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Retrospective evaluation of 16 patients who underwent spinal cord stimulation

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Abstract

The aim of this study was to examine the outcomes of patients who underwent Spinal Cord Stimulation (SCS) in our clinic. In this study, records of 16 patients who underwent SCS in the Algology and Neurosurgery Clinic of the Ministry of Health, Health Sciences University, Samsun Training and Research Hospital between 2015 and 2018 were retrospectively analysed. The pain levels of the patients before and after the procedure were evaluated with the Visual Analogue Scale (VAS). The mean age of the patients was 54.25 ± 11.45 years. After the SCS procedure, it was found that pain levels determined by the VAS decreased significantly ($p < 0.001$). Eleven (68.7%) patients reported that they were quite satisfied or partially satisfied after SCS, and seven patients (43.8%) underwent revision due to hardware malfunctions and post-surgical complications. Based on our study results, we believe that SCS is an effective treatment method that can be used to reduce pain.

Keywords: neuromodulation, spinal cord stimulation, pain, VAS, CSF

1. Introduction

Spinal cord stimulation (SCS) is a reliable, minimally invasive treatment method that is widely used in the treatment of chronic pain. In recent times, it has been successfully used for the management of chronic pain conditions, such as complex regional pain syndrome, failed back surgery syndrome, peripheral vascular disease, chronic refractory angina, and visceral pelvic pain (1, 2).

Studies report that 30%–40% of patients with SCS have device-related malfunctions or post-surgical complications (3). Device-related malfunctions that were reported included lead migration, lead breakage, high or low stimulation, hardware failure, generator failure or failure to connect with the generator. Post-surgical complications that were reported included infection, epidural bleeding, seroma, neurological damage, cerebrospinal fluid (CSF) leakage, pain at the implant site, allergic reactions, and skin erosion (4).

The present study aimed to guide and help clinicians to predict, prevent and manage these complications in the early post-operative period by retrospectively examining the indications for and common complications observed in SCS.

2. Materials and Methods

This study was designed as a retrospective descriptive study. Prior to the study, ethics approval was obtained from the Ministry of Health Samsun Training and Research Hospital Medical Specialization Training Board. Sixteen patients over the age of 18, who were not pregnant nor were planning for pregnancy soon and who applied to the Algology and Neurosurgery Clinic of the Ministry of Health, Health Sciences University, Samsun Training and Research Hospital between 2015 and 2018, were included in the study.

The severity of low back pain and satisfaction levels of the patients before and after the procedure were evaluated using the Visual Analogue Scale (VAS). In addition, complications that occurred after the procedure were recorded. The patients were evaluated during routine polyclinic controls after the procedure. Informed consent was obtained from all patients prior to the procedure.

2.1. Surgical technique

The patients were taken to the operating table in the prone position for the SCS procedure. After surgical asepsis 0.05 mg/kg of midazolam was administered for sedation, whereas fentanyl was titrated at a dose of 1–2 µg/kg for analgesia. A small incision was made in the midline over the intervertebral space at the surgical site where a local anesthetic was injected, and a pocket was created for the connection cables of the electrode over the lateral part of the incision. A 14 G Touhy/16 G R-K needle was used to gain access to the epidural space from the T12–L1 vertebral space through a paramedian approach at an angle of nearly 45°. A guide was sent through the epidural needle to allow easy access to the electrode in the epidural region. Later, the electrode was controlled with fluoroscopy and moved towards the relevant dermatome. By providing stimulation with different

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stimulation modes, the area where the patient felt paranesthesia and painful area were determined and the electrode was fixed. Interconnections of the electrode were passed under the skin and removed from a distant point. After the procedure, patients were followed for three hours, and stimulator settings were adjusted. Detailed information was given to the patients and their relatives about the device usage. In patients with successful results during the trial period, the part placed in the intervertebral space was connected to the permanent electrode so that a permanent system could be placed.

2.2. Statistical analysis

SPSS 22.0 software program was used for statistical analysis. The normality of numerical data was evaluated with the Shapiro–Wilk test. Descriptive statistics were presented in terms of frequency (n), percentage (%), mean ± standard deviation, minimum (min), maximum (max), median (median), 25th percentile and 75th percentile. The Chi-Square test was used to compare categorical variables. The difference between the values before and after SCS placement was analysed using the Wilcoxon test. Statistical significance was accepted as $p < 0.05$.

3. Results

Sixteen patients were evaluated in the present study. Nine (56.3%) of the patients included in the study were female, and seven (43.8%) were male (Fig. 1). The mean age of the patients was 54.25 ± 11.45 years, that of females was 54.33 ± 13.85 and that of males was 54.14 ± 9.48 years. There was no statistically significant difference between males and females in terms of age ($p = 0.976$). The most common location of pain was the waist and leg (43.8%), followed by only leg (31.3%), back (12.5%) and arm–foot pain (6.3%) (Fig. 2).

