



**Statistical Evaluation of an
Application Study with
SANUKEHL Staph D6 Drops**

by

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1. Introduction

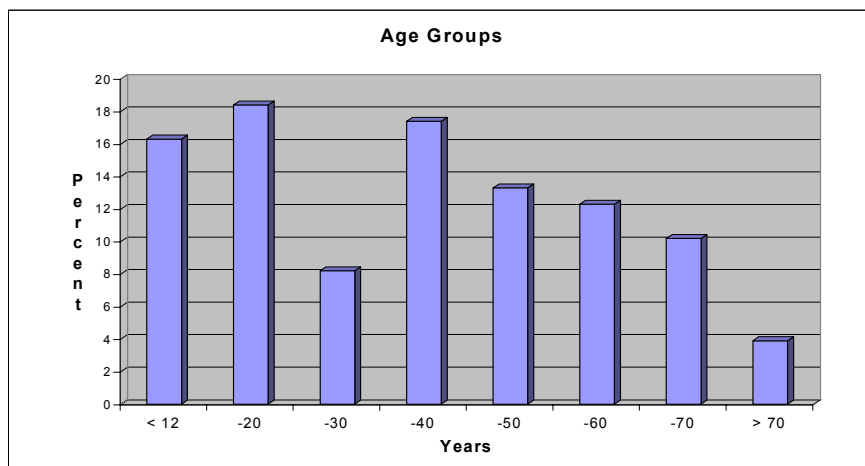
A total number of 98 patients in three medical practices, one specializing in internal medicine and two in general medicine, participated between August 1992 and May 2001 in an application study with the preparation SANUKEHL Staph D6 drops. The homoeopathic test preparation, SANUKEHL Staph, consists exclusively of *Staphylococcus aureus* e volumine cellulae in the 6th decimal potency.

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, especially amongst children.

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, which means that all those patients were included in the study who had at least received one dosage of the medicament.

2. Participating Patients

98 patients participated in the study, comprising of 44 men (44.9%) and 53 women (54.1%), the age of one patient was unknown. The age of the patients varied between 5 and 91 years, with an average age of 35.3 and a standard deviation of 21.5. Under 12 years were 16.3% of the patients. The largest group were patients between 12 and 20 (18.4%); between 21 and 30 years were only 8.2%. The second largest group were patients between 31 and 40 years (17.4%). The age groups



between 41 and 50 (13.3%), between 51 and 60 (12.3%) and between 61 and 70 years (10.2%) were nearly of the same size. Only 3.9% of the patients were over 70. In the age structure, the men with an average age of 37.9 ± 23.0 were on average 4 years older than the women with 33.2 ± 20.0 years.

Height varied between 110 and 180 cm, with an average height of $158.5 \text{ cm} \pm 19.0 \text{ cm}$. Weight varied between 14 and 99 kg with an average weight of $60.4 \text{ kg} \pm 22.1 \text{ kg}$.

2.1 Diagnoses and Secondary Diseases

The diagnoses leading to the prescription had to be entered in the study protocol. It showed that SANUKEHL Staph, according to Isopathy, is used in a very wide applicational range. The preferred application was independent of the patient's age. The main indications were Angina tonsillaris, Otitis media, sinusitis as well as recurrent infections of the urinary tract and enteritis. A thorough diagnosis was made before the start and end of the therapy and accompanying therapies were to be documented in the evaluation form.

In order to obtain a measure for chronic diseases, the patients were asked in the study protocol how long

