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Clinical effects of a Long-term Educational Program for Children with Asthma – Aironet®. A 1-yr randomized controlled trial

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Educational self-management programs for children with asthma have now become a routine feature in the management of the disease, as international guidelines underline. We designed this trial to find out whether Aironet®, an educational program developed for children with asthma, influenced asthma severity and improved parents' knowledge of the disease. In a multicenter, prospective, randomized controlled trial we enrolled 123 children, 72 boys, mean age 8.78 yr (±2.33 s.d.), with intermittent or mild persistent asthma. Participants were randomly assigned to an education group, who received Aironet® at baseline and 2 months later (60 children), or to a control group who did not (63 children). Follow-up lasted 12 months and included out-patient clinic visits and spirometry at 2, 4 and 12 months. At baseline and at 12 months follow-up, parents were questioned about their knowledge of asthma, and their children's asthmatic attacks, use of systemic corticosteroids, family physician or hospital emergency room visits, hospitalizations and asthma-related school absences. Questionnaire replies at 12-month follow-up reported significantly fewer asthma attacks in patients who received the program than in those who did not (1.65 ± 1.21 vs. 2.34 ± 1.73; $p < 0.05$). For the subgroup of children who had ≥3 asthma attacks at baseline, parents' knowledge improved significantly more in the educational group than in the control group. The out-patient educational program Aironet® reduces the number of asthma attacks in children with intermittent or mild persistent asthma and improves knowledge of the disease.

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Asthma is the most common chronic condition in childhood. The growing prevalence of diagnosed asthma over the past 20 yr has had a major impact on healthcare costs (1, 2).

We now have available several effective drugs for the pharmacological treatment of asthma, but patients' information and education remain a cornerstone of long-term management, as international guidelines underline (1–6). Educational programs for children with asthma and their families are intended to improve the knowledge of asthma, assess the severity of symptoms, know which medications to use, and decide when to seek medical care. Educational programs should also help to optimize long-term therapy to maintain control of asthma without restricting daily activities.

Although the consensus is that educational interventions for children with asthma improve the knowledge of the disease their real impact on asthma morbidity remains controversial. In a meta-analysis published in 1995 the investigators

concluded that self-management programs for asthma achieve scarce benefits insofar as they reduce neither the severity of disease nor the utilization of healthcare resources (7). Conversely, a more recent review involving children and adolescents with asthma reported more encouraging results by showing that, compared with traditional management, educational interventions improve lung function and feelings of self-control, and reduce the clinical symptoms of asthma, number of days with restricted activity, school absences and emergency visits (8). Few randomized controlled clinical trials have assessed the effectiveness of a health education program in reducing asthma exacerbations in children, and most of them included only a small number of patients (9–13) and had a relatively short follow-up, 7–12 months.

We designed this multicenter randomized controlled trial with a 12 month follow-up to assess whether a symptom-based long-term health educational program Aironet® improved the severity of disease (clinical and functional measures) and parents' knowledge of asthma, in children with intermittent or mild persistent asthma.

Material and methods

Patients and diagnosis

In an Italian multicenter, prospective, randomized controlled trial conducted between March 1 and June 30, 2005, consecutive children aged 6–14 yr with newly diagnosed intermittent or mild persistent asthma were enrolled among those attending three specialist pediatric asthma clinics (1).

On enrolment (baseline), the severity of asthma was assessed by collecting information from the previous year concerning the number of asthma attacks, use of systemic corticosteroids, number of unscheduled visits to the family physician or hospital emergency visits, number of hospitalizations for asthma and school absences during the previous 3 months (14).

We also defined two severity asthma subgroups according to the number of asthma attacks: < 3 or ≥ 3.

All recruits underwent skin-prick tests (SPT) with a panel of common inhalant and food allergens and spirometry for lung function testing. Parents completed a standard questionnaire, comprising 10 questions requiring yes/no answers, designed to elicit information on their knowledge of asthma.

