

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: RWE Comparative Effectiveness Study

ACTIVE INGREDIENT: N/A

Study No: NCT01623544 RWE Study code: RWE000015

Study Title: A U.S. Retrospective Database Analysis Evaluating the Comparative Effectiveness of Budesonide/formoterol (BFC) and Fluticasone propionate/salmeterol treatment (FSC) among Asthma Patients
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Developmental Phase: RWE

Study Completion Date: 9/30/2012 (Database Lock)

Date of Report: 02/18/2013

OBJECTIVES: The overall objective of this study was to compare the effectiveness of BFC and FSC in asthma patients who newly initiated ICS/LABA combination therapy in the US between 6/1/2007 and 9/30/2010.

Primary Objective:

Comparative effectiveness of ICS/LABA therapy in the avoidance of asthma exacerbations over a period of one year following the initiation of BFC or FSC. An asthma exacerbation was defined as any asthma-related inpatient hospitalization, asthma-related ED visit, or oral corticosteroid (OCS) prescription fills.

Secondary Objective:

Asthma-related healthcare resources utilization and costs during the 12 month post-index:

1. Asthma medication use (SABA, ICS, LABA, LTRA, Xolair, Theophylline)
2. Asthma-related healthcare utilization: office/outpatient visits, inpatient length of stay, ICU admission and length of stay
3. Asthma-related healthcare costs: costs of all asthma-related medication and asthma-related outpatient/office, ED, and inpatient visits

METHODS:

The current study was a retrospective cohort study utilizing administrative claims data from the HealthCore Integrated Research Database (HIRDSM). Asthma patients age 12 to 64 years with a fill for BFC or FSC between 6/1/2007-9/30/2010 were eligible for this study. Statistical testing (two-sided, comparing two independent samples) was done for comparisons between the propensity score matched FSC and BFC cohorts with BFC as the reference group.

For the primary outcome variable a negative binomial model with a log link was used to model the number of exacerbations during the post-index period. For the secondary objectives, differences between treatment cohorts were analyzed using different types of tests depending on the distribution of the variable including Normal regression, Gamma regression with a log link, Negative binomial regression with a log link, and Poisson regression.

RESULTS:

Propensity score matching resulted in a total of 6,086 patients (3,043 patients in each treatment group). Study subjects were well balanced on pre-index factors that were assumed to be the best predictors of asthma exacerbation rate, the primary outcome measure. Patients in BFC and FSC cohorts had a mean (\pm SD) age of 40 (\pm 14.8) years, and 63.5% were female. The majority of the patients in both cohorts (77% for FSC and BFC) were covered by PPO health plans, and their distribution across all geographic regions was similar.

Key Results

- Asthma patients initiating BFC had a lower rate of asthma exacerbation compared to FSC patients (covariate adjusted rate for BFC = 0.85, FSC = 0.93, rate ratio = 0.92, 95% CI = [0.85, 0.99], $P = 0.0255$).
- The difference in exacerbation rates was driven by the number of OCS fills during the post-index period (Adjusted mean number of OCS for BFC = 0.73, FSC = 0.79, 95% CI = [-0.12, -0.01]), and by the number of emergency department visits (Adjusted mean for BFC = 0.08, FSC = 0.10, 95% CI = [-0.03, -0.00]).
- Inpatient visit rates were identical between groups, with 1.5% of patients in each group having at least one asthma related inpatient visit during the post-index period.

- The use of other asthma medication was comparable between the two cohorts though ICS use was slightly lower in the BFC group, reflected by a smaller proportion of patients with at least one ICS fill (9.1% of BFC patients compared with 10.2% of FSC patients, OR = 0.86, 95% CI = [0.72, 1.02]) and fewer ICS fills (0.28 fills on average for BFC patients compared to 0.36 for FSC patients, 95% CI = [-0.13, -0.01]).
- A lower proportion of BFC patients had at least one fill for SABA (66.4% versus 71.2%, OR = 0.80, 95% CI = [0.72, 0.90]) and there were fewer overall fills of SABA (2.4 on average for BFC compared to 2.6 for FSC, 95% CI = [-0.32, -0.03]).
- The median length of stay for asthma related inpatient hospitalizations was a night and half longer for FSC patients (4.5 compared to 3.0), but the adjust means were nearly identical (4.3 for FSC versus 4.2 for BFC).