

Weill Medical College of Cornell University Reports on Men's Urologic Health

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Primary Care Physician vs Urologist: How Does Their Medical Management of LUTS Due to BPH Differ?

By *Martin Miner, MD**

Benign prostatic hyperplasia (BPH) due to lower urinary tract symptoms (LUTS) is the most common benign growth process in men. About one in four men experience BPH-related symptoms by age 55,¹ and up to 90% of men older

than 80 years have some degree of BPH.² The development of effective new pharmacologic therapies has resulted in a shift from surgery to medication as first-line treatment for LUTS due to BPH. Because of the advent of effective new medical

treatments and the growing recognition of the degree of bother associated with these symptoms, the initial management of LUTS due to BPH also has shifted, at least in part, from the urologist to the primary care physician (PCP).

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Warren Alpert Medical School of Brown University is home to a community of scholars and physicians dedicated to the highest standards in education, research, and health care. Brown Med alumni are consistently accepted to the top residency programs in the United States and go on to be practitioners, teachers, and leaders in academic medicine and other health-care-related professions.

In spring 2006, a new 168,800-square-foot, \$95 million Life Sciences Building opened adjacent to the Biomedical Center. The new facility houses more than 50 new laboratories, supporting research in the departments of Molecular Biology, Cell Biology, and Chemistry; Neuroscience; and Cognitive and Linguistic Sciences; and the interdisciplinary Brain Sciences program. The building will also contain new space for interdisciplinary initiatives in genetics and genomics. More than 50 current faculty members will relocate to the Life Sciences Building, and the expanding facility will support as many as 11 new researchers.



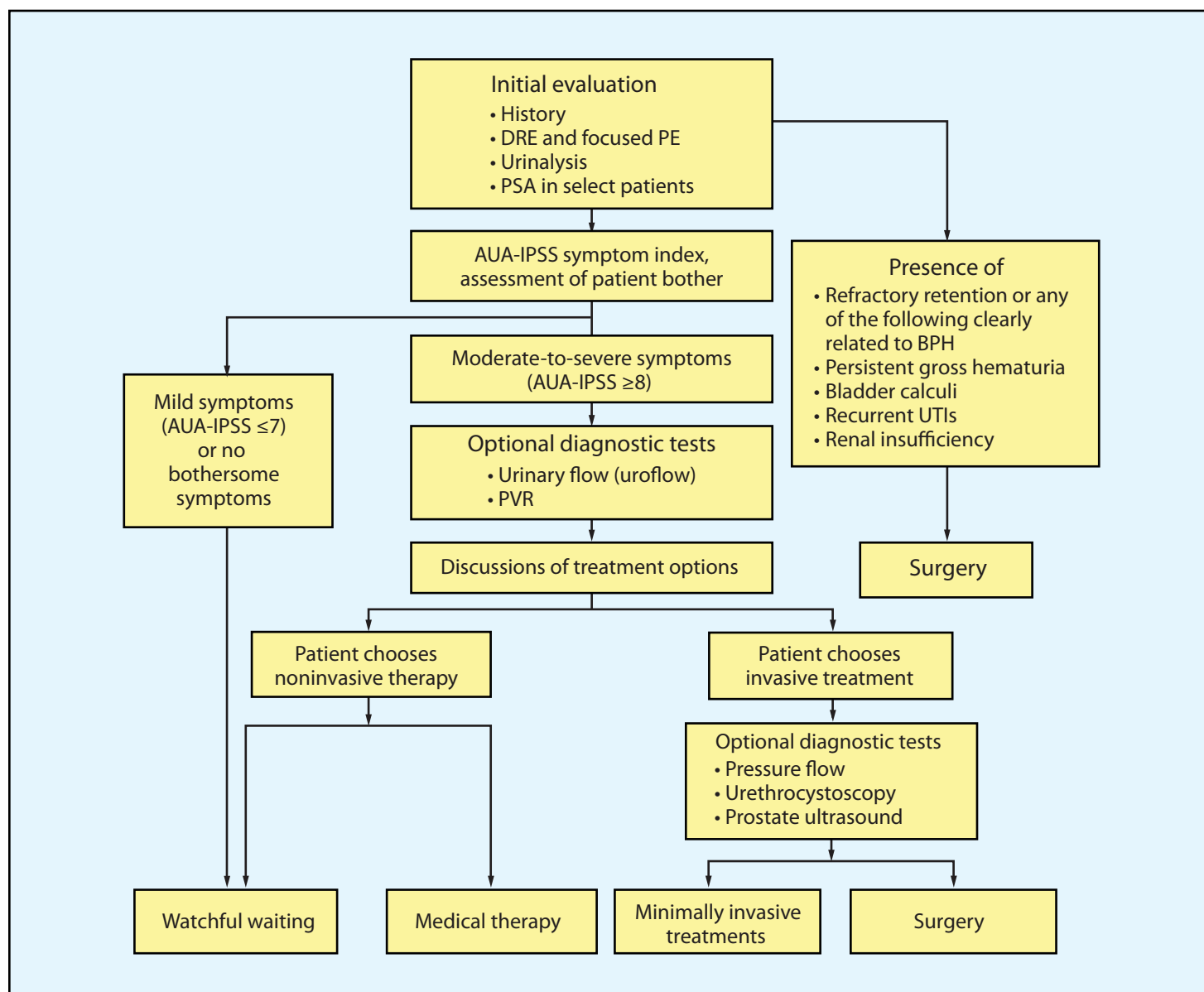


Figure 1. Algorithm for benign prostatic hyperplasia (BPH) diagnosis and treatment. AUA=American Urological Association; DRE=digital rectal examination; IPSS=International Prostate Symptom Score; PE=prostate enlargement; PVR=postvoid residual urine; UTI=urinary tract infection. Adapted from the American Urological Association algorithm. Used with permission.

