Air Charged and Microtip Catheters Cannot be Used Interchangeably for Urethral Pressure Measurement: A Prospective, Single-Blind, Randomized Trial

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Purpose: We determined and compared urethral pressure measurements using air charged and microtip catheters in a prospective, single-blind, randomized trial.

Materials and Methods: A consecutive series of 64 women referred for urodynamic investigation underwent sequential urethral pressure measurements using an air charged and a microtip catheter in randomized order. Patients were blinded to the type and sequence of catheter used. Agreement between the 2 catheter systems was assessed using the Bland and Altman 95% limits of agreement method.

Results: Intraclass correlation coefficients of air charged and microtip catheters for maximum urethral closure pressure at rest were 0.97 and 0.93, and for functional profile length they were 0.9 and 0.78, respectively. Pearson's correlation coefficients and Lin's concordance coefficients of air charged and microtip catheters were $r = 0.82$ and $\rho = 0.79$ for maximum urethral closure pressure at rest, and $r = 0.73$ and $\rho = 0.7$ for functional profile length, respectively. When applying the Bland and Altman method, air charged catheters gave higher readings than microtip catheters for maximum urethral closure pressure at rest (mean difference 7.5 cm H_2O) and functional profile length (mean difference 1.8 mm). There were wide 95% limits of agreement for differences in maximum urethral closure pressure at rest (−24.1 to 39 cm H_2O) and functional profile length (−7.7 to 11.3 mm).

Conclusions: For urethral pressure measurement the air charged catheter is at least as reliable as the microtip catheter and it generally gives higher readings. However, air charged and microtip catheters cannot be used interchangeably for clinical purposes because of insufficient agreement. Hence, clinicians should be aware that air charged and microtip catheters may yield completely different results, and these differences should be acknowledged during clinical decision making.

Key Words: urethra, urodynamics, catheterization, female, urinary continence

It is generally agreed that urethral pressure is of significant value for the urinary continence mechanism.[1] This is most commonly assessed by urethral pressure measurement. Water perfusion and fiber optic catheters have been used to evaluate urethral function but microtip catheters are widely considered the benchmark technology.[2] However, microtip catheters are expensive, require delicate handling, must be sterilized between uses and are no longer allowed at many institutions for hygienic reasons. Recently air charged 1-use disposable urodynamic catheters have become available. There is only 1 published study comparing air charged and microtip catheters.[3] Pollak et al reported high concordance in MUCP and VLPP with air charged and microtip catheters.[3] However, this study was not randomized for the order of catheter use. Also, the Lin concordance coefficient[4] instead of the more appropriate and generally accepted Bland and Altman 95% limits of agreement method[5] was used to assess agreement between the 2 catheters.[3]

Considering the limited data in the literature and the likelihood that at our institution hygienic regulations would prohibit the application of reusable catheters in the near future we compared the newly available and promising 1-use air charged catheter with the well established reusable microtip catheter in a prospective, randomized trial.

PATIENTS AND METHODS

Patients

A consecutive series of 64 women referred for urodynamic investigation for urinary tract symptoms were evaluated prospectively. All patients underwent urological evaluation, including medical history, physical examination, urinalysis and urine culture. Before urethral pressure measurement all patients were thoroughly informed about the procedure and provided informed consent.

Measurement Technique

Urethral pressure measurements, including MUCP and FPL, were performed in each patient using a T-DOC®-7FD 1-use disposable 7Fr air charged dual sensor balloon catheter with a diameter of 2.3 mm and maximum balloon diameter of 6.7 mm as well as a CTU-L2 reusable 10Fr microtip dual sensor microtransducer catheter (Gaeltec, Dunvegan, Scotland) with a diameter of 3.3 mm. This was performed by a single physician according to the standardization of ure-

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thral pressure measurement report.[1] A Laborie TRITON™ multichannel urodynamic system was used for all measurements.

