

Review: *Pygeum africanum* extracts improve symptoms and urodynamics in symptomatic benign prostatic hyperplasia

Wilt T, Ishani A, Mac Donald R, Rutks I, Stark G. *Pygeum africanum* for benign prostatic hyperplasia. Cochrane Database Syst Rev. 2002;(1):CD001044 (latest version in 16 Nov 2001).

QUESTION

In men with symptomatic benign prostatic hyperplasia (BPH), are extracts of the African plum tree, *Pygeum africanum*, more effective than placebo for improving symptoms and urodynamics?

DATA SOURCES

Studies were identified by searching MEDLINE (1966 through 2000), EMBASE/Excerpta Medica (1974 to 1999), the Cochrane Library, and Phytodok. Bibliographies of relevant articles were reviewed, and manufacturers and researchers were contacted for unpublished studies.

STUDY SELECTION

Studies in any language were selected if they were randomized controlled trials (RCTs) comparing preparations of *P. africanum* with placebo or medical therapies for ≥ 30 days in men with symptomatic BPH.

DATA EXTRACTION

Data were extracted on sample size, patient characteristics, intervention, study quality, dropouts, adverse effects, and outcomes. Outcomes included urologic symptom scores, peak and mean urine flow, residual urine volume, and nocturia.

MAIN RESULTS

18 RCTs (1562 patients) met the selection criteria. Comparisons included *P. africanum* extract with placebo (13 RCTs), *P. africanum*

extract with an anti-inflammatory drug (2 RCTs), *P. africanum* extract with another herbal agent (1 RCT), different daily doses of *P. africanum* extract (1 RCT), and 2 different doses of *P. africanum* extract in combination with another herbal extract (1 RCT). Improvement in the combined outcome of urologic symptoms and flow measurements was greater in the *P. africanum* group than in the placebo group (effect size -0.8 standard deviation [SD], 95% CI -1.4 to -0.3 , a moderate to large effect) (6 RCTs). Although not statistically significant, reduction in nocturia was 19% greater in the *P. africanum* group than in the placebo group (effect size -0.8 SD, CI -1.4 to -0.1 , 3 RCTs) (Table). More men in the *P. africanum* group than in the placebo group had an overall improvement in symptoms rated by their physician (5 RCTs) (Table). Increase in peak urine flow

was 23% greater in the *P. africanum* group than in the placebo group (4 RCTs) (Table). Reduction in residual urine volume was 24% greater in the *P. africanum* group than in the placebo group (2 RCTs) (Table). The groups did not differ for dropout rates and adverse effects.

CONCLUSION

Limited evidence suggests that *Pygeum africanum* extract is more effective than placebo for improving symptoms and urodynamics in men with benign prostatic hyperplasia.

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Pygeum africanum extracts vs placebo for benign prostatic hyperplasia at 30 to 122 days*

Outcomes	Weighted event rates		RBI (95% CI)	NNT (CI)
	<i>P. africanum</i>	Placebo		
Overall improvement in symptoms	64%	30%	101% (40 to 206)	3 (2 to 11)
Weighted mean difference (CI)				
Peak urine flow (mL/sec)	2.5 (0.3 to 5)			
Residual urine volume (mL)	-13 (-23 to -3)			
Nocturia (episodes/night)	-0.9 (-2.0 to 0.1)			

*Abbreviations defined in Glossary; RBI, NNT, and CI calculated from data in article using a fixed-effects model.

COMMENTARY

From the patient's perspective, the key result in trials of therapy for BPH is the effect of treatments on lower urinary tract symptoms. In the review by Wilt and colleagues, only 5 trials ($n = 430$) provided information on a global assessment of symptom improvement after treatment with *P. africanum* extract, which was rated by physicians, not patients. The clinical importance of the reported doubling of the proportion of men rated "improved" is hard to determine without ratings from the patients themselves. The weighted mean difference of -0.9 episodes of nocturia per night (3 RCTs, $n = 373$) did not meet strict criteria for statistical significance and is of uncertain clinical importance. Comparing these results with the symptomatic outcomes of such prescription medications as finasteride or α -blockers is difficult, primarily because the *P. africanum* trials were of short duration and did not use validated symptom scoring methods. Head-to-head comparisons were also lacking. These shortcomings are unfortunately ubiquitous in trials of phytotherapy for BPH (1).

The effect of *P. africanum* extract on symptoms, judging from these data, is unimpressive. Fortunately, like other phytotherapies, the extract does not seem to be harmful in men with lower urinary tract symp-

toms. Whether they take phytotherapies or prescription medications for lower urinary tract symptoms attributed to BPH, most of the perceived effect on symptoms can be attributed to the placebo effect.

One problem with phytotherapies is the uncertainty surrounding the dose persons are receiving when they buy a given product. In a recent study of the popular saw palmetto supplement, the content of 6 commercially available products ranged from 3% to 140% of the stated dose, and 3 of those products contained $< 20\%$ of the stated dose (2). RCTs done with the same methodologic rigor as that used for prescription medications are needed to determine whether any of the phytotherapies are really beneficial for lower urinary tract symptoms attributed to BPH. If they are, regulation of the content of the preparations is necessary so that men can expect results similar to those seen in the trials.

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References

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