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ORIGINAL ARTICLE

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Air-charged and microtransducer urodynamic catheters in the evaluation of urethral function

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Abstract This study aimed to compare measurements of urethral pressure profile and Valsalva leak point pressure (VLPP) obtained with air-charged and microtransducer catheters. Forty-five women with urogynecologic dysfunction underwent multichannel urodynamic evaluation including maximum urethral closure pressure (MUCP), functional urethral length (FUL), and VLPP with air-charged balloon catheters as well as microtransducer catheters. Lin's concordance coefficient was used to examine the agreement of MUCP, VLPP, and FUL measurements with the two catheters. The MUCPs measured with the two catheters had a high concordance coefficient of 0.69 (95% CI 0.50, 0.82). The VLPP measurements obtained with the catheters also agreed well, with a concordance coefficient of 0.71 (95% CI 0.43, 0.87). The measurements of mean FUL had a low concordance of 0.35 (95% CI 0.085, 0.57). Overall, air-charged and microtransducer catheters yield similar information when evaluating VLPP and MUCP. There were differences in FUL and these were likely due to different catheter diameters.

Keywords Leak point pressure · Urethral pressure profile · Urodynamic catheters

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Introduction

Various types of catheters may be used for the urodynamic investigation of urethral function. These catheters are used to measure intraurethral forces, interpreted as urethral "pressures," which is an idealized concept representing the ability of the urethra to maintain continence [1]. Traditionally, water-filled catheters with external pressure transducers have been used. The accuracy of these catheters is affected by air bubbles in the tubing and the position of the external transducer in relationship to the bladder position. The frequency response time, or how fast changes in pressure are detected, is also affected by the length and width of the tubing [2]. Most recently, catheter-mounted microtransducer catheters have become available with greater reliability and reproducibility. Thus, they have gained widespread popularity and have been regarded as the benchmark technology for multichannel urodynamic testing [3, 4].

Recently, a circumferential balloon monitoring catheter, the air-charged catheter, became available for urodynamic evaluation in the United States. This catheter uses a miniature, air-filled balloon placed circumferentially around a polyethylene catheter. External forces on the balloon are transmitted to the air-filled catheter lumen and communicated to an external semiconductor transducer. The technology of the balloon system allows circumferential measurement readings. The catheters are disposable and single use. A double-balloon catheter with an infusion port is available to measure simultaneous bladder and urethral pressures during filling cystometry, and a single-balloon catheter is used for abdominal pressure measurements (see Fig. 1).

The air-charged catheter is flexible, and has a 7F (2.33 mm) total diameter, with a 2.03-mm diameter internal chamber of air which transmits force signals to the electronic sensor in the connector. The maximum diameter of the balloon is 6.73 mm with a length of 6.35 mm. The balloons on the urethral/vesical catheter are 6 cm apart.

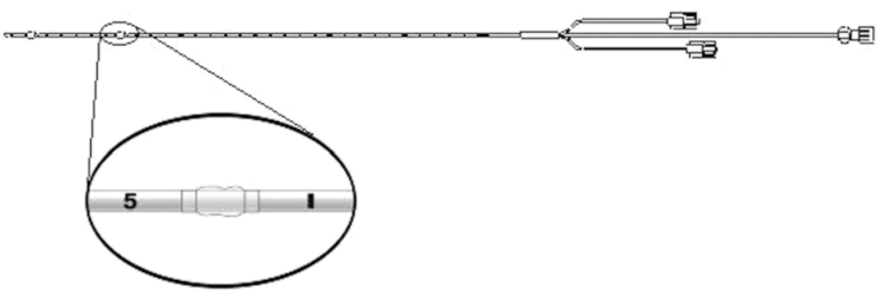


Fig. 1 Double-balloon air-charged catheter with infusion port for simultaneous vesical and urethral pressure measurements. Magnification shows balloon used to obtain circumferential pressure measurements

The air-charged catheter was shown to have improved reproducibility of maximum urethral closure measurements in a cadaveric urethral model, when compared with water transducer, fiber optic, and microtip catheters [5]. There was also a significant difference in the mean maximum urethral closure measurements between catheters.

The aim of our study was to compare the measurements of urethral function obtained with air-charged catheters and microtransducer catheters using identical techniques in patients undergoing multichannel urodynamics for routine indications.

