Statistical Evaluation of an Application Study with SANUKEHL Strep D6 Drops

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1. Introduction

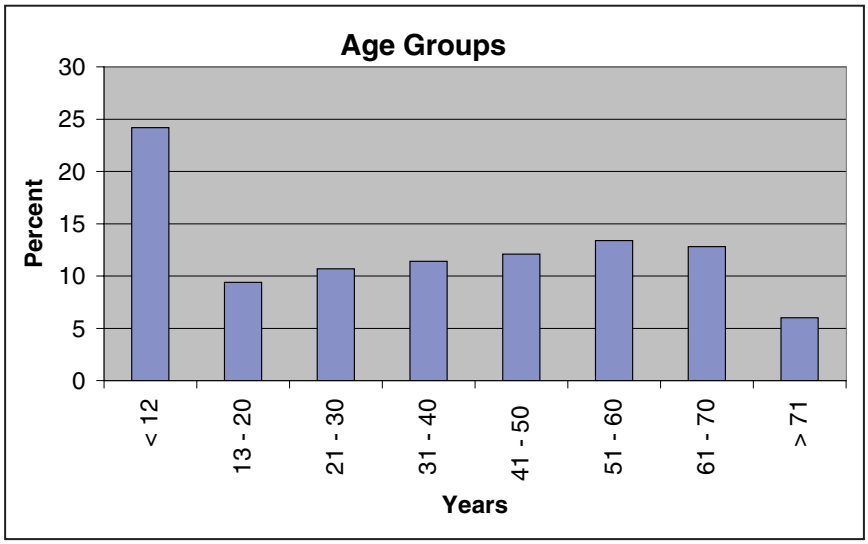
A total number of 150 patients in three medical practices, two specialising in general medicine and one in internal medicine, participated between June 1992 and May 2001 in an application study with the preparation SANUKEHL Strep D6 drops. The homoeopathic test preparation, SANUKEHL Strep, consists exclusively of Streptococcus pyogenes 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

150 patients participated in the study, comprising of 50 men (33.3%) and 100 women (66.6%). The age of the patients varied between 4 and 82 years, with an average age of 36.5 and a standard deviation of 22.2. The largest group comprised



of patients under 12 years (24.2%), all other groups between 13 and 20 (9.4%), between 21 and 30 (10.7%), between 31 and 40 (11.4%), between 41 and 50 (12.1%), between 51 and 60 (13.4%) and between 61 and 70 (12.8%) were almost of the same size. 6.0% of the patients were aged over 70. In the age structure, the men with an average age of 42.2 ± 21.4 were on average 9 years older than the women with 33.6 ± 22.0 years.

Height varied between 102 cm and 197 cm, with an average of 162.2 cm ± 16.7 cm. Weight varied between 15 kg and 115 kg with an average of 63.8 kg ± 19.8 kg.

