Statistical Evaluation of an Application Study with

SANUKEHL Myc 6X drops

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1. Introduction

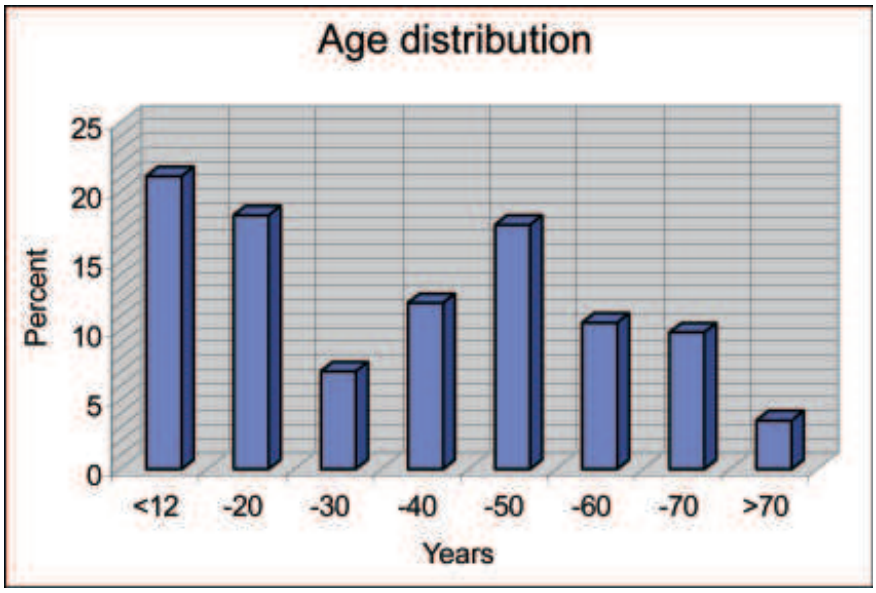
From April 1991 to April 2000, a total of 142 patients were admitted to an observation study with the preparation SANUKEHL Myc 6X drops in three medical practices, one specialising in internal medicine and two in general medicine. The homoeopathic test preparation, SANUKEHL Myc consists exclusively of the 6th decimal potency of Mycobacterium bovis (BCG) e volumine cellulae.

The aim of the observation study was to determine the actual application of the preparation and its tolerance under conditions of everyday practice. Further, knowledge concerning the acceptance of the product, especially with children, 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

142 patients participated in the study, 70 males (49.3%) and 72 females (50.7%). The age of the patients varied between 5 and 82 years with an average age of 33.8 years and a standard deviation of 21.0 years. The age groups of under 12 years (21.1%), between 13 and 20 (18.3%) and between 41 and 50 (17.6%) comprised almost the same number of patients. The groups between 31 and 40 (12.0%), between 51 and 60 (10.6%) and between 61 and 70 (9.9%) were also of comparable sizes. Between 21 and 30 years old were 7.0% and over 70 years old 3.5% of the patients. The male patients with an average age of 37.5 ± 21.4 years were on average 7 years older than the female patients with 30.2 ± 19.9 years.



