

## Lack of association between the ICIQ-SF questionnaire and the urodynamic diagnosis in men with post radical prostatectomy incontinence<sup>1</sup>

Falta de associação entre o questionário ICIQ-SF e o diagnóstico nos homens portadores de incontinência urinária pós-prostatectomia radical

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### ABSTRACT

**PURPOSE:** To analyze the correlation between the “International Consultation on Incontinence Questionnaire-Short Form” (ICIQ-UISF) survey and the urodynamic findings in men with urinary incontinence (UI) following radical prostatectomy (RP).

**METHODS:** 88 men who presented post-RP UI for a minimum of 1 year were enrolled prospectively. All answered the ICIQ-UISF survey and underwent urodynamic testing. Patients were divided in 3 Groups according to their urodynamic diagnosis: Group 1, patients with sphincteric incontinence (SI) alone; Group 2, patients with mixed UI (SI + Bladder Dysfunction (BD)); and Group 3, patients with BD alone. Data were analyzed using SPSS v16.0 software.

**RESULTS:** There were 51 men in Group 1 (57.9%); 30 in Group 2 (34%); and 7 (7.9%) in Group 3. BD was found in 37/88 patients (42%), but it was the main cause of UI in only 14 patients (15.9%). There was no statistically significant difference among the mean ICIQ-UISFs values from groups 1, 2, or 3 ( $p > 0.05$ ). The symptoms of stress incontinence correlated with the urodynamic finding of SI ( $r = 0.59$ ), and complaints of urinary urgency correlated with the presence of detrusor overactivity (DO) ( $r = 0.37$ ), but these complaints did not predict the main cause of UI.

**CONCLUSION:** The etiology of UI following RP cannot be predicted by the ICIQ-UISF survey. Symptoms of stress and urge incontinence predict the findings of SI and DO on urodynamic tests, but they cannot ascertain the main cause of UI. Urodynamic testing remains the gold standard to assess the etiology of post-RP UI

**Key words:** Urinary Incontinence. Prostatectomy. Urodynamic Questionnaires. Quality of Life.

### RESUMO

**OBJETIVO:** Analisar a relação entre as queixas clínicas mensuradas pelo “International Consultation on Incontinence Questionnaire-

Short Form” (ICIQ-UISF) e os achados urodinâmicos em homens com incontinência urinária (IU) após a prostatectomia radical (PR). **MÉTODOS:** 88 homens que apresentavam IU por um período mínimo de 1 ano após a PR foram incluídos prospectivamente. Todos responderam o questionário “ICIQ-UISF” e foram submetidos a avaliação urodinâmica. Os pacientes foram categorizados em 3 grupos de acordo com o diagnóstico urodinâmico: Grupo 1, pacientes com incontinência esfincteriana isolada (IE); Grupo 2, pacientes com IU mista (IE + disfunção vesical (DV)); e Grupo 3, pacientes com DV isolada. Os dados foram analisados utilizando o software SPSS v16.0.

**RESULTADOS:** Dos 88 pacientes avaliados, após a avaliação urodinâmica, 51 homens (57,9%) apresentaram IE isolada (Grupo 1); 30 homens (34%) apresentaram IE associada a DV (Grupo 2) e 7 homens (7,9%) tinham somente DV (Grupo 3). A DV foi encontrada em 37/88 pacientes (42%), mas foi a principal causa de IU em apenas 14 pacientes (15,9%). Não houve diferença estatisticamente significativa entre os valores das médias do “ICIQ-UISFs” entre os grupos 1, 2 ou 3 ( $p > 0,05$ ). Os sintomas de incontinência de esforço se correlacionaram com o diagnóstico urodinâmico de IE ( $r = 0,59$ ), e as queixas de urgência miccional se correlacionaram com a presença de hiperatividade do detrusor na avaliação urodinâmica ( $r = 0,37$ ), entretanto apesar da correlação encontrada, os sintomas não foram capazes de identificar a principal causa da UI.

