Akbas et al. The Egyptian Journal of Neurology, Psychiatry and Neurosurgery (2019) 55:84
https://doi.org/10.1186/s41983-019-0131-6

The Egyptian Journal of Neurology, Psychiatry and Neurosurgery

RESEARCH Open Access

Sensor driven-position adaptive versus conventional spinal cord stimulation in failed back surgery syndrome: a retrospective case series

Mert Akbas[1], Haitham Hamdy Salem[2*], Tamer Hussien Emara[2], Bora Dinc[1] and Bilge Karsli[1]

Abstract

Background: Failed back surgery syndrome (FBSS) is a common problem affecting 20–40% of cases undergoing spine surgeries. Spinal cord stimulation (SCS) has been shown to be an efficient and relatively safe treatment in managing many intractable chronic pain syndromes.

Objectives: This study compares the efficacy and safety of MR-compatible sensor driven-position adaptive SCS and conventional SCS in treating FBSS.

Methods: This is a retrospective case series of 120 consecutive FBSS patients who underwent SCS between February 2011 and March 2018. Pain levels, analgesic/opioid use, and sleep problems were assessed before and 3 months after the procedure in patients who received either conventional SCS (group 1; $n = 62$) or sensor-driven position adaptive SCS (group 2; $n = 34$). The degree of patient satisfaction, the change in the activities of daily living (ADLs) together with the rate of complications were compared in both treatment groups.

Results: The two treatment groups were homogenous at baseline. Patients in both groups improved significantly regarding pain, opioid consumption, sleep, and ADLs. The magnitude of improvement was statistically higher in group 2. An absolute reduction of 6 points on the VAS in patients who received position adaptive SCS vs a 3.3 point reduction in conventional SCS cases ($p < 0.0001$). Half of the patients in group 2 ($n = 17$) showed excellent satisfaction after the procedure versus 14.5% of cases in group 1 ($n = 9$).

Conclusion: SCS is an efficient and reliable treatment in FBSS. MR-compatible sensor driven-position adaptive SCS can be a more effective treatment in this patient group.

Keywords: Neuromodulation, Spinal cord stimulation, Position adaptive stimulation, Failed back surgery syndrome, Chronic back pain, VAS score

Introduction

Failed back surgery syndrome (FBSS) is increasing in frequency owing to the increase in the number of cases undergoing spine surgeries. This syndrome is considered when chronic longstanding back pain with or without a radicular component persists 6 months or more after a spine surgery. Unfortunately, 20–40% of cases develop FBSS after surgeries. The present standards for the management of failed back surgery syndrome (FBSS) include a multidisciplinary approach using pharmacological, psychological, physical therapies, and in resistant cases, surgical interventions can be an option [1–3].

At this point, neuromodulation can be an effective add on the therapeutic modality in alleviating patient suffering. Recent studies have shown that spinal cord stimulation (SCS) is an efficient, reliable and relatively safe treatment in many chronic pain syndromes including FBSS with 50 to 70% improvement rates [4, 5]. Comparative studies showed that SCS is better than reoperation in the short and long terms [1, 3].

* Correspondence: haithamhamdy@yahoo.com
[2]Department of Neurology, Ain Shams University, Cairo, Egypt
Full list of author information is available at the end of the article

Alteration in the intensity of neuro-stimulation occurring with changes of body position is a chief problem facing many patients who have received conventional SCS implants as excessive stimulation generates notable discomfort and hence manual programming is needed repeatedly [6–9]. MR-compatible sensor driven-position adaptive feature can address this problem as it is designed to identify changes in body position or activity and automatically adjust stimulation [8, 10].

The primary aim of this study is to assess the safety and efficacy of sensor driven-position adaptive SCS in comparison to conventional SCS. For this purpose, we retrospectively reviewed and compared data from all cases who received conventional or position adaptive SCS over a period of 7 years in our pain center.

Methods

Patients

We recruited 120 patients who received *SCS implants* at our pain clinic at Akdeniz university hospital, Antalya, Turkey, in the period from March 2011 to March 2018. Akdeniz University ethical committee approval was granted on 12 July 2018.

Inclusion criteria

Patients older than 18 years old, suffering from lumbar FBSS pain, with pain intensity > 5 VAS for at least 6 months after lumbar spinal surgeries, not responding to previous conservative medical therapy including NSAIDS, muscle relaxants and pregabalin, physical, and functional therapies.

