A Prospective, Multi-Site, Clinical Trial of the High-frequency Spinal Cord Stimulation at 10 kHz (HF-SCS) System in the Treatment of Chronic Pelvic Pain

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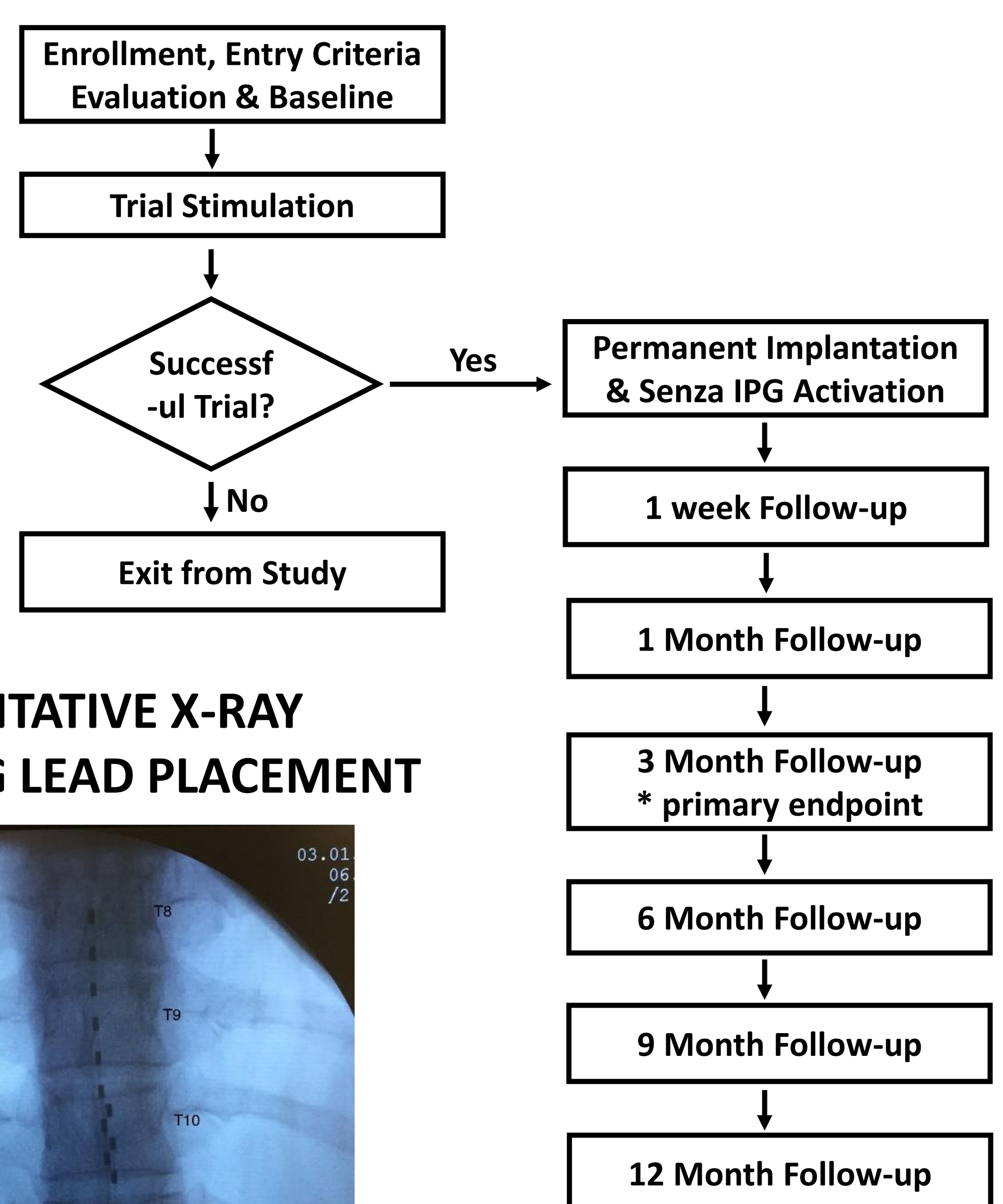
Introduction

Chronic pelvic pain (CPP) is known to disproportionately affect women and have multiple causes such as traumatic injury and post-surgical changes. Standard-of-care treatments often fail to resolve the pain, leaving CPP patients with long term disabilities. High-frequency SCS (HF-SCS) at 10 kHz has been previously shown to provide long-term relief for chronic low back and leg pain patients[1,2]. The objective of this study is to assess effectiveness of the HF-SCS at 10 kHz in the treatment of chronic intractable pelvic pain.

