Alternative Therapies for Benign Prostatic Hyperplasia

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Benign prostatic hyperplasia (BPH) is a non-cancerous increase in the tissue mass of the prostate, the muscular gland that produces seminal fluid. BPH is one of the most common medical conditions affecting older men. It may be diagnosed because of urinary symptoms, or identified when a large prostate is found during a routine screening rectal exam. Many men simply have a slow worsening of symptoms throughout their lifetimes, usually beginning in their 50's. Subclinical disease is very common: Approximately 80% of men older than age 60 will have histological changes indicative of BPH upon biopsy; by age 85, this percentage rises to 90%.[1] Some of these patients have severe disease progression, which can lead to incontinence, formation of calculi, frequent urinary tract infection, or permanent urinary tract damage.

Despite the possibility of progression and the bothersome symptoms, many men – perhaps half of those with the condition – never seek medical advice or treatment for BPH symptoms even when those symptoms are severe enough to warrant surgical intervention.[2] Patients may believe that urinary symptoms are part of the normal aging process, that nothing that can be done, or that the available treatments have unacceptable side effects.

Etiology/ Pathophysiology

BPH is related to age-associated changes in the body's hormone levels.[3] Although the clinical ramifications of these hormone changes are not completely characterized, it is known that the levels of serum testosterone decrease while dihydrotestosterone (DHT), the principle androgen responsible for prostatic growth,[4,5] accumulates. Until recently, it was believed that estradiol, converted from testosterone via the aromatase pathway, was implicated in initiating hyperplasia in the stroma and epithelium of the prostate.[4] That now seems unlikely.[6]

Factors that may accelerate disease progression are not well enumerated. Diet is one factor that has been implicated in the development of BPH. A Western diet characterized by high fat intake appears to be linked to earlier onset of BPH.[7,8] One study indicated that low intake of vegetables is positively associated with BPH risk,[9] whereas another drew a correlation between alcohol consumption (more than 25 ounces/ month) and BPH risk.[10] However, each of these studies had limitations and did not demonstrate a clear, direct correlation. Symptoms may be worsened by various factors such as evening intake of liquids, decongestant use, or caffeine, alcohol, or spicy food intake.

Symptoms

Urinary symptoms experienced by patients with BPH can be classified as obstructive or irritative (see Table 1). Obstructive symptoms, sometimes referred to as "voiding symptoms," include a decrease in the force of the urinary stream, difficulty in maintaining or initiating the stream, "dribbling" after ending the stream, or the inability to completely void the bladder. Although some obstructive symptoms can be directly correlated with restriction of urethral flow, others seem to be caused by a decrease in strength of the detrusor muscle or an increase in the excitability of the bladder muscle. Irritative symptoms of BPH also are referred to as "storage symptoms" and include dysuria, urge incontinence, urgency, nocturia, and increased frequency of urination during the day. These seem to be related to irritation of the epithelium of urethral and bladder structures.[3,4]

The International Prostate Symptoms Score (IPSS) is a validated instrument that is widely

accepted for staging the severity of the disease via scoring of subjective symptoms. It also is known as the American Urological Association Urinary Symptoms Index for Prostatism (AUA Index) and is a patient-completed instrument.[4] (See table 2). Score ranges equate to “mild” (0-7), “moderate” (8-19), and “severe” (20-35) symptoms. The Boyarsky Index and the Madsen-Iversen Score are additional instruments that are physician-completed.[11] Other instruments include the BPH Impact Index (BII), and various health-related quality of life (QOL) measurements. Interestingly, the severity of the symptoms experienced does not always correlate directly with the measured extent of glandular enlargement or with the objective measurements utilized to monitor disease progression.

Objective measurements include uroflowmetry, such as the maximum flow rate (MFR) in millimeters of urine passed per second (also termed peak urine flow rate) and post-void residual urine (PVR). Prostate volume usually is measured by transrectal ultrasonography.[3,4] Normal MFR ranges decrease with age. Generally, rates of less than 15 mL/s are considered to be diagnostic of a urinary flow problem; however, because of lower rates often found in older men, MFR rates alone do not indicate the need for therapy. They must be correlated with other physical findings and symptoms.[11]

Conventional Disease Management/ Treatment

“Usual” disease management can differ significantly based on the stage of the disease and the impact of symptoms on the patient’s lifestyle. The emphasis of BPH treatment has changed over the last several years from surgical intervention to medical intervention.[2,11] The first medical approach usually is “watchful waiting” – a recognition that the problem exists. Initiation of pharmacological treatment is delayed until symptoms become more bothersome to the patient. The next step generally involves α-1 blockers (doxazosin, tamulosin, or terazosin). These agents relax muscles of the prostate and bladder neck, thus providing symptomatic relief. They are associated with side effects including hypotenstion, dizziness, fatigue, and changes in sleep patterns. Another drug treatment choice is finasteride (a 5-α reductase inhibitor), which decreases the conversion of testosterone to the more active DHT. This agent has been associated with an increased incidence of sexual dysfunction.

