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Relationship of Urethral Retro-Resistance Pressure to Urodynamic Measurements and Incontinence Severity

M. Slack,[1]* P. Culligan,[2] M. Tracey,[3] K. Hunsicker,[3] B. Patel,[4] and M. Sumeray[4]
[1]*Hinchingbrooke and Addenbrooke's Hospitals, Cambridge, United Kingdom*
[2]*Division of Urogynecology and Reconstructive Pelvic Surgery, University of Louisville HSC, Louisville, Kentucky*
[3]*GYNECARE Worldwide, ETHICON, Inc., Somerville, New Jersey*
[4]*ETHICON, Inc., Somerville, New Jersey*

Aims: The urethral retro-resistance pressure (URP) is a retrograde urethral pressure profile measured by a new urodynamic measurement system.[1] URP is the pressure required to achieve and maintain an open sphincter. This clinical investigation focused on a comparison of URP to standard urodynamic measurements and an examination of their relationship to incontinence severity. **Methods:** Twenty-two centers enrolled 258 stress incontinent women in a randomized, crossover study of two groups: (1) test procedure followed by multichannel urodynamics, (2) multichannel urodynamics followed by test procedure. We defined incontinence severity categories using 24 hr urine loss and assessed these categories using incontinence quality of life (I-QOL), urinary incontinence severity score (UISS), incontinence visual analogue score (VAS), URP, maximum urethral closure pressure (MUCP), and leak point pressure (LPP). **Results:** The mean age was 56.2 (±12) years. No order effect was present. The correlation coefficient between URP and MUCP was 0.31 (95% CI 0.19−1, $P < 0.0001$); between URP and LPP was 0.28 (95% CI 0.12−1, $P = 0.003$); and between MUCP and LPP was 0.14 (95% CI − 0.04−1, $P = 0.101$). The mean values for URP across symptom severity categories were significantly different ($P = 0.028$) and decreased with increasing severity. The mean values for MUCP and LPP did not decrease with increasing severity. **Conclusions:** The study demonstrated that URP had a consistent relationship with incontinence severity. The data suggested that URP is a physiological measure of urethral function and may have clinical utility as a diagnostic tool. Future outcomes-based research is necessary to establish the predictive value of URP, MUCP, and LPP measurements in terms of incontinence cure rates and diagnosis of sphincter dysfunction. *Neurourol. Urodynam. 23:109–114, 2004.* © 2004 Wiley-Liss, Inc.

Key words: GYNECARE MoniTorr; intrinsic sphincter deficiency; leak point pressure; low pressure urethra; maximum urethral closing pressure; stress urinary incontinence; urethral retro-resistance pressure; urethral pressure profile; urinary incontinence severity; urinary incontinence; urodynamics

INTRODUCTION

Urinary incontinence is a common problem affecting millions of women worldwide. The successful treatment of these patients will depend on accurate assessment and diagnosis. The standard preoperative management includes a good history, complete examination, and urodynamic measurements. Although urodynamics has gained widespread clinical use, the value and accuracy of each individual urodynamic test employed remains controversial. Complex urodynamics involves assessment of the filling phase of the bladder, an assessment of flow, and the relationship of detrusor activity to leaks. The urethra is a key element in the continence mechanism. Over the last 75 years, researchers have introduced numerous tests of urethral function. The most commonly used tests are the maximum urethral closing pressure (MUCP) and leak point pressure (LPP). MUCP assesses the passive resistance (or resting tone) of the urethral sphincter, while LPP assesses the active resistance (or dynamic response) of the urethral sphincter under stress [Hseih et al., 2001]. These tests involve the introduction of a catheter into the

[1]GYNECARE MoniTorr Urodynamic Measurement System (ETHICON, Inc., Somerville, NJ).

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*Correspondence to: Mark Slack, 19 Post Street, Godmanchester, Cambridgeshire, UK PE29 2BA. E-mail: mark.slack1@btinternet.com
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urethra and with it a systematic artifact. This concern coupled with a large overlap between the results in normal and symptomatic patients have limited their use in clinical practice.

