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Factors associated with success of trial spinal cord stimulation in patients with chronic pain. Preliminary data on the prognostic value of standardized health-related scales in a clinical practice setting

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ABSTRACT

Objective: Spinal cord stimulation (SCS) is a widely employed technique in treating chronic pain, however, it still fails in significantly reducing pain in one-out-of-three cases. Poor consensus exists on the most predictive factors of SCS outcomes. Although psychological criteria such as emotional stability are recommended for this treatment, it is not well understood if the perception of patients' own health may impact the SCS success. Therefore, we retrospectively examine factors associated with the patient's subjective conditions, to investigate their relationship with SCS success.

Methods: Before the implantation of an SCS trial per routine clinical decision-making, and independently from the implanted devices**,** patients treated in our clinical practice underwent an extensive evaluation of pain, disability, depression and the overall quality of life. In those patients with successful SCS trials, the pain level was also evaluated at the end of the trial period. Regression analyses were performed to investigate factors predicting successful trial stimulation.

Results: Successful trial stimulation was effective in 15 patients (75%). Perceived disability, pain and general health resulted as independent predictive factors on SCS trial outcome. Further investigation showed perceived disability (i.e. Oswestry Disability Index) as a crucial factor, and ROC curve analysis identifies a cut-off of 38 as a predictive score of success.

Conclusions: Although preliminary, these findings suggest that standardized scales examining the overall patients' perceived health status, particularly the disability index may help shed light on predicting SCS trial success. Thus, it is argued the potential application of self-administered scales in SCS patients' selection in routine clinical practice.

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Introduction

Chronic pain is a debilitating condition that has a significant impact on patients' quality of life (QoL). The treatment of chronic pain is still challenging, involving many disciplines, including physical and psychological therapies, as well as pharmacological and surgical treatments [1]. Since its introduction in the last half-century [2], spinal cord stimulation (SCS) has been a reliable treatment for chronic pain conditions, with no pharmacological assumption. Although SCS can reduce pain symptoms up to 70% with a significant improvement in QoL, some clinical features expose at the risk of SCS failure [3]. For example, psychiatric comorbidities, older age, longer pain duration prior to intervention, are all predictive of poorer outcome [4]. Interestingly, psychological factors are assumed to be essential for the efficacy of SCS. In the light of this consideration, it is worth noting that there is a strong association between pain and depression, and the latter has often been suggested as a possible impacting factor on SCS efficacy [5,6]. Moreover, pain catastrophizing has been described to adversely affect pain-coping behavior and the overall prognosis in susceptible individuals when challenging with painful conditions [7,8]. Those evidences have been confirmed in a research examining whether carefully screening patients could predict pain-related and functional outcomes, highlighting that presurgical psychological factors including somatization, depression, anxiety, and poor coping were most predictive of poor response to SCS [9].

In this scenario, it appears crucial to better understand those features that may lead to poor SCS outcomes. Often, the disease-specific scale might not reflect the patient's functional outcome [10], not capturing the patients' self-perception of disability, as well as more general aspect of wellbeing and mental health. At the same time, there is to date no "gold standard" in psychological or health-quality related tests for the assessment of SCS outcome.

Based on the aforementioned theoretical hypothesis, the study aim was to investigate the influence of patients' self-perception of pain and disability, health related QoL and depression on the success of SCS trial stimulation in a representative case series, to identify those factors that may be more prone to play a role in shaping negative outcomes after SCS trial and, therefore, to drive clinical decision-making on SCS permanent placement.

Methods

Participants

To investigate factors associated with successful trial stimulation, the medical records of 20 patients were reviewed. Each of the patients underwent to the implantation of SCS electrodes at our institution (From March 2017 to November 2019) to treat different chronic pain conditions. Review of clinical variables, duration of pain and the score of standardized, self-administered questionnaires were investigated. The entire sample gave informed consent at the time of the hospitalization, and the appraisal was managed in accordance with the clinical practice. Participation in the study is completely voluntary and patients could withdraw from the study at any moment, for any reason, without providing any justification. The whole procedures were conducted according to the principles expressed in the Helsinki Declaration.

The mean age of patients (14 F) was 60.00±15.0 (mean ± standard deviation). The sample's demographic data are summarized in Table 1.

Features	Total Trial Group n=20	Success Group n=15	Failure Group n=5
Gender F:M (%)	14 (70%): 6 (30%)	12 (80%): 3 (20%)	2 (40%): 3 (60%)
Age, years (Mean ± SD)	60 ±15	59±15	62±15
Years since diagnosis (Mean ± SD)	6.30 ±5.71	6.93 ±6.40	4.40 ± 2.30
FBSS/radiculopathy/foraminal stenosis	13	11	2
Lower limbs neuropathy	3	3	
Chronic pelvic pain	2	1	1
Herpetic neuralgia	1	1	
Ulnar neuropathy	1	1	
Baseline VAS, cm (Mean±SD)	8.3 ± 0.9	8.6 ± 0.8	7.7 ± 1.2

Table 1. Demographic and clinical data
Demographic and clinical data of patients who underwent SCS trial, including pain data etiology and VAS evaluation.

