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Kirby A C[1], Nager C W[1], Litman H J[2], FitzGerald M P[3], Kraus S[4], Norton P[5], Sirls L[6], Rickey L[7], Wilson T[8], Dandreo K J[2], Zimmern P[9], For the UIT N[10]

1. *University of California, San Diego,* ***2.*** *New England Research Institute,* ***3.*** *Loyola University Medical Center,* ***4.*** *University of Texas Health Sciences Center,* ***5.*** *University of Utah Health Sciences Center,* ***6.*** *Beaumont Hospital Medical Center,* ***7.*** *University of Maryland,* ***8.*** *University of Alabama at Birmingham,* ***9.*** *University of Texas Southwestern,* ***10.*** *NIH/NIDDK*

PREOPERATIVE VOIDING DETRUSOR PRESSURES AND STRESS INCONTINENCE SURGERY OUTCOMES

Hypothesis / aims of study

The purpose of this study was to determine whether preoperative voiding detrusor pressures could predict overall success, stress-specific success, detrusor overactivity (DO), or treatment for postoperative urge urinary incontinence (UUI) in patients who underwent surgery for stress urinary incontinence (SUI).

Study design, materials and methods

Six hundred fifty-five women with pure or predominant SUI were enrolled in a multicenter surgical trial and were randomized to undergo Burch or autologous fascia sling procedures.[1] Preoperative free uroflowmetry, filling cystometry, and pressure flow studies (PFS) were performed in all women using a standardized urodynamic protocol.[2] Opening detrusor pressure (ODP), detrusor pressure at maximum flow (p_{det} at Qmax), closing detrusor pressure (CDP), and the presence or absence of voiding after-contractions were assessed from the valid PFS signals in a secondary analysis. We defined ODP and CDP as the detrusor pressure 1 second prior to onset of flow and 1 second prior to cessation of flow, respectively. Preoperative voiding detrusor pressures (ODP, p_{det} at Qmax, and CDP) were compared between subjects with overall success, stress-specific success, and postoperative detrusor overactivity (DO) and those without. Preoperative voiding detrusor pressures and the presence of after-contractions in subjects who were treated postoperatively for UUI were compared to those not treated postoperatively for UUI. Studies were not included if baseline measures did not meet our pre-determined plausibility criteria, if pressure measures were not properly functioning during the entire fill and flow, and if there was not 70% pressure transmission agreement in cough-induced abdominal and vesical pressure measure spikes prior to voiding. Overall success was defined as no self-reported SUI symptoms, negative 24-hour pad test (defined as less than 15 grams urine), no incontinence on a 3-day diary, negative provocative standardized 300 ml stress test, and no re-treatment for SUI 24 months after surgery. Stress-specific success was defined as no self-reported SUI symptoms, a negative stress test, and no SUI re-treatment. Treatment of postoperative UUI was defined as treatment of clinically diagnosed new-onset or persistent UUI after the 6-week follow-up visit with any clinically acceptable treatment for OAB. This parameter was assessed at 3, 6, 12, 18 and 24 months.[3] Independent sample t-tests were used to test for differences in ODP, p_{det} at Qmax, and CDP by overall and stress-specific success status, postoperative detrusor overactivity status, and treated UUI status. Pearson chi-square tests were used to test for the relationship between categorical variables (e.g. after-contractions).

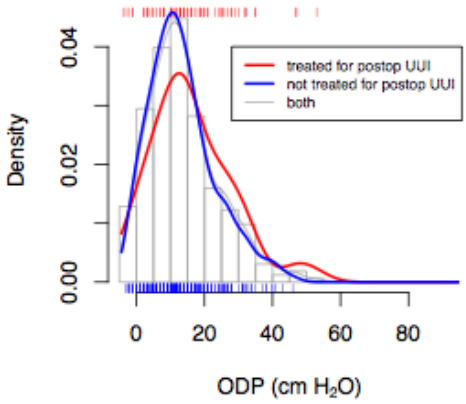
Results

Of the 520 subjects with evaluable overall success status, 260 had valid preoperative voiding detrusor pressures; of the 543 subjects with evaluable stress-specific success, 268 had valid preoperative voiding detrusor pressures; and of the 655 subjects evaluated for urge incontinence postoperatively, 326 had valid preoperative voiding detrusor pressures.

