I am writing this letter on behalf of the patient's we serve at the Oregon Health and Science University Comprehensive Pain Center and our clinic staff. This letter is in response to your Medical Advisory Committee public hearing on June 2nd 2017 related to the use of spinal cord stimulation for the treatment of pain. First, I will like to thank you for your work as custodians of our scarce healthcare resources. I do however want to point out the need for careful review of the evidence before making a decision which will almost certainly impact a lot of Oregonians in chronic pain. I have attached below a series of scientific studies supporting the use of this modality for specific pain syndromes. I also want to point out the fact that most of the data in multiple studies support the use. As a matter of fact, studies that do not support clinical efficacy are in the minority. While concerns about industry influence on these studies are valid, it does not change the validity of studies that meet the high standards of clinical evidence and peer review as accepted by the scientific community. I will also encourage you to focus on multiple studies done within and outside the United states which meet these high community standards. It is important to note that these devices are FDA approved which does matter. As you are aware the process of FDA approval involves industry experts evaluating not just safety but efficacy of a device. Use of these devices within FDA approved parameters should not be considered investigational, and denying coverage will consequently deny patients access to optimal care. It is reasonable to curb off-label use of these devices outside their FDA approved roles as this could in fact be investigational. Chronic pain patients already suffer from a paucity of options and cutting their access to spinal cord stimulation will unfairly further decrease their options.

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https://www.ncbi.nlm.nih.gov/pubmed/28030470

Pain. 2017 Apr;158(4):669-681. doi: 10.1097/j.pain.0000000000000814.

Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial.

Deer TR1, Levy RM, Kramer J, Poree L, Amirdelfan K, Grigsby E, Staats P, Burton AW, Burgher AH, Obray J, Scowcroft J, Golovac S, Kapural L, Paicius R, Kim C, Pope J, Yearwood T, Samuel S, McRoberts WP, Cassim H, Netherton M, Miller N, Schaufele M, Tavel E, Davis T, Davis K, Johnson L, Mekhail N.

Author information

Abstract

Animal and human studies indicate that electrical stimulation of dorsal root ganglion (DRG) neurons may modulate neuropathic pain signals. ACCURATE, a pivotal, prospective, multicenter, randomized comparative effectiveness trial, was conducted in 152 subjects diagnosed with complex regional pain syndrome or causalgia in the lower extremities. Subjects received neurostimulation of the DRG or dorsal column (spinal cord stimulation, SCS). The primary end point was a composite of safety and efficacy at 3

months, and subjects were assessed through 12 months for long-term outcomes and adverse events. The predefined primary composite end point of treatment success was met for subjects with a permanent implant who reported 50% or greater decrease in visual analog scale score from preimplant baseline and who did not report any stimulation-related neurological deficits. No subjects reported stimulation-related neurological deficits. The percentage of subjects receiving ≥50% pain relief and treatment success was greater in the DRG arm (81.2%) than in the SCS arm (55.7%, $P < 0.001$) at 3 months. Device-related and serious adverse events were not different between the 2 groups. Dorsal root ganglion stimulation also demonstrated greater improvements in quality of life and psychological disposition. Finally, subjects using DRG stimulation reported less postural variation in paresthesia ($P < 0.001$) and reduced extraneous stimulation in nonpainful areas ($P = 0.014$), indicating DRG stimulation provided more targeted therapy to painful parts of the lower extremities. As the largest prospective, randomized comparative effectiveness trial to date, the results show that DRG stimulation provided a higher rate of treatment success with less postural variation in paresthesia intensity compared to SCS.

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https://www.ncbi.nlm.nih.gov/pubmed/27584814

Neurosurgery. 2016 Nov;79(5):667-677.

Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-Month Results From a Multicenter, Randomized, Controlled Pivotal Trial.

Kapural L1, Yu C, Doust MW, Gliner BE, Vallejo R, Sitzman BT, Amirdelfan K, Morgan DM, Yearwood TL, Bundschu R, Yang T, Benyamin R, Burgher AH.

