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Long-term pain relief during spinal cord stimulation. The effect of patient selection

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We reviewed our experience with spinal cord stimulation (SCS) in treating 116 patients with pain in one or both legs. All these patients were selected for an initial week of trial stimulation by the criteria: pain due to a known benign organic cause, failure of conventional pain control methods and absence of major personality disorders. Selected patients included 78 with the Failed Back Surgery Syndrome (FBSS), in whom proven correlation existed between the clinical picture and the neuroradiological and electromyogram abnormalities. Eighty-four out of 116 selected patients underwent definitive SCS implantation after 1 week of trial stimulation with excellent results (more than 75% pain relief). They were followed clinically every 3 months for a mean follow-up period of 47 months. Forty-five patients (54%) continued to experience at least 50% of pain relief at the latest follow up. Seventy-seven patients (91%) were able to reduce their medication intake and 50 patients (60%) reported an improvement in lifestyle. FBSS patients responded more positively to the trial stimulation than the other patients. However, the later outcome was not affected by patient selection as long-term benefit was similar in all definitive SCS patients irrespective of aetiology.

Key words: Functional neurosurgery, intractable pain, spinal cord stimulation.

Introduction

Spinal cord stimulation (SCS) for control of pain was introduced by Shealy *et al.*[1] During the decade that followed, several thousand patients were subjected to the procedure in order to relieve pain.[2–5] This initial enthusiasm began to wane however, with ensuing reports of high failure rates.[6–9] Problems associated with SCS include: the anatomy and physiology of pain relative to neurostimulation is still controversial; the high cost of the device itself; high frequency of system-related technical failures, but most of all, the difficulty in identifying a patient population in whom reasonably long-term pain control might be achieved. The problem of patient selection is still under discussion and, up to the present time, no specific factors indicative of a successful outcome, have been identified.[10]

The present survey is based upon 116 patients with pain of varied benign organic aetiology of which 78 patients with failed back surgery syndrome (FBSS).[11] This series has been analysed retrospectively in an attempt to determine whether a uniform and well defined group of patients (FBSS), selected on the hand of neuroradiological and neurophysiological criteria, had better long-term results compared with the other patients and with the results of the literature.

Material and methods

Patient selection

General selection criteria. Our study population was drawn from a consecutive series of 116 patients with pain of varied benign organic cause who underwent SCS at our institution by a single neurosurgeon (CDLP) between July 1984 and June 1991. These included 63 men and 53 women, ranging in age from 29–73 years. The pain was caused by the following disorders: FBSS in 78 patients (mean age 57 years); peripheral vascular disease in eleven (mean age 74 years); postherpetic neuralgia in three (mean age 41 years), brachial plexus/peripheral nerve injury in 13 (mean age 32 years), phantom limb pain in three (mean age 73 years) and spinal cord pathology in eight (mean age 49 years). The mean duration of symptoms was 6.5 years (range 1.2–35 years).

All our selected patients fulfilled the following basic criteria:

(1) pain due to a known benign organic cause,
(2) all conventional methods of pain control had failed and

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(3) patients had no major abnormal personality traits.

All patients with major behavioural or drug habituation problems or with significant unresolved issues of secondary gain were not stimulated. If psychiatric consultation suggested a need for any form of psychiatric therapy, this was implemented prior to further consideration for pain treatment. If necessary, anxiety, depression and insomnia were treated.

Extensive psychologic testing was performed only pre-operatively and only to exclude patients with major abnormality traits. These data were not analysed in order to identify the differential response to treatment. The testing consisted of five rating tests. Firstly, the assessment involved a comprehensive pain questionnaire with a visual analogue scale.[12] Secondly, the symptom check list-90 (90-item inventory to evaluate the actual level of the main symptoms of psychological functioning) was carried out.[13] Thirdly, neuroticism, neurotic somatization and extraversion were examined by the Amsterdam Biographical Inventory.[14] Measurement of social desirability was done by the Marlowe-Crowne scale.[15] Lastly the trait anxiety was tested by the STAI test.[16]

