

A Comparative Study to Evaluate the Effect of Vilanterol/Fluticasone Furoate Versus Formoterol/Fluticasone Propionate in Bronchial Asthma Patients

Garima Verma¹, Arpita Singh², Ajay Kumar Verma³, Hemant Kumar⁴,
Pooja Shukla⁵, Atul Jain⁶, Punit Kanaujia⁷

¹Senior Resident, Department of Pharmacology, Dr. RMLIMS, Lucknow

²Professor & HOD, Department of Pharmacology, Dr. RMLIMS, Lucknow

³Professor & HOD, Department of Respiratory Medicine, Dr. RMLIMS, Lucknow

⁴Additional Professor, Department of Respiratory Medicine, Dr. RMLIMS, Lucknow

⁵Additional Professor, Department of Pharmacology, Dr. RMLIMS, Lucknow

⁶Professor, Department of Pharmacology, MMCMSR, Sadopur, Ambala

⁷Senior Resident, Department of Pharmacology, Dr. RMLIMS, Lucknow

Corresponding Author: Dr. Arpita Singh

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ABSTRACT

Background: Bronchial asthma is a chronic inflammatory airway disease affecting millions worldwide, especially children and adolescents. Inhaled Corticosteroids (ICS) and Long-Acting Beta-agonists (LABAs) are the cornerstone of treatment. Vilanterol/Fluticasone Furoate (VI/FF), a once-daily LABA/ICS combination, offers improved adherence, better lung function, and enhanced symptom control compared to traditional twice-daily regimens like Formoterol/Fluticasone Propionate (FM/FP).

Aims: To compare the effect of Vilanterol and Fluticasone Furoate versus Formoterol and Fluticasone Propionate combination on pulmonary functions in patients with bronchial asthma.

Methods: A prospective study was conducted over 18 months involving 92 asthma patients divided equally into two groups: VI/FF and FM/FP. Patients were assessed after 6 months of treatment for spirometric parameters (FEV₁ and FVC) and adherence using the ASK-12 questionnaire.

Results: Both groups showed significant improvements in FEV₁ and FVC over 6 months, with VI/FF demonstrating a more significant improvement in FEV₁ (p=0.001) and FVC (p=0.011). The adherence scores were better in the VI/FF group, particularly regarding inconvenience/forgetfulness and behaviour.

Conclusion: VI/FF showed superior improvement in lung function and better adherence compared to FM/FP. Once-daily dosing with VI/FF enhances convenience, making it a potentially preferred treatment for bronchial asthma.

Keywords: Bronchial asthma, Inhaled Corticosteroids (ICS), Long-Acting Beta-agonists (LABAs), Pulmonary function test

INTRODUCTION

Bronchial asthma is a chronic inflammatory disease of the airways that leads to fluctuating airflow limitation, hypersensitivity, wheezing, coughing, shortness of breath and chest tightness. Asthma affects 300 million people

worldwide, especially children and adolescents.[1] Global Initiative for Asthma (GINA) describes asthma as a multifaceted disease with many phenotypes caused by genetic predispositions, environmental influences and immunological mechanisms.[2]

LABAs and inhaled corticosteroids (ICS) are the main asthma treatments. The ICS Fluticasone furoate (FF) and Fluticasone propionate (FP) reduce airway inflammation and hyperresponsiveness, improving lung function and symptom management.[1] Vilanterol (VI), Formoterol and Salmeterol are LABA bronchodilators that relax airway smooth muscle beta-2 adrenoceptors and improve airflow. LABAs reduce symptoms and exacerbations most effectively with ICS. [3,4]

The British Thoracic Society (BTS) guidelines for the treatment of asthma recommend ICS as the main asthma treatment, especially for people who use salbutamol more than three times a week. Regular use of ICS reduces airway inflammation, hyperresponsiveness and symptom frequency, making it an important "preventative" treatment.[5]

Adherence to medication regimens is the mainstay for asthma management. The typical LABAs Formoterol and Salmeterol must be taken twice daily, which can be difficult for patients. Vilanterol, a once-daily LABA, is more convenient and can improve adherence.[1]

Vilanterol (VI) binds to the beta-2-adrenoceptors of airway smooth muscle and causes 24-hour bronchodilation. VI, a once-daily treatment, has advantages over Formoterol and Salmeterol, which are taken twice daily. LABA therapy is proven to improve symptoms, lung function and exacerbations in asthma patients. The extended duration of action of VI makes it ideal for ICS combination treatment and improves efficacy and convenience for patients.[3]

