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To cite this article: Lyne Scott MD, Marilyn Li MD, Salima Thobani MD, Breck Nichols MD, Tricia Morpew MS & Kenny Yat-Choi Kwong MD (2016): Asthma control and need for future asthma controller therapy among inner-city Hispanic asthmatic children engaged in a pediatric asthma disease management program (the Breathmobile program, Mobile Asthma Care for Kids Network), Journal of Asthma, DOI: [10.3109/02770903.2015.1050498](https://doi.org/10.3109/02770903.2015.1050498)

To link to this article: <http://dx.doi.org/10.3109/02770903.2015.1050498>



Published online: 24 May 2016.



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ORIGINAL ARTICLE

Asthma control and need for future asthma controller therapy among inner-city Hispanic asthmatic children engaged in a pediatric asthma disease management program (the Breathmobile program, Mobile Asthma Care for Kids Network)

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Abstract

Objective: To determine whether significant numbers of asthmatic children with initially rated intermittent asthma later suffer poor asthma control and require the addition of controller medications. **Methods:** Inner-city Hispanic children were followed prospectively in an asthma-specific disease management system (Breathmobile) for a period of 2 years. Clinical asthma symptoms, morbidity treatment, and demographic data were collected at each visit. Treatment was based upon National Heart, Lung, and Blood Institute (NHLBI) Expert Panel Report 3 asthma guidelines. Primary outcome was percentage of patients with intermittent asthma who had not well or poorly controlled asthma during subsequent visits and required controller agents. Secondary outcomes were factors associated with the maintenance of asthma control. **Results:** About 30.9% of the patients with initial rating of intermittent asthma had not well controlled and poorly controlled asthma during subsequent visits and required the addition of controller agents. Factors associated with good asthma control were compliance, no previous emergency room visits and previous visit during spring season. **Conclusion:** Asthmatic children with intermittent asthma often lose asthma control and require controller therapy. This justifies asthma guideline recommendations to assess asthma control at follow-up visits and adjust therapy accordingly.

Keywords

Asthma, children, intermittent, control, controller

History

Received 14 November 2014
Revised 4 May 2015
Accepted 7 May 2015

Introduction

Extensive data demonstrate that prescription of long-term asthma controller medications result in significantly diminished asthma-related morbidity and mortality in patients with persistent asthma [1–4]. National guidelines recommend initiation of specific type and dosing of asthma controllers depending on initial disease severity and stepwise adjustments according to asthma control assessed on regular basis [1].

Patients with intermittent asthma severity are unlikely to have chronic airway inflammation and by definition do not require chronic controller therapy [1]. Asthma disease activity however waxes and wanes in response to various factors such as allergic and irritant triggers, viral infections and atmospheric changes [1,5,6]. Therefore patients initially diagnosed with intermittent asthma may at later time points require the use of controller medications in response to worsening symptoms.

This highlights importance of regular asthma control assessments to guide stepping up or down of chronic therapy to maintain disease control [1].

It is currently unclear how many asthmatics with initially rated intermittent asthma eventually require initiation of long-term asthma controller therapy. The purpose of this study was to determine if inner-city Hispanic children with asthma initially rated as intermittent, lose disease control during the next 2 years and require step up of asthma therapy. These patients received specialty-based care in Los Angeles mobile asthma clinics (Los Angeles County + University of Southern California, LAC+USC, Breathmobile Program) and resided in the Greater Los Angeles inner cities areas, as previously described [7,8]. Secondary outcomes evaluated other associated factors that may contribute to asthma control in this patient population including controller medications, gender, age, body mass index (BMI) percentile, and seasonality.

Methods

Patient selection

Patient selection criteria included: (1) program enrollment between January 2011 and December 2012; (2) age 3–18 years;

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IMPAIRMENTDay time symptoms (wheezing, coughing due to asthma, chest tightness, dyspnea)*:

≤ 2 episodes per week

Night time symptoms (wheezing, coughing due to asthma, chest tightness, dyspnea)*:

≤ 2 episodes per month

0 episodes per month (children 0–4 years of age)

Use of short acting b2-agonists*:

≤ 2 episodes per week

Interference with normal activity*:

None

Pulmonary function testing@:

FEV1 > 80% predicted

RISKAsthma exacerbations requiring systemic steroid rescue

0–1 episodes per year

*Based upon a 2 week recall.

@ Some patients unable to perform due to young age.

Figure 1. Clinical criteria used to determine intermittent asthma severity at time of entry into the program. Patients satisfying all criteria were rated as having intermittent asthma. Patients who received an asthma severity rating by their primary care providers prior to program entry were allowed to keep their previous asthma severity rating regardless whether they were placed in asthma controllers in subsequent visits.

