Case Report

Are there a guidelines for implantable spinal cord stimulator therapy in patients using chronic anticoagulation therapy? - A review of decision-making in the high-risk patient

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Abstract

Background: Spinal cord stimulators (SCSs) are gaining increasing indications and utility in an expanding variety of clinical conditions. Complications and initial expenses have historically prevented the early use of SCS therapy despite ongoing efforts to educate and promote its utilization. At present, there exists no literature evidence of SCS implantation in a chronically anticoagulated patient, and neuromodulation manufacturers are conspicuously silent in providing warnings or recommendations in the face of anticoagulant use chronically. It would appear as through these issues demand scrutiny and industry as well as neuromodulation society advocacy and support in terms of the provision of coherent guidelines on how to proceed.

Case Description: A 79-year-old male returned to the neurosurgical clinic with persistent low back pain and leg heaviness due to adjacent level degenerative spondylosis and severe thoracic spinal stenosis. The patient had a notable history of multiple comorbidities along with atrial fibrillation requiring chronic anticoagulation. On initial presentation, he was educated with three choice of conservative medical therapy, intrathecal drug delivery system implantation, or additional lumbar decompression laminectomy with instrumented fusion of T10-L3 and a palliative surgical lead SCS implantation.

Conclusion: Our literature search did not reveal any evidence of SCS therapy among patients with chronic anticoagulation. This case illustrated a complicated clinical case scenario wherein a percutaneous SCS implantation would normally be contraindicated due to severe thoracic spinal stenosis and chronic anticoagulation which could lead to possible paralysis or even a lethal consequences associated with the possible formation of a thoracic epidural hematoma.

Key Words: Chronic anticoagulation, implantable device, neuromodulation, spinal cord stimulator, spinal epidural hematoma

INTRODUCTION

The utility of spinal cord stimulator (SCS) has proven to be excellent when compared to conservative medical management (CMM) or reoperation for failed back surgery syndrome (FBSS) patients.[21,26] However, even though rates of complications, cost, and adverse events favor SCS therapy, its utilization has been minimal in FBSS patients.[22,33] Although, there are no "gold standard" guidelines for utilization of SCS therapy, International Neuromodulation Society and Neuromodulation Appropriateness Consensus Committee (NACC) are leaders behind the creation of guidelines and determining the appropriate selection of patients, use of neuromodulation devices, and prevention of serious complications.[7,8] However, patients taking antiplatelet and anticoagulation medications are thought to be at high-risk for SCS implantation due to increased risks of spontaneous bleeding and epidural hematoma formation.

Anticoagulation therapy has been a very common medical practice, especially among elderly patients for prevention of thromboembolic events. It is not hard to imagine that the number of these patients will be growing exponentially as the baby-boom population ages, and the instancy to address practical guidelines for a number of interventional procedures is expected to persist. The American Society of Regional Anesthesia and Pain Medicine (ASRA) developed separate guidelines for interventional pain procedures for patients on anticoagulation and antiplatelet medications in response to the interventional pain management community outcry for independent guidelines.[2,25] However, it remains the discretion of a treating physicians to decide the appropriate indications and contraindications of SCS therapy for their patients without the acceptance or availability of any guidelines from the major neuromodulation manufacturers regarding risks for patients using chronic anticoagulation therapy. A dedicated literature search did not identify any reports of implanted SCS devices in patients on chronic anticoagulation and what the possible long-term risks and complications associated with that therapy might be.

We are presenting the case of an elderly patient with FBSS on chronic anticoagulation therapy for atrial fibrillation (AF), who was confronted with three options for managing his chronic, severe, and opioid-resistant pain; of either surgical decompression laminectomy and implantation of surgical lead SCS (if he presented in a stable surgical condition), implantation of an intrathecal drug delivery system (IDDS), or oral opioid therapy along with conservative medical management. This case addresses the needs for evaluation of continuous versus interrupted anticoagulation therapy for SCS implantation and long-term complication of chronic anticoagulation with implantable devices. A careful assessment for selecting between a percutaneous lead versus surgical paddle lead implantation.

