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The Diagnostic Values of Medical History, Physical Examination and Urodynamic Study in Women With Urinary Incontinence

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Abstract:

Introduction: To evaluate and compare the diagnostic values of medical history, physical examination findings and urodynamic study in women with urinary incontinence.

Materials and Methods: This prospective, clinical study was implemented on 50 patients in the urology department of our tertiary care center. Women suffering from complaints of urinary incontinence underwent clinical evaluation including medical history, physical examination and urodynamic study. Accuracy and predictive values of urologic history, clinical evaluation findings and urodynamic study results in the diagnosis of urinary incontinence were investigated.

Results: Based on clinical evaluation, 14 patients (28%) were diagnosed with stress urinary incontinence, while 19 cases (38%) had urge urinary incontinence and mixed urinary incontinence was detected in 17 patients (34%). Urodynamic study yielded that numbers of patients diagnosed with stress urinary incontinence, urge urinary incontinence and mixed urinary incontinence were 10 (20%), 14 (28%) and 12 (24%), respectively. Finally, definitive diagnoses were established as stress urinary incontinence in 13 (26%) patients, urge urinary incontinence in 18 (36%) cases and mixed urinary incontinence in 19 (38%) patients. Analysis of our data has shown there was a positive correlation between clinical, urodynamic and definitive diagnoses. The correlation between urodynamic and definitive diagnoses was moderate (κ: 0.60), whereas clinical and definitive diagnoses were highly correlated (κ: 0.70).

Conclusion: Our results indicated that urodynamic studies constitute an advanced diagnostic modality rather than a routine procedure. Medical history for micturition and a detailed clinical evaluation is the mandatory first-line step in evaluation of women with urinary incontinence.

Keywords: Medical history; physical examination; urodynamic study; urinary incontinence.

Introduction

Urinary incontinence (UI) is defined as any involuntary loss of urine that complicates normal daily life in addition to the restriction of the social activities of the patient [1] It is categorized as stress, urgency or mixed. In stress UI (SUI), the main symptom is involun tary loss of urine, which may occur during coughing, sneezing, standing or exercise. Urge UI (UUI) is leakage of urine due to the inappropriate contraction of bladder muscles regardless of the amount of urine. Its symptoms are frequent daily or nocturnal urination, together with involuntary loss of urine and sudden or urgent need to urinate. Mixed incontinence displays symptoms consistent with both SUI and UUI. Discrimination of the type of incontinence is crucial in order to establish the most appropriate therapy in each individual case [2].

Urodynamic tests are measurements performed to assess the bladder's function and efficiency. Even though some of the urodynamic tests are relatively simple, majority of these procedures necessitate expensive and sophisticated instruments for measurement of the amount of pressure experienced by the bladder and urethra [3].

Since the differential diagnosis of female urinary incontinence is a difficult task owing to the overlap of certain types of incontinence, a proper and well-organized diagnostic approach is necessary. The objective of the present study was to evaluate the diagnostic value of clinical evaluation (medical history and physical examination) and the urodynamic study in women with urinary incontinence.

Methods

Study Design: This prospective, clinical study was performed in the urology department of our tertiary care center in accordance with principles of the Helsinki Declaration of 1975, as revised in 2008. Informed consents were obtained from every patient prior to inclusion in the study.

A total of 50 consecutive women aged 18 to 70 suffering from urinary incontinence participated in this trial. All cases were willing for being included in the study and they were mentally and physically capable of implementation of the requisites of the study.

Exclusion criteria were diagnoses of metabolic or neurological disease that may lead to UI, current medical treatment or previous history of surgical treatment for UI, presence of a mechanical obstruction on the urinary bladder, severe uterine prolapsed, cystocele, rectocele, chronic constipation, history of pelvic radiotherapy and untreated urinary tract infection.

Evaluation and follow-up of patients have been accomplished at 6 aspects including medical history, laboratory investigation, urogynecological and neurological examination, voiding diary, urodynamic study and confirmation of definitive diagnosis. The first 4 steps were performed by the first urologist and "clinical diagnosis" was established. Another urologist unaware of the findings and diagnosis of the first urologist implemented the urodynamic tests and "urodynamic diagnosis" was set. These diagnoses were finally evaluated by the urology council and "definitive diagnosis" was concluded.

