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Urological Research

Pressure/cross-sectional area probe in the assessment of urethral closure function*

Reproducibility of measurement

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Summary. A probe, which enables measurement of related values of pressure and cross-sectional area, was used for in vitro studies and in vivo measurements in the female urethra. Six healthy females underwent two successive investigations. Measurements were performed at the bladder neck, in the high-pressure zone and distally in the urethra. The in vitro study showed that cross sectional areas of 13–79 mm^2 were determined with a SD of 1.4 mm^2. In vivo measurements revealed that the urethral parameters: elastance, hysteresis, pressure and power of contraction during coughing and squeezing were fairly reproducible. However, a certain interindividual variation of the parameters was found.

Key words: Female urethra – Pressure-cross-sectional area relations – Elastance – Compliance – Hysteresis – Power generation – Reproducibility of measurement

A new method has recently been described for assessment of urethral closure function, based on measurement of related valaues of cross-sectional area (CA) and pressure in the urethra (P_{ura}) [5, 10, 11, 17, 18]. This method provides a more detailed evaluation of the urethral closure function as compared with conventional urethral pressure profilometry. However, the clinical applicability of the method depends on 1) whether accurate inferences regarding the urethral function can be drawn from the produced data and 2) whether the obtained data are sufficiently reproducible. So far, there has been no information concerning the reproducibility of the parameters produced in women.

The purpose of this study was to assess the reproducibility of results obtained with the pressure/cross-sectional area probe (P/CA-p), both in vitro and in vivo for evaluation of urethral closure function in healthy women.

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Material and methods

P/CA-probe

The probe (Fig. 1) has been described previously [11, 12]. It enables simultaneous measurement of CA, P_{ura} and intravesical pressure (P_{ves}). CA is induced by means of a cylindrical balloon (length 1.5 cm, diameter 1.0 cm) and measured according to the field gradient principle, as modified by Colstrup et al. [5]. This implies that the impedance of the fluid in the balloon to a high-frequency alternating current is inversely proportional to the CA of the balloon and hence to CA of the tube where the balloon is placed. The probe allows measurement of the average CA of a 2 mm long segment of the urethra in the range of 13–79 mm^2. Maximum CA can be induced in about 50 ms.

Pressures are measured with a double microtip transducer (Honeywell). The proximal pressure sensor is placed in the balloon for measurement of P_{ura}, while the distal sensor is used for measurement of P_{ves}. Urethral pressure is measured in the range of 0–200 cm of water. The rise time of the pressure system is 2.5 ms corresponding to a frequency response of 189 Hz [11].

Before every measurement the pressure sensors and the CA measuring unit were calibrated and the system was checked to be free from air bubbles and without leakage. The detachable balloon was changed after every third investigation or once a week. The probe was sterilised in Corsolin® 3%.

In vitro measurement

For estimation of the measurement error of CA, as determined with the field gradient probe, we used a hard plastic block with cylindrical bore holes of known CA. In each of 11 holes, ranging from 20 to 83 mm^2, the measurements were repeated 10 times at 37°C.

In vivo measurement

Volunteers. Test-retest measurements were performed at three different sites in the urethra in 6 female volunteers, after given informed consent. The median age was 38 years (range 25–55 years). Median parity was 1 (range 0–3), 3 females were nullipara. None had previously undergone urogenital surgery and all were without gynecological or urological complaints. Five had normal

