Randomized trial of a comprehensive asthma education program after an emergency department visit

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Background: Patients with asthma who visit the emergency department (ED) may benefit from education that optimizes self-management and treatment.

Objective: To conduct a randomized trial of asthma education (AE) after an ED visit.

Methods: Patients who present with acute asthma and history consistent with moderate to severe persistent asthma or recent ED visits were stratified by age (adult, child) and randomly assigned to intervention or usual care during the ED visit. The intervention was conducted by trained asthma educators and included a facilitated office visit with the primary care physician followed by a home visit. Intention-to-treat analysis was conducted, with time to first asthma relapse (either ED or unscheduled urgent office visit) during the 6-month follow-up period used as the primary outcome.

Results: Of the 239 patients analyzed, 46% were adults, 46% were male, 30% were African American, and 56% had moderate to severe persistent asthma. Follow-up information was obtained on 191 patients (80%) at 6 months; 23.1% of the intervention group vs 31.1% of the usual care group had an urgent asthma visit (hazard ratio [HR], 0.79; 95% confidence interval [CI], 0.48–1.29). Overall, 39% of the 117 patients assigned to the intervention group did not comply with any of the post-ED activities. Subgroup analysis suggested greater benefit among children (HR, 0.62; 95% CI, 0.33–1.19) than adults (HR, 1.08; 95% CI, 0.50–2.33).

Conclusions: Delivery of a comprehensive AE program after an ED visit was ineffective in adult patients; however, it may be effective in children. Further research on alternative AE delivery strategies appears warranted to reduce the burden of asthma visits to the ED.

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INTRODUCTION

There are approximately 2 million asthma-related visits to emergency departments (EDs) in the United States every year, and relapse after an ED visit is a common and important problem.[1] In a large multicenter study, 17% of adults[2] and 10% of children[3] discharged from the ED required urgent medical treatment during the 2-week follow-up period. Although treatment-related issues are known to contribute to relapse, nontreatment factors have also been implicated. For example, inadequate knowledge of asthma management, lack of an asthma management plan (AMP), and inadequate coordination of primary care are all thought to be contributing factors to asthma relapse.[4–8] Furthermore, most patients have not received sufficient education regarding their asthma.

Patients with asthma who visit the ED represent a high-risk population that typically includes a higher proportion of minority and economically disadvantaged people.[9,10] Although asthma education (AE) is believed to be important to emergency physicians, the time for provision is sparse and the number of teaching items is long.[11] Furthermore, the effectiveness of AE interventions in the ED setting remains uncertain.[12] A systematic review of ED-based AE in adults demonstrated that providing only limited asthma information was not effective.[13] A study that assessed the effectiveness of a nurse-directed AE program after an ED visit in adults found benefits in patient-reported self-management but no change in subsequent ED visits or hospitalizations.[14] A systematic review of the effectiveness of AE programs for children after an ED visit also found no firm evidence to support the use of AE as a means of reducing subsequent ED visits.[15] However, these authors recommended further research, since some trials appear to show evidence of benefit whereas other trials do not, and the reasons for these differences remain unclear.[15]

The current study was designed to address ED AE and examine longer-term outcomes. We hypothesized that a structured comprehensive AE program delivered by an experienced asthma nurse-educator working with a local asthma coalition would be an effective method of reducing asthma relapse in patients who had moderate to severe persistent

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asthma or who had used the ED for asthma care at least once in the last year.

METHODS

Setting and Sample

This study was conducted at a community hospital in Grand Rapids, MI, with an ED census of 100,000 patient visits in 2004. A convenience sample was designed to reflect the target population by enrolling consecutive patients during selected ED shifts that represented a broad range of times of day and days of the week (ie, evenings, weekends). Patients were eligible for enrollment if they had moderate to severe persistent asthma or had used the ED for asthma care at least once in the last year. A trained ED-based research nurse was responsible for screening ED patients for eligibility, obtaining patient consent, randomizing patients using sealed envelopes, and forwarding the appropriate information to the local asthma coalition.

