

General

Biologic Complications Associated with Cylindrical Lead Spinal Cord Stimulator Implants: A Narrative Review

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Purpose of Review

Spinal cord stimulation (SCS) is a minimally invasive and reversible therapy for the treatment of severe neuropathic pain. There are several biologic complications that can arise during the implantation of SCS systems. This review aims to consolidate recent research on complications associated with SCS, specifically focusing on biologic complications.

Recent Findings

Biologic complications are less frequently encountered compared to device-related complications but may have more severe consequences. Biologic complications covered in this review include infection, seromas, hematomas, dural puncture, nerve/spinal cord injury, and therapy habituation.

Conclusion

The application of SCS remains a viable and effective choice for managing neuropathic pain conditions. It is crucial for physicians to carefully consider potential complications before proceeding with SCS trials and implantation. Familiarity with biologic complications is critical for patient safety and to optimize patient outcomes.

INTRODUCTION

The rising popularity of spinal cord stimulation (SCS) as a neuromodulation treatment option for chronic neuropathic pain conditions has dramatically increased in the last couple of decades.¹ While the complete mechanism of action of SCS is still debated, this modality has improved the quality of life and demonstrated cost-benefit effectiveness in pain management.^{2,3} Neuropathic pain conditions that can be effectively treated with SCS include, but are not limited to, post-laminectomy syndrome, complex regional pain syndrome, phantom limb pain, ischemic pain, and refractory angina.⁴ While SCS can effectively treat various conditions, it also exposes patients to potential complications linked to foreign body implants. Despite being minimally invasive, SCS implantation has reported complication rates as high as 30-40%.⁵⁻⁸ Hardware complications are more common and have been previously discussed in a prior review.⁷ Biologic complications include infection, seromas, hematomas, dural puncture, nerve or spinal cord

injury, and therapy habituation. The aim of this review is to synthesize recent studies in biologic complications pertaining to cylindrical SCS implantation and to discuss etiologies, symptoms and presentations, diagnostics, clinical implications, and treatment options.

INFECTIONS RELATED TO SPINAL CORD STIMULATION

Infection is a potential complication of SCS implantation and can result in negative clinical and economic outcomes. Infection is the second most common cause of explantation after hardware complications.⁷⁻⁹ The most common pathogens causing surgical site infections are gram-positive cocci (streptococcus, staphylococcus, and enterococcus spp.) with atypical pathogens reported to also be a causative agent.⁹ A 2019 retrospective study of the MarketScan Databases found that surgical site infections impact about 3.11% of patients within 12 months of implant.¹⁰ Infections usually present as pocket infections but

may progress to more devastating complications such as epidural abscess, meningitis, or vertebral osteomyelitis.

SUPERFICIAL INFECTIONS

Superficial infections typically present with local inflammatory signs including pain, erythema, edema, or drainage at the surgical incision. Localized incisional pain and wound erythema tend to be the most commonly presented signs.¹¹ There should be no associated clinical or imaging findings indicating deeper SCS implant infection. The first step in initial evaluation is obtaining a detailed clinical history and physical examination. Initial laboratory testing may include white blood cell (WBC) count, erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP). A 2017 multicenter retrospective analysis of SCS implants by Bendel et al. found that the mean WBC count in cases of infection was 15×10^9 cells/L, and 46% of cases had an abnormal count.¹¹ If there is purulent drainage from the surgical site, microbiological testing should be sent for Gram stain and bacterial cultures.

Management of superficial infections includes oral antibiotics directed at common SSI pathogens (staphylococcus and streptococcus spp.). The most common antibiotics prescribed postoperatively after SCS surgery are cephalexin (55.4%) and sulfamethoxazole-trimethoprim (10.6%).¹² Methicillin-resistant staphylococcus aureus coverage should be added for patients with risk factors or known colonization. In the case of superficial abscess formation, incision and drainage may be required in addition to antibiotic therapy. Treatment failure should raise suspicion of a deeper infection.

DEEP INFECTIONS

Deep SCS infections present with local inflammatory signs along with clinical or radiographic evidence of implant infection.¹³ Clinical signs include wound dehiscence, purulent drainage from the pocket site, device component erosion, or lack of response to conservative therapy. Systemic symptoms such as fever may present with deeper SCS infections.¹³ Imaging may be necessary to distinguish superficial versus deep infections when physical examination findings are insufficient. Ultrasonography is a convenient method of evaluating the presence of a fluid collection or abscess at the generator pocket site. Although ultrasonography is easily available and noninvasive, computed tomography (CT) is the preferred modality due to increased sensitivity.¹¹

Management of deep SCS infections includes antibiotic therapy and likely need for device removal.¹³ Partial removal of SCS devices has been associated with higher rates of treatment failure and relapse.¹⁴ For patients who are clinically stable and present with only local signs of infection, empiric antibiotic therapy may be held until operative cultures are obtained.¹⁰ For patients who are unstable or present with systemic signs of infection, empiric antibiotic therapy should be started immediately. Antimicrobial therapy should be tailored to causative pathogens once microbial culture results are received. Treatment with 7-10 days

of antibiotic therapy is usually sufficient if blood cultures are negative and source control is adequate.¹³ The authors recommend consideration of full SCS explant for cases of deeper infections.