Medical History

Age, menopause, obstetric history, previous surgery and presence of chronic diseases were recorded. Urological history involved duration of incontinence, presumable reasons that elicit incontinence, previous medications used for treatment of UI, duration and benefits of these treatment modalities, family history, quality of life (QoL) and questions for distinguishing the type of UI. Co-existence of both stress and urge UI in the same patient was consistent with mixed UI.

Laboratory Study: Urinalysis, fasting plasma glucose levels in addition to renal and hepatic function tests were evaluated routinely in every patient.

Urogynecological & Neurological Examination: Physical examination was performed to investigate of urethrocele and cystocele on the anterior wall and enterocele and rectocele on the posterior wall. Patients were instructed to cough for triggering urinary leakage (Stress test). Q-tip test was used for assessment of the anatomy and presence of hypermobility. Moreover, neurological examination focusing on the pathology was carried out.

Voiding Diary: A questionnaire was filled for recording data on numbers of daily and nocturnal voiding, continence status, amount of fluid intake, urinary output and number of urine pads used.

Urodynamic Study: Patients were evaluated with a multi-channel MMS® Solar (ADS Ltd, Enschede, Netherlands) urodynamic study device. Filling cystometry and uroflowmetry were performed and the residual amount of urine was measured. Isotonic saline was infused at a rate of 30 ml/min at room temperature. After filling the urinary bladder, volumes at first sensation for urination (ml), feeling of urination (ml), feeling of immediate urination (ml), bladder capacity (ml) and compliance (ml/cm H_2O) were measured. Detrusor contractions that exist after 15 cm H_2O and that cannot be inhibited during were recorded. During the procedure, maneuvers such as coughing and straining were performed to observe whether there was a urinary leakage from the external meatus. In case leakage occurs, valsalva leak point pressure (VLPP) was recorded. If VLPP was greater than 150 cmH_2O in the absence of detrusor contraction, urodynamic study was assigned as normal. Sensation of urgency during attempt to cease voiding at any pressure or detection of involuntary phasic detrusor contractions (>15cmH_2O) accompanying urinary leak were consistent with detrusor instability and urge UI. Co-existence of stress UI and detrusor instability were termed as mixed UI.

Definitive Diagnosis: The final evaluation and confirmation of diagnosis with respect to the results of aforementioned steps was made by the council comprised of urologists of our tertiary care center. Further treatment strategy was determined with respect to the definitive diagnosis.

Statistical Analysis: Analysis of data was performed using the IBM Statistical Package for Social Sciences v12 (SPSS Inc., Chicago, IL, USA). Parametric tests were applied to data of normal distribution and non-parametric tests were applied to data of questionably normal distribution. Continuous data were expressed as mean±standard deviation or median (minimum-maximum), as appropriate. All differences associated with a p value <0.05 were considered statistically significant. Different predictive models were compared by receiver operating characteristic–area under curve (ROC-AUC) statistics.

Results

The average age for our series was 46.7±7.4 (range, 22 to 65). No statistically significant difference was seen between groups in terms of average age and number of parity (Table 1).

Table 1. *Distribution of patients in our series with respect to age and parity.*

	Definitive diagnosis				
	SUI	**UUI**	**MUI**	**Mean**	***p* Value**
Age (years)	43.3±7.1	49.1±5.8	45.1±6.9	46.7±7.4	0.21
Parity	3.7±1.7	3.8±1.9	3.5±1.6	3.6±1.7	0.46

(Abbreviations: SUI: stress urinary incontinence; UUI: urge urinary incontinence; MUI: mixed urinary incontinence)

Numbers of patients suffering from UI for less than 1 year, between 1 to 5 years and more than 5 years are 11 (22%), 22 (44%), and 17 (34%), respectively (Table 2). Average duration of incontinence in the whole study group is 3.4±1.1 years.

