

# Non-invasive urodynamics predicts outcome prior to surgery for prostatic obstruction

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## Objective

- To assess whether the penile cuff non-invasive urodynamic test serves as an effective diagnostic tool for predicting outcomes prior to disobstructive surgery for men presenting with voiding lower urinary tract symptoms.
- Patients with proven urodynamic obstruction do better after surgery. The current gold standard, invasive pressure-flow studies, imposes cost, resource demand, discomfort and inconvenience to patients.

## Patients and Methods

- Patients undergoing surgery for prostatic obstruction at Palmerston North Hospital had pre-operative non-invasive urodynamics and completed an International Prostate Symptom Score (IPSS). Catheterised patients were excluded.
- Two months post-operatively they completed a further IPSS score.
- An improvement of seven or greater was defined as a clinically successful outcome.
- Results were compared with the outcome predicted by the nomogram supplied with the urodynamic device.

## Results

- Data was obtained for 62 patients with mean age 70 years (range 49 to 86 years; SD 9 years). Follow-up was complete for all patients.

- Thirty-eight patients underwent transurethral resection and 24 holmium laser enucleation of the prostate. Mean IPSS score was 21 (range 5 to 35; SD 6) pre-operatively and 11 (range 1 to 31; SD 9) post-operatively.
- Thirty-five patients were predicted obstructed and 27 not obstructed.
- 94% of those predicted obstructed had a successful outcome ( $p < 0.01$ ).
- 70% predicted as not obstructed did not have a successful outcome after surgery ( $p < 0.01$ ).

## Conclusion

- The penile cuff test is an exciting adjunct in the decision to proceed to surgery for prostatic obstruction.
- Patients predicted to be obstructed have an excellent likelihood of a good surgical outcome, yet 30% of those shown not to be obstructed will still do well.
- Whilst numbers in our study are small, outcomes compare favourably with published results on invasive urodynamic methods.

## Keywords

prostatic hyperplasia, urodynamics, urinary bladder neck obstruction, urethral obstruction, transurethral resection of prostate

## Introduction

Lower urinary tract symptoms in men are one of the most common reasons for referral from primary care to the urology outpatient clinic [1]. The clinical question that must be addressed prior to initiating treatment is whether the symptoms can be attributed to bladder outlet obstruction or whether they are secondary to a poorly contractile detrusor muscle [2–4]. Men who do not receive adequate symptomatic benefit from the medical therapies are likely to be offered disobstructive prostatic surgery [5] – in our institution, by way of transurethral resection of the prostate (TURP) or Holmium laser enucleation of the prostate (HoLEP) [6,7]. Conversely, men whose symptom-complex is due to a poorly functioning bladder will not respond to these treatments and therefore

potentially undergo unnecessary surgery, exposing them to the usual surgical risks as well as the specific risks of prostate surgery, such as incontinence and impotence.

The current gold standard in pre-operative diagnosis is invasive urodynamic studies [8–11]. This investigation, which measures intra-vesical pressure whilst the patient voids and generates a pressure-flow curve, has a number of drawbacks. It requires placement of two urethral catheters (a filling catheter and a vesical pressure line) and a rectal pressure line. It is invasive, inconvenient, time consuming, uncomfortable for patients and risks introducing infection. It also places an increased cost and resource demand on hospital urological services [12]. Indeed, good access to invasive urodynamic studies in many hospitals is limited. Furthermore, many

urologists believe its sensitivity for excluding obstruction is poor enough (between 60 and 80%) [13] not to justify its routine use in patients presenting with voiding-type lower urinary tract symptoms.

The hunt is therefore on for an alternative test that can predict bladder outlet obstruction in a more convenient, less invasive manner. This study prospectively analyses a device known as the penile cuff test. First designed in Newcastle-upon-Tyne, United Kingdom, in 2007, this is the first study of this device, to our knowledge, to be published outside the original unit [13].

A small inflatable cuff, similar to a blood pressure cuff, is placed around the penile shaft whilst the patient voids into a flow machine. This cuff gradually inflates and deflates, obstructing flow, several times until the patient's bladder is empty. The pressure at which flow ceases, known as the cuff pressure, is the urethral closing pressure which is a surrogate for intra-vesical pressure – the measurement usually obtained from formal invasive urodynamic testing [14–16]. This cuff pressure can then be read off a nomogram, validated for use with this device, and the patient categorised as obstructed or not obstructed. This test can be performed in the outpatient clinic similar to a routine flow test and is fast, simple and inexpensive. It is non-invasive and does not carry a risk of infection.

