International Journal of Life Sciences, Biotechnology and Pharma Research Vol. 13, No. 8, August 2024 Online ISSN: 2250-3137
Print ISSN: 2977-0122

DOI: 10.69605/ijlbpr_13.8.2024.55

ORIGINAL RESEARCH

Comparative Study to Assess the Effect of Inhalational therapy of Vilanterol with fluticasone combination versus Salmeterol with fluticasone combination in patients of Asthma

[1]Dr. Harmeet Singh, [2]Dr. Kiranjit Sidhu, [3]Dr. Raj Kumar, [4]Dr. Kuldeep Singh

[1]Junior Resident, [2]Professor & HOD, [4]Assistant Professor, Department of Pulmonary Medicine, GGSMCH, Faridkot, Punjab, India
[3]Professor & HOD, Department of Pharmacology, GGSMCH, Faridkot, Punjab, India

Corresponding Author
Dr. Harmeet Singh
Junior Resident, Department of Pulmonary Medicine, GGSMCH, Faridkot, Punjab, India

Received Date: 20 July, 2024 Acceptance Date: 22 August, 2024

ABSTRACT

Background: Asthma is a heterogeneous disease characterized by chronic airway inflammation and respiratory symptoms such as wheezing, shortness of breath, chest tightness and cough that vary over time and in intensity along with variable expiratory airflow limitation. The present study was conducted to compare two fixed drug combinations of vilanterol with fluticasone and salmeterol with fluticasone in tertiary care hospital. **Materials & Methods:** The Study was carried out on 140 patients of Asthma in the Department of Pulmonary Medicine, Guru Gobind Singh Medical College & Hospital Faridkot. Study medicines were allocated between two groups i.e. Group SF (n=70) and Group VF (n=70). Group SF was managed with inhalation therapy of Salmeterol & Fluticasone combination. Similarly, group VF was managed with inhalation therapy of the Vilanterol & Fluticasone combination. Spirometry was performed after 4 hours on 0 days. Furthermore, spirometry was performed after 7 days and 14 days of starting the treatment. RMS Helios 702 Spirometer was used for evaluation. Patients were divided equally and randomly into two groups: Group SF: - Mild and Moderate Persistent Asthma patients receiving inhalation With Salmeterol & Fluticasone Furoate. Group VF: - Mild and Moderate Persistent Asthma patients receiving inhalation with Vilanterol & Fluticasone Propionate. **Results**: No significant difference was observed in sex distribution in both groups (p=0.264) with 44.28% females in group SF and 40% in group VF whereas 55.72% males in group SF and 60% in group VF. It was observed that seasonal variation, allergic to dust/pollen and family history of Asthma were important risk factors for the causation of asthma in both groups. In contrast, smoking and occupational exposure seemed to be not significant as a causative risk factor for asthma. Group SF contained 81.42% of partially controlled patients and the rest had uncontrolled symptoms. Similarly, group VF had 85.71% of patients with partially controlled symptoms with the rest having uncontrolled symptoms. Both the groups were compared based upon improvement in FEV1, FEV1/FVC at 4 hours, after 7 days and after 14 days, more improvement was seen in the VF group with significant differences observed at each specified interval. **Conclusion:** Authors found significant improvement in the lung functions of the patient in the Vilanterol/Fluticasone group as compared to the Salmeterol/Fluticasone group. Bronchial Asthma is a chronic/heterogeneous disease warranting newer treatment for management. Novelty drugs with greater pharmacological properties with strong adherence to be studied.

Keywords: Asthma, Fluticasone, Vilanterol

INTRODUCTION

Asthma is a heterogeneous disease characterized by chronic airway inflammation and respiratory symptoms such as wheezing, shortness of breath, chest tightness and cough that vary over time and in intensity along with variable expiratory airflow limitation. It affects individuals of all ages but often starts in childhood. The severity and frequency of asthma symptoms may vary from person to person but can significantly impact a person's quality of life and if not properly managed can lead to severe exacerbations requiring hospitalization. This airflow

DOI: 10.69605/ijlbpr_13.8.2024.55

limitation may later become persistent (1) Asthma is an airway disease of inflammation and bronchoconstriction. Genetics and environmental factors play a significant role in producing different asthma phenotypes and various responses to controller medications.(2) Inhaled therapy is the preferred method for delivering asthma medications because it allows for direct delivery to the airways with minimal systemic exposure. The development of combination inhalers such as Vilanterol with Fluticasone and Salmeterol with Fluticasone has improved asthma management by providing both anti-inflammatory and broncho-dilatory effects in a single device.(3) The combination of Vilanterol and Fluticasone is used as a treatment for asthma and chronic obstructive pulmonary disease (COPD). This combination harnesses the complementary actions of both drugs to provide effective control of symptoms and improve overall lung function.(4) The combination of Salmeterol and Fluticasone is also widely used in the management of asthma and chronic obstructive pulmonary disease (COPD). This combination brings together the long-acting bronchodilator effects of Salmeterol with the anti-inflammatory properties of Fluticasone providing comprehensive control of respiratory symptoms. The present study was conducted to compare two fixed drug combinations of vilanterol with fluticasone and salmeterol with fluticasone in tertiary care hospital.

