

60-Day Percutaneous PNS vs. Standard Interventional Management for Chronic LBP: RESET Clinical Trial Primary Endpoint Results

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on 60-Day PNS

BACKGROUND

Treatments for chronic low back pain (CLBP) have varying levels of effectiveness, invasiveness, costs, and rates of complications^{1,2}, and include:

- Radiofrequency Ablation (RFA)
- Therapeutic Injections
- Comprehensive Care
- Neurostimulation (PNS, SCS)
- Surgical Procedures (e.g., Physical Therapy)

60-day Percutaneous Peripheral Nerve Stimulation (PNS) is increasingly recognized as an effective treatment modality for a variety of pain conditions, following multiple prior successful studies^{3,4}.



This large, Level 1 randomized controlled trial (RCT) compares the effectiveness of 60-Day Percutaneous PNS to Standard Interventional Management for CLBP.



RCT STUDY DESIGN & METHODS

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

Key Inclusion:

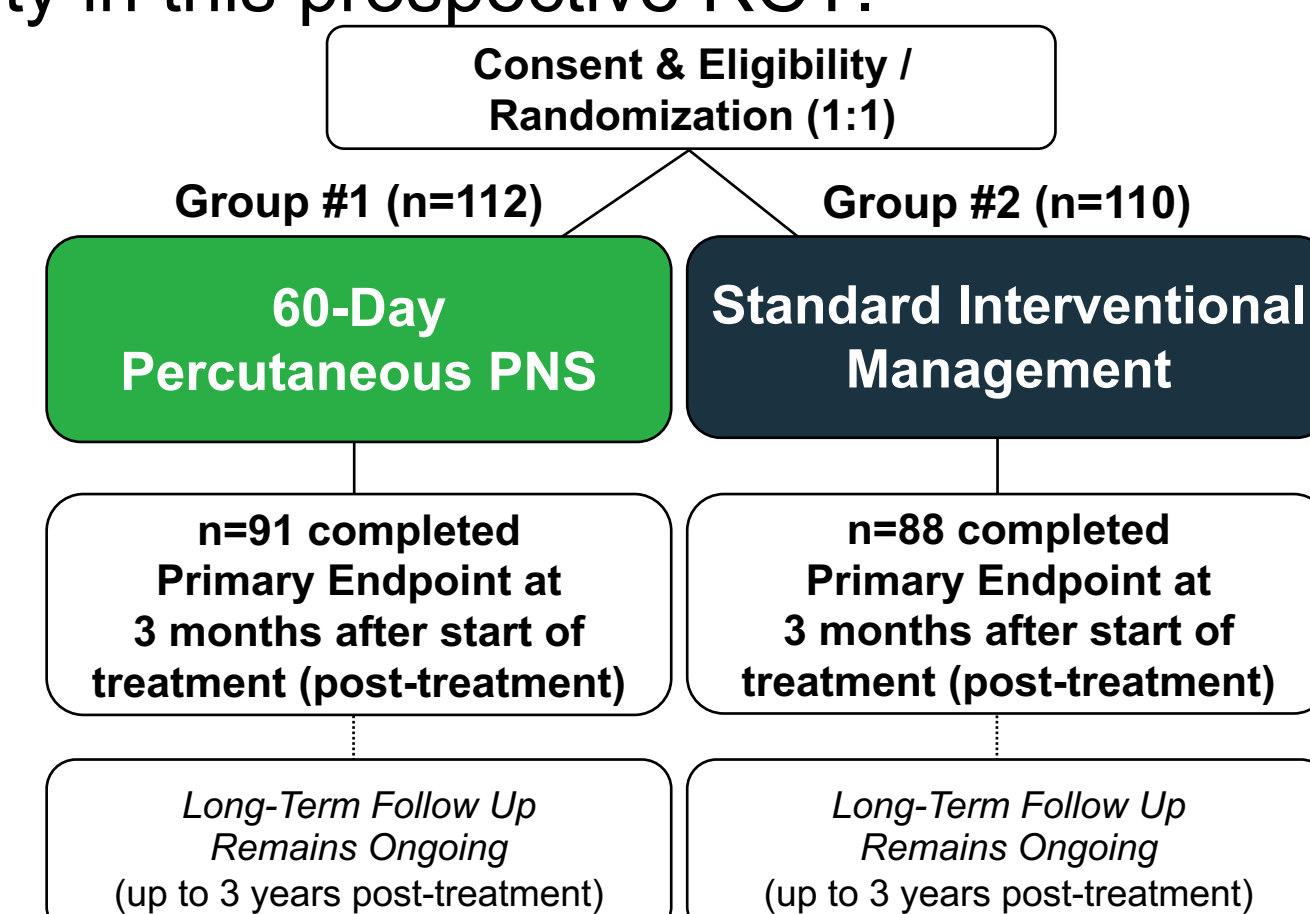
- Moderate to severe CLBP
- Failed multiple types of CLBP treatments

