

Real World Data Shows Long-Term Pain Relief with Peripheral Nerve Stimulation Delivered from micro-IPG

Authors: J. Hatheway 1, Ti Ratino 2, R Swain3, Th Ratino Th2, U. Latif4, S. Arulkumar5, J. Ruais 6, L. Hartley6, MJ Desai7

Affiliations: ¹ Northwest Pain Care, Spokane, WA; ² Ratino Interventional Pain Management, Fort Worth, TX; ³ Hurricane Pain Management, Springfield, OH; ⁴ University of Kansas Health System Kansas City, KS; ⁵ SSM Health Neurosciences; ⁶ Nalu Medical, Inc., Carlsbad, CA; ⁷ International Spine Pain and Performance Center, Washington, DC.

Introduction

Peripheral Nerve Stimulation (PNS) is an established modality for the treatment of chronic pain. Recent data from the COMFORT PNS RCT showed significant and sustained long-term improvements from use of a micro-IPG PNS system¹. In addition to RCT data, payors are requesting real-world data (RWD) to support PNS coverage policies; patient registries are a recognized valid source of RWD. We present RWD from the largest patient registry of PNS patients implanted with a micro-IPG device.

Methods

Anonymized patient records were reviewed from a national real-world, IRB approved registry of patients implanted with a micro-IPG device (Nalu Medical, Inc., Carlsbad, CA) between 4/19/22 and 7/24/2024. Patients without complete data were excluded from this analysis.

Patient Global Impression of Change (PGIC) data was available on **2,377 patients**. PGIC is a validated patient reported outcome instrument² that is recommended by the IMMPACT group³. Responders were defined as those patients who met the criteria for Minimal Clinically Important Difference (MCID), which is the report of minimally, much or very much improvement².

Discussion

These results are consistent with PGIC data reported in the COMFORT PNS RCT (95% PGIC responder rate)¹. This **RWD provides confirmatory evidence to the COMFORT PNS RCT**, providing further support for patient access to appropriate PNS therapy.

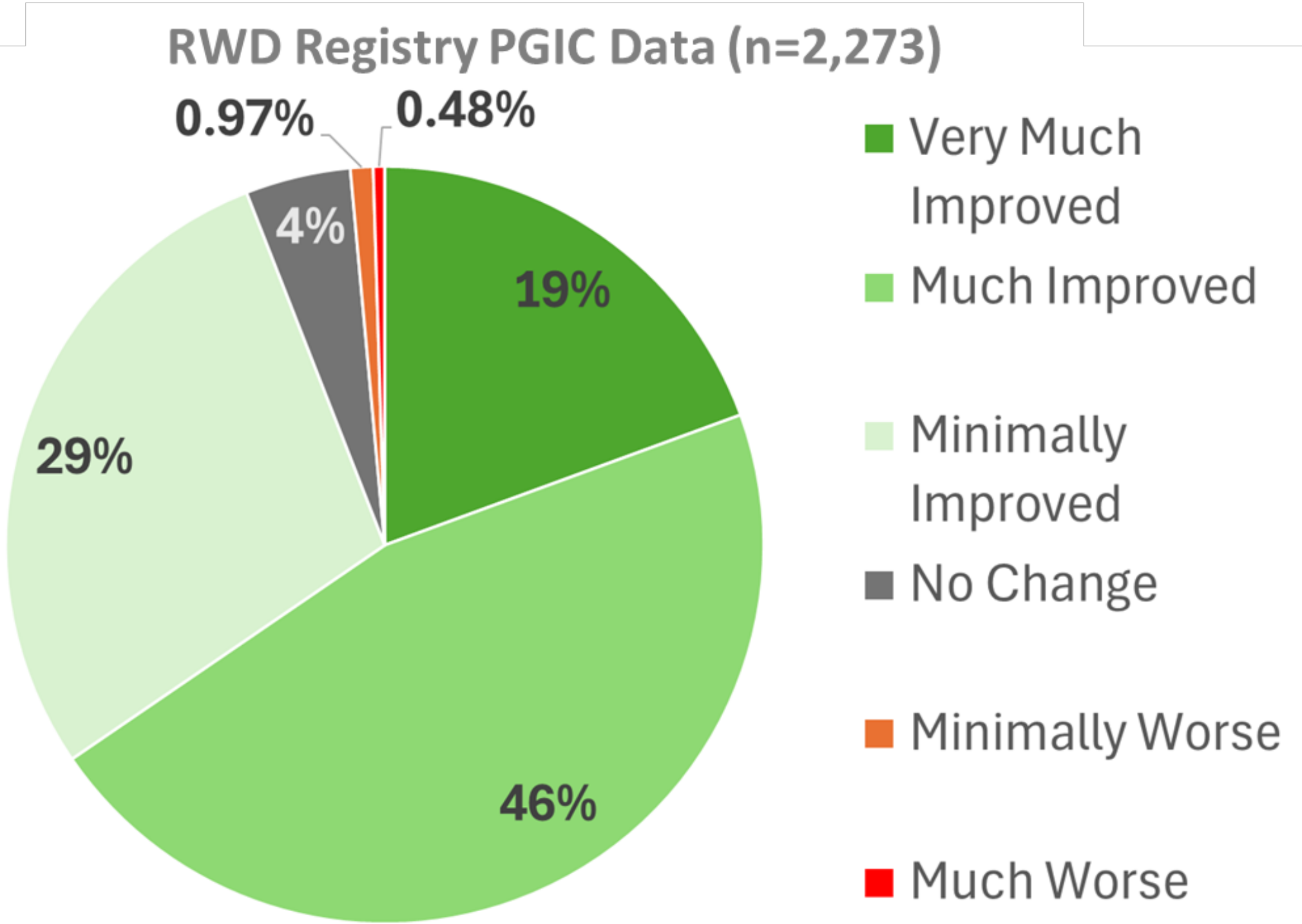


Link to
COMFORT
data in RAPM

References
1 Hatheway J, Hersel A, Engle M, et al. RAPM. November 20, 2024.
2 Smith S, Dworkin R, Turk D, et al, Pain, November 2020.
3 Dworkin R, Turk D, Wyrich, K, et al, J of Pain, February 2008.

Results

- **94% of patients were responders to PNS therapy using the micro-IPG PNS device.**
 - 19% Very Much Improved
 - 46% Much Improved
 - 29% Minimally Improved
 - 4% No Change
 - <1% reported any impression of worsening.



Over 40 different nerve targets and/or combinations were treated in this cohort.

The major anatomic targets included low back (43%), knees (19%), shoulders (11%), foot/lower leg (10%), other scattered areas 17%.

While not shown here, the response rate was comparable across all anatomic targets treated.

