Criteria for the Differential Indication of Asthma Education versus Asthma Instruction for Families of Preschoolers: Results from the Randomized DIAT^2 Study (Differential Indication of Asthma Trainings in Toddlers)

Kriterien für die Differenzielle Indikation für Asthmaschulung und Instruktion im Vorschulalter: Resultate der randomisierten DIAT^2-Studie

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Key words
- asthma
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Schlüsselwörter
- Asthma
- Kleinkinder
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Abstract

Background: Asthma management of preschoolers is more improved by a family oriented psycho-educational program provided by a multiprofessional team than by a short instruction alone. For some families however an instruction could be sufficient. Criteria to assign education or instruction to asthmatic schoolchildren (DIA) have been evaluated [12]. This paper describes the use of those criteria in the Preschoolers' and parents' asthma education trial (P^{2}AET) [14].

Patients: DIA at study entry were available of 233 children (aged 2–5 [mean 3.9] years) participating in the randomised controlled P^{2}AET (education, instruction, waiting group). Children had been included after having at least 3 obstructive episodes in their life plus chronic or recurrent wheeze in the 6 months before the start of the study. 74% were on inhaled corticosteroids.

Methods: Logistic regression procedures were used to assess the predictive value of DIA and possible confounders on the success of the interventions (education and instruction).

Results: Regarding the outcome "better in asthma management test" education is superior to instruction (OR 5.2; CI 1.7–16). DIA "quarrel about inhalation" indicates an even greater advantage of education (OR 19; CI 2–176). An equal high advantage was found, when there was NO "need for peer support" (OR 11; CI 2–64).

Conclusion: Families with asthmatic preschoolers displaying dysfunctional interaction, which can only be corrected in an educational process, should be provided with the psycho-educational program promptly.

Zusammenfassung

Hintergrund: Das Asthmamanagement von Vorschulkindern kann durch eine multiprofessionelle familienorientierte Schulung stärker verbessert werden als durch eine Instruktion [14]. Für einige Familien ist aber möglicherweise die Instruktion ausreichend, während für andere unmittelbar Schulungsbedarf besteht. Für Schulkinder sind Kriterien für die differenzielle Indikation zur Asthmaschulung (DIA) evaluiert [12]. Diese Arbeit beschreibt die Anwendung dieser Kriterien auf die Kinder und ihre Familien, die an der Studie zur Evaluation der Asthmaschulung im Vorschulalter (P^{2}AET) teilnahmen.

Patienten: Von 233 Kindern (2–5 [Durchschnitt 3,9] Jahre alt), die an der dreiarmigen (Schulung, Instruktion, Wartegruppe) P^{2}AET-Studie teilnahmen, lagen die initial erhobenen DIA vor. Zum Einschluss mussten die Kinder mindestens 3 obstruktive Episoden in ihrem Leben gehabt und in den letzten 6 Monaten ein intermittierendes oder persisitierendes Asthma haben. Regelmäßig Kortison inhalierten bei Einschluss 74%.

Methode: DIA und mögliche Störgrößen wurden in statistischen Modellen auf die Vorhersage für den Interventionserfolg (Schulung vs. Instruktion) getestet.

Ergebnisse: Beim Endpunkt „Verbesserung im Asthma-Management-Score" ist die Schulung der Instruktion überlegen (OR 5.2; CI 1,7–16). Besteht „Streit bei der Therapieanwendung" ist der Vorteil der Schulung noch größer (OR 19; CI 2–176), ein ähnlich erhöhter Vorteil (OR 11, CI 2–64) besteht, wenn KEIN „Bedarf für soziale Unterstützung" besteht.

Schlussfolgerung: Familien mit asthmatischen Vorschulkindern, in denen eine dysfunktionale Interaktion beobachtet wird, sollten unmittelbar eine multiprofessionelle familienorientierte Schulung erhalten.

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Introduction

In Germany 950 000 children and adolescents suffer from asthma [2]. It is a requirement of both the national asthma guidelines (NVL) [10] and of the national disease management program [4] that each of these children and adolescents is educated regarding her or his asthma. The certified educational program [1, 13] which has been implemented is effective with respect to its interdisciplinary approach and use of a family-orientated curriculum. However, because the program includes 30 units of 45 min each, it takes a great deal of time and effort, on both the providers' and the families' sides, to complete.

