Predictive value of clinical history compared with urodynamic study in 1,179 women

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Objective: to determine the positive predictive value of clinical history in comparison with urodynamic study for the diagnosis of urinary incontinence.

Methods: retrospective analysis comparing clinical history and urodynamic evaluation of 1,179 women with urinary incontinence. The urodynamic study was considered the gold standard, whereas the clinical history was the new test to be assessed. This was established after analyzing each method as the gold standard through the difference between their positive predictive values.

Results: the positive predictive values of clinical history compared with urodynamic study for diagnosis of stress urinary incontinence, overactive bladder and mixed urinary incontinence were, respectively, 37% (95% CI 31-44), 40% (95% CI 33-47) and 16% (95% CI 14-19).

Conclusion: we concluded that the positive predictive value of clinical history was low compared with urodynamic study for urinary incontinence diagnosis. The positive predictive value was low even among women with pure stress urinary incontinence.

Keywords: urodynamics, predictive value of tests, lower urinary tract symptoms, urinary incontinence, diagnosis.

INTRODUCTION

Urinary incontinence (UI) consists of involuntary loss of urine1 and it has a significant negative impact on patients’ quality of life.2,3

UI prevalence increases with age, reaching one in three older women.4 The prevalence of UI in young adults ranges from 20 to 30%, from 30 to 40% in middle-aged women, and from 30 to 50% in postmenopausal women.4,5

There is no consensus in the literature about the accuracy of diagnostic methods for UI.6 UI diagnosis is established based on: anamnesis (clinical history), physical examination, voiding diary, pad test, and urodynamic evaluation.7

Clinical history is a low-cost and less invasive method that can be used at all levels of health care. However, some previously published studies have considered urodynamic evaluation as a “gold standard” for UI diagnosis because it could reproduce the symptoms in an accurate and documented manner.7

Recent studies have questioned the value of urodynamics because it might not always reproduce the patient’s clinical complaints, also being more invasive and presenting a higher cost. Some authors recommend that only clinical history is used, especially in patients reporting pure stress urinary incontinence (SUI), even before they undergo surgical treatment.8,9

Conversely, other authors recommend urodynamic evaluation in the following situations: patients with recurrent urinary symptoms, difficulty to establish a diagnosis, or even for diagnostic clarification in the preoperative evaluation when there is clinical history of pure SUI because, according to some authors, these patients may have another disorder.10

The objective of this retrospective analysis was to evaluate the positive predictive value (PPV) of clinical history compared to urodynamic study in patients with urinary incontinence.

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Methods
The present study consisted of a retrospective medical record analysis of 1,179 multichannel urodynamic studies performed at the Sector of Urogynecology and Pelvic Floor Disorders of the Gynecology division, at Faculdade de Medicina da Universidade de São Paulo, between 2007 and 2009. The study was approved by the Research Ethics Committee of Hospital das Clínicas, Faculdade de Medicina da Universidade de São Paulo.

The mean age of our patients was 56.4 years. The results of database urodynamic studies performed in an urodynamic laboratory were correlated to the symptoms that were recorded during an outpatient visit immediately before the urodynamic study. The symptoms reported by the patients were: SUI, urgency, urge incontinence, frequency, and nocturia. After that, they were classified into three groups based on their clinical history: SUI – stress urinary incontinence; OAB – urgency with or without other symptoms, such as frequency, nocturia, and urge incontinence; MUI – stress urinary incontinence associated with urgency.

The results of the urodynamic studies included: stress urinary incontinence (SUIu), detrusor overactivity (DO), and mixed urinary incontinence (MUIu). According to the Valsalva leak point pressure (VLPP), SUIu and MUIu were subdivided into: less than 60 cmH₂O and more than 60 cmH₂O.¹¹

Symptoms reported by the patients, urodynamic studies and groups classification were all standardized according to the definitions in the joint report of the International Urogynecological Association (IUGA)/International Continence Society (ICS).¹

Sensitivity, specificity, PPV and negative predictive value (NPV) were included in the analysis. For SUI/SUIu, positive clinical history was considered when there was complaint of SUI alone, and positive urodynamic study was considered only when pure SUI was present. Similarly, when the OAB/DO group was analyzed, mixed urinary symptoms and mixed urodynamic findings were excluded.

