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A randomized comparison of microtip and air-charged catheter for the measurement of maximum urethral closure pressure

Porównanie maksymalnego ciśnienia zamknięcia cewki moczowej mierzone cewnikiem typu mikrotip i cewnikiem wypełnionym powietrzem – badanie randomizowane

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Abstract

Background: *Measurements of maximum urethral closure pressure (MUCP) are a part of urodynamic investigations preceding an incontinence surgery and a part of urethral function tests.*

Objectives: *The aim of the study was to compare maximum urethral closure pressure determined by a microtip catheter with those measured by an air-charged catheter.*

Material and methods: *A prospective randomized study in a tertiary referral centre.*

122 female patients with urodynamic stress incontinence were randomly assigned to have their urethral pressure profiles measured at rest by both microtip and air-charged catheters.

Intervention and Measurements: Each patient had three measurements taken by each catheter type. Means of the measurements were compared with regard to correlation and repeatability. For statistical analysis, an approach proposed by Bland-Altman was applied to assess the agreement between the two techniques.

Results: *Correlation coefficient between MUCP by the air-charged and the microtip catheter was r=0.8507(95% CI 0.7928 – 0.8934; p<0.0001).*

MUCP by the air-charged catheter was significantly lower than MUCP measured by the microtip catheter.

The two-tailed p value was <0.0001, considered extremely significant. (95% CI of the differences; mean difference = -3.033; mean of paired differences -3.730 to -2.335). Discrepancies between measurements of the microtip and the air-charged catheters suggest good agreement between the two catheters since the mean difference was 2.8 cmH_2O and the 95% CI of agreement were narrow with -0.03319 to 0.3151.

Conclusion: *Air-charged catheters give lower readings for MUCP than microtip catheters with a good agreement between the two catheters.*

Key words: **microtip catheter** / **air-charged catheter** / / **maximum urethral closure pressure** / **MUCP** /

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Streszczenie

Cel: *Pomiar maksymalnego ciśnienia zamknięcia cewki moczowej (MUCP) jest częścią badania urodynamicznego poprzedzającego operacyjne leczenie nietrzymania moczu i częścią testów czynnościowych cewki moczowej. Celem pracy było porównanie maksymalnego ciśnienia zamknięcia cewki moczowej zmierzonego przy pomocy cewnika microtip i cewnika wypełnionego powietrzem.*

Materiał i metoda: *Przeprowadzono prospektywne, randomizowane badanie w ośrodku trzeciego stopnia referencyjności. Do badania losowo włączono 122 kobiety z nietrzymaniem moczu, u których wykonywano profil ciśnień w cewce moczowej w spoczynku przy pomocy zarówno cewnika microtip jak i cewnika wypełnionego powietrzem. Każda pacjentka miała wykonane trzy pomiary przy pomocy obu cewników. Średnie z pomiarów porównano w odniesieniu do korelacji i powtarzalności. Do celów statystycznych użyto metody Bland-Altmana oceniającej zgodność obu technik pomiarów.*

Wyniki: *Współczynnik korelacji pomiędzy MUCP mierzonym cewnikiem powietrznym a cewnikiem microtip wynosił r=0,8507(95% CI 0,7928–0,8934; p<0,0001). MUCP mierzony powietrznym cewnikiem był istotnie niższy niż MUCP zmierzony cewnikiem microtip. Wartość p w teście dwustronnym była nadzwyczaj istotna statystycznie i wynosiła <0,0001. (95% CI pomiędzy różnicami; średnia różnica = -3,033; średnia par różnic od -3,730 do -2,335). Rozbieżności pomiędzy pomiarami cewnikiem microtip a cewnikiem powietrznym świadczą o dużej zgodności ponieważ średnia różnica pomiarów wynosiła 2,8 cmH2O a 95% przedział ufności był wąski i wynosił od -0,03319 do 0,3151.*

Wnioski: *Cewnik wypełniony powietrzem daje niższe wyniki MUCP niż cewnik microtip ale pomiary z obu cewników są w zgodzie ze sobą.*

Słowa kluczowe: **cewnik microtip** / **cewnik wypełniony powietrzem** / / **maksymalne ciśnienie zamknięcia cewki moczowej** / **MUCP** /

Introduction

The evaluation of urodynamic stress urinary incontinence involves testing of both, urethral and bladder functions. Urethral function is routinely assessed by urethral profilometry (UPP), delivering measurements for maximum urethral closure pressure (MUCP) and functional urethral length (FUL). For this purpose, microtip transducer, water perfusion or air-charged catheters are commonly used in clinical practice.