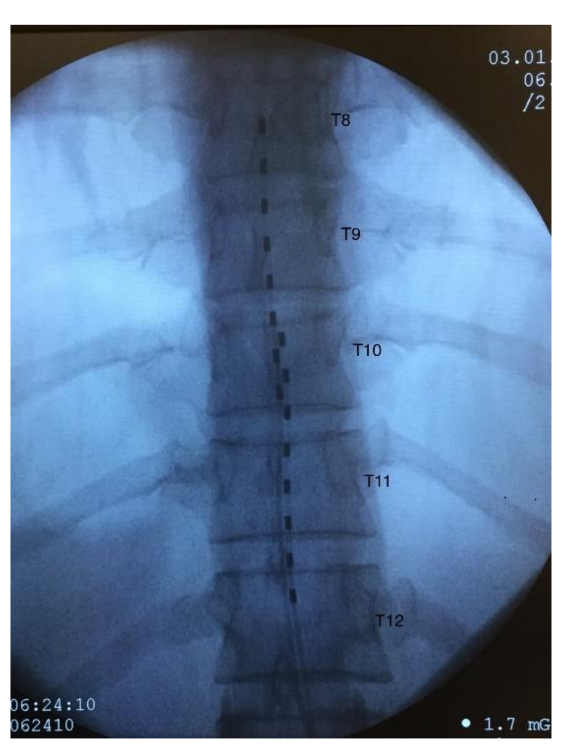
Methods

In this multicenter, prospective study, subjects clinically diagnosed with chronic pelvic pain of ≥5 cm (on a 0-10 cm visual analog scale [VAS]) refractory to conservative therapy for ≥3 months were enrolled following IRB approval. Significant spinal stenosis, epidural scarring or symptoms of myelopathy and other progressive neurological diseases were causes for exclusion. Subjects were implanted with two epidural leads spanning appropriate vertebral bodies as determined by the location of pain and were implanted with a Senza system (Nevro Corp., Redwood City, CA) if they had successful trial stimulation (≥50% pain relief). Safety and effectiveness endpoints were captured up to 12 months post-implant. Interim 3-month results are presented as mean ± 95% CI in the permanent implant population.

