First Results of a Real-World Survey of Patients Receiving Peripheral Nerve Stimulation to Treat Neuropathic Pain

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Introduction

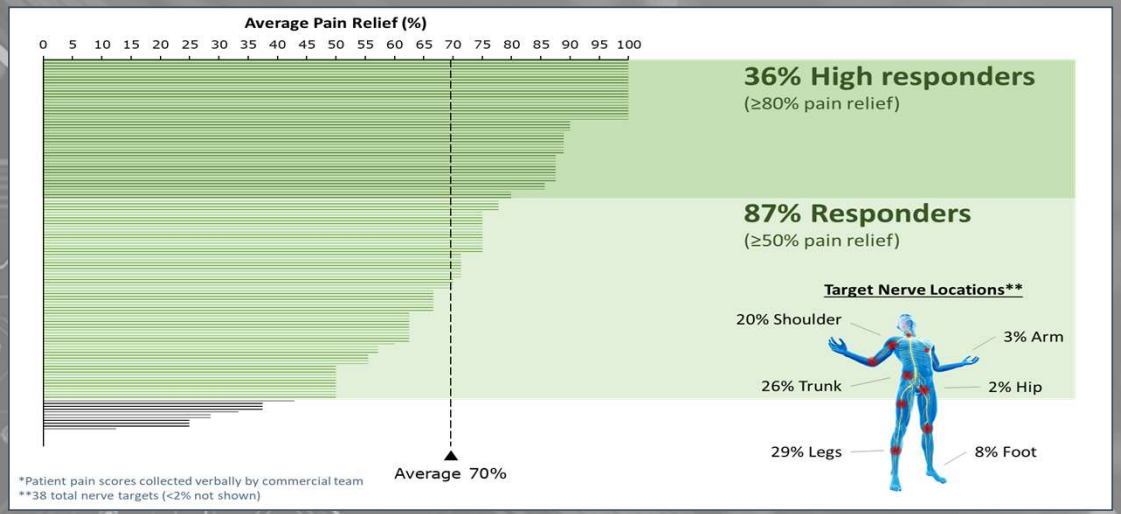
Peripheral nerve stimulation (PNS) is a well-established modality to treat severe intractable chronic pain of peripheral nerve origin. A novel neuromodulation system with a micro-implantable pulse generator (micro-IPG) and external, wearable battery source (Nalu Medical, Inc., Carlsbad, CA) has US market clearance for PNS and spinal cord stimulation (SCS) applications. This micro-IPG system has significant therapy options, with multiple electrodes, bi-directional communication, and advanced programming options. This is the first report of a large-scale survey of micro-IPG patients for PNS treatment of chronic pain.

Methods

One hundred ninety-eight (198) subjects with PNS implants provided consent to provide their clinical data to be housed in a company sponsored, secure, and controlled database; patients also agreed to be contacted by company representatives for telephonic follow up. Patient information was entered into the database through a secure web-based portal. Employees of the company contacted the patients for follow ups, and to collect data and resolve errors/omissions. Patients were asked a series of questions related to their pain profiles, quality of life, and overall satisfaction with therapy at various time points post implant of their micro-IPG system. The data collection is ongoing and will continue to house all commercial patients.

Results

- PNS therapy was used to treat thirty-eight (38) different nerve targets/nerve combinations. The top targets were legs (29%), trunk (26%), shoulder (20%), foot (8%), arm (3%), and hip (2%).
- 87% of all PNS patients had a successful treatment (defined as ≥50% pain relief), with an average pain relief across all patients of 70%.
- 36% of all PNS patients were high responders (defined as ≥80% pain relief).



Conclusions

This data is capturing real-world patient reported outcomes following permanent implant of a micro-IPG PNS system. Limitations of this survey include a small sample size and the use of non-validated instruments to capture patient reported outcomes; this will be addressed through an updated, recently implemented survey. This data indicates that PNS therapy delivered by a micro-IPG system can produce pain relief and improvement in general quality of life in most patients at a level usually associated with the SCS literature. A registry will be implemented to further the study of these positive results in a larger population.