



Clinical evaluation of long-term treatment using Cernitin pollen extract in patients with benign prostatic hyperplasia

Ryoi Tasumoto, MD,¹ Hironobu Kawanishi, MD,¹ Takashi Tsujino, MD,¹ Masaaki Tsujita, MD,¹ Nobuyasu Nishisaka, MD,² Akinori Horii, MD,² and Taketoshi Kishimoto, MD²
Department of Urology and Andrology,¹ Osaka Municipal Juso Citizen's Hospital, and ²Osaka City University Medical School, Osaka, Japan

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 cm³. 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 treatment 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 cm³. 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,¹ 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.^{2,3} It therefore provides better efficacy in urination. It has also been reported to suppress prostatic cell growth.^{4,5} For these reasons, cernitin pollen extract is thought to be useful in the treatment of patients with dysuria due to benign prostatic hyperplasia (BPH).

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, roentgenographic examination was performed. No abnormal findings in any patient were recorded.

Subjective assessment was based on a modified Boyarsky scoring scale⁷ for the symptoms of urgency and discomfort, dysuria, nocturia, incomplete emptying, prolonged voiding, delaying 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, residual urine volume at baseline were 9.3 ± 5.0 mL/s, 5.1 ± 2.7 mL/s, and 54.2 ± 78.8 mL, respectively. Mean prostatic volume was 33.2 cm³ 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. Blood pressure and laboratory values were recorded every 3 months. Clinical efficacy, based on symptoms and objective signs, was assessed as excellent, good, satisfactory, and 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, and are shown in Figure 1 for short-term treatment. Urgency or discomfort improved by 76.9 %; dysuria, by 71.45 %; nocturia, by 56.8 %; incomplete emptying, by 66.2 %; prolonged voiding, by 64.1 %; delayed voiding, by 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, respectively, 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 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.

During 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 cm³, 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.

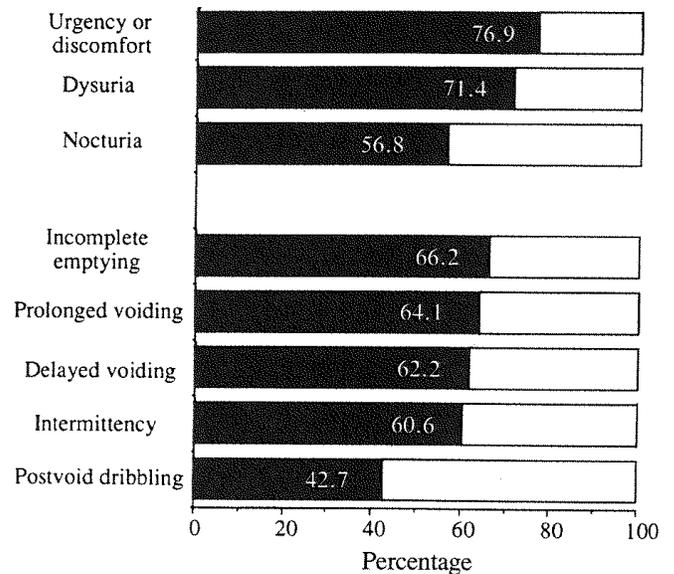


Figure 1. Mean improvement of subjective symptoms (%) of benign prostatic hyperplasia in 79 patients after 12 weeks of treatment with cernitin pollen extract.

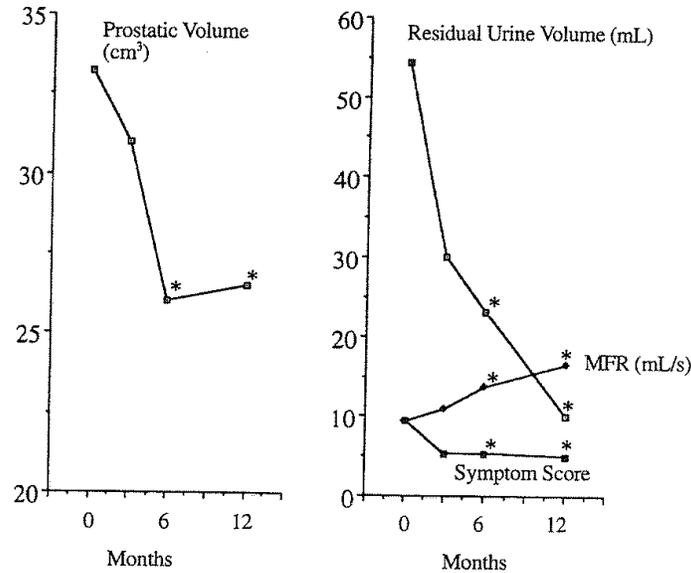


Figure 2. Change of symptom score and objective variables in patients with benign prostatic hyperplasia during treatment with cernitin pollen extract. A significant increase in flow rate and decrease in residual urine volume were noted in short-term follow-up (12 weeks, 79 patients), and a significant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

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 1988,⁸ 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 dilation, and laser prostatectomy) have been developed and performed throughout the world.⁹⁻¹¹ However, the long-term results of these new modalities are controversial.

