Impact of Asthma Control on Sleep, Attendance at Work, Normal Activities and Burden of Illness

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ABSTRACT

Background: The 2007 NIH-sponsored Expert Panel Report-3 (EPR-3) asthma treatment guidelines now place substantial emphasis on understanding the effectiveness of treatment strategies on real world outcomes such as disease control.

Objective and Purpose: We assessed the impact of asthma control on patient-reported outcomes and disease burden in a real world setting.

Methods: Moderate to severe asthma patients defined by medical and pharmaceutical use between the ages of 18-64 years were requested to participate in a cross-sectional survey of asthma care, control and burden. Patients were included with the following criteria: ICD-9-CM code for asthma, prescription for EPR-3-defined controller medication (or combinations), continuous eligibility 24 months pre-index period. Patients with COPD were excluded. Data from survey respondents were linked to claims information to create the research database. The well-validated Asthma Therapy Assessment Questionnaire (ATAQ) was used as the measure of control and the Work Productivity Assessment Instrument (WPAI-Asthma) was used to assess the extent of disease impact on work and regular activities. ATAQ scores range from 0-4, with 0 indicating no asthma control problems.

Results: A total of 582 patients (66.8% female) completed the survey and had their claims data linked for analysis. Age, gender and co-morbidity index measures did not differ between respondents and non-respondents. More than 80% of patients were currently using EPR-3 defined controller therapy. Only 13.7% of respondents scored 0 on the ATAQ, 74.1% scored 1 or 2 and 12.2% scored 3 or 4. ATAQ scores were moderately correlated with patient-rated severity (r=0.33942, p<0.001). Decreasing levels of asthma control were associated with a greater prevalence of sleep problems, depression, and impact on work and regular activities.

Conclusions: In a population of moderate and severe asthma patients, approximately 86% of patients were not fully controlled despite anti-inflammatory treatment. Lack of asthma control is associated with substantial patient burden.

BACKGROUND

- Asthma is a chronic disease affecting more than 22 million Americans.[1] The burden of this disease is significant in terms of reduced quality of life and increased morbidity and cost. Despite widespread acceptance of evidence-based clinical guidelines on the management of asthma, many patients remain poorly controlled. [2-3]

- The National Asthma Education and Prevention Program (NAEPP) released new treatment guidelines in 2007, the Expert Panel Report-3 (EPR-3), which now place substantial emphasis on understanding the clinical utility and effectiveness of treatment strategies on disease control.[1]

- In 2007, a prospective, observational study using data from the TENOR asthma registry by Chen et al. evaluated the effect of uncontrolled disease on quality of life and found that poor asthma control was associated with a significant degree of functional impairment. [4]

