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Preoperative Urodynamics in Women with Stress Urinary Incontinence Increases Physician Confidence, but Does Not Improve Outcomes

Philippe Zimmern, Heather Litman, Charles Nager, Larry Sirls, Steve Krauss, Kimberly Kenton, Tracey Wilson, Gary Sutkin, Nazema Siddiqui, Sandip Vasavada, and Peggy Norton

For the Urinary Incontinence Treatment Network

Abstract

Aims—To determine if pre-operative urodynamic testing (UDS) affects physicians' diagnostic confidence and if physician confidence affects treatment outcomes at 1 year.

Methods—The ValUE trial randomized 630 women with predominant stress urinary incontinence (SUI) to office evaluation (OE) or OE plus UDS prior to surgery. After OE, physicians completed a checklist of 5 clinical diagnoses: SUI, overactive bladder (OAB) wet and dry, voiding dysfunction (VD), and intrinsic sphincter deficiency (ISD), and reported their confidence in each. Responses ranged from 1 to 5 with; 1 = "not very confident (<50%)" to 5 = "extremely confident (95+%)". After UDS, investigators again rated their confidence in these 5 clinical diagnoses. Logistic regression analysis correlated physician confidence in diagnosis with treatment success.

Results—Of 315 women who received OE plus UDS, 294 had complete data. Confidence improved after UDS in patients with baseline SUI (4.52 to 4.63, $p < 0.005$), OAB wet (3.55 to 3.75, $p < 0.001$), OAB dry (3.55 to 3.68 $p < 0.005$), VD (3.81 to 3.95, $p < 0.005$), and suspected ISD (3.63 to 3.92, $p < 0.001$). Increased confidence after UDS was not associated with higher odds of treatment success although mean changes in confidence were slightly higher for those who achieved treatment success. Physician diagnoses shifted more from not confident to confident for ISD and OAB wet after UDS. (McNemar's p value < 0.001 for both).

Conclusions—In women undergoing UDS for predominant SUI, UDS increased physicians' confidence in their clinical diagnoses; however, this did not correlate with treatment success.

Introduction

The number of SUI surgeries has markedly increased over the past 20 years¹ Between 2000 and 2009 the rate of SUI surgery increased by 27%² corresponding to the widespread adoption of the mid urethral sling procedure initially introduced by Ulmsten in 1997³. The recently published Value of Urodynamic Evaluation (ValUE) study confirmed that in a group of women with no previous incontinence surgery, dominant stress incontinence symptoms, demonstrable stress incontinence on office evaluation, and a normal post-void residual office evaluation alone was not inferior to evaluation with urodynamic testing (UDS) and did not compromise surgical SUI treatment success⁴. Yet, despite the demonstration of SUI during office evaluation, many clinicians perform preoperative multichannel UDS. Although preoperative UDS do not impact surgical outcome, their

findings may aid in the diagnosis of detrusor overactivity, neurogenic bladder, intrinsic sphincter deficiency, and voiding dysfunction. These findings may affect the surgeon's confidence in the diagnosis of SUI, may influence the choice of anti-incontinence surgical procedure, may allow the surgeon to make intraoperative modifications to the procedure, or may influence the postoperative care of the patient.

Our objective was to determine if pre-operative UDS affects physicians' diagnostic confidence and if physician confidence affects treatment outcomes at 1 year. We hypothesized that UDS results would increase physician confidence and improve outcomes.

Methods

Study Design

This is a planned secondary analysis of women in the Value of Urodynamic Evaluation (ValUE) study, an 11-center, randomized non-inferiority trial that compared subjects who underwent an office evaluation with or without urodynamic testing (UDS) before planned surgery for SUI. Details of the ValUE trial and results of the primary outcomes are published^{4, 5}. The ValUE primary outcome was to assess treatment success, defined as a 70% decrease in Urinary Distress Inventory (UDI) score from baseline to the 12 month visit and patient response of "much better" or "very much better" to the Patient Global Impression of Improvement (PGI-I) at 12 months.^{6, 7} Secondary outcome measures included responses to the Incontinence Severity Index (ISI)⁸, the Incontinence Impact questionnaire (IIQ)⁶, Medical Epidemiologic Social Aspects of Aging (MESA)⁹ and the Patient Global Impression Index of Severity (PGI-S)⁷ as well as a bladder stress test. Inclusion criterion included: age ≥ 21 years old with at least a 3-month history of SUI, SUI score greater than urgency urinary incontinence (UII) score on the MESA questionnaire, urinary incontinence demonstrated on a provocative bladder stress test at any volume, a post void residual (PVR) less than 150 ml, a negative urinalysis or urine culture, and a desire for SUI surgery. Exclusion criteria included previous incontinence surgery, history of pelvic radiation, history of pelvic surgery within the last 3 months and anterior or apical pelvic organ prolapse $> +1$ cm. All participants provided written informed consent. The protocol was approved by the IRB at each site and monitored by an independent data safety and monitoring board.

