

TREATMENT

Asthma Severity in Patients Initiating Controller Monotherapy versus Combination Therapy

GREGORY B. DIETTE, MD,^{1,*} ANNE L. FUHLBRIGGE, MD,² FELICIA ALLEN-RAMEY, PH.D.,³
APRIL HOPPER, PHARM.D.,⁴ SHIVA G. SAJJAN, PH.D.,³ AND LEONA E. MARKSON, SC.D.³

¹*Pulmonary and Critical Care Medicine, The Johns Hopkins University, Baltimore, MD, USA.*

²*Pulmonary and Critical Care Division, Brigham and Women's Hospital, Boston, MA, USA.*

³*Global Health Outcomes, Merck & Co., Inc., Whitehouse Station, NJ, USA.*

⁴*Clinical Services Department, Rite Aid Health Solutions, Moon Township, PA, USA.*

Background: Asthma treatment guidelines recommend medications based on the level of asthma control. **Objective:** To evaluate differences in asthma control between patients who initiated asthma controller monotherapy versus combination therapy. **Patients and methods:** Children (5–16 years; $n = 488$) and adults (17–80 years; $n = 530$) with asthma and no controller therapy in the prior 6 months were included. Telephone surveys were conducted within 5 days of filling a new asthma controller prescription with either the caregiver of children or the adult patient. Demographics, asthma control before therapy, and asthma-related resource use were assessed for patients initiating monotherapy (filling one asthma controller prescription) and combination therapy (filling more than one controller medication or a fixed-dose combination). **Results:** Mean pediatric age was 10 years; 53% were male. Mean adult age was 47 years; 25% were male. There were no significant differences in asthma control score between patients receiving monotherapy and combination therapy. Children on combination therapy did not have more nighttime awakening or short-acting β -agonist use but were more likely to have been hospitalized due to asthma attack ($p = .05$) and have more unscheduled ($p = .0374$) and scheduled ($p = .009$) physician visits. Adults on combination therapy were more likely to have been hospitalized due to asthma attack ($p < .05$) and have regular doctor visits for asthma ($p < .01$). **Conclusions:** Assessment of asthma control scores in the 4 weeks before index medication suggests that asthma severity during a treatment-free period did not differ significantly for patients initiating controller monotherapy versus combination therapy. From these findings, it appears that although physicians may not focus on asthma control when choosing the intensity of initial controller therapy, the intensity of health-care encounters may be an influence.

Keywords adult, asthma, asthma controller medication, asthma severity, pediatric

INTRODUCTION

The National Asthma Education and Prevention Program (NAEPP) guidelines specify effective control of the clinical manifestations of asthma as an important goal of therapy. Achieving control involves assessment, education, control of environmental and comorbid factors, and appropriate medication (1). The most recent Global Initiative for Asthma (GINA) guidelines also emphasize asthma control, using a similar multifactorial approach (2). Daily use of asthma controller monotherapy is recommended for mild persistent asthma, whereas combination therapy is one of the recommended options for moderate persistent asthma and the recommended therapy for severe persistent asthma. In the past, assessment of asthma severity was considered central to the correct classification and treatment of asthma (3, 4).

Asthma control, rather than asthma severity, is now considered the focus of management (5, 6). Although asthma severity is the starting point for patients not currently on therapy, asthma control is often assessed for patients already receiving controller therapy or before changing therapy and provides a description of the

responsiveness of the patient to disease management (7). Standardized guideline-driven approaches to therapy by physicians can assist in achieving the goal of asthma control through consideration of disease burden and risk. Yet, treatment guidelines allow flexibility with regard to initiating and then stepping medication up or down and choosing monotherapy or combination therapy. This flexibility may give rise to some confusion, resulting in treatment decisions that are influenced by factors other than those directly supported in the guidelines (7, 8). Recent studies have suggested that physicians who care for children as well as those who care for adults with asthma use symptom frequency to guide treatment and that they may also use other information considered to be important such as patient symptom bother and trajectory of illness (8, 9).

