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Urologic Diseases in America

ANNUAL DATA REPORT

Chapter 2: Benign Prostatic Hyperplasia and Associated Lower Urinary Tract Symptoms in Men

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Note

This chapter is the second of four chapters in the 2023 *Urologic Diseases in America: Annual Data Report (ADR)*. It reports and discusses findings on benign prostatic hyperplasia and associated lower urinary tract symptoms (BPH/LUTS) in men. Other chapters in the 2023 ADR are Chapter 1: Introduction and Methods; Chapter 3: Urinary Stone Disease (USD); and Chapter 4: Urinary Incontinence (UI). These chapters are available under separate links on the UDA website. Chapter 1 introduces the 2023 ADR and describes the methodology underlying this chapter. Additional details on the methodology and data sources are provided in Appendices A and B, respectively, that accompany Chapter 1.

Suggested citation

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2 Benign Prostatic Hyperplasia and Associated Lower Urinary Tract Symptoms in Men

Main Takeaways

- The claims-based prevalence of BPH/LUTS among men aged 40-64 was 5-6% annually from 2012 to 2021, whereas for men aged 65 and above, it was 29-33%.
- BPH/LUTS often co-occurred with hypertension, coronary artery disease, and diabetes among men aged 65 and above. In 2021, the rates of these comorbidities were 81%, 39%, and 35% of patients with BPH/LUTS, respectively.
- In 2020, among men aged 65 and above who were newly identified with BPH/LUTS, 94% underwent serum creatinine testing, 69% had a urinalysis, 63% had a 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 above 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 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.

2.1 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 subsection summarizes the evaluation and treatment of BPH/LUTS. Section 2.2 reports results on prevalence, incidence, comorbidities, and diagnostic testing; prescription drugs filled and procedure use; and resource use, based on contemporary data on the two age cohorts (see Chapter 1 for details on databases and related methods). Section 2.3 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 2.1 below.

Table 2.1. 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)

2.2 Results

→ Study population

Table 2.2 shows the total number of patients with BPH/LUTS as well as the total population in each cohort in 2021.

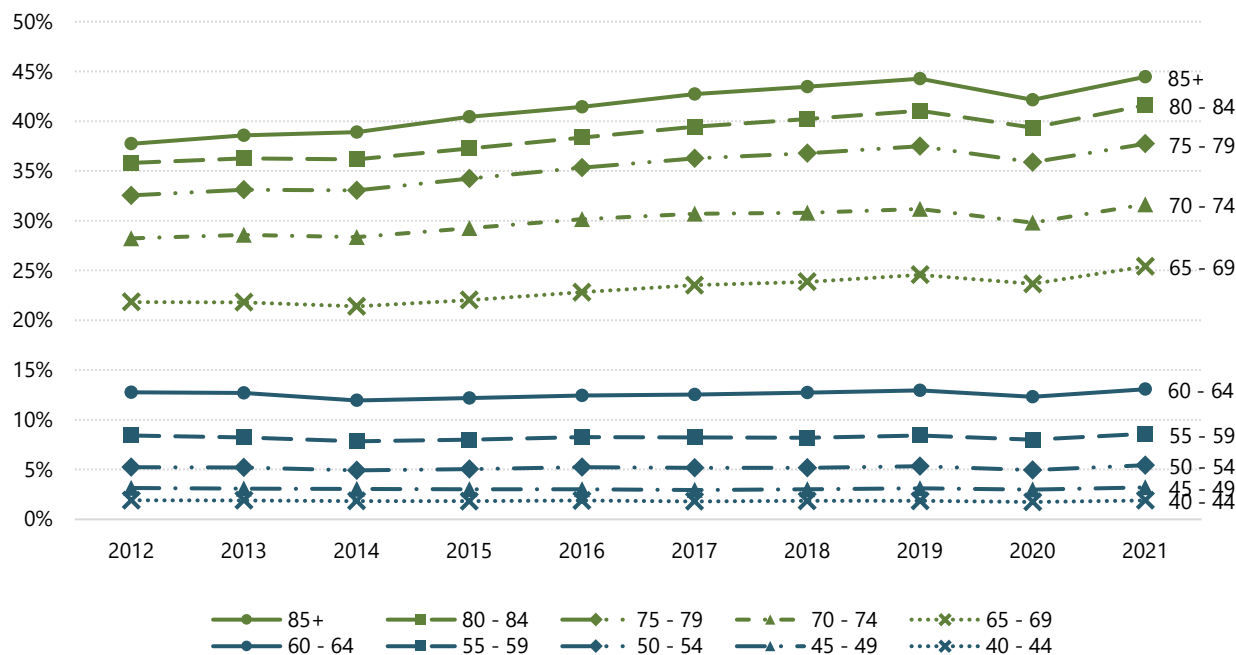
Table 2.2. Total number of patients with BPH/LUTS, 2021

