Urodynamics less likely to change diagnosis and management in uncomplicated overactive bladder

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Introduction: *Given the invasive nature of urodynamics and its unclear impact on altering patient management, we aimed to determine whether performing a urodynamic study (UDS) resulted in a change in either patient diagnosis or treatment offered in women with uncomplicated urinary incontinence.*

Materials and methods: *A retrospective review was performed of all female patients who underwent UDS for urinary incontinence at our practice between January 2014 and 2017. Patients with neurogenic lower urinary tract dysfunction, incomplete emptying, urinary retention, or prior anti-incontinence surgery were excluded. We compared the ICD-10 diagnosis and primary treatment offered in the absence of UDS to their post-UDS diagnosis and recommended therapy. Descriptive statistics, chi-squared, and multivariable analyses were performed.*

Results: *A total of 141 patient charts were analyzed. The indications for UDS were mixed urinary incontinence (MUI) (45.3%), stress urinary incontinence (SUI) (29.1%), and overactive bladder (OAB) (25.5%). A change in diagnosis following UDS was seen in 40.4% of the entire cohort including 53.1% of patients with MUI and 48.8% of those with SUI compared to 8.3% of those with OAB. A change in treatment was seen in 32.6% of patients including 54.9% with MUI, 41.7% with SUI, and 10% with OAB. When compared to patients with SUI on adjusted multivariate logistic regression, those with OAB were less likely to have a change in either diagnosis (OR 0.06 (0.01-0.31)) or management (OR 0.15 (0.04-0.62)).*

Conclusions: *Diagnosis and management are unlikely to change after UDS in patients presenting with uncomplicated OAB. Conversely, UDS provided important diagnostic information that often changed management in those presenting with MUI and SUI. Our results suggest that UDS may be omitted in patients with uncomplicated refractory OAB in favor of earlier initiation of third line therapies.*

Key Words: urodynamics, overactive bladder

Introduction

Urodynamic studies (UDS) assess the pressure-flow relationship of the urethra and the bladder. They are often utilized in the diagnosis and management of lower urinary tract dysfunction. A major drawback of UDS is its invasive nature and potential for morbidity. In addition to possible risks of traumatic catheterization and urinary tract infection (UTI), the use of urethral and rectal catheters for the study can be very uncomfortable. UTI rates after UDS range from 4.3% to 12%, with as many as 34% experiencing irritative voiding symptoms.[1,2] The study also causes anxiety and distress, which are not alleviated by interventions like music or educational videos.[3] Furthermore, UDS comes at both a material and labor cost to physician practices and patients. Therefore, the utility of UDS must be balanced with the drawbacks of the test.

It is not clear whether UDS is always necessary for diagnosis and management. In a randomized controlled trial (RCT) comparing immediate surgery to a plan based on UDS, Van Leijsen et al concluded

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that an immediate mid-urethral sling in women with stress urinary incontinence (SUI) was not inferior to specialized treatment based on the UDS results.[4] Another RCT demonstrated a basic office assessment was not inferior to UDS in women with uncomplicated SUI.[5] These studies did not evaluate other indications for UDS aside from SUI. In contrast, a more recent study suggests that UDS is a clinically useful tool that can change the diagnosis and management of select patients. A questionnaire was given to clinicians before and after the UDS was performed. Only 285 out of 836 patients who underwent UDS during the study period were included (33% response rate) suggesting possible selection bias.[6] Therefore, the literature is still not clear on when UDS is necessary for diagnosis and management and when it can be avoided.

The objective of our study was to retrospectively evaluate female patients who underwent UDS for storage complaints (urinary incontinence, urgency, frequency) and evaluate whether the pre- and post-study diagnosis and treatment changed after UDS. We hypothesized that diagnosis and treatment would not change when UDS was performed for pure stress urinary incontinence or overactive bladder symptoms.

Materials and methods

This study is a retrospective review of female patients who underwent urodynamics at our urology and urogynecology practices. All women 18 years and older who underwent UDS between January 2014 and June 2017 were identified using CPT codes (51725-29) for UDS.

