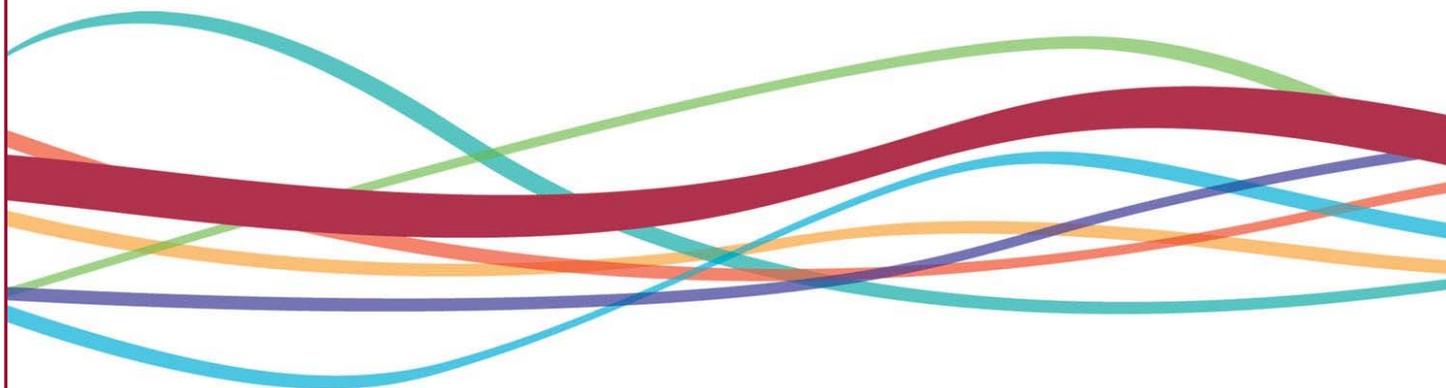


Evidence review

Mediplus CT3000 cuff machine for diagnosis of bladder outlet obstruction

CEP 07010

August 2007



Verdict

-  RECOMMENDED
-  SIGNIFICANT POTENTIAL
-  EVIDENCE INCONCLUSIVE
-  NOT RECOMMENDED

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The product

CT3000 cuff machine manufactured by Mediplus Ltd, UK.

Field of use

Bladder outlet obstruction (BOO) giving rise to lower urinary tract symptoms (LUTS) is a common problem for older men in the UK and effective diagnosis and treatment of BOO is extremely important.

Diagnosis based on symptoms and simple urinary flow rate measurement identifies only 70% of patients correctly (1). More accurate diagnosis is possible through an invasive urodynamics procedure, but some consider the expense and risks associated with the procedure outweigh its diagnostic accuracy, and consequently it is not routinely performed. The CT3000 is the most developed of several non invasive diagnostic techniques that offer better diagnostic accuracy than is achieved by flow rate measurement and symptomatic assessment. This review outlines the clinical usefulness of the Mediplus CT3000 cuff machine as an adjunct to current diagnostic methods, and also summarises evidence relating to some alternative non invasive methods.

Evidence reviewed

Reported clinical evidence on use of the CT3000 cuff method for non-invasive diagnosis of BOO in men was reviewed. Clinical validation studies of this innovative method are currently limited and have been conducted by the group of researchers who developed it (2,3).

CEP's verdict – **Significant potential**

The Mediplus CT3000 system offers greater accuracy in diagnosis of BOO than diagnosis based on flow rate measurement alone. Recent results (3) suggest its prediction of outcome from surgery rivals that offered by invasive urodynamic studies, though this has not been conclusively proven by this limited evidence. The invasive approach also provides additional information, and therefore remains the gold standard for the diagnosis of BOO in men. The existing evidence supports the manufacturer's claim that the CT3000 system has a useful role as an adjunct to current methods. Diagnoses based on CT3000 and urine flow measurement can be compared. Where there is agreement, surgery is indicated, and where there is disagreement or uncertainty, follow up invasive urodynamics are indicated. This approach may well reduce the number of ineffective surgical prostatectomies while also reducing the number of invasive studies, both of which carry associated costs and risks. Independent validating studies on the Mediplus CT3000 cuff system are recommended, and a multi-centre trial is reported to be underway (3). A detailed economic evaluation is also recommended, considering both the costs and consequences of the diagnostic accuracy of the CT3000 system.

