



Effective Health Care Complementary and Alternative Medicine for Benign Prostatic Hyperplasia Nomination Summary Document

Results of Topic Selection Process & Next Steps

- Complementary and alternative medicine (CAM) for benign prostatic hyperplasia (BPH) was found to be addressed by an existing systematic review by the Cochrane Collaboration and recently published guidelines by the National Institute for Health and Clinical Excellence (NICE) on the management of lower urinary tract symptoms (LUTS) in men. Given that the existing review and guidelines cover this nomination, no further activity will be undertaken on this topic.
 - Tacklind J, MacDonald R, Rutks I, Wilt TJ. Serenoa repens for benign prostatic hyperplasia. Cochrane Database Syst Rev. 2009 Apr 15;(2):CD001423. <http://onlinelibrary.wiley.com/doi/10.1002/1471-1875.cd001423.pdf>
 - National Institute for Health and Clinical Excellence. The management of lower urinary tract symptoms in men (Clinical guideline 97). 2010. www.nice.org.uk/CG97
- The following publications are also relevant to this topic:
 - American Urological Association. Guideline on the management of benign prostatic hyperplasia (BPH). 2003 (reaffirmed in September 2009).
 - Dedhia RC, McVary KT. Phytotherapy for lower urinary tract symptoms secondary to benign prostatic hyperplasia. Journal of Urology. 2008;179:2119-2125.

Topic Description

Nominator: Individual

Nomination Summary: The nominator is interested in complementary and alternative medicine (CAM) for benign prostatic hyperplasia (BPH) in older men. More specifically, the nominator is concerned with CAM treatments such as supplements (including herbal formulations) and ayurvedic medicine to reduce prostate-specific antigen (PSA) levels associated with BPH.

Staff-Generated PICO:

Population(s): Older male patients with mild to moderate urological symptoms associated with BPH.

Intervention(s): Supplements (including herbal formulations) and ayurvedic therapies.

Comparator(s): None or standard pharmacologic treatment such as alpha blockers, selective alpha blockers, and 5-alpha reductase inhibitors.

Outcome(s): Urologic symptom scores (American Urologic Association Symptom Index (AUA)), change in peak/mean urine flow, change in bladder residual volume, change in

prostate size, nocturia, sexual function, change in PSA levels, quality of life, side effects, and adverse events.

**Key Questions
from Nominator:**

1. What are the complementary and alternative medicine (CAM) treatments (supplements including herbal formulations) that are helpful in reducing PSA levels associated with benign prostatic hyperplasia (BPH)?

Considerations

- The topic meets EHC Program appropriateness and importance criteria. (For more information, see <http://effectivehealthcare.ahrq.gov/index.cfm/submit-a-suggestion-for-research/how-are-research-topics-chosen/>.)
- The study of phytotherapy (herbal therapies) for BPH is important. The use of phytotherapeutic agents among men for symptoms of BPH is common. However, comparisons of phytotherapies versus pharmacologic agents are limited as most studies compare phytotherapies against a placebo. Evidence for effectiveness is inadequate. The majority of studies evaluate short-term outcomes of symptom relief, and long-term safety and effectiveness data for these agents is lacking. Neither the American Urological Association nor the National Institute for Health and Clinical Excellence (NICE) recommend the use of phytotherapies for BPH or lower urinary tract symptoms.
- Scans of recent literature in the MEDLINE database revealed no English studies on ayurvedic therapies for BPH; thus, the evidence base for these therapies is limited at this time.
- Tacklind and colleagues recently updated their systematic review on the effectiveness of *Serenoa repens* (saw palmetto) for BPH. The authors included literature through 2008. Since their last report, which was published in 2007, 9 new trials involving 2053 additional men were identified and included in the update. However, the authors' conclusions remain the same. *Serenoa repens* was not more effective than placebo for treatment of urinary symptoms consistent with BPH.
- Additionally, NICE published clinical guidelines in 2010 on the management of lower urinary tract symptoms in men that include an in-depth review of the evidence. The review addresses the question of the effectiveness of CAM treatments in managing LUTS. The following CAM therapies were considered in this review: *Serenoa repens*, *Pygeum africanum*, *Urtica dioica* (stinging nettle), beta-sitosterols, and Cernilton (extract prepared from the rye grass pollen). This review looked at phytotherapy alone versus placebo and phytotherapies in combination with one another versus placebo. The reviewers also looked at phytotherapy versus pharmacologic therapy including alpha blockers and 5-alpha reductase inhibitors. NICE does not recommend offering phytotherapy for treating LUTS in men. The guideline developers explain that there was weak evidence for a benefit in using phytotherapy, they were concerned about side effects arising from potential interactions with other drugs, and there is a lack of standardization in formulation, source or quantity of active components, and doses provided by different suppliers of phytotherapies.