Additional criteria for the FBSS-group. Additional inclusion criteria in the FBSS-group were established. Patients initially underwent a clinical neurosurgical examination. They were evaluated radiographically and neurophysiologically. During the study period, water soluble contrast myelography, combined with computed tomography, was our standard imaging technique. In this setting, differentiating disc from scar (epidural fibrosis), Gd-DTPA-enhanced magnetic resonance imaging was performed, when available. In none of the selected patients was there evidence of a surgically correctable lesion. There had to be a correlation between the radiculopathy demonstrated by neuro-imaging techniques and the clinical and electromyographical findings. Patients with FBSS without sciatic pain, but only lumbar complaints were excluded. Evoked potential studies of both legs were carried out to exclude myelopathy which was an exclusion criterium for the FBSS-group. In all of the FBSS cases, there were multiple lumbar operations (averaging 3.6 previous operations).

All selected patients ($n = 116$) underwent percutaneous trial stimulation for 1 week and the system was internalized in those patients who experienced at least 75% pain relief. Eighty-four patients (72%) underwent a definitive implantation of the device; 64 (82%) in the FBSS-group and 20 (53%) other patients.

Surgical technique

Including electrodes replaced after initial fracture and those removed after unsuccessful trial stimulation, a total of 129 epidural implants were used; 78 Pisces electrodes and 33 Pisces Sigma electrodes (Medtronic) were introduced percutaneously under intermittent fluoroscopic control into epidural space dorsal to the spinal cord under local anaesthesia. All patients were treated with a monopolar device except one patient who had a bipolar trial stimulation with two Pisces electrodes. The site of the electrode tip was located between D7 and D12. It was imperative that intraoperative stimulation-induced paresthesias fully encompassed the area of pain. Since 1989 we also used nine Quad electrodes (Medtronic) and nine Resume electrodes (Medtronic) placed under general anaesthesia and by a small laminotomy at D10-D11. The patients were allowed to stimulate themselves through temporary percutaneous leads during a trial period lasting up to 1 week. During this period, stimulation parameters were varied. If the patient reported at least 75% pain-reduction, the system was internalized with a radio receiver implanted in the right fossa iliaca in 52 cases or an Itrel neurostimulator (Medtronic) in 23 and a Cordis unipolar device in nine patients depending on the amount of stimulation necessary for pain control during the test period.

Outcome measures

The follow-up period ranged from 1 to 7 years with a mean of 47 months. At the time of follow-up interviews, the clinician (CDLP) who saw the patient in the stimulator clinic every 3 months, rated the patient's apparent pain relief as a percentage estimate corresponding the Visual Analogue Scale (VAS).[17] Pain relief was assessed by a five-grade rating scale and the scores were expressed in relative percentages (Table 1). Furthermore, it was noted if the patient was satisfied with the result. Successful spinal cord stimulation was defined as a combination of two criteria commonly used in the literature on SCS: at least 50% pain relief at the latest follow up (good or excellent on

Table 1a. Pain relief pattern in the FBSS group

Pain relief (%)	Grade rating scale	Patients ($n = 64$)		
		1 month	1 year	latest follow-up (47 ± 24 months)
75–100	excellent	22	10	11 (17%)
50–74	good	30	27	24 (37%)
25–49	fair	10	17	12 (19%)
0–24	poor	2	10	14 (22%)
	worse	—	—	3 (5%)
Device removed		—	6	8 (13%)

Table 1b. Pain relief pattern in the non-FBSS group

Pain relief (%)	Grade rating scale	Patients ($n = 20$)		
		1 month	1 year	latest follow-up (47 ± 24 months)
75–100	excellent	7	6	4 (20%)
50–74	good	8	6	6 (30%)
25–49	fair	3	5	5 (25%)
0–24	poor	2	3	4 (20%)
	worse	—	—	1 (5%)
Device removed		—	1	1 (5%)

Table 1c. Pain relief pattern in the whole study population

Pain relief (%)	Grade rating scale	Patients ($n = 84$)		
		1 month	1 year	latest follow-up (47 ± 24 months)
75–100	excellent	29	16	15 (18%)
50–74	good	38	33	30 (36%)
25–49	fair	13	22	17 (20%)
0–24	poor	4	13	18 (21%)
	worse	—	—	4 (5%)
Device removed		—	7	9 (11%)

the grade rating scale) and patient satisfaction with treatment.[18] These findings were recorded immediately after trial stimulation, after 1 month, after 1 year and at the latest follow-up. The outcome was compared statistically for both patient groups at the latest follow-up.

