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URETHRAL PRESSURE REFLECTROMETRY, FIRST TRIALS IN THE MALE URETHRA

Hypothesis / aims of study

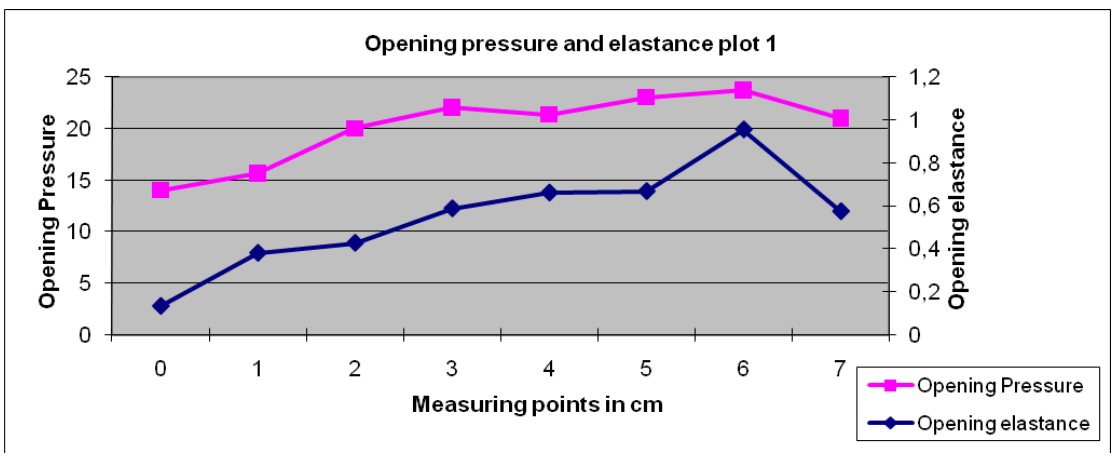
Bladder outlet obstruction (BOO) has always represented a large problem in the elderly male population. Understanding and diagnostics of BOO has been, and still is a major challenge in urology. Pressure-flow studies and analyses with the Abrams-Griffiths nomogram are still gold standards. Methods to simultaneously measure pressure and cross-sectional area (CA) in the urethra, have seemed promising in giving a better understanding of BOO, but have never been implemented. Therefore it is still desirable to develop new techniques, which have the potential to improve our understanding and hopefully treatment of BOO.
An earlier trial on men, showed a significant decrease in elastance of the bladder neck and prostate in healthy male subjects, after administration of tamsulosin. No change in opening pressure was found [1]. This could suggest that tamsulosin works by lowering elastance and thereby making elastance an important parameter to measure. The drawback of this study being, that the measuring catheter could only measure CA over 13 mm^2, and measurements could only be carried out at one site along the urethra at a time.
Urethral Pressure Reflectometry (UPR) is a new technique for simultaneous measurements of pressure and CA. In women, it has proved reliable and highly reproducible [2-3]. With UPR, a very thin and highly flexible plastic-bag is introduced into the urethra. The CA of the urethra is continuously measured with sound waves, while the pressure in the bag can be changed with a pump, thus the pressure needed to just open the closed urethra can be measured (opening pressure). In addition a stress-strain relation for the urethra can be made from the simultaneous measurements of pressure and CA. From the stress-strain relation biomechanical properties as the elastance and the hysteresis of the urethra can be obtained. The catheter consist of a very thin distensible approximately 5 cm long welded polyurethane-bag glued to a 45 cm long rigid PVC tube. The wall thickness of the bag is 0.025 mm. The diameter of the bag when fully inflated is 7.5 mm and fully deflated 0.4 mm. The range of measurement is 0.4 to 50 mm^2. The inner diameter of the PVC tube is 3.7 +/- 0.3 mm, and the outer diameter 5.3 +/- 0.3 mm. Pressures can be applied and measured between 0 and 200 cm H_2O. Approximately 13 measurements are made per second.
The aim of this study was to evaluate the applicability of UPR when applied to the male urethra in terms of measuring pressure and CA, and to evaluate side effects and placements of the catheters.