STUDY FLOWCHART



REPRESENTATIVE X-RAY SHOWING LEAD PLACEMENT



Results

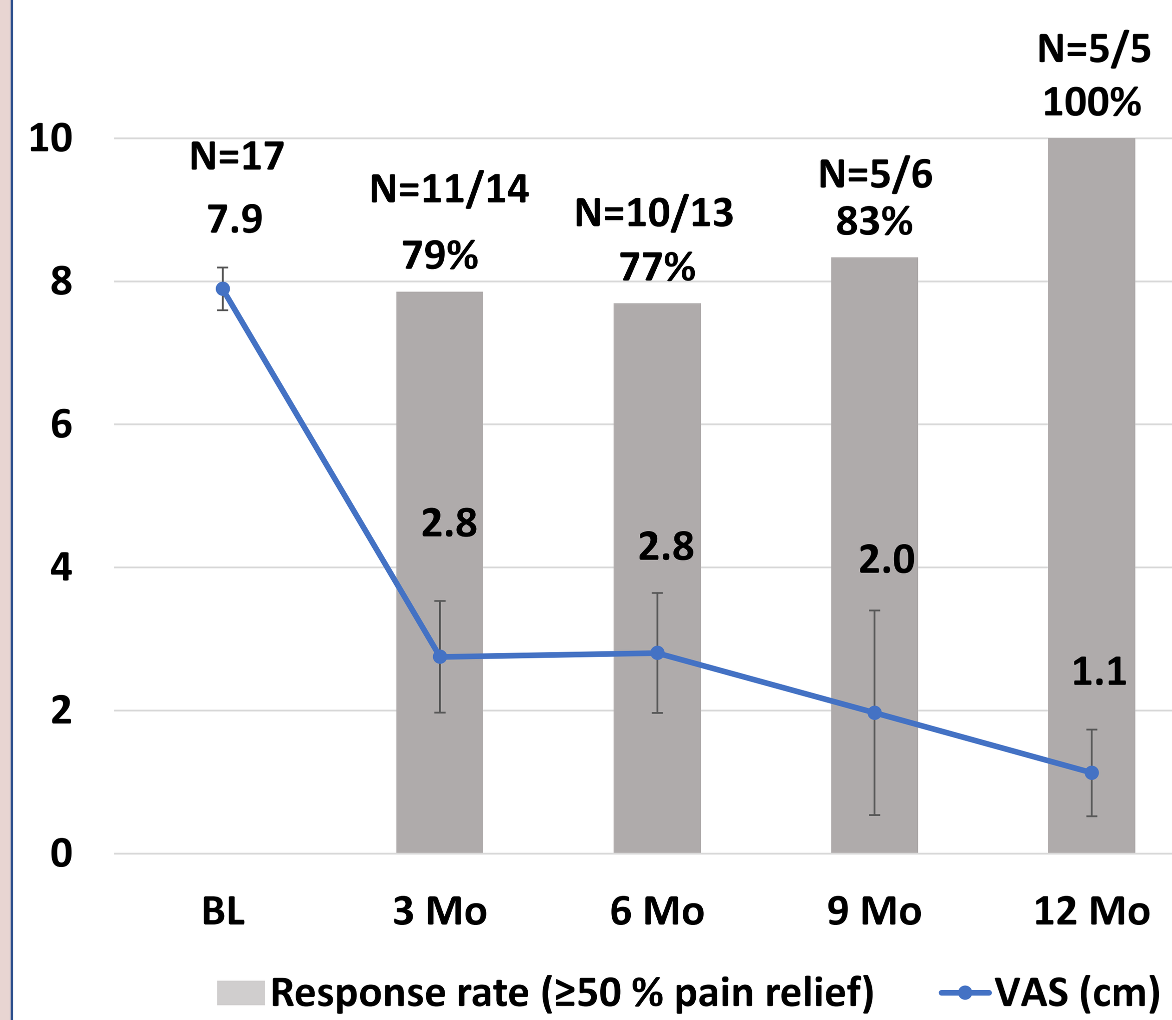
Patient characteristics

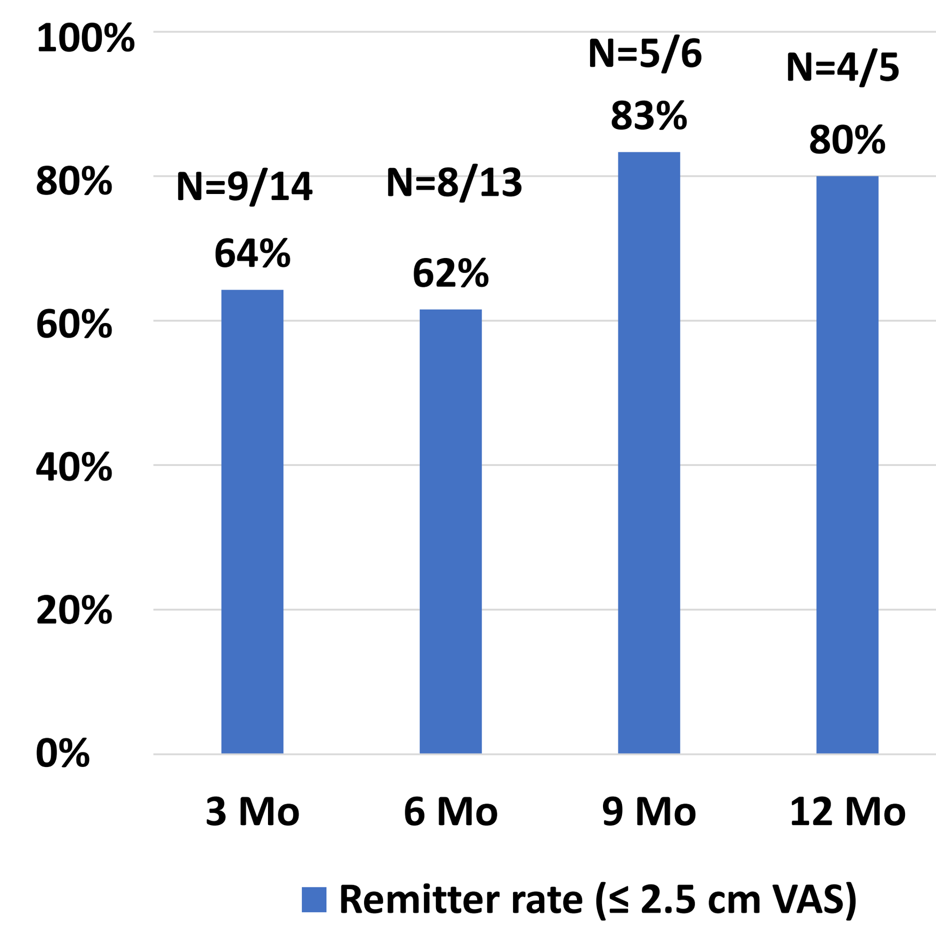
- Trialed: 21
  - Female: 19/21 (90%)
  - Median age: 49.3 years
- Trial success: 19/21 (90%)
- Etiology
  - Post Surgical complications: 11 (48%)
  - Pregnancy associated complications: 6 (26%)
  - Painful bladder syndrome: 6 (26%)

