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CONCURRENT VALIDITY, INTERNAL CONSISTENCY AND RESPONSIVENESS OF THE PORTUGUESE VERSION OF THE KING'S HEALTH QUESTIONNAIRE (KHQ) IN WOMEN AFTER STRESS URINARY INCONTINENCE SURGERY

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ABSTRACT

Objective: To evaluate the concurrent validity, internal consistency and responsiveness of King's Health Questionnaire (KHQ) in patients who underwent sling procedures for the treatment of stress urinary incontinence.

Materials and Methods: We performed a prospective open label multicenter study in 4 tertiary referral centers. Sixty-eight female patients were enrolled with urodynamically diagnosed urinary stress incontinence. Patients were treated using surgical procedures, mostly (73%) with the synthetic sling procedure, which has been considered one of the gold standard methods for the treatment of urinary incontinence. The patients were assessed before and after one month of postoperative follow up, using the KHQ in its validated Portuguese version. Patients also underwent preoperative urodynamic test, Stamey incontinence grading, pad usage and the assessment of number of pads used per day. After surgery, patients underwent stress test, Stamey incontinence grading pad usage and the assessment of number of pads used per day.

Results: The concurrent validity showed good correlations in some domains of KHQ to clinical parameters. The internal consistency was higher after treatment compared to preoperative values. Objective parameters, such as pad usage and the assessment of number of pads used per day, had significant correlation with changes in post-treatment scores on KHQ. The responsiveness expressed in terms of standardized effect size (SES) and standardized response mean (SRM) was large.

Conclusion: The results showed moderate concurrent validity, strong internal consistency and high responsiveness for KHQ, indicating that it is suitable for measuring outcomes in clinical trials among female patients with stress urinary incontinence.

Key words: urinary incontinence; quality of life; questionnaire
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INTRODUCTION

Quality of life is an abstract and highly subjective concept influenced by personal and cultural values, beliefs, self-concepts, goals, age and life expectancy. Its indicators have become an important outcome in clinical trials (1). These indicators are obtained by structured questionnaires. There is a wide

range of generic and disease-specific quality of life questionnaires covering different areas of life such as global quality of life, physical health, emotional functioning and social lifestyle among others. These questionnaires differ in length, varying from 3 or 4 to more than 100 items and are addressed for different goals in quality of life research. Short instruments are easier to administer and less burdensome to the patients, reaching high rate of complete responses. On the other hand, longer questionnaires are able to measure quality of life in different domains and thus, researchers can obtain more specific and detailed information from them (2).

Patient-reported outcomes including symptoms, functional status and perceived quality of life are increasingly used alongside objective clinical measurements to monitor the course of urinary incontinence (UI) and its treatment. Treatment outcomes, as perceived and reported by patients, complement clinical evidence and judgment of efficacy and effectiveness (3).

Well-designed and tested Quality of Life (QoL) scales for urinary incontinence exist and have been shown to be valid, reliable and internally consistent. A valid questionnaire measures what it is supposed to measure and if it is reliable, it can be reproduced (4). Apart from needing to be considered valid and reliable in this new context, such questionnaires should also be sensitive to changes in continence status after clinical or surgical treatment (responsiveness). According to Corcos et al. (5), the responsiveness of most quality of life questionnaires already published is either weak or has never been reported.

The King's Health Questionnaire (KHQ) (6) and the International Consultation on Incontinence Questionnaire - Short Form (ICIQ-SF) (7) were recently translated into Portuguese and had their psychometric parameters such as validity and reliability assessed (8,9).

The aim of this study was to determine whether the above-mentioned instrument named King's Health Questionnaire has good concurrent validity, internal consistency and also is sensitive to changes in continence status over time, with regard to internal and external responsiveness following surgery to treat genuine stress incontinence (GSI).

MATERIALS AND METHODS

A total of 68 consecutive female patients from 4 tertiary referral centers were included in this prospective open label study. The inclusion criteria were that patients should be aged ≥ 18 and have a complaint of GSI urodynamically diagnosed. Patients who were pregnant or breast-feeding, those who had past history of neurologic disease, actual urinary tract infection or who had clinically severe cognitive dysfunction were not enrolled in the study.

The study received prior approval from the Ethical Committee of the School of Medicine (# 82/ 2000).

Between January and December 2003, all new patients who underwent the sling procedure for the treatment of GSI were assessed by subjective and objective means, as well as by analysis of the (QoL) impact using the Portuguese version of King's Health Questionnaire.

