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1 Overview

Summary and Quick Facts for Benign Prostatic Hyperplasia (BPH)

- Benign prostatic hyperplasia (BPH) is a condition of prostate gland enlargement that often causes bothersome urinary symptoms. It primarily affects older men: about 25% of men in their 40s have BPH, but this increases to more than 80% between the ages of 70 and 79.
- This protocol will discuss the underlying causes of BPH and review conventional treatments along with their drawbacks. In addition, we will review several scientifically studied natural therapies that may ease BPH symptoms, as well as an innovative medical therapy that may provide relief to BPH sufferers who have failed to respond to conventional therapy.
- Natural interventions such as saw palmetto and beta-sitosterol may help keep the prostate healthy to prevent the development and/or progression of BPH.

What is Benign Prostatic Hyperplasia?

Benign prostatic hyperplasia (BPH) is a condition of prostate gland enlargement that often causes bothersome urinary symptoms. Enlargement of the prostate can cause obstruction of the lower urinary tract and the subsequent symptoms.

BPH is caused by several factors, including reduced prostate cell regulation, hormonal imbalance (abundance of dihydrotestosterone or estrogens), and increased levels of insulin-like growth factors and inflammatory markers.

Natural interventions such as **saw palmetto** and **beta-sitosterol** may help keep the prostate healthy to prevent the development and/or progression of BPH.

What are the Risk Factors for Benign Prostatic Hyperplasia?

- Advanced age (more than 80% of men in their 70s have BPH)
- Ethnicity (lower risk in Asian men, higher risk in Caucasian and Afro-Caribbean men)
- Obesity
- Diabetes

What are the Signs and Symptoms of Benign Prostatic Hyperplasia?

- Weak urinary stream
- Urinary hesitancy (delayed initiation of urination)
- Involuntary cessation of urination
- Straining to void
- Feeling of incomplete emptying of the bladder
- Increased frequency or urgency to urinate
- Nighttime urination
- Painful urination
- Incontinence

What are the Conventional Medical Treatments for Benign Prostatic Hyperplasia?

- In men with mild BPH, "watchful waiting" may be appropriate – annual exams and completion of the American Urological Association Symptoms Index (AUASI)
- In men with moderate-to-severe BPH, pharmacological treatment can be considered:
  - α1-adrenergic receptor blockers such as alfuzosin (Uroxatral) and terazosin
  - 5α-reductase inhibitors such as finasteride (eg, Proscar, Propecia) and dutasteride (Avodart)
  - Antimuscarinics such as darifenacin (Enablex) and tolterodine (eg, Detrol)
  - Phosphodiesterase-5 inhibitors such as tadalafil (Cialis)
- Surgery to remove the prostate or reduce its size

What are Emerging Therapies for Benign Prostatic Hyperplasia?

- Botulinum toxin relaxes muscles by preventing acetylcholine signaling. For this reason, intraprostatic botulinum toxin injections may relax the excessive smooth muscle contractions associated with BPH to relieve some urinary symptoms.

What Dietary and Lifestyle Changes Can Be Beneficial for Benign Prostatic Hyperplasia?

The following may reduce the risk of developing BPH:

- Diet high in vegetables and fruit and low in red meat and calories
- Maintaining a healthy body weight and blood sugar levels
- Physical activity and exercise
- Maintaining sufficient vitamin D levels

What Natural Interventions May Be Beneficial for Benign Prostatic Hyperplasia?

- **Saw palmetto**. Saw palmetto is the most used phytotherapeutic treatment for BPH. A pilot study found that supplementation reduced symptoms by 50%.
- **Beta-sitosterol**. Beta-sitosterol is a plant-derived compound similar to cholesterol. It has been shown to improve BPH symptoms in several clinical studies.
- ***Pygeum africanum***. Also known as African plum, *P. africanum* may prevent the growth of prostate cells. Moderate relief of urinary symptoms was seen in subjects with BPH who were treated with African plum.
- **Rye pollen**. Rye pollen extract has been shown to reduce nighttime urination, improve urinary flow rate, and shrink the prostate.
- **Stinging nettle**. Stinging nettle, either alone or in combination with saw palmetto, has been shown to improve BPH symptoms.
- **Isoflavones**. Soy isoflavones were found to reduce PSA levels in men with prostate cancer. Isoflavones may inhibit testosterone-mediated prostate cell growth.

- **Pumpkin seed oil**. Clinical evidence suggests that pumpkin seed oil may mitigate BPH symptoms, but the effect size is typically modest.
- **Lycopene**. Lycopene is a carotenoid that occurs abundantly in tomatoes. Men with higher lycopene levels are less likely to develop prostate cancer, and supplementation may decrease the growth of prostate cancer.
- **Essential fatty acids**. Fatty acids such as eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), and gamma-linolenic acid (GLA) may support prostate health.
- Other natural interventions such as **flaxseed oil** and **lignan extract**, **Boswellia serrata**, **selenium**, **garlic**, and **beta-carotene** and **vitamin C** may improve prostate health and reduce the risk of developing BPH.

