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Measurement of Dynamic Urethral Pressures with a High Resolution Manometry System in Continent and Incontinent Women

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Abstract

Objectives—Female stress urinary incontinence (SUI) is caused by urethral dysfunction during dynamic conditions, but current technology has limitations in measuring urethral pressures under dynamic conditions. An 8-French high resolution manometry catheter (HRM) currently in clinical use in gastroenterology may accurately measure urethral pressures under dynamic conditions because it has a 25ms response rate and circumferential pressure sensors along the length of the catheter (ManoScan® ESO, Given Imaging). We evaluated the concordance, repeatability, and tolerability of this catheter.

Methods—We measured resting, cough, and strain maximum urethral closure pressures (MUCPs) using HRM and measured resting MUCPs with water perfusion side-hole catheter urethral pressure profilometry (UPP) in 37 continent and 28 stress incontinent subjects. Maneuvers were repeated after moving the HRM catheter along the urethral length to evaluate whether results depend on catheter positioning. Visual analog pain scores evaluated the comfort of HRM compared to UPP.

Results—The correlation coefficient for resting MUCPs measured by HRM vs. UPP was high ($r = 0.79$, $p < 0.001$). Repeatability after catheter repositioning was high for rest, cough, and strain with HRM: $r = 0.92$, 0.89 , and 0.89 . Mean MUCPs (rest, cough, strain) were higher in continent than incontinent subjects (all $p < 0.001$) and decreased more in incontinent subjects than continent subjects during cough and strain maneuvers compared to rest.

Conclusions—This preliminary study shows that HRM is concordant with standard technology, repeatable, and well tolerated in the urethra. Incontinent women have more impairment of their urethral closure pressures during cough and strain than continent women.

Keywords

Maximum urethral closure pressures; stress urinary incontinence; urodynamics; high resolution manometry

Introduction

Stress urinary incontinence (SUI) is the involuntary loss of urine on effort or physical exertion such as exercise and cough(1). Urinary incontinence is prevalent, affecting 16% of adult women(2) and resulting in 260,000 anti-incontinence surgeries every year in the U.S. (3).

The physiologic basis of SUI is understood: bladder pressure exceeds urethral pressure during the dynamic conditions of cough, strain and other activities that increase intra-abdominal and therefore bladder pressure. To date, we have no good standard or accurate objective tools to measure this physiologic condition because our current measuring systems have significant limitations during dynamic conditions. Current techniques for measuring urethral pressures include microtip transducers, water-perfused side-hole catheters, urethral pressure reflectometry, and air-charged balloons on semi-rigid catheters(4–7). Although microtip transducers and air-charged balloon catheters may have reasonable response times to measure pressure during cough conditions, the single sensor can migrate away from peak urethral pressure during any dynamic condition and requires withdrawal techniques to measure maximum urethral pressure. Withdrawal techniques do capture the maximum pressure zone but take tens of seconds to perform, and straining or pelvic floor muscle contractions cannot be maintained for the duration of the withdrawal. Additionally, withdrawal techniques can produce discomfort that provokes a voluntary pelvic floor contraction. Although water-perfused systems are the only systems that measure urethral pressure as defined by the International Continence Society (the fluid pressure needed to open a collapsed urethra)(1), they do not have rapid response times to capture cough events. Therefore, at the current time we do not have measuring systems that distinguish continent from stress incontinent women during physiologic conditions like cough that cause stress incontinence, nor do we have tools to accurately measure treatment success on a physiologic basis.

The ideal tool for assessing urethral function would accurately measure pressures along the whole length of the urethra quickly enough to respond to pressure changes during exertional maneuvers such as coughing or bearing down.