Before the surgery, patients were assessed using subjective parameters such as Stamey incontinence grading (10): 0 = cured, 1 = leakage with stressful activities - coughing, sneezing, 2 = leakage with minimally stressful activities - e.g. walking, 3 = leakage at all times, with any activity, and the QoL impact on patients' lives by the Kings' Health Questionnaire. The objective parameters were the urodynamic test, by means of Valsalva leak point pressure (VLPP), according to the standard protocol (11), and analysis of pad usage (yes/no). If pads were used, the frequency of their usage was recorded (0 = no use; 1 = 1-2 units/day; 2 = 3-4 u/d and 3 ≥ 4 u/d).

Objective outcome testing for stress incontinence surgery was conducted with the patient in the standing position with the physiological bladder filled to maximum vesical capacity (strong desire to void without urge sensation). Patients were asked to perform repeated coughing and Valsalva maneuvers. Any transurethral urine leakage (even drops), without detrusor contraction, was recorded as an objective failure of the surgical procedure. The patients were also asked to re-rate their QoL assessment according to the King's Health Questionnaire after, at least one month of follow-up.

Quality of Life Questionnaire

The instrument known as the King's Health Questionnaire (6) evaluates the impact of lower urinary tract symptoms on women's quality of life. It comprises 21 questions divided into eight domains such as: general health perception, incontinence impact, role limitations, physical and social limitations, personal relationships, emotions, sleep/energy. Furthermore, it has 2 independent scales, which are severity measures and urinary symptoms. High scores in King's Health Questionnaire represent a worse quality of life. King's Health Questionnaire has already been submitted to the process of translation and cultural adaptation into Portuguese and is now available for use in clinical research in Brazil (8).

Reliability

The King's Health Questionnaire reliability was calculated by means of internal consistency, using Standardized Cronbach's Alpha coefficient and was based on the final scores from King's Health Questionnaire filled out by patients before the procedure and after, at least, one-month follow up.

Concurrent Validity

The concurrent validity was evaluated by determining the capacity of the King's Health Questionnaire to distinguish between different subgroups of patients with different clinical complaints, such as pad usage and frequency of changing pads per day. All of these parameters were obtainned by means of anamnesis.

Responsiveness

Outcome measurements should be stable in stable subjects (reproducibility), but should also be able to detect changes in unstable subjects (responsiveness) (12). Focusing on this latter attribute, responsiveness is defined as the ability of an outcome instrument to detect clinically important changes in a specific condition. It has been shown that incontinence (13) and its impact on daily activities (14) decrease after treatment of urinary incontinence.

Internal responsiveness is the ability of a measurement to change over a particular pre specified time frame. It can be assessed using a single-group repeated measurement design, in which patients are assessed before and after treatment that is known to be efficacious (e.g. the synthetic or fascial sling or Burch procedures). External responsiveness reflects the extent to which changes in a measurement over a specified time frame relate to corresponding changes in a reference measurement of health status (15).

Statistical Methods

The assessment of internal responsiveness involves statistical estimation of the size of the effect, i.e. an estimate of the magnitude of the change in health status (13). Standardized Effect Size (SES or ES I) and Standardized Response Mean (SRM or ES II) provide a standardized measurement of the change in score of an instrument. Both SES and SRM can be considered large (> 0.80), moderate (0.5 - 0.8) or small (< 0.5) (15,16).

To assess the reliability by means of internal consistency, standardized Cronbach's Alpha was used.

Wilcoxon's signed rank test was used to compare the scores between follow-up and baseline. The McNemar test or Stuart-Maxwell test was used to assess significant changes between proportions. The Mann-Whitney U-test for independent groups was used to compare instrument scores and pad usage (external responsiveness and concurrent validity). Kruskal-Wallis test was used to compare mean scores and frequency of pad usage per day.

RESULTS

The sociodemographic characteristics of the sample population are displayed in Table-1. Forty-four (73.3%) of the patients underwent the synthetic sling procedure and 16 (26.7%) underwent classic (fascial) sling. The mean preoperative value of VLPP was 86.5 ± 40.3 cm H_2O (mean ± SD). The mean (± SD) duration of follow-up was 4.7 (± 3.4) months.

A total of 27 out of 28 patients (96%; frequency missing = 40 cases) had a negative stress test after surgery.

Table 1 – *Background data on all patients assessed using the King's Health Questionnaire.*

Age (year, mean ± SD)		**52 ± 10.3**
Race (N)	Caucasian	43 (72.9%)
	Black	5 (8.5%)
	Brown	10 (16.9%)
	Asiatic	1 (1.7%)
	Frequency missing	9
Literacy (N)	Illiterate	4 (6.7%)
	Incomplete elementary school	25 (41.7%)
	Complete elementary school	19 (31.6%)
	High School	7 (11.6%)
	College	5 (8.4%)
	Frequency missing	8

Clinical Outcomes

Reliability and Concurrent Validity Studies

The reliability of the King's Health Questionnaire before and after treatment are shown in Table-2.

