A Novel Simple Clinical Scoring System to Guide the Utilization of Urodynamic Studies in Women with Overactive Bladder Symptoms: A retrospective Observational study

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Synopsis: We are suggesting a new clinical score that can be of value in the clinical evaluation of women with Overactive bladder symptoms.

Abstract

Background: To present a simple clinical scoring system that can be utilized in selecting women with overactive bladder symptoms who would benefit from further urodynamic assessment.

Materials and Methods: This was a retrospective study done at a tertiary centre. Filed data of 210 women with OAB symptoms who presented at urinary incontinence clinic were analyzed. Women were grouped into those with detrusor overactivity (DO) and those without DO according to filling cystometry. The variables which were independently associated with DO were used to create a score that can be used for selecting women for further urodynamics assessment.

Results: Women with DO had significantly higher incidence of nocturia (92% vs 62%, p <0.001) urgency (86% vs 66%, p=0.002) and frequency (76% vs 51%, p=0.001). The detrusor overactivity score was calculated by adding the value of the corresponding symptom as follows: nocturia = 3, urgency = 2, frequency = 1. The sensitivity and specificity were 83% and 52% respectively at a cut-off value of 4. Women with a score ≥4 are expected to have DO when assessed by further urodynamic studies.

Conclusion: Detrusor overactivity score can be utilized for selecting women with OAB symptoms who would benefit from performing further urodynamic assessment.

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BACKGROUND

The International continence society (ICS) defined detrusor overactivity (DO) as a urodynamic observation of spontaneous or provoked involuntary detrusor muscles contractions during the bladder filling phase (1). The accepted definition of overactive bladder syndrome (OAB) is "the storage symptoms of urgency with or without urgency incontinence, usually with frequency and nocturia" (2). DO has been reported to be detected in 22-58.4% of women with these symptoms (3)(4).

For assessment of a patient with urinary incontinence (UI), work-up involves history, examination, urine analysis and residual volume assessment (5). Additionally, exacerbating factors, the effect on the woman's quality of life and her desire for treatment should be addressed (6). After this comprehensive assessment, a provisional diagnosis is usually reached, and the most suitable treatment plan is selected (5).

Moreover, urodynamic studies (UDS) are used to objectively diagnose and demonstrate urinary incontinence. They are recommended when the results may change management, following treatment failure, or as part of both short and long-term surveillance programs (5).

The cost-effectiveness of UDS has been evaluated in cases with stress urinary incontinence (SUI) where the treatment is mainly surgical. Reduction in the need for surgery after testing has been found more or less effective (7). However, in OAB where therapy is mainly medical using usually non-expensive drugs, performing UDS is not usually justified before initiating treatment. Also, it has been documented that UDS may have a poor agreement with the patient's symptoms. So, in certain situations, the patient may undergo this invasive investigation without added benefit to the plan of treatment. Thus, in this study, we evaluated different clinical parameters and compared them to the UDS aiming to develop a simple clinical score that can help to select patients who would get the benefit of further UDS assessment.

MATERIALS AND METHODS

This is a retrospective study. We collected filed data of women who were referred to the Women Urinary Incontinence Clinic at Cairo University Hospital during the period from January 2018 to December 2020. The study was approved by the scientific and ethics committee of the Obstetrics and Gynecology department of Cairo university teaching hospitals (approval number O20005). All methods were carried out in accordance with relevant guidelines and regulations. The scientific and ethics committee has waived informed consent due to the retrospective nature of the study.

We collected the data of adult women who had OAB symptoms, namely frequency, urgency, urge incontinence or nocturia. We excluded cases with urinary tract infections, urinary lithiasis, uncontrolled diabetes mellitus, hemi/paraplegia, disseminated sclerosis, history of spinal cord injury, history of bladder injury or vesicovaginal fistula (whether present or repaired) as well as those on anticholinergics. Pregnant patients or women within 6 months of delivery, were also excluded. Patients' identities were coded by the 1ry investigator to ensure data confidentiality and to facilitate access.

All case files were reviewed to collect the following data:

- Demographic data (age, gravidity, parity, mode of delivery, presence of any complication of delivery, menopausal status, pelvic or vaginal surgery, weight, height, BMI).
- Symptoms of frequency, urgency, urge incontinence, stress incontinence and nocturia
- Pelvic organ prolapse quantification (POP-Q).