Interventions and assessment variables

Children were randomly assigned to one of two groups, an education group who received the Long-term Educational Program for Children with Asthma – Aironet® (LEPCA-A) or to a control group, who continued their usual care but did not receive the program. Randomization depended on the day (odd or even) of the month when the child first attended the out-patient clinic. All the children then underwent regular follow-up visits according to the clinics' booking system. Lung function was tested at 2, 4, 8 and 12 months. Children assigned to the education group and their parents took part in the LEPCA-A for self-management of asthma. The program lasted 1 h and was given by resident physicians and nurses who received previous training. After the program, children and their parents took part in an interactive discussion lasting 30 min. Children assigned to the education group and control group received a personalized treatment plan and a clinical diary where they regularly noted their symptoms. To avoid information transfer, the two groups attended on separate days. Follow-up assessments were done by physicians blinded as to the child's group assignment. At the first follow-up visit (2 months) the education group received the LEPCA-A again. At the last follow-up (12 months) the parents of all the enrolled children again filled in the standard questionnaire used at enrolment. At the end of the study, information related to the entire year was collected on the following five clinical outcome measures of severity: the number of asthma attacks, cycles of systemic corticosteroids, number of unscheduled visits, hospitalizations for asthma and school absences.

Long-term Educational Program for children with asthma – Aironet®

The LEPCA-A was developed by a scientific board appointed by the Italian Society of Pediatric Allergy and Immunology – SIAIP and the Italian Society for Pediatric Respiratory Diseases – SIMRI. The long-term program included the following topics: basic information on asthma and on preventive measures to identify and control trigger factors; learning to recognize the first symptoms of asthma and treat acute asthma; how to use asthma medications and healthcare facilities; and strategies for remaining active, for example avoiding asthma triggers, complying with therapy and engaging in outdoor activities. The long-term program also envisaged a series of games for children intended to provide informa-

tion and change potentially harmful daily behaviors. The games, developed for children aged from 4 to 14 yr, had various levels of complexity. We used jigsaw puzzles, asthma playing cards, an asthma coloring book and asthma memory.

Jigsaw puzzle. This game consisted of a house cut into sections. The puzzle had to be assembled using two series of pieces that differed in design but were identical in shape. One series illustrated a home suitable for a child with asthma (for example, a room furnished to reduce house-dust mites, with father sitting in an armchair reading the newspaper without smoking, and pets kept outside). The other depicted an unsuitable home (a room full of carpets and sofas, the cat lying on the sofa and father smoking). Children were asked to assemble the jigsaw puzzle using only the pieces illustrating settings, objects and actions they thought right, harmless and unlikely to trigger asthma.

Asthma playing cards. The playing cards illustrated the same pictures as the jigsaw puzzle. In rapid succession children were shown in pairs: the card showing the setting suitable for asthma and the card showing the unsuitable setting and the child was given a few seconds to choose the right card.

Asthma coloring book. This was used for children aged 4–10 yr. The book consisted of 12 illustrations that reproduced the most common triggers for asthma in infants. Each picture had an accompanying fairy story that for younger children could be read by adults. The aim was to draw children's attention to factors that can worsen asthma.

Asmemory. This competitive game comprised 25 identical pairs of playing cards illustrating more complex settings related to asthma management. A short sentence written on each pair reinforced the drawing's educational message.

Statistical analysis

In the descriptive analysis, the results were expressed as the absolute number and percentage for qualitative variables, and as both mean and standard deviation for quantitative variables. Parametric and nonparametric techniques were used for comparing the differences between the education group and control group. The tests used in the statistical analysis (SPSS Institute Inc., Chicago, IL, USA) were Student's *t*-test, the Mann–Whitney test, as appropriate for comparison of means and Pearson's chi-squared test, and Fisher's exact test for comparison of percentages. The significance level was 0.05. Data were analyzed with the software program SPSS.

Results

The controlled trial involved 6 Italian pediatric allergy-pulmonology Clinics. One hundred and twenty-three consecutive children with intermittent or mild persistent asthma (58% males, mean age 8.78 yr $\pm$2.33) were enrolled. Sixty of them were randomized to the education group. The two groups had homogeneous demographic and clinical characteristics at baseline (Table 1). Clinical assessment on enrolment (baseline) showed atopy in 26.0% of the children; a history of rhinitis in 59.3%; and eczema in 35.9%. A total 85.1% of the children had positive SPT reactions to at least one of the tested allergens: 71.5% to house-dust mites, 40.7% to grasses, 3.3% to cow's milk proteins and 4.1% to egg (Table 2).

At baseline, no significant difference was found between the education group and control group for the five clinical outcome measures of asthma severity assessed: number of asthma attacks, cycles of systemic corticosteroids, number of unscheduled visits and hospitalizations in the previous year, or number of school absences during the preceding 3 months. Lung-function values (FEV_1, FVC, and FEF 25–75, expressed in percent of predicted values) were within normal ranges, with no significant differences between the two groups (Table 3).

