

Pain Catastrophizing Does Not Predict Spinal Cord Stimulation Outcomes

A Cohort Study of 259 Patients With Long-Term Follow-Up

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TITLE PAGE

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Mr. Poulsen, Dr. Meier, Prof. Nikolajsen and Prof. Sørensen designed the study. Dr. Blichfeldt-Eckhard, Dr. Gulisano, Dr. Meier, Prof. Sørensen and Mrs. Knudsen helped with acquisition of data. Analysis of data was performed by Mr. Poulsen and Dr. Meier. Mr. Poulsen prepared the manuscript draft with important intellectual input from Dr. Meier and Prof. Sørensen. Mrs. Knudsen, Dr. Blichfeldt-Eckhard, Dr. Gulisano and Prof. Nikolajsen reviewed it critically. All authors approved the final manuscript.

Conflicts of Interest:

Jens Christian Hedemann Sørensen has received teaching fees and travel support from Abbott. He is also the co-owner of Neurizon. Morten Rune Blichfeldt-Eckhardt has received course and travel support from Abbott, Medtronic and Boston Scientific. Helga Angela Gulisano has received course and travel support from Abbott and Boston Scientific, teaching fees and course and travel support from Medtronic. Kaare Meier has received teaching fees and travel support from Abbott and teaching fees from Medtronic. He is also the co-owner of Neurizon. The remaining authors have no conflicts of interest to disclose.

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Abstract:

Objective: Spinal Cord Stimulation (SCS) is an important treatment modality used to treat chronic neuropathic pain. However, prevalent success rates of 50-75% entail an increased focus on patient selection. An area of core interest is psychological evaluation, often using scales such as the Pain Catastrophizing Scale (PCS). The aim of this study was to assess the relation between baseline PCS scores obtained prior to implantation and SCS outcomes defined as 1) Rating on Patients' Global Impression of Change scale (PGIC), 2) Pain relief on the Numeric Rating Scale (NRS), 3) Cessation of pain medication and 4) Risk of permanent explantation.

Materials and Methods: Using records from the Neurizon Neuromodulation Database, we performed a multicenter open cohort study of 259 permanently implanted SCS patients with a maximum follow-up of nine years. For each of the defined SCS outcomes, patients were grouped according to their latest follow-up registration. Subsequently, we used a one-way ANOVA and exact t-tests to compare mean baseline PCS scores between groups.

Results: No difference in mean baseline PCS scores was found between PGIC groups. Baseline PCS scores was not associated with the probability of obtaining 30% or 50% pain relief on latest registration. Baseline PCS scores of patients able to cease all usage of tricyclic antidepressants, antiepileptics or opioids during SCS treatment did not differ from baseline scores of continuous users. We found no association between baseline PCS scores and risk of permanent explantation.

Conclusion: This study did not demonstrate any associations between baseline PCS scores and SCS outcomes.

Keywords:

Spinal Cord Stimulation, Outcome predictors, Psychological evaluation, Catastrophizing, Registries.

INTRODUCTION

Management of chronic pain constitutes a growing challenge in the healthcare system with estimated annual costs of 635 billion dollars in the United States alone [1]. Spinal cord stimulation (SCS) is an important surgical treatment modality used to treat a subset of chronic pain conditions refractory to conventional treatment strategies. Currently, more than 30,000 new implantations are performed worldwide each year with prevalent success rates varying between 50-75 % depending on implantation center, indications and success criteria used [2, 3]. With SCS being expensive and invasive, patient selection is of great importance from both an economical and individual point of view.

Previous investigations have found multiple variables such as indication, pain duration, gender, age, smoking status and drug abuse to be of potential value when evaluating patients for SCS implantation [4-6].

In addition, many patients undergo some sort of psychological screening prior to implantation. Routine psychological screening consists of various scales assessing depression, anxiety and cognitive responses to the perceived pain experience [7]. Currently, there is only sparse evidence determining the value of these scales in predicting SCS outcomes [8].

One scale of particular interest is the Pain Catastrophizing scale (PCS) developed by Sullivan *et al.* in 1995 [9]. The relation between pain and catastrophic thinking measured on the PCS scale has been studied extensively. Numerous studies have documented an association between catastrophizing and inferior outcomes of pain treatment in various pain populations. These findings led Sullivan *et al.* to define clinically relevant catastrophizing as a PCS score of 30 or beyond [10].

However, in SCS patients the current evidence of an association between PCS scores and SCS outcomes is equivocal, with published studies having small sample sizes or showing mixed results [11-15]. Therefore, the aim of this cohort study is to investigate if baseline PCS scores can predict SCS outcomes in 259 permanently

implanted SCS patients having a maximum follow-up duration of nine years. We defined SCS outcomes as 1) Rating on the Patients' Global Impression of Change Scale (PGIC) [16] , 2) Pain relief measured using the 11-point Numeric Rating Scale (NRS), 3) Cessation of pain medication and 4) Risk of permanent explantation of the SCS system as indication of treatment failure.

MATERIALS AND METHODS

This paper conforms to the published guidelines of the STROBE statement for reporting of observational studies[17, 18].

The Neurizon Neuromodulation Database

We used an open cohort study design including Danish patients registered in the Neurizon Neuromodulation Database [19, 20]. The database is a comprehensive and free of charge registration tool intended for international collaboration in the field of neuromodulation. It is designed for easy management of all relevant patient and treatment characteristics as well as patient follow-up during treatment with SCS. In Denmark, three out of four national implanting centers are using the database for registration and management of SCS patients, while the last center does not use a registry for patient follow-up. The database contains data on patients with first implantation of an SCS device dating back to September 2006 at Aarhus University Hospital, March 2011 at Odense University Hospital, and March 2012 at Aalborg University Hospital.

The criteria used to select eligible patients is presented in table 1. It should be noted that the database also contains records of patients treated with other neuromodulation treatment modalities.

The Neurizon Neuromodulation Database is approved by the Danish Data Protection Agency. Prior to enrollment, all registered patients sign an informed consent form approved by the legal office of the hospital owners (Danske Regioner).

