Statistical Evaluation of an Application Study with

SANUKEHL Pseu D6 Drops

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Introduction

A total number of 168 patients in four medical practices, one specializing in internal medicine, one in surgery and two in general medicine, participated between May 1991 and May 2001 in an application study with the preparation SANUKEHL Pseu D6 drops. The homoeopathic test preparation, SANUKEHL Pseu, consists exclusively of pseudomonas aeruginosa in the 6th decimal potency.

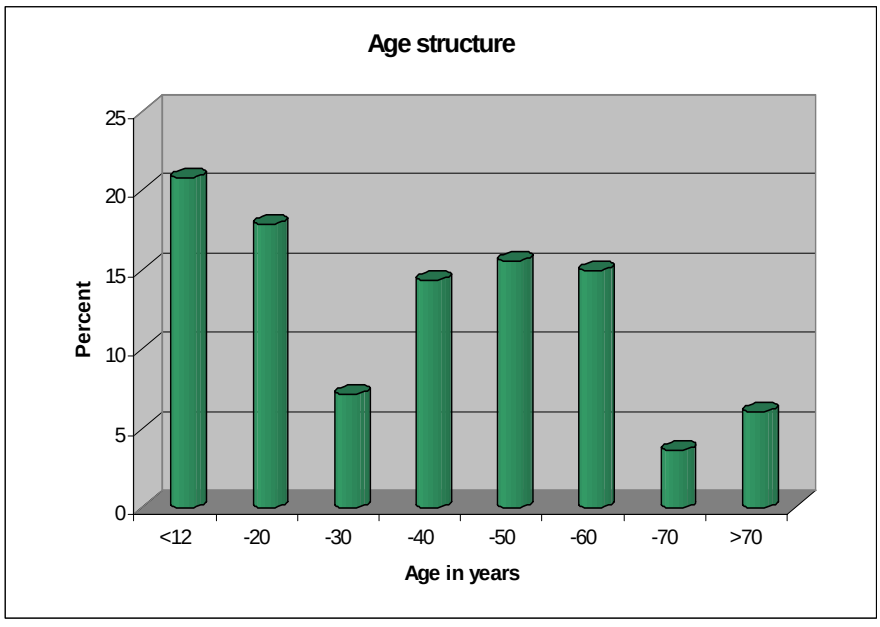
The aim of this application study was to determine the actual application of the preparation as well as its tolerance under the day to day conditions of a normal practice. Furthermore it was also of importance to determine the acceptance of the preparation on the market, especially among children.

In line with the study's set-up, only descriptive statistical methods were used. 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.

Participating Patients

168 patients participated in the study, comprising of 67 men (39.9 %) and 101 women (60.1 %). The age of the patients varied between 5 and 92 years of age, with an average age of 34.8 years and a standard deviation of 20.4 years. The two largest groups comprised of patients under 12 years (20.8 %) and between 13 and 20 years (17.9 %). Only 7.1 % of all patients were aged between 21 and 30 years, followed by the three age groups of 31 to 40, 41 to 50 and 51 to 60, which were almost equally represented at 14.3 %, 15.5 % and 14.9 %. 3.6 % of the patients were aged between 61 and 70 and 6 % of all patients belonged to the group aged over 70. The age structure was equal for both men and women. The moderate age of the men was evaluated at 34.0 ± 20.0 years, and the women were 33.7± 21.2 years.

Height varied between 110 cm and 190 cm, with an average of 159.4 cm ± 18.5 cm. Weight varied between 19 kg and 115 kg, with an average of 61.1 kg ± 19.8 kg.

