ORIGINAL RESEARCH

To Study the Efficacy of FF/VI Combination in Adult Asthma Patients

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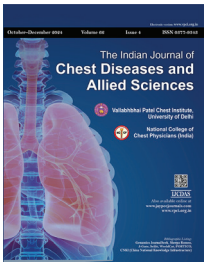

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Abstract

Background: Long-acting beta2-agonists (LABA) and inhaled corticosteroids require twice daily administration for effective treatment of bronchial asthma. This study aims to study the efficacy of fluticasone furoate/vilanterol (FF/VI) ICS/Ultra-LABA once-daily combination therapy in patients with bronchial asthma.

Materials and methods: This prospective observational study included 120 spirometry-diagnosed patients of bronchial asthma who were given FF/VI combination therapy and underwent follow-up at 2, 4, and 8 weeks of therapy. Patients were assessed during the follow-up period for the efficacy of therapy based on spirometric values.

Results: In the present study 61.7% were females and 38.3% were males. The commonest presenting symptom was cough present in 95% of patients followed by wheezing which was seen in 93.3% of patients and shortness of breath in 89.17% of patients. At 8 weeks of continuous therapy, only 5% of patients had a cough, 8.33% had wheezing and only 2.5% complained of shortness of breath. Forced expiratory volume (FEV) in one second (FEV1) at baseline, was 56.60 ± 1.26, and by the end of 8 weeks, it increased to 90.36 ± 11.38. Forced vital capacity (FVC) at baseline was 64.83 ± 12.63 and it increased to 91.8 ± 1035 at 8 weeks. Forced expiratory volume in one second (FEV1)/FVC at baseline was 63.31 ± 4.90 and it increased to 74.59 ± 3.19 at 8 weeks. Forced expiratory flow (FEF) 25–75% at baseline was 35.42 ± 14.74, and at 8 weeks of continuous therapy, it increased to 76.35 ± 8.85 and all these values were statistically significant ($p < 0.05$). The spirometric mean values were highly significant ($p < 0.001$) in between 2–4 weeks and 4–8 weeks.

Conclusion: Therapeutic continuity of FF/VI combination therapy is significantly effective in improving both symptoms and spirometric values in bronchial asthma patients. The safety profile and improvements in lung function irrespective of dosing time (morning or evening) strongly emphasize strict adherence to continuous once-daily use of the inhaler FF/VI to fully reverse the condition.

Keywords: Bronchial asthma, Fluticasone furoate, Spirometry, Vilanterol.

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Abbreviations used in this Article

FEV = Forced expiratory volume; FF/VI = Fluticasone furoate/vilanterol; FP = Fluticasone propionate; FP/SAL = Fluticasone propionate/salmeterol; HRQoL = Health-related quality of life; ICS = Inhalational route; LABA = Long-acting beta2-agonist; RCT = Randomized controlled trial; SABA = Short-acting beta2 agonists; VI = Vilanterol.

Introduction

Asthma a heterogeneous disease is characterized by chronic airway inflammation with a history that includes respiratory symptoms, like shortness of breath, wheezing, cough, and chest tightness that vary in intensity over time along with variable expiratory airflow limitations as per global initiative for asthma (GINA) guidelines 2024.[1] It is a chronic respiratory condition which affects approximately 1–29% of individuals across different nations.[2] Asthma affects approximately 235 million people worldwide and nearly 25 million Americans.[3] Spirometry serves as a gold standard physiological evaluation method to assess lung function objectively. It quantifies and documents the volume of air the patient can inhale and exhale maximally, and thus aids in disease diagnosis.

The airflow restrictions and symptoms can resolve spontaneously or with medical treatment, and may even be absent for extended periods. Conversely, patients may encounter periodic exacerbations of asthma, some of which can be severe and life-threatening, posing significant burdens to both patients and communities.[4] Majority of asthma-related mortality occurs in low to middle-income countries. Asthma is characterized by hyper-responsiveness of the airways to stimuli which may either be direct or indirect and chronic airway inflammation. These may present without symptoms or even in people with normal lung function but may improve with appropriate therapy.

