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The Neurostimulation Appropriateness Consensus Committee (NACC) Safety Guidelines for the Reduction of Severe Neurological Injury

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Introduction: Neurostimulation involves the implantation of devices to stimulate the brain, spinal cord, or peripheral or cranial nerves for the purpose of modulating the neural activity of the targeted structures to achieve specific therapeutic effects. Surgical placement of neurostimulation devices is associated with risks of neurologic injury, as well as possible sequelae from the local or systemic effects of the intervention. The goal of the Neurostimulation Appropriateness Consensus Committee (NACC) is to improve the safety of neurostimulation.

Methods: The International Neuromodulation Society (INS) is dedicated to improving neurostimulation efficacy and patient safety. Over the past two decades the INS has established a process to use best evidence to improve care. This article updates work published by the NACC in 2014. NACC authors were chosen based on nomination to the INS executive board and were selected based on publications, academic acumen, international impact, and diversity. In areas in which evidence was lacking, the NACC used expert opinion to reach consensus.

Results: The INS has developed recommendations that when properly utilized should improve patient safety and reduce the risk of injury and associated complications with implantable devices.

Conclusions: On behalf of INS, the NACC has published recommendations intended to reduce the risk of neurological injuries and complications while implanting stimulators.

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INTRODUCTION

The use of implantable devices to modulate nerve function has been an important part of the continuum of care for various disease processes in recent years. The techniques include accessing the spinal canal by either percutaneous or open surgical implantation, and accessing the peripheral nervous system, including some cranial nerves (trigeminal, vagus), deep brain targets, and, less commonly, the motor cortex. Recently, an evaluation of the risks of paddle spinal cord stimulation (SCS) leads in the spine was performed and some guidance was given. In that peer-reviewed publication, the device companies assisted the authors in identifying the incidence of problems and possible repercussions, including spinal cord injury (SCI) or major neurological dysfunction (1). That evaluation was an attempt to establish the extent of the problem and to make some recommendations. The issue of spinal cord, dorsal root ganglion (DRG), peripheral nerve and, in some cases, brain injury remains a concern in the practice of interventional pain medicine and neurosurgery. The purpose of this review is to identify possible risk factors and to provide recommendations to reduce the risk of severe neurological injury in our patients.

The International Neuromodulation Society (INS) has identified the potential for neurological injury related to implantable devices as a major healthcare concern in patients with access to these therapies worldwide. In the process of establishing best practices, the INS created the Neurostimulation Appropriateness Consensus Committee (NACC) to review and analyze the available evidence and provide guidance to improve patient safety and therapy efficacy. NACC authors were chosen based on nomination to the INS executive board and were selected based on publications, academic acumen, international impact, and diversity. The members were then given explicit instructions on evidence-based search methods and the completion of evidence scoring in the process of project evaluation. In areas in which evidence was lacking, the NACC used expert opinion to reach consensus. The focus of this manuscript is on safety, and in particular on preventing neurological injury for each area of the nervous system undergoing stimulation, and to recommend mitigation methods as best practices.

METHODS

The NACC reviewed the world literature in English by searching Medline, EMBASE, Cochrane CENTRAL, BioMed Central, Web of Science, Google Scholar, PubMed, Current Contents Connect, Meeting Abstracts, and Scopus to identify and compile the evidence for complications and management of neurostimulation therapies, exclusive of intrathecal therapy, as that was addressed in the Polyanalgesic Consensus Conference update (2). This evidence, obtained from the relevant literature, and clinical experience obtained from the convened consensus panel were used to make final recommendations on improving safety and reducing the risks for neurostimulation techniques.

Evidence Ranking and Consensus Development

As a carryover from the previous NACC publications of 2014, we again updated the literature regarding risk mitigation and safety for neurostimulation techniques. The identified peer-reviewed literature was critiqued using the United States Preventive Services Task Force (USPSTF) criteria for evidence synthesis and level of certainty of net benefit on evidence strength (Tables 1 and 2) (3), or the Centers for Disease Control and Prevention (CDC) evidence rankings when appropriate (4).

The authors were asked to complete evidence and reference forms for their section (Fig. 1), which were then compiled and reviewed by the executive committee and averaged. The working group then developed weighted recommendations based on the evidence ranking, and identified need for consensus when evidence

Table 1. Hierarchy of Studies by the Type of Design (U.S. Preventive Services Task Force, Ref [3]).

Evidence level	Study type
I	At least one controlled and randomized clinical trial, properly designed
II-1	Well-designed, controlled, non-randomized clinical trials
II-2	Cohort or case studies and well designed-controls, preferably multicenter
II-3	Multiple series compared over time, with or without intervention, and surprising results in noncontrolled experiences
III	Clinical experience-based opinions, descriptive studies, clinical observations or reports of expert committees.

was poor. The working group, via in-person meetings, teleconference, or electronic communications, created the consensus, with a quorum defined as 80% of the contributing authors. Consensus strength was described as strong, moderate, or weak, based on agreement (see Table 3).

Critically, this update to the previous NACC publication (5) provides recommendations on identification and management of neurologic injury surrounding neurostimulation modalities, but should not be interpreted to describe the standard of care, and is one of several companion articles being published by the NACC (6,7). Evidence-based medicine and the need for consensus are not juxtaposed positions, as is often described, and the need for clinical relevance and applicability drives the architecture of the paper.

REVIEW OF NEUROLOGICAL COMPLICATION RATES

Spinal Cord Stimulation

The placement of an SCS device into the appropriate anatomical position by definition incurs a risk of neurological injury. This injury may occur by direct trauma, ischemia, compression from bleeding or device volume, infection, or other iatrogenic mishaps. The methods of placement include the percutaneous method by needle or sheath or direct visualization by open laminectomy/laminotomy. A listing of complication rates reported in the peer-reviewed literature is detailed in Table 4.

In a large retrospective review of a MarketScan database over a 10-year period (2000–2009), with specific inclusion of SCI and hematoma within 30 days of the implant, 8326 patients were reviewed (5458 percutaneous vs. 2868 paddle electrodes) (8). The overall incidence was 2.13% (2.35% for percutaneous and 1.71% for paddle electrodes). No distinction was made between temporary or permanent sequelae from the neurologic injury. The incidence of spinal hematoma was 0.71% for percutaneous vs. 0.635% for paddle electrodes. No significant difference was found between either group for SCI. Levy et al. performed a retrospective review on complications associated with paddle type SCS leads via a MAUDE database review (1).

Table 2. Meaning of Recommendation Degrees (U.S. Preventive Services Task Force, Ref [3]).

Degree of recommendation	Meaning
A	Extremely recommendable (good evidence that the measure is effective and benefits outweigh the harms)
B	Recommendable (at least, moderate evidence that the measure is effective and benefits exceed harms)
C	Neither recommendable nor inadvisable (at least moderate evidence that the measure is effective, but benefits are similar to harms and a general recommendation cannot be justified)
D	Inadvisable (at least moderate evidence that the measure is ineffective or that the harms exceed the benefits)
I	Insufficient, low quality or contradictory evidence; the balance between benefit and harms cannot be determined.

Dorsal Root Ganglion Stimulation

The placement of a sheath into the epidural space is required to pass a cylindrical lead over the target dorsal root ganglion (DRG). This currently is being done by the percutaneous method. Current bench and animal work is ongoing to establish a surgical method of placement, but thus far no human experience is available with this method for paddle-type constructs, as they are under development. The complication experience from this form of spinal stimulation appears similar to that of dorsal column stimulation via the percutaneous route (9). Limited data for the European and Australian 1-year experience have shown no major neurological sequelae, and the United States prospective study showed a complication rate equal to that of the conventional arm of treatment. Table 5 shows complication rates and experiences with DRGS in the current peer-reviewed data (Accurate Study).

