

# Clinical Impact of a UroCuff Navigation Protocol for Patients With Medically Managed Benign Prostatic Hyperplasia

Aaron Berger, MD; Arpeet Shah, MD

Associated Urological Specialists, Chicago, Illinois

## KEYWORDS:

Prostatic hyperplasia; urodynamics; patient navigation; urinary bladder

## Abstract

**Background:** This study conducted noninvasive urodynamic testing before renewing patients' benign prostatic hyperplasia (BPH) medication prescriptions and assessed the impact of that urodynamic information on patients' clinical course of treatment.

**Methods:** Patients were informed by patient navigators that before renewing their BPH prescription they would have a noninvasive urodynamic testing visit. The visit included a UroCuff Test and a postvoid residual volume measurement. We recorded the number and type of advanced diagnostic testing and BPH treatment procedures performed from the visit through 180 days.

**Results:** A total of 362 patients with medically managed BPH completed the noninvasive urodynamic testing visit. The UroCuff Test showed that most patients were in the high-pressure high-flow quadrant (32.9%) or obstructed-flow quadrant (29.6%). More than 15% of patients had postvoid residual volumes greater than 200 mL. Within 180 days of the visit, 54% of patients underwent further diagnostic testing, and 21% of patients had surgical procedures. The odds of having advanced diagnostic testing were 2.5 and 3.6 times greater, respectively, for patients in the high-pressure high-flow and obstructed-flow quadrants than they were for patients in the unobstructed-flow quadrant, even after adjusting for age, voided volume, postvoid residual volume, and medications (high pressure high flow adjusted  $P = .011$ ; obstructed-flow adjusted  $P = .001$ ). The characteristics associated with the occurrence of a BPH procedure were similar to those associated with advanced diagnostic testing.

**Conclusions:** This protocol improved our understanding of our patients' urologic health, better educated patients, and resulted in earlier interventions without additional burden on the urologist.

**B**enign prostatic hyperplasia (BPH) is a noncancerous enlargement of the prostate gland that affects men as they age. Its histologic prevalence is 8% for men aged 40 to 45 years; it affects 60% of men by age 60 and 80% of men by age 80.<sup>1,2</sup> The increased bladder outlet resistance BPH causes results in a variety of lower urinary tract symptoms (LUTS), resulting in more than 5 million symptomatic patients seeking urologic care each year in the United States.<sup>3,4</sup>

Many challenges are associated with optimizing clinical care for this large and growing patient population. They include (1) the limited and declining number of practicing urologists and (2) other clinical care forces that create

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**Corresponding author:** Aaron Berger, MD, Associated Urological Specialists, 10400 Southwest Hwy, Floor 1, Chicago Ridge, IL 60415 ([a.berger@auspecialists.com](mailto:a.berger@auspecialists.com))

a tendency to treat symptoms with long-term BPH medication, which may result in prolonged outlet obstruction and a corresponding deterioration of bladder function.<sup>5,6</sup>

According to 2021 claims data, 33% of the US male population aged 65 years and older underwent care for BPH and LUTS.<sup>7</sup> A limited number of urologists are available to manage this large population. In 2020, there were only 23.8 urologists per 100 000 people (male and female) aged 65 years and older. By 2035, this ratio is expected to decrease to 15.8 urologists per 100 000 people.<sup>5</sup>

Prolonged bladder outlet obstruction is known to cause irreversible deterioration in bladder function because progressive bladder remodeling may be attributed to bladder outlet obstruction.<sup>8</sup> A substantial percentage of patients using BPH medications have obstructed bladders, have remained on BPH medications too long, and are at risk of bladder function deterioration. This position is supported by the results of the 2021 American Urological Association census, in which the majority of physician urologists agreed that widespread adoption of pharmacologic therapy has delayed needed surgical interventions.<sup>6</sup>

We believe that several reasons exist why patients remain on BPH medication when it is not effective. First, patients are generally unaware of the consequences of prolonged obstruction to bladder function; they may acclimate to their symptoms or have a fear of pursuing surgical treatments or even advanced diagnostics. This fear may lead to underreporting their symptom severity and masking their true urologic condition.

The American Urological Association BPH guidelines further recommend renewing prescriptions upon request for patients who report satisfaction with their medications,<sup>2,9</sup> and in an environment in which urologists' schedules are already stretched to capacity, BPH medications may be renewed without diagnostic testing or with limited patient interaction.

To address these concerns, we implemented a patient navigator–led protocol for patients with BPH in which we educated patients about the importance of maintaining their bladder health and the need for additional diagnostic procedures. The patients

## ABBREVIATIONS

BPH, benign prostatic hyperplasia

FRE, flow rate efficiency

HPHF, high pressure high flow

LPLF, low pressure low flow

LUTS, lower urinary tract symptoms

$p_{\text{cuff}}$ , maximum pressure required to interrupt the urine void

PVR, postvoid residual

$Q_{\text{max}}$ , maximum flow rate

then underwent noninvasive urodynamic testing visits before prescription renewal. The visit featured a urodynamic test (UroCuff Test; SRS Medical) and a measurement of postvoid residual (PVR) volume. We reviewed each patient's clinical care for 180 days after the visit and tracked the number of patients who obtained advanced diagnostic testing or underwent a BPH-related procedure. In this article, we present the results of the protocol for 362 patients with BPH.

## Methods

### PATIENT SELECTION

Through an electronic health record search, we identified eligible patients who

- were currently prescribed 1 or more of the following BPH medications: alfuzosin, doxazosin, silodosin, tamsulosin, terazosin, dutasteride, or finasteride;
- needed prescription renewal for their BPH medication;
- had no history of prostate cancer;
- had no history of BPH procedures; and
- had undergone no advanced BPH diagnostic testing within 60 days.