Our study aims to assess the predictive value of the cuff test prior to surgery for prostatic obstruction using the clinically relevant outcome of symptomatic improvement in a practical, clinically relevant manner. Whilst the use of flow rates provides an objective assessment, ultimately the success of disobstructive surgery is judged by the patient's satisfaction at follow-up and our study uses the patient's own subjective assessment as our primary outcome measure.

## Patients and Methods

Patients referred from primary care with voiding-type lower urinary tract symptoms and planned to undergo surgery for prostatic obstruction at Palmerston North Hospital, either TURP or HoLEP, were included in this study. Patients in urinary retention with a urethral or suprapubic catheter in situ were excluded from the study as their inability to void makes urodynamic assessment impossible. Ethical approval was obtained from the Multi-region Ethics Committee.

Patients completed an International Prostate Symptom Score (IPSS) questionnaire at the time of surgical booking, or immediately prior to surgery. This is a validated tool for the evaluation of lower urinary tract symptoms in men [12]. These men performed a cuff test prior to coming forward for surgery. A Urology Nurse Specialist at the Urology Outpatient Clinic performed the cuff test at the time of surgical booking or at the time of pre-anaesthetic assessment

prior to undergoing surgery. The cuff device was calibrated at the start of each case and was successfully performed in all patients.

Two surgeons at our institution perform TURP and three perform HoLEP. Patients underwent the operation that was the surgical preference of who assessed them in the outpatient clinic and not based on any clinical or surgical parameters.

At least two months following surgery, an IPSS questionnaire was posted to the patient. Patients who did not respond were posted a further questionnaire. If still no response was received they were asked to complete a questionnaire in person at the post-surgical follow-up visit with a Urology Nurse Specialist.

A data sheet was collected on each patient containing age, pre- and post-operative IPSS score and quality of life (QOL) score, the pre-operative maximum flow rate, voided volume and residual volume, type of surgery (TURP or HoLEP), surgeon, surgeon category (consultant or registrar) weight of prostate resected, presence of prostate cancer in the resected prostate, cuff test maximum flow rate and cuff test maximum cuff pressure.

The investigator, who was blinded to the pre- and post-operative IPSS score, used the cuff test flow and pressure results for the patient to obtain a prediction from the modified International Continence Society (ICS) nomogram, and categorised the patient as obstructed or not obstructed (see Appendix 1). The nomogram, which is specifically modified for the penile cuff measurement, was interpreted in a standard fashion using the guidelines supplied by the manufacturer.

An improvement in IPSS score post-operatively of seven or greater was defined as a clinically successful outcome. This is a validated outcome measure for this purpose [17]. The data was input into an Excel spread sheet and statistical analysis performed using GraphPad, calculating sensitivity, specificity, positive predictive value and negative predictive value. A two-tailed Fisher's exact test with an alpha value of 5% was used to determine statistical significance using a 2x2 contingency table for categorical data.

## Results

A total of 62 patients were enrolled, between February and November 2011. Follow-up was complete and full data was available in all patients. Thirty-eight patients underwent TURP and 24 patients underwent HoLEP. A urology registrar performed 19 operations and 43 were performed by one of four consultant urologists. Mean age, length of follow-up, pre-operative IPSS score, QOL score, maximum flow rate, voided volume and residual volume are shown in Table 1.

The mean weight resected was 26 g (range 1 to 103 g; SD 24 g) and prostate cancer was present in 13 specimens (21%).

**Table 1** Patient demographics and pre-operative IPSS and flow data.

	Mean	Range	Standard deviation
Age (years)	70	49–86	9
Follow-up (days)	82	46–139	18
Pre-op IPSS	21	5–35	6
QOL	5	2–6	1
Maximum flow (mL/s)	10	2–28	5
Voided volume (mL)	254	4–605	147
Residual volume (mL)	207	0–1000	183

**Table 2** Post-operative IPSS and cuff test data.

	Mean	Range	Standard deviation
Post-op IPSS	11	1–31	9
QOL	2	0–6	2
Difference in IPSS	10	–10–32	9
Difference in QOL	2	–4–6	2
Cuff test maximum flow (mL/s)	9	2–20	4
Maximum cuff pressure (cmH <sub>2</sub> O)	127	30–190	42

**Table 3** Clinical outcome and modified ICS nomogram prediction.

	Good outcome	Poor outcome	Total
Obstructed	33	2	35
Not obstructed	8	19	27
Total	41	21	62

Post-operative mean IPSS, QOL, difference in IPSS, difference in QOL, cuff test maximum flow and maximum cuff pressure are shown in Table 2.

