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Original Research Article

Refractory Chronic Pain Screening Tool (RCPST): A Feasibility Study to Assess Practicality and Validity of Identifying Potential Neurostimulation Candidates

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An international panel of pain specialists and research methodologists developed a screening tool to identify patients who may be suitable for spinal cord stimulation. Based on this feasibility study, the tool is considered practical for routine clinical practice and contains appropriate questions, but sensitivity may need to be improved.

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The Work Group, comprised of R. Baron, M. Backonja, P. Eldridge, R. Levy, K. Vissers, and R. Taylor, acted on behalf of the full panel and advised on all aspects of the study.

Abstract

Objective. An international panel of pain specialists (anesthesiology, neurology, neurosurgery, and psychology) and research methodologists developed a screening tool to identify patients who may be suitable for spinal cord stimulation (SCS)—the Refractory Chronic Pain Screening Tool (RCPST) prototype. We describe a feasibility study to explore practicality and validity of this prototype.

Design. Consecutive outpatients were screened in two centers (United Kingdom and United States). Sixty chronic pain adults without satisfactory pain relief despite treatment were assessed using RCPST (by pain specialist without expertise in neurostimulation) and then evaluated by two pain specialists experienced in SCS implantation and management to determine whether the patient should be referred for SCS. To maintain blinding, the participating physicians did not inform each other or the patient of assessment outcome. Sensitivity and specificity of the RCPST prototype were calculated using implanters' judgment as "gold standard."

Results. The average age of patients was 47.7 years; 53% were female. Fifty-seven patients completed the study (one withdrew consent, two lost to follow-up). The pain specialists agreed the prototype was easy to use and took <10 minutes to complete. Implanter agreement was moderate (Kappa: 0.63, 95% confidence interval: 0.35–0.91). The prototype had low sensitivity (40%, 19–61%) and moderate specificity (78%, 65–92%). Using the same questionnaire with a modified decision algorithm, new prototypes were generated with range of high sensitivity (80–100%) and specificity (89–97%) values.

Conclusions. The RCPST aims to identify patients that should be referred for consideration for neurostimulation. The final implant decision requires appropriate neurological diagnostic workup, psychological assessment, and trial stimulation. RCPST was considered practical for routine clinical practice and contained appropriate questions. Sensitivity needs to be improved. A future study should select and validate the ideal RCPST prototype.

Key Words. Neurostimulation; Screening; Refractory Pain; Neuropathic Pain; Validation

Introduction

In recent years, we have experienced major developments in the pharmacological and conservative management of chronic pain. This is particularly true for medications effective in neuropathic pain states, defined as "Pain caused by a lesion or disease of the somatosensory nervous system" [1]. Systematic reviews and guidelines for the drug treatment of neuropathic pain are now available [2–4]. Despite these advances, however, only 30–40% of patients across all neuropathic entities achieve sufficient pain relief and improvement in quality of life even though all evidence-based pharmacological strategies have been tried in adequate doses and for sufficient duration [5]. In the remaining patient population of "non-responders," a continued pharmacological rotation is often performed, which fails to produce the desired pain relief or induces intolerable side effects. These patients suffer from pharmaco-resistant neuropathic pain [5]. Ineffective pharmacological treatment and continued prescription of one drug after another is not only a considerable cost but may also lead to additional patient anxiety and frustration.

While regulatory approval varies from country to country, evidence supports the use of spinal cord stimulation (SCS) for a number of chronic pain conditions including neuropathic pain secondary to failed back surgery syndrome and complex regional pain syndromes (CRPS) type I, if pharmacological strategies fail and the pain is pharmaco-resistant [5–9]. Algorithms for patient selection in SCS have been proposed [10–12]. Nevertheless, many pharmaco-resistant patients are not referred (or with significant delay) to centers trained for implanting SCS devices and are not considered for interventional therapies, probably at least in part because scientific strategies on how to identify the appropriate patients are not available [13].

We therefore set out to develop an easy-to-use screening tool to identify patients with refractory neuropathic pain or CRPS type 1 who might be suitable for consideration for SCS therapy. It is not intended for this tool to identify responders to neurostimulation therapy but rather to identify those patients who should be considered for neurostimulation and thus receive normal pre-implant workup, such as in depth neurological examination, psychological assessment, and trial stimulation.