### PATIENT RECRUITMENT

The patient navigator contacted eligible patients by telephone to schedule the noninvasive urodynamic testing visit. The navigator's communication goals were to (1) inform the patient that the visit would be

scheduled before prescription renewal; (2) communicate the clinical need for this assessment, centered on preservation of bladder function; (3) instruct the patient on how to prepare for the diagnostic visit; and (4) tell the patient what to expect during the diagnostic visit. Depending on patient needs, the navigator also answered clinical questions about the disease state and gave the patient access to clinical videos on BPH diagnosis and treatment.

### NONINVASIVE URODYNAMIC TESTING VISIT

The noninvasive urodynamic testing visit included a UroCuff Test and an assessment of PVR volume using bladder ultrasonography. The UroCuff Test categorizes the patient's bladder health data into 1 of 4 pressure flow quadrants based on pressure and uroflow values. These tests were chosen because they are noninvasive and provide valuable information regarding the patient's bladder and urinary function.

### ADVANCED DIAGNOSTIC TESTING AND BPH PROCEDURES

Based on the information learned at the noninvasive visit, selected patients were scheduled for advanced diagnostic procedures (cystoscopy, transrectal ultrasound imaging, and catheterized urodynamics). We reviewed electronic health records for clinical activity from the day of the noninvasive testing visit for 180 days to determine the number and types of advanced diagnostic and BPH procedures performed.

### DATA COLLECTION

Protected health information was deidentified before data were extracted and made available for analysis.

### STATISTICAL ANALYSIS

The key characteristics included in this analysis were

- patient age;
- urodynamic function, defined by 1 of 4 pressure flow quadrants (unobstructed, high pressure high flow [HPHF], obstructed, and low pressure low flow [LPLF]);
- maximum pressure required to interrupt the urine void (cuff pressure [ $p_{\text{cuff}}$ ]);
- maximum flow rate (Qmax);
- voided volume;
- PVR volume;
- flow rate efficiency (FRE), defined as the amount of urinary flow per unit of pressure, reported in mL/cm H<sub>2</sub>O;
- BPH medications; and
- the type and timing of advanced diagnostic and BPH-related procedures.

Continuous variables were summarized using mean (SD), median (IQR), and ranges. Categorical variables were summarized using relative frequencies and percentages. Characteristics were summarized descriptively by urodynamic function quadrant and by any follow-up advanced diagnostics or BPH-related procedures.

Regression analyses examined patients' clinical characteristics and identified any associations between clinical characteristics and follow-up advanced diagnostic testing or BPH procedures. Univariable logistic regression models were fit to obtain unadjusted odds ratios for follow-up advanced diagnostic testing and BPH procedures. Multivariable logistic regression models were fit to adjust for the effects of age, voided volume, FRE, BPH medication, and urodynamic function. The  $p_{\text{cuff}}$ , Qmax, and FRE were excluded from multivariable logistic regression modeling as a result of multicollinearity with urodynamic function.

## Results

From May 2022 to March 2023, 366 patients with BPH underwent a noninvasive urodynamic testing visit. Of these patients, 362 (98.9%) successfully completed a UroCuff Test and were followed for 180 days.

Table 1 provides overall descriptive statistics for all patients. The patients' overall median (IQR) age was 71 (66-76) years. A total of 271 of 362 patients (74.9%) were in their 60s or 70s, and only 2.5% (9/362) were younger than 50 years of age. Median

voided volume was 171.5 mL, and 13.0% of patients (47/362) voided less than 76 mL. Median PVR volume was 60 mL, and 15.2% of patients (55/362) had a PVR volume of at least 200 mL. All patients were undergoing medical therapy, with 68.5% of patients (248/362) taking  $\alpha$ -blockers.

Within 180 days of the visit, 53.9% of patients (195/362) underwent advanced diagnostic testing; 86.7% of patients (169/195) who underwent advanced diagnostic testing did so within 90 days. Of 362 patients, 77 (21.3%) underwent a BPH procedure; 54.5% of these BPH procedures (42/77) occurred within 90 days of the noninvasive testing, and 83.1% (64/77) occurred within 120 days of the noninvasive testing. Four patients who underwent a procedure did not have advanced diagnostics performed between the noninvasive urodynamic testing visit and the procedure. Figure 1 shows the timing of advanced diagnostic testing and BPH procedures.

Table 1 also provides descriptive statistics stratified by urodynamic function. Enrolled patients were seeking to renew their medications, but only 19.6% of these patients (71/362) were in the unobstructed-flow quadrant. The 71 patients with unobstructed flow demonstrated good bladder health. They had the highest median Qmax (17.0 mL/s), the largest median voided volume (197.0 mL), and the smallest median PVR volume (33.0 mL). Their FRE, a measurement of  $Q_{\text{max}}/p_{\text{cuff}}$ , was 64.0, the highest median value of any urodynamic group. Comparatively higher FRE values indicate that less pressure is required to expel urine.

At the other end of the spectrum, the 65 patients in the LPLF quadrant presented with the lowest median Qmax (6.1 mL/s), the smallest median voided volume (89.0 mL), and the largest median PVR volume (73.0 mL). The median FRE for patients in the LPLF quadrant was 34.0.

Figure 2 illustrates the relationship between urodynamic measures and patient age group (<60, 60-69, 70-79,  $\geq 80$  years). There were patients with unobstructed flow in each age group, but the percentages were small, decreased with age, and ranged from 29% (12/42) for the youngest age group to

12% (6/49) for the oldest. The proportion of men with HPHF decreased with age, and there was a proportionate increase in the number of patients with obstructed flow.

