

VA PRACTICE *Matters*

JULY, 1998

VOL. 3 ISSUE 1

DIAGNOSIS AND MANAGEMENT OF BENIGN PROSTATIC HYPERPLASIA

- *Symptomatic benign prostatic hyperplasia (BPH) is one of the most common medical conditions in older men.*
- *As many as 40% of men in their 70s have lower urinary tract symptoms attributed to BPH.*
- *In the United States, treatment of BPH exceeds 2 billion dollars a year.*
- *Treatment of BPH accounts for 1.7 million office visits a year.*
- *BPH therapy results in more than 200,000 prostatectomies annually.*
- *Treatment options include lifestyle modification, device and surgical therapies and pharmaceutical and plant extracts.*
- *VA sponsored research has led to important advances in, and continues to focus on, the treatment and management of BPH.*

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TREATMENT GOALS

Treatment goals in the vast majority of men diagnosed with benign prostatic hyperplasia (BPH) are to relieve the bothersome irritative (urgency, frequency, and nocturia) and obstructive (weak stream, hesitancy, intermittency and incomplete emptying) symptoms. Treatment options include lifestyle modification, pharmaceutical and phytotherapeutic (plant extract) preparations, and device and surgical therapies.

Indications for and type of treatment recommended are based on many factors including:

- severity of voiding symptoms
- degree of bother and patient dissatisfaction related to symptoms
- complications due to BPH (urinary retention, recurrent urinary tract infection, renal insufficiency, gross hematuria, bladder calculi)
- underlying medical conditions

SYMPTOMS AND DIAGNOSIS

Lower urinary tract symptoms due to BPH are related to abnormalities in bladder emptying (weak urinary stream, incomplete bladder emptying, straining or dribbling) and/or bladder filling (urgency, frequency, night time disturbance). Symptoms of BPH can be due to either an enlarged prostate and/or due to increased smooth muscle tension of the prostate and bladder.

Quantitative assessment of voiding symptoms is obtained by using easily administered standardized and validated urologic symptom and bother scales such as the American Urologic Association Symptom Index and the BPH Impact Index Scales. These questionnaires determine the degree of bother and symptom severity. The severity of symptoms and degree of bother are the major factors in determining treatment options.

Regardless of symptom severity or bother, men should be referred for urologic evaluation if they have any of the following conditions believed to be due to BPH:

- recurrent urinary tract infections
- urinary incontinence

- urinary retention
- renal insufficiency
- bladder stones or hematuria.

Men with BPH symptoms are not at greater risk for having prostate cancer than men without symptoms. Because prostate specific antigen (PSA) levels are increased with prostate enlargement, routine prostate cancer screening with PSA testing in men with BPH symptoms will result in an increased number of falsely abnormal tests requiring additional evaluation. PSA testing for detection of prostate cancer in men with BPH symptoms is considered optional. Rather than routinely ordering a PSA test, doctors should inform patients of the known risks and uncertain benefits of prostate cancer screening. If routine PSA testing is performed, the assessment of the percentage of “free or unbound” PSA can help differentiate whether elevations in PSA levels are due to BPH or prostate cancer. This may reduce unnecessary biopsies and additional tests.

THERAPIES

Watchful Waiting

Watchful waiting consists of teaching patients various lifestyle changes and behavioral techniques including: taking extra time to urinate, urinating prior to taking long trips or going to bed, avoiding excess fluids, alcohol, caffeine, cold or allergy medications as well as switching prescriptions or adjusting dosages of medications such as diuretics and anticholinergics. This approach has proven beneficial in men with all degrees of symptom severity and should be considered first line therapy.

Medical Management

Medical management provides several new drugs which can provide relief for BPH symptoms.

- **alpha blockers** including terazosin, doxazosin, and tamsulosin improve both urinary symptoms and flow measures by reducing smooth muscle tone from alpha receptor stimulation in the prostate and the bladder. A large VA Cooperative Trial demonstrated that men with BPH treated with alpha

blockers had clinically and statistically significant improvement in urologic symptoms and flow rates compared to finasteride or placebo. The main side effects from alpha blockers are dizziness (25%), lethargy (15%) and low blood pressure (8%). Because of their proven effectiveness and lower cost, alpha blockers are considered the treatment of choice for pharmacological management of men with symptomatic BPH.