Exclusion criteria

Patients with other causes of refractory lumbar back pain, for example, facet arthropathy or myofascial pain. Patients who failed the trial period of SCS or those who did not show up in follow-up visits after the procedure were excluded from the final analysis.

Procedure

Retrospective evaluation of patient records was conducted. All procedures were performed in the operating theater under fluoroscopy equipped for monitoring patients' vital data as electrocardiogram, non-invasive blood pressure measurement and pulse oximeter. The patient is positioned in a prone position followed by sterilization and draping. Titration of 0.05 mg/kg midazolam and 1–2 mg/kg fentanyl were administered for patient sedation. Skin incision area was infiltrated with local anesthesia and a small incision was made in the intervertebral space with the creation of a small pocket for electrode connection cables placement. After identifying the L1–L2 intervertebral space with fluoroscopic guidance, a 14 G Touhy/16 G R-K injector was advanced paramedial at an angle near 45° till entering the epidural space, correct needle position was confirmed by fluoroscopic imaging. In order to facilitate electrode entry and advancement in the epidural area, a directive guide was advanced through the epidural injector followed by the electrode. Under fluoroscopic guidance, the electrode was advanced forward to the corresponding spinal cord segment. Stimulators were activated under various stimulation parameters to identify the most convenient scope of paresthesia for the patient's pain area and the electrode was fixed subcutaneously. Electrode interconnecting cables were subcutaneously passed through and extracted from a distant point. We used (Medtronic, Inc., Minneapolis, MN, USA) for conventional spinal cord stimulation and (Medtronic, Inc., Minneapolis, MN, AdaptiveStim ™, USA) for MR-compatible sensor driven-position adaptive SCS. Patients were monitored for 3 h after the operation in the recovery room. Patients and their relatives were educated on how they should use the device. At the end of a two week trial period, If the patient achieved a 50% reduction in VAS score with no disabling paresthesia, the trial was considered successful and the part placed in the intervertebral space was connected to the permanent system. Those who did not respond favorably in terms of pain reduction did not receive the permanent SCS system and were excluded from the final analysis.

Outcome measures

The primary outcome measure was a 50% reduction in Pain severity and was assessed using visual analogue scale (VAS). The number of patients using opioid analgesics, and/or experiencing sleep problems was counted before the procedure and was reassessed 3 months after it. Also, the degree of patient satisfaction (using a 5-point Likert scale) and the perception of patients regarding the performance of their activities of daily living (worsening, no change, less than 50% improvement, and more than 50% improvement) were recorded 3 months after the procedure. Operative and/or postoperative complications were recorded.

Data analysis

Analysis was done in SPSS version 22 (SPSS Inc., Chicago, IL, USA) using one-way ANOVA (continuous variables), Pearson correlation coefficient, Mann-Whitney test, and χ^2 test (dichotomous variables).

Results

The baseline characteristics of the studied sample (n = 96) showed no significant statistical difference ($p > 0.05$) between the two groups (Table 1).

Patients' VAS scores were evaluated before and after SCS (Fig. 1). The VAS scores of patients with MR-compatible sensor driven-position adaptive SCS were reduced from 9.00

Table 1 General characteristics of the study population[a]

	Conventional SCS (n = 62)	Position adaptive SCS (n = 34)
Gender		
Male	23 (37.1%)	13 (38.2%)
Female	39 (62.9%)	21 (61.7%)
Age	65.95±9.16	62.11 ±7.50
VAS baseline	7.92 ± 1.04	9 ± 1.07
Sleep problems	30 (88.2%)	51 (82.2%)
Opioid use	24 (38.8%)	20 (58.8%)

SCS spinal cord stimulation; *VAS* visual analog scale
[a]There was no statistical significance between the two groups $p > 0.05$

± 1.07 to 3.00 ± 2.08 with 66.6% improvement (6 points VAS absolute reduction) ($p < 0.001$). Similarly, VAS scores in conventional SCS patients were reduced from 7.92 ± 1.04 to 4.60 ± 1.77 with 41.9% improvement (3.3 points VAS absolute reduction) ($p < 0.001$). Moreover, on comparing both groups, sensor driven-position adaptive SCS was better than the conventional SCS in reducing patients' pain ($p < 0.001$).