Demographic and clinical variables collected included age, race, history of diabetes mellitus, previous clinical visit with a female and pelvic medicine and reconstructive surgery (FPMRS) specialist, and indication for urodynamics. Women with urinary retention requiring an indwelling foley or clean intermittent catheterization, incomplete emptying with post-void residual > 150 mL, neurogenic lower urinary tract dysfunction (e.g. multiple sclerosis, cerebrovascular event, Parkinson's disease, spinal cord injury, etc.), and prior anti-incontinence surgery were excluded since UDS is usually advised in these cases. Women with a history of prior pelvic organ prolapse surgery were still included.

UDS

Urodynamics studies were performed according to International Continence Society (ICS) good practices.[7] We use a wireless urodynamics system with 7 Fr single sensor air-charged abdominal and bladder catheters. Females are evaluated in the seated position and males are evaluated in the standing position, except for those who are unable to stand for the duration of the study. Perineal pads are applied for electromyography measurements. Patients routinely perform non-intubated uroflowmetry first, after which the patient is catheterized to drain the bladder and check the post-void residual. The air-charged catheters and perineal pads are placed. The bladder is filled with sterile water at a fill-rate of 30 mL/min. This rate is decreased to 10-20 mL/min if detrusor overactivity is present. Once capacity is reached, the patient is permitted to void. If unable to void the urethral catheter is removed. If still unable to void, the patient is advised to void in the bathroom while measuring simple uroflowmetry. We do not have fluoroscopy in the office and therefore do not perform video urodynamics.

Change in diagnosis

Diagnosis prior to UDS was determined by the ICD-10 diagnosis code under which the UDS study was ordered. Diagnosis after UDS was determined from the UDS interpretation recorded by the physician. Indications for UDS included: stress urinary incontinence (SUI), overactive bladder (OAB) and mixed urinary incontinence (MUI). If the pre-UDS and post-UDS diagnosis differed, this was considered a change in diagnosis after UDS. If patients had symptoms fitting multiple diagnoses they were categorized based on their predominant symptom e.g. a woman complaining of urgency, frequency, and incomplete emptying but primarily bothered by urgency was categorized as OAB.

Change in treatment

Treatment prior to UDS was the option offered in the absence of urodynamic evaluation. For women with SUI demonstrated on physical exam, the next treatment offered would be pelvic floor physical therapy, a vaginal incontinence device, urethral bulking agent injection or stress incontinence surgery. For patients with OAB refractory to behavioral modification or medical therapy, the next treatment offered would be third line therapies for OAB such a intradetrusor botox injections or neuromodulation. For women with MUI, treatment would address the predominant bothersome component of urinary incontinence based on reported symptoms. If the primary therapy offered to the patient following UDS differed from that offered prior to UDS, this was considered a change in treatment. An FPMRS specialist reviewed each chart to determine whether there was a change in diagnosis and treatment plan after UDS.

Statistical analysis

Demographic variables and indication for UDS were summarized using descriptive statistics. Chi-square and Fischer's exact test were used to compare categorical variables, and t-test was used to compare numerical variables. A $p < 0.05$ was significant. Multivariable logistic regression was performed to evaluate the association of indication for UDS with change in diagnosis and management while adjusting for potential confounders. All statistical analysis was performed using STATA version 14.2 (StataCorp. 2015. College Station, TX, USA).

Results

Out of 233 women identified who underwent UDS, 92 were excluded: 25 were pediatric patients less than 18 years of age, 58 had neurogenic lower urinary tract dysfunction, and 9 had incomplete data or inability to locate UDS tracing. Twenty-four patients were lost to follow up after their urodynamics test and therefore change in management could not be determined. The mean age of the cohort was 59. Over half of the patients were Hispanic (58.2%), while 20.6% were African American, 12.1% White, and 9.2% identified with other races, and 16.2% had a history diabetes mellitus. The most common indication for UDS was MUI (45.3%), followed by SUI (29.1%) and OAB (25.5%), see Table 1. Thirty-seven studies were considered normal (no detrusor overactivity or incontinence on storage phase, good compliance, normal detrusor contractility and empting on voiding phase), of which 14 clinically reported MUI, 12 reported SUI, and 11 OAB prior to undergoing UDS.

