pain at the implant site in 28 %, paresthesia in 15 %, and infection in 10 % at an average of 36 months post-implant.<sup>3</sup> Another review revealed that 33 % of implants require reoperation with lead migration being the cause in 16 %.<sup>4</sup> Here, we describe a case of SNM complicated by lead migration and rectal perforation that presented as drainage over the lead site, abdominal pain, and hematochezia five months post implantation with a subsequent discussion of the proposed etiology and management.

## 2. Case presentation

The patient is a 71-year-old female with a history of medication refractory urinary urgency and frequency. She initially presented to urology with complaints of worsening urinary frequency and incomplete voiding. Prior to this, urinary symptoms were well controlled with extended release tolterodine 4mg, once daily. She failed to respond and had intolerable side effects (including constipation) with higher-dose tolterodine (8mg daily), so work-up for medication-refractory OAB was initiated. A urodynamic study demonstrated detrusor overactivity and increased sensation with incontinence, and a cystoscopy identified no anatomic causes of urinary urgency. Based on this, the patient was offered third line OAB treatments, and she elected to undergo SNM with the InterStim® device.

The patient subsequently had a two-stage InterStim® implant performed. Her urinary urgency and frequency symptoms improved significantly after the stage 1 procedure and the patient elected to go forward with the stage 2 implantation. During the initial procedure, a single lead was placed through the right S3 foramen, and the position confirmed with fluoroscopy (Fig. 1) as well as S3 neural responses on the right. The patient was compliant with follow-up and wound check visits. At three months post-implant, the patient returned and reported scant, intermittent drainage with some fullness over the lead implantation site.

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There was no erythema, tenderness, or visible erosion at the site, and the patient reported no systemic symptoms of infection. The drainage was suspected to be from a resolving superficial infection and was treated with a course of oral antibiotics.

Two months later (now five months post-implant), the patient presented to her gastroenterologist with complaints of new hematochezia and abdominal pain. She also had some recurrent drainage over the lead site which did not respond to a second course of antibiotics. The patient was evaluated with a flexible sigmoidoscopy where a foreign body was found in the recto-sigmoid colon. The intra-procedure photographs demonstrated lead erosion into the rectum (Fig. 2).

Subsequent abdominal CT with contrast did not show abscesses or other fluid collections in the pelvis (Fig. 3). The drainage over the lead site was assessed as likely from communication with the rectal perforation from lead migration.

Due to this finding, the patient was scheduled urgently for removal of her InterStim® device and lead in a combined case with colorectal surgery. During the case, the patient was placed in a prone position. First, the InterStim® battery was exposed and then removed from its surgical pocket. A separate incision was made over the insertion site, and the lead was dissected down to the presacral fascia. The plan was to cut the external portion and have the internal portion removed endoscopically. However, likely due to tissue edema, the lead was removed in its entirety with very minimal force. At this point, colorectal surgery performed a flexible sigmoidoscopy and identified an area of pinpoint rectal perforation without evidence of surrounding tissue damage or infection. The defect was then closed by the placement of two endoscopic clips.

At follow-up, the patient had no evidence of persistent infection; but, as expected, her urinary symptoms returned to baseline. In addition, the patient developed new onset fecal urgency and urge incontinence. The patient resumed medical treatment with tolterodine with some improvement in her urinary symptoms. A postoperative Gastrografin enema study confirmed no evidence of leakage from the site of perforation and demonstrated that the endoscopic clips were still in place.

### 3. Discussion

InterStim® tined lead migration after SNM is an infrequent surgical complication with an overall 5-year adverse event rate of 5.9 %.<sup>5</sup> However, it is reported that lead-related complications contribute to 58.8 % of post-implant surgeries.<sup>6</sup> Lead migration is commonly detected as a loss of efficacy. One study reported that, in patients with loss of treatment efficacy after InterStim® placement for fecal incontinence, lead migration was present in 52 % and was presented as a potential cause.<sup>7</sup>

