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Impact of asthma severity on long-term asthma control

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ABSTRACT

Background: Asthma is a common childhood disease with significant morbidity. Severe asthma accounts for just 4–6% of patients, but this group is more difficult to treat and is responsible for up to 40% of asthma expenses.

Objective: The relationship between asthma severity and control is not well characterized. The main objective of this study was to determine impact of asthma severity on asthma control over time.

Methods: This was a three year, prospective observational cohort study at a tertiary care children's hospital. Results were compared over time and between patients with severe and non-severe persistent asthma. Intervention included therapy based on severity and control, accompanied by a NAEPP (EPR-3) guidelines based structured asthma education program.

Results: The sample included 471 children referred from primary care offices with the diagnosis of persistent asthma, mean age 6.4 ± 2.4 years. Forty-one children (8.7%) had severe persistent asthma and 430 (91.3%) children had non-severe persistent asthma (mild-moderate persistent). Our sample size decreased over the three-year period and the number of patients completing the third year were 176 (38%) and among them 20 (11.4%) had severe asthma. At the initial visit, children with severe persistent asthma had significantly more acute care needs, more daily symptoms, and lower mean Asthma Control TestTM scores compared to children with non-severe persistent asthma. Differences between groups decreased within six months with significant improvements in most indicators persisting throughout three-year follow up in both groups ($p < 0.05$).

Conclusion: Asthma control improves independent of severity if asthma guidelines are followed.

Abbreviations: ACT: Asthma Control test; NAEPP: National Asthma Education and Prevention Program; % predicted FEV₁: percent predicted forced expiratory volume in one second

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Asthma; children; pediatric asthma; severe asthma

Introduction

Asthma is the most common chronic disease in children and is associated with significant morbidity and in the United States alone, it affects more than six million children (1). Current guidelines focus on evaluating asthma control instead of severity when it comes on deciding on therapies (2,3). Asthma severity is established at initial visit and after that therapy is tailored to attain optimal control (2,3). As per guidelines, asthma control focuses on symptom control and aims to minimize future risk. Asthma control includes decrease in frequency of daytime and nighttime cough/wheezing, exercise limitation and decrease in

use of short acting beta agonist need. Future risk reduction includes preventing acute care needs such as severe asthma exacerbations requiring hospital admissions, emergency department/urgent care visits, systemic steroid use etc. Thus, asthma severity can also be measured by the kind of treatment needed to achieve and maintain adequate control (4).

In a small sub-group (4–5%), symptoms are more sustained and difficult to control despite treatment with inhaled corticosteroids and is thus labeled as severe asthma (5–7). Though this form of asthma is uncommon, it carries more morbidity, acute care need, as well as higher cost which in some estimates can be up to 40–50% of all asthma-related

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expenditures (7–9). Severe asthma is suggested to be of two types. Either *difficult to treat* asthma in which asthma control is poor because of poor adherence or inadequate therapy or wrong diagnosis/co-morbidities, or *therapy-resistant* asthma when asthma fail to convert to a well-control status despite adequate treatment (10,11). It is important to differentiate between these two sub-groups as it can impact control and may save health care resources.

It is well known that asthma control in general is inadequate for reasons including suboptimal adherence to National Asthma Education and Prevention Program (NAEPP) asthma guidelines (1,9,10,12). If providers follow asthma guidelines it is unclear whether asthma severity will have an impact on asthma control, morbidity and cost. The main objective of this study was to determine how asthma control changes over time in children managed by asthma guidelines and if asthma severity has an impact on control over time in this cohort. Asthma was managed as per NAEPP (EPR-3) guidelines (3) including appropriate medications and a structured education program over a three-year study period.

Methods

Design

This was a three-year, prospective longitudinal observational cohort study in children referred for uncontrolled asthma. Children received structured asthma education and adequate therapy to achieve and maintain asthma control. Outcomes were compared over time and were also compared between patients with severe persistent asthma and non-severe (mild-moderate) persistent asthma at baseline and over time.

Participants

After receiving approval from our local Institutional Review Board (IRB11-00174), children with the diagnosis of persistent asthma referred by local primary care practices, between January 2011 and December 2015, were enrolled in our pediatric asthma clinics. Inclusion criteria: Children, age 2 to 18 years, with physician-diagnosed asthma included in this study. All children had acute care need and recurrent wheezing during one year before referral and were on inhaled corticosteroids with clinical diagnosis of asthma by their primary care physicians. Primary caregivers who could communicate in English accompanied the children. Exclusion criteria included children less than 2 years or greater than 18 years old, coexistent morbidities such as

prematurity, cystic fibrosis, sickle cell disease or any other pulmonary disease. Patients with intermittent asthma were not included in this study. Written consent and assent were waived by the IRB.

