Validation of the Brazilian version of the Quality of Recovery - 40 Item questionnaire

Validação da versão brasileira do questionário Quality of Recovery - 40 Items

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Nursing assessment; Perioperative nursing; Nursing diagnosis; Validation studies; Prostatectomy/methods

Descritores

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Abstract

Objective: To validate the Brazilian version of the Quality of Recovery-40 Item (QoR-40) questionnaire, among patients submitted to radical prostatectomy.

Methods: A methodological study was conducted with 224 patients submitted to radical prostatectomy, with 24 for semantic analysis and 200 for psychometric properties, considering discriminant construct validities, reliability and responsiveness.

Results: The semantic analysis resulted in drafting alterations of three items. In the convergent construct validity, correlations between the QoR-40 and dimensions of quality of life and visual analogue scales of postoperative recovery were moderate. The discriminant construct validity determined statistically significant differences among patients with nursing diagnosis of retarded postoperative recovery and with urinary incontinence. Regarding reliability, Cronbach's alpha values were satisfactory. Responsiveness showed that the questionnaire obtained acceptable capacity for identifying changes over time.

Conclusion: The Brazilian questionnaire has acceptable validity, reliability and responsiveness.

Resumo

Objetivo: Validar, entre pacientes submetidos à prostatectomia radical, a versão brasileira do questionário *Quality of Recovery-40 Item* (QoR-40).

Métodos: Estudo metodológico realizado com 224 pacientes submetidos à prostatectomia radical, sendo 24 para análise semântica e 200 para as propriedades psicométricas, considerando validades de constructo e discriminante, fidedignidade e responsividade.

Resultados: A análise semântica resultou em alterações na redação de três itens. Na validade de constructo convergente, as correlações entre o QoR-40 e os domínios das escalas de qualidade de vida e visual analógica de recuperação cirúrgica foram moderadas. A validade de constructo discriminante constatou diferenças estatisticamente significativas entre pacientes com o diagnóstico de enfermagem Recuperação cirúrgica retardada e com incontinência urinária. Quanto à fidedignidade, valores de alfa de *Cronbach* foram satisfatórios. A responsividade demonstrou que o questionário obteve adequada capacidade em identificar mudanças no decorrer do tempo.

Conclusão: O questionário brasileiro possui adequadas validade, fidedignidade e responsividade.

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Introduction

Instruments for assessing health status are important to identify problems presented by patients, because they enable to investigate these responses from the records of patients who experience the situation; and to validate information and clinical indicators collected by nurses, increasing the accuracy in detecting problems.⁽¹⁾

These instruments favor patient safety because they increase the assessment accuracy, improve communication of the multidisciplinary team, reduce risks of less accurate nursing diagnosis of the patients' health problem and improve nursing healthcare quality, since they are assessment criteria of health status and outcome indicators of established interventions. (2)

Inaccuracy on the necessary time to the complete postoperative recovery and the complexity of this period evidence difficulties in monitoring patients' recovery evolution, due to the weakness in identifying characteristics that describe their commitment, extension and regression of clinical events, which are specific of the period. Nonetheless, measurements obtained from the patients' records are vital for appropriate monitoring of this period. (3)

Several assessment instruments of postoperative recovery have been developed. Among these, the Quality of Recovery-40 Item (QoR-40) stands out, because it is widely indicated for this purpose, presents good results regarding its psychometric properties, is the most commonly used in clinical trials and has been translated into several languages. (4)

The QoR-40 is composed of 40 items that measure the quality of postoperative recovery, considering five dimensions: emotional state (nine items), physical comfort (12 items), psychological support (seven items), physical independence (five items) and pain (seven items). It is composed of part A, which involves items associated with the perception and support of physical abilities; and part B, which comprises items associated with symptoms presented during recovery. The score distribution in each item is made by a five-point Likert scale, in which high values correspond to the best response. The

score is established by the sum of the responses in each item, ranging from 40 to 200, with the highest values representing better quality of recovery. (5)

The QoR-40 was translated into Portuguese language and validated among adult patients submitted to orofacial surgeries. (6) In view of the specificity of this sample, the objective of the present study was to analyze the psychometric properties of the Brazilian version of the QoR-40 in a sample of patients submitted to radical prostatectomy.