With the purpose of defining the gold standard in our study and the diagnosis method to be tested, we used two types of analysis to calculate the PPV. Each type of analysis considered SUI/SUIu, OAB/DO, and MUI/MUIu.

Since there is no literature consensus regarding a “gold standard” method for UI diagnosis,⁶ in order to determine the “gold standard” in this large cohort study our choice was to build two 2x2 tables between clinical history and urodynamic data and compare the PPVs. The PPV was chosen as comparison parameter because it expresses the actual positive cases in a population, when the diagnostic test has a positive result. Thus, PPV is an important parameter in clinical practice. Table 1 shows how tables were built for calculation.

When clinical history was considered the gold standard, the PPVs for diagnosing SUI, OAB and MUI were, respectively: 27, 19, and 68%. On the other hand, when the urodynamic study was used as the gold standard for determining the subtype of UI, PPVs for diagnosing SUI, OAB and MUI were, respectively: 37, 40, and 16%.

Then, the differences in PPV for each type of UI between clinical complaint and urodynamic study were evaluated, and the gold standard method was considered the one showing the highest PPVs.

<table>
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<th>TABLE 1 Table models for positive predictive value calculation for “gold standard” definition.</th>
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<td><strong>Clinical history</strong></td>
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Results
The analysis of PPV for each type of UI comparing clinical history and urodynamic study revealed that the urodynamic study had a higher PPV for the diagnosis of OAB/DO and for SUI/SUIu, whereas clinical history showed a higher PPV for symptoms of MUI/MUIu. Therefore, we defined that urodynamic study was the gold standard and clinical history was the new test to be evaluated.

We found that SUI was the only complaint (pure SUI) in 20.61% of patients (Table 2). In this group of patients, considering the clinical diagnosis in relation to the urodynamic finding, sensitivity was 27% (95%CI 22-31) and specificity was 82% (95%CI 79-84). NPV was 73% (95%CI 70-76). PPV was 37% (95%CI 31-44) (Table 3). Furthermore, among patients with pure SUI in our sample, 28.45% had VLPP less than 60 cmH₂O, and 71.55% had VLPP more than 60 cmH₂O.

As for the clinical history of OAB, its prevalence was 14.58%. Urodynamic study showed 31.38% of DO (Table 2). Regarding the clinical diagnosis of OAB compared with the urodynamic finding, sensitivity was 19% (95%CI 15-23), specificity was 87% (95%CI 85-90), and NPV was 70% (95%CI 67-73). PPV was 40% (95%CI 33-47) (Table 3).
Mixed symptoms were found in 64.8% of cases, whereas only 15.43% of urodynamic studies revealed MUI (Table 2). In this case, the sensitivity of the clinical history correlated to the urodynamic diagnosis of MUI was 68% (95%CI 61-75) and specificity was 36% (95%CI 33-39). NPV was 86% (95%CI 83-89). PPV was 16% (95%CI 14-19) (Table 3). Furthermore, among patients with MUI, the VLPP was less than 60 cmH\(_2\)O in 27.8%, and 71.9% had VLPP more than 60 cmH\(_2\)O.

**DISCUSSION**

The urodynamic study analyzes the stages of bladder filling and voiding, considering urinary loss as well as detrusor activity in a systematic and documented manner. Thus, urodynamic evaluation may clarify the diagnosis of UI as a complement to the clinical history and physical examination.\(^7,12\)

There is no consensus on the indication of urodynamic study prior to surgical treatment for SUI. Some medical organizations recommend it during the overall evaluation of patients with UI.\(^7\) Conversely, other organizations defend that urodynamic studies do not need to be performed before surgical treatment in patients who report pure SUI as a clinical complaint. Nonetheless, urodynamic studies should be performed when there is suspicion of MUI, failure of previous surgery for incontinence, or suspected difficulty in bladder voiding.\(^8,13\)

A recent prospective non-inferiority trial demonstrated that clinical history was non-inferior to the urodynamic study. However, in this study, the non-inferiority score was arbitrarily defined.\(^9\) The problem with non-inferiority trials is the endorsement of tolerance to the worst result, which means that, according to this study, 1 in 9 patients had a bad outcome that could have been avoided if an urodynamic test was undertaken.