- **5 alpha reductase inhibitors** (finasteride) decrease mechanical obstruction from hyperplastic tissue by suppressing formation of dihydrotestosterone and subsequently reducing prostate size. The treatment effectiveness is directly proportional to prostate size. A minority of men with BPH symptoms have very large prostates and moderate to severe symptoms. In these men, treatment with finasteride has been shown to improve urinary symptoms and flow measures. Additionally, finasteride reduces the risk of acute urinary retention or the need for surgery by about 6 in 100 compared to placebo. The main adverse effects of finasteride are impotence and loss of libido, occurring in 5-10% of men.

Alternative Therapies

Phytotherapeutic compounds (plant extracts) are readily available as over the counter health supplements. The most widely used preparation for BPH is an extract from the ripe fruit of the saw palmetto plant, *Serenoa repens*. The therapeutic mechanism of action is not known but it is the first line pharmacologic therapy for symptomatic BPH in Europe. A recent systematic review of 18 randomized trials determined the safety and efficacy of saw palmetto with either placebo or finasteride. The results indicate that saw palmetto improves urinary symptoms and flow measures more than placebo. Compared to finasteride, saw palmetto provides similar improvement in urinary symptoms and flow measures. It appears to be a safe and relatively inexpensive option for men with mild to moderate BPH symptoms. The long term effectiveness of saw palmetto is not established and it has not been adequately compared to alpha blockers.

Device Therapies

The potential advantages of minimally invasive device therapies over transurethral resection of the prostate (TURP) include: use in an outpatient setting under local anesthesia, fewer serious complications and reduced costs. Minimally invasive therapies for BPH treatment include:

- prostatic stents
- microwave therapy
- high frequency ultrasound, and
- transurethral needle ablation

Randomized trials have compared the effectiveness of several of these minimally invasive therapies to TURP. In appropriately selected individuals they appear to provide similar improvements in urinary symptoms and flow measures. Therefore, these minimally invasive therapies may be preferable in certain high risk patients or those men desiring less invasive treatment approaches.

Surgical Management

TURP is considered the gold standard therapy and the treatment of choice for improving urologic symptoms and flow measures in men with severe symptoms or complications related to BPH. A VA Cooperative Trial demonstrated that TURP was more effective than watchful waiting particularly among men with more bothersome disease. There were no differences in impotence and incontinence rates between men treated with and without surgery.

Alternate surgical procedures include:

- transurethral incision of the prostate
- laser prostatectomy and
- transurethral electro vaporization

For appropriate patients these surgical treatments can provide similar improvement in urinary symptoms with reduced risk of bleeding and/or other complications and can usually be performed on an out-patient basis.

CLINICAL VIEWPOINT

Benign prostatic hyperplasia, often referred to as “prostatism” by urologists, is extremely common in the aging male, affecting an estimated 14,000,000 men over the age of 50. The simplest and most effective tool available to evaluate this clinical problem is the American Urologic Association Symptom and Bother Score (AUASS). This instrument asks patients a series of seven questions, which have a range of answers scored from 0-5. Zero means the patient is completely asymptomatic, and five means that they have the severest possible symptoms. The sum total of all seven responses gives the patient’s final AUASS.

- Mild symptoms are defined as a score of ≤ 7
- moderate symptoms from 8-19, and
- severe symptoms from 20-35.

Therapeutic intervention is generally predicated on these scores as follows.

- mild symptoms managed by watchful waiting
- moderate symptoms with alpha adrenergic receptor blockers or 5-alpha reductase inhibitors (which are generally used only for glands ≥ 40 grams), and

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Acknowledgments

This Diagnosis and Management of Benign Prostatic Hyperplasia issue of *VA Practice Matters* was written by Timothy J. Wilt, M.D., M.P.H. of the VA Cochrane Review Group in Prostatic Diseases and Urologic Malignancies and the Minneapolis/VISIN 13 Center for Chronic Disease Outcomes Research. Other major contributors/reviewers were: Carol M. Ashton, M.D., M.P.H., Associate Director, Houston Center for Quality of Care and Utilization Studies; John G. Demakis, M.D., Director, VA Health Services Research and Development Service; Brian J. Miles, M.D., Associate Professor, Baylor College of Medicine; Ronald J. Gebhart, M.D., Chief Consultant, Primary and Ambulatory Care; Claus G. Roehrborn, M.D., The University of Texas, Southwestern Medical Center, Department of Urology. The issue was edited by Geraldine McGlynn, M.Ed. and Elaine Alligood, M.L.S. of VA’s Management Decision and Research Center.

