Linking Patient-Reported Outcome Measure Scores to Adverse Event Data to Gain Insight into Overestimation of Postoperative Patient-Reported Outcome Measure Improvement After Total Hip Arthroplasty and Total Knee Arthroplasty Due to Selective Nonresponse

IQ Joint Study Group

DOI
10.1016/j.arth.2024.06.064

Publication date
2024

Document Version
Final published version

Published in
Journal of Arthroplasty

Citation (APA)
IQ Joint Study Group (2024). Linking Patient-Reported Outcome Measure Scores to Adverse Event Data to Gain Insight into Overestimation of Postoperative Patient-Reported Outcome Measure Improvement After Total Hip Arthroplasty and Total Knee Arthroplasty Due to Selective Nonresponse. *Journal of Arthroplasty*, *40*(1), 45-52. https://doi.org/10.1016/j.arth.2024.06.064

The Journal of Arthroplasty 40 (2025) 45–52

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Primary Hip and Knee Arthroplasty

Linking Patient-Reported Outcome Measure Scores to Adverse Event Data to Gain Insight into Overestimation of Postoperative Patient-Reported Outcome Measure Improvement After Total Hip Arthroplasty and Total Knee Arthroplasty Due to Selective Nonresponse

Peter van Schie, MD [a, *], Leti van Bodegom-Vos, PhD [b], Tristan M. Zijdeman [b], Taco Gosens, MD, PhD [c], Rob G.H.H. Nelissen, MD, PhD [a], Perla J. Marang-van de Mheen, PhD [a, d], for the IQ Joint Study Group

[a] Department of Orthopaedics, Leiden University Medical Centre, Leiden, The Netherlands
[b] Department of Biomedical Data Sciences, Medical Decision Making, Leiden University Medical Centre, Leiden, The Netherlands
[c] Department of Orthopaedics, ETZ, Tilburg, The Netherlands
[d] Faculty of Technology, Policy & Management, Department of Safety & Security Science, Delft University of Technology, Delft, The Netherlands

ARTICLE INFO

Article history:
Received 4 March 2024
Received in revised form
23 June 2024
Accepted 26 June 2024
Available online 3 July 2024

Keywords:
total hip arthroplasty
total knee arthroplasty
patient reported outcome measures
arthroplasty register
clinical performance outcomes

ABSTRACT

Background: The purpose of the study was to gain insight into how clinically relevant improvement in patient-reported outcome measure scores after total hip arthroplasty (THA) and total knee arthroplasty (TKA) may be underestimated or overestimated, we compared patient-reported outcome measure respondents and nonrespondents on their adverse event rates and assessed whether adverse event occurrence was associated with clinically relevant patient-reported outcome measure improvement from those without adverse events.

Methods: All primary THAs and TKAs performed in 19 Dutch hospitals between January 2017 and December 2019 were included. The hip disability and osteoarthritis outcome score-physical function short form (HOOS-PS) and knee injury and osteoarthritis outcome score-physical function short form (KOOS-PS) were used to assess the physical function after THA and TKA, respectively. Adverse events included 1-year revision, 30-day readmission, 30-day complications, and long (ie, >75th percentile) length of stay. A clinically relevant improvement was defined as at least a 10-point decrease in HOOS-PS and 9 points in KOOS-PS scores. Associations between adverse events and clinically relevant HOOS-PS and KOOS-PS improvement were assessed using binary logistic regression models adjusted for patient characteristics and clustering of patients within hospitals.

Results: There were 20,338 THA and 18,082 TKA procedures included. Adverse events occurred more frequently in HOOS-PS and KOOS-PS nonrespondents than in respondents. The THA patients experiencing revision, complications, or long length of stay were less likely to experience clinically relevant HOOS-PS improvements (odds ratios of 0.11 [0.06 to 0.20], 0.44 [0.30 to 0.63], and 0.66 [0.50 to 0.88], respectively). The TKA patients experiencing revision or long length of stay were less likely to experience clinically relevant KOOS-PS improvements (odds ratios of 0.26 [0.12 to 0.55] and 0.63 [0.50 to 0.80], respectively).

Conclusions: Clinically relevant HOOS-PS and KOOS-PS improvements are likely overestimated, as nonrespondents had higher adverse event rates which were associated with lower likelihood to achieve clinically relevant HOOS-PS and KOOS-PS improvements.

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to https://doi.org/10.1016/j.arth.2024.06.064.

Ethics approval: The LUMC Medical Ethical Committee waived the need for ethical approval under Dutch law (CME, G18.140).

* Address correspondence to: Peter van Schie, MD, Department of Orthopaedics, Leiden University Medical Centre, Albinusdreef 2, Leiden 2333 ZA, The Netherlands.

https://doi.org/10.1016/j.arth.2024.06.064

Clinical performance outcomes such as revision, readmission, complications, and long length of stay (LOS) are unintended adverse events for patients and generally occur with low frequency after total hip and total knee arthroplasties (THA and TKA, respectively) [1]. However, up to 10% and 20% of patients following THA and TKA, respectively, are dissatisfied with the results, mainly related to continued pain and disability [2,3]. Patient-reported outcome measures (PROMs) measure the intended outcomes such as pain reduction, functionality improvement, and health-related quality-of-life gain, thereby complementing information provided by adverse events on possible areas for improvement [4–8].

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 preoperative and postoperative questionnaires to calculate the improvement in PROMs. Similar to 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 [9,10]. 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 (ie, underestimation or overestimation of PROM improvement). Nonresponse bias is challenging to assess because, by definition, nonrespondent data are unavailable and these nonrespondents 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 having lower rates of cognitive impairment, including dementia [11–15]. However, these may still provide only a partial view by representing baseline patient characteristics rather than outcomes and not showing the direction of the bias.