A final choice for treatment is surgical intervention, which generally achieves the greatest degree of efficacy. Surgical options include: localized cryotherapy or thermal therapy, transurethral incision of the prostate (TUIP), transurethral resection of the prostate (TURP), electrovaporization (modified TURP), laser surgery, or open prostatectomy. These procedures are costly and confer an increased risk of complications, such as bleeding, infection, incontinence, and sexual dysfunction.[3,4,11,12] All of the above treatment options, with the exception of watchful waiting, are associated with adverse effects and significant cost. For these and other reasons, patients and clinicians are beginning to consider the use of alternative therapies to treat BPH.

All of the treatments that will be discussed here are phytomedicinal in nature and are either whole extracts from botanical sources, or single extracted or manufactured constituents originally from botanical sources. Several of these treatments have been used in other parts of the world for many years. In fact, phytomedicinals are the initial treatments of choice in countries such as France and Germany. Many treatments show significant placebo effects in clinical trials; an examination of multiple BPH treatment trials provided estimates of this effect that ranged from 30% to 40%.[2] The maximal placebo effect usually is seen in the first 4-6 months of therapy.[2]

Pumpkin Seed

The use of pumpkin seed (*Cucurbitae peponis*) for treatment of symptoms associated with BPH has been approved by the Commission E, the German regulatory body responsible for phytomedicinals.

Pumpkin seed is theorized to act by displacing DHT from androgen receptors on human fibroblasts[13] or by antiandrogenic/anti-inflammatory effects.[14] Pumpkin seeds contain phytosterols and, therefore, may bind to androgen receptors. However, there are no human studies to support these proposed mechanisms. In addition, there have been a very limited number of clinical trials evaluating its efficacy, none of which are published in English.

Friedrich et al evaluated the efficacy of 1-2 capsules of Prosta Fink Forte, a brand-name standardized extract, in the treatment of 2,245 patients who were classified as "Alken stage I or II" (this scale has not been equated to other standardized scales).[15] The trial abstract reports that the results demonstrated a decrease in IPSS and quality of life improvement.

The average daily dose is 10 grams of the ground seeds in either single or divided doses.[14,16,17] No adverse reactions or interactions with other drugs have been reported with the use of pumpkin seeds.[14-17]

β-Sitosterol

β-Sitosterol is a dietary supplement used for cholesterol level modification as well as for the treatment of BPH. It is one of the principal phytosterols in pygeum, another supplement used to treat BPH symptoms.

Table 1
Symptoms of benign prostatic hyperplasia

Obstructive
Decreased force of urine stream
Hesitancy or difficulty in initiating stream
Straining to urinate
Dribbling after urination
Incomplete emptying of bladder
Urinary retention
Irritative
Increased urination frequency
Nocturia
Dysuria
Urgency
Urge incontinence

The mechanism of action of the sitosterols is not well understood. Multiple mechanisms have been proposed and include antiandrogenic and antiestrogenic effects, inhibition of prostaglandin synthesis, and anti-inflammatory action.[12,16]

A limited number of trials have evaluated the efficacy of β-Sitosterol. The β-sitosterol study group examined 200 patients and evaluated the efficacy of Harzol® brand β-sitosterol (extracted from African star grass [*Hypoxis rooperi*]) 20 mg three times per day for six months to treat the symptoms of BPH.[18] The researchers noted a significant decrease in modified Boyarsky score (6.7 in the treatment group vs. 2.1 in the placebo group) after four weeks of intervention. The study also showed statistically significant improvement in all of the following parameters in the treatment and placebo groups, respectively: IPSS (7.4 point vs. 2.1 point reduction), QOL (1.4 vs. 0.2 reduction), MFR (5.2 mL/s vs. 1.1 mL/s increase), median flow rate (3.0 mL/s vs. 0.3 mL/s increase), voiding time (15.5 s reduction vs. 2.8 s increase), and RUV (35.4 mL vs. 11.6 mL reduction). Those participants who continued in the β-sitosterol treatment group maintained the improvement in all parameters, but did not demonstrate further improvement during an 18-month follow-up to the study.[19]

A separate trial compared the efficacy of Azuprostat® 130 mg daily and placebo over a six-month period in 177 patients with symptomatic BPH.[20] The treatment group showed a statistically significant decrease in IPSS scores in favor of the treatment group compared to placebo, 8.2 vs. 2.8, as well as marked changes occurred during the first month of therapy, and then additional improvements were demonstrated more slowly throughout the course of treatment.