The need for opioid analgesics was reduced in both groups after SCS. After conventional SCS, the number of patients using opioid analgesics dropped by 50% from 24 (38.8%) to 12 (19.4%) patients, while 3 (4.8%) patients of those still on opioids reduced their previous opioid analgesics daily dosage. Similarly, in group of position adaptive SCS, the number of patients using opioid analgesics dropped 75% from 20 (58.8%) to 5 (14.7%) patients, while 3 (8.8%) patients of those still on opioids reduced their previous opioid analgesics daily dosage. However, Inter-group comparison did not show a statistically significant difference between both treatment groups after treatment ($p = 0.57$).

The degree of patient satisfaction after position adaptive SCS group was significantly higher when compared to patients who received conventional SCS ($p < 0.001$) (Table 2).

Regarding the change in activities of daily living, 24/34 (70.6%) patients reported that they have experienced "more than 50%" improvement while 9 (26.5%) reported "less than 50%" improvement. Of all conventional SCS patients, 31/62 (50%) patients reported that they have experienced "more than 50%" improvement while 30 (48.4%) reported "less than 50%" improvement. Two patients (one in each group) reported that they had experienced no change in their daily activities. In both studied groups, no patients reported any deterioration in their daily activities after the procedure. On comparing both groups, position adaptive SCS was statistically more efficient in improving daily activities ($p < 0.05$).

Upon following up sleep problems, in conventional SCS groups 26/51 (51%) and in position adaptive SCS group 26/30 (86.7%) reported improvement in their sleep pattern following the procedure. The sleep pattern of patients in both groups showed significant improvement ($p < 0.001$). However, patients with position adaptive SCS showed a better response ($p < 0.05$).

Only 6 (9.7%) patients with conventional SCS had complications related to the procedure. The most common complications were infection in two patients followed by electrode migration in two patient, and inadequate signal transmission in one patient. On the other hand, in cases of position adaptive SCS, three cases (8.8%) developed procedure-related complications with two patients experiencing wound infection and one patient had lead migration.

SCS revision was performed for one (3%) patient of position adaptive SCS group compared to three (4.8%) patients of the conventional SCS group. The device was removed from three (9.1%) patients who underwent position adaptive SCS implantation procedure as two patients were not able to use the system and the third due

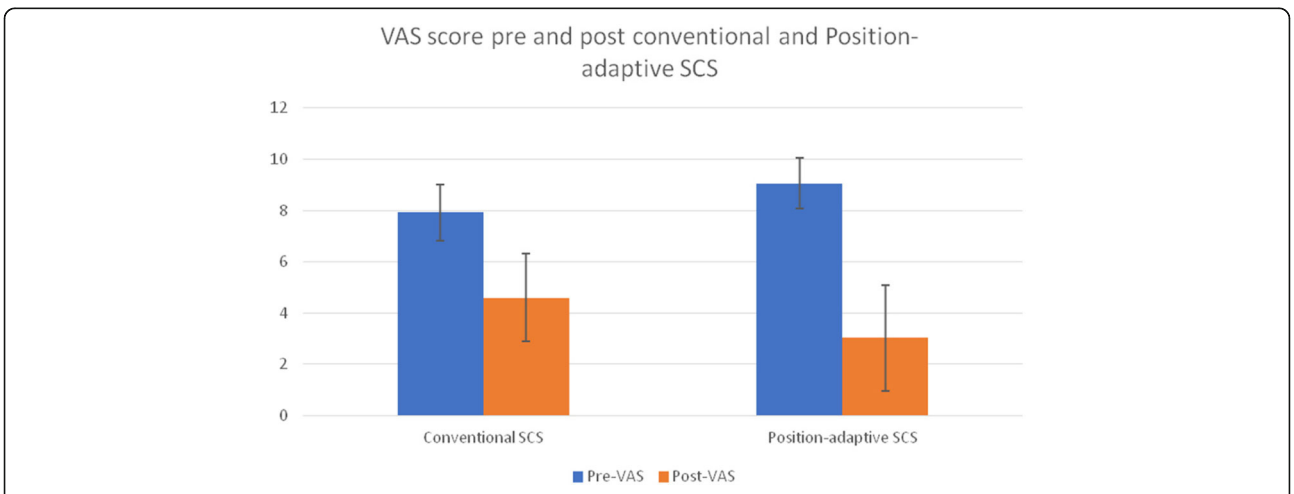

Fig. 1 Comparison between the two treatment groups regarding the change in VAS scores. VAS, visual analog scale. SCS, spinal cord stimulation

Table 2 The degree of patient satisfaction after the procedure in both treatment groups

Patient satisfaction	Conventional SCS (n = 62)		Position-adaptive SCS (n = 34)	
	Number	%	Number	%
Excellent satisfaction	9	14.5	19	55.9
Moderate satisfaction	22	35.5	8	23.5
Hesitant/no change	8	12.9	2	5.9
Not satisfied	18	29	3	8.8
Absolutely not satisfied	5	8.1	2	5.9

SCS spinal cord stimulation

to battery problems. While, for the group with conventional SCS, the system was removed from eight (13%) mostly due to poor response or pain recurrence.