	Age 40-64	Age 65+
	Male	Male
Total Population	1,548,599	10,779,115
Patients with BPH/LUTS	95,282	3,573,283

→ Prevalence

The overall claims-based period prevalence of BPH/LUTS ranged from 5% to 6% from 2012 to 2021 in men aged 40-64 and from 29% to 33% in men aged 65 and older. Claims-based period prevalence for BPH/LUTS was associated with age (Figure 2.1).

Figure 2.1. Claims-based prevalence of BPH/LUTS, by year and age (2012-2021)



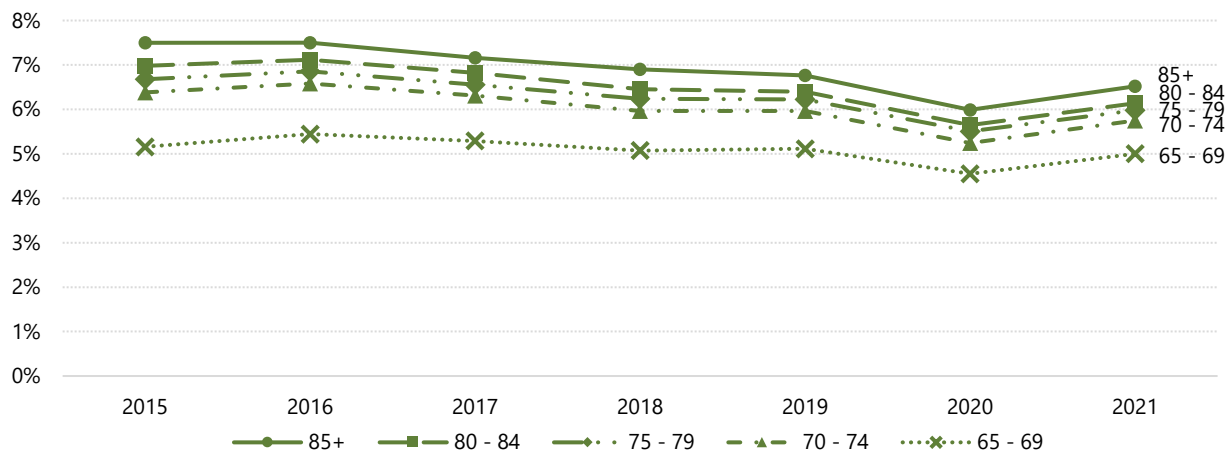
Notes: For ages 65 and older, denominator denotes number of restricted male Medicare FFS beneficiaries in each age bracket. For ages 40-64, denominator denotes number of restricted male privately insured CDM enrollees in each age bracket.

Among men aged 65 and older, the prevalence of BPH/LUTS was higher for patients identifying as Non-Hispanic White compared with patients reporting other races. In 2021, the prevalence of BPH/LUTS for Non-Hispanic 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.

