Real World Evidence of Sustained Improvements Following Percutaneous PNS: A Retrospective Cross-Sectional Follow-Up Survey of 354 Patients

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BACKGROUND

- A percutaneous PNS system was designed to provide PNS treatment for up to 60 days without the need for permanent implantation of hardware.
- In prospective studies across multiple common pain indications, a majority of patients experienced sustained pain relief following up to 60-days of PNS treatment.[1-8]
- This retrospective, cross-sectional, follow-up survey of patients that previously underwent implantation of 60-day PNS presents the largest set of real-world data to date regarding the effectiveness and long-term impact of the 60-day PNS treatment.

METHODS

- Retrospective, cross-sectional, follow-up survey distributed via email by device manufacturer to 2,028 patients who underwent treatment from 03/2018 to 12/2020 and opted-in to provide data. Patients were compensated $15 for their time to complete the survey.
- Survey data were combined with baseline and treatment data from the existing database.
- Survey items included:
  - Worst pain (BPI-3)
  - Average pain (BPI-5)
  - Percent pain relief (BPI-8)
  - Changes in medication usage
  - Patient Global Impression of Change (PGIC)

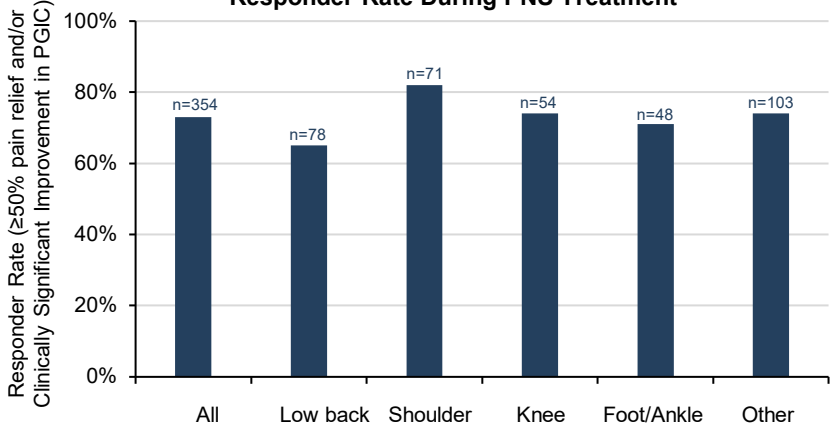
- Responders defined by ≥50% reduction in patient-reported percent pain relief and/or clinically significant improvement in PGIC
- Studies suggest composite endpoints that account for multiple domains can provide a more comprehensive and sensitive assessment of patient responses.[9,10]

RESULTS

60-Day PNS Treatment Outcomes

- 354 survey respondents with average duration of follow up of 7.6 months (ranging up to 30 months) from the start of PNS treatment.
- Most common treatment areas were low back, shoulder, knee, and foot/ankle.

Responder Rate During PNS Treatment

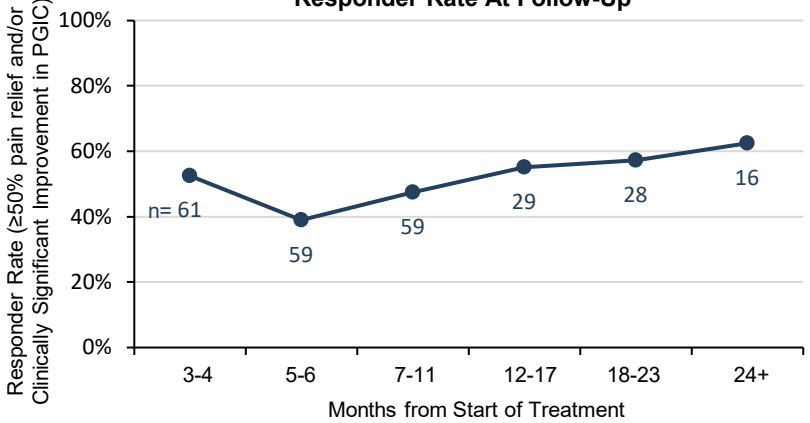


- Average and worst pain scores were categorized by severity as mild/none (≤4), moderate (>4 and ≤6), or severe (>6).[11]
- Mean average pain (BPI-5) rating dropped from severe at baseline (6.2 ± 1.9) to a mild severity (3.5 ± 2.4).
- Mean worst pain (BPI-3) decreased from severe (8.8 ± 1.5) at baseline to moderate severity (5.5 ± 2.8).

Long-term Follow-up Outcomes

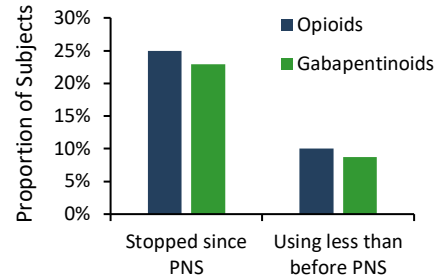
- A majority of patients had sustained long-term improvements at the time of survey completion, including those 24+ months post-PNS.

Responder Rate At Follow-Up



Among those using opioids or gabapentin at baseline:

- 35% had stopped or reduced opioid usage at the time of the survey (n=56/160)
- 32% had stopped or reduced gabapentin usage at the time of the survey (n=58/183)



CONCLUSIONS

- This study presents the largest body of real-world evidence to-date supporting the prolonged effectiveness of 60-day PNS treatment for pain previously published across multiple clinical trials.
- These real-world data coupled with published clinical trial outcomes support the use of a 60-day PNS treatment across a wide range of pain conditions in broader clinical practice.

REFERENCES

1. Yu et al., 2001; 2. Chae et al., 2005; 3. Rauck et al., 2014; 4. Chae et al., 2013; 5. Wilson et al., 2014a; 6. Wilson et al., 2014b; 7. Gilmore et al., 2020a; 8. Gilmore et al., 2020b; 9. Patel et al., 2018; 10. Pilitsis et al., 2021 11. Woo et al. 2015

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