Fluticasone furoate (FF), a potent inhaled corticosteroid, has a strong anti-inflammatory effect even at low doses due

to its affinity for glucocorticoid receptors. Regular use of FF reduces airway inflammation and hyperreactivity, improves lung function and symptom management. It is recommended as a "preventative" treatment for relieving symptoms in patients. Its pharmacokinetic features include a longer stay in the lungs, targeting central and peripheral airway inflammation.[4]

Many asthmatics have inadequate asthma control despite ICS/LABA combinations. Non-adherence, incorrect inhaler use technique and peripheral airway inflammation lead to chronic symptoms and exacerbations. These problems contribute to poor disease control in upto 90% of asthma patients.[1] Traditional ICS/LABA combinations such as Formoterol/Fluticasone propionate (FORM/FP) must be administered twice daily, making adherence difficult, especially in busy patients or those with low health literacy.[3] Masoli et al (2005) found that 81% of asthmatics preferred medication with fast symptom relief. A combination of rapid action, prolonged efficacy and optimized dosing regimens can improve patient satisfaction, adherence and clinical outcomes.[6]

The inhaler delivers Fluticasone furoate/Vilanterol (FF/VI) once daily to overcome the disadvantages of standard therapy. Its powerful ICS and long-acting LABA target airway inflammation and bronchodilation with once-daily dosing.[7] Terzano & Oriolo (2017) found that FF/VI significantly improved lung function, reduced exacerbation rates and improved asthma control compared to ICS monotherapy or a standard ICS/LABA combination.[5]

FORM/FP, a popular twice-daily ICS/LABA combination, controls central airway inflammation but may not affect peripheral airway involvement. In patients with uncontrolled symptoms or patients requiring intensive care, the twice-daily dosing regimen makes adherence to therapy more difficult.[8]

ICS/LABA combinations work because of their complementary mechanisms. FF and FP block pro-inflammatory cytokines, reduce eosinophil recruitment and stabilize mast cells to reduce airway inflammation. LABAs such as VI and Formoterol activate beta-2 adrenoceptors on airway smooth muscle to relax it and improve airflow.[1] FF has a stronger anti-inflammatory effect than FP due to its greater affinity for glucocorticoid receptors, while the 24-hour persistence of VI provides sustained bronchodilation. FF/VI is a potential treatment for patients with moderate to severe asthma seeking better adherence and symptom control.[4] Given these considerations, the present study was designed to compare the clinical efficacy, safety and adherence of VI/FF versus FM/FP in patients with bronchial asthma. By evaluating pulmonary function, treatment adherence and patient-reported outcomes, this research intends to provide valuable insights into optimizing asthma therapy and guiding future recommendations in routine practice.

MATERIALS & METHODS

Study Design and Setting

This was a prospective, comparative, non-randomized, open-label study conducted in the Department of Pharmacology in collaboration with the Department of Respiratory Medicine at Dr. Ram Manohar Lohia Institute of Medical Sciences, Lucknow, from May 2023 to October 2024. The study protocol was reviewed and approved by the Institutional Ethics Committee (IEC No. 2/23), and all participants provided written informed consent prior to enrollment.

Study Population

A total of 92 patients diagnosed with mild to moderate persistent bronchial asthma were included. Eligible patients were aged 18

years or older and demonstrated at least 12% reversibility in forced expiratory volume in one second (FEV₁) after administration of a bronchodilator. Patients with insufficient mental capacity to provide informed consent, thyroid disease, severe liver disease, congestive heart failure, rheumatoid arthritis, pregnancy, or lactation were excluded. Additional exclusion criteria included poor inspiratory effort that prevented the use of dry powder inhalers or metered dose inhalers and contraindication or hypersensitivity to any of the study drugs.

Study Groups and Intervention

Participants were divided into two groups according to their prescribed regimen. Group A (n=46) received Vilanterol/Fluticasone Furoate (100/25 µg, once daily), while Group B (n=46) received Formoterol/Fluticasone Propionate (125/5 µg, twice daily). All patients were followed up for a duration of six months. The primary outcome of the study was the change in pulmonary function parameters, specifically FEV₁ and forced vital capacity (FVC), assessed using spirometry at baseline and at six months. The secondary outcome was adherence to inhaler therapy, evaluated using the ASK-12 questionnaire.

Statistical Analysis

Data were expressed as mean ± standard deviation (SD). Baseline characteristics between groups were compared using independent t-tests or Chi-square tests/Fisher's exact test as appropriate.