General information

Bladder outlet obstruction (BOO) is a blockage at the base of the bladder that reduces or prevents the flow of urine. Enlargement of the prostate gland is one of the most common causes of BOO in men. Obstruction can lead to lower urinary tract symptoms (LUTS), including weak and/or frequent urination, the need to strain to pass urine and feeling that the bladder cannot be fully emptied. These symptoms are very common among older men, affecting the quality of life of about one third of men over 50 (4,5).

The Mediplus CT3000 system has been developed as a relatively simple non invasive method of assisting in the correct diagnosis of BOO in men.

Current diagnostic methods

A patient experiencing LUTS will typically report the symptoms to his GP and be referred to an outpatient urology clinic. At this clinic, symptoms are assessed and urine flow measurements are taken. If the maximum flow rate is low, a direct referral for corrective surgery may be made (6,7).

Surgical intervention by transurethral resection of the prostate (TURP) is a relatively common procedure – up to 56,000 are performed annually in the UK (8). Up to 30% of patients do not experience a reduction of symptoms following surgery however, and this may well be the result of patients being referred for surgery who do not actually have BOO (9,10). A low urine flow rate can result from poor bladder muscle contraction rather than outlet obstruction, and failure to distinguish these problems in diagnosis can result in inappropriate surgical intervention. Naturally all surgery is expensive and carries some risk for the patient, and it is important to avoid unnecessary procedures.

In addition to basic investigations into urine flow rate, a more sophisticated diagnostic approach is available, known as cystometry, pressure flow studies (PFS), or urodynamic studies (UDS). This is an invasive procedure involving catheterisation of the patient and the use of complex computational equipment to assess filling and emptying of the bladder by recording flow and pressure data. Good diagnostic accuracy for BOO is achieved, and a distinction can be made between bladder obstruction and weak bladder muscle contraction. However, the equipment is expensive, and the procedure is time consuming and requires a skilled operator. It is also uncomfortable for patients, and carries associated risks of urinary tract infections (UTI) and other complications due to its invasive nature (11-13).

Current practice leads to a high incidence of misdiagnosis and inappropriate referral for surgery (1,10). There is a clear role for a simple, easy-to-interpret, well tolerated, reliable technique that can be used in outpatient clinics to offer better diagnostic accuracy than flow rate measurements alone. Such an approach needs to distinguish between obstructed patients and those who have weak bladder muscle contractility to be of value. This could reduce the number of patients receiving inappropriate surgical intervention, and also reduce the number of patients needing referral to invasive UDS.

The potential role of CT3000

A number of non invasive diagnostic methods have been developed. None of them can reproduce the diagnostic accuracy of invasive UDS, which remains the 'gold standard' for the diagnosis of BOO. Their potential role is as an adjunct to UDS rather than a replacement for it.

This evidence review focuses on the CT3000 system. Of the non invasive methods described in the literature, the CT3000 system is at the most advanced stage of development towards possible widespread introduction to normal clinical practice within the UK healthcare system.

The Mediplus CT3000 system works in much the same way as blood pressure monitoring systems. Whereas blood pressure measurement uses a cuff on the arm and measures the inflation pressure needed to temporarily stop blood flow, with the CT3000 a cuff is placed around the penis before voiding urine (see figure 1). This is automatically inflated during the voiding process to stop urine flow, and then deflated again. The inflation/deflation cycle is repeated several times during a single emptying of the bladder and from this the cuff pressure needed to stop the flow of urine is determined. This provides a measure of the fluid pressure generated in the bladder which is used to diagnose voiding problems associated with BOO (which can be alleviated by prostate surgery), and to distinguish BOO from problems associated with a weak or under-active bladder muscle (for which prostate surgery will be ineffective).