The 2003 American Urological Association Guideline

The 1994 release of evidence-based guidelines for the diagnosis and treatment of BPH ultimately led to the development of new medical therapies and surgical treatments that prompted the American Urological Association (AUA) to publish a more relevant guideline in 2003. The primary differences between the two sets of guidelines are changes in the understanding of the biology of the prostate and the availability of new medical therapies, such as α -blockers and 5 α -reductase inhibitors (5ARIs). Following a thorough evaluation of BPH

literature from both before and after 1994 and a careful review of unpublished data, the 2003 Guidelines Panel agreed upon updated recommendations for treating moderate-to-severe LUTS due to BPH and revised the diagnostic algorithm (Figure 1).

Most of our current knowledge about the treatment of BPH is based on numerous controlled clinical trials conducted in the late 1990s, as well as in this decade. Two trials in particular have played an important role in the shift from surgery to medication as first-line therapy for BPH. The Medical Therapy of Prostatic Symptoms (MTOPS) study, sponsored by the National Institutes

of Health (NIH), was the largest and longest trial designed to test whether a 5ARI (finasteride) and an α -blocker (doxazosin), either alone or in combination, could delay or prevent the clinical progression of BPH.³ The trial, which ran for 4.5 years, involved more than 3,000 men with BPH symptoms who were randomly assigned to one of four treatment groups: finasteride, doxazosin, a combination of finasteride and doxazosin, or placebo (Figure 2). Investigators concluded that combination therapy appears to be more effective than taking either finasteride or doxazosin alone. When compared with placebo, the risk of progression (which

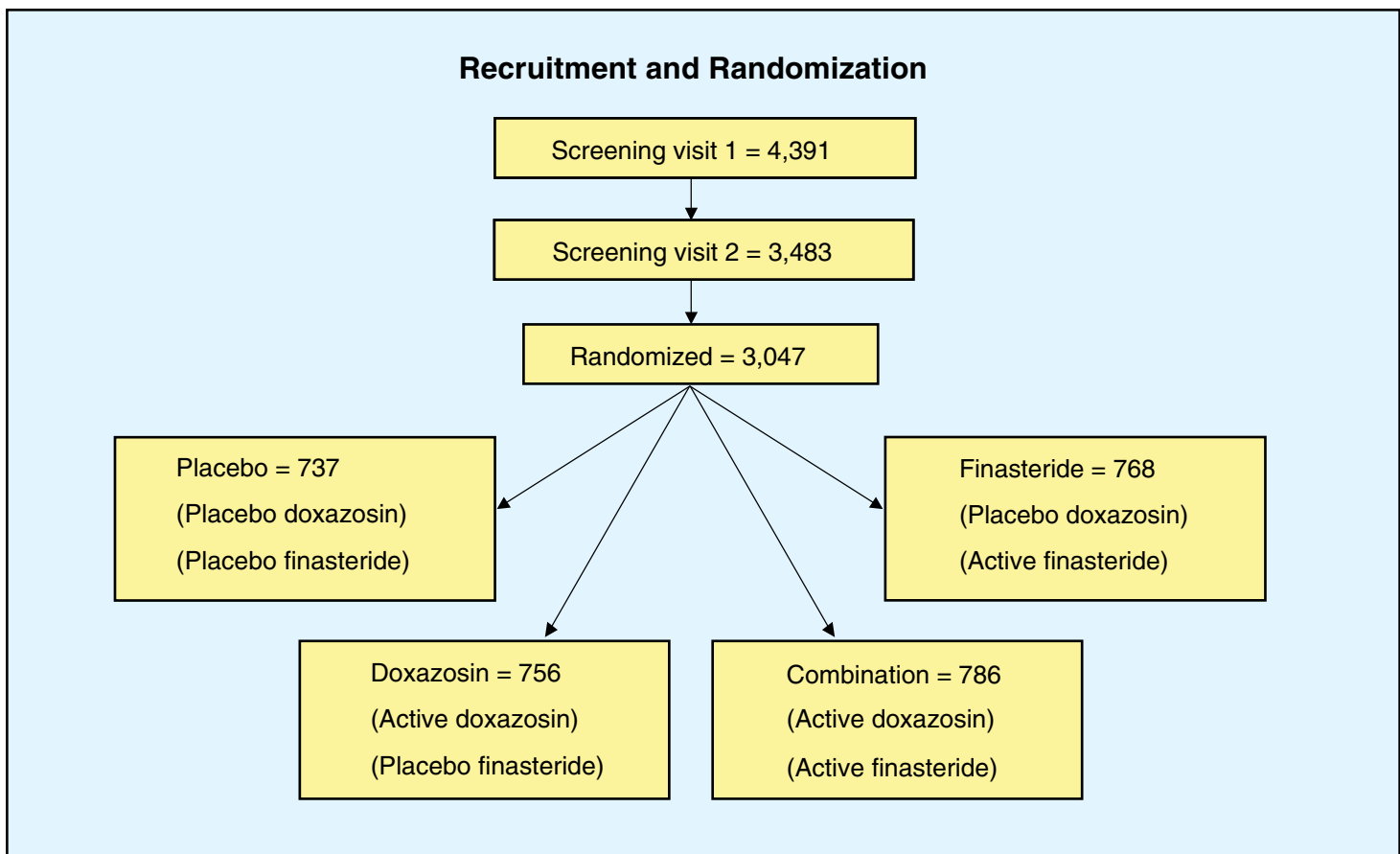


Figure 2. The Medical Therapy of Prostatic Symptoms (MTOPS) study recruitment and randomization. Patients were treated with 5 mg finasteride, 4 or 8 mg doxazosin, and/or placebo. Modified from McConnell et al.³

