

Noninvasive Pressure Flow Studies in the Evaluation of Men with Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia: A Review of 50,000 Patients



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Abbreviations and Acronyms

BPH = benign prostatic hyperplasia
FRE = flow rate efficiency
LUTS = lower urinary tract symptoms
NNN = Newcastle Noninvasive Nomogram
PFS = pressure flow study
PVR = post-void residual
Qmax = maximum flow rate
VV = voided volume

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Purpose: The UroCuff® Test is a noninvasive pressure flow study used to manage men with lower urinary tract symptoms. UroCuff Tests were performed on men with lower urinary tract symptoms to evaluate voiding characteristics and quantify changes in urodynamic parameters with age.

Materials and Methods: This cross-sectional study included all UroCuff Tests performed at 103 urology practices in the U.S. Tests were de-identified prior to collection and analysis. Inclusion criteria required initial pressure flow study with subsequent tests excluded, voided volume 50 ml or greater, at least 1 cuff inflation and patient age greater than 20 years. Pressure, maximum flow rate, flow rate efficiency (maximum flow rate/Pcuff), voided volume and post-void residual were plotted by age and stratified by Newcastle Noninvasive Nomogram category.

Results: A total of 50,680 patients 20 to 100 years old (median age 66.0) met inclusion criteria. Median Pcuff was 144.3 cmH₂O and 60.8% of patients were categorized in the obstructed or high pressure/high flow Newcastle Noninvasive Nomogram quadrants. Median maximum flow rate was 10.9 ml per second and 55.8% had maximum flow rate greater than 10 ml per second. Median voided volume and post-void residual were 219.0 and 75.0 ml, respectively. All measures deteriorated with age ($p < 0.0001$). Pcuff reflects the compensated/decompensated bladder function lifecycle. Values initially increased and reached peak pressure at age 62, then decreased by approximately 0.96 cmH₂O per year until age 90.

Conclusions: This study demonstrates that symptomatic patients enter urological practices at different urodynamic stages of bladder function and outlet obstruction, that Pcuff, maximum flow rate, voided volume, flow rate efficiency and post-void residual deteriorate with age, and that UroCuff is a sensitive evaluation of bladder performance.

Key Words: prostatic hyperplasia, lower urinary tract symptoms, urodynamics

BENIGN prostatic hyperplasia is progressive disease state in which the bladder is challenged with increasing outlet resistance in the prostatic urethra. Over time, as a result of chronic high outlet resistance caused by BPH, bladder function is gradually and eventually impaired. Without

intervention, patients with BPH can experience an initial phase of bladder compensation in which bladder pressure is increased during urination, followed by an eventual decompensation phase in which the bladder becomes trabeculated and loses its ability to sustain high contraction

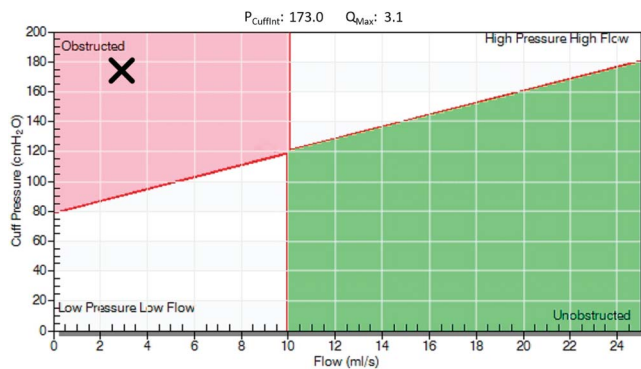


Figure 1. Example of NNN for obstructed patient tested with UroCuff.

levels.^{1,2} This deterioration of bladder function can ultimately lead to bladder failure and urinary retention which can only be managed with a chronic drainage catheter.

Led by the American Urological Association (AUA), urologists are increasingly interested in understanding bladder function and potential bladder outlet obstruction in men with lower urinary tract symptoms attributed to BPH and providing them optimal treatment. The 2018 version of the AUA Guideline on BPH calls for expanded use of pressure flow studies to diagnose certain male patients with LUTS as PFS improves the urologist's understanding of bladder function and bladder outlet obstruction.³

The UroCuff Test is a noninvasive PFS that assesses the relationship of vesical pressure and urine flow using a naturally filled bladder without the need for a urethral catheter. This noninvasive test simultaneously measures vesical pressure and urine flow rate and presents these results on a modified ICS (International Continence Society)

nomogram. The UroCuff Test has been shown to be reproducible,^{4–6} validated,^{7–9} and highly correlated with catheterized urodynamics studies.^{9–11} The UroCuff Test is sensitive to changes following BPH treatment and has been shown to be a strong predictor of BPH treatment outcomes.^{12–14}

In 2019 more than 90% of all PFSs performed on male patients with LUTS in the participating sites was performed with the UroCuff Test. The goal of this multisite observational, cross-sectional, retrospective study was to assess the voiding characteristics of men with LUTS as they initially present and to determine whether a deterioration of urodynamic function occurs with patient age.

