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Introduction

Urinary incontinence (UI) is one of the most common complications from radical prostatectomy (RP) in the male population (Abrams et al., 2017). It is estimated that 40% of men experience some degree of UI within one year after surgery (Hodges et al., 2020), requiring evaluation and treatment (Abrams et al., 2017).

Given that the severity of UI is a significant predictor of quality of life (QoL; Bernardes et al., 2019), the International Continence Society (ICS) recommends that therapeutic measures be assessed not only based on clinical parameters (urodynamic study, ultrasonography, and others) but also instruments for assessing the impact of UI on QoL (Abrams et al., 2017).

Specific questionnaires in this scope assess the impact of urinary symptoms on patients' lives (Abrams et al., 2017), namely the King's Health Questionnaire (KHQ; Kelleher et al., 1997). This questionnaire is comprehensive because it investigates both the presence of UI symptoms and their impact on individual aspects of QoL (Kelleher et al., 1997).

Considering the importance of analyzing an instrument to ensure that it is valid and reliable for a specific target group (Souza et al., 2017), this study was guided by the following question: "Is the KHQ valid and reliable to assess the impact of UI on the QoL of men undergoing RP?". Thus, this study aimed to analyze the validity and reliability of the KHQ in men undergoing radical prostatectomy.

Background

The ICS defines UI as any involuntary loss of urine. It should be described based on a set of specific factors such as type, frequency, severity, precipitating factors, social impact, effect on hygiene, and others (Abrams et al., 2017). UI may also be more frequent in older men with urinary tract infection, mobility problems, and functional or cognitive impairment (Abrams et al., 2017).

Thus, UI should be analyzed from a multifactorial perspective due to its impact on QoL, physical and mental well-being, and the performance of daily activities (Bernardes et al., 2019). In addition, other urinary symptoms such as low stream, hesitancy, and post-micturition leakage can also be associated with UI (Abrams et al., 2017), further affecting the patient's QoL.

It is known that the male population may experience different levels of urinary loss after surgery, which may lead to social isolation and trigger feelings such as low self-esteem, anxiety, and depression (Abrams et al., 2017). The KHQ was originally built and validated in English in 1997 (Kelleher et al., 1997) to assess the impact of UI on women's QoL. Validation studies in the male population were conducted in the United States (Margolis et al., 2011) and Taiwan (Huang et al., 2014), showing adequate content and construct validity and acceptable reliability. In Brazil, the KHQ was validated in the female population and showed adequate reliability and validity

(Tamanini et al., 2003). However, there are no studies on the process of validation of this instrument in Brazilian men undergoing RP.

Methodology

This methodological study aimed to assess the psychometric properties of the KHQ in men undergoing RP by analyzing the validity (structural, concurrent, and convergent) and reliability (internal consistency of the items) of the measurement instrument (Souza et al., 2017). The methodological guidelines were based on the COnsensus-based Standards for the selection of the health Measurement INstruments (COSMIN) checklist (Mokkink et al., 2019).

Data were collected from December 2016 to August 2017 in a high-complexity oncology unit of the National Cancer Institute (Instituto Nacional do Câncer) in Brazil. The minimum sample estimate (n = 152) was obtained from the criteria proposed for correlation coefficient between two variables. We considered the minimum correlation between the KHQ domains and the total score of another instrument to assess the impact of UI on QoL, that is, the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF; r =0.09; Gotoh et al., 2009). Other parameters were the finite population of patients treated at the institution in a two-year interval (n = 180), significance level of 5%, and a 95% confidence interval.

The following inclusion criteria were applied: aged over 18 years; undergoing RP and in postoperative follow-up for at least 2 months and a maximum of 2 years; report of any involuntary loss of urine; self-reported preserved hearing and verbal skills; and preserved cognitive ability (Mini-Mental State Examination). Individuals with a urinary catheter and preoperative UI were excluded.

