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A Spinal Cord Stimulation Service Review From a Single Centre Using a Single Manufacturer Over a 7.5 Year Follow-Up Period

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Background: Spinal cord stimulation (SCS) is a recognized management option for patients with refractory neuropathic pain. Despite randomized controlled trials reporting the effectiveness of SCS, there is a lack of long-term data reflecting usual SCS practice. The aim of this study is to present the long-term outcomes of a cohort of patients from a single centre undertaking SCS with devices from a single manufacturer.

Methods: Data were collected between January 2008 and July 2015 on 321 patients who had an SCS trial. Outcome measures included numerical rating scale of pain intensity (NRSPI), brief pain inventory (BPI), EQ5D and quality-adjusted life-years (QALYs). Adverse effects also were recorded.

Results: Statistically significant reductions in NRSPI and BPI and increases in health utility using the EQ5d were observed. SCS over a 15-year time period resulted in a mean projected gain of 6.2 QALY. The rates of implant infection and device explantation were 2.3% (2.4% not including legacy patients) and 6.7% (7.6% not including legacy patients) respectively but only 3.4% (4% excluding legacy patients) explanted due to late failure to relieve pain. Satisfaction with SCS was high with 92% of patients stating that they would have it all done again for the same result. 96.4% would have wanted SCS as a treatment option earlier.

Conclusions: Patients with neuropathic pain undertaking SCS experience long-term reductions in pain intensity and increases in health utility and associated QALY gains. The findings from this study associated with the increased longevity of rechargeable SCS devices suggest that the cost-effectiveness of SCS may become increasingly favourable when compared with conventional medical management.

Keywords: long-term outcomes, neuropathic pain, spinal cord stimulation

Conflict of Interest: Simon Thomson has received consultancy fees from Boston Scientific. The other authors have no conflicts of interest.

INTRODUCTION

Spinal cord stimulation (SCS) is reimbursed in the UK for refractory neuropathic pain and can be reimbursed for ischaemic pain syndromes in the context of research as part of a clinical trial (1). SCS is not reimbursed for visceral pain syndromes unless there is evidence of a neuropathic mechanism of pain.

Randomized controlled trials (RCTs) have observed that SCS is effective for the management of neuropathic pain, specifically failed back surgery syndrome (FBSS) (2), complex regional pain syndrome (CRPS) (3) and painful diabetic neuropathy (4,5). Long-term effectiveness data is usually derived from single arm longitudinal studies as it is unethical to keep participants with severe pain in randomized groups beyond six months. Long-term data, together with expert consensus is of value for the development of economic models of SCS, which assist the decision-making process. The aim of this service review is to present a comprehensive long-term outcome analysis of patients that underwent an SCS implant for all neuropathic indications with a sub-analysis of commonest indications, FBSS and CRPS.

METHODS

This study presents demographic and long-term outcome data of patients that underwent an SCS trial between January 2008 and July 2015. From January 2008 until July 2011 data were collected retrospectively (retrospective cohort), and thereafter it was collected

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prospectively. The multidisciplinary SCS service has been led by the same implanter since 1993 and has previously reported on outcomes and complications of SCS observed in this centre (6,7).

Patient Selection

Patients are referred to our pain management centre either from their primary care physician, another specialty such as orthopaedic spine or from other pain clinics in our region. The pain physician confirms the diagnosis and that appropriate evidence based pain therapies have been attempted but failed to achieve long-term satisfaction. An internal referral is made to pain psychology, nurse and physiotherapy. Each sees the patient and at a multidisciplinary team (MDT) meeting each patient is discussed. The MDT is led by a pain medicine consultant and consists of pain management trained clinical psychologists, physiotherapists and nurses. The MDT has ready access to colleagues in spinal surgery, rheumatology, neurology, cardiology, pediatrics, occupational therapy and imaging. If any member has a caution to proceed with SCS then a plan of action is created. If major concerns of a good therapeutic outcome from SCS remain, then the SCS pathway is discontinued. This process provides added time for each patient to consider the treatment and opt in or out of the SCS pathway. Alternative treatments such as cognitive and behavioral pain management program is readily available.

