ONLINE ISSN :3007-309X PRINT ISSN :3007-3081



Journal Of Medical & Health Science Review



COMPARISON OF SALBUTAMOL DELIVERED BY METERED DOSE INHALER WITH SPACER VERSUS NEBULIZER IN ASTHMATIC CHILDREN PRESENTING IN PAEDIATRIC EMERGENCY

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ARTICLE INFO

ABSTRACT

Keywords: salbutamol, Peak expiratory flow rate, metered dose inhaler.

Corresponding Author: Waqar Mushtaq, Paediatric Medicine, Unit-I, KEMU, Lahore, Email:<u>Waqar.mushtaq@gmail.com</u> **Background:** Asthma is one of the most common chronic respiratory diseases in children, often presenting with acute exacerbations requiring prompt management in emergency settings. Salbutamol, a short-acting beta-agonist, is frequently used for rapid bronchodilation, delivered either via nebulization or metered-dose inhaler (MDI) with spacer. While nebulization is a traditional method, MDIs with spacers are emerging as an effective, convenient, and cost-efficient alternative. However, evidence comparing their clinical efficacy in pediatric emergency settings remains limited, particularly in resource-constrained environments.

OBJECTIVE: To compare the clinical efficacy of salbutamol administered by metered-dose inhaler with a spacer by nebulizer for the treatment of asthmatic children in emergency.

MATERIAL and METHODS: This Observational analytical comparative study was conducted at the Department of Paediatric Medicine Unit I, King Edward Medical University, Lahore / Mayo Hospital, Lahore, from November 2011 to March 2013.A total of 230 patients (age 5-12y) were included in the study after randomization. They were divided in two groups. In Group-1, 109 patients were included and nebulization technique was used. In Group-2, 111 patients were included and meter dose inhaler with spacer was used. Clinical efficacy was measured at 3hours of treatment. Modified pulmonary index score <9 and \geq 20% increase in Peak exp flow rate were taken as parameters of improvement.

Results: Group-1 patients had mean age of 8.2±2.59y compared to 7.57±2.23y in Group-2. in group-1was 27.5±6.7/min on admission and 21.9±5.6/min on discharge. In Group-2, mean resp rate was 27.5±5.6/min on admission and 21.8±5.0/min at discharge. in Group-1was 125.6±9.6/min on admission and 98.7±10.0/min at discharge. In Group-2, mean heart rate was 115.6±5.9/min on admission and 97.3±8.5/min at discharge. Mean Oxygen saturation in Group-1, was 90.9±0.84% on admission and 93.6±1.17% at discharge. In Group-2, mean oxygen saturation 90.15±7.81% on admission and 93.64±0.97% at discharge. Mean Peak expiratory flow rate (L/min) in Group-1 was 149.2±47.5 on admission and 199.2±64.9 at discharge. In Group-2, mean peak expiratory flow rate (L/min) was 152.4±46.9 on admission and 230.4±27.2 at discharge. Mean modified pulmonary index score in Group-1was 8.7±0.68 on admission and 6.2±0.87 at discharge. In Group-2, mean modified pulmonary index score was 8.6±1.15 on admission and 6.2±0.95 at discharge. In Group-1 56.9% were male and 43.1% were females. In Group-2 61.3% were male and 38.7% were female.

Conclusion: Our results showed that clinical efficacy of both techniques measured as pulmonary index score < 9 and peak expiratory flow rate > 20% was achieved; hence both techniques were comparable and effective. Based on comparative efficacy, simplicity, convenience and financial advantages, meter dose inhalers with spacer can be recommended for use in children with asthma.

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INTRODUCTION

Wheezing is a common presenting symptom of respiratory disease in children. Epidemiologic studies conducted worldwide have shown that 10 to 15 percent of infants wheeze during the first year of life, and as many as 25 percent of children younger than five years of age present to their clinicians with wheezing respiratory illnesses¹. Most children with recurrent wheezing are very likely to have asthma, regardless of the age of onset, evidence of atopic disease, precipitating causes, or frequency of wheezing. However, other diseases can present with wheezing in childhood, and patients with asthma may not wheeze. Therefore, the initial evaluation of a wheezing child should be directed toward the exclusion of alternative diagnoses, followed by a therapeutic trial of bronchodilators.²

Administration of bronchodilators by nebulizers in busy emergency departments is often difficult, given the number of patients and the limited availability of oxygen ports. Metered-dose inhalers (MDIs) have provided a quicker and more cost effective way to deliver aerosolized bronchodilators for asthma treatment in older children and adults. However, younger patients are often unable to coordinate inspiration with activation of the MDI, thereby limiting the amount of drug inhaled. The introduction of spacer devices has helped solve this problem^{4, 5}. Use of nebulizers has some disadvantages like lack of portability, pressurized gas source required, lengthy treatment time, device cleaning required, contamination risk, not all medication available in solution form, does not aerosolize suspensions well ,device preparation required, performance variability and cost⁶. While MDI inhalers with spacers have advantages like portable and compact, short treatment time, no drug preparation required, no contamination of contents, dose-dose reproducibility high and being cheap when compared with nebulizers⁷⁻⁹. In children with wheezing, equivalent if not better outcomes have been reported with spacers vs. nebulizers for the delivery of aerosolized salbutamol. Few studies that have looked at the efficacy of MDIs with spacers in administering salbutamol have selectively enrolled children aged 2 years and older ¹⁰

The objective of study was to compare the clinical efficacy of Salbutamol administered by metered-dose inhaler (MDI) with a spacer device with the administration of Salbutamol by nebulizer for the treatment of asthmatic children in emergency.

