ORIGINAL ARTICLE
TRAUMA
http://dx.doi.org/10.1590/S1808-185120242301271651

MEDICINES FOR MANAGING LOWER PAIN IN PATIENTS WITH FAILED BACK SURGERY SYNDROME TREATED WITH NEUROMODULATION

MEDICAMENTOS PARA MANEJO DA DOR EM PACIENTES COM SÍNDROME DA FALHA DA CIRURGIA NA COLUNA TRATADOS COM NEUROMODULAÇÃO

MEDICAMENTOS PARA EL MANEJO DEL DOLOR EN PACIENTES CON SÍNDROME DE CIRUGÍA FALLIDA DE COLUMNA TRATADOS CON NEUROMODULACIÓN

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ABSTRACT

Objective: To compare the use of drugs to control low back pain in the pre- and postoperative periods among patients with Failed Back Surgery Syndrome (FBSS) undergoing neuromodulation. Methods: Retrospective observational study analyzing the medical records of patients with FBSS who underwent neuromodulation, followed up in an outpatient clinic from 2018 to 2020. The characteristics of the patients were evaluated: the use of medications, quality of life through the results of the Short Form 36 Health Survey Questionnaire (SF-36), and functional capacity using the Oswestry Disability Index (ODI) in the pre-surgical and post-surgical periods (06 months, 01 year). The criterion for establishing statistical significance was $p \leq 0.05$. Results: 56 patients were evaluated. There was a reduction in the use of pain control drugs after the institution of neuromodulation, including in the opioid class ($d=0.81$). An improvement was also observed in the ODI scores ($p<0.001$) and all the SF-36 domains ($p<0.02$) in the postoperative periods investigated. Conclusion: The data suggest that neuromodulation positively impacted back pain by reducing medication use and improving functional capacity and quality of life. ***Level of Evidence IV; Retrospective, Observational Study.***

Keywords: Pain; Chronic Pain; Low Back Pain; Postoperative; Pain Measurement.

RESUMO

Objetivo: Comparar o uso de medicamentos para o controle da dor lombar nos períodos pré e pós-operatórios entre pacientes com Síndrome da Falha da Cirurgia na Coluna (FBSS) submetidos à neuromodulação. Métodos: Estudo observacional retrospectivo de análise de prontuários dos pacientes com FBSS submetidos à neuromodulação, acompanhados ambulatorialmente no período de 2018 a 2020. Foram avaliadas as características dos pacientes; o uso de medicamentos; a qualidade de vida através dos resultados do Questionário Short Form 36 Health Survey Questionnaire (SF- 36) e a capacidade funcional utilizando o Oswestry Disability Index (ODI) nos períodos pré-cirúrgico e pós-cirúrgicos (06 meses, 01 ano). O critério para estabelecer significância estatística foi valores de $p \leq 0,05$. Resultados: Foram avaliados 56 pacientes. Verificou-se redução do uso de medicamentos para o controle da dor após a instituição da neuromodulação, inclusive na classe dos opioides ($d=0,81$). Observou-se ainda melhora nos escores do ODI ($p<0,001$) e de todos os domínios do SF-36 ($p<0,02$) nos períodos pós-operatórios investigados. Conclusão: Os dados sugerem que a neuromodulação teve impacto positivo na dor de coluna em termos de redução no uso de medicamentos, melhora da capacidade funcional e da qualidade de vida. ***Nível de Evidência IV; Estudo Retrospectivo, Observacional.***

Descritores: *Dor; Dor Crônica; Dor Lombar; Dor Pós-Operatória; Medição da Dor.*

RESUMEN

Objetivo: Comparar el uso de fármacos para el control de la lumbalgia en el pre y posoperatorio en pacientes con Síndrome de Cirugía Fallida de Columna (FBSS) sometidos a neuromodulación. Métodos: Estudio observacional retrospectivo analizando las historias clínicas de pacientes con FBSS que se sometieron a neuromodulación, seguidos en consulta externa de 2018 a 2020. Se evaluaron las características de los pacientes; el uso de medicamentos; calidad de vida a través de los resultados del Cuestionario Short Form 36 Health Survey Questionnaire (SF-36) y la capacidad funcional mediante el Oswestry Disability Index (ODI) en los períodos prequirúrgico y posquirúrgico (06 meses, 01 año). El criterio para establecer la significación estadística fue $p \leq 0,05$. Resultados: se evaluaron 56 pacientes. Hubo una reducción en el uso de medicamentos para el control del dolor después de la institución de la neuromodulación, incluso en la clase de opioides ($d = 0,81$). También se observó una mejora en las puntuaciones del ODI ($p<0,001$) y en todos los dominios del SF-36 ($p<0,02$) en los períodos postoperatorios investigados. Conclusión: Los datos sugieren que la neuromodulación tuvo un impacto positivo en el dolor de espalda en términos de reducción del uso de medicamentos, mejorando la capacidad funcional y la calidad de vida. ***Nivel de Evidencia IV; Estudio Retrospectivo, Observacional.***

