A preliminary investigation on the therapeutic effect of Cernilton in chronic prostatovesiculitis

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INTRODUCTION

It has been known for many years that chronic prostatovesiculitis is a very common disease. The highest incidence of cases reported in the literature on the subject is provided by Wiseman (1931). He accounted for 200 male patients selected at random, the majority of whom having sought medical advice on the grounds of extraurogenital symptoms. 54% percent of these cases were found to exhibit clinical signs of chronic prostatovesiculitis. Pelouze (1939) reported an incidence of 30-40% of all males over the age of 40 years, and Gartman (1960) gives a figure in excess of 40% in a material of 919 apparently healthy males aged between 17-40 years (routine military examination). Although Farman and McDonald (1961) do not state any incidence figures, they agree with Pelouze that this disease is probably the most prevalent chronic infection in men over 40 years of age.

The symptomatology of chronic prostatovesiculitis is extremely vague and, from his material, Gartman was able to record no less than 178 different symptoms (sic!). Because of the great variety of symptoms, and despite the fact that the symptoms occurring most frequently only constitute a fraction of the total number, diagnosis is seldom confirmed at an early stage. This delay leads both to a marked resistance to therapy and to a marked recidivism, two notable characteristics of the disease. The combination of these two characteristics often causes deviations from the normal in the psyche of the patients who may, for instance, become fixed in a sexual impotency that might otherwise have disappeared after a short time.

In spite of the fact that chronic prostatovesiculitis has been a well-known syndrome for so long therapeutic advances in this field have been negligible. Chemotherapeutics and antibiotics are of some value in the acute stage or during exacerbation periods, but they are worthless in the chronic course. The conservative treatment still consists of stripping and expulsions at regular intervals. The experienced urologist first handles the patient by stripping (to empty the gland and to diagnose the secretion) and follows up with massage (to eliminate adhesions and to stimulate the blood flow). Treatment given by an inexperienced person will, for the most part, only lead to negative results, and the patient will become disinclined to complete the treatment. This was illustrated by some American statistics which showed that only one-half of the patients persisted whereas the remaining number oscillated between different physicians only to find that the treatment recommended was practically identical and without any significant modification. In many cases, they gave up trying and only returned to the doctor when various sequalae became apparent (pelveospondylitis, uropolyarthritis, or sacral rhizopathy).

Cernilton was first mentioned as a possible therapeutic agent in chronic prostatovesiculitis in 1959 when Dr. Ask-Upmark, Sweden, published a short report on a typical case. The disease was so persistent that not even an antibiotic dose as large as 150 g chloromycin, administered over a two-month period, could prevent a relapse. The patient then began to take Cernilton on his own initiative. At that stage, the patient had been suffering from the disease for 5 years with practically continuous distress. He became symptom-free very rapidly and remained so, the last report being noted two years later. The only occasion upon which he experienced any distress during these two years was during a two-week trip when he did not have

access to the tablets. Owing to the rebellious nature of his particular case, the result naturally attracted attention. Later, Jönsson (1961) reported 10 cases who had received Cernilton for more than a year. As a result of his observations, Jönsson held the opinion that continued experimental therapy was motivated and emphasized the very great advantages which could be derived from a test series employing placebo tablets.

A preliminary Investigation

This investigation was based on a material consisting of 179 cases of chronic prostatovesiculitis selected from open urological praxis. The minimum observation period following the introduction of Cernilton was 4 months (14%) and the maximum period was 23 months (1 case). The mean observation period was 10 months. The entire investigation period dated from Dec. 1, 1959 to Oct. 31, 1961. Cases which had been under observation for less than 4 months by the terminal date, and those who came under observation afterwards, will be reported in a later article planned to cover a 3-year period and approximately 500 cases.

CERNILTON

The preparation was placed at the disposal of the author by the manufacturers, AB Cernelle, Vegeholm, Sweden. The raw material consists of an extraction taken from a given admixture of four types of pollen. The extraction is autolyzed and microbially digested before being spray dried. The purpose of this digestion is to break down any allergens which might be present. When the preparation is ready for use, it does not contain any precipitable protein and it is rich in certain B-vitamins. Tests have also been performed in order to determine whether the steroids present in the preparation contain the therapeutically active component. However, no results are available at the time of writing.

