ASRA PAIN MEDICINE
22nd Annual Pain Medicine Meeting
November 10-11, 2023 | New Orleans, Louisiana
#ASRAFall23

Abstract: 4731

Scientific Abstracts > Chronic Pain

DTM™ SCS FOR INDICATED CHRONIC BACK PAIN PATIENTS REFRACTORY TO SPINE SURGERY: US RCT OUTCOMES

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Introduction

There is plenty of clinical evidence of the efficacy of spinal cord stimulation (SCS) for the treatment of refractory axial low back pain (LBP) in patients with persistent spinal pain syndrome type 2 (PSPS-2, failed back surgery syndrome). In contrast, options for the treatment of axial LBP in patients with chronic back pain, refractory to spine surgery, with degenerative disc disease, herniated disc, or radiculopathy are limited. Among available SCS treatment options, Differential Target Multiplexed SCS (DTM(TM) SCS) is a promising alternative. A recent randomized controlled trial (RCT)[1] showed the superior long-term efficacy of DTM SCS when compared to conventional SCS (Conv-SCS) for LBP in PSPS-2 subjects. Additionally, a European RCT studying the effect of DTM SCS vs conventional medical management (CMM) in the treatment of surgery naïve PSPS-1 patients with refractory LBP reported primary endpoint results that were consistent with those reported in the RCT for PSPS-2 patients[2]. The current work presents an RCT that evaluated the efficacy of DTM SCS versus Conv-SCS on PSPS-1 patients with chronic LBP who are refractory to spine surgery across the USA.

Materials and Methods

This is a post-market, multicenter, prospective RCT study comparing DTM SCS to Conv-SCS in PSPS-1 patients with chronic LBP, refractory to spine surgery, with degenerative disk disease, herniated disk, or radiculopathy. The WCG and Ochsner IRBs approved the study. Table 1 shows key eligibility criteria. Subjects enrolled in the study were randomized (1:1) to either of the study arms. Subjects underwent a temporary SCS trial phase with their assigned treatment. Subjects reporting ≥40% LBP relief relative to baseline could proceed to permanent implantation of a neurostimulation system. Subjects that failed the trial (<40% LBP relief) were withdrawn from the study and their data carried forward. The primary endpoint was the axial LBP responder rate (percentage of subjects with ≥50% LBP relief relative to baseline) at 3-month post-device activation. Population for primary analysis consisted of all subjects who completed the trial phase. An optional two-way crossover was available to subjects at the 6-month visit. Patients were followed up to 12 months. Other data collected included change of LBP and leg pain, responder rates, changes in disability, quality of life, patient satisfaction, global impression of change, and safety profile. The RCT was designed to be statistically powered for robust comparison of the active treatments.

Results/Case Report

105 randomized subjects (51 in the DTM SCS group and 54 in the Conv-SCS group) at 20 sites across the USA completed the trial phase. LBP responder rates with DTM SCS were superior to Conv-SCS at the study timepoints (Figure 1A). Similarly, mean axial LBP reduction from baseline with DTM SCS was also superior to Conv-SCS at study time points (Figure 1B). DTM SCS was also significantly better in leg pain responder rate, reduction of leg pain, improvement of functional disability (ODI), improvement in quality of life (EQ-5D-5L index), patient satisfaction, and patient global impression of change. About 47% of subjects being treated with Conv-SCS opted to crossover to DTM SCS, with 92.3% of them being LBP responders at the end of the study. No patient crossed over from DTM SCS to Conv-SCS. Safety profiles were congruent with previous studies.

Discussion

This RCT demonstrated the long-term superior efficacy of DTM SCS relative to Conv-SCS for treating chronic axial LBP in PSPS-1 patients who were refractory to spine surgery. Significant clinical improvements in functional disability and quality of life provided by DTM SCS were sustained over the study period. The results of this RCT indicate that DTM SCS provides significant benefits on the management of PSPS-1 patients who are refractory to spine surgery, including those who were not treated satisfactorily by Conv-SCS.