MATERIALS AND METHODS

Study Design

This multisite, cross-sectional, retrospective study was categorized as exempt by Sterling IRB per 45 CFR §46.104 and informed consent was not required per 45 CFR §46.116. Registration on ClinicalTrials.gov was not required as this study is not an applicable clinical trial per 42 CFR §11.22.

UroCuff Test Protocol

The UroCuff Test PFS protocol simulates conditions of a natural void. The patient is instructed to drink fluids to naturally fill the bladder. After the patient reports a strong desire to void, the UroCuff/UroCuff DC Test is performed on the CT3000Plus Complete Urodynamics™ instrument or CT3000Pro Complete Urodynamics™ instrument (SRS Medical, North Billerica, Massachusetts). With the subject standing, a urethral cuff is applied to the patient. Optionally, surface electromyography electrodes are attached to the perineum to detect detrusor-sphincter dyssynergia, and/or surface electromyography electrodes are attached to the abdomen to detect abdominal straining. The patient is positioned over a flowmeter and begins

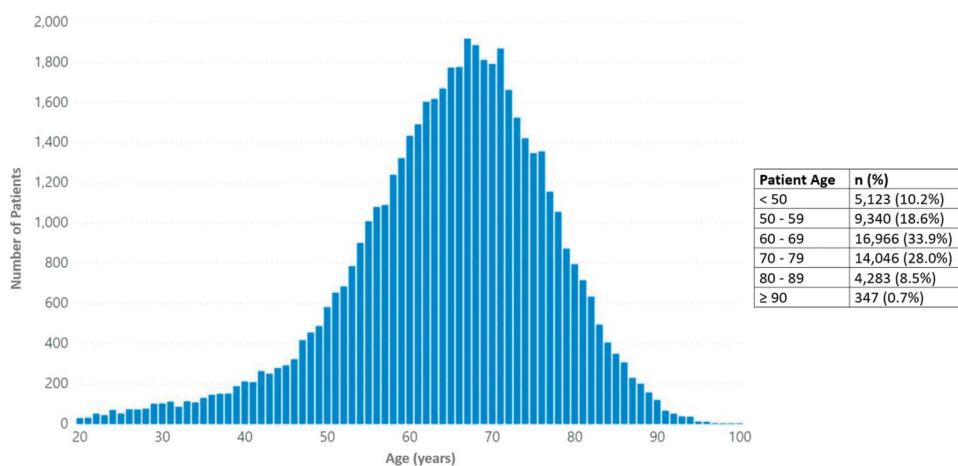


Figure 2. Distribution of patient age in 1-year increments. Overall 575 patients (1.1%) had invalid patient age and were excluded from calculation, so figure represents 50,105 patients.

