



**Statistical Evaluation of an
Application Study with the
Homeopathic Preparation
USNEABASAN**

in the administration form of drops

by Dr. Reiner Heidl

1. Introduction

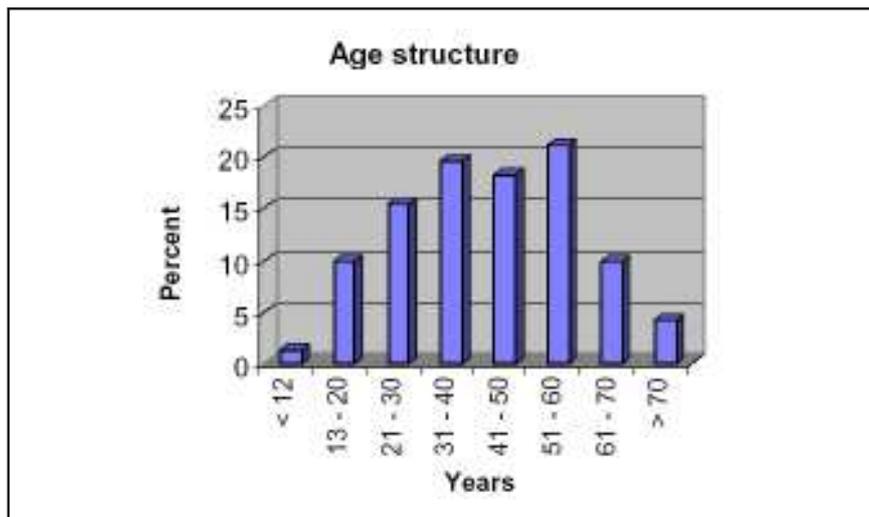
Between January 1997 and January 2011, a total number of 71 patients in a medical practices participated in an application study with the homeopathic preparation USNEABASAN. As an active ingredient, USNEABASAN drops for oral intake contain exclusively *Usnea barbata* e thallo siccato mother tincture in accordance with Prescription 4a HAB.

The aim of this application study was to determine the actual application of the preparation as well as its tolerance under the day-to-day conditions of a normal practice. It was also of importance to determine the acceptance of the preparation on the market.

In line with the study's set-up, only descriptive statistical methods were used. The application of inductive methods was not indicated. An „intention-to-treat“ evaluation was carried out, i.e. all those patients who had at least received one dose of the medicament were included in the study.

2. Participating patients

In total, 71 patients of both sexes participated in the study. 24 patients (33.8%) were male, 46 patients (64.8%) were female, and for one patient, there were no data available. The age of the patients varied between 12 and 81 years, with an average age of 42.4 ± 16.4 years. The male patients with an average age of 51.9 ± 15.4 years were on average 14 years older than the female patients with an average age of 37.4 ± 14.7 years.



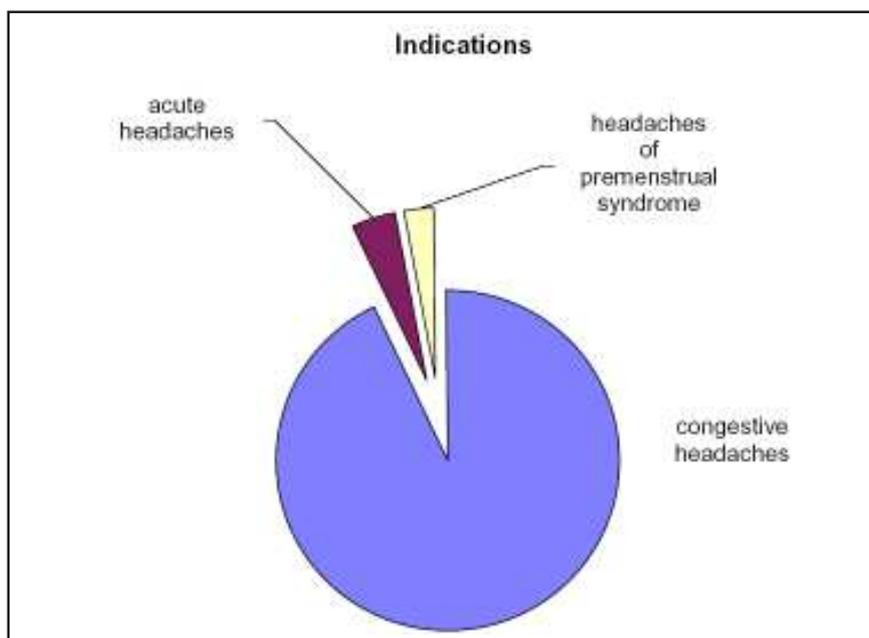
Height varied between 150 and 188 cm with an average height of 171.3 ± 6.4 cm (women: 169.4 ± 4.5 cm; men: 175.0 ± 7.8 cm).

