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

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Summary

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 urine[1] 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.[3] 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.

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 cmH_2O and more than 60 cmH_2O.[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 1 Table models for positive predictive value calculation for "gold standard" definition.

	Clinical history +	Clinical history -
Urodynamic study +		
Urodynamic study -		

	Urodynamic study +	Urodynamic study -	
Clinical history			+
Clinical history -			

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 cmH_2O, and 71,55% had VLPP more than 60 cmH_2O.

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).

TABLE 2 Number of patients with diagnosis of urinary incontinence based on clinical history and urodynamic study.

Clinical history	**% (n)**
Isolated symptom of stress urinary incontinence	20.61 (243)
Overactive bladder	14.58 (172)
Mixed symptoms of urinay incontinence	64.8 (764)
Urodynamic study	
Stress urinary incontinence	29.09 (343)
Detrusor overactivity	31.38 (370)
Mixed urinay incontinence	15.43 (182)
Other results*	24.08 (284)

*Normal test, infravesical obstruction, detrusor hypocontractility, reduced cystometric capacity.

TABLE 3 Patients with clinical history of pure stress urinary incontinence, overactive bladder, and mixed urinary incontinence and corresponding urodynamic finding.

	SUI on urodynamic study	**No SUI on urodynamic study**		**Detrusor overactivity on urodynamic study**	**No detrusor overactivity on urodynamic study**		**MUI on urodynamic study**	**No MUI on urodynamic study**
Pure SUI	91 (7.7%)	152 (12.8%)	Overactive bladder	69 (5.8%)	103 (8.7%)	MUI	124 (10.5%)	640 (54.2%)
No pure SUI	252 (21.3%)	684 (58.0%)	No overactive bladder	301 (25.5%)	706 (59.8%)	No MUI	58 (4.9%)	357 (30.2%)

MUI: mixed urinary incontinence; SUI: stress urinary incontinence.

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_2O in 27.8%, and 71,9% had VLPP more than 60 cmH_2O.

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

urinary disorder in our sample, we found a sensitivity of 27% for clinical history regarding the diagnosis of SUI. These studies showed a specificity of 56 and 57%, respectively. Such values are also in disagreement with the one found in our study (which was 82% for SUI). In an analysis of 537 patients, defining history as the gold standard, Caruso et al. found 57% of SUI on history and physical examination, with sensitivity of the urodynamic study for UI of 45%, specificity of 99%, PPV of 98.6%, and NPV of 57.5%.[15]

However, these reviews of the literature did not restrict their analysis to pure SUI. They also included any SUI complaint associated or not with other symptoms. In our study, however, SUI was defined as the single complaint of urinary loss during physical activity. Furthermore, the authors did not explain the reason why clinical history was chosen as the gold standard in their studies.[15] We established the urodynamic study as the gold standard based on the identification of the highest PPV between the two methods. Such analysis had not been performed before in studies comparing urodynamic studies and clinical history diagnosis.

In a review of the literature including 12 articles, Harvey and Versi demonstrated that the isolated symptom of SUI had a PPV of 56% for the diagnosis of pure SUI in comparison with urodynamic evaluation, with 23% of false positive results. If SUI was associated with other symptoms, the PPV for detection of SUI, with or without other abnormalities, was 77%. Also, the stress test showed PPV of 55% for the detection of SUI, with 29% false positive results.[16] In the study by Agur et al., which analyzed SUI detected by the urodynamic study, the prevalence of complaint of pure SUI was even smaller than in our study (11.4%), with a sensitivity of 11%, specificity of 98%, PPV of 74%, and NPV of 69%.[10] In comparison, our PPV was 37% for the complaint of pure SUI with a NPV of 73%.

In this study, OAB had a sensitivity of the diagnosis based on clinical history of 19%. This value is lower than those found in the studies previously cited (61% for the diagnosis of DO in Martin et al.,[6] and 69% in the study by Colli et al.[14] As for the specificity of the clinical history suggestive of OAB, we found a value of 87%, which is in disagreement with the lower values found in the literature (60%).[14] Caruso et al. found a prevalence of 51% for OAB symptoms. The diagnosis based on urodynamic study showed sensitivity of 59%, specificity of 84%, PPV of 84.5%, and NPV of 68.6%.[15] These authors found that clinical symptoms of OAB are not necessarily good predictors of detrusor activity,[15] which corroborates our findings of low sensitivity.

