

60-Day PNS vs. Standard Interventional Management for Chronic Low Back Pain: RESET RCT 6-Month Results

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Access 60-Day
PNS Posters

BACKGROUND

Usual care with standard interventional management for chronic low back pain (CLBP) includes physical therapy, injections, ablations, neurostimulation, and surgery ^{1,2}.

Percutaneous 60-day peripheral nerve stimulation (PNS) is an effective treatment option for a variety of pain conditions³, with a prior single-arm study showing potential for relief of CLBP^{4,5}.



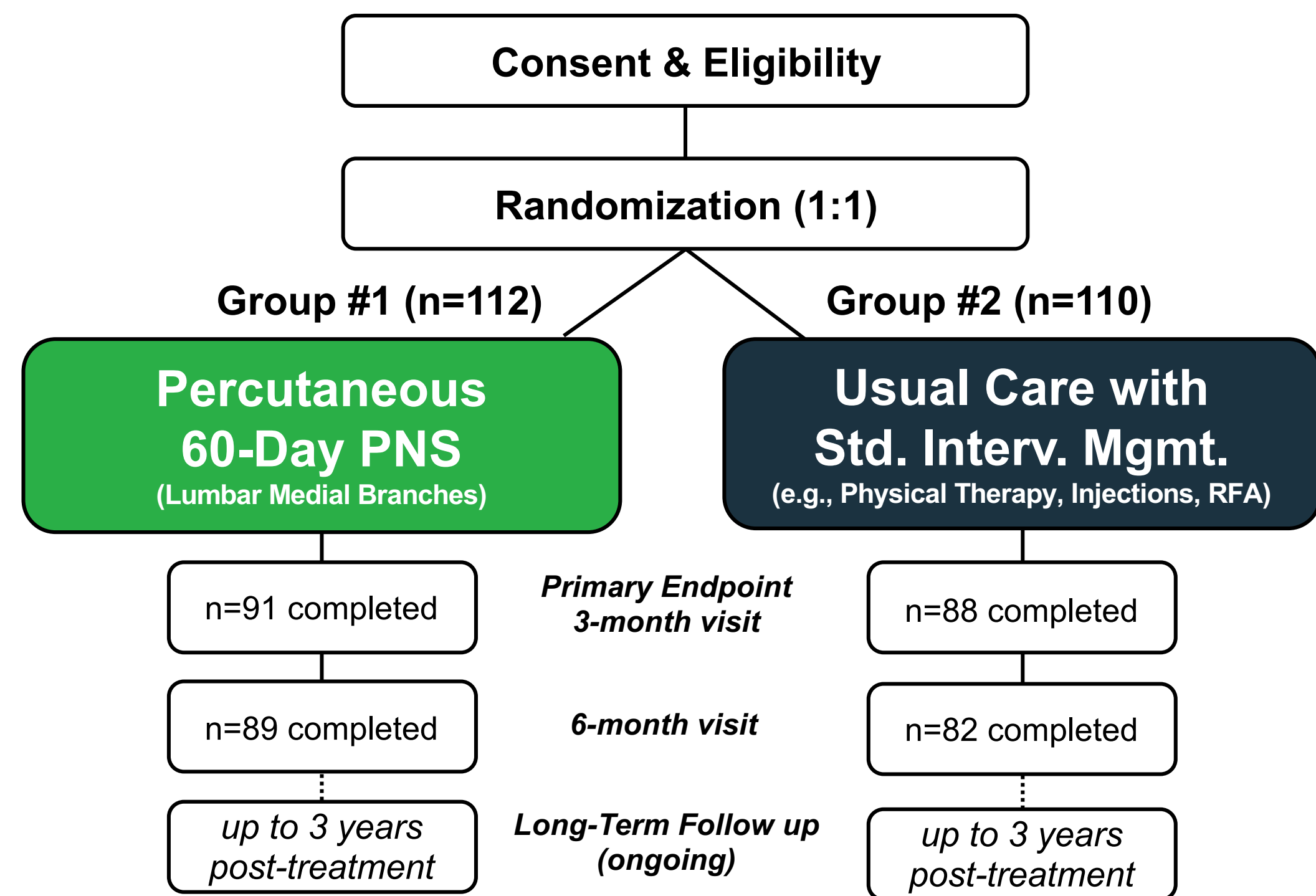
RESET Clinical Trial
This multicenter pragmatic randomized controlled trial (RCT) compares percutaneous 60-day PNS to usual care with standard interventional management for CLBP.