Patients were placed in a dorsal lithotomy position. Before urethral pressure measurement started the bladder was emptied by a disposable catheter using an aseptic technique and filled with 50 ml isotonic saline. A computer randomization system was applied to determine the order of urodynamic catheter use. Two consecutive urethral pressure measurements were performed via the catheter per patient. The patient was blinded to the type and sequence of catheter used. The air charged catheter was inserted in the open setting, the connector was switched to the charge position, air filled the balloon and the sensing membrane of the balloon was then ready to detect pressure changes. Microtip catheter measurements were made with the transducer oriented in the 3 o'clock position. Catheter position was observed during testing to avoid a change in orientation. Each catheter was withdrawn through the urethra using a mechanical puller set at a speed of 1 mm per second. All methods, definitions and units conform to the standards recommended by the International Continence Society.[6]

Outcome Measure

The primary outcome measure was the determination and comparison of urethral pressure measurements with the air charged and microtip catheters. Secondary outcome measures were adverse events of urethral pressure measurements with the air charged and microtip catheters. The adverse events considered were urinary tract infection requiring antibiotic treatment and urethral pain requiring analgesic treatment because of urethral pressure measurements.

Statistical Analysis

For a calculated sample size of 63 patients the study was designed to have 95% power ($\beta = 0.05$) for the paired t test to detect a difference of 10 cm H_2O in MUCP and a difference of 5 mm in FPL (these differences were estimated to be clinically relevant) between the air charged and microtip catheters at a 2-sided significance level of 2.5% ($\alpha = 0.025$), assuming a SD of difference in the response of matched pairs of 20 cm H_2O and 10 mm, respectively. Data were normally distributed and they are presented as the mean ± SD. Intraclass (within patient) correlation coefficients were used to determine the intra-observer reliability (repeatability) of the 2 catheter systems. Pearson's correlation coefficients (r) and Lin's concordance coefficients (ρ) were calculated to estimate correlation and concordance between the 2 catheter measurements. To compare related samples the paired t test was applied. Agreement between the 2 catheter systems was assessed using the Bland and Altman 95% limits of agreement, as estimated by the mean difference ± 1.96 SD of the differences, providing an interval within which 95% of the differences between measurements by the 2 methods are expected to lie.[5] Statistical analysis was performed using SPSS® 15.0.1 and Stata® 9.2.

RESULTS

Mean age of the 64 women was 57 ± 16 years. Most patients complained of storage symptoms, about a third experienced recurrent urinary tract infections and about half had pelvic organ prolapse. Nine of the 64 women (14%) underwent previous anti-incontinence surgery, including colposuspension in 4, a mid urethral synthetic sling in 4 and a complex pelvic procedure in 1. Urodynamic investigations revealed stress incontinence, detrusor overactivity with or without incontinence, or mixed incontinence in almost half of the patients and voiding dysfunction due to bladder outlet obstruction or an acontractile detrusor in 36% (see table).

The randomization process resulted in the air charged catheter being used first for urethral pressure measurement in 33 of the 64 patients (52%) in the study sample. The intraclass correlation coefficients of the air charged and microtip catheters across the 2 MUCP values were 0.97 (95% CI 0.95–0.98) and 0.93 (95% CI 0.89–0.96), respectively, indicating excellent repeatability for each catheter. The FPL intraclass correlation was better for the air charged catheter than for the microtip catheter (0.9, 95% CI 0.84–0.94 vs 0.78, 95% CI 0.65–86).

Regarding the high intraclass correlation, MUCP and FPL values of the 2 consecutive measurements with the same catheter were averaged for further analysis. Pearson's correlation coefficients and Lin's concordance coefficients of the air charged and microtip catheters were $r = 0.82$ ($p < 0.001$) and $\rho = 0.79$ (95% CI 0.7–0.89) for MUCP, and $r = 0.73$ ($p < 0.001$) and $\rho = 0.7$ (95% CI 0.57–0.82) for FPL, respectively, indicating a moderate to strong correlation and concordance between the 2 catheters (fig. 1).

Mean MUCP with the air charged catheter was significantly higher than with the microtip catheter (62 cm H_2O, 95% CI 55–69 vs 55, 95% CI 48–61, $p < 0.0004$). In addition, mean FPL with the air charged catheter was also significantly greater than with the microtip catheter (32 mm, 95% CI 31–34 vs 31, 95% CI 29–32, $p = 0.004$).