Intragroup and intergroup comparisons for pulmonary function parameters and adherence scores were analyzed using paired and unpaired t-tests. A p-value <0.05 was considered statistically significant. Statistical analyses were performed using SPSS version 26.0.

RESULT

Table 1. Demographic Characteristics of patients

Parameter	Group A (Vilanterol/Fluticasone Furoate), n=46	Group B (Formoterol/Fluticasone Propionate), n=46	p- value
Gender			
Male	30 (65.22%)	32 (69.57%)	0.82
Female	16 (34.78%)	14 (30.43%)	
Age (Years)			
(Mean± SD)	45.33 ± 12.81	42.50 ± 11.38	0.26
BMI (kg/m ²)			
(Mean ± SD)	22.51 ± 2.45	23.17 ± 2.90	0.73
Family history	2 (4.35%)	2 (4.35%)	1.00
Dietary habits			
Vegetarian	14 (30.43%)	13 (28.26%)	0.81
Non-vegetarian	32 (69.57%)	33 (71.74%)	
Smoking	12 (26.09%)	13 (28.26%)	0.81

*p-value <0.05 = statistically significant
n= number of patients

A total of 92 patients were enrolled in the study, with 46 patients in each treatment group: Group A (Vilanterol/Fluticasone Furoate) and Group B (Formoterol/Fluticasone Propionate).

The baseline demographic characteristics of the patients in both groups are summarized in Table 1. The gender distribution was comparable between the groups, with Group A comprising 30 males (65.22%) and 16 females (34.78%), while Group B included 32 males (69.57%) and 14 females (30.43%) (p = 0.82).

The mean age of patients in Group A was 45.33 ± 12.81 years, and in Group B, it was 42.50

± 11.38 years, showing no significant difference (p = 0.26). Body mass index (BMI) was similar between the groups, with a mean of 22.51 ± 2.45 kg/m² in Group A and 23.17 ± 2.90 kg/m² in Group B (p = 0.73).

A family history of asthma was reported in 2 patients (4.35%) in each group. Dietary habits were comparable, with 14 patients (30.43%) in Group A and 13 patients (28.26%) in Group B following a vegetarian diet, while the remainder were non-vegetarian (p = 0.81). Smoking prevalence was also similar, with 12 patients (26.09%) in Group A and 13 patients (28.26%) in Group B reporting a history of smoking (p = 0.81).

Table 2. Clinical Characteristics of patients

Parameter (At 6 months)	Groups	Baseline	Follow-up period	p- value
FEV ₁ %	VI/FF	68.50±6.40	77.65±6.22	0.001*
	FM/FP	69.60±6.11	74.70±5.85	0.001*
FVC%	VI/FF	84.93±12.06	91.26±11.32	0.01*
	FM/FP	82.60±13.58	87.69±12.49	0.06

*p-value <0.05 = statistically significant

The comparison of clinical characteristics from baseline to the six-month follow-up period is summarized in Table 2. FEV₁ (%) significantly improved in both groups at six months of treatment. In the VI/FF group, the mean FEV₁ increased from 68.50 ± 6.40% at baseline to 77.65 ± 6.22% at six months (p = 0.001). Similarly, the FM/FP group showed an increase from 69.60 ± 6.11% to

74.70 ± 5.85% (p = 0.001), indicating statistically significant improvement in lung function in both groups.

FVC (%) also showed improvement over the follow-up period. In the VI/FF group, FVC increased from 84.93 ± 12.06% to 91.26 ± 11.32% (p = 0.01), which was statistically significant. The FM/FP group demonstrated an increase from 82.60 ± 13.58% to 87.69 ±

12.49%, although this change did not reach statistical significance ($p = 0.06$).

Table 3. Comparison of ASK-12 score between Group VI/FF and FM/FP

ASK-12 Scales	Group A (Vilanterol/Fluticasone Furoate), n=46	Group B (Formoterol/Fluticasone Propionate), n=46	p- value
Inconvenience/forgetfulness	5.57±2.93	7.03±2.49	0.012*
Treatment beliefs	7.38±2.72	8.51±3.02	0.063
Behavior	7.27±2.21	9.12±3.88	0.005*
Total score	20.22±6.68	24.69±8.24	0.005*

*p-value <0.05 = statistically significant

Comparison of ASK-12 score between Group VI/FF and FM/FP Table.3, which assess adherence and barriers to inhaler use, were significantly lower in the VI/FF group compared to the FM/FP group at six months, indicating better adherence and fewer barriers in patients receiving VI/FF. The VI/FF group had a mean score of 20.22 ± 6.68 , whereas the FM/FP group had a mean score of 24.69 ± 8.24 ($p = 0.005$).