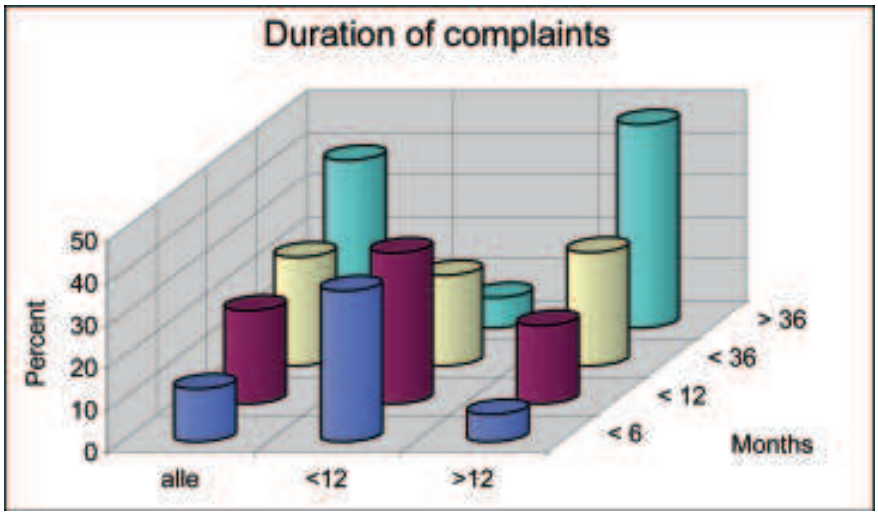
Height varied between 119 and 180 cm with an average height of 155.9 ± 20.0 cm and weight was between 19 and 93 kg with an average weight of 56.9 ± 20.9 kg.

2.1 Diagnosis and accompanying diseases

The diagnosis leading to prescription had to be recorded in the Study protocol. It showed that SANUKEHL Myc 6X, according to Isopathy, is used in a very wide application range. Preferred application was independent of the patients' age. The main indication areas named were bronchitis, bronchial asthma and skin diseases such as dermatitis, psoriasis and lupus. Medical findings were recorded both before and after completion of the treatment. Any accompanying therapies were to be documented in a survey form.

In order to obtain a measure of chronic diseases, the patients were enquired by 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.

For only 12.5% of the patients, the complaints had been present for less than 6 months. For 22.1%, the complaints had been present for a period between six and 12 months, and for 25.7% for a period between one and three years. More than one third (39.7%) of all patients had suffered the complaints for more than 36 months. In the age group of under 12-year-olds, the duration of the complaints had shifted towards acute conditions. Thus, 35.7% of these patients had suffered the complaints for less than



Duration of Complaints (Months)	Total Patient Population (%)	Patients < 12 years (%)	Patients > 12 years (%)
< 6	12.5	35.7	6.5
6 - 12	22.1	35.7	18.5
< 36	25.7	21.4	26.9
> 36	39.7	7.1	48.1

six months and between six and 12 months, but only 7.1% of the patients for more than three years. In the adults' group of over 12-year-olds, a chronic suffering period of more than 3 years was particularly pronounced with 48.1% of the patients.

Only 6.5% of the patients suffered from acute complaints with a duration of up to six months, 18.5% between six and 12 months, and 26.9% between one and three years.

Of the 142 patients included in the study, only a 36-year old female patient had already been treated with SANUKEHL Myc 6X drops before.

3. Dosage and duration of treatment

3.1 Time of consultation and duration of treatment

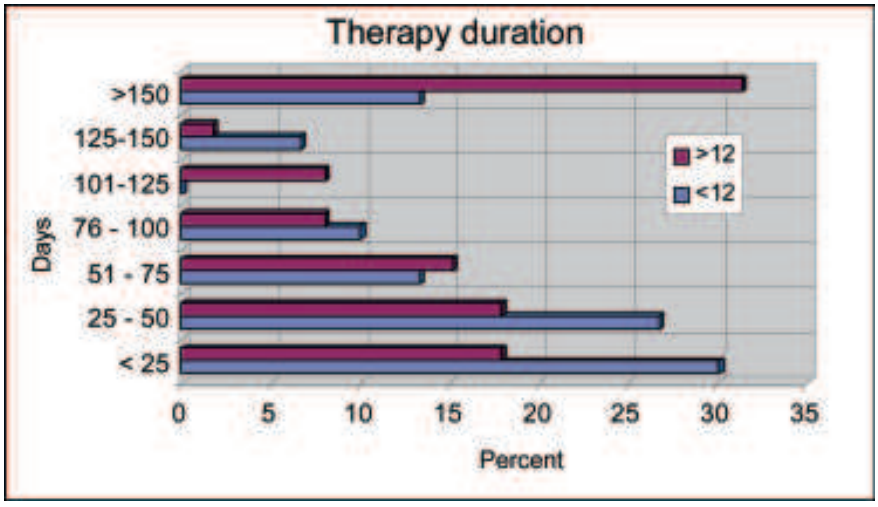
Corresponding to the nature of an application study, the doctors were not given a fixed schedule for the final examination. This final examination was carried out after a period of 5 to 368 days with an average of 127.1 ± 130.1 days.

