

Self-management teaching programs and morbidity of pediatric asthma: A meta-analysis

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Background: Self-management teaching programs are becoming an important asset in the management of pediatric asthma.

Objective: The study was designed to evaluate the impact of self-management teaching programs on the morbidity of pediatric asthma.

Methods: The meta-analysis included randomized clinical trials, published between 1970 and 1991, addressing the outcome of morbidity. Studies were retrieved from searches of MEDLINE, American Journal of Nursing International Index, and Dissertation Abstracts Online Database. The quality of studies was assessed with the scale of Chalmers. The pooled effect size was calculated by the method of Hedges.

Results: The literature search retrieved 23 randomized clinical trials, but 12 studies had to be excluded. Global score of quality of studies (Chalmers' scale) was fair, $51.6\% \pm 9.9\%$. As indicated by the effect size (ES) of the pooled studies, self-management teaching did not reduce school absenteeism (ES: 0.04 ± 0.08), asthma attacks (ES: 0.09 ± 0.14), hospitalizations (ES: 0.06 ± 0.08), hospital days (ES: -0.11 ± 0.08), or emergency visits (0.14 ± 0.09).

Conclusion: Self-management teaching programs do not seem to reduce morbidity, and future programs should focus more on intermediate outcomes such as behavior. (*J ALLERGY CLIN IMMUNOL* 1995;95:34-41.)

Key words: Pediatric asthma, morbidity, self-management, teaching programs, meta-analysis

Asthma is the most common chronic disease of childhood. The 1988 U.S. National Health Interview Survey, in which data from a nationally representative sample of 17,110 children younger than 18 years of age were used, estimated that 2.7 million children had experienced symptoms of asthma in the past year.¹ The impact on the everyday life of the child and his family is quite impressive in terms of school absenteeism,^{1,2} hos-

pitalizations,^{1,3,4} and emergency visits.³ In an effort to alleviate the morbidity associated with asthma, education of the child and his family on self-management skills is mandatory, and many programs have been developed over the past 20 years. Several narrative reviews⁵⁻¹³ have evaluated the existing literature on pediatric asthma self-management and demonstrated positive results of some programs and inconclusive results of others. They also pointed out the methodologic flaws of the evaluation studies.

Meta-analysis is an overview that combines statistically the results from a number of studies, after reviewing their scientific quality, in order to summarize the outcome of a particular medical intervention.¹⁴ We undertook a meta-analysis of randomized clinical trials of self-management teaching programs for childhood asthma to assess their impact on the morbidity of asthma. We elected to include in the meta-analysis only the randomized, controlled clinical trials because they

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are generally free of major biases because of randomization, inclusion of all randomized patients in "intention to treat" analyses, and outcome assessment performed by blinded observers.¹⁵

METHODS

Search of studies

A literature search of all studies, in either English or French, published between 1970 and 1991, was performed with the key words *asthma*, *education*, and *self-management programs*. Studies were identified through searches of *MEDLINE*, *Index Medicus*, *American Journal of Nursing International Index*, *Dissertation Abstracts Online Database*, and the bibliography of retrieved studies. Authors of preliminary or pilot studies were contacted in an attempt to obtain further definitive results.

Inclusion criteria

Only randomized, controlled clinical trials were included in the meta-analysis. The studied population was strictly confined to the pediatric age group from 1 to 18 years of age. The diagnosis of asthma had to be confirmed by either a pediatrician or an allergist, and the teaching intervention on self-management of asthma had to be interactive either on a one-to-one basis or in group settings. The outcome variables had to relate to one or more of five morbidity variables (emergency visits, hospitalizations, hospital days, asthma attacks, and school absenteeism).

Exclusion criteria

We excluded studies in which the teaching intervention was not interactive (e.g., self-teaching booklet mailed to patients) and those in which the outcome variables were not related to morbidity (e.g., knowledge assessment, behavioral components, and attitudes toward the disease).

