Design and baseline characteristics of The Epidemiology and Natural History of Asthma: Outcomes and Treatment Regimens (TENOR) study: a large cohort of patients with severe or difficult-to-treat asthma

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Background: Patients with severe and difficult-to-treat asthma represent a small percentage of asthma patients, yet they account for much of the morbidity, mortality, and cost of disease. The goal of The Epidemiology and Natural History of Asthma: Outcomes and Treatment Regimens (TENOR) study is to better understand the natural history of asthma in these patients.

Objective: To describe the methods and baseline characteristics of the TENOR study cohort.

Methods: The TENOR study is a 3-year, multicenter, observational study of patients with severe or difficult-to-treat asthma. From January through October 2001, more than 400 US pulmonologists and allergists enrolled patients. Patients 6 years or older who were considered to have severe or difficult-to-treat asthma by their physicians were eligible. Patients have been receiving care for 1 year or more, have a smoking history of 30 pack-years or less, and have current high medication or health care utilization in the past year. Data are collected semiannually.

Results: A total of 4,756 patients enrolled and completed a baseline visit. Overall, 73% of the TENOR study patients are adults, 10% are adolescents, and 16% are children. According to physician evaluation, 48% of patients have severe asthma, 48% have moderate asthma, 3% have mild asthma, and 96% have difficult-to-treat asthma. Severe asthmatic patients have the highest health care utilization in the past 3 months ($P < .001$).

Conclusions: The TENOR study is the largest cohort of patients with severe or difficult-to-treat asthma. Although patients are equally divided into moderate or severe asthma categories, most are considered difficult-to-treat. The TENOR study highlights the lack of control in moderate-to-severe asthma and provides a unique opportunity to examine factors related to health outcomes in this understudied population.

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INTRODUCTION

Asthma is a chronic disease associated with substantial morbidity, mortality, and health care utilization. Between 1980 and 1994, the self-reported prevalence of asthma increased 75% among all race, sex, and age groups in every region of the United States.[1] An estimated 14.6 million persons had asthma in the United States in 1996; however, it is not yet clear if the prevalence is increasing or decreasing.[2] The severity of asthma within the population also appears to be increasing, with asthma-related, age-adjusted mortality rising approximately 50% between 1980 and the mid-1990s.[3] The morbidity and mortality associated with asthma appear to disproportionately affect female, African-American, and elderly patients.[4,5]

In 2002, the direct and indirect costs of asthma in the United States were $14 billion.[3] A substantial portion of the $9.4 billion annual direct costs of asthma is related to hospital care and physician services, whereas prescription drug costs comprise the largest component at $3.7 billion.[3] An economic analysis of asthma costs in 1992 reported that the largest single contributor to the indirect costs of asthma was days of school missed, with more than 10 million days of school missed each year.[6]

Recent analyses of the economic burden of asthma suggest that the costs of asthma are largely attributable to uncontrolled disease.[7] Although patients with severe or difficult-to-

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treat asthma represent a small portion of the total asthma population, they account for much of the morbidity, mortality, and cost of the disease.[8–10] Relatively little is known about these patients and the treatments and outcomes associated with their disease.

The primary objective of The Epidemiology and Natural History of Asthma: Outcomes and Treatment Regimens (TENOR) study is to collect prospective data to better understand asthma's natural history in patients with severe and/or difficult-to-treat disease. Secondary objectives are to examine the relationship between features of asthma treatments and outcomes, to observe the frequency of predefined comorbid conditions, and to describe the relationship between IgE levels and disease. In this report, we present the TENOR study methods and describe baseline demographics and clinical characteristics of the population, with an emphasis on health care utilization.

METHODS

Study Design

The TENOR study is a prospective, observational, multicenter, 3-year (2001–2004) study of US patients diagnosed as having severe or difficult-to-treat asthma. The TENOR study patients continue to receive treatment for their asthma as indicated by their asthma specialist (both allergists and pulmonologists were recruited into the study). Study sites were selected from diverse geographical areas to represent typical settings in which patients receive care, including managed care organizations, community physicians or group practices, and academic centers. The design and protocol of the TENOR study were approved by a central institutional review board and, when necessary, by the institutional review board at each site.