Safety

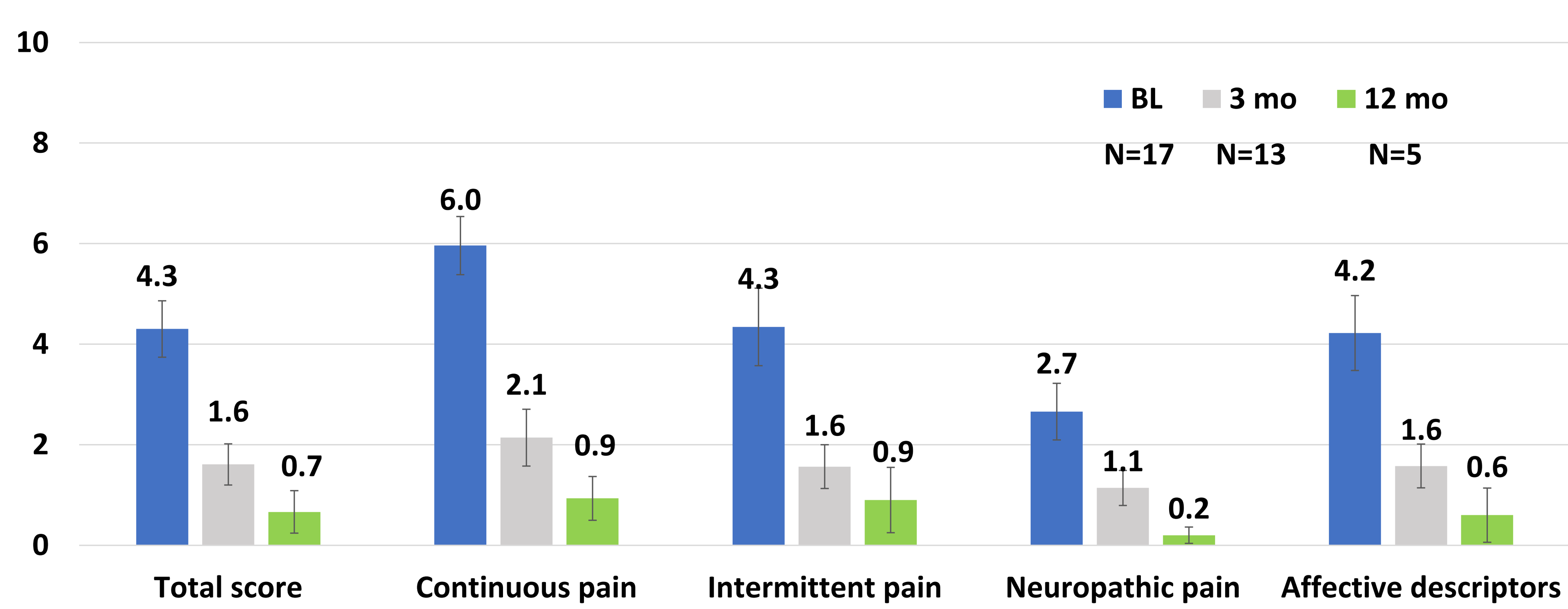
- No neurological deficits
- Six (6) device or procedure related adverse events (AEs)
- All AEs resolved without sequelae

