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CLINICAL ARTICLE - FUNCTIONAL

Epidural spinal cord stimulation for neuropathic pain: a neurosurgical multicentric Italian data collection and analysis

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Abstract
Background Spinal cord stimulation (SCS) is a technique used worldwide to treat several types of chronic neuropathic pain refractory to any conservative treatment. The aim of this data collection is to enforce evidence of SCS effectiveness on neuropathic chronic pain reported in the literature and to speculate on the usefulness of the trial period in determining the long–term efficacy. Moreover, the very low percentage of undesired side effects and complications reported in our case series suggests that all implants should be performed by similarly well-trained and experienced professionals.
Method A multicentric data collection on a common database from 11 Italian neurosurgical departments started 3 years ago. Two different types of electrodes (paddle or percutaneous leads) were used. Of 122 patients, 73 % (N=89) were submitted to a trial period, while the remaining patients underwent the immediate permanent implant (N=33). Statistical comparisons of continuous variables between groups were performed.
Results Most of the patients (80 %) had predominant pain to their lower limbs, while only 17 % of patients had prevalent axial pain. Significant reduction in pain, as measured by variation in visual analogue scale (VAS) score, was observed at least 1 year after implantation in 63.8 % of the cases, 59.5 % of patients who underwent a test trial and 71.4 % of patients who underwent permanent implant at once. No statistical differences were found between the lower-limb pain group and the axial pain group.

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Conclusions No relevant differences in long-term outcomes were observed in previously tested patients compared with patients implanted at once. Through this analysis we hope to recruit new centres, to give more scientific value to our results.

Keywords Spinal cord stimulation · Chronic pain · Neuropathic pain · Failed back surgery syndrome

Introduction

Neuropathic pain is a chronic condition, challenging to treat and deeply correlated with psychological aspects: it can be co-determined by emotional and behavioural factors, and it can play an important role in determining depression or in decreasing quality of life. Spinal cord stimulation (SCS) is a therapeutic option in patients with chronic/neuropathic pain with different aetiologies (i.e. failed back surgery syndrome [FBSS], chronic spine pathologies and neuropathic diseases) [8, 16, 18, 19, 21] not eligible for surgery and refractory to any pharmacological and other conservative treatment [11].

SCS is theoretically based on the Gate Control Theory developed by Melzack and Wall [23] in 1965, which explains physiopathology of such conditions as hyperalgesia, painful anaesthesia and spontaneous pain. The loss of large peripheral nerve fibres after a nerve injury produces a drop in the inhibition on the slow C-fibres inputs causing the "open-gate" condition responsible of these types of pain.

SCS has demonstrated to be more effective on neuropathic pain compared with nociceptive pain [11]. The best results of this technique were initially observed in patients affected by post-herpetic neuralgia and vasculopathic pain, with good pain relief in more than 60 % of patients [21]. The role of SCS in treating low-back pain was debated in the past because of the reduction of pain control at long-term follow-up [16, 21]. Some authors demonstrated that SCS associated with standard pharmacological therapy could reduce chronic pain more than common pharmacological therapies used alone and it could improve quality of life and patients' return to their own occupation [14, 20].

Various authors identified the important role of psychological factors on pain modulation and on effectiveness of SCS [1, 21, 23, 27, 36].

Thanks to technological improvements of both leads and implantable pulse generators (IPGs), and the more accurate selection of patients, SCS has gained increasing reliability in the armamentarium of surgical and analgesic techniques to control pain when conservative and other surgical treatments failed. FBSS is presently the main indication for SCS, followed by complex regional pain syndrome (CRPS), intractable angina pectoris and pain due to peripheral vascular disease [7, 32, 35]. Further indications comprise painful conditions related to peripheral nerve chronic diseases, in which this technique should be preferred to more invasive and ablative treatments [8, 19, 21].

