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HIGH LEVEL OF ANXIETY PREDICTS A POOR RESPONSE TO SPINAL CORD STIMULATION IN FAILED BACK SURGERY SYNDROME: A PROSPECTIVE STUDY

ABSTRACT

Spinal cord stimulation (SCS) is an established and cost-effective treatment for neuropathic pain resulting from failed back surgery syndrome (FBSS). Psychological distress is a risk factor both in the development of FBSS and for reduced efficacy in SCS. The impact of psychological factors on SCS outcome is still poorly understood, and more research is warranted to gain a better understanding of the matter. The objective of this prospective study was to investigate the prevalence of anxiety symptoms pre-surgically and at 6 and 12 months post-surgically, and to examine their association with depressive symptoms, pain intensity and pain-related disability in patients with FBSS treated with SCS. Beck Anxiety Inventory (BAI) was used to assess anxiety symptoms, Beck Depressive Inventory (BDI) to assess depressive symptoms, Numeric Pain Rating Scale (NRS) to assess pain intensity, painDETECT to assess neuropathic pain and Oswestry Disability Index (ODI) to assess pain-related disability at baseline and at 6- and 12-month follow-ups. A total of 118 consecutive consenting patients referred to SCS at Kuopio University Hospital (KUH) between January 1, 2015 and December 31, 2018 were assessed at baseline, of whom the follow-up data at 6 and 12 months was available for 59 patients. Among those who received a BAI score of <16 at baseline, signifying minimal to mild anxiety, statistically significant improvements were observed for the NRS ($p<0.001$), ODI ($p=0.001$) and painDETECT ($p<0.001$) at follow-up, whereas among those who reported a BAI score of ≥ 16 , signifying moderate to severe anxiety, statistically significant improvement was observed in painDETECT ($p=0.003$), but not in NRS ($p=0.267$) nor ODI ($p=0.110$). No statistically significant improvement was observed in depressive or anxiety symptoms at follow-up.

Conclusions

Among patients reporting moderate to severe anxiety at baseline, the SCS outcome was significantly worse at 1-year follow-up, than among those reporting only minimal to mild anxiety.

KEYWORDS: ANXIETY, SPINAL CORD STIMULATION, FAILED BACK SURGERY SYNDROME, CHRONIC PAIN, NEUROPATHIC PAIN, BECK ANXIETY INVENTORY

INTRODUCTION

Failed back surgery syndrome (FBSS) is a condition characterized by persistent pain and impaired function after lumbar spine surgery¹. In a recent large cohort study, Schoell et al. reported the incidence of FBSS to be 17%², with previous studies reporting incidence of 10-40%. FBSS is often associated with severe disability, loss of quality of life, psychological distress and has a major economic impact³. Psychological distress, namely depression, is shown to increase the risk of developing FBSS².

Spinal cord stimulation (SCS) is an established and cost-effective treatment for FBSS⁴.

In SCS, doses of electrical current are delivered to the dorsal column of the spinal cord. The specific mechanism producing analgesia is unknown⁵. Pain relief of greater than 50% is considered to be an excellent outcome, and the long-term success rate in SCS is reported to be between 57–83%^{6,7,8}. Despite technical achievements in SCS techniques, a significant number of patients fail to benefit, or lose the analgesic effect over time, in which psychological factors are considered to play a substantial role⁹. It has been suggested that psychological factors are particularly important in predicting the outcome in SCS implantation, perhaps more so than for other interventional spinal procedures and surgeries¹⁰. Depression is most consistently shown to diminish SCS outcome, while the association of anxiety with SCS outcome is less clear¹¹. Nevertheless, these symptoms are very common in these patients, with higher prevalence than seen in the general population¹².

In order to improve the success rate, preoperative psychological assessment is commonly used, often even mandated for insurance coverage, despite the fact that the predictive value of these assessments is frequently questioned¹³.

More research is needed to better understand the association of psychological factors and SCS outcome. In this prospective study, we investigated the prevalence of anxiety symptoms in FBSS patients referred to SCS, and their association with pain intensity, pain-related disability, anxiety and depressive symptoms at 6- and 12-month follow-ups. We hypothesized that patients with clinically significant anxiety at baseline experience less benefit from SCS.

