



Statistical Evaluation
of an Application Study with

EXMYKEHL 3X

in the administration form: suppositories

by Dr. Reiner Heidl
July 2001

1 Introduction

A total number of 99 patients in two medical practices, one specialising in internal medicine and one in general medicine, participated between January 1997 and February 2001 in an application study with the preparation EXMYKEHL 3X suppositories. The test preparation, EXMYKEHL 3X, consists of a combination of *Candida albicans* 3X, *Candida parapsilosis* 3X and *Penicillium roquefortii* 3X.

1 EXMYKEHL 3X suppository contains:

0.067g *Candida albicans* 3X trit. in accordance with provision 6, HAB
 0.067 g *Candida parapsilosis* 3X trit. in accordance with provision 6, HAB
 0.067 g *Penicillium roquefortii* 3X trit. in accordance with provision 6, HAB

The aim of the 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

99 patients participated in the study which comprised of 47 males (47.5%) and 52 females (52.2%). The age of the patients varied between 5 and 81 years, with an average age of 42.2 and a standard deviation of 20.6 years. 9.1% of the patients were under 12 years, between 13 and 20 years (15.2%) and between 21 and 30 years (7.1%). The age groups between 31 and 40 years (13.1%), 41 and 50 (11.1%) as well as 61 and 70 (14.1%) were approximately of the same size. The age group between 51 and 60 years (23.2%) was the largest. 7.1% of the patients were over 70 years. The males with an average age of 50.2 ± 19.7 were on the average 15 years older than the females with 35.0 ± 18.5 years.

Height varied between 115 and 190 cm with an average height of 168.6 ± 13.8 cm. The weight was between 20 and 110 kg with an average weight of 70.2 ± 17.4 kg.

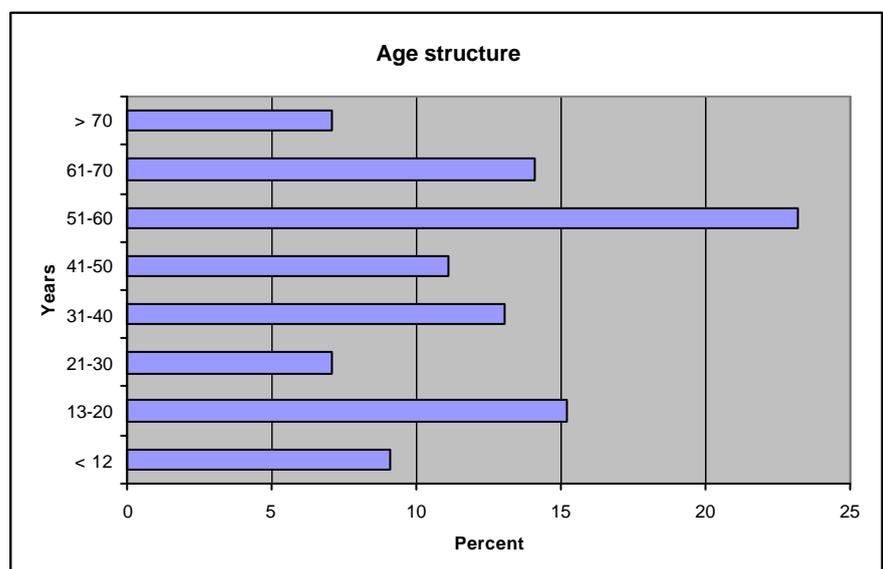
2.1 Diagnoses and Secondary Diseases

The diagnosis leading to the prescription was to be entered in the study protocol. It showed that EXMYKEHL 3X, 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 intestinal and vaginal mycoses as well as prostate hypertrophy. A diagnosis was made before the start and end of the therapy. 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.

