Treatment Patterns and Asthma Control Among US Allergy and Pulmonary Community Practices: Results of the CHARIOT Study

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ABSTRACT

Rationale: The aim of the Characterization of Allergic Asthma: A Chart Review In Moderate-to-Severe Disease to Assess Asthma Control, Allergies, Patient Outcomes and Treatment (CHARIOT) study was to examine the natural history, practice patterns and treatment of moderate-to-severe asthma patients.

Methods: A randomized chart review with data entry via a web-based case report form was conducted at 60 allergy and pulmonary US community practices. Using 12-month data from 2005-2007, we analyzed factors (e.g., atopy, resource utilization, pulmonary function, treatment medications/patterns and patient characteristics) associated with controlled (C) and uncontrolled (UC) asthma in 365 male and 644 female patients (mean age 43.2 ± 17.1 years) with moderate-to-severe asthma receiving at least inhaled corticosteroids. Control was assessed according to NAEPP/GINA[1,2] guidelines.

Results: Of the 1009 patients assessed, 18.1% and 81.9% were C and UC, respectively. Patient questionnaires to assess control were not used frequently (42% of clinics reported use). Atopy was detected in 92% of all patients and UC patients tended to have more comorbidities (89.5% UC vs 76.5% C). Patients with UC asthma were more likely to have elevated IgE levels (25% UC vs 4% C) and high resource use (154 days hospitalized/14 ICU days UC vs 0 days C).

Conclusions: Greater than 80% of patients from specialist practices have uncontrolled asthma and increased resource utilization. A high proportion of these patients have atopic characteristics. Therefore, the role of allergies should be assessed and alternative treatment options, as stated in Steps 5 and 6 of the newest NAEPP guidelines, should be explored.

ASTHMA CONTROL GUIDELINES

The control algorithm for this study was developed using both NAEPP/NHLBI[1] and GINA[2] guidelines

- **NAEPP/NHLBI**
  - Symptom frequency and severity
  - Presence of nocturnal symptoms
  - Exercise intolerance
  - Need for hospitalizations or ED visits
  - Exacerbations
  - Interference with normal activity
  - Responsiveness to therapy
  - Use of short-acting β_2 agonists
  - Pulmonary function
- **GINA**
  - Symptom severity
  - Presence of nocturnal symptoms
  - Exercise or activity intolerance
  - Use of short-acting β_2 agonists
  - Optimal lung function
  - Minimal medication side effects

STUDY OBJECTIVES

- Determine the proportion of patients who have uncontrolled (UC) asthma in community-based specialty practices
- Describe the prevalence and characteristics of atopy associated with UC asthma
- Characterize resource utilization, pulmonary function, medications, treatment patterns, and patient demographics
- Understand clinical practice characteristics associated with UC asthma

STUDY INCLUSION CRITERIA

This retrospective chart-review study included patients who met the following inclusion criteria based on the patient's history during the previous 12 months:

- ≥12 years of age
- Moderate or severe asthma (according to the NAEPP[1] criteria)
- Under continuous care of a physician for at least 12 months
- Used one of the following medication regimens
  - Inhaled corticosteroids equivalent to ≥880 mg of fluticasone MDI/day alone
  - Inhaled corticosteroids equivalent to ≥440 mg of fluticasone MDI/day plus any dose of an additional controller medication
    - Leukotriene inhibitors/receptor blockers (montelukast, zafirlukast, zileuton)
    - Long-acting β_2 agonist
    - Cromolyn sodium
    - Nedocromil
    - Theophylline

STUDY EXCLUSION CRITERIA

- Presence of a severe pulmonary or medical condition other than asthma, including the following:
  - Chronic obstructive pulmonary disease (COPD) or cystic fibrosis
  - Hypertension
  - Diabetes
  - Congestive heart failure
  - Cancer
  - Severe psychiatric disorder
  - Significant systemic disease
- Being a current smoker or having a smoking history of ≥20 pack-yrs
- Known alcohol or drug abusers
- Documented asthma medication non-compliance

CRITERIA USED TO DEFINE UNCONTROLLED (UC) ASTHMA

Occurrence of any of the following events in the most recent 12 months of continuous follow-up:

- Systemic corticosteroid burst
- Frequent (i.e., ≥3 times weekly) short-acting β_2 agonist use
- Emergency department visit for asthma
- Exacerbation, indicated by hospitalization over the past year and/or unscheduled visit
- Nocturnal asthma symptoms
- Limitations on activities, including exercise
- Clinically significant decline in lung function (< 80% predicted FEV1 or PEF)
- Daytime dyspnea > 2 times weekly
- Doubling of inhaled corticosteroid dose
- Addition of another controller medication

Patient Demographics

Characteristic	Controlled (n=183)	Uncontrolled (n=826)	Total (N=1,009)
Female (n,%)	120 (18.6%)	524 (81.4%)	644 (63.8%)
Age (mean + SD)	43.2 ± 16.5	43.2 ± 17.3	43.2 ± 17.1
Race/ethnicity (n,%)			
Caucasian	153 (18.4%)	681 (81.6%)	834 (82.6%)
African-American	8 (10.3%)	70 (89.7%)	78 (7.7%)
Hispanic	14 (16.3%)	72 (83.7%)	86 (8.5%)
Asthma duration, years (mean ± SD)	16.4 ± 14.4	15.8 ± 13.6	15.9 ± 13.7
Asthma severity (n,%)			
Moderate	26 (12.2%)	187 (87.8%)	213 (21.1%)
Severe	157 (19.7%)	639 (80.3%)	796 (78.9%)

*Other racial/ethnic backgrounds not shown include Asian, American Indian/Alaska Native, and unknown.