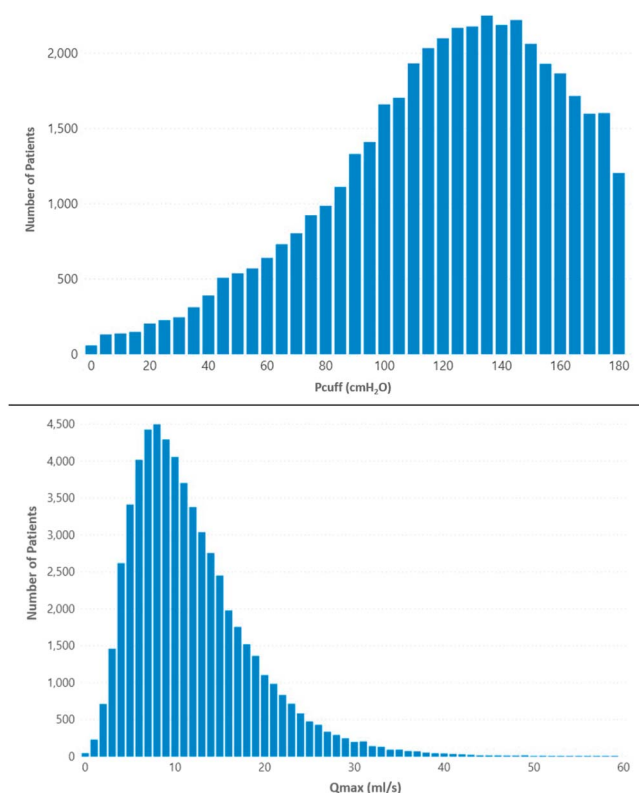


Figure 3. Distribution of Pcuff and Qmax. A, Pcuff results in increments of 5 cmH₂O, 38,014/50,680 patients truncated at Pcuff 185 cmH₂O or greater. B, Qmax results in increments of 1 ml, 50,566/50,680 patients truncated at Qmax 60 ml per second or greater.

to naturally void. As the void commences the urethral cuff is inflated, and the corresponding changes in urine flow rate and cuff pressure are measured.

Data Collection

Patient age is recorded and the UroCuff Test protocol performed. Pcuffint (Pcuff), defined as the maximum pressure required to interrupt the void, is calculated along with the maximum urine flow rate and voided volume. Post-void residual is optional and not required to complete the UroCuff Test.

Once the test is complete, the instrument plots pressure and flow data on the Newcastle Noninvasive Nomogram, which has the 4 categories of unobstructed, high pressure/high flow, obstructed and low pressure/low flow (fig. 1).¹⁵ All patient specific information is stored on the instrument.

Patient specific data for every initial UroCuff Test conducted at each of our centers were retrieved from the instrument (Appendix 1). Protected health information was de-identified before data were extracted and made available for analysis.

Selection Criteria

Initial UroCuff Tests for all patients were extracted. Only patients 20 years old or older with an initial UroCuff Test that resulted in a successful void were included in the analysis. Successful void was defined as VV 50 ml or greater and at least 1 successful cuff inflation.

Table 1. Distribution of PFS results by NNN diagnostic category

	No. (%)
Unobstructed	12,277 (24.2)
High pressure/high flow	16,005 (31.6)
Obstructed	14,821 (29.2)
Low pressure/low flow	7,577 (15.0)

Statistical Analysis

Continuous variables were tested for normality, and median and IQR are reported for summary stats. Pcuff, Qmax, VV, FRE and PVR were stratified by age groups and by obstruction category using the Newcastle Noninvasive Nomogram. Data analysis and graphing were performed with Microsoft® Power BI®. The Kruskal-Wallis test by ranks was used to test NNN and age versus the continuous variables. FRE is defined as the amount of flow per unit of pressure and is reported in ml/cmH₂O.

RESULTS

In total, data for 56,711 male patients tested at 103 locations were extracted from the instruments. Of the 56,711 patients 50,680 met inclusion criteria (89.4%) and were included in the analysis. Of the 50,680 patients 575 (1.1%) did not have a valid patient age entered, and, therefore, age data were available for 50,105 patients. As PVR is an optional field the complete data set was not available. Data were collected for 18,798 of 50,680 (37.1%) patients.

Age Distribution

Median patient age was 66 years (IQR 58–73) and 31,021 of 50,105 (61.9%) patients were in their 60s or 70s. More than 10%, or 5,123 of 50,105 men, were less than 50 years old (fig. 2).

PFS Distribution

Median Qmax was 10.9 ml per second (IQR 7.5–15.6) and 28,282 of 50,680 (55.8%) patients had maximum flow rates greater than 10 ml per second (fig. 3). Median Pcuff was 144.3 cmH₂O (IQR 109.5–185.0) and 30,826 of 50,680 (60.8%) patients had peak pressures categorized in the obstructed or high pressure/high flow NNN quadrants (table 1). The UroCuff classic protocol applies a maximum cuff pressure of 185 cmH₂O to address patient comfort. Overall 12,666 of 50,680 (25.0%) patients reached the maximum applied cuff pressure, indicating Pcuff values of 185 cmH₂O or greater.

VV and PVR Distribution

Median VV was 219.0 ml (IQR 138–337) and 28,226 of 50,680 (55.7%) of patients had a VV of 200 ml or greater (fig. 4). Median PVR was 75 ml (IQR 30–140) and 14,452 of 18,798 (76.9%) patients had a PVR less than 150 ml and 1,275 of 18,798 (6.8%) patients had a PVR of 300 ml or greater.