Microtip transducers measure the pressure of the urethral wall applied to the surface of the microtransducer. These catheters show a rapid frequency response of 2,000 Hz allowing the recording of rapid pressure changes, which occur during coughing [1] and sneezing. It is noteworthy that the catheter orientation might be more important compared with water perfused catheters since the microtransducer measures the pressure at a certain urethral spot and is dependant on catheter opening orientation [2]. Microtip MUCP measurement is not affected by patient position [3]. Due to potential debris deposit in the catheter holes, microtip catheters have been considered undesirable for hygienic reasons [4].

Air-charged catheters are a relatively novel product to assess urethral function: an air-filled balloon is placed circumferentially around a polyethylene catheter. The pressure administered to the balloon is transmitted by air-charged tubes and, subsequently, measured by an external transducer. These catheters are disposable and, compared to microtip catheters, relatively cheap. In comparison to water perfused catheters, air-charged catheters are unlikely to be susceptible to air-bubbles or inappropriate positioning of the transducer in relationship to the urethra.

Data comparing different technologies for assessing urethral function are scarce; particularly data comparing air-charged catheters and microtip transducers prospectively.

The aim of the study was to compare MUCP measurements obtained by air-charged and microtip transducer catheters in respect to reproducibility and comparability.

Patients and methods

The study was performed in a tertiary referral urogynecology centre. The patients gave their written and oral informed consent and the study was approved by the Local Ethics committee (KEK 123/07).

122 women with urodynamic stress incontinence who had their urodynamics performed as a routine procedure before commencement of treatment were enrolled in this study. Women with a prolapse greater than stage 1, using the ICS Pelvic Organ Prolapse classification, were excluded.

Urodynamic stress incontinence was defined as the occurrence of urinary leakage during cough in the absence of a detrusor contraction.

The external transducer was moved to the upper margin of the symphysis pubis and zeroing was performed to atmospheric pressure and placed at this level during the procedure as recommended by the ICS [5]. Before the investigations, calibration was performed as requested by the manufacturer (Sedia®, Fribourg, Switzerland). Vesical and urethral pressure was not equalized during the procedure. Abdominal pressure was measured rectally using disposable balloon catheters.

Three air-charged perfusion measurements were performed in each patient, at rest, in the 45° upright sitting position at bladder capacity of 250ml, using a 7F (2.33 mm) dual lumen catheter with a withdrawal speed of 1 mm/s. The air-charged catheter is flexible with a 2.03 mm internal chamber for air, which transmits force signals to the electronic sensor in the connector (T-Doc® air-charged polyethylene catheter).

Microtip measurements were also taken in the 45° upright sitting position with the patient at rest using an 8 French Gaeltec® double microtip transducer and the transducer opening was orientated in the three o'clock position with a withdrawal speed of 1mm/s. Catheter position was observed during the test to avoid change of orientation.

Each patient had three measurements of MUCP. The subjects were randomly assigned, using computer-assisted randomization, to have their urethral pressure profile obtained with either the air-charged or the microtip catheter first,.

Catheters were withdrawn with a simultaneous recording of the intravesical and intraurethral pressures, whereof electronic subtraction of these recordings was made. Urethral pressure was recorded as the difference between the urethral and the intravesical pressure.

Statistics were performed using Prism version 5.0 and Graph Pad StatMate version 2.0 for windows.

