Statistical Evaluation of an Application Study with NIGERSAN D5 drops

in patients with ovarian cysts, epididymitis and hyperthyreosis

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1. Introduction

In a resident medical practice, a total of 75 patients suffering from ovarian cysts, epidydimitis and hyperthyreosis was admitted to an observation study with Nigersan D5. The test preparation Nigersan D5 consists exclusively of the 5th decimal dilution of Aspergillus niger van Tieghem in purified water in accordance with rule 5a, HAB.

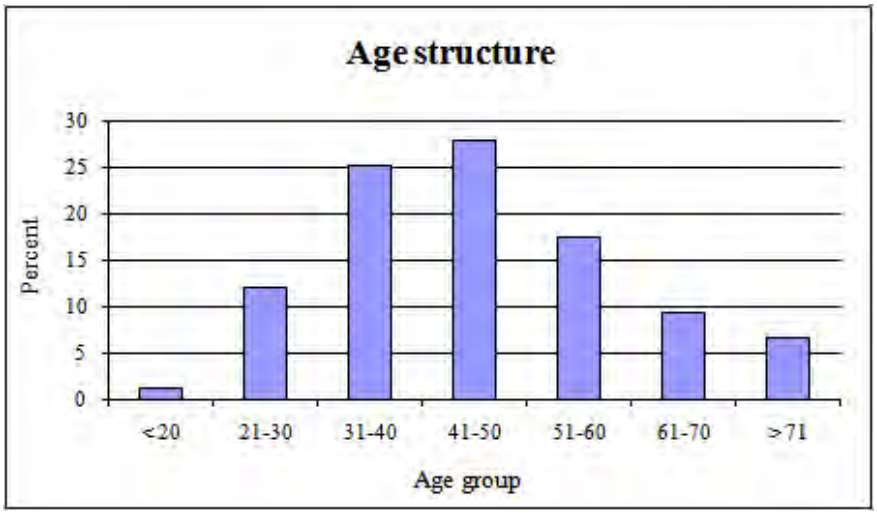
The aim of the observation study was to establish the actual application of the preparation and its tolerance under conditions in everyday practice. Further, knowledge concerning the acceptance of the preparation on the market should be gained.

In accordance with the structure of the investigation, exclusively descriptive statistical procedures were used. The application of inductive methods was not indicated. An "intention to treat" evaluation was carried out, i.e. all patients, who had received at least one dose of the medicament, were considered.

2. Participating patients

75 patients participated in the study, 33 men (44%) and 42 women (56%) with ovarian cysts, hyperthyreosis and epididymitis.

The age of the patients varied between 18 and 75 years with an average of 46.2 years and a standard deviation of 14.1 years. There was 1 patient (1.3%) up to age 20, 9 patients (12%) were between 21 and 30 years, 19 patients (25.3%) between 31 and 40 years, and 21 patients (28%) between 41 and 50. 13 patients



(17.4%) were between 51 and 60 years, and 13 patients (17.4%) between 61 and 70. 5 patients (6.7%) were over 71 years old. The men with an average age of 52.7 ± 12.4 were roughly 10 years older than the women with 41.1 ± 13.3 years.