All 123 children completed the 1-yr follow-up. At 2 and 4 months, none of the five

Table 1. Study population

Characteristics	Education group (n = 60)	Control group (n = 63)
Age (years)	8.78 (±2.33)	8.90 (±2.40)
Males (%)	63.0	54.0
Birth weight (g)	2931.48 (±1015.51)	3220.08 (±808.44)
Age at first asthma attack (years)	5.84 (±2.27)	6.01 (±2.63)
No. of siblings	1.21 (±0.42)	1.25 (±0.89)
Months breast feeding	4.63 (±3.17)	4.90 (±3.77)
Father's age (years)	43.02 (±7.14)	41.76 (±6.00)
Mother's age (years)	39.22 (±6.03)	39.28 (±5.43)
Father smoker (%)	36.7	34.9
Mother smoker (%)	19.0	26.7
Number of asthma attacks		
<3 episodes (%)	58.3	41.7
≥3 episodes (%)	44.8	55.2

All data are expressed as Means (± s.d.). None of the comparisons were statistically significant.

Table 2. Family and personal history of atopy

	Education group (n = 60)		Control group (n = 63)		Total (n = 123)	
	N	%	N	%	N	%
Family history of allergic diseases						
Father	12	20.0	20	31.7	32	26.0
Mother	19	31.7	14	22.2	33	26.8
Siblings	17	28.3	19	30.2	36	29.3
History of atopy						
Rhinitis	34	56.7	39	61.9	73	59.3
Eczema	22	36.7	21	33.3	43	35.9
Positive skin-prick test reactions for allergens						
House-dust mites	43	71.7	45	71.4	88	71.5
Grasses	29	48.3	21	33.3	50	40.7
Parietaria	10	16.7	7	11.1	17	13.8
Olea	16	26.7	8	12.7	24	19.5
Cat	12	20.0	11	17.5	23	18.7
Alternaria	12	20.0	6	9.5	18	14.6
Milk	2	3.3	2	3.2	4	3.3
Egg	2	3.3	3	4.8	5	4.1
At least one allergen	50	83.3	55	87.3	105	85.1

None of the comparisons are statistically significant.

variables assessed differed significantly between the two groups. At 12 month follow-up patients assigned to the education group had significantly fewer asthma attacks than patients assigned to the control group (1.65 ± 1.21 vs. 2.34 ± 1.73; $p < 0.05$); whereas no significant difference was found in use of systemic corticosteroids, number of unscheduled visits, and hospitalizations during the preceding year or school absences or lung-function (Figure). The subgroup analysis of the education and control groups, divided according to the severity of asthma (< 3 or ≥3 attacks at baseline), showed no differences in these clinical and functional measures.

Nearly all the questionnaire items elicited more than 80% of correct replies. Only questions 3 '*No warning signs exist for an acute asthma attack*', 4 '*No medications should be given when the first signs of asthma develop*' and 7 '*Inhaled medications work only for acute attacks*' elicited fewer than 50% of correct replies in both groups.

At the last follow-up the reported knowledge of asthma had improved though not significantly in the both stud groups, independently of the number of asthma attacks reported at baseline. The parents of the children in the education group with ≥3 attacks gave a larger number of correct answers to question 4 '*No medications should be given when the first signs of asthma develop*', than parents of the children in the control group with ≥3 attacks ($p < 0.02$).

Table 3. Clinical and functional data for asthma in the studied population at enrolment

Baseline	Education group (n = 60)	Control group (n = 63)
How many asthma attacks did child have during the past year?	3.66 ± 2.39	3.60 ± 2.75
How many times during the past year did your child need an emergency department?	1.75 ± 2.11	1.65 ± 2.31
How many times was your child hospitalized for asthma during the past year?	0.30 ± 0.86	0.26 ± 0.67
How many times did your child receive systemic corticosteroids for asthma during the past year?	2.31 ± 2.59	1.91 ± 2.69
How many days was your child absent from school for asthma during the past 3 months?	8.50 ± 10.93	5.93 ± 9.69
Flow-volume curves (% of predicted)		
FEV_1	95.68 ± 15.30	98.27 ± 11.88
FVC	96.53 ± 12.48	96.91 ± 13.45
FEF 25–75	79.48 ± 38.30	80.71 ± 42.70

None of the comparisons are statistically significant. All data are expressed as Means (± s.d.).

