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Master thesis | Original study

The Quality of Recovery-15 score as a Patient-Reported Outcome Measure for anesthesia and surgery after total hip and total knee arthroplasty

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Abstract

Background: **The Quality of Recovery-15 score is a patient-reported outcome questionnaire measuring the quality of recovery after anesthesia and surgery.**
Objectives: **To identify the optimal moment of scoring (after which the score no longer improves), explore why patients choose not to participate, and determine the dropout rate, as these outcomes can indicate whether the score could be suitable as a patient-reported outcome measure for anesthesia and surgery after total hip and knee arthroplasty.**
Design and setting: **A single-center cohort study in a regional general hospital of patients undergoing total hip or knee arthroplasty between April 2019 and March 2020. The Quality of Recovery-15 questionnaire was presented on postoperative days +1, +4, +7, +14 and +28.**
Results: **Of 374 patients screened for inclusion, 253 patients entered the study. 162 dropped out. Ninety-one patients ended the study, 46 for total hip arthroplasty, 45 for total knee arthroplasty. Scores improved for total hip arthroplasty between D1-D7 ($p < 0.001$), D1-D14 ($p < 0.0001$), D1-D28 ($p < 0.0001$), D4-D14 ($p < 0.0001$), D4-D28 ($p < 0.0001$), and D7-D28 ($p = 0.003$), and for total knee arthroplasty between D1-D14 ($p < 0.0001$), D1-D28 ($p < 0.0001$), D4-D28 ($p < 0.0001$) and D7-D28 ($p < 0.0001$)..**
Conclusions: **Although there are indications of a ceiling effect between D14-D28, we could not determine an optimal moment to score the Quality of Recovery-15, as the patients continued to improve 28 days after surgery. This score could be useful in identifying patients at a risk of impaired recovery. Despite efforts to limit this, we observed a high dropout rate, which could compromise the usefulness of this score as a patient-reported outcome measure.**

Keywords: **Quality of Recovery-15 score; PROM; arthroplasty.**

Introduction

Historically, outcomes measured in medical research were objective and easily measurable events or parameters which were not prone to interpretation, such as the length of hospital stay, laboratory measurements, and dose of analgesics used. Later, patient experiences were obtained using single-score measurements such as the Visual Analogue Scale for pain. Currently, questionnaires are used to measure patients' feelings and self-experienced well-being at various health-related levels. These questionnaires are known as patient-reported outcome measures (PROMs).

PROMs can be used to measure quality of recovery (QoR) after surgery. Patients define

Presentation: preliminary data for this study were presented as a poster presentation at the Euroanaesthesia meeting on 28-30 November 2020, and the Euroanaesthesia meeting on 17-19 December 2021.
The study was approved by the Committee for Medical Ethics (az Sint-Blasius, Kroonveldlaan 50, 9200 Dendermonde, chairperson Dr. Sabine Serry, approval number B012201939656) on 15 March 2019. Data collection was conducted between 24 April 2019 and 10 March 2020. Written informed consent was obtained from each participating patient.

recovery as a return to the state they are in before surgery, or even before they become ill. It is not only the absence of complications or negative symptoms but also a return to their former life without disability. This recovery usually has several dimensions, including nociception, emotional, social, and cognitive functioning, and satisfaction. The perception of recovery is also influenced by individual personality, knowledge of a normal recovery pathway, preparedness, coping strategies, and a global sense of security.

Several PROMs for measuring QoR have been developed, such as the Postoperative Recovery Profile, Postoperative Quality of Life Metric, Convalescence and Recovery Evaluation, Surgery Recovery Scale, Surgical Recovery Index, amongst others[1]. The International Consortium for Health Outcome Measurement (ICHOM) defines PROMs for hip and knee osteoarthritis[2]. These PROMs use several scores such as the Numeric Pain Rating Scale for hip and knee pain evaluation, the Knee Injury and Osteoarthritis Outcome Score - Physical Function Shortform and the Hip Disability and Osteoarthritis Outcome Score - Physical Function Shortform for physical functioning, and the EQ-5D-3L or the SF-12 to evaluate health-related quality of life.

