Evidence-based consensus guidelines on patient selection and trial stimulation for spinal cord stimulation therapy for chronic non-cancer pain

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ABSTRACT

Spinal cord stimulation (SCS) has demonstrated effectiveness for neuropathic pain. Unfortunately, some patients report inadequate long-term pain relief. Patient selection is emphasized for this therapy; however, the prognostic capabilities and deployment strategies of existing selection techniques, including an SCS trial, have been questioned. After approval by the Board of Directors of the American Society of Regional Anesthesia and Pain Medicine, a steering committee was formed to develop evidence-based guidelines for patient selection and the role of an SCS trial. Representatives of professional organizations with clinical expertize were invited to participate as committee members. A comprehensive literature review was carried out by the steering committee, and the results organized into narrative reports, which were circulated to all the committee members. Individual statements and recommendations within each of seven sections were formulated by the steering committee and circulated to members for voting. We used a modified Delphi method wherein drafts were circulated to each member in a blinded fashion for voting. Comments were incorporated in the subsequent revisions, which were recirculated for voting to achieve consensus. Seven sections with a total of 39 recommendations were approved with 100% consensus from all the members. Sections included definitions and terminology of SCS trial; benefits of SCS trial; screening for psychosocial characteristics; patient perceptions on SCS therapy and the use of trial; other patient predictors of SCS therapy; conduct of SCS trials; and evaluation of SCS trials including minimum criteria for success. Recommendations included that SCS trial should be performed before a definitive SCS implant except in anginal pain (grade B). All patients must be screened with an objective validated instrument for psychosocial factors, and this must include depression (grade B). Despite some limitations, a trial helps patient selection and provides patients with an opportunity to experience the therapy. These recommendations are expected to guide practicing physicians and other stakeholders and should not be mistaken as practice standards. Physicians should continue to make their best judgment based on individual patient considerations and preferences.

BACKGROUND

Spinal cord stimulation (SCS) is an established therapy for the treatment of chronic refractory pain.[1 2] Despite refinements in its technology[3] and expanding research efforts,[4] long-term challenges remain, with nearly 30%–40% patients reporting inadequate relief beyond 24–36 months.[5–8] SCS therapy is not effective in all patients and appropriate patient selection is critical. As SCS involves expensive and invasive spinal procedures and a long-term commitment to living with implanted equipment, treatment failure is associated with dissatisfaction, need for explant surgery, and undue costs to the health system and society. Studies indicate that SCS can be cost-effective only in the long run, as the initial costs outweigh those of conventional management.[9 10] Over the years, use of SCS has increased exponentially, with around 50,000 SCS devices implanted annually across the world,[11] and an estimated market size valued at US$1.88 billion in 2018 that is projected to grow to US$3.58 billion by 2026.[12] Patient selection for SCS needs to consider: (1) appropriate pain indication and (2) patient determinants (psychological/smoking/opioid use) that can predict poor response to therapy. Published reviews and recommendations assist us in considering the most appropriate indications for SCS therapy.[2 13] A trial of SCS therapy complements clinical screening by allowing the patient to go through the experience of SCS and assess efficacy and satisfaction. Based on medical device reports received between 2017 and 2020, the most frequent of which were failure to achieve or maintain adequate pain control, the US Food and Drug Administration recently issued an advisory indicating that an SCS trial needs to be conducted before any implant.[14] Considering some of the drawbacks of a trial, the need for its conduct is being questioned.[15] Our comprehensive literature review identified significant gaps in our understanding of patient characteristics and the overall importance of an SCS trial in patient selection, apart from variations in the interpretation, conduct, and evaluation of SCS trials.[16] None of the published guidelines specifically address patient selection and trial conduct.[1 17 18] To improve standards of clinical practice, we set out to develop evidence-based

guidelines that are pragmatic and clinically applicable to assist clinicians, and inform payers and decision makers, to improve patient outcomes and healthcare decisions.

METHODS

A formal proposal to formulate a multispecialty, multisociety guidelines on patient selection and SCS trial was submitted to the Advocacy and Regulatory Committee, as well as the Board of Directors of the American Society of Regional Anesthesia Pain Medicine (ASRA Pain Medicine) on December 13, 2020 and approved in March 2021. A steering committee was formed and entrusted with selecting additional members with clinical expertize to participate as committee members (online supplemental appendix 1). Selected professional organizations representing members involved in the care of chronic pain patients with SCS therapy including European Society of Regional Anesthesia and Pain Medicine, North American Neuromodulation Society were invited and requested to nominate members to participate in the committee. Invitations were sent out to members with a request to declare any potential conflicts of interest. At the initial conference call, the overall process, areas to cover and potential questions to be addressed in each area to guide drafting of statements and recommendations were discussed. To ensure we considered all published literature relevant to our task, it was considered necessary to conduct a comprehensive literature review on the role of patient selection and trial stimulation in improving SCS outcomes for chronic non-cancer pain. A separate team, including the members of the steering committee, were charged with completing this task. As part of this review, studies reporting on patient predictors of SCS therapy or the role and conduct of SCS trials and patient-important outcomes, published within Medline, EMBASE and Cochrane databases, were selected using a systematic search of literature. Relevant data and outcomes were extracted to synthesize evidence as narrative summaries and tables, categorized based on study design as systematic reviews, randomized controlled trials (RCTs), observational studies, database or registry studies, and case reports. A specific attempt was made to integrate patient values and preferences as reported within literature. These summaries and tables were circulated to the entire committee to facilitate evidence-informed voting. The review methods and results are being separately published.[16] Based on the evidence summaries and inputs from experts within the committee, statements and recommendations within each area were prepared by the steering committee. As per the US Preventive Services Task Force (USPSTF) grading of evidence guidelines, recommendations were graded on a scale from A to D, or as insufficient (table 1) and the level of certainty rated as high, medium, or low (table 2).[19] The USPSTF grading was modified to consider recommendations in the absence of high-quality level 1 studies, in view of the challenges in the conduct of RCTs in invasive procedures, similar to other interventional pain management guidelines published by ASRA Pain Medicine.[20] Drafts of statements and recommendations to specific areas, noted as sections, were circulated to all members for voting. We used a modified Delphi method to tabulate comments, incorporate changes and converge the answers toward a consensus over electronic correspondence rounds. At the initial conference call, it was decided that >50% panel agreement was sufficient to report a recommendation, but ≥75% agreement was required for consensus. Once a section was close to consensus, the committee chair facilitated any additional teleconference meetings or electronic correspondences to finalize consensus and assist with edits and formatting. The final draft was circulated to the entire committee for a final round of revisions without voting. After the committee completed the guidelines, it was sent out to organizations' boards of directors for approval with only minor changes permitted.

COMMITTEE STATEMENTS AND RECOMMENDATIONS

The scope of our guidelines includes appropriate patient selection and the importance and conduct of a screening trial of SCS. Chronic pain indications or diagnosis that need to be considered have been covered in other guidelines,[13] and are not included within the purview of our guidelines. We detail our statements and recommendations in seven individual sections along with a succinct summary. Detailed supporting evidence underlying our guidelines have been published separately.[16] We had 100% consensus on all recommendations from the committee members.