**CONCLUSÃO:** A etiologia da UI após a PR não pode ser previsto pelo escore de sintomas obtidos através do “ICIQ-UISF”. Os sintomas de perda urinária as manobras de estresse e de urgência miccional estão relacionados a presença de IE e hiperatividade detrusora na avaliação urodinâmica, entretanto estes sintomas não conseguem identificar com segurança qual é o principal fator da IU após a PR. O teste urodinâmico continua sendo o padrão ouro para avaliar a etiologia da IU após a PR.

**Descritores:** Incontinência Uinária. Prostatectomia. Questionários Urodinâmica. Qualidade de Vida.

## Introduction

Prostate cancer is the most common non-skin tumor that affects men. There are approximately 210,000 cases of prostate cancer annually in the United States, and the vast majorities (90%) are clinically localized or regional at diagnosis<sup>1</sup>. Radical prostatectomy (RP) is one of the most frequent treatments performed for localized prostate cancer, and approximately 65.000 men undergo RP in the United States annually.

Urinary incontinence (UI) is a well-known complication of RP and occurs in 2-87% of men after surgery<sup>2,3</sup>. In 1995, Fowler *et al*<sup>4</sup>. developed questionnaires to study the impact of post-RP UI on quality of life for patients. They found that half of the patients analyzed had daily urinary leakage, and 32% were using pads, diapers or a penile clamp.

The rate of UI tends to decrease with time post-surgery, and most researchers agree that it is necessary to follow patients for at least one year after surgery before proceeding with a more invasive investigation<sup>5</sup>. Although bladder dysfunction (BD) and sphincteric incontinence (SI) can contribute to UI,<sup>6</sup> SI has been considered to be the primary mechanism related to stress-induced incontinence following RP<sup>7,8</sup>.

Although the urodynamic test is invasive, time-consuming, bothersome and expensive<sup>9,10</sup>, it verifies the functional integrity of the lower urinary tract and determines the precise cause of UI in patients. Therefore, the urodynamic test guides clinicians to the most appropriate treatment.

Validated questionnaires can be used to record the presence and severity of urinary symptoms such as incontinence, and they can assess the impact of these symptoms on daily activities. The ICIQ-UISF is recommended by the International Continence Society<sup>11</sup>, and it was validated in a Portuguese population in 2004<sup>12</sup>. The ICIQ-UISF allows for a subjective evaluation of the severity of urine loss and quality of life, and it is also recognized as an important tool for patients reporting outcome assessments.

The aim of this study was to correlate the final ICIQ-UISF scores with the urodynamic findings in men with UI following RP. Additionally, we assessed for any correlation between the symptoms of urge and stress incontinence and the urodynamic findings of BD or SI as the main cause of UI.

## Methods

From January 2005 to January 2009, we prospectively recruited a total of 88 men complaining of UI for at least one year after retropubic RP.

The study was conducted with the approval of the local Research Ethics Committee, and the patients consented to participate in the study.

Patients with a past history of UI treatment, prostate cancer recurrence, urinary retention, insulin-dependent diabetes, urethral or vesico-urethral stenosis, neurological disease, urinary tract infection or patients taking medications that could affect the lower urinary tract were not eligible for the study.

All patients underwent subjective assessment of UI, urinalysis and urodynamic evaluation.

Subjective assessment of symptoms was performed using the ICIQ-UISF questionnaire before the urodynamic evaluation. Patients were classified in groups in according to their complaints of pure stress incontinence; mixed incontinence; and pure urge incontinence.

Urodynamic testing was performed by one experienced urologist in according to the standards of the International Continence Society<sup>13</sup>. The total vesical pressure was measured with a 7 Fr trans-urethral catheter, and the total abdominal pressure was measured by a rectal balloon catheter. The subtracted detrusor pressure (vesical minus abdominal) was calculated. The fill rate was 30-50 ml per minute. Compliance was determined by the capacity (volume) divided by the detrusor pressure at capacity before a detrusor contraction occurred.

