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**Original Research Article**

# Evaluation of suburethral transobturator sling procedure on urinary incontinence and quality-of-life

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## ABSTRACT

**Background:** Urinary incontinence has an estimated incidence of 25-50% in the adult female population. It has a profound physical and psychosocial impact, compromising women's quality-of-life (QoL). The suburethral sling is currently considered the surgical treatment of choice for stress urinary incontinence (SUI). The present study aimed to evaluate the impact of urinary incontinence on women's QoL before and after transobturator suburethral sling surgery, as well as the effectiveness of surgical treatment.
**Methods:** A prospective longitudinal, observational and analytical study was performed between June and December 2021. The study population included 64 women with urinary incontinence, to whom the King's Health Questionnaire (KHQ) was applied, before and after surgery.
**Results:** Of the 64 women included in the study, 59.4% (n=38) had SUI and 40.6% (n=26) had mixed urinary incontinence (MUI). There was an improvement in the global KHQ score in 96.9% (n=62) of subjects, with a statistically and clinically significant impact on QoL ($p<0.001$). Patients with MUI had higher preoperative KHQ global scores, reflecting a more substantial impact on their QoL. Surprisingly, postoperative improvement in QoL was equally significant, both clinically and statistically ($p<0.001$), with no differences when comparing to isolated sui patients ($p>0.05$).
**Conclusions:** QoL assessment questionnaires help to quantify individual impact of urinary incontinence and identify which patients benefited most from treatment. This study not only enhances our understanding of the true impact of urinary incontinence on QoL, but also emphasizes the effectiveness and importance of this minimally invasive surgery in improving the QoL of patients with SUI as well as MUI.

**Keywords:** Quality of life, Minimally invasive surgery, Suburethral sling, Stress, Transobturator tape, Urinary incontinence

## INTRODUCTION

An estimated 25-50% of adult female population presents with urinary incontinence (UI) symptoms.[1-4] The prevalence of this condition varies depending on the definition and the studied population.[1-4] In recent years, there has been a noticeable surge in UI prevalence, attributable to the increasing comorbidities associated with UI risk and growing number of patients seeking medical care.[1,5-7]

According to the International Continence Society (ICS) and the International Urogynecological Association (IUGA) terminology, UI is categorized into three main subtypes: stress urinary incontinence (SUI), urge urinary incontinence (UUI) and mixed urinary incontinence

(MUI).[2,3,5] SUI is the most prevalent subtype, accounting for 10-39% of cases, and is characterized by involuntary loss of urine during physical exertion, such as laughing, coughing, sneezing or engaging in physical activity. [1,3,4] There are two recognized pathophysiological mechanisms for SUI, that can coexist in the same patient: urethral hypermobility and intrinsic sphincter insufficiency.[1,4,5] When the loss of urine is accompanied by a sudden and compelling urge to urinate, it is classified as UUI.[1,3] When symptoms of both subtypes are present, diagnosis of MUI is established.[1,3] UI is a condition that profoundly affects women's overall health and quality of life (QoL), causing sexual dysfunction, feelings of depression, anxiety, personal devaluation and can lead to a substantial physical, professional and social impact.[1,4,5,7-10] Furthermore, UI is associated with public and private economic costs and imposes considerable individual burden.[1,2]

The primary goals of initial UI evaluation are to identify and classify the condition, while excluding potentially reversible causes.[1,5] This involves a comprehensive approach, including a detailed clinical history, gynecological examination, pelvic organ prolapse (POP) assessment, performing a cough stress test and urethral mobility evaluation and urine analysis.[1,2,4,5]

Applying QoL assessment questionnaires quantifies the personal impact of this pathology in an objective manner. This not only aids in the decision about the most appropriate therapeutic approach, but also enables the identification of patients who potentially benefit most from each treatment option.[1,11] Additionally, these questionnaires play an important role in evaluating, and contrasting the outcomes of various treatments, ensuring a comprehensive understanding of their efficacy.[1,11]