- Data of filling cystometry (reported according to the standard definitions of Drake et al., 2018 (8) with a report on the following parameters:
    a. Sensation at first urge to void in cm3
    b. Maximum bladder capacity in cm3
    c. The presence of DO is detected by the presence of spontaneous or provoked involuntary detrusor muscle contractions during the bladder filling phase
    d. Urodynamic leakage
    e. Cough test

Statistical analysis:

We calculated the needed sample size to detect the area under the receiver operating characteristic (AUROC) curve of 0.65, and we set the null hypothesis for the AUROC curve at 0.5. We took into consideration that the rate of DO in our records was approximately 25%; thus, we set the ratio between negative cases (patients with stable detrusor pressure curve) and positive cases (patients with detrusor overactivity) at 3:1. Thus, the minimum number of patients that were needed was 156 patients (with at least 39 positive cases) to have a study power of 80% and an alpha error of 0.05. Taking the average number of patients in our unit to be 120 patients per year we looked into the files of the previous 3 years assuming incomplete files and excluded patients to be at most 50% of the cases especially in the last year where the practice has been affected by the COVID-19 pandemic.

Statistical analysis was performed using SPSS 15 (Chicago, IL) and MedClac software. Categorical data were presented as frequency (%); continuous data were checked for normal distribution by inspection of histogram distribution. Normally distributed continuous data were presented as mean±SD, and abnormally distributed data were presented as median (interquartile range). Patients were classified into patients with DO and patients without DO. The Chi-square test was used to compare frequencies between the two groups. Unpaired t-test and Mann-Whitney test were used to compare the means for continuous data as appropriate. Multivariable logistic regression was used. Variables with a P value of less than 0.2 in univariate analysis were included in multivariate analysis. Variables with a P-value of < 0.05 in multivariate analysis were considered statistically significant. The variables which were independently associated with DO were used to create a score to confirm the diagnosis of OAB evaluate its severity. Receiver operating characteristic curves were constructed and the area under the curve (AUC) was determined for the new score to detect DO.

RESULTS

We found 210 women eligible for the study. 151 women (72%) had no DO (control group) and 59 (28%) had DO (study group) by the performed filling cystometry. Both groups shared similar demographics and baseline characteristics as shown in (Table 1).

The univariate analysis showed that women with DO had a higher incidence of nocturia (92% vs 62%, p <0.001), urgency (86% vs 66%, p=0.002), frequency (76% vs 51%, p=0.001) compared to the control group while all other clinical findings were comparable between the two groups of patients. (Table 2). That's why we have chosen those three variables (nocturia, urgency, frequency) to create the score. The multivariate regression model revealed that nocturia had the highest odds ratio (OR 4.81) as a predictor of DO followed by urgency (OR 2.86) and frequency (OR 1.46). (Table 3).

We developed a novel score (Detrusor Overactivity Score, DOS) based on the relative weight of each predictor in the multivariate analysis. Each symptom was given a weight as follow; nocturia = 3, urgency = 2, frequency = 1. The total score (DOS score) was cal-

culated by adding the weight of each symptom. The ability of the DOS for detecting DO was evaluated using the receiver operating characteristic curve analysis. The AUC (95% confidence interval) was 0.693 (0.626-0.754) (figure 1). The sensitivity, specificity, PPV, and NPV was 83%, 52%, 40% and 90% respectively at a cut-value of 4. The maximum score was 6 while the minimum was 1. The predictive values at different cut-off values are presented in (Table 4).

DISCUSSION

OAB syndrome is a widely prevalent and increasing condition affecting nearly 10.7 % of the worldwide population. Numbers are expected to increase from 19-31% over 10 years in different regions of the world affecting mainly developing Africa followed by Asia and Latin America(9). One cannot overlook the gap between the presence of complaints/symptoms and seeking/receiving treatments for them. Assessment of such a condition depends mainly on clinical evaluation. However, sometimes UDS are indicated in OAB cases whenever there is an uncertain diagnosis, failure or unsatisfactory response to empirical initial medical treatment or with previous lower urinary tract surgery (e.g. anti-incontinence surgery). As UDS is considered to some extent an invasive and expensive investigation, a method for selecting patients who are a candidate for such investigation is essential. We conducted this research to develop an easy scoring system to help the general practitioners confirm the diagnosis of OAB syndrome and select patients who will get benefit from undergoing urodynamic evaluation.

Our study included 210 women with the mean age at presentation 45.6 +/- 10 years denoting how this condition affects middle-aged and old age women where symptoms increase with age as previously noted by other authors (10)(11). We assessed parity, obesity and menopausal status and other risk factors for developing UI and OAB, as did other researchers from other countries (12)(13). Additionally, uterovaginal prolapse, as well as anterior and posterior compartment prolapse, are risks for developing UI, with and without DO, which was also observed by several authors (12)(14).

