The Effects of Spinal Cord Stimulation on Quality of Life in Patients with Therapeutically Chronic Refractory Angina Pectoris

Nienke C. C. Vulink* ▪ Deirdre M. Overgaauw* ▪ Gillian A.J. Jessurun, MD† ▪ Inge A.M. TenVaarwerk, RN† ▪ Thomas J. B. Kropmans, PT‡ ▪ Cees P. van der Schans, PT, PhD‡ ▪ Berrie Middel Msc§ ▪ Michiel J. Staal, MD, PhD¶ ▪ Mike J. L. DeJongste, MD, PhD‡

**Faculty of Medical Sciences, Departments of †Cardiology, ‡Rehabilitation/Physical Therapy, and ¶Neurosurgery, University Hospital of Groningen, and §Northern Center for Health Care Research, Faculty of Medical Sciences, University of Groningen, Groningen, The Netherlands*

■ ABSTRACT

Objective. For patients with refractory angina pectoris, spinal cord stimulation (SCS) is a beneficial and safe adjuvant therapy. However, it has not yet been established whether SCS alters the quality of life (QoL) in these patients.

Methods. In this study, 26 consecutive patients (age 61.3 ± 7.0 years, 13 females, angina duration 12.7 ± 6.0 years) were recruited. Social, mental, and physical aspects of QoL were determined by Nottingham Health Profile (NHP I), depression scale (CES-D), scoring of angina pectoris attacks and short-acting nitroglycerine intake, pain score on the Visual Analog Scale (VAS), perceived health percentage, Satisfaction With Life scale (SWLS), and one-aspect Linear Analog Self Assessment scale (LASA). QoL outcomes at baseline were compared with reference values from healthy subjects. Within-group changes and magnitude of changes (effect size, ES) were assessed after 3 months and 1 year of SCS.

Results. Compared to healthy subjects, the patients had significantly worse scores at baseline on NHP, SWLS, and LASA. After 3 months of SCS, NHP I aspect pain (ES = 1.39), AP-score (ES = 0.85), perceived health percentage (ES = – 0.80), NTG-use (ES = 1.08) and VAS-score (ES = 1.13) were all significantly improved ($p < 0.05$). After 3 months, moderate changes were observed; however, they were not statistically significant on the NHP-aspects ``emotion'' (ES = 0.57) and ``sleep'' (ES = 0.56). At the 1-year follow-up, significant and substantial improvements were found on NHP-I aspects: pain, energy, emotional reactions, social isolation, sleep, and physical mobility ($p < 0.05$) with changes that can be interpreted as large (ES > 0.80).

Conclusion. QoL in patients with refractory angina pectoris is poor. Both pain and health aspects of QoL improved significantly after 3 months of SCS. Social, mental, and physical aspects of QoL were found improved after 1 year of SCS. ■

KEY WORDS: Angina pectoris, quality of life, spinal cord stimulation.

Reprint requests to Mike J.L. DeJongste, MD, PhD, Department of Cardiology. Thoraxcenter, University Hospital of Groningen, P.O. Box 30.001, 9700 RB Groningen. The Netherlands. E-mail: M.J.L.De.Jongste@Thorax.AZG.NL

In patients with significant coronary artery disease (CAD) (*i.e.*, stenosis > 70%), myocardial ischemia is provoked when myocardial oxygen consumption exceeds myocardial oxygen supply. Subsequently, an anxious feeling (angina) in the chest (pectoris)

may be elicited. Mitchell et al. (1) investigated health-related Quality of Life (QoL) in healthy subjects, hypertensive patients, patients with CAD, and patients with both CAD and hypertension. Significant differences between these four groups were found in health-related QoL with respect to pain, physical mobility, energy, and social isolation. In general, patients suffering from moderate to severe angina pectoris, New York Heart Association (NYHA) class II or III, had reduced scores on aspects (mental, social, and physical well-being) of QoL compared to healthy subjects. (1-3) Moreover, the health-related scores in patients with angina pectoris were found to be inversely related to the NYHA classification. (2) In addition, patients with severe angina pectoris appear to have higher scores on psycho-social and emotional expression than patients with less severe angina pectoris. (4)

