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Original research article

Comparison of improvement in clinical, spirometric and oxygenation parameters after nebulisation with levosalbutamol and formoterol-budesonide in moderate to severe asthma

[1]Dr. Revathi Mogilappa, [2]Dr. Gattu Suresh Kumar, [3]Dr. V Nookaraju

[1]Assistant Professor, Department of Pulmonary Medicine, Government General Hospital, Kadapa, Andhra Pradesh, India

[2]Associate Professor, Department of Pulmonary Medicine, Government General Hospital, Kadapa, Andhra Pradesh, India

[3]Professor and HOD, Department of Pulmonary Medicine, Government General Hospital, Kadapa, Andhra Pradesh, India

Corresponding Author:
Dr. Gattu Suresh Kumar

Abstract

Introduction: Asthma is characterized by recurrent attacks of breathlessness and wheezing, which vary in severity and frequency from person to person.[1] Because asthma is a clinical syndrome, there is no gold standard for its diagnosis. As such, physicians employ non standardized algorithms for making the diagnosis, such as a history of wheezing or a parental history of asthma in conjunction with a favourable response to a bronchodilator at spirometry to identify the asthmatic patient. Effective inhaled bronchodilator and steroid therapy is the cornerstone of asthma management.

Aim: The aim of this study is to compare the improvement in clinical, spirometric and oxygenation parameters after nebulisation with levosalbutamol and formeterol-budesonide in moderate to severe persistent asthma patients.

Materials and Methods: This is a prospective, analytical study conducted among clinically diagnosed moderate and severe persistent asthma patients in the Department of Pulmonary Medicine, Govt. General Hospital between July 2022 and December 2022. 60 asthmatics (27 males and 33 females) who satisfied the clinical and spirometric essential criteria of moderate and severe persistent asthma were included. Spirometry was done prior to nebulisation. Consecutively, the patients were nebulised with Levosalbutamol or Formeterol-Budesonide. Clinical improvement, Spirometry and clinical parameters (pulse rate, respiratory rate, SpO_2) were noted at 15 min after nebulisation and again after 1 hr. The results were tabulated.

Results: Breathlessness and wheeze improved in 100% of the patients after 15 min. Oxygen saturation (SpO_2) also improved in 100% of the patients with in 15 min. However FEV1 with Levosalbutamol showed a moderate improvement (about 60% of predicted value) after 15 min but reached a plateau and continued to be the same at 1 hr. On the other hand, after nebulisation with Formeterol-Budesonide there was moderate to good improvement after 15 min of nebulisation and this continued to improve and after 1hr, in most patients it had reached normalcy (80%). No side-effects were reported in any of the patients.

Conclusion: Symptomatic improvement and improvement in Oxygenation were 100% within 15 min after nebulisation with both Levosalbutamol and Formoterol-Budesonide. However FEV1 showed early improvement with Levosalbutamol but had reached a plateau and continued to be the same after 1hr of nebulisation. On the other hand after nebulisation with Formoterol-Budesonide there was very good improvement after 15 min and this continued to increase & by 1hr had reached normal value of 80% of predicted.

Keywords: Bronchial asthma, formeterol-budesonide, levosalbutamol, spirometry, oxygenation, symptoms

Introduction

Background: Asthma is one of the major non communicable diseases of the world and in India the prevalence is about 2.38%. Recurrent attacks of breathlessness and wheezing, which vary in severity and frequency from person to person are the main features of this disease. Asthma is defined as a heterogenous disease, usually characterised by chronic airway inflammation. It is defined by the history of respiratory symptoms such as wheeze, shortness of breath, chest tightness and cough that vary over time and in intensity, together with variable expiratory airflow limitation [2]. The WHO estimates that globally about 235 million people currently suffer from asthma and this figure is projected to rise to

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400million by year 2025 [3], 1.5 million disability adjusted life years {DALY) are lost annually due to asthma [7].

The clinical course of this illness is influenced greatly by exposures, including respiratory viruses, indoor allergens, maternal tobacco smoke, and other physical and social aspects of the environment. While the prevalence of atopy is higher among asthmatics than nonasthmatics, the association may not be causal. Systematic reviews have shown that at a population level, there is no correlation between the prevalence of atopy and the prevalence of asthma [4-6]. It is likely that there are common factors that raise the risk of both conditions. Atopy and airway responsiveness may also occur together. Studies have shown that individuals who are sensitized to an allergen have bronchospasm when exposed to that allergen [7, 8] but individuals may have airway hyperresponsiveness without atopic manifestations. Asthma is a chronic inflammatory disorder of the airways characterized by marked variability in airflow obstruction that is often reversible, either spontaneously or with treatment [9].