Author information

Abstract

BACKGROUND:

Pain relief with spinal cord stimulation (SCS) has focused historically on paresthesias overlapping chronically painful areas. A higher level evidence supports the use of SCS in treating leg pain than supports back pain, as it is difficult to achieve adequate paresthesia coverage, and then pain relief, in the low back region. In comparison, 10-kHz high-frequency (HF10 therapy) SCS therapy does not rely on intraoperative paresthesia mapping and remains paresthesia-free during therapy.

OBJECTIVE:

To compare long-term results of HF10 therapy and traditional low-frequency SCS.

METHODS:

A pragmatic randomized, controlled, pivotal trial with 24-month follow-up was conducted across 11 comprehensive pain treatment centers. Subjects had Visual Analog Scale scores of ≥5.0/10.0 cm for both back and leg pain, and were assigned randomly (1:1) to receive HF10 therapy or low-frequency SCS. The primary end point was a responder rate, defined as ≥50% back pain reduction from baseline at 3 months with a secondary end point at 12 months (previously reported). In this article, 24-month secondary

results are presented. Non-inferiority was first assessed, and if demonstrated the results were tested for superiority.

RESULTS:

In the study, 198 subjects were randomized (101 HF10 therapy, 97 traditional SCS). One hundred seventy-one subjects (90 HF10 therapy, 81 traditional SCS) successfully completed a short-term trial and were implanted. Subjects averaged 54.9 ± 12.9 years old, 13.6 ± 11.3 years since diagnosis, 86.6% had back surgery, 88.3% were taking opioid analgesics. At 3 months, 84.5% of implanted HF10 therapy subjects were responders for back pain and 83.1% for leg pain, and 43.8% of traditional SCS subjects were responders for back pain and 55.5% for leg pain ($P < .001$ for both back and leg pain comparisons, non-inferiority and superiority). At 24 months, more subjects were responders to HF10 therapy than traditional SCS (back pain: 76.5% vs 49.3%; 27.2% difference, 95% CI, 10.1%-41.8%; $P < .001$ for non-inferiority and superiority; leg pain: 72.9% vs 49.3%; 23.6% difference, 95% CI, 5.9%-38.6%; $P < .001$ for non-inferiority and $P = .003$ for superiority). Also at 24 months, back pain decreased to a greater degree with HF10 therapy (66.9% ± 31.8%) than traditional SCS (41.1% ± 36.8%, $P < .001$ for non-inferiority and superiority). Leg pain also decreased to a greater degree with HF10 therapy (65.1% ± 36.0%) than traditional SCS (46.0% ± 40.4%, $P < .001$ for non-inferiority and $P = .002$ for superiority).

CONCLUSION:

This study demonstrates long-term superiority of HF10 therapy compared with traditional SCS in treating both back and leg pain. The advantages of HF10 therapy are anticipated to impact the management of chronic pain patients substantially.

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https://www.ncbi.nlm.nih.gov/pubmed/27739179

A Comprehensive Outcome-Specific Review of the Use of Spinal Cord Stimulation for Complex Regional Pain Syndrome.

Visnjevac O1, Costandi S2, Patel BA1, Azer G2, Agarwal P1, Bolash R2, Mekhail NA2.

Author information

Abstract

BACKGROUND: Complex regional pain syndrome (CRPS) is a painful, debilitating affliction that is often difficult to treat. It has become common international practice to use spinal cord stimulation (SCS) for the treatment of CRPS as other therapies fail to provide adequate relief, quality of life, or improvement in function. This comprehensive outcome-specific systematic review of the use of SCS for CRPS was performed to elucidate the available evidence with focus on clinically relevant patient-specific outcomes.

METHODS: A systematic review of the literature was conducted to evaluate the effects of SCS on patients with CRPS for the following outcomes and provide summary levels of evidence in regard to each outcome: perceived pain relief, pain score, resolution of CRPS signs, functional status, quality of life,

psychological impact, sleep hygiene, analgesic medication utilization, and patient satisfaction with SCS therapy. Search terms included "complex regional pain syndrome," "spinal cord stimulation," and "reflex sympathetic dystrophy," without restriction of language, date, or type of publication, albeit only original data were included in analyses. Of 30 studies selected, seven systematic reviews were excluded, as were four studies reporting combination therapy that included SCS and other therapies (ie, concurrent peripheral nerve stimulation, intrathecal therapy) without clear delineation to the effect of SCS alone on outcomes. A total of 19 manuscripts were evaluated.