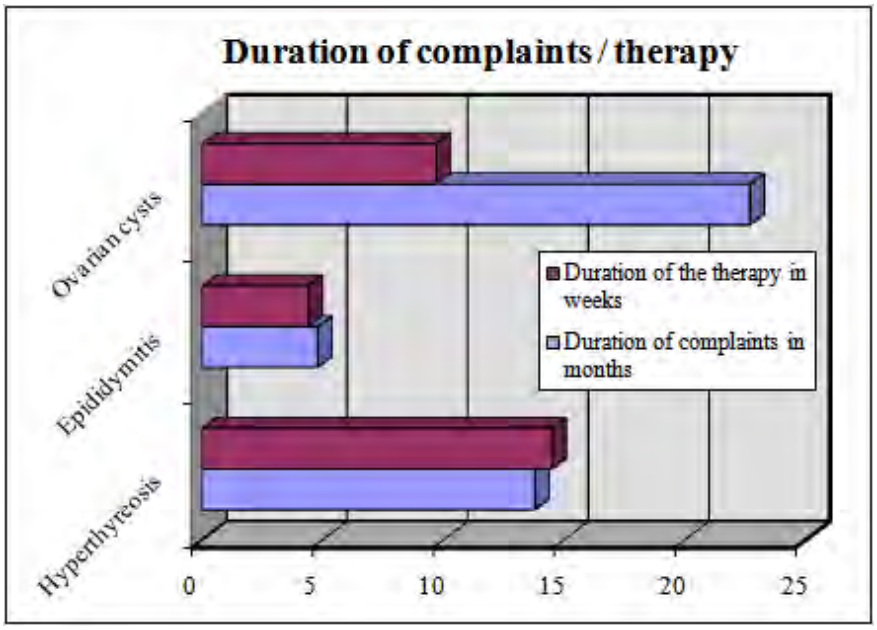
2.1 Diagnosis and accompanying diseases

According to the Study protocol, the diagnosis leading to prescription was ovarian cysts, epididymitis and hyperthyreosis for 25 patients each. Medical findings were collected before and after completion of the treatment. Accompanying therapies were to be documented in a survey form. No accompanying medication was administered with any of the 75 patients included in the study.

3. Dosage and duration of treatment

3.1 Time of consultation and duration of treatment

Corresponding to the nature of an application study, the doctor was not given a fixed schedule for the initial and final examinations. The duration of treatment was on average 8.1 weeks ± 5.5 weeks



with a minimum duration of 2 weeks and a maximum therapy duration of 6 months. All patients participated in the final examination.

Dividing the patients into the three diagnosis groups 'ovarian cysts', 'epididymitis' and 'hyperthyreosis', the longest therapy duration with 14.5 ± 6.6 weeks showed for hyperthyreosis, followed by a therapy duration of 4.4 ± 3.0 weeks for epididymitis, and a therapy duration of 9.7 ± 2.7 weeks for ovarian cysts. During anamnesis, patients were also asked for how long the complaints had been existent. Here, the indication of epididymitis showed a similar picture to its therapy duration, as it had also existed for the relatively short period of 4.8 ± 12.8 months. Hyperthyreosis had existed longer with 13.8 ± 10.6 months, and ovarian cysts had existed for an extremely long period with 22.7 ± 19.3 months.

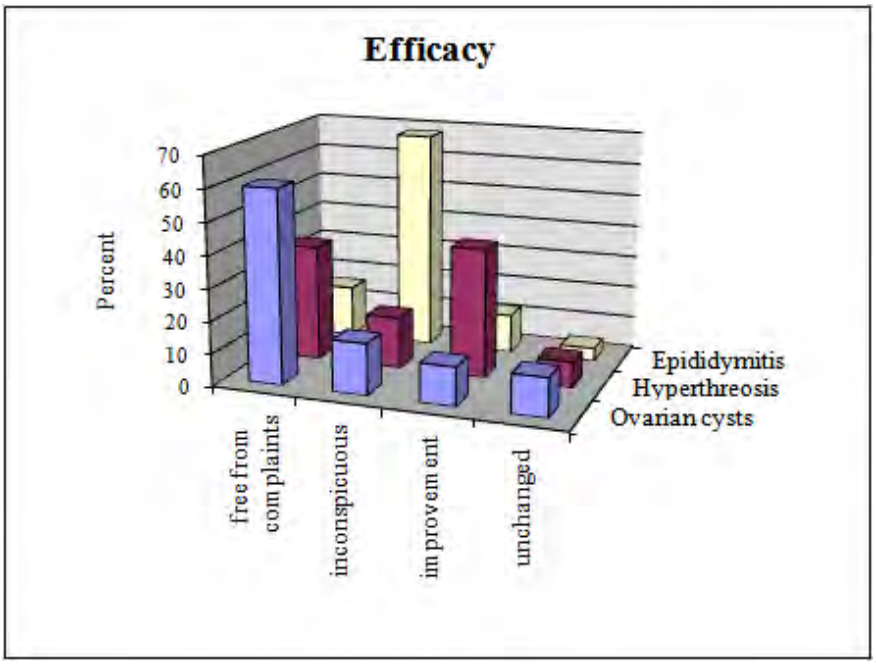
3.2 Dosage

For all patients in all three indication groups, dosage was specified with 8 drops once daily.