was defined as an increase of at least four points in the AUA symptom score), acute urinary retention (AUR), renal insufficiency, recurrent urinary tract infections (UTIs), or surgical intervention was reduced by 39% for those who took doxazosin alone and 34% for those who took finasteride alone. The reduction of risk for those on combination therapy was 66% when compared with placebo. Combination therapy also reduced the risk of urinary retention by 81% (Figure 3) and the risk for requiring invasive measures to treat BPH by 67%, primarily because of the 5ARI drug.

The Symptom Management After Reducing Therapy (SMART-1) trial looked at the combination of the 5ARI dutasteride and the α -blocker tamsulosin, followed by the withdrawal of tamsulosin in symptomatic men.⁴ This trial, which involved a smaller group of patients and was not placebo controlled, randomized patients to dutasteride and tamsulosin for 36 weeks, or to both for 24 weeks followed by dutasteride plus placebo for another 12 weeks. As with previous tri-

als, combination therapy produced a rapid improvement in symptoms. After tamsulosin was withdrawn, the condition of men with mild or moderate symptoms did not deteriorate significantly, but many patients with severe symptoms experienced worsening of LUTS due to BPH.⁵

The BPH Registry and Patient Survey

The BPH Registry and Patient survey, the first longitudinal, observational BPH registry in the United States, was designed to look at patient outcomes and current practice patterns in the evaluation and management of LUTS due to BPH in a real-world setting. From January 2004 to June 2005, 6,909 men with symptoms of BPH who were managed conservatively with either watchful waiting or medication were enrolled in the registry—4,537 were seen by urologists and 2,372 were seen by PCPs. In keeping with one of the original research objectives, data from the BPH Registry have been analyzed to determine the differences

in the approach to diagnosing and managing BPH between PCPs and urologists.

Differences in Evaluation

A recent study by Steers et al⁶ looked at the differences in approach of evaluating men with LUTS due to BPH between PCPs and urologists. Their objective was to examine both the impact of physician type on diagnostic evaluations performed at or before the baseline visit and adherence to the 2003 AUA guideline recommendations. Data collected at baseline included the following:

- Demographics;
- Clinical parameters (eg, digital rectal examination [DRE], urinalysis, prostate-specific antigen [PSA] measurement) before or at the enrollment visit;
- LUTS severity (International Prostate Symptom Score [IPSS] measurement);
- LUTS bother (IPSS bother score);
- Current disease management (ie, watchful waiting or specific medical therapies); and
- Physician type (urologist or PCP).