Key Exclusion:

- BMI >40
- Radicular leg pain
- Prior RFA within ≤6 months
- Prior lumbar surgery

Outcomes Assessed:

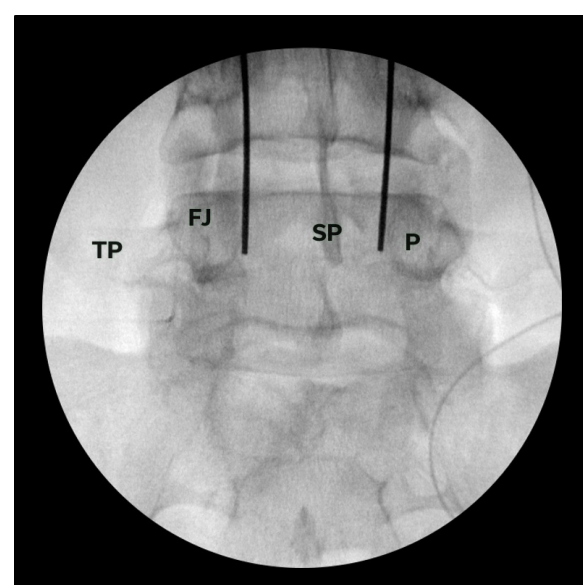
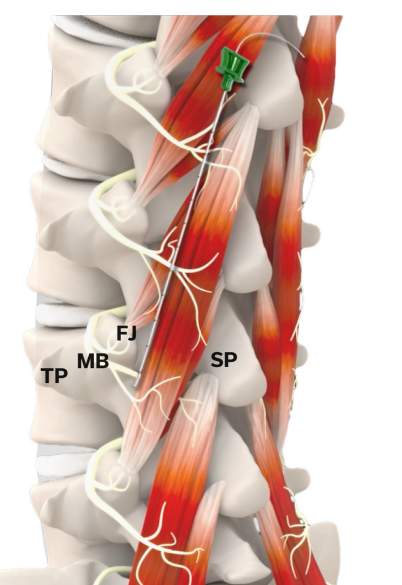
- Average Pain (BPI5), Disability (ODI), Pain Interference (BPI9), Worst Pain (BPI3), HRQoL, Analgesic Usage, PGIC



60-DAY PERCUTANEOUS PNS

60-Day Percutaneous PNS for Chronic Low Back Pain:

- Percutaneous PNS leads were implanted bilaterally under image guidance to target lumbar medial branches at the vertebral level in the center of painful region (SPRINT® PNS System, SPR Therapeutics, Cleveland, OH)



- PNS Parameters: 12 Hz, 50% duty cycle, 0-30mA, 10-200µs
- Participants were able to adjust stimulation to a comfortable level and used for 6-12 hrs/day
- Leads were removed with traction after up to 60 days

