Real-world safety and effectiveness of fluticasone furoate (Arnuity® Ellipta™) in patients with asthma: A Post-marketing Surveillance (PMS) in Korea

Poster No. P540

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Aim

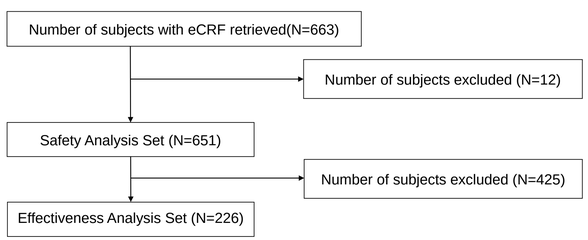
- To evaluate the safety and effectiveness of FF in Korean patients with Asthma.

Methods

- An open-label, observational, prospective study in patients diagnosed with asthma and newly treated with FF for 24weeks was conducted from November 2016 to June 2020 in accordance with re-examination regulation by the Korean Ministry of Food and Drug Safety.
- Primary objective was to monitor incidence and severity of adverse events(AEs) including adverse drug reactions(ADRs), reported after administrating at lease a dose of FF. Secondary objective was to monitor effectiveness of FF after 24weeks of administration.
- A total of 663 patients were completed through the electronic case report forms(eCRFs) in 16 institutions by 17 investigators. Among those with the surveillance completed, 12 patients were excluded. Out of the patients in the Safety Analysis Set, 226 patients were included in the Effectiveness Analysis Set, excluding 425 patients with 'un-assessable' results in the investigator effectiveness evaluation **(Figure 1).**

Key inclusion criteria	Key exclusion criteria
• Diagnosed with asthma,12years of age or older, who received a once-daily inhaler of either FF100μg or 200μg for maintenance treatment of asthma	• Persistent symptoms of acute asthma episodes requiring intensive treatment • Hypersensitivity to this drug or its components, severe protein hypersensitivity and genetic problems, including, but not limited to, those with galactose intolerance, Lapp lactase deficiency, or glucose-galactose malabsorption

Figure 1. Patient Composition



Results

Table 1. Patients demographics and baseline characteristics

Characteristic	Total N=651 n (%)
Age, mean±SD, years	58.66±15.42
<65 years	397(60.98)
≥65 years	254(39.02)
Women	359(55.15)
Duration of asthma, years*	
Mean ± SD	3.54±5.28
Smoking status	
Current smoker	72(11.06)
Ex-smoker	135(20.74)
Never Smoker	444(68.20)
Total smoking amount (pack-years) † (for "Current Smoker" or "Ex-smoker"), Mean ± SD	25.73±19.38
Comorbidities	488(74.96)
Allergic diseases	246(37.79)
COPD	43(6.61)
Asthma-COPD overlap	3(0.46)
Bronchiectasis	13(2.00)
Pretreatment‡	
Related to asthma	504(77.42)
Concomitant medications‡	
Related to asthma	461(70.81)
Not related to asthma	452(69.43)

*Asthma period (years) = (Start year of study drug administration) - (Year of asthma diagnosis); † No. of subjects with unknown annual smoking amount: 31 subjects; ‡ Overlapped, KIMS (Korean Index of Medical Specialties)

- Of the 651 patients, 55.15%(n=359) were female. The mean age was 58.66 ±15.42 years, ranging from 15 years to 101 years. The patients' mean asthma period was 3.54 ±5.28 years, ranging from 0 years to 48 years. In terms of patient's smoking status, 68.20%(n=444) were never smokers, followed by 20.74%(n=135) of ex-smokers and 11.06%(n=72) of current smokers. Among the 651 patients with asthma, 77.42%(n=504) had prior medication related to asthma from 4 weeks prior to administration of the study drug (**Table 1**).

Table 2. Incidence of AEs, ADRs and SAEs

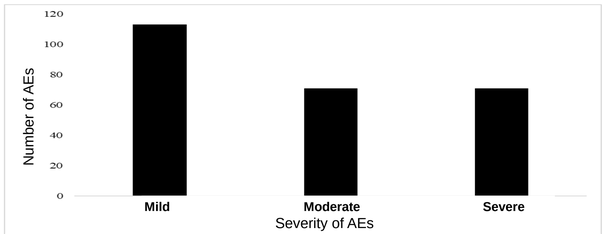
Adverse Events	n(%)	[No. of cases]	[95% , C.I]
Total AEs	113(17.36)	[192]	[14.53 , 20.49]
ADRs	6(0.92)	[8]	[0.34 , 2.00]
SAEs	21(3.23)	[26]	[2.01 , 4.89]
UAEs	73(11.21)	[132]	[8.89 , 13.89]

Abbreviations: ADR, adverse drug reaction; AE, adverse event; SAE, serious adverse event; UAE, unexpected adverse event.

