



## ORIGINAL ARTICLE

# Retrospective evaluation of patients with cervical spinal cord stimulator

## *Servikal spinal kord stimülatörü takılmış hastaların retrospektif değerlendirilmesi*

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### Summary

**Objectives:** Chronic pain is a cause that negatively affects quality of life and functional capacity. Spinal cord stimulation is used for various painful indications such as failed back surgery syndrome, complex regional pain syndrome (CRPS), and peripheral vascular disease (PVD). Our aim is to retrospectively investigate the effectiveness of cervical spinal cord stimulator therapy in nine patients.

**Methods:** Nine patients with chronic pain in the upper extremity who did not benefit from medical (pharmacological, physical therapy, etc.) and algological interventional procedures (such as nerve blocks) were included in the study. Cervical spinal cord stimulator was applied to these patients in our pain clinic between January 1, 2016, and January 1, 2019. The pain levels and analgesic and antiepileptic drug doses of the patients before and after the procedure were analyzed.

**Results:** The mean age of patients was 51.8±14.6% (29–76), 44.4% (4) were female and 55.6% (5) were male. Indications for cervical spinal cord stimulator insertion were CRPS type 1 (five patients), CRPS type 2 (two patients), previous neck surgery (one patient), and pain syndrome due to PVD (one patient). After the procedure, we saw a statistical decrease in the pain levels and drug doses of the study patients. SPSS 22.0 statistics package program was used to evaluate the data. NPar and Friedman tests were used for comparisons. Continuous variables are given as mean±standard deviation.  $p<0.05$  was considered statistically significant.

**Conclusion:** Cervical spinal cord stimulator is an effective method in the treatment of neck and upper extremity chronic pain.

Keywords: Complex regional pain syndrome; failed back surgery syndrome; neuropathic pain; spinal cord stimulation.

### Özet

**Amaç:** Kronik ağrı, hayat kalitesi ve fonksiyonel kapasiteyi olumsuz etkileyen bir nedendir. Spinal kord stimülatörü başarısız bel cerrahisi, kompleks bölgesel ağrı sendromu, periferik vasküler hastalıklar gibi ağrılı durumlarda uygulanan bir tedavi yöntemidir. Bu çalışmanın amacı, dokuz hastada servikal spinal kord stimülatörü tedavi etkinliğini retrospektif olarak araştırmaktır.

**Gereç ve Yöntem:** Yapılan medikal (farmakolojik, fizik tedavi vs.), algolojik girişimsel işlemlerden (sinir blokları gibi) fayda görmemiş üst ekstremité lokalizasyonlu kronik ağrısı olan dokuz hasta çalışmaya dahil edildi. Bu hastalara 01 Ocak 2016–01 Ocak 2019 tarihleri arasında ağrı kliniğimizde servikal spinal kord stimülatörü uygulandı. Hastaların işlemden önce ve sonraki ağrı düzeyleri, kullandıkları antiepileptik ve analjezik ilaç dozları analiz edildi.

**Bulgular:** Ortalama hasta yaşı 51,8±14,6 yıl (29–76) olup, %44,4'ü (n=4) kadın, %55,6'sı (n=5) erkekti. Servikal spinal kord stimülatörü takılma endikasyonları sırasıyla; kompleks bölgesel ağrı sendromu tip 1 (n=5), kompleks bölgesel ağrı sendromu tip 2 (n=2), geçirilmiş boyun cerrahisi (n=1) ve periferik vasküler hastalığa bağlı ağrı sendromu (n=1) idi. İşlemden sonra çalışma hastalarının ağrı düzeylerinde ve kullandıkları ilaç dozlarında istatistiksel olarak azalma olduğu görüldü. Verilerin değerlendirilmesinde SPSS 22.0 istatistik paket programı kullanıldı. Karşılaştırmalar için NPar ve Friedman testleri kullanıldı. Sürekli değişkenler ortalama±standart sapma olarak verildi.  $p<0,05$  istatistiksel olarak anlamlı kabul edildi.

**Sonuç:** Servikal spinal kord stimülatörü, boyun ve üst ekstremité kronik ağrı tedavisinde etkili bir yöntemdir.

Anahtar sözcükler: Başarısız bel cerrahisi sendromu; kompleks bölgesel ağrı sendromu; nöropatik ağrı; spinal kord stimülasyonu.

