Clinical Summary

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Clarkson B., Robson W., Griffiths C., McArdle F., Drinnan M., Pickard R. Department of Medical Physics (FM, BC, CG, MD) and Urology (WR, RP), Freeman Hospital and School of Surgical and Reproductive Sciences (RP) and School of Clinical and Laboratory Science (BC), Newcastle University (BC, RP), Newcastle upon Tyne, UK
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Harding C., Robson W., Drinnan M., Sajeel M., Ramsden P., Griffiths C., Pickard R. Department of Urology, Freeman Hospital, Newcastle upon Tyne, United Kingdom, Department of Medical Physics, Freeman Hospital, Newcastle upon Tyne, United Kingdom, School of Surgical and Reproductive Sciences, University of Newcastle upon Tyne, Newcastle upon Tyne, UK
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¹ E349 INSERM-Université Pierre et Marie Curie Paris FRANCE, ² E349 INSERM-Paris FRANCE
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Griffiths C\(^1\), Blake C\(^2\), Harding C\(^3\), McIntosh S\(^3\), Drinnan M\(^4\), Robson W\(^5\), Pickard R\(^3\), Abrams P\(^2\), Ramsden P\(^3\). 1. Regional Medical Physics Department, 2. Bristol Urological Institute, 3. Urology Department, Freeman Hospital, Newcastle upon Tyne, UK

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Drinnan MJ, McIntosh SL, Robson WA, Pickard RS, Ramsden PD, Griffiths CJ. Regional Medical Physics Department, Freeman Hospital, Newcastle Upon Tyne, United Kingdom

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McRae LP, Bottaccini MR, Gleason DM. Tucson Medical Center, University of Arizona College of Medicine, USA. *Neurourol Urodyn.* 1995;14(2):101-14.
A Pilot Evaluation of Two Non-Invasive Technologies in the Assessment of Bladder Outlet Obstruction

Britton J., Keane D., Williamson M., Harris N.
Leeds teaching Hospitals NHS Trust
ICS 2010

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). 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. 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
Can the Combination of Two Non-Invasive Evaluations of Bladder Outlet Obstruction (BOO) Rub Out Sources of Variability Using Penile Cuff Test (PCT)

Valentini F1, Nelson P2, Turner D1.
1. ER6/Université Pierre et Marie Curie - Paris 6, France, 2. Pilgrim Hospital, Boston, UK
ICS 2010

Hypothesis / aims of study
In men suspected of benign prostatic enlargement (BPE), the main problem is to evaluate BOO. ICS nomogram and the Abrams-Griffiths number (AG) allow the analysis of invasive pressure-flow studies (PFS). The PCT and its nomogram use non-invasive recordings of the flow vs. the penile cuff pressure (p_cuff) and analyze a critical point the coordinates of which are maximum flow rate (Q_max) and cuff pressure at flow interruption (p_cuff, int). That analysis suffers from the difficulty to accurately locate the coordinates, mainly p_cuff, int. Our objective was to try to rub out that deficiency using the D index derived from the VBN method which gives from a free flow (FF) a relationship between the VBN parameters: urethral compression (pucp) and detrusor contractility (k). AG is strongly correlated with pucp.

Study design, materials and methods
Retrospectively, 44 sessions (1 FF and 1 PCT the same day) of BPE patients were analyzed (16 patients 1 session, 14 patients 2 sessions at 1 month interval). The PCT obeys the general law of flow in an elastic pipe: the flow is governed by the prostatic compression at low p_cuff (equivalent to a FF) and by the cuff at high p_cuff. The D index was evaluated from the FF and the first part of the flow during the first cuff inflation leading to the relationship between the VBN parameters; the real values of k and pucp were obtained from the analysis of the 2 first cuff inflations. Then, AG was obtained from a theoretical voiding (initial volume = 300 mL, catheter 6F, above values of k and pucp).

Results
1. D index values were not significantly different between FF and PCT (1 session) or between 2 sessions (delta D = 0.24±1.67).
2. Evaluation of obstruction using the 3 methods was reached from 38 sessions; same evaluation only in 16 sessions (42.1%), under evaluation of obstruction by PCT in 22 other (57.9%). For patients with 2 sessions, PCT evaluation of obstruction was the same in 17/19 (89.4%) cases.
3. High discrepancies between PCT evaluation of obstruction and AG were observed when AG ≥70.

Interpretation of results
There are several, well known, sources of variability, contributing to the differences between invasive and non-invasive classifications. Often, combination with peak flow rate is proposed to obtain a high agreement. Analysis using the VBN model verifies that there is a brisk transition between flow governed by prostatic obstruction and flow governed by cuff compression. Evaluation of BOO using the Newcastle nomogram remains adequate for low or mild obstruction but is not accurate for high obstruction. So, Combination of VBN analysis (which takes into account possible abnormalities of the nervous control) and PCT allows obtaining AG free of all the possible effects due to the examination.

Concluding message
Indeed a complicated method, combination of the two non-invasive methods VBN and PCT allows an accurate evaluation of BOO in men suspected of BPE according with ICS criterion which avoids all causes of variability.
The Role of Non-Invasive Pressure Flow Study in Highly Symptomatic/Bothered Men with Bladder Outlet Obstruction

Nelson Batezini, Marcia Eli Girotti, Fernando Almeida, João Paulo Zambon, Eduardo Pinto, Milton Skaff, São Paulo, Brazil
The Journal of Urology, Volume 183, Issue 4, Supplement, Pages e623-e624, April 2010

Objective
The gold standard to evaluate BOO is the invasive pressure-flow study. The aim of this study is to evaluate non-invasive pressure flow test to predict BOO before surgery.

Methods
Between January 2008 and February 2009, they prospectively evaluated men with lower urinary tract symptoms (IPSS > 18 and QoL 3) scheduled for complete urodynamic study (UDS). Patients with urinary infection, neurological problems, bladder stones and indwelling catheters were excluded. Patients were underwent non-invasive pressure flow test (Mediplus CT 3000–Dynamed– Sao Paulo-Brazil), just before initiate the UDS. Non-invasive pressure-flow test (NIPF) was performed with a cuff around penile body that allowed registering the pressure necessary to stop urinary flow (MCCP- maximum closure cuff pressure). The MCCP and maximum flow rate were plotted in the Newcastle’s Nomogram and classified as: 1) bladder outlet obstruction (BOO) or 2) non obstructed. The UDS was performed following the International Continence Society good urodynamic practice. The pressure-flow study was performed with a 4 F catheter in stand position. The pressure-flow results were plotted in Schafer’s Nomogram and patients were classified from I – VI. Patients were considered as having BOO when classified as Schafer > III.

Results
We evaluated 50 men with mean age of 65 +/- 8years, IPSS ranging from 24 to 35 and Quality of life score was higher than 4 in all patients. Table 1 shows the results from NIPF and invasive pressure-flow study. Out of the 17 patients classified as non-obstructed by the non invasive study, 7 patients presented detrusor underactivity, 1 patient had BOO and 9 were non-obstructed with normal pressure-flow study by UDS. In the evaluation of BOO, the non-invasive pressure-flow demonstrated a sensitivity of 87.8 % and a specificity of 80.9%

Conclusions
The non-invasive pressure flow study demonstrated a sensitivity of 87.8 % and a specificity of 80.9% in diagnosis of significant BOO. It should be considered as an important tool in the diagnosis, treatment and follow up of men with voiding symptoms.

Table 1. Comparison of Invasive and non-invasive pressure flow study on diagnosis of BOO.

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<td>Invasive pressure flow study</td>
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<td>Non-invasive pressure flow</td>
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Role of Non-Invasive Urodynamics Using Penile Cuff Testing (CT3000) in Diagnosing BOO

Banerjee S., Unwin C., Srinivasan V., Toussi H.
Urology Department, Glan Clwyd Hospital, Betsi Cadwaladr University Health Board
BAUS 2010

Introduction

Video Urodynamic Studies (VUDS) are generally accepted as the Gold standard investigation for patients presenting with LUTS (1). However they are invasive and time consuming, as such they are reserved for a select few patients. Most of the patients undergoing TURP and BNI are offered surgery based on clinical diagnosis and flow rate alone. A technique of non invasive Urodynamic study for men has been developed by scientists at Newcastle hospital using penile cuff. It works on the principle of interruption of flow of urine using a cuff around the penis and indirectly measuring the intravesical pressure (P cuff= P urethra= P ves.). The CT3000 machine developed by Mediplus Ltd. works on the same principle and also measures the flow rate at the same time. The cuff is put around the penis and the patient is asked to void without straining. The cuff automatically inflates and deflates until voiding ceases. The P cuff at interruption of flow and Q max are plotted on a modified ICS nomogram to decide whether a patient is “obstructed” or “un-obstructed”.

We performed a prospective, blinded study on 50 male patients to assess the effectiveness of Non invasive Cuff Urodynamic studies (CUDS) using the CT3000 machine (Mediplus Ltd).

Materials and methods

Fifty male patients who were listed for VUDS were also offered CUDS. The results of these tests were analysed separately and the clinician performing one test was unaware of the result of the other making it a blinded study. Paraplegics, catheterised and intermittent self catheterisation (ISC) dependent patients were excluded from the study.

The result of the patients undergoing CUDS was analysed using the modified ICS nomogram and then compared with VUDS results and sensitivity and specificity were calculated.

Results

Total number of patients was 50. The mean age was 63.9-years (37-81-years); mean quality of life (QOL) 3.4 (1-4) and mean IPSS 19 (0-35). Eleven patients had previous outlet surgery (7 TURP, 3 BNI, 1 optical urethrotomy). The outcomes were as follows:

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<th>Obstructed</th>
<th>Non Obstructed</th>
<th>Inconclusive</th>
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<tr>
<td>CUDS (Penile Cuff Test)</td>
<td>52% (n=26)</td>
<td>12% (n=6)</td>
<td>36% (n=18)</td>
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<td>VUDS</td>
<td>54% (n=27)</td>
<td>20% (n=10)</td>
<td>14% (n=7)</td>
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12% (n=6) had DOA.

Sensitivity and specificity for CUDS are 96.2% and 60% respectively when compared to VUDS.

Discussion

A significant proportion of patients who undergo TURP/ BNI are offered surgery based on clinical grounds and Flow rate alone and it is not surprising that almost a third of them have unsatisfactory outcome (4). In an ideal world all of these patients should be offered VUDS before surgery although that is not cost effective and practical in the present day NHS. CUDS offers a potential of bridging that gap and as the above study shows that CUDS is a sensitive test in diagnosing BOO. Compared to flow rate alone it provides more information to diagnose underlying problem. It also has a potential of screening those patients who need VUDS and as such helps us to use the available resources more effectively.

Conclusion
Based on our current study we believe that CUDS has the potential to be an integral part of any dedicated LUTS clinic. It is quick, simple, non-invasive and provides more information compared to flow rate alone. It is quite sensitive and thus provides the clinician the opportunity to carefully select patients who are offered surgery thereby increasing the favourable outcome.

References
Positioning Invasive versus Non-Invasive Urodynamics in the Assessment of Bladder Outlet Obstruction

Arnolds M.; Oelke M
Department of Urology, Academic Medical Centre, Amsterdam, The Netherlands
Current Opinion in Urology: January 2009 - Volume 19 - Issue 1 - p 55-62

Abstract
Purpose of review: To provide evidence of promising tests to non-invasively diagnose bladder outlet obstruction (BOO) in men with benign prostatic hyperplasia.
Recent findings: Pressure-flow studies are usually performed to prove BOO prior to prostatectomy. However, pressure-flow studies are invasive, expensive, time consuming, and potentially harmful to the patient due to unwarranted side-effects. In the last decade, attempts were made to diagnose BOO non-invasively. Ultrasound-derived measurements such as bladder or detrusor wall thickness or intravesical prostatic protrusion and urodynamic-derived measurements such as isovolumetric bladder pressure by the condom catheter or penile cuff tests show promising results. Likelihood ratios of all tests were calculated for this study and indicated a good ability to detect BOO.
Conclusion: Non-invasive measurements of bladder/detrusor wall thickness, intravesical prostatic protrusion, or isovolumetric bladder pressure might replace invasive pressure-flow studies in the future if only information about BOO is needed. These tests are applicable for the majority of patients with lower urinary tract symptoms and suspected BOO. However, urodynamic investigations are still indicated in patients requiring detailed information about the bladder filling and voiding phases and to assess the precise cause of lower urinary tract symptoms.
Review of Invasive Urodynamics and Progress towards Non-Invasive Measurements in the Assessment of Bladder Outlet Obstruction

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Objective
This article defines the need for objective measurements to help diagnose the cause of lower urinary tract symptoms (LUTS). It describes the conventional techniques available, mainly invasive, and then summarizes the emerging range of non-invasive measurement techniques.

Methods
This is a narrative review derived from the clinical and scientific knowledge of the authors together with consideration of selected literature.

Results
Consideration of measured bladder pressure urinary flow rate during voiding in an invasive pressure flow study is considered the gold standard for categorization of bladder outlet obstruction (BOO). The diagnosis is currently made by plotting the detrusor pressure at maximum flow (PdetQmax) and maximum flow rate (Qmax) on the nomogram approved by the International Continence Society. This plot will categorize the void as obstructed, equivocal or unobstructed. The invasive and relatively complex nature of this investigation has led to a number of inventive techniques to categorize BOO either by measuring bladder pressure non-invasively or by providing a proxy measure such as bladder weight.

Conclusion
Non-invasive methods of diagnosing BOO show great promise and a few have reached the stage of being commercially available. Further studies are however needed to validate the measurement technique and assess their worth in the assessment of men with LUTS.
The Penile Cuff Test: A Clinically Useful Non-Invasive Urodynamic Investigation to Diagnose Men with Lower Urinary Tract Symptoms

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Objectives
To summarize the development of a novel non-invasive test to categorize voiding dysfunction in men complaining of lower urinary tract symptoms (LUTS) - the penile cuff test.

