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Urologic Diseases in America

ANNUAL DATA REPORT

**Benign Prostatic Hyperplasia and Associated
Lower Urinary Tract Symptoms**

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Note

This document is one of the seven that collectively comprise the 2024 *Urologic Diseases in America: Annual Data Report (ADR)*. This document reports and discusses findings on Benign Prostatic Hyperplasia and Associated Lower Urinary Tract Symptoms (BPH/LUTS). Other topics in the 2024 ADR are Introduction and Methods; Urinary Stone Disease (USD); Urinary Incontinence (UI); Urologic Chronic Pelvic Pain Syndrome (UCPPS); Fournier's Gangrene (FG); and Healthcare Expenditures of Urologic Diseases. These analyses are available as separate documents on the UDA website. Additional details on the methodology and data sources are provided in Appendices A and B, respectively, in the Introduction and Methods document.

Suggested citation

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Benign Prostatic Hyperplasia and Associated Lower Urinary Tract Symptoms

Main Takeaways

- The claims-based prevalence of benign prostatic hyperplasia and associated lower urinary tract symptoms (BPH/LUTS) among men aged 40-64 was 5-6% annually from 2012 to 2021; for men aged 65 and older, it was 29-35%.
- BPH/LUTS often co-occurred with hypertension, coronary artery disease, and diabetes among men aged 65 and older.
- In 2020, among men aged 65 and older who were newly identified with BPH/LUTS, 94% underwent serum creatinine testing, 69% had a urinalysis, 63% had a prostate specific antigen (PSA) test, and 22% underwent post-void residual evaluation within 15 months surrounding their diagnosis.
- In 2021, among men recorded with BPH/LUTS, 44% of those aged 40-64 and 60% of those aged 65 and older filled a prescription for a drug with a labelled indication for BPH/LUTS.
- From 2012 to 2021, there was a notable trend towards the utilization of minimally invasive surgical therapy (MIST) procedures. This shift can be attributed to a reduction in the number of patients who underwent laser prostatectomy for BPH/LUTS, and a corresponding increase in the utilization of prostatic urethral lift.

1 Overview

Benign prostatic hyperplasia (BPH) results from an increase in the total number of stromal and glandular epithelial cells within the transition zone of the prostate gland and consequent formation of large, discrete prostatic nodules. As BPH develops, men often experience obstructive and irritative lower urinary tract symptoms (LUTS), such as frequent urination, urgency, nocturia, difficulty starting and stopping urine flow, and a weak urine stream. The symptoms associated with BPH can lead to poorer health status.¹ This section summarizes the evaluation and treatment of BPH/LUTS. Section 2 reports results on prevalence, incidence, comorbidities, and diagnostic testing; prescription drugs filled and procedure use; and resource use, based on contemporary data on the different age cohorts (see 2024 Methods document for details on databases and related methods). Section 3 discusses these results in the context of peer-reviewed literature on BPH/LUTS.

According to the American Urological Association (AUA) guidelines, patients who present with bothersome BPH/LUTS should undergo a medical history, physical exam, assessment of symptom

score, and urinalysis.² The guidelines also suggest performing a post-void residual (PVR) and uroflowmetry if necessary. For patients that are considering surgical therapy, clinicians should consider evaluating prostate size and shape through transrectal or transabdominal ultrasound, cystoscopy, or cross-sectional imaging. In cases of diagnostic uncertainty, urodynamics can be used.³

The management of patients with bothersome BPH/LUTS includes medical and/or surgical therapy. Patients with bothersome BPH/LUTS can be offered an alpha blocker. Additionally, 5-alpha reductase inhibitors (5-ARIs) alone or in combination with alpha blockers can be used to prevent the progression of BPH/LUTS, reduce the risk of urinary retention, and lower the chances of needing BPH surgery. Other medications commonly used for the treatment of symptoms associated with BPH/LUTS includes daily tadalafil, antimuscarinics and beta-3 agonists.

Surgery is a consideration for patients with urinary retention, recurrent urinary tract infections, gross hematuria, and/or BPH/LUTS that is refractory to other therapies. Procedures and pharmacological classes used in the analysis are shown in Table 1 below.

Table 1. Procedures and pharmacological classes considered for BPH/LUTS analysis

Procedures	Pharmacological Classes
<ul style="list-style-type: none"> • Simple prostatectomy <u>Transurethral surgery</u> • Transurethral resection of the prostate (TURP) • Laser prostatectomy • Laser enucleation <u>Minimally invasive surgical therapy (MIST)</u> • Transurethral incision of the prostate (TUIP) • Transurethral needle ablation (TUNA) • Transurethral microwave therapy (TUMT) • Water vapor thermal therapy (WVTT) • Robotic waterjet treatment (RWT) • Prostatic urethral lift (PUL) • Prostate artery embolization (PAE) 	<ul style="list-style-type: none"> • Alpha blocker • 5-alpha reductase inhibitor • Alpha-blocker/5-alpha reductase inhibitor • Phosphodiesterase type 5 (PDE5) inhibitor (tadalafil 5mg)

2 Results

→ Study population

Table 2 shows the total number of patients with BPH/LUTS as well as the total population in each cohort in 2021 (note the cohorts in Medicare Advantage [MA] and Medicaid are only discussed for results on prevalence and comorbidities).