One of the exclusion criteria for implanting an SCS device is the presence of other stimulation devices like a cardiac pacemaker or implantable cardiac defibrillator. Nevertheless several reports provide evidence of safe combined use of SCS and ICD/PM [9, 12, 24, 33].

Other exclusion criteria include total loss of dorsal column fibres as in total paraplegia by complete spinal cord injury, coagulopathies and immunodeficiency disease, existing drug addiction and major psychiatric disorders [11].

Usually patients are submitted to psychological evaluation and quality-of-life assessment before undergoing the trial period for 15-21 days [1].

According to currently available evidence, the role of SCS in FBSS is particularly demonstrated in those conditions with prevalent lower-limb pain [6], with best results in unilateral leg pain [3, 10, 14, 21]. Some authors reported therapy-effectiveness and cost-effectiveness of SCS versus re-operation in FBSS, assuming the correct selection of patients and the importance of trial period. SCS is often used after all the surgical procedures available for spine pathologies, with possible reduction of its potential therapeutic role [13, 26, 30]. Furthermore, prevalent back pain has a reported lower response to SCS, which might be related to the nociceptive component of pain in this group of patient [11, 13, 26].

The aim of this data collection is to enforce evidence of SCS effectiveness in treating neuropathic chronic pain and to speculate on the usefulness of a trial period in determining the long–term outcome of this treatment.

Materials and methods

Between January 2009 and February 2012, 122 subjects among patients referred to 11 Neurosurgical Divisions were assessed in a multicentric data collection in the framework of the Italian ClinicalService Project [5]. This is a national data repository and medical care project aimed at describing and improving the use of implantable neurostimulation devices in Italian clinical practice [5]. The project was approved by each site's Institutional Review Board and conforms to the principles outlined in the Declaration of Helsinki. Each patient gave written informed consent for data collection and analysis.

All patients included in the Italian ClinicalService Project and eligible to SCS therapy were considered for analysis.

We analysed the characteristics of patients in terms of baseline features, implant indications, pain distribution, duration of pain, type of implanted device and type of surgical procedure (implant with or without trial period).

Patients who underwent the permanent implant were evaluated after 3, 6 and 12 months. In the present paper, we analysed SCS outcomes after 12 months.

The trial period is usually performed to evaluate patients' acceptance and compliance before permanent implant, but it could be uncomfortable. The implant without a trial period, although possibly hampered by blind result, could be more accepted by patients. The decision to avoid the trial period depended on the clinical practice and previous experience of neurosurgical units.

According to the actual procedure, patients will be therefore referred as belonging to the "Trial" group or "No-Trial" group.

Pre-implant data collection

Each patient was submitted to a pre-implant data collection form to evaluate the features of chronic pain. Within the total population of 122 patients, 64 were women (52 %) and 58 (48 %) men. The mean age of patients at the moment of permanent implant was 59.0±13.1 years old (range, 28–86) and the mean pain duration was 36 months (range, 12–60 months).

Prevalent pain was localised to the lower limbs in 98 patients (80 %), the lower back (also defined as "axial pain") in 21 patients (17 %) and the upper limbs in the remaining 3 patients (Table 1). The *prevalent visual analogue scale (VAS) value* is determined as the greater baseline value between the axial VAS value and lower-limb VAS value for each patient.

The mean onset VAS value was 79.9 (SD=14.5) for lower-limb pain and 79.8 (SD=21.2) for axial pain.

Pain was associated with one or more accompanying symptoms in 63 patients (53 %), including numbness (n=33, 52 %), allodynia (n=32, 51 %), weakness (n=14, 22 %), anaesthesia (n=5, 8 %) and other symptoms (n=4, 6 %).

Before implant, we asked the patients to list previous non-invasive therapies they had undergone for neuropathic pain, and currently ongoing pharmacological therapies. One-hundred and fifteen patients (94 %) had ongoing pharmacological therapy, while 73 patients (60 %) reported previous non-pharmacological treatment (Table 2).

