Single-Incision Approach to Implantation of the Pulse Generator and Leads for Dorsal Root Ganglion Stimulation: A Case Report

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Dorsal root ganglion (DRG) stimulation has recently emerged as a treatment for persistent neuropathic pain, but the permanent implantation of stimulator leads and the pulse generator can be difficult and is sometimes associated with complications. We used a single-incision approach to tunnel and implant the leads and pulse generator for DRG stimulation treatment in a patient suffering from intractable foot pain. At long-term follow-up, the patient experienced a decrease in pain intensity and improvement in function, without any complications. A single-incision implantation technique for DRG stimulator implantation may simplify implantation and decrease the risk of complications. (A&A Practice. 2018;10:23–7.)

According to the National Academy of Medicine, chronic pain affects more than 100 million Americans, an incidence rate that outpaces heart disease, cancer, and diabetes mellitus combined.[1] Neuropathic pain represents one of the most prevalent yet undertreated forms of chronic pain in the United States, with an estimated 1 in every 10 adults over the age of 30 years suffering from the condition.[2] Over the past decades, neuromodulation techniques such as spinal cord stimulation[3] and dorsal root ganglion (DRG) stimulation[4] have emerged as effective treatment modalities for neuropathic back and leg pain. However, the permanent implantation of stimulator leads and the pulse generator can be difficult and is sometimes complicated by lead migration or infection of the hardware.[5,6] We herein describe a technique to tunnel and implant the leads and pulse generator for DRG stimulation treatment.

Written informed consent was obtained from the patient for publication of this case report.

CASE DESCRIPTION

A 45-year-old Caucasian male patient was referred to our pain clinic in 2014 by his rheumatologist. He presented with pain in both feet (no back or leg pain) extending to the ankles. The patient described the pain as constant, burning, throbbing, present in both feet, but worst on the lateral sides of the feet. The pain had gradually worsened over several years. At presentation he rated the pain 9/10 on a visual analog scale. The symptoms were only mildly relieved by rest, ice, and heat. The patient used to be a gym teacher and basketball coach at a high school but was no longer able to perform those activities because of increasing pain. He had thorough work-ups by numerous neurologists, rheumatologists, and an orthopedic surgeon, and after several nerve conduction studies, he was diagnosed with idiopathic peripheral neuropathy. Different medications were tried over the past few years, including neuropathic pain medications such as Neurontin (gabapentin), Lyrica (pregabalin), Topamax (topiramate), and Cymbalta (duloxetine). Several opioid analgesics including hydrocodone, Nucynta (tapentadol), oxycodone, Oxycontin (oxycodone ER) also failed to provide adequate pain relief. At the time of presentation, the patient took methadone 20 mg 3 times a day. He previously had a lumbar epidural steroid injection at another pain clinic with no relief. Given the patient's persistent severe neuropathic pain and failure of conservative treatments, we proposed a traditional dorsal column spinal cord stimulation trial. After psychological clearance, he underwent this trial in December 2014. During the trial, the final position of the 8-contact leads was in the midline, with the top electrodes at the bottom of the T11 vertebral body. With the traditional spinal cord stimulation, we were able to achieve satisfactory coverage of his pain areas. However, the stimulation at high amplitude required for adequate coverage caused patient discomfort and the temporary leads were removed at the end of the trial.

Considering lack of improvement with previous medical and interventional treatments and the inability to get adequate coverage with conventional stimulation without discomfort, we discussed a DRG stimulation trial with the patient in November 2016. Our rationale was the potential for better coverage in the feet and the lack of paresthesias with the DRG approach.[7] We proposed a bilateral L5 and S1 DRG stimulation trial. The patient decided to proceed with the DRG stimulator trial and underwent psychological clearance prior to the procedure. During the 7-day trial, the patient rated his pain 1/10 on visual analog score, improved sleep hygiene, functioned better in general, and was actually able to do work and some activities on a daily basis without limitations. After the trial, the patient wished to proceed with permanent lead implantation.

Prophylactic intravenous antibiotics were administered by the anesthesiologist 30 minutes prior to the incision. The procedure was performed under conscious sedation

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Accepted for publication July 12, 2017.

