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Is refractory angina pectoris a form of chronic pain? A comparison of two patient groups receiving spinal cord stimulation therapy

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Abstract

Aim To compare psychological and pain-related characteristics of patients with chronic pain and patients with refractory angina pectoris who had been treated with spinal cord stimulation (SCS) therapy.

Method Twenty-four patients receiving SCS therapy were interviewed. Four psychological variables were assessed using standardised questionnaires for pain catastrophising, health locus of control, anxiety sensitivity, and self-efficacy. Patients also completed the revised version of the Short-Form McGill Pain Questionnaire, the Short-Form Health Survey, and self-reported measures of global perceived effect, pain, functionality, and satisfaction with SCS therapy.

Results Most patients reported improvements in pain, functionality, and improvement overall. Some health locus of control dimensions were significantly higher for the angina group than the chronic pain group, and chronic angina patients reported significantly lower levels of intermittent pain. Virtually all patients reported being satisfied with SCS therapy.

Conclusion Most self-rated psychological and pain-related characteristics were no different between the two groups, which gives some support to the view that refractory angina is a form of chronic pain. The results also add to evidence supporting the use of SCS therapy for refractory angina pectoris; however, differences observed on a few variables may indicate points of focus for the assessment and treatment of such patients.

Spinal cord stimulation (SCS) therapy has been used for over four decades in a variety of chronic pain conditions and for over two decades in refractory angina pectoris. The UK-based National Institute for Clinical Excellence (NICE) has recommended SCS therapy for chronic neuropathic pain conditions but not for refractory angina,[1] because, for the latter, randomised controlled trial evidence shows that SCS therapy is merely equivalent to coronary artery bypass grafting (CABG)[2] and percutaneous myocardial laser revascularisation.[3] This is an interesting perspective, given that the risks of CABG surgery are considerably greater than those of SCS.[2]

In New Zealand, patients with chronic pain and patients with refractory angina pectoris have been treated with SCS therapy in pain clinics for at least the past 15 years. In these clinics, prior to commencing SCS therapy, patients with chronic pain are typically assessed for intensive (e.g., three-week, full-time) pain management programmes consisting of education, relaxation training, and activation components.

In some cases, by contrast, patients with refractory angina pectoris may progress to SCS therapy without undergoing any psychological assessment or undertaking a pain management programme. However, given that several psychological characteristics that correlate with chronic pain may influence the outcomes of SCS therapy despite technical success,[4] it is worth asking whether this approach allows adequate opportunity to identify patients with refractory angina pectoris who may not respond well to SCS therapy.

As with other chronic pain conditions, it has been shown that cognitive-behavioural interventions for refractory angina pectoris can improve symptoms and quality of life[5] as well as reduce hospitalisations and myocardial infarctions.[6] While these studies add value as examples of applied research that addresses alternative treatment options for these patients, they also raise the theoretical question of whether refractory angina pectoris may be considered within the spectrum of chronic pain conditions. If so, this may place more emphasis on the importance of the psychological assessment of patients with refractory angina pectoris and may have implications for clinical pathways in treating the condition.

The aim of this study was to provide a descriptive account of psychological and pain-related characteristics of two patient groups receiving SCS therapy: patients with refractory angina pectoris and patients with chronic pain. We were interested in assessing variables that have been shown to predict aspects of functioning and outcomes in patients with chronic pain, and we also took the opportunity to assess levels of satisfaction with SCS therapy.

Method

Participants—Patients who had received SCS implantation through The Auckland Regional Pain Service (TARPS) in Auckland, New Zealand before the end of September 2010 and who were still using it were invited to participate in the study. The inclusion period ran from July 1991 through to September 2010, and there were no exclusion criteria for patients other than their decision to not participate.

Thirty-four out of a total of 57 patients were eligible to participate in the study. Exclusions included 13 patients who had stimulators inserted over the trial period but had discontinued using them (5 patients with chronic pain and 8 with refractory angina pectoris) and 10 angina patients who had since deceased. Of the 34 patients who met the inclusion criteria, 24 agreed to take part—12 patients with chronic pain, 12 with refractory angina pectoris. Patients who were unwilling to take part in the study cited poor health (n=4) and personal reasons (n=2), and of the four remaining non-participating patients, two were unable to take part because of pending surgery and overseas travel, respectively, and the remaining two were unable to be contacted by the researchers.