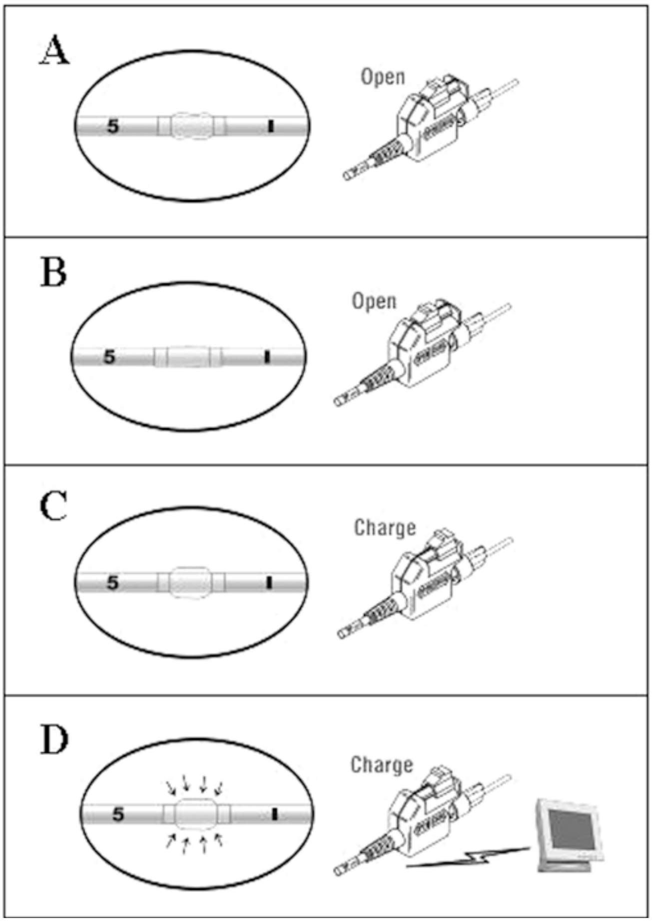


Fig. 2A–D Preparing the air-charged catheter for pressure sensing. **A** Sensing membrane at room temperature. **B** Upon insertion, body pressure flattens the sensing membrane (preparing system for charging). **C** Sliding the connector switch to the "Charge" position charges to sensing membrane. **D** Pressure put on sensing membrane is communicated to monitor

Materials and methods

Women with urogynecologic dysfunction who were undergoing multichannel urodynamic evaluation with microtransducer catheters were recruited for this study. Those who consented underwent repeat urethral pressure profile and leak point pressure testing with air-charged catheters by the same examiner. Nine (20%) had symptoms of stress incontinence, 13 (29%) had urge incontinence symptoms, and 16 (36%) had mixed symptoms. Seven women (16%) had pelvic organ prolapse with the leading edge of the prolapse to the hymen or beyond, without complaints of incontinence, and were undergoing urodynamics to evaluate for occult stress incontinence with the prolapse elevated. Maximum urethral closure pressure (MUCP), functional urethral length (FUL), and Valsalva leak point pressure (VLPP) were measured in each patient with air-charged balloon catheters (T-Doc, Wenonah, NJ) as well as dual sensor, 8F (2.7 mm) microtransducer catheters (Medtronic, Shoreview, MN). The Medtronic Duet (Medtronic, Shoreview, MN) urodynamic computer program was used for all studies.

The VLPP was measured at maximum cystometric capacity using a catheter placed in the vagina to measure abdominal pressures. Maximum capacity was chosen in order not to interfere with bladder filling and minimize any artifact bladder filling may create on sphincter dynamics. Leak point pressure testing was performed in the sitting position and measured during a slow, constant Valsalva effort. The leak point pressure was defined as the lowest valsalva pressure required to cause leakage. Four valsalva maneuvers were performed, and the average was reported as the VLPP. VLPP, rather than vesical LPP (detrusor LPP), was performed in order to evaluate urethral function and its relationship to stress urinary incontinence.

MUCP was defined according to the International Continence Society, noting that the microtransducer catheters do not directly measure the urethral pressure, but the stress on the transducer surface from the urethral tissue [6]. The MUCP represented the maximum difference between the urethral and the intravesical pressure. The urethral pressure profile was performed at rest in the horizontal position with a mechanical puller moving at 1 mm/s. The microtransducer tip was placed at the 9 o'clock orientation. MUCP was measured at maximum cystometric capacity in the absence of detrusor contractions. The FUL was calculated from the urethral pressure profile measurements. It was defined as the length over which the urethral pressures exceeded the intravesical pressures.

The air-charged catheters were used according to the manufacturer's guidelines. They were inserted in the open setting so that the patients' body pressure flattened the sensing membrane. The connector was then switched to the "charge" position, and 15 μl of air filled the balloon. The sensing membrane of the balloon was then ready to detect pressure changes (see Fig. 2).