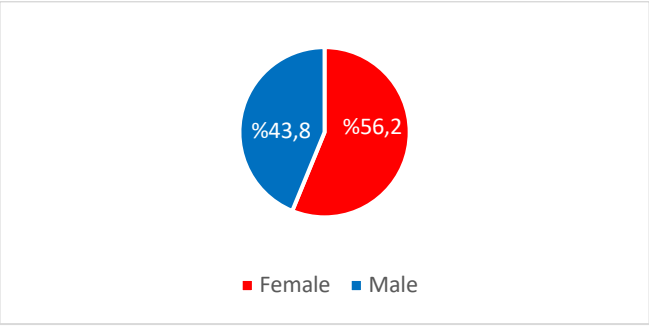

Fig. 1. Distribution of patients by gender

SCS was performed in more than half of the patients (n = 9; 56.25%) due to failed back surgery syndrome (FBSS), also known as post laminectomy syndrome (PLS), in four (n = 4; 20%) patients due to complex regional pain syndrome, in two patients due to spinal tumors (n = 2; 12.5%) and in one patient due to traumatic cauda equina syndrome (n = 1; 6.25%) (Table 1). It was determined that the median VAS score of the patients before the SCS procedure was 8 (min/max = 7/9), and it decreased to 2 (min/max = 1/8) after the procedure, which was statistically significant ($p < 0.001$) (Table 2).

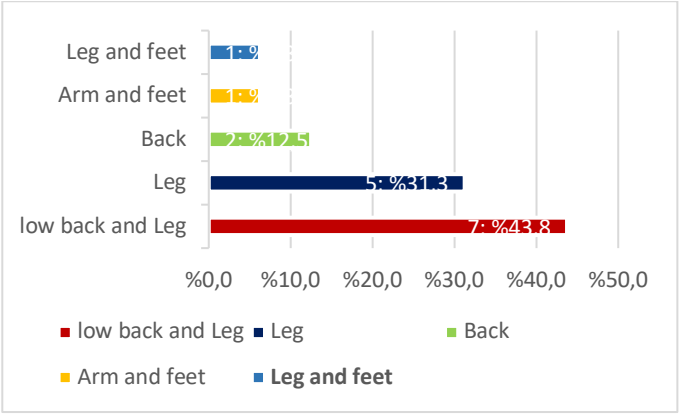

Fig. 2. Distribution of pain location

Table 1. Spinal cord stimulation (SCS) indications

	n (%)
Failed back surgery syndrome	9 (56.25)
Complex regional pain syndrome	4 (20)
Spinal tumour	2 (12.50)
Traumatic cauda equina syndrome	1 (6.25)

n: Number of cases, %: Percentage

When the satisfaction levels of the patients, changes in daily activity and time of return to work after the SCS procedure were examined, it was found that 11 (68.7%) patients were quite satisfied or partially satisfied, whereas the remaining patients reported that they were less satisfied or dissatisfied (Table 3). Within three years after the initial procedure, a revision procedure was performed in seven (43.75%) of 16 patients included in the study due to hardware malfunctions or post-surgical complications. The revision procedure was performed in five (71.43%) cases due to hardware malfunctions and in two (28.57%) cases due to post-surgical complications. It was determined that hardware malfunctions were most frequently caused by lead migration (n = 4, 80%) and due to failure to connect to the generator (n = 1, 20%). Post-surgical complications were observed in three patients. Seroma and infection requiring removal of the generator were observed in two of these patients. In the other patient, a hematoma was observed in the paravertebral tissues. Spontaneous resorption was observed during the controls in the patient who had hematoma in the paravertebral tissues.

Table 2. VAS scores of patients before and after the SCS procedure

Variables	X ± SS	Median (Min/Max)	p
Pre-VAS score	7.9 ± 0.7	8 (7/9)	< 0.001*
Post-VAS score	3.5 ± 2.2	2 (1/8)	

Wilcoxon test, *: $p < 0.05$, X: Mean, SD: Standard deviation, Min: Minimum, Max: Maximum

Table 3. Distribution of patients' satisfaction levels

Satisfaction level	n (%)
Quite satisfied	9 (56.2)
Partially satisfied	2 (12.5)
Neutral	1 (6.3)
Partially dissatisfied	2 (12.5)
Not satisfied at all	2 (12.5)

n: Number of cases, %: Percentage

4. Discussion

In the present study, the records of the patients who applied to our clinic between 2015 and 2018 for SCS were analysed retrospectively. A total of 16 patients were included in the study. Nine (56.3%) of the patients were female and seven (43.8%) were male. More than half of the patient population was female. In a study conducted with 707 patients in 2011, Mekhail et al. reported that 57.7% of the patient population was female (5). In another study conducted in Turkey with 62 patients in 2017, Özdemir et al. reported that 62.9% of patients who underwent SCS procedure were female (6). The results of the present study in terms of gender distribution are consistent with that in literature.