Intervention

All patients were randomly assigned to a provider (either a pediatric pulmonologist or a pulmonary-trained advanced nurse practitioner) and were followed by the same provider throughout the three-year study period. All patients were new to the program at the time of enrollment. Asthma severity was assessed at initial visit and patients were diagnosed with either mild or moderate or severe persistent asthma as per guidelines based on frequency of symptoms and acute care need. Patients were diagnosed with severe persistent asthma if they had daily daytime symptoms of cough/wheezing, frequent night time symptoms, daily albuterol need for rescue, frequent acute care need with emergency department/urgent care visits or unscheduled primary care office visits for acute symptoms and requiring short courses of oral steroids. At each visit (every 3–6 months), all patients received an asthma control assessment, as well as recommended treatment according to NAEPP asthma guidelines. Patients and caregivers were enrolled in a structured asthma education program, which was revisited at each visit. Patients/families were part of asthma control team and education was provided to improve confidence in self-management of asthma at home. Education plan included their individualized asthma action plan including red, yellow, and green zones and self-management strategies for each zone. Zones are part of individualized asthma action plan and are guide to asthma control. Green zone is also called safe zone without symptoms and with normal or $>80\%$ of personal best PEFR (peak expiratory flow rate) on peak flow meter (in children more than 5 year old) and patient is to continue daily maintenance medications. Yellow zone is when patient start having some symptoms and PEFR is less than 80% of personal best or between 60–80% of normal for age and patient need to call his/her primary care office and start short acting beta agonist therapy at home. Red zone is danger zone when peak flow is less than 60% of personal best, symptoms are frequent and patient need oral steroids along with frequent short acting beta agonist therapies and need to call his/her physician urgently or need to be seen in acute care settings such as urgent care, primary care office or emergency department. These strategies included when to call pulmonary clinic/provider. It also included basic information on NAEPP guidelines,

asthma triggers, and environmental control. Other components of asthma education included severity-specific diagnosis of asthma, adherence with treatment, discussion of asthma control, information about asthma medications, including demonstration and dispensing of appropriate spacer devices, and self-management strategies. Follow up appointments were scheduled at the end of each visit and information was shared with their primary care physicians. Adherence was discussed with patients/families at each visit. In those with ongoing poor asthma control, pharmacy was called to review prescriptions filled since last visit and were discussed with family. If adherence continued to be an issue, social workers were contacted to help families improve adherence with the prescribed medications.

Instruments

Demographic and clinical data form

Families were asked to complete a questionnaire at each visit, which included demographics, asthma-related symptoms and acute care needs since the prior visit ([Supplementary materials S1 and S2](#)). Demographic and clinical data included age at diagnosis, age at first visit, duration of symptoms, gender, race/ethnicity, family history of asthma, secondhand smoking exposure, and pets in the home. Asthma severity was categorized as mild persistent, moderate persistent or severe persistent.

Questionnaire included symptom scores, albuterol use and acute care need related information, to be completed by caregivers or by patients if they were 12 years or older at each visit. Clinical data included mean number of days/month with daytime wheezing, nighttime cough, exercise related symptoms or use of albuterol for rescue and school days missed. At initial visit, data was collected from patients/families on average number of days with symptoms/month in last three months whereas on follow-up visits, data was collected from patients/families on average number of days/month with symptoms since last visit. For acute care needs, data was collected on ED/UC visits, hospital admissions, unscheduled primary care office visits for acute care, use of short courses of oral steroids. At initial visit (baseline), we asked patients/families about acute care need in last 6–12 months. On follow-up visits, data were collected from patients/families on acute care need since last visit. Data was collected over time. We also looked into cost of acute asthma care in our cohort over time.

Data also included Asthma Control TestTM (ACT) (13) which was completed by caregivers for children ages 4–11 years (children 4–11 years old filled their

section with the help of parents) or by patients 12 years or older to evaluate asthma control over the previous four weeks. We used standard cut off score of above 19 as control. Low scores indicated poor asthma control. In children above five years of age, % predicted FEV1 was also measured every 6–12 months.

Data were collected at the first clinic visit (baseline), then at the 3-, 6-, 9-, 12-, 18-, 24-, 30 and 36-month follow-up visits, as determined by the provider. For analysis of asthma indicators over time, data were categorized in the following manner: the 9- or 12-month visit was the “1-year” follow-up but if there were visits both at 9 and 12 months then 12 month visit was considered 1-year visit, the 18- or 24-month visit was the “2-year” follow-up, and the 30- or 36-month visit was the “3-year” follow-up. Missing data values were not imputed.

Statistical analysis

The distribution of scores was measured by frequency and percentage, or mean and standard deviation depending upon the level of data. Univariate statistics were used to evaluate differences in demographic and clinical characteristics between children with severe asthma and non-severe asthma (mild and moderate persistent asthma). General linear model repeated measures generalized estimating equations (omnibus tests) were used to compare levels of improvement in asthma control indicators of the total sample *over time* for the total sample and between groups (between children with severe asthma and children with non-severe asthma). These analyses yield *Wald* χ^2 and p values. SPSS v(0).25 (IBM Analytics, Armonk, NY). The alpha level of significance for all analyses was ≤ 0.05 .

Results

Demographic and clinical asthma indicators

The sample included 471 children, ages 2–18 years, with the mean age of 6.4 ± 2.4 years at the first baseline visit ([Table 1](#)). Males comprised 60.1% ($n = 283$) of the sample ([Table 1](#)). For the purposes of this study, the non-severe asthma group consisted of children with mild persistent ($n = 106$, 22.5%) and moderate persistent asthma ($n = 324$, 68.8%) for a total of 430 children, and the severe asthma group included 41 (8.7%) children with severe persistent asthma. Our sample size decreased over the three-year period and the number of patients completing the 1st year were 396 (84%) and among them 36 (9%) had severe asthma. The number of patients completing the 2nd year was 257 (55%) and

among them 26 (10%) had severe asthma. The number of children completing 3rd year was 176 (38%) and among them 20 (11.4%) were with severe asthma. There were no significant differences in demographics between groups when race, exposure to cigarette smoke, having a pet at home, or family history of asthma (siblings or parents with asthma) were compared (Table 1).

