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The Neurostimulation Appropriateness Consensus Committee (NACC): Recommendations on Best Practices for Cervical Neurostimulation

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ABSTRACT

Introduction: The International Neuromodulation Society convened a multispecialty group of physicians based on expertise with international representation to establish evidence-based guidance on the use of neurostimulation in the cervical region to improve outcomes. This Neurostimulation Appropriateness Consensus Committee (NACC) project intends to provide evidence-based guidance for an often-overlooked area of neurostimulation practice.

Materials and Methods: Authors were chosen based upon their clinical expertise, familiarity with the peer-reviewed literature, research productivity, and contributions to the neuromodulation literature. Section leaders supervised literature searches of MEDLINE, BioMed Central, Current Contents Connect, Embase, International Pharmaceutical Abstracts, Web of Science, Google Scholar, and PubMed from 2017 (when NACC last published guidelines) to the present. Identified studies were graded using the US Preventive Services Task Force criteria for evidence and certainty of net benefit. Recommendations are based on the strength of evidence or consensus when evidence was scant.

Results: The NACC examined the published literature and established evidence- and consensus-based recommendations to guide best practices. Additional guidance will occur as new evidence is developed in future iterations of this process.

Conclusions: The NACC recommends best practices regarding the use of cervical neuromodulation to improve safety and efficacy. The evidence- and consensus-based recommendations should be utilized as a guide to assist decision making when clinically appropriate.

Keywords: Best practices, cervical spinal cord stimulation, consensus, dorsal root ganglion, neuromodulation

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INTRODUCTION

Since its inception, the use of spinal cord stimulation (SCS) for the treatment of various chronic pain syndromes has been focused predominantly on the thoracic or lumbar spine. By comparison, the yearly number of cervical spine surgeries in the United States between 2002 and 2011 was approximately half that of lumbar surgeries (307,188 vs 658,616, respectively).[1,2] Cervical SCS (cSCS) is used for a variety of conditions, including but not limited to upper extremity complex regional pain syndrome (CRPS), upper extremity radicular pain, various neuropathic pain syndromes arising from metabolic and chronic diseases, and those pain syndromes that accompany spinal surgery such as persistent spinal pain syndrome type 2[3] (formerly failed back/neck surgery syndrome) and postlaminectomy pain syndrome.[4] Despite wide acceptance of the use of SCS in the cervical region, the published literature examining cSCS is sparse compared with those examining the lumbar spine and lower extremities. The term failed neck surgery syndrome (FNSS) has been used to describe patients with upper extremity and neck pain that persists after surgery on the cervical spine.[5–8] Approximately 18% of patients undergoing anterior cervical discectomy and fusion surgery may continue to experience chronic upper extremity radiculopathy postoperatively.[4] Similarly, the development of axial neck pain and headache are common following cervical spine surgery.[5] Together, these clinical sequelae commonly present to interventionalists treating painful conditions. As such, the Neurostimulation Appropriateness Consensus Committee (NACC) has charged a working group with reviewing the literature regarding cSCS and creating an evidence- and consensus-based guidance for the use of cSCS. This manuscript will examine the best practices for patient selection, implantation, and outcomes with this treatment modality.

Background and Historical Perspectives

The cSCS and variations of cSCS have been used in thousands of patients for a variety of indications. Early data demonstrated the efficacy of cSCS for improvement in cerebral blood flow[9,10] and for treatment of atypical facial pain[11] and migraine,[12] upper extremity pain,[13] and combined cerebral and upper limb ischemia.[14] In 2014, the NACC guidelines found cSCS to have supporting data as a safe and effective treatment for pain in the upper extremities from either neuropathic or vascular etiologies.[15] This is the first NACC guidance to address cSCS separately as an independent therapy.

MATERIALS AND METHODS

Development Process

As part of its mission to improve patient care and access to advanced neuromodulation techniques, the International Neuromodulation Society (INS) formed the NACC, consisting of INS members worldwide who were chosen for their clinical expertise, familiarity with the current peer-reviewed literature, research capabilities, and previous publications. At regular intervals, NACC members have evaluated the level of current evidence in the peer-reviewed literature for topics that have been identified as critical for improving efficacy and patient safety.

Work groups were convened to conduct literature searches and examine the evidence for the topics developed by lead authors in outline form. After the literature search was completed, each author was asked to provide cited references and evidence rank. The section leaders then formulated the recommendation grade, based on the evidence, which was reviewed by at least three different, non-conflicted NACC working group members. If conflicts of interest were identified, recusal was required. The section leaders then created consensus points, which were voted upon by in-person meetings, teleconference, or other electronic or audio-video communications to define the consensus; agreement by at least 80% of the contributing authors was considered a majority opinion. If 100% of the contributing authors agreed, it was determined to be a majority opinion. Consensus strength was defined as described in previous NACC[15–18] and Polyanalgesic Consensus Conference (PACC)[19–21] publications. As in those earlier publications, if a recommendation was proposed with <50% consensus, based on assigned evidence rank and recommendation grade, then no consensus was achieved.

As a consensus guideline, this document provides recommendations in the form of consensus points regarding practices for cervical stimulation. However, these recommendations should not be construed as a standard of care but rather represent a guide to best practices. This guidance is based on several factors and peer-reviewed evidence and, regardless of the strength of evidence, requires interpretation for clinical application.

Management of Conflict of Interest

The INS policy for the guideline development and publication was followed. One of the co-primary authors is without conflict of interest and is the adjudication determination official for any issues of potential conflict of interest. All authors were asked to recuse themselves on any recommendation potentially affected by a disclosed conflict of interest. Additionally, authors without conflict of interest vetted all recommendations for bias.

Literature Search, Evidence Ranking, and Consensus Development

The English language literature was searched using 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 cervical neurostimulation therapies for the treatment of pain. Search words included "spinal cord stimulation" and "cervical spinal cord stimulation." Identified peer-reviewed literature was critiqued using the United States Preventive Services Task Force (USPSTF) criteria for quality of evidence,[22] with modifications for neuromodulation studies (Table 1). After USPSTF letter grading was assigned, the working subgroup then assigned the "level of certainty regarding benefit" as described in Table 2.

For each major section or topic, the NACC formulated consensus points. Consensus points should not be confused with recommendations based on consensus alone. Consensus points were based on the peer-reviewed literature (such as randomized controlled trials [RCTs], prospective observational studies, and retrospective cohort/case series). Consensus opinion alone is rendered as clinical guidance owing to the lack of evidence-based literature.

PEER-REVIEWED EVIDENCE FOR CERVICAL STIMULATION

As noted previously, the volume of literature concerning cSCS has been relatively limited, specifically in comparison with the studies of thoracolumbar SCS. Reports of outcomes for cSCS applications during its first three decades were often mixed with thoracolumbar SCS results, making interpretation of specific cSCS results and recommendations of best cSCS practices difficult. In addition, the first retrospective review of cSCS in the peer-reviewed literature appeared decades after the clinical introduction of cSCS.[4]

The development of evidence for cSCS followed a typical pattern in that retrospective studies and case series appeared first, followed by more formal prospective observational and multicenter trials. In 2014, Deer et al[23] published a systematic review of the literature highlighting the relative paucity of information available. This report will review retrospective/case series and both single and multicenter prospective studies. To date, no RCTs specifically evaluating cSCS have been performed, although clinical consensus is that the efficacy in this body region supports deployment of the therapy.

Note that in the following discussion, all outcome data relate to patients receiving permanent implants. In trials, this is often referred to as "modified intention to treat." True "intention to treat" analyses, which includes trial failures and participants lost during follow-up in outcome assessment, are often reported in RCTs but rarely available for case series, where these participants are not routinely followed. This important distinction must be borne in mind when judging how effective the treatment is in the patient population overall. Where available, we have included data on trial-to-permanent implant conversion rates in the discussion.