Funding: None.

The authors declare no conflicts of interest.

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DOI: 10.1213/XAA.0000000000000625

(propofol) and field infiltration anesthesia (1% lidocaine). The L5-S1 interlaminar space was aligned by tilting of the image intensifier caudally to square off the superior endplate of the L5 vertebral body. Then, bilaterally, 14-gauge Tuohy needles were inserted through the skin and epidural access was obtained using loss of resistance. The lead and delivery sheath (4-contact Axium lead, St Jude Medical, Saint Paul, MN) were fed through the Tuohy needle, after which the leads were steered through the epidural space and placed on the L5 DRG on either side. The loops at the L5-S1 levels were made in the usual manner and the Tuohy needles and introducers removed. Subsequently, the S1 foramina were aligned under fluoroscopic guidance. Then 14-gauge Tuohy needles were inserted through the skin and advanced until the tip of the Tuohy needle made bone contact just superolateral to the opening of the foramen. The needle was then walked medially until the S1 foramen was accessed with the Tuohy needle. The fluoroscopy was turned to the lateral position, and the Tuohy needle advanced to the posterior portion of the sacral canal. The lead was loaded into the introducer. At that point, the loaded introducer was passed into the Tuohy needle. In lateral fluoroscopic view, the introducer was manipulated to pass into the S1 foramen, and the electrodes were placed to have 1 contact just distal to the anterior border of the S1 vertebral body and the distal 3 electrodes in the foramen. After placement of the electrodes, the strain relief loops were placed. After confirmation of correct electrode placement and adequate strain relief loop length in the anteroposterior and lateral views (Figures 1 and 2), the Tuohy needle and introducer were removed while applying pressure on the lead to avoid the lead being pulled out with the introducer. A pocket was created for the pulse generator in the upper left buttock in the usual manner. Because of the proximity of the leads and the generator pocket and no need for anchoring of the leads in the subcutaneous fascia, the leads were tunneled to the generator site. An approximation of the distance from the medial border of the generator pocket and the lead entry points in the skin was made and the left- and right-sided lead entry points were <3 cm and approximately 4.5 to 5 cm from the pocket site, respectively. The 3.5-inch Tuohy needle that was used for lead placement was advanced subcutaneously from the inside of the generator pocket and passed toward the left-sided S1 lead entry site. As the Tuohy needle approached the lead entry point at the skin, pressure was placed around the lead site by pinching the skin around the site and allowing the Tuohy needle tip to pass out of the same site as the lead entry. By applying pressure on both sides of the lead, it allowed the Tuohy needle to exit at a more perpendicular angle and not transverse the upper dermal layers and thus increasing the probability of erosion through the skin. Attention was paid to pass directly adjacent to the lead and not to leave any skin between the lead and the Tuohy needle. After confirmation of this, the stylets were removed from the Tuohy needle and the lead. The lead was then passed though the Tuohy needle and exited the Tuohy needle in the pocket. The Tuohy needle was then withdrawn from the pocket while pressure was placed on the lead to prevent migration (Figure 3). With the Tuohy needle removed, forceps were used to push the final portion of the lead at the initial skin entry site into the subcutaneous tissue. This method was repeated at the L5-S1 level on the left side in the same manner. For the right-sided leads, given the distance from the generator site, a new 5-cm Tuohy needle was used to access the skin puncture sites of the leads. The procedure was repeated for the right L5-S1 and S1 leads in the same fashion. When all 4 leads were tunneled to the pocket generator site, the leads were attached to the battery. Impedances were checked and the generator was anchored with 2.0 Ethibond (Ethicon, Somerville, NJ) and the skin was closed with 2.0 Vicryl (Ethicon) for the deep layers and

