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COMPARISON OF FLOWRATES AND VOIDED VOLUMES DURING NON-INSTRUMENTED UROFLOWMETRY AND PRESSURE-FLOW STUDIES IN WOMEN WITH STRESS INCONTINENCE

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Abstract

Aims—The Blaivas-Groutz nomogram defines voiding obstruction in women using $Q_{\max}$ from the NIF and the maximum detrusor pressure ($P_{\det\max}$) from the PFS. The aim of this study was to understand the relationship between NIF and PFS maximum flow rates in women with stress incontinence.

Methods—We analyzed the UDS of 597 women with stress-dominant urinary incontinence. Each subject underwent a NIF and then a PFS. Mixed model was used to test the hypothesis that the relationship between flow rates and voided volume were similar for NIF and PFS.

Results—There were 452 subjects with both NIF and PFS studies that met the inclusion criteria and had max flow rate ($Q_{\max}$) for both NIF and PFS. The mean age was 53. Overall, higher voided volumes were observed during PFS compared to NIF and subjects had higher $Q_{\max}$ with NIF compared to PFS. The relationship between $Q_{\max}$ and VV was significantly different between NIF and PFS ($p < 0.004$). At 200 mL, NIF $Q_{\max}$ was 14% higher than PFS $Q_{\max}$ and this difference increased to 30% at 700mL.

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Conclusion—The difference between PFS $Q_{\max}$ and NIF $Q_{\max}$ increases as voided volumes increase. As a result, values from PFS and NIF cannot be used interchangeably as has been suggested in the Blaivas-Groutz nomogram for obstruction in women.

Keywords

Uroflowmetry; stress-incontinence; obstruction; urodynamics; pelvic organ prolapse; women

INTRODUCTION

Urodynamic studies, specifically non-instrumented uroflowmetry (NIF) and pressure-flow studies (PFS), can assist in the evaluation of women who present with symptoms of voiding dysfunction. Uroflowmetry involves the recording of urinary flow over time. Typically women undergoing NIF arrive with a comfortably full bladder and then void while seated. Pressure-flow studies involve the placement of catheters in the bladder and vagina or rectum so that detrusor pressure measurements can be calculated. Women are then asked to void after being filled to maximal cystometric capacity (MCC) and detrusor pressures and urine flow rates are obtained. Various characteristics of urine flow are obtained such as a flow curve, voided volume, peak and average flow rates, time to maximum peak flow and total void time. Pressure-flow studies in addition to obtaining flow rate variables, measure the bladder volume infused, the maximal detrusor pressure at the peak flow rate ($P_{\det}Q_{\max}$) and abdominal and detrusor pressure patterns. In women, both NIF and PFS peak and average flow rates ($Q_{\max}$ and Q_{avg}) are dependent on voided volume(1,2).

Women with and without clinical evidence of obstruction are often unable to void in the urodynamic laboratory during a PFS perhaps due to the presence of the catheter, failure to relax the pelvic floor or positioning. Authors have recognized this phenomenon and have developed pressure-flow nomograms for defining obstruction that use the $Q_{\max}$ from the NIF and the maximum detrusor pressure ($P_{\det\max}$) from the PFS (3). Using this method, the authors replace the instrumented PFS $Q_{\max}$ with the non-instrumented NIF $Q_{\max}$. One of the confounding factors, however, is that the voided volumes between the two are often dissimilar since patients arrive with a “comfortably full bladder” for NIF and subjects are filled to MCC during PFS.

The first aim of this study was to understand the relationship between NIF and PFS maximum flow rates in women with stress incontinence. A second aim was to better understand how NIF and PFS flow rates might change with voided volumes. To achieve these aims, we conducted a retrospective review of the NIDDK's Urinary Incontinence Treatment Network (UITN) trial of midurethral slings (TOMUS) (RW.ERROR - Unable to find reference:7450). The TOMUS trial was a multi-center, randomized equivalence trial comparing outcomes with retropubic and transobturator slings in 597 women with stress incontinence. Lastly, we wanted to compare the relationship of NIF and PFS $Q_{\max}$ vs. VV in women with stress incontinence to 2 different study populations: 1.) a similar study in women with pelvic organ prolapse and 2.) the 50th and 10th centiles of the Liverpool nomogram (4,5,6).