To date, the majority of patients with angina pectoris can be treated adequately with medication and revascularization (bypass surgery and percutaneous transluminal coronary angioplasty) procedures. However, there remains a group of patients on optimal anti-anginal therapy with severe angina pectoris who are not suitable for revascularization. Any therapy that improves the QoL in these patients without adversely influencing the life expectancy is worth considering. Spinal cord stimulation (SCS) may be an effective therapy for patients with this so-called refractory angina pectoris. The mechanism of action of SCS can be explained by the *gate control theory* (5) as a model for nociception. The theory implies that activation of large afferent non-nociceptive myelinated type-A fibers inhibit pain input mediated by smaller unmyelinated type-C fibers into the dorsal horn of the spinal cord. Since 1967, electrical stimulation of the dorsal spinal cord has been used as an adjuvant therapy in chronic pain syndromes. In general, the objective of stimulation of the spinal cord is to attenuate the discomfort by provoking paresthesia in the same area.

Previous studies have shown that SCS provides an anti-anginal effect with increased exercise capacity in conjunction with a reduction in ischemia and a reduction in NTG intake. (6-14)

Information is scarce, however, concerning the influence of SCS on both mental state and QoL in patients suffering from refractory angina pectoris. We speculate that SCS improves the QoL of patients suffering from therapeutically refractory angina pectoris.

In a group of patients with stable refractory angina pectoris treated with SCS, we studied the QoL longitudinally. The purpose of this study was to investigate changes in QoL in patients with intractable angina during a 1-year follow-up period of SCS, with baseline references to healthy subjects.

METHODS

Twenty-six consecutive patients(13 male, 13 female) with a mean age of 61.3 (SD ± 7.0) years (range: 46–75 years) participated in this study. The patients had suffered from angina pectoris for an average of 12.7 ± 6.0 years. Left ventricle ejection fraction was >40 in 88.5% of the patients, 42.3% of the patients had experienced a myocardial infarction, and 80.8% of the patients had undergone a revascularization procedure (Table 1).

Patients (baseline characteristics, Table 1) were included in our study if they fulfilled all of the following criteria: severe angina pectoris, class III or IV of the New York Heart Association despite optimal

Table 1. Patient Characteristics at Study Enrollment (n = 26)

Patient Characteristics		# Patients	% Patients
Men		13	50.0
Women		13	50.0
Mean age (SD)	61.3 (7.0)		
Mean number of years suffering from AP (SD)	12.7 (6.0)		
LVEF > 40		23	88.5
# VD	0	1	3.8
	1	1	3.8
	2	6	23.1
	3	18	69.2
Previous MI		11	42.3
Previous revascularization		21	80.8
# PTCA	0	17	65.4
	1	5	19.2
	2	3	11.5
	4	1	3.8
# CABG	0	8	30.8
	1	12	46.2
	2	4	15.4
	3	2	7.7

▫ Abbreviations: SD, standard deviation; #, number; % patients, percentage of patients; AP, angina pectoris; MI, myocardial infarction; LVEF, left ventricular ejection fraction; VD, vessel disease; PTCA, percutaneous transluminal coronary angioplasty; CABG, coronary artery bypass grafting.

pharmacological anti-anginal treatment, resulting from angiographically documented significant coronary artery disease; not suitable for revascularization procedures; in conjunction with reversible myocardial ischemia. Exclusion criteria for SCS were: short ($\leq$ 1 year) life expectancy, cognitive impairment, small vessel disease, vasospastic angina pectoris, expected insurmountable technical problems, artificial cardiac pacemaker dependency, and inappropriate use of opiates/drugs. Written informed consent was required.

The study was approved by the Hospital Ethical Committee.

After baseline measurements, the SCS device was implanted in patients according to a standard protocol.(10) The SCS induces paresthesia through application of a magnet. Health-related QoL was assessed at baseline, after 3 months, and after 1 year. Patients were instructed to stimulate 1 h, 3 times per day and during anginal attacks. The SCS was set at a 210-ms pulse width, 85 cycles/s, using continuous square wave pulses with individually tailored current. (5)

Assessment of Quality of Life

Two weeks before the patients visited the Department of Cardiology, they received a diary, a questionnaire, instructions and a covering letter. To encompass the different aspects of QoL as thoroughly as possible, several methods were used. An independent investigator coded the self-administered diaries and questionnaires and entered the data into a computer.

