In Response

To the Editor:

We thank Drs. Veech, Barna, and Stojanovic for their interest in our article (1). At the time of publication, there was only one reported case of bleeding that was specifically associated with a spinal cord stimulator (SCS) lead (2). We believe indwelling catheters and leads pose an increased risk of bleeding, when compared to single shot procedures (1). SCS implantation would be assigned a technique related bleeding risk score (T_{BR}) between 6 (medium) and 8 (high) (1). Aspirin and thienopyridine derivatives pose a moderate risk of bleeding, according to our patient-related bleeding risk scoring system (P_{BR}) (1). Even if both factors are considered, we could not address the question you pose—what is the bleeding risk in those patients, with existing SCS systems, who initiate thienopyridine or other anticoagulant therapy? Unfortunately, there is no data.

However, we share your concerns. We have presented similar questions to European colleagues. SCS systems are routinely implanted for cardiac and vascular disease in Europe. We have not received a satisfactory response. Several published reviews and recent clinical trials, on spinal cord stimulation for angina and peripheral vascular disease, fail to address these issues (3-7). In fact, one paper from your center described implantation of an SCS system in a patient that developed complex regional pain syndrome, following a myocardial infarction. There was no mention of anticoagulant use or discussion about this issue thereof (8).

Hautvast et al (3) conducted a randomized controlled trial investigating the efficacy of spinal cord stimulation in the management of intractable angina. Anticoagulation was not listed as a contraindication to enrollment! The authors only queried the patients about their consumption of nitrates, beta-blockers, and calcium channel blockers. In the ESBY study (4), 87% and 7.5% of patients randomized to the SCS arm, consumed anticoagulants and aspirin, respectively. Complications specific to spinal cord stimulation devices were not reported, in both studies (3, 4). Even in a large retrospective multicenter study investigating SCS clinical outcomes in angina (5), inquiries about the consumption of anticoagulants was conspicuously absent.

In a large randomized controlled trial investigating the efficacy of SCS on critical limb ischemia (6), anticoagulation was not listed as a contraindication. Furthermore, enrolled patients were not asked about anticoagulation use. Fortunately, there were no hematomas. Erdek and Staats (7), in a recent comprehensive review of SCS for angina and peripheral vascular disease, noted that the majority of complications included generator site infections, lead migration, and seromas. There were no instances of epidural hematoma.

Some additional factors must also be considered. A fibrous sheath develops around the SCS leads in the epidural space. This has been exploited to facilitate lead revision (9). While performing cervical and thoracic lead revisions, we have similarly encountered fibrous sheaths. Contrast instillation into these sheaths, via an angiocatheter, never demonstrated vascular uptake in our experience. Theoretically, this sheath could protect against lead migration or erosion into epidural vessels. However, several questions arise: (1) when does the sheath form following SCS implantation—when can anticoagulation be restarted following SCS implantation; (2) does the sheath completely encase the lead; (3) could the sheath increase the likelihood of vascular injury—does the sheath tether vessels and increase epidural venous pressure? Leads migrate a substantial portion of the time and require revision (7). In principle, leads may repeatedly be moving on a less discernible scale. Could this repetitive movement cause vascular injury?

Another issue is the diagnosis of an epidural hematoma. The ideal means of diagnosing a spinal epidural hematoma is with magnetic resonance imaging (10). MR imaging can be safely performed in the presence of a SCS system, under certain emergent circumstances (10). Nonetheless, the leading manufacturers of SCS systems consider MR imaging to be a contraindication in the presence of SCS. Arguably, most centers would not obtain an MRI in patients with SCS systems. One may be faced with a delay in diagnosis, if an epidural hematoma does occur.

We applaud Veech et al (1) in sharing their experience about a SCS patient that did not suffer any adverse consequences, when clodiprogel was started. Perhaps, similar, but confidential sharing of information through a database would be useful. We must, however, embrace all potential consequences of sharing data. If a single complication is reported, will pain physicians have the stomach to offer this treatment to prospective patients in our current medico-legal environment?

References

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