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VALSALVA LEAK POINT PRESSURE AND DETRUSOR OVERACTIVITY DO NOT PREDICT, BUT URODYNAMIC STRESS INCONTINENCE DOES PREDICT CONTINENCE OUTCOMES AFTER BURCH OR PUBOVAGINAL SLING PROCEDURES

Hypothesis / aims of study

To determine if preoperative urodynamic parameters predict surgical outcomes. Specifically we examined: 1) whether Valsalva leak point pressure (VLPP) measures differed in success or failure outcome groups and, 2) whether subjects with detrusor overactivity (DO) or urodynamic stress incontinence (USI) had success rates different than those subjects without DO or USI.

Study design, materials and methods

In a 9- center surgical trial, women with stress urinary incontinence (SUI) were randomized to a Burch or autologous fascia pubovaginal sling procedure and followed for 24 months post-surgery. The primary aim of the study was to compare the procedures, but a secondary aim was to determine if urodynamic parameters predicted continence outcomes. Women were eligible for the study if they had predominant SUI symptoms of > 3 months duration, a positive cough stress test at a bladder volume of $\leq$300 ml, a bladder capacity >200 ml, and urethral hypermobility defined as >30^{o} angle on a cotton swab test. USI was not required for study inclusion. Preoperative free uroflowmetry, filling cystometry, and pressure flow studies were performed in all women using a standardized research protocol that followed ICS recommended Good Urodynamic Practice Guidelines. Cystometry studies were performed at a fill rate of 50 ml/min with subjects in the standing position using $\leq$8 French dual lumen bladder catheters, fluid–filled rectal balloon catheters and external fluid transducers. Three VLPP measures were performed at 200mL or at 100 ml filling increments until leakage was seen. If leakage did not occur during Valsalva attempts, a cough was performed at maximum cystometric capacity (MCC) to establish whether USI was present. For VLPP data inclusion, the subject had to leak at least twice at the same volume and have properly functioning, plausible measuring systems (i.e. >80% agreement between p_{ves} and p_{abd} during the Valsalva maneuver). For each subject, the lowest VLPP ($VLPP_{min}$) and the average ($VLPP_{avg}$) were recorded. VLPP's are reported as actual vesical pressures (p_{ves}), with atmospheric pressure as the reference. The diagnoses of USI, DO and Detrusor Overactivity Incontinence (DOI) complied with ICS definitions. Surgeons were not blinded to the urodynamic data. "Overall" treatment success required a negative pad test (<15 mL/24 hrs), no urinary incontinence on a 3-day diary, a negative stress test, no self-reported SUI symptoms and no re-treatment for SUI. "Stress-specific" success required all of the last 3 criteria. The association of VLPP and success, controlling for treatment group, was compared using the analysis of variance (ANOVA). A Mantel-Haenszel chi-square test was used to assess the relationship between DO and USI with success, controlling for treatment assignment.

Results

655 women were randomized (326 sling, 329 Burch) and 520 (80%) completed 24 month overall outcome assessment. As reported previously (1), cumulative success rates were significantly higher for women randomized to the sling vs. the Burch for both overall (p=0.01) and stress-specific success (p<0.001) All 655 women had filling cystometry (CMG) performed. Five hundred ninety six (596) subjects met the inclusion criteria for CMG baseline pressure data. 21 leaked only after prolapse reduction (not included in VLPP data), 86 leaked only with cough at MCC and 60 subjects (10%) did not demonstrate USI (No USI group). Four hundred twenty eight (428) subjects leaked at least twice during Valsalva maneuvers and met VLPP plausibility criteria. The presence or absence of detrusor overactivity was reported for 645 patients, of whom 585 (91%) patients had no DO; 36 (6%) had DOI, and 24 (4%) had DO without leakage

VLPP- Table 1- Mean $VLPP_{avg}$ in cm H_2O (s.d) by surgical procedure and treatment outcome.

Surgical Procedure	Overall Success	Overall Failure	Stress-specific success	Stress-specific failure
Burch	**115**(40) n=57	**115** (37) n=104	**116** (40) n=80	**114** (37) n=87
Pubovaginal sling	**117** (33) n=71	**121** (39) n=105	**117**(34) n=109	**125** (41) n=72

Mean VLPP did not differ significantly by treatment outcome when stratified by treatment assignment (p>0.20 for all tests). Calculations with $VLPP_{min}$ produced similar results (data not shown).

DO- Of the 645 women with DO status available, 514 had overall outcome data and 536 had stress-specific outcome data. Of the 60 women with DO, 46 had overall outcome data and 49 had stress-specific outcome data.

Table 2- Percentage of subjects with successful outcomes for the No DO and DO groups

	No DO	**DO**	Odds ratio (95% C.I)

Overall success	**36%** (171/468)	**28%** (13/46)	1.46 (0.75 -2.85)
Stress-specific success	**53%** (257/487)	**47%** (23/49)	1.26 (0.70 -2.28)

When stratified by treatment assignment the differences in overall or stress-specific success rates for No DO and DO groups were not statistically different.

USI- Of 644 women with USI status available, 511 had overall outcome data and 534 had stress-specific outcome data. Of the 60 women without USI, 47 had overall outcome data and 50 had stress-specific data.

Table 3A- Percentage of subjects with successful outcomes for the USI and No USI groups

	USI	**No USI**	Odds ratio (95% C.I)
Overall success	**37%** (171/464)	**19%** (9/47)	2.46 (1.16 - 5.22)
Stress-specific success	**53%** (257/484)	**40%** (20/50)	1.7 (0.94 - 3.07)

Of the 47 subjects with No USI and overall success outcome data available, only 4 subjects had DO. When stratified by treatment assignment there was a significant difference in overall success rates for the USI and no USI groups, but differences in stress-specific rates did not reach statistical significance.

Interpretation of results

Our data suggest that VLPP does not predict surgical outcomes after Burch or pubovaginal sling procedures in women with predominant stress urinary incontinence and urethral hypermobility. These data, combined with our earlier findings that VLPP does not correlate with other measures of severity, suggests that the assessment of VLPP has limited clinical utility for patients similar to our cohort undergoing these procedures.

Preoperative DO was uncommon (10%) in this group of women with predominant SUI and was not significantly associated with overall or stress specific success rates. Even though our measures for overall success included a pad test and diary which should capture urge incontinence events, the difference in success rates was only 8 percentage points and unlikely to be clinically meaningful.

USI is present in 90% of women who met a set of clinical eligibility criteria for the treatment of SUI. The 10% of women without USI had a statistically significant lower overall success rate and a trend toward a lower stress-specific success rate than those with USI. The lower success rates are not explained by higher rates of DO. Further analysis is underway to try to understand the differences noted in success rates between the USI and no USI group.

Concluding message

In women with SUI and urethral hypermobility, the measurement of VLPP is not prognostic of outcomes nor should it serve as selection criterion for the Burch or sling procedures. In carefully selected women with stress predominant symptoms and a positive cough stress test, detrusor overactivity is uncommon and poorly predicts Burch or sling surgical failure. The lack of urodynamic confirmation of stress incontinence is uncommon, but does appear to predict inferior overall success rates for these procedures in this cohort.

References

(1) New England Journal of Medicine (accepted for publication March 26,2007)

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