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Association of Baseline Urodynamic Measures of Urethral Function With Clinical, Demographic and Other Urodynamic Variables in Women Prior to Undergoing Midurethral Sling Surgery

Toby C. Chai[1,*], **Liyuan Huang**[2], **Kim Kenton**[3], **Holly E. Richter**[4], **Jan Baker**[5], **Stephen Kraus**[6], **Heather Litman**[2], and **for the Urinary Incontinence Treatment Network (UITN)**

[1]Division of Urology, University of Maryland School of Medicine, Baltimore, MD

[2]New England Research Institutes, Watertown, MA

[3]Department of Obstetrics and Gynecology, Loyola University Medical Center, Maywood, IL

[4]Department of Obstetrics and Gynecology, University of Alabama Birmingham, Birmingham, AL

[5]Department of Obstetrics and Gynecology, University of Utah Health Sciences Center, Salt Lake City, UT

[6]Department of Urology, University of Texas San Antonio Health Sciences Center, San Antonio, TX

Abstract

Aims—To explore how baseline demographic, clinical and urodynamic variables correlate with measures of urethral function in women planning midurethral sling surgery.

Methods—Women with predominant stress urinary incontinence (SUI) as part of the Trial of Mid-Urethral Slings (TOMUS) were characterized preoperatively including: demographics, body mass index (BMI), responses to the Medical and Epidemiologic Social Aspects of Aging (MESA) and Urogenital Distress Inventory (UDI) questionnaires, pad weight (PW), incontinence duration, prior SUI surgery, prolapse, strength of pelvic contraction, Q-tip test, uroflow, cystometrogram and detrusor pressures at maximum flow (Pdet at Qmax). Multivariate regression analysis and modeling confirmed variables with significant correlations with maximal urethral closure pressure (MUCP), functional urethral length (FUL) and Valsalva leak point pressure (VLPP).

Results—Five-hundred thirty nine women were included in the analysis. In multivariable analyses, PW ($p=0.045$) and age ($p<0.0001$) were negatively correlated with MUCP (as PW and age increased, MUCP decreased); BMI ($p=0.02$) and Pdet at Qmax ($p<0.0001$) were positively correlated with MUCP (as BMI and Pdet at Qmax increased, MUCP increased). Age ($p=0.002$) was negatively correlated with FUL; Qtip delta ($p=0.006$), POPQ stage ($p=0.002$) and strength of pelvic contraction ($p=0.03$) were positively correlated with FUL. Duration of incontinence ($p=0.01$) was negatively correlated with VLPP; Qtip delta ($p=0.02$), BMI ($p=0.0005$) and Pdet at Qmax ($p=0.0005$) were positively correlated with VLPP.

Conclusions—Age, BMI, Qtip delta and Pdet at Qmax were variables that correlated with two or more measures of urethral function. These correlations may help direct future research in female urethral function.

*Corresponding author: University of Maryland Division of Urology, 29 S. Greene St., Suite 500, Baltimore, MD 21201, Voice Phone: 410-328-3083, FAX Phone: 410-328-0595, tchai@smail.umaryland.edu.

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Keywords

stress urinary incontinence; urethral pressure profile; valsalva leak point pressure; clinicodemographic variables; surgery

Introduction

Both static urethral pressure profilometry (UPP) and valsalva leak point pressures (VLPP) are viewed as measures of urethral competence and ultimately may reflect incontinence severity.[1] Urethral pressure measurements specifically are utilized to assess urethral closure and voiding function, where urethral pressure is defined as the fluid pressure needed to just open a closed (collapsed) urethra.[2] Two static UPP measures are maximum urethral closure pressure (MUCP) and functional urethral length (FUL).

The sensitivity and specificity of UPP parameters in predicting incontinence severity is variable[3–7]. Recently, categories of symptom severity based on the Incontinence Symptom Index were associated with urethral function as measured by VLPP and MUCP, supporting the concept that urethral competence is of primary importance in the urinary continence mechanism.[8] Similarly, DeLancey et al compared urodynamic (UDS) and clinical measures of urethral function and support in a large cohort of well-characterized women with stress urinary incontinence (SUI) to women without urinary symptoms[9,10]. Urethral closure pressure alone predicted half of the occurrence of SUI, while measures of urethral support only predicted 16% of SUI cases. The authors concluded that MUCP is the factor most strongly associated with SUI. Additionally, UPP measures have been controversial in whether they predict surgical failure with some studies showing they do[4,5] and some showing they do not[11].