Fluticasone furoate (FF) is a type of corticosteroid with the inhalational route (ICS) commonly used in asthma treatment. Inhalational route (ICS) medications are essential for managing asthma as they help reduce inflammation and hyper-responsiveness of the airways, leading to improvement of lung function and control of symptoms. They are typically recommended as preventive therapy

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for individuals who frequently use reliever medications such as short-acting beta2 agonists (SABA) like salbutamol. While most ICS treatments require twice-daily dosing, there are now once-daily options available, including ciclesonide and mometasone.[5] Fluticasone furoate is distinct from fluticasone propionate (FP) structurally and it has both more affinity and longer retention duration in respiratory tissues for the glucocorticoid receptor than FP.

Vilanterol (VI) is an Ultra long-acting beta2-agonist (LABA) class newer bronchodilator with an onset of action that is more rapid and has a long-lasting effect of up to 24 hours in asthma patients. An addition of LABA therapy with ICS treatment has further improved lung functions and reduced asthma symptoms and has also lowered the exacerbation rates. The current available LABAs for asthma treatment require twice-daily administration leading to reduced compliance. Thus clinicians believe that providing a single daily combination inhaler containing both FF and VI could improve long-term treatment adherence among asthma patients.[6]

This study aims to assess whether this combination therapy could have a positive impact on the compliance and management of chronic asthma in both adults and children. Determining the effectiveness of fluticasone furoate/vilanterol (FF/VI) combination therapy is crucial, as it would offer the convenience of once-daily dosing, thus potentially improving medication adherence among asthma patients. Once-a-day dosing is a more convenient schedule and so it has the potential to enhance medication adherence. Regular medical adherence thus elevates health-related quality of life (HRQoL) and alleviates asthma symptoms and exacerbations (top of form).

Materials and Methods

Study Design

It is a prospective observational study of the Department of TB and Respiratory Diseases of Tertiary Care Centre of North India, Sri Amritsar conducted from a time period of 1 January 2023 to 31 March 2024. Both outpatients and admitted patients were part of the study. This study was conducted after due approval by the ethics committee/institutional review board of the institute.

Patients who fulfilled the inclusion and exclusion criteria were a part of this study. All patients who were included in this study after screening received an FF/VI (200/25 µg) inhaler once a day and they all underwent an 8-week follow-up study period.

Inclusion Criteria

- All adults diagnosed with Asthma as per GINA guidelines were included.
- Patients who were not on any asthma treatment previously or if on treatment, then a drug-free interval of 2 weeks was given and as per GINA guidelines, were selected in this study.

Exclusion Criteria

- Patients with unstable angina, heart failure/recent acute myocardial infarction (MI) (within 4–6 weeks).
- Suspected presence of active TB and other communicable respiratory diseases.
- Patients with respiratory failure, patients with neurological, musculoskeletal, and peripheral vascular diseases.
- Patients with pneumonia and other respiratory illnesses limiting patient's movements abdominal or thoracic aortic aneurysm or active hemoptysis.
- Patients with irregular use of the prescribed inhalation therapy.

The present study was conducted as per the International Conference on Harmonization guidelines in accordance with the Declaration of Helsinki and Good Clinical Practice. Proper informed as well as written consent was obtained from each subject.

All the subjects who fulfilled the inclusion criteria were subjected to: History taking regarding symptomatology and risk factors of Asthma as per pre-designed proforma. The anthropometric parameters like weight, height, sex, and age of patients were documented. General physical examination and systemic examination were carried out with specific emphasis on the respiratory system. All routine investigations of complete blood count (CBC), fasting blood sugar (FBS), and chest radiographs were done. All subjects were given an FF/VI 200/25 µg inhaler and instructed to use it regularly once a day spirometry was done at 0 (baseline at first visit) and then in the follow-up period at, 2, 4, and 8 weeks of regular use of FF/VI 200/25 inhaler.