The study of the correlations between the scores of the King's Health Questionnaire and the clinical variable categories (pad usage and frequency of changing pads per day) was unable to detect any significant differences in most of the domains but in role, physical and social limitations and severity measures, as shown in Table-3.

Stamey Grading of Incontinence

Although only 20 out of 39 patients (51.3%) considered themselves cured (frequency missing = 29 cases), the cure/improvement rate was 84.6% (p-value < 0.0001, by the Wilcoxon's signed rank test).

Table 2 – *Reliability assessed by means of standardized Cronbach's alpha before and after treatment, in relation to King's Health Questionnaire (N=68)*

	Standardized Cronbach's Alpha Coefficient	
Instrument	**Before**	**After**
General King's Health Questionnaire	0.82	0.91
General Health Perception	-	-
Incontinence Impact	-	-
Role Limitations	0.53	0.84
Personal Limitations	0.41	0.83
Social Limitations	0.71	0.86
Personal Relationship	0.90	0.95
Emotion	0.83	0.92
Sleep / Energy	0.61	0.75
Severity Measures	0.60	0.87

Table 3 – *Concurrent Validity: descriptive statistics of mean scores from each King's Health Questionnaire domain and the clinical variables and respective comparisons among categories concerning to urinary incontinence.*

Variables		N	General Health Perception	Incontinence Impact	Role Limitations	Personal Limitations	Social Limitations	Personal Relationship	Emotion	Sleep / Energy	Severity Measures
Pad	Yes	49	30.98	32.07	33.20	34.13	32.31	23.85	31.81	31.53	33.81
usage	No	11	28.36	23.50	18.45	14.32	22.45	22.06	24.68	25.91	15.77
p-value[(a)]			0.627	0.100	0.010*	0.001*	0.089	0.714	0.216	0.329	0.002*
Total		60									
Use of	1-2	14	26.04	20.07	27.14	23.61	19.18	19.32	22.93	24.50	21.18
pad	3-4	20	22.30	26.38	21.02	25.02	23.40	16.41	24.13	22.80	22.35
units/day	>4	15	27.63	27.77	28.30	26.27	32.57	22.80	28.10	28.40	32.10
p-value[(b)]			0.475	0.202	0.248	0.878	0.032*	0.322	0.573	0.503	0.064
Total		49									

** = p < 0.05, [a] = Mann-Whitney test, [b] = Kruskal-Wallis test*

Pad Usage

Assessing this clinical variable, 35 out of 39 patients (89.7%; frequency missing = 29 cases) used pads before treatment. After surgery, only 6 (15.4%) patients were still using them (p-value < 0.0001, by McNemar test).

Frequency of Changing Pads Per Day

Most of the patients before surgery (27 out of 39, or 69.3%; frequency missing = 29 cases) used at least 4 pad units per day. On the other hand, 33 out of 39 (84.6%) patients stopped using pads after the surgical treatment (p-value < 0.0001 by Stuart-Maxwell test).

Responsiveness Study

The internal responsiveness study is shown in Table-4. It was quantified using standardized effect size (SES) and standardized response mean (SRM), which demonstrated a large effect size by both means. Similar results were found from the study of external

Table 4 – *Study of the internal responsiveness of King's Health Questionnaire - KHQ (sensitivity to change), using Effect Size I or Standardized Effect Size (SES) and Effect Size II or Standardized Response Mean (SRM).*

KHQ Domains	N	p-value *	SES	SRM
General Health Perception	68		-0.76	-0.54
Impact of Incontinence	68		-1.94	-1.61
Role Limitations	68		-1.50	-1.27
Physical Limitations	67		-1.49	-1.25
Social Limitations	68	0.0001	-1.33	-1.28
Personal Relationships	62		-0.76	-0.61
Emotions	68		-1.44	-1.17
Sleep/Energy	68		-0.86	-0.70
Severity Measures	68		-2.40	-1.52

***** = Wilcoxon's signed rank test***

responsiveness, when the post-treatment scores were compared with an external variable such as pad usage and the frequency of changing pads per day (Table-5).