Section 1: definitions on SCS screening trial

Although most practitioners agree on the general concept of an SCS trial, there is variability in the exact definition and interpretation of an SCS trial. Traditionally, an SCS trial involves placement of either percutaneously placed cylindrical electrodes or surgical paddle leads within the epidural space in a vertical

Table 1 US Preventive Services Task Force grading of evidence and suggestions for practice

Grade	Definition	Suggestions for practice
A	Our committee recommends this treatment, test, or strategy to improve outcomes. There is high certainty that the net benefit is substantial.	Offer or provide this service.
B	Our committee recommends this treatment, test, or strategy to improve outcomes. 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	Our committee recommends selectively offering or providing this treatment, test, or strategy to improve outcomes 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	Our committee recommends against the intervention. 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 Statement	Our committee concludes that the current evidence is insufficient to assess the balance of benefits and harms of the intervention. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of the Recommendation Statement. If the treatment or service is offered, patients should understand the uncertainty about the balance of benefits and harms

USPSTF, US Preventive Services Task Force

Table 2 Levels of certainty regarding net benefit as per USPSTF

Certainty	Definition
High	The available evidence mostly includes consistent results from well designed, well-conducted studies in representative populations of SCS therapy. The studies assess the effects of the treatment, test, or other intervention on treatment or other relevant outcomes. The conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the intervention on 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 individuals offered SCS therapy; ► High likelihood of bias; ► Lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and that change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on treatment and other outcomes of interest. 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. ► High likelihood of bias. ► Findings not generalizable to individuals offered SCS therapy. ► Lack of information on important outcome measures. More information may allow estimation of effects on treatment outcomes.

SCS, spinal cord stimulation; USPSTF, US Preventive Services Task Force.

location that overlap the afferent signaling from the painful area (tested using paresthesia coverage) and connected to an external pulse generator and application of SCS during a longitudinal observational period typically lasting a few days to allow for the assessment of treatment efficacy and guide decisions for permanent implantation.[18] Several studies (mostly observational) have indicated the performance of an 'on-table trial'.[21–23] This technique has significant limitations, such as the inability to assess effective pain relief in a patient who is positioned for surgery with limited movement; a patient who is often under at least some sedation; and no control on additional analgesic medications. As such, an 'on-table trial' cannot fulfill all the objectives of a true SCS trial. Moreover, the approach involved is reported differently in different studies. However, there may be circumstances when a physician considers not doing a traditional trial and proceeds directly to implant depending on patient circumstances or patient preferences (unsafe to stop anticoagulant for a period of days).[24] Such a modification of testing for on-table paresthesia coverage cannot be considered equivalent to a traditional trial. As such, the 'trial conversion rate' could be different than 'trial success rate' because some patients may not go forward with definitive implantation for reasons other than trial therapy failure.[25]

SCS systems using stimulation waveforms that produce pain relief independent of induced sensations can include, 'high frequency', '10 Khz stimulation', burst stimulation' and others. For the purpose of these recommendations, we collectively referred to these systems as 'paresthesia free'.

Position statements

- Definition of SCS trial: Insertion of SCS leads and application of stimulation therapy in a clinically appropriate patient, to assess for: (A) appropriate and adequate coverage of painful regions where the mode of stimulation elicits a sensation felt by the patient, (B) tolerability of any induced sensations, and (C) presence and magnitude of clinical benefit, before deciding on the performance of definitive SCS therapy. A trial may be performed using temporary or permanent leads. For SCS systems independent of induced sensation 'magnitude of clinical benefit' alone can be considered.
- On-table SCS trial: An on-table SCS trial cannot effectively assess for the presence and magnitude of clinical benefit as the patient is positioned for surgical procedure with limited movements and likely to be under the effect of sedation and/or analgesic medications.
- Trial success rate: This is the proportion of patients who report 'success' based on parameters and thresholds considered for their SCS trial procedure among the total number of patients who had the trial procedure. Many databases identify implantation of an implantable pulse generator (IPG) to be associated with the performance of a definitive procedure and may not capture the exact trial success rate because not all patients with successful trial may go with IPG implantation.
- Trial conversion rate: This is the proportion of patients who proceed to definitive SCS implantation after a successful trial.
- What is SCS therapy success rate: This is the proportion of patients who report 'therapy success' of SCS based on parameters/tests and thresholds considered for a prespecified clinical indication and over a defined follow-up period.

Section 2: benefits and limitations of SCS trials

Questions considered

1. Is there a clinical benefit in performing a trial of SCS therapy combined with clinical screening versus clinical screening alone?
2. Are there disadvantages in performing a trial of SCS therapy?
3. Does the benefit for a trial of SCS differ in terms of clinical indication for SCS?

The presumed value of a trial is in offering SCS therapy only to selected patients with higher chances of long-term therapy success, thereby complementing clinical screening. The alternative approach of no trial would involve clinical screening for an appropriate indication and excluding certain patients with other determinants as obtained by their medical history, typically psychosocial characteristics. As there is no accepted, standardized clinical approach that can be operationalized (including the domains and their thresholds) to screen patients, and as chronic pain and psychosocial characteristics influence each other, an approach that includes a trial has potential advantages. In clinical trials in which groups were randomized to two or more different SCS treatments, randomization was often performed after the screening trial,[6] like enrichment clinical trial designs to select potential responders to the treatment being studied. In fact, enrichment design is suggested as one of the ways to overcome challenges in studying chronic pain therapies as failures are common[26] and incorrect patient selection is considered the most important reason for patients failing to receive benefit from invasive pain therapies.[27]

Our literature review indicates that a majority of published studies report the use of a trial phase.[16] The main posited benefit of a trial is in identifying potential responders to go through the main implant (trial success rate), and the long-term status of responders can be assessed based on therapy success. Definition of therapy success can be considered at various periods. Most RCTs and observational studies of SCS therapies report outcomes at time points between 6 and 12 months postimplantation.[6 28–31] Although studies reporting outcomes from databases/registries report outcomes between 2 and 5 years,[32–34] 'therapy success' is not directly captured and in the most 'explant rates' are reported.

Recommendations based on Section 1: definitions on SCS screening trial

1. The following SCS trial definition should be considered in clinical practice. If a paresthesia-free SCS system is being used, one must document whether testing for adequacy of paresthesia coverage was part of the trial or not. Definition: Insertion of SCS leads and application of stimulation therapy in a clinically appropriate patient, to assess for: (A) appropriate and adequate coverage of painful regions where the mode of stimulation elicits a sensation felt by the patient, (b) tolerability of any induced sensations, and (C) presence and magnitude of clinical benefit, before deciding on the performance of definitive SCS therapy. A trial may be performed using temporary or permanent leads. For SCS systems independent of induced sensation 'magnitude of clinical benefit' alone can be considered.

   Grade A; *Level of Certainty: High.*

2. On-table trial should not be considered equivalent to a traditional SCS trial. On-table stimulation only achieves testing for paresthesia coverage in painful areas and to ensure that paresthesia is tolerable. Unless prespecified as a trial to indicate satisfactory patient response, one cannot assume 'on-table stimulation' to qualify as an SCS trial.

   Grade B; *Level of Certainty: Moderate.*

3. For on-table trials, one should document the trial parameters, anesthetic technique used (local anesthesia with or without sedation, or general anesthesia); and the specific patient responses elicited to assess the trial.