- Because of substantial residual disease burden, we find it important to assess the real-world impact of asthma control on work productivity, normal activities, sleep, and other components of burden.
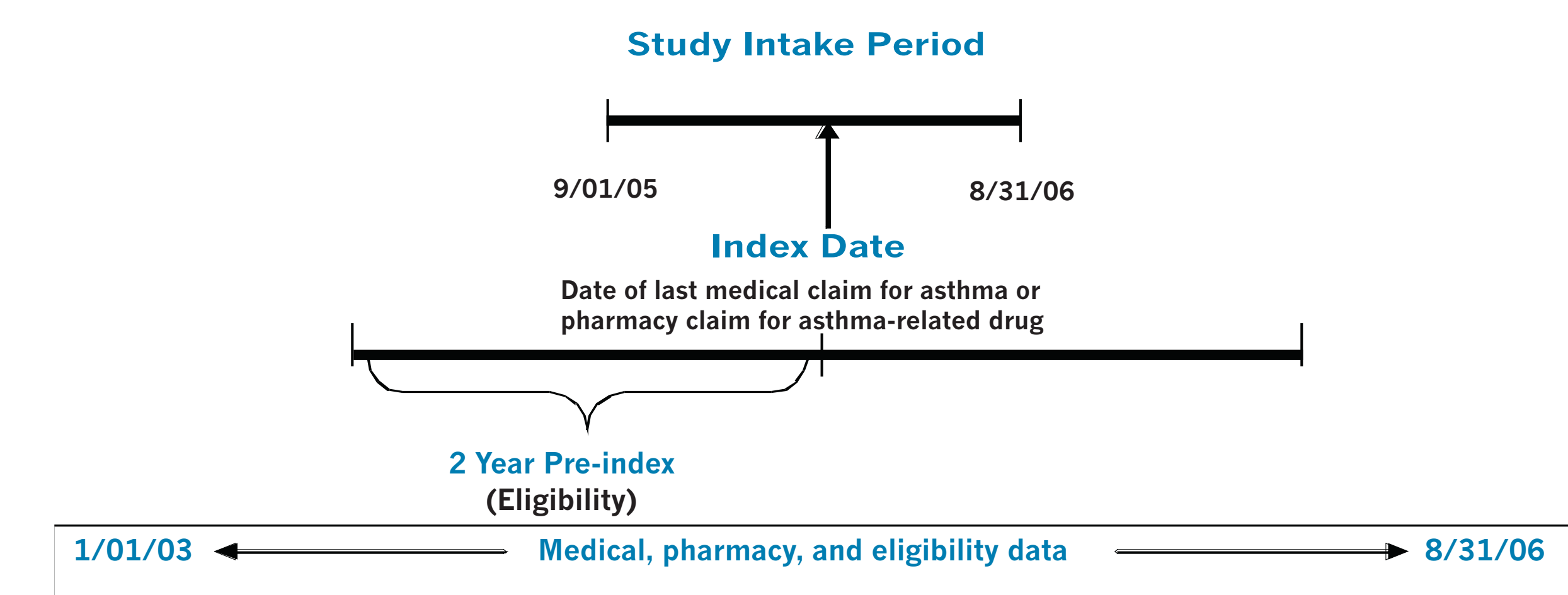
OBJECTIVE

- To assess the extent and impact of variation in asthma control on patient-reported outcomes and disease burden in a US managed care population in a real-world setting.

METHODS

- This was a cross-sectional survey of asthma care, control, and burden. Data from survey respondents were linked to claims information to create the research database.

- Moderate-to-severe asthma patients, aged 18 to 64 years, were identified from the HealthCore Integrated Research Database which contains medical and pharmacy claims data from U.S. managed care health plans representing 22.5 million privately insured members. Identified patients were asked to participate in a survey study.

- Patients were considered to have moderate-to-severe asthma if they had at least one medical claim for asthma (ICD-9: 493.xx) and at least one pharmacy claim for an EPR-3-defined asthma–controller medication (corticosteroid inhalant, leukotriene antagonist, or corticosteroid inhalant combination) between 9/1/05 and 8/31/06. The last (most recent) asthma-related medical or pharmacy claim during this time was considered the index date.

- Patients were excluded if they had COPD or an emphysema-related claim, less than 24 months of continuous pre-index eligibility, and no history of asthma as indicated by medical claim for asthma or pharmacy claim for an asthma-controller medication at least 1 year prior to the study index date (-366 to -730 days).

Figure 1: Overall Study Design

Study Intake Period
9/01/05   8/31/06
Index Date
Date of last medical claim for asthma or pharmacy claim for asthma-related drug
2 Year Pre-index (Eligibility)
1/01/03 ← Medical, pharmacy, and eligibility data → 8/31/06

Data Analysis

- Demographic and clinical characteristics were summarized by descriptive statistics.

- The Asthma Therapy Assessment Questionnaire (ATAQ)[5,6] was used as the measure of control status and the Work Productivity Assessment Instrument (WPAI-Asthma)[7] was used to assess the extent of disease impact on work and regular activities. In addition, patient-reported responses were also collected on non-validated survey questions pertaining to patient's co-morbidities, medical history, and asthma severity and disease progression.

- ATAQ scores range from 0 to 4, with 0 indicating "well-controlled", 1 or 2 indicating "not well-controlled" and 3 or 4 indicating "very poorly-controlled." The distribution of variables are described by the use of frequency distributions and cross-tabulations to examine the univariate relationship across the three ATAQ control classifications.

- Due to the volume of information garnered from these sources, statistical tests were performed on select outcomes directly related to the study objectives. Tests were not performed on all of the possible combinations of available outcomes.

