



Use of Cernilton in Patients with Prostatic Hypertrophy

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Introduction

Today the only radical therapy for prostatic hypertrophy is prostatectomy or transurethral prostatectomy. Prostatic hypertrophy is a kind of geriatric disease in urology whose incidence in Japan is now increased as high as that in European countries. Frequently, this disease involves such aged patients as are not indicated for surgical manipulation in general surgery. Under this situation, conservative therapy would be considered as treatment of choice if it can indeed effect curing or improvement of the disease. Thus, various drugs, chiefly female hormones, have been developed and placed for clinical evaluation in recent years.

The present report concerns the authors' recent experience with CERNILTON, a pollen product, whose samples were supplied by Tobishi Pharmaceutical Co., Ltd. Results are reported below.

Composition of CERNILTON

CERNILTON, when initially introduced in 1952, was used as a prophylactic agent against infections chiefly in convalescent patients having undergone treatment of infectious diseases or surgical operations, and it was by Ask-Upmark later in 1960 that the effectiveness in prostatitis was reported.

According to the literature, it contains in one tablet:

- Cernitin GBX – 3 mg
- Cernitin T60 – 60 mg
- Calcium glyconicum – 70 mg
- Saccharum lactis – 70 mg
- Calcium phosphoricum dibasicum – 140 mg

- Acidum alginicum – 10 mg
- Potato starch – 20 mg
- Pigment – 3 mg
- Magnesium stearate – 4 mg
- Talcum – 20 mg

Of these components, Cernitin GBX and Cernitin T60 are extracts of a mixture of 8 different pollen strains, namely, timothy, maize, rye, hazel, willow, aspen, oxeye daisy and pine, and their chemical structure, molecular formula and molecular weight are unknown. The drug is also reported to have bacteriostatic, tonic and desensitizing actions.

Materials and Methods

The subjects were 24 patients with prostatic hypertrophy seen at our Outpatient Clinic. The

drug was given in doses of 4 tablets once daily in the morning over periods ranging from 25 to 150 days. In general, other drugs were not employed. Of the 24 cases, complete follow-up study was made in 12 cases as to subjective symptoms and urinary retention before, during and after administration. The present report deals with these 12 cases.

Results

The results of the 12 cases where follow-up study was made are given in Table 1.

- Evaluation of effects was made on the basis of the follow criteria:
- Effective.. Subsidence of symptoms with marked improvement in urinary retention.
- Slightly Effective.. Slight subsidence of symptoms with little or slight improvement in urinary retention.
- Ineffective.. Symptoms and urinary retention unchanged or exacerbated.

Results according to these criteria were: "effective" 5 cases (41.7%), "slightly effective" 5 cases (41.7%), and "ineffective" 2 cases (16.7%). Two of the 5 "effective" cases underwent prostatectomy subsequently because of symptoms relapsed after withdrawal of the drug. It is to be noted that one case was already on the way toward spontaneous healing at the time of administration. One of the "slightly effective" cases also underwent prostatectomy markedly extended.

Clinical course: Urinary retention disappeared and relatively smooth urination was possible in one month. Anuresis, however, developed again one month after withdrawal of the drug and patient was thus readmitted for prostatectomy.

Case 5. H. Y. Age 83. No Occupation.

- First examination: April 18, 1966
- Chief Complaints: Anuresis, dysuria
- Past History: Nothing of note.
- Present Illness: Anuresis developed suddenly in May 1959. Diagnosed as

having prostatic hypertrophy, patient was admitted in June and underwent transurethral prostatectomy. Subjective symptoms subsided and a favorable clinical course ensued. Dysuria developed again in September 1964. The symptom gradually progressed reaching a state of anuresis in April 1966, when he visited our Outpatient subsequently.

Side effects due to the medication were observed in none of the cases. Five representative cases will be discussed in detail below.

Case 1. T. Y. Age 69. No Occupation.

- First Examination: September 2, 1966
- Chief Complaints: Dysuria, anuresis
- Past History: No history of venereal diseases, tuberculosis or trauma.
- Present Illness: Dysuria developed 3-4 years ago and catheterization was performed each time. The present episode was anuresis which developed after drinking of alcoholic drinks.
- Palpation of Prostate: Third degree hypertrophy, smooth surface, elastic hardness, symmetry, regular margin.
- Laboratory Findings: Residual urine 420 cc. Micropyuria present. Urethrocytography revealed the prostate protruding greatly into the bladder and the posterior urethra Clinic again. Thereafter, a balloon catheter was retained in the bladder for urination. The catheter was removed on July 27 and administration of CERNILTON instituted.
- Palpation of Prostate: First degree hypertrophy, smooth surface, elastic hardness, symmetry, regular margin.
- Laboratory Findings: Residual urine 350 cc. Micropyuria present.
- Clinical Course: Relatively smooth urination was possible one month after administration of CERNILTON, though voiding force was still somewhat weak.