An important question arises; do we need UDS to accurately diagnose OAB syndrome before starting treatment? Colleagues from the UK and Germany have summarized the evidence for the utility of urodynamics in evaluating several lower urinary tract conditions one of which was OAB. They concluded that UDS should be used for diagnoses whenever in doubt and they are probably not necessary before initiating medical treatments for OAB (15). This was contrary to what has been reported earlier in 2003, by a more or less similar group who stated that UDS are mandatory for the diagnosis of OAB (3).

In our study, we tried to fill the gap and shorten the distance between the two opinions. The gap between these two opinions arises from the fact that depending only on the patients' words to reach a diagnosis may be sometimes misleading or confusing. It seems as if patients and medical practitioners speak different languages and may even have different disease concepts (15).

As "typical SUI" exists there are patients with "typical OAB syndrome". However, those groups, expressing "typical symptoms and signs," represent only at best 20% each of the total population of women with symptoms of lower urinary tract dysfunction (LUTD) (17).

In such a situation, physicians are obliged to use objective methods to build up a solid diagnosis. In the case of OAB symptoms, UDS is the objective method of choice.

Additionally, one of the main causes of controversy regarding UDS assessment of OAB patients is that it has been reported that UDS fail to detect detrusor overactivity in 62-74%

in women with frequency and/or urgency symptoms and in 53- 62% of the women with urge urinary incontinence (UUI)(18). This means that over 60% of patients were exposed to an invasive investigation without any added benefit. This brings to our minds the term coined by Blaivas et al in 1996 that "The bladder is an unreliable witness" (19) and that sometimes there is poor agreement between urodynamic testing and clinical evaluation, especially when diagnosing OAB(20).

So, we believe there is a need for a simple method for selecting patients who will benefit from undergoing evaluation by UDS. This need was also realized by the International Consultation on Incontinence Research Society (ICI-RS) in 2014. They concluded that the treatment of UUI and OAB should depend on a diagnostic process with the least possible invasiveness yet with good reliability. They also concluded that there is a challenge to improve the diagnostic process for all patients with any symptom or sign of LUTD and to learn to select the patients who benefit from complete UDS(17).

In our study, the detrusor overactivity score (DOS) being based on the results of UDS offers a reasonable method of selecting patients who would benefit from UDS by using the cut off value of 4. At this cut off value, DO can be detected by 84 % sensitivity. Patients with OAB symptoms with DOS ≥ 4 are expected to have abnormalities detected by UDS while patients with a score less than 4 would probably have a UDS free of any abnormalities. Thus, it would be better for them not to undergo this invasive investigation.

To select the items included in this score, we statistically checked the relation between DO as detected by cystometry and many variables such as different urinary symptoms, stages of prolapse in addition to the demographic data. We reported that DO has a statistically significant association with nocturia (92%), urgency (86%) and frequency (76%).

We partially agree with colleagues from the Netherlands who conducted a cross-sectional study on 95 patients to report the association between OAB symptoms and results of objective parameters as filling cystometry and a self-reporting questionnaire addressing the four main symptoms of OAB (urgency, frequency, nocturia and urge incontinence). They concluded that the latter three could suggest DO with the frequency being the best symptom associated with DO detected by UDS (4). We believe that our different results could be attributed to our larger sample size and different methods used.

Numerous authors have evaluated specific symptoms for OAB with the development of several tools/questionnaires to aid in the diagnosis (21). The bladder control self-assessment questionnaire (sensitivity 85% and specificity 63%), the OAB awareness tool (V8 and V3- short form), the OAB symptom score and urinary symptom profile have been able to determine patients with OAB with great accuracy including assessing the severity of cases (22). However, these tools were designed neither as diagnostic tools nor as selecting methods for UDS and were only intended for awareness.

One of our main strengths is performing this study on a large number of patients over three years. Also, DOS is based on detrusor overactivity proven by UDS with the novel aim of selecting patients for UDS. Yet, there is no work without limitations. Our score needs further validation on other sets of patients in other centers. Additionally, we need to assess the usage of this score as a tool for the assessment of improvement after treatment.

Finally, we conclude that DOS can be offered as a reasonable method for selecting women with OAB symptoms to perform UDS whenever further objective evaluation is needed.

Conflict of interests: The authors declare that they have no conflict of interests.