The inclusion criteria involved eligibility to SCS trial, independently from stimulation frequencies and surgical management. Patients must be refractory to previous medical treatments, including analgesics, opioid analgesics, physical therapy, and pain blocks. The exclusion criteria were to not complete the

questionnaires or reporting a VAS score measured at baseline lower than 6/10.

Patients were randomly assigned to four different stimulation paradigms during the trial period: i) traditional tonic stimulation, Intellis SCS trial (Medtronic Inc, Minneapolis, MN, USA); ii) burst stimulation, BurstDR, (Abbott, Texas, TX USA); iii) High-Density (HD) stimulation, the St. Jude Medical Invisible Trial System (Abbott, Texas, TX USA); iv) High Frequency (HF) Stimulation, Senza system (Nevro Corp., California, CA, USA).

Questionnaire

As part of the assessment, an extended preoperative evaluation of health related QoL was collected using self-administered, standardized questionnaires to investigate pain, disability, global QoL and depression. We acquired pain measures through VAS [11,12] before the surgery and at the end of the trial period on those patients who reached SCS trial success.

The test battery includes: Pain Catastrophizing Scale (PCS), an instrument derived from the definitions of catastrophizing described in the literature [13] and items from the catastrophizing subscale of the Coping Strategies Questionnaire (CSQ) [14]. It allows the evaluation of the patients' mentalization of pain through three subscales, helplessness, magnification and rumination; the Oswestry Disability Index (ODI) was included in the battery [15], it is a tool able to assess the level of pain interference with various activities of daily living. Indeed, it has been recommended to measure pain-related disability when considering areas other than and including low back pain [16,17]; a generic health-related QoL assessment, EuroQol five-dimensional questionnaire (EQ-5D-3L), was administered, to better understand how pain impacts everyday life globally. The questionnaire evaluates the five dimensions of mobility, self-care, pain, anxiety, and activities of daily living [18]; the 36-Item Short Form Survey (SF-36) [19] was collected: an overall health-related QoL measure extensively used to discriminate, evaluate, and predict outcomes in several health and pathologic conditions [20]; the Hamilton Rating Scale for Depression (HAM-D) was included in the survey [21], due to the relevance of depressive symptoms on pain perception and on the SCS success rate.

Stimulation management

A percutaneous lead with eight contacts was placed under direct fluoroscopic guidance in the epidural space. The correct position was determined using intra-operative stimulation and was deemed successful if the induced paraesthesia had an adequate overlap with the painful area. After the surgery, the patients were randomly assigned to one of the four arms (in a 1:1:1:1: ratio), where they received a one-month combination of tonic, HD, HF and burst stimulation including one treatment modality per week and varying the order of the modality received within the four possible combinations. We used different types of adapters to connect the same provisory lead extension with the various trial stimulators.

The length of the trial period was 39±18 days. At the end of the trial, patients were classified into two groups, success and failure group. Each patient in the success group decided to proceed to the permanent implantation of the device that showed the highest delta VAS score, calculated as the difference between baseline VAS and VAS with any of the four devices tested.

Statistical analysis

We analysed the following factors: age, sex, duration of pain and the validated scales scores. The significant difference between VAS scores was evaluated through the Friedman test. Univariate analysis was performed to investigate the presence and the strength of any predictor factor on the trial outcome to identify those factors to be included in the logistic regression analysis. Then, the Generalised Linear Model (GLM) was developed. Receiver Operating Characteristic (ROC) curve analysis was performed to identify the best cut-off of the most significant predictor variable specified with the previous analysis. All statistical analysis has been completed with R Core Team 2020 software (R Foundation for Statistical Computing, Vienna, Austria. URL https://www.R-project.org/).

Results

Successful trial stimulation was reached in 15 out of 20 patients (75%). No significant differences at VAS score were registered among the four devices, whereas a significant reduction ($p<0.05$) in the VAS score compared to baseline VAS was observed in the whole success group, Fig. 1.