MATERIALS AND METHODS

This is an analysis of the urodynamic data from the Urinary Incontinence Treatment Network (UITN) Trial of Mid-Urethral Slings (TOMUS) study (N=597) that compared retropubic versus transobturator mid-urethral slings for stress urinary incontinence (SUI) (RW.ERROR - Unable to find reference:7450). That study was IRB approved and was a registered on clinicaltrials.gov (NCT 00325039). Eligibility criteria for the TOMUS study included: stress predominant urinary incontinence symptoms, objective demonstration of transurethral urine loss on stress testing, bladder capacity > 200mL, a post-void residual (PVR) <100mL in patients with Stage 0–I, by the Pelvic Organ Prolapse -Quantification (POP-Q) system (5). Patients with Stage II–IV POP were eligible for the study with PVR < 500 mL since the study allowed concomitant vaginal prolapse repairs. Patients with prior mesh midurethral sling were excluded, but other prior continence procedures were allowed. Concomitant surgical procedures were limited to vaginal procedures for pelvic organ prolapse (POP).

Measures

Urodynamic Studies (UDS)—Urodynamic tests described in this ancillary analysis were performed preoperatively and consisted of NIF followed by filling cystometry and PFS. Standardized testing procedures and interpretation guidelines were developed by an urodynamic work group utilizing the methods, definitions, and units recommended by the International Continence Society (6–8) according to a standardized research protocol. The details and specifics of the non-instrumented uroflowmetry (NIF), filling cystometry (CMG), and a pressure flow study (PFS) have been previously published (4). Only participants who met the following criteria were included in this ancillary analysis; 1.) voided volume VV ≥ 150 mL for both PFS and NIF and 2.) the vesical pressure catheter had to be functioning properly at Q_{max} to ensure that the catheter was in place during the void. Women with stage II–IV prolapse were manually reduced during the PFS. Variables of interest included maximum flow rate (Q_{max}) and time to maximum flow (T_{Q_{max}}).

Graphical representation of NIF and PFS Q_{max} vs. Voided Volume—In order to better understand the relationship of pooled Q_{max} and voided volumes, we performed scatter plots of NIF and PFS versus their respective voided volumes (Figure 1). Box plots of NIF and PFS peak and average flow rates were performed to remove outliers. Outliers were defined as being 1.5 times the interquartile range which resulted in excluding values for NIF Q_{max} > 49mL/sec and PFS Q_{max} > 45.8mL/sec. In total, 26 outliers were removed.

Graphical representation of the difference in NIF and PFS Q_{max}—For each patient we plotted the difference between NIF and PFS in the measurement of Q_{MAX} against the mean. We also computed the overall mean difference and the 95% limit of agreement as the mean difference ± 1.96 times the standard deviation of the difference (9).

Graphical representation of the CARE data—The linear regression equation of the CARE data in Figure 3 was taken from a prospective supplementary analysis to the NIH/ NICHD's Pelvic Floor Disorders Network (PFDN) colopexy and urinary reduction efforts

(CARE) trial (10). The CARE trial enrolled women without the symptoms of SUI undergoing sacrocolpopexy for POP with the primary aim of determining if adding a Burch colposuspension at the time of prolapse surgery would reduce symptoms of stress incontinence. The prospective supplementary study included 298 women with stages II–IV POP, divided into 4 groups. Group 1 was composed of stress continent women enrolled in the CARE clinical trial (n=67), Group 2 consisted of women who demonstrated occult incontinence with prolapse reduction during UDS, enrolled in the trial (n=84), Group 3 consisted of women who met the eligibility criteria (undergoing sacrocolpopexy) for the CARE trial *except* they were stress incontinent (n=74) and Group 4 consisted of women who had prolapse and stress incontinence symptoms but were not planning to undergo a sacrocolpopexy. The majority of women had advanced POP (stage II=20%, stage III=67% and stage IV=13%). Peak flow rates did not vary based on continence status so the data was pooled. Only participants who had VV ≥ 150 mL for both PFS and NIF were included in the graph for comparison (n=169). Box plots of NIF and PFS peak flow rates were performed to remove outliers. Outliers were defined as being 1.5 times the interquartile range which resulted in excluding values for PFS $Q_{\max} > 58$ mL/sec. There were no outliers for NIF $Q_{\max}$.

Graphical representation of the Liverpool nomogram data—The data for the Liverpool nomogram for women was taken from Haylen's publication in 1989. The data was obtained from 249 women who voided into a calibrated uroflow device (11). Although the data was fit using the following equation; $\ln(Q_{\max}) = 0.511 + (0.505 \times \ln(\text{voided volume}))$, Figure 5 in the manuscript plots the values of $Q_{\max}$ vs. VV and the curve is linear from 200 to 600 mL. Using the $Q_{\max}$ values at 200mL (24mL/sec) and 600mL (42 mL/sec) a line was constructed for the 50th and 10th percentiles. We made the assumption that the relationship between VV and $Q_{\max}$ would remain linear past 600 mL although these volumes were not included in the Liverpool nomogram.