Table 1 Localisation of prevalent pain in relation to the trial period

Painful area	No-Trial	Trial	Total
Prevalent axial	2 (6.1 %)	19 (21.6 %)	17 %
Prevalent lower limbs	31 (93.9 %)	67 (75.0 %)	80 %
Prevalent upper limbs	0	3 (3.4 %)	3 %
Low back	2 (6.1 %)	4 (4.6 %)	4 %
Low back and one inferior extremity	4 (12.2 %)	28 (31.8 %)	26 %
Low back and both inferior extremities	9 (27.3 %)	17 (19.3 %)	22 %
One inferior extremities	9 (27.3 %)	25 (28.4 %)	28 %
Both inferior extremities	9 (27.3 %)	11 (12.5 %)	16 %
Other (upper limbs)	0	3 (3.4 %)	3 %

Table 2 Rates of primary pathologies and previous non-invasive treatments

Primary pathology	No. of patients (%)
FBSS	78 (64 %)
Discectomy (single surgery)	35 (45 % of FBSS)
Discectomy (multiple surgery)	24 (31 % of FBSS)
Laminectomy (single surgery)	20 (26 % of FBSS)
Laminectomy (multiple surgery)	1 (1 % of FBSS)
Lumbar fusion (one surgery)	16 (21 % of FBSS)
Lumbar fusion (multiple surgery)	2 (3 % of FBSS)
Patients with more than one previous spine surgery	46 (59 % of FBSS)
Lumbar spine pathologies (without previous surgery)	15 (12 %)
CRPS I	2 (1.5 %)
CRPS II	2 (1.5 %)
Polyneuropathies	5 (4 %)
Others	20 (16 %)
Peripheral nerve injury	6 (5 %)
Arachnoiditis/myelitis	4 (3 %)
Postherpetic neuralgia	2 (1.5 %)
Neuromas	2 (1.5 %)
Pelvic pain	2 (1.5 %)
Vertebrectomy/vertebral trauma	2 (1.5 %)
Limb amputation	1 (1 %)
Dermoid tumour of cauda equina	1 (1 %)
Previous non-invasive therapies	
Pharmacological therapies	115 (94 %)
Opioids	56 (46 %)
NSAIDS	96 (79 %)
Antidepressants	38 (31 %)
Anticonvulsants	43 (35 %)
Steroids	54 (44 %)
Other drugs	32 (26 %)
Non-pharmacological therapies	73 (60 %)
Physiotherapy	53 (43 %)
TENS	26 (21 %)
Radicular blocks	18 (15 %)
Radiofrequency	17 (14 %)
Magnetic therapy	7 (6 %)
Other therapies	23 (19 %)

FBSS failed back surgery syndrome, *CRPS* complex regional pain syndrome, *NSAIDS* non-steroidal anti-inflammatory drugs, *TENS* transcutaneous electrical nerve stimulation

Patients' weight and the corresponding body mass index (BMI) were analysed, showing a mean weight of 71.5 kg (range, 42–104 kg) and a mean BMI of 25 (range, 19–38). With respect to smoking habit, we found that 64 patients (55 %) were non-smokers, 12 patients were past-smokers (10 %) and 41 patients (35 %) were present-smokers. Prevalence

of common disease, i.e. hypertension and diabetes, was comparable to the general population [29, 42].

Implant indications

Patients' selection was done by each neurosurgeon during outpatients clinic, following exclusion criteria reported in literature [11]:

- Complete lesions of the dorsal column (i.e. total paraplegia)
- Presence of pathological conditions (i.e. multiple sclerosis) needing a magnetic resonance imaging (MRI) follow-up
- Patients with chronic pain who have not tried non-invasive therapeutic options, pharmacological and non-pharmacological (i.e. physiotherapy, TENS)
- Patients with chronic pain associated with a pathological condition that could be surgically treated
- Coagulopathy or immunodeficiency disorders, which could interfere with neuromodulation procedures
- Major phychiatric disorders, drug or alcohol abuse, existing drug habituation problems, poor compliance or low/absent possibility to understand the therapy
- Cardiac pacemaker (PM) or implantable cardiac defibrillator (ICD)

The pathologies affecting our patients are summarised in Table 2.

