Retrospective Study

Spinal Cord Stimulation for Neurogenic Claudication Associated with Lumbar Spinal Stenosis

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Disclaimer: There was no external funding in the preparation of this manuscript.

Conflict of interest: Each author certifies that he or she, or a member of his or her immediate family, has no commercial association (i.e., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted manuscript.

Manuscript received: 12-19-2020
Revised manuscript received: 06-28-2021
Accepted for publication: 08-16-2021

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Background: There is a debate on the long-term outcomes of surgical decompression for lumbar spinal stenosis (LSS) as compared to conservative treatment, with even more limited outcomes in repeat surgeries. Hence, other less invasive treatment modalities, such as neuromodulation with a modern spinal cord stimulator (SCS), could be considered in the spectrum of management options for symptoms of neurogenic claudication (NC) related to LSS as an alternative to surgery.

Objective: Assessing the outcomes and efficacy of SCS in neurogenic claudication in patients with or without a prior lumbar surgery.

Study Design: This is a retrospective study of a prospectively collected database.

Setting: The research was conducted at the Medical College of Wisconsin (MCW), an academic medical center, in Milwaukee, Wisconsin.

Methods: This study reviewed all patients who had undergone SCS therapy for symptoms consistent with NC between 2013 through 2020. The data were collected from MCW. Only patients with at least one year of follow-up were included in outcome assessment.

Results: One hundred and eighteen patients with primary symptoms of NC underwent an SCS trial with an 86% pass-rate. A total of 69 of the 93 patients who underwent permanent SCS implantation had at least one year of follow-up. All patients reported initial improvement after permanent implantation. At one-year follow-up, 55 (80%) patients had sustained improvement of their pain levels and claudication symptoms, of whom 52 (75%) continued to experience benefit for an average of at least 27 months. For patients with no prior surgical decompression, 86% continued to experience sustained benefit at the latest follow-up.

Limitations: This study has several limitations. It is of a retrospective nature that includes selection and recall biases. It is a single-center study that limits its generalizability. More limitations are discussed in the main article.

Conclusions: With modern SCS techniques, the majority of patients can achieve sustained improvement of symptoms of NC of at least a 2-year duration regardless of previous history of lumbar decompressive surgery. SCS can be considered as part of the conservative treatment options before committing to surgical decompression.

Key words: SCS, neurogenic claudication, neuromodulation, spinal stenosis

Pain Physician 2021: 24:E1247-E1253

Spinal cord stimulation (SCS) is a well-accepted form of neuromodulation to treat neuropathic and chronic pain (1,2). Specifically, SCS has been effective for pain in failed back surgery syndrome, complex regional pain syndrome, arachnoiditis, ischemia, and more recently in functional recovery

from spinal cord injury (2-8). There is also emerging, although limited, data regarding the efficacy of SCS in treating symptoms of neurogenic claudication (NC) in patients with lumbar spinal stenosis (LSS) (9-12).

Lumbar stenosis is defined as a congenital or acquired narrowing of the spinal canal, lateral recess, or intervertebral foramen leading to various forms of pain syndromes and disability, including intermittent NC (13). Classically, NC is described as intermittent pain, tingling, or cramping in the lower back, in one or both legs, the hips, and buttocks that is triggered by prolonged standing and/or walking and is relieved over many minutes with sitting and/or bending forward, also known as the "shopping-cart sign" in the setting of lumbosacral root compression, typically by lumbar spinal stenosis (14,15).

The symptoms of degenerative LSS commonly occur in the elderly with associated pain, disability, and socioeconomic burden (16-18) and is the most common indication for spine surgery in adults older than 65 years (19). Surgical decompression is typically offered when conservative treatments fail. In 2007, more than 37,500 decompressive laminectomies with or without fusion for LSS were performed in the United States with an aggregated hospital bill of nearly $1.65 billion in Medicare recipients alone (17). In addition, the trends of fusion rates have dramatically increased, adding further financial costs and socioeconomic burden (20). In spite of this, there remains a debate on the long-term outcomes of surgical decompression for LSS compared to conservative treatment (21,22), with even more limited outcomes in those undergoing repeat surgeries. Hence, other less invasive treatment modalities, such as neuromodulation with modern SCS treatment algorithms and programs, could be considered in the spectrum of management options for symptoms of neurogenic claudication related to LSS as an alternative to surgery.