Methods
The test involves the controlled inflation of a penile cuff during micturition to interrupt voiding and hence estimate isovolumetric bladder pressure (pves.isv). The validity, reliability, and clinical usefulness of the test were determined in a number of studies in men with LUTS.

Results
The penile cuff test can be successfully performed in over 90% of men with LUTS. The reading of cuff pressure at flow interruption (p_cuff.int) gives a valid and reliable estimate of invasively-measured pves.isv and when combined with the reading for maximum flow rate obtained during the test (Q_max) produces an accurate categorization of bladder outlet obstruction (BOO). Use of this categorization prior to treatment allows improved prediction of outcome from prostatectomy.

Conclusion
The penile cuff test fulfils the criteria as a useful clinical measurement technique applicable to the diagnosis and treatment planning of men with LUTS.
Positioning invasive versus non-invasive urodynamics in the assessment of bladder outlet obstruction.

Arnolds M, Oelke M.
Department of Urology, Academic Medical Center, Amsterdam, The Netherlands.

Purpose of review
To provide evidence of promising tests to non-invasively diagnose bladder outlet obstruction (BOO) in men with benign prostatic hyperplasia.

Recent findings
Pressure-flow studies are usually performed to prove BOO prior to prostatectomy. However, pressure-flow studies are invasive, expensive, time consuming, and potentially harmful to the patient due to unwarranted side-effects. In the last decade, attempts were made to diagnose BOO non-invasively. Ultrasound-derived measurements such as bladder or detrusor wall thickness or intravesical prostatic protrusion and urodynamic-derived measurements such as isovolumetric bladder pressure by the condom catheter or penile cuff tests show promising results. Likelihood ratios of all tests were calculated for this study and indicated a good ability to detect BOO.

Conclusion
Non-invasive measurements of bladder/detrusor wall thickness, intravesical prostatic protrusion, or isovolumetric bladder pressure might replace invasive pressure-flow studies in the future if only information about BOO is needed. These tests are applicable for the majority of patients with lower urinary tract symptoms and suspected BOO. However, urodynamic investigations are still indicated in patients requiring detailed information about the bladder filling and voiding phases and to assess the precise cause of lower urinary tract symptoms.
Interobserver Agreement for Non-Invasive Bladder Pressure Flow Recording with Penile Cuff

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The Journal of Urology, Volume 182, Issue 5, Pages 2397-2403, November 2009

Purpose
We assessed variability in interpreting non-invasive measurements of bladder pressure and urine flow between experienced and novice users of the penile cuff.

Materials and Methods
Urodynamicists at 6 sites were asked to use the penile cuff test as part of clinical assessment in 30 men presenting with lower urinary tract symptoms. After a short training period they measured maximum flow rate and cuff interruption pressure from penile cuff test recordings to enable categorization of bladder outlet obstruction using a nomogram. Similar measurements were then made on the same traces by 2 expert observers from the originating center. Interobserver differences were assessed.

Results
Complete agreement on obstruction categorization was seen in 77% of subjects, which increased to 86% when plots positioned on category boundary lines were allocated to the favoured category. The 95% confidence limits of interobserver variability in maximum flow rate and cuff interruption pressure measurements were +/- 1.7 ml per second and +/- 13 cm H(2)O, respectively, although a small number of studies yielded discrepancies between observers that were larger than expected. They arose from complex recordings but were equally likely between experts as between expert and novice. Investigation of the causes suggested in some cases how such discrepancies may be avoided in the future.

Conclusions
The excellent level of agreement in measurement and categorization after a short training period suggests that introducing the penile cuff test as part of assessment in men with lower urinary tract symptoms would be straightforward.
The Urodynamic Evaluation of Lower Urinary Tract Symptoms in Men


CURRENT BLADDER DYSFUNCTION REPORTS Volume 3, Number 1, 49-57, DOI: 10.1007/s11884-008-0008-5

Abstract

Urodynamic investigation is recommended when it influences the management of patients and is used before invasive therapies for lower urinary tract dysfunction. Urodynamics has been shown to improve symptomatic and objective outcomes after surgical treatment of bladder outlet obstruction (BOO) of which benign prostatic obstruction (BPO) is the principal cause. The diagnosis of BOO is made from pressure-flow studies (PFS) of micturition using the International Continence Society nomogram, which places patients in three categories: obstructed (BOO index [BOOI] ≥ 40); equivocal (no definite obstruction; BOOI 20–40); and no obstruction (BOOI ≤ 20). PFS are reliable and reproducible; however, they are invasive tests, and efforts to find sensitive and specific methods of diagnosing BPO without catheterization are underway. Promising non-invasive techniques include the penile compression release index, the condom catheter method, and the penile cuff technique. Uroflowmetry and the ultrasound estimation of residual urine remain useful screening tests. Due to its diagnostic and prognostic value, urodynamics is recommended to assess lower urinary tract symptoms before surgery to relieve BOO.
Multisite Evaluation of Non-Invasive Bladder Pressure Flow Recording Using the Penile Cuff Device: Assessment of Test-Retest Agreement

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Purpose
We performed a pragmatic study of the penile cuff test, a non-invasive method of categorizing bladder outlet obstruction, at a number of United Kingdom urology centres remote from the originating site. We report the agreement of the test and the subsequent retest using the cuff test in the short term.

Materials and Methods
Men requiring urodynamic investigation for lower urinary tract symptoms were recruited from 6 sites to perform a penile cuff test twice at an interval of approximately 4 weeks. Tests were analyzed by a single interpreter to assess differences in the flow rate, cuff interruption pressure and diagnostic categorization in an individual between the 2 tests due to measurement and physiological error.

Results
A total of 136 men (69%) performed 2 suitable cuff tests at a median of 20 days (IQR 8–31). The mean ± SD difference between the 2 tests in the maximum flow rate was 0.2 ± 3.7 ml per second and in cuff interruption pressure was 4.0 ± 26 cm H₂O. Of the men 33% changed diagnostic category on the Newcastle nomogram, while 47% maintained a consistent diagnosis of obstruction or no obstruction.

Conclusions
Diagnostic category repeatability was similar to that of conventional urodynamics, although there was greater variability in pressure measurements. This supports widespread routine use of the penile cuff test.
Categorization of Obstruction Using Non-Invasive Pressure Flow Measurements: Sensitivity to Change Following Prostatectomy

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Purpose
We determined whether categorizing men with lower urinary tract symptoms using a non-invasive pressure flow nomogram is sensitive to change following the removal of obstruction.

Materials and Methods
A prospective cohort of men undergoing transurethral prostate resection was recruited, of whom 143 (69%) underwent non-invasive pressure flow study using the penile cuff technique before and 4 months following surgery. Cuff pressure required to interrupt voiding, estimated isovolumetric bladder pressure and maximum flow rate were recorded during a single void. Values were plotted on a nomogram categorizing cases as obstructed (upper left quadrant), not obstructed (lower right quadrant) or diagnosis uncertain (upper right and lower left quadrants). Changes in maximum flow rate, cuff pressure required to interrupt voiding and nomogram position following transurethral prostate resection were then analyzed.

Results
Transurethral prostate resection resulted in an improved flow rate for all diagnostic groups, which was highest for obstructed cases with a mean ± SD increase of 11 ± 6 ml second⁻¹ (p <0.01). Men categorized with obstruction and those placed in the upper right quadrant showed significant decreases in cuff pressure required to interrupt voiding following transurethral prostate resection with a mean decrease of −45 ± 35 and −48 ± 32 cm H₂O respectively (p <0.01). The number of cases classified as not obstructed increased from 28 (19%) preoperatively to 114 (80%) after transurethral prostate resection.

Conclusions
Sensitivity to change following the removal of obstruction further validates the usefulness of non-invasive measurement of bladder pressure by the penile cuff test and the categorization of obstruction by the non-invasive nomogram. Decreased isovolumetric bladder pressure following transurethral prostate resection may reflect a return to normal detrusor contraction strength.
Functional Studies to Assess Bladder Contractility

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Abstract
Bladder contractility refers to the intrinsic property of bladder smooth muscle to contract at a given length and intuitively represents not only the strength of the detrusor contraction, but the ability to adequately sustain a contraction. Suitable methods of measuring bladder contractility and approaches to quantifying these measurements are essential to accurately characterize voiding dysfunctions. Numerous techniques for functionally assessing bladder contractility, based on established biomechanical principles, have been described and thus the choice of methodological approach should be determined by the goals of the evaluation.

Key Findings
Penile cuff test has been shown to produce quantitative measures of bladder contractility that closely approximate maximum isovolumetric detrusor pressures measured invasively and represent promising approaches to the practical assessment of bladder contractile function.
Predicting the Outcome of Prostatectomy Using Non-Invasive Bladder Pressure and Urine Flow Measurements

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European Urology, Volume 52, issue 1, pages 1-306, July 2007

Objectives
To determine whether categorisation of bladder outlet obstruction (BOO) using measurements of bladder pressure and urine flow obtained by a novel non-invasive medical device (the penile cuff test) improves prediction of outcome from endoscopic prostatectomy (TURP).

Methods
A consecutive cohort of 208 men undergoing TURP following standard assessment in our institution was recruited, and 179 (86%) completed the protocol. Each subject underwent a penile cuff test prior to surgery; outcome was assessed by change in IPSS at 4 mo. The proportion of men with good outcome (>50% reduction in IPSS) was compared according to categorisation by non-invasive bladder pressure and urine flow measurements.

Results
The cuff test was completed by 93% of men with 2% experiencing an adverse event. Men categorised as having BOO by the test (37% of total) had an 87% chance of a good outcome from TURP ($p < 0.01$), whilst of those deemed not obstructed (19% of total) 56% experienced good outcome ($p < 0.01$). For the remaining men not categorised in these two groups, 77% had good outcome, which was identical to the result of the cohort as a whole (77%, $p = $NS).

Conclusions
Urodynamic categorisation using measurements obtained by the non-invasive penile cuff test improves prediction of outcome for men with LUTS undergoing TURP. This finding together with the ease and acceptability of the test suggest its suitability for office-based clinical use to assist men and their physicians in the selection for surgical treatment for relief of LUTS.

Take Home Message
This paper describes a prospective clinical study showing that preoperative categorisation of bladder outlet obstruction using non invasive measurement of bladder pressure by the penile cuff device can improve prediction of outcome following TURP.
The Origin of The Penile Compression Release

Belal M., Ellis-Jones J., Abrams P.
Bristol Urological Institute
ICS 2006

Hypothesis / aims of study
The penile compression release (PCR) index is thought to be a useful non invasive tool in the diagnosis of BOO [1,2]. Understanding of the origin of the PCR index is not well understood. An investigation into the origin of the initial surge of urine (Q_surge) after release of the penile compression will be undertaken. The aim was to test the hypothesis that the Q_surge was related to the volume of urine contained in the increased cross sectional urethra caused by the compression. An automated penile cuff device was used to produce the compression and release of the urine.

Study design, materials and methods
Following ethical approval and with informed written consent subjects underwent video urodynamic investigation according to ICS Good Urodynamic Practice [3].

Briefly the bladder was filled with radiopaque medium until the subject experienced a strong desire to void with continuous monitoring of abdominal (p_abd), bladder (p_ves) and subtracted detrusor pressure (p_dan) together with flow rate (Q). In addition, a 5cm metal wire was placed on the skin in the suprapubic area of the patient and a metal wire was placed circumferentially around the edge of the penile cuff.

The penile cuff was then positioned and the subject was asked to void. Once voiding commenced the cuff was automatically inflated until flow was interrupted or a safety limit of 200 cmH2O reached. The cuff then automatically deflated allowing flow to resume.

The cuff inflation cycle was repeated throughout the duration of the void. During the voiding cycle, fluoroscopy was undertaken in the posterior lateral position, observing the bladder neck and urethra region. The images were recorded digitally by the Dantec Duet urodynamic machine. The Dantec Duet video analysis software was length calibrated using the known marker of 5 cm on the patient. This allowed urethral lengths and widths to be measured.

In order to calculate the volumes observed, the two-dimensional video image of the contrast in the urethra was assumed to be circular in cross-section. However the urethras observed were irregular in shape, therefore a series of cylinders were used to calculate the volume contained in the urethra from the cuff to the bladder neck.

The volume of the surge of urine was calculated just prior to the release of the cuff, and this was subtracted from the volume contained in the urethra just after the cuff deflation. This calculated volume was compared to the volume measured by the flow meter during the Q_surge.

Results
A total of 20 patients were recruited into the trial.

The mean age was 68 (55 - 84). A total of 18 patients with a total of 43 cycles of penile cuff inflation and deflation were suitable for analysis.

A Student’s t-test showed that the 2 volumes were not significantly different (p= 0.09). The Pearson correlation coefficient was statistically significant at 0.931 (p< 0.0001). The correlation between the Q_surge and the isovolumetric detrusor pressure was also significant with a Pearson coefficient of 0.382 (p=0.026).

Interpretation of results
The results show that there is a close relationship between the calculated volume of urine contained in the urethra and the volume measured from the Q_surge in the flow meter. The Bland Altman plot shows good agreement between the 2 different measures of the Q_surge volume. A total of 95% of the measurements lie within 2 standard deviations of the mean difference. Therefore the assumption made to assume the cross-section was circular was reasonable.

The calculated volume was generally less than the measured volume from the flow meter.

The isovolumetric detrusor pressure derived from the penile compression and prior to the penile release provides the driving force to the expulsion of the urine and will contribute to the magnitude of the Q_surge. This factor may
explain some of the variability of the results but to a less extent than the volume contained in the urethra. Others have demonstrated a positive relationship of the isovolumetric detrusor pressure and the $Q_{\text{surge}}$ [1]. This was also shown in this study.

