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Spinal Cord Stimulator Electrode Fracture During Percutaneous Trial Lead Placement: A Case Report and Literature Review

Case Report

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Abstract

Spinal cord stimulation (SCS) has been used since 1967 for neuromodulation of chronic refractory pain, particularly failed back surgery syndrome (FBSS) and Complex Regional Pain Syndrome (CRPS) Type 1 [1, 2]. Despite improvements in materials, patient selection optimization, and surgical techniques, complication rates remain high. The most common complications include lead migration, fracture and disconnection from implanted generator [3-9]. This case report demonstrates a potentially catastrophic complication of lead fracture and dislodgment during percutaneous placement. To the best of our knowledge, this is only the second case described in the literature. A review of SCS complications and protocol is also presented. Awareness of this rare adverse outcome can influence SCS manufacturers and practitioners to work towards eliminating overall hardware failure risk and improving patient quality of care.

Introduction

Spinal cord stimulation (SCS) has been utilized since 1967 for neuromodulation of pain [1]. The main indication for SCS has been refractory chronic pain, particularly failed back surgery syndrome (FBSS) and Complex Regional Pain Syndrome (CRPS) Type 1 [2]. Additionally, neuroaugmentation of sympathetic tone has been observed in animal models and SCS has shown benefit in patients with coronary and peripheral vascular disease [3,4]. Neuromodulation was initially not a successful treatment due to problems in technique, patient selection, and high complication rates [5]. SCS implantation has increased at a compound annual rate of 25-30% with continued advancements in materials, patient selection optimization, and surgical techniques [6]. However, complication rates remain high to date, on average 30-40%, with the majority reported to be device-related [2]. The most common complications include lead migration, fracture and disconnection from implanted generator [7-9]. To the best of our knowledge, only one other case has been identified reporting electrode fracture and dislodgement into ligamentum flavum during percutaneous lead placement [10]. This is another case in which distal electrode fracture occurred during percutaneous trial SCS placement. A review of common complications will be presented and compared to this rare adverse outcome. In addition, medical treatment and surgical removal of the foreign body will be discussed.

Case Description

A 62-year-old female with FBSS and associated bilateral gluteal neuropathic pain presented for percutaneous trial SCS placement. Pertinent past medical/surgical history included multiple spine surgeries complicated by a remote history of osteomyelitis. At the time of the procedure, the patient remained on chronic oral antibiotics followed by Infectious Disease. Prior to the procedure, imaging was reviewed and demonstrated spinal fusion spanning T10-S1. Thus, a more proximal entry point (T10) was chosen to avoid hardware and scar tissue. The patient was positioned prone on the fluoroscopy table and prepped and draped in the usual sterile fashion. Local anesthetic was used for skin, subcutaneous tissue, and to anesthetize down to just posterior to the ligamentum flavum. A 14-gauge Tuohy needle was advanced using a right paramedian approach to contact the right lamina and then adjusted toward the superior medial direction until it entered the epidural space using loss of resistance technique. No resistance was met on advancement of the first lead, but there was difficulty in positioning the lead within the dorsal epidural space. Upon slight retraction to reposition prior to re-advancing, it was noted that the distal tip of electrode had separated from the main lead. No resistance was appreciated on retraction of the lead. The electrode fragment position was confirmed by fluoroscopy at approximately the T8 level as seen in Figure 1. Upon complete retraction of the broken

lead, further inspection revealed shearing/fracture of the distal tip as seen in Figure 2. The procedure was aborted, and the patient recovered from anesthesia. Vital signs were stable and no new focal neurological deficits were noted on exam. The patient was transferred to the ED for urgent evaluation.

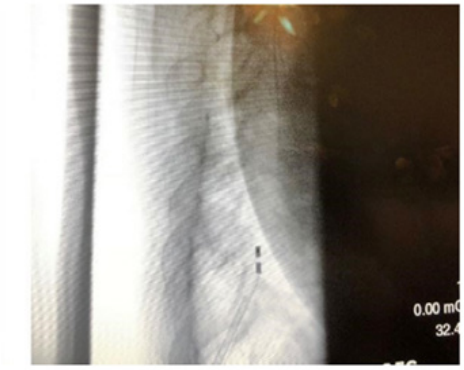

Figure 1: Lateral View on Fluoroscopy of a fragment consisting of 2 electrodes at about T8 level.