In accordance with guidelines for good clinical research, we sought to undertake a two-stage approach to the evaluation of the screening tool. Before undertaking a definitive evaluation study, we first sought to formally develop the tool and undertake a study to address issues of validation feasibility [14,15]. This paper describes the Refractory Chronic Pain Screening Tool (RCPST) development and a feasibility study undertaken to assess the practicality and validity of the RCPST and the practical aspects of undertaking this validation study design.

Methods

Development of the RCPST

The RCPST was developed by an international panel of pain specialists consisting of three implanting neurosurgeons, seven implanting anesthesiologists, four referring neurologists, a psychologist, and an epidemiologist, all with expertise in the field of neuropathic pain and neurostimulation.

The RCPST was designed to match pain specialists experienced in SCS implantation's decision to evaluate a patient for neurostimulation trial and to have the following properties:

- be physician-administered and easy to use
- use both physical and sensory bedside examination to identify neuropathic pain
- address both pain intensity and refractoriness to pain interventions
- have a minimum sensitivity of 80% and specificity of 60% compared with a "gold standard" (as defined below)

During two face-to-face meetings of the panel in 2007 and 2008, the content of the tool was developed based on:

- common components of all published neuropathic pain screening tools [16–18]
- best discriminators of neuropathic pain [19,20]
- a review of the evidence for treatment of neuropathic pain [2,12] to identify when a patient was suffering from refractory neuropathic pain
- expert judgment of panel members who implant and manage SCS patients regarding which symptoms are typically present at baseline in successfully implanted neuropathic pain patients

The resulting tool consisted of 14 items: a single screening question on generalized pain plus 13 questions grouped according to the following three domains:

1. Assessment of neuropathic pain descriptors (N = 4)
2. Physical bedside examination for sensory function in painful area (N = 3)
3. Assessment of refractoriness to pharmacotherapy (N = 6)

During 2008–2009, the tool was refined following interviews with 24 neurostimulation implanters/referrers, and based on results from a pilot study in four sites from Europe and the United States that applied the tool to 37 chronic pain patients (for more details, see Supporting Information Appendix S1). For most questions and bedside tests, one of three responses is chosen where each response has an associated score. The panel defined the total score for sections 1–3 as the sum of all individual scores and a cut-off value for a patient to be referred as a total score of at least 4 out of 14 for sections 1–3.

Feasibility and Validation Study

Aims and Design

In 2010, a validation feasibility study was launched in two centers: one in the United Kingdom (Dr. Jones, Mr. Crossman, and Mr. Jenkins at the Newcastle upon Tyne Hospitals National Health Service Foundation TRUST of Freeman Hospital in Newcastle), and one in the United States (Dr. Finnegan, Dr. Talbott, and Dr. Webster of Lifetree Clinical Research® in Salt Lake City, Utah). In accordance with previous screening tool validation studies, the "gold standard" employed in this study was expert clinical judgment of the implanters [22–28]. The specific aims of this study were: 1) to assess the practicality and acceptability of using the RCPST questionnaire (i.e., the questions themselves) to clinicians; 2) to assess the practical aspects of the validation study design; and 3) to assess the performance of the RCPST prototype (i.e., the proposed decision tree/flow chart derived from the questionnaire) in terms of its specificity and sensitivity against a "gold standard."

Participants

Consecutive adults (>18 years) attending a routine outpatient visit were screened. Patients were included based on the following criteria: 1) treated on an ongoing basis without satisfactory pain relief; 2) diagnosed with chronic pain for at least 1 year; 3) able to understand and follow study requirements; and 4) provide informed consent prior to any study specific screening procedures. Patient were excluded if they: 1) were participating or planning to participate in an investigational drug or device study that might impact RCPST questionnaire response; 2) had any condition or situation which, in the investigator's opinion, put the patient at significant risk, could confound the study results, or could interfere significantly with the patient's participation in the study; or 3) were implanted with an SCS system.

Given this was a feasibility study the number of included patients was not determined by a formal power calculation. To address the study feasibility objectives, we sought 50 complete patient data sets. Allowing for an attrition rate of 15–20%, a total of 60 patients were therefore enrolled across two sites (30 patients per site).

Study Flow and Procedures

The Institutional Review Board or Ethics Committee at each site approved the protocol.