There is limited international experience in measuring QoR, focusing on recovery after anesthesia. Initially, a questionnaire comprising forty questions (QoR-40) was developed[1,3-5]. Research has shown that patients were more reluctant to complete the long questionnaire than the shorter version, retaining only 15 questions (QoR-15), with a mean time to complete of less than three minutes[6]. In addition, the validation of the QoR-15 showed that this score allowed equally valid statements to be made about the quality of the recovery. The QoR-15 consists of 15 questions measuring different dimensions of recovery after surgery and anesthesia: able to breath easily, able to enjoy food, feeling rested, sleep quality, able to look after personal hygiene and toilet independently, able to communicate with friends and family, getting support from nurses and doctors, able to return to work or usual home activities, feeling comfortable and in control, having a feeling of well-being, moderate pain, severe pain, nausea/vomiting, anxiety, depression. Each question is scored between 0 and 10. Consequently, the scale ranges from 0 to 150. Several studies have examined QoR-15 in selected patient populations[7,8]. Other studies have validated translations of the original English language QoR-15[9,10]. Studies have conducted repeated surveys at fixed times[11-14]. However, no studies have examined the optimal moment at which QoR-15 should be determined; that is, whether there exists a moment at which QoR-15 stops improving.

QoR-15 could be suitable as a PROM for anesthesia and surgery because it is a comprehensive and validated score that covers most postoperative issues regarding recovery after anesthesia and surgery. Ideally, QoR-15 can be used to identify patients who are not evolving, recovering, or rehabilitating properly.

We designed this study to identify or reject the existence of an optimal moment of scoring within the follow-up duration of 28 days, that is, the moment at which the score did not improve. In addition, since failure to further improve QoR-15 may indicate impaired recovery, we studied the ability of QoR-15 to detect this. Finally, we examined whether there were outcomes that may confirm or limit the value of QoR-15 as a PROM. Since the success and usefulness of data collection depend on patient participation, the goal was to assess the reasons why patients were not included and how many dropped out.

Methods

This single-center prospective cohort study was performed in az Sint-Blasius (Dendermonde, Belgium), a 438-bed regional general hospital with university affiliation, between April 24, 2019 and March 10, 2020. This study was approved by the Committee for Medical Ethics of AZ Sint-Blasius (Kroonveldlaan 50, 9200 Dendermonde, chairperson Dr. Sabine Serry, registration number B012201939656) on March 15, 2019.

Inclusion criteria

All patients scheduled for elective TKA and THA were screened for participation during a pre-anesthesia assessment approximately 1 month before surgery. Written informed consent was obtained from all the participants.

Non-inclusion, exclusion criteria and dropout

Patients who declined participation, mentioned the absence of IT skills, showed cognitive impairment or language barriers (not Dutch-, French-, or English-speaking patients), and/or were analphabetic were not included. Patients assessed by an anesthesiologist unfamiliar with the study were not included. Exclusion criteria were non-primary surgery, urgent surgery, or missing patient contact information. Patients who reported no or incomplete results were excluded, and were considered dropouts. The reasons for non-inclusion and exclusion were documented.

Survey format

In this study, we used a Dutch translation of the original QoR-15. As no validated Dutch version existed at the start of the study, we made our own translation. After completion of our study, a Dutch version of the QoR-15 was validated by de Vlieger et al.14, which is available at https://www.umcg.nl/-/medisch-wetenschappelijk-onderzoek/gaps. Although there are minor linguistic differences, our translation differs only to a very limited extent. We found no restrictions in the literature or on Creative Commons to use the QoR-15 score. We received written permission from Professor Paul Myles to use the QoR-15 for this publication.