RESULTS: Perceived pain relief, pain score improvement, quality of life, and satisfaction with SCS were all rated 1B+, reflecting positive high-level (randomized controlled trial) evidence favoring SCS use for the treatment of CRPS. Evidence for functional status improvements and psychological effects of SCS was inconclusive, albeit emanating from a randomized controlled trial (evidence level 2B±), and outcomes evidence for both sleep hygiene and resolution of CRPS signs was either nonexistent or of too low quality from which to draw conclusions (evidence level 0). An analgesic sparing effect was observed in nonrandomized reports, reflecting an evidence level of 2C+.

CONCLUSIONS: Spinal cord stimulation remains a favorable and effective modality for treating CRPS with high-level evidence (1B+) supporting its role in improving CRPS patients' perceived pain relief, pain score, and quality of life. A paucity of evidence for functional improvements, resolution of CRPS signs, sleep hygiene, psychological impact, and analgesic sparing effects mandate further investigation before conclusions can be drawn for these specific outcomes.

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https://www.ncbi.nlm.nih.gov/pubmed/28467566

Agri. 2017 Jan;29(1):25-32. doi: 10.5505/agri.2016.08870.

[Spinal cord stimulation in 62 patients: Retrospective evaluation].

[Article in Turkish]

Özdemir İ, Akbaş M1, Yeğin A, Dağıstan G, Erkan DÖ.

Author information

Abstract

OBJECTIVES: Spinal cord stimulation (SCS) is used for various indications such as Failed Back Surgey Syndrome, peripheral causalgia, neuropathic pain, complex regional pain syndrome, reflex sympathetic dystrophy, peripheral vascular disease, ischemic heart disease and cancer pain.

METHODS: This is a retrospective study. 62 patients applied SCS were included in retrospective study from february 2011-january 2015 in Akdeniz University medicine faculty algology department. We asked about patients' VAS values before and after procedure, analgesic medicine usings, sleep disorders, pleasure after procedure, daily activity improvement and time of going back to work.

RESULTS: We found that decrease on the patients' pain severity and improvement on quality of sleep and daily activities.

CONCLUSION: As a result; our study and the other studies show that SCS is reliable and effective procedure on chronic pain management.

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https://www.ncbi.nlm.nih.gov/pubmed/23199157

Neuromodulation. 2013 Jan-Feb;16(1):59-65; discussion 65-6. doi: 10.1111/ner.12006. Epub 2012 Nov 30.

High-frequency spinal cord stimulation for the treatment of chronic back pain patients: results of a prospective multicenter European clinical study.

Van Buyten JP1, Al-Kaisy A, Smet I, Palmisani S, Smith T.

Author information

Abstract

OBJECTIVE: The objective of this prospective, open-label, multicenter European clinical trial was to quantify the efficacy and safety of a spinal cord stimulation (SCS) system that utilizes high-frequency (up to 10 kHz) waveforms, which do not produce paresthesia, for the treatment of chronic, intractable pain of the back and/or limbs.

MATERIAL AND METHODS: Eighty-three patients, with significant back pain, were recruited for a trial of high-frequency stimulation through two percutaneous eight-contact epidural leads. Patients' pain ratings, disability, sleep disturbances, and satisfaction, as well as complication rates, were assessed for up to six months.

RESULTS: After a trial period, 88% (72 out of 82) of patients reported a significant improvement in visual analog scale (VAS) scores and underwent permanent implantation of the high-frequency SCS system. Mean back pain VAS of 8.4 was reduced to 2.7 at six months ($p < 0.001$). Mean leg pain VAS of 5.4 was reduced to 1.4 at six months ($p < 0.001$). Seventy-four percent of patients had greater than 50% back pain relief at six months. There were significant improvements in Oswestry disability score and sleep, and reductions in pain medication use. Adverse events observed were those seen with conventional SCS therapy--lead migration, wound infection, and pain around implant site.

