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TUTORIAL

A paramedian approach for dorsal root ganglion stimulation placement developed to limit lead migration and fracture

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Abstract

Introduction: Dorsal root ganglion stimulation (DRG-S), has demonstrated superiority in the treatment of complex regional pain syndrome and causalgia. Lead migration and fracture impact DRG-S therapeutic stability. Lead anchoring reduces DRG-S lead migration without increasing lead fracture. Lead fracture may be related to lead entrapment in the superficial fascial plane. A novel medialized approach for lead placement and anchoring is presented to address these issues.

Methods: We suggest an alternative technique for implanting percutaneous DRG-S leads at the T10-L5 levels.

Results: A novel medialized ipsilateral technique for lead placement and anchoring for single, bilateral, and adjacent segment placement is presented. The Tuohy needle puncture site is medial to the pedicle and adjacent to the spinous process, two vertebral levels caudad to the target foramen. Trajectory is maintained in the sagittal plane, to access the caudad interlaminar space near the midline. This technique allows for ipsilateral or contralateral lead placement. After epidural access, the introducer sheath is rotated toward the targeted foramen and advanced. The guidewire followed by the lead is passed, and once lead position is confirmed, tension "S" loops are created, followed by anchoring to the deep fascia.

Conclusion: We describe a new paramedian technique for DRG-S lead placement. We propose it will decrease DRG-S complication rates through anchoring to reduce migration and by avoiding the fascial planes thought to be responsible for fracture. Long-term outcomes applying our proposed techniques are required for determining the true impact, however, early anecdotal results suggest that these new techniques are favorable.

KEYWORDS
dorsal root ganglion, electric stimulation therapy, operative, surgical procedures

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INTRODUCTION

Dorsal root ganglion stimulation (DRG-S) is a neuromodulation method approved by the US Food and Drug Administration (FDA) in 2016. DRG-S has demonstrated superiority to traditional dorsal column spinal cord stimulation (SCS) for the treatment of complex regional pain syndrome (CRPS) and is showing promise in the treatment of conditions, such as postsurgical pain, low back pain, and other pain syndromes.[1–5] Complications are a byproduct of all interventions, and recent literature has highlighted that lead migration and fracture hinder DRG-S therapeutic fidelity.[6–8]

The commercially available DRG-S Slim Tip lead measures 1.0 mm in diameter, compared to 1.2–1.3 mm of traditional SCS leads. The thinner DRG-S lead design invited speculation that tensile strength and fragility were the underlying causes for its speculated higher fracture propensity. However, a multicentered analysis demonstrated that DRG-S migration rates could potentially be reduced to less than 1% per lead through the placement of an anchor, without increasing risk of fracture.[9] Thus, contrary to contemporary belief, the above findings support DRG-S lead fixation, and negate lead fracture and migration as a solely material-related issue.[10] This new finding led the authors to scrutinize the potential technical and biomechanical influences on DRG-S lead mechanical failures.

From a procedural standpoint, skin puncture for DRG-S lead placement is traditionally initiated at the lateral aspect of the pedicle two vertebral levels caudad and contralateral to the targeted foramen.[11,12] The oblique needle path then traverses the multifidus and longissimus muscles before entering the epidural space. A curved introducer sheath is subsequently inserted through the epidural needle and directed toward the contralateral foramen with or without the use of a guidewire. After lead placement over the DRG, the "S" tension loop is created.

Following these traditional steps, it was observed in the above pooled analysis that seven of the 17 DRG-S lead fractures observed occurred just below the skin-Tuohy puncture site.[9] The authors surmised that routing the lead via the shallow depth of the stab incision or tunneled epidural catheter techniques led to lead entrapment in the superficial fascial plane (SFP), and this increased the risk for lead fracture (Figure 1).[9,13,14] Accordingly, it was hypothesized that a deeper incision is necessary to bypass the SFP and that one should anchor the DRG-S leads in a deeper plane.

Although anchor placement did not increase fracture rates, fracture risk remained at 3–4% per lead. Logically, thicker and more durable leads were still suggested as means of further mitigating lead fracture. However, complications reported in a recent L2 multifidus muscle stimulation study suggest that perhaps the lead itself may not be at fault, and the procedural technique may be the responsible factor.[15] That study used 1.2 mm leads, comparable to SCS leads, deployed via a similar oblique trans-multifidus and longissimus muscle fashion. In their study, these peripheral stimulation leads showed signs of fracture in 45% of leads, despite their larger diameter. Postulating SFP lead entrapment contributed to the above finding, the investigators modified their approach to be more midline and experienced improved results.[15]

