TECHNICAL DESCRIPTION OF URODYNAMIC PRESSURE MEASUREMENT CATHETERS

To perform urodynamic pressure measurements, various techniques have been used. The techniques can be divided into those using water-filled balloons, open-ended water-filled infused catheters, gas-infused catheters, catheter-mounted microtransducers (which includes semiconductor, fiber-optics and air-coupled balloon-tip catheters).[1]

WATER-FILLED BALLOONS

This technique employs a catheter with a latex balloon mounted on the tip. The balloon is filled with fluid, and the pressure is transmitted through the catheter and measured with an external-pressure transducer. Several early investigations of urethral pressure were performed using this technique.[2-4]

Enhörning[2] carried out pioneering work using the balloon technique, simultaneously recording intravesical and urethral pressures. Even if this technique is being used,[5-7] it has become less common during the last decade. Since the pressure exerted on the balloon is transferred to fluid pressure in the catheter, this technique permits both measurements of a fluid pressure and a mechanical force such as that in the urethra. The frequency response is determined by the properties of the catheter/manometer and is normally not influenced by the elasticity of the balloon.[8]

Using the balloon technique, a pressure is measured that is the average pressure along the balloon and in various radial directions. This radial pressure integration is an advantage of the technique, while the longitudinal integration decreases special resolution of the pressure profile along the urethra. A disadvantage of balloons is that they become deformed and the pressure is therefore not measured at a well-defined cross-sectional area at the sensing device.

The obtained static pressure is dependent on the fluid volume in the balloon and hence on the temperature of the fluid as well as the hydrostatic liquid it is measuring.[9] Thus the problem is that the H2O expands as the temperature rises influencing the pressures in an upward direction as well as a fluid wave effect and a difficulty in eliminating the air bubbles in the catheter and balloon.

SALINE/WATER-INFUSED CATHETERS

One of the first to record the pressure from the urethra was Bonney[10] in 1923, who measured the pressure needed to pass fluid in the retrograde direction through the urethra. A similar technique was used in cats by Langworthy et al.[11] in 1940 and was applied to humans by Bors.[12] By stepwise pulling through an intermittently infused catheter, Lapides et al.,[13] in 1956, determined a urethral pressure profile from readings on a water manometer.

The continuously infused catheter technique was introduced by Brown and Wickham[14] in 1965 for urodynamic applications. However, the measurement principle had been employed earlier for esophageal pressure measurement by Pope.[15]

The principle of pressure measurement with a continuously infused open-ended catheter in a closed organ such as the closed urethra, is that mechanical force from the organ is transferred to a fluid pressure in the catheter through a liquid column to an external transducer.[16] Assume that a constant pressure from the surrounding tissue, p, is momentarily obtained at time zero on the pressure-sensing catheter. At time zero no pressure increase is recorded due to blocking of the catheter hole. A pressure increase is built-up in the catheter until balance is obtained between pressure of the catheter fluid and tissue.[14, 17]

If the pressure generated from the tissue is described by a function p(t) and the measured pressure as $p_0(t)$, the measurement system can be described as above.[16] The continuous infusion is represented with a constant current generator with a current corresponding to the flow F. The compliance of the infusion system is described with a capacitor C.[18] The catheter is represented with a resistance R and an inertance L_m. The catheter compliance is usually small compared with that of the infusing system and can then be ignored. However, it can partly be included in the compliance C. The nonlinear coupling between the measuring catheter orifice and tissue, due to the tissue blocking that orifice, is represented with a diode and a compliance C_T. This compliance represents the elasticity of the tissue when intruding to the hole.

When the catheter orifice is blocked due to an increase in pressure, the flow through the orifice ceases but the flow builds up a counterpressure by "charging" the compliance C. At constant flow the pressure increases linearly with time according to the expression.[17, 19]

$$p(t) = \frac{F \cdot t}{C}$$

The ratio F/C therefore describes the pressure rise-rate.