CASE DESCRIPTION

A 79-year-old male returned to our neurosurgical clinic with weakness and increasing leg pain, due to extensive spinal stenosis (T11-L3), adjacent level degenerative spondylosis [Figures 1 and 2], peripheral vascular disease (PVD) of small vessels, neuropathy, and neurogenic claudication pain. He felt bilateral leg heaviness and pain exacerbation of the back and the leg below a knee while walking a short distance (<50 feet). Physical examination identified an abnormal tandem gait and weakly positive Romberg's sign. Back flexion improved the pain and back extension at 5–10° exacerbated back and leg pain. An L4-S1 lumbar laminectomy with fusion was performed 6 years prior to presentation and an L3-S1 fusion [Figure 3] 3 years later while taking warfarin for AF of 10 years. These surgeries were performed with successful discontinuation of warfarin and restarting anticoagulation therapy following surgery without complications for thromboembolic events. Additional surgeries were completed for cervical central spinal canal stenosis that required cervical fusion of C3-C5 [Figure 4] and ulnar nerve decompression surgery. Furthermore, he had a history of malignancy in the lung, urinary bladder, and prostate, which were surgically and medically treated and for which he was closely monitored by the specialists.

Patient's main concerns were leg heaviness and neurogenic claudication pain, which had affected his quality of life. Our intention was to improve his pain control without resorting to oral opioid medications, which were considered a relatively poor choice due to his advanced age and multiple comorbidities, which included obesity, chronic obstructive pulmonary disease, multiple malignancies, coronary artery disease, PVD, Type II diabetes mellitus, hypertension (HTN), and AF. Pain management options included CMM with physical
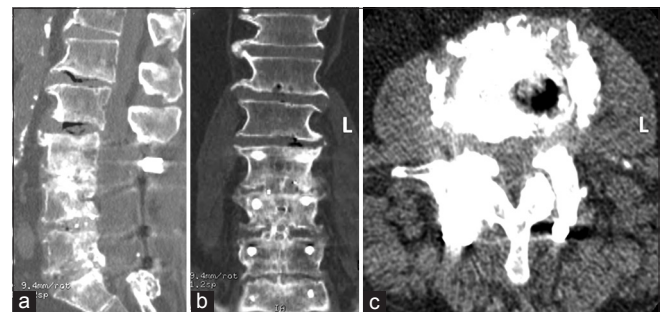

Figure 1: Lumbar computed tomography for instrumental spinal fusion at L3-S1 and adjacent level degenerative spondylosis: (a) Sagittal plane view, (b) coronal plane view, and (c) adjacent level degenerative spondylosis with spinal stenosis
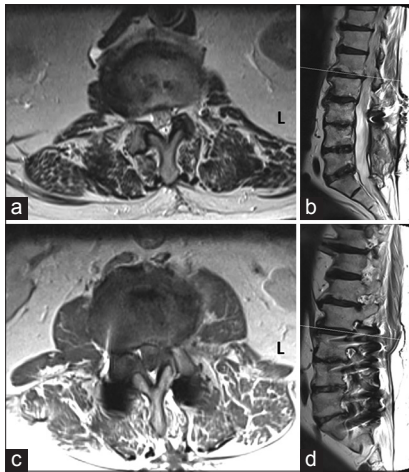
Figure 2: Lumbar magnetic resonance imaging of adjacent level disease with severe spinal stenosis at L1-L2 and L3. (a) Transverse plane view at L1-L2 intradiscal space, (b) sagittal plane view, (c) transverse plane view at L2-L3 intradiscal space, and (d) sagittal plane view with evidence of instrumental fusion at L3-S1
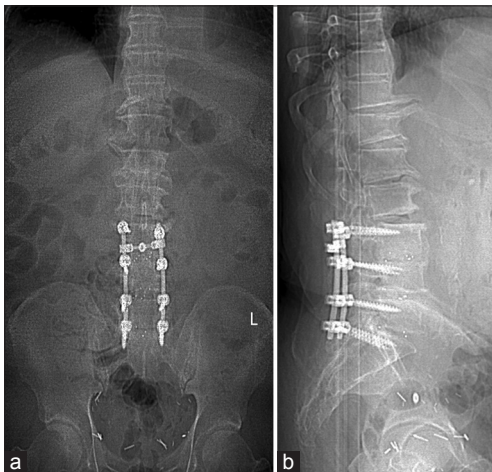

Figure 3: Lumbar X-ray of instrumented lumbar fusion of L3-S1. (a) Antero-posterior view and (b) lateral view

Figure 4: Cervical X-ray (lateral view): C-spine instrumental fusion

therapy, IDDS, surgical decompression and fusion with surgical lead SCS implantation, or percutaneous SCS therapy at the thoracic level.

