Application Study with CITROKEHL for injection in children

Statistical evaluation of the important characteristics

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1. Introduction

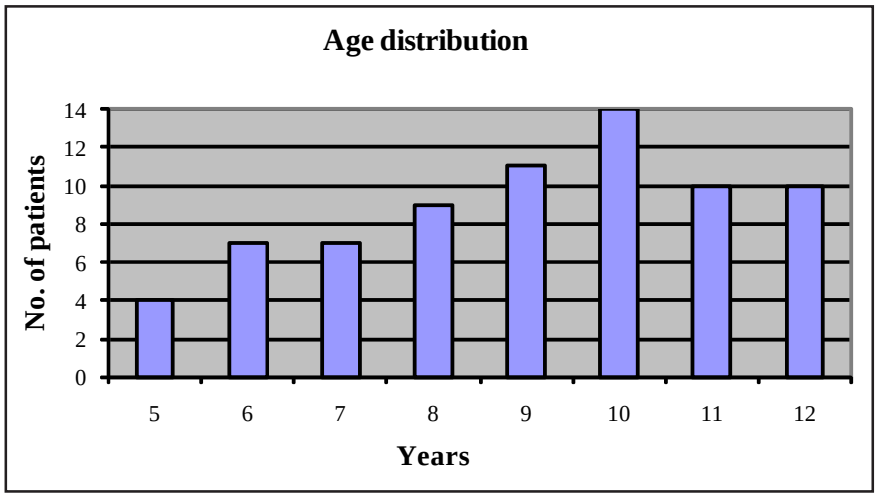
72 children in three doctor's practices were treated with the injection solution of the homeopathic remedy CITROKEHL. 1 ml CITROKEHL injection solution contains the potency chord of Acidum citricum 10x, 30x and 200x dil. as the remedially effective component in accordance with regulations 5 and 11 of the HAB [German Homeopathic Pharmacopoeia]. The aim of the clinical study was to discover the actual use of the remedy, its effectiveness and local tolerability under conditions of daily practice. All patients who received at least one dose of the remedy were taken into consideration.