Management

The diagnosis and standard management of acute asthma exacerbations in the ED were consistent with the National Heart, Lung, and Blood Institute (NHLBI) Expert Panel 2 Guidelines.[16,17] Before discharge from the ED, all patients received instruction by a respiratory therapist on the proper use of an inhaler and spacer device and, if age appropriate, a peak expiratory flow (PEF) meter. For all patients discharged from the ED, written discharge instructions included a recommendation to contact the primary care physician (PCP) within 3 to 5 days to schedule an appointment for follow-up. If the patient did not have a regular PCP, a referral was made using either a hospital-affiliated pediatric clinic for children or a roster of available local PCPs for adults. Finally, the ED physician dictation was faxed to the PCP.

Randomization

Since the issues related to the diagnosis, treatment, and management of asthma in children and adults are different, we used a stratified randomized controlled trial design, whereby children and adults were enrolled and randomized separately. Patients were randomized using computer-generated random numbers followed by the use of sealed opaque envelopes.

Intervention

The comprehensive AE program, which was delivered by a trained asthma nurse-educator from a local asthma coalition, was based on the following intervention strategies: (1) optimizing medical therapy based on the NHLBI guidelines (eg, advice on inhaled corticosteroid use to patient and PCP),[17] (2) optimizing the understanding of asthma management and control by stressing self-evaluation and self-monitoring, (3) developing or refining an individually tailored AMP, and (4) conducting a follow-up home visit to identify potential asthma triggers and to reinforce recent changes in treatment and management.

Patients randomized to the comprehensive AE intervention were contacted by the asthma nurse-educator by telephone 3 to 5 days after the ED visit to help arrange the follow-up appointment with the PCP. The goal was to complete the facilitated office visit within 3 weeks of the ED visit. The asthma nurse-educator was present at that appointment and, working with the PCP, reviewed the current treatments and suggested improvements, such as the appropriate use of inhaled corticosteroids based on NHLBI guidelines. A written AMP according to current NHLBI guidelines was developed or, if the patient already had an AMP, the plan was reviewed and updated. The patient was educated with regard to a planned response to further asthma exacerbations, including use of medications, contact with PCP, and appropriate use of the ED.

Approximately 6 weeks after the ED visit, the asthma nurse-educator conducted a home visit with the patient and reviewed the patient's current medications and inhaler, spacer, and PEF meter techniques. The AMP was also reviewed to ensure that the patient understood its purpose and content and encouraged its distribution to school, daycare, or work where appropriate. The asthma educator also provided basic AE related to the patient's triggers, early warning signs, and ways to prevent recurrent asthma exacerbations and conducted an in-home environmental evaluation to identify possible exposures to triggers.

Measurements

At the initial ED visit, detailed historical, clinical, and treatment data were collected by the research staff. Information obtained by patient interview included demographics, detailed asthma and atopy history, frequency of symptoms (during the last 4 weeks), exposure to potential asthma triggers (eg, smoking, workplace), history of emergency or unscheduled medical visits, current asthma treatment and management, details of current exacerbation, and knowledge and awareness of asthma management. Follow-up data were collected via 2 short telephone surveys conducted by the research staff 2 and 6 months after enrollment. All data were entered into Microsoft Access 2000 (Microsoft, Redmond, WA). To compensate the enrolled patients for their time, we provided two $10 gift certificates for use at a local grocery store.

Outcome Measurements

The primary outcome was the time to first asthma relapse, which was defined as either an asthma-related visit to the ED or an unscheduled urgent visit to a physician office during the 6-month follow-up period. Secondary outcomes included the total number of ED visits and hospitalizations for asthma during the 6-month follow-up period, self-reported compliance with spacer and PEF meter, use of an AMP, self-reported actions taken to reduce exposure to asthma triggers, and missed days of work or school. Subgroup analyses were specified a priori and selected based on previous studies that demonstrated differences in outcome after acute asthma care by age, sex, race/ethnicity, and severity of persistent asthma.[3,5,18–20]