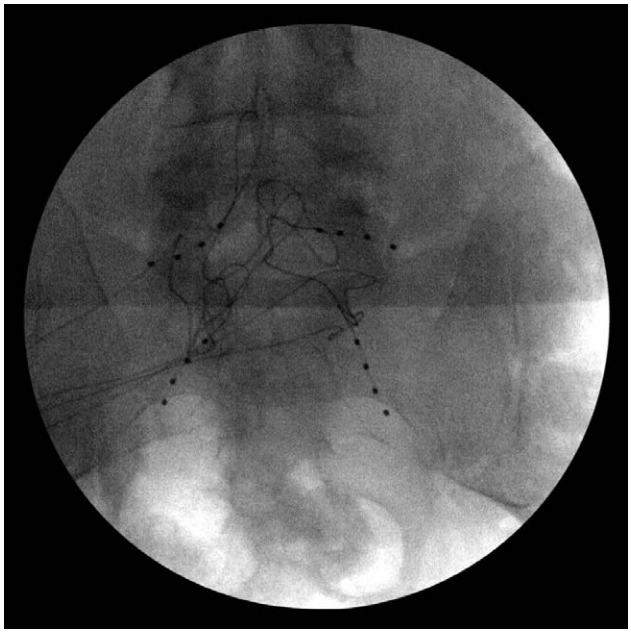

Figure 1. Anterior-posterior fluoroscopic view of final position of bilateral dorsal root ganglion stimulation leads on the L5 and S1 level.

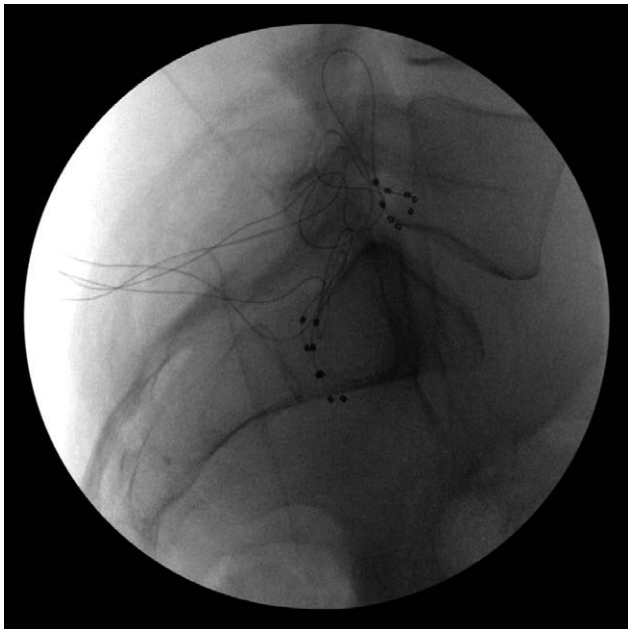

Figure 2. Lateral fluoroscopic view of final position of bilateral dorsal root ganglion stimulation leads on the L5 and S1 level.

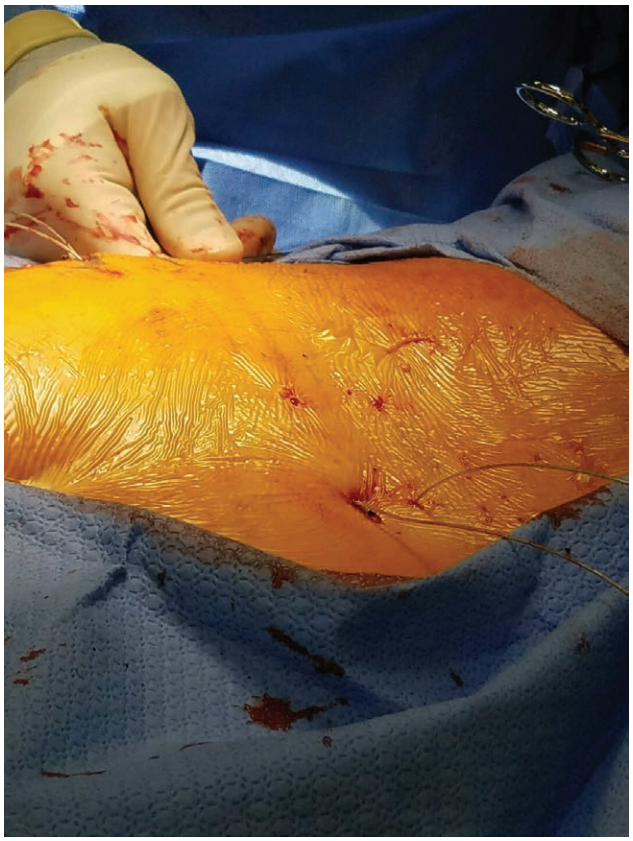

Figure 3. Initial dorsal root ganglion lead insertion sites on right side with left-sided leads already tunneled to the stimulator pocket.