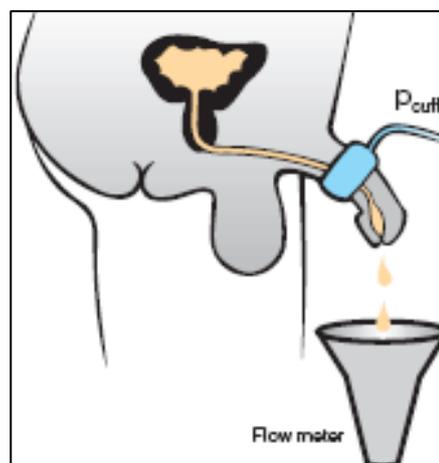


Figure 1: Measuring bladder pressure and urine flow

Developers of the CT3000 acknowledge that its role is not to replace conventional urodynamic studies. It has been proposed that where the diagnosis based on CT3000 agrees with that based on simple flow rate measurement, the case is sufficiently strong to recommend surgery. When however, the CT3000 diagnosis is uncertain or does not match the diagnosis found by flow rate analysis (31% - 45% of cases [2,3]), follow up invasive urodynamic studies should be used to give the best available diagnosis. A follow up invasive approach may also be of value for those diagnosed as *not* obstructed by the CT3000 method - a recent study showed 56% of this group also had a positive outcome from surgery (3).

The CT3000 system has significant potential to meet the aim of reducing ineffective surgery while also reducing the reliance on expensive and unpopular invasive studies. The reported surgical success rate is 87% when using the proposed diagnostic approach (3).

There are some limitations to the published evidence available for the CT3000 system and other non invasive diagnostic methods, and these are discussed in separate sections of this report, including a discussion of the evidence relating to economic issues. Publications relating to all of the non invasive methods covered in this evidence review are summarised in a detailed table within this report. Concluding remarks relating to the potential usefulness of the CT3000 system are made at the end of this report.

Studies on the use of non-invasive techniques for the diagnosis of bladder outlet obstruction in men were sought using Medline, Embase and Cochrane Library databases. The search was conducted by combining Mesh terms and free-text terms - use of Mesh terms alone was found to limit the search.

The “PICO” strategy for healthcare literature searching was used with the following keywords:

P (Patient or problem): free-text: bladder, BOO, bladder outlet obstruction, pressure and obstruction. Mesh terms: bladder neck-obstruction, urethral obstruction, bladder diseases.

I (intervention): noninvasive, non-invasive, urodynamics, nonurodynamics, cuff, condom catheter, uroflowmetry, Doppler urodynamics.

C (comparative technique): where possible, diagnostic accuracy was assessed by comparison with invasive methods. The terms used were: “gold standard”, pressure flow studies, PFS, UDS, urodynamics studies.

O (Outcome): Diagnosis (and derivatives).

The terms from each category were combined with “OR” and the different categories were combined with “AND” to ensure the relevancy of the articles. The “comparative technique” category was subsequently excluded from the search strategy, as this was found to limit the search excessively.

In Medline and Embase, the search was limited to papers published in English and relating to male humans.

All selected papers were grouped according to the methods of diagnosis of bladder outlet obstruction. Detailed analysis was conducted for papers relating to the cuff method (CT3000), developed by scientists from the Freeman Hospital, Newcastle-Upon-Tyne. Additional analysis was made for papers in which the reported model accuracy in diagnosis of BOO was compared to results from invasive urodynamic studies.

Economic issues relating to use of the cuff machine CT3000 are also discussed.

The studies included in this evidence review have all been published in peer reviewed journals.