Qualitative review

We assessed the quality of each study with the clinimetric scale of Chalmers et al.¹⁶ This scale was constructed specifically to evaluate the design, implementation, and analysis of randomized, controlled clinical trials that compare one therapeutic intervention with another. Although most therapeutic interventions pertain to pharmacotherapy, behavioral interventions, such as a teaching program, can be assessed with this scale, as long as the study was conducted as a randomized, controlled clinical trial.

The scale is constructed around two major aspects of a clinical trial, the quality of the experimental design and the quality of the data analysis. Because the scale has been developed primarily for clinical trials on drug efficacy, some items are not applicable to a teaching intervention and were removed after a consensus of the five coauthors was reached.

From the experimental design subscale, we removed

the following items: control appearance, control taste, stopping rules, biologic equivalent, and end-point duplicate variable. We used 10 criteria that are briefly described as follows. The selection description refers to the entry and rejection criteria, which give a clear picture of the patients studied. The reject log describes the eligible population not accepted for the trial and specific reasons for their noneligibility. The intervention definition gives full descriptions of the therapeutic intervention in the experimental group and the regimen given to the control group. Blinding procedures are the most important determinants of the quality of a randomized, controlled trial and are usually covered by four criteria. Randomization blinding implies that the investigator is unable to suspect which treatment is next in line. Blinding of patients refers to patients being unable to guess which treatment they are receiving. In this case of a teaching intervention, we considered that patients could not be totally blinded to the teaching intervention and scored the item according to the "partial blinding" scale. The third criterion for blinding procedures refers to blinding of observers or physicians as to treatment received. We removed that item because in a teaching intervention, the observer, who is also responsible for the teaching intervention, cannot be blinded. The fourth criterion on blinding procedures documents whether observers or physicians are blinded to the ongoing results of the study, although they are aware of any individual patient's outcome. The last group of four criteria refers to testing procedures. The prior estimate number is a calculation of the number of patients required in both experimental and control groups. Testing randomization compares demographic and prognostic features of both experimental and control groups. Testing of blinding is done at the end of the study by asking patients and physicians whether they guessed in which treatment group they were. Testing compliance refers to an objective method of verifying that patients are conforming to the protocol.

From the data analysis subscale, we removed only the item on side effect discussion. We used 12 criteria that are briefly described as follows. Dates of the study are important because the results can be interpreted in the light of other changes in therapy, which may have been going on at the same time. Results of prerandomization document whether the baseline comparability of both experimental and control groups has been assessed properly. Major end points should be reported with both the test statistic and the observed probability values. Post beta estimate refers to a discussion of the type II error when the difference between the compared treatments is not statistically significant. Confidence limits or intervals should be provided for the proportions, rates, or means used as trial end points. Repeated measures refer to a time-series statistical analysis for all discrete end points. Timing of events refers to the availability of the raw data in tabular form. Regression or correlation analyses should be carried out as applicable. Statistical

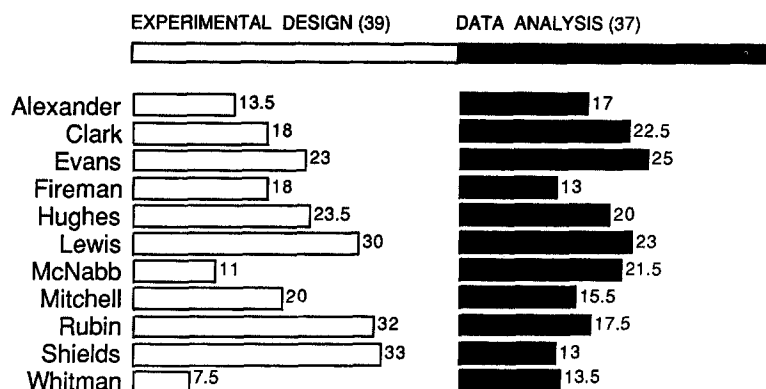


FIG. 1. Quality score of studies.

analysis is an overall assessment of the statistical methods that are used in the study. Withdrawals are almost unavoidable and should be listed by diagnosis, treatment, and reason for withdrawal and should not exceed 15%. Handling withdrawals should be approached in an appropriate way, depending on the type of study. Retrospective analysis refers to analysis of subgroups that were not specified at the outset of the study.