Unintended adverse events such as revisions or complications may help to provide insights into the direction of any selection bias, as these data are available for both PROM respondents and nonrespondents and likely related to improvement in PROMs. We can assess whether PROM nonrespondents are a selection of patients who had, for example, a higher occurrence of revision or complications, and assess the relationship between adverse event occurrence and the likelihood of achieving an improvement in PROM scores [4,7,16]. Assuming such relationships will be the same regardless of whether respondents fill in PROM questionnaires or not, combining these results will indicate the direction of any selection bias, that is, whether PROM improvements as estimated among respondents will likely provide an overestimation or underestimation of the PROM improvements in the total population.

This study, therefore, aimed to provide insight into how improvement in PROM scores may be underestimated or overestimated relative to all patients who received a THA or TKA by (1) comparing PROM questionnaire respondents and nonrespondents on their adverse event rates (ie, revision, readmission, complications, and long LOS) after THA and TKA; and (2) examining the relationship between the occurrence of these adverse events and clinically relevant improvement in PROM scores.

Materials and Methods

Study Design and Setting

This observational study was performed in 19 hospitals (2 university, 4 teaching, 7 general, and 6 private clinics), reflecting the distribution across the Netherlands, using routinely registry collected data (ie, data on revision and PROMs as well as patient characteristics) from the Dutch Arthroplasty Register (LROI) [1]. These were linked to routinely collected hospital data on readmissions, complications, and LOS. These hospitals participated in a cluster randomized controlled trial to assess the effectiveness of a prospective multifaceted quality improvement intervention on patient outcomes after THA and TKA [17,18]. The Leiden University Medical Center 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 the 20 Dutch hospitals participating in the aforementioned trial. 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 versus 1.7% for THA, $P = 1.00$ and 1.4 versus 0.9% for TKA, $P = .62$), suggesting a representative Dutch sample [18].

Data Source

Routinely collected 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, sex, body mass index, current smoking status (yes/no), American Society of Anaesthesiologists classification (I to IV), Charnley score (A/B1/B2/C/n/a), and indication for surgery (osteoarthritis/nonosteoarthritis); (2) whether a revision had taken place within 1 year after surgery; and (3) preoperative, 3-month postoperative (for THA), 6-month postoperative (for TKA), and 12-month postoperative PROM outcomes. The LROI procedure completeness is checked against Hospital Electronic Health Records and currently exceeds 99% for primary procedures and 97% for revisions [19]. Completeness is lower for PROM data, currently 63%, for preoperative PROMs for THA and 58% for TKA, and lower for postoperative PROM questionnaires [9,10]. The Landelijke Registratie Orthopedisch Interventies (LROI) data were linked to hospital data by an information and technology specialist from each hospital. A clear definition for each adverse event was provided below to avoid measurement variability.

Adverse Events

The occurrence of a revision within 1 year was calculated using LROI data based on the dates of primary and revision surgery. Other adverse events were calculated using the index hospitalization during which the primary THA or TKA was performed. The outcomes were defined as:

- Revision: Any change, removal, or addition of any component within 1 year after primary surgery;
- Readmission: An admission within 30 days after discharge of the index hospitalization;
- Complication: An adverse event other than revision during the index hospitalization or within 30 days after discharge;
- Long LOS: LOS of the index hospitalization 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 and because it is a deviation from the expected discharge data communicated to patients [19].

Patient-Reported Outcome Measures

The LROI routinely collects the Hip disability and Osteoarthritis Outcome Score-Physical function Short form (HOOS-PS) and Knee injury and Osteoarthritis Outcome Score-Physical function Short form (KOOS-PS), which are joint-specific PROMs and the most frequently collected PROMs in arthroplasty registries [16,20,21]. The PROMs were collected preoperatively at the time of indication for surgery (with a maximum of 182 days before surgery), 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-PS and KOOS-PS contain 5 and 7 questions to measure physical function, respectively [20,21]. 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 [22,23]. 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-point difference with the baseline PROM score was taken as a clinically relevant improvement or worsening for the 3 months or 12 months postoperative HOOS-PS score and a 9-point difference for the KOOS-PS, as approximately half an SD has been shown to reflect the minimal clinically relevant improvement in health-related quality of life for chronic diseases [24].

Data Analyses

Because both the preoperative and postoperative PROM scores are needed to calculate an improvement in PROM scores, respondents on preoperative, 3-month (THA), 6-month (TKA), and 12-month (THA and TKA) postoperative HOOS-PS/KOOS-PS questionnaires were compared with nonrespondents on their adverse event rates and patient characteristics using *t*-tests for continuous data and *Chi*-square tests for categorical data.

Data on patient characteristics were missing for less than 2% of patients. Missing data were considered missing at random and imputed using multiple imputations for 10 rounds, with predictive mean matching as the underlying model. All patient characteristics (ie, age, sex, body mass index, smoking, American Society of Anaesthesiologists score, Charnley score, and diagnosis), adverse events, and preoperative HOOS-PS/KOOS-PS scores were used as predictors, but only patient characteristics were imputed.

Associations between adverse events, and clinically relevant improvement in HOOS-PS/KOOS-PS scores were assessed using binary logistic regression models, separately for THA and TKA. The models included clinically relevant HOOS-PS/KOOS-PS improvement (yes/no) as the dependent variable and the adverse events as independent variables. All models were adjusted for all patient characteristics mentioned previously, as these have been shown to predict postoperative PROM scores [25]. Hospital was included as a random effect to account for the clustering of patients within hospitals, as for example, treatment received by patients within a hospital will be more similar than for patients in other hospitals, and by including hospital as a random effect, we adjust for such hospital-specific factors. For 30-day readmission, 30-day complications, and long LOS, we used improvement at the first postoperative HOOS-PS/KOOS-PS measurement (ie, 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 HOOS-PS/KOOS-PS measurement was used because the exact revision date was unknown to us as researchers, which could occur before or after the first postoperative HOOS-PS/KOOS-PS measurement.