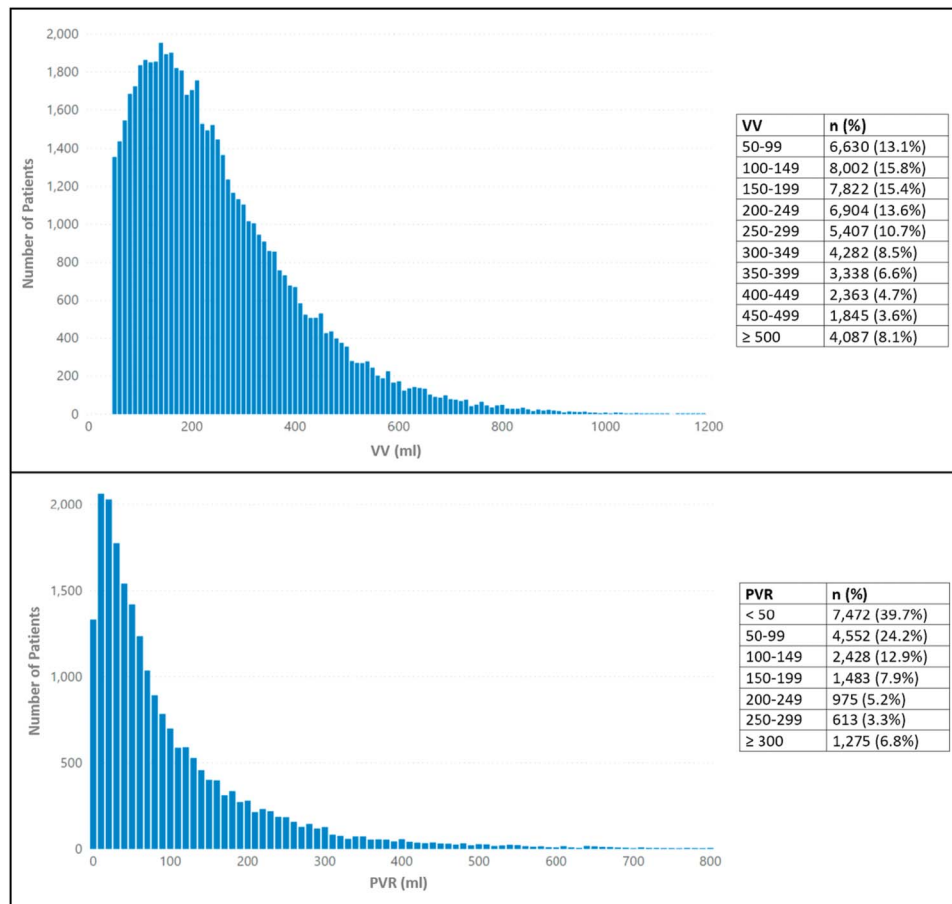


Figure 4. Distribution of VV and PVR. A, histogram of VV for all 50,680 patients plotted in increments of 10 ml. B, histogram of PVR plotted in increments of 10 ml. PVR is available for 18,806 patients. PVR 800 ml or greater is not shown in 67.

Relationship of Patient Age to PFS Results

Figure 5 depicts age related changes in Pcuff, FRE, Qmax, VV and PVR. Table 2 summarizes each urodynamic measure by decade. All 5 urodynamic measures deteriorated with age ($p < 0.0001$ for all).

Pcuff

Pcuff pressures initially increased then decreased with increasing age, reflecting the compensated/decompensated bladder function lifecycle (fig. 5). After reaching a peak pressure at patient age 62 years, Pcuff decreased by approximately 0.96 cmH₂O with each year until age 90.

Maximum Flow Rate

Median maximum flow rate decreased from 14.5 ml per second in men younger than 50 years to 9.9 ml per second in men 70 to 79 years old. Overall, we observed that 55.8% of patients present with Qmax greater than 10 ml per second (fig. 3). Qmax less than 10 ml per second was recorded in 1,307 of 5,123 (25.5%) men less than 50 years old and 7,091 of 14,046 (50.5%) men 70 to 79 years old. From age 50 to 80 years the overall decrease in

Qmax per decade is approximately 1.07 ml per second.

Voided Volume

Voided volume also decreased with increasing age, with a median of 302 ml for men younger than 50 years decreasing to a median volume of 194 ml for men 70 to 79 years old. From age 50 to 80 years VV decreased by approximately 3.64 ml with each year.