The patients also underwent routine urodynamic testing including multichannel cystometry, uroflowmetry, pressure voiding studies, and/or cough profile, as clinically indicated. The multichannel cystometrogram was performed using the air-charged catheter, followed by the urethral pressure profile and the VLPP testing. The catheters were then removed, and the microtransducer catheters were inserted. The urethral pressure profile and VLPP tests were then repeated. The protocol was approved by the institution's IRB committee. The study was initiated by the investigators and not supported by a grant.

Agreement between measurements from the air-charged and microtransducer catheters was assessed using Lin's concordance coefficient [7], calculated with SAS 8.0 (SAS Institute, Cary, NC). This score measures agreement ranging from −1 (complete disagreement) to 0 (agreement equal the agreement due to chance) to 1 (complete agreement). The measure is similar to correlation but adjusts for bias so that it measures agreement as well as linear correlation.

Results

Forty-five women with urogynecologic complaints were enrolled in the study. The mean (±SD) age of the patients was 68±12 years. Twenty-six (58%) had previous pelvic surgery. Eight patients had uterine/vault prolapse to the hymen or beyond. Fourteen had anterior vaginal wall prolapse to the hymen or beyond, and nine had posterior vaginal wall prolapse to the hymen or beyond. Urodynamics were performed in these patients with the posterior blade of a Grave's speculum elevating the prolapse. Detrusor instability, defined by the presence of involuntary detrusor contractions during the filling phase, was diagnosed in eleven (24%) of the patients. Thirty patients (67%) had stress incontinence defined by the occurrence of urinary leakage at the urethral meatus during cough in the absence of a detrusor contraction. Four of the seven patients with severe prolapse and no complaints of incontinence had occult stress incontinence. In the remaining three patients, only the MUCP measurements were compared.

The measurements of MUCP taken with the air-charged and the microtransducer catheters agreed well, with a concordance coefficient of 0.69 (95% CI 0.50, 0.82; see Fig. 3). These measurements of VLPP taken with the two catheters also had a high concordance coefficient of 0.71 (95% CI 0.43, 0.87; see Fig. 4). The measurements of functional urethral length had poor agreement with a concordance coefficient of 0.35 (95% CI 0.085, 0.57; see Fig. 5).

From an observational standpoint, the air-charged catheters were comparable to the microtransducer catheters as they had a quick response time to detect pressure changes. In addition, bell-shaped curves of similar configuration were generally obtained with both catheters during the urethral pressure profile. However, the tracings obtained with the air-charged catheters were typically smoother than those obtained with the microtransducer catheters (see Fig. 6). No biphasic patterns, which are sometimes noted with urethral diverticula, were seen in this series.

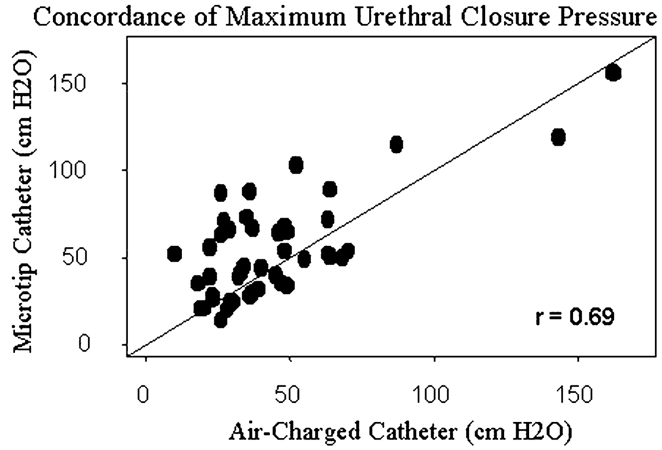


Fig. 3 Agreement of maximum urethral closure pressure measurements obtained with the air-charged and microtip catheters, analyzed using Lin's Concordance Test. Diagonal reference line shows where all points would fall if catheter measurements agreed perfectly