All *P* values were 2-sided, and values below 0.05 were considered statistically significant in all analyses. Analyses were performed using Statistical Package for the Social Sciences (version 25; International Business Machines, Armonk, NY) and STATA (version 14; StataCorp, Lakeway, TX).

There were 20,338 primary THA procedures and 18,082 primary TKA procedures from 19 hospitals included. Less than 10% of THA and TKA patients had missing data on readmission, complications, and LOS. Revision, readmission, complications, and long LOS rates were lower for TKA than THA (Table 1). The 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 [18].

Results

The mean HOOS-PS and KOOS-PS scores significantly improved postoperatively, regardless of whether adverse events occurred (Figure 1). However, patients undergoing revision had significantly worse postoperative HOOS-PS/KOOS-PS scores than patients who did not have a revision. Comparable results were found for readmission, complications, and long LOS. For THA patients, 86% had clinically relevant improvements in the HOOS-PS, and 2% had clinically relevant 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-PS, and 3% had clinically relevant worsened scores at 6 months postoperatively. At 12 months, it was 78 and 3%, respectively.

Preoperative and 3-month postoperative HOOS-PS questionnaires were completed by 7,731 (38%) THA patients, and 5382 (27%) completed both preoperative and 12-month postoperative questionnaires (Table 2). Adverse events occurred more frequently in patients not completing both the preoperative and postoperative HOOS-PS questionnaire compared to those completing it.

Table 1
Adverse Events and Patient Characteristics After THA and TKA in 19 Dutch Hospitals During 2017 to 2019.

	THA (n = 20,338)	TKA (n = 18,082)
Adverse events		
1-Y revision (%)	376 (1.8)	237 (1.3)
30-Ds readmission (%)	724 (3.9)	551 (3.4)
30-Ds complications (%)	735 (3.9)	417 (2.5)
Long LOS (%)	2,205 (11.8)	1,778 (10.9)
Patient characteristics		
Mean age in y (SD)	68.36 (10.3)	68.10 (8.8)
Sex, women (%)	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)
Nonosteoarthritis	2,315 (11.4)	569 (3.1)

Less than 10% of the values for adverse events were missing, and less than 5% for patient characteristics.
ASA, American Society of Anaesthesiologists; BMI, body mass index; LOS, length of stay; THA, total hip arthroplasty; TKA, total knee arthroplasty.