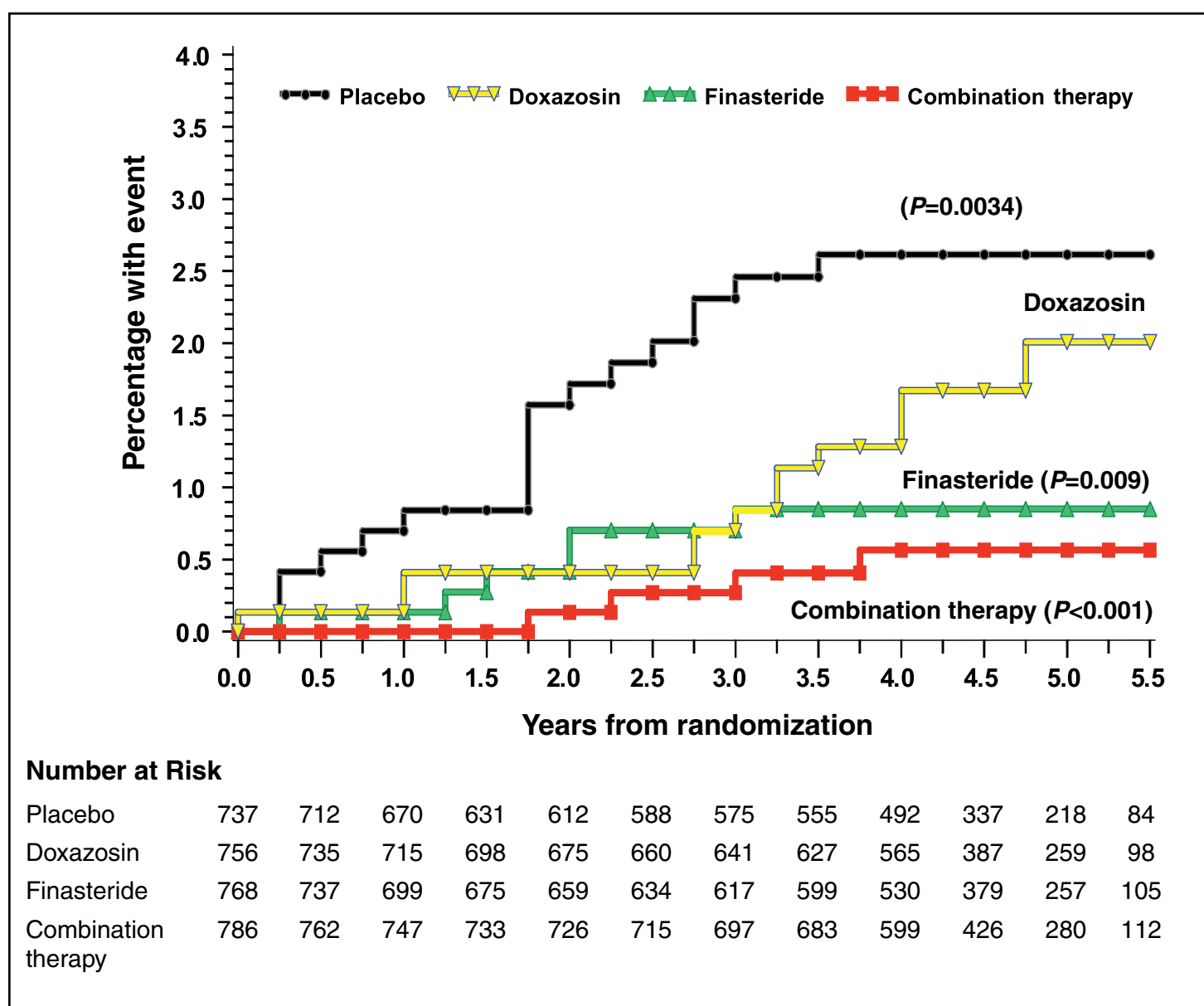


Figure 3. Cumulative incidence of acute urinary retention (AUR). From McConnell et al.³ Used with permission.

Comparisons of patient characteristics between men seen by urologists and men seen by PCPs were analyzed using the chi-square test or the analysis of variance (ANOVA) test. Odds ratios (ORs) for the use of diagnostic evaluations according to physician type were estimated using adjusted logistic regression models constructed for each evaluation. Significant differences were observed between urologists and PCPs (Table 1).

In multivariate analyses, after adjusting for age, IPSS, IPSS bother score, duration of symptoms, and enlarged prostate (EP) on DRE, urologists were more likely than PCPs to perform a urinalysis, DRE, prostate ultrasound, prostate biopsy, renal ultrasound, cystoscopy, postvoid residual urine (PVR), and

uroflowmetry. PCPs were more likely than urologists to measure serum creatinine and testosterone. No significant difference in the likelihood of obtaining a PSA measurement was found between urologists and PCPs.

These findings clearly indicate that not all men with BPH are evaluated in the same way and in keeping with the current evidence-based, best-practice guidelines. Some variation in the clinical evaluations that were conducted may be related to the fact that urologists have greater access to diagnostic equipment. However, the finding that a large percentage of PCPs did not document a urinalysis and a DRE suggests a lack of knowledge or acceptance of 2003 AUA guideline recommendations, or a lack

of knowledge regarding the disease state of BPH due to LUTS and its progressive nature and complications.

Differences in Medical Management

Wei et al⁷ used BPH Registry data to examine the differences in the way PCPs and urologists medically manage LUTS due to BPH. Data collected prospectively included the following:

- Demographics;
- Clinical parameters (eg, DRE, PSA);
- LUTS severity (IPSS);
- LUTS bother (IPSS bother score);
- Current disease management (watchful waiting, α -blocker, 5ARI, or anticholinergic); and
- Physician type (urologist or PCP).

Table 1: Adjusted Odds Ratios for Various BPH Evaluations According to Physician Type

	Urologist (N=4,537)	PCP (N=2,372)	Adjusted OR (95% CI)*
Urinalysis	81% (3,653/4,485)	49% (1,140/2,349)	3.4 (2.8-4.0)
DRE	84% (3,780/4,477)	59% (1,370/2,341)	3.2 (2.7-3.7)
PSA	85% (3,791/4,481)	71% (1,630/2,294)	1.2 (1.0-1.6)
PVR	47% (2,113/4,485)	3% (81/2,349)	16.0 (11.8-22.4)
Uroflow	23% (1,061/4,485)	1% (30/2,348)	12.6 (8.0-21.1)
Prostate ultrasound	21% (963/4,484)	2% (56/2,349)	6.4 (4.6-9.0)
Prostate biopsy	21% (944/4,485)	6% (151/2,348)	3.1 (2.4-4.1)
Renal ultrasound	12% (524/4,485)	3% (74/2,348)	2.3 (1.6-3.4)
Cystoscopy	17% (764/4,485)	4% (84/2,348)	4.9 (3.6-7.0)
Creatinine	37% (1,643/4,485)	69% (1,620/2,349)	0.1 (0.1-0.2)
Testosterone	11% (513/4,485)	12% (275/2,349)	0.7 (0.6-0.9)

CI=confidence interval; DRE=digital rectal examination; IPSS=International Prostate Symptom Score; OR=odds ratio; PCP=primary care physician; PVR=postvoid residual urine; PSA=prostate-specific antigen

*Adjusted for age, IPSS score, IPSS bother score, duration of symptoms, and DRE size enlarged.

CI >1 suggests greater utilization by urologists than PCPs.

From Steers et al⁶

Comparisons of patient characteristics between men seen by urologists and men seen by PCPs were analyzed using the chi-square test or ANOVA. Comparisons of watchful waiting vs medical therapy based on physician type were also analyzed using the chi-square test. Comparisons of specific medical therapies according to physician type and LUTS severity were analyzed with the chi-square test and Mantel-Haenszel test, respectively. ORs for use of specific medical therapies according to physician type were estimated using multivariate analysis. Significant differences between the way PCPs and urologists managed LUTS due to BPH were found.

