Basic principles of the Newcastle penile cuff test

ABSTRACT. In order to establish the cause of lower urinary tract symptoms, there is a need for pressure measurements during voiding. Conventional cystometry is expensive, time-consuming and has some morbidity, and so treatment may be undertaken on the basis of history and symptoms alone. We have developed a non-invasive technique to estimate bladder pressure during voiding using a penile cuff. We present the basic physical principles of the measurement, and evidence to suggest that these principles hold true in the clinic. We conclude with preliminary data from simultaneous application of the cuff test and conventional urodynamics, suggesting the role for this new test in clinical practice.

LIMITATIONS OF THE FLOW TEST

Reduced urine flow rate is a key urodynamic finding in men with lower urinary tract symptoms, but it does not indicate the cause. A reduced flow rate might be due to an obstruction to flow, typically the consequence of benign prostatic hyperplasia. Equally, the symptoms may be due to a weak bladder contraction. Flow rate alone will not distinguish these conditions since a measure of detrusor contractile strength is required. In men with poor flow, a normal or high bladder pressure is indicative of obstruction whereas a low bladder pressure would suggest a diagnosis of detrusor hypocontractility.

It is therefore established that bladder pressure measurements by conventional cystometry provide additional diagnostic information. Conventional cystometry using bladder and rectal catheters is time-consuming, unpleasant, and carries some risk for the patient. Some centres believe these negative factors out-
weigh the usefulness of the information gained from the test, and would proceed to treatment on the basis of symptoms and flow rate alone (1).

The cuff test is intended as an adjunct to a conventional flow study, adding measurements of isovolumetric bladder pressure during the course of a void. While it is not a replacement for cystometry, it gives non-invasive information on bladder contractility during voiding. We believe it can be used in some cases to make the diagnosis of obstruction, avoiding the need for cystometry.

The principle of the test is similar to blood pressure measurement. When the patient is ready to void, a small pneumatic cuff is fitted round the penis. When voiding has commenced, the cuff is inflated under automatic control at 10 cmH\(_2\)O s\(^{-1}\) until flow is interrupted (Fig. 1A). The cuff pressure required to interrupt flow should equal bladder pressure at the time of interruption (2, 3). Cuff pressure is then released, allowing flow to resume. The cycle is repeated typically 3-5 times until voiding is complete.

The data are best represented as a graph of flow rate versus cuff pressure (Fig. 1B); the downward slope of the flow versus cuff pressure graph can be extrapolated to estimate where it would reach zero flow. This forms our estimate of bladder pressure; around 120 cmH\(_2\)O in this case. Since most patients provide two or more usable measurements we would use the highest, which is closest to representing the bladder’s maximum contractility during voiding.

Since the measurement is made when flow is zero (volume is not changing), the cuff test measures isovolumetric bladder pressure. There is a sound theoretical basis for using isovolumetric pressure, which is a measure of bladder contractility (4, 5). It may therefore be a more appropriate measurement than \(P_{\text{det},Q_{\text{max}}}\) which is measured at maximum flow and does not reflect true contractility.

**PHYSICAL PRINCIPLES UNDERLYING THE CUFF TEST**

The cuff test depends on three key principles that we have tested under experimental conditions.

*Inflation pressure in the penile cuff is transmitted to the penile urethra*

First, pressure in the cuff must be transmitted to the penile urethra so that when cuff pressure exceeds the fluid pressure, flow stops. We have demonstrated that this is the case by making simultaneous measurements of cuff and urethral pressure for a range of cuff materials and sizes (Fig. 2) (6).

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[Figure 1 - A) The principle of the cuff test. B) A graph of flow rate versus cuff pressure with an estimate of interruption pressure.]
The bladder maintains its contraction throughout the test

When flow is interrupted, it is important that the bladder contraction be maintained during the interruption. To test this hypothesis, we used conventional cystometry to measure the bladder pressure within three seconds before and three seconds after the cuff inflation (Fig. 3) in 168 measurements from 31 subjects (7). There was a detectable but clinically insignificant mean decrease of 4 cmH₂O.