Deep Brain Stimulation

The placement of a lead into the targets in the substance of the brain lends to the potential of brain injury from direct trauma, bleeding, and infection. The complications rates are detailed in Table 6.

Motor Cortex Stimulation

The placement of an electrode onto the surface of the motor cortex can lead to bleeding, direct trauma, compression of tissue, infection, and seizure. Complication rates are detailed in Table 7.

Peripheral Nerve Stimulation

The placement of a lead in the vicinity of a peripheral nerve can lead to direct trauma, nerve compression, bleeding, or infection. There is a paucity of data regarding the risk of serious neurological complications of peripheral nerve stimulation (PNS).

CAUSATION AND REDUCTION OF NEUROLOGICAL COMPLICATIONS

Percutaneous SCS Methods

The spectrum of neurological complications from percutaneous SCS lead placement ranges from minor complications, such as extraneous evoked paresthesia, to infrequent catastrophic SCI and paralysis. Injury may occur due to needle/introducer device placement,

NACC/PACC Title: .....

Author: _____

Topic: _____

Key Statements (2-5 total)	Supporting References List the references that support the key statement.	Levels of Evidence Use Table 1 below to determine the level of evidence for each reference that supports a key statement.	Recommendation Strength Use Table 2 below to assign a degree of recommendation to each key statement based on the supporting evidence.
1.			
2.			
3.			
4.			
5.			

Figure 1. Contributor evidence assessment.

lead placement/manipulation, lead removal, and to biological reactions to the devices. The patient's pre-existing medical condition and the experience and skill of the implanting physician may contribute to or influence the likelihood of some complications.

The first publication of NACC discussed the frequency of procedural complications related to the device or surgical technique (5). Neurological injuries may occur during needle/introducer placement, lead placement/manipulation, or lead removal. Serious injury may also occur as a result of dural puncture. The incidence of severe neurological injuries is low, although the exact frequency is difficult to determine as many reports are of isolated cases or small series. The recently published American Society of Regional Anesthesiologists Practice Advisory on Neurologic Complications in Regional Anesthesia and Pain Medicine includes some data that pertain to this issue (10). A recently published series by Petraglia et al. examined the incidence of SCI within the 30-day postoperative period following percutaneous and surgical paddle lead implantation (8). That series included 5458 patients who had percutaneous leads and 2868 patients who had paddle leads. The overall incidence of SCI was 2.35% for percutaneous leads and 1.71% for paddle leads. Although the incidence of SCI is low, these numbers are higher than previously thought.

Dural Puncture

Background. Trauma or puncture to the meningeal coverings, typically termed dural puncture, may occur during placement of the introducer needle or the stimulator lead. The possible sequelae of this event include no symptoms, temporary headache, persistent headache, and rarely, neurological injury from intracranial hemorrhage (11–13).

Evidence. The frequency or incidence of accidental dural puncture during nonimage-guided epidural anesthesia is ~1–2% and the risk of headache following dural puncture can be as high as 50–60%, given that large-gauge needles are typically used (14–16). The incidence of accidental dural puncture and subsequent postdural puncture headache (PDPH) occurring from percutaneous SCS needle or lead placement is uncertain, with estimates ranging from 0.2 to 3% (5,17,18). Factors that are likely to increase the risk of dural puncture include a history of previous surgery at the site of needle entry,

Table 3. Strength of Consensus.

Strength of consensus	Definition*
Strong	>80% consensus
Moderate	50–79% consensus
Weak	<49% consensus

*Quorum defined as 80% of participants available for vote.

Table 4. Neurological Complication Rates for Percutaneous and Surgical Dorsal Column Stimulation Leads.

	Percutaneous leads	Paddle leads
Serious neurological complications	0–2.35%	0.54–1.71%
Paralysis/spinal cord injury	0.03*–2.35%	0.022–0.067%
Infection	3–6%	3–6%
Spinal/epidural hematoma	0.75%	0.19–0.63%
Cerebrospinal fluid leak	0.3%	0.05–0.001%

*Based upon on large series (1) of combined percutaneous/paddle leads with one case of paralysis (lead type not specified).

spinal stenosis at the site of needle entry, obesity, and spinal deformities (5,18).

Consensus Point 1. The NACC recommends a review of preoperative advanced imaging, as favorable and unfavorable anatomy can usually be identified and many of the previously mentioned risks can be mitigated with thoughtful preoperative planning.

Most patients can be successfully managed conservatively and most headaches resolve spontaneously within 1 week, but some patients ultimately require either an epidural blood patch or fibrin glue patch (5,19). The decision to utilize a dural patch procedure must be weighed carefully against the risk of doing so around newly implanted hardware, as there is a concern for increasing the possibility of infection, although there are no studies documenting this risk. In young patients, the likelihood of a PDPH is very high following a dural puncture with a 14-gauge needle. A PDPH may interfere with the patient's ability to function during an SCS trial and could render the trial period useless. Currently, there are insufficient data to recommend routine prophylactic epidural blood patch in every case; however, there may be circumstances in which the clinician feels

Table 6. Neurological Complication Rates: Deep Brain Stimulation.

	Percentage
Hemorrhage	1.8%
Infection	1.4–8.5%
Infection/erosion	6.7–20%

performing a prophylactic blood patch is warranted if a dural puncture occurs during the placement of trial SCS leads.

In a prospective study of 22 patients undergoing SCS for painful diabetic neuropathy, one patient experienced a symptomatic PDPH that evolved into a fatal subdural hematoma (20). In a large retrospective review, Cameron reported eight cerebrospinal fluid (CSF) leaks among 2972 patients (0.3%) (21). Mekhail et al. reported complications from SCS in a retrospective review of 707 patients but made no mention of dural puncture (22). Two small prospective-outcome trials reported relatively higher rates of dural puncture. Kemler et al. in 2000 reported an 11% dural puncture rate in 36 patients with complex regional pain syndrome (CRPS) who underwent a trial lead placement (23), and Slangen et al. in 2014 reported a dural puncture in one of 22 patients who had a percutaneous trial lead inserted (20). Eldrige et al. reported a case of successful management of a symptomatic PDPH after percutaneous lead implantation, with no adverse sequelae and continued normal function of the SCS system (19).

Recommendations. The incidence of PDPH from percutaneous lead placement is low in experienced and properly trained hands. Although two small prospective series reported an incidence of 4.5–11%, large retrospective and systematic reviews have demonstrated a much lower incidence with the largest series reporting an incidence of 0.3% (21). Simopuolus et al. recently reviewed placement of 745 leads at an academic institution, with an overall PDPH rate of 0.81% per lead insertion (24). Table 8 presents NACC recommendations regarding dural puncture.

Should a dural puncture occur during a trial lead insertion under local anesthesia, the physician may consider abandoning the trial as PDPH can confound the patient's ability to interpret pain relief from the SCS. There are no definite studies regarding management of PDPH in patients with implanted leads. The NACC believes the most prudent and logical initial treatment is conservative management with recumbency as needed, maintaining adequate fluid status, and administering over-the-counter analgesics for pain. If symptoms persist beyond 5–7 days, then shared decision-making between the implanting physician and the patient may be undertaken to consider the possibility of a fluoroscopic-guided epidural blood patch

Table 5. Neurological Complication Rates: Dorsal Root Ganglion Spinal Stimulation. Safety Results of the ACCURATE Study at 12 Months*.