DISCUSSION

This study provides a comprehensive evaluation of the efficacy, safety and patient-reported outcomes of the combination of Vilanterol/Fluticasone furoate (VI/FF) with Formoterol/Fluticasone propionate (FM/FP) in the treatment of bronchial asthma. Both treatment regimens significantly improved lung function scores, asthma management and quality of life during the six-month study period. The same safety profiles and adherence rates emphasize the reliability and applicability of both therapies in different patient populations.

This study, the mean age of bronchial asthma patients was comparable between group VI/FF (45.33 ± 12.81 years) and group FF (42.50 ± 11.38 years), with no statistically significant difference ($p = 0.266$). This observation is consistent with the findings of Terzano and Oriolo (2017) who, in their study comparing Beclomethasone/Formoterol and Fluticasone/Vilanterol, also found a comparable demographic distribution and no significant differences in baseline characteristics, including age and gender distribution, between the two cohorts.[5]

Figueiredo et al (2023)[9] also emphasized the importance of age and demographic characteristics on response to therapy in asthma; however, they found that these factors did not significantly affect the efficacy outcomes of the medications studied. The consistency between studies underscores the generalizability of our findings and confirms that baseline demographic similarities improve the reliability of comparative treatment evaluations in bronchial asthma.

In this study, the gender distribution between the two groups was comparable, with group VI/FF consisting of 65.22% males and 34.78% females and group FF consisting of 69.57% males and 30.43% females. There was no significant difference in the gender distribution ($p = 0.824$). This result is consistent with an earlier study by Terzano and Oriolo (2017), who also found no significant gender differences in their comparative study of Beclomethasone/Formoterol and Fluticasone/Vilanterol combinations for asthma therapy.[5] Shimizu et al. (2020) found a similar gender distribution in their study on the efficacy of Fluticasone furoate/Vilanterol, ensuring that treatment outcomes are not influenced by gender differences in asthma development or response to therapy.[10] The consistency between studies underlines the reliability of our results and confirms that gender has no significant impact on the comparative efficacy of different treatment regimens in bronchial asthma. In this study, anthropometric measures such as average height, weight and BMI were the same in both groups. The VI/FF group had an average height of 164.04 ± 3.07 cm, a

weight of 60.65 ± 7.46 kg and a BMI of 22.51 ± 2.45 kg/m². The FF group had an average height of 163.83 ± 3.11 cm, a weight of 62.15 ± 7.62 kg and a BMI of 23.17 ± 2.90 kg/m², with no statistically significant differences ($p > 0.05$). The results are consistent with those of Shimizu et al. (2020), who found no significant changes in anthropometric measures between groups treated with FF/VI and other combinations, confirming that baseline physical characteristics had no effect on treatment outcomes.[10] Terzano and Oriolo (2017) found comparable anthropometric parameters within their research groups, suggesting that these characteristics did not significantly affect the relative efficacy of the therapies studied.[5] This consistency with previous research increases the credibility of our findings and confirms that the therapies are equally relevant for individuals with analogous baseline physical characteristics. In this study, the mean FEV₁% at baseline was 68.50 ± 6.40 in the VI/FF group and 69.60 ± 6.11 in the FF group, with no significant difference between the two groups ($p = 0.401$). After six months of treatment, both groups showed significant improvements in FEV₁% ($p < 0.001$), with mean FEV₁% increasing to 77.65 ± 6.22 in the VI/FF group and 74.70 ± 5.85 in the FF group. Importantly, the difference between the groups reached statistical significance ($p = 0.021$), indicating that VI/FF was more effective in improving lung function over time. These results are consistent with previous studies, such as those by Tanninen et al. (2024) [8] which showed that both FF/VI and FP/FORM led to significant improvements in lung function, with no significant differences between the two groups. Similarly, Bareille et al. (2024) [4] reported that FF/VI led to superior improvements in FEV₁ compared to FF alone in pediatric asthma patients, supporting the role of Vilanterol as an effective bronchodilator. Shimizu et al (2020) also found that switching from other ICS/LABA combinations to FF/VI resulted

in better asthma control and lung function. In addition, Furuhashi et al. (2019) and Parimi M et al. (2020) observed comparable efficacy of FF/VI and other ICS/LABA combinations, but indicated that once-daily dosing of FF/VI improved patient adherence and comfort. [11,12] These results suggest that both VI/FF and FF are effective in improving lung function, but VI/FF may offer better long-term benefits. Future studies with larger sample sizes and longer follow-up could provide further insight into the clinical benefits of VI/FF over FF in asthma treatment.