EVIDENCE SUGGESTS:

- Initial BPH evaluation should consist of a history, physical examination including digital rectal examination, urinalysis and creatinine. Prostate specific antigen testing for the purpose of early detection of prostate cancer is optional. Rather than screening all men for prostate cancer, doctors should inform patients of the known risks and potential benefits of screening, diagnosis and treatment.
- Quantitative symptom assessment using validated questionnaires should be performed to determine symptom severity and degree of bother.
- Men with mild symptoms should be treated with watchful waiting and lifestyle management.
- Phytotherapy with saw palmetto may be a safe and effective alternative therapy for men with mild to moderate BPH symptoms.
- Alpha blockers are the preferred pharmacologic therapy for improving urinary symptoms and flow measures regardless of prostate size. Combination therapy with finasteride provides no greater improvement in symptoms or flow measures than alpha blockers alone.
- Men with moderate to severe symptoms should be offered treatment options that include pharmacologic, surgical and device therapies. Men with more severe symptoms and/or a higher degree of bother are more likely to benefit from surgical or device therapies.
- Finasteride is useful in improving symptoms and preventing urinary retention and the need for surgical intervention in men with large prostates who have moderate to severe symptoms.
- Urology referral should be made for urinary retention or any of the following: recurrent urinary tract infection, incontinence, hematuria, bladder stones or renal insufficiency.
- Incorporating shared decision making in the diagnosis and management of benign and malignant prostate conditions has been shown to improve patients’ knowledge and satisfaction and has influenced treatment decisions.

CLINICAL VIEWPOINT

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- severe symptoms with a trial of alpha blockers or surgical intervention

However, all men with moderate symptoms do not by definition require treatment. If a patient is not bothered by his symptoms then watchful waiting can be entertained. Virtually all men with severe symptoms will pursue and require medical/surgical therapy.

The evaluation of symptomatic benign prostatic hyperplasia remains somewhat controversial. Urologists strongly recommend a PSA in all patients. As listed by the American Cancer Society, the symptoms of BPH are also the symptoms of prostate cancer. When men seek an evaluation of their prostate, they are also seeking reassurance that they do not have prostate cancer. A PSA should not be performed without a patient's consent, but should always be offered. Furthermore, digital rectal exams should always be performed. Although the AHCPR lists postvoid residual and creatinine levels as optional, in patients with severe symptoms it is prudent to obtain these to rule out chronic retention or associated azotemia. Urologists invariably will perform urinary flow rates as an objective guide to therapeutic response, but for the primary care doctor, improvement in the AUASS is an adequate surrogate for other objective parameters.

The physician managing symptomatic benign prostatic hyperplasia must have a firm understanding of those diseases that can mimic or worsen the symptoms of this disease. For instance, diabetes mellitus with glycosuria will cause urinary frequency and urgency. It is also important for the primary care physician to know when to refer the patient to a urologist for further evaluation. The patient should be referred if hematuria is found on routine urinalysis, if they are refractory to medical therapy, if bladder calculi or urethral strictures are suspected, if they have an elevated PSA or abnormal digital rectal examination, and for severe symptoms in young men in their 40s or 50s.

Primary care physicians should be comfortable treating this disease with a complete and full understanding of its pathophysiology and a recognition of those factors that should lead to the referral to urologic surgeons.

*Brian J. Miles, M.D.
Associate Professor
Baylor College of Medicine
Scott Department of Urology*

The Under Secretary for Health recently appointed a committee to develop practice guidelines for BPH in VA. Guidelines will be available September, 1998.

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Information Dissemination Program Management Decision and Research Center (152-M)

150 South Huntington Avenue
Boston, MA 02130

Phone: COM (617) 278-4433
or FTS 839-4433

FAX: (617) 278-4438

Email: geraldine.mcglynn@med.va.gov

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VA Medical Center
Perry Point, MD 21902

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