All the patients were suffering from neuropathic pain, localised to the lower limbs, lower back or both. In FBSS group (78 patients, 64 %), 46 patients (59 %) underwent multiple spine surgeries, 59 patients (76 %) had single or multiple discectomies and 18 patients (23 %) were subjected to instrumented spine surgery.

Forty-four patients (36 %) suffered for chronic neuropathic pain of different origin and never had any spine surgery.

Technical notes

We used two types of epidural leads (Medtronic, Minneapolis, MN, USA): paddle leads (4-electrode, 8-electrode and 16-electrode) or percutaneous leads (4-electrode and 8-electrode). Paddle leads, also known as surgical leads, are implanted through a hemi-laminectomy, while percutaneous leads are inserted into the epidural space with a needle-guide and without opening the fascia. In both of the procedures a lateral X-ray scan was used to control the spine level. The number and shape of leads were selected according to the extension of painful area.

Within the 122 patients implanted, 73 (59.8 %) were subjected to the surgical implant and 49 (40.2 %) to the percutaneous procedure.

Leads were connected through an extension cable to non-rechargeable (Itrel III, Versitrel, Prime Advanced; Medtronic, Minneapolis, MN, USA) and a few rechargeable IPGs (Restore Sensor; Medtronic, Minneapolis, MN, USA).

We performed the temporary implant in 89 patients (73 %), connecting the lead to an external pulse generator for a trial period of 15–21 days, while in the remaining 33 patients (27 %) we performed surgery without trial period.

The temporary implant was performed with the patient in the prone position under local anaesthesia and deep sedation. Sedation was reduced after positioning the lead on the dural surface to evaluate pain coverage and acceptance of stimulation.

The procedure in the No-Trial group and the permanent implant in the Trial group were performed under general anaesthesia, with the patient positioned on one side.

Follow-up

We analysed results after 12 months of stimulation and we compared the outcomes between the Trial and No-Trial groups.

The present analysis evaluates results of SCS therapy after 12 months from permanent implant in terms of:

- Pain relief, pain coverage and presence of associated symptoms
- Ongoing pharmacological or other conservative therapies
- Adverse events and changes in stimulation settings
- Hamilton's Scale for depression
- Oswestry Disability Index (ODI)
- Short Form-36 (SF 36) health survey
- Euro Quol-5 Dimensions (EQ5D) score

EQ5D score evaluate health-related quality of life with a questionnaire focused on five points (mobility, self-care, usual activities, pain/discomfort, anxiety/depression).

Statistical methods

Descriptive statistics were reported as mean and standard deviation for normally distributed continuous variables, or median with 25–75 percentiles in case of skewed distribution. Normality was assessed by means of Shapiro-Wilk test. Absolute and relative frequencies are reported for categorical variables.

Statistical comparisons of continuous variables between groups were performed by Student's *t*-test or non-parametric test (Wilcoxon rank-sum test) for normal and non-normal distributions, respectively.

Differences between categorical variables were evaluated by means of the chi-squared test or Fisher's exact test, when appropriate.

Comparisons between preoperative and follow-up VAS values were evaluated with Wilcoxon matched-pairs signed-ranks test.

Differences in VAS variation between groups were evaluated by using a delta value (median difference between follow-up and pre-operative VAS value for each group) and by comparing it with a Wilcoxon rank-sum test.

In order to calculate the percentage of VAS improvement, difference between follow-up and baseline value was divided by baseline value.

Percentages of patients with at least a 50 % of VAS improvement were compared between groups using a Fisher's exact Test.

All two-tailed P value <0.05 was considered statistically significant.

For statistical analysis, Stata/SE 11.0 for Windows (StataCorp LP, TX, USA) was used.