Methods

A methodological study was conducted within the urological service of an oncologic hospital in a city in the state of São Paulo, after consent of the authors of the original instrument and those of the Brazilian version.

The sample was made up of patients submitted to radical prostatectomy, considering the inclusion criteria as follows: being 18 years or older, understanding the Portuguese language and absence of cognitive alterations. The exclusion criteria were: psychiatric disorders, cognitive alterations identified by the Mini-Mental State Examination, chemical dependency and unstable clinical condition at the time of interview.⁽⁷⁾

Semantic analysis was conducted to verify the instrument's understanding by patients and ways to solve its possible limitations. Model and forms developed by the DISABKIDS® group were used, which enable to perform general analysis of the instrument by verifying overall impressions, difficulty in answering it and relevance of items, besides specific analysis of items regarding their relevance, understanding and need to modify the drafting of any of them. The QoR-40 was divided in four subgroups of items: the first comprised items of the dimension physical comfort; the second, the dimension emotional state; the third, the dimension psychological support; and the last one, the dimensions physical independence and pain. Each subgroup was evaluated by three patients in two different age group (18 to 64 years and 65 years or more). (8)

The patients were invited to participate in the semantic analysis at the time they returned for post-operative outpatient appointment. After providing informed consent to participate in the study, they answered the QoR-40 and the semantic validation instrument.

Data were analyzed by calculating the percentage of responses to each instrument's component. Suggestions regarding drafting alterations were individually analyzed, considering the balance between the meaning of the item and its understanding by patients. The questionnaire's final format resulted from this analysis.

The psychometric properties investigated were convergent and discriminant construct validity, reliability and responsiveness. (9,10) The convergent construct validity verified the correlation among the QoR-40 measurements and the Visual Analogue Scale (VAS) of postoperative recovery and the 36-Item Short Form Health Survey Version 2.0° (SF-36v2°). (5-11) The discriminant construct validity was investigated by the comparison among groups of patients with or without a nursing diagnosis of retarded postoperative recovery and among groups of patients with or without urinary incontinence. (12) Reliability was verified by the internal consistency and responsiveness by the QoR-40 measurements over time.

The presence of floor and ceiling effects was investigated, by analysis of frequency of responses of each item. The floor effect occurs when more than 15% of the responses concentrate in the minimum value and the ceiling effect, in the maximum value of scales. (9)

The instruments used for data collection were: sociodemographic and perioperative characterization instrument, VAS of postoperative recovery, SF-36v2°, instrument for the identification of the defining characteristics of nursing diagnosis of retarded postoperative recovery and instrument for the identification of this nursing diagnosis by patients.

The VAS of postoperative recovery is made up of a 100mm horizontal line, with anchors at its end; the descriptor "totally recovered" is on the right, and "not recovered" on the left. The patients indicated

how much recovered they felt during the interview, marking the line with a score that determined the recovery level.

The SF-36v2° is a measurement instrument of health-related quality of life, composed of 36 items grouped in eight dimensions: functional capacity, physical aspects, pain, general health status, vitality, social aspects, emotional aspects and mental health, besides a comparative question of the patient's current quality of life and 12 months ago. The score in each dimension ranges from zero to 100, and values close to 100 indicate better health-related quality of life. (11)

In the postoperative period, after the identification of eligibility criteria, patients were invited to participate in the study. After providing consent, the first interview was conducted and the patients answered the QoR-40, the SF-36v2° and the sociodemographic and perioperative characterization instrument. In the first postoperative day, the QoR-40 and the VAS of postoperative recovery were applied, and characterization was completed with intraoperative and postoperative data. In the first and second outpatient returns, the patients answered the QoR-40, the SF-36v2° and the VAS of postoperative recovery; and the identification of defining characteristics of nursing diagnosis of retarded postoperative recovery and the identification of the occurrence of nursing diagnosis by patients were performed.

A sample of 200 patients was established, considering five patients per questionnaire item, according to the recommendations in literature for this type of study. (13)

Data were analyzed by means of the Statistical Package for the Social Sciences 20.0 software. Nominal and categorical variables were described in simple frequency, and continuous variables by central tendency (mean) and dispersion (standard deviation - SD) measures.