➔ **Incidence**

Among men 65 years 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 2.2). 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 2.2. 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 number of restricted male Medicare FFS age-eligible beneficiaries 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 2.3a,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 2.3a. Common comorbidities among men living with BPH/LUTS, age 40-64 (2021)

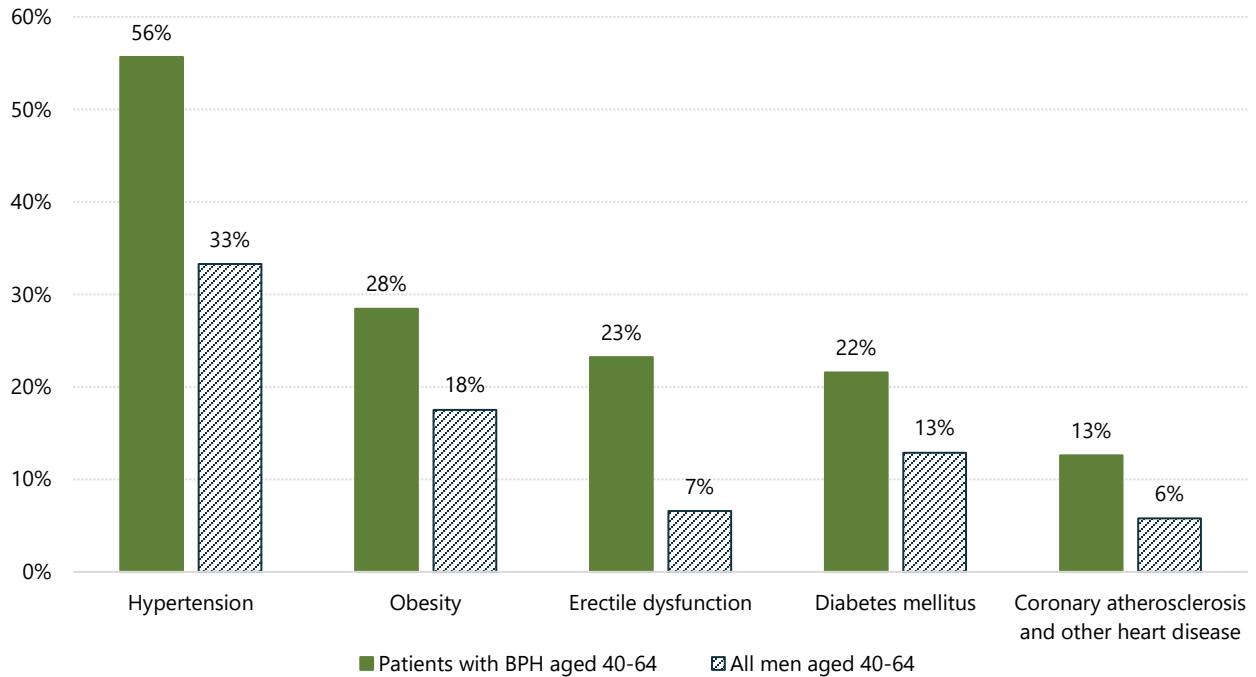
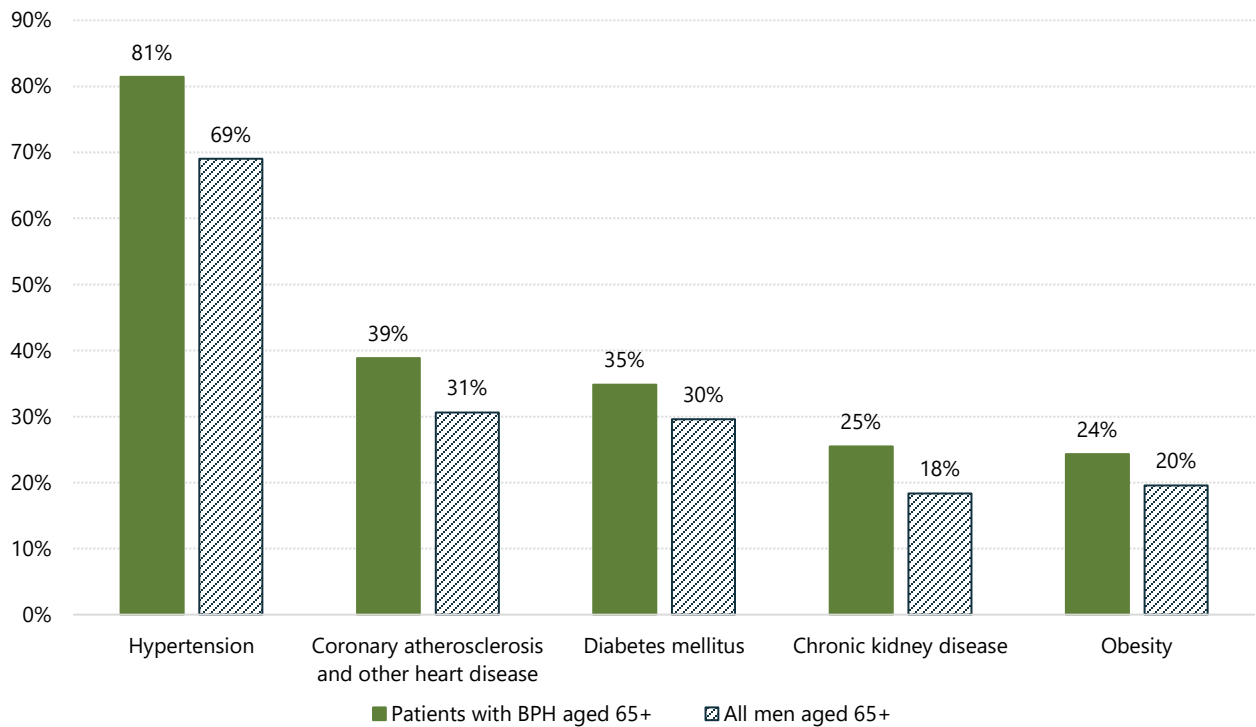