**Concluding message**

The magnitude of the $Q_{\text{surge}}$ of the PCR index is related to the volume of urine contained in the urethra prior to release of the penile compression. The isovolumetric detrusor pressure also provides a contribution to the magnitude of the $Q_{\text{surge}}$

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Neurourol Urodyn. 21, 167-78. 2002.

**Funding**

Non-Disclosures: None Human Subjects: This study was approved by the Southmead hospital ethics committee and followed the Declaration of Helsinki Informed consent was obtained from the patients.
The Role of Non-Invasive Bladder Pressure Measurement by the Penile Cuff Device for Assessment of Men with Lower Urinary Tract Symptoms

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Abstract
The invasive nature of conventional voiding pressure measurement limits routine diagnostic use for men with LUTS and has encouraged research into non-invasive methods of categorising obstruction. We have developed a technique to measure isovolumetric bladder pressure non-invasively, the penile cuff test, which is well tolerated and quick to perform. When combined with flow rate, a sufficiently accurate diagnosis of BOO is made to enable improved prediction of outcome from TURP for most men tested. In addition, release of penile compression allows derivation of the penile compression/release index, which is also useful for categorisation of detrusor function during voiding.
Basic Principles of the Newcastle Penile Cuff Test

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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 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.
Variation in invasive and non-invasive measurements of isovolumetric bladder pressure and categorization of obstruction according to bladder volume.

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The Journal of Urology, Volume 176, Issue 1, Pages 172-176, July 2006

Purpose
We developed a non-invasive test that provides an estimate of isovolumetric bladder pressure by measuring the pressure required to interrupt voiding using controlled inflation of a penile cuff. We noted variation in serial measurements obtained during a single void and, therefore, we determined whether this represents variation in detrusor contraction strength, as predicted in previous studies, or measurement error.

Materials and Methods
A total of 36 symptomatic men underwent simultaneous invasive and non-invasive pressure flow studies. Corresponding values of isovolumetric bladder pressure and cuff interruption pressure were recorded at each flow interruption and grouped according to bladder volume to calculate measurement error and bias at various points during a void. Individual variation in the 2 measurements across a range of normalized bladder volumes was then examined using ANOVA.

Results
Cuff interruption pressure showed a consistent level of accuracy as an estimate of isovolumetric bladder pressure across a range of volumes. There were similar, statistically significant differences in isovolumetric bladder pressure and cuff interruption pressure recorded at specific volume increments with the highest values seen in the mid range and the lowest seen at lower bladder volumes (each \( p < 0.01 \)). When plotting, the maximum recorded value of cuff interruption pressure in each individual on our proposed non-invasive pressure flow nomogram provided the best diagnostic accuracy for obstruction.

Conclusions
This study shows that cuff interruption pressure varies in the expected manner with bladder volume and provides a consistent estimate of isovolumetric bladder pressure throughout a void. These data provide important guidance for interpreting non-invasive pressure flow studies and classifying obstruction on the proposed nomogram.
Non-Invasive Methods of Diagnosing Bladder Outlet Obstruction in Men. Part 2: Non-Invasive Urodynamics and Combination of Measures

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The Journal of Urology, Volume 176, Issue 1, Pages 29-35, July 2006

Purpose
Many methods have been suggested to diagnose bladder outlet obstruction, as defined by the gold standard of pressure flow studies. Difficulty arises when comparing completely different methods of diagnosing bladder outlet obstruction. A comprehensive review of the literature on the different methods used to diagnose bladder outlet obstruction by non-invasive means was performed with a view to allow such a comparison.

Materials and Methods
A MEDLINE search was done of the published literature covering until the end of 2004 on non-invasive methods, including single measure and combinations of measures, to diagnose bladder outlet obstruction. A direct comparison of all of the different methods was made using the sensitivity, specificity, likelihood ratio, and pretest and post-test probability of diagnosing bladder outlet obstruction for each test. For many techniques these values were calculated from the data presented in the article.

Results
A multitude of methods has been applied to diagnose bladder outlet obstruction. Broadly the methods were divided into non-urodynamic and non-invasive urodynamic methods. Non-urodynamic methods were considered in part 1 of the review. Part 2 considered non-invasive urodynamic techniques, such as uroflowmetry, the penile cuff, the condom method and Doppler urodynamics. A combination of single measures was also considered and the relative merits of these approaches were discussed.

Conclusions
A combination of non-invasive urodynamics and ultrasound derived measures provide promising methods of diagnosing bladder outlet obstruction. However, pressure flow studies still remain the gold standard for assessing bladder outlet obstruction.
Variation in Invasive and Non-invasive Measurement of Isovolumetric Bladder Pressure and Categorisation of Obstruction According to Bladder Volume

Harding CK, Robson W, Drinnan MJ, Ramsden PD, Griffiths C, Pickard RS. Department of Urology and Regional Medical Physics Department, Freeman Hospital, Newcastle upon Tyne, UK
The Journal of Urology Volume 176, Issue 1, Pages 172-176, July 2006

Purpose
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Conclusions
This study shows that cuff interruption pressure varies in the expected manner with bladder volume and provides a consistent estimate of isovolumetric bladder pressure throughout a void. These data provide important guidance for interpreting non-invasive pressure flow studies and classifying obstruction on the proposed nomogram.
Diagnosis of bladder outlet obstruction using single or combined non-invasive measures of lower urinary tract function

AUA abstract 2005

Introduction
We have previously established that inflation of a penile cuff during voiding provides a valid and reliable measure of isovolumetric bladder pressure at the point of flow interruption (p_{cuff.int})\(^1\). Subsequently we have developed an automated penile cuff test device that is suitable for routine office use. We now aim to determine whether measurements made by the device have diagnostic accuracy in comparison to invasive pressure-flow studies (PFS). Preliminary work by our group has shown that a plot of maximum flow rate (Q_{max}) and p_{cuff.int} on a non-invasive pressure-flow nomogram shows good agreement with standard indices of bladder outlet obstruction (BOO) using invasive data\(^2\). In addition calculation of the penile compression-release (PCR) index using the post-compression flow surge (Q_{surge}) and the steady state flow rate (Q_{ss}) can also differentiate BOO\(^3\). (PCR_i = [Q_{surge} - Q_{ss}]/Q_{ss} \times 100). In this study we examine the diagnostic accuracy of these measurements both individually and combined using invasive PFS as gold standard.

Methods
We obtained complete data from 116 men with lower urinary tract symptoms (LUTS) attending 2 UK Urology centres for PFS. Each subject initially underwent invasive PFS and was classified according to ICS guidelines. Each subject then underwent a penile cuff test and values for Q_{max}, p_{cuff.int}, Q_{surge} and Q_{ss} were measured. These non-invasive data were used to predict the presence or absence of BOO, both on the non-invasive nomogram and by calculation of the PCR index. The diagnostic accuracy of these non-invasive variables individually or in combination was examined using receiver operator characteristics (ROC) curves.

Results
The results suggest that individually PCR index is diagnostically most useful. When all 3 variables are combined the diagnostic utility is maximised (Table 1).

<table>
<thead>
<tr>
<th>Non-invasive test</th>
<th>Area under ROC curve</th>
<th>Best diagnostic accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q_{max} alone</td>
<td>0.79</td>
<td>65% 85%</td>
</tr>
<tr>
<td>PCR index alone</td>
<td>0.88</td>
<td>80% 90%</td>
</tr>
<tr>
<td>Cuff test nomogram alone</td>
<td>0.82</td>
<td>73% 75%</td>
</tr>
<tr>
<td>Combined nomogram &amp; PCR index</td>
<td>0.92</td>
<td>86% 87%</td>
</tr>
</tbody>
</table>

Conclusion
The use of a combination of pressure flow variables obtained by the non-invasive penile cuff device allows sufficient diagnostic accuracy for BOO to encourage its routine office use. The data obtained using the test may be useful in the evaluation and selection of treatment for men with LUTS.

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Non-Invasive Measurement of Intravesical Pressure Using Penile Cuff

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Taiwan Urological Association 2005

Purpose
We reported the experiences to measure intravesical pressure using non-invasive penile cuff.

Materials and Methods
Between 2004 and 2005, 18 men aged from 53 to 78 were recruited from the outpatient clinics to investigate their lower urinary tracts symptoms. Urodynamics were performed according to the recommendations of the International Continence Society. To perform the cuff test an appropriately sized pediatric blood pressure cuff was placed around the shaft of the penis. Once voiding was established, the cuff was inflated until flow was interrupted.

Results
Data were completely recorded on 15 (83.3%) patients. Two patients strained excessively, preventing analysis, one patient was unable to void. Mean maximal intravesical pressure was 86.1 ± 10.8 cmH₂O. Mean cuff pressure was 80.4±13.6 cmH₂O. Intravesical pressure exceeded cuff pressure by an average of 5.6 ± 10.0 cm water. The differences between intravesical pressure and cuff pressure in patients with high bladder outlet obstruction index (BOOI >20) were significantly smaller than those of patients with low bladder outlet obstruction index (BOOI <20) (p<0.01).

Conclusions
This novel method provided non-invasive quantitative data on voiding bladder pressure.
A Nomogram to Classify Men with Lower Urinary Tract Symptoms Using Urine Flow and Non-Invasive Measurement of Bladder Pressure

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Purpose
Bladder pressure during voiding can be estimated by a non-invasive technique using controlled inflation of a penile cuff. This test provides a valid and reliable estimate of isovolumetric bladder pressure but to our knowledge the role of the test for the routine clinical treatment of patients with lower urinary tract symptoms (LUTS) has yet to be demonstrated. As a first step, we evaluated a proposed nomogram for the diagnosis of bladder outlet obstruction in men with LUTS using non-invasive measurements of pressure and flow.

Materials and Methods
Using a combination of theoretical calculation and experimental data the existing International Continence Society pressure flow nomogram was modified to allow non-invasive measurement of isovolumetric bladder pressure in place of detrusor pressure at maximum urine flow. Accuracy of the nomogram for classifying obstruction was then tested in a group of 144 men with LUTS who underwent an invasive and a non-invasive pressure flow study.

Results
The modified nomogram identified men with obstruction with 68% positive predictive value and 78% negative predictive value. Predictive accuracy could be improved by adding an additional criterion of obstruction, that is maximum urine flow less than 10 ml second, whereby an identifiable 69% of all cases could be classified as obstructed (88% positive predictive value) or not obstructed (86% negative predictive value). In the remaining 31% of patients invasive pressure flow studies would provide additional information, although some results would remain equivocal.

Conclusions
The proposed nomogram combined with the additional flow rate criterion can classify more than two-thirds of cases without recourse to invasive pressure flow studies. We must now evaluate the usefulness of this classification for the treatment of men with LUTS.
The Penile Compression-release Index is Sensitive to Change Following Prostatectomy

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ICS 2005

Hypothesis / aims of study
The penile compression-release index (PCRI) has been proposed as a non-invasive screening test for bladder outlet obstruction (BOO)\(^1\). The PCRI quantifies the relationship between the surge in urine flow seen following release of urethral compression (Q\(_{\text{surge}}\)) and the steady state flow rate (Q\(_{\text{ss}}\)) which is equivalent to Q\(_{\text{max}}\), by means of the formula:

\[
\text{PCR index} \ (\%) = \left[ \frac{(Q_{\text{surge}} - Q_{\text{ss}})}{Q_{\text{ss}}} \right] \times 100
\]

![Figure 1](image.png)

A typical flow rate trace obtained following penile compression and release

This diagnostic usefulness of this measurement has recently been evaluated using automated urethral compression and release by the controlled inflation of a pneumatic penile cuff\(^2\). Findings from this study suggested that values of PCRI above a threshold of 160% were indicative of BOO. The proposed use of PCRI as a non-invasive indicator of BOO suggests that it should decrease following treatment of BOO by transurethral prostatectomy (TURP).

We have therefore tested the hypothesis that PCRI is sensitive to change following TURP.

Study design, materials and methods
Following ethical approval and with prior written informed consent we prospectively recruited men who were already selected for surgical treatment of BOO in a single centre. Each patient underwent a symptom assessment and a non-invasive pressure flow study (penile cuff test) the day prior to surgery. All men were invited to return at 4 months following surgery for repeat symptom and non-invasive urodynamic assessment. A satisfactory surgical outcome was defined as a 50% or greater reduction in IPSS score.

For the purposes of measurement of PCRI, the penile cuff test provides an automated method of repeated urethral compression and release during voiding\(^2\). The cuff inflates at 10 cmH\(_2\)O s\(^{-1}\) until flow is interrupted. After 2 s of interrupted flow the cuff rapidly deflates to allow voiding to continue resulting in the characteristic flow surge followed by return to steady state flow. The highest value of PCRI obtained during the void was documented for each patient pre and 4 months post-operatively and the mean values compared using a paired Student’s test.

The change in values of Q\(_{\text{surge}}\) and Q\(_{\text{ss}}\) recorded before and after surgery were similarly examined. We also explored the relationship between change in PCRI and the outcome of surgery together with the pre-operative obstruction category defined by the proposed non-invasive pressure – flow nomogram\(^3\).

Results
We recruited a total of 194 men with median (range) age 68 (47-88) years. From this sample, we were able to obtain a valid PCRI reading for 87 (42%) men both before and after surgery.

Results are shown in Table 1. Analysis of the relationship between change in PCRI and surgical outcome revealed the mean (SD) decrease in PCRI was 141 (155)% for those reporting a good outcome compared to 66 (116)% for the
group with a poor outcome (P <0.05). In terms of obstruction grade those classified as definitely obstructed on the proposed non-invasive nomogram showed a mean (SD) decrease in PCRi of 168 (168)% compared with 86 (122)% in those unobstructed or not classified (P < 0.05).