In this study, the authors describe the efficacy of SCS for symptoms of NC associated with LSS in patients with or without prior surgical decompression for LSS. This is the largest such case-series study from a single academic center to date.

Methods

This is a retrospective study of a prospectively collected database of patients who underwent SCS therapy for symptoms consistent with NC between 2013 through 2020. After institutional review board approval, the data were collected from the Medical College of Wisconsin, the main hospital where paddle systems were implanted by neurosurgery (23) and the ambulatory surgery center where percutaneous cylindrical lead trial and permanent systems were implanted by pain medicine physicians.

Workflow for SCS implantation involves initial comprehensive assessment and optimization of conservative management and further evaluation at a pain management center (PMC), including neuropsychological testing and appropriate thoracolumbar neuroimaging such as magnetic resonance imaging (MRI) or computed tomography (CT). Percutaneous SCS trials were performed at the PMC for 5-7 days. A patient was considered to have had a successful SCS trial if they reported significant improvement in NC symptoms to the trialing physician, to include a combination of subjective pain relief of at least 50% on the visual analog scale (VAS), improvement in function (endurance for standing and walking), and with or without reduction in pain medication use (similar criteria as previously reported [9,10]). Functional improvement of NC symptoms was based upon patient estimates of improved standing times and walking endurance. Patients were not formally timed or tested on a treadmill. They were then subsequently counseled regarding permanent implantation options (surgical paddle vs percutaneous cylindrical leads), and then followed postoperatively at the PMC for continued evaluation, maintenance, and adjustments. Trial and permanent multielectrode array implants were placed to cover T9/10 levels; patients were offered modern paresthesia-producing or nonparesthesia-producing waveform algorithms.

The authors only included patients with dominant symptoms of NC with no associated progressive neurologic dysfunction, such as motor weakness or bowel/bladder deficits. The authors determined a clinical diagnosis of NC based upon a patient's signs and symptoms in the background of LSS on MRI or CT imaging. The consensus is that LSS is diagnosed clinically and findings from an MRI scan do not always correlate with severity of symptoms (14,24). However, imaging studies were performed to qualitatively determine the extent of LSS (mild/moderate/severe) as well as for safety screening of the implant, but the degree of LSS was not quantitatively measured or used as an inclusion criterion. Only patients with at least one year of follow-up were included in the final analysis for long-term clinical outcome assessment. Figure 1 describes our cohort, including the referral and surgical opinion.