Some of the non-invasive methods offer promising results in terms of diagnostic accuracy. A small number of studies have been conducted which successfully validate the results of initial findings for the CT3000 system (2,3). These follow up studies were, like the initial studies, conducted by the institutions that developed the method.

The condom catheter method (table 1) has also been validated in a longitudinal study with a large number of patients (N=730) (14). This too was conducted by the scientists who developed the method.

None of the other non invasive methods (table 1) has been validated by follow up studies conducted by institutions independent of those that developed the method. While this is not a negative judgement of the quality of the existing research, independent validation remains an important step in confirming the promising results published to date.

The majority of publications on the CT3000 system report development and improvement of the method, rather than validation of it. Examples include: optimisation of cuff inflation characteristics (12), estimation of the optimal cuff size and material to allow an accurate transmission of the cuff pressure to penile urethra (7), verification of the method's reliability in measuring isovolumetric pressure (12,15), possible extension of the method to measure minimum cross-sectional area of the urethra (16), and data analysis and interpretation (2,17,18). Only two papers reports clinical validation of the method per se (2,3).

The CT3000 cuff method cannot be used with all patients. Patients with no recovery in flow rate after cuff deflation, an erratic flow trace, continued urination above maximum inflation pressure, or voided volume less than 150 ml were excluded from the cuff test as there was ambiguity with interpretation of the data. This results in relatively high exclusion rates from the studies, ranging between 23% (7) and 46% (2).

The method that uses the concentration of transforming growth factor Beta-1 (TGF- β 1) for diagnosis (table 1) is not yet fully developed; only a single human study was uncovered in the literature. However, it does report significant correlation between BOO and TGF- β 1.

Limitations to economic analysis

Insufficient data is available for a detailed analysis of the economic impact of the CT3000 system. The potential financial benefits of the CT3000 are based on improvements in the success rate of prostatectomies and a reduction in unnecessary invasive urodynamic procedures.

Savings based on unsuccessful prostatectomies and unnecessary invasive studies are only two aspects of the cost associated with the diagnostic accuracy of BOO. Other healthcare costs, including equipment and consumables and resource use, would be required to produce a more comprehensive economic analysis. The additional cost of specialised equipment associated with introducing the cuff method is estimated to be £5000 per unit.

A cost analysis should calculate the cost per patient for diagnosis and treatment, accounting for the test accuracy through costs associated with successful treatments, and resource use associated with misdiagnosis and late treatment. This would include all resource use associated with the patient care pathway and include the staff costs, costs associated with complications, medication costs, consumables and equipment costs. This is of course challenging as costs associated with diagnosis and treatment of men with BOO can vary across the UK so any specific financial benefits cannot be published in a report such as this.

A full economic evaluation should consider the costs and consequences of the diagnostic accuracy of the CT3000 system, compared with the both the invasive approach, and the alternative non-invasive methods. The CT3000 could lead to a reduction in the number of unnecessary prostatectomies and a reduction in the number of invasive urodynamic studies performed on patients. However, the extent of this reduction is not entirely transparent from the published data (2,3).