The KHQ is an eight-domain instrument with 16 items to assess the perceived impact of UI on QoL. The domains of general health perception, incontinence impact, role limitations, physical limitations, social limitations, personal relationships, emotions, sleep/energy are scored from zero to 100, and the higher the score, the worse the perceived QL in the specific domain. The instrument includes two other independent subscales to assess the severity of UI (five items) and the presence of urinary symptoms (11 items). These Likert-type scales have four response options (not at all, slightly, moderately, a lot or *never, sometimes, often, very much*), except for the domains of general health perception (very good, good, fair, poor, very poor) and personal relationships (not applicable, not at all, slightly, moderately, a lot) with five response options (Tamanini et al., 2003).

Concurrent validity was assessed using the ICIQ-SF, which also assesses the impact of UI on QoL. This instrument was translated and validated for the Brazilian context in a sample of men and women (Tamanini et al., 2004). This instrument was considered a gold standard in this study because it has been widely used in national and international studies (Abrams et al., 2017). It consists



of four questions that assess the frequency, severity, and impact of UI, as well as eight items related to the causes and situations of UI experienced by the patients. The total score ranges from zero to 21, and the higher the score, the worse the QoL (Tamanini et al., 2004).

In addition to the UI-related QoL, the variables of urinary loss in grams assessed by the 1-hour pad test (Krhut et al., 2014), the number of daily pads assessed by 24 h pad-count (Angulo et al., 2018), and presence of stress and urge UI were used to assess convergent validity.

The 1-hour pad test involves placing a penile pad near the external urethral meatus. This pad is previously weighed on a scale, and, after positioning it, the patient is instructed to drink 500 milliliters of water and rest for 15 minutes. Then, the patient is submitted to a protocol that encourages the performance of activities of daily living. At the end of the protocol, the penile pad is removed, weighed again, and classified as follows: insignificant or continent (when the final weight of the pad is up to one gram, g); mild incontinence (1.1 to 9.9 g); moderate incontinence (10 to 49.9 g); and severe incontinence (above 50 g; Krhut et al., 2014).

The 24 h pad-count test aims to count the number of pads used in 24 hours. UI is classified as mild (one or two per day), moderate (three to five pads per day), and severe (more than six pads per day). Men who reported using no pads are considered continent (Ângulo et al., 2018). Urge UI was defined as the report of involuntary loss of urine from the urethra associated with a sudden desire to empty the bladder (Abrams et al., 2017). Stress UI was defined as the report of involuntary loss of urine due to any physical exertion (walking, sitting, coughing, or sneezing; Abrams et al., 2017).

Participants were invited on the day of the follow-up visit. Data were collected through individual interviews conducted by one of the researchers, a specialist in stomal therapy and master's student. The patients were interviewed before the medical appointment, in a private nursing room. Each interview lasted on average 60 minutes. The pad test is started by putting the pad and having the patient drink a liquid. Then, during the resting period (15 minutes), the other assessment instruments (KHQ, ICIQ-SF, 24 h pad-count, presence of urge and stress UI) were applied. At the end of the protocol simulating activities of daily living, each patient was taken back to the nursing room, where they were given a plastic bag to dispose of the pad. Finally, the researcher used a precision scale to weigh the pad.

Data were processed and analyzed using the IBM SPSS software, version 23.0 for Windows. The results obtained for the explanatory variables (sociodemographic and clinical characterization) were analyzed using descriptive statistics with measures of central tendency (mean or median) and variability (standard deviation or 25th and 75th percentiles - p25 and p75) for continuous variables and relative frequency for categorical variables. The Kolmogorov-Smirnov test was also applied to test the normality of the variables obtained through the KHQ domains, ICIQ-SF, pad test, and 24 h pad-count, and all these variables showed a non-normal distribution.

The exploratory factor analysis (EFA) was performed in the FACTOR software 12.01.02 for Windows. The purpose was to assess the structural validity of the scale using a polychoric matrix and a Robust Diagonally Weighted Least Squares (RDWLS) extraction method. Prior to the EFA, sampling adequacy was determined by the Kaiser-Meyer-Olkin (KMO) test, whose score should be equal to or greater than 0.60. The Bartlett's test of sphericity was also performed to check whether the correlation matrix is an identity matrix and determine whether there are any correlations. Ideally, the test should be significant, and the null hypothesis should be refuted (Damásio, 2012). The decision on the number of factors to be retained was made based on parallel analysis with random permutation of the data and Robust Promin rotation. Communalities and factor loadings were estimated based on the correlation matrix. It is recommended that items with factor loadings equal to or above 0.4 should remain on the scale (Damásio, 2012).