Urodynamics

Three hundred fifteen women randomized to receive urodynamics were included in this analysis. These women underwent noninvasive uroflowmetry, and filling cystometrogram with valsalva leak point pressure followed by pressure flow study. Urethral pressure profilometry studies were optional and performed by the study surgeon if this was his/her normal practice. The characterization of intrinsic sphincter deficiency as well as all the other parameters (voiding phase dysfunction, OAB-dry, OAB-wet) was self-defined by the surgeon. Procedural details of UDS testing and interpretation of results conformed to the International Continence Society's Good Urodynamic Practice and Standardized Terminology guidelines.^{10, 11}

Confidence Evaluation

All subjects underwent office evaluation after which investigators completed a comprehensive checklist of 5 clinical diagnoses (SUI, overactive bladder (OAB)-wet, OAB-dry, voiding phase dysfunction (VPD), suspected intrinsic sphincter deficiency (ISD)) (Figure 1) and reported their confidence in each diagnosis. Confidence was reported based on the range 1–5, with 1 = "not very confident (<50%)", 2 = "somewhat confident (50–74%)", 3 = "moderately confident (75–84%)", 4 = "very confident (85–94%) and 5

= "extremely confident (95+ %). After UDS was completed, the investigator reviewed the UDS results and then completed the same checklist of diagnoses again rating their level of confidence in each diagnosis selected (Figure 1).

Statistics

Paired t tests were used to compare mean confidence levels before and after UDS for each diagnosis. The differences in scores were assessed for normality. Logistic regression modeling was used to investigate whether increasing confidence in diagnosis (defined as mean change in confidence scores before and after UDS) was associated with a better primary outcome. For ease of interpretation, least squares means from linear regression models predicting the change in confidence scores, with success status as an independent variable, were also presented. McNemar's test was also used to compare pre and post UDS confidence as a dichotomous variable where "confident" was defined as "very confident" or "extremely confident" versus all other groups (denoted as "not confident"). Positive predictive value (PPV) [to answer the question: if a physician was confident pre-UDS, what are the chances that the physician was confident post-UDS?], and negative predictive value (NPV) [to answer the question: if a physician was not confident pre-UDS, what are the chances that the physician was still not confident post-UDS?] were presented as well, with "highly confident" defined as "very or extremely confident", and "less confident" being all the other groups. A 5% two-sided significance level was used for statistical testing. All statistical analyses were performed using SAS version 9.2.

Results

Of 315 women in the UDS arm, 307 received UDS and were included in the baseline analysis. Of these, 293 had complete data for pre and post UDS confidence scores. Clinical diagnosis scores both before and after UDS were high on the 5-point scale, particularly for SUI where mean (SD) was 4.52 (0.55) before UDS and 4.63 (0.60) after UDS. Median time interval between pre and post UDS was 21 days (25th percentile 8 days, 75th percentile 40 days). Table 1 shows physician confidence in clinical diagnosis before and after UDS. The second hypothesis was to investigate whether increased confidence after UDS was associated with better SUI treatment success. Table 2 indicates a trend in confidence scores which are larger for those who achieved success at the 12 month visit as indicated by the odds ratios for success being greater than 1, but none of the differences reached statistical significance. Table 2 also presents the mean change in confidence scores between pre and post UDS for those who succeeded compared to those who failed to improve after SUI surgery. This also indicates a trend towards larger changes in confidence scores among those who experienced treatment success; however, none of the differences reached statistical significance.

We also investigated whether change in confidence levels after UDS was associated with better secondary outcomes (e.g. change in UDI score, MESA urge score, ISI score, IIQ score, and PGI-S score, as well as PGI-I score, satisfaction and stress test at the 12 month visit). These analyses did not reveal any systematic relationships between increasing confidence and better secondary outcomes (results not reported).

Changes in physician diagnostic rating after UDS showed increased confidence for all diagnoses except SUI (Table 3). After UDS, nearly 70% of physicians who changed their diagnosis of OAB wet and ISD reported increased confidence. PPV values ranged from 63.3% for ISD to 98.6% for SUI, while NPV values ranged from 22.2% for SUI to 71.0% for OAB wet (Table 4).

Discussion

The ValUE trial showed that preoperative office evaluation alone did not result in inferior surgical treatment outcomes compared to office evaluation plus UDS in women with predominant SUI⁴. Yet, this secondary analysis suggests that UDS still increased physician confidence in many clinical diagnoses. Women whose surgeons reported increased confidence in their diagnosis after UDS did not have improved surgical outcomes compared to women who did not have UDS or to women who had UDS but whose surgeons did not report increased confidence.