Only 7.1% (3/42) of the younger men were incapable of voiding more than 76 mL; this percentage increased nearly 3 times in patients who were aged at least 80 years (10/49 [20.4%]). The percentage of men with a PVR volume greater than 226 mL also increased 2.6 times in patients who were aged at least 80 years, from 4.8% of patients younger than 60 years of age to 12.5% of men aged at least 80 years.

Table 2 shows patient characteristics stratified by the occurrence of advanced diagnostic testing or BPH procedures.

### Regression Analyses: Odds of Advanced Diagnostic Testing

The results from logistic regression modeling of advanced diagnostics are presented in Table 3. There was no evidence of an association between age or voided volume and the odds of a patient receiving advanced diagnostic testing.

Patient  $p_{\text{cuff}}$  values were associated with increased odds of a patient undergoing advanced diagnostic testing. For every 1-unit increase in  $p_{\text{cuff}}$ , the odds of a patient undergoing advanced diagnostic testing increased by 0.6% ( $P = .009$ ). Increasing Qmax values were associated with decreased odds of a patient undergoing advanced diagnostic testing. A 1-unit increase in Qmax was associated with a 3.3% decrease in the patient's odds of undergoing advanced diagnostics ( $P = .017$ ). A 1-unit increase in FRE was associated with a 2.3% decrease in the patient's odds of undergoing advanced diagnostic testing ( $P < .001$ ). A 1-unit increase in PVR volume was associated with a 0.2% increase in the patient's odds of undergoing advanced diagnostic testing ( $P = .017$ ). This association persisted after adjusting for age, voided volume, BPH medication use, and urodynamic function.

Compared with patients with unobstructed flow, patients with HPHF had more than twice the odds of undergoing advanced diagnostic testing, even

**Table 1. Patient Characteristics, by Urodynamic Function**

Characteristic	Overall (N = 362)	Unobstructed flow (n = 71)	High pressure high flow (n = 119)	Obstructed flow (n = 107)	Low pressure low flow (n = 65)
<b>Age, y</b>					
Mean (SD)	70.2 (8.8)	68.8 (8.3)	68.5 (10.0)	73.7 (7.8)	69.3 (6.7)
Median (IQR)	71.0 (66.0-76.0)	69.0 (64.0-75.0)	69.0 (65.0-75.0)	74.0 (69.0-80.0)	69.0 (66.0-73.0)
Range	31.0-91.0	44.0-87.0	31.0-89.0	54.0-91.0	48.0-85.0
<b>p<sub>cuff</sub><sup>c</sup>, cm H<sub>2</sub>O</b>					
Mean (SD)	144.1 (50.2)	109.2 (25.5)	185.9 (22.5)	162.4 (35.6)	75.4 (23.5)
Median (IQR)	145.9 (103.7-200.0)	106.0 (90.2-128.0)	200.0 (176.0-200.0)	167.2 (128.9-200.0)	75.6 (60.0-94.3)
Range	24.0-202.0	69.4-173.0	117.4-200.0	94.2-202.0	24.0-116.7
<b>Qmax, mL/s</b>					
Mean (SD)	12.4 (7.7)	17.9 (5.1)	17.7 (7.7)	6.8 (2.1)	5.9 (2.7)
Median (IQR)	10.2 (7.0-16.3)	17.0 (14.3-21.0)	15.9 (12.2-21.2)	7.2 (5.0-8.5)	6.1 (3.2-8.0)
Range	1.0-54.1	10.4-34.0	5.0-54.1	2.0-10.2	1.0-10.0
<b>Voided volume, mL</b>					
Mean (SD)	207.7 (138.6)	231.8 (128.5)	303.2 (149.8)	150.0 (75.5)	101.8 (70.0)
Median (IQR)	171.5 (111.0-273.6)	197.0 (140.0-294.0)	276.0 (183.0-393.0)	140.1 (93.4-191.0)	89.0 (55.0-124.0)
Range	14.0-917.0	74.0-673.0	52.0-917.0	19.0-386.0	14.0-323.0
<b>PVR volume, mL<sup>a</sup></b>					
Mean (SD)	97.8 (118.6)	80.7 (105.0)	83.8 (89.1)	112.3 (140.9)	118.4 (135.4)
Median (IQR)	60.0 (15.0-138.0)	33.0 (9.0-120.0)	55.0 (11.0-132.0)	80.0 (25.0-135.0)	73.0 (30.0-152.0)
Range	0.0-1000.0	0.0-520.0	0.0-365.0	0.0-1000.0	0.0-705.0
<b>FRE, mL/cm H<sub>2</sub>O<sup>b</sup></b>					
Mean (SD)	37.0 (21.4)	66.2 (18.1)	38.2 (14.8)	17.5 (5.9)	34.0 (9.2)
Median (IQR)	33.0 (21.0-48.0)	64.0 (49.0-77.0)	36.0 (28.0-44.0)	17.0 (13.0-21.0)	34.0 (27.0-39.0)
Range	5.0-100.0	35.0-100.0	9.0-100.0	5.0-30.0	14.3-54.0
<b>Patients taking BPH medications, No. (%)</b>					
5- $\alpha$ reductase inhibitors	19 (5.2)	3 (4.2)	4 (3.4)	10 (9.3)	2 (3.1)
$\alpha$ -blocker	248 (68.5)	54 (76.1)	87 (73.1)	61 (57.0)	46 (70.8)
Combination therapy	95 (26.2)	14 (19.7)	28 (23.5)	36 (33.6)	17 (26.2)