Procedure—The study was approved by the New Zealand Ministry of Health Northern Y Regional Ethics Committee (NTY/09/114/EXP). Eligible patients were contacted by mail and telephone and were invited to participate in the study. Participation involved an interview of approximately two hours in length at Mercy Hospital in Auckland. Patients' travel expenses were reimbursed through research donations provided by Medtronic and Advanced Neuromodulation Systems (ANS). The interviews were conducted by a medical student (NP) trained in interview methods by a clinical psychologist (MHJ), who also monitored the first day of interviews. Neither researcher was involved in the clinical management of the participants.

During the interviews, participants completed a questionnaire comprising various standardised measures to assess pain relief, quality of life, functionality, and a selection of psychological characteristics. After their interview, patients were offered the opportunity to be seen by the SCS nurse specialist for an adjustment of their stimulator and to discuss any unresolved issues if necessary. The research nurse was also present and available to provide assistance if required at all times during the interviews. Once all data were collected, analysis was conducted using SPSS statistical software. All

statistical tests conducted in the analysis were two-tailed, and statistical significance was considered to be established at the .05 level.

Measures

Pain Catastrophising Scale (PCS)[7]—The PCS is a 13-item questionnaire that assesses pain catastrophising—the disposition to negatively evaluate pain and one's ability to deal with it—which has been linked to higher levels of psychological distress and pain-related disability.[7] Patients are asked to indicate the degree to which particular thoughts and feelings are associated with their experience of pain on a 5-point Likert-type scale (0=not at all; 4=all the time). Item scores are summed to give an assessment of pain catastrophising (range=0–52), and scores for subscales measuring rumination, magnification, and helplessness are yielded similarly by summing the relevant items.

Pain catastrophising scores of 30 or more are considered clinically relevant, as 70% of chronic pain patients scoring above 30 describe themselves as totally occupationally disabled, and 66% report moderate depression.[8] Good to excellent levels of reliability and validity have been reported for the measure (including subscales) among chronic pain populations.[9]

Pain Self-Efficacy Questionnaire (PSEQ)[10]—Self-efficacy is a measure of confidence that someone has in his or her ability to engage in a course of action sufficient to achieve a desired outcome.[11] High self-efficacy has been correlated with lower pain, less psychological distress, and better outcomes to medical treatments.[10]

Comprising 10 items, the PSEQ assesses patients' confidence in accomplishing daily activities while in pain. Responses are made on a seven-point rating scale (0=not confident at all; 6=completely confident), and a final score is produced by summing all responses (range=0–60), with higher scores signifying stronger pain self-efficacy beliefs. Normative data from a large sample of patients with chronic pain show mean PSEQ scores ranging from 24.9 to 28.5, depending on the site of the pain, and an overall mean of 25.5 across all patients.[12] Studies have reported evidence of construct validity and excellent internal consistency in research involving patients with chronic pain.[13,14]

Anxiety Sensitivity Index (ASI)[15]—The 16-item ASI assesses beliefs about the harmful consequences of anxiety-related symptoms (i.e., anxiety sensitivity: the fear of anxiety and related sensations that arise from the belief that these sensations can have harmful physical, psychological, or social consequences).[16] Each item—a statement relating to a possible negative consequence (e.g., fear, embarrassment, etc.) of the experience of anxiety—is rated by patients on a five-point scale (0=very little; 4=very much).

Summing the scores of the items gives a final score of sensitivity to anxiety (range=0–64), with normative data indicating an overall ASI mean of around 19.0 among European and American samples.[17] Higher scores on the ASI in patients with persistent pain have been shown to be associated with greater disability, pain, and distress;[18] higher scores are also related to higher fear of pain, which in turn is linked to reduced activity and movement.[19] Research into the psychometric properties of the ASI has revealed high internal consistency (α=.88), with factor and correlational analyses demonstrating meaningful construct independence from standard measures of anxiety.[16]

Multidimensional Health Locus of Control (MHLC)[20]—The 18-item MHLC (Form C) measures individuals' beliefs about the extent to which they are able to control the status of their health—that is, whether control beliefs are oriented towards factors that are internal or external (i.e., *chance*, *doctors*, and *other people*).[21] The MHLC requires respondents to score each item, a statement about their health, on a six-point Likert-type scale (1=strongly disagree; 6=strongly agree). Scores are summed for each of the four Form C subscales (ranges=6–36 for the *internality* and *chance* subscales and 3–18 for the *doctors* and *other people* subscales).