As indirect measures of pain relief, the ability to perform a variety of daily activities and the medication intake were assessed.

The most important question regarding daily activities considered the professional work, in other words, did the patient return to work. Other daily activities were classified as self-reliant in eating, washing, toileting and dressing, using public transport or driving own car.

We did not use a standardized quality of life index. Besides the question about the satisfaction with the treatment result (as a part of the definition of success) we asked patients if their general feelings of well being did improve or not.

Patients were grouped into five different classes of medication consumption.[19] Class 0 represents those patients taking no medication at all; class 1 represents minor analgesics; class 2 tranquillizers and antidepressants; class 3 major analgesics and class 4 morphine or its derivatives.

Table 2.

Class	Medication	Patients ($n = 80$)		
		admission	implant	latest follow-up
0	None	17	40	34
1	Minor analgesics	27	18	22
2	Tranquillizers and antidepressants	21	19	11
3	Major analgesics	5	3	6
4	Morphine or derivatives	10	0	7

Results

Four aspects of the results of SCS will be considered: patient personal evaluation of pain, changes in medication and in lifestyle, and complications.

Patient personal evaluation of pain

Pain relief was recorded during consecutive controls as long as the patient was followed (Table 1a, b, c). The table reflects the patient's opinion at the various intervals during follow-up. Of 116 patients included in this study, 32 (28%) did not undergo internalization of the electrode system because of inadequate pain relief during 1 week trial stimulation. These 32 included 14 (18%) FBSS patients and 18 (47%) of the non-FBSS patients.

Fifty per cent or more pain relief was reported by 80 (95%) patients immediately after internalization of the device, by 67 (80%) 1 month later and by 49 (58%) 1 year after implantation (Table 1c). The results were excellent in 29 patients 1 month after implantation, in 16 patients after 1 year and in 15 (18%) at the latest follow-up. The largest group of patients was in the 'good' rating scale at all times. After one year, 22 patients had fair results and 13 patients noticed less than 25% or no pain relief at all. In seven of these patients the device was removed in the first postoperative year because they made no further use of the stimulation device (on the Tables noted as 'device removed').

At the end of the follow up period, which lasted from 1 to 7 years (mean 47 months, SD ± 24), the amount of pain relief was as follows: 45 patients (54%) reported at least 50% pain relief, 15 patients with excellent results, 30 with good results. Seventeen patients were reported with fair results and 18 patients with poor results. In four patients (5%) the pain was worse when compared with the pre-implant status. In two more patients the device was removed, due to poor results. For every different outcome group, the hypothesis that there was no statistical difference between the FBSS-group (Table 1a) and the non-FBSS-group (Table 1b) was accepted with a level of significance (alpha) = 0.10.

Twenty-six patients were followed for more than 4 years, 18 for 4 years, 8 for 3 years, 15 for 2 years and 17 for at least one year (Table 3).

All but one patient with good to excellent results at the latest follow-up were satisfied with the SCS. Successful SCS was reported in 44 of 84 stimulated patients (54%) at the latest follow up. Twelve patients out of 17 with fair pain relief were satisfied with the outcome; two out of 18 patients with poor results were satisfied and no patient rated as 'worse' was satisfied with the SCS. In total 58 patients (69%) out of 84 definitive SCS were satisfied with the results of the procedure.

Changes in medication

We divided the patients into five groups, according their medication used (Table 2). Each patient was classified in the highest class possible. The table also indicates the numbers of patients in each group on admission to the department, immediately after definitive SCS and at the latest follow-up. Four patients were excluded due to lack of accurate data.

