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The Role of Spinal Cord Stimulation (SCS) in the Management of Failed Back Surgery Syndrome (FBSS) - a Comprehensive Literature Review

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Abstract**Study Design**

A literature review.

Objective

The assessment of the efficacy of Spinal Cord Stimulation (SCS) in treatment of Failed Back Surgery Syndrome (FBSS) in terms of chronic pain management, reducing the use of pain medication, improvement of the overall quality of life and cost-effectiveness of the method in comparison to conventional medical management (CMM) and spinal revision surgery.

Methods

A review of the clinical data from prospective studies, clinical trials and systematic reviews was conducted to provide an overview of the effectiveness of Spinal Cord Stimulation (SCS) in treatment of Failed Back Surgery Syndrome (FBSS).

Results and Conclusion

Numerous studies have proven the efficacy and safety of SCS in this patient population, in terms of managing neuropathic pain, reduction of pain medication use, quality of life improvement and cost-effectiveness as compared to CMM and re-operation. Careful preoperative patient selection and psychological screening is required in order to ensure optimal treatment results.

Key Words:

Spinal Cord Stimulation (SCS), Failed Back Surgery Syndrome (FBSS), Conventional Medical Management (CMM), neurostimulation, chronic pain, spine surgery.

Introduction

Failed Back Surgery Syndrome (FBSS) is a complex and debilitating multifactorial condition characterised by persistent or recurrent low back pain following spinal surgery, often unresponsive to conventional treatments. [2][5] FBSS is a general term that groups the conditions with recurring low back pain after spine surgery with or without a radicular component, rather than describing a single pathology. It is commonly accepted that the condition occurs in 10% to 40% [1] of patients after spine surgery, with a multifactorial etiology and multidisciplinary management. Non-surgical treatment of FBSS, often referred to as Conventional Medical Management (CMM), include a combination of treatments aimed at managing chronic pain. These may involve:

1. **Pharmacotherapy:** Pain medications such as non-steroidal anti-inflammatory drugs (NSAIDs), opioids, anticonvulsants (e.g., gabapentin), or antidepressants.
2. **Physical therapy:** Exercises to improve mobility and reduce pain.
3. **Epidural steroid injections:** To reduce inflammation.
4. **Psychological therapies:** Cognitive-behavioral therapy (CBT) to manage pain perception.
5. **Lifestyle modifications:** Weight management, smoking cessation, etc.

Spinal cord stimulation (SCS) has emerged as a promising therapeutic intervention for managing FBSS-associated chronic pain. This paper reviews the role of SCS in FBSS, focusing on its mechanisms, clinical efficacy, patient selection criteria, and long-term outcomes. We discuss the neuromodulatory effects of SCS on pain pathways, emphasising its ability to reduce nociceptive transmission and improve quality of life. Recent advancements, including high-frequency and burst stimulation, are examined for their potential to optimise pain relief. Evidence from clinical trials and real-world studies indicates that SCS offers significant pain reduction and functional improvement in appropriately selected FBSS patients. [7] However,

long-term success depends on tailored patient selection, precision in device placement, and ongoing management. Further research is needed to refine indications, optimise programming, and assess cost-effectiveness in broader patient populations.

Spinal Cord Stimulation - general description

Spinal Cord Stimulation (SCS) is a neuromodulation technique used to manage chronic pain by delivering electrical impulses to the spinal cord. A small lead, implanted in the dorsal epidural space of the spinal cord, generates impulses, which are transmitted via electrodes, producing paresthesia in the painful area. The electrical stimulation modifies pain signal transmission before it reaches the brain, providing relief for various types of chronic pain. Neurostimulators can be either battery-powered implanted pulse generators (IPGs), which may be rechargeable or non-rechargeable, or radio frequency devices that receive energy via radio-wave pulses from an external source. Today, most IPG devices use rechargeable batteries, especially for patients requiring high-current use. The selection of the device type and neurostimulator parameters is determined by specialised SCS clinical teams, based on factors such as pain type, intensity, and location, to ensure the most effective treatment outcomes.