Out of 105 women who reported SUI (40 with pure SUI, 65 with MUI), 56 (53.3%) did not have SUI on exam and therefore UDS was performed to demonstrate SUI. Nineteen (18.1%) women had SUI on exam but underwent UDS due to report of MUI symptoms. Twenty-nine (27.6%) women did not undergo examination (or exam findings were not documented) for SUI and were referred directly to UDS. Seventeen of these women reported mixed symptoms and may have been referred for UDS regardless. Twelve of the women reported pure SUI and may not have needed UDS if SUI had been demonstrated on exam. One woman had SUI on exam and underwent confirmatory UDS to evaluate leak point pressure.

A change in diagnosis after UDS was most commonly seen in patients with MUI (53.1%), followed by those with SUI (48.8%) while those undergoing the test for OAB rarely underwent a change in diagnosis (8.3%), see Table 1. A change in management following UDS occurred in 54.9% and 41.7% of patients with

TABLE 1. **Patient characteristics and change in diagnosis or management (n = 141)**

		Change in diagnosis?			Change in management?*		
Variable	**Total**	**Yes**	**No**	**p value**	**Yes**	**No**	**p value**
Mean age (SD)	59.2 (12.7)	59.8 (11.7)	58.9 (13.4)	0.692	58.8 (12.3)	59.1 (12.7)	0.871
Race/ethnicity (%)				0.256			0.042
African American	29 (20.6)	7 (24)	22 (76)		4 (17.4)	19 (82.6)	
Hispanic	82 (58.2)	38 (46.3)	44 (53.7)		28 (41.2)	40 (58.8)	
White	17 (12.1)	5 (29.4)	12 (70.6)		7 (50)	7 (50)	
Other	13 (9.2)	6 (46.2)	7 (53.8)		7 (58.3)	5 (41.7)	
Diabetes (%)	23 (16.2)	8 (34.8)	15 (65.2)	0.645	7 (36.8)	12 (63.2)	1.00
FPMRS specialist (%)	134 (94.4)	53 (39.6)	81 (60.4)	0.715	42 (38.5)	67 (61.5)	0.710
Indication for UDS (%)				< 0.001			< 0.001
Mixed urinary incontinence	64 (45.3)	34 (53.1)	30 (46.9)		28 (54.9)	23 (45.1)	
Overactive bladder	36 (25.5)	3 (8.3)	33 (91.7)		3 (10)	27 (90)	
Stress urinary incontinence	41 (29.1)	20 (48.8)	21 (51.2)		15 (41.7)	21 (58.3)	

UDS = urodynamics; FPMRS = female pelvic medicine and reconstructive surgery
*change in management unknown in 24 patients who had no additional follow up after UDS

TABLE 2. **Change in diagnosis after UDS**

Indication for UDS	Diagnosis after UDS				
	SUI	**OAB**	**MUI**	**Normal study**	**Other***
SUI	14 (41.2%)	5 (14.7%)	2 (5.9%)	12 (35.3%)	2 (2.9%)
OAB	0	27 (69.2%)	0	11 (28.2%)	1 (2.6%)
MUI	25 (36.8%)	12 (17.7%)	15 (22.1%)	14 (20.6%)	1 (2.9%)

UDS = urodynamics; SUI = stress urinary incontinence; OAB = overactive bladder; MUI = mixed urinary incontinence
*other diagnoses included bladder outlet obstruction and detrusor underactivity

MUI and SUI respectively and only occurred in 10% of patients with OAB. All of these differences were statistically significant, see Table 1. Changes in diagnoses following UDS by indication are listed in Table 2.