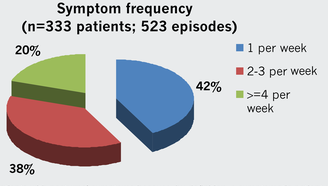
Patient Co-Morbid Conditions Associated with Allergic Asthma

Condition	Controlled (n=183)	Uncontrolled (n=826)	Total (N=1,009)
Allergic rhinitis	119 (65%)	612 (74%)	731 (72.4%)
Rhinoconjunctivitis	9 (4.9%)	70 (8.5%)	79 (7.8%)
Rhinosinusitis	10 (5.5%)	84 (10.2%)	94 (9.3%)
Sinusitis	33 (18.0%)	200 (24.2%)	233 (23.1%)
Atopic dermatitis/eczema	7 (3.8%)	50 (6.0%)	57 (5.6%)
Allergic conjunctivitis	9 (4.9%)	70 (8.5%)	79 (7.8%)

Allergy History for Controlled and Uncontrolled Asthma Patients

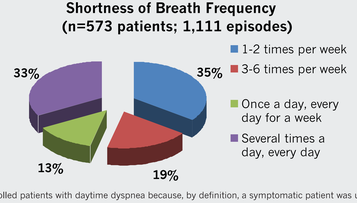
Condition	Controlled (n=183)	Uncontrolled (n=826)	Total (N=1,009)
No history of/unknown if allergies	17 (9.3%)	73 (8.8%)	90 (8.9%)
Early onset of asthma	57 (31.1%)	198 (23.9%)	255 (25.3%)
Antihistamine use	107 (58.5%)	470 (54.5%)	577 (57.2%)
Serum IgE levels, Mean value ± SD	320 ± 346 (N=39)	657 ± 1268 (N=252)	621.2 ± 1192 (N=291)
Eosinophilia on CBC	6 (3.3%)	40 (4.8%)	46 (4.6%)
Positive RAST test	17 (9.2%)	94 (11.4%)	111 (11.0%)
History of nasal steroid use	100 (54.6%)	429 (51.9%)	529 (52.4%)
Positive skin-prick test	125 (68.3%)	587 (71.4%)	712 (70.6%)
Number of allergens (mean ± SD)	3.41±2.42	3.61±2.38	3.57±2.39

Asthma Symptoms – Nocturnal Symptom Frequency for UC Patient Episodes* Over the Past 12 Months



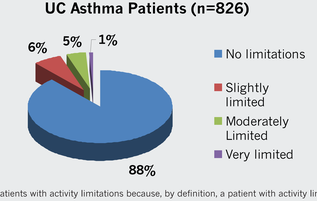
*There were no controlled patients with nocturnal symptoms because, by definition, a symptomatic patient was uncontrolled.

Asthma Symptoms – Daytime Dyspnea Frequency for UC Patient Episodes* Over the Past 12 Months



*There were no controlled patients with daytime dyspnea because, by definition, a symptomatic patient was uncontrolled.

Asthma Symptoms – Noted Limitations in Daily Activities for UC Patients* Over the Past 12 Months



*There were no controlled patients with activity limitations because, by definition, a patient with activity limitations was uncontrolled.

Respiratory Outcomes for UC vs C Patients

Condition	C (n=183)	UC (n=826)
PEF	481 ± 134	366 ± 139*
FEV_1	2.9 ± 0.75	2.4 ± 0.82
FVC	3.7 ± 0.96	3.2 ± 0.99

*p<0.0001 based on t-test.

Resource Use for C and UC Asthma Patients, Prior 12 Months

Response to Exacerbation	C (n=183)	UC (n=826)	Total (N=1,009)
Total Visits (Six people had 8 or more visits)			850 (n=433)
ER	0	41 (n=37)	41
Unscheduled Physician office (total visits, n)	0	734 (n=397)	734 (n=397)
Phone call	4	77	81
Self-treat	1	29	30
Increased ICS dose	0	2	2
Took oral CS	0	13	13
Used rescue inhaler	1	7	8
Used short-acting β_2 agonist	0	10	10
Used short-acting β_2 agonist ≥ 3 times weekly	0	7	7
Hospitalizations (total days, n)	0	154 (n=37)	154 (n=37)

Conclusions

- In this sample of moderate to severe asthmatic patients from community-based specialty practices, we found an overall 81.9% rate of UC asthma.
  - These patients consume a high level of healthcare resources
  - A high proportion of these patients have atopic characteristics
- Asthma severity was the only significant predictor of UC asthma
  - As compared to severe asthmatic patients, moderate asthmatic patients were more likely to be UC
  - This may suggest that this population is not being treated aggressively enough with current therapies
  - Once treatment is established that corresponds to severity, the emphasis is on assessing control to determine if the goals of therapy have been met and if further adjustments are needed.
- We found few correlates between patient characteristics, disease, treatment and practice parameters in this study.
- To improve asthma treatment, we suggest that moderate asthmatics may specifically require more aggressive treatment, as these patients have a statistically significantly greater probability of UC asthma.

References

1. National Institutes of Heath, National Heart, Lung, Blood Institute. National Asthma Education and Prevention Program Expert panel report 3: *guidelines for the diagnosis and management of asthma*. 2007.
2. Global Initiative for Asthma (GINA). (National Institutes of Health, National Heart Lung and Blood Institute). *Global strategy for asthma management and prevention. 2006.* Report No.: NIH Publication No 02-3659.

This study was supported by Novartis Pharmaceuticals Corporation and Genentech, Inc.