Statistical Evaluation of an Application Study with the preparation SANKOMBI Drops

in the application areas of convalescence and conditions of general weakness

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1. Introduction

A total number of 57 patients (convalescents or asthenia sufferers) from three medical practices took part in an application study with the preparation SANKOMBI drops between January 1998 and July 2002. The active ingredient of the homoeopathic preparation SANKOMBI drops consists of a mixture of Mucor racemosus 5X dil. and Aspergillus niger 5X dil. (in equal parts) in an aqueous dilution.

The aim of this application study was to determine the actual application of the preparation as well as its efficacy under day-to-day conditions of a normal practice. Not only the efficacy but also the tolerance of SANKOMBI drops was to be documented under practice conditions. The acceptance of the preparation on the market was also to be determined.

All findings from these therapeutic applications were documented in a report form.

Only descriptive statistical methods were used in line with the study's set-up. The application of inductive methods was not indicated. An „intention-to-treat" evaluation was carried out, which means that only patients who had already received at least one dose of SANKOMBI drops were considered to take part in the study.

2. Participating Patients

57 patients participated in the study, which comprised of 32 women (56.1%) and 25 men (43.9%).

The age of the patients varied between 4 and 80 years with an average age of 24.7 and a standard deviation of 16.8. 15 patients (26.3%) were under 12. The largest group of patients was between 13 and 20 with 17 patients (29.8%), 8 patients (14.0%) were between 21 and 30, 6 patients (10.5%) between 31 and 40 and 7 patients (12.3%) between 41 and 50 years. Two patients (3.5%) were in the age group between 51 and 60 years and between 61 and 70 and over 70 years was one patient (1.8%) each. The groups of women and men were comparable in their homogeneity.

2.1 Diagnoses and accompanying diseases

According to the study protocol, the following diagnoses led to prescriptions: Convalescence after a grippal infection, bronchitis, laryngitis/pharyngitis, angina/tonsillitis, rhinitis and surgical intervention. Multiple entries were possible. Single entries were: four patients with a grippal infection, two patients with bronchitis and one patient with laryngitis. There was no convalescent after surgical intervention. With respect to the multiple entries, the combination of grippal infections with two or three specified indications were predominant. Double entries were stated for nine patients, threefold for 12 patients, fourfold for 20 patients and fivefold for nine patients. Multiple indications with the following number of patients were:

Grippal infection + laryngitis/pharyngitis: 3

Grippal infection + rhinitis: 2

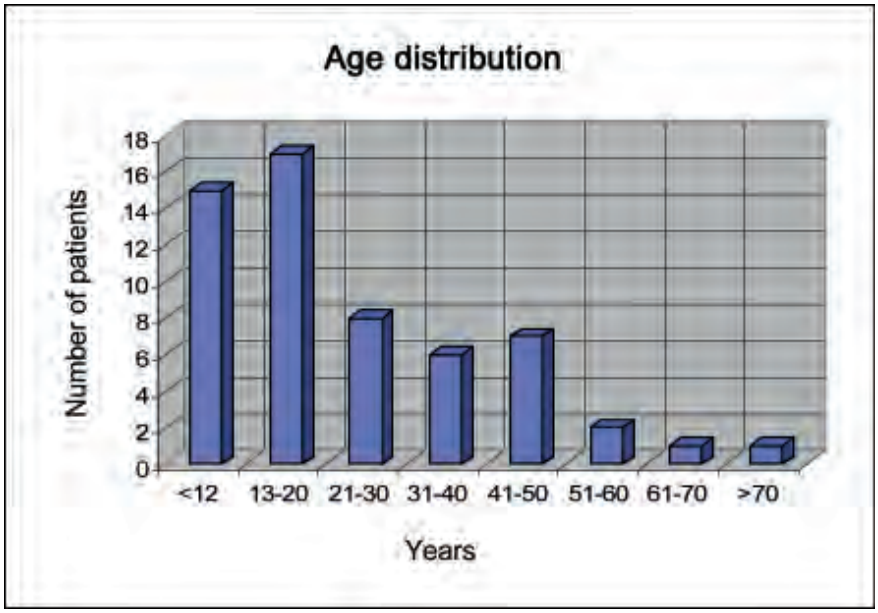
Grippal infection + angina: 1

Bronchitis + laryngitis/pharingitis: 1

Laryngitis/pharyngitis + angina: 2

Grippal infection + bronchitis + laryngitis/pharingitis: 6

Grippal infection + bronchitis + rhinitis: 3



Grippal infection + angina + rhinitis: 1

Grippal infection + laryngitis/pharyngitis + angina: 1

Bronchitis + laryngitis/pharyngitis + angina: 1

Grippal infection + laryngitis/ pharyngitis + rhinitis + angina: 8

Grippal infection + bronchitis + laryngitis/pharyngitis + angina: 3

Grippal infection + bronchitis + laryngitis/pharyngitis + rhinitis: 7

Bronchitis + laryngitis/ pharyngitis + angina + rhinitis: 2

Grippal infection + bronchitis + laryngitis/pharyngitis + angina + rhinitis: 9

Any long-term medication for other underlying diseases was to be continued. Ingestion was to be documented with name of preparations as well as dosages. Three patients with other underlying diseases and their respective medications were stated.

Other basic diseases	Medication
Pollinosis	Zyrtec
Asthma bronciale	Euphillin, ß-Sympathomimetics, Cortisone
Diabetes mellitus I	Insulin

2.2 Infection anamnesis

Within the infection anamnesis, the number of infections of the past autumn/winter was investigated. With the exception of three patients, all other patients had at least one infection during this period. No data was available for one patient. 33 patients had one, two or three infections during this period. Six patients had four infections and 14 patients more than five infections in the past autumn/winter season.

3. Dosage and Therapy Duration

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 initial and final patient assessment. Therapy duration (observation time) was to be stated according to the patient's individual symptom picture. The study plan proposed a first control check-up after one to two weeks and the final assessment after approximately four weeks. The first control check-up was made on average after 13.9 ± 2.3 days (minimum 4 days; maximum 21 days) and the final examinations were conducted after 29.8 ± 4.0 days with a minimum therapy duration of 18 days and a maximum therapy duration of 43 days. The therapy duration in children under 12 was not significantly different from those of the adults.

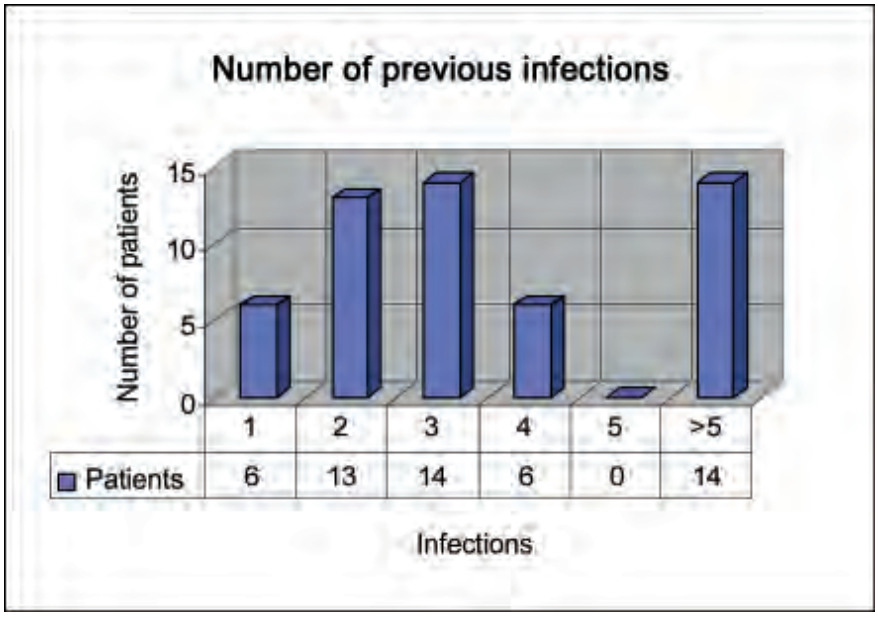
3.2 Dosage

According to the study plan, the dosage was determined as follows:

Oral intake: 5-10 drops 1x daily before meals

Rubbing in: 5-10 drops 1x daily into the inner side of the elbow

33 patients were only treated orally and 10 patients by rubbing in. The test preparation was administered orally as well as rubbed in with 14 patients. On



Therapy duration in days	1st control check			2nd control check		
	Average value	Minimum	Maximum	Average value	Minimum	Maximum
All patients	13.9 ± 2.3	4	21	29.8 ± 4.0	18	43
Children	12.7 ± 2.8	8	17	28.4 ± 2.9	24	35
Adults	13.3 ± 2.6	4	21	28.5 ± 4.2	18	43

average, the daily intake was 8.7 ± 1.6 drops (minimum 5 and maximum 10 drops), and daily rubbing in 6.4 ± 2.5 drops (minimum 3 and maximum 10 drops). The dosage stated was kept in all age groups as well as children.

4. Efficacy

4.1 Target parameter

According to the study plan, the following symptoms were investigated before starting treatment and upon the two following consultations:

- Subjective assessment with respect to lack of energy, exhaustion, vertigo, lack of appetite and sleeping disorders
  Intensity (none, slight, mild, strong and very strong)
- Clinical symptoms and findings
  Fever >38°C, head and limb pain, sniffles, cough, sore throat
  Intensity (none, slight, medium and strong)

4.2 Subjective assessment

The extent of lack of energy and drive/listlessness, exhaustion/tiredness/weakness, vertigo/disturbances of equilibrium, lack of appetite and sleeping disorders is expressed by a score sum, in which for "none" = 0, "slight" = 1, "mild" = 2, "strong" = 3 and for "very strong" = 4 score points are assigned.

Lack of energy and drive/listlessness were most noticeable with 102 score points in the initial phase of treatment, followed by exhaustion/tiredness/conditions of weakness, vertigo/disturbances of equilibrium, lack of appetite and sleeping disorders.

From the beginning of therapy to the first consultation (on average after 13.9 days), a 50% decrease was observed with all score sums, and from the first consultation to the end of the therapy (on average after another 15.9 days), such a decrease was also clearly seen.

If the score sum is set to 100% at therapy start, a reduction to the level of 6.9% is observed for lack of energy, to 9.3% for exhaustion, to 8.6% each for vertigo and lack of appetite and of 4.9% for sleeping disorders at the end of the therapy.

No different symptom developments were determined between the age groups of children and adults.

For this reason, the symptoms described here are always related to the total patient population.

The recuperation expressed by the score sums is even more clearly perceivable in the shifting of the degree of intensity of the individual symptoms. During the course of treatment, "very strong" intesity is shifted to "mild", then

Score sums of subjective assessment				
	Beginning of therapy	**1st consultation**	**End of therapy**	**Reduction to % level**
Lack of energy	102	45	7	6.9
Exhaustion	97	43	9	9.3
Vertigo	81	38	7	8.6
Lack of appetite	81	36	7	8.6
Sleeping disorders	82	30	4	4.9

to “slight“ and “none“. This shifting could be observed for all parameters of the subjective assessments.

As an example, the symptom “lack of energy and drive/listlessness“ is illustrated.

