

A Retrospective, Single-Site Evaluation into Spinal Cord Stimulation for Treating Individuals with Chronic Pelvic or Perineal Pain

Dr Nicola Johnson¹, Dr Beatrice Bretherton-Liu^{1,2}, Professor Ganesan Baranidharan^{1,2}

1. Pain Management Department, Leeds Teaching Hospitals NHS Trust, Leeds, UK. 2. School of Biomedical Sciences, Faculty of Biological Sciences, University of Leeds, UK

Introduction

The Pain Management Department at Leeds Teaching Hospitals (Yorkshire, UK) has been using spinal cord stimulation (SCS) for the management of chronic neuropathic pelvic pain for over 10 years. The team at Leeds Teaching Hospitals typically insert around 150 spinal cord stimulators a year, with five consultants, supported by a multidisciplinary team, delivering the service.

SCS for pelvic pain is growing in evidence with a number of small trials and case series reporting positive results^{1,2,3}. Here we present a case series and evaluation of outcomes for 26 pelvic pain patients treated with SCS for pelvic pain at our institution.

Results

The range of patients in this cohort includes patients whose underlying pathology is varied; cancer pain (2/26), post-surgical pain (10/26), pain of unknown aetiology (10/26) and pain related to other diagnoses (4/26); they are however united in their diagnosis of neuropathic pain. Trial insertion was utilised for the majority of patients 20/26.

One patient died prior to follow up. For those patients with available follow up, 11 (of 24, 45.8%) reported improvements $\geq 30\%$ in average pain and 5 (of 24, 20.8%) patients reported a $>50\%$ improvement in pain.

Remission (0-3 average pain NRS) occurred in 4 (of 25, 16%) of patients. Although gender was not significantly associated with pain response ($\chi^2 = 0.151$, $p > 0.05$), all remitters were female.

In both the ITT and currently implanted cohorts, statistically significant improvements in average pain, worst pain and QoL were seen ($P < 0.005$ for all). There was also no significant difference in age, baseline average pain and baseline QoL when assessing pain response to treatment.

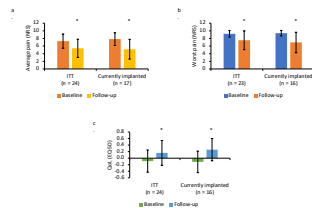
Eight (of 26, 31%) patients underwent at least one revision and the overall explant rate was 15% (4 of 26). Reasons for revision included lead fracture and insufficient pain relief. Explants were for failure of treatment, infection and patient concerns about the battery. Two patients had explantations of DRG stimulators due to failure of treatment before insertion of SCS with thoracic leads.

Conclusions

- Our findings suggest that SCS in chronic pelvic or perineal pain was associated with significant improvements in pain and QoL.
- SCS can induce remission for patients with chronic neuropathic pelvic pain.
- The rates of revision and explantation suggest this modality is a safe treatment for these chronic pain conditions.
- By using real-world data, it is hoped that findings from this retrospective evaluation will broaden insight into the outcomes associated with SCS in patients with chronic pelvic or perineal pain.
- Further prospective randomised clinical trials are needed to build on the findings.



Illustration detailing the most recent position of the SCS electrodes in our patient group. Each red oval illustrates the position of a single electrode in a given patient as detailed in the patient's operation note. Some patients had multiple electrodes, others two or one. Adapted from Gray's Anatomy⁴.



Graphs illustrating Average Pain, Worst Pain and QoL differences prior to treatment and at follow up for both the intention to treat and currently implanted cohorts. Total numbers * statistically significant difference.

Methods and Materials

Our implants were inserted percutaneously using minimally invasive techniques by a total of 4 different consultants in Pain Medicine in surgical day-case settings, typically without the need for general anaesthesia, allowing facilitation of on table mapping and same day discharge where appropriate. Patients were treated under the NICE Technology Appraisal guidance [TA159] which states SCS can be considered for any patient with chronic neuropathic pain of non-vascular origin.

The study received approval from the local institutional review board. Data were collected from two sources – a prospective follow up document used to facilitate assessment of the patient's response to treatment and the hospital's electronic patient record.

The following data was collected: age, gender, chronic pain diagnosis, SCS system, baseline and follow-up scores for average pain (numeric rating scale, NRS), worst pain (NRS), quality of life (QoL, EQ-5D-3L), lead positioning, revisions and explants. Data were statistically analysed by descriptive statistics and paired t-tests/Wilcoxon signed-rank tests.

As some patients were awaiting follow up whilst others had undergone explantation, statistical analysis was performed on both intention to treat (ITT) and currently implanted cohorts.

Discussion

Findings suggest that SCS in chronic pelvic or perineal pain was associated with significant improvements in pain and QoL. As illustrated, retrograde lead insertion is not always mandated to provide pelvic pain relief.

Compared to previously available studies and case reports on SCS for pelvic pain, our study had a smaller proportion of patients had a $>50\%$ reduction in average pain scores^{1,2}. The reasons for this are not clear, but may involve patient selection, duration of follow up and the use of the numeric pain scale rather than visual analogue scale. We have however demonstrated that some patients can expect remission after treatment. There was no relationship between underlying pathology and treatment response. Two of the patients with cancer related neuropathic pain passed away from their cancer within 18 months of insertion which has influenced the follow up for this sub-group and highlights that given the cost and invasive procedure of SCS, such patients should be consented carefully for potential benefits.

The rates of revision and explantation suggest this modality is a safe treatment for these chronic pain conditions

References And DOI

1. Tate JL, Stauss T, Li S, Rotte A, Subbarayan J. A Prospective, Multi-Center, Clinical Trial of a 10 kHz Spinal Cord Stimulation System in the Treatment of Chronic Pelvic Pain. *Pain Pract*. 2023;23(10):65-93. doi:10.1111/papr.12932
2. Lippof L, Narasim SN, Jankeli TL, Mekhal N. Spinal cord stimulation: an effective treatment for the chronic intractable visceral pelvic pain. *Pain Med*. 2006;7(5):440-3 doi: 10.1111/j.1526-4637.2006.00165.x
3. Bridger C, Prabhala T, Dawson R et al. Neuromodulation for Chronic Pelvic Pain: A Single-Institution Experience With a Collaborative Team. *Neuroepidemiology*. 2021 Mar 15;50(4):819-827. doi: 10.1159/000519537.
4. Gray, *Anatomy of the Human Body*. Philadelphia: Lea & Febiger, 1938; Bartley.com, 2000. Available at <https://www.bartley.com/107/14.html> [accessed 29/04/23]

Declarations of interest
NI – NIL

BB – BB has provided consultancy on medical writing and data analysis to Plattform SA.
GB – GB has consulting agreements with Saluda, Neuro Corp, Abbott, Medtronic, Boston Scientific, Stryker and Mainstay Medical. GB has had educational and Research Grants from Neuro Corp, Abbott and Boston Scientific. GB is on the advisory board for Abbott and Nalu Medical.