Study Participants

The TENOR study participants are 6 years or older and are considered by physician evaluation to have severe or difficult-to-treat asthma. Patients with mild or moderate disease were eligible for enrollment if their physician considered their asthma difficult-to-treat and they met the additional inclusion and exclusion criteria.

Physicians selected patients for the TENOR study if they (1) had received care from their physician or health care provider for at least 1 year, (2) were able to read and understand English, and (3) had either high use of the health care system or high medication use in the past 12 months. High health care utilization in the past 12 months was defined as 2 or more unscheduled care visits for asthma or 2 or more oral steroid bursts (defined as a short-term increase in steroid therapy to treat an exacerbation of symptoms). High medication use was defined as currently requiring 3 or more medications to control asthma or currently requiring long-term, daily high doses of inhaled steroids or use of 5 mg/d or more of oral prednisone. Daily high doses of inhaled steroids were defined by the American Thoracic Society (ATS) refractory asthma guidelines for adults[11] and by the National Heart, Lung, and Blood Institute (NHLBI) guidelines for children.[12] All patients or their guardians provided written informed consent.

Heavy smokers ($\geq$30 pack-years of smoking) and known alcohol or drug abusers were excluded from the TENOR study. Patients with any of the following conditions were also not enrolled: cystic fibrosis, severe cardiovascular disease (New York Heart Association class II or higher), cancer (not including nonmelanoma skin cancer or cancer clear or in remission for $\geq$5 years), severe psychiatric disorder (not including anxiety or depression), or significant systemic disease ($<$2–3 years of life expectancy).

Study Evaluations

Enrolled TENOR study patients complete 7 study visits during 3 years. This schedule corresponds with the NHLBI recommendations of at least 2 office visits per year for asthma patients.[12] Patients are seen at baseline visit and again every 6 months ($\pm$30 days). The data items collected at each visit are shown in Table 1.

Demographic, Clinical, and Laboratory Assessments

A debate exists regarding the use of clinical or epidemiologic measures to classify asthma patients based on disease severity.[13] Current guidelines, such as those from the 1991 National Asthma Education and Prevention Program, do not readily translate into a severity index that can be applied to clinical practice. Therefore, physicians' subjective opinion of patients' asthma severity, which can be used as a gold standard,[13] is used in the TENOR study. TENOR study physicians evaluate each participant's asthma severity annually and subjectively categorize patients as having mild, moderate, or severe asthma based on their clinical opinion. In addition, physicians annually report whether their patient's asthma is considered difficult to treat based on specified parameters (multiple reasons are allowed; Fig 1).

Demographic and clinical data collected by study coordinator interview and evaluation consist of age, sex, race, education, marital status, employment, height, weight, health care insurance coverage, asthma history, health care use, medical history, targeted comorbid medical conditions, and medication use (Table 1).

Total serum IgE levels were measured at baseline by each study site using any commercially available assay. All IgE assay tests used in the TENOR study have received 510 (k) approval from the US Food and Drug Administration and are considered substantially equivalent in terms of both accuracy and precision. In addition, all total IgE assays are calibrated to the World Health Organization's second international reference preparation for human serum IgE (WHO IRP 75/502).

Prebronchodilation and postbronchodilation pulmonary function is evaluated annually by spirometry and includes forced vital capacity, forced expiratory volume in 1 second (FEV_1), maximal midexpiratory flow, and peak expiratory flow rate. Sites are instructed to perform all spirometry mea-

Table 1. Data Collected by Assessment

Data	Baseline	Midyear clinic visit	Yearly clinic visit
Assessed by study investigator			
Asthma severity	X		X
Presence of difficult-to-treat asthma	X		X
Collected by study coordinator			
Date of visit or interview	X	X	X
IgE levels	X		
Spirometry	X		X
Demographics	X		X
Health care insurance coverage	X		X
Days of work or school missed in previous 14 days	X	X	X
Asthma history	X		
Health care utilization	X	X	X
Medical history (personal and family)	X		
Targeted comorbid conditions	X	X	X
Medication use	X		X
Subject self-report*			
Residential exposure information	X		X
Occupational exposure information	X		X
Quality of life†	X		X
Asthma symptoms/ control‡	X	X	X
Work or school productivity§	X		X