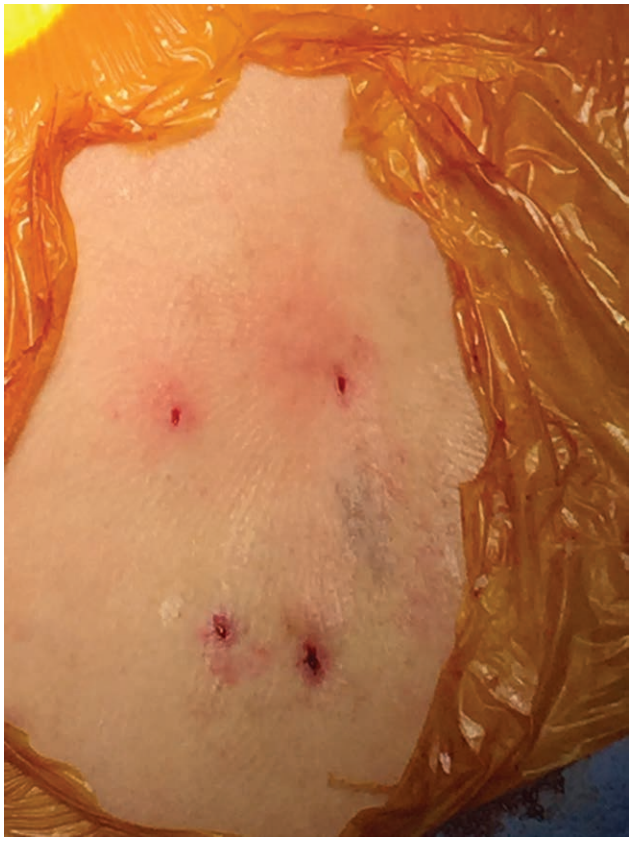

Figure 4. Needle incision sites after needle tunneling of the dorsal root ganglion leads.

3.0 Vicryl (Ethicon) sutures for the subcuticular layer. The lead puncture sites were assessed once again for depth. The puncture sites were approximately 4 mm in size (Figure 4). A single staple was placed over each site. The incisions were then dressed with gauze and Tegaderm (3M, Maplewood, MN). A final anterior posterior and lateral fluoroscopic image demonstrated that no migration had occurred during the anchoring process.

At 2 months postimplantation, the patient was experiencing improvements in everyday functioning and had 85% sustained pain relief in the feet on visual analog score (1/10). He himself tapered down his daily dose of 60 mg methadone, which he had been taking prior to implantation, to a daily dose of 30 mg. No lead or pulse generator–related complications were observed and a 2-month follow-up x-ray demonstrated that no changes in lead positioning had occurred (Figure 5). The original puncture sites had healed without scarring.

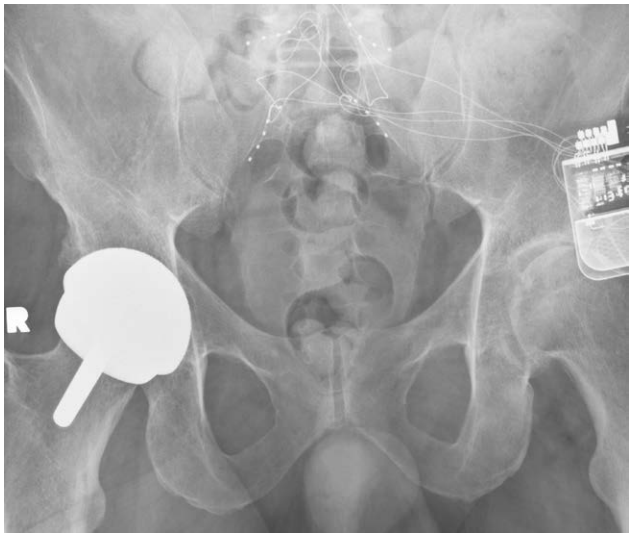

Figure 5. Anterior-posterior view of position of bilateral dorsal root ganglion stimulation leads at 2-month follow-up.

