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The Effect of Urodynamic Testing on Clinical Diagnosis, Treatment Plan and Outcomes In Women Undergoing Stress Urinary Incontinence Surgery

Larry T. Sirls, MD¹, Holly E. Richter, PhD, MD², Heather J. Litman, PhD³, Kimberly Kenton, MD, MS⁴, Gary E. Lemack, MD⁵, Emily S. Lukacz, MD⁶, Stephen R. Kraus, MD⁷, Howard B. Goldman, MD⁸, Alison Weidner, MD⁹, Leslie Rickey, MD¹⁰, Peggy Norton, MD¹¹, Halina M. Zyczynski, MD¹², John W. Kusek, PhD¹³, and for the Urinary Incontinence Treatment Network

¹William Beaumont Hospital, Royal Oak, MI

²University of Alabama at Birmingham

³New England Research Institutes, Watertown, MA

⁴Loyola University Chicago, IL

⁵the University of Texas Southwestern Medical Center, Dallas

⁶University of California at San Diego

⁷University of Texas, San Antonio

⁸Cleveland Clinic, Cleveland, OH

⁹Duke University, Durham NC

¹⁰University of Maryland Baltimore, Baltimore

¹¹University of Utah, Salt Lake City

¹²University of Pittsburgh, Magee–Womens Hospital, Pittsburgh

¹³National Institutes of Health, Bethesda, MD

Abstract

Purpose—To evaluate the influence of pre-operative urodynamic studies (UDS) on diagnoses, global treatment plan and outcomes in women having surgery for uncomplicated stress predominant urinary incontinence (SUI).

Materials & Methods—Secondary analysis from a multicenter, randomized trial of the value of preoperative UDS. Physicians provided pre- and post-UDS diagnoses and global treatment plans, defined as proceeding with surgery, surgery type, surgical modification, non-surgical therapy. Treatment plan changes and surgical outcomes between office evaluation (OE) and OE plus UDS were compared by McNemar's test.

Results—294 of 315 subjects randomized to UDS after OE had evaluable data. UDS changed the OE diagnoses in 167 women (56.8%), decreasing the diagnoses of OAB-wet (41.6% to 25.2%, $p < 0.001$), OAB-dry (31.4% to 20.8%, $p = 0.002$) and intrinsic sphincter deficiency (ISD) (19.4% to 12.6%, $p = 0.003$) but increasing the diagnosis of voiding dysfunction (2.2% to 11.9%, $p < 0.001$). After UDS, physicians cancelled surgery in 4/294 (1.4%), changed the incontinence procedure in 13/294 (4.4%), and planned to modify the midurethral sling tension (“more or less obstructive”) in 20/294 women (6.8%). Non-surgical treatment plans changed in 40/294 (14%). UDS driven treatment plan changes were not associated with treatment success (OR, 0.96 (0.41, 2.25), $p = 0.92$), but were associated with increased postoperative treatment for urge UI (OR 3.23, 95% CI 1.46, 7.14), $p = 0.004$).

Conclusions—UDS significantly changed clinical diagnoses and global treatment plan but infrequently influenced surgeon decision to cancel, change or modify surgical plans. Global treatment plan changes were associated with increased treatment for post operative urgency UI.

Keywords

urodynamic studies; office evaluation; stress urinary incontinence; midurethral sling; surgical outcomes; clinical diagnosis

Introduction

Urodynamic studies (UDS) are often performed before stress urinary incontinence (SUI) surgery despite absence of data that their findings alter surgical plans or improve outcomes. A Cochrane Review concluded that UDS may change clinical decision making, but there is insufficient evidence that UDS lead to better clinical outcomes¹.

Organizations including the International Urogynecological Association Guidelines for Research and Practice, and the Royal College of Obstetrics and Gynecology recommend UDS prior to surgery for SUI. However, the National Institute for Health and Clinical Excellence in the U.K. states that UDS “is not routinely recommended before surgery in women with a clearly defined clinical diagnosis of pure SUI”². Some called this report “unwise” noting that only 5% of patients with UI had pure SUI, and a quarter of them have other urodynamic diagnoses³. However, 80% of Dutch gynecologists and urologists would operate on a patient with a positive stress test regardless of the UDS findings, and only 9% indicated that they may change the sling type based on urethral pressure measures⁴.

