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ARTIGO ORIGINAL

Long-term Follow-up of Spinal Cord Stimulation with Percutaneous Leads: A Cross-Sectional Study in a Single Centre with 10-Years Experience

Seguimento a Longo Prazo de Neuroestimulação Medular com Elétrodos Percutâneos: Um Estudo Transversal num Único Centro com 10 Anos de Experiência

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ABSTRACT

Introduction: Chronic pain continues to be a leading cause of disability worldwide. Currently, spinal cord stimulation is approved for a variety of chronic pain syndromes, but there is insufficient long-term data regarding its effectiveness. Our goal is to evaluate the long-term outcome in patients treated with spinal cord stimulation with percutaneous leads.

Methods: We retrospectively evaluated a cohort of patients who underwent a spinal cord system implantation with percutaneous leads between January 2011 and December 2020. The long-term outcome was measured by evaluating patient global improvement with treatment using the Patient Global Impression of Change Scale, the explantation rate and the occurrence of complications. Potential effect modifiers were also assessed.

Results: Forty-one patients underwent spinal cord stimulation system implantation. The mean (±SD) follow-up time was 5.5 years (±2.6 years). By the end of the follow-up, 26 patients (67%) reported feeling better and nine (23%) reported feeling moderately better. Out of the 41 patients, nine (22%) devices were explanted. The estimated mean time to device explantation was 8.4 years (95% confidence interval [CI] = 7.6–9.3). A total of 14 (34.1%) complications occurred in 13 patients. Hardware complications were more prevalent (71.4%), with lead migration being the most frequent (42.9%). We did not find predictors of treatment success.

Conclusion: Spinal cord stimulation with percutaneous leads is safe and might have long-term efficacy in carefully selected patients. Nevertheless, further research is needed in order to find predictors of treatment success.

RESUMO

Introdução: A dor crónica continua a ser uma das principais causas de incapacidade mundialmente. A neuroestimulação medular está aprovada para uma variedade de síndromes dolorosas, mas a evidência relativamente à sua eficácia a longo prazo é insuficiente. O nosso objetivo foi avaliar os efeitos a longo prazo da neuroestimulação medular por elétrodos percutâneos.

Métodos: Foi avaliado retrospectivamente uma coorte de utentes submetidos a neuroestimulação medular através de elétrodos percutâneos entre Janeiro de 2011 e Dezembro de 2020. Os resultados a longo prazo foram aferidos pela melhoria global dos doentes com o tratamento, através da Escala de Percepção Global de Mudança, avaliação da taxa de explantação e ocorrência de complicações. Foram ainda avaliados potenciais modificadores dos resultados.

Resultados: Quarenta um utentes foram implantados com um sistema de neuroestimulação medular. A média (±DP) de tempo de seguimento foi de 5,5 anos (±2,6 anos). No fim do seguimento, 26 utentes (67%) referiram sentir-se melhor e nove (23%) moderadamente melhor. Dos 41 utentes, nove (22%) dispositivos foram explantados. O tempo médio de explantação foi de 8,4 anos (95% [IC] = 7,6–9,3). Um total de 14 (34,1%) complicações ocorreram em 13 utentes. As complicações associadas ao hardware foram mais prevalentes (71,4%), sendo a migração dos elétrodos a mais frequente (42,9%). Não foram encontrados preditores de sucesso de resposta ao tratamento,

Conclusão: A neuroestimulação medular com elétrodos percutâneos é segura e em doentes criteriosamente selecionados apresenta eficácia a longo-prazo. Contudo, é necessário maior investigação com o intuito de encontrar preditores de sucesso terapêutico.

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INTRODUCTION

Chronic pain continues to be a tremendous distressing problem with a remarkable impact on individuals and society.[1] In 1965, Melzack and Wall, first suggested that pain could be inhibited by the selective activation of large diameter fibers and invigorated the clinical arena to develop various forms of neuromodulation.[2] A spinal cord stimulator allows for specific electric currents to be delivered to selected levels of the spinal cord. It is composed of a pulse generator, an extension cable, an electrode lead placed in the spinal dorsal epidural space and a programmer. With the external patient programmer, patients can control the stimulation frequency and amplitude to better sustain pain relief.[3] Two types of leads can be implanted: percutaneous leads or paddle leads. Percutaneous leads are less invasive, by using the loss of resistance technique to implant the lead in the epidural space. On the other hand, a complete or partial laminectomy is needed for paddle leads implantation.