RESULTS

- A total of 24,631 patients meeting entry criteria were identified from the administrative claims data. From this total, 582 patients (67% female) completed the survey.

- Age, gender, and the mean co-morbidity index did not differ between respondents and non-respondents.

Table 1. Age and Gender Distribution of Survey Patients

	Well Controlled (ATAQ 0)		Not Well Controlled (ATAQ 1/2)		Very Poorly Controlled (ATAQ 3/4)	
	N/Mean	%/Median	N/Mean	%/Median	N/Mean	%/Median
Sample Size	80	13.7%	431	74.1%	71	12.2%
% Female	49	61.3%	290	67.3%	50	70.4%
% Male	31	38.8%	141	32.7%	21	29.6%
Age at interview years	47	49	47	49	42	42
Comorbid Conditions						
Insomnia	7	8.8%	32	7.4%	15	21.1%
Depression	14	17.5%	71	16.5%	21	29.6%
Coronary heart disease (CHD)	1	1.3%	20	4.6%	6	8.5%
Allergies	68	85.0%	378	87.7%	59	83.1%

- Of the respondents, 13.7% (n=80) scored a 0 on the ATAQ, 74.1% (n=431) scored a 1 or 2 and 12.2% (n=71) scored a 3 or 4. Mean age of respondents was different by ATAQ categorization, with "very poorly controlled" patients being significantly younger than both "well controlled" and "not well controlled" patients (42 vs 47 and 47 years, respectively; p<0.003).

- Decreasing levels of asthma control were associated with a greater prevalence of sleep problems (well controlled 8.8%, not well controlled 7.4%, and very poorly controlled 21.1%), depression (well controlled 17.5%, not well controlled 16.5%, and very poorly controlled 29.6%), and CHD (well controlled 1.3%, not well controlled 4.6% and very poorly controlled 8.5%) as described in the survey question as having ever been diagnosed by a doctor or other healthcare professional, treated or untreated, with these conditions.

Table 2. Concomitant Medication Use (Administrative Claims Data)

	Well Controlled (ATAQ 0)			Not Well Controlled (ATAQ 1/2)			Very Poorly Controlled (ATAQ 3/4)		
	Patients		Fills	Patients		Fills	Patients		Fill
	N	%	Mean	N	%	Mean	N	%	Mean
1st year prior to index/survey (-365)									
LABA	4	5.0%	8.75	24	5.6%	3.67	5	7.0%	4.60
SABA	30	37.5%	1.27	263	61.0%	3.16	57	80.3%	4.21
Leukotriene Antagonist	34	42.5%	8.06	195	45.2%	6.54	32	45.1%	5.31
Inhaled corticosteroids	15	18.8%	3.73	109	25.3%	2.84	15	21.1%	2.93
Inhaled cortico. combos	52	65.0%	4.50	255	59.2%	4.74	54	76.1%	4.80
Oral corticosteroids	22	27.5%	1.55	139	32.3%	1.89	34	47.9%	1.91
Injected corticosteroids	10	12.5%	1.50	53	12.3%	1.34	8	11.3%	2.13
Xanthines	1	1.3%	11.00	5	1.2%	8.20	0	0.0%	.
Sympathomimetics	0	0.0%	.	0	0.0%	.	0	0.0%	.
Cromolyn & nedocromil	1	1.3%	4.00	4	0.9%	1.25	1	1.4%	2.00
Xolair	1	1.3%	29.00	4	0.9%	6.00	3	4.2%	5.33
Other combinations	0	0.0%	.	1	0.2%	1.00	0	0.0%	.

- A greater percentage of patients with "very poorly controlled" asthma had a history of using short-acting beta-agonist (SABA) compared to "well controlled" and "not well controlled" patients (80% vs 61% and 38%, respectively)

- Mean number of fills for SABA's among "very poorly controlled" patients was 4.21 compared to 3.16 for "not well controlled" patients and 1.27 for "well controlled" patients.

