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Retrospective Study

# The Impact of Psychological Factors on Outcomes for Spinal Cord Stimulation: An Analysis with Long-term Follow-up

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**Background:** For more than 3 decades, spinal cord stimulation (SCS) has successfully been employed to treat neuropathic pain. Psychological factors are assumed to be important for the efficacy of SCS. However, the impact of psychological factors on the outcome of SCS has only rarely been studied.

**Objectives:** The aim of this study was to determine the influence of psychological factors such as anxiety and depression, perceived disability, and self efficacy on the outcome of SCS in a representative clinical sample.

**Study design:** Retrospective study.

**Setting:** Academic university interdisciplinary pain center.

**Methods:** We reviewed the records of 60 consecutive patients who had been treated at our institution with lumbar, thoracic, or cervical neurostimulators between July 1, 2008, and June 30, 2012. Information with respect to age, gender, diagnosis, age at time of implantation, disease duration, the preoperative Hospital Anxiety and Depression Test, German Version (HADS-D), the Pain Disability Index (PDI) and preoperative pain scores on an 11 point Numeric Rating Scale (NRS) were recorded. In addition, a questionnaire was mailed to participants that contained the following items: pain scores on the NRS with and without stimulation, time intervals of stimulation, paresthesia coverage, treatment satisfaction and medication intake, anxiety/depression (HADS-D and Beck Depression Index II [BDI-II]), PDI, and self efficacy using the Fragebogen zur Erfassung der schmerzspezifischen Selbstwirksamkeit (FESS).

**Results:** Preoperative HADS-D, PDI, and NRS pain scores were not different in those patients with an unsuccessful trial and those who underwent IPG implantation. Long-term outcomes were not affected by pre-implantation HADS-D or PDI scores. FESS scores showed a strong inverse correlation with HADS-D, BDI-II, and PDI scores and showed a tendency towards correlation with the percentage of pain reduction. HADS-D and PDI scores improved after SCS therapy.

**Limitations:** Retrospective study.

**Conclusion:** The outcome of SCS therapy could not be predicted on the basis of tested psychological factors anxiety/depression and pain-related disability. FESS correlated inversely with HADS-D, BDI-II, and PDI scores and showed a tendency towards correlation with the percentage of pain reduction. Further research is needed to define the impact of psychological factors on SCS outcomes.

**Key words:** Spinal cord stimulation, clinical efficacy, paresthesia, psychological factors, anxiety, depression, disability, self-efficacy

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Spinal cord stimulation (SCS) has been successfully used in the treatment of chronic pain syndromes for more than 3 decades (1-3). Successful outcomes have been reported for neuropathic pain syndromes such as failed back surgery syndrome (FBSS) (1-2,4-6), complex regional pain syndrome (CRPS) (7-9), and post-herpetic neuralgia (PZN) (10-11). Also in vasculopathic diseases, such as angina pectoris (12) and peripheral vascular disease (13), the clinical efficacy of SCS has been reported. In a retrospective single-center study the efficacy was maintained over several years (6). A review on SCS therapy of 49 studies reporting a long-term (> 6-month) success rate with implanted impulse generators (IPG) showed success rates of 57% in patients with spinal cord injury, 62% in patients with FBSS, and 83% in patients with CRPS (3). It is clear that there are inter-individual differences in SCS efficacy. While some of these differences might be explained by biomechanical factors (i.e., lead location), psychological factors have also been thought to explain variances in SCS outcome. In a recent review on psychological determinants of outcome for SCS, depression was identified as a factor that reduced the efficacy, but was also noted as a characteristic that can improve under SCS therapy (14).

Neuropathic pain is the most frequent indication for SCS therapy. One quality of neuropathic pain that can make it particularly troublesome for patients is spontaneous neuralgiform occurrence of pain (15), which, in contrast to load dependant pain, impedes the patients' ability to regulate their pain level with pain-adapted behaviour (i.e., to avoid painful movements). In our clinical experience the use of SCS often allows for patients to take action against their pain for the first time, thus enabling them to experience a sense of self-efficacy. In particular, the impact of perceived self-efficacy on the outcome of SCS therapy has not yet been reviewed in the literature.

The aim of our study was to determine how the outcome of SCS is affected by pre-existing anxiety/depression and/or pain-related disability. In addition, we wanted to ascertain if high perceived self-efficacy with SCS therapy is associated with improved outcome, particularly in patients performing intermittent stimulation.

## Methods

### Patients

The ethics committee of our institution approved this study. All patients who had been treated at our institution between July 1, 2008, and June 30, 2012, were eligible for the study if they presented for a SCS trial, a new implant, or for adjustment of a pre-existing SCS device (such as reprogramming, electrode revision, or IPG{sp} change). Prior to the SCS trial, a psychological examination had been performed in all these patients to rule out major psychiatric disorders.

