Narrative Review

Spinal Cord Stimulation for Chronic Pain Syndromes: A Review of Considerations in Practice Management

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Background: Chronic pain syndromes are clinically challenging to treat, and management with opioid medications is increasingly shown to be inappropriate and ineffective. Spinal cord stimulation (SCS) has been demonstrated across numerous high-quality and well-designed studies to be effective in treating various refractory chronic pain. The efficacy and overall success of SCS is highly dependent on compliance to and consideration of various practice patterns.

Objective: This manuscript is intended to compile and present comprehensive recommendations for key SCS management principles including: a) patient selection criteria, b) efficacy of SCS for various conditions, c) discussion of SCS waveforms, d) trial and permanent implantation considerations, e) periprocedural management, and f) complications and adverse events.

Study Design: An evidence-based narrative review.

Methods: PubMed, Medline, Cochrane Library, prior systematic reviews, and reference lists were screened by 2 separate authors for all randomized trials, meta-analyses, and observational studies relevant to each of the aforementioned management principles and considered for study inclusion.

Results: All high-level evidence studies that explored the various facets of SCS practice management were included for review.

Limitations: Both continued investigation into, and practice implementation of, the various facets of SCS management are necessary to optimize patient outcomes.

Conclusion: Implementation of and adherence to the evidenced-based recommendations delineated in this publication may help optimize efficacy outcomes and maintain safety profiles for persons treated with SCS interventions.

Key words: Chronic pain, practice patterns, spinal cord stimulation

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Up to approximately 8% of the population in the United States suffers from chronic pain (1). Unfortunately, this pathological phenomenon remains incompletely characterized, poorly understood, and challenging to treat (2-4). Extensive data has shown that opioid medications are inappropriate and ineffective in treating chronic pain and are burdened with numerous detrimental adverse effects ranging from addiction to mortality (5-7). Across the past decade, neuromodulation with spinal cord stimulation (SCS) has been utilized increasingly for treating chronic pain refractory to standard-of-care management with good efficacy (8-12).

There exist numerous high-level and high-quality

studies supporting the use of SCS in various chronic pain syndromes (8,9,12,13). These studies have not only demonstrated superiority of SCS over comprehensive medical management in delivering analgesia and improving functional outcomes, but have also shown that SCS may confer significant reduction in systemic opioid intake (14,15). Notably, SCS itself has also been shown across several longitudinal studies to be a relatively safe intervention (16-18).

Several considerations in management practices help ensure that SCS efficacy is optimized and safety profiles are maintained (19-21). There exists a paucity of comprehensive and readily generalizable literature clearly delineating recommendations for SCS management across these several contexts. Consequently, this manuscript is intended to compile and present comprehensive evidence for key SCS management principles including: a) patient selection criteria, b) efficacy of SCS for various conditions, c) discussion of paresthesia-free stimulation waveforms, d) trial and permanent implantation considerations, e) periprocedural management, and f) complications and adverse events.

Methods

Study Design

This study was an evidence-based narrative aimed at appraising the available literature for various facets for SCS management.

Data Sources

PubMed, Medline, Cochrane Library, prior systematic reviews, and reference lists were surveyed from 1966 through July 2019.

Study Selection

All randomized trials, meta-analyses, and observational studies relevant to each of the aforementioned management principles were identified and allocated to their relevant section(s). Studies for sections such as patient selection and periprocedural criteria in which SCS-specific literature was sparse were gathered largely from surveyed reference lists. All studies were independently appraised and collected by 2 separate authors.

Inclusion criteria included those human studies in the English language with a sample size of at least 10 persons that had pertinent relevance to the aforementioned SCS management practices of interest. Any author of a publication was exempted from being involved in the scoring or paper inclusion. No outside funding was provided for this assessment.

Results are shown in Fig. 1.

Discussion

Patient Selection Criteria

Given the resources, risk, and financial outlay associated with SCS therapy, all possible steps should be taken by the evaluating physician to ensure a high degree of success. The topics discussed in this section comprise the best practices in evaluation for SCS implantation.

As previously discussed, SCS systems have received US Food and Drug Administration (FDA) approval for the treatment of refractory uni- or bilateral trunk or limb pain associated with failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS), and chronic axial neuropathic pain refractory to other measures (22). Because there are multiple neurostimulator devices on the market with different software and hardware features, this section aims to provide a general overview of considerations the clinician should make when evaluating a patient for SCS therapy. Additional considerations can be made on an individual basis regarding the use of specific stimulator devices.

Existing guidelines from specialty societies recommend initiating conservative measures for the management of the above-mentioned pain syndromes (23). A multidisciplinary approach incorporating pain medication and cognitive-behavioral therapy alongside supervised exercise is recommended as the first line of treatment for low back pain independent of etiology (24). If the patient has failed these conservative options, device therapy can be considered.

The results of a 22-year study published by Kumar et al (25) in 2006 demonstrated that patients who have had long-standing pain respond more poorly than do those whose pain is of relatively recent onset. This finding is consistent with existing chronic pain literature exploring the psychological and central neurological phenomena and may help to explain why SCS therapy is not as successful in cases of higher chronicity.

Additionally, data from prior studies demonstrates a higher degree of success when the patient's pain corresponds to discrete spinal root levels (9,26). Patients who reported nonspecific or diffuse back pain responded less consistently to SCS therapy and were more likely to have their device explanted.