36.7% of the patients had suffered for less than six months, 4.1% between six and 12 months and 9.2% between one and three years. Half the patients suffered for more than



36 months. In the age group under 12 years, all patients (without any exception) suffered for less than six months. In the adult group over 12 years, chronic complaints of more than three years were clearly

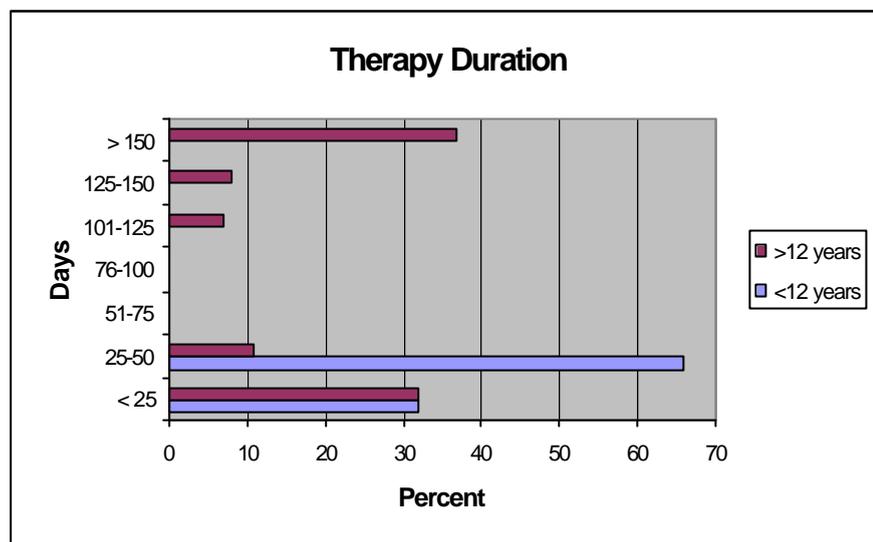
predominant (55.1). Two patients (both over 12 years) of the 99 patients included in the study had already been previously treated with EXMYKEHL 3X.

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 10 to 354 days, with an average of 106.7 ± 93.1 days.

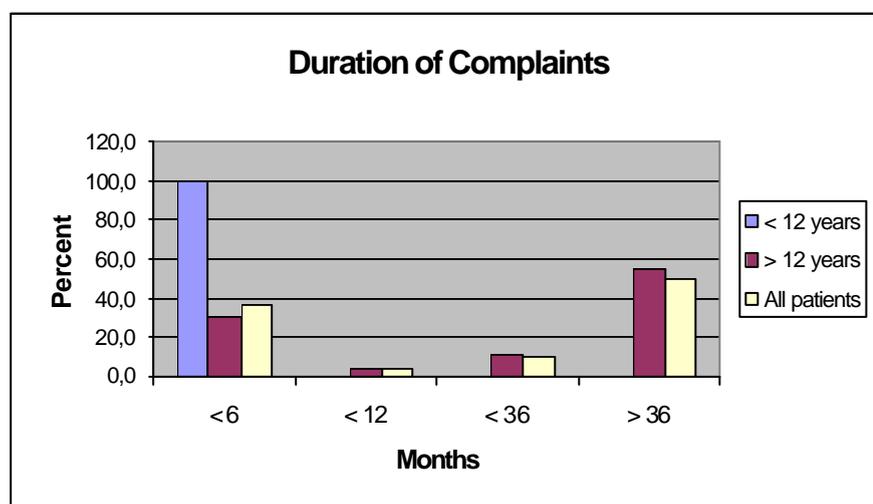
The therapy duration reflects the previous duration of complaints. Amongst the children (< 12 years) who exclusively suffered from acute complaints, the short therapy duration of 24.4 ± 5.0 days was clearly predominant. In the adult group, the therapy duration was on average 114.9 ± 93.7 days. 45% of these patients were treated up to 50 days and 55% over 100 days whereby 37.8% were treated over 150 days.