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## Introduction

Spinal cord stimulation (SCS) is a commonly used neuromodulation method in the treatment of chronic neuropathic pain today.<sup>[1]</sup> This method was first described in 1967 by Doctor Shealy et al.<sup>[2]</sup>

SCS was thought to be effective on chronic pain by activation of A beta fibers, inhibition of A delta and C fibers carrying pain sensation (gate control theory).<sup>[3]</sup> Since this theory has not been fully proven, many researchers have thought that the reduction of pain due to SCS is due to direct inhibition of pain pathways in the spinothalamic tract, not to selective stimulation in the thick fibers.<sup>[4]</sup>

Recent studies have shown that the effect of SCS is through more complex mechanisms.<sup>[5]</sup> The analgesic effect of SCS on sympathetic-mediated ischemic pain is thought to occur through inhibition of efferent sympathetic activity, resulting in a decrease in peripheral vasoconstriction and relief of pain by restoring a balance of oxygen demand and supply.<sup>[6]</sup>

SCS placement is indicated for the treatment of chronic intractable pain of the trunk or limbs including unilateral pain and bilateral pain. SCS is successfully applied in chronic pain conditions such as complex regional pain syndrome (CRPS) that does not respond to medical treatment, peripheral diabetic neuropathy, post-herpetic neuralgia, and after failed back surgery.<sup>[7-11]</sup>

Although there are data in the literature showing that thoracic and lumbar SCS are effective, information on cervical SCS is limited. The indications given above are also valid for cervical SCS. Cervical SCS is a treatment method applied in chronic painful conditions with neck and upper extremity localization.<sup>[12-19]</sup>

Our aim in this retrospective study is to evaluate the success rate of SCS in nine patients who were applied cervical spinal cord stimulator between 2016 and 2019 in our pain clinic.

## Material and Methods

Nine patients who underwent SCS due to neck and upper extremity pain between January 1, 2016 and January 1, 2019, were included in our study. Medical (pharmacological, physical therapy, and

psychological support) and interventional (steroid injections, nerve blocks, and radiofrequency applications) treatments were unsuccessful, it was decided to attach a spinal cord stimulator at the Council of Hospital. Informed consent for the use of medical data was obtained from the patients. Approval was obtained from the hospital ethics committee (approval number İ4-226-20, dated April 22, 2020). The demographic information (height, weight, and gender) of the patients before and after the procedure, pain levels, pain characteristics (neuropathic and nociceptive), and the drug doses they used were scanned and recorded with the pain tracking forms available in our clinic. Information such as SCS application indications and SCS application location was accessed through the electronic database of our hospital. The pain levels of the patients before the procedure and the pain levels in the 1<sup>st</sup>, 6<sup>th</sup>, and 12<sup>th</sup> months after the procedure numeric rating scale (NRS) and the results of the McGill questionnaire were analyzed. The doses of antiepileptic (pregabalin) and analgesic drugs (nonsteroidal anti-inflammatory and opioids) used by the patients were analyzed. The pain pattern of the patients before the procedure was determined with the 4-question neuropathic pain questionnaire (DN4).

## Results

About 55.56% (five patients) of the study patients were male and 44.44% (four patients) were female, and their demographic data are shown in Table 1.

Seven (77.78%) of the patients had CRPS, 1 (11.11%) had post-laminectomy (failed neck surgery syndrome-C-FBBS), and 1 patient (11.11%) had a history of peripheral vascular disease (PVD) (Table 2).

Information such as the pain localization of the study patients and the SCS electrode placement level are shown in Table 2.

**Table 1.** Demographic data of patients

Variable	Mean±SD	Min.	Max.
Age (year)	51.8±17.1	29	76
Height (cm)	169.1±6.3	160	180
Weight (kg)	71.2±7.7	62	85

SD: Standard deviation; Min.: Minimum value; Max.: Maximum value.

**Table 2.** Patients' surgery information

No. of patients	Causes of pain	Localization of pain	DN4 score	SCS electrode implantation level	No. of electrode implanted at that level	SCS stimulation mode
1	PVD	Right upper limb	5	C2-C5	1	Conventional tonic
2	CRPS 1	Left upper limb	6	C4-C7	1	
3	CRPS 1	Both upper limbs	7	C2-C5	2	
4	CRPS 1	Left upper limb	6	C4-C7	1	
5	CRPS1	Right upper limb	7	C2-T1	1	
6	CRPS 2	Left upper limb	8	C2-T1	1	
7	C-FBBS	Both upper limbs	6	C2-C5	2	
8	CRPS 2	Left upper limb	8	C5-T1	1	
9	CRPS 1	Left upper limb	5	C3-C7	1	

DN4: 4-question neuropathic pain questionnaire; SCS: Spinal cord stimulation; PVD: Peripheral vascular disease; CRPS: Complex regional pain syndrome; C-FBBS: Cervical-failed back surgery syndrome.