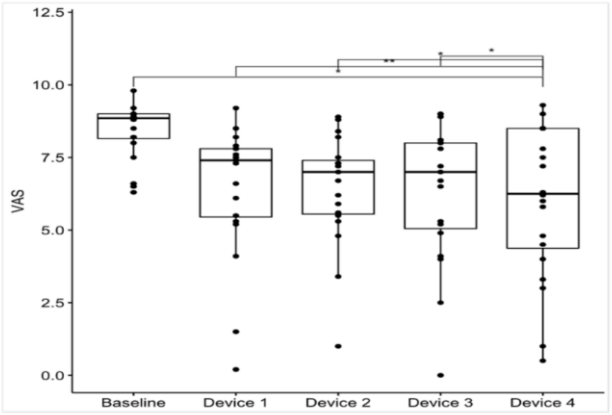

Figure 1. Preoperative VAS (Baseline) and VAS distribution for each Device tested

To investigate those factors associated with the success of trial stimulation, data were fit into a logistic regression model to verify whether any of the scores of the variables collected preoperatively correlated with the trial stimulation outcome. All the data are summarized in Table 2.

	Significance	Beta	P-value	SSE
VAS Baseline	Borderline	-	0.0811	85%
Degree of pain duration (years)	No	-	0.401	-
EQ-5D-3L	No	-	0.915	-
HAM-D	No	-	0.8087	-
ODI	Borderline	-0.1772	0.08	44.3%
PCS	No	-	0.914	-
PCS subscale - Pain Helplessness	No	-	0.970	-
PCS subscale - Pain Rumination	No	-	0.287	-
PCS subscale - Pain Magnification	Yes	-0.7292	0.0308	69.1%
SF-36 Physical Functioning	No	-	0.2620	-
SF-36 Physical role Limitations	No	-	0.1734	-
SF-36 Bodily pain	No	-	0.4491	-
SF-36 General Health Perceptions	Borderline	0.0567	0.0598	74%
SF-36 Energy/Vitality	No	-	0.573	-
SF-36 Social Functioning	No	-	0.589	-
SF-36 Emotional Role Limitation	No	-	0.2420	-
SF-36 Mental Health	No	-	0.804	-

Table 2. Logistic Regression

Logistic regression analysis on independent variables collected at baseline as predictor variables of trial outcome. SSE: Summary Squares Error.

Univariate analysis revealed that four of the analyzed independent factors were associated with the trial stimulation outcome. Therefore, we developed a GLM named "Comprehensive Model", which included ODI, Pain Magnification subscale, General Health subscale of SF-36 and preoperative VAS (model SSE 34.77%). However, the ANOVA test on the Comprehensive Model revealed that the deviance explained by General Health and preoperative VAS were not statistically significant (p=0.959 and p=0.299, respectively). Therefore, we removed these two variables from the Model and generated a simpler model, named PMO model, which included only two variables, i.e., the Pain Magnification and ODI (model SSE 39.9%). The equation of the PMO model is as follows with β_1 = -0.49853 as estimated parameter of the Pain Magnification predictor variable and β_2= -0.14349 as the estimated parameter of the ODI predictor variable and α =6.27127:

$$\eta = \alpha + \beta_1 \times (Pain\ Magnification\ Score) + \beta_2 \times (ODI\ Score)$$

$$P(Trial\ failure) = \frac{e^{\eta}}{1 + e^{\eta}}$$

To further reduce the complexity of the model, we developed a univariate parsimonious predictive model based only on the ODI variable (model SSE 44.3%). The equation of the ODI model is as follows with β_1 = -0.1772 as estimated parameter of ODI predictor variable and α = 5.4513:

$$\eta = \alpha + \beta_1 \times (ODI)$$

$$P(Trial\ failure) = \frac{e^{\eta}}{1 + e^{\eta}} = \frac{e^{\alpha + \beta_1 \times (ODI)}}{1 + e^{\alpha + \beta_1 \times (ODI)}}$$

$$P(Trial\ failure) = \frac{e^{5.4513 - 0.1772 \times (ODI)}}{1 + e^{5.4513 - 0.1772 \times (ODI)}}$$

The predicted probability of trial failure based on the univariate ODI model is reported in Table 3. In the "minimal disability" category (ODI ≤20), the predicted probability of the trial failure increases drastically, while in the "severe disability" category (ODI ≥60) it is strongly avoided.

Therefore, to confirm the correlation estimated by the ODI model and identify the ODI best cut-off that shows the greatest correlation with the trial outcome, we developed a ROC curve analysis that

revealed that a ODI score of 38 is the best cut-off with the highest accuracy or optimal sensitivity (100%) and specificity (85.7%) in our case series. Hence, highest ODI scores (i.e., worse disability perception) are associated with higher SCS trial success.

ODI	0	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75
P (failure)	.996	.99	.975	.942	.871	.735	.534	.321	.163	.074	.032	.013	.006	.002	.001	0

Table 3. ODI Score Predicted efficacy on SCS trial
Predicted probability of trial failure based on the univariate ODI model.

