Real World Registry Data Shows Significant and Sustained Long-Term Pain Relief In Patients Receiving Peripheral Nerve Stimulation for Medial Branch Stimulation with a Micro-IPG Device.

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Introduction

Peripheral Nerve Stimulation (PNS) is an established modality for the treatment of chronic peripheral neuralgia/neuropathy.[1] Recent data from the COMFORT RCT showed significant and sustained long-term improvements.[2]

Real-world evidence can help confirm outcomes outside of the research environment and provide insights into common clinical practice. This work looks at patients treated with Medial Branch stimulation in the lower and upper back and the cervical regions.

Methods

Anonymized patient records were reviewed from a national real-world, IRB approved database of patients implanted between 4/19/22 and 5/2/2024 with the Nalu micro-IPG (Nalu, Medical, Inc.) Data included patient responses to standardized surveys on pain score (0-10 scale) and Patient Global Impression of Change (PGIC).

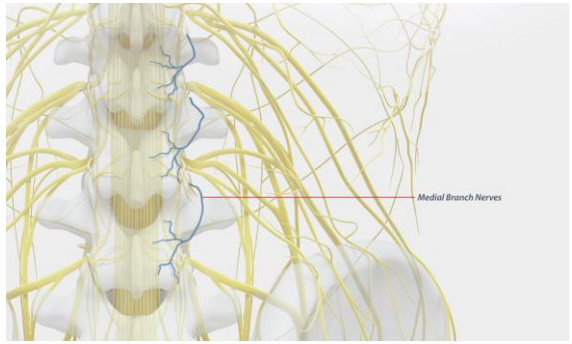
Patients included in this evaluation

- Baseline pain score ≥4/10
- completed the surveys prior to implant
- Completed at least one survey 6 to 9-month intervals post implant
- A responder was defined as those achieving ≥50% pain reduction and/or improvement in PGIC

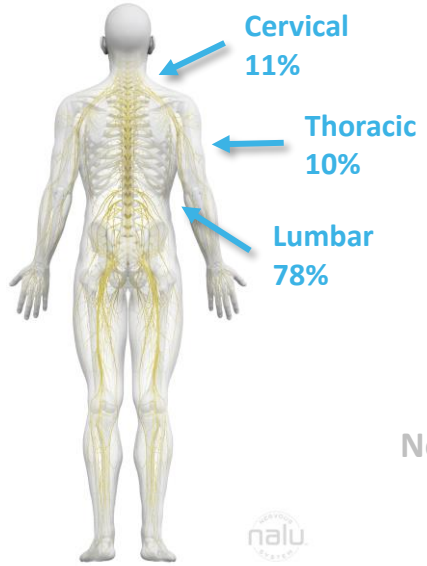
Results & Discussion

- **n=79** patients met the inclusion criteria.
- **5 months** average time since permanent implant (range of 1 to 18 months)

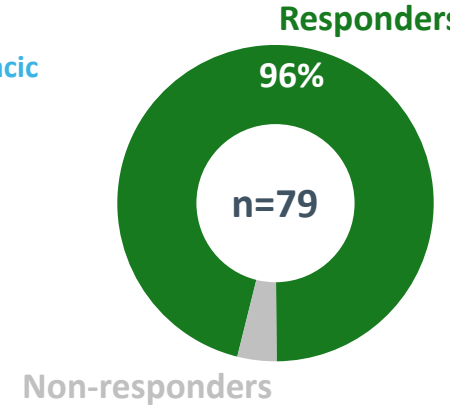
Lumbar Medial Branch Targets



Medial Branch Targets (%)



Responder Rates (%)



- **96%** (76/79) of all patients were **responders**
- **67% average pain relief** for responders (≥50% pain relief)
- All patients received a temporary **trial** (indicating rapid onset of pain relief) and utilized **sensory stimulation for pain relief**

References

1. Slavin KV (ed): Peripheral Nerve Stimulation. Prog Neurol Surg. Basel, Karger, 2011, vol 24, pp 1–15 https://doi.org/10.1159/000323002

2. Hatheway J, et al A Report on Interim Long-term Pain Outcomes from the COMFORT Peripheral Nerve Stimulation Randomized Control Trial, presented at the 2024 World Congress of the International Neuromodulation Society

Conclusions

These real-world PNS results demonstrate rapid onset and durability of benefit for treatment of the medial branch at different targets. Additional data will be reported as it becomes available.