Table 1. Summary of studies reviewed

Ref	Methods	Claims/model diagnostic accuracy	Model limitations	Notes
Non-invasive measurement of isovolumetric bladder pressure				
Griffiths et al, 2005 (2,3,7,12, 17)	<p>Cuff penile compression method (after voiding started)</p> <p>Cuff around penis automatically inflated after initiating voiding, until flow ceased, to measure isovolumetric pressure. Once flow is stopped the cuff automatically and rapidly deflates to allow voiding to resume. Several cycles of inflation and deflation performed during each void.</p> <p>Max. cuff pressure and max flow rate used for analysis.</p> <p>BOOI bladder outlet obstruction index developed.</p> <p>BOOI >40 indicates obstruction.</p> <p>Flow rate Q<10ml/s used as another diagnostic parameter.</p>	<p>For BOOI >40 and</p> <p>Q<10ml/s</p> <p>Sensitivity = 70%</p> <p>Specificity = 96%</p> <p>PPV = 89%</p> <p>NPV = 86%</p>	<p>High failure rate was reported: 23% (7) and 46% (2) due to:</p> <ul style="list-style-type: none"> • no recovery of flow after cuff deflation • erratic flow trace • continued flow above the inflation limit of 200 cmH₂O; • voided volume less than 150 ml. <p>Size of the cuff and its fixation method affect accuracy of the measured isovolumetric pressure.</p> <p>Straining can result in isovolumetric pressure reading being high.</p> <p>Adverse events (incidence = 2%)</p> <ul style="list-style-type: none"> • self limiting urethral bleeding • pain 	<p>144 patients in one study (2), 193 patients in another (3).</p> <p>Intravesical pressure increases under isovolumetric conditions.</p> <p>Isovolumetric pressure, flow rate and voided volume can be measured simultaneously for immediate analysis.</p> <p>Flow rate patterns can also be analysed.</p> <p>Excellent patient acceptability reported – 80% preferred cuff method to UDS.</p> <p>Good repeatability (for patients voiding more than 150 ml).</p>
McRae et al, 1995, (19) and Gleason et al, 1997 (20)	<p>Cuff penile compression method (before voiding initiated)</p> <p>Cuff used to occlude penile urethra before voiding; voiding was against the occluded urethra and pressure was gradually released on fluid entering urethra. Pressure recorded at flow initiation. Patient controls deflation of the cuff. Isovolumetric pressure and flow rate patterns analysed and compared for obstructed and non-obstructed patients.</p> <p>Energy transfer ratio (R) derived</p> <p>R > 3 obstructed</p> <p>1 < R < 3 equivocal</p> <p>R < 1 non-obstructed</p>	<p>For R>3</p> <p>Sensitivity = 61 %</p> <p>Specificity = 100%</p> <p>PPV = 100%</p> <p>NPV = 39%</p>	<p>Small number of patients in the study (N=23).</p> <p>Premature cuff release could result in wrong estimation of the pressure.</p> <p>Some patients were unable to initiate voiding against occlusion (21).</p> <p>Good patient understanding and cooperation required.</p>	<p>23 patients in the study.</p> <p>Good reproducibility of the measured isovolumetric pressure was reported.</p>

Ref	Methods	Claims/model diagnostic accuracy	Model limitations	Notes
Pel et al, 2002, (22)	<p>Condom catheter method.</p> <p>Condom catheter with two outlets, one attached to pressure transducer and the other free to allow urine flow. Pressure required to occlude the free outlet and stop flow is measured. Maximum pressure in the condom from multiple interruption cycles is taken as an isovolumetric pressure (Pmax). Maximum flow rate (Qmax) is measured from free flow. These two parameters are used for diagnosis.</p> <p>Diagnosis based on flow rate alone: Q <4.5 ml/s obstruction 4.5 < Q < 13.8 equivocal Q >13.8 ml/s no obstruction</p>	<p>Obstructed and equivocal patients considered against non-obstructed patients:</p> <p>Sensitivity = 62 % Specificity = 90% PPV = 94 % NPV = 47%</p> <p>Obstructed patients considered against non-obstructed and equivocal patients:</p> <p>Sensitivity = 64% Specificity = 80% PPV = 67 % NPV = 77%</p>	<p>1. Failure rate 20-25% due to:</p> <ul style="list-style-type: none"> • straining • condom leakage • low flow rate • inability to void in the presence of investigator • equipment problems • 16% of patients reported pain at interruption of flow (23). <p>Interruption of flow should be only done when steady state is reached – difficult to judge this.</p> <p>Method is not applicable for Q <5.4 ml/s.</p> <p>Elastic properties of condom can affect measurement accuracy.</p> <p>One case of urine retention and one case of bacterial infection after trial reported (14).</p>	<p>56 patients in the study.</p> <p>Grouping the data in different ways affects the reported diagnostic accuracy of the model.</p> <p>No significant pressure differences reported between obstructed and equivocal cases, but significant difference b/n obstructed and non-obstructed isovolumetric pressures.</p> <p>Large scale 5 year-longitudinal study reported good reproducibility (N=730) (14).</p> <p>Patient acceptance not reported.</p>
Sullivan et al, 2000 (21)	<p>Manual penile compression-release manoeuvre.</p> <p>Flow rate patterns and magnitude of flow rate change during penile compression–release manoeuvre were analysed. Patients with low flow rates were separated into obstructed and detrusor under-activity by the relationship between surge flow rate Q(surge) and quasi steady flow rate Q(s). Penile compression release index (PCR) derived from these flow rates.</p>	<p>For PCR=100%</p> <p>Sensitivity = 91 % Specificity = 70% PPV = 74 % NPV = 89%</p> <p>Note: these data were not verified as actual numbers were not given in the paper.</p>	<p>Good patient cooperation is required</p> <p>6% failure due to:</p> <ul style="list-style-type: none"> • inability to follow the instructions, • inadequate compression of urethra <p>some discomfort during manoeuvre was reported</p> <p>PCR cannot differentiate between obstruction and detrusor hypo contractility.</p>	<p>PCR of obstructed patients was significantly higher than PCR of non-obstructed patients.</p> <p>Isovolumetric pressure not measured in this study but detrusor contractility was assessed qualitatively.</p>