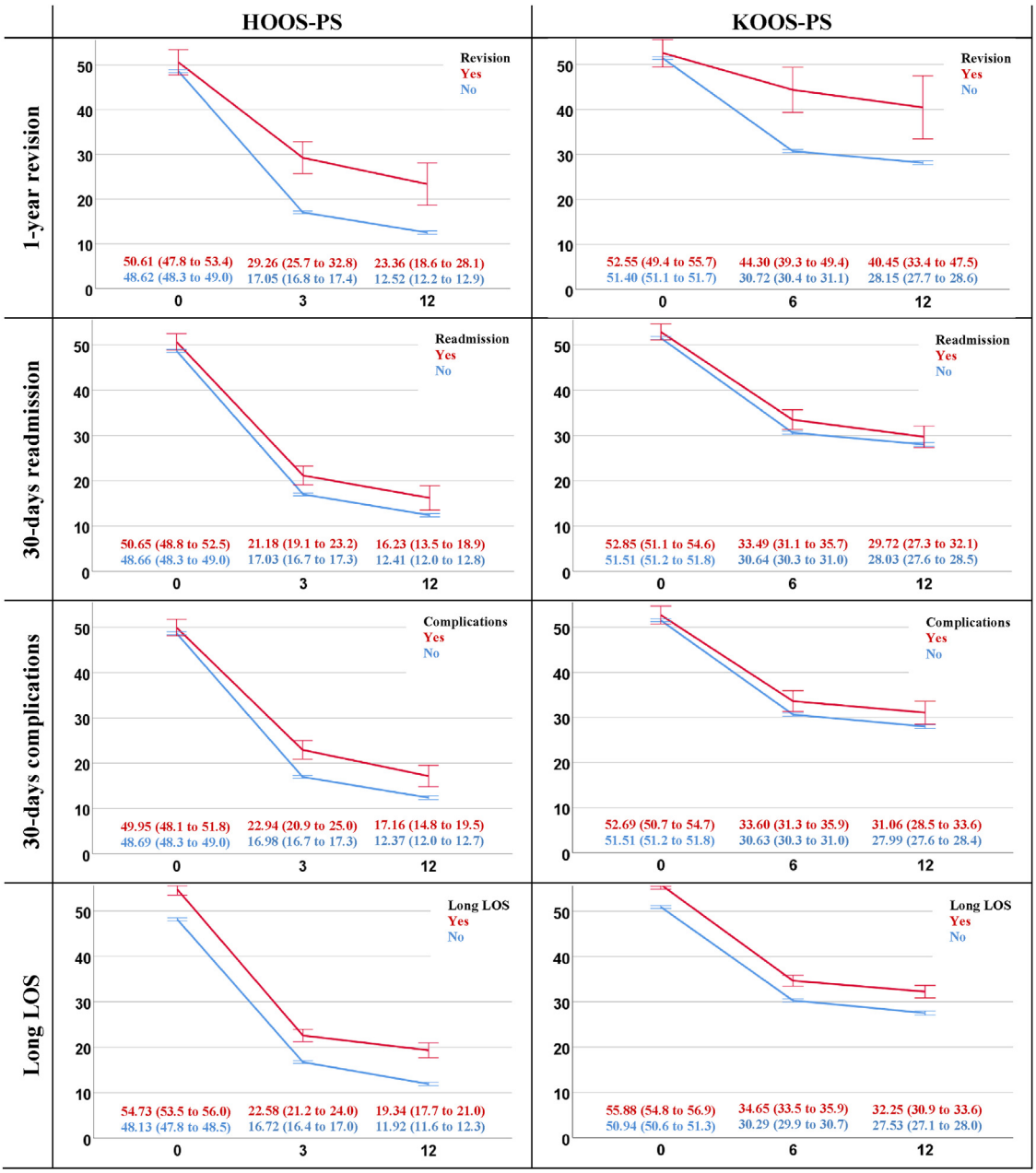

Fig. 1. Mean PROM scores over time for adverse events. The line graphs show the mean and 95% CI for preoperative and 2 postoperative PROM scores for patients with and without revisions, readmission, complications and long LOS. X-axis: 0, preoperative; 3, 3-month postoperative; 6, 6-month postoperative; 12, 12-month postoperative. Y-axis: HOOS-PS or KOOS-PS scores. HOOS-PS, hip disability and osteoarthritis outcome score-physical function Short form; KOOS, knee injury and osteoarthritis outcome score-physical function short form; LOS, length of stay; PROM, patient-reported outcome measures.

Considering the 3,206 patients who had at least one adverse event, 2,212 (69%) did not return both the preoperative and 3-month postoperative questionnaires, compared with 59% of patients experiencing no adverse event, and thus were more likely to be nonrespondents. For not returning the preoperative and 12-month questionnaires, these figures were 80 and 71%, respectively. Although the absolute differences between respondents and non-respondents for most patient characteristics were small, they were nevertheless significant due to the large sample size. For the KOOS-PS, preoperative and 6-month postoperative questionnaires were completed by 5,519 (31%) TKA patients, and 4,319 (24%) completed both preoperative and 12-month postoperative questionnaires (Table 3). Revision and readmission occurred more frequently in patients who did not complete both the preoperative and post-operative KOOS-PS questionnaires, but they had comparable complication rates and lower long-term LOS rates. Of 2,549 patients who had at least 1 adverse event, 1,988 (78%) did not return both preoperative and 6-month postoperative questionnaires, compared with 67% of patients experiencing no adverse event. For not returning the preoperative and 12-month postoperative questionnaires, these figures were 82 and 74%, respectively. Significant differences were found for most patient characteristics, except sex, smoking, and body mass index. Patients experiencing a revision, complications, or long LOS were less likely to achieve a clinically relevant improvement in the HOOS-PS (89, 56, and 34% less likely, respectively). A similar, but nonsignificant association was found

Table 2
Respondents Versus Nonrespondents of the HOOS.

	Preoperative and Postoperative HOOS-PS					
	Respondent Preoperative and 3-mo Postoperative (n = 7,731; 38.0%)	Nonrespondent Preoperative and 3-mo Postoperative (n = 12,607; 62.0%)	95% CI Around Difference; P Value	Respondent Preoperative and 12-mo Postoperative (n = 5,382; 26.5%)	Nonrespondent Preoperative and 12-mo Postoperative (n = 14,956; 73.5%)	95% CI Around Difference; P Value
Adverse events						
1-y revision (%)	93 (1.2)	283 (2.2)	0.69, 1.45; <.01	66 (1.2)	310 (2.1)	0.47, 1.22; <.01
30-d readmission (%)	252 (3.4)	472 (4.2)	0.17, 1.28; <.01	166 (3.3)	558 (4.1)	0.17, 1.37; <.01
30-d complication (%)	239 (3.3)	496 (4.3)	0.05, 1.63; <.01	170 (3.4)	565 (4.1)	0.11, 1.31; <.01
Long LOS (%)	566 (7.7)	1,639 (14.5)	5.85, 7.63; <.01	403 (8.1)	1802 (13.2)	4.20, 6,10; <.01
Patient characteristics						
Mean age in y (SD)	68.98 (9.7)	67.98 (10.7)	−1,30, −0.71; <.01	69.02 (9.9)	68.12 (10.5)	−0.81, −0.09; .01
Sex, women (%)	4,876 (63.1)	8,153 (64.7)	0.24, 2.96; .02	3,379 (62.8)	9,650 (64.5)	0.24, 3.24; .02
Mean BMI in kg/m^2 (SD)	27.07 (4.4)	26.85 (4.5)	−0.35, −0.10; <.01	27.05 (4.4)	26.89 (4.4)	−0.07, 0.24; .30
Current Smokers (%)	719 (9.3)	1,403 (11.1)	0.98, 2.68; <.01	499 (9.3)	1,623 (10.9)	0.66, 2,50; <.01
ASA classification (%)						
ASA I	1,376 (17.8)	2,477 (19.6)	$P \leq .01$	944 (17.5)	2,909 (19.5)	$P \leq .01$
ASA II	4,983 (64.5)	7,639 (60.6)		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)	$P \leq .01$	2,161 (40.2)	5,997 (40.1)	$P \leq .01$
B1	2,694 (34.8)	3,547 (28,1)		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 (94.2)	10,741 (85,2)	8.16, 9.78; <.01	5,061 (94.1)	12,958 (86.6)	6.61, 8.27; <.01
Nonosteoarthritis	450 (5.8)	1865 (14.8)		318 (5.9)	1,997 (13.4)	

Percentages might not sum to 100 because of rounding.
ASA, American Society of Anaesthesiologists; BMI, body mass index; HOOS-PS, hip disability and osteoarthritis outcome score-physical function short form; LOS, length of stay; N/A, not applicable.

for readmission (Table 4). Patients experiencing revision or long LOS were less likely to achieve a clinically relevant improvement in the KOOS-PS (74 and 37% less likely, respectively), with associations for readmission and complications in the same direction but nonsignificant.