Table 1 Results of pre and post operative values of PCRi and its components. P values are derived from Student’s t-tests comparing paired values pre and post operatively.

<table>
<thead>
<tr>
<th></th>
<th>PCRi %</th>
<th>Qsurge mls⁻¹</th>
<th>Qmax mls⁻¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRE OP</td>
<td>226 (133)</td>
<td>19 (8)</td>
<td>6 (3)</td>
</tr>
<tr>
<td>POST OP</td>
<td>106 (95)</td>
<td>26 (14)</td>
<td>14 (10)</td>
</tr>
<tr>
<td>P value</td>
<td>&lt; 0.01</td>
<td>&lt; 0.01</td>
<td>&lt; 0.01</td>
</tr>
</tbody>
</table>

**Interpretation of results**

If a valid recording of PCRi can be made, a marked change in the recorded value is seen following surgery to remove BOO. The decrease in PCRi is caused by a relatively greater increase in steady state flow which is roughly equivalent to $Q_{\text{max}}$ compared to a smaller increase in $Q_{\text{surge}}$. The surge in flow following release of compression is thought to relate to capacitance of the bulbar penile urethra together with detrusor contraction strength and therefore is likely to be less subject to change following TURP than $Q_{\text{max}}$. This change in PCRi gives further validation to its possible role as a screening examination for BOO in preference to invasive PFS. This is also supported by analysis of its relationship with preoperative obstruction category as defined by the proposed non-invasive nomogram which showed a significantly greater reduction in PCRi in the group of men classified as definitely obstructed. Furthermore those men reporting a good outcome from surgery also showed significantly greater reduction in PCRi.

The main problem associated with PCRi is the difficulty in ensuring an adequate recording which requires flow to return to its previous steady state after cuff deflation. This was hampered by small voided volumes pre-operatively and dramatically reduced voiding times post-operatively and we were able to calculate values for only half of the men recruited. If PCRi were to become clinically applied then more rapid automated inflation could be easily programmed in the existing penile cuff device.

**Concluding message**

These data provide further encouragement for the use of the penile compression-release index as a non-invasive indicator of bladder outlet obstruction. Sensitivity of the PCRi was mainly accounted for by the expected large increase in steady state flow that is equivalent to $Q_{\text{max}}$.

**References**

Comparison of Invasive and Non-Invasive Bladder Pressure Measurement by Calculation of the Bladder Outlet Obstruction Index (BOOI)

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ICS 2005

Hypothesis / aims of study
Non-invasive isovolumetric bladder pressure (p_{ves,int}) can be estimated from the penile cuff pressure required to interrupt flow (p_{cuff,int}), and this was used with a proposed modified ICS nomogram to compare non-invasive classification of obstruction with classification from an invasive pressure flow study (PFS)(1). However, the use of discrete categories for the invasive classification (“obstructed” or “not obstructed”) did not facilitate a more detailed analysis of the errors between the invasive and non-invasive techniques. The aim of this study was to avoid this limitation by comparing the non-invasive and invasive measurements as continuous variables allowing a more detailed analysis of the measurement errors. An additional aim was to assess the predictive accuracy of the non-invasive classification when combined with flow rate.

Study design, materials and methods
Data from the previous study (1) were used to calculate the invasive bladder outlet obstruction index, BOOI(PFS) (= AG number). The non-invasive equivalent, BOOI(Cuff), was calculated using the same correction factors that were used to construct the modified ICS nomogram(1). 144 patients referred for investigation of LUTS at two centres provided p_{det,Qmax} and Q_{max} from an invasive PFS, along with p_{cuff,int} and Q_{max,cuff} from a separate non-invasive cuff test(1).

For the invasive data: BOOI(PFS) = p_{det,Qmax} – 2xQ_{max}
For the non-invasive data: BOOI(CuffTest) = p_{cuff,int} – 4xQ_{max,cuff} – 40
{-40 removes the mean abdominal pressure; and the extra
-2xQ_{max,cuff} compensates for the mean isovolumetric pressure rise(1).}

Data were plotted and analysed using the technique of Bland-Altman(2). The differences between the two estimates of BOOI were compared with the calculated error, estimated from the summation of the known sources of error (using variance component analysis).

To assess predictive accuracy, positive predictive value (PPV) and negative predictive value (NPV) were calculated using the criterion BOOI > 40 cm H2O to classify obstruction. They were also calculated for the subset of patients where a flow rate criterion of <10ml/s as an additional indicator of obstruction agreed with the non-invasive classification.

Results
Figures 1 and 2 demonstrate the relationship between BOOI(PFS) and BOOI(Cuff) using the Bland-Altman method of analysis. (●) indicates Q_{max,cuff} <10 ml/s; (○) Q_{max,cuff} >= 10 ml/s.
Table 1 summarises the estimated variability for the different factors contributing to the overall variability of BOOI(Cuff) – BOOI(PFS). The variation in $Q_{\text{max}}$ and the subtracted repeat estimates for the BOOI(PFS) are from reference (3).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Standard (SD) (cm H$_2$O)</th>
<th>Deviation (cm H$_2$O)</th>
<th>Variance (SD$^2$ (cm H$_2$O)$^2$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal pressure + height</td>
<td>9</td>
<td>81</td>
<td></td>
</tr>
<tr>
<td>Isovolumetric pressure rise</td>
<td>10</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Additional 2x$Q_{\text{max}}$ (3)</td>
<td>4</td>
<td>18</td>
<td></td>
</tr>
<tr>
<td>Cuff pressure measurement</td>
<td>20</td>
<td>400</td>
<td></td>
</tr>
<tr>
<td>Subtracted repeat invasive PFS BOOI (3)</td>
<td>20</td>
<td>400</td>
<td></td>
</tr>
<tr>
<td>Total (Estimated)</td>
<td>32</td>
<td>$\sum = 997$</td>
<td></td>
</tr>
</tbody>
</table>

The random variability of the difference between measurements was estimated to be 32 cm H$_2$O (Table 1). This is close to the standard deviation of 36.1 cm H$_2$O from the Bland-Altman plot (Figure 2), which reduces to 31.7 cm H$_2$O if the 2 obvious outlying points are excluded. There is also a systematic mean (95% CI) difference of -14 (6) cm H$_2$O.

The horizontal and vertical lines at BOOI = 40 cm H$_2$O divide Figure 1 into 4 quadrants. Patients above the horizontal line are obstructed by the non-invasive measurements. Patients to the right of the vertical line are obstructed by the invasive PFS (the ‘gold standard’). Both methods agree that patients in the top right of Figure 1 are obstructed and patients in the bottom left are not obstructed. The number of patients in each quadrant is shown in the figure.

For the non-invasive test, PPV = 68% (36/53) and NPV = 78% (71/91).

For 69% (100/144) of patients, the non-invasive BOOI classification agreed with classification using a flow rate criterion of $Q_{\text{max,cuff}} < 10$ ml/s as an indicator of obstruction (Figure 1: closed circles above horizontal line, open circles below). Restricting the analysis to these patients gave PPV = 88% (23/26) and NPV = 86% (64/74).

**Interpretation of results**

The results demonstrate a reasonable quantitative agreement between the non-invasive and invasive estimates of BOOI considering the approximations made and other sources of variability. The magnitude of the variability between the two measurements can be accounted for by known contributory factors. The systematic difference, mean (95% CI) of -14 (6) does not include zero and we do not have an obvious explanation for this effect.

Classification of obstruction using the non-invasive criterion gave results that compare favourably with results for flow rate measurements alone. When the non-invasive classification was combined with classification from peak flow rate, measured during the same test, 2/3 patients were classified more accurately, with PPV and NPV approaching 90%.

**Concluding message**

BOOI derived from non-invasive data is in moderate agreement with invasive measurement. The limitations of the accuracy are consistent with the known sources of variability. The predictive accuracy in classifying obstruction is comparable to that achieved with flow rate alone but when combined with a flow rate criterion of $< 10$ ml/s, recorded during the same test, an identifiable 2/3 of patients were correctly classified with a predictive accuracy approaching 90%.

**References**


**Funding**

Action Medical Research
A Questionnaire Study of Patients’ Experience During Non-Invasive Urodynamics

Freeman hospital
ICS 2005

Hypothesis / aims of study

The penile cuff test is a novel non-invasive pressure flow study (PFS) involving automated inflation of a pneumatic penile cuff to interrupt voiding (1). Early clinical experience using the device suggested that patients found it acceptable and preferable to conventional invasive PFS (1). The present study aimed to confirm the favourable patient experience of the device using a questionnaire previously developed for conventional urodynamics (2). The validity of this questionnaire when applied to the non-invasive technique was also assessed.

Study design, materials and methods

The questionnaire, which assesses patients’ experience of urodynamic studies in the 5 domains of anxiety, embarrassment, pain, distress and willingness to have the test repeated, was adapted for use in the UK and applied to patients who had undergone a penile cuff test.

Each question required a rating on a 100 mm visual analogue scale (VAS).

A total of 20 consecutive men attending the department for investigation of lower urinary tract symptoms who consented to undergo a penile cuff test and to complete the questionnaire were recruited. Following the cuff test, the patient was left to self-administer the questionnaire in private after simple instruction from the research nurse. The subjects were then interviewed by an independent blinded researcher who completed the questionnaire with the patient, giving a second set of ratings for the 5 domains. Differences between the two sets of responses were examined using the weighted Kappa statistic. A second group of 22 men attending for invasive PFS agreed to complete the questionnaire in a similar fashion and differences between patient and observer-assisted scores were again assessed. Scores for the penile cuff test were then compared with those obtained in the group undergoing invasive PFS by Student’s t-test. If patients in the penile cuff test group had previously attended for invasive cystometry they were asked to express a preference for one or other of the tests.

Results

All patients completed the questionnaire (n=42). There was excellent agreement between scores using self-completion and those obtained during the observer-led interview with weighted Kappa values in the non-invasive group ranging from 0.65 (anxiety) to 0.96 (embarrassment). Similar Kappa values were seen for invasive PFS ranging from 0.60 (willingness to repeat) to 0.89 (embarrassment). The agreement was consistent throughout all five domains for both the invasive and non-invasive test groups (Figures 1 and 2).

Comparison of self-administered ratings recorded by men having a penile cuff test with those from the invasive urodynamics group showed a statistically significant decrease in both pain (P < 0.01) and distress (P < 0.01). Furthermore men undergoing a penile cuff test showed increased willingness to have the test repeated (P < 0.03).
contrast, differences in the domains of anxiety and embarrassment were not statistically significant (Figure 3). In a subset of 8 patients from the penile cuff test group who had previously undergone invasive urodynamics, 75% preferred the penile cuff test.

Interpretation of results
The close agreement between self-administered and interviewer-administered ratings for both invasive and non-invasive PFS suggests that this questionnaire gives a reproducible account of the patient’s experience of urodynamic investigations across the 5 domains examined. The questionnaire therefore represents a useful tool which can be self-administered by the patient to assess the acceptability of differing urodynamic investigations. The comparative data, although obtained from a different sample, suggest that non-invasive urodynamics are perceived as causing less pain and distress than invasive studies and consequently men are more willing for the test to be repeated. The smaller differences found in scores for anxiety and embarrassment suggest that such feelings result from features common to both types of studies, such as voiding in a clinical environment and ‘performance anxiety’. The sensitivity of the questionnaire to detect differences only in expected domains, such as pain and distress and willingness to repeat, adds an element of construct validity. This is reinforced by the similar scores in the domains assessing features common to both techniques.

Concluding message
Findings support the use of this simple questionnaire for the evaluation of urodynamic investigations. The penile cuff test causes less pain and distress than conventional PFS and is consequently preferred by patients.

Acknowledgement
We thank Jongno Ku, Department of Urology, Seoul National University College of Medicine, Seoul, Korea for permission to adapt and use their questionnaire in our study.

References
A Non-Invasive Method for the Measurement of Urethral Opening Pressure

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1. Royal Cornwall Hospital, 2. Bristol Urological Institute
ICS 2005

Hypothesis / aims of study
Urethral opening pressure (p_{uo}) is the minimum fluid pressure required to open the urethra during voiding. For a given intravesical pressure (p_{ves}) and an ideal fluid, urine flow rate is determined by p_{uo} and cross sectional area at the “flow controlling zone” (FCZ). The FCZ is located at the level of the pelvic floor in normal men and in the prostatic urethra in those with benign prostatic obstruction (BPO).

p_{uo} may be estimated during invasive pressure flow studies (PFS) by measurement of the vesical pressure at the start of flow (p_{ves,0beg}). In practice vesical pressure is often lower at the end of flow and may represent a closer estimation to p_{uo}. This may be measured as the vesical pressure 10mls prior to the end of flow (p_{ves,0end}). (1)

Theoretically it is possible to estimate p_{uo} directly using the technique of voiding urethral pressure profile (VUPP) measurement. During voiding, pressure falls along the urethra from bladder neck to distal urethra. The total available pressure is p_{ves}, which can be split into driving pressure (pdp), converted into velocity, and p_{uo}, i.e. p_{ves} = p_{dp} + p_{uo}. (2)

Experimental work using a penile cuff suggests that the “knee pressure” (p_{cuff,knee}) taken from plots of flow rate against cuff pressure may give an estimate of p_{uo}. (3)

We set out to test the hypothesis that “knee pressure” corresponds to urethral opening pressure as estimated from invasive PFS and VUPP.

Study design, materials and methods
Men with LUTS were recruited. Each patient underwent invasive PFS, simultaneous invasive PFS and cuff test and VUPP measurement. Invasive urodynamics were performed in accordance to the recommendations of the International Continence Society. A 6Ch double lumen Urethral Pressure Profile catheter (Mediplus, UK) was used throughout.

