

UNIVERSITY OF BIRMINGHAM

University of Birmingham
Research at Birmingham

Analysis of psychological characteristics impacting spinal cord stimulation treatment outcomes

Sparkes, Elizabeth; Duarte, Rui V.; Mann, Stacey; Lawrenc, Tony R.; Raphael, Jon H.

License:

None: All rights reserved

Document Version

Peer reviewed version

Citation for published version (Harvard):

Sparkes, E, Duarte, RV, Mann, S, Lawrenc, TR & Raphael, JH 2015, 'Analysis of psychological characteristics impacting spinal cord stimulation treatment outcomes: a prospective assessment', *Pain physician*, vol. 18, no. 3, pp. E369-E378.

[Link to publication on Research at Birmingham portal](#)

Publisher Rights Statement:

Eligibility for repository: Checked on 07/12/2015

General rights

Unless a licence is specified above, all rights (including copyright and moral rights) in this document are retained by the authors and/or the copyright holders. The express permission of the copyright holder must be obtained for any use of this material other than for purposes permitted by law.

- Users may freely distribute the URL that is used to identify this publication.
- Users may download and/or print one copy of the publication from the University of Birmingham research portal for the purpose of private study or non-commercial research.
- User may use extracts from the document in line with the concept of 'fair dealing' under the Copyright, Designs and Patents Act 1988 (?)
- Users may not further distribute the material nor use it for the purposes of commercial gain.

Where a licence is displayed above, please note the terms and conditions of the licence govern your use of this document.

When citing, please reference the published version.

Take down policy

While the University of Birmingham exercises care and attention in making items available there are rare occasions when an item has been uploaded in error or has been deemed to be commercially or otherwise sensitive.

If you believe that this is the case for this document, please contact UBIRA@lists.bham.ac.uk providing details and we will remove access to the work immediately and investigate.

**Analysis of psychological characteristics impacting on spinal cord stimulation
treatment outcomes: a prospective cohort study**

Elizabeth Sparkes,^{1,2} Rui V. Duarte,^{2,3} Stacey Mann,^{2,4} Tony R. Lawrence,¹ Jon H. Raphael^{2,4}

¹ Psychology Department, Coventry University, Coventry, UK

² Department of Pain Management, Russells Hall Hospital, Dudley, UK

³ School of Health and Population Sciences, University of Birmingham, Birmingham, UK

⁴ Faculty of Health, Birmingham City University, Birmingham, UK

Corresponding author:

Rui V. Duarte

University of Birmingham, School of Health and Population Sciences, Room 124, Learning
Centre, Edgbaston B15 2TT, Birmingham, United Kingdom

Tel.: +44 (0) 121 414 7784

E-mail address: ruivduarte@gmail.com

Short title: Impact of psychological characteristics on SCS outcome

ACKNOWLEDGEMENTS

Financial support and sponsorship: This work was supported by the Faculty of Health,
Birmingham City University, Birmingham, UK.

Conflicts of interest: none.

Presentation: Preliminary data for this study were presented as a poster presentation at the
Neuromodulation Society of the UK & Ireland (NSUKI), 19-20 September 2013, Oxford, UK.

ABSTRACT

Background: Psychological factors are recognised as influencing the outcome of spinal cord stimulation (SCS) although there is currently no consensus as to which factors impact upon SCS efficacy.

Objective: To identify psychological characteristics that may impact on the efficacy of SCS.

Design: Prospective cohort study.

Setting: Single secondary care centre in Dudley, United Kingdom.

Patients: Seventy-five patients were initially recruited and 56 patients (31 female and 25 male) were followed-up for 12-months.

Intervention: SCS for the management of chronic non-cancer pain.

Main outcome measures: Outcome measures assessed at baseline, six-months and 12-months following SCS implantation included the visual analogue scale (VAS), Oswestry disability index (ODI), hospital anxiety and depression (HAD) scale and the pain coping strategies questionnaire (PCSQ).

Results: Statistically significant improvements were observed for the VAS ($p < 0.001$), ODI ($p = 0.011$), anxiety ($p = 0.042$) and depression ($p = 0.010$) in the HAD scale and for the subscales reinterpreting pain sensation ($p = 0.018$), control over pain ($p = 0.001$) and ability to decrease pain ($p < 0.001$) of the PCSQ. We observed that depression and autonomous coping (control over pain, ability to reduce pain and catastrophising) may impact on sensory aspects such as pain intensity and disability scores affecting the outcome of SCS treatment. Age at time of implant and duration of pain prior to implant were also found to impact upon SCS efficacy.

Conclusions: This study demonstrates that psychological aspects such as depression and autonomous coping may impact on SCS treatment. Addressing these issues prior to SCS implantation may improve SCS long-term outcome.