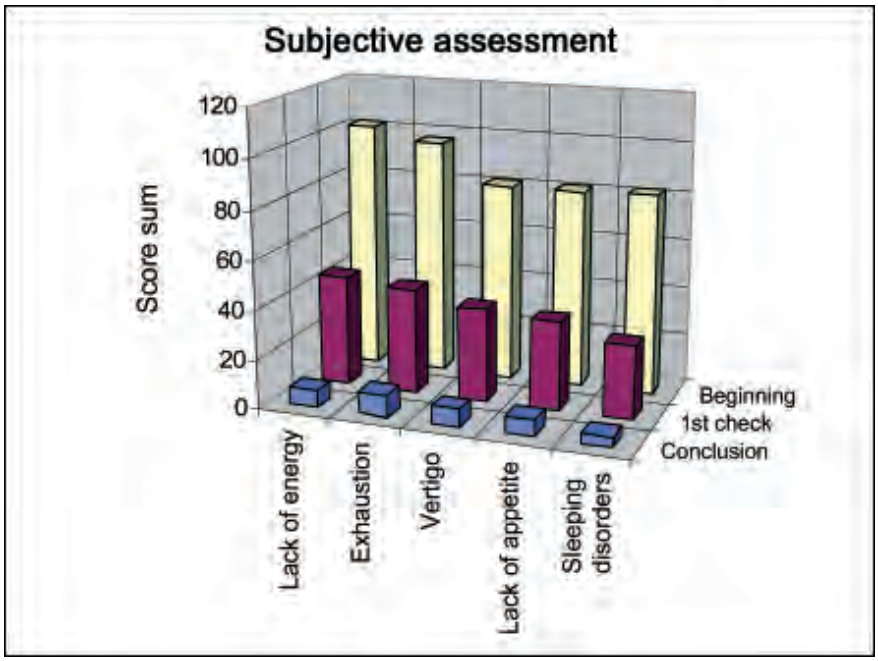
4.3 Clinical symptoms

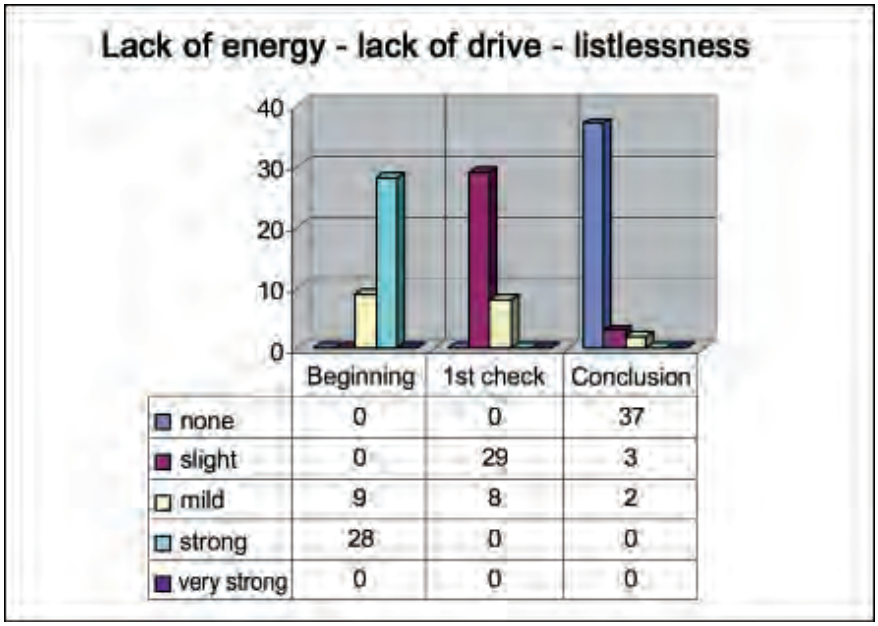
The extent of head and limb pain, sniffles, cough, sore throat and dysphagia is also expressed by a score sum, in which the following score points are observed: “none“ = 0, “slight“ = 1, “medium“ = 2 and “strong“ = 3.

The extent of fever was not determined; fever > 38°C could only be answered with “yes“ or “no“. In the initial phase of the study, 24 patients had a body temperature of > 38°C. All patients were free of fever already at the first control check-up, and also at the end of the study. The score sum for “cough“ was most noticeable with 97 score points at the beginning of treatment, followed by “sore throat“ and “dysphagia“, “sniffles“ and “head and limb pain“.