All studies were evaluated by each of the five coauthors, who assigned a score to each item of the adapted clinimetric scale of Chalmers et al.¹⁶ Item scores were discussed in order to reach a consensus and were subsequently added to obtain a score for the experimental design (range, 0 to 39), a score for the data analysis (range, 0 to 37), and a total quality score (range, 0 to 76).

Quantitative meta-analysis

Results of statistical tests (e.g., *F* values, *t* ratios, means, standard deviations, degrees of freedom, *p* values) were derived from each study. For each of the outcome variables considered (emergency visits, hospitalizations, hospital days, asthma attacks, and school absenteeism), the studies addressing this specific outcome were assessed in terms of homogeneity of the teaching intervention effects. The test of homogeneity of effects across studies was performed with a chi square statistic.¹⁷ When the hypothesis of homogeneity of effects was confirmed, the studies were combined to calculate a "pooled effect size" by the method suggested by Hedges and Olkin.¹⁸ The effect size was defined as the difference in mean outcome scores between a treatment group and a control group divided by the average of the standard deviation of the outcome measure of both groups. The effect size was interpreted through Cohen classification (small = 0.2, medium = 0.5, large = 0.8).¹⁹

RESULTS

An initial literature search retrieved 106 references in which 23 studies were identified as clinical trials. A more extensive review excluded 12 studies for the following reasons. Three studies were not randomized,²⁰⁻²² three studies evaluated a nonin-

teractive teaching intervention consisting of a self-teaching booklet^{23, 24} or an audiovisual teaching aid,²⁵ and six studies addressed outcomes not related to morbidity such as compliance,²⁶ knowledge,²⁷ attitudes,^{28, 29} or a combination of knowledge and attitudes.^{30, 31} Eleven remaining studies,³²⁻⁴² published between 1981 and 1991, were included in the meta-analysis, for a total of 716 patients from experimental groups and 574 patients from control groups.

Qualitative review

Overall, the quality of studies was fair, with a mean global score of 39.2 ± 9.9 (for a total possible score of 76). The mean score for the quality of the experimental design was 20.9 ± 8.4 (for a total possible score of 39), and 18.3 ± 4.3 for the quality of the data analysis (for a total possible score of 37). As shown in Fig 1, only six studies were scored higher than 50% of the total possible points.^{33, 34, 36, 37, 40, 41}

Weaknesses in the experimental design of the studies are summarized in Table I. Randomization blinding is a major criterion, to which a score of 10 points was assigned. Only three studies received a full score. One study received a partial score, and seven studies did not receive any points for randomization blinding. The second major criterion is blinding of patients, to which a full score of 4 points was assigned, which was obtained by eight of the studies. Two studies obtained a partial score, and one study did not obtain any points. Two criteria (i.e., prior estimate number and testing blinding) were not met by any study.

Weaknesses of the data analysis are summarized in Table II. Four main criteria were assigned a full score of 4 points each, and their fulfillment among the studies was poor. Only four studies obtained a

TABLE I. Qualitative review of the studies:
Experimental design

Criterion	No. of studies meeting the criterion (n = 11)		
	Full score	Partial score	None
Selection description	9	2	—
Reject log	5	2	4
Intervention definition	11	—	—
Randomization blinding*	3	1	7
Blinding of patients*	8	2	1
Observers blind to results	7	2	2
Prior estimate number	—	—	11
Testing randomization	7	3	1
Testing blinding	—	—	11
Testing compliance	4	4	3

*Major criterion.

full score for the major end points, six studies for the criterion of withdrawals, and two studies for the quality of the statistical analysis. No study obtained a full score for the handling of withdrawals.

Quantitative meta-analysis

There were only three studies that considered asthma attacks as a morbidity outcome, and it was possible to pool the results of five studies for the other outcomes (school absenteeism, hospitalizations, hospital days, and emergency visits). Mean outcome scores for the experimental and control groups of each study are shown in Table III. There was no heterogeneity of effects across the pooled studies for each of the outcomes. Overall, pooled effect sizes were quite small, with a range between -0.11 and 0.14 (Table IV).