Results

All the patients were affected by neuropathic pain, mostly localised to one or both lower limbs, with radicular localisation, and associated with low-back pain in several cases. In a few cases patients were suffering from isolated axial pain or other type of pain. The rates of patients who were suffering from prevalent lower-limb pain were 93.9 % in the No-Trial group and 75 % in the Trial group respectively.

Good primary outcome (VAS improvement≥50 %) in pain relief was obtained in 63.8 % of patients considering prevalent VAS, in 54.6 % of patients with prevalent axial pain and in 66 % of patients with prevalent lower-limb pain.

Clinical results: Trial versus No-Trial group

Seventy-three patients (82 % of Trial group) who reported clinical efficacy of SCS underwent permanent implant.

Two patients were still performing the trial test at the moment of analysis. Fourteen patients had removal of temporary device after the trial period for the following reasons:

- Non-responders, 10 patients
- Patient's request (other than clinical ineffectiveness), 3 patients
- Infection, 1 patient

Analysing VAS score (prevalent, axial and lower limbs pain) at baseline and after 12 months of stimulation, we found similar results in both of the groups, in particular for lower-limb pain. Reduction of VAS reached statistical significance in both of the groups for lower-limb pain and for prevalent pain (P<0.001). Reduction of axial pain VAS could be reported as statistically significant in the Trial group only (P=0.003), as the No-Trial group included only one patient with axial pain (Table 3).

Comparing the variation of VAS at 12 months between the Trial and No-Trial groups, we did not find any statistical significance (P=0.915 for the lower limbs VAS, P=0.559 for prevalent VAS). Moreover, rates of patients with pain relief≥50 % were not statistically different between the two groups (P=0.408 for prevalent VAS, P=0.584 for lower-limb VAS, P=NA for axial VAS).

Considering quality of life improvement at 12 months, ODI and Physical Component Score (PCS) of SF36 questionnaire significantly improved in both the Trial and No-Trial groups (P<0.001), while EQ5D questionnaires were statistical significant for the Trial group only and the SF36 Mental Component Score (MCS) questionnaire reached borderline statistical significance for both groups (Table 4).

Clinical results: surgical versus percutaneous leads

As mentioned earlier, 73 within the 122 patients (59.8 %) received surgical leads (paddle leads), while 49 patients (40.2 %) had a percutaneous implant.

In the group of surgical leads, 59 patients (80.8 %) referred prevalent lower-limb pain and 14 (19.2 %) had prevalent axial pain. Within the patients subjected to percutaneous implant, 39 (79.6 %) had prevalent lower-limb pain, 7 (14.3 %) were suffering from prevalent axial pain and the remaining 3 (6.1 %) referred superior-limb pain.

Variation of VAS after 12 months in prevalent pain and lower-limb pain group was statistically significant (P<0.001) for both types of lead implanted, while in patients affected with axial pain this variation was statistically significant (P<0.05) only for percutaneous leads.

We reported similar results for both of the groups in terms of VAS variation and primary outcome at 12 months. Primary outcome after surgical implant was reported in 24 patients (60 %) with prevalent lower-limb pain and 5 (50 %) with prevalent axial pain. After percutaneous implant instead the reported rates were 70.6 % (12 patients) and 57.1 % (four patients) respectively. Considering prevalent pain, 24 patients with surgical implant (61.5 %) and 13 patients with percutaneous lead (68.4 %) reached primary outcome.

Adverse events and causes of device removal

Seventeen complications occurred in 15 patients (14 % of implanted subjects) and were grouped as technical (n=8) and clinical (n=9).