Physician confidence after office evaluation may be influenced by patient history including the extent of urgency symptoms, demographic data such as age and BMI, symptom severity or pad use and the presence of urethral hypermobility or a positive stress test on physical examination. In clinical practice, UDS is often performed to confirm SUI, to evaluate urethral function for suspected ISD, and to assess bladder filling and voiding pressures. Possibly because of the expertise of the physicians in this study, and the criteria for enrollment (women with no previous incontinence surgery, dominant stress incontinence symptoms, demonstrable stress incontinence on office evaluation, and a normal post-void residual), confidence scores in all clinical diagnosis were skewed upward at baseline and after UDS testing.

Since a positive stress test was an inclusion criterion for this study, it is logical that physicians reported their highest level of confidence in the diagnosis of SUI after office evaluation (“very confident” or “extremely confident”) with little increase in confidence after UDS. Interestingly, the greatest increase in physician confidence after UDS was the diagnosis of ISD, although physicians remained only “moderately confident” and varied considerably. The variability in physician confidence when diagnosing ISD even after UDS may reflect that no standardized or agreed upon definition for ISD exists. While some surgeons consider valsalva leak point pressures and maximum urethral closure pressures when making a diagnosis of ISD, evidence for a discrete cut-off value associated with surgical outcomes is lacking^{12–14}.

After office evaluation, physicians were least confident in their diagnosis of OAB dry and OAB wet, at “moderately confident”. The common presence of OAB symptoms in patients presenting for SUI surgery¹⁵ is reinforced by the office-based diagnosis of OAB in more than 1/3 of patients in ValUE⁴. The increased confidence after UDS to diagnose OAB dry and wet is not surprising since OAB is a clinical diagnosis based on symptoms of urinary frequency, urgency, and UI, and there are almost no objective measures. The presence of detrusor overactivity during urodynamics would be expected to improve confidence in the clinical diagnosis of OAB and indeed it did. But physicians are also aware of the poor sensitivity of UDS to confirm urge incontinence with detrusor overactivity¹⁶. In fact, detrusor overactivity was infrequently observed during UDS in this study. Why experienced UITN investigators would increase their confidence in the diagnosis of OAB, and decrease the incidence of OAB diagnoses after UDS is unclear. The non-validated instrument we used to capture physician confidence before and after UDS may have contributed to this variability.

We previously demonstrated that voiding phase dysfunction on preoperative UDS does not predict bladder outlet obstruction or post operative voiding dysfunction after SUI surgery¹⁷, but many surgeons are still influenced by voiding phase data, perhaps believing that bladder outlet obstruction is one of the most modifiable outcomes. Even with experienced UITN investigators, a normal UDS voiding phase appears to improve physician confidence over

their opinion based on the combination of clinical and demographic data, physical exam and post void residual volume.

A limitation of our study is that this study was designed prior to the publication of the IUGA/ICS Joint Report on the Terminology for Female Pelvic Floor Dysfunction which describes Overactive Bladder as a syndrome and not a clinical diagnosis as it was described in this study. We would have used the IUGA/ICS definitions if they had been published prior to implementation and it is possible our results could have been different.¹⁸

Though statistically significant, the changes in confidence that we observed were small, and there is no literature or experience to tell us whether these changes are clinically significant. Lack of clinical significance may explain why increased physician confidence was not associated with improved patient outcome in this study. The relative homogeneity of this stress predominant hypermobile population may also limit the influence of UDS on physician confidence and on patient outcome, although these urinary characteristics were similar to those patients in TOMUS. The findings are applicable to evaluation by clinicians experienced in the evaluation and treatment of UI.

Conclusion

For women enrolled in the ValUE study, UDS increased physician confidence in all of their clinical diagnoses, although this confidence was not associated with improved surgical outcomes. UDS influenced physicians to change the clinical diagnosis of ISD and voiding dysfunction from not confident to confident. However, improved physician confidence did not lead to better surgical outcomes.