The ValUE study reported 12-month outcomes in women with uncomplicated stress predominant UI planning surgery and showed that women with office evaluation (OE) alone had non-inferior outcomes compared to those undergoing OE plus UDS⁵. This secondary analysis of the ValUE trial, reports on the subgroup of women randomized to UDS after OE to evaluate the effect of UDS on clinical diagnoses, global treatment plan, and patient outcomes.

Methods

STUDY DESIGN AND OVERSIGHT

ValUE was a multicenter, randomized trial of 630 women whose design and methods have been reported⁶. Briefly, women had a standardized OE (provocative stress test, postvoid residual volume (PVR) and urine dipstick) after which surgeons provided a diagnosis, “global treatment plan” including any of the following: proceed with surgery, define type of surgery, proceed with or add a non-surgical treatment plan (pharmacotherapy, pelvic floor physical therapy, other), and any planned modifications to the surgery (tension “more obstructive” or “less obstructive”). Women randomized to UDS had their data reviewed by the surgeon, who again defined a global treatment plan that may modify any component of the original plan. Surgeons reported which UDS finding changed the global treatment plan and after surgery if the surgery was performed, if the procedure was changed and/or if the procedure was modified. In this study we evaluate whether UDS changed clinical decision-making in the selection / performance of SUI surgery, the addition of non-surgical treatment and whether these changes altered the primary outcome, post-operative voiding dysfunction or urgency UI. A successful outcome was defined as a 70% reduction in the UDI⁷ score from baseline to 12 months and a PGI-I⁸ score of “very much better” or “much better” at 12 months⁵.

Briefly, ValUE inclusion criterion included: age>21 years, minimum 3-month history of SUI, a MESA SUI score greater than urgency UI score⁹, positive stress test at any volume, a PVR<150 ml, and a desire for SUI surgery. Exclusion criteria included previous UI surgery, pelvic radiation, pelvic surgery within the last 3 months, and anterior or apical pelvic organ prolapse +1 cm. All participants provided written informed consent. IRB approval was obtained at each site.

STUDY PROCEDURES AND MEASURES

After OE investigators completed a clinical diagnosis and treatment plan. Subjects randomized to UDS had a non-invasive uroflow, filling cystometry with absolute or relative valsalva leak point pressure (VLPP) and/or maximum urethral closure pressure (MUCP), and a pressure flow study (PFS). UDS data and interpretation were recorded on a separate form using ICS definitions¹⁰. Suspected “intrinsic sphincter deficiency (ISD)” was self-defined by the surgeon. After UDS, investigators completed another clinical diagnosis and global treatment plan, whether UDS influenced their treatment plan, and if so, which components of UDS influenced the plan..

Variables selected *a priori* for potential association with clinical diagnosis change were: demographic (age, race), medical/surgery factors (BMI, duration of UI, parity, menopausal/HRT status, prior pelvic surgery), physical examination (urethral hypermobility, PVR)and UDS event categories of “filling phase” [maximum cystometric capacity (MCC) detrusor overactivity (DO)], “measures of urethral function” (VLPP, MUCP), “voiding phase” (free uroflow and pressure / flow data and patterns) and absence of urodynamic stress incontinence (USI).

STATISTICAL ANALYSIS

Descriptive statistics of the clinical diagnosis variables were reported. McNemar's test compared differences between pre-UDS and post-UDS measures. The UDS event categories are not mutually exclusive. Multivariable logistic regression models were fit to predict clinical diagnosis considering variables listed above, to characterize UDS event categories and other clinico-demographic findings that changed "global treatment plan," describe efficacy outcomes and impact on post-operative urgency UI in women who had a change in their "global treatment" plan compared to those that did not. Predictors with p-values less than 0.05 in separate single predictor logistic regression models were placed in a preliminary multivariable model; p-values less than 0.05 in this preliminary model were included in the final multivariable model. Odds ratios (ORs) and 95% confidence intervals (CIs) describe associations between clinical parameters and outcomes. A 5% two-sided significance level was used for statistical testing. No formal adjustment to the individual alpha levels for multiple comparisons were made, thus caution should be used interpreting results. Analyses were performed with SAS statistical software, version 9.2 (SAS Institute, Cary, NC).

