Statistical Evaluation

of an Application Study with the Preparation Series

Quentakehl

in the administration forms:
capsules, drops, suppositories and injections

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1 Introduction

A total number of 44 patients in seven medical practices, three specialising in internal medicine, three in general medicine and one in ENT, participated between January 1998 and December 1999 in an application study with the preparation series QUENTAKEHL in different application forms: capsules, drops, suppositories and injections. The homoeopathic test preparation, QUENTAKEHL, consists exclusively of Penicillium glabrum (synonym Penicillium frequentans) in the 3rd - 6th decimal potency according to the administration form.

1 ml drops contains: 1ml Penicillium glabrum (synonym Penicillium frequentans) D5 dil. in accordance with HAB, 5a.
1 ampoule QUENTAKEHL aqueous dilution for injection contains: 1 ml Penicillium glabrum (synonym Penicillium frequentans) aqueous dilution in accordance with HAB, 5b and 11.
1 capsule QUENTAKEHL contains: 330 mg Penicillium glabrum (synonym Penicillium frequentans) D4 trit. in accordance with HAB, 6.
1 suppository QUENTAKEHL contains: 0.2 g Penicillium glabrum (synonym Penicillium frequentans) D3 trit. in accordance with HAB, 6.

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 who had at least received one dosage of the medicament, were included in the study.

2 Participating Patients

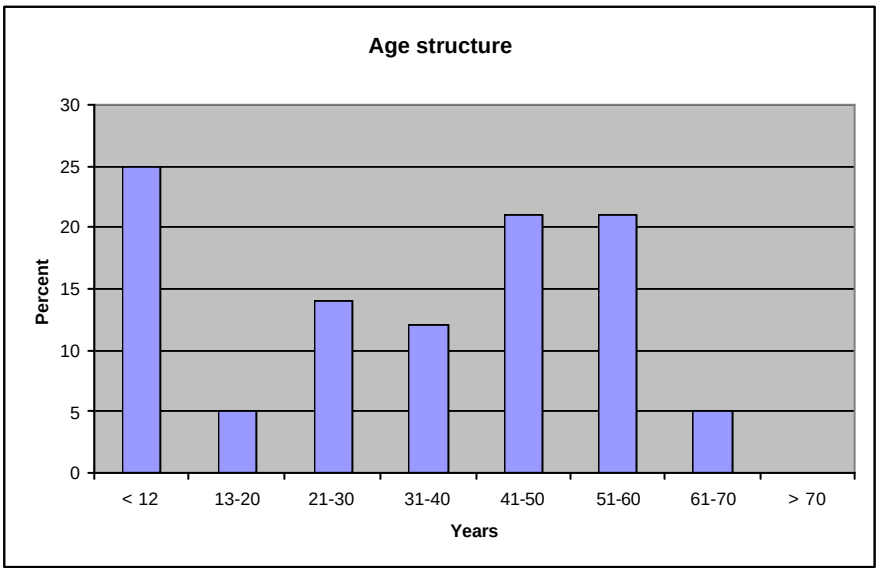
44 patients participated in the study which comprised of 56.8% males and 43.2% females. The age of the patients varied between six months and 63 years, with an average age of 33.2 and a standard deviation of 18.8 years. One quarter of the patients was under 12 years, between 13 and 20 years (4.5%), between 21 and 30 years (13.6%), 31 and 40 years (11.4%) and 20.5% respectively in the age groups between 41 and 50 years and 51 and 60 years. The oldest group were the patients between 61 and 70 (4.5%). The males with an average age of 33.4 ± 20.0 were of similar age as the females with 32.5 ± 17.8 years.

Height varied between 59 and 191 cm with an average height of 158.0 ± 28.3 cm. The weight was between 5 and 86 kg with an average weight of 62.2 ± 20.4 kg.