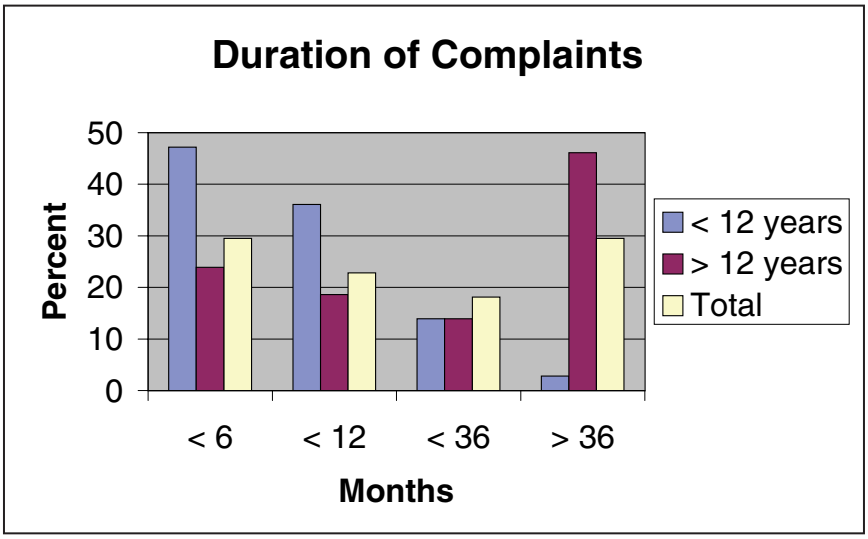
2.1 Diagnoses and Secondary Diseases

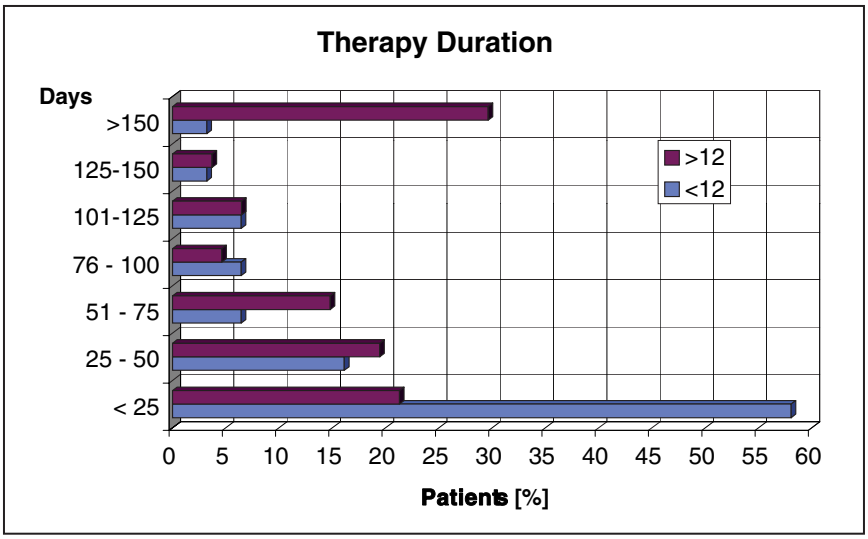
The diagnoses leading to the prescription had to be entered in the study protocol. It showed that SANUKEHL Strep, according to Isopathy, is used in a very wide applicational range. The preferred application was independent of the patient's age. The main indications were Angina tonsillaris, Otitis media and sinubronchitis as well as in addition arthritis and functional hear complaints in the adult groups. 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.

The application with acute indications was also reflected in the duration of complaints. The under 12 patients had suffered complaints for

Duration of Complaints (Months)	Patient < 12 years (%)	Patients > 12 Years (%)	Total Patient Population (%)
< 6	47,2	23,9	29,5
< 12	36,1	18,6	22,8
< 36	13,9	13,9	18,1
> 36	2,8	46,1	29,5





less than six months and represent the main part with 47.2%, followed by 36.1% of the patients who had suffered complaints between six and 12 months and 2.8% for more than 36 months. In the adult group of patients chronic complaints were in the foreground with 38.1%. 23.9% had suffered for less than 6 months, 18.6% between 6 and 12 months and 13.9% between one and three years. 5 of the 150 patients included in the study had been treated before with Sanukehl Strep D6 drops.

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 examination was conducted after a period of 7 to 1133 days, with an average value of 115.6 days ± 147.8 days.

Amongst the children (< 12 years) the therapy lasted with 50.7 days ± 90.6 days approx. one half shorter than in the adult group with 134.1 days ±155.5 days. The differentiated evaluation within specific therapy periods allows for a clear picture. It reveals that among the age group of the children under 12 years, the therapy duration of up to 25 days stood clearly in the foreground (58.1% of all patients). Amongst the adults, the largest groups with 29.6% was the one with more than 150 therapy days and 21.3% with a therapy duration of up to 25 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.