Twice-daily PEF measurements, morning and evening, may also demonstrate diurnal variation, which is a typical feature of asthmatic patients. Simple spirometry is important for objectively demonstrating airflow obstruction, confirming the diagnosis of asthma, establishing the severity of the disease, and monitoring the response to therapy. Patients with asthma typically show a reduced forced expiratory flow in 1 second (FEV1), reduced PEF, preserved forced vital capacity (FVC) and an FEV1/FVC ratio of 0.7 or greater, but with worsening disease, FEV1 less than 60% predicted the FEV1/FVC ratio is more usually <0.7 [10]. The successful management of asthma requires an appreciation of the heterogeneity of the disease with respect to etiology, clinical presentation, severity, natural history and response to therapy. It is unlikely that a single management approach will work for all patients and hence, treatment should be tailored to the individual patient.

Inhaled glucocorticoids are considered the first line treatment for patients with moderate to severe persistent asthma. Corticosteroids (CSs) are potent anti-inflammatory agents and when administered by the inhaled route are the most effective therapy available for treating and controlling asthma, and have greatly contributed to a reduction in asthma mortality in the Western world [11].

Aim: To compare the improvement in clinical, spirometric and oxygenation parameters after nebulisation with levosalbutamol and formeterol-budesonide in moderate to severe persistent asthma patients.

Materials and Methods

A prospective, analytical study conducted among clinically diagnosed moderate and severe persistent asthma patients in the Department of Pulmonary Medicine at Govt General Hospital over a period of July 2022 and December 2022.

Sample size: 60 asthmatics (27 males and 33 females) who satisfied the clinical and spirometric essential criteria of moderate and severe persistent asthma were included. Spirometry was done prior to nebulisation. Consecutively, the patients were nebulised with Levosalbutamol or Formeterol-Budesonide. Clinical improvement, Spirometry and clinical parameters (pulse rate, respiratory rate, SpO_2) were noted at 15 min after nebulisation and again after 1 hr.

Inclusion criteria

- Patient age of >18 years.
- Spirometric criteria satisfaction.
- No history of smoking.

Exclusion criteria

- Patients < 18 years.
- Smokers.
- Co morbidities like pulmonary kochs (new and old), COPD, cardiac diseases.
- Patient unable to perform PFT.
- Chest x ray showing abnormalities.

Patient selection: All patients who presented with respiratory symptoms of shortness of breath, wheezing, chest tightness, cough who presented either to emergency department or chest OPD were informed about the study. Spirometry was done to all patients and patients with FEV1> 70% and above and bronchodilator reversibility of >200ml were diagnosed as bronchial asthma. Alternatively the patients were given either levosalbutamol/formeterol-budesonide nebulisation. Oxygen saturation (spo2), pulse rate, respiratory rate of the patients were noted.

After 15 min of nebulisation with either of the above drugs, same parameters were assessed. FEV1 before nebulisation and after 15 min of nebulisation was noted.

At 1 hr after nebulisation spirometry was performed again and pulse rate, respiratory rate and spo2 were

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noted. Results were tabulated.
Software used EPI info 2.4 version.

Results

Sex distribution

Total no. of patients n = 60
Males = 27
Females = 33

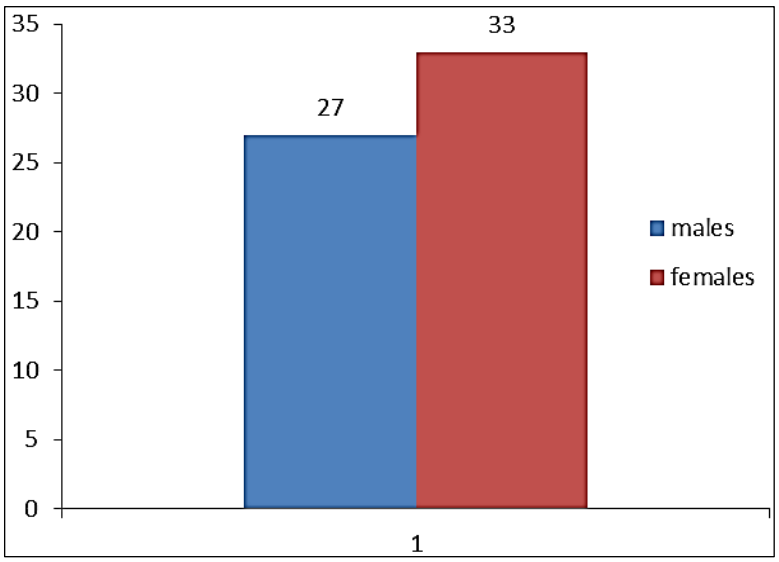

Fig 1: Sex distribution among study population

Age distribution

Total no. of patients n = 60
Age group of 20-40 yrs = 22
Age group of 40-60 yrs = 24
Age group of >60 yrs = 14