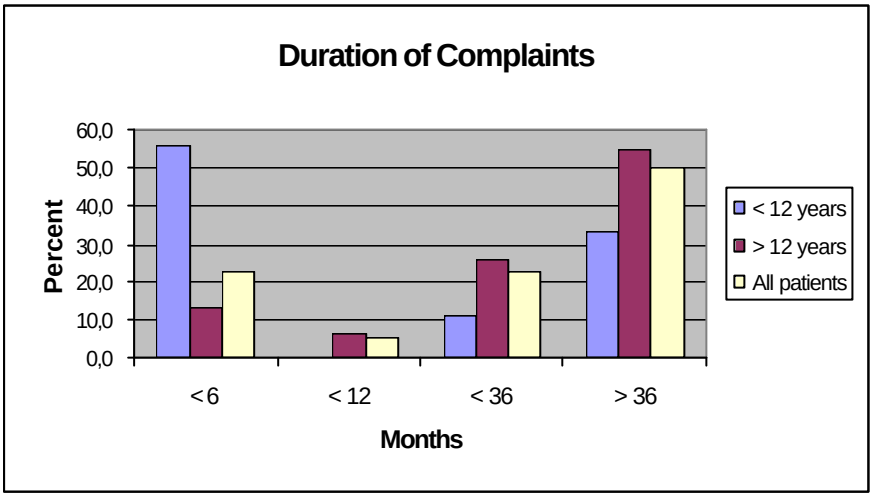
2.1 Diagnoses and Secondary Diseases

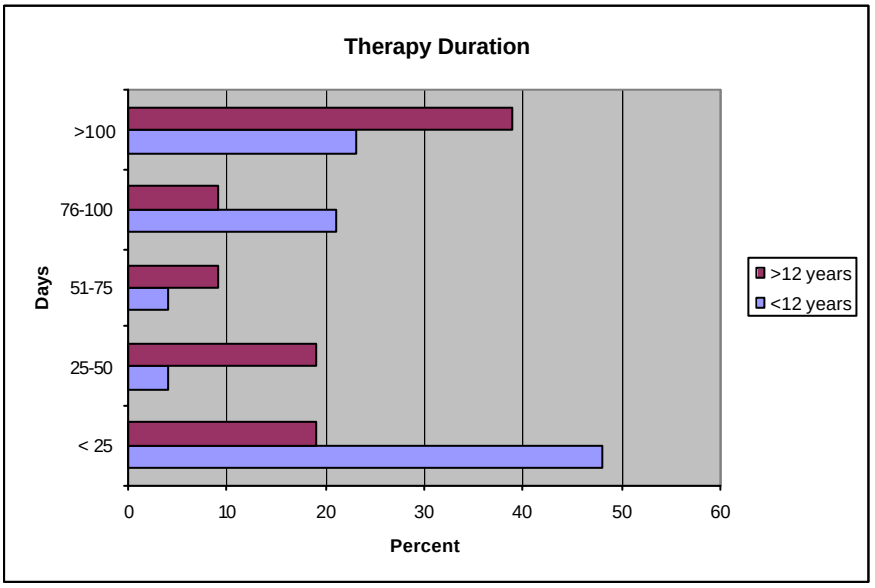
The diagnosis leading to the prescription was to be entered in the study protocol. It showed that QUENTAKEHL, according to Isopathy, is used in a very wide application range. The preferred application was independent of the patient's age. The main indications were bronchitis, sinusitis, tonsillitis and influenzal infections. A 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 of chronic diseases, the patients were asked in the study protocol how long they had 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.



Duration of Complaints (Months)	Patients < 12 years (%)	Patients > 12 years (%)	Total Patient Population (%)
< 6	55.6	12.9	22.5
6-12	0.0	6.5	5.0
< 36	11.1	25.8	22.5
> 36	33.3	54.8	50.0





Almost one quarter (22.5%) of the patients had suffered for less than six months, 5% between six and 12 months and 22.5% up to three years. Half the patients suffered for more than 36 months. In the patient group under 12 years more than half part of the patients (55.6%) suffered for less than six months and one third for more than 36 months. In the adult group over 12 years, suffering periods between one and three years (25.8%) and for more than three years (54.8%) stood clearly in the foreground. No information was available for four patients. Six patients (two under 12 and four over 12 years) of the 44 included in the study were previously treated with QUENTAKEHL.

3. Dosage and Therapy Duration

3.1. Consultation Times, Therapy Duration

According to the nature of an application study, the physicians were not given a preset time limit for the final patient assessment. The final examinations were conducted after a period of 2 to 399 days, with an average of 76.2 ± 87.5 days.

