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ORIGINAL ARTICLE

Efficacy of Inhaled Steroid Over Systemic Steroid in Stabilizing Acute Asthma in Emergency Room

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Abstract

Background: Acute exacerbation of asthma is one of the most common illnesses presenting to Emergency Department. Glucocorticoids are good anti-inflammatory agents, effective at treating asthma and decreasing inflammation of the airways. Although systemic use of steroids is commonly being used, inhaled steroids could be also beneficial in acute asthma. AIM: To compare the efficacy of inhaled corticosteroid over systemic steroid in acute asthma. **Materials & Methods**: This was randomized, prospective, comparative study done on a total of 48patients in Emergency Department and ICU. All patients were assigned in random consecutive case fashion to one of the three groups such as Group I(inhaled steroid), Group II(intravenous steroid) and Group III(inhaled beta-2 agonist). The changes in respiratory rate, heart rate, oxygen saturation, peak expiratory flow and pulmonary score were recorded at 30minutes, 60minutes and 120minutes after treatment and were analysed. **Results**: Out of 48patients, highest number (n=13)(26.5%) of patients were of aged 30-39years and lowest being(n=2)(4.1%) aged 10-19years. There was female preponderance (n=21)(56.3%). Breathlessness grades were Grades 0 and 1(0%), Grade 2(n=13)(27.1%), Grade 3(n=26)(54.2%) and Grade 4(n=9)(18.7 %). Wheeze was present in 46(95.8%) patients. Accessory muscles of respiration were used in 34(70.8%) patients. There was no statistical difference ($p>0.05$) in decrease in respiratory rate, decrease in heart rate, increase in oxygen saturation, increase in peak flow and decrease in pulmonary score among all 3groups. **Conclusion**: The use of inhaled steroids is an effective treatment approach with faster clinical improvement compared to intravenous steroids in managing acute exacerbation of bronchial asthma in emergency room.

Keywords: Inhaled steroid, Systemic steroid, Asthma

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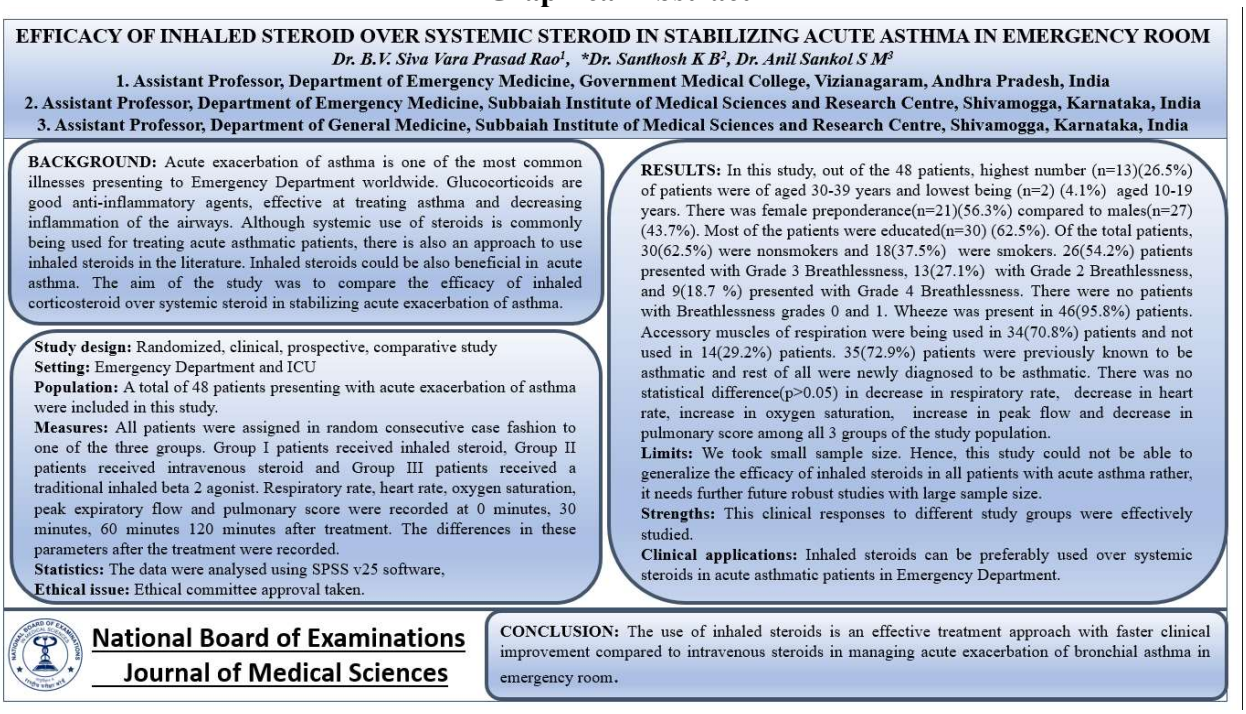
Graphical Abstract



