Comparison of Microtransducer and Fiberoptic Catheters for Urodynamic Studies

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OBJECTIVE: To assess the validity and reproducibility of a fiberoptic transducer urodynamic catheter for urethral closure pressure profiles and leak point pressure determination, using a microtransducer catheter as the standard.

METHODS: Ninety women without significant pelvic organ prolapse underwent urodynamic evaluations with both fiberoptic and microtransducer catheters. Maximal urethral closure pressures and "leak point pressures" were repeatedly measured by the two catheters and statistically compared. The order of catheter use was randomized.

RESULTS: Significantly lower mean maximal urethral closure pressures were recorded by the fiberoptic system than by the microtransducer system (28.9 cmH_2O ± 17.3 versus 43.2 cmH_2O ± 24.9, $P < .001$). The fiberoptic catheter predicted microtransducer values for maximum urethral closure pressure only within a range of 27 cmH_2O. Mean "leak point pressure" recorded by the fiberoptic catheters (66.9 cmH_2O ± 2.9) was not significantly different than that recorded by the microtransducer catheters (66.4 cmH_2O ± 2.9, $P = .97$).

CONCLUSION: There is a significant difference between maximum urethral closure pressure values recorded by the microtransducer and fiberoptic catheter systems. No significant difference was found between the two systems in measurement of Valsalva "leak point pressure." (Obstet Gynecol 2001;98:253–7. © 2001 by the American College of Obstetricians and Gynecologists.)

Maximum urethral closure pressure and leak point pressure represent the two urodynamic measurements used most frequently for classifying severity of incontinence, guiding therapy, and evaluating treatment outcomes. Intrinsic sphincter deficiency is a diagnosis based upon a variety of factors including abnormally low maximum urethral closure pressure and leak point pressure values. Intrinsic sphincter deficiency is considered a more severe variety of stress urinary incontinence with higher long-term failure rates when treated with a retropubic urethropexy.[1] As a result, in many continence centers, including our own, suburethral sling procedures are considered first-line therapy for intrinsic sphincter deficiency. In contrast, stress incontinence with "normal" urodynamic findings may be effectively corrected by retropubic urethropexy. To properly advise patients regarding these clinical decisions and assess long-term surgical outcomes for various types of incontinence, it is important to evaluate new technologies as they are introduced into the evolving field of urodynamics.

Microtransducer electronic catheters have been widely regarded as the benchmark technology for urodynamic pressure measurement.[2] Using a mechanical transducer, these devices convert pressure directly into an electrical signal, which is then transmitted to a recording device. Because microtransducer catheters detect pressure in a unidirectional fashion, lateral orientation of the pressure diaphragm during measurement of maximum urethral closure pressure is necessary to avoid high-pressure artifact resulting from direct force applied by coaptation of the urethral walls.[3] Other relative disadvantages of microtransducer catheters include their expense, fragile nature, and the need for routine care to prevent the accumulation of protein deposits along their delicate pressure sensors.

Largely because of these characteristics of microtransducer systems, fiberoptic pressure transducers were introduced as an alternative. Fiberoptic catheters are generally less delicate and require minimal maintenance compared to microtransducer catheters. The Lumax fiberoptic pressure transducer (MedAmicus Inc., Minneapolis, MN), used for this study, contains a silicon diaphragm sensor located near the catheter tip that deflects in response to pressure, modulating the amplitude of a reflected light signal, which is translated into an electrical signal directly related to the initial pressure. Because they

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are available in both disposable and reusable forms and are much less expensive than microtransducer systems, fiberoptic systems such as the one in our study are widely used by gynecologists for preoperative urodynamic testing.

Previous investigation has shown these two catheter types to be comparable for single-channel cystometry in an animal model[4]; however, their comparability during multichannel urodynamics testing, particularly with respect to the measurement of maximum urethral closure pressure and leak point pressure, has not been well established. Elser et al[5] compared a fiberoptic transducer catheter (FST 200 System, C. R. Bard Inc., Covington, GA) to a microtransducer catheter for measuring urethral pressures among women with genuine stress incontinence. In this study, the fiberoptic system recorded significantly lower mean maximum urethral closure pressure values and pressure transmission ratios, compared with the microtransducer catheter; however, the sample size for this study was relatively small ($n = 30$), and leak point pressure measurements were not included.

In this prospective cohort study, we compared maximum urethral closure pressure and "leak point pressure" measurements obtained using the disposable LuMax fiberoptic catheter with pressures recorded by a microtransducer catheter (Mikrotip, Millar Instruments Inc., Houston, TX). Our aim was to evaluate the performance of the fiberoptic catheter in comparison to microtransducer pressure-sensing technology, and thereby determine its clinical utility.