The Trial of Mid-Urethral Slings (TOMUS) is a large well characterized surgical cohort, providing a unique opportunity to characterize the correlation of a variety of baseline clinical, demographic and cystometric variables with the pre-operative urodynamic measures of urethral function, including MUCP, FUL and VLPP. Previously published work demonstrated that advancing age, lower body mass index (BMI), higher maximum flow rate and lower voiding pressures are all independently associated with higher VLPP[12]. Similarly, it is well established that MUCP decreases with advancing age[13,14,15]. Better understanding of other factors associated with urodynamic measures of urethral function may help us understand urethral function.. The purpose of this study was to explore the correlations of demographic, clinical and urodynamic variables with pre-operative MUCP, FUL and VLPP in women planning a midurethral sling for the treatment of SUI.

Materials and Methods

The subjects for this baseline analysis were those randomized in the TOMUS trial. The primary outcome, inclusion/exclusion criteria, and complications are published[16]. All subjects underwent standardized preoperative urodynamics (including MUCP, FUL and VLPP measures) as previously described[17]. The UDS was standardized at all sites according to protocol and the processes describing our filling cystometry and pressure flow studies have been published[18,19]. Nomenclature conformed to ICS recommendations[20] and technique conformed to ICS recommended good urodynamic practice guidelines[21]. The quality control evaluation of our signals and interpretations has been published and acceptable inter-rater reliability measures have been demonstrated[18,19,22].

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Demographic variables collected included age, BMI, race/ethnicity, parity, smoking history, hormone use, prior incontinence surgery, hysterectomy and duration of incontinence in months. Clinical parameters include stage of prolapse and point Aa from the pelvic organ prolapse quantification examination (POPQ), Q-tip test (delta angle), strength of pelvic contraction, 24-hour pad weight (PW) and incontinence episode frequency (IEF from a 3-day bladder diary). Patient self report measures included the Urogential Distress Inventory (UDI) and Medical, Epidemiologic and Social Aspects of Aging (MESA) urge and stress subscale scores.

Descriptive statistics were summarized by mean and standard deviation (SD) for continuous variables and frequency and percentage for categorical variables. To explore the correlations of the independent variables in each of the three domains (clinical, demographic and UDS) with MUCP, FUL and VLPP, bivariate regression analyses were performed. A preliminary multiple regression model was fit with all variables of each domain that had a p-value less than 0.20 in bivariate analysis. Variables that were no longer statistically significant ($p > 0.05$) were removed from the model to construct a "final" multivariable model for each domain (Table 2). Finally, all of the variables in the three "final" multivariable models that were statistically significant were combined to construct a single multivariable model (Table 3). For continuous explanatory variables, the slope coefficient for the correlation between a particular independent variable and MUCP/FUL/VLPP controlling for the other variables in the model is presented. For categorical variables, the adjusted mean MUCP/FUL/VLPP value controlling for the other variables in the model is reported for each level of the categorical variable. Statistical analyses were performed using SAS Version 9.2 (SAS Institute, Inc., Cary, NC). A 5% two-sided significance level was used for all statistical testing.

Results

Baseline Characteristics

Baseline clinical, demographic, UDS and urethral measure characteristics are presented in Table 1 (these were all the variables that were used for bivariate regression analyses – see Methods). The mean values, standard deviation and ranges of the 3 urethral functional measures are also shown in Table 1.

Multivariate regression of clinical, demographic, and UDS variables with MUCP

The correlation of clinical, demographic and urodynamic variables with MUCP on multivariable analysis is shown in Table 2. Pad weight (PW) ($p=0.002$) and Q-tip delta ($p=0.04$) were clinical values significantly associated with MUCP after controlling for each other. As PW increased, MUCP decreased (slope coefficient of −0.07 under "Est." column which denotes negative correlation); as Q-tip delta increased, MUCP increased (slope coefficient 0.15 which denotes positive correlation). Age ($p<0.0001$), BMI ($p=0.01$) and prior UI surgery ($p=0.001$) were demographic variables significantly associated with MUCP after controlling for the others. As age increased, MUCP decreased (negative correlation); as BMI increased, MUCP increased (positive correlation); and subjects with prior UI surgery had significantly lower mean MUCP (56.50 cm water) compared with those without prior UI surgery (69.69 cm water, $p=0.001$). Regarding UDS variables, only Pdet at Q max was significantly associated with MUCP ($p<0.0001$); as Pdet at Qmax increased, MUCP increased (positive correlation). As described in the methods section, the variables reaching statistical significance from each domain (clinical, demographic and UDS) were combined to construct a final multivariable model with all domains included as shown in Table 3, under column titled MUCP. This combined model showed significant correlations for all of the previously demonstrated variables except for the Qtip delta variable.

