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PREOPERATIVE URODYNAMICS IN WOMEN WITH PREDOMINANT STRESS URINARY INCONTINENCE INCREASES PHYSICIAN CONFIDENCE, BUT CONFIDENCE INCREASE IS NOT ASSOCIATED WITH BETTER OUTCOMES.

Hypothesis / aims of study

To determine if pre-operative urodynamic testing (UDS) effects physicians' diagnostic confidence and treatment outcomes at one year.

Study design, materials and methods

ValUE trial randomized 630 women with predominant stress urinary incontinence (SUI) to preoperative office evaluation (OE) or OE plus UDS prior to surgery (1). After OE, physicians completed a comprehensive check list of 5 clinical diagnoses and reported their confidence in each of these 5 clinical diagnoses. Subjects randomized to UDS had non-invasive uroflow, filling cystometry with Valsalva leak point pressure determination attempts and a pressure flow study. Urethral Profilometry studies were optional. UDS data and interpretation were recorded using ICS definitions and "suspected intrinsic sphincter deficiency (ISD)" was self-defined by the surgeon. Responses ranged from 1 to 5 with; 1 =being "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, investigators again rated how confident they were using the same scales as above for those same five clinical diagnoses (See Table 1).

Paired t tests were used to compare mean confidence levels before and after UDS for each diagnosis. McNemar's test was used to compare pre and post UDS dichotomous confidence variable where confident was defined as = "very confident" or "extremely confident" versus not confident. To investigate whether increasing confidence led to better outcomes, logistic regression modelling was used to predict primary outcome (70% decrease in UDI score from baseline to the 12 month visit and a score of 1 "very much better or 2 "much better" on the PGI-I at the 12 month visit) before and after UDS. For ease of interpretation, least squares means from linear regression models predicting change in confidence scores, with success status as an independent variable, were also analyzed. A 5% two-sided significance level was used for statistical testing.

Results

Of 315 women in the UDS arm, 307 received UDS. 294 had complete data for pre and post UDS confidence scores. Because of the expertise of the physicians and the criteria for enrolment (stress-predominant urinary incontinence), the clinical diagnosis scores were skewed at baseline and after UDS testing. 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, with a small, but statistically significant increase in confidence after UDS for all clinical diagnoses.

Confidence in clinical diagnosis	n	Confidence in clinical diagnosis before UDS (mean/SD)	n	Confidence in clinical diagnosis after UDS (mean/SD)	Difference (after – before) in confidence scores (mean/SD)	p-value
SUI	315	4.52 (0.55)	293	4.63 (0.60)	0.12 (0.65)	0.002
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	312	3.81 (0.87)	292	3.95 (0.84)	0.17 (1.03)	0.005
dysfunction						
Suspected ISD	312	3.63 (1.04)	293	3.92 (0.85)	0.32 (1.17)	<0.001

Table 1: Confidence in clinical diagnosis before and after UDS.

Table 2 indicates a trend in confidence scores which are larger for those who achieved success at the 12 month visit, but none of the differences reach statistical significance. There was more shift from not confident to confident than towards decreasing confidence for key parameters like ISD or voiding dysfunction after surgery (McNemar's p value=0.07 for VPD and <0.001 for ISD).

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 in ValUE	Mean change in confidence scores for those having failure in ValUE
SUI	1.29 (0.83, 2.02)	0.26	0.12	0.02
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
VPD	1.23 (0.93, 1.62)	0.15	0.24	0.02
ISD	1.13 (0.88, 1.45)	0.34	0.35	0.18

Interpretation of results

For women enrolled in the ValUE study, UDS increased physicians' confidence in their clinical diagnoses. However, improved confidence did not lead to better primary outcome. An increase in shift from not confident to confident was noted for ISD and voiding phase dysfunction variables.

Concluding message

UDS improves physician confidence in their clinical diagnoses in women with predominant SUI planning surgery. This change in confidence was not associated with improved treatment success.

References

1. Nager CW, Brubaker L, Daneshgari F, Litman HJ, Dandreo KJ, Sirls L, et al. Design of the Value of Urodynamic Evaluation (ValUE) trial: A non-inferiority randomized trial of preoperative urodynamic investigations. Contemp Clin Trials. 2009;30(6):531-9. Epub 2009/07/29.

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