A retrospective chart review was conducted with regard to personal data, diagnoses, duration of disease, dates of electrode and IPG implantation, pre- and post-operative pain-scores on an 11 point (0 - 10) numeric rating scale (NRS), preoperative duration of disease, the preoperative Hospital Anxiety and Depression Test, German Version (HADS-D) scores and the preoperative Pain Disability Index (PDI) scores. In addition, a questionnaire was sent to patients who had been implanted with an IPG and actually continued SCS therapy. The questionnaire contained the following items: pain scores on the NRS with and without stimulation, time intervals of stimulation, paresthesia coverage, treatment satisfaction and medication intake, anxiety/depression (HADS-D and Beck Depression Index II [BDI II]), PDI, and self-efficacy as measured using a slightly modified Fragebogen zur Erfassung der schmerzspezifischen Selbstwirksamkeit (FESS) (16), a German adaptation of the Pain Self-Efficacy Questionnaire (PSEQ) (17).

### Statistical Analysis

A computer software package (GraphPad Prism, Version 5.01, GraphPad Software, Inc. La Jolla, California, USA) was used to conduct the statistical analyses. Descriptive statistics were initially applied to all measures. To calculate the statistical significance of the differences a paired or an unpaired t-test was used when the observation followed a Gaussian distribution. In measures that did not follow a Gaussian distribution, the Wilcoxon matched pairs test or the Mann-Whitney U test was used depending on whether the measure was paired. A $P < 0.05$ was considered to be statistically significant. Depending on whether the variables followed a Gaussian distribution, Spearman or Pearson correlations were calculated.

## Results

### Patient Characteristics

Of the 46 evaluable patients, 37 (80.4%) completed the follow-up questionnaire (23 women and 14 men) (Fig. 1). In these patients the mean age at the time of implant was 52.7 years (range 33.4 – 74.7 years, stan-

