

A rare case of tined lead migration of InterStim device into the rectum with subsequent novel combined surgical-endoscopic removal technique

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ABSTRACT

After the introduction of self-anchoring tined leads in 2002, lead migration after sacral neuromodulation (SNM) in the form of InterStim™ (Medtronic, Minneapolis, MN) has been reduced; however, it remains a considerable complication of this otherwise low-risk procedure. As intestinal perforation through lead migration or primary incorrect positioning portrays a rarity and has been scarcely reported in the literature, no algorithm for explantation in such cases has been determined. We present a case of a young man with an SNM device implant (InterStim II®) because of neurogenic urinary retention, who was admitted with inflammation, localized at the sacral lead insertion site. Our diagnostic algorithm revealed a tined lead electrode protruding into the rectum without concomitant abscess. We performed an interdisciplinary surgical approach combining regular incisions over the sacrum and buttocks for dissection of the lead and the implanted pulse generator, respectively, with an endoscopic transanal lead extraction. This method prevented further bacterial seeding in the surrounding tissues of the colon and, therefore, presacral abscess formation or sacral osteomyelitis. Combined surgical-endoscopic removal of the InterStim device is an effective and safe procedure that should be included in the armamentarium of urologists performing neuromodulation surgery in cases of intestinal perforation.

Keywords: Implantable neurostimulators; implanted stimulation electrodes; intestinal perforation; postoperative complications.

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Introduction

Sacral neuromodulation (SNM) in the form of InterStim™ (Medtronic, Minneapolis, MN) is an established treatment for fecal incontinence and urinary disorders such as refractory overactive bladder and non-obstructive urinary retention as well as an “off-label” treatment for neurogenic lower urinary tract dysfunction and bladder pain syndrome. Although SNM is a relatively safe surgical procedure, a high revision rate of 24.4%, as well as a removal rate of 19%, is reported because of adverse events during a 5-year follow up.^[1] The most common complications are implant site pain in up to 32.5%, paresthesia in up to 19%, and implant site infection in up to 10% of the cases, followed by decrease or loss of device efficacy.^[2] In a multicenter trial with a total infectious complication rate of 3.3%, a difference between

early (<1 month after implantation) vs. late (>1 month) infections was noticed. The time of infection implicated different treatment strategies, as 70% of early device infections were successfully treated with antibiotics, while all late infections required device removal after failed conservative treatment.^[3] The complication of lead migration could be successfully decreased after Food and Drug Administration approval of self-anchoring tined leads with four sets of silicone tines proximal to the electrodes with a reported dislodgment rate of up to 2.1%.^[4] Last but not least, a lead fracture could also portray a possible source of complications. Although current evidence suggests that it is generally safe for residual lead fragments to remain in situ long-term, including in patients undergoing MRI, a secondary rectal injury through a fragmented lead has been described in the literature.^[5]

Case presentation

A 25-year-old man presented with significant right-sided sacral pain, inflammation, and ulceration, localized at the sacral lead insertion site. At the time of presentation, no gastrointestinal-related symptoms were reported (Figure 1). He had undergone a bilateral full-system SNM implant (InterStim II®) in the S3 sacral foramina 1-year earlier because of neurogenic urinary retention because of a lower motor neuron lesion (LMNL) caused by a car accident.

Within the context of our diagnostic algorithm, SNM generator interrogation revealed a normal impedance test but lost sensory response of the right-sided implant even to high stimulation amplitudes. A reprogramming failed to re-establish the initial postoperative responses. An anterior/posterior sacral x-ray was performed, in which a suspicious profound and medial projection of the right lead was noticed (Figure 2a). Comparing the current localization with the archived fluoroscopic images from the original implantation, a distinct migration of the right-sided lead was perceived (Figure 2b). Blood analysis showed no leukocytosis, with a slight rise of C-reactive protein (CRP) (35 mg/L).

To assess the presence of a profound abscess and to exclude a visceral perforation, a computer tomography (CT) of the pelvis was performed, suspecting a penetration of the rectum with a 2 cm protrusion of the right-sided quadripolar lead into the colonic lumen. The left-sided lead, as well as both implanted pulse generator (IPGs), were located in proper position (Figure 2c, d). A diagnostic sigmoidoscopy revealed a rectal wall perforation by the electrode 11 cm proximal to the anus (Figure 3a, b).