Data collection

We offered two ways to report the QoR-15. Patients with limited IT skills completed a paper-based questionnaire. Patients with sufficient IT skills received e-mails with a link to QoR-15 in their electronic medical files. The questionnaire was presented on postoperative days +1, +4, +7, +14, and +28. All data were collected in accordance with the General Data Protection Regulation (EU) 2016/679 of the European Community. The study was stopped on March 10, 2020, at the start of the COVID-19 pandemic, due to a stop of all planned surgical activities, and after an interim analysis showing statistically significant improvement of QoR-15 during the study time course.

Anaesthesia and analgesia

All surgical procedures were performed under general anesthesia. Perioperative analgesia consisted of parenteral analgesics (paracetamol, NSAIDS in the absence of contraindications, tramadol, and opiates, if necessary) and infiltration with local anesthetics. After 24 hours, parenteral administration was replaced by peroral administration, as soon as possible.

Interventions to minimize dropout

The study was presented during preoperative hip and knee education sessions for patients at az Sint-Blasius hospital. Once included, patients were visited by an investigator on postoperative day 1 (D1) to remind them of study participation and to see if they had all the resources to participate. The discharge from the hospital was usually scheduled on day 4 (D4). Patients who opted for electronic reporting received an e-mail reminder that a new questionnaire was available on postoperative days D1, D4, D7, D14, and D28. Through telephonic contact, patients were reminded when questionnaires were not completed in a timely manner. Patients who chose to answer on paper were repeatedly reminded by email or telephone to return papers, up to eight weeks after surgery. Through these contacts we also tried to collect the reasons for stopping participation.

Statistical tests

TThe zero hypothesis H0 states that there is no difference in QoR-15 for THA and TKA during the study period, and the alternative hypothesis H1 states that there is a difference. QoR-15 scores were analyzed separately for THA and TKA. In accordance with Myles et al., we considered the predefined value of 6 points between two QoR-15 measurement points as clinically relevant 15. Statistical tests were performed using XLSTAT (Addinsoft, 2022; XLSTAT Statistical and Data Analysis Solution, New York, USA). https://www.xlstat.com), and the free online statistical tests VassarStats (https://www.vassarstats.net), and Statistics Kingdom (https://www.statskingdom.com).

We used the chi-square test for sex comparisons. The Shapiro-Wilk test was used to assess data normality. Two-tailed Mann-Whitney U-tests were used for non-normal distributions for age comparisons. Friedman's tests and pairwise post hoc comparisons using the two-tailed Wilcoxon-Nemenyi-McDonald-Thompson test were performed to compare QoR-15 at different study time points for THA and TKA. Statistical significance was set at $P < 0.05$. Bonferroni-corrected significance levels of $p < 0.005$ were used, where appropriate, to correct for multiple comparisons (10 pairwise comparisons for 5 different time points).

Results

Study population

Data were collected between April 24, 2019, and March 10, 2020. During preoperative assessment, 374 patients met the inclusion criteria (Fig 1).
A total of 267 patients were included in this study. In total, 107 patients (28.6%) were not included. The most frequent reason for non-inclusion was the lack of interest in participating in the study (50.5%). Other reasons were the absence of IT skills (11.2%), cognitive impairment (18.7%), pre-anesthesia consultation by an anesthesiologist who was not familiar with the study (12.1%), language barriers (6.5%), and unspecified reasons (0.9%). There was no significant difference in age between included and not included patients. (median 66 y (IQR 14) vs. 68 y (IQR 20); $p = 0.069$). Fourteen patients were excluded later (technical problems with the electronic application, wrongfully included revision surgery, postponed surgery, and absence of an email address).

A total of 253 patients were included in the study: 121 (47,8%) underwent THA, and 132 (52,2%)

underwent TKA. The chi-square test showed no sex differences between the patients (p = 0.442). A total of 165 patients (65.2%) chose a paper questionnaire and 88 (34.8%) preferred to answer the questionnaire electronically. Participants who chose the electronic questionnaire were significantly younger than participants who chose the paper questionnaire (62 y (IQR 17) vs. 69 y (IQR 13); p < 0.0001).