Table 2. *Distribution of patients with respect to duration of incontinence.*

Duration of incontinence	Patient groups (definitive diagnosis)			
	SUI	UUI	MUI	Total
	n (%)	n (%)	n (%)	n (%)
<1 year	3 (23%)	4 (22%)	4 (21%)	11 (22%)
1-5 years	5 (38.5%)	8 (44%)	9 (47%)	22 (44%)
>5 years	5 (38.5%)	6 (34%)	6 (32%)	17 (34%)
Total	13 (100%)	18 (100%)	19 (100%)	50 (100%)

(Abbreviations: SUI: stress urinary incontinence; UUI: urge urinary incontinence; MUI: mixed urinary incontinence)

Based on clinical evaluation, 14 patients (28%) were diagnosed with stress UI, while 19 cases (38%) had urge UI and mixed UI was detected in 17 patients (34%). Urodynamic study yielded that numbers of patients diagnosed with stress UI, urge UI and mixed UI were 10 (20%), 14 (28%) and 12 (24%), respectively. Finally, definitive diagnoses were established as stress UI in 13 (26%) patients, urge UI in 18 (36%) cases and mixed UI in 19 (38%) patients (Table 3).

Table 3. *Patient groups according to diagnostic modalities used.*

Diagnostic groups	Patient groups				
	SUI	UUI	MUI	Normal	Total
	n (%)	n (%)	n (%)	n (%)	n (%)
Clinical diagnosis	14 (28%)	19 (38%)	17 (34%)	0 (0%)	50 (100%)
Urodynamic study	10 (20%)	14 (28%)	14 (28%)	12 (24%)	50 (100%)
Definitive diagnosis	13 (26%)	18 (36%)	19 (38%)	0 (0%)	50 (100%)

(Abbreviations: SUI: stress urinary incontinence; UUI: urge urinary incontinence; MUI: mixed urinary incontinence)

The average of scores in QoL according to the complaints expressed subjectively was 6.8±1.1 (Table 4). The average QoL score was 6.4±0.7 in stress UI group, 6.7±0.9 in urge UI group and 7.1±1.2 in mixed UI group. No remarkable difference was noted between these groups with respect to QoL (p=0.08) (Table 4).

Table 4. *Distribution of quality of life scores in groups ($\chi 2$ =12.6, p=0.08).*

Quality of life scores	Definitive diagnosis			
	SUI	UUI	MUI	Total
	n	n	n	n
Mild (0-4)	4	5	7	16
Moderate (5-7)	5	7	7	19
Severe (8-10)	4	6	5	15
Average	6.4 ± 0.7	6.7 ± 0.9	7.1 ± 1.2	-

(Abbreviations: SUI: stress urinary incontinence; UUI: urge urinary incontinence; MUI: mixed urinary incontinence)

Analysis of our data has shown there was a positive correlation between clinical, urodynamic and definitive diagnoses (Table 5). The correlation between urodynamic and definitive diagnoses was moderate (κ: 0.60), whereas clinical and definitive diagnoses were highly correlated (κ: 0.70) (Tables 6, 7).

Table 5. *Comparison of clinical diagnoses to urodynamic diagnoses (χ^2=15.1, p=0.04).*

Clinical diagnosis	Urodynamic study				
	SUI	UUI	MUI	Normal	Total
	n (%)	n (%)	n (%)	n (%)	n (%)
SUI	8 (16%)	1 (2%)	2 (4%)	3 (6%)	14 (28%)
UUI	0 (0%)	11 (22%)	3 (6%)	5 (10%)	19 (38%)
MUI	2 (4%)	2 (4%)	9 (18%)	4 (8%)	17 (34%)
Total	10 (20%)	14 (28%)	14 (28%)	12 (24%)	50 (100%)

(Abbreviations: SUI: stress urinary incontinence; UUI: urge urinary incontinence; MUI: mixed urinary incontinence)

Table 6. *Comparison of clinical diagnoses to definitive diagnoses (Kappa=0,698, p<0.01).*

Clinical diagnosis	Definitive diagnosis			
	SUI	UUI	MUI	Total
	n (%)	n (%)	n (%)	n (%)
SUI	11 (22%)	0 (0%)	3 (6%)	14 (28%)
UUI	0 (0%)	16 (32%)	3 (6%)	19 (38%)
MUI	2 (4%)	2 (4%)	13 (26%)	17 (34%)
Total	13 (26%)	18 (36%)	19 (38%)	50 (100%)