The percentage of men on medical therapy rather than watchful waiting at the end of the initial visit was significantly greater for those seen by urologists than for those seen by PCPs, regardless of LUTS severity (Figure 4). Urologists and PCPs also differed significantly in the use of specific medical therapies, and this difference re-

mained significant across all LUTS severity classifications (Figure 5). Men seen by urologists were more likely to be on medical therapy than men examined by PCPs, based on a multivariate analysis that adjusted for patient age, IPSS, IPSS bother, and prostate size (Table 2).

Looking at all the men who received medical therapy, urologists prescribed 5ARIs, combination therapy with an α -blocker and a 5ARI, and anticholinergic therapy significantly more often than PCPs. In contrast, the use of nonselective α -blockers was appreciably greater among men seeing PCPs than men seeing urologists. Although the use of selective α -blockers was greater among men seeing urologists than those seeing PCPs, the difference was not significant.

LUTS Due to BPH From the Primary Care Perspective

Because PCPs are usually the first point of medical contact for men experiencing LUTS due to BPH, they can play an

important role in educating patients and diagnosing the condition. And now that the development of effective new pharmacologic therapies has resulted in a shift from surgery to medication as a first-line therapy, most men with EP (usually defined as a prostate volume >30 g, or a PSA >1.4 ng/mL)⁸ can be both identified and effectively managed in the primary care setting.⁹ The analyses of the BPH Registry data conducted by Steers et al⁶ and Wei et al⁷ reveal significant differences in the way urologists and PCPs evaluate and manage men with LUTS due to BPH that can seriously affect disease outcomes.

Although it is possible that some of the variation in the way urologists and PCPs evaluate LUTS due to BPH is related to the fact that urologists have greater access to diagnostic equipment, it is also possible that PCPs do not prioritize LUTS due to BPH because they are not aware that it is a progressive disease state. They view it as solely a quality-of-life issue, which, of course, it is not. In addition, PCPs do not know how

