ORIGINAL ARTICLE

Validation of translated Quality of Recovery-15 questionnaire in a south Indian population

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Abstract

Background: The Quality of Recovery -15 (QoR-15) questionnaire has not been validated in an Indian population, so this study aimed to translate and then validate it in Kannada speaking surgical patients. Aims and Objectives: The objectives of our research were to assess the validity, reliability, responsiveness, and feasibility of Kannada translated edition of QoR-15 in Kannada speaking population undergoing elective surgery. Material and Methods: Consenting patients were instructed to fill their translated preoperative QoR-15 Kannada questionnaire on the previous day of surgery. They were approached again on postoperative day 1 to fill out their QoR-15 questionnaire. Global postoperative recovery was graded from 0-100 by the patient postoperatively. Results: The Pearson correlation between QoR-15 Kannada score and visual analog scale measuring postoperative recovery on a scale of 0-100 was found to be 0.74 (95% CI 0.87-1.17; p < 0.01). Correlation between Kannada version of QoR-15 and extent of surgery in minutes was -0.67(95% CI: 0.17, -0.12, p <0.01). Correlation between postoperative QoR-15 Kannada score and days of admission was -0.61 (95% CI: - 6.35, - 4.13, p < 0.01). Postoperative QoR-15 Kannada score in minor surgery was 113.13 ± 15.07 , intermediate 110.6 ± 14.79 and major 88.74 ± 17.97 (p < 0.01), which decreased from minor to major. Cronbach's alpha coefficient was 0.89, split-half alpha was 0.83. The Cohen's effect size was 1.22 which is large and standardized response mean was 1.67. Majority (98.6%) of patients accomplished the research protocol successfully. Conclusion: The Kannada version of QoR-15 proved to be generalizable to an entirely different population than in which it was originally developed. The results show that the translated version is feasible, reliable, valid and responsive and it is an apt tool for measuring the recovery in Kannada speaking elective surgical patients.

Keywords: QoR-15, quality of recovery, validation

Introduction

Postoperative recovery involves multiple dimensions and its assessment can be multifaceted too [1]. Factors which were generally considered for assessing recovery in the postoperative period are morbidity, mortality, physiological endpoints as well as readmission rates [2]. The best way to improve any standard of care is to understand the patient's viewpoint coupled with the doctor's understanding of the patient's recovery and improvise accordingly [1]. Patient satisfaction is the ultimate endpoint of perioperative care and evaluation of standard of recovery fundamentally does the same [3]. Standardized scales can be useful in evaluating the quality of recovery from surgery and anaesthesia. Multiple scales have been developed for assessing patient satisfaction and recovery rate involving varying number of assessment factors but standardization in research becomes difficult when there is no uniformity [4]. Quality of Recovery-15 (QoR-15) scale developed by Stark *et al.*, which is less time consuming than many other scales, has been validated in various populations across the world. Having a numerical endpoint has an advantage that it will offer an improved outcome measurement [5].

This questionnaire has not been validated in an Indian population, so this study aimed to translate the original version to Kannada and validate it in Kannada speaking surgical patients. We assumed that the Kannada version of QoR-15 questionnaire would be comparable to the original version in evaluating the quality of recovery in the postoperative period. The purpose of the research was to assess the validity, reliability, responsiveness, and feasibility of Kannada translated version of QoR-15 in the Kannada speaking population undergoing elective surgery.

Material and Methods

The study was initiated after obtaining permission from the institutional review board, following which it was registered with the Clinical Trials Registry – India. The study was carried out from June 2023 to August 2023 in a tertiary care hospital. Patients of American Society of Anesthesiologists Physical Status (ASA-PS) Classification grades 1, 2, 3 with age more than or equal to 18 years undergoing elective surgical procedures were included in the study. The criteria for exclusion were: age <18 years and >80 years, pregnant, emergency surgery, ASA-PS grade 4 and above, mental illness, postoperative delirium, patients not fluent in Kannada and patients likely to be mechanically ventilated postoperatively.