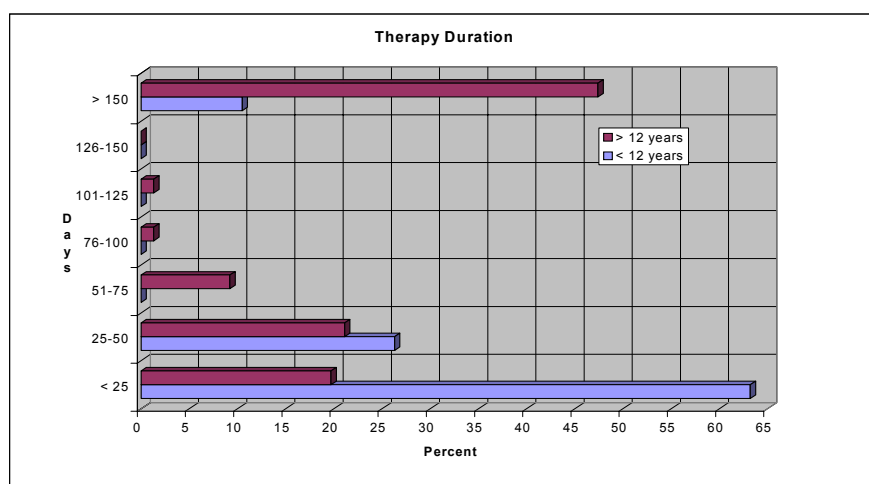
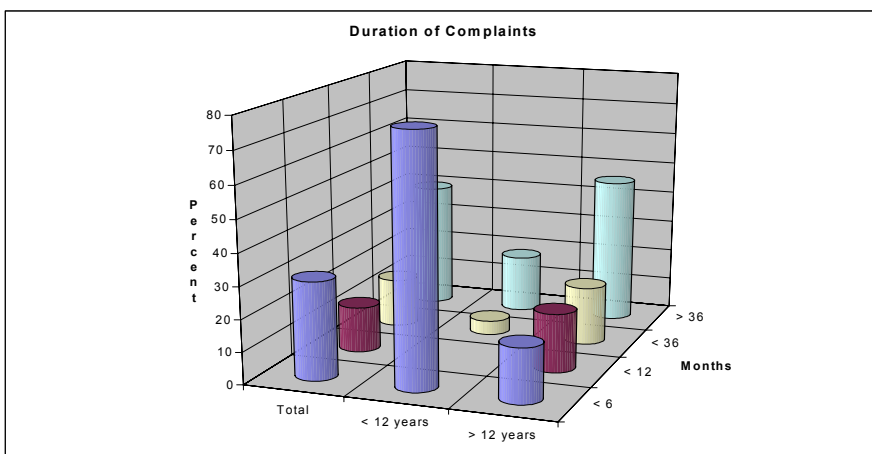
they have endured the disease or complaints. Time-frames were given of less than six months, up to one year, up to three years and more than three years. 30.6% of the patients had suffered complaints for less than six months, two groups of approximately the same size with 14.3% and 15.3% between six and 12 months and one and three years respectively. 39.8% suffered more than 36 months. The existence of the complaints was shifted more in the direction of acute conditions in the under 12 patients. 77.3% of these patients suffered for less than six months and only 18.2% for a period of over three years. In the adult group of patients over the age of 12, the proportion of patients with a period of complaints over 36 months was especially pronounced at 46.1%. Only 17.1% suffered from acute complaints with a duration of up to six months, whilst the share of patients with complaints of between six and 12 months and one and three years was the same with 18.4%. All 98 patients included in the study had been treated with Sanukehl Staph D6 drops for the first time.

3. Dosage

3.1 Consultation Times, Therapy Duration

According to the nature of an application study, the physician was not given a preset time-limit for the final patient assessment. This final

| Duration of complaints (months) | Total patient population (%) | Patients < 12 years (%) | Patients > 12 years (%) |
|---------------------------------|------------------------------|-------------------------|-------------------------|
| < 6 | 30.6 | 77.3 | 17.1 |
| <12 | 14.3 | 0 | 18.4 |
| < 36 | 15.3 | 4.5 | 18.4 |
| > 36 | 39.8 | 18.2 | 46.1 |



examination was conducted after a period of 11 to 396 days, with an average value of 160.1 days \pm 157.2 days.

Amongst the children (< 12 years) the therapy lasted 58.5 days \pm 105.6 days, approx. two thirds shorter than in the adult group with 186.4 days \pm 157.3 days. The scattering range in the group under 12 years was caused by two patients with 365 and 366 days respectively. If the two 'fugitives' were to be ignored, this would make a compact result of 22.4 \pm 8.7 therapy days. The differentiated evaluation within specific therapy

periods allows for a clear picture. It reveals that among the age group of the children below 12 years, the primary therapy duration up to 25 days (63.2 % of all patients) was clearly in the foreground. Amongst the adults, the largest groups were those with 47.4% with more than 150 therapy days and 21.1% with a therapy duration between 25 and 50 days.