INTRODUCTION

One in five adults (19%) in Europe suffers from chronic pain and over one third of European households have at least one chronic or acute pain sufferer (1). Successful treatment outcomes are difficult to achieve for chronic pain, causing a great impact on an individual's health, healthcare services and society (2). Spinal cord stimulation (SCS), a treatment for chronic pain has been in use since 1967 (3). The SCS electrodes are connected to a pulse generator and programmed in anode and cathode combinations to create an electric field stimulating the dorsal root and dorsal column fibres in the spinal cord (4). It has been suggested that stimulation in this area results in supra-spinal mechanisms, reduced activity in the ascending pain pathway (spinothalamic tract) and increased activity in the descending antinociceptive pathway (5). Animal studies have shown inhibition of hyperexcitatory actions in the dorsal horn and increased levels of GABA released (6). SCS is an expensive and invasive therapy; therefore, careful selection for suitability is imperative. A trial period usually takes place in most centres prior to SCS implantation to investigate the efficacy of the treatment based on pain reduction. Although a successful trial may be achieved initially this does not appear to guarantee long-term success. Loss of analgesia can be experienced after 12-24 months (7,8).

Reduced efficacy of SCS may be attributed to technical factors, resulting in loss of target area paraesthesia and analgesic efficacy (8). More recently, it has been suggested that the impact of psychological factors should be taken into consideration when investigating SCS efficacy (9,10). Specific cognitions and methods of coping are understood to interact with the pain experience, impacting on the response to pain and subsequent response to treatment (11). A recent systematic review observed a lack of consistent evidence to suggest any particular psychological factors linked with SCS efficacy (12). Depression was suggested by the majority of the studies included in this review as a possible impacting factor; however it was concluded that successful treatment could modify the level of depression if it was a state in reaction to the pain rather than a trait characteristic. The most common psychological factor associated with the onset and continuation of chronic pain is catastrophising, alongside a lack of perceived internal control (13-16). It can therefore be hypothesised that certain psychological factors, specifically coping strategies may interact with the experience of pain and response to SCS. The aim of this prospective study was to identify psychological characteristics that may impact on the efficacy of SCS.

METHODS

Participants

Participants over 18 years of age, with chronic neuropathic pain were recruited for this prospective, longitudinal, cohort study following assessment by a multidisciplinary team and referral for SCS trial. The multidisciplinary team comprises of a pain consultant, physiotherapist and a clinical psychologist to evaluate the different facets of pain and to determine patient suitability for SCS according to NICE TA159 (17). Patients are excluded on the grounds of being medically unfit for implant surgery, having unrealistic expectations of the treatment, lack of comprehension and unrealistic beliefs surrounding their pain. Prior to full implantation of the IPG (implantable pulse generator), under local anaesthesia with sedation, the SCS electrodes are implanted percutaneously and positioned to obtain maximal paraesthetic coverage of the painful area. Electrical parameters are set to obtain maximal pain relief and trialled for one week. During the trial period if less than 50% pain relief is reported the electrical parameters are altered to try to achieve this level of pain reduction. If more than 50% pain relief is reported consistently at the end of the trial week the patient proceeds to have a fully implanted SCS. If less than 50% pain relief is reported, the leads are removed.

The study was explained and written informed consent was obtained from all participants. The patients completed questionnaires and rated their pain at baseline (one week prior to SCS trial), six-months and 12-months following SCS implantation. All data were collected during routine follow-up appointments. Ethical approval was granted by Birmingham, East, North and Solihull Research Ethics Committee (REC reference: 08/H1206/183).

Seventy-five consecutive patients were initially recruited to participate in the study. Diagnoses comprised failed back surgery syndrome (42.6%), complex regional pain syndrome (33.3%) and other (24.1%) which included for example arachnoiditis and coccydynia. Seven of the participants (9.3%) obtained less than 50% pain reduction during SCS trial despite adequate topographical mapping and according to current recommendations were not implanted (17). Twelve participants were lost to follow-up within one year following implantation (16%). A total of 56 patients were included in the final analysis.

Sensory and psychological measures

Assessments were carried out at baseline (one week prior to SCS trial), six-months and 12-months following SCS implantation. Participants were asked to rate their average pain intensity on a 100 mm horizontal visual analogue scale (VAS) (18). The VAS has been

shown to be a reliable and valid measure of subjective phenomena including chronic pain (18-20). Clinical changes were calculated from the VAS scores measured at baseline and after 12-months of SCS implantation (21). Clinically important changes were classified in accordance with a consensus statement that established a 10-20% decrease as minimally important, $\geq 30\%$ as moderately important and $\geq 50\%$ as a substantial change (22).

The Oswestry Disability Index (ODI) was used to assess the level of pain interference with various activities of daily living. The ODI is a valid measure of condition-specific disability (23). The ODI consists of 10 items/activities with 6 levels (range 0-5). This questionnaire has been recommended as a tool to measure pain related disability when considering areas other than and including low back pain (24). ODI scores between 0-20% were considered as minimal disability; 21-40% moderate disability; 41-60% severe disability; 61-80% crippled; and 81-100% as bed-bound or exaggerating their symptoms (23). A change from baseline of 10.5 points was considered as a minimal clinically important difference (25).