METHODS

STUDY LOCATION AND PATIENT SELECTION

Kuopio University Hospital (KUH) is a tertiary referral hospital located in Eastern Finland. KUH Neurosurgery has conducted SCS implantations since 1997, providing evaluation, treatment and follow-up to the patients sent for consultation by other healthcare units. Since 2015, all relevant clinical data concerning SCS patients has been prospectively compiled into the Kuopio Neuromodulation Database, which encompasses all patients who have received a permanent SCS device. The database is run by a dedicated nurse coordinator, who is responsible for gathering the clinical data from hospital periods and follow-up visits. The dedicated nurse interviews all patients as a part of the multidisciplinary assessment of SCS candidates. If the patient is considered appropriate for SCS and has given an informed consent, baseline data is collected. Prior to the implantation of the permanent SCS device, patients undergo a one-week trial stimulation period, when percutaneous or surgical paddle electrodes are implanted and positioned to obtain maximal coverage of the painful area. Stimulation parameters can be set during the trial period in an effort to achieve an optimal pain reduction. After the one-week trial, the outcome is assessed with the painDETECT questionnaire and a seven-level rating scale for global perceived effect of the therapy. If sufficient pain relief or significant increase in quality of life is reported by the patient at the end of the trial, the patient proceeds to have a permanent SCS device implanted. If adequate pain relief is not achieved, the leads are removed. In the current study, we analysed all consecutive FBSS patients referred to SCS and admitted to KUH between January 1, 2015 and December 31, 2018, who had given an informed consent and completed the questionnaires at the baseline. We grouped the patients into low and high anxiety groups using BAI score of 16 as a cut-off. For the outcome analyses, we analysed patients who had been implanted with a permanent SCS device and had completed the questionnaires at 6- and 12-month follow-ups.

QUESTIONNAIRES

Anxiety was measured using Beck Anxiety Inventory (BAI) and depressive symptoms using Beck Depression Inventory (BDI), both of which are 21-item self-report questionnaires with a 4-point response scale (range 0–63). A BAI score under 7 is considered to indicate a minimal level of anxiety,

8–15 mild anxiety, 16–25 moderate anxiety and 26–63 severe anxiety¹⁴. BDI score of 0–13 indicates no depression, 14–19 mild depression, 20–29 moderate depression and 29–63 severe depression. BDI is shown to have construct validity and internal consistency for assessing depressive symptoms in patients with chronic pain¹⁵.

Disability was measured with the Oswestry Disability Index (ODI), which consists of 10 items with 6 statements. Each statement has a value from 0 to 5 and the statements are then summed up. The total score is presented as a percentage of the maximum score. A score of 21% to 40% is interpreted as moderate disability, 41% to 60% as severe disability and 61% to 80% denotes a crippled individual. Scores under 20% are non-concerning¹⁶. Pain intensity was measured with Numeric Pain Rating Scale (range 0–10), where 0 is no pain, 1–3 mild pain, 4–6 moderate pain and 7–10 severe pain¹⁷. The likelihood of neuropathic pain was measured with painDETECT questionnaire (range 0–35). PainDETECT scores exceeding 19 suggest a high likelihood (>90%) of neuropathic pain¹⁸.

STATISTICAL METHODS

The baseline measures were compared using Fisher's exact test for nominal and the independent samples t-test for scale variables, or Mann–Whitney U test if the data was non-normally distributed. Variables used to measure the outcome of surgery were temporally compared using one-way repeated-measures ANOVA. The significance cut-off level was set at 5%. IBM SPSS Statistics V22 was used for the appropriate statistical tests.

ETHICAL ASPECTS

The study was approved by the Ethics Committee of the Kuopio University Hospital. The SCS registry has the permission of Ministry of Social Affairs and Health.