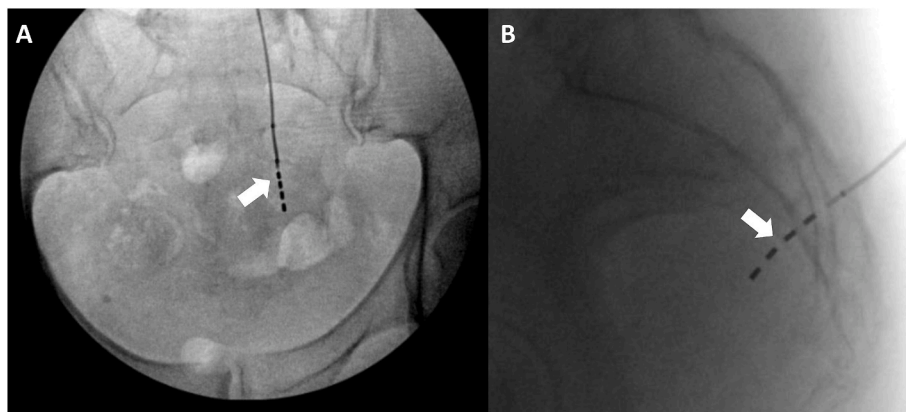
In terms of the complication of rectal perforation, only three other cases have been reported. In the first, a 26-year-old female patient

received an InterStim® tined lead implant for persistent urinary retention which required her to perform clean intermittent self-catheterization.<sup>8</sup> After the implant, the patient reported greater than 50 % treatment response and no longer required self-catheterization.<sup>8</sup> The treatment response was durable at eight months follow up. However, she returned at 15 months post-implant with three weeks of severe diarrhea and gastroenteritis before the identification of a foreign body in the rectal canal.<sup>8</sup> The lead was removed, the patient received antibiotics and presented at follow up after six weeks with no surgical site infection or pain and with preserved micturition.<sup>8</sup> Another case describes a 25-year-old male patient who presented one year post-implantation with pain, inflammation, and ulceration over the site of sacral lead insertion but without gastrointestinal symptoms.<sup>9</sup> A third case by Shannon and colleagues describes a patient who underwent attempted lead removal that resulted in lead fragmentation and subsequent fragment migration into to the sigmoid colon which caused infection.<sup>10</sup>

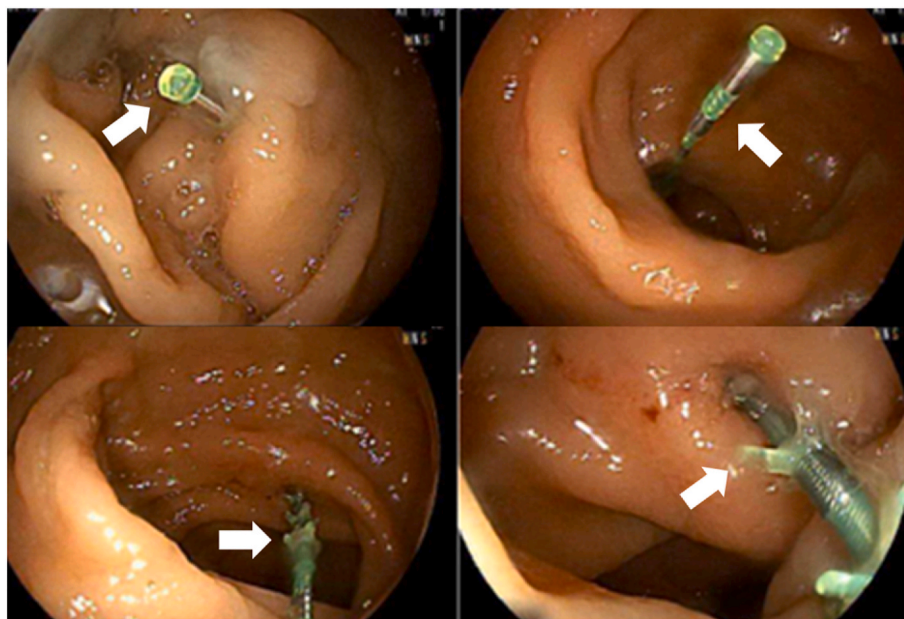
While tined leads are believed to reduce the rate of migration, there is still some risk. Tined leads reduce lead migration compared to the original InterStim® protocol.<sup>5</sup> Deng and colleagues reported a 2.1 % InterStim® failure rate with the use of tined leads and showed that 4/5 (80 %) of these cases were due to lead migrations.<sup>11</sup> Ezra and colleagues proposed that tined leads used in the treatment of fecal incontinence are more susceptible to forward migration because the shape of the leads allows for inward as opposed to outward migration.<sup>7</sup> Post-implantation lead migration is suspected to occur from insufficient scar fixation or mechanical strain as opposed to primary rectal injury during surgery.<sup>7</sup> Specifically, in the current case and in at least one of the prior reports,<sup>9</sup> intraoperative fluoroscopic imaging demonstrated appropriate lead position.

