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What makes the best performing hospital? the IQ Joint study

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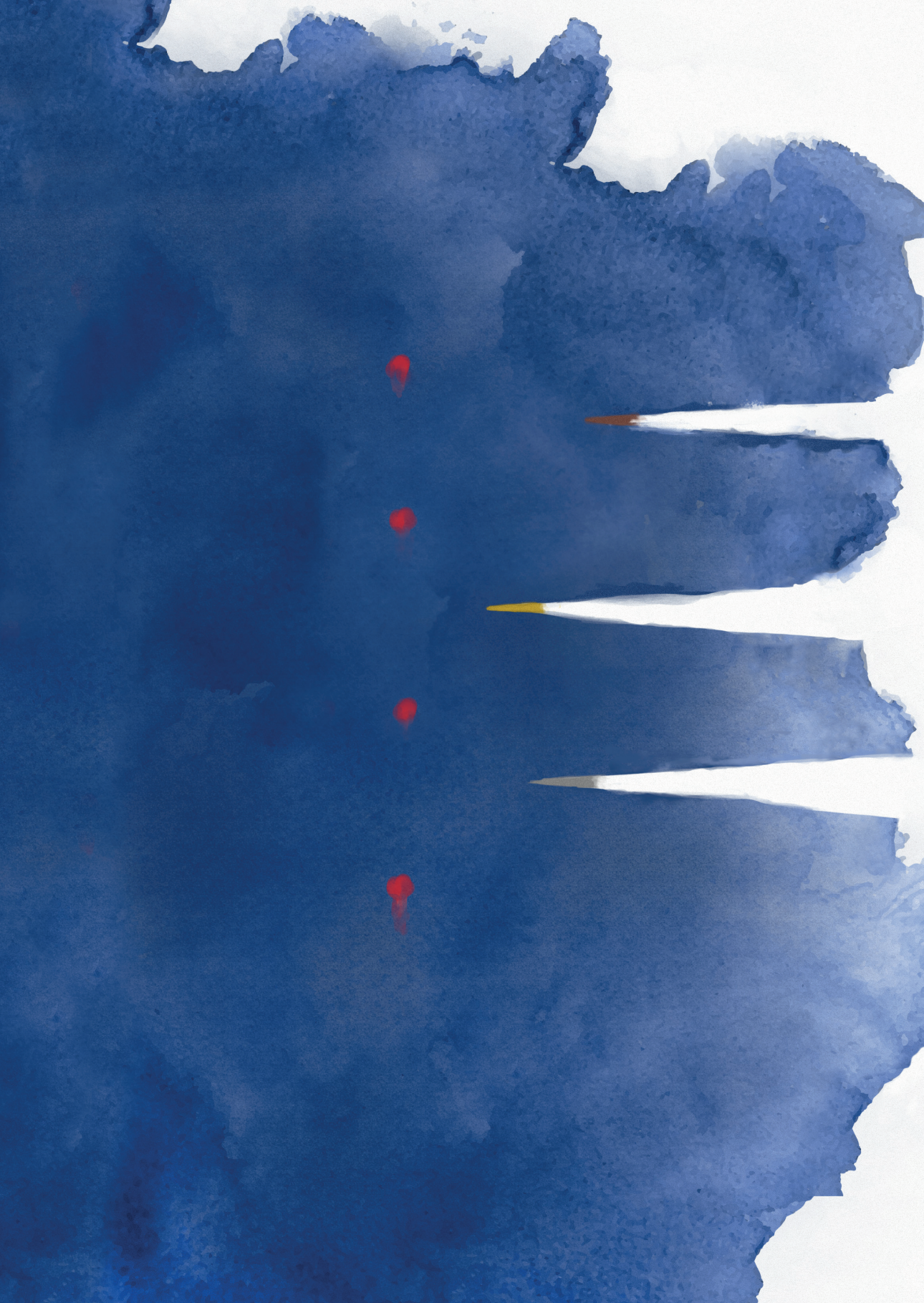
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Chapter 6

Is postoperative improvement in PROM scores after THA and TKA overestimated due to selective non-response? Linking PROM scores to adverse event data provides insights

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Submitted

Abstract

Background and purpose: Improvement in Patient Reported Outcome Measure (PROM) scores may be under or overestimated after total hip and knee arthroplasty (THA and TKA) as questionnaires are filled in by a selection of patients (PROM respondents). Linking PROM scores to adverse event data may provide insight in the direction of bias as these are known for all patients and likely associated with improvement in PROM scores. We, therefore, compared PROM respondents and non-respondents on their adverse event rates, examined whether patients experiencing adverse events had different improvement rates in PROM scores and whether hospitals with better adverse event rates showed different PROM response rates and improvement in PROM scores.

Methods: All primary THAs and TKAs performed in 19 Dutch hospitals between January 2017 and December 2019 were included. The HOOS and KOOS were used to assess the physical function after THA and TKA, respectively. Adverse events included were 1-year revision, 30-day readmission, 30-day complications, and long (i.e., >75th percentile) length-of-stay (LOS). A clinically relevant improvement was defined as at least a 10point decrease in HOOS and 9 points in KOOS scores. Patient-level associations were assessed using binary logistic regression models adjusted for patient characteristics, baseline PROM score, and clustering of patients within hospitals. Hospital-level correlations were assessed using Pearson correlations.

Results: 20,338 THA and 18,082 TKA procedures were included. HOOS and KOOS respondents mostly had more favourable adverse event rates than non-respondents. THA patients experiencing revision, complications, or long LOS were less likely to experience clinically relevant HOOS improvements (Odds ratios 0.11 [0.06-0.20], 0.44 [0.30-0.63] and 0.66 [0.50-0.88] respectively). TKA patients experiencing revision or long LOS were less likely to experience clinically relevant KOOS improvements (Odds ratios 0.26 [0.12-0.55] and 0.63 [0.50-0.80], respectively). Hospital performance on adverse events, and PROM response rates were not associated. Hospitals with better adverse event rates also had higher percentages of THA patients achieving clinically relevant HOOS improvements, while no associations were found for TKA patients.

Interpretation: Clinically relevant improvement in PROM scores are likely overestimated as PROM non-respondents had less favourable adverse event rates, which were associated with a lower likelihood to achieve a clinically relevant PROM improvement. Hospital differences are unlikely to be affected as hospital PROM response rates were not associated with adverse event rates.

