INTRODUCTION

Differential Target Multiplexed (DTM) spinal cord stimulation (SCS) is a unique programming approach where electrical signals are multiplexed spatially and temporally. Differential target multiplexed SCS was inspired from pre-clinical research demonstrating that multiplexed signals can differentially modulate neurons and glial cells to balance interactions perturbed by neuropathic pain1 and is an established therapy that has shown superior back pain relief to traditional SCS.2 Derivatives of the SCS waveform are being investigated to understand opportunities to tailor therapy delivery based on different patient profiles. This study will provide clinical evidence on the efficacy and energy use of a differential target multiplexed SCS derivative (DTM SCS endurance therapy).

METHODS

The primary outcome at 3-months was change in overall (back and leg) pain intensity, as measured by VAS, from Baseline to 3-Month visit. Additional outcomes included changes in back pain, changes in leg pain, programming parameters associated with energy use, satisfaction, function, quality of life, and safety data. At 3- and 6-months, outcomes were reported for the per-protocol analysis (subjects that were implanted with a rechargeable neurostimulation system and programmed to the differential target multiplexed SCS derivative for the duration of follow up). Differential Target Multiplex™ SCS, DTM™ SCS, Intellis™ neurostimulators, and Vanta™ neurostimulators are Medtronic products and/or trademarks. Medtronic is located in Minneapolis, MN, USA.

RESULTS

Change in VAS (Primary Endpoint: Overall Pain at 3-Months): The mean retrospective pre-SCS VAS score of 7.8 (SD ±1.07). The mean reduction in VAS for subjects was -3.9 (SD ±2.45) at the 3-month follow-up and -4.1 (SD ±2.43) at the 6-month follow-up (Figure 1).

Change in ODI: 68.8% of subjects improved to a less disabled category at the 3-month visit (Figure 2).

DISCUSSION AND CONCLUSIONS

SCS patterns can employ energy conserving programming approaches through therapy cycling as well as alterations in amplitude, frequency, and pulse width. Energy-conserving approaches have the potential to impact patient experience with rechargeable devices and to benefit those patients best suited for recharge-free devices. The use of a differential target multiplexed SCS derivative therapy in this study resulted in clinically meaningful pain relief, improved function, and a high degree of patient satisfaction at 3 months with clinically sustained pain relief through the 6-month follow-up. Further research into energy dosing will help to increase understanding of the therapeutic window and mechanism of action, which may improve therapy efficacy or durability and reduce side effects.

REFERENCES


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