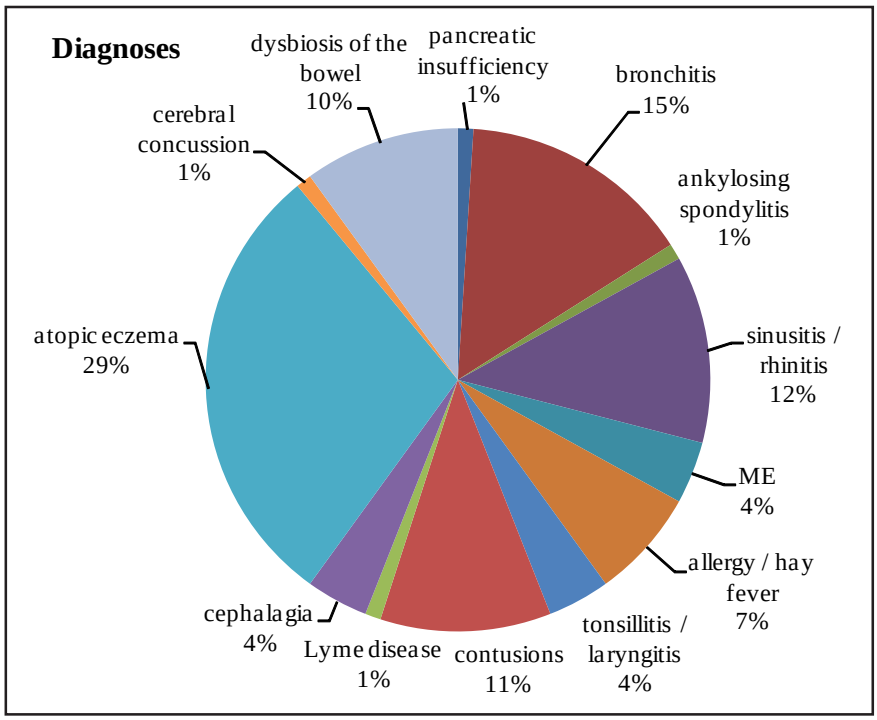
2. Participating patients

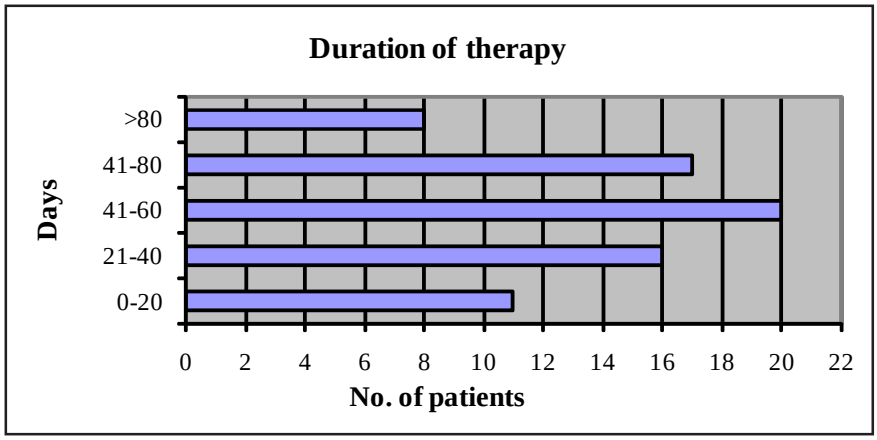
In all, 72 subjects of both sexes took part in the clinical study: 41 males (56.9%) and 31 females (43.1%). The age of the patients varied from five to twelve years with a mean of 9.1 ± 2.1 years. The male patients, with an average age of 8.7 ± 2.1 years, were about 10% younger than the female patients who had an average age of 9.5 ± 1.9 years. Their heights varied between 85 and 167 cm with a mean of 132.9 ± 20.9 cm (girls 133.0 ± 22.3 cm; boys 132.9 ± 19.9 cm). Their weights were between 18 and 60 kg with a mean of 35.3 ± 9.0 kg (girls 36.2 ± 7.7 kg; boys 34.6 ± 9.9 kg).

2.1 Diagnosis and accompanying diseases

The diagnosis leading to the prescription had to be declared in the study protocol. The spread of diagnoses and associated diseases resulted from the varied uses according to the homeopathic remedy picture. It turned out here that the use of the remedy was preferred in cases of atopic eczema, bronchitis and sinusitis. Almost 50% of the patients treated came from these areas of indications.







In order to obtain a measure of the chronic illnesses, a question was asked in the study protocol about how long the illness or problems had existed. Here, the choice was less than six months, up to one year, up to three years or over three years. For 25 subjects (=35.7%), the problems had been present for less than six months. The 22 patients (= 31.4%) who had already had problems for more than three years were the next largest group. 16 patients (= 22.9%) stated a period of 6 months to one year and seven patients (= 10%) between one and three years. Two patients did not reply to this question.

Of the 72 patients involved in the study, only one (an 11-year-old boy with acute sinusitis) had already been treated with CITROKEHL. No complications had arisen at the time of this earlier treatment.

3. Dosage and duration of treatment

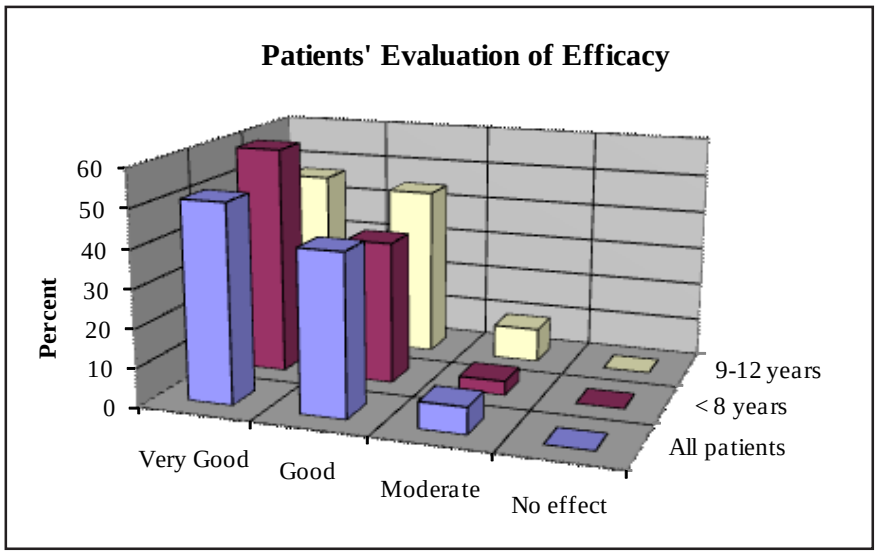
3.1 Time of consultation and duration of treatment