Duration of Complaints (Months)	Patients < 12 years (%)	Patients > 12 years (%)	Total Patient Population (%)
< 6	100.0	30.3	36.7
2	0	4.5	4.1
< 36	0	10.1	9.2
> 36	0	55.1	50.0

3.2 Dosage

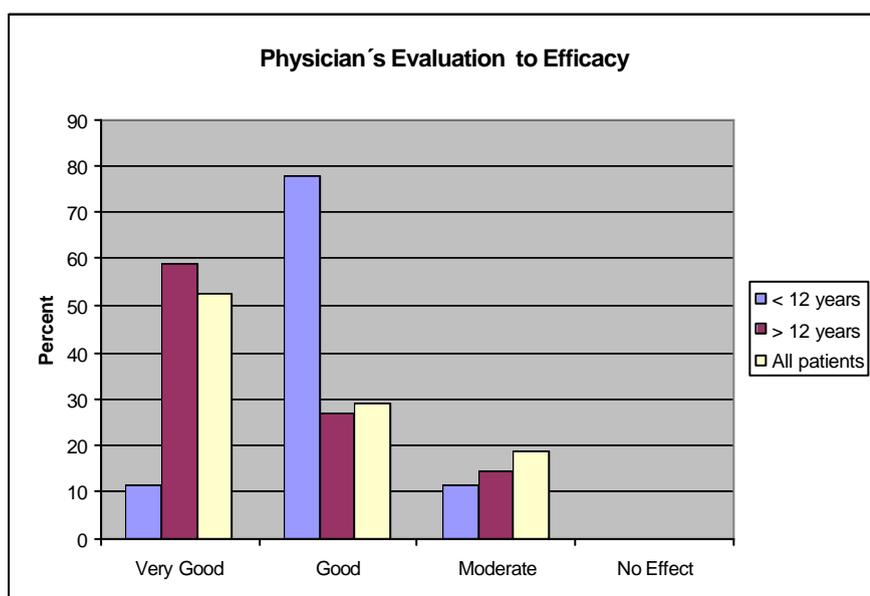
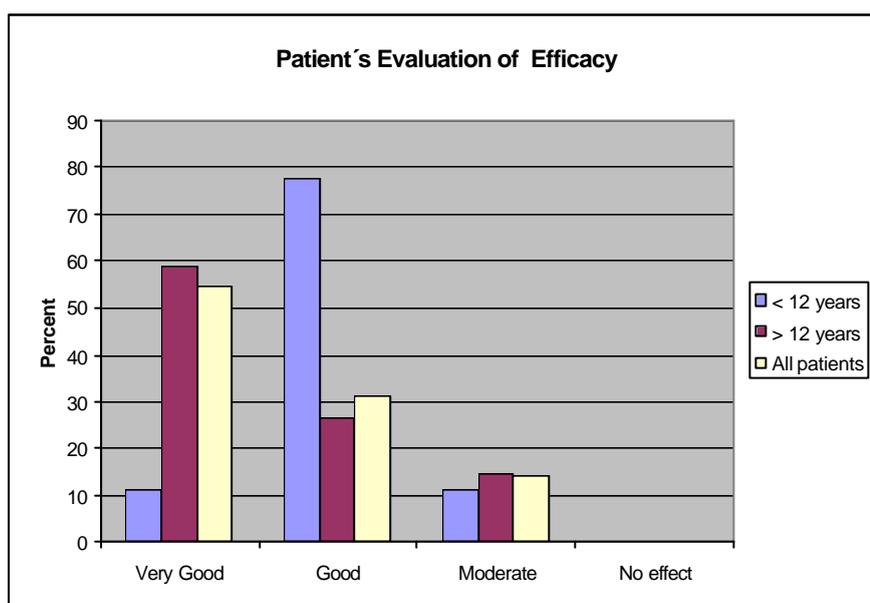
The dosage was set according to the patient information leaflet: 1 suppository 1 - 3x weekly to insert rectally before going to bed. For all patients (children and adults) the dosage was 1 suppository per week.