This high-risk patient with multiple comorbidities was confronted with the following choices. Standard conservative medical management with analgesic medications and physical therapy were largely unsuccessful in treating adjacent level degenerative spondylosis. Surgical options might include considerations of a decompression laminectomy of L1-L3 with an extended instrumental lumbar fusion of T10-L3 that would also include palliative intervention by implanting surgical paddle leads at T10-T12 for SCS therapy. These procedures would be performed by withholding warfarin and restarting it postoperatively, as for the previously performed neuraxial surgical procedures. Decompression laminectomy would address his leg heaviness as a result of the compressive nature of symptoms and associated neurogenic claudication. SCS therapy should provide coverage for the leg pain, due to inoperable PVD. The choice of a surgical paddle lead was preferred due to severe low-level thoracic spinal stenosis on magnetic resonance imaging (MRI) [Figure 3] that would create significant challenges to advancement of percutaneous leads and which would be considered a relative contraindication for implantation of a percutaneous lead SCS. IDDS therapy would be used strictly as a palliative intervention since it is associated with opioid-related risks. However, it would not be the optimal approach for a relatively short interval pain lasting between 3 and 5 h/day and leg heaviness as a predominant symptom.

The main concerns for this patient were presented to him during the educational process regarding his use of chronic anticoagulation, choice of intervention, and its potential for catastrophic risks. A surgical paddle lead was recommended over a percutaneous lead to decrease the chances of him developing a catastrophic thoracic spinal-epidural hematoma upon lead migration, repeated epidural needle insertions, multiple lead advancements in the epidural space, and/or micromotion trauma. An elderly patient should be presumed to have a greater chance of traumatic and spontaneous bleeding risk due to poor international normalized ratio control on warfarin, fragile venous vessels, and a high risk for accidental trauma due to expected poor balance and limited mobility. One-time discontinuation of anticoagulation medications might carry less risk in this patient rather than repeated abstinence of warfarin for the several procedures required with percutaneous lead placement for trial and permanent implantation and any revision or re-implantation unless a "perm-trial" type of procedure was selected for use. All these considerations may lead to a potentially catastrophic intraspinal thoracic hematoma,

which may carry with it severe morbidity and mortality among elderly patients, and the proximity to the spinal cord water shadow zone has a potential for a high risk of permanent paralysis.

Despite neurosurgical recommendations of fusion and a surgical paddle lead, the patient elected to receive percutaneous lead SCS therapy with another group of pain specialists without consulting us as to his decision and choice. We believe the complexity of this case deserves a multispecialty approach of consulting and including a trained and experienced neurosurgeon and/or pain specialist in the area of surgical and percutaneous leads placement for patients on chronic anticoagulation therapy.

DISCUSSION

The elderly population is often ideal candidates for SCS therapy while being vulnerable to polypharmacy and the unwanted side-effects due to narcotic analgesics. SCS is a safe, relatively minimal invasive procedure that is reversible when it is ineffective or leads to complications. A good safety rating of SCS compared to opioid analgesics was evident from comparing safety profiles of both therapies among chronic pain patients.[7] Favorable evidence of efficacy, cost-effectiveness, and safety for implantable SCS in chronic pain disorders, such as FBSS, complex regional pain syndrome, and PVD is noted in the peer-refereed literature. A systemic review for SCS therapy in FBSS patients with intractable chronic pain suggested that SCS is highly effective in providing pain relief during the short- and long-term period in nine observational studies and two randomized trials.[10] However, utilization of SCS therapy remains modest with a mere 2.4% of patients who underwent SCS implantation in a retrospective analysis of 16,455 patients with FBSS versus 97.6% of these patients who were re-operated.[22]

In the past two decades, the discipline of spine surgery has expanded the number of invasive procedures that has led to well-recognized complications, including the entities of chronic pain and disability. Lad et al. noted that 16,060 (97.6%) patients required repeated operation after undergoing initial surgery.[22] North et al. found that FBSS patients assigned to an SCS group were less likely to cross over to the re-operative group. Opioid use was decreased in 87% of SCS patient versus 58% of re-operative patients.[26] These results are promising in the face of clear evidence consistently demonstrating opioid-related health-related risks and lack of opioid long-term analgesic efficacy. The Centers for Disease Control and Prevention reported an alarming 75.2% (16,651) of all prescription overdose deaths as being due to opioid pain analgesics.[14]

