

Assessment of spinal cord stimulation and radiofrequency

Chronic pain and psychological impact

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Abstract

Pain has a major impact on anxiety and depression levels. The aim of this study is to demonstrate how these symptoms (depression and anxiety) could positively influence the perception of pain after neurostimulation system implantation.

We enrolled 100 patients and divided in 2 different groups, by using tests screening such as Beck Depression Inventory (BDI), Hamilton Anxiety Rating Scale (HAM-A), Nursing Rating Scale (NRS): the group with spinal cord stimulation (SCS) and the group with pulsed spinal cord radiofrequency (RFP).

We highlighted a significant decrease of scores (BDI, HAM-A, NRS) in each group between T0 (baseline) and T1. Moreover, the intra-group analysis showed a positive significant correlation between NRS and depressive and anxiety symptoms.

We assert that the use of alternative methods (SCS and RFP) to the traditional pharmaceutical-surgical treatments, provide the reduction of the algic and anxiety-depressant symptoms, restoring also the perception of psychological well-being.

Abbreviations: BDI = beck depression inventory, GAD = general anxiety disorder, HAM-A = Hamilton Anxiety Rating Scale, NRS = numerical rating scale, PD = panic disorder, RFP = Pulsed spinal cord radiofrequency, SCS = spinal cord stimulation.

Keywords: anxiety, chronic pain, depression, neurostimulator system, psychological impact

1. Introduction

Pain has a major impact on levels of anxiety and depression. Several studies showed a high prevalence of depression and anxiety associated with chronic pain.^[1–3] Anxiety plays an important role in acute pain: the fear of suffering and/or anticipatory anxiety may lead to a more pronounced perception of pain. Chronic pain and depression are linked in a bidirectional way, that is, one feeds the other, thus entering a vicious circle. A

possible explanation for this bi-directionality could be given by social isolation and depressive symptoms^[4] that encourage the increase of symptoms. Some studies highlighted the correlation between mood disorders and acute and/or chronic pain. In particular, depression and anxiety seem to be associated with a greater perception of the pain severity and less tolerance of it, moreover the prolonged exposure to pain would lead to mood dysregulation.^[5] The recognition of the depressive state is not easy, because the patient complains of physical pain and not psychological disturbances; thus, the algic experience can lead to a series of negative thoughts that can have a significant impact on levels of functionality and tolerance to pain.^[6–8]

However, good emotional regulation can improve the understanding of risk and protective factors that contribute to the onset and maintenance of chronic pain.^[9]

Anatomically, the areas involved in pain and depression are amygdala and hypothalamus, playing an important role in both disorders.^[10]

To date, there are not many researches on the use of alternative methods to pharmacological treatments, to encourage a decrease in algic symptoms related to the psychological one. Neuro-modulation methods are a valid alternative when pharmacological and surgical treatments are not effective in pain control. Spinal cord stimulation (SCS) and pulsed spinal cord radiofrequency (RFP) are the most effective system in the pain treatment. The SCS has been used for the treatment of chronic severe neuropathic pain since its first description by Shealy et al in 1967.^[11] Several studies reported that more of 50% of patients treated with neurostimulation achieve a marked improvement in pain relief.^[12–20] It also leads to a 50% reduction in opioid use and quality of life improved in most patients treated with SCS.^[21]

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The study protocol was approved by the Local Ethics Committee according to Declaration of Helsinki.

Informed written consent was obtained from the patient for publication of this study.

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RFP currents have been useful for the treatment of radical pain, attributing the analgesic response to the electromagnetic field generated around the tip of the cannula. RFP appears to be suitable for the management of different neuropathic pain conditions. SCS is used in the following conditions: chronic intractable back pain, complex regional pain syndrome, chronic lumbar and cervical radiculopathy, secondary neuropathic pain due to peripheral nerve injury, post-traumatic or post-irradiation brachial plexopathy, while RFP is often applied in cervical root pain, trigeminal neuralgia, Arnold's neuralgia, chronic shoulder pain and chronic lumbago pain.

The aim of our study was to evaluate the effect of 2 alternative methods (SCS and RFP system) on patients with chronic pain for at least 3 months and to investigate the relationship between pain and anxiety-depressant symptoms. Moreover, we assumed a negative correlation between the two different symptoms, that is, decreasing the algic symptoms through the use of SCS and RFP decreased the anxiety-depressant symptoms.