(3) Hispanic ethnicity; (4) initial visit: asthma diagnosis and guideline-based intermittent baseline severity recorded [1]; Figure 1 shows the clinical criteria used to determine intermittent asthma symptoms. Patients who received an asthma severity rating by their primary care providers prior to program entry were allowed to keep their previous asthma severity rating. In the event there was a discrepancy between baseline severity rating determined by the Breathmobile provider and the primary care provider, the former provider's asthma severity rating was used; (5) follow-up visit within 6-month post-program entry. Two follow-up visits were sufficient as intent to treat methodology employed; and (6) enough clinical data consisting of impairment and risk at follow-up visit to rate asthma control status determinable by National Heart, Lung, and Blood Institute (NHLBI) Expert Panel Report 3 (NHLBI EPR-3) asthma guidelines [1]. Patients had to have minimum clinical data consisting of frequency of daytime symptoms, frequency of night time symptoms, interference with normal activities, frequency of rescue medication use, frequency of systemic steroid rescue and lung function testing if cooperative. Patients were excluded if there were insufficient data during first follow-up visit to rate asthma control.

Patients were diagnosed with asthma based upon clinical criteria and spirometry (including episodic symptoms of airflow obstruction or airway hyperresponsiveness which were at least partially reversible based upon clinical examination and/or spirometry) in accordance with NHLBI-EPR-3 asthma guidelines. Patients were diagnosed with allergic rhinitis based

upon clinical history (nasal purities, sneezing, rhinorrhea, and nasal congestion), physical examination and sensitization to seasonal and perennial allergens as demonstrated by skin testing.

Data were recorded prospectively using an asthma-specific asthma disease management electronic health record program (AsmaTrax) [7,8]. Baseline characteristics of age, gender, BMI percentile group, diagnosis of allergic rhinitis, emergency department (ED) visits, missed school days, season at initial enrollment were recorded. At follow-up visits asthma control at follow-up visits was assigned to one of the three NHLBI EPR-3 defined categories (well-controlled asthma – WCA, not well-controlled asthma – NWCA, and very poorly controlled asthma – PCA). The most severe indicator across components defined asthma control [1]. Additional data recorded at interval visits included height, weight, school days missed since last visit, visit interval (days), controller therapy prescribed, and patient reported adherence to therapy prescribed. Adherence was stratified to less than 5 days or more than 5 days/week adherent to prescribed controller treatment (self-reported).

The effect of controller therapy use during each visit interval on time towards maintenance of well-controlled asthma during the 2-year study period was assessed. Potential confounding and interaction effects between controller medication use and additional factors upon ability to maintain asthma control was assessed using multi-variant analysis. These additional factors included: height, weight, sex, allergic rhinitis diagnosis, ED visits (prior year), school days missed (prior year), season

and visit interval (days). The study was approved by the Institutional Review Board of University of Southern California.

Statistical methods

Factors investigated in analysis included: (1) patient characteristics: gender, age (3–4, 5–11, 12–18 years), and BMI percentile (<85% = normal, 85–94% = at risk, > 95% = overweight), (2) time factors: season of entry, month of visit, and visit interval defined as elapsed days since last visit (<60, 61–90, >90 days), (3) treatment factors: patient reported adherence with controller medications (<5 days or > = 5 days/week), time to achieve WCA, and therapy prescribed (step of therapy determinable by 2007 NHLBI EPR-3 asthma guidelines).

Generalized estimating equations method was used to analyze factors associated with WCA at follow-up visits 1–6 after control was first achieved. After adjustment for other significant contributory variables, factors that significantly influenced likelihood of WCA were investigated by categorical contrast comparisons. Probability of maintaining WCA was estimated based on the average value of covariates included in the final model. Analyses were adjusted for potential clustering effects of care site and cohort effects of year of program entry.

SAS version 9.1 software (SAS Institute Inc, Cary, NC, USA) was used for cox regression and generalized estimating equations analyses, and remaining analyses were conducted with SPSS version 12.0 software (SPSS Inc., Chicago, IL).

Results

Patient population

The patient population characteristics for this study are described in Table 1. All patients were of Hispanic ethnicity. 63.8% of the patients were male with 75.0% being ages 5–11 at time of program enrollment. 55.2% of patients were overweight or obese. 59.7% of patients were diagnosed with allergic rhinitis in addition to asthma. 29.2% of patients reported at

Table 1. Characteristics of Hispanic patient population with intermittent asthma baseline severity.