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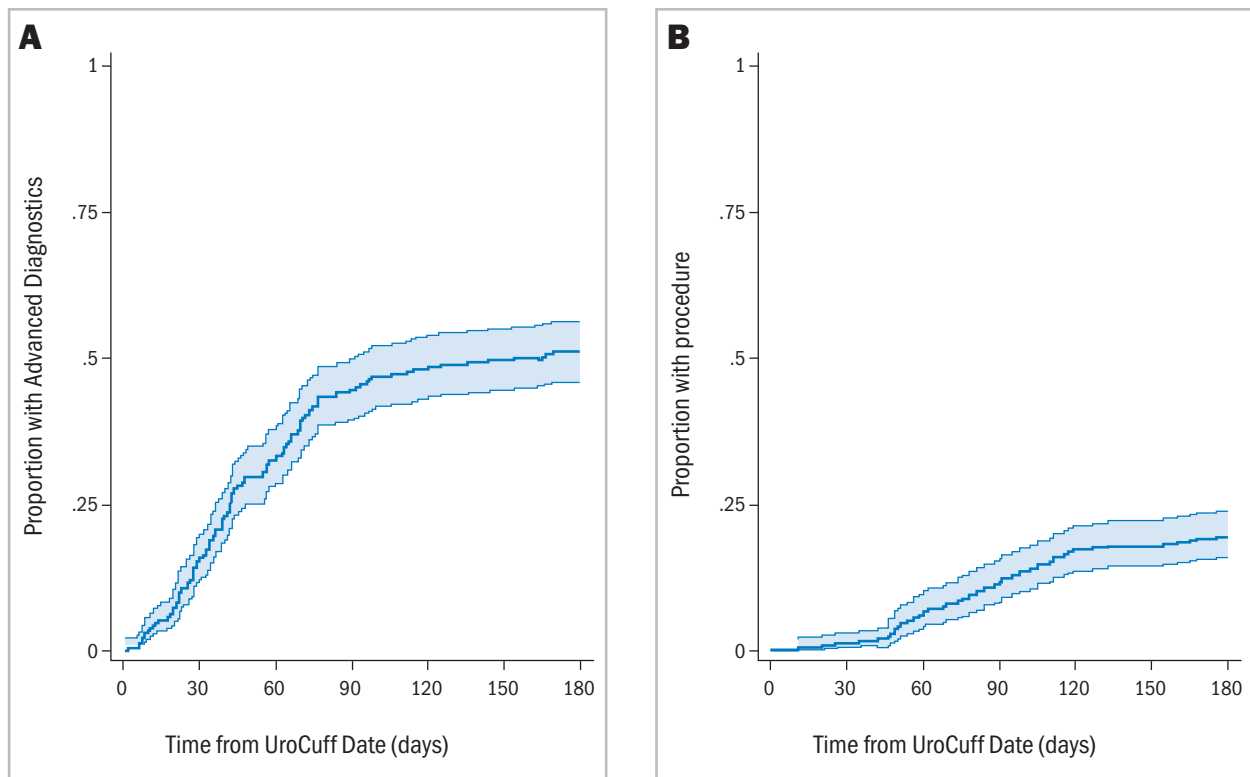
**Table 1. Patient Characteristics, by Urodynamic Function, Continued**

Patients who underwent any advanced diagnostic procedure, No. (%)	195 (53.9)	25 (35.2)	67 (56.3)	70 (65.4)	33 (50.8)
Patients who underwent a specific advanced diagnostic procedure, No. (%)					
Cystoscopy	60 (16.6)	5 (7.0)	23 (19.3)	23 (21.5)	9 (13.8)
Cystoscopy and transrectal ultrasound imaging	104 (28.7)	15 (21.1)	35 (29.4)	38 (35.5)	16 (24.6)
Transrectal ultrasound imaging	26 (7.2)	3 (4.2)	9 (7.6)	8 (7.5)	6 (9.2)
Urodynamic studies (invasive)	4 (1.1)	2 (2.8)	0 (0.0)	1 (0.9)	1 (1.5)
Cystoscopy and urodynamic studies (invasive)	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (1.5)
Time to first advanced diagnostics procedure, d					
No.	195	25	67	70	33
Mean (SD)	51.5 (38.4)	47.8 (35.0)	51.2 (36.8)	51.7 (39.8)	54.3 (42.2)
Median (IQR)	42.0 (25.0-70.0)	43.0 (21.0-69.0)	42.0 (27.0-70.0)	40.5 (28.0-70.0)	49.0 (28.0-70.0)
Range	0.0-179.0	7.0-136.0	0.0-166.0	0.0-179.0	0.0-164.0
Patients who underwent any BPH procedure, No. (%)	77 (21.3)	11 (15.5)	28 (23.5)	23 (21.5)	15 (23.1)
Patients who underwent a specific BPH procedure, No. (%)					
Photoselective vaporization of prostate	20 (5.5)	5 (7.0)	4 (3.4)	5 (4.7)	6 (9.2)
Rezūm (Boston Scientific)	19 (5.2)	1 (1.4)	5 (4.2)	11 (10.3)	2 (3.1)
Simple prostatectomy	1 (0.3)	1 (1.4)	0 (0.0)	0 (0.0)	0 (0.0)
Transurethral resection of the prostate	8 (2.2)	1 (1.4)	2 (1.7)	3 (2.8)	2 (3.1)
UroLift (Teleflex Inc)	29 (8.0)	3 (4.2)	17 (14.3)	4 (3.7)	5 (7.7)
Missing	1 (0.3)	5 (7.0)	4 (3.4)	5 (4.7)	6 (9.2)
Time to BPH procedure, d					
No.	77	11	28	23	15
Mean (SD)	87.6 (39.8)	92.3 (47.1)	77.8 (33.2)	94.4 (42.1)	92.1 (42.2)
Median (IQR)	84.0 (56.0-110.0)	68.0 (50.0-152.0)	79.5 (53.0-100.0)	86.0 (60.0-133.0)	98.0 (56.0-111.0)
Range	10.0-175.0	47.0-168.0	10.0-153.0	25.0-175.0	18.0-175.0

Abbreviations: BPH, benign prostatic hyperplasia; FRE, flow rate efficiency;  $p_{cutoff}$ , maximum pressure required to interrupt the urine void; PVR, postvoid residual; Qmax, maximum flow rate.

