Do We Need Trials In Spinal Cord Stimulation?

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Abstract

Traditionally, a temporary trial (screening) has been an integral part of the spinal cord stimulation (SCS) therapy. This screening phase allows the practitioner and the patient to assess the efficacy of the therapy prior to full implantation. Although the SCS trial is the mainstay, many articles have been recently published stating that an SCS trial is not a must, especially after the development of new subperception stimulation paradigms. The current work reviews the available literature, and thoroughly highlights the physicians´ and the patients´ perspective on the topic. Emphasis is placed on the cost-effectiveness studies which indicate that there is no evidence that an SCS screening trial is cost-effective compared to a no trial screening approach.

1. INTRODUCTION

Traditionally, a temporary trial (screening) has been an integral part of the SCS therapy. The externalized SCS-lead can be activated using a device external to the body (external implantable pulse generator, IPG), allowing the patient and doctor to participate in a preimplantation trial period. This screening phase allows the practitioner and the patient to assess the efficacy of the therapy prior to full implantation. Patients can experience the sensation generated by SCS and how it interacts with body movements. Physicians can determine the optimal lead location, and estimate the current consumption guiding the choice of an SCS-IPG and the choice between paddle or percutaneous leads [1]. If it is determined that complete implantation is not appropriate, this strategy can allow for reducing expense and invasiveness.

2. DEFINITION OF SUCCESSFUL TRIAL

A successful trial should be defined as the patient having had at least 50% pain relief [2] with reduced (or at least stable) pain medications and the same amount of daily activity. Objective data, such as hours of sleep or walking distance can also be considered but it is advised to be obtained by an independent observer [3].

3. DO WE REALLY NEED TRIALS?

Although the SCS trial is the mainstay, many articles have been recently published stating that an SCS trial is not a must, especially after the development of new subperception stimulation paradigms [1]. Advantages of this approach include: avoidance of double surgical procedures (temporary and permanent lead placement), less surgical pain, lower infection risk, poor wound healing, and lower epidural bleeding risk [1].

3.1 THE PHYSICIAN´S PERSPECTIVE

Weinand et al. investigated the he hypothesis that pain relief during acute (15 minute intraoperative) and prolonged (5 day) SCS trial have equivalent predictive value for long-term successful SCS control of chronic low back pain and/or lower extremity pain [4]. Fifty-four patients underwent thoracic implantation (percutaneous (n=33) and laminectomy (n=21) of SCS leads for acute (15 minutes intraoperatively) and prolonged (5.0 ± 0.3 days) SCS screening for pain relief. The authors found that the correlation between successful (>50%) pain relief during acute (n=53/54, PPV=98%) and prolonged (n=47/52, PPV=90%) trial was significant (SRCC=0.462, $p< 0.01$). After the permanent SCS implantation, at mean follow-up of 9.4±1.5 months, acute and prolonged SCS trial % of pain relief and PPVs were each statistically significant for predicting long-term SCS pain relief (n=31/38, PPV=82%; n= 31/36, PPV=86%, SRCC=0.462 and 0.433, respectively, $p< 0.01$). It was concluded that successful pain relief during acute SCS trial correlates strongly with long-term successful SCS screening for relief of chronic low back and/or lower extremity pain. Acute and prolonged SCS screening appear to have equivalent predictive value for successful long-term SCS control of chronic pain.

Simopoulos et al. compared two trial methods: with temporary lead (TL) or permanent lead (permanent anchored) (PL) [5]. One hundred forty-eight patients were included in the TL group and 138 in the PL group. The rate of success in the trial phase was equal in both groups but the false positive rate of trial was higher ($p < 0.05$) in the PL group as compared to the TL group (6.35 vs. 1.35%). The cumulative wound infections (6.52 vs. 1.35%), and poor wound healing (4.35 vs. 0%) were also significantly higher in the PL group. The authors concluded that the TL group was associated with fewer false positives and wound related complications as compared to PL group.