Dropout (Figure 1)

Of the 165 participants who preferred the paper questionnaire, 106 (64.2%) did not complete it. In the electronic questionnaire group, fifty-six of the eighty-eight participants (63.6%) dropped out. The chi-square test showed no significant differences (p = 0.92). Only ninety-one patients completed the questionnaires (46 THA and 45 TKA).

For THA, participants that dropped out were significantly older (68 y (IQR 15) vs. 64 y (IQR 18); p = 0.023). For TKA, the participants who dropped out showed no significant difference in age (66.5 y (IQR 15) vs. 65.5 y (IQR 11); p = 0.514). There was no difference in age between the dropouts after THA and TKA (p = 0.147).

QoR-15 for THA

The QoR-15 scores for THA on D1, D4, D7, D14, and D28 are shown as box plots in Figure 2. Box plot statistics are shown in Table I. QoR-15 scores continued to improve throughout the study, although the minimal clinical important difference of 6 points was not reached at every measurement point. The QoR-15 scores were not normally distributed, except for D1 (Shapiro-Wilk test: W = 0.958; p = 0.095). The Friedman's test revealed a significant difference (Q = 77.181; p < 0.0001). Pairwise comparisons with Wilcoxon-Nemenyi-McDonald-Thompson test and Bonferroni corrected significance level at 0.005 showed significant differences between D1-D7 (p < 0.001), D1-D14 (p < 0.0001), D1-D28 (p < 0.0001), D4-D14 (p < 0.0001), D4-D28 (p < 0.0001), and D7-D28 (p = 0.003).

QoR-15 for TKA

TThe QoR-15 scores for TKA on D1, D4, D7, D14, and D28 are shown as box plots in Figure 3. Box plot statistics are shown in Table I. Here too, the minimum clinically important difference of 6 points was not reached at every measurement point. The QoR-15 scores were normally distributed, but with borderline significance for non-normality for D1 (Shapiro-Wilk test: W = 0.95; p = 0.049). The Friedman's test revealed a significant difference (Q = 73.367; p < 0.0001). Pairwise comparisons using Wilcoxon-Nemenyi-McDonald-Thompson test and Bonferroni corrected significance level at 0.005 showed significant differences between D1-D14 (p < 0.0001), D1-D28 (p < 0.0001), D4-D28 (p < 0.0001) and D7-D28 (p < 0.0001).

Discussion

Is there an optimal moment for determining QoR-15?

A single and optimal moment for determining QoR-15 would simplify the process; beyond this point, no further data collection would be necessary. This would limit the efforts of both patients and healthcare providers. However, determining the optimal moment and time window is difficult. The

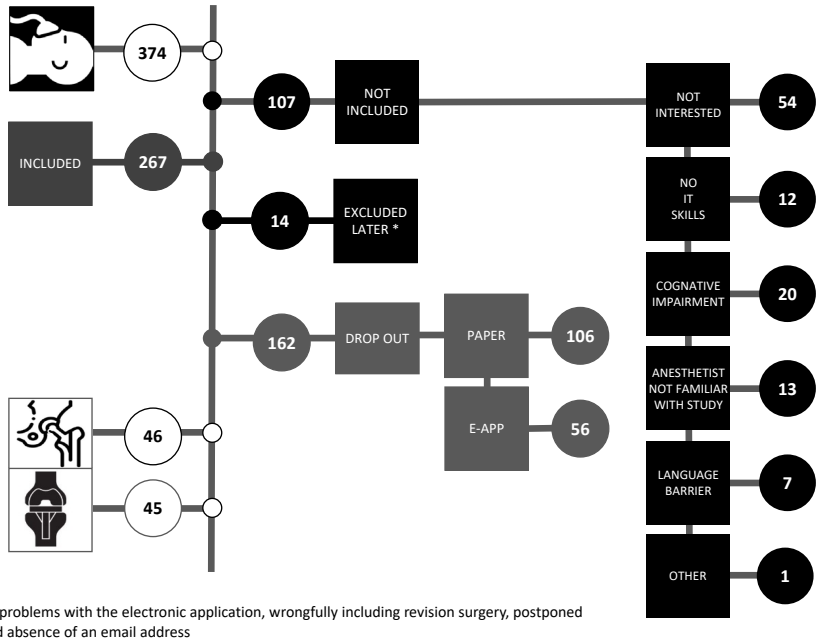

Fig. 1 — Quality of Recovery-15 study population.