A high resolution manometry (HRM) system, currently used in the field of gastroenterology to measure esophageal pressures, may meet these requirements for measuring urethral pressures during dynamic conditions because it has numerous circumferential pressure sensors all along the catheter and a fast response rate (ManoScan® ESO, Given Imaging, Yoqneam, Israel)(8). It does not require withdrawal to capture maximum pressures. The purpose of this pilot study using this system in the bladder and urethra was to evaluate the concordance with standard technology, repeatability of measurements with catheter position change, and tolerability of this catheter in the evaluation of SUI. We hypothesized that the HRM system would compare favorably with water-perfusion manometry, discriminate between continent and incontinent subjects, and be well tolerated.

Materials and Methods

Settings and participants

Female volunteers were recruited from the Women's Pelvic Medicine Center at University of California San Diego Health System as well as from the community through flyers and online advertisements. We enrolled continent and incontinent women. The study was approved by our Institutional Review Board, and written consent was obtained. All subjects were at least 18 years of age, not pregnant, without evidence of a UTI, and without prolapse beyond the hymen.

Continent subjects were defined as women without subjective stress incontinence or objective urinary leakage during strain or cough and no prior continence surgery. Stress incontinent subjects had demonstrable urinary leakage during strain or cough, with or without prior continence surgery. Each subject completed demographic information including age, height, weight, parity, medical history, and surgical history as well as the Incontinence Severity Index (ISI, scale 0 to 12) (9), Incontinence Impact Questionnaire Short Form (IIQ-7, scale 0 to 100), and Urogenital Distress Inventory Short Form (UDI-6, scale 0 to 100) questionnaires (10). Question 3 of the UDI-6 was specifically used to capture subjective SUI: "Do you experience and, if so, how much are you bothered by urine leakage related to activity, coughing, or sneezing?"

Urethral pressure measurements

After voiding, all subjects had a 14-French Red Rubber Robinson catheter inserted in the bladder. Any post-void residual was drained, and then the bladder was filled to 250ml with sterile water or to the maximum volume she could comfortably hold for 15 minutes if this was less than 250ml. The catheter was removed, and a stress test was performed during cough and strain, supine and then standing if no leakage was observed supine. All subjects then underwent assessments with both the HRM system and water perfusion side-hole urethral pressure profilometry (UPP) in random order.

HRM catheter

We used a pediatric esophageal catheter produced by Given Imaging for use in gastroenterology (ManoScan® ESO, Given Imaging)(8). This catheter is 2.75mm in diameter (approximately 8-French) and has circumferential pressure sensors along 26.5cm of its length. The miniaturized solid state sensors are 4mm long with 2mm of active sensing area separated by 3mm of flexible molding giving a 7.5mm on center spacing between each of the 36 sensors. Each individual sensor has 16 pressure sensitive segments circumferentially distributed around it (Figure 1). Computer processing of the signal comes from the pressure sensing elements and calculates average circumferential pressures (Figure 2). Pressures between sensing elements are interpolated.

The tip of the HRM catheter was placed approximately 5cm in the bladder. A resting pressure was obtained, and then the subject was asked to cough three times and then bear down (strain) three times. The catheter was moved several millimeters, and the resting,

cough, and strain maneuvers were repeated to evaluate whether pressures were dependent on catheter positioning given the 5mm gap between pressure sensors.

Maximum urethral closure pressures (MUCPs) were calculated by subtracting maximum bladder pressure from maximum urethral pressure at rest and during each cough and strain maneuver. Maximum bladder pressure at rest was measured by recording the highest bladder pressure approximately 2cm inside the bladder while the patient was instructed to relax 10 seconds after placing the catheter, and maximum urethral pressure at rest was the highest urethral pressure during this same time period on the color display output. Maximum bladder pressure during cough or strain was, similarly, the highest bladder pressure 2cm inside the bladder at any point during the maneuver, and maximum urethral pressure was the highest pressure anywhere in the urethra at any point during the maneuver. The color display output of the pressure measurements during coughs and strains are shown in Figure 2.