For these reasons, it has been questioned whether indeed every child with asthma needs the full educational program, or, whether in some cases a briefer instruction might be equally effective. An asthma instruction consists of training with the inhalation device, plus explanation and a handout regarding asthma treatment and emergency plans. This reflects the minimum requirement, as defined by the national asthma guidelines.

In the **DIA** (**D**ifferential **I**ndication for **A**sthma training program for children and adolescents) study [12] which looked at German schoolchildren, Schulte im Walde et al. characterized those children and families for whom an adequate asthma (self-) management could not be accomplished through instruction alone. These children and their families were described as: (1) having first degree relatives themselves struggling with asthma; (2) being unable (either the child or the parents) to reliably assess the degree of asthma severity; (3) experiencing – as the child – a feeling of fear or anxiety (German: Angst) with respect to asthma; (4) experiencing – as the parents – a feeling of fear or anxiety with respect to asthma; (5) having family quarrels when asking to do or when executing the inhalation therapy; and (6) expressing need for peer support.

In 2010, Szczepanski et al. [14] in the **P**reschoolers' and **P**arents' **A**sthma **E**ducation **T**rial (P^2AET) were able to demonstrate that in children aged 2–5 years, asthma education was superior to instruction with respect to successful asthma management. Furthermore, in children having need of continuous corticosteroid inhalation, the education program lowered the number of emergency visits, as compared to instruction.

The question, however, is which children and families may be adequately supported by an instruction alone. Therefore, our study asked whether the above-mentioned characteristics might be able to identify the "difficult to train" families in P^2AET as well.

Patients and Methods

P^2AET is a randomized, controlled trial with 2 interventions (education, instruction) and with one control group waiting 6 months for the intervention. In this multicenter (15 cities) study, children from 24 to 60 months of age were included. In order to be included in the study, they must have had 3 or more episodes of wheezing in their lives, plus recurrent or chronic wheezing in the 6 months prior to the start of the study, as witnessed by their primary health care physician. This physician also was required to state which of the DIA characteristics applied to the child and her or his family. Asthma severity was assessed according to the questions of the ROSIER-Score [11], which may be applied to this age group.

Both the instruction and the education were given in groups of 6–8 families. The instruction lasted one hour and was aimed at the teaching the goals of the NVL. By contrast, the education was given in a series of group trainings (9.5 h each, usually divided into 3 sessions), plus personalized inhalation training with each child. This standardized family-oriented psycho-educational program was taught by an interdisciplinary team. The outcome variables regarding knowledge, skills, and competencies were the same as those used by the certified program of AG Asthmaschulung [1].

The success of the intervention (education vs. training) was measured by the following outcomes, which are also goals of the German asthma disease management program:

1. Having a written medication and emergency plan at hand.
2. Being able to help the asthmatic child according to the asthma emergency management guidelines.
3. The number of emergency visits.

Besides asthma severity, the following circumstances were also regarded as possible confounders in a logistic regression model: 1) a hospitalization due to asthma before study entry, as it could result in feeling of fear or anxiety with asthma; and 2) the need for continuous inhalation of corticosteroids, as this is known to result in family quarrels regarding inhalation practice.

With regard to the outcome "number of emergency visits", the availability of a systemic corticosteroid as emergency medication also was taken into account as a confounder.

The study was approved by the Medical Ethics Committee of the University Hospital Freiburg, and the participating families had to sign an informed consent document.

Statistical methods

Data were analyzed with SAS 9.2. Group comparisons of binary endpoints were conducted by means of the χ^2 test. Multivariate logistic regression models were used to investigate the impact of potentially influential factors for the endpoints describing success of the education program at 6 months (written emergency plan at hand, improvements in asthma management test, less emergency visits). Results are presented in terms of odds ratios (ORs) with accompanying 2-sided 95 % confidence intervals (CI). Odd ratios describe the risk ratio between 2 groups, and as the logistic regressions model success probabilities, an OR > 1 indicates a higher chance of success within the respective group.

We focused on comparing the intervention success in the instruction group vs. the education group. First, we conducted a variable selection procedure (backward elimination with $p = 0.1$) in order to determine relevant factors among a list of hypothetically influential factors [12], separated for each success variable. (Confounders describing asthma severity at study entry included: continuous inhalation of corticosteroids; number of emergency visits >0 in the 6 months before study entry; number of asthma hospitalizations >0 in the 6 months before study entry. Confounders describing asthma management at study entry included: Having a written management plan at hand, having the prescribed drugs at hand.) Subsequently, selected factors were entered into a logistic model together with the group indicator (instruction vs. education) in order to present an adjusted estimate of the education program's impact.