<sup>a</sup> Postvoid residual volume data were collected for 106 of 107 patients with obstructed flow, which means data are available for 361 of 362 total patients.

<sup>b</sup> The formula for FRE is calculated from  $p_{cutoff}$  and Qmax but only for  $p_{cutoff}$  values greater than 60 cm. Flow rate efficiency was calculated for 38 of 65 patients with low-pressure low-flow function, which means data are available for 335 of 361 total patients.



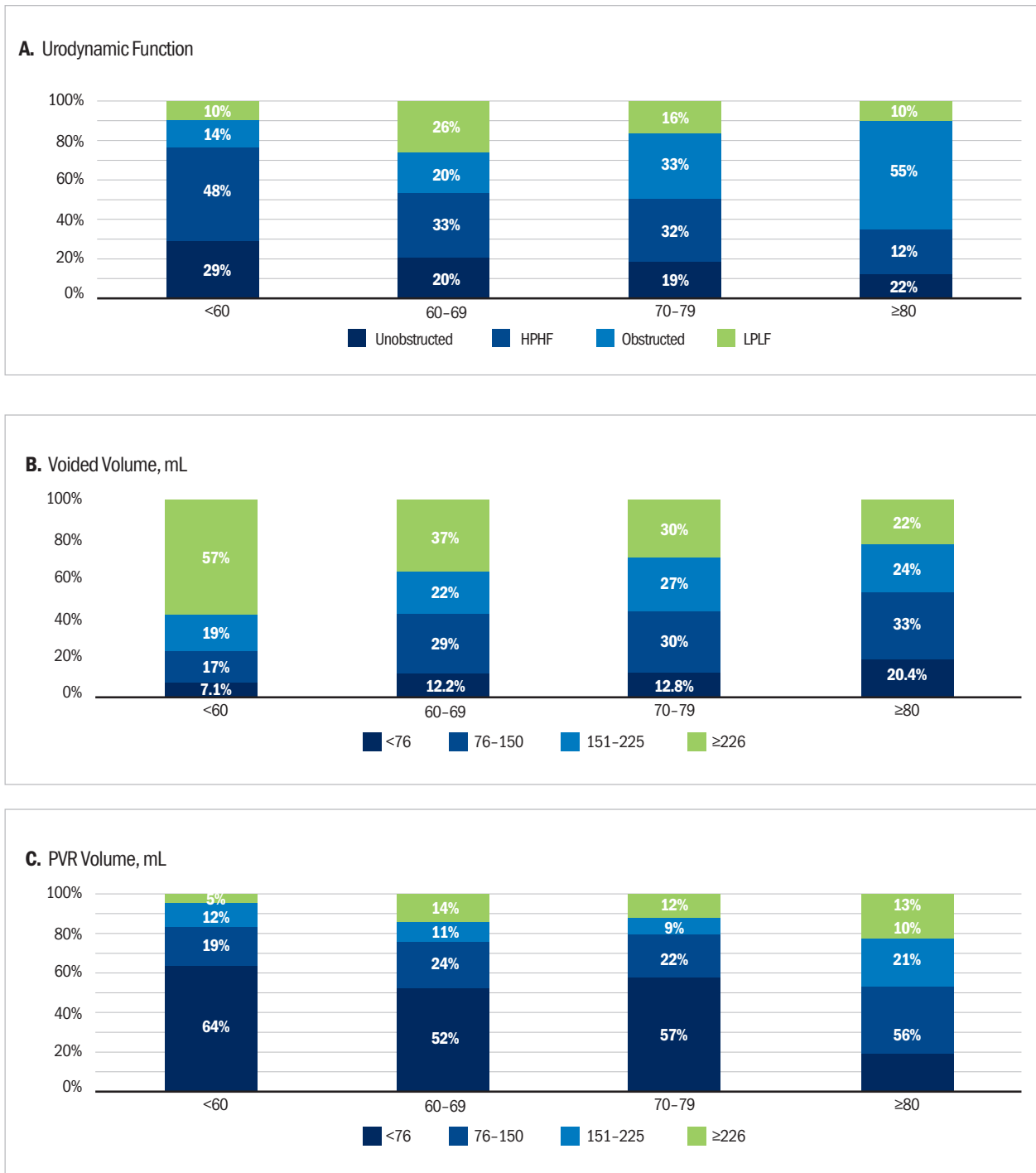
**Figure 1.** Kaplan-Meier curves estimate the proportion of patients who underwent (A) advanced diagnostic testing and (B) benign prostatic hyperplasia procedures for 180 days after the UroCuff Test navigation visit.

after adjusting for age, voided volume, PVR volume, and BPH medication uses (unadjusted  $P = .005$ ; adjusted  $P = .004$ ). Patients with obstructed flow had more than 3 times the odds of undergoing advanced diagnostic tests compared with patients with unobstructed flow, even after adjusting for age, voided volume, PVR volume, and BPH medication use (unadjusted  $P = .001$ ; adjusted  $P = .001$ ). There was no statistically significant difference in the odds of a patient undergoing advanced diagnostic testing between patients with unobstructed flow and patients in the LPLF quadrant, although patients in the LPLF quadrant may have been trending toward increased odds of undergoing advanced diagnostic tests (unadjusted odds ratio, 1.898; adjusted odds ratio, 1.563). Compared with patients on combination therapy—that is, on both 5- $\alpha$  reductase inhibitors and  $\alpha$ -blockers—patients on 5- $\alpha$  reductase inhibitors

alone had 73% lower odds of undergoing advanced diagnostic testing ( $P = .020$ ), an association that remained after adjusting for age, voided volume, PVR volume, and urodynamic function. There was no evidence that patients on  $\alpha$ -blocker therapy had different odds of undergoing advanced diagnostic tests than patients on combination therapy.