Asthma acute care needs

Both groups (severe and non-severe) had a reduction in acute care services for asthma symptoms over the three-year period (Table 2). At initial baseline visit, children with severe asthma required significantly higher mean number of short courses of oral steroids and emergency room visits for the previous six

Table 1. Demographic characteristics of the sample of children with asthma ($N = 471$) and a comparison between children with non-severe asthma and severe asthma.

	Total cohort ($N = 471$) n (%)	Non-severe asthma ($n = 430$, 91.3%) n (%)	Severe asthma ($n = 41$, 8.7%)	p^1
Gender				.506
Male	283 (60.1)	256 (59.5)	27 (40.5)	
Female	188 (39.9)	174 (65.9)	14 (34.1)	
Family history asthma	347 (73.7)	313 (72.8)	34 (82.9)	.159
Smoking exposure	125 (26.5)	111 (26.5)	11 (26.8)	.965
Pet at home	258 (54.8)	239 (44.4)	19 (46.3)	.256
Race/Ethnicity				.157
Caucasian	314 (66.7)	292 (67.9)	22 (53.7)	
African-American	126 (26.8)	110 (25.6)	16 (39)	
Hispanic	31 (6.6)	28 (6.5)	3 (7.3)	
		Mean $\pm$ Standard Deviation		p
Age at first visit	6.4 ± 2.4	6.4 ± 4.1	7.3 ± 4.6	.168
Age at diagnosis	2.4 ± 4.1	2.4 ± 2.5	2 ± 2.4	.272
Duration of symptoms	4.1 ± 3.5	4 ± 3.4	4.9 ± 4.2	.217

¹ p = significance of the difference in demographic and clinical characteristics between children with non-severe asthma and severe asthma at each clinic visit.

Note. Alpha level of significance ≤ 0.05 .

Table 2. Significance of improvements in mean asthma acute care needs/patient over a 3-year period, and comparisons between children with non-severe and severe asthma.

	6 months pre	At 3month follow-up	At 6 month follow-up	1 year follow- up ($n = 396$)	2 year follow- up ($n = 257$)	3 year follow-up ($n = 176$)	Change in total cohort over Time Wald χ^2 (p) ¹	Difference between severity groups over time Wald χ^2 (p) ³
Mean $\pm$ Standard Deviation								
Short courses of oral Steroids								
Total sample	2.7 ± 2.9	0.3 ± 0.7	0.2 ± 0.5	0.4 ± 0.7	0.4 ± 0.7	0.5 ± 0.7	6.049 (.014)*	
Non-severe	2.5 ± 2.7	0.3 ± 0.6	0.2 ± 0.5	0.3 ± 0.7	0.4 ± 0.7	0.5 ± 0.7		
Severe	4.5 ± 4	0.5 ± 0.9	0.2 ± 0.5	0.7 ± 0.8	0.6 ± 0.8	0.7 ± 0.8		
p^2	.003*	.066	.697	.006*	.089	.231		9.522 (.002*)
Hospital admissions								
Total sample	0.5 ± 1.0	0.1 ± 0.3	0.1 ± 0.3	0.1 ± 0.3	0.1 ± 0.2	0.1 ± 0.3	3.699 (.054)	
Non-severe	0.4 ± 0.9	0 ± 0.3	0.1 ± 0.3	0 ± 0.2	0.1 ± 0.2	0.1 ± 0.3		
Severe	0.9 ± 1.6	0.2 ± 0.5	0.1 ± 0.2	0.2 ± 0.6	0.1 ± 0.3	0.2 ± 0.4		
p	.099	.042*	.958	.055	.458	.284		3.156 (.076)
Emergency room visits								
Total sample	1.7 ± 2.7	0.1 ± 0.5	0.1 ± 0.4	0.2 ± 0.5	0.3 ± 0.9	0.2 ± 0.5	6.843 (.009)*	
Non-severe	1.5 ± 2.2	0.1 ± 0.4	0.1 ± 0.4	0.1 ± 0.4	0.2 ± 0.9	0.2 ± 0.5		
Severe	3.8 ± 5.3	0.5 ± 1.1	0.1 ± 0.3	0.4 ± 0.6	0.4 ± 0.7	0.4 ± 0.8		
p	.008*	.043	.688	.013*	.200	.411		12.671 (<.001)*
Urgent care visits								
Total sample	1.5 ± 2.9	0.1 ± 0.4	0.1 ± 0.4	0.2 ± 0.5	0.2 ± 0.5	0.2 ± 0.7	6.652 (.010)*	
Non-severe	1.4 ± 2.6	0.1 ± 0.3	0.1 ± 0.5	0.1 ± 0.5	0.1 ± 0.4	0.2 ± 0.6		
Severe	2.9 ± 5.3	0.4 ± 0.8	0.1 ± 0.3	0.3 ± 0.7	0.4 ± 0.9	0.6 ± 1.0		
p	.073	.037*	.865	.305	.125	.186		6.798 (.009)*
Primary Care visits for acute care								
Total sample	4.4 ± 5.7	0.3 ± 0.7	0.2 ± 0.5	0.3 ± 0.7	0.4 ± 0.7	0.5 ± 0.8	4.520 (.034)*	
Non-severe	4.4 ± 5.7	0.2 ± 0.7	0.2 ± 0.6	0.3 ± 0.7	0.4 ± 0.7	0.5 ± 0.9		
Severe	5.0 ± 5.0	0.5 ± 0.9	0.1 ± 0.3	0.4 ± 0.7	0.6 ± 0.8	0.4 ± 0.5		
p	.484	.065	.095	.418	.106	.995		1.736 (.188)