Spirometry was performed on the patients using Ultrasound based technology easy one spirometry machine. The following steps were performed during spirometry:

- The patient's height and weight were calculated in cm and kg respectively and documented on the machine.
- Patient was asked to fully inspire through the nose.
- Patient was then instructed to expire immediately and fully through the mouth into the mouthpiece for a minimum of 6 seconds.
- Then the patient was asked to fully inspire through the mouthpiece. Consequently, an Inspiratory Expiratory curve was made.
- After the above steps were performed, the patient was given SABA in a dose of 400 µg, and repeat spirometry was done after 10–15 minutes to see the effect of the bronchodilator on the spirometric values forced expiratory volume in one second FEV1, forced vital capacity (FVC), FEV1/FVC, and forced expiratory flow (FEF) 25–75%).[6]

The endpoint documented was the change in FEV1 from baseline to 8 weeks of the treatment. The secondary endpoint documentation was taken as:

- Change from baseline of FEV1 at 2 and 4 weeks.
- Change from baseline of FEV1 in between 2–4 weeks and 4–8 weeks.

Statistical Analysis

The collected data obtained was compiled and documented in a spreadsheet computer program (Microsoft Excel 2010) and then exported to the editor page of SPSS version 23. Data was presented in the form of numbers, percentages, mean, standard deviation, median, etc. Normally distributed data was analyzed by paired *t*-test and data not normally distributed was analyzed by Wilcoxon signed rank test. The *p*-value of < 0.05 was taken as statistically significant. All analysis was done using the SPSS 23.0 version.

Results

Demographic Profile

The present study included 120 patients of which 74 (61.7%) were female patients and 46 (38.3%) were male patients. Among females, a maximum of 22 (29.73%) patients were in the 31–40 age-group, while 16 (21.62%) patients each were in the (21–30) and (41–50)

Table 1: Frequency of bronchial asthma patients with symptoms of cough, wheezing and shortness of breath

	Baseline		*2 weeks*		*4 weeks*		*8 weeks*	
Symptoms	*No. of patients*	*Percentage*	*No. of patients*	*Percentage*	*No. of patients*	*Percentage*	*No. of patients*	*Percentage*
Cough	114	95.00	38	31.67	19	15.83	6	5.00
Wheezing	112	93.33	50	41.67	27	22.50	10	8.33
Shortness of breath	107	89.17	24	20.00	9	7.50	3	2.50

Table 2: Association of spirometry means values of FEV1, FVC, FEV1/FVC, FEF 25–75% during follow-up period

		2 weeks		*4 weeks*		*8 weeks*	
Spirometry values	*Baseline*	*Mean ± SD*	*p*	*Mean ± SD*	*p*	*Mean ± SD*	*p*
FEV1	56.60 ± 1.26	78.70 ± 10.20	0.014*	86.78 ± 12.67	0.043*	90.36 ± 11.38	0.037*
FVC	64.83 ± 12.63	80.29 ± 8.42	0.001**	88.89 ± 11.31	0.010*	91.80 ± 10.35	0.005*
FEV1/FVC	63.31 ± 4.90	71.56 ± 4.34	0.317	73.44 ± 7.46	0.046*	74.59 ± 3.19	0.003*
FEF 25–75%	35.42 ± 14.74	53.57 ± 10.41	0.688	64.15 ± 9.22	0.857	76.35 ± 8.85	0.748

*$p < 0.05$, statistically significant; **Statistically highly significant

age-group. Rest age-groups had<10 patients in them. In males, a maximum of 19 (41.30%) patients were in the (21–30) age-group, while there were 8 (17.39%) patients each in the (31–40) and (41–50) age-groups. Rest age-groups had ≤5 patients in them. In the present study, 87 (72.5%) patients had a family history of Bronchial Asthma and only 6 (5%) patients were smokers.

Symptoms at Baseline, 2, 4, and 8 Weeks of Therapy

The commonest presenting symptom was cough present in 114 (95%) patients followed by wheezing which was seen in 112 (93.3%) patients and shortness of breath in 107 (89.17%) patients. After 2 weeks of therapy, the overall symptoms had reduced. Now, 38 (31.67%) patients complained of cough, followed by 50 patients (41.67%) complaint of wheezing, and rest 24 (20%) patients had shortness of breath. At 4 weeks of therapy, 19 (15.83%) patients had a cough, 27 (22.50%) patients had wheezing, and 9 (7.5%) patients had shortness of breath. At 8 weeks of therapy, only 6 (5%) patients had a cough, 10 (8.33%) patients had wheezing, and only 3 (2.5%) patients complained of shortness of breath (Table 1).