Brown and Wickham[14] used and infusion system consisting of an infusion bottle and a drip set, where the flow was controlled by a throttle. The compliance of this system was calculated to be in the range 0.027 to 0.063 $mm^3/cm\ H_2O$ ($2.7 \cdot 10^{-4}\ mm^3/PA$ to $6.7 \cdot 10^{-4}\ mm^3/PA$) depending on which catheter type was used.[8] <u>These rise-rates seem to be sufficient for most urodynamic pressure recordings but insufficient to measure pressure in coughing accurately.</u>

The compliances of the infusion system presented above should be compared to those of the catheters. Polyethylene catheters of a length of 1 m and I.D. 0.9 – 1.7 mm have a compliance in the range 0.0017 $mm^3/cm\ H_2O$ ($1.7 \cdot 10^{-5}\ mm^3/PA$) to 0.0039 $mm^3/cm\ H_2O$ ($3.9 \cdot 10^{-5}\ mm^3/PA$); compliance is somewhat higher for polyvinyl catheters.[16] <u>This explains variations between measurements between different H2O filled catheters sold by different manufacturers</u>

One type of infusion system is the syringe-infusion pump.[20-22] Available data on compliance of syringe pumps show values typically 100 times larger that that of the catheter compliances presented above.[16] This corresponds to an upper cut-off frequency as low as 1 Hz. Some investigators found a rise-rate as low as 17 cm H_2O/s (1.7 kPa/s).[22] They concluded that this speed of response was sufficient for accurate recording of urethral pressure profiles at an infusion flow of 2 ml/s and catheter withdrawal speed of 0.7 cm/s.

Abrams et al.[22] also investigated the pressure drop due to viscous losses as the fluid flows through the catheter. This drop may have a substantial magnitude, but if flow is constant so is the pressure drop. Therefore, the pressure drop can be compensated for by changing the baseline of the recordings.

Griffiths[23] has shown that the recorded pressure to some extent depends upon the infusion rate. The size of the slit through which the infusion fluid will escape will increase with increasing flow due to viscous losses of the flow in the slit. However, the obtained dependence of the pressure with infusion flow is small and will not significantly affect recorded pressure. This might be a reason to minimize the infusion flow. In addition, calibration due to changing hydrostatic head column makes this system difficult to use.

As can be realized, the water-infused catheter design is inherently complex, and fraught with variables which cause inaccuracies in urodynamic pressure measurement.

GAS-INFUSED CATHETERS

Gas-perfused systems using CO_2[24-30] have the same principal function as water-infused systems. These systems have been used for urethral profilometry and cystometry. The response time is limited due to the compliance of the internal gas volume of the catheter/manometer system.[31] Furthermore, the patients might find the gas infusion uncomfortable. Shawer et al.[31] found that even for as high an infusion rate as 200 ml/min, the pressure rise-rate was only 38 cm H_2O/s. Hence, accurate static urethral pressure profiles can only be obtained at low withdrawal speeds of the catheters.

For esophageal pressure measurements, low-compliance perfusion systems have been designed[32-33] and have also been adopted for the use in urodynamic investigations.[34] These systems use a flow resistance placed where the infusion system is connected to the catheter/manometer. By choosing a high overpressure of the infusion-fluid reservoir, the perfusion flow will be approximately constant. With high enough flow resistance, the frequency response and pressure rise-rate of the system will be determined by the properties of the catheter/manometer system only. For properly designed systems, a bandwidth of 20 Hz and above can be obtained.[33] With polyethylene catheters, or catheters of comparable compliance, a theoretical rise-rate of 2000 to 5000 cm H_2O/s (200 to 500 kPa/s) can be obtained for a flow of 0.5 ml/s.[8] These systems could therefore, if optimized, fulfill the demands on dynamic characteristics for accurate pressure measurement mentioned earlier.

Similar problems, as described for liquid-filled systems are involved with the gas-infused systems which has made it impractical for urodynamic monitoring.

CATHETER-MOUNTED MICROTRANSDUCERS

Catheter-mounted microtransducers for urethral pressure measurements were introduced by Karlson[35] in 1953. The microtransducer was the author's own design,[36] and the sensing part consisted of a small rubber tube filled with granular carbon. The resistance of these granules changed as the pressure exerted on the device changed.

Microtransducers available today are either of semiconductor,[37-39] fiber-optic type,[40-42] or (as disclosed in this study) air-charged balloon sensing catheters. These catheters are commonly used in clinical studies.[9, 43-45] The main advantage of catheter-tipped sensors are that they measure pressure at the catheter location where the sensor is located thus greatly simplifying calibration and zeroing of the system, except TDOC which zeros to atmosphere by the open system before closing the air column..