Introduction

Asthma is traditionally defined as intermittent, reversible obstructive airway disease [1]. Acute exacerbation of bronchial asthma is one of the most common illnesses presenting to Emergency Departments worldwide. Appropriate, adequate and timely intervention is the cornerstone in the management of acute exacerbation of bronchial asthma.

The *Global Strategy for Asthma Management and Prevention* Guidelines define asthma as 'a chronic inflammatory disorder of the airways associated with increased airway hyper-responsiveness, recurrent episodes of wheezing, breathlessness, chest tightness, and coughing. Airway inflammation produces airflow limitation through acute bronchoconstriction, chronic mucus plug formation and airway wall swelling or remodeling. It can occur at any age of which in half the cases the onset is before 10 years of age. Recent concept is that asthma as an inflammatory disease requires a change of conventional treatment strategy i.e., the need for anti-inflammatory medications [1]. Glucocorticoids are potent anti-inflammatory agents, reducing the inflammation of airways and thereby effective at treating asthma. Although the exact mechanism by which its molecule functions being unclear, important attempts have been made in understanding of its action [2,3]. During acute asthma crises, corticoids are generally administered systemically. But the use of systemic steroids can be associated with critical short and long-term adverse effects. As a result, it is now relatively common about the unpleasant systemic adverse effects that are associated with systemic corticosteroids therapy. Inhaled corticoids are effective for chronic asthma treatment and although some

recent studies have been done to assess the action of inhaled corticoids in acute respiratory diseases, their independent role in acute crises is still not yet been defined [4]. The use of inhaled corticosteroids can decrease the need for systemic corticosteroids and the side effects associated with these medications. The delivery of regionally active corticosteroids directly to the airways by inhalation has revolutionized the anti-inflammatory treatment of asthma. Comparisons of oral corticosteroids with inhaled corticosteroids has also demonstrated in few studies that both the routes are similar in terms of efficacy but, that repeat acute episodes are lesser when the medication is inhaled [5,6].

Aim

To compare the efficacy of inhalational and systemic steroid in stabilizing the patients presented with acute exacerbation of bronchial asthma.

Material and Methods

Study design: Randomized, clinical, prospective, comparative study.

Study area: Department of Emergency Medicine and ICU of Tirumala Hospitals, Vizianagaram, Andhra Pradesh.

Study population: Patients with acute exacerbation of asthma satisfying the following inclusion and exclusion criteria were taken for the present study.

Inclusion criteria: Patients between 15 years and 60 years of age of both sexes with acute asthma were included.

Exclusion criteria: The following exclusion criteria were considered.