Association of Spirometric Values FEV1, FVC, FEV1/FVC, FEF 25–75% during the Follow-up Period (Table 2; Fig. 1)

The FEV1 at baseline was 56.60 ± 1.26, and at 2 weeks of therapy, it improved to 78.70 ± 10.20. At 4 weeks and 8 weeks, it further improved to 86.78 ± 12.67 and 90.36 ± 11.38, respectively. These values are significant statistically ($p < 0.05$).

The FVC at baseline was 64.83 ± 12.63 and it increased to 80.29 ± 8.42 at 2 weeks of therapy. Thereafter it further increased in 4 weeks and 8 weeks to 88.89 ± 11.31 and 91.80 ± 10.35 respectively. These values at 4 and 8 weeks were significant statistically ($p < 0.05$) while at 2 weeks the values were highly significant ($p = 0.001$).

The FEV1/FVC at baseline was 63.31 ± 4.90 and it increased to 71.56 ± 4.34 at 2 weeks of therapy. Thereafter it further increased in 4 and 8 weeks to 73.44 ± 7.46 and 74.59 ± 3.19, respectively. The values at 4 and 8 weeks were significant statistically ($p < 0.05$).

The FEF 25–75% at baseline was 35.42 ± 14.74, and at 2 weeks of continuous therapy it increased to 53.57 ± 10.41. At 4 and 8 weeks, it further increased to 64.15 ± 9.22 and 76.35 ± 8.85, respectively. These values were not significant statistically ($p > 0.05$) (Table 2; Fig. 1).

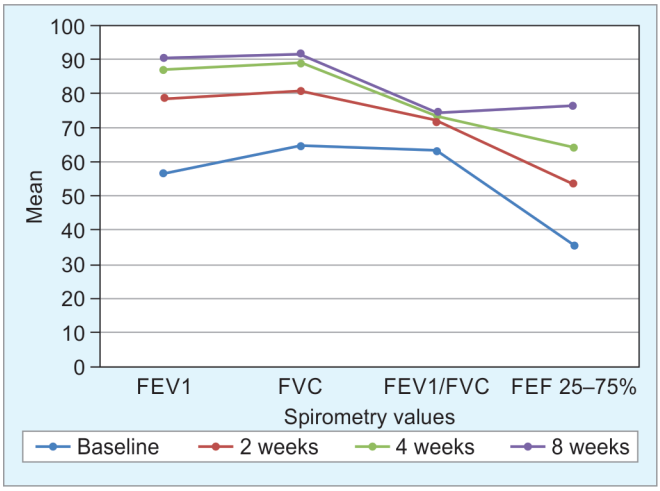

Fig. 1: Association of spirometry mean values of FEV1, FVC, FEV1/FVC, FEF 25–75% during follow-up period

Association of Spirometry Mean Values of FEV1, FVC, FEV1/FVC, FEF 25–75% in between Weeks (Table 3; Fig. 2)

The mean FEV1 at 2–4 was 86.78 ± 12.67 and at 4–8 weeks it was 90.36 ± 11.38. These values were highly significant statistically ($p = 0.001$).

The mean FVC at 2–4 and 4–8 weeks was 88.89 ± 11.31 and 91.80 ± 10.35, respectively. These values were highly significant statistically ($p = 0.001$). The mean FEV1/FVC at 2–4 and 4–8 weeks were 73.44 ± 7.46 and 74.59 ± 3.19, respectively. These values were highly significant statistically ($p = 0.001$).

The mean FEF 25–75% at 2–4 and 4–8 weeks was 64.15 ± 9.22 and 76.35 ± 8.85, respectively. These values were highly significant statistically ($p = 0.001$) (Table 3; Fig. 2).