Model fit was assessed using the chi-square test (χ^2) and the following fit indices: Root Mean Square Error of Approximation (RMSEA), Comparative Fit Index (CFI), and Tucker-Lewis Index (TLI). The chi-square test checks whether the model fits the data and is calculated based on the chi-square to degrees of freedom ratio (χ^2/df), with the maximum value equal to three for an adequate fit (Damásio, 2012). RMSEA values should be less than 0.08, and CFI and TLI values should be above 0.90 or preferably 0.95 (Damásio, 2012).

Concurrent validity was analyzed by comparing the consistency of the measurements in each KHQ domain with the ICIQ-SF. To determine convergent validity, KHQ domains were compared to the results of the 1-hour pad test (Krhut et al., as cited by Ângulo et al., 2018), urge UI, and stress UI. The variable Number of pads/day was analyzed as a discrete quantitative variable and urge UI and stress UI as nominal categorical variables (*yes* or *no*). Thus, Spearman's coefficient was used to assess the correlation between the KHQ domains and the ICIQ-SF, pad test, and number of pads/day. The Mann-Whitney test was used to compare the KHQ domains and urge/ stress UI. Correlations were analyzed as follows: correlation coefficients < 0.4: weak correlation; > 0.4 to < 0.7: moderate correlation; and > 0.7: strong correlation; Schober et al., 2018).

The internal consistency of the KHQ items was estimated using Cronbach's alpha and McDonald's omega coefficients. Values between 0.7 and 0.9 indicate high reliability (Viladrich et al., 2017). The domains of General health perception and Incontinence impact consist of single items, so their internal consistency was not calculated. A significance level of 5% was considered for all analyses. This study was approved by the ethics committee of the leading institution under opinion number 1.866.160/2016, in compliance with the principles established by the Brazilian National Health Council. Thus, the objectives and steps of the study were explained to the volunteers, and those who agreed to participate signed the informed consent form (ICF).



Results

The sample consisted of 152 men undergoing radical prostatectomy, with a mean age of 66.8 years (standard deviation: 7.8) and a median number of four years of schooling (p25 = 2; p75 = 4). The median per capita income was 937 reais (p25 = 937; p75 = 1405); 78.9% were inactive (retired or unemployed); and 80.3% reported having a partner.

Concerning the clinical characteristics, there was a predominance of 'open' surgeries (97.4%). As for postoperative time, 68 (44.7%) participants had undergone surgery between 2 and 6 months prior to study participation, 40 (26.3%) between 6 months and 1 year, and 44 (28.9%) between 1 and 2 years. Therefore, the median time after surgery was 209.5 days (p25 = 99; p75 = 402), which corresponds to approximately 7 months. Concerning comorbidities, 61.2% reported a diagnosis of high blood pressure (HBP), and 61.8% had a Gleason score higher than seven. As for UI-related data, 13.2% and 56.6% of the participants reported the presence of urge UI and stress UI, respectively. The mean number of pads in 24 hours was 0.9 (standard deviation: 1.6). The pad test on urinary loss in grams indicated that 81 (53.3%) of the participants were continent, 52 (34.2%) had mild UI, 16 (10.5%) had moderate UI, and only three (2.0%) had severe UI. The median urinary loss in grams was 0.95 (p25 = 0.4; p75 = 2.2).

Concerning the psychometric properties, the domain Personal relationships (Three items: 5a - does your bladder problem affect your relationship with your partner?; 5b - does your bladder problem affect your sex life; and 5c - does your bladder problem affect your family life) presented a significant number of missing data (n = 122/80.3%) and was, therefore, not considered for analysis.