Introduction

Clinical performance outcomes such as revision, readmission, complications, and length-of-stay (LOS) are unintended adverse events for patients and generally occur with low frequency after total hip and total knee arthroplasty (THA and TKA). (Van Schie et al. 2022) However, up to 10% and 20% of patients following THA and TKA, respectively, are dissatisfied with results, mainly related to continued pain and disability. (Rolfson et al. 2011, Dunbar et al. 2013) Patient Reported Outcome Measures (PROMs) measure the intended outcomes such as pain reduction, functionality improvement, and health-related quality of life gain and thereby complement the information provided by adverse events by identifying additional areas for improvement. (FDA 2009, Black 2013, Franklin et al. 2014, Rolfson et al. 2016, Johnston et al. 2019, Docter et al. 2021, Makhni 2021)

Similar to the need for high data completeness regarding adverse events to ensure no selection bias is at play, we also need high response rates of patients completing both pre- and postoperative questionnaires to calculate the improvement in PROMs. As for other national and regional arthroplasty registries, Dutch PROM response rates are low, with approximately 60% of patients completing the preoperative questionnaire for THA and TKA patients. In the absence of better response rates, we should at least gain insight into how those who complete questionnaires are a selection of all patients and in what direction this may cause bias (i.e., under- or overestimation of PROM improvement). Non-response bias is challenging to assess because, by definition, non-respondent data are not available and these non-respondents may differ systematically from respondents which would introduce bias. Previous studies have shown differences in patient characteristics, such as patients completing questionnaires being healthier, more likely to be white, having higher literacy rates, and lower rates of cognitive impairment, including dementia. (Norquist et al. 2000, Hutchings et al. 2013, Jahagirdar et al. 2013, Gibbons 2016, Kaur et al. 2023) However, these may still provide only a partial view by representing baseline patient characteristics rather than outcomes. Unintended adverse events are likely associated with improvement in PROM scores, and given the 97% completeness in registries for both THA and TKA, these seem well-suited to provide further insights into the relation between adverse event rates and postoperative PROM scores. (FDA 2009, Black 2013, Rolfson et al. 2016, Johnston et al. 2019, Bohm et al. 2021, Makhni 2021)

This study, therefore, aimed to provide insight into how improvement in PROM scores may be under- or overestimated relative to all patients who received a THA or TKA by 1) comparing PROM questionnaire respondents and non-respondents on their adverse event rates (i.e., revision, readmission, complications, and long LOS)

for THA and TKA, 2) examining whether patients experiencing adverse events had different improvement in PROM scores and 3) whether hospitals with better adverse event rates showed different PROM response rates and improvement in PROM scores.

Patients and Methods

Study design and setting

This observational study was performed in 19 hospitals (two university, four teaching, seven general, and six private clinics), reflecting the distribution across the Netherlands, using routinely collected data (i.e., data on revision and PROMs as well as patient characteristics) from the Dutch Arthroplasty Register (LROI). (van Steenberg et al. 2015, Van Steenberg et al. 2021, Van Schie et al. 2022) These were linked to hospital data on readmissions, complications, and LOS. These hospitals participated in a cluster randomised controlled trial to assess the effectiveness of a prospective multifaceted quality improvement intervention on patient outcomes after THA and TKA.(van Schie et al. 2023) The LUMC Medical Ethical Committee waived the need for ethical approval under Dutch law (CME, G18.140). This study was funded by the Van Rens Foundation (VRF-2018-001).

Participants

Anonymous data of all patients undergoing a primary THA or TKA between January 1, 2017, and December 31, 2019, were included from 20 Dutch hospitals. One general hospital did not provide PROMs data to the LROI and was therefore excluded, leaving data from 19 hospitals eligible for this study. Participating hospitals were comparable to all other Dutch hospitals in the distribution of median revision rates (1.7% vs 1.7% for THA, $p=1.00$ and 1.4% versus 0.9% for TKA, $p=0.62$). (van Schie et al. 2023)

Data source

Routinely submitted LROI data regarding patient characteristics, revision, and PROMs were used, which were linked for each patient to hospital data on readmission, complications, and LOS. The following data were provided by the LROI for each patient: (1) patient characteristics; age at surgery, gender, body mass index (BMI; kg/m²), current smoking status (yes/no), American Society of Anaesthesiologists (ASA) classification (I-IV), Charnley score (A/B1/B2/C/n/a), and indication for surgery (osteoarthritis/non-osteoarthritis); (2) whether a revision had taken place within 1 year after surgery; and (3) preoperative, 3-months postoperative (for THA), 6-months postoperative (for TKA) and 12-months postoperative PROM outcomes. The LROI data completeness is checked against Hospital Electronic Health Records and currently

exceeds 99% for primary procedures and 97% for revisions. Completeness is lower for PROMs data, currently 63% for preoperative PROMs for THA and 58% for TKA and lower for postoperative PROM questionnaires. LROI data were linked to hospital data by an IT specialist from each hospital. A clear definition for each adverse event was provided below to avoid measurement variability.

Adverse events

The one-year revision was calculated using LROI data based on primary surgery and revision dates. Other adverse events were calculated using the index hospitalisation during which the primary THA or TKA was performed. The outcomes were defined as:

- Revision: Any change, removal, or addition of any component within one year after primary surgery;
- Readmission: An admission within 30 days after discharge of the index hospitalisation;
- Complication: An adverse event other than revision during the index hospitalisation or within 30 days after discharge;
- Long LOS: LOS of the index hospitalisation is longer than the 75th percentile, based on all patients in the 19 hospitals, which was included because of possible hospital differences in sensitivity to report complications.