* Children (ages 6–12 years) are permitted to obtain assistance in completing the questionnaire from an adult who is not their parent.
† Measured using the Juniper Mini Asthma Quality-of-Life Questionnaire in patients 13 years or older and the Pediatric Asthma Quality-of-Life Questionnaire with Standardized Activities in patients aged 6 to 12 years.
‡ Measured using the Asthma Therapy Assessment Questionnaire.
§ Reported using an adapted section of the Work Productivity and Activity Impairment instrument.

surements in accordance with ATS guidelines, which were provided to sites.[14]

Patient Self-Reported Assessments

Patients complete several self-administered questionnaires at baseline and annual visits. These instruments capture occupational and residential exposures (eg, dust, chemicals, pets) and provide a global health status evaluation of circumstances that may trigger worse asthma symptoms.

The Asthma Therapy Assessment Questionnaire (ATAQ) is self-administered at baseline and semiannually thereafter to evaluate asthma symptoms and level of asthma control.[15] The

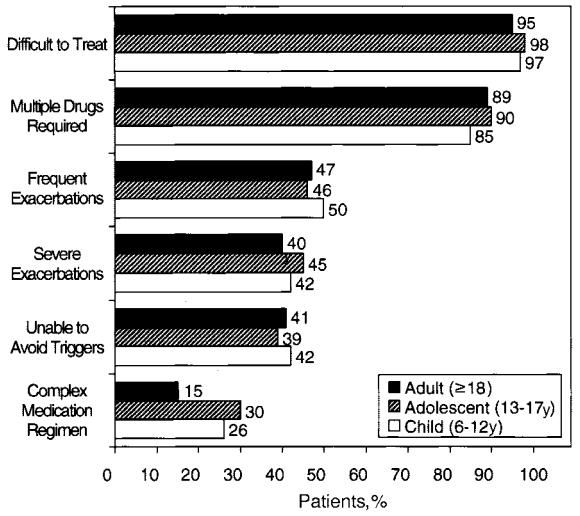

Figure 1. Physician evaluation of treatment difficulty.

ATAQ contains questions reflecting 5 conceptual domains essential to optimal asthma management: control, symptoms, communication and knowledge gaps, behavior/attitude, and self-efficacy barriers. These domains have been shown to correlate with other measures of impairment, health care utilization, and quality of life.[16]

Asthma-related quality of life is measured at baseline and annual visits by the Juniper Mini Asthma Quality-of-Life Questionnaire (MiniAQLQ) in patients 13 years and older and the Pediatric Asthma Quality-of-Life Questionnaire with Standardized Activities (PAQLQ[S]) in patients 6 to 12 years old.[17,18] Items include questions designed to evaluate the daily impact of asthma on patients' activities, emotions, and symptoms. Additionally, the MiniAQLQ contains questions on environmental stimuli. Both instruments have shown good responsiveness, reliability, and construct validity.[17,18]

Lost work productivity due to asthma symptoms is measured by an adapted section of the allergy-specific Work Productivity and Activity Impairment (WPAI-AS) instrument. The WPAI-AS instrument has been validated to measure allergy-related work and/or classroom productivity impairment and regular daily activity impairment.[19]

Outcome Measures

The primary outcomes of the TENOR study, derived from both study coordinator interview and patient self-evaluation, include emergency department visits, overnight hospitalizations, steroid bursts, unscheduled office visits, and the need for intubation or mechanical ventilation in the past 3 months (history of intubation was collected at baseline). Other primary outcomes are days of school or work missed, indirect costs associated with asthma symptoms, asthma symptoms and control, and asthma-related quality of life. Secondary outcomes are derived from clinical examination and study coordinator interview and include lung function, medication

use, and targeted comorbid conditions. The TENOR study does not capture long-term medication use (eg, long-term steroid use).

Data Retrieval and Monitoring

The TENOR study uses a Web-based system for data collection (developed using Quintiles' WebCollect services and PhaseForward's InForm application; Quintiles Transnational Corp, Research Triangle Park, NC). Data are entered directly on electronic case report forms and transferred in encrypted form onto a secure server. Registered study coordinators and principal investigators have unique identifications and passwords that provide access to the study Web site.

To participate in the TENOR study, study sites were required to provide their own computer hardware and to meet minimal technical requirements. All study coordinators received Web site and study protocol training. Site support is available throughout the study via a telephone help desk.