RESULTS

BASELINE CHARACTERISTICS

In total, 118 FBSS patients were included in the study, of which 53 (45%) were male. Forty-two (36%) patients had had a posterior lumbar fusion performed as a previous spine surgery. The mean age at baseline was 52.2 years

(SD=12.5). The mean NRS score was 6.8 (SD=1.2), the mean ODI was 47.6 (SD=13.2) and the mean painDETECT score was 20.4 (SD=5.6), signifying moderate to severe pain, severe disability and high likelihood of neuropathic pain, respectively. The mean BAI score was 11.7 (SD=7.8) and the mean BDI score was 13.2 (SD=8.0), signifying mild anxiety and mild depression, respectively. A total of 102 patients received a permanent SCS device after the one-week trial period. Compared to those who did not receive a permanent SCS device, these patients reported significantly higher pain intensity, the mean NRS 6.9 (SD=1.3) vs. 6.1 (SD=0.9), $p=0.017$, and significantly more depressive symptoms, the mean BDI 13.8 (SD=8.2) vs. 9.3 (SD=4.8), $p=0.034$. Thirteen patients had the permanent SCS device explanted during the follow-up.

At the time of the study, 79 patients with a permanent device had been followed up for a year, of whom the complete follow-up data was available for 59 (75%) patients. Patients were divided into low and high anxiety groups based on BAI scores <16 ($n=43$) and ≥ 16 ($n=16$), signifying minimal to mild and moderate to severe anxiety, respectively. At baseline, patients in the high anxiety group did not report higher pain than those in the low anxiety group, the mean NRS 6.7 (SD=1.5) vs 6.7 (SD=1.3), $p=0.991$, but were significantly more disabled, the mean ODI 57.3 (SD=11.8) vs 42.7 (SD=13.0), $p<0.001$, had significantly higher likelihood of having neuropathic pain, the mean painDETECT score 22.5 (SD=5.4) vs 19.2 (SD=5.6), $p=0.02$, and reported significantly more depressive symptoms, the mean BDI 20.4 (SD=7.2) vs 10.1 (SD=5.8), $p<0.001$. The baseline characteristics are presented in *Table 1* and *Table 2*.

THE FOLLOW-UP

Among the low anxiety group, a significant improvement from the baseline was seen in reported pain intensity at 6 months and the improvement remaining at 12-month follow-up, with the mean NRS score decreasing from 6.7 (SD=1.3) to 4.8 (SD=2.4) and 4.8 (SD=2.2) ($p<0.001$), respectively. Likewise, the low anxiety group experienced a significant improvement in functioning, with the mean ODI decreasing from 42.7 (SD=13.0) to 35.1 (SD=14.1) and 36 (SD=14.8) ($p=0.001$). In contrast, the high anxiety group did not experience a significant reduction in pain intensity during the follow-up, with the mean NRS score 6.7 (SD=1.5) at baseline, 6.0 (SD=1.8) at 6 months and 6.4 (SD=2.1) at 12 months ($p=0.267$). The high anxiety group experienced

an improvement in functioning at 6 months, but had deteriorated at 12 months, with the mean ODI 57.3 (SD=11.8), 48.3 (SD=17.6) and 51.6 (SD=19.7), respectively ($p=0.110$). Though both the low and high anxiety groups showed a statistically significant reduction in painDETECT scores during the follow-up, $p<0.001$ and $p=0.003$ respectively, the high anxiety group still exhibited a high likelihood of neuropathic pain at the end of the follow-up, as opposed to a slight component of neuropathic pain of the low anxiety group. Neither group experienced significant reduction in anxiety or depressive symptoms, with the high anxiety group reporting a significantly higher degree of both anxiety and depressive symptoms at 6- and 12-month follow-ups. The findings are presented in [Table 3](#).

