Statistical evaluation of an observational study of the use of Mucokehl 5X eye drops (a homeopathic remedy) by patients with cataracts and conjunctivitis

by

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Introduction

In an established medical practice, a total of 50 patients with cataracts and conjunctivitis were involved in an observational study using Mucokehl 5X eye drops, a homeopathic remedy, between January 1995 and March 1996. 5 ml of the product under investigation, Mucokehl 5X, consist of 4,999.95 mg of the 5th decimal dilution of *Mucor racemosus* in isotonic saline solution plus 0.05 mg chlorhexidine diacetate as a preservative.

The aim of the observational study was to find out how the remedy was actually applied and how effective it was under daily practice conditions. In addition, it was hoped to gain an insight into the acceptance of the remedy on the market.

In line with the arrangements for the trial, only descriptive statistical procedures were drawn upon. The use of inductive methods was not indicated. An „intention to treat“ analysis was carried out: i.e. that all patients who had received at least one dose of the medication were taken into consideration.

The patients involved

50 patients were included in the study: 26 men (52 %) and 24 women (48 %). The patients' ages varied from 2 to 87 years with an average age of 49.4 years and a standard deviation of 20.8 years. 6 patients (12 %) were under 20 years of age. 4 patients (8 %) were aged between 21 and 30 years; there were 8 patients (16 %) in each of the age groups 31–40 and 41–50 years. 6 patients (12 %) were between 51 and 60 and again 8 patients (16 %) were between 61 and 71. 10 patients (20 %) were above 60 years of age. The age structures of the sexes were almost the same. The men recorded an average age of 49.1 ± 20.7 years and the women 51.6 ± 22.1 years. However, because of the diagnosis, there were significant differences in age between the patients with cataracts and those with conjunctivitis. 76 % of the cataract patients were above 50 years of age whilst 80 % of the conjunctivitis patients were below 50.

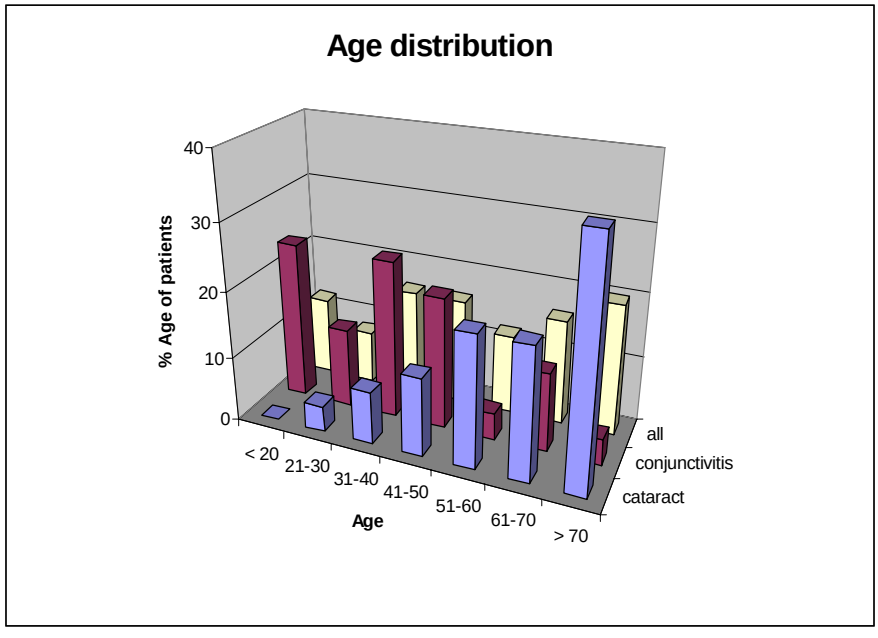
Diagnoses and concomitant diseases

According to the study protocol, conjunctivitis and cataract in 25 patients each were named as the diagnoses which led to the prescription. In each case an examination was carried out before and on completion of the course of treatment. Any concomitant courses of treatment were to be documented in the anamnesis notes. No concomitant medication was being administered to any of the 50 patients included in the study.

Dosage and duration of treatment

Dates of consultations and duration of treatment

As is appropriate for the nature of an observational study, no fixed time plan was prescribed for the



doctor to carry out the initial and final examination. Of course both the time the problem continued and the length of the course of treatment were essentially decided by when the doctor made his diagnosis. If one divides the patients involved into the two groups „cataracts“ and „conjunctivitis“ according to their diagnosis, the average length of the course of treatment works out at 3.4 ± 1.3 months for cataract patients and 3.1 ± 2.0 weeks for conjunctivitis patients. During the anamnesis the patient was also asked when the problem had begun. This resulted in a picture which reciprocated the duration of the treatment. By their very nature, the cataracts were a relatively long-term complaint (3.2 ± 3.0 years) compared to the conjunctivitis (18.9 ± 26.1 days). All patients took part in the final examination.

Dosage

The same dosage was prescribed for all patients in both diagnostic groups: one drop twice daily in the affected eye.