Statistics—As described above, plots and descriptive statistics were used to assess the distributions and detect outliers of NIF and PFS measures. To assess the agreement between NIF and PFS measures, we compared the means and computed the correlation coefficients. For $Q_{\max}$ and voided volume, we used the paired t-test and Pearson correlation coefficient. Because time to $Q_{\max}$ was skewed, we used the signed rank test to compare the medians and the Spearman correlation coefficient. The relationships between flow rates and voided volume (VV) were investigated via the mixed model analysis that regressed $Q_{\max}$ on VV. The model included UDS test type (NIF vs. PFS) and the interaction between test type and VV, controlling for subject as a random effect. The test of the UDS test type tested the equality of intercepts while the test of interaction effect tested the equality of slopes. All analyses were carried out with SAS statistical software, version 9.2 (SAS Institute).

RESULTS

Demographic characteristics and physical examination findings of study participants are listed in Table I. Uroflowmetry variables are listed in Table II. Seventy-six percent (452/597) of the participants had voiding variables that could be used in this analysis which stipulated that voided volumes for both the NIF and PFS were ≥ 150mL and a value for

$Q_{\max}$ was available. The correlation between NIF and PFS variables varied substantially with relatively high values for $Q_{\max}$ (0.52), moderate for voided volume (0.4), and low for time to $Q_{\max}$ (0.28). The mean values for $Q_{\max}$ were 10% higher during NIF despite the mean NIF voided volumes being 21% lower.

We tested the hypothesis that the correlation between NIF and PFS $Q_{\max}$ and $T_{Q_{\max}}$ obtained for an individual woman would improve if the voided volumes were within 25% of each other. We found that nearly two-thirds (64%) of women had NIF and PFS voided volumes that differed by $\leq 25\%$. In the remaining women with values that differed less than 25%, both correlations for NIF and PFS $Q_{\max}$ and median $T_{Q_{\max}}$ had a small but insignificant improvement (0.56 vs. 0.52, 0.31 vs. 0.28) with the correlation between NIF and PFS $Q_{\max}$ as strong and moderate for median $T_{Q_{\max}}$.

We then analyzed the impact of pelvic organ prolapse on voiding variables and found that the 31 participants with stage III/IV POP had lower values for NIF and PFS $Q_{\max}$ (NIF: 19 vs. 25 ml/sec, PFS: 18 vs. 22 ml/sec, $p=0.07$) compared to women with stage 0–II POP. The variable that was statistically different for women with advanced POP was the median $T_{Q_{\max}}$. The median time to reach $Q_{\max}$ for women with stage 0–1 and 2 POP was 3.2 seconds longer compared to those with stage 3–4 POP during pressure flow studies. Likewise, the presence of a catheter in women with advanced prolapse resulted in *lowering* the median $T_{Q_{\max}}$ by 1.3 seconds compared to the median value calculated during NIF.

In order to better understand the relationship of pooled flow rates and voided volumes, we performed a mixed effect linear regression analysis of $Q_{\max}$ on voided volume and measurement type (NIF or PFS) as described in the methods. Peak flow rates for NIF and PFS increased with increasing voided volumes and are represented by the following equations,

$$NIF: Q_{\max} \text{ mL/sec} = 0.030 (\text{VoidedVolume}) + 13.4 \text{ mL/sec}, n=426$$

$$PFS: Q_{\max} \text{ mL/sec} = 0.019 (\text{VoidedVolume}) + 13.2 \text{ mL/sec}, n=426$$

While the y-intercepts are similar ($p=0.86$), the slopes of the lines differ significantly ($p=0.004$). Figure 2 plots the difference in the NIF and PFS $Q_{\max}$ measures for each participant against the mean with 95% limits of agreement. It shows that the agreement between the two measures is quite good.

Because this study was modeled after a similar prospective supplementary analysis in women who were undergoing surgical repair for POP, we plotted the regression equations of $Q_{\max}$ and voided volume from this study and the CARE supplementary analysis (describe in Methods) in a single graph. We also plotted as a reference the Liverpool nomogram data from the 50th and 10th centile of mean $Q_{\max}$ versus VV (11). This is demonstrated in Figure 3.