Although national asthma guidelines have been available in the United States since 1991, there is still little information about the extent to which the initiation of asthma controller medications is consistent with the guideline schema. For example, although it might be expected that patients with more symptoms would be more likely to receive combination therapy, this expectation has not been confirmed. This survey examined differences between patients with asthma initiated on controller monotherapy compared with patients initiated on controller combination therapy. Of primary interest was

*Corresponding author: Gregory B. Diette, MD, The Johns Hopkins University, 1830 East Monument St., Room 553, Baltimore, MD 21205, USA; Tel: +410-955-3467; Fax: +410-955-0036; E-mail: gdiette@jhmi.edu

the level of asthma severity just before initiating controller therapy.

METHODS

Patients and Methods

This survey used retail pharmacy records from a single 3400-store pharmacy chain located in 28 states, primarily on the east and west coasts of the United States, to identify patients filling a new prescription for asthma controller medications from 2006 to 2007. Surveys were conducted by phone within 5 days of the time the first asthma controller prescription (index prescription) was filled. Adult asthma patients and caregivers (parent or guardian for pediatric patients) were surveyed (Figure 1). Informed consent was obtained verbally by call center staff as part of the screening and invitation process before administering the study questionnaire.

Pediatric patients (5–16 years old) and adults (17–80 years old) who had filled a retail prescription for an asthma controller medication within the prior 1–5 days, with self-reported asthma, and who had no evidence of controller therapy use in the 6 months before the index prescription were included. Patients with self-reported cystic fibrosis, bronchopulmonary dysplasia, chronic obstructive pulmonary disease, chronic bronchitis, emphysema, or bronchiectasis were excluded.

Monotherapy patients were defined as those filling a single prescription for inhaled corticosteroids (ICS) or leukotriene modifiers. Patients whose index medication was cromolyn, nedocromil, or theophylline were excluded because of low prescribing frequency. Combination therapy patients were defined as those filling a prescription for more than one asthma controller based on fixed-dose combination or two controller medications filled on the same day. The two controller medications could include

ICS and long-acting β 2-adrenergic agonists (LABA), ICS and leukotriene modifiers, or LABA and leukotriene modifiers.

Surveys of patients and caregivers were obtained using the Health Insurance Portability and Accountability Act (HIPAA)-compliant process approved by Essex Institutional Review Board. The following information was collected: demographics (age, gender, race, education); modified Asthma Therapy Assessment Questionnaire (ATAQ) to measure the level of asthma control in the 4 weeks before the use of current asthma controller medication(s); shared decision-making process, plan for step-care if symptoms worsen, and instructions for taking current medication; allergies and allergic triggers; seasonal asthma patterns; short-acting β -agonist usage; allergic rhinitis medication usage; physician type (i.e., a generalist or a specialist); health-care utilization in the past 12 months; general health status; and comorbidities. Adult and pediatric versions of the ATAQ have been developed and validated. The adult ATAQ summary score generates a five-level measure of asthma control (0 = no control problems to 4 = four control problems), whereas the pediatric ATAQ summary score ranges from 0 to 7; for both the adult and pediatric instruments, a higher score indicates more control problems (10–12).

Data Analysis

We estimated that 222 completed interviews would be needed for each of four patient groups (monotherapy vs. combination therapy for pediatric and adult patients) for a total of 888 patients to achieve 80% power with the ability to detect a 0.4 difference in the asthma control score between monotherapy and combination therapy groups with a two-sided test at 5% significance level.