to minimum and maximum values. Dots:

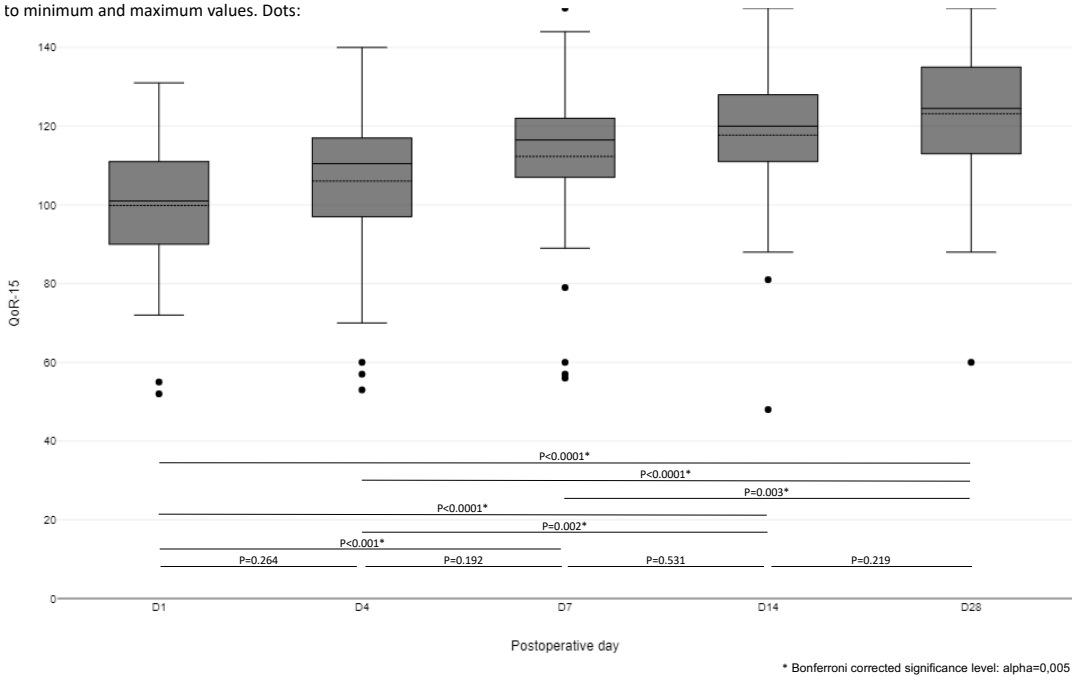

Fig. 2 — QoR-15 for THA - box plots. Box plot demonstrating median (solid line), mean (dotted line), and interquartile range of all QoR-15 scores (46 patients) at each postoperative time point (1, 4, 7, 14, and 28 days) after total hip arthroplasty. Whiskers extend to minimum and maximum values. Dots: outliers.

