ASRA PAIN MEDICINE
23rd Annual Pain Medicine Meeting
November 21-23, 2024 | Las Vegas, Nevada
#ASRAFALL24

Abstract: 5775

Scientific Abstracts > Chronic Pain

Evaluating SCS and Medical Management for Chronic Pain Without Prior Surgery: 1-Year Outcomes (SOLIS RCT)

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Introduction

Given the often-mixed clinical success of conservative treatment approaches and invasive back surgery procedures, there is growing interest in utilizing Spinal Cord Stimulation (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 (5,6). Here, we describe clinical assessment of outcomes out to 1-year in SCS 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 the therapeutic effectiveness of SCS versus CMM only in patients with chronic low back and/or leg pain with no prior spinal surgery

(Clinicaltrials.gov: NCT04676022). As such, enrolled non-surgical back pain (NSBP) patients who met inclusion criteria were randomized to SCS combined with CMM (SCS + CMM arm) or a CMM-only arm. Those selected to receive SCS were implanted with a multimodal SCS system capable of engaging multiple mechanisms of action (Wavewriter SCS Systems). 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. Data collected out to 6- and 12-months follow-up was obtained and analyzed. 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

One hundred and twenty-eight treatment-activated study participants were randomized (63-subjects to the SCS + CMM arm and 65 subjects to the CMM-only arm). Primary endpoint analysis demonstrated that multimodal SCS combined with CMM was superior to CMM alone ($p<0.0001$) in treating NSBP patients at 3-months follow-up on the basis of obtained responder rates (SCS + CMM: 89.5% [51/57] versus CMM: 8.1% [5/62]). Assessment of disability in those randomized to the multimodal SCS + CMM arm indicated a 28-point reduction in ODI score in comparison to a

7-point reduction in those randomized to CMM only. Out to 12-months follow-up: a high profound responder rate (≥80% pain relief) of 51.2%; significant improvement in disability (Δ 25-point ODI decrease vs Baseline); ≥21.1% improvement (EQ-5D-5L) . Subjects randomized to CMM who crossed over to SCS+CMM arm achieved comparable results at long-term follow-up.

Discussion

The data obtained in this RCT demonstrates that utilization of multimodal SCS provides for superior outcomes when compared to use of CMM alone for treatment of NSBP. 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 an opportunity to address a clinically important need.

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Disclosures

Yes

Tables / Images