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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

J. Christiaan Keurentjes[a,*], Marta Fiocco[b], Rob G. Nelissen[a]

[a]Department of Orthopaedic Surgery, Leiden University Medical Center, Albinusdreef 2, 2333 ZA Leiden, The Netherlands
[b]Department of Medical Statistics and Bioinformatics, Leiden University Medical Center, Einthovenweg 20, 2333 ZC Leiden, The Netherlands

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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.

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.

* Corresponding author. Secretariaat Orthopaedie, Postbus 9600, 2300 RC Leiden, The Netherlands. Tel.: +31-647641786; fax: +31-(0)71-5266816.

E-mail address: j.c.keurentjes@lumc.nl (J.C. Keurentjes).

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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.

To verify whether the estimated CIDs are consistent across different subpopulations, we calculated the CIDs separately for different subgroups and compared these with the overall CID estimates. Subgroup CID estimates were calculated for strata of the following variables: sex, age (<65 vs. ≥65 years old), and Charnley classification (class A, patients in whom the index operated hip or knee is only affected; class B, patients in whom the other hip or knee is affected as well; and class C, patients with a hip or knee replacement and other affected joints and/or a medical condition that affects the patients' ability to ambulate) [18,19].

3. Results

3.1. Population

Patient characteristics are presented in Table 1; 586 patients underwent THR and 400 underwent TKR. The average follow-up period was similar for THR and TKR patients [3.2 years (SD, 1.1), both for THR and TKR]. THR patients were slightly younger at joint replacement surgery [mean age at joint replacement (SD): THR, 66 (10.6); TKR, 69.1 (9.6)]. The proportion of males was similar (THR, 34.1%; TKR, 33.3%). TKR patients had a higher mean body mass index and were more often obese or morbidly obese. Most patients underwent joint replacement for primary osteoarthritis.

Table 1. Patient characteristics

Characteristic	Primary THR, n = 586	Primary TKR, n = 400
Follow-up (yr)		
Mean (SD)	3.2 (1.1)	3.2 (1.1)
Median (IQR)	3.0 (2.3–4)	2.9 (2.3–4)
Age (yr)		
Mean (SD)	66 (10.6)	69.1 (9.6)
Median (IQR)	67 (60.4–73.6)	70.4 (63.1–76.5)
≤50 (%)	46 (7.8)	9 (2.3)
51–60 (%)	95 (16.2)	65 (16.5)
61–70 (%)	221 (37.7)	118 (30.0)
71–80 (%)	187 (31.9)	156 (39.7)
>80 (%)	37 (6.3)	45 (11.5)
Number of men (%)	200 (34.1)	132 (33.3)
BMI (kg/m^2)		
Mean[a] (SD)	27.1 (4.2)	29.2 (4.9)
Median (IQR)	26.6 (24.2–29.4)	28.5 (25.8–32)
<25 (%)	191 (34.3)	68 (18.0)
25–30 (%)	243 (43.6)	168 (44.4)
30–35 (%)	98 (17.6)	97 (25.7)
>35 (%)	25 (4.5)	45 (11.9)
Indication for joint replacement		
Osteoarthritis (%)	501 (86.2)	354 (89.4)
Rheumatoid arthritis (%)	13 (2.2)	26 (6.6)
Other (%)	68 (11.7)	16 (4.0)

Abbreviations: THR, total hip replacement; TKR, total knee replacement; SD, standard deviation; IQR, interquartile range; BMI, body mass index.

[a] Measured at follow-up.

A total of 2206 patients underwent primary joint replacement and were eligible for inclusion in this follow-up study. Two hundred eighty-five patients did not complete all the preoperative questionnaires and 63 patients died, leaving 1,858 patients with primary joint replacement eligible. Nine hundred eighty-six patients agreed to participate and returned the questionnaires sufficiently completed (response rate, 53%). Nonresponding THR patients were on average 3.95 years older than participants [95% confidence interval (CI): 2.6, 5.3 years]; nonresponding TKR patients were on average 3.31 years older than participants (95% CI: 2.0, 4.7 years). The proportion of males was similar in participants and nonresponders.

3.2. Phase 1: CID estimation

The mean preoperative scores of the SF-36 subscales are presented in Table 2. For THR patients, the following improvements in HRQoL scores after joint replacement constitute a CID: PF, 17.9; RP, 31.1; BP, 16.8; GH, 15.5; VT, 17.3; SF, 22.0; RE, 33.7; and MH, 14.8. For TKR patients, the following improvements in HRQoL scores after joint replacement constitute a CID: PF, 16.7; RP, 33.4; BP, 16.2; GH, 15.7; VT, 16.7; SF, 19.9; RE, 33.6; and MH, 14.1.