MATERIALS AND METHODS

The eligible study population included women who underwent standardized comprehensive histories and physical evaluations at our center, and were scheduled for multichannel urodynamic studies, between January 1998 and May 1999. At their initial evaluation, postvoid residual volumes and urine cultures were checked for all subjects. Women with urinary tract infections, and those found to have any pelvic organ prolapse greater than stage 1,[6] were excluded from the sample. Our institutional review board approved the study, and informed consent was obtained from all enrolled subjects.

Ninety women ranging in age from 26 to 90 years (mean 58) agreed to participate, and all subjects completed the full study protocol. Immediately before each urodynamic study, a random number table was used to determine the order of catheter use for maximum urethral closure pressure measurement. All urodynamic studies were performed with patients in the upright, sitting position. For the microtransducer catheter, the vesical and urethral pressures were simultaneously recorded with a dual-sensor 8-French Millar Mikrotip catheter. Abdominal pressure was recorded with a similar 8-French Millar catheter placed in the vagina. All microtransducer values were recorded with a Urolab 1156 (Life-Tech, Inc., Stafford, TX). The fiberoptic studies were conducted with disposable, 10-French LuMax catheters and recorded by the LuMax urodynamic system.

Maximal urethral closure pressure was defined according to the International Continence Society[7]; genuine stress incontinence was defined by leakage of urine at the external urethral meatus, during a maximal cough in the absence of a detrusor contraction.[8] Maximum urethral closure pressures were measured at maximum cystometric capacity for all patients in the absence of a detrusor contraction. Because the LuMax catheter used in this study had only one fiberoptic transducer, simultaneous measurement of urethral and vesical pressure during maximum urethral closure pressure assessment could not be accomplished. Therefore, the examiners used clinical clues such as urgency and suprapubic discomfort to exclude any values suspected to have been measured during a detrusor contraction. Both catheters were withdrawn through the urethra using a mechanical profilometer set at a speed of 1 mm/second. Four consecutive urethral profiles were performed, allowing the calculation of four maximum urethral closure pressure values per catheter per patient.

To facilitate comparison of "leak point pressures" and minimize the variability associated with this clinical measure, patients performed four consecutive Valsalva maneuvers with both the fiberoptic and microtransducer catheters simultaneously positioned in the bladder. "Leak point pressure" was defined as the lowest pressure required to cause leakage, calculated by subtracting the intravesical resting pressure from the intravesical pressure at the time leakage first occurred. The lowest of these values recorded by each catheter during leakage was reported as the "leak point pressure." If no leakage occurred, the highest pressure recorded during the Valsalva effort was reported as the "leak point pressure." Any measurements recorded during a detrusor contraction were disgarded.

The fiberoptic and microtransducer catheters could not be connected to the same recording system, so we included an informal periodic calibration system in our study protocol. A polyvinyl chloride pressure chamber was constructed, which allowed the delivery of a known amount of pressure to the pressure transducers of the two systems individually. The pressure recorded during each of these calibrations was identical to the known pressure for both the fiberoptic and microtransducer systems. This calibration protocol was performed four

times during the study period for each system. Meticulous cleaning and storage techniques were used for the microtransducer catheters at all times during the study period. The fiberoptic catheters were disposable.

Statistical analyses were performed with Minitab 12.1 (Minitab Inc., State College, PA), SPSS for Windows 9.0 (SSPS Inc., Chicago, IL), and SAS Version 8 (SAS Inc., Cary, NC). Differences in mean maximum urethral closure pressure and "leak point pressure" were compared using Student two-tailed *t* test; the paired *t* test was used to assess within-subject differences. Intraclass correlation coefficients were used to assess the intrarater reliability of each catheter system (ie, four measures for each patient using each of the two systems); these coefficients were obtained using the SAS *Proc Varcomp* procedure. Simple linear regression was used to evaluate validity by assessing the ability to statistically predict "actual" pressures from fiberoptic readings. A multiple regression model was used to account for potentially important covariates influencing this predictive relationship. It was not possible to perform prestudy power calculations because no sample data or normal values for maximum urethral closure pressure or leak point pressure were available. Therefore, poststudy power calculations were performed.

RESULTS

The study sample was characterized by a mean age of 58.2 years (range 26, 90), mean parity 2.2 (range 0, 6), and an average straining cotton swab angle of 34° (range −11, +76). Twenty-six women (29%) had histories of suburethral slings, retropubic urethropexies, or needle suspensions. The mean maximum cystometric capacity was 484 mL (range 100–1229). The randomization process resulted in the LuMax fiberoptic catheter being used first for measurement of maximum urethral closure pressure in 53% of the study sample. The intraclass (within-patient) correlation coefficients of the microtransducer and fiberoptic catheters across the four maximum urethral closure pressure values were 0.97 and 0.95, respectively, indicating excellent reproducibility for both catheters. "Leak point pressure" intraclass correlations were similarly close: 0.85 for Millar and 0.85 for LuMax.

