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Percutaneous 60-Day Peripheral Nerve Stimulation Provides Effective Pain Relief from Occipital Head Pain in the Presence of Migraine: Results from a Prospective, Single-Arm, Multicenter Pilot Study

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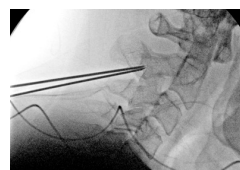
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INTRODUCTION

- Refractory occipital head pain due to cervicogenic headache (CGH) or occipital neuralgia (ON) can produce substantial disability, including significant reductions in physical function, and mental health,^{1,2} which is compounded in the presence of migraine and migraine symptoms (e.g., photophobia, nausea).³
- There is a substantial need for effective treatment options for patients with concurrent occipital head pain and migraine.
- A recent prospective, single-arm study found percutaneous 60-day peripheral nerve stimulation (PNS) produced significant relief in patients with CGH or ON, enabling improvement in quality of life and function.⁴
- However, that study cohort excluded patients with migraine or migraine-like features
- The goal of this study cohort was to collect data on the efficacy and safety of the 60-day PNS treatment among patients with CGH or ON with concurrent migraine.

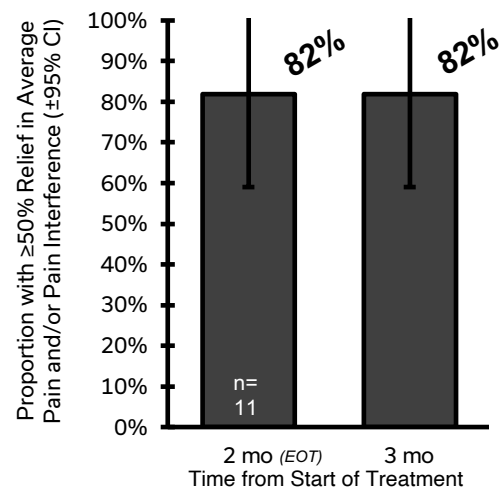
METHODS

- IRB-approved, multicenter, prospective case series (n=11).
- Key eligibility criteria: occipital head pain due to CGH or ON, presence of migraine-like features, baseline average pain and pain interference $\geq 4/10$, and Beck Depression Inventory ≤ 20 .
- Percutaneous leads placed targeting the greater and third occipital nerves (e.g., at the C2 lamina) for 60 days.
- Participants controlled stimulation intensity using a handheld remote.
- Treatment success in this analysis: the proportion of participants with $\geq 50\%$ reduction in average pain intensity and/or pain interference at end of treatment (EOT) and follow-up visits.
- Additional outcomes:
 - Patient Global Impression of Change (PGIC)
 - Neck Disability Index (NDI)
 - Migraine Disability Assessment (MIDAS).
- Prospective long-term follow-up is ongoing

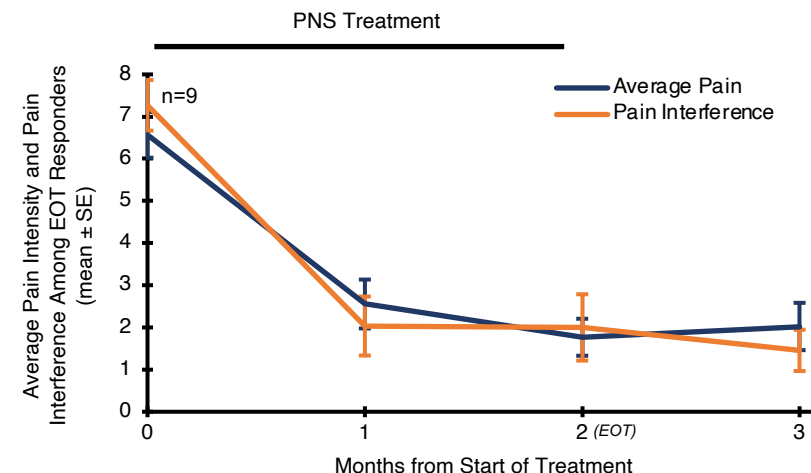


RESULTS

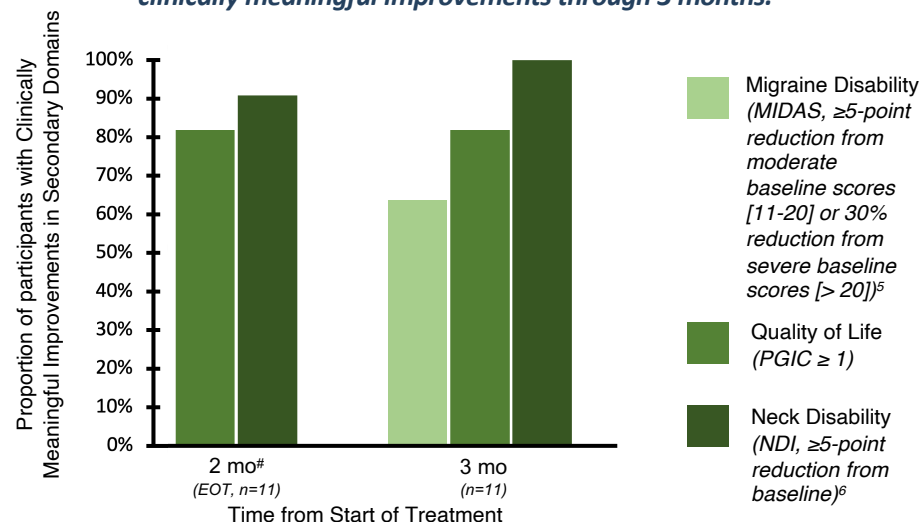
82% of participants (9/11) reported substantial reductions ($\geq 50\%$) in average pain and/or pain interference at 2 months (EOT), and relief was sustained through 3 months in a majority of participants.



Participants who responded to treatment had reduced pain intensity and pain interference through 3 months, with average reductions of $67\% \pm 9\%$ and $80\% \pm 6\%$, respectively (n=9).



For disability and quality of life outcomes, a majority of participants had clinically meaningful improvements through 3 months.



Safety: The most common AEs were skin irritation or itching. In this cohort, two infections were reported in 2 participants at the lead exit sites (1 classified as serious), and both resolved after a course of antibiotics with no sequelae.

#MIDAS data not included at 2 months (EOT) because 3-month recall period included time prior to start of PNS treatment.

CONCLUSIONS

- Percutaneous 60-day PNS treatment reduced pain and pain interference among patients with occipital head pain and concurrent migraine-like features.
- On average, responders to treatment had decreased pain intensity and pain interference beyond the treatment period (through 3 months, with further data collection pending).
- Pain relief facilitated improvements in additional domains: improved quality of life and decreased neck- and migraine-related disability.

REFERENCES

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