2. Materials and methods

This observational study was conducted on a sample of 100 patients with chronic pain (56 females, 44 males) divided in two groups: with SCS and with RFP. All patients were recruited from January 2018 for one year in the antalgic therapy unit of our Institute. All subjects not respond to traditional pharmacological therapies of pain (paracetamol, FANS, opioids, anticonvulsants and cortisone). The study protocol was presented to the participants by trained healthcare professionals. Informed consent was provided, and confidentiality was guaranteed. The study was approved by local ethics committee.

The choice of treatment (SCS or RFP) depended to pain etiology and chronic pain level. The patients that showed a severe algic symptomatology were included in SCS group. These subjects were affected to chronic cervical and lumbar radiculopathy, post-traumatic brachial plexopathy and back pain. The RFP group consisted of patients with moderate chronic pain. In this group, the patients presented trigeminal neuralgia and fibromyalgia.

Therefore, the inclusion criteria have been dictated by the presence of severe and moderate chronic pain for at least 3 months. The first group (with SCS) consisted of 50 subjects with mean age of 70.0 ± 13.23 years and mean education of 9.0 ± 5.20 years; the second group (with RFP) consisted of 50 patients with mean age of 62.0 ± 13.73 years and mean education of 8.0 ± 4.76 years.

The exclusion criteria were: the presence of psychiatric disorders accompanied by antidepressants and anxiolytics use, severe cognitive changes, neurodegenerative disorders. All subjects had chronic pain associated with high levels of anxiety and depression. In the group with SCS, we introduced a cable located in the epidural space using a Tuohy needle and connected to a subcutaneously implantable pulse generator, which contains the power source and electronics to provide programmable stimulations. In the group with RFP, the procedure was performed in awake patients, under local anesthesia, and consists of introducing one or more thin needles into specific areas, without creating brain damage.

Each patient underwent to BDI-II, HAM-A and NRS at baseline evaluation (T0) and after 6 months from T0 (T1).

BDI-II is a self-assessment tool composed of 21 multiple choice items. Each item has a score of 0–3. It was considered a 0–13

score as an absence of depressive content, scores ranging from 14 to 19 mild depression, between 27–29 moderate degree depression and ultimately 30–63 severe grade depression.^[22]

HAM-A measures the subjective severity of anxiety symptoms within the previous 7 days. It has long been used as an indicator of anxiolytics in panic disorder (PD) and general anxiety disorder (GAD). Each element is marked on a scale from 0 (not present) to 4 (severe), with a total score range of 0–56, where <14 indicates no symptoms, ≥ 14 –17 indicate mildness, 18–24 from mild to moderate, > 25 severe. Anxiety and depression levels were compared with pain levels, extrapolated from the NRS results.^[23,24]

NRS is a one-dimensional quantitative clinical scale of 11-point pain assessment; in this scale the patient selects the number that describes the intensity of pain, from 0 to 10.

Two different alternative methods, SCS and RFP, to traditional treatments have been used, as already mentioned, compared to the decrease in pain and anxiety-depressant symptoms.

2.1. Statistical analysis

The analysis was conducted with descriptive statistic of respondent's sociodemographic characteristic of two groups. Normal distribution of the data evaluated using the Shapiro-Wilk normality test. The Wilcoxon signed-rank test used in order to compare, for each group (SCS or RFP), the results in 2 times (intra-groups analysis) while, the Mann-Whitney *U* test used for the comparison between the 2 groups (inter-group analysis) a T0 and T1. Finally, we performed an interaction effect analysis (improved time) by calculating the T1–T0 differences in clinical variables (BDI-II and HAM-A) scores and NRS scores determining their correlations using the Spearman's coefficient in each group. Analyses performed using an open source R3.0 software package (R Foundation for Statistical Computer, Vienna, Austria). A 95% of confidence level was set with a 5% alpha error. Statistical significance was set at $P < .05$.