Table 1. Baseline characteristics of FBSS patients referred to SCS (n=118) who completed the questionnaires at the baseline and at 12-month follow-up divided into low and high anxiety groups treated in Kuopio University Hospital between 2015 and 2017.

| | FBSS patients (n=118) | BAI<16 (n=43) | BAI≥16 (n=16) | p-value |
|---------------------------------------|--------------------------|---------------|---------------|------------------|
| Age (mean, SD) | 52,2 ± 12,5 | 51,4 ± 13,2 | 57,0 ± 15,0 | 0.169 |
| Gender (male, %) | 53 (45 %) | 20 (47 %) | 8 (50 %) | 1.00 |
| Posterior lumbar fusion (n, %) | 42 (36 %) | 11 (26 %) | 7 (44 %) | 0.212 |
| Numeric Pain Rating Scale (mean ± SD) | 6,8 ± 1,2 | 6,7 ± 1,3 | 6,7 ± 1,5 | 0.991 |
| PainDETECT (mean ± SD) | 20,4 ± 5,6 | 19,2 ± 5,6 | 22,5 ± 5,4 | 0.023 |
| Oswestry Disability Index (mean ± SD) | 47,6 ± 13,2 | 42,7 ± 13,0 | 57,3 ± 11,8 | 0.002 |
| Beck Anxiety Inventory (mean ± SD) | 11,7 ± 7,8 | 7,8 ± 4,4 | 20,9 ± 4,0 | <0.001 |
| Beck Depression Inventory (mean ± SD) | 13,2 ± 8,0 | 10,1 ± 5,8 | 20,4 ± 7,2 | <0.001 |

The P-values were calculated by comparing the low-anxiety and high-anxiety groups using Fisher's exact test for nominal and the independent- samples t-test for scale variables or Mann-Whitney U test if the data was non-normally distributed. FBSS=failed back surgery syndrome SCS=spinal cord stimulation, BAI= Beck Anxiety Inventory.

Table 2. Baseline comparison of FBSS patients based on whether a permanent SCS device was implanted after the one-week trial stimulation.

| | Permanent device implanted (n=102) | No permanent device implanted (n=16) | p-value |
|---------------------------------------|------------------------------------|--------------------------------------|--------------|
| Age (mean, SD) | 52,0 ± 12,9 | 53,5 ± 10,2 | 0.647 |
| Gender (male, %) | 49 (48 %) | 4 (25 %) | 0.108 |
| Posterior lumbar fusion (n, %) | 37 (36 %) | 5 (31 %) | 0.785 |
| Numeric Pain Rating Scale (mean ± SD) | 6,9 ± 1,3 | 6,1 ± 0,9 | 0.009 |
| Oswestry Disability Index (mean ± SD) | 47,9 ± 13,3 | 45,6 ± 13,1 | 0.534 |
| Beck Anxiety Inventory (mean ± SD) | 11,8 ± 7,9 | 10,9 ± 7,8 | 0.868 |
| Beck Depression Inventory (mean ± SD) | 13,8 ± 8,2 | 9,3 ± 4,8 | 0.031 |

The P-values were calculated using Fisher's exact test for nominal and the independent-samples t-test for scale variables or Mann-Whitney U test if the data was non-normally distributed. SCS=spinal cord stimulation, BAI= Beck Anxiety Inventory.

Table 3. The changes in the outcome variables at 6 and 12 months post-surgery for the low anxiety (n=43) and the high anxiety group (n=16).

| Outcome variables | At baseline (mean ± SD) | At 6 months (mean ± SD) | At 12 months (mean ± SD) | Wilks' Lambda | F (df, df error) | p-value |
|----------------------------------|-------------------------|-------------------------|--------------------------|---------------|-------------------|------------------|
| Numeric Pain Rating Scale | | | | | | |
| BAI<16 | 6.7 ± 1.3 | 4.8 ± 2.4 | 4.8 ± 2.2 | 0.504 | F (2.39) = 19.157 | <0.001 |
| BAI≥16 | 6.7 ± 1.5 | 6.0 ± 1.8 | 6.4 ± 2.1 | 0.828 | F (2.14) = 1.453 | 0.267 |
| OSWESTRY | | | | | | |
| BAI<16 | 42.7 ± 13.0 | 35.1 ± 14.1 | 36 ± 14.8 | 0.698 | F (2.38) = 8.210 | 0.001 |
| BAI≥16 | 57.3 ± 11.8 | 48.3 ± 17.6 | 51.6 ± 19.7 | 0.712 | F (2.13) = 2.627 | 0.110 |
| PainDETECT | | | | | | |
| BAI<16 | 19.2 ± 5.6 | 13.9 ± 7.2 | 14.4 ± 6.1 | 0.521 | F (2.40) = 18.396 | <0.001 |
| BAI≥16 | 22.5 ± 5.4 | 18.1 ± 5.9 | 19.2 ± 5.9 | 0.411 | F (2.13) = 9.301 | 0.003 |
| Beck Anxiety Inventory | | | | | | |
| BAI<16 | 7.8 ± 4.4 | 7.8 ± 6.5 | 8.1 ± 6.3 | 0.996 | F (2.39) = 0.086 | 0.918 |
| BAI≥16 | 20.9 ± 4.0 | 17.7 ± 8.1 | 17.1 ± 6.4 | 0.693 | F (2.14) = 3.103 | 0.077 |
| Beck Depression Inventory | | | | | | |
| BAI<16 | 10.1 ± 5.8 | 9.1 ± 7.4 | 8.3 ± 7.5 | 0.915 | F (2.36) = 1.673 | 0.202 |
| BAI≥16 | 20.4 ± 7.2 | 19.1 ± 10.4 | 19.8 ± 10.6 | 0.955 | F (2.14) = 0.328 | 0.726 |