COMMENTS

Pubovaginal slings are considered the gold standard technique for the treatment of female stress urinary incontinence because of the excellent results after long-term follow-up (17). There is a consensus in the literature that urinary incontinence may adversely affect quality of life, with significant implications in many spheres, such as the psychological, social, physical, economic, personal relational and sexual domains (18). The standardization sub-committee of the International Continence Society (ICS) considers urinary incontinence to be "a complaint of any involuntary loss of urine". This committee recommended, in 1997, that quality of life measurements should be included in all clinical research on urinary incontinence, as a complementary addition to the traditional clinical parameters (19).

Validity, reliability and responsiveness are psychometric properties that should be systematically tested in every questionnaire used in clinical research in order to allow scientific conclusions to be reached regarding the efficacy of the procedures. Reliability assessed after the surgical procedure showed results more homogeneous compared to the same results before treatment. This aspect shows a tendency of homogeneity from the answer of the patients when satisfied with the treatment as shown by the high-

Table 5 – *Study of the external responsiveness of King's Health Questionnaire, comparing post-treatment questionnaire scores and pad usage.*

Pad Usage	King's Health Questionnaire Domain Score after Treatment	N	Mean	± SD	p-value[#]
No	General Health Perception	34	23.5	16.2	0.1145
Yes		6	33.3	12.9	
No	Incontinence Impact	34	10.8	21.3	0.0022
Yes		6	55.6	40.4	
No	Role Limitations	34	9.3	19.3	0.0829
Yes		6	36.1	41.4	
No	Physical Limitations	34	10.8	21.7	0.2741
Yes		6	33.3	45.9	
No	Social Limitations	34	2.6	8.7	0.0221
Yes		6	18.5	30.4	
No	Personal Relationships	34	8.8	25.4	0.0367
Yes		6	41.7	49.2	
No	Emotions	34	11.8	22.7	0.0396
Yes		6	53.7	51.4	
No	Sleep/Energy	34	18.2	21.8	0.1434
Yes		6	44.4	39.0	
No	Severity Measures	34	17.8	20.1	0.0099
Yes		6	56.7	35.2	

[#] = *Mann-Whitney test*

standardized Cronbach's alpha coefficient (Table-2). This means that most of patients had the same perception of improvement in quality of life after surgery. These findings are corroborated by objective results such as decrease in pad usage, stress test, and Stamey incontinence grading.

The King's Health Questionnaire was able to distinguish between different subgroups of patients with different clinical complaints, which were diagnosed by means of anamnesis. Higher scores were associated to presence of pad usage and higher number of pad changes per day, showing positive correlation with these clinical parameters. These correlations were statistically significant in the domains role, physical, social limitations and severity measures, as shown in Table-3.

A common method for demonstrating the responsiveness of a health status measurement is to compare instrument scores before and after a specific treatment, that has known efficacy (16).

All the patients included in this prospective, multicentric, open label trial underwent sling procedure and King's Health Questionnaire was applied before and after it. The results from the internal responsiveness study are shown in Table-4 and confirm that the Portuguese version of King's Health Questionnaire captures changes over time. Responsiveness expressed in terms of the Standardized Effect Size (SES or ES I) and Standardized Response Mean (SRM or ES II) showed large values for effect size studies, for all the domains in King's Health Questionnaire, except for the domains general health perception and sleep/energy, both with values under 0.8, which denotes only moderate responsiveness.

As shown in Table-5 (external responsiveness study), there was a good correlation between the King's Health Questionnaire domain scores post-treatment regarding pad usage analysis. The King's Health Questionnaire domain scores showed a significant difference when the 2 groups (yes/no) were compared after treatment (p value < 0.0002), especially those strictly related to incontinence, i.e. incontinence impact (p value < 0.0022) and severity measures (p value < 0.0099). Although individual incontinence symptoms may improve quickly after surgical treatment, alterations in lifestyle may take longer. Therefore, it would be interesting to explore remote effects of treatment in lifestyle (20). The Portuguese version of the King's Health Questionnaire has now all the psychometric properties assessed including validity, reliability and responsiveness, being the first Quality of Life questionnaire related to female urinary incontinence ready for use clinical research in Portuguese language, as it has been recommended by ICS standardization sub-committee.

In conclusion, King's Health Questionnaire demonstrated moderate concurrent validity and strong internal consistency, mainly after treatment. It also appears to capture changes, i.e. has good responsiveness in its multifaceted domains such as the social, emotional and personal domains, and in the domains strictly related to the incontinence symptom.

On the basis of our findings, we believe that King's Health Questionnaire can be used for measuring the quality of life after the treatment of urinary incontinence. It is now available for use in national or international multicenter clinical trials, thus allowing scientific conclusions to be reached regarding the efficacy of such procedures.

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