DISCUSSION

This meta-analysis shows that self-management teaching programs have surprisingly little influence on morbidity outcomes. In the case of each morbidity variable, pooled effect size remained below 0.2 , which we have already described as a small effect size.

We must emphasize that the number of clinical trials included in the meta-analysis was limited to 11 studies and that not all of the 11 studies addressed the five morbidity outcomes selected for the overview. Consequently, pooling of the studies according to each outcome left us with a total of five combined studies or less for each outcome. It was not possible to stratify studies within one specific morbidity outcome, because the number of

TABLE II. Qualitative review of the studies:
Data analysis

Criterion	No. of studies meeting the criterion (n = 11)			
	Full score	Partial score	None	Not applicable
Dates of study	5	—	6	—
Results of prerandomization	5	5	1	—
Major end points*	4	7	—	—
Post beta estimate	1	—	8	2
Confidence limits	8	—	3	—
Repeated measures	4	5	2	—
Timing of events	5	5	1	—
Regression/correlation	4	—	7	—
Statistical analysis*	2	9	—	—
Withdrawals*	6	—	5	—
Handling withdrawals*	—	7	2	2
Retrospective analysis	—	7	4	—

*Major criterion.

pooled studies under each stratum would have become even smaller and inappropriate for the estimation of an overall effect size.

For instance, a stratification of studies according to sociodemographic characteristics might have provided more information on the impact of teaching programs. Generally, studies restricted to school-age children showed a more significant reduction of morbidity during the year after the teaching intervention. The study by Evans et al.³⁴ of children aged 8 to 11 years showed that asthma health education reduced episodes of asthma but did not influence school absenteeism. The comprehensive ambulatory program for children aged 6 to 16 years, described by Hughes et al.,³⁶ reduced school absenteeism and the number of days spent in the hospital, but there were more admissions in the experimental group. Lewis et al.³⁷ showed significant reductions in emergency room visits and days of hospitalization among children aged 8 to 12 years receiving the Asthma Care Training. In her short-term (3 months) study on a small sample of 16 children aged 9 to 13 years, McNabb³⁸ reported a reduction of emergency visits in the group participating in an individualized self-management teaching program. In contrast, there was no reduction in emergency room use in the study of Shields et al.⁴¹ who designed an educational program for inner-city children aged 1 to 18 years belonging to minority ethnic groups with a low socioeconomic status. Similarly, Mitchell et al.³⁹ found no reduction in school absenteeism, number of hospitaliza-

TABLE III. Mean outcome scores for experimental and control groups of each study

Study	School absenteeism (days/mo)		Asthma attacks (no./mo)		Hospitalizations (no./mo)		Hospital days (no./mo)		Emergency visits (no./mo)	
	Exp	Cont	Exp	Cont	Exp	Cont	Exp	Cont	Exp	Cont
Alexander et al. ³²	—	—	—	—	—	—	—	—	0.05	0.2
Clark et al. ³³	1.55	1.39	—	—	0.009	0.02	—	—	0.14	0.21
Evans et al. ³⁴	1.61	1.64	0.75	0.98	—	—	—	—	—	—
Fireman et al. ³⁵	—	—	0.12	0.5	0.00	0.02	—	—	—	—
Hughes et al. ³⁶	0.48	0.73	—	—	0.03	0.04	0.10	0.18	0.04	0.05
Lewis et al. ³⁷	—	—	—	—	0.02	0.05	0.05	0.13	0.19	0.31
McNabb ³⁸	—	—	—	—	—	—	—	—	0.1	0.8
Mitchell et al. ³⁹	1.43	1.05	—	—	0.08	0.04	0.66	0.42	—	—
Rubin et al. ⁴⁰	1.17	1.55	—	—	—	—	0.07	0.08	—	—
Shields et al. ⁴¹	—	—	—	—	—	—	0.02	0.02	—	—
Whitman et al. ⁴²	—	—	2.08	1.49	—	—	—	—	—	—

Exp, Experimental; Cont, control.