References

1. Fishman M, Cordner H, Justiz R, Provenzano D, Merrell C, Shah B, et al. Twelve-Month results from multicenter, open-label, randomized controlled clinical trial comparing differential target multiplexed spinal cord stimulation and traditional spinal cord stimulation in subjects with chronic intractable back pain and leg pain. Pain Pract. 2021 Nov;21(8):912-923.
2. Kallewaard JM, Billet B, Van Paesschen R, Smet I, Mendiola A., Peña I, et al. European randomized controlled trial to study the effects of differential target multiplexed SCS in treating intractable chronic back pain without previous lumbar spine surgery. INS 15th World Congress. 21-26 May 2022. Barcelona, Spain.

Disclosures

Yes

Tables / Images

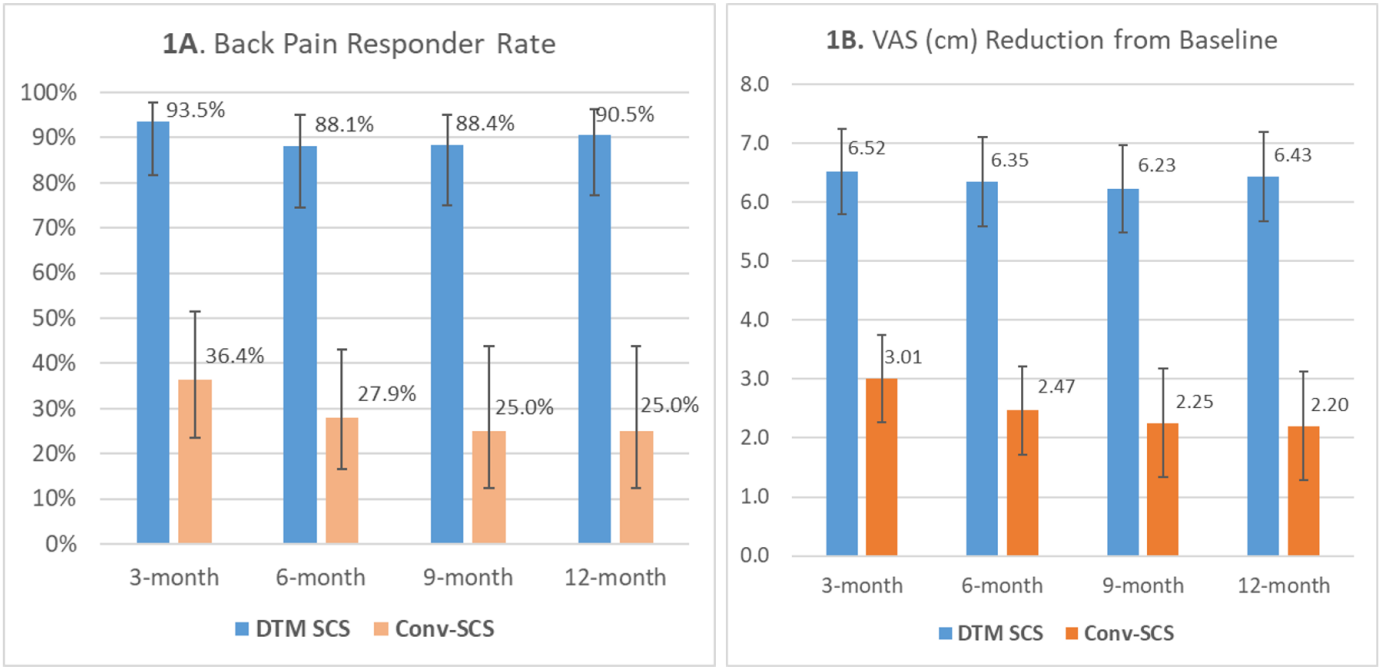

Figure 1. A. Back pain responder rate **B.** Mean back pain VAS reduction from baseline. Analyses for randomized subjects who completed the trial phase using imputation (repeated measures model) for missing data. Error bars are 95%CI. Crossover data was censored in these analyses. DTM SCS was superior to Conv-SCS at all time points ($P < 0.0001$).

Table 1. Key Eligibility Criteria

Inclusion	Exclusion
Adult subjects	Previous lumbar spine surgery
Non-eligible for spine surgery	Contraindications for SCS
≥ 5 cm LBP VAS with or without leg pain	Mechanical spine instability.
SCS candidate per approved labeling	
Under a stable pain medication regime.	