Cuff pressure vs. flow rate traces were analysed for the presence of a knee pressure (Fig1A).

Bland – Altman Limits of agreement plots have been used to compare knee pressures with p_{ves,0beg} and p_{ves,0end}, taken from invasive PFS, and with urethral pressures at bladder neck, prostate, pelvic floor and distal urethra as well as pressure gradients between these points measured using VUPP (Fig1B).

Figure 1.A. Plot of cuff pressure against flow rate, knee pressure indicated. B. VUPP trace showing pressure change from the bladder neck (BN) across the prostatic urethra (PU) and pelvic floor (PF) to the distal urethra (DU).

Results
From the traces of cuff pressure against flow, p_{cuff}, knee was recorded. Of the 113 patients who successfully underwent simultaneous PFS and cuff test 103 (91%) produced an identifiable knee pressure. In those patients in whom a knee pressure was seen in more than one cuff inflation cycle then the highest value was recorded.
Theoretical urethral opening pressures were measured; vesical pressures at the start and end of flow $p_{ves,Q_{beg}}$ and $p_{ves,Q_{end}}$ were available for all 113 patients. In 23 patients an after contraction was seen at the end of voiding which would have given a falsely elevated value for $p_{ves,Q_{end}}$, these values were therefore discounted.

After a third fill patients underwent VUPP measurement. 88 patients produced interpretable results.

Limits of agreement between $p_{cuff,knee}$ and urethral opening pressures derived from invasive PFS, and between $p_{cuff,knee}$ and urethral pressure measurements and pressure gradients derived from VUPP are shown in the table.

<table>
<thead>
<tr>
<th></th>
<th>$p_{cuff,knee}$ - $p_{ves,Q_{beg}}$</th>
<th>$p_{cuff,knee}$ - $p_{ves,Q_{end}}$</th>
<th>$p_{cuff,knee}$ - $p_{(bladder neck)}$</th>
<th>$p_{cuff,knee}$ - $p_{(prostate plateau)}$</th>
<th>$p_{cuff,knee}$ - $p_{(pelvic floor plateau)}$</th>
<th>$p_{cuff,knee}$ - $\Delta p_{(bladder neck - prostate plateau)}$</th>
<th>$p_{cuff,knee}$ - $\Delta p_{(bladder neck - pelvic floor plateau)}$</th>
<th>$p_{cuff,knee}$ - $\Delta p_{(bladder neck - distal urethra)}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean difference (cmH2O)</td>
<td>-20.5</td>
<td>-3.2</td>
<td>-9.9</td>
<td>26.1</td>
<td>52.6</td>
<td>54.8</td>
<td>26.2</td>
<td>-16.1</td>
</tr>
<tr>
<td>95% confidence interval</td>
<td>-27.5 to -13.5</td>
<td>-12.2 to 5.9</td>
<td>-16.3 to -3.6</td>
<td>18.0 to 34.8</td>
<td>45.0 to 60.2</td>
<td>46.4 to 63.2</td>
<td>19.3 to 33.2</td>
<td>-23.6 to -8.5</td>
</tr>
<tr>
<td>SD (cmH2O)</td>
<td>35.4</td>
<td>41.2</td>
<td>28.2</td>
<td>32.6</td>
<td>33.9</td>
<td>32.6</td>
<td>31.2</td>
<td>33.5</td>
</tr>
<tr>
<td>Lower limit of agreement (cmH2O)</td>
<td>-91.4</td>
<td>-85.4</td>
<td>-66.4</td>
<td>-38.7</td>
<td>-15.2</td>
<td>-10.3</td>
<td>-36.1</td>
<td>-83.1</td>
</tr>
<tr>
<td>Upper limit of agreement (cmH2O)</td>
<td>50.4</td>
<td>79.1</td>
<td>48.5</td>
<td>91.5</td>
<td>120.5</td>
<td>120.0</td>
<td>88.6</td>
<td>51.0</td>
</tr>
</tbody>
</table>

**Interpretation of results**

When $p_{cuff,knee}$ are compared with $p_{ves,Q_{end}}$ the 95% confidence levels of the mean difference include the value zero, representing equivalence. Thus there is evidence to suggest a statistically significant relationship between the two. This suggests that knee pressure may represent a method of measuring $p_{uo}$. However, in view of the wide limits of agreement $p_{cuff,knee}$ may not be a very precise measure for individuals.

From the VUPP measurements $p_{cuff,knee}$ lies consistently between the pressures measured at bladder neck and prostate. $p_{cuff,knee}$ is also slightly less than the total pressure change from bladder neck to distal urethra. If $p_{cuff,knee}$ does represent opening pressure, as suggested by the $p_{ves,Q_{end}}$ comparison, then it would appear that the opening pressure component of the FCZ lies between the bladder neck and prostate, where pressure is falling rapidly, and may exist over a short distance that we are not able to measure using VUPP, rather than over a longer distance producing a plateau of pressure. This is a reasonable proposition as one would expect to see pressure changing across the FCZ.

**Concluding message**

Knee pressures measured using a penile cuff inflated during voiding may represent a non-invasive technique for the estimation of urethral opening pressure.

**References**


Aims
The use of discrete categories for the invasive classification (“obstructed” or “not obstructed”) did not facilitate a more detailed analysis of the errors between the invasive and non-invasive techniques. The aim of this study is to avoid this limitation by comparing the non-invasive and invasive measurements as continuous variables allowing a more detailed analysis of the measurement errors. An additional aim is to assess the predictive accuracy of the non-invasive classification when combined with flow rate.

Method
Data were plotted and analysed using the technique of Bland-Altman. The differences between the two estimates of BOOI were compared with the calculated error, estimated from the summation of the known sources of error. To assess predictive accuracy, positive predictive value (PPV) and negative predictive value (NPV) were calculated using the criterion BOOI > 40 cm H2O to classify obstruction. They were also calculated for the subset of patients where a flow rate criterion of <10ml/s as an additional indicator of obstruction agreed with the non-invasive classification.

Results
For 69% (100/144) of patients, the non-invasive BOOI classification agreed with classification using a flow rate criterion of $Q_{\text{max,cuff}}<10$ ml/s as an indicator of obstruction. Restricting the analysis to these patients gave PPV=88% (23/26) and NPV=86% (64/74).

Conclusions
BOOI derived from non-invasive data is in moderate agreement with invasive measurement. The limitations of the accuracy are consistent with the known sources of variability. The predictive accuracy in classifying obstruction is comparable to that achieved with flow rate alone but when combined with a flow rate of <10 ml/s, recorded during the same test, an identifiable 2/3 of patients were correctly classified with a predictive accuracy approaching 90%.
Non-invasive Bladder Function Test (penile cuff test, CT3000) for Men With Lower Urinary Tract Symptoms

National Horizon Scanning Centre, New and Emerging Technology Briefing, University of Birmingham, July 2005

Summary
Non-invasive bladder pressure flow analysis for men (the penile cuff test, CT3000) indirectly measures intra-vesical pressure using controlled inflation of a flexible cuff placed around the penis during voiding of urine, until flow is interrupted. The CT3000 is a diagnostic technique that could be used as a screening technique for men with lower urinary tract symptoms (LUTS) prior to more time consuming, invasive and expensive studies, and as a guide for the chance of a good outcome with prostatectomy. A study in 150 men showed that a penile urethral compression release index of greater than 160% diagnosed bladder outlet obstruction with a 78% sensitivity, 84% specificity and a positive predictive value of 69%.

Developer – Mediplus Ltd.
NHS or Government priority - No, although could prevent some unsuccessful surgery.
Burden of disease - Endoscopic operations on the bladder outlet, including all forms of endoscopic prostatectomy, are performed on about 30,000 men in the England and Wales each year. Fewer than 50% of men who underwent prostatectomy in four regions in England had their flow rates measured; a smaller percentage have invasive urodynamic tests.
Potential clinical benefit - A proportion of men (25% - 36%; 7,500 – 10,800) do not benefit from prostatectomy, many failures are due to misdiagnosis of outlet obstruction. If the penile cuff test gives sufficient diagnostic information, then prostatectomy could be better targeted.
NHS or societal resource impact - If the CT3000 increases the targeting of prostatectomy and increases the overall success rate of prostatectomy from around 70% to 90%, then an estimated 6,667 procedures may be prevented, with a saving of £11.3M. Additional savings include: a reduction in invasive urodynamic studies undertaken (£1.45M) and associated staff time, and a reduction in treatment costs for the complications of prostatectomy (urinary tract infection: £0.38M). Costs incurred will include purchase and use of the CT3000 system: £6.1M if all 550 urologists purchase one system.
Change in Bladder Contraction Strength Following TURP

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Neurourology and Urodynamics, Volume 24, Issue 5/61, Pages529-531, September 2005

Aim
To investigate changes in bladder contraction strength occurring after surgical treatment for BPE by comparing non-invasive pressure flow data provided by the cuff test. Our null hypothesis was that \( P_{cuff,int} \) (representing contraction strength) was unchanged following TURP.

Method
We prospectively recruited men already selected for TURP from a single centre. A penile cuff test and symptoms assessment (IPPS score) was performed the day prior to surgery. All patients were invited to undergo a second cuff test and symptoms assessment 4 months following their surgery. The difference between pre-operative and 4-month post-operative \( P_{cuff,int} \) was calculated for each individual and significance examined by Student’s test. We also examined the relationship between change in contraction strength within each subject and their pre-operative obstruction category derived from the proposed non-invasive nomogram using Student’s test. In order to investigate the timing of possible change in contraction strength we tested a sub-group of 10 consecutive patients 2 months post-operatively.

Results
Over a 2-year period we recruited 194 men with median (range) age of 68 (47-88) years. Histological BPH was confirmed in all cases. From this group we obtained valid measurements of \( P_{cuff,int} \) before and after surgery for 132 (68%) subjects. The post-operative measurement took place at a median (range) of 134 (65-200) days after TURP. Overall, mean (SD) \( P_{cuff,int} \) decreased from 139 (36) cmH\(_2\)O to 108 (30) cmH\(_2\)O (\( P < 0.01 \)). The magnitude of change in \( P_{cuff,int} \) was significantly greater in those classified pre-operatively as having BOO using the proposed non-invasive nomogram. Valid paired data were obtained from 9 men who were tested 2 months after surgery. For this sub-group mean (SD) \( P_{cuff,int} \) decreased from 133 (41) cmH\(_2\)O to 98 (26) cmH\(_2\)O following TURP (\( P < 0.05 \)).

Conclusions
The consistent fall in non-invasively measured isovolumetric bladder pressure represents a compensatory decrease in detrusor contraction strength following removal of BOO by TURP.
Is Evaluation of Urethral Obstruction and Detrusor Force Possible from Coupling of Data from One Free Uroflow and One Penile Cuff Test in Patients with Benign Prostatic Enlargement (BPE)? Preliminary Study

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ICS 2004

Hypothesis / aims of study
A technique for non-invasive measurement of isovolumetric bladder pressure has been developed in Newcastle [1]. Our purpose was to show that, by using the VBN mathematical micturition model [2], data from one free flow and one cuff test are sufficient to evaluate the detrusor pressure at maximum flow rate (p_{det}.Q_{max}) and thereby usual obstruction indices such as the Abrams-Griffiths (AG) number.

Study design, materials and methods
We studied 42 male patients attending with lower urinary tract symptoms. Each underwent one pressure-flow study (PF), one pressure-flow study with cuff test (PFC) and one free cuff test without vesical pressure measurement (FC).
Applying the VBN mathematical micturition model [2] to urodynamic recordings, one can determine two parameters that characterize the obstructive status of a patient:

(i) the prostatic urethra counter-pressure (pucp) is the pressure exerted on the urethra by the enlarged prostate (equivalent to prostatic opening pressure);
(ii) the detrusor force coefficient (k) quantifies the detrusor function and so the effect of the urethral obstruction on the muscle function.

To analyze cuff recordings, we used a slightly improved version of the VBN model which makes a distinction between intra- and extra-abdominal compartments. This is necessary since the flow controlling zone moves from the prostate to the penile urethra as the cuff is inflated.

We applied the VBN model according to the following procedure:
1) Since the cuff test is non-invasive, we used the PF study simply to obtain a free flow trace FF. VBN analysis of this trace does not give absolute values of k or pucp, just a relationship between them. In addition we used the PFC to obtain one free cuff test FC2.
2) Using the standard cuff test analysis, we determined the cuff pressure required to arrest flow for each inflation cycle. These cuff pressures give one or more point estimates of isovolumetric bladder contraction pressure p_{ves,ivs}.
Since bladder contractility varies with time, we also recorded the time or times at which flow interruption occurred (t_{stop}).
3) Using these point estimates of p_{ves,ivs}, we used the VBN model to determine from the P-F study the best fit for k and pucp.
4) Finally, we used to VBN model with these parameters to predict Q_{max}, the detrusor pressure at maximum flow (p_{det}.Q_{max}), and thereby the AG number (p_{det}.Q_{max} - 2 Q_{max}).

Results
1) A simple graphical use of the recorded flow and pressure curves of PFC led to evaluate the transmission coefficient T: T = 0.85 +/- 0.15.
2) 30 from the 42 files (70%) were usable. The FC computed flow curves were very alike the recorded ones except during a short time (about 3 seconds) after deflation of the cuff. Then, a spike of flow rate was observed. VBN calculations using unsteady hydrodynamics found spikes shorter than observed.
3) Because of the good fitting of the curves, evaluation of the detrusor pressure was possible for 27 of the 30 files. The main result was that the accuracy of the evaluation was better with the VBN-cuff coupling than with the only cuff. As an example, in a case with Q_{max}=13 mL/s, the measured and evaluated values of p_{det}.Q_{max} in cm H2O were:
measured from PFstudy: 110
cuff test FC: 40 to 93; cuff test FC2 (2 cuff inflations): 65 to 119 and 53 to 118
VBN method from FC: 91 to 127; VBN method from FC2: 80 to 114.

