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Case Information

Presenting Symptom: Warfarin use during SCS trial

Case Specific Diagnosis: Anticoagulation in SCS

Learning Objectives:

- To review the Neurostimulation Appropriateness Consensus Committee (NACC) and American Society of Regional Anesthesia & Pain Medicine (ASRA) anticoagulation guidelines during spinal cord stimulation trials
- To provide a framework for decision making when guidelines are not followed

History:
A 63-year-old male with a PMH of atrial fibrillation (currently on Warfarin) and chronic low back pain s/p lumbar laminectomy and fusion from L3-L5 three years ago. Pain is located diffusely in the lumbar spine but is worse in the midline around his surgical incision. The pain radiates into the LLE down to the lower leg and is worse with activity. He denies any weakness, but reports he does occasionally get numbness/tingling in the LLE.

After surgery the pain was initially improved, but it has steadily increased to pre-surgery levels. He has tried physical therapy, multiple medications including gabapentinoids and TCAs, and "some back injections" at an outside facility. He rated his pain 7/10 on average. The pain was negatively impacting his ability to go on walks with his wife, sit for prolonged periods, and sleep well. None of these treatments have provided satisfactory pain relief.

Pertinent Physical Exam Findings:

- Slowly ambulates into exam room with forward-leaning posture
- Bruising noted on bilateral upper extremities
- Able to heel/toe walk
- Well healed incision in lumbar spine over spinous processes, no erythema, allodynia, or swelling

- Diffuse tenderness to palpation throughout low back, worse at midline and around incision
- Severely limited ROM with both lumbar flexion and extension due to low back pain
- Strength testing is limited due to low back pain, but is at least 4/5 throughout BLEs - no focal deficits
- Sensation intact to light touch throughout BLEs
- Reflexes 2+, symmetric, throughout BLEs
- Palpable pulses at DP and PT in BLEs
- Straight leg raise unremarkable

Diagnostic Imaging and Results:

- Basic labs (All WNL)
- Coagulation panel (PT: 34 seconds, INR: 2.6, PTT: 32 seconds)
- Recent lumbar x-ray
    - s/p lumbar laminectomy and fusion with intact hardware from L3-L5
    - no signs of hardware loosening or failure
    - diffuse LDDD
    - no significant spondylolisthesis identified
- Recent lumbar MRI
    - no spinal stenosis identified
    - moderate bilateral L3 nerve impingement at L3-L4 and mild right L4 nerve impingement at L4-L5

Diagnosis:

- Failed Back Surgery Syndrome

Medications and Interventions:

Because conservative and interventional measures have failed this patient already, you discuss spinal cord stimulation with the patient. He has persistent axial and radicular pain complaints and spinal cord stimulation currently has USPSTF Level 1A evidence supporting its use in these instances. The patient agrees with our plan and opts to trial a SCS. However, the patient is currently taking Warfarin and has a therapeutic PT/INR, therefore proper planning must take place to manage his anticoagulation throughout the trial and implant periods.

NACC/ASRA Guidelines:

- Bleeding during neuromodulation procedures is relatively rare (0.3-0.7% of cases). However, spinal cord stimulation trial and implant is classified as a high-risk procedure for bleeding due to the use of large gauge needles and stiff epidural leads that are placed within the neuraxis. This puts the patient at risk for epidural hematoma. Additionally, due to the history of previous back surgery, the epidural space venous plexus may be distorted, further increasing his risk of bleeding.
- The discontinuation of anticoagulation therapy in this patient warrants consideration of the risk-benefit ratio. Stopping the anticoagulation medication places him at risk of thrombus formation and cardiovascular/neurologic issues. However, sufficient time is

needed to properly trial the SCS. Overall, limiting the length of time of the SCS trial is recommended.

