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Original Article

A Comparative Evaluation of Racemic Salbutamol and Levosalbutamol in Asthmatics

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***ABSTRACT*:**

Background: Asthma is a chronic respiratory disease. The present study was conducted to compare racemic Salbutamol and Levosalbutamol in patients with asthma. **Materials & Methods:** The present study was conducted on 180 patients of both genders (males- 88, females- 92). All were divided into 2 groups of 90 each. Group I received 0.63 mg levosalbutamol and group II received 2.5mg salbutamol. Respiratory rate (RR), Heart rate (HR) oxygen saturation in room air (SPO_2), PEFR (peak expiratory flow rate) & Serum K+ levels were recorded initially and after giving 3 nebulizations at 20 min. **Results:** Mean age was 45.24± 4.8 and 42.06± 3.6 in group I and group II respectively. The difference was non- significant (P> 0.05). Pre treatment respiratory rate (RR) was 28.32 and 27.45 in group I and group II respectively. Heart rate was 110.25 and 106.34 in group I and group II respectively. SPO_2 was 96.37 and 96.75 in group I and group II respectively. PEFR was 194.31 and 195.29 in group I and group II respectively. Serum K level was 4.87 and 4.81 in group I and group II respectively. Asthma score was 7.7 and 9.32 in group I and group II respectively. The difference was non-significant (P> 0.05). Post treatment respiratory rate (RR) was 25.4 and 26.81 in group I and group II respectively. Heart rate was 112.35 and 125.21 in group I and group II respectively. SPO_2 was 98.11 and 98.82 in group I and group II respectively. PEFR was 267 and 265 in group I and group II respectively. Serum K level was 4.41 and 3.52 in group I and group II respectively. Asthma score was 5.3 and 6.9 in group I and group II respectively. The difference was significant (P< 0.05). **Conclusion:** It was found that PEFR, SPO2 and asthma score was better with Levosalbutamol as compared to racemic Salbutamol.

Key words: Asthma, Levosalbutamol, Salbutamol.

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INTRODUCTION

Asthma is a problem worldwide, with an estimated 300 million affected individuals. The World Health Organization has estimated that 15 million disability-adjusted life years are lost annually due to asthma, representing 1% of the total global disease burden. Annual worldwide deaths from asthma have been estimated at 250,000 and mortality does not appear to correlate well with prevalence.[1]

The term asthma comes from the ancient Greek word for panting or gasping. It was Hippocrates (460-357 BC), the Greek physician, who first described asthma and its resulting "spasms". Salbutamol, the most commonly used bronchodilator, is a chiral drug with R and S Isomers. The commonly used formulation is a racemic mixture that contains equal amounts of both R and S isomers. Levosalbutamol (LEV) the R isomer is the therapeutically active isomer and has all the β2 agonist activity.[2] Until recently S- salbutamol was considered inert filler in the racemic mixture but animal as well as human studies have shown that S- salbulamol is not inert, rather it may have some deleterious effects. Formulation of salbutamol containing only R-isomer (Levosalbutamol) has been available in international market for the last few years.[3]

Studies have shown that in asthmatic patients, treatment with levosalbutamol decreased hypersensitivity to methacoline to a greater degree and with longer duration of action than does treatment with racemic salbutamol. In studies of outpatient asthma patients who were treated with levosalbutamol they experienced a significantly greater increase in FEV1, a longer duration of action and fewer side effects.[4] The present study was conducted to compare racemic Salbutamol and Levosalbutamol in patients with asthma.

MATERIALS & METHODS

The present study was conducted on 180 patients of both genders (males- 88, females- 92). Patients' age ranged 18-58 years were included. Patients on preventive therapy (steroids or LABA), first episode of wheezing, known case of hypersensitivity to salbutamol, cyanotic or uncorrected CHD, cystic fibrosis and any other chronic lung disease were excluded from the study. All were informed regarding the study and written consent was obtained. Ethical clearance was obtained prior to the study.

General information such as name, age, gender etc. was recorded. All were divided into 2 groups of 90 each. Group I received 0.63 mg levosalbutamol and group II received 2.5mg salbutamol.

2.5 ml of drug was used in nebulizing chamber & nebulized over a period of 8-10 minutes and patient was instructed to inhale from his mouth. PEFR was measured using MINI-WRIGHT'S peak flow meter. Respiratory rate (RR), Heart rate (HR) oxygen saturation in room air (SPO_2), PEFR (peak expiratory flow rate) & Serum K+ levels were recorded initially and after giving 3 nebulizations at 20 min. Results were tabulated and subjected to statistical analysis. P value less than 0.05 was considered significant.

