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Abstract: 4541

Scientific Abstracts > Chronic Pain

COMPARING SPINAL CORD STIMULATION AND CONVENTIONAL MEDICAL MANAGEMENT IN PATIENTS WITH NO PRIOR BACK SURGERY (SOLIS RCT)

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Introduction

Use of Spinal Cord Stimulation (SCS) as a treatment for chronic pain has been historically designated for patients who have had at least one prior spinal surgery. Considering the opioid drug crisis and the often-mixed clinical success of conservative treatment approaches and invasive back surgery procedures, there is growing interest in utilizing SCS in chronic pain patients who have not yet undergone previous surgical intervention (1-4). Recent SCS devices offer substantially more novel technological capabilities and neurostimulative approaches than older-generational SCS systems. Correspondingly, interventional treatment approaches capable of multimodal therapeutic strategies are now actively recommended by pain care advocates in support of an effort to foster approaches enabling more precision medicine that can be tailored to the individual patient (5,6). Here, we describe our clinical assessment of SCS in patients with no prior history of surgery implanted with a device capable of customizable programming engaging multiple mechanisms of action in a prospective, multicenter, randomized controlled trial (RCT) compared with Conventional Medical Management (CMM).

Materials and Methods

This is a prospective, multicenter randomized, controlled study (SOLIS) that compares SCS (WaveWriter SCS Systems) versus Conventional Medical Management (CMM) in patients with chronic low back and/or leg pain with no prior spinal surgery (Clinicaltrials.gov: NCT04676022). Enrolled non-surgical back pain (NSBP) patients who met inclusion criteria were randomized to SCS versus CMM. CMM includes oral and topical pain medications, epidural steroid injections, nerve blocks, facet/sacroiliac joint injections, physical therapy, occupational therapy, cognitive behavioral therapy, psychological care, chiropractic care, transcutaneous electrical nerve stimulation and acupuncture. Conventional medical management was optimized based on Investigator judgement. Of note: the system under study in this trial is not approved for sale in the USA to treat NSBP. Key inclusion criteria include diagnosis of chronic low back pain, with or without leg pain, for ≥6 months, and documented care of chronic pain for ≥90 days. The primary endpoint is responder rate (≥ 50%reduction in pain) with no increase in baseline opioid medications to treat pain at 3-months following treatment activation. Other secondary and/or exploratory measures include Quality-of-Life (SF-36; EQ-5D-5L), Disability (Oswestry Disability Index, ODI), and Safety Outcomes. This study was approved by

relevant Institutional Review Boards (IRB) for each site. Written informed consent was obtained from each prospective participant prior to enrollment in the study.

Results/Case Report

The study successfully met its primary endpoint (Figure 1; $p<0.0001$) and secondary endpoints based on a prespecified cohort (Figure 2). The primary endpoint analysis demonstrated that multimodal SCS combined with CMM was superior to CMM alone in treating NSBP patients at 3-months follow-up (SCS [n = 57]: 89.5% versus CMM [n = 62]: 8.1%). Additionally, at 3-months follow-up, a 28-point reduction in ODI score (improvement in disability) was noted in the SCS group in comparison to a 7-point reduction in the CMM group. Eighty-six percent of subjects with SCS reported treatment satisfaction (i.e., much, or very much improved) at 3-months versus only 3.2% in the CMM group. Follow-up at 6-months in those being treated with SCS and CMM, demonstrated a responder rate (i.e., ≥50% pain relief) of 91.3% (n = 46), and a 26-point reduction in ODI score thereby reflecting significant improvement in disability (Figure 3). Responder rate in those initially randomized to CMM only, who then later crossed over to the SCS + CMM arm, was 83.9% (Figure 3; n = 31).

Discussion

Given the prevalence of non-surgical, refractory back pain and the increasing economic and societal burden it poses, providing SCS as an additional tool within the therapeutic armamentarium for chronic pain represents a key opportunity to address a clinically important need. Data from the SOLIS RCT demonstrated that SCS with multiple modalities is effective in treating chronic pain in patients with no prior back surgery demonstrating superior outcomes compared with CMM. These evaluated outcomes are consistent with those reported in a preceding RCT assessing patients diagnosed with currently-approved "on-label" chronic pain indications (7).

References

1. Finnerup NB, Attal N, Haroutounian S, McNicol E, Baron R, Dworkin RH, Gilron I, Haanpää M, Hansson P, Jensen TS,Kamerman PR, Lund K, Moore A, Raja SN, Rice AS, Rowbotham M, Sena E, Siddall P, Smith BH, Wallace M. Pharmacotherapy for neuropathic pain in adults: a systematic review and meta-analysis. Lancet Neurol.2015 Feb;14(2):162-73.
2. Al-Kaisy A, Van Buyten JP, Kapural L, Amirdelfan K, Gliner B, Caraway D, Subbaroyan J, Edgar D, Rotte A. 10 kHz spinal cordstimulation for the treatment of non-surgical refractory back pain: subanalysis of pooled data from two prospective studies. Anaesthesia. 2020 Jun;75(6):775-784.
3. Kapural L, Jameson J, Johnson C, Kloster D, Calodney A, Kosek P, Pilitsis J, Bendel M, Petersen E, Wu C, Cherry T, Lad SP, Yu C,Sayed D, Goree J, Lyons MK, Sack A, Bruce D, Rubenstein F, Province-Azalde R, Caraway D, Patel NP. Treatment of nonsurgical refractory back pain with high-frequency spinal cord stimulation at 10 kHz: 12-month results of a pragmatic, multicenter, randomized controlled trial. J Neurosurg Spine. 2022 Feb 11:1-12.
4. Kapural L, Calodney A. Retrospective Efficacy and Cost-Containment Assessment of 10 kHz Spinal Cord Stimulation (SCS) in Non-Surgical Refractory Back Pain Patients. J Pain Res. 2022 Nov 16;15:3589-3595.
5. U.S. Department of Health and Human Services, Alliance to Advance Comprehensive Integrative Pain Management (2019).Pain Management Best Practices Inter-Agency Task Force Report. https://painmanagementalliance.org/resources/hhs-report-2019/. Accessed October 28th, 2022.
6. Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain - United States, 2022.MMWR Recomm Rep.2022 Nov 4;71(3):1-95.
7. Wallace MS, North JM, Phillips GM, Calodney AK, Scowcroft JA, Popat-Lewis BU, Lee JM, Washabaugh