Very few adverse effects have been reported; the most common side effect is GI disturbance. Two incidents of sexual dysfunction have been reported.[18] The daily dose range is 60-130 mg of

β-sitosterol. Theoretically, interactions could include an additive effect with antihyperlipidemics. For that reason, firm adherence to scheduled cholesterol monitoring is recommended for patients on lipid-lowering medications.

Rye Grass

Rye grass pollen extract is supplement traditionally used for the relief of BPH symptoms. It is believed to work by multiple mechanisms that include antiandrogenic effects, increased bladder muscle control, relaxation of urethral smooth muscle,[21] and inhibition of prostaglandin and leukotriene synthesis.[22]

Several studies have evaluated the efficacy of a particular brand of extract called Cernilton®. One randomized, double blind, clinical trial evaluated Cernilton 126 mg twice daily for six month vs. placebo in 60 patients awaiting operative treatment for outflow obstruction.[23] The results indicated statistically significant improvement in symptoms of nocturia and incomplete emptying. The study also showed a statistically significant decrease in anteroposterior diameter (18.2% in the Cernilton group vs. 4.6% in the placebo group) and a decrease in residual urine volume (101.9 ± 87.3 mL vs. 113.4 ± 87.3 mL). The authors also reported no adverse effects in the treatment group.

One study in 159 patients compared Cernilton to Paraprost®, another product used for BPH symptoms that is a mixture of the amino acid L-glutamine, L-ariginine, and glycine.[24] The study noted significant improvements in the Cernilton group in respect to RUV, MFR, and prostate weight. The investigators determined that the intervention was “moderately effective” in 49.1% of the Cernilton patients as compared to 41.2% in Paraprost group. There were no adverse effects or clinical abnormalities noted.

Another study evaluating Cernilton 126 mg twice daily for 12 weeks in 79 men with mild-to-moderate symptomatic BPH concluded that the rye grass pollen extract caused improvement from baseline in all subjective symptoms measured as well as in flow rate and residual urine volume.[25] The symptoms examined were urgency/discomfort, dysuria, nocturia, incomplete emptying, prolonged voiding, delayed voiding, intermittency, and post-void dribbling. One major limitation to the validity of the study was the lack of a control group.

A more recent study evaluated the efficacy of Cernilton compared to Tadenan® in 89 patients (ages 50-68 years) with Stage I BPH.[22] Tadenan is *Pygeum africanum* extract standardized to 14% triterpenes and 0.5% n-docosanol. The results indicated that both products provided increased flow rate and decreased urine volume.

Table 2

American Urological Association (AUA) Urinary Symptom Index for Prostatism

Symptom	Score: Not at All	< 1 in 5 Times	< ½ the Time	= ½ the Time	> ½ the Time	Almost Always
1. Over the past month or so, how often have you had a sensation of not emptying your bladder completely after you finished urinating?	0	1	2	3	4	5
2. Over the past month or so, how often have you had to urinate again less than two hours after you finished urinating?	0	1	2	3	4	5
3. Over the past month or so, how often have you found you stopped and started several times when you urinated?	0	1	2	3	4	5
4. Over the past month or so, how often have you found it difficult to postpone urination?	0	1	2	3	4	5
5. Over the past month or so, how often have you had a weak urinary stream?	0	1	2	3	4	5
6. Over the past month or so, how often have you had to push or strain to begin urination?	0	1	2	3	4	5
7. Over the past month or so, how many times did you most typically get up to urinate from the time you went to bed at night until the time you got up in the morning?	0 times	1 time	2 times	3 times	4 times	5 times

Interpretation of AUA Symptom IndexAUA Symptom Score = Sum of Questions 1-7 = _____

Mild prostatism ≤ 7

Moderate prostatism 8-18

Severe prostatism > 18

Highest possible score = 35

Adapted from: Barry M, et al. The American Urological Association symptom index for benign prostatic hyperplasia. *J Urol* 1992;148:1549-1557.

