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Spinal Cord Stimulation Compared With Medical Management for Failed Back Surgery Syndrome

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Introduction

It has been 40 years since the first report of spinal cord stimulation (SCS) with electrical energy, written by Shealy et al. [1]. The effectiveness of SCS has been studied in many chronic pain states. Pain relief has been demonstrated in back and leg pain, failed back surgery syndrome, chronic regional pain syndrome, peripheral vascular diseases of the lower extremities, multiple sclerosis, and peripheral neuropathy [2].

In SCS, electrodes are placed in the epidural space, which are attached to an implantable neurostimulating generator. The electrodes are positioned over the posterior columns of the spinal cord. State-of-the-art neurostimulating generators are programmable and allow patients to control certain stimulating parameters with a hand-held programmer.

In this randomized controlled clinical trial, Kumar et al. studied SCS compared with conventional nonsurgical treatment of neuropathic pain in patients with failed back surgery syndrome. SCS has been the topic of numerous publications [3–5]. However, many of these publications have been case reports or retrospective studies; few have been randomized controlled trials [6,7].

Aims

The aim of this study was to compare the effectiveness of SCS plus conventional medical management with conventional medical management in failed back surgery syndrome.

Methods

The clinical trial included patients who had undergone at least one anatomically successful surgery for herniated disc and continue to have neuropathic pain, leg greater than back, in the L4, L5, and S1 dermatomes. Pain was at least 50 mm on a visual analogue scale (VAS [0, no pain, to 100 mm, worst possible pain]). Patients were randomized equally to each of the two treatment groups. In addition to receiving an SCS, this group also received conventional

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Disclosures

Neither Dr. Mackey nor Dr. Coleman has received monies from Medtronic, Inc.

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Rating: •• Of major importance.

medical management (CMM). The CMM group had medications actively managed by the investigator. Medications included oral opioid, NSAID, antidepressant, and anticonvulsant/antiepileptic. Other therapies included nerve blocks, epidural corticosteroids, physical and psychological therapy, and chiropractic care.

Patients in the SCS group underwent implantation (Synergy System; Medtronic, Inc., Minneapolis, MN) if they experienced 80% overlap of their pain with stimulation-induced paresthesia and at least 50% reduction of leg pain during screening trial. The proportion of patients with at least 50% reduction of leg pain at 6 months was the primary end point. After 6 months, patients could request crossover to the other group. Patients completed pain diaries to obtain VAS assessments. In addition, patients were evaluated with Short-Form 36 (SF-36) to assess quality of life and the Oswestry Disability Index (ODI) to assess disability.

Results

One hundred patients were enrolled. Fifty-two patients were assigned to the SCS group, and nine failed to achieve implantation criteria on screening trial; however, five of these patients requested implantation, for a total of 48 patients who received the implants. Forty-eight patients were assigned to the CMM group. At 6 months, primary outcome data were available for 93 patients (50 from the SCS group and 43 from the CMM group).

Twenty-four patients (48%) in the SCS group and four patients (9%) in the CMM group achieved the primary end point of 50% reduction of leg pain ($P < 0.001$). Patients crossing over after 6 months included 32 patients (73%) in the CMM group who received screening trial, and 28 patients underwent implantation. The primary reason for crossover was inadequate pain relief. Only five patients (10%) who received SCS crossed over to the CMM group.

Secondary outcomes at 6 months indicated that the patients in the SCS group had lower levels of back and leg pain, greater treatment satisfaction, and improvement on 7 of 8 dimensions of the SF-36. There was a significant improvement in function on the ODI for patients who received SCS compared with CMM ($P = 0.0002$). Thirty-three patients (66%) in the SCS group noted satisfaction with pain relief compared with eight (18%) in the CMM group. In addition, eight SCS patients and one CMM patient discontinued opioids.

There were a total of 40 device-related complications in the 84 patients who underwent a screening trial, 76 of whom went on to SCS implantation. The 40 events occurred in 27 (32%) patients, and 20 (24%) patients required surgery for the complication. Lead migration (8 patients [10%]), infection/wound breakdown (7 patients [8%]), and loss of therapeutic effect, loss of paresthesia, or unpleasant paresthesia (6 patients [7%]) were the most common SCS-related complications. Non-SCS adverse events (primarily adverse drug events or new illness) occurred in 25 (52%) patients in the CMM group and 18 (35%) patients in the SCS group.

Discussion

The authors conclude that in patients with neuropathic pain in failed back surgery syndrome, SCS improves pain relief, quality of life, functional capacity, and patient satisfaction when compared with CMM.

Comments

This study has many strengths, including appropriate power size assessments; use of both pain and secondary validated outcome measures on quality of life; a conservative intent to treat analysis; detailed patient flow through the study; and detailed reporting of complications. The finding that 48% of patients implanted with SCS versus 9% of patients treated with CMM

achieved 50% reduction of leg pain at 6 months is very favorable toward the use of SCS in failed back surgery syndrome. This result is in the range of other published studies [2,4,5,6].

There are some weaknesses and areas for follow-up in this study. There are not many details about the CMM treatment and it is assumed that the treatment was highly variable. It would have been useful in comparing efficacy to know if the CMM group was a multidisciplinary pain treatment approach or if it consisted of the more typical unimodal therapies done sequentially. There were 27 of 84 patients who underwent screening trial or screening trial and implantation who had device-related complications. This is a rate similar to previous publications [5,6].

Finally, as noted in other studies, over time, some patients lose adequate pain control even though the SCS unit is functioning properly and there are paresthesias over the pain locations [3,5,7]. The data in this 6-month follow-up do not demonstrate tolerance; however, data covering a longer duration of treatment may add insight into this issue. Detailed data on 1 year of follow-up on these patients are planned for a future publication.

Since this trial has been published, it has been a subject of debate. This is particularly so with groups formulating evidence-based guidelines for chronic pain therapies. On one hand, this study represents one of the few randomized controlled trials of a procedural intervention for chronic pain. On the other hand, it was funded by the device manufacturer whose intervention was studied; therefore, the study was vulnerable to bias and influence. Some guidelines have even argued for excluding this paper based on this issue. Although we recognize the potential for bias and influence, we also note it went through an appropriate peer-reviewed process in a highly reputable pain journal. Additionally, our field desperately needs more well-controlled interventional therapy studies. The National Institutes of Health rarely funds these studies. They are expensive to conduct. We are therefore dependent on the device companies for that study funding. Obviously, there needs to be an appropriate firewall between the device companies and the researchers conducting the clinical trials to prevent influence. In conclusion, we must be wary of the sources of funding and potential influences for a study, but we should still evaluate the study based on its merits and not just the source of funding. The Kumar et al. paper represents such a meritorious study and we are hoping to see more like this in the future.

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