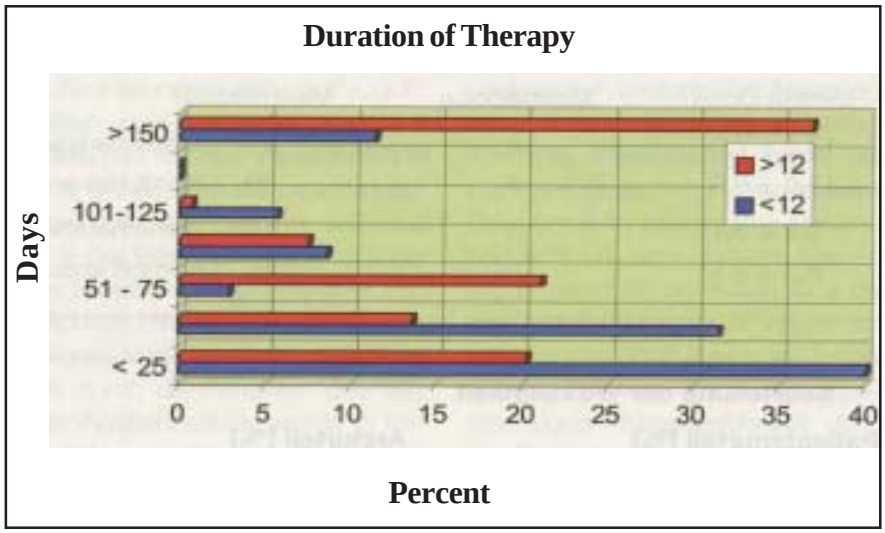


Diagnoses and Secondary Diseases

The diagnoses leading to the prescription had to be entered in the study protocol. It showed that SANUKEHL Pseu, according to the Isopathy, is used in a very wide applicational range. The preferred application was for angina, sinusitis, bronchitis, laryngitis and pharyngitis in both the children's as well as the adult groups. A thorough diagnosis was made before the start and end of the therapy respectively. Accompanying therapies were to be documented in the evaluation form.

In order to obtain a measure for chronic diseases, it was asked in the study protocol how long they have endured the disease or complaints. The time-frame was given of less than six months, up to one year, up to three years and more than three years. 19.1 % of the patients had suffered complaints less than six months, and 17.3 % less than 12 months. 11.1 % had been ill for a time period between one and three years, and more than half the participants (52.5 %) had been ill or had suffered complaints for more than 36 months. The existence of the complaints was shifted more in the direction of acute conditions in the under 12 patients. 52.9 % of these patients suffered for less than six months and 26.5 % for a period between six and 12 months. Only 11.8 % of the patients in this age group had complained of symptoms for a time period between one and three years and a remainder of only 8.8 % of patients had recurrently shown symptoms for more than three years. In the adult group of patients over the age of 12, the proportion of patients with a period of complaints of 36 months and longer was especially pronounced at 64.1 %. Only 10.2 % 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 were still represented with 14.8 %. 10.9 % of the patients in the adult group registered a duration of complaints between one and three years. Because in both patient groups the main indications were given as angina, sinusitis, bronchitis, laryngitis and pharyngitis, the comparison of the age groups shows that children were most frequently treated for acute conditions of these diseases, while chronic complaints stood in the foreground among the adults.

