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URODYNAMIC URETHRAL FUNCTION, THE SUPINE EMPTY BLADDER STRESS TEST, AND INCONTINENCE SEVERITY

Hypothesis / aims of study

To determine whether urodynamic measures of urethral function [valsalva leak point pressure (VLPP); maximal urethral closure pressure (MUCP); functional urethral length (FUL)] and the results of the supine empty bladder stress test (SEBST) correlate with each other and with subjective and objective measures of urinary incontinence severity.

Study design, materials and methods

Data were collected preoperatively from subjects enrolled in a multicenter surgical trial of midurethral slings. Subjective measures included self–reported total urinary incontinence symptoms from the Medical Epidemiological Study of Aging (MESA) and the stress subscale (MESA-S), symptom bother with the Urogenital Distress Inventory (UDI), total and stress subscale scores (UDI-S), and quality of life with the Incontinence Impact Questionnaire (IIQ). Objective measures included the amount of urine loss from a 24-hour pad weight test (PW), incontinence episode frequency (IEF) from a 3-day diary, and the SEBST. VLPP and MUCP were stratified and analyzed in quartiles ranges. Relationships between VLPP / MUCP / FUL and subjective and objective parameters were analyzed using Spearman's rank correlation coefficients (rho), linear regression modelling and Wilcoxon tests as appropriate.

Results

Five hundred ninety-seven (597) women were enrolled. 372 women had valid VLPP values and 539 had valid MUCP/FUL values. Mean (SD) VLPP (cm water), MUCP (cm water) and FUL (mm) values were 119.4 (42.4), 67.9 (32.5) and 31.7 (8.1), respectively. Mean (SD) scores for subjective measures were 19.3 (4.6) for stress symptoms (MESA-S), 74.4 (21.5) for stress symptom bother score (UDI-S), and 151.5 (97.4) for quality of life (IIQ). Median (interquartile range) IEF (leaks/day) and PW (gm) were 2.7 (3.4) and 12.5 (27.5).

The subjective measures of severity had weak to moderate correlation with each other and with the objective measures of severity. (Table 1) The objective measures (PW and IEF) had moderate correlation (r= 0.53, p<0.001) with each other. VLPP and MUCP had moderate correlation with each other (r =0.36, p<0.001). Urodynamic measures of urethral function (VLPP, MUCP, and FUL) had little or no correlation with subjective or objective measures of severity.

Table 1. Spearman correlation coefficients for subjective, objective, and urodynamic measures of severity (p-values in parentheses)

	MESA-S	**UDI-S**	**IIQ**	**PW**	**IEF**	**VLPP**	**MUCP**
UDI-S	0.28 (<0.001)						
IIQ	0.43 (<0.001)	0.25 (<0.001)					
PW	0.34 (<0.001)	0.06 (0.18)	0.31 (<0.001)				
IEF	0.45 (<0.001)	0.17 (<0.001)	0.34 (<0.001)	0.53 (<0.001)			
VLPP	-0.13 (0.01)	-0.09 (0.10)	0.02 (0.66)	-0.06 (0.24)	-0.09 (0.09)		
MUCP	-0.11 (0.01)	-0.07 (0.13)	0.01 (0.87)	-0.04 (0.40)	-0.03 (0.52)	0.36 (<0.001)	
FUL	-0.05 (0.26)	0.04 (0.31)	-0.05 (0.29)	-0.06 (0.14)	-0.02 (0.69)	0.20 (<0.001)	0.13 (0.002)
	MESA-S	**UDI-S**	**IIQ**	**PW**	**IEF**	**VLPP**	**MUCP**

To determine if there was any threshold effect for urodynamic variables, VLPP (Table 2) and MUCP were stratified into quartile ranges. VLPP was significantly associated with MESA (p=0.03), PW (p=0.04), and IEF (p=0.001). There were no significant associations between quartile ranges of MUCP and subjective or objective measures of UI severity (data not shown).