DISCUSSION

In 2006, Pyles and Khodavirdi[8,9] introduced the notion of a single-incision technique for the implantation of the pulse generator device in the lumbar spine, by placing the generator for traditional spinal cord stimulation in the original lead incision, off the midline in the lumbar region. Hayek et al[10] reported 26 patients receiving single-incision implants using this approach and found reduced operating time that may subsequently reduce the likelihood of time-sensitive complications such as infection, which usually occurs at the generator incision site. Additionally, having only 1 incision may decrease postoperative pain intensity. A potential disadvantage that is unique to the Hayek single-incision paramedian technique is that revision surgery is more difficult if the generator is enveloped in the same planes of scar tissue as the electrodes and the anchors. Moreover, if an infection occurs, the potential of

Table. Potential Advantages and Disadvantages of the Conventional Stimulator Implantation Technique, the Single-Incision Technique as Described by Hayek et al,[10] and the Technique Detailed in the Current Report

Conventional Implantation Technique Using 2 Incisions		Single-Incision Implantation Technique Using 1 Paramedian Incision		Single-Incision Implantation Technique Using 1 Lateral Incision and Tunneling Needles	
Pros	**Cons**	**Pros**	**Cons**	**Pros**	**Cons**
• Extensive experience with the approach and associated complication rates	• Midline incision may be difficult to close	• Shorter operating time	• Paramedian implantation is not possible in all patients depending on paraspinal anatomy	• Improved esthetic result	• Limited experience and no data on associated complication rates
	• Suboptimal esthetic result	• Improved esthetic result	• If hardware becomes infected this potentially could spread easier to the epidural space	• Applicable in all patients that would be suitable for conventional implantation	• Lack of FDA and manufacturer approval
	• Two incisions may lead to increased postoperative pain and infection rate	• Reduced postoperative pain and possibly reduced infection rate	• Midline incision may be difficult to close	• Lateral incision is easy to close	
			• Limited experience and data on associated complication rates	• Shorter operating time	
				• Reduced postoperative pain and possibly reduced infection rate	

Abbreviation: FDA, Food and Drug Administration.

spread to the epidural space may be higher because of proximity of the generator to the spine. Additionally, it is not possible to use the Hayek approach in thin patients or in those with increased paraspinal muscle bulk.[9] Our single-incision implantation technique for DRG stimulation leads further simplifies the implantation procedure since it obviates the need for a midline incision, because DRG leads normally do not require anchoring to the fascia in the midline. The technique described in the current report may have several potential advantages of the Hayek single-incision approach, such as decreased operating time, pain, and infections, without having the potential disadvantages of the Hayek approach, such as scar tissue in the midline and a potential infectious source close to the epidural space when placing the generator in the midline (Table). The technique we describe can be used in thinner patients as well. The technique we used to tunnel the DRG stimulation leads is well known in the placement of epidural catheters, and in that context tunneling significantly reduces incidence and extent of catheter dislocation and potentially that of bacterial contamination.[11–13] It is important to note that the single-incision technique described in this report was not used in the original study for Food and Drug Administration approval and is not officially endorsed by St Jude. Furthermore, the use of DRG stimulation in this case is off-label use of DRG stimulation, which is currently only Food and Drug Administration approved for complex regional pain syndrome.

We permanently implanted DRG stimulation leads and a pulse generator using a single incision for the pulse generator and tunneling needles. This technique may simplify DRG stimulator implantation and decrease the risk of complications. Further prospective studies aimed at corroborating the effectiveness of this approach are warranted.

DISCLOSURES

Name: Valery van Velsen, BS.
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Contribution: This author helped perform the procedures described in this report and revise the manuscript.
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