EPIDURAL ABSCESS

Epidural abscess is a rare complication of SCS infection.¹³ Clinical signs and symptoms of epidural abscesses include new neurological deficits, focal back pain, and fever. Magnetic resonance imaging (MRI) is the preferred imaging modality over CT due to its higher sensitivity and specificity. Treatment of epidural abscesses includes complete removal of all hardware and antimicrobial treatment. Infectious disease should be consulted for antimicrobial therapy selection and duration of therapy. Close follow-up is vital to monitor disease progression. Surgical drainage of the abscess may be required, and a spine surgeon should be involved for possible surgical interventions. Other complications of deep SCS infections include osteomyelitis, discitis, and meningitis.¹¹ However, these are extremely rare.

Spinal cord stimulators may be re-implanted after successful treatment of the epidural abscess.^{15,16} The optimal time for reimplantation has not been extensively studied. There are limited data regarding re-infection rates due to high variability in implant location change, timing of surgery, and preoperative preparation practices.¹⁵ General recommendations for consideration of device reimplantation is the resolution of infectious symptomatology for at least 90 days.^{5,15,16}

HEMATOMAS AND SEROMAS

Hematoma formation, such as superficial subcutaneous hematoma and spinal epidural hematoma (SEH), can become serious complication of SCS insertions. A 2022 meta-analysis by West et al. estimated the total incidence of neuraxial hematomas and non-neuraxial hematomas in patients with temporary SCS lead placement and permanent SCS with implantable pulse generator (IPG) placement.¹⁷ These studies included randomized controlled trials, prospective observation studies, and retrospective observational studies reporting an overall incidence of hematomas ranging from 0-4.5% with a pooled incidence of 0.81%.¹⁷

SUPERFICIAL HEMATOMAS/SEROMAS

Superficial or subcutaneous hematomas may form secondary to the formation of a pocket site outside of the neuraxial space. These pocket sites accommodate the lead or, more commonly, the IPG.¹⁸ Damaging tissue and larger superficial blood vessels during implantation of hardware can lead to blood extravasation. Patients may present with discoloration, inflammation, focal tenderness, erythema, or pain. Small, superficial hematomas often self-resolve and no intervention is needed. If the hematoma is larger and there is concern for wound dehiscence or infection, the hematoma may need to be evacuated via needle aspira-

tion.¹⁹ For expanding hematomas, patients may need to return to the operating room for incision, drainage, and cauterization.¹⁷

Seromas are serous fluid accumulations on the surface of the skin. They may develop postoperatively and contribute to poor wound healing. Seromas secondary to surgical incisions occur due to various factors such as lymphatic disruption, tissue damage, inflammatory mediators, and the creation of dead space. Seromas commonly present with inflammation or swelling over the surgical incision. Fluid drainage may be yellow or clear in color. Discolored, hemorrhagic, or foul-smelling fluid may indicate infection. Seromas present at highly variable times postoperatively, ranging from 6 days to 1 year. Conservative management is usually the initial treatment, with pressure application to the wound site with bandages or dressings. If the seroma persists, needle aspiration may be considered.^{18,19} Open incision and drainage may be required if conservative management fails or if infection is suspected.

EPIDURAL HEMATOMAS

Spinal epidural hematomas (SEH) may occur as a result of instrumenting the neuraxial space during SCS lead insertion. Bleeding of epidural blood vessels does not often lead to a space-occupying lesion, although SEH can occur in some cases. Risk factors of SEH include intrinsic clotting disorders, drugs that affect clotting, liver disease, or severe tears to blood vessels.⁶ SEH may present up to 72 hours after lead placement and should remain on the differential diagnosis for at least this period.²⁰ The 2022 meta-analysis by West et al. estimated the incidence of SEH to be 0.23%.¹⁷ SEH often go unnoticed and are therefore thought to be underreported and underdiagnosed. If the hematoma compresses the spinal cord, neurological deficits may occur, with paraplegia being a serious complication. Signs and symptoms of SEH include postoperative numbness along with severe back or leg pain. The mainstay of diagnosis for SEH is urgent imaging followed by treatment with hematoma evacuation and laminectomy with decompression.^{17,20}