Anxiety and depression were measured using the Hospital Anxiety and Depression (HAD) scale (26). The HAD consists of 14 items allowing the patient to select how frequently they experience a particular situation (e.g. I feel tense and wound up: most of the time/ a lot of the time/ from time to time/ not at all). The maximum score for each subscale (anxiety and depression) is 21. Scores can be divided into four ranges representing the severity of symptoms: normal (0-7), borderline (8-10), abnormal (≥ 11). The depression items of this scale focus on the anhedonic state, therefore avoiding the measurement of depression affected by a physical condition. The HAD has been considered a sensitive measure and suitable for assessing anxiety and depression in primary care patients and the general population (27). Internal consistency of the HAD scale has been examined with reports of Cronbach's alpha coefficients between 0.80 – 0.93 for the anxiety scale and 0.81 – 0.90 for the depression scale (28). Zigmond and Snaith support the HAD usefulness for repeated administration at sequential follow-up clinics (26).

The Pain Coping Strategies Questionnaire (PCSQ) is a 44-item designed to measure coping strategies such as diverting attention, reinterpreting pain sensations, coping self-statements, ignoring pain sensations, praying or hoping, catastrophising and increased behavioural activities (29). Each of these seven subscales has a maximum score of 36 and a minimum score of zero, with higher scores indicating greater use of that particular coping strategy. Two additional subscales assess control over pain and ability to decrease pain, each of these items has a maximum score of six and minimum score of zero. Participants rate their thoughts and feelings about their pain using a seven-point scale ranging from 0 (never do) to

6 (always do that). The PCSQ has demonstrated high internal consistency and higher test-retest reliability when compared to other questionnaires including the multidimensional health locus of control questionnaire, the pain responses self-statements questionnaire and the pain responses coping statements questionnaire (30,31).

Statistical analysis

Repeated-measures ANOVA were performed to investigate changes in the variables between baseline, six-months and 12-months follow-ups. Assumption of sphericity was verified through Mauchly's test. If the assumption of sphericity were violated, the degrees of freedom were corrected using Greenhouse-Geisser estimate of sphericity.

Preliminary checks on assumptions for multiple regression, and regression diagnostics, were assessed. These included checks on multicollinearity of predictors (using tolerance statistics), checks for influential cases using Cook's D, checks for independence of residuals using the Durbin-Watson statistic, checks for linearity of relationship and heteroscedasticity of residuals using a plot of standardised residuals against standardised predicted values. Histograms of residuals were checked to ensure normality of the residuals for each analysis also. None of these checks and diagnostics revealed any breach of assumptions for any of the hierarchical multiple regression analyses that were carried out.

The 9 subscales of the PCSQ were subjected to a Principal Component Analysis for coping strategies subscales at the baseline stage. The main reasons for doing this were to avoid the higher likelihood of type I errors on a per predictor basis if regression analysis were conducted using individual subscales for the perceived coping strategies scale, and to produce independent factor scores summarising subscale variability thus avoiding multicollinearity issues that might arise if regression analysis using the PCSQ was conducted at a item based level. For both principal component analyses two factors were selected for varimax rotation, judged by visual inspection of a scree plot of eigenvalues. The plot of eigenvalues in each instance revealed a clear and marked jump in eigenvalues from factor three to factor two. In both component analyses the first factor was clearly identified with loadings on subscales relating to cognitive and behavioural strategies (CBS) for coping with pain, whilst the second factor was identified with loadings on subscales relating predominantly to an autonomous coping strategy (ACS), which broadly centred on the patient's belief that they had the capacity to decrease their pain. Factor scores were calculated for each participant in the study using the regression method.

For the hierarchical regression the demographic variables gender, age at time of implant and duration of pain prior to SCS treatment were entered in stage 1 of the regression analysis. This was considered particularly important in the case of the gender variable as any gender differences in predicted pain scores would imply the existence of heterogeneous

subsamples which might bias the estimate of the relationship between the psychological predictors entered into stage 2. In stage 2 of the analysis the psychological variables HAD anxiety, HAD depression, CBS, and ACS were entered. At both stages variables were entered using standard forced entry rather than stepwise techniques. Data is reported as mean \pm standard error of mean (range). Statistical significance was judged at 5% level. Statistical tests were performed using the IBM Statistical Package for the Social Sciences (SPSS) software (version 19.0, SPSS Inc., Chicago, IL, USA).

RESULTS

There were no statistically significant differences between patients who obtained $\geq 50\%$ pain reduction during the SCS trial and those who had an unsuccessful SCS trial ($p > 0.05$). Fifty-six patients (31 female and 25 male) were included in the final analysis. The mean age and duration of pain prior to SCS implant were 47.4 ± 1.5 years (24-70) and 8.2 ± 0.8 years (1-25) respectively. Pain topography included buttock/leg/foot ($n=25$), back ($n=6$), arm/hand ($n=5$), head/neck ($n=2$) and multiple sites ($n=18$). Statistically significant improvements were observed for pain as measured with the VAS, disability, anxiety, depression, reinterpreting pain sensation, control over pain and ability to decrease pain (Table 1).