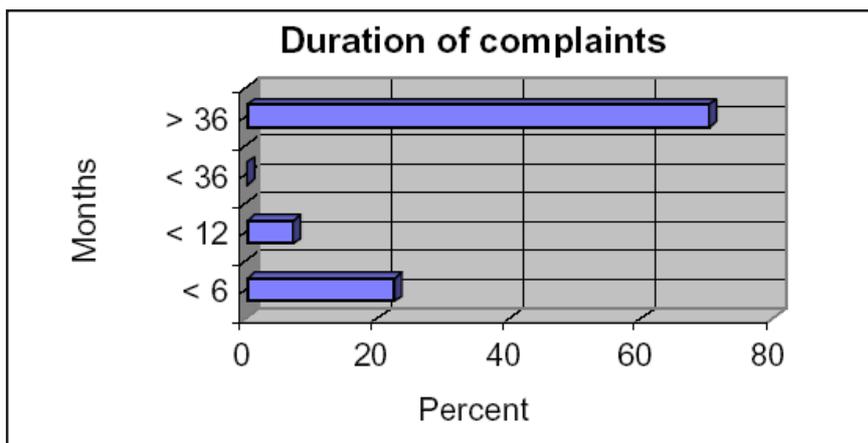
The weight was between 40 and 97 kg with an average weight of 74.4 ± 9.6 kg (women: 71.3 ± 7.0 kg; men: 80.2 ± 11.2 kg).

2.1 Diagnosis and accompanying diseases

The diagnosis leading to the prescription was to be entered in the study protocol. The diversifica-

tion of diagnoses resulted from the application area according to the homeopathic remedy picture. In homeopathy, *Usnea barbata* is used in cases of congestive headache. The symptoms also comprise reddening of the face, throbbing or a bursting sensation of the temples, in the eyes and in the back of the head. The preferred area of application in cases of congestive headache also emerged in this survey. In 93% of the cases, USNEABASAN was employed with con-



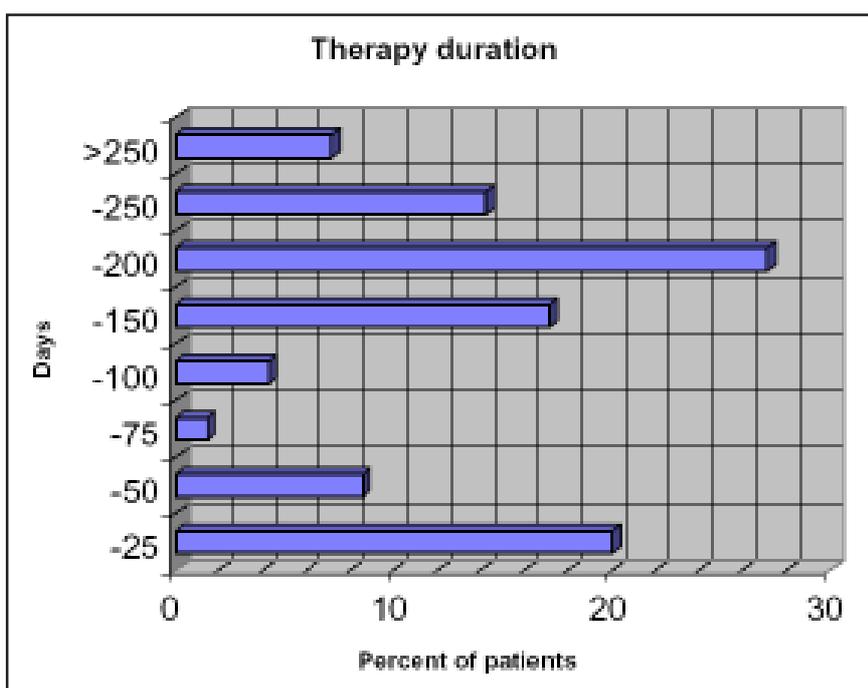


gestive headaches, in 4.2% with acute headaches, and in 2.8% with premenstrual syndrome.

In order to obtain a measure of chronic diseases, the patients were asked in the study protocol for how long they had suffered the disease or complaints. Time frames were given of less than six months, up to one year, up to three years and more than three years. 16 patients (= 22.5%) had suffered for less than six months. The patients having suffered of the complaints for more than

three years, constituted the next largest group with 50 patients (= 70.4%). 5 patients (= 7.0%) indicated a period within 6 months to 1 year. No patient stated a duration of complaints of 1 to 3 years. Accordingly, USNEABASAN was used mainly in the area of chronic complaints.