Correlation of these measurements with symptom severity and treatment outcome is absent. Stress urinary incontinence (SUI) due to intrinsic weakness of the urethral closing mechanism is considered more severe, and known as intrinsic sphincter deficiency (ISD) or "low-pressure urethra." ISD is an obscure term not currently defined by the International Continence Society (ICS). The urodynamic methods and cutoffs used to define ISD remain elusive and controversial [Hseih et al., 2001]. Nonetheless, many clinicians today associate ISD with values of MUCP $\leq$ 20 cmH_2O and LPP $\leq$ 60 cmH_2O [McGuire, 1981; McGuire et al., 1981; Sand et al., 1987; Koonings et al., 1990; Nitti and Combs, 1996].

Researchers have previously explored the concept of retrograde urethral measurements [Bonney, 1923; Bors, 1948; Lapides et al., 1956]. We have devised a new measurement of urethral function based on the retrograde infusion of sterile fluid against a closed sphincter. We have termed the urethral retro-resistance pressure (URP) as the pressure required to achieve and maintain an open urethral sphincter. This method eliminates the need for a catheter during the measurement, avoiding any resultant artifact.

URP may be a useful measure that can provide an assessment of urethral function associated with SUI. Assuming the severity of incontinence has a relationship to degree of urethral dysfunction, one would expect lower pressure values to correspond with higher severity and vice versa. According to the ICS, the clinical utility of current urethral pressure measurement is unclear. There is no urethral pressure measurement that: (1) discriminates urethral incompetence from other disorders, (2) provides a measure of the severity of the condition, or (3) provides a reliable indicator to surgical success [Lose et al., 2002]. This unmet need has precipitated the URP concept and subsequent clinical research on URP measurement in women.

This publication describes a clinical investigation focused on a comparison of URP to other urodynamic measurements. We examine the relationship to incontinence severity and the influence of covariates. We explore the URP concept as a new measurement of urethral function.

MATERIALS AND METHODS

This investigation was a multicenter, randomized evaluation of 258 women at 22 international centers. All centers received ethics committee or institutional review board approval and study participants provided informed consent. Procedures were in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 1983.

Of the patients scheduled to undergo urodynamics, centers included patients who were at least 18 years old and complained of SUI. Patients were excluded if they had (1) a history of SUI surgery within the past 6 months, (2) a history of bulking agent injection within the past 12 months, (3) current pregnancy, (4) active infection demonstrated by catheterized urine dipstick analysis, (5) a known active lesion or present injury to the perineum or urethra, or (6) a known urethral obstruction. Only patients whose anterior wall could be adequately reduced to a grade <1 were eligible.

Before randomization, patients underwent a physical examination and completed a 24 hr pad test with bladder diary, an incontinence quality of life (I-QOL) questionnaire, a visual analogue score (VAS) of incontinence severity, and an incontinence severity score (UISS) questionnaire [Patrick et al., 1999; Stach-Lempinen et al., 2001]. Clinicians performed a standardized approach to hypermobility determination (Q-Tip Test) and prolapse identification [Baden and Walker, 1992]. If prolapse was present, it was reduced prior to testing.

To identify bias related to the order of assessment, centers performed the test procedure and multichannel urodynamic evaluations in random order. Centers randomized patients according to a computer-generated sequence. Those randomized to group 1 underwent the test procedure followed by multichannel urodynamics, and patients randomized to group 2 underwent multichannel urodynamics followed by the test procedure.

The new urodynamic measurement system[1] was used to measure URP, LPP, and single channel cystometry. Clinicians obtained the URP measurement by placing a cone-shaped meatus plug 5 mm into the external urethral meatus, thus creating a seal. The device infuses fluid at a controlled rate of 1 ml per second. The measuring device displays the pressure required to open the sphincter. The URP is the pressure at which the graph plateaus (Fig. 1). The reproducibility of the measurement technique and device has been previously validated in a multicenter study of 61 healthy women without urinary incontinence [Slack et al., unpublished data].