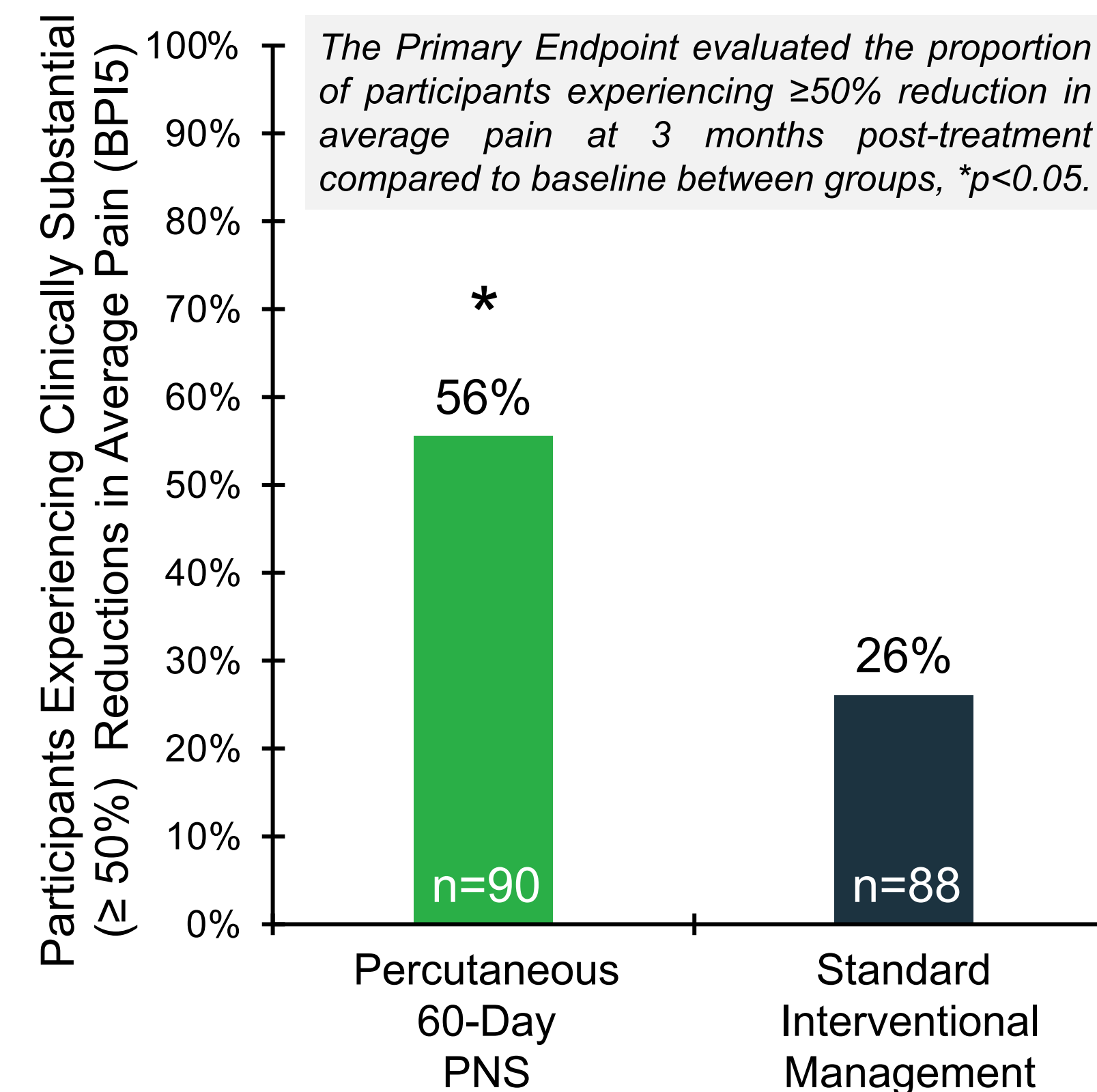
RESULTS: 60-DAY PERCUTANEOUS PNS VS STANDARD INTERVENTIONAL MANAGEMENT

Primary Endpoint: ≥50% Pain Relief

60-Day Percutaneous PNS was statistically superior to Standard Interventional Management at the Primary Endpoint at 3 months post-treatment (p<0.001)

Standard Interventional Management (Group #2):

- The most common CLBP interventions reported by Group #2 were: lumbar RFA (n=40), therapeutic injections (n=36), and comprehensive care (e.g., PT, chiropractic, spinal manipulation; n=10).



Participant Demographics (n=222)

