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Four-year follow-up from a prospective, multicenter study of 60-day medial branch nerve stimulation for chronic axial back pain

Christopher Gilmore, Timothy Deer, Mehul Desai, Sean Li, Michael DePalma, Brandon Swan, Meredith McGee, Joseph Boggs
SPR Therapeutics, Inc.

Introduction

Chronic low back pain (LBP) is a leading cause of long-lasting pain and disability in adults[1]. Treatment of chronic LBP is associated with significant healthcare and economic burdens[2] resulting from the difficulty of effectively treating the issue, which has historically included a range of interventions with increasing levels of invasiveness. Sixty-day percutaneous peripheral nerve stimulation (PNS) is a minimally invasive neurostimulation treatment that has been shown to be a safe and effective treatment for chronic axial LBP[3] and has been shown to provide sustained reductions in pain and/or disability in responders through at least one year following treatment[4-5]. The present work explores the long-term clinical outcomes approximately four years after treatment for chronic LBP with 60-day PNS.

Materials and Methods

Five sites that participated in a prior post-market study for the treatment of chronic LBP (NCT03179202) obtained IRB approval to send follow-up surveys to subjects who were previously consented, completed study participation, and reported clinically significant improvement in at least one of the three outcome measures (≥30% reduction Brief Pain Inventory Question #5 [BPI-5], ≥10-pt reduction Oswestry Disability Index [ODI], or ≥30% reduction Brief Pain Inventory Question #9 [BPI-9]) at the final study visit 12 months after completing PNS treatment. These subjects previously had undergone bilateral percutaneous PNS lead placement (SPRINT PNS® System) to stimulate medial branches of the dorsal rami innervating the multifidus muscles in the lower back. Subjects received 6-12 hours of stimulation every day for up to 60 days (two months) and were followed until 12 months after PNS lead removal. The present long-term follow-up survey included validated measures to assess current levels of LBP, pain interference, disability, and Patient Global Impression of Change (PGIC); subject satisfaction and LBP treatments used since the subject's last study visit were also surveyed. Safety outcomes were not assessed in the survey.

Results/Case Report

A total of 23 subjects completed and returned the long-term follow-up survey. An average of 4.6 years (range: 3.6-5.9 years) had elapsed since percutaneous PNS lead placements and initiation of treatment. A majority of survey respondents (65%, n=15/23) reported sustained, clinically significant (≥30%) relief of back pain compared to baseline. Among these long-term responders, the average relief reported was 63%. Further, 70% of subjects

reported highly clinically significant (≥50%) pain relief and/or clinically significant improvement in disability (≥10-point reduction in ODI).

Discussion

Treatment with 60-day PNS provided clinically significant pain relief and/or improvements in disability among a majority of surveyed respondents an average of more than four years after the treatment. These results demonstrate that percutaneous PNS can provide remarkably durable outcomes that are often sustained for multiple (4+) years for patients with chronic axial LBP, which may mitigate the need for more invasive treatment interventions.

References

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Disclosures

Yes

Tables / Images