Amongst the children (< 12 years),with an average of 135.0 ± 141.3 days, the therapy was approximately twice as long compared with the adult group with 78.9 ± 86.5 days. For 40% of the young patients (< 12 years) the long therapy duration over 100 days was clearly predominant whilst 48.5% of the adults were treated only up to 25 days prepredominant whilst 48.5% of the adults were treated only up to 25 days.

3.2 Dosage

The dosage for the respective application forms was set as follows, according to the patient information leaflet:

QUENTAKEHL drops
Oral application: 1 - 8 drops daily before meals.
External application:
a) 5 - 10 drops once a day on the affected area or in the cubital fossa.
b) With injection treatment, 2x weekly 5 - 10 drops on injection-free days.

Total Population			
	medium dose	minimum dose	maxiumum dose
Capsules	2.1 ± 1.9	1	4
Drops für oral intake	9.7 ± 4.2	4	16
Drops for external application	9.0 ± 1.0	8	10
Suppositories	1.0	1	1
Injection 1 ml	1.9 ± 1.0	1	4

All patients under 12 years				
	medium dose	minimum dose	maxiumum dose	patients
Capsules	1.0	1	4	1
Drops für oral intake	11.0 ± 5.2	4	16	4
Drops for external application	9.0 ± 1.0	8	10	2
Suppositories	1.0	1	1	3

All patients over 12 years				
	medium dose	minimum dose	maxiumum dose	patients
Capsules	2.1 ± 1.0	1	4	28
Drops für oral intake	8.0	8	8	3
Drops for external application	1.0	1	1	4
Suppositories	1.9 ± 1.0	1	4	14

QUENTAKEHL injections
2x weekly 1.0 ml i.m., s.c., i.c. or i.v.

QUENTAKEHL capsules
1 - 3 capsules (with some liquid) daily before breakfast or before going to bed.

QUENTAKEHL suppositories
1 suppository once a day to insert rectally before going to bed

With respect to the administration forms, 30 patients were treated with capsules, 7 orally, 2 externally, 7 with suppositories and 14 with injections. Multiple counts were necessary if several application forms were combined. The following table states the medium dosage of the application forms. Injection volumes are related to 1x weekly, the other administration forms to the daily dosage.

In both age groups (under and over 12 years) the dosages (except capsules) were not considerable different. The dosage for capsules was twice as high for the adults compared with the group under 12 years.

Treatment was made as a monotherapy with one application form, but different administration forms were also combined. As injections were administered in a weekly rotation, 10 patients were treated additionally with capsules on injection-free days. Three patients were treated with a combination of injections, capsules and drops for oral intake. No other administration forms were combined. In the age group under 12 years, no different administration forms were combined.