CONCLUSIONS: In a cohort of patients with difficult-to-treat chronic back pain, high-frequency SCS provided significant and sustained low back pain and leg pain relief to more than 70% of treated

subjects. Notably, this was achieved without paresthesia. Patients also experienced significant improvement in disability and sleep. Overall, the results confirm a favorable safety and efficacy profile of the high-frequency SCS system.

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https://www.ncbi.nlm.nih.gov/pubmed/24308759

Pain Med. 2014 Mar;15(3):347-54. doi: 10.1111/pme.12294. Epub 2013 Dec 5.

Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study.

Al-Kaisy A1, Van Buyten JP, Smet I, Palmisani S, Pang D, Smith T.

Author information

Abstract

OBJECTIVE: The aim of this study was to investigate the long-term efficacy and safety of paresthesia-free high-frequency spinal cord stimulation (HF10 SCS) for the treatment of chronic, intractable pain of the low back and legs.

DESIGN: Prospective, multicenter, observational study.

METHOD: Patients with significant chronic low back pain underwent implantation of a spinal cord stimulator capable of HF10 SCS. Patients' pain ratings, disability, sleep disturbances, opioid use, satisfaction, and adverse events were assessed for 24 months.

RESULTS: After a trial period, 88% (72 of 82) of patients reported a significant improvement in pain scores and underwent the permanent implantation of the system. Ninety percent (65 of 72) of patients attended a 24-month follow-up visit. Mean back pain was reduced from 8.4 ± 0.1 at baseline to 3.3 ± 0.3 at 24 months ($P < 0.001$), and mean leg pain from 5.4 ± 0.4 to 2.3 ± 0.3 ($P < 0.001$). Concomitantly to the pain relief, there were significant decreases in opioid use, Oswestry Disability Index score, and sleep disturbances. Patients' satisfaction and recommendation ratings were high. Adverse Events were similar in type and frequency to those observed with traditional SCS systems.

CONCLUSIONS: In patients with chronic low back pain, HF10 SCS resulted in clinically significant and sustained back and leg pain relief, functional and sleep improvements, opioid use reduction, and high patient satisfaction. These results support the long-term safety and sustained efficacy of HF10 SCS.

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https://www.ncbi.nlm.nih.gov/pubmed/17889577

Eur J Pain. 2008 Jan;12(1):53-9. Epub 2007 Sep 21.

Spinal cord stimulation in adolescents with complex regional pain syndrome type I (CRPS-I).

Olsson GL1, Meyerson BA, Linderoth B.

Author information

Abstract

Complex regional pain syndrome type I (CRPS-I) is not uncommon in children, particularly in adolescent girls. Most often, the condition involves a foot and is characterized by spontaneous pain, tactile allodynia and dysautonomic signs. There is usually a history of a minor, local trauma but sometimes no reasonable cause can be identified, and there are no signs of persistent tissue injury giving rise to ongoing nociception. Common analgesics are generally of no benefit, and the standard treatment includes sociopsychological support, physiotherapy, tricyclic antidepressants and antiepileptic drugs, sympathetic blocks (SB), and cognitive-behavioural therapy. For a minority of patients who prove to be resistant to such therapies, spinal cord stimulation (SCS) may be tried. The present study comprises seven girls, 11-14 years of age, presenting with severe, incapacitating and therapy-resistant CRPS-I, who were subjected to SCS. In two of them, percutaneous electrode implantation had to be performed in general anaesthesia. Trial stimulation was performed in all, but one. In two cases, it was not possible to produce paraesthesias that entirely covered the pain area. A pain relieving effect of SCS was usually not reported until after 1-2 weeks of trial stimulation. After another 2-6 weeks, pain alleviation was complete in five of the seven patients, one to eight years after the intervention. In one case, a local infection necessitated the removal of the electrode; nevertheless a few days of trial stimulation produced substantial pain relief that still persists. In four patients, the SCS use was gradually diminished and eventually the device could be removed. The favourable outcome in all seven cases with no or minor remaining symptoms and without severe recurrences illustrates that SCS may also be an efficient treatment in paediatric cases with exceptionally therapy resistant forms of CRPS I.