Interpretation of results
The main problem is the accuracy of the evaluations. The causes of inaccuracy seem to be
a) the dispersion of the values of the transmission coefficient T, the presence of the catheter can affect it.
b) a delay of roughly 3 seconds which can be due to an instrumental artifact or a change in the compliance of the
distal urethra, widens the spikes duration and replaces the brisk interruption of the flow by a smooth curve; thus,
t_{stop} is badly defined.
c) anxiety of the subjects may cause a delayed opening of the urethra and involuntary contractions of perineal
muscles and sphincter. Our method seems able to eliminate the effect of the third cause, to reduce the effect of the
second, but cannot reduce the effect of T dispersion.

Our method seems able to eliminate the effect of the third cause, to reduce the effect of the second, but cannot
reduce the effect of T dispersion.

Concluding message
Coupling of theoretical analysis and recorded data of penile cuff test allows to discuss the accuracy and the reliability
of the method. Theoretical analysis of the recorded data improves the quantitative evaluation of the obstruction due
to BPE.

References
Combination of Non-Invasive Urodynamic Parameters from a Single Penile Cuff Test for Diagnosis of Bladder Outlet Obstruction

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ICS2004

Hypothesis/aims of study
The penile cuff test is a recently developed non-invasive urodynamic investigation which relies upon automated inflation of a penile cuff to interrupt urine flow. The cuff pressure required to stop flow (p_cuff,int) provides an estimate of isovolumetric bladder pressure (1).

Two methods are established by which the cuff test can diagnose bladder outlet obstruction (BOO). First, p_cuff,int can be plotted in conjunction with maximum urine flow rate on a non-invasive equivalent to the ICS nomogram (2). Alternatively, BOO can be diagnosed from the same cuff test using Sullivan & Yalla’s Penile Compression-Release (PCR) index (3).

The aim of this study was to investigate the diagnostic value of combining non-invasive nomogram data (2) and PCR index (3) from a single cuff test into one diagnostic parameter, using ICS standard classification from invasive cystometry as the gold standard.

Study design, materials and methods
Ethical approval and informed written consent for the penile cuff test were obtained. Data from 116 men with lower urinary tract symptoms attending two UK Urology centres for invasive cystometry were analysed retrospectively.

Gold standard classification: Each subject underwent conventional cystometry according to the ICS guidelines, and was classified as obstructed or other (equivocal or unobstructed) according to the provisional ICS nomogram.

The penile cuff test: Each subject then underwent a penile cuff test (2), where we measured overall peak urine flow rate (Q_max, excluding surges), and cuff interruption pressure (p_cuff,int) for each cuff inflation. Where more than one cuff inflation was possible, we took the highest value of p_cuff,int across all inflations.

Calculation of PCR Index: The PCR method relies upon comparison of the surg in urine flow (Q_surge) seen at cuff release following penile urethral compression, with the steadystate flow rate (Q_ss). For each cuff inflation we measured Q_surge and Q_ss, then calculated mean PCR index across all inflations;

\[
\text{PCR index} = \left( \frac{Q_{\text{surge}} - Q_{\text{ss}}}{Q_{\text{ss}}} \right) \times 100
\]

Assessment of test performance: For many clinical tests there is a trade-off where sensitivity can be improved at the expense of specificity, by moving the threshold used to delimit the normal and diseased states. The receiver-operator characteristic (ROC) curve shows this trade-off graphically. The area under the ROC curve is a pragmatic indicator of the test’s performance, and ranges from 0 (the test is always wrong) to 1 (always right).

Using the ICS classification of obstruction as gold standard, we calculated ROC curves for:
(i) Peak urine flow rate (Q_max) alone;
(ii) PCR index alone;
(iii) the non-invasive cuff test nomogram, incorporating Q_max and p_cuff,int;
(iv) the combination of Q_max, p_cuff,int and PCR, using linear discriminant analysis as below.

Linear discriminant analysis: Each subject was plotted on a 3-dimensional nomogram (figure 1) with axes of Q_max, p_cuff,int and PCR index; linear discriminant analysis establishes the plane best separating obstructed from other subjects. In order to generate the ROC curve, we altered the position of the plane while keeping its gradient constant (figure 2).

Results
49 (42%) of the subjects were obstructed according to the provisional ICS nomogram. The combination of Q_max, p_cuff,int and PCR index improves the discriminating ability beyond that of
the simpler tests (Table 1, figures 1 & 2).

<table>
<thead>
<tr>
<th>Non-invasive test</th>
<th>Area under ROC curve</th>
<th>Best diagnostic accuracy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q_{max} alone</td>
<td>0.79</td>
<td>65% 85%</td>
</tr>
<tr>
<td>PCR index alone</td>
<td>0.88</td>
<td>80% 90%</td>
</tr>
<tr>
<td>Cuff test nomogram (Q_{max} &amp; P_{max})</td>
<td>0.82</td>
<td>73% 75%</td>
</tr>
<tr>
<td>Combined nomogram (Q_{max} &amp; P_{max} &amp; PCR)</td>
<td>0.92</td>
<td>55% 67%</td>
</tr>
</tbody>
</table>

Table 1 Diagnostic performance for four non-invasive tests. We also give the test overall diagnostic accuracy (ie. at which the most subjects were correctly classified).

Interpretation of results
The addition of PCR index to the data plotted on the non-invasive nomogram improves the diagnostic accuracy of the cuff test. The combined parameter diagnosed BOO with good accuracy in relation to the gold standard of invasive cystometry.

Concluding message
The combination of flow rate, penile cuff interruption pressure and PCR index measured from a single cuff test shows promise in the non-invasive diagnosis of bladder outlet obstruction. Given the test’s simplicity it could be utilised in the outpatient or prostate assessment clinic setting as an adjunct to uroflowmetry.

References
(1) J Urology 2002; 167: 1344-47.

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Non-Invasive Assessment of Bladder Contractility in Men

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The Journal of Urology, Volume 172, Issue 1, Pages 1394-1398, October 2004

Purpose
Preoperative assessment of detrusor function by pressure flow study (PFS) improves outcome from prostatectomy but is invasive and uncomfortable for the patient. We report on a large scale validation of a novel non-invasive assessment of detrusor contractility.

Materials and Methods
A flexible cuff placed around the penis was inflated automatically during voiding until flow interruption. Cuff pressure at interruption (pcuff.int) reflects isovolumetric bladder pressure (pves.isv), a measure of detrusor contractility. For comparison 151 symptomatic men performed the cuff test with simultaneous PFS monitoring. Test/retest agreement was assessed in 91 subjects who performed a cuff test without PFS on 2 occasions.

Results
For the 117 (77%) subjects with an acceptable cuff pressure flow trace, Bland Altman analysis showed that pcuff.int overestimated pves.isv by a mean (s.d.) of 16.4 (27.5) cm H2O, predominantly due to the cuff being positioned below the bladder. For test/retest analysis 52 (57%) of the men who were able to attend twice provided acceptable cuff data on both occasions with a mean (s.d.) difference in pcuff.int of -3.3 (32.0) cm H2O, improving to 0.0 (20.3) cm H2O in a subgroup of 39 subjects who voided more than 150 ml. On questionnaire assessment 121 (80%) subjects preferred the cuff test to PFS.

Conclusions
The cuff test gives a valid and reproducible estimate of isovolumetric bladder pressure in a manner acceptable to patients, although test failure and variability of agreement require improvement. The test may be of value in the assessment of urinary symptoms and may aid in patient selection for prostatectomy.
An Automated Penile Compression Release Maneuver as a Non-Invasive Test for Diagnosis of Bladder Outlet Obstruction

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The Journal of Urology Volume 172, Issue 6, Part 1, Pages 2312-2315, December 2004

Purpose  
We tested the hypothesis that the previously described penile urethral compression release (PCR) maneuver provides a valid diagnosis of bladder outlet obstruction (BOO) using automated rather than manual penile compression by controlled inflation of a penile cuff. We also investigated urodynamic events underlying generation of the PCR index.

Materials and Methods  
A total of 150 subjects attending for pressure flow studies were studied using conventional and non-invasive cystometry. Patients were classified into urodynamic diagnostic groups using standard invasive studies. The PCR index was calculated for each individual from non-invasive penile cuff data and the results were summarized for each group. ROC analysis of the PCR index was performed to define an optimum threshold for BOO diagnosis. Simultaneous invasive and non-invasive data were used to define the relationship between the PCR index, bladder contractility and the maximum flow rate.

Results  
The mean PCR index ± SD was significantly higher in the BOO group compared to the normal cystometry group (215% ± 84% vs 93% ± 39, p <0.01). ROC analysis showed that a PCR index of greater than 160% diagnosed BOO with 78% sensitivity, 84% specificity and a positive predictive value of 69%. There was a strong positive correlation between the PCR index and isovolumetric detrusor pressure, which is a measure of bladder contractility (r = 0.44, p <0.01).

Conclusions  
The results of this study suggest that the PCR index combines valid estimates of bladder contractility and the maximum flow rate, and it represents a clinically useful, non-invasive urodynamic parameter for the diagnosis of BOO.
Non-Invasive Technique for the Measurement of Isovolumetric Bladder Pressure

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The Journal of Urology Volume 171, Issue 1, Pages 12-19, January 2004

Purpose
A total of 184,000 prostatectomies were performed in the United States in 2000 for the relief of presumed bladder outlet obstruction. However, it has been reported that prostatectomy using current indications fails to bring about symptomatic improvement in approximately one-fourth of patients. Pressure flow studies are currently recognized as the gold standard for the diagnosis of bladder outlet obstruction. However, these studies are associated with a number of disadvantages. They are time consuming, invasive and expensive, and carry some morbidity for the patient. It has been suggested that the use of pressure flow studies should be mandatory before surgery. The invasive nature of this test limits its application, and a variety of non-invasive methods have been suggested to circumvent the need for conventional urodynamics.

Materials and Methods
We conducted a MEDLINE search of the published literature on the use of non-invasive techniques to measure bladder pressure.

Results
Two promising techniques involve the non-invasive measurement of isovolumetric detrusor pressure. The first of these methods uses an external condom catheter and the second an inflatable cuff around the penis. Both of these methods rely on the interruption of urinary flow and the measurement of the bladder pressure transmitted along the fluid column between bladder and site of urethral occlusion. An alternative strategy analyzes flow patterns following compression and release of the urethra during voiding.

Conclusions
Of the methods reported the penile cuff, which is inflated during voiding, or the penile squeeze technique, which infers bladder pressure from flow patterns, would seem the most likely to be clinically useful. A non-invasive measure of bladder pressure, allied to a free flow rate, would give a useful adjunct to the assessment of men with lower urinary tract symptoms.
Does the presence of a urethral catheter affect pressure-flow parameters measured non-invasively by the penile cuff technique?

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Aims of Study
The validation of non-invasive methods of measurement of voiding parameters necessarily involves the simultaneous invasive measurement of intra-vesical pressure which is most easily achieved by urethral catheters. Our studies of flow interruption by inflation of a penile cuff suggest that the penile cuff pressure sufficient to interrupt flow ($P_{\text{cuff,int}}$) should be equivalent to isovolumetric bladder pressure ($P_{\text{ves,inv}}$). Validation of the technique has compared of $P_{\text{cuff,int}}$ with $P_{\text{ves,inv}}$ measured using a urethral catheter [1,2]. Though the results are encouraging, the variation in accuracy is greater than anticipated from measurements of pressure within the penile urethra compared to cuff pressure [3]. It is possible that the presence of a urethral catheter may influence the reliability of the technique. In this paper we test the null hypothesis that the presence of the catheter does not affect the measurement obtained. If true, repeated cuff tests on the same patients should have the same consistency, whether or not a catheter is present for one of the tests.

Methods
Ninety one men with lower urinary tract symptoms (LUTS) referred for invasive pressure flow studies (PFS) and non-invasive urodynamic assessment using the cuff method were included in this study. The non-invasive cuff method was performed both with and without the presence of a urethral urodynamic catheter (6F calibre) and the results compared. Agreement was investigated by the Bland Altman method plotting the difference of the two measures of $P_{\text{cuff,int}}$ versus the mean [4]. The values of $P_{\text{cuff,int}}$ with and without lines were analysed for significant differences using Student’s t-test.

In addition sixty two subjects returned for repeat cuff tests and these results were compared with the previously obtained data using the Bland Altman method and Student’s t-test. The repeat cuff tests were performed within a four week period to prevent disease progression influencing the results. Data sets were excluded if voided volume (VV) was less than 150ml in any of the voids analysed as this has previously been shown to be a minimum VV requirement [2].

Results
Following exclusions, sixty two data sets were included for analysis of the effect of the presence of urethral urodynamic catheters. The values of cuff pressure at flow interruption ($P_{\text{cuff,int}}$) with and without urethral lines were plotted and agreement assessed. The data obtained is shown below:

![Graphs and Table]

Table 1: Effect of urethral lines on $P_{\text{cuff,int}}$
These results show a significantly higher mean $P_{\text{cuff,int}}$ with a urethral urodynamic catheter present. Inspection of the Bland Altman plot reveals an offset towards higher values of $P_{\text{cuff,int}}$ in the presence of urethral lines. Application of Student’s t-test has shown a very low probability that this difference is due to chance. Following exclusion, again on the basis of voided volume less than 150ml, the test/retest reliability of the cuff method was examined using the data from thirty four subjects who attended for follow up cuff tests. The values of $P_{\text{cuff,int}}$ pertaining to the two tests were plotted and any difference examined as shown below:

**Table 2:** Comparison of $P_{\text{cuff,int}}$ in two separate cuff tests. This data shows no significant difference between values of $P_{\text{cuff,int}}$ from the repeat cuff test when compared with the original investigation.

