The Open Access Journal of Science and Technology
Vol. 3 (2015), Article ID 101116, 3 pages
doi:10.11131/2015/101116

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Case Report

Pain as the Sole Presenting Symptom of Infected Sacral Nerve Stimulation Implantable Pulse Generator

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Received 24 August 2014; Accepted 04 December 2014

Academic Editor: Shalev Eliezer

Abstract. Two patients presented from outside hospitals with complaints of pain at the site of implantable pulse generator (IPG). Neither patient had constitutional or local signs and symptoms of infection; however, during operations performed for revision and/or troubleshooting of the device, infection was encountered and all components were removed. Both individuals recovered well from the operation, and one patient underwent subsequent placement of a new InterStim device with good results. Possibility of infection should be considered in patients with complaint of pain associated with IPG site.

Keywords: Implantable pulse generator (IPG); infection; pain; Sacral neuromodulation

1. Brief Summary

Pain and/or discomfort over the implantable pulse generator site may be the only presenting sign or symptom of a patient with an infected sacral nerve stimulation device.

2. Introduction

Sacral nerve stimulation (SNS) is a safe and accepted treatment modality for refractory voiding and bowel dysfunction. Complications mainly consist of pain at the implantable pulse generator (IPG) site, infection, and lead migration, all of which generally occur at low rates [1]. Here we present two patients with an infection at the IPG site, both of whom presented with a complaint of pain over the IPG. One patient was later successfully re-implanted with good results.

3. Case Report

Patient 1 is a 60-year-old Caucasian female who had a staged SNS InterStim device placed for refractory urinary frequency, urgency, and urge incontinence at an outside facility two years prior to presentation. She was referred for evaluation of a poorly functioning device. On exam she had mild tenderness to palpation over the device but there were no other local or constitutional signs of infection. Programming confirmed a dead IPG battery. She was later taken to the operating room for InterStim lead testing and possible

replacement of components. Upon entrance into IPG capsule, a copious amount of purulent material was encountered. All components were removed and the wound was copiously irrigated and packed open. After a week of packing changes the wound was closed loosely with interrupted sutures. The final wound culture grew a *Candida* species. Two months later the wound had completely healed and she continued to complain of refractory urge incontinence. She was taken back to the operating room and a new lead and stimulator were implanted on the opposite side. Her urinary complaints improved post-operatively and her wounds healed without any complications. She was satisfied with the final outcome.

Patient 2 is a 41-year-old Caucasian female who had a staged SNS InterStim device placed at an outside facility for chronic constipation and incomplete bladder emptying approximately 4 months prior to referral. The patient presented with complaints that her bladder and bowel symptom had shown no improvement. The initial evaluation included an unremarkable physical exam, a plain pelvic radiograph revealing leads in the appropriate position, and device analysis showed all leads to be functioning properly. Several months later she called with complaints of pain at the IPG site. Physical exam was remarkable for tenderness around the IPG in the left buttock. She had no constitutional symptoms or any local signs of infection over the IPG. Conservative therapy with a non-steroidal anti-inflammatory medication was not effective. Prophylactic antibiotics were not contemplated given the atypical presentation of this infection. The IPG was turned off and this did not lead to resolution of the pain either. Two days later she was taken to the operating room for removal of IPG and lead. Upon incision of the capsule, purulent material was encountered. Thereafter, all components were removed and the wound was copiously irrigated with antibiotic solution. A flat drain was placed and the wound was loosely approximated. The wound cultures grew *Pseudomonas aeruginosa*. She was treated with 10 days of ciprofloxacin and the drain was removed on post-operative day 5. On follow-up exam she denied having any pain and the wound was healing well by secondary intention without drainage or any evidence of infection.

4. Discussion

Both of these patients complained of non-functioning or poorly functioning device and pain over the IPG site several months to two years after device implantation. In both cases, buttock pain may represent the only sign of IPG infection especially with evidence of intra-operative purulent material that mandates removal of all the InterStim components. The first patient had InterStim SNS device replaced on the opposite side with satisfactory results. Wound cultures for patient's 1 and 2 revealed *Candida* species and *Pseudomonas aeruginosa*, respectively.

An article published in 2007 on the characteristics of infections in patients with SNS reported 5 infections out of 45 patients who had IPG placed [2]. All five patients had clinical signs and symptoms including erythema and pain at the IPG site and one patient was febrile with a temperature of 101˚F. Four of those cultures grew *Staphylococcus aureus* and occurred within 1 month of placement. The fifth patient had repeated aspirations of an initially sterile wound seroma and eventually developed a wound infection with *Pseudomonas aeruginosa*. In all 5 cases, conservative management with antibiotics failed, and the patients required surgical removal of the infected device and its associated components.

Another article published in the Journal of Gastrointestinal Surgery in 2010 reported on infection rates of SNS placed for fecal incontinence [3]. Thirteen patients (10.8%) had an implant site infection. Nine of these patients had early infection (within 21 days of permanent implantation) in which five where treated with antibiotics, one was explanted and then successfully re-implanted, and two required permanent system explantation. The remaining four patients presented with a late infection (13–41 months post-implantation), which was treated with permanent explantation. Two of the late infections were from *Staphylococcus aureus.* They also found that patients presenting with "late" infection do not respond to medical treatment and ultimately require complete explantation of the device, similar to both cases presented herein.

Any sign of infection in such scenarios needs to be addressed by evaluating for local signs of infection, erythema, tenderness overlying the IPG or the surrounding tissue, febrile illness, and purulence if present. Furthermore, with pain as an isolated finding, one should evaluate for IPG-induced stimulation-related pain. This represents current leakage from the IPG to the surrounding buttock tissues. This may be assessed by turning the IPG off and assessing for pain. In patient 1, the IPG battery was already dead, and patient 2 had the IPG turned off and still complained of localized pain. Conservative therapy with non-steroidal anti-inflammatory medications and empiric antibiotics may also be attempted prior to surgical removal of the IPG and leads. When conservative options fail then one should consider device relocation vs. explantation and then at surgery one might encounter purulence confirming infection, forcing device explantation.

One of the limitations of this case series is the lack of a standardized definition for infection after SNS and IPG placement. The limited number of patients in this series is also a limitation however it emphasizes the importance of localized pain presenting remote from surgery as a surrogate marker of infected IPG or any other SNS component.

5. Conclusion

Pain may be the sole complaint of a patient with SNS device infection. Physicians and mid-level practitioners should have a high index of suspicion of infection in patients presenting with complaints of pain and/or discomfort around IPG site

even if the patient's implantation was performed several months to years before presentation. This case series emphasizes the need to evaluate pain complaints and consider possible infection of the IPG even when local and/or systemic signs of infection are absent, especially when identified remotely from surgery. Patients with "late" infections should be counseled that all components of the device may need to be removed and select patients may be candidates for placement of a new device once infection is appropriately treated.

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