Table 1. Sensory and psychological characteristics assessed

Variable	Baseline (n = 56)	Six-months (n = 56)	12-months (n = 56)	Test statistic	P
Visual Analogue Scale	7.02 \pm 0.18 (4.9-10)	5.04 \pm 0.29 (0-9)	5.60 \pm 0.30 (1-10)	$F(2, 110) = 23.53$	< 0.001***
Oswestry Disability Index	52.18 \pm 2.26 (16-88)	47.16 \pm 2.67 (0-86)	46.48 \pm 3.02 (0-84)	$F(2, 110) = 4.69$	0.011*
Hospital Anxiety and Depression					
HAD anxiety	9.11 \pm 0.62 (2-20)	8.00 \pm 0.55 (1-19)	8.16 \pm 0.56 (0-20)	$F(1.76, 97.15) = 3.43$	0.042*
HAD depression	8.55 \pm 0.61 (1-19)	6.98 \pm 0.56 (0-17)	7.46 \pm 0.63 (0-20)	$F(1.60, 88.29) = 5.39$	0.010*
Pain Coping Strategies Questionnaire					
Diverting attention	16.00 \pm 0.97 (0-33)	16.36 \pm 1.08 (0-36)	15.57 \pm 1.06 (0-36)	$F(2, 110) = 0.46$	0.633
Reinterpreting pain sensation	8.10 \pm 0.98 (0-34)	10.39 \pm 1.17 (0-36)	8.69 \pm 1.20 (0-36)	$F(2, 110) = 4.15$	0.018*
Catastrophising	15.25 \pm 1.27 (0-36)	14.16 \pm 1.24 (0-36)	13.94 \pm 1.35 (0-36)	$F(2, 110) = 1.18$	0.310
Ignoring sensations	13.69 \pm 1.09 (0-32)	14.00 \pm 1.17 (0-36)	13.80 \pm 1.14 (0-36)	$F(2, 110) = 0.06$	0.938
Praying or hoping	16.16 \pm 1.09 (0-34)	15.21 \pm 1.20 (0-36)	14.71 \pm 1.18 (0-36)	$F(2, 110) = 1.61$	0.205
Coping self-statements	22.09 \pm 0.95 (3-34)	22.23 \pm 1.05 (3-36)	21.59 \pm 0.98 (4-43)	$F(2, 110) = 0.30$	0.739
Increased behavioural activities	17.89 \pm 0.91 (1-33)	18.77 \pm 0.94 (0-36)	18.27 \pm 0.96 (0-36)	$F(2, 110) = 0.48$	0.616
Control over pain	2.39 \pm 0.19 (0-6)	3.14 \pm 0.20 (0-6)	3.04 \pm 0.18 (0-6)	$F(2, 110) = 7.98$	0.001**
Ability to decrease pain	2.08 \pm 0.18 (0-5)	3.07 \pm 0.21 (0-6)	2.75 \pm 0.21 (0-6)	$F(2, 110) = 12.71$	< 0.001***

Mean \pm SEM (range)

* $p < 0.05$; ** $p < 0.005$; *** $p < 0.001$

At the 12-month follow-up, minimally important clinical changes ($\geq 10\%$ and $< 30\%$) in pain were experienced by 16 patients (28.6%), moderately important clinical changes ($\geq 30\%$ and

<50%) were obtained by five participants (8.9%) and substantial clinical changes ($\geq 50\%$) were observed by 14 subjects (25%).

Based on the ODI classification of disability, there was a decrease in the number of patients with disability scores between 21-80% and an increase in the proportion of patients rating their disability as minimal (Table 2). Minimal clinically important changes (> 10.5 points) from baseline were observed at 12-months for 19 patients (33.9%).

Table 2. Classification of patients at the different assessments according to ODI and HAD questionnaires

	Baseline 56 (100%)	Six-months 56 (100%)	12-months 56 (100%)
ODI			
0-20% Minimal disability	2 (3.6%)	6 (10.7%)	8 (14.3%)
21-40% Moderate disability	13 (23.2%)	13 (23.2%)	12 (21.4%)
41-60% Severe disability	24 (42.9%)	24 (42.9%)	22 (39.3%)
61-80% Crippled	15 (26.8%)	12 (21.4%)	12 (21.4%)
81-100% Bed-bound (exaggerating)	2 (3.6%)	1 (1.8%)	2 (3.6%)
HAD Anxiety			
0-7 Normal	23 (41.1%)	26 (46.4%)	27 (48.2%)
8-10 Borderline	13 (23.2%)	13 (23.2%)	12 (21.4%)
≥ 11 Abnormal	20 (35.7%)	17 (30.4%)	17 (30.4%)
HAD Depression			
0-7 Normal	25 (44.6%)	32 (57.1%)	32 (57.1%)
8-10 Borderline	16 (28.6%)	12 (21.4%)	12 (21.4%)
≥ 11 Abnormal	15 (26.8%)	12 (21.4%)	12 (21.4%)