When applying the Bland and Altman method, the air charged catheter showed higher readings than the microtip catheter for MUCP (mean difference 7.5 cm H_2O) and FPL (mean difference 1.8 mm). There were wide 95% limits of agreement for differences in MUCP and FPL (−24.1 to 39 cm H_2O and −7.7 to 11.3 mm, respectively, fig. 2).

No adverse events, ie urinary tract infection requiring antibiotic treatment and urethral pain requiring analgesic

Patient characteristics

	No. Pts (%)
Lower urinary tract symptoms:	
Storage	32 (50)
Voiding	22 (34)
Storage + voiding	10 (16)
Recurrent urinary tract infections	23 (36)
Menopausal status:	
Premenopausal	23 (36)
Postmenopausal	41 (64)
Parity:	
0	23 (36)
1	13 (20)
2	19 (30)
3 or Greater	9 (14)
Previous anti-incontinence surgery	9 (14)
Pelvic organ prolapse	30 (47)
Urodynamic diagnosis:	
Stress incontinence	11 (17)
Detrusor overactivity with/without incontinence	13 (20)
Mixed incontinence	7 (11)
Voiding dysfunction due to bladder outlet obstruction	14 (22)
Voiding dysfunction due to acontractile detrusor	10 (16)
Normal	9 (14)

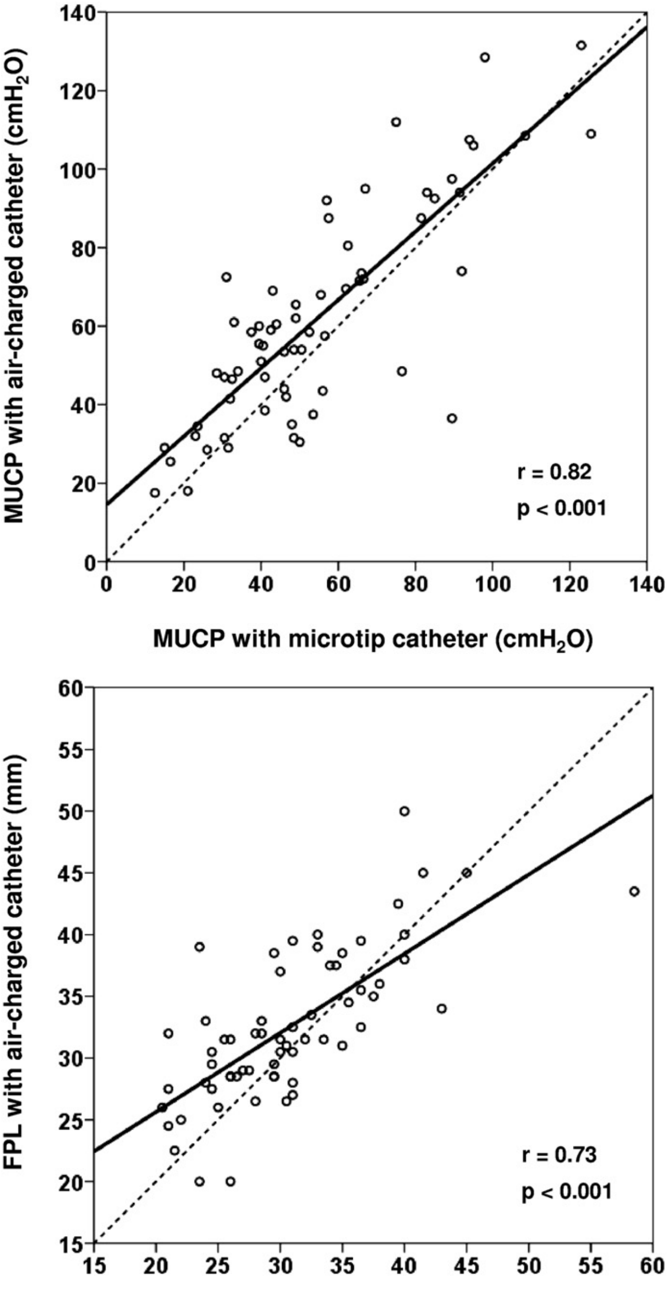

FIG. 1. MUCP and FPL measured by air charged and microtip catheters with regression line (solid line) and line of equality (dashed line). Perfect correlation is observed when points lie along any straight line but there is perfect agreement only when points lie along line of equality.[5] Despite high Pearson's correlation coefficients air charged and microtip catheter did not agree.

treatment, related to urethral pressure measurements occurred during the study period.

