



PROSTATE SUPPORT:

GRAMINEX Flower Pollen Extract

Clinical evaluation of Cernilton in chronic prostatitis

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1. Introduction

Chronic prostatitis and spermatocytosis are known to have long persistence of subjective symptoms. The diseases are not fully defined yet, and it is speculated that many of the cases classified as falling in these diseases are of primary psychosomatic origin.

As early as 1960 Ask-Upmark of Sweden reported that a pollen preparation was effective in the treatment of prostatitis. Though its mechanism of action is not known, the preparation is considered to prevent growth of bacteria and exert roborant and desensitizing actions.

The purpose of this trial was to study the effectiveness of Cernilton, a pollen preparation used for treatment of prostatitis in Europe, by a double blind test using placebos.

2. Composition

Pollen species used in Cernilton are:

Timothy	26 %
Maize	26 %
Rye	40 %
Pine	5 %
Orchard grass	2 %
Alder	1 %

One Cernilton tablet contains:

Cernitin GBX	3 mg
Cernitin T60	60 mg
Calcium gluconate	70 mg

Lactose	70 mg
Calcium hydrogen phosphate	140 mg
Alginate acid	10 mg
Potato starch	20 mg
Pigment	3 mg
Talc	20 mg

One placebo contains:

Lactose	180 mg
Avicel (microcrystal cellulose)	60 mg
Dextrin	152 mg
Carbon wax	20 mg
Pigment	3 mg

3. Subjects and Method of Administration

The subjects were selected from among the patients with prostatitis and non-gonorrhoeal urethritis visiting the Outpatient Clinic. Those with acute inflammatory symptoms were excluded.

Administration was made once daily, 4 tablets in the morning. Patients with even-numbered dates of birth were given Cernilton while those with odd-numbered dates were given placebos. Administration was made in such a way that neither patients nor physicians would know which was given.

4. Grading System and Criteria of Evaluation

A. Grading System

- Subjective Symptoms
 - Disappearance.....2 points
 - Some improvement.....1 point

2. Number of leukocytes in urine after massage of prostate
Less than 15 in one visual field (magnified 100 times).....normal
Decrease from above 15 to normal.....2 points
Decrease by more than 15.....1 point
3. Number of bacteria in urine after massage of prostate
Disappearance..... 2 points
Number decreased..... 1 point
4. Other findings
Decreased hardness of prostate.....1 point
Improvement of leukocytosis.....1 point
Disappearance of comma shreds....1 point

B. Criteria of Evaluation

- Effective: Cases with a total of 3 or more points or with normal findings in all items.
- Slightly Effective: Cases with a total of 1-2 points.
- Ineffective: Cases with no points

5. Therapeutic results

Cernilton was given in 17 cases. Of these, the clinical courses were followed in 14 cases, and the results were: “effective” in 10 cases, “slightly effective” in 3 cases, and “ineffective” in 1 case. Placebos, on the other hand, were given in 21 cases, and the clinical courses were followed in 16 cases, with “effective” in 7 cases and “ineffective” in 9 cases.

In subjective symptoms, disappearance was noted in 10 cases and subsidence in 4 cases in the Cernilton group, with all cases showing some sort of improvement. In the placebo group, disappearance was seen in 5 cases, subsidence in 2 cases, no-change in 7 cases, and exacerbation in 2 cases. The results show a great difference, but it must be emphasized that objective evaluation of subjective symptoms is all but impossible.

The findings in urinary deposits after the massage of the prostate were, in the Cernilton group, normalization in 5 cases, improvement in 1 case, persistence of abnormal state in 2 cases, exacerbation in 1 case, and persistence

of normal state in 4 cases; result was unknown in one case because the urine was not examined. In the placebo group, normalization was noted in 3 cases, improvement in 2 cases, persistence of abnormal state in 3 cases, and persistence of normal state in 8 cases; exacerbation was not noted.

The findings in bacteria in the urine after the massage of the prostate were: disappearance in 3 cases, no-change in 2, and persistence of normal state in 9 in the Cernilton group and disappearance in 1 case, no-change in 2, reappearance in 1, and persistence of normal state in 12 in the placebo group.