Patient material

The 179 cases were selected from about 400 cases available at the time in question. 80 cases were eliminated from the total when it was found that the placebo tablets given initially differed from the real Cernilton tablets both in colour and consistancy. Other cases were eliminated because they had undergone surgery or some other manipulation (apart from panendoscopes for diagnostic purposes), and, further, all cases suffering from serious diseases outside the urogenital tract. Cernilton treatment was not employed in cases of ascertained or suspected malignant degeneration of the gland although the material does include a few cases exhibiting a concurrent, but negligible, benign enlargement of the gland which, however, in no way affected the actual infection.

The age distribution of the material is given in Fig. 1. It should be noted that prostatovesiculitis can occur at any age; there are references in literature to new-born infants with the disease (Mann, Giannastasio).

Fig. 2 provides information concerning the duration of distress prior to the introduction of the therapy.

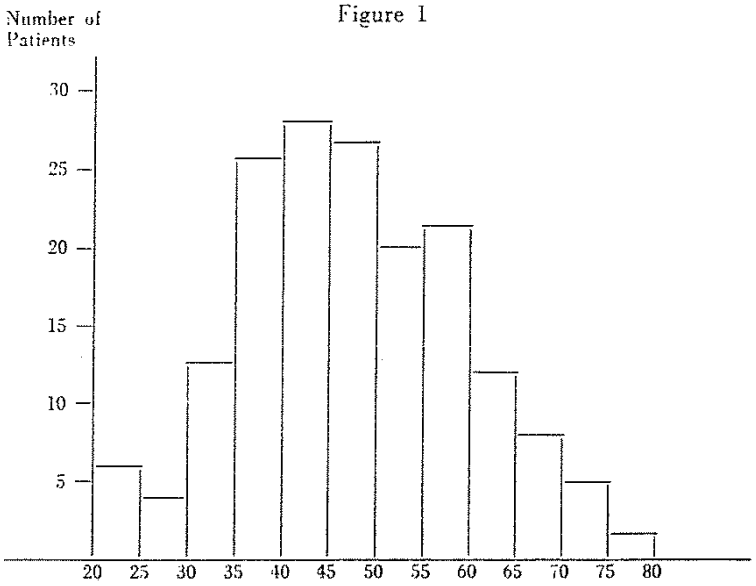
The patient material was not sufficiently large to permit the same age distribution in the different groups.

Method

The investigation was planned partly as a double-blind test and the material was divided into two groups for the treatment.

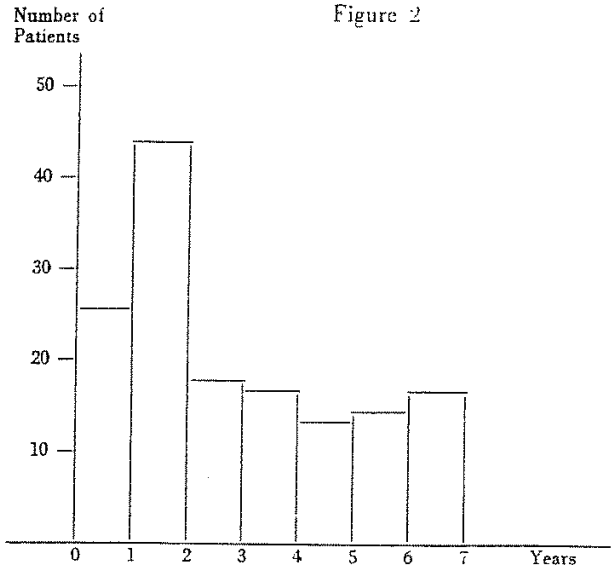
A. In this group, comprising 65% of the cases, the patients were supplied with Cernilton on prescription (druggist's Cernilton). The physician in charge was therefore fully aware of the nature of the preparations.

Figure 1



Age distribution of the patient material.

Figure 2



Duration of symptoms prior to combined Cernilton + conservative therapy.