4. Comparison with former treatment

Two adult patients had already been treated with EXMYKEHL 3X suppositories within the past five years. By a comparison of efficacy and tolerance in both patient groups (first-time and repeated application users) hints of a possible sensitisation towards the ingredients

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	11,1	77,8	11,1	0	11,1	77,8	11,1	0
> 12 years	58,9	26,7	14,4	0	58,9	26,7	14,4	0
All patients	54,5	31,3	14,2	0	52,7	28,8	18,5	0



The therapy duration of these two patients was very brief lasting for 25 and 27 days respectively.

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 54.5% of the patients thought efficacy to be „very good“ and 31.3% „good“, whilst 14.2% assessed efficacy with „moderate“. The results of the physicians' evaluation for efficacy, was similarly positive as that of the patients. The physicians evaluated efficacy in 52.7% of the cases as „very good“, 28.8% as „good“ and 18.5% as „moderate“. Neither physician nor patient assessed with „no effect“. In the group under 12 years, in the evaluation of physicians and patients there was a shifting from „very good“ to „good“, however, the addition of the „very good“ and „good“ assessments remained the same in both age groups.

could be stated but the group of the repeated application users (2 patients) is so negligible that reliable data concerning a possible

sensitisation couldn't be produced. Both patients assessed tolerance with „very good“ and the physicians rated with „very good“ and „good“.

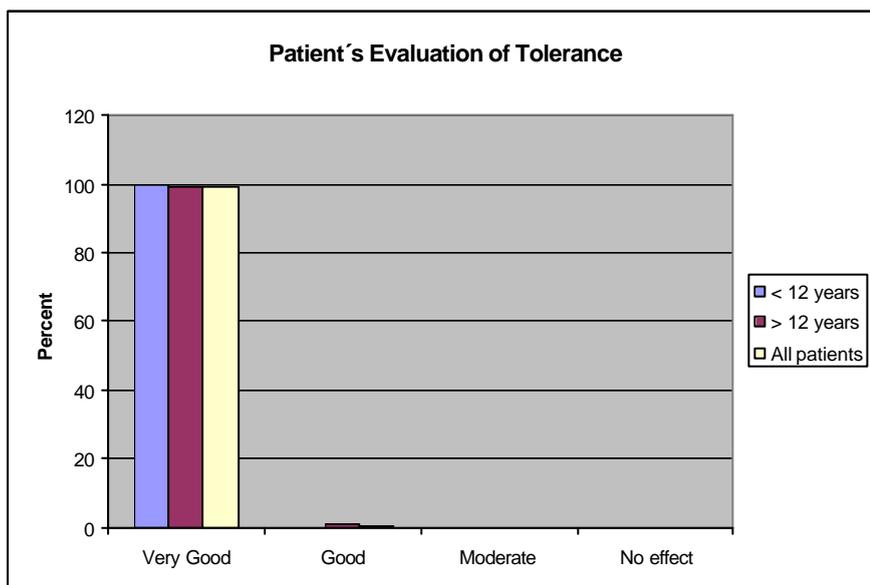
Evaluation of Tolerance								
Patient Group	Patient's evaluation (%)				Physician's evaluation (%)			
	Very good	Good	Moderate	No effect	Very good	Good	Moderate	No effect
< 12 years	100,0	0	0	0	88,9	11,1	0	0
> 12 years	98,9	1,1	0	0	97,8	2,2	0	0
All patients	99,0	1,0	0	0	97,0	3,0	0	0

Compliance (N = 99) was assessed by the physicians to be „very good“ for 82 patients and „good“ for 17 patients, hence all of the patients participating in the study were given a „good“ or „very good“ compliance 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“