3.3. Phase 2: validation

Box plots of the improvement in the eight dimensions of HRQoL after joint replacement in relation to the CID threshold for each dimension, stratified by the response to the VQ, are shown in Fig. 1 for THR patients and Fig. 2 for TKR patients. THR patients who reported having a larger improvement in PF, RP, BP, GH, SF, and RE than the CIDs had also expressed willingness to undergo surgery again more often. These findings are also reflected in the odds ratios, which are more than 1 (Table 3). TKR patients who reported having a larger improvement in PF, RP, BP, and SF than the CIDs had also expressed willingness to undergo surgery again more often. These findings are also reflected in the odds ratios, which are more than 1 (Table 3). All the contingency tables from which these odds ratios were calculated are presented in Appendix A at www.jclinepi.com.

Sensitivity analyses showed similar odds ratios for different CID thresholds, indicating a robustness of the association between achieving a CID and expressing willingness to undergo surgery again for different thresholds (Appendix B at www.jclinepi.com). CIDs were similar for men and women, patients younger and older than 65 years, and different Charnley classes (data not shown).

4. Discussion

We have established CIDs in HRQoL after THR and TKR and have validated these estimates using a relevant

Table 2. Preoperative HRQoL and CIDs in HRQoL of primary THR and TKR

SF-36 subscale	THR		TKR	
	Mean preoperative score (SD)	CID (95% CI)	Mean preoperative score (SD)	CID (95% CI)
Physical functioning	40.1 (22.3)	17.9 (16.9, 19.0)	40.3 (20.8)	16.7 (15.5, 18.0)
Role-physical	30.9 (38.9)	31.1 (29.4, 33.1)	38.8 (41.8)	33.4 (31.2, 36.0)
Bodily pain	40.3 (20.9)	16.8 (15.8, 17.8)	44.9 (20.3)	16.2 (15.1, 17.5)
General health	67.8 (19.3)	15.5 (14.6, 16.4)	62.8 (19.7)	15.7 (14.7, 16.9)
Vitality	61.0 (21.6)	17.3 (16.3, 18.4)	60.9 (20.9)	16.7 (15.6, 18.0)
Social functioning	65.6 (27.5)	22.0 (20.8, 23.4)	70.5 (24.9)	19.9 (18.6, 21.5)
Role-emotional	68.9 (42.2)	33.7 (31.8, 35.9)	68.8 (42.0)	33.6 (31.3, 36.2)
Mental health	74.3 (18.5)	14.8 (14.0, 15.7)	73.5 (17.7)	14.1 (13.2, 15.2)

Abbreviations: HRQoL, health-related quality of life; CIDs, clinically important differences; THR, total hip replacement; TKR, total knee replacement; SF-36, Short Form 36; SD, standard deviation; CI, confidence interval.

VQ. The CID estimates of PF, RP, BP, and SF are both precise (judged by the narrow CIs) [20] and accurate (because of the validation procedure), enabling further research in HRQoL gains after THR or TKR at the individual level. CIDs of all other SF-36 subscales should be used cautiously.

A limitation of our study is the variable length of follow-up, which ranges from 1.5 to 6 years after surgery. CIDs might be different for patients with different lengths of follow-up. However, recent evidence suggests that gains in HRQoL are sustained up to 7 years after joint replacement [21,22].

In establishing a CID for a specific outcome measure, it is recommended to use multiple approaches and triangulation of methods [6]. Anchor-based approaches are preferred as these are explicitly attached to observed mean changes. Distribution-based approaches have been criticized for being nonintuitive and arbitrary in the choice of the individual effect size standards [5,16]. However, anchor-based methods might not be feasible in THR or TKR. Quintana