Results

Diagnoses

Three hundred and fifteen subjects randomized to UDS underwent an OE, 307 completed UDS and 294 had complete data on clinical diagnosis and treatment plan. Clinical and demographic characteristics are described in the primary paper⁵. After UDS the clinical diagnoses changed in 167 (56.8%) women reflecting decreases in OAB-wet, OAB-dry, ISD diagnoses and increased the diagnosis of voiding dysfunction (Table 1).

Single predictor logistic regression models determined what clinico-demographic, physical examination and/or UDS factors were associated with a change in clinical diagnosis (n=167, SUI, OAB-wet, OAB-dry, ISD, "filling phase", urethral function" and "voiding phase" events) compared to those without a change (n=127). Age per 10 year units (OR 1.28, 95% CI 1.02, 1.60), BMI per 5 units (OR 1.39, 95% CI 1.13, 1.71) menopausal not on HRT (OR 1.95, 95% CI 1.17, 3.26) and "voiding phase" events (OR 4.91, 95% CI 1.65, 14.58) were associated with a diagnosis change. In multivariate analysis, BMI and "voiding phase" events continued to be contributory in the model of clinical diagnosis change with multiple exploratory variables.

Treatment

Surgical and non-surgical treatment plans before and after UDS (Table 2) show that 40/294 (14%) had a change in planned post-operative non-surgical treatment, 4/294 (1.4%) surgeries were cancelled, 3/294 (1%) surgeries changed from MUS to non-MUS or vice versa, and 13/294 (4.2%) changed from one MUS to the other MUS.

UDS-driven change in "global treatment plan" was reported in 41/294 (14%) patients: planned surgical modification (n=18), additional non-surgical therapy (n=14), cancelled surgery with additional non-surgical therapy (n=3), surgical modification with additional

non-surgical therapy (n=2), switched sling type (n=2), switched sling type with additional non-surgical therapy (n=1), and cancelled surgery with no additional therapy (n=1).

Surgeons reported 24 planned surgery modifications (tension "more obstructive" or "less obstructive") after OE and UDS, 20 of which were UDS driven. Eighteen of the UDS driven planned modifications were "less obstructive", 1 was "more obstructive", and 1 was unknown. However, in only 7 of the 20 women was the planned surgery actually performed, and these were all "less obstructive".

Surgeons reported specific UDS event type (filling phase, measures of urethral function, voiding phase) that changed their "global treatment plan" in 29 of the 41 patients identifying a total of 75 separate UDS "events". Most events were in the voiding phase yet all events influenced change to the "global treatment plan" (Table 3). Though only 7/294 (2.4%) women had no USI on UDS, 5/7 (71.4%) had their treatment plan changed: 1 TMUS "less obstructive", 1 RMUS with additional non-surgical therapy and 3 had surgery cancelled for initial non-surgical therapy.

Outcomes

Change in global treatment plan after UDS was not associated with successful treatment outcome (OR, 0.96 (0.41, 2.25), $p = 0.92$). Although most treatment plan changes were based on voiding phase events, women with a global treatment plan change did not have an increased odds of self-voiding at discharge (OR 0.89 (0.41, 1.94), $p = 0.76$), or a decreased odds of treatment for voiding dysfunction at the 3 or 12 month visit (OR 1.39 (0.59, 3.31), $p = 0.45$). Fewer women with UDS voiding dysfunction met the primary outcome (18/29, 62.1%) than did women without UDS voiding dysfunction (180/230, 78.3%), but this did not reach statistical significance ($p=0.064$). Women with a global treatment plan change did have increased odds of treatment for urgency UI at 3 or 12 months post-operatively (OR 3.23 (1.46, 7.14), $p = 0.004$).

The 20 patients with UDS driven planned sling tension modification had similar odds of self-voiding at discharge (OR 0.79 (0.29, 2.14), $p=0.64$) and treatment for voiding dysfunction at 3 or 12 months (OR 1.82 (0.61, 5.43), $p=0.28$) as the entire cohort. In addition, the 7 women whose surgeons reported performing a sling modification (all "less obstructive") had similar odds of self-voiding at discharge ($p=0.62$) and treatment for voiding dysfunction at the 3 or the 12 month visit ($p=0.25$) as the 11 women whose surgeons planned but did not performing a less obstructive sling.