MATERIALS & METHODS

A total of 140 mild and moderate asthmatic patients were enrolled from the outpatient/inpatient department of Pulmonary Medicine and General Medicine, Guru Gobind Singh Medical College and Hospital, Faridkot. Each patient's written consent was obtained before enrolment. Inclusion criteria was clinically diagnosed cases of Mild and Moderate Persistent cases of Bronchial Asthma with subsequent confirmation by spirometry. Exclusion criteria was acute exacerbation of bronchial asthma patient, patients who were on cardiac medications, patients unable to perform spirometry, pregnant and lactating females.

Detailed history and clinical examination, baseline spirometry, baseline FeV1, FVC, and FeV1/FVC ratio were recorded in all patients. A reversibility test was performed to confirm the diagnosis of bronchial asthma. Routine investigations including CBC, and chest x-ray were done at the time of enrolment of the patient. Study medicines were allocated between two groups i.e. Group SF (n=70) and Group VF (n=70) by computer-generated randomized table equally in two groups. Group SF was managed with inhalation therapy of Salmeterol & Fluticasone combination. Similarly, group VF was managed with inhalation therapy of the Vilanterol & Fluticasone combination. Spirometry was performed after 4 hours on 0 days. Furthermore, spirometry was performed after 7 days and 14 days of starting the treatment. RMS Helios 702 Spirometer was used for evaluation.

Patients were divided equally and randomly into two groups: Group SF: - Mild and Moderate Persistent Asthma patients receiving inhalation With Salmeterol & Fluticasone Furoate. Group VF: - Mild and Moderate Persistent Asthma patients receiving inhalation with Vilanterol & Fluticasone Propionate. Data thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

RESULTS

Table I: Sex-wise distribution in patients with Bronchial Asthma

Sex	Group SF		Group VF		p-value
	N	%	N	%	
Female	31	44.28	28	40	0.264
Male	39	55.72	42	60	
Total	70	100	70	100	

No significant difference was observed in sex distribution in both groups (p=0.264) with 44.28% females in group SF and 40% in group VF whereas 55.72% males in group SF and 60% in group VF.

Table II: Risk Factors in Bronchial Asthma Patients

Parameters	Group SF		Group VF		p-value
	Yes	No	Yes	No	
Smoking	17	53	8	62	3.94
Seasonal Variation	35	35	44	26	2.56
Occupational Exposure	5	65	6	64	0.99
Allergic to Dust/pollen	45	25	34	36	1.56
Family h/o asthma	29	41	39	31	2.85

It was observed that seasonal variation, allergic to dust/pollen and family history of Asthma were important risk factors for the causation of asthma in both groups. In contrast, smoking and occupational exposure seemed to be not significant as a causative risk factor for asthma.

DOI: 10.69605/ijlbpr_13.8.2024.55

Table III: Distribution of patients depending upon Level of asthma control

Level Of Asthma Control	Group SF		Group VF		p-value
	N	%	N	%	
Well-Controlled	0	0	0	0	0.468
Partially Controlled	57	81.42	60	85.71	
Uncontrolled	13	18.58	10	14.29	
Total	70	100	70	100	

Considering, daytime symptoms >2 times a week, night waking, use of SABA>2 times a week, and activity limitation, patients were distributed as Well-Controlled (none of the symptoms present), Partly Controlled (1-2), and Uncontrolled (3-4). Group SF contained 81.42% of partially controlled patients and the rest had uncontrolled symptoms. Similarly, group VF had 85.71% of patients with partially controlled symptoms with the rest having uncontrolled symptoms

Table IV: Comparison of improvement in FEV1 between both the study groups

Time Duration	Group SF (N=70)	Group VF (N=70)	p-Value
	Improvement in FEV1	Improvement in FEV1	
Baseline FEV1	63.17	62.75	0.325
After 4 hours	63.17 +5.33	62.75 +12.66	<0.001
After 7 days	63.17 +16.69	62.75 +24.99	<0.001
After 14 days	63.17 +26.67	62.75 +31.74	<0.001

On comparing improvement in FEV1 at 4 hours, after 7 days and after 14 days, more improvement was seen in the VF group with significant differences observed at each specified interval.

Table IV: Comparison of improvement in FEV1/FVC between the study groups

Time Duration	Group SF (N=70)	Group VF (N=70)	p-Value
	Improvement in FEV1/FVC	Improvement in FEV1/FVC	
BASELINE	61.25	62.45	0.432
After 4 hours	61.25 +4.70	62.45 +12.25	<0.0001
After 7 days	61.25 +15.65	62.45 +24.52	<0.001
After 14 days	61.25 +25.26	62.45 +31.20	<0.001

Both the groups were compared based upon improvement in FEV1/FVC at 4 hours, after 7 days and after 14 days, more improvement was seen in the VF group with significant differences observed at each specified interval.