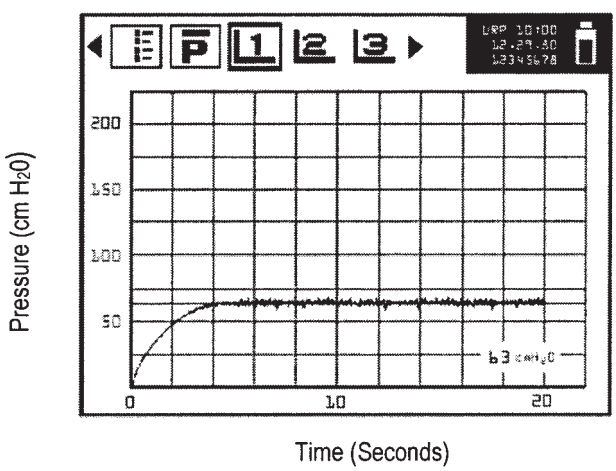

Fig. 1. Sample graph of the urethral retro-resistance pressure (URP) reading.

In order to standardize urodynamic systems, each center calibrated their urodynamic equipment as per manufacturers' recommendations and used 7–7.5 French microtip transducer catheters. Clinicians zeroed the catheters at atmospheric pressure before inserting. Before each procedure, the clinician emptied the bladder and placed the patient in a relaxed, semi-lithotomy position. Clinicians performed multichannel urodynamics and the test procedure according to a set protocol below.

For the standardized multichannel urodynamic procedure the urethral catheter was inserted 4–5 cm with the transducer in the 3 o'clock position and withdrawn until a rise in Pura was noted, indicating proper placement of dual-sensing catheter [Lose et al., 2002]. The vaginal catheter was inserted 3–5 cm into vagina until minimally fluctuating Pabd measurements were achieved. Pabd and Pves readings were to be comparable at the start. Multichannel filling cystometry was performed at 50–80 ml per min, using sterile solution at room temperature. The patient was asked to report first sensation, strong desire, and urgency (maximum cystometric capacity, MCC). Any evidence of detrusor overactivity was noted. A set of three MUCP readings at 100 ml and a set of three MUCP readings at MCC were obtained using a pull rate of 1–4 mm per sec.

For the standardized test procedure, the meatus plug was inserted approximately 5 mm and two or three URP measurements were obtained. Following the URP tests, the bladder was emptied. The catheter was automatically zeroed to atmosphere when entering the test mode. The urethral catheter was inserted 6 cm for a Pves reading. Single channel filling cystometry was performed at 60 ml per min, using sterile solution at room temperature. The patient was asked to report first sensation, strong desire, and urgency (MCC). Any evidence of detrusor overactivity was noted.

For both procedures, clinicians obtained three LPP (baseline Pves not subtracted) at 250 ml. Clinicians encouraged the patient to bear down (not cough) until the patient reached a pressure between 60 and 100 cmH_2O. At the precise moment a leak was observed, the event marker was activated. The LPP was automatically recorded on the screen.

In addition, clinicians observed a dynamic cough profile at MCC, noting any leakage of urine. Centers collected adverse events during the study visit and for a period of 1 week after testing.

The study objectives were to:

1. evaluate the correlation between URP and both MUCP and LPP by performing all measurements on each patient at the same visit;
2. assuming a linear relationship between all measures, apply sensitivity, and specificity analyses to establish a value of URP that corresponds to ISD;
3. evaluate the relationship between URP and incontinence severity using both subjective and objective measures; and
4. examine the influence of covariates on URP.

Statistical Methods

For sample size determinations, we assumed that there is a moderate correlation coefficient ($\rho > 0.40$) between two parameters (i.e., between URP and MUCP; between URP and LPP). A sample size of 228 achieves 90% power to detect a difference of -0.15. We chose 250 patients in order to maximize ISD cases and account for missing or unusable data. This sample size was appropriate when assessing a positive linear relationship ($\rho > 0$). We used SAS 8.2 software for the statistical analysis. We performed all statistical tests at a 5% significance level.

We evaluated the order effect by comparing the difference between: (1) mean URP and mean MUCP and (2) mean URP and mean minimum LPP for each group.

We employed the Pearson product moment correlation to correlate URP to MUCP and the Fisher's z-transformation to perform a one sided test of null hypothesis that $\rho = 0.40$ versus the alternative hypothesis that $\rho > 0.40$. We provided a one-sided 95% CI for ρ. The primary efficacy variable was the average value of the URP measurements. We utilized a two-tailed analysis of variance (ANOVA) technique to detect the statistically significant difference between means. We used the multiple regression approach with backward elimination method to identify the most significant baseline characteristics affecting URP.