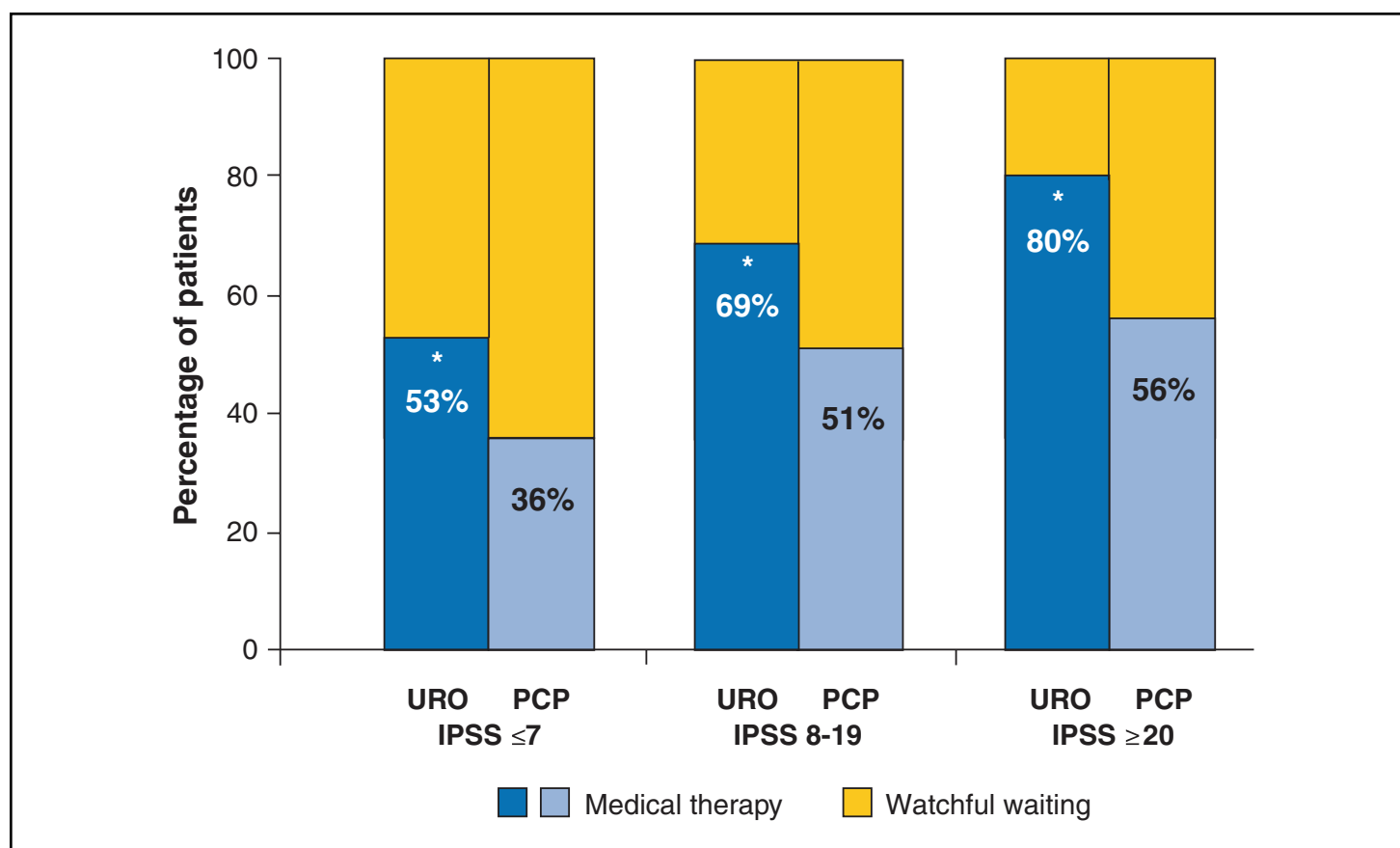


Figure 4. Percentage of men on watchful waiting or medical therapy for LUTS due to BPH after initial visit according to physician type and LUTS severity. * $P < 0.0001$ for comparison URO vs PCP; IPSS of ≤ 7 = mild LUTS; IPSS of 8-19 = moderate LUTS; IPSS of ≥ 20 = severe LUTS. LUTS = lower urinary tract symptoms; PCP = primary care physician; URO = urologist. Modified from Wei et al.⁷

to define prostate size because they do not use ultrasound, PVR, and uroflowmetry, and they also do not use the IPSS to rate symptom severity. In many cases, PCPs may only ask one or two questions about the patient's urinary function. Hence, we need to ask if this is adequate. Is it going to open a dialogue with the patient to discuss their urinary symptoms? Will it disclose degree of bother, which is a significant issue in patients with symptomatic LUTS, with or without EP? Based on the findings of Steers et al,⁶ further dissemination of BPH management guidelines to PCPs and their patients, along with educational programs describing their use in clinical practice, seem warranted.

The findings of Wei et al⁷ raise some important questions about the way PCPs treat men with LUTS due to BPH. If patients are found to have EP, are they being treated as if it is a progressive condition that puts them at risk for urinary retention and possible subsequent surgery? Is their

condition being managed with a disease-modifying agent, such as a 5ARI, or are they just being treated symptomatically with an α -blocker? The differences Wei et al⁷ observed in the specific therapies urologists and PCPs use for treating LUTS due to BPH may serve as the foundation for future educational and quality improvement efforts.

Evaluating BPH in the Primary Care Setting

Because LUTS symptoms alone cannot be used to definitively diagnose EP, the initial evaluation of men with LUTS should include a thorough medical history, symptom assessment, physical examination (including DRE), PSA measurement, focused neurologic examination, and urinalysis. Differential diagnosis is important to rule out other possible causes of LUTS, such as overactive bladder (OAB). An assessment of symptoms, using the AUA Symptom Index (AUA-SI) or IPSS if the

bother question is included, is necessary to ascertain the severity of the condition and determine if treatment is necessary. A sample IPSS form is included on page 8 of this monograph. A serum PSA measurement and DRE are recommended for men older than 50 years with a life expectancy of 10 years or more, for African-American men older than 40 years, and for all men who have a family history of prostate cancer. A neurologic examination should be performed to rule out neurologic problems that may cause urinary symptoms, especially in men with neuromuscular diseases. A urinalysis should be performed to rule out hematuria or UTI, which could be the cause of the LUTS. It is also important to assess a patient's risk factors for progression of BPH, which include increasing age, EP (≥ 30 mL and PSA of ≥ 1.4 ng/mL); moderate-to-severe symptoms (AUA-SI score > 7); signs of negative impact on quality of life (bother), and weak urinary flow (uroflow).¹⁰