Flow Rate Efficiency

Flow rate efficiency is a calculated value dividing maximum flow rate by Pcuff pressure. As with all the other PFS parameters this ratio also demonstrated age related changes. As FRE decreases more pressure is required to generate flow, reflecting higher outlet resistance. For men younger than 50 years median FRE was 0.110, decreasing to 0.074 for men age 70 to 79 years.

Post-Void Residual

PVR data were available for 18,798 of 50,680 men (37.1%). PVR volume increased with age, with a median of 48 ml for men younger than

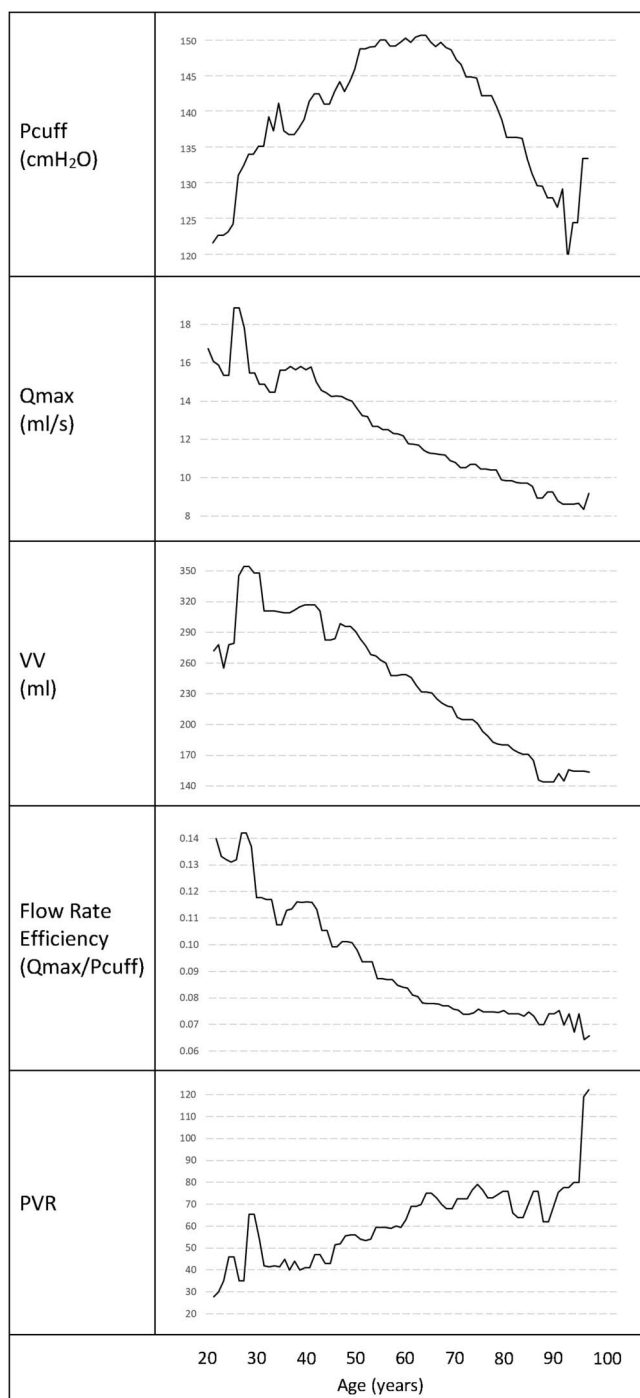


Figure 5. PFS results by age, moving average over 3 years

50 years up to a median volume of 194 ml for men 70 to 79 years old. PVR 150 ml or greater was recorded in 304 of 1,820 (16.7%) men less than 50 years old and 1,318 of 5,410 (24.4%) men 70 to 79 years old.

Obstruction Category

The NNN quadrant obstruction category also changed with age ($p < 0.0001$). Men less than 50 years old were more than twice as likely as men 70

to 79 years old to be categorized as unobstructed (41.4% vs 20.2%), while men age 70 to 79 years were more than twice as likely as men younger than 50 years to be categorized as obstructed (34.1% vs 14.7%) (table 3).

DISCUSSION

In this observational, cross-sectional study we reviewed the voiding characteristics of more than 50,000 men with LUTS attributed to BPH as measured by their initial UroCuff Test during a diagnostic workup. These real-world urodynamic data from the U.S. patient population provide insight into the progression of this disease.