The convergent construct validity was investigated using Pearson's correlation coefficient. Moderate and strong correlations were considered acceptable (0.40<r<1). The discriminant validity was investigated using Mann-Whitney test, establishing p<0.05 for acceptable differ-

ence among the groups. Reliability was examined by internal consistency, according to Cronbach's alpha statistic. Results $\geq 0.70^{(9,10)}$ were considered acceptable. Responsiveness was investigated by the mean of standardized answers (Standardized Response Mean - SRM), obtained by the equation: initial measure - final measure/SD of the difference. For the identification of the magnitude of change in measures, values <0.20 were considered as having an insignificant effect, ≤ 0.20 to <0.50 a small effect, ≤ 0.51 to <0.80 a moderate effect and ≥ 0.80 a significant effect. (14) A 5% significance level was adopted in all analysis.

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The study was registered in the Plataforma Brasil under Certificate of Presentation for Ethical Appreciation (CAAE, as per its acronym in Portuguese) number 23347613.3.0000.5434.

Results

Semantic analysis involved 24 patients with a mean of 4.5 postoperative months; 12 patients were under 65 years of age (mean of 59 years), had a mean education level of 8.1 years; and 12 were aged 65 years or older (mean of 71 years) and mean of 4.1 years of education level.

Regarding the QoR-40 general evaluation, all participants considered the questionnaire good, 70% referred easy understanding of questions and 54% reported difficulty with the response scale, which was higher in the group of patients aged 65 years or older (75%). Most participants (91.6%) considered the QoR-40 items very important for the health status of patients who were submitted to radical prostatectomy, and 16.6% suggested more specific questions on urinary incontinence and erectile dysfunction.

Regarding the analysis of items, the majority was well understood by the participants. Only three items had their drafting altered, due to the patients' difficulty to understand them.

Analysis of the psychometric properties involved 200 patients with a mean age of 63.3 years (SD=7). The majority was submitted to radical prostatectomy by the perineal area (84.5%); the others performed it by the retropubic area (4%) and 11.5% were also submitted to retroperitoneal lymph node dissection. The mean length of hospital stay was 3.3 days (SD=0.8), 95.5% of patients did not require reoperation; among those who required it, about 90% were submitted to retroperitoneal lymph node dissection.

All patients were submitted to general anesthesia. The mean length of the surgical procedure was 77.7 minutes (SD=18.7). The length of stay in the surgical center was 127.7 minutes (SD=22.6), and in the post-anesthesia recovery room was 65.6 minutes (SD=29.5).

Complications developed in the postoperative period were urinary incontinence (54.5%), erectile dysfunction (41.0%), surgical wound dehiscence (5.0%), urinary infection (4.5%), anal fistula (3.5%), vesical fistula (2.0%), hydrocele (0.5%), extensive hematoma (0.5%) and urinary retention (0.5%).

Means of the QoR-40 score were 190.2 (SD=7.3), 181.4 (SD=10.3), 187. (SD=10.4) and 192.1 (DP=7.5) in preoperative, postoperative, first and second return, respectively. From the distribution of frequency of responses in each item, the ceiling effect was detected in all items.

On average, the individuals answered the QoR-40 in the preoperative period in 8.9 minutes (SD=3.6), in the postoperative period in 7.3 (SD=2.0), in the first return in 7.7 (SD=1.8) and in the second return in 7.4 (SD=1.3).

The convergent construct validity, obtained by Pearson's correlation coefficient, from the measurement of the QoR-40 dimensions with the SF-36v2° dimensions in the preoperative period, resulted in moderate correlations between the QoR-40 emotional state dimension and the SF-36v2° dimensions: vitality (r=0.52; p<0.05), emotional aspects

(r=0.50; p<0.05), social aspects (r=54; p<0.05) and mental health (r=60; p<0.05); and between pain dimension of both instruments (r=0.51; p<0.05).