All clinical complications occurred in the Trial group and included three cases of infections, one IPG-pouch sieroma, one subcutaneous haematoma, one immunity reaction, one cerebrospinal fluid leak, one loss of efficacy and one case of myalgia following connecting cable fracture. Seven of

Table 3 Reduction of VAS, reported as median value (range) and rates of good primary outcome (VAS reduction≥50 %) after 12 months of SCS in the Trial and No-Trial groups (Prevalent VAS score explained in "Materials and methods")

Parameters	Baseline	12 months	Primary outcome	*P* value
No-Trial				
Axial VAS	30	20	0 % (one patient)	–
Lower limbs VAS	90 (80–90)	30 (20–50)	68.8 %	<0.001
Prevalent VAS	90 (80–90)	30 (20–50)	71.4 %	<0.001
Trial				
Axial VAS	80 (55–90)	40 (10–65)	56.3 %	0.003
Lower limbs VAS	80 (70–90)	30 (10–60)	60 %	<0.001
Prevalent VAS	80 (70–90)	30 (10–60)	59.5 %	<0.001

technical complications occurred in the Trial group and one in the No-Trial group. Technical complications included three connecting cable fractures (one in the No-Trial group), three early battery depletions, one lead dislocation and one lead fracture.

Complications were equally distributed between surgical and percutaneous leads (four clinical and four technical with surgical leads, five clinical and four technical with percutaneous leads).

Eight patients underwent revision surgery: lead connection repositioning, lead replacement, lead exploration, lead removal, IPG replacement, IPG removal, IPG-pouch exploration, haematoma drainage (one case each).

Eight of the 106 patients (8 %) were explanted after permanent implant for different reasons:

- Infection of the device, 1 (1 %)
- Loss of clinical efficacy, 2 (2 %)
- Pain in device's location (IPG or lead), 2 (2 %)
- Uncomfortable paresthesia, 1 (1 %)
- Uncomfortable psychological aspects, 1 (1 %)
- Referred resolution of clinical symptoms (with system switched off), 1 (1 %)

Table 4 Quality of life outcomes

Parameter	Baseline	12 months	*P* value
No-Trial			
EQ5D Index	0.38±0.36	0.66±0.10	0.044
EQ5D VAS	53.3±27.4	78.9±10.5	0.025
ODI	47.0±14.1	19.8±10.4	<0.001
SF-36 PCS	28.4±4.6	43.1±7.3	<0.001
SF-36 MCS	35.6±8.1	40.3±6.1	0.245
Trial			
EQ5D Index	0.26±0.33	0.65±0.28	<0.001
EQ5D VAS	41.4±20.4	68.3±17.9	<0.001
ODI	47.7±13.9	24.9±19.0	<0.001
SF-36 PCS	29.9±5.8	42.5±10.9	<0.001
SF-36 MCS	38.9±10.1	44.2±10.0	0.164

*PCS*Physical Component Score, *MCS*Mental Component Score

Mean time between permanent implant and device's removal was 10.8±8.7 months (range, 6–28).

Technical aspects

We checked the distribution of the two types of lead implanted in relation to the prevalent location of pain (axial and lower limbs). These considerations are summarised in Fig 1. We did not find any statistically significant difference between the groups, but surgical leads are more commonly used.

Discussion

We discuss about three aspects of SCS implant, comparing the Trial group with the No-Trial group: pain reduction, quality of life and complications.

Pain reduction

In the literature we found a significant reduction of VAS at 1 year, ranging from 39.3 % [34] to 73.7 and 79.8 % of the patients included [35].

Evidence in obtaining primary outcome is reported as variable: Kumar et al. [14] reported a rate of 58 % after 6 months, which decreases to 38 % after 24 months of stimulation [15]. Sears et al. [34] reported good primary outcome at 12 months in 42.9 % of patients, with best results in CRPS in comparison to FBSS. In the same study, the degree of satisfaction (indexed as the rate of patients who would undergo the same procedure again) was reported as >70 % in patients with FBSS and CPRS.

Primary outcome was achieved in 63.8 % of patients, with no statistically significant difference between the Trial and No-Trial groups (59.5 and 71.4 % respectively) and between percutaneous and surgical procedure (68.4 and 61.5 % respectively).

