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## NON-INVASIVE UROFLOWMETRY AND FILLING CYSTOMETRY VALUES IN A LARGE COHORT OF WOMEN UNDERGOING SURGERY FOR PURE OR PREDOMINANT STRESS URINARY INCONTINENCE

### Hypothesis / aims of study

To establish plausibility and quality control parameters for preoperative urodynamic studies in women undergoing surgery for pure or predominant stress incontinence by describing non-invasive uroflowmetry (NIF) and filling cystometry (CMG) values in a large cohort of women from nine U.S. centers.

### Study design, materials and methods

655 women with pure or predominant stress incontinence were enrolled in a multi-center surgical trial and were randomized to undergo Burch or autologous fascial sling procedures. A postvoid residual >150 mL in patients without prolapse was an exclusion criteria for study participation. Preoperative NIF and CMG studies were performed in all women using a standardized protocol, a standardized script for ICS defined bladder sensation parameters, and standardized interpretation guidelines. Filling cystometry studies were performed with subjects in the standing position using fluid filled catheters and fluid-filled external transducers. Valsalva Leak Point Pressures (VLPP) were reported as actual vesical pressure (Pves); atmospheric pressure is the reference. VLPP measures were first attempted at 200mL and then repeated at 100mL intervals until leakage occurred or until maximum cystometric capacity (MCC). If leakage did not occur during Valsalva attempts, a cough stress test was performed at MCC to establish if urodynamic stress incontinence was present. 64 Subjects with  $\geq$  Stage 3 anterior prolapse had VLPP measures also attempted after prolapse reduction but only unreduced VLPP values are included in this analysis. Inclusion criteria for the NIF study included a void of at least 150 mL, and recorded values for maximum flow rate, average flow rate, time to maximum flow, voided volume, and postvoid residual (PVR). Inclusion criteria for CMG baseline pressure data included: a) legible signals, b) system zeroed to atmosphere at start of study, and c) properly functioning Pves and abdominal pressure (Pabd) measuring system at CMG baseline. CMG studies were then considered plausible for Valsalva Leak Point Pressure (VLPP) analysis and subsequent pressure measurements only if detrusor pressure (Pdet) at CMG baseline was between -5 and +10 cm. Compliance was calculated as  $MCC / (P@MCC - P@baseline)$ . 25 vesical and 43 detrusor compliance calculations had a zero denominator and in these instances the denominator was changed to the number 1 so that compliance calculations were not infinity.

### Results

The study subjects had a mean age of 51, with a range of 27 to 81 years.

NIF- 582 subjects met NIF study inclusion criteria. The distribution of NIF data was skewed to the right for each parameter and is best described by the median (50<sup>th</sup> percentile) and percentiles shown in Table 1.

Table 1- NIF parameters (N = 582)

	5 <sup>th</sup> percentile	25 <sup>th</sup> percentile	<b>50<sup>th</sup> percentile</b>	75 <sup>th</sup> percentile	95 <sup>th</sup> percentile
Qmax (mL/s)	11.4	17.5	<b>23.6</b>	32.0	45.6
Qmean (mL/s)	4.9	8.6	<b>12.3</b>	16.8	24.8
Time to Peak Flow (s)	3.0	5.4	<b>8.0</b>	14.0	31.0
Voided Vol.(mL)	165	218	<b>283</b>	347	563
PVR (mL)	0.0	5.0	<b>10.0</b>	30.0	90.0

CMG- 585 subjects met CMG baseline pressure inclusion criteria and 567 met subsequent plausibility screening. 422 had at least 2 VLPP measurements, 19 leaked only after prolapse reduction (not included), 69 leaked only with cough at MCC, and 57 did not demonstrate urodynamic stress incontinence. For each patient, VLPP measurements were reproducible - 50% of subjects had a VLPP intra-patient range of  $\leq 15$  cm H<sub>2</sub>O.

Table 2- CMG pressure values (cm H<sub>2</sub>O)

	Pves baseline (n=585)	Pabd baseline (n=585)	Pdet baseline (n=585)	Pves MCC (n=562)	Pabd MCC (n=562)	Pdet MCC (n=562)	VLPP Min. (n=422)	VLPP Avg (n=422)
Mean (S.D)	37 (12)	35 (12)	2 (4)	44 (13)	38 (13)	6 (7)	107 (37)	117 (38)
2.5 %ile	14	12	-4	19	14	-7	49	55
97.5 %ile	58	60	8	69	63	22	185	199

Table 3- Bladder sensation parameters (mL) and compliance calculations (mL/cm H<sub>2</sub>O)

	1 <sup>st</sup> desire (n=633)	Strong desire (n=632)	MCC (n=631)	Vesical Compliance (n=562)	Detrusor (n=562)	Compliance
Median	123	236	364	49	58	
2.5 %ile	30	67	200	-200	-393	
97.5%ile	385	600	750	433	493	

574 (91%) patients had no detrusor overactivity, 34 (5%) had detrusor overactivity incontinence, and 24 (4%) had detrusor overactivity without leakage.

Interpretation of results

95 % of this sample of women undergoing surgery for pure or predominant stress incontinence had NIF maximum urinary flow rates > 11 mL/sec and baseline Pves and Pabd pressures between 12 and 60 cm H<sub>2</sub>O. Patients in this cohort had very compliant bladders and showed only a 7cm H<sub>2</sub>O increase in vesical pressure between mean baseline and MCC. VLPP's were reproducible and there was only a 10 cm H<sub>2</sub>O difference between the means of minimum and average values. 10% of women who qualified for stress incontinence surgery with a positive cough stress test did not demonstrate urodynamic stress incontinence. Less than 10% of patients undergoing surgery in this study demonstrated detrusor overactivity which likely reflects our selection of pure or predominant stress incontinence subjects.

Concluding message

Many women undergoing surgery for pure or predominant stress incontinence have preoperative NIF and filling cystometry studies. Results from a large cohort of these women are now available for plausibility and quality control assessments or as reference values for similar groups of women.

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