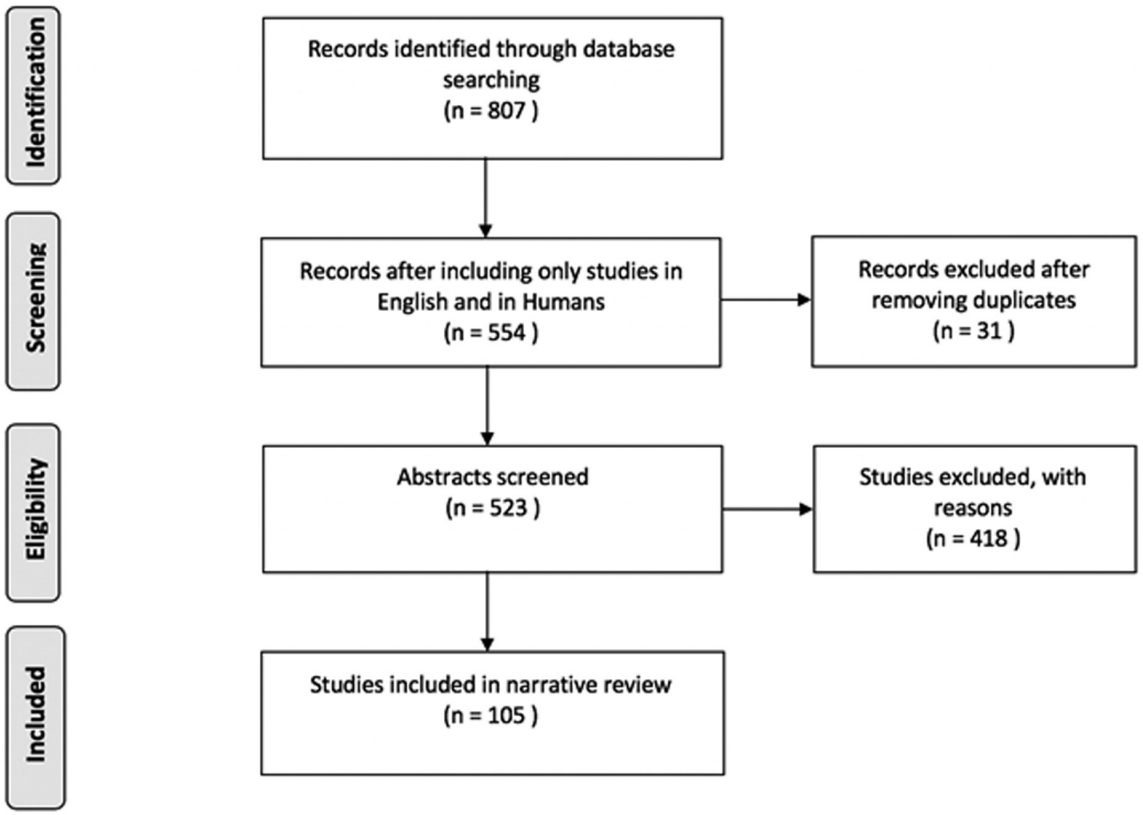

Fig. 1. *PRISMA flowchart identifying methodology for study selection.*

Psychological Screening

Psychological screening is a critical component of the patient selection process. Psychological variables such as depression, somatization, anxiety, and poor coping are linked to poorer outcomes after device implantation. This was demonstrated by Celestin et al (27) in 2009, and again by Paroli et al (28) in 2018. Patients with other psychiatric comorbidities also tend to fare poorly with SCS therapy. When a patient is being considered for SCS therapy, then, evaluation by a psychologist is strongly recommended. Furthermore, the requirements for SCS therapy reimbursement by most insurance companies include a mandatory psychological evaluation to help assess whether a patient is likely to succeed with SCS therapy (29).

Efficacy of SCS for Various Conditions

There are several randomized controlled trials (RCT) and many more open-label studies demonstrating statistically significant improvements in pain and quality of life with SCS therapy as compared to comprehensive medical management (CMM) or surgery. While most studies have explored efficacy in treating FBSS, other pain conditions have also been investigated. Efficacy has been measured not only by subjective pain scores, such as the Numeric Rating Scale (NRS-11) and Visual Analog Scale (VAS), but also by several functional measures, such as the Roland-Morris Disability Questionnaire (RDQ).

Much of the sentinel evidence supportive of SCS utilized tonic stimulation; however, more recently burst and high-frequency (HF) stimulation waveforms have demonstrated similarly favorable benefit. These novel waveforms are further explored in detail in a subsequent section. Given the heterogeneity of studies in patient selection, methods, data collection, and duration, we were unable to perform a meta-analysis in keeping with PRISMA guidelines (Table 1).

Retrospective studies by North et al (30) in 1991 and van Buyten et al (36) in 1999 demonstrated statisti-

Table 1. *Highest available evidence for use of SCS in treating failed back surgery syndrome.*

Author and Year	Study Type	Intervention	Patients	Primary Outcome	Results	Duration	Conclusion
North 1991 (30)	Case Series	Tonic SCS	50 (2 yr), 45 (5 yr)	50% or greater pain relief, patient satisfaction	53% (2.2 yrs), 47% (5 yrs)	5 years	Prospective study needed
Kumar 2007 (31)	RCT	Tonic SCS vs CMM	100	50% pain relief	51% vs 9% (6 mos), 34% vs 7% (12 mos)	1 year	SCS superior to CMM for neuropathic pain related to FBSS
North 2005 (13)	Crossover RCT	Tonic SCS vs repeat surgery	50	50% pain relief, crossover	47% vs 12% pain relief, 21% vs 54% for crossover	2 years	SCS superior to re-operation, primary SCS superior to crossover after surgery
Schu 2014 (32)	RCT	Burst SCS vs Tonic SCS vs Placebo	20	NRS 11 pain intensity	Significant decrease in mean NRS 11 score with burst	3 weeks	Burst superior to tonic in short term
Leveque 2001 (33)	Case Series	Tonic SCS	30	50% pain relief	75% with pain relief	66 months	SCS effective for FBSS
Turner 2010 (34)	Cohort Study	Tonic SCS vs usual care	158	50% pain relief, 2 pt improvement on RDQ, and less than daily opioid use	Small improvement with SCS at 6 months. No significant difference at 12 or 24 months.	2 years	No evidence for SCS vs usual care after 6 months
Sears 2011 (35)	Retrospective Cohort	Tonic SCS via paddle leads	17	50% pain relief, satisfaction	29% pain relief, 70% satisfied	Retrospective	High degree of satisfaction despite low rate of pain relief
Van Buyten 1999 (36)	Retrospective Cohort	Dual lead SCS	20	VAS decrease	4.4 VAS decrease	2 years	SCS effective for FBSS
Kinfe 2016 (37)	Prospective Observational	Burst SCS vs HF10 SCS	16	VAS decrease	3.1 to 1.8 burst, 3.1 to 2.2 HF10	3 months	Burst and HF SCS safe and effective

Abbreviations: CMM, comprehensive medical management; FBSS, failed back surgery syndrome; HF10, high frequency stimulation at 10k Hz; NRS-11, Numeric Rating Scale; RCT, randomized controlled trial; RDQ, Roland-Morris Disability Questionnaire; SCS, spinal cord stimulation; VAS, Visual Analog Scale.

cally significant improvements in pain control with SCS therapy for patients with a diagnosis of FBSS. These studies prompted interest in more rigorous prospective studies comparing SCS therapy to CMM or repeat lumbar surgery.

The earliest prospective studies, including North et al (13) in 2005 and the PROCESS trial by Kumar et al (31) in 2007, demonstrated statistically significant improvements in pain control with SCS vs repeat lumbar surgery (North et al) or CMM (Kumar et al). Importantly, the study by North et al demonstrated increased pain relief with primary SCS implantation vs patients who crossed over to SCS implantation after repeat lumbar surgery (13). Further study by Schu et al (32) in 2014 demonstrated superior outcomes with SCS therapy vs CMM, and significantly improved pain control with burst stimulation vs tonic stimulation (Table 2).