The pain levels of the patients were evaluated with the NRS and McGill pain scores. While the mean NRS score before the procedure was 8.7, the NRS scores at 1 month, 6 months, and 1 year after the procedure were recorded as 5.2, 4, and 2.7, respectively. Although there was no significant decrease in NRS value in the 1<sup>st</sup> month after the procedure, a statistical decrease was observed in the NRS value in the 6<sup>th</sup> and 12<sup>th</sup> months after the procedure ( $p < 0.005$ ) (Table 3).

It was observed that there was a decrease of at least 50% and a maximum of 77% in the NRS values of the patients in the 12<sup>th</sup> month after the procedure (Table 4).

**Table 3.** NRS and McGill scale score changes

No. of patients (n=9)	NRS scale score mean±SD	McGill score mean±SD
Pre-procedure	8.8±0.9	70.2±3.1
Post-procedure		
1 <sup>st</sup> month	5.22±0.4	31.2±4.5
6 <sup>th</sup> month	4.0±0.0	25.7±6.3
12 <sup>th</sup> month	2.7±0.9	16.21±6.6

The NRS and McGill score values before and after the procedure in the 1<sup>st</sup>, 6<sup>th</sup>, and 12<sup>th</sup> months were analyzed using the Friedman test. NRS: Numeric rating scale; SD: Standard deviation.

**Table 4.** Decrease in NRS and McGill values of patients after the procedure (%)

No. of patients	Decrease in NRS value in the 1 <sup>st</sup> month after the procedure	Decrease in NRS value in the 6 <sup>th</sup> month after the procedure	Decrease in NRS value in the 12 <sup>th</sup> month after the procedure	Decrease in McGill value in the 1 <sup>st</sup> month after the procedure	Decrease in McGill value in the 6 <sup>th</sup> month after the procedure	Decrease in McGill value in the 12 <sup>th</sup> month after the procedure
1	-37.50	-50.00	-75.00	-42.86	-57.14	-85.71
2	-33.33	-55.56	-77.78	-55.88	-63.24	-85.29
3	-37.50	-50.00	-50.00	-54.79	-64.38	-72.60
4	-44.44	-55.56	-77.78	-51.43	-65.71	-84.29
5	-44.44	-55.56	-77.78	-56.92	-67.69	-69.23
6	-40.00	-60.00	-70.00	-60.81	-66.22	-68.92
7	-28.57	-42.86	-71.43	-64.18	-70.15	-88.06
8	-50.00	-60.00	-70.00	-58.33	-72.22	-75.00
9	-44.44	-55.56	-55.56	-54.79	-45.21	-64.38
p value	0.602	0.003	0.000	0.407	0.011	0.000

NRS: Numeric rating scale.

**Table 5.** Pregabalin doses

Pregabalin (mg)	Mean±SD	p
Pre-procedure	345.0±100.6	
Post-procedure		
6 <sup>th</sup> month	210.0±82.2	0.246
12 <sup>th</sup> month	105.0±100.6	0.008

Comparisons of the mean drug dose used before and after the procedure were analyzed using the Mann-Whitney U-test. SD: Standard deviation.

Although an insignificant decrease was observed in the McGill pain score in the 1<sup>st</sup> month after the procedure ( $p>0.05$ ), the decrease in the 6<sup>th</sup> and 12<sup>th</sup> month values was statistically significant ( $p<0.05$ ) (Table 4).

It was observed that there was a decrease of at least 64% and a maximum of 88% in the patients' McGill values in the 12<sup>th</sup> month after the procedure (Table 4).