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Multivariate regression of clinical, demographic, and UDS variables with FUL

The correlations of clinical, demographic and urodynamic variables with FUL on multivariable analysis is shown in Table 2. Qtip delta (p=0.0004), POPQ stage (p=0.01) and strength of PC contractions (p=0.01) were clinical variables significantly correlated with FUL. As Qtip delta increases, FUL increases (positive correlation); the mean of FUL in women with stage 3 or 4 POPQ stage was significantly higher than that in women with lower stages. Women with strong squeeze contractions had a higher mean FUL compared with women with weak or moderate squeeze. Age was the only demographic variable significantly associated with FUL; as age increases, FUL decreases (negative correlation). No UDS variables were found to be significantly associated with FUL. When the combined model was constructed, all of the variables remained significantly associated with FUL (Table 3, under column titled "FUL").

Multivariate regression of clinical, demographic, and UDS variables with VLPP

The correlations of clinical, demographic and UDS variables with VLPP are shown in Table 2. Qtip delta (p=0.004) had a positive correlation with VLPP. Regarding demographic variables, BMI (p<0.001) was also positively correlated whereas duration of incontinence (p=0.009) was negatively correlated with VLPP. Pdet at Qmax (p<0.0001) was the only UDS variable significantly associated (positive correlation) with VLPP. Subjects who were randomized to transobturator midurethral slings (TMUS) had significantly higher (p=0.01) VLPP compared to those randomized to retropubic midurethral slings (RMUS). When the combined model was constructed, all of the variables remained significantly associated with VLPP (Table 3, column titled "VLPP").

Discussion

Urodynamic measurements of urethral function include static UPP (MUCP and FUL such as that performed in this trial) and VLPP. We found a correlation between decreasing MUCP / FUL values and increasing age confirming other urodynamic reports that urethral function changes with aging[13,14,15]. Histologic studies also demonstrate urethral changes with aging as intramuscular nerve density and muscle fiber density in the striated urethral sphincter decline with age[23].

The positive relationship of BMI and urethral function, meaning with increasing BMI, both VLPP and MUCP increased, is consistent with our previous publications[12,24]. Obese women have worse UI severity at baseline in both the SISTEr and TOMUS trials[24]. Weight loss can significantly decrease urinary incontinence episodes, specifically of the SUI type[25]. However, since urethral function was not measured in this weight loss reduction trial, it is unknown whether weight loss in of itself changed (improved) urethral function and/or whether the beneficial effects of weight loss resulted from decreased strain on the pelvic floor/urethra without changes in urethral function. Another possible explanation for our finding is that gradually increasing pressure on the pelvic floor/urethra due to increasing BMI may serve to strengthen the urethral sphincteric mechanism. It is theorized that obese women require greater muscle contraction of the urethral sphincteric unit to maintain continence at rest. Therefore, there would be utilization of larger and more motor units to maintain continence with resultant increased bulk of the urethral sphincteric unit. This hypothesis is consistent with a principle that states as the requirement for greater muscle contraction is needed, more and larger motor units are recruited[26]. With stress or valsalva, obese women may be unable to recruit any additional muscle motor units resulting in SUI although the urethral resistance to SUI, as measured by different urodynamic tests, would be greater than non-obese females due to this increased bulk which developed during rest.

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It could be argued that because the TOMUS population was not enriched with sufficient number of subjects with poorly functioning urethras (e.g. intrinsic sphincteric deficiency or ISD), our statistical analysis was less robust. However, in a recent publication (Nager CW et al., Baseline Urodynamic Predictors of Treatment Failure One Year after Midurethral Sling Surgery, in press *J Urol* for August 2011 publication), we found that 16% of TOMUS subjects had VLPP values < 86 cm water (which corresponded to 25th percentile cut-point value) and 23% of subjects had MUCP values <45 cm water (which corresponded to 25th percentile cut-point value). This showed that approximately 1/5th to 1/4th of our TOMUS cohort had urethral dysfunction approaching ISD-levels. Furthermore, the TOMUS protocol had no inclusion/exclusion criteria based on either VLPP or MUCP value. Therefore, we believe that our TOMUS cohort does not solely represent women with non-ISD SUI (urethral hypermobility).