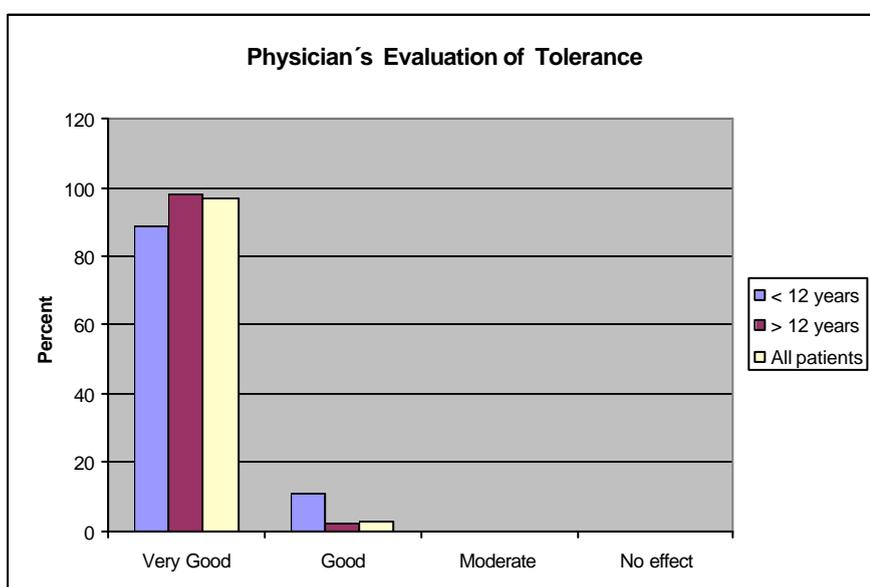
and „no effect“ could be chosen. 99% of patients and 97% of physicians rated the tolerance to be „very good“, whilst 1% of patients and 3% of physicians gave EXMYKEHL 3X a „good“ tolerance rating. No case was assessed with „moderate“ or „no effect“.



In the age group under 12 years, patients rated the tolerance exclusively with „very good“. The assessment of the physicians was more differentiated in this age group. In patient's and physician's evaluation of tolerance there was no significant difference between the age groups under and over 12 years.

5.3 Side Effects and Termination of Therapy

No patient discontinued the therapy with EXMYKEHL 3X and no side effects were reported.



6. Summary

A total number of 99 patients in two medical practices, one specialising in internal medicine and one in general medicine, participated between January 1997 and February 2001 in an application study with the preparation EXMYKEHL 3X suppositories. The homoeopathic test preparation, EXMYKEHL 3X, consists of a combination of Candida albicans 3X, Candida parapsilosis 3X and



Penicillium roquefortii 3X. The age of the patients varied between 5 and 81 years with an average age of 42.2 years.

EXMYKEHL 3X 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 intestinal and vaginal mycoses and prostate hypertrophy. Accompanying therapies were to be documented in the evaluation form.

Amongst the children under 12 years, who exclusively suffered from acute complaints, the short period therapy with 24.4 ± 5.0 days was clearly predominant. In the adult group, the therapy lasted on the average 114.9 ± 93.7 days. 45% of these patients were treated up to 50 days and the therapy duration of the remaining 55% of the patients was over 100 days,

whereby 37.8% were treated over 150 days.

Two adult patients had already been treated with EXMYKEHL 3X suppositories within the past five years. The group of repeated application users with only two patients was negligible and therefore reliable data concerning a possible sensitisation couldn't be produced.

The therapeutic progress was determined by evaluations conducted at the beginning and at the end of the therapy.

54.5% of the patients rated the efficacy as „very good“ and 31.3% as „good“, whilst 14.2% rated efficacy to be only „moderate“. The physicians' assessment of efficacy was similarly positive than that of the patients, as 52.7% of the patients were assessed with „very good“ and 28.8% with „good“, whilst 18.5% were rated with „moderate“. Neither physician nor patient rated

with „no effect“. In the group under 12 years, there was a shifting from „very good“ to „good“ in the evaluation of physicians and patients, however, the addition of the „very good“ and „good“ assessments remained the same in both age groups.

Tolerance was rated with „very good“ and „good“ by patients and physicians alike.

No therapy was discontinued and no side effects and intolerances were reported.

Werdorf, 18 July 2001

Dr. Reiner Heidl

© Copyright 2006 by Semmelweis-Institut GmbH, 27318 Hoya, Weser Germany

All Rights Reserved