¹Wald χ^2 = significance of changes in asthma acute care indicators over time of the total sample.

² p = difference in asthma acute care indicators between children with non-severe and severe asthma at each clinic visit.

³Wald χ^2 = significance of changes in asthma acute care indicators between children with non-severe and severe asthma over time.

* = alpha level of significance ≤ 0.05 .

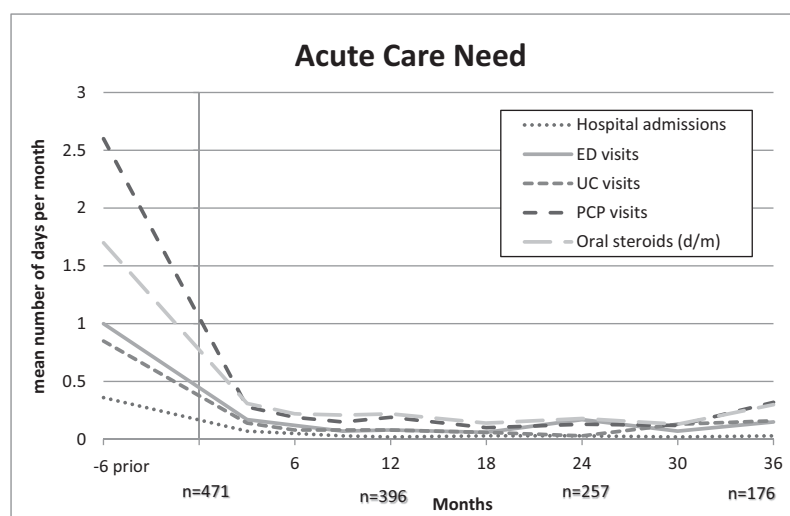


Figure 1. Changes in mean acute care need over time.

months compared to children with non-severe asthma ($p < 0.05$ for both) (Table 2). These univariate group differences were less apparent at each of the following visits (Table 2 and Figure 1). There were no other significant differences between groups in acute care needs at the baseline visit (Table 2). Patients with severe asthma had a significantly higher rate of reduction in acute care need over time in number of short courses of oral steroids, emergency room visits and urgent care visits when compared to patients with non-severe asthma (mild or moderate persistent asthma) ($p < 0.05$) (Table 2).

Asthma acuity measures

Mean ACT scores improved significantly ($p < 0.05$) in our cohort over the three-year study period. At baseline, children with severe asthma had significantly lower ACT scores compared to children without severe asthma but there was no significant difference in % predicted FEV1 between the groups at baseline (Table 3). At each clinic visit, univariate group differences tended to decrease (Figure 2). Comparing change between groups over time revealed that children with severe asthma continue to have lower mean ACT scores compared to children with non-severe asthma but differences were no longer significant (Table 2). Patients with severe asthma had significantly higher rate of improvement in mean ACT scores compared to patients with non-severe asthma ($p < 0.001$) (Table 3).

Asthma symptom indicators

All asthma symptom indicators except for prolonged colds improved significantly over time in our cohort

($p < 0.05$). Children with severe asthma had significantly more days/month of self-reported symptoms at baseline (wheezing, night time cough, exercise symptoms, and albuterol use) compared to children without severe asthma ($p \leq 0.05$ for all) (Table 4). There were no significant differences between groups in the number of self-reported school days missed at baseline. Over time, children with severe asthma continue to experience more self-reported school days missed, wheezing, nighttime cough, exercise symptoms, and albuterol use compared to children without severe asthma but differences between the groups continue to decrease. Patients with severe asthma had significantly higher rate of improvement in mean number of self-reported school days missed, wheezing, nighttime cough, exercise symptoms, and albuterol use/month when compared to patients with non-severe asthma ($p < 0.001$) (Table 4). Severity of asthma was not a significant factor in asthma control over time.

Savings

Though this was not a cost-effectiveness study, we looked into cost of acute asthma care over time. We used current average national reimbursement rates for a hospital admission in US dollars (\$3,600/visit), emergency department (ED) visit (\$1,100/visit), urgent care (UC) visit (\$150/visit), and primary care (PC) visit (\$150/visit) for acute asthma symptoms (14–18). Based on either hospital records and/or self-reported data by patient/family, over the one-year period prior to patients' referral to our center, our cohort of 471 patients experienced a total of 223 hospital admissions, 759 ED visits, 692 UC visits, and 2,073 PCP (primary care physician) visits for acute asthma

Table 3. Comparison of changes in mean Asthma Control Test scores and mean % predicted FEV1 at each clinic visit and changes over a 3-year period between children with non-severe versus severe asthma.