The pressure-sensing element of the semiconductor-type transducer (such as Millar Instruments Mikro-Tip™ Uro-catheter*, or Browne Medical Systems, MicroTransducer catheter**) consists of sidewall-mounted silicon membranes with semiconductor diffused resistors in silicon, the resistance of which changes with pressure due to the piezoresistive effect.[38] This element is mounted in a catheter wall usually along the tip. The transducer with sidewall-sensing element is capable of measuring both fluid and mechanical forces exerted on the sensing surface.[8] The dynamic characteristics of these transducers are such that they well exceed the demands required. A major disadvantage of this design is the artifact inaccuracy of the directional dependent measurement of the urethral wall defects. In fact, recent studies **(references)** have shown these directional side wall sensing catheters to be inaccurate for UPP. In addition, they are expensive, fragile, and over time become inaccurate due to accumulation of debris on the sensor surface and deterioration of the mounting assembly.

The fiber-optic transducer presented by Hansen[42] in 1983 and first used by Kvarnstein et al.[46] has the pressure-sensing membrane oriented perpendicular to the longitudinal probe direction. The transducer is based on the same principle as the one presented by Ramirez et al.[40] and Lindstrom.[41] The commercially available version of Hansen's transducer has a cage in front of the membrane equipment with two sideholes to transmit the pressure from the surrounding medium to the fluid in the cage cavity. This design permits accurate measurement of a surrounding fluid pressure.

However, the transducer has similar limitations to a noninfused water-filled catheter when measuring a mechanical force such as the urethral closure pressure. The pressure from the urethra causes tissue to probe into the sidehole of the transducer. This happens because the fluid in compressed air may be trapped or because the tissue does not seal the holes completely, and fluid can leak out to the urethra.[8] Therefore, the transducer cannot measure this mechanical force accurately.

A fiber-optic sensor was recently developed by Tenerz and Hök.[47] The sensor has a diameter of only 0.5 mm. The transducer has a sensing area located laterally and consists of a fiber-optic glass beam that is deflected by the pressure. A micromachined silicon element with a mirror surface reflects parts of the light from the glass fiber. The amount of reflected light is related to the pressure.

To measure intraurethral pressure simultaneously at several locations, a multipoint pressure transducer was introduced by Ulmsten et al.[48] This transducer had a comparatively small circumference and was based on an electrolytic catheter-tip transducer principle presented by Hök.[49] Bard's Urodynamic Fiber-Optic catheters*** and MedAmicus LuMax Fiber-optic catheters**** suffer the same technological directional artifactual sensing problems of the solid-state semiconductor catheters, and are expensive to use.

AIR-CHARGED BALLOON CATHETERS

This study compares a newly design pressure measurement system which involves microair charging of a balloon which is circumferentially placed around the catheter at appropriate locations. A miniature air-filled lumen communicates the pressure signal to an external semiconductor transducer in the cable. This design utilizes all the advantages and theory (refer to discussion above) of water-filled balloons with none of the disadvantages of water-filled hydrostatic head pressure and frequency response. This design is the ultimate for elimination of directional artifactual sensing and due to its small concentric balloon, in theory can accurately monitor UPP. It is inherently inexpensive and is a single-use catheter system.

ADDITIONAL MEASUREMENT CHARACTERISTICS

Besides the linearity of the pressure voltage relation and frequency response, other properties of importance constitute the principal difference between systems with water-filled catheters and sensor-tipped catheters.[8, 50] It is well known that water-filled systems measure the hydrostatic pressure relative to the height of the transducers, whereas sensor-tipped catheters measure the total pressure, usually in relation to the atmospheric pressure. This difference is significant when, for example, pressure differences are studied in the lower urinary tract.

To illustrate this, let us study a simplified model where the abdomen is represented with a fluid-filled vessel. The pressure at a certain point relative to the atmospheric pressure is given by hpg, where h is the vertical distance between that point and the fluid surface, p is the density of the fluid, and g is the gravitational constant.

With catheter-mounted microtransducers placed to measure bladder pressure and abdominal pressure in the rectum, the recorded pressures are the sum of active contraction pressures, P_{C1} and P_{C2}, respectively, and hydrostatic pressures that are determined by the height at which the transducers are located. The detrusor pressure, estimated as the difference between the two pressures, will then be influenced by the hydrostatic pressure difference due to the level difference between the transducers. This difference in height may correspond to a recorded pressure to 5 to 15 cm H_2O (0.5 to 1.5 kPa). On the other hand, when employing water-filled catheters to measure the same pressure and placing the external transducers at the same level, the measured pressure will not depend upon level differences of the different catheter holes.

