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Original Research Article

Comparison of clinical efficacy of nebulised salbutamol and salbutamol metered dose inhaler in children with mild or moderate exacerbation of bronchial asthma

Jose O.*, Sunil Daniel, Minu Krishnan

Department of Pediatrics, Government T D Medical College Alappuzha, Vandanam, Kerala 688005, India

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***Correspondence:**
Dr. Jose O.,
E-mail: jeenajos1968@gmail.com

ABSTRACT

Background: Bronchial asthma is the commonest chronic disease in industrialized nations. Aerosol therapy has revolutionized the treatment of bronchial asthma in children as in adults. Even though nebulisation is a simple technique, it is expensive and there is a need for power source. The aim of the study was to compare the clinical efficacy of nebulised salbutamol and salbutamol metered dose inhaler (MDI) in children with mild or moderate exacerbation of Bronchial asthma.
Methods: This study was a hospital based randomized control study carried out between March 2009 to December 2009 on children attending OP or casualty of Government Medical College, Alappuzha with mild or moderate exacerbation of bronchial asthma.
Results: 60 subjects were selected for the study out of which 30 were assigned to salbutamol MDI group and the other 30 to salbutamol nebulisation group. After the administration of drug, all the studied variables showed significant improvement in both groups (p value <0.001). Percentage predicted PEFR increased by about 27% in nebulisation group and 26% in MDI group; however this difference was not statistically significant (P value = 0.99).
Conclusions: In this study we concluded that the efficacy of salbutamol in mild or moderate acute exacerbation of asthma was similar when the drug is delivered either by nebuliser or MDI with spacer.

Keywords: Bronchial asthma, Randomized control study, Salbutamol MDI

INTRODUCTION

Bronchial asthma is the commonest chronic disease in industrialized nations. According to ISAAC study group (International study on asthma and other allergies in children) worldwide prevalence of bronchial asthma is 36%-38% in the year 1992.[1] The prevalence of asthma in India has increased significantly in the last 20 years i.e. from 9% in 1979 to nearly 30% in 1999.

Aerosol therapy has revolutionized the treatment of bronchial asthma in children as in adults. Different delivery systems used in children has its own unique advantages and disadvantages. Commonly used delivery systems include pressured metered dose inhaler (MDI) with or without spacer, dry powder inhaler (DPI) and nebulisers. Even though nebulisation is a simple technique, it is expensive and there is a need for power source.[2-4] Some inconvenience is there with its use and there is a risk for bacterial contamination.

So we conducted a study to compare the clinical efficacy of nebulised salbutamol and salbutamol metered dose inhaler (MDI) in the management of mild to moderate exacerbation of bronchial asthma in children.

METHODS

This was a hospital based randomized control study carried out between March 2009 to December 2009 on children attending OP or casualty of Government Medical college, Alappuzha with mild or moderate exacerbation of bronchial asthma.

A total number of 60 children were made a part of this study. Of this 30 children were assigned to Salbutamol nebulisation group. Other 30 were assigned to salbutamol MDI group. There were 17 boys and 13 girls in salbutamol nebulisation group. The number of boys and girls in salbutamol MDI group were 13 and 17.

Inclusion criteria

Children of 2 to 10 years age group presents with acute exacerbation of asthma, children belonging to classification of mild intermittent/mild persistent asthma and who are having pulmonary score index of 3 to 6 were included in the study.

Exclusion criteria

Patients of age less than 2 years, pulmonary score index who are having more than 6, clinical and or radiological evidence of pneumonia, children on inhaler therapy, children with other systemic diseases and children with duration of symptoms more than 12 hours at the time of presentation were excluded from the study.

Study procedure

Those children satisfying inclusion criteria were taken for the study. Informed consent is taken from the parents after explaining the details of study, the effects and side effects of drugs used in the present study. For half of the study group nebulised salbutamol were given in the dose of 0.15 mg/kg (0.25 ml for less than 6 months, 0.5 ml for children more than 6 months, 0.5 ml – 1 ml for older children).

All patients received 3 nebulisations at 20 minutes interval with oxygen and cardiac monitoring. And for the other group Salbutamol MDI (100 micrograms/puff) 4 puffs at a time 20 minutes interval for 3 doses is given with the help of spacer with valve. heart rate, pulmonary score index, peak expiratory flow rate and the oxygen saturation were monitored in both groups before treatment and after each dose of drug.

The heart rate and Oxygen saturation of the patients were monitored with the help of pulse oxymeter. Pulmonary score index is assessed clinically which includes respiratory rate, accessory muscle (sternomastoid) activity and wheezing. Peak expiratory flow rate was assessed with peak expiratory flow meter. Three measurements were taken with flow meter, of which the best value is taken. Heights of all patients were measured with stadiometer in centimeters. This is for calculating the predicted PEFR of the patient.

Predicted PEFR = (Height in cm–100) × 5 + 100.

The Questionnaire included questions regarding family history of Bronchial asthma and pulmonary tuberculosis, duration of the disease and the duration of present symptoms.

Statistical analysis

The data was entered into Microsoft Excel before analysis. Median value and the 95% confidence interval were calculated for age, duration of disease, heart rate, PSI, SpO_2 and percent predicted PEFR separately for salbutamol nebulisation group and salbutamol MDI group. The difference in these variables between the Salbutamol nebulisation and Salbutamol MDI groups were done using Student's t- test for independent samples.

The Baseline characteristics such as sex, family history of bronchial asthma and family history of pulmonary tuberculosis in salbutamol nebulisation and salbutamol MDI groups were compared using chi- square test for association. The improvement in the Heart rate, PSI, SpO_2 and percent predicted PEFR within the Salbutamol nebulisation group and Salbutamol MDI group after treatment were compared to the baseline values using paired t- test for statistical significance.