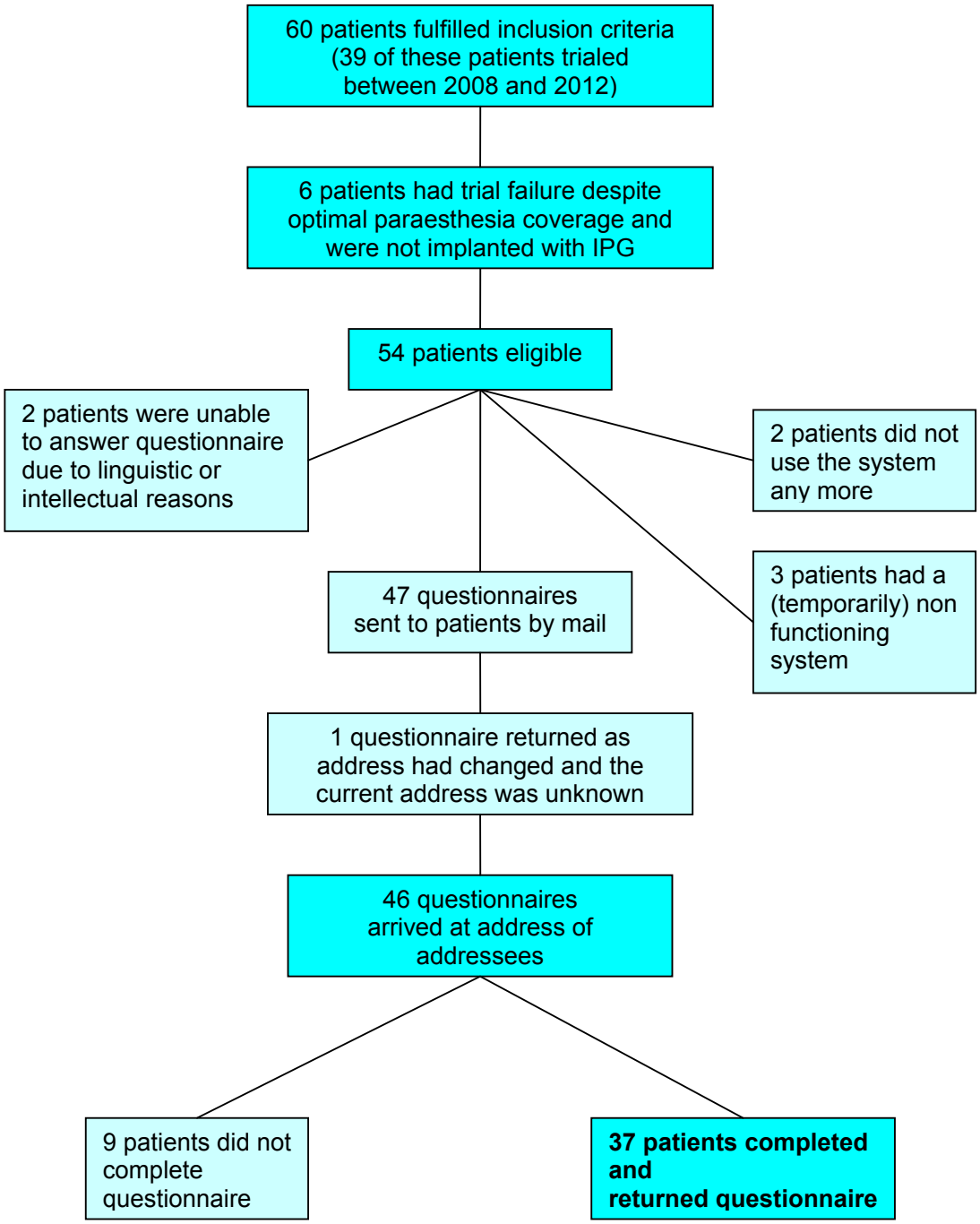



*Fig. 1. Analysis of patients eligible for the study.*

dard deviation [SD] 11.4 years). At the time of completing the questionnaire, the mean age was 57.5 years (range 34.5 - 77.3 years, SD 10.6 years). The average time that had elapsed since IPG implantation was 4.8 years (range 0.1 - 14.5 years, SD 4.3 years). At the time of implantation the average duration of pain had been mean 7.5 years (range 0.8 – 27.9 years, SD 6.2 years). Sixteen patients had FBSS, 8 had peripheral neuropathic pain, 5 had peripheral arterial occlusive disease (PAOD), 4 had CRPS, 3 had chronic cluster headache (CCH), and one had angina pectoris (AP). Lead location was cervical in 11 patients, thoracolumbar in 24 patients, thoracic in one patient, and combined cervical and thoracolumbar in one patient.

During the inclusion period (July 1, 2008 to June 30, 2012) 6 patients had an unsuccessful SCS trial. These patients had a mean age of 50.6 (range 35.6 – 62.1 years, SD 11.8) years and a mean duration of pain of 7.86 years (range 2.1 – 25.1 years, SD 8.6 years). These values were not significantly different from patients with successful trials, either from the whole patient group or from those patients (n = 22) who had been implanted during the inclusion period. Five of the 6 patients had received thoracolumbar electrodes for FBSS, while one patient had received a cervical electrode for occipital (post craniotomy) headache (Table 1).

## Pain Scores Prior to SCS Implantation and at the Time of Follow-up (After SCS Implantation)

Prior to SCS implantation, in the 37 patients studied, the average mean pain intensity on the NRS was 7. 4 (range 4 – 10, SD 1.7). Average maximal pain intensity on the NRS was 9.2 (range 6 – 10, SD 1.1), and average

*Table 1. Characteristics of patients with successful and unsuccessful trial.*

| | Patients with a successful trial and IPG implant | Patients with an unsuccessful trial |
|---|---|---|
| Gender | 23 f / 14 m | 4 f / 2 m |
| Age * | 52.8 (11.4) | 50.6 (11.9) |
| Time since pain onset* | 7.5 (6.2) | 7.9 (8.6) |
| **Diagnoses** | | |
| FBSS[1] | 16 | 5 |
| Peripheral neuropathy | 8 | |
| CRPS[2] | 4 | |
| Headache | 3 | 1 |
| PAOD[3] | 5 | |
| Angina Pectoris | 1 | |
| **Lead location** | | |
| Thoracolumbar | 24 | 5 |
| Thoracic | 1 | |
| Cervical | 11 | 1 |
| Thoracolumbar and cervical | 1 | |
| **Pain on the NRS**** | | |
| Mean | 7.2 (1.6) | 8.1 (2.4) |
| Maximal | 9.2 (1.1) | 9.2 (1.2) |
| Minimal | 4.4 (3.1) | 5.2 (3.4) |
| **Anxiety / Depression**** | | |
| HADS-A | 8.6 (5.3) | 9.5 (6.2) |
| HADS-D | 9.8 (5.5) | 9.5 (5.2) |
| HADS total | 18.5 (0.5) | 19.0 (11.1) |
| **Perceived Pain related Disability**** | | |
| PDI | 44.2 (13.9) | 41.8 (19.8) |