Each patient was first assessed by a pain specialist without expertise in neurostimulation ("RCPST Evaluator") using the RCPST questionnaire (for more details, see Supporting Information Appendix S2) and then independently by two pain specialists experienced in SCS implantation ("Clinical Assessors") to determine whether the patient should be referred to an implanter clinician for consideration of neurostimulation. For every patient and for each of the three assessments, a decision of "refer yes" or "refer no" was recorded. In addition, the implanters completed a visual analogue scale (VAS) indicating their level of confidence in their assessment decision. As a change in treatment may influence the "refractoriness" aspect of the RCPST, clinical assessors were asked not to take into account any change in the patient's treatment as the RCPST assessment took place when making their decision. The order of the two clinical assessments was randomized. To ensure blinding, the RCPST evaluator and clinical assessors did not inform each other or the patient of the assessment outcome. The study flow and procedures are summarized in Figure 1.

During the study, any protocol deviation or any particular difficulty occurring in the patient assessment was recorded. Each RCPST evaluator completed a satisfaction questionnaire twice (after the first 15 patients and after the remaining 15 patients had been evaluated at that site). The RCPST evaluator was asked to report his or her overall experience using the RCPST questionnaire, the key criteria to define whether or not a patient should be referred for consideration of neurostimulation, and his or her opinion on the practicality of the study protocol. At the end of the study, each clinical assessor completed a satisfaction questionnaire reporting his or her overall opinion on the practicality of the validation study protocol and the key criteria to define whether or not a patient should be referred for consideration of neurostimulation.

Methods and Data Analysis

1. Practicality of the RCPST questionnaire was evaluated through review of missing data and the investigator satisfaction questionnaire.
2. Practical aspects of the study design were assessed through protocol deviations, enrolment duration, patient withdrawals, and agreement between referrals and investigator satisfaction. Agreement between the referral decisions ("refer yes" vs "refer no") of the two assessors was assessed by the Kappa statistic.
3. The sensitivity and specificity of the RCPST were determined by cross-tabulating the RCPST referral decisions for each patient with the clinical assessment referral decision for that patient. Where there was disagreement between clinical assessors, the referral decision made with the greatest confidence level was retained for this analysis (referred to as "unified clinical assessment"). Sensitivity and specificity values were also calculated in the subgroup of patients for whom the two clinical assessors were in agreement. Given the feasibility objective of the study, a number of sensitivity and specificity values were also computed for different RCPST scoring algorithms (RCPST prototypes) based on the answers to the medication section of the questionnaire that collects information on patients' past and current pain treatment and clarifying generalized pain. We focused our sensitivity analysis on the pain medication for two reasons—first, the patient self-report nature of these data, and second, the lack of consen-

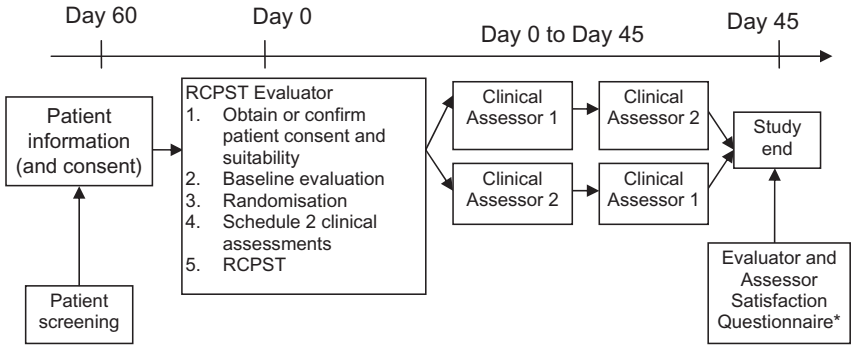

Figure 1 Study flow and procedures.
*The RCPST evaluators were asked to complete the RCPST evaluator satisfaction questionnaire twice: once after 15 patients, once at the end of the study. The clinical assessors were only asked to complete the assessor's satisfaction questionnaire at the end of the study.