Promising retrospective studies by Kumar et al (44) in 1997 and Bennett et al (42) in 1999 led to the first open-label prospective trial by Oakley et al (40) in 1999. This study, repeated with a larger sample by Harke et al (39) in 2005, demonstrated statistically significant decreases in VAS pain scores after SCS implantation (Table 3).

Among neuropathic pain syndromes studied, the most robust evidence exists for painful diabetic neuropathy (PDN). Several open-label prospective studies and 2 randomized controlled trials demonstrate statistically significant pain relief with SCS therapy vs conventional medical management. Specifically, the studies performed by de Vos et al (47) in 2014 and Slangen et al (51) in 2014 demonstrate durable pain relief, with

Table 2. *Highest available evidence for use of SCS in treating complex regional pain syndrome.*

Author and Year	Study Type	Intervention	Patients	Primary Outcome	Results	Duration	Conclusion
Sears 2011 (35)	Retrospective Cohort	Paddle SCS	17	50% pain relief, satisfaction	29% pain relief, 70% satisfied	Retrospective	High degree of satisfaction despite low rate of pain relief
Kemler 2008 (38)	RCT	SCS vs physical therapy	36	VAS decrease	1.7 for SCS, 1.0 for PT (not significant)	5 years	No significant improvement from SCS vs physical therapy at 5 yr mark
Harke 2005 (39)	Prospective Trial	SCS	29	VAS (deep pain, allodynia)	VAS reduction from 10 to 0-2	35.6 months	SCS effective for CRPS 1
Oakley 1999 (40)	Prospective Trial	Tonic SCS	19	VAS decrease	VAS decrease from 6.7 to 4.5	7.9 months (1-26.6)	SCS effective for CRPS 1
Olsson 2007 (41)	Case Series	Tonic SCS	7	Subjective pain relief	5/7 reported relief	6 weeks	SCS may be effective for CRPS 1 in pediatric patients
Bennett 1999 (42)	Retrospective Cohort	Tonic SCS	101	VAS decrease	7.97 to 4.27 for Group 1, 8.17 to 2.17 for Group 2	18.7 mos for Group 1, 23.5mos for Group 2	SCS effective for CRPS 1. Dual lead may be better than single
Geurts 2013 (43)	Prospective Cohort	Tonic SCS	84	VAS decrease	41% of patients had at least 30% VAS decrease	11 years	SCS provides long term pain relief for CRPS 1
Kumar 1997 (44)	Retrospective Cohort	Tonic SCS	12	VAS decrease	8 pts with 75-100% relief, 4 pts with 50-75% relief	41mos	SCS effective for CRPS 1
Eijs 2011 (45)	Prospective Trial	Tonic SCS	6	NRS 11 reduction 50%	35% reduction at 1 year	1 year	Feasibility of early SCS for CRPS 1 is low

Abbreviations: CRPS, complex regional pain syndrome; NRS-11, Numeric Rating Scale; RCT, randomized controlled trial; SCS, spinal cord stimulation; VAS, Visual Analog Scale.

patients being followed out to 6 months with sustained benefit.

SCS Waveforms

Ascending Pain Pathways

The initiation of pain signaling starts with afferent peripheral nociceptors that detect noxious stimuli such as heat, pressure, and chemicals and transmit sensory information via A-delta and C fibers to the central nervous system (CNS) (2,3,53). Fast myelinated A-delta fibers, which are responsible for acute localized pain, and slower unmyelinated C fibers, which attribute to delayed poorly localized achy or burning pain, both synapse at the level of the substantia gelatinosa (in rexed lamina 2) of the dorsal horn of the spinal cord (54,55). Thereafter, second-order neurons cross midline via the anterior white commissure and ascend the dorsal column and anterolateral system to the thalamus. During ascension, pain processing is likely integrated into 2 pathways: lateral discriminatory and medial affective (26). The lateral pathway provides input on the location, quality, and intensity of pain while the medial pathway drives attention or perception to the pain. Other second-order neurons include those various neural phenotypes such as multimodal wide-dynamic range (WDR) neurons and nociceptive-specific (NS) neurons, which can be targeted in SCS to disrupt ascending pain transmission (56,26). For instance, WDR neurons, which are activated in tonic stimulation, are integrated into the lateral discriminatory pathway, whereas NS neurons, which are activated in burst stimulation, provide input into the medial affective pathway.

Both in vitro and animal studies have shown that CNS neurons propagate signals via both tonic and burst action potential frequencies (57-60). Burst waveforms, which are comprised of 5 1000-millisecond pulses at 500 Hz followed by a brief quiescent period to be repeated at 40 Hz, have been shown in animal models to be more effective at activating cortical areas (59-62).

Table 3. *Highest available evidence for use of SCS in treating chronic neuropathic pain.*

Author and Year	Study Type	Intervention	Patients	Primary Outcome	Results	Duration	Conclusion
Kumar 2007 (31)	RCT	Tonic SCS vs CMM	100	50% pain relief	51% vs 9% (6 mos), 34% vs 7% (12 mos)	1 year	SCS superior to CMM for neuropathic pain related to FBSS
Tesfaye 1996 (46)	Prospective Trial	Tonic SCS, stim vs placebo	10	VAS decrease	8/10 positive trial, 7/7 with significant pain relief at 3, 6, and 14 months	14 months	SCS effective for PDN
de Vos 2014 (47)	RCT	CMM vs CMM + SCS	60	50% pain relief at 6 months	60% of pts with SCS had 50% pain relief at 6 mos	6 months	SCS effective for PDN
Kumar 1996 (48)	Retrospective Cohort	SCS	30	VAS decrease	14/30 pts with at least 50% pain relief	87 months (average)	SCS effective for painful neuropathy
Daousi 2004 (49)	Retrospective Cohort	Tonic SCS	6	VAS decrease	100% with at least 50% pain relief at 7yr follow up	7 years	SCS effective over long term for PDN
de Vos 2007 (50)	Prospective Trial	Tonic SCS	11	50% pain relief	7/11 patients with at least 50% pain relief at 12 months	12 months	SCS effective for PDN
Slangen 2014 (51)	RCT	CMM vs CMM + SCS	36	50% pain relief	59% success in SCS group, 7% in CMM	6 months	SCS effective for PDN
Pluijms 2012 (52)	Prospective Trial	SCS	15	NRS 11 decrease	10/15 patients with "clinically relevant" pain relief	12 months	SCS seems to be efficacious for PDN

Abbreviations: CMM, comprehensive medical management; PDN, painful diabetic neuropathy; SCS, spinal cord stimulation; NRS-11, Numeric Rating Scale; RCT, randomized controlled trial; VAS, Visual Analog Scale.