Patient referral and data collection

Patients were initially referred to the implanting centers from general practitioners, pain clinics, or other hospital departments. Patient demographics, comorbidities, and pain condition were registered in the

database during one of the first clinical visits in the outpatient clinic. Before visiting the outpatient clinic, patients were asked to fill out a set of questionnaires containing registration of pain intensity score (0-10 Numerical Rating Scale, NRS [21]), consumption of pain medication, and the Pain Catastrophizing Scale. These measurements are termed baseline data and only considered valid if obtained less than six months before time of first implantation.

Follow-up was performed using the same set of questionnaires as before SCS implantation in addition to the Patients' Global Impression of Change scale (PGIC) [16]. The PGIC scale is a 7-item Likert scale asking the respondent to rate their overall level of improvement since start of treatment as "very much worse", "much worse", "minimally worse", 'no change', 'minimally improved', 'much improved' or 'very much improved'. Additional pain intensity scores and PGIC ratings were obtained by the treating clinician during follow-up visits in the outpatient clinic. The three participating implanting centers had minor differences in their follow-up interval during the first year of SCS treatment, but all patients were invited to a yearly follow-up visit at their respective outpatient clinic. To account for this, we used the latest data collection point of each of the selected outcomes. Time from first implantation to latest data collection point was calculated in order to prevent potential bias from varying follow-up periods.

New implantations, revisions, and explantations of the SCS device were registered in the Neurizon database by the surgeon or his/her assistant. Patients undergoing explantation of their SCS system were not routinely followed after explantation.

Implantation procedure

The implantation procedure varied between patients. Some patients were implanted with an on-table trial stimulation technique. With this technique, permanent implantation of an implantable pulse generator (IPG)

was performed if sufficient paresthesia coverage of the pain affected area was achieved during the procedure [3, 22]. Other patients were implanted by using a conventional approach with a trial period of up to 14 days before the implanter decided upon permanent implantation of an IPG. In those cases, a traditionally used threshold of 50% pain reduction was not an absolute requirement for subsequent implantation of a permanent IPG. Instead, the implanter evaluated the individual trial outcome before deciding on permanent IPG implantation. Furthermore, it should be noted that preoperative PCS scores were not part of clinical decision making at any of the included implantation centers.

Implanted SCS systems were manufactured by Abbott (Chicago, Illinois, USA), Boston Scientific (Natick, Massachusetts, USA), or Medtronic (Minneapolis, Minnesota, USA).

Handling of PCS scores

The PCS scale comprises 13 items, which are statements of thoughts and feelings. The respondent is asked to indicate the degree to which they experience these statements on a scale from 0 (not at all) to 4 (all the time) while reflecting upon previous painful experiences. From these ratings a total PCS score between 0 (no pain catastrophizing) and 52 (highest possible pain catastrophizing) is calculated by summarizing all item values. We handled missing item values as follows: Questionnaires with more than four missing items were excluded. If an item value was missing, it was replaced with the calculated average value of the other items from the same questionnaire.

Sullivan *et al.* suggested a PCS cut-off value of 30 to group patients into those being clinical catastrophizers and those not catastrophizing on a clinically relevant level [10]. However, such dichotomization is particularly associated with information loss and reduction of statistical power [23]. Therefore, baseline PCS scores were

kept as a continuous variable throughout the analyses. Where necessary, e.g. in table 2 presenting patient characteristics, patients were divided into quartiles based on their baseline PCS score.

Handling of outcome measurements

For each outcome analysis, patients were omitted if they had a missing baseline measurement (not PGIC rating), a missing follow-up measurement, or if the latest follow-up measurement was obtained less than six months from first implantation (Figure 1).

We assessed the relation between PGIC ratings and PCS scores by dividing patients into groups based on their latest PGIC rating followed by comparison of mean PCS scores between groups.

For reduction in pain intensity, we identified patients perceiving at least 30 % pain relief on their latest registration compared to baseline. The mean PCS score of these patients was compared with the mean PCS score of patients not obtaining 30 % pain relief. In addition, we regrouped the patients using 50 % pain relief as cut-off and performed a repeated comparison of mean PCS scores. Pain intensity was evaluated by the 11-point Numeric Rating Scale (NRS) with 0 being 'no pain at all' and 10 being 'pain as bad as you can imagine' [21]. We used an average NRS score during the past week across all registered pain indications of the patient.

The association between PCS scores and cessation of pain medication was evaluated by identifying baseline users of analgesic agents from each of the following three pain medication classes: 1) Tricyclic antidepressants (TCA), 2) Antiepileptics (AED) and 3) Opioids (Table 3 displays the generic names of included analgesic agents).

By assessment of their latest medicine registration, we grouped these baseline users into a continuous group still using some sort of analgesic agent from the pain medication class and a discontinuous group having ceased

usage of all agents from the class. Then, we compared mean PCS scores between the continuous group and the discontinuous group. This comparison was performed three times, one for each pain medication class.

The last analysis involved assessment of patients undergoing permanent explantation of their SCS system. The mean PCS score of these patients (permanently explanted) were compared with the mean PCS score of patients who still have their SCS system in place (active stimulation).

In addition to using the latest follow-up measurement, we performed sub-group analysis of each year of follow-up. All follow-up measurements were grouped into yearly intervals (year 1 = 6-18 months of treatment, year 2 = 18-30 months of treatment etc.) and mean PCS scores of each group from the same year was compared. In case a patient had more than one follow-up measurement in the same yearly interval, the measurement obtained closest to the exact date of yearly follow-up was used. These sub-group analyses can be found in table 4-6 under supporting information.

Statistical methods

Continuous variables with normal distribution are presented as mean \pm SD, alternatively as median and interquartile range (IQR). Categorical variables are expressed in absolute figures and proportion of total. Statistical analyses were performed with Stata 15.1 (StataCorp, College Station, Texas, USA), using a significance level of $\alpha=0.05$.

Difference in mean PCS scores between PGIC groups was assessed with a one-way ANOVA. Before testing, assumptions of normality and equal variance within each PGIC group were evaluated with QQ-plots and a Bartlett's test, respectively.