After 2 months, urination was almost normalized, but urinary retention was still noted. In 3 months dysuria disappeared totally with residual urine decreased to about 10 cc.

Case 7. K. S. Age 72. No Occupation.

- First examination: June 27, 1966
- Chief Complaints: Dysuria, pollakisuria.
- Past History: Nothing of note.
- Present Illness: Pollakisuria, retardation and protraction of urination, and sense of retention appeared about one year ago, associated with dull pain in the lower abdomen but not with such bladder symptoms as voiding pain and cloudiness of urine. Dysuria was particularly exacerbated lately.
- Palpation of Prostate: First degree hypertrophy, smooth surface, elastic hardness, symmetry regular margin.
- Laboratory Findings: Residual urine 20 cc. Urinary findings nearly normal. Urethrocytography revealed the posterior urethra slightly extended.
- Clinical Course: Subjectively, dysuria disappeared completely in one month. Pollakisuria, too, disappeared and frequency of urination became normal. Residual urine was decreased to about 10 cc.

Case 8. T.K. Age 68. Company Employee.

- First examination: April 25, 1966.
- Chief complaints: Dysuria, anuresis
- Past History: nothing of note
- Present Illness: patient was seen at this clinic in November 1963 with complaints of dysuria and pollakisuria. Operation was recommended under a diagnosis of prostatic hypertrophy but was ignored. Then, anuresis occurred in early April 1966 and catheterization was performed by some doctor. Anuresis developed further, eventually to a state where urination occurred only in drops.

- Palpation of Prostate: Second degree hypertrophy, smooth surface, elastic hardness, symmetry.
- Laboratory Findings: Residual urine 600 cc. Urinary findings nearly normal. Urethrocytography revealed the prostate slightly protruding into the bladder and the posterior urethra slightly extended.
- Clinical Course: Dysuria was improved considerably after one month, together with pollakisuria. On palpation hypertrophy was somewhat improved. Two months later, dysuria disappeared subjectively and residual urine was decreased to about 20 cc.

Case 9. T.S. Age 63. No Occupation.

- First Examination: May 23, 1966.
- Chief Complaints: Dysuria, anuresis.
- Past History: Nothing of note.
- Present Illness: Dysuria developed in October 1964 and catheterization was performed. A diagnosis of prostatic hypertrophy was made and admission was recommended, but as the symptom somewhat subsided the recommendation was ignored. In early May 1966, anuresis occurred after drinking of alcoholic drinks and catheterization was again performed. Retardation and protraction of urination had since been exacerbated and sense of retention come to be associated.
- Palpation of Prostate: Third degree hypertrophy, smooth surface, elastic hardness, symmetry.
- Laboratory Findings: Residual urine 30 cc. Urinary findings normal. Urethrocytography revealed marked extension of the posterior urethra.
- Clinical Course: One month later, the urine stream became somewhat larger, sense of retention slightly decreased to 5 cc. Two months later, the urine stream became even larger and the retarded urination disappeared. Urethrocytography revealed no

significant changes. Three months later, the urine stream remained almost unchanged from one month before. Anuresis occurred once during this period but favorable urination ensued with residual urine of about 10 cc. No changes were noted in the prostate on palpation. The patient, however, developed anuresis one month after withdrawal of the drug and eventually underwent prostatectomy two months later.

Discussion

From an absolute pathological point of view, formation of nodules in the urethral area of the prostate is an aging process seen in all males over the age of 70, and it is only part of them that actually develop clinical symptoms such as pollakisuria, dysuria and anuresis and receive treatment for prostatic hypertrophy. On the other hand, as urologists would often experience, these symptoms sometimes disappear or subside without any specific treatment, and there are even cases where patients with sudden development of anuresis are improved to their premorbid state by mere catheterization or chemotherapy. Experience shows, moreover, that clinical symptoms are not always correlated to prostatic adenoma.

Under the circumstances, it is extremely difficult to decide what criteria to be used for evaluation of effects. Review of clinical reports on other similar drugs shows that more or less the same problem is encountered by other authors. Their conclusions are essentially the same, i.e., drugs are usable for treatment of prostatic hypertrophy if they can improve subjective symptoms without side-effects and can be employed for long-term administration.