2 Introduction

Benign prostatic hyperplasia or "BPH" is a condition of prostate gland enlargement often leading to bothersome urinary symptoms (Untergasser 2005; Harvard Health 2012; Mayo Clinic 2011; Merck Manual 2008; NKUDIC 2012). It primarily affects older men: about 25% of men in their 40s have BPH, but this increases to more than 80% between the ages of 70 and 79. According to 2007 data, BPH is responsible for 1.9 million doctor's visits and more than 202000 trips to the emergency department (Sarma 2012).

Benign prostatic hyperplasia can cause significant urinary symptoms in men. In fact, more than 50% of men in their 60s and approximately 90% of men over the age of 80 have lower urinary tract obstruction due to prostate enlargement. This causes symptoms such as a weak urinary stream, urinary hesitancy (delay in initiating urination), involuntary cessation of urination, straining to void, and a feeling of incomplete emptying of the bladder. Blockage of the urethra, the "tube" through which urine leaves the body, by the prostate can also affect the bladder. This may result in increased urinary frequency/ urgency, need to urinate during the night, bladder pain, painful urination, and/or incontinence (Sarma 2012).

Sex hormones exert significant influence over BPH development and progression. While many men are aware of a pro-growth role of a testosterone metabolite called DHT (*dihydrotestosterone)* in prostatic hyperplasia, few know that ***estrogen*** may also contribute to BPH (Ho 2008; Matsuda 2004). Aging in men is associated with an increase in the activity of an enzyme called aromatase, which converts testosterone into estrogen (Vermeulen 2002). Some research suggests increased estrogen levels in prostate tissue may promote hyperplasia (Ho 2008; Sciarra 2000; Jasuja 2012; Barnard 2009; Kozak 1982; Burnett-Bowie 2008).

This protocol will discuss the underlying causes of BPH and review conventional treatments along with their drawbacks. In addition, we will review several scientifically studied natural therapies that may ease BPH symptoms, as well as a novel medical therapy that may provide relief to BPH sufferers who have failed to respond to conventional therapy.

3 Prostate Function and Causes of BPH

The main function of the prostate is to facilitate male fertility. This is accomplished through the liquid volume of ejaculate, rich in fructose, which functions as a fuel source for sperm, and also contains a protein called prostate-specific antigen (PSA). PSA is believed to help liquefy the ejaculate and promote sperm motility (McNicholas 2008).

The development of BPH is a multifactorial process. As men age, prostate cell growth becomes less well controlled by cell signaling activity. Also, the cells in the prostate become less responsive to signals that induce apoptosis or "programmed cell death". This results in an overabundance of cells in the prostate, also known as prostate hyperplasia (McNicholas 2008).

This breakdown in cellular regulation that occurs with aging allows prostate cells to proliferate and promote the formation of additional tissue. This additional tissue is smooth muscle, and this tends to increase the overall muscle tone of the prostate, which can contribute to blockage of the urinary tract (McNicholas 2008).

Imbalanced hormone levels contribute to BPH. A derivative of testosterone called **dihydrotestosterone** (DHT) stimulates growth of the prostate. DHT is derived from testosterone via conversion by the enzyme *5α-reductase*, which is an important pharmacologic target for BPH therapies (Lepor 2004). In addition, high levels of insulin-like growth factors and inflammatory markers (eg, C-reactive protein) can also contribute to BPH (Sarma 2012;

McNicholas 2008).

Furthermore, ethnic differences have been reported, such as lower rates of BPH and prostate surgery among Asian men relative to Caucasian men. Furthermore, one study reported higher rates of moderate-to-severe lower urinary tract symptoms among Afro-Caribbean men relative to Caucasian men, whereas other studies have shown similar rates of BPH diagnosis and hospitalization among Afro-Caribbean men and Caucasian men (McNicholas 2008).

Estrogen and BPH

Estrogens appear to contribute to prostate tissue growth and may represent an underappreciated piece of the BPH puzzle (Ho 2008; Matsuda 2004).

As men age, estrogen (eg, estrone and estradiol) levels appear to increase. Aromatase, an enzyme which converts testosterone into estrogen, also increases with age in men (Vermeulen 2002). BPH risk also increases with age and studies have identified high concentrations of estradiol in cells from hyperplastic prostates (Jasuja 2012; Barnard 2009; Kozak 1982). Further investigations into the action of estrogen receptors in prostate cells led one group of researches to conclude that "*…estrogens… may contribute at some level to the etiology of the most prevalent prostatic diseases including… BPH…*" (Prins 2008).

Therefore, based on these and other findings, Life Extension suggests that aging men strive to maintain estradiol blood levels between 20 and 40 pg/mL for optimal prostatic and overall health.

A potentially useful strategy to help aging men control estradiol levels is to take an aromatase inhibiting drug like anastrazole (Arimidex®). One study showed that men 60 or older with low testosterone levels who took anastrazole for 12 months exhibited a reduction in serum estradiol levels without significant increases in BPH symptoms (Burnett-Bowie 2008). However, evidence is inconsistent regarding the efficacy of aromatase inhibitor therapy in BPH, as these drugs can increase DHT levels (Suzuki 1998). Fortunately, there are *5-alpha reductase*-inhibiting drugs like Avodart® and finasteride that can block DHT formation and thus neutralize this factor behind so many cases of prostatic enlargement. Men who have BPH, and whose estradiol levels are above the optimal range of 20 – 40 pg/mL, are encouraged to discuss use of aromatase inhibiting drugs with their healthcare provider.