Descriptores: *Dolor; Dolor Crónico; Dolor de la Región Lumbar; Dolor Postoperatorio; Medición del Dolor.*

Study conducted by the Hospital Ortopédico AACD, São Paulo, SP, Brazil.
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Received on 01/31/2023 accepted on 01/15/2024
Reviewed by: Murilo Daher

INTRODUCTION

Low back pain is considered a public health problem due to its high prevalence and the limitations it imposes on sufferers. In this sense, many investigations in different contexts have been carried out to establish possible preventive measures.[1] A recent publication by the World Health Organization revealed that 80% of the world's population has had at least one episode of back pain, highlighting the importance of properly managing this clinical condition.[2]

The literature shows that between 10% and 20% of cases of low back pain can become chronic, requiring some kind of long-term intervention. This is characterized by persistent pain for more than three months. The economic burden on society and government organizations regarding absenteeism, early retirements, and loss of quality of life is quite high.[3]

Initial treatment for low back pain is mostly conservative, but surgery may be necessary when clinical treatment fails to provide adequate relief. In this context, Failed Back Surgery Syndrome (FBSS) is defined as pain in the lumbar spine persisting even after the surgical procedure or starting after it has been performed. It is a condition that can occur in between 10% and 40% of operated patients and does not necessarily indicate failure of the surgical intervention.[4]

Many specialists widely debate the etiology of pain disorders, as it includes numerous factors, including those associated with the underlying pathology, psychosocial factors, and those related to the surgical treatment instituted. In these cases, pain relief can be provided through Spinal Cord Stimulation (SCS). This method is used to control intractable chronic pain, mainly of neuropathic origin, offering an important treatment alternative to the long-term use of analgesic drugs, including opioids.[5,6]

It should be noted that evaluating the results of lumbar surgery is of great importance, as it helps to improve medical-surgical techniques and materials and to understand the psychological and physical aspects of the patient that may interfere with the outcome. The main determinants for assessing post-surgical outcomes are pain, medication use, quality of life questionnaires, and disability.[7]

In the national context, no studies were identified that set out to investigate the use of pain control medication as an outcome measure of SCS. In this sense, considering the high prevalence of chronic low back pain and its medical, economic, and social consequences, this study aimed to compare the use of medication to control low back pain in the pre-and post-operative periods among patients with FBSS undergoing neuromodulation.

METHODS

This is a retrospective observational study analyzing information obtained from the medical records of outpatient patients treated at a tertiary care service in the state of São Paulo between 2018 and 2020.

Out of a total of 75 medical records available, the study sample comprised 56 individuals over the age of 18 with FBSS of degenerative etiology, refractory to conservative treatment, and undergoing epidural spinal cord stimulation, who had information on the use of medication at least six months before electrode implantation and one year after neuromodulation (performed by the same surgeon). On the other hand, data from the medical records of patients who were lost to follow-up or needed more information on medication use during the periods of interest were not evaluated.

Just one researcher collected data based on information in medical records using a standardized form with variables related to patient characteristics and medication use; the information was obtained through self-reporting. To assess the participants' functional capacity and quality of life, the Oswestry Disability Index (ODI) and the Quality-of-Life Questionnaire (SF-36) were used in the pre-operative, 6-month, and 1-year postoperative periods. It should be noted that both questionnaires were used in translated and validated versions for the Brazilian population.[8,9]

The ODI consists of a functional assessment tool for the lumbar spine, made up of 10 items that represent different aspects of health, such as pain intensity, physical functioning, impacts on sleep and social activities. The total ODI score is presented in percentage terms, where lower values are assigned to better functionality.[10]

The SF-36 is used to assess general health and quality of life. It contains 36 items measured in eight domains: Functional Capacity (FC), Limitation by Physical Aspects (LAF), Pain (DOR), General State of Health (EGS), Vitality (VIT), Social Aspects (AS), Limitation by Emotional Aspects (LAE) and Mental Health (SM). The number of answer options for each domain varies from three to six, the calculations of which produce scores of up to 100 points. The evaluation of scores advocates that higher scores are related to better health status.[10]

