Failed Back Surgery Syndrome and Spinal Cord Stimulation Clinical Trials – Where Are We Now?

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Citation


Abstract

Failed back surgery syndrome (FBSS) is a term embracing a constellation of conditions describing persistent or recurring low back pain, with or without sciatica following one or more spine surgeries [1,2]. The FBSS patients with severe neuropathic pain experience greater levels of pain, greater disability, lower quality of life, and a higher rate of unemployment compared with other chronic pain models [2,3]. Spinal cord stimulation (SCS) has been shown to be a cost effective treatment option [4]. By stimulating one or more electrodes implanted in the posterior epidural space, paresthesias are felt in the pain areas, and thus the level of pain is reduced [5].

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world [6]. At the moment, a total of 13 clinical trials are listed concerning the condition “Failed Back Surgery Syndrome” and the intervention “Spinal Cord Stimulation” (Table 1). The most common inclusion and exclusion criteria met in those trials are presented in Tables 2 and 3 respectively.

Table 1
Overview of the collected studies [6]
In the majority of the trials (10/13), three large medical technology companies (Medtronic, Boston Scientific, St. Jude Medical) were involved. Universities participated in three trials and various hospitals in two. The countries where the studies were conducted were: United States of America (8/13), United Kingdom (3/13), France (3/13), Belgium (3/13), Netherlands (3/13), Canada (2/13), Germany (1/13), Spain (1/13), Norway (1/13), and Sweden (1/13). As long as the status of the trials is concerned, four studies have been already completed, five of them are still recruiting patients, one has suspended recruitment (enrollment was temporarily suspended to align study materials with field safety notice) and two were terminated due to slow enrollment. The status of one trial is unknown.

The investigated primary outcome was a self-reported pain improvement of ≥50% (VAS). Quality of life, extent of disability, pain medication intake, sleep, and patients’ satisfaction were defined as secondary outcomes. Results were listed only for two trials.

The first one (NCT01036529) was early terminated due to the small number of participants. The primary outcome measures were not analyzed. However, adverse events were noted in 13 patients with a stimulator: implant site hematoma, pain, and arthralgia. The second (NCT00205855) evaluated 46 patients with SCS. Thirty-five of them reported >50% VAS improvement. Infection, lead migration, IPG movement, device malfunction, and pain were considered as serious adverse events. Some other adverse events were also encountered: CSF leak, over and under stimulation during the SCS trial, and unpleasant stimulation.

For those patients with FBSS, an interdisciplinary care model for pain control and function improvement is of utmost importance. Attention to social as well as psychological factors is crucial too [2]. Spinal cord stimulation (SCS) provides relief to patients with a variety of painful disorders including FBSS [2, 5]. Moreover, SCS has been shown to be safe and effective, and the technique is also cost-effective as compared with medical management alone [5]. Yet, it seems that the number of ongoing clinical trials is limited. It is certain that a more extended conduction of such trials (with more patients, from more countries, and over a longer time-frame) would be of benefit to both patients and health care providers.

References

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