Retrospective Studies

The retrospective studies to date and USPSTF ratings are summarized in Table 3. Simpson et al[24] reported on 41 patients with undefined cervical spine pathology who were followed up for an average of four years. Whitworth and Feler[25] reported the outcomes in 20 patients with defined axial and radicular pain over an

Table 1. Quality of Evidence Ranking Using USPSTF Criteria Modified for Neuromodulation.

Grade	Definition	Suggestions for practice
A	The NACC recommends the service. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	The NACC recommends the service. There is high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial.	Offer or provide this service.
C	The NACC recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.	Offer or provide this service for selected patients depending on individual circumstances.
D	The NACC recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I (insufficient) statement	The NACC concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF recommendation statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

Table 2. Levels of Certainty Regarding Net Benefit.

Level of certainty	Description
High	The available evidence includes consistent results from well-designed, well-conducted studies in representative primary care populations. These studies assess the effects of the preventive service on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies. Evidence Level: I-A—At least one controlled and randomized clinical trial, properly designed
Moderate	The available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by such factors as: • The number, size, or quality of individual studies. • Inconsistency of findings across individual studies. • Limited generalizability of findings to routine primary care practice. • Lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion. Evidence Level I-B—Well-designed, controlled, non-randomized clinical trials (prospective observational studies conforming to STROBE criteria) or Evidence Level I-C—Retrospective cohort or large case studies (>20 participants)
Low	The available evidence is insufficient to assess the effects on health outcomes. Evidence is insufficient because of: • The limited number or size of studies. • Important flaws in study design or methods. • Inconsistency of findings across individual studies. • Gaps in the chain of evidence. • Findings not generalizable to routine primary care practice. • Lack of information on important health outcome Evidence Level II—Expert opinion based on risk:benefit or based upon case reports

STROBE, Strengthening the Reporting of Observational studies in Epidemiology.

average of four years. Both of these early reports evaluated cSCS provided through the relatively more invasive laminotomy placement approach and using paddle-type leads.

Additional retrospective analyses have reported outcomes associated with SCS therapy in heterogeneous diagnostic categories.[26,35,37] In the largest of these studies, a cohort of 121 patients diagnosed with CRPS (n = 33), FNSS (n = 23), and other pain syndromes achieved a trial-to-permanent implant conversion rate of 82.6%.[26] Pain reduction averaged 56.6% at a mean follow-up of 4.2 years. In a recently published review of 47 consecutive patients with chronic upper limb and/or neck pain, >75% of patients had ≥50% pain relief at last follow-up visit.[37] Of note, 72% reported improved function, 53% reported improved sleep, and 36% reported decreased medication use.

Several retrospective studies have focused on treatment of craniofacial pain syndromes. Treatment with cSCS that demonstrated durable efficacy in patients includes pain because of trigeminal neuropathy,[27] cluster headaches,[28,34] occipital neuralgia,[28] migraine headaches,[34] and chronic short-lasting unilateral neuralgiform headache attacks with autonomic features.[34] Patients with vasospastic disorders of the upper limb, including Raynaud's disease and CRPS, exhibit observable parallels between increases in blood flow and improvements in pain.[29,34] Moderate or marked improvement in spasmodic torticollis was observed in 68.3% (43 of 63) of patients treated with cSCS, whereas even mildly improved patients demonstrated decreases in spasms, pain, and mobility restrictions.[38] Emerging areas for therapeutic application, including amelioration of gait freezing in Parkinson disease, warrant continued exploration.[36] De Agostino et al[33] reported significant relief of headache with a wide-lateral lead placement. A recent case series of three participants using a high density mode of stimulation demonstrated 70% to 80% relief over 21 months.[39]

Prospective Studies

Table 4 summarizes the prospective studies of cSCS. The earliest prospective studies by Deer et al[23] in 2014 and Haider et al[40] in 2017 did not exclusively include a specific cervical spine condition, but rather several patients were experiencing upper limb neuropathic pain from diagnoses such as CRPS, Raynaud's syndrome, metabolic disease, and scleroderma. The first study evaluated 38 patients from 16 clinical sites prospectively followed up after implantation of cSCS.[23] Patients were followed up at three, six, and 12 months, with 16 patients completing the study. Outcome measures of pain relief and reduction in disability were significant despite the appreciable dropout rate. A total of 28 patients were treated with percutaneous coaxial leads, whereas ten received laminotomy paddle-type leads. The anatomical targets were not disclosed. This early prospective study using tonic stimulation demonstrated encouraging outcomes. Subsequently, Haider et al[40] in a single-center study demonstrated similar results using tonic stimulation. They evaluated 24 patients with percutaneously placed leads for treating radicular pain and paddles placed using a retrograde technique at C1-C2 for axial neck pain. Significant reduction in pain (visual analog scale [VAS] at 6 and 12 months) and Oswestry Disability Index (ODI) scores were noted using paresthesia-based stimulation. FNSS comprised 13% of patients with the remaining having neuropathic pain of other causes. In this study, the level of the C2-C3 vertebral bodies appeared to be the optimal target for coaxial leads.[40]

Multiple recent prospective studies support the use of cSCS for FNSS. A prospective case series by Hunter et al,[42] examining data extracted from the EMPOWER and PAIN registries, assessed outcomes in 15 patients following treatment with cSCS for FNSS. Participants had a mean age of 54.6 years and received both percutaneous coaxial leads (n = 13) and paddle-type leads (n = 2).

Table 3. Retrospective Studies of cSCS.

Study	Number of participants	Type of lead (*n*)	Pain type (*n*)	Outcomes	Anatomical location	Complications (*n*)	Follow-up
Studies using paddle leads							
Simpson et al,[24] 2003	41	Paddle	Upper limb and face pain syndromes	51% had "significant benefit," 10% had "moderate benefit"	C1-T1	Lead fracture (6) Lead migration (3) Infection (2)	Median 4 y, 7 mo
Whitworth and Feler,[25] 2003	20	Paddle	Radicular and axial neck pain	63% mean reduction in VAS scores, 70% had "good or excellent outcome"	C1-C2	Infection (1) Suboptimal placement (1)	Mean 26 mo
Chivukula et al,[5] 2013	6	Paddle	FNSS	Mean patient reported pain reduction of 55.2%, 66% would undergo procedure again, 100% patient satisfaction	Undefined cervical spine	No complications reported	Mean 24 mo
Chivukula et al,[26] 2014	100	Paddle (75) and percutaneous (25)	Neck and/or extremity, or head/facial pain	57.6% mean reduction in pain	C1-C7	Revision surgery (24) Infection (5) CSF leak (4)	Mean 4.2 y
Velásquez et al,[27] 2018	12	Paddle	Trigeminal neuralgia	Average pain reduction 57.1%	C1-C2	Revision surgery (19) Infection (1)	Mean 4.4 y
Texakalidis et al,[28] 2019	2	Paddle	Occipital neuralgia	35.7% VAS reduction	C1-C3	No complications reported	Mean 3 mo
Studies using percutaneous leads							
Robaina et al,[29] 1989	11	Percutaneous (10) and paddle (1)	CRPS (8), Raynaud disease (3)	90.9% of patients had "good or excellent results"	C5-C7	Infection (1) Lead migration (2)	Mean 27 mo
Vallejo et al,[30] 2007	4	Percutaneous	Radicular and axial neck pain	75% improvement in patient-reported pain relief	C2-C4	No complications reported	Mean 5 mo
Wolter et al,[31] 2011	7	Percutaneous	Cluster headache	Mean attacks per day reduced by 76.7%, mean duration of attacks reduced by 54%, mean NRS of attacks reduced by 39.2%, all patients would recommend the treatment	C2	Lead fracture (1) Lead migration (2) IPG end of life (3)	Mean 23 mo
Al-Kaisy et al,[32] 2015	8	Percutaneous (HF-SCS)	Arm	4 patients reported excellent results, 3 good results, and 1 was not satisfied	C2-C6	Infection (1) Lead migration (2) No adverse neurological events	6 mo
De Agostino et al,[33] 2015	17	Percutaneous	Intractable migraine	Mean NRS decreased by 60.5%, mean migraine days per month decreased by 39.7%, patients not requiring medication went from 0% to 37.5%	Paramedian C1-C2	Infections (3) Lead dislocations (3)	Median 15 mo
Lambru et al,[34] 2016	7	Percutaneous (HF-SCS)	Chronic refractory headache disorders	All patients had at least a 50% reduction in headache days per month and/or attack duration	C2-C3 target	Lead migration (2)	Mean 28 mo
El Majdoub et al,[35] 2019	23	Percutaneous (HF-SCS)	Neck and/or upper limb pain	74% mean reduction in VAS scores, ODI reduction of 39.4%, mean OME reduction of 55.9%, 85% reported "satisfied or very satisfied"	C2-C5	Infection (3) Lead migration (1)	Mean 12 mo
Mazzone et al,[36] 2019	18 (6 tonic, 12 burst)	Percutaneous	Parkinsonian motor disorder	Burst stimulation had greater improvement in tremor and motor disabilities compared with traditional stimulation	Lead tips C1-C3	No complications reported	Mean 12 mo