The basis for this large scale study was to evaluate enough men presenting with LUTS to visualize the underlying urological patterns. We surmised that urological function deteriorates with age and we wanted to investigate the effects of age on urodynamic function. Our findings support those of long-standing natural history studies. In the U.S. the natural history of BPH is best evidenced by the observational studies of community dwelling men conducted in Olmsted County.^{16–18} These landmark studies evaluated the prevalence and progression of urinary characteristics in 2,115 randomly selected men who were followed for 12 years. They demonstrated that as men age, the severity of their urological symptoms and bother increase, maximum flow rates decrease and prostate growth rates increase. However, PFS was not included in Olmsted County Study and to our knowledge, there are no observational studies defining changes in bladder pressure with age.

This large data set of initial PFS on male patients presenting with LUTS reflects the systematic changes that take place on a population basis in urodynamic parameters with advancing age, including decreased flow rates, voided volumes, flow rate efficiencies and increased PVR. The data also reveal the manner in which the bladder is affected by chronic obstruction on a population basis, with increasing pressures up until average age 62 years (compensation phase) followed by decreasing pressures (decompensation phase) (fig. 5).

BPH is a progressive disease state in which outlet resistance typically increases over time as the prostatic urethra gradually narrows. Figure 6 demonstrates how the pressure flow relationship changes in chronically obstructed patients on a population basis. Patients presenting in their 70s and older are 1.7 times more likely to be categorized as low pressure-low flow than patients in their 50s or younger. Conversely, patients in their 50s or

Table 2. PFS parameters vs age cohort

Age Grouping	Median (IQR)				
	Pcuff (cmH ₂ O)	Qmax (ml/sec)	VV (ml)	FRE (Qmax/Pcuff)	PVR (ml)
Younger than 50	139.3 (106.1–178.3)	14.5 (9.9–20.3)	302.0 (184.0–455.0)	0.110 (0.075–0.157)	48.0 (25.0–102.5)
50–59	148.1 (113.8–187.2)	12.1 (8.3–17.3)	257.5 (162.0–388.0)	0.088 (0.060–0.128)	60.0 (28.0–131.0)
60–69	148.6 (113.6–187.0)	10.8 (7.5–15.3)	225.0 (143.0–338.0)	0.078 (0.054–0.114)	70.0 (31.0–148.0)
70–79	142.3 (108.2–182.3)	9.9 (6.9–14.0)	194.0 (124.0–287.0)	0.074 (0.052–0.108)	74.0 (32.0–148.0)
80–89	131.9 (98.4–172.0)	9.0 (6.3–12.9)	164.0 (106.0–247.0)	0.072 (0.051–0.104)	65.0 (32.0–134.0)
90 or Older	123.0 (83.8–168.5)	8.1 (5.5–11.8)	150.0 (92.0–222.5)	0.071 (0.048–0.098)	87.0 (35.5–188.5)
Overall	144.3 (109.5–185.0)	10.9 (7.5–15.6)	219.0 (138.0–337.0)	0.081 (0.055–0.119)	66.0 (30.0–141.0)