6. Cases

Several cases are illustrated below.

Case 1. 26. Effective

Chief Complaints: heavy pressure sensation in the lower abdomen and abnormal sensation in the penis.

Findings and Treatment:

March 24: Prostate normal on palpation. No tenderness. Deposits of urine examined after massage of prostate. RBC8- 10/1GF. WBC slightly increased/ 1GF. Epithelial cells 3-4/ 1GF. Culture of bacteria, negative. Peripheral blood examined. WBC 5300. Hemogram, slight shift to the left. Administration of Cernilton started.

April 1: 32 tabs of Cernilton given in 8 days with persistence of chief complaints. Medication continued.

April 12: 60 tabs of Cernilton given in 15 days. Abnormal sensation in the penis disappeared (29 days).

May 21: 116 tabs of Cernilton given. Heavy pressure sensation in the lower abdomen subsided. No tenderness. Deposits of urine reexamined after massage of prostate. RBC not found. WBC 8-10/1 GF. Epithelial cells 5 6/1 GF. Culture of bacteria, negative. No side-effects.

Remarks: The chief complaints persisted for a long time, but urinary findings were markedly improved.

Case 2. 23. Effective.

Chief complaints: Initial voiding pain.

Findings and Treatment:

March 24: Prostate normal in size and hardness, but tenderness present.

Examination of urinary deposits after massage of prostate: RBC 10-13/ 1 GF, WBC 20-30/ 1GF, cocci positive.

April 2: Chief complaints, left untreated for a week, persisted without improvement.

Administration of Cernilton started.

May 31: 56 tabs of Cernilton given in 14 days.

Chief complaints subsided on the 6th day.

Prostate normal. Tenderness disappeared.

Examination of urinary deposits after massage of prostate: RBC 1/2 – 3GF, WBC 5-6/ 1GF, culture of bacteria negative.

June 14: 112 tabs of Cernilton given in 14 days. Medication discontinued.

Remarks: This is a case in which both subjective and objective symptoms have disappeared.

Case 3. 27. Effective.

Chief complaints: Sense of urinary retention.

Findings and Treatment:

March 25: Findings in urine and prostate both within normal limits. Slight tenderness seen.

Administration started.

April 1: 28 tabs of Cernilton given in 7 days without improvement of chief complaint.

Urinary findings after massage of prostate: RBC (-), WBC 5-8/ 1GF, epithelial cells 1/1 – 2GF, culture of bacteria negative.

April 15: 140 tabs of Cernilton administered in 35 days, with improvement of chief complaint.

April 28: 196 tabs of Cernilton in 49 days. Chief complaint disappeared completely. Medication withdrawn. No side-effects.

Remarks: This is a case in which only subjective symptoms were found. In all three cases, the initial effect appears to have taken place after administration of more than 10 days.

Case 9. 23. Cernilton effective, placebo ineffective.

Chief complaint: Sense of urinary retention.

Findings and Treatment:

Dec. 3: Induration found in right lower part of prostate. E.coli 56540/ ml revealed after massage. Urocydal and Wintomylon given.

March 28: Anti-inflammatory agents and antibiotics had no effect, though given for 4 months. Slight voiding pain appeared.

Induration still noted in the prostate.

Pseudomonas 5600/ ml noted in urine after massage of prostate. Examination of peripheral blood: WBC 5000, hemogram no shift to the left. Administration of placebo started to observe the course.

April 11: 56 placebo tablets given in 14 days. Total voiding pain somewhat exacerbated.

May 23: 168 placebo tablets given in 42 days.

Total voiding pain subsided but sense of urinary retention persisted. Induration noted in prostate. Examination of urinary deposits after massage of prostate: RBC(-), WBC 10 11/ 1FG, St. epidermis 6 160/ml.

Administration of Cernilton started.

June 13: 84 tablets of Cernilton administered in 21 days. Voiding pain disappeared and sense of retention subsided.