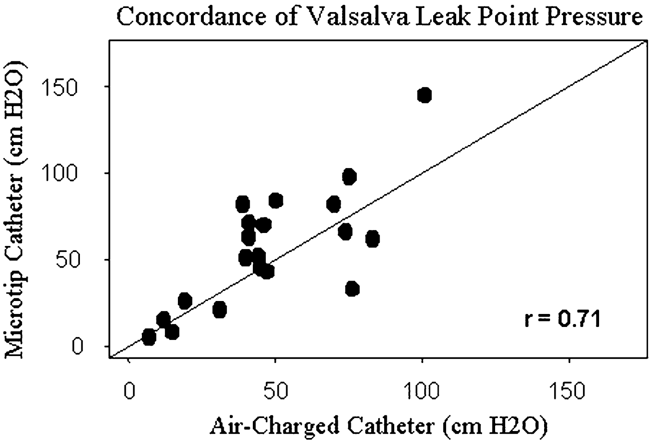


Fig. 4 Agreement of Valsalva leak point pressure measurements obtained with the air-charged and microtip catheters, analyzed using Lin's Concordance Test. Diagonal reference line shows where all points would fall if catheter measurements agreed perfectly

Comment

The disposable air-charged catheter measures forces circumferentially via a concentric balloon, which, in theory, should allow for more accurate urethral "pressure" measurements. Microtransducer catheters record a unidirectional, mechanical force. Because the orientation of the catheter sensors affects urethral pressure profile measurement, artifacts may result [8]. In addition, microtransducer catheters are expensive and require delicate handling. They must also be sterilized between uses [2].

As previously stated, microtransducer catheters do not directly measure the urethral pressure, but the force on the transducer surface from the urethral tissue. As such, air-charged catheters may provide a more accurate assessment of urethral pressure as measurements of forces are performed circumferentially. McKinney et al. [5] previously showed that mean maximum urethral pressure measurements in a cadaveric model taken with

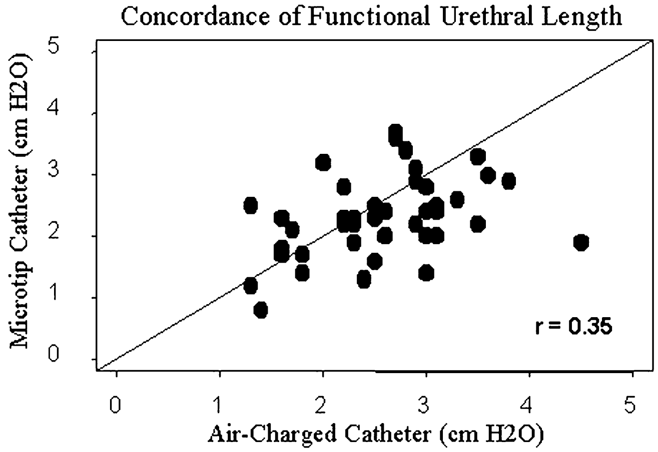


Fig. 5 Agreement of functional urethral length measurements obtained with the air-charged and microtip catheters, analyzed using Lin's Concordance Test. Diagonal reference line shows where all points would fall if catheter measurements agreed perfectly

water transducer, microtransducer, and fiberoptic catheters were statistically different from those taken with the air-charged catheter. They also demonstrated better reproducibility of the air-charged catheter measurements as compared with the other catheters. However, this study was performed in a cadaveric model. More research is necessary to evaluate the reproducibility of the air-charged catheter measurements between and within observers in living subjects.

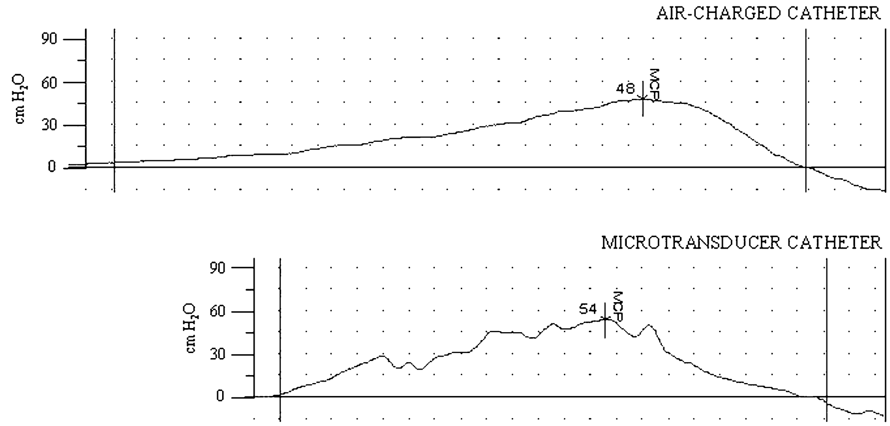
We demonstrated high concordance in MUCP and VLPP measurements obtained with air-charged and microtransducer catheters. These parameters measure a maximum force at a given point, which is less likely to be affected by catheter diameter. The measurements of FUL had lower concordance. These measurements may be affected by changes in catheter balloon diameter and altered with funneling of the bladder neck. This lower concordance was also due to a high variability of the measurements. However, our clinical decision-making was not affected by the differences in FUL measurements obtained with the two catheters.