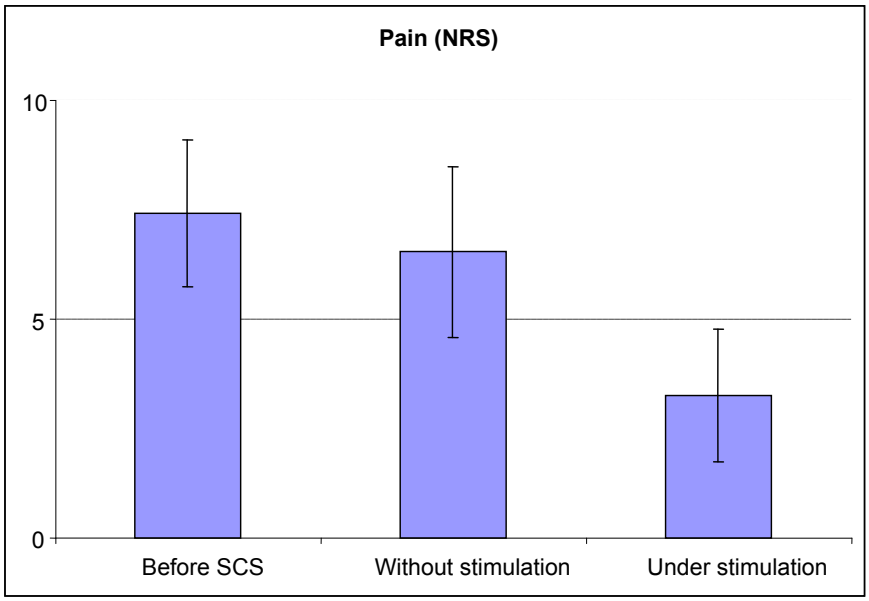
*at time of trial, **prior to trial, [1]failed back surgery syndrome, [2]complex regional pain syndrome, [3]peripheral arterial occlusive disease

minimal pain intensity was 4.5 (range 0 – 10, SD 3.1).

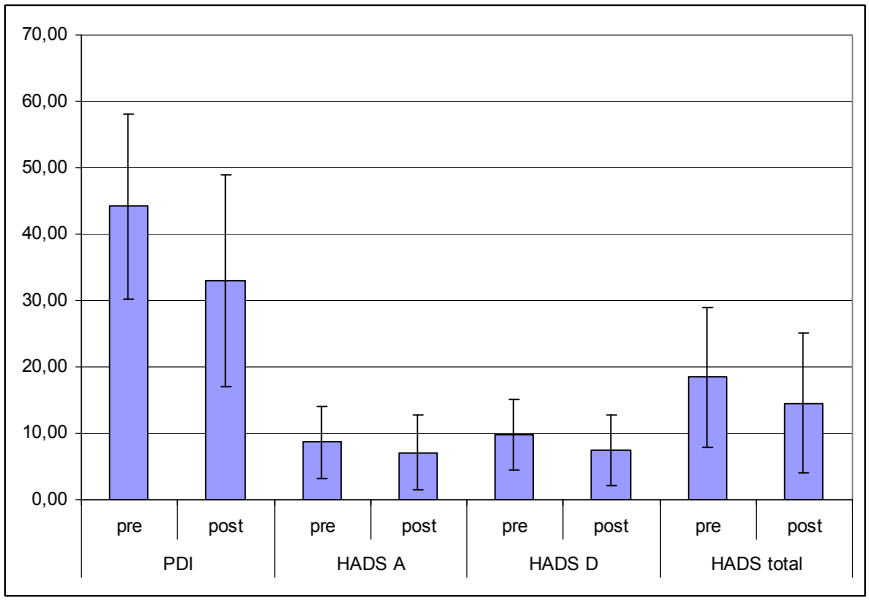
On the follow-up questionnaire, these patients reported an average mean pain intensity without neurostimulation (NRS) of 6.5 (range 1 – 10, SD 1.9). Maximal pain intensity averaged 8.0 (range 2 – 10, SD 1.7) and mean minimal pain intensity was 4.7 (range 0 – 10, SD 2.6).

During SCS, the average pain scores decreased to a mean pain intensity of 3.3 (range 0–- 6, SD 1.5), while the maximal pain score decreased to 4.4 (range 1 – 10, SD 2.0), and the minimal pain score decreased to 2.2 (range 0 – 5, SD 1.5) (Fig. 2a).

There was no statistically significant difference in




A.




B,

Fig. 2. *A. NRS scores before SCS implantation and after SCS implantation with and without stimulation. B. PDI scores, HADS A (anxiety), HADS D (depression) and HADS total scores before and after SCS implantation.*

preoperative NRS pain scores between those patients with a successful SCS trial and those with an unsuccessful trial. Also, no statistically significant difference could be found when this analysis was limited to only those patients who had been implanted between July 1, 2008, and June 30, 2012.