After collecting the data on a specific form, it was tabulated in a Microsoft Office Excel 2019 spreadsheet. The Statistical Package for the Social Sciences 25.0 was used to conduct the relevant statistical analyses. In this respect, the means and standard deviation for the ODI and SF-36 scores were evaluated, as well as the normality test of the data distribution using the Shapiro-Wilk method. Measures of statistical significance in terms of values and $p \leq 0.05$ at all observation times were obtained using the Student's T-test for variables with a normal distribution. Given the non-normality of the distribution, the Wilcoxon test was used. The magnitude of the difference in means was checked using Cohen's test (d), with values ≥ 0.8 being considered large effects.

The research project was submitted to the Ethics and Research Committee of the Centro Universitário da Faculdade de Medicina do ABC and approved under registration CAAE: 54880021.9.0000.0082. To guarantee the confidentiality of the information, a single researcher collected the data, and the participants were not identified by name.

RESULTS

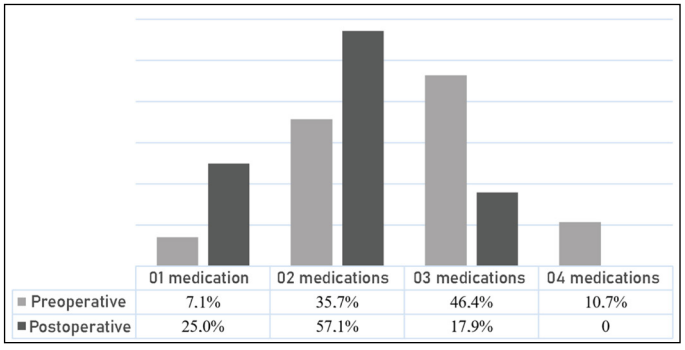
The study population was mostly female (67.9%), whose weight ranged from 50kg to 105kg (mean=75.2; standard deviation=16.7). Analysis of the profile of medication use revealed that in the preoperative period, most of the participants used therapy with a combination of 03 drugs, in contrast to the use of 02 drugs in the postoperative period. (Figure 1)

In both periods, the most used class of medication was opioids, but there was a reduction in their use. The greatest impact was felt in the corticosteroid class. (Figure 2)

The average number of drugs used in the preoperative period was 2.61 (95%CI=2.32 - 2.90), and in the postoperative period, it was 1.97 (95%CI=1.72 - 2.21). The difference in means (DM) for the number of medicines used was 0.68 (p=0.001). Cohen's coefficient for this finding showed a high correlation (d=0.81). (Figure 3)

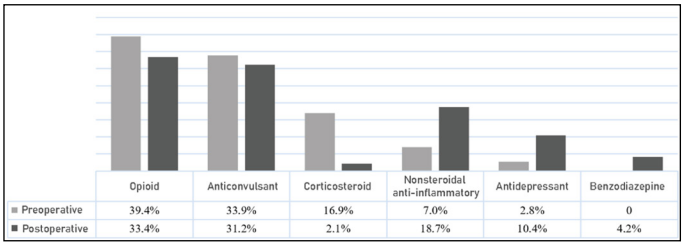
Estimating the correlation between the use of medication in the periods evaluated revealed that the amount of medication used in the preoperative period did not significantly influence the reduction in the amount used in the postoperative period (p=0.12). Analysis of the results for the ODI showed a decrease in score values over time, with statistical significance (p<0.001). (Figure 4)

Regarding the findings of the SF-36, there was an increasing



	01 medication	02 medications	03 medications	04 medications
Preoperative	7.1%	35.7%	46.4%	10.7%
Postoperative	25.0%	57.1%	17.9%	0

Figure 1. Characterization of medication use in the pre- and one-year post--operative periods.



	Opioid	Anticonvulsant	Corticosteroid	Nonsteroidal anti-inflammatory	Antidepressant	Benzodiazepine
Preoperative	39.4%	33.9%	16.9%	7.0%	2.8%	0
Postoperative	33.4%	31.2%	2.1%	18.7%	10.4%	4.2%

Figure 2. Classes of medication used in the pre- and one-year post-operative periods.

