



Functional Urology

Allergic reaction to sacral neuromodulation device components: A case report

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ABSTRACT

Sacral neuromodulation (SNM) is an established therapy for refractory bladder dysfunction, with allergic reactions considered exceedingly rare. We report a 27-year-old woman with Fowler's syndrome who developed severe localized and systemic skin reactions after implantation of an SNM lead and extension cable. Epicutaneous testing confirmed hypersensitivity to SNM components, while standard material testing was negative. Symptoms resolved after device removal and antiallergic therapy. Clinicians should consider allergy to SNM materials when unexplained postoperative skin reactions occur, as early recognition allows prompt intervention and prevents systemic complications.

1. Introduction

Sacral neuromodulation (SNM) is a minimally invasive procedure used to treat refractory bladder and bowel dysfunction. The technique involves percutaneous unilateral placement of a tined lead through the S3 or S4 sacral foramen.¹ This lead is a quadripolar wire insulated with polyurethane, reinforced with a tantalum braid, and equipped with distal platinum/iridium electrode contacts and soft silicone anchors. During the initial test phase, the lead is connected to an extension cable and an external stimulator. If the test phase is successful, a second procedure is performed in which the extension cable is removed, and the lead is connected to an implantable pulse generator. Because SNM therapy requires implantation of several device components, patients are exposed to a variety of implantable materials. While allergic reactions to implanted materials have been documented in some cases involving comparable devices such as cardiac pacemakers, only few reports of hypersensitivity to SNM system components have been published, none with direct proof of allergy to tined lead itself.

2. Case presentation

We report the case of a 27-year-old woman with Fowler's syndrome treated with SNM (InterStim X, Medtronic). Complete restoration of voiding function was achieved within two weeks. However, two weeks

after tined lead implantation, she developed a localized skin rash at the site of contact with the extension cable, which rapidly progressed. Three weeks after surgery, she presented to the outpatient clinic with a 25 × 25 cm area of urticaria over the left gluteal region (Fig. 1) and systemic allergic reaction including generalized rash and facial swelling. The extension cable was immediately cut at skin level and the rest of the extension cable was surgically removed within a few hours. The removed materials were sent for microbiological analysis, which was negative. She received treatment for an allergic reaction and was admitted for further management. Due to the allergic reaction, a more detailed allergy history was obtained from the patient. This revealed a known pollen allergy requiring occasional antihistamine treatment; however, there was no history of serious or systemic allergic reactions.

During hospitalization, a new tined lead was first taped to the patient's forearm for epicutaneous testing. This produced a delayed hypersensitivity reaction within four days, indicating sensitization to the lead material (Fig. 2). In parallel, a comprehensive panel of epicutaneous tests was performed, including substances and metals commonly used in osteosynthetic materials as well as components of the InterStim electrode, as detailed in Tables 1 and 2. The patient exhibited positive reactions to Peru balsam and fragrance mix, while all routinely tested metals and other standard substances were negative. However, a distinct positive reaction occurred in response to the InterStim lead. These findings, in combination with the confirmed allergic reaction to the

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Fig. 1. Allergic skin reaction in SNM patient. Skin changes at the exit point of the extension cable.



Fig. 2. A SNM tined lead taped to the forearm already displaying allergic skin changes at the points of contact.

external extension cable, demonstrated hypersensitivity to multiple components of the SNM system.

Given the documented allergy to both implanted components, the tined lead was removed, and the antiallergic treatment was continued until complete symptom resolution. Although she reported a history of pollen allergy, she had no prior reactions to medical devices or other materials.

Table 1

Results of the epicutaneous testing for osteosynthetic materials after 48 hours and 72 hours. In addition, parts of InterStim tined lead were added to the test. The only positive result – proving hypersensitivity – was to parts of the tined lead. The results are labelled as » - «: negative, » +/- «: partially positive and » + «: positive.

Substance	48 h	72 h	result
Titanium (IV) oxide 0.1 %	-	-	-
Chromium (III) sulfate hydrate 0.5 %	-	-	-
Molybdenum (V) chloride 0.5 %	-	-	-
Indium (III) chloride 1 %	-	-	-
Cadmium chloride 0.5 %	-	-	-
Aluminium hydroxide 10 %	-	-	-
Silver nitrate 1 %	-	-	-
Zinc sulfate 1 %	-	-	-
Ammonium heptamolybdate (VI) 1 %	-	-	-
Vanadium pentoxide 10 %	-	-	-
Copper (II) sulfate pentahydrate 2 %	-	-	-
Potassium chromium (III) sulfate 2 %	-	-	-
Manganese (II) chloride 0.5 %	-	-	-
Ferric chloride 2 %	-	-	-
Tantalum 1 %	-	-	-
Silver colloidal 0.1 %	-	-	-
Ferrous sulfate 5 %	-	-	-
Tin (II) chloride 0.5 %	-	-	-
Zinck powder	-	-	-
Ammoniated mercury 1 %	-	-	-
Potassium dicyanoaurate 0.002 %	-	-	-
Mercury 0.5 %	-	-	-
Palladium chloride 1 %	-	-	-
Gold sodium thiosulfate 0.5 %	-	-	-
Interstim tined lead	+/-	+	+
Interstim tined lead (abrasion)	+/-	+	+
Blind probe	-	-	-