The highly significant association of the spirometric values clearly indicates that this drug combination (FF/VI 200/25 µg inhaler) inhalational therapy is highly effective in the management of bronchial asthma and the statistically significant association of these values in between the weeks indicates that contiguity of this

Table 3: Association of spirometry values FEV1, FVC, FEV1/FVC, FEF 25–75% in between weeks

	2–4 weeks		*4–8 weeks*	
Spirometry values	*Mean ± SD*	*p*	*Mean ± SD*	*p*
FEV1	86.78 ± 12.67	0.001**	90.36 ± 11.38	0.001**
FVC	88.89 ± 11.31	0.001**	91.80 ± 10.35	0.001**
FEV1/FVC	73.44 ± 7.46	0.001**	74.59 ± 3.19	0.001**
FEF 25–75%	64.15 ± 9.22	0.001**	76.35 ± 8.85	0.001**

**$p = 0.001$, highly significant

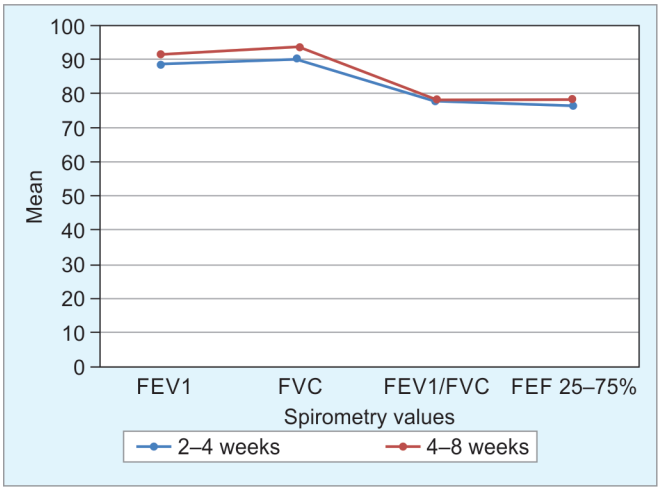

Fig. 2: Association of spirometry values FEV1, FVC, FEV1/FVC, FEF 25–75% in between weeks

therapy is the key to the treatment and hence reduced morbidity of this disease.

Discussion

Bronchial asthma is a chronic respiratory condition affecting approximately 235 million people worldwide.[3] This disease entity has a varied prevalence in countries/geographical regions and also within countries with different geographies and socioeconomic strata. The total burden of asthma in India is 34.3 million, accounting for 13.09% of the global burden and 1.32 per hundred deaths due to asthma as reported by Global Burden of Disease (GBD, 1990–2019).[7–9] The incidence and prevalence of allergic diseases in particular asthma are increasing due to an increase in air pollution, environmental exposure, industrialization, smoking, and vaping.

Family history of asthma and smoking does play a very significant role in the development of Bronchial Asthma. Laboratory tests can also corroborate these findings by indicating the presence of increased levels of eosinophils. Definitive diagnosis of Bronchial Asthma is by spirometry. Radiological examination does not diagnose Bronchial Asthma but rules out other causes of dyspnea. It does not help to diagnose patients as it's a reversible condition and usually chest radiographs are normal and show no abnormality.

In clinical practice, cases of bronchial asthma most often are treated based on clinical assessment corroborated with the history of the patient along with spirometric values. By definition increase in FEV1 > 12% and >200 mL post-bronchodilation is needed to label the patient as having bronchial asthma.[10]

Medications used to control asthma reduce airway inflammation and thus prevent and control asthma symptoms. Inhaled corticosteroids (ICS) are the spine of the treatment regimen of asthma, while rescue medicines or quick-relief (reliever) quickly ease symptoms that arise acutely. The SABAs act rapidly by causing relaxation of airway smooth muscles, thus reducing airway bronchoconstriction. To achieve total relief the amount of the controller treatment is given in accordance with the severity of the disease which varies from a combination of low-dose ICS/LABA or medium-dose ICS/LABA, up to high-dose ICS/LABA, as the preferred controller choice, with additional SABA as the rescue medication.[11]