**Conclusions**

This study strongly suggests that the presence of a urethral urodynamic catheter significantly alters values of parameters measured using the cuff method. The variability between individual cuff tests has been shown, via the test/retest data, to be minimal and the difference in $P_{\text{cuff,int}}$ values seen in the invasively validated data could be assumed to be due to the presence of lines. Care must be taken therefore when any cuff parameters are measured in the presence of urethral lines. One possible reason for the differences seen may be that in the presence of a urethral line, compression and therefore occlusion of the penile urethra requires higher pressure from the cuff. Further work using supra pubic catheters to compare invasive measurements with those determined from the cuff test is needed.

**References**

1: J Urol 2002; 167: 1344-1347
2: Proceedings of 32nd Annual Meeting of the International Continence Society 2002
3: J Urol 2001: 166: 2545-2549
Evaluation of the non-invasive estimation of bladder pressure using a penile cuff: An alternative to pressure-flow studies in men?

Blake C, Baldry L, Hassine A, Abrams P
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ICS 2003

Aims of Study
Both urine flow studies and pressure-flow studies (PFS) improve selection for, and outcome from TURP, in men with lower urinary tract symptoms (LUTS). Pressure/flow studies are currently recognised as the gold standard for the diagnosis of bladder outlet obstruction in men with lower urinary tract symptoms (LUTS). These do, however, come with a number of disadvantages; they are time consuming, invasive and expensive, and carry with them some morbidity for the patient.

A non-invasive technique to measure bladder pressure is being developed using a penile cuff inflated during the voiding cycle (1). We are currently undertaking a study to validate the method and to assess its role as a partial replacement for “invasive” pressure-flow studies, and to determine whether subsets of patients may be identified who are clearly obstructed or definitely not obstructed.

Methods
Male patients with LUTS were recruited from outpatients referred to our department. Each patient attended our flow clinic, performing 3 consecutive urinary flow rates. At a separate visit the patients underwent a cuff test in the absence of a urethral catheter, followed by catheterisation and conventional invasive PFS. A second cuff test was then performed with synchronous invasive pressure/flow measurement.

For the cuff test a specially designed penile cuff (Mediplus, UK), similar to a neonatal blood pressure cuff, was placed around the penis. Once voiding commenced the cuff was automatically inflated until flow was interrupted or a cuff pressure of 200cmH₂O was reached.

The cuff then deflates allowing voiding to continue. This cycle was repeated until the end of voiding, allowing several cycles per void (2).

Conventional PFS were performed using a 6fr double lumen, fluid filled, catheter (Mediplus, UK) connected to external pressure transducers zeroed at the level of the symphysis pubis. Men were classified according to the ICS nomogram as obstructed, equivocal and unobstructed (3).

Isovolumetric bladder pressure, the bladder pressure generated at interruption of flow, (pves,int) and cuff pressure at interruption of flow (p_cuff,int) were compared. For each patient, the highest p_cuff, int was plotted against the highest free flow rate Q_{max}.

Results
Data on the first 104 (mean age 66 years, range 42-86) of 120 patients who have been investigated with a simultaneous cuff test and invasive pressure/flow study yielded 173 separate inflation cycles suitable for analysis (Figure 1). The measured pcuff, int (range 40-190cmH₂O, mean 110cm H2O) is on average 3cmH₂O ± 24cmH₂O (SD) greater than pves, isv, with a correlation coefficient of 0.78. The test is simple and straightforward to perform and produced analysable data in 83% (86/104) of patients.

Of the 104 patients who underwent invasive pressure flow studies, free flow data was available on 81 (7 had flow studies performed elsewhere and results were not available, 16 are awaiting flow studies). Of these 81 all underwent
a free cuff test without a urethral catheter. 10 were unable to void due to inadequate bladder filling or voiding inhibition, 19 did not provide interpretable data and 52 provided a measurable $p_{cuff, int}$. Of these 52, 9 were classified as unobstructed, 13 as equivocal and 30 as obstructed according to their conventional pressure flow data. Highest $p_{cuff, int}$ was graphically compared to highest $Q_{\text{max}}$ obtained from free flow rate examination (Figure 2).

Conclusions
Previous experimental work has shown that there is good transmission of cuff pressure to the penile urethra(4) and that the urethra between bladder and cuff remains open during the test(5). Our results confirm that this technique does enable an estimation of isovolumetric bladder pressure and therefore gives information relating to bladder contractility. The overestimation seen is less than that seen in previously published data (1; 2).

From the graph of $p_{cuff, int}$ vs. $Q_{\text{max}}$ (Figure 2) it may be seen that all those patients lying to the upper left, with high $p_{cuff, int}$/low $Q_{\text{max}}$ are obstructed. Similarly there is a group to the lower right, none of whom are obstructed. In this way it may be possible to classify a proportion of patients into “definitely obstructed” and “definitely unobstructed/equivocal” using a combination of $p_{cuff, int}$ and free flow rate.

It seems likely that this technique could replace pressure-flow studies in two subsets of patients: those with low free flow rates and high non-invasively measured bladder pressure, and those with high flow and low non-invasively bladder pressure.

References
Assessment of Minimum Voiding Pressure Using a Penile Cuff

Blake C., Baldry L., Hassine A., Abrams P.,
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ICS 2003

Aim of Study
We are currently conducting a study evaluating the use of a penile cuff (similar to a neonatal blood pressure cuff) inflated during voiding, as a method of determining isovolumetric bladder pressure. The technique produces a graphical plot of cuff pressure against urinary flow rate. This enables us to determine the cuff pressure at which flow is interrupted, and it is suggested that this corresponds to isovolumetric bladder pressure.

Work in an experimental model, which included an area that could be pressurised to mimic an obstructive prostate, revealed that inflation of the cuff to a certain pressure, corresponding to a known external pressure exerted on the “prostatic urethra”, did not affect flow rate, which remained constant (Figure 1a: A to B). Above this pressure, however, the cuff starts to govern flow rate and flow falls to zero at the point where bladder pressure is exceeded (Figure 1a: B to C). These patterns of cuff pressure and flow are also seen in clinical recordings. The point at which flow rate starts to fall has been termed the “knee” pressure (Figure 1a: point B).

We have been investigating this “knee” pressure to determine its relationship with bladder pressures during voiding.

Figure 1. 2 traces taken from the experimental model both with a “bladder pressure” of 120cmH2O. a) “prostate pressure” was set at 80cmH2O; b) “prostate pressure” set at 110cmH2O.

Methods
Male patients with LUTS were recruited from outpatients referred to our department. A specially designed penile cuff (Mediplus, UK) was placed around the penis and inflated during voiding using the Newcastle technique.

Simultaneous intravesical pressures were recorded using a 6fr double lumen, fluid filled catheter (Mediplus, UK), connected to external pressure transducers zeroed at the level of the symphysis pubis, in accordance with the recommendations of the ICS standardisation committee.

Cuff pressure vs. flow rate traces were analysed for the presence of a knee pressure. This pressure was then compared to vesical pressure at the point at which cuff inflation commenced, i.e. vesical pressure under conditions of normal flow.

Results
104 men (mean age 66 years, range 42-86) underwent simultaneous cuff test and invasive pressure flow studies. 3 patients voided their urethral catheters and declined recatheterisation, one patient was unable to void and in one patient no data was recorded by the equipment. 73 of the remaining 99 patients (74%) produced cuff pressure/flow plots with an identifiable knee pressure. In total 107 separate inflation cycles were included in the analysis. The knee pressures identified have been graded as “definite” (59/107) and “probable” (48/107) knee pressures. Graphical plot of knee pressure ($p_{cuff\_knee}$) against vesical pressure at initiation of cuff inflation ($p_{ves,pre}$) is shown below.
Conclusions
Where there is an identifiable knee pressure, allowing for the height difference between the cuff and bladder, bladder pressure at the start of cuff inflation ($p_{ves, pre}$) is approximately equal to or greater than the knee pressure. We therefore believe that $p_{cuff, knee}$ reflects bladder pressure under flow conditions, giving a reliable minimum value of $p_{ves}$ during flow.
Non-Invasive Measurement of Bladder Pressure Does Mechanical Interruption of the Urinary Stream Inhibit Detrusor Contraction?

McIntosh SL, Griffiths CJ, Drinnan MJ, Robson WA, Ramsden PD, Pickard RS. Department of Urology, Freeman Hospital, Newcastle upon Tyne, United Kingdom. The Journal of Urology, Volume 169, Issue 3, Pages 1003-1006, March 2003

Purpose
As part of developing a non-invasive method to measure bladder pressure using an inflatable penile cuff, we tested the hypothesis that detrusor contraction is maintained without inhibition during the test.

Materials and Methods
Five healthy volunteers and 26 male patients with lower urinary tract symptoms underwent interruption of established urine flow by controlled inflation of a cuff placed around the penis with simultaneous invasive bladder pressure monitoring. After interruption of flow the cuff was rapidly deflated and voiding was allowed to resume. The bladder pressure was recorded before, during and after interruption of flow by cuff inflation.

Results
During flow interruption an isovolumetric increase in detrusor pressure was observed. When the cuff was deflated the detrusor pressure quickly returned to preinflation values and urine flow immediately resumed. Intra-abdominal pressure did not change during the cuff inflation cycle.

Conclusions
Mechanical interruption of urine flow by controlled inflation of a penile cuff during voiding does not inhibit detrusor contraction. This finding further validates our non-invasive technique of bladder pressure measurement and supports ongoing studies into its clinical usefulness.

Relationship of Abdominal Pressure and Body Mass Index in Men with LUTS


Aim
In the development of a non-invasive method for estimating isovolumetric intravesical pressure (pves,isv) we looked for a relationship between intra-abdominal pressure (pabd) and general build, expressed as body mass index (BMI) in men with lower urinary tract symptoms (LUTS).

Materials and Methods
In 100 consecutive male patients undergoing an invasive pressure flow study (PFS) the pabd was recorded continuously during filling and voiding. The magnitude at four set points was measured: before filling, after filling, during voiding and at the end of voiding. Patients’ weight (kg) and height (m) were also recorded and their BMI (weight/height(2)) was calculated.

Results
During the fill/void cycle pabd increased during bladder filling from 37 +/- 7 cm H2O (mean +/- SD) to 38 +/- 8 cm H2O, fell during voiding to 35 +/- 9 cm H2O before increasing to 36 +/- 8 cm H2O at the end of voiding. There was a clear relationship between the individual values of pabd and BMI (correlation co-efficient = 0.52) and to a lesser extent weight (correlation co-efficient = 0.42). The relationship with BMI was clarified by separating the subjects into groups of normal, overweight and obese.
Conclusions

A clear relationship between BMI and pabd was demonstrated, but because of the difficulties in quantifying it for an individual, it is impractical to apply an adjustment to non-invasive estimates of Pves, isv.
Non-Invasive Bladder Pressure: The Case for Using a Modified ICS Nomogram

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Aims of Study
The ICS nomogram classifies patients as obstructed (O), equivocal (E) or unobstructed (U) using maximum flow ($Q_{\text{max}}$) and detrusor pressure at maximum flow ($p_{\text{det,Qmax}}$) from an invasive pressure flow study (PFS) (1). The penile-cuff pressure required to interrupt flow ($p_{\text{cuff,int}}$) provides a non-invasive estimate of isovolumetric bladder pressure ($p_{\text{ves,int}}$) (2). This paper considers the expected relationship between $p_{\text{cuff,int}}$ (or $p_{\text{ves,int}}$) and $p_{\text{det,Qmax}}$ and the modification required to the ICS nomogram to produce a nomogram for the cuff test. Non-invasive data from 2 large urology departments were used to assess the modified nomogram.

Methods
On the ICS nomogram, the line separating obstructed from equivocal (O/E) line passes through 40 cm water at zero flow and has a slope of 2$x_{\text{max}}$. Previously reported results (see below) suggest two possible adjustments for non-invasive data: offset and slope.

Step 1 (Offset): The cuff test estimates bladder pressure ($p_{\text{ves}}$), which includes abdominal pressure and also a small component due to the height difference between the cuff and bladder. The mean (+ SD) abdominal pressure during voiding and height difference were measured in patients with lower urinary tract symptoms to estimate the correction required.

Step 2 (Slope): The non-invasive technique measures $p_{\text{ves},\text{int}}$, flow being zero at the time of measurement. $p_{\text{ves},\text{int}}$ is expected to be higher than $p_{\text{ves}}$ at full flow, by an amount dependent on the flow rate (Q) prior to interruption. The slope of the O/E line should be increased to allow for this. The pressure increase was plotted against pre-interruption flow rate in patients undergoing cuff test plus PFS in order to estimate the required correction.

Step 3 (Modified Nomogram): Using the results from steps 1 and 2, a modified nomogram was proposed.

Step 4 (Patient data): Data was collected using an identical non-invasive technique from 2 UK urology departments. Patients underwent a cuff test and, on a separate occasion, invasive PFS. From the cuff test, $p_{\text{cuff,int}}$ and $Q_{\text{max}}$ (excluding surges after cuff release) were estimated for each patient and plotted on the proposed nomogram. The symbol used indicated their classification from their separate invasive PFS.

Results
Step 1: The mean (+ SD) abdominal pressure during voiding for 76 patients was 35 (+9) cm water (3). With the measured height difference of 8.8 (+ 1.4) cm, the O/E line should be offset approximately 40 cm, giving an intercept of 80 cm water.

Step 2: Figure 1 illustrates the pressure rise to $p_{\text{ves},\text{int}}$ as a function of pre-interruption flow rate for 13 subjects (64 inflation cycles). There is variability between individuals, but the average pressure rise is approximately 2 times the flow rate (4).
**Step 3**: Figure 2 illustrates the development of the modified nomogram using the results from steps 1 and 2. The total slope after applying step 2 is 4xQ.