   Grade B; *Level of Certainty: Moderate.*

4. Physicians must document reasons for a particular patient not proceeding with SCS therapy despite a successful trial.

   Grade A; *Level of Certainty: High*

Explant rates can give us an indirect estimate of therapy success, but these are not the interchangeable. Explant could be due to complications that require explantation to manage the issue, or patients who claim unsuccessful therapy (non-responders); it can also include successful cases with full remission of symptoms. At the same time, differences in clinical practices may not allow all unresponsive patients to be explanted. Studies of SCS reporting long-term outcomes must consider the possibility that the original pain diagnosis and location necessitating the SCS therapy may evolve or change over time and the success/failure of the existing SCS therapy should be considered in relation to the original indication. Based on reported RCTs and observational studies capturing patient-relevant clinical outcomes, the median trial success rate ranges between 72% and 82%, and therapy success is between 65% and 61% at 12 months, respectively.[16] Although it is notable that Eldabe *et al* were able to publish the only reported RCT comparing SCS trial with a no trial approach,[22] it was a relatively small study in a mixed population including complex regional pain syndrome (CRPS) with some salient limitations such as using on-table SCS trial, a small number of patients failing a trial (5/54), and also in having a relatively low responder rate of 40% at 6 months. Among the clinical indications, we observe that all RCTs of anginal pain do not include a trial phase (except one noting a on-table stimulation capture),[35–38] whereas all RCTs of SCS for the treatment of diabetic neuropathy include a trial phase.[28 39 40] Although CRPS is a common indication, and another review noted four reported RCTs,[4] only two reported on patient-important outcomes,[41 42] both of which were included in our review.[16] In comparison we observe 33 RCTs for persistent spinal pain syndrome (PSPS, formerly known as failed back surgery syndrome, FBSS),[4] with a majority including a screening trial.[16] A trial of SCS has the potential for temporary and long-term complications such as spinal cord and nerve root injury. These can lead to additional morbidity apart from possibly influencing patient satisfaction and trial outcome assessment. Potential adverse effects include procedural pain, infection, lead fracture, lead migration, and headache due to inadvertent dural puncture.[18] The existing literature indicates that the incidence of such complications (usually minor) to be approximately 2%–5%. Epidural fibrosis around a trial SCS electrode can theoretically cause difficulties in permanent lead insertion but has not been reported in any studies. Overall, based on available literature the benefits of performing an SCS trial override its potential limitations.

Economic analysis

Cost analysis is an important aspect of understanding the overall value of a trial. However, there are several factors that determine the costs including country-specific payment system, payors and insurance coverage involved, aspects of trial conduct including number and type of leads, costing involved in procedural expenses, and others. Because of these factors we do not include any specific statements or economic considerations within our recommendations. A cost-analysis paper noted that SCS trials may be cost saving if at least 20% of patients who underwent a trial of SCS did not go through to a full implant, indicating the benefit gained from identifying non-responders. However, this was based on the use of permanent leads (with temporary percutaneous extensions) and may not be generalizable to practices in the USA where temporary leads are commonly used for SCS trials.[43] Recently, a budget impact analysis considered a scenario where all patients would use temporary leads for the SCS trial.[44] The study observed that considering a 10% SCS trial failure rate, the incremental cost associated with SCS trials for each 100 patients would range between £61,325 (US$73,769) and £87,837 (US$105,661). Estimates from the budget impact analysis suggest that SCS trials with temporary leads may become cost saving if at least 13.5%–14.75% of patients undergoing trials do not proceed to full SCS implant. Estimates were generated using the UK's National Health Service reference costs and it is plausible that these costs may differ from one country to another. A microcosting exercise may provide a more accurate estimate of the cost of an SCS trial.

Position statements

- There are clinical benefits in performing a trial of SCS therapy before performing a definitive SCS implant. The value of an SCS trial as compared with patient selection with clinical screening alone can be considered using measures of 'diagnostic accuracy' for predicting long-term therapy success or failure. Although a direct comparison of diagnostic accuracy between the two approaches has never been performed or reported, the widely practiced approach has

been to use a trial because of the lower confidence associated with 'clinical screening alone' that may be affected by the variability in approaches, expertize of the team or the operator.

- Based on estimation of diagnostic parameters from published studies, SCS trial has good sensitivity (77%–100% based on RCTs) and moderate specificity (35%–53% based on RCTs) in identifying candidates for SCS therapy (considered across all pain conditions) (online supplemental file 1).
- There are potential procedure-related adverse effects related to the implantation of either temporary or permanent leads as part of a trial. These include neurological injury, procedural pain, infection, lead fracture, lead migration, and headache due to dural puncture. The differences in potential risk associated with the two techniques are shown in online supplemental file 2.
- Anginal pain: The benefit of a trial of SCS for anginal pain in patients with non-operable (referring to coronary artery bypass graft surgery) cardiac disease is less certain as all but one RCT do not include a trial phase.
- Peripheral vascular disease (PVD): The literature suggests that performing an SCS trial for treatment of PVD is useful based on evidence from both observational studies and RCTs.[16] Improvement in transcutaneous oxygen tension ($TcPO_2$), which can be an objective marker assessed during the SCS trial, has been observed to be associated with therapy success for improved pain and a lower rate of amputation.
- CRPS: Although CRPS is a common indication for SCS therapy, we observed only two RCTs specifically on this population and fewer high-quality observational studies performed selectively on this population.[16] Apart from the RCT by Eldabe *et al* (mixed population including CRPS),[22] no studies compared a trial versus no trial approach.
- Diabetic neuropathy: All three RCTs specific to the use of SCS for treatment of painful diabetic neuropathy have included a trial phase, indicating typicality of performing a trial of SCS for this indication.[16]

Recommendations based on Section 2: benefits and limitations of SCS trials

1. In patients with chronic low back pain and/or leg pain, a trial of SCS should be performed prior to a definitive SCS implant.

   Grade B; *Level of Certainty: Moderate*

2. In patients with critical limb ischemia due to peripheral vascular disease, a trial of SCS should be performed before a definitive SCS implant.

   Grade B; *Level of Certainty: Moderate.*

3. In patients with chronic painful diabetic neuropathy, a trial of SCS should be performed before a definitive SCS implant.

   Grade B; *Level of Certainty: Moderate.*

4. In patients with complex regional pain syndrome type I or II, a trial of SCS should be performed before a definitive SCS implant.

   Grade B; *Level of Certainty: Moderate.*

5. In patients with chronic anginal pain who are not considered as surgical candidates for coronary artery bypass surgery, a trial of SCS may not need to be performed prior to a definitive SCS implant.

   Grade B; *Level of Certainty: Moderate.*

Section 3: screening for psychosocial factors influencing SCS patient selection

Questions considered

1. Are there any psychosocial risk factors that can be considered as absolute contraindications for SCS therapy?
2. What psychosocial factors have been associated with higher risk of poor outcomes with SCS therapy?
3. What are the suggested tools to diagnose the presence and severity of psychological factors associated higher risk of poor outcomes with SCS therapy?
4. Is there any role for psychological therapy, education provision, counseling, or other such approaches to modify potential risk factors and hence long-term outcomes?

Screening for psychosocial factors is considered important for SCS therapy, as they can influence long-term outcomes, especially patient satisfaction.[45] Patient perceptions as tied to their expectations are covered in section 4. There is lack of consensus on the best method, domains, and tools to be used for screening, as evidenced by 20 different screening questionnaires utilized across 25 different studies.[45 46] We have taken into consideration the consistency of results among studies, generalizability of findings to practice, coherence in the chain of evidence, and the potential magnitude of effect. Most publications related to SCS patient selection highlight the importance of patient's understanding regarding the application and the use of SCS therapy.[47 48] Patients need to be aware of the components involved (leads and IPG), and its expected effects so that therapy can be optimized and titrated with appropriate programming. There are no RCTs evaluating outcomes based on randomizing patients with or without a particular set of psychological traits to SCS therapy.[16] In published studies, reviews and guidelines, presence of ongoing substance abuse and major psychological disorders, such as active psychosis, are consistently considered as absolute contraindications because patients with these conditions are known to exhibit loss of insight and non-compliance to treatment.[17 18 47 48] Among observational studies, most studies involve mixed populations or patients with chronic leg pain with or without back pain, with only one study evaluating patients with CRPS,[49] and no studies involving SCS for angina, PVD or diabetic neuropathy. The most commonly used tool reported in studies is the Minnesota Multiphasic Personality Inventory (MMPI) and its different versions.[46 50–52] Despite studies noting association of catastrophizing using the Pain Catastrophizing Scale (PCS) with poor outcomes, its value as a predictor of long-term outcomes is not consistent.[53 54] Similarly, social factors such as poor social support and their associations with outcomes are not consistent and the tools to identify such social factors are not foolproof. Although presence of anxiety and post-traumatic stress disorder was noted to be predictive of poor outcomes in small observational studies,[55 56] the findings were not consistent.[52] Dumoulin *et al* described a predictive indication factor (IF %) for preimplantation psychological evaluation using 24 factors developed