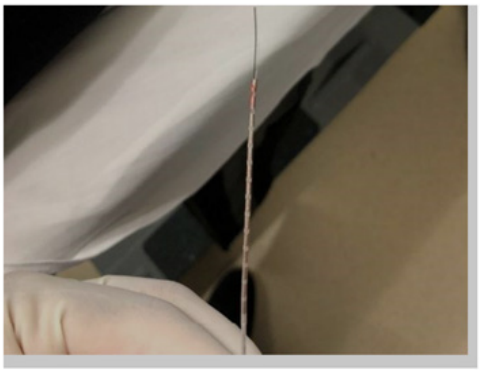

Figure 2: Distal tip of the lead wire demonstrating electrode shearing/ fracture.

The patient was assessed by the ED and CT of the thoracolumbar spine without contrast was completed on day 0. Imaging revealed a 5mm metallic density in the right posterior epidural space at the level of T7, shown in Figure 3. She was admitted for 24-hour observation and neurovascular checks. The patient was discharged the following day after a care-plan was delineated by her neurosurgeon. She ultimately had thoracic laminectomy on day 38 with removal of retained electrodes and placement of paddle leads. Subsequent implantation of generator was completed on day 41. She had continued follow up with Interventional Spine and Neurosurgery without any new focal neurological deficits. The patient reported improved lumbar and gluteal pain on 1 month follow up with Interventional Spine.

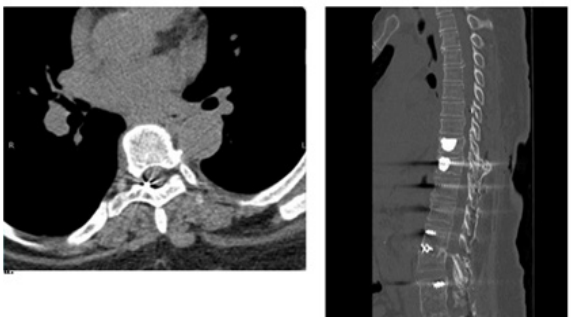

Figure 3: Axial (a) and Sagittal (b) views of thoracolumbar spine visualizing 5mm metal density at T7 epidural space.

Discussion

This case presents a rare, but potentially catastrophic complication of SCS implantation. The patient was an optimal candidate for SCS given her history of FBSS, neuropsychological clearance, and overall patient compliance. Her procedure was performed by an experienced interventionalist whose practice incorporates percutaneous SCS trial placement routinely. A PubMed search dating back to 1967 shows the literature has described only one case of electrode dislodging from the lead during implantation. Martin et al described electrode shearing and dislodging within the ligamentum flavum during percutaneous implantation of SCS in a patient with FBSS and chronic lumbar radiculopathy [10]. The interventional team decided against surgical intervention due to stability of the fragment, material magnetic resonance (MR) compatibility, and retrieval risk at the time of the procedure. These cases demonstrate a potential complication that practitioners must be aware of during implantation of SCS, as most reported electrode fractures occur at sites of fixation [11,12]. The need of practitioners to recognize this potential adverse outcome is important to take the correct measures for prevention and treatment. Although adverse events have decreased overall, complication rates ranging from 8-75% are reported in the literature [5]. Kumar et al reported a mean complication rate of 31.9%, while systematic reviews by Turner et al and Cameron et al., reported 34% and 36% mean incidence of adverse outcomes, respectively [2,13]. It must be noted that although complication rates are high, the number of life-threatening complications is low [5]. With technological advancements in the last several decades and the emergence of percutaneous techniques for trial and implantation, there has been an overall positive shift in outcomes as seen in rates of return to work, reduction in medication use, reduction in visual analog pain scores, and improvement in activities of daily living [3].

The most common complications of SCS placement are electrode migration, electrode fracture, and disconnection from implanted generator [7-9]. Other complications include CSF leak (0.3% -7%), pain at the implantable generator site (0.9-12%), infection (2.5%-14%), and subcutaneous hematoma (up to 9%). Very rarely, direct injury to the spinal cord or epidural hematoma (0.19%) has been reported [5]. It is once again apparent that complications associated with greater morbidity are much rarer compared to hardware-related complications.