The impact of health problems on different aspects of QoL was measured by the Nottingham Health Profile (NHP). (15) Several studies have indicated that this is a useful and valid questionnaire assessing perceived health as well as aspects of QoL. (16-17) The NHP comprises two parts. The first part (NHP-I) consists of 38 statements which are weighted and categorized as either energy, pain, emotional reactions, social isolation, sleep, or physical mobility aspects. The total score of each aspect ranges between 0 and 100. A higher score reflects more health-related problems. (18) The second part (NHP-II) is related to factors not likely to be influenced by the therapy. Therefore, we did not include this part in the assessment.

We used as reference values for the NHP-I a random sample from a population of healthy subjects with a mean age of 68 (SD $\pm$ 4.0) years, as determined in a study by Mitchell et al. (1)

Emotional well-being of the patients was assessed among others, making use of the Center for Epidemiological Studies Depression (CES-D) Scale. (19) The CES-D scale comprises 20 questions: 16 questions related to feelings of mental depression (negative questions) and 4 questions related to the absence of feelings of mental depression (positive questions). All questions refer to the situation during the last week. There are four possible answers for each question: seldom or never (less then one day), sometimes (1–2 days), regularly (3–4 days) and often or always (5–7 days). The total CES-D score ranges from 0 to 60. A CES-D score of greater than 16 often indicates depression. Reference values for the CES-D obtained from a random sample out of the Northern provinces of the Netherlands were used. This sample consisted of 255 healthy persons between 55 and 64 years.(20) In a random sample of a normal population a score $\geq$ 16 was found in 20% of respondents.

QoL was further quantitated using the Dutch version of the Satisfaction With Life Scale (SWLS) (21) and the Linear Analog Self Assessment scale (LASA, 1-item version). (22)

The SWLS assesses the overall satisfaction with the respondents' general QoL. The SWLS contains five statements related to satisfaction with life in general. The respondent can indicate to what extent he or she agrees with the statement. Seven answers are possible, ranging from total disagreement to total agreement with the statement. The total score of the SWLS ranges from 5 to 35. A high score reflects high satisfaction with life in general. The LASA (1-item version) is a linear analog self assessment scale of 10 cm. The respondents are asked to give an indication of their overall QoL on a horizontal line with a length of 10 cm, as a continuum with the left extreme position indicating "the worst possible situation" (a score of 0) and the right extreme position indicating "the best possible situation" (a score of 10).

A high score reflects a good perceived QoL. As controls (N = 2663) for LASA and SWLS we used the values from a random sample Dutch population of one million male inhabitants obtained from a study by Ranchor et al. (23)

Four variables were measured by a daily account of the patient over a 2-week period:

1. the VAS-score is a pain-score on a scale ranging from 1 to 10;
2. NTG-use is defined as the amount of NTG tablets taken per day;

Table 2. Baseline Outcomes AP-Patients versus Healthy Controls[a]

		AP-patients		Healthy controls		Wilcoxon	
Scale	Range	median (min/max)	n	mean (SD)	n	z-value	p-value
NHP I							
energy	0–100	65.2 (6.0–100.0)	24	3.8 (11.2)	76	−4.357	0.000[b]
pain	0–100	45.5 (16.0–100.0)	17	4.8 (12.2)	76	−3.624	0.000[b]
emotion	0–100	25.3 (18.0–80.7)	20	2.9 (7.4)	76	−3.950	0.000[b]
social isolation	0–100	10.0 (10.0–68.7)	24	0.9 (4.4)	76	−4.560	0.000[b]
sleep	0–100	42.7 (10.0–100.0)	24	15.9 (21.9)	76	−3.331	0.001[b]
physical mobility	0–100	49.9 (16.0–80.7)	23	3.2 (6.6)	76	−4.207	0.000[b]
CES-D	0–60	10.0 (1.3–36.3)	22	7.0 (6.2)	255	−1.770	0.077
SWLS	5–35	21.0 (5.0–35.0)	23	26.9 (6.6)	2663	−2.556	0.011[c]
LASA	0–10	5.0 (0.7–9.8)	23	6.9 (2.0)	2663	−2.890	0.004[b]

[a] Abbreviations: min, minimum score; max, maximum score; n, number of patients; SD, standard deviation; NHP I, Nottingham health profile I; CES-D, Centre for Epidemiological Studies depression; SWLS, satisfaction with life scale; LASA, linear analog self assessment scale.

[b] *P*-value < 0.01 using Wilcoxon matched pairs-signed ranks test.

[c] *P*-value < 0.05 using Wilcoxon matched pairs-signed ranks test.

3. health percentage is the patient's rating of experienced health on a scale 0% to 100%;
4. the AP-score is the number of attacks of angina per day.

