



Statistical Evaluation of an Application Study with the preparation USTILAKEHL

**in the administration forms of
drops and suppositories**

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1. Introduction

From November 2002 to June 2003, a total of 71 patients was admitted to an observation study with the preparation USTILAKEHL in its administration forms of drops and suppositories in 2 medical practices (1 surgical practice, 1 ENT practice and 2 internist practices). The homeopathic test preparation USTILAKEHL consists of the 5th decimal dilution of the sprout cells of *Ustilago zeae*.

USTILAKEHL drops contain exclusively *Ustilago zeae sporibus rec. D5 dil.* in accordance with method 5a HAB.

1 USTILAKEHL suppository contains 0.2 g *Ustilago zeae sporibus rec. D5 trit.* in accordance with method 6 HAB.

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

In accordance with the structure of the study, 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 were considered, who had received at least one dose of the remedy.

2. Participating patients

Included in the study were 72 patients, which comprised of 8.3% men and 91.7% women. The age of the patients varied between 13

and 76 years with an average age of 44.6 years and a standard deviation of 13.7 years. 4.2% of the patients were between 13 and 20 years. 8.3% of the patients belonged to the age group of 21 and 30 years. The largest group of 30.6% was constituted by the 31 to 40 years olds, followed by the 51 to 60 years olds with 25.0%. The age group of 41 to 50 year olds was represented with 18.1%. 11.1% were 61 to 70 years old and over 71 years were 2.8% of the patients. With respect to the age structure, women with an average age of 44.7 ± 13.0 years were approximately the same age as men with an average age of 44.0 ± 22.3 years.

Height varied between 158 and 193 cm with an average of 169.3 ± 7.0 cm. Body weight lay between 42 and 91 kg with an average of 69.34 ± 8.0 kg

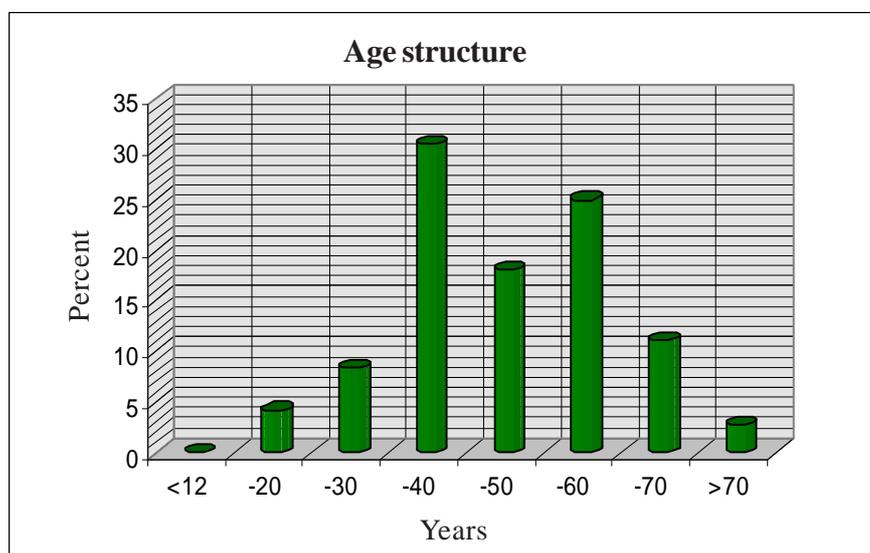
2.1 Diagnosis and accompanying diseases

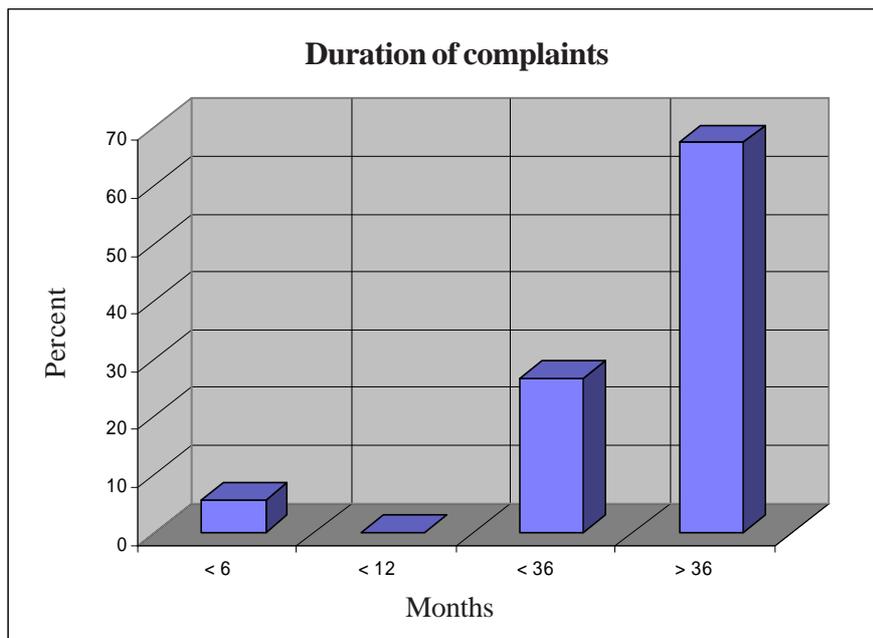
The diagnosis leading to the prescription was to be entered into the study protocol. It emerged here-with that USTILAKEHL, in accor-

dance with isopathy, is applied in a very wide area of application. Independently of the age, the preferred use was with migraine, and in women specifically with headache during menstruation, but also with climacteric syndrome and dysmenorrhoea. Collected findings were carried out each before and after completion of the treatment, and accompanying therapies were to be documented in a survey form.