Patient-Reported Outcome Measures

The LROI routinely collects the HOOS-Physical function Short form (HOOS) and KOOS-Physical function Short form (KOOS), which are joint-specific PROMs and the most frequently collected PROMs in arthroplasty registries.(Bohm et al. 2021) The PROMs were collected preoperatively at the time of indication for surgery (with a maximum of 182 days before surgery), and 3 months (for THA), 6 months (for TKA), and 12 months postoperatively. The LROI does not compute an overall score when one or more questions are incomplete. The HOOS and KOOS contain 5 and 7 questions, respectively, to measure physical function.(Davis et al. 2008, Perruccio et al. 2008) Despite their brevity, these questionnaires have sufficient internal consistency and reliability and have been included in the standard set of outcome measures for hip and knee osteoarthritis of the International Consortium for Health Outcomes Measurement (ICHOM).(Braaksma et al. 2020) The scores range from 0 to 100, with higher scores reflecting more effort to perform activities (and thus worse function). Since patients are unlikely to notice a small improvement in PROM scores, a 10 points difference with the baseline PROM score was taken as a clinically relevant

improvement or worsening for the 3 months or 12 months postoperative HOOS score and a 9 points difference for the KOOS, as approximately half a standard deviation (sd) has been shown to reflect the minimally clinical relevant improvement in health-related quality of life for chronic diseases.(Norman et al. 2003)

Statistical analysis

Because both the pre-and postoperative PROM scores are needed to calculate an improvement in PROM scores, respondents on preoperative, 3 months (THA), 6 months (TKA), and 12 months (THA and TKA) postoperative PROM questionnaires were compared with non-respondents on their adverse event rates and patient characteristics using t-tests for continuous data and chi-square tests for categorical data.

Before examining patient-level and hospital-level correlations, missing data for patient characteristics (occurring in less than 5% of patients) were imputed. Missing data were considered missing at random and imputed using multiple imputations for ten rounds with predictive mean matching as the underlying model. All patient characteristics (i.e., age, gender, BMI, smoking, ASA score, Charnley score, and diagnosis), adverse events, and preoperative PROM scores were used as predictors, but only patient characteristics were imputed.

Patient-level associations between adverse events, and clinically relevant improvement in PROM scores were assessed using binary logistic regression models, separately for THA and TKA. The models included clinically relevant PROM improvement (yes/no) as the dependent variable and the adverse events as independent variables. For 30-day readmission, 30-day complications, and long LOS, we used improvement at the first postoperative PROM measurement (i.e., 3 months postoperative for THA and 6 months for TKA) as the dependent variable as this time point is more likely to reflect the impact of surgery. For revision, the 1 year postoperative PROM measurement was used because the exact revision date was unknown to us as researchers, which could occur before or after the first postoperative PROM measurement. All models were adjusted for the preoperative PROM score and all patient characteristics, as these have been shown to predict postoperative PROM scores.(Hofstede et al. 2016, Rolfson et al. 2016) Hospital was included as a random effect to account for the clustering of patients within hospitals.

Hospital-level correlations between standardised adverse event rates and standardised rates of patients with clinically relevant PROM improvements were estimated using Pearson correlation. We also examined correlations between standardised adverse event rates and PROM response rates. As mentioned above, the first postoperative PROM measurement was used for readmission, complications, and long LOS, and

the 12 months postoperative measurement for revision. Standardised rates were used to adjust for the possible differences between hospitals in their patient-mix, which would influence their risk on adverse events. Therefore, the observed (O) number of events in a hospital was divided by the expected (E) number based on the hospital's patient-mix to give an O/E ratio per hospital for each adverse event. For each patient, the expected adverse event risk was calculated using logistic regression analysis among all patients from all hospitals, including the patient characteristics described above as independent variables and the adverse event as the dependent variable. (Berliner et al. 2016, Hofstede et al. 2016, Rolfson et al. 2016, van Schie et al. 2020) The expected number for a hospital was then obtained by summing all patients' expected probabilities. The expected number of patients with a clinically relevant improvement was calculated similarly with the baseline PROM score additionally included as an independent variable.

All p-values were two-sided, and values below 0.05 were considered statistically significant in all analyses. Analyses were performed using SPSS (version 25; IBM) and STATA (version 14; StataCorp).

Results

20,338 primary THA procedures and 18,082 primary TKA procedures from 19 hospitals were included. Less than 10% of THA and TKA patients had missing data on readmission, complications, and LOS. Revision, readmission, complication, and long LOS rates were lower for TKA than THA (Table 1). LOS data were not normally distributed, making it challenging to create equal quartiles, so the closest integer value was chosen, which resulted in above 4 days being defined as long LOS for both THA and TKA. The mean LOS was 3.1 days (sd 2.5) for THA and 3.2 days (sd 1.9) for TKA. Revision rates were comparable to those observed among all Dutch hospitals. (van Schie et al. 2023)

Table 1 Clinical outcomes and patient characteristics after THA and TKA in 19 Dutch hospitals during 2017-2019.

	THA (n=20,338)	TKA (n=18,082)
Clinical outcomes		
1-year revision (%)	376 (1.8)	237 (1.3)
30-day readmission (%)	724 (3.9)	551 (3.4)
30-day complication (%)	735 (3.9)	417 (2.5)
Long LOS (%)	2,205 (11.8)	1,778 (10.9)
Patient characteristics		
Mean age in years (SD)	68.36 (10.3)	68.10 (8.8)
Sex, female (%)	13,029 (64.1)	11,199 (61.9)
BMI (SD)	26.94 (4.4)	29.29 (4.9)
Current Smokers (%)	2,122 (10.4)	1,524 (8.4)
ASA classification (%)		
• ASA I	3,853 (18.9)	2,507 (13.9)
• ASA II	12,622 (62.1)	11,997 (66.4)
• ASA III-IV	3,860 (19.0)	3,575 (19.8)
Charnley score (%)		
• A	8,158 (41.8)	6,587 (36.6)
• B1	6,241 (32.0)	6,743 (37.5)
• B2	4,502 (23.1)	3,994 (22.2)
• C	630 (3.2)	663 (3.7)
Diagnosis (%)		
• Osteoarthritis	18,019 (88.6)	17,510 (96.9)
• Non-Osteoarthritis	2,315 (11.4)	569 (3.1)

Less than 10% of the values for clinical outcomes were missing, and less than 5% for patient characteristics.

ASA=American Society of Anaesthesiologists; BMI=body mass index; LOS=length of stay; SD=standard deviation.