Chi-square tests for categorical variables and *t*-test or Wilcoxon rank sum tests for continuous variables were

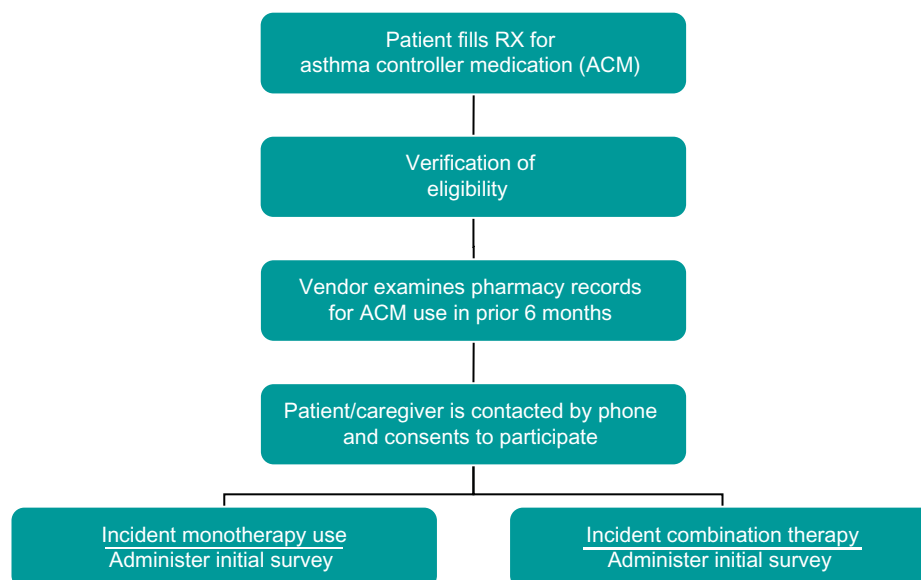


FIGURE 1.—Patient recruitment flow chart.

used in the bivariate analysis to assess the differences between the two therapy groups (monotherapy vs. combination therapy) for patient demographics and clinical characteristics, including the level of asthma severity and asthma-related resource use. Asthma control was assessed as a continuous and binary variable based on predefined cutoffs. All statistical analyses were performed using SAS 9.1 (SAS Institute Inc., Cary, NC, USA).

RESULTS

Pediatric Survey

Patient Characteristics. The mean age of pediatric patients at the time of survey completion was 10.3 ± 3.7 years of age (Table 1). The majority of patients were white (63.7%) and considered to be in good (28.3%), very good (37.5%), or excellent health (23.3%). Patients initiating monotherapy ($n = 262$) were significantly younger than those initiating combination therapy ($n = 226$) (9.6 vs. 11.2 years, $p < .0001$). Among patients initiating combination therapy, 212 (74.7%) were prescribed ICS+LABA either as separate products ($n = 2$; 0.8%) or as a fixed-dose combination product ($n = 210$; 73.9%) and only six patients (2.1%) were prescribed ICS+leukotriene receptor antagonist (LTRA). The remaining 66 patients initiating combination therapy were on other combinations of asthma controller therapies (i.e., three controller medications ($n = 64$; 22.5%) or other two controller combinations ($n = 2$; 0.7%)). Boys were more likely than girls to be given monotherapy rather than combination therapy (43.1% vs. 51.8%) although this difference was not statistically significant.

Asthma Status and Resource Use. Most pediatric patients received their prescription for asthma controller medication at their doctor's office (93.0%) rather than the emergency room or after hospital discharge, primarily receiving it because of worsening asthma symptoms (80.9%) (Table 2). Primary care physicians were responsible for care in the majority of children (79.8%). The patients in this study seeing primary care physicians were

more likely than the patients of specialists to be prescribed monotherapy rather than combination therapy (84.0% vs. 75.0%; $p = .014$).

Asthma control scores were similar for patients receiving monotherapy (2.87 ± 1.93) and combination therapy (2.72 ± 1.79), and a similar percentage in each group was reported to be feeling well controlled (Table 2; Figure 2). Patients seen by a specialist had lower (i.e., worse) average control scores than those seen by primary care physicians, regardless of the type of therapy, although the differences were not statistically significant. The majority of patients used an inhaler for quick relief (84.2%); more patients in the combination therapy group (14.2%) than in the monotherapy group (9.7%; $p = .046$) did not need the inhaler in the prior 4 weeks. Patients receiving combination therapy were not more likely to wake up with difficulty breathing, miss days of school, miss activities, or change exercise behaviors due to asthma compared with those receiving monotherapy. The only significant asthma-related health differences noted were that more patients receiving combination therapy versus monotherapy had asthma worsening in very cold weather (79% vs. 66.9%; $p = .003$) or had seasonal summer asthma symptoms (68.8% vs. 59.8%; $p = .04$). With regard to other aspects of asthma management, fewer patients in the monotherapy group versus the combination therapy group had received written instructions for taking asthma medications from the health-care provider (90.4% vs. 98.2%; $p = .003$), monitored asthma symptoms using peak expiratory flow (22.1% vs. 33%; $p = .007$), or scheduled physician visits (67.6% vs. 78.1%; $p = .009$) during the survey period.