EP 3rd, Paez J, Bolash RB, Noles J, Atallah J, Shah B, Ahadian FM, Trainor DM, Chen L, Jain R. Combination therapy with simultaneous delivery of spinal cord stimulation modalities: COMBO randomized controlled trial. Pain Manag. 2023 Mar;13(3):171-184.

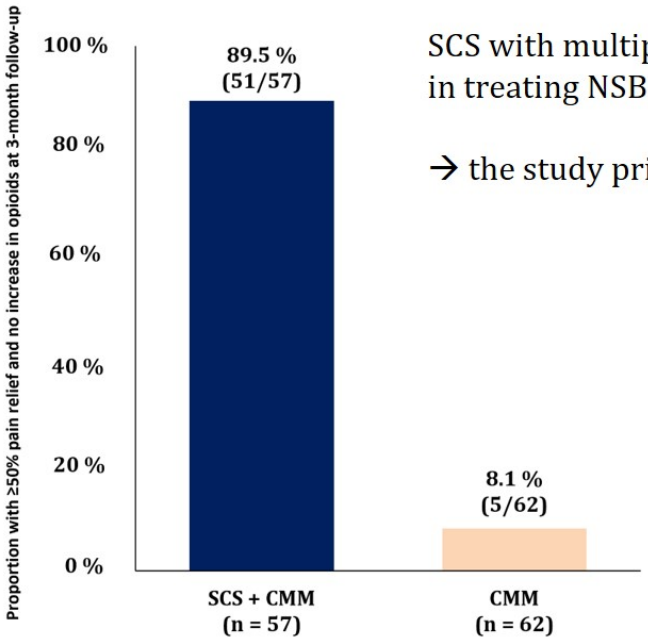
Disclosures

Yes

Tables / Images

Primary Endpoint Analysis (3-months post-activation)

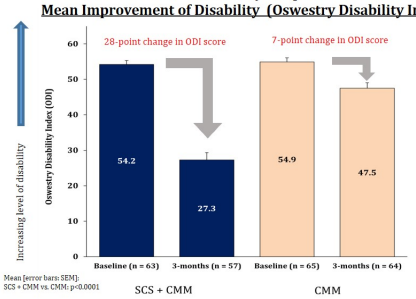
Proportion of subjects with ≥50% reduction from Baseline in average overall (low back and/or leg) pain intensity at 3-months post-activation, with no increase in baseline average daily opioid medications used to treat pain, compared between SCS and CMM.



SCS with multiple modalities was superior to CMM in treating NSBP patients at 3-months (p<0.0001)

→ the study primary endpoint was met

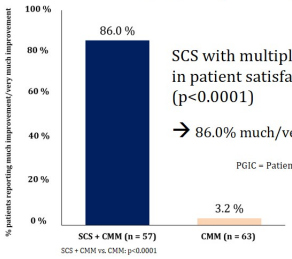
Secondary Endpoint:
Mean Improvement of Disability (Oswestry Disability Index, ODI)



SCS with multiple modalities is superior to CMM in improving functional outcomes when treating NSBP patients (p<0.0001)

→ 28-point vs. 7-point ODI improvement

Secondary Endpoint:
Patient Satisfaction (very much/much improved [PGIC]) at 3-months



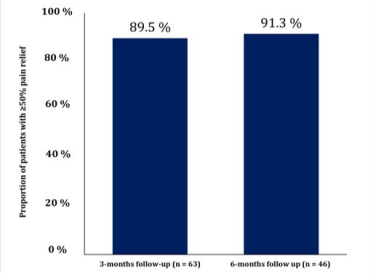
SCS with multiple modalities is superior to CMM in patient satisfaction when treating NSBP patients (p<0.0001)

→ 86.0% much/very much improved vs 3.2% for CMM

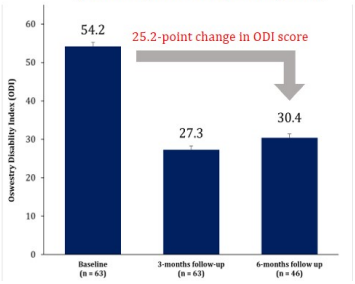
PGIC = Patient-reported Global Impression of Change

Preliminary 6-month follow-up outcomes in the SCS + CMM arm

Responder Rate
(Proportion with ≥50% Pain Relief)



Mean Improvement of Disability
(Oswestry Disability Index, ODI)



CMM crossover with available 6-month follow-up data:

- Responder Rate: 83.9% (n=31)
- ODI: 29.0 (n=30) → Δ 26-points vs. Baseline Measurement