26 January 2000 DEVELOPMENTS IN FLUID FILLED PATIENT CATHETERS AND EXTRA-CORPOREAL PRESSURE TRANSDUCERS FOR URODYNAMICS TESTING OR PUTTING THE DYNAMICS INTO URODYNAMICS

Tony Wynter Neomedix, PO Box 890 Mona Vale, NSW, 2103 Email: tony@neomedix.com

HISTORY:

Neomedix has invested considerable time evaluating the direction to take in the recording of Pves, Pabd and Pura using fluid coupled external transducers. This is not as straight forward an issue as one would first think. The cystometrogram (CMG) was originally undertaken by using fluid filled Pves and Pabd catheters. The lowest cost catheter that provoked minimal patient discomfort and was able to register pressure changes was chosen. For the more complex (female) urethral testing, most Australian laboratories have been using dual (Pves and Pura) micro-pressure-transducer tipped catheters, which do not require fluid filling and flushing, but are much more expensive and fragile. They are immune to hydrostatic pressure changes arising from the patient's vertical separation from the transducer. Furthermore, microtipped catheters are able to follow (rapid) physiological changes in pressure.

It is worth pointing out that the microtipped catheter devices are "force" rather than "pressure" transducers. Artifactual signals from "force contact" can occur if the sensing area of the catheter impinges upon the body of the bladder, rectum, or impacted faeces.

For over thirty years, manufacturers of monotipped catheters have recommended that they be cleaned/sanitised with the use of Gluteraldehyde (Cidex)TM. In Australia, however, a recent combination of worksafe health regulations and hospital infection control standards has abolished the routine use of Gluteraldehyde for this purpose.

For these reasons there has been a move towards the 'single use' multilumen fluid-filled pressure catheters, in conjunction with low cost extra-corporeal physiological transducers for urethral, vesical and abdominal pressure measurement. The potential problems, which may occur when converting to the use of fluid coupled external pressure transducers, are discussed, as these often go unrecognized.

BACKGROUND & PROBLEMS WITH PRESSURE MEASUREMENT TECHNIQUES:

Abdominal pressure catheters usually have a balloon incorporated at the distal end(to reduce the risk of particulate faecal occlusion of the pressure sensing port). However, removing the residual air from the balloon increases set up time. Therefore the balloon is frequently given a venting cut, or needle prick, allowing air to be more easily expelled. As a result some rectal catheters are supplied Developments in Fluid Pressure Recording NS02314A page 1

by the manufacturer with a precut balloon fitted. In most cases the rectal catheter deadspace volume is inappropriate for the characteristics of the pressure sensing transducer. This is generally not obvious (nor may it matter), in cases where the rate of changes in pressure encountered are relatively slow. A problem occurs when the measurement of rapidly changing cough pressures forms part of the clinical evaluation. Any combination of patient catheter/pressure lines/stopcock/transducers need to be evaluated and optimally 'tuned' to enable adequate tracking performance (frequency response) during fast cough or rapid valsalva testing. A good frequency response requirement is relevant to all of the pressure recording channels (Pabd, Pves and Pura).

<u>Vesical</u> pressure recording systems are generally capable of accurately measuring resting pressures and the relatively slow increases of pressure during an involuntary detrusor contraction. The frequency response of the vesical channel is usually better than that for the average abdominal pressure channel set-up, as the internal deadspace of the vesical catheter is usually less, and there is no balloon incorporated (which may harbour trapped air pockets).

Urethral pressure measurement is a recording from within a sphincter zone. As such a quite different pressure monitoring technique is required, so as to be able to adequately record either resting or rapidly changing pressures. A perfused lumen technique is used, which is crucial to recording fast pressure changes and to also provide accurate resting pressures. This technique is broadly adopted by most urodynamics laboratories, however its implementation is sometimes inadequate. As a consequence urethral pressure measurement is often considered as an 'unhelpful' parameter due to its inaccuracy and/or poor reproducibility.

<u>Subtracted detrusor</u> pressure recordings are the most problematic. Difficulties with inadequate recording arrangements are obvious in many labs: a significant artifact in the Pdet subtraction often occurs when the patient is asked to cough. Frequently the problem is blamed on the subtraction electronics of the data acquisition system. The effects can be (and usually are) ignored during a CMG cystometrogram, as detection of unstable detrusor contractions is the prime interest. The detrusor pressure change is relatively slow and so the effect of poor matching or 'tuning' of the pressure device is minimal, compared to that experienced during a cough. The problem does become significant when coughs or rapid abdominal pressure changes are required as part of dynamic cough "pressure transmission ratio" or testing of the cough leak point pressure. A subtraction error is often caused by the different frequency responses (or times taken by each recording channel to respond to a transient pressure change) in the Pves and Pabd catheter recording channels.