- Age less than 15years and more than 60 years
- Cardiac illness on surgery or medications
- High grade fever
- Super added Pneumonia
- H/o foreign body aspiration
- Patients who received oral or parenteral corticosteroids within last 24 hours.
- Known case of renal or hepatic insufficiency
- Prior enrolment in the study
- known liver or kidney disease, of congenital heart disease
- Worsening clinical status during the evaluation period.
- Concurrent Stridor
- Pregnancy
- Patients with tracheostomy
- Already mechanically ventilated or intubated before arrival to ED

Sample size: To determine the sample size, the following formula was used and their values were considered based on based on previous similar study, conducted by Go J [11].

$$n = [Z_{a/2} + Z_b]^2 \times [(p_1(1-p_1)] + [p_2(1-p_2)] / [p_1 - p_2]^2$$

Where, n= desired sample size
Z=standard normal deviate, usually set at 1.96 (95% confidence interval)
a = alpha error
$Z_{a/2}$ based on level of significance (5%) =1.96
b = power=80%
Z_b = 0.84
P_1= proportion group 1 =0.65
P_2= proportion in group 2 =0.35

Minimum sample size needed according to above formula was ≈ 40.

Duration of the study

Ten months

Methodology

The study was approved by Institutional Ethics Committee. The written informed consent was taken by the patients after explaining about the study. Details of cases were recorded including history, clinical examination and investigations. mMRC (modified Medical Research Council) [13] dyspnea grade and the clinical severity score (Pulmonary score) were determined in all the patients. The average transcutaneous hemoglobin saturation (SpO2) was measured with a standard pulse oximeter. Then all the patients were allocated in random consecutive case fashion to one of the three groups as follows.

Group I (Inhalation group: Nebulized budesonide)

Group II (Intravenous group: Hydrocortisone)

Group III (Control group: Nebulization with salbutamol)

All three groups were treated with salbutamol by nebulization 2.5mg (2.5ml) in NaCl 0.9% solution q20 minutes in the initial first hour at ED. Nebulized bronchodilators were continued as per the patient's clinical status.

Group I patients received inhalation of budesonide 0.5mg (2ml) by nebulization within the first 30 minutes after admission.

Group II patients received intravenous injection of hydrocortisone 5mg per kg upto a maximum of 200mg within the first 30 minutes after admission.

Group III patients were treated by salbutamol nebulization.

All patients received oxygen supplementation at a rate of 5 L/min and was titrated to maintain the oxygen saturation of above 94%. Peak expiratory flow, oxygen saturation, heart rate, pulmonary score were recorded at 0 minutes, 30 minutes,60 minutes 120 minutes after treatment

Pulmonary Score

Pulmonary score, also called as Asthma clinical severity score designed by American Academy of Allergy Asthma and immunology is a useful indicator for clinical assessment of severity of acute exacerbation of bronchial asthma (Table 1).

Table 1. Pulmonary score

SCORE	***RESPIRATORY RATE (cycles per minute)***	***PRESENCE OF WHEEZE***	***USE OF ACCESSORY MUSCLES***
0	≤ 20	None	No apparent increase
1	21 – 35	Terminal expiration with stethoscope	Mild increase
2	36 – 50	Entire expiration with stethoscope	Increased
3	> 50	Inspiration & expiration without stethoscope	Maximal activity
Interpretation: Mild - Pulmonary score ≤ 3 Moderate - Pulmonary score 4-6 Severe- Pulmonary score >6			

Statistical methods

The descriptive and inferential statistical analysis of the collected data was carried out using software statistical package for social sciences (SPSS) 25.0. Descriptive analysis was used to describe the data and distribution of variables quantitatively. Univariate analysis was used to evaluate quantitative variable like heart rate, respiratory rate, Spo2, peak expiratory flow rate and pulmonary score to compare in different categorized groups. The p (probability) value of ≤0.05 was considered statistically significant.

Results

In this randomized, clinical, prospective, comparative study, 48 patients who presented with acute asthma satisfying the inclusion and exclusion criteria were studied. Out of the 48 patients, there were 2 (4.1%) (lowest) patients in 10-19 years group, 6(12.2%) patients in 20-29 years, 13(26.5%) (highest) patients in 30-39 years, 12(24.5%) patients in 40-49 years and 15 (30.6%) patients in 50- 60 years. This has been illustrated in Table 2. There was female preponderance (n=21) (56.3%) compared to males (n=27) (43.7%) (Table 3). Most of the patients were educated (n=30) (62.5%) (Table 4). Out of total patients included in the study, 30(62.5%) were nonsmokers and 18 (37.5%) were smokers (Table 5).