Bartlett's test of sphericity (χ^2 (78) =1679.0; p < 0.001) and KMO (0.885) suggested interpretability of the correlation matrix, which justified the EFA. The parallel analysis showed that the scale fits a two-dimensional structure because the variance explained by the (empirical data) was greater than the variance explained by the random (simulated) data in two factors. The variance explained by the two factors was 66.9%. Factor loadings were greater than 0.40 in all items, except for item 1, whose value was 0.339 (Table 1).

Table 1

Results of the exploratory factor analysis of the KHQ and their factor loadings

KHQ domains and items	Factor l		
	Factor 1	Factor 2	h^2
General health perception			
1 How would you describe your health at the present?		0.339	0.136
Incontinence Impact			
2 How much do you think your bladder problem affects your life?	0.499		0.478
Role Limitations			
3.a To what extent does your bladder problem affect your household tasks (e.g., cleaning, cooking, etc.)?	0.750		0.608
3.b To what extent does your bladder problem affect your job or your normal daily activities outside the home?	0.798		0.702
Physical and social limitations			
4.a Does your bladder problem affect your physical activities (e.g., going for a walk, run, sport, gym, etc.)?	0.898		0.639
4.b Does your bladder problem affect your ability to travel?	0.737		0.632
4.c Does your bladder problem restrict your social life?	0.843		0.757
4.d Does your bladder problem limit your ability to see/visit friends?	0.846		0.709
Emotions			
6.a Does your bladder problem make you feel depressed?		0.856	0.758
6.b Does your bladder problem make you feel anxious or nervous?		0.809	0.606
6.c Does your bladder problem make you feel bad about yourself?		0.937	0.786
Sleep and energy			
7.a Does your bladder problem affect your sleep?		0.556	0.453
7.b Do you feel worn out or tired?		0.739	0.568
Explained variance	51.39	15.57	
Random variance	16.64	14.08	

Note. h2 = Communalities. Factor loadings with item-factor correlation values above 0.30 are presented here (Damásio, 2012).



The factor structure of the two-dimensional theoretical model showed adequate fit indices (χ^2 =1135.35, df=78, χ^2 /df=0.97; RMSEA=0.058; CFI=0.97; TLI = 0.96). The analysis of concurrent validity showed that all KHQ domains, except the General health perception, had a statis-

tically significant positive correlation of moderate to strong magnitude with the ICIQ-SF. Since both instruments assess the same outcome, the results indicate that the higher the impact of UI on QoL assessed by KHQ domains, the higher the impact of UI on QoL assessed by the ICIQ-SF (Table 2).

Table 2

Results of Spearman's correlation between KHQ domains and the variables of ICIQ-SF, Pad Test, and 24 h pad-count

Variables		GHP	II	RL	PL	SL	E	S/E	SM
ICIQ-SF	r	0.223	0.809	0.476	0.526	0.515	0.453	0.413	0.614
ICIQ-5F	p	0.006	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
Pad test	r	0.061	0.431	0.306	0.433	0.437	0.279	0.236	0.517
I ad test	p	0.458	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	0.003	< 0.001
24 h pad-count	r	-0.115	0.135	-0.071	0.060	0.026	-0.068	-0.062	0.533
24 ii pad-count	p	0.371	0.292	0.578	0.639	0.840	0.599	0.628	< 0.001

Note. GHP = general health perception; II = incontinence impact; RL = role limitations; PL = physical limitations; SL = social limitations; E = emotions; S/E = sleep/energy; SM = severity measures; ICIQ-SF = International Consultation on Incontinence Questionnaire - Short Form.

The analysis of convergent validity showed statistically significant positive correlations of weak to moderate magnitude between the severity of UI assessed by the pad test and all KHQ domains, except for the domain General health perception (Table 2). A statistically significant positive correlation of moderate magnitude was also found between 24 h pad-count and the domain Severity measures in the KHQ, indicating that the more pads/ liners/ diapers men use, the greater the impact of UI on the QoL in this domain.