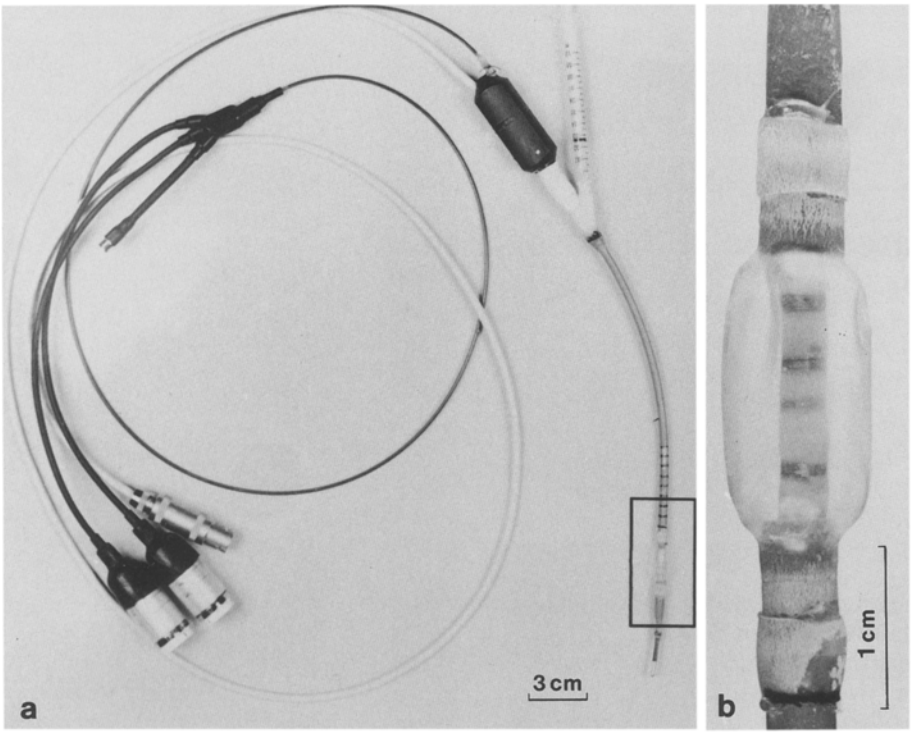

Fig. 1. **a** The probe for simultaneous measurement of urethral pressure, cross-sectional area of the urethra and bladder pressure. The balloon is maximally inflated. Scales in centimeters. **b** The 4 ring electrodes can be seen inside the balloon

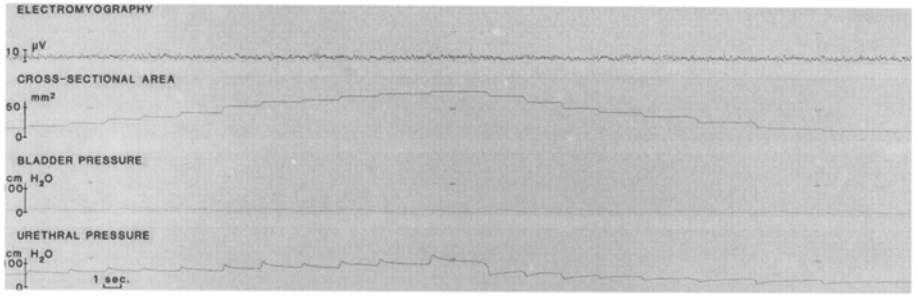

Fig. 2. Stepwise induction of increasing and decreasing cross-sectional areas with simultaneous recording of related urethral pressure, intravesical pressure and urethral sphincter EMG. Measurement was performed in the high pressure zone

menstruation while 1 was postmenopausal. All had a normal pelvic examination, negative urine culture and a normal spontaneous uroflowmetry.

This study was approved by the regional ethical committee.

Investigative procedures

All measurements were performed with the subject in the supine position and with an empty bladder. In each person two successive investigations were carried out with an interval of 1 h.

Throughout the investigation EMG was registered with surface electrodes inserted in the vagina just behind the mid-urethra [13]. Before insertion the distal part of the probe was dipped in lidocaine jelly. The probe was placed with the two microtransducers in the bladder. This position and the pressure transmission was checked by asking the subject to cough. To avoid reflex activity during measurement, recordings were not initiated until 5 min after insertion of the probe. The balloon was inflated to its maximum CA and the probe was retracted until the balloon entered the urethra as indicated by a marked increase in pressure. The balloon was totally deflated and the probe retracted until the entire balloon was positioned in the urethra. Measurements were performed with the sensing electrodes located at three different positions in the urethra: a) proximally (0.75 cm from the urethrovesical junction), b) midurethrally (in the high pressure zone) and c) distally (0.75 cm from the external meatus). At each position the following procedures were carried out:

I) The CA of the balloon was increased stepwise (5–10 mm^2 per step) by fast inflations of small volumes of saline using 1 ml syringe. Simultaneously the related changes in P_{ura} were recorded (Fig. 2). After each step of the inflation, steady state was awaited between the balloon and the intraurethral pressure as indicated by constant pressure. Induction of CA's were continued until maximum CA of the balloon or a pressure of 200 cm water was reached. The balloon was then deflated stepwise in the same manner until empty.

II) After induction of a CA of about 50 mm^2 each subject was asked to cough and then to squeeze (hold urine) three times. The most effective cough and squeeze was used for calculation of the power of contraction. During these manoeuvres related values of CA and P_{ura} were registered with the balloon open to a reservoir to allow for emptying of the balloon (Fig. 3) [11, 12].