Spinal cord stimulation (SCS) was first reported as a treatment for pain in 1967 by Taslitz Shealy and the FDA has currently approved SCS for chronic painful peripheral neuropathy, failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS), multiple sclerosis, postherpetic neuralgia, and phantom limb pain.[3]

Evaluating the long-term outcomes of interventions for chronic pain is challenging due to the inherently subjective nature of quantifying the level of chronic pain experienced.[4] The analysis of the effectiveness requires a consideration of the assessment of multiple outcome domains to adequately characterize the impact of an intervention. Adverse events resulting from the treatment might outweigh the benefits of pain reduction, and pain reduction alone does not guarantee that physical or emotional functioning will improve.[5] Therefore, global evaluations ratings of improvement provide an opportunity for patients to integrate the different aspects of their response to treatment, such as pain relief, improvement in functioning and side effects, into one evaluation. The Patient Global Impression of Change Scale (PGICS) was recommended by the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) for use in chronic pain clinical trials as a core outcome measure of global improvement with treatment. This is a single-item rating scale with 7 items that range from "A great deal better" to "No change".

Although technological refinements have improved SCS hardware and software over the years, problems persist and failures still occur in this invasive and expensive treatment. Therefore, finding patient factors that could be predictive of future device removal and that may influence the differing degree of pain relief is crucial to enhance long-term success and guide future clinical decision-making.

We present a retrospective analysis of SCS in a single institution for a 10-year period. Our aim is to evaluate the long-term outcome of patients treated with percutaneous lead SCS systems. The focus of this study was to evaluate the overall improvement with the therapy and the explantation rate, as well as to attempt to find factors of treatment success.

METHODS

Study Design

This study is a cross-sectional study that followed a cohort of 48 patients over 10 years.

Setting

The study recruited patients with chronic pain who were implanted with SCS systems with percutaneous leads at the Hospital de Santa Maria - Centro Hospitalar Universitário Lisboa Norte (CHULN), Chronic Pain Unit, Lisbon, Portugal from January 2011 to December 2020. Data collection started in February 2021 and ended in March 2021. Data was gathered from the hospital's electronic medical records and crosschecked with the manufacturer's anonymised commercial database (MedTronic). The Hospital Ethics committee approved the study, which followed the ethical principles for medical research in human beings enshrined in the Declaration of Helsinki of the World Medical Association. Written informed consent was obtained.

Participants

Subjects selected were adults with at least fifty per cent pain relief during a 7 to 15-day SCS trial. All patients underwent a prior psychological evaluation by a psychologist, as untreated depression was considered as a contraindication for SCS. A pain physician, rheumatologist, neurosurgeon, orthopaedic surgeon, vascular surgeon and a gynecologist provided the diagnosis of failed back surgery syndrome (FBSS), chronic low back pain, chronic painful peripheral neuropathy, complex regional pain syndrome (CRPS), Raynaud's phenomenon or pelvic pain. Before the SCS implantation, a neurosurgeon or orthopaedic surgeon ruled out any surgically treatable pathology, such as lumbar disc prolapse with radiculopathy or symptomatic spinal stenosis with severe or progressive motor weakness or signs and symptoms of cauda equina syndrome. The number of SCS systems implanted at our Hospital during the study period determined the sample size.

Variables

Long-term outcome of SCS was measured by evaluating patient global improvement with treatment, the explantation rate and the occurrence of complications.

We used the validated Portuguese Version of the PGICS[7] (Appendix 1) to determine patient global improvement with treatment. In the end of the follow-up, a non-independent evaluator contacted all patients and assessed the PGICS, a

Likert-type scale with 7 items where patients rate their change as "7 – A great deal better" "6 - Better" "5 – Moderately better" "4 – Somewhat better" "3 – A little better" "2 – Almost the same" or "1 – No change." Complications and side effects were classified as hardware or biologic-related. We considered a clinically significant lead migration when a patient reported diminished pain relief that demanded revision to correct the lead location. In the statistical analyses, factors considered potential clinical outcomes modifiers were age, sex, number of percutaneous leads, years with SCS treatment, duration of pain syndrome prior to SCS, number of previous surgical procedures, etiology of pain syndrome, level of electrodes, professional situation (retired/unemployed/sick leave vs employed), migrations and complications.