4 Diagnosis

Symptoms of BPH (eg, weak stream, urinary hesitance, incomplete emptying, etc.) are usually related to obstruction of the urinary tract. Severity of the symptoms can be measured using the American Urological Association Symptom Index (AUASI), a widely used questionnaire that quantifies the severity of lower urinary tract blockage symptoms (Sarma 2012). The International Prostate Symptom Score, or IPSS (Zhang 2008), is another questionnaire often used for quantifying symptoms of BPH in research studies.

The first step in evaluating patients with BPH-related symptoms includes a complete overview of the patient's general medical, neurological, and urological history, as well as their fluid and caffeine consumption, to rule out other causes of urinary tract symptoms. Medications should also be reviewed, since diuretics and antihistamine drugs may cause urinary symptoms (Sarma 2012).

Next, a digital rectal exam (DRE) is performed and PSA levels are measured (Sarma 2012). PSA levels are important because while BPH is associated with some elevation of PSA levels, a very high or quickly-rising PSA level can be a sign of prostate cancer. For example, in one study, the median PSA value in patients with BPH was 1.8 ng/mL, whereas the median PSA value among patients with prostate cancer was 13.2 ng/mL (Lakhey 2010). Still, PSA levels are not a perfect measure since levels can be normal in men with prostate cancer. Therefore, the DRE (digital rectal exam) is also important, both to help rule out prostate cancer (a smooth prostate accessible by rectal examination is less likely to be cancerous than one with hard nodules and irregularities) and to determine the size of the prostate. Classification of the prostate size as "normal," "big," and "very big" can help determine therapy. Measuring urine flow rates using uroflowmetry can also help assess bladder outflow obstruction (McNicholas 2008). Additional testing such as free PSA and PSA velocity also help to differentiate BPH from prostate cancer. For more information see the *Life Extension Magazine* article entitled "*Life Saving Advances in Prostate Cancer Testing*".

The PSA Controversy

In May 2012 the United States Preventive Services Task Force (USPSTF), a panel of experts that makes recommendations on preventive medicine practices to healthcare providers in the United States, proclaimed that regular PSA testing should not be used as a screening tool for prostate cancer based upon their analysis (USPSTF 2012).

There were several problems with the USPSTF analysis. The report de-emphasized a major, high quality trial that showed robust mortality benefits by including trials of poor/ lesser quality that did not show mortality benefits, and therefore, diluted the over-all statistical effect of the higher quality trial on mortality (benefit) in their analysis.

This high quality trial was the European Randomized Study of Screening for Prostate Cancer (ERSPC), which randomized 182000 men aged 50 to 74 from 7 countries to PSA testing every 2 to 7 years (depending on center and year) or to usual care. A prespecified analysis of 162243 men aged 55 to 69 found that screening was associated with 20% reduction in prostate cancer-specific mortality, for an estimated 1410 men undergoing PSA screening (Schroder 2009).

After publication of the main ERSPC results, a participating center (Göteborg, Sweden) reported their results separately. This site determined that a PSA screening threshold of **2.5** to **3.0** µg/L every 2 years in 20,000 men aged 50 to 64 years decreased risk for prostate cancer-specific mortality by 44% after a median of 14 years (Hugosson 2010).

Poor-quality trials included by the USPSTF in their analysis statistically diluted the beneficial effect observed in the higher quality ERSPC trial in their over-all assessment. Several lesser/ poor quality trials found no difference between screening-invited and control groups in prostate cancer-specific mortality risk (Kjellman 2009; Sandblom 2011). Major methodological flaws in these trials included failure to adequately control for randomization and/ or poor allocation blinding, poor attempts to capture lost data points, etc. One trial even used an exorbitantly high PSA cut point – **10** µg/L – as a screening threshold (Kjellman 2009).

Life Extension advocates the use of PSA screening to prevent prostate cancer deaths, with an important caveat– PSA results should be tracked and monitored over time (ie, PSA velocity) with less emphasis being placed on individual test results. Life Extension issues a cautionary advisory whenever PSA levels exceed **1.0** ug/L. A level of say **1.4** should be closely followed with PSA blood tests every 6-12 months to carefully track any consistent increase indicative of an early stage prostate tumor that may be treatable with lifestyle changes and medications with low side effect profiles.

Life Extension has examined this issue in detail. For more information please see the Life Extension magazine multi-part series entitled "*The PSA Controversy*".

5 Conventional Treatment

Conventional BPH treatments typically depend on the severity of the patient's symptoms. In men with mild or asymptomatic BPH, watchful waiting is appropriate, which includes an annual physical examination and completion of the AUASI (Sarma 2012).

Pharmacologic Treatment

Pharmacological treatment options can be employed for men who have moderate-to-severe (AUASI score ≥ 8) and/or bothersome symptoms after consideration of the risks and benefits (Sarma 2012). Currently, four different classes of medications and/or surgery are used to treat BPH.