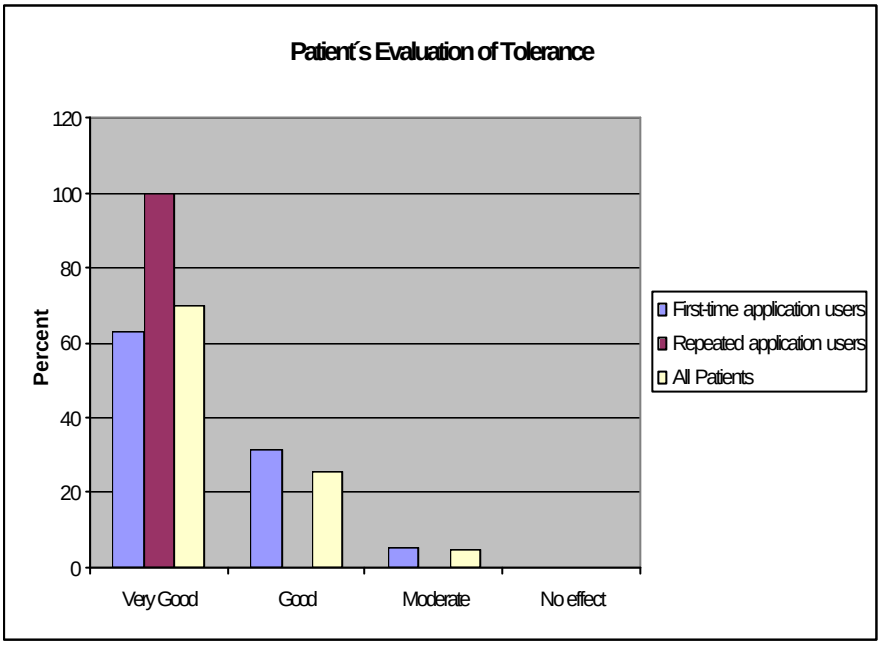
4. Comparison with former treatment

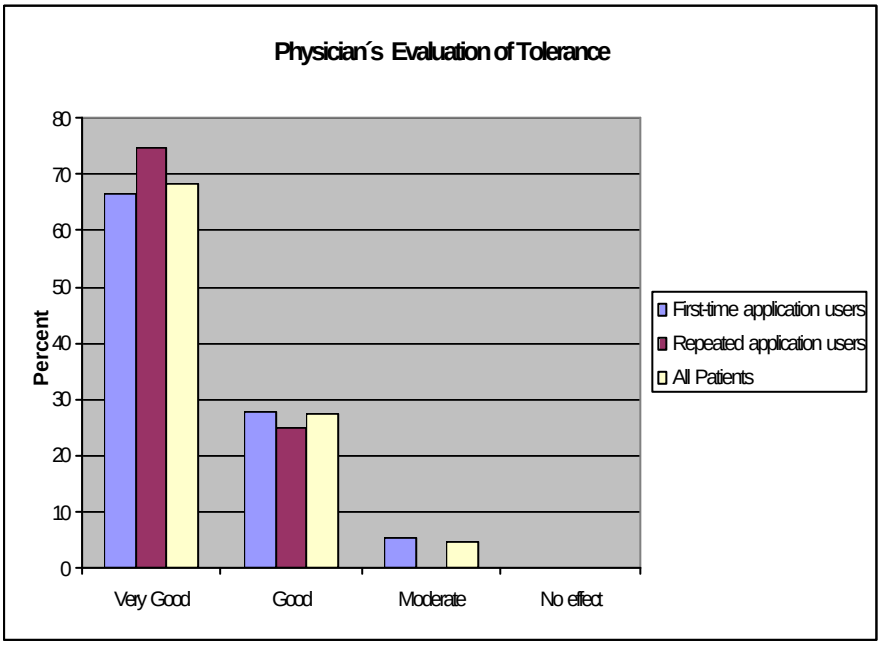
Eight patients underwent previous treatment with one or more administration forms of QUENTAKEHL during the past five years. By a comparison of efficacy and tolerance in both patient groups (first-time and repeated application users) hints for a possible sensitisation towards the ingredient should be stated.

The evaluation of tolerance was, according to tendency, better with repeated application users than with first-time users. With the tolerance being generally good, in the group of repeated application users there was a clear shifting to „very good“. In the group of repeated application users, neither patient nor physician assessed „moderate“ or „no effect“. No hazard potential by the ingredient Penicillium glabrum can be seen from these data concerning sensitisation.

The evaluation of efficacy with „very good“ was, according to tendency, better with repeated application users than with first-time users. No

Evaluation of Tolerance								
Patient Group	Patient´s evaluation (%)				Physician´s evaluation (%)			
	Very good	Good	Moderate	No effect	Very good	Good	Moderate	No effect
First-time-application users	62,9	31,4	5,7	0	66,7	27,8	5,5	0
Repeated application users	100,0	0	0	0	75,0	25,0	0	0
All patients	69,8	25,6	4,6	0	68,2	27,3	4,5	0