An interesting study on the topic was published in 2020 [1]. Eldabe et al. conducted a multicentre, single-blind, parallel 2-group randomised trial (TRIAL-STIM study) to determine the clinical utility of an SCS screening trial. One hundred-five participants were randomly assigned to one of two groups: either a screening trial approach followed by SCS implantation based on the screening trial outcome (TG, n=54) or a no trial screening SCS implantation alone method (NTG, n=51). In the NTG, all patients had to have a good (i.e., 80%) on-table paraesthesia coverage of the pain region, and no dislike of sensations. For paraesthesia-free devices, a satisfactory anatomical lead position was the only criterion. The most common primary diagnosis was FBSS with a mean pain duration of 117 months. Ninety-three participants were on opioids and 103 on analgesics. The mean NRS was 7.5 for both groups, the mean ODI 56.9, and the mean EQ-5D index 0.31. At 6-month follow-up, NRS was reduced to 4.3 and 4.5 for the TG and NTG respectively (mean group difference: 0.2, 95% confidence interval [CI]: −1.2 to 0.9, P = 0.89). EQ-5D was increased to 0.57 and 0.53 for the TG and NTG group respectively (mean group difference: -0.06, 95% confidence interval [CI]: −0.16 to 0.04). ODI was decreased to 36.2 and 41.4 for the TG and NTG group respectively (mean group difference: 1.7, 95% confidence interval [CI]: −5.8 to 9.2). The Patient Global Impression of Change (PGIC) was 97% and 87% for the TG and NTG group respectively (mean group difference: 0.2, 95% confidence interval [CI]: 0.0 to 2.6). No significant subgroup effects for NRS by site (P = 0.25), sex (P = 0.17), age (P = 0.96), FBSS or not (P = 0.85), and type of stimulation (P = 0.70) could be shown. The NTG experienced less device-related AE (n=2) compared to the TG (n=5). Interestingly, a screening trial had a sensitivity of 100% (95% CI: 78-100) and specificity of only 8% (95% CI: 1-25). The authors state: “Our results indicate that although an SCS screening trial may have some diagnostic utility, it provides no patient outcome benefits compared to a no screening trial and direct to permanent SCS implantation strategy” [1].

Considering that the success of screening studies (i.e. ≥50% pain relief) ranges from 88% [2] to 93% [6] in recent RCTs, it seems that screening studies could be avoided. On the other hand, it has been suggested that even by limited pain relief during temporary trialing, the long-term outcomes could be satisfactory. Oakley et al. reported on 12 patients with less than 50% pain relief after a trial period (average pain relief 21%) [7]. Nevertheless, they received a permanent SCS System. At all follow-up time points (maximum zo to 1.5 year), at least a third of the subjects reported better than 50% pain relief, and the average pain relief varied over time between 44% and 83%. The researchers state that “the arbitrary benchmark of 50% pain relief that is typically used to define the success of a temporary trial may be too stringent and unreliable” [7].

3.2 THE PATIENTS´ PERSPECTIVE

Currently, many implanting physicians seem to consider an SCS-trial a prerequisite for superior patient outcomes as compared with a one-stage procedure approach. Undoubtedly, performing a screening trial has many advantages (as well as disadvantages). However, many but not all chronic pain patients seem to prefer the elimination of trials. Chadwick et al. published recently a paper on this topic [8]. As part of the TRIAL-STIM study [1], the authors organized a qualitative study to investigate patients´ preferences (screening trial: yes or no?). Thirty-one participants were interviewed prior to implantation and 23 patients again after the implantation.

Two main themes arose from the preimplant interviews: SCS expectations and preference for one- or two-stage procedures. More specifically, patients expected that the therapy would improve quality of sleep, social life, and employment. Most of patients preferred one-stage procedures. They did not opt for two-stage procedures because of fear of dislodgement of wires, distance to the hospital, time needed, burden on relatives for support, childcare, and health care resources. They did, however, comment on the ease of removal of wires only instead of a bulky neurostimulator.

Many more themes arose from the postimplant interviews: clinical outcomes, practical routine with an SCS system, discomfort, information, consistency of aftercare, and need to manage expectations. Pain relief was an important issue; most of the participants were satisfied with the pain

reduction. The number and dose of pain medications was also reduced and the function (walk longer distances, sit longer, housework) was improved. Such changes were frequently observed by family members too. The ability to change the device settings (many reported continued relief with cycling through different settings) and regular charging of the device were also important. Other issues included strange sensations since having a device implanted and new pain in the area of the leads or of the IPG (when applying pressure, movement of the IPG in the implant site). Moreover, participants valued the amount of information directly from physicians, other patients, online forums or internet research. Most patients were satisfied with the aftercare they had received although some had to seek support from sites local to them. Managing expectations was a crucial issue. Most patients could describe the positive and negative aspects of the therapy but their expectations seemed to be higher than it was actually achieved. As in the preimplant interviews, patients repeated their preference for one-stage procedures but this time they commented on the extent and potential impact of the surgery. Notably, 26 of 31 participants expressed a strong preference for a one-stage procedure. Of these 26, 17 participants were of the same opinion after implantation. Furthermore, three participants in the preimplant interview expressed a preference for one-stage procedure, which resulted in a strong preference for one-stage postimplant (all had gone through two-stage procedures) [8]. The findings indicated "an overwhelming preference among participants for a one‐stage SCS procedure both before and after the implant, regardless of which procedure they had undergone."