The precise pathophysiological mechanisms for these differences have yet to be fully elucidated. However, it is largely thought that the burst waveforms produce a monophasic charge accumulation during the burst that delivers greater electrical current per second relative to tonic waveforms, despite utilizing lower amplitudes. Other theories suggest that burst waveforms activate different neural mechanisms than tonic waveforms, thereby "unmasking dormant synaptic phenotypes" to differentially disrupt ascending pain pathways (63).

Tonic Stimulation Waveforms

Tonic stimulation involves the production of 200-millisecond pulses across a 40-Hz frequency in a constant fashion (26,64). Much of the conventional evidence supportive of SCS details the use of tonic waveform stimulation to modulate dorsomedial ascending pain pathways to confer analgesia. The majority of the evidence and high-impact studies delineate the efficacy of tonic stimulation as an effective modality for FBSS, CRPS type 1, and chronic neuropathic pain (65). However, conventional tonic stimulation has various limitations including paresthesia production, suboptimal benefit in persons with protracted chronic pain preceding SCS implantation, and varying evidence of chronic efficacy.

While tonic waveform utilizes painless paresthesias to cover chronic pain distributions, SCS-associated paresthesias are not infrequently reported to be uncomfortable and even distressing (66). Advanced waveforms, such as burst and high-frequency stimulation, are promising due to their capacity to confer analgesic benefit without paresthesia production (8,12). While paresthesias are thought to result from waveform amplitudes, advanced waveforms are able to deliver greater quanta of electrical current to the dorsal columns while maintaining lower waveform amplitudes (67,68). Consequently, these advanced waveforms stimulate dorsal columns by way of greater electrical charge delivery and diminished amplitude formation (66-68).

Burst Stimulation Waveforms

Burst stimulation is an advanced mode of programmed pulse stimulation that mirrors the dual-firing qualities of the thalamus, attributing to more potent activation of the dorsal anterior cingulate and right dorsolateral prefrontal cortex compared to tonic stimu-

lation (8,26,64). It can therefore better moderate affective and discriminatory pain. Since burst provides more electrical stimulation per second to achieve temporal summation, burst SCS can activate more neurons than conventional tonic stimulation.

Burst SCS has been shown to be superior to tonic stimulation in treatment for refractory back and leg pain such as with FBSS (11,47,50,66,69). Burst SCS may be used as second-line therapy in those refractory to tonic SCS, with 62.5% of tonic nonresponders reporting pain relief with burst SCS (47). Furthermore, 60% of tonic responders reported a greater improvement in relief with a burst SCS trial (47).

Compared to traditional tonic simulation, burst is also known to not cause paresthesia. Many patients cite this effect as their primary determinant of preference of burst over tonic (8,66,69). Because burst stimulation requires lower intensity and thus subthreshold intensity for A-beta fiber activation, it spares the A-beta fibers known to generate paresthesia deployed in tonic stimulation (32,70). Furthermore, since burst is considered a paresthesia-free modality, intraoperative paresthesia mapping is not needed to deliver therapeutic analgesia. This allows for shorter procedures with more reliable analgesic benefit (37,69).

Work by Deer et al (8) in 2018 showed that the number of programming sessions required for pain relief seemed to be less for burst stimulation (117 sessions) compared to tonic stimulation (141 sessions), leading to less delay in achieving therapeutic effect, better patient satisfaction, and improved resource allocation.

High-Frequency Stimulation Waveforms

High-frequency (HF) stimulation is another paresthesia-sparing SCS paradigm that has been shown by several studies to be superior to conventional tonic stimulation in eliciting pain relief (71-73). While tonic stimulation was conventionally administered at 40 Hz, newer technologies allow for higher frequencies to be delivered. Nonetheless, HF stimulation is thought to be all frequencies greater than 1,000 Hz, with 10,000 Hz in particular being extensively evidenced (12,69,73,74).

The mechanism of action for HF SCS has not been fully elucidated. It is believed to have an influence on the spinal and supraspinal pathways similar to tonic stimulation (75). However, much like burst SCS, lack of paresthesias and greater pain relief have provided HF SCS patients with improved activity capacity, function, and quality of life (72). A prospective multicenter study by Kapural et al (12) showed a reduction in disability after 24 months of SCS, showing a reduction from 90% of patients with severe and crippling disability at baseline to 49% of patients with severe and crippling disability post treatment as measured by Oswestry Disability Index scores.

Furthermore, SCS device placement for HF stimulation also precludes the need for intraoperative paresthesia mapping. Patients with HF SCS also had a statistically significantly higher tolerance threshold of current than they did with burst SCS (37,69).

Studies have shown HF SCS to be particularly effective in FBSS intractable back pain, with long-term (> 6-month) improvement in both radicular and central lower back pain; HF SCS may also be more effective in a spinal surgery-naive population (72). HF SCS has also been shown to be more cost-effective in the long term compared to CMM (70).

Complication rates for HF appear to be on par with tonic SCS. However, some patients treated with HF at 10,000 Hz have experienced overstimulation effects that can manifest as worsening of existent pain or development of novel pain, which can be mitigated by discontinuation of HF stimulation (75). Furthermore, there are discussions of CNS neuroplasticity changes secondary to long-term HF SCS use, which may induce habituation and subtherapeutic analgesia (69).

Newer technologies that are entering the market offer patients access to both standard lower-frequency (40 Hz) and higher-frequency (1,000 Hz) tonic stimulation, both in isolation and concomitantly (76). However, given the novelty of such products, robust longitudinal evidence is lacking.

Other Considerations

While commonly offered SCS waveforms differ by type and frequency, the precise electroceutical dose and conferred analgesic response have yet to be clearly established. However, as per the aforementioned evidence, both SCS waveform and frequency are both, separately, thought to advantageously modulate the ascending pain pathways. While traditional tonic SCS had battery spans of approximately 5 years, newer waveforms require more electrical charge. Fortunately, advances in battery life are evident given that novel IPGs now offer battery spans of approximately 10 years despite the utilized waveform. Wireless SCS systems, however, require daily charging and thus may not be optimal in persons who may be noncompliant with charging.

With increasing long-term outcome data for SCS therapy, our understanding of SCS-associated analgesic tolerance is growing (77). Much evidence exists suggesting that the response to tonic SCS may diminish across time in certain patients (77). While it is unclear which patients develop analgesic tolerance, studies have shown that a change to subperception SCS waveforms carries much promise as a salvage therapy. Salvage SCS therapies may also help ameliorate explantation rates, the largest contributor to which is inadequate pain relief.