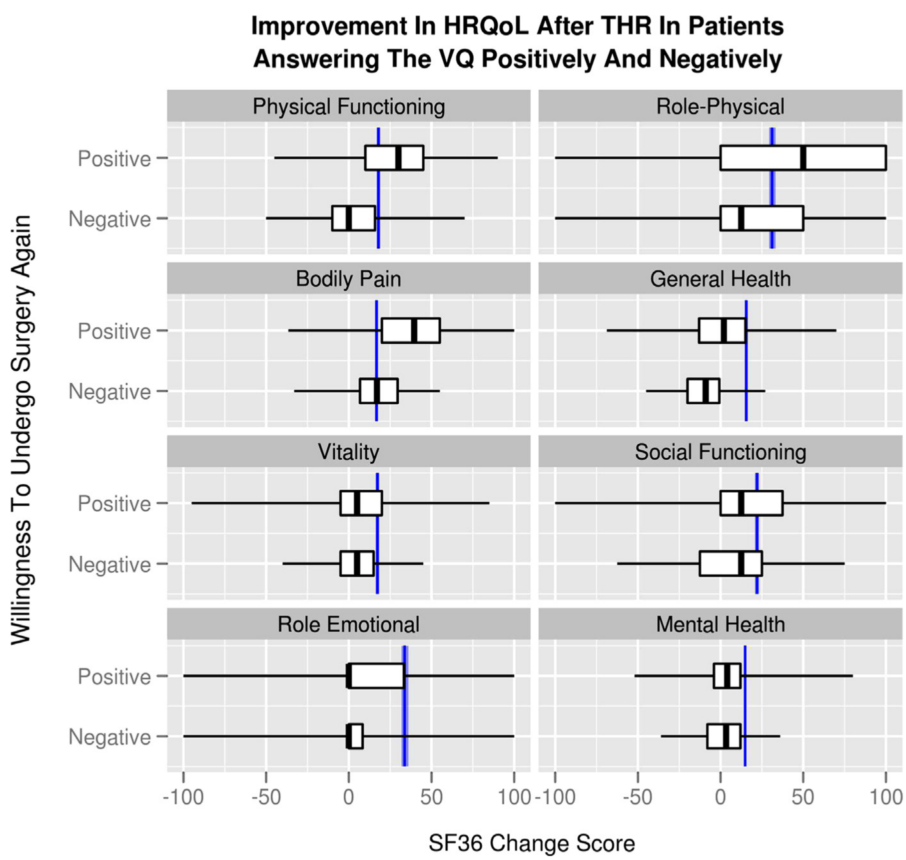

Fig. 1. Improvement in health-related quality of life after total hip replacement per validation question (VQ). The vertical blue lines indicate the clinically important difference of each subscale with its confidence interval shown in purple; the box plots indicate the median, interquartile range, and range of patients, who answered the VQ positively and negatively. SF-36, Short Form 36. (For interpretation of references to color in this figure legend, the reader is referred to the web version of this article).