An exact t-test was used to test for group difference in mean PCS scores in the other analyses concerning reduction in pain intensity, cessation of pain medication and risk of permanent explantation. Before performing

the tests, assumptions of normality were checked by QQ-plots, and an F-test was used to evaluate equal standard deviation among groups.

RESULTS

Characteristics of included patients

The total output of the Danish mirror of the Neurizon Neuromodulation Database contained 893 unique patient records of which 259 patients met the study eligibility criteria (figure 1). The eligible patients were implanted with an SCS device between May 2010 and December 2019. Baseline PCS scores ranged from 5 to 52 with a mean of 30.4 (± 10.6). Patients were divided into quartiles based on baseline PCS scores with subsequent uniformity assessment of basic characteristics (table 2). Compared to the fourth quartile, the first quartile tended to be women, to suffer more frequently from failed back surgery syndrome (52 % vs 43 %) and less from neuropathy (18 % vs. 25 %) and to report lower pain intensity scores at baseline (6.9 vs 7.8). All other basic characteristics were comparable across baseline PCS quartiles.

In the following section, we report the analyses of latest outcome measurements. The sub-group analyses of yearly follow-up can be found in table 4-6 under supporting information.

Patients' Global Impression of Change

One hundred eighty-five patients were included in the analysis of latest PGIC rating (figure 2). No patients rated their PGIC 'Very much worse', one rated PGIC 'Much worse' (PCS=34), while two patients rated PGIC 'Minimally worse' (PCS=18+50). Mean baseline PCS scores of the remaining PGIC groups were: 'No change' (30.8, CI95% [23.9; 37.8], n=13); 'Minimally improved' (31.5, CI95% [28.0; 34.9], n=39); 'Much improved' (29.3, CI95% [26.9; 31.7], n=72) and 'Very much improved' (28.8, CI95% [26.2; 31.4], n=58). A one-way ANOVA demonstrated no overall statistically significant difference in mean PCS scores between PGIC groups ($p = 0.80$). Follow-up duration of latest PGIC rating was equally distributed across baseline PCS scores with a median of 3.0 years (figure 3).

Reduction in pain intensity

One hundred seventy-seven of the included patients had a baseline pain intensity score as well as a follow-up score obtained more than six months from time of first implantation (figure 2). Compared to baseline, 80 of these patients obtained 30 % pain relief on their latest registration, while 97 patients did not. There was no evidence of group difference in mean PCS scores (29.1, CI95% [26.8; 31.4] vs. 30.4, CI95% [28.4; 32.5]; Diff = 1.3, CI95% [-1.7; 4.3], $p = 0.40$). Only 44 patients obtained 50 % pain relief on their latest registration, 133 patients did not. A t-test found no difference in mean PCS scores between the two groups (29.1, CI95% [25.8; 32.4] vs. 30.1, CI95% [28.3; 31.8]; Diff = 0.9, CI95% [-2.6; 4.4], $p = 0.60$). Follow-up duration of latest pain intensity score did not vary with baseline PCS scores. Median follow-up duration was 3.0 years (figure 3).

Cessation of pain medication

We identified 44 baseline TCA users, 100 baseline AED users and 123 baseline opioid users.

Eighteen of the baseline TCA users eliminated all TCA usage during SCS treatment, 26 continued to use some sort of TCA. No difference in mean PCS score between the two TCA groups was found (31.8, CI95% [26.0; 37.6] vs. 31.6, CI95% [27.8; 35.4]; Diff = -0.2, CI95% [-6.6; 6.2], $p = 0.94$).

Twenty-six of the baseline AED users eliminated all AED usage during SCS treatment, 74 patients continued to use some sort of AED. No difference in mean PCS score between the two AED groups was found (28.2, CI95% [23.7; 32.7] vs. 30.4, CI95% [28.1; 32.8]; Diff = 2.3, CI95% [-2.4; 7.0], $p = 0.34$).

Thirty-two of the baseline opioid users eliminated all opioid usage during SCS treatment, 91 patients continued to use some sort of opioid. No difference in mean PCS score between the two opioid groups was found (30.2, CI95% [26.8; 33.7] vs. 30.1, CI95% [27.9; 32.3]; Diff = -0.1, CI95% [-4.4; 4.1], $p = 0.95$).

Median follow-up duration of latest medicine registration was 2.9 years and individual follow-up durations appeared evenly distributed across baseline PCS scores (figure 3).

Risk of permanent explantation

Thirty-two of the 259 eligible patients underwent permanent explantation of their SCS system during follow-up. Mean PCS score of these patients were 30.3 (CI95% [26.2; 34.4]) and comparable to patients still having their SCS device in place (30.7, CI95% [29.4; 32.1]; Diff = 0.4, CI95% [-3.5; 4.4], $p = 0.83$). There was no association between PCS scores and time to explantation among the 32 patients undergoing permanent explantation with median treatment duration being 1.8 years (figure 3).

DISCUSSION

Key results and interpretation

The objective of this study was to evaluate the relation between baseline PCS scores and SCS outcomes through a multicenter open cohort design of 259 patients with a maximum follow-up of nine years. We found no associations between baseline PCS scores and PGIC ratings, pain relief, cessation of pain medication or risk of undergoing permanent explantation of the SCS system. Thereby, our study lends support to the growing body of research questioning the predictive role of baseline pain catastrophizing in SCS patients [11, 13, 14]. Multiple studies have found that PCS scores correlate well with pain intensity ratings both at baseline and during SCS treatment [13, 24-30]. It is therefore possible that PCS scores should be considered an important supplementary outcome measure aiding in the evaluation of SCS treatment [31]. *Lame et al.* hypothesized that the lack of predictive value of PCS may result from high baseline PCS scores in SCS patients [11]. Indeed, in most studies, mean PCS scores are about 30 or beyond, corresponding to the 75 % percentile in the development work of the PCS scale [10]. They further speculated that the longevity of the pain condition in combination with multiple failed treatments may have induced a high level of catastrophic thinking in otherwise non-catastrophizing patients [11]. This theory may explain the correlation between changes in PCS scores and pain intensity scores during SCS treatment.