	DRG group		Control group†		
	No. of events	% subjects with events	No. of events	% subjects with events	*P* value
Stimulation-induced neurological deficit	0	0.0	0	0.0	1.0000
Serious adverse event	8	10.5	13	14.5	0.6248
Device-related adverse event	39	36.8	24	26.3	0.2217
Unanticipated device-related adverse event	0	0	0	0	1.0000

*Unpublished data presented at a CME event at the North American Neuromodulation Society meeting, December 2015.
†Control group treated with Medtronic percutaneous spinal cord stimulation.

Table 7. Neurological Complication Rates: Motor Cortex Stimulation.

	No. of events, percentage
Hemorrhage	11/351 cases 3.1%
Infection/erosion	9/351 cases 5.4%
Seizure	2.8%

(24,25). If possible, fluoroscopic guidance may help localize the necessary interlaminar space where the injury occurred.

In rare cases subdural hematomas have been reported after a SCS dural puncture. The subdural hematoma may result from intracranial hypotension and tearing of the bridging dural veins. Signs and symptoms of concern with a subdural hematoma include neck stiffness, nausea and vomiting, disorientation, and loss of the positional component to headache. If there is a concern for a subdural hematoma, appropriate radiographic imaging should be ordered (26).

Nerve or Spinal Cord Injury

Background. Direct injury to the spinal cord or the spinal nerve roots is possible from needle/introducer puncture or SCS lead trauma of the spinal cord or nerve roots. The frequency of SCI after percutaneous lead placement has been reported to be between 0 and 2.35%. Two large series of complications from percutaneous SCS did not mention any cases of known or suspected SCI (21,22). Recently, Petraglia et al. reviewed the incidence of SCI in 2868 patients in the United States who underwent percutaneous SCS implantation and reported an overall incidence of 2.35% (8). The sequelae of cord puncture may range from no obvious injury to sensorimotor deficits, paralysis, and/or neuropathic pain. It is essential that the implanting physician review advanced preoperative imaging to understand important anatomic concerns, such as the location of the conus medullaris and the presence of anatomic issues that might increase the potential for injury, such as spinal stenosis or a thin ligamentum flavum. There are many different techniques that can be used to identify the epidural space with the introducer needles, including most commonly loss of resistance with air or saline, hanging drop, "feel," and guidewire passage. There are no data on whether one technique is safer than another. Factors that may increase the risk of spinal cord or nerve puncture include previous surgery at the site of needle placement, spinal canal stenosis, and spinal deformity (1,5).

It is likely that the use of deep sedation or general anesthesia increases the risk of unrecognized needle puncture, and unless there is a sound medical reason to the contrary, if sedation is used for the procedure, it should be light enough so that the patient is alert and responsive during needle and/or lead placement and able to accurately report paresthesia sensation (5,10,27).

Epidural hematoma has been reported following SCS percutaneous lead placement and is potentially one of the most serious complications, as it may be associated with long-term neurological sequelae including paraplegia, and often requires major spine surgery to treat (1,5,18,26,28). Epidural hematoma has also been reported with removal of percutaneous SCS leads (28,29). Petraglia et al. reviewed the incidence of epidural hematoma in a large group of percutaneous SCS patients and found it to be 0.71% (41/2868) (8). It is essential to question every patient about bleeding tendencies and the use of coagulation-altering medications, and to examine patients for signs of excessive bleeding or bruising when placing SCS leads. It should be understood that a symptomatic epidural hematoma is a true emergency. Suspected epidural hematoma requires immediate imaging to diagnose and immediate neurosurgical consultation. If surgical treatment is necessary, the ideal time for draining the lesion is within 8 hours of the occurrence in order to assure the best possible outcome, and within 24 hours to reduce the risk of irreversible injury (30).

Evidence. The incidence of nerve injury or SCI is low based on a large body of literature demonstrating low rates of serious neurologic injury or complications. In Mekhail et al.'s retrospective review of 707 percutaneous trial lead placements and 527 percutaneous implants, there were no permanent neurological deficits or deaths (22). Kumar et al. in 2006 reported no serious neurological events in 162 percutaneous lead placements (31). A recently published prospective clinical trial of high-frequency spinal cord stimulation (HF-SCS) noted no neurological events in 82 trials and 72 percutaneous implants (32). Cameron's 20-year review of the literature reported one case of paralysis among 2972 patients, presumed to be related to an epidural abscess from infection. It was uncertain if this was in a percutaneous or paddle case (21). As mentioned previously, Petraglia et al. reviewed the incidence of SCI in 2868 patients in the United States who underwent percutaneous SCS implantation and reported an overall incidence of 2.35% (8).

The true incidence of epidural hematoma from percutaneous SCS placement is unknown but, based upon a large body of literature and only a few isolated cases identified, it is a rare event, although likely underreported. Risk factors include altered coagulation status,

Table 8. Recommendations and Evidence Regarding Dural Puncture by the Neurostimulation Appropriateness Consensus Committee (NACC).

Statement	Evidence level	Recommendation grade	Consensus strength
Dural puncture incidence in experienced hands should be less than 2%.	II-3	B	Strong
After dural puncture, the decision to continue with the procedure at the same spinal level or a different level, or to abandon the procedure is best left to the clinical judgment of the clinician.	III	C	Strong
Prophylactic blood patch should be performed after an inadvertent dural puncture at the time of the incident.	III	C	Weak
In the event of dural puncture, conservative therapy should be trialed first compared to more invasive treatments.	III	B	Strong
If postdural puncture headache lasts longer than 5-7 days, a blood patch may be required.	II-3	B	Strong

Table 9. Recommendations and Evidence Regarding Imaging and Bleeding Risk by the Neurostimulation Appropriateness Consensus Committee (NACC).

Statement	Evidence level	Recommendation grade	Consensus strength
Serious neurologic injury during percutaneous lead placement is low.	II-3	A	Strong
Advanced neuraxial imaging should be performed in the region of anticipated needle placement preoperatively.	III	C	Moderate
Advanced neuraxial imaging should be performed in the location of the ultimate lead placement.	III	C	Moderate
Anticoagulation and bleeding risk should be assessed and managed appropriately.	II-2	A	Strong

spinal stenosis, male gender, and advanced age (5). Clearly, the most significant and manageable risk factor is the coagulation status, and risk factors should be mitigated to the extent possible. It is very important for the implanter to know that epidural hematoma has been reported from withdrawal/removal of percutaneous SCS leads. Accordingly, the implanting physician should be vigilant regarding coagulation status until completion of the percutaneous trial period. A guideline with input from multiple pain and neuromodulation societies was recently published and provides the implanting physician with recommendations for the management of antiplatelet and anticoagulation medications in patients undergoing interventional spine and pain procedures (33). The NACC has also published a companion article with recommendations on bleeding and coagulation management in neurostimulation devices (6).

Recommendations. The incidence of serious permanent neurologic injury from percutaneous SCS lead placement is low, and based upon the published studies is 2.35% or less (8,34).

Consensus Point 2. Percutaneous SCS is a safe and effective strategy for treating neuropathic pain of the trunk and limbs.

In order to minimize the risk of serious neurologic injury from percutaneous lead placement or removal, the NACC recommends the following: preoperative risk assessment and mitigation, and advanced imaging, preferably an MRI of the relevant spinal anatomy looking especially for spinal canal narrowing, scar tissue, and/or ligamentum flavum abnormalities that would potentially predispose the patient to an increased risk of injury. If an MRI is contraindicated, then a CT scan should be sufficient in most cases. If possible, needle placement should be avoided in areas of significant spinal stenosis and/or previous surgical scarring.

Consensus Point 3. Neuraxial advanced imaging is routinely recommended in the location of planned needle entry.

Consensus Point 4. Neuraxial advanced imaging in the location of the ultimate lead placement should be determined based on each clinical scenario, but is recommended with the cervical spine.