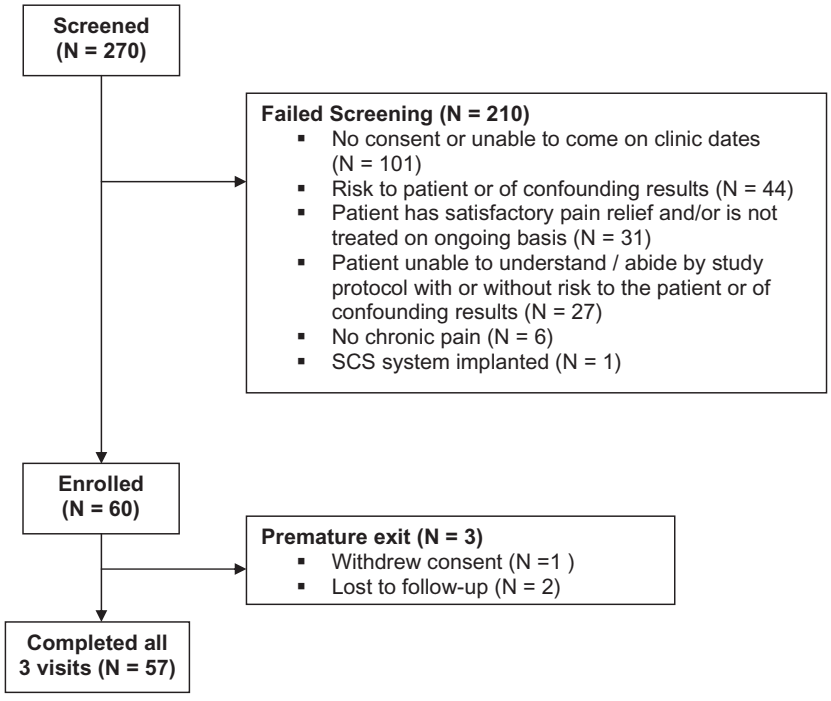

Figure 2 Patient flow.

sus on what formally constitutes pharmaco-resistance. Additionally, segmentation analyses (CART method [29]) that use a decision tree approach rather than a scoring system were used to derive prototypes to optimize RCPST sensitivity and specificity. All statistical analyses were conducted using SAS version 9.2 (SAS Institute Inc., Cary, NC, USA).

Results

Between November 2009 and March 2010, 270 chronic pain patients treated on an ongoing basis without satisfactory pain relief were screened to enroll 60 patients. The principal reasons for failed screening were that patients did not consent to study participation or were unable to come to the clinic to undergo assessments. Three patients prematurely exited the study after the RCPST evaluator visit (one patient withdrew consent and two were lost to follow-up). Fifty-seven patients therefore completed the study (see Figure 2).

Study Population

The mean age of enrolled patients was 47.7 years (standard deviation [SD] 12.7) and 53% were female. The mean duration of pain was 12.1 years (SD 9.5 years) with a mean pain severity (on 0–100 scale) of 76.2 (SD 11.5). Fifty-seven percent of patients were suffering from back and/or leg pain and 13% from a form of generalized pain (fibromyalgia or osteoarthritis/rheumatoid arthritis; Table 1a). Most (83%) patients were taking tramadol and/or opioids (Table 1b). Nonsteroidal anti-inflammatory drugs, tricyclic antidepressants/serotonin–norepinephrine reuptake inhibitors and antiepileptic drugs were each currently taken by at least 30% of patients. Patients had also utilized several nondrug therapies in the past (Table 1c), most of which were physical rehabilitation (73%) and block (50%).

Table 1a Enrolled population characteristics

	N = 60
Age in years—mean (SD)	47.7 (12.7)
Gender—N females (%)	32 (53)
Duration of pain in years—mean (SD)	12.1 (9.5)
Severity of pain—mean (SD)	76.2 (11.5)
Diagnosis N (%)	
FBSS	12 (20)
CRPS type I	1 (2)
Lumbar spondylosis	6 (10)
Chronic low back pain	5 (8)
Lumbar radiculopathy	3 (5)
Fibromyalgia	3 (5)
Osteoarthritis/Rheumatoid arthritis	5 (8)
Cervical spondylosis	2 (3)
Other	23 (38)
Location of pain N (%)	
Upper extremity, unilateral	4 (7)
Truck	4 (7)
Back only	7 (12)
Back and leg	22 (37)
Leg, unilateral	2 (3)
Leg, bilateral	3 (5)
Multifocal	10 (17)
Other	8 (13)

Table 1b Enrolled population characteristics—Drug treatment for pain classified by class