ODI, Oswestry Disability Index; HAD, Hospital Anxiety and Depression

Predictors of pain reduction (Table 3)

At stage 1 of the regression analysis the demographic variables did not significantly predict pain reduction at 12-months follow-up ($R = 0.341$, adjusted R -square = 0.116; $F(3,53) = 2.320$, $p = 0.086$). With the addition of the psychological variables at stage 2 the overall model was significant ($R = 0.498$, adjusted R -square = 0.248; $F(7,49) = 2.310$, $p = 0.041$). The examination of the individual regression coefficients at stage 2 indicated that both the variables age at time of implant ($Beta = 0.330$, $t(49) = 2.576$, $p = 0.013$) and ACS factor score ($Beta = 0.329$, $t(49) = 2.206$, $p = 0.032$) were significant predictors of pain reduction following 12-months of SCS.

Table 3. Predictors of pain reduction

Baseline predictors of pain at 12-months				
Stage	Predictor	Standardised Coefficients (Beta)	t	P
1	Sex	-0.054	0.421	0.676
	Age at time of implant	0.324	2.452	0.018
	Duration of pain prior to implant	-0.186	-1.409	0.165
2	Sex	0.023	0.184	0.855
	Age at time of implant	0.33	2.576	0.013 *
	Duration of pain prior to implant	-0.213	-1.618	0.112
	HAD anxiety	0.23	1.373	0.176
	HAD depression	-0.152	-0.83	0.411
	Cognitive and Behavioural Strategies Component	0.009	0.072	0.943
	Autonomous Coping Component	0.329	2.206	0.032 *
Summary statistics				
Model 1: R=0.341, R2=0.116, F(3,53)=2.320, p=0.086				
Model 2: R=0.498, R2=0.248, F(7,49)=2.310, p=0.041 *				

* p < 0.05

Predictors of improvement in ODI scores (Table 4)

Demographic variables entered at stage 1 of the regression analysis did not significantly predict ODI improvement at 12-months (R = 0.246, adjusted R-square = 0.061; F(3,53) = 1.140, p = 0.341). The psychological predictors entered at stage 2 generated a significant model (R = 0.579, adjusted R-square = 0.336; F(7,49) = 3.538, p = 0.004). The examination of the individual regression coefficients at stage 2 showed that the variables duration of pain prior to implant (Beta = 0.320, t(49) = 2.583, p = 0.013) and HAD depression (Beta = 0.470, t(48) = 2.728, p = 0.009) were significant predictors of ODI reduction at 12-month follow-up.

Table 4. Predictors of improvement in ODI scores

Baseline predictors of ODI at 12-months				
Stage	Predictor	Standardised Coefficients (Beta)	t	P
1	Sex	-0.082	-0.615	0.541
	Age at time of implant	-0.152	-1.117	0.269
	Duration of pain prior to implant	0.212	1.556	0.126
2	Sex	-0.118	-0.987	0.328
	Age at time of implant	-0.101	-0.841	0.404
	Duration of pain prior to implant	0.32	2.583	0.013 *
	HAD anxiety	0.028	0.176	0.861
	HAD depression	0.47	2.728	0.009 *
	Cognitive and Behavioural Strategies Component	-0.087	-0.713	0.479
	Autonomous Coping Component	-0.069	-0.489	0.627
Summary statistics				
Model 1: R=0.246, R2=0.061, F(3,53)=1.140, p=0.341				
Model 2: R=0.579, R2=0.336, F(7,49)=3.538, p=0.004 **				

* p < 0.05; ** p < 0.005

DISCUSSION

This study demonstrates that SCS may provide statistically and clinically significant improvements in pain intensity and disability. Moreover, we observed that characteristics such as duration of pain prior to implant, age at time of implant and psychological characteristics including depression and autonomous coping (control over pain, ability to reduce pain and catastrophising) may impact on the outcome of SCS treatment based on pain intensity and disability. A recent study has found self-efficacy to impact on longer-term outcomes for SCS and depression and anxiety to have no significant impact (32). Previous studies have suggested similar concepts such as dispositional optimism and activity engagement aspect of acceptance as having an impact on reduction of perceived pain (33,34). These concepts describe a situation where patients do not allow pain to influence

every aspect of their lives. Self-efficacy, activity engagement and dispositional optimism can be likened to the autonomous coping factor (control over pain, ability to decrease pain and catastrophising) which was a significant factor in the current study.