DISCUSSION

The aim of our study was to characterize the relationship between voiding variables obtained during NIF and PFS in women with stress incontinence, specifically $Q_{\max}$ and voided volume. When we pooled the data from each subject's NIF and PFS study and performed a linear regression, we found that while $Q_{\max}$ increased with voided volume, it varied depending on whether the catheter was present or not. The slope of the line is defined as the y/x and in this case is the change in peak flow rate ($Q_{\max}$) divided by the change in voided volume (VV). The slope of the linear equation for NIF is 58% higher than the slope of PFS (0.030 vs. 0.019) and is significantly different in mixed model analysis ($p < 0.004$). Since the y-intercepts are practically identical $Q_{\max}$ is dependent on the slope of the line and the voided volume. As voided volumes increase the discrepancy between NIF and PFS flow rates increase. For example, using the linear regression equation, at 200 mL, NIF $Q_{\max}$ was 14% higher than PFS $Q_{\max}$ and this difference increased to 30% at 700 mL. This data demonstrates clearly that flow rates from NIF and PFS should not be used interchangeably since they vary significantly throughout all voided volumes.

Figure 3 compares the $Q_{\max}$ and VV relationships in 3 distinct populations. The Liverpool nomogram was constructed from 249 asymptomatic female volunteers with a median age of 32. Seventy percent of the participants were nulliparous and only 20% of the women had 2 or more children. The current study was composed of women with a mean age of 53 and parity of 2 who had symptoms of stress incontinence and a positive stress test. The supplementary study of the CARE trial consisted of women with primarily advanced POP (80% were stage II or IV), a median age of 60 and parity of 3. Both stress-incontinent and incontinent women were included in the CARE supplementary analysis. Women who are seeking care at urogynecology or urology practices are likely to be older, parous and have pelvic floor symptoms of stress urinary incontinence and POP. Nomograms that reflect age and parity should be used to determine “normality”. It is clear that the Liverpool nomogram for women does not represent the older, parous patients in our practice. Electronic flow meters that use the Liverpool nomogram to determine “normality” should not be considered a reliable resource.

Our literature is replete with urodynamic studies that compare voiding variables between women with urinary incontinence and those with pelvic organ prolapse (12–15). While these studies consistently show that urinary flow rates are higher in women with stress incontinence, voided volume is not controlled for and as a result, the actual impact of prolapse or stress incontinence on $Q_{\max}$ is unknown. From Figure 1, younger, asymptomatic women had the highest $Q_{\max}$, followed by the older stress-incontinent women in this study. Women with the highest mean age, parity and advanced prolapse (CARE trial) had the lowest $Q_{\max}$. Although smaller studies have demonstrated no change in women's flow rates with age, studies in men do show that flow rate decrease with age (2,11). This is often felt to be a function of outlet obstruction in men but decreasing bladder contractility may play a role in age related differences in flow rate. Larger studies that enroll patients across age groups are needed to better understand the impact of age on voiding in women.

The graphical data seems to dispute the idea that women with stress-incontinence are “supervoiders”. While women with stress-incontinence have higher flow rates for PFS and NIF when compared to women with POP, their flow rates are less than the Liverpool nomogram 50th percentile. In fact, urinary flow rates may have little to do with storage disorders such as stress incontinence. An ancillary analysis of the CARE data demonstrated no difference in flow rates between women with advanced POP who did and did not have urodynamic stress incontinence and also supports the observation that inability to store urine has minimal impact on voiding parameters (16). One curious observation between the TOMUS and CARE analysis included in this study is that the slopes between Q_{max} and VV are remarkable similar for such a diverse population.

Advanced POP does seem to affect voiding parameters. Although there were only 31 women (7%) with advanced prolapse in this study, the decrease in NIF and PFS Q_{max} *approached* statistical significance. This is not a new finding and is supported by other prospective studies that have shown women have a reduction in urethral closure pressures and increased flow rate when the POP is reduced during UDS (17,18). We studied the impact of POP and the presence of a transurethral catheter on the median time to Q_{max}. Women with stage 3–4 POP reached Q_{max} sooner (2–3 seconds) with a catheter in place compared to NIF. This finding is not intuitive and, in fact, maybe due to a Type 1 error.

CONCLUSION

The difference between PFS and NIF Q_{max} increases as voided volumes increase in women with stress incontinence and POP. As a result, values from PFS and NIF cannot be used interchangeably as has been suggested in the Blaivas-Groutz nomogram for obstruction in women. Flow rate and voided volume nomograms that account for age are needed in women.

