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Usefulness of Cernilton in the Treatment of Benign Prostatic Hyperplasia

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A total of 89 patients with benign prostatic hyperplasia (BPH) were treated pharmacologically for 4 months: 51 received Cernilton and 38 Tadenan (controls). Significant subjective improvement was found in 78% of the patients in the Cernilton group compared to only 55% of the Tadenan-treated patients. The obstructive and irritative symptoms responded best to the therapy. In the Cernilton-treated patients a significant improvement in the uroflow rate, decrease in residual urine and in prostate volume were found. This study shows that Cernilton is an effective therapy for patients with BPH.

Benign prostatic hyperplasia (BPH) is a major problem for the patient, the urologist and health care systems. Pharmacologic treatment may be indicated for patients with moderate BPH-related symptoms. Although plant extracts may not effectively alter the natural history of clinical BPH, their use is favoured in patients with mild symptoms in a number of countries. Plant extracts are inexpensive and have virtually no side effects [4, 6].

Among plant extracts Cernilton, the Graminaceae flower pollen extract, is an interesting product. Results of clinical studies with Cernilton demonstrate a marked reduction in residual urine, prostate volume and substantial improvement in urinary flow rate in patients with BPH [2]. Enlargement and congestion of the prostatic gland are the principal factors responsible for the obstructive symptoms in BPH. The anticongestive effect of Cernilton leads to a marked reduction in prostate volume [10]. The anticongestive action of Cernilton is based on the inhibition of prostaglandin and leukotriene biosynthesis. The activities of both the 5-lipoxygenase and cyclo-oxygenase enzymes are substantially reduced and the arachidonic cascade is interrupted. The inhibition of the arachidonic acid cascade by Cernilton prevents intraprostatic tissue oedema and fibrosis and leads to a significant reduction in clinical symptoms [2, 9].

The aim of the study was to assess the effectiveness of Cernilton therapy of BPH.

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Patients and methods

Studied were 89 patients with clinical stage I and II BPH, aged 50–68 years. For the first two weeks Cernilton was administered in doses of two tablets three times daily, followed by one tablet three times a day for up to a total of 4 months of treatment. The remaining 38 patients were given Tadenan, 2 tablets twice daily (control group). Subjective assessment was made by using our own symptom score system [4] and objective evaluation by physical examination, uroflowmetry and ultrasound examination of residual urine and prostate size. Additionally, biochemical blood and urine tests, including urine culture, were performed in all patients prior to and after the therapy.

Qualified were patients with short history, i.e. with symptoms of no longer than a few weeks' duration. No patient had complete urine retention. The results of the blood tests did not differ significantly from the normal laboratory reference values. All urine cultures proved sterile but in 12 patients leukocyturia was found and adequate antimicrobial therapy was instituted (Tarivid 2 tablets twice daily). The tests were done also after completion of the treatment and no significantly abnormal results were observed.

Results

The following tables show objective and subjective parameters measured before (I) and after (II) Cernilton (C) and Tadenan (T) therapy of BPH patients: peak flow rate (ml/s) – Table 1; residual urine volume (ml) – Table 2; prostate volume (cm^3) – Table 3; obstructive symptom score – Table 4; irritative symptom score – Table 5.

The therapeutic response was positive in 40 (78%) and 21 (55%) patients in the Cernilton and Tadenan groups, respectively. Both drugs were well tolerated and no adverse reactions were seen.

Table 1
Peak flow rate (ml/s) in BPH patients before (I) and after (II) therapy with Cernilton (C) and Tadenan (T)

Drug (No. of patients)		Peak flow rate (ml/s)					
		Mean	Max.	Min.	SD	Mean change	% improvement
I	C (51)	12.49	15.6	8.0	3.0	–	–
	T (38)	13.54	15.9	8.5	3.2	–	–
II	C (51)	15.51	19.0	11.2	4.3	+3.20	19.5
	T (38)	15.18	17.2	9.0	4.5	+1.67	10.8

Table 2
Residual urine volume (ml) in BPH patients before (I) and after (II) therapy with Cernilton (C) and Tadenan (T)