Ref	Methods	Claims/model diagnostic accuracy	Model limitations	Notes
Combined parameters models				
Rosier et al, 1996 (24)	<i>Parameters measured:</i> prostate volume, max. urinary flow rate, post-void residual volume, voided volume. <i>Measured by:</i> transrectal and abdominal ultrasound, free uroflowmetry. Parameters combined to give prostate score (R).	For R>11 Sensitivity = 57% Specificity = 64% PPV = 72% NPV = 48%	Reported results are not better than from free uroflowmetry alone.	871 patients in the study. Lowering the threshold increases model sensitivity but lowers specificity.
van Venrooij and Boon, 1996 (25)	<i>Parameters measured:</i> prostate volume, max. urinary flow rate, relative residual volume (RRV) <i>Measured by:</i> transrectal ultrasound free uroflowmetry, abdominal ultrasound. Bladder outlet obstruction index (ψ) derived from the measured parameters.	for $\psi = -2$ Sensitivity = 60% Specificity = 76 % PPV = 90 % NPV = 34 % For $\psi = 13$ PPV = 96% (no other data were given)	Analysis sensitive to the method of correlating the parameters.	196 patients in the study.
Ockim et al, 2001, (26)	<i>Parameters measured:</i> prostate volume, max. urinary flow rate, post-void residual volume, voided volume. <i>Measured by:</i> transrectal ultrasound, free uroflowmetry, abdominal ultrasound. Multiple linear regression analyses to determine coefficients for bladder outlet obstruction index (BOOI). BOOI>40 indicates obstruction	For BOOI>40 Sensitivity = 86% Specificity = 93% PPV = 92% NPV = 89%	Sensitivity and specificity depend on the cut-off value for regression models. Linear regression analysis is not sensitive to non-linear relationship between variables.	384 patients in the study. Post-void residual volume and voided volume were excluded from the final equation (small contribution to the model). Final BOO index is based on 2 parameters – flow rate and prostate volume
Kuo, 1999 (6)	<i>Parameters measured:</i> prostate volume, max. urinary flow rate, flow patterns, voided volume, post-void residual volume, transition zone index (TZI) prostate configuration. <i>Measured by:</i> transrectal ultrasound, free uroflowmetry, abdominal ultrasound. Data correlated with conventional urodynamics data to determine sensitivity of each parameter and assign a score. Total score then used to indicate obstruction.	Score >3 Sensitivity = 87% Specificity = 61% PPV = 81% NPV = 71 % Score >=5 Sensitivity = 98% Specificity = 38% PPV = 75 % NPV = 91%	Low specificity of the model results in fewer patients being treated and more patients undergoing further UDS for definite diagnosis.	324 patients in the study. Including data on flow pattern+prostate configuration improves specificity but not sensitivity, e.g. up to 61% for (R>3). Additional parameters used by this model: flow patterns, transitional zone index of prostate, prostate configuration.