Permission was taken from Dr. Myles to use the QoR-15 questionnaire. Translation was done according to standard practices [6, 7]. The initial translation from the English to Kannada was done by two independent translators who were fluent in

Kannada and English. Discrepancies among the two translators were discussed and resolved between them. Subsequently, a temporary edition of the Kannada questionnaire was agreed upon. The initial translation was independently backtranslated by 2 translators unaware of the QoR-15 questionnaire measures, to ensure that the translation is accurate. A consensus was reached on the pre-final version, retranslated questionnaire was compared with the original and discrepancies were corrected. A trial was done with this pre-final Kannada version of the QoR-15 on 10 patients who were chosen randomly. The trial proved that every question was comprehensible. All patients were able to answer all questions without any difficulty, and therefore this edition of the questionnaire was finalized. No cultural adaptations were made. The sample size required for the study was decided based on the guidelines which proposed that for an instrument scale, at least ten subjects are required for every item on the scale. As the QoR-15 questionnaire consisted of 15 questions, the minimum sample size of patients needed for the research was deliberated as 150 [7]. Patients in the preoperative wards who were eligible were explained about the study and willing patients were included after obtaining informed consent. The consent form included a patient information page explaining the motive of the study and details pertaining to the questionnaire. On the day prior to the planned surgical procedure, consenting patients were instructed to fill and give back the preoperative QoR-15 Kannada questionnaire. They were approached again on postoperative day 1 to answer their postoperative QoR-15 Kannada questionnaire. All patients were advised to cautiously follow the instructions that were given, so as to make sure that they would not miss any questions.

The QoR-15 Kannada questionnaire, like the original English version, consists of 15 questions focusing on five domains which measures the patient's physical and mental well-being. The participants had the option of rating every question on a scale ranging from zero to ten. The maximum score of 150 would mean an ideal postoperative recovery. Age of the patients, gender, Body Mass Index (BMI), ASA-PS grading, type of surgical procedure and time taken for the same, type of anaesthesia, postoperative complications, postoperative global Visual Analogue Scale (VAS) score (0 to 100) were recorded. Surgeries were categorized as minor, intermediate or major according to the kind of intervention and the anticipated stress response to the surgical procedure [8, 9]. Minor surgeries included removal of a skin lesion or breast abscess drainage while intermediate surgeries included procedures such as inguinal hernia repair, removal of varicose veins in the leg, tonsillectomy or knee arthroscopy. Major surgeries included procedures such as a full hysterectomy, endoscopic prostatectomy, discectomy or thyroidectomy, lung surgeries. Duration of surgery was calculated from the time of commencement of the procedure to completion of the surgery, and the duration of postoperative period was determined from end of surgical procedure to the time of discharge. Global postoperative recovery was graded from 0-100 by the patient postoperatively. As doing a test-retest of the patients participating in the study was not possible as it is a questionnaire answered by the patient themselves, a convenience sample of 25 postoperative patients were selected to estimate test-retest reliability of the QoR-15 Kannada score by making them to complete the questionnaire for a second time half an hour to one hour after the

questionnaire was filled initially. If patients refused or were not able to complete all or part of the questionnaires at any time, their data was not included.

Statistical analysis

The responses from the study protocol were entered into Microsoft Excel and analyses were done with Microsoft Excel 2016 and R version 3.4.3 software (R Foundation for Statistical Computing, Vienna, Austria). Frequency and percentage were used for qualitative data. Mean and Standard Deviation (SD) or median (range) were used for presenting quantitative data, in accordance with data distribution. For continuous data, statistical analysis was performed using the Student's or Mann Whitney U test as relevant. Correlations were determined with Pearson correlation coefficient and Spearman correlation coefficient for Gaussian and non-Gaussian data respectively. A value of p < 0.05 was taken as statistically significant. Full validation was done by assessing the following criteria:[8]

<u>Feasibility</u> was assessed by successful completion rate and the time taken for participants to finish the QoR-15 Kannada.