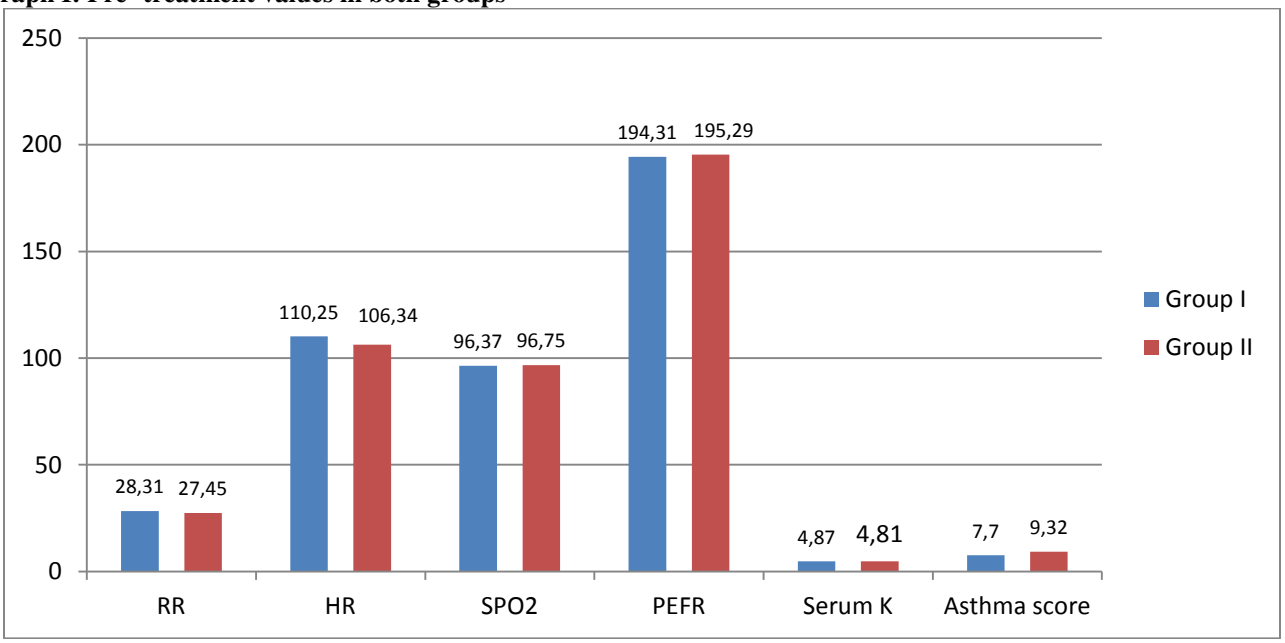
RESULTS

Table I Baseline data of patients

Parameters		Group I	Group II	P value
Mean age (years)		45.24± 4.8	42.06± 3.6	0.1
Duration of illness (in 1 year)	0	64	72	0.5
	>1	26	18	0.4
Hospitalization (in 1 year)	0	66	63	0.2
	>1	24	27	0.3

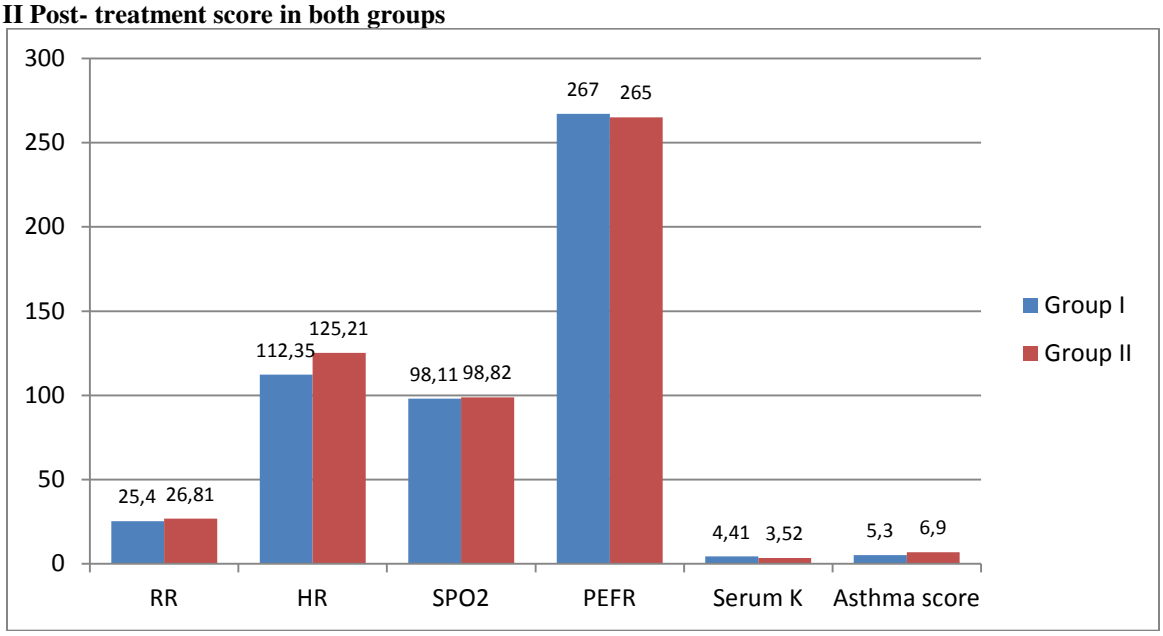
Mean age was 45.24± 4.8 and 42.06± 3.6 in group I and group II respectively. The difference was non- significant (P> 0.05).