Therapy duration for the children (< 12 years) was on average 81.4 days ± 102.1 days, and thus, approximately only half as long as that for the adults' group with 139.4 ±133.4 days. The spread range in the age group of under 12-year-olds is due to three patients with 366 therapy days each. The differentiated evaluation within specific therapy periods allows for a better picture. It reveals that amongst the under 12-year-olds, the therapy duration up to 50 days was clearly in the foreground (56.7% of all patients). Amongst the adults, the largest group was that of more than 150 therapy days with 31.3% of the patients.

3.2 Dosage

Dosage was prescribed according to the patient information leaflet:

Oral application:
For acute conditions 5-10 drops



(every 12 to 24 hours); for chronic conditions 10 drops every other 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.

122 patients took the drops orally and 74 patients were treated externally. Multiple counts were necessary, as 54 patients were treated both orally and externally. The following table states the medium dosage of the application forms. The drops are related to the daily oral intake or external application, respectively.

The recommended dosage was complied with. In the group of under 12-year-olds, the drops for oral and topical application were dosed according to age. The medium dosage in monotherapy was not significantly different from that in combination therapy. The dosage for external application in monotherapy was almost twice as high as in combination therapy.

4. Comparison with Former Therapy

Only one adult female patient had been treated with SANUKEHL Myc 6X drops in the past five years.

Therefore, a comparison between first-time and repeated users was not possible. By comparing efficacy and tolerance in both patient groups of first-time and repeated users, hints for a possible sensitisation towards the medically active ingredient could be identified. However, this patient as well as her doctor evaluated

Dosage according to administration form (total population)

	Medium Dose	Minimum Dose	Maximum Dose
Drops (oral)	14.3 ± 6.5	3	30
Drops (topical)	7.2 ± 2.8	1	12

Dosage according to administration form (all patients under 12 years)

	Medium Dose	Minimum Dose	Maximum Dose
Drops (oral)	7.9 ± 2.1	5	10
Drops (topical)	4.9 ± 2.1	1	10

Dosage according to administration form (all patients over12 years)

	Medium Dose	Minimum Dose	Maximum Dose
Drops (oral)	16.3 ± 6.1	5	30
Drops (topical)	8.0 ± 2.6	3	12

Monotherapy / Combination therapy (total population)

	Medium Dose	Minimum Dose	Maximum Dose	
Drops (oral)	14.9 ± 6.6	5	30	**Monotherapy**
Drops (oral)	13.5 ± 6.2	5	20	**Combination therapy**
Drops (topical)	10.0 ± 0	10	10	**Monotherapy**
Drops (topical)	6.2 ± 2.6	1	12	**Combination therapy**

tolerance with "good" for repeated application.

5. Efficacy and tolerance

5.1 Evaluation of efficacy by doctor and patient

In a final assessment, physicians and patients were asked to evaluate efficacy and tolerance. Efficacy could be rated as "very good", "good", "moderate" or as having "no effect". The doctors were also requested to rate patient compliance as "very good", "good", "moderate" or "poor".

Efficacy was rated as "very good" by 26.1% of the patients and as "good" by 63.4%, whilst 10.6% rated efficacy as "moderate". The doctors' evaluation was as positive as that of the patients. The doctors rated efficacy as "very good" for 37.3 % of the patients, as "good" for 54.9%, and as "moderate" for 7.7%. No doctor and no patient evaluated the treatment as having "no effect". In the adults' group, efficacy tended to be rated better; compared with the childrens' group, there was a shift from "good" to "very good" in the evaluation.

