Salvage of previously failed spinal cord stimulation using 10 kHz SCS through a 'pocket trial' technique

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Introduction

It is estimated that close to 30% of patients who receive permanent implants with conventional low frequency SCS (LF-SCS) would require an explant of their SCS devices for reasons including loss of efficacy, hardware discomfort, mechanical failures and infection[1,2]. Previous studies demonstrated the efficacy of 10 kHz SCS in providing long-term pain relief to patients with low back and leg pain[3,4]. Our clinic has been using a "pocket trial" technique, in which patients are trialed with 10 kHz SCS by externalizing the existing implanted leads, as an alternative to explantation and the results are presented in this retrospective case series.

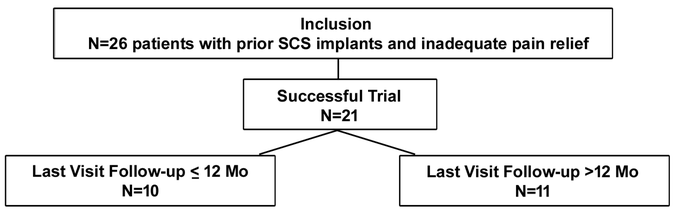
Purpose

The purpose of this retrospective case series is to document the responder rate, changes in sleep, medication, function and quality of life outcomes in patients who were potential candidates for explant due to lack of long-term pain relief with their LF-SCS devices but were salvaged with 10 kHz SCS.

Methods

Twenty-six consecutive patients who had failed previous LF-SCS therapy were trialed with 10 kHz SCS through a 'pocket trial' technique. The technique involved accessing the previously implanted LF-SCS leads in the IPG pocket and externalizing them using a connected adaptor, thereby allowing delivery of the trial 10kHz signal. Patients who reported ≥50% pain relief during the trial received a new implantable pulse generator (Senza™ system, Nevro Corp., Redwood City, CA, USA). Due to the retrospective nature of the analyses and use of anonymized data listings, ethical committee approval was not required for this study. At last visit, minimal clinically important change (MCIC, ≥30% pain relief), responder rate (≥50% pain relief), overall change in function, sleep, quality of life, and medication intake versus baseline were recorded.

STUDY FLOWCHART

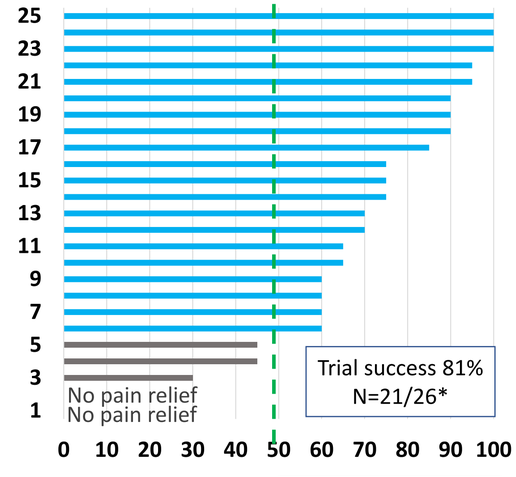


Results

Patient characteristics

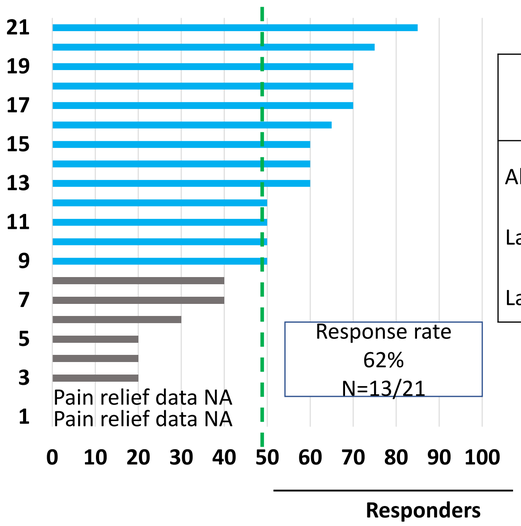
Pain location	N (%)
Low back	14 (53.8%)
Right leg	4 (15.4%)
Left leg	5 (19.2%)
Bilateral leg	3 (11.5%)
Previous spine surgery N (%)	8 (30.8%)
Median follow up time (months)	12.5
Mean VNRS at baseline (SEM)	8.2 (0.3)
Lead placement	N (%)
T4-T5	1 (3.8%)
T7-T8	4 (15.4%)
T7-T9	1 (3.8%)
T8-T9	5 (19.2%)
T9-T10	12 (46.2%)
T11-T12	2 (7.7%)
No details	1 (3.8%)

Trial response



*-pain relief data not available for 1 patient who had successful trial and received permanent implant

Responder rate at last follow-up



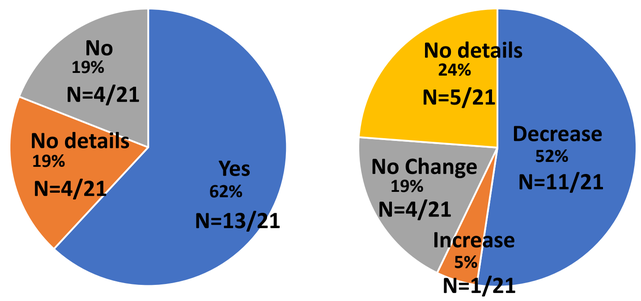
	Median follow-up (mos)	Responder Rate (%, n/N)*	MCIC Responder Rate (%, n/N)**
All implanted patients	12.5	61.9% (13/21)	76.2% (16/21)
Last follow up <12 mo	7.9	60.0% (6/10)	60.0% (6/10)
Last follow up >12 mo	21.3	63.6% (7/11)	90.9% (10/11)

MCIC, Minimum Clinically Important Change
*, ≥50% pain relief
**, ≥30% pain relief

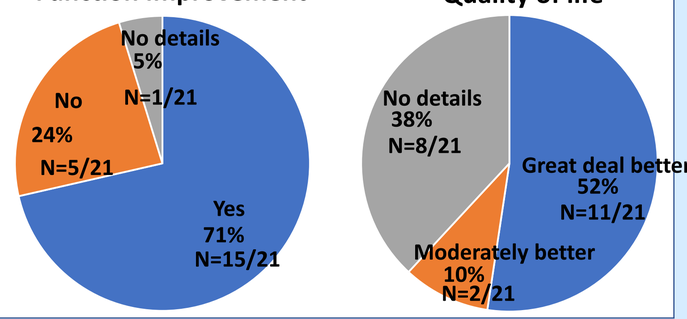
6 OUT OF EVERY 10 PATIENTS HAD RESPONSE (≥50% PAIN RELIEF) WITH 10 kHz SCS

Results (contd.)

IMPROVED SLEEP AND REDUCED MEDICATION



IMPROVED FUNCTION AND QUALITY OF LIFE



Conclusions

10 kHz SCS, with minimally disruptive trialing via the IPG pocket, can be a potential salvage strategy for failed LF-SCS patients. The therapy can provide long-term pain relief and symptom improvement in these patients without requiring lead revision. With over 25% of the patients with less than ideal recommended lead placement for 10 kHz SCS, it is plausible that the responder may have been higher in this cohort with a T8-T11 lead placement.

References

1. Dupre DA et al Pain Pract. 2018 Apr;18(4):500-4.
2. Kapural L et al Anesthesiology, 2015 (123) 851-860.
3. Al-Kaisy A et al Pain Medicine, 2014 (15) 347-354