

The UroCuff Test[®]

A non-invasive pressure-flow diagnostic for male LUTS patients

Summary of supporting evidence

SRS
MEDICAL

Introduction

The UroCuff Test is a technology with 40 peer-reviewed clinical publications. It is utilized by urologists in 20 countries around the world with 200,000 procedures performed, to-date. We introduced The UroCuff Test to the US in 2007, and there are currently several hundred urology practices using this diagnostic tool to improve patient outcomes.

Summary of clinical evidence

Prospective and retrospective studies have been published in major peer-reviewed urology journals, including several publications in *The Journal of Urology*, among others:

The UroCuff Test non-invasive pressure-flow has been validated as equivalent to urodynamics pressure-flow for the diagnosis of bladder outlet obstruction.

- Multiple independent clinical trials, including a recent study at Northwestern University, directly compared UroCuff to urodynamics pressure-flow. Each of these studies have demonstrated the diagnostic equivalence of the two techniques.^{3,5,21}

The UroCuff Test is a proven predictor of BPH treatment outcomes.

- Multiple independent trials proved The UroCuff Test's ability to reliably and consistently predict surgical outcomes prior to intervention.^{1,2,22} For example, a recent study on 62 patients undergoing BPH surgery found The UroCuff Test to be a highly accurate predictor of surgical outcomes. Specifically, 94% of patients predicted to be obstructed had a successful outcome ($p < 0.01$), and 70% of patients predicted to be not obstructed had unsuccessful outcomes after surgery ($p < 0.01$).²

The UroCuff's published clinical literature has been extensively reviewed.

- International Continence Society (ICS) recently updated its comprehensive, evidence-based review of uro-diagnostic testing. The ICS conducted a complete review of The UroCuff Test's literature, and concluded that "non-invasive measurements of pressure and flow in men by the penile cuff [...] seem to be as clinically useful as the traditional invasive measurement of pressure and flow". ICS recommendations state that "[...] non-invasive measurements of pressure and flow should be considered when the patient is not required to undergo an invasive assessment of the storage function of the lower urinary tract."^A
- The United Kingdom's National Health Service performed a formal evidence review of clinical literature, concluding that The UroCuff Test "[...] offers greater accuracy in diagnosis of BOO than diagnosis based on flow rate measurement alone." Furthermore, the NHS Centre for Evidence-based Purchasing concluded "[...] its prediction of outcome from surgery rivals that offered by invasive urodynamic studies."^B

A complete bibliography of The UroCuff Test's peer-reviewed publications is included in this document. Reprints and summaries of each of these publications is available upon request.

The UroCuff Test is intended to replace a standalone uroflow in male patients with LUTS. Our US urology clients utilize the UroCuff data to predict surgical outcomes and identify appropriate patients for BPH treatments. This use model is discussed in the following pages.

Procedure description

UroCuff measures urine flow rate, bladder pressure, abdominal straining and detrusor-sphincter dyssynergia non-invasively with a penile pressure cuff and surface EMG electrodes. The principle of The UroCuff Test is similar to blood pressure measurement.

When the patient is ready to void, a small pneumatic cuff is fitted to the penis and surface electrodes are placed on the perineum and abdomen. When voiding has commenced, the instrument slowly inflates the cuff until the stream is interrupted.

The cuff pressure required to interrupt flow equals bladder pressure at the time of interruption. Cuff pressure is then quickly released, allowing flow to resume. The cycle is repeated until voiding is complete.

Clinical applications

The UroCuff Test is a proven predictor of BPH treatment outcomes.

Poor BPH treatment outcomes are often a result of compromised bladder health. Patients who have limited bladder health may not realize symptomatic improvements from treatments which reduce urethral resistance.

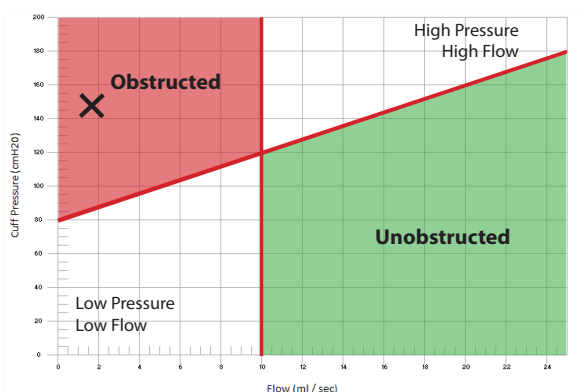
Performing a UroCuff Test instead of a uroflow provides an accurate diagnosis of bladder health and has been proven to be a strong predictor of BPH treatment outcomes. The nomograms below illustrate how The UroCuff Test can identify patients who have low bladder contractility and are at a high risk of poor BPH treatment outcome.

The nomogram to the left is an example of an obstructed patient with good bladder health and a low urine flow rate. This patient is likely to have symptomatic relief from a BPH treatment when the resistance in his prostatic urethra is reduced.