We calculated an 80% power to detect a difference between means of Δ8.5 with 20 patients necessary for each group and a significance level α of 0.05 (unpaired t-test, two-tailed). Standard deviation was assumed as 9.36 for microtip measurements and 1.30 for air-charged catheters as described in another study [6].

The average maximum urethral closure pressure in resting status was used to assess agreement between the two catheters by an approach proposed by Bland Altman [7]. Reproducibility of the techniques was determined using coefficient of variation and repeatability as appropriate.

Pearson's correlation coefficient was used for correlation.

Results

Median age of our subjects was 72 years (range 47-91), median parity of 2 (range 0-3) and a median body mass index of 29 kg/m^2 (range 23-31). Before the study 23 patients had incontinence surgeries and 18 had hysterectomies for various reasons.

Data for MUCP were normally distributed.

Figure 1 shows the correlation between MUCP as determined by the air-charged catheter and MUCP measured by the microtip catheter. The correlation coefficient was r=0.8507 (95% CI 0.7928 – 0.8934; p<0.0001).

Figure 2 shows the means for MUCP as determined by the microtip and air-charged catheters. MUCP by the latter was significantly lower. The two-tailed p value was p<0.0001, considered extremely significant. (95% CI of the differences; mean difference = -3.033; mean of paired differences -3.730 to -2.335).

The discrepancies between measurements of the microtip and the air-charged catheters are demonstrated in figure 3. The results suggest good agreement between the two catheters since the mean difference was 2.8 cmH_2O and the 95% CI of agreement were narrow with -0.03319 to 0.3151 reflecting small variation of the differences.

Discussion

Much controversy exists regarding the general clinical value of urethral function tests. The current study was intended to compare MUCP measured by microtip catheter to those by air-charged catheter. FUL was assessed but we do not relay on its value when deciding on the course of action. MUCP measurements are higher when using a microtip catheter than when conducting urethral pressure profiles with an air-charged catheter. Furthermore, both methods showed a very good reproducibility with a good intraindividual variation. Finally, mean MUCP values of both methods correlated strongly in our population.

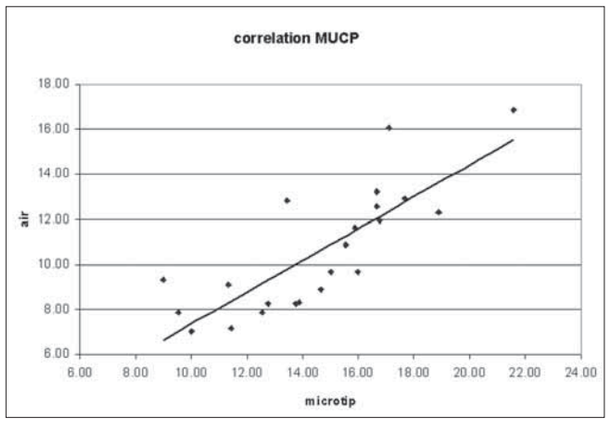

Figure 1. Correlation of MUCP by the microtip catheter (x-axis) and the air-charged catheter (y-axis); cm H_2O.

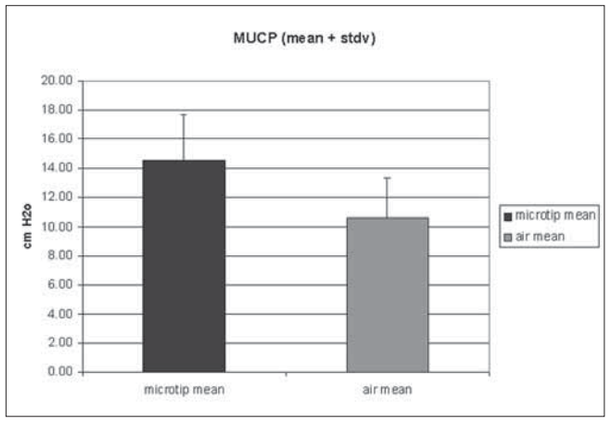

Figure 2. MUCP by the microtip catheter (Column A) and by the air-charged catheter (Column B).