The mean HOOS and KOOS scores significantly improved postoperatively regardless of whether adverse events occurred (Figure 1). However, patients undergoing revision had significantly worse postoperative PROM scores than patients without revision. Comparable results were found for readmission, complications, and long LOS. For THA patients, 86% had clinically relevant improvements in the HOOS, and 2% had worsened scores at 3 months postoperatively. At 12 months, it was 90% and 2%, respectively. For TKA patients, 73% had clinically relevant improvement in the KOOS, and 3% had worsened scores at 6 months postoperative. At 12 months, it was 78% and 3%, respectively.

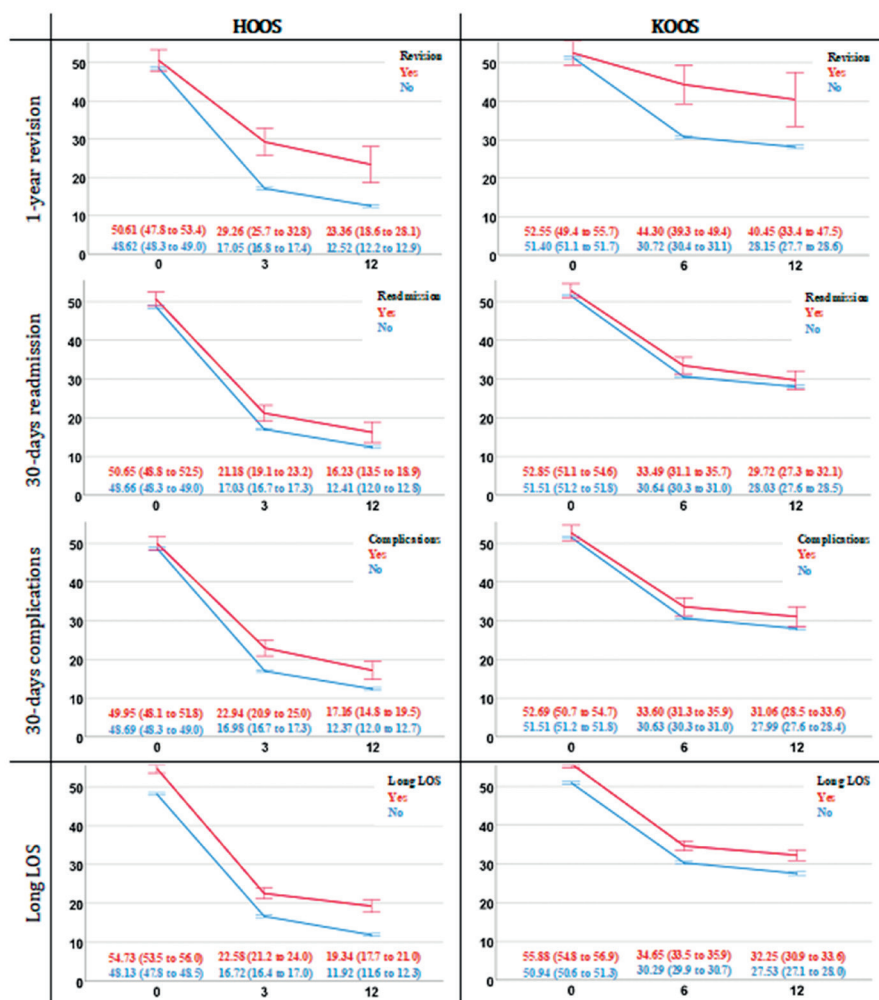


Figure 1 Mean PROM scores over time for clinical outcomes.

The line graphs show the mean and 95% confidence interval for preoperative and two postoperative PROM scores for patients with and without revisions, readmission, complications and long LOS.

X-axis: 0=preoperative; 3=3-months postoperative; 6=6-months postoperative; 12=12-months postoperative.

Y-axis: HOOS or KOOS scores.

Table 2 Respondents versus non-respondents of the HOOS.

Preoperative AND postoperative HOOS					
Respondent preoperative and 3 months postoperative (n=7,731; 38.0%)	Non-respondent preoperative and 3 months postoperative (n=12,607; 62.0%)	p-value	Respondent preoperative and 12 months postoperative (n=5,382; 26.5%)	Non-respondent preoperative and 12 months postoperative (n=14,956; 73.5%)	p-value
Clinical outcomes					
1-year revision (%)	93 (1.2)	283 (2.2)	<0.01	66 (1.2)	310 (2.1)
30-day readmission (%)	252 (3.3)	472 (3.7)	<0.01	166 (3.1)	558 (3.7)
30-day complication (%)	239 (3.1)	496 (3.9)	<0.01	170 (3.2)	565 (3.8)
Long LOS (%)	566 (7.3)	1639 (13.0)	<0.01	403 (7.5)	1802 (12.0)
Patient characteristics					
Mean age in years (SD)	68.98 (9.7)	67.98 (10.7)	<0.01	69.02 (9.9)	68.12 (10.5)
Gender, female (%)	4,876 (63.1)	8,153 (64.7)	0.02	3,379 (62.8)	9,650 (64.5)
Mean BMI in kg/m ² (SD)	27.07 (4.4)	26.85 (4.5)	<0.01	27.05 (4.4)	26.89 (4.4)
Current Smokers (%)	719 (9.3)	1403 (11.1)	<0.01	499 (9.3)	1623 (10.9)
ASA classification (%)					
• ASA I	1,376 (17.8)	2,477 (19.6)		944 (17.5)	2,909 (19.5)
• ASA II	4,983 (64.5)	7,639 (60.6)	<0.01	3,556 (66.1)	9,066 (60.6)
• ASA III-IV	1,370 (17.7)	2,490 (19.8)		880 (16.4)	2,980 (19.9)
Charnley score (%)					
• A	3,078 (39.8)	5,080 (40.3)		2,161 (40.2)	5,997 (40.1)
• B1	2,694 (34.8)	3,547 (28.1)	<0.01	1,828 (34.0)	4,413 (29.5)
• B2	1,644 (21.3)	2,858 (22.7)		1,161 (21.6)	3,341 (22.3)
• C	217 (2.8)	413 (3.3)		158 (2.9)	472 (3.2)
Indication (%)					
Osteoarthritis	7,278 (94.1)	10,741 (85.2)	<0.01	5,061 (94.0)	12,958 (86.6)
Non-Osteoarthritis	450 (5.9)	1865 (14.8)		318 (6.0)	1197 (13.4)

Percentages might not sum to 100 because of rounding.