Detrusor overactivity (DO) was defined as any rise, provoked or spontaneous, of detrusor pressure during filling. DO did not have to be associated with urge.

The presence of DO or lowered bladder compliance on the urodynamic test was used to diagnose BD.

The abdominal leak point pressure (ALPP) was assessed by filling the bladder at a rate of 30 to 50 ml per minute to a final volume of 250 ml. The filling was interrupted after every 50 ml infused, and the Valsalva test and stress maneuvers were performed. If no leakage was demonstrated after the 250 ml infusion, the urethral catheter was removed and stress maneuvers were repeated with only the rectal balloon in place.

SI was demonstrated by urine loss due to increased abdominal pressure during coughing or a Valsalva maneuver that was not accompanied by an elevation in detrusor pressure.

Patients were categorized into 3 groups according to the urodynamic diagnosis: Group 1: patients with a diagnosis of SI alone; Group 2: patients with a diagnosis of SI associated with BD (mixed incontinence); and Group 3: patients with a diagnosis of BD alone.

In patients with mixed urinary incontinence, BD was considered to be the main cause of UI when, during the urodynamic test, the majority of urinary leakage resulted from an uninhibited involuntary detrusor contraction that triggered the voiding mechanism and minimal losses were documented when the Valsalva or cough maneuvers were performed. When an involuntary detrusor contraction produced minimal urinary leakage and the stress maneuvers resulted in a greater amount of urine loss, SI was considered the main cause of UI.

Correlations were carried out between individual items

on the ICIQ-UISF and the urodynamic diagnoses of DO and SI.

Data were analyzed using the Statistical Package for the Social Sciences (SPSS v16.0). The power of associations between the quantitative variables was determined using a Pearson's linear correlation, and Fisher's exact test was used to determine the level of significance. Two-sided p-values <0.05 were considered significant.

## Results

The subjective assessment of symptoms revealed that 66 patients (75%) complained of stress incontinence, 17 patients (19.3%) experienced mixed incontinence, and 5 patients (5.7%) felt urge incontinence.

The presence of UI was confirmed in all patients. Of the 88 patients studied, 51 (57.9%) were urodynamically categorized as Group 1, 30 (34%) as Group 2, and 7 (7.95%) as Group 3. Only 4 patients (4.5%) presented with low bladder compliance 3 associated with SI and one with DO.

The mean age of the patients and time from prostatectomy are summarized in Table 1.

**TABLE 1** - Mean age and time from prostatectomy in groups 1, 2 and 3 (p>0.05)

Groups (n)	Age (Mean +/- SD)	Months from prostatectomy (Mean +/- SD)
1 (n = 51)	64.51 (+/- 6.34)	17.02 (+/- 4.34)
2 (n = 30)	65.03 (+/- 7.17)	16.59 (+/- 3.89)
3 (n = 7)	60.70 (+/- 7.50)	15.90 (+/- 1.83)

BD was documented in 37 patients (42% - 37/88), but it was the main cause of UI in only 14 (15.9% - 14/88) individuals. The occurrence of DO was significantly more frequent in groups 2 and 3 (p <0.001).

SI was detected in 81 patients, but it was the main cause of UI in 74 (84.1% - 74/88).

No patients presented with impaired detrusor contractility, and only 1/88 (1,1%) presented with impaired bladder filling sensation associated with SI.

Table 2 summarizes the mean values of the ICIQ-UISF for Groups 1, 2 and 3. There was no statistically significant difference ( $p>0.05$ ) among the 3 Groups despite the small number of patients in Group 3.

The symptom of stress incontinence correlated with the urodynamic diagnosis of SI ( $r = 0.59$ ;  $p<0.001$ ), and complaints of urinary urgency correlated with detection of DO on the urodynamic test even in cases of mixed incontinence ( $r = 0.37$ ;  $p<0.05$ ).