(Continued)

Table 3. *Continued*

Study		Number of participants	Type of lead (*n*)	Pain type (*n*)	Outcomes	Anatomical location	Complications (*n*)	Follow-up
Sayed et al,[37]	2020	47	Percutaneous (HF-SCS)	Neck and upper extremity pain	76% had at least 50% VAS reduction, mean VAS reduction of 58%, 72% of patients reported improved function, 53% of patients reported improved sleep, 36% of patients reported decreased medication use	C2-C6	Pain at implant site (1) Overstimulation (2) Lack of efficacy (2)	Median 19.4 mo
Waltz et al,[38]	1985	63		Spasmodic torticollis	48 patients had mild, moderate, or marked improvement			

HF-SCS, high-frequency spinal cord stimulation; NRS, numerical rating scale; OME, opioid milligram equivalents.

The mean percentage pain relief on a numerical rating scale was 65.2%, 62.4%, and 71.9% at three, six, and 12 months following implant. The Pain Disability Index scores were reduced across these same time points from a baseline mean of 51.2 to 35.3 at three months, 29.6 at six months, and 23.7 at 12 months. During the annual follow-up visit, ranking of overall quality-of-life changes was described categorically as "improved to greatly improved," whereas overall satisfaction achieved a mean rating of "satisfied to greatly satisfied."[42]

A single-center observational pilot study by Grider and Harned[44] characterized the efficacy of cSCS in both axial neck and upper extremity radicular pain one year following implant. This study used passive recharge burst waveforms to treat axial neck pain (n = 15) with headache (n = 3) or upper extremity radicular pain (n = 12), with lead programming centered over the C2-C3 disc interspace. The trial-to-permanent implant conversion rate was 65%, with those proceeding to permanent implant achieving a mean improvement of 12.4 points in the neck-specific ODI and a reduction in pain intensity from 8.1 to 3.9 on a 10-point pain rating scale.[42]

In a study evaluating high-frequency cSCS, Amirdelfan et al[45] reported the results of a six-center prospective trial in the United States that characterized outcomes in patients with intractable neck and/or upper limb pain over 12 months. The neck pain VAS decreased from 7.6 to 1.5. The upper extremity VAS pain intensity decreased from 7.1 to 1.0. Of note, 89.2% of participants with neck pain and 95% of participants with upper extremity pain achieved at least a 50% decrease in pain intensity during the annual follow-up. Furthermore, 30% either reduced or eliminated reliance on opioids. Similar results were observed in an Australian multicenter cohort of comparable design[43]; 82.6% proceeded to implant following a successful trial, with a decrease in neck pain intensity from 8.1 to 2.9 and a decrease in upper extremity pain intensity from 7.3 to 2.5. Improvements in disability measures were observed at the primary end point.

Arcioni et al[41] reported outcomes of a 14-participant prospective study evaluating cervical placement of percutaneous leads at C2-C6 for the treatment of headache using a 10-kHz stimulation. This study demonstrated a 30% reduction in headache days.

Evidence Grading

Based on the retrospective case series (Table 3) and prospective studies (Table 4), we evaluated how the evidence for cSCS varies by indication. In the treatment of cervical radicular pain or CRPS upper extremity pain, several prospective studies support a Grade B level of evidence with moderate level of certainty based upon I-B evidence for cSCS, ie, there is high certainty that the net benefit is moderate. For treatment of cervical axial pain, retrospective cohort or case series and well-designed prospective studies support a Grade B recommendation for cSCS, ie, there is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. For treatment of headache and facial pain, retrospective and prospective studies support a Grade C recommendation for cSCS, ie, there is moderate certainty of net benefit for selectively offering the treatment to individual patients based on professional judgment and patient preferences.

Cervical radicular pain	Grade B: level of certainty, moderate, I-B
CRPS upper extremity pain	Grade B: level of certainty, moderate, I-B
Cervical axial pain	Grade B: level of certainty, moderate, I-B
Headache and facial pain	Grade C: level of certainty, moderate, I-B

Table 4. Prospective Studies of cSCS.

Study	Number of participants	Type of lead (*n*) and stimulation	Pain type (*n*)	Outcomes	Anatomic location	Complications (*n*)	Follow-up
Deer et al,[23] 2014	38	Percutaneous (28) and paddle (10) Not known	Chronic neck and upper extremity pain	Patient-reported pain relief of 54.2% (3 mo), 60.2% (6 mo), 66.8% (12 mo); patient disability and quality of life improved at all periods; 87.6% of patients were satisfied or very satisfied at 12 mo	C2-C7	IPG pocket site pain (3) Infection (2) Suboptimal IPG placement (1)	3, 6, 12 mo
Haider et al,[40] 2016	24	Percutaneous (18) and paddle (6)	Neuropathic pain (14), CRPS (7), FNSS (3)	Mean NRS reduction of 25.7%, mean ODI reduction of 9 points	C2-C5	Lead migration (3) Incision pain (2) IPG pocket-site pain (2) Suboptimal pain coverage (2)	12 mo
Arcioni et al,[41] 2016	14	Percutaneous (HF-cSCS)	Refractory migraine	Average reduction of 7 headache days per month, 8 of 15 patients experienced <15 headache days per month, triptan use >9 d per mo decreased from 64% of patients to 36%, average headache intensity and frequency decreased by 37% and 17%, respectively	Lead tip at C2	Lead migration (2) Lead fracture (1) Infection (2) IPG pocket-site pain (2)	6 mo
Hunter et al,[42] 2018	15	Percutaneous (13), paddle (2), and tonic SCS	FNSS	PRPR decreased 65.2% (3 mo), 62.4% (6 mo), 71.9% (12 mo), PDI significantly reduced at 12 mo, QOL significantly improved at all periods, satisfaction >70% at all periods	C2-C6	No complications reported	3, 6, 12 mo
Verrills et al,[43] 2020	31	Percutaneous (HF-cSCS)	Neck and/or upper extremity	Pre 7.3 to post 2.8 VAS at 12 mo (upper extremity), pre 8.2 to post 2.2 VAS at 12 mo (neck), 76.5% responder (≥50% pain relief) for limb pain and 85.2% for neck pain at 12 mo, PDI reduced from 42.6 to 21.2 at 12 mo	C2-C6	Lead migration (4) Infection (2) IPG pocket-site pain (2)	12 mo
Grider and Harned,[44] 2020	15	Percutaneous, monophasic burst stimulation	Axial neck (15), headache (3), upper extremity radiculopathy (12)	Average VAS improvement of 52.6%, ODI improved by 12.4 points	C2-C3 vertical target for axial neck C2 pillar for headache	IPG pocket-site pain (1) Lead migration (1)	12 mo
Amirdelfan et al,[45] 2020	45	Percutaneous (HF-cSCS)	Neck and/or upper extremity	Pre 7.6 and post 1.5 VAS at 12 mo (neck), 7.1 to 1.0 VAS at 12 mo (upper extremity), 95% responder (≥50% pain relief) for limb pain, and 89.2% for neck pain at 12 mo	C2-C6	Epidural hematoma (1) Infection (1)	3, 6, 12 mo

HF-cSCS, high-frequency cervical spinal cord stimulation; PDI, Pain Disability Index; PRPR, patient reported percentage pain relief; QOL, quality of life.