α1-adrenergic receptor blockers

Increased smooth muscle tone in the prostate is responsible, at least in part, for some of the urinary symptoms associated with BPH (McNicholas 2008). Smooth muscle tone is regulated by α1-adrenergic receptors, which respond to levels of certain hormones in the body. One BPH treatment option includes α1-adrenergic receptor blocker medications, since the α1A subtype of these receptors is thought to be the main regulator of smooth muscle tone in the neck of the bladder and prostate (Nickel 2008a). Treatment with α1-adrenergic receptor blockers is generally considered first-line therapy for symptomatic BPH (Elterman 2012),

even though some of these drugs were initially developed as high blood pressure treatments (Nickel 2008a).

There are many different α1-adrenergic receptor blockers, and the four most prescribed – alfuzosin (Uroxatral®), terazosin (Hytrin®, Zyasel®), doxazosin (Cadura®, Carduran®), and tamsulosin (eg Flomax®) – all effectively increase urinary flow rate and relieve BPH symptoms. However, these medications also have side effects, such as low blood pressure and dizziness, although tamsulosin may have a reduced risk of these side effects (Nickel 2008a). Furthermore, these medications do not prevent BPH progression and are usually only effective for up to 4 years (Elterman 2012).

5α-reductase inhibitors

Medications in the 5-α-reductase inhibitor class block the conversion of testosterone to dihydrotestosterone, helping to shrink the prostate and prevent further growth.

Finasteride (eg, Proscar®, Propecia®) and dutasteride (Avodart®) are two FDA-approved 5α-reductase inhibitors. Both medications are capable of reducing prostate size by as much as 25% and can reduce AUASI scores by 4–5 points in men with large prostates (Sarma 2012). Combining α1-adrenergic receptor blockers with 5α-reductase inhibitors may increase the benefits for men with BPH (Azzouni 2012).

Medications in the 5α-reductase inhibitor class are associated with significant sexual side effects, including decreased libido, impotence, reduced ejaculate volume, and problems with ejaculation (Sarma 2012; Azzouni 2012). In addition, some men experience breast enlargement and tenderness. Although sexual side effects associated with 5α-reductase inhibitors tend to decrease over time (Azzouni 2012), some men experience persistent diminished libido, erectile dysfunction, and depression when using these drugs (Traish 2011).

Some important considerations should be taken into account when choosing between finasteride and dutasteride in the management of BPH. First, there are 2 variants (ie, *isoforms*) of the 5α-reductase enzyme – type 1 and type 2; both are present in prostate tissue. However, evidence suggests that the type 1 isoform may be more active in malignant prostate tissue (Thomas 2008). This is significant because dutasteride inhibits both type 1 and 2 isoforms, whereas finasteride inhibits only type 2. This means that dutasteride may more effectively control growth of cancerous tissue than finasteride. Since several studies suggest the two drugs confer similar benefits and risks in BPH, dutasteride appears to be a better choice as it might also provide some cancer protection (Fenter 2008; Choi 2010; Nickel 2011; Festuccia 2008; Makridakis 2005).

Antimuscarinics

Many men with BPH also have an overactive bladder, which can cause symptoms such as urinary urgency and incontinence (Elterman 2012). Antimuscarinic drugs block muscarininc receptors in the detrusor muscle. This muscle contracts and squeezes the bladder to facilitate urination, and remains relaxed otherwise, allowing the bladder to stretch and fill. Activation of muscarininc receptors stimulates contraction of the detrusor muscle. Pharmacologic blockade of these receptors decreases the incidence of overactive-bladder symptoms of BPH (Sarma 2012).

Many antimuscarinic drugs have been approved to treat symptoms of overactive bladder, including darifenacin (Enablex®), tolterodine (eg, Detrol®), fesoterodine (Toviaz®), trospium chloride (Sanctura®), oxybutynin (Ditropan®), and solifenacin (Vesicare®) (Sarma 2012). Combining antimuscarinic medications with α-adrenergic blockers can improve BPH symptoms, particularly the number of times patients need to urinate during the day and night as well as episodes of urinary urgency (Borawski 2011). However, there is insufficient evidence that these medications are effective when used as a single therapy for individuals with predominantly storage problems (Sarma 2012).

One concern with these medications is that they can cause increased urinary retention, although studies in men with good emptying (post-voiding residual urine volume less than 250 mL) have not identified any

adverse effects associated with urinary retention. However, caution should be used in men with incomplete bladder emptying (Borawski 2011). Common side effects associated with these medications include dry mouth, dry eyes, and constipation (Sarma 2012).

Phosphodiesterase-5 Inhibitors

Men with lower urinary tract symptoms sometimes experience erectile dysfunction, which has led some researchers to speculate that the two symptoms may be linked (Roumeguere 2009). Phosphodiesterase inhibitors are used to treat erectile dysfunction, but may also relieve lower urinary tract symptoms in men with BPH (Sarma 2012).

These medications may work via several mechanisms. One postulated mechanism is that phosphodiesterase-5 inhibitors block a signaling pathway that causes smooth muscle contraction. They may also increase levels of nitric oxide, a compound that relaxes smooth muscles in the lower urinary tract. They have also been proposed to decrease hyperactivity of the autonomic nervous system affecting the bladder, prostate, and penis (Laydner 2011).