The patient should be questioned regarding bleeding tendencies and whether there were concerns about excessive bleeding with previous surgeries, dental procedures, or injuries. If there are concerns about a possible bleeding disorder, consider preoperative consultation with a hematologist. If the patient is on coagulation-altering medications, the implanting physician should consult with the patient's managing physician regarding whether or not such medications can be safely discontinued prior to the procedure and, in the case of a trial, throughout the trial period.

Consensus Point 5. Management of anticoagulant medications for neuraxial procedures has been described and updated within this edition of the NACC (6). We recommend a multidisciplinary approach with management of cessation or continuance of anticoagulants perioperatively.

Consensus Point 6. The placement and removal of SCS percutaneous leads in the presence of altered coagulation increases the risk of epidural hematoma. This is based on numerous series and case reports.

The NACC believes that the implanting physician should not typically make a unilateral decision to discontinue coagulation-altering medications that are being prescribed for stroke or myocardial infarction protection, as there may be significant risks associated with stopping these medications, even for short periods of time. Depending on the result of input from the patient's medical team, bridging with low molecular weight heparin may be necessary. We are in agreement with the recently published multisociety guidelines that shared decision-making between the implanting physician, the patient's prescribing physician, and the patient is an important and essential step in the preoperative planning process (33). Only properly trained and credentialed individuals should place percutaneous SCS leads. NAAC recommendations were outlined in a previous publication (5) and a recent update (6). NACC recommendations regarding imaging and bleeding risk are detailed in Table 9.

Infection and Neurologic Injury

Background. Surgical site infections (SSIs) associated with SCS implantation can lead to serious neurological complications (5,18,35–39). Both epidural abscess and meningitis have been reported in the setting of SCS-related SSIs (5,18,22,35,38–42). If not diagnosed and treated promptly, SSIs can lead to sequelae including paralysis and death. Prompt recognition and appropriate treatment of SCS-related SSI significantly reduces the likelihood of epidural abscess formation and adverse neurological outcome.

Evidence. The incidence of SSI is reported to be between 3 and 6% (5,17,18,21,36,38–40,43). SCS-related infections are broadly categorized into superficial infections, deep tissue infections, and epidural abscess. Fortunately, the incidence of epidural abscess is low. Prompt recognition of a possible infection, followed by expeditious management with appropriate antibiotics and, when necessary, device removal, usually leads to resolution of the infection without neurologic sequelae. A previously published NACC guideline discussed recommendations for infection prevention related to SCS implants (5), and that publication is being updated and expanded this year (7). Epidural abscess related to SCS leads, much as for epidural hematoma, is an emergency.

Recommendations. The NACC recommends that its previously published guidelines be followed for the prevention of SSI related to SCS implants (5,7) (see Table 10). If a deep tissue infection occurs,

Table 10. Recommendations and Evidence for Percutaneous Leads by the Neurostimulation Appropriateness Consensus Committee (NACC).

Statement	Evidence level	Recommendation grade	Consensus strength
To minimize the risk of epidural hematoma, the patient's coagulation status should be optimized.	II-3	B	Strong
For patients taking coagulation-altering medications, the relative safety and timing of temporarily discontinuing anticoagulation medication(s) and the need for bridging therapy should be coordinated with the patient's prescribing physicians.	II-3	A	Strong
Surgical site infection (SSI) can lead to severe neurologic injury (44), and risk-mitigating strategies should be employed as recommended (5,7).	I to II-3	A	Strong
Intraoperative sedation should be used to maintain a quiet operative field and allow for an appropriate response to avoid direct spinal cord or nerve injury.	III	B	Moderate
Intraoperative neural monitoring is helpful in mitigating direct neurologic injury and should be considered when appropriate.	II-2	B	Moderate
Dorsal root ganglion stimulation is a safe strategy to treat refractory pain, and neurologic injury is rare and its incidence similar to SCS.	II-3	A	Strong

the device should be explanted and appropriate tissue and fluid bacterial cultures and antibiotic sensitivities should be obtained. The NACC recommends consultation, if available, with an infection control expert or medical microbiologist to outline appropriate antibiotic therapy. If there are sensorimotor signs or symptoms, intense local pain, or meningism that suggest possible epidural involvement, an MRI or CT scan should be obtained. Even in the absence of signs or symptoms, MRI imaging, if possible, is suggested to rule out subclinical epidural involvement, as this would potentially affect duration of antibiotic therapy. If there is evidence suggestive of epidural involvement, a spine surgeon should be consulted. Small and asymptomatic epidural abscesses can be managed expectantly but this requires close neurologic surveillance.

Consensus Point 7. Management of risk mitigation and surgical site infection are crucial to a successful outcome. These points were reviewed and graded in a companion paper (7). To summarize, preoperative, intraoperative, and postoperative strategies need to be employed to improve outcomes, with vigilance, appropriate imaging, and expert consultation performed when needed.

Foreign Body Reaction

Background and Evidence. As foreign bodies, SCS leads may be expected to create a host reaction. Adverse outcomes due to epidural fibrosis and/or peri-SCS lead granulomatous masses have been reported (45–48). Recently, Scranton et al. reported a case of loss of stimulation efficacy followed by the development of spastic quadriparesis in a patient with a percutaneous cervical spine SCS lead (48). Imaging revealed a mass around the distal end of the SCS lead. Surgical decompression revealed fibrotic/granulomatous tissue. The patient's condition improved after decompression.

Recommendations. Host reaction leading to fibrous tissue formation is a recognized phenomenon with SCS implanted hardware. In most instances, the worst case outcome is an alteration in paresthesia perception and/or stimulation parameters, and only very rarely does the reaction lead to neurological injury.

Consensus Point 8. The NACC recommends that any new neurological signs or symptoms in a patient with percutaneous SCS leads be evaluated immediately. This includes a detailed physical examination specifically looking for signs of radiculopathy or radiculomyelopathy. There should be a very low threshold for ordering advanced imaging and neurosurgical consultation in this setting.

Paddle/Open Surgical Methods

Background

Neurological injury is a rare, but serious, complication of SCS. Intraoperative injury is possible during implantation, and in the postoperative period epidural hematoma can be a cause of neurological deficit. This can occur both with percutaneous or laminotomy electrode placement. In addition, although rare, there have been reports of percutaneous needle placement resulting in direct penetration of the spinal cord or nerve root (49).

Evidence

A review of the literature demonstrates that many publications do not report the incidence of neurological injury, and a literature search for neurological injuries associated with SCS yields very little. This is secondary to neurological injury being a rare occurrence that is difficult to comment upon with traditional study sample sizes. Mekhail et al. reported having no neurological complications in a review of more than 700 patients (22). Case reports describe the development of an epidural hematoma following electrode placement via laminotomy (50) and also during the trial phase (51). Smith et al. reported on a case series of four patients experiencing neurological injury during the trial or following implantation, which included percutaneous leads for the trial and either percutaneous or paddle leads for the permanent implantation (52). One of the injuries was secondary to cord contusion in a patient having a permanent implantation with a paddle electrode, while the other three were secondary to cord compression with percutaneous leads. Two of these compressions were due to epidural hematomas and one secondary to implantation in the setting of broad-based thoracic disc herniation. Recently, Petraglia et al. reviewed the incidence of SCI and epidural hematoma in a large group of American patients undergoing paddle lead SCS implantation (8). Of 5458 patients, 49 (1.71%) reportedly had evidence of SCI and 10 (0.63%) had evidence of epidural hematoma. This study was performed using an analysis of diagnosis codes from the Thomson Reuter's MarketScan database. Diagnosis codes confirmed either SCI or epidural hematoma; however, long-term outcomes were not assessed.