SCS has been provided since 1993 at this centre. The centre wanted a rechargeable platform from a single manufacturer to help with the internal working of a large SCS provider centre. From January 2008 the implant centre switched from a non-rechargeable, 4 or 8 contact platform to a 16 or 32 contact rechargeable platform for most patients. As manufacturers innovate there has been an increase in numbers of contacts per lead (4, 8, 16 contacts/lead) and the introduction of rechargeable technology to support more effective programming of the devices.

Three databases (DB) covered the periods from January 2008 to July 2011 (DB1), July 2011 to November 2014 (DB2), and November 2014 to July 2015 (DB3). Information on the outcome of the SCS device for DB1 was obtained through a retrospective case-notes review, whereas for DB2 and DB3 the data was collected prospectively.

Legacy patients ($N = 50$) with end of life non-rechargeable SCS systems that have needed replacement were included as part of DB1, DB2, or DB3 according to the timing of their implantable pulse generator (IPG) replacement. These legacy patients are SCS responders and 48 had an on-table trial for topographical mapping with immediate full implant and 2 had a repeat one-week trial. SCS procedures occurring prior to initiation of this data collection exercise (January 2008) were not included in the current study. In addition there were 7 patients involved in a refractory angina study where the protocol demanded full implantation if satisfactory topographical coverage of pain area on the table and another 5 new patients to SCS who were implanted directly after an on table trial. In total 60 patients were on-table trial only. On-table trial is where both new leads and IPG are tested for topographical coverage of pain and implanted. The majority of patients were new to SCS and had a staged trial of SCS with the definitive percutaneous leads connected to tunneled extension leads. After careful occlusive dressing the patients were allowed home for an extended week; rarely a two-week trial period ($N = 5$; 3 who needed more time to decline and 2 who tried a different stimulation mode with same device). If trial outcome was successful as judged by the multidisciplinary team, a full implant was completed. The minimum success requirement of the screening trial was if the patient reported $\geq$50% pain relief as judged by the percentage reduction in numerical rating scale of pain intensity (NRSPI) and satisfactory paresthesia coverage (i.e. $\geq$80%) of the pain area. All patients who received a trial of an SCS device (Precision or Precision Spectra, Boston Scientific, Valencia, CA, USA) were included in this study. A mechanical anchor fixation device was used in all patients.

Follow-Up and Outcome Measures

All patients who had an existing full implant were included in the postal survey (Appendix 1). Amongst the survey questions were specific questionnaires that are routinely collected as part of our usual care since July 2011; including a NRSPI during the preceding week at worst and at usual levels (8), the Brief Pain Inventory (BPI) (9), and EuroQol five dimensions questionnaire (EQ5D) (10). The EQ5D questionnaire was not completed by DB1 patients who had no baseline data. Responses to the EQ5D descriptive system were converted into single (utility) indices using the UK tariff reflecting population preferences for the particular health state. Quality-adjusted life-years (QALYs) were calculated by the area-under-the curve (AUC), involving linear interpolation of utility indices over the follow-up period (11). A QALY is a measure of benefit that represents the equivalent of one year of life in full health and is calculated by weighting the period of time a person spends in a particular health state by the health-related quality of life he or she experiences during this period.

Each patient received a letter explaining the purpose of the survey and was asked to make contact with the clinical team to have re-programming of the SCS if they felt the coverage was sub-optimal and then complete the questionnaire a few days later. Patients that did not return the questionnaire within four weeks were contacted by telephone to attempt to confirm address and a second questionnaire was sent. An independent third party employed by the centre research department sent and managed the questionnaire administration.

Statistical Analysis

Non-parametric Wilcoxon's rank sum tests were applied to evaluate changes in BPI and NRSPI scores from baseline to follow-up. Comparisons of proportions in survey results between patients with baseline data and patients without baseline data were evaluated with Fisher's exact test. Subgroup analyses were evaluated with linear models using baseline pain, age, gender and follow-up time as covariates in both propensity matched and unmatched settings. p-Values < 0.05 were considered statistically significant. All analyses were conducted using R 3.3.1 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Trial to Permanent Implant Ratio

Three hundred and twenty-one patients who had an SCS trial were identified (Fig. 1). Twenty-six patients had leads removed, 22 were failed trials where the success criteria (50% pain reduction) was not achieved, and 4 were successful trials but developed an anchor site infection (1.5% of total extended trials) of which three were later implanted with on table trial; the fourth had died due to unrelated causes. Thus, there were 298 patients who underwent implantation of the SCS system. 50 were legacy patients (prior to DB1) having their device upgraded after their previous non-rechargeable device had become end of life and/or leads had developed high impedance. These patients were already responders to SCS, 48 of these had an on table trial to confirm topographical coverage with full