In addition, there was no statistically significant correlation between the duration of SCS therapy (years since IPG implantation) and the mean decrease in NRS scores elicited by stimulation or the mean NRS scores under stimulation (r (35) = 0.1910, $P = 0.2574$ and r (35) = -0.1789, $P = 0.2895$, respectively). However, there was a significant difference between NRS scores prior to SCS implantation and NRS scores without stimulation, as assessed by the questionnaire ($P = 0.0121$, paired t-test).

When comparing NRS scores prior to SCS implantation with those during stimulation, 24 of 37 patients (64.9%) had a decrease in pain of 50% or more, 6 patients (16.2%) had a decrease in pain of 75% or more and 4 patients (10.8%) had a decrease of less than 25%. The average reduction in pain intensity was 54.1%. Patients were divided into those who had a pain reduction of less than 50% and greater than 50%. There was no statistically significant difference between the successful and unsuccessful groups in terms of preoperative pain on NRS, but the preoperative mean pain rating showed a tendency towards significance with 7.8 (SD 1.6) in the successful group compared to 6.7 (SD 1.7) in the unsuccessful group. The characteristics of patients and factors influencing outcome in these 2 groups are noted in Table 2.

## Stimulation Mode

Of the patients, 25 performed continuous stimulation, while 12 patients performed intermittent stimulation. There were no statistically significant differences in NRS scores, HADS, FESS, and PDI values between patients who performed intermittent and continuous stimulation.

## Medication Intake

Nonsteroid anti-inflammatory drugs (NSAIDs) were taken by 14 (38%) of the patients, 7 (19%) took weak opioids, 16 (43%) took strong opioids, 5 (14%) took muscle relaxants, 10 (27%) took anticonvulsants or antidepressants, and 5 (14%) patients took other pain medications. Six patients (16%) did not take any pain medication. Ten (27%) of the patients took a single medication, 11 (30%) took 2 different medications, and 10 (27%) took 3 or more different medications.

## Unpleasant Side Effects, Paresthesia Coverage, and Patient Satisfaction

Four patients (11%) reported pain at the IPG site or unwanted stimulation as adverse side effects. Three patients had pain at the electrode site, 2 patients reported pain both at the pocket site and at the electrode site, and one patient had pain at the electrode site and unwanted paresthesia. Twenty-three patients (62%) reported that they had had no unpleasant side effects. Twenty patients (54%) reported incomplete paresthesia coverage (often in the low back or in the leg), while it was complete in 17 patients (46%).

Seventeen patients were "very content" with SCS, 18 patients were "content," and 2 patients were "undecided." No patient was "discontent" or "very discontent" with SCS. Thirty-six patients (97%) stated that they would undergo SCS implantation again, while one patient would not.

## Pain-related Disability Before and After SCS Implantation

Prior to SCS implantation the mean score for perceived pain-related disability was 44.2 (range 12 – 67, SD 13.9) as measured by the PDI. In the postoperative questionnaire, the PDI score was 33.0 (range 2 – 63, SD 15.9) (Fig. 2b). This difference was statistically highly significant ($P < 0.001$, paired t-test). The respective pre- and postoperative values for the single items were 7.4 and 5.5 for "familiar and domestic duties," 7.8 and 5.5 for "recreation," 7.1 and 4.7 for "social activities," 8.0 and 5.6 for "profession," 5.8 and 6.1 for "sexual life," 5.2 and 3.1 for "self supply," and 4.7 and 3.1 for "vitally indispensable activities." With the exception of "sexual life," these differences were statistically significant ($P < 0.05$).

There was no statistically significant difference in preoperative PDI scores in those patients with successful and unsuccessful SCS trials.

## Depression Scores Before and After SCS Implantation

The mean HADS anxiety subscores were 8.6 (range 2 - 20, SD 5.5) before SCS implantation and decreased to 7.1 (range 1 - 21, SD 5.6) after SCS implantation. This difference was not statistically significant ($P = 0.1365$, Wilcoxon signed rank test).