In 2013, Bendersky and Yampolsky performed a nonsystematic literature review dealing with complications associated with SCS

Table 11. Neurologic Injury Following Implantation of Spinal Cord Stimulation Paddle Electrodes in 44,587 Patients (1).

Adverse event	Rate No. (%)	Outcome No. (%)
Major motor deficit	111 (0.25)	
Complete recovery		30 (27.0)
Partial recovery		34 (30.6)
Not recovered		16 (14.4)
Unknown		31 (279)
Limited motor deficit	61 (0.14)	
Complete recovery		24 (39.3)
Partial recovery		16 (26.2)
Not recovered		2 (3.3)
Unknown		19 (31.1)
Autonomic changes	6 (0.013)	
Complete recovery		2 (3.3)
Partial recovery		0 (0.0)
Not recovered		2 (33.3)
Unknown		2 (33.3)
Sensory deficit	46 (0.10)	
Complete recovery		21 (45.7)
Partial recovery		7 (15.2)
Not recovered		0 (0.0)
Unknown		18 (39.1)
Cerebral spinal fluid leakage due to a dural puncture	21 (0.047)	
Complete recovery		11 (52.4)
Partial recovery		1 (4.8)
Not recovered		0 (0.0)
Unknown		9 (42.9)

Reprinted with permission from Levy et al. *Neuromodulation* 2011;14:412–422 (Table 5).

placement (17). They determined that epidural hematoma formation and SCI were rare occurrences. Epidural hematoma incidence was reported at ~0.19%, with SCI being reported as having extremely low frequency. Levy et al. performed the same type of literature search specifically for patients in the United States, and their conclusion was that the best source of pertinent data was the device manufacturers' own databases (1). Data collated from this investigation on the incidence of neurologic injury following implantation of SCS paddle electrodes are presented in Table 11. During the 3-year period, 44,587 paddle electrodes were implanted, and 239 (0.54%) neurologic complications were reported. An additional 21 (0.05%) cases of CSF leak were reported.

In the evaluation of cases by Levy et al., the total percentage of patients who permanently lost motor function, with or without an epidural hematoma, ranged from 0.022 to 0.067% (1). Sensory deficit was reported in 46 cases (0.1%) of SCS paddle lead patients, with complications consisting of sensory deficit only; 21 (46%) recovered completely, 7 (15%) recovered partially, and recovery was not reported in 18 (39%). Autonomic changes, including bowel and bladder dysfunction (e.g., incontinence) or sexual dysfunction, occurred in 6 (0.013%) of 44,587 patients. Two recovered fully (33%), two did not recover (33%), and results were not reported in two (33%).

Given the possibility of patient movement and discomfort with awake placement of stimulators, some have advocated for placement of spinal cord stimulators in an asleep patient, which involves placing the patient under general anesthesia and utilizing electromyography (EMG) responses or somatosensory evoked potential (SSEP) collision testing to determine whether the patient has adequate paresthesia coverage. Neuromonitoring is used to determine myotomal coverage, as a marker that corresponds with dermatomal coverage in the case of using EMG responses (53,54), while SSEP collision testing uses the elimination of sensory responses with stimulation as a marker of paresthesia coverage. Several studies have shown this method to be as safe and efficacious as implantation in awake patients and it may lead to fewer adverse events (AEs) (54,55). The implantation procedure in asleep patients was also shown to have a 33% decrease in intraoperative time compared to the awake surgical technique (55).

Recommendations

Neurologic injury is a rare but serious complication of SCS paddle electrode implantation, with potential direct injury occurring during placement or occurring secondary to an epidural hematoma immediately or in a delayed fashion. Few cases have been reported in the literature, with the few studies demonstrating a very low risk of neurological compromise. The incidence of SCI is reported between 0.19 and 1.71%. Implanters should be aware of the risks (Table 12).

Consensus Point 9. Complications of SCS paddle lead placement can be direct trauma, or secondarily with early- or late-onset epidural hematoma. These complications are relatively rare, and patient selection, risks, and benefits need to be assessed prior to proceeding.

Deep Brain Stimulation

Introduction

Placement of stimulating leads within the brain in a variety of targets (deep brain stimulation or DBS) has been used for several disorders including Parkinson's disease, tremor, dystonia, chronic pain, severe refractory cluster headaches, obsessive-compulsive disorder (OCD), depression, anxiety, addictive disorders, eating disorders, and epilepsy. While DBS continues to be effective for several of these disorders, many other indications continue to be studied for efficacy and safety. Complications of this therapy include hemorrhage, infection, skin erosions, stroke, seizures (either during surgery itself or in follow-up longer term), and adverse neurological or psychiatric changes. It is worth considering the two main complications (hemorrhage and infection), because they both have a significant effect on how patients perceive the procedure, as well as determining the comparative risk of alternative therapies.

Beyond simply assessing these complication rates, it is helpful to render a recommendation for the most commonly encountered decisions regarding DBS therapy. These include: whether or not to operate on patients of advanced age or with poorly controlled diabetes or hypertension; should infected or eroded hardware be completely removed or can it be salvaged, either in part or wholly; and whether there is increased risk of hemorrhage in traversing the ventricular wall with a microelectrode or DBS lead itself. Although many relatively large series have been published, primarily discussing results and efficacy of DBS, this review specifically focuses more on series and reviews that assessed the question of hemorrhage and infection risk. Within that context, other questions regarding patient comorbidities and techniques could also better be evaluated. NACC recommendations for DBS are detailed in Table 13.

Hemorrhage Risk

Background and Evidence. Six major papers specifically evaluated hemorrhage risk in DBS and/or stereotactic procedures, including

Table 12. Recommendations and Evidence for Paddle Leads by the Neurostimulation Appropriateness Consensus Committee (NACC).

Statement	Evidence level	Recommendation grade	Consensus strength
Neurological injury is a rare, but serious, complication of SCS.	II-3	A	Strong
Neurological injury can occur with percutaneous or laminotomy electrode placement.	II-3 to III	B	Strong
The risk of permanent neurological deficit is extremely rare and can occur from spinal cord contusion and/or epidural hematoma.	II-3	A	Strong
Intraoperative risk can be mitigated by awake placement or asleep placement with appropriate intraoperative monitoring and interpretation.	III	B	Strong

ablation and biopsy procedures, spanning from 2002 through 2015 (56–61). One hundred sixty-two hemorrhages were described in 9065 patients/procedures, which are mixed and sometimes not clearly separated. Some patients may be duplicated in different series. The resulting rate of hemorrhage is 1.8%. Most of the hemorrhages were symptomatic, but if all *asymptomatic* hemorrhages were included in published totals the rate would likely be higher. This total includes the 4961 patients reviewed by Rughani et al. (60) from The Nationwide Inpatient Sample (Agency for Healthcare Research and Quality, Rockville, MD, USA), wherein the rate was 1.75%. Attempts were made to include only DBS procedures when discrete data were available. These series include single-center and surgeon-series over many years, and DBS procedures outside the United States as well as the large American national database; the complication rates appear to be internally consistent. Additionally, most of the large series of DBS cases studying efficacy were included in the literature reviews of these papers and are thus included in these totals.

Recommendations. The primarily symptomatic hemorrhage rate of 1.8% for DBS procedures does not appear to be a hindrance to pursuing this therapy, and is within accepted rates for other invasive brain procedures.

Consensus Point 10. DBS is safe strategy for the treatment of movement disorders, and has a hemorrhage rate in line with other intracranial brain procedures.