Reported electrode fractures rates are approximately 3-9%, with lower occurrence rates observed with surgically implanted electrodes vs. percutaneously implanted electrodes [5]. As per Kumar et al, the most common site of percutaneous electrode fracture was just cephalad to the site of anchoring. Incidence of fracture was higher in electrodes implanted via midline approach compared to paramedian approach. A more shallow angle of entry seen with paramedian approaches allows for less shearing forces on electrode leads along the Tuohy needle. Surgically implanted electrodes tend to fracture at the paddle-lead junction, between their 2 fixed points, the epidural space, and the thoracolumbar fascia. Implementation of a stress relief loop during surgical implantation is recommended to reduce breaks during flexion and extension movements [11,12]. Electrode fracture occurs most commonly within the first four weeks of implantation. The damage to the electrode is commonly caused by a small breakage in the insulation of the leads (from shearing forces between the lead and introducer needle) or damage to the wire within the insulation from repetitive folding and straightening of the lead with spinal movements [5]. Electrode fractures have been reported in patients after falls, normal activity of daily living, and increased girth size in the setting of a third pregnancy [14-16].

Despite relatively high complication rates, SCS is an emerging and increasingly popular strategy for chronic pain management [6]. North and Wetzel reported SCS to be more effective than reoperation (FBSS) for 90% of patients at a three year follow up. They also reported

patients with reoperation used significantly more opiate analgesics than those with SCS [17]. Proper patient selection is essential for long-term success of SCS. An ideal patient is motivated, compliant, and free of drug dependence [3].

When performing percutaneous trial or implantation it is important for the interventionalist to review the most recent imaging to familiarize with the patient's anatomy. Patients with FBSS frequently have had multiple spinal surgeries predisposing them to increased scar tissue and extension of hardware [17]. Both entities pose potential difficulty in percutaneous passage of leads and therefore require more proximal points of entry. This alone may increase the risk for neurovascular injury as entry proximal to the level of L1-L2 involves entry into the epidural space where the diameter of the spinal canal is smaller. Therefore, a paramedian approach more parallel to the epidural space is recommended to minimize shear forces during lead advancement and reduce the risk of damaging anterior structures [11,12]. A cut-down approach with a scalpel can help decrease angle of entry in patients with larger body habitus. Advancement of the lead requires slow, controlled movements and no passage against increased resistance.

Nonetheless, if electrode fracture does occur, it is prudent for the interventionalist to confirm position and potential for migration, assess the patient for hemodynamic instability, assess for new focal neurological deficits and discuss need for potential urgent removal. If there are signs of hemodynamic instability and new focal neurological deficits, the patient should be evaluated emergently by a neurosurgical team. If the patient is otherwise stable, then the risk of infection, risk of migration, and MR compatibility should be considered when determining the need for removal.

As a basic tenant of medicine, a foreign body is likely to increase infection risk. Hoelzer et al. [18] reported an overall infection rate of 2.45%. This multisite, retrospective review on 2737 unique implants or revisions of SCS systems found that diabetes, tobacco use, and obesity did not increase infection rates. However, they did note implants performed at academic centers had higher rates of infection compared to implants performed in nonacademic settings [18]. Thus, cleaning of the procedure site and use of sterile technique is emphasized. In this case, the patient's risk of infection was likely higher, but further studies are needed to determine if prior history truly predisposes a patient to an increased infection rate associated with SCS placement and whether chronic antibiotic use may reduce such risk.

As lead migration is the most common complication of SCS placement, it is no surprise that an electrode fragment may migrate within the epidural space. Migration was suspected in this patient as the fragment was originally identified at about T8 level on fluoroscopy while formal CT demonstrated the fragment at T7 in the epidural space. Confirming placement and establishing suspicion of fragment migration is of high importance as it may predict the need for surgery. Risk of potential anterior migration is low, but does introduce potential injury of the dura mater, spinal cord, vertebral venous plexus, and traversing/exiting nerve roots. Furthermore, MR incompatibility of components may potentially cause heating/burning of structures, unintentional stimulation, and possible migration in the setting of a magnetic field [19]. Removal was indicated in this case as the fragment was not MR compatible, imaging showed possible evidence of migration, the patient had a prior history of osteomyelitis, and the neurosurgical preference for removal and open SCS trial/ implant.

Conclusion

The most common complications of SCS are electrode migration, electrode fracture, and disconnection from implanted generators. Although rare, electrode fracture during the time of placement must be considered as a potential complication. This is the second reported case of electrode fracture during implantation (using different SCS systems). Increased awareness of this complication can influence SCS manufacturers and practitioners to work towards eliminating overall hardware failure risk and improving patient quality of care.

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