**Step 4**: Figure 3 illustrates the non-invasive data plotted on the modified nomogram for 57 and 86 patients from the two centres, with indication of their ICS classification from the separate invasive PFS (•=O, Δ=E, ~=U).

**Conclusions**
A rationale and supporting data have been provided for a modified ICS nomogram which could be used for non-invasive data recorded with the cuff interruption technique. The separation of patients classified invasively looks encouraging but further refinement may be required. The technique may provide useful, objective data intermediate between flow rate alone and full PFS for men with LUTS.

**References**
(3) Neurourol & Urodyn (In press)
Inter-Observable Agreement in the Estimation of Bladder Pressure Using a Penile Cuff

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Aims
Objective data are useful in quantifying a patient’s lower urinary tract symptoms (LUTS). We are investigating the use of an inflatable penile cuff to obstruct flow progressively during voiding, and thereby determine the pressure $p_{\text{cuff,int}}$ at which flow is interrupted. The aim of this study was to determine the agreement between experienced observers in their estimates of $p_{\text{cuff,int}}$.

Methods
We recorded 486 cuff inflation cycles during 142 voids from 42 subjects recruited from urology out-patient’s and prostate assessment clinics. Each inflation cycle was assessed independently by three experienced observers, a total of 1,458 ratings. According to our standard assessment procedure, the observers (i) indicated whether the inflation should be analyzed, (ii) estimated $p_{\text{cuff,int}}$ for those inflation cycles judged suitable for analysis, and (iii) discarded measurements that were clearly inconsistent with others from the same voiding cycle.

Results
Overall, 689 of the 1,458 ratings (45%) were excluded, with just 4% of all ratings discarded for inconsistency. For 385 of the 486 inflation cycles (79%) there was complete agreement that the cycle should or should not be analyzed. Thereafter, for the 262 inflation cycles analyzed by two or three observers, the overall SD error in measurements of $p_{\text{cuff,int}}$ was 4.6 cm H(2)O.

Conclusions
We conclude that there is good agreement between experienced observers in their interpretation of data from the cuff test. For practical purposes, there is no need for multiple observers in the clinical application of the cuff method.
Assessment of Prostatic Obstruction: A Cuff May Be Enough

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Aims
To investigate the use of an inflatable perile cuff to obstruct flow progressively during voiding in order to provide a non-invasive measure of bladder pressure.

Methods
In this study, we explain the observed relationship of flow rate with applied cuff pressure by analogy with a simple physical model. The model comprised a fixed-pressure reservoir (simulating the bladder), a collapsible tube around which a fixed pressure could be applied (simulating the prostatic urethra), connected by rigid conduit to a further collapsible tube around which pressure could be applied (simulating the penile urethra and cuff). Flow was progressively obstructed by incremental increase of pressure applied to the "penile urethra," with the experiment being repeated for a range of fixed pressures applied to the "prostatic urethra."

Results
The model reproduced the typical pressure/flow curves recorded during voiding by using penile cuff inflation in normal and obstructed men.

Conclusions
Our data led us to hypothesise that the relationship between cuff pressure and flow rate can be used to deduce bladder pressure during voiding, prostatic opening pressure, and urethral diameter at the flow-controlling zone, three indicators of lower urinary tract function. These measurements may add to the accuracy of diagnosis and quality of care for a large number of men with lower urinary tract symptoms.
Non-Invasive Measurement of Bladder Pressure by Controlled Inflation of a Penile Cuff

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Purpose
A non-invasive test providing reliable objective quantification of bladder pressure during the voiding cycle would make an important contribution to the management of lower urinary tract symptoms. We developed a new non-invasive test to measure bladder pressure in males based on controlled inflation of a penile cuff during voiding. We compared the new technique with simultaneous invasive bladder pressure measurement.

Materials and Methods
We evaluated 7 volunteers and 32 patients. A conventional pressure flow study was performed first. The bladder was refilled, a penile cuff was fitted and after voiding commenced the cuff was inflated in steps of 10 cm. water every 0.75 seconds until urine flow was interrupted. The cuff was rapidly deflated, allowing flow to resume, and the cycle was repeated until the end of voiding. The flow rate was graphed against cuff pressure for each interruption cycle to determine the pressure at which flow was interrupted. This pressure was compared with simultaneous invasive isovolumetric bladder pressure.

Results
Invasive and non-invasive pressure measurements agreed well. Average cuff pressure at interruption of flow exceeded mean simultaneous isovolumetric bladder pressure plus or minus standard deviation by 14.5 +/- 14.0 cm. water.

Conclusions
The new method provides non-invasive quantitative information on voiding bladder pressure in males. Further study is required to assess whether the technique can contribute to the management of lower urinary tract symptoms.
Non-Invasive Measurement of Bladder Pressure in the Assessment of Men with LUTS

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Abstract
The initial assessment of the cuff test is very encouraging and ongoing clinical study should allow an accurate evaluation of its clinical value. If it can be used to classify patients, or even if it is just allows assessment of bladder contractility, we feel it is a valuable and easily performed addition to pre-operative assessment of patients being considered for prostatic surgery. Knowledge of a patient’s detrusor performance does have implications for operative success, and faced with an increasing patient desire for knowledge of their condition, and accurate pre-operative counselling, the cuff test is a simple way to obtain another piece of relevant urodynamic information. We do not believe that the cuff will completely replace PFS, particularly for clarification of non-specific or unreliable histories (eg. young people, severe symptoms in the presence of normal flow rate and neurological disease), but if a form of PFS is considered to be desirable in all preoperative patients, a cuff test performed in the Prostate Assessment Clinic would remove the need for catheterisation in a significant proportion, and should result in better patient selection for invasive studies.
Reproducibility of non-invasive urodynamics, using the cuff-uroflow, for the diagnosis of bladder outlet obstruction in males

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Objective
To determine the repeatability of the parameters obtained from non-invasive urodynamics, using the cuff-uroflow, for the diagnosis of bladder outlet obstruction.

Materials and Methods
The study was carried out in a consecutive series of 34 males with functional urinary tract symptoms. The test-retest reproducibility of isometric pressure, flow in response to isovolumetric pressure and the energy transfer ratio obtained at two different times using the cuff-uroflow method was determined.

Results
Very good agreement for the flow in response to isovolumetric pressure measurement (intraclass correlation coefficient 0.96) and good agreement for the isovolumetric pressure measurement (intraclass correlation coefficient 0.87) and the energy transfer ratio (intraclass correlation coefficient 0.84) were demonstrated. The patients were classified into three groups according to the value of the energy transfer ratio, and it was found that there was very good agreement between the groups into which patients were classified as a result of the first and second measurements (kappa index 0.81).

Conclusions
The parameters obtained with the cuff-uroflow are reliable and the energy transfer ratio allows one to classify patients into reproducible groups.
Transmission of Penile Cuff Pressure to the Penile Urethra

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The Journal of Urology, Volume 166, Issue 6, Pages 2545-2549, December 2001

Purpose
We developed a non-invasive method to measure voiding bladder pressure by inflating a penile cuff to interrupt flow. We tested the underlying assumption that cuff pressure is transmitted to the penile urethra.

Materials and Methods
In 35 men we simultaneously recorded penile cuff and urethral pressure during 2 experimental protocols for 6 cuffs of various widths and manufactures. Initially a urethral pressure transducer was placed at the mid point of the cuff and urethral pressure was continuously recorded during cuff inflation. In experiment 2 cuff pressure was set at 120 cm. water and the urethral pressure profile was measured by withdrawing the urethral transducer through the cuff width.

Results
There was excellent agreement of cuff with urethral pressure over the range of 0 to 200 cm. water for cuffs 37 to 54 mm. wide. Narrower cuffs showed wider variation with less efficient transmission of cuff pressure to the urethral lumen. Similarly maximum pressure in the urethral pressure profile showed best agreement for cuffs 38 and 46 mm. wide. Wider cuffs produced higher and narrower cuffs produced lower transmitted pressure within the urethra. Cuff performance was also related to penile size. Results had good within-subject repeatability.

Conclusions
We demonstrated that pressure transmission from cuff to urethra is optimal at a cuff width of 40 to 50 mm. and recommended this width for other investigations of non-invasive bladder pressure measurement.
A New Method for Non-Invasive Measurement of Voiding Pressure? Assessment of Penile Cuff Occlusion

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Neurourology and Urodynamics, Volume 18, pages 256-257, 1999

Aim
To investigate a new non-invasive method for measuring bladder pressure during voiding using distal urethral occlusion achieved by step-wise inflation during voluntary voiding of a paediatric blood pressure cuff placed around the penile shaft. To report the results of a series of experiments in healthy volunteers designed to test the validity of the basic assumption of this technique, namely that cuff inflation pressure is equal to urethral pressure, in particular at the point of occlusion.

Methods
Four asymptomatic volunteers were studied. In each subject urethral pressure within the segment encircled by a paediatric blood pressure cuff was measured with a microtip transducer. For one subject, measurements were repeated using an air filled balloon. Penile cuffs of width 3.7, 4.6 and 5.4 cm were inflated in turn and urethral pressure recorded. The pressure transducer was placed at the midpoint of the cuff which was then inflated with 10 cm H₂O increments throughout the range 0-300 cm H₂O using a specially constructed apparatus. This procedure was repeated for each cuff size after displacing then repositioning the catheter. The mean urethral pressure recorded at each 10 cm H₂O increment of cuff inflation was then calculated and expressed graphically. For 3 of the subjects, for each cuff size, the transducer was withdrawn through the cuff region to give a profile measurement and the peak pressure measurement.

Results
The 3 graphs below show urethral pressure measured with the microtip transducer plotted against the cuff pressure in 10 cm H₂O increments for each of the 3 cuff sizes. For each pressure, the mean and standard deviation of 8 values are shown (4 subjects x 2 measurements each).

![Graphs showing urethral pressure measurements](image)

Above 50 cm H₂O, the balloon catheter (sensing length 1.5 cm) gave very similar results to the microtip transducer for the 5.4 cm cuff, but increasingly underestimated for the narrower cuffs. The peak pressures measured during the withdrawal were 127 ± 12, 120 ± 22 and 109 ± 14 cm H₂O (mean ± SD) respectively

Conclusions
It is concluded that pressure generated by stepwise inflation of a penile pressure cuff is a valid and reliable method of controlling intraurethral pressure of mid-cuff level. Of the cuff widths investigated, the wider cuffs (5.4, 4.6 cm) allow greater accuracy whilst the narrowest of the cuff investigated (3.7 cm) underestimates urethral pressure by
approximately 20% in the range of interest. These data encourage the use of incremental penile cuff inflation as a non-invasive method of measuring isovolumetric bladder pressure during voiding.

Penile Urethral Compression-Release Maneuver as a Non-invasive Screening Test for Diagnosing Prostatic Obstruction

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Abstract
The purpose of this study was to evaluate the feasibility of using a penile urethral compression and quick release maneuver during urination as a potential non-invasive clinical screening tool in the evaluation of patients with voiding dysfunction and the diagnosis of prostatic obstruction. The penile compression-release maneuver was performed in adult men with symptomatic voiding dysfunction and in asymptomatic normal men by compressing the penile urethra for 2–3 seconds after the initiation of flow and quickly releasing the compression. The penile compression-release index, calculated from the resulting flow rate surge (Q_{surge}) and the steady flow rate (Q_{surge}−Q_s/Q_s), was analyzed with respect to the type of voiding dysfunction. A comprehensive urodynamic study was performed in each patient to determine the presence and severity of prostatic obstruction and to measure detrusor contractility. The penile compression-release indices measured with this maneuver in patients with bladder outlet obstruction (183 ± 76%, n = 4, 43) or detrusor instability (157 ± 65%, n = 4, 13) were significantly greater than the index observed in non-obstructed patients with normal contractility (67 ± 37%, n = 4, 24) or in non-obstructed patients with impaired detrusor contractility (70 ± 32%, n = 4, 10). In asymptomatic younger men who had normal free flow rates (>15 mL/s), the penile compression-release index (55 ± 29%, n = 4, 20) was significantly less than that observed in patients with outlet obstruction or detrusor instability.

These findings suggest that the magnitude of the flow rate change generated after the penile compression-release maneuver depends on the magnitude of the isometric detrusor contraction developed during penile urethral compression and on the conduit status of the outlet. In patients determined to have poor urinary flow rates, this non-invasive maneuver has been able to differentiate prostatic obstruction associated with normal detrusor contractility from other causes of low urinary flow rates. Despite these encouraging trends, further studies in a larger cohort are required to determine its potential clinical utility as a screening tool for diagnosing prostatic obstruction.
Non-invasive quantitative method for measuring isovolumetric bladder pressure and urethral resistance in the male: I. Experimental validation of the theory.

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Abstract
Non-invasive measurement of intravesical pressure, impulsive flow rate, and localized urethral resistance is achieved by clamping the penis immediately above the glans with a pneumatic cuff and then instructing the patient to initiate voiding. The cuff is then deflated slowly until urinary flow of at least 1 ml/s is detected and is then released rapidly to permit unimpeded flow. Cuff pressure, voided volume, and flow rate are recorded as functions of time. From the resulting tracings it is possible to determine the isovolumetric bladder pressure, the impulsive flow rate, and the flow pattern specific to the test. We studied 53 male patients demonstrating that data thus obtained are reproducible and that the cuff pressure at the initiation of voiding does measure the bladder pressure at this moment. We then modeled the lower urinary tract by an analog electrical circuit which facilitated the analysis of the urodynamic data. This analysis suggests that it is possible to separate the effects of bladder dysfunction from the effects of urethral resistance and to localize the resistance to the proximal or distal urethra without invasive testing.