Table 2. Total number of male patients with BPH/LUTS, 2021

Population	Commercial insurance Age 40-64	Medicare FFS Age 65+	Medicaid Age 40+	MA Age 65+
Total	1,548,599	10,779,115	5,974,818	9,268,173
Patients with BPH/LUTS	95,282	3,573,283	339,768	3,198,826

→ Prevalence

The overall claims-based period prevalence of BPH/LUTS ranged from 5% to 6% from 2012 to 2021 among privately insured men aged 40-64 and from 29% to 33% among men aged 65 and older in Medicare FFS (Figure 1a). Prevalence of BPH/LUTS ranged from 31% to 35% from 2015 to 2021 for men aged 65 and older in MA. Prevalence of BPH/LUTS was approximately 6% from 2016 to 2021 for men aged 40 and older in the Medicaid population. Prevalence for BPH/LUTS was associated with age (Figure 1b).

Figure 1a. Claims-based prevalence of BPH/LUTS, by year and insurance type (2012-2021)

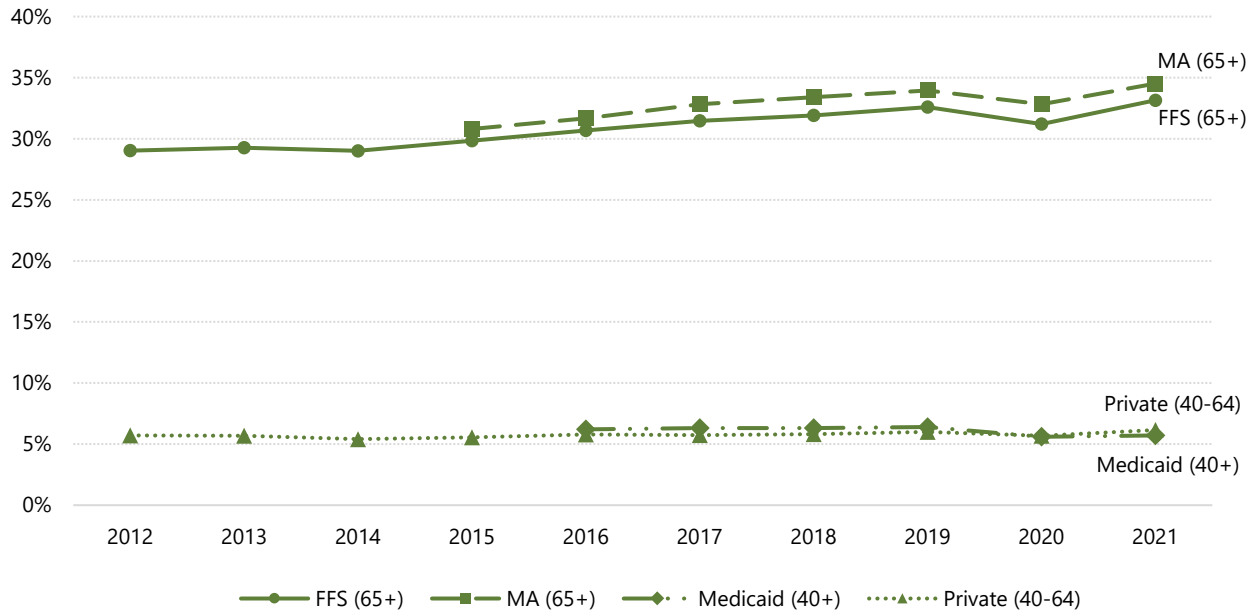
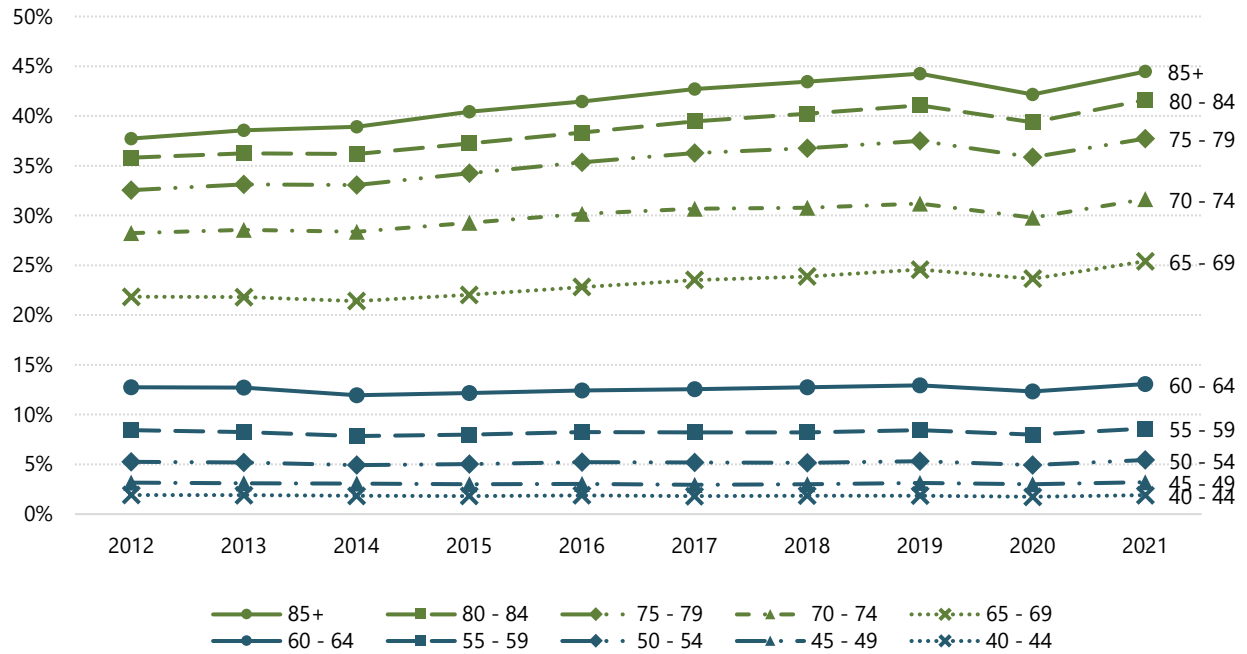