DURAL PUNCTURES AND POST-DURAL PUNCTURE HEADACHES

Accidental dural puncture may occur during either the SCS trial or permanent implant of cylindrical leads.^{5,21} Accidental dural puncture can occur when the needle punctures the dura during epidural space access but can also occur with aggressive advancement of a cylindrical lead. A retrospective review by Simopoulos et al. reported a rate of dural puncture with SCS procedures at 0.81% with all patients developing postdural puncture headache (PDPH).²¹ Despite dural punctures being the most common neurological complication of SCS, it still has a relatively low incidence likely due to the use of fluoroscopy.^{4,6,21,22}

Examining the risk factors associated with dural puncture and understanding the clinical features and progres-

sion of PDPH is essential. Research shows that individuals with specific risk factors have a higher likelihood of experiencing a dural puncture during SCS lead placement. These risk factors include female gender, individuals aged 31-50, having a history of PDPH, previous surgeries at the needle entry site, obesity, spinal stenosis, scoliosis, calcified ligamentum flavum, and patient movement during the procedure.^{5,6,23} Procedural techniques that increase the risk of dural puncture include steep needle entry angle, maintaining a perpendicular bevel orientation during the procedure, and using the retrograde approach for lead placement.⁴⁻⁶ Employing the contralateral oblique (CLO) approach may potentially reduce the risk of unintentional dural puncture by better identifying the laminar border.²⁴

Dural puncture is diagnosed intraoperatively via the presence of cerebral spinal fluid (CSF) during epidural access and/or lead placement and positioning. Postoperatively, patients may develop PDPH which presents as frontal or occipital positional headaches which improve when in the supine position. These headaches occur within 72 hours after a dural puncture, though patients may report onset up to 2 weeks later.^{23,25-28} Most PDPH are self-limiting, resolving within 4 days to 1 week.^{23,29} CT or MRI is typically not necessary and only indicated to exclude other causes if symptoms do not resolve.³⁰ Diagnostic lumbar puncture is advised against due to potentially worsening an existing PDPH. If performed, low opening pressure or dry tap with increased protein and lymphocytes may be present.²⁹ Concurrent symptoms occur in up to 70% of patients and include nausea, neck stiffness, low back pain, vertigo, diplopia, blurred vision, photophobia, dizziness, tinnitus, hearing loss, or a hygroma at the lead-anchoring site. A study of 133 patients with PDPH reported neck stiffness in 56% of patients, shoulder stiffness in 46.6%, nausea and vomiting in 33%, tinnitus in 22%, and photophobia in 23%.²⁶ Hearing loss has been reported in some patients though is typically transient and thought to occur due to intracranial hypotension.

The recommended initial management of PDPH is conservative treatments such as bed rest, oral analgesics, antiemetics, caffeine, and oral or IV hydration.³⁰⁻³² Oral analgesics typically include acetaminophen or a nonsteroidal anti-inflammatory drug (NSAID).³² For patients with PDPH refractory to conservative therapies, an epidural blood patch (EBP) may provide immediate relief and has success rates between 65-98%.^{31,33-37} EBP is performed by injecting the patient's own blood through a needle into the epidural space. The mechanism of action by which EBP relieves PDPH is unclear, but it is thought that the injection of blood compresses the thecal sac, increasing lumbar and intracranial CSF pressure. Clotting of the injected blood may plug the CSF leak and begin an inflammatory reaction that helps heal the puncture site. Contraindications for EBP include coagulopathies, anticoagulation, systemic infections, or an infected epidural needle placement site. A common complication of EBP occurring in 25-35% of patients is back pain, which usually resolves within 48 hours.^{33,37} Alternative treatments for PDPH include peripheral nerve

blocks such as transnasal sphenopalatine ganglion block (SPGB) and occipital nerve blocks.³⁸⁻⁴⁰

DIRECT NEURAL TRAUMA AND SPINAL CORD INJURY

SCS can lead to spinal cord injury (SCI) and other neurologic complications such as direct cord trauma or compression. Reported rates of direct SCI are low, varying between 0.42-2.13% in retrospective database studies.⁴¹⁻⁴³ A 2022 retrospective study of 71,172 SCS implants performed between 2010 and 2019 showed a 0.42% incidence of SCI within 45 days of implantation, with no significant difference based on using percutaneous or paddle leads.⁴³ Other factors associated with SCI following SCS include low molecular weight heparin use within 30 days before the procedure, male gender, a diagnosis of osteoporosis within one year, and a diagnosis of cervical or thoracic spinal canal stenosis within one year. A 2016 retrospective review of 8326 patients who received SCS between 2000-2009 reported a 2.13% incidence of SCI.⁴¹ A possible explanation for the higher SCI incidence in the 2016 study is that it preceded many current SCS guidelines focusing on risk assessment, patient selection, and screening. Although direct spinal trauma is a rare complication of SCS placement, there was an isolated case report of quadriparesis following percutaneous SCS.⁴⁴ Local anesthesia has been recommended over general anesthesia for most patients which allows the patient to report pain, potentially indicative of nerve trauma. However, a study in 2021 by Hasoon et al. revealed that many physicians perform SCS lead placement under deep sedation and general anesthesia and discussed the potential risks and benefits of this practice.⁴⁵