109 patients took the drops orally and 80 externally. Multiple counts were necessary as 39 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 children's as well as in

Total population

Total Population			
	Average Dose	Minimum Dose	Maximum Dose
Drops for oral intake	13.6 ± 5.9	4	30
Drops for extemal application	8.0 ± 2.9	2	15

All Patients under 12 years			
	Average Dose	Minimum Dose	Maximum Dose
Drops for oral intake	12.9 ± 5.9	4	30
Drops for extemal application	6.3 ± 2.5	3	10

All Patients over 12 years			
	Average Dose	Minimum Dose	Maximum Dose
Drops for oral intake	13.9 ± 5.9	5	24
Drops for extemal application	8.6 ± 2.7	2	15

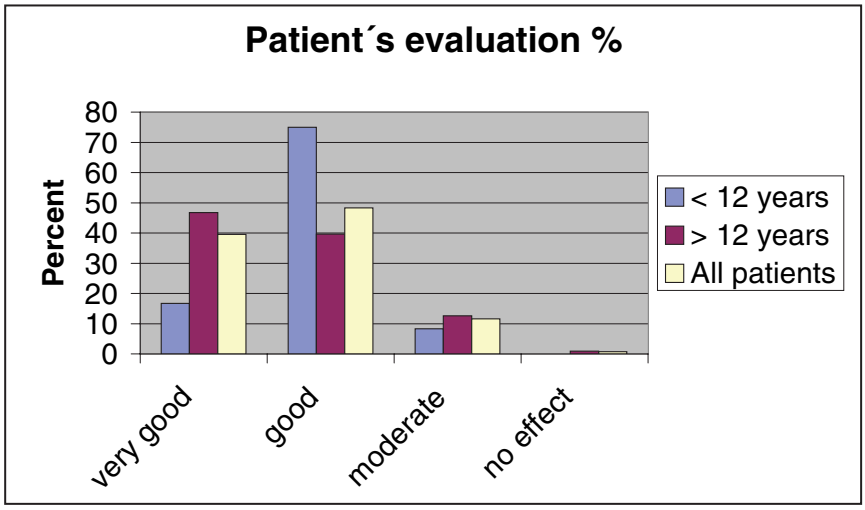
Monotherapy / combination therapy (total population)			
	Average Dose	**Minimum Dose**	**Maximum Dose**
Drops for oral intake	13.8 ± 6.4	4	30 monotherapy
Drops for oral intake	13.3 ± 4.9	5	20 comb.therapy
Drops for external application	10.0 ± 0.4	8	12 monotherapy
Drops for external application	5.9 ± 2.8	2	15 comb.therapy

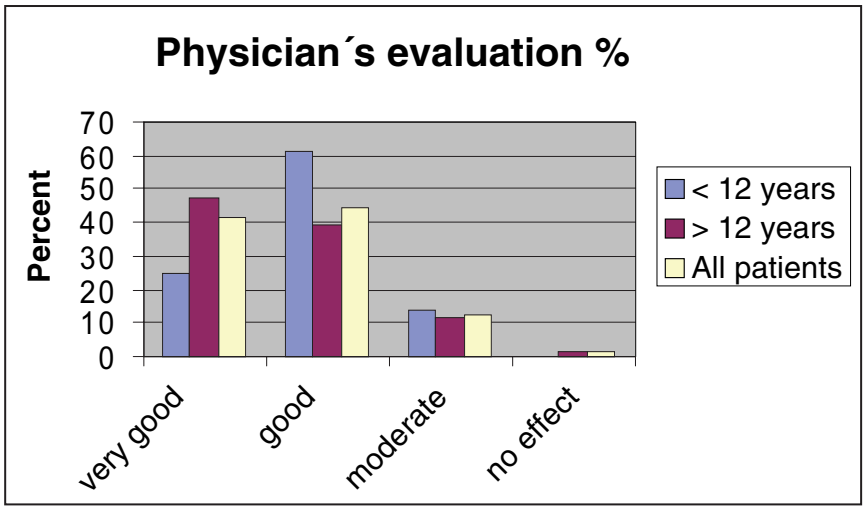
the adult group, the dosage was almost the same. The medium dosage was the same in monotherapy and in the combination therapy. The dosage of external application in the combination therapy was nearly one half lower than that used in monotherapy.