Placement in the Treatment Algorithm

The published evidence on neurostimulation has focused mostly on thoracolumbar SCS treatment, yet the anatomical and pathophysiological similarities between the lumbar and cervical spine suggest that cSCS should have effectiveness similar to thoracolumbar SCS.[40] Indeed, studies have shown cSCS to be effective in reducing pain in the neck and upper limbs and reducing disability for selected patients.[23,42–45]

Indications, Pain Etiology, and Product Labeling

Most of cSCS cases involve either pain secondary to cervical spine surgery (postlaminectomy syndrome) or preexisting pain not relieved or worsened by surgery performed with the intent of relieving pain (FNSS).[45] Additional indications for cSCS may include upper extremity CRPS. Possible etiologies of the pain can be epidural fibrosis, a recurrent herniated disc, a new herniation, a new herniation at the adjacent levels, or inadequate surgical correction of the original defect, and these conditions should be in the differential diagnosis; cSCS can be considered in these scenarios but only in the absence of a progressive neurological deficit. A spine surgery consultation should be considered if a surgical lesion is possible.

Physicians should consult the manufacturers' labeling and directions for the most current information on magnetic resonance imaging (MRI) conditionality for stimulation devices preoperatively, because the MRI status of devices may change over time.

Treatment Algorithm

Initial treatment of chronic neck and/or upper limb pain should include a combination of conservative treatments, such as physical modalities (eg, chiropractic care, physical therapy) and medications (eg, anti-inflammatory drugs, nonaddictive analgesics) as appropriate to the specific case.[46] Patients who do not receive adequate relief from these treatment modalities may be candidates for injection therapies (eg, epidural steroid injection, nerve block), and radiofrequency nerve ablation.

Surgical interventions (eg, anterior cervical discectomy, laminectomy) are options where there is clear imaging evidence of neural compression together with concordant symptomatology. As in the lumbar spine, the results of surgery are, in general, better for extremity pain than axial pain, and fusion surgery for purely axial pain in the absence of neural compression is not generally recommended. SCS is usually only considered after surgery fails to resolve pain, but evidence to support this sequence is limited. cSCS may be considered for patients if surgery is not recommended (Fig. 1). Additional research is required to evaluate cSCS for patients with neuropathic neck/cervical radicular pain without weakness or spinal instability, or neural compression, before surgical interventions. New evidence could build on previous studies of SCS for back and leg pain that show benefits for patients who have not previously had surgery[47] or that show that SCS appears to be more beneficial than reoperation for patients who have completed one lumbar spine surgery.[48]

For patients having CRPS, there is evidence that the effectiveness of SCS is greater for those treated within 12 months of diagnosis.[46] Although conservative modalities should still be utilized as appropriate for these patients, this finding underscores the importance of accelerating the implementation of SCS treatment for these patients (Fig. 2).

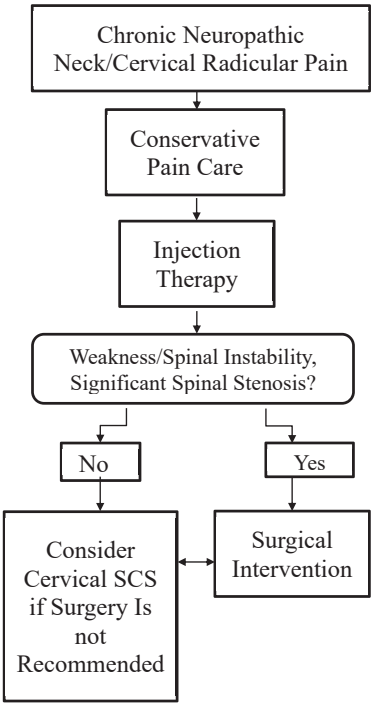

Figure 1. The suggested role of cSCS in the treatment algorithm for chronic neuropathic neck/cervical radicular pain. An individualized treatment plan for patients with chronic neck/cervical pain includes multiple treatment options from the pain management toolbox.[49,50] For example, conservative care may include nonopioid analgesics and/or other medications, physical therapy, behavioral health measures, yoga, or acupuncture.

Consensus Point 1: The NACC recommends cSCS be strongly considered after failure to achieve therapeutic goals with pharmaceutical or injection therapies for cervical radicular pain and upper extremity CRPS. Grade A; level of certainty: moderate, I-B.

Consensus Point 2: The NACC recommends that neurological/surgical evaluation be obtained in the presence of weakness or instability. Grade A; level of certainty: high, I-A.

Consensus Point 3: In the presence of cervical radicular pain with or without cervical axial neck pain and without clear surgical pathology, the NACC recommends a trial of cSCS. Grade B; level of certainty: moderate, I-B.

ANATOMICAL CONSIDERATIONS

The cSCS involves electrical stimulation to the dorsal columns of the spinal cord from C1 to C7/T1 (C8 nerve root). The anatomical location of the stimulating electrodes is within the posterior epidural space of the cervical spine, adjacent to the anatomical midline or within the intervertebral foramen (cervical dorsal root ganglion stimulation). Far lateral stimulation may be used to treat headache and facial pain, which may target the trigeminal tract (nucleus caudalis).

The spinal canal is contained within the bony elements, bound anteriorly by the vertebral bodies, intervertebral discs, and posterior longitudinal ligaments, laterally by the pedicles and transverse processes, and posteriorly by the laminae and ligamentum flavum.

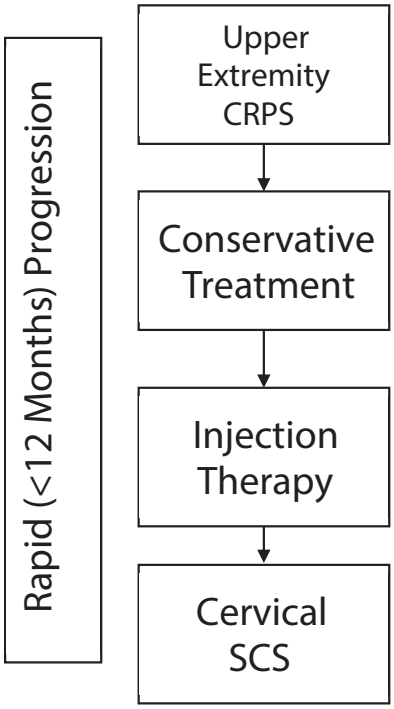

Figure 2. The suggested role of cSCS in the treatment algorithm for CRPS. An individualized treatment plan for patients with CRPS includes multiple treatment options from the pain management toolbox.[49,50] For example, conservative care may include nonopioid analgesics and/or other medications, physical therapy, or behavioral health measures.

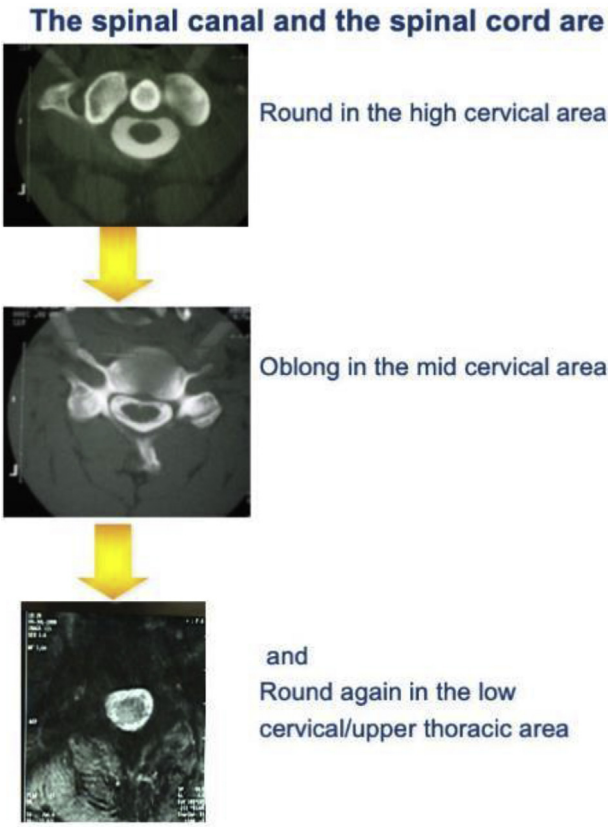

Figure 3. Spinal canal and spinal cord configuration in the cervical spine.