High scores on a particular subscale indicate stronger representations of the related locus of control—higher scores on the *internality* subscale, for example, represent stronger beliefs that one's health status is largely influenced by personal factors, indicating that these individuals are more likely to take responsibility for their own health, while high *doctors* and *other people* scores suggest the individuals are more likely to believe that interventions by others will be necessary to manage their health. Since publication, the MHLC has been used widely, with a majority of studies showing good support for the validity, reliability, and the multidimensional structure of the measure.[21-23]

Demographic and other pain-related variables—The study questionnaire also comprised some standard, psychometrically robust measures commonly used in pain research. Patient disability was assessed using the physical functioning scale of the Short-Form Health Survey (SF-36),[24] a widely used

health-related quality-of-life measurement tool that incorporates assessments of physical and mental health status. Sensory and affective dimensions of pain experience were measured with the 22-item revised version of the Short-Form McGill Pain Questionnaire (SF-MPQ-2),[25] which has been validated for both neuropathic and non-neuropathic pain conditions. In addition, we collected data on a range of demographic variables (age, gender, and ethnicity), and, using three seven-point scales (1=completely recovered; 7=worse than ever), self-reported perceptions of global effectiveness, pain, and functionality in relation to SCS therapy were also measured (e.g., "How would you rate your level of function now compared with before you had your spinal cord stimulator inserted?").

Finally, as an assessment of patients' satisfaction with SCS therapy, two dichotomous items on patients' willingness to (1) go through the procedure again and (2) have their spinal cord stimulator repaired (should the need arise) were also included in the study questionnaire.

Results

Patient information across the two groups is displayed in Table 1.

Table 1. Patient information (demographic and spinal cord stimulation [SCS]-related data) across the two study groups

Demographic data	Patient group	
	Pain (n=12)	Angina (n=12)
Male	10	11
Age, M (range)	56.3 (37–79)	66.2 (48–81)
Ethnicity		
New Zealand European	9	8
Māori	1	–
Other European	–	3
Indian	1	1
Not specified	1	–
SCS therapy data		
Stimulation months, *M (range)*	51 (6–222)	37 (6–150)
Complication-free patients	3	3
Total complications, *n*	14	16
Total procedures, *n*	35	40
Procedures following SCS insertion		
Stimulator inserted	12	12
Battery replacement	6	12
Stimulator replacement	4	7
Trial lead inserted	6	1
Other procedures	3	1
Lead replacement	1	3
Lead revision	1	3
Stimulator removed	2	1
SCS complications		
Infection of stimulator site	3	4
Technical problems with stimulator	4	1
Unsatisfactory coverage, reprogrammed	2	3
Undesired stimulation effects	2	2
Lead migration	1	1
Stimulator unit caused discomfort	2	–

Note: Except where indicated, values represent number of participants.

In general, the two groups were fairly evenly matched in demographic and SCS-related variables, including procedures on SCS and experience of SCS-related complications. They were also well balanced in respect of their perception of the effects of SCS and in their satisfaction with this therapy (see Table 2). However, patients with refractory angina pectoris were, on average, older than patients with chronic pain (mean difference of 11.4 years, p=0.03), and while all but one of the patients with chronic pain had a formal psychological assessment prior to stimulator insertion, no patients with angina underwent such assessment.

Table 2. Pain characteristics (pain experience, self-reported disability) and patient-perceived spinal cord stimulation [SCS]-related outcome variables across the two study groups

Characteristic	Patient group		P value
	Pain	Angina	
SF-MPQ-2 subscales			
Continuous, *M (SEM)*	18.25 (4.20)	10.67 (3.42)	0.18
Intermittent, *M (SEM)*	15.08 (5.08)	3.33 (1.98)	0.05*
Neuropathic, *M (SEM)*	13.92 (3.37)	9.00 (2.26)	0.24
Affective, *M (SEM)*	12.75 (3.45)	7.17 (1.37)	0.15
Total score, *M (SEM)*	60.00 (13.81)	30.17 (8.43)	0.08
SF-36			
Physical functioning, *M (SEM)*	18.09 (1.96)	17.33 (1.26)	0.74
Perceived effects of SCS therapy			
Improved overall	11	12	
Improved pain	9	11	
Improved functionality	9	12	
Patient satisfaction with SCS therapy			
Would repeat the procedure	10	12	
Would have repairs done	12	12	

Note: Except where indicated, values represent number of participants. SF-MPQ-2=revised version of the Short-Form McGill Pain Questionnaire; SF-36=Short-Form Health Survey. *p=0.05.