Mean HADS depression subscores decreased from 9.8 (range 1 – 19, SD 5.3) prior to SCS implantation to 7.4 (range 1 – 19, SD 5.3) after implantation (difference statistically significant, $P = 0.0053$, paired t-test). In ad-

Table 2. *Characteristics of patients with < and > 50 % pain reduction.*

| | **Patients with ≥ 50 % pain reduction** | **Patients with < 50 % pain reduction** | ***p*** |
|---|---|---|---|
| Gender | 12 m / 12 f | 2 m / 11 f | |
| Age* | 54.0 (12.9) | 50.5 (7.9) | 0.3861 |
| Time since pain onset* | 6.4 (5.4) | 9.3 (7.5) | 0.3010 |
| **Diagnose** | | | |
| FBSS[1] | 10 | 6 | |
| Peripheral neuropathy | 7 | 2 | |
| CRPS[2] | 2 | 2 | |
| Headache | 1 | 2 | |
| PAOD[3] | 3 | 1 | |
| Angina Pectoris | 1 | | |
| **Lead location** | | | |
| Thoracolumbar | 15 | 9 | |
| Thoracic | 1 | | |
| Cervical | 7 | 4 | |
| Thoracolumbar and cervical | 1 | | |
| **PRE-SCS** | | | |
| Pain on the NRS* | | | |
| Mean | 7.8 (1.6) | 6.7(1.7) | 0.0713 |
| Maximal | 9.5 (0.6) | 8.8 (1.5) | 0.0697 |
| Minimal | 4.9 (3.4) | 3.8 (2.6) | 0.3809 |
| **Anxiety / Depression*** | | | |
| HADS-A | 9.3 (5.0) | 7.7 (6.3 | 0.4393 |
| HADS-D | 10.2 (4.9) | 9.2 (6.1 | 0.6330 |
| HADS total | 19.5 (9.6) | 16.9 (12.0) | 0.5186 |
| **Perceived Pain related Disability*** | | | |
| PDI | 45.7 (12.2) | 41.7 (16.4) | 0.4357 |
| **POST-SCS** | | | |
| Duration of SCS therapy | 5.3 (4.5) | 3.9 (4.0) | 0.3815 |
| **Pain on the NRS**** | | | |
| Mean | 2.5 (1.2) | 4.6 (1.0) | < 0.0001 |
| Maximal | 3.7 (1.9) | 5.9 (0.9) | 0.0001 |
| Minimal | 1.7 (1.4) | 3.0 (1.6) | 0.0224 |
| **Anxiety / Depression**** | | | |
| HADS-A | 6.4 (5.2) | 8.4 (6.3) | 0.3056 |
| HADS-D | 6.6 (4.5) | 9.0 (6.3) | 0.1875 |
| HADS total | 13.0 (9.3) | 17.4 (12.5) | 0.0006 |
| BDI II | 15.5 (12.0) | 23.3 (19.6) | 0.1437 |
| **Perceived Pain related Disability**** | | | |
| PDI | 29.8 (14.8) | 38.5 (16.9) | 0.1198 |
| **Self efficacy**** | | | |
| FESS | 41.0 (11.9) | 34.2 (14.0) | 0.1276 |

mean values (SD), *prior to IPG implantation, **at time of follow-up (questionnaire), [1]failed back surgery syndrome, [2]complex regional pain syndrome, [3]peripheral arterial occlusive disease

dition, the total HADS showed a statistically significant decrease from 18.5 (range 4 – 37, SD 10.5) to 14.5 (range 1 – 40, SD 10.6) ($P$ = 0.0375, Wilcoxon signed rank test) (Fig. 2b). The mean BDI-II value was 18.1 (range 1 – 59, SD 15.1). BDI-II values correlated strongly with the HADS and PDI scores (r (33) = 0.7147, $P$ < 0.0001 and r (34) = 0.9223, $P$ < 0.0001, respectively). There was no statistically significant difference in preoperative HADS scores between those patients with successful and unsuccessful SCS trials.

### Perceived Pain-related Self-efficacy

The mean score for perceived pain-related self efficacy post-SCS, as measured using the FESS, was 38.6 (range 13 – 67, SD 12.9). FESS showed a strong negative correlation with the HADS (r (34) = -0.7773, $P$ < .0001), the PDI (r (34) = 0.8267, $P$ <.0001), and the BDI- II (r (34) = -0.7680, $P$ < 0.0001).

No correlation was found between the degree of pain relief elicited by SCS (mean pain on the NRS without stimulation - mean pain on the NRS under stimulation) and FESS values (r (34) = -0.1306, $P$ = 0.4477), while a correlation was found between FESS values and mean NRS values under stimulation (r (35) = 0.5334, $P$ < .0009). No differences were found for FESS values between those patients who performed either intermittent or continuous stimulation ($P$ = 0.3999). The percentage of pain reduction showed a tendency towards correlation with FESS values (Table 3).

## Discussion

In the present study, analysis of the pre-implantation data revealed that the tested parameters — depression, anxiety and perceived disability — were no predictors of therapy success with respect to pain reduction, either for the trial outcome or for long-term outcome. This is the first study to examine perceived self-efficacy in the context of SCS. Under SCS, a strong inverse correlation was observed between perceived self-efficacy and anxiety/depression scores as well pain-related disability scores. Of the factors that could influence SCS outcomes, self-efficacy measured post-implantation showed a tendency towards correlation to pain reduction following SCS. Pain scores, depression scores, and pain-related disability, but not anxiety scores, were significantly reduced following SCS therapy.