Still regarding the convergent validity, the analysis of the difference between KHQ domains and the presence or not of urge/stress UI showed statistically significant differences only for the cases of urge UI. In men with urge UI, the impact of UI on QoL was higher for the domains of Emotions (p = 0.020) and Severity measures (p = 0.013; Table 3).

Table 3

Results of the Mann-Whitney test of the difference between the presence or not of stress UI and urge UI and the KHQ domains

Variables		GHP	II	RL	PL	SL	Е	S/E	SM
	Yes	25.0	33.3	0.0	0.0	0.0	0.0	0.0	33.3
SUI	No	25.0	0.0	0.0	0.0	0.0	0.0	0.0	4.7
	P	0.895	0.583	0.462	0.642	0.285	0.921	0.561	0.591
	Yes	25.0	50.0	16.7	16.7	0.0	0.0	8.3	41.7
UUI	No	25.0	33.3	0.0	0.0	0.0	0.0	0.0	16.7
	P	0.702	0.111	0.522	0.454	0.315	0.020	0.066	0.013

Note. SUI = stress urinary incontinence; UUI = urge urinary incontinence; GHP = general health perception; II = incontinence impact; RL = Role limitations; PL = physical limitations; SL = social limitations; E = emotions; S/E = sleep/energy; SM = severity measures.

The reliability of the instrument assessed by Cronbach's alpha coefficient was 0.88. In the analysis of reliability by domains, the scores ranged from 0.64 (Sleep/energy)

to 0.84 (Emotions, Physical limitations, and Social limitations), as shown in Table 4.



Table 4

KHQ domains and items	Number of items	Cronbach's alpha	McDonald's omega
General health perception	1	-	
Incontinence impact	1	-	
Role Limitations	2	0.83	
Physical and social limitations	4	0.84	
Personal relationship	3	-	
Emotions	3	0.84	
Sleep/energy	2	0.64	
All items of the instrument*	-	0.88	0.91

Internal consistency of the KHQ domains

Note. KHQ = King's Health Questionnaire.

*the items related to the Personal relationships domain were excluded from the analysis.

Discussion

The KHQ met the criteria for assessment of psychometric properties, proving reliable and relevant for Brazilian men undergoing radical prostatectomy. The main characteristic of the instrument is its ability to assess the impact of urinary symptoms on various aspects of QoL, such as activities of daily living, social limitations, emotions, and quality of sleep.

It is common for participants to have erectile dysfunction after the surgery (Azevedo et al., 2018). Domain 5 refers to Personal relationships and includes items that address the impact of urinary loss on sexual life (Tamanini et al., 2003). In this study, most respondents answered "not applicable" in the first two items, which did not allow for the psychometric analysis of this domain.

Concerning the structural analysis of the instrument, it should be noted that the original author (Kelleher et al., 1997) did not present those results in his study. Two studies (Huang et al., 2014; Okamura et al., 2009) with women and men with urinary symptoms found a three-factor structure. Despite the divergence about the data in the literature, the two-factor structure found here showed satisfactory fit indices (Damásio, 2012), which supports the structural validity of the instrument in this population.

The factor loadings ranged from 0.499 to 0.898 for Factor 1 and from 0.339 to 0.937 for Factor 2. Although the factor loading of the item related to the domain General health perception was below 0.40, we decided to keep it because the literature also reported values very close to those found here (Huang et al., 2014; Okamura et al., 2009).

The KHQ proved to have adequate concurrent validity given the statistically significant and positive correlations found between the KHQ domains and the ICIQ-SF. Overall, although UI symptoms do not imply risk of death, they can impact physical and psychological aspects, leading to poor sleep quality, a feeling of constant irritation, and impotence, and, consequently, influencing patients' activities of daily living and QoL (Abrams et al., 2017). Patients with more severe UI symptoms tend

to score higher on both the KHQ and the ICIQ-SF (Tamanini et al., 2004). In a sample of men (16.4%) and women (83.6%) with UI, a study on the validity of the Japanese version of the ICIQ-SF found moderate to high correlations between all domains of the KHQ and the ICIQ-SF (Gotoh et al., 2009).