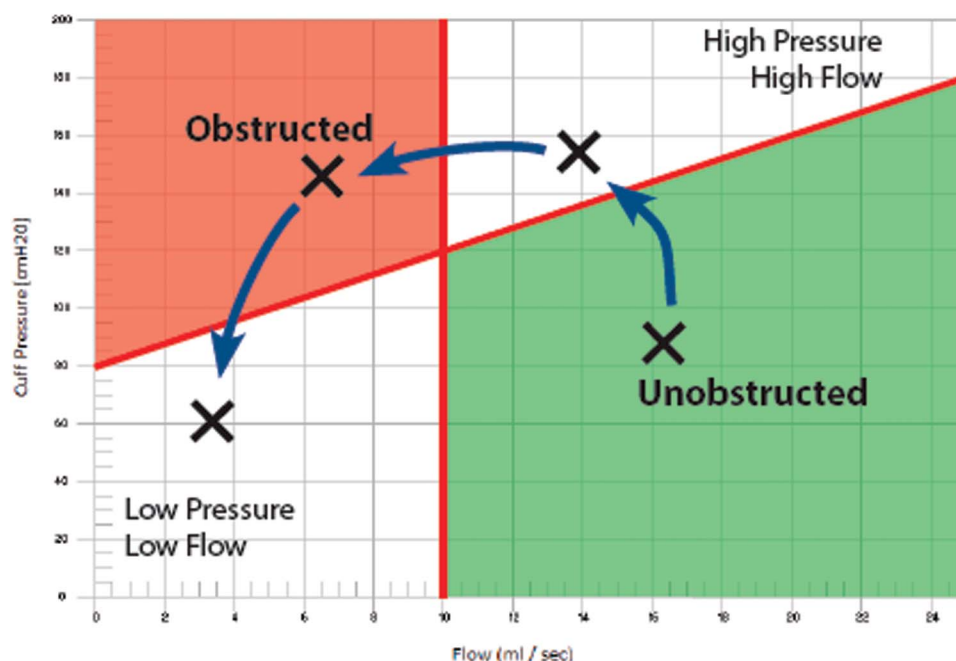
Table 3. NNN quadrant vs age cohort

Age Grouping	No. NNN Category (%)				Totals
	Unobstructed	High Pressure/High Flow	Obstructed	Low Pressure/Low Flow	
Younger than 50	2,119 (41.4)	1,684 (32.9)	755 (14.7)	565 (11.0)	5,123 (100.0)
50–59	2,588 (27.7)	3,365 (36.0)	2,277 (24.4)	1,110 (11.9)	9,340 (100.0)
60–69	3,752 (22.1)	5,650 (33.3)	5,232 (30.8)	2,332 (13.7)	16,966 (100.0)
70–79	2,838 (20.2)	4,067 (29.0)	4,792 (34.1)	2,349 (16.7)	14,046 (100.0)
80–89	790 (18.4)	1,011 (23.6)	1,483 (34.6)	999 (23.3)	4,283 (100.0)
90 or Older	54 (15.6)	68 (19.6)	114 (32.9)	111 (32.0)	347 (100.0)

younger are more than twice as likely to present as unobstructed and 1.2 times more likely to present as high pressure-high flow as patients in their 70s or older. Overall, as patients age, flow rates decrease by a higher percentage than their pressures decrease, reflecting a bending of the pressure flow relationship caused by more significant outlet obstruction.

Given the changes that occur over time, the value of earlier bladder outlet obstruction

relieving procedures is more evident. The U.S. Veterans Affairs BPH Cooperative Study Group highlighted the detrimental effects of delaying surgery in men with moderate symptoms of BPH.¹⁹ More recently, Young et al published a 20-year observational series demonstrating that in 2010, men presenting for surgery were older, sicker and had more postoperative complications than in 1990.^{20,21} After surgery the percentage of men with bladder dysfunction, either persistence

**Figure 6.** Typical progression of pressure flow relationship over time as BPH increases

storage LUTS or failure to void requiring long-term intermittent or indwelling catheterization, markedly increased from 1% to 7.9%, and 2% to 11.5%, respectively. Our aggregated PFS data on more than 50,000 patients presenting with LUTS reveal that underlying deterioration in bladder function occurs as men enter their 60s. This study supports the theory that bladder dysfunction may contribute to suboptimal treatment outcomes in older patients.

The UroCuff technique offers several advantages over traditional catheterized cystometry studies using artificial filling. Artificial filling often results in bladder overfilling, provoked detrusor contractions, excessive voiding pressure and voiding volumes, thus providing data that may not reflect actual clinical symptoms.²² Artificial media such as water or saline (instead of urine) have been shown to affect pressure and flow rate.²³ The presence of a catheter in the bladder impacts sensation during filling by irritating the bladder neck or retards flow rate during void by occluding the urethra.²⁴ In addition, the placement of an abdominal channel catheter in the rectum has been shown to cause vasovagal syncope.²⁵

The data available for this study were limited to the information entered and stored in the Complete Urodynamics instrument. Diagnosis, symptom assessment and treatment outcome data were not available, which consequently restricted the

application of selection criteria and analysis. The population in this study was clinic based, exclusively including men who presented in urology practices with LUTS for whom a PFS was conducted. Therefore, these findings cannot be applied to a normal population, and as diagnosis was not available, we cannot conclude that these data represent only patients with BPH.

This was a cross-sectional study design intended to collect data about individuals at 1 time point, and while cross-sectional studies are an efficient method of quantifying the prevalence of a disease or risk factor, they can only establish an association between variables. This study is limited in that it only provides PFS data and the relationship to age but cannot demonstrate causality. Future studies that include additional diagnostic and outcome data are needed.