In addition, both treatment groups noted an improvement in subjective symptom scores. However, methodological limitations of the study limit its usefulness in clinical decision-making.

Additional studies evaluating the efficacy of Cernilton in the treatment of BPH have reported significant improvements in objective as well as subjective parameters; however, these studies have not been published in English and, therefore, the quality of methodology could not be evaluated.[26,27]

Clinical trials have reported no adverse effects associated with rye grass pollen extract therapy.[24-27] The typical dose of extract studied in trials is 126 mg twice or three times daily for 3-6 months. There are no known interactions with prescription medications. Recommended monitoring is limited to that associated with the disease state.

Stinging Nettle Root

The root of the stinging nettle (*Urtica dioca*) contains polysaccharides which are believed to be responsible for its anti-inflammatory effects. Unidentified components present in certain aqueous, but not lipophilic, extracts reduce the binding of sex hormone binding globulin (SHBG) to prostatic membrane receptors[28] and inhibit 5-α-reductase and prostatic aromatase.[13]

Although four double-blind, placebo-controlled studies have been performed, the quality of the evidence could not be analyzed for this review, because none of the trials have been published in English. Tertiary sources have summarized the results of the trials, which included a total of 210 patients. The most recent trial reported a significantly larger decrease in the IPSS for the nettle root group, but differences in MFR, PVR and QOL score were not significant. Other trials reported an improvement in symptoms, as well as significant improvements in urinary output and MFR and a reduction of SHBG.[13]

An observation study of 67 patients with BPH, ages 53-87 years, was conducted using an aqueous alcohol extract of *Urtica dioica* and *Urtica urens* (dog nettle) roots for six months.[29] The investigatiors documented clinically

Table 3

Clinical trials of alternative therapies for benign prostatic hyperplasia

Supplement	Dose	Urodynamics	Symptoms	Prostate Size	PSA	Nocturia	Side Effects	Efficacy Evidence
Pygeum (14% triterpenes and 0.5% n-docosanol)	75-200 mg/d	+	+	—	U	+	GI discomfort constipation, nausea, diarrhea	Good
Saw Palmetto (> 85% fatty acids and sterol)	160 mg bid	+	+	—	—	+	GI discomfort headache, dizziness, impotence (with high doses)	Good
Stinging Nettle (hydroalcoholic root extract)	600-1,200 mg/d	+	+	—	U	+	GI distress, skin reactions, hyperhidrosis	Fair
Rye Grass Pollen Cernilton®	126 mg bid or tid	+	+	+	U	+	None reported	Fair
β-Sitosterol	60-130 mg QD	+	+	—	U	U	GI upset, nausea, diarrhea	Fair
Pumpkin Seed	10 g/d ground seed	U	+	U	U	U	None reported	Poor

Legend: + = positive effect; — = no effect; U = unknown effect

Efficacy Evidence

Excellent: Several well-designed, controlled human trials with minimal limitations
Good: Controlled human trials, with moderate design limitations
Fair: Controlled human trials, with major design limitations or very small populations
Poor: Few uncontrolled human studies

significant reductions from baseline in episodes of nocturia and corresponding decreases in post-void bladder volume. Prostate volume, as measured by ultrasound, was unchanged.

Stinging nettle root is well tolerated. A six-month study in 4,087 patients were reported very few adverse events. These were GI distress, allergic skin reactions, and hyperhidrosis. There are no known drug interactions with stinging nettle root, although there is a theoretical interaction with finasteride, based on the possibility of a clinically significant level of 5-α-reductase inhibition. Until more is known, concomitant use with finasteride should be avoided or carefully monitored.

Doses of stinging nettle root used in majority of clinical trial ranged from 600 to 1,200 mg/d of hydroalcoholic root extract. Patients who choose to use stinging nettle need to be aware that products are available that use the leaves and other above ground parts of the plant; these products have different chemical components and indications and cannot be used interchangeably.[14]

