

## A PILOT EVALUATION OF TWO NON INVASIVE TECHNOLOGIES IN THE ASSESSMENT OF BLADDER OUTLET OBSTRUCTION

### TOPIC: BLADDER OUTLET OBSTRUCTION (BOO)

#### Hypothesis / aims of study

Bladder Outlet Obstruction (BOO) is a common urological problem in ageing men, but conclusive diagnosis cannot be made from symptoms alone. Currently, the only accepted diagnostic test to confirm the presence of BOO is by pressure-flow studies (PFS) [1]. However, PFS have significant drawbacks: it is expensive, time-consuming, needs skilled analysis, specialised equipment and the invasive nature of the test carries a significant risk of urinary tract infection (UTI).

In an attempt to reduce the requirement for pressure flow studies considerable effort has been put into the development of non-invasive tests that can diagnose BOO with an accuracy similar to that of PFS. Two of the most promising are: controlled inflation of a cuff around the penis during voiding – the cuff test; bladder wall thickness (BWT) measurement using an ultrasound scanner. The diagnostic potential of these two non-invasive tests were evaluated as part of a clinical audit and the outcomes compared to pressure flow studies within a routine Urodynamics Clinic.

#### Study design, materials and methods

A sample of all male patients referred for PFS between September 2009 and March 2010 were asked to undergo the cuff test as part of the audit. The only patients excluded from the cuff test were those that clearly did not have the ability to undertake the investigation, such as those patients with indwelling catheters or those who could not hold the necessary volume of urine. The cuff tests were performed and analysed in accordance with the methods described in the operator manuals accompanying the system. The presence of BOO was analysed by recording the results on a modified nomogram.

PFS were performed and analysed according to ICS Good Urodynamic Practice and terminology [2]. BOO was diagnosed using the ICS Nomogram and calculation of the AG number.

Residual urine was measured following voiding as part of the Urodynamics assessment with a portable ultrasound scanner and this also provided an estimate of bladder wall thickness, overall surface area and calculated bladder volume.

The results from PFS were independently compared with the outcomes from the cuff test and measurements of detrusor wall thickness.

At the end of the investigations, each patient was asked to fill in a questionnaire. This asked the patient to indicate the level of discomfort and embarrassment felt during PFS and the cuff test. The patient was asked to indicate which of the two procedures they would prefer to have again if referred for Urodynamics tests in the future.

#### Results

In total 60 cuff tests were performed, 20 of these were not included in the audit for technical reasons. In the successful 40 tests, 10 patients were assessed as obstructed and 30 patients were measured either as being equivocal or un-obstructed. 59 of the 60 patients were able to complete the questionnaire. For the 40 patients who had a successful cuff test 5 did not have a full pressure flow study. Example results from the cuff test were plotted on the modified nomogram as shown in figure 1.

Attempts were made to assess bladder wall thickness using the portable ultrasound scanner in 41 patients and 22 valid results were obtained. Of these only 15 had successful pressure flow studies and these were used for comparative purposes.

#### Interpretation of results

There was good correlation between the variables classifying obstruction in the cuff-test and PFS ( $n=35$ ,  $r=0.72$ ,  $p<0.001$ ). These findings also correlate with similar audits carried out in other hospitals in the UK. Patients experienced significantly less discomfort ( $1.3$  vs  $3$ ,  $p<0.0001$ ) and embarrassment ( $1.2$  vs  $2.0$ ,  $p<0.0001$ ) in the cuff-test compared to PFS.

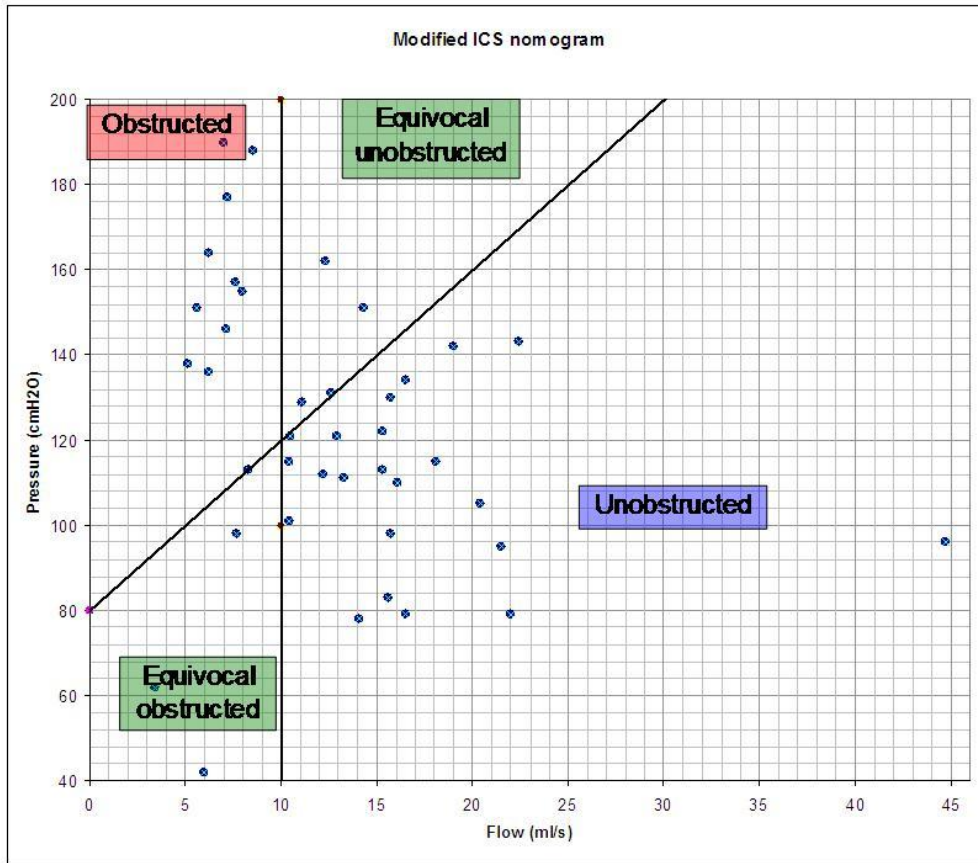
There was poor correlation between DWT and the PFS variable ( $n=41$ ,  $r=0.02$   $p>0.2$ ) and the mean DWT of obstructed individuals and unobstructed individuals, as assessed by PFS was not significantly different.

#### Concluding message

The pilot results suggest the cuff-test could have a significant role in diagnosing and managing BOO and is also the diagnostic test of preference for the patients. Further evaluation is needed to determine how the technique could be incorporated into patient pathways.

Despite previously reported data to the contrary, this evaluation does not support the use of DWT as a diagnostic tool but this may be related to the very small sample size evaluated as part of the audit.

Figure 1: Modified Nomogram for Penile Cuff tests including sample patient data



<b>Specify source of funding or grant</b>	NHS Technology Adoption Centre
<b>Is this a clinical trial?</b>	No
<b>What were the subjects in the study?</b>	HUMAN
<b>Was this study approved by an ethics committee?</b>	No
<b>This study did not require ethics committee approval because</b>	The abstract reports the findings from a service audit of routine urodynamics services provided at the Hospital. The technology concerned had also been evaluated by the Centre for Evidenced Based purchasing in the UK and had recommended it as having significant diagnostic potential in assessing patients for Bladder Outlet Obstruction.
<b>Was the Declaration of Helsinki followed?</b>	Yes
<b>Was informed consent obtained from the patients?</b>	Yes