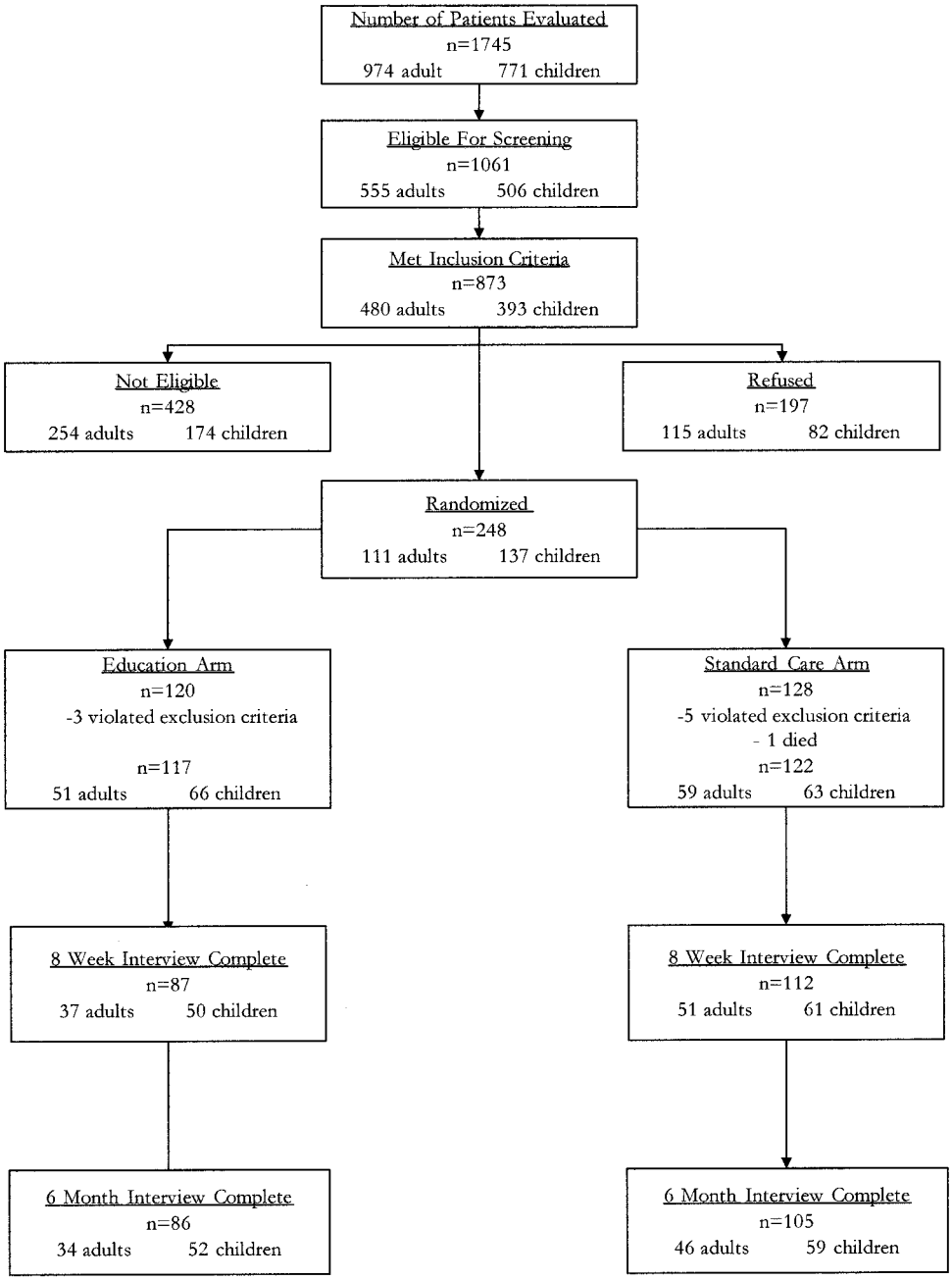

Figure 1. CONSORT flow diagram.

Sample Size

A clinically important intervention effect size was regarded as a 50% reduction in the risk of relapse; a baseline relapse rate of 30% was assumed. A sample size of 242 was estimated based on using a 2-tailed test with an α of .05 and power of 80%. Although the study was not adequately powered to evaluate differences based on age, the randomization was stratified to achieve a similar distribution within adults and children.