by a psychologist for screening in 40 patients and its correlation at 6 months with evaluation factor (EF %) consisting of a six-point evaluation scale.[57] Although there was a good correlation, the IF factors were evaluated subjectively by an experienced psychologist and covered various domains not commonly used in clinical practice (neurosis, psychosis, perversion, hysteria, somatization, depression, expectations, sexual orientation, guilt, substance use, and others). Notably, it has never been replicated. Prabhala *et al* developed a tool for SCS candidacy screening with 14 questions evaluating four subsets (emotive, depression, other type, therapy). This was completed by the psychologist but what tools were used for interviewing are unclear, for example, rating of aberrant body concerns or demoralization or differentiating between depression that would benefit from medication versus other.[58] Depression, commonly identified using MMPI scale 2 (depression), is noted to be the only relatively consistent factor indicative of poor long-term outcomes,[46 59 60] and also for trial success as identified in one study.[61] At the same time, depression can be a consequence of chronic pain and may improve with SCS therapy. Consideration to identify if it was antecedent or a consequence of chronic pain is helpful in certain patients.[62]

Position statements

- Based on the published literature and the likelihood of such potential associations in chronic pain patients with other therapeutic interventions, psychosocial factors considered to influence long-term outcomes of SCS therapy can be categorized under the following domains: major psychological, emotional, cognitive, personality disorder, pain-related coping and behavior, expectations and insight, social support, and secondary gains.
- Common traits or characteristics associated with the risk of poor long-term SCS outcomes may include depression, anxiety, catastrophizing, poor coping or self-efficacy, aberrant personality, abnormal pain acceptance, demoralization, self-doubt, poor social support, post-traumatic stress disorder and presence of secondary gain. However, there is no common set of characteristics or factors that are used for screening patients for SCS therapy.
- Presence of 'substance abuse (untreated or ongoing)' and 'major psychological disorder (such as active psychosis)' are associated with the risk of poor long-term outcomes, with or without explantation. Hence, most consider the presence of either condition as absolute contraindications for SCS therapy.
- Based on available evidence, presence of inadequately managed depression at baseline is a predictor of poor SCS outcome. Depression can be a consequence of chronic pain. Some studies indicate the potential for improvement of depressive symptoms with SCS therapy, which may or may not be observable within the short period of SCS trial.
- High pain catastrophizing at baseline could be a predictor of poor long-term SCS outcomes. However, reported studies have observed inconsistent effects of catastrophizing (mostly measured using PCS) on outcomes.
- The most commonly reported tool used to screen patients for risk factors is the MMPI or its adaptations, or revised versions. In many controlled studies, approaches that combine other established tools like the Hospital Anxiety Depression Scale, Beck Depression Inventory or PCS, along with clinical judgment, have been used.
- In patients offered SCS therapy and are identified to have certain high-risk psychological characteristics predictive of poor outcomes), continued therapy in the form of non-pharmacological (such as cognitive behavioral therapy) and/or pharmacological' treatments can improve psychological status and therefore potentially improve long-term SCS outcomes.

Recommendations based on Section 3: screening for psycho-social factors influencing SCS patient selection

1. Do not offer SCS therapy for patients with a diagnosis of active psychosis or ongoing substance use disorder (SUD) (including alcohol). However, when the SUD is mild (rated using DSM-V as 2–3 symptoms), remote, or under treatment, individualized clinical judgment must be used in regard to offering a trial of SCS.

   Grade D; *Level of Certainty: Moderate.*

2. All patients must be assessed for the patient's overall understanding of the SCS therapy procedure, its risks, benefits, and requirements for long-term maintenance.

   Grade B; *Level of Certainty: High.*

3. Appropriate screening for high-risk psycho-social factors must be performed before a patient is offered a trial of SCS. This should be carried out using (an) objective validated instrument(s) or questionnaire(s) and should include screening for depression. Such screening would ideally be performed by a psychologist or psychiatrist working as part of a multidisciplinary program.

   Grade B; *Level of Certainty: Moderate.*

4. Identification of poorly controlled depression during screening requires a more detailed assessment and need for appropriate therapy before an SCS trial is offered. Attempts to identify if depression was a consequence of chronic pain and not antecedent could facilitate screening decisions in some patients with treatment resistant depression.

   Grade C; *Level of Certainty: Low.*

5. In patients offered SCS therapy and identified at baseline as having psychological characteristics associated with poor long-term outcomes, therapy in the form of non-pharmacological and/or pharmacological interventions, where possible and appropriate, should be continued as part of a multidisciplinary treatment plan.

   Grade B; *Level of Certainty: Moderate.*

Section 4: patient perceptions on SCS therapy, patient selection and the use of SCS trial

Most existing guidelines do not specifically include or integrate patient perceptions. However, these are important to the final decision about deciding on long-term SCS therapy. The following questions were considered as part of assessing patient perceptions and expectations.

1. How do patients perceive SCS (preimplant) as a therapy for their chronic pain?

2. How do patients perceive the role of SCS trial as a screening tool for SCS therapy?
3. What do patients perceive as gaps in clinical care relevant to SCS therapy, particularly as applicable to the role of SCS trial?

The majority of studies evaluating patient perceptions or expectations are observational and qualitative or mixed in design. Qualitative surveys are usually rated as low with regards to their quality of evidence, and we have also taken into consideration the consistency of observing a particular finding or observation. The intent is to provide this information (despite the low certainty) to be integrated into decision making within clinical practice. Apart from variability in their perceptions on SCS, patients are anxious to know their chances of success (as possible rates), which could influence their understanding and interpretation regarding the utility of SCS therapy in their context.[63 64] Qualitative studies on patients' experiences on SCS treatment report on the importance of accepting and coping of chronic pain state as an important attribute.[65 66] Qualitative interviews indicate that emotions and expectations have a significant influence on how a person can cope with pain. As an example of negative coping and unreasonable expectations, some patients hope that SCS could be a fix or expect a complete pain free state.[63 66] Specific to the importance of SCS trials, patients indicate uncertainty on its role, depending on the study design and stage at which patients were interviewed. During postimplant interviews in a study randomizing patients to 'trial' versus 'no trial', the majority of patients questioned the need for a two-stage procedure after their participation, while others wondered if a trial would have been a better idea to know if they were among the 20% in whom SCS does not work.[24] In a separate study, nearly all patients perceived a screening trial to be beneficial, as it provided a chance for them to understand their pain in the context of the SCS system.[64] During interviews conducted after the trial or implant, many patients express concerns around SCS trial in the form of: (1) pain during and after the procedure and (2) scarring and body image issues due to external leads. Some express anxiety around managing trial-related paraphernalia (such as externalized leads) and practical aspects of wound management (managing oozing/bandages/dressing).[64 65] It is important to note that some patients can perceive the trial experience to be a bad one regardless of the outcome, but even more so if it fails.[64 66]

Position statements

- Patients' perceptions around the role of SCS in decreasing their chronic pain are variable. Although the majority of patients have realistic expectations around the amount of improvement in their pain relief, some incorrectly tend to consider SCS as a 'a fix', or 'expect a pain free state'.
- As patients' understanding of SCS therapy is variable, balancing hopes and negative expectations can be challenging. Assessment of individual patient acceptance of pain and existing coping skills could be helpful.
- Reported studies indicate uncertainties around overall patient perceptions on the importance of SCS trial.
- In interviews conducted after the trial, patients often note deficits in the amount and kind of information conveyed regarding the conduct and experience of a trial, with some patients expressing concerns around trial related issues including pain and aspects of wound management.
- In most interviews, patients expressed the desire to speak to other patients who have previously lived through the SCS experience, both successful and failed. It would be ideal to provide such an opportunity to all potential SCS patients as part of their selection process.
- A formal process to elicit patient information and gauge acceptance of the chronic pain state within a multidisciplinary framework should be considered prior to proceeding with SCS.