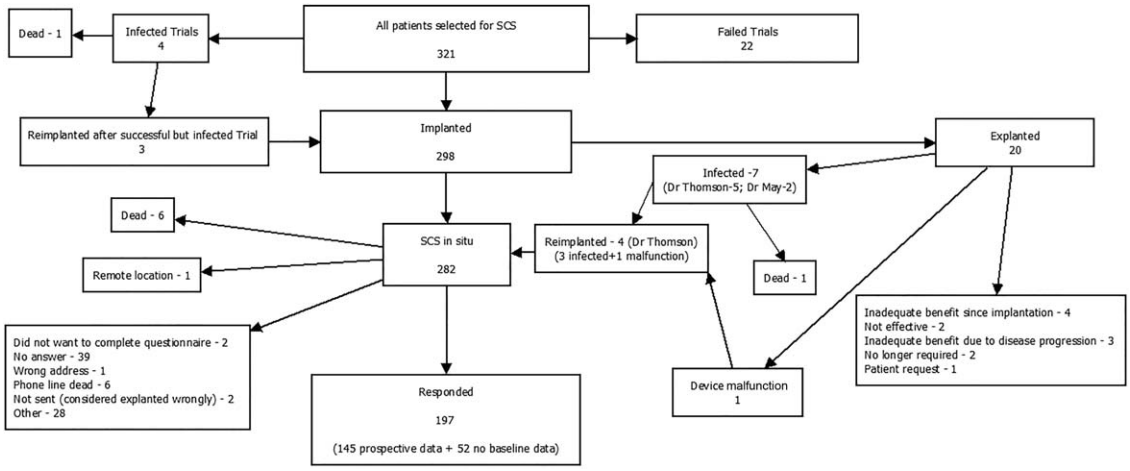

Figure 1. Flow diagram detailing the treatment journey of patients selected for SCS.

implantation but the other 2 were thought necessary to have an extended trial to confirm benefit of the new SCS. 261 non-legacy patients had an extended trial of SCS. There were 22 failed trials out of these 261 patients new to SCS with an extended trial (321–60) giving a trial to implant ratio of 91.6%.

SCS Devices Explanted

During the follow-up period there were 20 SCS explants (6.7%) one of which was a legacy patient (Fig. 1). Not considering legacy patients this rate would equal to 7.6% (19/248). 7 of these, including a legacy patient were due to implant infection (2.3% overall or 2.4% excluding the legacy patient) and 1 due to an IPG malfunction; 4 of these were re-implanted and 4 of those who had the implant explanted due to infection did not elect to have re-implantation. Of the other 12 explants, 2 were because the SCS was no longer required as the pain syndrome had resolved (both chronic CRPS), 4 stated that the SCS had never helped them since implantation, 2 that it was no longer effective, 3 due to disease progression, and 1 was removed at patient's request. Overall the late failure rate resulting in explantation was 3.4% (4% excluding legacy patients) but if the 4 infected cases that did not have re-implantation are included, then the late failure rate is 4.7% (5.6% excluding legacy patients).

Revision Procedures

There were 13 cases of lead revisions in 12 patients and 6 IPG pocket revisions. The lead revision rate of 13 cases in 298 implanted patients over the follow-up period was 4.4% and pocket revision of six cases in 298 was 2%. These rates excluding legacy patients are 5.2% and 2.4%, respectively.

Response to Postal Survey

The postal survey was sent to 282 patients with an SCS in situ with 197 responding (70% response rate). 145 had prospective data and 52 had no baseline data. Of those that failed to respond 6 had died, 1 lived in a remote location, 7 had no current contact details, 2 stated that they would not complete the questionnaire, 2 were not sent questionnaires as they were thought incorrectly to have been explanted, 39 did not answer, and 28 failed to respond for other reasons.