ASA=American Society of Anaesthesiologists; BMI=body mass index; LOS=length of stay; N/A=not applicable; SD=standard deviation.

Table 3 Respondents versus non-respondents of the KOOS.

Preoperative AND postoperative KOOS					
	Non-respondent preoperative and 6 months postoperative (n=5,519; 30.5%)	p-value	Respondent preoperative and 12 months postoperative (n=4,319; 23.9%)	Non-respondent preoperative and 12 months postoperative (n=13,763; 76.1%)	p-value
Clinical outcomes					
1-year revision (%)	51 (0.9)	61 (1.4)	0.03	35 (0.8)	202 (1.5)
30-day readmission (%)	155 (2.8)	169 (3.8)	<0.01	115 (2.7)	436 (3.2)
30-day complication (%)	139 (2.6)	107 (2.4)	<0.01	108 (2.6)	309 (2.2)
Long LOS (%)	577 (10.5)	574 (12.9)	<0.01	485 (11.2)	1,293 (9.4)
Patient characteristics					
Mean age in years (SD)	68.50 (8.5)	67.93 (8.9)	<0.01	68.58 (8.5)	67.95 (8.8)
Gender, female (%)	3,393 (61.5)	7,806 (62.1)	0.40	2,641 (61.1)	8,558 (62.2)
Mean BMI in kg/m ² (SD)	29.43 (4.8)	29.22 (4.8)	<0.01	29.38 (4.8)	29.26 (4.8)
Current Smokers (%)	451 (8.2)	1,073 (8.5)	0.14	352 (8.2)	1,172 (8.5)
ASA classification (%)					
• ASA I	666 (12.1)	1,841 (14.7)		525 (12.2)	1982 (14.4)
• ASA II	3,718 (67.4)	8,279 (65.9)	<0.01	2,937 (68.0)	9,060 (65.8)
• ASA III-IV	1,135 (20.6)	2,440 (19.4)		857 (19.8)	2,718 (19.7)
Charnley score (%)					
• A	2,103 (38.1)	4,484 (35.7)		1,627 (37.7)	4,960 (36.0)
• B1	2,024 (36.7)	4,719 (37.6)		1,586 (36.7)	5,157 (37.5)
• B2	1,147 (20.8)	2,847 (22.7)	<0.01	913 (21.1)	3,081 (22.4)
• C	227 (4.1)	436 (3.5)		175 (4.1)	488 (3.5)
Indication (%)					
• Osteoarthritis	5,374 (97.4)	12,136 (96.6)	0.02	4,205 (97.4)	1,3305 (96.7)
• Non-Osteoarthritis	145 (2.6)	424 (3.4)		114 (2.6)	455 (3.3)
					0.04

Percentages might not sum to 100 because of rounding.

ASA=American Society of Anaesthesiologists; BMI=body mass index; LOS=length of stay; N/A=not applicable; SD=standard deviation.

Pre- and 3 months postoperative HOOS questionnaires were completed by 7,731 (38%) THA patients, and 5382 (27%) completed both pre- and 12 months postoperative questionnaires (Table 2). Patients who completed the pre- and postoperative HOOS questionnaire differed from those not completing it in having more favourable adverse event rates. Considering the 3206 patients with at least one adverse event, 2212 (69%) did not return both the preoperative and 3 months postoperative questionnaires compared with 59% of patients experiencing no adverse event, and thus were more likely to be a non-respondent. For not returning the preoperative and 12 months questionnaires, these figures were 80% and 71% respectively. Although absolute differences between respondents and non-respondents for most patient characteristics were small, they were nevertheless significant likely due to the large sample size. For the KOOS, pre- and 6 months postoperative questionnaires were completed by 5,519 (31%) TKA patients, and 4319 (24%) completed both pre- and 12 months postoperative questionnaires (Table 3). Patients who completed the pre- and postoperative KOOS questionnaires differed from those not completing it in having more favourable revision and readmission rates, but comparable complication rates and less favourable long LOS rates. Of 2549 patients with at least one adverse event, 1988 (78%) did not return both preoperative and 6 months postoperative questionnaires compared with 67% of patients experiencing no adverse event. For not returning the preoperative and 12 months postoperative questionnaires, these figures were and 82% respectively 74%. Significant differences were found for most patient characteristics, except gender, smoking and BMI.

Patients experiencing revision, complications, or long LOS were less likely to achieve a clinically relevant improvement in the HOOS (89%, 56%, and 34% less likely, respectively), with the association for readmission going in the same direction but non-significant (Table 4). Patients experiencing revision or long LOS were less likely to achieve a clinically relevant improvement in the KOOS (74% and 37% less likely, respectively), with associations for readmission and complications in the same direction but non-significant.

Table 4 Patient-level associations between clinical outcomes and clinically relevant improvement in PROM scores.

	HOOS	KOOS
	OR (95% CI)	OR (95% CI)
1-year revision	0.11 (0.06 – 0.20)	0.26 (0.12 – 0.55)
30-days readmission	0.71 (0.48 – 1.06)	0.70 (0.46 – 1.05)
30-days complications	0.44 (0.30 – 0.63)	0.79 (0.51 – 1.23)
Long LOS	0.66 (0.50 – 0.88)	0.63 (0.50 – 0.80)

A difference of 10 points was taken as a clinically relevant improvement for the HOOS and 9 points for the KOOS. LOS=length of stay.