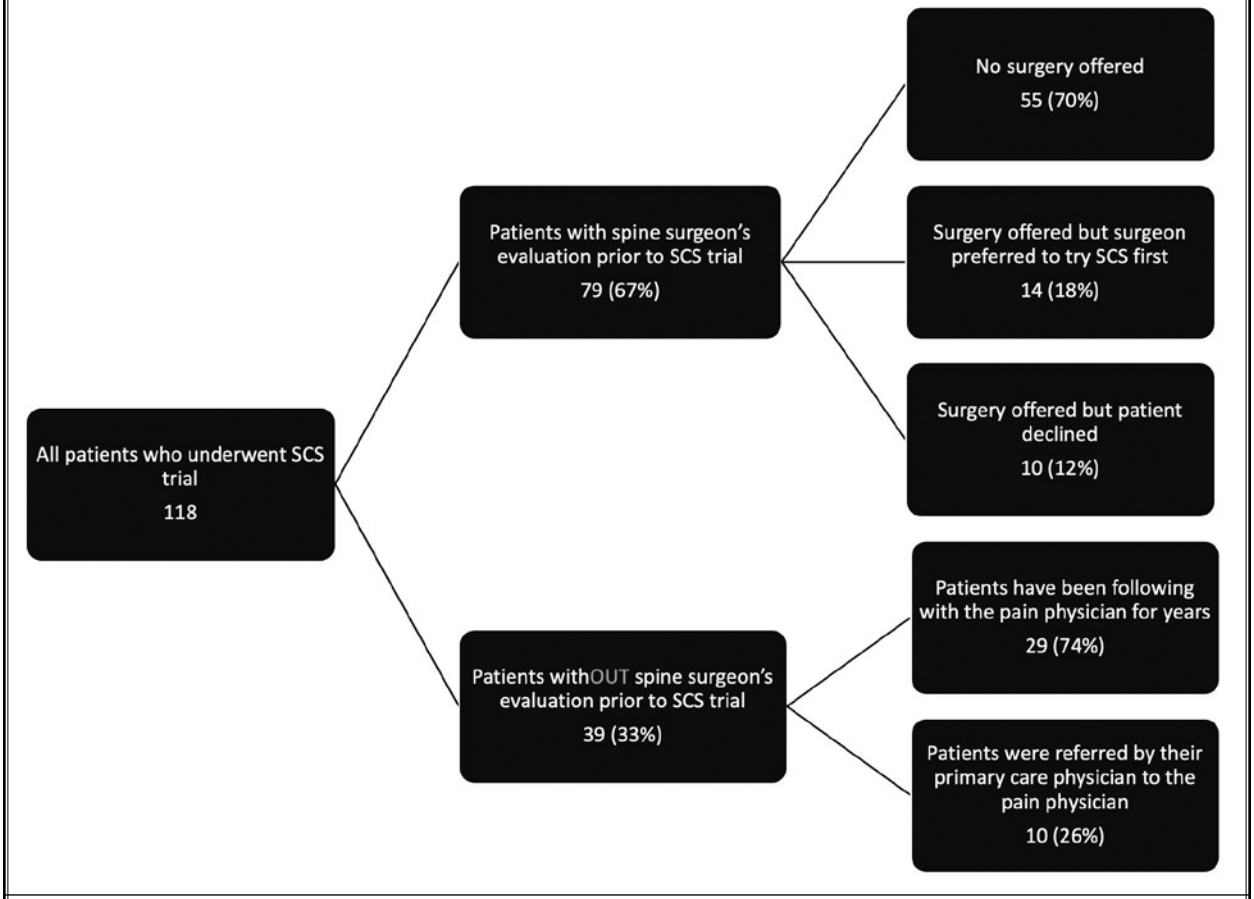

Fig. 1. *Flow diagram for the spinal cord stimulation cohort based on the referral and surgical opinion.*

Results

Patients' Characteristics

One hundred and eighteen patients with primary symptoms of NC underwent an SCS trial with an 86% pass-rate (Fig. 2). Six patients declined implant and 2 patients are awaiting implant. Of the 93 patients who underwent permanent SCS implantation (76 receiving systems from one manufacturer), 69 had at least one year of follow-up (18 were lost to follow-up and 6 are actively being followed). The trial result VAS (0-10) scores for these 69 patients expressed as the mean and standard error of the mean (SEM) were: pretrial resting: 2.9 (0.3); pretrial claudication standing/walking: 8.7 (0.2); posttrial resting: 1.0 (0.1); posttrial claudication: 3.2 (0.2). These patients had a median pretrial standing time of 5 minutes (range 2 minutes – 15 minutes); median walking distance of <one block (range < one-half block to 3 blocks); posttrial median standing time of 30 minutes (range 7 minutes to > 60 minutes); posttrial median walking distance of 10 blocks (range > one block to no limit). Of these 69 patients (average age 72 years; 54% women), 70% received surgical paddle-lead systems, and 80% had previous lumbar surgery. All had at least mild (9), moderate (15), or severe (44) LSS on imaging study reports, except for one with no clear LSS on imaging. The average clinical follow-up period for these 69 patients was 27 months (range: 12 months – 67 months). Table 1 summarizes the patients' demographic and clinical characteristics.

Outcomes

All 69 patients reported initial improvement after permanent implantation. At one-year follow-up, 55 (80%) patients had sustained improvement of their pain levels and claudication symptoms, of whom 52 (75%) continued to experience benefit for an average

of at least 27 months (range: 12 months – 67 months). The VAS scores at latest follow-up were (mean [SEM]): resting: 0.9 (0.2); claudication standing/walking: 4.2 (0.4). At one year, symptom improvement was observed in 79% of patients with paddles and in 81% with cylindrical leads. Similarly, sustained improvement was observed in 77% (paddles) and 71% (cylindrical leads) of patients at latest follow-up (average 27 months). Of the 14 patients with no prior surgical decompression, 12 continued to experience sustained benefit at latest follow-up. Patients with mild, moderate, or severe lumbar LSS on preoperative imaging reports experienced 70%, 73% and 77% sustained improvements respectively at latest follow-up. No patients developed motor or bowel/bladder symptoms nor were there any biological or device-related complications. Four implanted patients underwent subsequent lumbar decompressive surgery (9 months – 34 months after SCS implantation) due to persistent or recurrent symptoms of NC refractory to SCS, where only one of them did not report improvement after their spinal surgery (Table 2).