RCT DESIGN AND METHODS

Patients with CLBP confined to the lumbar region without radiation to the extremities were screened for eligibility in this prospective RCT.

Key Inclusion: Moderate to severe CLBP, failed 2+ CLBP treatments

Key Exclusion: RFA within ≤6 months, radicular leg pain, BMI >40, prior lumbar surgery

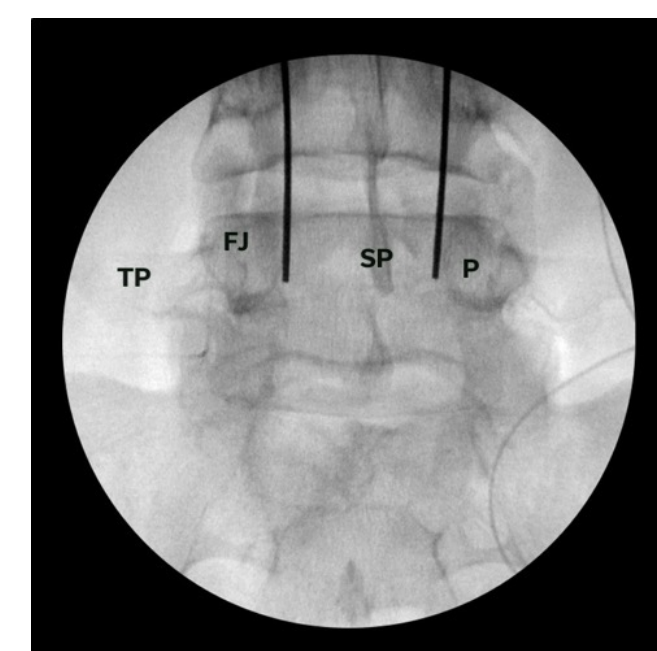


Statistical Methods: Imputation for missing data was conducted using predictive mean matching, with results from imputed endpoints (BPI3, BPI5, BPI9, ODI, and PGIC) pooled across 50 datasets to ensure variability and robustness of outputs; final imputed outcomes are presented as proportion estimates.

PERCUTANEOUS 60-DAY PNS

Bilateral Percutaneous PNS of the lumbar medial branches (SPRINT® PNS System, SPR).

- 12 Hz, 0-30mA, 10-200µs
- 6-12 hrs of stimulation per day
- Leads removed with gentle traction after ≤60 days