Infections and Skin Erosions

Background and Evidence. There are three primary sources for infection data in DBS procedures: Sillay et al. 2008 (62), Sixel-Doring et al. 2010 (63), and Piacentino et al. 2011 (59). If skin erosions are included and data are only taken from follow-up within the first year, the combined overall rate of either infection or erosion is 6.7% (41/611) in the first year. But there are two caveats that are important in assessing these data. First, DBS typically involves at least two incisions per side, with four incisions that need to heal in patients with bilateral implants. If there is staging of procedures, the lead wire is often coiled under the scalp and the incision re-opened to place implantable pulse generators (IPGs) later, thus requiring that incision to heal twice on the scalp, potentially requiring the healing of six incisions to avoid a single erosion and infection. Very conservatively, then, one might divide the infection and erosion rate by six to obtain the actual *incisional* rate—approximately 1.1%—which is very similar to typical infection rates in *all* surgeries.

However, not all patients have staged procedures, or even use two IPGs, having a Kinetra IPG implanted, for example. So the true incisional infection/erosion rate is unknown, as more refined data are simply not available in most studies. The authors of these studies have made attempts, however, to break down the data sufficiently to estimate infection/erosion per procedure. Sillay et al. report their per incision rate as 1.4%, but per patient rate as 4.5% (62). Piacentino et al. reported a higher rate of 4.5% per procedure and 8.5% per patient (59).

Second, credible evidence from Sixel-Doring et al. demonstrate that a large number of erosions or infections can occur after the first year—40% in their series (63), resulting in a cumulative 24.7% of all consecutive patients who had DBS over >5 years developing erosion or infection. If that is representative of all centers, and there are no other reliable data for this yet, it is a notable finding.

Recommendations. The per-incision infection rate appears to be similar to the infection rate of most other single-incision surgeries—perhaps slightly higher, which would not be surprising as DBS hardware is implanted in the subcutaneous tissue atop bone (in the scalp at least). It is important for authorities that insist on measuring infection rates that the differences between typical infection rates in single-incision surgeries are appropriately compared to these multiple-incision surgeries. Often the per-patient infection rate is used. Overall, on a per-incision basis, DBS is recommended for indicated uses. On a per-patient basis, the rate is higher and does not compare favorably with most other surgeries, especially if erosions and the need for revision are included. These rates over longer follow-up periods may show that infection and/or erosion occur in

Table 13. Recommendations and Evidence for Deep Brain Stimulation by the Neurostimulation Appropriateness Consensus Committee (NACC).

Statement	Evidence level	Recommendation grade	Consensus level
Bleeding risk for DBS procedures is similar to that of other intracranial procedures and is not prohibitive in the DBS applications, including movement disorders.	II-3	B	Strong
Infection rate associated with these DBS procedures is similar to other surgeries, when defined as incisional rate per incision, and should not preclude clinicians from offering this therapy to patients.	II-3	B	Moderate

Table 14. Recommendations and Evidence for Motor Cortex Stimulation by the Neurostimulation Appropriateness Consensus Committee (NACC).

Statement	Evidence level	Recommendation grade	Consensus level
MCS is a valuable tool in the treatment of refractory neurolgic disorders.	II-3	B	Strong
MCS has an incidence of bleeding that does not preclude the use of the therapy.	II-3	A	Strong
When MCS is complicated by an infection, timely and appropriate treatment is critical, and risk- mitigating strategies should be employed.	II-3	B	Strong
Seizure is a common complicating feature of MCS and resources for seizure management should be available.	II-3	B	Moderate
Prophylactic seizure treatment should be employed mindfully in MCS therapy.	III	I	Moderate

20–25% of all patients. Patients should be appropriately apprised of these data during the consent process.

Consensus Point 11. Infection rates vary based on how they are defined: per incision or per patient. Overall, an informed consent for the procedure should discuss these new infection rates.

Patient Selection and Technique Decisions

Surprisingly, there are no significant overall data supporting higher hemorrhage rates for DBS procedures in patients >70 years old, hypertensives, diabetics, or smokers. There was only a slightly higher overall complication rate in-hospital for patients >70 years old from the large Rughani et al. U.S. database review (60). Nor has there been a clearly higher infection rate in older patients. Salvaging hardware erosions and infections may be reasonably attempted based on the Sillay et al. study, as single-site removals (e.g., of the IPG only) were successful 64% of the time (62). Overt infections, especially involving all hardware, continue to warrant complete removal of the system. Finally, traversing the ventricular wall increases the hemorrhage rate based on findings in the Ben-Haim et al. study (56), and is taken as a truism in the field anecdotally.

Motor Cortex Stimulation

Introduction

In 1991, Tsubokawa et al. (64) first reported their experience in 12 patients with deafferentation pain treated with epidural motor cortex stimulation (MCS). A continuously stimulating electrode was placed epidurally such that stimulation of the underlying cortex produced motor contractions in the painful region. Since that report, placement of epidural strip/plate electrodes over the motor cortex has been tried for several disorders including chronic pain (post-stroke central pain and other types), Parkinson's disease, and stroke rehabilitation. Complications of MCS may include hemorrhage, infection, and seizures (either during surgery itself or in follow-up longer term). Other complications may occur with procedures of this nature (i.e., any complication related merely to performing a craniotomy), including hemorrhage, stroke, or death. We will consider the larger studies to date in compiling and analyzing the complication profile of MCS.

More than 500 cases of MCS have been reported in the literature to date, though many of these reports involve very few patients. Because MCS is performed in substantially the same way regardless of the clinical indication, complications are evaluated together. There are several variations in technique (e.g., trialing the lead, subdural lead placement), but too few cases to make any firm judgment about differential complication rates with those technique variations. This analysis, therefore, considers only studies with 10 or more patients. One study was prospective and randomized with 10 total patients where only six were surgical, but was included because it was a higher quality study.

Complications included only four categories: infection (either IPG site or craniotomy site), hemorrhage, seizures (in testing, programming, or long-term—per patient, not total number of seizures), or stimulation-related paresthesias (either transient or recurring). These studies combined to include 351 patients. Overall, combining these four categories of complications resulted in a maximum of 14.5% complication rate if all occurred in separate unique patients (non-overlapping). In general, however, rates within each category are not too dissimilar from those found using other implantable device technologies.

NACC recommendations for MCS are detailed in Table 14.

Hemorrhage

Background and Evidence. As the majority of MCS procedures implant electrodes in the epidural space, hemorrhage most often manifests itself as epidural, rather than intracerebral, bleeding. Saitoh et al. (65) placed electrodes in the subdural space instead, and 2 of the 19 patients experienced intracranial hemorrhage resulting in significant neurologic deficits. Monsalve's review included only 1 hemorrhage (epidural) in a total of 118 trialed patients, almost all of whom had epidural electrodes (66). The combined MCS literature reveals a 3.1% (11/351) incidence of hemorrhage.

Recommendations. Surgeons implanting MCS systems should take extra care in obtaining hemostasis prior to closing. Dural tack-up sutures may help prevent an epidural hematoma from spreading further than the craniotomy site. If the electrodes are placed in the subdural space, care should be taken to ensure that the electrodes do not impinge on the bridging subdural veins.

Consensus Point 12. Motor cortex stimulation is complicated by hemorrhage with an incidence higher than other neurostimulation strategies. As with any surgical procedure, vigilance with hemostasis prior to closing is recommended.

Infection

Background and Evidence. Analysis of the MCS literature reveals a 5.4% (19/351) incidence of infection. In Nguyen et al.'s analysis of 155 patients in nine series, there were nine reported infections (5.8%) and two cases (1.3%) of hardware erosion through the skin (67). Sachs' group explanted two of 14 (14%) patients due to hardware infection (68). Nuti et al. reported that one of 31 patients had a frank SSI and 2 had delays in wound healing (69). Monsalve reported a total of seven infections in 100 implanted patients (66). The overall risk of infection with MCS is higher compared with other neuromodulation implant techniques including SCS. There is no evidence in the literature that an externalized trial before full implant carries a

higher risk of postoperative infection compared to implanting the system without an externalized trial.

