Reductions in Opioid Consumption with Percutaneous Medial Branch Peripheral Nerve Stimulation for Chronic Low Back Pain

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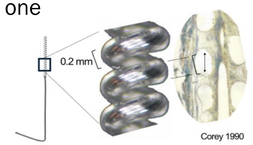
INTRODUCTION

- Chronic low back pain (LBP) is one of the most prevalent and challenging musculoskeletal conditions[1] and is the leading cause of disability in adults.

CONVENTIONAL NEUROMODULATION:

- Requires surgery and permanent implant
- Cost may relegate therapy to use later in the treatment continuum

MINIMALLY INVASIVE, PERCUTANEOUS PNS:



- Wearable stimulator and percutaneous fine-wire, coiled lead (designed to anchor in tissue with excellent safety profile[2]) could overcome limitations of previous systems

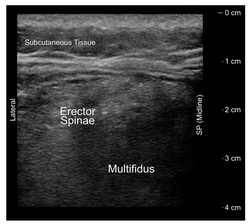
Goal: Evaluate feasibility of 60-day percutaneous PNS to reduce opioid use in patients with chronic LBP.

MATERIALS & METHODS

Ongoing IRB approved study; informed consent was obtained from each participant.

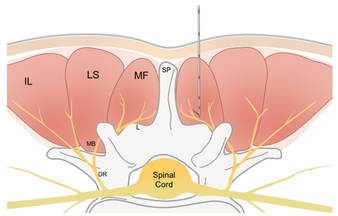
Key Eligibility Criteria:

- Participants with chronic LBP (≥ 3 months); no radicular pain
- Stable medication usage at least 1 month prior to baseline
- No prior lumbar surgery or RFA within prior 6 months
- No anesthetic injections within prior 3 months
- Score of ≤ 20 on Beck Depression Inventory



Lead Placement: Bilateral, percutaneous PNS leads, targeting medial branches of the dorsal ramus in the center of the region of pain

- *Image Guidance:* ultrasound and/or fluoroscopy
- *Confirmation:* Stimulation of medial branch confirmed by selective activation of multifidi



PNS Treatment: Stimulation for 6-12 hrs/day for up to 60 days

- Participants continued normal activities
- Leads removed with gentle traction
- Participants return for long-term follow-up visits

Figure Abbreviations: Dorsal Ramus (DR), Iliocostalis (IL), Lamina (L), Longissimus (LS), Medial Branch (MB), Multifidus (MF), Spinous Process (SP).

RESULTS

Participant Demographics (n = 11):

- Average Age: 60.8 years (40.1 – 82.1)
- Average Baseline Pain Score: 6.3 (BPI-5)
- Average Duration of LBP: 17.0 years
- Spinal Level of Lead Placement: L2 (n=1), L3 (n=1), L4 (n=6), L5 (n=3)

Outcomes:

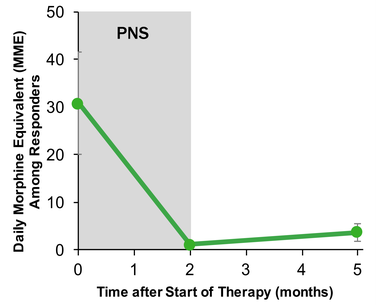
- At End of Treatment (EOT) 64% reported ≥50% reduction in opioid consumption with PNS (n=7/11)
  - *Avg. 29.7 mg morphine equivalent (MME) reduction among responders at EOT*
- At 3 months post EOT, 73% reported ≥50% reduction in opioid (n=8/11)
  - *Avg. 23.1 MME reduction among responders at 3 months post-EOT*
- Majority of participants experienced clinically-significant reductions in average pain intensity, disability, and pain interference.

Safety:

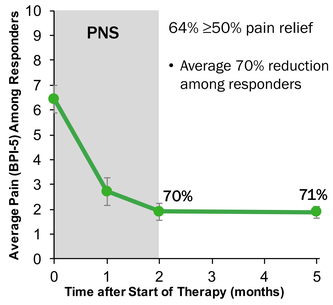
- No serious or unanticipated device-related adverse events

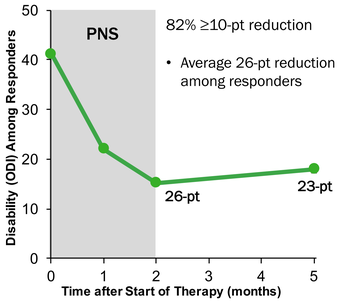
Substantial Reductions in Opioid Analgesic Consumption with PNS:

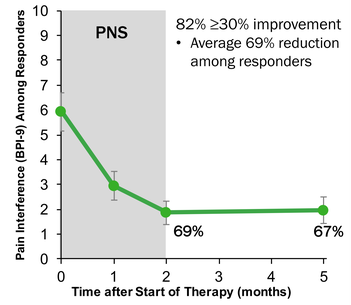
Participant	Baseline mg Morphine Equivalent (MME)	End of Treatment (EOT)			3-mo Post-EOT		
		MME	MME Reduction from Baseline	% MME Reduction	MME	MME Reduction from Baseline	% MME Reduction
1	80.0	0.0	80.0	100%	0.0	80.0	100%
2	22.1	2.9	19.3	87%	0.0	22.1	100%
3	3.6	0.0	3.6	99%	2.9	0.7	19%
4	13.6	0.0	13.6	100%	6.4	7.1	53%
5	66.4	47.1	19.3	29%	57.8	8.6	13%
6	10.0	9.3	0.7	7%	10.0	0.0	0%
7	3.2	4.3	-1.1	-34%	1.1	2.1	67%
8	1.4	1.4	0.0	0%	0.0	1.4	100%
9	57.9	4.3	53.6	93%	15.0	42.9	74%
10	7.1	0.0	7.1	100%	1.4	5.7	80%
11	31.0	0.5	30.5	98%	5.8	25.2	81%
Average All Participants	*26.9*	*6.3*	*20.6*	*62%*	*9.1*	*17.8*	*63%*



Clinically Significant[3] Reductions in Average Pain Intensity, Disability, and Pain Interference with PNS:







CONCLUSIONS

- Percutaneous PNS treatment for up to 60 days can significantly reduce usage of opioid analgesic medications in patients with chronic LBP.
- These results support earlier findings that percutaneous PNS delivered for up to 60 days can relieve chronic LBP, which leads to improvement in disability and quality of life, without a permanently implanted device.

REFERENCES & ACKNOWLEDGEMENT

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