In the literature, there is a lack of standardization for performing abdominal (valsalva) leak point pressure testing, including using the catheter in the vagina or rectum to evaluate abdominal forces. Both are subject to artifact: a catheter in the rectum may detect rectal contractions/peristalsis and a vaginal catheter may be problematic for women with prolapse. Both the rectum and vagina may be empty and the walls collapsed down on each other. Both may have problems of measuring "pressure" since they may not be fluid-filled organs. However, the measurements are clinically useful for evaluating the severity of stress incontinence because they allow evaluation of the ability of the urethra to resist changes in abdominal pressure. This is different from the vesical (detrusor) leak point pressure which measures the resistance of the urethra to rises in the detrusor pressures. The clinical use for this measurement relates to the fact that those with high vesical leak point pressures have a higher propensity for upper urinary tract disease. As we wished to evaluate urethral function, we chose to measure abdominal leak point pressures. At our institution, we use a vaginal catheter to measure abdominal pressures due to patient comfort and the problem of rectal contractions. As a matter of technique, we obtain three measurements and record an average, in hopes of minimizing artifact.

The air-charged catheters were more flexible than the microtransducer catheters, resulting in increased difficulty inserting the catheters and occasional increased discomfort for the patients. However, the stiffer microtransducer catheters may record more artifact during the urethral pressure profile [9].

Weaknesses of the study include the fact that we did not randomize the order of catheter use. The patients underwent testing with the air-charged catheters, and the testing was then repeated with the microtransducer

Fig. 6 Comparison of urethral pressure profiles (P_{ure}–P_{ves}) obtained with air-charged (*top panel*) and microtransducer (*bottom panel*) catheters in the same patient. The air-charged and microtransducer catheters yielded maximum urethral closure pressure (MUCP) measurements of 48 and 54 cm H_20, respectively, and functional urethral length measurements of 2.3 and 1.9 cm, respectively. From an observational standpoint, the tracings obtained with the air-charged catheters were typically smoother than those obtained with the microtransducer catheters



catheters. Although this may have affected our results, further testing would be necessary to clarify the effect of catheter order on the outcomes. In addition, two observers, each performing the testing using one of the catheters and blinded to the results of the other catheter, would have been ideal to minimize the potential for bias. However, this was not logistically or economically feasible.

We observed mild obstruction from the air-filled balloon; some patients who did not leak urine during coughing with the urethral catheter in place leaked easily with the catheter removed. This may be explained by the fact that the area occupied by the sensor balloon is greater than that occupied by the microtip catheter. This is relevant in VLPP testing. Because lower leak point pressures have been detected with smaller diameter catheters and with removal of transurethral catheters, some investigators have suggested that the urodynamic catheters are obstructive [10]. We feel the balloon catheter may be more obstructive than the microtransducer catheter, and therefore suggest performing VLPP using a vaginal or rectal single-balloon sensor to measure abdominal pressures and removing the urethral catheter when using air-charged catheters.

In women with prolapse, we place both the catheter and the speculum blade into the vagina. Using a standard technique, we place the posterior blade gently into the vagina up to the apex without manipulating the anterior vagina and bladder neck. We tape the speculum with a long piece of tape against the buttocks and urodynamics chair. We then insert the catheter into the vagina until it reaches the apex. Since our goal was to compare the two catheters and since each patient served as her own control, and the speculum was not moved during the entire test, any artifact that may have been created with the speculum should be canceled out when comparing the two catheter measurements. Unfortunately, there is no consensus in the literature on how to perform leak point pressure testing in women with exteriorized prolapse.

Much controversy exists regarding the urodynamic evaluation of urethral function and using force measurements to assess the urethral pressure profile. The goal of this study was simply to evaluate the clinical utility of the air-charged catheters. We obtained values using two types of catheters under near-identical scenarios. It is beyond the scope of this paper to discuss the intricacies and physics of urethral function assessment using these and other currently available catheters.

Air-charged catheters are newly available and yield similar urodynamic readings to microtransducer catheters when evaluating urethral function with urethral pressure profiles and Valsalva leak point pressure testing. The technology is innovative and requires more extensive study. The catheters offer several advantages over existing catheters, namely, the ease of use, the disposability, and the circumferential measuring capabilities.

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Editorial comment

This preliminary data indicates that a disposable air-charged catheter yields similar data to that obtained with microtransducer catheters. This technology is innovative and requires more extensive study. This study is hampered by the fact that the order of catheter use was not randomized.