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COMPARATIVE STUDY OF INHALATION OF SALBUTAMOL VIA METERED DOSE INHALER WITH SPACER AND VIA NEBULISER IN ACUTE BRONCHIAL ASTHMA

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ABSTRACT

Background: Effective management of Acute bronchial asthma may reduce the mortality and morbidity in adults which can be achieved by educating the patient with aerosol inhalation devices. Now a days salbutamol administration with metered- dose inhaler and spacer play a unique role in treatment of acute asthma.

Objective: Our study analyse the efficacy of salbutamol administered by a nebuliser compared to metered- dose inhaler and spacer in adults with Acute asthma.

Materials and Methods: The study was conducted on 52 patients admitted in the Medical ward of tertiary care hospital. We categorised them into two groups. Group I received salbutamol Via MDI with spacer and Group II received salbutamol via nebuliser. Approval from the hospital ethical committee was obtained. The study was a cohort study conducted for a period of 6 months from May 2012 to October 2012.

Results : There is stastistically significant improvement in PEFR , FEV_1 and FVC at 30 mts and at end of treatment with the MDI-Spacer group than with the nebulised group. There is no statistically significant difference between MDI-spacer and nebuliser groups in the heart rate and respiratory rate at 30 minutes and at the end of treatment. Change in oxygen saturation at 30mts was 3.92±0.404 (MDI-Spacer) and 2.23±0.430 (nebulised group) .It was significant with p<0.001 at 30mts.At the end of treatment the corresponding values were 2.23±0.430(MDI-spacer) and 2.12± .33)(nebulised group). There was no statistically significant difference (p 0.304). The requirement of salbutamol in MDI-spacer is significantly lower than nebulizer as suggested by p value less than .001.We concluded there was no significant difference between the two groups, moreover MDI with spacer was better than nebuliser for the treatment of severe acute asthma attack in adults.

Conclusion: Our study supported and confirmed the evidence that MDI with spacer is as effective as nebuliser in the management of acute asthma.

KEYWORDS

MDI, spacer, Nebuliser, Salbutamol, inhaler.

INTRODUCTION :

In the modern era, Bronchial asthma is a disease that is becoming a major health issue in many developing countries. Increased urbanisation may have modified the traditionally low incidence of bronchial asthma in the third world[1]. In 2004, Masoli et al and the global initiative for asthma(GINA) with combined data from the phase 1 International study of Asthma and Allergies (ISACC) study conducted in 1992-1996 and the European Community Respiratory Health Survey (ECRHS) in 1994-1998 generated the global estimate of asthma burden, which suggested that the prevalence of asthma symptoms has world wide variations[2]. This report estimated that at present three hundred million people were affected by asthma world wide and by 2025 it would be around four hundred million with increasing urbanisation. The first line of treatment in the management of acute asthma is inhaled beta2 agonists (salbutamol) and is now the main stay of treatment.[3] Earlier Nebuliser has been accepted to be the main therapeutic way of management of acute asthma. Though it is comfortable, require 15–20 min to administer the prescribed dose and need nursing staff or skilled attenders to initiate the management in acute asthmatic patients. Later evidence hadbeen changed that MDI+spacer could be as effective as a nebuliser in the management of acute asthma and also self manageable in acute conditions.

MATERIALS AND METHODS

The cohort study was conducted on 52 patients admitted in the Medical ward of tertiary care Hospital for a period of 6 months after informed consent. Approval from the hospital ethical committee was obtained.

Inclusion criteria: Acute bronchial asthma patients above 13 years of age who fulfilled American Thoracic Society criteria with Peak Expiratory flow rates, Forced Expiratory Volume in 1 second below fifty percent of predicted value were eligible for the study

Exclusion criteria: Patients <13 yrs age, Patients with co-morbid factors like acute respiratory tract infections, COPD , restrictive lung disease, heart failure, renal failure and hepatic failure .

All fifty two were received bronchodilator- short acting Beta 2 agonist, salbutamol. The patients were divided into two groups depending on mode of delivery of salbutamol. The first group received salbutamol by nebuliser and the second group by metered dose inhaler and spacer. The drug dosage was increased in both the groups depending upon the patient's clinical improvement.The following values were calculated before medication , after thirty minutes of drug delivery, and at the end of the treatment.The variables were PEFR. FEV1, FVC, heart rate, respiratory rate, oxygen saturation and drug dosage. The PEFR was measured with a mini-wright peak flow meter. The highest of three values were recorded. FVC and FEV1 were measured using spirometer. Curves of expiration were recorded at each time and the maximum value was selected. This was done in 3 successive manners according to the American Thoracic society guidelines. Oxygen saturation was calculated using pulse oximeter. Drug dosage, heart rate and respiratory rate were also measured.