Several studies have demonstrated the capacity of HF SCS waveforms to restore analgesic benefit at the 6-month timepoint in those patients with tonic SCS who have developed analgesic tolerance (73,78). Studies have also shown the capacity of burst SCS to salvage tonic SCS nonresponders or even supplant the analgesic benefit in responder patients (11,47,79). Notably, these studies only report this benefit up to the 2-week time point; longer duration outcomes are unpublished. Yang and Hunter (80) have also published findings of burst SCS rescuing failed HF SCS and tonic SCS patients.

SCS Trial, Permanent Implantation

After identifying patients as appropriate candidates for SCS intervention, but before the implantation of a pulse generator, the SCS screening trial is instrumental in determining which patients will have success with SCS therapy. While the SCS screening trial process lacks standardization, it is largely reliant on 3 main variables: trial type, trial length, and definition of trial success (81-83).

Trial Type

Percutaneous placement of cylindrical electrodes is typically utilized in most scenarios for SCS screening as it is minimally invasive and can take place in an ambulatory setting. The procedure involves utilizing fluoroscopic guidance to introduce 2 percutaneous electrode leads to the lumbar epidural space, via 2 paramedian 14-gauge needles (82). The percutaneous electrodes are then directed superiorly and paramedian until placed at the target destination in a slightly staggered fashion. The ideal lead destination for chronic back and leg pain is thought to be at the T8 level. While securing the lead tails, the 14-gauge needles should be removed. Extension wiring is then used to connect the lead tails externally to a pulse generator, after which paresthesia mapping helps determine the most effective final electrode placement for paresthesia coverage. Following this precise localization, the lead tails are anchored externally.

Unfortunately, the externally anchored lead electrodes in the percutaneous approach are highly susceptible to lead migration. However, the correlation between lead migration and paresthesia change remains unclear. Kim et al (84) have reported an average 3.05-mm inferior lead migration from a standing to sitting position at the end of a 7-day SCS trial. They did not find a correlation between the presence and/or degree of lead migration to paresthesia change. Others exploring this phenomenon, however, have suggested that lead migration is the likely etiology responsible for loss of paresthesia coverage (16,17,82). Of note, novel technical approaches like those proposed by Shaparin et al (85) and Mironer et al (86) presented some evidence of reduced lead migration by using subcutaneous tunneling, contralateral advancement, nonentry exit anchor suturing, and midline anchoring of the lead using the plica mediana dorsalis, respectively, in diminishing lead migration. However, such techniques have yet to validated by other groups and have failed to be widely adopted.

Surgically implanted paddle leads are expectedly more invasive but are pursued as a second line alternative when percutaneous electrode placement is suspected or proven to be technically challenging (87). Persons with a history of multiple spinal surgeries often have extensive epidural scar tissue burden that impedes passage of percutaneous electrodes. Also, aberrant spinal alignment (i.e., severe scoliosis) can make percutaneous electrode placement challenging. Surgical lead implantation involves performing bilateral laminotomies at the target level for internalized and adjacent anchoring of paddle leads, which is thought to make electrode migration less likely. Similar to persons undergoing percutaneous trials, successful screening trials are followed by internalization of the pulse generator and electrode lead extensions.

Pahapill et al (88) previously reported their experience with a retrospective cohort of 22 patients who underwent surgical paddle lead placement and concluded similar long-term success rates relative to persons who underwent percutaneous lead placement. A higher level of evidence comparing long-term outcomes of patients with SCS who underwent percutaneous vs surgical lead trials is lacking. However, given that paresthesia change is thought to be greater with percutaneous trialing, it is possible that surgically implanted electrode trials confer fewer false negatives relative to percutaneous trials.

Trial Length

The majority of conventional trials last 5 to 10 days, with most occurring across 7 days (81,83,84). The length of these screening trials is largely limited by infectious risks posed by the presence of the percutaneous lead extension connecting the internalized electrodes and externalized pulse generator. Kin et al (89) have also previously suggested that formation of site-specific fibrous tissue formation secondary to percutaneous lead placement can make subsequent internalization of the electrodes technically challenging in trials with prolonged length. Given these considerations and limitations, the conventional trial length of 5 to 10 days hinders the number of SCS settings, frequencies, and waveforms that can be trialed.

Recent work by North et al (90) explored the promise of a fully internal single-stage wireless electrode system that allows for longer screening trial length. They showed that 30-day SCS screening trials produced high trial success rates for both high- and low-frequency treatment arms and minimal complication rates. This novel system would allow for implanted patients to not only experience and trial multiple SCS programs, but also to trial identified programs of interest for longer timeframes. Such a model may limit both false positives and false negatives that would occur in trials with shorter lengths. On the contrary, Chincholkar et al (83) found that a majority of patients were able to determine device efficacy within 9 days and that those persons with successful SCS trials were more likely to make a determination of trial benefit earlier than later. These findings serve to support and maintain conventional 5- to 10-day SCS trials, with some thought that longer trials may obfuscate true trial success and benefit.

Trial Success

Determining SCS trial success requires consideration of numerous variables that include, but are not limited to, degree of pain relief (82,91). The most conventional outcome variable considered, as suggested by the Neurostimulation Appropriateness Consensus Committee (NACC) guidelines, is > 50% pain relief with the screening trial. This approach is derived from the > 50% pain relief primary outcome measure in numerous high-level studies investigating SCS efficacy across numerous contexts, and is also correlated with the likelihood of long-term SCS success in persons with > 50% pain relief in the trial phase (8,12,72,81,82,91). However, opioid reduction must also be an important consideration in determining trial success. Many of the aforementioned high-level studies found SCS interventions to not only lower systemic opioid use, but also lower opioid-specific complications (92). Consequently, those screening trials that result in persons having moderate but < 50% pain relief, but who also have moderate to severe reductions in opioid use, may be deemed appropriate candidates for permanent SCS implantation.

Persons with chronic pain syndromes are often burdened with numerous functional impairments in vocational participation, sleep quality, ambulation, and even activities of daily living. Given the importance of these parameters in contributing, in part or collectively, to an improved quality of life, they must also be strongly considered in determining the success of an SCS trial. In essence, as alluded to previously, a multifactorial consideration including pain relief, opioid reduction, and functional improvement parameters must all be considered when determining the success or failure of a screening trial. Lastly, a discussion between the practitioner, patient, and caregivers will be instrumental in weighing all of the aforementioned factors and considering the possibility of permanent pulse generator implantation.

Implantation Costs

Despite SCS efficacy demonstrated for numerous chronic pain conditions and cost-effectiveness of SCS continue to be challenged and investigated, especially in the context of novel wireless SCS systems (90,93,94). The traditional trial-to-implantation algorithm is associated with multiple costs including the SCS trial with percutaneous leads (base care value $6,423) followed by the cost of the permanent IPG implantation for long-term use (base care value $26,757) in candidates with positive trials (95). On the contrary, the algorithm in novel wireless SCS systems is one of implant trial for potential long-term use (base care value $26,757) (95).