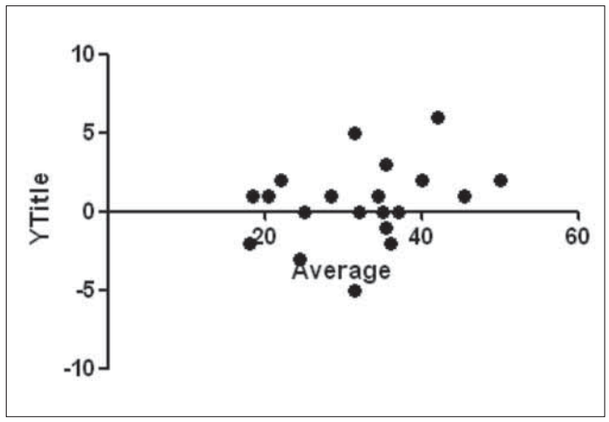

Figure 3. Differences between the air-charged and the microtip catheters compared to average.

MUCP might play an important role in the process of informing patients before stress incontinence operations and the method can obviously influence medical counseling. We need to be cautious which catheters we use and this should be noted in professional urodynamic reports.

McKinney [6] presented higher MUCP readings comparing air-charged, fiberoptic, microtip and water filled catheters for the evaluation of the urethral pressure measurements in favor of the air-charged catheters. In that study, air-charged catheters proved to have a better reproducibility than microtip catheters, which is different from our results. However, this study used cadaveric models with suburethral slings in situ and may be not comparable to our results as the vascular component of urethral pressure is missing.

Pollak [8] compared MUCP, FUL and Valsalva leak point pressure (VLPP), obtained with air-charged and microtransducer catheters. The authors state that both methods provide similar information in regard to VLPP and MUCP, but a low concordance of FUL. These findings were hampered by the fact that the order of catheters used was not randomized. In contrast, a randomization of catheters used was performed in our study.

Zehnder [9] performed a prospective, single-blinded, randomized trial of 64 women comparing air charged and microtip catheters, reporting good reliability of both methods. Interestingly, mean MUCP with an air-charged catheter was significantly higher than the microtip catheter, unlike in our results. However, 47% of the enrolled patients suffered from pelvic organ prolapse, which might have influenced the measurements. Another factor was the microtip catheter diameter, which was 10 French in Zehnder`s and only 8 French in our study.

A maximum urethral closure pressure of <20cm H_2O has been used to define a "low pressure urethra" and intrinsic sphincter deficiency [10; 11]. The clinical relevance of maximum urethral closure pressure related to the continence function remains controversial [12; 13]. There appears to be an increased surgical failure rate in the presence of a low pressure urethra [1; 10; 14]. However, in more recent reports it has been suggested that a diagnosis of a low pressure urethra might not be important in choosing the type of incontinence surgery [15; 16]. Nevertheless, many clinicians consider the urethral closure pressure parameter while deciding on the appropriate operative procedure, particularly as treatment becomes more specific (e.g. slings, bulking agents) [1; 14; 17].

A negative aspect of the current study is the different diameter of the catheters, which may also influence MUCP and FUL [18]. However, catheter diameter differed by one French only and catheters of the same size were not available at the time of the study. Additionally, stiffness and weight of the catheters may affect MUCP as well [19]. Air-charged catheters are more bendable than microtip catheters, which may explain differences in readings.

Repeat catheterization of the urethra might have an effect on the urethral pressure measurement. However, intra-individual variations in maximum urethral pressure do not exceed 5 mmH_2O, as stated by Obrink [20].

Microtip transducers are expensive, require delicate handling and need to be sterilized between patients, [21; 22] which is another potentially negative aspect of microtip catheters.

To conclude, air-charged catheters and microtip transducers are both reliable methods. MUCP by microtip catheters was significantly higher in our study than in air-charged catheters. Both the air-charged and the microtip catheter measurement techniques of the urethral pressure have a very good reproducibility, Regardless, both methods are not interchangeable and should not be mixed in scientific studies.

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