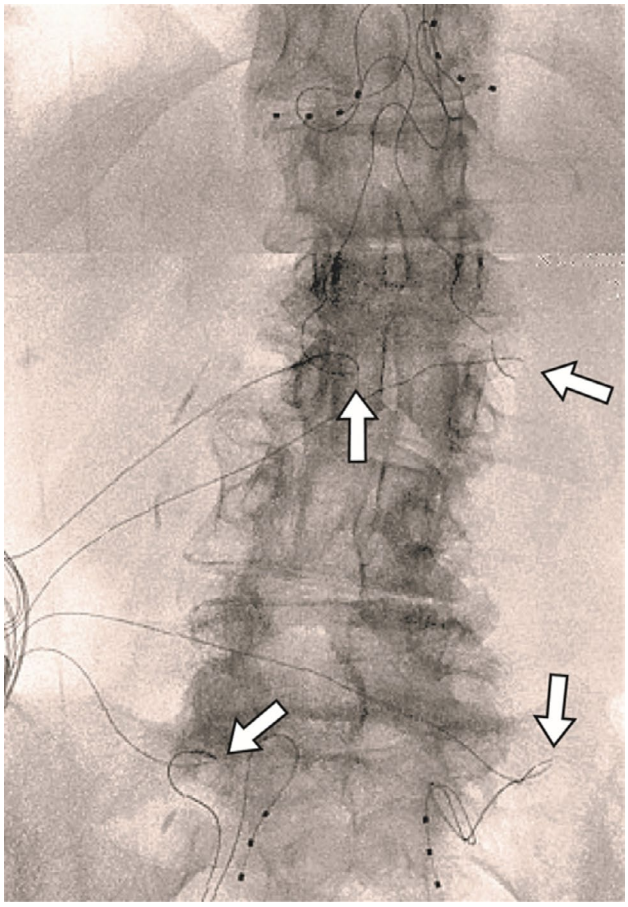

FIGURE 1 Fluoroscopic image of four leads fractured at the Tuohy needle puncture site under the skin

The similarities in muscle and fascial plane transection coupled with comparably high fracture rates with both procedures led us to conclude that the standard contralateral pedicle entry approach for DRG-S requires modification. This manuscript aims to describe an implant technique using a paramedian and ipsilateral approach for DRG-S lead entry and anchoring. The method that follows is designed to intentionally avoid lead-entrapment in the paraspinal musculature, thoracolumbar fascia (TLF; informally termed deep fascia), and the SFP.

Main Principles:

1. DRG-S lead implantation requires lead fixation.
2. The paramedian, ipsilateral approach for lead placement avoids paraspinal musculature, TLF, and SFP entrapment.

3. The paramedian approach may cause less post-procedural discomfort as the sensitive paraspinal muscles are avoided.
4. A paramedian approach is designed for ipsilateral lead placement, however, it still allows for contralateral placement.

MATERIALS AND METHODS

The authors propose an alternative method for implanting percutaneous leads over the DRG using a commercially approved DRG-S system (Proclaim; Abbott, Chicago, IL). Based on previously published and widely implemented methods,[11,12,16] these modifications are intended to mitigate migration risks via lead fixation and lead fractures by limiting trans-fascial planar tension. Although any procedural method carries inherent perils, the techniques presented demonstrate improved results to date.

Our technique is designed for lead placement at the T10-L5 levels, which are within the range approved by the FDA for DRG-S therapy. This technical recommendation is meant to serve as a potential replacement technique for DRG-S implantation to reduce the likelihood of migration and fracture, however, practitioners may use variations of our proposed techniques as they deem appropriate.

This novel DRG-S technique is based on accumulated lead migration and fracture data.[9,15] The authors derived the proposed methods by reflecting on their implanting experiences, proctoring, and training other physicians throughout Europe, Australia, and the United States.

Implantation techniques

Preprocedural considerations

Potential candidates for DRG-S should be appropriately screened and worked up as per current neuromodulation standards.[17,18] Two considerations prior to DRG-S are anesthetic parameters during lead placement and radiological evaluation of foraminal patency.

Safe lead placement for DRG-S requires permitting spinal and epidural anatomy. Therefore, a review of neuroimaging studies should be performed prior to consideration of this therapy. This includes an evaluation for severe central or lateral recess stenosis, which raises concern for lead-induced mass effect and safe lead placement. Foraminal diameter varies throughout the spine, and there is an increased incidence of foraminal stenosis in the lower lumbar levels. Additionally, an ipsilateral approach may be challenging in the setting of severe loss of disc height (reduced caudal: cephalad margin) resulting in steeper than desired access, necessitating a contralateral approach.

Lead navigation toward the targeted DRG through a medialized access point requires a curved introducer sheath. Care must be used when advancing the semi-rigid sheath as the delicate central nervous system tissue is susceptible to trauma. To monitor and hopefully prevent such injuries, forms of neural monitoring are becoming standard practice.[19,20] An awake, responsive, patient with minimal sedation can serve as a self-monitor of neural protection. In a patient receiving deep sedation or general anesthesia, monitoring options include intra-operative neuromonitoring (IONM): somatosensory evoked potentials (SSEPs), triggered motor evoked potentials (MEPs), and spontaneous electromyography (EMG). For the purposes of intra-operative DRG-S neuromonitoring, SSEP and EMG are most beneficial. Keep in mind that an awake patient or use of IONM does not directly prevent neural injury. However, it alerts to the potential impending event and allows for avoiding further or more significant injury or damage.