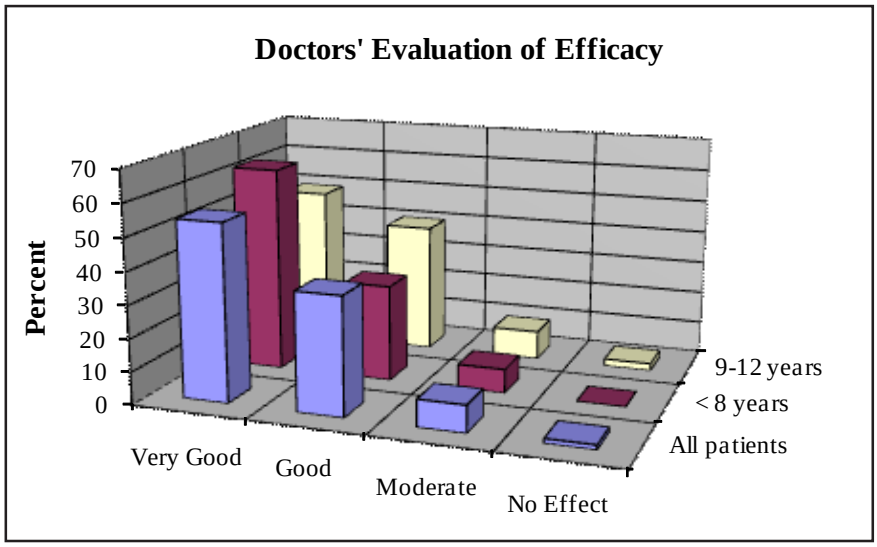
As appropriate for the nature of a clinical study, no firm time scheme was given to the doctor for a final examination. This final examination was carried out in a period of between 7 and 161 days with a mean of 51.8 ± 28.7 days.

The duration of the treatment in female patients (53.9 ± 27.8 days) was comparable with that of the male patients (50.1 ± 29.2 days).

3.2 Dosage

The dosage was prescribed as on the package leaflet: 2 ml to be injected i.m. one to three times weekly. The average dosage was 4.7 ± 1.7 ml per week, with a minimum dose of 1 ml and a maximum dose of 8 ml per week. If all the patients are divided into two age-groups, up to eight years and from nine to twelve years, it can be established that the same dosages were given in these two age-groups. The patients up to eight years of age received 4.5 ± 1.7 ml, and the





Evalulation of efficacy								
Patient Group	**Patients' evaluation (%)**				**Doctors' evaluation (%)**			
	Very Good	Good	Moderate	No Effect	Very Good	Good	Moderate	No Effect
All Patients	51.4	41.7	6.9	0	54.2	36.1	8.3	1.4
< 8 years	59.3	37.0	3.7	0	63.0	29.6	7.4	0
9-12 years	46.7	44.4	8.9	0	48.9	40.0	8.9	2.2

Evaluation of tolerance								
Patient Group	**Patients' evaluation (%)**				**Doctors' evaluation (%)**			
	Very Good	Good	Moderate	Poor	Very Good	Good	Moderate	Poor
All Patients	97.2	2.8	0	0	98.6	1.4	0	0
< 8 years	96.3	3.7	0	0	96.3	3.7	0	0
9-12 years	97.8	2.2	0	0	100.0	0	0	0

patients between the ages of nine and twelve years received 4.8 ± 1.6 ml per week.