In order to obtain a measurement of the chronic diseases, it was asked in the study protocol, for how long the disease or discomfort had been in existence. For this, a time grid of less than 6 months, up to 1 year, up to 3 years and over 3 years was set. For 67.6% of the patients, the complaints had existed for more than 3 years. About a quarter of the patients (26.8%) had been suffering of their discomfort for between 1 and 3 years. Only 5.6% of the patients indicated having had the symptoms for less than 6 months.

All patients included in the study were treated with Ustilakehl for the first time.





Duration of Complaints (Months)	Total Patient Population (%)
< 6	5.6
6 - 12	0
< 36	26.8
> 36	67.6

3. Dosage and duration of treatment

3.1 Time of consultation, duration of treatment

Corresponding to the nature of an application study, no rigid schedule was given to the doctors for the final examination. This final examination was carried out in a time frame between 5 and 130 days with an average of 66.3 ± 37.1 days.

3.1 Dosage

Dosage was prescribed according to the package insert for each administration form:

- USTILAKEHL drops
For oral intake: 1x 8 drops daily before mealtimes
For topical application: rub 1x 5-10 drops daily into the affected area or the crease of the elbow.
- USTILAKEHL suppositories
1x 1 suppository daily to be inserted rectally before bedtime.

As to the application forms, 35 patients were administered drops for oral intake, 8 patients drops for

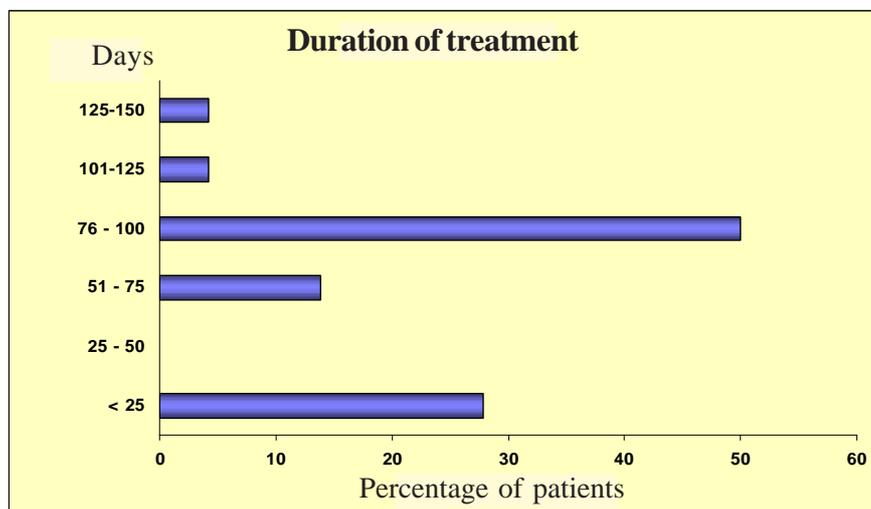
topical application, and 31 patients suppositories. Multiple entries were necessary where various administration forms were combined. The following table shows the medium daily dosage of each administration form.

In two cases of topical application of drops, the administration of 16 drops each exceeded the recommended dose. In all other cases, the dosage as recommended by the manufacturer was strictly complied with.

Beside the monotherapy using only one administration form, also a combination of both administration forms was used in the therapy. 2 patients were administered drops both for oral intake and for topical application. In 4 patients, the suppositories were combined with drops for topical application.

4 Comparison with former therapy

None of the patients had received any therapy involving one or more administration forms of USTILAKEHL in the last 5 years. Therefore, no statement with respect to multiple use of the preparation can be made.





Dosage			
	Medium Dose	Minimum Dose	Maximum Dose
Drops (oral)	8 ± 0	8	8
Drops (topical)	9.3 ± 4.7	3	16
Suppositories	1 ± 0	1	1

5 Efficacy and tolerance

5.1 Evaluation of efficacy by doctors and patients

In a final evaluation, doctors and patients were asked to evaluate efficacy and tolerance. Efficacy could be rated as 'very good', 'good', 'moderate' or 'no effect'. In addition, doctors were asked about the compliance of their patients, which could also be rated as 'very good', 'good', 'moderate' or 'poor'. Efficacy was evaluated as 'very good' by 60.6% of the patients and as 'good' by 25.4%, while 9.9% experienced a 'moderate' efficacy and 4.2% 'no effect' of the therapy. The doctors' evaluation of efficacy was as positive as that of the patients. The doctors rated efficacy as 'very good' for 64.8% of the patients, as 'good' for 21.1%, as 'moderate' for 9.9% just like the patients, and as having 'no effect' for 4.2% of the patients.