4. Efficacy

4.1 Ovarian cysts

Of the 25 patients with ovarian cysts who participated in the study, 22 (= 88%) had experienced improvement by the end of the treatment. 15 patients (= 60%)were reported as free from complaints, 4 patients (= 16%) as „inconspicuous“, and in 3 patients (= 12%) the cyst or number of cysts had diminished. The condition of 3 patients (= 12%) had remained unchanged.



4.2 Epididymitis

24 of the 25 patients suffering from epididymitis, who were admitted to the study, responded positively to the therapy. At the end of the therapy, 4 patients (= 16%) were free from complaints, the conditin of 17 patients (= 68%) was described as „inconspicuous“, and 3 patients (= 12%) had experienced improvement of complaints. The condition of one patient (= 4%) had remained unchanged.

4.3 Hyperthyreosis

In the 25 patients suffering from hyperthyreosis, efficacy was similar. At the end of the therapy, 23 patients (= 92%) had been treated successfully or had at least experienced improvement. 7 patients (= 28%) had experienced a clear and 3 patients (= 12%) a slight improvement. 9 patients (= 36%) were free from complaints, 4 patients (= 16%) were inconspicuous, and in two patients (= 8%), no change of the symptoms could be observed .

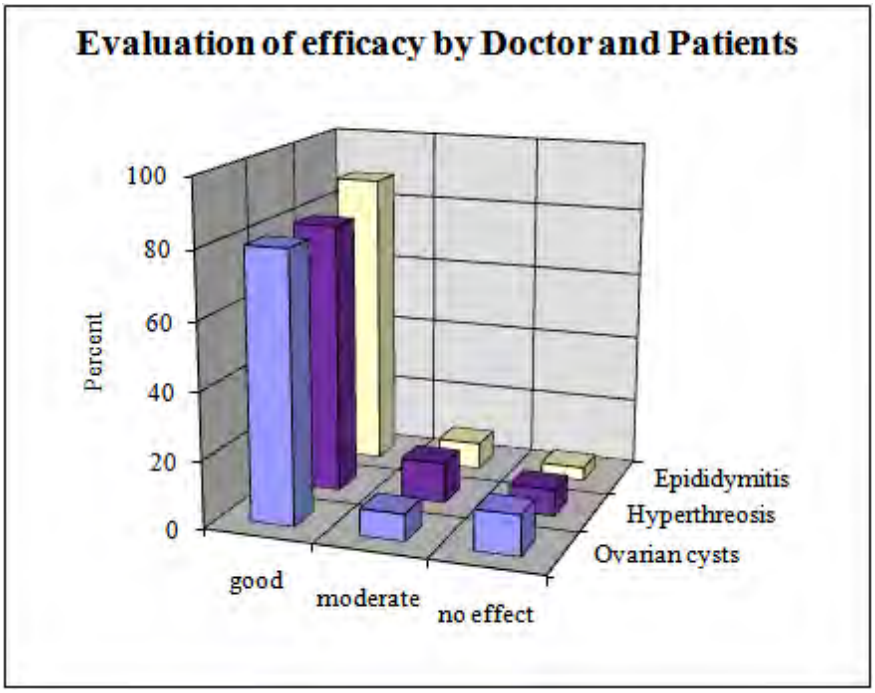
4.1 Evaluation of efficacy

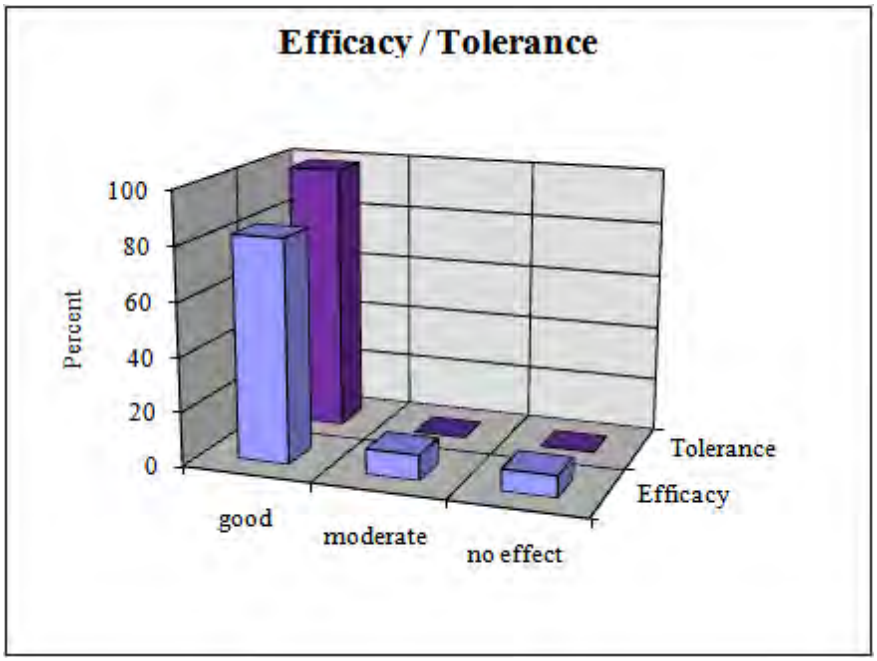
In a final assessment, doctors and patients were asked to evaluate efficacy and tolerance. Efficacy could be rated as ‘good’, ‘moderate’ or ‘no effect’. Globally, efficacy was rated as ‘good’ in 62 cases (= 82.7%), as ‘moderate’ in 7 cases (= 9.3%) and as ‘no effect’ in 6 cases (= 8%) by both doctors and patients.

No significant difference was observed within the three indications. In hyperthyreosis, doctor and patient rated efficacy as ‘good’ in 20 cases, as ‘moderate’ in 3 cases, and as ‘no effect’ in two cases. In epididymitis, ‘good’ was rated in 22 cases, ‘moderate’ in two cases, and ‘no effect’ in one case. Also in the indication group ‘ovarian cysts’, ‘good’ was rated in 20 cases, ‘moderate’ in two cases, and ‘no effect’ in 3 cases.

5. Tolerance

In the survey form, patients were required to report on possible initial