Ref	Methods	Claims/model diagnostic accuracy	Model limitations	Notes
Sonke, et al, 2000, (27)	Parameters measured: prostate volume, max. urinary flow rate, post-void residual volume. Associations between parameters derived using an artificial neural network (ANN).	Sensitivity = 71% Specificity = 69% PPV = 65 % NPV = 75%	1. ANN results were not better than from linear regression model. 2. Associated difficulty in constructing and using the model.	1903 patients in the study.
Bladder wall thickness (measured by ultrasound)				
Manieri et al, 1998, (11)	Measurement of bladder wall thickness by suprapubic ultrasound at 150 ml filled bladder volume for all patients	For bladder wall thickness ≥ 5 mm Sensitivity = 53% Specificity = 97% PPV = 88 % NPV = 63 %	Detrusor wall thickness decreases continuously while the bladder fills to 50% of its capacity and afterwards stays unchanged (28). This has not been taken into account in this study as all patients had their bladder filled with 150 ml.	170 patients in the study.
Oelke et al, 2002, (28)	Measurement of detrusor wall thickness by suprapubic with full bladder.	For detrusor wall thickness ≥ 2 mm Sensitivity = 76% Specificity = 92% PPV = 89% NPV = 81%	Abnormal derivation of sensitivity, specificity, PPV and NPV.	70 patients in the study.
Kessler, et al, 2006, (29)	Measurement of detrusor wall thickness by suprapubic ultrasound positioned horizontally with bladder more than half full.	For detrusor wall thickness ≥ 1.5 mm Sensitivity= 100% Specificity = 15 % PPV = 64 % NPV = 100 % For detrusor wall thickness ≥ 2.9 Sensitivity = 43% Specificity= 100% PPV = 100 % NPV = 54 %	Predictive accuracy depends on the chosen cut off value for detrusor wall thickness.	102 patients in the study. Weak to medium correlation between detrusor wall thickness and UDS parameters.
Kojima et al, 1997, (30)	Bladder weight estimated by combining data from the ultrasonic measurement of bladder wall thickness and intravesical volume, assuming a spherical bladder.	For cut off weight value = 35g, "diagnostic accuracy" reported = 86%	Sensitivity, specificity, PPV and NPV of the model are not reported. A spherical bladder may not be a valid assumption.	65 patients in the study.

Ref	Methods	Claims/model diagnostic accuracy	Model limitations	Notes
Intravesical prostate protrusion (IPP) measured by ultrasound				
Chia et al, 2005 (31), Nose et al, 2005 (32)	Vertical distance from the tip of protrusion to the circumference of the bladder at the base of the prostate gland was measured using pencil-type ultrasound electroprobe Obstruction grading IPP < 5 unobstructed 5<IPP<10 equivocal IPP>10 obstruction	For length of protrusion >=10mm "diagnostic accuracy" reported 90%.	Sensitivity, specificity, PPV and NPV of the model are not reported. Quantification of IPP length for bladder volume was not performed.	30 patients in the study.
Urine flow velocity (Doppler urodynamics)				
Ding et al, 2000 (33) Nose et al, 2005 (32)	Flow velocity measured in the distal prostatic urethra and membranous urethra by ultrasound image-directed colour Doppler system operated by robotic manipulator	For velocity ratio >1.6 PPV=100% sensitivity, specificity and NPV not reported.	Specialised, expensive equipment is required. Measurement conducted with patients urinating in a sitting position. Difficulty with locating images affects accuracy and reproducibility of measurements (34).	31 patients in the study.