Data Analysis

Statistical analysis was performed using standard intention-to-treat principles. Categorical outcomes were analyzed using χ^2 methods. The cumulative survival rates for the intervention and standard care groups (ie, the proportion of patients who were event free during the 6-month follow-up period) were first compared using Kaplan-Meier curves. Cox proportional hazards models were then used to generate adjusted hazard ratios (HRs) and 95% confidence intervals (CIs) using the

Table 1. Baseline Characteristics of the Study Population

Characteristic	Intervention, No. (%) (n = 117)	Control, No. (%) (n = 122)	*P* value
Age, y			.46
≥18	51 (43.6)	59 (48.4)	
<18	66 (56.4)	63 (51.6)	
Sex			.93
Male	54 (46.2)	57 (46.7)	
Female	63 (53.8)	65 (53.3)	
Race			.71
African American	36 (30.8)	36 (29.5)	
White	66 (56.4)	74 (60.7)	
Other	15 (12.8)	12 (9.8)	
Education			.29
<High school	23 (19.6)	19 (15.6)	
High school graduate	37 (31.6)	40 (32.8)	
1–3 years of college	35 (29.9)	48 (39.3)	
≥4 years of college	22 (18.8)	15 (12.3)	
Chronic severity			.82
Mild intermittent	28 (23.9)	27 (22.1)	
Mild persistent	21 (18.0)	28 (23.0)	
Moderate persistent	23 (19.7)	23 (18.9)	
Severe persistent	45 (38.5)	44 (36.1)	
Primary care physician	99 (84.6)	112 (91.8)	.08
Asthma action plan	25 (21.4)	32 (26.2)	.58
Spacer	61 (52.1)	76 (62.3)	.21
Inhaled corticosteroid	94 (80.0)	95 (77.9)	.85
Peak flow meter	50 (42.7)	57 (46.7)	.37

time to first asthma relapse as the outcome.[21] The HR provides a summary measure of the risk of first relapse in the intervention group during the follow-up period relative to that in the control group. The Cox model accounts for patients who are lost to follow-up (censored) and also allows for the adjustment of any potentially confounding variables. Both 2-way and 3-way interaction terms involving the intervention, age, and sex were investigated within the Cox model. Statistical significance was defined as $P < .05$. All statistical analyses were performed with the SAS statistical application program (version 9.1, SAS Institute Inc, Cary, NC). The study was approved by the institutional review boards of Spectrum Health, Michigan State University, and the Centers for Disease Control and Prevention, Atlanta, GA.

RESULTS

Sample

A total of 1,745 patients were screened for inclusion, and 248 patients were enrolled and randomized (Fig 1). Eight patients violated exclusion criteria, and 1 patient in the control arm died 1 day after enrollment; these 9 patients were not included in the analysis. The final study population (n = 239) was representative of the local ED population in terms of their demographics; 46% were adults, 46% were male, and 30% were African American. Fifty-six percent had moderate to severe persistent asthma, and 71% had at least 1 prior ED visit or hospitalization for asthma in the past year. No significant baseline differences occurred between the intervention and control groups (Table 1). Six-month follow-up information was obtained for 191 (80%) of the 239 patients.

Primary Outcome

The intention-to-treat analysis using the time to first relapse for asthma during the 6-month follow-up period demonstrated a statistically nonsignificant reduction with intervention; 23.1% (27/117) of the intervention group and 31.1% (38/122) of the usual care group had an urgent asthma visit (HR, 0.79; 95% CI, 0.48–1.29; $P = .34$) (Fig 2). However, after stratifying by age (child vs adult), a much stronger trend toward benefit was seen among children; 22.7% (15/66) of children in the intervention group and 38.1% (24/63) of children in the usual care group had an urgent asthma visit during the 6 months (HR, 0.62; 95% CI, 0.33–1.19; $P = .29$) (Fig 3). However, no effect was seen among adults; 23.5% (12/51) of the intervention group and 23.7% (14/59) in the usual care group experienced disease relapse (HR, 1.08; 95% CI, 0.50–2.33; $P = .85$) (Fig 4). None of the 2-way or 3-way interaction terms involving the intervention were statistically significant.