SCS is considered a safe and effective treatment for various pain conditions, with careful patient selection and technical considerations ensuring optimal outcomes. [4][21] Furthermore, SCS is more effective than conventional medical management alone in providing pain relief, improving quality of life, and enhancing functional capacity in FBSS patients, with many studies reporting substantial pain relief and functional improvements. [8][9][10][18]

Mechanism of Action in Pain Reduction

SCS primarily affects the dorsal columns of the spinal cord, where sensory information, including pain signals, is processed. Its most significant mechanism can be described as:

1. **Gate Control Theory:** SCS modulates pain through the gate control theory, proposed by Melzack and Wall, which suggests that stimulation of larger sensory nerve fibres inhibits the transmission of pain signals by smaller nociceptive (pain-carrying) fibres. By overriding the painful input, SCS reduces the perception of pain. [11][12]
2. **Inhibition of Nociceptive Transmission:** SCS affects the transmission of nociceptive signals by reducing hyperactivity in pain pathways. It dampens the excitability of neurons in the dorsal horn, decreasing the release of excitatory neurotransmitters (such as glutamate and substance P), which are involved in the transmission of pain signals to the brain. [13]
3. **Activation of Inhibitory Pathways:** SCS enhances the activation of inhibitory interneurons and neurotransmitters like gamma-aminobutyric acid (GABA) in the dorsal horn. This increases the body's natural pain-inhibiting mechanisms, further reducing nociceptive transmission. [14][15]

Methods

This literature review was conducted by selecting various articles, studies and reviews from clinical trials from PubMed in order to assess the effectiveness of Spinal Cord Stimulation techniques in managing chronic pain in patients suffering from Failed Back Surgery Syndrome (FBSS).

Results and discussion

An article by P. Rigoard et al. (2019) show the result of a multicenter randomised controlled trial conducted at 28 investigational sites in Belgium, Canada, Colombia, France, Germany, the Netherlands, Spain, the United Kingdom, and the United States. Authors compared the effectiveness of spinal cord stimulation (SCS) versus conventional medical management (CMM) in treating a total of 218 randomised patients with failed back surgery syndrome (FBSS). According to the study, at 6 months follow-up period, about 60% of patients receiving SCS treatment in addition to CMM experienced a reduction in pain intensity by at least 50%, whereas only 35% of patients in the CMM group reached the same level of pain relief. The therapy also leads to decreased opioid use and improvements in physical function. However, the success of SCS is influenced by proper patient selection, device programming, and long-term follow-up for optimal results. [16]

K. Kumar et al. in a prospective, randomized, controlled, multicenter study, published in 2007, evaluate the clinical effectiveness of SCS as an addition to Conventional Medical Management (CMM) vs. CMM alone in patients with Failed Back Surgery Syndrome for at least 6 months. A randomised group of 100 patients with FBSS. The primary outcome was the proportion of patients achieving 50% or more pain relief in the legs. Secondary outcomes were improvement in back and leg pain, health-related quality of life, functional capacity, use of pain medication and non-drug pain treatment, level of patient satisfaction, and incidence of complications and adverse effects. Compared with the CMM group, where 9% of patients experienced improved back pain relief, the SCS group (48% of patients) experienced improved back pain relief. In addition, at 6 months, patients randomized to SCS achieved greater improvement in functional capacity and quality of life (QOL) and functional capacity, compared with CMM patients. [8][17]

In a systematic review by L. Kapural et al. (2017), prospective studies were analysed, resulting in the conclusion that SCS is a safe, effective and also cost effective treatment for FBSS patient population. The authors further underlined the fact that technological advancements in the field of SCS, including higher stimulation frequencies and new waveforms, have increased the effectiveness and applicability of this method. The use of newer high-frequency (HF) modality of SCS (10 kHz SCS), as opposed to traditional low-frequency stimulation, which produces paresthesias in 49% to 71% of the patients, causing loss of efficacy over time, was not observed in HF SCS. [17][18][19]

North et al. (2005) conducted a crossover study, which involved 50 patients, who were treated with either SCS or spinal revision surgery, with a follow up for up to 3 years among 45 patients. 9/19 subjects (47.4%) with SCS and only 3/26 subjects (11.5%) who underwent revision surgery had greater than 50% pain relief. The crossover rate was lower in the SCS group than in the group undergoing repeated surgery (5/24 vs. 14/26), indicating patient preference for SCS over revision surgery. [18][20]

The cost-effectiveness of Spinal Cord Stimulation has been mentioned numerous times by various authors. R. Taylor et al. in their 2010 analysis have emphasised that Spinal Cord Stimulation is cost-effective in selected patients with failed back surgery syndrome, both as an adjunct to conventional medical management and as an alternative to re-operation, with rechargeable Implantable Pulse Generators (IPGs) being more cost-effective than a non-rechargeable device, where IPG longevity is shorter, thus requiring more frequent replacement.