Timing of lead migration is another factor for potential discussion. In our case, the patient presented symptomatically, resulting in imaging identifying the migration at five months post-implant. Ezra and colleagues found in their work an average 22-month period between implant and symptoms requiring imaging showing the migration.<sup>7</sup> A limitation of this conclusion is that this does not describe the time period between start of migration and development of symptoms as pointed out by the authors. When comparing the timing of our patient with the other data cited here (15 months, one year, 22 months) our patient did present earlier in the post-operative course. A future direction could include observing patients before they develop symptoms due to migration to better understand the dynamics of lead migration.

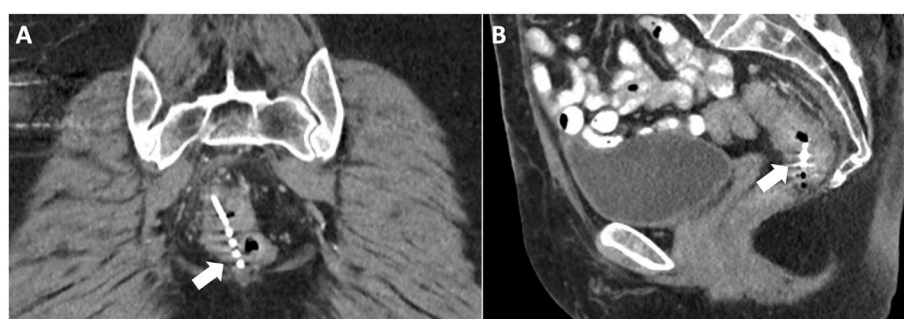
As in the other case reports, we propose that the current patient's rectal lead perforation was due to spontaneous forward migration of the implanted lead. All cases were associated with a delayed presentation (5–15 months) and most were associated with de novo abdominal/gastrointestinal symptoms. In addition, no patients presented with peritonitis, and rapid and complete lead removal did not result in the



**Fig. 1. Fluoroscopic Confirmation of Lead Position.** Intraoperative anterior-posterior (A) and lateral (B) fluoroscopic images of the pelvis showing the lead in good position in the S3 sacral foramen.



**Fig. 2. Flexible Sigmoidoscopy Images.** Images taken during flexible sigmoidoscopy showing erosion of the tined lead (arrow) into the rectum.



**Fig. 3. Sacral CT with Contrast.** Coronal (A) and Axial (B) sacral CT images with IV and oral contrast showing the tined lead (arrow) within the lumen of the rectum.

development of further infection or complications.<sup>9</sup>

#### 4. Conclusion

We present a patient who developed drainage, abdominal pain, and rectal bleeding five months post-implantation with an InterStim® device for treatment of overactive bladder refractory to pharmacotherapy. This is a rare complication (only three other cases reported in the literature) which typically presents in a delayed fashion with new-onset abdominal/gastrointestinal symptoms. In addition, the cause is most likely postoperative lead migration as intraoperative imaging confirms proper placement. Furthermore, the current case is the only example where the identified rectal perforation was closed with rectal clips.

#### CRediT authorship contribution statement

**Bridget S. Kastelberg:** Writing – original draft, Writing – review & editing, Data curation, Formal analysis. **Madeline C. Donnelly:** Writing – original draft, Data curation, Methodology. **George B. Smallfield:** Writing – review & editing, Conceptualization, Methodology. **Stephen P. Sharp:** Conceptualization, Data curation, Methodology, Writing – review & editing. **Laura R. Carucci:** Formal analysis, Writing – review & editing, Methodology. **Adam P. Klausner:** Conceptualization, Data curation, Formal analysis, Supervision, Writing – review & editing,

Methodology, Writing – original draft.

#### Data availability statement

All data, imaging and materials created and analyzed for the purposes of this case report are included in this article.

#### Disclosures

None.

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