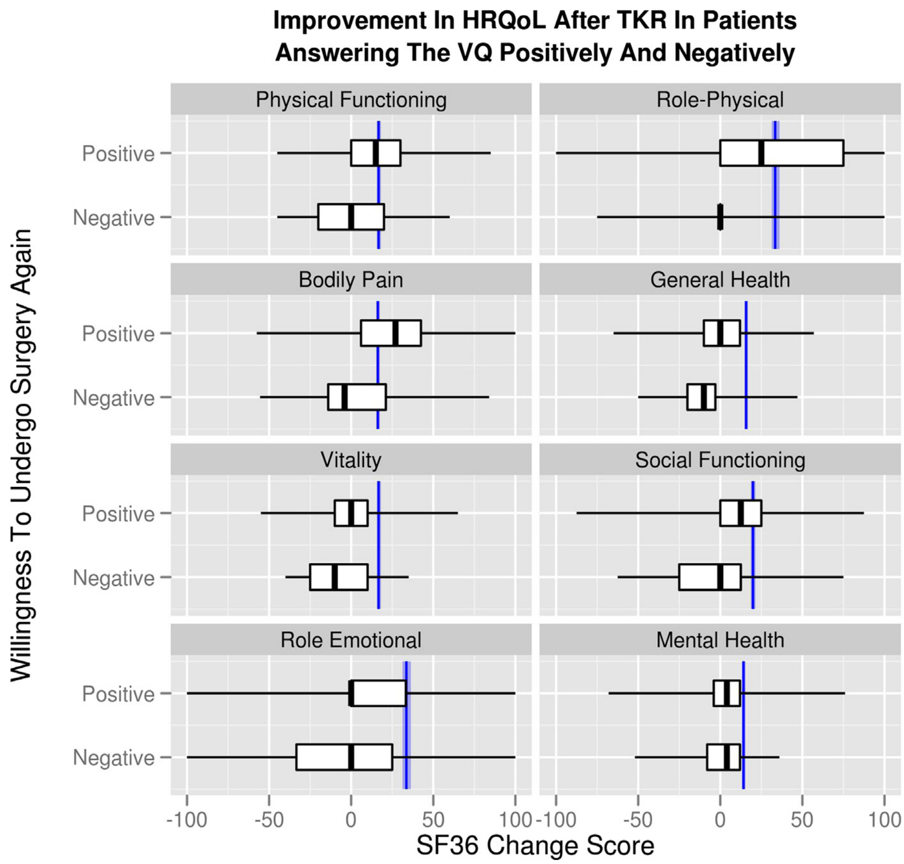

Fig. 2. Improvement in health-related quality of life after total knee replacement per validation question (VQ). The vertical blue lines indicate the clinically important difference of each subscale with its confidence interval shown in purple; the box plots indicate the median, interquartile range, and range of patients, who answered the VQ positively and negatively. SF-36, Short Form 36. (For interpretation of references to color in this figure legend, the reader is referred to the web version of this article).

et al. [9] and Escobar et al. [8] advise against using their MCIDs because of the imprecision of these estimates. To augment the precision of these estimates, one would need very large cohorts. For instance, Quintana started with 586 eligible THR patients and ended with 33 patients at 2-year follow-up, who described their status as somewhat better. To end up with 100 patients and achieve a more precise CID, approximately 1,750 eligible patients would be necessary. Additionally, arbitrary thresholds also play a role in anchor-based approaches. Chesworth et al. [10] have defined the CID as the mean improvement in the WOMAC score of patients who indicated +5 on a 15-point general transition Likert scale. Similar to the arbitrary effect sizes of Cohen, +5 might be reasonable but remains an arbitrary choice.

Table 3. Odds ratios of CIDs and the VQ

	Odds ratio (95% confidence interval)	
SF-36 subscale	**THR**	**TKR**
Physical functioning	5.86 (3.13, 11.7)	1.80 (0.78, 4.52)
Role-physical	2.08 (1.13, 3.95)	2.98 (1.19, 9.20)
Bodily pain	3.30 (1.81, 5.98)	4.72 (2.07, 11.8)
General health	4.92 (1.76, 21.2)	1.26 (0.46, 4.51)
Vitality	1.11 (0.59, 2.22)	0.78 (0.32, 2.20)
Social functioning	1.89 (1.02, 3.62)	3.35 (1.25, 11.9)
Role-emotional	2.84 (1.11, 9.83)	0.68 (0.29, 1.81)
Mental health	1.06 (0.55, 2.18)	0.95 (0.39, 2.70)

Abbreviations: CIDs, clinically important differences; SF-36, Short Form 36; THR, total hip replacement; TKR, total knee replacement; VQ, validation question.

An odds ratio >1 indicates that that particular CID is able to discriminate the patients who answered the VQ positively from the patients who answered the VQ negatively.

Our new approach overcomes these limitations in treatments with large effect sizes. To ensure precise estimates, we estimated CIDs using the distribution-based approach. This approach uses data of the entire cohort, enhancing the precision of the estimate as compared with anchor-based approaches. To overcome the nonintuitivity of the distribution-based approach, we have validated the CID estimates using a patient-relevant external criterion. Clinical meaningfulness is regained using the odds ratios.

Why are CIDs useful in treatments with large effect sizes? Although on average patients improve markedly after THR or TKR, not all patients benefit from these surgeries. Persistent pain is reported in 9% of THR patients and 20% of TKR patients at long-term follow-up [23]. Additionally, up to 30% of patients are dissatisfied with the surgical results [24–27]. Therapeutic options are limited in patients with persistent pain or dissatisfaction after joint replacement: the outcome of revision surgery performed without a specific mechanical or physiological indication is highly unpredictable. Furthermore, revision surgery is associated with a higher probability of orthopedic and medical complications. Unfulfilled patient expectations are thought to play a crucial role in unfavorable outcomes after joint replacement [28]. CIDs might bridge the gap between patient expectation and satisfaction. Using CID thresholds, it will be possible to predict the probability of a relevant improvement in various relevant areas of HRQoL, using clinical prediction models. These predictions for individual patients could be made before surgery has taken place and could form a solid base for expectation management. Such a tailored approach could lower the probability of unfavorable outcomes after joint replacement in future patients.

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Appendix

Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.jclinepi.2013.04.010.

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