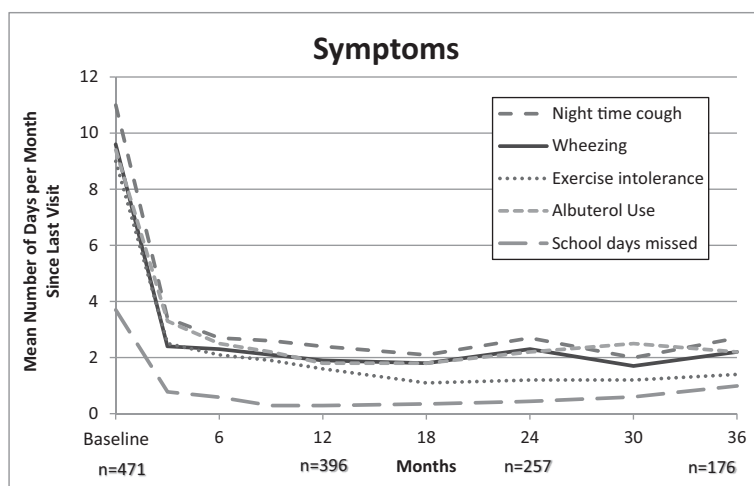
	Baseline	3 months	6 months	1 year	2 years	3 years	Change in total cohort over time Wald χ^2 (p) ¹	Difference between severity groups over time Wald χ^2 (p) ³
Mean $\pm$ Standard Deviation (SD)								
Asthma Control Test (ACT) Score (n = 382) (n = 340) (n = 306) (n = 185) (n = 128)								
Total sample	15.9 $\pm$ 5.7	20.3 $\pm$ 4.9	21 $\pm$ 4.7	21.2 $\pm$ 4.2	21.3 $\pm$ 4.5	21.9 $\pm$ 4	11.577 (.001)*	18.218 (<.001)*
Non-severe	16.3 $\pm$ 5.6	20.6 $\pm$ 4.8	21 $\pm$ 4.7	21.6 $\pm$ 3.9	22.5 $\pm$ 4.4	21.9 $\pm$ 4.1		
Severe	11.5 $\pm$ 4.8	17.4 $\pm$ 5.5	21 $\pm$ 4.5	18.1 $\pm$ 4.5	20 $\pm$ 5.1	21.4 $\pm$ 3.4		
p ²	<.001*	.003*	.995	<.001*	.115	.655		
Mean % predicted FEV1 (n = 326) (n = 248) (n = 158) (n = 106)								
Total sample	93 $\pm$ 17	98 $\pm$ 15	96 $\pm$ 15	98 $\pm$ 17	98 $\pm$ 15	102 $\pm$ 15	.192 (.661)	
Non-severe	93 $\pm$ 17	98 $\pm$ 16	96 $\pm$ 15	98 $\pm$ 16	98 $\pm$ 15	101 $\pm$ 14		
Severe	92 $\pm$ 15	100 $\pm$ 16	95 $\pm$ 5	95 $\pm$ 24	89 $\pm$ 15	116 $\pm$ 20		
p	.799	.643	.843	.644	.081	.022*		.998 (.318)

¹Wald χ^2 = significance of changes in asthma acute care indicators over time of the total sample.

²p = difference in asthma acute care indicators between children with non-severe and severe asthma at each clinic visit.

³Wald χ^2 = significance of changes in asthma acute care indicators between children with non-severe and severe asthma over time.

* = alpha level of significance $\leq$ 0.05.

**Figure 2.** Changes in frequency of asthma symptoms over time.

symptoms (PCP visits for routine care were excluded) (Table 5). The total cost was \$2,052,450 and an average cost/patient of \$4,357. During the first year of follow-up (n = 396), hospital admissions decreased to 63, ED visits to 151, UC visits to 131 and PCP visits to 304 (Table 5). The total cost of acute care in the first year of follow-up was \$458,170 and an average cost/patient of \$1,157. Table 5 shows the declining number of acute care visits over the 3-year period. By the third year (n = 176) the cost of acute care services was \$109,600 (\$622/patient). The estimated cumulative savings over the three-years of follow up was approximately \$2.9 million dollars (Table 5).

Discussion

Our current study focused on changes in asthma control over time in children whose asthma management was based on NAEPP asthma guidelines (3). This study

provides data on the subset of children who were adherent with therapies thus conclusions cannot be generalized to all children with asthma but rather only to those who are adherent. Our interventions included structured asthma educational program for patients and families and it included management appropriate for asthma severity to achieve and to maintain asthma control over time. The results of this study suggest that providing asthma care that includes an appropriate level of therapy (based initially on asthma severity and then on asthma control) accompanied by a structured asthma education program for patients/families, improves asthma control as early as the first 3-month follow-up visit, and improvements in asthma control sustained through the three-years follow up. Providers followed guidelines including structured educational program leading to improvement in asthma control indicators irrespective of asthma severity. Patients with severe asthma and those with non-severe asthma had similar clinical

Table 4. Changes in asthma symptom indicators at each clinic visit and over a 3-year period, with comparisons between children with non-severe and severe asthma.