Multivariable logistic regression analysis was performed to compare UDS diagnosis and management outcomes. No significant changes were noted with regard to changes in diagnoses between patients of difference races. Black patients were significantly less likely to have a change in management (OR 0.21 ((0.05-0.95)). This difference was no longer statistically significant on adjusted analysis. A previous clinic visit with an FMPRS specialist had no significant impact on either changes in diagnosis or management. When compared to SUI, patients with OAB were significantly less likely to undergo a change in diagnosis (OR 0.06 (0.01-0.31)), as well as management (OR 0.15 (0.04-0.062)), see Table 3.

Discussion

The key finding of this study is that in our practice, diagnosis and management are unlikely to change after UDS in most patients presenting with uncomplicated OAB. The use of UDS to aid in treatment of OAB continues to be controversial. First, the UDS in many of these individuals may be normal. Digesu et al conducted a study to assess the utility of UDS in women with OAB symptoms and found that nearly 50% of patients did not have detrusor overactivity.[8] In a study by Varghese et al of 687 women with urge-predominant MUI and urgency-frequency who underwent UDS, 26% (n = 175) had a normal study.[9] In our study, 28.2% of patients with OAB had normal UDS. Second, demonstration of detrusor overactivity is not necessary to initiate pharmacotherapy treatment for OAB. Malone-Lee and Al-Buheissi found that in adult patients with urinary frequency and urgency, urodynamic findings (detrusor

TABLE 3. **Multivariable logistic regression comparing UDS diagnosis and management outcomes**

	Odds ratios (95% confidence interval)			
	Change in diagnosis (n = 141)		**Change in management (n = 117)**	
	Unadjusted	**Adjusted**	**Unadjusted**	**Adjusted**
Race/Ethnicity (vs. White)				
Black	0.80 (0.21-3.08)	1.09 (0.24-4.92)	0.21 (0.05-0.95)*	0.22 (0.04-1.21)
Hispanic	2.07 (0.67-6.42)	2.25 (0.66-7.69)	0.70 (0.22-2.22)	0.63 (0.18-2.23)
Other	2.06 (0.45-9.30)	2.57 (0.49-13.6)	1.40 (0.30-6.62)	1.90 (0.33-10.8)
Age	1.00 (0.98-1.03)	1.02 (0.98-1.05)	0.99 (0.97-1.03)	0.99 (0.97-1.03)
FPMRS specialist (vs. No)				
Yes	0.66 (0.16-2.76)	0.30 (0.05-1.88)	0.63 (0.15-2.64)	0.25 (0.04-1.39)
Indication for UDS (vs. SUI)				
OAB	0.09 (0.02-0.35)*	0.06 (0.01-0.31)*	0.16 (0.04-0.61)*	0.15 (0.04-0.62)*
MUI	1.10 (0.50-2.41)	1.26 (0.55-2.89)	1.70 (0.72-4.03)	1.81 (0.73-4.52)

UDS = urodynamics; FPMRS = female pelvic medicine and reconstructive surgery; SUI = stress urinary incontinence; OAB = overactive bladder; MUI = mixed urinary incontinence

overactivity on UDS versus negative UDS) did not predict treatment outcomes among patients randomized to tolterodine-ER versus placebo.[10] An additional study by Malone-Lee found that patients with OAB symptoms and normal UDS findings responded to oxybutynin antimuscarinic therapy plus bladder retraining equally well compared to patients whose symptoms were confirmed with UDS.[11]

On the other hand women with OAB may have other diagnoses that would only be uncovered after doing UDS. In the same study by Varghese et al, 14% (n = 92) were diagnosed with SUI alone. Women may have difficulty differentiating SUI from urge incontinence or OAB. Thus, if treated empirically for OAB, these women may not have noted improvement. Varghese et al concluded that UDS findings influenced treatment decisions and women with treatment plans tailored to UDS results were more likely to have symptomatic improvement. If the goal of UDS is to rule out concomitant or primary SUI, one could argue that a good physical exam both supine and standing, with the bladder full, would be able to do so.