Treatment Compliance

The median time between the initial ED visit and the facilitated primary care visit was 10 days (interquartile range, 7–17 days), whereas the median time from the ED visit to the home visit was 48 days (interquartile range, 40–60 days). In the intervention group, 44 (38%) of 117 patients received both the facilitated PCP office visit and home visit, whereas 10 (9%) received only the PCP visit and 17 (15%) received only the home visit. Overall, 46 patients (39%) in the intervention group did not comply with *any* of the planned educational activities. However, the results of the per protocol analysis (which excludes noncompliant patients) was not meaningfully different (HR, 0.75; 95% CI, 0.42–1.31, $P = .32$).

Twenty percent of the study population (48/239) was lost to follow-up at 6-months. The rate of loss to follow-up was higher in the intervention (26%, 31/117) compared with the usual care group (14%, 17/122). The higher rate of loss to follow-up in the intervention group was primarily due to the 46 noncompliant patients, 23 (50%) of whom were lost to follow-up.

Secondary Outcomes

Secondary outcomes are reported in Table 2. Self-reported actions taken to reduce exposure to asthma triggers was the only secondary outcome that was found to be statistically significant ($P = .02$). At 6-month follow-up, 56 (65%) of 86 of those in the intervention group had made some attempt to reduce asthma triggers vs 51 (49%) of 105 in the usual care group.

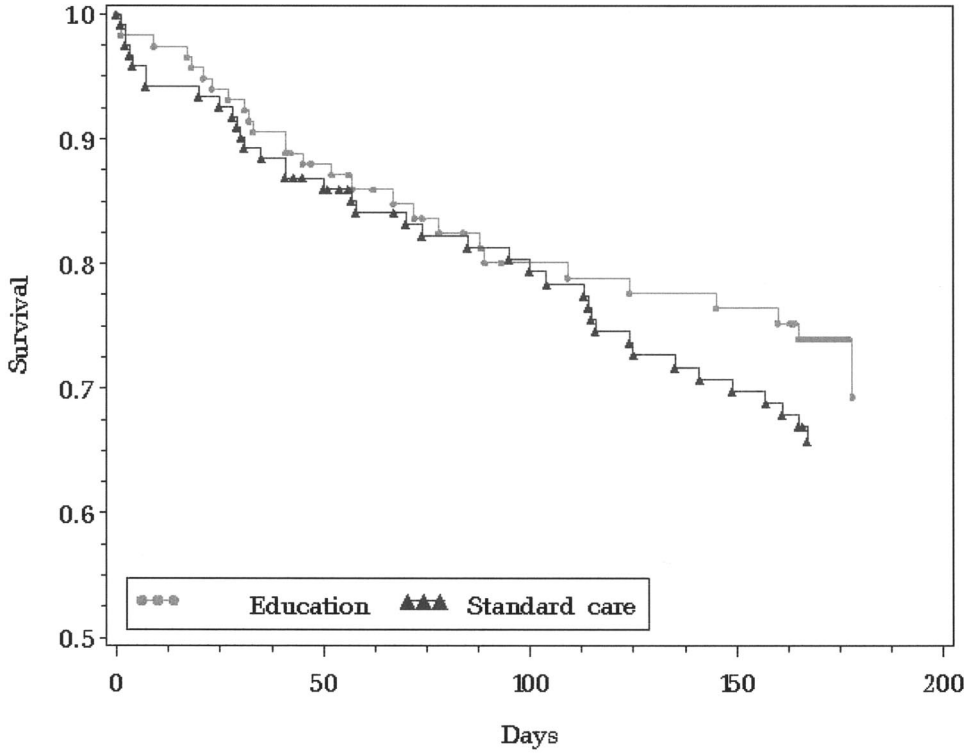

Figure 2. Cumulative survival curves for asthma relapse among education and standard care arms during the 6-month follow-up period for all patients combined.