3.2 Dosage

The dosage was set as follows, according to the patient package insert:

Oral application: for acute conditions: 5–10 drops (every 12 to 24 hours); for chronic conditions: 10 drops every second day.

External application: Every 1 - 2 days, 5 - 10 drops on the affected area or in the cubital fossa. After eight weeks, the therapy should be discontinued for several months.

58 patients took the drops orally and 58 externally. Multiple counts were necessary as 18 patients took the drops orally as well as externally. The medium dosage based on the form of application is shown in the following table. The drops are based on the daily oral and external application.

The recommended dosages were taken. In the group of patients under the age of 12, the drops for oral and external application were dosed according to age. The medium dosage for external application in monotherapy was almost twice as large as in the combination therapy.

4. Comparison to Previous Therapy

All 98 patients included in this study had not previously been treated with SANUKEHL Staph D6 drops. For this reason a comparison between first and repeated application was not possible. By a comparison of efficacy and tolerance in both patient groups of first-time application users and repeated application users it would have been possible to evaluate a possible sensitisation towards the active ingredient.

5. Evaluation of Efficacy

5.1 Evaluation of Efficacy by Physician and Patient

In a closing assessment, physicians and patients were asked to evaluate efficacy and tolerance. Efficacy could be assessed with „very good“, „good“, „moderate“ or „no effect“.



| Total population | | | |
|--------------------------------|--------------|--------------|--------------|
| | average dose | minimum dose | maximum dose |
| Drops for oral intake | 13.7 ± 6.2 | 6 | 20 |
| Drops for external application | 8.8 ± 2.2 | 4 | 10 |

| All Patients under 12 years | | | |
|--------------------------------|--------------|--------------|--------------|
| | average dose | minimum dose | maximum dose |
| Drops for oral intake | 7.9 ± 1.7 | 6 | 10 |
| Drops for external application | 6.0 ± 2.2 | 4 | 10 |

| All Patients over 12 years | | | |
|--------------------------------|--------------|--------------|--------------|
| | average dose | minimum dose | maximum dose |
| Drops for oral intake | 16.7 ± 5.5 | 6 | 20 |
| Drops for external application | 9.2 ± 1.8 | 5 | 10 |

The physicians were also requested to evaluate patient compliance as above with „very good“, „good“, „moderate“ or „non-compliant“. The evaluation of efficacy showed that 42.3% of the patients thought efficacy to be „very good“ and 44.3% „good“, whilst only 10.3% assessed the evaluation with „moderate“ and 3.1% stated „no effect“. The results of the physicians' evaluation for efficacy was similarly positive as that of the patients. The physicians evaluated efficacy in 48.5% of the cases as „very good“, 40.2% as „good“, 10.3% as moderate and 1.0% as „no effect“. The evaluation by physicians and patients alike was according to tendency better in the adult's group. However, in the children's group the

assessments were exclusively „very good“ and „good“.

Compliance (N = 97) was assessed by the physicians to be „very good“ for 45 patients and „good“ for 37 patients, hence 83.7% of all patients participating in the study were given a „good“ or „very good“ compliance rating. 15 patients were given a „moderate“ compliance rating and no patients were evaluated as „non-compliant“.

5.2 Evaluation of Tolerance by Physician and Patient

An evaluation of tolerance was submitted by the physicians and patients at the conclusion of the study, whereby an assessment of „very good“, „good“, „moderate“

and „non-compliant“ could be chosen. 62.9% of patients and 59.8% of physicians rated the tolerance to be „very good“, whilst 33.0% of patients and 39.2% of physicians gave SANUKEHL Staph a „good“ tolerance rating. 4.1% of the patients and 1.0% of the physicians rated it „moderate“. No case was assessed as „no effect“ with the patients and physicians alike.

In the children's group under 12 years, the patients rated the tolerance with „very good“ and „good“ and was a little better than that of the age group over 12 years. In the younger age group, the assessment shifted a little more from „good“ to „very good“, and additionally in this age group no case was assessed with „moderate“ and „no effect“.

5.3 Side Effects and Termination of Therapy

No patient discontinued the therapy with SANUKEHL Staph and no side effects were reported.