Discussion

Chronic pain is one of the main leading causes of physical and emotional disability, social disruption, and work absenteeism. Neuromodulation with SCS is one of the most exciting modalities for managing refractory chronic pain [11]. The mechanism of its action is believed to be through inhibiting pain by stimulating the large diameter afferent nerve fibers in the spinal cord, which is based on the gate control theory of pain proposed by Melzack and Wall [12]. Previous work showed the effectiveness of SCS in cases of FBSS not responding to conventional medical treatment.

In our case series, patients' pain level measured by VAS score decreased significantly in both conventional SCS and position adaptive SCS groups. The results were similar to previous randomized trials [5, 6, 13–16]. Furthermore, position adaptive SCS was superior over conventional SCS in reducing VAS score ($p > 0.001$). Similarly, Shultz and colleagues [7] demonstrated that automatic position-adaptive stimulation is effective in terms of patient-reported pain relief and convenience compared with using manual programming.

Ramineni and colleagues reported that pain lessening after SCS increased sleep quality and improved quality of life [17]. Likewise, our results proved to be concomitant as patients' quality of sleep after both conventional and position adaptive SCS patient populations was observed to improve significantly ($p < 0.001$). Position adaptive SCS patients' group showed better sleep quality compared to conventional SCS, this could be attributed to the ability of Position adaptive SCS to prevent pain bouts that can be triggered by changing position during sleep.

The role of SCS in reducing opioids analgesic demand was controversial. Several studies reported a significant decrease in the use of opioid analgesics after SCS operation [15, 18, 19]. Another study, however, argued that SCS operation did not result in a decrease in opioid need [14]. In our study, we evaluated changes in patients' analgesic usage after SCS implantation. We found that 50% of patients stopped using their opioid medication after SCS implantation while 75% stopped using opioids in the position adaptive SCS group. Nevertheless, the difference between the two groups was not statistically significant.

In our study, we analyzed the satisfaction levels of patients after SCS. In the position, adaptive SCS group, 79.4% of cases were satisfied after treatment (55.9% reported excellent satisfaction) whereas in the conventional SCS group 50% of cases were satisfied (14.5% with excellent satisfaction). Similarly, In the multicentric prospective randomized control study by Kumar and colleagues [6]. and the large trial done by Sanders and colleagues reported that 84.27% of the patients were satisfied with SCS implantation [18]. Improvement in daily activities of patients is an important indicator of the efficiency of treatment. In our study, 51.6% of the patients reported more than 50% improvement in their daily activities while 43.5% reported less than 50% improvement. Similar results were conformed in many studies [10, 16, 18].

Our study had some limitation including unknown analgesics dosages. Reasons for this were patients' low socio-cultural and educational levels and irregular drug usage. Therefore, information related to analgesics usage in our patient follow-up records were evaluated such as "using in the same way," "reduced dosage," and "not using". Follow-up of pain relief and patient satisfaction was studied after 3 months only yet, longer study duration would be favorable in confirming the results.

In conclusion, SCS is an efficient and reliable treatment modality in chronic pain palliation in line with the findings of our study and other supporting studies found in the literature. Moreover, MR-compatible sensor-driven position adaptive SCS may be preferred in terms of clinical effectiveness, patient satisfaction, and ease of use compared to conventional SCS.

Acknowledgements
Not applicable

Consent to participate
This is a retrospective study and data was de-identified, whoever all patients' consents to undergo SCS procedure were reviewed.

Authors' contribution
MA participated in the design of the study, performed some of the procedures for radiofrequency thermocoagulation, and revised the manuscript. HHS performed some of the procedures for radiofrequency thermocoagulation and participated in the manuscript production.THE participated in data analysis and participated in the manuscript production. BD collected the data and participated in data analysis.BK participated in the design of the study and revised the manuscript. All authors read and approved the final manuscript.

Funding
None

Availability of data and materials
Available on request.

Ethics approval and consent to participate
Akdeniz university ethical committee approval was granted on 12 July 2018.

Consent for publication
Not applicable

Competing interests
The authors declare that they have no competing interests.