Psychological testing prior to SCS implantation is recommended by several guidelines for SCS (18-20). Although the recommended psychological exclusion criteria for SCS seem somewhat unclear, there is some agreement that patients with major psychiatric disorders (psychosis, schizophrenia, major depressive disorder, addiction, etc.) should not be subjected to SCS testing, and that psychological testing should rule out these condi-

Table 3. *Correlations between influencing factors and change in pain scores (% pain reduction), change in HADS scores and change in PDI scores*

| Influencing Parameter | | Outcome Parameter | | | | | |
|---|---|---|---|---|---|---|---|
| | | % Pain Reduction | | Change in HADS Score | | Change in PDI Score | |
| | | $r_s$ | $P$ | $r_s$ | $P$ | $r_s$ | $P$ |
| pre SCS | Pain duration prior to SCS implantation | -0.3215 | *0.0523* | -0.06849 | 0.7191 | 0.03887 | 0.8384 |
| | Mean pain intensity | **0.3903** | **0.0169** | -0.1474 | 0.4371 | 0.01560 | 0.9360 |
| | HADS anxiety | 0.2257 | 0.2304 | **-0.3896** | **0.0333** | 0.1405 | 0.4673 |
| | HADS depression | 0.2097 | 0.2661 | *-0.3400* | *0.0660* | 0.04084 | 0.8334 |
| | HADS total | 0.2242 | 0.2337 | **-0.3625** | **0.0490** | 0.02887 | 0.8818 |
| | PDI | 0.04672 | 0.8029 | -0.1099 | 0.5632 | **-0.3987** | **0.0322** |
| post SCS | Duration of SCS therapy | 0.1074 | 0.5271 | 0.2056 | 0.2758 | -0.1296 | 0.4948 |
| | Mean pain intensity | **-0.8735** | **< 0.0001** | 0.2399 | 0.2017 | 0.2379 | 0.2056 |
| | HADS anxiety | -0.1155 | 0.4960 | **0.3885** | **0.0339** | **0.3918** | **0.0323** |
| | HADS depression | -0.2030 | 0.2282 | 0.3522 | 0.0563 | **0.3837** | **0.0363** |
| | HADS total | -0.1627 | 0.3361 | **0.4117** | **0.0238** | **0.3993** | **0.0288** |
| | PDI | -0.2493 | 0.1426 | 0.2409 | 0.2080 | **0.6229** | **0.0002** |
| | BDI II | -0.1567 | 0.3615 | **0.4428** | **0.0162** | *0.3630* | *0.0530* |
| | Self- efficacy | *0.3114* | *0.0606* | -0.3052 | 0.1010 | 0.1786 | 0.3450 |

**bold = statistically significant correlation**. *italic= tendency towards significance*

tions (20). Psychological testing, however, could also identify subclinical psychological conditions which may influence SCS outcome. Thus, it is possible that "relative" psychological recommendations regarding SCS trials may be helpful in improving outcomes (21).

In a recent review, it was noted that psychological factors may account for 25 – 50% of cases of loss of analgesia (14) and it has been further highlighted that research has been focused on operational factors (e.g., lead positioning, electrical parameters, and complications). In the present study, the overall efficacy of SCS was not significantly decreased in patients whose implant had been maintained for many years, which suggests that loss of analgesia did not play a large role in our sample. In our experience, partial loss of analgesia often occurs as a result of scarring, and can be easily stopped by reprogramming the device. A complete loss of analgesia might occur as a consequence of lead complications, such as migration or breakage, and can likewise be adjusted by electrode revision. If, however, the loss of analgesia occurs without evidence of electrode dysfunction, it seems appropriate to assume that psychological factors may account for this result. Moreover it is known that 17 – 20% of SCS trials fail, often despite optimal paresthesia coverage (22). It is unclear whether these trial failures should be ascribed to "technical" or to psychological factors. Some studies aimed at exploring the influence of pre-existing depression on trial outcome. In a study on 43 patients undergoing SCS trials, Olson et al (23) found that SCS trials outcomes were negatively influenced by depression and mania, as MMPI depression and mania subscores were significantly elevated in patients with trial failure. Ruchinskas and O'Grady (24) surveyed 47 patients consecutively referred for possible SCS implantation and found that the MMPI-2 was able to predict final implantation status. This study, however, also included patients who were offered a SCS trial but just declined it. Those patients who had a negative trial outcome did not significantly differ with respect to depression and hypochondriasis MMPI subscores. In a study on 58 patients, North et al (25) found that pre-existing depression, as assessed by the MMPI, impacted outcomes on SCS testing (thus the implantation rate) but not the long-term efficacy of SCS. Schocket et al (21) evaluated prognostic recommendations regarding outcomes from surgery for implantable pain therapy devices and classified these patients into 4 prognostic groups from low to increasing risks. These authors collected 6-months follow-up data on 32 patients, 8 of whom had received SCS systems. Due to the small sample size they were not able to detect statistically significant differences in outcome among the different prognostic groups (21). Overall, the published data on the influence of depression on trial outcomes seem to be inconclusive.