Normally, the infused catheter with side hole or the microtransducer measures the urethral pressure in only one radial direction. Investigations have, however, shown that the recorded pressure is dependent on that particular radial direction.[21, 51-55] The measured radial-pressure difference concerns both the static-pressure profile and the pressure transmission in coughing. To measure pressure in different radial directions simultaneously, a special catheter probe have been developed.[56]

The radial-pressure differences have been attributed both to asymmetry of the urethral musculature[52] or to be of artifactual origin.[57-59] A physical condition of all pressure profiles in a closed organ like the urethra is that the sum of the pressure or force components in the various directions shall be equal to zero. For published pressure profiles, this is generally not the case.

The obtained asymmetry can therefore not be solely caused by asymmetric muscle configurations but also must have other causes. In a model study, Plevnik et al.[58] have investigated the way in which the stiffness and weight of the catheter contribute to the directional differences of the pressure profile. They found that the directional difference increased with increasing stiffness and weight of the catheter. The finding was attributed to the fact that the bending of the catheter causes a reaction force on the catheter, and part of this force is sensed by the pressure-sensitive part of the catheter. Since the urethra is a bent organ, the catheter has to follow this bending. Hence, reaction forces are produced. The effects due to catheter weight are explained by the torque obtained from the catheter outside the meatus.

Griffiths[23] discussed differences in the way side hole and end hole catheters produced errors associated with the bending of the catheter. Since the side hole catheters in principle sense the pressure in the radial direction of the hole and therefore might pick up bending forces, he claimed that these catheters in this respect are inferior to the end hole ones. However, the recorded pressure with the end hold catheter can also be expected to be influenced by bending forces. Whether end hold and side hole catheters are the best remains to be shown.

The influence on the urethral pressure measurements from the factors mentioned above are substantial and must be minimized by the use of light and highly flexible catheters. The corresponding errors may very well be the reason behind the debated clinical usefulness of the urethral closure-pressure profile.[60]

The design of the new air-charged coupling catheter-tipped sensor has overcome these hydrostatic effects by employing air in a microlumen and the urethral anatomical pressure artifacts by using a small integrating concentric balloon around the catheter tube.

Another source of error is the movement of the catheter in coughing described by Plevnik et al.[57-58] and Hertogs and Stanton.[59] This may give an erroneous pressure-transmission ratio in the urethra. The artifact is either explained by a dynamic reaction force due to the movement of the pelvic floor in coughing[58] or by the fact that the movement of the catheter relative to the urethra displaces the catheter to an area with another static urethra pressure.[61] A physiologically unexpected S-shaped longitudinal pressure-distribution curve of the cough pressure-transmission ratio has been reported.[50, 62] By compensating for catheter movements, de Jonge et al.[61] obtained a U-shaped transmission ratio curve that is the type one would expect.

Varying the catheter or probe diameter may alter the recorded urethral pressure profile. Some investigators have reported few or no changes,[63, 64] while others have reported more pronounced alterations.[65-66] Plenvic presented a model where he described the pressure change in radial distension of the urethra. He suggested a method where the pressure could be extrapolated to a zero cross-sectional area. Plevnic and Janez[66] found the pressure area relation to vary between normals and patients with obstructed urethras and that the information obtained was useful as a diagnostic indicator.

In conclusion, the studies referred to point to the fact that the pressure may depend on the cross-sectional area. Therefore, when comparing urethral-pressure measurements from different studies, the diameter of the catheter/probe must be considered.

Urethral elasticity is relatively high for the closed resting urethra but decreases in relaxation during micturition. At rest, the compliance of the urethra, expressed as the intraluminal volume increase as a function of the intraluminal pressure, is expected to be related to the urethral closure function.

A multichannel, essentially conically infused catheter probe for measurement of urethral compliance has been devised by Regnier et al. From the measurements, the urethra is characterized by the pressure corresponding to a zero cross-sectional area and a constant describing an exponential pressure/area dependence.

An alternative approach to estimate compliance of the urethra has been described by Colstrup et al.[67-69] The probe consists of a distensible balloon mounted on a catheter. The balloon is filled with varying amounts of fluid. The cross-section of the balloon is determined from impedance measurements using a field gradient principle.

As described above, the Micro-air-charged catheter combines the best of all designs overcoming the artifactual pressure effects and provides accurate bladder, urethral and abdominal static and dynamic urological pressures.

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