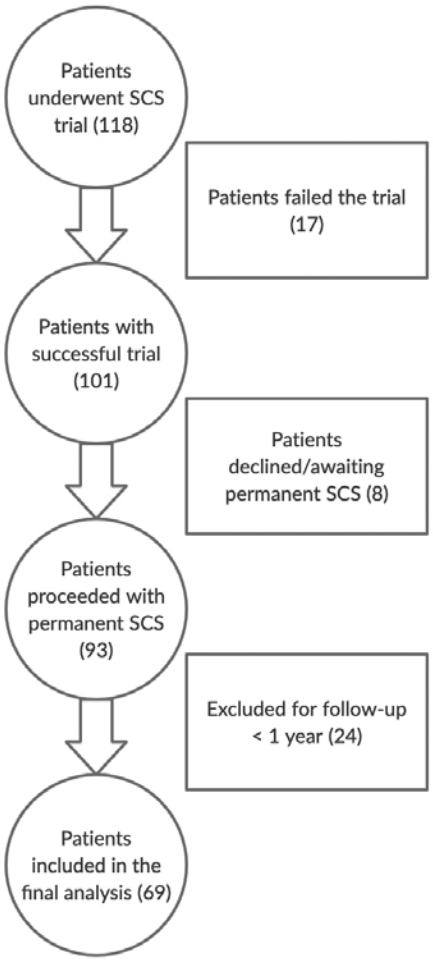

Fig. 2. *Flow diagram for the breakdown of patients who underwent the trial and the permanent implantation of spinal cord stimulation.*

Discussion

Comparison with Previous Studies

There are 3 main studies that assessed SCS in treating symptoms from LSS (9-11). In 2003, Chandler and colleagues (9) published their study with surgical paddle leads in which 14 of 21 patients continued to experience persistent analgesia at 1.5 years. This is the only previous study that focused mainly on symptoms of NC. In 2010, Costantini et al (10) pooled 44 patients with NC who had "successful trials" from 3 different European centers. All patients were implanted with one or 2 parallel Quad leads to cover the painful areas with paresthesias. At a median follow-up of 24 months, pooled data were consistent with a decrease in pain levels and medication needs and 75% of the patients had significantly decreased self-reported NC. Both these studies assessed pain levels, medication reduction, and functional improvement. Finally, in 2014, Kamihara and colleagues (11) reported on 91 patients with radiographic LSS and symptoms of back/leg pain. Some patients had NC but the number was not defined. The extent of LSS was not evaluated. One or 2 Quad leads were used for trials to cover painful areas with paresthesias, with 41 undergoing permanent implantation with percutaneous systems. At an average follow-up of 34.5 months, 39 of the 41 continued to have good relief of leg pain, regardless of the type of leg pain.

Table 1. *Patients' Demographic and Clinical Characteristics.*

Age	Mean: 72 years	
Gender	Women: 37 (54%)	Men: 32 (46%)
History of lumbar surgery	Yes: 55 (80%)	No: 14 (20%)
Treatment modality	Paddle system: 48 (70%)	Percutaneous system: 21 (30%)
Follow-up	Mean: 26 months	

Table 2. *Breakdown of Good Outcomes.*

At initial year	Yes: 55 (80%)	No: 14 (20%)
At mean 27 months (range: 12-67)	Yes: 52 (75%)	No: 17 (25%)
Per treatment modality	Paddle: 38 (79%)	Percutaneous: 17 (81%)

There was no description of the effects on NC per se. All of the above studies used older lead systems with limited electrode contacts spanning short distances with standard paresthesia-producing waveforms.

