Title: High Healthcare Utilization in a Severe Asthma Population Despite Use of High Dose ICS/LABA

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ABSTRACT

Rationale: Asthma patients with severe disease are often prescribed a combination of high-dose ICS/LABA. We sought to better understand medical resource use in asthma patients receiving the highest approved combination dosage of fluticasone/salmeterol by examining healthcare service and pharmaceutical claim records.

Methods: Using ThomsonReuters MarketScan claims databases, which includes inpatient, outpatient, and pharmaceutical healthcare service claims, we identified study subjects that were >17 years of age; had 4 years of continuous claims data excepting mortality; that had filled 90 days supply of fluticasone/salmeterol 500/50 within a 6-month Index Period beginning in 2004; and had an asthma diagnosis code. Exclusion criteria included mortality during the Index Period and evidence of change to controller medications used other than fluticasone/salmeterol 500/50. Healthcare utilization and costs for respiratory and non-respiratory services were evaluated during a Post-Index Period (average 2.7 years).

Results: 6321 patients (age 58 ±14 years) met study criteria with the following health insurance coverage: commercial 64%, Medicare 36%. Sixty-one percent of this population had an emergency department (ED) visit in the Post-Index Period, resulting in 23.8 respiratory ED visits per 100 patient years (69.5 all-cause ED visits per 100 patient years). Thirty-eight percent of respiratory ED visits resulted in a hospital admission. 1,248 patients (19.7%) had a respiratory hospital admission in the Post-Index Period, resulting in 12.9 hospitalizations per 100 patient years (43.0% had an admission for any reason). Seventy-one percent of respiratory hospitalizations originated from an ED visit. Average total healthcare cost per admission was \$12,196 \pm \$29,701.

Conclusion: Despite use of high dose ICS/LABA, this population with severe asthma has significant healthcare utilization and cost.

Rationale: According to the National Asthma Education and Prevention Program (NAEPP) guidelines, asthma patients with severe disease – defined as Step 5 or 6 of these guidelines -- are prescribed a combination of high-dose inhaled corticosteroid (ICS) and long-acting beta-agonists (LABA) as the preferred line of therapy. The purpose of this study was to analyze the medical service utilization patterns of patients on the highest dose of fluticasone/salmeterol combination medication (i.e. Advair 500), and to better understand the impact of medication compliance on medical resource use in this patient population, by examining healthcare service and pharmaceutical claim records.

Methods:

Study Population

Patients meeting study criteria were selected from ThomsonReuters MarketScan claims databases covering private insurance and Medicare patients, and including inpatient, outpatient, and pharmaceutical healthcare service claims.

- Time Periods Evaluated.
 - Index Date the first fill date of prescriptions covering 90 days of dosages for Advair 500 that qualified the patient for the study
 - Pre-Index Period -- six months prior to the Index Date
 - o Index Period -- six months beginning on the Index Date
 - Post-Index Period -- from the end of the Index Period until 6/30/2007 or mortality
- Study Inclusion Criteria
 - Age >17 years of age;
 - Continuous insurance coverage from 6/30/2003 through 6/30/2007, excepting death;
 - Minimum of 90 days supply of fluticasone/salmeterol 500/50 filled within a 6-month Index Period beginning in 2004;
 - Documented asthma diagnosis code (including all subcodes under ICD9 493.0, 493,1, 493.2, 493.8 and 493.9) in claims record.
- Study Exclusion Criteria
 - Death during Index Period;
 - Evidence of change to controller medications other than fluticasone/salmeterol 500/50
- Study Design
 - We calculated a Medication Possession Ratio (MPR) of fluticasone/salmeterol defined as: (Number of In-Period Days Supply) ÷ (Number of Days in the Post-Index Period).

- Other independent variables included:
 - Age
 - Gender
 - COPD
 - Sleep Apnea
 - Post-Index Rescue Medication MPR
 - Pre-Index Emergency Department (ED) and Inpatient Initiation (6 month period)
- We examined healthcare utilization and costs for respiratory and nonrespiratory services during a Post-Index Period averaging 2.7 years.
- We examined the relationship between varying percentiles of MPR, MPR as a continuous variable, and respiratory-related medical services utilization.
- We performed univariate and multivariate analysis to explore the predictive power of medication compliance.
- Definitions:
 - ED initiations = Number of patients presenting for Emergency Services
 - ED visits = Number of visits for Emergency Services
 - o IP initiations = Number of patients admitted as hospital inpatients
 - IP admissions = Number of inpatient admissions to the hospital
 - OR = Odds Ratio
 - Respiratory-related = primary diagnosis in the Respiratory Major Diagnostic Category (MDC), or a respiratory sign/symptom (includes shortness of breath but not chest pain)