Figure 1b. Claims-based prevalence of BPH/LUTS, by year and age (2012-2021)



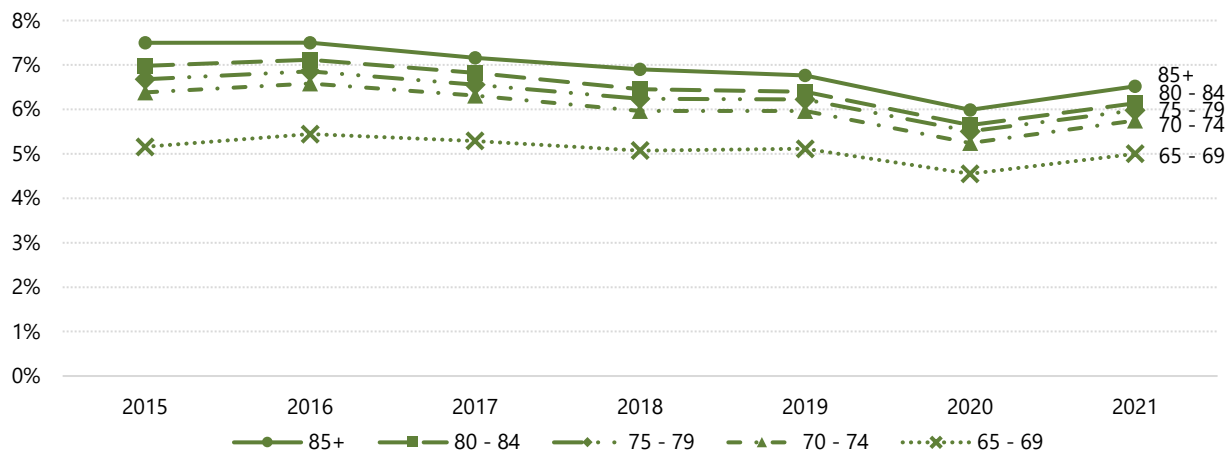
Notes: In panel (a), for each age cohort, denominator denotes the total number of persons under each type of insurance. In panel (b), denominator denotes the total number of persons in each age cohort among those in commercial insurance (age 40-64) or in Medicare FFS (age 65+).

Among men aged 65 and older in Medicare FFS, the prevalence of BPH/LUTS was higher for patients identifying as White compared with patients reporting other races. In 2021, the prevalence of BPH/LUTS for Whites aged 65 and older was 34%, compared to 30% for Blacks, 32% for Asians, and 24% for Hispanics. Prevalence was higher in the Northeast (36%; 2021) and South (34%) compared to the Midwest (31%) and West (31%). We did not see substantial differences in prevalence rates between patients who were eligible for Medicare and Medicaid compared with patients who were not. Patterns were similar for men aged 65 and older in MA.

→ Incidence

Among men aged 65 and older, the average incidence of BPH/LUTS was approximately 600 per 10,000 men (or 6%) per year from 2015 through 2021. This translates into an average of approximately 600,000 men aged 65 and older who were newly identified with BPH annually. Average annual incidence ranged from 4% to 8% across age subgroups (Figure 2). The percentage of men with incident BPH/LUTS declined slightly throughout 2015-2020 but to a greater extent in 2020, presumably a result of fewer (or delayed) diagnoses for patients who may not have been (or were not able to be) seen in clinics due to the COVID-19 pandemic.

Figure 2. Claims-based incidence of BPH/LUTS, by year and age (2015-2021)



Notes: Numerator denotes number of patients with incident BPH/LUTS aged 65 and older in each year. Denominator denotes total number of beneficiaries (Medicare FFS) in each year.