The current study is unique for several reasons: 1) use of the latest techniques of SCS, including placing multiple-electrode array leads at T9/10 levels with modern nonparesthesia-producing waveforms; 2) demonstration of success of both surgical paddle-lead and percutaneous cylindrical-lead systems within the same study; 3) patient selection was based upon a clinical diagnosis of NC, irrespective of the extent of LSS, without the requirement for severe LSS. The relationship between the severity of NC symptoms and the extent of LSS on MRI scans remains unclear (14,24); 4) the follow-up period is the longest to date for NC, averaging well over 2 years; 5) the trial conversion rate was high (86%) compared to the other studies (60% – 65%) (9,11).

The reason for the high trial conversion rate is unclear, but one can speculate that the use of modern SCS leads and techniques of stimulation may have been a factor. Additionally, the high conversion rate may be due to thoughtful patient selection utilizing a multidisciplinary neuromodulation team to review all patients considered for spinal cord stimulation candidacy and consideration of alternatives. This high conversion rate was reflected in the high percentage of patients with sustained improvements at an average of 27 months. Furthermore, our results suggest that there was no clear advantage of surgical paddle leads over percutaneous cylindrical leads, supporting the conclusion that the latter is sufficient for at least medium-term results. This is of significance as our cohort of patients is older than those in most SCS studies, with an average of 72 years at implant.

Surgical Decompression vs Neuromodulation

Based upon previous limited studies on SCS for LSS over the last 5 years – 15 years (9-12), there has been some acceptance supporting offering SCS to patients with LSS, but only in those who had declined or were refused surgery. In our present study, utilizing state-of-the-art SCS technologies and methodologies, we observed a high trial conversion rate and high rate of sustained improvements in VAS scores and symptoms of NC with an average follow-up of over 2 years. This provides support to the notion that SCS for NC associated with LSS should deserve consideration as an intermediate method of treatment or even a potential substitute for initial or subsequent surgical decompression in patients with refractory NC symptoms from LSS. This patient population tends to be elderly (with an average age of more than 70 in all SCS for LSS studies) with relatively high morbidity risks for surgery; our results with SCS (surgical paddle lead or percutaneous cylindrical leads) compare favorably to surgical decompression. Spinal cord stimulation may also be more cost-effective, at least in the short-term, for this patient population (25), although no previous study has assessed this for NC per se. SCS is nondestructive, reversible and does not prevent future surgery. It may not be in our patients' best interests to potentially first transform them to a failed back surgery syndrome patient before considering neuromodulation techniques.

Limitations

This study has several limitations. It is of a retrospective nature that includes selection and recall biases. It is a single-center study that limits its generalizability. Although VAS was utilized, standing time and walking distance outcomes were also subjective with no utilization of objective measurements or scales such as actual timed standing times or formal walking distance measurements, or utilization of the Zurich Neurogenic Claudication Scale (26). However, the potential strength of the last feature is its practicality in everyday, real-world practice. Although all our patients had classic symptoms of NC with associated LSS, we may have included patients with a vascular claudication component secondary to peripheral vascular disease, which is also known to respond to SCS (27).

Future Research Directions

Traditionally, SCS therapies have been considered to be more successful for constant as opposed to intermittent pain phenotypes. However, the success of SCS for refractory angina (8,28), peripheral vascular disease (27), and more recently for neck pain(29), challenge this premise. Intermittent, positional pain, such as NC may also be related to activity and postural vascular insufficiency, and may therefore be fundamentally different from constant pain phenotypes as has been speculated with recent functional MRI studies and may therefore respond differently to neuromodulation therapies (30-33). Hence, more research is needed in the pathophysiology of pain patterns to potentially have targeted neuromodulation techniques based on the pain pattern. In the same vein, comparative studies between the mode of stimulation and frequency are

needed to achieve the best response. Another future direction could be comparing among decompressive surgery, SCS, and other available minimally invasive treatment options for NC secondary to LSS, such as percutaneous image-guided lumbar decompression (34) or indirect interspinous decompression (35). The authors suggest the idea of a crossover study which is more practical and less cumbersome than a randomized controlled trial.

Conclusion

NC associated with LSS is a common pain phenotype in the aging population. With modern SCS techniques, the majority of patients can achieve sustained improvement of symptoms of NC for at least 2 years regardless of a previous history of lumbar decompressive surgery. SCS can be considered as part of the conservative treatment options before committing to surgical decompression.

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