Within the spinal canal, the epidural space envelops the dural sac, containing the spinal cord, rootlets, and cerebrospinal fluid (CSF).[51]

The cervical epidural space extends cranially from the foramen magnum to the lower margin of C7. The epidural space contains fat, blood vessels, and connective tissue that encases the exiting spinal nerves. The size and shape of the spinal canal and spinal cord vary throughout the cervical spinal levels (Fig. 3). The anteroposterior (AP) depth of the posterior epidural space at C6 is 1.5 to 2 mm,[52] though the space increases to 3 to 4 mm with neck flexion.[52–56] Myodural bridges link the suboccipital fascia and dura and obstruct the epidural space at the C1-C2 level, a capacious area for CSF, a noteworthy barrier that limits cervical lead placement cephalad and laterally.[53] The posterior cervical epidural space progressively diminishes in width from the C7-T1 level cephalad. It is common for the epidural space to be unidentifiable on MRI above the C6 level.

Epidural access is typically achieved in one of two ways. In the first, Tuohy needles are passed into the epidural space, usually in the upper thoracic region, using the paramedian oblique approach and the loss-of-resistance method. Percutaneous leads are then passed through the Tuohy needles. In this approach, some of the technical aspects of needle access can differ from epidural access in the upper lumbar/lower thoracic region. The proceduralist will need to account for the angulation of the kyphotic curve of the thoracic spine as it transitions at the cervicothoracic junction. Adapting to use a shallow angle or a steeper, more lateral approach is patient dependent and part of the nuance of cSCS.

The second method involves laminotomy paddle lead placement and is achieved by predefining the ideal anatomical position of the lead. A laminotomy is then performed one or two spinal segments below the most inferior part of the cervical spinal cord level to be stimulated. With the cervical spine in flexion, the ligamentum flavum and, if necessary, the inferior border of the lamina above are removed, carefully avoiding damage to the underlying dura, and leaving as much of the lamina as possible intact. The paddle electrode is passed rostrally under direct vision and with imaging guidance. X-rays are performed after insertion to verify optimal lead position.

The spinal canal changes angle in the sagittal plane from the foramen magnum to the coccyx. Relevant for cSCS is the relative central location of the spinal cord within the spinal canal in the upper cervical spine, which changes to a more posterior position because of the cervical lordosis in the midcervical spine. The spinal cord returns to the center of the spinal canal at the bottom of the cervical spine and then moves to the anterior spinal canal in the upper thoracic spine because of the thoracic lordosis. The spinal cord is closest to the posterior dura between C3 to C7. There is limited underlying CSF between the posterior dura and the spinal cord in this region.

The cervical epidural space differs from the thoracic and lumbar regions, and these differences can affect lead placement. For example, the spinal canal is almost circular in the axial plane just below the foramen magnum, and then becomes ovoid at the C2 level. The spinal cord is larger in the cervical enlargement from C3 to C7, where nerve roots supplying the upper limb arise. Therefore, the cross-sectional area of the spinal cord relative to the spinal canal changes as it descends, with the region of least CSF to spinal

cord ratio at C4-C5. In that the midcervical spine is also most prone to the development of osteophytes and disc herniation, significant cervical spinal stenosis may well be encountered, especially in the elderly. This has important implications for the safe passage of a lead into the epidural space. Cervical decompression may be required before safely placing either coaxial or paddle-type SCS leads if stenosis is particularly severe. The width of the spinal canal relative to the spinal cord may also affect the stimulation parameters necessary for optimal therapeutic effect because of the closer approximation of the electrodes to neural tissue at these levels.

The cervical spine is significantly more mobile than either the thoracic or lumbar spine. Although most of the cervical movement occurs at the atlanto-occipital joint between the skull base and C1 and the atlanto-axial joint between C1 and C2, the smaller cervical vertebrae, the orientation of the cervical facet joints, and the absence of ribs and small transverse processes allow for considerable flexion, extension, lateral flexion, and rotation throughout the cervical spine. Although this may suggest that SCS lead movement and migration might occur significantly more frequently than at other spinal levels, the relatively small spinal canal and epidural space compensate for this increased range of movement, and rates of lead movement and migration are similar to SCS leads in other areas.[48,57–60]

Head and neck positioning during a cSCS trial or implant can greatly affect the ease of the procedure. To facilitate placement, a flexed neck that is neutral in the sagittal plane is typically preferred for awake percutaneous cylindrical or surgical paddle lead placement. For paddle electrodes inserted under general anesthesia, the skull may be clamped in some settings to maintain head position.

The cervical epidural space contains a rich epidural venous plexus, creating a risk of epidural hematoma following lead placement or removal. Implications of a hematoma in the confines of the cervical canal are serious and potentially life-threatening. Meticulous attention to hemostasis is required for all open cSCS procedures. In all cases, careful consideration needs to be given to reducing any risk of bleeding within the cervical epidural space. This may include preoperative coagulation studies and altering medications perioperatively.[18] This is best achieved in collaboration with the physician prescribing those medications.

A common indication for cSCS is persistent neuropathic pain of the neck and/or upper limb following cervical spinal surgery. In general, surgery of the neck using an anterior approach is not considered a contraindication to cSCS. However, posterior cervical surgery can result in scarring and loss of viability of the posterior epidural space, making the placement of percutaneous leads difficult or unsafe. This is not usually the case with posterior spinal fusion instrumentation without laminectomy. Consideration should be given to an open surgical placement rather than a percutaneous one if a patient has had a laminectomy at a cervical level across which a percutaneous lead would traverse during placement. Even with a laminotomy approach, there is increased risk of dural tearing and CSF leak in this scenario.

RECOMMENDATIONS FOR IMAGING REQUIREMENTS BEFORE cSCS

The value of preoperative imaging before cSCS lead placement cannot be overstated. The goal of preoperative imaging is to ensure a safe and effective placement of the lead(s). At a minimum, this requires an evaluation of canal patency at the target level, and along the lead course from the point of entry into the epidural space to the final desired position, to ensure that insertion can be accomplished without causing acute or long-term compression of the spinal cord and/or nerve roots.

Table 5. Average Anatomical Dimensions (mm).[62]

Spinal level	Thickness of dorsal CSF layer	Thickness of ventral CSF layer	Spinal cord anterior-posterior diameter	Spinal canal diameter
C4	2.6	3.4	7.3	13.6
C5	2.6	3.8	6.9	13.4
C6	2.2	4.6	6.7	13.0

Imaging Impact on Preprocedural Planning

cSCS implantation is less commonly performed than thoracolumbar SCS procedures and entails unique risks. The narrower diameter of the epidural space in the cervical spine and the small distance between the ligament flavum and the spinal cord (2–3 mm) together with concomitant spondylosis and stenosis of the cervical canal are variables that can impede safe lead placement.[61] Thus, during preprocedural planning, the size of the spinal canal and the thickness of the dorsal CSF should be assessed (Table 5) to determine whether there is sufficient space to allow for safe lead placement.

Best visualization of the intraspinal contents is obtained with MRI followed by computed tomography (CT)-myelography. Plain CT scan may be adequate to assess the size of the spinal canal but does not give optimal visualization of the various intraspinal components and their size. No current imaging technique can give useful information about the presence of epidural fibrous bands or epidural scar tissue.