A comprehensive review found that phosphodiesterase-5 inhibitors alone effectively treat lower urinary tract symptoms and erectile dysfunction, and that treatment with both phosphodiesterase-5 inhibitors and alpha-blockers leads to a small improvement in flow rates in men with BPH. This class of medication may even be effective in patients without erectile dysfunction (Gacci 2012). Tadalafil (Cialis®) is the only medication of this class that has been approved by the Food and Drug Administration (FDA) for treating urinary symptoms. It can cause headaches, flushing, indigestion, back pain, and nasal congestion, and may lead to low blood pressure when combined with α1-adrenergic blockers or organic nitrates (eg, nitroglycerin) (Sarma 2012).

Surgery

BPH can also be treated surgically. The purpose of surgery is to either remove the prostate or reduce its size, thereby relieving the lower urinary tract symptoms.

Two minimally invasive treatments — transurethral needle ablation of the prostate and transurethral microwave thermotherapy — have been developed to treat BPH, although there is some uncertainty regarding which patients will respond well, and more studies need to be done to evaluate the effectiveness of these treatments. More invasive procedures can be used for patients with moderate-to-severe symptoms of BPH, particularly for patients who have not responded to pharmacologic therapy (McVary 2011).

Transurethral protastectomy (TURP), a procedure in which the prostate is endoscopically removed, is the benchmark surgical therapy for BPH (McVary 2011). Endoscopic procedures involve insertion of fine surgical and viewing devices directly into the patient's body through small incisions; this type of surgery is less invasive than traditional "open" surgery. However, approximately 14% of men who undergo TURP will become impotent (Roehrborn 1999). This procedure can also cause transurethral prostatectomy syndrome, a serious complication in which fluid used to irrigate the surgical area enters the intravascular space. This can result in cardiopulmonary (heart and lung) complications (eg, high or low blood pressure, slow heart rate, irregular heartbeat, respiratory distress, shock), hematologic and renal (blood and kidney) systems (eg, excess ammonia in the blood, electrolyte disturbance, anemia, acute renal failure), and the central nervous system (eg, nausea/vomiting, confusion/restlessness, blindness, twitches/seizures, lethargy/paralysis, dilated/nonreactive pupils, coma), as well as death (Gravenstein 1997). Other complications include voiding failure, urinary tract infections, and bleeding during or after surgery (Reich 2008).

Men with very large prostates may benefit from an *open prostatectomy*, in which the entire prostate is removed, but this treatment can result in significant blood loss, incontinence, impotency, pain, and longer hospital stays (McVary 2011).

Transurethral laser therapy is another surgical option that is gaining momentum. This treatment option may reduce the length of stay in the hospital, although more information regarding the safety of this therapy is needed (McVary 2011). The adoption of laser-based operations for BPH has led to more cases of BPH being treated

surgically (Schroeck 2012).

Intraprostatic botulinium toxin injections – an emerging BPH therapy

Botulinum toxin is a bacteria-derived neurotoxin that relaxes muscles by preventing certain neurotransmitter (acetylcholine) signals. Since lower urinary tract symptoms are attributable in part to excessive smooth muscle contraction around the bladder and prostate in men, scientists have hypothesized that injecting botulin toxin directly into the prostate may relax those muscles and relive some urinary symptoms (Mangera 2010).

In a preliminary trial, 10 men with lower urinary tract symptoms suggestive of BPH received intra-prostatic injections of botulinum toxin. Significant improvements were noted, including a nearly 50% reduction of urinary symptoms assessed by a standardized assessment, a significant reduction in PSA levels and prostate volume, and a 42% reduction in frequency of nighttime urination. The investigators in this study concluded that "*[i]ntraprostatic injection of Botulinum-A may be an effective and safe treatment for symptomatic BPH in selected patients whose medical treatment has faced failure and are poor surgical candidates*" (Hamidi Madani 2012). Another similarly designed study on 10 men with BPH demonstrated similar efficacy: "*Intraprostatic [purified botulinum neurotoxin] injection induces prostate shrinkage and is effective in men with BPH*" (Yokoyama 2012). A slightly larger study (34 men with BPH who failed medical treatment) published in September 2012 reported very similar findings (Arnouk 2012).

6 Dietary and Lifestyle Considerations

There are many factors associated with reduced risk of developing BPH. These include:

Healthy diet. Excessive calories, animal proteins (red meat, dairy, poultry), and fats are associated with the development of BPH. Conversely, diets high in vegetables and fruits are associated with less risk of developing BPH (Parsons 2010).

Weight loss and blood sugar control. Fat mass (adiposity) is strongly associated with prostate size; and weight, as well as body mass index (BMI), have shown similar associations (Parsons 2010). One study found obese men are 3.5 times as likely to experience prostate enlargement as normal weight men (Parsons 2006). Diabetes, as well as high insulin and fasting glucose levels, have also been linked to prostate enlargement and BPH (Parsons 2010).

Exercise. Exercise and physical activity reduce the risk of developing BPH. An analysis of 11 studies involving over 43,000 men found moderate or vigorous physical activity reduced BPH risk as much as 25% compared with a sedentary lifestyle. Higher levels of physical activity were associated with greater protection (Parsons 2008).