Table 3. Patient Reported Severity and Progression

	Well Controlled (ATAQ 0)		Not Well Controlled (ATAQ 1/2)		Very Poorly Controlled (ATAQ 3/4)	
	N/Mean	%/Median	N/Mean	%/Median	N/Mean	%/Median
Asthma Severity						
Mild	61	76.3%	253	58.7%	15	21.1%
Moderate	17	21.3%	160	37.1%	42	59.2%
Severe	2	2.5%	18	4.2%	14	19.7%
Asthma Progression						
Much worse	0	0.0%	11	2.6%	12	16.9%
Somewhat worse	2	2.5%	40	8.3%	24	33.8%
Stayed the same	35	43.8%	192	44.5%	28	39.4%
Somewhat better	23	28.8%	106	24.6%	5	7.0%
Much better	20	25.0%	82	19.0%	2	2.8%

- As expected, a gradient was observed across the categories of asthma control and patient-reported level of asthma severity and asthma progression (defined over the past year). Seventy-six percent of "well-controlled" patients reported their asthma as mild, whereas 59% of "not well controlled" and 21% of "very poorly controlled" patients reported their asthma as mild. Over the past year, 2.5% of "well-controlled" patients reported their asthma as becoming somewhat or much worse, whereas, 10.9% of "not well controlled" and 50.9% of "very poorly controlled" patients reported the same.

- ATAQ scores were moderately correlated with patient-rated severity (r=0.33942, p<0.001).

Table 4. WPAI-Asthma Questions

	Well Controlled (ATAQ 0)			Not Well Controlled (ATAQ 1/2)			Very Poorly Controlled (ATAQ 3/4)		
	N/Mean	%/Median	Mode	N/Mean	%/Median	Mode	N/Mean	%/Median	Mode
Currently Employed	62	77.5%		330	76.6%		58	81.7%	
Work hours/wk	40.11	40	40	39.18	40	40	40.19	40	40.11
Hours missed	0.03	0		0.14	0		2.02	0	0.03
Asthma affects your typical work day*									
Avg. Overall Response	0.13	0	0	0.57	0	0	2.97	3	0
No effect on work (0)	57	91.9%		256	77.6%		16	27.6%	
1-3	5	8.1%		60	18.2%		18	31.0%	
4-6	0	0.0%		11	3.3%		18	31.0%	
7-9	0	0.0%		2	0.6%		5	8.6%	
Prevented work (10)	0	0.0%		1	0.3%		1	1.7%	
Asthma affects your daily activities									
Avg. Overall Response	0.26	0	0	1.02	0	0	3.99	4	4
No effect on activities (0)	68	85.0%		278	64.5%		8	11.3%	
1-3	12	15.0%		112	26.0%		23	32.4%	
4-6	0	0.0%		32	7.4%		25	35.2%	
7-9	0	0.0%		7	1.6%		11	15.5%	
Prevented activities (10)	0	0.0%		2	0.5%		4	5.6%	

*Question is contingent upon answering yes to working (previous question)

- Ninety-two percent of patients with "well controlled" asthma reported that their asthma had no effect on their typical work day, whereas 78% of the "not well controlled" and only 28% of patients with "very poorly controlled" asthma responded in the same manner (p<0.0001).

- When the question is rephrased in the scope of usual daily activities such as shopping, child care, work, studying and exercising, the same gradient is observed across the levels of asthma control. Approximately 85% of "well controlled" patients reported that their condition had little or no effect on their daily activities compared with 65% of "not well controlled" and 11% of "very poorly controlled" patients (p<0.0001).

LIMITATIONS

- While we did identify moderate to severe asthma patients through administrative claims regardless of control status, there may be residual selection bias in that patients who are more/less controlled may differ in their willingness to respond to the survey. Although, the comparison of co-morbidity between responders and non-responders did not suggest differences in illness burden.

- Although the benefit of administrative claims data arises from its "real-world" nature, there may be unobserved factors and other temporal differences affecting responses since patients were surveyed at a time point more current than their identification date in administrative claims.

- Furthermore, the impact of medication compliance on patient-reported outcomes was not assessed in this study and could have influenced patients' level of control.

CONCLUSIONS

- In a population of moderate-to-severe asthma patients, approximately 86% of patients were not fully controlled despite anti-inflammatory treatments.

- Lack of asthma control is associated with substantial patient burden.

- These findings are particularly important given the emphasis placed on disease control by the NAEPP.

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