Concerning the correlations between the KHQ domains and the instruments used to assess UI severity (pad test and 24 h pad-count) that indicated worse QoL in individuals with severe UI, a study on the reliability and validity of the KHQ in Chinese men found that the KHQ scores among participants with severe and moderate urinary symptoms were statistically higher than those found in the group with mild urinary symptoms (p < 0.05; Huang et al., 2014).

The higher impact of UI on QoL for the domain Severity measures among men who use a higher number of pads can be explained by the fact that the items of this domain include questions on the frequency of pad changes and the occurrence of leaks in underwear. It is also known that men who use pads may restrict certain activities, especially in situations of presence of odor causing undue strain in relationships, which has a negative effect on their QoL (Teixeira et al., 2020).

As for the lack of correlation between the severity of UI assessed by the pad test and the KHQ domain of General health perception, it is known that health perception refers to an assessment that involves physical, cognitive, and emotional aspects of each individual (Tamanini et al., 2003). Thus, men with cancer undergoing RP may experience some level of uncertainty due to the possibility of cancer recurrence or the need for other complementary treatments after the surgery (Abrams et al., 2017), which may explain the lack of correlation between health self-perception and the level of UI severity.

In the sample under study, individuals with urge UI had worse QoL levels than individuals with stress UI, as shown in the KHQ domains of Emotions and Severity measures. Scholars argue that the high impact of urge UI on QoL may be associated with patients' uncomfortable feeling of sudden and intense desire without the



possibility of control before they can get to the toilet (Abrams et al., 2017).

Concerning the analysis of the overall reliability of the KHQ in men undergoing RP, this study found a high level of reliability (Cronbach's alpha coefficient of 0.88), demonstrating that the instrument is capable of obtaining consistent results in the population under study (Souza et al., 2017).

The analysis of reliability by domains found that Cronbach's alpha values for the domains of Sleep/energy and Severity measures and the Urinary symptoms scale were below 0.7, ranging from 0.64 to 0.67. An international study with 393 men who had different lower urinary tract symptoms found a satisfactory internal consistency of the KHQ, with coefficients ranging from 0.75 to 0.94 (Huang et al., 2014). Although Cronbach's alpha coefficients were low in some domains, all items were kept because the alpha values for all domains, except for the domain Personal relationships, and the McDonald's omega were satisfactory. Unlike the alpha coefficient, the omega coefficient works with factor loadings, making the calculations more stable, with a higher level of reliability and independently of the number of items in the instrument (Viladrich et al., 2017). It should be noted that no validation studies of the KHQ using this estimator were identified.

Concerning the fact that the reliability of the KHQ domain of Personal relationships could not be calculated, it is known that, despite the presence of erectile dysfunction in approximately 79 to 88% of patients (Abrams et al., 2017), sexual recovery should be based not only on penile stimulation but also on other forms of bodily stimuli capable of promoting a satisfactory and healthy sexual life for patients and their partners (Clavell-Hernández et al., 2018). Thus, it is suggested that it is important to maintain the KHQ items related to the Personal relationships domain because they reflect the broader impact of UI on sexual life and not only on the penile erectile function. A limitation of this study was the lack of assessment of the reliability of the KHQ domain of Personal relationships because the study participants understood the term *sexual dysfunction* only as erectile dysfunction. Despite being a cultural paradigm, future studies should assess the content validity of this domain and the responsiveness of its items in men with different sociodemographic and cultural characteristics. Another limitation was the profile of the researcher responsible for conducting the interview (female, young adult), which may have compromised the frankness of the answers. The majority of participants were older people, which may have hindered the sharing of information related to physical and sexual health.

Conclusion

The KHQ was found to have adequate reliability and structural, concurrent, and convergent validity in men undergoing RP. This questionnaire can be applied to assess the impact of urinary symptoms on the QoL of men undergoing RP and, consequently, provide data to support health professionals regarding treatment and rehabilitation options. Moreover, the scale may be a useful tool for intervention strategies to deliver high-quality health care to men and, consequently, improve the QoL of patients undergoing RP.

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