Discussion

The ValUE study showed that the addition of preoperative UDS in the evaluation of women with uncomplicated stress predominant UI did not change the treatment outcome over a baseline OE.⁵ This secondary analysis showed that UDS after OE commonly changed the clinical diagnosis (57%) yet infrequently changed the global treatment plan (14%) or influenced physicians to cancel (1.4%), change (5.4%) or modify (6.8%) the planned surgery. Women who had a UDS driven change in their treatment plan did not have improved outcomes compared to women who did not have a treatment plan change.

UDS decreased the OE based diagnoses of OAB-wet and dry, and ISD, and increased the diagnosis of voiding dysfunction. Others have shown that UDS influences physicians to change their clinical diagnosis.^{11,12} In a study of 42 women randomized to UDS, 26% had their diagnosis changed from the general practitioner's initial diagnosis,¹¹ lower than the diagnosis change noted (56%) here. Their lower rate may reflect their inclusion of women with any type of incontinence and use of filling phase data without voiding phase data. OAB and ISD were the most common diagnoses changed by UDS in our study, but voiding phase events most commonly changed the treatment plan. Clinicians often consider the clinical, demographic and UDS data as integrated pieces of the diagnostic puzzle. This comprehensive thought process was confirmed by our finding that increasing BMI and UDS voiding phase events were significantly associated with a change in clinical diagnosis. A decrease in the diagnosis of OAB is surprising since this clinical diagnosis is based on symptoms of urinary frequency, urgency and urgency UI. The common observation of OAB in patients presenting for SUI surgery¹³ is reinforced by the OE-based diagnosis of OAB in over 40% of patients in this study. However, UDS has poor sensitivity for detrusor overactivity¹⁴, and why experienced investigators in this study would reduce their clinical diagnosis of OAB by 1/3 after UDS is unclear. The non-validated instrument used to capture the physicians' diagnosis before and after UDS may contribute to this variability.

We wondered whether the decrease in the diagnosis of ISD after UDS was secondary to the subjective definition of ISD on clinical examination. Clinicians likely base the OE diagnosis of ISD on subjective variables including the degree of hypermobility and the observer's opinion of the amount or severity of urine leakage. If UDS testing demonstrated higher VLPP or MUCP, surgeons may have reconsidered the original diagnosis. We further evaluated this OE-based ISD subgroup and found no difference in urethral hypermobility, severity of SUI by questionnaire, or in VLPP or MUCP versus those without OE-based suspected ISD. In fact, patients with suspected ISD on OE had less self reported UI severity on PGI-S⁸ than those without suspected ISD (data not shown).

The increase in the diagnosis of voiding dysfunction following UDS may be explained by heightened attention to flow curves and pressure flow data. Retrospective studies have shown that preoperative voiding dysfunction may predispose to obstructive voiding after pubovaginal sling or failure of surgery with low quality of life scores after TVT.^{15,16} Data from the SISTEr trial showed that preoperative UDS did not predict post-operative voiding function after Burch colposuspension or pubovaginal sling, suggesting that in women at low risk for voiding problems, pressure flow data should not influence surgical technique.¹⁷ However, physicians may feel that potential obstructive voiding after surgery is one of the most modifiable outcomes, often requiring re-intervention, and pay close attention to the non-invasive uroflow and pressure flow data. In this study UDS voiding phase events were the most common reason cited by physicians for modification of surgical approach with nearly all planned modifications to make the surgery "less obstructive". Importantly, this UDS driven surgical modification did not influence the rate of self-voiding at discharge, subsequent treatment for voiding dysfunction or treatment efficacy rates. Therefore, women with SUI who are neurologically normal and have no prior UI surgery or prolapse should be at low risk for post-operative obstructed voiding.

Despite the high rate of clinical diagnosis change after UDS, and that UDS data on bladder filling, urethral function, absence of USI and voiding dysfunction had a significant effect on global treatment plan, surgery was infrequently canceled or actually modified. Interestingly, the majority of the planned procedure changes occurred between the two MUS procedures. As the TOMUS study showing the TMUS and RMUS procedures have similar success rates had not yet been published,¹⁸ the change from one MUS to another likely reflected physician bias on the efficacy and complications of each MUS. The only outcome associated with women who underwent a UDS-driven treatment plan change was an increased odds of treatment for urgency UI at 3 and 12 months. We examined this subgroup to determine whether these women had clinical, demographic or UDS findings associated with increased risk of postoperative OAB. Only the absence of USI was associated with postoperative treatment for urgency UI. No USI, even in patients who had a positive stress test, may heighten the clinicians' concern for post operative urgency UI and may prompt counsel and treatment planning for urgency UI prior to or after surgery.