Commonly defined neuroanatomical coverage with SCS therapy targeting lower extremity pain (radiculopathy or neuropathy), and chronic axial low back pain (LBP) continue to have poor coverage with SCS.[17] Stidd et al. have utilized advances of SCS therapy to show that chronic axial LBP patients can attain pain relief with surgical paddle lead implantation. A case series found that 89% (eight out of nine) of patients had >50% relief of chronic axial LBP with a mean follow-up of 19.9 months after SCS implantation.[34] As mentioned above, we believed our patient would gain relief from surgical decompression using a laminectomy and that a surgical paddle lead would provide a palliative pain control of chronic LBP and leg pain as a result of FBSS. Even so, laminectomy or laminotomy is an invasive procedure, and the benefits of surgical paddle leads are gained with durable pain coverage and reduced likelihood of lead migration.[27,28] Babu et al. examined 9072 patients that have shown a greater preference for surgical paddle lead SCS when a repeated procedure was required regardless of initial lead placement: Percutaneous or surgical lead implantations.[1]

SCS complications can be characterized as mechanical (27–30%), biologic (3–5%), and other (3–4%). Most common mechanical complications of SCS are lead migration (13%), fracture (9%), and hardware malfunction.[18] Biological complications are most commonly associated with infection (3–5%), cerebrospinal fluid leak (0.3%), and symptomatic hematoma (0.3%). Levy et al. gathered 44,587 cases of surgically implanted SCS paddle leads between 2007 and 2010 and found a mere 83 patients who developed epidural hematoma and 43 patients who had a complete recovery of neurologic deficits, while 12 patients sustained partial recovery and eight patients did not recover.[23] Neuraxial interventions present with some risk of epidural hematoma, which is reported to be 0.014% for epidural catheter placement and 0.19% for SCS.[23,32]

The epidural space has a rich network of valveless veins (Batson's plexus), which covers anterior and lateral portions of the epidural space. Epidural veins anastomose freely with the veins connecting the head and pelvis. Venous return from the pelvis passes through the extradural venous plexus to the azygous veins, which drains into the inferior vena cava. The epidural space also contains lymphatics and segmental arteries. The dura mater is a spinal meninges that is at the floor (anterior) to the epidural space. The dura is acellular, but the inner edge is highly vascular, which is important in drug delivery from the epidural space.[16]

Serrano et al. summarized of ASIPP guidelines which reconfirm a generally conservative approach for neuraxial interventional procedures in anticoagulated patients.[32]

Heparins (unfractionated heparin or low-molecular-weight heparin [LMWH]) carry the greatest risk of epidural hematoma with high dosing or close timing of therapy to intervention. Combinations of heparin and a Vitamin K antagonist (VKA) are prohibited before and immediately after epidural procedures. It is believed that aspirin alone carries a low risk of epidural hematoma, and yet in combination with other antiplatelet products results in higher risks. However, a recent cases of spinal epidural hematoma developing in a patient taking a baby aspirin (81 mg/day) after SCS implantation and lead removal has been described, which has been found to have the highest risk of epidural hematoma among male patients in the fifth and sixth decades of life.[5,12] Most recently, Covert and Nobles have shown that successful SCS implantation is possible in patients with chronic dual antiplatelet therapy while following conservative recommendations and holding clopidogrel.[6]

However, a risk of epidural hematoma has not been formally assessed for SCS implantation among chronically anticoagulated patients on VKA or new oral anticoagulants. Neuromodulation device companies continue to promote their product in accordance with an increasing need for this invaluable therapy. Even so, there are no general manufacturer guidelines or warnings regarding the use of SCS and anticoagulation therapy. Subsequently, NACC recommendations were based on conservative recommendations promoted by ASRA, which has advised an interruption of anticoagulation therapy before procedures in accordance with the family practitioner or cardiologist.[8,25] One dilemma of anticoagulation therapy discontinuation existed in interventional cardiology which was formally explored during implantation of intracardiac devices. Birnie *et al.* found that continuation of warfarin had no increase of device pocket hematoma with an incidence of 12 of 343 patients (3.5%) compared to 54 of 338 patients (16.0%) in the heparin-bridging group (relative risk =0.19; confidence interval -95%: 0.10–0.36; $P < 0.001$). The authors concluded that warfarin continuation is a reasonable practice for selected procedures.[3] Furthermore, Douketis *et al.* showed in a randomized clinical trial that refrained bridging upon restarting warfarin was noninferior to bridging with LMWH for the prevention of arterial thromboembolism and decreasing the risk of major bleeding.[9]