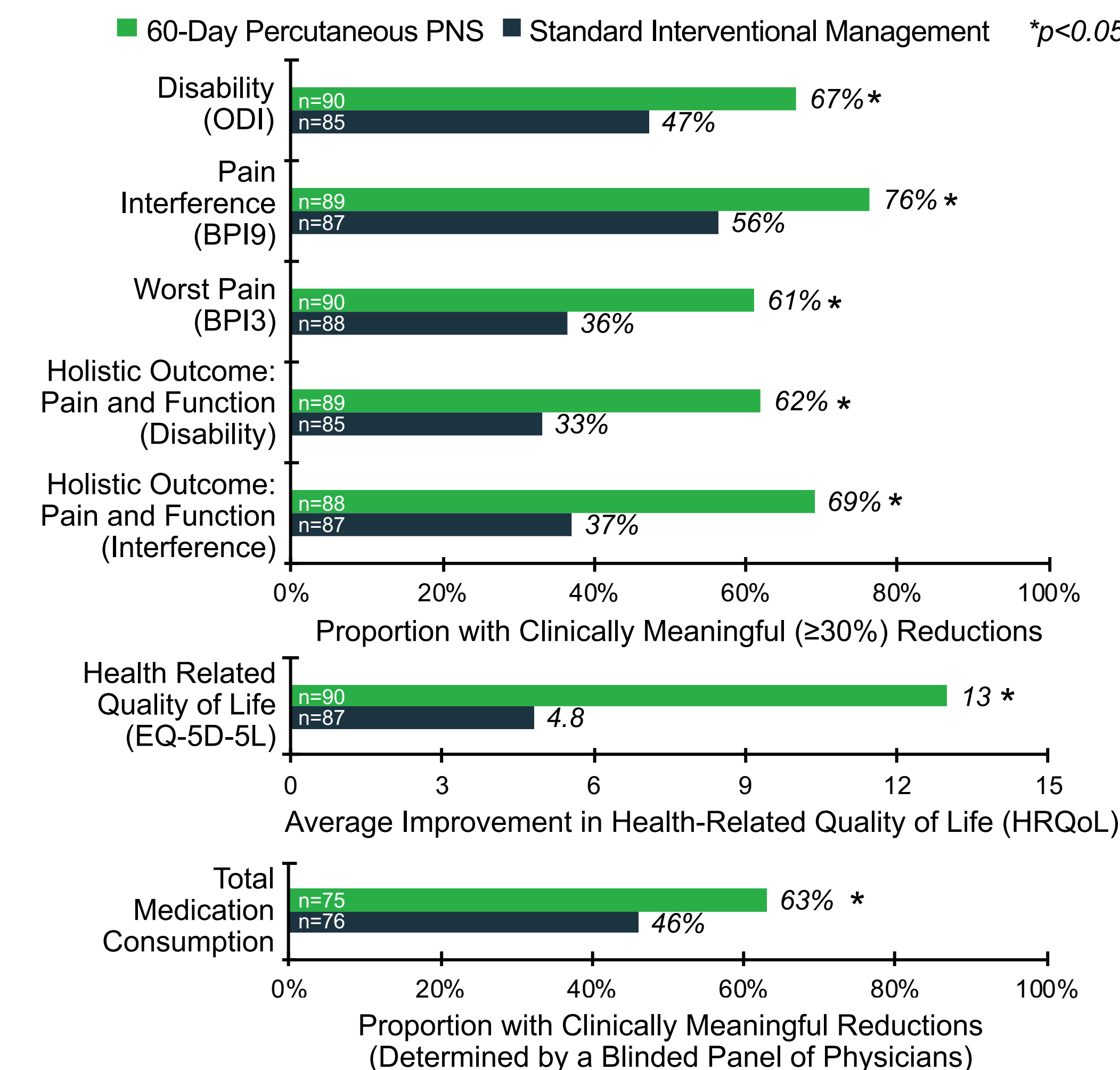
Participant Demographics	
Age (years), mean (SD)	53 (14)
BMI (Body Mass Index), mean (SD)	29 (5.5)
CLBP duration (years), mean (SD)	14 (13)
Female, % (n/N)	52% (115/222)
Diagnosis or Cause of CLBP, % (n/N)	
Facetogenic (i.e., Lumbar Spondylosis)	56% (125/222)
Discogenic (i.e., Degenerative Disc Disease)	38% (84/222)
Nonspecific Low Back Pain	2.3% (5/222)
Other (e.g., injury)	5.9% (13/222)

Baseline Characteristics (n=222)

Baseline Pain & Function, mean (SD)	
Average Pain Intensity, BPI5	6.1 (1.2)
Oswestry Disability Index, ODI	43 (16)
Pain Interference, BPI9	6.3 (1.5)
Worst Pain Intensity, BPI3	7.5 (1.2)
Health Related Quality of Life, EQ-5D-5L	64 (18)
Baseline Medication Usage	
Reporting analgesic use, % (n/N)	65% (145/222)
Opioid use at baseline, avg. MME (n/N)	25 (28/222)

