

## **Clinical Evaluation of Long-Term Treatment Using Cernitin Pollen Extract in Patients with Benign Prostatic Hyperplasia**

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### **ABSTRACT**

Seventy-nine patients with benign prostatic hyperplasia (BPH) were treated with cernitin pollen extract. Patient ages ranged from 62 to 89 years (mean, 68 years). Mean baseline prostatic volume was 33.2 cm<sup>3</sup>. Cernitin pollen extract was administered in a dosage of 126 mg (2 tablets, 63 mg each), three times a day, for more than 12 weeks. Symptom scores, based on a modified Boyarsky scoring scale, uroflowmetry, prostatic volume, residual urine volume, and urinalysis results were examined before and after administration of cernitin pollen extract. Symptom scores significantly decreased from baseline, and the favorable results continued during the treat-

ment period. Urine maximum flow rate and average flow rate increased significantly from 9.3 mL/s to 11 mL/s and from 5.1 mL/s to 6 mL/s, respectively. Residual urine volume decreased significantly from 54.2 mL to less than 30 mL. There was no change in prostatic volume. However, 28 patients treated for more than 1 year showed a mean decrease of prostatic volume to 26.5 cm<sup>3</sup>. No adverse reactions were observed. Clinical efficacy at 12 weeks was rated excellent, good, satisfactory, and poor in 11%, 39%, 35%, and 15% of patients, respectively. Overall clinical efficacy was 85%. In conclusion, cernitin pollen extract showed a mild beneficial effect on prostatic volume and urination variables in patients with symptomatic BPH.

## INTRODUCTION

Because cernitin pollen extract\* has anti-inflammatory and anticongestive effects,<sup>1</sup> it is useful for the treatment of nonbacterial prostatitis and prostatodynia. Recent studies have demonstrated that cernitin pollen extract improved detrusor activity and decreased resistance of the prostatic urethra.<sup>2,3</sup> It therefore provides better efficacy in urination. It has also been reported to suppress prostatic cell growth.<sup>4,5</sup> For these reasons, cernitin pollen extract is thought to be useful in the treatment of patients with dysuria due to benign prostatic hyperplasia (BPH).<sup>6</sup>

We report here the efficacy of cernitin pollen extract in patients with BPH.

## PATIENTS AND METHODS

Seventy-nine patients with mild or moderate symptomatic BPH, who did not require prostatectomy, were selected for this study. Patients provided informed consent to participating in the study. Ages ranged from 62 to 89 years (mean, 68 years). For the evaluation of BPH, serum prostatic specific antigen, digital examination, transrectal ultrasonography, and roentgenographic examination were performed. No abnormal findings in any patient were recorded.

Subjective assessment was based on a modified Boyarsky scoring scale<sup>7</sup> for the symptoms of urgency and discomfort, dysuria, nocturia, incomplete emptying, prolonged voiding, delayed

voiding, intermittency, and postvoid dribbling, with a score of 0 (normal) to 3 (severe) for each of these symptoms. The average baseline symptom score was 9.6. Sixty-six percent of the patients urinated more than three times during the night. Maximum flow rate, average flow rate, and residual urine volume at baseline were  $9.3 \pm 5.0$  mL/s,  $5.1 \pm 2.7$  mL/s, and  $54.2 \pm 78.8$  mL, respectively. Mean prostatic volume was  $33.2$  cm<sup>3</sup> on transrectal ultrasonography.

Cernitin pollen extract was administered orally in a dosage of 126 mg (2 tablets, 63 mg each), three times a day, for more than 12 weeks. For subjective and objective assessments, symptom score, uroflowmetry, prostatic volume, residual urine volume, and urinalysis results were examined before treatment and monthly during treatment. Blood pressure and laboratory values were recorded every 3 months. Clinical efficacy, based on symptoms and objective signs, was assessed as excellent, good, satisfactory, or poor.

Values of measured variables are given as mean  $\pm$  SD. For statistical analysis, the chi-square test and paired *t* test were used. A *P* value of  $<0.05$  was considered statistically significant.