The urethra acts as a fluid-filled catheter

When flow is interrupted, there must be a continuous column of fluid between the bladder and the urethra beneath the cuff; in effect, the urethra serves as a fluid filled catheter. In 11 patients we used a triple-lumen catheter to measure cuff and urethral pressures at the time of flow interruption (8) (Fig. 4). The three pressure measurements were closely related, giving evidence that the pressure in the bladder is transmitted along an open urethral lumen.

VALIDATION OF THE CUFF MEASUREMENT IN VIVO

In 153 patients we performed the cuff measurement with simultaneous invasive cystometry (9). For each cuff inflation cycle we estimated the cuff pressure $p_{\text{cuff,int}}$ at which flow was reduced to zero, and from the cystometry data measured the simultaneous bladder pressure $p_{\text{ves,ISV}}$. On average, $p_{\text{cuff,int}}$ over-estimated $p_{\text{ves,ISV}}$ by a mean (SD) of 16 (28) cmH₂O (Fig. 5). This effect is discussed
later, but is mostly attributable to the height difference between the pubic symphysis (the reference for cystometric measurements) and the cuff.

A proportion of patients agreed to return on a second occasion within four weeks for repeat cuff tests without invasive cystometry lines. Figure 6 shows the relationship of the two measurements in the same individual. In common with flow rate measurements, within-patient reproducibility was better for voided volumes of 150 ml or more. We recommend that where the voided volume is <150 ml, the test be repeated.

Interpreting the test

Before making the estimate of bladder pressure, there is in some cases a theoretical basis for excluding an inflation cycle and we have developed a set of rules for doing so. In a study on inter-observer agreement (10), 486 inflation cycles were rated by 3 independent observers, a total of 1458 ratings. Of these 769 measurements were acceptable and 689 were discarded according to the following rules:

There was no recovery of flow after cuff deflation (n=428)

When the cuff is released, one expects a surge of urine stored in the proximal urethra, followed by the resumption of flow (Fig. 1A). If there is no flow recovery, this indicates that the void finished sometime during the current inflation cycle, and that the cuff may not have been responsible for stopping the flow.

There was an erratic flow trace, with ambiguity about the cuff pressure at flow interruption (n=168)

As with uroflowmetry, an erratic trace may be due to abdominal straining, but can also be caused by contractions in the pelvic floor or urethral sphincter.

Flow was not interrupted at the instrument’s maximum pressure of 200cmH₂O (n=34)

This is normally associated with a highly

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Figure 4 - The relationship of cuff (P_{cuff}) and urethral (P_{ure}) pressures with actual bladder pressure (P_{ves}) at the moment of flow interruption.

Figure 5 - The relationship of cuff interruption pressure (P_{cuff,int}) and actual bladder pressure (P_{ves}) at flow interruption. Data are presented (left) as a conventional XY plot, and (right) according to Bland & Altman, showing the mean difference and limits of agreement.
contractile bladder developing an unusually high isovolumetric pressure; for safety, 200 cmH\textsubscript{2}O represents the upper limit of the instrument’s pressure source. Although a precise interruption pressure cannot be measured, hypocontractility can in most cases be ruled out, so this measurement is nevertheless clinically useful.

Review of the entire void (n=59)

According to urodynamic theory, one would expect a relatively constant value of bladder pressure during a void, diminishing towards the end of the void. Three or more inflation cycles from an individual void are common, with ten or more in isolated cases. This gives an opportunity to assess repeatability, and to discard measurements that are clearly out of keeping with the rest of the void or with urodynamic theory. This might be due to the cuff slipping (leading to an artificially high value of pressure) or a mid-void contraction of the pelvic floor muscles (leading to an artificially low value of pressure). In the clinic we would prefer to repeat the test; 90% of patients provide usable data on at least one of two occasions (9).

Inter-rater agreement for acceptable inflations (n=769)

On the basis of the remaining 769 inflations (Fig. 7), we believe inter-observer agreement for the cuff measurement is excellent.