New medications,¹²⁻¹⁴ such as antiandrogen drugs, α_1 -blockade, and 5α -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 impotence¹² and hypotension,¹³ 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 growth²⁻⁵ and thus has been used for the treatment of BPH patients. Buck and others⁶ reported that

cernitin pollen extract produced 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 28 patients who continued treatment with Cernitin pollen extract. Compared with chlormadinone acetate,¹² prazosin,¹³ and finasteride,¹⁴ 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.

Acknowledgement

This study was supported in part by Tobishi Pharmaceutical Co., Ltd., Tokyo, Japan.

Address Correspondence to:

R. Yasumoto, MD, Department of Urology and Andrology, Osaka Municipal Juso Citizen's Hospital, 2-3-7 Juso-Higashi, Yodogawa-Ku, Osaka 532, Japan.

References

1. Ito R, Noguchi K, Yamashita S, et al. Anti-inflammatory effects of Cernitin pollen extract (Cernilton). *Pharmacometrics*. 1984; 28:55-65.
2. Nakaarai K, Sonoda T. Effect of the prostatic extract (Robaveron) on bladder function: An experimental study. *Acta Urol Jpn*. 1972; 18:501-515.
3. Kimura M, Kimura I, Nakase K, et al. Micturition activity of pollen extract: Contratile effects on bladder and inhibitory effects on urethral smooth muscle of mouse and pig. *Planta Med*. 1986;2:148-151.
4. Habib FK, Ross M, Buck AC, et al. In vitro evaluation of the pollen extract, Cernitin T-60, in regulation of prostate cell growth. *Br J Urol*. 1990;66:393-397.
5. Ito R, Ishii M, Yamashita S, et al. Anti-prostatic hypertrophic action of Cernitin pollen extract (Cernilton). *Pharmacometrics*. 1986;31:1-11.
6. Buck AC, Cox R, Rees RWM, et al. Treatment of outflow tract obstruction due to benign prostatic hyperplasia with pollen extract, Cernilton. A double-blind, placebo-controlled study. *Br J Urol*. 1990;66:398-404.
7. Boyarsky S, Jones G, Paulson DF, et al. A new look at bladder neck obstruction by the Food and Drug Administration regulators: Guidelines for investigation of benign prostatic hypertrophy. *Trans Am Assoc Genitourin Surg*. 1977;68:29-32.
8. Barry MJ, Mully AG, Fowler FD, et al. Watchful waiting vs immediate transurethral resection for symptomatic prostatism. *JAMA*. 1988;82:196-203.
9. Yasumoto R, Wada S, Kiyota A, et al. Hyperthermic treatment in patients with benign prostatic hypertrophy. *Jpn J Urol*. 1991;82:196-203.
10. Yasumoto R, Yoshihara H, Kawashima H, et al. The use of metallic stent in 32 patients with benign prostatic hypertrophy. Preliminary results and 3 months of follow-up. *Jpn J Urol*. 1992;83:473-482.
11. Hori A, Kyo M, Yasumoto R, et al. Transurethral balloon dilation of the prostate: Initial results, indication and complication. *Acta Urol Jpn*. 1991;37:1455-1461.
12. Kogawa T, Yanagiya H, Takashima T, et al. Clinical evaluation of the long-term treatment with chlormadinone acetate on patients with benign prostatic hypertrophy. *Acta Urol Jpn*. 1993;39:281-287.
13. Kirby RS, Coppinger SW, Corcoran MO, et al. Prazosin in the treatment of prostatic obstruction: A placebo controlled study. *Br J Urol*. 1987;60:136-142.
14. Vermeulen A, Giagulli VA, De Schipper P, et al. Hormonal effects of 5 α -reductase inhibitor (finasteride) on hormonal levels in normal men and in patients with benign prostatic hyperplasia. *Eur Urol*. 1991;20:82-86.