## RESULTS

Mean improvement of subjective symptoms, irritative symptoms, and obstructive symptoms, compared with baseline, are shown in Figure 1 for short-term treatment. Urgency or discomfort improved by 76.9%; dysuria, by 71.4%; nocturia, by 56.8%; incomplete emptying, by 66.2%; prolonged voiding, by 64.1%; delayed voiding, by

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\*Trademark: Cernilton® (Tobishi Pharmaceutical Co., Ltd., Tokyo, Japan).

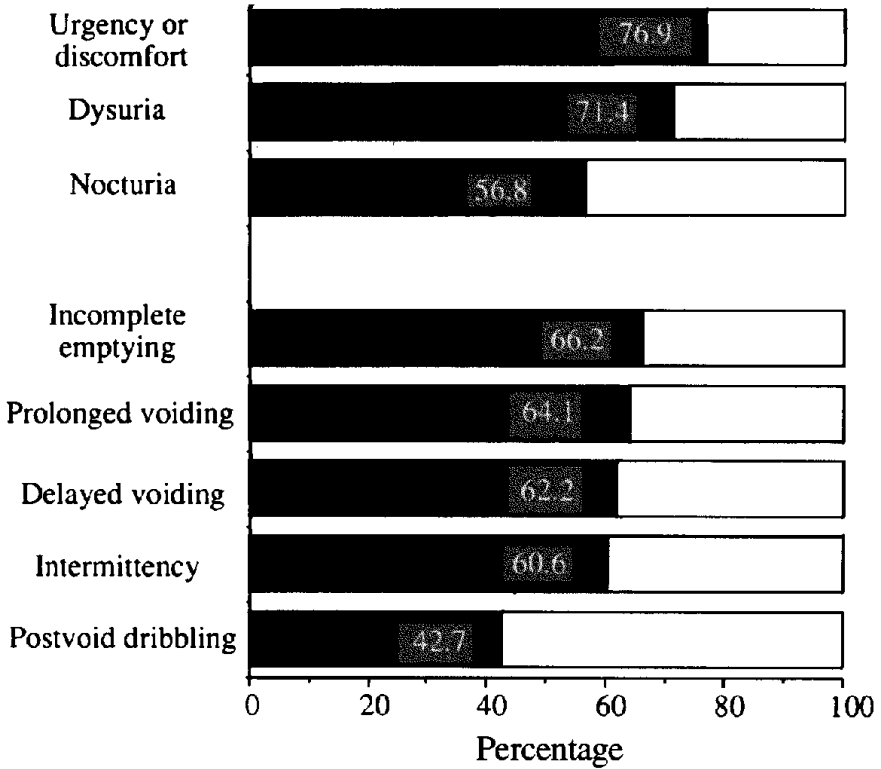


Figure 1. Mean improvement of subjective symptoms (%) of benign prostatic hyperplasia in 79 patients after 12 weeks of treatment with cernitin pollen extract.

62.2%; intermittency, by 60.6%; and postvoid dribbling, by 42.7%. Figure 2 shows change of symptom score during treatment. Average symptom score decreased significantly from 9.6 to 6.0 after the first 4 weeks of treatment and decreased continually to 5.4 during the following 8 weeks.

Results of the objective assessment are shown in Figure 2; maximum flow rate and average flow rate increased significantly from 9.3 mL/s and 5.1 mL/s to 11 mL/s and 6 mL/s, respec-

tively, after the first 12 weeks of treatment. Residual urine volume decreased from 54.2 mL to less than 30 mL. However, no changes in prostatic volume and urine volume were observed. In the short-term follow-up, 11% of patients had excellent results; 39%, good; 35%, satisfactory; and 15%, poor. Overall clinical efficacy was 85%. No adverse reactions, such as impotence or hypotension, and no abnormal laboratory findings were observed.