(Abbreviations: SUI: stress urinary incontinence; UUI: urge urinary incontinence; MUI: mixed urinary incontinence)

Table 7. *Comparison of urodynamic diagnoses to definitive diagnoses (Kappa=0.601, p<0.01).*

Urodynamic diagnosis	Definitive diagnosis			
	SUI	UUI	MUI	Total
	n (%)	n (%)	n (%)	n (%)
SUI	8 (16%)	0 (0%)	2 (4%)	10 (20%)
UUI	0 (0%)	11 (22%)	3 (6%)	14 (28%)
MUI	2 (4%)	3 (6%)	9 (18%)	14 (28%)
Normal	3 (6%)	4 (8%)	5 (10%)	12 (12%)
Total	13 (26%)	18 (36%)	19 (38%)	50 (100%)

(Abbreviations: SUI: stress urinary incontinence; UUI: urge urinary incontinence; MUI: mixed urinary incontinence)

Accuracies of clinical and urodynamic diagnoses with respect to definitive diagnoses is demonstrated in Table 8. In SUI diagnosis, clinical evaluation had a specificity of 85% and sensitivity of 80%; the positive predictive value (PPV) and negative predictive value (NPV) were 57% and 94%, respectively. On the other hand, urodynamic study had 94.5% specificity and 61.5% sensitivity; while the PPV and NPV were 80% and 87.5%, respectively.

Table 8. *Accuracies of clinical diagnosis and urodynamic study in diagnosis of UI.*

	Specificity (%)	Sensitivity (%)	PPV (%)	NPV (%)	ODV (%)
Clinical diagnosis -SUI	85%	80%	57%	94%	84%
Urodynamic study - SUI	94.5%	61.5%	80%	87.5%	86%
Clinical diagnosis - UUI	90.6%	88.8%	84.2%	93.5%	90%
Urodynamic study - UUI	90.6%	61.1 %	78.6%	80.5%	80%
Clinical diagnosis - MUI	87%	68.4%	76.5%	81.8%	80%
Urodynamic study - MUI	83.8%	47.3%	64.3%	72.2%	70%

(Abbreviations: SUI: stress urinary incontinence; UUI: urge urinary incontinence; MUI: mixed urinary incontinence; PPV: positive predictive value; NPV: negative predictive value; ODV: overall diagnostic value)

In UUI diagnosis, clinical evaluation had a specificity of 90.6% and a sensitivity of 88.8%; the PPV was 84.2% and NPV was 93.5%. Urodynamic study had a specificity of 90.6% and a sensitivity of 61.1%; while the PPV was 78.6% and NPV was 80.5%.

For ruling in MUI, specificity of clinical evaluation was 87% and sensitivity was 68.4%; whereas the PPV and NPV were 76.5% and 81.8%, respectively. For urodynamic study, specificity was 83.8% and sensitivity was 47.3%; the PPV was 64.3% and NPV was 72.2%.

Discussion

The present study was implemented for determination of appropriate algorithms for diagnosis and treatment of UI. A properly filled voiding diary and a detailed clinical evaluation seems to be the first-line and most important tool for evaluation of the patient and setting the appropriate management strategy. Even though urodynamic study provides valuable data, it must be used as an advanced diagnostic modality rather than a screening method.

Medical history and physical examination have been used for establishing indications in urologic surgery; however, UI recurs in approximately 15% of patients. Failure of surgical treatment mostly ensources from an insufficient preoperative assessment [4].

Medical history possesses an important role for ruling in UI, however, it has certain limitations for determining subtypes of UI [5,6]. Recently, several publications have focused on comparison of clinical diagnosis established by means of history and urodynamic diagnosis [2,7,8].