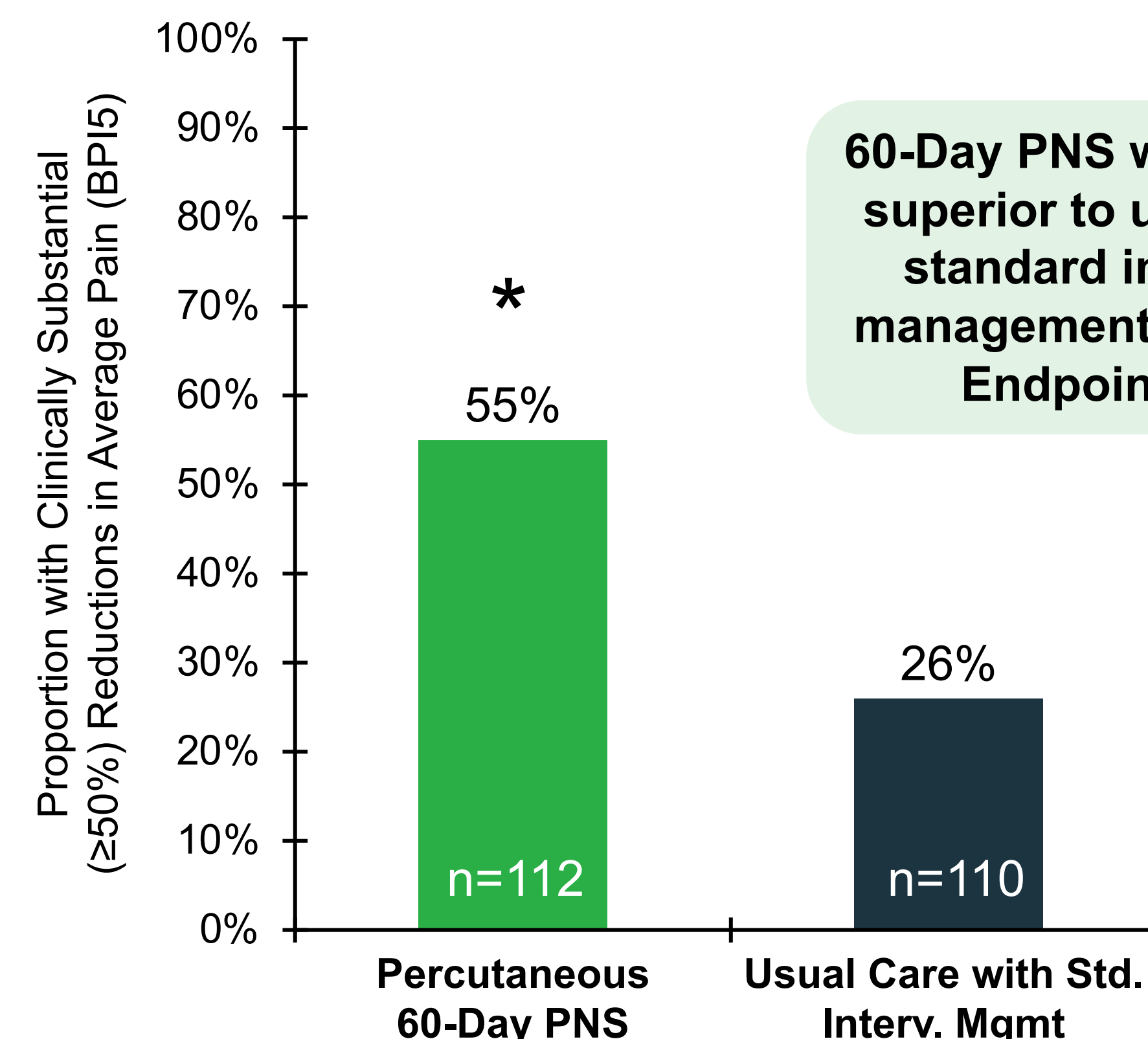


PRIMARY ENDPOINT: ≥50% PAIN RELIEF

The Primary Endpoint evaluated the proportion of participants with ≥50% pain relief at 3 months post-treatment compared to baseline.

Usual Care with Standard Interventional Management (Group #2):

- Most common interventions were lumbar RFA (n=40), injections (n=36), and comprehensive care (e.g., used only PT, chiropractic, spinal manipulation; n=10).