Water-perfused side-hole catheter UPP

UPP was performed on each subject at rest. Sterile water, pressured to 300 cm H₂O with an IV pressure bag, was connected to two Uniflow Flush Device 30ml/h (Edwards Lifesciences, Irvine, CA, USA, which were then connected to the tip (bladder) and side-hole (urethra) lumens of a 7-French triple lumen Laborie water perfusion catheter. At the beginning of each study, with the patient in lithotomy position so that the catheter was horizontal, the catheter was inserted such that the tip and side-hole apertures were in the bladder, and then both vesical and urethral pressures were equalized to zero because urethral closure pressures (subtracted pressures) rather than absolute measures were of interest. Three maximum urethral closure pressure measurements (urethral pressure minus vesical pressure) were obtained from three separate withdrawals at 1mm/s with the catheter oriented laterally.

Tolerability

Subjects completed a 10 cm visual analog scale (VAS) of their discomfort with each of the two catheters. The responses were recorded to the nearest 0.5 cm

Statistical analysis

Wilcoxon tests compared baseline demographics that were not normally distributed. Bland-Altman(11) limits of agreement and Pearson correlation coefficients were calculated for resting MUCPs obtained by HRM compared to UPP and for HRM MUCPs in the first compared to second set of maneuvers after moving the catheter in the urethra. Independent sample t-tests compared rest, cough, and strain MUCPs in continent versus incontinent subjects with Bonferroni method to correct for multiple comparisons. Independent sample t-tests were also used to compare the percent change in MUCP from rest to cough and rest to strain in continent subjects compared to incontinent subjects. $p < 0.05$ was considered significant. With 28 subjects in each arm, we had 85% power to detect a difference of 25cm H₂O between continent and incontinent groups. Analyses were performed using R (<http://r-project.org>).

Results

37 continent subjects and 28 incontinent subjects were enrolled in this study. Demographic information is presented in Table 1. Continent subjects were younger, had lower BMI's, had fewer vaginal deliveries, and had lower scores on all questionnaires.

The mean difference between the pressures obtained by the two technologies was 1.6 cm H₂O (95% confidence interval for limits of agreement -45.1 cm H₂O to 48.5 cm H₂O) by the Bland-Altman method (Figure 3)(11). The correlation coefficient between resting MUCP obtained by UPP and HRM was $r = 0.79$ (95% CI 0.67 to 0.87, $p < 0.001$) (data not shown).

Continent subjects had higher MUCPs (mean in cm H₂O, SE) than incontinent subjects at rest (94.2 (6.4) vs 55.4 (3.8)), cough (94.3 (6.0) vs 38.8 (4.0)), and strain (87.2 (6.2) vs 38.2 (4.1)), all $p < 0.001$.

Mean MUCPs measured by HRM decreased significantly during cough and strain maneuvers in incontinent subjects but not in continent subjects (paired t-tests $p = 0.974$ and 0.12 for cough and strain, respectively in continent subjects compared to $p < 0.001$ for cough and strain in incontinent subjects). MUCPs did not change on average between rest and cough in continent subjects (increased 3.5%, 0.2 cm H₂O) but decreased significantly in incontinent subjects (28.9%, 16.6 cm H₂O) ($p < 0.001$). Similarly, MUCPs did not change on average in continent subjects (decreased 4.9%, 7.0 cm H₂O) but decreased significantly in incontinent subjects (29.1%, 17.1 cm H₂O) ($p = 0.006$) (Figure 4).

Mean differences between the first set of maneuvers and the second set, which was performed after moving the HRM catheter, in cm H₂O (Bland-Altman 95% limits of agreement) were 5.6 (-25.3 to 36.7) for rest, 2.2 (-37.3 to 41.6) for cough, and -2.4 (-40.7 to 35.9) for strain. MUCPs were highly correlated and significant between the two sets of maneuvers: Pearson correlation coefficients for rest, cough, and strain were $r = 0.92$ (95% CI: 0.87, 0.95, $p < 0.001$), 0.89 (0.81, 0.93, $p < 0.001$), and 0.89 (0.82, 0.94, $p < 0.001$), respectively (data not shown).