One consideration of SCI previously mentioned includes epidural hematomas. SEH is a rare complication in SCS patients with normal coagulation. Petraglia et al. reported a 0.71% incidence of SEH in patients who underwent SCS.⁴¹ SCS is contraindicated in patients with severe thrombocytopenia and uncontrolled coagulopathy.⁴⁶ Preoperative guidelines for anticoagulant and antiplatelet medication management should be followed due to the increased risk of SEH for patients on anticoagulants. SEH can manifest within days to weeks following SCS placement. If a patient experiences heightened back pain or worsening neurological symptoms, it is important to consider SEH as a possible cause. If there are additional symptoms such as sensory deficits, weakness in the lower extremities, or bladder or bowel incontinence, immediate action should be taken.^{17,20} As discussed earlier, SEH are surgical emergencies, requiring timely hematoma decompression to minimize potential permanent neurological damages.

LOSS OF EFFICACY OR HABITUATION

Although SCS therapy has been shown to be effective in treating a variety of pain conditions, its long-term efficacy has been questioned. A 2017 study by Aiudi et al. found that patients who received a spinal cord stimulator experienced an increase in Visual Analogue Scale (VAS) scores over time.⁴⁷ The Aiudi et al. study defined loss of efficacy as an increase in VAS score equal to or greater than 2 points from the baseline VAS score after spinal cord stimulator therapy for 2 consecutive visits.⁴⁷ The study found that pain scores increased by 0.62 VAS points at the 3-month follow-up, 1.21 VAS points at the 6-month follow-up, 1.37 VAS points at the 1-year follow-up, and 1.95 points at the 2-year follow-up compared to the 1-month follow-up (baseline) score. A 0.01 VAS point increase was found for every month after the first year of treatment. Of note, the study found that 65.5% of patients did not experience a loss of efficacy.

Habituation associated with SCS therapy refers to the body becoming accustomed to the stimulation and the pain relief diminishing over time.⁴⁸ Loss of SCS efficacy over time may be attributed to habituation. A 2022 retrospective analysis investigated a treatment strategy called a stimulation holiday, during which spinal cord stimulation therapy is stopped for a period of time and later restarted.⁴⁸ Forty patients who experienced loss of efficacy underwent a stimulation holiday at a mean of 452.7 days after initial implantation.⁴⁸ The authors found that pain relief 1 month after the stimulation holiday was significantly higher than before the holiday. These findings suggest that patients experiencing habituation may benefit from a stimulation holiday instead of abandoning spinal cord stimulation therapy. Alternatively, patients may benefit from switching waveforms or combining stimulation parameters and waveforms to combat habituation.⁴⁹

A 2020 randomized control trial by Levy et al. compared habituation rates in dorsal root ganglion (DRG) stimulation and SCS in 152 subjects with complex regional pain syndrome (CRPS) type I or II associated lower extremity pain.⁵⁰ The authors found that DRG stimulation and SCS CRPS-II patients did not experience habituation while the SCS CRPS-I patients did. The mechanism of action for these results is not clear. A 2008 study by Kemler et al found that at 5 years post-treatment, SCS combined with physical therapy produced results similar to those following physical therapy alone for pain relief and all other measured variables in patients with CRPS type I.⁵¹ However, despite the diminishing effectiveness of SCS over time in these patients, 95% of patients would elect to repeat SCS treatment. Additionally, this study had a small sample size. A 2022 study by Gill et al, reported that loss of efficacy still remains the main reason for SCS explant emphasizing the importance of this issue.⁵²

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CONCLUSION

Previous literature has promoted the impact SCS can have on patients with chronic pain. Biological complications can cause serious morbidity if not recognized in a timely fashion. Preemptive evaluation and consideration of biological complications before implantation can improve patient outcomes. Finally, knowledge and a thorough understanding of these complications can guide clinicians in recognizing

ing and treating biologic complications from SCS trials and implants to ensure patient safety. Submitted: July 13, 2024 EST, Accepted: July 29, 2024 EST

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