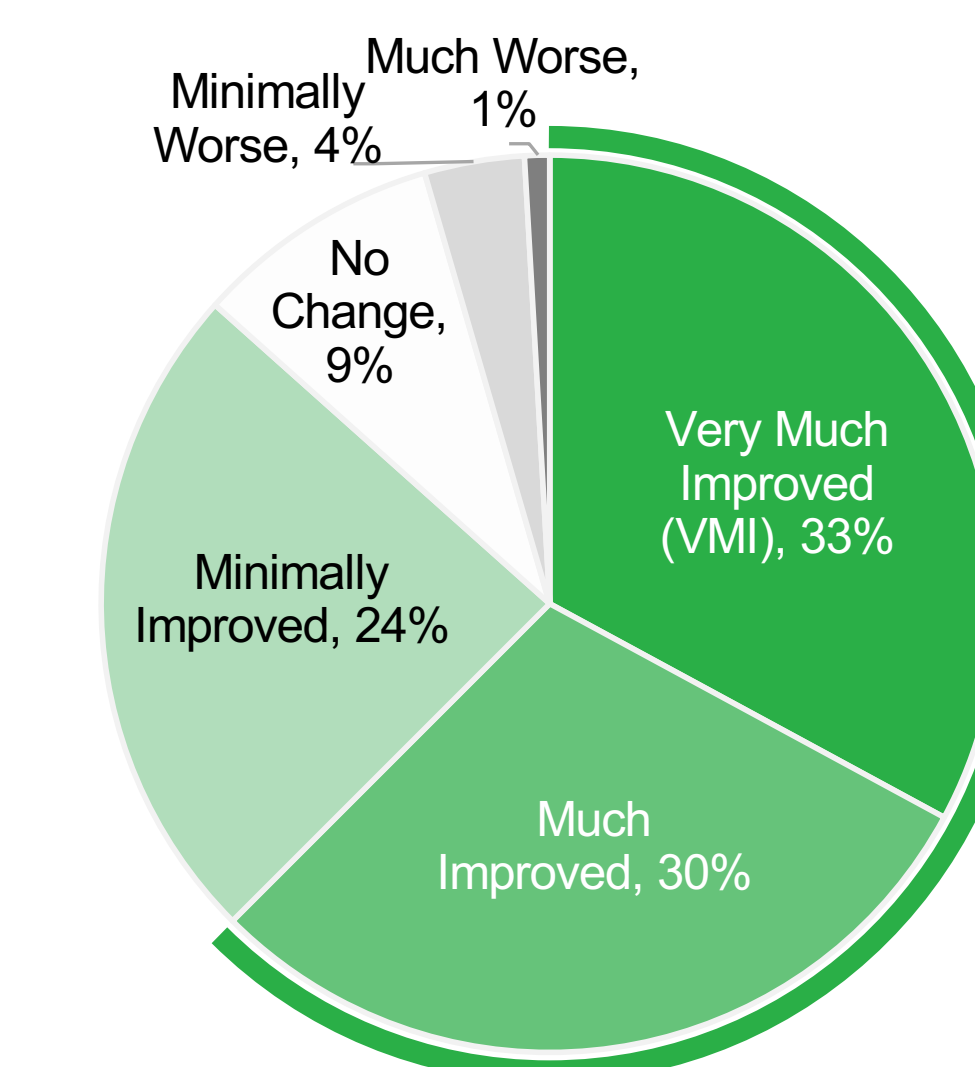


60-Day PNS was statistically superior to usual care with standard interventional management at the Primary Endpoint, *p<0.05.

- Primary Endpoint results among the full dataset (n=222, above) were consistent with the analysis of the observed dataset (Group #1: 56%, n=50/90; Group #2: 26%, n=23/88; p<0.05).