SUSTAINED PAIN RELIEF, RESPONDER AND REMITTER RATES



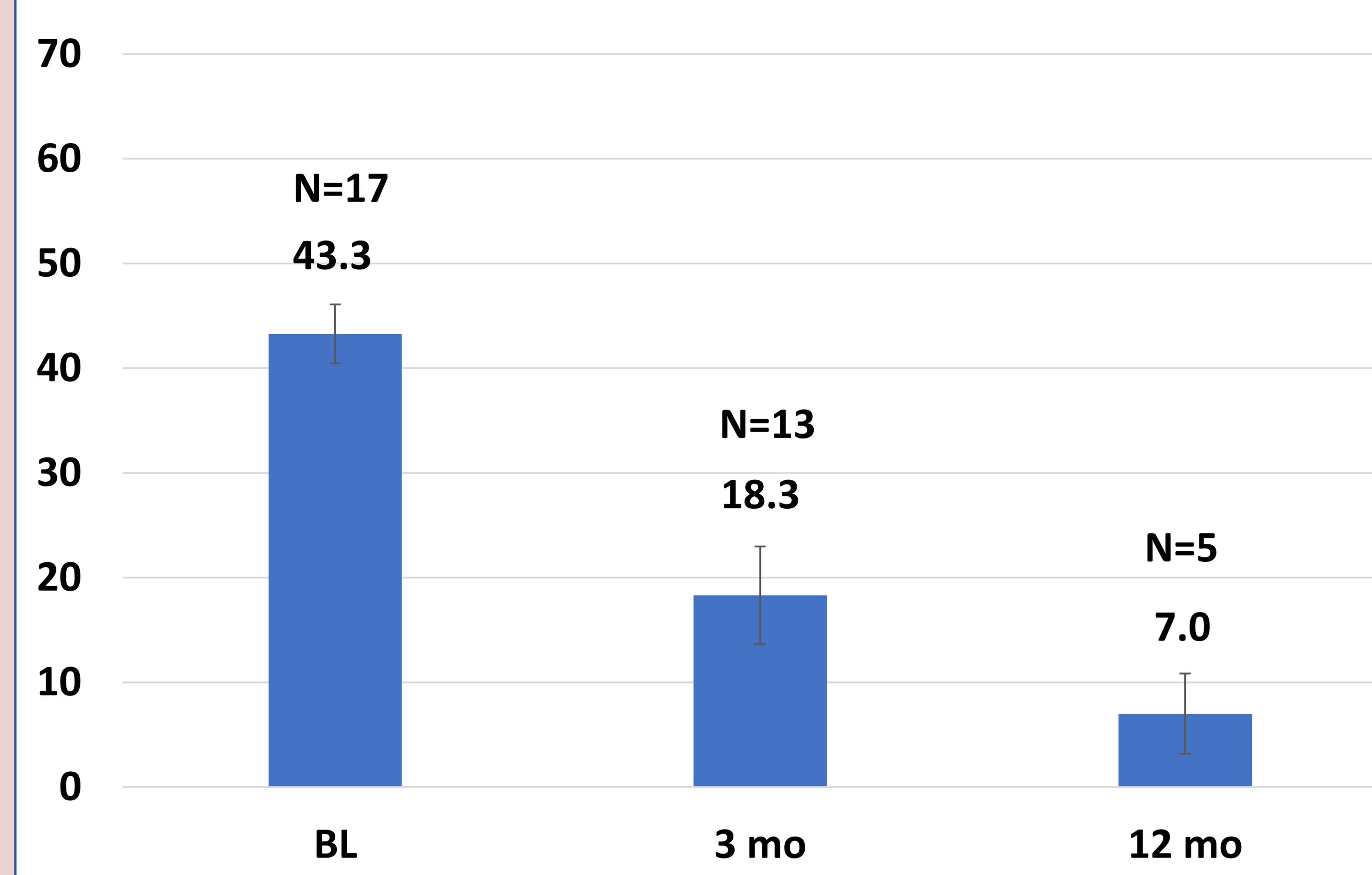


SUSTAINED REDUCTION IN ALL COMPONENTS OF PAIN INTERFERENCE (McGILL PAIN QUESTIONNAIRE, SF-MPQ-2)