A recent study by Suskind et al similarly looked at the value of UDS. They utilized a prospective questionnaire in which clinicians recorded pre- and post- UDS clinical impression and management plan. The most common indication for UDS was to distinguish the predominant type of urinary incontinence in patients presenting with mixed urinary incontinence symptoms. The authors concluded that UDS was a clinically useful tool that altered the clinical impression (46.4%) and treatment plan (42.5%) in a large percentage of their carefully selected patients. Contrary to our results, they reported a change in diagnosis in 22.4% of their patients undergoing UDS for OAB type symptoms.[6] An additional recent study by Malik et al prospectively evaluated 102 patients undergoing UDS, stratifying them as either neurogenic or non-neurogenic lower urinary tract symptoms. Their data showed a change in treatment plan in 78% of patients, a more substantial proportion than both the Suskind study and our own.[12]

The more selective utilization of UDS has several implications. There is avoidable morbidity associated with UDS. An often-cited issue that patients encounter before or during UDS is anxiety and discomfort, which multiple research teams have attempted to address. One group used pre-procedure music and educational videos to relax patients, but found that it did not alter or improve apprehensive feelings. Another team randomized patients to a phone call before the procedure versus no phone call, and found that patients who received the intervention did not have a decrease in anxiety.[13] It is difficult to attenuate this emotional reaction to a procedure that is inherently uncomfortable and anxiety-provoking. This is in addition to the risk of UTI and irritative voiding symptoms after UDS.

The economic burden of UDS is also significant. Goranitis et al, performed a model-based economic evaluation of the cost-effectiveness for bladder sonography versus clinical history versus UDS in women with OAB and urge predominant MUI. They concluded that UDS was most cost-effective when restricted to woman presenting with mixed urinary incontinence only. Additionally, the analysis concluded that treating women with a clinical history of overactive bladder without diagnostic testing was the most cost-effective method to address symptoms of uncomplicated overactive bladder.[14]

Even the ICS recognizes "that the disease management paradigm of LUTD is changing from "diagnosis—disease/dysfunction—treatment" to the paradigm: "symptoms and signs- presumed diagnosis/dysfunction—pragmatic management and if subsequently necessary: diagnosis—disease/dysfunction- further management," because of the newer interventions with lesser chance of potential harm".[7] UDS may not always be necessary for diagnosis and progression to treatment.

A major strength of this study was the inclusion of multiple indications for UDS among our patients. Past studies have primarily focused on SUI or MUI independently, but our study elucidates the utility of UDS for all storage symptoms. Additionally, this study avoided selection bias because all women (over 18 years) who underwent UDS at our practice were included. We recognize however, that patients generally referred for UDS may have more complex histories than those in whom UDS is not deemed necessary. Additionally, chart review was done by a clinician unrelated to the care of the patient. This helps reduce bias from self-responding clinicians who may feel more inclined to indicate a change in diagnosis/management in his or her own patients.

This study was limited by its patient demographics. This is a single institution study with a predominantly Hispanic and publicly insured population, which may limit generalizability to other patient populations and institutions. Additionally, the interpretation of the pre/post UDS diagnosis and management was performed by a physician unrelated to the patient case. Each clinician documents patient encounters differently, which leaves room for misinterpretation when a second party surveys the notes. Furthermore, there is potential for misclassification bias in patients with multiple diagnoses.

Our findings imply that UDS can be omitted in patients in our population with uncomplicated OAB refractory to behavioral modification and medical therapy, and that advanced therapies may be offered earlier. For patients with MUI and SUI, UDS appears to provide useful information that guides management and should be conducted on a case-by-case basis. The female urgency, trial of urodynamics as routine evaluation (FuTURE) is currently enrolling women with overactive bladder and randomizing them to clinical assessment or UDS to see if there is difference in bladder symptoms, quality of life, and satisfaction with treatment.[15] This trial will complete enrollment in 2021 and should provide further insight into this question.

Conclusions

Our study showed that diagnosis and management do not change after UDS in most patients presenting with uncomplicated refractory OAB in our practice. In contrast, UDS altered management in just over half of patients with MUI and greater than forty percent of patients with SUI. Our findings imply that UDS can be omitted in patients with uncomplicated refractory OAB in favor of earlier initiation of advanced therapies. □

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