60-Day PNS Treatment May Improve Identification of Delayed Responders and Non-Responders

Naidu R, MD[1], Li S, MD[2], Desai MJ, MD[3], Sheth S, MD[4], Crosby ND, PhD[5], Boggs JW, PhD[5]

[1]California Orthopedics & Spine, Larkspur, CA; [2]Premier Pain Centers, Shrewsbury, NJ; [3]ISPPC, Washington, DC; [4]Sutter Roseville Pain Management, Roseville, CA; [5]SPR Therapeutics, Cleveland, OH

Background

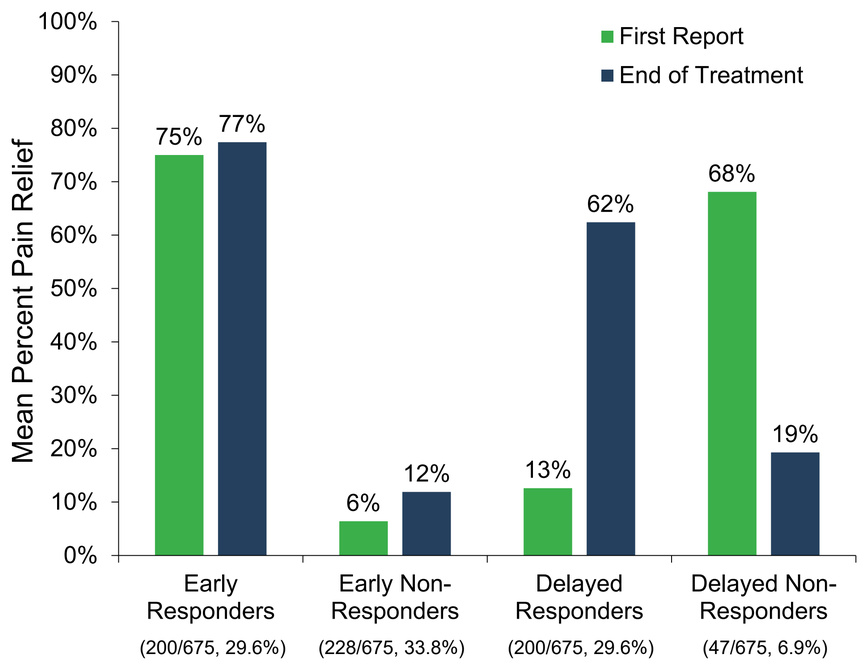
- Conventional neurostimulation for pain relief in the United States typically involves either no trial or a brief (e.g., ~7-day) trial to assess patient responsiveness.
- Low real-world trial conversion rates (41-65%) and lack or loss of efficacy following implantation as a leading cause of system explant suggest that improved patient identification strategies are needed.[1-5]
- A novel percutaneous PNS system has demonstrated that treatment over a 60-day period may obviate the need for a permanently implanted system altogether in some patients by providing long-term relief.[6-13]
- A 60-day treatment period may also facilitate a more detailed evaluation of the patient response over time to better identify delayed responders and non-responders to neurostimulation therapies.

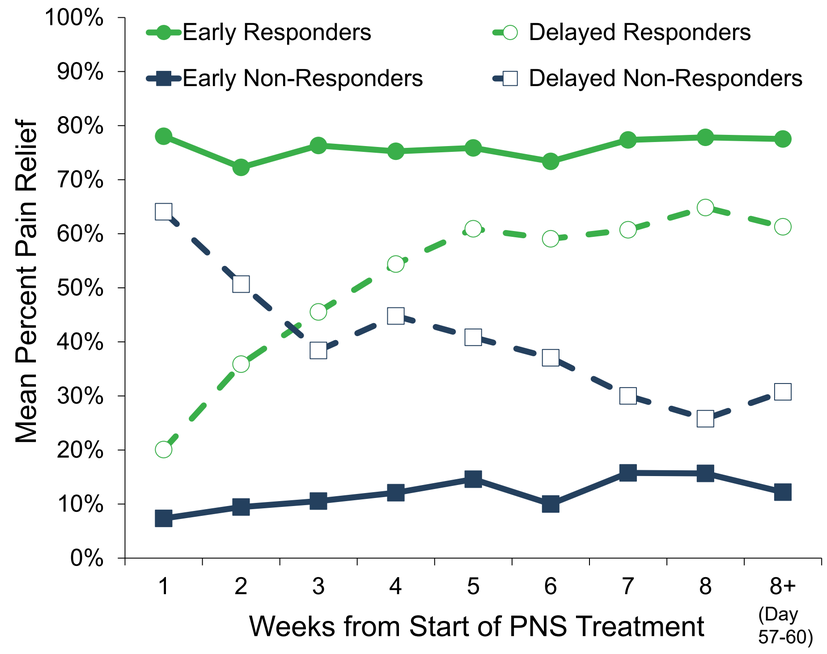
Methods

- Anonymized real-world treatment data compiled from patients that previously underwent implantation of temporary percutaneous leads and opted-in to provide real-world data to the device manufacturer
- Patient reports of percent pain relief collected in-person or by phone during routine interactions with device representatives as-needed throughout the 60-day treatment (e.g., for device support, programming, etc.)
- Inclusion in the analysis required:
  a) at least one report of percent pain relief within the first 14 days of treatment; b) at least two reports total during 60-day treatment.
- Responder = ≥50% pain relief

Results

- A total of 675 anonymized patient records were identified for inclusion, including 4091 individual reports (an average of 6.1 reports per patient from baseline through the end of the 60-day treatment).





- 36.5% of patients changed from non-responder to responder or vice versa before the end of the 60-day treatment period.
- Delayed responders did not reach their maximum mean pain relief and delayed non-responders did not reach their minimum mean pain relief until the final two weeks of the 60-day treatment.

- **60-day treatment may help identify delayed responders, providing the opportunity for sustained relief and improving access to effective PNS treatment that would likely have been deemed ineffective when a short trial period is used.**
- **60-day treatment may also improve delayed non-responder identification whose favorable responses wane over time.**
- **These scenarios support the notion of a prolonged temporary stimulation period, ideally for up to 60 days, to help inform PNS treatment strategies that may optimize patient outcomes while reducing cost and invasiveness.**

1. Huang et al., 2015; 2. Murphy et al., 2017; 3. van Buyten et al., 2017; 4. Pope et al., 2017; 5. Dupre et al., 2018; 6. Wilson et al., 2014a; 7. Wilson et al., 2014b; 8. Rauck et al., 2014; 9. Gilmore et al., 2019; 10. Gilmore et al., 2020; 11. Gilmore et al., 2021; 12. Deer et al., 2021a; 13. Deer et al., 2021b

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