Author details
[1]Department of Pain Medicine, Akdeniz University, Antalya, Turkey.
[2]Department of Neurology, Ain Shams University, Cairo, Egypt.

Received: 25 August 2019 Accepted: 12 November 2019
Published online: 12 December 2019

References

1. Taylor RS, Taylor RJ. The economic impact of failed back surgery syndrome. Br J Pain. 2012;6(4):174–81.
2. Thomson S. Failed back surgery syndrome–definition, epidemiology and demographics. Br J Pain. 2013;7(1):56–9.
3. Van Buyten JP, Linderoth B. "The failed back surgery syndrome": definition and therapeutic algorithms - An update. Eur J Pain Suppl. 2010;4(4):273–86.
4. Manchikanti L, Singh V, Smith HS, Hirsch JA. Evidence-based medicine, systematic reviews, and guidelines in interventional pain management: part 6. Systematic reviews and meta-analyses of observational studies. Pain Physician. 2009;12(5):819–50.
5. Mekhail NA, Mathews M, Nageeb F, Guirguis M, Mekhail MN, Cheng J. Retrospective Review of 707 Cases of Spinal Cord Stimulation: Indications and Complications. Pain Pract. 2011;11(2):148–53.
6. Kumar K, Taylor RS, Jacques L, Eldabe S, Meglio M, Molet J, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: a multicentre randomised controlled trial in patients with failed back surgery syndrome. Pain. 2007;132(1-2):179–88.
7. Schultz D, Webster L, Kosek P, Sun M, Tan Y. Position-adaptive spinal cord stimulation (SCS) for chronic pain: Results of the restoresensor study. Pain Pract. 2012;15(1):668.
8. Schade CM, Schultz D, Tamayo N, Iyer S, Panken E. Automatic adaptation of neurostimulation therapy in response to changes in patient position: Results of the posture responsive spinal cord stimulation (PRS) research study. Pain Physician. 2011;14(5):407–17.
9. Kumar K, Taylor RS, Jacques L, Eldabe S, Meglio M, Molet J, et al. The effects of spinal cord stimulation in neuropathic pain are sustained: a 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation. Neurosurgery. 2008;63(4):762–70.
10. Frey ME, Manchikanti L, Benyamin RM, Schultz DM, Smith HS, Cohen SP. Spinal cord stimulation for patients with failed back surgery syndrome: a systematic review. Pain Physician. 2009;12(2):379–97.
11. Jeon YH. Spinal cord stimulation in pain management: a review. Korean J Pain. 2012;25(3):143–50.
12. Wolter T. Spinal cord stimulation for neuropathic pain: current perspectives. J Pain Res. 2014;18(7):651–63.
13. Dario A, Fortini G, Bertollo D, Bacuzzi A, Grizzetti C, Cuffari S. Treatment of failed back surgery syndrome. Neuromodulation. 2001;4(3):105–10.
14. Burchiel KJ, Anderson VC, Brown FD, Fessler RG, Friedman WA, Pelofsky S, et al. Prospective, multicenter study of spinal cord stimulation for relief of chronic back and extremity pain. Spine (Phila Pa 1976). 1996;21(23):2786–94.
15. North RB, Ewend MG, Lawton MT, Kidd DH, Piantadosi S. Failed back surgery syndrome: 5-year follow-up after spinal cord stimulator implantation. Neurosurgery. 1991;28(5):692–9.
16. De La Porte C, Siegfried J. Lumbosacral spinal fibrosis (Spinal arachnoiditis) its diagnosis and treatment by spinal cord stimulation. Spine (Phila Pa 1976). 1983;8(6):593–603.
17. Ramineni T, Prusik J, Patel S, Lange S, Haller J, Fama C, et al. The Impact of Spinal Cord Stimulation on Sleep Patterns. Neuromodulation. 2016;19(5):477–81.
18. Sanders RA, Moeschler SM, Gazelka HM, Lamer TJ, Wang Z, Qu W, et al. Patient Outcomes and Spinal Cord Stimulation: A Retrospective Case Series Evaluating Patient Satisfaction, Pain Scores, and Opioid Requirements. Pain Pract. 2016;16(7):899–904.
19. Obuchi M, Sumitani M, Shin M, Ishii K, Kogure T, Miyauchi S, et al. Spinal cord stimulation ameliorates neuropathic pain-related sleep disorders: A case series. Neuromodulation. 2015;18(3):191–3.

Publisher's Note