In this study, both VI/FF and FF showed an improvement in FVC% over the 6-month duration, with no statistically significant differences observed between the two groups at any time point. This suggests that both combinations are equally effective in maintaining lung capacity in asthma patients. Tanninen et al. (2024) reported similar results and showed significant improvements in FVC% with FF/VI and FP/FORM treatment, supporting their comparable efficacy.[8] Bareille et al. (2024) further substantiated this by showing that FF/VI significantly improved FEV₁ in pediatric asthma patients compared to FF alone, suggesting that the addition of a long-acting β_2 -agonist enhances bronchodilation.[4] Shimizu et al (2020)[10] investigated the efficacy of FF/VI in practice in patients switched from FP/Salmeterol or Budesonide/Formoterol to FF/VI and found significant improvements in asthma control and lung function, suggesting that FF/VI may be an effective alternative therapy. Similarly, Furuhashi et al (2019) [11] compared FF/VI with Budesonide/Formoterol in stable asthma patients and found no significant differences in lung function outcomes, but noted better adherence with FF/VI due to once-daily dosing. Parimi M et al (2020) [12] also found comparable efficacy between FF/VI and FP/Formoterol, but emphasized the advantage of FF/VI in handling. These results suggest that although both treatment combinations are efficient in preserving

lung function, they may differ in aspects such as treatment adherence, ease of use and patient preference.

In this study, the Ask-12 adherence barrier survey was conducted to compare adherence-related challenges between Group VI/FF and Group FF across different domains, including inconvenience/forgetfulness, treatment beliefs, behavior, and total adherence barriers. The results showed that Group VI/FF had significantly lower adherence barriers in most domains compared to Group FF. The mean inconvenience/forgetfulness score was significantly lower in Group VI/FF (5.57 ± 2.93) compared to Group FF (7.03 ± 2.49) ($p = 0.012$), indicating that participants in the VI/FF group were less likely to forget their medication or find it inconvenient to adhere to their regimen. Similarly, the mean behavior score was also significantly lower in Group VI/FF (7.27 ± 2.21) than in Group FF (9.15 ± 3.88) ($p = 0.005$), suggesting that participants in the VI/FF group exhibited better medication-taking behaviors and faced fewer behavioral barriers. The total adherence barrier score was significantly lower in Group VI/FF (20.22 ± 6.68) compared to Group FF (24.69 ± 8.24) ($p = 0.005$), highlighting that the VI/FF group experienced fewer overall adherence challenges. However, the health beliefs score was lower in Group VI/FF (7.38 ± 2.72) compared to Group FF (8.51 ± 3.02) but did not reach statistical significance ($p = 0.063$), suggesting that while there was a trend toward better perceptions about medication adherence in the VI/FF group, the difference might have occurred by chance. Overall, these findings indicate that the VI/FF regimen may lead to better adherence outcomes by reducing forgetfulness, improving medication-taking behaviors, and lowering overall adherence barriers compared to the FF regimen. These findings are consistent with studies by Furuhashi et al. (2019) and Parimi M et al. (2020), which highlighted that adherence may be lower with FF/VI compared to other ICS/LABA combinations due to factors

such as inhaler complexity or patient perception of symptom control.[11,12] Similarly, Shimizu et al (2020) found that while FF/VI showed superior clinical efficacy in asthma control, adherence remained a challenge, possibly due to patient-related factors such as treatment perception and inhaler technique.[10] In contrast, Bareille et al. (2024) reported that FF/VI led to improved asthma control and lung function, but had no significant effect on adherence barriers compared to FF alone.[4] Overall, these results suggest that while both treatment regimens are effective in improving asthma outcomes, careful consideration should be given to adherence-related factors when prescribing FF/VI, particularly in patients who may have difficulty with inhaler use or adherence.

CONCLUSION

Vilanterol/Fluticasone Furoate (VI/FF) was superior to Formoterol/Fluticasone Propionate (FM/FP) in improving lung function, adherence, and asthma control. The once-daily regimen offers practical advantages in real-world settings, where adherence remains a challenge. Given its efficacy, safety, and convenience, VI/FF represents a valuable therapeutic option for long-term management of bronchial asthma in Indian patients. However, further large-scale studies are recommended to validate these results in different populations

Declaration by Authors

Ethical Approval: Approved

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