Spinal cord stimulation in management of chronic pain

A 9-year experience

MARIO MEGLIO, M.D., BEATRICE CIONI, M.D., AND GIAN FRANCO ROSSI, M.D.

Institute of Neurosurgery, Catholic University, Rome, Italy

Between 1978 and 1986, 109 patients with chronic pain underwent spinal cord stimulation (SCS) at the authors' institute as part of their pain treatment program. The results of SCS in these patients at the end of the test period and at the latest follow-up examination are analyzed in relation to the etiology of their pain. In 40 patients pain was associated with an obstructive peripheral vasculopathy, in 10 with a previous herpes zoster infection, in 15 with an incomplete traumatic spinal cord lesion, in nine with root and/or nerve damage, in 11 with cancer, and in 19 with previous back surgery. The etiology of the pain in five patients was uncertain. This experience supports the conclusion that the best indications for SCS are vasculopathic pain and post-herpetic neuralgia. No clinical usefulness was found for SCS in cancer pain or in central deafferentation types of pain.

KEY WORDS • spinal cord stimulation • post-herpetic pain • chronic pain • ischemic pain • deafferentation pain

Twenty years after the first report of spinal cord stimulation (SCS) for pain relief in man there is still skepticism regarding this technique. This might be due in part to the difficulties of managing patients with chronic pain, to technical problems related to the devices used, and to the lack of objectivity in assessing the results of stimulation. It might also be ascribed to the natural attitude of the surgeon toward handling these problems in more aggressive and definitive ways.

Nine years of personal experience with this technique have convinced us that this negative attitude is hardly justified. In this report we present our personal results and discuss the role of SCS in clinical practice with regard to the control of chronic pain.

Clinical Material and Methods

During a 9-year period from 1978 to 1986, 109 patients received SCS for the treatment of their chronic pain syndrome at our institute. These included 69 men and 40 women, ranging in age from 32 to 84 years. The pain was caused by the following disorders: obstructive vascular disease of the extremities in 40 patients; previous herpes zoster infection in 10; an incomplete traumatic spinal cord lesion in 15; root and/or nerve damage in nine; and cancer in 11. In 19 patients a diagnosis of low-back pain was made; all of these had previously undergone surgery at least once, and leg pain (unilateral in eight patients and bilateral in 11 patients) was present in all. The remaining five patients suffered from a pain syndrome of uncertain origin.

In all cases traditional methods of treatment either were not possible or had failed. Patients with major psychiatric problems were excluded from receiving SCS. Implantation of the electrodes was attempted in every case by a percutaneous technique, aiming the tip for a position where stimulation could produce paresthesia over the painful area; this location was usually between the C-6 and T-1 vertebral levels for upper-extremity pain and between T-9 and T-11 for lower-extremity pain. In five patients, attempts to place the electrode via a percutaneous technique were unsuccessful, so the electrode (a Myelostat or Resume*) was positioned through a small laminectomy. Satisfactory paresthesiae could not be obtained in 10 patients. A percutaneous trial of SCS was usually performed while the patient was hospitalized, lasting 5 to 60 days (average 20 days). A radiofrequency system was used in the initial 34 cases; thereafter, all patients (30 cases) re-

* Electrodes manufactured by Medtronic, Inc., Minneapolis, Minnesota.
ceived a totally implantable and programmable stimulator (Itrel system).† Stimulation was monopolar in 44 cases and bipolar, with the electrodes spaced 3 to 6 cm apart, in the remaining 20. Patients with the radiofrequency system were instructed to self-stimulate for periods of 20 to 30 minutes two or three times a day with the exception of the vasculopathic patients who were invited to stimulate every other hour during the daytime hours. In patients with the Itrel system, regardless of the etiology of their pain condition, the stimulator was programmed as follows: 85 cycles/sec, 210 μsec, cycled mode (64 seconds on, 1 to 4 minutes off) at an amplitude producing comfortable paresthesiae.