Recommendations based on Section 4: patient perceptions on SCS therapy, patient selection and the use of SCS trial

1. Because of substantial variability, an individualized approach to setting realistic expectations for pain relief from a trial of SCS should be considered, based on the particular patient's expectations and psychological factors such as mood, behaviors, and coping.

   Grade B; *Level of Certainty: Moderate.*

2. All patients must be provided education about SCS treatment and potential long-term outcomes before a trial. Individual patient discussions apart from handing over written information are likely to be more effective.

   Grade B; *Level of Certainty: High.*

3. Specific information discussed with patients regarding an SCS trial should include its role in their management, process of trial conduct, management of trial equipment, and expectations of trial related pain and potential complications. This process must be separate from the discussion about permanent SCS implant system and therapy.

   Grade B; *Level of Certainty: Moderate.*

Section 5: other patient predictors of SCS therapy

Questions considered

1. Are there any other patient characteristics that influence the outcomes of SCS therapy?
2. Can we consider potential strategies to modify patient factors as noted in#1, to optimize patient selection and influence outcomes of SCS therapy?

Patient demographic factors

Relatively few studies have explored the differences in long-term outcomes based on patient's age, sex or gender. Retrospective observational studies indicate that younger age is associated with increased conversion to full implant[25] and increased age was a predictor of higher explantation risk,[33] although a recent small study found no difference in pain scores with age.[67] Women have been noted to have a higher rate of explantation, mostly because of device-related discomfort,[68] and men with refractory angina pectoris who are treated with SCS have been noted to have a larger improvement in quality of life compared with women with SCS for refractory angina.[34] Although the number of patients with obesity having SCS implants have increased over the years the cost of hospitalization was not different when compared with non-obese individuals undergoing SCS implant.[69] Other observational studies have observed obesity to be an independent predictor of 30-day readmission after SCS implantation,[70] as well as higher risk of complications including mechanical

complications and lead migration.[71] A significant negative association of body mass index (BMI) with SCS effectiveness was observed in a study with 2% reduction of SCS success with each unit increase of BMI[72]; and a BMI >36.5 kg/m^2 was associated with less improvement in depression and catastrophizing in patients on SCS therapy.[73]

Smoking

Influence of smoking has been studied in some observational studies. It is unclear whether smoking directly accelerates the underlying pain pathology. However, smoking is associated with accelerated spine degeneration, impaired surgical wound healing, and increased risk of infection in patients having spine surgery.[74 75] A systematic review observed an overall smoking prevalence of 38% in patients with SCS,[76] with differing rates among subgroups (56% when considered only for patients with PVD; and 28% in patients with lumbar spine diagnosis). Mekhail *et al* demonstrated that current smokers report significantly higher pain scores and opioid use (2.4 times) compared with non-smokers or former smokers.[30 77] Despite this evidence, other considerations do not allow us to decline SCS therapy for current smokers.[78]

Use of opioids and other medications

Although some studies indicate no difference,[79 80] most studies indicate a negative association with opioid use and long-term SCS outcomes. In a database study of 5476 patients opioid use of >90 mg morphine equivalent dose was highly predictive of explants,[81] with another prospective study observing a cut-off of 35 mg morphine equivalents to predict SCS failures over 2 years.[82] Many studies also indicate decreased opioid use after successful SCS therapy, with a potential for better response with high frequency SCS.[83] A recent study of 145 patients noted that morphine equivalent daily dose of <65 mg predicted decreased long-term opioid use of >20% in nearly 50% patients.[84] It is likely that preimplant neuropathic pain medications (considered as gabapentinoids, tricyclic antidepressants, serotonin, and norepinephrine reuptake inhibitors) have no influence,[80] although a recent study observed reduced risk of explant in those using gabapentinoid medications prior their SCS trial.[85] A case–control study that tested the association of benzodiazepine use and SCS outcomes, noting that benzodiazepine use during the 24-month period before or after SCS implantation was associated with increased risk of explantation and unsuccessful trial stimulation.[86] We need to consider that the use of benzodiazepine may be a reflection of an underlying diagnosis of depression, which is noted to be associated with poor outcomes, and also others such as anxiety or stress related disorders.

Position statements

- A higher BMI is associated with risk of explantation or long-term therapy failure. We found no studies investigating the effectiveness of diet or weight reduction strategies before or after trial and long-term outcomes in selected patients.
- History of current smoking status is associated with increased risk of therapy failures in the form of higher pain scores and higher opioid use in SCS patients. We found no studies investigating the effectiveness of smoking reduction attempts before or after SCS trial and long-term outcomes in selected patients.
- Higher dose of baseline opioid use, particularly >90 mg of oral morphine equivalents per day, has been associated with increased risk of therapy failures or explants in patients using SCS. We found no studies investigating the effectiveness of opioid reduction attempts before or after SCS trial and long-term outcomes in selected patients. Rapid opioid tapering could be associated with opioid withdrawal and increased pain symptoms.
- The association between baseline (pre-SCS implant) benzodiazepine use and long-term SCS outcomes is uncertain.

Recommendations based on Section 5: other patient predictors of SCS therapy

1. In patients with high BMI considered for SCS therapy, potentially higher risk of complications and failure should be disclosed. Patients must be educated and counseled about the benefits of weight reduction strategies and exercises and appropriate referral should be considered.

   Grade C; *Level of Certainty: Moderate.*

2. In patients who are currently smoking and are being considered for SCS therapy, potentially higher risk of failure and complications should be disclosed. Patients must be educated and counseled about the benefits of smoking reduction strategies.

   Grade C; *Level of Certainty: Moderate.*

3. In patients on high doses of opioid therapy (>90 mg of morphine equivalent per day) at baseline being considered for SCS therapy, higher risk of therapy failure and explants should be disclosed. Since active opioid reduction risks opioid withdrawal, it should not be considered necessary, but may be considered in discussion with the patient, prior to the trial of SCS.

   Grade C; *Level of Certainty: Moderate.*

Section 6: considerations for the conduct of SCS trials

Questions considered

1. Does the type of approach (laminotomy/laminectomy vs percutaneous) for trial influence trial-related considerations and outcomes?
2. Can trial leads be placed under deep sedation or general anesthesia (GA) for either percutaneous or paddle leads?
3. Does the type of SCS trial influence trial-related considerations and outcomes?
4. Does the number of leads inserted during a percutaneous trial influence SCS trial-related considerations and outcomes?
5. Does the approach to lead positioning for percutaneous trials (anatomical-based vs paresthesia-based) influence SCS trial-related considerations and outcomes?
6. Does the trial duration influence SCS trial-related considerations and outcomes?
7. Does the mode of stimulation used during the SCS trial influence trial-related considerations and outcomes?
8. What are the best antibiotic practices to use for preventing infection associated with SCS trials?
9. Are there any benefits in salvaging SCS trial based on indeterminate or failed response?