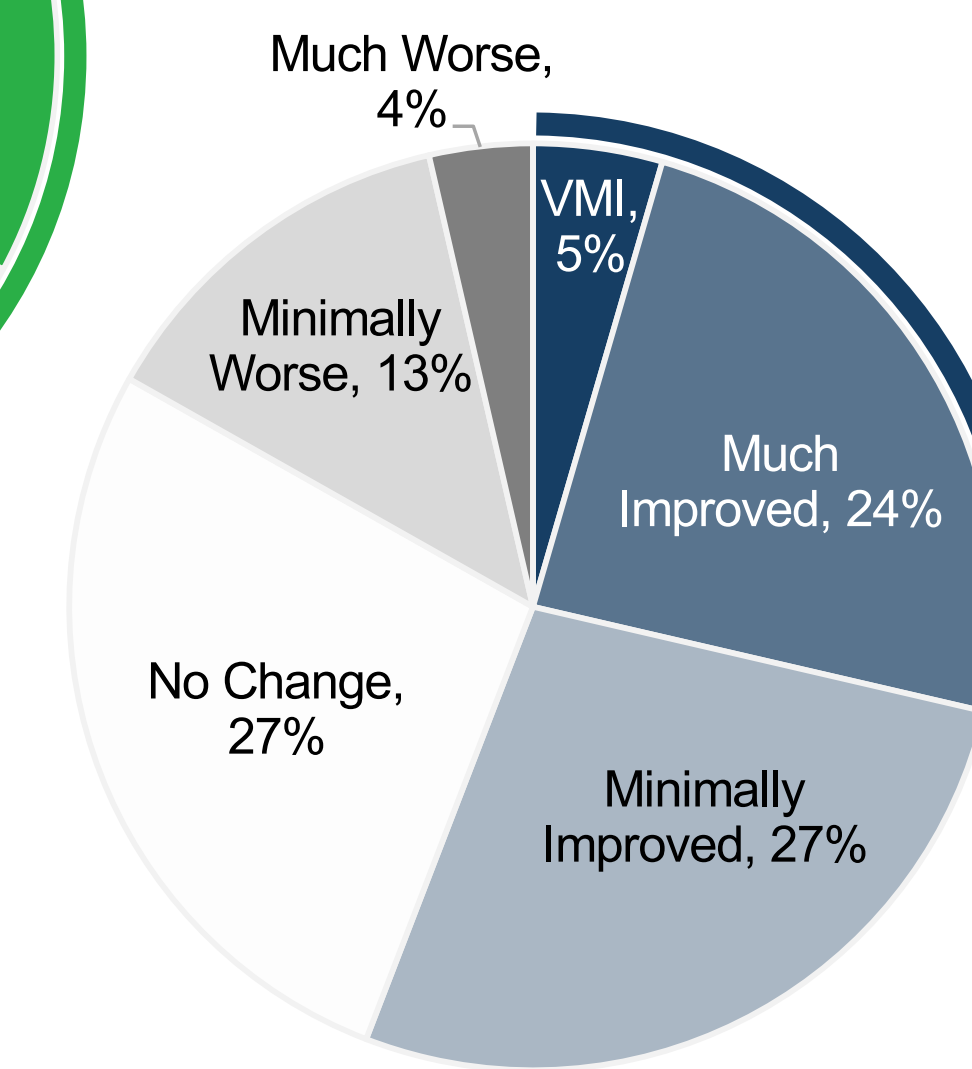
SECONDARY ENDPOINTS

60-Day PNS demonstrated significantly greater reductions in pain, which in turn were associated with improvements in function, health-related quality of life, patient global impression of change, and analgesic consumption at 3 months post-treatment (*p<0.05).