RESULTS

60 subjects were selected in this study, out of which 30 were assigned to salbutamol MDI group and the other 30 to salbutamol nebulisation group. In this study, boys were more in nebulisation group but girls were more in MDI group. Bronchial asthma was present in family history of 16 cases of nebulisation group and 17 cases in MDI group.

A positive family history of pulmonary tuberculosis was seen in 2 cases of nebulisation group and 3 cases of MDI group. The difference in the two samples in terms of age in years, sex, family history of bronchial asthma, pulmonary tuberculosis and duration of the disease were comparable and was found to be statistically significant as given in Table 1.

The baseline characteristics of the study population includes heart rate, pulmonary score index, oxygen saturation level and percent predicted PEFR and observed that there was no statistical significance between the 2 groups as given in Table 2.

Table 1: Demographic and disease related characteristics of the samples.

Characteristics		Nebulisation group (n = 30)	MDI group (n= 30)	P value
Age (years)	Median (95% CI)	7.0 (6.6, 7.6)	7 (7.1, 8.1)	0.12
Sex	Male:Female	17:13	13:17	0.44
FH/O BA	Present	16	17	0.79
FH/O PTB	Present	2	3	0.64
Duration of disease (years)	Median (95% CI)	3 (2.8, 3.6)	3 (2.6, 3.6)	0.75

Table 2: Characteristics of sample at baseline.

Characteristic	Nebulisation group (n = 30)	MDI (n = 30)	P value
Heart Rate *	104 (102.6, 109.4)	102 (101.4, 107.9)	0.55
PSI*	6 (5.3, 5.7)	6 (5.2, 5.8)	0.99
SpO_2*	94 (93.3, 94.2)	94 (93.2, 94.6)	0.70
Predicted %PEFR*	66.2 (64.91-67.49)	66.4 (65.38-67.42)	0.78

* Median and 95% confidence interval.

Table 3: Characteristics of sample at third dose (post-treatment).

Characteristic	Nebulisation group (n = 30)	MDI (n = 30)	P value
Heart Rate *	129 (125.6, 131.2)	124 (123.1, 129.2)	0.29
PSI*	2 (1.6, 2.0)	2 (1.8, 2.0)	0.34
SpO_2*	98 (98.0, 98.4)	98 (98.1, 98.6)	0.53
% Imprvt PEFR*	27 (25.50, 27.56)	26 (25.44, 27.62)	0.99

* Median and 95% confidence interval.

Outcome variables were subjected to statistical tests for significance. There was no statistically significant difference between the two groups. Percentage predicted PEFR increased by about 27% in nebulisation group and 26% in MDI group; however this difference was not statistically significant (P value = 0.99) as given in Table 3. After the administration of drug, all the studied variables showed significant improvement in both groups (p value <0.001) as shown in Table 4.

Table 4: P values of variables in baseline vs. post treatment.

	Nebulisation group	MDI group
Heart rate	0.001	0.001
PSI	0.001	0.001
SpO_2	0.001	0.001
Predicted % PEFR	0.001	0.001

DISCUSSION

Aerosol therapy has been a major breakthrough in the treatment of asthma. It is very safe and effective in the management of bronchial asthma. Nebulisers play the major role in the hospital management of asthma. It is easy to operate but it requires power supply and the patient should be monitored during the treatment. MDI on the other hand is also safe and effective but patient compliance and effort of patient determines optimal effect and no power supply or monitoring required for its use. Incoordination of inhaler actuation with inspiration in the most important error made by most of the patients. The use of a spacer device eliminates the need for breath-hand co-ordination.

In the present study we observed that the efficacy of salbutamol in mild or moderate acute exacerbation of asthma were similar when the drug is delivered either by Nebuliser or Metered dose inhaler with spacer. There are a number of studies regarding the efficacy of salbutamol MDI and salbutamol Nebulisation both in adults and children.[5-7] The bronchodilator, cardiovascular and tremerogenic effects following administration of salbutamol, terbutalin and fenotrol by intermittent nebulisation was compared by Scalabrin et al.[5] The authors reported equal efficacy in the treatment of acute asthma. They also reported similar onset of action for all the drugs. They also demonstrated drug delivery by metered dose inhaler with spacer is equally effective as that achieved by nebulisation. Kabra et al compared the efficacy of salbutamol MDI and salbutamol DPI in acute exacerbations of asthma. In their study they concluded that MDI with spacer and DPI have equal efficacy is delivering salbutamol in therapy of mild to moderate acute exacerbation of bronchial asthma in children.[6,7] Kabra et al also compared the efficacy of terbutaline and salbutamol inhalation in children with mild or moderate exacerbation of Asthma. The final conclusion in that study was that terbutaline and salbutamol when administered by MDI with spacer are equally efficacious

in children with mild or moderate exacerbation of asthma.[7]

The other concern was about the side effects of the drug administered. In our study there was an increase in heart rate from the baseline of 104 to 129 in nebulisation group and 102 to 124 in MDI group. Tachycardia was more in case of nebulisation group. However the after treatment heart rate of either groups when compared showed no statistical significance. This means salbutamol nebulisation and salbutamol MDI has equal potential in causing tachycardia.

Even though we designed this study in 2-10 year old age group, we have included only the children of 5-10 years because of the inability of children below 5 years to cooperate for the PEPR evaluation.

CONCLUSION

Salbutamol when administered by MDI with spacer or with nebulizer had shown equal efficiency in children with bronchial asthma and we recommend the salbutamol MDI in the OP management of mild or moderate exacerbation of bronchial asthma in children in office practice and centers where there are only limited facilities and health care professionals.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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