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Comparing Postoperative Spectral Features During Clinically Optimized Spinal Cord Stimulation in Two Representative Patients

Ilknur Telkes, PHD, Shelby Sabourin, HS, Marisa DiMarzio, PHD, Olga Khazen, MS

Introduction: Given the complex nature of the treatment of chronic pain, biomarkers that have the potential to objectively assess pain are an emerging topic of interest. Specifically, electroencephalography (EEG) has been implicated in underlining the pathways modulated by spinal cord stimulation (SCS) therapy[1]. This study sought to elucidate spectral features 3 months following SCS surgery in responder and non-responder cases.

Methods: Data was assessed in two representative patients undergoing SCS surgery: one responder (M/53) and one non-responder (F/65). Patients were classified as responders when reporting >50% pain relief post-operatively and non-responders when reporting <30% improvement in pain, using the Numerical Rating Scale (NRS). Sixty-channel scalp EEGs were recorded preoperatively (6.5±1.5 days) and at approximately three months postoperatively (80.5±2.5 days). Following standard preprocessing approaches[2], a modified Welch periodogram method was used to analyze the spectral dynamics over regions of interest (ROIs).

Results: Both patients were implanted with bilateral 8-contact percutaneous thoracic leads. The responder was programed only with 90Hz tonic stimulation while non-responder was programed with combination of 90Hz and 200Hz. Both patients had the same current intensity (1.8mA) and pulse width (210μs). The responder patient showed stronger alpha/theta power ratio (dB) and faster rhythms in primary and secondary somatosensory cortices (S1, S2), and the prefrontal cortex (PFC) as compared to the non-responder patient. Specifically, in S1 peak frequency was localized to higher alpha range (≥12 Hz) in the responder case and lower alpha-theta(<8 Hz) along with prominent beta frequencies (13-20 Hz) in the non-responder case. Comparison of power spectra in S1 preoperatively (stim OFF) and postoperatively (stim ON) in each case showed consistent morphology despite the recordings being collected 3 months apart. Particularly, responder patient demonstrated enhanced alpha power with no change in theta power postoperatively while non-responder patient showed no change in alpha band and enhanced theta power.

Conclusion: The data in these two representative cases is the first to assess the relation between alpha band features in an awake state and chronic pain relieved by SCS. Specifically, these cases highlight localized spectral differences in a responder and non-responder case and might indicate a correlation between the mechanism of tonic stimulation and the role of S1 in pain processing. Furthermore, this is the first pilot study to examine the longitudinal EEG changes from preoperative to postoperative period in the same subjects.

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Multiple RCTs of SCS Show Consistent Outcomes in the Treatment of Painful Diabetic Peripheral Neuropathy

Michael Fishman, MD, MBA, Maddie LaRue, PHD, Brooke Kelley, PhD, Lisa Johanek, PhD, Melissa Murphy

Introduction: Diabetic peripheral neuropathy (DPN) is the most common neuropathic syndrome seen in patients with diabetes. DPN symptoms include stabbing or burning pain eventually progressing to numbness in the lower extremities resulting in loss of protective sensation. Traditionally, pain associated with DPN has been treated with gabapentin/pregabalin, tricycling antidepressants, and serotonin-norepinephrine reuptake inhibitors[1]. These treatment approaches are often unsuccessful in the long-term, with many DPN patients abandoning initial prescription analgesics within months[1]. Spinal Cord Stimulation (SCS) has been examined in 3 randomized controlled trials (RCTs)[2,3,4] comparing SCS to conventional treatments.

Methods: Three RCTs[2,3,4] comparing SCS to treat painful DPN were compared and contrasted by primary outcome measures, primary endpoint duration, intervention, demographics, treatment-effect-size and quality-of-life outcomes based on the intention-to-treat principle.

Results: Two RCTs[2,3] using traditional SCS programming were independently designed, conducted and reported, with industry grant support, in western Europe. One RCT[4] using high frequency SCS programming was industry-sponsored and conducted in the United States. Primary outcome measures included a composite primary endpoint where patients could be identified as treatment responders by reduction in pain diary scores or Patient Global Impression of Change, ≥50% reduction in VAS measurement for pain, and a compound primary endpoint of ≥50% reduction in pain score and no neurologic decline (Table 1). Primary endpoint duration was 6 months in two studies and 3 months in one study. All three studies included mostly patients with Type 2 diabetes. The difference in treatment success between SCS and control groups for the primary endpoint in the Intention-to-Treat populations ranged from 52% to 58% (Table 1). Improvement in EQ-5D index scores at 6 months ranged from 0.124 to 0.380 (Table 2).

Conclusion: Three RCTs[2,3,4] have all shown SCS as effective over the standard of care for treating DPN pain symptoms. The variety of primary endpoints were all meaningful measures of reduction in pain symptoms and ranged from pragmatic measures to measures that included neurological deterioration, though very few subjects regressed. Multiple RCTs proving the effectiveness of SCS to treat DPN have clearly established effectiveness of the therapy and represents possibly the strongest body of evidence for any indication for SCS.

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