To address the question whether DIA can be used to determine the best measure (education or instruction) for a specific child, we investigated a possible intervention*DIA interaction. We therefore compared ORs for the education program impact within subgroups stratified according to DIA answer. Unadjusted ORs from two by two tables and adjusted ORs from logistic regression are presented, calculated with SAS PROC FREQ and PROG LOGISTIC. Homogeneity of ORs is tested via the Breslow-Day test [3].

Table 1 Characteristics of patients and families at point of study entry: items from the Differential Indication for Asthma training program for children and adolescents study [12].

	P²AET intervention								
	education			instruction			control		
n	79			75			79		
DIA characteristics (%)	Yes	No	Don't know	Yes	No	Don't know	Yes	No	Don't know
assessment difficulties	41	49	10	42	51	7	44	48	8
child with fear/anxiety	21	60	19	20	53	26	20	60	20
parents with fear/anxiety	72	20	8	75	21	4	71	26	3
quarrel about inhalation	34	63	3	37	61	3	40	56	4
need for peer support	68	28	4	65	23	12	53	39	8
relatives struggling with asthma	41	53	6	40	52	8	43	53	4

Results

Patients

The recruitment of the P²AET participants has been described by Szczepanski et al. [14]. In this paper, we report only on the subgroup of children for whom the DIA-items were available. Differences in numbers reported arise from missing values in the DIA-items or outcome variables. The number of probands were as follows (randomized in P²AET – analyzed in P²AET – analyzed in DIAT²): the education group 112–94–79; the instruction group 110–90–75; and the waiting control group 116–104–79.

The participants had a mean age of 3.9 years. Due to the multicentric nature of the study, they represented a mixture of both an urban and rural German population.

Table 1 displays the frequencies of DIA characteristics (equally distributed) for the different intervention groups. We also tested whether asthma severity had an influence on the frequency of DIA characteristics. Using a modified Rosier-Score [11] the probands were assigned to a group with not-so-severe asthma (Score up to 8) and to a group with medium-severe and severe asthma (Score above 8). The equal distribution of the DIA characteristics (**Table 2**) shows that assignment of DIA characteristics and severity of asthma are unrelated.

Intervention and its differential indication

Table 3 demonstrates that this subgroup of P²AET patients was helped significantly more through an education than through instruction, with respect to achieving the stated asthma training goals. Through the education program, an improvement in the asthma management score was achieved 5 times more often than through instruction alone, an effect that was maintained for a period of 6 months or longer.

The decision regarding which group of patients and their parents should be targeted through an education program may be informed by the results shown in **Table 4**. These data show that the effects of the intervention varied considerably among DIA stratified groups, although heterogeneity could not be confirmed by the Breslow-Day test.

Families with "quarrel about inhalation" do considerably better after education (OR 18.7; CI 2–167) than after instruction, a point which is less marked in those who do not "quarrel about inhalation" (OR 2.44, n. s.). "Feelings of fear or anxiety with respect to asthma" in parents do not seem to have a significant impact regarding the relative superiority of education as an approach. In turn, for families who are helped by "peer support", the education program has no obvious advantage over the instruction approach (OR 3.2, n. s.), whereas in cases where "peer support" was not considered helpful, the interdisciplinary education program should be considered a first choice (OR 12.5, CI 2.2–70).

Table 2 Characteristics of patients and families at point of study entry (DIA [12]) and asthma severity during the last 6 months (Rosier Score [11]) (n = 233).

	DIA characteristics present (%)		
Asthma severity (Rosier-Score)	0–8 (n = 133)	>8 (n = 100)	p*
assessment difficulties	42.1	42.0	1
child with fear/anxiety	16.6	25.0	0.16
parents with fear/anxiety	71.4	74.0	0.77
quarrel about inhalation	32.3	44.0	0.12
need for peer support	61.6	63.0	0.94
relatives struggling with asthma	40.1	43.0	0.76

* χ^2-test (continuity adj.) on all answers (yes vs. no/don't know)

Discussion

Those preschool children with asthma who quarreled about inhalation and who were not helped by peer support were more likely to benefit from education than instruction only. The differences in the effect size were substantial. Small numbers might explain why the Breslow-Day, (which is not powerful), failed to rule out homogeneity.