The finding of a significant relationship between increased Q-tip delta and increased FUL and VLPP, suggesting that higher Q-tip delta is associated with better urethral function, also seem to be counter-intuitive. Investigators who correlated changes in Q-tip delta with MUCP before and after using incontinence dish pessary[27] found that MUCP increased as Q-tip delta decreased. However, urethral functional and anatomic measurements were performed with an incontinence pessary in place which provided physical support to the urethra. Thus it is expected that Q-tip delta would decrease with physical support of the urethra. Furthermore, an external force on the urethra applied by the pessary is also expected to increase MUCP. Our urethral function measurements for this study were performed pre-operatively prior to any surgery in the urethral area. It could be possible that a loss of urethral support, leading to increased Q-tip delta, might lead to longer FUL due to stretching of the urethra. The relationship between higher Q-tip delta with higher VLPP suggests that loss of urethral support require a higher abdominal pressure to drive fluid across the urethra. However, it should be noted that that Q-tip delta does not entirely reflect urethral support mechanisms as a third SUI patients with Q-tip delta ≥ 30° had POP-Q point Aa values of −2 cm or less[28].

The correlation between higher voiding pressures (Pdet at Qmax) with higher MUCP and VLPP values suggests that urethral function impacts bladder behavior. The relationship of higher urethral resistance promoting a higher voiding pressure has been documented[29]. This study suggested that urethral afferents which are activated during voiding (by fluid flow through urethra) augmented bladder contraction pressures via motor efferents. This reflex was termed a urethrovesical reflex. In our particular study, higher MUCP and VLPP might be associated with higher more afferent activity in the urethra during voiding due to the higher urethral resistance, thus resulting in higher voiding pressures due to an augmented urethrovesical reflex.

It might be tempting to infer similarity of the MUCP and VLPP tests due to similarity of clinicodemographic variables which were significantly associated in the multivariate models (Tables 2 and 3). BMI and Pdet at Qmax were consistently associated with MUCP and VLPP. While prior UI surgery was associated with MUCP, duration of incontinence was associated with VLPP. These two variables (prior UI surgery and duration of incontinence), while not precisely identical, may be thought of as measures of severity of SUI. While prior UI surgery was a categorical variable and duration of incontinence was a continuous variable, the correlation was in the anticipated direction, meaning presence of prior UI surgery was associated with lower MUCP and longer duration of incontinence was associated with lower VLPP. The literature on whether MUCP and VLPP are correlated varies with some finding significant correlation[30,31], whereas others finding no correlation[32].

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In a previous randomized surgical trial comparing Burch to autologous rectus sling (SISTEr), investigators compared baseline clinicodemographics with VLPP[12]. Pdet at Qmax and BMI were consistent parameters that were significantly associated with VLPP in both trials; however, age and Qtip delta were inconsistently associated in the two trials. A comparison of results using similar analyses between these two randomized trials (SISTEr and TOMUS) must be done with caution as the cohorts in these two trials had different eligibility criteria and different characteristics. For example in SISTEr, there was requirement for Q-tip delta to be ≥ 30° whereas this was not required in TOMUS. Furthermore, SISTEr subjects had much higher 24-hour pad weights (43 grams)[33] compared to TOMUS subjects (12 grams)[15]. Also, the POPQ stages were higher in SISTEr (stage 0–1=25%, stage 2=59%, stage 3–4=16%) compared to TOMUS (stage 0–1=45%, stage 2=47%, stage 3–4=8%). Therefore, the SISTEr and TOMUS populations are not equivalent.

One of the strengths of this analysis is the large number of subjects (n=597) across nine clinical sites from which the data were acquired and analyzed. In addition, urodynamic evaluations were standardized and validated across participating sites. To our knowledge, this sample size is larger than any other cohort in the published literature. One weakness is the fact that these subjects are women with stress predominant urinary incontinence willing to participate in a randomized surgical trial for SUI and may not be generalizable to all women with SUI.

Conclusion

Baseline clinicodemographic and urodynamic variables that were significantly correlated with two or more measures of urethral function were age, BMI, Qtip delta and Pdet at Qmax. These factors should be taken into consideration when future studies of urethral function are contemplated and may be associated with pathophysiology of stress urinary incontinence.