We compared our results with the main studies of the last 20 years in which primary outcome was defined as reduction of VAS≥50 % after 12 months (Table 5) [3, 6, 14–18, 25, 34, 35, 37–41].

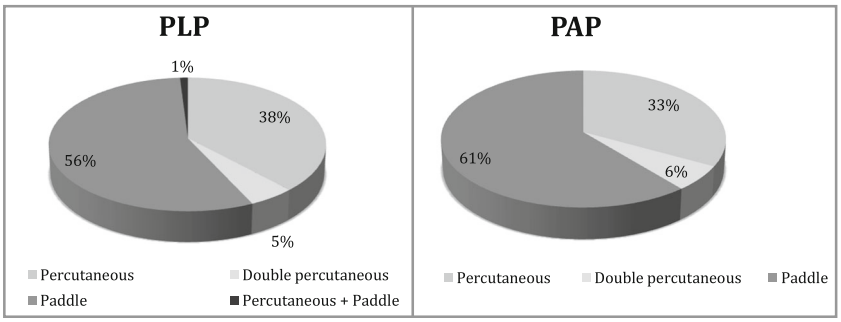

Fig. 1 Distribution of type of leads used in relation to type of prevalent pain (*PLP* prevalent lower-limb pain, *PAP* prevalent axial pain)

We had a mean reduction of VAS after 12 months (Delta VAS) of 60 in No-Trial group and 50 in Trial group. Slavin et al. [35] reported a mean reduction of VAS (in a 1–10 scale) of 3.5 after 1 year of stimulation analysing two long-term studies.

Reduction of VAS after 12 months was lower in the group of patients treated for prevalent axial pain in comparison to lower limbs pain group (Table 3), probably due to the importance of nociceptive pain component in axial pain.

No statistically significant differences were found between lower limbs pain group and axial pain group.

Quality of life

We analysed quality of life outcomes using three rating scales: ODI, EQ5D and SF36 questionnaire and we also tested patients with Hamilton's scale for depression.

It is generally known that SCS has good outcome in terms of return to work and patient satisfaction [14, 15, 28, 34, 35, 38]. Patient satisfaction on pain relief is reported to be 66 % after 6 months [14] and 62 % after 24 months [15], while patient satisfaction for the treatment is 93 % after 6 months [14] and 86 % after 24 months [15].

Kumar et al. [14] reported a statistically significant difference after 6 months between SCS treatment and conservative therapies in the ODI, physical function and bodily pain in PROCESS Trial.

In our analysis, we also found a general improvement of quality of life in terms of ODI, EQ5D and SF36 questionnaires. ODI improvement after 12 months was greater than 50 % from baseline in 62.2 % of patients, with no statistically significant difference between the Trial and No-Trial groups (57.1 and 77.8 % respectively, P=0.434).

Given the different assessment scales and the lack of general consensus on the most appropriate parameters for therapy efficacy evaluation in terms of quality of life, is anyway difficult to perform a close comparison of different studies.

Complications and causes of explant

Starting from an initial population of 122 patients, only 10 patients (9 %) decided not to have the permanent implant after the trial period, reporting poor efficacy of the SCS, and only one patient disliked paresthesia induced by stimulation. Three patients refused the permanent implant for personal reasons and one patient was explanted due to infection.

Analysing clinical outcomes in the 106 patients that underwent permanent SCS implant, we want to emphasise that only four patients (4 %) were explanted because of loss of satisfaction or discomfort. In the literature we found a reduction of effectiveness rated 6 % at 1 year [35] and 11 % at 24 months [15].

Complications of SCS have been summarised in different classifications, and some authors define them as neurological, non-neurological and hardware-related [14, 15, 22].

Some previous studies aimed at analysing complications and cost-effectiveness reported an overall rate of SCS-related complications of 35 % [4] or 32 % of device related complications [14]. In a review of 707 cases, the rate of hardware-related complications (including lead migration, lead connection failure and lead break) was 38.1 %, while the rate of 'documented infections' was 4.5 % with one case of epidural infection [22]. One study about the 11-year experience with SCS reported an infection rate of 4.9 % [31].