Recommendations. Infection is of particular concern with surgical procedures involving implanted devices. The NACC recommends that surgeons implanting MCS systems follow accepted best practices and administer prophylactic antibiotics within 1 hour of skin incision. These may be continued for up to 24 hours postoperatively. If an externalized trial is performed, use of prophylactic antibiotics during the length of the trial is at the surgeon's discretion. Clinicians should monitor patients for wound breakdown and other signs and symptoms of device infection, understanding that most device infections require partial or complete device removal, in addition to antibiotic treatment for eradication of the infection. A postoperative infection in the region of the craniotomy often results in involvement of the craniotomy flap. Given the isolation of this section of bone it may serve as a privileged space for retention of infectious organisms despite antibiotic therapy. Therefore, it is prudent in many instances where there is gross purulence in the craniotomy to discard it to allow full treatment of the infection.

Consensus Point 13. Careful attention to the surgical site risk-mitigation strategies should be employed during MCS procedures. If infections should arise, they should be treated aggressively.

Seizure

Background and Evidence. Electrical stimulation of the cortex carries with it an inherent risk of seizure. This risk may be enhanced by the chronic nature of motor cortical stimulation for pain. Nguyen et al.'s review found that 18.7% of patients experienced a seizure during programming but none were reported to have suffered chronic seizures (70). Similarly, only one of his own 100 patients suffered a seizure and that was during a trial using high-amplitude stimulation (67). However, seizures can significantly hamper the therapy due to the limitation on stimulation amplitude. Henderson et al. (71) published a series in which five of 19 patients experienced persistent seizures from the therapy. Some of these patients even experienced seizures during times when the stimulator was turned off. Moreover, the stimulation parameters required to induce a seizure decreased over time in some patients, indicating persistent excitation or irritation of the underlying cortex. Of the 31 patients reported on by Nuti et al., three developed partial seizures that responded to decreasing stimulation intensity (69). However, the effect of such decreased stimulation intensity on the level of pain relief obtained is not described. Rasche et al. (72) stated that 7 of the 17 patients trialed in their cohort experienced intraoperative seizures only, but none occurred with chronic stimulation lasting as long as 10 years. In reviewing the literature, Monsalve included 16 studies totaling 100 implanted patients (66). In at least 10 of these series, patients were reported to have stimulation-induced seizures. Nonetheless, other small series reported no seizures among their patients (73–78).

Patients being treated with MCS are at risk for seizure episodes related to the therapy. In most cases, the seizures are attributable to programming parameters. Programming-related seizures are most often related to the amount of energy (voltage or current) applied. In these cases, reducing the voltage or current will usually resolve the problem. There are cases of seizure activity that do not appear to be directly related to programming or stimulation and in these cases, the seizure activity may be related to the presence of the device itself or to persistent effects of chronic stimulation. The incidence of seizures related to MCS is difficult to determine, as it is likely to be under-reported. Analysis of the current MCS literature reveals a 2.8% (10/351) incidence of seizures related to MCS.

Recommendations. The NACC recommends that individuals and facilities involved in MCS programming be experienced and have the necessary support staff, equipment, and medications needed to manage a seizure. A sensible precaution during initial programming is to have venous access, antiseizure medications ready (a syringe of lorazepam or midazolam), access to oxygen, and a team of caregivers present or immediately available. Programming MCS systems should be done cautiously with attention to the onset of neurologic signs (such as motor contractions) that could herald the onset of a seizure.

There is not enough evidence to make a recommendation regarding the use of prophylactic anticonvulsants either during MCS trial or long-term after implant.

Consensus Point 14. Vigilance and anticipation of seizure during initial and subsequent reprogramming is recommended with appropriate seizure-management resources available.

Other Neurologic Deficits

Rasche et al. reported that one patient experienced complete speech arrest for 3 months before recovering (72). Nuti et al. had two patients with transient postoperative neurologic issues (one with speech disorder and one with motor deficits) that resolved spontaneously (69).

Peripheral Nerve Stimulation

Background

Peripheral nerve and peripheral nerve field stimulator leads can be placed via an open surgical approach with direct vision or via a percutaneous approach using cylindrical leads advanced through percutaneously placed needles or sheaths. Percutaneous placement can be done with or without image guidance, and image guidance techniques include fluoroscopy and ultrasound (79). A peripheral nerve stimulator is used to guide percutaneous placement of peripheral nerve stimulation (PNS).

The early and now less commonly used approaches to PNS lead placement involved direct visualization of the nerve with cut-down and a different set of risks and complications exist than with percutaneous approaches (80,81). Percutaneous approaches are now more commonly used than direct open surgical approaches. It has been presumed that percutaneous approaches have a lower complication rate, but it should be noted that no direct comparison studies exist (82,83).

Regardless of the technique used, each approach has the potential to cause harm including neurological injury. Nerve injury may potentially occur via direct surgical trauma from surgical dissection, needle/sheath placement, and/or lead placement. Foreign body or allergic reactions to the leads have been described and have the potential to cause perineural scarring or fibrosis. As with SCS, SSIs have the potential to cause neurological injury.

NACC recommendations for PNS are detailed in Table 15.

Evidence

There is a paucity of data regarding the true risk of serious neurological complications from PNS. The major reason for this is that most of the published experience consists of case reports, small case series, and retrospective analyses. The largest prospective PNS clinical trial is a recently published multicenter trial of PNS of the occipital nerves for headache by Dodick et al. (84). One-year follow-up safety data from this trial involving 157 patients revealed a

Table 15. Recommendations and Evidence for Peripheral Nerve Stimulation by the Neurostimulation Appropriateness Consensus Committee (NACC).

Statement	Evidence level	Recommendation grade	Consensus level
PNS has not been associated with direct neurologic trauma and its risk is low.	II-3	B	Strong
Imaging guidance, as well as intermittent nerve stimulation, is recommended for percutaneous PNS placement.	II	I	Strong
Specialized equipment designed for PNS will likely improve efficacy, safety, and reduce complication rates.	III	B	Strong

relatively high incidence of AEs, but there were no reports of serious neurological damage. The most common AE was persistent pain at the hardware site(s) in 38 patients. There were 11 infections, 8 skin erosions, and 11 cases of unexpected pain or numbness (84). Ishizuka et al., in a retrospective review of causes for surgical revision in patients with CRPS Type II, who previously experienced initial pain relief from an implanted peripheral nerve stimulator, demonstrated that in 33% of their patients lead migration was the most common complication of PNS (85). There were no reports of neurological injury. Stevanato et al. recently reported an enhanced implantation technique for patients with post-traumatic brachial plexus injury or distal peripheral nerve lesions with chronic severe intractable neuropathic pain (86). The authors report that by implanting quadripolar leads proximal to the site of injury and close to the axilla, there was no lead migration or any other complication at 12-month follow-up in all seven patients studied. Deer et al., in a recent randomized double-blind multicenter PNS trial involving 147 patients, where both fluoroscopy and intermittent nerve stimulation were used to guide proper placement of PNS leads, did not report any complications or AEs (87).

Finally, peripheral nerve field stimulation (PNfS) is a novel approach to peripheral stimulation in which the electrodes are implanted in the painful region without directly targeting a discreet peripheral nerve. The electrodes are tunneled and connected to an implanted pulse generator. Key determinants of effectiveness have been found to include depth and orientation of the lead. AEs include lead migration and failure (88–91). McRoberts et al. reported the results of a prospective multicenter trial of percutaneously placed cylindrical PNfS leads to treat axial spine pain (92). In this trial, 32 patients had trial leads placed and 24 patients went on to permanent implantation. As with the occipital stimulation trial, there were no reported cases of serious neurological complications.

