Real World Evidence of Sustained Improvements Following Percutaneous PNS: A 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.1-4
• This cross-sectional follow-up survey of patients that previously underwent implantation of 60-day PNS presents real-world data regarding the effectiveness and long-term impact of the 60-day PNS treatment.

METHODS

• Cross-sectional, follow-up survey distributed via email by device manufacturer to 2,028 patients who underwent treatment from 03/2018 to 12/2020. Respondents 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)
  • PGIC
  • Changes in medication usage
• Responders: ≥50% reduction in patient-reported percent pain relief and/or minimal 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 7.6 ± 6.9 months from the start of PNS treatment.
• Most common treatment areas were low back, shoulder, knee, and foot/ankle.
• 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 improvements at the time of survey completion, including those 24+ months post-PNS.

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.