DISCUSSION

Although the value of urethral pressure measurement is still a matter of debate, this urodynamic investigation is often used to classify the severity of urinary incontinence, guide therapy and evaluate treatment outcomes.[2] Thus, to properly advise patients an evaluation of new urodynamic tools, such as the recently introduced air charged catheter, becomes imperative.

Traditionally water perfusion catheters with external pressure transducers have been used for the urodynamic evaluation of urethral function. However, setup and calibration are time-consuming and the accuracy of these catheters is affected by kinks and air bubbles in the tube system as well as the position of the external transducer with regard to the bladder. In addition, tube length and diameter affect the detection of pressure changes. Consequently the more reliable, reusable microtip catheter has gained widespread popularity and it is considered the benchmark technology for urethral pressure measurements.[2] A mechanical transducer does not measure urethral pressure directly, but rather converts the normal stress component on the surface of the transducer into an electrical signal. The stress is due to the interaction between the urethral tissue and the transducer, and it depends in part on catheter stiffness and form. In addition, the orientation of the microtip catheter sensors affects measurements.

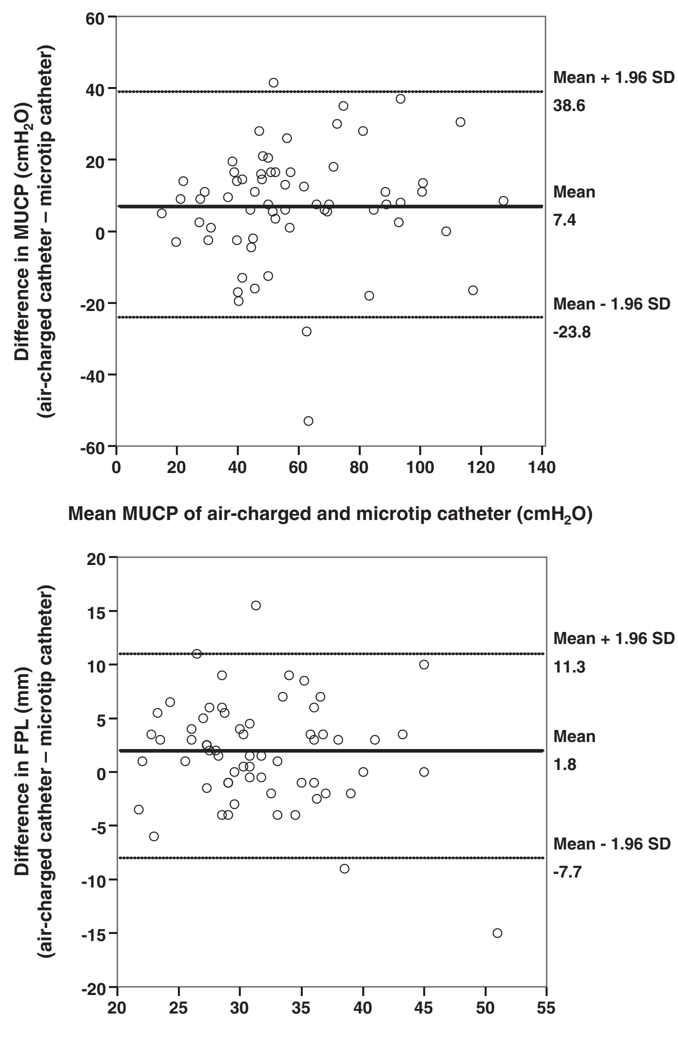

FIG. 2. Difference against mean plot for MUCP and FPL measured by air charged and microtip catheters. Air charged catheter gave higher readings than microtip catheter for MUCP and FPL with wide 95% limits of agreement (mean ± 1.96 SD), reflecting considerable and clinically unacceptable discrepancies between 2 catheter systems.

