

## IS THE SENSITIVITY OF T-DOC AIR-CHARGED CATHETERS STABLE ENOUGH FOR AMBULATORY URODYNAMIC MONITORING?

### Hypothesis / aims of study

Urinary incontinence reduces the quality of life of around 30 % of men and up to 25 % of women over the age of 65.

Urodynamic assessment in the clinical environment aims to reproduce symptoms while accurately measuring pressures within the bladder and abdomen. If conventional cystometry is unable to reproduce symptoms, ambulatory studies may be indicated allowing the patient to move freely around while wearing a holster that records the pressure traces for analysis later.

Measurement of pressure for urodynamic studies requires catheterisation. Disposable catheters usually use a fluid-filled line to transmit the pressure to an external transducer. While water-filled catheters are suitable for conventional urodynamics, movement artefacts make them unsuited for use in ambulatory studies. Consequently, solid-state transducers mounted on the tip of the catheter remain the preferred choice for ambulatory studies, but these devices are expensive and so in general reusable and hence require cleaning after use.

Air-charged catheters (ACCs) are disposable alternatives. A volume of air is used rather than water to transmit the pressure at the catheter tip to an external transducer, almost eliminating artefacts due to the weight of fluid in the catheter. As yet, however, it is unclear whether clinical measurements of pressure made using ACCs are equivalent to measurements made with other technologies [1], [2], and no study has investigated whether ACCs are stable enough with time to use for ambulatory urodynamics. Consequently, the aim of this study was to assess the stability of pressure measurements made using air-charged catheters over a six hour time period.

### Study design, materials and methods

We used one abdominal and one vesicle pressure transducer (T-DOC A and T-DOC V cables, Laborie UK, Coventry, UK) to evaluate 5 abdominal and 5 vesicle catheters (T-DOC-7FA and T-DOC-7FS). The catheters were placed inside a pressurised chamber. The chamber was connected to a computer controlled custom barostat which was capable of generating arbitrary pressure waveforms. The pressure chamber and barostat were also connected to a calibrated pressure gauge which provided an independent measurement of the pressure within the chamber. A custom-made printed circuit board connected electrically to the T-DOC transducer which attached to the catheter under test. The electrical signal across the transducer bridge was amplified and then digitised by a microcontroller (MCU) 10 times per second. The MCU synchronously recorded the analogue signal from the calibrated pressure gauge. The pressure data were sent via a serial connection to a PC running custom software that displayed and recorded the raw signal in analogue to digital converter units (ADCu).

The barostat controlled the pressure within the chamber. To measure the sensitivity and zero offset of the ACC, the pressure was increased linearly from 0 cmH<sub>2</sub>O to 300 cmH<sub>2</sub>O in 30 s then decreased linearly to 0 cmH<sub>2</sub>O in a further 30 s (Figure 1, upper left panel). The pressure waveform repeated every five minutes allowing the sensitivity and zero offset to be measured from each ramp. After completion of each ramp, the pressure was maintained at 0 cmH<sub>2</sub>O for 20 seconds, then pressurised to 100 cmH<sub>2</sub>O for 3 min 20 s. After this, the chamber was depressurised to 0 cmH<sub>2</sub>O for 20 s, before the cycle was repeated (Figure 1, lower left panel). After each hour, the transducer switch was moved to OPEN from CHARGE during the 100 cmH<sub>2</sub>O phase for a minimum of 5 s. After this, the switch was moved back to CHARGE. There were a total of 7 charges, at 0, 1, 2, 3, 4, 5 and 6 hours.

The data were analysed using custom software written in Python 2.7 (numpy, scipy and matplotlib). To calculate the sensitivity of the catheter for each ramp of the pressure waveform, the ramp phases were extracted from the data using a gradient threshold. A straight line was fitted to the data for each ramp. (The independent variable was the calibrated pressure and the dependent variable was the pressure measured from the T-DOC catheter.) The transducer sensitivity was obtained by converting the gradient from ADCu to mV and subsequently dividing by the system gain.

### Results

10 T-DOC catheters were tested. During each ramping waveform, the combined non-linearity and hysteresis in the measurement system was approximately 5 cmH<sub>2</sub>O (Figure 1, upper central panel). All the catheters leaked measurably within one hour. Recharging the catheters every hour returned each one to its initial sensitivity. Excepting failure to recharge one catheter on one occasion, the sensitivity of every catheter relative to its initial sensitivity was always better than 4 % (Figure 1, right panel).