A comparison of subjective and objective findings revealed that 81 of the 83 patients who complained of stress incontinence, both alone and in combination with urge, presented with SI on urodynamic testing for positive predictive value of 97%. Of the 22 men who complained of urgency, both alone and in association

**TABLE 2** - Mean values of the ICIQ-UI SF for groups 1, 2 and 3 ( $p>0.05$ )

ICIQ-UI SF score	Group 1	Group 2	Group 3
Mean value	16.8	15.4	13.9
SD	-/+ 2.4	-/+ 1.9	-/+ 2.1

with stress incontinence, 14 presented with UI related to BD on the urodynamic test for a positive predictive value of 63.6%. For the 5 patients who did not complain of stress UI, none presented with SI on urodynamic evaluation, which resulted in a negative predictive value of 100%.

All patients scored at least a 7 (on a scale of 0 to 10) regarding the quality of life on the ICIQ-UISF questionnaire. The UI caused by SI alone, BD alone, or the combination of both did not significantly differ in impact on the quality of life ( $p>0.05$ ).

## Discussion

UI is one of the most devastating complications of RP. It adversely impacts quality of life, limits daily activities and not infrequently results in depression.

A complete clinical and laboratory evaluation of this complication is critical to diagnose the precise cause of UI and to provide the best treatment.

Urodynamic studies should provide useful information to clinicians. These studies should be able to identify or rule out factors contributing to incontinence and assess their relative importance. Because urodynamic testing is invasive, expensive

and bothersome to the patient, many attempts have been made to predict urodynamic findings using clinical parameters.

Validated questionnaires are important tools for measuring “subjective” phenomena, such as symptoms and quality of life, in an objective way. The ICIQ-UISF is a simple, robust, brief and easy-to-answer questionnaire. The assessment of its internal consistency and instability demonstrated that the ICIQ-UISF is highly reliable and provides reproducible data<sup>11</sup>. In 2004, the ICIQ-UISF was translated and validated in Portuguese, which allowed for its use in research protocols and clinical practice<sup>12</sup>.

The Third Consultation on Incontinence highly recommended the ICIQ-UISF for evaluation of symptoms and impact on quality of life in men and women with UI<sup>14</sup>.

Several studies in the literature have assessed for correlations between the ICIQ-UISF and urodynamic findings. Karantanis *et al.* found a positive correlation between the 24-hour pad test and the ICIQ-UISF in women<sup>15</sup>. Espuña-Pons *et al.* demonstrated a positive correlation between the ICIQ-UISF combined with the stress test and the urodynamic diagnosis of UI in women<sup>16</sup>. Rotar *et al.* found a positive correlation between the ICIQ-UISF and the urodynamic findings in men and women with lower urinary tract symptoms who attended urology and gynecology outpatient clinics<sup>17</sup>.

To our knowledge, our study is the first to evaluate for correlations between the ICIQ-UISF and urodynamic findings in men with UI following RP.

Despite the correlations found in women, the total score of the ICIQ-UISF could not discriminate whether SI or BD was the main cause of UI in this study. This finding confirms the hypothesis that is not possible to ascertain the main cause of UI following RP based on subjective assessment alone.

A possible explanation relies on the fact that the ICIQ-UISF was designed to generically assess for UI symptoms, lower urinary tract symptoms and their impact on the quality of life for men and women. Therefore, the ICIQ-UISF is not specifically designed or validated to assess post-RP incontinence.

The ICIQ-UISF questionnaire is composed of 4 questions. The first 3 are related to the frequency of incontinence, the amount of leakage and the impact on the quality of life. The final score is obtained by adding the results of the first 3 questions. Clearly, none of these questions are related to the symptoms that may elucidate the main cause of UI. Furthermore, SI can co-exist with BD, and it is difficult to distinguish which component is the main cause of UI only based on symptoms.

Our results demonstrated that SI alone or in combination with BD is present in 92% (81/88) of patients with UI after RP.

This finding confirms the reports of other studies that SI, regardless of association with BD, is the most frequent etiology of UI post-prostatectomy<sup>7,18,19</sup>.