From these variables the mean scores within the 2-week period of each patient were used in the statistical analysis to estimate the daily impact of the disease. Missing data during this 2-week period were replaced by the mean score, calculated by using the completed diary days with a minimum registration of 10 days. The mean number of missing diary days was 1.2 (8.5%).

Statistical Analyses

Analyses have been performed with SPSS/PC +, version 7.0.1 (SPSS Inc., Chicago, IL)**.** Descriptives are given as means, standard deviation, median, minimum and maximum-score, and within-group effect size. Differences between the group of angina pectoris patients and the mean (SD) reference values were analyzed using Wilcoxon signed-rank test. Intra-individual differences between the values obtained at baseline, 3-month and 1-year of treatment were analyzed using Wilcoxon matched-pairs signed-rank test, using only cases with no missing data of the analyzed variable at any time. A *p*-value < 0.05 was considered statistically significant.

To estimate the responsiveness, the ability of an instrument to detect the magnitude of change over time within one group, we used Cohen's effect size statistic **d** for paired observations. (24) As the variance of the post-test measure is partly explained by the pre-test scores, estimating the magnitude of the change between baseline and post-test in the treated group requires adjustment of the effect size **d′** for the correlation (r) between the scores of paired observations.

$$d = \frac{d'}{\sqrt{1-r}} \quad d' = \frac{\bar{X}_{\text{baseline}} - \bar{X}_{\text{outcome}}}{SD(X_{\text{baseline}}\ X_{\text{outcome}})}$$

where d′ = effect size = mean change/pooled SD baseline and post-test score; d = effect size adjusted for r; and r = correlation coefficient.

An effect size of 0.20 has to be interpreted as a small effect; an effect size of 0.50, a medium effect; and an effect size of > 0.80, a large effect. (21-25)

RESULTS

Angina Pectoris Patients vs. Healthy Subjects

Compared to references values of QoL in healthy subjects (Table 2), baseline scores of patients with intractable angina were significantly worse on all NHP-I aspects (higher score): energy ($p = 0.000$), pain ($p = 0.000$), emotion ($p = 0.000$), social isolation ($p = 0.000$), sleep ($p = 0.001$), physical mobility ($p = 0.000$), SWLS(lower score) ($p = 0.011$) and LASA (lower score) ($p = 0.004$). In contrast, CES-D scores did not differ significantly when compared to the reference values of healthy controls *($p = 0.077$).*

Changes in Quality of Life After a Period of SCS

After 3 months of SCS, a significant and substantial improvement was observed on the NHP-I aspect of pain ($p = 0.009$; ES = 1.39), angina pectoris score ($p = 0.021$; ES = 0.85), perceived health percentage ($p = 0.032$; ES = – 0.080), NTG use ($p = 0.010$; ES = 1.08), and VAS-scores ($p = 0.004$; ES = 1.13) (Tables 3 and 4). Although not statistically significant, there was a moderate effect size on NHP aspects "emotion" (ES = 0.57, $p = 0.162$) and "sleep" (ES = 0.56, $p = 0.091$). After 1 year of SCS a significant improvement was observed on NHP-I aspects: pain ($p = 0.002$), energy ($p = 0.007$), social isolation ($p = 0.002$), emotional reactions ($p = 0.005$), sleep ($p = 0.007$) and, physical mobility ($p = 0.044$) with effect sizes ≥ 0.80, except for the NHP aspect "energy" (ES = 0.68) and "social

Table 3. Mean and Median Patient Scores at Baseline, After 3-months Treatment and After 1-year Treatment[a]