Discussion

Interpretation of the Results

To investigate whether missing HOOS-PS/KOOS-PS data for THA and TKA may result in underestimation or overestimation of HOOS-PS/KOOS-PS improvement scores, we used adverse event rates to examine how these differed between respondents and nonrespondents and their association with HOOS-PS/KOOS-PS improvement scores. We found that adverse events occurred more frequently in HOOS-PS nonrespondents and that revision and readmission occurred more frequently in KOOS-PS nonrespondents. In patients who had completed HOOS-PS or KOOS-PS scores, the occurrence of revision, complications, or long LOS after THA made it less likely to achieve a clinically relevant improvement in the HOOS-PS, with results for readmission in the same direction but nonsignificant. 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-PS. Since adverse events generally occur more frequently in patients not completing HOOS-PS/KOOS-PS questionnaires, and these adverse events would make it less likely to achieve a clinically relevant improvement, this means that improvements in HOOS-PS/KOOS-PS scores in the total population are likely lower (ie, are overestimated) than those in HOOS-PS/KOOS-PS respondents. 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-PS and KOOS-PS, respectively, had all patients been considered.

Strengths and Limitations

To our knowledge, 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 current estimates of improvement after THA and TKA are likely overestimated if based on those completing PROM questionnaires. However, some potential limitations should be noted. 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 (ie, 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 [18]. In addition, this study can only provide indirect evidence due to the lack of information about changes in PROM scores among nonrespondents. Also, nonresponse is known to be affected by patient characteristics. So, if nonrespondents would systematically have more favorable patient characteristics (eg, younger and who had better health status) known to be related to more improvement in PROMs, then this could be the case for the nonrespondents who did not have adverse events. However, Tables 2 and 3 did not indicate such systematic differences, as respondents were older, but less often smoked and had American Society of Anaesthesiologists 3+. Potential risk factors such as mental health and emotional health status were not included to adjust the associations between

Table 3
Respondents Versus Nonrespondents of the KOOS.

	Preoperative and Postoperative KOOS-PS					
	Respondent Preoperative and 6-mo Postoperative (n = 5,519; 30.5%)	Nonrespondent Preoperative and 6-mo Postoperative (n = 12,563; 69.5%)	95% CI Around Difference; P Value	Respondent Preoperative and 12-mo Postoperative (n = 4,319; 23.9%)	Nonrespondent Preoperative and 12-mo Postoperative (n = 13,763; 76.1%)	95% CI Around Difference; P Value
Adverse events						
1-y revision (%)	51 (0.9)	186 (1.5)	0.22, 0.89; .03	35 (0.8)	202 (1.5)	0.32, 0.99; <.01
30-d readmission (%)	155 (2.8)	369 (3.5)	0.24, 3.62; <.01	115 (3.0)	436 (3.5)	0.20, 1.10; <.01
30-d complication (%)	139 (2.8)	278 (2.4)	−0.91, 0.16; .16	108 (2.9)	309 (2.4)	0.20, 1.00; <.01
Long LOS (%)	577 (11.7)	1,201 (10.6)	−2.20, −0.05; .04	485 (12.8)	1,293 (10.3)	−3.71, −1.33; <.01
Patient characteristics						
Mean age in y (SD)	68.50 (8.5)	67.93 (8.9)	0.09, 0.60; <.01	68.58 (8.5)	67.95 (8.8)	0.28, 0.40; <.01
Sex, women (%)	3,393 (61.5)	7,806 (62.1)	−0.88, 2.20; .40	2,641 (61.1)	8,558 (62.2)	−0.63, 2.70; .22
Mean BMI in kg/m^2 (SD)	29.43 (4.8)	29.22 (4.8)	−0.18, 0,20; .91	29.38 (4.8)	29.26 (4.8)	−0.09, 0.29; .15
Current Smokers (%)	451 (8.2)	1,073 (8.5)	−0.51, 1.23; .14	352 (8.2)	1,172 (8.5)	−0.58, 1.30; .35
ASA classification (%)						
ASA I	666 (12.1)	1,841 (14.7)	$P \leq .01$	525 (12.2)	1982 (14.4)	$P \leq .01$
ASA II	3,718 (67.4)	8,279 (65.9)		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)	$P \leq .01$	1,627 (37.7)	4,960 (36.0)	$P \leq .01$
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)		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)	0.22, 1.28; <.01	4,205 (97.4)	13,305 (96.7)	0.10, 1.23, .03
Nonosteoarthritis	145 (2.6)	424 (3.4)		114 (2.6)	455 (3.3)	

Percentages might not sum to 100 because of rounding.
ASA, American Society of Anaesthesiologists; BMI, body mass index; KOOS, knee injury and osteoarthritis outcome score-physical function short form; LOS, length of stay; N/A, not applicable.