Fluoroscopy

Fluoroscopic imaging optimization is the vital first step for success and to reduce preventable technical challenges during interventional pain procedures. We recommend placing an abdominal pillow or wedge to accentuate kyphosis, which widens foraminal diameters. A thorough fluoroscopic survey properly identifies anatomic levels and planned trajectories. Anatomic variants, such as transitional segments, sacralization, or a floating rib, may lead to misidentification of the target levels.

After optimization of the interlaminar space view, the proceduralist should assess whether an ipsilateral or contralateral approach should be taken. Anatomic variations, such as facet hypertrophy and disc degeneration, may reduce the interlaminar window indicating an ipsilateral or contralateral approach as the preferred trajectory. Contralateral placement should still be performed with a paramedian approach, medial to the medial aspect of the pedicle to decrease fracture risk at the Tuohy needle puncture site.

Planned trajectories, confirmation of the desired level of entry, appropriate neural monitoring, and adherence to the Neurostimulation Appropriateness Consensus Committee guidelines[17,18] throughout the stages of the implantation are pivotal for safe, optimal results.

Ipsilateral lead placement using a paramedian approach

To maintain a medial approach in the sagittal plane, an ipsilateral approach is recommended. Placement of the lead ipsilateral to the Tuohy puncture site holds several advantages, including ease and safety of placement given

the paramedian trajectory, allowing for lateralization of leads in the epidural space and pocket, and minimizing the need for 90 cm leads.

The paramedian approach and required sagittal trajectory of the Tuohy needle causes a more lateralized entry point into the epidural space. As such, using the paramedian approach for contralateral access entails passing over the apex of the thecal sac, bypassing the often-hypertrophied ligamentum flavum, and then traversing ventrolaterally to the foramen. These obstacles can increase compression on the thecal sac, nerve roots, or spinal cord during a potentially more challenging placement. On the other hand, contralateral placement using the paramedian approach requires a more oblique angle for optimal midline epidural access and may not avoid the fascial and muscular planes suspected of contributing to lead fracture.

Ipsilaterally placed leads lessen entanglement concerns in the epidural space and the incisional pocket for bilateral and adjacent level lead placement. The less oblique entry decreases the need for 90 cm leads when placing contralateral to the implantable pulse generator (IPG) site. Utilizing the 50 cm leads maintains magnetic resonance imaging (MRI) conditional compatibility.

Ipsilateral placement technique:

The entry for paramedian approach to DRG-S lead placement is between the pedicle and the spinous process (SP) using a vertical plane trajectory, ipsilateral to the target foramen.

To optimize placement:

1. Align the rostral border of the lamina below the target interlaminar space using a cephalocaudal tilt on the fluoroscopy unit.
2. With the laminar border aligned, rotate the fluoroscope 5–10 degrees to the side of Tuohy entry; this important step maximizes visualization of the working surface of the lamina and shifts the SP out of the planned trajectory (Figure 2).

Advance toward the rostromedial lamina while maintaining the needle position over the lamina throughout, until contact is made with the periosteum. Staying over and then contacting the periosteum serves as a guide for needle depth prior to entering the ligamentum flavum.

After contacting lamina, redirect and advance the needle tip into the lower portion of the interlaminar space, close to midline. Entering lower in the space maintains the shallow angle and maximizes clearance proximally for the introducer sheath bevel. Levering the hub of the Tuohy vertically after crossing the laminar border during loss of resistance assists in walking off the lamina to access the lower aspect of the interlaminar space. After epidural access, the introducer sheath with guidewire is inserted into the Tuohy needle.

Reposition the fluoroscope to midline and then align the inferior endplate of the level of the target DRG, as this maximizes the infra-pedicular/foraminal view.

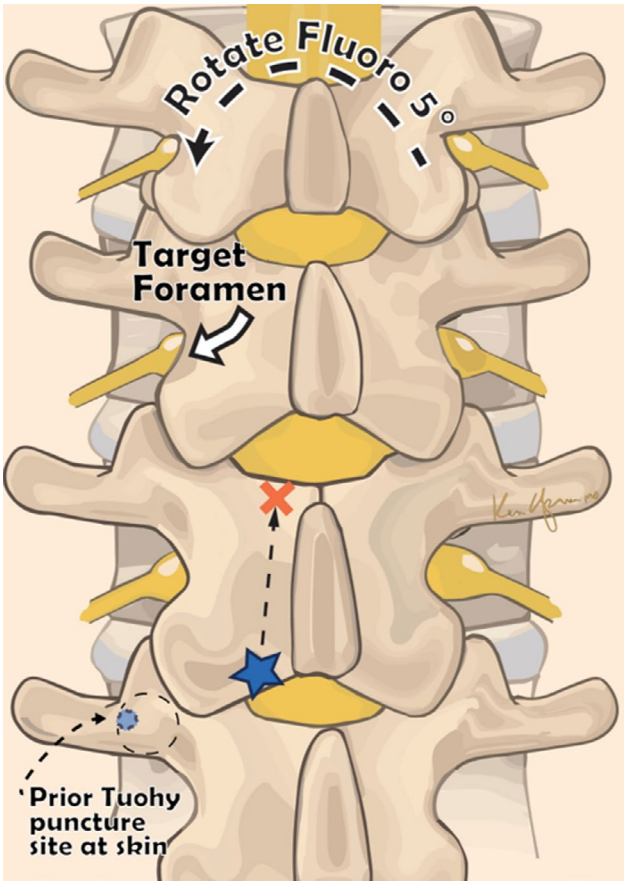

FIGURE 2 Anatomic landmarks for paramedian ipsilateral approach. The blue star (*) denotes the puncture site. X represents laminar target to contact prior to epidural access. The light blue circle represents the traditional Tuohy needle puncture site