Mekhail et al. reported that the mean age of patients was 46 ± 15 years in their study (5), whereas Özdemir et al. reported that the mean age was 57.95 ± 13.16 years in theirs (6). In the present study, the mean age was calculated as 54.25 ± 11.45 years. Thus, in terms of age, our patient population was like that in the study by Özdemir et al., whereas it was older compared with that in the study by Mekhail et al.

When the indication distribution of SCS, a neuromodulation method applied in the treatment of many chronic pain cases, was examined, it was determined that more than half of the patients in our study underwent this procedure due to FBSS. The second most common indication after FBSS was complex regional pain syndrome. While the most common indication was Complex Regional Pain Syndrome (CRPS) in a study by Mekhail et al., it was followed by FBSS (5). Like the results of the present study, Özdemir et al. reported that FBSS was the most common indication for SCS, followed by angina and CRPS (6, 7).

In a study conducted by Kumar and Toht to determine the effectiveness of SCS, 182 patients who underwent SCS with a diagnosis of FBSS were followed for 8.8 ± 4.5 years, and it was determined that 48% of the patients had a 50% or more reduction in pain intensity. Taylor et al. conducted a systematic review of 63 studies in 2014 to examine the reduction in pain levels of patients who underwent SCS due to chronic low back and leg pain and found that there was a statistically significant pain reduction in 58% of the patients (8).

In a randomized controlled study conducted by North et al. (2005), 50 patients with a diagnosis of PLS who had undergone surgery three years ago were randomly divided into two groups, and while SCS was performed on participants in one group, those in the other group were reoperated. It was reported that opioid use was higher in patients who underwent reoperation compared with that in the SCS group. In addition, they reported that SCS application in patients with persistent radicular pain after spine surgery was more cost-effective than surgery for reducing pain (9). Our study results found that the median VAS score was 8 (min/max = 7/9) before the SCS procedure, and it decreased to 2 (min/max = 1/8) after the procedure; this decrease was statistically significant and consistent with literature.

In a multicenter prospective randomized controlled study conducted by Kumar et al. (2007) to examine the effectiveness of SCS and conventional medical treatment, 100 patients with FBSS were divided into two groups as a conventional treatment group and SCS treatment group and were followed for a year. The study results found a decrease in axial pain intensity, an increase in quality of life and treatment satisfaction in the SCS group (3). In another study conducted by Sanders et al. on 199 patients who underwent SCS between 2001 and 2011, it was reported that 84.27% of the patients were satisfied with the implant (10, 11). In the present study, we found that more than half of the patients (n = 11, 68.7%) were quite satisfied or partially satisfied after the SCS procedure, like that observed in literature.

In literature, complications have been reported in 30%–40% of patients undergoing SCS due to device-related malfunctions, such as lead migration, lead breakage, high or low stimulation, hardware failure, generator failure or failure to connect with the generator, or due to post-surgical factors, such as infection, epidural bleeding, seroma, neurological damage, CSF leakage, pain at the implant site, and allergic reactions (3, 4).

In a 20-year systematic review published by Cameron in 2004, 68 studies and 3679 patients were evaluated. In this review, it was reported that the most common complication after SCS was lead migration seen in 13.2% (n = 361) of the patients (12). In a case series by Mekhail et al., which included 707 patients, it was reported that none of the patients had serious complications, such as permanent neurological deficit or death due to the SCS procedure. Infection was occurred in 32 (4.5%) of 707 patients. Seroma without signs of infection was reported in 1 patient, pain on the generator side was reported in 86 (12%) patients. Lead migration was reported in 119 (22.6%) patients, lead connection failure was reported in 50 (9.5%) patients and lead breakage was reported in 33 (6%) patients out of 527 patients who had IPG implantation. (5). In the study conducted by Özdemir et al., it was reported that complications occurred after the SCS procedure in 14.5% of the patients, and the most common complication was infection with a rate of 33.3% (6). In the present study, it was determined that the most common complication in the three-year period was lead migration (n = 4; 25%), like that observed in Cameron's study (12).

SCS application is an important treatment method that can be used in reducing pain scores and improving the quality of life of patients as it is a minimally invasive method, has lesser side effects compared with pharmacotherapies and is highly cost-effective. To the best of our knowledge, this is the first study in literature reporting results obtained from the Middle Black Sea region regarding the SCS procedure.

Therefore, we believe that this study can significantly contribute to literature. However, the limitations of the present study are that this was a single-center study, which cannot be generalized to the whole population, and the retrospective study design. Therefore, there is a need for future multi-center studies that will contribute to the determination of appropriate treatment strategies by clinicians along with defining the indications for and complications of SCS.

Conflict of interest

None to declare.

Acknowledgments

None to declare.

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