### Regression Analyses: Odds of a BPH Procedure

The results from logistic regression modeling of BPH procedures are presented in Table 4. The associations between key characteristics and the occurrence of BPH procedures were similar to but weaker than the associations between key characteristics and the occurrence of advanced diagnostic tests. There was no statistically significant evidence of an association between age,  $p_{\text{cuff}}$ ,  $Q_{\text{max}}$ , or voided volume and the odds of a patient undergoing a BPH procedure.



**Figure 2.** Bar graphs depict (A) urodynamic function, (B) PVR volume, and (C) voided volume, stratified by age group. HPHF, high pressure high flow; LPLF, low pressure low flow; PVR, postvoid residual.



**Table 2. Patient Characteristics, by Occurrence of Advanced Diagnostics and BPH Procedures**

Characteristic	Any advanced diagnostics (n = 195)	No advanced diagnostics (n = 167)	Any BPH procedure (n = 77)	No BPH procedure (n = 285)
<b>Age, y</b>				
Mean (SD)	70.1 (8.7)	70.3 (8.9)	70.8 (7.4)	70.0 (9.1)
Median (IQR)	71.0 (66.0-76.0)	71.0 (66.0-76.0)	72.0 (67.0-76.0)	70.0 (66.0-76.0)
Range	31.0-89.0	44.0-91.0	47.0-85.0	31.0-91.0
<b>Urodynamic quadrant, No. (%)</b>				
Unobstructed	25 (12.8)	46 (27.5)	11 (14.3)	60 (21.1)
High pressure high flow	67 (34.4)	52 (31.1)	28 (36.4)	91 (31.9)
Obstructed	70 (35.9)	37 (22.2)	23 (29.9)	84 (29.5)
Low pressure low flow	33 (16.9)	32 (19.2)	15 (19.5)	50 (17.5)
<b>p<sub>cuff</sub><sup>c</sup>, cm H<sub>2</sub>O</b>				
Mean (SD)	150.5 (47.8)	136.6 (52.2)	148.7 (47.9)	142.8 (50.9)
Median (IQR)	158.2 (108.0-200.0)	129.1 (93.4-200.0)	152.4 (115.1-200.0)	144.1 (101.1-200.0)
Range	24.0-200.0	30.9-202.0	37.7-200.0	24.0-202.0
<b>Q<sub>max</sub>, mL/s</b>				
Mean (SD)	11.5 (6.9)	13.5 (8.4)	11.4 (7.6)	12.7 (7.7)
Median (IQR)	9.5 (7.0-15.3)	12.1 (7.0-18.0)	10.0 (6.1-15.2)	10.4 (7.0-17.0)
Range	1.8-54.1	1.0-42.0	1.8-54.1	1.0-42.0
<b>Voided volume, mL</b>				
Mean (SD)	202.4 (132.9)	214.0 (145.0)	201.2 (138.6)	209.5 (138.7)
Median (IQR)	166.5 (110.0-264.0)	174.1 (114.0-285.0)	161.4 (107.0-269.0)	175.0 (115.2-273.6)
Range	16.0-662.0	14.0-917.0)	(20.0-645.0)	(14.0-917.0)
<b>PVR volume, mL<sup>a</sup></b>				
No.	194	167	77	284
Mean (SD)	111.9 (132.0)	81.4 (98.5)	124.3 (112.3)	90.6 (119.4)
Median (IQR)	75.0 (25.0-150.0)	45.0 (10.0-112.0)	75.0 (34.0-207.0)	53.0 (11.5-122.5)
Range	0.0-1000.0	0.0-520.0	0.0-466.0	0.0-1000.0
<b>FRE, mL/cm H<sub>2</sub>O<sup>b</sup></b>				
No.	185	150	71	264
Mean (SD)	32.3 (18.2)	42.8 (24.2)	31.7 (17.6)	38.5 (22.5)
Median (IQR)	28.0 (19.0-41.0)	37.0 (25.0-60.0)	28.0 (17.0-41.0)	34.0 (21.0-49.0)
Range	6.0-100.0	5.0-100.0	7.0-100.0	5.0-100.0

