

Evaluation of Patients Undergoing Spinal Cord Stimulation Using the e-Health Tool

Spinal Kord Stimülasyonu Uygulanan Hastaların e-Health Tool ile Değerlendirilmesi

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Abstract

Objectives: The aim of the study is to evaluate patients undergoing spinal cord stimulation (SCS) using an online decision support system (SCS e-health tool).

Materials and Methods: In this study, data of patients who underwent SCS between 2005 and 2023 at the Department of Algology, Ankara University Faculty of Medicine, were retrospectively analyzed. The clinical characteristics of the patients were assessed using an e-health tool scoring system proposed by the panel and presented online. Furthermore, the alignment of the implanted SCS devices with the recommendations of this scoring system was evaluated.

Results: It was determined that the median SCS appropriateness score for the 117 patients who underwent SCS implantation was 7, and only 3 patients had the SCS removed during the trial period. All the patients who underwent SCS implantation in our study met the eligibility criteria for SCS according to the e-health tool algorithm.

Conclusion: We observed a much lower rate of SCS removal during the trial period compared to the literature. We believe this is attributable to the multidisciplinary evaluation conducted at our hospital by highly competent specialists from various fields who assess patients for SCS suitability.

Keywords: Spinal cord stimulation, health information systems, decision support systems, chronic pain

Öz

Amaç: Çalışmanın amacı, spinal kord stimülasyonu (SKS) için özel klinik karar destek sistemi (SCS e-health tool) ile SKS uygulanan hastaları değerlendirmektir.

Gereç ve Yöntem: Bu çalışmada, Ankara Üniversitesi Tıp Fakültesi, Algoloji Anabilim Dalı'nda 2005-2023 yılları arasında SKS uygulanan hastaların verileri retrospektif olarak analiz edildi. Hastaların klinik özellikleri, panel tarafından önerilen ve çevrimiçi olarak sunulan bir özel klinik karar destek sistemi (SCS e-health tool) puanlama sistemi kullanılarak değerlendirildi. İmplant edilen SKS cihazlarının bu puanlama sisteminin önerileriyle uyumu değerlendirildi.

Bulgular: SKS uygulanan 117 hasta için uygunluk puanının medyan değeri 7 olduğu ve deneme süresi sonunda sadece 3 hastada SKS çıkarıldığı belirlendi. Çalışmamızda SKS uygulanan tüm hastalar, çevrimiçi karar destek sistemi algoritmasına göre uygunluk kriterlerini karşıladı.

Sonuç: Deneme süresi sonunda literatüre kıyasla çok daha düşük bir SKS çıkarılma oranı gözlemledik. Bu durumun, hastanemizdeki SKS uygunluğunu değerlendiren, çeşitli alanlardan yetkin uzmanların yer aldığı multidisipliner konseyden kaynaklandığını düşünmekteyiz.

Anahtar Kelimeler: Spinal kord stimülasyonu, sağlık bilgi sistemleri, klinik karar destek sistemleri, kronik ağrı

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Introduction

Spinal cord stimulation (SCS) is considered a therapeutic option for managing refractory pain in conditions such as failed back surgery syndrome, postherpetic neuralgia, traumatic nerve injury, refractory angina pectoris, peripheral vascular disease, neuropathic pain syndromes (NPS), and complex regional pain syndrome (CRPS) (1,2). The efficacy of SCS is mainly based on the gate control theory. Through SCS, A β fibers are activated, which inhibits the excitation generated by C fibers in the same area (3). SCS is also believed to activate descending pain inhibitory pathways (2).

Appropriate patient selection and accurate identification of indications are critical for the success of SCS. Patients must be evaluated for eligibility by a multidisciplinary team of experts before the procedure. Additionally, applying an SCS requires lifelong patient cooperation and the ability to manage the device effectively (4). Eligibility criteria for SCS implantation include chronic refractory pain lasting longer than six months, the presence of objective pathology consistent with the reported pain, lack of response to conventional pain management methods, being 18 years of age or older, the ability to understand and accept the risks associated with the treatment, the capability to operate the device, not being pregnant, and the absence of emotional instability or psychiatric disorders (5).