While the algorithm used for novel SCS systems favors appropriate candidates who are second permanent implantation procedures and the costs of trial-only procedures, it may be cost-ineffective overall given the lost-costs spent on inappropriate SCS therapy candidates (93-95). Notably, given that wireless SCS systems do not require transcutaneous hardware placement, practitioners are afforded longer trial periods which thereby likely reduce both false positive and false negative trial rates. A recent study by North et al (95) on cost-effectiveness modeling per quality-adjusted

life year (QALY) found the use of wireless SCS ($35,486 per QALY) to be more cost-effective than traditional SCS systems ($40,729 per QALY) and CMM ($44,838 per QALY).

Periprocedural Management

The periprocedural care of persons being considered for a permanent SCS implantation can be vital to optimizing positive outcomes and safety profiles associated with these elective procedures. Through several research studies and published guidelines, a few key factors have been identified that need to be assessed periprocedurally, including: bleeding risk, infection control, psychiatric screening, and postprocedural systemic opioid reduction.

Bleeding Risk

With any surgical procedure, there exists an inevitable risk of hemorrhagic complications. Careful consideration for bleeding risk is thus warranted, especially since SCS implantation is considered a high- to intermediate-risk procedure per the NACC guidelines (89-91). Although only rare cases of hemorrhage or hematoma formation have been reported in the literature, given the close proximity of the procedural site to the spinal cord and spinal nerves, measures to mitigate risk of hemorrhagic complications are necessary to prevent devastating neurological outcomes (16-18).

Bleeding risk can be physiologic, as in patients with bleeding diatheses secondary to hematologic, hepatic, or renal disease; or iatrogenic, as in patients on anticoagulant or antiplatelet medications. Given the increased bleeding risk that these patients confer, they require appropriate preprocedural screening and management before SCS implantation can safely be pursued (96,97).

In any patient taking anticoagulation or antiplatelet medications, the primary indication for the medication should be strongly considered. This consideration requires a multidisciplinary effort among the interventional pain physician, the physician prescribing the anticoagulant or antiplatelet agent, and the patient. The NACC and American Society of Regional Anesthesia and Pain Medicine (ASRA) recommend a temporary suspension of these medications before SCS implantation if indications are reasonable and appropriate (96,97).

For anticoagulant medications, the most commonly used are novel oral anticoagulants (NOACs) and warfarin. For NOACs, the NACC recommends a discontinuation interval of at least 5 half-lives before the procedure, and reinitiation no earlier than 24 hours post procedure (96). If a patient is at high risk for thromboembolic disease, it may be reasonable to give half the usual dose of a NOAC 12 hours before the procedure. For warfarin, the NACC recommends discontinuing therapy 5 days before the procedure, assuming a normalized International Normalized Ratio (INR) (96,97). One study supported the recommendation that anticoagulants be discontinued before SCS implantation, showing that anticoagulant-suspended patients had normalized risks profiles for intraoperative hemorrhage relative to nonanticoagulated patients (98). One noteworthy finding of this study was that 3 patients on enoxaparin in addition to other anticoagulants had more bleeding-related complications relative to those patients on monotherapy.

For antiplatelet medications, the most commonly used are aspirin (ASA), NSAIDs, and serotonin reuptake inhibitors (SRI). Recent ASA and NSAID use did not lead to a single event of bleeding during SCS implantation in a study of over 100 patients (99). SRIs have antiplatelet effects; patients with psychiatric conditions requiring SRIs will have a higher bleeding risk. For SRIs, the NACC does not recommend discontinuing them before pain procedures unless patients are at high risk for bleeding, in which case a gradual taper is recommended (96,97). A collaborative review involving several different groups proposed guidelines on the timing of anticoagulation discontinuation and reinitiation (96,97). For patients on ASA for primary prophylaxis, recommendations are to discontinue for 6 days. There are no specific recommendations concerning ASA for secondary prophylaxis. In that same review, the ASRA did not offer global recommendations for anticoagulation; rather, they recommended discontinuation of NSAIDs based on the particular drug's half-life and pharmacokinetics (97). Specific to SCS procedures, if prospective patients are currently on clopidogrel for anticoagulation, ASRA recommends stopping the medication 5 days prior to the SCS trial initiation (97). For intravenous and subcutaneous heparin, the recommendation is to stop it 6 hours and 24 hours prior, respectively (97).

Overall, the recent guidelines suggest that anticoagulant and antiplatelet medications should be weaned preprocedurally to mitigate bleeding complications, including epidural hematoma formation and hemorrhage, which can pose devastating outcomes such as paraplegia and death, respectively (96,97). However, given the vast prevalence of cardiovascular diseases in our society and the necessity of anticoagulant and

antiplatelet medications to prevent other devastating outcomes, including myocardial and cerebral infarcts depending on the indication, the weaning and/or discontinuation of these medications requires careful consideration. Because many of these medications need to be discontinued for a week or longer to ensure that the patients achieve normal hemostatic profiles for their implantation procedures, discontinuation should only be considered if reasonable and appropriate and if the increased risk of cardiovascular and cerebrovascular complications is not too significant. These considerations are highly vital given that SCS implantation is an elective procedure that is not life-saving.

Infection Control

Infection control should be strongly considered from preoperative to postoperative care through follow-up stages. Despite considering implicated risk factors and providing antibiotic prophylaxis, the risk of infections can prove threatening, and thus, a threshold of suspicion must always be maintained. Across all SCS procedures, the infectious prevalence is 3.4%, according to one literature review that examined 51 different papers containing 2,972 patients total (100). Appropriate diagnosis and management can help prevent lethal and devastating complications. Infections can be related to the incisional site, SCS leads, pulse generator, or even pump pocket. Thus, sometimes device explantation may be necessary for infectious source control.

Preoperatively, risk factors for procedural infections should be evaluated for appropriate risk mitigation strategies to take place. Most common modifiable risk factors include diabetes mellitus and smoking status, both of which have been shown to confer a higher likelihood of developing surgical site infections (101-103). However, improved glycemic indices in patients with diabetes mellitus and smoking cessation can normalize risk for infection development. Sorenson et al (102) found that 4 weeks without cigarette smoking lowers infection rates to that of nonsmokers. Interestingly, SCS implantation in patients with cancer may have comparable infection rates to those without cancer (104). Current medications also modulate infection risk. Patients on steroids may encounter greater rates of surgical site infections, wound dehiscence, and even mortality (105). The NACC also recommends optimizing nutrition status and screening for methicillin-resistant staphylococcus auerus to mitigate risk of procedural site infection (106).

