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KING'S HEALTH QUESTIONNAIRE TO ASSESS SUBJECTIVE OUTCOMES AFTER SURGICAL TREATMENT OF URINARY INCONTINENCE – CAN IT BE USEFUL?

Hypothesis / aims of study

Midurethral slings (MUS) are the mainstay of treatment of stress urinary incontinence (UI), nevertheless, comparison between procedures might be difficult to assess because of the heterogeneous outcomes used to evaluate success and cure and the lack of widely accepted efficacy criteria [1]. The King's Health Questionnaire (KHQ) was designed to evaluate the impact of urinary incontinence on the quality of life (QoL) and has been used to assess subjective outcomes following treatment [2]. We hypothesized that the KHQ could be useful for postoperative quantitative assessment of subjective outcomes. The primary aim of this study was to calculate KHQ cut-off scores for subjective cure and improvement rates. The secondary endpoint was to ascertain the mid-term global success.

Study design, materials and methods

This is a retrospective analysis of data from an ongoing database designed for prospective clinical research about the use of MUS in the management of women with stress or mixed UI. This study included patients who underwent incontinence surgery using TVT™ Obturator System Gynecare Ethicon Inc. (TVT-O) or TVT Abbrevo® Gynecare Ethicon Inc. (TVT-A) between 2004 and 2013, at a tertiary referral urogynecology unit of a teaching hospital. A standard information sheet was used pre-operatively to register the medical history, symptom severity assessment and physical exam. Post-operative follow-up was planned at 6, 12 and 24 months and involved a symptom evaluation, pelvic exam and cough stress test. The KHQ was applied at baseline and follow-up visits. We used the global score calculated through the sum of the crude results obtained at each item and missing values were scored as zero. Exclusion criteria were previous failed MUS procedure, concomitant vaginal surgery for urogenital prolapse, unavailable data from pre-operative assessment or follow-up. Receiver operating characteristic (ROC) curves were outlined at each follow-up visit for the KHQ global score having as "gold standard" the cough stress test findings. A cut-off value was calculated for each follow-up visit. The minimal important clinical change was calculated with a distribution-based method (effect size). We analyzed the minimal change score that would be needed to achieve a large effect size determined at 0.80 of the standard deviation of the global score at baseline. Objective cure was defined as the absence of urine leakage during the cough stress test. Subjective cure was defined by a KHQ global score less or equal to the cut-off value calculated. Subjective improvement applied to patients not subjectively cured and with a difference between their post-operative and baseline KHQ crude global score more or equal to the minimal important clinical change.

Results

Our study group included 204 patients, 170 cases underwent incontinence surgery with TVT-O and 34 cases with TVT-A. Mean age was 57 years, 35% were obese and two thirds were postmenopausal. Pure stress UI was present in 42% and mixed UI in 58%. The mean KHQ crude global score at baseline was 55 (±13). At 24 months, follow-up rate was 84%. Objective cure rates, presented in table 1, were 97%, 96% and 95% at 6, 12 and 24 months, respectively. The median post-operative KHQ global score at 6, 12 and 24 months was 24 and comparing to baseline, there was a significant improvement on QoL ($p<0.001$). Three percent (6/190), 4% (7/177) and 2% (4/169) of patients referred deterioration of the QoL at 6, 12 and 24-months, respectively. These patients complaint of mixed or urge UI, urgency or dyspareunia and 3 had a positive cough stress test at 12 months and 1 at 24 months. ROC curves delineated for each follow-up visit showed areas under the curve of 0.90 (95%CI 0.83-0.97), 0.88 (95%CI 0.78-0.99) and 0.72 (95%CI 0.47-0.96) at the 6, 12 and 24-month visit, respectively. The KHQ global score of ≤ 31 was established as the cut-off score and had a sensitivity of 100% and sensitivity of 82% at 6 months, 88% sensibility and 85% sensitivity at 12 months and 63% sensitivity and 86% specificity at 24 months. The minimal important clinical change was set at 10 points. Using this difference for inferring subjective improvement in patients not subjectively cured, rates varied from 10 to 13%.