Continued

**Table 2. Patient Characteristics, by Occurrence of Advanced Diagnostics and BPH Procedures *Continued***

<b>Patients taking BPH medications, No. (%)</b>				
5- $\alpha$ reductase inhibitors	5 (2.6)	14 (8.4)	2 (2.6)	17 (6.0)
$\alpha$ -blocker	136 (69.7)	112 (67.1)	51 (66.2)	197 (69.1)
Combination therapy	54 (27.7)	41 (24.6)	24 (31.2)	71 (24.9)
Patients who underwent any advanced diagnostic procedure, No. (%)	195 (100.0)	0 (0.0)	73 (94.8)	122 (42.8)
<b>Patients who underwent a specific advanced diagnostic test, No. (%)</b>				
Cystoscopy	60 (30.8)	0 (0.0)	11 (14.3)	49 (17.2)
Cystoscopy and transrectal ultrasound imaging	104 (53.3)	0 (0.0)	48 (62.3)	56 (19.6)
Transrectal ultrasound imaging	26 (13.3)	0 (0.0)	12 (15.6)	14 (4.9)
Urodynamic studies (invasive)	4 (2.1)	0 (0.0)	1 (1.3)	3 (1.1)
Cystoscopy and urodynamic studies (invasive)	1 (0.5)	0 (0.0)	1 (1.3)	0 (0.0)
<b>Time to first advanced diagnostic test, d</b>				
No.	195	0	73	122
Mean (SD)	51.5 (38.4)	–	40.8 (30.7)	57.9 (41.1)
Median (IQR)	42.0 (25.0-70.0)	–	39.0 (20.0-62.0)	44.5 (29.0-74.0)
Range	0.0-179.0	–	0.0-147.0	0.0-179.0
Patients who underwent any BPH procedure, No. (%)	73 (37.4)	4 (2.4)	77 (100.0)	0 (0.0)
<b>Patients who underwent a specific BPH procedure, No. (%)</b>				
Photoselective vaporization of prostate	20 (10.3)	0 (0.0)	20 (26.0)	0 (0.0)
Rezūm (Boston Scientific)	15 (7.7)	4 (2.4)	19 (24.7)	0 (0.0)
Simple prostatectomy	1 (0.5)	0 (0.0)	1 (1.3)	0 (0.0)
Transurethral resection of the prostate	8 (4.1)	0 (0.0)	8 (10.4)	0 (0.0)
UroLift (Teleflex Inc)	29 (14.9)	0 (0.0)	29 (37.7)	0 (0.0)
<b>Time to BPH Procedure, d</b>				
No.	73	4	77	0
Mean (SD)	87.5 (39.8)	89.0 (44.7)	87.6 (39.8)	–
Median (IQR)	86.0 (56.0-110.0)	77.0 (62.5-115.5)	84.0 (56.0-110.0)	–
Range	10.0-175.0	49.0-153.0	10.0-175.0	–

Abbreviations: BPH, benign prostatic hyperplasia; FRE, flow rate efficiency;  $p_{cutoff}$ , maximum pressure required to interrupt the urine void; PVR, postvoid residual; Qmax, maximum flow rate.

<sup>a</sup> Postvoid residual volume data were collected for 194 of 195 patients who underwent advanced diagnostic testing and 284 of 285 patients who underwent no BPH procedure.

<sup>b</sup> The formula for FRE is calculated from  $p_{cutoff}$  and Qmax but only for  $p_{cutoff}$  values >60 cm. Flow rate efficiency was calculated for 185 of 195 patients who underwent any advanced diagnostic tests, 150 of 167 patients who underwent no advanced diagnostic tests, 71 of 77 patients who underwent any BPH procedure, and 264 of 285 patients who underwent no BPH procedure.

**Table 3. Odds Ratios for the Occurrence of Advanced Diagnostic Testing, by Patient Characteristic**

Characteristic	Unadjusted odds ratios		Adjusted odds ratios	
	Odds ratio (95% CI)	P value	Adjusted odds ratio (95% CI)	P value
Age	0.997 (0.974-1.021)	.790	0.985 (0.959-1.012)	.286
p <sub>cuff</sub> <sup>a</sup>	1.006 (1.001-1.010)	.009	–	–
Q <sub>max</sub> <sup>a</sup>	0.967 (0.940-0.994)	.017	–	–
Voided volume	0.999 (0.998-1.001)	.431	0.999 (0.997-1.001)	.331
FRE <sup>a</sup>	0.977 (0.966-0.987)	<.001	–	–
PVR volume	1.002 (1.000-1.004)	.017	1.002 (1.000-1.005)	.021
<b>Urodynamic function</b>				
Unobstructed flow	[Reference]	–	[Reference]	–
HPHF	2.371 (1.292-4.350)	.005	2.545 (1.349-4.799)	.004
Obstructed flow	3.481 (1.856-6.531)	<.001	3.650 (1.859-7.168)	<.001
LPLF	1.898 (0.953-3.776)	.068	1.563 (0.736-3.259)	.249
<b>Medications</b>				
Combination therapy	[Reference]	–	[Reference]	–
5- $\alpha$ reductase inhibitor	0.271 (0.090-0.814)	.020	0.219 (0.070-0.685)	.009
$\alpha$ -blocker	0.922 (0.572-1.485)	.738	1.024 (0.614-1.709)	.927

Abbreviations: FRE, flow rate efficiency; HPHF, high pressure high flow; LPLF, low pressure low flow; p<sub>cuff</sub>, maximum pressure required to interrupt the urine void; PVR, postvoid residual; Q<sub>max</sub>, maximum flow rate.

<sup>a</sup> Data for p<sub>cuff</sub>, Q<sub>max</sub>, and FRE were excluded from multivariable logistic regression modeling because of their multicollinearity with urodynamic function.

A 1-unit increase in PVR volume was associated with a 0.2% increase in the odds of a patient undergoing a BPH procedure ( $P = .033$ ). This association persisted after adjusting for age, voided volume, BPH medication use, and urodynamic function. A 1-unit increase in FRE was associated with a 1.6% reduction in the odds of a patient undergoing a BPH procedure ( $P = .020$ ).

Patients with HPHF, obstructed flow, and LPLF had higher odds of undergoing a procedure than patients without obstructions, but none of these associations was statistically significant.

Although the association did not reach statistical significance, compared with patients on combination therapy, patients on 5- $\alpha$  reductase inhibitors alone had 83% lower odds of undergoing a BPH procedure

( $P = .097$ ). This trend remained after adjusting for age, voided volume, PVR volume, and urodynamic function. There was no evidence that patients on  $\alpha$ -blocker therapy had different odds of undergoing a procedure than patients on combination therapy.