Table 2. Age distribution

AGE IN YEARS	NUMBER OF CASES (%)
10 – 19	2(4.1%)
20 – 29	6(12.2%)
30 – 39	13(26.5%)
40 – 49	12(24.5%)
50 – 59	12(24.5%)
60+	3(6.1%)
Total	48(100%)

Table 3. Gender distribution

GENDER	NUMBER OF CASES (%)
Male	21(43.7%)
Female	27(56.3%)
Total	48(100%)

Table 4. Education Status

EDUCATION	NUMBER OF CASES (%)
Educated	30(62.5%)
Uneducated	18(37.5%)
Total	48(100%)

Table 5. History of smoking

SMOKING	NUMBER OF CASES (%)
Yes	18(37.5%)
No	30(62.5%)
Total	48(100%)

Out of 48 patients, number of cases with mMRC breathlessness grade 2 were 13(27.1%), with grade 3 were 26(54.2%) and with grade 4 were 9(18.7%). We did not receive any patient with breathlessness grades 0 and 1. The same has been depicted in Table 6. As wheeze is a common finding in asthma, it was present in majority (n=46) (95.8%) patients in our study and absent in only 2(4.2%) patients (Table 7). Accessory muscles of respiration such as sternocleidomastoid, scalene, trapezius,

pectoralis and intercostal muscles were being used in 34(70.8%) patients and not used in 14(29.2%) patients (Table 8). Out of total patients included in the study, number of patients with new onset of asthma were 13(27.1%) and remaining 35(72.9%) patients were previously known to be asthmatic (Table 9). All the patients were allocated in random consecutive way to one of the three groups such as Group I (nebulized budesonide), Group II (intravenous hydrocortisone) and Group III (nebulization with salbutamol) with 16(≈33.3%) patients in each group (Table 10).

Table 6. mMRC Breathlessness grade

BREATHLESSNESS GRADE	NUMBER OF CASES (%)
2	13(27.1%)
3	26(54.2%)
4	9(18.7%)
Total	48(100%)

Table 7. Presence of Wheeze

WHEEZE	NUMBER OF CASES (%)
Present	46(95.8%)
Absent	2(4.2%)
Total	48(100%)

Table 8. Use of Accessory Muscles

USE OF ACCESSORY MUSCLES	NUMBER OF CASES (%)
Yes	34(70.8%)
No	14(29.2%)
Total	48(100%)

Table 9. Type of onset

ONSET	NUMBER OF CASES (%)
New	13(27.1%)
Old	35(72.9%)
Total	48(100%)

Table 10: Categorization into groups

GROUP	NUMBER OF CASES (%)
I - NEBULISATION WITH BUDESONIDE	16(≈33.3%)
II - INTRAVENOUS HYDROCORTISONE	16(≈33.3%)
III - NEBULISATION WITH SALBUTAMOL	16(≈33.3%)
Total	**48(≈100%)**

Decrease in Respiratory Rate

Decrease in mean respiratory rate (RR) at 30min of treatment in group I was 3.43 cycles per minute (cpm), in group II it was 3.43cpm and in group III it was 2.93cpm. (P=0.67) Decrease in mean respiratory rate (RR) at 60min of treatment in group I was 8.8 cpm, group II was 7.4cpm and group III was 7.25 cpm. (P=0.26) Decrease in mean respiratory rate (RR) at 120min of treatment in group I was11.56cpm, group II was 11.25cpm and group III was 10.37cpm. (P=0.71). All of them were not statistically significant among the groups at 30min, 60min and 120min after treatment. It has been depicted in Table 11.

