ORIGINAL ARTICLE

Patient selection for spinal cord stimulation: The importance of an integrated assessment of clinical and psychosocial factors

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Abstract

Background: A previously developed educational e-health tool considers both clinical and psychosocial factors when selecting patients with chronic pain for spinal cord stimulation (SCS). The validity of the composite recommendations was evaluated in a retrospective study, demonstrating a strong relationship with patient outcomes after SCS.

Methods: An additional retrospective analysis was performed to determine the added value of a psychosocial evaluation as part of the decision-making process on SCS. Data concerned 482 patients who were considered for SCS in 2018–2019. The analysis focused on the relationship between the different layers of the tool

recommendations (clinical, psychosocial, composite) with trial results and patient outcomes at 6 months after SCS. Of the initial study population, 381 patients underwent SCS and had follow-up data on at least one of three pain-related outcome measures.

Results: Pain improvement was observed in 76% of the patients for whom SCS was strongly recommended based on merely the clinical aspects. This percentage varied by the level of psychosocial problems and ranged from 86% in patients without any compromising psychosocial factors to 60% in those with severe problems. Similarly, the severity of psychosocial problems affected trial results in patients for whom SCS was either recommended or strongly recommended.

Conclusions: The strong relationship between psychosocial factors embedded in the SCS e-health tool and patient outcomes supports an integrated and multidisciplinary approach in the selection of patients for SCS. The educational e-health tool, combining both clinical and psychosocial aspects, is believed to be helpful for further education and implementation of this approach.

Significance statement: This study confirms the relevance of the psychosocial factors embedded in the educational SCS e-health tool (https://scstool.org/). The strong relationship between the severity of psychosocial factors with patient outcomes supports conducting a comprehensive psychological and behavioural assessment when determining the eligibility of patients for SCS.

1 | INTRODUCTION

Spinal cord stimulation (SCS) is used to treat various forms of refractory chronic neuropathic/nociplastic and/or ischemic pain. The most common indications are pain associated with persistent spinal pain syndrome (PSPS), complex regional pain syndrome (CRPS), neuropathic pain syndrome (NPS) and ischemic pain syndromes (IPS; Fontaine, 2021; Hoydonckx et al., 2019; Pan et al., 2017; Provenzano et al., 2021; Ubbink & Vermeulen, 2013). Despite being highly effective for these indications, a substantial number of patients fail to achieve long-term pain relief, partly due to poor patient selection (Block et al., 2017; De La Cruz et al., 2015). To assist physicians with the identification of SCS responders, assessment of patients by a multidisciplinary pain and neuromodulation team consisting of, but not limited to, a clinical psychologist (or psychiatrist), physiotherapist and nurse specialist is recommended. Generally, uncontrolled major psychiatric disorders are considered absolute contraindications for SCS by both the International Association for the Study of Pain (IASP) and Neuromodulation Appropriateness Consensus Committee (NACC; Campbell et al., 2013; Deer et al., 2014; Gybels et al., 1998). However, consistently excluding patients with feelings of depression and/or anxiety would deny potential responders to benefit from SCS, a treatment that is associated with improvement

in a patient's mental state (Burke et al., 2015; Falowski et al., 2021; Ho et al., 2011). Although attempts were made to correlate different psychosocial factors with SCS outcomes, conflicting results have been reported on the predictive value of each of these factors (Block et al., 2017; Burchiel et al., 1995; Fama et al., 2016; Lamé et al., 2009; Poulsen et al., 2021; Rosenberg et al., 2015; Sparkes et al., 2015). Because no single psychosocial factor could be identified, current literature suggests a more comprehensive psychological and behavioural assessment when determining the eligibility of patients for SCS (Paroli et al., 2018; Prabhala et al., 2019).

Recently, an educational e-health tool (https://scstool.org/), intended to aid physicians with the selection of patients for SCS, was developed by a multidisciplinary group of experts (Thomson et al., 2020). In addition to relevant clinical variables, a set of eight psychosocial factors was included in the tool. After completing a patient profile, the tool produces a composite recommendation on SCS (strongly recommended, recommended, not recommended). The validity of the e-health tool was recently evaluated in a retrospective study, demonstrating a strong relationship between the composite tool recommendations and patient outcomes after SCS (Thomson et al., 2022). This study focuses on the added value of considering the psychosocial factors, embedded in the e-health tool, when selecting patients for SCS.