Recently air charged 1-use disposable urodynamic catheters with circumferential measuring capabilities have become available. The key question is whether we can use measurements by air charged and microtip catheter interchangeably, ie whether the method of measurement can be ignored. In a cadaveric urethral model the air charged catheter was shown to have improved reproducibility of MUCP compared to water perfusion, fiber optic and microtip catheters.[7] Pollak et al found that MUCP and VLPP agreed well between air charged and microtip catheters but FPL did not.[3] However, that study is hampered by the fact that the order of catheter use was not randomized and the statistical method was inappropriate.

In the current study we found good to excellent repeatability for the air charged and microtip catheters with best results for the air charged catheter. This is in line with the results of McKinney et al.[7] Good catheter specific repeatability validates the results and comparison of values obtained by the same measurement method and allows valid conclusions in these circumstances.

Regarding Pearson's correlation and Lin's concordance coefficients, it may be suggested that the air charged and microtip catheters yield similar information when evaluating urethral pressure measurements. However, these results are misleading. Although correlation, regression and comparison of means are widely used in the medical literature to assess agreement between different measurement methods, these statistical approaches are inappropriate, yield misleading conclusions and should be avoided.[8] Agreement is not something that is present or absent, but rather something that must be quantified.[8] This is best assessed by the Bland and Altman 95% limits of agreement.[5] Using this statistical method the air charged catheter showed higher readings than the microtip catheter for MUCP and FPL. Most importantly the 95% limits of agreement were wide, reflecting considerable discrepancies between the 2 catheter measurements: Even by the most optimistic interpretation MUCP differences of −24.1 to 39 cm H_2O and FPL differences of −7.7 to 11.3 mm are not acceptable in clinical practice. Thus, air charged and microtip catheters cannot be used interchangeably because of insufficient agreement. Similarly water perfusion[9,10] and fiber optic[2] catheters also do not sufficiently agree with microtip catheters and they cannot be used in place of each other.

Regarding urethral pressure measurements, there were no safety concerns for the air charged and microtip catheters. In particular no adverse events related to urethral pressure measurements occurred during the study period. We found that handling the air charged catheter was simple. This catheter is also more flexible than the microtip catheter and, therefore, it may have fewer artifacts. Another potential advantage is the circumferential measurement of pressure, which is less dependent on catheter positioning, as reflected by the better repeatability of the air charged catheter, especially considering FPL in the current study.

Although we present an adequately powered, single-blind, prospective, randomized trial, our study has limitations. 1) Urethral pressure measurements with the air charged and microtip catheters were performed unblinded by the same physician. Thus, an examiner induced bias based on his knowledge of catheter type and sequence cannot be completely excluded. However, this seems to be of limited concern regarding the high repeatability of measurements with the 2 catheters and the fact that measurements with the different catheters were performed in randomized order with the patient blinded to catheter type and sequence. 2) The air charged and microtip catheters were different sizes. The air charged catheter is 2.3 mm in diameter but may be up to 6.7 mm at the maximum diameter of the balloon, while the microtip catheter is 3.3 mm. Hypothetically this could have an influence on urethral pressure measurements but differences in catheter diameter hardly seem relevant in the current study, considering that we compared MUCP and FPL but not VLPP. 3) We did not include VLPP. This is not measured at our department because we do not rely on this value for clinical decision making. 4) Although the methodology of urethral pressure measurement is standardized, to our knowledge there are no generally accepted normal or reference values. In addition, based on the literature[2,7,9,10] and the results of the current study, different catheter systems cannot be used interchangeably for urethral pressure measurements because of insufficient agreement. Hence, clinicians should be aware that, despite good catheter specific repeatability, different urodynamic catheters may yield completely different results and these differences should be acknowledged during clinical decision making. Consequently further studies establishing catheter specific normal and reference values are imperative.

CONCLUSIONS

For urethral pressure measurement the air charged catheter is at least as reliable as the microtip catheter and it generally gives higher readings. However, air charged and microtip catheters cannot be used interchangeably for clinical purposes because of insufficient agreement. Hence, clinicians should be aware that air charged and microtip catheters may yield completely different results, and these differences should be acknowledged during clinical decision making.

Abbreviations and Acronyms

FPL	=	functional profile length at rest
MUCP	=	maximum urethral closure pressure at rest
VLPP	=	Valsalva leak point pressure

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