Patients with appropriate indications for SCS are evaluated by a multidisciplinary council comprising specialists in neurosurgery, physical medicine and rehabilitation, algology, neurology, and psychiatry at our institution. Following approval by the council, a trial period of SCS is initiated for eligible patients. Patients who achieve at least a 50% reduction in pain intensity and express satisfaction with the treatment during the 7-10 day trial period are subsequently implanted with a permanent internal generator (6). In cases where patients report insufficient pain palliation during the trial period, the leads and generator are removed.

Recently, a multidisciplinary panel comprising 18 experts (including 10 anesthesiologists, 3 neurosurgeons, 3 psychologists, a specialist nurse, and a physiotherapist) from nine European countries convened to develop an e-health tool. This panel identified absolute indications and contraindications for SCS. Additionally, four main indication areas for SCS were outlined: chronic low back/leg pain (CLBP), CRPS, NPS, and ischemic pain syndromes (IPS). The panel assessed the suitability of SCS based on clinical variables associated with patients meeting these diagnostic criteria (7).

SCS has been used in our clinic for the past 15 years. After being approved by our multidisciplinary team for the trial phase, SCS leads and a temporary generator are implanted.

During the trial period, if patients report inadequate pain relief or complications develop, the SCS components are removed. This study aims to evaluate the data of patients presented to the council for SCS implantation and to assess their suitability based on the e-health tool parameters.

Materials and Methods

This study was conducted at Ankara University. The study protocol was approved by the Ankara University Human Research Ethics Committee (decision no.: İ07-543-23, date: 12.09.2023) and was conducted in full compliance with the principles of the Declaration of Helsinki. Patients who were considered for SCS implantation and presented to the Ankara University Faculty of Medicine Movement Disorders Council between January 1, 2005, and August 1, 2023, were included in the study.

SCS e-health tool is accessible via www.scstool.org. A multidisciplinary panel comprising 18 experts (including 10 anesthesiologists, three neurosurgeons, three psychologists, a specialist nurse, and a physiotherapist) from nine European countries convened to develop an e-health tool. Four main indication areas for SCS were outlined: CLBP, CRPS, NPS, and IPS. The panel assessed the suitability of SCS based on clinical variables associated with patients meeting these diagnostic criteria (7). Suitability was determined using the RAND/UCLA appropriateness method (8), applied across 386 potential scenarios. Clinical variables included treatment history, the type/nature and location of pain, anatomical abnormalities, pain distribution, and response to previous procedures. For patients considered for SCS implantation, the system assigns a score on a 9-point scale based on diagnoses and clinical variables. The scoring categorizes 1-3 points as "inappropriate", 4-6 points as "uncertain", and 7-9 points as "appropriate". Additionally, the e-health tool identifies eight psychosocial factors that may influence SCS outcomes, including lack of willingness to participate, impaired coping abilities, unrealistic expectations, inappropriate levels of daily activity, social support issues, secondary gain, psychological stress/mental health concerns, and reluctance to reduce high-dose opioid use (5,7,9).

Statistical Analysis

Demographic data, including age, gender, pain etiology, pain intensity, pain characteristics, and physical examination findings, were collected from hospital records and patient files. Patients approved and not approved by the council and those who underwent trial and permanent SCS implantation were recorded. E-health tool scores for the patients were determined online via <https://www.scstool.org>. The demographic data and e-health tool scores of patients who underwent trial and permanent SCS were statistically compared. Additionally, any potential complications observed in these patients were documented. The data were

analyzed using IBM SPSS Statistics (Version 29.0.1 for MacOS, Armonk, NY, IBM Corp). The demographic data and e-health tool scores of patients who underwent trial and permanent SCS were analyzed by descriptives and crosstabs. Data were presented as units (n), percentage (%), mean \pm standard deviation, median, minimum, and maximum.