	<i>n</i> = 72
Male	63.8%
Age at baseline, years~mean (SD)	8.5 (3.4)
3–4 years	6.9%
5–11 years	75.0%
12–18 years	18.1%
BMI percentile	
Normal (<85%)	44.8%
Overweight (85–94%)	14.9%
Obese (> = 95%)	40.3%
Allergic rhinitis diagnosis ^a	59.7%
Prior year morbidity due to asthma-related symptoms	
ED visits (any)	29.2%
Hospitalizations (any)	5.6%
School absenteeism (> = 5 days)	18.1%
Season of entry:	
Winter	25.0%
Spring	36.1%
Summer	12.5%
Fall	26.4%

^aAllergic Rhinitis diagnosis reported at any year one visit (majority of patients had diagnosis reported at baseline visit)

least one ED visit and 5.6% of patients reported at least one hospitalization due to asthma-related symptoms at the time of program enrollment. The greatest percentage of patients (36.1%) entered the program in the spring with 25.0%, 12.5%, and 26.4% respectively entering the program in the winter, summer, and fall and had a total of 304 visits during the study period. Mean number of visits per patient was 4.19. 19.5% of patients with intermittent baseline severity reported being prescribed controller therapy by an independent provider at the point of program entry. Almost 45% of these patients reported non-adherence with prescribed controller (use less than 5 days/week) at program entry. Seven patients who were rated as having intermittent asthma by primary care were changed to persistent asthma after additional history was obtained by Breathmobile provider. These patients were excluded from the intermittent cohort. No patients rated with persistent asthma were found to have additional history on the Breathmobile that would re-classify them as baseline intermittent asthmatics.

Asthma controller requirement and asthma control among intermittent asthmatic patients

About 69.1% of the asthmatic patients initially rated with intermittent asthma severity did not require any addition of controller at any visit. Significant numbers of patients (30.9%) with intermittent baseline severity required controller therapy (Step 2 or higher) at follow-up visits during the study period based on reported domains of impairment and risk (Table 2). Patients who did not require controller medication at any time (and were subsequently not prescribed any) were 2.9 (1.3–6.5, *p* = .009) times more likely to maintain well-controlled asthma at follow-up compared to patients who needed and were prescribed controller medication but reported use <5 days/week. Patients who were directed to use controller therapy (Step 2 or higher) and reported use > = 5 days/week were 2.3 (0.9–6.0, *p* = 0.82) times more likely to maintain well-controlled asthma at follow-up compared to patients who were prescribed controller therapy but reported use <5 days/week (Table 3).

Table 2. Therapy prescribed for intermittent asthmatic Hispanic patients by National Asthma Education Prevention Program guideline-defined steps of therapy

Steps of therapy	Baseline therapy visit <i>n</i> = 72	All visits <i>n</i> = 304
Step 1: SABA only	80.6%	69.1%
Controller use <5 days/week	8.3%	9.5%
Controller use > = 5 days/week	(11.2%)	(21.4%)
Step 2:		
(alt 1) Low-dose ICS	5.6%	12.8%
(alt 2) LTRA only	—	1.3%
Step 3:		
(alt 1): Medium dose ICS	1.4%	3.3%
(alt 2): Low-dose ICS + LABA	4.2%	3.6%
(alt 3): Low-dose ICS + LTRA	—	—
(alt 4): Low-dose ICS + LABA + LTRA	—	—
Step 4: any combination	—	0.3%

ICS, inhaled corticosteroids; LABA, inhaled long-acting β2-agonist; LTRA, leukotriene receptor antagonist; SABA, inhaled short-acting β2-agonist. Steps of therapy determined by patient age, medication type and dose prescribed.

Table 3. Maintenance of Well-controlled asthma: significant factors associated with asthma control for intermittent baseline Hispanic patients.

