THE EFFECTS OF 10 KHZ SPINAL CORD STIMULATION IN CHRONIC NON-SURIGAL LOW BACK PAIN WITH NEUROPATHIC FEATURES: THE FIVE-YEAR RESULTS FROM THE MAIDEN BACK STUDY

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Introduction

Spinal cord stimulation (SCS) is a recommended treatment for chronic neuropathic pain. Preliminary evidence suggests SCS may improve symptoms in patients with chronic non-surgical back pain. This prospective, open label trial with five-year follow-up aimed to explore SCS in patients with chronic non-surgical back pain with neuropathic features.

Methods

Back and leg pain (visual analogue scale [VAS]), pain-related disability (Oswestry Disability Index [ODI]), health-related quality of life (HRQoL, EQ-5D-5L), employment and medications were recorded at baseline. Following full implant, participants were followed-up at 6-, 12-, 24-, 36-, 48- and 60-months. At each follow-up, the same questionnaires were completed together with patient global impression of change (PGIC).

An intention-to-treat approach was adopted, and data analysed by repeated measure Analysis of Variance, Friedman tests and descriptive statistics.

Results

Thirty-three patients with non-surgical back pain with hyperalgesia or allodynia were enrolled. Twenty-seven patients had a SCS trial, and one went straight to full implant.

There were 25 full SCS implants (frequency: 10 kHz; pulse width: 30 µs) and participants were followed up at 6- (n=25), 12- (n=21), 24- (n=20), 36- (n=19), 48- (n=19) and 60-months (n=19) post-implant.

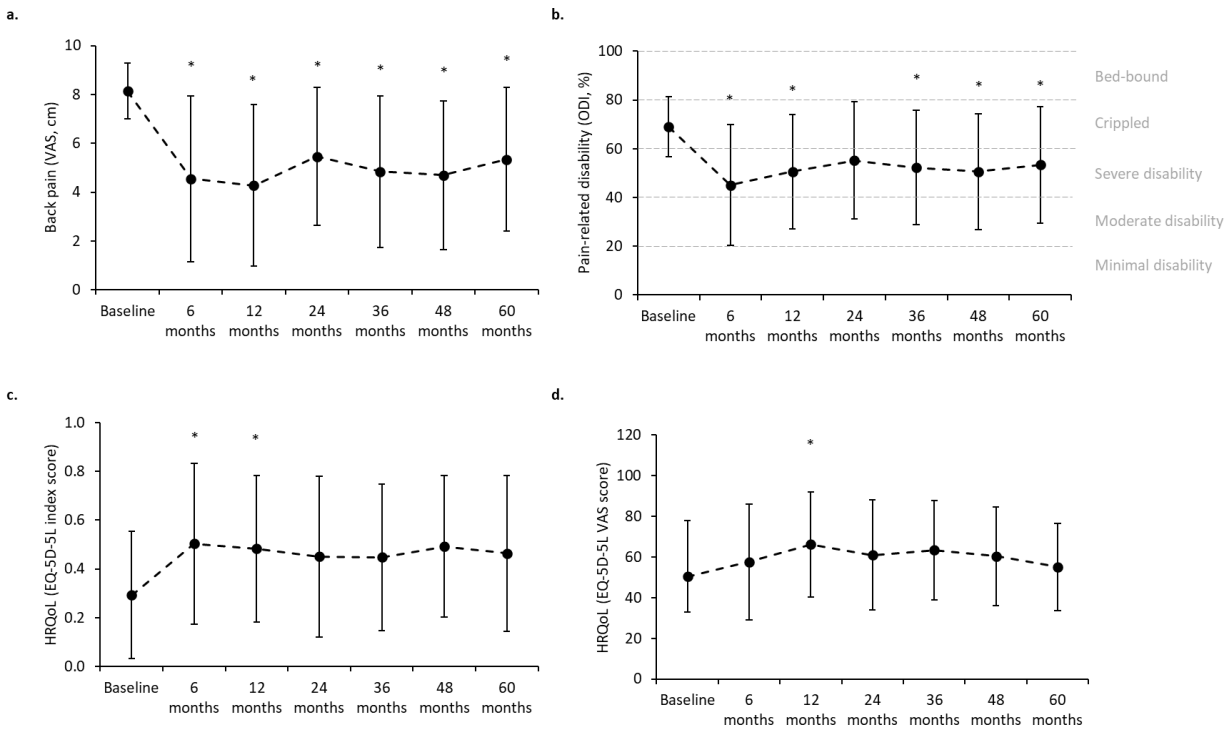

Fig 1: Back pain (a), pain-related disability (b) and HRQoL (c, d) at each time-point. * = significantly different to baseline. Data presented as mean (standard deviation).

Back pain significantly improved at all follow-ups compared to baseline ($p<0.001$, see Fig 1a).

Pain-related disability ($p<0.001$) and HRQoL (EQ-5D-5L index: $p=0.006$; EQ-5D-5L VAS: $p=0.013$) significantly improved at specific follow-ups compared to baseline (see Fig 1b-d).

There were no statistically significant changes in leg pain ($p>0.05$).

At 60 months, 72% of participants reported improved symptoms (PGIC) and 60% were working.

Clinically meaningful improvements were seen in back pain (36% reported ≥50% improvement), pain-related disability (36% reported ≥30% improvement) and HRQoL (56% reported ≥ 0.074 improvement) at 60 months.

Discussion

SCS may be an effective treatment option for individuals with non-operative back pain of neuropathic origin. We intend to implement and communicate widely these learning's to reach key beneficiaries and to bring benefit to patients. We will conduct larger, follow-on research to improve the quality of evidence of SCS as a treatment option in this patient group.

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