	Drug (No. of patients)	Residual urine volume (ml)					
		Mean	Max.	Min.	SD	Mean change	% improvement
I	C (51)	77	112	56	15.7	–	–
	T (38)	61	101	31	14.1	–	–
II	C (51)	45	63	0	21.0	–32	47.8
	T (38)	50	70	20	15.8	–11	21.6

Table 3
Prostate volume (cm^3) in BPH patients before (I) and after (II) therapy with Cernilton (C) and Tadenan (T)

	Drug (No. of patients)	Prostate volume (cm^3)					
		Mean	Max.	Min.	SD	Mean change	% improvement
I	C (51)	53.83	61.2	41.0	6.6	–	–
	T (38)	51.12	59.1	39.0	5.9	–	–
II	C (51)	48.58	58.0	32.0	4.4	–9.6	5.15
	T (38)	50.67	59.0	39.0	5.8	–0.9	0.45

Table 4
Obstructive symptom score in BPH patients before (I) and after (II) therapy with Cernilton (C) and Tadenan (T)

	Drug (No. of patients)	Obstructive symptom score					
		Mean	Max.	Min.	SD	Mean change	% improvement
I	C (51)	5.1	9	2	2.1	–	–
	T (38)	4.8	8	1	1.9	–	–
II	C (51)	1.9	4	0	1.2	–	62.75
	T (38)	2.6	8	0	1.8	–	45.80

Table 5
Irritative symptom score in BPH patients before (I) and after (II) therapy with Cernilton (C) and Tadenan (T)

	Drug (No. of patients)	Irritative symptom score					
		Mean	Max.	Min.	SD	Mean change	% improvement
I	C (51)	3.8	7	1	1.9	–	–
	T (38)	3.5	8	0	2.0	–	–
II	C (51)	1.2	6	0	2.1	–	68.4
	T (38)	2.1	8	0	2.8	–	40.0

Discussion

BPH is a universal concomitant of male ageing but its epidemiology and natural history are incompletely understood [1]. The natural history of BPH can be divided into two phases: a pathologic phase in which there are no clinical symptoms, and a clinical phase when the patients develop symptomatic dysuria. Although macroscopic enlargement of the prostate is necessary for the development of clinical BPH, it is not sufficient by itself for the progression to clinical BPH. Additional factors are required, for example: prostatitis, vascular infarct, tensile strength of the glandular capsule [7]. The clinical manifestations of BPH are often attributed to infravesical obstruction. Therefore pharmacologic strategies for the treatment of BPH have been targeted to decrease bladder outlet obstruction resulting from the prostate enlargement and eliminate instable bladder [4, 8].

Medical treatment of BPH is presently dominated by α-adrenoceptor blockers but plant extracts are used extensively in a number of countries. Treatment with other drugs has also proven to be effective symptomatically, notably with finasteride (5α-reductase inhibitor). Some plant extracts are claimed to exert α-adrenergic blocking or 5-α-reductase inhibiting effects. A few controlled studies have shown that some of the preparations provide both subjective and objective improvement [6].

In BPH patients the decongestive effect of Cernilton leads to a lasting improvement of voiding difficulties. The residual urine volume decreases significantly.

In comparison to *Pygeum africanum* extract (brand name Tadenan), for 20 years in wide use in stage I BPH patients, Cernilton proved much more effective. Objective evaluation of maximal urethral flow, residual volume and prostate size gave almost twice better results with Cernilton. Similarly, the obstructive symptom score improved by 62.75% with Cernilton and by 45.8% with Tadenan, and the irritative symptom score by 68.4% and 40%, respectively.

Positive therapeutic responses totalled 78% and 55% with Cernilton and Tadenan, respectively. Although Tadenan is also characterized by decongestive activity, it decreases bladder instability, increases detrusor elasticity and probably inhibits fibroblast proliferation, and alleviated voiding problems in over 2000 cases [5]. In our study the benefit of Cernilton therapy proved to be far greater than that of Tadenan. During the 4 months of treatment none of the drugs produced side effects in the BPH patients; both Cernilton and Tadenan were well tolerated.

Conclusions

1. Cernilton markedly reduces residual urine and prostate volume in BPH patients. It also significantly improves the voiding difficulties.

2. In the therapy of BPH Cernilton proved to be effective, well tolerated and safe.

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