**Table 6.** Analgesic drug usage information of the patients before and after the procedure

No. of patients	Causes of pain	Pre-procedure analgesic drugs and doses	Analgesic drug and its doses in the 1 <sup>st</sup> month	Analgesic drug after the procedure and its doses in the 6 <sup>th</sup> month after the procedure	Analgesic drug and its doses in the 12 <sup>th</sup> month after the procedure
1	PVD	Tramadol 50 mg p.o. (q6h)	Tramadol 50 mg p.o. (q6h)	Tramadol 37.5 mg+ paracetamol 325 mg p.o. (q6h)	Tramadol 37.5 mg+paracetamol 325 mg p.o. (b.i.d.)
2	CRPS 1	Tramadol 37.5 mg+paracetamol 325 mg p.o. (q6h) Diclofenac 50 mg p.o. (b.i.d.)	Tramadol 37.5 mg+paracetamol 325 mg p.o. (b.i.d.)	-	-
3	C-FBBS	Fentanyl transdermal patch 12 mcg/h (q72h) Dexketoprofen trometamol 50 mg p.o. (b.i.d.)	Fentanyl transdermal patch 12 mcg/h (q72h)	-	-
4	CRPS 1	Naproxen 250 mg p.o. (b.i.d.)	-	-	-
5	CRPS 1	Dexketoprofen trometamol 50 mg p.o. (b.i.d.)	-	-	-
6	CRPS 2	Fentanyl transdermal patch 24 mcg/h (q72h) Diclofenac 50 mg p.o. (q8h)	Fentanyl transdermal patch 12 mcg/h (q72h) Diclofenac 50 mg p.o. (q8h)	Tramadol 37.5 mg+paracetamol 325 mg p.o. (q8h) Diclofenac 50 mg p.o. (q8h)	Tramadol 37.5 mg+paracetamol 325 mg p.o. (q8h) Diclofenac 50 mg p.o. (q8h)
7	CRPS 1	Tramadol 37.5 mg+ paracetamol 325 mg p.o. (q6h)	Tramadol 37.5 mg+ paracetamol 325 mg p.o. (q8h)	-	-
8	CRPS 2	Fentanyl transdermal patch 12 mcg/h (q72h) Diclofenac 50 mg p.o. (q8h)	Fentanyl transdermal patch 12 mcg/h (q72h) Diclofenac 50 mg p.o. (q8h)	Fentanyl transdermal patch 12 mcg/h (q72h) Diclofenac 50 mg p.o. (q8h)	Fentanyl transdermal patch 12 mcg/h (q72h) Diclofenac 50 mg p.o. (q8h)
9	CRPS 1	Tramadol 100 mg p.o. (q8h) Acemetacin 90 mg p.o. (q8h)	Tramadol 100 mg p.o. (b.i.d.) Acemetacin 90 mg p.o. (q8h)	- Acemetacin 90 mg p.o. (b.i.d.)	- Acemetacin 90 mg p.o. (q.d.)

p.o. – per os; q72h – every 72 h; mg – milligram; mcg/h – microgram/h; q6h – every 6 h; b.i.d. – 2 times a day; q8h – every 8 h; q.d. – once a day. PVD: Peripheral vascular disease; CRPS: Complex regional pain syndrome; C-FBBS: Cervical-failed back surgery syndrome.

**Table 7.** Analgesic drug usage information of the patients before and after the procedure

Patient information	n	%
Number of patients using opioids before SCS	7	77.8
Number of patients not using opioids before SCS	2	22.2
Number of patients using opioids after SCS	3	33.3
Number of patients who decreased opioid dose after SCS	1	11.1
Number of patients not requiring opioids after SCS	4	44.4
Number of patients using NSAIDs before SCS	7	77.8
Number of patients not using opioids before SCS	2	22.2
Number of patients using NSAIDs after SCS	3	33.3
Number of patients who decreased NSAIDs dose after SCS	1	11.1
Number of patients not requiring NSAIDs after SCS	4	33.3

SCS: Spinal cord stimulation.

It was observed that all patients benefited from SCS and there was a serious decrease in their pain and an increase in the quality of life.

It was observed that pregabalin, which was used at an average dose of 345 mg before the procedure, decreased to 210 mg in the 6<sup>th</sup> month, and 105 mg was used in the 12<sup>th</sup> month, and two patients discontinued the drug. The decrease in the pregabalin drug dose used was found to be statistically significant ( $p < 0.05$ ) (Table 5).

The analgesic drug information used by the study patients before and after the procedure is shown in Tables 6 and 7.