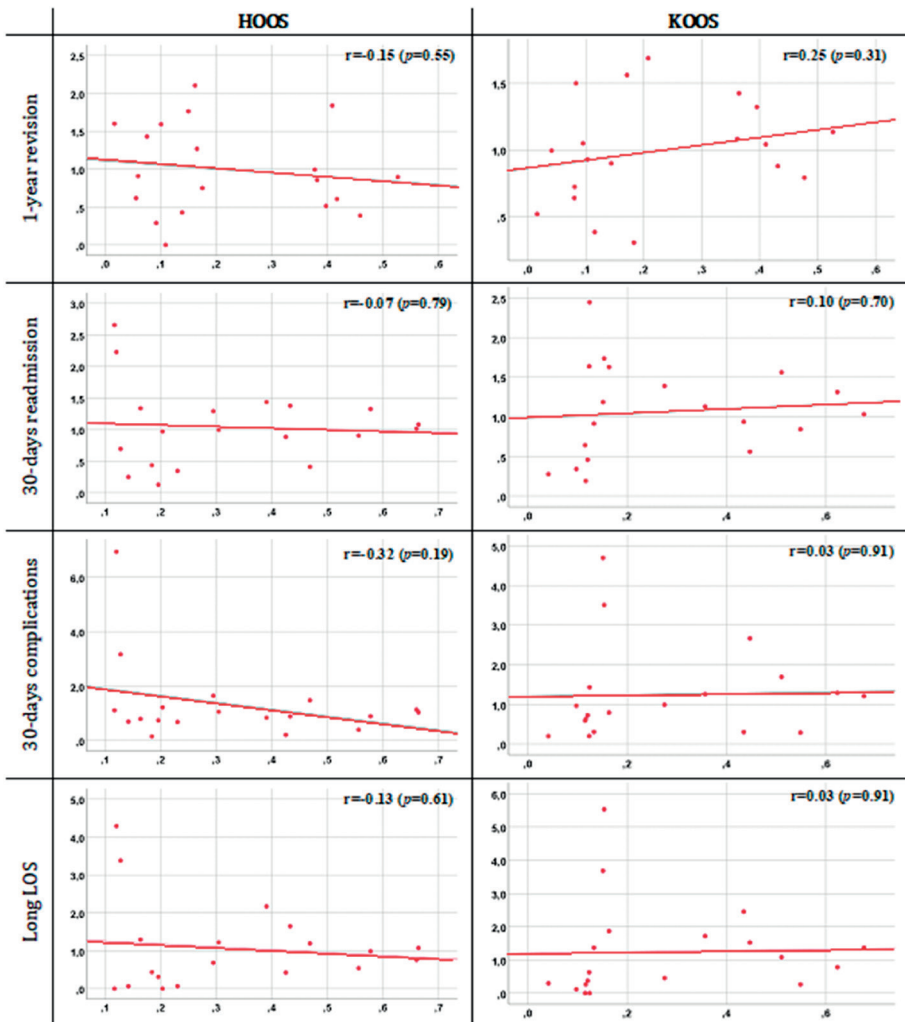


Figure 2 Hospital-level correlations between clinical outcomes and PROM response rates.

The y-axis shows the standardised (O/E ratio) clinical outcomes, with a higher value representing hospitals with more events than expected based on patient characteristics (worse performance).

The x-axis shows the PROM response rates for the hospitals.

The strength of correlations is defined as: ≤ 0.35 weak >0.35 - 0.67 moderate and >0.67 strong (47).

LOS=Length of stay; O/E=Observed divided by expected; r=correlation coefficient.

Considerable between-hospital variation as shown by the interquartile range was found in (standardised) adverse event rates, patient characteristics, response rates on PROM questionnaires, mean PROM scores, and to a smaller extent in the standardised percentage of patients achieving clinically relevant improvement in PROM scores (Table 5). There was no association between hospital performance on standardised adverse event rates and PROM response rates (Figure 2). Hospitals with lower (i.e.,

better) standardised readmission, complications, and long LOS rates also had higher standardised percentages of patients with clinically relevant improvements in the HOOS ($r=-0.58$ $p<0.01$, $r=-0.82$ $p<0.01$ and $r=-0.65$ $p<0.01$ respectively), with correlations for revision in the same direction but non-significant ($r=-0.19$, $p=0.44$) (Figure 3). For TKA, no significant correlations were shown with improvement in the KOOS.