Vitamin D levels. Vitamin D deficiency is associated with prostate enlargement, and increasing vitamin D intake reduces the risk of BPH and can help reduce prostate size in men with BPH (Espinosa 2013; Zhang 2016).

7 Nutrients

Treatment of BPH with plant-derived compounds dates back to the 15th century BC in Egypt and natural therapies comprise approximately 50% of all treatments for BPH in Italy (Wilt 1998).

Saw Palmetto – Saw palmetto, also known as *Seronoa repens* (*S. repens*) or *Sabal serrulata* (*S. serrulata*), is the most widely used phytotherapeutic treatment for BPH (Wilt 1998; Gordon 2003). It has been documented as a treatment for swollen prostate glands since the 1800s (Wilt 1998). Saw palmetto has been found to be effective in treating the lower urinary tract symptoms of BPH. Evidence suggests that saw palmetto has similar efficacy to finasteride and tamsulosin, two medications used to treat BPH (Suter 2013). Saw palmetto extract appears to inhibit the activity of the 5α-reductase enzyme. It may also have anti-inflammatory properties and a tendency to promote apoptosis of prostate cells (Habib 2009; Suter 2013).

A pilot study examining the effects of 320 mg of saw palmetto extract found that this herbal treatment reduced BPH symptoms by over 50% after 8 weeks of treatment (Suter 2013). Another study found a combination of saw palmetto and stinging nettle root extract to be as effective as finasteride at treating BPH (Sokeland 2000). However, a review of studies found that saw palmetto was not significantly better than placebo (Tacklind 2012).

But differences in methodological quality of the studies included in this review limit the interpretation of the results.

Saw palmetto has not been reported to cause any significant side effects. A study found no difference in the rate of serious and non-serious symptomatic adverse events between saw palmetto and placebo (Avins 2008). Most studies examining the benefits of saw palmetto for BPH have used doses of 320 mg daily (Dedhia 2008). Saw palmetto is rich in phytosterols, including beta-sitosterol (see below), and this may contribute to its therapeutic effects (Sorenson 2007).

Beta sitosterol – Beta-sitosterol belongs to a family of plant-derived compounds chemically similar to cholesterol. These compounds are called ***phytosterols***. The impact of human intake of phytosterols has been studied in a variety of contexts, including cardiovascular disease and cancer (Jones 2009; Choudhary 2011; Rocha 2011; Genser 2012; Othman 2011). A beneficial role for phytosterols, and beta-sitosterol in particular, in prostate conditions is supported by a considerable body of research in both laboratory and clinical settings (Coleman 2002; Wilt 1999; Wilt 2000; Shi 2010; Shenouda 2007; Kobayashi 1998; Klippel 1997; Berges 1995).

A comprehensive review of 4 studies comprising data on 519 men with BPH showed that beta-sitosterol improved urinary symptoms and flow measures (Wilt 2000). A clinical trial in which men with symptomatic BPH consumed beta-sitosterol or placebo for 6 months, and were then followed for another 12 months, gave men the option to discontinue therapy after 6 months, or continue. Those men who chose to continue taking beta-sitosterol showed stable results on standardized prostate/urinary symptom and quality of life assessments at the 18-month follow-up, while men who chose not to continue therapy experienced a decline in some of the prostate/urinary scores (Berges 2000). In another clinical trial, 200 men with symptomatic BPH were randomized to receive either 20 mg of beta-sitosterol 3 times daily or placebo for 6 months. Men who took beta-sitosterol experienced greater improvements on 2 standardized assessments of prostate/urinary symptoms than men who took a placebo. Beta-sitosterol recipients also experienced improvements in peak urine flow rate and residual urinary volume; these parameters were unaffected by the placebo (Berges 1995). These results were corroborated in a later study of similar design, but which employed a higher dose of beta-sitosterol (130 mg daily). Men who took beta-sitosterol in this study not only experienced improvements in standardized prostate/urinary symptom assessments over placebo, but also in quality of life (Klippel 1997). In a clinical trial on 127 men with BPH, a combination of saw palmetto, beta-sitosterol, vitamin E, and rye flower pollen extract was superior to placebo in improving urinary frequency at night and during the day and also led to more significant improvements on a standardized prostate/urinary symptom assessment (Preuss 2001).

Pygeum Africanum – *Pygeum africanum* (*P. africanum*), also known as African plum, is used as a treatment for BPH in Europe (Lowe 1999). *P. africanum* may prevent the proliferation of cells within the prostate (Lowe 1999; Quiles 2010). A review of studies examining the effects of African plum on BPH found that it provides moderate relief from urinary symptoms (Wilt 2011; Dedhia 2008). The typical dose used in studies is between 75–200 mg daily (Dedhia 2008).

Flower Pollen Extract– Promising evidence from several clinical trials suggests that various preparations of a mix of flower pollens, prominently featuring rye pollen (*Secale cereale* L.), have potential benefits for prostate health and lower urinary tract symptoms in men. Rye pollen contains a variety of phenolic compounds and sterols that may support prostate health in part by reducing inflammation (Csikós 2021).