→ Comorbidities

The prevalence and type(s) of comorbidities among men with BPH/LUTS varied by age group. In 2021, among men aged 40-64 with BPH/LUTS, hypertension (56%), obesity (28%), diabetes (22%), and erectile dysfunction (23%) were common comorbidities. Among men aged 65 and older, hypertension (81%), coronary artery disease (39%), diabetes (35%), and chronic kidney disease (25%) were common comorbidities (Figure 3a,b). Notably, the prevalence of these comorbidities was higher among men with BPH/LUTS compared to the overall male population in the same age group.

Figure 3a. Common comorbidities among men living with BPH/LUTS, age 40-64 (2021)

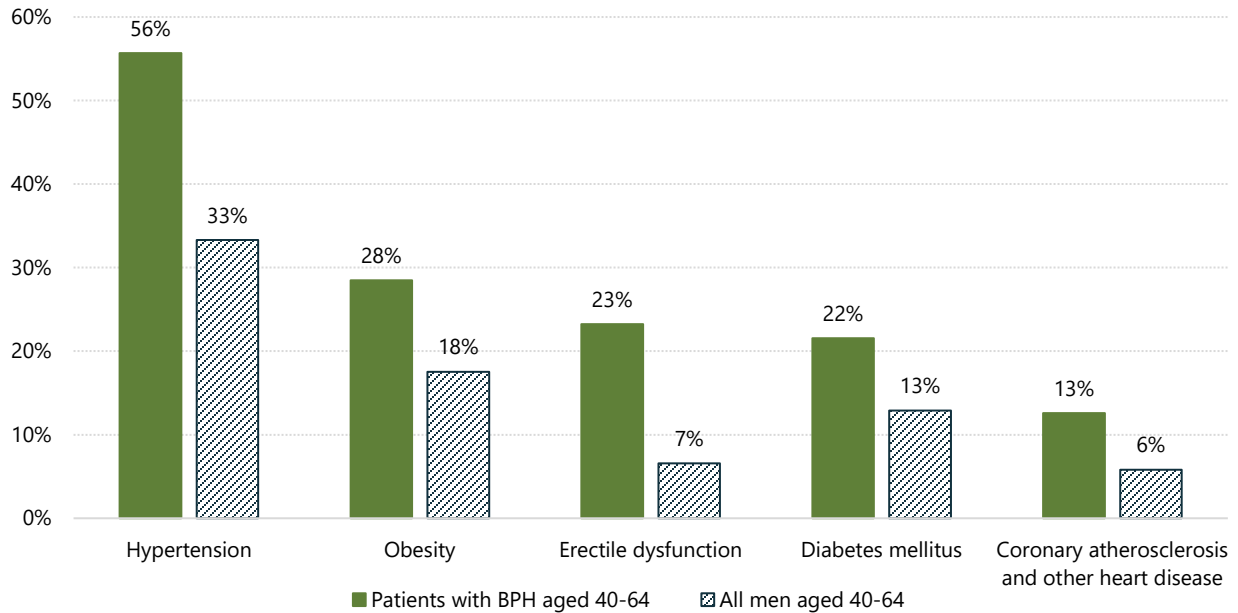
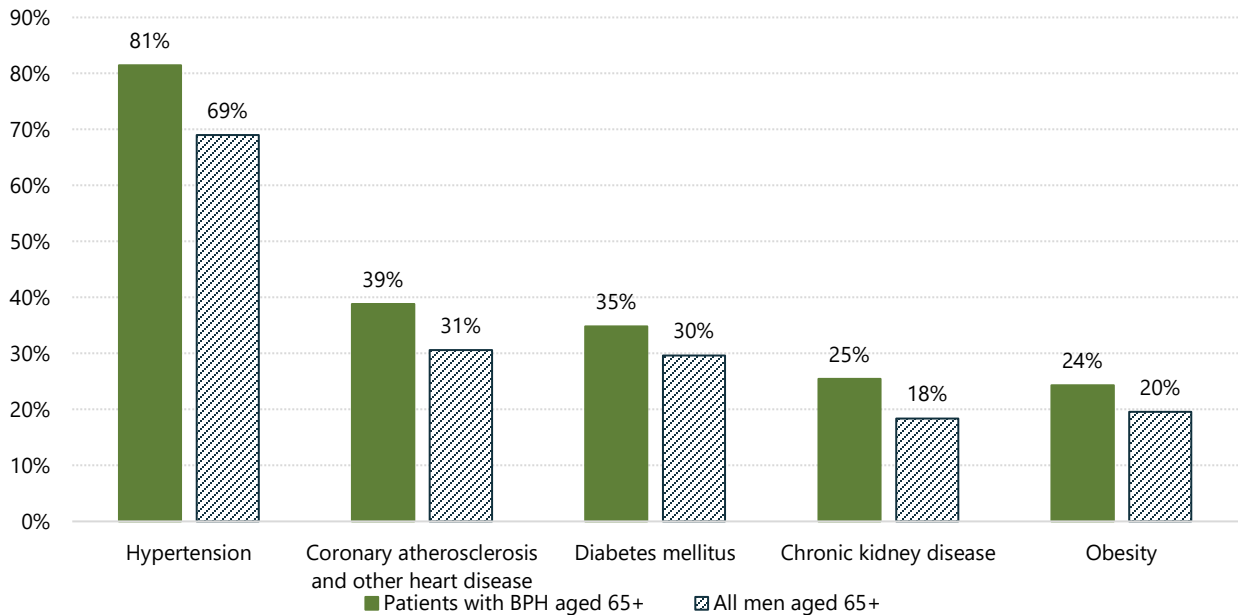


Figure 3b. Common comorbidities among men living with BPH/LUTS, age 65+ (2021)



Notes: Columns in solid denote percentage of patients with BPH/LUTS who were also identified with the comorbidity referenced. Columns in patterns denote the analogous metric for all men (including those without BPH/LUTS) in each referenced age cohort. The age 40-64 cohort refers to those in commercial insurance, while the age 65+ cohort refers to those in Medicare FFS.