Follow-Up

After device implantation, patients were followed up at seven to fifteen days post intervention. By protocol, they were seen at one, six, and twelve-month intervals. If medically necessary, patients were also seen between these time intervals and whenever required, device representatives would join the medical consultation for programming adjustments.

Statistical Analysis

The statistical analyses were performed using the SPSS version 26.0 (IBM Corporation, Armonk, New York). Data analysis included descriptive statistics, as well as a bivariate analysis, which was performed to determine predictive factors for patients' PGICS items and explantation rate. The normally distributed variables were analyzed by calculating the means and standard deviations. For the other variables we calculated medians and interquartile ranges. One-way analysis of variance (ANOVA) and the Kruskal-Wallis Test were used to determine differences in age, number of percutaneous leads, years with SCS treatment, time from chronic pain diagnosis to SCS implant and number of previous surgical procedures between PGICS items. Fisher's exact tests were used to examine the association between PGICS items and sex, etiology of pain syndrome, level of electrodes, employment status and complications. The Kaplan–Meier product-limit method, a survival analysis technique, was used to generate a Kaplan–Meier curve for the time to device explantation. Since not at least 50% of patients had had their device explanted, the median time was not possible to determine – therefore, the mean time to SCS systems explantation was presented instead. The Log-rank test and the Tarone-Ware test were used to compare time to device explantation between groups. The factor age and duration of pain syndrome prior to SCS were recoded in two different groups (Age < 65 years and > 65 years; Pain < 5 years and > 5 years). A p-value of <0.05 was considered statistically significant.

RESULTS

Participants

Forty-eight patients underwent SCS implantation. Seven patients had no clinical response in the trial period. Of the remaining 41 patients, two died before the final questionnaire follow-up. The mean (± standard deviation (SD)) age of the 48 patients during the trial period was 50.3 years (±12.2 years) and 50% were female (Table 1). The mean (±SD) follow-up time (defined as the date of implantation until the last follow-up appointment or date of explant) was 5.5 years (±2.6 years). The most frequent pathology was failed back surgery syndrome (N = 28, 58.3%) and the median (interquartile range) time from chronic pain diagnosis to SCS implantation was 5 years.[7]

Out of the 48 patients, 41 received an implantable pulse generator (IPG) after a 7 to 14 day trial period, resulting in an implant-to-trial ratio of 85%. The remaining seven patients did not experience pain relief and we removed their electrode (Fig. 1). The percutaneous lead location was thoracic in 38 (92%) patients and cervical in three (8%) patients. The median (interquartile range) number of percutaneous leads was two.[1] The implantable SCS systems consisted of percutaneous leads (Models 977A260, 977A275, or 977A290 Vectris SureScan magnetic resonance imaging (MRI) 1 x 8 Compact, or models 3877, 3876 subcompact eight-electrode lead) and an implantable conventional rechargeable neurostimulator (RestoreSensor™ SureScan™ MRI System model 97714, RestoreAdvanced® System model 37713, Intellis™ implantable neurostimulator) or a conventional nonrechargeable neurostimulator (PrimeAdvanced® System model 37702). We also used the Injex™ Model 97791 Anchor Accessory kit in all patients. All of these devices were acquired from Medtronic (Minneapolis, Minnesota).

Patient Global Improvement

Of the 41 patients with permanent SCS devices, 39 (95%) answered the PGICS questionnaire, with a mean (SD) follow-up time of 5.5 years (± 2.6 years). Twenty-six (67%) reported "6 – Better and a definite improvement that has made a real and worthwhile difference", nine (23%) reported "5 – Moderately better and a slight but noticeable change" and four (10%) reported "4 – Somewhat better, but the change has not made any real difference". The two patients that did not answer died before the application of the questionnaire. The cause of death was an acute myocardial infarction and a cerebrovascular accident and not due to SCS complications. In the bivariate analysis, variation in age, sex, etiology of pain syndrome, number of previous surgical procedures, time from chronic pain diagnosis to SCS implant, number of percutaneous leads, number of years with SCS treatment, complications, level of electrodes and employment status did not predict a better outcome.