In the United States, flower pollen is available as a supplement under the brand name Graminex G63, which uses a different extraction method than Cernilton. A preclinical study demonstrated that Graminex G63 reduced reactive oxygen species and inflammatory compounds in prostate cells (Locatelli 2018). Additionally, a randomized controlled trial evaluated Graminex G63 in 30 people with BPH or lower urinary tract symptoms following laser surgery. Participants received either Graminex G63 or a placebo, postoperatively, to assess its effects on recovery. After 30–45 days, the experimental group reported a significant reduction in pelvic discomfort compared with the placebo group (Di Pasquale 2020).

Cerniltona, pharmaceutical grade pollen extract, has been used in Japan since 1969 for the treatment of chronic prostatitis, chronic pelvic pain syndrome, and BPH. However, it is not available in the United States. In a randomized controlled trial, Cernilton reduced BPH symptoms and prostate size, and increased urinary flow

compared with placebo over four years (Xu 2008).

These findings suggest that rye flower pollen extract may offer supportive benefits for prostate health and symptom management.

***Urtica Dioica* ("stinging nettle")** – Stinging nettle root extracts have shown effectiveness as natural therapeutics for BPH (Alt Med Rev 2007; Nahara 2012). A study found that a combination of saw palmetto and 120 mg of stinging nettle extract was as effective as finasteride in the treatment of BPH; the herbal combination also had fewer side effects than finasteride (Sokeland 2000). Another study showed that stinging nettle alone had beneficial effects in patients with symptomatic BPH (Safarinejad 2005). This finding is supported by animal studies showing that stinging nettle extract reduced the size of the prostate, weekly urine output, and PSA levels, perhaps by disrupting prostate cell growth (Nahara 2012).

Isoflavones and Lignans – Plant-derived compounds called *isoflavones,* which are abundant in soybeans*,* and *lignans*, which are abundant in flax and Norway spruce, modulate estrogen signaling in the human body via interaction with estrogen receptors. Thus, these compounds are sometimes classified as "***phytoestrogens***". Isoflavones and lignans have been investigated for their anti-cancer effects, but their ability to affect hormone-responsive tissues appears to influence the prostate (Kumar 2004).

Evidence suggests that isoflavones may inhibit testosterone-mediated prostate cell growth (Kumar 2004). These compounds were also shown to block the activity of 5α-reductase, the enzyme that converts testosterone to dihydrotestosterone (DHT), which promotes prostate growth (Evans 1995). One study suggested that men with BPH may have lower dietary intake of soy isoflavones than men with healthy prostates, as determined by lower prostate tissue concentrations of *genistein*, a potent isoflavone (Hong 2002). Genistein levels may also correlate with the size of the prostate in BPH: men with small-volume BPH have been found to have higher levels of genistein in their prostate tissue than men with large-volume BPH (Brossner 2004).

Supplementation with soy isoflavones has been found to reduce PSA levels in men with prostate cancer (Kumar 2004). In addition to preventing prostate cell proliferation, isoflavones may increase programmed cell death (ie, apoptosis) in low-to-moderate grade tumors from prostate cancer patients (Jared 2002). Another study found that isoflavones are very well tolerated (Wong 2012).

Lignans have also been evaluated as a treatment for BPH, and one study found that a flaxseed lignan extract reduced both BPH symptoms and the grade of lower urinary tract symptoms experienced by some patients (Zhang 2008).

Pumpkin Seed Extracts – Pumpkin seed (*Cucurbita pepo*) has been studied in various forms, including seed powder, pumpkin seed oil, and various extracts, as a remedy for lower urinary tract symptoms linked to BPH. Clinical trials to date indicate that pumpkin seed preparations may offer modest symptom relief with generally good tolerability, but evidence is inconsistent, products differ across studies, and more robust studies are recommended (Antoniou 2023).

Many studies of BPH treatments use symptom questionnaires as a main endpoint. One such questionnaire is the International Prostate Symptom Score (IPSS), which has been used in a number of studies of pumpkin seed products. It rates symptoms on a 0–35 scale where higher scores mean worse urinary symptoms (frequency, weak stream, nighttime urination, etc.). A change in IPSS reflects day-to-day symptom burden (Antoniou 2023).

A randomized trial compared pumpkin seed oil with tamsulosin. In a single-blind, three-month, randomized controlled trial conducted in Iran, men received either 0.4 mg tamsulosin nightly or 360 mg pumpkin seed oil twice daily. The primary outcome (IPSS change) improved in both arms, but the mean IPSS reduction at three months was larger with tamsulosin (about -5.33 points) than with pumpkin seed oil (about -3.2 points)—a 66% difference favoring tamsulosin; quality-of-life scores improved in both groups, and known tamsulosin side effects (dizziness, headache, rash with itching, retrograde ejaculation) occurred in the tamsulosin arm (Zerafatjou 2021). Another randomized study compared a commercial pumpkin seed oil product ("Prostafit") dosed as two tablets daily versus prazosin (Minipress) (Shirvan 2014). The drug prazosin is an alpha-1 adrenergic blocker that is FDA approved for the treatment of hypertension and occasionally prescribed off-label for BPH (Generali 2013). The pumpkin seed oil was dosed as two capsules daily for six months. Both groups improved, but prazosin produced somewhat larger average IPSS and quality-of-life improvements.