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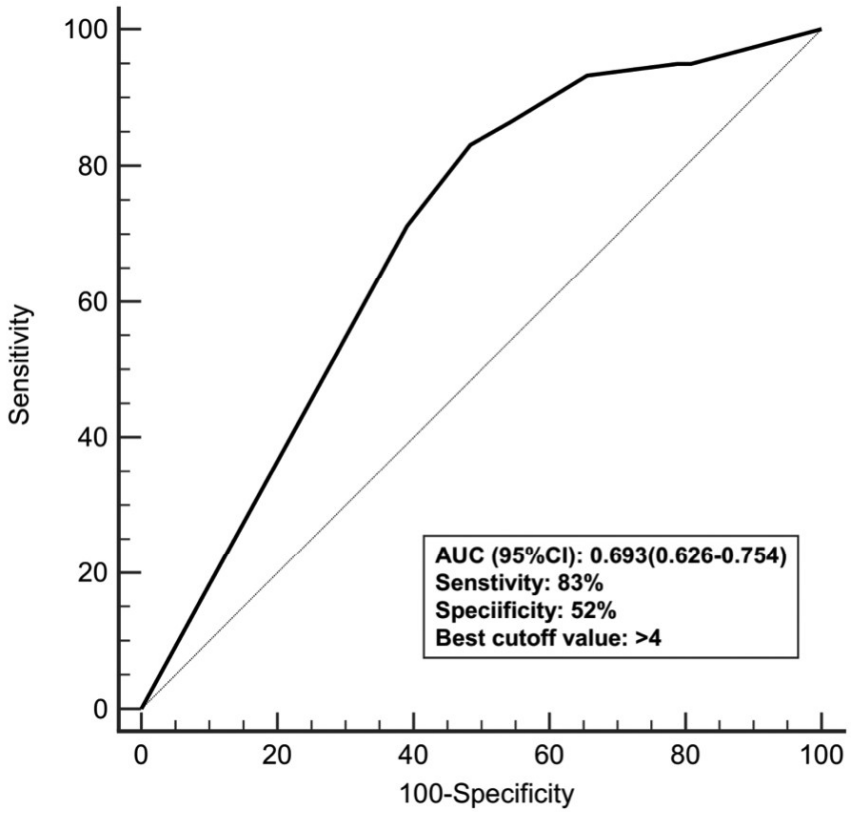

Figure 1 : Receiver operating characteristic curve for the ability of the DOS to detect detrusor overactivity. AUC: Area under curve, CI: confidence interval, DOS: detrusor overactivity score.

Table 1: demographic data and baseline characteristics. Data are presented as mean±-standard deviation, median(quartiles), and frequency (%).

	No detrusor overactivity (n=151)	Detrusor overactivity (n=59)	P value
Age	44±9	45.6±10	0.26
Gravidity	5(3-6)	5(3-6)	0.81
Parity	4(3-5)	4(3-5)	0.24
Obesity	105(70%)	44(75%)	0.50
Menopause	43(29%)	23(39%)	0.20
Previous vaginal deliveries			0.16
None	3(2%)	3(5%)	
One	8(5%)	1(2%)	
Two	19(13%)	16(27%)	
Three or more	121(80%)	39(66%)	
Previous cesarean deliveries			0.32
None	119(79%)	44(75%)	
One	27(18%)	10(17%)	
Two or more	5(3%)	5(8%)	
Previous pelvic surgeries	25(17%)	10(17%)	1.00

Table 2: clinical symptoms and risk factors for detrusor overactivity. Data are presented as frequency (%).

	No detrusor overactivity (n=151)	Detrusor overactivity (n=59)	P value
Frequency	77(51%)	45(76%)	**0.001**
Urgency	99(66%)	51(86%)	**0.002**
Urge incontinence	100(66%)	46(78%)	0.13
Nocturia	93(62%)	54(92%)	**<0.001**
Stage of anterior vaginal prolapse			0.75
0	28(19%)		
1	42(28%)		
2	56(37%)		
3	15(10%)		
4	10(6%)		
Stage of posterior vaginal prolapse			0.96
0	16(11%)		
1	19(12%)		
2	98(65%)		
3	18(12%)		

Table 3: Multivariate analysis for risk factors of detrusor overactivity.

	Odds ratio	95% confidence interval	P value
Frequency	1.46	0.64-3.34	0.37
Urgency	2.86	0.84-9.7	0.09
Urge incontinence	0.51	0.17-1.52	0.23
Nocturia	4.81	1.61-14.33	0.005

Table 4: Sensitivity, specificity, and predictive values for the DOS at different cut-off values.

Cut-off value	Sensitivity	Specificity	PPV	NPV
DOS>1	95%	21%	32%	92%
DOS>2	93%	34%	36%	93%
DOS>3	86%	46%	38%	90%
DOS>4	83%	52%	40%	90%
DOS>5	71%	61%	42%	84%
DOS>6	0%	100%	100%	72%

DOS: detrusor overactivity score, NPV: negative predictive value, PPV: positive predictive value.