Table 11. Decrease in respiratory rate (Mean±SD) (cycles per minute)

Time	Group I	Group II	Group III	P value
30mins	3.43±1.31	3.43±2.33	2.93±1.65	**0.67**
60mins	8.87±3.09	7.43±3.82	7.25±1.80	**0.26**
120mins	11.56±4.56	11.25±5.05	10.37±2.55	**0.71**

Decrease in Heart Rate

The mean decrease in heart rate (HR) at 30 minutes of the treatment in group I was 9.56 beats per minute(bpm), group II was 8.5bpm and in group III it was 7.87 bpm. (P=0.64) The mean decrease in heart rate (HR) at 60 minutes of the treatment in group I was 15.56 bpm, group II was 12.68 bpm and in group III it was 14.18 bpm. (P=0.42) The mean decrease in heart rate (HR) at 120 minutes of the treatment in group I was 21.12 bpm, group II was 16.56 bpm and in group III it was 19.3 bpm. (P=0.20) All of them were not statistically significant among the groups at 30min, 60min and 120min after treatment. It has been depicted in Table 12.

Table 12: Decrease in heart rate (Mean±SD) (beats per minute)

Time	Group I	Group II	Group III	P value
30mins	9.56±5.79	8.50±5.29	7.87±3.98	**0.64**
60mins	15.56±5.86	12.68±6.75	14.18±5.67	**0.42**
120mins	21.12±7.70	16.56±7.53	19.31±6.21	**0.20**

Increase in SpO2 (Table 13)

Improvement of mean oxygen saturation after 30min in group I was 3.0%, group II was 2.9% and group III was 3.0%. (P=0.99) Improvement of mean oxygen saturation after 60min in group I was 4.9%, group II was 4.56% and group III was 4.5%. (P=0.79) Improvement of mean oxygen saturation after 120 min in group I was 6%, group II was 5.8% and group III was 5.06%. (P=0.47) All of them were not statistically significant among the groups at 30min, 60min and 120min after treatment. It has been depicted in Table 13.

Table 13. Increase in SpO2 (Mean±SD) (%)

Time	Group I	Group II	Group III	P value
30mins	3.00±1.93	2.93±1.61	3.00±1.26	**0.99**
60mins	4.93±2.04	4.56±1.99	4.50±1.89	**0.79**
120mins	6.00±2.16	5.81±2.40	5.06±2.29	**0.47**

Increase in Peak Flow (Table 14)

At 30min, there was ~ 47mL increase in mean peak expiratory flow in group I, ~45mL in group II and ~40mL in group III (P=0.72). At 60min, there was ~78mL increase in mean peak expiratory flow in group I, ~86mL in group II and ~ 76mL in group III. (P=0.74) At 120min, there was ~103mL increase in mean peak expiratory flow in group I, ~122mL in group II and ~102mL in group III. (P=0.44) All of them were not statistically significant among the groups at 30min, 60min and 120min after treatment. It has been depicted in Table 14.

Table 14. Increase in Peak expiratory flow (Mean±SD)(mL)

Time	Group I	Group II	Group III	P value
30mins	47.50±22.36	45.62±25.55	40.62±26.94	**0.72**
60mins	78.75±34.22	86.25±32.63	76.87±42.22	**0.74**
120mins	103.12±48.67	122.50±42.50	102.50±57.67	**0.44**

Decrease in Pulmonary Score (Table 15)

At 30min, mean decrease in pulmonary score in group I was 1.7, group II was 1.4 and group III was 1.3. (P=0.14) At 60min, mean decrease in pulmonary score in group I was 2.8, group II was 2.3 and group III was 2.4 (P=0.39). At 120min, mean decrease in pulmonary score in group I was 3.8, group II was 3.5 and group III was 3.3**.** (P=0.64) All of them were not statistically significant among the groups at 30min, 60min and 120min after treatment. It has been depicted in Table 15.