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Abbreviation Key

MESA	questionnaire
NIF	non-instrumented uroflow
PFS	pressure flow studies
VV	voided volumes
Q_{max}	Maximum flow rate
POP-Q	Prolapse stages
T_{Qmax}	the median time to Q _{max}

Q_{max} and Q_{avg}	peak and average flow rates
CARE	Colpopexy and Urinary Reduction Efforts
SPUI	stress predominant urinary incontinence
UITN	Urinary Incontinence Treatment Network
SUI	stress urinary incontinence
POP	Pelvic organ prolapse
CMG	filling cystometry
ANCOVA	analysis of covariance
MCC	Maximum cystometric capacity
SUI	supervoiders

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Figure 1.
Scatterplot of Pooled TOMUS Qmax vs. Voided Volume

Figure 2.
Qmax difference vs. average of values measured by NIF and PFS with 95% limits of agreement

* Regression equation from CARE supplementary study $\geq$ stage II POP, age = 60, 80% stage III/IV⁴.

[^]Regression equation from TOMUS study, women with SUI symptoms, age = 53, few advanced POP (7%).

** Data from Liverpool nomogram 50th and 10th centile for women, median age = 32 yrs, 70% nulliparous⁵.

Figure 3.
Qmax vs. Voided Volume Based on Model Equations from Various Populations

Table I

Demographic Data

BASELINE DEMOGRAPHICS		n=452
Age in years: Mean $\pm$ SD		52.9 $\pm$ 11.15
Number of vaginal deliveries: Median (Range)		2 (0 – 7)
Race: n (%)		
Non-Hispanic White		354 (78.3%)
Hispanic		56 (12.4%)
Non-Hispanic Black		12 (2.7%)
Non-Hispanic Other		30 (6.6%)
POP-Q Stage: n (%)		
Stage O/I		200 (44.2%)
Stage II		221 (48.9%)
Stage III/IV		31 (6.9%)
Prior Surgery for POP: n (%)		20 (4.4%)
Prior Surgery for UI: n (%)		64 (14.2%)
Mean point Ba (cm): Mean $\pm$ SD		–1.31 $\pm$ 1.33
Mean point C (cm): Mean $\pm$ SD		–6.69 $\pm$ 3.07
Maximal change in Q-tip angle (degrees): Mean $\pm$ SD		38° $\pm$ 19°
Urodynamic evidence of stress incontinence: n (%)		392 (87.3%)

Table II Uroflowmetry variables by Prolapse stage (NIF and PFS voided volumes > 150mL)

Characteristic	TOMUS (n=452)	Stage O-II (n=421)	Stage III/IV (n=31)	p-value ⁴	p-value ⁵
Qmax Mean ± SD (mL/sec)					
NIF	24.1 ± 11.6	24.5 ± 11.7	18.6 ± 8.9		
PFS	21.9 ± 10.3	22.2 ± 10.4	17.9 ± 6.9		
NIF – PFS Correlation, r (p-value¹)	0.52 (<0.0001)	0.52	0.54	0.07	0.19
Voided Volume Mean ± SD (mL)					
NIF	309 ± 132	310 ± 135	292 ± 80		
PFS	392 ± 136	393 ± 138	375 ± 108		
NIF – PFS Correlation, r (p-value¹)	0.40 (<0.0001)	0.41	0.19	0.62	0.68
Time to Qmax Median (Range)					
NIF	9.2 (1.1 – 184.1)	9.2 (1.1 – 184.1)	10.5 (3.4 – 134.2)		
PFS	13.0 (1.0 – 661.0)	13.2 (1.0 – 422.8)	10 (2.8 – 661)		
NIF – PFS Correlation, r (p-value³)	0.28 ² (<0.0001)	0.30	0.10	0.02 ⁶	0.07 ⁶

Note:

¹ p-value is from paired t-test comparing NIF with PFS² Spearman's correlation was reported for time to max flow; For the other measures, Pearson's correlation was reported³ Signed Rank Test was used to test whether NIF time to max flow and PFS time to max flow were equal⁴ P-value is from ANCOVA model, testing whether the correlation between NIF and PFS measures differ between POP-Q stage 0–2 with stage 3/4.⁵ P-value is from the ANCOVA model testing whether the correlation between NIF and PFS measures differ between POP-Q stage 0–2 with stage 3/4, after controlling for age⁶ Time to Qmax was transformed to log scale when running the ANCOVA analysis