4. Comparison to Previous Therapy

5 adults were treated with SANUKEHL Strep D6 drops during the last five years. This group is too small to make a comparison between first and repeated application. 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. However, it is remarkable that patients as well as physicians evaluated tole-

Evaluation of efficacy								
Patient Group	Patient´s evaluation %				Physician´s evaluation %			
	Very good (%)	Good (%)	Moderate (%)	No Effect (%)	Very good (%)	Good (%)	Moderate (%)	No Effect (%)
All Patients	39.5	48.3	11.6	0.7	41.9	44.6	12.2	1.4
< 12 Years	16.7	75.0	8.3	0	25.0	61.1	13.9	0
> 12 Years	46.8	39.6	12.6	09	47.3	39.3	11.6	1.8





rance with repeated application users to be “very good“ and “good“.

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“. Additionally the physicians were requested to evaluate patient compliance with “very good“, “good“, “moderate“ or “non-compliant“. The evaluation of efficacy showed that 39.5% of the patients thought efficacy to be “very good“ and 48.3% “good“, whilst only 11.6% assessed the evaluation with “moderate“ and 0.7% stated “no effect“.

The results of the physicians’ evaluation for efficacy were similarly positive as those of the patients. The physicians evaluated efficacy in 41.9% of the cases as “very good“, 44.6% as “good“, 12.2% as moderate and 1.4% as “no effect“.

The evaluation by physicians and patients alike was according to tendency better in the adult’s group, as here the assessment shifted from “good“ to very good“ compared with the children’s group.

Compliance (N = 145) was assessed by the physicians to be “very good“ for 91 patients, “good“ for 41 patients and 13 patients with moderate, hence 88% of all patients participating in the study were given a “good“ or “very good“ compliance rating. No patient was given a “non-compliant“ rating.

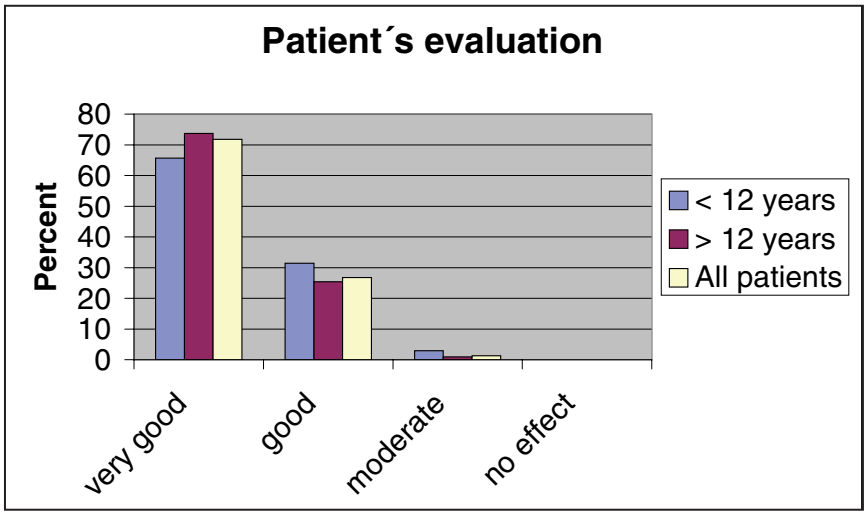
5.2 Evaluation of Tolerance by Physician and Patient