Dimension		Baseline		3-months-treatment		1-year-treatment	
	n	Mean (SD)	Median (min/max)	Mean (SD)	Median (min/max)	Mean (SD)	Median (min/max)
AP	18	3.5 (2.5)	2.3 (1.0/9.5)	2.2 (1.6)	1.9 (0.0/6.6)	3.2 (3.0)	2.2 (0.3/11.1)
Health %	20	60.0 (22.1)	61.0 (8.0/92.0)	71.4 (10.5)	72.5 (46.0/93.0)	65.7 (10.5)	70.5 (27.0/90.0)
NTG-use	16	3.3 (3.0)	2.5 (0.0/9.3)	1.6 (1.8)	0.9 (0.0/6.5)	2.9 (1.8)	2.5 (0.0/6.5)
VAS	20	3.8 (2.1)	3.2 (0.7/7.4)	2.5 (1.5)	2.5 (0.0/6.0)	3.2 (1.9)	3.2 (0.0/6.0)
CES-D	19	13.0 (9.7)	10.0 (1.3/36.3)	10.6 (2.3)	10.0 (0.0/30.0)	10.5 (8.7)	8.8 (0.0/30.0)
NHP Emotion	15	32.5 (17.7)	25.3 (18.0/80.7)	28.0 (10.8)	25.3 (18.0/58.8)	15.7 (20.4)	9.3 (0.0/74.0)
Energy	20	63.4 (39.1)	65.2 (6.0/100.0)	57.3 (35.2)	65.2 (6.0/100.0)	51.1 (41.2)	62.0 (0.0/100.0)
Physical	19	48.1 (23.5)	49.9 (16.0/80.7)	46.3 (23.0)	49.9 (16.0/90.5)	35.7 (28.1)	47.8 (0.0/87.3)
Pain	13	48.0 (24.8)	45.5 (16.0/100.0)	28.8 (11.6)	29.1 (16.0/44.1)	15.3 (20.7)	5.8 (0.0/69.8)
Sleep	20	45.4 (31.1)	42.7 (10.0/100.0)	34.3 (26.6)	30.4 (10.0/100.0)	31.8 (33.2)	22.4 (0.0/100.0)
Social	21	15.7 (14.2)	10.0 (10.0/68.7)	16.4 (12.5)	10.0 (10.0/48.1)	7.7 (18.6)	0.0 (0.0/80.6)
LASA	21	5.3 (2.2)	5.0 (0.7/9.8)	4.8 (2.1)	4.4 (1.5/9.0)	5.3 (2.2)	4.4 (0.7/9.8)
SWLS	17	21.4 (8.9)	21.0 (5.0/35.0)	21.4 (8.7)	22.0 (6.0/35.0)	20.9 (10.2)	22.0 (5.0/35.0)

[a] Abbreviations: n, number of patients; SD, standard deviation; min, minimum score; max, maximum score.

Table 4. Effect-size, Pearsons Correlation, and Wilcoxon Matched-Pairs Signed-ranks Test Measuring Differences between Baseline Results and 3-months/1-year Treatment[a]

Dimension		Baseline-3-months treatment				Baseline-1-year treatment			
				Wilcoxon				Wilcoxon	
	n	Effect size	r	z-value	p-value	Effect size	r	z-value	p-value
AP	18	0.85	0.52	−2.31	0.021[b]	0.11	0.10	−4.36	0.663
Health %	20	−0.80	0.41	−2.15	0.032[b]	−0.37	0.33	−1.07	0.287
NTG-use	16	1.08	0.66	−2.59	0.010[b]	0.35	0.76	−0.80	0.426
VAS	20	1.13	0.67	−2.92	0.004[c]	0.41	0.48	−1.27	0.204
CES-D	19	0.44	0.61	−1.28	0.199	0.50	0.70	−1.75	0.079
NHP Emotion	15	0.57	0.80	−1.40	0.162	1.41	0.62	−2.79	0.005[b]
Energy	20	0.28	0.67	−0.92	0.360	0.68	0.80	−2.68	0.007[b]
Physical	19	0.15	0.69	−0.41	0.699	0.80	0.65	−2.01	0.044[c]
Pain	13	1.39	0.64	−2.62	0.009[c]	2.42	0.66	−3.11	0.002[b]
Sleep	20	0.56	0.54	−1.69	0.091	0.84	0.75	−0.27	0.007[b]
Social	21	−0.06	0.24	−0.04	0.715	0.51	−0.10	−3.06	0.002[b]
LASA	21	0.29	0.44	−1.21	0.225	0.02	1.00	−1.00	0.317
SWLS	17	−0.01	0.74	0.00	1.000	0.11	0.80	−0.44	0.660

[a] Abbreviations: n, number of patients; Effect size, within group effect size; r, Pearson's correlations; Wilcoxon, Wilcoxon matched-pairs signed-ranks for paired observations.

[b] *P*-value < 0.01 using Wilcoxon matched-pairs signed-rank test.

[c] *P*-value < 0.05 using Wilcoxon matched-pairs signed-rank test.

isolation" (ES = 0.51). Compared to baseline, the change in CES-D score was not statistically significant after 3-months and 1-year follow-up, however, after 1 year a moderate effect size (ES = 0.50, p = 0.079) was observed. Moreover, CES-D score was ≥ 16 in 22.8% of the patients at baseline, after 3 months, and after 1-year follow-up.