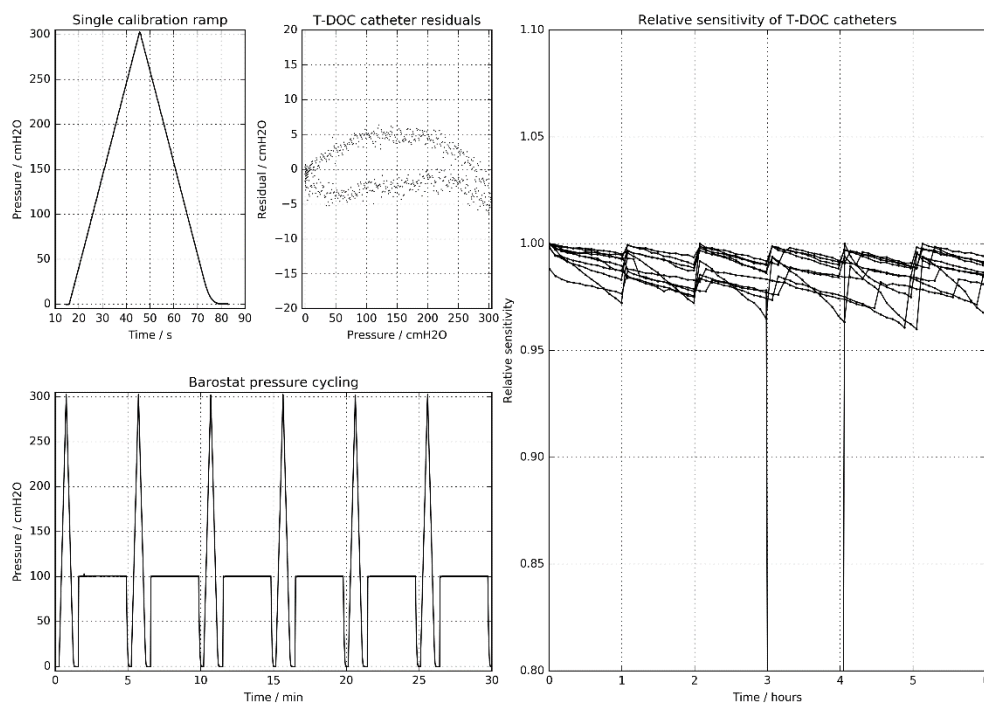


Figure 1: Computer controlled pressure in the chamber over a single ramp and 30 minutes (upper and lower left panels). The difference between the calibrated pressure and T-DOC pressure (upper central panel). Relative sensitivity of each T-DOC catheter compared with its initial sensitivity (right panel). At 3 hours, one catheter was set to OPEN in error, and not reset to CHARGE until 4 hours. This catheter measured atmospheric pressure (zero relative sensitivity) for the entire hour (off scale).

#### Interpretation of results

T-DOC catheters leak air, producing a gradual reduction in the sensitivity of the pressure measurement. Within one hour, this error is less than 4 %, a figure that would appear clinically acceptable for conventional urodynamics. To prevent accumulation of this error during longer, ambulatory studies, the sensitivity of the catheters can be returned to 100 % by recharging the catheter each hour. In our study, for each recharge, we left the switch in the OPEN position for a minimum of 5 seconds, prior to moving it back to the CHARGE position. With this caveat, the stability of the pressure measurements made using T-DOC catheters would appear to be adequate for ambulatory cystometric studies.

#### Concluding message

T-DOC air-charged catheters are metrologically suitable for ambulatory urodynamic studies if they are recharged every hour.

#### References

1. P. Abrams et al., 'Air filled, including "air-charged," catheters in urodynamic studies: does the evidence justify their use?', *Neurourol. Urodyn.*, doi: 10.1002/nau.23108, 2016.
2. A. Gammie et al., 'Simultaneous in vivo comparison of water-filled and air-filled pressure measurement catheters: Implications for good urodynamic practice: Simultaneous Comparison of Water-filled and Air-Filled Catheters', *Neurourol. Urodyn.*, vol. 35, no. 8, pp. 926–933, 2016

#### Disclosures

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