A PROSPECTIVE CLINICAL TRIAL TO ASSESS HIGH FREQUENCY SPINAL CORD STIMULATION (HF-SCS) AT 10 KHZ IN THE TREATMENT OF CHRONIC INTRACTABLE PAIN FROM PERIPHERAL POLYNEUROPATHY (PPN)

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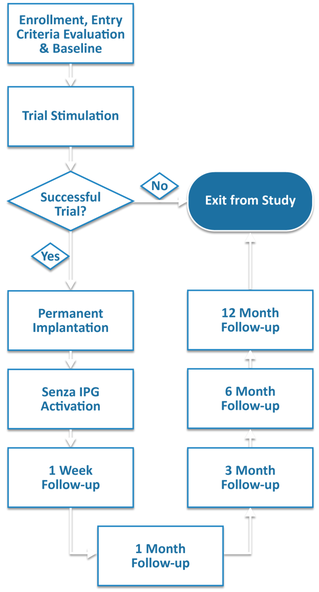
17th Annual Pain Medicine Meeting
November 15-17, 2018
San Antonio, Texas
#ASRAFALL18

Introduction

Peripheral neuropathy is caused by damage to or dysfunction of peripheral nerves, resulting in pain, numbness, and/or weakness. Damage may affect small (myelinated Aδ and unmyelinated C) fibers along with injury to large myelinated fibers. The goal of this study is to assess the safety and effectiveness of paresthesia-independent, high frequency SCS (HF-SCS) at 10 kHz in the treatment of chronic intractable pain from peripheral polyneuropathy.

Materials & Methods



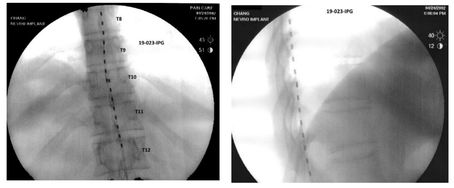


Figure 1: Study flow diagram (left). Anterior-posterior (top left) and lateral views (top right) of thoracic lead placements.

- Prospective, multi-center study
- Clinical diagnosis of peripheral polyneuropathy (PPN) of the upper or the lower limb(s) pain of ≥5 cm (on a 0-10 cm visual analog scale [VAS]) enrolled
- Major exclusion criteria: Mononeuropathies, prior failed SCS
- Each subject implanted with two epidural leads spanning T8-T11 vertebral bodies (Figure 1)
- Subjects with successful trial stimulation (≥40% pain relief) implanted with a Senza system (Nevro Corp., Redwood City, CA)
- Primary safety and effectiveness endpoints (≥50% pain relief) assessed at 3 months post-implant
- Permanent implant population results reported (mean ± standard error of the mean)
- Complete results at primary endpoint (3 months) presented

Results: Trial Stimulation

- Enrolled: 28
- Failed Screening: 2
- Trialed: 26
- Trial Success Rate: 22/26 (85%)
- Implanted: 18

Results: Demographics and Etiology

Sex	N	%
Male	9	50.0
Female	9	50.0

Age (N=18)	Years
Mean	62.8
SD	11.3
Min	42.6
Max	79.0
Median	66.4

Diagnoses (n=18)*

- Idiopathic polyneuropathy (n=15)
- Painful diabetic neuropathy (PDN, n=9)
- Medication induced polyneuropathy (n=1)
- Trauma induced polyneuropathy (n=1, surgery)
- Radiation induced polyneuropathy (n=1)
- Hereditary polyneuropathy (n=1)

* Some subjects have multiple diagnoses

Race	N	%
Caucasian	16	88.9
Black/African-American	2	11.1

Results: Safety

Adverse events (AEs) and serious adverse events (SAEs)

- Procedure related – 4
  - 3 AEs, 1 SAE (All resolved)
- Non-study related – 13
  - 7 AEs, 6 SAEs
- No neurological deficits

Neurological assessment

- Administered at baseline, end of trial and 3 months post-implant
- 12/25 subjects (48%) had improvement at the end of trial
  - Sensory improvement – 11
  - Motor improvement – 1
  - Reflex improvement – 1

Results: Pain Scores and Responder Rates

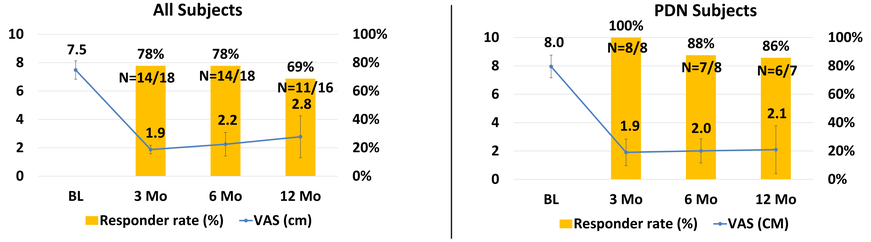


Figure 2: Pain scores & responder rates for all subjects (L) and PDN subjects (R)
Significant pain relief and nearly 70% responder rates (≥50% pain relief) seen at 12-mo

Results: Pain Disability and Interference

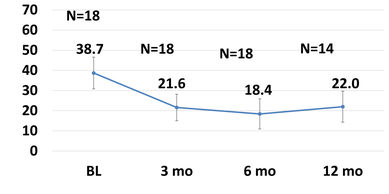


Figure 3: Pain Disability Index (PDI)
At 12-mo 16.7 point reduction observed (Minimal clinically important difference, MCID: 8.5-9.5)

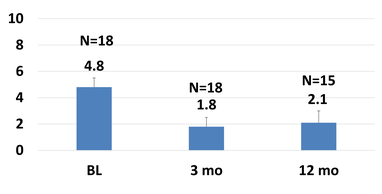


Figure 4: McGill Pain Questionnaire (SF-MPQ-2)
Significant reduction in all dimensions of pain including affective component

Results: Global Impression of Change

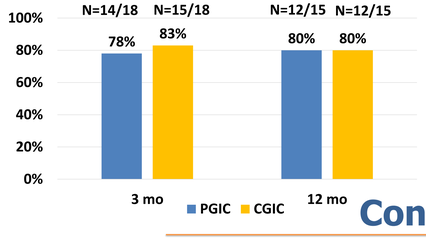


Figure 5: Patient & Clinician rated GIC as better or great deal better (rate, %)
Nearly 80% subjects reported feeling better or great deal better at 12 month

Conclusions

Results from this multicenter study demonstrate that HF-SCS at 10 kHz provides clinically meaningful and sustained pain relief in subjects with PPN with concomitant improvement in quality of life and pain interference. Subjects also reported improvements in neurological assessments.