Meta-analysis performed by Jensen et al. has demonstrated that medical history had a sensitivity of 90.6%, specificity of 51.1%, PPV of 74.9% and NPV of 77.1% for diagnosis of stress UI [5]. Our results yielded that sensitivity, specificity, PPV, NPV and diagnostic value of clinical diagnosis were 80%, 85%, 57%, 94% and 84%, respectively. We noted that only sensitivity was low compared to other parameters and clinical evaluation was positively correlated with urodynamic and definitive diagnoses. Recent publications imply that medical history alone can result in misdiagnosis in 15-25% of stress UI patients [4]. However, urodynamic study has been accepted as gold standard in the vast majority of these studies. On the other hand, 25-35% of stress UI patients did not exhibit relevant symptoms in urodynamic study [9]. Moreover, some authors suggest that urodynamic study is unnecessary in many UI patients [10,11].

Urodynamic study is prone to patient related factors such as stress and environmental conditions [2,9]. In spite of this circumstance, false positive and false negative results are not taken into account [2]. In the present study, 12 patients that did not reveal any pathological urodynamic results were diagnosed with mixed UI (n=5), urge UI (n=4) and stress UI (n=3) in their clinical evaluation.

Detrusor instability or mixed UI can be detected after urodynamic study of patients suffering from stress UI. Similarly, detrusor instability and mixed UI can mimic stress UI during rapid inhibition of detrusor muscle contraction due to contraction of external urethral sphincter [5].

Relying on medical history alone can cause selection of inappropriate treatment modalities and urge UI symptoms have high rates of false negativity and false positivity [5]. In another publication, 50-72% of patients with detrusor instability admitted with complaints consistent with stress UI [12]. These rates are higher than our report and may remind that clinical evaluation may be insufficient for establishing diagnosis. On the other hand, high predictive rates of clinical evalution in our series must be noted.

A highly sensitive test must be used to determine uncontrolled bladder contractions that define detrusor instability. Cystometry is a standard measure, but its results are dependent on rate of filling, position of the patient, substance used to fill the bladder and provocative maneuvers applied [13]. These are important limitations that interfere with the diagnostic capability of urodynamic study.

In our study, role of clinical evaluation for diagnosis of mixed UI diagnosed with urodynamic study was assessed. Our rates of sensitivity, specificity, NPV and PPV were higher than report by Jensen [5]. We observed a moderate level of correlation between clinical evaluation and urodynamic study. The association between clinical evaluation and urodynamic study for stress UI and urge UI is less prominent. Whether this difference can be attributed to the limitations of urodynamic study in diagnosis of mixed UI or limitations that interfere with obtaining an informative medical history is debatable.

Our results imply that clinical evaluation is more valuable than urodynamic study in the diagnosis of stress, urge and mixed UIs. Superiority of clinical evaluation over urodynamic study is more obvious in urge and mixed UIs. This data is contradictory to data in relevant literature [5,13,14]. This may be attributed to the fact that most of these publications are based on comparison of medical history and urodynamic study. Moreover, urodynamic study was accepted as gold standard in these articles. In contrast, definitive diagnosis was based on the conclusive decision by the urology council in the current study. We have excluded entities that such as urinary tract infection, fistula, urethral instability and urethral syndrome diverticula that may mimick UI. This may be another factor which may contribute to the difference between our results and the literature.

Insufficient preoperative evaluation together with misdiagnosis can lead to unnecessary surgical interventions, decreased therapeutic success and increased postoperative complications. It is accepted that the most successful incontinence procedure is the initial intervention. Urodynamic study aims to determine the specific cause of

incontinence and direct the treatment regimen accordingly. Since urodynamic study may be insufficient in this purpose, priority must be given to a thorough clinical evaluation. Urodynamic study can be implemented postoperatively to evaluate the surgical outcomes and to distinguish patients to be treated with either medical or surgical measures [5,6,10].

To sum up, assessment of UI must be based on clinical evaluation, medical history and physical examination initially. Diagnosis and subtyping of UI as well as determination of treatment plan can be made with respect to this data. From this point of view, a meticulous clinical evaluation can limit the need for urodynamic study.

Conclusion

To conclude, results of the current study indicated that urodynamic studies constitute an advanced diagnostic modality rather than a routine procedure. History for micturition and a detailed clinical evaluation is the mandatory first-line step in evaluation of women with urinary incontinence.

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