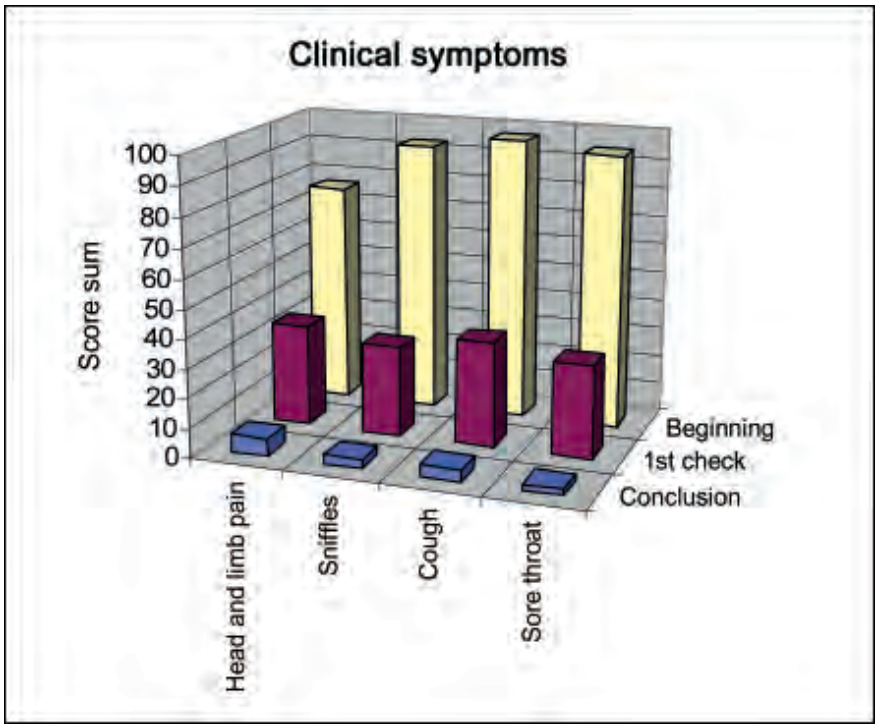
Upon the first consultation, all cold symptoms had already decreased to a level of 50 % of the starting value. Towards the end of the therapy, all typical acute cold symptoms such as head and limb pain, cough, sniffles, sore throat and dysphagia had almost completely disappeared.

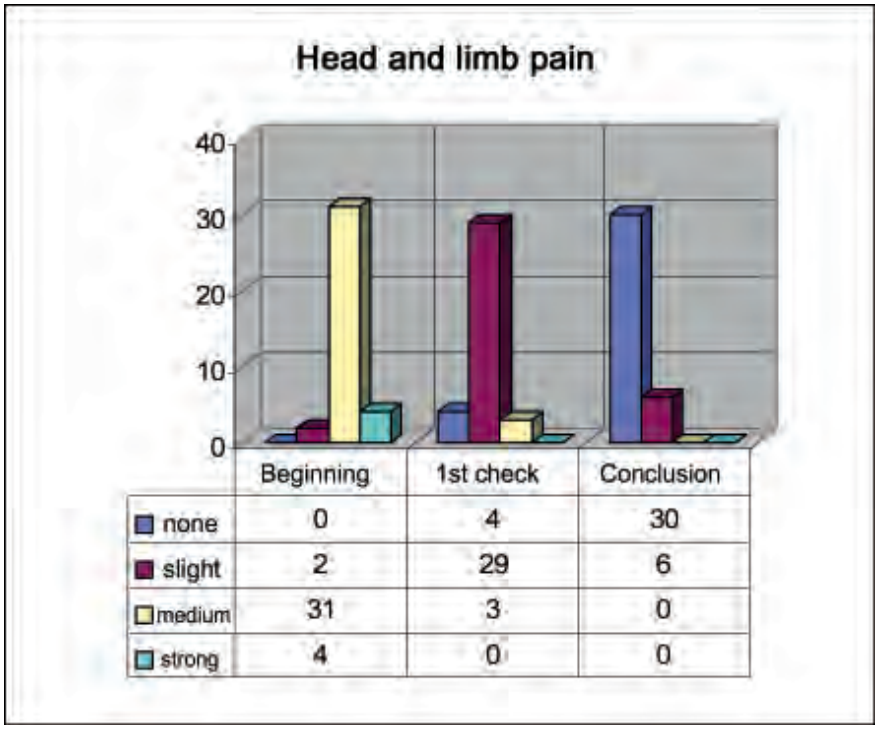
If the score sum is set to 100 % at therapy start, there was a reduction to the level of 7.9% for head and limb pain, 4.1%