All measurements were performed by the same investigator (G. Lose)

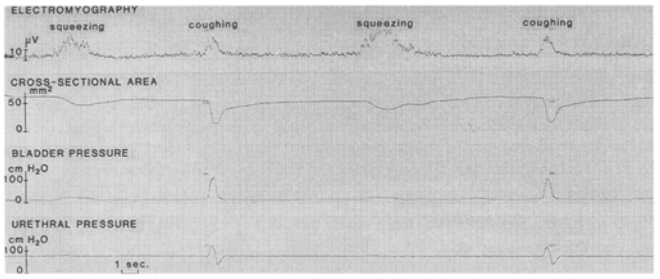

Fig. 3. Measurement of cross-sectional area (CA) in the urethra after induction of a constant pressure of 75 cm H_2O and the CA-pressure changes during squeezing and coughing. The pressure was induced by means of a reservoir which allows emptying of the balloon when the urethral pressure exeeds the reservoir pressure. Measurement was performed in the high pressure zone. Paper speed 15 mm/s

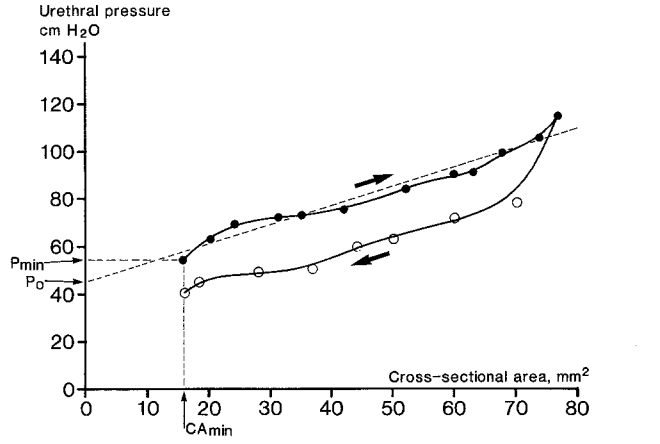

Fig. 4. Related values of urethral pressure and cross-sectional area obtained at steady state between the balloon and the urethra from the investigation shown in Fig. 2. The dashed line is the regression function: $P_{ura} = (dP_{ura}/dCA)\ CA + P_0$, dP_{ura}/dCA being the elastance and P_0 the theoretical non-instrumented urethral pressure. The maximum distance between the curves obtained during inflation (●——●) and deflation (○——○) indicate the hysteresis. P_{min} is the pressure measured at CA_{min} (i. e. the minimum CA of the probe)

Methodological considerations and parameters

Compliance of a biologic tube is defined as $dV/d(\Delta p)$, where dV is the volume change and $d(\Delta p)$ is the change in transmural pressure Δp (intraurethral minus extraurethral pressure). If a segment of the urethra is considered cylindrical with a constant length of 1 mm and a cross-sectional area of CA (mm^2), the volume change dV can be expressed as dCA × 1 (mm^3) and hence the compliance as $dCA/d(\Delta p)$ (mm^3/cm H_2O).

All structures surrounding the urethra are considered to contribute to intraurethral pressure. Consequently, the pressure outside the urethra is the atmospheric pressure. Thus, changes in transmural pressure $d(\Delta p)$ is equal to changes in intraurethral pressure P_{ura} and hence compliance may be defined as dCA/dP_{ura}. *Elastance* is defined as the reciprocal of compliance i. e. dP_{ura}/dCA [3].

Procedure I. The related values of CA and P_{ura}, measured at steady state during stepwise inflation of the balloon, were plotted against each other for each urethral position (Fig. 4). Elastance was determined as the slope of the linear regression function: $P_{ura} = (dP/dCA)CA + P_0$, obtained from the linear part of the curve. This means that the points at the greatest CA's, where pressure rises steeply, were excluded. The intercept on the pressure axis, P_0, denotes the theoretical closure pressure of the uninstrumentated urethral. P_{min} is the urethral pressure measured at the minimum CA of the probe, i. e. 13 mm^2. The hysteresis of the urethra was expressed as the maximum pressure difference between the curves obtained during inflation and deflation of the balloon.

Procedure II. The work (W) produced by the urethra to deflate the balloon is the volume reduction dV of the balloon multiplied by the pressure in the balloon (P_{ura}), i. e., $W = P_{ura} \times dV$. If we consider the balloon to be cylindrical with a length of 0.01 m, the volume can be expressed as CA × 0.01 (m^3). The work produced by voluntary contraction of a cylindrical segment with the length of 0.01 m with uniform properties would be $W = P_{ura} \times dCA \times 0.01$ (kPa × m^2 × m = Joule; 1 kPa = 10 cm H_2O). Since the duration of work can be read from the tracing, the power (J/s = watt) of the contraction can be calculated.

Data recording equipment

CA, P_{ura} press and EMG were registered, processed and displayed on a 6-channel recording system (DISA UROsystem 21F 16 2100). The frequency response of the amplifying system was 100 Hz. Paper speed of 15 mm s^{-1} was used. EMG activity was recorded in the range 4–10 μV/Div.

Statistical methods

The statistical analysis was based on standard parametric methods [7].