In the first return, the correlations were moderate between the OoR-40 emotional state dimension and the SF-36v2° dimensions: functional capacity (r=0.49; p<0.05), physical aspects (r=0.52; p<0.05), pain (r=0.45; p<0.05), general health condition (r=0.48; p<0.05), vitality (r=0.59; p<0.05), emotional aspects (r=0.50; p<0.05), social aspects (r=0.61; p<0.05) and mental health (r=0.69;p<0.05); between the QoR-40 psychological support dimension and the SF-36v2® dimensions: functional capacity (r=0.53; p<0.05), physical aspects (r=0.53; p<0.05), general health condition (r=0.48;p<0.05), vitality (r=0.46; p<0.05) and emotional aspects (r=0.46; p<0.05); and between the QoR-40 pain dimension and the SF-36v2[®] dimensions: functional capacity (r=0.43; p<0.05) and physical aspects (r=0.43; p<0.05). A strong correlation was detected between the pain dimensions of both instruments (r=0.70; p<0.05).

In the second return, correlations were moderate between the QoR-40 physical comfort dimension and the SF-36v2° dimensions: pain (r=0.49; p<0.05), vitality (r=0.59; p<0.05), social aspects (r=0.42; p<0.05) and mental health (r=0.45; p<0.05); and between the QoR-40 emotional state dimension and the SF-36v2° dimensions: social aspects (r=0.61; p<0.05) and mental health (r=0.60; p<0.05); between the QoR-40 psychological support dimension and the SF-36v2° dimensions: pain (r=0.40; p<0.05), vitality (r=0.40; p<0.05), social aspects (r=0.54; p<0.05) and mental health (r=0.49; p<0.05); and between the QoR-40 pain dimension and the SF-36v2° dimensions: vitality (r=0.55; p<0.05), social aspects (r=0.44; p<0.05)

and mental health (r=0.40; p<0.05). A strong correlation was detected (r=0.80; p<0.05) between the pain dimensions of both instruments.

Table 1 presents the correlations between the QoR-40 score measures and the SF-36v2° dimensions.

Table 1. QoR-40 measures and SF-36v2® dimensions

SF-36v2®	Preoperative	First return	Second return*	
Functional capacity	0.18**	0.58**	0.02	
Physical aspects	0.24**	0.59**	0.21**	
Pain	0.44**	0.51**	0.60**	
General health status	0.41**	0.51**	0.39**	
Vitality	0.40**	0.60**	0.55**	
Emotional aspects	0.34**	0.43**	0.15	
Social aspects	0.37**	0.61**	0.66**	
Mental health	0.41**	0.60**	0.63**	

*n=106; ** Pearson's correlation coefficient= 0.01<p<0.05

Correlations between the QoR-40 and the VAS of surgical recovery were poor in the postoperative period (r=0.38; p<0.05) and strong in the first return (r=0.76; p<0.05) and second return (r=0.85; p<0.05).

The discriminant construct validity investigation showed that differences of QoR-40 means between groups with and without a nursing diagnosis of retarded postoperative recovery and groups with and without urinary incontinence were statistically significant (p<0.01).

As presented in table 2, the QoR-40 internal consistency had satisfactory results.

Responsiveness showed the instrument's ability in identifying differences in postoperative recovery in different periods (Table 2). The SRMs demonstrated a significant effect in the difference of measures between the pre- and postoperative periods and a moderate effect between the other two periods.

Table 2. Distribution of Cronbach's alpha values and standardized response means

Items	Preoperative	Postoperative	First return	Second return*	SRM preoperative/ postoperative	SRM postoperative/ first return	SRM first/ second return
QoR-40 total	0.75	0.82	0.86	0.84	0.93	-0.59	-0.53
Physical comfort	0.49	0.70	0.43	0.60	0.73	-0.76	-0.21
Emotional state	0.71	0.65	0.80	0.75	0.24	-0.01	-0.43
Psychological support	0.76	0.64	0.72	0.68	1.11	-0.32	-0.27
Physical independence	-	0.70	0.31	-	1.00	-0.85	0.03
Pain	0.41	0.21	0.46	0.61	0.36	-0.29	-0.22

*n=106 - analysis not processed due to the absence of variability of responses in items 8, 9 and 10; SRM - Standardized Response Mean

Discussion

The study limitations stand in the small variability of responses in each item, which resulted in the occurrence of the ceiling effect. Possible verifications in future studies refer to the discriminant validity, considering the development of late complications, since the present study focused on the analysis of the first outpatient return for the discrimination of groups with urinary incontinence.