Some differences in medical resource use in the last year were noted for patients in each therapy group. Significantly more patients receiving monotherapy had unscheduled physician visits during the past year (54.5% vs. 45.1%; $p = .0374$) and required a visit for worsening asthma (65.5% vs. 55.7%; $p = .0487$). However, more patients receiving combination therapy versus monotherapy had been hospitalized due to an asthma attack (20.5% vs. 13.8%; $p = .048$).

TABLE 1.—Patient characteristics.

Characteristics	Pediatric therapy group			Adult therapy group		
	Monotherapy ($n = 262$)	Combination ($n = 226$)	P -value ^a	Monotherapy ($n = 246$)	Combination ($n = 284$)	P -value ^a
Age at survey (years), mean $\pm$ SD ^a	9.6 $\pm$ 3.7	11.2 $\pm$ 3.4	<.0001	47.5 $\pm$ 16.9	46.5 $\pm$ 15.9	.480
Age at first asthma prescription (years), mean $\pm$ SD	5.6 $\pm$ 4.3	6.4 $\pm$ 4.4	.039	33.9 $\pm$ 21.0	33.7 $\pm$ 20.0	.881
Race			.134			.557
Caucasian (%)	62.2	65.5		74.9	71.8	
African American (%)	21.0	23.9		16.1	16.3	
Other (%)	16.8	10.6		9.1	11.9	
Parent rating of child's health or adult health rating			.492			.257
Excellent (%)	21.1	25.9		11.9	7.6	
Very good (%)	40.2	34.4		24.2	26.8	
Good (%)	27.6	29.0		39.8	37.0	
Fair/poor (%)	11.1	10.7		24.1	28.6	

Notes: SD, standard deviation.

^a P -values were based on chi-square test for proportions and t -test for means.

TABLE 2.—Asthma status and characteristics.

Characteristics	Pediatric therapy group			Adult therapy group		
	Monotherapy (n = 262)	Combination (n = 226)	P-value	Monotherapy (n = 246)	Combination (n = 284)	P-value ^a
Who do you see most often for your asthma?			.014			.434
PCP (%)	84.0	75.0		81.3	78.5	
Specialist (%)	16.0	25.0		18.3	19.7	
ER doctor (%)				0.4	1.1	
Asthma control score, mean $\pm$ SD	2.87 $\pm$ 1.93	2.72 $\pm$ 1.79	.368	1.83 $\pm$ 0.89	1.86 $\pm$ 0.94	.676
You feel asthma is well controlled (%)	69.5	66.1	.424	75.2	63.3	.013
Questions characterizing asthma						
Ever had asthma attack resulting in hospitalization (%)	13.8	20.5	.048	13.9	20.5	.046
Asthma worsens in very cold weather (%)	66.9	79.0	.003	69.7	72.7	.451
Seasonal asthma symptoms (a lot/little vs. none) (%)						
Winter	93.1	96.4	.103	89.0	91.9	.040
Spring	82.8	83.9	.731	77.6	80.6	.103
Summer	59.8	68.8	.040	69.9	71.8	.166
Fall	87.4	84.8	.409	80.5	80.3	.139
Health-care encounters in the last year						
Unscheduled physician visit for worsening asthma last year (%)	54.5	45.1	.037	32.5	35.2	.514
No visits for worsening asthma last year (%)	35.5	44.3	.049	56.9	53.9	.483
Monitor asthma symptoms with PEF (%)	22.1	33.0	.007	18.4	27.7	.012
Schedule visits with your doctor (%)	67.6	78.1	.009	60.6	70.9	.012

Notes: SD, standard deviation; PEF, peak expiratory flow; PCP, primary care physician.