**DIAGNOSTIC USE OF THE CUFF TEST – THE MODIFIED ICS NOMOGRAM**

The ICS nomogram (11) is the recommended method for classifying bladder outlet obstruction. Q\textsubscript{max} and p\textsubscript{det,Qmax} are determined from cystometry, and are plotted as a point on the ICS nomogram; the point will lie in one of the regions unobstructed, equivocal or obstructed. Cuff measurements cannot be plotted directly on the ICS nomogram because isovolumetric bladder pressure is recorded by the cuff, rather than detrusor pressure at maximum flow as recorded dur-

![Figure 6 - Test-retest agreement in P\textsubscript{cuff,int} for 42 patients. Those with voided volumes >150 ml on both visits are shown as solid circles. Data are presented (left) as a conventional XY plot, and (right) according to Bland & Altman, showing the mean difference and limits of agreement.](image1)

![Figure 7 - 769 individual measurements of the same cuff inflations by 3 different observers (vertical axis) plotted against the mean of the measurements, our best estimate of the true value. The within-patient SD, an estimate of rating error, was 4.6 cmH\textsubscript{2}O.](image2)
ing invasive cystometry. To allow for these differences, the lines on the ICS nomogram must therefore be modified in two steps (12). The nomograms of the ICS (11), Schäfer (13), and Abrams & Griffiths (14) all agree on the position of the uppermost (obstructed vs equivocal) line, and so we describe the modification of that line. A similar argument can be applied to the lower line (equivocal vs unobstructed) but that has not been described.

**STEP 1 - Correction for abdominal pressure**

In the absence of any detrusor contraction, the viscera create a resting pressure in the bladder. In conventional cystometry, this is estimated by a rectal catheter and subtracted from vesical pressure to give detrusor pressure. However, the cuff measurement estimates total bladder pressure, including the abdominal component. Abdominal pressure as measured by a rectal line is reasonably consistent between individuals; the mean (SD) abdominal pressure during voiding for 76 patients was 35 (9) cm water (15), and this is in broad agreement with other literature. There is also a systematic effect associated with body mass index, but this is too small to be of clinical importance.

There is a further small offset because the cuff is positioned typically 8 cm below the pubic symphysis, the reference point for invasive measurements. Beneath the cuff, the fluid pressure will be correspondingly 8 cmH\textsubscript{2}O higher due to the hydrostatic gradient. On the nomogram, the combined effect of these two factors is to shift the line of separation vertically upwards by 43 cmH\textsubscript{2}O. This is rounded for convenience to 40 cmH\textsubscript{2}O. Some men augment the detrusor contraction by straining the abdominal muscles. In conventional cystometry, this has little or no effect on the subtracted detrusor pressure. For the cuff test, straining will affect the measured pressure, but cannot reliably be detected. During trials with invasive lines, patients were asked not to strain. Eighty-three percent were able to comply, as judged from their abdominal pressure measurements. We therefore recommend that the instruction “please do not strain to pass water” is given before the cuff test.

**STEP 2 - Correction for isovolumetric pressure rise**

Figure 8A shows invasive data recorded during a cuff test. As the cuff is inflated (fourth trace, \( P_{\text{cuff}} \)), the flow is reduced and finally stops (bottom trace). The detrusor pressure \( P_{\text{det}} \) has risen from \(~50\) cmH\textsubscript{2}O to the isovolumetric pressure of \(~90\) cmH\textsubscript{2}O, as predicted by the Hill equation and bladder physiology (16). To a crude approximation the bladder operates at a constant power – power is the product of flow rate and pressure, and so

![Figure 8](image.png)

**Figure 8** - A) The effect predicted by the Hill equation – the isovolumetric rise in detrusor pressure as a consequence of the cuff test. B) Predicting the isovolumetric pressure rise, which is approximately proportional to the change in flow rate. A regression line (constrained to pass through the origin) is shown.
the bladder can contract at a higher pressure when producing less flow. We have assessed the pressure rise from maximum to zero flow in three separate studies. One set of results is shown in Figure 8B; the effect amounts to a pressure rise of 2 cmH₂O for each 1 ml/s reduction in flow, and this value was consistent (within 5%) between the three studies. The effect on the nomogram is to increase the slope of the line of separation by 2 cmH₂O per ml/s.