RESULTS

A total of 52 patients with acute Bronchial asthma who received salbutamol therapy participated in the study. The patients were divided into 2 groups: 26 (50%) patients in the MDI-Spacer group and 26 (50%) patients in the Nebuliser group. The baseline characteristics of over all cohort were expressed in percentage. The two treatment groups were comparable as regards change in PEFR, FEV_1, FVC, Oxygen saturation, heart rate, respiratory rate and drug dosage at thirty minutes and at the end of treatment. Mean PEFR,FEV_1FVC and oxygen saturation values improved significantly over base line values in both nebuliser and MDI-spacer groups. They were expressed as mean and standard deviation (Table-1).The magnitude of improvement in PEFR at 30 minutes were 212.31 ±7.65 in the MDI-Spacer group and 189.62±9.16 in the nebulised group and at the end of treatment 227.31±10.02 in the MDI-spacer group and 210.77±9.77 in the nebulised group PEFR has statistically significant difference (p <0.001) in MDI-spacer than nebulised group at 30 mts and at the end of treatment. Change in FEV_1 in the MDI-spacer group and nebulised group at 30 minutes were 1.408±0.011 and 1.371±0.023 and at the end of treatment were 1.635±0.028 and 1.602±0.015 respectively(Table-1). FEV_1 has statistically significant difference (p <0.001) in MDI-spacer than nebulised group at 30 mts and at the end of treatment. The same pattern was held for change in FVC in the MDI-spacer group and nebulised group;the values at 30 minutes were 1.425±0.025 and 1.396±0.020 and at the end of treatment were 1.656±0.022 and 1.622± 0.013 respectively.FVC has statistically significant difference (p <0.001) in MDI-spacer than nebulised group at 30 mts and at the end of treatment. Change in oxygen saturation at 30mts was 3.92±0.404

(MDI-Spacer) and 2.23±0.430 (nebulised group) .It was significant with p<0.001 at 30mts.At the end of treatment the corresponding values were 2.23±0.430(MDI-spacer) and 2.12± .33)(nebulised group). There was no statistically significant difference (p 0.304). The change in heart rate at 30 mts and at the end of treatment were 15±0.63 and 9.92±0.27 in the spacer group and 14.92±0.69 and 9.42±1.40 in the nebulised group respectively(p 0.677), Change in Respiratory rate at 30 mts and at the end of treatment were14.81±0.57 and 5.07±5.07 in the spacer group and 14.54±0.51and 5.04±0.19 in the nebulised group .p values were 0.07(30mts) and 0.5619(end of treatment)(Table-1). Heart rate and respiratory rate changes were not significantly affected by the mode of delivery. Drug dosage in the MDI group was 1192.3±146.76 and 4365.3±1836.07 in the nebulised group, it was statistically significant,with p<0.001.(Table-2)

Statistical analysis:

Analysis was performed with SIGMA STAT VERSION 3.5 statistical package. All continuous variables were presented as mean ±standard deviation if they were normally distributed. One way Anova Analysis and Chi square test was performed to study the comparison between nebuliser and MDI -spacer. Differences in the normally distributed variables were assessed using *t*-test and paired *t*-test for dependent variables. Comparisons between the two individual groups were performed using the unpaired *t*-test (parametric) All tests were two-sided and a probability value of $p < 0.05$ was considered as significant.

DISCUSSION

The most relevant treatment options for acute exacerbation of asthma are: Bronchodilators- short acting beta 2 agonist (salbutamol, terbutaline, fenoterol), Anticholinergics and Corticosteroids. Short acting beta 2 agonist is the treatment option which quickly relieves bronchospasm. Reversibility with bronchodilators predicts a good outcome in acute bronchial asthma. It can be delivered by Nebuliser and MDI with spacer. Now-a-days MDI and spacer is useful in acute asthma. The clinical significance of MDI and spacer lies is the amount of drug that reaches lower airways. It depends upon the aerodynamic mass median diameter. According to Mazhar SH et al study[4], in nebuliser only ten percent of the dose reaches the lungs after leaving the nebuliser. In contrast, in MDI with spacer approximately twenty percent of drug dosage is deposited in the peripheral airways. Spacers are known to improve the compliance of the patient, increase the efficacy of drug delivery and reduce oral absorption compared to MDI without spacers or holding chamber. Their use is particularly valuable in patients who have poor timing and do not adequately coordinate inhalation from an MDI with the actuation of the device. MDI requires less drug dosage compared to a nebuliser.