A closer examination of the literature shows that also for the long-term outcome of SCS, the role of depression is not as clear as clinical experience might suggest. An early study on the use of the MMPI in patients with SCS showed that higher levels of depression were associated with treatment failure (26). Kupers et al (27) studied the prognostic value of an individual psychological interview. The interview, apart from ruling out major psychiatric disorder or litigation problems, led to 2 types of advice: either "no contraindication for SCS" or "no firm contraindication but some reservation." While a 64% success rate was observed in the "no contraindication" group after 6 months, the "some reservation" group had a success rate of 18% (27).

A prospective study on 70 patients showed statistically significant correlations for pain scores, the Oswestry Disability Questionnaire (ODI), and the sensory and affective McGill subscales with the percentage of pain reduction at one year post-implantation. However, the BDI scales did not correlate with the percentage of pain reduction (28). North et al (25) studied 57 patients by means of the MMPI, the Symptom Check List 90 (SCL 90), and the Derogatis Affects Balance Scale (DABS). Using multivariate analysis, they found no statistically significant predictors of long-term outcomes for SCS (25).

In addition, other psychological variables such as mania, hysteria, and hypochondriasis have been analyzed in a number of studies (21,24-26); however, results thus far have been inconclusive (14).

To date, perceived "self-efficacy" has not been studied in the context of SCS. For many patients, the possibility of adjusting their pain level using the hand programmer restores some control of their own fate. Insights of pain psychology concerning coping mechanisms suggest that the induction of improved self-efficacy by SCS might contribute to its pain-relieving effect. Our study could not detect such an effect with certainty; however, self-efficacy showed a tendency towards correlation with the percentage of pain reduction. Overall, the correlation between self-efficacy and outcomes for SCS therapy was smaller than expected. This might be explained to some extent by the fact that the FESS measures general pain-related self-efficacy, but not, distinctly, the gain in autonomy elicited by SCS therapy. Further, one would expect patients performing

intermittent stimulation to be more likely to experience enhanced self-efficacy by SCS. In the present sample the percentage of patients performing intermittent stimulation was smaller than described in a previous study (29), and therefore, the present study might be underpowered to establish such a correlation.

In our study, as in some previous studies (28,30), a decrease in depression scores following SCS therapy was observed. Although this improvement might be a result of overall pain reduction through SCS therapy, this conclusion cannot be drawn with certainty as situational factors might contribute to the amelioration of depression. Nevertheless, the extent of improvement in depression was considerable and was paralleled by a decrease in PDI scores in our study.

The present study is limited by its retrospective design. Moreover, pre-intervention data on depression only included scores on the HADS but not the BDI (31) and there were no pre-intervention data on perceived self-efficacy. Pre-intervention data were taken from the German Pain Questionnaire, which was completed by the patients as a matter of routine prior to their first presentation to our institution. The HADS-D and the PDI but not the BDI and the FESS were included in this questionnaire. The BDI-II (32) was included in the follow-up questionnaire because it is a recognized and validated short screening instrument. In most of the studies on the influence of psychological factors on SCS outcomes, the MMPI is used (14). In our study, however, the follow-up instruments were determined by the available pre-intervention data. The additional use of the MMPI would have notably increased the length of the questionnaire, thus potentially reducing the return rate. Nevertheless, the high return rate of 80% is a strength of the study and contributes to its validity. Another strength is the length of the follow-up and its sample size which is sufficient to draw clinically relevant conclusions.

## Conclusion

In conclusion, the present study did not denote depression, anxiety, or perceived pain- related disability scores as prognostic factors for the outcome of SCS therapy. Scores for both, depression and pain-related disability, under SCS therapy showed a significant inverse correlation to perceived self-efficacy, although the scores did not correlate with the degree of pain reduction on the NRS. However, perceived self-efficacy showed a tendency towards correlation to the percentage of pain reduction under SCS. Future clinical research is necessary to more precisely define the impact of psychological factors on outcomes for SCS therapy.

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