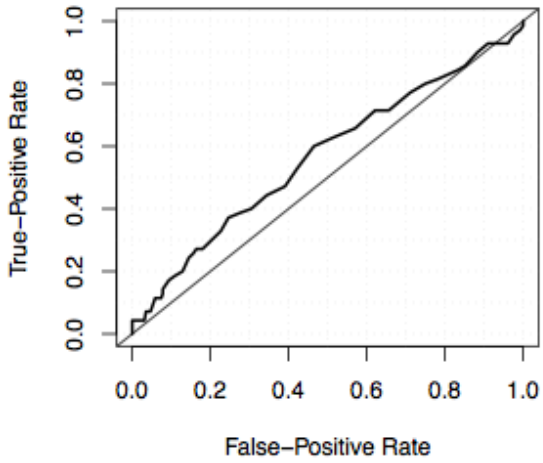
Of the subjects with valid preoperative voiding detrusor pressures, 95 of 260 (36.5%) had overall success at 24 months, 132 of 268 (49.3%) had stress-specific success and 70 of 326 (21.5%) were treated for UUI postoperatively. Mean ODPs were 3 cm H_2O lower in subjects with overall success (11.3 vs 14.5, $p = 0.01$) and in subjects with stress-specific success (12.2 vs. 14.8, $p = 0.041$). Subjects treated for UUI had a mean ODP 3 cm H_2O higher than the subjects not requiring treatment for UUI (16.1 vs 13.4, $p = 0.047$). Histogram and receiver operator characteristic (ROC) curve analysis demonstrate that these small group differences are not predictive; Figure 1 shows the histogram and ROC curve for postoperative UUI. Of subjects with valid preoperative and postoperative urodynamic studies (UDS), 19 of 221 (8.6%) had postoperative de novo DO, and there was no significant difference in mean ODP in patients with and without DO (11.3 vs. 13.3, p=0.39). There were no significant differences in p_{det} at Qmax or CDP in any comparison above. There was no difference in after-contraction rates in the groups of subjects who were (24%) and were not treated (21%) for postoperative UUI ($p = 0.65$).

Figure 1: Histogram (A) and ROC Curve (B) for ODP and treatment for postoperative UUI.

A



B



Interpretation of results

In this analysis of preoperative urodynamic data from a large stress incontinence surgery trial, we did not find that preoperative voiding detrusor pressures (ODP, p_{det} at Qmax, or CDP) could be used clinically to predict which patients would have overall success, stress-specific success, postoperative DO, or treatment for UUI after SUI surgery. Specifically, although ODPs were statistically lower among subjects who had overall success and stress-specific success and higher among subjects treated for postoperative UUI, the 3 cm H_20 mean difference between groups is small and not clinically meaningful. The overlapping histograms and receiver operator curve in Figure 1 clearly demonstrate the absence of a threshold value and therefore the lack of predictive value. There were no statistical or clinical differences between overall success, stress-specific success, postoperative DO, or treatment for postoperative UUI for Pdet at Qmax or CDP. We find no evidence that these two detrusor values (p_{det} at Qmax, and CDP) provide any predictive or prognostic value in women with predominant SUI undergoing SUI surgery. There was no difference in the prevalence of after-contractions when we compared those who received treatment for postoperative UUI to those who did not, so the significance of this urodynamic finding is still not understood. The strengths of this study include the large subject population, multiple sites which improve generalizability, and our standardized UDS quality control process. We acknowledge that this quality control process resulted in the exclusion of a large number of urodynamic studies (especially the pressure-flow studies which are the most prone to quality challenges), but we think this a priori quality control process strengthens rather than weakens our results and conclusions.

Concluding message

We find no evidence to recommend recording preoperative voiding detrusor pressure values in patients with stress dominant urinary incontinence at low risk for voiding dysfunction undergoing urodynamic evaluation before surgical intervention.

References

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**ClinicalTrials.gov number, NCT00064662**
Is this a Randomised Controlled Trial (RCT)?	**Yes**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**All study procedures were approved by the institutional review board of each participating clinical center and the Biostatistical Coordinating Center.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**