4. Efficacy and tolerance

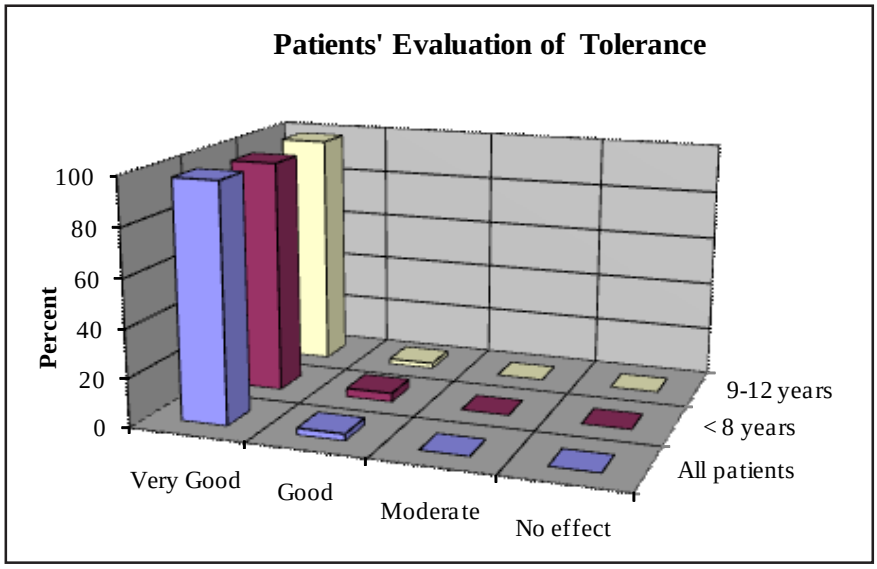
4.1 Evaluation of efficacy by doctor and patient

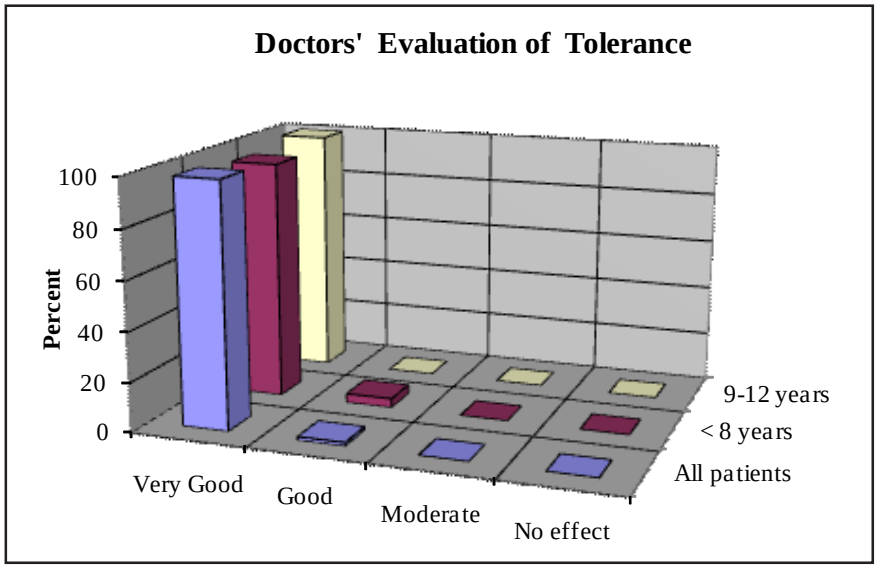
In a final assessment, the doctor and patient were asked to assess effectiveness and tolerability. The effectiveness could be assessed as "very good", "good", "poor" or "no effect". All the patients and all the doctors expressed an opinion on the effectiveness. 37 patients (51.4%) classed the effectiveness as "very good", whilst 30 patients (41.7%) said it was "good" and five patients (6.9%) said it was "poor". None of the patients questioned the effectiveness.

The doctors' assessment turned out to be just as positive as that of the patients. The doctors assessed the effectiveness for 39 patients (54.2%) as "very good" and for 26 patients (36.1%) as "good". In six patients (8.3%), the doctors saw only a poor effect, and in one patient (1.4%) no effect. In the under-8s age group, the effectiveness tended to be evaluated more as "very good" by both doctor and patient him/herself. There are no significant differences between the two age groups in their assessment of effectiveness.

4.2 Evaluation of tolerance by doctor and patient

At the conclusion of the investigation, doctors and subjects gave their assessment of tolerability; they could choose between "very good", "good", "poor" or "bad". All the patients and all the doctors expressed an opinion on the tolerability and assessed it only as "very good" or "good". In total, 70 patients (97.2%) assessed it as "very good" and two (2.8%) as "good". In the opinion of the doctors the rating was "very good" for 71 patients (98.6 %) and "good"





for one patient (1.4%). This excellent result applies to both the under-8s age-group and the nine- to twelve-year-olds. The doctors' opinion on tolerability in the nine- to twelve-year-olds' group was 100% "very good".

4.3 Side effects and discontinuation of the therapy

No patient discontinued therapy with CITROKEHL. No side-effects or undesirable incidents were observed.

First published in the German language in the SANUM-Post magazine (49/ 1999)