Score sums of clinical symptoms				
	Beginning of therapy	**1st consultation**	**End of therapy**	**Reduction to % level**
Head and limb pain	76	35	6	7.9
Sniffles	93	31	3	3.2
Cough	97	36	4	4.1
Sore throat and dysphagia	94	32	2	2.1





	Beginning	1st check	Conclusion
none	0	4	30
slight	2	29	6
medium	31	3	0
strong	4	0	0

for cough, 3.2% for sniffles and finally, 2.1% for sore throat and dysphagia at the end of the therapy. No different symptom developments were determined between the age groups of children and adults for the clinical symptoms.

For this reason, the symptoms are always related to the total patient population.

The extent of the individual symptoms is clearly shifted to lack of symptoms. Whilst there is a decrease in "strong" and "medium", "slight" and "none" show an increase. At the therapy end, the slight complaint situation is also reduced to the credit of lack of symptoms. As an example, the symptom extent of head and limb pain is illustrated.

4.4 Overall evaluation of efficacy

In a closing assessment, physicians and patients were asked to evaluate efficacy with "very good", "good", "moderate" or "no effect". In the overall evaluation of efficacy, all physicians and 98.2% of the patients assessed efficacy to be "very good" and "good", whilst 1.8% assessed the therapy success with "moderate". Neither physicians nor patients assessed efficacy with "no effect". Significant evaluation differences between the children's and adult groups could not be stated.

The difference between the physician's and patient's efficacy evaluation in the children's group is not discussed any further, as there were only 15 children in the children's group.