Pygeum africanum

The lipid-soluble constituents within the bark of the pygeum tree are the most pharmacologically active. The bark contains approximately 14% triterpenes; ferulic acid esters, such as n-docosanol and n-tetracosanol; and several phytosterols.[13,30,31] The anti-inflammatory activity associated with pygeum is due primarily to the action of the triterpenes, which inhibit enzymes implicated in connective tissue deterioration.[13,32] Prostaglandin formation within the prostate also is inhibited.[33] The phytosterols components inhibit prostaglandin synthesis and compete with precursors of androgens.[13] N- docosanol, specifically, has been demonstrated to decrease levels of testosterone, luteinizing hormone (LH), and prolactin in animal studies,[31] although one human study examining testosterone, follicle-stimulating hormone, LH, and estrogens did not find significant changes.[34] Pygeum also has an effect on glandular epithelium, causing "normalization" of histological changes. Inhibition of fibroblasts proliferation and increase in prostatic secretions have been noted, as well as estrogenic and antiestrogenic activity.[35] The slight

decrease in prolactic (which stimulates intraprostatic DHT synthesis and testosterone uptake) and possibly in testosterone; a decrease in proliferation of fibroblasts within the gland;[36,37] and a reduction in the excitability of the detrusor muscle[37] all contribute to alleviation of obstructive symptoms. Irritative symptoms may be relieved more by the increase in prostatic secretions. Although pygeum does inhibit 5-α-reductase, as well as the androgen receptors' binding of DHT, these actions are so minimal they probably are clinically insignificant.[34]

Although 46 investigations of pygeum extract have been conducted to date, only 11 have been placebo-controlled trials. A review of available trials, completed in 1995, concluded that pygeum extract did provide some benefit for both objective and subjective BPH symptoms and should be investigated further in comparison to standard pharmacological treatments.[37] The 43 trials covered in the analysis included a total of 2,262 patients.

Of the placebo-controlled studies, the largest to date (n=263) was published in German by Barlet et al in 1990.[38] A moderately detailed description of the trial was based on an English translation was published in 2000.[39] Results of this trial showed statistically significant improvement compared to placebo for symptoms of daytime and nighttime micturations, residual urine volume (24.5% and 3.5% reduction, respectively), urine volume (12% and 3.2% increase, respectively) and MFR (17.2 and 4.3% increase, respectively), with no change in the prostate volume.

A more recent meta-analysis of pygeum trials was published in 2000.[40] Eighteen trials met the inclusion criteria for the meta-analysis and presented the experiences of 1,562 patients. Thirteen trials were placebo-controlled and five were compared to other treatments such as NSAIDS or other herbal products. No comparisons to finasteride or α-blockers have been conducted. Twelve of the 13 placebo-controlled trials reported more improvement in outcome measures for pygeum groups and one did not find any difference in outcomes. Based on the effect size calculated for each of the trials, an overall effect size was estimated using six trials, an overall effect size was estimated using six trials of pygeum (n=474) that were judged by the authors to be sufficient for result pooling. The overall summary effect size of -0.8 (95% CI, -1.4 to -0.3) calculated by the authors is equivalent to an improvement that is both large and statistically significant. A summary effect size for improvement in nocturia was calculated separately and also was -0.8 (95% CI of -1.4 to -0.1), a moderate to large effect. The authors concluded that overall results of the analysis support improvements in urinary symptoms, peak urine flow, and nocturia that are moderate and statistically significant and that *Pygeum africanum* extracts may be an effective short-term treatment option for patients with BPH symptoms.

Pygeum is well tolerated. Adverse effects reported in studies are mild and include nausea, constipation, diarrhea, and gastrointestinal discomfort.[37,38,40] No interactions with any pharmaceutical agents have been identified or reported, although the possibility of additive hormonal effects should be kept in mind.

Doses used in clinical trials have ranged from 75 to 200 mg/d. One trial compared a 100 mg/d dosage given once daily or in two divided doses and found no difference in outcome.[41] The extract should be standardized to contain 14% triterpenes and 0.5% n-docosanol.

Saw Palmetto

The lipophilic extract of *Serenoa repens* (also known as *Sabal serrulata*) inhibits 5-α-reductase activity, theoretically decreasing the amount of DHT produced from testosterone. Although finasteride more specifically inhibits type two 5-α-reductase, *Serenoa repens* (saw palmetto) inhibits both types one and two.[42] The extent and significance of this activity in vivo is not completely understood, and measurements of the reductase activity are not always significantly decreased.[43] In addition, saw palmetto may decrease prolactic and have anti-inflammatory activity, as well as inhibit fibroblast and epidermal growth factors. Although antiestrogenic effects

may exist, this action has not been well described.