An imminent interdisciplinary surgical treatment was performed under general anesthesia. The patient was placed in a prone position with abducted hips and prepped, draping the anus in a separate surgical field. The right-sided pocket at the lateral buttocks was incised and the IPG extracted. The right-



Figure 1. Ulceration over the lead insertion point (asterisk) and unremarkable scar over implanted pulse generator at the right buttocks (arrow)

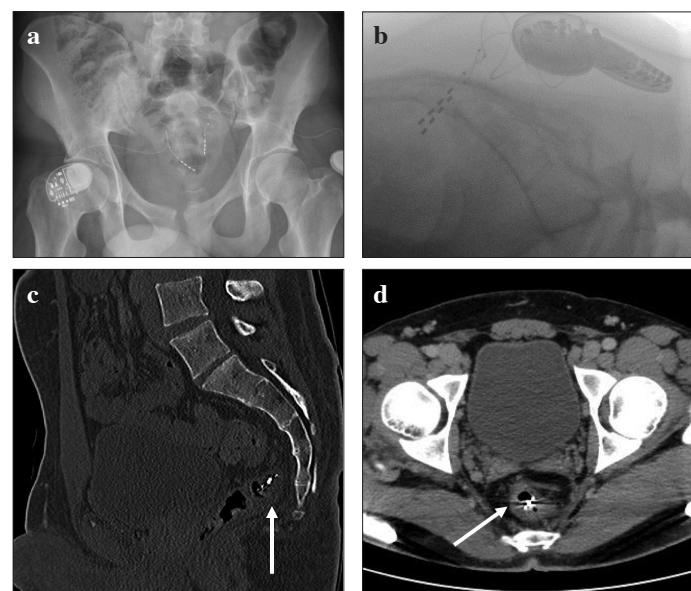


Figure 2. a-d. Anterior/posterior x-ray showing a too deep and medial projection of the right lead (a), lateral intraoperative fluoroscopic imaging proving a correct localization of both leads (b), CT-Scan imaging with sagittal (c), and axial view (d) of bilateral sacral neuromodulation device with a displacement of the right-sided lead in the rectum (arrows)

Main Points:

- Tined lead migration after sacral neuromodulation is a rare but considerable complication.
- Colonic injury through migration of the lead is a rarity but should be kept in mind in case of wound inflammation or bowel symptoms including peritonitis.
- Diagnostic algorithms using sacral x-ray and computer tomography should be performed in case a lead fracture or dislocation is suspected.
- In case of bowel injury, a multidisciplinary approach combining a minimal surgical measure with an endoscopic removal technique should be used for the removal of intact InterStim® devices.

sided inflammatory scar over the sacrum was resected and sent for microbiological examination. The lead wire was dissected down to the fascia and cut sharply with scissors without extracting it through the sacral foramen to avoid fecal seeding at the

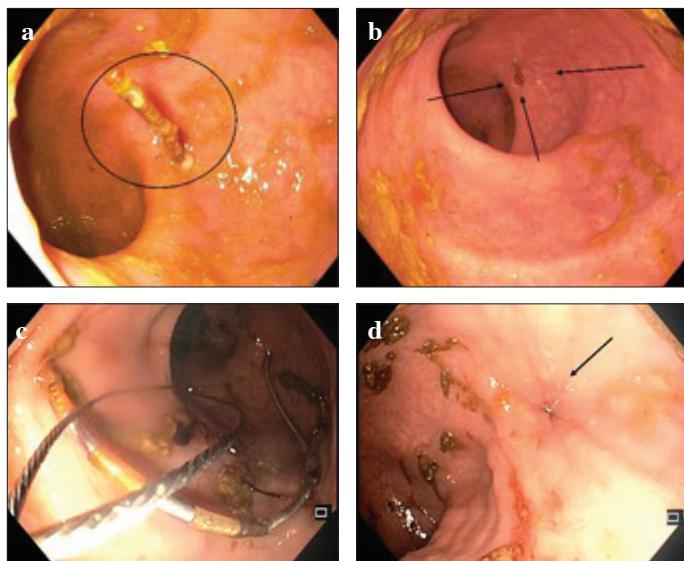


Figure 3. a-d. Sigmoidoscopy findings with visible 2 cm of the tip of the lead in the rectal lumen (a and b), Intraoperative images of grasping the lead with a snare, and the rectal wall defect after lead removal (c and d)

surgical site. Simultaneously, a flexible endoscopy (GIF-H190; Olympus Tokyo Olympus Corporation, Tokyo, Japan) was performed. The endoscope was moved toward to the perforation site. Once the desired position had been reached, the lead was grasped with a snare (MTW; Endoscopy Manufacture, Germany), and a transanal extraction was performed (Figure 3c, d). After thorough consideration, the extraperitoneal rectal wall defect was left open to secondary healing, since the lead diameter of 1.27 mm was considered small and a primary closure not beneficial. The surgical site above the sacrum was washed-out with an antibiotic solution of vancomycin and gentamycin and closed primarily, leaving a 10-F closed suction drainage over the sacrum for 24 hours. The total surgical time was 43 minutes. Bacterial culture revealed colonization of the surgical site by *Escherichia coli* and *Morganella morganii*; blood cultures remained negative.