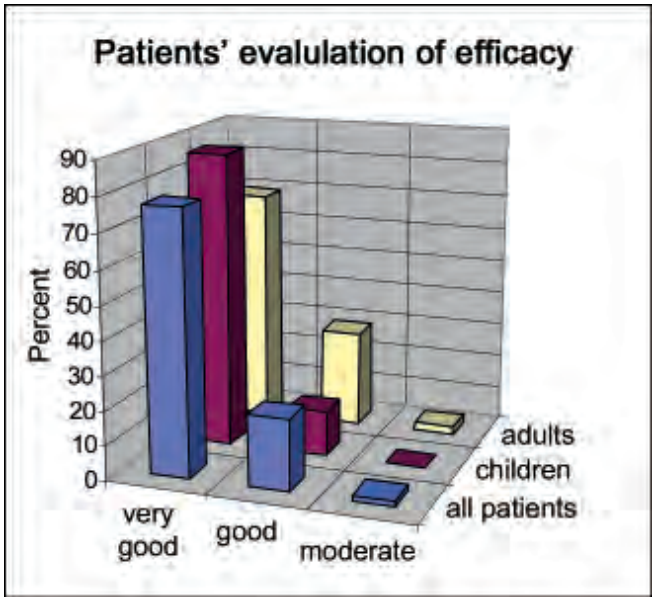
5. Tolerance

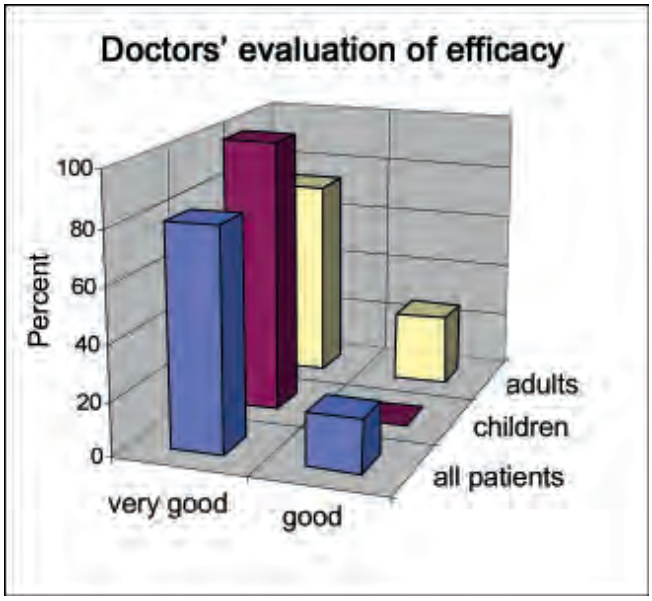
The patients were asked about possible side effects, incompatibilities as well as therapy discontinuations. No patient suffered from side effects or incompatibilities during therapy and neither administration with the test preparation nor any therapy was discontinued.

5.1 Overall evaluation of tolerance

In a closing assessment, physi-

Overall evaluation of efficacy			
Patient	All patients (%)	Children (%)	Adults (%)
Very good	77.2	86.7	69.0
Good	21.0	13.3	28.6
Moderate	1.8	0	2.4
Doctor			
Very good	80.7	100	73.8
Good	19.3	0	26.2





cians and patients were asked to evaluate efficacy with "very good", "good", "moderate" or "poor". In the overall evaluation of tolerance, all physicians and patients assessed tolerance to be "very good" and "good". Concerning the total patient population, 94.7% assessed tolerance with "very good" and 5.3% with "good", whilst 98.2% of the physicians evaluated with "very good" and only 1.8% with "good".

As with the evaluation of efficacy, no significant evaluation differences between the children's and adult groups were determined.

6. Compliance

At the end of the therapy, physicians were to evaluate compliance with "very good", "good", "moderate" and "poor". Compliance for 52 patients was evaluated to be "very good" and for 4 patients "good". No statement was available for one patient. According to physician's evaluation, no patient had a "moderate" or "poor" compliance.

