Cernilton for Benign Prostatic Hyperplasia

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Background

Benign prostatic hyperplasia (BPH), nonmalignant enlargement of the prostate, can lead to obstructive and irritative lower urinary tract symptoms (LUTS). The pharmacologic use of plants and herbs (phytotherapy) for the treatment of LUTS associated with BPH has been growing steadily. Cernilton, prepared from the rye-grass pollen Secale cereale, is one of the several phytotherapeutic agents available for the treatment of BPH.

Objectives

This systematic review aims to assess the effects of Cernilton on urinary symptoms and flow measures in men with benign prostatic hyperplasia (BPH).

Search Strategy

Trials were searched in computerized general and specialized databases (MEDLINE, EMBASE, Cochrane Library, Phytodok), by checking bibliographies, and by contacting manufacturers and researchers.

Selection Criteria

Trials were eligible if they were: (1) randomized controlled trials or controlled clinical trials comparing Cernilton with placebo or other BPH medications in men with BPH; and (2) included clinical outcomes such as urologic symptom scales, symptoms, or urodynamic measurements.

Data collection and analysis

Information on patients, interventions, and outcomes was extracted by at least two independent reviewers using a standard form. Main outcome measure for comparing the effects of Cernilton with placebo and standard BPH medications were the change in urologic symptoms scales. Secondary outcomes included changes in nocturia as well as urodynamic measures (peak and mean urine flow, residual volume, prostate size). Main outcome measure for side effects was the number of men reporting side effects. MAIN RESULTS: 444 men were enrolled in 2 placebo-controlled and 2 comparative trials lasting from 12 to 24 weeks. Three studies used a double-blind method although treatment allocation concealment was unclear in all. Cernilton improved "self rated urinary symptoms" (percent reporting satisfactory or improving symptoms) versus placebo and Tadenan. The weighted risk ratio (RR) for self-rated improvement versus placebo was 2.40 [95% CI = 1.21, 4.75], and the weighted RR versus Tadenan was 1.42 [95% CI = 1.21, 4.75]. Cernilton reduced nocturia compared with placebo and Paraprost. Versus placebo, the weighted RR was 2.05 [95% CI = 1.41, 3.00], and versus Paraprost, the WMD was -0.40 times per evening [95% CI = -0. 73, -0.07]. Cernilton did not improve urinary flow rates, residual volume or prostate size compared to placebo or the comparative study agents. Adverse events were rare and mild. The withdrawal rate for Cernilton was 4.8% compared to 2.7% for placebo and 5.2% for Paraprost.

Reviewer's Conclusions

The Cernilton trials analyzed were limited by short duration, limited number of enrollees, gaps in reported outcomes, and unknown quality of the preparations utilized. The comparative trials lacked a proven active control. The available evidence suggests Cernilton is well tolerated and

modestly improves overall urologic symptoms including nocturia. Additional randomized placebo and active-controlled trials are needed to evaluate the long-term clinical effectiveness and safety of Cernilton.

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