4. COST ANALYSIS: TRIAL VS. NO TRIAL

The cost of a therapy is always considered when health care systems prepare therapeutic algorithms. This is why cost analyses of SCS (with or without trials) are always helpful. According to Eldabe et al., from a National Health Service (NHS, UK) perspective, a screening trial was estimated to cost £19,073.38 per patient in TG, while a no screening trial strategy was estimated to cost £17,487.90 per patient in NTG (mean difference £1,341.22 (95% CI −34.26 to 2,832.85) [1]. The authors suggested that the TG strategy generated more QALYs but at an increased cost, thus producing an incremental cost-effectiveness ratio (ICER) of £78,895 per additional QALY gained. The probability of a screening TG being cost-effective at £20,000 or £30,000 per additional QALY gained (which is the threshold by NICE) was 9.2% and 13.8%, respectively. These results indicate that there is no evidence that an SCS screening TG is cost-effective compared to a no trial screening approach.

Duarte & Thomson also showed that considerable savings could be obtained by adopting an implantation strategy without a screening trial [9]. The authors conducted a cost-impact analysis considering only the costs associated with the screening trials and devices. Using the implant rates reported in the literature (91.6%), savings between £16,715 (upper bound 95% CI of rechargeable IPG cost) and £246,661 (lower bound 95% CI of non-rechargeable IPG cost) per each 100 patients by adopting a no-trial strategy could be achieved. In addition, a failure rate of less than 15% seems to be cost saving to the NHS. A failure rate as high as 45% can also be cost saving if the less expensive non-rechargeable IPGs are used. In conclusion, the authors state: "It is plausible that accounting for other factors, such as complications that can occur with a screening trial, additional savings could be achieved by choosing a straight to implant treatment strategy" [9].

5. CONCLUSION

In the light of recent studies, it seems that although SCS trials still have a certain diagnostic utility, there is no sound evidence that such trials provide superior patient outcomes. Moreover, SCS trials do not seem to be cost-effective.

References

1. Eldabe S, Duarte R, Gulve A, Thomson, S, Baranidharan G, Houten R, et al. Does a screening trial for spinal cord stimulation in patients with chronic pain of neuropathic origin have clinical utility and cost-effectiveness (TRIAL-STIM)? A randomised controlled trial. Pain. 2020;161(12):2820-2829.
2. 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):179–188.
3. Deer TR, Mekhail N, Provenzano D, Pope J, Krames E, Leong M, et al. The appropriate use of neurostimulation of the spinal cord and peripheral nervous system for the treatment of chronic pain and ischemic diseases: the Neuromodulation Appropriateness Consensus Committee. Neuromodulation. 2014;17(6):515-550.
4. Weinand ME, Madhusudan H, Davis B, Melgar M. Acute vs. prolonged screening for spinal cord stimulation in chronic pain. Neuromodulation. 2003;6(1):15–19.
5. Simopoulos T, Sharma S, Aner M, Gill JS. A temporary vs. Permanent anchored percutaneous lead trial of spinal cord stimulation: a comparison of patient outcomes and adverse events. Neuromodulation 2018;21(5):508–512.
6. Kapural L, Yu C, Doust MW, Gliner BE, Vallejo R, Sitzman BT, Amirdelfan K, Morgan DM, Brown LL, Yearwood TL, Bundschu R, Burton AW, Yang T, Benyamin R, Burgher AH. Novel 10-kHz high-frequency therapy (HF10 therapy) is superior to traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain: the SENZA-RCT randomized controlled trial.

Anesthesiology. 2015;123(4):851–860.
7. Oakley JC, Krames ES, Stamatos J, Foster AM. Successful long-term outcomes of spinal cord stimulation despite limited pain relief during temporary trialing. Neuromodulation. 2008;11(1):66–73.
8. Chadwick R, McNaughton R, Eldabe S, Baranidharan G, Bell J, Brookes M. To Trial or Not to Trial Before Spinal Cord Stimulation for Chronic Neuropathic Pain: The Patients' View From the TRIAL-STIM Randomized Controlled Trial. Neuromodulation. 2021;24(3):459-470.
9. Duarte RV, Thomson S. Trial Versus No Trial of Spinal Cord Stimulation for Chronic Neuropathic Pain: Cost Analysis in United Kingdom National Health Service. Neuromodulation. 2019;22(2):208-214.

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