Figure 2.3b. Common comorbidities among men living with BPH/LUTS, age 65+ (2021)



Notes: Columns in solid denote percentage of patients with BPH/LUTS who are also identified with the comorbidity referenced. Columns in patterns denote the analogous statistic for all men (including those without BPH/LUTS) in each referenced age cohort.

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 men aged 40-64 and 15% of men aged 65 and older developed urinary retention. Furthermore, 10% of men aged 40-64 developed a urinary tract infection, compared to 18% of men aged 65 and above. 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 above.

→ 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 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 above 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 above, 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 above 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 above 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.

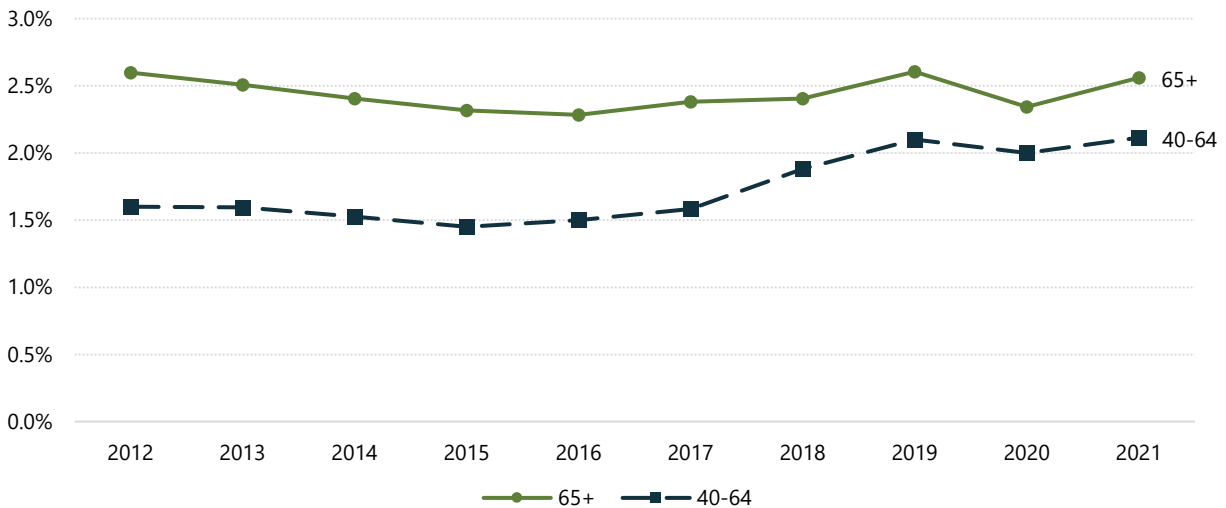
Among men aged 65 and older and newly identified with BPH/LUTS, 63% of patients filled a prescription for a drug with a labelled indication for BPH/LUTS within 5 years of diagnosis. 85% of patients' first drug prescribed was an alpha blocker; and 14.3% was for alpha reductase inhibitors.