CONCLUSIONS

Patients with LUTS/BPH represent, on average, a third of all urology patient visits in our practices. The LUTS/BPH disease state is best managed by careful assessment of patient symptoms, patient tolerance of symptoms, the nature of the outlet obstruction and the function of the bladder. The UroCuff Test improves clinical decision making and patient compliance, with the goal of ultimately improved treatment outcomes.

Appendix 1. Data retrieved from the Complete Urodynamics Instrument

Patient age at date of test (years)

Pcuffint (cmH₂O)

Qmax (ml/sec)

Voided Volume (ml)

Newcastle Noninvasive Nomogram (NNN) Quadrant Assignment (Obstructed, Unobstructed, High Pressure/High Flow, Low Pressure/Low Flow)

PVR (ml)

Data stored in the Complete Urodynamics Instrument for each patient. Patient age must be entered into the Complete Urodynamics Instrument prior to the conduct of the UroCuff Test. Pcuffint, Qmax, VV and NNN are measured or calculated during the conduct of the test. PVR is an optional field.

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EDITORIAL COMMENTS

In recent years an increasing number of noninvasive tests have been described to replace the pressure flow study in diagnosing bladder outlet obstruction in men with LUTS, avoiding the burden and morbidity associated with invasive urodynamics.¹ As reported in a systematic review, several noninvasive tests demonstrated high specificity and sensitivity in diagnosing bladder outlet obstruction in men. However, the available evidence is limited by heterogeneity. Even if several noninvasive assessments of bladder outlet obstruction have shown promising results, invasive urodynamics remain the gold standard.

The authors evaluated voiding characteristics of 50,680 men with LUTS who underwent a UroCuff test, a noninvasive PFS. The aim of the study was to document the deterioration of urodynamic bladder function that occurs with age. The most relevant

evidence is that flow rates, voided volumes, flow rate efficiencies and post-void residual get worse with advancing age as well as the bladder efficiency with a decompensation phase starting from age 62.

The main limitation of the study is the lack of data about diagnosis, symptoms and treatment outcomes. Nevertheless, the results cannot be extended to a general population considering that study included exclusively men with LUTS enrolled in urological outpatient visits. Further studies comparing UroCuff with validated predictive models as a control tool are needed to better define the clinical efficacy of this new test.²



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Understanding the compensation/decompensation response of the bladder to long-term outlet obstruction is critical in determining the need for, and timing of, surgical intervention. However, it is unclear whether bladder decompensation is a ubiquitous response to bladder outlet obstruction and, if so, over what time frame this occurs. Few studies have assessed the long-term progression of urodynamic changes related to bladder outlet obstruction.^{1,2} The present cross-sectional study provides important and interesting insights by analyzing noninvasive urodynamics from an impressive 50,000-patient cohort. As expected, voiding urodynamic parameters deteriorate with age, with bladder outlet obstruction more likely in older men. More interesting is the finding that isovolumetric bladder pressure initially increases, peaking at age 62, after which there is a decline of 1 cmH₂O per year, demonstrating the compensation/decompensation response to bladder outlet obstruction at a population level.

However, many unanswered questions remain. Is there a point at which bladder dysfunction

becomes irreversible? Do the severity and duration of bladder outlet obstruction affect this response? For how long is it safe to defer surgery in men with bladder outlet obstruction? How does treatment affect this natural urodynamic history? At what point in the compensation/decompensation cycle is surgical intervention futile? The lack of individualized patient level clinical data does not allow the present study to answer these questions. Longitudinal urodynamic studies of asymptomatic and symptomatic men, focusing on intra-individual variability and evaluating the effects of pharmacological and surgical treatment, while also considering the numerous confounding factors that affect detrusor function, would be required. This valuable study has provided some answers but has raised many questions.



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REPLY BY AUTHORS

The comments address what we see as a fundamental issue in male LUTS management. How long should we allow a bladder to contract against high outlet resistance without intervention, and what is the long-term impact on bladder function from the compensation/decompensation response of the detrusor? More research is needed to address this vital issue to further optimize intervention strategies. Our collective clinical experience is that the

timing and extent of bladder function recovery resulting from a de-obstructive procedure are highly variable by patient, particularly when measured through the lens of actual LUTS relief. We also agree that more research is needed to extend results to a general population and to ascertain applicability to different populations (including those on oral medications for LUTS) and more importantly optimal intervention.



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