adverse events and improvements in PROM scores, as these variables are not collected by the LROI [26,27]. Although the available patient characteristics are likely the most relevant, some residual confounding may remain [25,28]. Furthermore, 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 who did and did not have 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 clinically relevant worsening, with 8 and 19% showing no relevant change, respectively. 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 [2,29–31]. It should be noted that while patients who had worse preoperative PROM scores may improve more, they do not achieve the same postoperative level as patients who had better preoperative function scores [28]. 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 [32,33]. Satisfaction rates may improve further by addressing preoperative expectations, a significant predictor of dissatisfaction following TKA [3]. In the Dutch registry, 63 and 58% of patients completed the preoperative HOOS-PS and KOOS-PS questionnaires, 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 [7,9,10]. 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 accordance with our results, one study including THA patients found that nonresponse during follow-up was not at random; nonrespondents had significantly lower PROM scores at the previous time point than respondents, thereby indicating that patients reporting good outcomes were overrepresented [34]. In another study, TKA patient respondents reported a higher mean Knee Society Score, mean function score, and lower mean pain score than nonrespondents [35]. Comparable results were reported in another study, including patients after shoulder arthroplasty, and another study identified a trend of worse outcomes for nonrespondents [15,36].

The PROMs Working Group of the International Society of Arthroplasty Registries stated that a response rate above 80% is recommended for reliable outcome assessment but proposes a 60% threshold for an acceptable response rate [7]. Only 6 of the 16 arthroplasty registries collecting PROMs capture >80% of their preoperative and postoperative PROMs; the remaining registries reported response rates less than 60% [4,6,7,16,37–42]. Another

Table 4
Associations Between Adverse Events and Clinically Relevant Improvement in PROM Scores.

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

A difference of 10 points was taken as a clinically relevant improvement for the HOOS-PS and 9 points for the KOOS-PS.
HOOS-PS, hip disability and osteoarthritis outcome score-physical function short form; KOOS, knee injury and osteoarthritis outcome score-physical function short form; LOS, length of stay; OR, odds ratio; PROM, patient-reported outcome measures.

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 analyzed, resulting in unreliable outcomes [43]. This seems only feasible if PROM collection is mandatory and becomes part of the doctor-patient conversations on THA and TKA care goals [44].

Conclusions

Patients not completing HOOS-PS and KOOS-PS questionnaires more often experienced adverse events, which were associated with a lower likelihood of achieving a clinically relevant improvement in HOOS-PS or KOOS-PS. This means that the percentage of patients achieving clinically relevant improvements after THA and TKA is likely lower when assessed in all patients. Higher HOOS-PS or KOOS-PS response rates are therefore needed for reliable outcome assessment.

CRediT authorship contribution statement

Peter van Schie: Writing – original draft, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Leti van Bodegom-Vos:** Writing – review & editing, Writing – original draft, Conceptualization. **Tristan M. Zijdeman:** Writing – original draft, Data curation, Conceptualization. **Taco Gosens:** Writing – review & editing. **Rob G.H.H. Nelissen:** Writing – review & editing, Supervision, Funding acquisition, Conceptualization. **Perla J. Marang-van de Mheen:** Writing – review & editing, Validation, Supervision, Project administration, Methodology, Funding acquisition, Formal analysis, Conceptualization.

Acknowledgments

In addition to the authors, the IQ Joint study group consists of (in alphabetic order): Antonius Hospital, Sneek (S.T. Hokwerda, MD); Bergman Clinics (P.M. van Kampen, PhD); Bergman Clinics, Arnhem (I. Buchholz, MD); Bergman Clinics, Breda (J. Schrier, MD); Bergman Clinics, Delft (F. de Graaff, MD); Bergman Clinics, Naarden (H. Bouma, MD); Bergman Clinics, Rijswijk (T. Hogervorst, MD, PhD and J. Wolkenfelt, MD); Bergman Clinics, Rotterdam (M. Vischjager, MD, PhD); Catharina Hospital, Eindhoven (R.W.T.M. van Kempen, MD); Dijklander Hospital, Hoorn (G.C. Huitema, MD); Dijklander Hospital, Hoorn (L. de Vries, PhD); Elisabeth-TweeSteden Hospital (T. Gosens, MD, PhD); Gelderse Vallei Hospital, Ede (W. Beijneveld, MD); Maxima Medical Center, Eindhoven (M. van den Besselaar, MD); Medical Spectrum Twente, Enschede (W. Verra, MD, PhD); OLVG, Amsterdam (R.W. Poolman, MD, PhD); OLVG, Amsterdam (V.A. Scholtes, PhD); Sint Anna Hospital, Geldrop (W. van der Weegen, PhD); Sint Franciscus Hospital, Schiedam (A. Polak, MD); Tjongerschans Hospital, Heerenveen (M. Mulder, PhD); University of Groningen University Medical Center Groningen, Groningen (M. Stevens, PhD). We thank the Dutch Arthroplasty Register for providing data for this study (L.N. van Steenbergen, PhD).

References

[1] Van Schie P, Van Bodegom-Vos L, Van Steenbergen LN, Nelissen R, Marang-van de Mheen PJ. A more comprehensive evaluation of quality of care after total hip and knee arthroplasty: combining 4 indicators in an ordered composite outcome. Acta Orthop 2022;93:138–45. https://doi.org/10.2340/17453674.2021.861.

[2] Rolfson O, Kärrholm J, Dahlberg LE, Garellick G. Patient-reported outcomes in the Swedish Hip Arthroplasty Register: results of a nationwide prospective observational study. J Bone Joint Surg Br 2011;93:867–75. https://doi.org/10.1302/0301-620x.93b7.25737.

[3] Dunbar MJ, Richardson G, Robertsson O. I can't get no satisfaction after my total knee replacement: rhymes and reasons. Bone Joint J 2013;95-b:148–52. https://doi.org/10.1302/0301-620x.95b11.32767.

[4] Black N. Patient reported outcome measures could help transform healthcare. BMJ 2013;346:f167. https://doi.org/10.1136/bmj.f167.

