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Prospective, Multicenter Study Utilizing an SCS-System Designed to Engage Surround Inhibition Using FAST: 1-Year Outcomes

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Introduction

Novel Fast-Acting Sub-Perception Therapy (FAST) has demonstrated robust and rapid (seconds to minutes) onset of analgesia in chronic pain patients implanted with Spinal Cord Stimulation (SCS) systems (1). Initial published work is now supported by similar research at other centers (2). Further, data derived from the long-term, real-world use of FAST-SCS has now shown sustained improvement for up to 3-years follow-up (3). Recent published work indicates that FAST-SCS engages the Surround Inhibition mechanism of action, and computational modeling suggests that FAST-SCS activates dorsal column axons and inhibits dorsal horn projection neurons (4). Correspondingly, precise stimulation location and optimal neural dose is required to generate analgesia using Fast-Acting Sub-Perception Therapy (FAST). We studied the effectiveness of FAST and additional SCS therapy options for chronic pain in a prospective, multicenter, single-arm clinical study and report our findings, including initial data from those patients who have reached their 12-month timepoint.

Materials and Methods

The FAST study is a prospective, multi-center, single-arm study (with adaptive design) of patients implanted with SCS systems (WaveWriter Systems, Boston Scientific) for chronic pain. The primary endpoint is based on the targeted pain responder rate (≥50% reduction) 3-months post-activation with no increase in average daily opioid medications. Secondary endpoints include (but are not limited to) patient satisfaction (Patient Global Impression of Change, PGIC) and other functional outcomes including disability (Oswestry Disability Index, ODI) and sleep. Key inclusion criteria include diagnosis of predominantly neuropathic pain of trunk and/or limbs for at least 6- months, and no back surgery within 6-months prior to screening. Data was assessed as collected at 3-, 6-, and 12-months follow-up. 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

As reported previously, the primary endpoint ($p<0.0001$) was met as demonstrated by 80% (16/20) of a prespecified cohort of patients achieving a ≥50% reduction in targeted pain with no increase in opioid medications at 3-months follow-up. Additional data subsequently collected at 3- (n = 52), 6- (n = 38), and 12-months (n = 30) follow-up

demonstrated treatment responder rates of 81%, 84%, and 90%, respectively. Onset of ≥50% pain relief was observed to occur at a mean onset duration of 2.6 minutes. In those patients who so far have reached 12-months follow-up, a mean 5-point reduction in VRS low back pain score was observed corresponding to a mean score of 7.41 at baseline which decreased to 2.48 ($p<0.0001$). In addition, a 28-point mean improvement in ODI score at 12-months follow-up was determined. Consistently high levels of patient satisfaction were also found at all follow-up timepoints (>84% reporting much or very much improved).

Discussion

In this prospective study, chronic pain patients who preferred treatment with FAST-SCS achieved significant and durable sub-perception pain relief with associated improvement in disability and satisfaction out to 12-months follow-up. These outcomes are consistent with real-world observational studies in the USA and EU (3, 5).

References

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Disclosures

Yes

Tables / Images