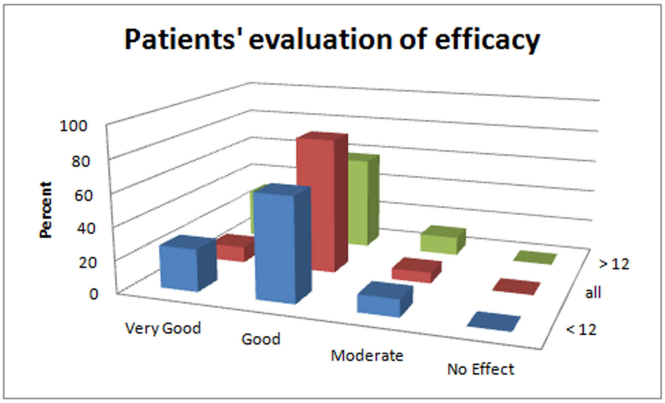
Compliance (N=140) was judged as "very good" for 42 patients and as "good" for 77 patients by their doctors. Thus, "good"' and "very good" compliance, respectively, was attested to 83.8% of the patients. For 21 patients, compliance was judged as being "moderate", and for no patient as being "poor".

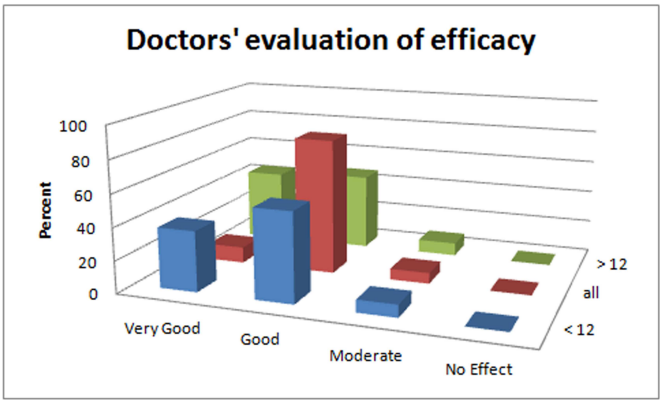
5.2 Evaluation of tolerance by doctor and patient

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". 40.1% of the patients and 41.5% of the doctors rated tolerance as "very good", while 57.7% of the patients and 54.2% of the doctors attested "good" tolerance to SANUKEHL Myc 6X. "Moderate" tolerance was stated by 2.1% of the patients and 4.2% of the doctors. "Poor" tolerance was attested in no case by both patients and doctors.

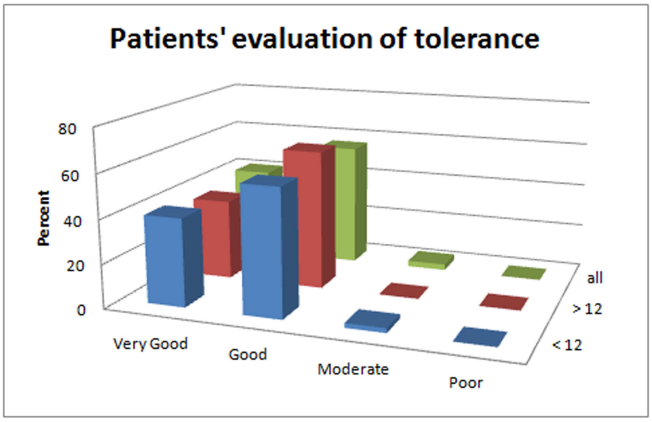
In the adults' group of over 12-year-olds, patients evaluated tolerance in the ratings of "very good" and "good" a little better than those of the age group of under 12-year-olds. In the younger age group, patients and doctors rated tolerance as being "moderate" or "poor" in no case.