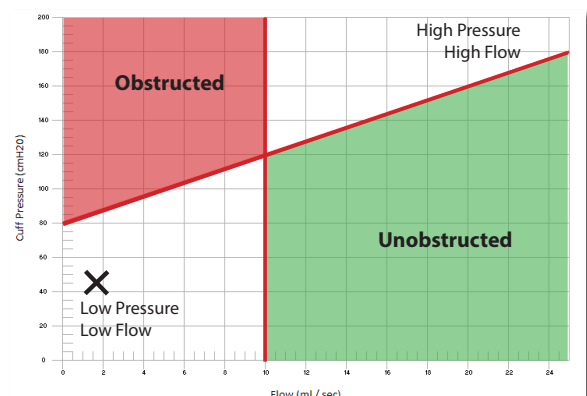
The nomogram to the right is an example of a patient with poor bladder health and a low urine flow rate. This patient is at risk to have limited symptomatic relief when the resistance in his prostatic urethra is reduced, as his bladder may not be capable of emptying.

If these patients performed a uroflow instead of a UroCuff, they may have had identical uroflow results to one and other, as one patient has low flow rate due to bladder outlet obstruction and the other patient has a low flow rate due to low bladder contractility.

High Pressure-Low Flow Example



Low Pressure-Low Flow Example

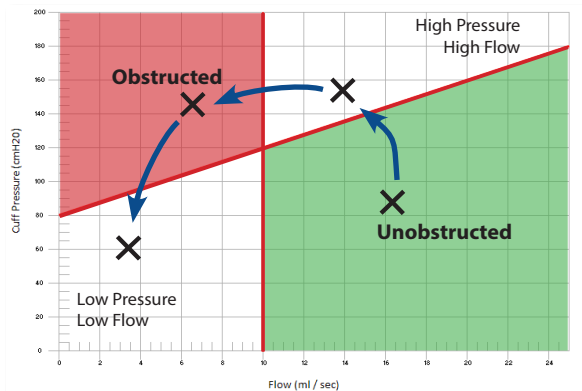


Clinical applications (cont.)

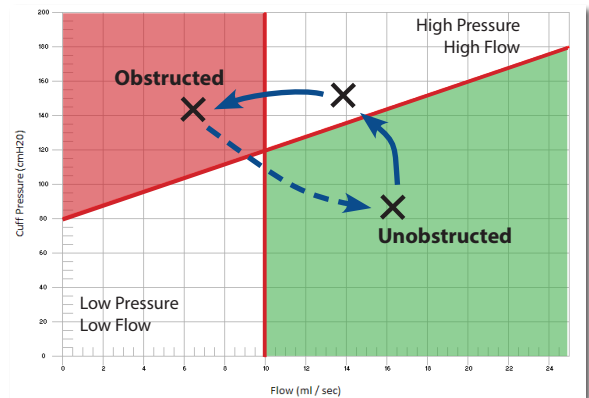
The UroCuff Test identifies patients who are good candidates for successful BPH treatments.

Patients who are being medically managed, or who are in watchful waiting, can be periodically evaluated to monitor bladder health. Rather than relying only on the patient's self-reported symptoms, the urologist can use bladder health as a clinical trigger to identify patients whose bladder health is at risk and could benefit from a BPH treatment. This results in performing more successful BPH treatments with improved certainty and patient satisfaction.

Unmanaged Patient Example



Managed Patient Example



Complete list of peer-reviewed clinical publications

1. Correlation between penile cuff test and pressure-flow study in patients candidates for trans-urethral resection of prostate. Bianchi D, Di Santo A, Gaziev G, Miano R, Musco S, Vespasiani G and Agrò EF, BMC Urology (2014), 1471-2490/14/103
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3. A Phase IV, prospective, controlled study of the SRS Medical CT3000 UroCuff Test in adult males with lower urinary tract symptoms secondary to bladder outlet obstruction. J. Hairston, Manuscript in Process
4. The role of invasive and non-invasive urodynamics in male voiding lower urinary tract symptoms. Parsons BA, Bright E, Shaban AM, Whitehouse A, Drake M. World Journal of Urology (2011), Apr;29(2):191-7
5. The Role of Non-Invasive Pressure Flow Study in Highly Symptomatic/Bothered Men with Bladder Outlet Obstruction. N Batezini, ME Girotti, F Almeida, JP Zambon, E Pinto, M Skaff, Journal of Urology (2010), Volume 183, Issue 4, Supplement , Pages e623-e624
6. Review of invasive urodynamics and progress towards non-invasive measurements in the assessment of bladder outlet obstruction. CJ Griffiths, RS Pickard. Indian Journal of Urology (2009), Volume 25, Issue 1. p83-91
7. Positioning Invasive versus Non-Invasive Urodynamics in the Assessment of Bladder Outlet Obstruction. Arnolds M. Current Opinion in Urology (2009): Volume 19 - Issue 1 - p 55-62
8. The penile cuff test: A clinically useful non-invasive urodynamic investigation to diagnose men with lower urinary tract symptoms. C. Harding, W. Robson, M. Drinnan, S. McIntosh, M. Sajeel, C.J. Griffiths, R.S. Pickard. Indian Journal of Urology, (2009), Volume 25, Issue 1 p116-121
9. Interobserver agreement for noninvasive bladder pressure flow recording with penile cuff. McArdle F, Clarkson B, Griffiths C, Drinnan M, Pickard R. Journal of Urology (2009), Vol. 182, 2397–2403
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Technology assessments

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The UroCuff Test

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