3. Results

In the intra-group analysis, we compared the clinical test at baseline (T0) and at T1 (follow-up after six months) (Fig. 1). In SCS group, we observed a decrease highly significant of scores in BDI ($P < .001$), HAM-A ($P < .01$) and in NRS ($P = .04$) (Table 1). In RFP group, we highlighted a decrease highly significant of scores in BDI ($P < .001$), HAM-A ($P < .001$) and in NRS ($P < .001$) (Table 1).

Inter-groups analysis showed a positive significant correlation between groups in NRS at T0 ($P = .02$) and T1 ($P < .001$) (Table 1). Correlation analysis showed a relation significant between NRS and BDI-II ($r = 0.48$; $P = .04$), and HAM-A ($r = 0.51$; $P = .03$) in SCS group. Moreover, in RFP group we highlighted a positive significant correlation between NRS and BDI-II ($r = 0.56$, $P = .01$), and HAM-A ($r = 0.50$, $P = .02$).

4. Discussion

Our observational study showed a decrease of algic, psychological and physical symptoms after treatment in both groups.

Significant results ($P < .001$) to T1 (follow-up after six months) in NRS showed that the pain perception scores are lower in both groups, and the two different methods provided a positive response in pain perception decrease. The effectiveness of the SCS

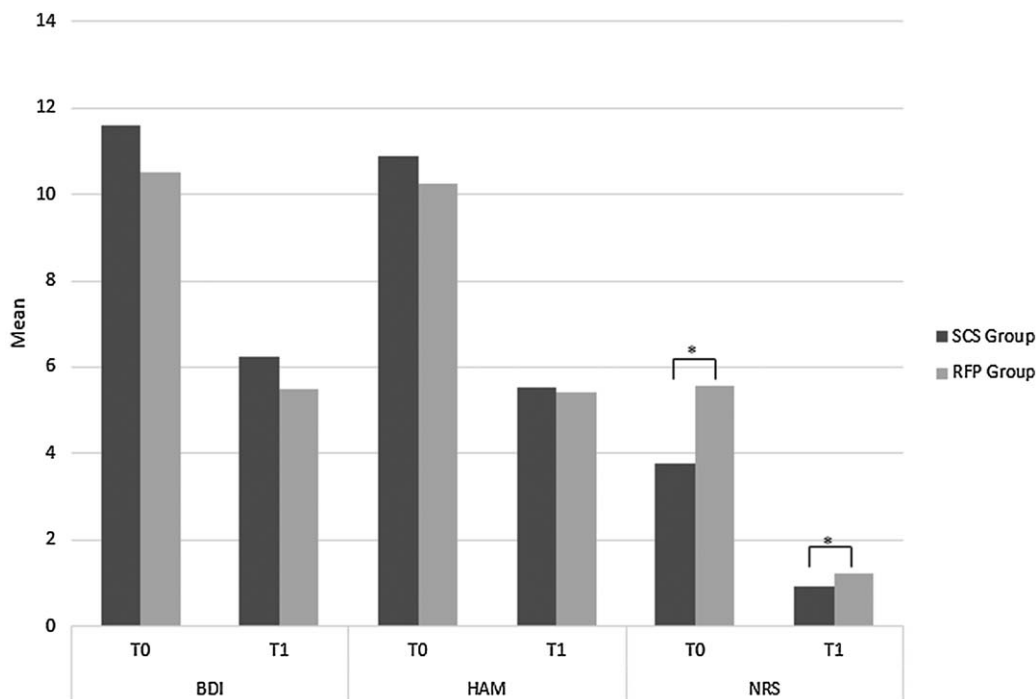


Figure 1. Inter group analysis of neuropsychological scale at baseline and T1 (follow-up after six months). BDI-II=beck depression inventory, HAM=Hamilton Anxiety Rating Scale, NRS=numerical rating scale, RFP=pulsed medullar radiofrequency, SCS=spinal cord stimulation.

and RFP treatment, therefore, can stop or correct chronic excessive pain. Statistically significant responses were obtained to HAM-A ($P < .001$) and BDI-II ($P < .001$) in both groups.

The comparison between two methods showed that pain perception decreased considerably in both conditions, resulting the decrease of anxious-depressant symptoms. Therefore, the alternative methods to traditional pharmacological treatments lead relief to patients and ensure an improvement of psycho-physical wellbeing.

