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Clinical Study

What level of pain are patients happy to live with after surgery for lumbar degenerative disorders?

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Abstract

BACKGROUND CONTEXT: A new approach to the interpretation of treatment success comprises the reporting of the proportion of patients whose symptoms have reduced to an acceptable level, ie, who have reached a satisfactory state.

PURPOSE: We sought to evaluate the acceptable level of pain in patients after surgery for painful degenerative lumbar disorders.

DESIGN: This is a cross-sectional study of outcome data, 12 months postoperatively.

PATIENT SAMPLE: The sample includes 6,943 patients registered in our in-house Spine Outcomes Registry, nested within the EUROSPINE "Spine Tango" registry, undergoing surgery for degenerative disorders of the lumbar spine (disc herniation [DH; N=1,608], spinal stenosis [SS; N=1,782], degenerative spondylolisthesis [DS; N=1,000], degenerative deformity [DegDef; N=612], and degenerative disc or segment disease [DegSeg; N=473], and 1,468 degenerative but no specific category).

OUTCOME MEASURES: The Core Outcome Measures Index (COMI) was the outcome measure. The specific items used for this analysis were the two 0 to 10 graphic rating scales for back and leg pain and the symptom-specific well-being (SSWB) item "if you had to spend the rest of your life with the symptoms you have now, how would you feel about it?", with a 5-point response scale from "very satisfied" to "very dissatisfied."

METHODS: The COMI was completed before and at 3, 12, and 24 months after surgery. Answers on the SSWB were dichotomized and used as the external criterion in receiver operating characteristics (ROC) analysis to derive the cutoff score for pain (the higher of back and leg pain) indicating being at least "somewhat satisfied" with the symptom state 12 months postoperatively. Sensitivity analyses were carried out for various subgroups (sex, age, pathology, comorbidity status, smoking status, preoperative pain level, previous surgery, type of health insurance, and time of follow-up [3 and 24 months]). The study was funded by the Schulthess Klinik Research Funds; there were no potential conflict of interest-associated biases for any of the authors.

RESULTS: Of 6,943 patients, 6,248 (90%) returned a 12-month questionnaire, of which 47% reported being at least somewhat satisfied with their symptom state (52% [DH], 45% [SS], 53% [DS], 44% [DegDef], 45% [DegSeg], and 44% [others]). The areas under the curve for the ROCs were 0.89 to 0.91 for the different pathologies, indicating a good ability of the pain score to discriminate between being in a satisfactory state or not. The cutoff indicating a satisfactory symptom state was ≤2 points for DH (sensitivity: 76%; specificity: 88%) and ≤3 points for all other pathologies (sensitivity: 79%–84%; specificity 81%–85%). The sensitivity analyses revealed ≤3 points to be the most common cutoff for the various subgroups.

FDA device/drug status: Not applicable.

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CONCLUSIONS: Most spine interventions decrease pain but rarely do they totally eliminate it. Reporting of the percent of patients achieving a pain score equivalent to the "acceptable symptom state" may represent a more stringent target for denoting surgical success in the treatment of painful spinal disorders. For DH, this is ≤2, and for other degenerative pathologies it is ≤3.

Keywords: Acceptable symptom state; Degenerative spinal disorders; Pain; Patient-rated outcome; Spine surgery; Success of surgery

Introduction

There is increasing recognition of the notion that the success of elective spine surgery should be judged in relation to the patient's perception of the benefits gained in domains that are of relevance to them, eg, symptoms, disability, and quality of life [1]. To this end, self-administered questionnaires assessing health-related quality of life are being implemented with greater frequency, and are now seen as an indispensable part of the patient assessment procedure. However, health-related quality of life measures can sometimes be difficult to interpret and understand because of the numerous available instruments and their diversity in items, response options, approaches to aggregation, and scoring [2]. There is an increasing demand for the reporting of health outcomes using concepts that are relevant to the individual patient and are readily understood by clinicians. The most popular method in spine outcomes research has focused on the concept of "improvement" and involves determination of the achievement of a certain minimal score change—the minimal clinically important change score for improvement ($MCIC_{imp}$)—compared with the preoperative state. The methods used for determining the $MCIC_{imp}$, whether statistical or anchor-based, have been the subject of much criticism [3], and it is known that the achievement of a given change score can sometimes be dependent on the starting point, being easier to achieve when starting out with a more extreme score in the range (indicating worse status) [4]. The use of percentage change can overcome this shortcoming to a certain extent, but dealing in percentages is not without its own problems [5]. Another criticism of the use of the $MCIC_{imp}$ is that although it may indicate the achievement of relevant improvement, it still does not indicate whether an acceptable symptom state has actually been reached (ie, whether the patient "feels good"), a factor that might be expected to govern whether the patient goes on to seek further health care or treatment. In most cases, spine interventions are aimed at decreasing pain, but rarely do they totally eliminate it. It is easy to conceive of a situation where a high initial pain level (eg, a score of 9 on a 0–10 visual analog scale) may be reduced by as much as 50% after an intervention, yet still represent an ongoing problem for the patient.

In the field of rheumatology, the concept of the patient acceptable symptom state (PASS), defined as the highest symptom level below which patients feel well, has become an increasingly popular outcome measure [6]. After treatment, patients are classified as "responders" if their symptoms are less severe than the threshold deemed "acceptable." This same phenomenon has not yet been widely applied in the field of spine surgical outcomes. The present study sought to determine the pain score on the commonly used 0 to 10 scale corresponding to a "satisfactory symptom state" in patients undergoing surgery for various painful degenerative diseases of the lumbar spine.

Materials and methods

Inclusion criteria and Spine Tango Surgery Form documentation

The study was carried out using data in our own in-house spine surgery outcomes database, collected within the framework of the EUROSPINE Spine Tango Registry and using Tango's standardized forms. It included the prospectively collected data of consecutive patients who had undergone surgery for painful lumbar degenerative disorders by qualified, specialized spine surgeons in our own spine center (part of an orthopedic hospital) from 2005 to 2013. To be included, patients had to have a good understanding of written German or English, or (after 2006) French, Spanish, Italian, or Portuguese; be at least 1 year postoperative; and fulfill the study's surgical admission criteria. The latter made use of the options ticked in relation to the given fields on the Spine Tango Surgery Form and were as follows: surgery in the lumbar or lumbosacral region of the spine, degenerative disease as the main pathology, and pain relief as at least one of the goals of surgery. The Spine Tango Surgery Form also provided details on the presenting pathology, other baseline medical information, and surgical procedures, allowing sensitivity analyses to be carried out for subgroups of patients (see later).

Patient self-report questionnaires

Preoperatively and at 3, 12, and 24 months after surgery, patients were requested to complete the Core Outcome Measures Index (COMI) questionnaire [7,8], sent to them by post at home. The COMI contains (among other items) 0 to 10 graphic rating scales for back pain and leg pain (the higher of the two was used for further analysis) and an item ("symptom-specific well-being") concerning the acceptability of symptoms: "if you had to spend the rest of your life with the symptoms you have now, how would you feel about it?", answered on a 5-point Likert scale from "very satisfied"