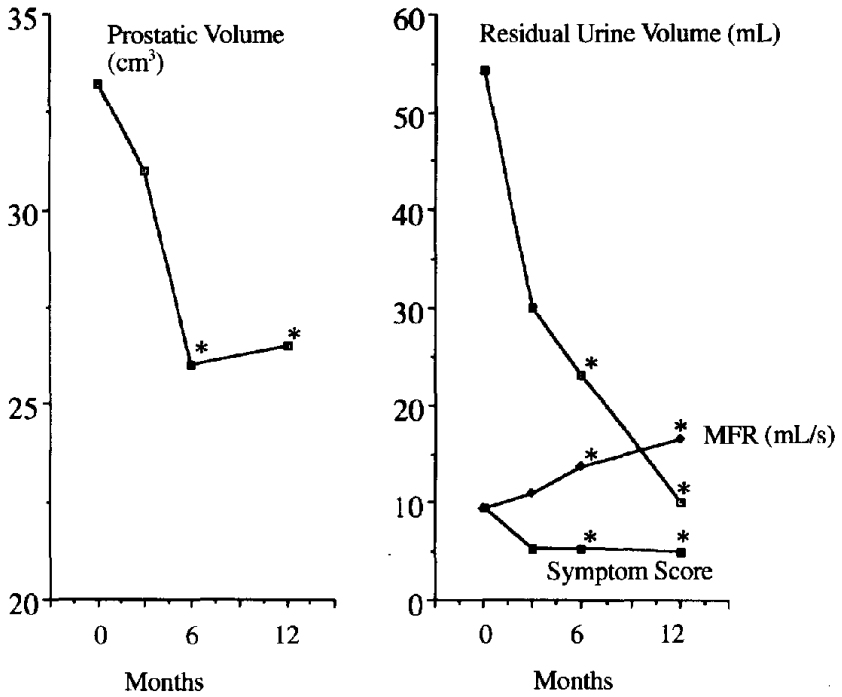


Figure 2. Change of symptom score and objective variables in patients with benign prostatic hyperplasia during treatment with cernitin pollen extract. A significant increase in flow rate and decrease in residual urine volume were noted in short-term follow-up (12 weeks, 79 patients), and a significant decrease in prostatic volume was also observed in long-term treatment (1 year, 28 patients). MFR = maximum flow rate. \**P* < 0.05 versus baseline.

During the long-term follow-up, 28 patients who had good results after short-term treatment continued treatment with cernitin pollen extract for more than 1 year. A significant decrease in prostatic volume to 26.5 cm<sup>3</sup>, a significant increase in maximum flow rate, and a significant decrease in symptom score and residual urine volume were observed (Figure 2). During the long-term treatment, no abnormal hematologic or biochemical findings were observed.

**DISCUSSION AND CONCLUSION**

Transurethral resection of the prostate (TURP) is considered the gold standard for the treatment of BPH. Mortality and morbidity of TURP and quality of life of patients after TURP were studied in 1988,<sup>8</sup> and the results were not good. In place of TURP, many modalities for the treatment of BPH (eg, hyperthermia or thermotherapy, urethral stent, urethral balloon dilatation, and laser prostatectomy) have been de-

veloped and performed throughout the world.<sup>9-11</sup> However, the long-term results of these new modalities are controversial.

New medications,<sup>12-14</sup> such as anti-androgen drugs,  $\alpha_1$ -blockade, and  $5\alpha$ -reductase inhibitors, have also been developed and used for treatment of patients with BPH. These drugs have excellent efficacy, but a few adverse reactions, including impotence<sup>12</sup> and hypotension,<sup>13</sup> have been reported.

Since 1970, many investigations on cernitin pollen extract have been done. As a result, it is well known that this extract improves detrusor activity, decreases resistance of the prostatic urethra, and suppresses prostatic cell growth<sup>2-5</sup> and thus has been used for the treatment of BPH patients. Buck and others<sup>6</sup> reported that cernitin pollen extract produced a statistically significant improvement of 69% in subjective symptoms compared with an improvement of 30% with placebo. A significant decrease in residual urine volume and in the anterior-posterior diameter of the prostate was observed in patients treated with this drug. Our short-term results were satisfactory in 85% of 79 patients with BPH, and long-term treatment reduced prostatic volume in the 28 patients who continued treatment with cernitin pollen extract. Compared with chlormadinone acetate,<sup>12</sup> prazosin,<sup>13</sup> and finasteride,<sup>14</sup> cernitin pollen extract has a slightly lower clinical efficacy. However, the advantage of cernitin pollen extract is the rare occurrence of side effects during long-term use.

Based on our results, we conclude that cernitin pollen extract has beneficial effects, especially a decrease in

prostatic volume and an improvement in urination, in patients with symptomatic BPH.

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