These results showed that the painful perception and anxiety-depressant symptomatology decreases in both conditions, highlighting a significant correlation between pain and psychological disorders. Pain is associated with rapid neuro-vegetative, affective-emotional and cognitive changes. The correlation

between chronic pain and psychological disorders (anxiety and depression) was analyzed by several authors. In fact, some studies showed that the anxiety appears in patients with chronic pain (e.g., rheumatologically patients than in healthy controls).^[25] Heer et al^[2] correlate with anxiety and cardio-respiratory pain, respect to a lower correlation with gastrointestinal and musculoskeletal pain.

The chronic pain reduction, obtained to our patients with alternative methods, decreased anxiety and depression levels with changes in the daily life of the subject. Therefore, we confirm that to severity pain increasing, the psychological symptoms worsen. Our evaluation, unlike other studies, was carried out in 2 different types of patients, based on the severity of pain (SCS vs RFP treatment). In particular, the anxiety and depression levels, as detected by the HAM-A and BDI-II scales, are significantly represented in all patients. In literature, pain and depression often appear associated, even if a causal relationship is difficult to establish; it has been hypothesized that the depressed mood causes to altered perception of painful stimuli, and the intensity of pain is an element with a significant influence on the tone of mood.^[26] The importance of our study is to highlight how anxiety and depression is not related to a mood disorder, but rather related to a physical condition that disables people. In fact, the pain decrease matched with levels of anxiety and depression, thus increasing the quality of life of each subject.

Our results show as the pain is slightly more intense in the RFP group, while anxiety and depression are equally present in both groups. A study conducted by Morone et al,^[27] shows that patients with chronic pain are more predisposed to anxiety disorders than pain less patients (35% vs 18%). The study suggests that subjects with GAD (general anxiety disorder), related to chronic pain, were less responsive to first treatment, while subjects with mild or absent pain were more responsive to treatment. Another study, Xie et al^[28] investigated the correlation

Table 1
Intra- inter-group differences in clinical variables at T0-T1 of patients with SCS and patients with RFP.

	SCS Group Median (I-III quartile)	RFP Group Median (I-III quartile)	P (U-Mann Whitney)
BDI T0	11 (8.0–16.0)	10 (8.25–13.75)	.73
BDI T1	6 (4.0–10.0)	6 (3.25–8.0)	.78
P (Wilcoxon)	.0003**	<.001**	
HAM T0	12 (9.0–14.0)	10 (8.0–14.0)	.49
HAM T1	6 (5.0–8.0)	6 (5.0–8.0)	.49
P (Wilcoxon)	.0003**	<.001**	
NRS T0	3 (1.0–7.0)	5.5 (4.0–7.0)	.02*
NRS T1	0 (0–2.0)	3 (2.25–4.0)	<.001**
P (Wilcoxon)	.004*	<.001**	

* $P < .05$.

** $P < .001$.

BDI-II=beck depression inventory, HAM=Hamilton Anxiety Rating Scale, NRS=numerical rating scale, RFP=pulsed medullar radiofrequency, SCS=spinal cord stimulation.

between anxiety and depression in painful patients by using hospital anxiety and depression scales and visual analogue scale. This study identifies the relationship between anxiety and depression related to degree of physical pain. This outcome could help to better conceptualize the relationship between physical pain and psychological symptoms, which are closely related. Other studies,^[29–30] focused attention on chronic pain, in particular migraine patients.

A study conducted by McWilliams et al,^[30] unlike our research, showed that the anxiety in patients with chronic pain is more related to chronic algic symptomatology than depression. However, as suggested in our study, the efforts are needed to detect and treat anxiety disorders in pain condition.

Non-invasive neuromodulation methods are a valid alternative when pharmacological and surgical treatments are not effective in pain management. The use of two different methods highlighted, as analgesic treatments, can provide not only a decrease of pain perception, but also a decrease of anxiety-depressive symptomatology. In our study, the SCS and RFP methods facilitate a reduction of pain levels. Previous studies focused only on the efficacy of SCS,^[31] or RFP in chronic headache.^[32] We confirm that the two treatments are effective for the our sample. There are no studies that analyze the differences between the two methods, particularly in correlation with psychological disorders. Therefore, our study can be a starting point to evaluation of alternative methods to pharmacological/surgical treatment, improving the quality of life and psychophysical state of patients with chronic pain.

Author contributions

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