An SCS trial is usually carried out using percutaneously placed leads, even if the final implant involves a paddle lead.[87] The use of laminotomy/laminectomy approach is less common and considered in patients with technical challenges to placement, such as high BMI or previous instrumentation,[88–90] and exposes the patient to higher procedural complications, including post procedural pain that could interfere with the assessment of trial. Studies over the years report the use of laminectomy for SCS trial paddle lead placement, but in most the reasons are unclear.[21 91 92] If paddle leads are used, they are likely to be permanent leads placed usually under GA. Use of minimally invasive technique with avoidance of GA is possible, but it can be challenging.[93] The neurostimulation appropriateness consensus committee (NACC) guidelines suggest that when the risk-to-benefit ratio favors deep sedation or GA, then intraoperative neurophysiological monitoring (IONM) should be considered.[94] The practice parameters publication from North *et al*, also note that, 'under GA, the unconscious patient cannot describe paresthesia coverage or react to changes in stimulation parameters or intraoperative events, which might increase the risk of neurologic injury'.[18] A recent survey of ASRA and Spinal Injection Society members indicate the following findings: 77% of physicians reported using deep sedation for permanent SCS implants and 45% reported using GA for 10 kHz implants (not requiring paresthesia testing). Although 6% reported a complication related to the use of GA, it was unclear how many were technical complications leading to neural injury.[95] There seems to be geographic variation in the use of permanent leads or temporary leads for SCS trials, with temporary lead insertions being more common in the USA and a mix of both approaches being used in European countries.[96] Differences between them are summarized in online supplemental file 2. There is no prospective comparison of permanent percutaneous leads versus temporary percutaneous leads during the trial period. Retrospective studies indicate no differences in trial success rate but higher procedural pain, potential time, and operating room requirements with permanent leads, whereas lesser lead migration than with temporary leads.[97 98] Although higher infection and poor wound healing has been noted with permanent leads, a large retrospective study observed an increased rate of infection in the main system with the use of temporary leads. However, other variables that could influence infection between temporary trials and permanent implants were unclear.[99] Temporary trials could be considered to increase the overall expense considering the need to discard the temporary leads.

Most studies do not specify the number of leads used for trialing, and as such they are not predictive of trial outcomes.[100] Traditionally, testing for paresthesia has been considered to reflect technical success of a trial procedure.[101] In studies comparing paresthesia-based positioning versus anatomical positioning, there were no differences in trial success, but physicians indicate preference for anatomical positioning, which would take less time.[102 103] Although some studies indicate no such preference by patients, paresthesia coverage might be an important predictor of long-term success, as found in a subgroup analysis of patients from the Franco-Canadian multicolumn SCS prospective study comparing optimized lead positioning versus a non-optimized lead positioning.[104] In certain countries, the duration of trial has been mandated by their health regulatory agencies; France: 10 days, Netherlands: 1 weeks, Germany 6–12 days, Belgium: 4 weeks. We observed a median trial duration of 7 days in observational studies and 10.5 days in RCTs, with the most common period ranging between 3 and 7 days.[16] Some considered extending the trial duration in patients who were uncertain about the trial outcomes.[105] There is observational evidence to suggest that the rate of trial success gets lower, and the risk of procedural pain gets higher in patients with increased trial duration.[97] Prolonged trial exposes a patient to higher risk of infection.[106] In many RCTs, the trial phase involved paresthesia-based stimulation even if the therapy was based on paresthesia-free modes.[6 107] De Ridder *et al* compared burst versus paresthesia versus placebo stimulation in a 1 week crossover randomization during the trial phase. The outcomes were better with burst stimulation for back and leg pain as compared with paresthesia-based stimulation.[91] De Andres *et al* for PSPS and Canós-Verdecho *et al* for CRPS compared high-frequency versus paresthesia stimulation and noted similar trial success rates.[41 108] North and Bolash report a wireless system and compared high frequency and paraesthesia stimulation during trial and therapy phase, noting a success rate of 92% vs 84%, not found to be significantly different.[109] A retrospective study of 174 patients observed a higher odds of trial success with paresthesia-based conventional stimulation compared with others, OR: 10.3 (95% CI 1.7 to 62).[100] There are no prospective studies related to antibiotic use and infection during SCS trialing. The NACC guidelines indicate weight-based prophylactic antibiotics for all SCS trials and postoperative use of antibiotics (limited to 24 hours) to be considered in other patients with higher risk or comorbidities, on a case-to-case basis.[1] However, a recent publication based on registry data noted that 35% practitioners still use antibiotics >24 hours.[110] Recent developments in the field allow different types of stimulation, and the ability to check for responses to different waveforms/technologies during the trial phase.[111] If a patient demonstrates an indeterminate response with one type of waveform, adapting the inserted leads to use a different type of stimulation or a different technology without the need for another trial procedure is considered in clinical practice.[112] However, there is limited literature to indicate the benefits achieved, in terms of improving trial success rate and subsequent long-term therapy. Newer technological advancements could lead to improved design and efficiency, thereby influencing the concept of conventional trials as we understand. The use of newer wireless devices (incorporating the miniaturized components of pulse generator within the lead) does not require externalization of lead wires thus decreasing the risk of infection and allowing for longer duration of testing, if appropriate.[109] Based on a Markov model analysis, North *et al* demonstrate both improved clinical and cost-effectiveness using such wireless SCS devices.[113] However, there is presently limited literature around these devices to make firm conclusions for clinical practice.

Position statements

Trial approaches

- Insertion of paddle leads using laminotomy/laminectomy approach for an SCS trial is not common. Among studies that reports its use, only some have provided appropriate rationale for this choice (patient factors that do not permit a safe or effective percutaneous trial). In general, this approach requires the need for sedation or anesthesia beyond locoregional anesthesia, which may not allow paresthesia mapping. Performance of laminotomy/laminectomy may be associated with higher procedural pain, complications, higher resource consumption and surgical expertize.
- Insertion of percutaneous leads under GA or deep sedation increases the risk of spinal cord or neural injury. However, insertion under GA can be considered if the risk-benefit ratio favors using GA such as in a patient with difficult airway,

significant patient agitation and movement compromising safety.
- Performance of trial procedure (either for percutaneous or paddle leads) under GA will not allow for paresthesia-based lead positioning. In circumstances when leads dependent on elicited sensations are placed under GA, IONM should be considered.
- There is no difference in the trial success rates between permanent lead (staged) or temporary lead (separate) approaches. However, the risk of infection related to the trial period, can be potentially higher in the permanent lead (staged) approach, especially with longer duration (online supplemental file 2).

Number of leads and their placement
- The number of leads used during the percutaneous SCS trials are based on clinical indication and when used appropriately the number of leads used does not affect the trial outcomes.
- For systems dependent on elicited sensations, lead placement using paresthesia coverage has advantages; confirming appropriate positioning with stimulation leads, and possibly influencing long-term success as indicated by some observational studies. This can also allow checking for uncomfortable paresthesia experienced by some patients.
- For systems or technology independent of elicited sensations, leads are typically placed using anatomical positioning with targets chosen based on decades of experience with paresthesia mapping. As such, the benefits of lead placement using real time paresthesia coverage is unclear for these systems, for so long as they continue using paresthesia-free stimulation.

Duration
- The duration of an SCS trial must be a balance between providing enough time and opportunity to experience the use of SCS in different contexts of daily life, and patient safety (including the possible need for shorter trials in patients on chronic antithrombotic therapy) and comfort. Based on the available literature, studies report most commonly a duration of 5–7 days.
- Increased duration of SCS trial is associated with higher risk of infection. Based on the available evidence, it is reasonable to consider a trial duration of >10 days to be associated with higher risk.
- The newer wireless SCS systems may potentially allow longer duration of trials with decreased risk of infection.

Mode of stimulation during the trial
- There is no clear superiority of one mode or type of stimulation over others during the trial period. However, certain patients may find paresthesia-based stimulation mode/type to be more effective during the trial.

Antibiotics
- Use of prophylactic antibiotics using weight-based dosing administered during lead insertion reduces the risk of infection with any approach or type of SCS trial.
- Rate of infection has not been shown to be influenced by the routine use of postoperative antibiotics for SCS trials. Hence, postoperative antibiotics should only be considered if there are additional predisposing risk factors for infection.

Salvaging SCS trials
- Newer developments allow trial of more than one technology or manufacturer during the same trial using an adapter. It is unclear whether prolonging the duration (with the added risk of infection) or repeating an indeterminate SCS trial is likely to change the trial outcome.