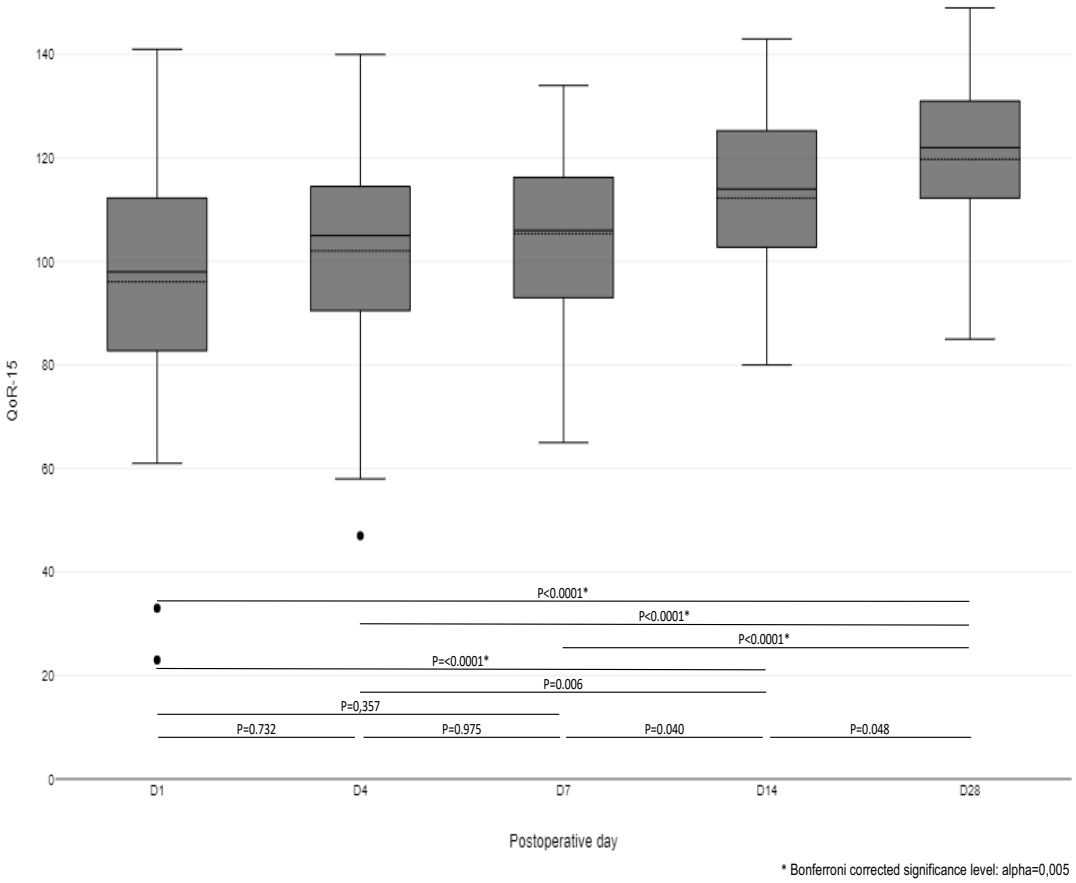

Fig. 3 — QoR 15 for TKA - box plots. Box plot demonstrating median (solid line), mean (dotted line), and interquartile range of all QoR-15 scores (45 patients) at each postoperative time point (1, 4, 7, 14, and 28 days) after total knee arthroplasty. Whiskers extend to minimum andnmaximum values. Dots: outliers.

Table I. — Box plot statistics for THA and TKA.

THA	D1	D4	D7	D14	D28
Min	52	53	56	48	60
Q1	90.25	98	107	111.5	113
Median	101	110.5	116.5	120	124.5
Q3	110.5	117	122	127.75	134.75
Max	131	140	150	150	150
Mean	99.85	106.07	112.33	117.72	123.17
TKA	D1	D4	D7	D14	D28
Min	23	47	65	80	85
Q1	83	91	93	103	113
Median	98	105	106	114	122
Q3	112	114	116	125	131
Max	141	140	134	143	149
Mean	96.07	102.04	105.38	112.24	119.73

THA: Total Hip Arthroplasty; TKA: Total Knee Arthroplasty; D: postoperative day.

need for long-term follow-up has been suggested in literature[16,17]. Previous research has shown an improvement in QoR-15 total score over time[18-20]. We attempted to meet this with a follow-up of one month, which is longer than the follow-up in many other studies using QoR-15. As indicated in other studies, our study also showed progressive and continuous improvement in QoR-15 scores during the first 28 days after THA and TKA. Although we found some indications of a ceiling effect between D14 and D28, we were unable to document the cessation of improvement. Initially, Myles et al. suggested that the minimal clinically important difference in QoR-15 to detect positive or negative changes in patient conditions needed to be 8 points[5]. After further analysis, this difference was updated to a value of 6 points in 2021[15]. In both THA and TKA, this minimal difference was achieved at different time points but not invariably at each successive study time point. This makes the single-questionnaire approach less effective, because progression would be missed.