Whole Survey Responder Cohort

Sixty per cent of responders to the survey were female, the mean age was 58 years and the mean follow-up was 2.7 years. The diagnosis was FBSS for 66% of the patients and CRPS for 12%. The majority of the patients that responded to the survey (94.0%) continue to use their SCS for pain relief, with 52.2% using it continuously day and night, 19.9% by day only and 21% only when required. Some to complete pain reduction with SCS was reported by 94.7% with 5.3% describing no pain relief when using the SCS device. 91% considered their pain to be better now than before SCS and 8.3% stated it was the same. 92% of the patients would have it all done again for the same result, 95.8% had all or some of their expectations met and 96.4% would possibly or definitely recommend to another patient. Importantly 96.4% of patients would have wanted SCS earlier as a pain management option. The mean duration of refractory neuropathic pain by the time they received SCS was 77 months.

At the time of survey only a few (< 5) patients were established on a sub-threshold programme. Of the patients that underwent paresthesia led topographical pain coverage 70% found the paresthesia to be neither pleasant nor unpleasant to very pleasant and 4% were not aware of paresthesia. However, 25% found the paresthesia to be mildly to moderately unpleasant and 1% severely unpleasant.

The anchor site wound was found to be either pain free or mildly uncomfortable by 81% of the patients, 15.3% considered the wound to be moderately uncomfortable and the remainder finding it severely uncomfortable. The IPG site was found to be pain-free or mildly uncomfortable by 75.4% of the patients, moderately uncomfortable by 19.8% and severely uncomfortable by the remaining 4.8%. The SCS device was recharged at least every week or a longer interval by 53.8% of the patients, at a two- to six-day interval by 34% and daily by 5.8%. Seventy-five per cent would charge from one to three hours a time, and 25% for longer.

Comparison of Cohort Without Baseline vs. Prospective Cohort

Patients in DB1 had their SCS device implanted for up to 7.5 years, whereas those in DB2 for up to 4 years and in DB3 for up to 1 year.

There were 145 responders with prospective data and 52 without. The prospective cohort was similar to the cohort without baseline with reference to sex, age, and diagnosis (2/3 were FBSS) but

Table 1. Demographic Characteristics of Survey Responders.

	Cohort with baseline	Cohort without baseline
N	145	52
Gender		
Male	40%	38%
Female	60%	62%
Age	58 (13)	57 (13)
Refractory time	64 (62)	97 (88)
Follow-up time (years)	2.1 (1.1)	1. (1.7)
0–12 months	21%	8%
12–24 months	25%	2%
24–36 months	32%	0%
36+ months	22%	90%
Diagnoses		
FBSS ($N = 130$)	66%	66%
FBSS (Leg > Back)	46%	35%
FBSS (Back >= Leg)	19%	29%
FBSS Other	0.7%	2%
CRPS ($N = 26$)	14%	10%
CRPS Type 1	9.7%	10%
CRPS Type 2	4.8%	0%

CRPS, complex regional pain syndrome; FBSS, failed back surgery syndrome.

showed a shorter follow-up interval (2.1 vs. 4.7 years) and a shorter refractory time period before being treated with SCS (Table 1).

Survey results were similar in both groups. Greater than 90% used their SCS device for pain relief ranging from "Only when I need to" to "Continuously day and night". Nearly all of the responders in both groups (>90%) experience some reduction of pain when using the SCS device.

A higher proportion of respondents in the prospective cohort had more profound pain reduction (75% vs. 68%) and required more recharging (44% recharging at least once every week vs. 26%) perhaps reflecting their proportionate greater requirement for use than the cohort without baseline; however no statistically significant differences were observed. There were no differences between groups for anchor site or IPG discomfort, pleasure/displeasure with stimulation sensation, therapy goals achieved, overall satisfaction as reflected by affirmative answers to questions about recommendation to others and having the procedure done again for the same result.

Prospective Data Cohort

Numerical ratings of pain intensity before and at follow-up for usual and worst pain reduced from 7/10 to 4/10 (43% reduction, $p < 0.001$) and 8.6/10 to 5.6/10 (35% reduction, $p < 0.001$), respectively (Fig. 2). However the pain reduction reported is less the longer the follow-up interval (Fig. 3). BPI scores were reduced overall from 7.2/10 to 4.2/10 (42% reduction, $p < 0.001$) and across all 7 domains (Fig. 4). Similarly, the BPI reduction is less the longer the follow-up interval.

