FOMEPIKEHL drops for the Treatment of Prostatic Adenoma

Results of an Application Study

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Introduction

60 patients in two medical practices were treated with the homeopathic preparation FOMEPIKEHL 5X in the form of drops. The active constituent in FOMEPIKEHL 5X drops is Fomitopsis pinicola e muribus mycelii, in the 5X dilution according to the German Homeopathic Pharmacopoeia (HAB), Instruction 5a.

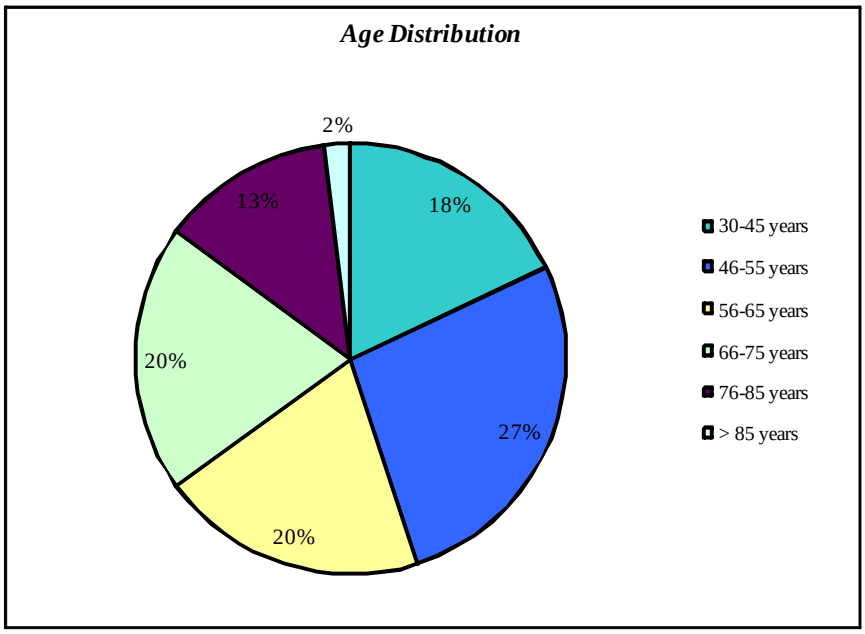
The objective of this observation was to establish the effectiveness of this preparation, and how well it was tolerated in conditions of day-to-day practice. In view of the conditions under which the investigation took place, purely descriptive, statistical procedures were adopted. The use of inductive methods was not indicated. What was carried out was an "intention to treat" evaluation, i.e. all patients were taken into account, who had been given at least one dose of the medicine.

The aim was to prove that FOMEPIKEHL 5X homeopathic drops may be used unreservedly and successfully in treating cases of prostatic adenoma.

Diagnoses and Concomitant Complaints

60 patients took part in this study. The diagnosis, which led to the prescription had to be declared in the study protocol. The doctors were instructed to include patients in the study, who were suffering from prostatic adenoma. All 60 patients were included in the study under the diagnosis of "prostatic adenoma". No mention was made of any subsidiary diagnoses.

The participants in the study covered an age-range of 30 to 88 years, with



an average age of 59:

30 - 45 years	11	(18%)
46 - 55 years	16	(27%)
56 - 65 years	12	(20%)
66 – 75 years	12	(20%)
76 – 85 years	8	(13%)
> 85 years	1	(2%)

Thus, the patient sample involved in the study covered a cross-section with a mid-range average age, including several older people. So far, as age is concerned, we see that the patient sample more or less corresponded to the distribution of those in the general population, who present with the medical condition under investigation.

Time of Consultation and Length of Treatment

In keeping with the nature of an Observation of Application, the doctor was given no fixed time-scale for examination of the patient with a view to termination of treatment. Such examinations took place over a time-span ranging from seven to 193 days, the average being 48 days.

Dosage:

The average daily dose was 11 drops. On four of the survey sheets, no dosage was given.

Other medicines prescribed concurrently

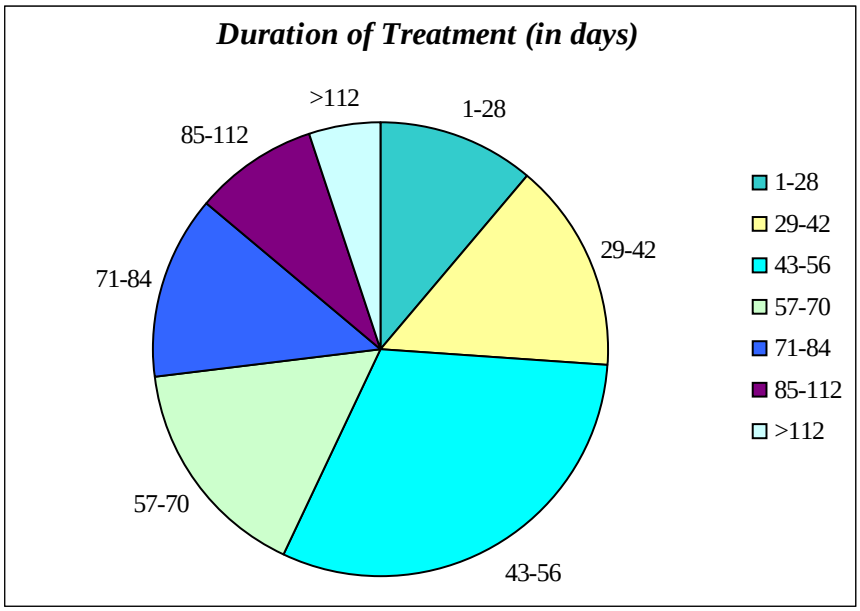
In a few cases, other medicaments were employed concurrently alongside the medication under trial. In some cases, these were medicaments, which are not specifically indicated for the presenting condition under observation:

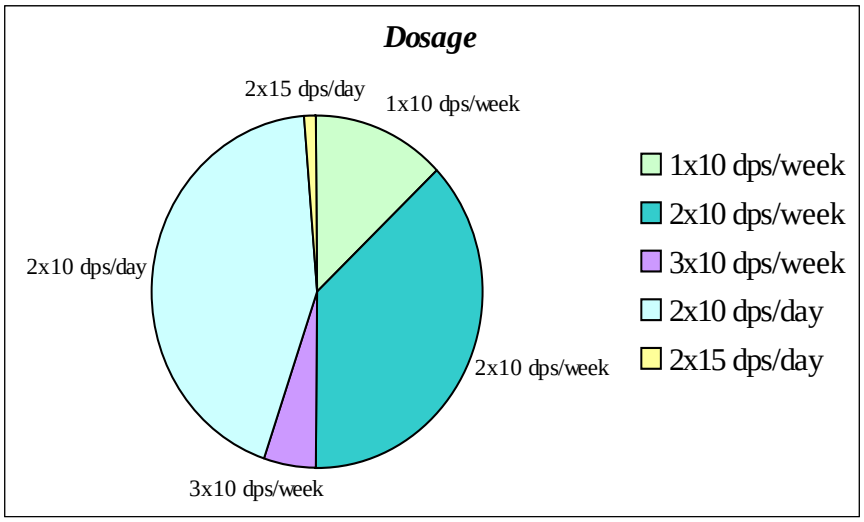
Medicament	No. of patients
Plantago	10
Vitamin C	1
Phlogenzym	1

In other cases, however, these were preparations, which do have a specific action on the presenting condition under observation.

Medicament	No. of patients
Sabal (Saw Palmetto)	6
Vitamin E	3
Sabal with Neural Therapy	1

Sabal is employed as a specific





against prostatic adenoma. Vitamin E is known to lower the risk of cancer, particularly cancer of the prostate. In these ten cases, it is difficult to evaluate the action of the medication being tested. However, we may proceed on the assumption that these medicaments were only given intermittently, since the doctors were enjoined only to include patients in the study, who were being treated exclusively with FOMEPIKEHL 5X drops.

Treatment results

As far as possible, the global evaluation of efficiacy and tolerance of the trial preparation was delivered by doctor and patient separately.

The evaluation of efficacy was classified as follows:

- cured (doctor) or free of complaint (patients)
- improved
- slightly improved
- no change

The doctors evaluated the treatment result as "cured" in 26 patients, as "improved" in 23 patients, as "slightly improved" in 8 patients, and as "no change" in 3 patients.

The patients evaluated the results of the treatment as "free of complaints" in 28 cases, as "improved" in 24 cases, as "slightly improved" in 6 cases, and as "no change" in 2 cases.

The doctors' opinion as to the results of the treatment bears a strong similarity to that of the patients.

Five times, it was mentioned that the dribbling of urine ceased on taking the medicine. In each case, the doctor reported that urination was now easier, or that the length of time before emptying the bladder at night had increased.

Compared with the 47 positive outcomes, the doctors noted 13, who did not respond (slightly improved, no change).

Evaluation of toleration, undesired side-effects and terminations of treatment

The evaluation of how well the medicine was tolerated was classified as follows:

- no side-effects
- names of the side-effects

In 56 patients, the doctors rated the toleration as "good" or "no side-effects". In four patients side-effects occurred and, in three out of the four cases, these coincided with an unsatisfactory treatment outcome. Twice, it was diarrhoea alone that was mentioned as a side-effect, in one case diarrhoea with pruritus, and in one case nausea with pruritus. This type of side-effect does not make sense in the light of the mode of action of FOMEPIKEHL 5X drops; not only this, but to date no side-effects have been reported in the use of this medicine. We therefore have

to proceed on the assumption that that these side-effects were not caused solely by the medicine, but by other additional factors. Of course, all these side effects are unpleasant for the patients concerned, but these do not seriously affect the health. In no case was treatment discontinued because of them.

Evaluation

This study was conceived as an open-ended, uncontrolled study of application. It was to demonstrate that FOMEPIKEHL 5X homeopathic drops may be applied unreservedly and successfully in the treatment of prostatic adenoma cases.

60 patients were accepted on to the study, and 60 reports were able to be evaluated. In the case of 10 reports, another medication was prescribed concurrently, which also had an action on the condition for which FOMEPIKEHL 5X homeopathic drops were indicated. However, since the doctors were informed that only the medication being tested was to be given, it is assumed that the concurrent medicine was only used sporadically by the patients.

In a patient sample of mixed ages, taking an average daily dose of 11 drops, in a majority of cases the efficacy was described both by the doctors and subjectively by the patients as “cured“ or “improved“.

In the majority of cases, the medicine was well tolerated, even after a treatment duration of several weeks. In four cases, side-effects occurred (diarrhoea, pruritus, nausea), although it is assumed that they were not triggered solely by the medicine, but by other additional factors. In none of the cases were the side-effects sufficient to cause a termination of treatment.

In this study, FOMEPIKEHL 5X homeopathic drops were shown to be a well-tolerated, efficacious form of therapy in the treatment of prostatic adenoma.

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