This observation was made in the P²AET multi-center, prospective, randomized trial which studied 2–5-year-old asthmatic children in order to compare the efficacy of standard instruction with that of an educational program. Indeed, education proved superior to instruction, especially among those taking inhaled corticosteroids [14]. This specific finding is in line with more general evidence regarding efficacy of asthma training and education [5, 7, 15, 16]. However, as an education program requires more time, effort and financial expenditure to complete, it was worthwhile to determine, which families should receive this intervention with priority. DIAT² used a set of characteristics which had been validated in German schoolchildren with asthma in order to assign to them the appropriate method of training, either instruction or education [12].

In DIAT², too, education was superior to instruction for the purpose of empowering the families to cope with asthma. In contrast to what has been found in schoolchildren, only 3 of the DIA characteristics were kept in the statistical model which was used to search predictors for a higher effectiveness of an educational program.

outcome	N	education (n/N)	instruction (n/N)	difference (χ^2-Test, continuity adjusted)
emergency plan in writing at hand*	134	36/69 (52.2%)	21/65 (32.3%)	p = 0.032
better in asthma management test**	118	56/61 (91.8%)	39/57 (31.4%)	p = 0.0003
less emergency visits***	134	37/69 (53.6%)	35/65 (53.9%)	p = 1

* no plan presented at study entry, but at the 6-month control; 10 in each instruction group had a plan at hand at point of study entry

** higher scores in the test at 6 months after the intervention as compared to the test at study entry; participants having only one test result are not reported

*** comparing the 6 months before study entry with the 6 months after the intervention; 10 in each instruction group had no emergency visits before study entry

Table 3 Effects of the type of intervention upon the key outcomes of asthma training, as defined by the National Asthma Guideline [NVL, 10].

Table 4 Success of the education program: Outcome "Higher scores in the asthma management test 6 months after the intervention" education compared to the instruction group stratified by DIA characteristics.

Population/subgroup		Unadjusted ORs (95% CI)	Adjusted ORs by logistic regression* (95% CI)	Breslow-Day test for homogeneity of ORs (p value)
ALL (complete cases, n = 117)		5.31 (1.81; 15.5)	5.24 (1.70; 16.1)	
DIA: need for peer support	yes (N = 77)	3.20 (0.78; 13.1)	3.29 (0.78; 13.8)	0.23
	no (N = 40)	12.5 (2.23; 70.2)	11.18 (1.95; 64.0)	
DIA: quarrel about inhalation	yes (N = 39)	18.7 (2.09; 167.3)	19.0 (2.04; 176.9)	0.10
	no (N = 78)	2.44 (0.65; 9.1)	2.90 (0.74; 11.4)	
DIA: parents with fear/anxiety	yes (N = 89)	4.30 (1.41; 13.1)	4.12 (1.32; 12.9)	0.37
	no (N = 28)	→∞ (not estimable)**	→∞ (not estimable)**	

* controlling for DIA "Need for peer support", "Quarrel about inhalation"

** due to empty cells in the two by two table

Regarding the learning goal "asthma emergency management" the most prominent predictor was "quarrel with inhalation". This seems understandable, as quarreling indicates a dysfunctional interaction, which can only be corrected through an educational process and not through a single instruction. In turn, families who are regarded as functional if they only receive "peer support", might only need instruction in order to be able to adequately manage their asthmatic child.

Because the majority of the patients had not-so-severe asthma, and due to the short observation period as well as the small sample size, we were not able to deduce differential indications using the outcome for "emergency visits". Thus, one apparent weakness of DIAT^2 is its sample size. This results from the fact that the study was only embedded in P^{2}AET, for which the power calculation had been made. Because only a few DIA characteristics were meaningful in toddlers, it seems advisable to look out for and to evaluate additional predictors.

Identifying children at risk for lifelong health problems and preventing those problems through education is also an aim in another childhood epidemic: obesity. Intervention programs in families with obese children in Germany show that they help most when they are initiated very early [8], that they must be educational and interdisciplinary [9], and that they will have nearly no effect if first administered as late as adolescence [6].

In conclusion, DIAT^2 demonstrates that in 2–5-year-old asthmatic children, an education program is superior to instruction for the purpose of achieving adequate asthma emergency management. This is especially so in families who already experience quarrel with the inhalation. DIAT^2 also provides a basis upon which the differential indication of asthma training interventions in toddlers may be studied.

Conflict of interest: The authors have no conflict of interest to disclose.

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