DISCUSSION

This study attempted to reduce asthma relapses using a comprehensive AE program delivered in the ED and after discharge to a group of adult and pediatric patients seen in a community hospital ED. Despite a detailed ED approach, facilitated PCP appointments, and reinforcement, many patients were unable to complete this intervention. Follow-up appointments were frequently missed, and 4 in 10 patients were unable to do anything more than the initial ED visit. The intention-to-treat analysis failed to demonstrate any clear benefit for the ambulatory ED patient population. However, a priori subgroup analysis demonstrated a strong trend toward benefit among children (HR, 0.62). Although other investigators have noted differences based on sex, race/ethnicity, and persistent severity,[3,5,18–20] our study did not identify any significant differences among these subgroups.

To decrease the health care burden of chronic disease, innovative strategies aimed at reducing recidivism in high-risk patient groups, such as the ED asthma population, are needed.[4,10] Although AE in the ED is acknowledged as one potential strategy to improve the care of asthma patients who visit the ED, this strategy is rarely used in EDs of North America.[11] Others have shown that providing only information on AE is not effective,[13] and there is insufficient evidence to support the use of written self-management plans as the sole intervention for asthma control.[22] More comprehensive strategies using coordinated approaches of self-management AE, coupled with regular medical review and written action plans, have been shown to provide benefit when implemented in the hospitalized patient population, in the primary care environment, or with a captive patient population, such as those enrolled in a managed care organization.[23–26] The success of comprehensive educational interventions in the ED setting, however, remains uncertain given the high-risk patient population in the ED[12] and the fact that a recent systematic review found no firm evidence to support the use of AE as a means of reducing subsequent ED visits.[15]

The conclusions drawn from this study are somewhat limited by the poor compliance of patients assigned to the intervention group. Although an ED visit may very well represent a teachable moment, we found that despite the intense efforts of the research staff to assist patients with the education intervention, many patients did not complete it. Although the typical intervention performed by our local asthma coalition is much more intensive (18 visits) and may provide a greater likelihood of benefit, our intent was to test an education program that would be sensible and feasible in other EDs that serve similar patient populations. Even with this less intensive AE program and diligence on the part of the research staff and asthma nurse-educator, the compliance was disappointing. This experience serves to illustrate the unique challenges of dealing with ED populations. The ob-

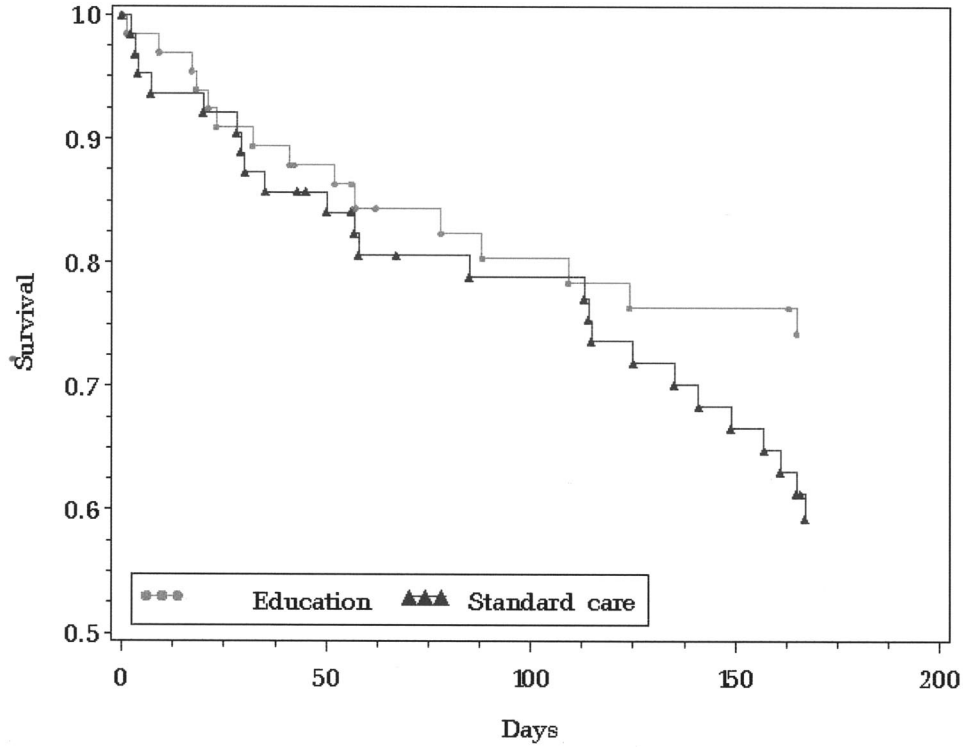

Figure 3. Cumulative survival curves for asthma relapse among education and standard care arms during the 6-month follow-up period for children only.