Saw palmetto is the most investigated of all natural product therapies used for treatment of BPH. A systematic review of saw palmetto trials was published in 1998.[44] The investigators analyzed 18 of the 24 trials located in an exhaustive literature search. Analysis revealed 24-28% improvements in nocturia, MFR, mean urine flow, and "urinary tract symptoms" compared to placebo. Improvements were similar when compared to finasteride. The authors concluded that saw palmetto extracts do improve BPH symptoms and that improvements are similar to those experienced with finasteride treatments; however, fewer adverse effects were reported in the saw palmetto groups.

One of the placebo-controlled studies is of particular interest because of the investigators' attempt to reduce the influence of the placebo effect (i.e., BPH symptoms are known to be associated with placebo response rates of 30-40% or more clinical trials[2]). Descotes et al designed a trial in which all patients with a 30% or greater improvement in symptom scores during a 30-day placebo run-in period were excluded from the study population. The remaining patients (n=176) were randomized to receive placebo or a standardized saw palmetto extract 160 mg (Permixon®) twice daily for 30 days. Results included a significantly greater increase in MFR in the Permixon group (28.9% vs. 8.5% for Permixon and placebo, respectively). There also was a significant difference between groups in the decrease of nocturnal urinations (-32.5% vs. -17.7% for Permixon and placebo, respectively). Despite the differences in these more objective parameters, however, the patient-based and physician-based global assessments of efficacy did not reveal significant differences, although they did favor Permixon. The investigators concluded that the overall clinical significance of Permixon treatment probably was less than what might be indicated by the statistically significant differences between treatment groups.[45]

A three-year observational study of the IDS 89 extract of saw palmetto in 435 patients noted an increase in MFR of 6.1 mL/s (13.4 mL/s to 19.5 mL/s) and a 50% reduction in RUV (64 ± 41 mL to 32 ± 36 mL). Nocturia resolved or improved in 73.3% of patients. According to the Boyarsky scale, 53-80% of patients were classified as symptom-free or improved. The investigators noted that the deterioration rate at three years for the 315 patients who completed the study was significantly lower than would be expected in BPH patients not receiving pharmacological or surgical treatment.[46]

Additionally, the standardized saw palmetto lipophilic extract, Permixon, has been compared to the 5-α-reductase inhibitor finasteride.[47] Patients (n=1,098) were randomized to receive Permixon 160 mg twice daily or finasteride 5 mg once daily for 26 weeks. The primary outcome measure was improvement in the IPSS. Assessments of QOL, sexual function, prostate-specific antigen (PSA), urodynamics, and prostate volume were also performed. The IPSS decreased by 37% and 39% and MFR increased by 25% and 30% in the Permixon and finasteride groups, respectively. QOL improved approximately 40% in both groups. Differences were noted between the Permixon and finasteride groups for prostate volume, which decreased 6% vs. 18% respectively, and for PSA, which was unaffected by Permixon, but decreased 41% in the finasteride group. Adverse event reports indicated that sexual function was less affected by Permixon than by finasteride.

Saw palmetto generally is well tolerated. A few reports include adverse events of nausea, headache, dizziness, dysuria, and GI discomfort. A three-year study in 435 patients reported mild adverse events in 34 patients.[13] High doses have been associated with impotence and decreased libido. Although no interactions with pharmaceutical agents have been specifically identified, recommendations to avoid use in conjunction with hormonal or antihormonal therapies seem sound, based on the known pharmacological actions.

Saw palmetto products should be standardized to contain 85% or more fatty acids and sterols. The dose is 160 mg twice daily and may be taken with meals if GI upset occurs.

Conclusions

The most important contradiction to any alternative or complementary therapy is lack of a medical diagnosis. As with any BPH therapy, the possibility of prostate cancer must be eliminated before patients begin any symptomatic treatment.

Monitoring of patients taking any of the alternative treatments discussed should be the same as for any BPH patient: digital rectal exam to observe for increase in prostate size, a scored symptom questionnaire, and a regular serum PSA. An increase in or exacerbation of symptoms may indicate the necessity for uroflowmetry studies, urine culture, or biopsy. In addition, an inquiry into any possible side effects should be a part of any regular clinic visit.

Because BPH usually is a long-term, slowly processing disease state whose standard treatment often includes “watchful waiting,” the use alternative therapies for symptom reduction can be very appropriate. Unfortunately, those products tested in BPH clinical trials are not widely accessible in the United States. Therefore, successful treatment requires products standardized to the same component percentages as the tested products, good patient education to ensure safety, and reasonable patient and physician expectations.

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