Statistical Analyses

The TENOR study is a large, observational, epidemiologic study that is not powered to test a single hypothesis. The large sample size permits relevant analyses, including important subgroup (eg, sex, age, race) and exploratory analyses, such as multivariate statistical modeling. The size of the TENOR study ensures that the study's primary and secondary objectives are met.

Descriptive statistics were produced for demographic and baseline characteristics. Means and SDs were generated for continuous outcomes. Frequencies and percentages were generated for categorical outcomes. The χ^2 test was used to evaluate the association between measures of health care utilization and disease severity. All statistical analyses were completed using the SAS System for Windows, Version 8.02 (SAS Institute Inc, Cary, NC).

RESULTS

The 283 participating TENOR study sites represent a cross-section of asthma treatment settings in the United States: 63% office-based private practice, 27% hospital based, and 10% other. Allergists (54%) and pulmonologists (41%), including pediatric specialties, comprise the TENOR investigators. This report presents TENOR baseline study visit data. From January 2 through October 10, 2001, 4,923 patients were screened for inclusion in the study. Of these, 4,756 patients were enrolled and completed a baseline study visit.

Demographics

Baseline demographics and clinical characteristics of the TENOR study cohort are shown in Table 2. Overall, 73% of the cohort are adults (18 years or older), 10% are adolescents (13–17 years), and 16% are children (6–12 years). Most adult patients are female, whereas most adolescents and children are male. In the overall cohort, 75% of patients are white, 15% black, 6% Hispanic, and 2% Asian. Most TENOR study patients never smoked (73.1%), whereas 23.6% have a smoking history and very few (3.4%) currently smoke. Lung function (as measured by the percentage of predicted prebronchodilator FEV_1) was highest in children (mean, 87.0%) followed by adolescents (mean, 84.0%) and adults (mean, 74.2%). Despite the high mean FEV_1 values, 23.5% of the overall cohort had an FEV_1 of less than 60% (Table 2). When stratified by smoking status, never smokers and past smokers had higher prebronchodilator percentage of predicted FEV_1 (mean, 78.9% and 73.0%, respectively) compared with current smokers (mean, 70.0%).

IgE levels. IgE levels were elevated across all 3 asthma patient age groups. The IgE geometric mean values were 85.2 IU/mL in adults, 223.8 IU/mL in adolescents, and 182.5 IU/mL in children. When stratified by asthma severity, the overall IgE geometric mean values were lowest in patients with mild asthma (99.9 IU/mL) compared with those with moderate (102.1 IU/mL) and severe asthma (112.0 IU/mL). In children, IgE levels increased with asthma severity: mild asthma, 137.8 IU/mL; moderate asthma, 145.8 IU/mL; and severe asthma, 280.2 IU/mL. A similar trend was shown in adolescents (mild asthma, 108.1 IU/mL; moderate asthma, 224.0 IU/mL; and severe asthma, 280.2 IU/mL) but not in adults (mild asthma, 84.3 IU/mL; moderate asthma, 82.1 IU/mL; and severe asthma, 88.2 IU/mL). Overall, the proportion of patients with mild asthma and IgE levels less than 100 IU/mL (55.7%) was greater compared with those patients with moderate (48.7%) and severe (47.7%) asthma. Similarly, a smaller proportion of patients with mild asthma had IgE levels 100 IU/mL or higher (44.3%) compared with those with moderate (51.3%) and severe (52.8%) asthma.

Asthma severity. Most TENOR study patients had moderate or severe asthma according to physician evaluation. Approximately 50% of adolescent and adult patients were considered to have severe asthma compared with only 36% of children (Table 2). However, Figure 1 shows that 96% of patients were considered to have difficult-to-treat asthma. The top 3 reasons for physician-evaluated treatment difficulty were the need for multiple drugs, occurrence of frequent exacerbations, and occurrence of severe exacerbations. Similar patterns were observed across age groups.

Medication use. Because adolescents are usually treated and dosed similarly to adults, adolescent and adult data have been combined for medication data reporting purposes.