<u>Responsiveness</u> was evaluated using Cohen effect size (the average change in QoR-15 score from preoperative to postoperative divided by the SD at baseline) and standardized response mean (the average change in QoR-15 Kannada score divided by the SD of the average change in QoR-15 Kannada score).

<u>Validity</u>: 1) Convergent validity was checked by hypothesizing that the correlation between postoperative QoR-15 Kannada score and global VAS score would be positive. 2) Construct validity was checked by hypothesizing that the correlation between age, duration and type of surgery would be negative. 3) Discriminant validity was checked by hypothesizing that participants with postoperative problems and poor VAS scores would have lower QoR-15 Kannada scores postoperatively.

<u>Reliability</u> was assessed using internal consistency (measured using Cronbach's alpha with higher values indicating higher agreement between items) and test–retest reliability.

Results

Out of the recruited 150 participants, 148 completed the protocol. Table 1 shows demographic details and clinical features of the participants. The mean duration of surgery was 100.56 ± 79.87 minutes and mean stay in the hospital was 3 days \pm 2.01. The mean QoR-15 Kannada total score in the preoperative period was 130.33 ± 11.82 and in the postoperative period was 106.68 ± 18.07 .

Table 1: Patient characteristics							
Age in years, Mean±SD	41.34±13.7						
Gender, number (%)							
Male	69 (46.62%)						
Female	79 (53.37%)						
ASA-PS grades – number of participants (%)							
1	84 (56.75%)						
2	53 (35.81%)						
3	11 (7.43%)						
Type of surgery – number of participants number (%)							
Minor	39 (26.35%)						
Intermediate	78 (43.33%)						
Major	31 (20.9%)						
Type of anaesthesia – number of participants (%)							
General	65 (43.91%)						
Neuraxial block	77 (52.02%)						
Nerve block	6 (4.05%)						
Complications, number	9						

 $SD-Standard\ deviation,\ ASA-PS-American\ Society\ of\ Anesthesiologists-Physical\ Status$

Psychometric evaluation Validity

Convergent validity- The Pearson correlation between QoR-15 Kannada score and VAS measuring postoperative recovery on a scale of 0-100 was found to be 0.74 (95% CI: 0.87-1.17; p < 0.01). Table 2 shows the inter-item correlation matrix *Construct validity*-Correlation between QoR-15 Kannada and duration of surgical procedure was - 0.67 (95% CI: -0.17, -0.12, p < 0.01). Correlation between postoperative QoR-15 Kannada score and days of admission was -0.61 (95% CI: -6.35, -4.13, p < 0.01). Correlation between age and postoperative QoR-15 was -0.24 (95% CI: -0.52,-0.10, p < 0.01)

Postoperative QoR-15 Kannada score in minor surgery was 113.13 ± 15.07 , in intermediate surgery was 110.6 ± 14.79 and in major surgery was $88.74 \pm$ 17.97 (p < 0.01), which decreased from minor to major. Preoperative score was 130.15 ± 10.74 in minor surgery, 130.78 ± 112.49 in intermediate surgery and 129.42 ± 11.9 in major surgery (p=0.861).

Postoperative QoR-15 Kannada score in patients with postoperative complications and without complication was 82.67 ± 19.53 and $108.25 \pm 16.90 (p < 0.01)$, respectively.

Discriminant validity was assessed by comparing participants with a postoperative global recovery VAS score less than 70 and more than or equal to 70. The QoR-15 Kannada score was $< 91.32 \pm 16.74$ and 113.84 ± 13.72 (p < 0.01) in patients with global VAS score less than 70 and ≥ 70 , respectively.

Reliability: Cronbach's α coefficient was 0.89 and split-half α was 0.83

Responsiveness assessed using Cohen's effect size was 1.22 which is large and standardized response mean was 1.67. Test–retest concordance coefficient was 0.98. Table 3 shows responsiveness assessment.