[5] Docter S, Fathalla Z, Lukacs MJ, Khan MCM, Jennings M, Liu SH, et al. Interpreting patient-reported outcome measures in orthopaedic surgery: a systematic review. J Bone Joint Surg Am 2021;103:185–90. https://doi.org/10.2106/jbjs.20.00474.

[6] Makhni EC. Meaningful clinical applications of patient-reported outcome measures in orthopaedics. J Bone Joint Surg Am 2021;103:84–91. https://doi.org/10.2106/jbjs.20.00624.

[7] Rolfson O, Eresian Chenok K, Bohm E, Lübbeke A, Denissen G, Dunn J, et al. Patient-reported outcome measures in arthroplasty registries. Acta Orthop 2016;87(Suppl 1):3–8. https://doi.org/10.1080/17453674.2016.1181815.

[8] FDA. Guidance for industry: patient-reported outcome measures: use in medical product development to support labeling claims. 2009. https://www.fda.gov/media/77832/download. [Accessed 16 November 2022].

[9] Dutch PROM response rates for THA. https://www.lroi-report.nl/hip/proms/response/. [Accessed 17 June 2023].

[10] Dutch PROM response rates for TKA. https://www.lroi-report.nl/knee/proms/response/. [Accessed 17 June 2023].

[11] Hutchings A, Grosse Frie K, Neuburger J, van der Meulen J, Black N. Late response to patient-reported outcome questionnaires after surgery was associated with worse outcome. J Clin Epidemiol 2013;66:218–25. https://doi.org/10.1016/j.jclinepi.2012.09.001.

[12] Jahagirdar D, Kroll T, Ritchie K, Wyke S. Patient-reported outcome measures for chronic obstructive pulmonary disease : the exclusion of people with low literacy skills and learning disabilities. Patient 2013;6:11–21. https://doi.org/10.1007/s40271-013-0004-5.

[13] Gibbons E. Patient-reported outcome measures and the evaluation of services. Health Serv Deliv Res 2016;4:55–68.

[14] Kaur S, Alhaug OK, Dolatowski FC, Solberg TK, Lønne G. Characteristics and outcomes of patients who did not respond to a national spine surgery registry. BMC Musculoskelet Disord 2023;24:164. https://doi.org/10.1186/s12891-023-06267-3.

[15] Norquist BM, Goldberg BA, Matsen 3rd FA. Challenges in evaluating patients lost to follow-up in clinical studies of rotator cuff tears. J Bone Joint Surg Am 2000;82:838–42. https://doi.org/10.2106/00004623-200006000-00010.

[16] Bohm ER, Kirby S, Trepman E, Hallstrom BR, Rolfson O, Wilkinson JM, et al. Collection and reporting of patient-reported outcome measures in arthroplasty registries: multinational survey and recommendations. Clin Orthop Relat Res 2021;479:2151–66. https://doi.org/10.1097/corr.0000000000001852.

[17] ClinicalTrial.gov. https://clinicaltrials.gov/ct2/show/NCT04055103?term=Arthroplasty&cntry=NL&city=Leiden&draw=2&rank=2. [Accessed 28 November 2022].

[18] van Schie P, van Bodegom-Vos L, Zijdeman TM, Nelissen R, Marang-van de Mheen PJ. Effectiveness of a multifaceted quality improvement intervention to improve patient outcomes after total hip and knee arthroplasty: a registry nested cluster randomised controlled trial. BMJ Qual Saf 2023;32:34–46. https://doi.org/10.1136/bmjqs-2021-014472.

[19] Marang-van de Mheen PJ, van Hanegem N, Kievit J. Effectiveness of routine reporting to identify minor and serious adverse outcomes in surgical patients. Qual Saf Health Care 2005;14:378–82. https://doi.org/10.1136/qshc.2004.013250.

[20] Davis AM, Perruccio AV, Canizares M, Tennant A, Hawker GA, Conaghan PG, et al. The development of a short measure of physical function for hip OA HOOS-Physical Function Shortform (HOOS-PS): an OARSI/OMERACT initiative. Osteoarthritis Cartilage 2008;16:551–9. https://doi.org/10.1016/j.joca.2007.12.016.

[21] Perruccio AV, Stefan Lohmander L, Canizares M, Tennant A, Hawker GA, Conaghan PG, et al. The development of a short measure of physical function for knee OA KOOS-Physical Function Shortform (KOOS-PS) - an OARSI/OMERACT initiative. Osteoarthritis Cartilage 2008;16:542–50. https://doi.org/10.1016/j.joca.2007.12.014.

[22] International Consortium for Health Outcomes Measurement. Hip and knee osteoarthritis standard set. https://connect.ichom.org/standard-sets/hip-knee-osteoarthritis/. [Accessed 16 November 2022].

[23] Braaksma C, Wolterbeek N, Veen MR, Prinsen CAC, Ostelo R. Systematic review and meta-analysis of measurement properties of the hip disability and osteoarthritis outcome score - physical function shortform (HOOS-PS) and the knee injury and osteoarthritis outcome score - physical function shortform (KOOS-PS). Osteoarthritis Cartilage 2020;28:1525–38. https://doi.org/10.1016/j.joca.2020.08.004.

[24] Norman GR, Sloan JA, Wyrwich KW. Interpretation of changes in health-related quality of life: the remarkable universality of half a standard deviation. Med Care 2003;41:582–92. https://doi.org/10.1097/01.Mlr.0000062554.74615.4c.