HRM was better tolerated than water-perfusion UPP with median VAS pain score 1.0 (1st and 3rd quartile 0.5 and 3) compared to 3.0 (25.5) with UPP ($p < 0.001$).

Discussion

The technological advances of the HRM system are its fast response rate and ability to measure approximately 5 evenly-spaced circumferential pressures along the urethra at once. The 25ms (40Hz) response rate of the pressure sensors in the HRM catheter is much faster than water perfusion (4, 5) and fast enough to capture the quick pressure changes during cough. The evenly spaced pressure sensors along the length of the urethra allow for more accuracy in measuring maximum pressures during dynamic conditions because the multiple sensors are more likely to capture a high pressure zone with any catheter migration than a single side-hole or microtip transducer that migrates.

The results of this study of the HRM system demonstrate reasonable agreement with conventional water-perfusion pressures, repeatability with catheter position change, and tolerability. We chose to compare this technology's measurements of resting MUCPs with those obtained by water-perfusion UPP because it measures urethral pressure according to the International Continence Society (ICS) definition: "the fluid pressure needed to open a collapsed urethra"(12). Resting pressure measurements correlated reasonably well between the two technologies.

We found good repeatability of MUCPs using the HRM system twice in the same subject after moving the catheter, which suggests that catheter positioning relative to the maximum urethral pressure does not affect pressure measurements despite the 5mm gaps between sensors. Our limits of agreement for MUCPs with repeated measures using HRM technology were similar to repeated measures with withdrawal water-perfusion side-hole manometry(13). This catheter was tolerable to patients and normal volunteers with a median score of 1 on a VAS scale 0–10 and was more comfortable than water-perfusion UPP despite being a larger catheter, likely because the side-hole and withdrawal technique are less comfortable than the smooth HRM catheter that stays in place and does not require withdrawal.

As expected, mean MUCPs in incontinent women were lower than in continent women. More interestingly, with this catheter that can measure urethral pressures under dynamic conditions, we also found that the percent decrease in MUCPs during cough and strain compared to rest was greater in incontinent than continent women. While the MUCPs hardly changed between rest and cough or strain in continent subjects, they decreased almost 30% between rest and cough or strain in incontinent subjects. These results suggest that maybe MUCP changes during these dynamic maneuvers are more important for stress incontinence than resting pressures, which have not been shown to distinguish well between continent and incontinent subjects using UPP(5). This is consistent with the pathophysiology of SUI; SUI subjects are continent at rest but not during cough and strain. It is likely that these incontinent subjects do not compensate enough during cough and strain to prevent leakage. This would also be consistent with earlier studies that demonstrated that women with SUI had lower pressure transmission ratios during microtip withdrawal MUCP measures (14). Although pressure transmission ratios are lower in women with SUI and may help explain the pathophysiology of SUI, pressure transmission ratios measured using withdrawal techniques have not been found to be useful for diagnosis(15). The new HRM technology can measure MUCPs without withdrawal and therefore is a significant advance over the inaccuracies and technical difficulties of measuring multiple cough pressure spikes over a urethral pressure profile. Future studies will examine its utility for diagnosis of SUI and the evaluation of surgical outcomes. This new technology, which is becoming standard in gastroenterology, may help us better understand urethral physiology during stress maneuvers and may even guide therapy for incontinent patients in the future.

A limitation of the interpretation of our results comparing continent to incontinent women is that the incontinent women had a mean age 9 years older than the continent women, and urethral pressures decrease as a function of age(16). Continent subjects in this study also had a lower BMI, lower parity, and fewer prior surgeries. Age, obesity, and parity are risk

factors for stress urinary incontinence, and the fact that our continent subjects were not matched on these factors limits our ability to draw conclusions. This was a pilot study to assess the use of this technology in the urethra and bladder, and further studies are planned to control for these factors.