## Discussion

Spinal cord stimulator is a proven neuromodulation treatment method in the treatment of chronic pain and has been widely used for more than 50 years. Examples of SCS application indications are chronic painful conditions such as failed back surgery syndrome, neuropathic pain, CRPS, PVD, and ischemic heart disease.<sup>[20,21]</sup> CRPS-it is a neuropathic pain condition known by many names such as Sudeck's atrophy, reflex sympathetic dystrophy syndrome, and causalgia. This disease, which often occurs as a result of trauma, surgery, or extremity immobilization, is very painful and it is known that approximately 10–20% of the cases become chronic and become resistant to treatment. CRPS occurs in two types. CRPS 1 often develops after any trauma (e.g., bone fracture and surgical intervention) that does not cause

significant nerve damage in the extremity. Type 2 CRPS occurs after a distinct nerve injury. Although its pathophysiology has not been fully explained, it is considered to be multifactorial. These include neurogenic inflammation, immunological mechanisms, and structural changes.<sup>[22]</sup>

CRPS treatment is very difficult and requires a multidisciplinary approach (physical therapy, psychosocial support, and pain management). In cases where there is no response to other methods in the treatment of CRPS, interventional procedures are widely used (percutaneous sympathetic blocks and SCS). All treatment methods should be selected individually, and in cases where a response to medical treatment is predicted (advanced stage CRPS patients), interventional procedures should be applied early.

SCS was applied due to CRPS in seven out of nine patients included in our study. Of these, five patients were diagnosed with CRPS 1, while the other two patients were diagnosed with CRPS 2. There was no response from the applied physical, pharmacological, and psychosocial treatment, and the effectiveness of the percutaneous sympathetic block was short term or negative. We observed a significant decrease in pain scores in the 6<sup>th</sup> and 12<sup>th</sup> months after the procedure in patients who underwent SCS. These results are compatible with the data in the literature.<sup>[22,23]</sup>

The patients we applied SCS are mostly advanced stage CRPS patients, and other treatment methods

have not benefited. Calvillo et al.<sup>[24]</sup> reported in their study that they provided long-term pain control with SCS in advanced stage CRPS patients.

There are publications proving the efficacy of SCS in the treatment of CRPS patients who do not respond to sympathetic blocks. Especially when applied in combination with SCS and other treatment methods (e.g., physical therapy), its long-term effects have been evaluated positively.<sup>[25]</sup>

When we examine the SCS application indications of the patients included in the study, we see that one patient had post-laminectomy syndrome, and one patient had vascular neuropathic pain. Significant decrease was observed in the pain levels after the procedure in both patients.

It is supported by the literature data that SCS is also effective in cases of brachial plexus damage, spinal cord injury, after C-FBSS, and vascular neuropathic pain.<sup>[26]</sup>

In all of the study patients, there was a significant reduction in pain levels after the procedure, and a reduction in the need for antiepileptic drug was also observed. Although there was no significant change in the antiepileptic drug (pregabalin) doses used by the patients in the 6<sup>th</sup> month follow-up after the procedure, it was observed that the drug was not needed in two patients at the 12<sup>th</sup> month follow-up. It was noticed that there was a significant decrease in the drug doses used by other patients.

There was a decrease in the analgesic drug doses used by the patients after SCS. Some patients reduced the doses of opioids and nonsteroidal anti-inflammatory drugs they used, and some patients no longer needed analgesic use.

Some complications may occur during or after SCS insertion. Wound infection and electrode rupture and migration are among the most common complications.<sup>[27]</sup> The complication rate is higher in cervical SCS. Electrode migration and breakage are the most common causes requiring reoperation.<sup>[28]</sup> In our clinic, no complications were observed in any of the nine patients who underwent cervical SCS during and after the procedure.

## Limitations

One of the limitations of our study is that since it is a retrospective study, the information was obtained from the patients' files and phone calls.

Another limitation of our study is the low number of patients included in the study.

## Conclusion

In this study, in which we aimed to evaluate the long-term effectiveness of the method in patients undergoing cervical SCS. Our SCS application indications were CRPS, PVD, and C-FBSS. We found statistically significant post-procedural pain level and drug dose changes of the patients. We think that SCS is an effective and reliable treatment method in chronic pain palliation in line with other studies and our study.

**Ethical Approval:** *The study was approved by The Ankara University Faculty of Medicine Human Research Ethics Committee (Date: 22/04/2020, No: İ4-226-20).*

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