Based on work by Stach-Lempinen et al. [2001], we defined severity categories using the 24 hr urine loss: mild (0–8 g), moderate (8.1–30 g), and severe ($\geq$30.1 g). We assessed severity of incontinence using: I-QOL, UISS, incontinence VAS, and number of stress accidents in 24 hr. We reported the mean $\pm$ SD for all measures corresponding to severity categories.

We determined the evaluability status for each subject before executing the analysis. According to terms set before the analysis, we used the evaluable population in the correlation analysis and the intent-to-treat population in the remaining analyses. The evaluable population was patients without major protocol deviations, defined as factors that influence primary outcome measurements. The intent-to-treat population was all randomized patients with at least one URP measurement.

RESULTS

The mean age of the population was 56.2 ($\pm$12) years; with a mean weight of 166.7 ($\pm$35.7) pounds, mean height of 63.9 ($\pm$2.6) inches, and mean body mass index (BMI) of 28.2 ($\pm$6.2). The average parity was 2.4 ($\pm$1.5), and 79 women (31.6%) were premenopausal, with the remainder 171 (68.4%) postmenopausal.

We detected no statistically significant difference between groups, confirming the absence of order effect (all $P \geq 0.28$). Therefore, we performed all analyses ignoring the order in which these measurements were taken.

The mean MUCP@100 ml and MUCP@MCC were 57 ± 28 and 53 ± 27 cmH_2O, respectively. The mean LPP at

250 ml was 87 ± 35 cmH_2O. The mean URP was 71 ± 28 cmH_2O. The distributions of MUCP and LPP, using univariate analyses, were not Gaussian. The histogram indicated that they have a longer tail on the right and therefore, skewed to the left. The distribution of URP was Gaussian.

The average within patient standard deviations were 6.40, 5.78, and 12.44 cmH_2O for MUCP (100 ml and MCC), and LPP measures, respectively. For URP, the average within patient difference was 9.6 cmH_2O.

The correlation coefficient between URP and MUCP was 0.31 (95%CI 0.19−1, $P < 0.0001$); between URP and LPP was 0.28 (95%CI 0.12−1, $P = 0.003$); and between MUCP and LPP was 0.14 (95% CI, −0.04−1, $P = 0.101$, Table I). Since the data showed no statistically significant positive linear relationship between MUCP and LPP, we did not perform sensitivity, and specificity analysis to establish a URP value corresponding with ISD. Descriptive statistics for the primary efficacy variables were similar for both the intent to treat and evaluable populations.

The mean values for URP across symptom severity categories were significantly different ($P = 0.028$) and decreased with increasing severity. Neither URP nor the severity tools could differentiate severity categories. The mean values for MUCP and LPP did not decrease with increasing severity (Table II). In addition, we analyzed different classifications of severity using urine loss in grams ($\leq$8, 8.1−20, $\geq$20.1, and $\leq$20, 20.1−60, $\geq$60.1). These additional severity analyses showed similar results.

In our determination of the effect of demographic and baseline variables on URP, we found a significant association of age to URP ($P < 0.0001$). Since age and menopausal status are linked, we also investigated the effect of menopausal status. Premenopausal women (N = 79) had a mean age of 44 years and mean URP of 77 cmH_2O, while postmenopausal women (n = 171) had a mean age of 62 years and a mean URP of 67 cmH_2O. The ANOVA technique indicated that menopausal status has a statistically significant effect on URP ($P = 0.0068$).

We elected to divide patients into two groups, using a cut-off of 45 years. We chose this cut-off because the mean age in the premenopausal women was 44.3 years. Using regression approach, we examined the relationship between age and URP in both of these subgroups. We found in the subgroup <45 years, there was no statistically significant relationship between age and URP ($P = 0.101$). In contrast, in the subgroup >45 years, the estimated regression line showed a slope that was statistically significantly different from zero ($P = 0.0003$). When we examined the subgroup of postmenopausal women as a whole, we found that age has a statistically significant effect on URP. The slope of this regression line was negative, indicating that as age increases in the postmenopausal subgroup, URP decreases.