Table 15. Decrease in Pulmonary score (Mean±SD)

Time	Group I	Group II	Group III	P value
30mins	1.75±0.68	1.43±0.72	1.31±0.47	**0.14**
60mins	2.81±1.16	2.37±0.80	2.43±0.89	**0.39**
120mins	3.81±1.75	3.50±1.46	3.31±1.30	**0.64**

Discussion

Glucocorticoids are good anti-inflammatory medications, effective in treating asthma by decreasing inflammation of the airways. Asthma management consensus recommends to use of oral corticoids for moderate acute episodes that do not respond or relapse after treating with inhaled β2-agonists. However, in severe crises the use of corticosteroids is highly essential [3]. It is conventional that, during acute asthma exacerbations, corticosteroids are commonly administered systemically. Although inhaled corticoids are effective in treating chronic asthma while their importance in acute crises has not yet been defined [4]. It is interesting to note that inhaled corticosteroids can be the preferred agents in the treatment of acute severe asthma owing to its direct action at the site of inflammation. Budesonide is one such drug, which is a non-halogenated corticosteroid which can be used as nebulization, in which it seems to have better efficacy during acute crises due to better binding with the intra-cellular lipophilic receptor than sprays. It could be an effective adjunct to intravenous steroid with acute asthma. This study was conducted to find the efficacy of inhaled steroids over intravenous steroids in acute asthmatic patients.

In this study, a total of 48 patients with acute asthma were included. The average age distribution shown in Table 2 coincides with prevalence rate of bronchial asthma in India. There was narrowing of prevalence at 15 to 29 years of age and widening beyond 29-years of age. This finding correlates with the results of a similar study by Prakash Kumar et.al. (2017) [7]. The gender distribution of the subjects studied in Table 3 shows 43.7% in males and 56.3% in females. This corroborates with the previous study by Prakash Kumar et.al. (2017) [7]. This is also in accordance with international prevalence of bronchial asthma. The Education status of the subjects studied in Table 4 shows 62.5% educated and 37.5% uneducated patients. Education

status was considered in this study possibly that could help us to make them understand better the hospital and home based treatment strategies and prevention of asthma exacerbations. The Smoking status of the subjects of this study shown in Table 5 shows 37.5% smokers and 62.5% non smokers.

In this study as shown in Table 6, majority (54.2%) patients presented with Breathlessness Grade 3, 27.1% presented with Breathlessness Grade 2, 18.7% presented with Breathlessness Grade 4. There were no patients with Breathlessness grades 0 and 1. Out of the 48 patients included in this study as shown in Table 7, 95.8% presented with Wheeze. Table 8 shows that 70.8% were using Accessory muscles and 29.2% were not using Accessory muscles. Majority (73%) of the patients had Old Onset Asthma and only 27% had New Onset Asthma. Table 10 shows the distribution of all the patients into three groups namely *GROUP I – NEBULISATION WITH BUDESONIDE, GROUP II – INTRAVENOUS HYDROCORTISONE and GROUP III – NEBULISATION WITH SALBUTAMOL.* All 48 patients were equally distributed among the three groups i.e. each group contains 16 patients.

In this study, as shown in Table 11, the decrease in mean respiratory rate at 30 minutes seemed to be similar both in nebulization with budesonide group and intravenous hydrocortisone group and the decrease was a little less in the nebulization with salbutamol group when compared with the other two groups. The decrease in mean respiratory rate at 60 minutes was more in nebulization with budesonide group when compared with intravenous hydrocortisone group and nebulization with salbutamol group. The decrease in mean respiratory rate at 120 minutes seemed to be almost similar both in nebulization with budesonide group and intravenous hydrocortisone group and the decrease was a little less in the nebulization with salbutamol group when compared with the other two groups. The decrease in respiratory rate at 30min, 60min and 120min had no statistical difference between all the three groups. These results were similar to the study by Edmonds et al. (2000) [8].