Drug Class	Patients Taking Class of Medication in the Past N (%)	Patients Currently Taking Class of Medication N (%)	Number of Patients Experiencing AE Link to this Class of Medication N (%)
AEDs	17 (28)	18 (30)	10 (17)
Muscle relaxant	2 (3)	9 (15)	0 (0)
NSAIDs	20 (33)	20 (33)	7 (12)
Paracetamol	7 (12)	17 (28)	1 (2)
SSRIs	0 (0)	5 (8)	0 (0)
TCAs & SNRIs	13 (22)	20 (33)	12 (20)
Topical lidocaine	1 (2)	2 (3)	0 (0)
Tramadol and/or opioids	44 (73)	50 (83)	23 (38)
Other	9 (15)	16 (27)	0 (0)

AEDs = antiepileptic drugs; NSAIDs = nonsteroidal anti-inflammatory drugs; SNRIs = serotonin–norepinephrine reuptake inhibitors; SSRIs = selective serotonin reuptake inhibitors; TCAs = tricyclic antidepressants.

Practicality of Using RCPST

Both evaluators agreed that the RCPST questionnaire was easy to use, that it worked within their practice dynamics, and that it took them less than 10 minutes per patient to complete. Comments were made regarding the wording of the RCPST questions and the instructions for its use. This feedback provided suggestions for minor revisions (e.g., clarifying in instructions for use that "generalized pain" does not refer to multifocal pain; adding an option "unknown" to the answers to the medication section of the questionnaire) that should be implemented in a future validation study. The RCPST questionnaire was answered with no missing responses.

Practical Aspects of the Study Design

There were no major protocol deviations, and investigators had few comments on the study design, mainly pertaining to the collection of medication data. The two clinical assessors agreed that 29 patients (51%) should not be referred for consideration of neurostimulation, that 17 patients (30%) should be referred and disagreed in the referral decision for 11 (19%) patients. This corresponded to a Kappa of 0.63 (confidence interval [CI] 95% [0.35–0.91]), indicating a moderate level of agreement [30]. Comments provided by the assessors indicated the reasons for disagreement included 1) ambiguity on whether to refer or 2) confusion on the main pain diagnosis. Based on the outcome of a unified clinical assessment, where in case of disagreement, the judgment of the implanter with the highest confidence in his assessment is taken, the prevalence of suitable referrals according to the implanters was similar across the two study sites (31% and 39%).

Table 1c Enrolled population characteristics—Non-drug treatment for pain

Non Drug Treatment	Tried in the Past (N = 60) N (%)	Currently Used by the Patient (N = 60) N (%)
Physical rehabilitation	44 (73)	2 (3)
Psychological rehabilitation	16 (27)	5 (8)
Acupuncture*	16 (27)	4 (7)
Block	30 (50)	2 (3)

* For one patient, it was unknown if he/she had tried acupuncture (or was currently using it). This was counted as not being administered for the purposes of this table.

Sensitivity and Specificity of RCPST

As shown in Table 2, when compared with the unified clinical assessment, the RCPST was found to have sensitivity of 40% (95% CI: 19–61%) and specificity of 78%, (95% CI: 65–92%). A similar level of sensitivity (35%, 95% CI: 13–58%) and specificity (76%, 95% CI: 60–91%) was seen in the subgroup of 46 patients where the clinical assessors were in agreement. There was some difference estimates between centers—the US centre: sensitivity of 44% (95% CI: 12–77%) and specificity of 60% (95% CI: 39–82%) and UK centre: sensitivity: 36% (95% CI: 8–65%) and specificity of 100% (95% CI: 100–100%).

Two factors influenced the sensitivity and specificity of RCPST: 1) the medication component of the questionnaire and 2) the mismatch on pain diagnosis between the RCPST evaluators and the clinical assessors. Eleven of the 12 cases of mismatch between evaluators and assessors impacting specificity were the result of an RCPST decision of "refer no" because the medication questions led to the conclusion that the patient had not tried all appropriate drugs/classes at an appropriate dose and duration. In addition, for five of the eight "wrong"

Table 2 Agreement between RCPST evaluators vs clinical assessors and sensitivity and specificity levels

		Clinical Assessor's Decision		
		Refer No	Refer Yes	Total N
		Unified clinical assessment		
RCPST decision	Refer No	29 (78%)	12 (60%)	41
	Refer Yes	8 (22%)	8 (40%)	16
	Total N	37	20	57
	Sensitivity	40% (95% CI: 19 to 61%)		
	Specificity	78% (95% CI: 65 to 92%)		
		Clinical assessment where assessors agreed		
RCPST decision	Refer No	22 (76%)	11 (65%)	33
	Refer Yes	7 (24%)	6 (35%)	13
	Total N	29	17	46
	Sensitivity	35% (95% CI: 13 to 58%)		
	Specificity	76% (95% CI: 60% to 91%)		

RCPST = Refractory Chronic Pain Screening Tool.