Considering the characteristics of urodynamic studies and the remaining controversy regarding its use prior to the surgical treatment for UI, it is questionable whether the analysis of clinical history could be enough to establish a proper diagnosis and treatment of this prevalent disease.

According to a review of the literature conducted by Colli et al.\(^14\) that included 23 studies, most patients (90%) with UI had an abnormal urodynamic study, which is in agreement with our findings.

Conversely, Martin et al.,\(^6\) in a systematic review that analyzed various diagnostic methods for UI, found sensitivity of 92% for the diagnosis of SUI based only on clinical history. Similarly, the review by Colli et al.\(^14\) demonstrated a sensitivity of 82%. After analyzing each type of
In this study, most patients complained of MUI (64.8%), a finding also present in the study by Agur et al., but different from the results of the Norwegian study EPINCONT, which showed that half of the patients had SUI and only 1/3 of the urinary disorders had characteristics of mixed incontinence. Regarding urodynamic findings, we found only 15.43% of MUI among all the tests, with a sensitivity and specificity of clinical history in comparison with the urodynamic study of 68 and 36%, respectively. Colli et al. also found low values of sensitivity and specificity for cases of MUI (51 and 66%, respectively).

In a systematic review of the literature, Holroyd-Leduc et al. concluded that a positive bladder stress test may be useful for diagnosing SUI. An assessment including clinical history, physical examination, and stress test can only modestly increase the probability of clinical diagnosis of SUI. In this review, urodynamic studies were not included in the analysis.

Urodynamic study helps to confirm the diagnosis in positive cases, but it is not able to rule out the disease in the cases showing normal results. When, in addition to clinical history and noninvasive tools, patients also undergo urodynamic study, they are more prone to receive surgical treatment for UI. Performance of the urodynamic study can lead to greater adherence to follow-up and treatment.

Furthermore, some authors recommend the use of the urodynamic study prior to surgery, because they indicate specific surgical treatment (retropubic sling) for patients with intrinsic sphincteric deficiency.

Therefore, some researchers would argue that a large number of cases of UI could be diagnosed only based on clinical history and then, the non-surgical treatment could be initiated, and those patients with pure SUI could undergo surgery. However, our results lead us to agree with those who concluded that performing an urodynamic study is important at least before invasive treatments such as surgery in patients with UI.

Thus, further studies with large populations like this one (1,179 patients) and prospective studies with adequate sample power and statistical significance are needed for the elucidation of these disagreements, mainly demonstrating which diagnostic method is related to better treatment outcomes.

**Conclusion**

Positive predictive value of clinical history was low compared with urodynamic study for urinary incontinence diagnosis. The positive predictive value was low even among women with pure stress urinary incontinence.
Resumo

Valor preditivo positivo da história clínica comparado ao estudo urodinâmico em 1.179 mulheres

Objetivo: determinar o valor preditivo positivo da história clínica em comparação ao estudo urodinâmico para o diagnóstico da incontinência urinária.

Método: análise retrospectiva comparando história clínica e avaliação urodinâmica em 1.179 mulheres com incontinência urinária. O estudo urodinâmico foi considerado padrão-ouro, e a história clínica, o novo teste a ser avaliado. Isso foi estabelecido após análise de cada método como padrão-ouro pela diferença entre seus valores preditivos positivos.

Resultados: o valor preditivo positivo da história clínica comparado ao estudo urodinâmico para diagnóstico de incontinência urinária de esforço, bexiga hiperativa e incontinência urinária mista foram, respectivamente, 37% (IC95% 31-44), 40% (IC95% 33-47) e 16% (IC95% 14-19).

Conclusão: o valor preditivo positivo da história clínica foi baixo quando comparado ao estudo urodinâmico para diagnóstico de incontinência urinária. O valor preditivo positivo foi baixo mesmo em mulheres com incontinência urinária de esforço pura.

Palavras-chave: diagnóstico, incontinência urinária, urodinâmica, valor preditivo dos testes, sintomas do trato urinário inferior.

Referências