EQ5D utility scores increased from 0.19 at baseline to 0.43 at follow-up ($p < 0.001$). SCS for at least five years results in a mean projected gain of 1.9 ± 1.2 QALYs. SCS over a 15-year time period results in a mean projected gain of 6.2 ± 3.9 QALYs.

Subgroup analysis revealed tendencies towards better outcomes in patients diagnosed with CRPS against the rest and FBSS with leg pain > back pain against back pain >/= leg pain but none demonstrated statistically significant differences.

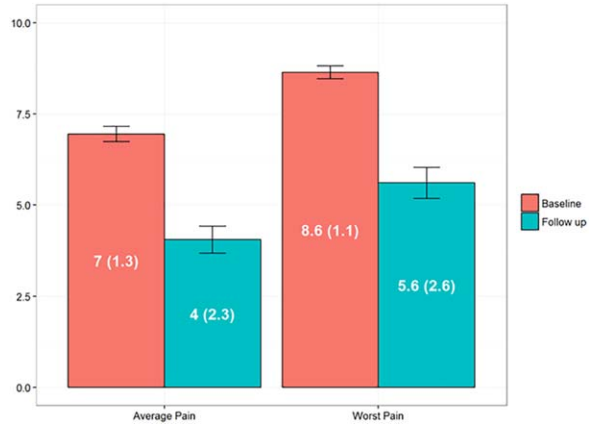

Figure 2. Change in average pain and worst pain from baseline to follow-up in the prospective data cohort ($N = 145$). Mean (standard deviation). [Color figure can be viewed at wileyonlinelibrary.com]

DISCUSSION

This is the third service review of the same hospital based SCS service provider. We wanted to track the effects of the adoption of a rechargeable multiple independent current control 16 or 32 contact SCS system. Previous reviews had been concerned with complications such as infection, revision rates and clinical outcome (6,7). Since 2011 all patients with prospective data are collected on databases that are the pilots of the UK's National Neuromodulation Registry (NNR). We wanted to review a larger number of patients over a longer follow-up, so we included a cohort without baseline data from an early registry of devices (DB1), which at the very least provides credible data as to the fate of SCS in such patients.

Since we improved and adopted standard operating procedures concerning biological security we had reduced the SCS trial infection rate to 1.6% and the SCS completion implant rate to 3.6% (7). This new service review shows that these rates are little changed with extended trial infection rate at 1.5% but implant infection rate at 2.6% suggesting that the service at a whole has internal consistency. A difference between implanting physicians was identified by Rudiger and Thomson with potential impact in the rate of trial and

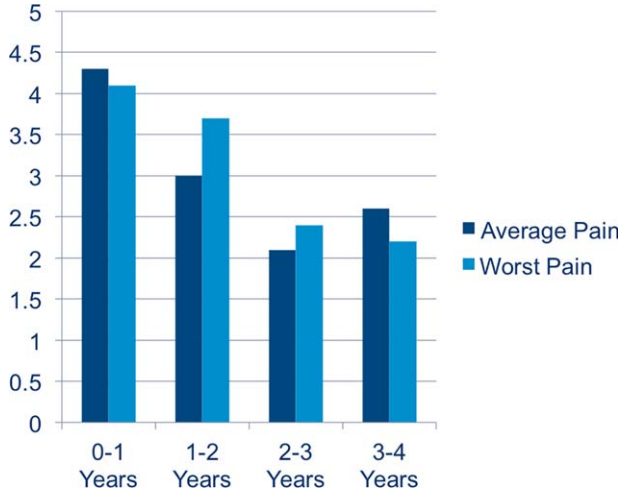

Figure 3. Change from baseline to follow-up in average and worst pain across different follow-up intervals. Patient reported pain reduction appears to decrease the longer-the time since initiation of SCS. [Color figure can be viewed at wileyonlinelibrary.com]