^aP-values were based on chi-square test for proportions and *t*-test for means.

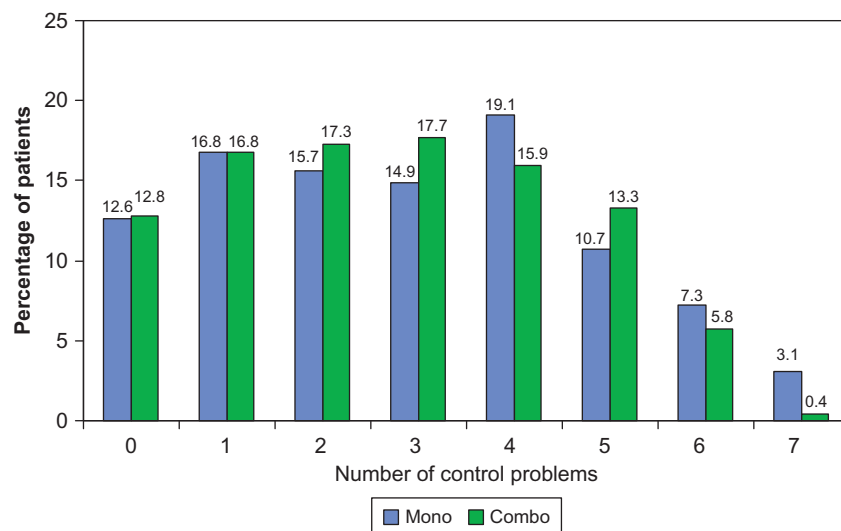


FIGURE 2.—A similar number of asthma control problems were observed among pediatric patients receiving monotherapy and combination therapy groups.

Comorbid and Environmental Conditions. The majority of patients were taking medications for other health conditions in addition to their asthma medication (68.0%). Many (25.5%) had eczema or other comorbid conditions (27.4%) and some were exposed to smoking (16.3%), but no significant differences were observed between patients receiving monotherapy and combination therapy. Overall 62.0% of pediatric patients were reported by their caregivers to have multiple environmental triggers, of which pollen, grass, or flowers (81.8%); dusty environments

(77.5%); molds (57.1%); animals (52.2%); cigarette smoke (51.0%); and strong smells (49.0%) were among the most common triggers.

Adult Survey

Patient Characteristics. Adult patients were primarily female (75.5%) and white (73.3%), and many had high school (41.7%) and college educations (44.9%) (Table 1). The mean age ($\pm$ SD) of adults in the monotherapy group in this survey was 47.5 ($\pm$ 16.9) years old whereas those

in the combination therapy group were 46.5 (± 15.9) years old ($p = .881$). Among patients initiating combination therapy, 174 (77.0%) patients were prescribed ICS+LABA either as separate products ($n = 1$; 0.5%) or as a fixed-dose combination product ($n = 173$; 76.5%) and 13 patients (5.8%) were prescribed ICS+LTRA. The remaining patients initiating combination therapy ($n = 39$; 17.3%) were on other asthma controller combinations (i.e., three controllers ($n = 37$; 16.4%) or other combinations of two controllers ($n = 2$; 0.9%)). Similar to pediatric patients, the majority of adults in the survey were seen by a primary care physician for asthma (79.8%) and received their prescriptions at the physician's office (89.1%).