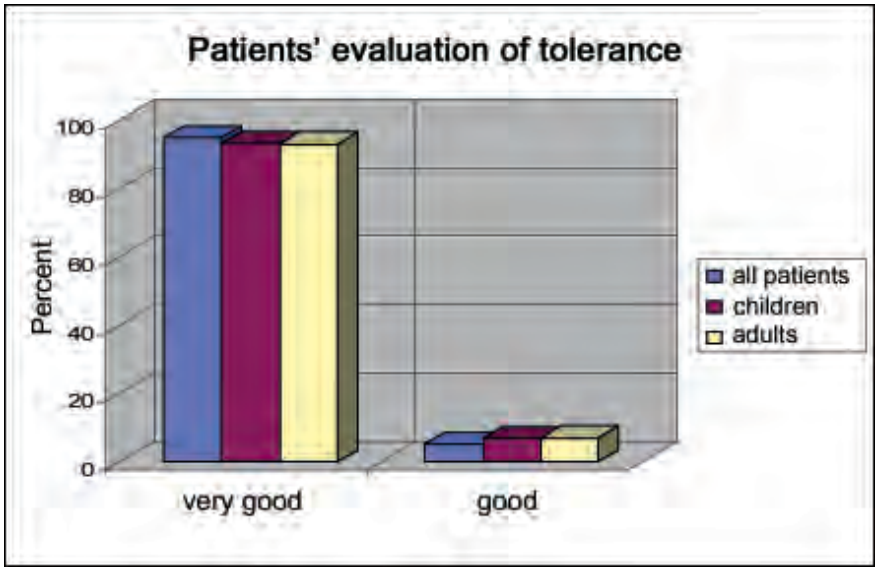
7. Summary

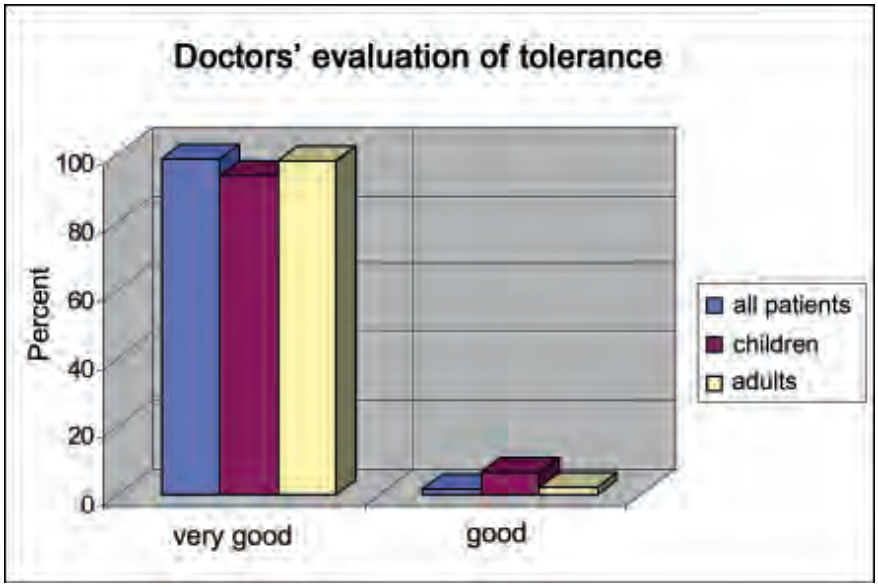
A total number of 57 patients (convalescents or asthenia sufferers) from three medical practices took part in an application study with the preparation SANKOMBI 5X drops between January 1998 and July 2002.

The age of the patients varied between 4 and 80 years with an average of 24.7 and a standard deviation of 16.8 years.

According to the study protocol, the following diagnoses lead to

Overall evaluation of tolerance			
Patient	All patients (%)	Children (%)	Adults (%)
Very good	94.7	93.3	92.9
Good	5.3	6.7	7.1
Doctor			
Very good	98.2	93.3	97.6
Good	1.8	6.7	2.4





prescriptions: Convalescence after a grippal infection, bronchitis, laryngitis/pharyngitis, angina/tonsillitis, rhinitis and after a surgical intervention. Multiple entries were possible.

The first control check-up was made on average after 13.9 ± 2.3 days (minimum 4 days; maximum 21 days) and the final examinations were conducted after 29.8 ± 4.0 days with a minimum therapy duration of 18 days and a maximum of 43 days. The daily dosage was on average 8.7 ± 1.6 drops (minimum 3, maximum 10 drops), and daily rubbing in was 6.4 ± 2.5 drops (minimum 5, maximum 10 drops). All age groups as well as the children adhered to the prescribed dosage.

According to the study plan, before treatment start and also with the following two consultations, the subjective evaluation concerning the extent of clinical symptoms of head and limb pain, sniffles, cough, sore throat and dysphagia was required.

All symptoms improved very much according to the score sum values up to 50% in the period between therapy start and the first control check-up. The individual grades of the symptom's extent show a general course from "strong" over "moderate"

and “slight“ to finally “none“ during the course of treatment. This shifting was stated for all symptoms. No different symptom courses could be stated between the age groups of children and adults.

In the global evaluation of efficacy, all physicians and 98.2% of the patients evaluated with “very good“ and “good“. A moderate therapy success was stated by 1.8% of the patients. Neither physicians nor patients evaluated with “no effect“. No significant differences were stated concerning the evaluations of the children and the adult group.

No side effects or incompatibilities were reported. No therapy was discontinued.

In the global evaluation of tolerance, physicians and patients evaluated tolerance exclusively with “very good“ and “good“. With respect to the total patient population, 94.7% of the patients evaluated tolerance with “very good“ and 5.3% with “good“, whilst 98.2% of the physicians evaluated with “very good“ and only 1.8% with “good“. As with the evaluation of efficacy, no significant differences between the children’s and adult groups could be stated.

All patients were certified with a “very good“ and “good“ compliance.

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