

Clinical Study

Assessment of spine surgery outcomes: inconsistency of change amongst outcome measurements

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Abstract

BACKGROUND CONTEXT: Outcomes of spinal treatments are evaluated by clinical relevance: the proportion of patients who reach a minimum clinically important outcome change. Outcomes are evaluated through multiple measurements, and the inconsistency of outcome change across measurements is not known.

PURPOSE: The primary purpose of this study was to illustrate outcome inconsistencies after spinal surgery. Secondary goals of this study were to develop an index of overall change that incorporates outcome inconsistencies, to relate the index of overall change to patients' global assessment and satisfaction with treatment, to relate the index of global change to an intuitively understandable outcome: the level of tolerable pain.

STUDY DESIGN: This study is a review of prospectively collected patient-reported outcomes data.

PATIENT SAMPLE: Four hundred sixty patients from a large multicenter database were chosen. Those patients were included in the sample because they had undergone lumbar surgery and had baseline and 1-year follow-up scores. Baseline and 1-year follow-up scores for Oswestry Disability Index (ODI), physical component summary (PCS) of the Medical Outcome Study Short Form-36 (SF-36), numerical back and leg pain scales, and 1-year scores for satisfaction with results were included in the study.

OUTCOME MEASURES: The outcome measures of the study were preoperative and 1-year postoperative scores for ODI, PCS, back pain scale, leg pain scale, health transition item of the SF-36, and satisfaction with results scales.

METHODS: Oswestry Disability Index, SF-36, and pain scales were administered before and 1 year after spinal surgery. Satisfaction with results questionnaires were administered 1 year after surgery. The following threshold values were previously established and were used to evaluate outcome changes: minimum clinically important difference (MCID), substantial clinical benefit (SCB), and standard error of the mean. The following proportions of patients were determined according to outcome changes: "deteriorated," "no change," "below MCID," "above MCID," and "above SCB." The consistency of outcome change was determined amongst the four outcome measures. An index of overall change was developed and related to patients' answers to the health transition item of the SF-36 and to the satisfaction with results scale. The overall change index was also compared with the tolerable pain level.

FDA device/drug status: not applicable.

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RESULTS: Only 40.5% of patients report consistent outcome changes on all four measures. The overall change index was significantly correlated to the global change and satisfaction scale ($\rho=.67$, p less than .001). The overall change index was clearly associated with the tolerable pain level.

CONCLUSIONS: Efforts should be made to take into account the inconsistency of outcomes and to make clinical relevance more readily understandable by patients and clinicians. © 2010 Elsevier Inc. All rights reserved.

Keywords: Outcome measures; Lumbar fusion; Oswestry Disability Index; SF-36; Pain scales; Clinical relevance

Introduction

With the ongoing effort to promote an evidence-based approach to lumbar spine surgery, the prospective collection of patients' outcomes has been more consistent [1]. Spinal surgery has relied on assessments of health, such as the Medical Outcome Study (MOS) Short Form-36 (SF-36) [2], assessments of disability, such as the Oswestry Disability Index (ODI) [3], and assessments of pain, such as numerical rating scale [4]. Concurrently, the limits of statistical analyses based on group averages have come under closer scrutiny. Clinical relevance (benefits to the patients) has become as important as statistical significance (effect beyond some level of chance) [5]. Efforts have been made to define the minimum clinically important difference (MCID) as the benchmark measure of clinical relevance. Improvement beyond the MCID threshold value is considered clinically relevant improvement, and treatment effects may be assessed by the proportion of responders, that is, patients who reach MCID.

In the field of spinal surgery, several values have been proposed as MCID candidates for a variety of health-related quality-of-life (HRQOL) measurements [6–11]. The multiplicity of MCID values is the result of the multiplicity of methods and populations used for its determination. Although there is no current agreement on the methods to determine MCID, there is, at least, some consensus as to what constitutes reasonable MCID values [9].

Furthermore, MCID provides a yardstick of clinical relevance but is unlikely to represent a desirable treatment outcome from the patient's point of view. The substantial clinical benefit (SCB) has been proposed as a threshold value representing a relevant and desirable outcome [12].

The use of multiple outcome measures allows assessment of different health components. When treatment effects are evaluated by the proportion of responders, the use of multiple outcome measures creates a new predicament: the inconsistency of outcomes. Individual patients may be simultaneously responders and nonresponders depending on the outcome measure. There has been no mention of the inconsistency of outcomes in the literature. Therefore, the primary purpose of this study was to empirically illustrate the inconsistency of outcomes in the measurement of spinal surgery outcomes. Score changes were gauged against several threshold values and compared across four HRQOL measures for each patient. Consistency of outcomes consisted in score changes reaching the same threshold on all four HRQOL measures for individual patients.

The secondary purpose of this study was to develop an index of change incorporating outcome inconsistencies. This index of change was compared with the patient's global assessment, satisfaction with surgery, and threshold of tolerable pain. Threshold of tolerable pain is not typically included in spinal surgery studies, but it was used in this study for two reasons: it provides more intuitive meaning to the HRQOL scores and it is not influenced by the baseline scores. A drawback of assessing treatment outcome through score change (whether through group average or individual score) is its lack of intuitive meaning. For instance, there is no straightforward description of the functional improvement brought about by a 20-point as opposed to a 25-point improvement in the ODI. Furthermore, the magnitude of change is associated with the initial score: the patients with higher pain and disability are more likely to experience a greater change [13,14]. The concept of tolerable pain was derived from pain research, which considers that pain is limiting at lower intensities and only becomes disabling beyond a certain threshold. The disabling intensity threshold has been defined as a level of "5" on a scale of 0 to 10. This threshold of "5" has been established in different pathologies, including back pain [15,16].

Materials and methods

Patient sample

This sample of patients has previously been described [10,12]. The sample purposefully includes a mix of diagnoses and surgeries to represent the types of patients encountered in clinical practice. Values of MCID and SCB have been calculated with the present patient sample. From a database of prospectively collected outcomes data, 460 patients were retained because they had answered the "satisfaction with results" questions. The following number of patients had both baseline and 1-year scores: 457 for ODI, 460 for physical component summary (PCS), 427 for back pain, and 430 for leg pain. The exact number of patients included in specific analyses varies slightly because of the fact that a few patients incompletely filled out the questionnaires (such as skipping the health transition item or some of the satisfaction with results questions).

The average age of the patients was 54.4 years, and the average body mass index was 29.9 kg/m². In this sample, 17.3% of the patients were smokers and 59.1% were female. The most frequent diagnoses were spinal stenosis

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