5 Efficacy and tolerance

5.1 Evaluation of Efficacy by Physician and Patient

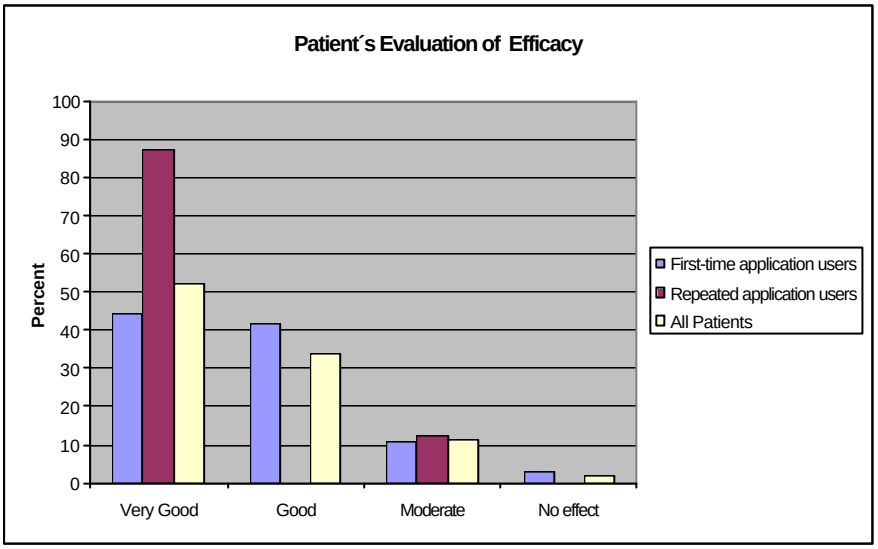
In a closing assessment, physicians and patients were asked to evaluate efficacy and tolerance. Efficacy could be assessed with „very good“, „good“, „moderate“ or „no effect“. The physician was also requested to evaluate patient compliance with „very good“, „good“, „moderate“ or „non-compliant“. The evaluation of efficacy showed that 52.3% of the patients thought efficacy to be „very good“ and 34.1% „good“, whilst 11.4% assessed efficacy with „moderate“ and 2.2% with „no effect“. The results of the physicians' evaluation for efficacy, was similarly positive as that of the patients. The physicians evaluated efficacy in 54.5% of the cases as „very good“, 27.3% as „good“, 15.9% as moderate and only 2.3% as „no effect“. The evaluation by physicians and patients alike was according to tendency better in the group under 12 years, which was exclusively assessed with „very good“ and „good“.

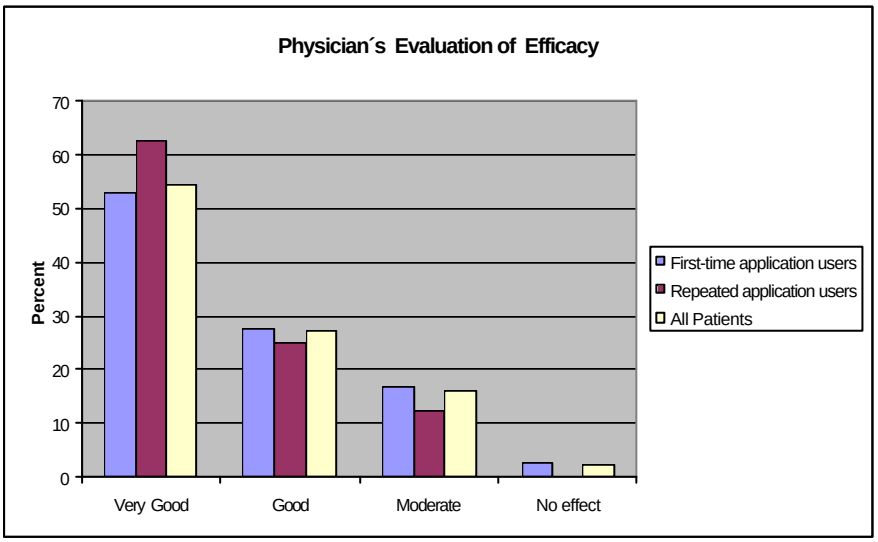
repeated application user assessed „no effect“. The differences in both groups were not significant.

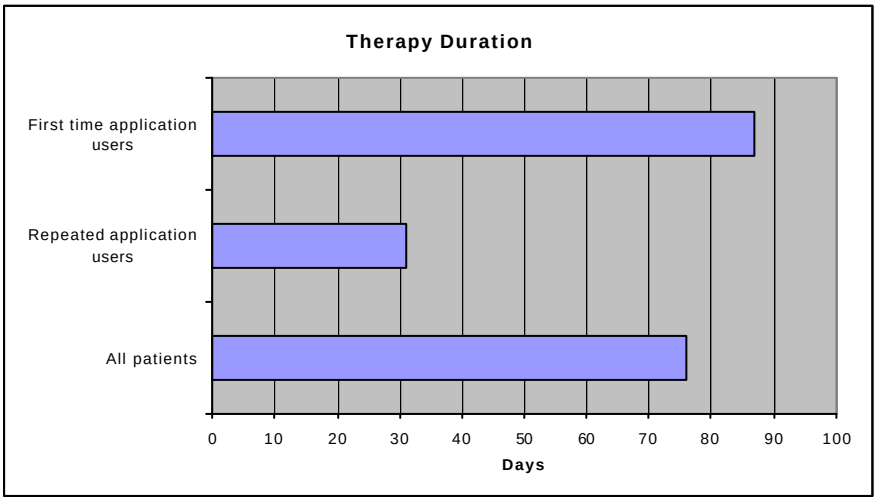
With respect to the therapy duration, there is a significant difference between repeated application (31.0 ± 26.4 days) and first-time users (86.0 ± 93.2 days) and the total of all patients (76.2 ± 87.5 days).

