

Minimally important change values of a measurement instrument depend more on baseline values than on the type of intervention

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Abstract

Objectives: Multi-item questionnaires are frequently used to measure outcomes in randomized controlled trials (RCTs) in patients with sciatica. Knowing the minimally important change (MIC) values for these instruments will facilitate interpretation of change scores. MIC values have been shown to be dependent on baseline values. The question is whether they also depend on the type of intervention. To estimate the MIC of the Roland Morris Disability Questionnaire (modified 23 item version) (RMDQ) and of intensity of leg pain measured by a Visual Analogue Scale (VAS) in patients with sciatica and to assess to what extent MIC values depend on type of intervention and on baseline values.

Study Design and Setting: This is a secondary analysis of RCT data of the effects of early surgery vs. prolonged conservative treatment in patients with sciatica. Baseline and 8-week data were used to assess MIC of the RMDQ-23 and VAS leg pain. We used the receiver operator characteristic (ROC) method to assess the MIC. Global Perceived Recovery (rated 8 weeks after baseline) was used as anchor. Subgroups were created based on type of treatment and baseline severity.

Results: The MIC value of the RMDQ-23 for the total group of sciatica patients was 7.5. The values were 8.1 and 6.9 for surgery and conservative treatment, respectively. For high and low baseline values, the MICs were 9.0 and 4.9, respectively, irrespective of treatment received. The MIC values of the VAS leg pain were 34.4 for the total group. For surgery and conservative treatment, the MIC values were 38.5 and 30.4, respectively, whereas for groups with high and low baseline values, MIC values of 53.5 and 17.2 were found.

Conclusion: The MIC values of the RMDQ-23 and VAS leg pain were found to be highly dependent on their baseline values, although the type of intervention appeared to influence the MIC value only slightly. © 2015 Elsevier Inc. All rights reserved.

Keywords: Minimally important change; Sciatica; RMDQ-23; VAS leg pain; ROC method; Mean change method

1. Introduction

Sciatica is a common health problem causing severe pain and disability in individual patients and high costs to society [1]. Sciatica (lumbar radiculopathy) is characterized by radiating pain in the leg typically served by one nerve root in the lumbar or sacral spine. It is sometimes also associated with sensory and motor deficits. The most common cause of sciatica is a herniated disk with associated nerve

root compression. The most important symptoms are pain in the leg and related disability. The diagnosis is mainly based on history taking and physical examination. Diagnostic imaging is indicated directly when severe underlying pathology is suspected (infections, malignancies), otherwise only after 6–8 weeks when severe symptoms fail to respond to conservative care. Surgery is indicated when computed tomography and/or magnetic resonance imaging show disk herniation, but only when the clinical findings and symptoms (eg, location of leg pain) correspond well with the imaging findings [2].

The natural history of acute sciatica is favorable, with resolution of leg pain within 8 weeks from the onset in most patients [2,3]. From this perspective, optimal care starts

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What is new?**Key findings**

- In sciatica patients, the minimally important change (MIC) values of Roland Morris Disability Questionnaire (modified 23-item version) and visual analogue scale for intensity of leg pain are hardly dependent on type of intervention.

What this adds to what was known?

- This is the first time that the dependency of MIC on type of intervention (surgery vs. conservative treatment) is examined.

What is the implication and what should change now?

- The MIC value can be seen as a characteristic of a measurement instrument.

with symptomatic and conservative treatment. Only in case of persistent severe complaints, more invasive treatment might be indicated.

To assess health status and outcome of interventions for sciatica patients, patient-reported outcomes assessing disability and pain are most relevant. The Roland Morris Disability Questionnaire (RMDQ) [4] is frequently used to measure functional status in back pain-related disability. The RMDQ was modified for sciatica patients by Patrick et al. [5], by deleting one item and exchanging four others with alternative statements resulting in a 23-item questionnaire with increased responsiveness to sciatica. In this study, we used this RMDQ-23 for measuring disability in sciatica patients.

As leg pain is often more pronounced than back pain in patients with sciatica, we also assessed pain intensity in the leg, using a visual analogue scale (VAS) [6].

In randomized controlled trials (RCTs), statistical significance of a difference in change of scores over time does not necessarily imply that this change is clinically relevant. To facilitate interpretation of outcomes, benchmarks in pain improvement have been suggested, for example by the IMMPACT group, for minimal important improvement (10–20% pain reduction), moderate improvement ($\geq 30\%$), and substantial improvement ($\geq 50\%$ pain reduction). [7] A minimally important change (MIC), defined as the smallest change in score that patients perceive as important, is assumed to be a characteristic of a measurement instrument and therefore assumed not to depend on the type of intervention that patients receive. However, there is little evidence to support the assumption. Some studies have shown that the MIC is dependent on the initial baseline scores [8,9] and it has been suggested that MIC might also depend on the invasiveness or inconvenience

of the intervention [10]. We used data from a RCT [ISRCTN26872154] that compared early surgery with prolonged conservative treatment among patients with sciatica due to lumbar disc herniation [11]. In this population with patients receiving quite different treatments, we examined whether the assumption holds that MIC values are independent of type of intervention received. Additionally, we also examined the influence of baseline values.

2. Materials and methods

In the multicenter RCT, 283 patients who had severe sciatica for 6 to 12 weeks were randomly assigned to early surgery or to prolonged conservative treatment with surgery if needed. The details of this study can be found elsewhere [11,12]. Briefly, patients recruited were aged 18 to 65 years, with a radiologically confirmed disc herniation and lumbosacral radicular syndrome diagnosed by the attending neurologist who had lasted for 6 to 12 weeks. Early surgery was scheduled within 2 weeks after randomization and canceled only if spontaneous recovery occurred before the date of surgery. The disc herniation was removed through a unilateral transflavial approach using magnification. Prolonged conservative care was provided by the general practitioner. If sciatica persisted at 6 months after randomization, surgery was offered. Increasing leg pain not responsive to drugs and progressive neurologic deficit were reasons for performing surgery earlier than 6 months. Patients were advised to resume their regular jobs when they were able to, depending on the nature of their work. The study was approved by the Medical Ethics Committee of Leiden University Medical Center and participating hospitals.

For the present study on MIC values, we used data on the outcomes assessed at randomization and at 8-week follow-up. As we were interested in whether the MIC value is different for patients who underwent surgery or conservative treatment, we omitted 17 patients from the “early surgery” group who did not get surgery and 16 patients allocated to the prolonged conservative treatment group who underwent surgery before the 8-week assessment. After omitting the patients who had no follow-up data after 8 weeks on the RMDQ-23 or on VAS for leg pain (seven patients), a total of 243 patients remained for MIC analyses, that is, 121 patients in the surgery group and 122 patients who received prolonged conservative treatment.

2.1. Outcome measures

The RMDQ-23 for sciatica patients consists of 23 questions, which can be answered with “yes” or “no” by the patients; the score is the sum of the item scores and ranges from 0 to 23 [5]. Example items are “I change position frequently to try and get my back or leg comfortable” and “I only stand for short periods of time because of my

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