

## INVESTIGATING VARIABILITY IN THE MEASUREMENT OF PENILE CUFF INTERRUPTION PRESSURE COMPARED TO SIMULTANEOUSLY MEASURED INVASIVE BLADDER PRESSURE

### Hypothesis / aims of study

The penile cuff test allows an accurate non-invasive assessment of bladder contractility in men with lower urinary tract symptoms (1). This previous work has recognised variability in the agreement between the pressure at which the penile cuff interrupts urine flow ( $p_{\text{cuff.int}}$ ) and simultaneously measured isovolumetric bladder pressure ( $p_{\text{ves.isv}}$ ). The cause for the significant variability between the measurements remains unknown but we have previously reported a relationship between the error of non-invasively estimated isovolumetric bladder pressure with cuff size suggesting that larger diameter penile cuffs are more accurate. We aimed to investigate whether any other variables affected the error between  $p_{\text{cuff.int}}$  and  $p_{\text{ves.isv}}$ , specifically;

- i) magnitude of  $p_{\text{cuff.int}}$
- ii) stage of contraction
- iii) time point within the void at which cuff test was performed

We also investigated whether the error was consistent within each patient (for those who had multiple inflations).

### Study design, materials and methods

Data recorded during the previous study assessing bladder contractility using the penile cuff test were retrospectively analysed using MATLAB software to generate plots of flow rate against cuff pressure allowing further statistical analysis. An allowance was made for a 1 second delay in the flow rate recording as per the original protocol. A full description of the study protocol has been previously published (1). To summarise; all patients were investigated with an automated penile cuff test, which inflates several times during a void to interrupt flow. A simultaneous pressure flow study was conducted via a double lumen cystometry catheter and rectal manometer line. All traces were evaluated for our current analysis by two separate authors to exclude those which did not meet previously defined quality control criteria.

### Results

The 117 previously described studies were analysed and a further seven studies were excluded due to erratic/uninterpretable traces. 110 studies comprising 318 inflations were included in the analysis.

#### Difference between $p_{\text{cuff.int}}$ and $p_{\text{ves.isv}}$

We compared two measurements of intravesical pressure taken at different timepoints during flow cessation – firstly the intravesical pressure taken immediately at flow arrest ( $p_{\text{ves.int}}$ ) and secondly the pressure at the end of the 2 second cuff inflation period ( $p_{\text{ves.endinf}}$ ) immediately prior to cuff deflation and re-establishment of flow. In 225 inflations (71%) the intravesical pressure was higher after a 2 second period of flow arrest.

#### $p_{\text{cuff.int}}$ VS. $p_{\text{ves.int}}$

For 46 inflations  $p_{\text{cuff.int}}$  underestimated  $p_{\text{ves.int}}$  and in 271 inflations (85%) overestimated  $p_{\text{ves.int}}$ . The mean (standard deviation) of the error was 21.4 (21.8) cmH<sub>2</sub>O.

#### $p_{\text{cuff.int}}$ VS. $p_{\text{ves.endinf}}$

76 inflations underestimated  $p_{\text{ves.endinf}}$  and 242 inflations (76%) overestimated. The mean (standard deviation) of the error was 16.4 (21.9) cmH<sub>2</sub>O.

Figure 1 below demonstrates the spread of errors between  $p_{\text{cuff}}$  and  $p_{\text{ves}}$  for both of the above measurements.

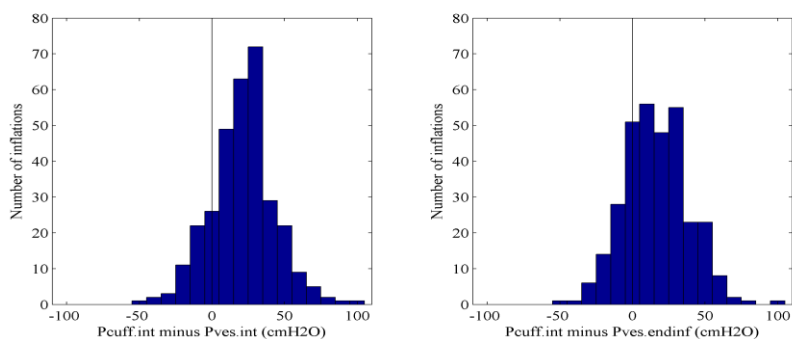


Fig 1: Spread of error between  $P_{\text{cuff.int}}$  and  $P_{\text{ves.int}}$  (Lt) and  $P_{\text{cuff.int}}$  and  $P_{\text{ves.endinf}}$  (Rt)