Of the 71 patients included in the study, only one 20 years old female patient had been treated with USNEABASAN before, in 1996. No complications occurred during this former therapy.



3. Dosage and duration of treatment

3.1 Time of consultation, duration of treatment

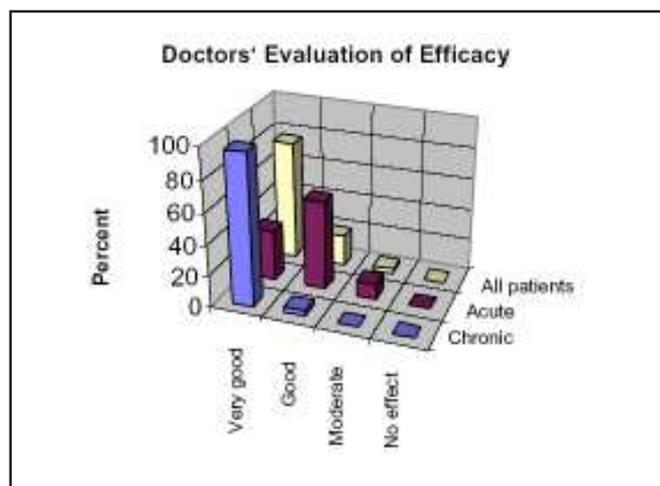
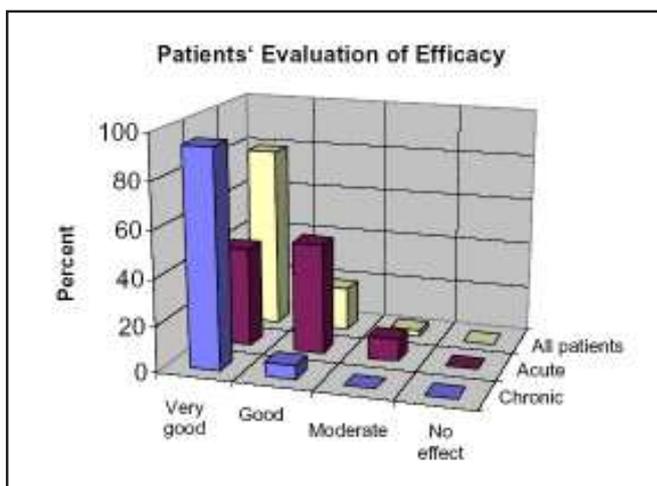
According to the nature of an application study, the physicians were not given a preset time limit for the final patient assessment. The final examinations were conducted after a period of 5 to 328 days, at an average of 129.7 ± 84.1 days.

In 20% of the cases, the therapy duration was up to 25 days. Mostly, however, the therapy lasted for more than 100 days, in 17.1% between 100 and 150 days, in 27.1% between 151 and 200 days, in 14.3% between 201 and 250 days, and in still 7.1% for more than 250 days.

The therapy duration amongst the female patients was on average 117.1 ± 87.6 days and was thus over one quarter shorter than that of the male patients with 149.4 ± 72.1 days.

A significant difference in therapy duration arose by comparison of the patients having had complaints for up to one year with the patients having suffered from headaches for more than three years. The shorter the complaints had persisted, the shorter the therapy duration. In the patient group of a duration of complaints of up to one year, the therapy duration was only 20.0 ± 12.8 days compared with the patients having had complaints for more than 3 years with an average therapy duration of 176.7 ± 51.7 days.

Evaluation of efficacy								
Patient Group	Patients' evaluation (%)				Doctors' evaluation (%)			
	Very Good	Good	Moderate	No Effect	Very Good	Good	Moderate	No Effect
All Patients	78.9	18.6	2.8	0	77.1	20.0	2.9	0
Acute	42.9	47.6	9.5	0	33.3	57.1	9.6	0
Chronic	93.9	6.1	0	0	95.9	4.1	0	0



3.1 Dosage

The dosage was set as follows, according to the patient information leaflet: in acute states: take 5 drops orally every half an hour to one hour. In chronic forms: take 5 drops orally 3x daily.

For all patients, the daily dose was on average 20.8 ± 15.0 drops. There was no difference in the dosage for females (21.0 ± 15.0 drops) and males (20.6 ± 14.9 drops). By the patients having suffered from headaches for more than 3 years, the chronic dosage of 3x 5 drops daily was adhered to exactly. In the therapy of acute states, 34.6 ± 22.1 per day drops were administered on average with a maximum daily dose of 60 drops and a minimum dose of 15 drops.