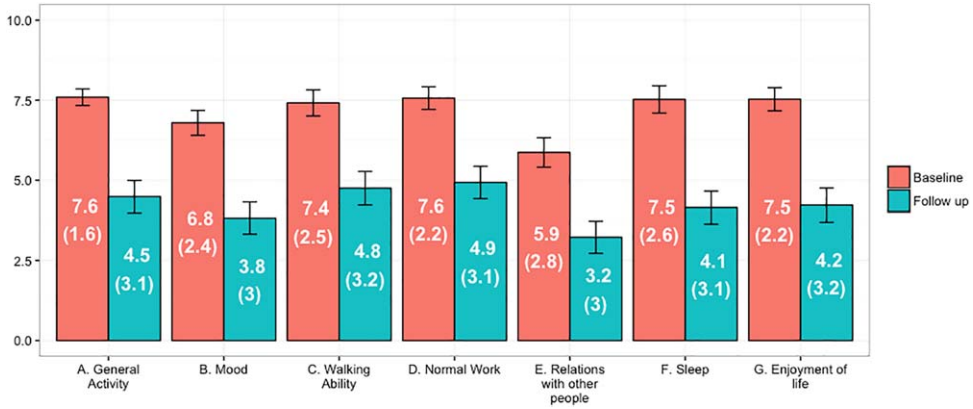

Figure 4. Changes across Brief Pain Inventory domains at baseline and at follow-up in the prospective data cohort ($N = 145$). [Color figure can be viewed at wileyonlinelibrary.com]
Mean (standard deviation)

implant infections due to the learning curve associated with the procedure and adherence to standard operating procedures.

Hayek et al. published a similar service review focusing on treatment limiting complications of SCS implants over an eight-year period using an academic centre database (12). SCS is delivered there as a separate trial and later a full implantation, rather than staged with temporary extensions. Many experts assume that the staged procedure is associated with a higher incidence of trial and implant infections. Hayek's team reports a 4.3% implant infection rate (12).

Trial to implant ratio if high may indicate comprehensive selection and patient expectation management providing that the explant rate is not too high. On the other hand it may be that some patient's who may benefit from SCS may be excluded, as the selection criteria are too tight. At our centre, the current trial to implant rate is 91.6% with an explant rate of 6.7% (7.6% not including legacy patients). Hayek et al. report a trial to implant rate of 67.8% with an explant rate of 23.9%.

Our survey did reveal that about 5% of patients who continued to be implanted but were dissatisfied with the effect of their SCS and will be offered explantation unless the issue can be rectified with advanced programming or revision procedure. Only one implantable pulse generator had to be replaced. This was due to a malfunction and was detected within a week of implantation and was exchanged under warranty. The total lead revision rate of 4.4% (5.2% not including legacy patients) observed in our study in which a mechanical anchor fixation device was used compares favourably to Hayek et al. migration and fracture combined of 12.8% and to previous reports from our centre (13).

Patient satisfaction with the therapy remains high with 92% or more believing they would have it all done again for same result and 95% recommend to another. Similar satisfaction rates have been observed in RCTs of SCS for neuropathic pain (2,3).

Paresthesia and non-paresthesia led programming can provide pain relief. Nearly all of our survey responders had evoked paresthesia with 70% finding the paresthesia pleasant or indifferent to them. However 25% of them did find the paresthesia unpleasant. It remains to be seen whether these patients will respond to a sub-threshold programme now that we have the capability to apply these programs with the same device.

The anchor site and implantable pulse generator site were found to be moderately to severely uncomfortable by 20% and 25% of implanted patients, respectively. All our implants are in the back pocket position and experience has taught us in the last few years that there is better tolerability now that we site at level of iliac crest rather than greater sciatic foramen.

Nowadays we advise patients recharge strategy to be that of keeping it topped up. With the advent of high energy sub-threshold programming, recharging technique and time spent doing it will become increasingly important. Those patients from DB1 are an older cohort, but there were no signs of increased charging frequency that might have suggested deterioration in the battery to hold a charge.

The increases in utility scores observed in this study resulted in a mean projected gain over 15 years of 6.2 QALYs. The projected QALY gains are similar to those observed in the economic evaluation of SCS for FBSS and larger than those reported for conventional medical management (4.06) or reoperation (4.15) (14). The cost-utility analysis by Taylor and colleagues reported a 89% probability of SCS being cost-effective when compared with conventional medical management at a willingness to pay threshold of £20,000 and a 98% probability at a willingness to pay threshold of £30,000 per QALY. Time before a replacement IPG is needed was one of the factors having the greatest impact on the cost-effectiveness of SCS. Considering that the longevity of a rechargeable IPG is greater than a non-rechargeable system, this would lead to the cost-effectiveness of SCS becoming increasingly favourable.