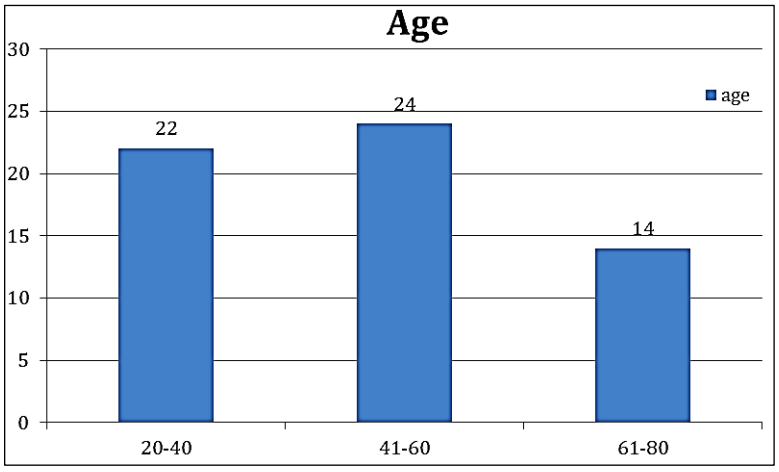

Fig 2: Age distribution among study population

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Symptomatology

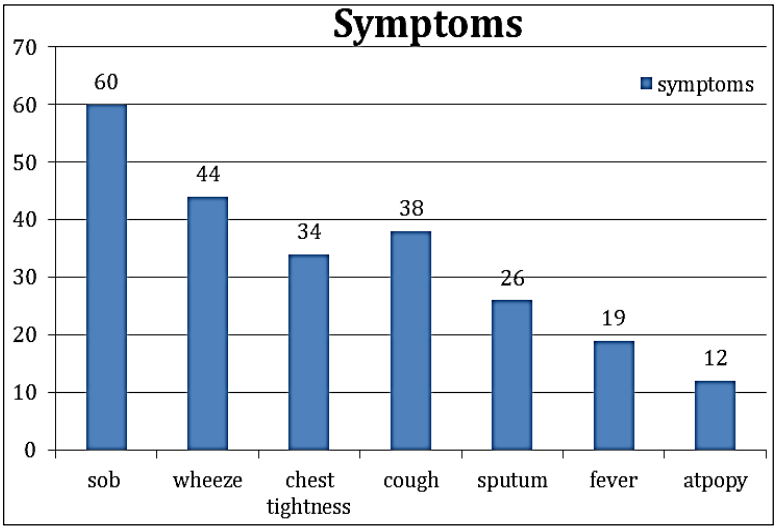
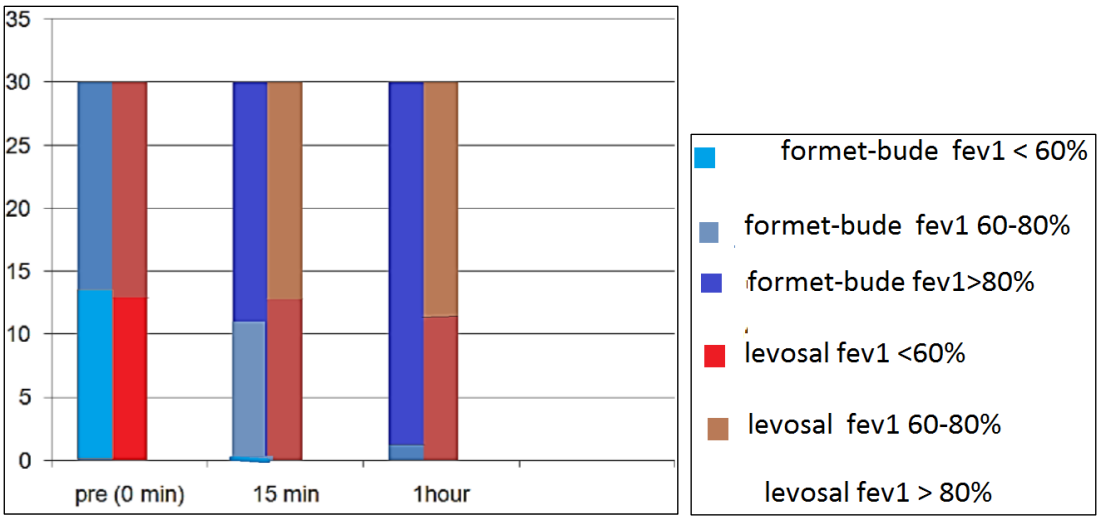


Fig 3: Symptomatology of study population

- Cough, shortness of breath (sob), chest tightness, wheeze came down in all 60 patients irrespective of the drug which they had nebulised.
- Oxygen saturation (spo2) of all the 60 patients as measured with pulse oximetry has improved from 88-92% before nebulisation to more than 95% after nebulisation with both drugs.

