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Scientific abstract: Chronic pain

Minimally invasive percutaneous peripheral nerve stimulation (PNS) reduces pain and disability in chronic low back pain

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Introduction

Chronic back pain is the leading cause of disability among adults in the United States¹ and one of the most challenging conditions to treat. The objective of this case series study was to evaluate the feasibility of a percutaneous peripheral nerve stimulation (PNS) therapy for the treatment of chronic low back pain (LBP). Neuromodulation provides an opportunity to reduce or eliminate the use of opioids², but the cost and invasiveness of existing permanently implanted systems have the potential to limit therapy adoption, preventing their consideration earlier in the treatment continuum. A wearable stimulator coupled with a percutaneous fine-wire coiled lead³ is designed to address limitations of previous neurostimulation systems.

Materials and methods

A case series study was conducted in nine individuals with LBP confined to the lumbar region lasting ≥ 3 months. Written informed consent was obtained from each individual prior to participation in this FDA investigational device exemption (IDE) and institutional review board (IRB) approved study. Subjects underwent bilateral ultrasound-guided placement of percutaneous open-coil PNS leads targeting the medial branches of the dorsal rami in the painful region, which were connected to miniature wearable stimulators (SPRINT® PNS System, SPR Therapeutics®, Cleveland, OH) for the duration of the 30-day therapy period. Stimulation therapy was programmed to produce comfortable cycling contractions of the multifidus for 6 hrs/day, during which subjects were encouraged to continue their normal daily activities. At the end of the therapy period, leads were withdrawn using gentle traction. Pain and disability were assessed using validated questionnaires (Brief Pain Inventory, BPI, and Oswestry Disability Index, ODI). Subjects completed long-term follow-up visits up to 7 months after start of therapy.

Results/Case report

The majority of subjects (67%) experienced highly clinically significant reductions ($\geq 50\%$) in average pain intensity with treatment (BPI-5) compared to baseline (avg. 80% reduction among responders; $p < 0.0001$, ANOVA, $n=9$). Clinically significant reductions in pain were sustained in a majority (60%) of responders completing long-term follow up visits at 7 months (avg. 57% reduction in pain intensity among responders) after start of treatment. Subjects using analgesic medications substantially reduced their medication dosages with treatment (avg. 76% reduction in non-opioid analgesics, $n=6$ taking non-opioids at baseline; 100% reduction in opioid analgesics, $n=1$ taking opioids at baseline), and these reductions were sustained. A majority of subjects also experienced clinically significant improvements in disability (67% had ≥ 10 -pt reduction; avg. 23-pt reduction in ODI among responders), pain interference (75% had $\geq 30\%$ reduction; avg. 75% reduction in BPI-9 among responders), and quality of life (avg. PGIC of “much improved”) with treatment. There were no serious or unanticipated adverse events.

Discussion

This work, consistent with previous trials for post-amputation pain and shoulder pain, demonstrates the promising clinical utility of percutaneous PNS designed to provide sustained relief of LBP and improvements in disability and quality of life. Percutaneous PNS has the potential to shift the pain management paradigm by providing a non-destructive and effective neuromodulation therapy to patients earlier in the treatment continuum than has otherwise previously been considered viable or reasonable.

References

¹ US Burden of Disease Collaborators. The State of US Health, 1990-2010 Burden of Diseases, Injuries, and Risk Factors. *JAMA*. 2013; 310(6):591-606.



² Kumar, K 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):179-88.

³ Ilfeld, BM et al. Infection Rates of Electrical Leads Used for Percutaneous Neurostimulation of the Peripheral Nervous System. *Pain Practice*. 2017;17(6):753-62.

Disclosures

I confirm that I am aware of conflicts of interest in my presentation.

Details:

Study funded by SPR Therapeutics. M. McGee is an employee of SPR Therapeutics.