Asthma-Related Exacerbations and SABA Use Associated with Once-Daily Fluticasone Furoate/Vilanterol Compared to Twice-Daily Budesonide/Formoterol

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Introduction

There is limited real-world data on asthma symptom control and exacerbations in asthma patients receiving fluticasone furoate/vilanterol (FF/VI) versus other ICS/LABAs in the US. This study compared SABA use and exacerbations among asthma patients receiving once-daily FF/VI 100/25 mcg or twice-daily budesonide/formoterol (B/F) 160/4.5 mcg in a large US claims database.

Methods

Study Design: Retrospective matched cohort study using the IQVIA™ Real-World Data Adjudicated Claims US Database, of adult asthma patients initiating FF/VI 100/25 mcg or B/F 160/4.5 mcg between January 1, 2015 and December 31, 2018. Patients treated with FF/VI 100/25 mcg were propensity score matched on baseline demographics to patients treated with B/F 160/4.5 mcg.

Inclusion criteria

- ≥1 pharmacy claim for FF/VI 100/25 or B/F160/4.5 between January 1, 2015 and December 31, 2018 (index date = first dispensing date)
- Age ≥18 at index
- ≥12 months of continuous enrollment pre-index (baseline)
- ≥3 months of continuous enrolment post-index (12 months maximum follow-up)
- ≥1 asthma diagnosis during baseline or on index date

Exclusion criteria

- ≥1 pharmacy claim for fixed-dose ICS/LABA (including index ICS/LABA) during the 12-month baseline
- ≥1 pharmacy claim for multiple fixed-dose ICS/LABAs on the index date
- ≥1 diagnosis for COPD, acute respiratory failure, or cystic fibrosis diagnosis during baseline or on the index date

Outcomes

Primary Endpoint	Secondary Endpoints	
Number of SABA canisters per patient-year	Time to first overall or severe asthma-related exacerbation	Rates of overall and severe asthma-related exacerbations

Asthma Exacerbation Definitions

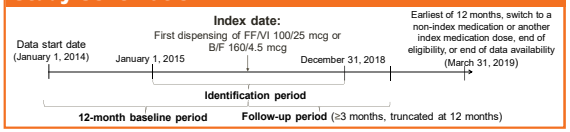
Overall asthma exacerbations were defined as:

- An asthma-related outpatient visit or emergency department (ED) visit with a systemic corticosteroid dispensing within ± 5 days, OR
- An asthma related ED visit leading to an asthma-related hospitalization within +1 day, OR
- An asthma-related hospitalization

Severe asthma exacerbations were defined as:

- An asthma-related hospitalization or an asthma-related ED visit that results in a hospitalization within +1 day

Study Schematic



Results

A total of 18,531 FF/VI and 51,537 B/F initiators met the study selection criteria. Of these, 18,531 patients in the FF/VI cohort were matched to 18,531 patients in the B/F cohort. Matched cohorts were well balanced on baseline characteristics (Table 1).

Table 1. Post-Match Baseline Characteristics

Characteristic	FF/VI 100/25 mcg (N=18,531)	B/F 160/4.5 mcg (N=18,531)	Standardized Difference (%)
Age, mean (SD)	46.7 (13.6)	46.8 (13.5)	0.2
Female, (%)	63.4	63.8	0.8
Respiratory Medication Use			
AMR, mean (SD)	0.63 (0.30)	0.64 (0.29)	0.6
≥1 ICS, %	13.2	14.3	3.3
≥1 OCS, %	47.0	46.6	0.8
# of SABA canisters, mean (SD)	1.8 (3.1)	1.9 (4.3)	1.2
Asthma-related HRU			
Asthma ED visits, mean (SD)	0.05 (0.31)	0.06 (0.29)	1.3
≥1 Asthma hospitalization, %	0.9	0.9	0.1
Asthma Exacerbations			
Overall exacerbations, mean (SD)	0.21 (0.52)	0.21 (0.52)	0.8
≥1 overall exacerbation, %	17.2	17.5	0.9
Severe exacerbations, mean (SD)	0.01 (0.10)	0.01 (0.10)	0.2
≥1 severe exacerbation, %	0.9	0.9	0.2
Asthma-related Healthcare Cost, US$ 2019, mean (SD)			
Asthma-related total cost	$1,003 (7,291)	$993 (3,421)	0.2
Patient-paid cost of index medication fill	$75 (103)	$70 (101)	4.9
Post-index Follow-up Time, days mean (SD)	314 (84)	315 (83)	1.1

Abbreviations: SD: standard deviation; AMR: Asthma Medication Ratio; ICS: inhaled corticosteroid; OCS: oral corticosteroid; SABA: short-acting beta-agonist, HRU: healthcare use; ED: emergency department;

Results

Patients on FF/VI had a 13% lower risk of overall asthma exacerbation and a 22% lower risk of severe exacerbation compared to patients on B/F (Figs 1 and 2).

Figure 1. Time to First Overall Asthma Exacerbation

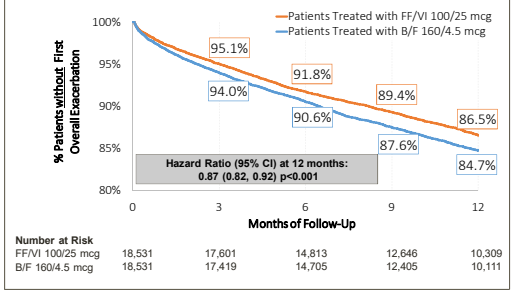
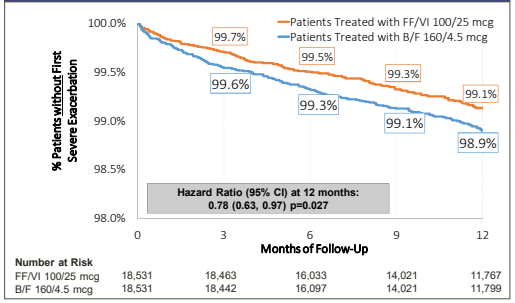


Figure 2. Time to First Severe Asthma Exacerbation



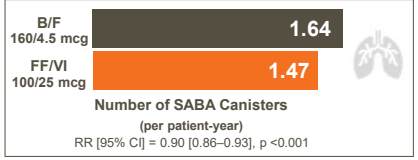
Rates of overall and severe asthma-related exacerbations were significantly lower in the FF/VI cohort relative to the B/F cohort (Table 2).

Table 2. Rate of Asthma-Related Exacerbations

Variable	Rate (per patient per year)		Rate (per 100 patient-days)		Rate Ratio (95% CI)	P-value
Asthma Exacerbation	FF/VI	B/F	FF/VI [A]	B/F [B]	[A] / [B]	
Overall	0.1796	0.2081	0.0475	0.0558	0.85 (0.81, 0.91)	<0.001
Severe	0.0097	0.0131	0.0026	0.0033	0.78 (0.62, 0.96)	0.020

There was 10% lower SABA use among FF/VI users relative to B/F users (Fig 3).

Figure 3. SABA Use During 12-Month Follow-up



Limitations

- This study used claims data and thus lacked specific clinical measures (e.g. symptoms, lung function).
- As an observational study, residual confounding not addressed by matching could still be present; outcomes attributable to treatment are by association only.

Conclusions

The use of once-daily FF/VI 100/25 mcg when compared to use of twice-daily B/F 160/4.5 mcg was associated with lower use of SABA which may indicate better asthma control, and fewer asthma-related exacerbations.

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