

Creation of a Database for Monitoring Patients Undergoing Spinal Cord Stimulation and Analysis of Outcomes in the First 115 Patients: A Real-World Data Analysis

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Abstract

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Abstract

Introduction

Every year, approximately 70 patients at our Institute undergo spinal cord stimulator implantation. We believe that monitoring outcomes and continuously reviewing our practices are essential for improving the quality of our activities.

Methods

Using REDCap software, a database was created to collect patients' anamnesis characteristics, indications, intraoperative factors, outcomes, and complications for those undergoing spinal cord stimulation.

Results

The analysis of the first 115 patients from 2021 to 2022 (54M / 61F) showed that the main indication for placement was PSPS type 2 (persistent spinal pain syndrome) in 55 patients (47.8%). Twenty-one patients (18.3%) underwent a trial before implantation, which was successful in 100% of cases; the others proceeded directly with implantation. For all patients, the scs e-tool value was retrospectively calculated and has been included in the medical record since 2023.

All patients were evaluated by a psychologist before the procedure, and no evaluated patients were excluded. In 66% of cases, the system used was Boston, and in 33% Nevro. For Nevro, 47% of patients had one electrode placed, and 53% had two; for Boston, 37% had one, 59% had two, and 4% had three electrodes. The final programming for Boston was Tonic (50%), Burst (26%), FAST (17%), HF1200 (7%); for Nevro, HF (93%) and Burst (7%). There were 8 (7%) revisions for electrode dislocation and 15 explants (13.5%) at 12 months, of which 2 were due to infection and the remaining due to inefficacy.

The scs e-tool score was lower in patients who underwent explantation, no statistical significance. The overall VAS score decreased from 86 to 55 after 12 months, the Oswestry Disability Index decreased from 48 ± 13 to 37 ± 5, and the quality of life on the EQ5D5L questionnaire increased from 39 ± 20% to 55 ± 10% (p<0.05 for all, ANOVA for repeated measures). Outcome variables showed no significant differences based on entry diagnosis, age, or preoperative opioid use.

Fifty patients (43.5%) were taking opioids (56 ± 66 mg morphine equivalents), which reduced to 39 ± 39 mg at 12 months (p<0.05). For all analyzed outcomes, the most significant reduction occurred in the first 3 months and then stabilized until 12 months. The explantation rate was not higher in patients who underwent trials compared to those who had direct implantation, nor in patients taking opioids.

Conclusions

The initial analysis supports our selection procedures, particularly the policy adopted since 2023 to reduce the number of trials, which seems associated with an unjustified increase in resource use, a finding confirmed in our practice as well. In the near future, the utility of the systematic use of the scs e-tool score introduced in 2023 will be locally validated, and cost-benefit and cost-utility analyses will be introduced using the utility index derived from the EQ5D5L.

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