Recommendations

There is a significant need for large-scale PNS clinical trials with long-term follow-up to better determine efficacy and the relative risk of AEs, including neurological complications. Although the overall risk of AEs associated with PNS is relatively high, owing mainly to hardware-related problems, the available data indicate that the risk of serious neurological injury associated with PNS is very low (84,85,92,93). Two large prospective clinical trials involving PNS did not have any documented cases of serious neurological injury (84,87).

Consensus Point 15. Peripheral nerve stimulation has not been linked to nerve injury in the peer-reviewed literature, and appears as a safe strategy for the treatment of pain.

Several of the methods described to reduce the risk of neurological injury from SCS also apply to PNS (5). This includes attending to published guidelines to reduce the risk of SSIs (94), and also managing sedation during percutaneous needle/sheath and lead placement in the vicinity of nerves such that the patient is able to report a paresthesia (5).

Finally, there is a need for dedicated PNS equipment and devices. The majority of AEs from current PNS/PNfS devices relate to hardware issues including peri-hardware pain and lead migration. The relatively high incidence of these AEs relates to the fact that most of the current PNS devices were designed for SCS and are used off-label for PNS. It is likely that devices designed for and dedicated specifically to PNS would have a lower rate of these AEs (95). In addition, some advances in SCS lead and electrode technology, including a novel MRI-compatible lead that is powered by wireless radiofrequency technology, allow for an externally worn IPG, obviating the need for an implanted IPG, thus mitigating the risk of lead migration and implanted hardware-related AEs (96).

SUMMARY OF CONSENSUS POINTS

Consensus Point 16. The NACC recommends that for percutaneous and surgical SCS lead placement and removal, the patient's coagulation status should be optimized to prevent neurological injury from spinal hematoma. For patients taking anticoagulation medications for prophylaxis to prevent neurological or cardiovascular thrombosis, this requires careful coordination and communication with the patient and the patient's managing medical physicians. The recently published *NACC Recommendations on Bleeding and Coagulation Management in Neurostimulation Devices* provides more detailed guidance (6).

Consensus Point 17. Surgical site infection can lead to severe neurological injury including epidural abscess and meningitis. The NACC recommends that the risk of SSI should be minimized by following the infection control measures recommended by the United States Centers for Disease Control (4). These recommendations apply to all neuromodulation implant procedures and have been further elucidated and strengthened in the recently published *NACC Recommendation for Infection Prevention and Management in Neurostimulation Devices* (7).

Consensus Point 18. To minimize the risk of spinal cord or nerve injury during percutaneous SCS lead placement, the NACC recommends that the management of sedation should be such that the patient is sufficiently alert to provide feedback to the implanting physician, including the ability to report pain or paresthesia that may provide valuable information to the implanting physician. In some settings, the risk-to-benefit ratio may lead the physician to implant under deep sedation or general anesthesia. This should be considered when the risks are acceptable and may be a better option than abandoning neurostimulation. If percutaneous lead placement under deep sedation or general anesthesia is performed, then the intraoperative monitoring recommendations for paddle

lead placement under deep sedation or general anesthesia should be considered (see Consensus Point 19).

Consensus Point 19. In the case of paddle lead placement under deep sedation or general anesthesia, motor evoked potential (MEP) and SSEP monitoring should be considered. Although there have been no studies specifically evaluating the use of MEP and SSEP monitoring during asleep placement of stimulator leads, NACC suggests that the use of these monitoring modalities can be a helpful adjunct in determining whether cord function has been compromised. Anecdotally, there have been cases wherein a lead was changed or removed because of monitoring changes, but the topic has not been researched sufficiently to make a stronger recommendation at present. Confirmation of correct lead placement has been advocated with either awake intraoperative confirmation of paresthesia coverage or use of neuromonitoring in asleep placement such as EMG responses or SSEP collision testing.

Consensus Point 20. The NACC recommends that the relevant spine imaging should be personally reviewed by the implanting physician or by a radiologist who is familiar with the need for sufficient space in the canal prior to percutaneous or surgical SCS lead placement. Significant spinal canal stenosis where space-occupying SCS leads are to traverse or be implanted may increase the risk of neurological injury. SCS leads typically should not be implanted or navigated through an area of severe spinal canal narrowing. For the purpose of SCS lead placement, severe stenosis is present when there is significant compression, or loss of the epidural space and CSF space in the AP dimension of the CT or MRI images, such that placement of one or more leads has the potential to compress the spinal cord. Paddle placement after surgical decompression is an option and is at the clinical judgment of the clinician.

Consensus Point 21. Based on a recent evaluation of neurological risks, the rate of SCI from lead placement has been demonstrated to be low, and without statistically significant difference between percutaneous and paddle leads (1,8,21,31,97). The recent publication by Petraglia et al. is notable in that the results suggest that neurological damage occurs more frequently than previously thought following SCS placement, and neurological injury following percutaneous lead placement is as frequent as during paddle lead placement, although the reasons for this are not entirely clear (8).

Consensus Point 22. Grand mal seizure activity is a risk with MCS programming. The NACC recommends that individuals and facilities involved in MCS programming be experienced and have the necessary support staff, equipment, and medications needed to manage seizures. A sensible precaution during initial programming is to consider venous access, and have a syringe of diazepam or other fast-acting anticonvulsant on hand, and a nurse or other assistant present or immediately available. Programming MCS systems should be done cautiously with attention to the onset of neurologic signs (such as motor contractions) that could herald the onset of a seizure.

CONCLUSIONS

Serious neurologic injury is an inherent concern when the intended site of surgery is near neural tissue. Complications can occur with direct injury, or secondarily due to hemorrhage or infection. With mindful approaches and risk-mitigating strategies, these therapies can be employed to improve treatment for refractory diseases and minimize potential complications. Improved assessment of the surroundings, either with patient feedback or neural monitoring, may be helpful to improve safety. Specifically designed equipment for delivery of neurostimulation may also improve efficiency, efficacy, and overall safety, as modifications of existing equipment are less than ideal.

The NACC has examined the evidence to give the clinician best practices to improve safety for those undergoing neuromodulation. The NACC group has provided an evidence-based strategy to mitigate complications and to manage those issues that arise in a manner that provides the best outcomes. This ongoing process will continue, with each update being based on new evidence and consensus opinion based on clinical practice, and with an international emphasis on global access and global improvements that result in enhanced disease management by electrical targeting of the nervous system.

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Authorship Statement

Dr. Deer served as primary author, project organizer, and editor; Drs. Lamer, Arle, Falowski, Pope, and Williams performed literature searches; Drs. Lamer, Falowski, Pope, and Arle prepared evidence tables; Drs. Simpson and Mekhail served as senior editors; all authors acquired or interpreted data, wrote sections of the manuscript, and provided critical reviews and editing.

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COMMENTS

This article presents guidelines on security in neurostimulation. Knowledge about the safety and appropriateness of procedures is essential in our daily professional activities and also a great protection for physicians and patients. The article is also fundamental in the fields of law and medical litigation. This article is very important for experienced physicians and for doctors who are starting to use these surgical techniques.

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This paper represents consensus opinions regarding many aspects of implantation of neurostimulators throughout the neuraxis. The basis for these consensus statements is review of the literature available. While some may debate a consensus, these are written with a conservative approach and as such should be carefully reviewed.

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As with other publications from the NACC, this document provides a thorough review of the evidence for neurologic injury with recommendations for their reduction in the future. These reviews will become the gold standard for years to come.

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Comments not included in the Early View version of this paper.