Additionally, administering preoperative antibiotic prophylaxis is a standard and conventional practice proven to decrease infection risk. One animal study showed that injection of local vancomycin reduced infection rates on postoperative day one (107). NACC guidelines recommend choosing antimicrobial agents that are effective against common pathogens like Staphylococcus aureus and Staphylococcus epidermidis while also considering local resistance patterns. It lists cefazolin as the first-line prophylactic agent, clindamycin in the case of a beta-lactam allergy, and vancomycin for known MRSA colonization (106). Intravenous cefazolin, clindamycin, and vancomycin should be administered 30 to 60 minutes, 30 to 60 minutes, and 120 minutes before the procedure, respectively, as indicated, with appropriate weight-based dosing. Intrasite vancomycin powder has become an alternative method of prophylaxis; however, due to limited evidence, NACC does not currently recommend this non-Food and Drug Administration [FDA]-approved method for routine use (106). The NACC also recommends stopping antibiotics within 24 hours of surgery.

As aforementioned, there are many possible sources and sites of infection, which include: the incisional site, SCS leads, pulse generator, and the pump pocket (16,17,106). Though most infections related to SCS implantation can be controlled with preimplantation screening and antibiotic prophylaxis, SCS-associated device infectious complications can be devastating and include bacteremia and/or neurogenic complications secondary to epidural abscess formation and secondary compression. Therefore, maintaining a healthy index of suspicion for these infectious complications can be vital in early and appropriate management, which can prevent explantation or devastating outcomes.

Psychiatric Screening

There exists a strong correlation between chronic pain and psychiatric disorders, including catastrophizing presentations. Therefore, an appropriate psychological evaluation is instrumental in persons with a diagnosed or suspected psychiatric illness. These evaluations can help distinguish between those persons with syndromes of organic chronic pain susceptible to SCS intervention vs those with chronic pain syndromes driven largely by psychiatric disorders. This determination can help to identify more appropriate SCS candidates and subsequently better patient outcomes. Consequently, preprocedural psychological evaluations should be strongly considered as a conventional practice.

A prospective SCS patient may have psychological factors that affect the outcome of the implantation. Therefore, a thorough psychiatric screening is advised to holistically evaluate and manage the chance of implant success. There are several questionnaires, inventories, and tests that have been implemented to screen for underlying psychiatric concerns that may affect outcomes. A combination of the VAS, the Minnesota Multiphasic Personality Inventory (MMPI-D), and the McGill Pain Questionnaire (MPQe) correctly predicted a successful or unsuccessful SCS outcome in 88% of study patients (108). Scores on the MMPI that indicate depression or mania can lead to unsuccessful SCS trials (109). Higher preimplant scores on a similar scale, the MMPI-2-Restructured Form, can predict poor SCS outcomes and patient satisfaction (110). In one study, patients were interviewed by psychiatrists prior to SCS implantation. In patients about whom the psychiatrist had reservations due to psychiatric factors alone, 18% of the implantations were considered to be a success; whereas, in patients about whom the psychiatrist had no reservations, 64% of the implantations were considered to be a success (111). This study showed that a psychiatrist evaluating the presence of contraindications in potential patients via a physician-patient interview can increase positive outcomes.

Another important factor is patient expectations. One study showed that pain relief and perceived quality of life (QOL) were highly reliant on preimplant expectations. Blackburn et al (112) found that those patients with unrealistic expectations (i.e., 100% pain relief) endorsed dissatisfaction with SCS implantation despite reporting > 50% pain relief. Additionally, despite 62% of this cohort reporting that they believed SCS to be effective, only 30% reported undergoing SCS implantation again. Similarly, Henssen et al (113) report that analgesia alone did not correlate to satisfaction. Rather, this cohort reported other domains of quality of life, including daily activities, sleep, and return to work, to be more highly correlated with satisfaction.

Opioid Weaning

Preoperative weaning is an important step to undergo. It can help to optimize the most appropriate SCS program. Without preoperative weaning, it may be challenging to attribute the post-SCS implant to neuromodulation alone given the concomitant use of systemic opioids. Postoperative weaning is also important, as it can help reduce opioid-associated adverse effects.

Preexisting opioid use can affect the outcome of a SCS implantation. A preoperative morphine equivalent dose (MED) of 22.6 mg/day and higher was associated with increased rates of SCS failure warranting explantation (14). However, a study done by Pope et al (114) demonstrated no relationship between opioid intake and rate of explant for treatment failure. Madineni et al (115) showed that increased MED (greater than 100 mg) may also lead to longer postoperative stays compared to lower-dose opioid therapy. Simopoulos et al (116) posited that the discontinuation of postoperative opioid use may be related to preoperative opioid dose. Additionally, they found that a daily dose of 30 morphine milligram equivalents (MME) or less was associated with discontinuation of opioid therapy following SCS implantation.

Complications and Adverse Events

With recent advances in SCS, such as screening parameters for patient selection and implementation of novel waveforms, so too has there been much research exploring SCS-specific complication management. A thorough understanding of these complications serves to not only improve our understanding of implicated risk factors, but also allows us to maintain a healthy threshold of suspicion for the development of these adverse events. Ultimately, this understanding is vital to help preserve safety profiles associated with SCS implantation.

While most analyses of complications are limited to review studies, recent evidence suggests a 30% to 40% overall incidence rate of complications in patients with SCS device implants (17). These various complications are categorized into those related to hardware complications and biological complications (17,117). Despite these recognized complications, neuromodulation with SCS is considered to be safe, with a minimal risk of mortality (106,117,118) (Table 4).

Hardware Complications

Hardware-related complications are those most frequently associated with spinal cord stimulators. These include lead migrations or fracture, pulse generator failure, painful stimulation, and loss of paresthesia. Mekhail et al (119) reported a hardware-related complication rate of 38%, consistent with many other studies.

Electrode migration is the most common hardware-related complication, with retrospective reviews showing rates ranging from 11.3% to 13.2% (16). Within the studies, there were lead migration rates ranging

Table 4. *Highest available characterizing complications and adverse events associated with the use of SCS.*