Radiologically defined spinal stenosis can be characterized as relative or absolute. The anteroposterior diameter of the normal adult male cervical canal has a mean value of 17 to 18 mm at vertebral levels C3-C5.[63] The lower cervical canal measures 12 to 14 mm. Cervical stenosis is associated with an AP diameter of ≤10 mm, whereas diameters of 10 to 13 mm are relatively stenotic in the upper cervical region.

The term "absolute spinal stenosis" is used when the diameter is ≤10 mm or when there is no CSF posterior to the spinal cord. The cSCS leads further occupy space, so the linear size and volume of implanted lead(s) must be considered during preprocedural planning. Cylindrical leads have a diameter of 1.2 to 1.3 mm. There is wide heterogeneity in paddle lead sizes in the commercial market, necessitating assessment for the type of paddle lead being used. The length, width, and depth of the paddle lead must be evaluated; it is insufficient to determine the greatest width of the spinal canal compared with the width of the paddle lead. The size of the spinal cord must be considered as well as the width of the spinal canal dorsal to the spinal column, because this is where the paddle lead will safely sit.

The presence of spinal stenosis or the absence of CSF posterior to the spinal cord is not an absolute contraindication to implantation of paddle leads. In stenotic patients, adequate decompression of the spinal canal, by either laminotomy, laminectomy, or laminoplasty, can be performed before insertion of the paddle lead to prevent compression of the neural elements. Decompression is not routinely used when placing cylindrical leads, because locating

the epidural space involves electrode placement with a loss-of-resistance technique rather than direct open surgical visualization and the lead follows a pathway over several vertebral levels to reach its target. The feasibility of inserting cylindrical leads in the presence of severe stenosis must be carefully evaluated on a case-by-case basis, particularly in the presence of concomitant spinal cord signal myelopathy (ie, myelomalacia indicated by cord hyperintensity on T2-weighted imaging and hypointensity on T1-weighted imaging). In general, because there are safer alternatives, including decompression followed by paddle lead placement or retrograde C1-C2 paddle lead placement, percutaneous lead implantation in the setting of severe spinal stenosis, especially with spinal cord signal changes on MRI, should be discouraged. Known chronic myelomalacia in the absence of spinal stenosis as evidenced by stable imaging and clinical signs/symptoms may be an exception.

Architecturally, paddle leads comprise both electrical contacts and an insulated backing providing unidirectional spread of electricity. With their greater volume, paddle leads occupy a greater proportionate volume of the cervical spinal canal than cylindrical leads, and they carry a greater inherent risk of damage to the neural structures if paddle leads are too large to fit in the available epidural space. Particular attention must, therefore, be paid to the preoperative assessment of canal diameter and to the intraoperative technique. In clinical practice, however, the risk of neurological injury using paddle-type SCS leads may be less than that using coaxial percutaneous leads.[58] Dynamic cervical spine films (flexion/extension) may be important to exclude translational movement before implanting plate electrodes.

Table 6 provides guidance on the various epidural approaches to cSCS. Although a paddle lead can be implanted, the extent of scarring after laminectomy may make implantation technically complex. Placement in virgin territory above the level of previous surgery (eg, at C3-C4 where the previous surgery was at C5, C6, or C7) or in a retrograde manner at C1-C2 is often a technically easier option.

Consensus Point 4: The NACC recommends recent cervical imaging (MR/CT myelogram) as required to guide preprocedural planning before trial or permanent implantation of a cervical percutaneous or paddle lead. Grade: A; level of certainty: low, II (consensus opinion).

Consensus Point 5: The NACC recommends consideration of intraoperative neuromonitoring while performing cervical implant under a general anesthetic. Grade: A; level of certainty: low, II (consensus opinion).

Table 6. Feasibility of Inserting Epidural Leads in the Presence of Previous Spine Surgery.

Surgical procedure previously performed	Cylindrical leads	Paddle leads
Anterior approach	Yes	Yes
Laminectomy	No	Yes
Laminoplasty	Yes	Yes
Hemi-laminotomy	Yes, on the contralateral side (rarely used method)	Yes
Foraminotomy	Yes, on the contralateral side Possibly on the ipsilateral side, depending on the extent of bone removal and consequent epidural scarring* (rarely used method)	Yes

*MRI is recommended prior to consideration for lead placement with careful consideration of potential anatomical barriers.

NACC RECOMMENDATIONS ON SURGICAL TECHNIQUE FOR CERVICAL PERCUTANEOUS AND PADDLE LEAD PLACEMENT

Positioning

Percutaneous Placement

For both cSCS trial and implant surgeries, the patient should be positioned prone on a radiolucent procedural/surgical table. Padding under the chest may allow increased cervical spine flexion, opening the interlaminar windows and increasing the width of the cervical spine epidural space. The upper extremities should be tucked at the patient's side, outside of the fluoroscopy beam, or alternatively forward on padded armrests, to augment visualization of the cervical spine. Patient comfort is imperative because these procedures are typically performed with moderate sedation, and minimization of patient movement is key to a safe placement. Skin cleansing should be wide and cover multiple cervicothoracic levels to allow for procedural adjustments, if necessary. The patient should be draped in the usual sterile fashion.

Surgical Placement

With paddle lead placement, the cSCS trial and implant are typically performed in a staged manner with either general anesthesia and the consideration of neurophysiological monitoring (motor evoked potentials, somatosensory evoked potentials, and/or electromyography) or local anesthetic and conscious sedation. The patient should be positioned prone on a radiolucent surgical table. With general anesthesia, the cervical spine may be held in a flexed position with a skull clamp. With conscious sedation, the patient should be positioned as for a percutaneous trial. The upper extremities should be tucked at the patient's side, outside of the fluoroscopy beam, to increase visualization of the cervical spine. Skin cleansing should be wide and cover multiple cervicothoracic levels to allow for procedural adjustments, if necessary. Surgical drapes should be placed in the usual sterile fashion.

Trialing Techniques

Percutaneous Trial

With percutaneous cSCS trials, the cylindrical leads are placed through the skin into the epidural space through an epidural introducer needle (straight Tuohy or curved tipped Coudé needle). With the patient appropriately positioned, a fluoroscope is used to confirm the appropriate interlaminar window on the AP view. The fluoroscope should be tilted caudally to open the interlaminar window and optimize the caudal-to-cephalad approach using a Tuohy needle. The fluoroscope can be minimally tilted in a caudal direction to improve visualization when using a Coudé needle, but the needle approach is steeper given the curve of the introducer needle. In both instances, the overlying skin and soft tissues are anesthetized. Using a paramedian oblique approach and a loss-of-resistance technique, the introducer needle is placed into the epidural space at the appropriate interlaminar window, the stylet is removed, and the stimulator lead is inserted through the needle into the epidural space. A second introducer needle may be placed

in a similar fashion, either contralateral to the first needle, or the epidural space can be accessed at an adjacent level ipsilaterally. After steering the stimulator lead(s) to the appropriate levels within the dorsal epidural space, paresthesia mapping may be performed to ensure stimulation is provided to the patient's painful area. This is particularly important when using a tonic mode of SCS. After this, the introducer needle(s) are removed, leaving the stimulator leads in place. Stimulator leads are secured to the skin using suture, Steri-Strips, or other anchoring devices, and the skin-entry sites are covered with a sterile dressing. The externalized leads are connected to an external pulse generator (EPG). The EPG is attached to the skin using a vendor-provided pouch or waistband device or with a standard tape on the side of the patient's preference. Usual trial duration typically spans three to ten days. After this time, the patient returns to the clinic for lead removal. An assessment of the trial is performed, and if deemed successful, then the permanent implant procedure is planned. Some practitioners, based on preference or regulatory bodies, may choose to secure the lead to the ligament or fascia and use it in a staged fashion as a permanent lead if the trial is successful. The lead may need to be removed surgically if the trial fails to provide appropriate relief. Patient education on the implant procedure often occurs at this point, including anesthetic options, and the risks and benefits of the procedure.