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Based on your clinical evaluation, circle "Yes" or "No" for whether you think the patient has this clinical diagnosis.			For every "Yes" or "No" response, please rate how confident (sure) you are about the presence or absence of this clinical diagnosis.				
	Yes	No	Not Very Confident (<50%)	Somewhat Confident (50-74%)	Moderately Confident (75-84%)	Very Confident (85-94%)	Extremely Confident (≥ 95%)
B1. Stress urinary incontinence	1	2	1	2	3	4	5
B2. OAB with incontinence (or OAB-wet, Urge Incontinence)	1	2	1	2	3	4	5
B3. OAB without incontinence (or OAB-dry, Urgency/Frequently syndrome)	1	2	1	2	3	4	5
B4. Voiding phase dysfunction (Emptying Problems)	1	2	1	2	3	4	5
B5. Suspected intrinsic sphincter deficiency (ISD)	1	2	1	2	3	4	5

Overall, how confident are you that you have made the best treatment plan for this subject? Please circle one. **NOTE: This question is not about the efficacy of the treatment itself.**

Not Very Confident (<50%)	Somewhat Confident (50-74%)	Moderately Confident (75-84%)	Very Confident (85-94%)	Extremely Confident (≥ 95%)
1	2	3	4	5

NOTE: TO BE COMPLETED AFTER FORM 505 (URODYNAMIC DATA) AND WITHOUT REVIEWING FORM 514 (BASELINE SURGEON DIAGNOSIS AND TREATMENT)

Based on your clinical evaluation which now includes the additional urodynamic diagnostic testing, circle "Yes" or "No" for whether you think the patient has this clinical diagnosis.	For every "Yes" or "No" response, please rate how confident (sure) you are about the presence or absence of this clinical diagnosis.
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Figure 1.

Table 1

Confidence scores in clinical diagnosis before and after UDS.

Confidence scores in clinical diagnosis	n	Before UDS Mean (SD)	n	After UDS Mean (SD)	Difference (after – before) in confidence scores Mean (SD)	p-value
Stress urinary incontinence (SUI)	315	4.52 (0.55)	293	4.63 (0.60)	0.12 (0.65)	0.002
Overactive bladder (OAB)-wet	313	3.55 (0.89)	293	3.75 (0.88)	0.23 (1.05)	<0.001
OAB-dry	315	3.55 (0.87)	293	3.68 (0.83)	0.17 (1.02)	0.005
Voiding phase dysfunction (VPD)	312	3.81 (0.87)	292	3.95 (0.84)	0.17 (1.03)	0.005
Suspected intrinsic sphincter deficiency (ISD)	312	3.63 (1.04)	293	3.92 (0.85)	0.32 (1.17)	<0.001

Table 2

Odds ratios and Mean change in confidence scores (least squares means) between pre and post UDS for those who succeeded vs. failed

Variable	OR (95% CI)	p-value	Mean change in confidence scores for those having success*	Mean change in confidence scores for those having failure
Stress urinary incontinence (SUI)	1.29 (0.83, 2.02)	0.26	0.12	0.02
Overactive bladder (OAB) Wet	1.10 (0.83, 1.45)	0.52	0.23	0.13
OAB Dry	1.16 (0.87, 1.54)	0.31	0.17	0.02
Voiding phase dysfunction (VPD)	1.23 (0.93, 1.62)	0.15	0.24	0.02
Suspected intrinsic sphincter deficiency (ISD)	1.13 (0.88, 1.45)	0.34	0.35	0.18

* Success is defined as a 70% decrease in UDI score from baseline to the 12 month visit and a score of “very much better” or “much better” on the PGI-I at the 12 month visit.

Table 3

Change in confidence status before and after UDS.

Variable	Number confident after UDS but not before UDS	Number discordant (either confident before UDS and not after UDS or vice versa)	Percent confident after UDS but not before UDS as a proportion of number discordant	p-value from McNemar's test
SUI	4	11	36.4%	0.37
OAB wet	65	96	67.7%	<0.001
OAB dry	63	107	58.9%	0.07
VPD	51	85	60.0%	0.07
ISD	77	111	69.4%	<0.001

Table 4

Positive and negative predictive values comparing confidence pre- and post-UDS for each variable.

SUI:				
		Post		
		Highly confident	Less confident	
Pre	Highly confident	280	7	287
	Less confident	4	2	6
		284	9	293
PPV: 280/284 = 98.6%; NPV: 2/9 = 22.2%				
OAB wet:				
		Post		
		Highly confident	Less confident	
Pre	Highly confident	120	31	151
	Less confident	65	76	141
		185	107	292
PPV: 120/185 = 64.9%; NPV = 76/107 = 71.0%				
OAB Dry:				
		Post		
		Highly confident	Less confident	
Pre	Highly confident	113	44	157
	Less confident	63	73	136
		176	117	293
PPV: 113/176 = 64.2%; NPV = 73/117 = 62.4%				
VPD:				
		Post		
		Highly confident	Less confident	
Pre	Highly confident	159	34	193
	Less confident	51	46	97
		210	80	290
PPV: 159/210 = 75.7%; NPV = 46/80 = 57.5%				

SUI:				
ISD:				
		Post		
		Highly confident	Less confident	
Pre	Highly confident	133	34	167
	Less confident	77	47	124
		210	81	291
PPV: 133/210 = 63.3%; NPV = 47/81 = 58.0%				