Asthma Status and Resource Use. Results for adults differed from that of pediatric patients in a few ways (Table 2). Overall, asthma control scores and use of inhalers for quick relief were similar between adults receiving monotherapy (1.83 ± 0.89) versus combination therapy (1.86 ± 0.94) (Figure 3). However, patients receiving monotherapy were more likely to report feeling well controlled in the past 4 weeks (75.2% vs. 63.3%; $p = .01$). Significantly fewer patients in the monotherapy group versus the combination therapy group reported taking medications before exercise (33.7% vs. 42.8%; $p = .033$) or having an asthma attack that resulted in hospitalization (13.9% vs. 20.5%; $p = .046$). Regarding other aspects of asthma treatment, significantly fewer patients in the monotherapy group versus the combination therapy group monitored asthma symptoms using peak expiratory flow (18.4% vs. 27.7%; $p = .012$) or scheduled physician visits (60.6% vs. 70.9%; $p = .012$).

DISCUSSION

Asthma control, as measured by a standardized survey, the modified ATAQ, recommended for use by national guide-

lines (expert panel report 3 (EPR-3)), was not associated with initiation of monotherapy or combination therapy for children or adults in this study. Within the broader concept of control, indicators of impairment, such as symptom frequency and need for rescue medication, did not seem to influence the choice of therapy. Indicators of risk, including recent health-care encounters, did, however, seem to determine medication choice. Children receiving monotherapy were more likely to have seen a primary care provider and less likely to schedule regular doctor visits for asthma care than children receiving combination therapy. Adults receiving combination therapy appeared to self-manage more than those receiving monotherapy as indicated by significant differences in the number of patients taking asthma medications before exercise and monitoring asthma status using a peak flow meter.

The most recent update to the asthma treatment guidelines (EPR-3) introduced the concepts of impairment (frequency and intensity of symptoms, low lung function, and limitations of daily activities) and risk (likelihood of exacerbations, progressive loss of lung function, or adverse side effects from medications) as key domains of severity and control. The EPR-3 encourages physicians to approach treatment with the goal of reducing impairment and risk. The factors measured in this study using the ATAQ instrument corresponded to those of the impairment domain. Although our hypothesis was that patients prescribed combination therapy would report less well-controlled asthma, the data collection for this study just preceded the dissemination of the EPR-3 guideline update. Therefore, the emphasis on asthma control in the management of patients had not achieved widespread adoption by physicians. We did, however, expect more distinct differences in patient profiles to exist among those prescribed controller monotherapy versus combination therapy. The current focus on impairment and risk as elements of control and the recommended use of validated questionnaires may lead to such distinctions in the future.

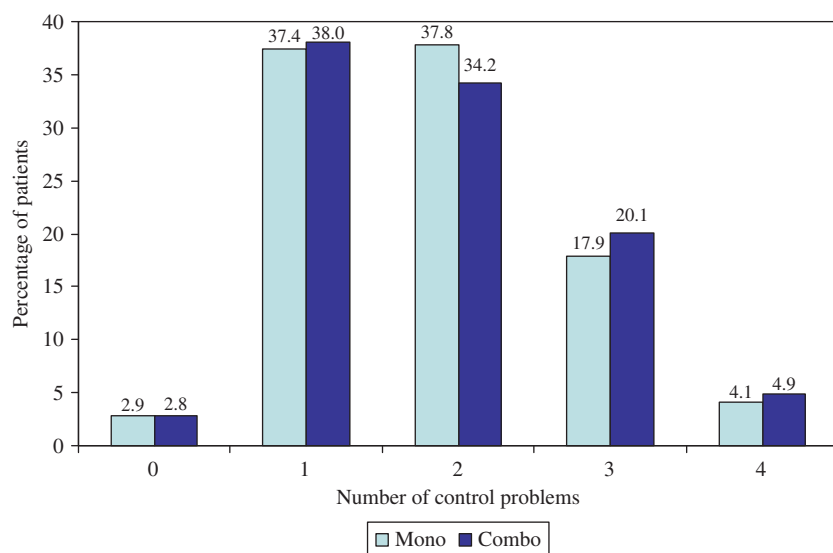


FIGURE 3.—A similar number of asthma control problems were observed among adult patients receiving monotherapy and combination therapy groups.