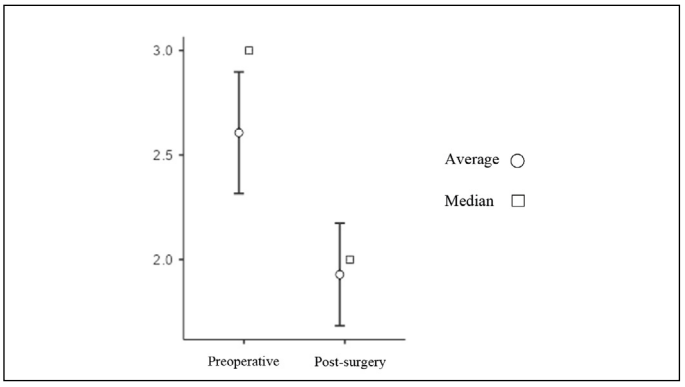
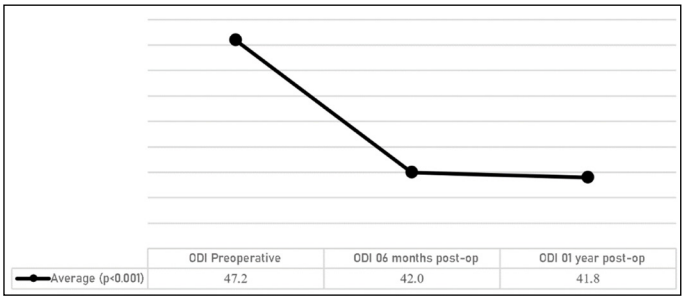


Figure 3. Mean and median values for the medication used in the pre- and one-year post-operative periods.



	ODI Preoperative	ODI 06 months post-op	ODI 01 year post-op
Average (p<0.001)	47.2	42.0	41.8

Figure 4. ODI values for the follow-up times.

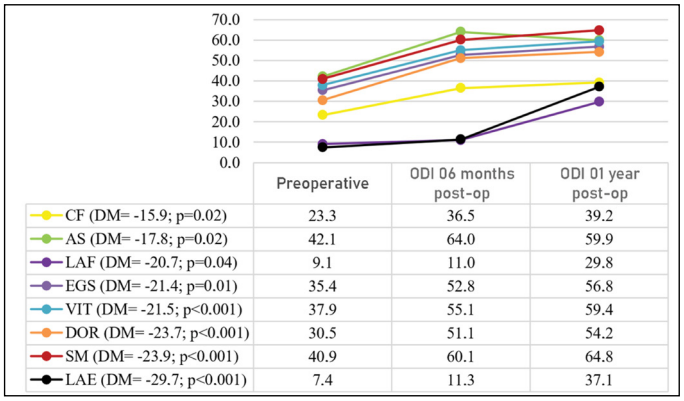
average for all the domains investigated. More expressive findings were identified for SM. However, comparing the difference in means (DM) between the preoperative periods and one year after the procedure showed a greater gain in the LAE dimension. DOR had the third-best result. Statistical significance was observed with values of $p \leq 0.02$. (Figure 5)

DISCUSSION

This study showed a reduction in the use of pain control medication, including opioids, up to one year after neuromodulation, and statistical analysis strengthened the hypothesis that this reduction was related to the surgical procedure. There was also an improvement in ODI scores and all domains of the SF-36 in the postoperative periods investigated.

The treatment of chronic pain is a major challenge in clinical practice. A thorough assessment of these patients means that treatment needs to be individualized, including the pharmacological approach, which should primarily aim at the pain mechanism and not just its manifestation.[11] In some patients, pain relief does not seem to be related to the potency of the analgesic drugs used since its occurrence may be related to factors not responsive to analgesia, such as psychological and emotional factors.[12]

In this scenario, a cautious assessment of pain management becomes necessary since its intensity may not necessarily require the use of highly potent drugs, and the patient's history of pain, surgical



	Preoperative	ODI 06 months post-op	ODI 01 year post-op
CF (DM= -15.9; p=0.02)	23.3	36.5	39.2
AS (DM= -17.8; p=0.02)	42.1	64.0	59.9
LAF (DM= -20.7; p=0.04)	9.1	11.0	29.8
EGS (DM= -21.4; p=0.01)	35.4	52.8	56.8
VIT (DM= -21.5; p<0.001)	37.9	55.1	59.4
DOR (DM= -23.7; p<0.001)	30.5	51.1	54.2
SM (DM= -23.9; p<0.001)	40.9	60.1	64.8
LAE (DM= -29.7; p<0.001)	7.4	11.3	37.1

Figure 5. SF-36 values for the follow-up times.