Glossary

In the summary table above, several specific urological and statistical terms and abbreviations are used. The meanings of these terms are defined here to aid understanding:

AUA score	The American Urological Association symptom index
Bladder wall thickness	Thickness of bladder wall including detrusor muscle and other tissues
BOO	Bladder Outlet Obstruction
Detrusor	The muscle of the urinary bladder wall

Isovolumetric bladder pressure The pressure generated by contraction of the bladder against a closed outlet, i.e. pressure within the bladder when flow is completely stopped

LUTS Lower Urinary Tract Symptoms

PCR Penile Compression/Release

Q_{surge} Surge flow rate

Q_{ss} Steady state flow rate

Urethral sphincter The muscular mechanism that controls the retention and release of urine from the bladder

Urodynamics (UDS) A diagnostic procedure, including invasive measurements of bladder pressure and abdominal pressure, urine flow rates during voiding, and muscle activity

UTI Urinary Tract Infection

Statistical terms:

Sensitivity The number of patients identified by the test as having BOO divided by the total number of patients within the cohort who genuinely have BOO

Specificity The number of patients identified by the test as not having BOO divided by the total number of patients within the cohort who genuinely do not have BOO

PPV (Positive Predictive Value) The proportion of patients identified by the test as having BOO who actually have BOO

NPV (Negative Predictive Value) The proportion of patients identified by the test as not having BOO who actually do not have BOO

Invasive urodynamic studies (UDS) offer the best diagnostic accuracy for BOO, but the expense and inconvenience of the method reduce its usefulness and there is clear value in a simple non invasive method to act as an adjunct to conventional approaches.

The cuff method offered by the Mediplus CT3000 system has been reported to be easy to perform, rapid, inexpensive (the cost of a disposable cuff is £5.80), and is preferred over invasive urodynamics by 80% of patients (7).

A relatively high proportion of patients (89%) diagnosed as having BOO by the cuff method were confirmed by urodynamics studies to have bladder outlet obstruction (2). Also, when using CT3000 to make a referral for surgery, a high proportion (87%) of patients had a good outcome from the TURP procedure (3). This ability to predict surgical outcome is equivalent to that offered by invasive urodynamic studies, though it remains to be proven whether this finding can be generalised beyond the population of that particular study.

There is an argument that use of the CT3000 system is not advantageous to patients who are diagnosed as 'not obstructed' by the method (19% in one study), since a significant number will in-fact have symptoms which may be improved through surgery (3). Further refinement of the proposed diagnostic approach may be indicated to provide better follow up for this group.

The degree of accuracy offered by the Mediplus CT3000 system, in two clinical trials (144 and 193 patients), is greater than the accuracy achieved by flow rate measurement and symptomatic assessment (2,3). The cuff method also provides clinicians with an estimated value of isovolumetric bladder pressure - an important diagnostic parameter which is currently only measured by invasive techniques.

Based on these promising results, reported in peer-reviewed publications, the evidence confirms that the Mediplus CT3000 system shows significant potential for use in outpatient urology clinics. Such use may reduce the proportion of ineffective surgical interventions and also reduce (but not eliminate) the requirement for invasive urodynamic studies.

Studies on the CT3000 cuff machine published to date are primarily from the institutions involved in the method design. The majority of papers report development and improvement of the method, rather than validation of it.

It is recommended that independent studies validating the effectiveness of the method would add weight to the current evidence. A multi-centre trial of the CT3000 system is reported to be underway (3). A detailed economic analysis of the costs and consequences of introducing the CT3000 system to clinical practice would also be of value. Such an economic analysis should be based on a comparison between current clinical practice and the expected practice when using the CT3000 system as an adjunct. Ideally, consideration of the possible alternative non invasive diagnostic techniques should also be included in the economic analysis.

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Mediplus CT3000 cuff machine for diagnosis of bladder outlet obstruction

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