Table 2

Results of the typical substances used for epicutaneous testing after 48 hours and 72 hours. Final hypersensitivity result is given in the last column. The results are labelled as » - «: negative, » +/- «: partially positive and » + «: positive.

Substance	48 h	72 h	result
colophony 20 %	-	-	-
clioquinol 5 %	-	-	-
paraben mix 16 %	-	-	-
potassium dichromate 0.5 %	-	-	-
nickel sulfate 5 %	-	-	-
formaldehyde	-	-	-
paraphenylenediamine 1 %	-	-	-
cobalt chloride 1 %	-	-	-
peru balsam 25 %	+	+	+
benzocaine 5 %	-	-	-
neomycin sulfate 20 %	-	-	-
mercaptobenzothiazole 2 %	-	-	-
mercapto mix 1 %	-	-	-
thiuram mix 1 %	-	-	-
N-isopropil-N-paraphenylenediamine 0.1 %	-	-	-
fragrance mix 8 %	+/-	+/-	+/-
epoxy resin 1 %	-	-	-
lanolin alcohol 30 %	-	-	-
p-tert-butylphenol formaldehyde resin 1 %	-	-	-
quaternium 1 %	-	-	-
5-Chloro-2-methyl-4-isothiazolin-3-one + 2-Methyl-4-isothiazolin-3-one (3:1) 0.01 %	-	-	-
sesquiterpene lactone mix 0.1 %	-	-	-
primin 0.01 %	-	-	-
tixocortol pivalate 1 %	-	-	-
budesonide 0.1 %	-	-	-
fragrance mix II 14 %	+	+	+
dibromodicyanobutane 0.3 %	-	-	-
hydroxymethylpentilciclohexene carboxaldehyde 5 %	-	-	-
Methylisothiazolinone 0.2 %	-	-	-
textile dye mix 6.6 %	-	-	-

3. Discussion

Reports from 2023 indicated over 350,000 implanted patients worldwide, with current figures now exceeding 400,000. The procedure is well established, safe, and associated with a low rate of complications, most commonly device-related issues, loss of efficacy, wound complications, lead migration, and stimulation-related discomfort.²

Allergic reactions to SNM components have not previously been reported. Because SNM therapy involves the implantation of the device, patients are directly exposed to several materials and substances. According to manufacturer specifications, these materials include MP35N (nickel-cobalt-chromium-molybdenum alloy), polyurethane, platinum/iridium, titanium, and fluoropolymer. Although hypersensitivity to these substances is considered extremely rare, isolated cases of allergic reactions to comparable materials used in cardiac pacemakers have been documented^{3,4} suggesting that similar reactions may occur in SNM devices.

In the presented case, epicutaneous testing confirmed hypersensitivity to both the extension cable and the tined lead itself, with all other osteosynthetic materials and tested substances – aside from fragrance mix and Peru balsam – yielding negative results. Notably, there were no prior indications of a possible allergic reaction to implanted materials, as the patient had no known history of contact allergy and reported only a mild, non-severe pollen allergy. This case demonstrates that pronounced allergic reactions to implanted materials may occur even in individuals without a remarkable allergic history. Importantly, detailed epicutaneous testing revealed no hypersensitivity to implantable materials other than the specific SNM tined lead. Because hypersensitivity to the tined lead was demonstrated, removal of the extension cable alone would not have been sufficient to resolve the allergic reaction. The patient experienced a systemic allergic reaction that resolved fully after removal of the implanted components and appropriate antiallergic treatment. To our knowledge, this is the first reported case of hypersensitivity to sacral neuromodulation tined lead.

4. Conclusion

Although hypersensitivity to materials used in neuromodulation systems is exceedingly uncommon, it should remain an important consideration when patients develop unexplained postoperative dermatologic symptoms. Prompt recognition of a potential device-related allergic reaction is essential, as early diagnosis can prevent progression to systemic manifestations and supports timely removal of the implicated components.

CRedit authorship contribution statement

Urska Kogovsek: Writing – review & editing, Writing – original draft, Methodology, Data curation, Conceptualization. **Mirko Omejc:** Writing – review & editing, Writing – original draft, Conceptualization. **Melita Rotar:** Writing – review & editing, Writing – original draft, Supervision, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

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