### Magnitude of cuff pressure

A good correlation was observed between  $p_{\text{cuff.int}}$  and error (difference between  $p_{\text{cuff.int}}$  and  $p_{\text{ves.int}}$ ): Spearman's rho = 0.6,  $p < 0.001$ , with no relation observed between invasively measured  $p_{\text{ves.isv}}$  and error.

### Stage of contraction

There was no correlation found between whether the detrusor contraction was increasing or decreasing and error between  $p_{\text{cuff.int}}$  and  $p_{\text{ves.isv}}$  (Spearman's  $\rho = 0.04$   $p = 0.4$ ).

### Intra-case variability

The error between  $p_{\text{cuff.int}}$  and  $p_{\text{ves.isv}}$  was consistent within some patients but not others. Of the 85 patients with more than one valid cuff inflation, for 34 patients (40%) the errors were within 10cmH<sub>2</sub>O, but in the rest the range was much greater, up to a maximum of 88 cmH<sub>2</sub>O.

### Timing of cuff test within void

There was a weak correlation between voided volume as a proportion of total voided volume at the point of cuff interruption and the difference between  $p_{\text{cuff.int}}$  and  $p_{\text{ves.isv}}$  (Spearman's  $\rho = -0.2$ ,  $p = 0.002$ ). This demonstrated that the closer towards the end of the void inflation occurred, the smaller the difference between  $p_{\text{cuff.int}}$  and  $p_{\text{ves.isv}}$ .

### Interpretation of results

These results and our previous work suggest that the cuff interruption pressure recorded during the penile cuff test is a valid estimate of the maximum isovolumetric bladder pressure. The difference between absolute values of  $p_{\text{cuff.int}}$  and  $p_{\text{ves.isv}}$  is in part accounted for by the height difference between the reference point for the two measurements (upper border of pubic symphysis for invasively measured bladder pressures and mid-point of the penile urethra for cuff pressures). However significant variability still exists and this study has suggested possible reasons for this. Our analysis has shown that  $p_{\text{cuff.int}}$  is closer aligned to the intravesical pressure at the end of the 2 second period of flow arrest rather than the intravesical pressure measured immediately after flow arrest. This is largely explained by the fact that the majority (71%) of men exhibited a rise in bladder pressure after isovolumetric conditions were imposed, which is supported by previous observations (2). However this was not always the case and for nearly 1/3 of inflations a fall in intravesical pressure during isovolumetric conditions. For some, this was because detrusor contraction was already decreasing in magnitude before flow was interrupted. This may reflect a degree of voluntary inhibition or an inability to produce sustained contractions. The finding of a reduction in the error between  $p_{\text{cuff.int}}$  and  $p_{\text{ves.isv}}$  during inflations occurring later in the void suggests that voluntary inhibition during initial inflations may be occurring in some patients. We also observed correlation between the error with magnitude of  $p_{\text{cuff.int}}$  which may suggest that the error is proportional rather than fixed.

### Concluding message

This work suggests that one of the reasons for error between non-invasively derived cuff interruption pressure and isovolumetric bladder pressure may be a degree of voluntary inhibition during cuff inflation. This may be minimised by improved patient counselling and the use of interruption pressures in the latter part of the void. Further work is underway to examine whether this results in reduced variability and improved accuracy of cuff test parameters.

### References

1. McIntosh S et al. Noninvasive assessment of bladder contractility in men. J Urol 2004;172:1394-1398
2. McIntosh S et al. Noninvasive measurement of bladder pressure. Does mechanical interruption of the urinary stream inhibit detrusor contraction? J Urol 2003;169:1003-1006

### Disclosures

**Funding:** None **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Initial study approved by: Joint Ethics Committee Newcastle and North Tyneside Health Authority Ref 99/155 **Helsinki:** Yes **Informed Consent:** Yes