Our overall complication rate (14 %) is comparable [2, 28] or lower than that reported in the main literature (Table 5). In particular, complications were 3 % in the No-Trial group and 18 % in the Trial group. One possible explanation could be recognised in the short follow-up of our study; however, the low rate of adverse events is probably due to the homogeneity and expertise of the teams involved.

Conclusions

Our results enforce the evidence of efficacy of SCS therapy in terms of pain reduction, patient satisfaction and quality of life, according to previously published studies.

The broad expertise of participating centres and physicians, together with shared and strict patient selection criteria, allowed a very low rate of complications, especially in the No-Trial group, and positive results in primary outcome, which is similar in both the Trial and No-Trial groups.

Table 5 Comparison of our analysis with literature (studies in which VAS reduction≥50 % was used as primary outcome)

Study	Pain aetiology	Patients, total	Patients implanted	Patients with primary outcome at 12 months	ODI baseline	ODI 12 months	SF36	Complication rate
Kupers 1994	FBSS, CRPS, other neuropathic, PVD		700	52 %				
Van de Kelft 1994		116	84	54 %				
Burchiel 1996	FBSS	219 (6 centres)	182	55 %	0.542(SD 0.14)	0.469(SD 0.2) P=0.003		17 %
Kumar 1998	FBSS, CRPS, other neuropathic, PVD	235	189	59 %				
Van Buyten 2001	FBSS	254	217	68 %				
Dario 2001	FBSS	49		71 %				
North 2005	FBSS	24		47 %				
Taylor 2006	FBSS, CRPS, other neuropathic	3,313 (65 studies)	1,992	62 % (56–69 %)				18 %
Kumar 2007, 2008 (PROCESS)	FBSS	52		58 % (6 months); 48 % (12 months)	52	44,9 (6 months) P<0.001		45 %
Turner 2010	FBSS, CRPS, other neuropathic		51	15 %				16 %
Sears 2011	FBSS, CRPS		52	42.50 %				
Slavin 2013	FBSS, other neuropathic	334 (4 studies)	300	3 months: 75.4 %; 12 months 76.3 % (2 out of 4 studies)			Improving: 77.9 % at 3 months, 75 % at 1 year	51.5 %
Our analysis	FBSS, CRPS, other neuropathic	122	106	63.8 %	Trial: 47.7 (SD 13.9) No-Trial: 47.0 (SD 14.1)	Trial: 24.9 (SD 19.0) No-Trial: 19.8 (SD 10.4) Total: greater than 50 % in 62.2 % patients	P<0.001 for physical component score at 12 months	14 %

ODI Oswestry Disability Index, *FBSS* failed back surgery syndrome, *CRPS* complex regional pain syndrome, *PVD* peripheral vascular disease

It is interesting to note that VAS reduction and ODI improvement reached statistical significance versus baseline in all the groups of patients, considering either the surgical procedure (Trial or No-Trial) or the type of lead used (percutaneous or paddle).

The decision to do the procedure without a trial period could be feasible only assuming a deep experience in the selection of patients, in association with pre-surgical evaluation of quality of life, psychological statement and definition of pain in terms of features and extension.

Performing the SCS implant in a single procedure, without the temporary implant, could give an important reduction of discomfort related to the trial period (surgical wound, temporary device care, days of admission to hospital, rate of complications) while opportunely presuming a similar rate of success.

The number of patients included in this analysis does not allow us to draw a conclusion about the issue of a trial period, but the results we reported could be the beginning of a new discussion.

Although more data need to be collected, we can suppose that, assuming a correct selection of the patients, together with a wide experience of the surgeons/clinicians, in the future the trial period could become an optional step in a lot of cases.

It is hoped that this analysis will help to recruit new centres and thereby build a database with more patients, to give greater scientific value to our initial results.

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Conflicts of interest None.

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