The results are expressed as a percentage of analgesia (0% denotes no effect, 100% denotes complete pain relief) and were evaluated based on the patient's report on the visual analogue scale and on their request for medications. The patients were invited to indicate the intensity of their pain on a 10-cm line where “no pain” was at one end and “worst pain possible” at the other. The length of the line produced by the subject's mark was the visual analogue of his pain. This is the most popular and simple method for rating pain in clinical practice. Only a reduction of more than 50% of the original pain was regarded as a consistent result (responders) and led to continuation of this form of treatment.

Results

Pain Relief

Vasculopathic Pain. Of the 40 patients who experienced vasculopathic pain, 34 noted more than 50% analgesia (mean 90.1%) during the test period (Fig. 1). Two of these required electrode removal because of complications (cerebrospinal fluid (CSF) leakage in one case and subcutaneous hematoma in the other). Thus, 32 patients were left with a permanent implant. The mean follow-up period for this group of patients was 19.2 months (range 3 to 62 months).

The results of SCS in this group of patients are shown in Fig. 2. After 3 months of chronic stimulation, all of these patients reported a good analgesic effect (mean 79.6% of analgesia). After 6 months, 26 patients were available for follow-up evaluation: three patients had died, one required removal of the system because of infection, one had stopped using the stimulator after amputation relieved the pain, and one had not reached the 6-month follow-up limit. The analgesic effect persisted in all 26 cases (mean analgesia 76.7%). At 12 months, 19 patients were enjoying a mean of 75% analgesia, five had died, and two were lost to follow-up review. Reduction in pain relief occurred in one patient; this was found to be related to loss of adequate paresthesiae; replacement of the electrode restored pain relief. After 2 years, 13 patients were still successfully using the stimulator and reported a mean of 82.6% analgesia, two patients had died, two had undergone removal of the system (one because of CSF leakage and the other became pain-free after amputation), and one patient was lost to follow-up review; one had not reached the 2-year follow-up period. Seven patients reported 85.7% analgesia after 36 months of stimulation. At this time one patient had died, and one was lost to follow-up review.

Low-Back Pain. Of the 19 patients with low-back pain, 13 reported satisfactory pain relief at the end of the test period (mean analgesia 72.4%) and were connected to a chronic stimulation system (Fig. 1). The mean follow-up period in this group of patients was 40.4 months (range 3 to 102 months).

The results of SCS in this group of patients are shown in Fig. 3. After 3 months of stimulation, all 13 patients with chronic stimulation systems were using the system and reported a mean of 79.6% of analgesia. After 6 months, 12 patients were available for follow-up evaluation: two patients had died, one required removal of the system because of infection, one had stopped using the stimulator after amputation relieved the pain, and one had not reached the 6-month follow-up limit. The analgesic effect persisted in all 12 cases (mean analgesia 76.7%). At 12 months, 9 patients were enjoying a mean of 75% analgesia, five had died, and one was lost to follow-up review. Reduction in pain relief occurred in one patient; this was found to be related to loss of adequate paresthesiae; replacement of the electrode restored pain relief. After 2 years, 13 patients were still successfully

† Itrel stimulation system manufactured by Medtronic, Inc., Minneapolis, Minnesota.
Spinal cord stimulation in management of chronic pain

FIG. 3. Results of chronic spinal cord stimulation in patients with low-back pain.

FIG. 4. Results of chronic spinal cord stimulation in patients with paraplegic pain.

FIG. 5. Results of chronic spinal cord stimulation in patients with peripheral deafferentation pain.

months. At 12 months only three patients were still using the stimulator and they reported 30%, 50%, and 75% analgesia. Two patients were lost to follow-up review, and six had completely lost any analgesic effect (five of these subsequently required removal of the system).

There was no correlation between the analgesic effect of SCS in these patients and radiological evidence of arachnoiditis, or with pain distribution (unilateral or bilateral leg pain).

Paraplegic Pain. Acute pain relief (mean analgesia 68.2%) was achieved in six of the 15 tested patients with paraplegic pain (Fig. 1). A permanent system was implanted in these six patients and in one additional patient because of a marked improvement in bowel function with stimulation. The mean follow-up period in this group of patients was 9.5 months (range 3 to 25 months).