Choice of outcome measures

The outcome measurements were chosen on basis of recommendations from the "Initiative on Methods, Measurement, and Pain Assessment in Clinicals Trials" (IMMPACT) working group [32-34]. They recommend the use of PGIC for outcome assessment as it provides the patient with an opportunity to aggregate all relevant components of their experience with the treatment into one overall measure.

For reductions in pain intensity scores, the IMMPACT working group also suggests using a 30 % cut-off value reflecting a moderate reduction and a 50 % cut-off value corresponding to a substantial reduction. In addition, this approach allows for comparison with other studies assessing pain relief in SCS patients.

In clinical pain trials, consumption of rescue treatment and change in concurrent pain treatment are often used as outcome measures [35]. Therefore, we included an assessment of change in pain medication during SCS treatment. Although scales for quantifying total change in medication usage in chronic pain populations exist [36], they are not recommended by the IMMPACT working group, as the psychometric properties of these scales are not well established [33]. Consequently, we only assessed complete cessation in the use of analgesic agents from three pain medication classes (tricyclic antidepressants, antiepileptics and opioids). Agents from these pain medication classes demonstrate a high rate of side effects and may therefore severely impact the lives of patients. Since we did not employ a scale specifically validated for measuring change in pain medication usage, the results of these tests should be interpreted with caution.

We assessed the risk of undergoing permanent explantation of the SCS system as an indication of treatment failure. Hypothetically, some patients experiencing treatment failure could still have their SCS device in place. However, the number of these patients is judged to be low as each of the participating implanting centers make an active effort to explant patients no longer using their systems. Thus, we argue that the included outcome analyses are highly relevant and recommended for studies of SCS patients.

Study limitations

The follow-up interval varied between the participating implanting centers. In addition, a significant proportion of patients had missing outcome measurements at the fixed follow-up intervals. Hence, we chose to include only the latest follow-up registrations in the main analyses. This could give rise to concerns regarding the

internal validity of our study. Firstly, one could speculate that there might be a difference in follow-up duration between patients with a high versus a low baseline PCS score, potentially introducing bias. To assess this concern, we plotted the association between baseline PCS scores and time to latest follow-up measure (Figure 3). These plots showed no such association, making this bias unlikely. Secondly, in some patients, the effect of SCS has been shown to attenuate over time [37]. Hence, may be hypothesized that the predictive power of baseline PCS scores is more prominent in the early phases of SCS treatment. To attend this issue, we performed subgroup analyses of yearly follow-up measurements. Overall, these sub-group analyses also failed to demonstrate any predictive value of baseline PCS scores.

The proportion of eligible patients omitted from each analysis was 29 % (PGIC), 32 % (Reduction in pain intensity) and 27 % (Cessation of pain medication). It might be suggested, that these patients have a pain catastrophizing score different from the rest of the population. However, the mean baseline PCS score of patients omitted from the analyses were comparable with included patients (data not shown).

We considered by what means the multiplicity arising from performing multiple tests of significance should be addressed [38]. As our study was explorative rather than confirmatory in nature, we chose not to adjust the significance level of the statistical tests. Therefore, readers should interpret any positive statistical tests with caution as they could merely result from performing multiple statistical tests.

We argue that the findings of this paper are applicable to SCS patients in general. The study included patients from three different implantation centers with a broad range of pain conditions. Both gender and age varied significantly among included patients and the characteristics of patients excluded because of a missing baseline PCS score were comparable with those of included patients (table 3). In addition, the mean PCS score of included patients was 30.4 and thus similar to other published work within the field [13, 24, 26-29].

CONCLUSIONS

This study failed to demonstrate any associations between baseline PCS scores and SCS outcomes defined as PGIC rating, pain relief, cessation of pain medication, and risk of undergoing permanent explantation of the SCS system. The findings of this study do not provide support for withholding SCS therapy in patients with a high baseline level of pain catastrophizing.

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Tables

Table 1. Study eligibility criteria

Inclusion criteria	Exclusion criteria
<ul style="list-style-type: none"> Implanted at the University Hospitals of Aarhus, Odense or Aalborg, Denmark Implanted with a full SCS system (lead(s) and IPG) Completion of the Pain Catastrophizing Scale before first implantation 	<ul style="list-style-type: none"> Failed trial (no permanent implantation) Concurrent treatment with DRG, ITDD, PNS or PNfS

Table 1. DRG, Dorsal root ganglion stimulation; ITDD, Intrathecal drug delivery; PNS, Peripheral nerve stimulation; PNfS, Peripheral nerve field stimulation.