TABLE IV. Morbidity outcomes of the self-management teaching programs

Morbidity outcome	No. of studies	No. of patients		Heterogeneity		Pooled effect size
		Exp	Cont	χ^2	p Value	
School absenteeism	5	407	299	8.28	NS	0.04 ± 0.08
Asthma attacks	3	125	100	3.32	NS	0.09 ± 0.14
Hospitalizations	5	406	295	8.42	NS	0.06 ± 0.08
Hospital days	5	286	308	8.25	NS	-0.11 ± 0.08
Emergency visits	5	323	199	4.69	NS	0.14 ± 0.09

Exp, Experimental; Cont, control; NS, not significant.

tions, and number of hospital days in their program of asthma education for children aged 2 to 14 years. The pooling of studies without regard to these sociodemographic variables may have diluted the impact of the teaching interventions.

It would have been interesting to stratify studies with regard to the severity of asthma within respective morbidity outcomes. Unfortunately, in some studies the initial data on the severity of the disease before the teaching intervention were missing or incomplete.^{35-37, 39-41} Overall, severity of the disease was classified as mild to moderate. Under these circumstances, it is less surprising that self-management teaching programs have a modest impact on a condition already considered to be mild to moderate, when the range of reduction of morbidity is obviously quite narrow. The study of Clark et al.³³ provides an eloquent demonstration of how comparisons restricted to subgroups stratified with regard to severity can uncover positive effects of a health education program, although there is no improvement in morbidity when the sample is considered as a whole. In their sample of

310 children with asthma, they found no significant reduction of morbidity when the experimental group was compared with the control group without regard to severity of morbidity. However, when the comparison was restricted to children with previous hospitalizations, the teaching program had a significant effect on morbidity outcomes. Moreover, it was among children with high baseline numbers of hospitalizations and emergency visits that the greatest subsequent reduction in morbidity was observed. Because the study of Clark et al.³³ was the only one that stratified with regard to severity of asthma, it was not possible to pool from other studies subgroups of children who had more severe asthma. Nonetheless, it can be speculated that we would have obtained a larger effect size in the stratum of more severely affected children.

Furthermore, the reliance on outcome measures such as emergency visits, hospitalizations, and school absenteeism to indicate success of the intervention is somewhat arbitrary. For example, it is well known that for the same asthmatic condition,

one family will come to the emergency room, whereas another family will manage at home with phone advice from the health care provider. Only one study³⁶ described pulmonary function tests in the assessment of the asthmatic condition of the patients.

Another difficulty lies in the fact that none of the studies disclosed hospitalization criteria, which are quite subjective and could be different from one study to another and within the same study from one physician to another. Moreover, therapeutic strategies have gone through important changes during the past decade, with the emphasis on antiinflammatory therapy, the widespread use of aerosolized agents, and decreased use of theophylline. The studies we combined for the meta-analysis were published during this period of therapeutic changes, between 1981 and 1991. Because ambulatory therapeutic regimens were not specified in any of the studies, it can be assumed that they were different between studies and possibly between subjects in the same study. This obviously has an impact on hospitalization rate, because more aggressive ambulatory treatment may reduce the need for hospitalization.

The modest impact on the morbidity of asthma could be attributed, in part, to the fact that our selection criteria for the teaching intervention were quite broad. The teaching sessions were interactive, but another stratification on individual teaching versus group sessions could not be introduced because of the small number of pooled studies addressing the same morbidity outcome. One could anticipate that individual teaching is more adapted to the patient and more easily understood, with a higher impact on outcome. The combining of studies with individual teaching or group sessions probably led to a reduction of the pooled effect size for each of the morbidity outcomes.

It can also be hypothesized that the teaching programs had a paradoxical effect as patients became more knowledgeable and more conscious of their symptoms and sought medical advice more often and possibly more quickly.