The statistical test used was one-way repeated-measures ANOVA. BAI=Beck Anxiety Inventory

DISCUSSION

In this prospective study of consecutive FBSS patients treated with SCS, we demonstrated that patients with moderate to severe anxiety at baseline did not significantly benefit from the treatment in 1-year follow-up, in terms of pain intensity according to NRS and pain-related disability according to ODI, despite sufficient pain relief in the 1-week trial period prior to the implantation of the permanent SCS device. Patients with moderate to severe anxiety at baseline reported higher pain-related disability at baseline, as well as higher prevalence of depressive symptoms, and they had a significantly higher likelihood of having neuropathic pain before SCS operation. Though a statistically significant reduction in painDETECT score was observed in patients with moderate to severe anxiety at baseline, they still exhibited a high likelihood of neuropathic pain at the end of the follow-up.

In contrast, in patients with minimal to mild anxiety symptoms, a significant reduction in pain intensity was achieved according to NRS, as well as a significant improvement in functioning according to ODI, demonstrating the efficacy of SCS in FBSS.

In this study, the treatment did not seem to affect the severity of the depressive or anxiety symptoms, regardless of the severity of the symptoms at baseline, which is contrary to the findings of Sparkes et al. who reported significant improvement in both depressive and anxiety symptoms after SCS implantation¹⁹. It should be noted that patients with untreated severe depression or untreated severe anxiety are not considered for SCS treatment, but are referred to a psychiatrist if feasible. Adequately managed depression or anxiety disorder are not a contraindication for SCS. Unfortunately, we were unable to control for the putative ongoing psychiatric treatment these patients might have had, as there is evidence that concurrent pharmacological treatment can significantly alleviate depressive symptoms after SCS¹³. Further research is required to examine whether concurrent treatment of anxiety would alleviate these symptoms or enhance the outcome in SCS. Further, as severe cases of anxiety and depression were excluded from SCS, our findings may not reflect the prevalence of anxiety and depressive symptoms among other patient populations with chronic pain. In general, our findings are in line with previous studies, and further highlight the importance of psychological factors affecting the SCS outcome. As a

strength of the present study, we had an unselected patient cohort of 118 consecutive FBSS patients referred to SCS between January 1, 2015 and December 31, 2018, reducing the risk of selection bias. In addition, to assess clinical outcome reliably, the present study had two follow-ups, at six months and one year, after the SCS operation. It has been reported that loss of analgesia may be experienced within 12 to 24 months after the SCS implantation, and this limitation should be addressed in future studies.

CONCLUSION

In conclusion, this study demonstrated that anxiety may diminish the long-term efficacy of SCS. Among patients reporting moderate to severe anxiety at baseline, the SCS outcome was significantly worse at 1-year follow-up than among those reporting only minimal to mild anxiety before SCS treatment. This study can potentially help decision making relating to the suitability of SCS therapy for patients with neuropathic pain, and our data supports multidisciplinary treatment of patients with chronic pain.

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