A PROSPECTIVE, RANDOMISED, CROSSOVER, CONTROLLED FEASIBILITY STUDY USING SPINAL CORD STIMULATION TO TREAT VISCERAL PAIN SECONDARY TO CHRONIC PANCREATITS: THE PANACEA TRIAL

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Introduction

Spinal cord stimulation (SCS) is a recommended treatment for chronic neuropathic pain. Preliminary evidence shows promising findings for SCS in individuals with visceral pain secondary to chronic pancreatitis. This prospective, randomised, crossover, feasibility study aimed to evaluate SCS compared to conservative medical management (CMM) in this patient group.

Methods

Pain levels (numerical rating scale [NRS]), pancreatitis quality of life (PANQOLI), sleep (Pittsburgh Sleep Quality Index [PSQI]), health-related outcomes, employment, medications and number of attendances to the Emergency Department, out of hours' services and GP in the previous 4 weeks including hospital admissions were captured at baseline.

Participants were randomly allocated to SCS or CMM and attended a follow-up visit at 4 months, where those randomly allocated to CMM crossed-over to SCS. All participants were followed-up at 8 and 12 months. The same questionnaires were completed at each follow-up visit together with patient global perceived effect.

An intention-to-treat approach was adopted, and data analysed by mixed Analysis of Variance and descriptive statistics.

Results

Twelve participants were randomly allocated to SCS and followed-up at 4- (n=12), 8- (n=10) and 12-months (n = 11). Eleven were randomly allocated to CMM and attended at 4-months post-baseline (n=10), SCS implantation (n=10), and 8-months (n=8) and 12-months (n=6) post-implant.

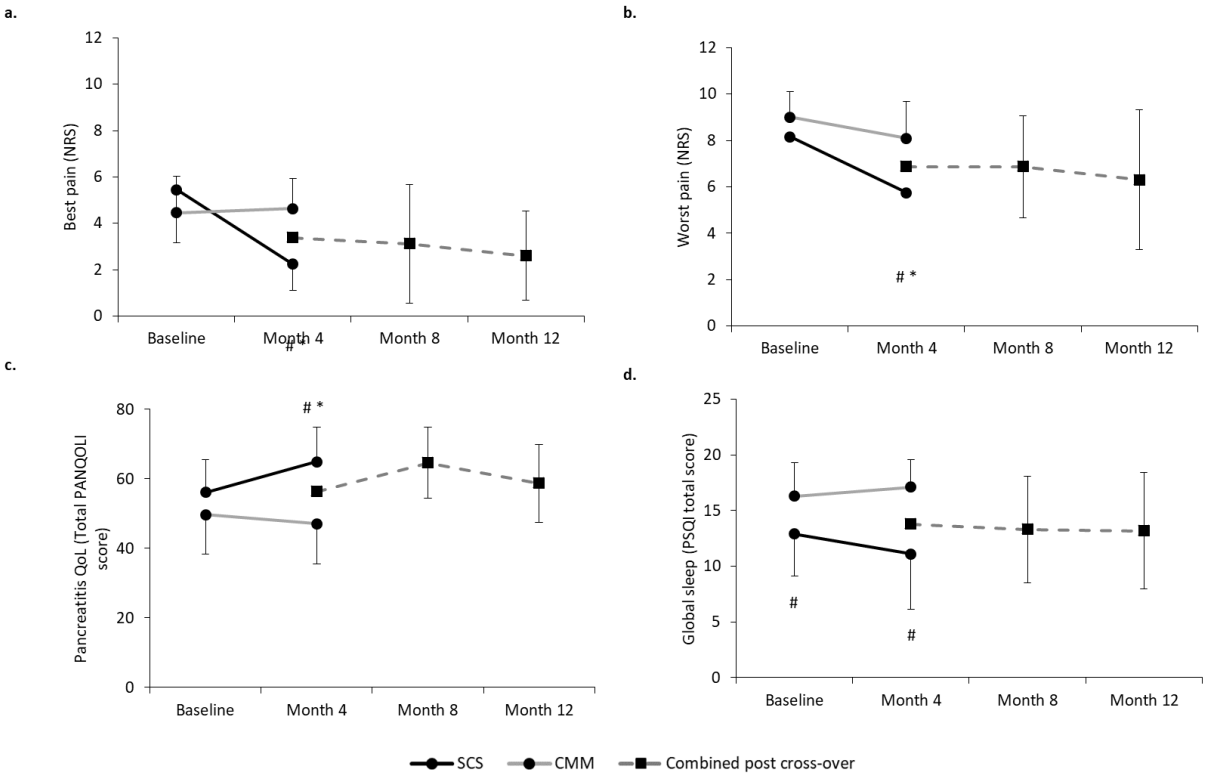

Fig 1: Best pain (a), worst pain (b), PANQOLI (c) and sleep (d) at each time-point. * = significantly different to baseline; # = significantly different to CMM. Data presented as mean (standard deviation).

With SCS, pain (see Fig 1a-b), PANQOLI (see Fig 1c) and sleep (PSQI, see Fig 1d) were significantly improved at the four-month cross-over compared to baseline (all $p<0.05$). Additionally, at this time-point, scores were better for SCS than CMM (all $p<0.05$, see Fig 1). Scores improved from 4 months onwards.

At 4 months in the SCS group, 33% were working, pain response rate (≥30% improvement in pain) was 58% and 42% achieved remission (NRS ≤3). Rates were lower in the CMM group (18%, 27% and 9% respectively).

Discussion

SCS may be an effective treatment option for individuals with visceral pain secondary to chronic pancreatitis. We intend to implement these learning's and communicate widely 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.