Rotate the bevel of the Tuohy and curved introducer sheath toward the targeted foramen and advance the sheath. When nearing the medial pedicle border, attempt to pass the guidewire (Figure 3a). Care must be taken to prevent passing the introducer sheath into the foramen as blunt trauma to the DRG may result in postprocedural neuropathic pain.

Avoid rotation of the bevel of the introducer sheath ventrally (see special considerations) and stabilize the introducer sheath when passing the guidewire. Use gentle, intermittent tapping pressure when attempting to pass the guidewire through the foramen. Rigid or calcified intraforaminal ligaments, the intervertebral disc, bony overgrowth, or the DRG itself may prevent passage. An apparent intraforaminal obstruction may deflect the sheath and guidewire. Applying gentle sheath stabilization and small movements may safely help to circumvent such challenges.

If the guidewire is unable to traverse the foramen, consider withdrawing the sheath, and approach the foramen after repositioning the introducer sheath at a different point (e.g., repositioning rostral or caudal to the failed foraminal path). After successful passage of the guidewire through the foramen, the sheath position

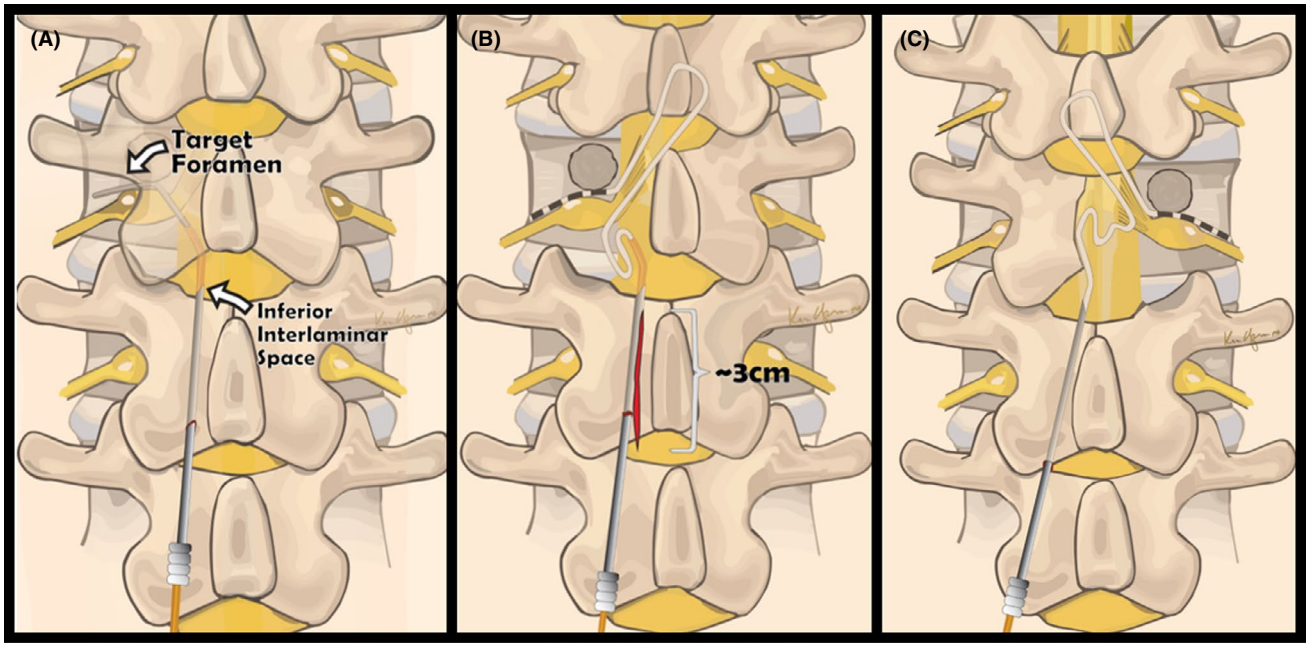

FIGURE 3 (a) After ~ 5 degrees ipsilateral rotation, contact of lamina, and then epidural access, the guidewire is used to access the foramen. (b) Ipsilateral lead and loop placement. An incision after lead placement is illustrated. (c) Contralateral placement using a paramedian entry. Tuohy skin puncture site is medial to the pedicle to avoid the superficial fascial plane.

should be maintained with a gentle forward pressure while exchanging the guidewire with the lead. In optimal conditions, a lateral fluoroscopic view may be used to position the lead in the appropriate foraminal plane. Once the lead is in adequate anterior-posterior (AP) and lateral position, tension "S" loops are created in the usual manner (Figure 3b). The paramedian approach also allows for contralateral lead placement (Figure 3c). For trial lead placement, we recommend anchoring to the skin and dressing appropriately.