Table 3 presents the study results: the predictive category based on the modified ICS nomogram (obstructed or not obstructed) and the clinical outcome based on IPSS score (a good clinical outcome defined as an improvement in IPSS score of seven or greater).

Of the 41 patients defined as having a good clinical outcome, 33 had been predicted obstructed, giving a sensitivity of 80.5% ( $p < 0.01$ ). Of the 21 patients defined as having a poor clinical outcome, 19 had been predicted as not obstructed, giving a specificity of 90.5% ( $p < 0.01$ ).

Of the 35 patients predicted obstructed, 33 were defined as having a good clinical outcome, giving a positive predictive value of 94.3%. Of the 27 patients who were predicted as not obstructed, 19 were defined as having a poor clinical outcome, giving a negative predictive value of 70.4%.

## Discussion

Our data shows that the cuff test is a promising and useful adjunct in the decision to proceed to surgery in men presenting with voiding-type lower urinary tract symptoms.

The positive predictive value that we demonstrated of 94% shows that men who are proven to be obstructed on the pre-operative non-invasive urodynamic study/cuff test are likely to have an excellent outcome after surgery. Furthermore, the cuff test can easily and simply be performed in the clinic setting at the time of initial urological review, greatly aiding decision-making and improving the patient journey towards surgery, if that indeed is the outcome which is likely to be in their best interests.

Our negative predictive value of 70% means that 30% of men who are predicted as not obstructed will still do well. This figure is similar to that obtained by the current gold standard, formal invasive urodynamic studies [8,13]. This information is still useful and aids an informed pre-operative discussion with patients. Men whose pre-operative non-invasive urodynamic investigation predicts them in the not obstructed category still have a 30% chance of a good clinical outcome. For many men who wish to avoid a surgical approach, or whose medical co-morbidity would make anaesthesia high-risk, these odds may facilitate a decision not to proceed with an operation. On the other hand, some men who are very debilitated from lower urinary tract symptoms, and who would tolerate an operation, may still wish to take the informed risk to proceed with surgical disobstruction – with the pre-operative knowledge that there is an increased likelihood of no significant clinical improvement [6,7]. This test allows them a more informed choice.

There are several limitations of our study that require mention. The sample of men used in this study had already been selected for surgery in a single institution on the basis of symptoms and reduced urinary flow rate. They therefore represent a particular subgroup of the population of men complaining of lower urinary tract symptoms, and it remains uncertain whether the encouraging results of the present study are repeatable in different centres and across different patient groups. Our findings are however consistent with those from the original Newcastle-upon-Tyne reports [13].

We did not specifically assess whether the method of surgery, TURP or HoLEP, affected outcome. If one operation was to provide inferior disobstruction, it is possible that more of these patients would have a poor clinical outcome and therefore the cuff test would appear to be poorly predictive in these patients. Given only two of our patients with a poor clinical outcome had been predicted obstructed, this effect seems unlikely.

A number of our patients were known to have prostate cancer pre-operatively (21%) and these were included in the study analysis. Whilst the presence of prostate cancer can affect the long-term outcome and durability of disobstructive surgery, we elected to include these patients as they form an important cohort of men seeking relief from voiding-type lower urinary

tract symptoms and the relevance of the cuff test in predicting their outcome is equally as important.

Until now, formal invasive urodynamic studies have provided the only definitive investigation demonstrating the likely aetiology in men presenting with voiding-type lower urinary tract symptoms. Its modest sensitivity for excluding obstruction, usually quoted as between 60 and 80%, combined with its invasive nature and resource demand, have not firmly established its place as a routine investigation in the work-up of men presenting with these symptoms. Our study shows that the cuff test, a non-invasive alternative, is a viable option, which can be performed easily and with outcomes that are comparable to the current gold standard. This is an exciting development in the investigation and management of male lower urinary tract symptoms.

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## Conflicts of Interest

None declared.

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## Appendix 1. Modified IPSS nomogram