- The overall incidence rate of AEs was reported 17.36% (n=113), of which 0.92%(n=6) were reported as ADRs. There were 3.23% (n=21) of SAEs were reported, whereas serious ADR was not reported (**Table 2**).

- AEs were reported by 113 patients (17.36%) in 192 cases. In the analysis of AEs by system organ class (SOC), 'Infections and infestations' were reported the most in 6.14% (n=40), followed by 'Respiratory, thoracic and mediastinal disorders' in 5.84% (n=38) and 'Gastrointestinal disorders' in 2.76% (n=18). ADRs for which the causality with the study drug could not be excluded were reported by 6 patients. SAEs were reported by 21 patients (3.23%) in 26 cases. The most common SAE was pneumonia (n=4, 0.61%), followed by cerebral infarction in 0.31% (n=2). Serious UAEs were reported by 20 patients (3.07%) in 23 cases.

Figure 2. Severity of AEs: Safety Analysis Set



- Among the 191 cases of AEs, most of them were 'mild' (n=113, 59.16%), whereas 'moderate'(n=71, 37.17%) and 'severe'(n=71, 37.17%) were minor portions (**Figure 2**).

- Age, asthma period, concomitant medication not related to asthma and mean daily dose were identified to be the factors affecting the AE incidence with a statistical significance (p=0.0047, 0.0010, <0.0001 and 0.0078, respectively). That is, the AE incidence increased according to increased age (odds ratio=1.02, 95% C.I: 1.01, 1.04) and increased asthma period (odds ratio=1.07, 95% C.I: 1.03, 1.11); the AE incidence was higher in the patients with concomitant medication not related to asthma compared to those without it (odds ratio= 6.41, 95% C.I: 2.56, 16.09) and higher upon increased mean daily dose (odds ratio=1.01, 95% C.I: 1.00, 1.02) (**Table 3**).

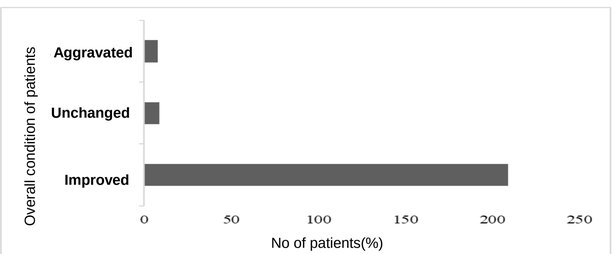
- Out of 226 patients analyzed for efficacy, most patients (92.48%, n=209) showed overall improvement of disease after treatment of FF (**Figure 3**). Unchanged' and 'Aggravated' as 'Ineffectiveness' for analysis. 'Improved' accounted for 92.48% (n=209), 'Unchanged' for 3.98% (n=9) and 'Aggravated' for 3.54% (n=8). Therefore, 'Effectiveness' accounted for 92.48% (n=209) and 'Ineffectiveness' 7.52% (n=17) (**Figure 3**).

Table 3. Logistic Regression for Adverse Event Incidence

Factor	Description	Estimate	p-value	Odds Ratio	[95% C.I]
Age	1 year	0.02	0.0047*	1.02	[1.01, 1.04]
Asthma period	1 year	0.07	0.0010*	1.07	[1.03, 1.11]
Medical history	Yes	-0.02	0.9505	0.98	[0.45, 2.10]
	No	Reference			
Prior medication related to asthma	Yes	0.40	0.4134	1.48	[0.58, 3.83]
	No	Reference			
Concomitant medication related to asthma	Yes	0.15	0.7206	1.16	[0.51, 2.66]
	No	Reference			
Concomitant medication not related to asthma	Yes	1.86	<0.0001*	6.41	[2.56, 16.09]
	No	Reference			
Total administration period	1 day	0.00	0.3642	1.00	[1.00, 1.00]
Mean daily dose	1μg /day	0.01	0.0078*	1.01	[1.00, 1.02]

Result variable: Adverse event (Yes/No)
*Statistically significant

Figure 3. Investigator Effectiveness Evaluation at week 24



Improved categorized as "Effective" (n=209,92.48%)
Unchanged and aggravated as "Ineffective" (n=17, 7.52%)

Conclusions

FF administered to Korean patients according to the prescribing information was well tolerated and can be considered an effective option for asthma treatment.

Abbreviations

COPD, chronic obstructive pulmonary disease; ICS, inhaled corticosteroid; LABA, long-acting beta-2-agonist; LABD, long-acting bronchodilator; LAMA, long-acting muscarinic antagonist; SD, standard deviation;

Disclosures

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