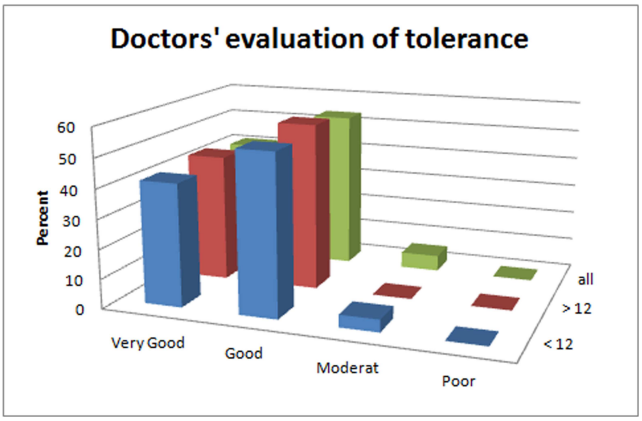
Evalulation of efficacy								
Patient Group	**Patients' evaluation (%)**				**Doctors' evaluation (%)**			
	Very Good	Good	Moderate	No Effect	Very Good	Good	Moderate	No Effect
All Patients	26.1	63.4	10.6	0	37.3	54.9	7.7	0
First User	10.0	83.3	6.7	0	10.0	83.3	6.7	0
Multiple User	30.4	58.0	11.6	0	44.6	47.3	8.0	0





Evaluation of tolerance								
Patient Group	**Patients' evaluation (%)**				**Doctors' evaluation (%)**			
	Very Good	Good	Moderate	Poor	Very Good	Good	Moderate	Poor
All Patients	40.1	57.7	2.1	0	41.5	54.2	4.2	0
First User	36.7	63.3	0	0	43.3	56.7	0	0
Multiple User	41.1	56.3	2.7	0	41.1	53.6	5.4	0





5.3 Side effects and discontinuation of the therapy

No patient discontinued the therapy with SANUKEHL Myc 6X drops, and no adverse drug reactions were reported.

One 62 year old male patient with chronic cholecystitis complained of diarrhoea after having taken 10 drops 2x daily for one day, which disappeared after a tea pause of one day without any additional therapy. The treatment with the test preparation was continued. At the end, patient and physician rated tolerance as "good".

6. Summary

From April 1991 to April 2000, a total of 142 patients were admitted to an observation study with the preparation SANUKEHL Myc 6X drops in three medical practices, one specialising in internal medicine and two in general medicine. The homoeopathic test preparation, SANUKEHL Myc consists exclusively of the 6th decimal potency of Mycobacterium bovis (BCG) e volumine cellulae.

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The main indication areas named were bronchitis, bronchial asthma and skin diseases such as dermatitis, psoriasis and lupus. Any accompanying therapies were to be documented in a survey form.

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122 patients took the drops orally and 74 patients were treated externally. Multiple counts were necessary, as 54 patients were treated both orally and externally. Only one adult female patient had been treated with SANUKEHL Myc 6X drops in the past five years. Therefore, a comparison between first-time and repeated users was not possible.

Progress of the treatment was determined by means of a collection of medical findings both at the beginning and the conclusion of the therapy.

89.5% of the patients and 92.2%

of the doctors rated efficacy of the treatment as "very good" and "good". In the adults' group, efficacy tended to be rated better; compared with the childrens' group, there was a shift from "good" to "very good" in the evaluation. "Very good" and "good" compliance was attested to 83.8% of all patients included in the study.

40.1% of the patients and 41.5% of the doctors rated tolerance as "very good", while 57.7% of the patients and 54.2% of the doctors attested "good" tolerance to SANUKEHL Myc 6X. "Moderate" tolerance was stated by 2.1% of the patients and 4.2% of the doctors. "Poor" tolerance was attested in no case by both patients and doctors.

One 62 year old male patient with chronic cholecystitis complained of diarrhoea after having taken 10 drops 2x daily for one day, which disappeared after a tea pause of one day without any additional therapy.

No patient discontinued the therapy, and there were no adverse events.

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