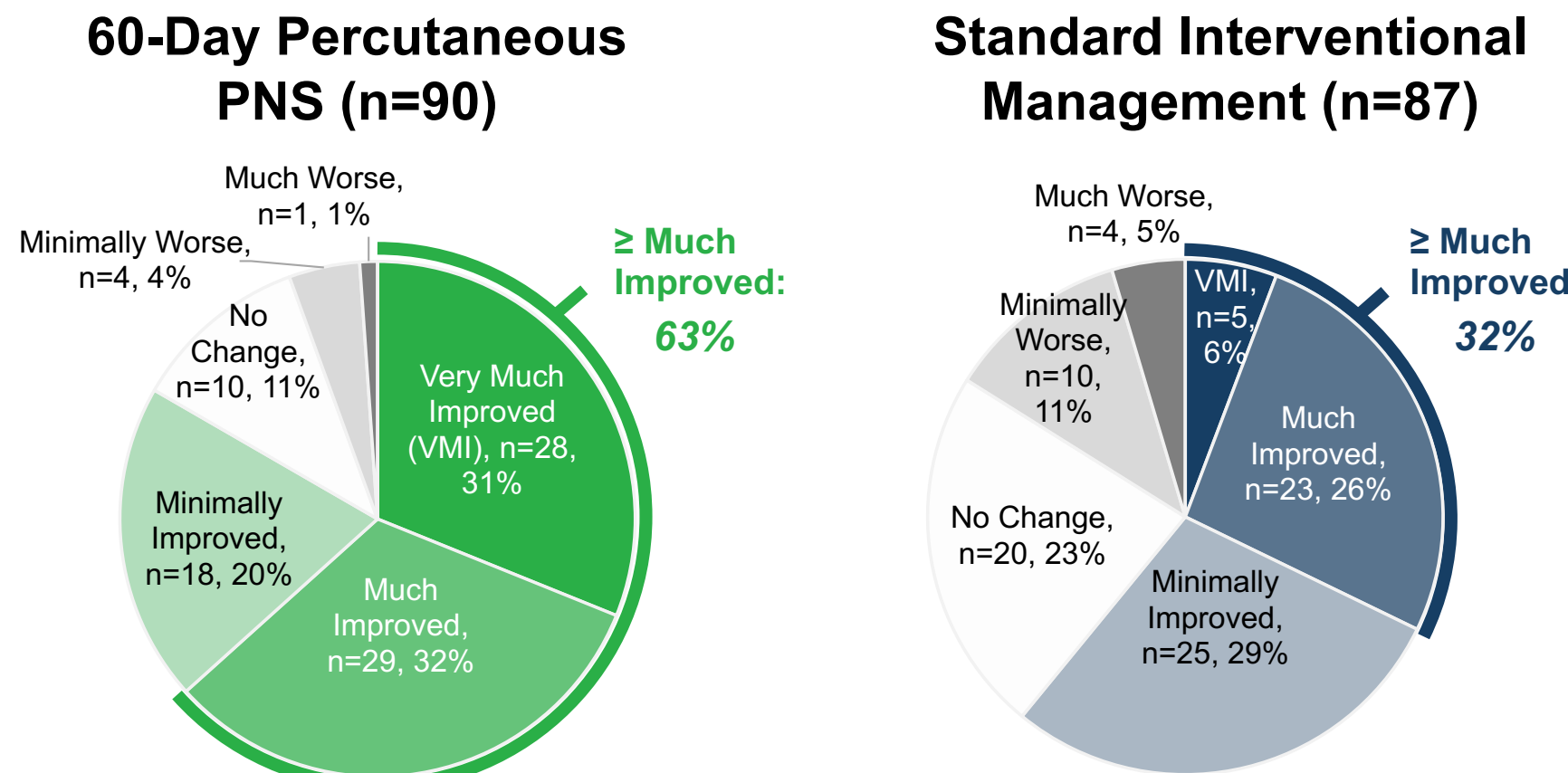
Patient-Centric Secondary Endpoints

60-Day Percutaneous PNS demonstrated significantly greater improvements in pain, function, health-related quality of life, and analgesic usage at 3 mo post-treatment *p<0.05