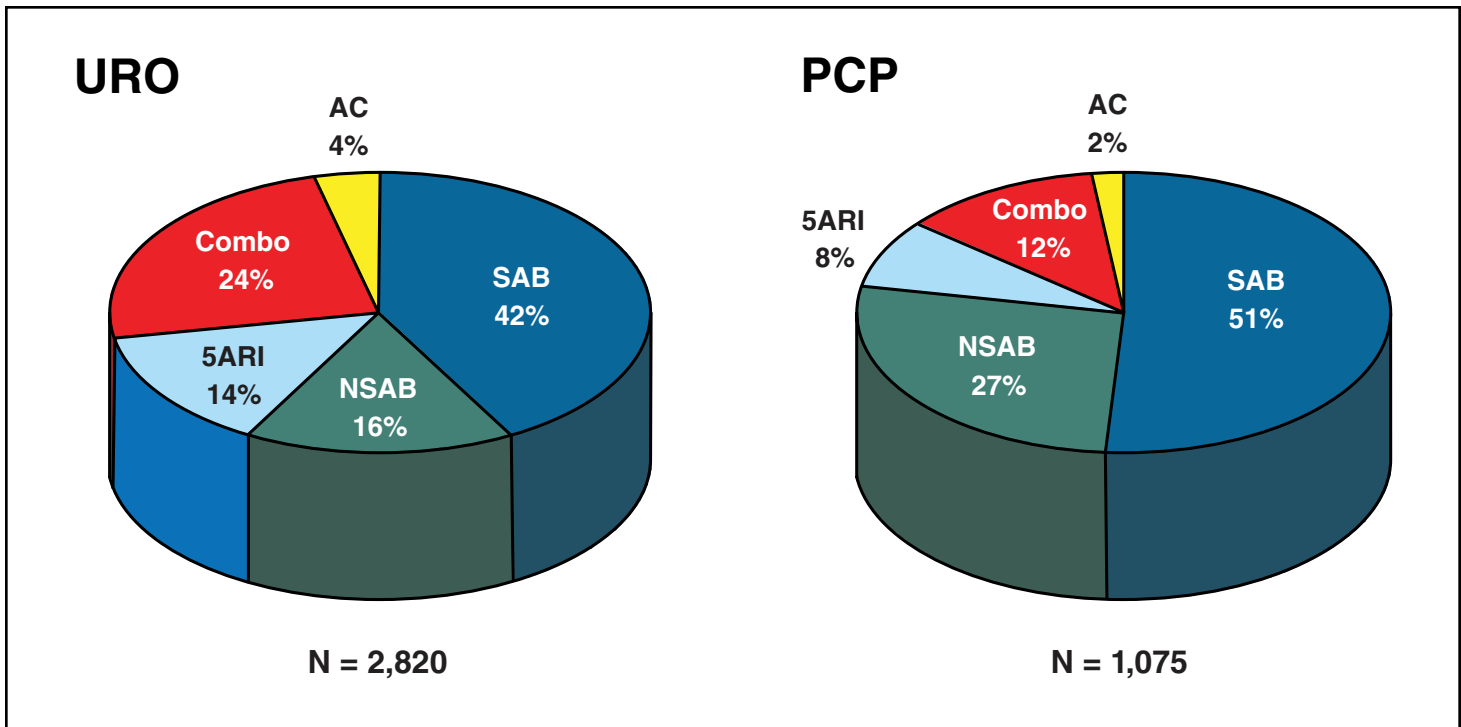


Figure 5. Use of specific medical therapies for LUTS due to BPH according to physician type. $P < 0.0001$ for comparison URO vs PCP based on the chi-square analysis. 5ARI=5 α -reductase inhibitor; AC=anticholinergic; Combo=AB+5ARI; NSAB=all other α_1 -blockers; SAB=uroselective α_1 -blockers alfuzosin and tamsulosin. Modified from Wei et al.⁷

Table 2: Use of Medical Therapies for LUTS Due to BPH According to Physician Type (Multivariate Analysis)

	Adjusted OR*	95% CI
Use of any medical therapy	2.4	2.1-2.8
Use of specific medical therapy		
Selective α -blocker	0.8	0.7-1.0
Nonselective α_1 -blocker	0.5	0.4-0.6
5ARI	2.0	1.4-2.9
Any α_1 -blocker + 5ARI	1.7	1.3-2.2
Anticholinergic	1.8	1.1-3.3

*Adjusted for patient age, IPSS, IPSS bother, and prostate size. OR >1 indicates greater use by urologists than PCPs.

5ARI=5 α -reductase inhibitor; BPH=benign prostatic hyperplasia; CI=confidence interval; LUTS=lower urinary tract symptoms; selective α_1 -blockers=uroselective alfuzosin and tamsulosin; nonselective α_1 -blockers=all other α_1 -blockers; OR=odds ratio.

Modified from Wei et al.⁷

Referral to a Urologist

PCPs should use their clinical judgment when considering if referral to a urologist is warranted. Indications for more urgent referral include the following:

- Recurrent UTIs;
- Suspicious nodules on DRE;
- Symptom deterioration with adequate treatment;
- Renal insufficiency;
- AUR or chronic urinary retention;
- Hematuria;
- Abnormal PSA related to age-defined parameters;
- More than a 0.75-ng/mL/year rise in PSA;
- Failure to achieve expected 50% reduction in PSA after 6 to 9 months of treatment with a 5ARI; and
- Unsatisfactory improvement in LUTS after 3 to 6 months of treatment.

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International Prostate Symptom Score Sample Form

Name: _____ Date: _____

	Not at all	Less than 1 time in 5	Less than half the time	About half the time	More than half the time	Almost always	Your score
Incomplete emptying: Over the past month, how often have you had a sensation of not emptying your bladder completely after you finish urinating?	0	1	2	3	4	5	
Frequency: Over the past month, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5	
Intermittency: Over the past month, how often have you found you stopped and started again several times when you urinated?	0	1	2	3	4	5	
Urgency: Over the past month, how difficult have you found it to postpone urination?	0	1	2	3	4	5	
Weak stream: Over the past month, how often have you had a weak urinary stream?	0	1	2	3	4	5	
Straining: Over the past month, how often have you had to push or strain to begin urination?	0	1	2	3	4	5	
Nocturia: Over the past month, many times did you most typically get up to urinate from the time you went to bed until the time you got up in the morning?	0	1	2	3	4	5	
Total IPSS score							
	Delighted	Pleased	Mostly satisfied	Mixed—about equally satisfied and dissatisfied	Mostly dissatisfied	Unhappy	Terrible
Quality of life due to urinary symptoms							
If you were to spend the rest of your life with your urinary condition the way it is now, how would you feel about that?	0	1	2	3	4	5	6
Total score: 0-7 mildly symptomatic; 8-19 moderately symptomatic; 20-35 severely symptomatic.							

Treating BPH in the Primary Care Setting

In recent years, there has been a shift in priorities in the treatment of LUTS due to BPH from short-term symptom relief to treating the underlying condition and preventing long-term negative outcomes. According to the 2003 AUA Guideline for the Diagnosis and Treatment of BPH, pharmacotherapy is an appropriate option for many men with LUTS with and without an EP. α -Blockers and 5ARIs are the most commonly used medications.