aggravation, side effects and incompatibilities. No patient experienced initial aggravation, side effects or incompatibility, even during long therapy phases of a maximum period of 12 weeks.

5.1 Evaluation of tolerance

At the end of the examination, doctor and patients evaluated tolerance, which could be rated as 'good', 'moderate' or 'no effect'. For 74 of the 75 patients admitted to the study, both doctors and patients evaluated tolerance with 'good'. For one female patient suffering from hyperthyreosis, who had evaluated efficacy with 'good', no evaluation of tolerance was available. No study was discontinued.

5. Summary

In a resident medical practice, a total of 75 patients suffering from ovarian cysts, epidydimitis and hyperthyreosis were admitted to an observation study with Nigersan D5 drops. The age of the patients varied between 18 and 75 years with an average of 46.2 years.

According to the Study protocol, the diagnosis leading to prescription was ovarian cysts, epididymitis and hyperthyreosis for 25 patients each. All 75 patients admitted to the study were treated with a monotherapy with Nigersan D5 drops. No accompanying medication was administered.

The duration of treatment was on average 8.1 ± 5.5 days with a minimum duration of 2 weeks and a maximum of 6 months.

The dosage was 8 drops daily for all patients.

Progress of the treatment was determined by means of a collection of medical findings before and after completion of the treatment. At the end of the therapy, 88% of the female patients with ovarian cysts, 96% of the patients with epididymitis and 92% of the patients with hyperthyreosis had been treated successfully. The test preparation showed no efficacy with 6 patients (= 8%) in total.

Of the 75 patients admitted to the study, 62 patients rated efficacy of the treatment as 'good', whilst 7 patients attested 'moderate' efficacy and 5 patients 'no effect' to the preparation. The doctor's opinion was identical to that of the patients.

For 74 of the 75 patients admitted to the study, both doctors and patients evaluated tolerance with 'good'. For one female patient suffering from hyperthyreosis, who had evaluated efficacy with 'good', no evaluation of tolerance was available. No study was discontinued. Initial aggravations, side effects and incompatibilities were not observed.

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