DISCUSSION

Asthma is a heterogeneous disease characterized by chronic airway inflammation and respiratory symptoms such as wheezing, shortness of breath, chest tightness and cough that vary over time and in intensity along with variable expiratory airflow limitation. It affects individuals of all ages but often starts in childhood.[1] It is one of the leading causes of school absenteeism and workday loss, thereby causing a significant burden on individuals, families, and healthcare systems.(5) The present study was conducted to compare two fixed drug combinations of vilanterol with fluticasone and salmeterol with fluticasone in tertiary care hospital.

We found that no significant difference was observed in sex distribution in both groups (p=0.264) with 44.28% females in group SF and 40% in group VF whereas 55.72% males in group SF and 60% in group VF. It was observed that seasonal variation, allergic to dust/pollen and family history of Asthma were important risk factors for the causation of asthma in both groups. In contrast, smoking and occupational exposure seemed to be not significant as a causative risk factor for asthma. Considering, daytime symptoms >2 times a week, night waking, use of SABA>2 times a week, and activity limitation, patients were distributed as well- controlled (none of the symptoms present), partly controlled (1-2), and uncontrolled (3-4). Group SF contained 81.42% of partially controlled patients and the rest had uncontrolled symptoms. Similarly, group VF had 85.71% of patients with partially controlled symptoms with the rest having uncontrolled symptoms.

We found that on comparing both the groups based upon improvement in FEV1, FEV1/FVC at 4 hours, after 7 days and after 14 days, more improvement was seen in the VF group with significant differences observed at each specified interval. Similar results were shown in a study by Bleeker et.al. 2014 conducted a randomised conrol trial comparing fluticasoe furoate/vilanterol (FF/VI) with fluticasone propionate/salmeterol (FP/SAL) in asthma patients and demonstrated that FF/VI provided superior lung function improvement as measured by FEV1 and better asthma control compared to FP/SAL. The once daily dosing of FF/VI also contributed to better adherence and patient satisfaction. (6) Similar results were also shown in a study by The Salford Asthma Trial in 2017 evaluated the effectiveness of fluticasone furoate/vilanterol (FF/VI) compared to

DOI: 10.69605/ijlbpr_13.8.2024.55

usual care in asthma management. The trial used integrated electronic health records and community-based approach to everyday clinical practise to prove that patients receiving FF/VI had a significantly higher probability of achieving well-controlled asthma, reducing exacerbations and improving quality of life compared to those receiving usual care.(7)

Our results were in concordance with the Relvar Ellipta for Real Asthma Control Study (RERACS study) conducted by Yasuo Shimizu et. al.(2019) where they assessed the real-life effectiveness of fluticasone furoate/ vilanterol when switched from fluticasone/ salmeterol or budesonide/ formoterol therapy in patients with symptomatic asthma. In their study, the primary endpoint was % FEV1 which showed improvement at 4 weeks after switching therapy, and this improvement was maintained until 12 weeks ($P<0.05$). They concluded that in symptomatic asthma patients showing insufficient control, improvement of asthma was obtained by switching to FF/VI at the equivalent corticosteroid dose accompanied by the improvement of biomarkers. Thus, FF/VI can be a useful option for better control of asthma because of its high efficacy, long duration of action, and delivery via a single-action device.

The shortcoming of the study is small sample size.

CONCLUSION

Authors found significant improvement in the lung functions of the patient in the Vilanterol/Fluticasone group as compared to the Salmeterol/Fluticasone group. Bronchial Asthma is a chronic/heterogeneous disease warranting newer treatment for management. Novelty drugs with greater pharmacological properties with strong adherence to be studied. We recommend the use of a Vilanterol/Fluticasone combination in patients of mild/moderate asthma with a recommendation for more studies to be conducted in a larger population assessing improvement in lung function using Spirometry.

REFERENCES

1. Global Initiative for Asthma. (2024). Global Strategy for Asthma Management and Prevention. Available at: https://ginasthma.org/2024-report/ (Global Initiative for Asthma - GINA) (INHALE CQI).
2. Busse, W. W., &Lemanske, R. F. (2001). Asthma. New England Journal of Medicine, 344(5), 350-362
3. O'Byrne, P. M., & Pedersen, S. (2018). Assessing future risk in asthma: the role of biomarkers. Journal of Allergy and Clinical Immunology, 141(6), 1999-2006.
4. Kew, K. M., & Karner, C. (2013). Long-acting beta2-agonists versus placebo as add-on therapy to inhaled corticosteroids for chronic asthma. Cochrane Database of Systematic Reviews, (2), CD010137
5. Global Asthma Network. (2022). Asthma in India. In The Global Asthma Report 2022. Retrieved from Global Asthma Report.
6. Bleecker, E. R., Lötvall, J., O'Byrne, P. M., Woodcock, A., Follows, R. M., Thoren, A., ... & Bateman, E. D. (2014). Fluticasone furoate/vilanterol compared with fluticasone propionate/salmeterol in asthma: a randomized trial. Journal of Allergy and Clinical Immunology, 133(4), 987-995.
7. New, J. P., Slee, A., Gray, J., Harris, S., FitzGerald, P., & Baxter, N. (2017). The Salford Lung Study: A pragmatic, randomised phase III real-world effectiveness trial in asthma. Respiratory Medicine, 130, 105-117.