Compliance (N = 38) was assessed by the physicians to be „very good“ for 31 patients and „good“ for 6 patients, hence 84.1% of all patients participating in the study were given a „good“ or „very good“ compliance

Evaluation of Efficacy								
Patient Group	Patient´s evaluation (%)				Physician´s evaluation (%)			
	Very good	Good	Moderate	No effect	Very good	Good	Moderate	No effect
First-time-application users	44,4	41,7	11,1	2,8	52,8	27,8	16,7	2,7
Repeated application users	87,5	0	12,5	0	62,5	25,0	12,5	0
All patients	52,7	34,1	11,4	2,2	54,5	27,3	15,9	2,3







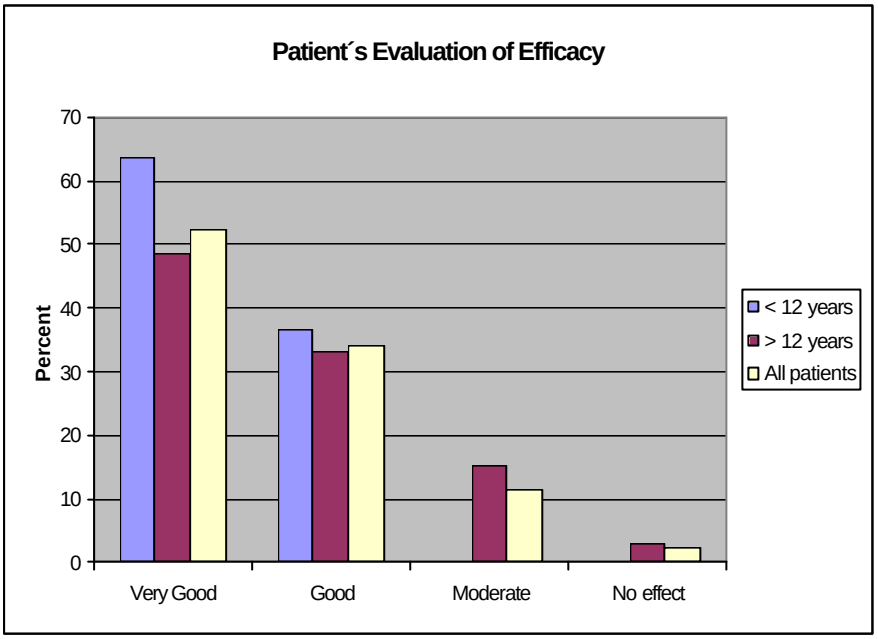
rating. One patient was given only a „moderate“ and no patient a „non-compliant“ rating.

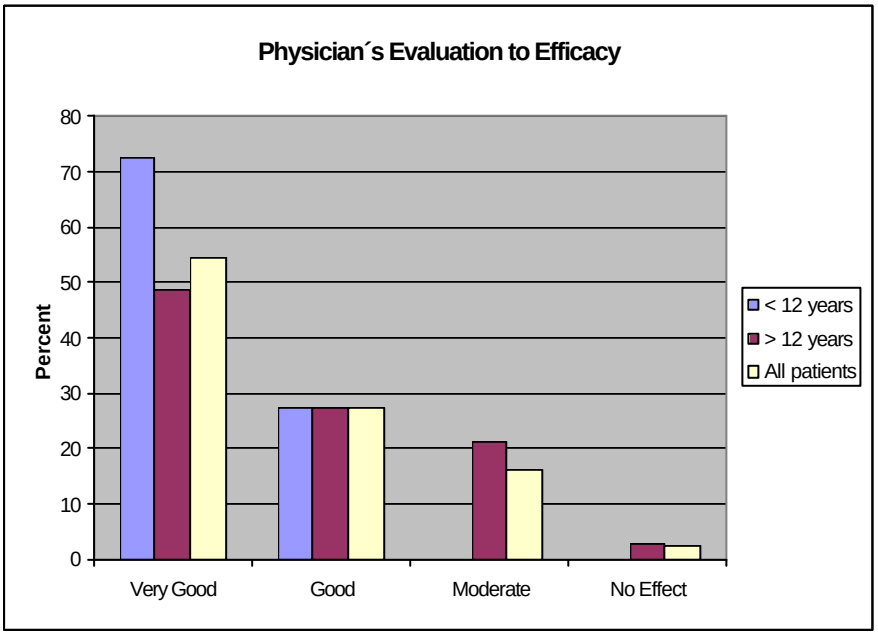
5.2 Evaluation of Tolerance by Physician and Patient