Correcting the ICS nomogram

In principle the instrument could apply an automatic correction for both these factors, but we prefer to present the data as recorded. Therefore using the ICS nomogram as a starting point, a comparable nomogram can be constructed for data from the cuff test (Fig. 9).

Validation of the modified nomogram

To validate this nomogram, we present data from 143 subjects who had free cuff tests (i.e. without simultaneous cystometry) in either Newcastle or Bristol. We used the ICS standard of invasive cystometry as the gold standard (Fig. 10). In Figure 11 we show the receiver-operator characteristics for the cuff test and for flow rate alone. The ROC shows the trade-off of sensitivity and specificity as the decision threshold is changed. The area under the curve is a measure of diagnostic performance in separating the two populations. For example, in flow rate its interpretation is “the probability that an obstructed man chosen completely at random would have a lower flow rate than a non-obstructed man chosen completely at random”. A value of 1.0 would indicate complete separation of obstructed and unobstructed men, whereas a value of 0.5 indicates complete overlap, with a diagnostic performance no better than chance. Table 1 summarises the classification accuracy for the cuff nomogram with the decision line as derived above and for a flow criterion of 10 ml s⁻¹, for comparison with the data from the ICS BPH study, the largest single series for uroflowmetry to date (17). The cuff test performed slightly better than flow

Figure 9 - Corrections to the upper line of the ICS nomogram to account for (step 1) the resting abdominal pressure, and (step 2) the pressure rise from full flow to isovolumetric conditions.

Figure 10 - 143 subjects plotted on the modified ICS nomogram; the diagonal classification line is as derived in Fig. 9. The classification according to invasive cystometry is indicated by the symbol. The vertical line shows a flow threshold for obstruction at 10 ml s⁻¹ for comparison with the ICS BPH study.
rate, but it was noteworthy that the diagnostic performance of flow rate was markedly better than reported in the ICS BPH study (sensitivity 47%, specificity 70%) (17). Since the cuff test has a similar predictive value to uroflowmetry, it seems reasonable to treat the two tests as independent predictors of obstruction. The bottom line in table 1 summarises what we believe to be the most useful algorithm for using the cuff test (12). If flow and cuff measurements agree the patient is obstructed, there is an 88% probability they are obstructed. If flow and cuff measurements agree the patient is not obstructed, there is an 86% probability they are not obstructed. In the 31% of patients where flow and cuff measurements disagree, the patient may be referred for cystometry for diagnosis.

Knee pressure

In many subjects the inflating cuff has little or no effect on flow rate until some knee pressure (around 100 cm H₂O in Figure 1), after which the flow falls steadily. We have established the theoretical basis for the knee pressure in an experimental model; it is analogous to prostatic opening pressure in humans (2). We are currently investigating the potential use of this measurement.

CONCLUSIONS

The new cuff test is an adjunct to a conventional flow study. It is not a replacement for cystometry, but gives a valid and reliable estimation of isovolumetric bladder contraction pressure. As with uroflowmetry and cystom-

Table 1 - Summary of classification accuracy for the patients presented in Fig. 10.

<table>
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<th>Algorithm</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
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</thead>
<tbody>
<tr>
<td>Modified ICS Nomogram</td>
<td>64%</td>
<td>81%</td>
<td>68%</td>
<td>78%</td>
</tr>
<tr>
<td>Qmax&lt;10 ml/s</td>
<td>59%</td>
<td>89%</td>
<td>77%</td>
<td>77%</td>
</tr>
</tbody>
</table>

For the 69% of patients where flow classification and cuff classification agree:

<table>
<thead>
<tr>
<th>Algorithm</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combined cuff &amp; flow</td>
<td>70%</td>
<td>96%</td>
<td>88%</td>
<td>86%</td>
</tr>
</tbody>
</table>
etry, proper application requires experience and qualitative decision-making. We believe it can be used in some cases to confirm or refute the suspicion of obstruction, and so avoid the need for full cystometry.

REFERENCES