Implant techniques

Akin to SCS lead implantation, the paramedian, ipsilateral implant technique utilizes a paramedian incision and lead anchoring to the TLF. Initiating the surgical incision before or after lead placement depends on the surgeon's discretion. An incision before lead placement allows for optimal unobstructed preparation for access, placement, and anchoring of leads, and is the recommended technique due to these benefits.

The size and location of the incision depends on several factors, including the number of leads, the targeted foramen, the planned trajectory, body habitus, dorsal adipose thickness, or any other patient-specific concerns. Depending on the depth, typical incision length should be ~ 2.5 to 4 cm. In the event there is excess lead length beyond that required to traverse to the IPG pocket, loops can be placed at the lead insertion site after anchoring to limit extraneous lead loops in the pocket, which may become entangled.

Implant techniques for various levels with the incision placed prior to lead placement are described in detail, along with single, bilateral, and adjacent-level lead anchoring techniques. In all cases, dissection must be made below the SFP, optimally to the TLF, where the leads are anchored.

Unilateral single-lead implant

After fluoroscopic alignment, mark the skin at specific locations: the puncture site, the periosteum contact point, and the interlaminar target. The incision should be aligned with the projected Tuohy trajectory. Incisional length typically spans from approximately the mid-pedicular line to the disc space of the level below, depending on body habitus. Following incision and dissection to the TLF, the Tuohy is introduced at approximately the lower one-third of the vertebral body through the TLF. When placing the Tuohy needle through the TLF, entry will be rostral to the skin puncture site as the skin and adipose tissue have been dissected.

After epidural access, the lead is placed in the manner described above for ipsilateral placement.

Bilateral-lead implant, same level

Making the incision prior to lead placement offers several advantages, namely utilizing a single incision while optimizing conditions for surgical exposure of the

pocket, and avoidance of lead entanglement in both the epidural space and the pocket.

Measure and demarcate the planned midline incision using the infra-pedicular line to infra-pedicular line of the level below, roughly 4 cm, as landmarks. If there is limited soft tissue thickness dorsal to the spinous processes, the incision can be made slightly adjacent to midline, ipsilateral to the side of the planned IPG site. After dissection to the TLF, undermine the lateral walls of the incision. Then deflect the undermined tissue laterally using the Tuohy needle to permit the correct trajectory to the epidural space (Figure 4a).

When placing the Tuohy needle through the deep fascia rather than the skin, the needle puncture site will be rostral to the skin entry point. Entering deep fascia at the level of the lower half of the vertebral body compensates for distance created from tissue dissection (Figure 4b and 4c). Repeat the procedure for the contralateral side and lateralize extraneous lead with loops if needed. Figure 5 demonstrates fluoroscopic images of the steps for lead placement.

Performing the midline incision after percutaneous lead placement, the leads will need to be pulled into the midline incision above the TLF and anchored deep to the SFP.

Ipsilateral adjacent-level implant

Ipsilateral adjacent level lead placement may also be performed through a single skin incision. Performing the incision after lead placement with two rostro-caudal Tuohy needles is typically challenging, so the authors recommend an incision prior to epidural needle placement.

The incision for adjacent level placement is slightly longer than for bilateral placement, approximating the infra-pedicular line of the rostral level to the lower third of the vertebral body of the level below. Given the limitation of incisional length vertically, the leads should be placed individually to maximize working space.

The (first) upper Tuohy should be placed as rostrally in the incision as possible, often at the infra-pedicular line of the targeted DRG rostral level. After the lead is confirmed in its final position, one can remove the Tuohy needle, anchor the lead, and move the remaining lead from the surgical field. Then, attention is turned to the second lead. The (second) lower Tuohy needle will enter the TLF at approximately the lower third of the vertebral body at a level below and is placed in the same manner. Lateralize excess lead with tension loops if needed (Figure 6a–c).

Lead Anchoring

In all instances, after lead deployment, the lead should be anchored to the deep fascia, ensuring the silastic anchor's distal tip fully advances via the fascial defect created by the Tuohy needle. The nonabsorbable sutures should seek to cinch the anchor to the lead and secure the anchor flush to the fascia. Placing the anchor suture to the fascia prior to Tuohy needle removal may protect the lead from damage during suture placement.