The average time to first filled prescription within 5 years after initial diagnosis in 2015 was 9.0 months.

→ 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 above underwent any BPH/LUTS-related procedure (Figure 2.4).

Figure 2.4. 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 2.1. Ages 40-64 refers to male CDM privately insured enrollees. Ages 65+ refers to male Medicare FFS beneficiaries.

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 above, the most commonly performed transurethral surgery was transurethral resection of the prostate (TURP) (Figure 2.5a), whereas the use of laser prostatectomy declined over the study period, likely due to the increasing popularity of laser enucleation and MIST (Figures 2.5a,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 2.5a and b were similar among men aged 40-64.

Of the 2015 incident cohort aged 65 and above with BPH/LUTS, 7.6% 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 (21 percent) and PUL (12 percent). On average, patients received their first procedure 23 months after the initial diagnosis in 2015.

Figure 2.5a. Transurethral surgery types and their frequencies among patients aged 65+ with BPH/LUTS (2012-2021)

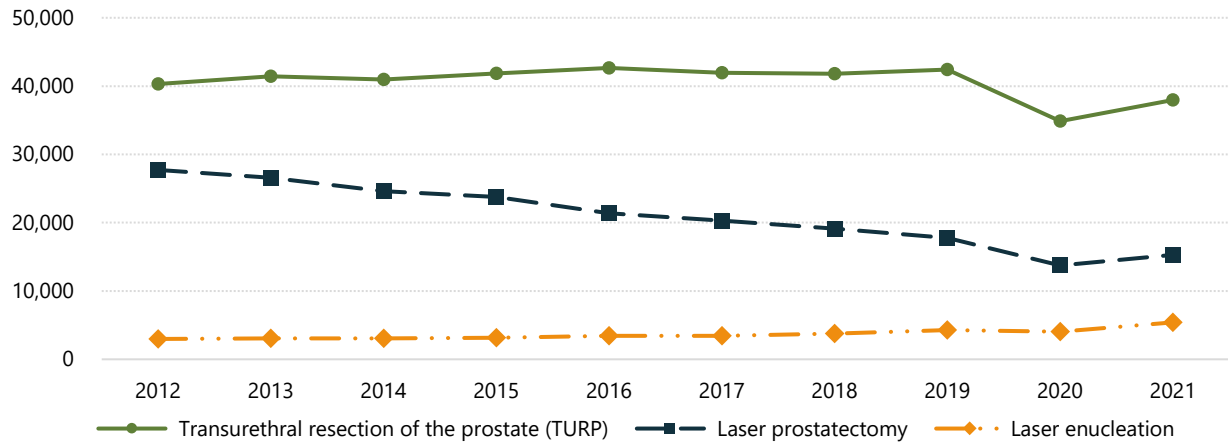
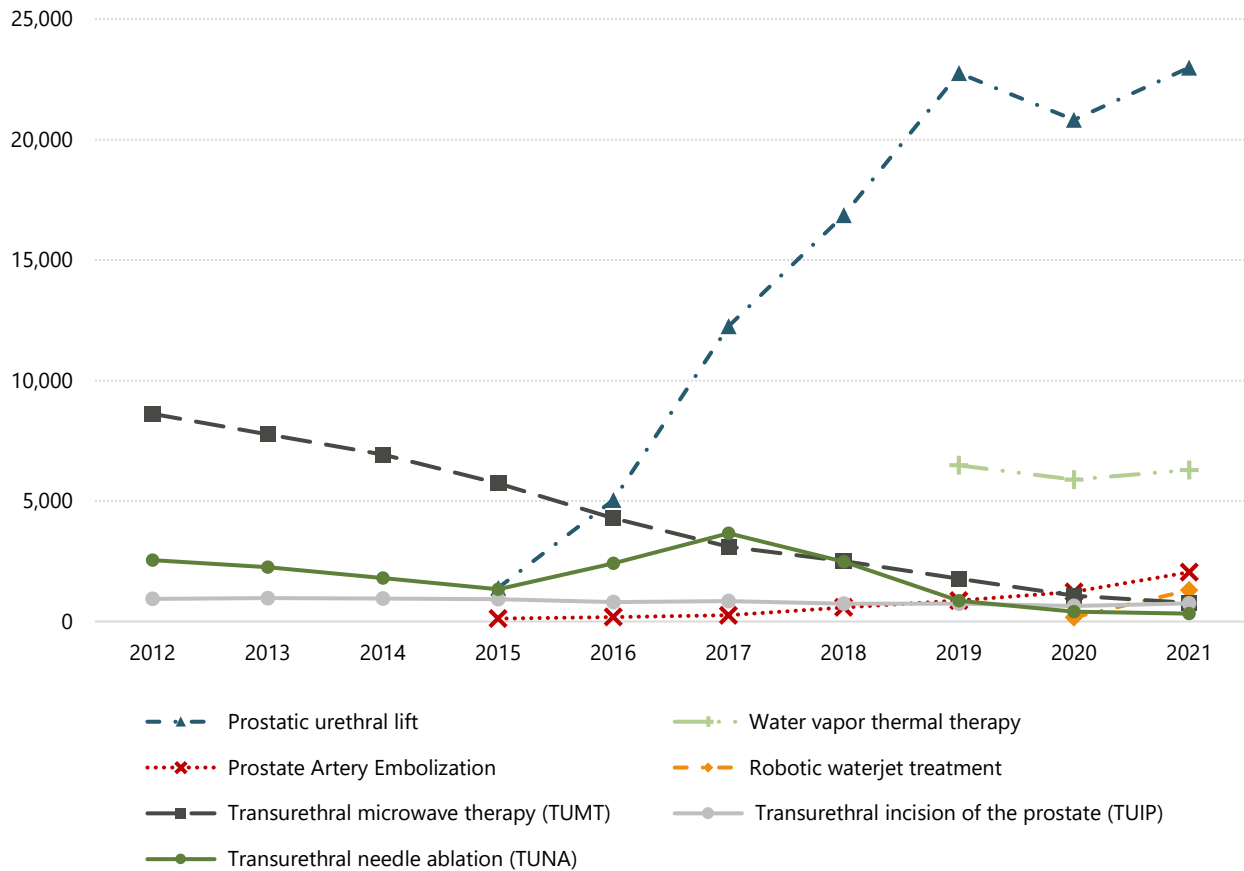


Figure 2.5b. MIST surgery types and their frequencies among patients aged 65+ with BPH/LUTS (2012-2021)