Use of QoR-15 as a predictor of impaired recovery?

Although one could argue that it is only natural for patients to improve progressively after surgery and anesthesia, the collection of QoR-15 data at several time points creates an interesting opportunity: QoR-15 could be used to identify patients who are not evolving, recovering, or rehabilitating properly. Since the first postoperative consultation with an orthopedic surgeon is traditionally planned to be 4–6 weeks after surgery, these patients could benefit from an earlier postoperative consultation. Kleif et al. were the first to categorize QoR-15 scores to optimize the clinical interpretation of the absolute score value 7. The QoR-15 can be classified as excellent (QoR-15 > 135), good (122 ≤ QoR-15 ≤ 135), moderate (90 ≤ QoR-15 ≤ 121), or poor (QoR-15 < 90). This study showed a significant difference in the incidence of postoperative complications within 30 days after laparoscopic appendectomy between patients in different recovery classes on the first postoperative day. In another study, Kleif et al. repeated measurements over 30 days and showed that better QoR-15 scores were associated with an increased chance of resuming recreational and occupational activities and a lower incidence of postoperative complications[21]. A recent study by Campfort et al., which included patients undergoing different types of elective surgery, reported similar results[22]. In our study, we did not focus on any postoperative complications, but over a period of 28 days, QoR-15 scores improved significantly. Patients need sufficient time to reach the good or excellent recovery classes defined by Kleif et al. Therefore, the classification system of QoR-15 could be a useful tool for identifying patients at risk for impaired recovery, especially those with lower QoR-15 scores (e.g., under the 25th percentile). Further research on this topic in larger populations with different types of surgeries would be interesting. Therefore, it is important to establish recovery classes for each type of surgery.

Could the QoR-15 serve as a PROM for anesthesia and/or surgery?

PROMs play a key role in collecting information about patients' self-experienced well-being with the aim of improving quality of care[15] and are important as they provide science with a

means to measure an outcome, for example, QoR in a replicable way so that data can be compared easily[23-24].

Following the Consensus-based Standards for the Selection of Health Status Measurement Instruments (COSMIN) checklist for PROMs, a good PROM should be screened at different levels, including validity (the degree to which an outcome measure measures what it claims to measure), reliability (the degree to which the measurement is free from measurement error), responsiveness (the ability to detect change over time), and acceptability and feasibility[25,26]. Stark et al., who derived QoR-15 from QoR-40, found excellent validity, reliability, responsiveness, acceptability, and feasibility[6]. Chazapis et al. tested QoR-15 at 24h, 48h and seven days after orthopedic day-case surgery[17]. They found good validity, reliability, and responsiveness but proposed measuring only at 48h, to limit time and resource consumption. Myles et al., as an answer to the published COSMIN guidelines, performed additional tests to demonstrate good structural validity and concluded that the 15 items of QoR-15 together measure a similar construct, that is, patient-centered quality of recovery[27]. Kleif et al. performed a meta-analysis on QoR-15, including the articles by Stark and Chazapis, and found that it met all the criteria for good measurement properties, as proposed by the COSMIN group[28]. Their study provided high-quality evidence supporting the use of the QoR-15 for measuring the quality of recovery. The European Society of Anaesthesiology (ESA)/ European Society of Intensive Care Medicine (ESICM) joint task force proposed using QoR-15 to measure QoR[29]. We conclude that QoR-15 is an extensively validated, short questionnaire that enquires about patients' perspectives on their recovery in five different health-related dimensions: patient support, comfort, emotions, physical independence, and pain[4,6,30]. The presented arguments indicate that the QoR-15 can serve as a PROM after THA and TKA.