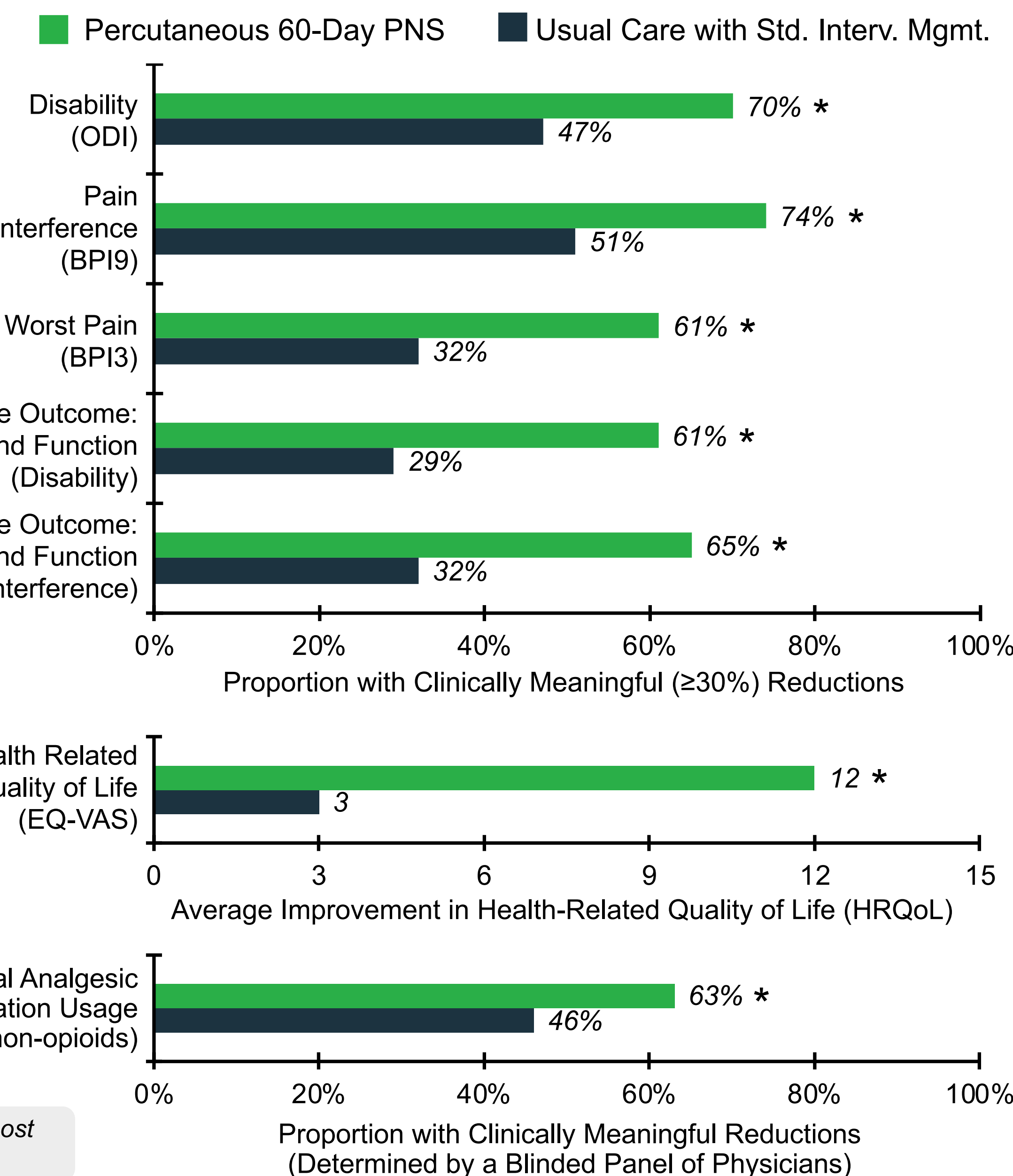


Usual Care with Std. Interv. Mgmt. ≥ Much Improved: 29%

Percutaneous 60-Day PNS ≥ Much Improved: 62%*

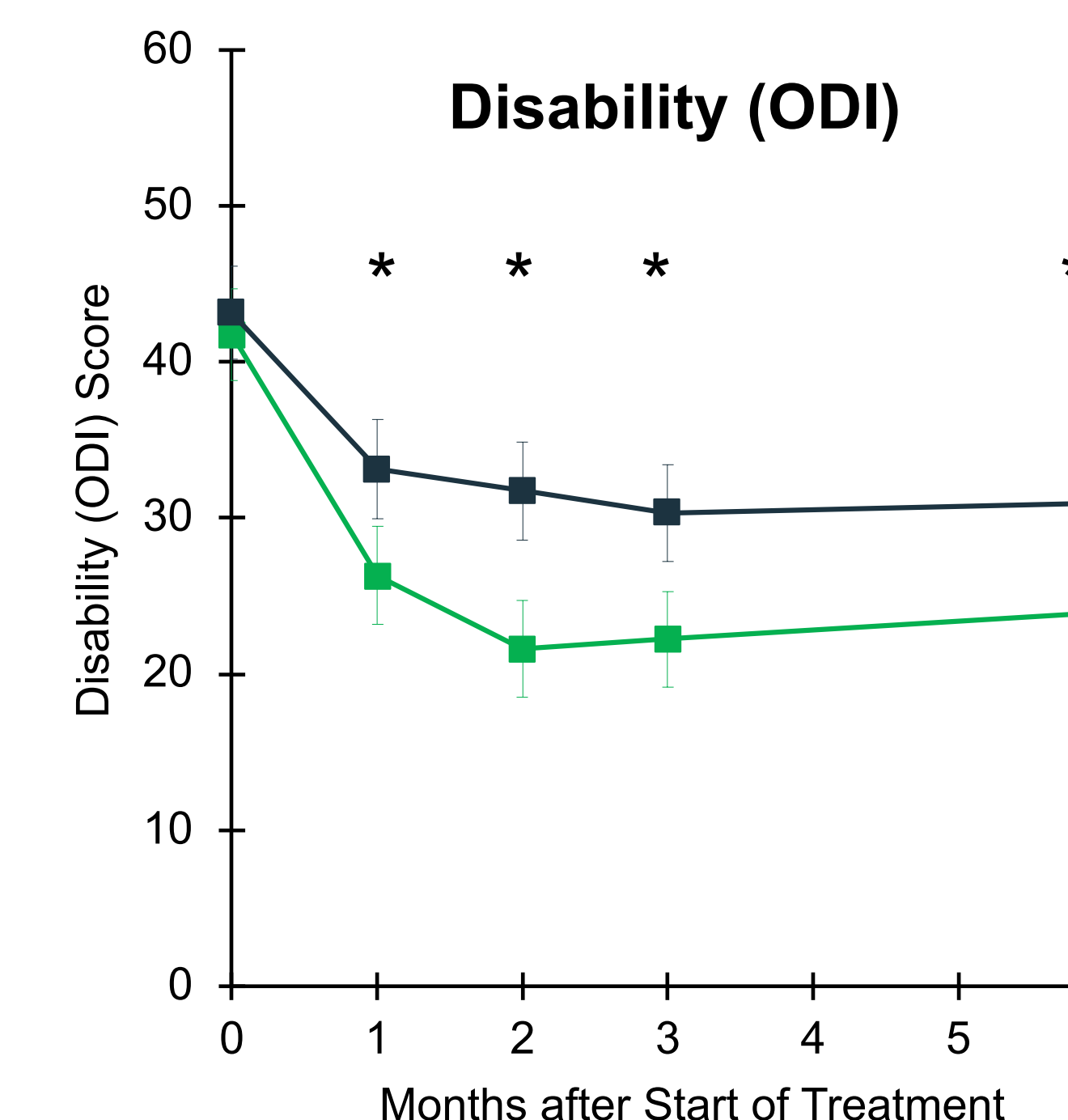
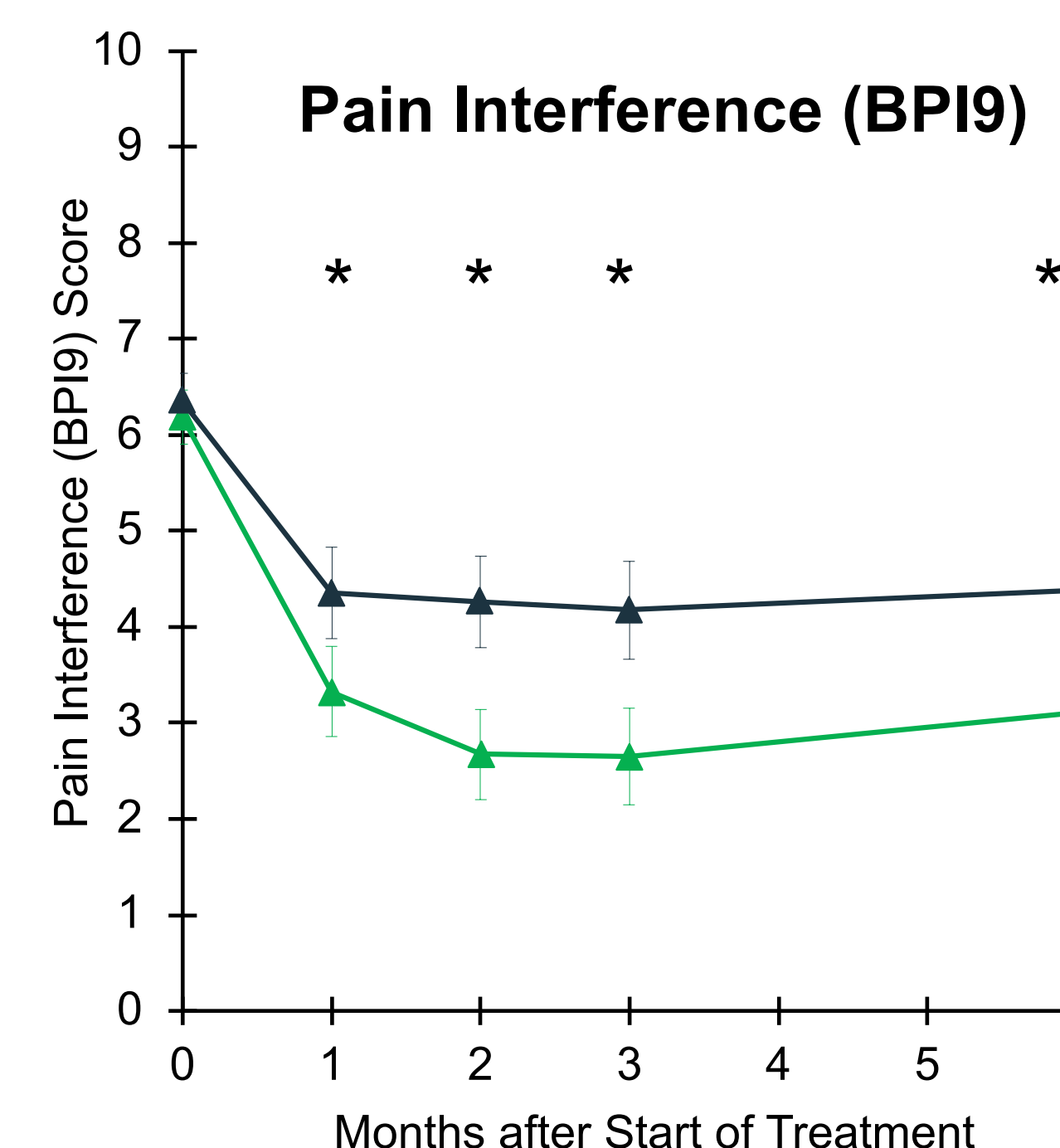
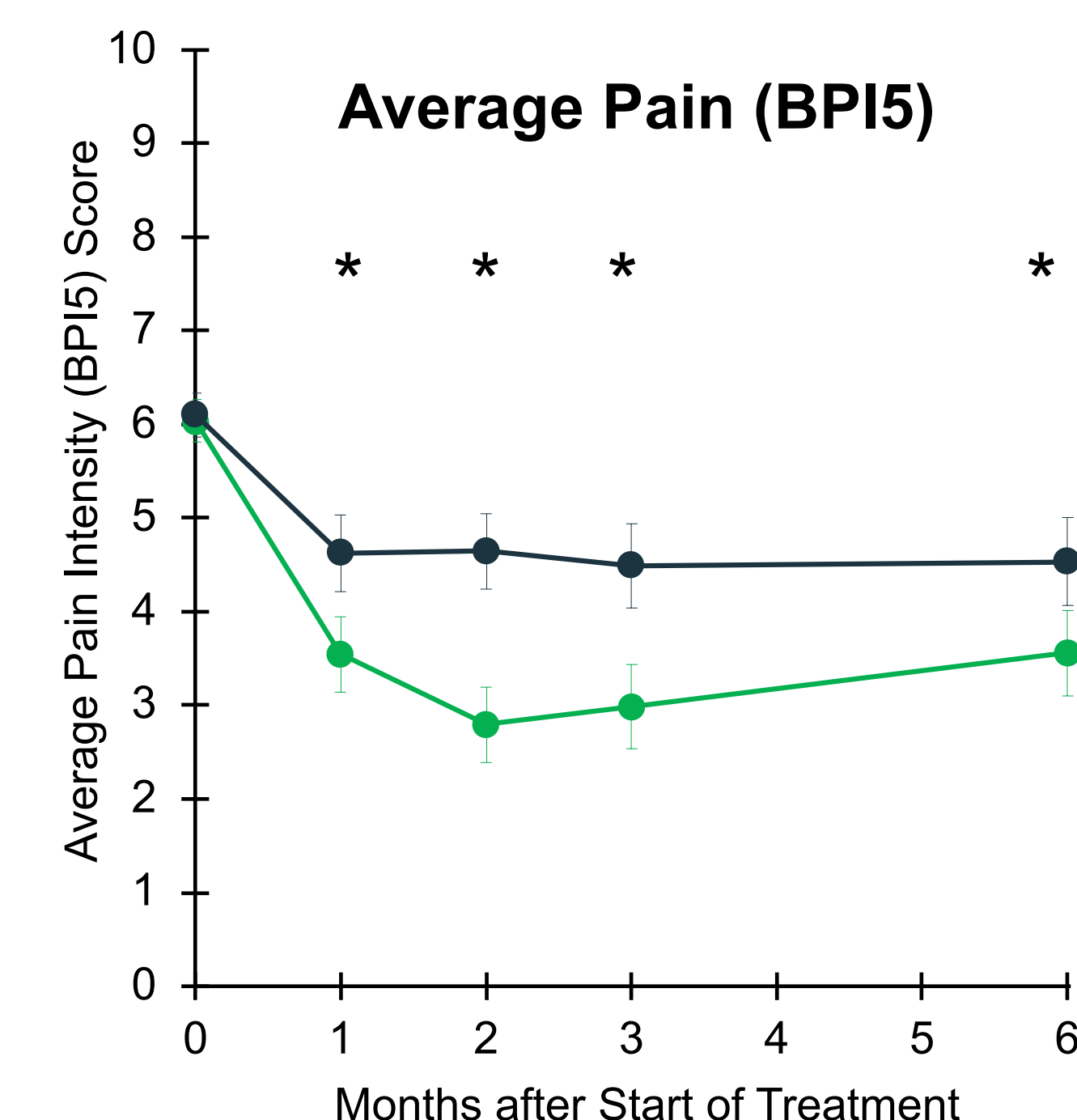


Safety No serious, unanticipated study-related adverse events (AEs) occurred for any participant. The most common AEs related to Percutaneous 60-Day PNS were mild skin irritation or itching at the bandage.



DURABILITY OF RELIEF

60-Day PNS
Usual Care with Std. Interv. Mgmt.



CONCLUSIONS

- Multicenter pragmatic RCT of 60-day PNS met its primary endpoint, with a greater proportion in the 60-day PNS group reporting ≥50% reductions in CLBP at 3 months compared to usual care with standard interventional management.
- 60-Day PNS group reported greater improvements in pain interference, disability, health-related quality of life, and analgesic consumption.
- Collectively, the results from this study complement existing literature and support the use of percutaneous 60-day PNS as a treatment option for CLBP.

REFERENCES

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