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https://www.ncbi.nlm.nih.gov/pubmed/17845835

Pain. 2007 Nov;132(1-2):179-88. Epub 2007 Sep 12.

Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome.

Kumar K1, Taylor RS, Jacques L, Eldabe S, Meglio M, Molet J, Thomson S, O'Callaghan J, Eisenberg E, Milbouw G, Buchser E, Fortini G, Richardson J, North RB.

Author information

Abstract

Patients with neuropathic pain secondary to failed back surgery syndrome (FBSS) typically experience persistent pain, disability, and reduced quality of life. We hypothesized that spinal cord stimulation (SCS) is an effective therapy in addition to conventional medical management (CMM) in this patient population. We randomized 100 FBSS patients with predominant leg pain of neuropathic radicular origin to receive spinal cord stimulation plus conventional medical management (SCS group) or conventional medical management alone (CMM group) for at least 6 months. The primary outcome was the proportion of patients achieving 50% or more pain relief in the legs. Secondary outcomes were

improvement in back and leg pain, health-related quality of life, functional capacity, use of pain medication and non-drug pain treatment, level of patient satisfaction, and incidence of complications and adverse effects. Crossover after the 6-months visit was permitted, and all patients were followed up to 1 year. In the intention-to-treat analysis at 6 months, 24 SCS patients (48%) and 4 CMM patients (9%) (p<0.001) achieved the primary outcome. Compared with the CMM group, the SCS group experienced improved leg and back pain relief, quality of life, and functional capacity, as well as greater treatment satisfaction (p<or=0.05 for all comparisons). Between 6 and 12 months, 5 SCS patients crossed to CMM, and 32 CMM patients crossed to SCS. At 12 months, 27 SCS patients (32%) had experienced device-related complications. In selected patients with FBSS, SCS provides better pain relief and improves health-related quality of life and functional capacity compared with CMM alone.

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https://www.ncbi.nlm.nih.gov/pubmed/18981888

Neurosurgery. 2008 Oct;63(4):762-70; discussion 770. doi: 10.1227/01.NEU.0000325731.46702.D9.

The effects of spinal cord stimulation in neuropathic pain are sustained: a 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation.

Kumar K1, Taylor RS, Jacques L, Eldabe S, Meglio M, Molet J, Thomson S, O'Callaghan J, Eisenberg E, Milbouw G, Buchser E, Fortini G, Richardson J, North RB.

Author information

Abstract

OBJECTIVE:

After randomizing 100 failed back surgery syndrome patients to receive spinal cord stimulation (SCS) plus conventional medical management (CMM) or CMM alone, the results of the 6-month Prospective Randomized Controlled Multicenter Trial of the Effectiveness of Spinal Cord Stimulation (i.e., PROCESS) showed that SCS offered superior pain relief, health-related quality of life, and functional capacity. Because the rate of crossover favoring SCS beyond 6 months would bias a long-term randomized group comparison, we present all outcomes in patients who continued SCS from randomization to 24 months and, for illustrative purposes, the primary outcome (>50% leg pain relief) per randomization and final treatment.

METHODS:

Patients provided data on pain, quality of life, function, pain medication use, treatment satisfaction, and employment status. Investigators documented adverse events. Data analysis included inferential comparisons and multivariate regression analyses.

RESULTS:

The 42 patients continuing SCS (of 52 randomized to SCS) reported significantly improved leg pain relief (P < 0.0001), quality of life (P <or= 0.01), and functional capacity (P = 0.0002); and 13 patients (31%) required a device-related surgical revision. At 24 months, of 46 of 52 patients randomized to SCS and 41 of 48 randomized to CMM who were available, the primary outcome was achieved by 17 (37%)

randomized to SCS versus 1 (2%) to CMM (P = 0.003) and by 34 (47%) of 72 patients who received SCS as final treatment versus 1 (7%) of 15 for CMM (P = 0.02).