The mean maximum urethral closure pressure recorded by the fiberoptic catheters (28.9 $cmH_2O \pm 17.3$) was significantly lower than that recorded by the microtransducer catheters (43.2 $cmH_2O \pm 24.9$, $P < .001$); the mean difference was 14.1 cmH_2O (95% confidence interval [CI] 11.2, 17.0, $P < .001$). The statistical power to detect this difference was 99%. Figure 1 illustrates the linear regression between average microtransducer and fiberoptic catheter readings for maximum urethral closure pressure. Using fiberoptic readings, the "actual" microtransducer maximum urethral closure pressure values could be predicted only within 27 cmH_2O pressure, with 95% CI. The coefficient of determination (R^2) for this model was 0.72, indicating that only 72% of the variation in "actual" pressure could be explained by fiberoptic readings. No other potential predictors–including age, maximum cystometric capacity, functional urethral length, or the presence of detrusor instability–added significantly to the regression, or improved the ability to precisely predict microtransducer from fiberoptic catheter readings. Moreover, the order of catheter use did not influence the recorded difference in maximum urethral closure pressure measurement between the two catheters ($P = .57$).

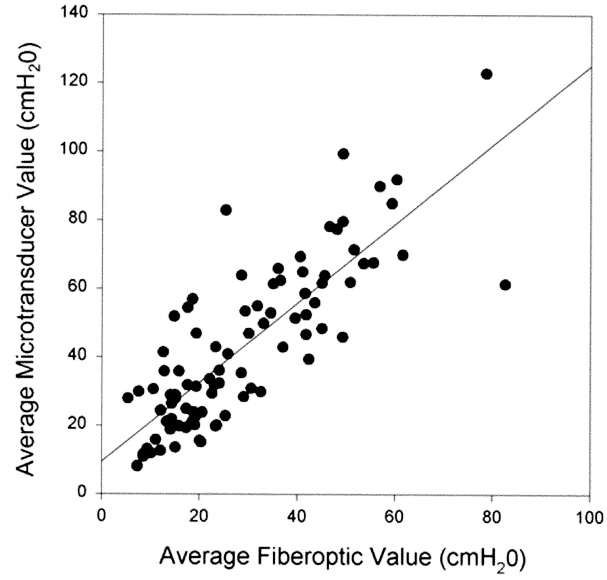

Figure 1. Linear regression model of mean maximal urethral closure pressure values: Model: y = 9.55 + 1.16 (x), where y = microtransducer value; x = fiberoptic value; $P = .001$ for intercept = 0; $P > .05$ for slope = 1; $R^2 = 0.72$. *Culligan. Microtransducer and Fiberoptic Catheters. Obstet Gynecol 2001.*

If the fiberoptic system was used to classify patients as having either "normal" (greater than 20 cmH_2O) or "low" (at most 20 cmH_2O) maximum urethral closure pressure, 27.3% of the patients would have been "falsely" categorized. Table 1 indicates the sensitivity, specificity, negative predictive value, and positive predictive value of using the fiberoptic catheter system to place patients in the "low" or "normal" maximum urethral closure pressure categories.

Mean "leak point pressure" recorded by the fiberoptic catheters (66.9 $cmH_2O \pm 2.9$) was not significantly different than that recorded by the microtransducer catheters (66.4 $cmH_2O \pm 2.9$, $P = .97$). The power to detect

Table 1. Comparison of Fiberoptic and the Standard Microtransducer Catheter Systems in Classification

	Microtransducer MUCP ≤ 20 cm H_2O	Microtransducer MUCP > 20 cm H_2O	Total
Fiberoptic MUCP ≤ 20 cm H_2O	12	25	37
Fiberoptic MUCP > 20 cm H_2O	2	51	53
Total	14	76	90

MUCP = mean maximum urethral closure pressure; sensitivity = 0.86; specificity = 0.67; positive predictive value = 0.32; negative predictive value = 0.96.

a 10% difference in "leak point pressure" was greater than 95%. Figure 2 illustrates the linear regression between average microtransducer and fiberoptic catheter readings for "leak point pressure." The coefficient of determination (R^2) for this model was 0.97, indicating that 97% of the variation in "actual leak point pressure" could be explained by fiberoptic readings.

Genuine stress incontinence was diagnosed in 60 women (67%) and mixed incontinence in 32 (36%). Fifty-one study subjects (55%) were diagnosed with detrusor instability; the presence of detrusor instability did not statistically influence the maximum urethral closure pressure differences between the fiberoptic and microtransducer catheters.