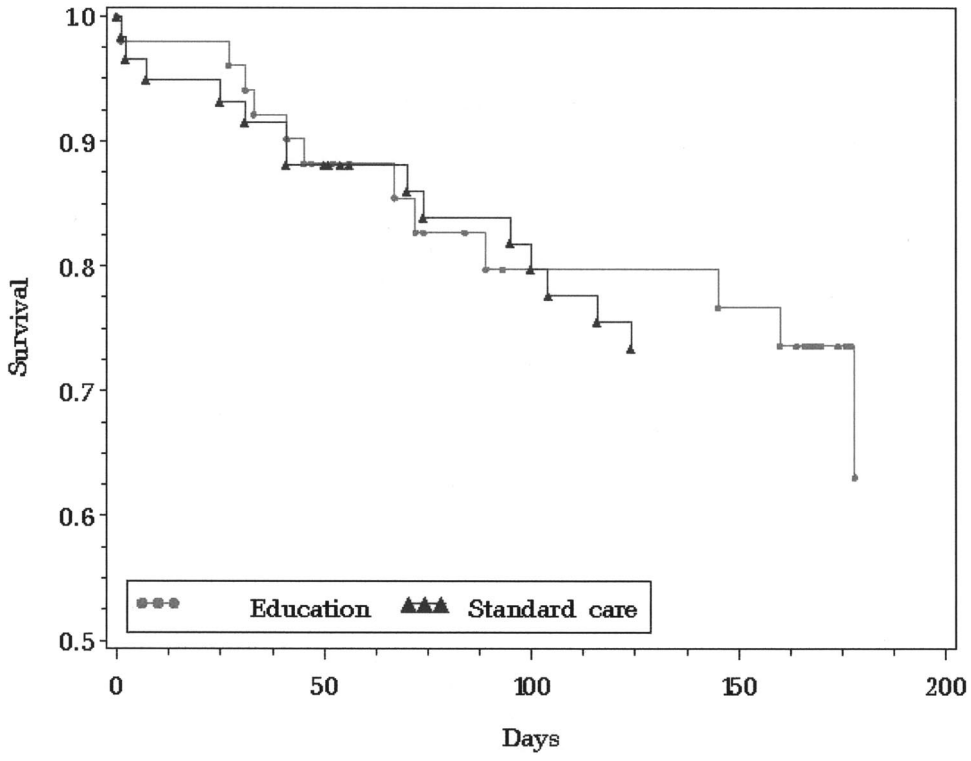

Figure 4. Cumulative survival curves for asthma relapse among education and standard care arms during the 6-month follow-up period for adults only.

Table 2. Secondary Outcomes During the 6-Month Follow-up

Outcome	Intervention, No. (%)	Control, No. (%)	*P* value
Total No. of urgent visits*			.37†
1	18 (64.3)	24 (64.9)	
2	9 (32.1)	7 (18.9)	
3	1 (3.6)	4 (10.8)	
4		2 (5.4)	
No. of asthma hospitalizations‡			.60
0	8 (66.7)	12 (52.2)	
1	4 (33.3)	10 (43.5)	
2		1 (4.3)	
Always or usually use AMP§	30 (69.8)	26 (81.3)	.26
Self-reported compliance with PEF meter‖			.83†
Never or rarely	45 (61.6)	52 (62.6)	
Occasionally	15 (20.6)	19 (22.9)	
Usually or always	13 (17.8)	12 (14.5)	
Self-reported compliance with spacer¶			.78
Never/rarely	18 (22.2)	28 (32.2)	
Occasionally	10 (12.4)	9 (10.3)	
Usually/always	43 (53.1)	50 (57.5)	
Self-reported actions to reduce triggers**	56 (65.1)	51 (48.6)	.02
Missed days of school or work††	68 (58.1)	67 (54.9)	.62

Abbreviations: AMP = asthma management plan; PEF = peak expiratory flow.