4. Efficacy and tolerance

4.1 Evaluation of Efficacy by Doctor and Patient

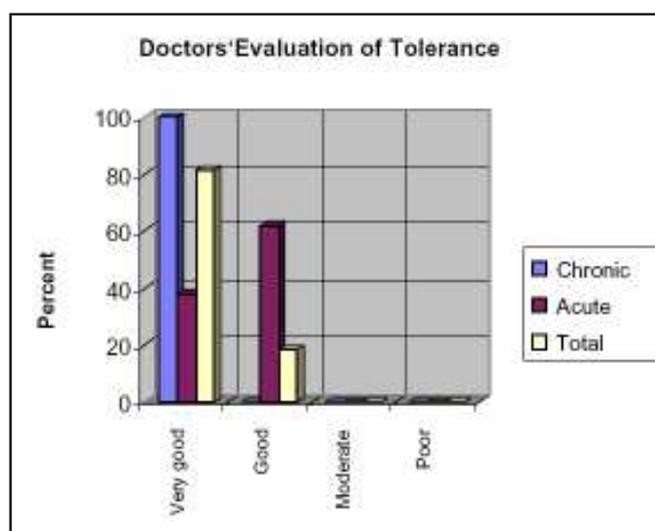
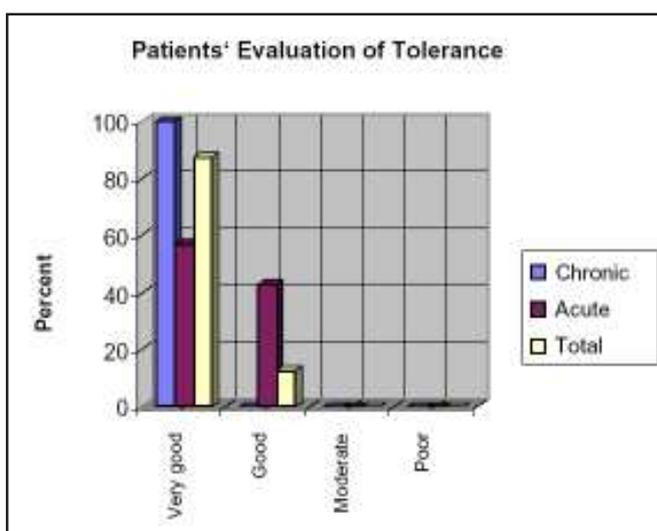
In a closing assessment, doctors and patients were asked to evaluate efficacy and tolerance. Efficacy could be assessed with „very good“, „good“, „moderate“ or „no effect“. 78.6% of the patients assessed efficacy as „very good“, 18.6% as „good“ and 2.8% as „moderate“. No patient questioned efficacy (= assessment „no effect“). The results of the doctors' evaluation of efficacy was as positive as that of the patients. Doctors rated efficacy for 77.1% of the patients as „very good“ and for 20.0% as „good“. For 2.9% of the patients, doctors considered efficacy only „moderate“. „No effect“ was also not assessed with by the doctors. There were, however, significant differences in the therapy

assessment of the acutely and the chronically ill persons. While the patients with acute complaints had a tendency to the assessment of „good“, over 90% of the chronically ill persons rated efficacy „very good“.

4.2 Evaluation of Tolerance by Doctor and Patient

At the conclusion of the study, an evaluation of tolerance was submitted by the doctors and patients, which could be assessed with „very good“, „good“, „moderate“ and „poor“. Both patients and doctors exclusively rated tolerance to be „very good“ and „good“. In total, 87.1% of the patients gave a „very good“ and 12.8% a „good“ rating. The doctors gave a „very good“ rating for 81.4% of the patients and a „good“ rating for 18.6% of the patients.

Evaluation of Tolerance								
Patient Group	Patients Opinion				Doctors Opinion			
	Very Good	Good	Moderate	Poor	Very Good	Good	Moderate	Poor
All patients	87.1	12.9	0	0	81.4	18.6	0	0
Acute	57.1	42.9	0	0	38.1	61.9	0	0
Chronic	100	0	0	0	100	0	0	0



In the patient groups „acute“ and „chronic“, a similar picture as in the assessment of efficacy emerges. Tolerance was assessed by patients as well as by doctors of the group of chronically ill persons as „very good“ at 100%. In the patient group with acute complaints, the ratings of „very good“ and „good“ were almost evenly distributed.

4.3 Side effects and discontinuation of the therapy
The therapy with USNEABA-SAN was not discontinued by any of the patients. There were no cases of side effects or adverse reactions observed.

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