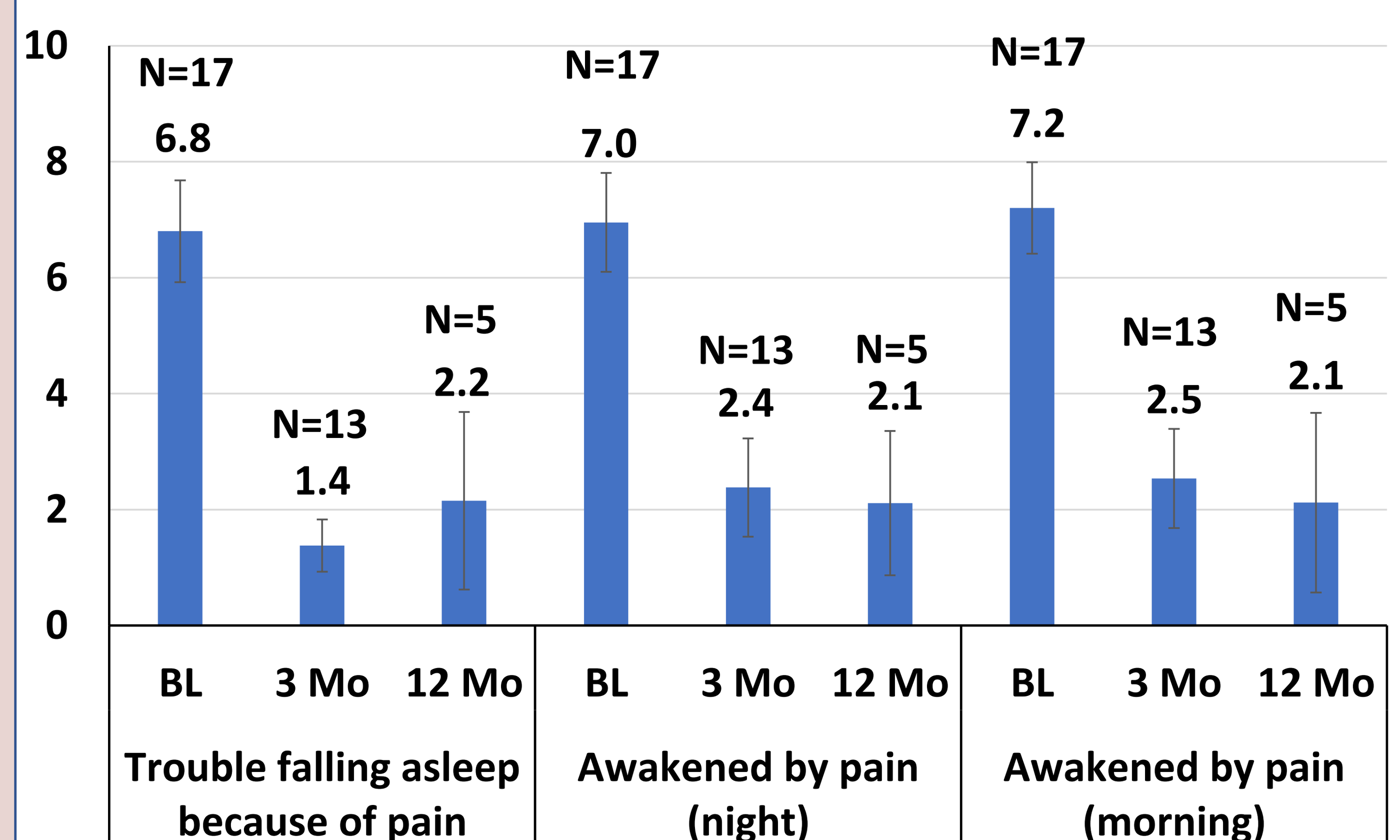


Results (contd.)

SUSTAINED REDUCTION IN DISABILITY (PAIN DISABILITY INDEX, PDI)



SUSTAINED IMPROVEMENTS IN SLEEP



Conclusions

Interim study results show HF-SCS 10 kHz could potentially provide clinically meaningful pain relief to the patients with CPP, a condition that is traditionally difficult to treat.

References

1. Kapural L et al. Anesthesiology. 2015 Oct;123(4):851-60
2. Kapural L et al. Neurosurgery. 2016 0:1-10