Concerning conservative treatment, it consists of lifestyle changes, pelvic floor physiotherapy, biofeedback, and electrostimulation.[1,4,5] This is the initial approach recommended for all patients dealing with SUI, particularly those awaiting surgical intervention or planning pregnancy, as well as for individuals who possess surgical contraindications or hold reservations about surgery.[1,4,5]

Since 1995, when Ulmstem and Petros introduced the retropubic middle urethral sling, subsequently endorsed by the Food and Drug Administration (FDA) in 1996, the surgical implementation of slings for SUI treatment has gained global recognition, currently representing one of the most extensively studied procedures known for its robust safety profile.[1,2,4,6,12] This technique is currently the preferred surgical option for SUI treatment.[1-3,6] It's a minimally invasive procedure, which involves the placement of a synthetic mesh via either a retropubic or transobturator approach (inside-out or outside-in) through the anterior vaginal wall.[1] Transobturator surgery has a cure rate of 80-90% and exhibits similar efficacy in the short, medium, and long term, compared to the retropubic route, while carrying a reduced risk of complications and requiring shorter operative and hospitalization durations.[1,2,12,13]

For patients with MUI, it is crucial to determine the predominant UI component; in such cases, surgical outcomes tend to be less successful than those observed in individuals with isolated SUI, with reported cure rates ranging from 50 to 74%.[1,2]

The aim of this study was to assess the impact of SUI on women's QoL both before and after transobturator suburethral sling placement surgery, measured through the application of a disease-specific QoL assessment questionnaire.

## METHODS

A prospective longitudinal, observational and analytical study was carried out at Hospital Centre Tâmega e Sousa (HCTS), between June and December 2021, aiming the assessment of the severity of symptoms associated with SUI, the impact of this pathology on the QoL of women, as well as the effectiveness of surgical treatment. Sixty-four women from the Gynecology Outpatient Clinic at HCTS with symptoms compatible with SUI and criteria for surgical treatment with placement of a suburethral sling were included. The following exclusion criteria were considered: age under 18 years, history of neurological pathology and inability to establish contact post-surgery to complete the investigation. Detailed information regarding the investigation was provided to all patients, both orally and in writing, and informed consent was requested to participate in it. A disease-specific QoL questionnaire for women with UI, validated for the Portuguese population and recommended by the European Clinical Practice Guidelines for its reproducibility, sensitivity and simplicity of use- the King's Health Questionnaire (KHQ)- was applied (Appendix).[1,14-17] The KHQ consists of 30 questions, addressing 9 different domains: general health perception; UI impact; role limitations; physical and social limitations; personal relationships; emotions; sleep and severity coping measures. Additionally, it contains an independently scored scale to assess the severity of UI symptoms.[14,15] The KHQ is scored in each of its answers, with the values evaluated by domain. The score varies between 0 (less impaired QoL) and 100 (more impaired QoL) for all domains, except for the Symptom Severity domain, whose score varies between 0 and 30. A more considerable decrease in the score is associated with a more significant improvement in QoL.[14,15,18] The scoring algorithm applied is in accordance with the recommended bibliography.[18] The KHQ was applied at two different times: before treatment and 8-12 weeks after SUI correction surgery with placement of the ObtryxTM Transobturator Mid-urethral Sling System (HaloTM®, Massachusetts, USA).[19] All surgeries were performed by the same surgical team. Preoperative assessment was carried out in accordance with national and international recommendations, comprising: comprehensive medical history, gynecological examination with assessment and