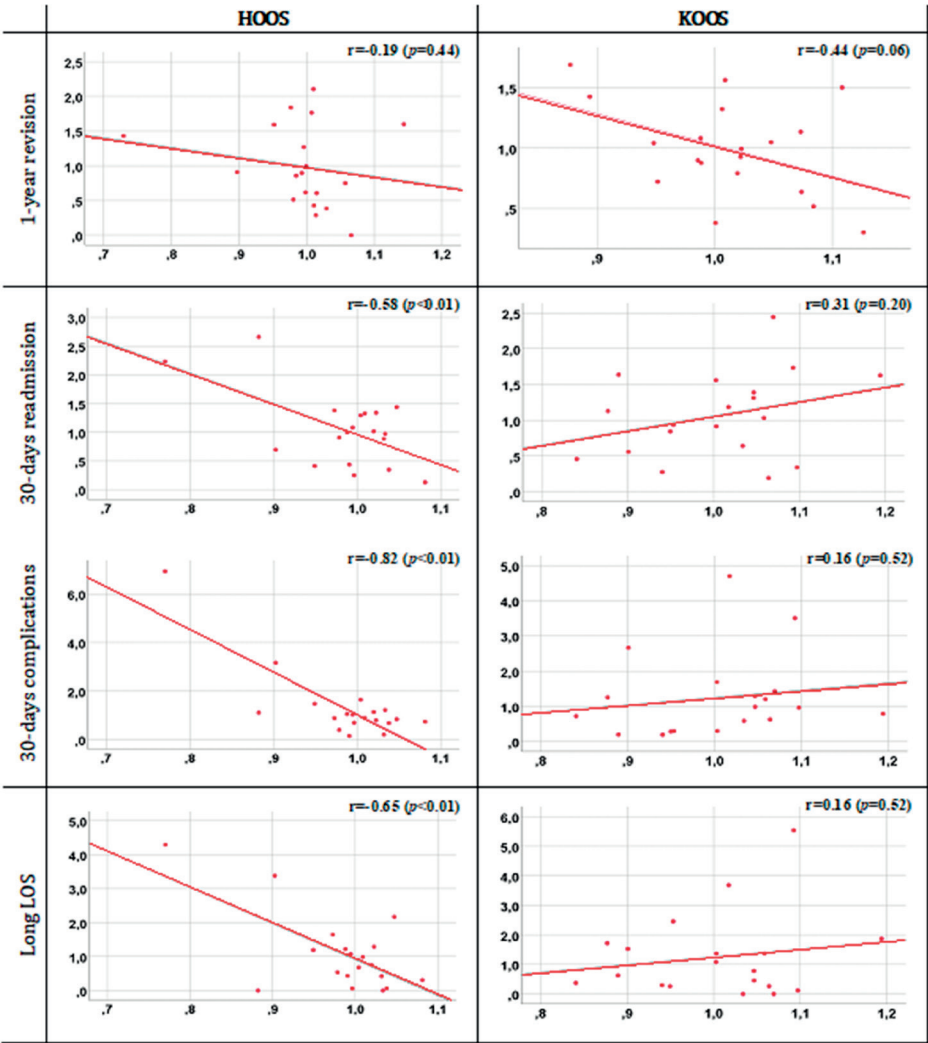


Figure 3 Hospital-level correlations between clinical outcomes and clinically relevant improvement. The y-axis shows the standardised (O/E ratio) clinical outcomes, with a higher value representing hospitals with more events than expected based on patient characteristics (worse performance). The x-axis shows the standardised (O/E ratio) percentages of patients with clinically relevant improvement in PROM scores, with a higher value representing hospitals with more patients with clinically relevant improvement than expected based on patient characteristics and preoperative PROM scores (better performance). The strength of correlations is defined as: ≤ 0.35 weak $>0.35-0.67$ moderate and >0.67 strong (47). LOS=Length of stay; O/E=Observed divided by expected; r=correlation coefficient.

Table 5 Hospital-level variation between 19 Dutch hospitals performing THA and TKA during 2017-2019.

	THA (<i>n</i> =19 hospitals)	TKA (<i>n</i> =19 hospitals)
	Median (IQR)	Median (IQR)
Procedures (<i>n</i>)	1,144 (615-1,388)	838 (580-1,378)
<u>Clinical outcomes</u>		
1-year revision (%)	1.7 (0.9-2.7)*	1.3 (0.9-1.7)**
<i>Standardised</i>	0.9 (0.6-1.5)	1.0 (0.8-1.2)
30-day readmission (%)	4.0 (2.0-6.0)	3.9 (1.8-5.5)
<i>Standardised</i>	1.0 (0.6-1.3)	1.0 (0.6-1.5)
30-day complication (%)	3.7 (2.3-4.5)	2.0 (1.0-3.5)
<i>Standardised</i>	0.89 (0.4-1.3)	1.0 (0.4-1.4)
Long LOS (%)	9.0 (2.6-19.8)	9.4 (2.5-20.9)
<i>Standardised</i>	0.8 (0.4-1.3)	0.8 (0.3-1.6)
<u>Patient characteristics</u>		
Mean age (years)	69.1 (64.3-70.0)	68.9 (66.3-69.6)
Sex, female (%)	63.7 (62.1-65.1)	62.7 (59.9-64.0)
Mean BMI	27.1 (26.7-27.2)	29.5 (28.6-30.0)
Current smokers (%)	10.7 (9.2-12.2)	9.1 (7.5-10.3)
ASA classification (%)		
• ASA I	14.6 (9.8-19.9)	9.8 (7.7-14.3)
• ASA II	62.7 (58.7-66.8)	67.3 (60.9-71.0)
• ASA III-IV	22.3 (7.1-27.2)	22.7 (13.1-30.2)
Charnley score (%)		
• A	43.1 (37.8-47.1)	38.7 (28.2-41.5)
• B1	30.4 (28.1-33.0)	32.6 (31.6-42.1)
• B2	22.6 (19.4-24.1)	22.5 (19.0-24.4)
• C	2.9 (1.2-5.3)	2.2 (1.2-5.2)
Indications (%)		
• Osteoarthritis	89.4 (83.6-91.3)	97.1 (95.8-97.8)
• Non-Osteoarthritis	10.6 (7.7-16.8)	2.9 (2.3-4.4)
<u>HOOS/KOOS response rate</u>		
Pre- and 3-months postop (%)	29.5 (17.4-45.9)	N/A
Pre- and 6-months postop (%)	N/A	15.4 (12.2-44.4)
Pre- and 12-months postop (%)	16.2 (9.6-39.3)	17.1 (8.9-38.7)
<u>Mean HOOS/KOOS scores</u>		
3-months postoperative	17.5 (15.8-18.9)	N/A
6-months postoperative	N/A	31.0 (29.5-34.1)
12-months postoperative	12.8 (9.7-14.4)	28.0 (24.9-29.7)
<u>Standardised percentage of patients with clinically relevant improvement</u>		
Pre- and 3-months postop	1.00 (0.98-1.03)	N/A
Pre- and 6-months postop	N/A	1.02 (0.95-1.06)
Pre- and 12-months postop	1.00 (0.98-1.01)	1.01 (0.99-1.06)

The value under “Median (IQR)” indicates the median hospital’s mean or percentage. Standardised clinical outcomes were adjusted for patient characteristics (age, sex, BMI, current smokers, ASA classification, Charnley score, and diagnosis). Standardised percentages of patients with clinically relevant improvements were adjusted for patient characteristics and preoperative PROM scores.

*Dutch 1-year revision percentage for THA was 1.7%.(20)

**Dutch 1-year revision percentage for TKA was 0.9%.(20)

ASA=American Society of Anaesthesiologists; BMI=body mass index; IQR=interquartile range.

Discussion

Interpretation of the results

To investigate whether missing PROM data for THA and TKA may result in under- or overestimation of PROM improvement scores, we used adverse event rates to examine how these differed between respondents and non-respondents and their association with PROM improvement scores. We found that PROM respondents had more favourable adverse event rates than non-respondents for the HOOS, and also for revision and readmission for the KOOS. Patients experiencing revision, complications, or long LOS after THA were less likely to have a clinically relevant improvement in the HOOS, with results for readmission in the same direction but non-significant. The strongest association was found for revision, suggesting that quality improvement initiatives should focus most on reducing revision rates to benefit patient care. Comparable results were found for the KOOS. Since patients completing PROM questionnaires generally have more favourable adverse event rates than non-respondents, this means that part of the patients who were less likely to achieve a clinically relevant improvement would be missed, and therefore that PROM improvement scores are likely overestimated. This means, for example, that less than our estimated 90% of THA and 78% of TKA patients had a clinically relevant improvement at 12 months postoperatively in the HOOS and KOOS, respectively.