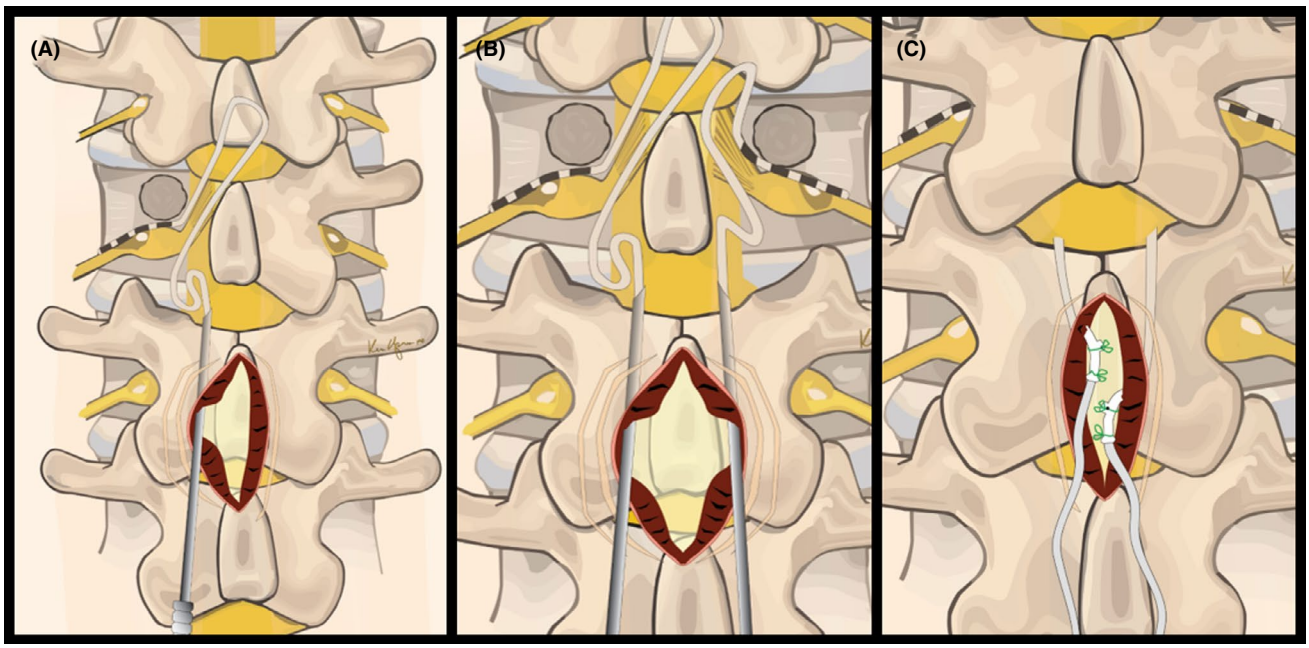

FIGURE 4 (a) After undermining of the lateral wall of the incision, the Tuohy needle is advanced through the thoracolumbar fascia (TLF) at the lower third of the vertebral body and the lead is placed. (b) The contralateral lead is placed in the same fashion above. (c) Each lead is anchored and secured to the TLF.