The autonomous coping factor which comprises the variables PCSQ control over pain, PCSQ ability to decrease pain and PCSQ catastrophising was predictive of pain reduction at 12-months. This finding suggests that patients with increased perceived control over pain and ability to decrease pain alongside lower levels of catastrophising at baseline achieve greater reductions in pain following 12-months of SCS. High levels of catastrophising have previously been associated with increased pain intensity and poor treatment efficacy (13,14,35). Catastrophising alone has not been found to be a predictor SCS outcome in a recent study (36). The authors however stated that the lack of effect may have been due to the fact that almost all patients scored highly on the catastrophising scale. Catastrophising may increase pain intensity as patients maintain attention to their pain, which results in rumination and subsequent magnification of painful sensations (15). Catastrophising is also likely to interrelate with decreased perceptions of control over pain and ability to decrease pain. Control over pain and catastrophising have been reported as the most common psychological factors associated with the onset and continuation of chronic pain (13-16).

Age at time of implant and duration of pain prior to implant were found to impact upon reductions in pain and ODI scores. Older participants obtained higher pain reduction and decreased disability following 12 months of SCS. When investigating postoperative pain reports, it was observed that younger patients report higher levels of pain (37,38). This may be related with the higher expectations younger individuals may have regarding a treatment. Nevertheless, contradictory findings have been reported with increased aged correlating negatively with percentage of pain change three months following SCS implantation (39) or no role of age in predicting the outcome of SCS (40). Additional research is required to further elucidate the potential role of age in SCS outcome. Previous research has observed duration of pain to influence reduction of pain following implantation of the SCS (40). We do not intend to suggest that SCS should come earlier in the pain treatment algorithm, as many patients will obtain good pain relief with more conservative treatments. However, the time spent assessing if a patient's pain relief is satisfactory before proceeding to the next therapy should be decreased.

The HAD depression score was found to be a significant predictor of reduction in disability at 12-months but not a predictor of pain reduction. Previous studies have observed that depression is associated and impacts upon the experience and perception of pain

(10,16,41). However, we did not assess if the patients' depression was state or trait. A 'trait' is recognised as a stable personality characteristic whereas a 'state' is a temporary personality feature in response to environmental circumstances. A recent systematic review of psychological characteristics impacting upon SCS suggested that depression associated with the onset of pain may not be a complete contraindication for SCS (12). However, pre-morbid depression to the onset of pain may reduce the efficacy of SCS. An additional systematic review suggested that psychological factors such as somatization, depression, anxiety, and poor coping, are important predictors of poor outcome (42).

There is good support for psychological factors affecting pain from both clinical work, neuroimaging, and also for SCS affecting pain at higher centres, including the anterior cingulate cortex (43-45). It is therefore reasonable to hypothesise that the pain relief achieved and psychological outcome are linked. Our focus was on constitutional psychological factors and their impact upon outcome. We can only conjecture as to the possible mechanisms. A neurochemical basis could explain less responsiveness due to greater diffuse noxious inhibitory control. A positive trial phase may occur due to an early placebo effect. The mechanisms of SCS however are still not completely understood (46,47).

This study has limitations which could be addressed by future research. It has been reported that loss of analgesia may be experienced within 12-24 months following SCS implantation and therefore, it would be of interest to follow-up patients over a longer period. We did not collect information from the notes on other treatments implemented or changes in medication. At this centre oral rescue medication has been provided to the patients on an individual basis to cope with occasional flare-ups. Moreover, all of these patients have previously tried and failed more conservative options for the management of their pain. Therefore, systemic medication as well as other interventions that might have been undertaken during the study period would be occasional to cope with flare-ups and would therefore have limited impact in the results verified. Collecting information about the patients average daily use of SCS would also allow to produce a more comprehensive report on the patients pain relief profile and investigate associations between psychological characteristics and average usage of SCS. Twelve patients were lost to follow-up. All of the patients were contacted prior to a follow-up to attend a review clinic to assess if the SCS is working adequately and data collection would occur at this time. The patients who were lost to follow-up were contacted several times to attend this clinic but failed to respond on all occasions. It would be beneficial to distinguish whether impacting psychological variables are state or trait as research investigating predictors of pain intensity in patients scheduled for elective

abdominal surgery found that whilst state anxiety was a significant predictor of pain intensity, trait anxiety was not (48). Trait depression may impact upon long-term efficacy of SCS but needs further investigation. State depression should not be considered as contraindicative for implantation as it may improve with successful SCS. We did not include patients with unrealistic expectations of the treatment and unrealistic beliefs surrounding their pain as assessed by a multidisciplinary team including a clinical psychologist. Beliefs and expectations are associated with psychological variables and the inclusion of these patients could potentially lead to clearer psychological predictors of pain relief. However, the inclusion of these patients is currently not recommended and would carry ethical concerns considering the invasiveness of therapy and unlikely patient benefit.