July 4: 168 tablets of Cernilton in 42 days.

Subjective symptoms all disappeared and induration not palpable.

Remarks: This is a case which has been completely cured with Cernilton. The

patient was not informed of the change of drugs during the treatment.

Case 10. 47. Cernilton effective, placebo ineffective.

Chief Complaint: Dull pain in the perineum.

Findings and Treatment:

March 17: Prostate somewhat enlarged with tenderness. Examination of urinary deposits after massage of prostate: RBC (-), WBC 12/ 1GF, epithelial cells 1/ 1GF, culture of bacteria negative. Administration of Cernilton started.

April 4: 68 tabs of Cernilton administered in 17 days. Chief complaint and tenderness disappeared and prostate became normal in size. Medication withdrawn.

April 27: Chief complaint recurred. Prostate normal in size. Examination of urinary deposits after massage of prostate: RBC (-), WBC 1-2/ 1GF, bacteria negative. Administration of placebo started.

May 13: 56 placebo tablets given in 14 days with no improvement of chief complaint. Placebo withdrawn.

7. Side Effects

No complaints compatible with side-effects were noted among the cases studied (Cernilton group 17 cases, placebo group 21 cases). Neither were abnormal objective symptoms noted, in the cases where clinical courses were followed.

Reportedly, Cernilton must be administered in the morning as it produces a caffeine-like action. This, however, was observed in none of our cases. Case 12 mistakenly took the drug in the afternoon for some days, but he said he did not suffer from insomnia at all. One of the authors, too, had 4 tablets at 10 o' clock every night for 5 days; and he did not experience excitement or insomnia, either. This may be a matter of individual susceptibility. Yet, our impression is that the drug is not necessarily one to be taken in the morning.

8. Discussion

There are no definite criteria for diagnosis of prostatitis at present. On the contrary, the presence of chronic prostatitis itself is sometimes doubted. Generally, positive finding in the culture of bacteria and increase in the number of leukocytes in urinary deposits after the massage of the prostate, are the criteria used for diagnosis of chronic prostatitis, through diagnosis based solely on tenderness has also been employed since old times.

On the other hand, it comes gradually to be known that chronic prostatitis is often attributable to allergy. It was Stewart and Wray who first described pathological changes of allergic prostatitis, and many cases of eosinophilic granulomatous prostatitis have since been reported. In some cases asthma is claimed associated. Since Cernilton has the actions of desensitization and increasing physical resistance, as well as bacterial and bacteriostatic actions, it can be expected to exert considerable effects on pathological changes of allergic prostatitis, granting that the mechanism of action is not precisely known.

The cases of prostatitis selected for the present study were mainly diagnosed on the basis of subjective symptoms and findings on palpation. Thus, many cases showed no abnormal findings in the secretion of the prostate or in the urine. Care, however, was taken to select only such cases as would comply with the diagnostic criteria laid down by Campbell in his text-book. Naturally, some cases of psychosomatic origin were included. On the other hand, the cases where placebos proved effective were not necessarily of psychosomatic origin. A good number of them can be considered to have healed spontaneously. Yet the fact that the rate of effectiveness was higher than 90% in Cernilton group as against below 50% in the placebo group, suggests that there must have been cases where Cernilton was indicated. This is supported by the significant difference of effects registered in the two cases where both Cernilton and placebos were employed and

further by the fact that improvement of subjective symptoms was more difficult to obtain in the placebo group.

Cernilton was administered over periods ranging from 10 to 56 days, but no side-effects were noted. It is considered that a longer period of administration is possible. The onset of effect was rather slow, taking place in 7-10 days. Therefore, administration should at least be maintained for two weeks. Recurrence of symptoms was noted in two cases after withdrawal of the drug. Since the drug is experimentally confirmed to cause little toxicity, maintenance of medication even after disappearance of symptoms is advisable.