In the present study, too, we have been unable to set up definite criteria and thus based our evaluation on the changes of subjective symptoms and residual urine and the findings of the prostate on palpation. Results were, as already seen, "effective" 5 cases, "slightly effective" 5 cases, and "ineffective" 2 cases.

While 10 out of 12 cases showed improvement in subjective symptoms, the objective improvement in residual urine was obtained in only 6 cases and there was no case which showed a marked diminution in the size of the prostate on palpation. Of the 10 cases which showed improvement in subjective symptoms, 3 cases were in the first degree of hypertrophy, 4 cases in the second degree, and 3 cases in the third degree, when judged by the findings of the prostate on palpation. All the patients in the third degree of hypertrophy subsequently underwent prostatectomy. From this point of view, it may be said that the drug improves only dysuria due to so-called "variable elements" such as hyperemia and congestion around the neck of the bladder and the posterior urethra and does not reduce the size of the prostatic adenoma itself. This means the drug is still far from being able to substitute for radical therapy. In other words, it is to be used only in cases where surgical management is contradicted or to improve clinical symptoms when the disease is still in its early phase. It should not be employed indiscriminately for long-term administration, for it may aggravate the renal function and thus increase the risk in surgical operations.

Conclusions

- A. A pollen product, CERNILTON, was used in 12 cases of prostatic hypertrophy. Results were "effective" 5 cases, "slightly effective" 5 cases, and "ineffective" 2 cases. In the 2 of 5 "effective" cases the symptoms relapsed within one month after withdrawal of the drug and the patients eventually underwent prostatectomy. Both had the third degree of hypertrophy. Prostatectomy was also subsequently performed in one "slightly effective" case which also had the third degree of hypertrophy.
- B. Side-effects were observed in none of the cases treated.

Table 1. Results of Treatment

Case	Age	Before Administration				After Administration					
		Symptoms	Findings of Prostate on Palpation	Residual urine	Dosage Cernilk	Symptoms	Findings of prostate on Palpation	Residual urine	Side-effect	Effect	Remarks
1	69	Dysuria, Anuresis	Third degree hypertrophy	cc 420	T. Day 4x25	Improved	Third degree hypertrophy	cc 0	—	Effective	Anuresis appeared one month after cessation of therapy and prostatectomy was carried out.
2	74	Dysuria	Second degree hypertrophy	45	4x25	Slightly improved	Second degree hypertrophy	25	—	Slightly effective	
3	67	Dysuria, Pollakisuria	First degree hypertrophy	130	4x25	Unchanged	First degree hypertrophy	40	—	Ineffective	
4	60	Dysuria, Sense of retention	First degree hypertrophy	100	4x150	Slightly improved	First degree hypertrophy	20	—	Slightly effective	
5	83	Anuresis, Dysuria	First degree hypertrophy	350	4x75	Improved	First degree hypertrophy	10	—	Effective	
6	79	Dysuria,	First degree hypertrophy	600	4x25	Unchanged	First degree hypertrophy	500	—	Ineffective	
7	72	Dysuria, Pollakisuria	First degree hypertrophy	20	4x25	Improved	First degree hypertrophy	10	—	Effective	
8	68	Dysuria, Anuresis	Second degree hypertrophy	600	4x50	Improved	First to second degree hypertrophy	20	—	Effective	
9	63	Dysuria, Anuresis	Third degree hypertrophy	30	4x75	Improved	Third degree hypertrophy	10	—	Effective	Anuresis appeared one month after cessation of therapy and prostatectomy was carried out two months later.
10	67	Dysuria, Pollakisuria, Sense of retention	Second degree hypertrophy	80	4x25	Slightly improved	Second degree hypertrophy	20	—	Slightly effective	
11	78	Dysuria Sense of retention	Second degree hypertrophy	400	4x100	Slightly improved	Second degree hypertrophy	200	—	Slightly effective	
12	78	Dysuria, Pollakisuria	Third degree hypertrophy	200	4x25	Slightly improved	Third degree hypertrophy	150	—	Slightly effective	Prostatectomy subsequently performed.

Table 2. Therapeutic effect and degree of hypertrophy on palpation

*N.B.: Indicates a case in which prostatectomy was performed later.

Effect Degree of hypertrophy	Good	Fair	None
First degree	2	1	2
Second degree	1	3	0
Third degree	2*	1*	0
Total	5	5	2