Results

A total of 117 patients underwent SCS implantation. Our clinic's initial SCS application was identified as taking place in 2009. The mean age of the patients was 52 ± 12.9 years (range: 18-80). The demographic and clinical characteristics of the patients are presented in Table 1. CLBP (n=95) was the most common condition among the patients, followed by NPS (n=17). The SCS appropriateness score, calculated after analyzing clinical information using the tool, had median values of 7, 7, 7.5, and 5.5 for CLBP, NPS, CRPS, and IPS, respectively. Unwillingness to reduce high-dose opioids (n=2), inadequate daily activity levels

(n=1), and both (n=3) were the most common psychosocial factors associated with unfavorable SCS outcomes.

Among the 117 patients, only three patients had NPS had the device removed during the trial period. The mean age of patients with CLBP was 53.7 ± 12 years (range: 26-80), while the mean age of patients with NPS was 45 ± 14.7 years (range: 18-79). The demographic and clinical characteristics of patients with CLBP and those with NPS are shown in Table 2 and Table 3, respectively.

Discussion

SCS is most commonly applied to the thoracic region in our clinic for chronic low back and leg pain. According to the e-health tool, the median score was 7, and no patients were identified as unsuitable for SCS based on this tool. However, due to its insufficient effectiveness, only three patients had their devices removed during the trial period.

SCS has been a technique used in chronic pain management for over 50 years. It is applied in conditions such as NPS, CRPS, and CLBP (1,6). Consistent with the data in the literature, the most common indication for SCS in our patient population was CLBP (10).

Table 1: Demographic and clinical characteristics of the patients	
Variables	n=117
Gender n (%)	
Male	62 (53)
Female	55 (47)
Main indication n (%)	
Chronic low back/leg pain	95 (81.2)
NPS	17 (14.5)
IPS	3 (2.6)
CRPS	2 (1.7)
Dominant type of pain n (%)	
Neuropathic	109 (93)
Nociceptive	-
Ischemic	3 (2.6)
Mixed	5 (4.3)
Response to previous treatments n (%)	
Partial/temporary	37 (31.6)
No relief	80 (68.4)
SCS recommendation grade n (%)	
Suitable	96 (82.1)
May be suitable	21 (17.9)
SCS implantation site n (%)	
Thoracic	102 (87.2)
Cervical	15 (12.8)
Decision after trial period n (%)	
Permanent implantation	114 (97.4)
Removal	3 (2.6)
n: Patient number, %: Percentage, CRPS: Complex regional pain syndrome, NPS: Neuropathic pain syndromes, IPS: Ischemic pain syndrome, SCS: Spinal cord stimulation	

Table 2: Demographic and clinical characteristics of patients with chronic low back/leg pain	
Variables	n=95
Gender n (%)	
Male	46 (48.4)
Female	49 (51.6)
Previous spine surgery (Yes/No) n (%)	89/6 (93.7/6.3)
Main location of pain n (%)	
Leg	72 (75.8)
Back	-
Mixed (leg and back)	23 (24.2)
Dominant type of pain n (%)	
Neuropathic	92 (96.8)
Nociceptive	-
Mixed	3 (3.2)
Anatomic abnormality n (%)	
Iatrogenic nerve lesion	7 (7.4)
Spinal/foraminal stenosis	-
Recurrent disc	12 (12.6)
Scar tissue	76 (80)
Spinal instability	-
Response to previous treatments n (%)	
Partial/temporary	28 (29.5)
No relief	67 (70.5)
n: Patient number, %: Percentage	

Table 3: Demographic and clinical characteristics of patients with neuropathic pain syndromes