This study contributed to validate an assessment instrument of postoperative recovery with potential to be used in clinical context and future studies.

Responsiveness showed that differences of measures identified among the four periods of application of the questionnaire suggest clinical state changes in face of SRM values, which demonstrated the capture of these changes over time. (14) The QoR-40 responsiveness in other cultures was investigated between measures of pre- and postoperative periods, obtaining similar results - a moderate to significant effect. (15-18) When investigating long term responsiveness, measurement between pre- and postoperative (90 days) of patients submitted to neurological surgeries, Australian researchers identified the QoR-40 good ability in detecting recovery changes (SRM>0.80). (19)

The recovery monitoring over time showed that in the second return (about seven months after surgery), the QoR-40 scores were higher than the ones found in the preoperative period, characterizing an improvement in health status identified by the instrument.

The ability to detect clinically important changes is essential for instruments that measure health status. It should be emphasized that since the QoR-40 is often used for this purpose, good results for responsiveness are mandatory.⁽⁴⁾

The reliability verified by Cronbach's alpha statistic in each dimension was similar to values identified in other studies of QoR-40 validation. In Turkey, the internal consistence of the total was 0.93, with a variation in dimensions of 0.82 to 0.92; in Iran, alpha was 0.89 for the total, and 0.89 to 0.93 for dimensions; in Japan, it was 0.91 for the total and 0.74 to 0.88 for dimensions. (3,16,18)

Despite the questionnaire's acceptable reliability, items that might have interfered negatively in the results were identified. Items that investigate skills of communication and self-care did not receive variability of responses (preoperative and second return), i.e., all patients pointed to the best response. It is worth mentioning that speaking was a requirement for the inclusion of patients in the study, being the possible reason for not identifying this alteration. Among patients, there were no physical limitations for the performance of self-care and activities of daily living before surgery, evidenced by the fact that 60% of the patients were professionally active and were evaluated by the American Society Anesthesiologist (ASA) classification I or II; therefore, they did not present clinical conditions that suggested problems to perform these activities.

Items of the dimensions physical comfort (items associated with post-anesthetic effects) and pain (items about pain in mouth, throat and head) did not present response variation in the preoperative, first and second returns, but they presented internal consistency weaknesses, with low Cronbach's alpha values, especially in the pain dimension. In an Australian study, the same dimensions resulted in low alpha values; questions that evaluated pain in non-surgical areas showed propensity in reducing consistency regarding questions that evaluated pain in an overall way.⁽²⁰⁾

Regarding items that describe effects of medications and anesthetic procedures, it is believed that these events could be identified in the postoperative period of early surgeries, and in fact they were, because they presented variability of responses in this period. The acceptable evolution of postoperative recovery predicts that these events will not occur late.

In Sweden, the QoR-40 was adapted for the assessment of outpatient postoperative recovery, and therefore, some items were excluded, because the authors believed that they would not capture relevant information on this postoperative recovery. The excluded items were from the dimensions physical comfort and pain, which did not present variability. The same exclusion was identified in a study that developed a short version of the QoR-40.

(19) This suggests that these items may not be essential to evaluate patients submitted to less invasive surgeries, as it was the case of the present study.

Correlations between the QoR-40 and the SF-36v2° dimensions were moderate, as well as in the studies from Turkey, Japan, Iran and in the original version. (3,5,18,20)

The correlation of the QoR-40 with the VAS of surgical recovery was acceptable and superior when compared to values obtained in other cultures, whose results ranged from r=0.45 to 0.68. (3,5,15,16,18,19)

Conclusion

The results achieved with the present study, which analyzed the psychometric properties of the Brazilian version of the Quality of Recovery-40 Item (QoR-40), showed that the instrument obtained convergent and discriminant construct validity, satisfactory reliability and responsiveness, as per the research conducted with a sample of patients submitted to radical prostatectomy.

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Collaborations

Eduardo AHA, Santos CB, Carvalho AMP and Carvalho EC participated in the project's conception, data analysis and interpretation, writing of the article, critical review of its intellectual content and final approval of the version to be published.

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