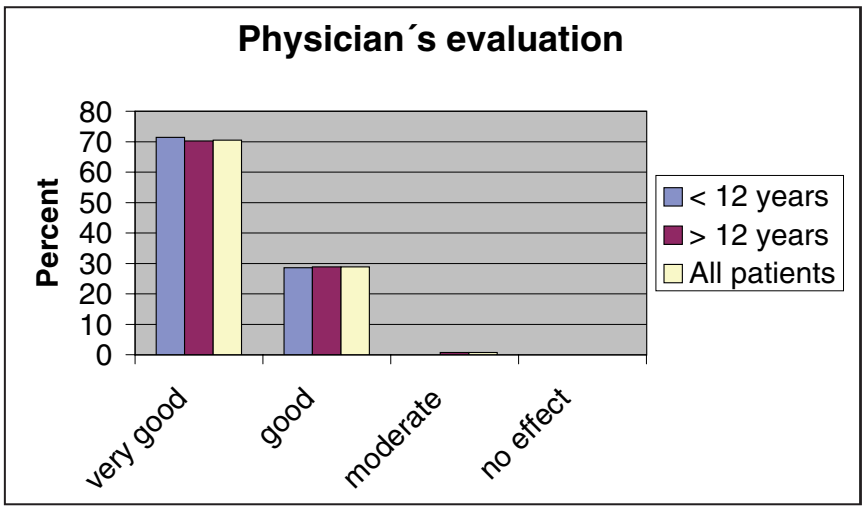
An evaluation of tolerance was submitted by the physicians and patients at the conclusion of the study, whereby an assessment of “very good“, “good“, “moderate“ and “no effect“ could be chosen. 71.8% of patients and 70.5% of physicians rated the tolerance to be “very good“, whilst 26.8% of patients and 28.9% of physicians

Evaluation of Tolerance								
Patient Group	**Patient´s evaluation %**				**Physician´s evaluation %**			
	Very good (%)	**Good (%)**	**Moderate (%)**	**No Effect (%)**	**Very good (%)**	**Good (%)**	**Moderate (%)**	**No Effect (%)**
All Patients	71.8	26.8	1.3	0	70.5	28.9	0.7	0
< 12 Years	65.7	31.4	2.9	0	71.4	28.6	0	0
> 12 Years	73.7	25.4	0.9	0	70.2	28.9	0.7	0

gave SANUKEHL Staph a "good" tolerance rating. 1.3% of the patients and 0.7% of the physicians rated it "moderate". No case was assessed as "no effect".

In the children's group over 12 years, the patients rated the tolerance with "very good" and "good", a little better than that of the age group under 12 years. In the younger age group, the assessment shifted from "very good" to "good". The physicians' rating was the same in both age groups.





5.3 Side Effects and Termination of Therapy

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

6. Summary

A total number of 150 patients in three medical practices, one specialising in internal medicine and two in general medicine, participated between June 1992 and May 2001 in an application study with the preparation SANUKEHL Strep D6 drops.

The homoeopathic test preparation, SANUKEHL Strep, consists exclusively of Streptococcus pyogenes e volumine cellulae in the 6th decimal potency. SANUKEHL Strep was used in a very broad application range in accordance with Isopathy, whereby the preferred application was independent of the patient's age. The main indications were Angina tonsillaris, Otitis media and sinubronchitis as well as in addition arthritis and functional heart complaints in the adult groups. Accompanying therapies were to be documented in the evaluation form.

Among children (<12 years) the therapy lasted with 50.7 days ± 90.6 days approx. one half shorter than in the adult group with 134.1 days ±155.5 days. The differentiated evaluation within specific therapy periods allows for a clear picture. It

reveals that among the age group of the children under 12 years, the therapy duration of up to 25 days stood clearly in the foreground (58.1% of all patients). Among the adults, the largest groups with 29.6% was the one with more than 150 therapy days and 21.3% with a therapy duration of up to 25 days.

109 patients took the drops orally and 80 patients took them externally. Multiple counts were necessary as 39 patients took the drops orally as well as externally. 5 adults were treated with SANUKEHL Strep D6 drops during the last five years. This group is too small to make a comparison between first and repeated application.

The therapeutic progress was determined by evaluations conducted respectively at the beginning and the end of the therapy. 87.8% of the patients and 86.5% of the physicians rated the efficacy of the therapy as “very good“ and “good“. The evaluation by physicians and patients alike was according to tendency better in the adult’s group, as here the assessment shifted from “good“ to very good“ compared with the children’s group. For 88% of all patients participating in the study, compliance was certified to be “good“ or “very good“.

71.8% of patients and 70.5% of physicians rated the tolerance to be “very good“, whilst 26.8% of patients and 28.9% of physicians gave SANUKEHL Strep D6 a “good“ tolerance rating. 1.3% of the patients and 0.7% of the physicians rated it “moderate“. No case was assessed as “no effect“. No therapy was discontinued and no side effects occurred. □