In a 12-month, randomized, placebo-controlled, partially blinded trial, 1,431 men (ages 50–80 years) with bothersome lower urinary tract symptoms suggestive of BPH were assigned to either pumpkin seed consumption (5 grams twice daily), pumpkin seed extract (500 mg twice daily), or placebo. Pumpkin seed consumption (unblinded) led to a clinically important reduction in IPSS compared with placebo. Responder rates were similar for pumpkin seed extract versus placebo. Treatment-related adverse events were very low in all groups (Vahlensieck 2015).

An open-label, single-arm, pilot study enrolled 60 men (average age of about 62 years) with at least moderate BPH symptoms and gave them an oil-free hydroethanolic pumpkin seed extract, 500 mg once daily at bedtime, for 12 weeks. The primary outcome (change in IPSS) improved from about 15.7 at baseline to 10.8 at 12 weeks, with symptom improvement evident by four weeks and strengthening through eight and 12 weeks. Secondary measures also improved, including the need to urinate at night (about 0.56 fewer nighttime bathroom trips) and post-urination residual urine volume. The extract was well tolerated (Leibbrand 2019).

These human trials, taken together, suggest pumpkin seed oil may mitigate BPH symptoms, but the effect size is typically modest and likely smaller than standard alpha-blocker therapy, particularly early in treatment. A number of limitations in the available clinical studies precludes generalization from this data. Larger, well-controlled trials using standardized preparations are necessary (Antoniou 2023).

Preclinical studies provide plausible mechanisms that could explain the effects observed in the clinical studies. In a rat model, oral pumpkin seed oil given alongside testosterone for 20 days inhibited testosterone-induced increases in prostate size ratio, with stronger effects at higher doses (Gossell-Williams 2006). Another rat study isolated phytosterols from pumpkin seed oil and administered the phytosterols directly to the stomach for four weeks; this reduced pathological prostate enlargement and suppressed expression of 5-alpha reductase and androgen-pathway markers, while shifting signaling toward less proliferation and more apoptosis (Kang 2021).

Lycopene – Lycopene is a carotenoid occurring abundantly in tomatoes. Men with higher lycopene levels in their blood, suggesting greater dietary lycopene consumption, are less likely to develop prostate cancer (Gann 1999). One laboratory experiment found that lycopene inhibited the growth of normal human prostate cells (Obermuller-Jevic 2003). Another study suggested that lycopene supplementation may decrease the growth of prostate cancer (Kucuk 2001).

Fatty Acids – Healthy fats, such as eicosapentaenoic acid (EPA), decosahexoaenoic acid (DHA), and gamma-linolenic acid (GLA), exhibit a wide range of beneficial effects on the human body and may support prostate health (Simopoulos 1999).

Flaxseed oil and fish oil are rich sources of essential fatty acids (Shaikh 2012; James 2000). A pilot study found that flaxseed supplementation, combined with a low-fat diet, lowered PSA levels in men who were scheduled to have a repeat prostate biopsy. This special diet also reduced the rate of prostate cell proliferation (Demark-Wahnefried 2004). Another study found that the essential fatty acids gamma-linolenic acid (GLA) and eicosapentaenoic acid (EPA), and their metabolites, suppressed the activity of 5α-reductase (Pham 2002).

Additional Support

Several other dietary constituents may also be able to protect against BPH, although more studies are needed.

Boswellia serrata - Boswellia serrata is an African tree whose bark yields an oily, resinous extract that has been used in traditional medicine (Alt Med Rev 2008). Compounds in Boswellia resin, particularly acetyl-11-keto-β-boswellic acid (AKBA), have potent anti-inflammatory properties (Abdel-Tawab 2011). Inflammation plays a role in the development of BPH and is associated with an increase in BPH symptoms (Altavilla 2012; Nickel 2008b). Several studies indicate that AKBA may slow growth of prostate cancer cells and induce apoptosis (Pang 2009; Yuan 2008; Lu 2008). Although studies have yet to formally evaluate the effect on Boswellia in men with BPH, its documented anti-inflammatory and cancer-fighting properties suggest it may deliver some benefits in this population.

Selenium - Selenium is a mineral the body needs in small quantities (Thomas 1999); however, increased selenium intake may help prevent BPH. A study found that a combination of selenium, lycopene, and saw palmetto was more effective than saw palmetto alone at preventing hormone-dependent prostate growth (Altavilla 2011).

Another study found that higher serum levels of selenium were associated with a reduced risk of BPH (Eichholzer 2012).

Garlic - Garlic has anti-inflammatory, anti-cancer, and antioxidant effects, all of which may help prevent the development of BPH and prostate cancer. Although its mechanism of action is not clear, several animal and cell culture studies have suggested that garlic may be beneficial for BPH. In addition, combining garlic with other foods beneficial for the prostate, such as olive oil and tomatoes, may enhance its effects (Devrim 2007).

Beta-carotene and vitamin C - Increased intake of beta-carotene and vitamin C is associated with a decreased risk of having BPH requiring surgical treatment (Tavani 2006).

Update History

Disclaimer and Safety Information

References

†Ratings based on results of the 2025 ConsumerLab.com Survey of Supplement Users. Multivitamin rating based on results of the 2024 ConsumerLab.com Survey of Supplement Users. For more information, visit **www.consumerlab.com/survey**.