	Baseline PCS scores				Missing PCS scores (n = 255)
	PCS < 22 (n = 61)	22 ≥ PCS < 31 (n = 64)	31 ≥ PCS < 39 (n = 67)	PCS ≥ 39 (n = 67)	
Gender (%):					
Male	23 (38 %)	35 (55 %)	43 (64 %)	35 (52 %)	145 (57 %)
Female	38 (62 %)	29 (45 %)	24 (36 %)	32 (48 %)	110 (43 %)
Mean age (SD):	53.2 (11.0)	53.0 (11.2)	54.1 (14.2)	53.8 (12.4)	56.1 (13.4)
Mean age at first implant (SD):	48.5 (12.0)	49.8 (10.5)	50.0 (13.2)	50.7 (13.0)	48.7 (12.7)
Implanting center (%):					
Aarhus	28 (46 %)	31 (48 %)	32 (48 %)	29 (43 %)	99 (39 %)
Odense	14 (23 %)	15 (23 %)	11 (16 %)	23 (34 %)	85 (33 %)
Aalborg	19 (31 %)	18 (28 %)	24 (36 %)	15 (23 %)	71 (28 %)
Trial method:					
On-table trial	38 (62 %)	43 (67 %)	41 (61 %)	47 (70 %)	177 (69 %)
Conventional trial	23 (38 %)	21 (33 %)	26 (39 %)	20 (30 %)	78 (31 %)
Implanting method:					
Percutaneous	58 (90 %)	62 (97 %)	66 (99 %)	67 (100 %)	233 (91 %)
Surgical	3 (10 %)	2 (3 %)	1 (1 %)	0 (0 %)	22 (9 %)
Time since first implant - Median years (IQR):	4.3 (2.1-7.3)	3.7 (2.1-5.7)	3.9 (2.0-7.7)	2.7 (1.1-5.6)	7.0 (4.1-8.6)
Main implanting indication (%):					
Complex regional pain syndrome	10 (16 %)	11 (17 %)	11 (16 %)	11 (16 %)	28 (11 %)
Failed back surgery syndrome	32 (52 %)	30 (47 %)	21 (31 %)	29 (43 %)	74 (29 %)
Back/Radicular back pain (no surgery)	4 (7 %)	5 (8 %)	2 (3 %)	3 (4 %)	13 (5 %)
Neuropathy	11 (18 %)	10 (16 %)	20 (30 %)	17 (25 %)	53 (21 %)
Post-amputation pain	2 (3 %)	1 (2 %)	3 (4 %)	0 (0 %)	9 (4 %)
Other*	2 (3 %)	6 (9 %)	4 (6 %)	4 (6 %)	23 (9 %)
Unknown	0 (0 %)	1 (2 %)	6 (9 %)	3 (4 %)	55 (22 %)
Total number of implanted leads (%):					
1	33 (54 %)	32 (50 %)	39 (58 %)	36 (54 %)	136 (53 %)
2	22 (36 %)	25 (39 %)	21 (31 %)	29 (43 %)	75 (29 %)
3	5 (8 %)	6 (9 %)	6 (9 %)	2 (3 %)	22 (9 %)
4+	1 (2 %)	1 (2 %)	1 (2 %)	0 (0 %)	22 (9 %)
	(n = 43)	(n = 48)	(n = 49)	(n = 37)	(n = 89)
Mean pain intensity score at baseline (SD):	6.9 (1.2)	6.9 (1.7)	7.3 (1.6)	7.8 (1.6)	7.1 (1.7)
Pain onset to first implant – Median years (IQR):	(n = 48) 5.2 (2.5-7.6)	(n = 55) 5.0 (2.3-10)	(n = 43) 5.0 (2.8-9.0)	(n = 54) 6.0 (2.9-10.2)	(n = 139) 5.1 (3.0-9.0)
Usage of pain medication at baseline (%):	(n = 47)	(n = 51)	(n = 50)	(n = 40)	(n = 117)
Tricyclic antidepressants					
Users at baseline	9 (19 %)	12 (24 %)	12 (24 %)	11 (28 %)	25 (21 %)
Non-users at baseline	38 (81 %)	39 (76 %)	38 (76 %)	29 (72 %)	92 (79 %)
Anticonvulsants					
Users at baseline	25 (53 %)	27 (53 %)	26 (52 %)	22 (55 %)	70 (60 %)
Non-users at baseline	22 (47 %)	24 (47 %)	24 (48 %)	18 (45 %)	47 (40 %)
Opioids					
Users at baseline	31 (66 %)	34 (67 %)	29 (58 %)	29 (73 %)	75 (64 %)
Non-users at baseline	16 (34 %)	17 (33 %)	21 (42 %)	11 (27 %)	42 (36 %)
Cardiovascular disease (%):					
Yes	3 (5 %)	9 (14 %)	7 (11 %)	6 (9 %)	27 (11 %)
No	39 (58 %)	41 (64 %)	33 (49 %)	44 (66 %)	87 (34 %)
Unknown	19 (28 %)	14 (22 %)	27 (40 %)	17 (25 %)	141 (55 %)
Psychiatric disease (%):					
Yes	1 (2 %)	4 (6 %)	6 (9 %)	8 (12 %)	12 (5 %)
No	37 (61 %)	40 (63 %)	33 (49 %)	41 (61 %)	94 (37 %)
Unknown	23 (37 %)	20 (31 %)	28 (42 %)	18 (27 %)	149 (58 %)

Table 2. Patient characteristics with patients grouped into quartiles using baseline PCS scores. Characteristics of patients without a baseline PCS score is included in the left column for comparison. Missing values are indicated in a separate category for categorical variables and with number of patients included in the calculation of the mean or median value for continuous variables. *Angina pectoris (n=17), medullar lesion (n=6), pain from surgery, not FBSS (n=2), visceral pain (n=5), pain from trauma (back/extremities) (n=3), peripheral vascular disease (n=2), migraine (n=2), coccydynia (n=1), Von Hippel-Lindau Disease (n=1).

Table 3. Analgesic agents used by included patients

Pain medication class	Agents from pain medication class
Tricyclic antidepressants (TCA)	Amitriptyline, clomipramine, imipramine, nortriptyline
Antiepileptics (AED)	Carbamazepine, gabapentin, lamotrigine, oxcarbazepine, pregabalin, topiramate, valproate
Opioids	Buprenorphine, codeine, fentanyl, hydromorphone, ketobemidone, methadone, morphine, nicomorphine, oxycodone, pethidine, tapentadol, tramadol

Table 3. Detailed data of pain medication usage of included patients. Only agents from the three selected pain medication classes are shown. Each agent is presented by its generic name.

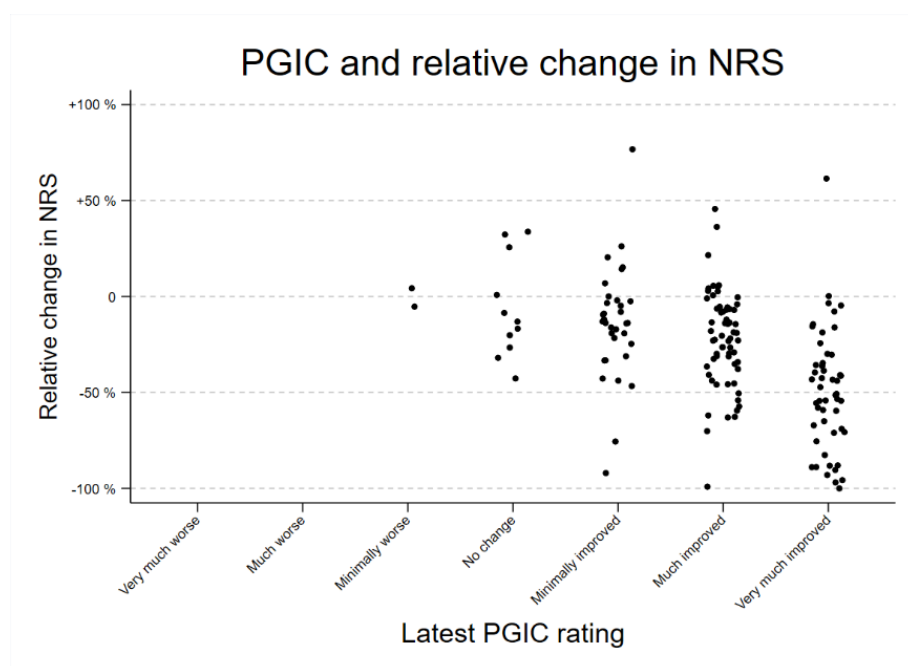
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Figure 1. Selection of included patients and data analysis workflow. DRG, Dorsal root ganglion stimulation; ITDD, Intrathecal drug delivery; PNS, Peripheral nerve stimulation; PNfS, Peripheral nerve field stimulation.