classification of POP using the Pelvic Organ Prolapse Quantification System (POP-Q) when applicable, stress test, evaluation of urethral mobility (Q-tip Test), urine analysis, and urodynamic study in selected patients with MUI to determine the dominant type of UI.[1-3,5,12] The study population was characterized in terms of age, education, place of birth, occupation, marital status, medical and surgical history, harmful habits, physical activity, usual medication, obstetric and gynecological history, weight, height, and duration of UI. Additionally, information regarding the surgery(s) performed and the occurrence of postoperative complications was verified. A clinically significant improvement in QoL was defined as a reduction of 3 points in the Symptom Severity domain and 5 points in each of the remaining domains of the KHQ, as this reduction was considered perceptible by the patient, representing a clinically relevant improvement.[18] This study was conducted after approval by the Institution's Ethics Committee (Health Ethics Committee of HCTS on the 01-15-2021; no. 42/2020) and in accordance with the principles stated in the Declaration of Helsinki by the World Medical Association. The calculated sample size was 38 patients.[20] Statistical analysis was performed using SPSS® (IBM SPSS Statistics for Windows, version 26, Armonk, N.Y. USA). The normality of continuous variables was assessed using the Shapiro-Wilk test. Parametric data were expressed as mean (μ) and standard deviation (σ), while nonparametric data were presented as median (M) and interquartile range (IQR). Categorical variables were depicted as absolute (n) and relative (%) frequencies. The t-test was employed for paired samples, the t-test for independent samples for comparing parametric data, and the Wilcoxon signed-rank test for comparing nonparametric data.

## RESULTS

The sample included 64 women diagnosed with UI: 59.4% (n=38) with SUI and 40.6% (n=26) with MUI. The mean age was 51 years, and all participants were of Portuguese nationality. Regarding education, 82.8% (n=53) of participants had only completed basic schooling. In terms of marital status, 84.4% (n=54) of patients were married. Participants reported depressive and/or anxious disorders in 29.7% (n=19) of cases; however, 56.3% (n=36) were medicated with tricyclic antidepressants, antipsychotics, and/or benzodiazepines. Concerning surgical history, 54.7% (n=35) had previous pelvic surgeries, including cesarean section in 28.1% (n=18), hysterectomy in 14.1% (n=9), and correction of UI with transobturator sling placement in 9.4% (n=6). Most participants were premenopausal and multiparous (60.9% and 79.7%, respectively), with a history of vaginal delivery in 87.5% of cases. The mean Body Mass Index (BMI) was 28.8 kg/m$^2$ (σ=4.5), with most participants having a normal BMI. All patients had symptoms consistent with UI for more than 1 year. Further demographic and clinical data regarding the studied population are detailed in Table 1.

**Table 1: Patient demographic and clinical characteristics (n=64).**

| Characteristics | Mean (μ)±SD / M (IQR)/ N (%) |
|---|---|
| **Age (years)** | 51±9.6 |
| 18-50 | 34 (53.2) |
| 51-65 | 23 (35.9) |
| >65 | 7 (10.9) |
| **Scholarity** | |
| Basic education | 53 (82.8) |
| High school education | 9 (14.1) |
| University education | 2 (3.1) |
| **Marital status** | |
| Married | 54 (84.4) |
| Divorced | 8 (12.5) |
| Single | 2 (3.1) |
| **Professional activity** | |
| Light to moderate activity | 33 (51.6) |
| Moderate to intense activity | 31 (48.4) |
| **Medical background** | |
| Cardiovascular disorders (chronic hypertension) | 21 (32.8) |
| Psychiatric disorders (depression, anxiety) | 19 (29.7) |
| Endocrine disorders (diabetes) | 6 (9.4) |
| Gastrointestinal disorders (chronic constipation) | 3 (4.7) |
| Respiratory disorders (asthma) | 3 (4.7) |
| No relevant medical background | 12 (18.7) |
| **Surgical background** | |
| Cesarean section | 18 (28.1) |
| Hysterectomy | 9 (14.1) |

Continued.

| Characteristics | Mean (μ)±SD / M (IQR)/ N (%) |
|---|---|
| UI surgery | 6 (9.4) |
| POP surgery | 2 (3.1) |
| No relevant surgical background | 29 (45.3) |
| **Current medication** | 43 (67.2) |
| Benzodiazepine | 18 |
| Tricyclic antidepressant | 9 |
| Antipsychotic agent | 9 |
| Diuretic agent | 4 |
| Alpha-adrenergic agonist | 3 |
| **Gynecological background** | |
| Postmenopausal | 25 (39.1) |
| **Obstetric background** | |
| **Parity** | |
| 0 | 2 (3.1) |
| 1 | 11 (17.2) |
| ≥2 | 51 (79.7) |
| Previous vaginal birth | 56 (87.5) |
| Smoking habits | 4 (6.3) |
| **High intensity and impact exercise** | |
| ≥2 times per week | 25 (39.1) |
| **BMI (kg/m$^2$)** | 28.8±4.5 |
| <25.0 | 18 (28.1) |
| 25.0-29.9 | 19 (29.7) |
| 30.0-34.9 | 22 (34.4) |
| ≥35.0 | 5 (7.8) |
| **UI type** | |
| SUI | 38 (59.4) |
| MUI | 26 (40.6) |