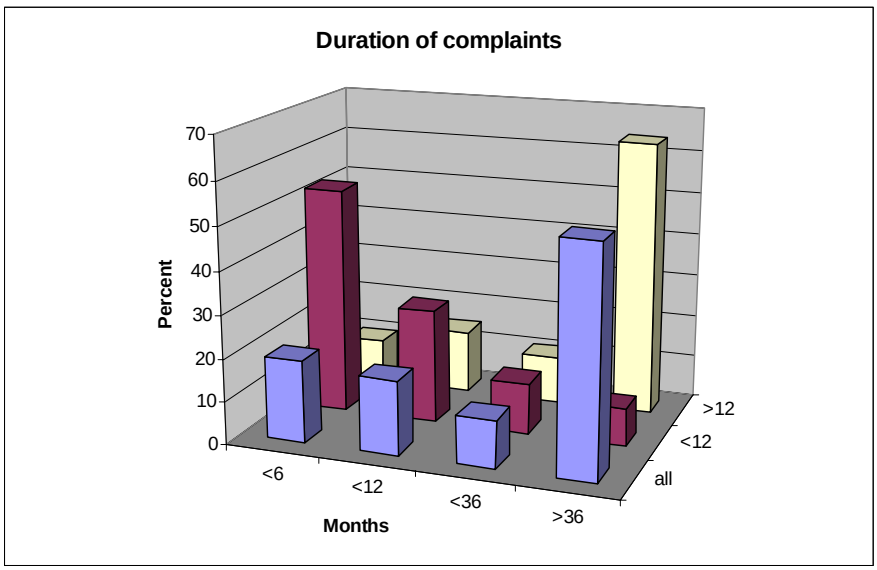


Consultation Times, Therapy Duration

According to the nature of an application study, the physician was not given a preset timelimit for the final patient assessment. This final examination was conducted after a period of 12 to 370 days, with a moderate of 137.5 days ± 140.9 days.

Among children (< 12 years) the therapy lasted with 69.8 days ± 90.7 days; less than half the lenght of time than in the adult group with 155.1 days ±146.3 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 lasted up to 25 days (40 % of all patients) and between 25 and 50 days (31.4 %). Among the adults, the largest group with 36.8 % was the one with more than 150 therapy days and only 20.3 % with a therapy duration of up to 25 days.

Duration of complaints (months)	Total patient population (%)	Patients >12 years (%)	Patients <12 years (%)
< 6	19,1	52,9	10,2
<12	17,3	26,5	14,8
< 36	11,1	11,8	10,9
>36	52,5	8,8	64,1



Dosage

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

Oral application: 5 –10 drops (every 12 to 24 hours) with acute conditions; 10 drops every 2nd day with chronic progressive forms.

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

156 patients took the drops orally and 72 externally. Multiple counts were necessary as 58 patients took the drops orally as well as externally. 97 patients only took the drops orally (monotherapy), and 13 patients

Total Population

	med. dosage	min. dosage	max. dosage
Drops for oral application	13.3 ± 7.5	4	30
Drops for external application	6.6 ± 2.3	5	15
<u>All patients below 12 years of age</u>	med. dosage	min. dosage	max. dosage
Drops for oral application	9.4 ± 3.5	4	20
Drops for external application	6.6 ± 2.2	5	10
<u>All patients over 12 years of age</u>	med. dosage	min. dosage	max. dosage
Drops for oral application	14.3 ± 7.9	5	30
Drops for external application	6.6 ± 2.8	5	15

Monotherapy / Combination Therapy (Total Population)

	med. dosage	min. dosage	max. dosage	
Drops for oral application	13.8 ± 7.0	4	30	mono
Drops for external application	12.6 ± 8.3	4	30	combo
Drops for oral application	8.2 ± 3.1	5	15	mono
Drops for external application	6.3 ± 2.4	5	15	combo

exclusively for external application. The average dosage based on the form of application is shown in the following table. The drops are based on the daily oral and external applications.

The recommended dosage was 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 oral as well as for external application in monotherapy did not differ significantly from that used in the combination therapy.

Comparison to Previous Therapy

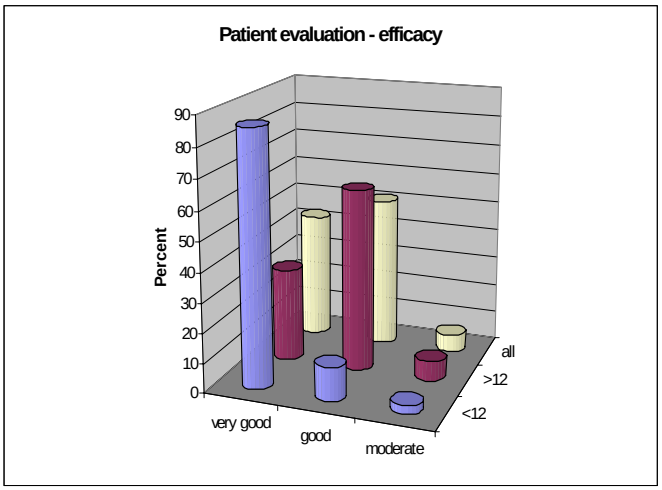
Only five patients had been previously treated with SANUKEHL Pseu D6 drops from 1992 to 1995, at that time used exclusively for oral application. Since this patient group was too small, the comparison of efficacy and tolerance in two patient groups of first-time application users and repeated application users became redundant. It should, however, be noted that these five patients tolerated both the previous as well as the current therapy well and without side effects.