The United States has identified more than 2.3 million persons with AF.[24] In consideration of the prediction of an imminently increasing average age in the US, the number of AF cases is expected to more than double to 5.6 million by 2050.[15] A growing aging population has a greater prevalence of developing AF with 5% at age >65 years and approximately 10% at age >80 years.[13] An anticipated number of people taking anticoagulation therapy would therefore be expected to grow in the near future. Anticoagulation therapy is associated with bleeding as one

major complication and age is an independent risk factor for bleeding.[33] Currently, warfarin is the most extensively utilized oral anticoagulant agent, and risk of major bleeding is a viable problem.[31] The elderly are especially at risk of warfarin's narrow therapeutic range, individual variability of dose-response, drug-drug interactions, and general patient compliance with medications. Bleeding risk among elderly on warfarin therapy increases with age (≥75 years: 9.9% vs. <70 years: 6.6%, $P = 0.7$) but significantly higher risk of intracranial hemorrhage (ICH) with age (≥75 years: 1.1% vs. <70 years: 0.2%, $P = 0.05$).[30] Other comorbidities also have an impact on the risk of bleeding with anticoagulation therapy, such as HTN, cerebrovascular disease, ischemic stroke, serious heart disease, diabetes, renal insufficiency, alcoholism, and liver disease.[33] Elderly patients with AF are at higher risk of falls and associated ICH, which has a higher rate of mortality in patients on warfarin (51.8% vs. 33.6% for those without warfarin; $P = 0.007$).[11] However, the author concluded that high risk of falling should not outweigh the benefit of anticoagulation therapy for AF patients with high risk of stroke (CHA2DS2-VASc >4).

Technological improvements of SCS devices and improvement of specialists' techniques in SCS implantation contributes to a reduced rate of complications. However, a choice of percutaneous lead or surgical paddle lead implantation must be strongly calculated with regards to previous spine surgery with the development of epidural fibrosis and the location of epidural lead placement in consideration of catastrophic complications (e.g., death or permanent paralysis due to thoracic epidural hematoma).[4] Whereas, IDDSs may carry a lower risk of epidural hematoma due to lack of veins in the intrathecal space except for the risk of bleeding with the insertion of a catheter and accidental catheter tip mobility or displacement. The epidural space has a rich network of valveless veins, lymphatics, segmented arteries, and highly vascular inner edge of dura matter, which can be presumed to have a high risk of spontaneous bleeding in permanent lead placement with chronically anticoagulated patients. Hence, long-term risks of implantable devices in chronically anticoagulated patients remain to be addressed by neuromodulation community.

Percutaneous implantation, while being fluoroscopically guided, is essentially a blinded advancement (vis-à-vis the vessels) of leads along the epidural space into a superior position to the site of pain. Percutaneous leads proved to have a relatively easy access to the epidural space at any level except for areas of previous posterior lumbar fusion, severe spinal stenosis, or laminectomy, due to obstructive or narrower spaces to advance leads along the epidural space. Bosscher and Heavner examined 78 FBSS patients with epiduroscopy, which revealed severe epidural fibrosis in 83.3% of all patients and significant fibrosis in 91.0%

of patients.[4] They also noted that the severity of fibrosis was more prevalent (more than 90%) in patients with a history of extensive spine surgery. Standard preprocedural evaluation with MRI revealed epidural fibrosis only in 16.1% of all patients which was statistically different to the epiduroscopy findings. Dr. Pahapill presented a number of technically failed percutaneous SCS trials due to previous epidural scarring, obstructive spinal instrumentation, excessive spinal scoliosis, lead migration during the outpatient trial period, ongoing warfarin therapy, or previous spinal cord tumor resection.[29] The author suggested an alternative SCS trials for these patients by utilizing a surgical paddle lead trial, which had 100% adequate pain coverage, which translated to 73% (16 out of 22) fully implanted patients. Similarly, Kumar et al. identified 54 patients who underwent surgical lead placement under spinal anesthesia with more than 50% (34 patients) of patients who had previous failed percutaneous lead implantation.[19] Surgical paddle leads generally required fewer reoperations than percutaneous SCS leads (7.7% vs. 10.7%, adj. P < 0.0002) among 4536 patients in each group according to Babu et al.[1]