At the conclusion of the study, an evaluation of tolerance was submitted by the physicians and patients, whereby an assessment of „very good“, „good“, „moderate“ and „no effect“ could be chosen. 69.8% of patients and 68.2% of physicians rated the tolerance to be „very good“, whilst 25.6% of patients and 27.3% of physicians gave QUENTAKEHL a „good“ and 4.6% of patients and 4.5% of physicians a „moderate“ tolerance rating. No case was assessed with „no effect“.

In the children’s group under 12 years, physicians rated the tolerance with „very good“ and „good“ and was much better than that of the age group over 12 years. In the younger age group, 100% of patients and physicians alike rated tolerance to be „very good“, whilst in the group over 12 years only 59.4% of patients and 57.6% of physicians did so. No case was assessed with „no effect“ by both patients and physicians.

Evaluation of Efficacy								
Patient Group	Patient´s evaluation (%)				Physician´s evaluation (%)			
	Very good	Good	Moderate	No effect	Very good	Good	Moderate	No effect
< 12 years	63,6	36,4	0	0	72,7	27,3	0	0
> 12 years	48,5	33,3	15,2	3,0	48,5	27,3	21,2	3,0
All patients	52,3	34,1	11,4	2,2	54,5	27,3	15,9	2,3





5.3 Side Effects and Termination of Therapy

No patient discontinued the therapy with QUENTAKEHL. One side effect was reported, i.e.:

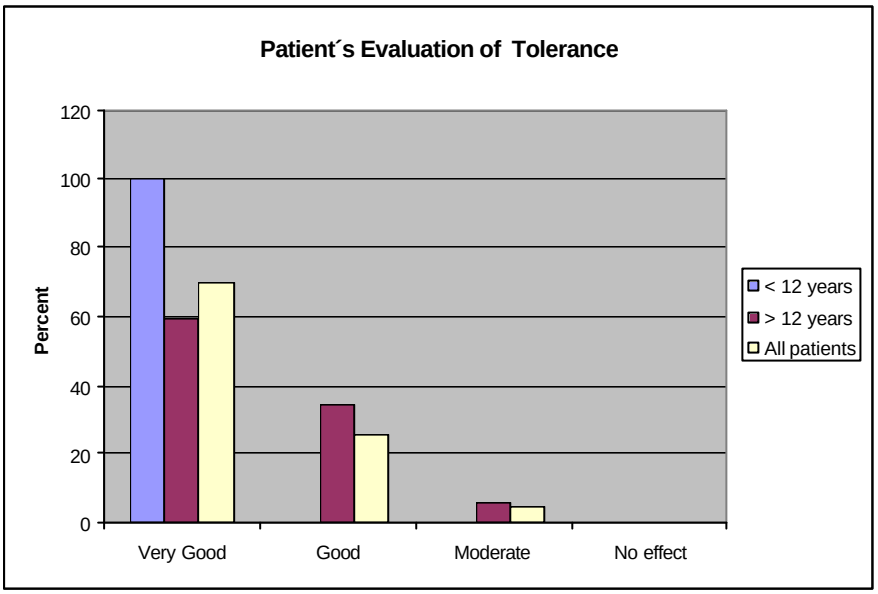
Ten days after treatment begin with 1 suppository daily, a 52 year old patient with mamma cancer, complained of diarrhoea that lasted for three days. The therapy was continued without alteration to the dosage. Presumably there is no connection with QUENTAKEHL, as at the same time a further chemotherapy had begun.