In vitro measurement. The differences between the measured and the true CA were plotted against the true CA. The distribution of these differences seemed independent of the true value. Therefore, the variance for the individual cylinders could be pooled to constitute the methodological error, which was expressed in termes of 1 SD.

In vivo measurement. Reproducibility and normal range were estimated for each of the variables: elastance, hysteresis, P_{min} and power of contraction during squeezing and coughing. First, data were examined by a plot of the test-retest differences against their mean. This would disclose any possible relationship between the measurement error and the true value [4]. Normality was confirmed using normal scores from the statistical package Minitab. In order to check whether reproducibility differed between subjects or between urethral position the test-retest differences were subjected to analysis of variance. Finally reproducibility was expressed as the 95% confidence interval (± 2 SD of log. data).

In contrast to the test-retest differences, the measurements themselves did not follow the Normal distribution. However, after logarithmic transformation normality could be confirmed for all five variables. The normal range was determined as the 95% confidence interval (mean ± 2 SD).

Since up to five comparisons were involved for each variable, the Bonferroni method was applied taking account of multiplicity [9] and throughout the study the significance was taken as $p < 0.01$.

Results

In vitro measurement

The method error, in terms of the SD of the difference between the measured and true CA, was 1.4 mm^2. This

Table 1. Normal range and reproducibility of various urethral parameters at three different sites in the urethra in normal, healthy women

Parameters	Normal range (95% level)	Reproducibility (95% level)
Elastance (cm H_2O/mm^3)	0.5– 2.2	± 0.5
Hysteresis (cm H_2O)	7 –44	± 13
P_{min} (cm H_2O)		
prox and dist	13 –57	± 16
mid	31 –67	± 16
Squeeze power (mWatt)		
prox and mid	0.5–13	± 2
dist	0.3– 6	± 2
Cough power (mWatt)		
prox and mid	3 –24	± 3
dist	2 –13	± 3

Prox = at the bladder neck; Mid = midurethrally; Dist = distally in the urethra

means that measurement error of CA in vitro was ± 3 mm^2 using a 95% confidence limit.

In vivo measurement

For all 5 variables, analysis of the test-retest data showed that repreducibility did not differ significantly at the three urethral sites investigated. Thus, data could be pooled. The 95% confidence intervals for the difference between two successive measurements are shown in Table 1.

Concerning the normal range of the investigated variables a difference in the urethral position appeared for P_{min} and for the power produced during squeezing and coughing. P_{min} was significantly higher in the mid-urethral position than in the other two sites ($p < 0.01$). The power during both squeezing and coughing was significantly lower in the distal position ($p < 0.001$). The level of elastance and hysteresis did not differ significantly along the urethra. The normal values, in terms of the 95% confidence intervals, are given in Table 1.

Discussion

This study has demonstrated, that the field gradient principle is an accurate and reproducible method for determination in vitro of cross sectional area of small lumina, corroborating previous reports [5, 11]. In vivo measurement of CA, on the other hand, is influenced by methodological as well as biological factors. The theoretical main source of error is related to slope of the wall of the balloon between the sensing electrodes caused significantly pressure differences outside the balloon [5, 11]. This source of error, however, is probably of minor importance in this study, since extreme pressure differences within at short distance in the female urethra (i. e. 2 mm) are unusual [6].

The microtip transducer, used for pressure measurement with the P/CA-probe has proved, in vitro, to be a reliable technique with a high frequency response [2, 8]. In the present design the proximal pressure-sensor, used for urethral pressure measurement, was placed in a waterfilled balloon. This ensured that the recorded pressure was a real fluid pressure and prevented rotational artefacts due to stiffness of the catheter. The latter is a well described problem with in vivo use of microtip transducers for intraurethral pressure measurement [16].

All the tested parameters in the vivo study were fairly reproducibile in the particular individual. This implies that the parameters may be useful especially in sequential measurements e. g. before and after treatment of an individual patient. This is in agreement with the results reported by others using various techniques for assessment of urethral closure function in females [1, 14, 15, 19, 20].

The normal ranges which were established based on a few women, showed a certain variability. This is not surprising, especially as for the dynamic parameters, since they involve most individual maneouvers such as coughing and squeezing which are difficult to standardize. For the static urethral pressure profile parameters it is well established, that they are widely variable [15, 19, 20]. This, mainly due to biological factors such as the degree of relaxation of the pelvic floor [15]. Although all the parameters evaluated showed a certain degree of interindividual variability, they may still be useful when larger series of patients are studied for the understanding of normal physiology and patho-physiologic mechanisms. The value as a diagnostic tool in the individual patient may seem less convincing. The potential value, however, depends on the overlap in the distribution between normal persons and patients. Future studies of larger groups of patients will elucidate this aspect.

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