DISCUSSION

Urodynamic studies are widely used by clinicians to document genuine stress incontinence before surgical correction. Two of the most common procedures for the treatment of stress incontinence are the retropubic urethropexy as described by Burch[9] and the suburethral sling. The Burch procedure and its various modifications all work by creating a shelf of endopelvic connective tissue and vaginal tissue at the level of the bladder neck and fastening it to the iliopectineal ligament with permanent sutures. Many different techniques and materials have been used for sling procedures, but the basic design of all of them involves placing a nonabsorbable autologous, heterologous, or synthetic piece of material under the urethra and anchoring it to retropubic structures, abdominal wall structures, or both. Many factors influence a surgeon's decision of which technique to use. Because suburethral slings have been associated with higher rates of postoperative voiding dysfunction and detrusor instability,[10] some clinicians reserve these procedures for patients diagnosed with intrinsic sphincter deficiency. Currently, the urodynamic measurements most widely used to identify patients with "intrinsic urethral sphincter deficiency" are Valsalva leak point pressures and maximum urethral closure pressures. However, it is widely accepted that clinicians should not use urodynamics alone to classify patients as having intrinsic sphincter deficiency.[11] Instead, consideration of a patient's entire clinical picture including urodynamic measurements, symptom diaries, pad-weight tests, and physical findings is recommended when deciding about treatment options for stress incontinence.[12]

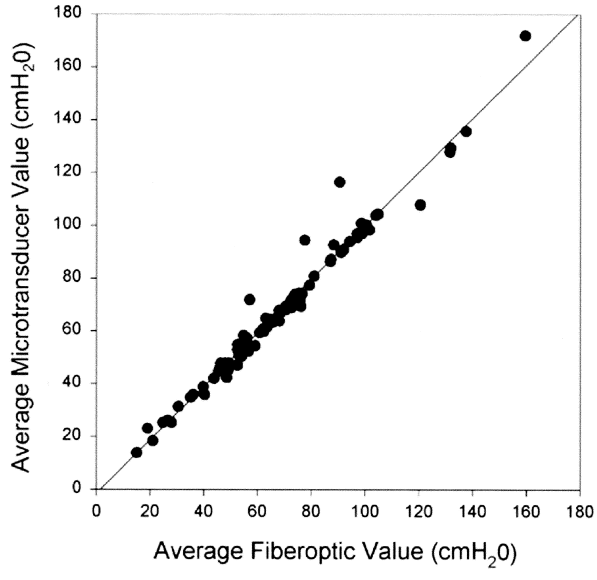

Figure 2. Linear regression model of mean maximal urethral closure pressure values: Model: y = −1.46 + 1.03 (x), where y = microtransducer value; x = fiberoptic value; $P = .29$ for intercept = 0; $P > .05$ for slope = 1; R^2 = 0.97.

Culligan. Microtransducer and Fiberoptic Catheters. Obstet Gynecol 2001.

The established "cut-off" value of 20 cmH_2O for the diagnosis of "low" urethral closure pressure was originally determined using microtransducer catheters.[1] The aim of this study was to determine whether the values obtained for maximum urethral closure pressure with a fiberoptic system were comparable to the microtransducer standard. We found that the LuMax values for maximum urethral closure pressure only predicted the microtransducer readings within a range of 27 cmH_2O. These differences were not predictable (ie, no equation could be applied to the fiberoptic values that would consistently predict the microtransducer values). However, when the fiberoptic system was used to simply classify patients as having either "low" or "normal" maximum urethral closure pressures, the negative pre-

dictive value of the system was 96% (Table 1). Therefore, if a clinician used the LuMax fiberoptic catheter system to rule out "low" urethral closure pressure, he or she would be "correct" 96% of the time.

Comparing leak point pressure values recorded by two different catheters is problematic because of the variation between the quality and intensity of individual Valsalva efforts and the technical challenge of recording the precise moment of leakage. To reduce the potentially confounding variables associated with such a comparison, we recorded "leak point pressure" simultaneously with both catheters in the bladder. The limitation of this study design was that clinically relevant leak point pressure values could not be obtained. However, this strategy facilitated comparison and correlation of the two catheter measurements during the same physical event, and eliminated the need to control for differing Valsalva efforts and subtle delays in marking leakage with the hand-held event recorder. We decided that this simultaneous comparison of the two catheter technologies is the most relevant way to assess the utility of the fiberoptic system for measuring leak point pressure.

Our findings will enable clinicians to compare urodynamic indices from these two different pressure-sensing technologies. Because the ideal surgical treatment algorithm for stress incontinence has not been established, clinicians must use their judgment each time they decide to offer a continence surgery to a given patient. Urodynamic studies play a role in the decision-making process, but the values obtained from these studies are only useful if they are comparable to values obtained during previous and future outcomes-based research.

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