As Healthcare policy makers and payers require cost-effectiveness evidence to inform their treatment funding decisions, in 2008, the United Kingdom's National Institute of Health and Clinical Excellence analysed the cost effectiveness of SCS compared with CMM and with re-operation and recommended approval of SCS in selected patients with FBSS. Over the 15-year time period of the model authors have concluded that the incremental cost-effectiveness of SCS compared with CMM was £5624 per quality-adjusted life year, with 89% probability that SCS is cost effective at a willingness to pay threshold of £20,000. Compared with repeated surgery, the incremental cost-effectiveness of SCS was £6392 per quality-adjusted life year, with 82% probability of cost-effectiveness at the £20,000 threshold. When the longevity of an IPG is 4 years or less, a rechargeable (and initially more expensive) IPG is more cost-effective than a non-rechargeable IPG. [22]

Similar conclusion have also been reported by M. Bala et al. (2008) in a systematic review. In the mean period of follow-up between 6 months and 8.8 years, studies have concluded that SCS is effective in reducing pain for people with failed back surgery syndrome, but has an initial high cost associated with device implantation and maintenance. [10]

Many authors have mentioned the importance of including psychological factors among the criteria used to screen chronic pain patients for spinal implantation, emphasising psychological aptitude as the most important selection criteria for the procedure. According to D. Long et al. the success rate of 33% for a group of unscreened chronic pain patients who received spinal implants was reported, in contrast to patients who were screened based on the presence of significant psychological complications, where the success rate increased to 70%. [23] The psychological screening included factors such as pain duration, number of unsuccessful operations a patient has undergone in the past, previous rehabilitative interventions or even patients' philosophy and ethics.

L. Atkinson et al. have further underlined the importance of multidisciplinary selection of appropriate patients for SCS in order to achieve maximal benefit from the procedure. The authors broaden the contraindications for spinal cord stimulation (SCS) to include patients with unresolved psychological conditions such as active psychosis, untreated major mood disorders, and somatisation disorder. Additionally, active or unmanaged substance abuse, including alcohol, drugs, or medications (e.g., opioids), is considered a contraindication. These conditions must be addressed before SCS can be considered, as determined by a multidisciplinary team during pre-screening to ensure appropriate treatment and patient safety. [24]

Conclusions

Spinal cord stimulation (SCS) has emerged as an effective solution for managing neuropathic pain in patients with Failed Back Surgery Syndrome (FBSS). Recent advancements in SCS technology have contributed to improved patient outcomes, particularly in reducing long-term pain and enhancing functional capacity, overall quality of life as well as proving to be a cost-effective treatment method in comparison to conventional medical management methods and re-operations in a long enough follow-up period. Meticulous preoperative patient selection ensures that those most likely to benefit from this treatment are accurately identified. While SCS can be a significant factor in the successful treatment of chronic pain associated with FBSS, it is not a standalone solution and requires a careful patient preparation and psychological evaluation, followed by supplementary multidisciplinary management.

Disclosures

Authors' contribution:

Conceptualisation, Paweł Połujański and Joanna Kowal; methodology, Robert Parobczak; software, Anna Jaroszyńska; check, Filip Jaroszyński, Piotr Cyran, Jan Paleczny; formal analysis, Piotr Cyran; investigation, Joanna Winciorek; resources, Adrianna Wiśniewska; data curation, Joanna Kowal; writing - rough preparation, Paweł Połujański; writing - review and editing, Robert Parobczak, Filip Jaroszyński; visualisation, Jan Paleczny; supervision, Adrianna Wiśniewska; project administration, Joanna Winciorek; receiving funding, Anna Jaroszyńska.

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Conflict of Interest Statement

The authors declare no competing of interest.

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