B. In this group, comprising 35% of the cases, the patients received either placebo or the real tablets (code Cernilton). The physician in charge did not have access to the code and was therefore unaware of the nature of the preparation. The code number was noted in the journal and the results assessed objectively. This procedure made it possible to determine whether the physician exerted any influence over the patients (psychic supportation) when he knew the true composition of the tablets. Once the aforementioned eliminations had been made and the selection of patients completed, the tablets used all had exactly the same shape, size, smell, taste, and appearance.

All the patients underwent a complete urological examination including urography, urethrocystrography and, when necessary, panendoscopy. In connection with these examinations, the patients were given

chemotherapy for a few days but otherwise during the course of the treatment, both chemotherapeutics and antibiotics were to all intents and purposes banned.

Ataractics were administered when the patient exhibited an obvious psychogenic state. When impotence persisted even after the secretion had become normalized, hormone treatment was introduced (i.m. injections of hormone derivatives).

The conservative treatment — in 2/3rds of the cases in combination with druggist's Cernilton and in 1/3rd with code Cernilton —consisted of expulsion and subsequent massage performed initially once a week to once in 10 days. Concurrent to the normalizing of the secretion and to the reduction of the secretionary stasis in the gland, the interval between expulsions was extended to 2—3 up to 4 weeks, and even longer in some cases.

The dosage of both druggist's and code Cernilton was the same: 4 tablets each morning swallowed whole or chewed as preferred. More recently, a double dose has been given during the first 2—3 weeks, the patient being supplied with 4 tablets in the morning and another 4 at lunchtime.

Evaluation

Although the symptomatology of chronic prostatovesiculitis is very heterogeneous, the object of the therapy is quite definite: to achieve, as quickly and as effectively as possible, improved drainage of the gland and, simultaneously, to eliminate the prevailing stasis of the secretion which contains greater or lesser quantities of pus. When evaluating the results, two clinical findings have been most intensely investigated: the appearance of the secretion and urethrocystoscopy and microscopy, and the content of the prostate gland and the vesicles on rectal palpation. When an infection is in progress, the prostate and the vesicles have a doughy consistancy, they are tender when palpated and they contain a more or less pus-filled secretion. When therapy is successful, evacuation is improved and, consequently, the secretionary stasis is eliminated. This can be easily confirmed by palpation. Concurrently, the secretion reverts to normal and this too is easily confirmed by direct microscopy. A secretion containing a count of more than 10 white blood cells per field (enlargement x 240 diameters) is obviously pathological but even a secretion containing 4—6 cells per field should be considered pathological if these white blood cells form aggregations. A secretion is considered normal when the number of white blood cells does not exceed 6 and occur individually. A healed gland has a tough, indurated consistancy, is no longer tender when palpated and does not retain any secretion.

The therapy results were assessed as being positive when there was no more than one exacerbation in the course of six months and two exacerbation periods during a time of one year or longer. Most of these mild relapses were due to the fault of the patient who, since he became symptom-free at relatively early stage, became nonchalant in following up his treatment. However, these relapses were generally harmless and could be coped without difficulty. A temporary doubling of the Cernilton dose brought about a rapid improvement.

Results and Discussion

One the basis of the above, the results were assessed for three groups:

a) Tablet composition known to the physician in charge (Fig.3 (K)).
Total: 118 cases.

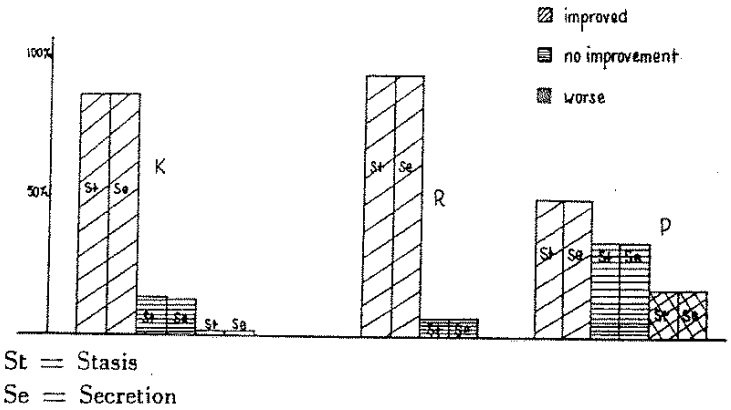
B) Real Cernilton tablets in the code group (Fig. 3 (R)).