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STEERING COMMITTEE

Elizabeth A. Gormley, Chair (Dartmouth Hitchcock Medical Center, Lebanon, NH); Larry Sirls, MD, Salil Khandwala, MD (William Beaumont Hospital, Royal Oak, MI and Oakwood Hospital, Dearborn, MI; U01 DK58231); Linda Brubaker, MD, Kimberly Kenton, MD (Loyola University Chicago, Stritch School of Medicine, Maywood, IL; U01 DK60379); Holly E. Richter, PhD, MD, L. Keith Lloyd, MD (University of Alabama, Birmingham, AL; U01 DK60380); Michael Albo, MD, Charles Nager, MD (University of California, San Diego, CA; U01 DK60401); Toby C. Chai, MD, Harry W. Johnson, MD (University of Maryland, Baltimore, MD; U01 DK60397); Halina M. Zyczynski, MD, Wendy Leng, MD (University of Pittsburgh, Pittsburgh, PA; U01 DK 58225); Philippe Zimmern, MD, Gary Lemack, MD (University of Texas Southwestern, Dallas, TX; U01 DK60395); Stephen Kraus, MD, Thomas Rozanski, MD (University of Texas Health Sciences Center, San Antonio, TX; U01 DK58234); Peggy Norton, MD, Ingrid Nygaard, MD (University of Utah, Salt Lake City, UT; U01 DK60393); Sharon Tennstedt, PhD, Anne Stoddard, ScD (New England Research Institutes, Watertown, MA; U01 DK58229); Debuene Chang, MD (until 10/2009), John Kusek, PhD (starting 10/2009), Rebekah Rasooly, PhD (National Institute of Diabetes & Digestive & Kidney Diseases).

CO-INVESTIGATORS

Amy Arisco, MD; Jan Baker, APRN; Diane Borello-France, PT, PhD; Kathryn L. Burgio, PhD; Ananias Diokno, MD; MaryPat Fitzgerald, MD; Chiara Ghetti, MD; Patricia S. Goode, MD; Robert L. Holley, MD; Yvonne Hsu, MD; Margie Kahn, MD; Jerry Lowder, MD; Karl Luber, MD; Emily Lukacz, MD; Alayne Markland, DO, MSc; Shawn Menefee, MD; Pamela Moalli, MD; Elizabeth Mueller, MD; Leslie Rickey, MD, MPH; Elizabeth Sagan, MD; Joseph Schaffer, MD; Robert Starr, MD; Gary Sutkin, MD; R. Edward Varner, MD; Emily Whitcomb, MD.

STUDY COORDINATORS

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Laura Burr, RN; JoAnn Columbo, BS, CCRC; Tamara Dickinson, RN, CURN, CCCN, BCIA-PMDB; Rosanna Dinh, RN, CCRC; Judy Gruss, RN; Alice Howell, RN, BSN, CCRC; Chaandini Jayachandran, MSc; Kathy Jesse, RN; D. Lynn Kalinoski, PhD; Barbara Leemon, RN; Karen Mislanovich, RN; Elva Kelly Moore, RN; Caren Prather, RN; Jennifer Tabaldo; Tia Thrasher; Mary Tulke, RN; Robin Willingham, RN, BSN; Kimberly Woodson, RN, MPH; Gisselle Zazueta-Damian.

DATA COORDINATING CENTER:

Kathleen Cannon, BS; Kimberly J. Dandreo, MSc; Liyuan Huang, MS; Rose Kowalski, MA; Heather Litman, PhD; Marina Mihova, MHA; Anne Stoddard, ScD (Co-PI); Kerry Tanwar, BA; Sharon Tennstedt, PhD (PI); Yan Xu, MS.