Variables	n=17
Gender	
Male	14 (82.4)
Female	3 (17.6)
Origin of pain	
Traumatic nerve lesion	11 (64.7)
Cervical radicular pain	2 (11.8)
Phantom pain	1 (5.9)
Small fiber neuropathy	1 (5.9)
Brachial plexus injury	1 (5.9)
Arteriovenous malformation	1 (5.9)
Dominant symptom	
Neuropathic	15 (88.2)
Nociceptive	-
Mixed	2 (11.8)
Spread of pain	
Leg(s)	12 (70.6)
Arm(s)	5 (29.4)
Mononeuritis	-
Response to previous treatments	
Partial/temporary	8 (47.1)
No relief	9 (52.9)
SCS implantation site	
Thoracic	13 (76.5)
Cervical	4 (23.4)
n: Patient number, %: Percentage, SCS: Spinal cord stimulation	

In the panel, patients were assessed through questions regarding their treatment history, pain type, and whether they benefited from previous interventional treatments. Based on patient-specific responses, a tool scores out of 9 was assigned. Additionally, the psychosocial status of the patients was evaluated, focusing on factors such as lack of engagement, dysfunctional coping mechanisms, unrealistic expectations, inadequate daily activity levels, problematic social support, secondary gain, psychological distress/mental health problems, and unwillingness to reduce high-dose opioid use (7). Inadequate daily activity levels and unwillingness to reduce high-dose opioids were the most observed compromising factors in our study.

SCS is a more invasive technique compared to other procedures that we perform in pain medicine and is also an expensive method in the context of our country's healthcare conditions. Since SCS is ineffective in some patients, appropriate patient selection is crucial (11). In studies, the median trial success rate has been reported to range between 72% and 82%

(12). Common characteristics or factors associated with the risk of poor long-term SCS outcomes include depression, anxiety, catastrophizing, poor coping skills or self-efficacy, abnormal personality traits, inadequate pain acceptance, self-doubt, weak social support, post-traumatic stress disorder, and the presence of secondary gain. Substance use and major psychiatric disorders are also associated with poor outcomes in SCS and may even be considered contraindications for the procedure (11). Additionally, a high BMI, smoking, and high-dose opioid use at baseline are also factors that negatively impact the effectiveness of SCS (11). Typical characteristics associated with poor outcomes include substance dependence, pain catastrophizing, depression, anxiety, and several other factors (6,13). In the study, 3% of patients strongly recommended for SCS experienced failed trials, whereas 46% of patients not recommended based on the e-health tool had unsuccessful trials (9). It was reported that 308 patients (64%) had one or more psychosocial factors to consider when determining suitability for SCS. The three most commonly reported psychosocial factors were psychological distress/mental health problems (42.2%), inadequate daily activity levels (38.1%), and dysfunctional coping (27.2%) (9). In contrast, 95% of the patients who underwent SCS in our clinic had no psychosocial risk factors. The psychosocial risk factors identified in the remaining 5% were inadequate activity levels and/or unwillingness to reduce opioid use. We believe the high success rate of SCS in our clinic is due to the comprehensive psychological evaluation we perform before presenting patients to the multidisciplinary committee. Additionally, the appropriateness score of 7/9 calculated by the e-health tool for our patients underscores our focus on selecting appropriate candidates for committee evaluation.

Study Limitations

Our study has some limitations, including retrospective single-center study design and the short-term follow-up of the patients.

Conclusion

In conclusion, our clinic's workflow correlates with the SCS e-health tool. We believe that this tool can be important to reduce healthcare costs and save time.

Ethics

Ethics Committee Approval: The study protocol was approved by the Ankara University Human Research Ethics Committee (decision no.: İ07-543-23, date: 12.09.2023) and was conducted in full compliance with the principles of the Declaration of Helsinki.

Informed Consent: Consent was not obtained since it was a retrospective study.

Footnotes

Authorship Contributions

Surgical and Medical Practices: G.E.Ö., İ.A., Concept: H.A.Ü., İ.A., Design: H.A.Ü., İ.A., Data Collection and/ or Processing: H.E.A., A.B., Analysis and/or Interpretation: H.A.Ü., E.S., G.E.Ö., İ.A., Literature Search: H.A.Ü., E.S., Writing: H.A.Ü., E.S.

Conflict of Interest: There is no potential conflict of interest to declare.

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