Hospital-level results for THA and TKA patients showed no association between adverse event rates and PROMS response rates, and for THA that better adverse event rates were associated with higher percentages of patients achieving clinically relevant improvement in the HOOS. Despite the large between-hospital variation in PROM response rates, which in general tends to remove those with less favourable adverse events, there was no association between hospital adverse events and their PROM response rates. In other words, hospitals with different PROM response rates do not systematically have different adverse event rates, suggesting that hospital differences in PROM improvement scores are likely unaffected.

Strengths and limitations

This study is the first to report associations between a set of commonly used adverse events and the likelihood of achieving a clinically relevant improvement in physical functioning after THA and TKA. Given the observed associations, it seems likely that initiatives to improve the quality of care by reducing revision, readmission, complications, and long LOS rates will be accompanied by increased percentages of patients achieving clinically relevant improvement in physical functioning, but also that improvement after THA and TKA is likely overestimated. However, we found no evidence that this has affected the estimated between-hospital differences

in PROM improvement rates. Some limitations should be noted. First, data were obtained from 19 hospitals rather than all Dutch hospitals performing THA and TKA in the Netherlands. However, these hospitals reflected the national distribution of hospital types (i.e., university, teaching, general, and private clinics) and had comparable revision rates to national data, so it seems unlikely that the selection of hospitals would affect our results.(van Schie et al. 2023) Second, this study can only provide indirect evidence due to the lack of information about changes in PROM scores among non-respondents. Third, non-response is known to be affected by patient characteristics. So, if non-respondents would systematically have more favourable patient characteristics (e.g., younger and with better health status) known to be related to more improvement in PROMs, then this could be the case for the non-respondents without adverse events. However, Tables 2 and 3 did not indicate such systematic differences, as respondents were older, but less often smoked and ASA 3+. Potential risk factors such as mental health and emotional health status were not included to adjust the associations between adverse events and improvement in PROM scores as these variables are not collected by the LROI.(Ayers et al. 2013, Giesinger et al. 2013) Although the available patient characteristics are likely the most relevant, some residual confounding may remain.(Hofstede et al. 2016, Rolfson et al. 2016) We could not think of other reasons why non-respondents would be expected to experience a greater or lesser improvement in PROM scores after an adverse event. Fourth, patients undergoing THA or TKA may not improve as much in their PROM scores if another joint is also affected. The latter will influence associations when the prevalence of such patients is unevenly distributed among patients with or without adverse events.

Comparison to the literature

This study showed that 1 year after surgery, 90% of THA patients achieved a clinically relevant improvement and 78% of TKA patients. However, 2% of THA and 3% of TKA patients reported a clinically relevant worsening, with respectively 8% and 19% showing no relevant change. The lower percentages of improvement in PROM scores for TKA than THA are consistent with earlier studies from our group and others in Sweden and the United States.(Rolfson et al. 2011, Keurentjes et al. 2013, Keurentjes et al. 2013, Keurentjes et al. 2014, Lyman et al. 2018) It should be noted that while patients with worse preoperative PROM scores may improve more, they do not achieve the same postoperative level as patients with better preoperative function scores.(Hofstede et al. 2016) Additionally, previous studies have reported higher satisfaction rates for THA than TKA, which would seem consistent with more patients achieving clinically relevant improvement in PROM scores.(Bourne et al. 2010, Dunbar et al. 2013, Haanstra et al. 2015, Tilbury et al. 2016) Satisfaction rates may improve further by addressing preoperative expectations, a significant predictor

for dissatisfaction following TKA.(Dunbar et al. 2013)In the Dutch registry, 63% and 58% of patients completed the preoperative HOOS and KOOS questionnaire, respectively, which are low compared with the Scandinavian registries but higher than the Italian Register of the Orthopaedic Prosthetic Implants and the Michigan Arthroplasty Register.(Rolfson et al. 2016) This would suggest that the extent of overestimation in PROM improvement is likely smaller for countries with better response rates, provided that adverse event rates are similar. In line with our results, one study including THA patients found that non-response during follow-up was not at random; non-respondents had significantly lower PROM scores at the previous time point than respondents, so indicating that patients reporting good outcomes were overrepresented.(Imam et al. 2014) In another study, TKA patients respondents reported a higher mean Knee Society Score (KSS), mean function score and lower mean pain score than non-respondents.(Kim et al. 2004) Comparable results were reported in another study, including patients after shoulder replacement, and another study identified a trend of worse outcomes for non-respondents (Norquist et al. 2000, Polk et al. 2013).

The PROMs Working Group of the ISAR stated that a response rate above 80% is recommended for reliable outcome assessment but proposes a 60% threshold for an acceptable response rate.(Rolfson et al. 2016) Only six of the 16 arthroplasty registries collecting PROMs capture >80% of their preoperative and postoperative PROMs; the remaining registries reported response rates less than 60%.(FDA 2009, Black 2013, Rolfson et al. 2016, Johnston et al. 2019, Bohm et al. 2021, Makhni 2021) Another study stated that a 100% response rate is needed to adequately evaluate PROM difference scores because of a change in the distribution of predictors when a selection of patients is analysed, resulting in unreliable outcomes.(Pronk et al. 2020) This seems only feasible if PROM collection is mandatory and becomes part of the doctor-patient conversations on THA and TKA care goals.(Murthy et al. 2022)

Conclusions

Respondents to PROM questionnaires less often experienced adverse events. This likely results in an overestimation of the clinically relevant improvement in PROMs as adverse events were associated with a lower likelihood to achieve a clinically relevant PROM improvement. Hospital differences in PROM response rates were not associated with differences in adverse event rates, suggesting that estimated between-hospital differences in PROM improvement are likely unaffected. Ultimately, patients undergo THA and TKA to improve their function, and our results suggest that this may be further improved by continued efforts to reduce adverse event rates.

Author contributions

PvS: Conceptualisation and design of manuscript; Methodology; Formal analysis; Data curation; Writing (original draft); Project administration. LvB: Conceptualisation and manuscript design; Writing (review & editing); Supervision. TZ: Conceptualisation and manuscript design; Data curation; Writing (original draft). TG: Writing (review & editing). RN: Conceptualisation and design of manuscript; Writing (review & editing); Supervision; Funding acquisition. PM: Conceptualisation and design of manuscript; Conceptualisation of the manuscript; Methodology; Formal analysis; Writing (review & editing); Supervision; Project administration; Funding acquisition.

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