In some instances, the progression of BPH/LUTS may lead to concurrent conditions like gross hematuria. Our analysis of three concurrent conditions that may be consequences of BPH/LUTS

progression (urinary retention, urinary tract infection, and gross hematuria) indicated that in 2021 among men with BPH/LUTS, 8% of privately insured men aged 40-64 and 15% of men aged 65 and older in Medicare FFS had urinary retention. Furthermore, 10% of privately insured men aged 40-64 had a urinary tract infection, compared to 18% of men aged 65 and older in Medicare FFS. The occurrence of gross hematuria was also common among men with BPH/LUTS, with rates of 8% for men aged 40-64 and 11% for those aged 65 and older. Patterns were broadly similar among those in MA and Medicaid for the same age groups.

Seven percent of patients with incident BPH/LUTS were recorded with urinary retention within 4 years of the incident diagnosis. Of these patients, 23% had a procedure within a year of recording of urinary retention, with TURP being the most common procedure (58% of the procedures). The average time from the recording of urinary retention to the procedure was 68 days.

→ Diagnostic tests

We evaluated the use of diagnostic testing 3 months before and 12 months after diagnosis in men who were newly identified with BPH/LUTS and who were aged 65 and older. Use of diagnostic tests varied little between 2015 and 2020, with more than 97% of patients receiving any diagnostic test in 2020. The use of diagnostic testing among North American Natives (84%) was lower than for other groups (95-97%).

Serum creatinine (94%), urinalysis (69%), and prostate specific antigen (PSA) (63%) were the most commonly ordered diagnostic tests. Post-void residual urine was assessed in 22% of cases, while other tests such as renal ultrasound (20%), cystoscopy (12%), transrectal ultrasound (5%), urodynamics (2%), and pelvic MRI (4%) were performed less frequently.

→ Prescription drugs

In 2021, among men diagnosed with BPH/LUTS, 44% of those aged 40-64 and 60% of those aged 65 and older filled a prescription for a drug with a labeled indication for BPH/LUTS.

In 2021, alpha blockers were the most commonly prescribed medication with a labeled indication for BPH/LUTS, accounting for 39% and 53% of prescriptions filled among men aged 40-64 and 65 and older, respectively. 5-alpha-reductase inhibitor prescriptions were filled by 8% and 22% of patients in the same respective age groups. Meanwhile, prescriptions for phosphodiesterase type 5 inhibitors (specifically tadalafil 5mg) were filled by 5% and less than 1% of patients, respectively.

The percentage of men aged 65 and older filling prescriptions for alpha blockers increased slightly, from 49% to 53% between 2012 and 2021. In contrast, prescriptions for 5-alpha-reductase inhibitors remained relatively stable at around 23%. The percentage of men aged 65 and older who filled prescriptions for phosphodiesterase type 5 inhibitors (tadalafil 5mg) and combination therapy drug formulations that include both an alpha blocker and 5-alpha reductase inhibitor into a single pill remained less than 1% throughout the study period.

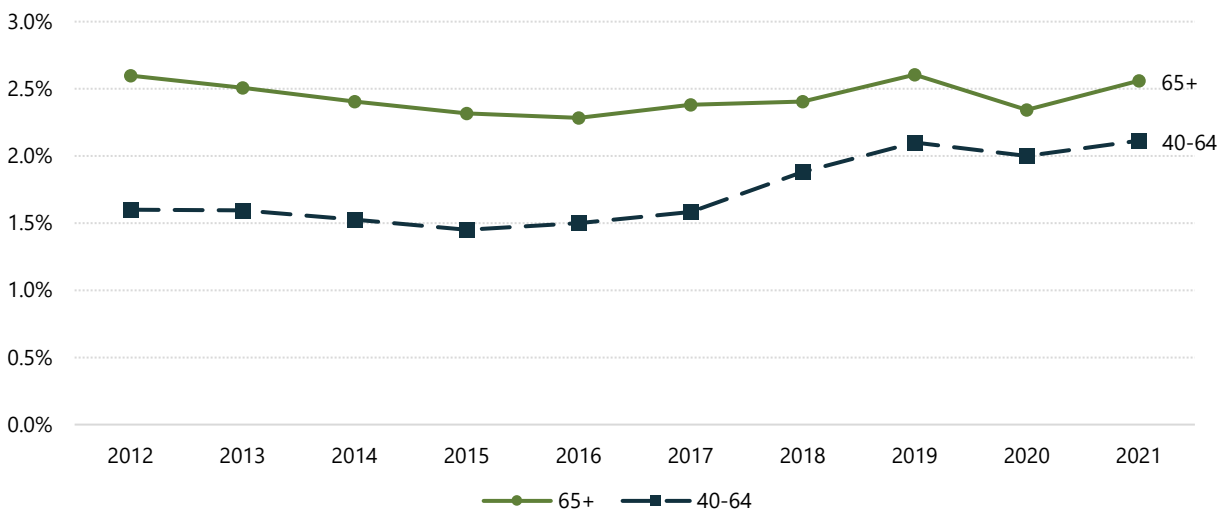
Among men aged 65 and older and newly identified with BPH/LUTS, 63% of patients filled a prescription for a drug with a labelled indication for BPH/LUTS within 5 years of diagnosis. 85% of patients' first drug prescribed was an alpha blocker; and 14.3% was for alpha reductase inhibitors. The average time to first filled prescription within 5 years after initial diagnosis in 2015 was 9.0 months.