	Baseline (n = 471)	3 months	6 months	1 year (n = 396)	2 years (n = 257)	3 years (n = 176)	Change over time Wald χ^2 (p) ¹	Difference between severity groups over time Wald χ^2 (p) ³
Mean $\pm$ Standard Deviation								
School days missed (Mean number of days/month/patient)								
Total sample	5.5 $\pm$ 7.6	0.7 $\pm$ 2.3	0.6 $\pm$ 2	0.8 $\pm$ 1.7	1 $\pm$ 1.9	1.5 $\pm$ 2.4	5.154 (.023)*	
Non-Severe	5.3 $\pm$ 7.5	0.7 $\pm$ 2.3	0.6 $\pm$ 1.7	0.7 $\pm$ 1.7	0.9 $\pm$ 1.6	1.4 $\pm$ 2.4		
Severe	7.9 $\pm$ 9	1.4 $\pm$ 2.9	1.3 $\pm$ 3.7	1.7 $\pm$ 1.9	2.4 $\pm$ 3.1	2.5 $\pm$ 2.8		
p ²	.078	.094	.224	.007*	.015*	.074		6.110 (.013)*
Wheezing (Mean number of days/month/patient)								
Total sample	10 $\pm$ 9.3	2.6 $\pm$ 4.4	2.6 $\pm$ 5	3.1 $\pm$ 4.6	3.5 $\pm$ 4.7	3.3 $\pm$ 3.6	11.339 (.001)*	
Non-Severe	8.9 $\pm$ 8.5	2.3 $\pm$ 3.8	2.3 $\pm$ 4.6	2.6 $\pm$ 3.8	3.1 $\pm$ 4	3.1 $\pm$ 3.5		
Severe	21.2 $\pm$ 9.8	5.2 $\pm$ 7.7	5.4 $\pm$ 7.1	6.9 $\pm$ 8.1	6.7 $\pm$ 8.2	4.8 $\pm$ 3.6		
p	<.001*	.021*	.014*	.004*	.003*	.051		31.216 (<.001)*
Nighttime cough (Mean number of days/month/patient)								
Total sample	11.7 $\pm$ 10.4	3.5 $\pm$ 5.8	2.9 $\pm$ 5.4	3.8 $\pm$ 5.5	5.5 $\pm$ 6.1	3.4 $\pm$ 4.1	9.002 (.003)*	
Non-Severe	10.7 $\pm$ 9.9	3.1 $\pm$ 5.3	2.8 $\pm$ 5.3	3.4 $\pm$ 4.8	5 $\pm$ 5.5	3.3 $\pm$ 4		
Severe	21.9 $\pm$ 10.6	7.3 $\pm$ 8.6	4.1 $\pm$ 5.5	7.7 $\pm$ 8.4	9.6 $\pm$ 9.1	4.6 $\pm$ 4.3		
p	<.001*	.004*	.154	.006*	.027*	.184		24.718 (<.001)*
Exercise limitation (Mean number of days/month/patient)								
Total sample	9.1 $\pm$ 11.1	2.3 $\pm$ 5.6	2 $\pm$ 4.8	2.3 $\pm$ 5	2.1 $\pm$ 3.7	2.3 $\pm$ 4.9	6.967 (.008)*	
Non-Severe	8.3 $\pm$ 11.6	2 $\pm$ 5	1.9 $\pm$ 4.9	2.1 $\pm$ 4.6	1.7 $\pm$ 3.1	2 $\pm$ 4.5		
Severe	17.2 $\pm$ 12.6	5.6 $\pm$ 9.1	2.4 $\pm$ 4.5	4.1 $\pm$ 7.4	4.8 $\pm$ 6.6	4.8 $\pm$ 7.4		
p	<.001*	.018*	.563	.138	.025*	.126		13.360 (<.001)*
Prolonged cold (Mean number of episodes/month/patient)								
Total sample	0.7 $\pm$ 0.7	0.2 $\pm$ 0.5	0.1 $\pm$ 0.5	0.2 $\pm$ 0.4	0.1 $\pm$ 0.4	0.2 $\pm$ 0.6	3.384 (.066)	
Non-Severe	0.7 $\pm$ 0.6	0.2 $\pm$ 0.4	0.2 $\pm$ 0.5	0.2 $\pm$ 0.4	0.1 $\pm$ 0.4	0.2 $\pm$ 0.6		
Severe	0.7 $\pm$ 0.7	.03 $\pm$ 0.5	0.1 $\pm$ 0.2	0.1 $\pm$ 0.3	.02 $\pm$ 0.4	0.2 $\pm$ 0.4		
p	.761	.207	.043*	.539	.705	.929		.623 (.430)
Albuterol use for acute care (Mean number of days/month/patient)								
Total sample	10 $\pm$ 9.8	3.3 $\pm$ 5.9	2.6 $\pm$ 5	3.0 $\pm$ 4.2	3.3 $\pm$ 4.1	3.6 $\pm$ 4	6.471 (.011)*	
Non-Severe	9.2 $\pm$ 9.3	3.1 $\pm$ 5.6	2.6 $\pm$ 5.2	2.9 $\pm$ 4	3 $\pm$ 3.5	3.5 $\pm$ 4.1		
Severe	17.8 $\pm$ 11.1	5.7 $\pm$ 8.1	2.8 $\pm$ 3.8	4.7 $\pm$ 5.6	6.4 $\pm$ 6.5	4.5 $\pm$ 3.2		
p	<.001*	.050*	.751	.015*	.011*	.323		17.398 (<.001)*

¹Wald χ^2 = significance of changes in asthma acute care indicators over time of the total sample.²p = difference in asthma acute care indicators between children with non-severe and severe asthma at each clinic visit.³Wald χ^2 = significance of changes in asthma acute care indicators between children with non-severe and severe asthma over time.* = alpha level of significance $\leq$ 0.05.**Table 5.** Cost of acute care need for our cohort of children with asthma over three year.