* Among those reporting an urgent asthma visit during the 6-month follow-up period (n = 28 intervention group; n = 37 control group).

† Fisher exact test.

‡ Among those reporting an emergency department asthma visit during the 6-month follow-up period (n = 12 intervention group; n = 23 control group).

§ Among those reporting having an AMP during the 6-month follow-up period (n = 43 intervention group; n = 32 control group).

‖ Among those reporting access to a PEF meter during the 6-month follow-up period (n = 63 intervention group; n = 73 control group).

¶ Among those reporting access to a spacer during the 6-month follow-up period (n = 71 intervention group; n = 87 control group).

** Among those who completed the 6-month follow-up call (n = 86 intervention group; n = 105 control group).

†† Among all patients (n = 117 intervention group; n = 122 control group).

served level of noncompliance was not anticipated by the research team, since the coalition previously had good success in terms of implementing its more comprehensive program. However, the bulk of these patients are referred to AE by managed care organizations rather than directly from the ED.

Other investigators have demonstrated similar difficulties with arranging follow-up during an ED visit for asthma.[27] Some investigators have explored the factors related to the lack of adherence to an asthma management protocol, but these factors may not be applicable to the ED population.[28] A post hoc analysis of variables associated with poor compliance in the intervention group was performed; not having a PCP was the only statistically significant predictor of noncompliance (P = .04). Unfortunately, ED patients without a PCP may have the most to gain from an intensive AE program.

Apart from the compliance issues, several other study limitations should be discussed. First, the sample size was powered to detect a relatively large treatment effect (50% risk reduction) in adults and children combined. We surmised that for EDs to take on this additional role, a large treatment effect would need to be demonstrated. This sample size, although small, is similar to other recent studies that assessed the effectiveness of AE programs.[14,23] Clearly, though, a larger study powered to examine the intervention effect within each age strata (ie, children and adults) would have been preferable. Second, this study was conducted in a community where AE skills appear to be high. Other research has demonstrated much less use of spacer devices and inhaled corticosteroids than was seen in the control group in this study.[11] Consequently, a ceiling effect may have been reached in this community, and application of the same intervention in a community with fewer resources and baseline asthma knowledge may demonstrate greater effectiveness. Third, the duration of follow-up, although longer than most studies, was only 6 months. The time series figures[2–4] suggest a separation of the curves after 4 months, and it may be that longer follow-up is needed to see a true benefit of AE on acute asthma relapses. Finally, this is a single-center study, and we cannot generalize these results to other locations.

FUTURE RESEARCH

A number of additional studies are suggested by this research. Based on our findings, a further study that targets children seems to be justified given the large potential effect of our intervention. We can only speculate as to why the intervention appears to be more effective in children than adults. It may be that adults have more established health behavior patterns that are more resistant to change or that the parents are more motivated to improve their child's health status.

Given the compliance problems demonstrated in this study, an area for future research is the development of either a valid method of targeting the subgroup of the ED asthma population that would comply with an intensive AE intervention or an incentive program that would improve participation. Future research may also identify subgroups of the ED asthma population where such interventions are demonstrated to be cost-effective. For insured children who receive care from managed care practitioners, low-income status and nonwhite race are the strongest correlates of increased asthma-related costs,[28] and there is at least one study that demonstrated cost-effective benefits after implementation of a comprehensive social worker–based education program and environmental control in children in an inner-city primary care setting.[29]

CONCLUSIONS

In this ED-based study, a comprehensive AE program did not significantly reduce urgent adult asthma visits; however,

there was a strong trend toward an effect in children. Further research on alternative AE delivery strategies appears warranted to reduce the burden of asthma visits to the ED. In addition, a more efficient approach to the provision of a comprehensive AE program to children who have had ED visits should be explored in future studies.

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