The level of percutaneous epidural entry is dictated by several factors, including pain location, anatomical constraints, and physician experience and comfort. The patient's pain location will influence the level of epidural entry because there needs to be a sufficient distance caudal to the more cephalad target to allow all the electrodes access to the epidural space and to minimize the risk of migration. If entry occurs too near the target location, there may not be enough room to accomplish these goals.

Anatomical constraints, such as previous surgery, spinal stenosis or other congenital or degenerative conditions, must also be considered when choosing the site of epidural entry. These anatomical variations will be different for each patient and radiographic evaluation is imperative to ensure patient safety and optimize outcomes. Typically, if a lesion is identified that limits safe SCS lead placement or epidural transit, the epidural entry site will need to be cephalad to that area. Such placement avoids those areas of concern, and epidural entry can proceed in a standard fashion.

Finally, physician experience and comfort need to be considered. Given that implanting physicians are likely comfortable with thoracolumbar epidural entry for thoracic lead placement, some physicians may elect to enter at this level for cSCS lead placement as well. Of course, this requires longer SCS lead epidural navigation, and given the presence of epidural fat, vascular structures, and epidural septae, steering the lead over this distance may prove challenging. Furthermore, cervical leads have been reported to have higher migration rates than thoracic leads. An anchor point at a significantly increased distance from the lead tip might increase the risk for migration with a thoracolumbar entry site. However, studies have not evaluated these theoretical risks, so definitive recommendations and guidance cannot be made at this time.

Surgical Trial

In surgical cSCS trials, the paddle lead is placed under direct visualization into the epidural space. After initiation of general anesthesia or conscious sedation with appropriate cleansing and draping, fluoroscopy is used to correctly identify the incision location based on the planned site of epidural entry. The skin and soft tissues are anesthetized, and an incision is made. Dissection is carried down to the spinous processes, the paraspinous muscles are dissected from the spinous processes, and the superior and inferior laminae are exposed. The inferior aspect of the superior spinous process is removed, and, if necessary to provide a safe entry angle into the epidural space, the spinous process of the inferior level is removed as well. A laminotomy of the inferior lamina of the superior level and/or superior lamina of the inferior level is performed with subsequent visualization of the ligamentum flavum. The ligamentum flavum is opened exposing the epidural space. The paddle lead is placed into the dorsal epidural space through this window and advanced into the appropriate position. The lead placement is checked with fluoroscopy to verify the desired position of the lead paddle, after which the lead wires are secured to the lamina, spinous process, or deep tissues with nonabsorbable sutures, or a nonanchoring technique can be considered.[64] The paddle leadis then connected to an extension that is externalized to a site distant from the potential implantable pulse generator (IPG) pocket site. The incision is irrigated, closed, and covered with a sterile dressing. The externalized lead is connected to an EPG. The EPG is attached to the skin using a vendor-provided pouch or waistband device or with a standard tape on the side of the patient's preference. Patients who have a successful trial are brought back to the operating room, and the implant will be completed.

Consensus Point 6: The NACC recommends that the level of percutaneous epidural entry site for cSCS lead placement should be chosen based on pain location, anatomical variations, and physician experience. Grade: A; level of certainty: low, II (consensus opinion).

Permanent Implant

Very little guidance specifically regarding permanent cSCS implantation techniques has been provided in the neuromodulation literature. Some important points were gleaned from the literature and noted previously.

Percutaneous Implantation/High Thoracic Entry

The site of entry into the epidural space will determine the location of the skin incision. If high thoracic entry (T1-T4) is chosen, then a midline or paramedian incision should be made with dissection to the thoracodorsal fascia. A small pocket should be made over the thoracodorsal fascia to accommodate the stimulation hardware and to provide room for anchoring to this fascia. The tunneling strategy is determined by the desired location of the IPG, with many implanters selecting locations with an upper limit outside of the range of motion of the scapula and a lower limit below the belt line. Tunneling to the anterior chest wall over the trapezius has also been described. Anchoring is accomplished using traditional techniques, but attention to range of motion at the anchoring site should be considered. A recent review of the literature suggested that despite the mobility in the cervical spine, lead migration was not a significant issue.[57] The pocket and IPG location can again be ipsilateral to the anchoring site and placed in the paravertebral tissue. Should a rechargeable device be selected, attention should be paid to the ability of the patient to communicate with the device; a lower flank placement may be necessary. In some individuals, depending upon the length of the cervical

lead, a secondary incision and lead extension may be required. Advantages to this high thoracic entry approach include: 1) increased ability to steer the lead through a short axis entry point and 2) anchoring just below the cervicothoracic junction. Disadvantages include: 1) physicians are often less familiar with this entry point and this may lead to the possibility of difficulty with placement; 2) if inadvertent dural puncture occurs, the substance of the spinal cord is in close proximity to the dura because CSF volumes are decreased in this region; and 3) the frequent need to tunnel to the IPG pocket and the need for lead extensions may affect MRI conditionality or signal degradation. This can be overcome by using longer leads.

Percutaneous Implantation/Low Thoracic/Upper Lumbar

Clinicians have also reported placement of cervical leads through the lower thoracic (T8-T12) to upper lumbar (L1 to L3) approach. The advantages of this technique include: 1) familiarity to the clinician because it is very similar to lead placement for lower extremity and lumbar sites, 2) lack of need to tunnel the lead to a remote pocket location over long distances over the rib cage region, and 3) ability to place the IPG in a location that is familiar to the implanter. Disadvantages include: 1) frequent need to utilize a lead introducer device because bowing may occur while traversing the long distance of the thoracic spine, which leads to difficulty steering the device; 2) difficulty traversing the thoracocervical junction (usually overcome by cervical flexion); and 3) a possible increased risk of lead migration owing to the long intraspinal distance as the lead traverses the very mobile low back. There are no prospective studies comparing these methods.

Surgical Paddle Lead Placement

Both anterograde and retrograde surgical paddle lead placements have been described for placement of cSCS. The retrograde placement as described by Haider et al[40] involves rostral lead introduction under the arch of C1 and the lamina of C2 and anchoring within the investing fascia. Beyond the spine surgical techniques unique to this placement, the anchoring, tunneling and IPG placement concepts mentioned previously remain valid. Table 6 outlines basic considerations for presurgical planning for surgical paddle lead placement.

Sedation for cSCS implantation

There is a wide variation in practice regarding sedation/anesthesia for percutaneous cSCS, ranging from local anesthesia only during lead placement with subsequent deeper sedation and monitored anesthesia care (MAC) for IPG implantation to general anesthesia with or without neuromonitoring throughout the procedure. Paddle lead implantation may be accomplished with general anesthesia or MAC.[64] Where general anesthesia is used, some surgeons advocate the use of neuromonitoring for cSCS, and it has been utilized in at least one recent study.[44]

NACC RECOMMENDATIONS ON CERVICAL DRG STIMULATION

Overview

Dorsal root ganglion stimulation (DRG-S) is approved by the Food and Drug Administration (FDA) for chronic intractable pain of the lower extremities in adults with CRPS I and II. In the United States, current labeling permits marketing of the device for placement at or below the T10 vertebral level. However, many US physicians place DRG-S leads at locations cephalad to T10 on an off-label basis, and in other continents, including Europe and Australia, there are no restrictions on the vertebral levels of DRG-S lead placement. Benefits of DRG-S in the cervical spine are similar to lumbothoracic placement, including subthreshold, paresthesia-free effects with potentially better distal dermatomal coverage, fewer positional changes in stimulation level, and the ability to cover several dermatomes through convergence within the spinal cord or through sympathetic amplification.[65–68] DRG-S of the cervical and upper thoracic spine has been utilized successfully for many conditions, including CRPS Type I and causalgia (CRPS Type II) of the upper extremity, postamputation syndrome, brachial plexopathy, peripheral vascular disease, and nerve injury.[69–72]

Consensus Point 7: The NACC recommends that cervical DRG should only be considered after failure to achieve therapeutic goals with pharmaceutical, injection, and cSCS therapies for upper extremity neuropathic pain and CRPS. Grade: C; level of certainty: low, II.