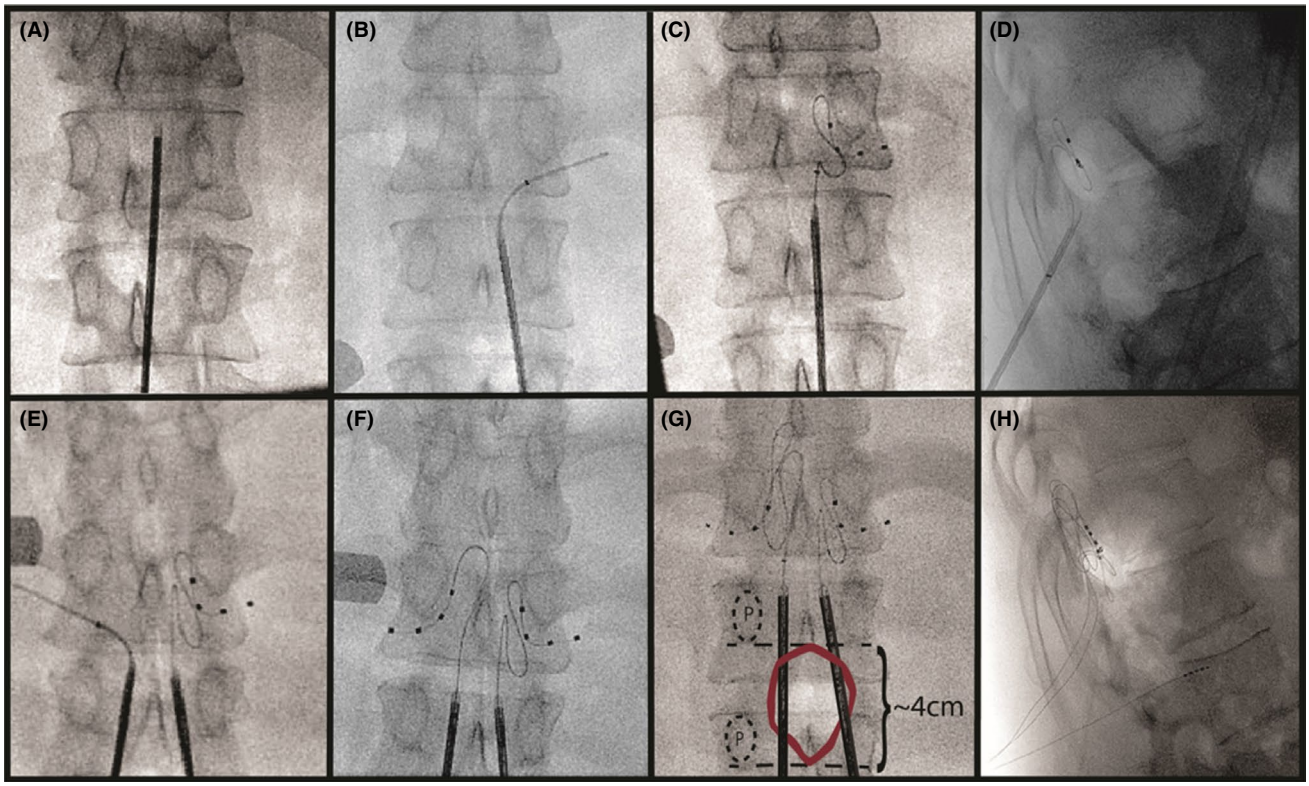

FIGURE 5 (a) Epidural access. (b) Aligning the endplate of the target foramen and access with guidewire. (c) Lead placed and loop created. (d) Lateral view of lead placed. (e) Left lead placed through incision and guidewire. (f) Superior loop created. (g) Demonstrates landmarks and incision through which leads placed. (h) Lateral view of bilateral leads placed

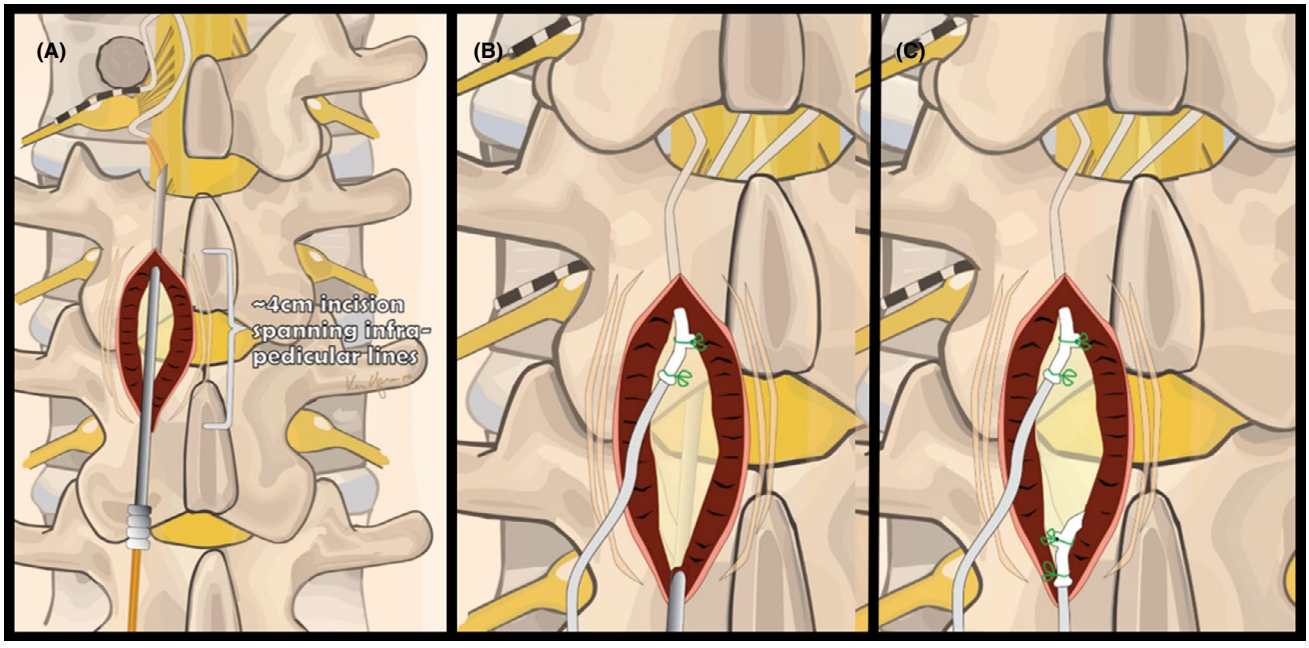

FIGURE 6 (a) Ipsilateral adjacent level lead placement into the incision. (b) The upper lead is anchored before installing the lower lead. (c) The caudad lead placed and anchored

IPG Placement

The IPG pocket is created in the usual manner.[17] Using the tunneling device or Tuohy needle for a close IPG incision, tunnel from the IPG pocket to the caudad border of the midline incision. Doing so avoids the SFP adjacent to the spinous processes, as the adipose between fascial planes narrows at that point. Careful attention

to the depth is required when passing the tunneler as a transection of the superficial fascia can occur with initial tunneler entry at the IPG pocket, when passing between incisions, and/or upon entry to the medialized incision. After arrival in the pocket, copious irrigation with normal saline should be performed.[21] Nonabsorbable anchoring sutures should be placed to prevent movement or rotation of the IPG. Closure of the incision should be performed in a standard surgical fashion.