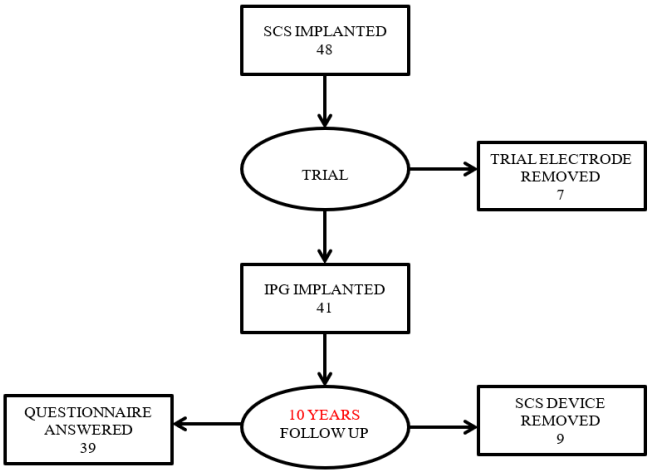

Figure 1. Flow chart of 48 patients who underwent SCS system implantation from January 2011 to December 2020

one (11.1%) wound dehiscense post abdominoplasty, one (11.1%) battery depletion and one (11.1%) new pain outside the coverage area. Fig. 2 illustrates the proportion of implanted devices that were not explanted over time using a Kaplan-Meier survival curve analysis. The estimated mean time to explantation was 8.4 years (95% confidence interval [CI] = 7.6–9.3). Using a log rank test and a Tarone-Ware test, we found no differences in the survival distribution when groups were divided by age (Age < 65 years and > 65 years) (p = 0.11), sex (p = 0.29), etiology of pain syndrome (p = 0.84), previous surgical procedures (p = 0.27), number of percutaneous leads (p = 0.98), time from chronic pain diagnosis to SCS implant (Pain < 5 years and > 5 years) (p = 0.84), complications (p = 0.97), lead migration (p = 0.66) and professional situation (p = 0.48).

Table 1. Baseline characteristics of the participants and bivariate analysis of variables associated with global improvment at the end of the follow-up period

		Permanent SCS implanted n=39*			
		PGICS			
	All (n=48)	Better (n=26)	Moderately better (n=9)	Somewaht better (n=4)	*p* value
Age (years) - mean ± SD	50.3 ± 12.2	49.1 ± 8.9	51.3 ± 13.8	50.0 ± 7.6	0.85
Gender - n (%)					1.00
Male	24 (50.0)	10 (38.4)	4 (44.4)	2 (50.0)	
Female	24 (50.0)	16 (61.6)	5 (55.6)	2 (50.0)	
Etiology of pain syndrome - n (%)					0.19
FBSS	28 (58.3)	19 (73.1)	5 (55.6)	2 (50.0)	
Chronic painful peripheral neuropathy	8 (16.7)	2 (7.7)	2 (22.2)	0 (0.0)	**
CRPS	3 (6.3)	2 (7.7)	1 (11.1)	0 (0.0)	**
Raynaud's phenomenon	3 (6.3)	0 (0.0)	1 (11.1)	1 (25.0)	**
Pelvic Pain	2 (4.1)	1 (3.8)	0 (0.0)	1 (25.0)	**
Chronic low back pain	4 (8.3)	2 (7.7)	0 (0.0)	0 (0.0)	**
Time from chronic pain diagnosis to SCS implant (years) - median (IQR)	5.0 (7.0)	5.0 (7.0)	9.0 (14.0)	2.5 (4.0)	0.05
Number of previous surgical procedures - median (IQR)	1.0 (2.0)	1.0 (2.0)	1.0 (2.0)	0.5 (2.0)	0.29
Number of percutaneous leads - mean ± SD	***	2 (1.0)	2 (1.0)	2 (1.0)	0.92
Time with SCS treatment (years) - mean ± SD	***	5.7 ± 2.7	5.7 ± 2.5	4.0 ± 2.9	0.48
Complications	***				0.38
No		17 (65.4)	5 (55.6)	4 (100.0)	
Yes		9 (34.6)	4 (44.4)	0 (0.0)	**
Professional situation	***				0.88
Unemployed / Retired		17 (65.4)	5 (55.6)	3 (75.0)	
Employed		9 (34.6)	4 (44.4)	1 (25.0)	**