- With this in mind, Khan et al. reported on the rates of adverse events following SCS placement in 225 patients of which 43 were on at least one anticoagulant medication. All of the medications were held according to 2017 NACC guidelines. Adverse events were defined as hematoma formation, gastrointestinal bleed, myocardial infarction, stroke, deep vein thrombosis, pulmonary embolism, infection, and mesenteric ischemia. In the 43 "anticoagulant suspended" patients, 46 surgeries were done and four adverse events occurred (two hematomas, one intracranial hemorrhage, and one infection). Two events occurred in the 39 cases on one anticoagulant and two events occurred in the seven cases on two or more anticoagulants. Overall, anticoagulation was determined to have no significant effect on rates of adverse events. However, when comparing cases without anticoagulant use with those with two or more anticoagulants (both being bridged on/off enoxaparin for chronic warfarin use), a significant effect of anticoagulant use on risk of adverse events was determined ($p<0.05$). When patients were further split into groups determined by the type of anticoagulant used, it was found that enoxaparin prior to surgery had a significant effect on risk of adverse events ($p<0.01$). All other anticoagulant medications or combinations of anticoagulants were determined to not significantly effect surgery outcomes. They concluded that there was no risk of adverse effects with anticoagulants, but special care should be used when bridging for epidural lead placement with enoxaparin.
- A thorough discussion of procedural risk and patient's risk of VTE should occur with the team managing the patient's anticoagulation medications.
- NACC/ASRA guidelines recommend discontinuing Warfarin five days before the epidural trial leads are placed. The pain physician should also have laboratory evidence of normal INR (<1.2) before proceeding.
- Throughout the trial period, the patient should remain OFF of anticoagulation.
- NACC/ASRA guidelines recommend restarting anticoagulation 24 hours after the trial leads are removed.

Table 1. The NACC Recommendations for Commonly Used Medications and Neurostimulation Placement

Medication	**Discontinue -> Procedure**	**Procedure -> Restart**
Warfarin	5 days, INR <1.2	24 hours
Aspirin (1° prophylaxis)	6 days	24 hours
Diclofenac	1 day	24 hours
Ibuprofen	1 day	24 hours
Naproxen	4 days	24 hours
Meloxicam	4 days	24 hours
IV Heparin	4 hours	24 hours
Subcutaneous Heparin	8-10 hours	24 hours
LMWH (prophylactic)	12 hours	12-24 hours
LMWH (therapeutic)	24 hours	12-24 hours
Clopidogrel	7 days	12-24 hours
Dabigatran	4-6 days	24 hours
Rivaroxaban	3 days	24 hours
Abciximab	2-5 days	8-12 hours

Case:

After discussion with the patient's primary team, his Warfarin was discontinued five days before trial lead placement. Upon arrival to the hospital on the morning of surgery, a PT/INR was checked and these lab values were normal (INR 1.1). The SCS lead placement was successful and the patient was discharged home with plans for a three day trial. On POD#1 a phone call was placed to the patient to check on his response to the SCS. He reported that his pain was dramatically improved, but he had taken his Warfarin by accident. He denied any new motor or sensory abnormalities and the lead placement site was clean and dry. He was instructed to refrain from taking any additional Warfarin during the trial period and to call the clinic or go to the ER immediately if he experienced any new neurologic symptoms. Phone calls were placed to the patient daily and the trial period progressed uneventfully.

Case Discussion

- The patient accidently took his Warfarin during the SCS trial period. This puts the patient at increased risk of developing an epidural hematoma.
- The risk of bleeding and subsequent epidural hematoma is highest during placement and removal of SCS leads. Therefore, the trial leads should be left in place following the patient taking his Warfarin. The leads should only be removed when the labs are back to baseline levels.

Treatment Plan:

The patient underwent a three-day trial period and on POD#4 the patient returned to the hospital. Upon arrival to the preop area, an updated PT/INR was drawn and showed normal values. Because the patient had no clinical signs or symptoms of bleeding and the PT/INR was normal, the trial leads were removed. Per NACC/ASRA guidelines, the patient was restarted on Warfarin 24 hours after the trial leads were removed.

Take Home Points:

- The NACC/ASRA anticoagulation guidelines were designed to assist interventional pain physicians in providing safe care. As medicine becomes increasingly complex it is necessary understand the best practice guidelines, to apply them to each unique patient and clinical circumstance, and to communicate with colleagues involved in our patient's care.
- In regards to Warfarin, it is recommended that it be stopped five days before trial lead placement. Throughout the trial period, the patient should remain off any anticoagulation medications. Following removal of the trial leads, the patient can resume Warfarin after 24 hours.
- If guidelines are not followed, it is best to take a conservative approach. Communication with the patient during these instances is extremely important. If the patient consumes anticoagulation medication during the trial period, the leads should be left in place and labs should be rechecked to ensure coagulation status is back to normal before they are removed. Remember, the risk of epidural hematoma is highest during placement and removal of the leads.

References:

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