Section 7: evaluation of SCS trial

Questions considered
1. What are the parameters that should be evaluated during an SCS trial to decide on the use of permanent SCS therapy?
2. What are the outcomes or domains that should be evaluated to consider a successful trial for a pain indication?
3. How to evaluate each outcome evaluating SCS trials?
4. Are there any objective markers/outcomes to be considered for non-pain indications?

Evaluation of SCS trial is as crucial as the proper conduct of the trial. Traditionally, three distinct parameters have been considered for evaluation: (1) treatment efficacy, (2) paresthesia coverage and overlap of painful area, and (3) tolerability of induced sensations. Although acceptability of SCS is not always considered, patients may not prefer this treatment for other reasons: change to body/scarring; need to adapt their lifestyle; perception of SCS device as a foreign body; negative connotations of having electricity within their body and others.[66] Lastly, the evaluation should consider the threshold of approval by insurance or other payers.[48] With respect to paresthesia coverage threshold, some consider >80%[22 114] and others have considered >50% coverage.[16] This factor could also dictate the use of single or double leads.[115] However, an overlap of 80% or higher is a more robust criteria and suggests potentially higher chances of patient satisfaction. Tolerability and acceptance may be evaluated either during or at the end of a trial. Tolerability indicates perceiving treatment-induced sensations/paresthesia as pleasurable or tolerable and is usually judged as yes or no (tolerable/intolerable). Evaluating efficacy of the SCS therapy is challenging. This is most commonly performed using patient-reported percentage improvement in pain (PIP) relief or change on the numeric pain rating scale, a subjective outcome. Objective parameters indicating improved blood flow have been used in PVD conditions and refractory angina.

Efficacy outcome

Pain is a multidimensional experience, and it is recommended that chronic pain patients be evaluated using multiple domains that indicate improvement in pain relief, functions, sleep, emotional status, global improvement, and decreased medication use.[116] Improved pain relief can be expected to lead to improvement in other outcomes. Most studies consider 'pain relief ≥50%' as a threshold to define trial success,[16] although others have considered different outcomes: a combination of pain relief, stable/decreased medications, improved daily functioning,[87 117] or a categorical outcome such as three consecutive 'yes' for agreeing to proceed to stimulator implant given improvement in pain.[97] Use of a composite outcome that combines different dimensions or domains could be useful. Such approaches have been tried to evaluate long-term SCS success[118] or attempts to recognize a definition of pain remission reflected by pain score threshold corresponding with overall improvement.[119] In the latter study, a VAS 3.0 cms cut-off predicted patient global impression of change with 76.3% sensitivity, 76.8% specificity and 76.5% accuracy. However, no such composite outcome has been used for trial evaluation.

Recommendations based on Section 6: considerations for the conduct of SCS trials

1. Percutaneous lead approach should be preferred for SCS trials, compared with any surgical approach (laminotomy or laminectomy), unless there are technical considerations based on patient factors.

   Grade B; *Level of Certainty: Moderate.*

2. Either a permanent lead (staged) approach or a temporary lead approach, can be safely used for SCS trial; based on technical expertize, clinical factors, and local practice considerations. However, one needs to consider the potential for increased infection risk with permanent lead approach in association with prolonged trials.

   Grade B; *Level of Certainty: Moderate.*

3. The number of percutaneous leads to be used for SCS trial should be based on the clinical judgment.

   Grade C; *Level of Certainty: Low.*

4. Percutaneous SCS trial leads should not be inserted under GA or deep sedation due to the risk of spinal cord injury, unless there are specific technical challenges or patient factors.

   Grade D; *Level of Certainty: Low.*

5. If trial leads were placed under GA or deep sedation (unable to elicit patient response), the specific indication should be noted in the patient record, along with use of intraoperative neurophysiological monitoring for appropriate placement with paresthesia-based systems.

   Grade C; *Level of Certainty: Low.*

6. For SCS systems using paresthesia-based stimulation systems, lead placement should be guided by paresthesia coverage with attempts to capture 80% or more of painful areas.

   Grade B; *Level of Certainty: Moderate.*

7. For SCS systems independent of paresthesia, final trial lead placement may be performed based on anatomical placement, with or without real time paresthesia testing.

   Grade C; *Level of Certainty: Low.*

8. An SCS trial duration of more than 10 days is not recommended ordinarily, as extended duration is associated with higher risk of infection and usually has no clear advantages.*

   Grade D; *Level of Certainty: Moderate.*

9. All patients undergoing SCS trials should receive a prophylactic antibiotic using weight-based dosing.

Continued

Recommendations based on Section 6: considerations for the conduct of SCS trials Continued

Grade A; *Level of Certainty: High.*

10. Routine use of postoperative antibiotics is not recommended, either for a shorter duration or for the entire trial period, unless there are patient specific comorbidities that warrant consideration.

    Grade D; *Level of Certainty: Low.*

11. Presently, there is insufficient evidence to recommend attempts at salvaging a trial in patients who were unsuccessful or indeterminate in response.

    Grade I; *Level of Certainty: Low.*

*We recognize that in some countries the duration of trial is stipulated as per their local/regional/country specific health regulatory authorities or payment systems and that may not be superseded.

Measuring and interpreting pain relief using a threshold

There are two ways to capture adequate pain relief: comparing pain scores before and during/after SCS trial or patient-reported PIP during/after SCS trial. Although they can be correlated, there may be important differences. There are limitations when using pain scores at different time points and their differences: ceiling effect; different interpretations for anchoring; and changes are not linear and hence cannot consider similar change as equal.[118] Pain intensity may also change or differ during different days of the trial. Moreover, Hagedorn *et al* showed that PIP is a better reflection of improvement and was significantly associated with greater odds of experiencing better long-term outcomes.[120]

Measuring functional improvement

Although some studies considered functional improvement as a necessary condition for trial success, the instrument used, and the threshold considered was non-specific to the condition or not provided. Moreover, improved functions can be in simple daily activities, or within a specific activity indicated by the patient. Such patient-specific activity with SCS,[121] or as a Specific, Measurable, Achievable, Realistic, and anchored within a Time Frame goal could be useful to evaluate.[122]

Indication specific evaluation and use of objective markers

Use of SCS therapy in PVD and angina could be associated with improved pain and other objective outcomes, such as limb salvage and better cardiac blood flow. Considering high long-term success rates of SCS in non-operable angina patients, trial stimulation is not routinely used.[48] In patients with PVD, improvement in $TcPO_2$ is considered an additional marker of improved blood flow, specifically microcirculation.[123]

Position statements

- The following four parameters can influence whether SCS therapy is a good option for the long-term management of a chronic pain condition and are considered as part of trial evaluation: (1) efficacy of therapy, (2) paresthesia coverage, (3) tolerability of induced sensations, and (4) general understanding and reasonable expectations of long-term SCS

Recommendations based on Section 7: evaluation of SCS trial

1. As part of an SCS trial, patients should be evaluated for 'efficacy of therapy', 'tolerability of any induced sensations', and 'understanding and reasonable expectations of SCS technology and therapy as a long-term option'. These evaluations could be either during or at the end of the trial as appropriate.

   Grade A; *Level of Certainty: High.*

2. For patients having an SCS trial with a paresthesia-based system, one should evaluate adequate paresthesia coverage, with a threshold of 80% or more. Inability to achieve adequate paresthesia, due to a known area of sensory deficit within the target area, should be noted.

   Grade B; *Level of Certainty: Moderate.*

3. For patients undergoing a trial of SCS, therapeutic efficacy should be evaluated multidimensionally, using validated measures for pain relief, functional improvement, stable or decreased analgesic use, and overall satisfaction.

   Grade B; *Level of Certainty: Moderate.*

4. For patients having SCS trial for pain indications, improved pain relief of ≥50% must be demonstrated using a validated outcome instrument, during or at the end of trial, to be considered successful.