Five patients in the chronic pain group participated in a clinic-administered pain management programme, which focussed on education, relaxation, and activation across an intensive 3-week period. No patients with refractory angina pectoris underwent such a programme.

Pain characteristics (see Table 2) were mostly comparable across the two patient groups: between-group differences in subscale scores of the SF-MPQ-2 were not observed for most of the measure's pain dimensions (i.e. continuous pain, neuropathic pain, and affective descriptors). However, patients with chronic pain reported experiencing significantly more intermittent pain than patients with angina (15.08 vs. 3.33, p<0.05). Levels of disability (*physical functioning* scale of the SF-36) were similar across the two groups—18.09 for patients with chronic pain and 17.33 for patients with refractory angina pectoris.

In the questionnaire, patients were asked to rate their perceptions of the effect of SCS. To assist analysis, we split participants' responses (which were made on seven-point scales) into two categories: (1) *improved*, which incorporated responses of

'completely recovered', 'much improved', and 'slightly improved' (scores 1–3 on the scale) and (2) *not improved*, which combined the 'no change', 'slightly worsened', 'much worsened', and 'worse than ever' responses (scores 4–7).

Results showed that perceptions of the efficacy of SCS therapy were mostly favourable: with few exceptions, the majority of patients in both groups reported improvement overall (global effect) since beginning SCS therapy; likewise, most patients in both groups reported improvements in pain and functionality. Patient satisfaction with SCS therapy was high across both groups, with nearly all patients indicating they would repeat the procedure and would have their spinal cord stimulator repaired (e.g., new lead inserted) if the need arose. Two patients in the chronic pain group indicated they would not undergo the procedure again.

Analysis of the psychological characteristics data (see Table 3) revealed many parallels between the two patient groups. Specifically, no significant between-group differences were found with regard to pain catastrophising, self-efficacy, and anxiety sensitivity. It is worth noting, however, that PCS scores for patients with refractory angina pectoris appeared to be approaching clinical significance cut-offs for pain catastrophising.

Between-group differences were observed for some of the MHLC subscales: the *chance* dimension of the MHLC was significantly higher in the angina group than in the chronic pain group (14.08 vs. 20.09, p=0.01), indicating that patients with refractory angina pectoris were more likely to hold beliefs about fate and luck as determinant factors of their pain condition and outcomes. The same trend was found for the *doctors* subscale, where significantly higher scores (which indicate stronger beliefs that health status is predominantly influenced or determined by doctors and medically trained professionals) were observed among patients with refractory angina pectoris (11.46 vs. 15.08, p=0.01).

Table 3. Psychological characteristics (pain catastrophising, self-efficacy, anxiety sensitivity, and health locus of control) across the two study groups

Characteristic	Patient group		P value
	Pain	Angina	
Pain catastrophising (PCS)	16.08 (4.01)	23.33 (3.29)	0.18
Self-efficacy (PSEQ)	34.92 (4.06)	33.42 (3.44)	0.78
Anxiety sensitivity (ASI)	17.42 (3.63)	18.83 (3.03)	0.77
Health locus of control (MHLC subscales)			
Internality	26.42 (1.25)	26.08 (1.07)	0.84
Chance	14.08 (1.00)	20.09 (1.82)	0.01
Powerful others	20.83 (1.74)	24.50 (2.10)	0.19
Doctors	11.46 (1.18)	15.08 (0.65)	0.01
Other people	11.27 (1.02)	11.75 (1.04)	0.75

Note: Values represent means, with standard error of the mean in parentheses. PCS=Pain Catastrophising Scale; PSEQ=Pain Self-Efficacy Questionnaire; ASI=Anxiety Sensitivity Index; MHLC=Multidimensional Health Locus of Control.