RCPST referral decisions impacting sensitivity, clinical assessors answered "refer no" because of absence of neuropathic pain and/or a possible discrepancy in the pain assessed.

Different post-hoc RCPST decision algorithm prototypes were generated and sensitivity and specificity recalculated. Across these prototypes and after correcting for this mismatch in medication intake and the generalized pain assessment, sensitivity ranged from 45% to 90% and specificity from 65% to 76% (see Table 3). Following the classification tree segmentation methods, a set of RCPST prototypes were generated. These prototypes resulted in sensitivity varying from 80% to 100% and a specificity varying from 89% to 97%. Figure 3 displays an example prototype based on segmentation.

Discussion

Controlled studies and recent guidelines have convincingly shown that interventional therapies and in particular SCS can reduce pain and improve quality of life for selected neuropathic pain patient indications and CRPS type I (6–9). However, only a minority of the patients suitable for neurostimulation are referred to specialized centers [13]. Correct patient selection remains a major barrier for referral even when the clinical data are convincing and the implanting physician is well known to the referrer. Thus, referring physicians would welcome clearer guidelines on who should be referred for consideration. We therefore sought to develop an easy-to-use screening tool for these patients that can be used in daily clinical practice. As subgroups of patients with peripheral

Table 3 Sensitivity and specificity according to different RCPST prototypes, after correction of medication and diagnosis

RCPST Prototype	Sensitivity (95% CI)	Specificity (95% CI)
*At least AEDs tried or not applicable	70 (50–90)	70 (56–85)
*At least TCAs and/or SNRIs tried or not applicable	60 (39–81)	73 (59–87)
*At least Topical Lidocaine tried or not applicable	50 (28–72)	76 (62–90)
*At least Tramadol/Opioids tried or not applicable	90 (77–100)	65 (49–80)
*At least 3 drug classes tried or not applicable	55 (33–77)	70 (56–85)
*At least 2 drug classes tried or not applicable	85 (69–100)	68 (52–83)
*At least 1 drug classes tried or not applicable	90 (77–100)	65 (49–80)
*Both AEDs and TCAs tried or not applicable	45 (23–67)	73 (59–87)

* Additional RCPST prototype variations were created by the adjusting the decision rule for the medication section of the questionnaire to "Yes, continue" if: . . . .

AEDs = antiepileptic drugs; RCPST = Refractory Chronic Pain Screening Tool; SNRIs = serotonin–norepinephrine reuptake inhibitors; TCAs = tricyclic antidepressants.