Table 3.

Grade rating scale	Latest follow-up (in years)				
	1	2	3	4	4–8
Excellent	3	2	1	3	6
Good	4	6	3	6	11
Fair	3	4	2	4	4
Poor	4	3	2	5	4
Worse	3	—	—	—	1

Immediately after implantation we noticed a tremendous reduction of medication intake; no single patient used morphine or its derivatives any more. Forty patients used no medication at all.

At the latest follow-up, 34 patients (43%) were medication-free instead of 17 (21%) on admission. In seven patients (9%) drug consumption was increased and still consisted of morphine or its derivatives. All other patients were able to reduce their major analgesics, morphine or its derivatives in favour of minor analgesics or tranquillizers.

Lifestyle

Fifty patients (60%) reported a change in their lifestyle, in that their ability to perform daily activities had improved significantly at the latest follow-up. Of 84 patients, 18 returned to work. The 42 other patients felt more self-reliant in eating, washing, toileting and dressing, using public transport or driving own car. Fifty-six patients (70%) reported an improvement their general feelings of well-being. All these patients reported at least fair pain relief.

Complications

Complications in our series related mostly to hardware problems, especially displacement of the stimulating electrode (ten cases), infection (five cases), fractured electrode confirmed at operation (eight cases), and battery depletion (eight cases). One hundred and twenty-four interventions were performed (trial stimulation procedure not included) on 84 patients. Forty (32%) reinterventions were necessary due to complications.

Discussion

This study confirms the efficacy of SCS in only 50% of selected patients. Despite the important selection criteria in the FBSS-group, we did not find a better outcome. Several authors have stressed the importance of a more subtle selection of patients in order to improve outcome, but have not offered well-founded guidelines, neither has this statement been previously proven.[20–28] It is not easy to correlate a particular pain condition with an expected success rate, but SCS seems to be more effective for neurogenic pain of well known origin. Therefore we compared the results of patients with pain due to FBSS (which is a well-defined clinical entity including neuroradiology, electromyogram and evoked potentials), with patients suffering pain due to another benign organic cause.[23] Our long term results on pain relief in the FBSS-group seem to be as good as those reported elsewhere, but they are not better than the results of our whole study population.[21] In definitive SCS, the success rate after a mean follow-up of 47 months is 54% (54% in the FBSS-group and 50% in the other group). The well defined selection of FBSS-patients was correlated with an important reduction of unsuccessful trial stimulations (18% *vs.* 47% in the non-FBSS-group). It could be argued that a group of patients with diagnostic or physiologic characteristics similar to the FBSS group might be more likely to benefit from spinal cord stimulation. If we do not consider the trial stimulations, 35 out of 78 FBSS patients (46% are successfully treated at the latest follow-up, whereas only ten out of 38 other patients (27%) do well. This difference is not a statistical one, but close to ($\chi^2 = 3.70$, $p < 0.06$). Some have mentioned that patients with an unsuccessful trial stimulation are examples of a population whose primary pain pathways are anatomically unsuitable for this treatment, or whose epidural anatomy in some way obviates correct electrode positioning. From our study we learned that the FBSS-group responded best to the trial stimulation. It is difficult to explain, however, why this particular subgroup would have pain pathways that are more suitable for SCS than others. If we could find an answer to this, much of the mystery around SCS probably would disappear.

In their review, Spiegelmann and Friedman examined trial stimulation as indicator of late outcome.[10] They stated that a positive response to transcutaneous electrical neural stimulation (TENS) correlated with a good outcome for SCS, but its value as prognostic factor is lessened by the fact that many in whom TENS fails, subsequently benefit from SCS. We were not able to find out whether trial stimulation influenced late outcome, since we only stimulated patients with at least 75% of pain relief during their trial stimulation. There was no control group with definitive SCS without successful trial stimulation. Long *et al.*[4,7] claimed to have improved their results considerably by employing an extensive battery of psychological tests. We do not know whether our experience favours the exclusion of psychologically disturbed patients, since we made no sub-group. We excluded these patients from the study. Patient

selection criteria remain to be defined, if at all they must be concerned as the most important determinants of success.[29]

We think that our second group of patients is really too small and too heterogenous to look for specific correlations between patient characteristics and outcome. We only compared the well circumscribed group of FBSS with a mixture of other patients.