CRPS - complex regional pain syndrome; FBSS - failed back surgery syndrome; IQR - Interquartile Range; SD - Standard deviation; PGICS - Patient Global Impression of Change Scale.
* questionnaire answered; ** *p*-value not possble to compute; *** data not colected from excluded patients.

Explanation Rate

The mean (SD) follow-up time was 5.5 years (± 2.6 years). During follow-up, two patients died. Out of the 41 patients, nine (22%) SCS devices were explanted for the following reasons: four (44.4%) ineffective pain control, one (11.1%) no longer needed (pain remission), one (11.1%) need for an MRI,

Complications

Among the 41 patients who received an IPG, a total of 14 (34.1%) complications occurred in 13 patients. Therefore, one patient experienced two complications, subcutaneous hematoma and lead migration. Hardware complications were more prevalent (71.4%), with lead migration being the

Table 2. Summary of complications

	Number of complications (%)	% of total implants
All complications	14 (100.0)	34.1
Hardware		
IPG discomfort	3 (21.4)	7.4
IPG migration	1 (7.1)	2.4
Lead migration	6 (42.9)	14.7
Biologic		
Wound dehiscence	1 (7.2)	2.4
Skin erosion	1 (7.2)	2.4
Subcutaneous hematoma	1 (7.1)	2.4
Skin burn during IPG charge	1 (7.1)	2.4

IPG - implantable pulse generator

most frequent (Table 2). One complication resulted in SCS explantation.

DISCUSSION

Patient Global Improvement

Long-term data regarding patient satisfaction with SCS with percutaneous leads is sparse. Furthermore, a recent Cochrane systematic review reported that in the long-term there is limited evidence to draw conclusions about higher quality of life after spinal cord stimulation of one year or more.[8] In our study, at the end of the follow-up period, which reached 10 years in some patients, all patients had answered the PGICS questionnaire and 67% of them reported feeling better and a definite improvement that has made a real and worthwhile difference, regarding activity limitations, symptoms, emotions and overall quality of life. Nissen and colleagues reported similar results but with paddle leads.[9] This highlights the long-term effectiveness of SCS with percutaneous leads when patients are meticulously selected. However, in clinical practice, patient selection remains challenging and we also did not find predictors of long-term treatment success measured by evaluating patient global improvement. Previous studies are inconsistent regarding the influences of prolonged neuropathic pain prior to SCS in patient satisfaction, some suggesting that it is predictive of poorer outcomes[10,11] and others showing no interference.9 Our results show that the number of previous surgical procedures and the duration of a pain syndrome prior to SCS did not lead to a better PGICS scoring, which might indicate that SCS is a valid treatment even after a long-lasting pain syndrome and previous multiple surgical interventions. There is a strong relationship between psychiatric co-morbidities and a poor response to SCS treatment.[10] In this context, the psychological evaluation by a psychologist before the SCS implantation and the exclusion of patients with untreated psychiatric co-morbidities might also be one of determinants of treatment success. More investigations of the interactions between patient-reported outcomes are needed to better understand what variables can be potential predictors of measures of success, such as post-implant patient satisfaction with treatment.