Watchful Waiting

Watchful waiting, when symptoms are monitored but no medical treatment is prescribed, may be appropriate for patients with an AUA-SI <7, minimal prostate enlargement, and no signs of renal insufficiency, urinary retention, or other complications. However, findings from a recent longitudinal study found that symptoms worsened in 87% of men with mild symptoms of bladder outlet obstruction (BOO) who had experienced watchful waiting over a period of 4 years; symptoms improved or remained stable in only 13% of men managed with watchful waiting.¹¹ This suggests that watchful waiting may just delay treatment rather than avoid it. Many men managed by watchful waiting may eventually need BPH-related surgery, and men with risk factors for disease progression require more aggressive management.

5 α -Reductase Inhibitors

5ARIs (finasteride, dutasteride) work by blocking the conversion of testosterone to dihydrotestosterone (DHT), the androgen primarily responsible for prostate enlargement. These 5ARIs are an appropriate and effective option for treating men with LUTS associated with demonstrable prostate enlargement.¹² Results from several clinical studies demonstrated that 5ARIs reduced prostate volume, improved urinary symptoms, improved uroflow, and reduced the risk of AUR and BPH-related surgery compared with placebo.^{3,13-15} The most commonly reported adverse events associated with 5ARIs include decreased libido, ejaculatory disorders, and impotence.¹⁶

α -Blockers

α -Blockers (alfuzosin, doxazosin, tamsulosin, terazosin) improve LUTS associated with EP by relaxing the smooth muscle

in the prostate and bladder neck.¹⁷ A number of clinical trials have demonstrated that all α -blockers provide comparable efficacy by increasing uroflow rates and rapidly improving LUTS as measured by the AUA-SI.^{3,18-21} The most commonly reported adverse events associated with α -blockers include orthostatic hypotension, dizziness, tiredness, ejaculatory problems, and nasal congestion.²² In some men, the short-term benefits of α -blockers may diminish as the prostate continues to grow.^{23,24}

Combination Therapy

Because 5ARIs and α -blockers work through different mechanisms, men with EP and moderate-to-severe LUTS may benefit from a course of treatment with both a 5ARI and an α -blocker. This combination treatment may offer patients both rapid symptom relief and long-term disease management. As mentioned previously, the MTOPS study concluded that the combination of finasteride and doxazosin is more effective than either drug used alone. In addition, the SMART-1 trial demonstrated that most patients can have an α -blocker successfully withdrawn after 6 to 12 months of combination therapy.

The Impact of Treatment on Sexual Function

Considering the prevalence of LUTS due to BPH in aging men and the relationship between LUTS and sexual dysfunction, it is good practice for PCPs to initiate discussions about sexual function with their adult male patients.²⁵ This is especially important because PCPs are often the only physicians that patients consult. Men experiencing LUTS due to BPH may be afraid, or unaware, of the effects treatment has on sexual function, particularly in the case of surgical treatments. They may also be unaware of the association of sexual dysfunction with LUTS. The Multinational Survey of the Aging Male (MSAM-7) found that, although 90% of the participants experienced LUTS, only 19% sought medical help and only 11% received treatment for their symptoms.²⁶ In addition, the MSAM-7 established LUTS as an independent risk factor for sexual dysfunctions in men of all types, including erectile and ejaculatory dysfunction. For this reason, it is important for PCPs to be knowledgeable about the prevalence

of LUTS in association with sexual dysfunction, and about the various treatment options for LUTS and the effects each has on sexual function.

Conclusion

Because PCPs are usually the first point of medical contact for men experiencing LUTS due to BPH, they can play a vital role in diagnosing the condition. Because of the development of effective new pharmacologic therapies, PCPs can also effectively manage most men with LUTS who do or do not have EP. Recent analyses of BPH Registry data reveal significant differences in the way urologists and PCPs evaluate and manage men with LUTS due to BPH that can seriously affect disease outcomes. It is important for PCPs to recognize that BPH is a progressive disease state and to treat it as such by becoming familiar with and following the 2003 AUA Guideline for the Diagnosis and Treatment of BPH.

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Self Test

This self-assessment test is presented as an educational adjunct to the monograph. Completion of this brief test will help reinforce the material you have read. Answers are elsewhere on this page.

1. Approximately one in four men experience BPH-related symptoms by the age of:
 - a. 55
 - b. 70
 - c. 65
 - d. 45
2. The MTOPS trial is significant because it:
 - a. confirmed the safety of α -blockers for treating LUTS.
 - b. demonstrated that 5ARIs can reduce the size of the prostate.
 - c. concluded that combination therapy with an α -blocker and a 5ARI seems to be more effective than taking either alone.
 - d. suggested that surgery is a better option for treating BPH than medical therapy.
3. Watchful waiting is appropriate for patients with:
 - a. an AUA-SI <7 .
 - b. minimal prostate enlargement.
 - c. no significant renal insufficiency or other complications.
 - d. all of the above.
4. 5α -reductase inhibitors work by:
 - a. converting testosterone to dihydrotestosterone
 - b. blocking the production of testosterone.
 - c. blocking the conversion of testosterone to dihydrotestosterone.
 - d. increasing the production of testosterone.
5. The MSAM-7 trial found that:
 - a. there is no association between LUTS and sexual function.
 - b. LUTS is an independent risk factor for all types of sexual dysfunction in men.
 - c. treating LUTS with α -blockers and 5ARIs has no impact on sexual function.
 - d. the majority of men who experience LUTS seek immediate medical attention.

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Self-Test Answers for This Issue:

1. a 2. c 3. d 4. c 5. b

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