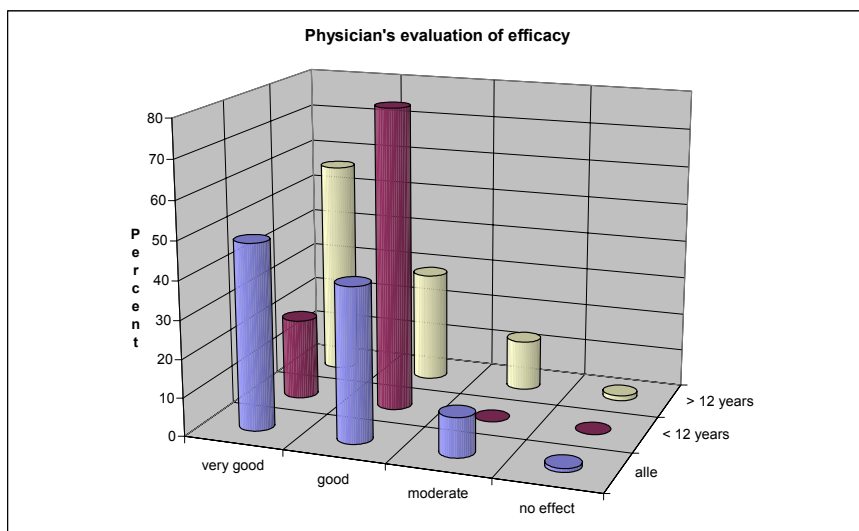
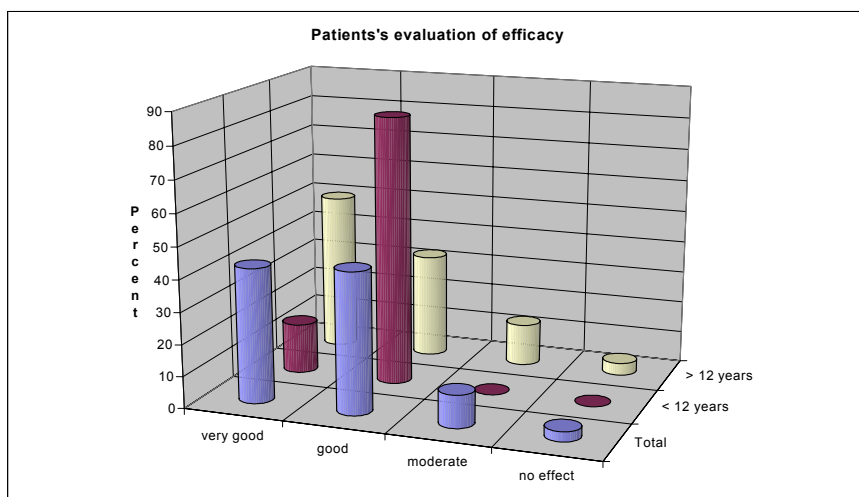
6. Summary

A total number of 98 patients in three medical practices, one specialising in internal medicine and two in general medicine, participated between August 1992 and February 2001 in an application study with the preparation SANUKEHL Staph D6 drops.

The homoeopathic test preparation, SANUKEHL Staph, consists

| Monotherapy / combination therapy (total population) | | | | |
|--|--------------|--------------|--------------|---------------|
| | average dose | minimum dose | maximum dose | |
| Drops for oral intake | 13.1 ± 6.3 | 6 | 20 | monotherapy |
| Drops for oral intake | 15.0 ± 5.7 | 6 | 20 | comb. therapy |
| Drops for external application | 10.0 ± 0.3 | 8 | 10 | monotherapy |
| Drops for external application | 6.1 ± 2.1 | 4 | 10 | comb. therapy |

| Evaluation of efficacy | | | | | | | | |
|------------------------|--------------------------|----------|--------------|---------------|----------------------------|----------|--------------|---------------|
| Patients group | Patient's evaluation [%] | | | | Physician's evaluation [%] | | | |
| | very good (%) | good (%) | moderate (%) | no effect (%) | very good (%) | good (%) | moderate (%) | no effect (%) |
| All patients | 42.3 | 44.3 | 10.3 | 3.1 | 48.5 | 40.2 | 10.3 | 1.0 |
| < 12 years | 15.8 | 84.2 | 0 | 0 | 21.1 | 78.9 | 0 | 0 |
| > 12 years | 50.0 | 32.9 | 13.2 | 3.9 | 56.6 | 28.9 | 13.2 | 1.3 |



exclusively of *Staphylococcus aureus* e volumine cellulae in the 6th decimal potency. SANUKEHL Staph was used in a very broad application range in accordance with Isopathy, whereby the preferred application was independent of the patients' age. The main indications were Angina tonsillaris, Otitis media, sinusitis as well as recurrent infects of the urinary tract and enteritis. A thorough diagnosis was made before the start and end of the therapy and accompanying

therapies were to be documented in the evaluation form.