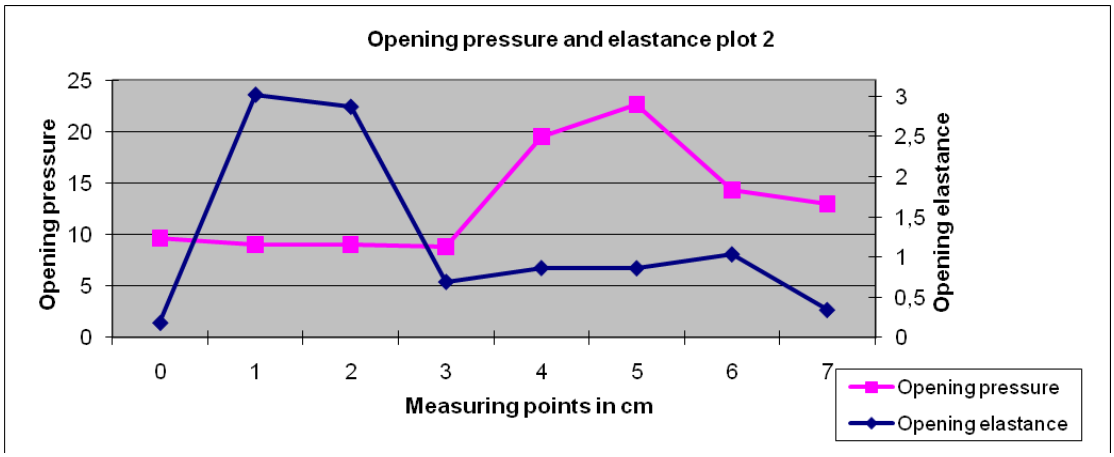
Study design, materials and methods

Five patients between 77 and 89 years old, all with indwelling catheters because of episodes with retention, were examined in the supine position and with empty bladder. All were given oral antibiotics in the form of fluorquinolon 30 min. before the trial and five days afterwards. The examinations were conducted by inserting the PVC tube with the polyurethane-bag pulled back over the tube, until the bladder was reached. With the catheter in the bladder, the polyurethane-bag was filled with air until it had expanded. Hereafter it was emptied and retracted, until measuring indicated resistance when the bag was inflated. From this point on, regular measurements were recorded with the pressure steadily increased with 5 cm H_2O/sec. until 100 cm H_2O, and thereafter steadily decreased to 0 cm H_2O. Three measurements were made at every point with two minutes intervals, to make sure the urethra was in its resting state. Hereafter the catheter was retracted 1 cm and the measurements repeated. All trials were terminated when the distal high-pressure zone was passed.

Results

The catheter is able to measure pressure and CA simultaneously in the male urethra. None of the volunteer patients reported any more discomfort during the trials, compared to having a normal indwelling catheter inserted, reported no minor or major side effects in the weeks following the trials, and the high-pressure zone was easy to locate during measurements.
Figure 1 shows the median values of opening pressure and elastance, for an 80 years old patient with episodes of retention, at 1.5 cm within the polyurethane-bag. The measuring points illustrate the bladder (0 cm), bladder neck (1 cm), prostate (2-5 cm), high-pressure zone (6 cm) and the end of the high-pressure zone (7 cm). Figure 2 shows the median values of opening pressure and elastance for an 89 years old patient, who was the only patient out of the five with prior trans-urethral resection of the prostate, again at 1.5 cm within the polyurethane-bag. The measuring points are the same as in figure 1.





Interpretation of results

Figure 1 roughly illustrates the results of the remaining three patients, with a steady increase in both opening pressure and elastance through the prostatic part of the urethra and peaking at the high-pressure zone. In figure 2 the opening pressure curve from point 1-3 illustrates the prior resection area, with a low opening pressure because of reduced tissue volume. The opening elastance curve from point 1-2 illustrates that the tissue is very stiff and rigid, giving an almost exponential curve, and suggesting a stricture, which is passed at point 3. From point 4, and onwards both opening pressure and elastance look like figure 1.

With UPR it is possible to measure/estimate opening and closing pressure, opening and closing elastance and hysteresis. Simultaneous measurements are made through the entire polyurethane-bag at every 1 mm, and measurements of the CA are made down to approximately 2 mm^2. These improvements compared to earlier techniques, will probably produce more valid and reproducible results.

Concluding message

UPR is feasible in the male urethra. The examination provides sound physiological parameters, which characterize the prostate and sphincter area of the male urethra and as illustrated, makes it possible to localize obstructed areas of the urethra.

Further trials planned for the nearest future on patients with BOO and healthy volunteers are needed, to evaluate the difference between sick and healthy patients and reproducibility. These will determine if UPR has a role in the urodynamic field for male patients.

References

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Specify source of funding or grant	**Funding from Gunnar Lose, the department of Obstetrics and Gynaecology, Herlev Hospital, Denmark.**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**The Local Ethical committee D for Region Hovedstaden, Registration number H-D-2009-056**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**The Local Ethical Committee D for Region Hovedstaden**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**