All participants underwent UI correction with transobturator sling placement without intraoperative complications recorded. The most common postoperative complication was persistent SUI, occurring in 15.6% (n=10) of patients. Of these, 8 patients were proposed and accepted surgical reintervention. One case of tape extrusion occurred, which was surgically corrected. Additionally, 29.7% (n=19) reported worsening urgency symptoms after surgery, with 13 of them having a previous diagnosis of MUI. Postoperative complications are detailed in Table 2.

**Table 2: Postoperative complications (n=64).**

| Complication | M (IQR)/ N (%) |
|---|---|
| **Total postoperative complications** | 13 (20.3) |
| **Persistent SUI** | 10 (15.6) |
| **Dyspareunia** | 3 (4.7) |
| **Urinary retention** | 1 (1.6) |
| **Mesh erosion** | 1 (1.6) |

Regarding the results of the KHQ application: a global improvement in KHQ score was observed in 96.9% (n=62) of participants undergoing UI correction surgery with transobturator sling placement, with a clinically relevant impact on QoL and statistical significance ($p<0.001$). There was a particular improvement in the domains of "UI Impact" (88.6±19.6), "Role Limitations " (79.6±24.7), "Physical Limitations" (78.4±22.1), and "Severity Measures" (75.9±18.6). Regarding the "Emotions" domain, 62.5% (n=40) of patients reported that UI had a moderate to high psychological impact, with symptoms of sadness, anxiety, and self-devaluation. After surgery, only 9.3% (n=6) reported a negative impact in this domain due to UI. Pre- and postoperative KHQ results are detailed in Table 3.

An additional analysis was conducted to compare the mean differences in global KHQ scores pre- and postoperatively for the subgroups "type of UI" and "BMI." It was found that patients with MUI had a higher global KHQ score compared to patients with isolated SUI (MUI μ=522.8; IQR: 266.7-658.3; SUI μ=492.3; IQR:277.8-97.2). Both groups showed a clinically relevant improvement in QoL with statistical significance ($p<0.001$), but there was no difference in the observed improvement (independent samples t-test: $p>0.05$). The impact of surgery on QoL was also evaluated in patients with normal BMI (18.5-24.9 kg/m$^2$) and overweight (≥25.0 kg/m$^2$), showing a clinically relevant and statistically significant improvement in QoL

for both groups (p<0.001), with no difference between patients with normal BMI and overweight (independent samples t-test: p>0.05). Subgroup analysis is detailed in Table 4.

**Table 3: Pre and postoperative KHQ results (n=64).**

| Domain | | Mean (μ)±SD (minimum - maximum score) | | P value |
|---|---|---|---|---|
| | | Preoperative | Postoperative | |
| Part I | General health perception | 47.0±18.6 (0-100) | 35.9±15.9 (0-100) | <0.001* |
| | Urinary incontinence impact | 88.6±19.6 (0-100) | 19.8±26.8 (0-100) | <0.001* |
| Part II | Role limitations | 79.6±24.7 (0-100) | 11.7±23.7 (0-100) | <0.001* |
| | Physical limitations | 78.4±22.1 (0-100) | 12.8±24.3 (0-100) | <0.001* |
| | Social limitations | 51.5±28.8 (0-100) | 8.9±22.2 (0-100) | <0.001* |
| | Personal relationships | 32.5±19.3 (0-100) | 5.4±14.8 (0-100) | <0.001* |
| | Emotions | 67.8±21.9 (0-100) | 15.6±24.6 (0-100) | <0.001* |
| | Sleep | 53.7±31.4 (0-100) | 16.4±19.2 (0-100) | <0.001* |
| | Severity coping measures | 75.9±18.6 (0-100) | 17.9±25.2 (0-100) | <0.001* |
| Part III | Symptom severity scale | 11.9±4.7 (0-30) | 4.3±3.9 (0-30) | <0.001* |
| | Global score (excluding KHQ Part III) | 491.9 (IQR 242-697) | 131.7 (IQR 25-658) | <0.001* |