At enrollment, 450 children (58%) and 2,230 adolescents and adults (56%) in the TENOR study were using 3 or more long-term asthma control medications. The proportions in each age group using 1 control medication (9% and 7%, respectively) or 2 control medications (31% and 35%, respectively) were similar. The most commonly used long-term control medications were inhaled corticosteroids, long-acting β_2-agonists, and leukotriene modifiers (Fig 2). Approximately 56% of children and 26% of those 13 years or older were taking high-dose inhaled corticosteroids (for definition, see *Study Participants*).

Table 2. Baseline Demographics and Clinical Characteristics of The Epidemiology and Natural History of Asthma: Outcomes and Treatment Regimens Study Cohort

Variable	Overall	Adults (≥18 y)	Adolescents (13–17 y)	Children (6–12 y)
Patients, no. (%)	4,756 (100)	3,489 (73.36)	497 (10.45)	770 (16.19)
Age, mean ± SD, y	38.9 ± 20.92	48.9 ± 14.85	14.5 ± 1.34	9.5 ± 1.88
Weight, mean ± SD, kg	75.2 ± 26.53	83.9 ± 22.22	66.9 ± 21.03	41.1 ± 16.64
BMI, mean ± SD	28.3 ± 8.59	30.4 ± 7.73	25.4 ± 9.86	20.7 ± 6.17
IgE, geometric mean, IU/mL	106.6	85.2	223.8	182.5
Sex, no. (%)				
Female	2,945 (62.2)	2,475 (71.2)	213 (42.9)	257 (33.5)
Male	1,792 (37.8)	999 (28.8)	283 (57.1)	510 (66.5)
Race/ethnicity, no. (%)				
White	3,555 (75.1)	2,769 (79.8)	323 (65.3)	463 (60.4)
Black	712 (15.0)	404 (11.6)	115 (23.2)	193 (25.2)
Hispanic	303 (6.4)	197 (5.7)	36 (7.3)	70 (9.1)
Asian or Pacific Islander	72 (1.5)	57 (1.6)	7 (1.4)	8 (1.0)
Other	91 (1.9)	44 (1.2)	14 (2.8)	33 (4.3)
Physician assessment of severity, no. (%)				
Mild	149 (3.2)	91 (2.6)	19 (3.8)	39 (5.1)
Moderate	2,285 (48.4)	1,595 (46.1)	237 (47.9)	453 (59.1)
Severe	2,285 (48.4)	1,771 (51.2)	239 (48.3)	275 (35.9)
Smoking history, no. (%)				
Never smoked	3,454 (73.1)	2,207 (63.7)	483 (97.8)	764 (99.6)
Past smoker	1,113 (23.6)	1,110 (32.0)	3 (0.6)	0 (0.0)
Currently smoke	159 (3.4)	148 (4.3)	8 (1.6)	3 (0.4)
FEV_1				
No. (%) with predicted prebronchodilator				
≤60%	1,015 (23.5)	893 (27.8)	69 (15.7)	53 (8.0)
>60% to <80%	1,292 (29.9)	1,015 (31.6)	104 (23.7)	173 (26.0)
≥80%	2,007 (46.5)	1,302 (40.6)	266 (60.6)	439 (66.0)
Prebronchodilator (% predicted), mean ± SD	77.2 ± 23.28	74.2 ± 23.45	84.0 ± 21.63	87.0 ± 19.57
Postbronchodilator (% predicted), mean ± SD	82.5 ± 23.04	79.0 ± 23.08	91.1 ± 21.03	93.9 ± 18.50
Quality of life,* mean overall score	NA	4.6	5.2	5.4

Abbreviations: BMI, body mass index; FEV_1, forced expiratory volume in 1 second; NA, not applicable.

* Asthma-related quality of life as measured using the Juniper Mini Asthma Quality-of-Life Questionnaire in patients 13 years or older and the Pediatric Asthma Quality-of-Life Questionnaire with Standardized Activities in patients aged 6 to 12 years.

Health care utilization and school or work days missed stratification by age. A high frequency of asthma-related health care utilization was observed among all age groups. At enrollment, 5% of adults, 10% of adolescents, and 9% of children had been hospitalized in the prior 3 months. The percentage of patients who required emergency care in the previous 3 months was 15% among adults, 17% among adolescents, and 22% among children. A high percentage of patients, across all age groups, reported a history of intubation (10% to 13%). The use of steroid bursts in the past 3 months occurred in 48% of adults, 42% of adolescents, and 49% of children. Unscheduled office visits in the previous 3 months occurred in 46%, 37%, and 48% of adults, adolescents, and children, respectively. The percentage of patients missing one or more school or work days in the previous 2 weeks was 14%, 19%, and 18% among the 3 age groups (adults, adolescents, and children, respectively).