Graph I: Pre- treatment values in both groups



Pre treatment respiratory rate (RR) was 28.32 and 27.45 in group I and group II respectively. Heart rate was 110.25 and 106.34 in group I and group II respectively. SPO_2 was 96.37 and 96.75 in group I and group II respectively. PEFR was 194.31 and 195.29 in group I and group II respectively. Serum K level was 4.87 and 4.81 in group I and group II respectively. Asthma score was 7.7 and 9.32 in group I and group II respectively. The difference was non- significant (P> 0.05).

Graph II Post- treatment score in both groups



Post treatment respiratory rate (RR) was 25.4 and 26.81 in group I and group II respectively. Heart rate was 112.35 and 125.21 in group I and group II respectively. SPO_2 was 98.11 and 98.82 in group I and group II respectively. PEFR was 267 and 265 in group I and group II respectively. Serum K level was 4.41 and 3.52 in group I and group II respectively. Asthma score was 5.3 and 6.9 in group I and group II respectively. The difference was significant ($P< 0.05$).

DISCUSSION

In the emergency department studies showed levosalbutamol improved pulmonary function significantly more than racemic salbutamol and significantly decreased the number of hospitalizations compared to racemic salbutamol. Though salbutamol is an effective treatment of acute exacerbation, its use is associated with undesirable side effects like tachycardia and hypokalemia.[5] Search for a more effective drug with fewer side effects is still on. The purpose of the present study is to evaluate the impact of levosalbutamol on clinical effectiveness and assess the patient outcome. Formulation of salbutamol containing only R-isomer (levosalbutamol) has been available on the national and international market for the last few years.[6]

Mean age was 45.24± 4.8 and 42.06± 3.6 in group I and group II respectively. We observed that Pre treatment respiratory rate (RR) was 28.32 and 27.45 in group I and group II respectively. Heart rate was 110.25 and 106.34 in group I and group II respectively. SPO_2 was 96.37 and 96.75 in group I and group II respectively. PEFR was 194.31 and 195.29 in group I and group II respectively. Serum K level was 4.87 and 4.81 in group I and group II respectively. Asthma score was 7.7 and 9.32 in group I and group II respectively. Post treatment respiratory rate (RR) was 25.4 and 26.81 in group I and group II respectively. Heart rate was 112.35 and 125.21 in group I and group II respectively. SPO_2 was 98.11 and 98.82 in group I and group II respectively. PEFR was 267 and 265 in group I and group II respectively. Serum K level was 4.41 and 3.52 in group I and group II respectively. Asthma score was 5.3 and 6.9 in group I and group II respectively. Our results are in agreement with Perrin.[7]

Levosalbutamol (LEV) has approximately 2 fold greater affinity than the racemic salbutamol for the β2 adrenergic receptor and approximately 100 fold greater binding affinity than S-salbutamol.[8] LEV elevates intracellular concentration of cylic AMP (cAMP) by activating adenyl-cylase. In the airways, increased concentration of cAMP relaxes bronchial smooth muscle by reducing intracellular calcium and prevents contraction of hyper responsive airways. Increased concentration of cAMP also inhibits the release of inflammatory mediators from mast cells and eosinophil.[9]

Khara et al[10] in their study among 100 patients who were divided in two groups. After performing baseline spirometry, group A and group B subjects were given 2.5 mg salbutamol and 1.25 mg levosalbutamol, respectively, through nebulizer. After 20 minutes, repeat spirometry was performed to measure bronchodilatory response. Two groups are comparable for base line characteristics, as there is no age & sex wise and symptom wise significant difference in the distribution of patients. Overall picture is suggestive of no significant statistical difference in bronchodilatory potential between Salbutamol and Levo-Salbutamol. Positive raise in FEV1, FEV1/FVC% and PEFR is statistically not significant in both groups.

CONCLUSION

It was found that PEFR, SPO2 and asthma score was better with Levosalbutamol as compared to racemic Salbutamol.

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