Factor investigated	Outcome: well-controlled asthma Adjusted odds ratio ^a (95% CI, <i>p</i> value)
Controller medication use (compared to patients prescribed controller medication who reported use <5 days/week)	
No controller medication prescribed	2.92 (1.3–6.5, <i>p</i> = .009)
Controller medication prescribed and reported use > = 5 days/week	2.34 (0.9–6.0, <i>p</i> = .082)
Gender: male vs. female	0.72 (0.4–1.4, <i>p</i> = .319)
Age at prior visit:	
5–11 vs. 3–4 years	2.06 (0.5–7.9, <i>p</i> = .292)
12–18 vs. 3–4 years	2.90 (0.6–13.7, <i>p</i> = .178)
BMI percentile at prior visit:	
<85% vs. 85–94%	1.15 (0.5–1.28, <i>p</i> = .797)
<85% vs. >= 95%	0.70 (0.30–1.4, <i>p</i> = .327)
Allergic rhinitis: + vs. – diagnosis	0.58 (0.3–1.3, <i>p</i> = .168)
School missed year prior to entry: >= 5 vs. < 5 days	1.40 (0.5–3.7, <i>p</i> = .498)
ED visit (any) year prior to entry: any vs. none	0.48 (0.2–0.9, <i>p</i> = .045)
Season of prior visit	
Spring vs. winter	2.69 (1.1–6.4, <i>p</i> = .025)
Spring vs. summer	2.93 (1.3–6.4, <i>p</i> = .007)
Spring vs. fall	2.63 (1.1–6.4, <i>p</i> = .033)
Visit interval: <= 90 days vs. >90 days	1.27 (0.6–2.5, <i>p</i> = .502)
Follow-up visit after control first achieved:	
First vs. second follow-up	0.44 (0.2–1.0, <i>p</i> = .112)
First vs. third or higher follow-up	0.54 (0.3–1.2, <i>p</i> = .292)

^aOdds ratios based on model that adjusts for controller therapy, gender, age at prior visit, BMI percentile group at prior visit, allergic rhinitis diagnosis, ED visits year prior to baseline (Y/N), school missed year prior (<= 5 vs. >5 days), season of prior visit, visit interval (<= 90 vs. >90 days), and follow-up visit # after control first achieved (first, second, third, or higher).

Other factors associated with asthma control

Patients who had asthma-related ED visit(s) during the year prior to program entry were 52% (odds ratio = 0.48 [0.2, 0.9, *p* = 0.045]) less likely to maintain well-controlled asthma at follow-up. The lowest percentage of patients entered program in summer and highest percentage of patients entered in the spring. When prior visit occurred in the spring, patients were 2.7, 2.9, and 2.6 times more likely to maintain well-controlled asthma at their next follow-up compared to visits that occurred in winter, summer, and fall, respectively (*p* < .05). Patients diagnosed with allergic rhinitis were no more likely to lose asthma control compared to those without such diagnosis (Table 3).

Discussion

In this study, we show that in a large inner-city asthma disease management system significant number of Hispanic pediatric patients initially rated as having intermittent asthma often fall out of control during subsequent visits. These patients if adherent to prescribed controller medications are almost 3 times more likely to maintain asthma control compared to those who

are non-compliant. Other independent factors that predicted loss of control were previous ED visits and season of program entry. These results justify guideline-based recommendations that asthma control is assessed continuously using impairment and risk domains and therapy adjusted to achieve and maintain disease control.

The Breathmobile program is a mobile disease management program which treats underserved inner-city children with asthma regardless of insurance status and does not require patients and their families to pay for any “out of pocket” expenses. Socio economic and geographic barriers to specialty care are therefore removed. Patients receive ongoing asthma specific care on a 2- to 3-month recurring basis long term [7,8]. More than three quarters of patients enrolled in the Breathmobile program are primarily of Hispanic ethnicity and therefore in this study we decided to limit entry criteria to only Hispanic patients [5].

Despite engagement in such a tightly regulated disease-specific program with dedicated resources to track patient outcomes in real time, up to one-third of intermittent patients required step up therapy. Our results are congruent with other studies which show that baseline asthma severity may not predict course of asthma severity over time [1,5,9–12]. This highlights the importance of more frequent follow-up visits even of intermittent patients, shorter than the guideline recommended every 6 months. Previously we have shown that follow-up visits of 8–10 weeks significantly improve ability to maintain asthma control long term [3,8].

Up to 19.5% of patients with intermittent asthma were prescribed a controller agent before entry into our program. 5.6% of patients were prescribed step 2 therapy while similar percentage was given Step 3 therapy. It is likely that many of these patients were not intermittent asthmatics when controller naïve and were actually “treated” patients with persistent asthma. This reinforces guideline recommendations that initial asthma severity should be used as a rough estimate on first contact with patients and asthma control used as a continuous assessment for treatment [1]. It is also likely that some of these intermittent patients had baseline intermittent severity but were prescribed controllers during isolated disease exacerbations triggered by allergens or respiratory infections [1,13,14]. This again highlights need for real-time asthma control assessment and not reliance upon initial asthma severity. In this, study the significant number of patients prescribed controllers by independent providers however reported they were not compliant with therapy. It is possible that when given an intermittent diagnosis asthma patients may feel less of a need to take controllers during the periods of exacerbations.