Results:

- Study Population Demographics
 - o 6321 patients
 - Average Age = 58 ± 14 years
 - o 36% Medicare Insurance, 64% Private Insurance
 - o 60% Female
 - MPR of fluticasone/salmeterol 500/50:
 - Median: 0.53
 - 75th Percentile: 0.81
 - 90th Percentile: 0.95
- Average Study Population Healthcare Utilization:

Respiratory-Related

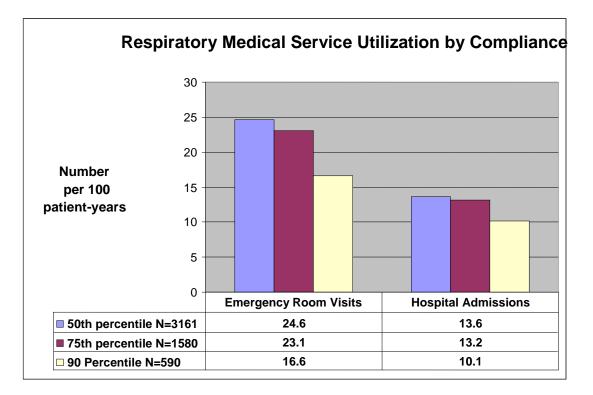
- o 23.8 respiratory ED visits per 100 patient years
- o 37.8% of respiratory ED visits resulted in a hospital admission
- o 12.9 respiratory inpatient (IP) hospital admissions per 100 patient years

All Causes

• 61% had at least one ED visit

- 43% had at least one IP hospital admission
- Average total healthcare cost per admission of \$12,196 ±\$29,701.
- Average costs for Respiratory-Related Events (in 2009 \$)
 - Physician Office Visit: \$98
 - Emergency Department Visit: \$389
 - Hospital Admission: \$7,271
- Univariate Analysis: MPR Levels and Utilization per 100 Patient Years (Figure 1)

Figure 1. Respiratory-Related Medical Service Utilization for Patients Compliant with Fluticasone/Salmeterol 500/50



 Multivariate Regression Analyses of Fluticasone/Salmeterol 500/50 Compliance on Respiratory-Related Utilization (Table 1)

 Table 1. Effect of Compliance on Initiation and Utilization of Emergency Department and Inpatient Services

	ED initiations	ED visits	IP Initiations	IP Admissions
Median	OR = 0.814,	$\beta = -0.022,$	OR = 0.892,	$\beta = -0.033$,
Compliance:	P = 0.001	P = 0.088	P = 0.119	P = 0.007
MPR=0.53	[Cl: 0.720 - 0.920]		[CI: 0.773 - 1.30]	

75 th Percentile	OR = 0.781	β = -0.040	OR = 0.828	β = -0.047
Compliance:	P = 0.001	P = 0.001	P = 0.021	P = 0.000
MPR 0.81	[CI: 0.679 - 0.898]		[CI: 0.706 - 0.972]	
MPR as	OR =0.683	β = -0.033	OR = 0.803	β = -0.046
Continuous	P = 0.000	P = 0.011	P = 0.065	P = 0.000
Variable	[CI: 0.558 - 0.835]		[CI: 0.646 - 1.014]	

Definitions:

 \circ β = Beta: Predictive power of independent variable, i.e. how much does utilization change in response to compliance levels.

compliance levels.CI = 95% Confidence Intervals

Conclusion:

In this population of severe asthma patients, despite receiving care as prescribed in Step 5 and 6 of the National Asthma Education and Prevention Program (NAEPP) guidelines (i.e. fluticasone/salmeterol 500/50), medical service utilization remained high. While being on fluticasone/salmeterol 500/50 reduced medical service utilization, this reduction was not significant until patient compliance reached 95% or greater. Since less than 10% of patients demonstrated a greater than 95% compliance rate over the follow-up period, it would be reasonable to conclude that even when patients with severe asthma are treated according to current guidelines, they still demonstrate significant health care utilization in emergency room visits and admissions to hospital. This observation is in keeping with the findings reported by the NIH Severe Asthma Research Program (SARP) report on characterization of severe asthma¹.

This study confirms that full compliance is uncommon in patients with severe asthma, and that treatment of these patients with the highest approved dosage of fluticasone/salmeterol 500/50, is insufficient to significantly reduce health care utilization in this population.

References

¹ Moore WC, Peters SP. Severe asthma: an overview. J Asthma and Clin Immunol; 2006: 177: 487-494

Poster #4217, Session #A30 ATS 2009 (San Diego, CA, May 17, 2009) Annual Meeting of the American Thoracic Society

Study funded by Asthmatx, Inc