	Expenses/encounter	1 yr pre	1 yr post	2 yr post	3 yr post
Number of patients		471	396	257	176
Hospital admissions/year	\$3,600.00	223	63	11	13
Emergency Department visits/year	\$1,100.00	759	151	59	38
Urgent care (UC) visits/year	\$150.00	697	131	41	48
PCP visits for acute care/year	\$150.00	2073	304	107	92
Expenses					
Hospital admissions/year	\$3,600.00	\$ 802,800.00	\$226,800.00	\$39,600.00	\$46,800.00
Emergency Department visits/year	\$1,100.00	\$834,900.00	\$166,100.00	\$64,900.00	\$41,800.00
Urgent care (UC) visits/year	\$150.00	\$104,550.00	\$19,650.00	\$6,150.00	\$7,200.00
PCP visits for acute care/year	\$150.00	\$310,950.00	\$45,600.00	\$16,050.00	\$13,800.00
Total		\$2,053,200.00	\$458,150.00	\$126,700.00	\$109,600.00
Expenses for acute care/patient/year		\$4,359.24	\$1,156.94	\$493.00	\$622.73
Expenses based on 1 yr pre acute care need			\$1,726,257.32	\$1,120,323.57	\$767,225.48
Actual expenses			\$458,150.00	\$126,700.00	\$109,600.00
Savings			\$1,268,107.32	\$993,623.57	\$657,625.48
Three year savings			\$ 2,919,356.37		

outcomes with significant improvement in asthma control over time. Our results also suggest that in our model, cost of acute asthma care was decreased by about 75% within a year and improvement persisted over the three-year study duration. In our study, most of the children with significant acute care need and day-

to-day symptoms were not therapy resistant asthmatics but had difficult to treat asthma because of either inadequate therapy or poor adherence or both. Once they were started on adequate medications and asthma education was provided as per guidelines, their asthma control improved within months. These patients were on

low dose inhaled corticosteroids (ICS) at the time of enrollment into this study but their asthma was still not controlled. Treatment changes were individualized. In many patients, adherence was the primary issue and the same medication was continued with focus on improving adherence. In others, either dose of ICS was changed or they were switched to the combination therapy of inhaled corticosteroids and long acting beta agonist (ICS + LABA) with or without leukotriene receptor antagonists (LTRA). Medications were reviewed at each visit to maintain control. Our outcomes suggested that these patients were not treatment resistant because, with adequate adjustments in medications and with structured asthma educational program, their asthma control significantly improved. None of these patients required prolonged daily oral steroids or biologics. This observation suggest that the majority of children with uncontrolled asthma in primary care settings are probably inadequately treated asthmatics and are not difficult to treat asthmatics thus importance of implementation of guidelines in primary care settings is even more important.

NAEPP asthma guidelines are available and accessible, but adherence to guidelines is less than adequate (3,19–21). It is also noted that implementing specific parts of the asthma guidelines, such as adjusting therapy based on assessment of control can improve outcomes (22). NAEPP guidelines focus on severity over time to reflect the level of control achieved and recommend revising (step-down) therapy once control is achieved for at least three months (3) Use of these guidelines can occur through primary care offices, which will have a much greater reach and impact on a population level (23,24). High cost of uncontrolled asthma and the disproportionate burden of cost among those with severe asthma is an important factor in asthma control as severe asthmatics, representing about 4–6% of asthmatics (25), do consume much higher percent of resources because of their increased symptoms and acute care needs (8,9,26–28). Our study shows this burden can be eased with guidelines-compliant care.

It is also suggested that environmental factors may be playing a role in poor control for some patients with severe asthma (29). In our study there was no significant difference between groups when exposure to cigarette smoke, having a pet at home, or family history of asthma (siblings or parents with asthma) were compared. We did not measure allergen sensitization and exposure in the home and home environmental assessment of indoor air quality was not done. Our conclusion was based on self-reporting by

patient/family of presence or absence of pet at home and self-reporting of exposure to cigarette smoking.

Poor adherence by patients is associated with poor asthma control (30). Similarly, if health care providers are not following asthma guidelines, poor asthma control is the most likely outcome (31). Thus, asthma education is an essential part of asthma management and is strongly recommended by asthma guidelines (3,11,32). Asthma education is important to improve patients' understanding of asthma severity and adequate control. This education includes understanding potential side effects of medications and patient/family understanding that they have the ability to self-manage asthma at home. One of the limitations of this study is lack of data on adherence with prescribed medications before and during the study but it is well known that a structured asthma educational program significantly improves adherence (33) thus we assume that one of the factors playing a role is improvement in adherence to therapies during asthma education program though we lack data to confirm. To reduce severity of asthma, key factors of asthma education programs include education on environmental control, adherence with treatment, proper use of inhalers, and using an adequate asthma control assessment (11,34,35).