Dropout as a factor limiting the usefulness of QoR-15 as a PROM

An important shortcoming of our study was the dropout: 64% did not complete the study. The dropout rate was independent of the reporting method (paper versus electronic). Age was of limited importance; only THA patients who dropped out were older in age. It is remarkable that patients stopped cooperating despite several reminders, especially in times of increasing acceptance of the importance of patient-centered care guided by self-reported outcomes. A non-communicated study of PROMs in robot-assisted laparoscopic radical prostatectomy (RALP) at our institution showed even worse participation; up to 89% dropped out. In contrast to our study, Berning et al. reported that 81% of the recruited patients completed four questionnaires, which was 64% of the eligible patients 18. Based on their experience, they aimed for a participation rate of only 65%, which was their full completion rate. In addition, Stark et al. found that the rates of participation and successful completion of their study were high 6. The reason the population remained reticent is unclear. Only a limited number of contacted patients were willing to provide an explanation of why they stopped participating in the study. In almost all cases, they indicated that they were no longer interested in repeatedly completing the questionnaires. Were these patients unready for PROMs? Were they dropping out of the study because there were no direct or clear benefits to participating? Is it the older age of THA and TKA patients? Are older patients less familiar with and willing to share information? Alternatively, does the orthopedic surgeon play a more central role in patient motivation? Traditionally, the first postoperative consultation with the surgeon is planned 4–6 weeks after surgery. We involved orthopedic surgeons and the orthopedic secretary in informing, preparing, and motivating the patients. We visited the patients during their hospital stay and contacted them via telephone or mail after discharge. Despite efforts to minimize dropouts, we were unable to motivate more patients to continue participating in the study. In the RALP study conducted at our institution, the surgeon was the driving force behind patient motivation and data collection. Nevertheless, the dropout rate was even higher. This finding could seriously complicate the organization of structured data collection: the data collection workload appears to be enormous, and the cost-added value ratio may be negative. In any case, the high dropout rate weakens the usefulness of QoR-15 as a PROM, as the acceptability and feasibility of the COSMIN criteria are less well met. The patient recruitment and successful completion rates of the questionnaire were substandard. However, in the near future, there will be opportunities to improve patient participation and reduce the dropout rate. Patients can be surveyed regularly using mobile patient journey applications. If patients perceive that this gives them direct benefit, they will be more likely to continue participating. Through these applications, patients who do not progress favorably can be identified early. In our study, the direct benefit was absent. Therefore, integrating QoR-15 into these applications may be interesting. Dropout was also directly responsible for the

second limitation of our study, the limited sample size. To reach the desired number of 200 patients in both groups, we would have to conduct the study for 3 more years. However, even with fewer than 50 patients in both groups, we were able to show a statistically significant improvement in QoR-15 between the data acquisition moments and obtained good to excellent power. After adding a severe Bonferroni correction, the results remained significant. This finding emphasizes the excellent stability and power of the sample size.

Limitations

Our study has several limitations. The study was conducted at a single center, a regional general hospital. Therefore, generalizability outside this setting is unknown. The study cohort was limited to patients undergoing total hip or knee arthroplasty. We suggest that further studies should focus on multicenter studies assessing patients undergoing different types of surgery. The ESA-ESICMA joint task force recommends completing the QoR-15 questionnaire before surgery and considering this measurement as the baseline QoR-15. We chose to use the value of D1 as the baseline value. As a result, we were unable to make any statements about the existing preoperative limitations and discomfort. In contrast, the guideline also recommends re-assessment of QoR-15 only once, 24 hours after surgery. No statements were made regarding the measurements to be performed later.

Conclusion

This study shows that there is no single optimal moment to determine the QoR-15 score after THA and TKA; scores continue to improve during the first 28 days after surgery. Since the QoR-15 score has an interesting and correct profile of a PROM, QoR-15 could be used to identify patients who are not evolving or rehabilitating well. However, the important dropout in this study shows that setting up and keeping this data collection up and running could create a huge workload, which might have a negative cost- added value ratio.

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