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Clinical Study

Determination of the Oswestry Disability Index score equivalent to a "satisfactory symptom state" in patients undergoing surgery for degenerative disorders of the lumbar spine—a Spine Tango registry-based study

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Abstract

BACKGROUND CONTEXT: The achievement of a given change score on a valid outcome instrument is commonly used to indicate whether a clinically relevant change has occurred after spine surgery. However, the achievement of such a change score can be dependent on baseline values and does not necessarily indicate whether the patient is satisfied with the current state. The achievement of an absolute score equivalent to a patient acceptable symptom state (PASS) may be a more stringent measure to indicate treatment success.

PURPOSE: This study aimed to estimate the score on the Oswestry Disability Index (ODI, version 2.1a; 0–100) corresponding to a PASS in patients who had undergone surgery for degenerative disorders of the lumbar spine.

STUDY DESIGN/SETTING: This is a cross-sectional study of diagnostic accuracy using follow-up data from an international spine surgery registry.

PATIENT SAMPLE: The sample includes 1,288 patients with degenerative lumbar spine disorders who had undergone elective spine surgery, registered in the EUROSPINE Spine Tango Spine Surgery Registry.

OUTCOME MEASURES: The main outcome measure was the ODI (version 2.1a).

METHODS: Surgical data and data from the ODI and Core Outcome Measures Index (COMI) were included to determine the ODI threshold equivalent to PASS at 1 year (±1.5 months; n=780) and 2 years (±2 months; n=508) postoperatively. The symptom-specific well-being item of the COMI was used as the external criterion in the receiver operating characteristic (ROC) analysis to determine the ODI threshold equivalent to PASS. Separate sensitivity analyses were performed based on the different definitions of an "acceptable state" and for subgroups of patients. JF is a copyright holder of the ODI.

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The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

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RESULTS: The ODI threshold for PASS was 22, irrespective of the time of follow-up (area under the curve [AUC]: 0.89 [sensitivity {Se}: 78.3%, specificity {Sp}: 82.1%] and AUC: 0.91 [Se: 80.7%, Sp: 85.6] for the 1- and 2-year follow-ups, respectively). Sensitivity analyses showed that the absolute ODI-22 threshold for the two follow-up time-points were robust. A stricter definition of PASS resulted in lower ODI thresholds, varying from 16 (AUC=0.89; Se: 80.2%, Sp: 82.0%) to 18 (AUC=0.90; Se: 82.4%, Sp: 80.4%) depending on the time of follow-up.

CONCLUSIONS: An ODI score ≤22 indicates the achievement of an acceptable symptom state and can hence be used as a criterion of treatment success alongside the commonly used change score measures. At the individual level, the threshold could be used to indicate whether or not a patient with a lumbar spine disorder is a "responder" after elective surgery.

Keywords: Oswestry Disability Index; Patient acceptable symptom state; Patient-reported outcome; Satisfaction; Sensitivity; Specificity; Spine; Success; Surgery

Introduction

In Western societies, low back pain (LBP) has the largest disease burden [1]. It is associated with a substantial amount of morbidity, and complaints are multidimensional. Functional status is an important patient-related outcome when evaluating surgical and non-surgical interventions for LBP. One important feature of outcome instruments measuring functional status is their ability to detect meaningful change from the patient's perspective. In the absence of appropriate objective clinical outcome measures, the use of patient-reported outcome measures (PROM) to assess treatment outcome is commonly accepted [2]. The Oswestry Disability Index (ODI) [3], and the ODI version 2.1a [4,5] in particular, is widely accepted and recommended as a condition-specific PROM in interventional studies [6]. As such, medical decision-making increasingly relies on this measure. Although most clinicians and researchers agree that the success of any intervention should be judged from the patient's perspective, to date no consensus exists for criteria indicating "success."

In health services research, it is important to define clear criteria for treatment "success." Success can be conceptualized in two ways: (1) relevant change or improvement, and (2) achievement of an acceptable state. With the first concept, the emphasis is on whether or not an individual has improved after an intervention [7], whereas with the second the emphasis is on whether or not the achieved outcome is acceptable from the patient's perspective [7]. The concept of change (minimum clinically important difference or change) is frequently used in spine research to assess treatment success. In relation to this, it is important to specify whether the observed change in an individual's scores is merely the result of measurement error or whether it constitutes a real change, and whether that change is also clinically relevant to the patient [8]. However, it is difficult to measure what is clinically relevant to patients [9], and methodological issues such as population dependency and baseline dependency [10] are encountered. Moreover, assessment of change does not indicate whether a "normal" or "healthy" symptom state is reached. For these reasons, we have previously used a more stringent definition of success based on achievement of values seen in "normal," healthy populations [11]. The threshold used was the achievement of an ODI value, derived from "normal" subjects with little or no back pain, of ≤22 [4,11]. The use of "normal, healthy population" values as the reference might, however, be criticized as the ODI is a condition-specific instrument.

An alternative approach to measuring success is to identify the value beyond which patients consider themselves well or consider their health state to be acceptable, ie, the concept of the patient acceptable symptom state (PASS) [12,13]. Determination of the absolute cutoff value (threshold) at follow-up, equivalent to achievement of a PASS, would assist in interpreting scores at the individual level and would allow determination of the proportion of patients within a group who achieve this level, when evaluating the effectiveness or success of interventions. Achievement of this threshold might be more important than the achievement of a given change value, and it probably reflects the ultimate goal of treatment from the patient's perspective [12,14]. The concepts of "feeling better" and "feeling good" are complementary but distinctly different; a patient's condition can be markedly improved by the intervention but can still be suboptimal [7,12,13].

The purpose of the present study was to estimate the score on the ODI (version 2.1a) corresponding to a "patient acceptable symptom state" in patients undergoing surgery for degenerative disorders of the lumbar spine. To assess the robustness of the findings, we performed sensitivity analyses with different definitions for "acceptable state" and in various subgroups of patients.

Materials and methods

Study population

This cross-sectional study was performed using postoperative data from the Spine Tango Spine Surgery Registry of EUROSPINE, the Spine Society of Europe (SSE) [15,16], and according to the STARD statement for reporting studies of diagnostic accuracy [17]. The study dataset was prepared in August 2014 by linking the surgical data, recorded on the