*T test for paired samples

**Table 4: Subgroup analysis: pre and postoperative KHQ results.**

| | | KHQ global score* - Mean (IQR) | | P value |
|---|---|---|---|---|
| | | Preoperative | Postoperative | |
| UI type | SUI (n=38) | 492.3 (277.8-697.2) | 126.6 (25.0-658.3) | <0.001† |
| | MUI (n=26) | 522.8 (266.7-658.3) | 140.0 (25.0-641.7) | <0.001† |
| BMI (kg/m$^2$) | 18.5-24.9 (n=18) | 471.9 (277.8-616.7) | 140.7 (25.0-475.0) | <0.001† |
| | ≥ 25.0 (n=46) | 518.3 (266.7-697.2) | 129.5 (25.0-658.3) | <0.001† |

*Excluding KHQ Part III; †T test for independent samples

## DISCUSSION

There are no studies evaluating the impact of UI on QoL in patients undergoing transobturator sling surgery in the Portuguese population. The relevance of this topic is linked not only to the economic impact this condition has on women and society but also to its profound physical and psychosocial impact.[1,2,6,8,21] The sample size of this study and the distribution of UI types were comparable to those found in the international literature on the subject.[1,3,9,13,21-24] Despite being considered a minimally invasive surgery, the risk of complications after sling placement is higher in the presence of comorbidities.[4,25] The most frequent postoperative complication was persistent SUI, which is consistent with the literature.[4] Additionally, about a third of patients reported worsening urgency symptoms after surgery, most of whom had a previous diagnosis of MUI- in such cases, preoperative counseling regarding the potential exacerbation of urgency symptoms is essential, as it is a frequently reported occurrence.[2,11,25] In this study, the application of the KHQ revealed a clinically significant improvement in QoL among 96.9% of participants who underwent UI correction surgery with transobturator sling placement, demonstrating statistical significance. These findings unveil a positive surgical impact on a more substantial subset of patients compared to what has been described by other researchers.[9-12,21-24,26] The domains most significantly impacted in this study included "UI Impact", "Role Limitations", "Physical Limitations" and "Symptom Severity", aligning consistently with similar international studies.[7,8,10] Specifically, patients with MUI exhibited a higher preoperative KHQ global score, indicative of a more pronounced impact of this condition on their QoL. This finding did not differ from international literature on the subject.[8,9,13,21] Nevertheless, in this study, although some patients with MUI reported worsening urgency symptoms post-surgery, they globally showed a clinically relevant and statistically significant improvement in QoL. Another significant finding was that even in the presence of postoperative complications, including persistence of SUI symptoms, patients still showed an improvement in the KHQ global score.

Limitations of this study include the absence of a long-term postoperative evaluation.[21-23]

## CONCLUSION

QoL questionnaires are indeed a useful tool in the clinical setting, due to their reproducibility, non-invasiveness, swift applicability, and cost-effectiveness. They facilitate the objective identification of patients whose symptoms have a greater impact on their QoL, particularly in cases where statistical significance may be marginal but QoL improvement remains substantial. This study significantly advances our understanding of the profound impact of UI on QoL and underscores the effectiveness and significance of transobturator sling placement surgery. Notably, it not only treats SUI but also ameliorates symptoms of MUI,

thus notably enhancing the QoL of affected patients. As the pioneering research of its kind in this specific context, it involved a thorough characterization of the study population, coupled with a critical evaluation of outcomes using a validated disease-specific QoL questionnaire among Portuguese women undergoing UI correction surgery with transobturator sling placement.

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