Compliance (N=69) was judged as 'very good' for 51 patients and as 'good' for 17 patients by their doctors. Thus, 'good' and 'very good' compliance, respectively, was attested to 94.4% of the patients. For 1 patient, compliance was judged as being 'moderate', and for no patient as being 'poor'.

5.2 Evaluation of tolerance by doctors and patients

To conclude the examination, an evaluation of tolerance was submitted by doctors and patients, wherein tolerance could be rated as 'very good', 'good', 'moderate' and 'poor'. 71.8% each of the patients and doctors rated tolerance as 'very good', while again 26.8% of both patients and doctors attested 'good' tolerance to Ustilakehl. 'Moderate' tolerance was stated by 1.4% each of patients and doctors.

5.3 Side effects and discontinuation of the therapy

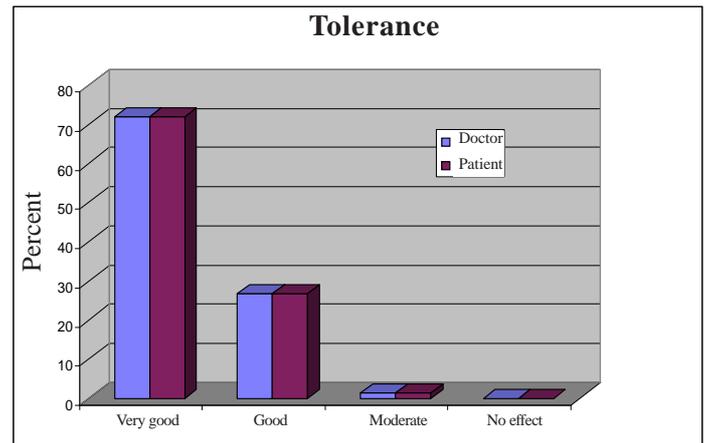
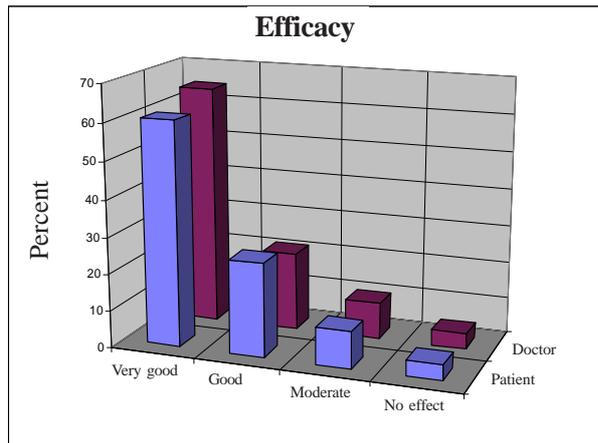
No patient discontinued the therapy with Ustilakehl. A 26 years old female patient who had orally taken drops, complained about taste impairments, which disappeared without any treatment. The same happened to a 33 years old female patient complaining about mouth dryness during the therapy. Both patients did not stop, but continued taking the test preparation. In conclusion, both patients evaluated tolerance as 'very good' and 'good', respectively.

6. Summary

From November 2002 to June 2003, a total of 71 patients was admitted to an observation study with the preparation Ustilakehl in its administration forms of drops and suppositories in 2 medical practices (1 surgical practice, 1

Evaluation of efficacy							
Patients' evaluation (%)				Doctors' evaluation (%)			
Very Good	Good	Moderate	No Effect	Very Good	Good	Moderate	No Effect
60.6	25.4	9.9	4.2	64.8	21.1	9.9	4.2

Evaluation of tolerance							
Patients' evaluation (%)				Doctors' evaluation (%)			
Very Good	Good	Moderate	Poor	Very Good	Good	Moderate	Poor
71.8	26.8	1.4	0	71.8	26.8	1.4	0



ENT practice and 2 internist practices). The homeopathic test preparation Ustilakehl consists of the 5th decimal dilution of the sprout cells of *Ustilago zae*. The age of the patients varied between 13 and 76 years. Corresponding to isopathy, Ustilakehl is applied in a very wide area of application. Independently of the age, the preferred use was with migraine, in women specifically with headache during menstruation, but also with climacteric syndrome and dysmenorrhoea.

Therapy duration was on average 66.3 ± 37.1 days. Dosage was in accordance with the information of the package insert.

Progress of the treatment was determined by means of a collection of medical findings.

86% of the patients and 85.9% of the doctors rated efficacy of the treatment as 'very good' and 'good'. Tolerance was rated as 'very good' and 'good' by 98.6% each of the patients and the doctors.

No study was discontinued. Side effects and incompatibilities were documented. All of them were fully reversible without any additional treatment.

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