In conclusion, this study has observed that psychological characteristics such as depression and autonomous coping strategies may influence and predict the long-term efficacy of SCS. Also age at time of implant and duration of pain prior to implant were found to impact upon SCS outcome. Support for patients with low autonomous coping strategies and long standing depression prior to implant may prove efficacious to long-term SCS outcome.

REFERENCES

1. Breivik H, Collett B, Ventafridda V, Cohen R, Gallacher D. Survey of chronic pain in Europe: Prevalence, impact on daily life, and treatment. *Eur J Pain* 2006; 10: 287-333.
2. Smith BH, Macfarlane GJ, Torrance N. Epidemiology of chronic pain, from the laboratory to the bus stop: time to add understanding of biological mechanisms to the study of risk factors in population-based research? *Pain* 2007; 127: 5-10.
3. Shealy CN, Mortimer JT, Reswick JB. Electrical inhibition of pain by stimulation of the dorsal columns: preliminary report. *Anesth Analg* 1967; 46: 489-491.
4. Raphael JH, Mutagi HS, Kapur S. Spinal cord stimulation and its anaesthetic implications. *Contin Educ Anaesth Crit Care Pain* 2009; 9: 78-81.
5. Linderoth B, Foreman RD. Physiology of spinal cord stimulation: Review and update. *Neuromodulation* 1999; 2: 150-164.
6. Yakhnitsa V, Linderoth B, Meyerson BA. Spinal cord stimulation attenuates dorsal horn neuronal hyperexcitability in a rat model of mononeuropathy. *Pain* 1999; 79: 223-233.
7. Kupers RC, Van den Oever R, Van Houdenhove B, Vanmechelen W, Hepp B, Nuttin B, Gybels JM. Spinal cord stimulation in Belgium: a nationwide survey on the incidence, indications and therapeutic efficacy by the health insurer. *Pain* 1994; 56: 211-216.
8. Cameron T. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: 20 year literature review. *J Neurosurg* 2004; 100: 254-267.

9. Deer T, Masone RJ. Selection of spinal cord stimulation candidates for the treatment of chronic pain. *Pain Med* 2008; 9: S82-S92.
10. Doleys DM. Psychological factors in spinal cord stimulation therapy: brief review and discussion. *Neurosurg Focus* 2006; 21: E1.
11. Turk DC, Audette J, Levy RM, Mackey SC, Stanos S. Assessment and treatment of psychosocial comorbidities in patients with neuropathic pain. *Mayo Clin Proc* 2010; 85: S42-50.
12. Sparkes E, Raphael JH, Duarte RV, LeMarchand K, Jackson C, Ashford RL. A systematic literature review of psychological characteristics as determinants of outcome for spinal cord stimulation therapy. *Pain* 2010; 150: 284-289.
13. Jensen MP, Turner JA, Romano JM. Changes in beliefs, catastrophizing, and coping are associated with improvement in multidisciplinary pain treatment. *J Consult Clin Psychol* 2001; 69: 655-662.
14. Spinhoven P, Ter Kuile MM, Linssen AC, Gazerdam B. Pain coping strategies in a Dutch population of chronic low back pain patients. *Pain* 1989; 37: 77-83.
15. Sullivan MJ, Rodgers WM, Kirsch I. Catastrophizing, depression and expectancies for pain and emotional distress. *Pain* 2001; 91: 147-154.
16. Turk DC, Okifuji A. Psychological factors in chronic pain: evolution and revolution. *J Consult Clin Psychol* 2002; 70: 678-690.
17. NICE Technology Appraisal Guidance 159. *Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin*. London: National Institute for Health and Clinical Excellence, 2008.
18. Price DD, McGrath PA, Rafii A, Buckingham B. The validation of Visual analogue scales as ratio scale measures for chronic and experimental pain. *Pain* 1983; 17: 45-56.
19. Gift A. Visual analogue scales: measurement of subjective phenomena. *Nurs Res* 1989; 38: 286-288.
20. McCormack HM, Horne DJ, Sheather S. Clinical applications of visual analogue scales: a critical review. *Psychol Med* 1988; 18: 1007-1019.
21. Farrar JT, Young JP Jr, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain* 2001; 94: 149-158.
22. Dworkin RH, Turk DC, Wyrwich KW, Beaton D, Cleeland CS, Farrar JT, Haythornthwaite J, Jensen MP, Kerns RD, Ader DN, Brandenburg N, Burke LB, Cella D, Chandler J, Cowan P, Dimitrova R, Dionne R, Hertz S, Jadad AR, Katz NP, Kehlet H, Kramer LD, Manning DC, McCormick C, McDermott MP, McQuay HJ, Patel S, Porter L, Quessy S, Rappaport B, Rauschkolb C, Revicki D, Rothman M, Schmader KE, Stacey BR, Stauffer JW, von Stein T, White RE, Witter J, Zavisic S. Interpreting the clinical importance of

- treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. *J Pain* 2008; 9: 105-121.
23. Fairbank JC, Pynsent PB. The Oswestry Disability Index. *Spine* 2000; 25: 2940-2952.
 24. McDowell I, Newell C. *Measuring health: A guide to rating scales and questionnaires*. New York: Oxford University Press, 1996.
 25. Davidson M, Keating JL. A comparison of five low back disability questionnaires: reliability and responsiveness. *Phys Ther* 2002; 82: 8-24.
 26. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983; 67: 361-370.
 27. Bjelland I, Dahl AA, Haug TT, Neckelmann D. The validity of the Hospital Anxiety and Depression Scale. An updated literature review. *J Psychosom Res* 2002; 52: 69-77.
 28. Mykletun A, Stordal E, Dahl AA. Hospital Anxiety and Depression (HAD) scale: factor structure, item analyses and internal consistency in a large population. *Br J Psychiatry* 2001; 179: 540-544.
 29. Rosentiel AK, Keefe FJ. The use of pain coping strategies in chronic low back pain patients: relationship to patient characteristics and current adjustment. *Pain* 1983; 17: 33-44.
 30. Main CJ, Waddell G. A comparison of cognitive measures in low back pain: statistical structure and clinical validity at initial assessment. *Pain* 1991; 46: 287-298.
 31. Snow-Turek AL, Norris MP, Tan G. Active and passive coping strategies in chronic pain patients. *Pain* 1996; 64: 455-462.
 32. Wolter T, Fauler I, Kieselbach K. The impact of psychological factors on outcomes for spinal cord stimulation: an analysis with long-term follow-up. *Pain Physician* 2013; 16: 265-275.
 33. Scheier MF, Carver CS. Optimism, coping, and health: Assessment and implications of generalized outcome expectancies. *Health Psychol* 1985; 4: 219-247.
 34. Bargiel-Matusiewicz K, Krzyzkowska A. Dispositional optimism and coping with pain. *Eur J Med Res* 2009; 14 Suppl 4: 271-274.
 35. Smeets RJ, Vlaeyen JW, Kester AD, Knottnerus JA. Reduction of pain catastrophizing mediates the outcome of both physical and cognitive-behavioral treatment in chronic low back pain. *J Pain* 2006; 7: 261-271.
 36. Lamé IE, Peters ML, Patijn J, Kessels AG, Geurts J, van Kleef M. Can the outcome of spinal cord stimulation in chronic complex regional pain syndrome type I patients be predicted by catastrophizing thoughts? *Anesth Analg* 2009; 109: 592-599.
 37. Perry F, Parker RK, White PF, Clifford PA. Role of psychological factors in postoperative pain control and recovery with patient-controlled analgesia. *Clin J Pain* 1994; 10: 57-63.

38. Svensson I, Sjöström B, Haljamäe H. Influence of expectations and actual pain experiences on satisfaction with postoperative pain management. *Eur J Pain* 2001; 5: 125-133.
39. Burchiel KJ, Anderson VC, Wilson BJ, Denison DB, Olson KA, Shatin D. Prognostic factors of spinal cord stimulation for chronic back and leg pain. *Neurosurgery* 1995; 36: 1101-1110.
40. Kumar K, Hunter G, Demeria D. Spinal cord stimulation in treatment of chronic benign pain: challenges in treatment planning and present status, a 22-year experience. *Neurosurgery* 2006; 58: 481-496.
41. Vlaeyen JW, Linton SJ. Fear-avoidance and its consequences in chronic musculoskeletal pain: a state of the art. *Pain* 2000; 85: 317-332.
42. Celestin J, Edwards RR, Jamison RN. Pretreatment psychosocial variables as predictors of outcomes following lumbar surgery and spinal cord stimulation: a systematic review and literature synthesis. *Pain Med* 2009; 10: 639-653.
43. Beauregard M. Mind does really matter: evidence from neuroimaging studies of emotional self-regulation, psychotherapy, and placebo effect. *Prog Neurobiol* 2007; 81: 218-236.
44. Lidstone SC, Stoessl AJ. Understanding the placebo effect: contributions from neuroimaging. *Mol Imaging Biol* 2007; 9: 176-185.
45. Kishima H, Saitoh Y, Oshino S, Hosomi K, Ali M, Maruo T, Hirata M, Goto T, Yanagisawa T, Sumitani M, Osaki Y, Hatazawa J, Yoshimine T. Modulation of neuronal activity after spinal cord stimulation for neuropathic pain; H(2)15O PET study. *Neuroimage* 2010; 49: 2564-2569.
46. Oakley JC, Prager JP. Spinal cord stimulation: mechanisms of action. *Spine* 2002; 27: 2574-2583.
47. Prager JP. What does the mechanism of spinal cord stimulation tell us about complex regional pain syndrome? *Pain Med* 2010; 11: 1278-1283.
48. Granot M, Lavee Y. Psychological factors associated with perception of experimental pain in vulvar vestibulitis syndrome. *J Sex Marital Ther* 2005; 31: 285-302.