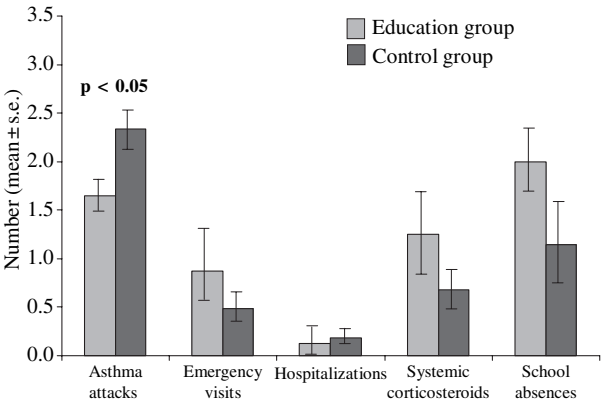

Fig. 1. Clinical data for asthma in the studied population at 12 months.

Discussion

In this Italian multicenter randomized controlled trial, the LEPCA-A targeted to a group of children with intermittent or mild persistent asthma and their parents helped to reduce the severity of asthma. Our results, at 12 months, show fewer asthma attacks in children who received asthma care supplemented with the educational program than in those who merely continued their usual asthma care. This outcome

is especially encouraging given that the children we enrolled all had intermittent or mild persistent asthma and therefore relatively few asthma attacks before receiving the program.

An adequate follow-up seems a major factor in determining whether an education program is effective (9, 11, 13). In this trial, we included a 12-month follow-up independently of the severity of asthma. Hence, Aironet® seems a valid health educational program for this chronic disease, even in children with intermittent or mild persistent asthma. Although our findings preclude us from demonstrating a direct relationship between Aironet® and adherence to treatment, the program diminishes the severity of asthma at 1 yr and possibly does so by increasing children's and their parents' compliance with preventive measures and therapy. Whether our program also improves self efficacy and coping ability (both in children and parents), and whether these improvements depend on the Hawthorne effect (15) is an interesting question for further research.

In our study, school absences and emergency visits diminished during the 12 month follow-up in both groups independently of asthma severity. We therefore failed to confirm the results of other studies showing that education reduces the number of school absences (9, 13, 16–19), and emergency visits (9, 12, 14, 20–22) in relation to asthma severity. Presumably the reductions achieve significance only in children with moderate-to-severe asthma and could not be detected in our sample of children who had few school absences, and emergency visits for asthma at enrolment.

Another factor that might have reduced the difference between the education group and control group in this study was that all the children we enrolled were attending specialist centers for allergy-pulmonology, where they received all the information necessary to improve asthma management and were cared for by highly qualified health care staff especially aware of the problem. The Aironet® program would be even more effective and hence highly desirable in less experienced health care settings where asthma education is overlooked.

Another debatable point is whether an educational program for asthma involves a single session or multiple sessions. In an earlier study, we found that two educational programs that differed in duration, one 8 sessions and the other 4 sessions, obtained similar results (14). To improve memory and comprehension (23), Aironet® envisaged two interactive sessions, each lasting 60 min. Assessing the severity of asthma and parents' knowledge of the disease relative to the duration of Aironet® was outside the scope of the study.

When we enrolled the children and their parents, the questionnaire suggested that they had a reasonable knowledge of asthma which had improved further at the end of the follow-up. Replies to question 4 – whether medications should be given when the first signs of asthma develop – increased, however, only in the education subgroup with more frequent asthma attacks. Because proper use of medications is of crucial importance in achieving asthma control, this response might explain why asthma exacerbations diminished significantly in children who received the educational program.

Possible limitations of our study include the small sample size related mainly to the reluctance of some centers to participate in a time-consuming collaboration. We were also unable to assess the usefulness of the various games in asthma education, because we failed to analyze our children's responses to these materials. Another limitation is that because the negatively formulated questions, 3 and 4, and possibly question 7, were harder to understand than the others they could have elicited fewer correct answers.

In conclusion, Aironet® seems a valid health educational program, able to reduce the number of asthma exacerbations in children with intermittent or mild persistent asthma. Our experience suggests that it should be included in the management of childhood asthma. Future trials should focus on ways of improving communication, possibly testing one strategy against another rather than one strategy against none.

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