In this study, most patients complained of MUI (64.8%), a finding also present in the study by Agur et al.,[10] but different from the results of the Norwegian study EPINCONT,[5] 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).[14]

In a systematic review of the literature, Holroyd-Leduc et al.[17] 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.[14] When, in addition to clinical history and noninvasive tools, patients also undergo urodynamic study,[18] 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.[18]

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.[11]

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.

References

1. Haylen BT, de Ridder D, Freeman RM, Swift SE, Berghmans B, Lee J, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. Int Urogynecol J. 2010;1(21):5-26.
2. Frick AC, Huang AJ, Van den Eeden SK, Knight SK, Creasman JM, Yang J, et al. Mixed urinary incontinence: greater impact on quality of life. J Urol. 2009;182(2):596-600.
3. Goode PS, Burgio KL, Richter HE, Markland AD. Incontinence in older women. JAMA. 2010;303(21):2172-81.
4. Hunskaar S, Burgio K, Diokno A, Herzog AR, Hjalmas K, Lapitan MC. Epidemiology and natural history of urinary incontinence in women. Urology. 2003;62(4 Suppl 1):16-23.
5. Hannestad YS, Rortveit G, Sandvik H, Hunskaar S. A community-based epidemiological survey of female urinary incontinence: the Norwegian EPINCONT study. Epidemiology of Incontinence in the County of Nord-Trondelag. J Clin Epidemiol. 2000;53(11):1150-7.
6. Martin JL, Williams KS, Sutton AJ, Abrams KR, Assassa RP. Systematic review and meta-analysis of methods of diagnostic assessment for urinary incontinence. Neurourol Urodyn. 2006;25(7):674-83; discussion 84.
7. Blaivas JG, Appell RA, Fantl JA, Leach G, McGuire EJ, Resnick NM, et al. Standards of efficacy for evaluation of treatment outcomes in urinary incontinence: recommendations of the Urodynamic Society. Neurourol Urodyn. 1997;16(3):145-7.
8. Urinary Incontinence. The clinical management of urinary incontinence in women. National Institute for Health and Clinical Excellence. [cited 2011 oct 6]. Available from: http://www.nice.org.uk/nicemedia/live/10996/30282/30282.pdf.
9. Nager CW, Brubaker L, Litman HJ, Zyczynski HM, Varner RE, Amundsen C, et al. A randomized trial of urodynamic testing before stress-incontinence surgery. N Engl J Med. 2012;366(21):1987-97.
10. Agur W, Housami F, Drake M, Abrams P. Could the National Institute for Health and Clinical Excellence guidelines on urodynamics in urinary incontinence put some women at risk of a bad outcome from stress incontinence surgery? BJU Int. 2009;103(5):635-9.
11. Lim YN, Dwyer PL. Effectiveness of midurethral slings in intrinsic sphincteric-related stress urinary incontinence. Curr Opin Obstet Gynecol. 2009; 21(5):428-33.
12. Takacs EB, Zimmern PE. Recommendations for urodynamic assessment in the evaluation of women with stress urinary incontinence. Nat Clin Pract Urol. 2006;3(10):544-50.
13. Urinary incontinence in women. Obstet Gynecol. 2005;105(6):1533-45.
14. Colli E, Artibani W, Goka J, Parazzini F, Wein AJ. Are urodynamic tests useful tools for the initial conservative management of non-neurogenic urinary incontinence? A review of the literature. Eur Urol. 2003;43(1):63-9.
15. Caruso DJ, Kanagarajah P, Cohen BL, Ayyathurai R, Gomez C, Gousse AE. What is the predictive value of urodynamics to reproduce clinical findings of urinary frequency, urge urinary incontinence, and/or stress urinary incontinence? Int Urogynecol J. 2010;21(10):1205-9.
16. Harvey MA, Versi E. Predictive value of clinical evaluation of stress urinary incontinence: a summary of the published literature. Int Urogynecol J Pelvic Floor Dysfunct. 2001;12(1):31-7.
17. Holroyd-Leduc JM, Tannenbaum C, Thorpe KE, Straus SE. What type of urinary incontinence does this woman have? JAMA. 2008;299(12):1446-56.
18. Majumdar A, Latthe P, Toozs-Hobson P. Urodynamics prior to treatment as an intervention: a pilot study. Neurourol Urodyn. 2010;29(4):522-6.