The results of SCS in this group of patients are shown in Fig. 4. At 3 months after implantation, only four patients were still using the stimulator with satisfactory results (mean analgesia 62.5%), one patient had died from unrelated causes, and the sixth patient was lost to follow-up review. At 6 months, one patient underwent removal of the system because of electrode lead rejection. The remaining three patients still benefited from stimulation at 7, 15, and 25 months, respectively.

Deafferentation Pain. Nine patients with deafferentation pain underwent a percutaneous test trial of SCS; good pain relief was obtained in only three cases with analgesia levels of 75%, 90%, and 100% (mean analgesia 88.3%) (Fig. 1). The mean follow-up period was 16 months (range 13 to 20 months).

The results of SCS in this group of patients are shown in Fig. 5. At 3 months after implantation, the analgesic effect was unchanged. At 6 and 12 months, all three patients utilizing the stimulator reported a mean of 75% analgesia. At 13 months, the only patient reporting 100% analgesia asked for removal of the system because of inability to tolerate the tonic muscle contraction, a side effect of the SCS in his case. We were not able, by changing the position of the electrode, to produce adequate paresthesiae without concomitant activation of the pyramidal tract. He was successfully treated subsequently with thalamic stimulation. The other two patients reported 50% analgesia after 15 and 20 months of SCS.

Post-Herpetic Pain. Six of the 10 patients with postherpetic pain reported satisfactory pain relief at the end of the test period (mean analgesia 82.5%), and therefore underwent permanent implantation (Fig. 1). The mean follow-up period was 14.5 months (range 3 to 46 months). At 3 months after implantation, a mean analgesia of 74% was reported and persisted unchanged in all patients (Fig. 6).

Cancer Pain. The results achieved in the 11 cancer patients in this series have already been reported in 1982. Since then we have not used SCS for cancer pain. Three of the 11 patients tested reported a satisfactory level of analgesia (mean 75%) and received a permanent system (Fig. 1). During the 1st month of chronic stimulation, one patient lost the therapeutic effect; the two remaining patients experienced 50% analgesia until death at 2.5 and 5 months after implantation (Fig. 7).
FIG. 6. Results of chronic spinal cord stimulation in patients with post-herpetic pain.

FIG. 7. Results of chronic spinal cord stimulation in patients with cancer pain.

Complications

After electrode implantation, four patients developed aseptic meningitis. In two cases it cleared spontaneously within a few days while in the other two it required electrode removal. Bacterial infection occurred in two patients at the electrode site and in a third at the subcutaneous pocket containing the receiving antenna. The system was removed in these three patients. Despite electrode removal and antibiotic therapy, one of these patients became paraplegic within a few days. A myelographic block at the level of the electrode tip was found. He was immediately operated on, and a bacterial epidural and intradural abscess was found and removed. Recovery was good but not complete. This was the only major complication encountered among 200 patients submitted to endorachideal implantation for different reasons at our institute.

Rejection of the electrode leads (two cases), CSF leakage (three cases), subcutaneous hematoma (three patients under anticoagulant therapy), and pinprick-like pain at the electrode site (two cases, both using a Myelostat electrode) were the other causes for system removal. One patient accidentally removed the percutaneous electrode and underwent repeat implantation. In four cases a failure of the system was suspected.

Loss of adequate paresthesiae due to a documented dislodgement of the electrode was proved in three patients. In one patient, using an Itrel monopolar system, very high current intensity was necessary to achieve paresthesiae and an early battery depletion occurred. Repositioning of the electrode overcame the problem in this patient.

Side Effects

Headache, asthenia, and dizziness occurred during stimulation in five patients. In two patients with spinal cord lesions, SCS increased muscle spasms. Muscle twitches due to radicular stimulation were described by three patients, and in one patient muscular contraction due to activation of the pyramidal tract was observed.