<u>Subtracted urethral closure pressure recording presents a similar situation to that with Pdet and,</u> with the cough leak point or cough transmission ratio measurements, in that significant errors occur. As explained above, this is due to the subtraction error caused by the different times taken Developments in Fluid Pressure Recording NS02314A page 2

by Pves and Pura recording channels to respond to a transient pressure change. The transient cough pressure rise times can be relatively high, exceeding 700cmH₂O sec⁻¹. Many standard non perfused Pves channel configurations cannot follow this pressure change as well as the perfused Pura channel. Thus a cough transmission ratio of greater than 100% may be recorded. If a cough generates a transient abdominal pressure increase of 120cmH₂O, but the recorded Pves can only increase to a peak value of 100cm H₂O, whilst the same 120cm H₂O Pabd increase is faithfully recorded in the urethra then the cough transmission ratio will incorrectly read 120%. This is a measurement error, which many assume to be simply due to the patients physiology. We see many examples of a cough transmission ratio of greater than 100% being recorded and it is our suggestion that many of these are recording errors due to poor (or no) attention to the characteristics of pressure recording system. It can be seen that to use any subtraction data clinically, it is important that the two primary pressure recording channels exhibit exactly the same characteristics over the physiological range of rates of pressure change.

<u>Cough Leak Point</u> Pressure measurement is recommended by the International Continence Socity to be recorded from the Pabd catheter placed within the rectum. This parameter is measured to determine the pressure at which the point of urine loss occurs during a single strong cough (or during a stepped increase in abdominal, and transmitted vesical pressure). Many clinics prefer to use a cough as the stimulus as in real life, this is the more likely form of stimulus to provoke urine loss. Simultaneously during pressure recording, the urodynamicist must monitor and annotate the recording, as to the exact moment of urine loss.

Two issues present in this situation. The first is that there is the same demand here upon the recording system to produce a faithful pressure recording of Padb during the cough. If the response time of that channel is poor, then the pressure trace will never reach the true maximum pressure amplitude during the cough pressure transient. The second difficulty is the almost impossible task of manual detection and recording of the precise moment of urine loss. The pressure channel data could well be changing at a rate of over 500cm H_2O sec⁻¹, so one can see that operator response times taken to detect urine loss and then actuate an event key are too long to allow accurate correlation with the actual leak point pressure.

In summary, significant pressure recording problems may occur during routine urod-*dynamics* testing. These may be due to non-uniform, low and undefined response times of all pressure recording channels caused by a multiplicity of reasons including; air (bubbles) anywhere in the recording systems fluid coupled pathway, over compliant catheter and stopcock materials, transducers with an unacceptably large displacement volume, unmatched catheter-to-transducer deadspace volumes and ineffective fluid perfusion due to the inappropriate hydraulic design of many perfusion pumps for this application.

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As a solution to these problems, we have developed a perfused lumen pressure system which has matched response times, so as to facilitate reliable measurement of rapidly changing urodynamics pressure values. Except for what could almost be called uro*static* recording (such as during a filling cystometrogram) clinical evaluation suggests that all pressure channel response times need to be capable of recording a change of nearly 500cmH₂O sec⁻¹. The Pura recording must accurately follow the fast cough pressure times. The Pves must match the fast response of Pura, and thus not cause subtraction errors (Puc). The Pabd must also respond rapidly to pressure changes, as it is increasingly being used to measure the cough leak point pressure (CLPP).

The improved technique involves a pressurised sterile saline or water source, and a fluid delivery catheter with either two or three specially integrated hydraulic resistors. Each resistor line also incorporates a low compliance stopcock. Included also are low volume displacement pressure transducers and optional low compliance pressure extension lines. There are two different types of perfusate pressure source, one for routine clinical use and the other for high fidelity research applications. The latter is capable of dynamic pressure changes at up to 1000cmH₂O sec⁻¹. Defining and providing a satisfactory technique has involved considerable effort and has resulted in the need for five different 'kits' to cover general testing requirements from the 'simple' cystometrograms through to complex urethral function testing. Documenting clinical experience with this new system is now in progress.

¹ Note: Gaeltec Ltd. recently advised that its microtipped catheters may be sterilised using SterradTM without reducing the expected lifespan of the catheter.