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

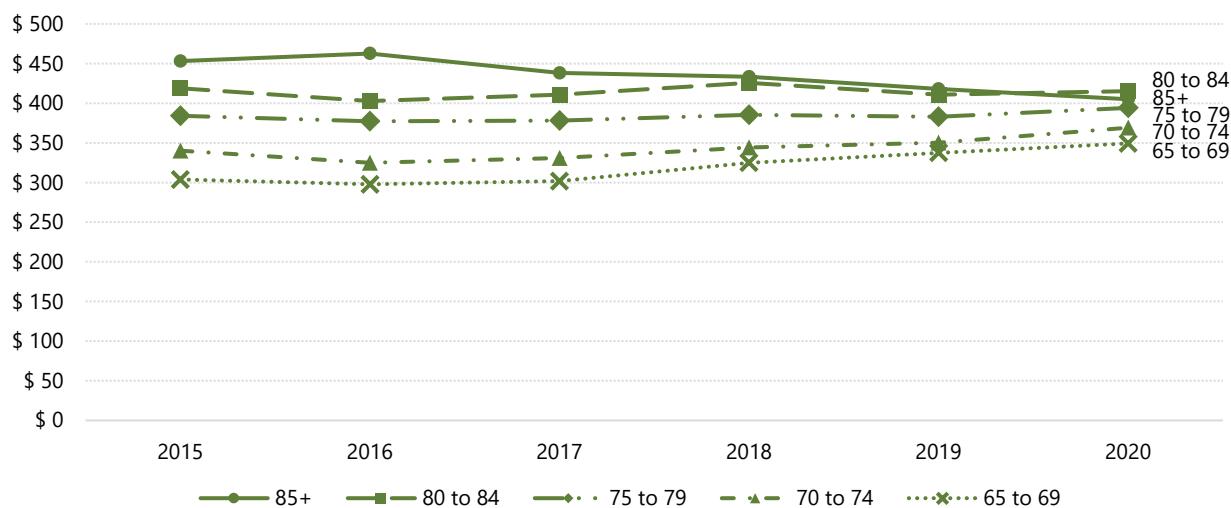
→ Service utilization

On average, patients aged 65 and older with an incident diagnosis of BPH/LUTS between 2015 and 2020 had 2.7 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.

→ Expenditure

For patients aged 65 and older with an incident diagnosis of BPH/LUTS, the total expenditures (in nominal dollars) associated with services that were submitted with a primary diagnosis of BPH/LUTS within 12 months after initial diagnosis was approximately \$200 million annually from 2015 to 2020. The expenditure per patient with incident BPH/LUTS increased modestly from an average of \$370 in 2015 to \$381 in 2020, and tends to be higher for older age subgroups (Figure 2.6).

**Figure 2.6. Medicare FFS expenditures per patient
12 months after incident BPH/LUTS, by age (2015-2020)**



Notes: Numerator denotes total FFS expenditures with primary diagnosis of BPH/LUTS within first 12 months after initial diagnosis. Denominator denotes number of patients aged 65 and older with incident BPH/LUTS in each year. Units denote nominal dollars.

2.3 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 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, but at this time, we did not determine the sequence of when these concurrent conditions occurred.

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.¹⁰

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 above who received 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. While we assessed newer drug formulations that include both an alpha blocker and 5-alpha reductase inhibitor, we did not assess the prevalence of true “combination therapy”. Nevertheless, 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, suggesting that most patients on medical therapy for BPH/LUTS were not using combination therapy. 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.

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 viewed as a “middle ground” between medical management and surgical management. Given that our analysis found that overall rates of all BPH surgery remained consistent from 2012 through 2021, it is more likely that MIST is replacing transurethral surgery rather than serving as that “middle ground”.