In three studies it was mentioned that control groups were receiving some instruction, although it was less comprehensive than that for experimental groups.^{37, 40, 42} However, all control groups were receiving standard care for asthma, which necessarily includes some information on pathophysiology, triggers of attacks, environmental control, and medication use. Moreover, control patients knew they were participating in a study, and they might

have been more inclined to follow the advice of their physicians with a consequent reduction in the morbidity, introducing a bias known as the "Hawthorne effect," or the attention bias.⁴³

However comprehensive the teaching intervention may be, it does not necessarily translate into a significant change of behavior and attitudes toward a better control of environmental triggers of asthma. Acquisition of knowledge was evaluated by some studies^{36, 39, 40, 42} but was not considered in the meta-analysis because scales of measurement of knowledge were not comparable from one study to another. Moreover, more knowledge does not necessarily translate into healthier behavior and attitudes. Only one study analyzed the modification of the home environment through home visits and showed no changes in the presence of pets and no significant difference between the experimental and control groups in the reduction of passive smoking.³⁶ It can be postulated that the persistence of triggering factors in the home environment was a factor that diminished the impact of the teaching programs on morbidity. Another well-known triggering factor in preschoolers is viral upper respiratory tract infections. Their seasonal incidence and easy dissemination in day care centers may hinder the full benefit of a teaching intervention. Because we could not stratify for age because of the small number of studies, this represents another possible explanation for the minimal impact of the teaching programs because many studies included preschoolers in their sample population.^{32, 33, 35, 39, 41}

The quality of studies was reported as fair. The main weaknesses of the experimental design of studies were concerned with randomization that was not blinded in seven studies and with poor or absent documentation of the reject log in six studies. The qualitative review of data analysis disclosed generally fair statistical analysis with underutilization of regression or correlation statistics and repeated measures and with fair presentation of raw data for timing events. Moreover, withdrawals were not documented in five studies, and no study handled them in an entirely appropriate way. Finally, nine studies showed some negative results, but only one discussed the post beta estimate.

We do not believe that weaknesses and flaws of the studies had an impact on the results of the meta-analysis. In fact, six studies^{33, 34, 36, 37, 40, 41} obtained a score above 50% of the total possible points and at the same time had larger samples of patients than studies of a lesser quality. Future

research should try to correct problems of quality. Even if a study focuses on "soft" outcomes such as behavior, it can be designed as a randomized clinical trial with strict adherence to its inherent rules. Moreover, "soft" data can be "hardened" by a rigorous experimental design and statistical analysis.

We already mentioned that we did not consider acquisition of knowledge as an outcome indicator in the meta-analysis because scales of measurement were not comparable from one study to another. For the same reason, we did not evaluate self-management skills, health beliefs, and self-management behaviors and attitudes. However, these outcomes can be considered as intermediate outcomes, more directly related to the teaching intervention, and less susceptible than morbidity outcomes to confounding factors that "dilute" the teaching intervention effect. In fact, studies that reported negative results on morbidity outcomes showed beneficial effects in regard to other aspects of asthma. Mitchell et al.³⁹ observed improved compliance in their experimental group. The teaching program had a significant positive impact on knowledge, skills, and behavior related to management of asthma as described by Rubin et al.⁴⁰ and Whitman et al.⁴² Future studies examining the impact of self-management teaching programs should focus on these intermediate outcomes and evaluate them with standard scales of measurement.

In conclusion, this meta-analysis shows a modest impact of self-management teaching programs on the morbidity of pediatric asthma, most probably because of multiple confounding factors not directly amenable to change by education. However, the well-being and the quality of life of the asthmatic child and his family are not solely measured by "hard" morbidity data. Other intermediate outcomes such as knowledge, health beliefs, and self-management skills and behavior are important benefits more closely related to the teaching intervention and less imbalanced by confounding factors such as environmental triggers of asthma. Future research should focus on the psychologic and behavioral benefits of asthma self-management teaching programs by using randomized designs with standard scales of measurement of behavioral outcomes. Moreover, teaching programs should be designed for targeted audiences with well-defined characteristics such as age, socioeconomic setting, severity of the disease, and therapeutic protocol. Within such targeted samples of asthmatic children, it is more likely that clinical

trials will show benefits in regard to morbidity, as well as behavioral outcomes through self-management teaching programs specifically designed for selected audiences.

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