In this study, as shown in Table 12, the decrease in mean heart rate at 30 minutes in nebulization with budesonide group was more when compared with intravenous hydrocortisone group and nebulization with salbutamol group. The decrease in mean heart rate at 60 minutes was more in nebulization with budesonide group when compared with the other two and less decrease in mean heart rate was observed in intravenous hydrocortisone group. The decrease in mean heart rate at 120 minutes was more in nebulization with budesonide group when compared with intravenous hydrocortisone group and nebulization with salbutamol group and less decrease in mean heart rate was observed in intravenous hydrocortisone group. Similar results were shown in the study by Rowe et al. (2012) [9].

In this study, as shown in Table 13, the increase in mean oxygen saturation at 30 minutes seemed to be similar both in nebulization with budesonide group and nebulization with salbutamol group and the

decrease was a little less in the intravenous hydrocortisone group when compared with the other two groups. The increase in mean oxygen saturation at 60 minutes was more in nebulization with budesonide group when compared with intravenous hydrocortisone group and nebulization with salbutamol group. The increase in mean oxygen saturation at 120 minutes seemed to be almost similar both in nebulization with budesonide group and intravenous hydrocortisone group and the increase was a little less in the nebulization with salbutamol group when compared with the other two groups. This corroborates with the previous similar study by Alangari et al. (2014) [10].

As shown in Table 14, the increase in mean peak expiratory flow at 30 minutes is more in nebulization with budesonide group when compared with intravenous hydrocortisone group and nebulization with salbutamol group. This corroborates with the previous study by Rodrigo (2009) [11]. The increase in mean peak expiratory flow at 60 minutes was more in intravenous hydrocortisone group when compared with nebulization with budesonide group and nebulization with salbutamol group. The increase in mean peak expiratory flow at 120 minutes was more in intravenous hydrocortisone group when compared with nebulization with budesonide group and nebulization with salbutamol group. This coincides with similar study in comparision of systemic and inhalational steroids by Alangari et al. (2014) [10].

In this study, as shown in Table 15, the decrease in mean pulmonary score at 30 minutes in nebulization with budesonide group was more when compared with intravenous hydrocortisone group and nebulization with salbutamol group. The decrease in mean pulmonary score at 60 minutes was more in nebulization with budesonide group when compared with intravenous hydrocortisone group and nebulization with salbutamol group and less decrease in mean pulmonary score was observed in intravenous hydrocortisone group. The decrease in mean pulmonary score at 120 minutes was more in nebulization with budesonide group when compared with intravenous hydrocortisone group and nebulization with salbutamol group. No significant adverse reactions were noticed in any of groups.

This study results support similar studies conducted in various places comparing nebulization vs. intravenous steroids. Study conducted in Federal university, Brazil on budesonide vs. intravenous steroid showed similar correlation and results. Study conducted by Rodrigo (2005) [12], showed the same results on inhaled vs systemic corticosteroids in acute asthma. An independent study conducted in University Medical School, Jerusalem, Israel, conducted on nebulized fluticasone vs. intravenous steroid also showed the same observations and similar results.

In our study mean values of decrease in respiratory rate, decrease in heart rate and decrease in pulmonary score seemed to be similar both in inhalation and intravenous groups. Improvement of oxygen saturation was observed in both inhalation and intravenous groups, with a statistically little margin. There was improvement of peak expiratory flowmetry in both groups after

the desired therapy. According to the results of our present study and previous reports of comparative studies on inhalation steroids, we are having the opinion that nebulized steroids may be used alone or be combined with systemic corticosteroids in treating acute attacks of asthma presenting to the emergency department. Our results highlight the effectiveness of inhaled steroids in the treatment of acute asthma and found to be beneficial in the management at par with intravenous steroids.

Conclusion

The use of inhaled steroids is an effective treatment approach with faster clinical improvement compared to intravenous steroids in managing acute exacerbation of bronchial asthma in emergency room.

Limitation

We took small sample size. Hence, this study could not be able to generalize the efficacy of inhaled steroids in all patients with acute asthma rather, it needs further future robust studies with large sample size.

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Statements and Declarations

Conflicts of interest

The authors declare that they do not have conflict of interest.

Funding

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Ethical Clearance

Institutional Ethical clearance approved.

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