It is unclear whether the current recommendation in the asthma guidelines to use asthma control to guide treatment decisions will impact physician behavior. Several studies support the ability to use evaluation of asthma control as a means to differentiate patients likely to require emergency care or more resource use for asthma. A longitudinal study examining the ATAQ control index revealed an association between the level of control and the risk of future acute events among younger patients who did not have prior acute health care (13). In a recent retrospective pooled analysis, Bateman et al. examined the relationship between weekly changes in guideline-defined control and future risk of instability and exacerbations and found current control to be predictive regardless of monotherapy or combination therapy regimen (14). A retrospective cohort study proposed similar stratification schemes, based on some of the components of asthma impairment to identify patients at low, medium, or high risk of emergency care based on a hospital system database (15). Collectively, these studies support the predictive value of asthma control. Focusing on asthma control can lead to the dual benefit of informing treatment decisions and identifying patients at risk of a future acute event. Future studies may find more of a distinct separation of asthma control levels among patients initiating monotherapy versus combination therapy as guideline adoption evolves over time.

It is recognized that the treatment decision-making process involves several factors extending beyond asthma control. Studies have shown that a more participatory approach to decision-making is associated with greater treatment satisfaction and better health outcomes (16, 17). Our study did not solicit information from the physician on whether such an approach was taken. It is possible that the final regimen prescribed was influenced by multiple factors weighed by both patient and physician to meet their ultimate treatment goals. This shared-decision model approach was reported by the majority of parents (data not shown) and may have influenced the lack of association between treatment regimen and asthma control observed in this study.

In a study focused on factors used by pediatricians, Okelo et al. reported the use of multiple dimensions of asthma health status to make treatment decisions along with consideration of patient and parental preferences (8). Dimensions of acute health-care use, bother, asthma control, and wheezing independently influenced increases in asthma therapy. Tools that capture information on these dimensions may assist physicians working in fast-paced environments with decision-making. Children may not be forthcoming with information so that even the parent may not be completely aware of what the child is experiencing. Studies point to the impact of different factors on patient behaviors, which may in turn affect treatment. For example, shared decision-making encourages an active partnership between the patient and the provider that can result in improved self-management skills and reduced

emotional burden (16). Tools that are easy to use, employ shared decision-making, and incorporate the guideline concepts of control and risk as well as consider physician concerns such as emotional burden and disease direction may provide needed assistance for the physician.

Limitations

This study was limited by the absence of information from the patient–physician interactions that may have influenced prescribing decisions. The survey may not have captured data from patients initiated with drug samples, therefore the observed therapy may not always be the first treatment offered. The survey did not include physician data such as whether the physicians endorsed the guidelines approach. Although some information on patient medical and asthma history was available, a complete understanding of how patients may have responded to treatment in the past was not available. Data collection occurred before the latest guideline update in which there is an increased emphasis on assessment of asthma control (1). The survey was completed by patients or caregivers and may have been subject to patient or caregiver recall. Participants were selected from a single pharmacy chain with stores in 28 states; therefore, results are not fully representative of national prescribing trends. Finally, forced expiratory volume in 1 second (FEV₁) data were not available for the assessment of severity. Asthma is a heterogeneous condition; some patients are poor perceivers and will be categorized as more severe when objective measures such as FEV₁ are used than if severity is categorized by symptoms alone. If FEV₁ was measured, it may have influenced the decision regarding monotherapy versus combination therapy.

CONCLUSIONS

Clinicians in this study did not rely solely on the elements of impairment (nighttime awakenings, short-acting β -agonist use, or asthma control) to delineate patients prescribed controller monotherapy versus combination therapy. Elements of risk as evident by unscheduled office visits and hospitalizations among pediatric patients and hospitalizations among adult patients did influence prescribing of combination therapy. It may be important to learn more about what constitutes ideal practice; practicing clinicians may be cued by other important factors and are perhaps achieving the desired outcomes. Further investigation may help to clarify the decision-making process involved in selecting controller monotherapy and combination therapy.

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DECLARATION OF INTEREST

The authors report no competing interests. The authors alone are responsible for the content and writing of this paper.

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