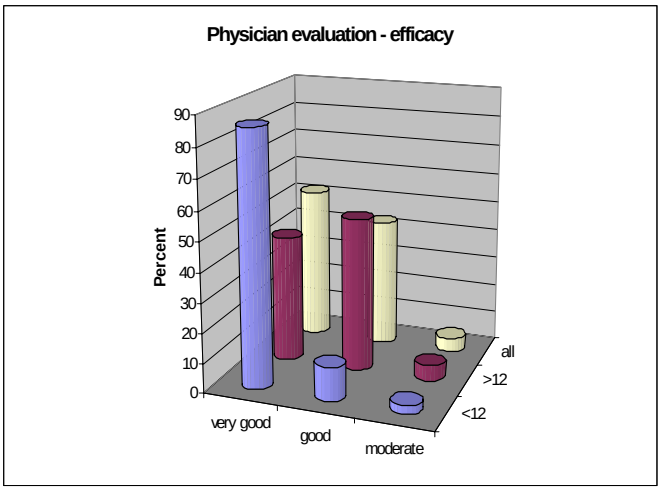
Evaluation of Efficacy by Physician and Patient

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“. 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 94 % of the patients thought efficacy to be „very good“ and „good“, while only 6 % thought it was „moderate“. Neither physicians nor patients assessed the evaluation with „no effect“. The result of the physicians' evaluation for efficacy was like that of the patients. The physicians evaluated efficacy in 51.8 % of the cases as „very good“, in 43.5 % as „good“ and in 4.8 % as „moderate“. The evaluation by physicians and patients alike was significantly better in the childrens' group than in the adult group. Significantly more chronic disorders were treated in the adult group than that of the children, which may have

Evaluation of Efficacy

Patient group	Patient evaluation (%)				Physician evaluation (%)			
	Very good	good	moderate	ineffective	very good	good	moderate	ineffective
All patients	42.9	51.2	6.0	0	51.8	43.5	4.8	0
< 12 years	85.7	11.4	2.9	0	85.7	11.4	2.9	0
> 12 years	31.6	61.7	6.8	0	42.9	51.9	5.3	0





lead to a slightly worse evaluation. Summing up more than a total of 90 % of the adults evaluated the efficacy to be „good“ or „very good“. The compliance (N = 168) was assessed by the physicians to be „very good“ for 85 patients and „good“ for 68 patients. Hence 91 % 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“.

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. 60.9 % of patients and 57.7 % of physicians rated the tolerance to be „very good“, whilst 38.1 % of patients and 42.3 % of physicians gave SANUKEHL Pseu a „good“ tolerance rating. 1.8 % of the patients rated it „moderate“. No case was assessed as „moderate“ with the physicians.

In the childrens' group, tolerance was rated „very good“ by 100 % of children and the physicians alike.

Side Effects and Termination of Therapy

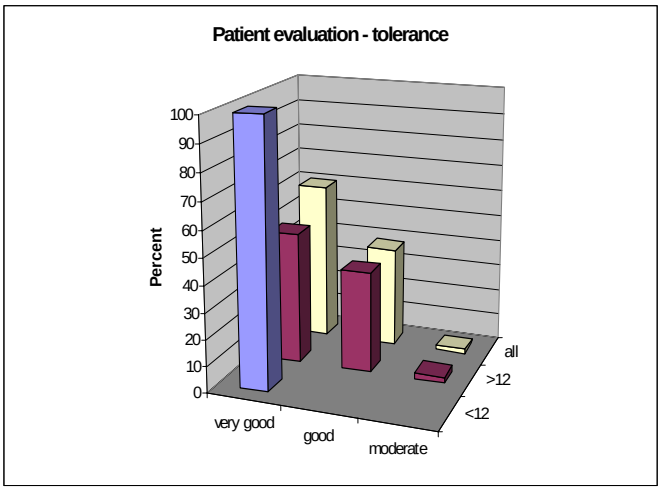
A 57-year old female patient prone to infections after an encephalitis and neuropathy of the legs did not return for her follow-up examination. Upon telephonic inquiry she indicated that she had terminated the therapy, because she could not determine any improvement. Both patient and physician rated tolerance as „very good“. The patient did not discontinue the treatment for reasons of intolerance or side effects. The physician put her unauthorized therapy termination down to the fact that the patient was known to suffer from depression. No other therapies were discontinued and further side effects of the medicament did not occur.