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

Patient Global Impression of Change

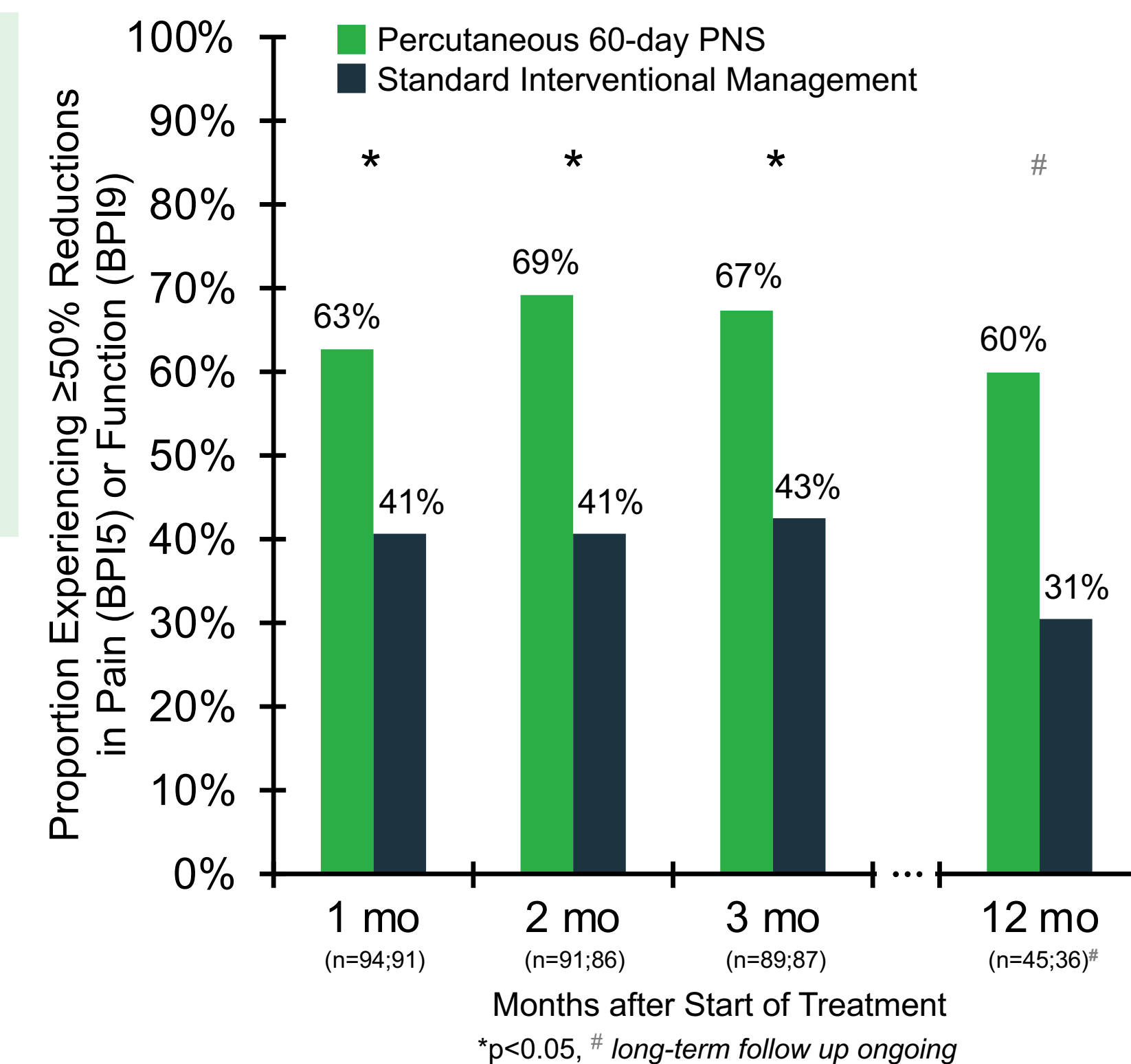


Significantly greater improvements reported in PGIC at 3 months post-treatment (p<0.05)

Durability of Relief

Clinically meaningful reductions in pain and improvements in function appear sustained through 12 months post-treatment

- **60%** (60-Day Percutaneous PNS, n=45) **vs. 31%** (Group #2, n=36) reported ≥50% reduction in Pain (BPI5) and/or Function (BPI9) at 12 months post-treatment (long-term follow up ongoing)



CONCLUSIONS: SUCCESSFUL PRIMARY ENDPOINT + SUPERIOR RELIEF

Largest RCT of 60-Day Percutaneous PNS to Date

This prospective, multicenter **Level 1 RCT** demonstrates the **superior clinical utility of 60-Day Percutaneous PNS** of the lumbar medial branches **over Standard Interventional Management** for the treatment of CLBP.

Superior Relief in Primary and Secondary Endpoints

60-Day Percutaneous PNS provided **clinically meaningful and statistically superior reductions in pain and improvements in function and quality of life** at 3 months post-treatment compared to Standard Interventional Management.

Effective, Non-Destructive, Non-Opioid, & Minimally-Invasive

These results **demonstrate the comprehensive positive impact of 60-Day Percutaneous PNS on CLBP** participants' lives, and deliver physicians, patients, and payers the direct comparisons needed to facilitate informed decisions.

REFERENCES

1. Kern KU. Pain Manag. 2023.
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