Stratification by physician-evaluated severity. Asthma-related health care utilization and school or work days missed, independently reported by TENOR study patients, were associated with physician-evaluated asthma severity. Patients with severe asthma, in the clinical opinion of their treating physician, reported the highest health care utilization compared with patients with mild or moderate asthma ($P < .05$ for all outcomes; Fig 3). Among patients with severe asthma, 10% required an asthma-related overnight hospitalization in the previous 3 months. Emergency care was required in the previous 3 months by 6% of patients with mild asthma, 11% with moderate asthma, and 21% with severe asthma ($P < .001$). In addition, 17% of patients whose asthma was categorized as severe had a history of intubation. An unscheduled office visit in the previous 3 months occurred in 51% of patients with severe asthma, 40% with moderate asthma, and 32% with mild asthma ($P < .001$). The percentage of patients missing at least 1 day of work or school in the previous 2 weeks was also significantly ($P < .001$) higher in the group with severe asthma (19%) than in the group with either moderate asthma (13%) or mild asthma (12%; $P < .001$).

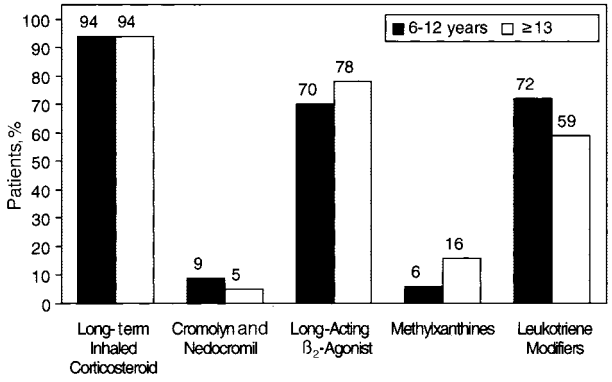

Figure 2. Use of long-term control medications.

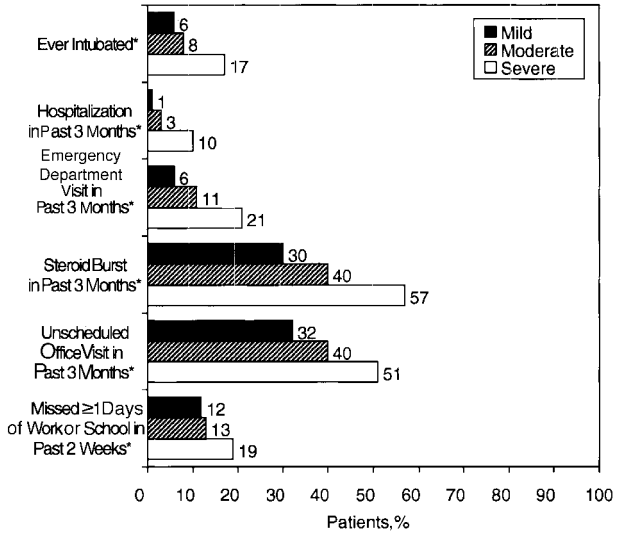

Figure 3. Health care utilization and missed work or school days by asthma severity. *$P < .05$ for χ^2 test for difference among severity groups.

DISCUSSION

The TENOR study is the largest observational study undertaken in patients with moderate-to-severe and/or difficult-to-treat asthma and represents children, adolescents, and adults of diverse racial and ethnic backgrounds. It provides a unique opportunity to examine factors related to poor health outcomes in this understudied population. The longitudinal design of the TENOR study tracks health care outcomes, quality of life, and school or work productivity during 3 years so that asthma control and associated health outcomes can be analyzed over time. Because patients with known cystic fibrosis and a history of heavy smoking (≥30 pack-years) were excluded, there is a low likelihood that the cohort includes patients with conditions frequently misdiagnosed as asthma. However, the possibility exists that the TENOR study contains some patients with vocal cord dysfunction.