2 | METHODS

2.1 | SCS educational e-health tool

The RAND/University of California at Los Angeles Appropriateness Method (RUAM) was used to establish patient-specific criteria for the referral/selection of patients for SCS. The criteria were embedded in an educational e-health tool (https://scstool.org/) of which the development is described in Thomson et al. (2020). Following the completion of a patient's clinical profile, the tool generates a recommendation on the appropriateness of SCS. This first layer is based on the median panel score for clinical aspects (1–3 = inappropriate; 4–6 = equivocal/uncertain; 7–9 = appropriate) of a multidisciplinary group of 18 European experts who rated the appropriateness of a total of 386 clinical scenarios across four indications (PSPS, CRPS, NPS, IPS). In the next layer, the tool generates a panel recommendation related to the presence and severity of eight psychosocial factors, including lack of engagement, dysfunctional coping, unrealistic expectations, inadequate daily activity level, problematic social support, secondary gain, psychological distress/mental health problems and unwillingness to reduce high-dose opioids. For each factor, three categories are distinguished (absent/mild, moderate, severe). For the composite outcome (third layer), SCS is strongly recommended if the clinical appropriateness score ranges between 7 and 9 and the patient has no compromising psychosocial factors. If one or more psychosocial factors are moderate in severity, the composite outcome is either not recommended or recommended depending on a patient's clinical profile. Any psychosocial outcome in the severe category is considered a strong contraindication for the consideration of SCS, regardless of the clinical appropriateness.

2.2 | Study population, design and data collection

The study population, design and data collection have been previously described by Thomson et al. (2022). In summary, the study included data from all patients considered for SCS between January 1, 2018, and June 30, 2019, by 12 implant centres previously involved in the RUAM panel study. In this period, the e-health tool was not yet available. Data on the baseline characteristics, e-health tool variables, centre decisions on SCS and patient outcomes were retrieved from the medical records of the included patients. After data collection, the clinical and psychosocial variables were retrospectively applied to the e-health tool, determining the relationship between the composite tool recommendations with both the trial results and patient outcomes 6 months after SCS. The herein presented analysis focused on the association between the different layers of the tool recommendations (clinical, psychosocial, composite) and the level of pain reduction after an SCS trial and at 6-month follow-up in patients receiving SCS either directly or after a positive trial. Data on the numeric rating scale of pain (NRS) and global perceived effect (GPE) by the patient and observer were collected as pain-related outcome measures. The GPE was assessed on a 7-point Likert scale going from very much deterioration to very much improvement.

2.3 | Data analysis

The relation between the e-health tool recommendations with the trial results and patient outcomes was analysed using frequency tables and cross-tabulations. Pain was considered improved when patients had substantial pain relief on at least one of three pain-related outcome measures with pain improvement defined as ≥50% pain relief by the NRS or much to very much improvement by the GPE as assessed by the observer and patient. Kruskal-Wallis One-Way ANOVA was applied for continuous baseline variables. Chi-square statistics were used for categorical outcome data, comparing SCS outcome (improved/not improved) and trial outcome (positive/negative) for the three categories of psychosocial factors (no/mild, moderate, severe). The Spearman's rank order correlation coefficient (R_s) was used as a measure of association between ordinal variables.

2.4 | Ethics committee review and approval

Patient data were anonymised and collected retrospectively. Data collection was in agreement with all necessary national/local ethics committee and institutional requirements.

3 | RESULTS

3.1 | Patient population

In total, 483 patients were considered for SCS and included in the study population. Data on the psychosocial variables were complete for 448 (92.8%) of these patients. A detailed description of the presence and degree of the psychosocial factors in the included patients can be found in Thomson et al. (2022). As previously described, it was assumed that aspects not reported in the medical record

were most likely absent, not affecting the e-health tool recommendations. With the exception of gender (women presented with more psychosocial symptoms than men, $p < 0.01$), the baseline characteristics were largely similar between patients with no/mild, moderate or severe psychosocial factors (Table 1). In addition, the distribution of patients according to the severity of psychosocial factors was comparable between the different indication areas. However, severe psychosocial problems were significantly less frequently experienced by patients receiving SCS than by those who were considered for SCS but eventually did not receive an implant due to a negative trial or any other reason such as the presence of concurrent diseases or refusal of SCS by the patient (χ^2 [2, $N = 483$] = 49.1; $p < 0.001$; Figure 1).