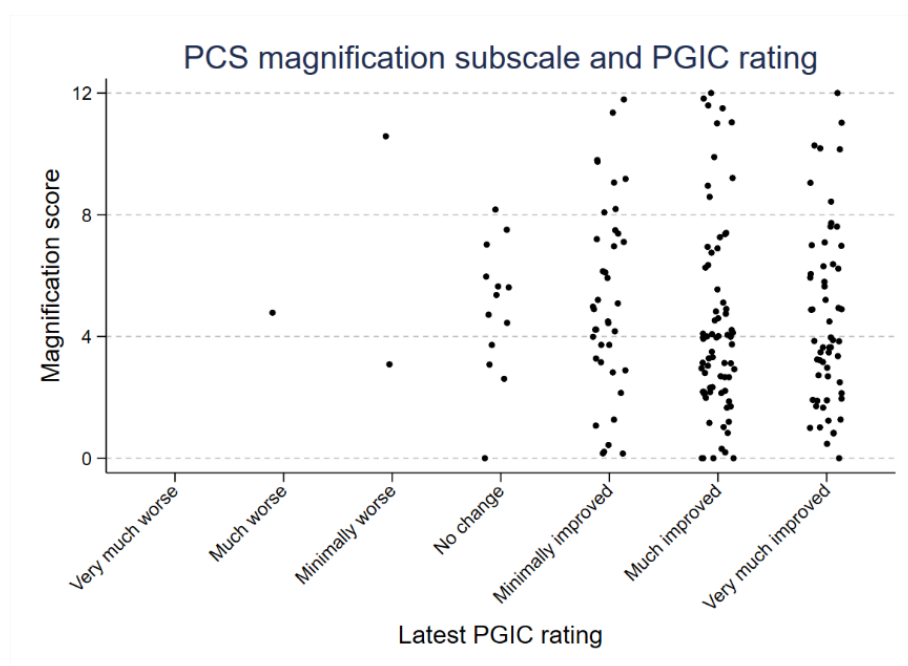
Figure 2. Scatterplots of baseline PCS scores grouped according to the treatment outcome in question. Each gray dot represents a patient, black lines mark the group mean and CI95%. For exact numbers of patients and mean PCS scores within each category see Results section. **A:** Patients' global impression of change rating. One hundred eighty-eight patients had a registered latest PGIC rating. A One-way ANOVA demonstrated no difference in mean PCS scores between PGIC groups ($p=0.80$). **B:** Reduction in pain intensity. One hundred seventy-seven patients were included in the analysis of reduction in pain intensity. Patients were grouped into those obtaining at least 30 % reduction in pain intensity on the latest pain intensity score compared with their baseline score and those not perceiving such high pain relief. Eighty patients obtained at least 30 % pain relief, while 94 patients did not ($p=0.40$). Patients were regrouped with 50 % pain relief as cut-off. Here, forty-four patients obtained 50 % pain relief while 133 did not ($p=0.60$). **C:** Cessation of pain medication. 44 patients were using tricyclic antidepressants (TCA) at baseline. Twenty-six patients continued consuming TCA agent(s) during SCS treatment, while 18 ceased all usage of TCA agents ($p=0.94$). One hundred patients consumed antiepileptics (AED) at baseline. Seventy-four sustained usage of antiepileptics during SCS, while 26 ceased usage of all antiepileptics ($p=0.34$). One hundred twenty-three patients consumed opioids at baseline. Ninety-one continued to consume opioids during SCS treatment, while 32 ceased usage of all opioids ($p=0.95$). **D:** Risk of permanent explantation. Thirty-two patients underwent a permanently explantation of their SCS device during follow-up, 227 patients did not ($p=0.83$).