Strengths and Weaknesses of This Service Review

The strengths of this service review are that there are significant numbers of patients treated at a single institution with a single device manufacturer. Practices have remained stable over time as evidenced by maintenance of satisfactorily low infection rates. Revision rates appeared lower than previous service reviews at the same institution with no IPG replacements for end of life and few lead revisions or replacements reflecting the more robust leads, better anchoring and perhaps more programming opportunities to maintain topographical mapping.

Routine prospective baseline data collection using the NNR will help each implant centre to accurately present their clinical outcomes and complications and together create a national picture. Since 2011 the clinical team routinely collects prospective data at time of SCS trial. The survey was by postal questionnaire. The patient's were reassured that their data would be confidential and not seen by the clinical team. As such the results of this study can be considered to be based on pragmatic data rather than that seen within a research protocol or collected by an interested party.

The weaknesses of this review are the retrospective nature and missing baseline data from DB1 and that 30% of patients did not respond to postal survey. Enquiries revealed that some did not receive the questionnaire or forgot to complete and return it. Several took so long to get their SCS re-programming done that the study window had closed. In future it would be of interest to try to follow up the failed trials and explanted patients.

CONCLUSIONS

Spinal cord stimulation resulted in significant reductions in pain intensity and increases in health utility and consequent QALY gains for patients with neuropathic pain. These outcomes are further reinforced by high patient satisfaction levels and a willingness to have all done again for same result if required. Low rates of implant infection, revision and device explantation were observed. These findings, associated with the increased longevity of rechargeable SCS devices suggest that the cost-effectiveness of SCS is becoming increasingly favourable when compared with conventional medical management.

Comparison with data from a USA institution with similar numbers of patients and follow-up period is of interest. There are differences in practice across the Atlantic. Some or all of the following factors may help to explain this; patient selection, use of multidisciplinary team in assessment and management, patient expectations, healthcare funding source for the citizen or individual, technology and follow-up arrangements may all play a part in the differences in SCS fate and outcomes. More work needs to be done to accurately define the phenotype for SCS success.

This service review brings into question the value of an extended trial period (91.6% trial to permanent implant ratio). Perhaps with tight selection and use of a multidisciplinary pain management and neuromodulation team an on table trial to confirm topographical coverage will be clinically and cost effective. A definitive prospective randomized controlled trial to answer "the trial or not to trial" question is planned.

Finally it is hoped that the National Neuromodulation Registry, when finally rolled out, will help to drive up standards and increase national patient access.

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Authorship Statements

Dr. Thomson and Dr. Kruglov conceived and designed the service review. Dr. Kruglov liaised with the independent data collection team. Dr. Thomson and Dr. Kruglov collected baseline data from examination of databases and case records where required. Dr. Kruglov collated the data for analysis. Dr. Thomson wrote the initial draft with Dr. Duarte providing the health economic analysis. Dr. Duarte and Dr. Thomson provided manuscript revision responses. Dr. Kruglov approved all.

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APPENDIX

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Dataset questionnaire for Survey 300 PRO

1 Do you still have an SCS device?

Yes ☐ **No** ☐

If you answered 'No' please confirm the

- **Date when SCS was removed:** _____
- **Name of hospital where it was removed:** _____

If you answered 'Yes' please continue with the next question.

2 When the device is switched on, can you feel the electrical stimulation (tingling sensation)?

Yes ☐ **No** ☐

3 Do you think the device needs re-programming?

Yes ☐ **No** ☐

If you answered 'Yes' please arrange to see SCS re-programming team:

Neuromodulation Clinical Nurse Specialist
Tel: 01268 59 2389 or 01268 59 2260

Once you have seen the Neuromodulation team please complete the rest of this questionnaire. If you answered 'No' please continue with the next question.