It takes some time to change patient/family behaviors. Studies have revealed that significant improvement in asthma morbidity and acute care need may take from 6 months to more than a year (33–36) thus long duration studies are needed to monitor asthma control with educational programs especially in children with severe persistent asthma as year to year morbidity may differ every year. Our study revealed significant improvement in acute care need by 6 months follow up (Table 2 and Figure 1) and impact of ongoing asthma education persisted throughout three-year follow up. We also noted that symptom control, albuterol need, and mean ACT significantly improved even at the 3-month follow up (Tables 3 and 4 and Figure 2).

We evaluated cost of acute asthma care over time among those who were adherent to our study. This was not a cost benefit study but estimated cumulative savings over the three-years of follow up was approximately \$2.9 million dollars (Table 5). It was not possible to determine total cost of care, as we were not able to quantify the increase expenses of ICS and specialty care to allow for net saving but our study do suggest that adherence with guidelines based therapy and educational program can lead to savings in health care cost.

Our study has limitations such as use of self-reported data from parents regarding their children's asthma symptoms and acute care need. In our study

design, patients were their own controls and clinical data from 6–12 months period before initial visit was compared with data during 3-year study period. Limitations included lack of data on socio-economic status, insurance and housing issues such as indoor allergen exposure and lack of data on those who were lost to follow-up. In children, there is a general expectation of reduction in disease severity owing to the natural history of the disease. It is unlikely that in large number of patient, such decrease in severity happened so fast across all ages within few months. Our sample size decreased over the three-year period, reasons are unclear but this pattern is not unusual as other studies (even with smaller duration) have noticed dropout rate as high as 40% (37–39). Strengths of our study were the long-term follow-up period, assessment of multiple data points over time, and better asthma control over time.

Conclusion

This study suggest that asthma control improves independent of severity among participants who followed a structural educational program with regular follow-ups with continued asthma care in a clinical setting that aligned services with asthma guidelines.

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Declaration of interest

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Notes on contributor

Dr. Sheikh: Contributed to the study design, study conduct, data collection, and manuscript preparation. He had full access to all of the data in the study and takes responsibility for data integrity, accuracy of the data analysis, and serves as the guarantor of the manuscript. Nancy A Ryan-Wenger: Contributed to the study conduct, data analysis and interpretation, and manuscript preparation. Judy Pitts: Contributed to the study design, study conduct, data collection, and manuscript preparation. Christopher J. Nemastil:

Contributed to the study design, study conduct, data collection, and manuscript preparation. Sabrina Palacios: Contributed to the study design, study conduct, data collection, and manuscript preparation.

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Asthma Follow up visit Survey:**Date:** _____**Date of Last Asthma visit:** _____**Demographics:**

Name of Child: _____

Acute Care Need since last visit:

	Since last visit ____ months ago
Hospital admission for asthma	
Emergency department visits for asthma	
Urgent care visits for asthma	
Primary care office visits for acute asthma care	
School days missed for asthma	
Short courses of oral steroids	
Albuterol for acute asthma care (days/month)	

Symptom control since last visit:

Since last visit	yes or NO	How many days/month
Day time wheezing		() days/month
Night time cough/awakening		() days/month
Exercise limitation		() days/month
Using albuterol before exercise		() days/month
Prolonged colds (>10 days)		() days/month

	yes or NO	details
Seasonal variation	yes or NO	symptoms are worse in _____
Triggers	yes or NO	
Pets at home	yes or NO	
Smoking exposure	yes or NO	Who smoke

To be filled by Physician/NP**Asthma Control Test (ACT) score:** _____**PFT: FEV1 _____, FEV1/FVC _____, FEF25-75 _____****Medication change** _____

Asthma Initial Evaluation Survey:

Date: _____

Demographics:

- Name of Child: _____
- Gender: Male ____ female ____ Date of Birth _____ Age (in years) ____, ethnicity _____
- Names of your child's current **daily** asthma medications: _____
- Age at onset of symptoms ____ age at diagnosis of asthma ____ duration of symptoms ____

	In last 6 months	In last one year
Hospital admission		
Emergency Department visits		
Urgent care visits		
Primary care office visits for acute asthma care		
School days missed		
Short courses of oral steroids		
Albuterol for acute care (days/month)		

	Yes or No	In last three months
Day time wheezing		() days/month
Night time cough/awakening		() days/month
Exercise limitation		() days/month
Prolonged colds (>10 days)		() times/month

	Yes or No	Please give details
Seasonal variation		More symptoms in _____
Asthma Triggers (makes asthma worse)		Which triggers
Pets at home		which pets
Smoking exposure		Who smoke
Family history of Asthma		Who has asthma
Family history of Allergies		Who has allergies
Family h/o any chronic lung disease		

To be filled by Physician/NP

Asthma Severity: _____

Asthma Control Test (ACT) score: _____

PFT: FEV1 _____, FEV1/FVC _____, FEF25-75 _____

Medication change _____