3.2 | Use of an integrated assessment versus patient outcomes

At 6-month follow-up, 97.4% ($N = 381$) of patients receiving SCS ($N = 391$) had data available on at least one of three pain-related outcome measures. Based on solely the clinical factors, SCS was not recommended in three of these patients. For the remaining patients, SCS was either recommended ($N = 177$) or strongly recommended ($N = 201$). Upon completion of the clinical factors without

consideration of the patients' psychosocial profile, 68% ($N = 121$) and 76% ($N = 153$) of patients had improvement in at least one of three pain-related outcome measures when the tool outcome was recommended or strongly recommended, respectively (Figure 2).

When the same patients ($N = 381$) were categorised according to the severity of psychosocial problems but without considering the patients' clinical profile, the percentage of patients with pain improvement ranged between 85% ($N = 126$) and 50% ($N = 12$) for patients experiencing no/mild ($N = 148$) and severe ($N = 24$) psychosocial problems, respectively (Figure 2).

Using an integrated assessment, improvement in pain-related outcome measures was highest in patients not experiencing any compromising psychosocial factors for whom SCS was strongly recommended, showing a gradual decrease with the severity of psychosocial problems (χ^2 [2, $N = 201$] = 8.2; $p < 0.05$). A similar pattern was seen in patients for whom the tool outcome was recommended (χ^2 [2, $N = 177$] = 13.3; $p < 0.01$; Figure 2). The group for whom SCS was not recommended included only three patients who all had moderate psychosocial problems, not showing substantial pain relief on any of the three outcome measures at 6-month follow-up.

The number of psychosocial problems identified, irrespective of the level of severity, was negatively correlated with the degree of improvement for all outcome measures (GPE observer: $R_s = -0.38$, $p < 0.001$; GPE patient: $R_s = -0.35$, $p < 0.001$; NRS: $R_s = -0.25$, $p < 0.001$).

3.3 | Use of an integrated assessment versus trial results

Two-hundred and ninety (290) patients underwent a screening trial prior to SCS. Similar to the long-term
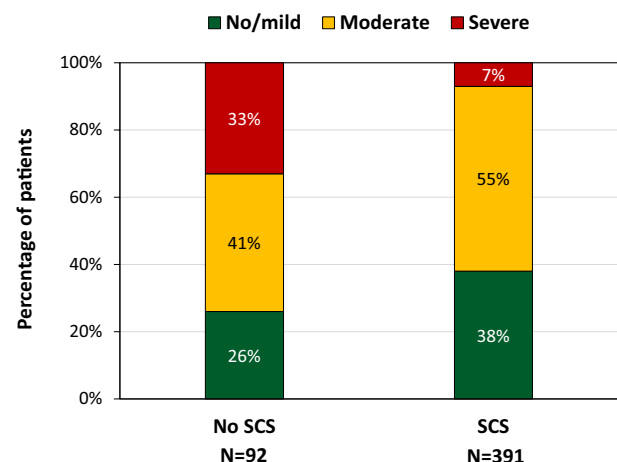
TABLE 1 Demographics of the patients according to the severity of psychosocial variables

	Severity of psychosocial variables		
Demographics	No/mild ($N = 174$)	Moderate ($N = 253$)	Severe ($N = 56$)
Age, years			
Mean (SD)	54 (15)	52 (13)	53 (12)
Median [IQR]	55 [43;66]	51 [43;61]	53 [43;63]
Gender, N (%)			
Female	90 (52)	164 (65)	34 (61)
Male	84 (48)	89 (35)	22 (39)
Baseline pain level (NRS)			
Mean	7.9	8.0	8.3
Median	8.0	8.0	9.0
Indication areas, N (%)			
PSPS ($N = 357$)	120 (69)	195 (77)	42 (75)
NPS ($N = 65$)	31 (18)	28 (11)	6 (11)
CRPS ($N = 57$)	21 (12)	28 (11)	8 (14)
IPS ($N = 4$)	2 (1)	2 (1)	0 (0)

Abbreviations: CRPS: Complex Regional Pain Syndrome; IPS: Ischemic Pain Syndromes; NPS: Neuropathic Pain Syndromes; NRS: Numeric Pain Rating Scale; PSPS: Persistent Spinal Pain Syndrome.

FIGURE 1 Severity of psychosocial factors according to the final centre decision.

patient outcomes, trial success was dependent on a patient's clinical profile and the severity of psychosocial factors with trial success being as high as 97% when SCS was either recommended or strongly recommended and no psychosocial factors were present (Figure 3a). Patients of whom the psychosocial problems were reported to be moderate ($N = 169$) or severe ($N = 23$) were less likely to respond to an SCS trial, even though SCS was recommended or strongly recommended based on the clinical appropriateness score (χ^2 [2, $N = 290$] = 23.3; $p < 0.001$).