Table 1. Objective cure and subjective cure and improvement rates at each follow-up point.

	6 months	12 months	24 months
Objective cure (negative stress test)	97% (194/199)	96% (177/185)	95% (163/171)
KHQ Global Score (median)	24 (22-29)	24 (22-28)	24 (22-28)
Subjective cure (Global KHQ ≤ 31)	80% (152/190)	82% (145/177)	83% (141/169)
Subjective improvement (Global KHQ > 31, ΔKHQ≥10)	13% (25/190)	10% (17/177)	13% (22/169)

Interpretation of results

Different research groups use different outcome measurements to assess success of UI treatment. Without a consensual definition of cure, outcomes vary considerably across studies and are usually lower when subjective measures are considered. In our study, objective cure rates were similar to the general success rates appointed to this technique [3]. However subjective cure rate was lower than the objective cure rate, indicating that although objectively cured, some patients had a deterioration of their QoL emphasizing the need for a subjective assessment. The KHQ has been used by other research groups to assess

subjective outcomes and has shown to be sensitive to change after surgical and pharmacological treatment of UI and overactive bladder. This studies usually show that there is a statistically significant improvement in all or certain domains, but, to our knowledge, this is the first report that aimed to calculate thresholds for the KHQ for assessment of subjective cure. This study identified clinically relevant cut-off scores for the KHQ to establish its use as an outcome assessment tool. The threshold score for subjective cure was determined to be ≤ 31 which was the value with a better relation between sensitivity and specificity across all visits. Subjective improvement was inferred from the minimal clinical important change and set at a difference ≥ 10 points on the KHQ global score in those patients not subjectively cured. It is noteworthy that the sum of the rate of patients subjectively cured and improved approaches the rate of patients objectively cured. Limitations to our study include the lack of a standard questionnaire to assess post-operative symptoms and their severity and the use of the cough stress test without assessment of the exact bladder volume and as the only objective outcome. For our KHQ global score we use the crude sum of the points given on each item instead of converting them to a percentage score because we felt it would be easier and faster to use in clinical practice and more clear to show improvements to patients, specially those still having urinary symptoms. We included patients who underwent incontinence surgery with two types of MUS, but the objective of this analysis was not to compare results between slings. Notwithstanding the retrospective nature of this analysis, the collection of data was predefined, surgical protocols were uniform and follow-up visits were thoroughly scheduled. We also underline the large sample size used and the agreement of results throughout different post-operative time points. Patient adherence to mid-term follow-up was significant.

Concluding message

This study showed the value of the KHQ as an evaluation tool after UI surgery and determined clinically relevant threshold scores to define subjective outcomes. The use of this questionnaire in the post-operative follow-up can identify women that although having a negative cough stress test can have clinically relevant symptoms that hinder their QoL allowing a better understanding of the real impact of surgery on daily life activities. This analysis of the KHQ global score results after UI surgery is an intelligible way to provide simple and personally relevant information, to enable eligible patients to make decisions regarding their treatment and to show post-treatment symptomatic patients that they have improved.

References

1. hé V, Zimmern P, Chartier E. Outcome measures for stress urinary incontinence treatment?: Can we minimally agree?? 2015
2. Kelleher CJ, Cardozo LD, Khullar V, Salvatore S. A new questionnaire to assess the quality of life of urinary incontinent women. Br J Obstet Gynaecol. 1997;104(12):1374–9
3. Tommaselli G a., Di Carlo C, Formisano C, Fabozzi A, Nappi C. Medium-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: a systematic review and metaanalysis. Int Urogynecol J. 2015;26(9):1253–68

Disclosures

Funding: None **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** Written informed consent regarding medical procedures and the use of clinical data in future research studies, previously approved by the Ethics Review Board (ERB) was obtained from all women pre-operatively. Since this analysis was retrospective and did not affect any decision or procedure, further ERB approval was considered redundant. **Helsinki:** Yes **Informed Consent:** Yes