C) Placebos (Fig. 3 (P)).
Total B) + C): 61 cases.

Figure 3

Cernilton effect on prostatovesiculitis.

Changes in stasis and secretion in per cent of patients in each group.



St = Stasis
Se = Secretion

It can be seen from Fig. 3 that the effect of the tablets in the K and R groups is practically identical. The number of symptom-free or considerably improved patients is about 90%. This also serves to show that the personal influence of the doctor is negligible and can be discounted entirely in the final results.

The improvement shown by the patients in the placebo group (P) is about 50%. Since the total material received absolutely uniform conservative treatment, the results of this preliminary investigation can be expressed as follows:

The results of the combination of conservative and Cernilton therapy were 60-30% better than those achieved with conservative treatment alone.

Taking into account the marked resistance of the disease to earlier therapeutic measures, its frequency, and, not least, the complications occurring later and leading to a high degree of invalidity if left untreated, this therapeutic result must be acknowledged with satisfaction.

It can further be seen from the figures that the pus content of the secretion and the secretionary stasis run a parallel course during changes in the state of the disease. The occurrence of a pus-containing secretion when the gland is indurated and free from secretion is highly exceptional. Apart from the two main symptoms mentioned, attention has been paid to only one other of the numerous symptoms reported, namely the sacral rhizopathies described by Bohm, Franksson and Peterson (1956). The author of the present paper felt this to be motivated since the connection between chronic prostatovesiculitis and sacral rhizopathy has not been elucidated and further, as the patient can nearly always give a clear picture of the area of pain, diagnosis of this particular syndrome is not difficult. However, so far the results of Cernilton therapy have not provided any statistically significant values in any direction.

A number of other observations have been made concerning miction frequency, elimination of residual urine, etc., but these symptoms have not been dealt with statistically.

Cernilton appears to have an antiphlogistic effect. The results obtained also indicate that the preparation improves or facilitates the drainage of the gland. The active component(s) of the substance has not been

isolated. A new and thorough double blind test with synthetic tablets containing exactly the same composition of vitamins and amino acids as Cernilton and with real Cernilton tablets will be commenced very shortly. Further, a test series is planned involving the use of only pollen steroids for the purpose of isolating and defining the active therapeutic component.

Complications

Cernilton treatment has not given rise to any serious complications. One case developed an obvious gynecomastia after two months of treatment. During this time, his prostatovesiculitis had improved considerably and the preparation could be discontinued, and he subsequently received only conservative therapy. The gynecomastia disappeared shortly afterwards. One other patient complained of a swelling sensation in the mammae although no changes in glandular substance could be confirmed. This symptom also disappeared rapidly when Cernilton was withdrawn. There were no other cases of similar side effects and it is obviously impossible to form any opinion of the hormonal effect on the basis of these two solitary cases (out of a material which, to date, consists of more than 500 cases).

A number of patients exhibiting clearly allergic reactions have been treated. The therapy has not caused any exacerbation although in a couple of cases it was found necessary to reduce the dose because of intestinal symptoms arising during therapy. As similar intestinal symptoms also occurred in a few isolated non-allergic patients, these symptoms can hardly be registered as allergic. Helander has, in fact, stated that the substance does not cause any allergic reactions when administered orally. However, in two cases included in a section of the primary material not included here, treatment had to be discontinued owing to nausea and pruritis. As soon as the drug was eliminated, the symptoms disappeared. When the substance is to be administered to patients who are highly allergic, the author suggests commencing the treatment with a small dose (e.g. 1 tablet each morning and, if not distress is experienced, gradually increasing to normal dose). In summarizing the complications, it can be stated without reservation that side effects were negligible and without any practical importance to the results as a whole.

Summary

A preliminary report is given of a current investigation on the effect of Cernilton in the treatment of chronic prostatovesiculitis. The investigation indicates the conservative treatment in combination with Cernilton gives results which are 60—80% better than those obtained with conservative treatment alone.

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