Spiromeric analysis

Total no. of study population n = 60.
No. of formeterol-budesonide patients = 30.
No. of levosalbutamol patients = 30.



FEV1 is assessed with Levosalbutamol in 30 patients of which 45% showed moderate improvement (about 60% of predicted value) after 15 min but reached a plateau and continued to be the same at 1 hr. On the other hand, after nebulisation with Formeterol-Budesonide there was moderate to good improvement after 15 min of nebulisation and this continued to improve and after 1hr, and 93% of patients it reached normalcy (80%).

Table 1: Spirometry results pre, at 15 min and at 1 hr of nebulisation

Nebulisation	Pre fev1			At 15 min			At 1 hr		
	<60%	60-80%	>80%	<60%	60-80%	>80%	<60%	60-80%	>80%
Formet-bude	14	16	0	0	12	18	0	2	28
Levosal	13	17	0	0	13	17	0	12	18

Total no. of study population n =60.
Nebulised with formeterol-budesonide = 30.
Nebulised with levosalbutamol = 30.

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Discussion

In 2007, the National Asthma Education and Prevention Program Expert Panel Report 3 (NAEPPR3) [12] defined asthma as a chronic inflammatory disorder of the airways in which many cells and cellular elements play a role: in particular, mast cells, eosinophils, neutrophils (especially in sudden onset, fatal exacerbations, occupational asthma and patients who smoke), T lymphocytes, macrophages and epithelial cells. In susceptible individuals, this inflammation causes recurrent episodes of coughing (particularly at night or early in the morning), wheezing, breathlessness, and chest tightness. These episodes are usually associated with widespread but variable airflow obstruction that is often reversible either spontaneously or with treatment.

Asthma is a heterogeneous disease, usually characterized by chronic airway inflammation.

It is defined by the history of respiratory symptoms such as wheeze, shortness of breath, chest tightness and cough that vary over time and in intensity, together with variable expiratory airflow limitation [13].

In the present study out of 60 patients 22 (36.6%) were between 20-40 years, 24(40%) were between 41-60 years and 14(23.4%) were between 61-80 years age group.

Out of 60 patients females were predominantly found to be asthmatic 33 (55%) and males were 27(45%).

In the present study out of Patients, SOB was present in all 60 patients (100%), Wheeze was present in 44 patients (73.3%), Chest tightness-present in 34 (56.6%), Cough was present in 38 (63.3%), Sputum-present in 26 (43.4%), Fever was present in 19 (31.7%) and history of atopy present in 12 patients (20%).

FEV1was assessed with Levosalbutamol in 30 patients, of which 45% showed moderate improvement (about 60-80% of predicted value) after 15 min of nebulisation but reached a plateau and continued to be the same at 1 hr. FEV1 assesment in 30 patients was done after nebulisation with Formeterol-Budesonide and there was moderate to good improvement after 15 min of nebulisation and this continued to improve and after 1hr and 93% of patients it reached normalcy (80%).

Breathlessness and wheeze improved in 100% of the patients after 15 min. Oxygen saturation (SpO2) also improved in 100% of the patients with in 15 min.

Conclusion

Clinically levosalbutamol and formeterol-budesonide nebulisation show the same results. Cough, breathlessness and wheeze came down. Accessory muscle usage, pulse rate and respiratory rate grossly decreased and were towards normalacy. Oxygen levels of blood as assessed by pulse oximeter also improved with both drugs. In most patients the spo2 before nebulisation was between 88-92%. After nebulisation with both levosalbutamol and formeterol-budesonide, the spo2 levels showed a minimum of 95%. The difference between the two drugs however obvious at spirometry. Levosalbutamol showed a moderate improvement (about 60%) in FEV1 after 15 minutes but reached a plateau and continued to be the sameat one hour whereas with formeterol-budesonide there was moderate to good (about 60-75%) improvement after 15 minutes of nebulisation and this continued to improve, and after one hour it had reached normalacy (>80%) in almost all the patients. None of the patients showed tremors or giddiness after nebulisation with either drug.

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