Although the group was small, only one out of five patients with a not recommended tool outcome responded to an SCS trial.

Out of the 258 patients with a successful trial, 251 had long-term follow-up data after SCS. Despite positive trial results ($N = 251$), strong improvement at 6-month follow-up was limited to 75% ($N = 188$) of these patients and dependent on the severity of psychosocial comorbidities. For patients without any compromising psychosocial factors ($N = 93$), a successful trial was predictive of long-term

FIGURE 2 Association between an integrated assessment of both clinical and psychosocial factors with patient outcomes. Numbers in each cell represent the percentage of patients with pain improvement at 6-month follow-up.
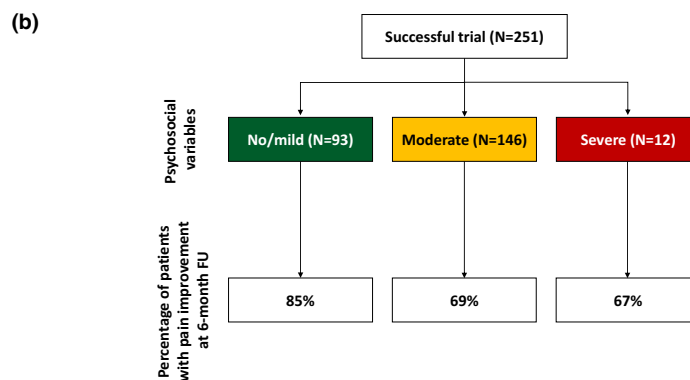

FIGURE 3 Relationship between the tool recommendations and trial results. (a) Association between an integrated assessment of both clinical and psychosocial factors with trial results. Numbers in each cell represent the percentage of patients with a successful trial. (b) Severity of psychosocial factors as a predictor of longer-term pain relief in patients with a successful trial.

pain relief in 85% ($N = 79$) of patients. This percentage decreased to 67% ($N = 8$) if patients experienced any severe psychosocial problems (Figure 3b).

4 | DISCUSSION AND CONCLUSIONS

A relationship between psychosocial factors and SCS outcomes has been previously described but evidence on their predictive value is often conflicting (Fama et al., 2016; Prabhala et al., 2019). Rather than focusing on isolated factors, recent studies are considering comprehensive tools or assessment scales for the selection of patients considered for SCS. Because the assessment of a patient's complete psychosocial profile is preferred, the previously developed educational e-health tool (https:// scstool.org/en/) considers eight psychosocial factors to determine the appropriateness of performing SCS. These factors were based on a literature review supported with the observations from clinical practice including input from three psychologists (Thomson et al., 2020). The psychosocial factors embedded in the e-health tool are largely in agreement with those incorporated in a recently developed psychological evaluation tool for SCS candidacy, including aspects that pertain to unrealistic expectations, dysfunctional coping, substance abuse and mental health problems (Fama et al., 2016; Prabhala et al., 2019). In addition to these factors, the e-health tool considers lack of engagement, inadequate daily activity level, problematic social support and secondary gain important in the selection of patients for SCS. While psychological testing generally requires the involvement of trained psychologists, especially when scores are abnormal, the educational SCS e-health tool can be completed by referrers and implanters at the time of patient consideration. The tool should be seen as a checklist, encouraging physicians to consult a clinical psychologist or multidisciplinary team when psychosocial factors are flagged or cannot be adequately judged. Although the tool should not replace a multidisciplinary assessment, it can help centres with the initial screening, especially when psychological services are not immediately accessible.

The relevance of the psychosocial factors embedded in the e-health tool has been recently demonstrated in a study that retrospectively applied the tool to real-life patient data (Thomson et al., 2022). In this retrospective study, the e-health tool showed good applicability on patient data with a very low number of missing data for both the clinical and psychosocial aspects. In addition, all psychosocial factors were prevalent in the included patient population. The initial data analysis showed a strong relationship between the composite tool recommendations with both SCS trial results and patient outcomes at 6-month follow-up (Thomson et al., 2022). Given the uncertainty around the predictive value of psychosocial factors for SCS outcomes, this analysis aimed to assess the added value of using an integrated approach considering psychosocial factors in addition to performing a clinical examination.