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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- ¹ Kim, Sang-Kyu, Ki-Ho Kim, Seon-Ha Kim, Seok-Ju Yoo, and Yeo-Won Jeong. 2019. "Health-Related Quality of Life in Adult Males with Lower Urinary Tract Symptoms." *Quality of Life Research* 28 (9): 2419–2428. <https://doi.org/10.1007/s11136-019-02205-w>.
 - ² Lerner, Lori B., Kevin T. McVary, Michael J. Barry, et al. 2021. "Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA Guideline Part I–Initial Work-up and Medical Management." *Journal of Urology* 206 (4): 806–817. <https://doi.org/10.1097/JU.0000000000002183>.
 - ³ Lerner, Lori B., Kevin T. McVary, Michael J. Barry, et al. 2021. "Management of Lower Urinary Tract Symptoms Attributed to Benign Prostatic Hyperplasia: AUA Guideline Part I–Initial Work-up and Medical Management." *Journal of Urology* 206 (4): 806–817. <https://doi.org/10.1097/JU.0000000000002183>.
 - ⁴ Launer, Bryn M., Kevin T. McVary, William A. Ricke, and Granville L. Lloyd. 2021. "The Rising Worldwide Impact of Benign Prostatic Hyperplasia." *BJU International* 127 (6): 722–728. <https://doi.org/10.1111/bju.15286>.
 - ⁵ In contrast to our analysis, the studies cited in the subsequent discussion use symptom scores, survey responses, or a longer diagnosis lookback window to define incidence.
 - ⁶ Kristal, Alan R., Kathryn B. Arnold, Jeannette M. Schenk, Marian L. Neuhaus, Noel Weiss, Phyllis Goodman, Colleen M. Antvelink, David F. Penson, and Ian M. Thompson. 2007. "Race/Ethnicity, Obesity, Health Related Behaviors and the Risk of Symptomatic Benign Prostatic Hyperplasia: Results from the Prostate Cancer Prevention Trial." *Journal of Urology* 177 (4): 1395–1400. <https://doi.org/10.1016/j.juro.2006.11.065>.
 - ⁷ Sarma, Aruna V., Debra J. Jacobson, Michaela E. McGree, Rosebud O. Roberts, Michael M. Lieber, and Steven J. Jacobsen. 2005. "A Population Based Study of Incidence and Treatment of Benign Prostatic Hyperplasia among Residents of Olmsted County, Minnesota: 1987 to 1997." *Journal of Urology* 173 (6): 2048–2053. <https://doi.org/10.1097/01.ju.0000158443.13918.d6>.
 - ⁸ Platz, Elizabeth A., Corinne E. Joshu, Alison M. Mondul, Sarah B. Peskoe, Walter C. Willett, and Edward Giovannucci. "Incidence and Progression of Lower Urinary Tract Symptoms in a Large Prospective Cohort of United States Men." *Journal of Urology* 188, no. 2 (August 2012): 496–501. <https://doi.org/10.1016/j.juro.2012.03.125>
 - ⁹ McVary, Kevin T. 2006. "BPH: Epidemiology and Comorbidities." *American Journal of Managed Care* 12 (5 suppl): S122–S128.
 - ¹⁰ Based on multivariate analysis for BPH, Wei et al. (2011) found that urologists are more likely to perform urinalysis, renal ultrasound, cystoscopy and other tests than primary care physicians, but less likely to measure creatinine. Wei, John T., Martin M. Miner, William D. Steers, et al. 2011. "Benign Prostatic Hyperplasia Evaluation and Management by Urologists and Primary Care Physicians: Practice Patterns from the Observational BPH Registry." *Journal of Urology* 186 (3): 971–976. <https://doi.org/10.1016/j.juro.2011.04.081>. For other studies on the role of primary care physicians versus urologists in BPH test prescription, see Collins, Mary McNaughton, Michael J. Barry, Lin Bin, et al. 1997. "Diagnosis and Treatment of Benign Prostatic Hyperplasia. Practice Patterns of Primary Care Physicians." *Journal of General Internal Medicine* 12 (4): 224–229. <https://doi.org/10.1046/j.1525-1497.1997.012004224.x>; and Hollingsworth, John M., Brent K. Hollenbeck, Stephanie Daignault, Simon P. Kim, and John T. Wei. 2009. "Differences in Initial Benign Prostatic Hyperplasia Management Between Primary Care Physicians and Urologists." *Journal of Urology* 182 (5): 2410–2414. <https://doi.org/10.1016/j.juro.2009.07.029>.