Feasibility: 98.6% of the patients successfully fulfilled the study procedure. The time taken to complete the questionnaire was 237.62 ± 62.89 and 249.68 ± 72.41 seconds in preoperative and post-operative period, respectively. There were no patients who reported the lowest possible score of 0 and no patient reported the highest possible score of 150, therefore no significant floor or ceiling effect was noticed.

Table 2: Inter-item correlation matrix for Qok-15 Kannada scale															
Questions	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1															
2	0.35														
3	0.33	0.72													
4	0.23	0.50	0.51												
5	0.32	0.40	0.4	0.29											
6	0.12	0.26	0.31	0.24	0.36										
7	0.21	0.36	0.30	0.21	0.23	0.4									
8	0.28	0.36	0.42	0.4	0.56	0.22	0.22								
9	0.44	0.42	0.48	0.36	0.52	0.48	0.31	0.56							
10	0.29	0.38	0.45	0.37	0.41	0.62	0.11	0.36	0.75						
11	0.33	0.34	0.28	0.04	0.41	0.39	0.31	0.24	0.54	0.48					
12	0.12	0.13	0.08	0.15	0.1	0.23	0.28	0.27	0.37	0.29	0.29				
13	0.25	0.21	0.23	0.2	0.18	0.03	0.22	0.22	0.22	0.02	0.01	0.04			
14	0.36	0.54	0.43	0.44	0.41	0.35	0.25	0.42	0.59	0.57	0.35	0.20	0.38		
15	0.32	0.48	0.45	0.51	0.35	0.30	0.21	0.45	0.47	0.45	0.24	0.22	0.41	0.75	

Table 2: Inter-item correlation matrix for QoR-15 Kannada scale

Table 3: Mean values, change and responsiveness of QoR-15 Kannada										
Item	Preoperative	Postoperative	Absolute change from baseline	Baseline change (%)	Cohen's effect size					
1	9.82± 0.45	9.1±1	-0.75 (-0.9,-0.6)	7.63	0.89					
2	8.26±1.59	5.9±2.1	-2.34 (-2.68,-2.01)	28.33	1.06					
3	8.16± 1.55	6±2.2	-2.16 (-2.51,-1.8)	26.47	0.99					
4	8.16±1.5	5.21±2.15	-2.95 (-3.31,-2.58)	36.15	1.25					
5	9.59±0.98	6.58±2.12	-3.01 (-3.32,-2.69)	31.39	1.35					
6	9.42±1.09	9.11±1.62	-0.31 (-0.54,-0.08)	3.29	0.22					
7	9.28±0.76	9±0.9	-0.3 (-0.47,-0.13)	3.23	0.36					
8	8.95±0.76	4.45±2.25	-4.51 (-4.88,-4.13)	50.39	1.51					
9	8.12±1.6	6.57±2.29	-1.55 (-1.84,-1.27)	19.09	0.76					
10	7.24±1.91	6.37±2.59	-0.87 (-1.16,-0.58)	17.36	0.38					
11	8.85±1.47	7.34±1.8	-1.51 (-1.83,-1.19)	17.06	0.83					
12	9.64±1.09	8.91±1.27	-0.67 (-0.94,-0.4)	6.95	0.54					
13	9.82±0.7	8.6±2.06	-1.28 (-1.63,-0.93)	13.03	0.77					
14	7.5±1.58	7±1.9	-0.45 (-0.77,-0.13)	6	0.25					
15	7.63±1.63	6.64±2.07	-0.99 (-1.33,-0.65)	12.98	0.52					
Total	130.33±11.86	106.68±18.07	-23.64 (-25.92,-21.36)	18.14	1.22					

Mean (standard deviation) or (95% confidence interval)

Discussion

A total of 148 patients completed the study protocol. Out of 148 patients, 53.37% of the patients were females. We included patients undergoing general anaesthesia and regional anaesthesia. We included patients undergoing general surgery, orthopedic patients, gynecology, ENT and urology in our study, and the psychometric evaluation proved that the Kannada version of the questionnaire is a feasible, valid, reliable and responsive instrument for evaluating recovery of patients in the postoperative period.