Besides the screening problem, we would like to address the fall in the initial success rate over a period of time reported in our, as well as in most, series. The main reasons for this decline include first of all the known system related-technical failures. Nevertheless, these failures can be managed most of the time and rarely should be held responsible for definitive treatment failure (recent reports on this subject do not mention better long term results, compared with the much older series, reported when hardware problems were more common). It seems obvious that we must look for other reasons responsible for the decline of good results after some time. More fundamental pathophysiological and psychological factors might be responsible for the late decline in efficacy. Many authors believe that unless the immediate improvement is at least 50% of pain relief, the results are, or surely will become poor.[10] At the end of follow-up, four patients reported that their pain was worse compared with the pre-implantation period. It is difficult to believe that SCS itself was responsible for the worsened pain problem. Probably a deterioration of psychological and behavioural attitudes should be held responsible. We only used psychological testing as a pre-operative selection criterion. Psychological testing during the follow-up may be very interesting and is planned for the future. Then we might find an answer to the question whether the procedure itself has a placebo effect on pain. One must remember that it is the patient's own interpretation of the results that is the most important criterion. The need for a prospective controlled study on SCS for pain control is obvious, but difficult, if not impossible, to realize. The patient study should be carried out in a double-blind fashion, in which the experimenter and patient are unaware of the parameters and location of stimulation. The potential for at least short-term placebo response is substantial, considering the elaborate nature of the surgical procedure, the mysterious electronic technology involved and the close interpersonal relationship which exists between the pain patient and the attending physician.[30] Furthermore, sham stimulation is not possible because the patient experiences real stimulation while inserting the device and controlling the position of it. As long as these problems cannot be solved, we must rely on review studies. These should be based on selection criteria and an attempt to look for prognostic factors should also be made.

Since our patients exhausted all conservative attempts (including pain medication) at pain control before SCS, reduction in medication during SCS may be interpreted as an additional success.

Sixty per cent of stimulated patients reported an improving lifestyle as regards their ability to perform daily activities. We wanted to investigate the pain relief pattern during SCS by means of the VAS method. As an indirect measurement of pain relief, the medication intake and patient satisfaction was recorded. We think it would be wise, however, to score the quality of life and of life satisfaction in a more structural manner (indices) than we did until now.

When the patient satisfaction regarding the treatment is considered, most of these patients were satisfied with the results and experienced at least 50% pain relief (Table 4). The improving lifestyle probably reflects the patients' personal evaluation of pain control since no improvement was noticed in patients with poor results. The

Table 4. Main issues compared at the latest follow-up

Pain relief		Success	Medication intake*					Return to work
			0	1	3	4	5	
Excellent	15	15	15	0	0	0	0	10
Good	30	29	19	9	0	0	0	7
Fair	17	12	0	10	1	0	0	1
Poor	18	2	0	3	7	5	4	0
Worse	4	0	0	0	3	1	3	0

$n = 84$ patients.
* Medication intake was recorded for 80 patients and according to the different grades (Table 2).

results of SCS should be interpreted not only as regarding pain relief but also as an improvement in lifestyle and a reduction of medication intake. Under these circumstances our results should read thus: during SCS 91% of patients could reduce their medication intake, 60% improved their lifestyle, 54% of patients experienced at least 50% pain relief and 18 returned to work.

Conclusions

Our study supports the contention that success rates of 54% during SCS may reasonably be expected in patients with intractable pain due to benign organic pathology. In the FBSS-group, more patients responded well to their trial stimulation, suggesting the existence of a subgroup of patients that is more likely to benefit from SCS than others. Considering the patients with definitive SCS, no statistical difference was noticed between the two patient groups.

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