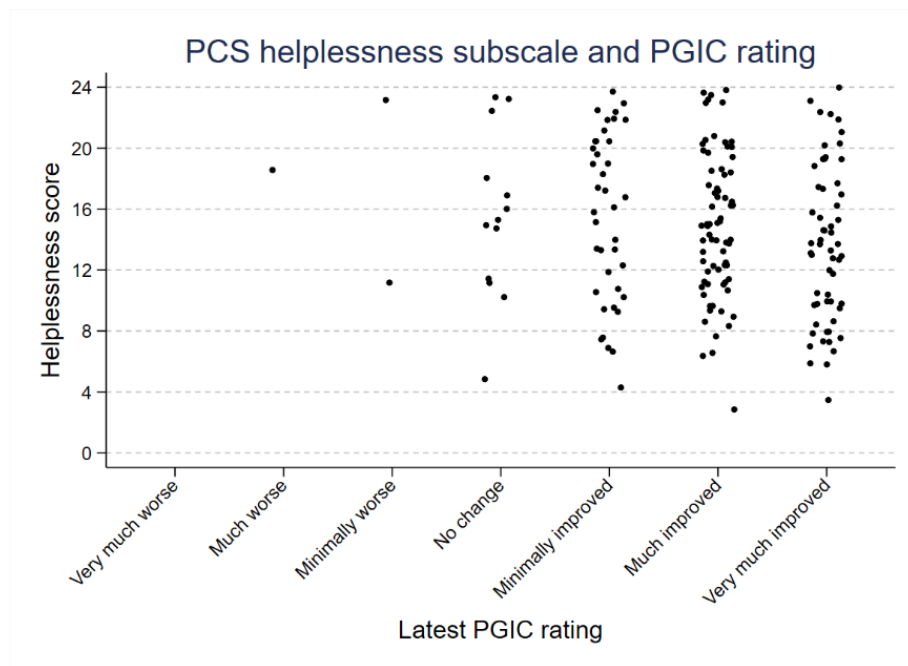
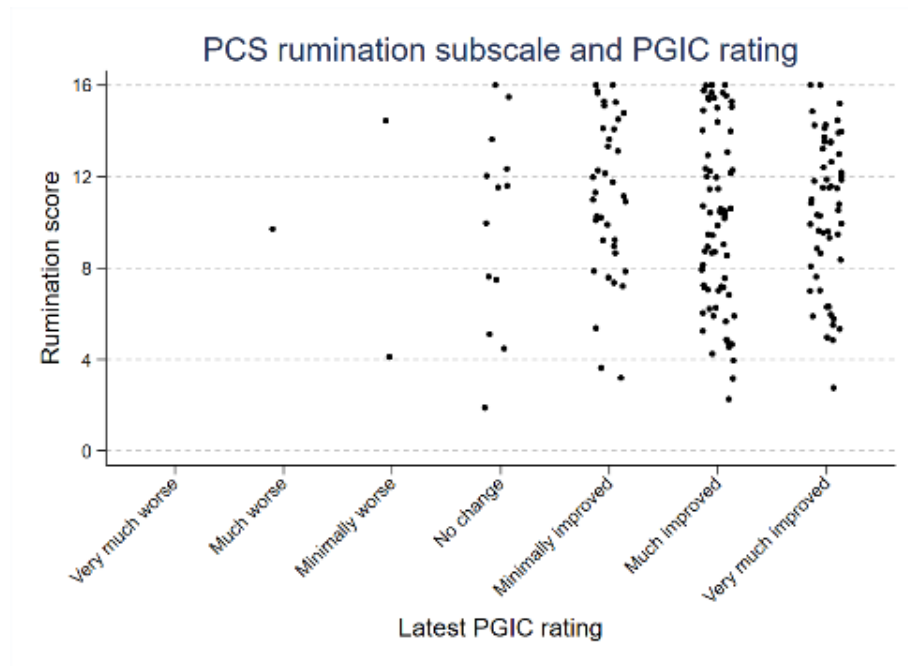
Figure 3. Scatterplots of the association between latest follow-up measurement and baseline PCS score. Each gray circle represents a patient, black dashed lines illustrate the criteria of at least six months follow-up. Median (IQR) of the follow-up duration is shown in the graph. **A.** Latest follow-up of the 185 patients included in the PGIC analysis. **B.** Latest follow-up of the 177 patients included in the analysis of reduction in pain intensity. **C.** Latest follow-up of the 188 patients included in the analysis of cessation of pain medication. **D.** Time to explantation in the 32 permanently explanted patients.

Correlation of latest PGIC rating and change in NRS score



Post hoc analysis of PCS subscales and latest PGIC rating





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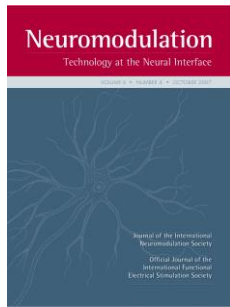
Mr. Poulsen, Dr. Meier, Prof. Nikolajsen and Prof. Soerensen designed the study. Dr. Blichfeldt-Eckhard, Dr. Gulisano, Dr. Meier, Prof. Soerensen and Mrs. Knudsen helped with acquisition of data. Analysis of data was performed by Mr. Poulsen and Dr. Meier. Mr. Poulsen prepared the manuscript draft with important intellectual input from Dr. Meier and Prof. Soerensen. Mrs. Knudsen, Dr. Blichfeldt-Eckhard, Dr. Gulisano and Prof. Nikolajsen reviewed it critically. All authors approved the final manuscript. The Lundbeck Foundation provided funding for the study.