Secondary outcomes revealed several factors that were associated with good asthma control. Similar to most studies, adherence was a highly significant factor in predicting asthma control. Patients who were prescribed controllers but were compliant less than 5 days/week were significantly less likely to maintain control compared those who were more compliant more than 5 days/week. Potential reasons include poor perception of disease symptoms, denial of asthma severity, or premature discontinuation because of improvement of symptoms while on therapy. Patients must be educated at each visit about importance of adherence to therapy regimens.

For patients with a history of a previous asthma-related ED visit prior to program entry, there is an increased risk of not maintaining well-controlled asthma over time. Even though intermittent at baseline, if the patient had a history of asthma related ED visit, our results suggest there may be benefit in initiating controller therapy to decrease risk of asthma exacerbations. This is consistent with guideline recommendations that patients who require more than one systemic steroid rescue for exacerbations per year be rated as persistent asthma and prescribed controller medications even if their impairment is intermittent or controlled. Results of this study suggest that in at least a subset of patients a single severe exacerbation may warrant consideration of controller medication and/or more frequent follow-up visits.

Spring season of prior visit implies that the follow-up visit when control was assessed likely occurred in the late spring or summer. The patient was more likely to have well-controlled asthma during that late-spring or summer. Breathmobile units treat patients on a regular basis year round as many greater Los Angeles area schools sites remain open year round for various activities although show rates are lower during this time due to many students leaving the city for summer vacations. Most likely decreased exposure to viral infections, allergens and fewer extremes of weather triggers resulted in better disease control during this time. The literature reports well-known correlations of asthma exacerbations in the fall with the September wheezing epidemic [1,15]. Similar risks for our study are noted in the winter that may be attributable to viral infections and weather changes.

Of interest, the diagnosis of allergic rhinitis did not have a significant association with patients' ability to maintain asthma control. There was a trend that upper airway disease was associated with less asthma control but it did not reach statistical significance. This finding is contrary to what has been reported by other investigators [1,16,17]. Our study findings may be due to the unique disease management aspects of the Breathmobile program. All patients are assessed for allergic rhinitis at the initial visit with documented skin testing within the first three visits when allowable. Patients are treated for both upper and lower airway disease when present potentially minimizing the effect of allergic rhinitis on the ability to maintain asthma control. Over 80% of asthma patients were skin test positive for perennial and/or seasonal allergens (data not shown).

Younger children (3–4 years of age) were not at higher risk to have worse asthma control compared to children 5–11 and 12–18 years of age. This is in contradistinction to other studies where asthma exacerbations and symptoms were more likely in younger age groups. These patients often have extended periods of time with intermittent symptoms but suffer severe exacerbations in response to viral infections [1,18–21]. Our results could in part be due to the fact that patients who were experiencing frequent asthma symptoms due to respiratory infections (but had long periods of intermittent symptoms between episodes) were classified into persistent asthma cohort versus intermittent cohort. Alternatively, we had a relatively small sample size and if larger number of patients were included significant differences in asthma control may have been detected between the age groups.

Results of this study should be interpreted with certain considerations. This prospective but observational "real world"

study is subject to patient recall bias. This bias is minimized by recording visit interval asthma-related morbidities at a visit level and focusing on asthma symptom recall over the preceding two weeks prior to visit. Two-way interaction effects (interdependency) of factors on outcomes were not examined due to limited power (e.g. influence of therapy on ability to maintain asthma control may depend on whether patient has co-morbid diagnosis of allergic rhinitis; analyses adjusted for influence of allergic rhinitis but did not assess potential interaction with therapy). This study applies to an inner-city Hispanic population and results may not be applicable to other patient populations.

Conclusion

This study highlights importance of regular assessment of asthma symptoms and adherence to guidelines defined therapy for patients with intermittent baseline asthma. Fluctuations in the need for controller therapy prescribed reinforce dynamic nature of asthma symptoms and need to reassess asthma control at each visit. Adherence to prescribed controller medication use >5 days/week improves these patients' ability to maintain well-controlled asthma. Future studies should be planned to determine whether a certain phenotype of intermittent asthmatics are more likely to lose asthma control and interventions made early to reduce asthma related morbidity.

Declaration of interest

Marilyn Li is a speaker for Meda. Kenny Kwong has received grant support and serves as a consultant and speaker for Thermo Fisher. Salima Thobani, Breck Nichols and Tricia Morphew declare no conflicts of interest. The authors alone are responsible for the content and writing of this article.

Funding

Lyne Scott has received funding for health disparities research from the NIH Loan repayment Program.

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