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THE EFFECT OF URODYNAMIC TESTING ON CLINICAL DIAGNOSIS, TREATMENT PLAN AND OUTCOMES IN WOMEN UNDERGOING STRESS URINARY INCONTINENCE SURGERY

Hypothesis / aims of study

Pre-operative urodynamic studies (UDS) are often performed before stress urinary incontinence (SUI) surgery although their value in altering surgical plans or outcomes is not established. We report a planned secondary analysis of a subgroup of women enrolled in the Value of Urodynamic Evaluation (ValUE) trial randomized to UDS after Office Evaluation (OE) to evaluate the effect of UDS on change in diagnosis, modification of treatment (surgical / non-surgical), and patient reported outcomes.

Study design, materials and methods

The ValUE study was a multicentre randomized trial of pre-operative UDS in 630 women undergoing surgery for SUI. Value primary outcomes were 70% reduction in the UDI score from baseline to 12 months and a PGI-I score of "very much better" or "much better" at 12 months (1). After OE, surgeons recorded a clinical diagnosis and treatment plan and women randomized to UDS had a non-invasive uroflow, filling cystometry with optional absolute or relative valsalva leak point pressure (VLPP) and/or maximum urethral closure pressure (MUCP), and a pressure flow study (PFS). The control group had no UDS. Study surgeons reported findings and interpretation of the UDS according to ICS definitions. "Suspected intrinsic sphincter deficiency (ISD)" was self-defined by individual surgeons. Change in global treatment plan was defined as change in any of the following: decision to proceed with surgery, type of surgery, planned modification to the surgery or addition of non-surgical treatment. We evaluated a range of baseline factors for association with clinical diagnosis change including age, race, medical/surgery data (BMI, duration of UI, parity, menopausal/HRT status, prior pelvic surgery), physical examination (urethral hypermobility), PVR and UDS measures (maximum cystometric capacity (MCC), VLPP, detrusor overactivity (DO) and urodynamic stress incontinence (USI). Multivariable logistic regression models were fit to predict variables associated with clinical diagnosis change to characterize UDS and other clinico-demographic findings associated with change in treatment plan and compare outcomes in women who did and did not have a change in their treatment plan. Women with a treatment plan change were also evaluated for clinical, demographic or UDS findings associated with the risk of post-operative urgency UI. Odds ratios (ORs) and 95% confidence intervals (CIs) describe associations between clinical parameters and outcomes.

Results

Of the 315 subjects who underwent an OE and randomized to the UDS arm, 307 completed UDS and 294 (93%) had complete data on diagnosis and treatment plan. Mean age was 51±10.5 years and most were over-weight (mean BMI 29.3) and Caucasian (77.5%). The interpretation of UDS resulted in a change in the original OE diagnoses in 167 women (57%), Table 1. In multivariate analysis, only BMI was independently associated with a diagnosis change. A change in the global treatment plan after UDS was reported in 41/294 (14%) patients. Summary of surgical and non-surgical treatment plans based on OE alone and OE with UDS are reported in Table 2. Surgeons reported the actual UDS findings that influenced their "global treatment plan" in 29 of 41 patients identifying 75 discrete UDS findings (Table 3). Among these findings, only the absence of USI (OR, 95% CI: 17.4 (3.26, 93.2), p<0.001) was associated with a change in the "global treatment plan". Change in global treatment plan after UDS was not associated with primary surgical outcome (OR, 0.96 (0.41, 2.25), p = 0.92), but was associated with increased odds of treatment for urgency UI at 3 or 12 months post-operatively (OR 3.23 (1.46, 7.14), p = 0.004).

Table 1. Clinical diagnosis based on OE alone and OE with UDS.

Clinical diagnosis*	After OE N (%)	After OE with UDS N (%)	
SUI	315/315 (100%)	292/294 (99.3%)	>0.99
OAB-wet	131/315 (41.6%)	74/294 (25.2%)	<0.001
OAB-dry	99/315 (31.4%)	61/294 (20.8%)	0.002
Voiding phase dysfunction	7/315 (2.2%)	35/294 (11.9%)	<0.001
Suspected intrinsic sphincter deficiency (ISD)	61/314 (19.4%)	37/294 (12.6%)	0.003

P-value McNemar's test *A woman could have more than one clinical diagnosis.

Table 2. Summary of surgical and non-surgical treatment plan after OE and then 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%)
Traditional 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 OE Pharmacotherapy	52/315 (16.5%)** 29/50 (58%)	40/294 (13.6%)*** 25/39 (64.1%)

Pelvic floor therapy Other	27/51 (52.9%) 13/51 (25.5%)	19/39 (48.7%) 14/38 (36.8%)
Specific UDS driven changes to surgical plan		
Surgery Cancelled		4/294 (1.4%)
Surgical procedure changed RMUS to TMUS TMUS to RMUS RMUS to fascial PVS Fascial PVS to RMUS Retropubic urethropexy to RMUS		16/294 (5.4%) 8 5 1 1 1

*315 patients had planned surgical treatment after OE, 294 patients had complete data after OE and UDS and 289 had planned surgery 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 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 Free uroflowmetry pattern Free uroflowmetry numerical values (e.g. Qmax, voided volume, PVR) Pressure flow study voiding pattern Voiding phase diagnosis	44/75 (59%) 8/28 5/29 16/28 15/28
Filling phase events Sensation Maximum cystometric capacity Detrusor function during filling	17/75 (23%) 6/29 7/29 4/29
Measures of Urethral Function Urethral closure mechanism Valsalva leak point pressure (VLPP) Maximum urethral closure pressure (MUCP)	14/75 (19%) 3/29 10/29 1 yes, 24 no, 4 not applicable

Interpretation of results

UDS changed the OE diagnoses in most women, decreasing the diagnoses of OAB-wet, OAB-dry and ISD and increasing the diagnosis of voiding dysfunction. Despite this, surgeons rarely cancelled or changed the surgical plan. UDS driven treatment plan changes were not associated with surgical success but were associated with increased post-operative treatment for urgency UI. The increased diagnosis of voiding dysfunction did not change the treatment plan and did not influence post-operative obstructive voiding or surgical outcomes. UDS treatment plan change was only associated with a greater likelihood of having additional post-operative treatment for urgency UI.

Concluding message

Although preoperative UDS may alter urologic diagnoses in women undergoing surgery for uncomplicated SUI, they rarely influence the surgical plan and do not improve postoperative outcomes.

References

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Disclosures

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