The correlation between QoR-15 Kannada and the global VAS score given by the patient was 0.74 which is a strong correlation. This was similar to the original study which showed a correlation of 0.68 [8] and another similar study [7]. The correlation between age and postoperative QoR-15 Kannada score was -0.24 which is very weak, this could be because older people tend to report less complaints [8]. A negative correlation was established between duration of surgery and extent of hospital stay as in previous studies [8, 10]. The reliability was shown to be very good with Cronbach's alpha coefficient of 0.89 and split–half alpha of 0.83. The range of Cronbach's α is from 0 to1. Value of 0 means there is no internal consistency while a value of 1 indicates optimal internal consistency. A value of 0.7 has been suggested to reflect satisfactory internal consistency [6].

Good responsiveness is the most important characteristic of any evaluation tool [10] as it can better detect changes in patients' recovery status in the postoperative period. This study showed a large Cohen's effect size of 1.22. Cohen's effect size helps in evaluating the relative size of change with 0.2 reflecting small, 0.5 showing medium, and 0.8 or greater showing large effect size [8].

High rate of response for the study points that the QoR-15 Kannada is an acceptable and feasible method to record the quality of recovery in the postoperative period in the Indian setting too. A completion rate of 98.6% was found in our study, which is very high. As there are only 15 questions, it is less time consuming, probably the reason for excellent completion rates. While a Danish study showed only 56% completion rate when the questionnaire was done through the postal route, most other validation studies have demonstrated good completion rates [11]. Evaluation tools centered on patients require them to be acceptable to the patient to ensure high return rates [12]. Postoperative recovery is a process that requires energy to return to normality and wholeness [13, 14].

Most perioperative complications are preventable and to date there is no gold standard quality indicator. QoR-15 could be considered as it has proven validity and its feasibility looks promising in routine clinical practice [15]. Moreover, evaluation of any procedure or treatment can be done subjectively as well as objectively [16]. It measures several domains including pain, physical comfort and independence, psychological state and emotional support making it a holistic questionnaire [17]. High percentage of completion rate is also an advantage for using this questionnaire for assessing recovery quality in clinical trials. The score has the ability to gauge the changes in a patient's health status in the postoperative period and therefore optimize treatment [18, 19].

Leger et al. suggested QoR scales could be translated and validated widely and be used as endpoints in future randomized control trials [1]. The questionnaire could also be incorporated into the feedback systems in hospitals and could prove useful to doctors and nurses and other health care workers who play a cardinal role in patient care [20]. Outcomes of quality recovery programs can be assessed and improved if there are competent quality measuring techniques [21-23]. Patient centered approaches will empower patients in choosing options and will enable shared decision making [24]. QoR-15 has been validated in various languages and is very promising in these regards [25-27]. Compared to other scales assessing the quality of recovery such as QoR-40 which is widely used [28], this scale with only 15 items is highly recommended [1, 4] as measuring outcomes is easier with patient focused questionnaires requiring lesser duration in comparison to lengthy questionnaires [29, 30]. The limiting factors in the study were that all patients were recruited from a single-centre tertiary teaching hospital and only elective surgical cases were included. Therefore, the reliability in emergency cases was not assessed.

Conclusion

We translated and assessed the QoR-15 scale in Kannada speaking patients who were subjected to elective surgical procedures. The questionnaire proved to be generalizable to an entirely different population than in which it was originally developed. The results show that the translated version is feasible, reliable, valid and responsive and it is an apt tool for measuring the recovery in elective surgical patients. It could be used for quality surveys in the postoperative period as well as in other clinical trials in the Indian setting.

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