As is typical of an asthmatic population, the TENOR study patients have elevated IgE levels. Across all age groups, IgE levels were substantially higher than those found in a general population of nonasthmatic subjects.[20] The estimated US general population geometric mean IgE is approximately 30 IU/mL.[21,22] Overall, the TENOR study patients with severe asthma had elevated geometric mean IgE values compared with patients with moderate and mild asthma. IgE values for children and adolescents increased with asthma severity, whereas such a relationship was not apparent in adults. This key finding reflects the uniqueness of the TENOR study.

When stratified by physician-evaluated severity, the TENOR study patients were nearly equally divided into moderate and severe asthma categories, although nearly all study patients were considered by their physician to have difficult-to-treat asthma. The most commonly reported asthma treatment difficulty reasons (multiple medications, frequent and severe exacerbations, and inability to avoid triggers) confirm that multiple asthma control issues confront both patients and physicians.

Efforts to define patients as having severe or difficult-to-treat asthma are complicated, because disease severity is typically viewed as a stable attribute of asthma, whereas a patient's level of control (ie, whether their asthma is well or poorly controlled) can vary over time. Level of control is evaluated primarily on asthma symptoms and is typically based on a short-term evaluation (ie, days to weeks).[13] Additionally, the terms *severity* and *control* are often used interchangeably in clinical practice and medical research. Thus, accurate identification and categorization of patients to identify relationships between asthma severity and treatment control is difficult. In the TENOR study, this type of confusion is minimized, since disease severity is captured annually by physician evaluation and patient control is measured separately using validated patient-reported instruments such as the ATAQ, MiniAQLQ, and PAQLQ. In this context, disease severity is expected to remain stable over time, reflecting physician clinical judgment of their asthma patients' inherent disease severity.

More children were categorized as having mild or moderate asthma compared with adolescents or adults. This is in line with the general concept that the longer one has asthma, the more likely the disease will be considered severe. In addition, most children and adolescents in the TENOR study were male, whereas most adults were female. This is consistent with demographic data from a large epidemiologic survey[23] of adults with predominately moderate-to-severe asthma and a large epidemiologic study[24] of children with mild-to-moderate asthma. The reasons for asthma age-associated sex differences are not clear but may reflect smaller airway size or caliber in women.[25]

The TENOR study patients are taking multiple asthma medications. Although half of adults and adolescents have severe asthma, the use of high-dose steroids is not as high as might be expected. Reasons for this are not clear but could reflect either a continued aversion to steroids or that an increase in dose is ineffective in this population. Medication

use among children was the same as or higher than that among adolescents and adults, even though the severe asthma prevalence was lowest in children. This is consistent with data showing that the most common reason physicians categorized patients as having difficult-to-treat asthma was their need for multiple medications.

A high level of hospitalizations, emergency department visits, history of intubation, and use of steroid bursts was consistent across all age groups, despite fewer children being categorized as severe compared with adolescents or adults. The high proportion of patients requiring hospitalization or emergency care in the previous 3 months and the proportion with a history of intubation are of particular concern. Higher than expected levels of health care utilization and missed work or school days were observed in those patients with more severe asthma; however, this may be due to the inclusion criteria of high health care utilization in the previous 12 months.

In general, lung function measured by FEV_1 was better in children and adolescents than in adults. In the TENOR study, the small proportion of current smokers had worse FEV_1 compared with past and never smokers. Interestingly, FEV_1 was much lower in past smokers compared with never smokers, whose lung function was close to normal. Pack-year information was not collected in the TENOR study; therefore, it is unclear whether these differences are due solely to smoking exposure or other factors.

CONCLUSION

Despite more mild disease, both children and adolescents reported high levels of health care utilization. In particular, unscheduled office visits and the use of steroid bursts in the previous 3 months were equally high among adults, adolescents, and children. A greater proportion of children and adolescents had a history of intubation compared with adults. These data suggest that even patients considered to have mild or moderate asthma have symptom control problems. Future TENOR study analyses will provide valuable information on patient perception of asthma control, as well as potential barriers to asthma control and disease self-management. This important observational study provides an opportunity to identify differences in asthma control and health outcomes by age, sex, and race or ethnicity. The TENOR study is the largest prospective cohort study of severe or difficult-to-treat asthma, providing a unique opportunity to explore the unmet need of asthma in this understudied and poorly controlled patient population.

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