Assessment of the efficacy

In the final assessment the doctors and patients were asked to rate the effectiveness and tolerance of the treatment. The efficacy could be rated „good“, „satisfactory“ or „poor“. In the overall assessment of efficacy the doctors and patients gave the same answers: in 43 cases (86 %) they said „good“, in 4 cases (8 %) „satisfactory“ and in 2 cases (4 %) „poor“. Nothing was reported for one patient.

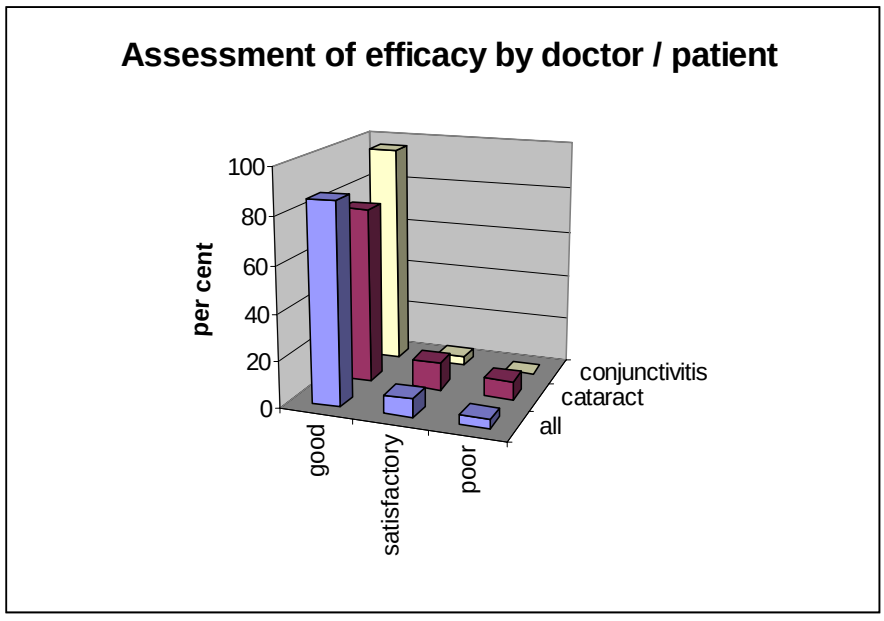
Within the two partial indications the success of the treatment for conjunctivitis was rated significantly more positively than for cataract. For conjunctivitis, freedom from the complaint at the end of the course of treatment was diagnosed in 64 % of cases. In 12 % there was a significant improvement and in 4 % a slight improvement. In 20 % of patients there were no pathological findings as regards their condition, which is equivalent to being free of the complaint. In addition, 24 of the 25 patients (= 96 %) classified the success of the course of treatment as „good“ and only one patient (= 4 %) reported it as „satisfactory“. In the cataracts group, 19 patients (= 76 %) deemed it to be „good“, 3 patients (= 12 %) „satisfactory“ and 2 patients (= 8 %) „poor“. Nothing was reported for one patient. In each case the doctor’s assessment was the same as that of the patient.

Tolerance

As part of the anamnesis, questions were asked about any possible initial exacerbation, side effects and intolerance. No patient reported either any initial exacerbation, side effects or intolerance, even during the six-months term of treatment for cataracts.

Assessment of the tolerance

At the end of the trial the doctor and patients made an assessment of the tolerance, whereby they could choose to rate it „good“, „satisfactory“ or „poor“. In the



case of 49 out of the 50 patients included in the study, both the doctor and patient rated the tolerance as „good“. Nothing was reported for one patient. No break was recorded in the study.

Summary

In an established medical practice, a total of 50 patients with cataracts and conjunctivitis were involved in an observational study using Mucokehl 5X eye drops between January 1995 and March 1996. The patients' ages varied from 2 to 87 years with an average age of 49.4 years.

According to the study protocol, conjunctivitis and cataract in 25 patients each were named as the diagnoses which led to the prescription. For each of the 50 patients included in the study a single course of treatment was carried out using Mucokehl 5X eye drops. No other medication was administered at the same time.

The average length of the course of treatment was 3.4 ± 1.3 months for cataract patients, with treatment lasting a minimum of 1 month and a maximum of 6 months. The conjunctivitis patients were treated on average for 3.1 ± 2.0 weeks: a minimum of 1.5 weeks and a maximum of 2 months.

The same dosage was prescribed for all patients: one drop twice daily in the affected eye. The progress of the course of treatment in the conjunctivitis group was determined by medical examination before and after the course of treatment. At the end of the course of treatment, there was evidence of an improvement of the condition in all 25 patients, 64 % indicating that they were free of the complaint with 20 % showing no pathological findings compared to the start of treatment, significant improvement in 12 % and slight improvement in 4 %.

Of the 50 patients involved in the study, 43 rated the efficacy of the treatment as „good“ whilst 4 patients reported the effects of the remedy as „satisfactory“ and another 2 reported it as „poor“. The doctor's assessment was identical to that of the patients. Nothing was reported for 1 patient.

49 out of the 50 patients involved said that tolerance of the remedy was „good“. Nothing was reported for one patient. No break was recorded in the study. No initial exacerbation or any side effects or intolerance were observed. Once again the doctor's assessment was identical to that of the patients.

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