The strengths of this study are its multicenter, large sample, randomized design, with standardized UDS and experienced surgeons. Limitations include a failure to understand the outcomes for patients who did not have their procedures altered by the UDS.

Conclusion

In women with uncomplicated stress predominant UI planning surgery, UDS information commonly changed the clinical diagnosis; however, infrequently changed the global treatment plan or influenced the surgeon to cancel, change or modify the initial surgical plan. The increased diagnosis of voiding dysfunction did not change the surgical treatment plan and did not influence post-operative urinary symptoms or treatment outcomes. Women undergoing a UDS-driven treatment plan change was associated with a greater likelihood of them having additional post-operative treatment for urgency UI.

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Table 1

Clinical Diagnoses After Office Examination (OE) and After Urodynamics (UDS)

Clinical diagnosis*	After OE N (%)	After OE (of those with UDS assessments) N (%)	After OE and UDS N (%)	P- value**
SUI	315/315 (100%)	294/294 (100%)	292/294 (99.3%)	>0.99
OAB-wet	131/315 (41.6%)	124/294 (42.2%)	74/294 (25.2%)	<0.001
OAB-dry	99/315 (31.4%)	90/294 (30.6%)	61/294 (20.8%)	0.002
Voiding phase dysfunction	7/315 (2.2%)	7/294 (2.4%)	35/294 (11.9%)	<0.001
Suspected intrinsic sphincter deficiency (ISD)	61/314 (19.4%)	57/293 (19.5%)	36/293 (12.3%)	0.003

* A woman could have more than one clinical diagnosis.

** P value from McNemar's test calculated on those with UDS assessments.

Table 2

Summary of Surgical and Non-surgical Treatment Plan After Office Evaluation (OE) and After UDS.

	After OE	After OE and UDS
Planned surgical treatment*		
RMUS	206/315 (65.4%)	192/289 (66.4%)
TMUS	86/315 (27.3%)	78/289 (27.0%)
Mini-sling	8/315 (2.5%)	7/289 (2.4%)
Fascial pubovaginal sling	11/315 (3.5%)	9/289 (3.1%)
Retropubic urethropexy	1/315 (0.3%)	0
Urethral bulking injection	3/315 (1.0%)	3/289 (1.0%)
Additional non-surgical treatment planned after BOE	52/315 (16.5%)**	40/294 (13.6%)***
Pharmacotherapy	29/50 (58%)	25/39 (64.1%)
Pelvic floor therapy	27/51 (52.9%)	19/39 (48.7%)
Other	13/51 (25.5%)	14/38 (36.8%)
Specific UDS driven changes to surgical plan		
Surgery Cancelled		4/294 (1.4%)
Surgical procedure changed		16/294 (5.4%)
RMUS to TMUS		8
TMUS to RMUS		5
RMUS to fascial PVS		1
Fascial PVS to RMUS		1
Retropubic urethropexy to RMUS		1

* 315 patients had surgical treatment plan after OE, 294 patients had complete data after OE and UDS and 289 had surgical treatment plan after OE and UDS (4 surgeries cancelled, 1 had no data).

** 28 patients had additional non surgical treatment planned after OE that was changed to no additional treatment after UDS.

*** 20 patients had UDS driven additional non surgical treatment plans that had not been planned after OE

Table 3

Summary of UDS test findings (“events”) that changed the global treatment plan*

UDS Variable	Number of UDS events that changed the treatment plan (75 events in 41 patients)
Voiding phase events	44/75 (59%)
Free uroflowmetry pattern	8/28
Free uroflowmetry numerical values (e.g. Qmax, voided volume, PVR)	5/29
Pressure flow study voiding pattern	16/28
Voiding phase diagnosis	15/28
Filling phase events	7/75 (23%)
Sensation	6/29
Maximum cystometric capacity	7/29
Detrusor function during filling	4/29
Measures of Urethral Function	14/75 (19%)
Urethral closure mechanism	3/29
Valsalva leak point pressure (VLPP)	10/29
Maximum urethral closure pressure (MUCP)	1 yes, 24 no, 4 not applicable

* Note that in only 29 of the 41 patients did the surgeon specifically identify the UDS finding that influenced their treatment plan. Since more than one UDS event can occur per patient there is a total of 75 events.