A study by Twiss *et al.* analyzing men with UI after RP found a positive correlation between the complaints of stress incontinence and the detection of SI by the urodynamic test (positive predictive value = 95%)<sup>20</sup>. Our study confirmed this finding, and we found a positive predictive value of 97% in patients with complaints of stress UI and a urodynamic diagnosis of SI. Furthermore, of the 22 patients who complained of urinary urgency, 14 presented UI related to BD, which resulted in a positive predictive value of 63.6%. Of the 5 patients who did not complain of stress UI, none presented with SI on the urodynamic evaluation, resulting in a negative predictive value of 100%. This fact highlights that the absence of stress urinary incontinence on clinical evaluation predicts the absence of SI on the urodynamic test.

SI is almost always associated with UI after RP, but the bladder component is not always related to surgery. Carlson and Nitti found that post-RP BD may be demonstrated with a urodynamic examination even in the absence of UI or other signs and symptoms reported by patients<sup>21</sup>. Our study confirmed this finding, of the 37 patients who presented with BD, 22 (59.5%) felt urge incontinence and only 14 had BD as the main cause of UI on urodynamic evaluation.

A possible explanation for this finding is that DO, when associated to SI, may be caused by activation of the vesicourethral reflex due to low urethral resistance and is not related to real detrusor changes. This finding highlights the importance of preserving the continence mechanism (striated urinary sphincter, urethral innervations, urethral length and the bladder neck) during RP.

Functional studies have demonstrated that RP causes both sphincter damage and detrusor dysfunction. These changes can vary from patient to patient and are influenced by the voiding status prior to the operation, age and surgical technique. These dysfunctions can also vary in intensity, and they may also explain why some patients present with BD in conjunction with SI even though one of them contributes more to the UI process.

It is well documented that the standard urodynamic test can fail or over detected the presence of DO despite urinary urgency symptoms in 50% of the patients. This fact may explain why the positive correlation between symptoms of urgency and the urodynamic diagnosis of DO was lower than the correlation between SI and the symptom of stress incontinence in our study.

SI and BD, either together or alone, did not differ

significantly in their impact on daily activities and the quality of life in men with UI following RP. This finding highlights that after RP patients are bothered by the urinary leakage in general, regardless of its etiology.

The role of urodynamics in patients with UI after RRP was assessed by Foote *et al*<sup>22</sup> and by Leach and Yun<sup>23</sup>. A “socially acceptable” level of continence was achieved in 87%– 88% of patients as a result of treatment established according to urodynamic findings (anticholinergics and/or artificial urinary sphincter). Thus, it seems that preoperative urodynamic investigation permits a precise diagnosis of the postoperative dysfunction and avoids any inappropriate therapy<sup>24</sup>, particularly when invasive treatment should be applied. In fact 84%–100% of patients who refused or did not tolerate therapy recommended on urodynamic findings reported no significant improvement in urinary incontinence<sup>22,23</sup>.

The fact that we did not have any information regarding voiding function prior the surgical procedure may not be a major confounder, as the majority of men undergoing RP typically have no significant BD prior to surgery.

Despite all tests being performed by an experienced physician, a shortcoming of this study is that the main cause of UI in patients with mixed incontinence was determined by clinical observation of the amount of urine loss during the urodynamic evaluation.

## **Conclusion**

SI is the most frequent cause of UI in men who have undergone RP, and BD is rarely an isolated cause.

The mechanism of post-prostatectomy urinary incontinence cannot be predicted by the total score of the ICIQ-UISF, despite the fact that the symptoms of stress and urge incontinence predict for SI and DO on urodynamic testing.

The absence of stress urinary incontinence on clinical evaluation predicts the absence of SI on the urodynamic test.

The ICIQ-UI SF is easy to answer and reliable. It provides excellent data regarding patient perception of UI symptoms. Although it cannot be used to determine the etiology of UI following radical prostatectomy, it can be used to verify the impact of UI on quality of life, and it is an important tool to address treatment outcome.

The urodynamic evaluation remains the gold standard to assess detrusor function and the etiology of incontinence following radical prostatectomy.

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