A second limitation of this study is artifact that may be introduced by the catheter's circumference and rigidity. The HRM catheter is 8-French compared to the 7-French water perfusion catheter. Larger diameter catheters can produce higher urethral pressures. The MUCPs during coughs and strain maneuvers usually remained greater than zero as measured by this catheter, even though the pressure difference from bladder to urethra could not have actually been positive when urine was flowing out through the urethra in incontinent subjects. The catheter distends the urethra compared to its natural state, and it has some inherent rigidity that may result in a stenting effect that allows for incontinence. Any catheter interferes with urethra mucosa to urethral mucosa coaptation, and the continence mechanism will be different than what exists in the natural state. It is also possible that a part of the force required to bend the catheter in the urethra will create a force on the pressure sensing part of the catheter, causing the average pressure to be artificially high(17). Additionally, we calculated MUCP by subtracting the maximum bladder pressure from the maximum urethral pressure during a given maneuver, so the pressure measurements may not have been precisely concurrent, and there may have been moments in which bladder pressure equaled urethral pressure. A smaller diameter and more flexible catheter could reduce any potential stenting artifact.

HRM is a new technology with potential for clinical use in Urogynecology. In comparison to water-perfusion urodynamic equipment, which costs approximately \$15,000–\$30,000 for the software and reusable hardware plus a few dollars for disposable catheters and tubing each study, the HRM system costs approximately \$50,000, and the catheters are reusable.

In summary, the HRM system agrees reasonably well with water-perfusion technology, does not rely on catheter positioning, and is well tolerated in the female urethra. The ability to measure urethral pressures during dynamic conditions without withdrawal and movement artifact can possibly allow new insights into the continence mechanism. This preliminary study suggests that, while incontinent subjects have more urethral dysfunction than continent subjects at rest, this difference is more pronounced during cough and strain events. Further research is underway to assess how these measures change with continence surgery.

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Figure 1.

This image shows the 2.75mm diameter high resolution manometry (HRM) catheter with 4mm copper pressure sensors spaced 3mm apart (left). Each sensor has 16 circumferential pressure sensing foci each (right).

Figure 2.

High resolution manometry (HRM) catheter output display. Y-axis is distance along the catheter and x-axis is time. Color display pressures are shown during 3 coughs (left) and 3 strains (right) measured in a continent subject.

Figure 3.

Left: Bland-Altman plot of resting maximum urethral closure pressures (MUCPs) by water-perfusion side-hole urethral pressure profilometry (UPP) and high resolution manometry (HRM). Right: Scatterplot of MUCPs by UPP and HRM with dotted line of equality.

Figure 4. Percent change in mean maximum urethral closure pressures (MUCPs) during cough and strain compared to rest as measured by high resolution manometry (HRM). Mean MUCPs decreased significantly in incontinent but not continent subjects.

Table 1

Demographics and measures of continent and incontinent subjects

	Continent (n=37)	Incontinent (n=28)	p-value ***
Age *	49 (32,55) (26–76)	58 (50,63) (39–74)	p = 0.001
BMI *	24.7 (22,28) (19–36)	28.1 (24,33) (19–40)	p = 0.03
Vaginal deliveries *	1 (0,2) (0–5)	2 (1,2.3) (0–5)	p = 0.01
ISI *	0 (0,0.5) (0–4)	8 (4,8) (0–12)	p < 0.001
UDI-6 *	0 (0,11.1) (0–40)	50 (44–58) (6–72)	p < 0.001
UDI-6 * Q3	0 (0,0) (0–1)	3 (3,3) (0–3)	p < 0.001
IIQ-7 *	0 (0,0) (0–81)	33 (21,57) (0–100)	p < 0.001
Prior continence surgery **	0 (0%)	9 (32.1%)	p < 0.001

BMI: body mass index. ISI: Incontinence Severity Index (scale 0 to 12). IIQ-7: Incontinence Impact Questionnaire Short Form (scale 0 to 100). UDI-6: Urogenital Distress Inventory Short Form (scale 0 to 100). UDI-6 Q3: the third question regarding bother from urine leakage related to activity, coughing, or sneezing.

* median (1st and 3rd quartiles)(range),

** n(%),

*** wilcoxon tests.