Amongst the children (< 12 years) the therapy lasted with 58.5 days ± 105.6 days, approx. two thirds shorter than in the adult group with 186.4 days ± 157.3 days. The differentiated evaluation within specific therapy periods allows

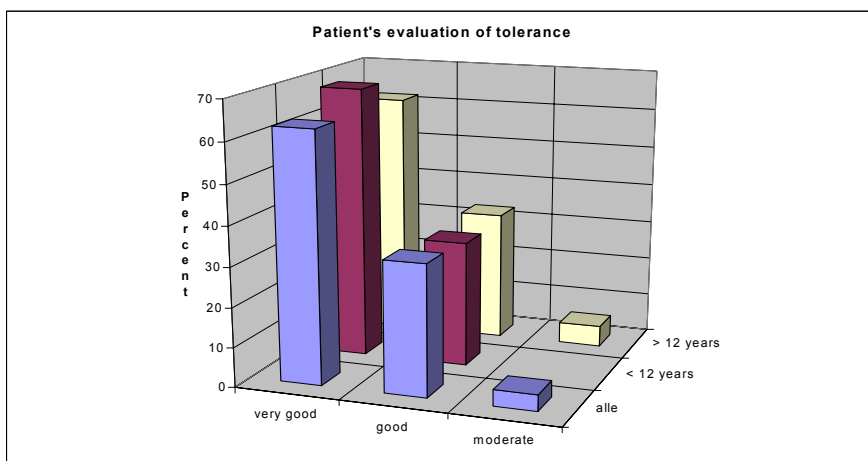
for a clear picture. It reveals that among the children under 12 years, the primary therapy duration lasted up to 25 days (63.2% of all patients). Amongst the adults were the largest groups with 47.4% of the patients with more than 150 therapy days and 21.1% with a therapy duration between 25 and 50 days.

58 patients took the drops orally and 58 patients were treated externally. Multiple counts were necessary as 18 patients took the drops orally as well as externally. The recommended dosage was taken. In the group of patients under 12 years, the drops for oral and external application were dosed according to age. In monotherapy the medium dosage for external application was almost twice as large as in the combination therapy. In the combination therapy the dosage of the drops was even higher than in the monotherapy.

All 98 patients included in this study had not previously been treated with SANUKEHL Staph D6 drops. For this reason a comparison between first and repeated application was not possible.

The therapeutic progress was determined by evaluations conducted respectively at the beginning and the end of the therapy. 86.6% of the patients and 88.7% of the physicians rated the efficacy of the therapy as „very good“ and „good“. The evaluation by physician and patient

| Evaluation of tolerance | | | | | | | | |
|-------------------------|--------------------------|----------|--------------|---------------|----------------------------|----------|--------------|---------------|
| Patients group | Patient's evaluation [%] | | | | Physician's evaluation [%] | | | |
| | very good (%) | good (%) | moderate (%) | no effect (%) | very good (%) | good (%) | moderate (%) | no effect (%) |
| All patients | 62.9 | 33.0 | 4.1 | 0 | 59.8 | 39.2 | 1.0 | 0 |
| < 12 years | 68.4 | 31.6 | 0 | 0 | 63.2 | 36.8 | 0 | 0 |
| > 12 years | 61.8 | 32.9 | 5.3 | 0 | 59.2 | 39.5 | 1.3 | 0 |



was better in the adult's group, whilst the children's group was evaluated exclusively with „very good“ and „good“. For 83.7% of all patients participating in the study, compliance was certified to be „good“ or „very good“.

62.9% of patients and 59.8% of physicians rated the tolerance to be „very good“, whilst 33.0% of patients and 39.2% of physicians gave SANUKEHL Staph a „good“ tolerance rating. 4.1% of the patients and 1.0% of the physicians rated it „moderate“. No case was assessed as „no effect“ with patients and physicians alike.

No therapy was discontinued and no side effects occurred.

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