Author & Year	Sample Size	Hardware Complications Sample size, %	Neurological Complications Sample size, %	Soft Tissue Complications Sample size, %	Notes
Tesfaye 1996 (46)	10	3, 30% Lead migration: 2, 20% Loss of paresthesia: 1, 10%	Not Reported	2, 20% Infection: 2, 20%	
De Vos 2014 (47)	40	5, 12.5% Pain from Implanted Pulse Generator: 2, 5% Lead Migration: 1, 2.5% Loss of Paresthesia: 2, 5%	Not Reported	1, 2.5% Infection: 1, 2.5%	
Slangen 2014 (51)	22	Not Reported	1, 4.55% Subdural Hematoma: 1, 4.55%	1, 4.55% Infection: 4.55%	Overall self reported complication rate of 9%
Kemler 2008 (38)	36	9, 25% Generator or Lead Revision: 9, 25%	Not Reported	8, 22% Pocket Revision: 8, 22%	Overall self reported complication rate of 38%
Kumar 2007 (31)	52	22, 42.3% Lead Migration: 8, 15.4% Lead Fracture: 2, 3.8% IPG Migration: 1, 1.9% Pain at IPG: 5, 9.6% Loss of Paresthesia: 6, 11.5%	Not Reported	11, 21.2% Infection: 7, 13.5% Pocket Fluid Collection: 4, 7.7%	Overall self reported complication rate of 32%
Turner 2010 (34)	51	5, 9.8% Persistent Pain: 5, 9.8%	Not Reported	7, 13.7% Infection: 3, 5.9% Abscess: 1, 2% Other biologic problems: 3, 5.9%	Overall self reported complication rate of 16%

Abbreviations: IPG, implantable pulse generator

from 2.5% to 31%. Lead migration can be attributed to factors such as poor technique and excessive patient movement (117). Decreased migration rates have also been attributed to increased practitioner experience (18).

Complication rates of lead fractures ranged from 5.9% to 9.5% (17). Lead fractures have more commonly been associated with more cephalad positions such as the cervical region and retrograde approaches (117). This in turn can lead to system failure, requiring use of surgical revision for correction, highlighting the importance of correct initial placement.

Battery failures result in the need for replacement before initially intended. While relatively rare, Cameron et al (100) found the battery failure rate to be 1.7%, which historically would require surgical correction. With the introduction of rechargeable batteries, this may be a complication that can be avoided in the future, but will still require further study (17).

Within our included studies, 10% to 32% showed complication rates related to IPG, painful stimulation, or loss of paresthesia. Site of entry and location for IPG are important points of consideration when it comes to the etiology of painful stimulation (118). Overall, though, these risks attributed to SCS devices and hardware are minimal compared to repeat back surgery (117).

Neurological Complications

The most significant risks involve neuroaxial structures including the spinal column and dural

space. Vascular compromise with a punctured blood vessel can cause spinal cord compression leading to sudden onset and worsening weakness (17,106,117). This is an extremely rare complication, with risk estimated at 0.3%, and is associated more often with surgical paddle lead implantation (100). Spinal canal abscess is also a neurological emergency that warrants immediate attention but is also rare, with the Turner cohort study finding only one such case; overall incidence is less than one in 1000 (34,117). In limited studies, epidural fibrosis can also occur, which limits the ability to program a device and causes painful stimulation.

An inadvertent accident during lead placement is a dural puncture with an entry needle, which can lead to CSF leakage and possibly postdural puncture headache. Incidence has been found to be variable with the Kemler et al study (38) showing a rate of 11%, while Cameron (100) suggested a more minor 0.3%; however, most incidence rates are based on review analyses. Symptoms can include headache, neck discomfort, diplopia, and photophobia. Patient risk factors for dural puncture include morbid obesity, previous spinal surgery in the same area, as well as severe spinal degeneration. Techniques associated with this complication include a midline approach, an angle of entry that is greater than 60 degrees, and a retrograde approach of entry.

The most severe complication would be neurological injury from direct trauma to the spinal cord with needle entry or lead placement. However, such complication rates are minimal, with the US FDA Manufacture and User Facility Device Experience database review showing a complication rate of 0.58% (96,106). The Kleiber et al study (118) shows a range of 0.19% to 1.58%, while also including epidural hematoma as part of this study. Overall, while complications that involve compromise of the spinal cord itself can be significant, the likelihood of developing a life-threatening complication is low (16).

Soft Tissue Complications

Surgical site and other soft tissue infections are a common complication reviewed over a variety of trials and review studies. The majority of publications find rates of infection that fall between 4% and 10% (119). Risk factors that have been documented in the literature include diabetes, tobacco use, limited functional status, malnutrition, obesity, corticosteroid use, bowel or bladder incontinence, as well as decubitus ulcer or other preexisting infections (17). Most infections are found to be in the generator pocket, followed by SCS leads, and then the lumbar incision site. Typical organisms include Staphylococcus from skin flora as well as Pseudomonas, but SCS patients are also at higher risk for MRSA due to high likelihood of previous hospital or operating room visits for spinal procedures (16). Treatment options include oral or intravenous antibiotics, incision, and drainage, and as a last resort, device removal (117). If a device is removed, there should be strong consideration to work with an infectious disease specialist before reimplantation is attempted.

Another common source of soft tissue infections is seromas, which is the development of serosanguinous fluid from surrounding tissues within a contained space, often arising after surgery. Risk factors for seroma formation include tissue trauma from either excessive sharp or blunt dissection or prolonged cautery use (117). While both soft tissue infections and seromas can present clinically as erythematous, or warm areas of swelling, seromas are not associated with fevers or increased lab markers such as leukocytosis or elevated erythrocyte sedimentation rate and C-reactive protein. The most common site of seromas are also within the generator pocket and can be found in up to 9% of patients (16). Treatment typically revolves around fluid removal, either through aspiration or indwelling drains; however, persistent presence of seromas may warrant device removal (96,106).

Skin erosions are more often a complication with peripheral nerve stimulation, but in rare instances can also be seen with SCS; they are more often found with leads or generators closer to the surface. Cameron et al (100) reported a 0.2% incidence rate. This can also occur in patients with low body mass index or those with large amounts of weight loss (117). Surgical revision is often needed in such situations.

Lastly, while not as significant of a complication, surgery-induced pain either at the site of entry or generator-pocket placement can become particularly bothersome for patients who already suffer from chronic pain. While not an area of focus for many studies, the Cameron review (100) reported a rate of only 0.9%, while the Kleiber et al study (118) found that up to 6.4% of their patients had surgery-induced pain. Prevention can be guided by both pre- and postoperative analgesia as well as avoidance of placement in front of ribs or other bony structures.

Conclusion

Neuromodulation with SCS has been well-evidenced to treat patients suffering from various chronic pain conditions. Advanced SCS modalities are increasingly utilized given the opportunity for paresthesia-free analgesia. The overall success of SCS interventions is highly reliant on implementation of various practice patterns across the spectrum of management. Firstly, careful patient selection allows practitioners to screen out those persons who are inappropriate candidates. Thereafter, a comprehensive understanding of SCS efficacy, various waveforms offered, and pain conditions studied will allow for selection and utilization and appropriate interventions. Lastly, rigorous consideration of peri-procedural parameters and known complication risks can help maintain safety profiles associated with SCS placement. In summary, SCS has extensive high-level evidence supporting its use and efficacy and its safety profiles can be optimized with prudent and judicious adherence to the spectrum of considerations in practice management.

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