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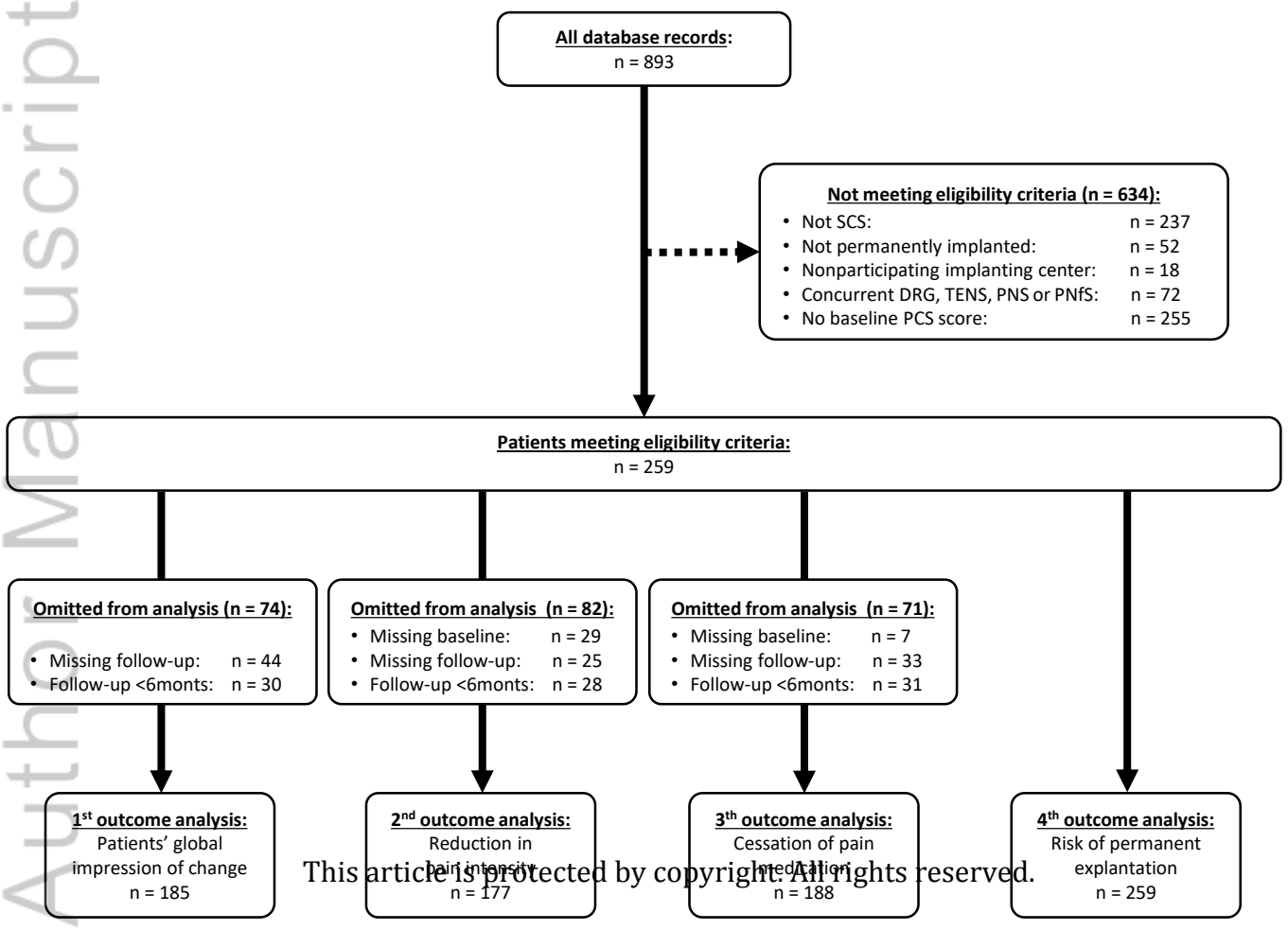
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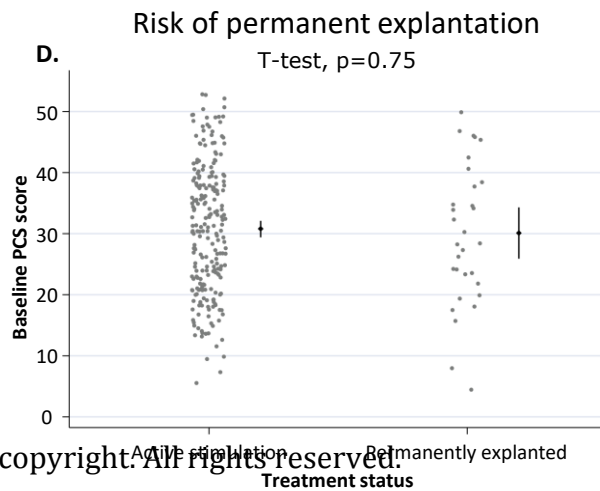
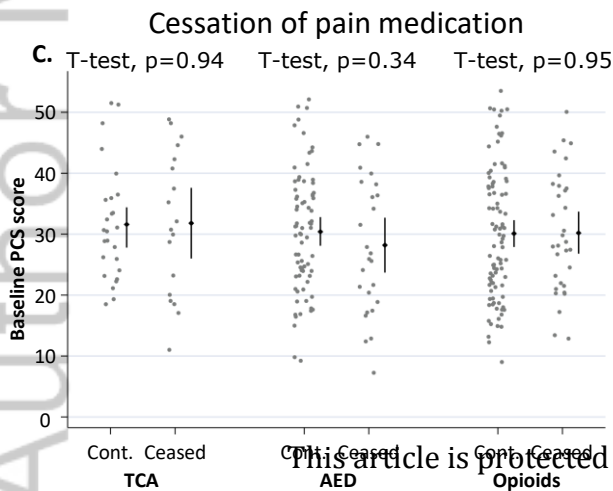
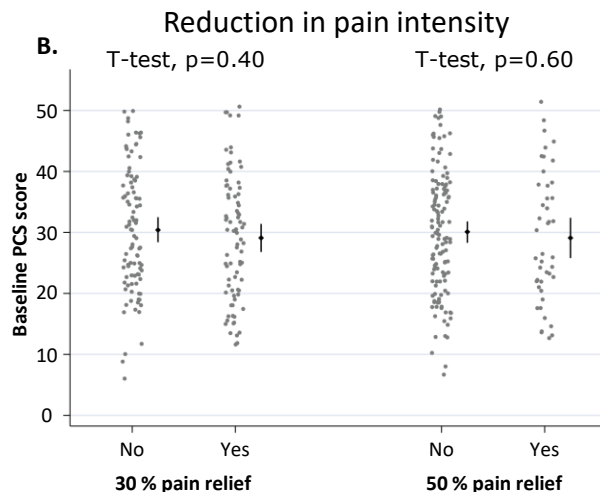
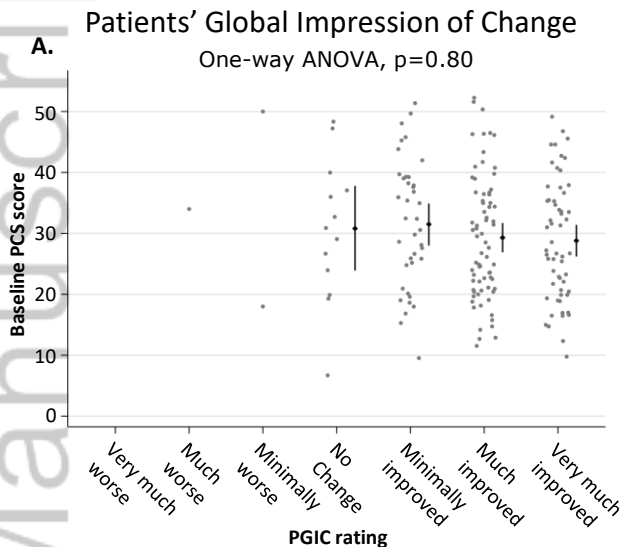
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Association of baseline PCS scores and treatment outcomes



Association of baseline PCS scores and latest follow-up