DATA SAFETY AND MONITORING BOARD

J. Quentin Clemens MD, (Chair) Northwestern University Medical School, Chicago IL; Paul Abrams MD, Bristol Urological Institute, Bristol UK; Deidre Bland MD, Blue Ridge Medical Associates, Winston Salem NC; Timothy B. Boone, MD, The Methodist Hospital, Baylor College of Medicine, Houston, TX; John Connett PhD, University of Minnesota, Minneapolis MN; Dee Fenner MD, University of Michigan, Ann Arbor MI; William Henderson PhD, University of Colorado, Aurora CO; Sheryl Kelsey PhD, University of Pittsburgh, Pittsburgh PA; Deborah J. Lightner, MD, Mayo Clinic, Rochester, MN; Deborah Myers MD, Brown University School of Medicine, Providence RI; Bassem Wadie MBBCh, MSc, MD, Mansoura Urology and Nephrology Center, Mansoura, Egypt; J. Christian Winters, MD, Louisiana State University Health Sciences Center, New Orleans, LA

Abbreviations

MUCP	maximal urethral pressure profile
FUL	functional urethral length
VLPP	Valsalva leak point pressure
PW	pad weight
BMI	body mass index
PFS	pressure flow study
MESA	Medical Epidemiologic Study of Aging questionnaire for stress/urge incontinence
NIF	non-instrumented flowmetry
PC	pubococcygeal muscle
HRT	hormone replacement therapy
POPQ	pelvic organ prolapse quantification
UDI	urogenital distress index
UI	urinary incontinence
SUI	stress urinary incontinence
Pdet at Qmax	detrusor pressure at maximum flow in the pressure flow study
MCC	maximal cystometric capacity
UDS	urodynamic
TOMUS	Trial of Mid-Urethral Slings
TMUS	transobturator midurethral slings
RMUS	retropubic midurethral slings
SISTEr	Burch to autologous rectus sling

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SD	standard error

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Table 1

Baseline Clinical, Demographic, UDS Characteristics

Covariates	Mean (SD) or N(%)*	Range
Clinical Parameters		
POPQ stage		
Stage 0 and 1	267(45%)	
Stage 2	282(47%)	
Stage 3 and 4	48(8%)	
Point Aa	−1.4(1.3)	−3.0 — 3.0
Qtip delta	37.6(19.1)	−25.0 — 100.0
Pad weight (gms)	35.8 (66.6)	0 – 46.4
Incontinence episodes per day	3.3 (3.0)	0 – 25.7
MESA urge score (MESA-U)	6.3(4.0)	0.0 – 17.0
MESA stress score (MESA-S)	19.3(4.6)	3.0 – 27.0
UDI stress symptoms (UDI-S)	74.4(21.5)	0.0 – 100.0
UDI irritative symptoms (UDI-I)	41.2(25.4)	0.0 – 100.0
UDI obstructive symptoms (UDI-O)	19.0(18.3)	0.0 – 100.0
Strength of PC contractions		
No response	42(7%)	
Weak squeeze	244(41%)	
Moderate squeeze	220(37%)	
Strong squeeze	89(15%)	
Demographic Characteristics		
Age in years	52.9(11.0)	24.9 – 86.6
BMI	30.3(6.7)	16.8 – 63.6
Race/ethnicity		
Hispanic	71(12%)	
Non-hispanic White	473(79%)	
Non-hispanic Black	17(3%)	
Non-hispanic Other	36(6%)	
Smoking status		
Never smoked	319(53%)	
Former smoker	198(33%)	
Current smoker	80(13%)	
Number of pregnancies		
Never pregnant	25(4%)	
One/two pregnancies	227(38%)	
Three/four pregnancies	231(39%)	
Five or more pregnancies	114(19%)	
Menopausal Status/Hormone Replacement Therapy (HRT) Use		
Post-Menopausal Non-user of HRT	244(41%)	
Post-Menopausal User of HRT	171(29%)	

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Covariates	Mean (SD) or N(%)*	Range
Pre-Menopausal	180(30%)	
Hysterectomy		
No	427(72%)	
Yes	168(28%)	
Prior Urinary Incontinence (UI) surgery		
No	516(87%)	
Yes	79(13%)	
Duration of UI (months)	101.1(104.6)	
Assignment		
RMUS (Retropubic Midurethral Sling)	298(50%)	
TMUS (Transobturator Midurethral Sling)	299(50%)	
Urodynamic Parameters		
Non-instrumented Uroflowmetry		
Max Flow Rate (Qmax, ml/sec)	25.0(12.3)	4.1 – 79.6
Mean Flow Rate (Qavg, ml/sec)	11.7(5.8)	1.4 – 40.2
Time to max flow (sec)	14.5(18.3)	1.1 – 184.1
Post Void Residual (PVR, ml)	24.0(42.3)	0.0 – 520.0
Urethral Function Tests		
MUCP (cm water)	67.9 (32.5)	10.3 – 246.3
FUL (mm)	31.7 (8.1)	10.0 – 50.0
VLPP (cm water)	119.4 (42.4)	25.0 – 266.0
Filling Phase UDS		
Detrusor overactivity		
Yes	70(12%)	
No	519(88%)	
First desire (ml)	116.4(80.4)	7.0 – 475.0
Strong desire (ml)	227.0(117.7)	21.0 – 807.0
Maximum cystometric capacity (MCC) (ml)	351.4(122.6)	21.0 – 938.0
Emptying Phase UDS (Pressure-flow Study, PFS)		
Qmax (ml/s)	22.1(10.8)	1.9 – 76.6
Pdet at Q max (cm water)	19.3(13.2)	−30.0 – 86.0
Voiding Pattern of Flow during PFS		
Continuous, smooth	216(39%)	
Continuous, fluctuating	248(45%)	
Intermittent	86(16%)	

