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
• Responders defined by ≥50% pain relief and/or Clinically Significant Improvement in PGIC

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.
• 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.
  • 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)
  • Proportion of subjects 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


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