For patients with incident BPH/LUTS, 16% were on combination therapy (using alpha blockers and 5 alpha reductase inhibitors simultaneously) within 5 years after incident diagnosis. For patients on combination therapy, more than half were on it within a year of incident diagnosis.

➔ **Procedures**

Between 2012 and 2021, an average of 1.7% of men aged 40-64 with BPH/LUTS and 2.4% of men aged 65 and older underwent any BPH/LUTS-related procedure (Figure 4).

Figure 4. Percent of patients with BPH/LUTS who underwent any BPH/LUTS-related procedure, by age (2012-2021)



Notes: BPH/LUTS-related procedures refer to those listed in Table 1. The age 40-64 cohort refers to those in commercial insurance, while the age 65+ cohort refers to those in Medicare FFS.

Transurethral surgery remained the most frequently utilized surgical category, though there had been growing use of minimally invasive surgical therapies (MIST). Among men aged 65 and older, the most commonly performed transurethral surgery was transurethral resection of the prostate (TURP) (Figure 5a), whereas the use of laser prostatectomy declined over the study period, likely due to the increasing popularity of laser enucleation and MIST (Figures 5a,b). The growing use of MIST is contributed by the rise of prostatic urethral lift (PUL). Additionally, the use of transurethral microwave thermotherapy (TUMT) decreased over time. Trends in the use of individual BPH surgeries observed in Figures 5a and b were similar among men aged 40-64.

Of the 2015 incident cohort aged 65 and older with BPH/LUTS, 7.0% underwent BPH-related procedures within five years of diagnosis. During this period, TURP was the most commonly performed procedure, accounting for half of the initial procedures, followed by laser prostatectomy (22%) and PUL (12%). On average, patients received their first procedure within 23 months after the initial diagnosis in 2015.

For patients with incident BPH/LUTS, 5.6% had a BPH-related procedure within 4 years of diagnosis. For these patients, 5.0% had a retreatment within 2 years of the first surgery. The rates of retreatment for MIST and transurethral procedures were 11.0% and 3.3%, respectively. The average times to retreatment after transurethral procedures and MIST were 333 and 307 days, respectively.

Figure 5a. Transurethral surgery types and their frequencies among patients aged 65+ with BPH/LUTS (2012-2021)