Discussion

The efficacy of SCS was quite different in the several groups of patients studied. The worst outcome was observed in patients with cancer pain. Taking into account the short life expectancy of these patients and the excellent results obtained with other procedures, particularly with opiates in the CSF, we consider SCS not to be indicated in the treatment of cancer pain.

Pain associated with incomplete spinal cord lesions does not, at least in our hands, respond to SCS. However, patients with spinal cord lesions might be considered as candidates for SCS if the main goal of therapy is not pain relief but improvement of motor control or amelioration of bowel and/or bladder function. Pain due to peripheral deafferentation responds to SCS in only a few patients, but the result tends to stabilize with time. Comparable results have been reported by Nielson, et al., and by Krainick, et al. In this group of patients, SCS should be proposed if peripheral procedures have failed or are not indicated and before considering central procedures, either augmentative (deep-brain stimulation) or destructive (dorsal root entry zone lesions).

It is important to stress the findings in our post-herpetic pain patients, 60% of whom benefited from SCS. The stability of the result achieved was remarkable. Therefore, we now recommend the use of SCS as first choice in the treatment of post-herpetic pain.

Spinal cord stimulation relieves low-back pain in an appreciable number of patients but its effectiveness decreases quite rapidly. No correlation was found in our patients with low-back pain between the radiological evidence of arachnoiditis and SCS induced-analgesia. The difficulty in maintaining good initial results over a long period has been remarked upon by others. Long, et al., reported much better results and stressed the importance of accurate psychological screening for patient selection. Despite our discouraging results, SCS is still considered in the therapeutic protocol of low-back pain, but with prolongation of the test period to at least 3 months. The analgesia induced by stimulation, even if temporary, may in fact be sufficient to break the pain-stiffness-immobility-in-
Spinal cord stimulation in management of chronic pain

flammmation-pain cycle. It is therefore particularly important in these patients to utilize SCS as part of a comprehensive pain-treatment program.

The efficacy of SCS in vasculopathic pain and its possible correlation with changes in peripheral blood flow was noted in 1976 by Cook, et al., and Dooley and Kasprak, but their findings received little attention for many years. Their reports were reconsidered following publication of the good results obtained by our group. Meglio, et al., documented modifications of the central mechanism of heart rate regulation in patients under SCS, and concluded that at least one of the effects of SCS in man is a reversible reduction of the sympathetic outflow (so-called “functional sympathectomy”). Studies to evaluate the degree and distribution of blood flow changes in the macaque monkey by Myklebust, et al., strongly support our conclusions.

As is well known, SCS was proposed as the clinical application of the gate control theory of Melzack and Wall. Experiments in laboratory animals indicate that gating mechanisms at the level of the first sensory synapse are antidromically activated by the stimulation of the dorsal columns. Whether a gating mechanism plays a role in SCS-induced analgesia in man can only be argued. According to the concept that post-herpetic neuralgia is associated with the loss of large fibers and relative preservation of small fibers, such a condition has been referred to as an example of clinical pain caused by insufficient gating. The results we have achieved in such a condition support the idea that at least one of the mechanisms activated by SCS is a gate mechanism.

On the other hand, the demonstrated reversible functional sympathectomy could account for the impressive results achieved in patients with peripheral vasculopathy. We believe that both mechanisms play a role in mediating the analgesic effect of SCS and that their relative importance varies according to the clinical situation.

There is no doubt that SCS has an important place in the armamentarium that modern medicine offers for the control of chronic pain. We believe that a patient with chronic pain of benign origin should not be treated with destructive procedures without having previously undergone a percutaneous test trial of SCS.

References

24. Meglio M, Cioni B, Sandric S: Evaluation of cardiac

Manuscript received September 22, 1987. Accepted in final form August 29, 1988. This work was supported by CNR: Progetti Finalizzati — SP8 Controllo del dolore No. 71373. Address reprint requests to: Mario Meglio, M.D., Istituto di Neurochirurgia, Università Cattolica, Lg A. Gemelli 8, 00168 Rome, Italy.