Centers exposed all patients to both GYNECARE Moni-Torr and multichannel urodynamics. The two most frequent events reported were pain [1.9% (5/258)] and dysuria [1.6% (4/258)]. The centers reported no serious adverse events. Other adverse events, that may or may not have been related to either procedure, included abdominal bloating, discomfort, pain, dysuria, cramping, frequency, hematuria, vaginal spotting, light-headedness, and transient urinary retention (all $\leq$0.8%). All adverse events resolved quickly.

DISCUSSION

Physiologists have been measuring urethral pressure in a variety of ways for many years. Retrograde pressure is not a new concept. Bonney [1923], Bors [1948], and Lapides et al. [1956] all experimented with retrograde measurements. These were all crude methods of measuring the pressure required to force fluid in a retrograde fashion through the urethra. The techniques were cumbersome and never correlated with severity or outcome. Together with Ulmsten, we revived the concept of retrograde pressure measurements. By delivering fluid at a constant rate, the device is able to measure the pressure required to open the urethral sphincter without the placement of a urethral catheter. We confirmed the principle on a bench model and in animal studies (unpublished data, ETHICON, Inc., Somerville, NJ).

In this study, the average within-patient difference of two URP measurements was 9.6 cmH_2O. In a separate study of

TABLE I. Correlation of URP With Standard Urodynamic Measurements

	Correlation results[a]			
Measurements	N	Correlation coefficient	*P* value	One-sided 95% CI for ρ
URP versus MUCP (100 ml)	181	0.21	0.002	0.090, 1
URP versus MUCP (MCC)	178	0.31	<0.001	0.189, 1
URP versus LPP (250 ml)	94	0.28	0.003	0.120, 1
LPP versus MUCP (100 ml)	91	0.14	0.101	−0.039, 1
LPP versus MUCP (MCC)	91	0.14	0.101	−0.039, 1
MUCP (100 ml) versus MUCP (MCC)	175	0.81	<0.001	0.759, 1

URP, urethral retro-resistance pressure; MUCP, maximum urethral closure pressure; MCC, maximum cystometric capacity; LPP, leak point pressure.

[a]Analysis on the intent-to-treat population produced similar results.

TABLE II. Relationship of Urethral Measurements to Symptom Severity

Severity[a]	URP	Total UISS	Total IQOL	Number of stress accidents	VAS	MUCP@100 ml	MUCP@MCC	Minimum LPP
Mild	77.05 ± 33 (n = 71)	37.84 ± 20 (n = 71)	62.17 ± 22 (n = 68)	1 ± 1.5 (n = 63)	5.7 ± 2.5 (n = 71)	61.57 ± 29 (n = 70)	55.43 ± 25 (n = 67)	90.79 ± 38 (n = 29)
Moderate	69.14 ± 26 (n = 77)	48.03 ± 18 (n = 77)	55.11 ± 21 (n = 77)	1.7 ± 2.2 (n = 68)	6.4 ± 2.4 (n = 77)	47.85 ± 32 (n = 73)	44.38 ± 34 (n = 72)	75.32 ± 23 (n = 38)
Severe	65.60 ± 22 (n = 89)	59.56 ± 19 (n = 89)	43.29 ± 22 (n = 89)	3.5 ± 2.9 (n = 71)	8.0 ± 1.9 (n = 89)	52.90 ± 27 (n = 84)	47.66 ± 25 (n = 82)	84.59 ± 38 (n = 51)
P value	0.028	<0.001	<0.001	<0.001[b]	<0.001	0.020	0.064	0.167

[a]Severity results based on pad loss categories of: mild (0–8 g), moderate (8.1–30 g), and severe (≥30.1 g). Mean ± SD values are provided for all measures.
[b]Kruskal–Wallis test.

asymptomatic women, the within-patient consistency of the URP measurement was demonstrated and the test–retest analysis showed a good correlation [Slack et al., unpublished data].