Kenneth B. Newman *et al*[5] who reported there was a statistically greater improvement in peak flow rates in the MDI/spacer group vs nebulized group (126.8 vs 111.9 L/minute, respectively; p value equal to .002), had showed a lesser total salbutamol dosage (one thousand and hundred twenty five micro gm and six thousand and seven hundred micro. gm, respectively; p value less than 0.001), and showed a maximum improvement in Sa O_2 (p value equal to 0.043).According to Rodrigo et al[6] study there was a significant improvement in PEFR, FEV_1FVC at 30 mts and at the end of treatment in MDI spacer group compared to nebulised group. The magnitude of improvement of PEFR at 30 minutes was (77+/-46Litre/minute) in the nebuliser category and (83+/-61 Litre/minute) in the Metered Dose Inhaler-spacer category ; (p value less than .01)and at the end of therapeutic trial(112+/-52Litre/minute in the nebuliser category and 119 Litre /minute) in the Metered Dose Inhaler –spacer category ;(p value less than 0.001) .The improvement of average Forced Vital Capacity was significant over pretreatment values in both nebuliser and Metered Dose Inhaler-spacer categories;(p value less than .001);the values at thirty mts being (.7+/- .4 Litres and .7+/-.6 Litres), respectively for nebulised and MDI spacer; (p value less than .01) and (1+/- .6Litres and 1.0+/-0 .7 Litres,) respectively; (p value less than .001) after the cessation of therapy. Similar changes in measurements was held for FEV_1. At thirty minutes, FEV_1 increased by (0.5+/-0.3Litres) in nebuliser category and (0.6+/-0.5 Litres) in Metered Dose Inhaler-spacer category (p value less than .01). At the end of therapeutic trial Forced Expiratory Volume in 1 second increased (.8 +/- .4 Litres) in nebuliser category and (.9 +/- .5 Litres) in Metered Dose Inhaler-spacer category (p value less than .001) But there was no statistically significant difference in heart rate between the nebulised and Metered Dose Inhaler-Spacer group. Dosage of salbutamol in Metered Dose Inhaler group was lower compared to nebulised group.

Idris et al[7] reported that a significant improvement occurs in average Forced Expiratory Volume in 1second at thirty minutes (p value less than .02) and at sixty minutes (p value less than .02) and in maximum average (p value is less than .001). According to Christopher J Cates[8], statistically significant differences were seen between the two categories in baseline pulmonary function. Results were presented only as change in Pulmonary function from the baseline, and this favoured the spacer. There were no significant differences demonstrated between the two categories in their outcomes : change in respiratory rate and oxygen saturation.

This study supported and confirmed the evidence that MDI+spacer is equivalent to nebuliser in the management of acute attack of asthma. Overall care strategy of any management guidelines should include evidence on efficacy, ease of use, acceptability and cost of each treatment modality. Nebulisers are expensive, time consuming and inconvenient during travel.

CONCLUSION:

Base line characters were not comparable in the study. The patients were equally divided into two groups for better comparison.PEFR improvement was significant at 30 mts and at end of treatment with the MDI-Spacer group than the nebulised group.FEV_1 improvement was also significant at 30 mts and at end of treatment with the MDI-Spacer group than the nebulised group.FVC improvement was also significant at 30 mts and at end of treatment with the MDI-Spacer group than the nebulised group. For oxygen saturation, the magnitude of improvement was significant at 30 mts in the spacer group, but at the end of treatment the improvements were similar in both the groups.Heart rate and respiratory rate improvement was present in both groups and were similar in both at 30 mts and at the end of treatment.Clinical improvement was achieved even at a lower dosage in the MDI-spacer group compared to nebuliser group. Salbutamol administration by metered dose inhaler and spacer is as efficacious as nebuliser in adults with acute asthma. Now-a-days Metered Dose Inhaler and Spacer is the best alternative to nebuliser in acute asthma.

LIMITATIONS :

Some patients did not respond to short acting beta2 agonists even after maximum doses were given, they were switched over to systemic medications like corticosteroids. Others were not able to perform pulmonary function tests before the medication because of poor compliance. Patients presenting with Status asthmaticus and Near fatal asthma required life saving measures apart from routine medications. Reversibility with Bronchodilators did not occur with a few patients, who had associated chronic obstructive pulmonary disease or had developed chronic inflammatory process in asthma leading to irreversible air flow obstruction. These patients were not included in the study.

Table1 Characteristics of patients

Characteristics of patients	MDI-Spacer Group (n = 26) Mean±SD	Nebulized Group (n = 26) Mean±SD	*'P'*
SPO2 (30 min)	3.92+0.404	2.23+0.430	< 0.001 Significant
SPO2 (end)	2.23+0.430	2.12+0.326	0.304 Not Significant
PEFR (30 min)	212.31+7.65	189.62+9.16	< 0.001 Significant
PEFR (end)	227.31+10.02	210.77+9.77	< 0.001 Significant
FEV1 (30 min)	1.408+0.011	1.371+0.023	< 0.001 Significant
FEV1 (end)	1.635+0.028	1.602+0.015	< 0.001 Significant
FVC (30 min)	1.425+0.025	1.396+0.020	< 0.001 Significant
FVC (end)	1.656+0.022	1.622+0.013	< 0.001 Significant
HR (30min)	15.00+0.632	14.923+0.688	0.677 Not Significant
HR (end)	9.923+0.272	9.423+1.391	0.078 Not Significant
R R (30 min)	14.808+0.567	14.538+0.508	0.077 Not Significant
RR (end)	5.077+5.077	5.038+0.196	0.561 Not Significant

(Values are expressed as mean -+ SD)

Table2 Salbutamol in MDI-spacer Vs Nebulizer

Drug Doses	Mean+ SD
MDI – S (26)	1192.3 + 146.76
Nebulizer (26)	4365.3+1836.07
'p' value	< 0.001 Significant

(Values are expressed as mean -+ SD)

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