Percutaneous Spinal Cord Stimulation for Chronic Pain: Indications and Patient Selection

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KEYWORDS

• Spinal cord stimulation • Failed back surgery syndrome • Complex regional pain syndrome • Surgical indications • Psychological evaluation • Surgical risk assessment

KEY POINTS

- Percutaneous spinal cord stimulation (pSCS) is an effective treatment of patients with complex regional pain syndrome or failed back surgery syndrome refractory to conventional medical management.
- Although frequently used for other indications, the data supporting the use of pSCS remain limited for other types of chronic, peripheral, neuropathic pain.
- Selecting patients who may benefit from pSCS is based on the cause of the pain, rigorous psychological evaluation, and medical comorbidities, including opioid dependence and risk of perioperative infection.

INTRODUCTION

Percutaneous spinal cord stimulation (pSCS) or dorsal column stimulation is a safe, minimally invasive, reversible treatment of patients with chronic neuropathic pain refractory to conventional medical management (CMM). Electrical stimulation of the dorsal columns was shown to inhibit pain transmission more than 40 years ago by Shealy.[1] Since then, multiple studies have demonstrated superior clinical benefit to other treatments in properly selected patients.[2,3] It is cost-effective over the long-term and complements other therapies in multimodal treatment. However, these devices continue to be used as a treatment of last resort despite known advantages.

INDICATIONS

Spinal cord stimulation (SCS) is currently approved in the United States by the Food and Drug Administration for the treatment of chronic pain of the back or limbs. In Europe, SCS for refractory angina pectoris (RAP) is frequently used in some centers but it is not considered a routine treatment in all countries. Several studies, including eight randomized controlled trials (RCTs) have tested SCS for RAP. However, the studies were small and several had methodological flaws.[4] The Refractory Angina Spinal Cord stimulation and usuAL care (RASCAL), a pilot RCT on the effectiveness and cost-effectiveness of SCS for refractory angina, was recently completed at three centers in the United Kingdom.[4] SCS has also been extensively

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studied in the treatment of inoperable chronic critical leg ischemia. A 2013 Cochrane review concluded that SCS may be better than conservative treatment alone in both pain relief and amputation risk reduction in select patients.[5] However, the surgical risk of implanting an SCS, coupled with the costs of the implant in patients with expected short life spans (10%–30% mortality in 6 months), continues to favor amputation.[5]

Over the last several years, several international expert panels have convened to establish the indications for pSCS based on a review of the available literature. Though a clear consensus has not been reached on many of the indications, the recommendations for SCS are relatively consistent with some notable exceptions. Almost universally, the panels agree that patients with failed back surgery syndrome (FBSS) or complex regional pain syndrome (CRPS) benefit from pSCS. Those with peripheral neuropathic pain due to illness or injury, including plexopathies, also seem to benefit. However, to date, this has not been evaluated with a properly powered study. Patients with central pain syndromes originating in the brain or spinal cord, including root avulsion, seem to benefit less with SCS except when the posterior columns are only minimally injured in the case of spinal cord injury. A synthesis of these recommendations is compiled into **Table 1**.[6–10] SCS has only been studied in a rigorous RCT on three occasions (see later discussion).

FBSS

In the United States, the most common indication for an SCS implant is FBSS. Patients with FBSS who did not achieve the goals of the spinal operation, specifically the anticipated pain relief, or who developed recurrent pain following surgery and have limited response to nonsurgical therapies may be candidates for SCS. In the United States in 2002, more than 1 million spinal procedures were performed and it estimated that the rate of back surgery is nearly 40% higher in the United States than in any other country.[11] It is difficult to measure the frequency of FBSS in the general population but it is estimated that between 0.02% and 2% of lumbar spinal surgeries have unsuccessful outcomes.[11] Furthermore, the health-related quality of life and economic costs often exceed other chronic pain and medical conditions. Even if only a small portion of these patients were candidates for pSCS, the potential for improvement in health and cost savings could be considerable.

In addition to multiple long-term outcome studies and retrospective case series that support the use of SCS, there were two published RCTs in the last decade that specifically addressed the use of SCS for FBSS. In 2005, North and colleagues[12] published the results from a RCT comparing reoperation to SCS for FBSS in an effort to move SCS ahead of reoperation in the treatment algorithm. Only subjects with radicular pain that exceeded or was equal to the axial back pain were included in the study. Subjects who experienced at least 50% pain relief with the trial were offered a permanent implant with a paddle electrode. Although the sample size was relatively small (24 in the SCS treatment arm and 26 in the reoperation arm), there were statistically significant differences between the two groups. At a mean follow-up of 2.9 years (+/− 1.1 SD), 47% of subjects randomized to SCS versus 12% of subjects randomized to reoperation achieved pain relief of at least 50% ($P<.01$). Narcotic use remained stable or decreased in subjects randomized to SCS compared with reoperation subjects ($P<.025$) and 54% of subjects who initially underwent reoperation crossed over compared with only 21% in the SCS group ($P = .02$). In this study, improvements in work status and activities of daily living were not improved following treatment.

In 2007, Kumar and colleagues[3] reported the outcomes from a RCT that compared SCS to CMM for subjects with FBSS. The Prospective Randomised Controlled Multicentre Trial of the Effectiveness of Spinal Cord Stimulation (PROCESS) tested the hypothesis that SCS plus CMM (SCS+CMM) is more effective than CMM alone. Permanent lead type, percutaneous or paddle, was at the discretion of the surgeon. Unlike the study by North and colleagues,[12] this was not a single institutional experience. The primary endpoint of the study was to calculate the proportion of subjects with at least 50% relief of leg pain at 6 months. One hundred subjects were initially included in the randomization. At 6-month follow-up, 44 subjects in the CMM-alone group were available for follow-up and 50 in the SCS+CMM group. After the 6 months, 28 (64%) of the subjects in the CMM group crossed over and received an implantable system. Twenty-four (48%) of the subjects in the SCS+CMM achieved the primary endpoint versus only four subjects (9%) in the CMM-alone group. Secondary outcomes at 6 months showed statistical significance favoring SCS+CMM versus CMM alone, including improvements in health-related quality of life, superior function, and greater treatment satisfaction. Nine subjects were able to wean off opioids in the SCS+CMM versus only one subject in the CMM group. There was no difference in return to work status between the two groups.

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