   Grade A; *Level of Certainty: High.*

5. In some patients, where pain improvement is <50%, a substantial improvement in functions (≥50%) or substantial reductions on ongoing opioid use (>50% decrease) can be considered as successful on a case-by-case basis.

   Grade C; *Level of Certainty: Low.*

6. With respect to pain relief, a patient-reported percentage improvement in pain relief, assessed during or at the end of trial, may be preferred over an absolute difference between before and after trial pain scores.

   Grade C; *Level of Certainty: Low.*

7. For patients undergoing a trial of SCS, evaluation for functional improvement should be performed using an appropriate patient-specific activity or goal setting, or a disease-specific instrument.

   Grade B; *Level of Certainty: Moderate.*

8. In patients with PVD undergoing a trial of SCS, assessment of transcutaneous oxygen tension (TcPO2) should be performed as an objective marker of blood flow improvement, in addition to other parameters of therapeutic efficacy.

   Grade A; *Level of Certainty: High.*

therapy. For SCS systems independent of induced sensations, paresthesia coverage may not be necessary.

- For paresthesia-based SCS systems, maximum overlap of paresthesia with patient's predominant anatomic area of pain indicates adequacy of coverage and improves the chances of trial response and long-term success. In some patients with known sensory deficits, paresthesia may not be elicited.
- For SCS using paresthesia-based stimulation, minimization or elimination of painful paresthesia correlates with tolerability and acceptance of treatment.
- Evaluating patients understanding of the technology, its function, and reasonable expectations of treatment corresponds with greater satisfaction and treatment experience.
- As chronic pain is a multidimensional experience, successful trial of SCS can be reflected in various measures, mainly including pain relief, functional improvement, medication usage and satisfaction with pain control.
- A reduction in pain of 50% or more on a validated scale such as the numerical rating scale is generally accepted the threshold for pain relief.
- Use of patient-reported PIP may be a better reflection of pain improvement compared with differences in patient reported numeric pain scores.
- Decreased use of analgesics may or may not be possible during the trial in all patients. Hence any 'increase' (unsuccessful trial), 'decrease or stable use' (potentially a successful trial) is to be considered as one component of trial evaluation.
- Studies assessing functional improvement have considered improvement in different disease-specific functional scales, in addition to significant (≥50%) pain relief, as indicative of trial success. In general, functional improvement is best evaluated using a patient-specific activity that can be measured, realistic, and achievable within the trial time frame.
- In patients with PVD, use of SCS can improve pain relief and microcirculation, and potentially reduce the need for amputation. Objective measurement of blood flow, such as $TcPO_2$ assessment, may be used as a surrogate biomarker of therapeutic efficacy.

CONCLUSIONS

Patient selection for SCS therapy is crucial and has traditionally included a screening trial. However, this continues to be a challenge aside from evolving technology and practice standards, along with differing perceptions and views about the importance of a trial. These multisociety guidelines on various aspects of patient selection and the role and conduct of a trial is the first ever attempt to create an evidence-based consensus framework. These recommendations not only can guide practicing physicians but can be helpful for multiple stakeholders as a blueprint to structure their programs and/or policies to facilitate a more uniform and consistent practice. At the same time, we emphasize that these should not be mistaken as practice standards that need to be enforced. Physicians should continue to make their best judgment based on individual patient considerations, incorporating the best possible evidence and patient values and preferences, as considered in the overarching context of evidence-based medicine.

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Supplemental File 1: Diagnostic parameters estimated based on published studies

	Sensitivity 95% CI	**Specificity 95% CI**	**+ predictive value 95% CI**	**- predictive value 95 CI**
RCTs (assuming all trial failures as true negatives)	100%	53% (48%-57%)	65% (61%-69%)	100%
RCTs (assuming 50% trial failures as true negatives)	77% (73%-81%)	35% (30%-41%)	65% (61%-69%)	50% (43%-56%)
Observational studies (assuming all trial failures as true negatives)	100%	36% (23%-49%)	61% (50%-72%)	100%
Observational studies (assuming all trial failures as true negatives	85% (76%-94%)	22% (9%-35%)	61% (50%-72%)	50% (27%-73%)

CI, confidence interval; RCT, randomized controlled trial

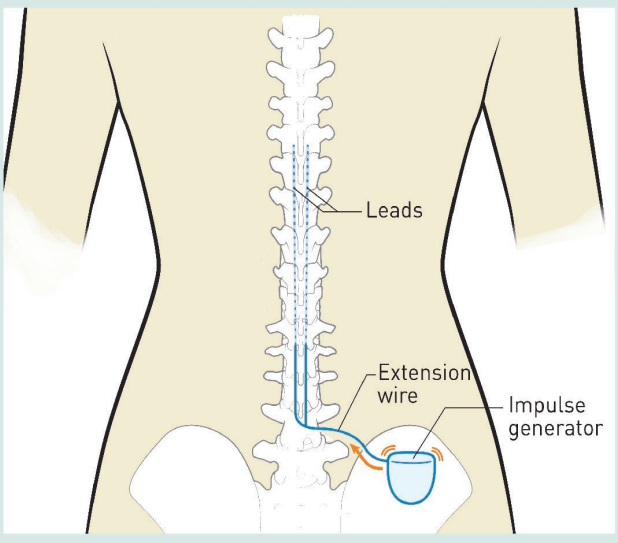
Supplemental File 2: Differences between permanent and temporary lead trials

Factors considered	**Permanent lead trial***	**Temporary lead trial**
Approach	Cylindrical leads anchored and tunneled during the trial, inserted with the intent to continue for therapy after a successful trial by connecting to an IPG	Cylindrical leads inserted with an intent to discard after the trial, and followed by insertion of another set of leads connected to an IPG for therapy
Difference in trial success rate	No relative difference	No relative difference
Time for insertion	Relatively higher	Relatively lower
Infection risk	Potentially higher	Lower
Patient discomfort or pain post procedure	Potentially higher	Lower
Lead migration risk	Lower	Potentially higher
Conduct of the trial	Requires operating room	Can be considered outside the operating room
Overall radiation exposure	Lower	Higher (considering additional final phase implant)
** It does not apply to wireless trials in which there is no separate IPG; IPG: implantable pulse generator*		

Evidence-Based Guidelines on Patient Selection and Trial Stimulation for Spinal Cord Stimulation (SCS) Therapy for Chronic Pain

Developed by ASRA Pain Medicine in collaboration with ESRA, NANS, and IoN

15-member guidelines panel with multidisciplinary representation from anesthesiology, physical medicine and rehabilitation, neurosurgery, psychology, epidemiology, and a patient partner



Patient Selection and the Need for Trial

USPSTF Grading; Level of Certainty

Grade B (moderate certainty): A trial should be performed before offering a definitive SCS implant.

Grade B (moderate certainty): Do not consider an on-table trial equivalent to a traditional SCS trial.

Grade B (low certainty): Screen all patients for high-risk psychosocial factors before offering SCS therapy.

Grade B (moderate certainty): Use individualized approach to set realistic expectations regarding trial outcomes.

Grade C (moderate certainty): Disclose higher failure and complications risk in patients with high BMI, smokers, high opioid doses (>90 mg of morphine/day).

Trial Conduct and Evaluation

USPSTF Grading; Level of Certainty

Grade B (moderate certainty): Use percutaneous approach with attempts to capture paresthesia* in >80% of pain areas (*paresthesia-based stimulation).

Grade D (moderate certainty): Avoid placement of trial leads under GA and a trial duration of >10 days.

Grade A (high certainty): Administer prophylactic antibiotic for all patients having SCS trials.

Grade B (moderate certainty): Evaluate a trial for pain relief, functional improvement, stable or decreased analgesic use, and overall satisfaction.

Grade A (high certainty): Consider ≥50% pain relief for trial success.

Grade C (low certainty): If pain improvement is <50%, look for substantial changes in functions or analgesic use.

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