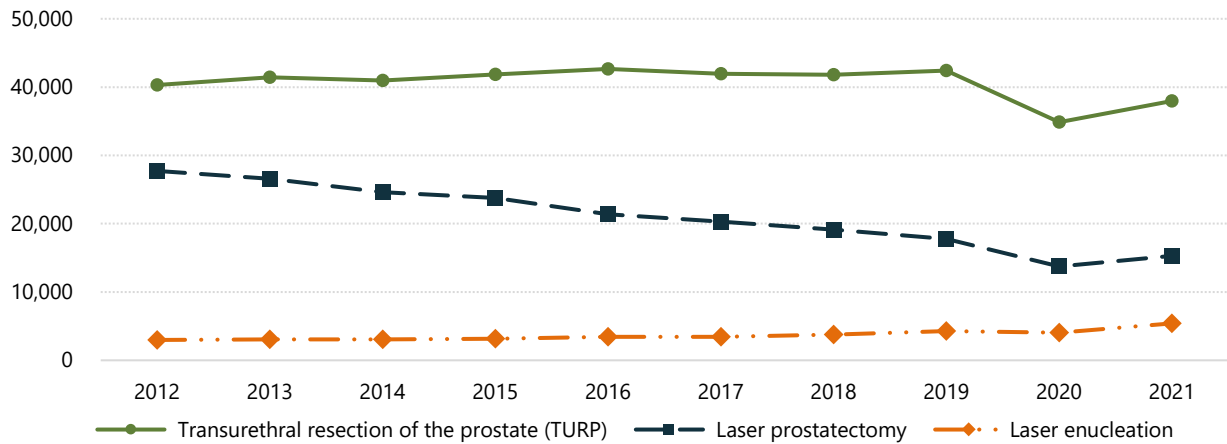
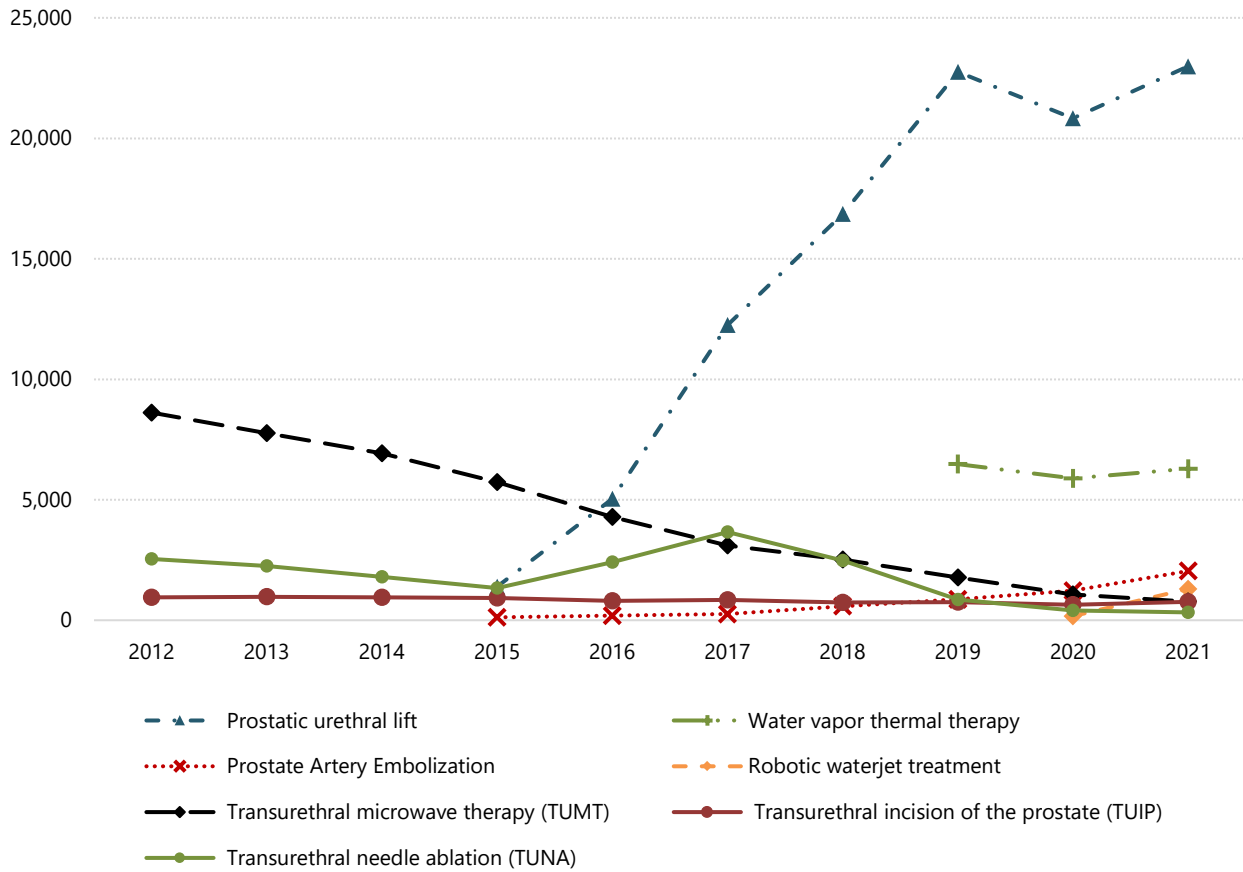


Figure 5b. MIST surgery types and their frequencies among patients aged 65+ with BPH/LUTS (2012-2021)



Notes: This panel shows the number of patients with BPH/LUTS who received each BPH/LUTS-related procedure referenced (Medicare FFS). Data points where values are less than 100 are not shown for presentational clarity.

→ Service utilization

On average, patients aged 65 and older with an incident diagnosis of BPH/LUTS between 2015 and 2020 had 2.7 Evaluation and Management (E&M) visits within 12 months. During the same period, less than 1% of the same group had an inpatient hospitalization, less than 1% had an observation stay, and 4% had an emergency department visit with a primary diagnosis of BPH/LUTS within 12 months after their initial diagnosis.

For patients with incident BPH/LUTS, 53% underwent an E&M visit with a urologist within five years of their initial diagnosis and the average time to the urologist visit was under 7 months. Additionally, 47% of patients with incident BPH/LUTS saw a urologist within 3 years of their incident diagnosis, and 9% underwent a procedure within the following 2 years after their urologist consultation.

3 Discussion

BPH/LUTS is a very common disorder among men aged 65 and older, affecting 1 in 3; an average of approximately 600,000 new cases are identified annually. BPH/LUTS commonly co-occurs with hypertension, obesity, diabetes, and coronary artery disease. Lab and urine tests are the most frequently performed in the first year after BPH/LUTS diagnosis, with low frequency of cystoscopy and imaging. Medical management of BPH/LUTS was stable over the years studied, with 3 out of 5 men aged 65 and older filling a prescription drug with a labeled indication for BPH/LUTS. While TURP remained the most frequent procedure, there was a trend towards more MIST for BPH/LUTS.