More describes that chronic prostatitis is found in more than 35% of male adults over the age of 35, while, according to another report, it is found in 85% of male adults over the age of 30. The participating factors are trauma, drinking and car-driving, and the incidence may even increase in future. In most cases bacteria are either totally absent or only sparsely detected, and thus positive use of antibiotics is not justified. On the other hand, long-term administration of anti-inflammatory drugs does not always result in improvement of symptoms. In this sense, the pollen preparation Cernilton points to a new approach. It may not be effective in all cases of chronic prostatitis, but it certainly

can be effective in many such cases, especially those of allergic origin. For treatment of acute prostatitis, however, it is desirable to use antibiotics since Cernilton does not possess potent bactericidal action. Finally, it is reported that the drug is to be carefully administered to patients allergic to pollen.

Conclusions

Cernilton and placebos have been used for treatment of chronic prostatitis and following results obtained:

1. Of a total of 14 cases in the Cernilton group, 10 cases were effective and 3 cases slightly effective.
2. Results obtained in the placebo group were much less favourable, effective in 7 cases and ineffective in 9 cases.
3. Side-effects were observed in none of the 38 cases studied.

Table 1. Cernilton Group

No.	Age	Dosage tab. X time	Adm. Days	Combined Drugs	Effects	Subjective symptoms	After Massage of Prostate		Remarks
							Urinary findings	Bacteria in Urine	
1.	26	4 X 1	43	—	Effective	++ > +	++ > —	—	Tenderness of prostate disappeared.
2.	23	"	28	—	"	++ > —	+	+ > —	"
3.	27	"	49	—	"	+ > —	—	—	Same patient as No. 9 in Table 2.
4.	33	"	10	—	"	++ > —	++ > ±	++ > —	
5.	38	"	21	—	"	++ > —	—	—	
6.	44	"	56	Urocydal 21 days before Cernilton	"	++ > —	++ > —	—	
7.	32	"	42	—	"	++ > —	—	—	Recurred after withdrawal.
8.	34	4 X 1 2 X 1	7 28	—	"	++ > —	—	—	
9.	23	4 X 1	42	Placebos 42 days before Cernilton	"	++ > ±	+ > —	—	Same patient as No. 9 in Table 2.
10.	47	"	24	—	"	++ > —	+ > —	—	Later changed to placebo same patient as No. 10 in Table 2.
11.	57	"	21	—	Slightly effective	++ > —	?	—	Ureteral calculus subsequently found and treatment changed
12.	61	"	56	Panvitan 3 tabs daily	"	++ > —	++	+	Induration of prostate disappeared.
13.	52	"	10	Antibiotics	"	++ > +	++ > —	+	Hypertrophy of prostate associated.
14.	37	"	14	—	Ineffective	++ > +	++ > ++	—	Same patient as No. 16 in Table 2.

Table 2. Placebo Group

No.	Age	Dosage tab. X time	Days Adm.	Combined Drugs	Effects	Subjective symptoms	After Massage of Prostate		Remarks
							Urinary findings	Bacteria in Urine	
1.	38	4 X 1	49	—	Effective	++ > +	++ > —	+ > —	
2.	60	"	28	—	"	++ > —	++ > ++	—	
3.	53	"	7	—	"	++ > —	++ > ++	—	
4.	31	"	14	—	"	++ > —	—	—	
5.	33	"	35	—	"	++ > —	++ > —	—	
6.	41	"	21	—	"	++ > —	—	—	
7.	25	"	42	—	"	++ > —	++ > —	—	
8.	27	"	27	—	Ineffective	++	—	—	
9.	23	"	42	—	"	++	+	+	Vaginal trichomonas found transiently in urine. Same patient as No. 9 in Table 1. Subsequently changed to Cernilton.
10.	47	"	14	Cernilton 24 days before placebo	"	++ > +	—	—	Same patient as No. 10 in Table 1.
11.	21	"	28	—	"	++	—	—	
12.	29	"	14	—	"	++	—	—	
13.	42	"	7	—	"	++	—	—	
14.	60	"	28	—	"	++	+	—	
15.	33	"	21	—	"	++	+	—	
16.	52	"	10	—	"	++ > ++	—	+	Same patient as No. 16 in Table 1.