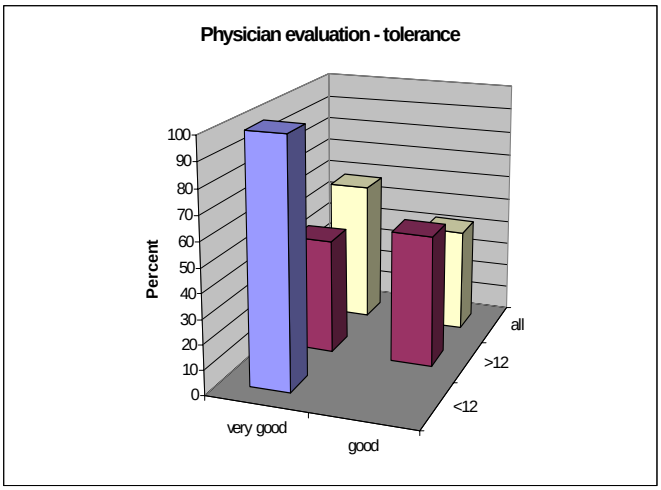
Summary

A total number of 168 patients in four medical practices, one specializing in internal medicine, one in surgery and two in general medicine, participated between May 1991 and May 2001 in an application study with the preparation SANUKEHL Pseu D6 drops. The homoeopathic test preparation, SANUKEHL Pseu, consists exclusively of pseudomonas aeruginosa in the 6th decimal potency.

Evaluation of tolerance

Patient group	Patient evaluation (%)				Physician evaluation (%)			
	Very good	good	moderate	poor	very good	good	moderate	poor
All patients	60,1	38,1	1,8	0	57,7	42,3	0	0
< 12 years	100	0	0	0	100	0	0	0
> 12 years	49,6	38,1	2,3	0	46,6	53,4	0	0





SANUKEHL Pseu was used in a very broad applicational range according to the Isopathy. The preferred application was for angina, sinusitis, bronchitis, laryngitis and pharyngitis in both, children as well as the adult groups. A thorough diagnosis was made previous to the start of the therapy as well as after its completion. Accompanying therapies had to be documented in the evaluation form.

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The therapeutic progress was determined by evaluations conducted respectively at the beginning and the end of the therapy. 94 % of the patients and 95.2 % of the physicians rated the efficacy of the therapy as „very good“ and „good“. The evaluation by physician and patient was much better in the children’s group than in the adult group. For 91 % of all patients participating in the study, compliance was certified to be „very good“ or „good“.

60.1 % of the patients and 57.7 % of the physicians rated tolerance as „very good“, while 38.1 % of the patients and 42.3 % of the physicians gave SANUKEHL Pseu a „good“ tolerance rating. 1.8 % of the patients rated it „moderate“. None of the physicians rated tolerance in any of the tested cases as „moderate“. In the childrens’ group, tolerance was rated „very

good“ by 100 % of the children and physicians alike.

A 57-year old female patient did not return for her follow-up examination. Upon telephonic inquiry, she indicated that she had terminated the therapy, because she could not determine any improvement. Both patient and physician rated the tolerance as „very good“. The patient did not discontinue the treatment for reasons of intolerance or side effects. The physician put her unauthorized therapy termination down to the fact that the patient was known to suffer from depression. No other therapies were discontinued and further side effects of the medicament did not occur.

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