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Clinical Study

Determination of minimum clinically important difference (MCID) in pain, disability, and quality of life after revision fusion for symptomatic pseudoarthrosis

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Abstract

BACKGROUND CONTEXT: Spinal surgical outcome studies rely on patient reported outcome (PRO) measurements to assess the effect of treatment. A shortcoming of these questionnaires is that the extent of improvement in their numerical scores lacks a direct clinical meaning. As a result, the concept of minimum clinically important difference (MCID) has been used to measure the critical threshold needed to achieve clinically relevant treatment effectiveness. Post hoc anchor-based MCID methods have not been applied to the surgical treatment for pseudoarthrosis.

PURPOSE: To determine the most appropriate MCID values for visual analog scale (VAS), Oswestry Disability Index (ODI), Short Form (SF)-12 physical component score (PCS), and European Quality of Life 5-Dimensions (EQ-5D) in patients undergoing revision lumbar arthrodesis for symptomatic pseudoarthrosis.

STUDY DESIGN/ SETTING: Retrospective cohort study.

METHODS: In 47 patients undergoing revision fusion for pseudoarthrosis-associated back pain, PRO measures of back pain (BP-VAS), ODI, physical quality of life (SF-12 PCS), and general health utility (EQ-5D) were assessed preoperatively and 2 years postoperatively. Four subjective post hoc anchor-based MCID calculation methods were used to calculate MCID (average change; minimum detectable change; change difference; and receiver operating characteristic curve analysis) for two separate anchors (health transition index (HTI) of SF-36 and satisfaction index).

RESULTS: All patients were available for a 2-year PRO assessment. Two years after surgery, a significant improvement was observed for all PROs; Mean change score: BP-VAS (2.3 ± 2.6; $p<.001$), ODI ($8.6\%\pm13.2\%$; $p<.001$), SF-12 PCS (4.0 ± 6.1; $p=.01$), and EQ-5D (0.18 ± 0.19; $p<.001$). The four MCID calculation methods generated a wide range of MCID values for each of the PROs (BP-VAS: 2.0–3.2; ODI: 4.0%–16.6%; SF-12 PCS: 3.2–6.1; and EQ-5D: 0.14–0.24). There was no difference in response between anchors for any patient, suggesting that HTI and satisfaction anchors are equivalent in this patient population. The wide variations in calculated MCID values between methods precluded any ability to reliably determine what the true value is for meaningful change in this disease state.

CONCLUSIONS: Using subjective post hoc anchor-based methods of MCID calculation, MCID after revision fusion for pseudoarthrosis varies by as much as 400% per PRO based on the calculation technique. MCID was suggested to be as low as 2 points for ODI and 3 points for SF-12.

The author WNA is an independent statistician.

FDA device/drug status: Not applicable.

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These wide variations and low values of MCID question the face validity of such calculation techniques, especially when applied to heterogeneous disease and patient groups with a multitude of psychosocial confounders such as failed back syndromes. The variability of MCID thresholds observed in our study of patients undergoing revision lumbar fusion for pseudoarthrosis raises further questions to whether ante hoc or Delphi methods may be a more valid and consistent technique to define clinically meaningful, patient-centered changes in PRO measurements.

Keywords: Minimum clinically important difference; MCID; Pseudoarthrosis; Revision fusion

Introduction

Patient reported outcome (PRO) questionnaires have become the standard measure for treatment effectiveness after spinal surgery. The Visual Analog Scale (VAS) [1,2], Oswestry Disability Index (ODI) [3–5], Short Form of the Medical Outcomes Study (SF-36) [6], and European Quality of Life 5-Dimensions (EQ-5D) health survey [7,8] are some of the most often used PRO questionnaires. A deficiency of these questionnaires is based on the fact that their numerical scores lack a direct, clinically significant meaning [9]. In light of this, the concept of minimum clinically important difference (MCID) has been put forth as a measure for the critical threshold needed to achieve treatment effectiveness. Using this measure, treatment effects reaching the MCID threshold value imply clinical significance and justification for implementation into clinical practice. In other words, MCID can be thought of as the smallest change in outcome measure that is important from a patient's perspective [10].

The most often used methods to calculate MCID values are post hoc anchor-based approaches. A post hoc anchor-based approach compares the change in PRO score after surgery to another measurement (patient-perceived improvement after surgery and patient satisfaction with surgery). In the literature, multiple anchors have been used and several anchor-based MCID calculation methods have been described, resulting in substantial variability in MCID values [11]. Some have suggested that measures of preoperative patient expectations serve as a more valid criteria for defining meaningful change. As a result of this variability, no consensus has been reached regarding the optimal MCID calculation method; and subsequently, definitive MCID values for the above mentioned PRO questionnaires used in spine surgery are yet to be established.

Attempts to determine MCID of VAS, ODI, and SF-36 in mixed spine surgery populations with various etiologies and surgical procedures have been made by previous investigators [12–15]. In a patient population of mixed spine pathologies and surgeries, Copay et al. [16] assessed MCID for VAS, ODI, and EQ-5D and demonstrated a wide variability in MCID, based on MCID calculation method. A previous study by our group [17] found similar variability in MCID, based on calculation method in patients undergoing transforaminal lumbar interbody fusion (TLIF) for spondylolisthesis-associated back and leg pain. To date, no studies have determined MCID values specifically for patients undergoing revision lumbar arthrodesis for pseudoarthrosis-associated back pain. In light of this, we set out to determine the most appropriate pseudoarthrosis revision surgery-specific MCID values for VAS, ODI, SF-12 physical component score (PCS), and EQ-5D, and whether various subjective post hoc anchor-based MCID methods provide similar results in patients undergoing revision lumbar arthrodesis for symptomatic pseudoarthrosis.

Methods

Patient selection

A total of 47 patients with symptomatic pseudoarthrosis who underwent revision-instrumented fusion at our institution were included in this study. The primary inclusion criteria were dynamic radiography and computed tomography (CT) evidence of pseudoarthrosis; corresponding mechanical low back pain; prior lumbar instrumented fusion; an age of 18 to 70 years; and failed at least 3 months of nonoperative care. At the time of presentation, no patients had fractured rods or screws; all had nonunion with pathological motion and corresponding mechanical spine pain. Patients were excluded if they had an extraspinal cause of back pain; trauma, infection, or neoplasm; underwent revision lumbar surgery for adjacent segment disease or same-level persistent stenosis; an active workman's compensation lawsuit; or were unwilling to participate with the study's follow-up.

The diagnosis of symptomatic pseudoarthrosis was made using the following criteria: symptomatic mechanical back pain with radiographic evidence of pathological movement on dynamic films or haloing or screw loosening on the postoperative CT scans. In general, pathological movement was defined as the translation of greater than 3 mm and angulation of greater than 5° on flexion-extension radiographs [18]. However, as there has been general disagreement regarding the threshold of movement on dynamic films that indicate a lack of fusion [19], any pathological movement in the presence of correlating mechanical back pain and/or screw haloing or loosening on CT scan was classified as pseudoarthrosis. The definition of pseudoarthrosis was consistent throughout the duration of the study and applied both as an inclusion criterion as well as postoperative follow-up criterion.