Anatomical Considerations

As noted in the previous sections, the cervical spine has several unique anatomical properties that must be considered when implanting a DRG-S device. Most contrasting from lumbar DRG-S lead placement is the presence of the spinal cord ventrally, surrounded by a limited CSF barrier. Because the spinal cord and DRG are sensitive neural structures, they are susceptible to blunt trauma caused by the introducer sheath. Primarily using the short bevel sheath and avoiding bevel rotation ventrally are methods to limit inadvertent pressure on the cord.

In the cervical spine, the transverse processes form a bony canal through which the DRG is positioned, outside of the spinal canal. The vertebral artery bisects this canal through the transverse foramen, ventral to the DRG. As such, the semirigid introducer sheath should not be advanced beyond the medial pedicular border because entering the bony canal raises the risk of vascular injury. The canal and nerve slope ventrolaterally, and thus lead position in the lateral fluoroscopic view may be ventral to the posterior vertebral border. In addition, a review of preoperative imaging is required given the space-occupying sheath. Cervical DRG-S should be avoided in cases of moderate to severe stenosis caudad to the target foramen.

Technical Considerations

Given the risks mentioned previously, DRG-S placed in the cervical spine should be reserved for experienced DRG-S implanters. A means of monitoring neural status is required for placement. This can be either an awake, responsive patient, or intraoperative neural monitoring should general anesthesia be utilized. Application of DRG-S should be limited to the lower cervical spine with epidural access from the C6-C7 to T1-T2 levels. Once the epidural access needle is safely within the epidural space, the sheath should be advanced slowly toward the target foramen, and either the guidewire or the lead gently advanced through the transforaminal ligaments. Importantly, gentle pressure should be used to advance the sheath through the foramen. One should avoid extensive pressure because this may cause bowing of the sheath, which can place compression on the spinal cord or exiting nerves. The lead should be placed with the target electrodes superimposed under the lateral masses, with the most proximal contact under the pedicle or slightly within the epidural space. Current programming

should be initiated with a simple bipolar array with low pulse widths, frequencies (usually less than 20 Hz), and amplitudes (typically 1.0 mm).

Consensus Point 8: The NACC recommends recent cervical imaging (MR/CT) to guide preprocedural planning before trial or permanent implantation of a cervical DRG lead. Grade: A; level of certainty: low, II (consensus opinion).

Consensus Point 9: The NACC recommends that cervical DRG-S only be performed by physicians with considerable previous DRG-S experience at the thoracolumbar and sacral spinal levels. Grade: A; level of certainty: low, II (consensus opinion).

RECOMMENDATIONS FOR RISK MITIGATION AND MANAGEMENT OF COMPLICATIONS WITH cSCS

The strategies for risk mitigation of SCS have been reviewed extensively in previous NACC publications,[16–18] and the NACC is currently preparing an updated article with recommendations for mitigation of complications of neurostimulation.[73]

Infection

The Centers for Disease Control recommendations for orthopedic and pain management procedures were last updated in 2017.[74] That year, the incidence of postprocedural infectious complications for SCS was just under 2.5%,[75] as reported in a multicenter retrospective study of 2737 neuromodulation implants. Very low infection rates for surgical paddle implants have been reported.[64,76,77] The American Association of Regional Anesthesiologists (ASRA) also released a practice advisory regarding infectious complications for neuraxial techniques in 2017,[78] and new ASRA infection control guidelines are currently being prepared. A separate review published in 2020 offers guidance on diagnosis, management, and prevention of SCS infections.[79]

Bleeding

Recommendations for prevention of bleeding complications were reviewed in the previous NACC guidance,[18] in the ASRA advisory,[78] and in multisociety guidelines for patients being treated with interventional spine and pain procedures.[80] The risk of epidural hematoma occurs with both device entry and exit, so decisions about anticoagulant therapy throughout the trial period should extend 24 hours beyond lead removal. The risk of continuing nonsteroidal anti-inflamatory medications or selective serotonin reuptake inhibitors (which reduce platelet aggregation), along with the possibility of prescribing alternative medications, should be evaluated on an individual patient basis.

Severe Nerve Injury

In a retrospective review, the incidence of spinal cord injury was 2.35% ($n = 2868$) with percutaneous and paddle lead placements.[81] NACC has previously offered guidance on reducing neurological injury[16] and is currently updating recommendations.[73]

Salvage Strategies

Loss of efficacy is the leading cause of SCS therapy discontinuation and device explant.[82–85] With technological advances (eg, new waveforms and stimulation delivery programs) and new neural targets, the effectiveness of SCS can sometimes be restored. Therapy salvage and outcome optimization are the subjects of new NACC recommendations to be published in 2021.[86]

FUTURE DIRECTIONS

The use of cSCS and cervical DRG-S is evolving, and good-to-excellent results have been reported for many chronic pain conditions. Unfortunately, there remains a paucity of Level 1 evidence supporting its efficacy and safety. Additional high-level studies are needed to both expand indications and improve patient access to cSCS and cervical DRG-S.

In the near term, these cervical spinal neurostimulation procedures should benefit from advances in artificial intelligence, wireless communication, device miniaturization, and MRI compatibility. Initial reports have demonstrated the measurement of the spinal cord response to epidural stimulation with automated feedback regulation using a closed-loop mechanism.[87] Although this technology has been shown to work in the thoracic and lumbar regions, the physiological effect should be applicable to the cSCS as well. Furthermore, cSCS is currently hampered by the distance between the site of power generation and power delivery, resulting in the risk of wire fracture and migration. The development of a device that could be both powered and programmed by an external source would alleviate these concerns for cSCS.

cSCS would also be improved by advances in battery technology, allowing for the decreased size and increased power of future IPGs. Future devices should be much smaller and have a minimum or no recharge burden. Finally, current devices are conditionally approved for MRI, and the limit on that conditional approval varies based on the manufacturer and FDA labeling. Patient experience and long-term outcomes of cSCS could be improved by setting industry-wide standards, and future devices should strive to have MRI conditional labeling regardless of MRI type, stimulation device manufacturer, or body region.

CONCLUSIONS

The NACC has carefully considered many issues to improve patient care and move cervical neurostimulation forward in a patient-centric manner. The recommendations given in this guidance are based on evidence and consensus opinion with the goal to improve patient safety and the effectiveness of cSCS. The NACC is meant to be a living document, and additional guidance will continue as more evidence is developed.

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Timothy R. Deer served as primary author and coordinator. Marc Russo and Jay S. Grider served as primary authors. Robert M. Levy served as senior manuscript editor and worked on manuscript editing and revision. Tim J. Lamer, Vishal Varshney, Brad L. Lindsey, Asokumar Buvanendran, and Brandon Gish performed final review for commercial bias. All authors participated in the research and writing of their assigned sections, and all reviewed the manuscript

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COMMENTS

As another in a series of articles by an experienced group of implanters, this publication set out to provide evidence-based guidance on the use of cervical neurostimulation to improve outcomes. This is a well-researched and well-written article, which does reflect the fact that, unlike thoracolumbar SCS, the body of literature is limited. This may be due in part to its questionable level of approval by insurance carriers in the United States, thus limiting its use in a major market. I do take issue with their recommendations regarding cervical dorsal root ganglion (DRG) stimulation. I believe that there is insufficient evidence to make any recommendations at this time regarding cervical DRG. I would also point out that their statement "DRG-S placed in the cervical spine should be reserved for experienced DRG-S implanters" is problematic. How do they define an experienced implanter? Does this imply that "inexperienced" implanters get the green light to place standard cervical SCS systems? Reports of significant complications with cervical DRG are worrisome, and I would have preferred this entire section to have been omitted and held for the next iteration of this publication. That notwithstanding, I strongly recommend that all cervical SCS implanters avail themselves of the information provided in the publication.

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Thank you for your submission. An interesting and comprehensive approach to cervical SCS. I thought the summary of evidence to date and description of the cervical anatomy was excellent. The

approach and overview of evidence for this topic will be of benefit for neuromodulators undertaking these procedures or setting up a service.

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