We found URP values to be distributed in a symmetrical fashion within the patient population. This distribution is a pattern seen in other physiologic measures, such as height, weight, and age. In contrast, MUCP and LPP were skewed to the left. We hypothesize that the absence of a catheter during URP may provide a more physiologic testing condition. We found the upper limit of the one-sided 90% CI for URP to be 105 cmH_2O. Based on the data, we can conclude that the likelihood of a URP value $\geq$105 cmH_2O, in women with SUI, is $\leq$10%.

This study demonstrated a statistically significant, but weak, positive linear relationship to standard urodynamic measures. However, the clinical significance of this is unclear. We found no statistically significant positive linear relationship between MUCP and LPP. One may speculate that each measurement is assessing something different about the urethra. MUCP is a static urethral measurement, where as LPP is a dynamic urethral measurement. We propose, however, that the URP measurement assesses overall function of the urethra.

A large body of urologists has recognized LPP as the optimum measure of urethral function. This view is not necessarily shared by all specialties in the urodynamic community. LPP values within low ranges suggest more severe incontinence and LPP values in higher ranges suggest less severe incontinence [Theofrastous et al., 1995]. Data about LPP are conflicting since it is likely that this measure assesses only one of the factors of incontinence. Additionally, variables such as positioning, bladder volume, and difficulties with Valsalva attempts are among the factors that may influence the LPP measurement. URP may be another way of looking at urethral function in a less invasive manner. A few single-center studies examined the correlation of MUCP and LPP finding variable correlations [Swift and Ostergard, 1955; Sultana, 1995; Nager et al., 2001].

Bump et al. [1997] demonstrated correlation but found a substantial lack of concordance between low MUCP and low VLPP. This lack of concordance of low values raises doubt regarding the diagnostic utility of MUCP and LPP for determining ISD. Our research further supports this finding as only four of 184 (2%) patients met both the MUCP and LPP criteria for defining ISD. Because we defined ISD using MUCP and LPP cut-offs, sensitivity, and specificity analysis to generate a URP cut-off for ISD may not appropriate.

Nager et al. [2001] found a very low and insignificant correlation between urodynamic parameters and both pad loss and quality of life (QOL) measures. Others showed that symptom scores and QOL measures lack correlation to urodynamic measures and are inadequate predictors of urodynamic outcome [Swift and Ostergard, 1955; Fitzgerald and Brubaker, 2002]. In agreement with previous studies, there was no rela-

tionship between these severity categories and MUCP or LPP measurements. As anticipated, we found a significant relationship between IQOL, UISS, and VAS and incontinence severity. This study suggests that URP also has a significant and consistent relationship to incontinence severity. However, neither URP nor the severity tools could differentiate severity categories.

The analysis of the effect of age on URP demonstrated a statistically significant influence. However, on further examination, we found that this effect was due to a strong influence of age in postmenopausal women. As expected URP values decreased with increasing age. This suggests that time spent in menopause is associated with declining urethral function.

The patient population consisted of women referred to specialty centers for complex urodynamic investigation. This will have resulted in a patient population with more severe incontinence, and therefore, would not be representative of the total SUI population. This may have limited our ability to discriminate between different categories of symptom severity. Future studies that represent the total SUI population, may address this issue.

CONCLUSIONS

This work supports the concept that URP is a physiological test that reflects incontinence severity. Comparison with the data from the asymptomatic group of women will give further insight into its role in the diagnosis of urinary incontinence. In a separate publication, we discuss URP values and the correlation of test–retest in asymptomatic women. This clinical investigation was the first step in introducing and examining the URP measurement. Future outcomes-based research is necessary to establish the predictive value of URP, MUCP, and LPP measurements in terms of incontinence cure rates and diagnosis of sphincter dysfunction. Until outcome studies have been performed, the full clinical utility of the URP, MUCP, and LPP measurements remains to be defined.

CONFLICT OF INTEREST STATEMENT

This research was organized, data managed, analyzed, and financially sponsored by GYNECARE a division of ETHICON, Inc., a Johnson and Johnson company.

M. Slack has acted as an honorary medical adviser to GYNECARE and ETHICON. Apart from trial expenses, he has received no payment for the work performed. Dr. Slack is also on the medical advisory boards of Lilly Pharmaceuticals and Pfizer, Inc. P. Culligan received no payments for this work other than study expenses. He is a consultant for CR Bard and Lilly Pharmaceuticals as well.

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