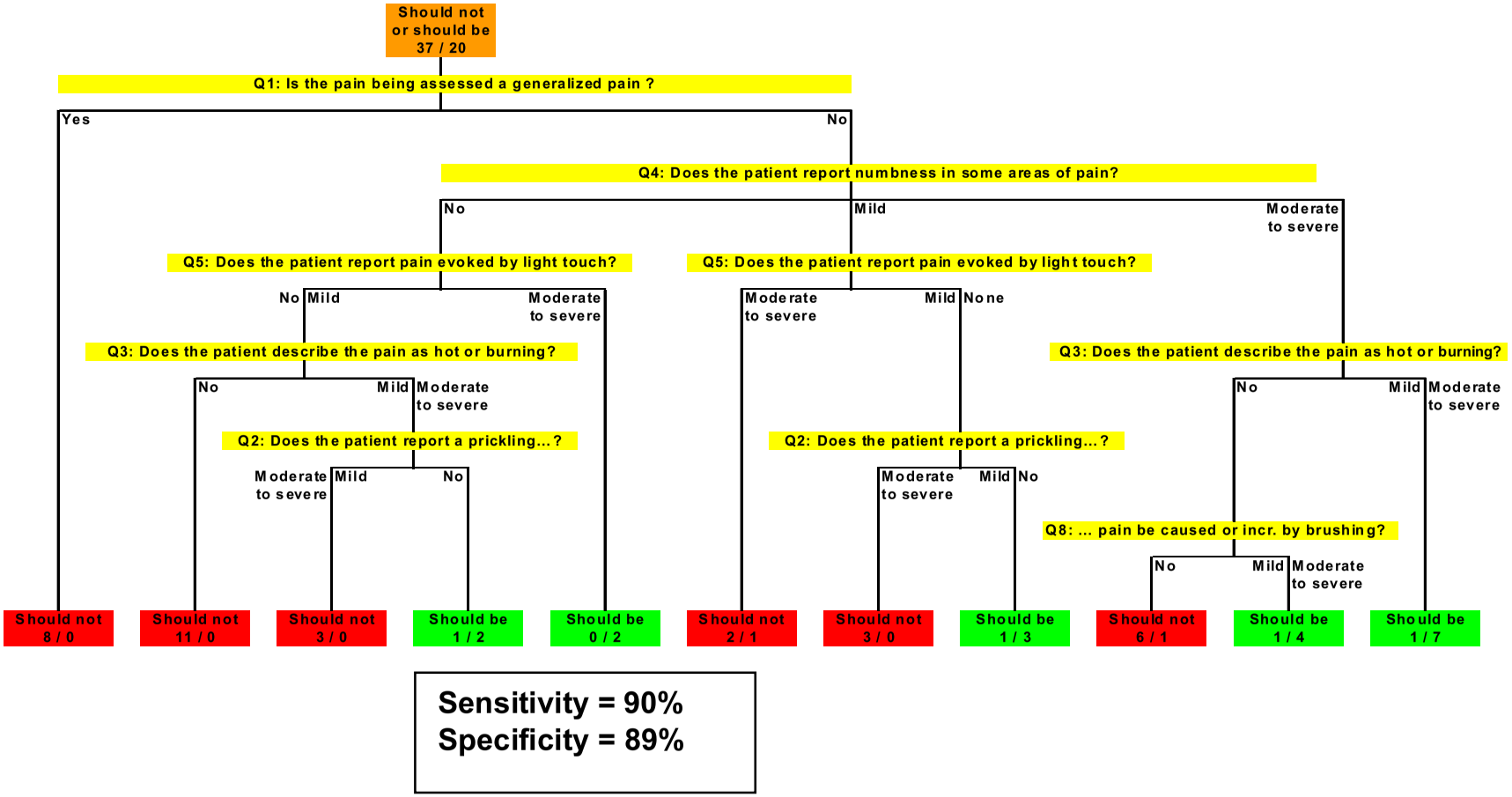

Figure 3 Example of prototype and classification tree derived from segmentation method.
In this tree, the numbers x/y represent the number of patients of a particular subgroup that assessors considered “should not be” or “should be” considered for referral for neurostimulation. At the top of the tree, the algorithm starts with the full group of patients (37/20). At the bottom of the tree, each box represents a final subgroup, split according to the answer to specific items of the questionnaire. The order of items and the options for answering a question are merged (or not) in one arm as a result of the method optimization. Red (should not be) or green (should be) colors represent the decision proposed by the new RCPST prototype for the whole subgroup according the majority number of patients in the subgroup. For example, there were eight patients for which the pain being assessed was not generalized pain, who reported mild or severe numbness in the area of pain and for whom the pain was hot or burning (either mild, moderate, or severe). The implanters identified seven of these patients should be referred (one should not be referred).

neuropathic pain states are particularly responsive to SCS [6], we have utilized typical clinical symptoms and signs, which are known to be characteristic of neuropathic pain. As the prior use of medical treatment is another criterion for patient selection [6], we included questions to document the pharmaco-resistance of the pain.

We have shown that it is possible to identify suitable referral patients, using a questionnaire of 11 questions and 3 bedside tests. The questionnaire can be completed in less than 10 minutes on average. The study design also appears practical as the study was completed in 4 months, with no major deviations and a low attrition rate (5%). The sensitivity of the initial RCPST prototype is below the target set by the expert panel; however, this threshold of 80% was achieved by other prototypes. We also demonstrated that statistical methods can be used to optimize the combination of questions either in a score or in a decision tree.