Vilanterol, a long-acting beta2-agonist (Ultra-LABA) binds to the $beta_2$-adrenoceptor of the airway smooth muscle causing bronchodilation. Fluticasone furoate is ICS and is the central component in the treatment of asthma as it causes a reduction in both airway hyper-responsiveness and airway inflammation. Regular use of ICS causes significant improvement in symptoms and lung function. Fluticasone furoate/vilanterol an ICS/Ultra-LABA combination therapy licensed for the once-daily treatment of asthma is highly recommended in adults aged ≥ 18 years in the United States (US) as well as adults and adolescents aged ≥ 12 years in Europe too. This combination of FF/VI is also recommended by GINA as an alternative controller therapy for step 3. Once-daily use of FF/VI 200/25 µg has been shown to significantly improve lung function and reduce the risk of severe asthma exacerbations when compared with FF alone.[12]

The present study was conducted on 120 patients with Bronchial Asthma based on history, clinical symptomatology, laboratory tests, and spirometry values including 61.7% female patients and 38.3% male patients. In females, 29.73% of patients were in the (31–40) age-group, and 21.62% of patients each were in the (21–30) and (41–50) age-group. The rest of the age-groups had <10 patients in them. In males maximum of 41.30% of patients were in the (21–30) age-group, and 17.39% of patients each in the (31–40) and (41–50) age-groups. The rest of the age-groups had less than or equal to five patients in them. Leynaert et al.[13] in their study observed that there was a higher incidence of asthma in women than in men. Singh et al.[14] revealed that women were almost twice as common as men in acute asthma. Symptomatology revealed that 95% of patients had a cough, followed by symptoms of wheezing which was seen in 93.3% of patients, and shortness of breath in 89.17% of patients. At 8 weeks the overall symptoms had reduced markedly and only, 5% of patients had cough, 8.33% of patients had wheezing and only 2.5% of patients had shortness of breath. A similar study conducted by Boskabady et al.[15] revealed that asthma symptoms like cough and wheeze were significantly improved by the given bronchodilators in the third visit as is seen in the current study ($p < 0.01$). Amongst the total of 120 patients, 72.5% of patients had a family history of bronchial asthma, whereas

only 5% of patients were smokers. Liu et al.[16] in their study revealed that lifetime asthma prevalence was strongly associated with family history, and this association remained significant after adjustments for other risk factors.

As per the spirometric values FEV1 at 0, 2, 4, and 8 weeks were 56.60 ± 1.26, 78.70 ± 10.20, 86.76 ± 12.67, 90.36 ± 11.38, respectively and all the values were significant statistically ($p < 0.05$). FVC at 0, 2, 4, and 8 weeks was 64.83 ± 12.63, 80.29 ± 18.42, 88.89 ± 11.31, and 91.80 ± 10.35, respectively and all the values were significant statistically ($p < 0.05$). Forced expiratory volume in one second (FEV1)/FVC at 0, 2, 4, and 8 weeks were 63.31 ± 4.90, 71.56 ± 4.34, 73.44 ± 7.46, and 74.59 ± 3.19, respectively and the values at 4 and 8 weeks were significant statistically ($p < 0.05$). FEF 25–75% at 0, 2, 4, and 8 weeks were 38.42 ± 14.74, 53.57 ± 10.41, 64.15 ± 9.22, and 76.35 ± 8.85 respectively and these values were not significant statistically ($p > 0.05$). Tanninen et al.[17] in their study on 47 adolescents with chronic bronchial obstruction aged between 12 and 17 years in whom FF/VI in the Ellipta inhaler (92 mg/22 mg per dose) was administered daily, observed that ICS/LABA combinations showed a significant improvement in FEV 1 and maximal expiratory flow at 50% of the FVC *z* scores. Their study revealed that more than one-third of the asthmatic adolescents with prolonged bronchial obstruction achieved a normal prebronchodilator FEV1/FVC ratio which was statistically significant.