4 Do you still use the SCS device for pain relief?

- ☐ **Continuously – day and night**
- ☐ **Always at night**
- ☐ **Always by day**
- ☐ **Only when I need to**
- ☐ **No, I do not need it anymore because I have no more pain**
- ☐ **No, I do not need it anymore because my pain is better controlled with something else**
- ☐ **No, because it does not help me so is not worth using**

5 Do you still have pain reduction when you use the SCS device?

- ☐ **No reduction of pain**
- ☐ **Some reduction of pain**
- ☐ **Moderate reduction of pain**
- ☐ **Much reduction of pain**
- ☐ **Complete reduction of pain**

6 Where the device lead are attached to you, is the area …

- ☐ **Very uncomfortable**
- ☐ **Moderately uncomfortable**
- ☐ **Slight discomfort only**
- ☐ **No trouble at all**

7 Is the implantable pulse generator (battery or box) site itself …

- ☐ Very uncomfortable
- ☐ Moderately uncomfortable
- ☐ Slight discomfort only
- ☐ No trouble at all

8 Is the stimulation from the device …

- ☐ Very uncomfortable
- ☐ Moderately uncomfortable
- ☐ Slightly uncomfortable
- ☐ Neither uncomfortable nor pleasant
- ☐ Slightly pleasant
- ☐ Moderately pleasant
- ☐ Very pleasant
- ☐ I do not feel stimulation when SCS is switched on

9 How often do you recharge the device …

- ☐ More than once a day
- ☐ Once a day, every day
- ☐ Once every 2 to 6 days
- ☐ Once a week
- ☐ Once every 8 to 13 days
- ☐ Once every two weeks
- ☐ Other recharging frequency
- ☐ Don't recharge at all
- ☐ Other, please state –

10 How long does the device take to recharge?

- ☐ **Up to 1 hour**
- ☐ **1 to 2 hours**
- ☐ **2 to 3 hours**
- ☐ **3 to 4 hours**
- ☐ **Other, please state –**

11 When you think back about the pain you were in before you had your SCS and compare this to now, do you think you are …

- ☐ **Better with SCS**
- ☐ **Same as before**
- ☐ **Worse with SCS**

12 Knowing what you know now about your SCS and given all that you have been through with having the SCS fitted and living with it long term, would you have it all done again for the same result?

- ☐ **Yes, definitely**
- ☐ **Yes, possibly**
- ☐ **No, definitely**
- ☐ **No, possibly**

13 Knowing what you know now about your SCS, has the results been what you wanted?

- ☐ **Yes, all of them**
- ☐ **Some of them**
- ☐ **No, none of them**

14 Knowing what you know now about your SCS, would you recommend SCS to another patient who has a similar problem to yours?

- ☐ **Yes, definitely**
- ☐ **Yes, possibly**
- ☐ **No, definitely**
- ☐ **No, possibly**

15 Knowing what you know now about your pain symptom history and your SCS, would you have liked to have your SCS fitted earlier in your pain management?

- ☐ **Yes, definitely**
- ☐ **Yes, possibly**
- ☐ **No, definitely**
- ☐ **No, possibly**

16 BRIEF PAIN INVENTORY

17 EQ5D-5L or EQ5D-3L depending upon prospective baseline tool

Thank you for taking the time to complete this questionnaire.

Please return the completed questionnaire in the enclosed stamped addressed envelope to:

Data Manager
Research and Development Department
Postgraduate Education Centre
Basildon and Thurrock University Hospitals NHS Foundation Trust
Nethermayne
Basildon
Essex, SS16 5NL

COMMENTS

Long-term studies at a single institution as to the effectiveness of spinal cord stimulation for neuropathic pain are sparse. A literature search identified a 1993 publication by Richard North, MD et al that spanned a 20 year period (1). Although the current article only covers 7.5 years, the results are important in that implanting pain medicine physicians are frequently asked to prove to insurance companies that SCS provides long-term benefits, both physically and financially. This article provides both.

Miles Day, MD
Lubbock, TX, USA

REFERENCE

1. North R, Kidd D, Zahurak M et al. Spinal cord stimulation for chronic, intractable pain: Experience over two decades. *Neurosurgery* 1993;32(3):384–395.

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I would like to commend the authors for publishing this well-characterized patient series. As they very correctly state in the introduction, most of what we know about long-term performance of SCS devices is derived from follow-up on RCTs, which obviously in many ways differ significantly from how patients are treated in an everyday setting. This service review is based on a single center with a remarkably good setup, which may limit the generalizability of the published data. It does, however, form a very nice background for future, similar studies based on more centers, and national and trans-national databases will play a crucial role in this all-important effort.

Kaare Meier, MD, PhD
Aarhus, Denmark

Comments not included in the Early View version of this paper.