Literature-based prevalence of BPH/LUTS vary, presumably as a consequence of differences in the definition and clinical assessments of BPH/LUTS. Herein, we defined prevalence as the number of men per year who had a claim for BPH/LUTS. BPH typically begins to develop by the age of 40, with autopsy studies indicating that 90% of men over the age of 80 exhibit histological evidence of BPH.⁴ Although our claims-based prevalence suggests that a considerable number of men with BPH/LUTS seek medical attention from clinicians, self-reported rates of BPH/LUTS may be higher. This is because the latter may encompass persons who do not seek medical care for their symptoms.

Literature-based incidence also has varied among published studies, again likely due to variance in ascertainment criteria among studies.⁵ The Prostate Cancer Prevention Trial reported an incidence of 34 cases of BPH per 1000 person-years, while the Olmstead County study estimated the overall incidence of BPH to be 854.7 cases per 100,000 men.^{6,7} The Health Professionals Follow-up Study reported that the incidence of moderate and severe LUTS was 41 and 19 cases per 1000 person-years, respectively.⁸

We found that obesity, diabetes, erectile dysfunction, coronary artery disease, and chronic kidney disease were common comorbidities among men with BPH/LUTS. This finding aligns with other studies that have explored comorbidities in men with BPH/LUTS.⁹ Furthermore, we found that urinary retention, gross hematuria, and urinary tract infections were associated with BPH/LUTS. These conditions may be a consequence of BPH/LUTS progression. Our results showed that 7% of patients developed urinary retention within 4 years of incident diagnosis. This is higher than estimates in the literature.¹⁰ These differences could be due to compositional differences in patient characteristics such as age and comorbid conditions.

Our findings indicated that serum creatinine was the most frequent diagnostic test ordered 15 months surrounding BPH/LUTS diagnosis, followed by urinalysis and PSA. The utilization of post-void residual, cystoscopy, and prostate imaging tests was lower than what the AUA guidelines might suggest, potentially because patients in our cohort may have been mildly symptomatic and did not warrant further diagnostic testing. Furthermore, diagnostic practices may have varied among treating physicians based on their specialties.¹¹

Our analysis on prescriptions filled for drugs indicated for BPH/LUTS did not show major changes in the medical management of BPH/LUTS. In the 2018 ADR, we observed a rising trend in the

percentage of men aged 65 and older who filled a prescription for a drug indicated for BPH/LUTS, increasing from 57% in 2006 to 61% in 2013. However, this trend has since stabilized. Alpha blockers remain the most commonly prescribed medication for BPH/LUTS. We found that the percentage of patients aged 65 and older who filled a prescription for a 5-alpha reductase inhibitor was 2.5 times lower than those who filled a prescription for an alpha blocker. Additionally, despite FDA approval for over a decade, daily tadalafil 5mg usage remained low, with less than 1% of patients filling a prescription from 2012 to 2021. Our results showed that only 16% of incident patients were put on combination therapy (alpha blocker and 5-alpha reductase inhibitor) within 5 years of incident diagnosis. Given that combination therapy has been found to be an effective intervention for patients with BPH/LUTS, exploring the reasons behind its relatively low uptake may be a worthwhile area for future research.¹²

The use of MIST relative to transurethral surgery increased. The growth of MIST coincided with the introduction of new therapies such as prostatic urethral lift and water vapor thermal therapy. While evidence suggests that MIST may not mitigate LUTS to the same degree as surgical therapy, it is often associated with a more favorable side effect profile and is marketed as an alternative to medical and surgical management. Given that our analysis found that overall rates of all BPH surgery remained consistent from 2012 through 2021, it appears that MIST is being used as a substitute for transurethral surgery. Our results showed that patients who had MIST procedures had higher rates of subsequent BPH procedure within 2 years compared to those that had transurethral surgeries. This important finding should be incorporated by urologists when counseling patients regarding the risks and benefits of MIST. Further, TURP was the most common form of retreatment after first MIST or transurethral surgery, which suggests TURP remains a highly utilized and effective treatment method for BPH. The lower retreatment rate of TURP relative to MIST in our findings is consistent with results from a recent study.¹³

Our results showed that more than 50% of patients had an E&M visit with a urologist within 5 years of the incident diagnosis, most within 3 years. This suggests that in the long run, a sizable portion of patients with BPH/LUTS is seen by a urologist.

Our analysis has several limitations. It is not feasible to assess symptom level/score from claims data. Any claims-based approach is likely to underestimate the prevalence and incidence of BPH/LUTS, and would not capture precisely the severity or complications of BPH/LUTS. In addition, some clinical evaluations may be done in the office – such as urine dipsticks and PVR – but not result in the filing of a claim for reimbursement. Because the uncertainty in estimating the full burden of illness associated with BPH/LUTS, future research to bridge this gap would assist policy makers in prioritizing research funding, medical staff training, and creating financial incentives to address the needs of the large – known and unknown – population of men with BPH/LUTS.

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