Explanation Rate

In a period of 10 years, 22% of patients had to have their SCS devices removed. This is consistent with other previous studies that reported a 24% explantation rate for percutaneous leads during an eight-year period.[12] Elevated explantation rates threaten the cost-effectiveness and overall efficacy of SCS therapy. Therefore, serious attention must be drawn towards finding patient factors that could be predictive of future device removal. We reviewed age, sex, etiology of pain syndrome, previous surgical intervention, duration of pain syndrome prior to SCS, number of percutaneous leads, migrations, complications and employment status in order to improve patient selection and device engagement for patients. As reported previously, there were no strong predictors for SCS explantation.[9,13] Understanding the most common reasons for explantation could also improve patient and device selection, which enhances the long-term therapeutic benefit. The principal cause for explant was lack/loss of efficacy (44%), despite adequate paresthesia coverage. It has been suggested that these are patients that probably developed tolerance or progression of their chronic neuropathic pain condition tolerance.[12] There is great heterogeneity between previous results, but loss of efficacy is generally the most frequent reason for explantation. Simopoulos *et al* reported that the most frequent reason for explantation was the loss of efficacy in 15% of explants over a 15 year period.[12] Over a 4 year period, Pope *et al* and Van Buyten *et al* respectively, reported up to 44% and 50% explant rate due to loss of efficacy.[13,14] This highlights the need for salvage therapies and new SCS therapy modalities that are clinically validated with real-world data. The new combinations of waveforms and patterns that are being developed may modify the appearing of tolerance. On the other hand, although neurostimulation has no meaningful disease modifying

effect, one patient with the diagnosis of failed back surgery syndrome, after 6 years of treatment, requested hardware removal due to great improvement in pain score relief, feeling no advantages of having a neurostimulator implanted. The lack of MRI compatibility forced device removal in only one patient however, this will cease to be a problem in the future, since all newly SCS manufactured devices are 1.5 tesla MRI conditional.

Complications

SCS continues to show a high rate of complications, influencing patient satisfaction and healthcare costs. Our complication rate was 34.1%, which is consistent with previous literature with reports ranging from 30% to 40%.[15-17] Only minor complications were found and the absence of infections during trial stimulation was also notable. The majority of complications were hardware-related (71.4%), with lead migration being the most frequent (14.6%). In these patients, revisions or replacements are generally required to correct the problem, which increases the risk of further complications. Even though recent advancements have been made to provide better lead anchors and more reliable lead connections, as well as break resistant leads, lead migration continues to be the most common complication of SCS with a mean rate raging from 11.3% to 22.6%.[15] Paddle electrodes may have a decreased risk of lead migration[9,18] but are associated with slightly higher initial postoperative complications, such as neurologic injury and epidural hematoma.[18] Besides, long-term healthcare costs are not different between paddle and percutaneous leads.[18]

Limitations of the Study

This study describes a retrospective evaluation of patients in a single-center, which limits the sample size. Furthermore, during the follow-up period, there was variation among the anesthesiologists performing the implantation and the SCS equipment. Additionally, a non-independent evaluator assessed the global improvement questionnaire. For all that, an interviewer and a social desirability bias must be taken into consideration.

CONCLUSION

Chronic pain has a colossal impact in physical, mental health and also on society. Technological breakthroughs are improving chronic pain treatment but long-term data remains limited. This study retrospectively evaluated our experience with spinal cord stimulation over a 10-year follow-up period, reinforcing the effectiveness and safety of the treatment in carefully selected patients. Patient selection remains challenging, which highlights the need for further research in order to develop predictors of success.

CONTRIBUTORSHIP STATEMENT / DECLARAÇÃO DE CONTRIBUIÇÃO

GSC: Conception, design of the study; acquisition, analysis and interpretation of data; redaction; approval of the final version to be published.
ER: Data acquisition; critical review of the manuscript; approval of the final version to be published.
TF and LO: Critical review of the manuscript; approval of the final version to be published.
GSC: Concepção, desenho do estudo; aquisição, análise e interpretação dos dados; redção; aprovação da versão final a ser publicada.
ER: Aquisição dos dados; revisão crítica do manuscrito; aprovação da versão final a ser publicada.
TF e LO: Revisão crítica do manuscrito; aprovação da versão final a ser publicada.

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Proteção de Pessoas e Animais: Os autores declaram que os procedimentos seguidos estavam de acordo com os regulamentos estabelecidos pelos responsáveis da Comissão de Investigação Clínica e Ética e de acordo com a Declaração de Helsínquia revista em 2013 e da Associação Médica Mundial.
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