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Table 2

Multivariable Regression Models For Each Domain (Clinical, Demographic, and UDS)

Covariates	Mean (SD) or N(%)*	MUCP		FUL		VLPP	
		p-value	Est.*	p-value	Est.*	p-value	Est.*
Clinical Parameters							
POPQ stage				0.01			
Stage 0 and 1	267 (45%)				32.79[1]		
Stage 2	282 (47%)				31.21[1]		
Stage 3 and 4	48 (8%)				34.66[1]		
Point Aa	−1.4 (1.3)						
Qtip delta (degrees)	37.6 (19.1)	0.04	0.15	0.0004	0.07	0.004	0.34
Pad weight in grams	35.8 (66.6)	0.002	−0.07				
Strength of PC contractions				0.01			
No response	42 (7%)				32.95[2]		
Weak squeeze	244 (41%)				31.32[2]		
Moderate squeeze	220 (37%)				32.50[2]		
Strong squeeze	89 (15%)				34.78[2]		
Demographic Characteristics							
Age in years	52.9 (11.0)	<0.0001	−0.75	0.0006	−0.11		
BMI	30.3(6.7)	0.01	0.50			<0.0001	1.58
Prior UI surgery		0.001					
No	516 (87%)		69.69[3]				
Yes	79 (13%)		56.50[3]				
Duration of incontinence (month)	101.1(104.6)					0.009	−0.05
Assignment						0.01	
RMUS	298 (50%)						114.05[4]
TMUS	299 (50%)						124.67[4]

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Covariates	Mean (SD) or N(%)*	MUCP		FUL		VLPP	
		p-value	Est.*	p-value	Est.*	p-value	Est.*
Urodynamic Parameters							
Pdet at Q max	19.3(13.2)	<0.0001	0.61			<0.0001	0.84

*The numbers in the “Est” columns are slope values of the correlation between continuous covariates with MUCP, FUL or VLPP. However, for covariates that are categorical and not continuous, the numbers in “Est” column are **not** the slope, but rather the mean values of MUCP, FUL or VLPP for that particular covariate as denoted by the footnotes below.

[1] These numbers represent mean FUL values for subjects with these stages of prolapse: Stage 0 and 1 (32.79 mm), Stage 2 (31.21 mm), Stage 3 and 4 (34.66 mm).

[2] These numbers represent mean FUL values for subjects with these categories of strength of PC contractions: No response (32.95 mm), Weak squeeze (31.32 mm), Moderate squeeze (32.50 mm), Strong squeeze (34.78 mm).

[3] These numbers represent mean MUCP values for subjects with no prior UI surgery (69.69 cm water) and prior UI surgery (56.50 cm water).

[4] These numbers represent mean VLPP values for subjects who underwent RMUS (114.05 cm water) and TMUS (124.67 cm water).

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Table 3

Combined Multivariable Regression Models

	MUCP	FUL	VLPP
Covariates	**p-value**	**p-value**	**p-value**
POPQ stage		0.002	
Stage 0 and 1			
Stage 2			
Stage 3 and 4			
Qtip delta		0.006	0.02
Pad weight (gms)	0.04		
Strength of PC contractions		0.03	
No response			
Weak squeeze			
Moderate squeeze			
Strong squeeze			
Age in years	<0.0001	0.002	
BMI	0.02		0.0005
Prior UI surgery	0.02		
No			
Yes			
Duration of UI (months)			0.01
Assignment			0.01
RMUS			
TMUS			
Pdet at Q max	<0.0001		0.0005