Compared with patients who were tested with cystoscopy alone, patients who were tested with both cystoscopy and transrectal ultrasound imaging had more than 4 times the odds of undergoing a BPH procedure ( $P < .001$ ), and patients who were tested with transrectal ultrasound imaging alone had more than 3 times the odds of undergoing a BPH procedure ( $P = .009$ ). There was no evidence that patients who were tested with invasive urodynamic studies had different odds of undergoing a procedure than patients who were tested with cystoscopy alone.

**Table 4. Odds Ratios for the Occurrence of a BPH Procedure, by Patient Characteristic**

Characteristic	Unadjusted odds ratios		Adjusted odds ratios	
	Odds ratio (95% CI)	P value	Adjusted odds ratio (95% CI)	P value
Age	1.011 (0.982-1.041)	.471	1.010 (0.978-1.044)	.531
p <sub>cuff</sub> <sup>a</sup>	1.002 (0.997-1.007)	.366	–	–
Q <sub>max</sub> <sup>a</sup>	0.976 (0.942-1.012)	.185	–	–
Voided volume	1.000 (0.998-1.001)	.641	0.999 (0.997-1.002)	.680
FRE <sup>a</sup>	0.984 (0.970-0.997)	.020	–	–
PVR volume	1.002 (1.000-1.004)	.033	1.002 (1.000-1.004)	.030
<b>Urodynamic function</b>				
Unobstructed flow	[Reference]	–	[Reference]	–
HPHF	1.678 (0.777-3.624)	.187	1.722 (0.780-3.803)	.179
Obstructed flow	1.494 (0.677-3.295)	.320	1.294 (0.564-2.969)	.543
LPLF	1.636 (0.690-3.882)	.264	1.392 (0.551-3.515)	.485
<b>Medications</b>				
Combination therapy	[Reference]	–	[Reference]	–
5- $\alpha$ reductase inhibitor	0.348 (0.075-1.618)	.178	0.337 (0.071-1.595)	.170
$\alpha$ -blocker	0.766 (0.439-1.335)	.463	0.821 (0.460-1.466)	.506
<b>Advanced diagnostics</b>				
Cystoscopy	[Reference]	–	–	–
Cystoscopy and transrectal ultrasound imaging	3.818 (1.787-8.157)	.001	–	–
Transrectal ultrasound imaging	3.818 (1.389-10.494)	.009	–	–
Urodynamic study (invasive)	1.485 (0.141-15.659)	.742	–	–

Abbreviations: BPH, benign prostatic hyperplasia; FRE, flow rate efficiency; HPHF, high pressure high flow; LPLF, low pressure low flow; p<sub>cuff</sub>, maximum pressure required to interrupt the urine void; PVR, postvoid residual; Q<sub>max</sub>, maximum flow rate.

<sup>a</sup> Data for p<sub>cuff</sub>, Q<sub>max</sub>, and FRE were excluded from multivariable logistic regression modeling because of their multicollinearity with urodynamic function.

## Discussion

Multiple studies have shown that men using medical therapy for BPH have a reduced risk of BPH progression.<sup>10-12</sup> These studies, however, typically define BPH progression as an increase in LUTS or the occurrence of urinary retention or surgical intervention and do not include a urodynamic measure of bladder health. Our study underscores the importance of conducting additional diagnostic testing when assessing the progression of BPH.

As men age, they may experience worsening bladder health, which may occur independently of worsening LUTS. We accordingly implemented a navigator-led protocol for patients with BPH featuring the UroCuff Test to assess bladder function and to enhance the standard of care for our growing number of patients with medically managed BPH. The protocol identified and educated patients taking medications for BPH, and then conducted noninvasive urodynamic tests before renewing their prescriptions.

The noninvasive urodynamic testing indicated that a majority of patients on BPH medications had compromised bladder function. The UroCuff Test indicated that only 20% of men had unobstructed urinary flow, and more than 15% of patients had PVR volumes greater than 200 mL. With this new knowledge regarding their bladder function, 53.9% of the men attending noninvasive urodynamic testing visits underwent further diagnostic testing. Upon learning their test results and in consultation with their urologist, 21.3% of these patients had surgical procedures within 180 days of the visit. We believe that these proportions are higher than historically experienced.

Regression testing analyzed the characteristics of patients who underwent advanced diagnostic testing, showing that  $p_{cuff}$ , Qmax, PVR volume, FRE, and urodynamic function results were associated with increased odds of the patient undergoing advanced diagnostic testing. The characteristics associated with the occurrence of a BPH procedure were similar to those associated with the occurrence of advanced diagnostic testing, but most of the associations did not reach statistical significance. This outcome may be a result of the smaller number of patients undergoing BPH procedures, but it also suggests that receiving the results of one's advanced diagnostic tests and consultation with one's urologist had a substantial impact on the final decision to proceed with a BPH procedure.

## Conclusions

The integration of this navigator-led BPH protocol has allowed us to assess bladder health and voiding function before BPH prescription renewal while educating our patients about the importance of maintaining bladder health without putting an additional burden on urologists. We believe this protocol improves clinical outcomes and improves patient satisfaction.

## LIMITATIONS

This study evaluated patient care during the 180 days following a navigated noninvasive urodynamic testing visit. The study was observational and therefore was

not powered to prove a hypothesis. Though we saw trends indicating the influence of urodynamic testing on the occurrence of a subsequent BPH procedure, the sample size was likely too small to statistically demonstrate its impact. In the future, we intend to conduct a statistically powered trial to compare patient care in a navigated group with a control group to better understand the impact of the noninvasive urodynamic testing visit. We will also monitor long-term objective and patient-reported outcomes to better document the factors that influence care for patients with BPH.

## Article Information

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