The patient got discharged on the third postoperative day with oral antibiotics. Outpatient follow-up examinations 3 and 12 weeks later revealed no surgical site infection and no symptoms. Micturition was unchanged with an IPSS-Score of 2 points, without any significant postvoid residual because of the still functioning left-sided neurostimulator; thus, no reimplantation of the right-sided device was required.

Discussion

To the best of our knowledge, we present the first case of an interdisciplinary, complete SNM device removal after migration of an intact tined lead through the rectum wall with con-

sequent lead-implant site infection. A primary rectal injury at the moment of implantation through a misplaced lead could be excluded through a retrospective investigation of the archived intraoperative fluoroscopic imaging. The initial surgery was performed by a senior consultant with many years of experience. The choice of bilateral implantation was based on a previous percutaneous nerve evaluation showing superior effectiveness of bilateral, compared to unilateral, leads. Although a deep insertion of the guidewire intraoperatively cannot be excluded, the correct localization of the implanted tined leads is an operational standard in our clinic.

We hypothesize that the rectum penetration occurred through spontaneous migration over time, as the patient reported no inciting events or trauma as a trigger for this complication. Obvious causes of migration could not be identified, as the patient, with a normal body-mass-index (24 kg/m^2), was not obese. However, the formation of a presacral hematoma with temporary affection of the lumbosacral plexus, contributing to lead migration, could be hypothesized. On checking the record files retrospectively, we found the patient had reported painful paresthesia at the right thigh immediately after the implantation, but after spontaneous resolution in a few days, no further investigations were done at that time. However, in follow-up investigations at 6 and 24 weeks postoperatively, bilateral impedance tests were normal ($<4000 \text{ ohms}$) and the patient indicated no loss of effectiveness or altered perineal/scrotal sensory response to stimulation. No further clinical signs could be identified, which could have led to a suspicion of migration at that time.

This case led to a change in our clinical practice, as any neurological symptoms present postimplant are currently investigated through imaging (x-ray and/or CT-scan) irrespective of the duration of symptoms. Suspected hematoma as well as lead migration should be ruled out, or, if confirmed, treated as soon as possible. In cases of small presacral hematomas, a “surveillance” strategy can also be chosen, as spontaneous resolution without long-term complications is expected.

It has been debated whether a lead should be left in situ or removed by all means in case of a lead fracture, because of the possible risk of migration into the surrounding tissues or organs, highlighting the major complication of peritonitis following intestinal perforation. Shannon et al.^[5] reported a successful endoscopic retrieval of a migrated tined lead fragment from the sigmoid colon following a previous accidental lead wire fracture during a removal attempt four months earlier. In our case, the SNM device was unfractured, so a combined surgical-endoscopic approach was required to explant both the lead wire and the IPG simultaneously. Okhunov et al.^[6] described a standardized surgical technique for the removal of tined lead wires for InterStim devices through the sacral foramina using surgical

dissection deep to the level of the fascia and gentle traction using a right-angle clamp. However, this is contraindicated in cases of intestinal injury because of the risk of bacterial seeding along the lead passage through soft tissues, possibly causing postoperative presacral abscess formation. Sufficient drainage of such abscesses is proven tricky and, in the worst case, may require open surgery.

The above-presented technique of combined surgical-endoscopic retrieval of the penetrating lead wire prevents bacterial seeding in the surrounding tissues of the colon and, therefore, abscess formation or sacral osteomyelitis. In this particular case, the rectal wall defect was tiny, and was left open to secondary healing. Although primary closure of small extraperitoneal defects has not been proven beneficial in a multicenter oncological series, an endoscopic sealing of the intestinal wall through clipping could be considered in case of larger defects or intraperitoneal localization.^[7]

Physicians should maintain a high index of suspicion in cases of delayed implant site infections, which do not respond to antibiotics, as the underlying cause may be retrograde fecal bacteria colonization after colonic injury. Tined lead migration is still an existent complication, but since colonic injury through migration is a rarity, so far no existent protocol for removal has been determined. We propose that a multidisciplinary approach combining a minimal surgical measure with an endoscopic removal technique should be implemented in the salvage strategy regarding neuromodulation surgery.

Informed Consent: Written informed consent was obtained from patients who participated in this case.

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