complexity, and entire biopsychosocial context must therefore be taken into account, i.e., parameters for an individualized analgesic approach. The literature suggests possible factors that contribute to the inadequate treatment of postoperative pain, including intense pain and the previous and prolonged use of opioids.[13]

The use of drugs in the treatment of low back pain is aimed at symptomatic relief. Several studies have evaluated the analgesic effects of non-steroidal anti-inflammatory drugs (NSAIDs), opioids, antidepressants, and anticonvulsants in the management of acute and chronic low back pain. However, evidence of the efficacy of these drugs is limited due to the wide variation in results between studies. In chronic low back pain, both nociceptive and neuropathic components are present. Individualized treatment requires a multi-modality approach, combining drugs with different mechanisms of action.[14]

Opioids are drugs that target nociception and, to a lesser extent, neuropathic pain. The scientific evidence shows low to moderate efficacy on low back pain and function when used for a short period. In prolonged treatment, its benefits and risks are unknown.[15,16]

In this respect, the analgesic guarantee and opioid-sparing effects of non-steroidal anti-inflammatory drugs are well described in the literature. Still, their effects on osteogenesis during spinal fusion are dose-dependent. NSAIDs act on nociception without influencing the neuropathic mechanism of pain, but they are effective in the short term for the treatment of acute and chronic low back pain.[17] The effectiveness of corticosteroids in low back pain is felt when the inflammatory component is present, offering additional advantages over the use of NSAIDs.[18]

The use of anticonvulsants to relieve pain with a neuropathic component is scarcely mentioned in the specialized literature.[19] There is evidence pointing to their use as a therapeutic strategy to reduce postoperative pain scores, even with a significant reduction in opioid consumption.[20] Antidepressants, in turn, are widely used in the management of low back pain, even when not associated with depression.[21] However, there is no clear evidence of the benefit of their use in low back pain. Benzodiazepines do not seem to be useful in isolated low back pain, i.e., for pain control only.[16]

Considering pain as a complex phenomenon, the use of these drugs for the management of chronic pain is based on addressing the neuropathic component of pain and secondary outcomes associated with the condition, such as disability, neurological deficits, well-being, and mood changes, among other related symptoms.[22]

The specialized literature contains many outcome measures aimed at measuring quality of life. However, the SF-36 is a responsive tool for patients with chronic low back pain and is therefore considered reliable in clinical practice, especially among post-surgical patients. Regarding the ODI, it is among the most cited functional outcome measures in the literature to assess the effectiveness of treatment for chronic low back pain. It is considered a valid instrument for treatment outcomes.[23]

Considering the measures observed in this study, namely the increase in the mean SF-36 scores and the decrease in ODI indicators, it can be said that epidural spinal cord stimulation promoted

effective clinical improvement with sustained responses over time. In terms of observable clinical response, patients reported reduced pain levels, the ability to perform activities of daily living, and improved quality of life. These findings are corroborated by experimental studies showing SCS effectively reducing low back pain, with results maintained for several months.[24]

In this respect, there is evidence of the positive effects of neurostimulation on the prospect of returning to work, which unequivocally affects the cost-benefit ratio of the results. It is worth noting that the pain relief provided by the procedure is the indicator that has shown the greatest patient satisfaction.[25]

The study's limitations include its retrospective nature, whose findings were based on data produced by third parties. The variables assessed were based on self-reports and were susceptible to memory bias. In addition, the possible selection bias and small sample size may limit the extrapolation of the results to other realities. In this respect, the fact that all the patients were operated on by a single surgeon and the coherent statistical treatment for the sample studied allow our findings to be validated and corroborate the results obtained.

This research was an unprecedented study in the context of specialized literature, making its contribution to evaluating clinical practice evident and pointing to the need to conduct more robust studies.

CONCLUSION

The average number of drugs used was significantly lower in the postoperative period compared to the preoperative period, showing that neuromodulation can reduce the number of drugs needed to control low back pain in patients with FBSS.

All authors declare no potential conflict of interest related to this article.

CONTRIBUTIONS OF THE AUTHORS: Each author has made an individual and significant contribution to the development of this article. GLM: conception of the work; analysis and interpretation of the data, writing of the manuscript; OWHA: revision of the intellectual concept of the article and final approval of the version of the manuscript to be published; RLMR: revision of the intellectual concept of the article and final approval of the version of the manuscript to be published; LFA: data analysis and revision of the article; CAEM: substantial contribution to the design of the work and critical revision of its intellectual content; de SRC: revision of the intellectual concept of the article and final approval of the version of the manuscript to be published.

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