Surgical paddle leads have advanced in their size, which allows for directly visualized placement through a small laminotomy during paddle implantations. Surgical paddle leads placement allows the interventionist to control the critical time: Stopping and restarting anticoagulants, visualizing level of bleeding, and controlling the amount of trauma. Leads are inserted superiorly from the surgical site after minimal decompression and laminectomy which are performed under direct visualization of the epidural space.[19] Intraoperative efficacy trial can be performed prior to permanent attachment of leads with specialized cement, which prevents lead migration and fracture (commonly observed with percutaneous leads). Micromotion trauma is also eliminated as the leads migration and catheter micromotions are nonexistent compared to percutaneous leads as a result of dermal level fixation. Dr. Pahapill's case series reported no infections, paddle lead migrations, or revisions in 16 implanted patients during an average 23 months follow-up.[29] Visualized implantation and removal of surgical paddle leads allow control of the surgical site hemostasis and limit the number of times to stop anticoagulation (one time compared with two or more times).

Even so, surgical paddle leads have shown to be an excellent alternative to percutaneous leads. Specialists must be versed in both procedures (percutaneous and surgical implantation) prior to initiating SCS trial in carefully selected patients where an adequate risk-to-benefit ratio must be determined with proposed interventions, ongoing therapies, and comorbidities. It should also be imperative that these considerations should not delay an SCS trial. The ProCESS study evaluated more than 50% of patients with more than one low back surgery, and a delay of SCS implantation averaged 4.7 years.[35] Furthermore, Kumar et al. suggested a common paradigm among clinicians to consider SCS therapy as a last resort measure, which led to a higher number of failed SCS interventions with a linear correlation for implantation delay.[18] A retrospective analysis of 437 SCS patients was conducted by Kumar et al. who presented a staggering 65.4 months delay in SCS implantation from the onset of chronic pain.[20] Patients were managed for their pain by family physicians for 11.9 months, and specialists managed pain for an additional 39.8 months. Interestingly, neurosurgeons and neurologists referred patients for SCS implantation after an average of 32 months, whereas nonimplanting anesthesiologists and orthopedists referred their patients after 58.08 months and 51.6 months, respectively.[20]

Elderly patients on chronic anticoagulation therapy present with a series of risks: Spontaneous and induced bleeding, clot formation upon discontinuation of anticoagulation therapy or poor compliance, adverse events due to polypharmacy, and impending consequences of interventions or multiple comorbidities. An experienced and closely involved specialists would help the SCS or IDDS candidate patient make an appropriate decision for the most optimal therapeutic choice. More so, this clinician will anticipate possible complications either as a collaborative or individual effort for the best outcome in patient's well-being with close monitoring and appropriate patient education for complications. Although there presently exist no "gold standard" guidelines which are evident from literature evidence, such guidelines would be useful if forthcoming. Clinicians have a duty not abandon their patients during periods of intense suffering. Therefore, we call on all clinicians invested in the process of providing invasive pain-relieving modalities to agree on further collaboration with manufacturers involved with SCS therapy to develop guidelines that will address the real concerns associated with the use of these devices in chronically anticoagulated patients.

CONCLUSIONS

To the best of our literature review, we could not identify an actual number of SCS implantation for patients using chronic anticoagulation. Thus, we remain unaware of the true incidence of complications that can arise in a pain population on chronic anticoagulation with neuraxially implanted devices. We have highlighted concerns with chronic anticoagulation and spinal implantable devices in our patient so that manufacturers and the clinical pain management community continue to assess risks and create appropriate guidelines and warnings in long-term use of implantable neuromodulators with chronic anticoagulants. These guidelines and warning

should differ from current evidence supported guidelines regarding neuraxial injections and minor procedures. Furthermore, we would like to advocate for different considerations among anticoagulated patients referred to the interventional pain specialist, who should base a therapeutic decision on most recently proposed guidelines and weighing on the risk-to-benefit factors when implanting spinal devices.[25] Furthermore, we believe that a specialist must be versed in the percutaneous lead and surgical paddle lead implantation similarities and differences when advising the prospective SCS patient presenting with severely obstructed epidural space.

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Conflicts of interest
There are no conflicts of interest.

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