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Willingness to undergo surgery again validated clinically important differences in health-related quality of life after total hip replacement or total knee replacement surgery

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Abstract

Objectives: To determine clinically important differences (CIDs) in health-related quality of life (HRQoL) after total hip replacement (THR) or total knee replacement (TKR) surgery, using the Short Form 36 (SF-36).

Study Design and Setting: SF-36 scores were collected 2 weeks before and at 1.5−6 years after joint replacement in 586 THR and 400 TKR patients in a multicenter cohort study. We calculated distribution-based CIDs (0.8 standard deviations of the preoperative score) for each SF-36 subscale. Responders (patients with an improvement in HRQoL $\geq$ CID of a particular subscale) were compared with nonresponders using an external validation question: willingness to undergo surgery again.

Results: CIDs for THR/TKR were physical functioning (PF), 17.9/16.7; role-physical (RP), 31.1/33.4; bodily pain (BP), 16.8/16.2; general health, 15.5/15.7; vitality, 17.3/16.7; social functioning (SF), 22.0/19.9; role-emotional, 33.7/33.6; and mental health, 14.8/14.1. CIDs of PF, RP, BP, and SF were validated by the validation question.

Conclusion: Valid and precise CIDs are estimated of PF, RP, BP, and SF, which are relevant in HRQoL subscales for THR and TKR patients. CIDs of all other subscales should be used cautiously. © 2014 Elsevier Inc. All rights reserved.

Keywords: Clinically important differences; Health-related quality of life; Total hip replacement; Total knee replacement; Short form 36

1. Introduction

Total hip replacement (THR) and total knee replacement (TKR) alleviate pain and improve health-related quality of life (HRQoL) at the population level [1]. This information may not be meaningful for individual patients in clinical practice, who are interested in the likelihood of experiencing a meaningful improvement for the risk they take with an intervention [2]. Clinically important differences (CIDs), defined as a difference in scores of an outcome measure that is perceived by patients as beneficial or harmful [3,4], can be used to estimate the probability of achieving a meaningful improvement. Patients experience a meaningful improvement if their improvement is equal to or larger than the CID threshold; patients who improve less or deteriorate are considered nonresponders.

As risks, costs, and expected benefits vary widely between different interventions [5], CIDs for a generic HRQoL instrument [eg, the Short Form 36 (SF-36)] may vary across applications [6]. Minimal CIDs (MCIDs) after THR and TKR for the SF-36 were recently summarized in a systematic review [7−9]. However, these estimates were not validated using external criteria [7]. Additionally, the relevance of a ''minimal'' improvement after THR or TKR is debatable as one would generally expect a larger improvement after joint replacement [10]. Finally, the recommended anchor-based approach yielded imprecise CID estimates, which are not suitable for clinical practice. As large improvements in HRQoL are expected from joint replacement, the number of patients who rated their improvement after joint replacement as ''somewhat better'' was small, rendering imprecise CID estimates.

To overcome this limitation of anchor-based CID estimates in treatments with large effect sizes, such as joint replacements, we propose a new approach combining efficient distribution-based CID estimation with anchor-based external validation. We used this approach to estimate CIDs in HRQoL after THR and TKR.

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What is new?

Key findings

- Using a new approach, which combines efficient distribution-based clinically important difference (CID) estimation with anchor-based external validation, one can establish CIDs in health-related quality of life (HRQoL) for treatments with large effect sizes.

What this adds to what was known?

- Establishment of CIDs in HRQoL after total hip and knee replacement.

What is the implication and what should change now?

- Using these CIDs, the probability of a relevant improvement in all eight dimensions of HRQoL can be the subject of study in a clinical prediction model. Such a model could improve patient expectation management to decrease the dissatisfaction rate.

2. Methods

The present study is part of a multicenter follow-up study of HRQoL after THR or TKR (NTR2190) [11,12]. Institutional Review Board approval was obtained from all the participating centers, and all patients gave written informed consent (CCMO-Nr: NL29018.058.09; MEC-Nr: P09.189). The data used in this report comprise a subset of patients, who underwent primary THR or TKR and have completed preoperative and postoperative HRQoL questionnaires.

2.1. Assessments

HRQoL was measured 2 weeks before TKR/THR and 1.5–6 years after surgery, using the Dutch SF-36 [13,14]. The 36 items cover eight domains [physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role-emotional (RE), and mental health (MH)], for which a subscale score is calculated (100 indicating no symptoms and 0 indicating extreme symptoms). Missing items were imputed according to Ware [15] whenever possible.

A validation question (VQ) was included in the questionnaire: ''knowing what your hip or knee replacement surgery did for you, would you still have undergone this surgery (yes/no)?'' This VQ was previously used in a similar study that validated WOMAC (Western Ontario and McMaster Universities Arthritis Index) CIDs after THR and TKR [10].

2.2. Outcome measures

CIDs can be established using anchor-based or distribution-based methods [5,6,16]. In an anchor-based approach, the target instrument is related to an independent measure (an anchor) [5]. Typically, within-patient global change ratings (measured using a Likert scale) are used as anchors; the CID is estimated by the mean improvement of patients who report that their condition is at least somewhat better [16]. In a distribution-based approach, the magnitude of the effect is related to a measure of variability of results [5]. Typically, effect size benchmarks by Cohen [17] are adapted for individual effect sizes, giving 0.3× or 0.5× the standard deviation (SD) of the baseline score for a MCID and 0.8× the SD of the baseline score for a CID [16].

To estimate CIDs, we chose the following two-phased approach. In the first phase, we estimated the CID using a distribution-based approach. This approach generates a more precise estimate of the CID because information from the entire cohort is used, instead of only a part of the population as is the case in anchor-based methods. In the second phase, the distribution-based CIDs were validated by the VQ.

2.3. Statistical analyses

Baseline characteristics were compared using descriptive statistics. Distribution-based CIDs in HRQoL of THR and TKR patients were calculated by multiplying the SD of the untransformed subscale scores at baseline by 0.8, which indicates a large group change [16].

We validated the CIDs using the VQ. Each individual patient's improvement (ie, the postoperative score minus the preoperative score) was computed and compared with the CID. A 2 × 2 contingency table was constructed for each subscale of the VQ to display the numbers of individuals who had an improvement equal to or larger than the CID threshold and gave positive or negative answers to the VQ or had an improvement smaller than that of the CID and gave positive or negative answers to the VQ. For each contingency table, an odds ratio was calculated, which can be interpreted as the ratio of the odds of having experienced a CID when patients have expressed willingness to undergo surgery again, relative to the odds of not having experienced a CID when patients have expressed willingness to undergo surgery again. An odds ratio of more than 1 indicates that that particular CID is able to discriminate patients who answered the VQ positively from patients who answered the VQ negatively.

2.4. Sensitivity analyses

To check whether the odds ratios of the validation procedure were robust across different arbitrary CID threshold, we repeated all analyses using the following CID thresholds: 0.3 × SD and 0.5 × SD.

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