CONCLUSION:

At 24 months of SCS treatment, selected failed back surgery syndrome patients reported sustained pain relief, clinically important improvements in functional capacity and health-related quality of life, and satisfaction with treatment.

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https://www.ncbi.nlm.nih.gov/pubmed/15617591

Neurosurgery. 2005;56(1):98-106; discussion 106-7.

Spinal cord stimulation versus repeated lumbosacral spine surgery for chronic pain: a randomized, controlled trial.

North RB1, Kidd DH, Farrokhi F, Piantadosi SA.

Author information

Abstract

OBJECTIVE:

Persistent or recurrent radicular pain after lumbosacral spine surgery is often associated with nerve root compression and is treated by repeated operation or, as a last resort, by spinal cord stimulation (SCS). We conducted a prospective, randomized, controlled trial to test our hypothesis that SCS is more likely than reoperation to result in a successful outcome by standard measures of pain relief and treatment outcome, including subsequent use of health care resources.

METHODS:

For an average of 3 years postoperatively, disinterested third-party interviewers followed 50 patients selected for reoperation by standard criteria and randomized to SCS or reoperation. If the results of the randomized treatment were unsatisfactory, patients could cross over to the alternative. Success was based on self-reported pain relief and patient satisfaction. Crossover to the alternative procedure was an outcome measure. Use of analgesics, activities of daily living, and work status were self-reported.

RESULTS:

Among 45 patients (90%) available for follow-up, SCS was more successful than reoperation (9 of 19 patients versus 3 of 26 patients, P <0.01). Patients initially randomized to SCS were significantly less likely to cross over than were those randomized to reoperation (5 of 24 patients versus 14 of 26 patients, P=0.02). Patients randomized to reoperation required increased opiate analgesics significantly more often than those randomized to SCS (P <0.025). Other measures of activities of daily living and work status did not differ significantly.

CONCLUSION:

SCS is more effective than reoperation as a treatment for persistent radicular pain after lumbosacral spine surgery, and in the great majority of patients, it obviates the need for reoperation.

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https://www.ncbi.nlm.nih.gov/pubmed/10965008

N Engl J Med. 2000 Aug 31;343(9):618-24.

Spinal cord stimulation in patients with chronic reflex sympathetic dystrophy.

Kemler MA1, Barendse GA, van Kleef M, de Vet HC, Rijks CP, Furnée CA, van den Wildenberg FA.

Author information

Abstract

BACKGROUND:

Chronic reflex sympathetic dystrophy (also called the complex regional pain syndrome) is a painful, disabling disorder for which there is no proven treatment. In observational studies, spinal cord stimulation has reduced the pain associated with the disorder.

METHODS:

We performed a randomized trial involving patients who had had reflex sympathetic dystrophy for at least six months. Thirty-six patients were assigned to receive treatment with spinal cord stimulation plus physical therapy, and 18 were assigned to receive physical therapy alone. The spinal cord stimulator was implanted only if a test stimulation was successful. We assessed the intensity of pain (on a visual-analogue scale from 0 cm [no pain] to 10 cm [very severe pain]), the global perceived effect (on a scale from 1 [worst ever] to 7 [best ever]), functional status, and the health-related quality of life.

RESULTS:

The test stimulation of the spinal cord was successful in 24 patients; the other 12 patients did not receive implanted stimulators. In an intention-to-treat analysis, the group assigned to receive spinal cord stimulation plus physical therapy had a mean reduction of 2.4 cm in the intensity of pain at six months, as compared with an increase of 0.2 cm in the group assigned to receive physical therapy alone ($P<0.001$ for the comparison between the two groups). In addition, the proportion of patients with a score of 6 ("much improved") for the global perceived effect was much higher in the spinal cord stimulation group than in the control group (39 percent vs. 6 percent, $P=0.01$). There was no clinically important improvement in functional status. The health-related quality of life improved only in the 24 patients who actually underwent implantation of a spinal cord stimulator. Six of the 24 patients had complications that required additional procedures, including removal of the device in 1 patient.

CONCLUSIONS:

In carefully selected patients with chronic reflex sympathetic dystrophy, electrical stimulation of the spinal cord can reduce pain and improve the health-related quality of life.