Discussion

SCS is a reliable technique in treating chronic pain, improving patients QoL and with a low rate of complications [6]. Nevertheless, the heterogeneity of patients and their symptomatology makes it often difficult to establish which patients are eligible for this treatment. Indeed, many conditions may expose to the risk of no SCS success in reducing pain [22]. Psychosocial factors such as dysfunctional coping, poor daily activity level and psychological distress are considered relevant for SCS selection [23]. To this purpose, when patients are determined to be eligible and potential candidates for SCS, a psychological assessment, including subjective pain intensity, mood and personality, daily activity interference, pain beliefs and coping, is required to help identify the ideal patient to achieve maximum benefit from an implanted device [24-26]. However, the interaction of clinical and psychosocial factors in determining the eligibility of patients with chronic pain to SCS implantation has led to a lack of clarity in selection criteria, and often poor consistency among surgical centers [23].

Patients typically undergo a trial stimulation to determine SCS efficacy and drive clinical judgment regarding appropriateness for permanent implantation. Overall, many factors are likely to play a role in shaping pain outcomes of SCS, nevertheless, no consensus exists on what factors are most consistently predictive of these outcomes. Reliable data are still missing and the available guidelines [27-29], due to the great heterogeneity of patients, are quite clear in their recommendations [30-34].

Beyond non-modifiable risk-factor of non-success, such as older age or long pain duration [32], it is crucial to better understand how psychological conditions may play a role in the SCS efficacy in pain reduction, to maximize patients' QoL [35].

To identify any predictive factors associated with the success of SCS trial stimulation, we evaluate, in a cohort of patients treated at our institution, the preoperative patients' self-perception of pain and disability, as well as more global aspect of wellbeing, including QoL and mental health scale.

In line with the literature data [32], the 75% of the sample reached a successful SCS trial, with a significant postoperative reduction in the pain level measured through VAS. Therefore, based on the preoperative data on the self-administered questionnaire, we design a predictive model on SCS trial outcome. It came out that the degree of perceived pain (VAS) and the General Health score of SF36 questionnaire, both measured at baseline, seem to play a marginally significant role in the SCS trial success in our representative case series. Interestingly, the analysis also identifies the pain magnification scale as a predictor of SCS success. This result is not surprising, due to the role of pain catastrophizing in negatively affecting pain-coping behavior [7,8]. However, considering that pain mentalization may have divergent impact on other dimension of QoL, and depressed mood [36], investigating the unique contributions of each PCS subscales could be crucial to predict the therapies success rate. Here emerged that the idea "that something serious may happen", associated to pain magnification, mainly could lead to a poor efficacy of SCS trial.

Furthermore, the patients' self-perception of disability, measured through ODI scale, results to be the strongest predictor of SCS trial success in our model. This result shows the role of patients' daily abilities level in affecting SCS outcome and identify the ODI score of 38 as the best cut-off in predicting SCS success, with optimal sensitivity and high specificity. That is, moderate or severe disability is related to grater SCS success. In other words, SCS may be more efficient on those patients with a worse

perception of their functional status related to the pain. This result could be seen in term of greater reward with respect to pain relief in those patients with a higher degree of perceived disability compared to those with a preserved functional status, in which the degree of pain reduction could be weaker.

Although the patients' mental health, such as depression or psychological distress, is thought to have a major influence on the SCS success, our results suggest the importance to take into account even the patients' own perception of their functional status in the routinely SCS eligibility evaluation. Not secondarily, the ODI scale is a self-administered scale, fast and easy to collect, that do not require clinical judgment and may be easily implemented in the clinical practice.

Taken together these evidences suggests the crucial importance of an extensive evaluation on patients' candidates for SCS with a multidisciplinary model of care and aims at proposing the adoption of self-administered scales in the routine clinical assessment as a good tool in investigating the patients' perception of health quality, overcoming the more disease-specific aspects of clinical evaluations.

Although further research is needed to clarify the role of self-reported scales in a larger cohort of patients and though the impact of several subjective determinants on SCS outcome is still unclear and these factors are still rarely studied, our preliminary data highlight that pain and disability perception may become routinely measures when evaluating consensus to SCS implantation.

Beyond the undoubtful limitation of our study is the reduced sample size, the main advantage is the heterogeneity of the sample, being representative of patients' profiles in a clinical setting, so it is considered to be the environment best suited for developing a predictive model, taking into account the great heterogeneity in SCS treatments.

Our preliminary data suggest that pain and disability perception may become routinely measures when evaluating consensus to SCS implantation. The self-administered scale, fast and easy to collect, may help predicting SCS trial success and may drive clinicians' consensus to permanent implantation.

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