[25] Rolfson O, Bohm E, Franklin P, Lyman S, Denissen G, Dawson J, et al. Patient-reported outcome measures in arthroplasty registries report of the patient-reported outcome measures working group of the international society of arthroplasty registries Part II. Recommendations for selection, administration, and analysis. Acta Orthop 2016;87(Suppl 1):9–23. https://doi.org/10.1080/17453674.2016.1181816.

[26] Ayers DC, Franklin PD, Ring DC. The role of emotional health in functional outcomes after orthopaedic surgery: extending the biopsychosocial model to

orthopaedics: AOA critical issues. J Bone Joint Surg Am 2013;95:e165. https://doi.org/10.2106/jbjs.L.00799.
[27] Giesinger JM, Kuster MS, Behrend H, Giesinger K. Association of psychological status and patient-reported physical outcome measures in joint arthroplasty: a lack of divergent validity. Health Qual Life Outcomes 2013;11:64. https://doi.org/10.1186/1477-7525-11-64.
[28] Hofstede SN, Gademan MG, Vliet Vlieland TP, Nelissen RG, Marang-van de Mheen PJ. Preoperative predictors for outcomes after total hip replacement in patients with osteoarthritis: a systematic review. BMC Musculoskelet Disord 2016;17:212. https://doi.org/10.1186/s12891-016-1070-3.
[29] Keurentjes JC, Blane D, Bartley M, Keurentjes JJ, Fiocco M, Nelissen RG. Socio-economic position has no effect on improvement in health-related quality of life and patient satisfaction in total hip and knee replacement: a cohort study. PLoS One 2013;8:e56785. https://doi.org/10.1371/journal.pone.0056785.
[30] Keurentjes JC, Fiocco M, Nelissen RG. 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 Clin Epidemiol 2014;67:114–20. https://doi.org/10.1016/j.jclinepi.2013.04.010.
[31] Keurentjes JC, Fiocco M, So-Osman C, Onstenk R, Koopman-Van Gemert AW, Pöll RG, et al. Patients with severe radiographic osteoarthritis have a better prognosis in physical functioning after hip and knee replacement: a cohort-study. PLoS One 2013;8:e59500. https://doi.org/10.1371/journal.pone.0059500.
[32] Haanstra TM, Tilbury C, Kamper SJ, Tordoir RL, Vliet Vlieland TP, Nelissen RG, et al. Can optimism, pessimism, hope, treatment credibility and treatment expectancy Be distinguished in patients undergoing total hip and total knee arthroplasty? PLoS One 2015;10:e0133730. https://doi.org/10.1371/journal.pone.0133730.
[33] Tilbury C, Haanstra TM, Leichtenberg CS, Verdegaal SH, Ostelo RW, de Vet HC, et al. Unfulfilled expectations after total hip and knee arthroplasty surgery: There is a need for better preoperative patient information and education. J Arthroplasty 2016;31:2139–45. https://doi.org/10.1016/j.arth.2016.02.061.
[34] Imam MA, Barke S, Stafford GH, Parkin D, Field RE. Loss to follow-up after total hip replacement: a source of bias in patient reported outcome measures and registry datasets? Hip Int 2014;24:465–72. https://doi.org/10.5301/hipint.5000141.
[35] Kim J, Lonner JH, Nelson CL, Lotke PA. Response bias: effect on outcomes evaluation by mail surveys after total knee arthroplasty. J Bone Joint Surg Am 2004;86:15–21.
[36] Polk A, Rasmussen JV, Brorson S, Olsen BS. Reliability of patient-reported functional outcome in a joint replacement registry. A comparison of primary responders and non-responders in the Danish Shoulder Arthroplasty Registry. Acta Orthop 2013;84:12–7. https://doi.org/10.3109/17453674.2013.765622.
[37] Johnston BC, Patrick DL, Devji T, Maxwell LJ, Bingham III CO, Beaton DE, et al. Chapter 18: patient-reported outcomes. In: Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ, et al., editors. Cochrane Handbook for Systematic Reviews of Interventions; 2019. www.training.cochrane.org/handbook. [Accessed 23 July 2024].
[38] Dutch Arthroplasty Register (LROI). Online annual report. https://www.lroi-report.nl/. [Accessed 2 February 2023].
[39] Danish Hip Arthroplasty Register (DHAR). Annual report 2020. http://danskhoftealloplastikregister.dk/wp-content/uploads/2020/11/dhr-aarsrapport-2020_til_offentliggoerelse-1.pdf. [Accessed 17 June 2023].
[40] Swedish Hip Arthroplasty Register (SHAR). Annual report 2018. https://registercentrum.blob.core.windows.net/shpr/r/Arsrapport_2018_Hoftprotes_ENG_26mars_Final-rJepCXNsLI.pdf. [Accessed 17 June 2023].
[41] American Academy of Orthopaedic Surgeons (AAOS). Joint replacement registry. https://www.aaos.org/registries/registry-program/american-joint-replacement-registry/. [Accessed 17 June 2023].
[42] National Joint Registry (NJR). Annual report 2021. https://reports.njrcentre.org.uk/Portals/0/PDFdownloads/NJR%2018th%20Annual%20Report%202021.pdf. [Accessed 17 June 2023].
[43] Pronk Y, van der Weegen W, Vos R, Brinkman JM, van Heerwaarden RJ, Pilot P. What is the minimum response rate on patient-reported outcome measures needed to adequately evaluate total hip arthroplasties? Health Qual Life Outcomes 2020;18:379. https://doi.org/10.1186/s12955-020-01628-1.
[44] Murthy S, Clapp JT, Burson RC, Fleisher LA, Neuman MD. Physicians' perspectives of prognosis and goals of care discussions after hip fracture. J Am Geriatr Soc 2022;70:1487–94. https://doi.org/10.1111/jgs.17642.