Upon retrospective application of merely the clinical factors, 76% of patients with a strongly recommended tool outcome (appropriateness score = 7–9) had substantial pain relief at 6-month follow-up. This percentage further increased to 86% if no compromising psychosocial factors were reported to be present. For patients with either a recommended or strongly recommended tool outcome, the extent of pain improvement was negatively correlated with the number of psychosocial variables, showing that the percentage of patients who achieved substantial pain relief largely varied by the severity of psychosocial factors. Although a similar pattern was seen when considering solely the psychosocial factors irrespective of the clinical factors, a thorough clinical examination of each patient considered for SCS should not be disregarded. Data collection by centres with profound experience in SCS patient selection most likely contributed to the preferential inclusion of good candidates for SCS. This was reflected by the low number of patients who received SCS but for whom the tool outcome was negative (not recommended). To allow for sufficient outcome data per category of psychosocial factors, all indications were combined in the current manuscript. Nevertheless, detailed analyses by main indication showed that psychosocial factors were least prevalent in NPS (50%; $N = 60$) versus 63% and 62% in PSPS ($N = 357$) and CRPS ($N = 57$), respectively. Because IPS was seen in only four patients, these were excluded from the analyses. The percentage of patients with improvement after SCS was slightly higher in NPS (79%) than in PSPS (71%) and CRPS (72%). These figures support the relationship between psychosocial factors and SCS outcome in general but do not answer the question if adverse psychosocial factors affect SCS outcome more or less for each of these indications, as the number of patients per subgroup was too small to allow further analysis.

Similar to the long-term patient outcomes, trial success was greater in patients without compromising factors for whom SCS was recommended or strongly recommended compared to those experiencing any moderate or severe psychosocial problems. Because trial

success was as high as 97%, the data suggests a limited added value of performing a trial in patients with a favourable psychosocial profile and a recommended tool outcome, although this should be confirmed in a prospective follow-up study. Due to the design, the study did not allow to evaluate pain deterioration beyond 6 months after SCS. Therefore, we were unable to exclude a potential "honeymoon" effect. The only measure to assess the lack of substantial pain relief was to evaluate if there were any false positives among the patients with a positive trial. In the current study, 25% of patients with a positive trial did not experience strong improvement at 6-month follow-up. The lack of long-term pain relief after a positive trial could to some extent be explained by the higher prevalence of compromising psychosocial factors in patients with poor SCS outcomes compared to those without any psychosocial problems. This emphasises the importance of conducting a comprehensive psychological evaluation, even in the context of a screening trial, to understand and, if possible, reduce a patient's psychosocial problems prior to surgery, ultimately resulting in better patient outcomes.

The limitations of the herein presented study are similar to the ones discussed in Thomson et al. (2022) and include the retrospective study design, evaluation of the tool from the implanter perspective, limited follow-up time and the low number of patients for whom SCS was not recommended due to the inclusion of implant centres with substantial expertise in SCS patient selection (Thomson et al., 2022). Besides the aforementioned limitations, the use of validated questionnaires was not required to assess a patient's psychosocial state. Because the psychosocial profile consists of trichotomous variables, a correlation analysis between assessment scores and patient outcomes could not be performed. In addition, the e-health tool is intended as an initial screen to evaluate if further psychological evaluation is needed. Therefore, a patient's psychosocial profile could have been completed by a non-expert who may have under- or overestimated the severity of the psychosocial variables included in the tool. It should also be mentioned that the psychosocial variables were reported at the moment of patient consideration, not capturing any benefits of counselling, pain management education or prehabilitation (before SCS), which could influence the final tool recommendation and the subsequent association with patient outcomes.

In conclusion, the strong relationship between the composite tool recommendations and patient outcomes was related to the use of an integrated assessment. Both the clinical factors and severity of psychosocial factors correlated with SCS outcomes, suggesting predictive value of the e-health tool for SCS trial results and patient outcomes, which will be further examined in a prospective study collecting follow-up data at 6 and 12 months after SCS. The current study strongly recommends consultation with a multidisciplinary pain and neuromodulation team consisting of, but not limited to, a clinical psychologist, physiotherapist and nurse specialist, especially if any compromising psychosocial factors are present at the initial screening of patients considered for SCS.

AUTHOR CONTRIBUTIONS

Simon Thomson, Frank Huygen and Herman Stoevelaar designed the study. Herman Stoevelaar and Nicky Helsen performed the data analyses and prepared the manuscript draft together with Frank Huygen and Simon Thomson. All authors, except Herman Stoevelaar and Nicky Helsen, contributed to the data collection. All authors have reviewed and approved the final manuscript.

CONFLICT OF INTERESTS

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