In the present study FEV1 in between weeks, 2–4 weeks and 4–8 weeks were 86.78 ± 12.67 and 90.6 ± 11.38, respectively. FVC between 2–4 weeks and 4–8 weeks were 88.89 ± 1.31 and 91.82 ± 10.35, respectively. Forced expiratory volume in one second (FEV1)/FVC between 2–4 weeks and 4–8 weeks were 73.44 ± 7.46 and 74.59 ± 3.19, respectively. FEF 25–75% between 2–4 weeks and 4–8 weeks were 64.15 ± 9.22 and 76.35 ± 8.85, respectively. These values were highly significant statistically ($p = 0.001$). A multicenter, double-blind, randomized, double-dummy, parallel-group study conducted in 63 centers in six countries by O'Byrne et al.[18] on 588 subjects with bronchial asthma revealed that treatment with fluticasone furoate/vilanterol significantly ameliorated pulmonary function indices and decreased asthma exacerbations and rescue drug utilization compared to fluticasone furoate alone. The pulmonary function indices and quality of life of once-daily administration of the combination regimen were comparable to twice-daily fluticasone propionate/salmeterol (FP/SAL). There was a significant change in FEV1 values from 4 to 8 weeks. The baseline FEV1% predicted was 66.59 ± 12.614 and after giving FF/VI and when reassessed at 24 weeks it increased to 94.07 ± 11.65. These results showed that FF/VI had promising results like in our study.

In a randomized controlled trial (RCT) involving children and adults diagnosed with asthma, a comparative study of the combination of VI and FF with placebo or other ICSs and/or LABAs was conducted. The review included ten comparisons: three involving FF/VI 200/25 µg and seven involving FF/VI 100/25 µg. Due to the restricted number of studies, meta-analyses were constrained, so data were tabulated for the pre-specified primary outcomes. Notably, there was a lack of sufficient information to determine whether twice-daily (FP/SAL) was inferior or superior in terms of efficacy and safety to once-daily FF/VI. Only one study assessed HRQoL, showing a statistically significant advantage of FF/VI 100/25 µg combination vs placebo, while two studies comparing FF/VI 100/25 µg vs placebo did not report any exacerbations in either treatment arm. Five studies did not report any adverse events of concern in the FF/VI 100/25 µg or placebo arms. There were no relevant comparisons for FF/VI 200/25 µg and placebo arms. Fluticasone furoate/vilanterol combination therapy showed advantages over placebo, especially in peak expiratory flow and FEV1.[19]

Another study was conducted to evaluate the tolerability and safety of FF/VI over 52 weeks in asthma patients the previously diagnosed adult asthma patients who were already on inhaled corticosteroid therapy were randomly assigned (in a 2:2:1 ratio) to receive either FF/VI 100/25 µg or FF/VI 200/25 µg once daily in the evening, or FP 500 µg twice daily. This study concluded that FF/VI (100/25 µg or 200/25 µg) or administered regularly only once a day over 52 weeks was well tolerated by asthma patients aged 12 years and older and the safety profile of the FF/VI combination did not reveal any significant clinical concerns.[20]

A randomized, double-dummy, double-blind, parallel-group study conducted on 806 patients received FP/SAL (250/50 µg, $n = 403$) twice a day using the DISKUS/ACCUHALER vs FF/VI (100/25 µg, $n = 403$) once a day using the ELLIPTA dry powder inhaler. The study concluded that the efficacy of once-a-day FF/VI was the same as two times a day FP/SAL in improving lung function in patients with persistent asthma.[21] Previous studies also reveal that FF/VI demonstrated comparable improvements in lung function irrespective of dosing time (whether in the evening or morning) in patients with persistent asthma.[22]

Conclusion

Fluticasone furoate/vilanterol combination was found to be effective in diagnosed patients of bronchial asthma as it improves the patients symptomatically along with improvement in serial spirometric values. The symptoms gradually improve from 0 to 8 weeks as we advance in continuation of the treatment. The present study revealed that the safety profile of combination therapy of FF/VI did not show any clinical concerns and it demonstrated comparable improvements in lung function irrespective of dosing time (morning or evening). So this study strongly concludes and emphasizes strict adherence to continuous once-daily use of the inhaler FF/VI to fully reverse the condition.

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