Special considerations

Thoracic leads

The presence of the spinal cord above the L1-2 level introduces an additional variable. In an awake patient, after achieving loss of resistance, inject 5 cc of preservative-free normal saline into the epidural space to create a buffering effect to allow for easier passage of the introducer, potentially decreasing the risk of dural puncture and spinal cord trauma. When IONM is being applied, this should likely be avoided, as fluid may increase resistance and alter results.

The second, and perhaps the more important consideration, is to avoid rotating the introducer sheath curve ventrally when placing DRG-S leads in the thoracic spine. The semi-rigid introducer has the potential to deflect the dura and contact the spinal cord. The introducer side port coincides with the curved tip; accordingly, it should not be rotated past the 3 and 9 o'clock positions (Figure 6). Performing lead placement in an awake, responsive patient or in an asleep patient utilizing intra-operative neuromonitoring may help identify and prevent injury, and should be implemented in all cases.[19,22]

DISCUSSION

Evidence-based techniques across the field of medicine inevitably evolve over time as challenges to long-term efficacy of a therapy are better recognized, understood, and addressed by clinicians. Through diverse and unique mechanisms of action, DRG-S is being effectively applied in a variety of "off label" pain syndromes.[23–29] As such, there is an impetus to limit complications, such as lead migration, lead fracture, and the concerns over revision surgery, as these issues have the potential to reduce the therapeutic value of DRG-S to patients. The introduction of the novel paramedian, ipsilateral lead placement technique described in this article for DRG-S implantation seeks to further minimize complications, particularly lead fracture, through leveraging the shared experience and developed techniques of the authors. Promoting anchor securement and paramedian ipsilateral lead implantation that avoids traversing the paraspinal muscles and the potential entrapment of the leads in the SFP and TLF should minimize lead fracture incidence and migration.

During the initial development of DRG-S lead placement techniques, the paramedian ipsilateral approach was abandoned over concern that the lead would direct anteriorly. The authors have not found this to be the case in their experience thus far. A secured, functioning lead with two contacts positioned within the foramen in the lateral view is sufficient to capture the target DRG in most instances.

In the setting of a DRG-S trial, postprocedural pain is of particular concern as it limits the ability to assess device efficacy over the initial days of the trial phase. Thus, reducing postprocedural pain offers additional benefit with this modified ipsilateral approach. Paraspinal muscle manipulation during spinal surgery is responsible for a significant portion of postsurgical pain and discomfort. DRG-S placement via the traditional contralateral approach traverses the same musculature as manipulated in spinal surgical procedures. Accordingly, less postprocedural pain and muscle spasm may also occur with the ipsilateral approach by avoiding this irritating and painful phenomenon, and anecdotally, the authors have found this to be true. Last, the medialized, paramedian needle trajectory resembles that of traditional SCS, providing a level of familiarity for most practitioners and potentially reducing the learning curve for physicians in training to provide DRG-S.

CONCLUSION

We describe new techniques for DRG-S implantation, which we propose will decrease DRG-S complication rates, particularly lead migration and fracture. Long-term outcomes applying our proposed techniques for device implant are required for determining the true impact on lead fracture rates, migration rates, and other complications. However, early experience suggests that these new techniques have significant potential for improved patient outcomes through minimization of complications and improved physician procedural comfort.

Because different techniques may be applied, the authors encourage practitioners' comments, critiques, and opinions regarding the proposed methods. The goal of these recommendations is to improve DRG-S treatment outcomes and decrease complications for the betterment of our patients.

CONFLICT OF INTEREST

J.W.K. is on the advisory board Abbott, Saluda, Nevro, Boston Scientific. T.D. is a consultant for Abbott, Medtronic, Boston Scientific, Nevro, Nalu, Saluda. He

has equity in Saluda, SPR, Spinethera, Nalu, Cornerloc, Paintec and Vertos. Research funding with Boston Scientific, Abbott, Saluda. Jonathan Hagedorn is consultant for Abbott, Boston Scientific, and Nevro. B.B. is a consultant for Medtronic, Abbott, Nevro, Salvia Bioelectronics and received speaker fees from StimWave. D.M.D. is a consultant for SPR Therapeutics, Vertos Medical, Abbott, and Fresenius Kabi. A.A. is a consultant for Abbott, Boston Scientific, Nalu, Painteq, and Vertos and research funding from Abbott, Boston Scientific, Nalu, Painteq, and SPR. C.H. is consultant for Abbott, Biotronik, Boston Scientific, Mainstay, Nalu, PainTEQ, and Saluda. He has equity in Mainstay, Nalu, Vivex, Spine Biopharma, and PainTEQ. K.P. is a consultant and speaker for Abbott. K.C., M.S., N.v.H., and A.Y. have nothing to disclose.

AUTHOR CONTRIBUTIONS

All authors contributed to the paramedian, ipsilateral technique concept. K.B.C. and M.S. authored the report with significant contributions from all authors. All authors approved the final version of the manuscript.

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