DISCUSSION

The results of our study demonstrated that all aspects of QoL, expressed in physical, social, and psychological well-being, are poor in patients with therapeutically refractory angina pectoris when compared to healthy subjects. (1,3) In addition, our study indicates that after a period of SCS significant improvements can be achieved in QoL indices of patients with angina pectoris refractory to conventional therapies.

Our Hospital Ethical Committee did not allow us to implant a SCS device in a control group and not activate the device for 1 year, only to exclude an "operation bias". Therefore, our study does not unambiguously show whether the improvements in QoL we found can be specifically ascribed to SCS. Since the majority of the patients were stable, suffering from angina pectoris for over 10 years, the beneficial influence of SCS is suggestive. Furthermore, it is known from the literature that a placebo effect tends to decrease over time. This finding is in favor of an independent beneficial long-term influence of SCS on QoL. However, further randomized control studies are needed to confirm the favorable effect of interventions such as SCS on QoL in patients with severe angina pectoris refractory to conventional therapies.

In view of the course of coronary atherosclerotic disease it is most likely that angina pectoris yields to both physical problems and an affected mental state. However, an alternative explanation is that poor psychological well-being induces complaints related to angina pectoris and health-related problems. The latter has been reported for chronic musculo-skeletal pain. Musculo-skeletal pain may cause mental depression, and mental depression may induce musculo-skeletal pain. (26)

After three months of SCS all anginal pain-related indices were improved. In agreement with these findings, a remarkable improvement was noted in the aspect of pain of NHP-I, albeit that only 13 of the 26 patients completed the pain-related questions on the NHP-I. The pain-related aspect of the NHP-1 may have been incompletely scored by the patients as a result of the yes/no (dichotome) mode of questioning. With the exception of the NHP-1 subscale of pain, incomplete data were a minor problem in the variables associated with the occurrence of anginal pain (NTG use, angina pectoris score, health percentage, and VAS-pain score)

The elements of health-related QoL (social, emotional, physical, sleep, and energy) of the NHP did not show a significant improvement after 3 months of SCS, although the patients' emotions and sleep pattern were moderately affected.

There are two possible explanations for the discrepancy among the scores on NHP-I for pain and the remaining NHP-I aspects. First, with the exception of the aspect of pain of NHP-I, the improvement in outcomes of NHP-I indices was flawed by the lack of sensitivity of NHP-I to detect alterations after three months. A disease-specific instrument would probably have been more sensitive in assessing changes over time. The second explanation is that SCS induces instantaneous pain relief, influencing pain scores more quickly than the other items. This reflects a direct alteration in anginal pain by the SCS, necessary to enhance the ensuing improvement of other QoL aspects of the NHP-I.

After one year, all NHP-I aspects demonstrated statistically significant changes over time with effect sizes ranging from 0.51 (moderate) to 2.42 (large). With the exception of the aspect of pain of the NHP-I, a significant and substantial improvement no longer was observed for all indices that had been significantly changed at 3 months.

This may reflect an alteration in the patient's condition as a consequence of the improvement in pain and health. After 1 year of SCS, the patient has become accustomed to the reduced level of pain and subsequently the social, physical, and mental aspects of QoL become more significant outcome measures. The number of anginal attacks, NTG use, and VAS-pain score have less of an impact on the patient's situation and are no longer expressed as significant and substantial improvement. Further studies are needed to investigate the incidence, prevalence, and severity of symptoms of depression in patients with severe angina pectoris.

Finally, the CES-D, SWLS and LASA scores did not change significantly. Apparently, these question-

naires are less sensitive to detect changes over time in this patient group. Referring to the nature of refractory angina pectoris, it is worth including quality of life assessment in future intervention studies with SCS.

CONCLUSIONS

Based on the above, we propose that patients with intractable angina pectoris be considered as "chronic pain" patients. This point of view may possibly anchor new therapeutic approaches. Potential beneficial interventions should be developed in order to break through the negative vicious cycle of invalidating pain leading to social isolation. From our and other studies we may conclude that SCS as an adjuvant treatment for patients with refractory angina pectoris improves these patients' quality of life. Finally, one of the patients expressed exactly how many patients feel about the SCS treatment, "SCS makes me feel like I can master my angina pectoris."

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