Discussion

In this study we used a range of psychometrically robust measures to assess important pain and psychological characteristics of two patient groups receiving SCS therapy. For the most part, between-group differences in self-reported disability and pain experience across the dimensions of the SF-MPQ-2 could not be detected in the data—the only exception being the results from the *intermittent* subscale, where patients with refractory angina pectoris reported significantly less intensity with regard to intermittent-type symptoms (e.g., 'shooting pain', 'sharp pain'). Virtually all patients reported improvements following insertion of their spinal cord stimulators and indicated that they would repeat the procedure or repair their spinal cord stimulator if the need arose.

Our results show many parallels between these two patient groups in terms of psychological characteristics. Specifically, we found no differences in pain catastrophising, self-efficacy, or anxiety sensitivity, with both groups demonstrating, on average, at least moderate ratings on the respective measures (although it is noteworthy that pain catastrophising scores were approaching clinical significance among the angina group). We did, however, find some key differences in some dimensions of health locus of control: analysis revealed significantly higher scores on the *chance* and *doctors* subscales among patients with refractory angina pectoris. These findings indicate stronger beliefs that health status is predominantly influenced or determined by particular externality-related factors.

Taken together, these data indicate that the two patient groups shared many similarities where psychological characteristics are concerned, and the findings perhaps give some support to the view that refractory angina pectoris lies somewhere in the spectrum of the chronic pain syndrome and may therefore be amenable (at least in terms of its psychological sequelae) to integrated psychological-based pain management interventions.[5,6]

Research involving patients with angina has shown that maladaptive beliefs about angina appear to have a negative effect on functional and psychological outcomes.[26] Such findings, along with the controversial view that refractory angina pectoris could be conceptualised as a chronic pain condition, not only challenge assumptions about conventional clinical pathways for patients with refractory angina pectoris, they also support the call for considering, as is the case with other chronic pain conditions, the integration of psychological and educational treatment approaches.[27,28]

The differences between the groups, where observed, perhaps have some implications for specific health outcomes, particularly for patients with refractory angina pectoris. The MHLC provides an assessment of expectancies associated with health status and health care, and the measure has been demonstrated to be a good predictor of health behaviours[29] and recovery.[30] Patients with refractory angina pectoris reported significantly higher scores on two subscales related to externality, and this raises an interesting research question of whether these relatively greater externality beliefs among these patients might be related to poorer health outcomes, as has been shown in other pain-related conditions.[31,32]

The pain catastrophising results, although not entirely conclusive, at least raise the possibility that among patients with refractory angina pectoris there could be a

tendency towards maladaptive cognitive and emotional coping responses to pain, particularly in terms of rumination and feelings of helplessness (e.g., 'ticking time bomb' beliefs). While we remain cautious about overstating any unfounded implications of these data, we are of the view that they do at least suggest that such patients would most likely benefit from psychological assessment prior to SCS implantation, as is typically done in the case of patients with chronic pain conditions. And while interventions tailored specifically for this group of patients may have benefits for their symptoms and quality of life,[5,6] further research into pain catastrophising among patients with refractory angina pectoris is needed to warrant its inclusion as a theme of intervention in any such programme. The same caveat could also extend to the health locus of control dimensions mentioned above or any other putatively important psychological characteristics for that matter.

There are some limitations to consider regarding the generalizability of the study findings, chiefly because, first, the chronic pain group comprised patients across a number of different conditions and, second, because of the small number of study participants. Indeed, the small sample size is a major limitation that restricts the extent to which strong conclusions can be drawn from the data. Nevertheless, it is worth highlighting that even though the sample of patients was relatively small for both groups, we were yet able to detect significant differences in a few psychological and pain-related characteristics. And even though it may well be that there are other important differences that exist and that the present study was not sufficiently powered to detect, the differences that were observed may suggest topics of research involving patients with refractory angina pectoris.

In conclusion, the similar patterns in psychological characteristics give some credence to the view that refractory angina is a form of chronic pain, and this supports (but also raises some interesting questions about) psychological-based treatment for these patients. Therefore, while it is encouraging that studies involving patients with refractory angina pectoris have reported positively on the effects of psychological-based interventions that are modelled on interventions for chronic pain, the results from the present study suggest that perhaps such programmes could be enhanced by addressing some of the unique psychological and pain-related characteristics of these patients.

Competing interests: Nil.

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