The RCPST validation feasibility study design is similar to that of other neuropathic pain tool validation studies, although the inclusion criteria were much broader in this study. Indeed, tools such as Leeds assessment of neuropathic symptoms and signs, Douleur Neuropathique 4, Neuropathic Pain Questionnaire, and painDetect were developed with well-defined patient populations, where uncertain/unclear diagnoses were excluded [18–20,22] and/or where cases in which two assessors disagreed were excluded [18–20].

Strengths

Our feasibility study has a number of strengths. The study fulfilled the criteria for validation of screening questionnaires [31]. To ensure validity of content, expert clinical opinion was obtained and the relevant literature was consulted. Moreover, the RCPST questions have graded answers, rather than binary yes/no responses. This fine division may enhance the questionnaire's value in daily clinical practice. Limiting exclusion criteria increased the potential representativeness of patients entered in the study. Assessment bias was addressed through blinding and random assessment order and selection bias through screening all consecutive patients. The inter-rater reliability was moderate (assessors agreed in 81% of cases leading to a Kappa statistic of 0.63) even though all cases were included (i.e., not only patients that were clearly "yes referred" or "do not refer"). The prevalence of suitable referrals was also similar across the two study sites (31% and 39%).

Limitations

Potential limitations of this study include only two clinical sites and the use of expert opinion to determine whether a patient should be referred or not. However, in the absence of a validated objective measure, an expert implanter's clinical judgment is accepted as the current "gold standard" [22–28] and the design included two blinded implanters to assess the patient independently and in random order. Further, in one center, the implanters were neurosurgeons, while they were anesthesiologists in the other. The sites were located in different countries, thereby attempting to cover different types of implanters, practice patterns, and geographies to better reflect potential variability in the "gold standard." Nonetheless, the opinion of the two assessors at each site may not be fully independent because clinical judgment in the same clinic may follow the same school of thinking.

This feasibility study did not include assessment of "test–retest" reliability of the RCPST; not only would this have been practically difficult but also ethically difficult to justify because it would have required that patients travel potentially long distances to specialized hospitals on two separate occasions.

The RCPST prototype was found to have a relatively low sensitivity of 40% and an acceptable specificity of 78%. Thus, the prototype tested may miss many patients who might benefit from neurostimulation therapy.

Post-hoc analyses identified the questions regarding medication intake as a likely cause for this relatively low sensitivity of the prototype. Many implanters do not necessarily require a pharmacological trial with "strong opioids" before neurostimulation is considered. In fact, they argue that even if strong opioids are effective, long-term opioid use with potential side effects might be more harmful to the patients than an interventional therapy. This issue should be re-evaluated when designing the next RCPST version.

It should be emphasized that RCPST was designed as a screening tool rather than as a diagnostic tool. The expert panel deliberately omitted some aspects of the normal workup of a potential neurostimulation patient from the screening tool because it is believed that these elements (e.g., MRI assessment, psychological assessment, comorbidities) are the prerogative of the implanting physician who has the final determination of whether the patient is a candidate for neurostimulation therapy.

Summary and Future Steps

The RCPST as designed does not identify responders to neurostimulation therapy. Rather it is aimed at identifying patients that should be referred for consideration for neurostimulation and should therefore receive the appropriate diagnostic workup, such as psychological assessment and trial stimulation. The RCPST was considered easy to use, practical for routine clinical practice, and contained appropriate questions. The study design and inter-rater reliability of the gold standard (clinical assessment) were judged to be satisfactory. The sensitivity of 40% for the RCPST prototype tested is below the desired target of 80% sensitivity set by the expert panel. However, this threshold was achieved by modifying the decision algorithm, and opportunities for improvement of the tool (i.e., clarification of the prototype questions and

instructions for use) and future study design (i.e., inclusion criteria and medication data collection) were identified.

A future RCPST validation study should implement these changes and create and validate new algorithms. The ideal referral tool would then be selected from these new algorithms by experts based on sensitivity, specificity, clinical relevance, and simplicity. Once fully validated, this tool could play a role in improving patient selection and in also helping improve neurostimulation long-term outcomes.

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Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Appendix S1 RCPST prototype tested in the feasibility study—this tool is not validated
Appendix S2 RCPST Questionnaire and Instructions for use tested in the feasibility study (Version 2 19 Aug 09)—these are not validated