Table 2. Continuous urodynamic severity measures by VLPP≤86 cmH_2O, 86 <VLPP≤117.3 cmH_2O, 117.3 <VLPP≤144.5 cmH_2O or VLPP>144.5 cmH_2O

	VLPP			
Variable	**VLPP≤86** (N=95)	**86<VLPP≤117.3** (N=92)	**117.3<VLPP≤144.5** (N=93)	**VLPP>144.5** (N=92)

	N	Mean(SE)	N	Mean(SE)	N	Mean(SE)	N	Mean(SE)	*P-Value
MESA total	95	27.6(0.8)	92	26.8(0.8)	93	24.6(0.8)	92	25.4(0.8)	0.03
MESA-S	95	20.8(0.5)	92	19.5(0.5)	93	19.0(0.5)	92	19.1(0.5)	0.03
UDI total	95	137.1(4.8)	92	139.4(4.9)	93	139.8(4.8)	92	136.1(4.9)	0.94
UDI-S	95	78.4(2.2)	92	76.6(2.2)	93	75.8(2.2)	92	72.5(2.2)	0.27
IIQ	95	162.3(9.9)	92	146.8(10.1)	93	156.3(10.0)	92	160.9(10.1)	0.69
PW[1]	95	18.1(7.0-66.5)	92	12.9(5.6-26.5)	93	10.0(6.0-29.1)	92	15.3(6.1-38.6)	0.04
IEF[1]	95	3.3(2.0-6.3)	91	2.3(1.3-4.3)	93	2.0(1.3-4.0)	92	3.0(1.3-4.8)	0.001

1. PW and IEF were presented with median and interquartile range, and both p-values come from Wilcoxon test.

Subjects with a positive SEBST had more severe subjective and objective severity measures compared to the negative SEBST group, but they did not have significantly different VLPP and MUCP values.

Table 3. Severity measures grouped by supine empty bladder stress test (SEBST) results

	SEBST(N=595)				
	Positive(N=287)		**Negative**(N=308)		
Variable	**N**	**Mean(SD)**	**N**	**Mean(SD)**	**p-value**
MESA total	287	26.5(7.4)	308	24.7(7.6)	0.003
MESA-S	287	20.1(4.4)	308	18.6(4.7)	<0.001
UDI total	287	137.0(44.4)	308	132.1(46.4)	0.19
UDI-S	287	75.2(21.1)	308	73.5(21.8)	0.35
IIQ	287	163.5(102)	308	140.4(91.8)	0.004
PW[1]	286	16.1(6.9-45.6)	307	9.8(5.3-28.3)	<0.001
IEF[1]	285	3.0(1.7-5.0)	307	2.3(1.0-4.0)	<0.001
FUL	251	31.3(8.3)	286	32.0(7.9)	0.35
MUCP	251	67.5(35.3)	286	68.5(30.0)	0.71
VLPP	194	118.7(44.6)	176	120.4(40.1)	0.71

[1.] PW and IEF were presented with median and interquartile range and p-values come from Wilcoxon test.

Interpretation of results

VLPP and MUCP have moderate correlation with each other. VLPP was more strongly associated with subjective and objective measures of severity than MUCP, but this association is not robust. Subjects with a positive supine empty bladder stress had more severe subjective and objective measures, but did not have MUCP or VLPP measures that are different than subjects with a negative supine empty bladder stress test; therefore the supine empty bladder stress test does not predict low MUCP or low VLPP values.

Concluding message

This data from a large population of women undergoing surgical correction of stress urinary incontinence suggests that the urodynamic measures of urethral function commonly thought to be related to severity are not strongly related to subjective or objective measures of severity. These urodynamic measures do not distinguish patients' pre-operative perceptions of incontinence severity, quality of life impact, incontinence episodes, or measured urine loss on pad testing. The role of urodynamics and urodynamic measures of urethral function do not seem to predict baseline incontinence severity; however, their role in predicting surgical outcomes needs further investigation.

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Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
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What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethics Comittee approval obtained at all nine clinical sites and the biostatistical coordinating center**
Was the Declaration of Helsinki followed?	**Yes**
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