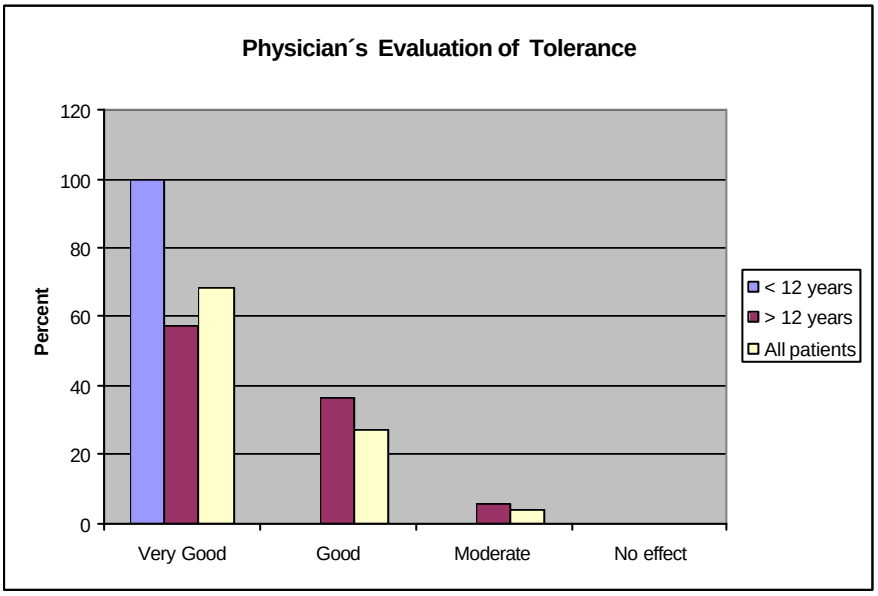
With QUENTAKEHL injection, two cases of local irritation at the injection site were reported, which disappeared without any further therapy. Concerning the other therapy forms, one patient reported „vomitus, diarrhoea, strangury and dryness of the mouth“ and for two patients „tiredness“, but there was no connection with the QUENTAKEHL therapy. No difficult controllable reactions occurred and all reported side effects were fully reversible.

6. Summary

A total number of 44 patients in seven medical practices, three specialising in internal medicine, three in general medicine and one in ENT, participated between January 1998 and December 1999 in an application study with the preparation QUENTAKEHL in different application forms: capsules, drops, suppositories and injections. The homoeopathic test preparation, QUENTAKEHL, consists exclusively of Penicillium glabrum (synonym Penicillium frequentans) in the 3rd - 6th decimal potency according to the administration form. The age of the patients varied between 6 months and 63 years. One quarter of the patients was under 12 years.

Evaluation of Tolerance								
Patient Group	Patient´s evaluation (%)				Physician´s evaluation (%)			
	Very good	Good	Moderate	No effect	Very good	Good	Moderate	No effect
< 12 years	100,0	0	0	0	100,0	0	0	0
> 12 years	59,4	34,4	6,2	0	57,6	36,4	6,0	0
All patients	69,8	25,6	4,6	0	68,2	27,3	4,5	0





QUENTAKEHL 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 bronchitis, sinusitis, tonsillitis and influenzal infections. Accompanying therapies were to be documented in the evaluation form.

Amongst the children under 12 years, the therapy lasted on average 135.0 ± 141.3 days and was approximately twice as long compared with the adult group with 78.9 ± 86.5 days. For 40% of the young patients under 12 years, the long therapy duration of over 100 days was clearly predominant, whilst 48.5% of the adults were treated only up to 25 days. The therapeutic progress was determined by evaluations conducted respectively at the beginning and end of the therapy.

86.4% of the patients and 81.8% of the physicians rated the efficacy of the therapy as „very good" and „good". 95.4% of patients and 95.5% of physicians rated the tolerance to be „very good" and „good". No therapy was discontinued. Side effects and intolerances were reported, but were all completely reversible without required additional therapy. Only in two cases (irritation at the injection site) existed a connection with the QUENTAKEHL therapy. In the age group under 12 years, the tolerance was rated much better than that in the patient group over 12 years by patients and physicians alike.

Werdorf, 8 June 2001

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