Clinical efficacy was measured by Improvement in modified pulmonary index score to <9 and a Rise in Peak Expiratory Flow Rate, more than 20% of the predicted value. Salbutamol inhaler (<u>metered-dose inhaler</u>) was used in a strength of 100μ g/puff. Salbutamol Nebulization solution was used, which comes in strength of 5mg/ml for nebulization.

METHODOLOGY

It was a cross-sectional analytical study which was conducted from November 2011 to March 2013 in the emergency section of Paediatric Medicine King Edward Medical University, Lahore / Mayo Hospital Lahore. Two hundred children with asthma reporting consecutively to emergency section of Paediatric Medicine KEMU / Mayo Hospital Lahore will be enrolled. Children aged between 5- 12 years, having either gender, known asthmatics and moderate asthma (MPIS 9-12) were included. Children with clinical and radiological evidence of pneumonia, Pneumothorax, pleural effusion, altered level of consciousness; Respiratory failure, Shock, Congenital Heart Diseases, Tuberculosis, Foreign body, Non co-operative patients and severe asthma were excluded from study. It was Non Probability purposive sampling technique was used and patients were divided in two groups, one hundred in each group.

Group one was managed with nebulization of salbutamol while group two was managed with salbutamol inhaler with spacer device. The sample size was calculated by taking incidence rate of Asthma 20% with 95% confidence interval and taking the absolute precision at 5.5% or 0.055. After taking informed consent Two hundred children were enrolled who fulfilled the

inclusion criteria were selected from emergency section Paediatric Medicine KEMU / Mayo Hospital Lahore.

Sociodemographic profile i.e. name, age, sex and socioeconomic background was recorded. History of previous attack of asthma and visit to emergency department or admission in the hospital was recorded. Heart rate, Respiratory rate, auscultatory findings, oxygen saturation, Inhalational / Exhalation ratio and use of accessory muscles was recorded at admission and one hourly for four hours. Disease severity was categorized according to modified pulmonary index score (MPIS¹³). Peak Expiratory Flow Rate (PEFR) was recorded on admission then one hourly for three hours, which was taken as separate variable. PEFR, less than 60% of predicted value was labeled as severe asthma. PEFR, 60 – 80% of predicted value was taken as mild asthma¹⁴. X-Ray chest of all the patients was done. Group 1 was nebulized with 0.5 ml of salbutamol solution with addition of 2ml of normal saline in each hour for three hours and group 2 patients were treated with 4 puffs of salbutamol inhaler was given in each hour for three hours).

Data was entered and analyzed in SPSS v13.0. The Quantitative data was presented in the form of Mean \pm SD. The Qualitative data was presented in the form of frequency and percentage. Paired sample t-test was used to compare the effectiveness of respiratory rate, oxygen saturation and Peak Expiratory Flow Rate. Chi-Square test was used to see the effectiveness of both techniques in the qualitative outcome (Auscultatory findings, Chest Retractions, Dyspnea and Cyanosis). P-value <0.05 was taken as significant.

RESULTS

Group-1 patients had mean age of $8.2\pm2.59y$ compared to $7.57\pm2.23y$ in Group-2. in group-1was $27.5\pm6.7/min$ on admission and $21.9\pm5.6/min$ on discharge. In Group-2, mean resp rate was $27.5\pm5.6/min$ on admission and $21.8\pm5.0/min$ at discharge. in Group-1was $125.6\pm9.6/min$ on admission and $98.7\pm10.0/min$ at discharge. In Group-2, mean heart rate was $115.6\pm5.9/min$

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TABLE-1

AGE DISTRIBUTION IN TREATMENT GROUPS

	Group-A	Group-B	
n	100	100	
Male	56	62	
Female	44	38	

TABLE-2

FINAL OUTCOME IN TREATMENT GROUPS

	Group-A	Group-B
Effective	91	90
Not Effective	9	10
Total	100	100

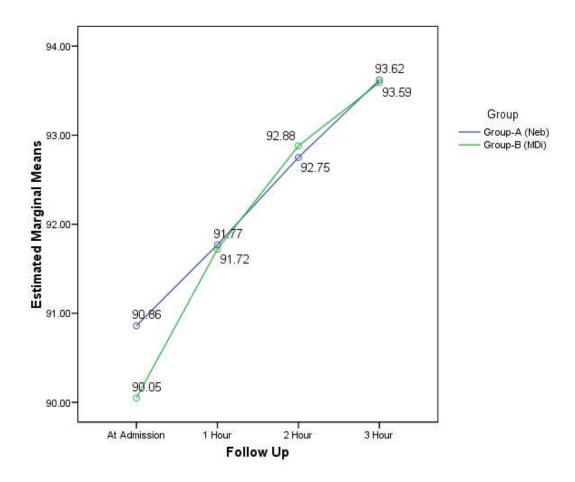
Chi-Square Test= 0.58

p-value= 0.809

Group-A= Salbutamol+ 2ml of normal saline

Group-B= Salbutamol inhaler with spacer

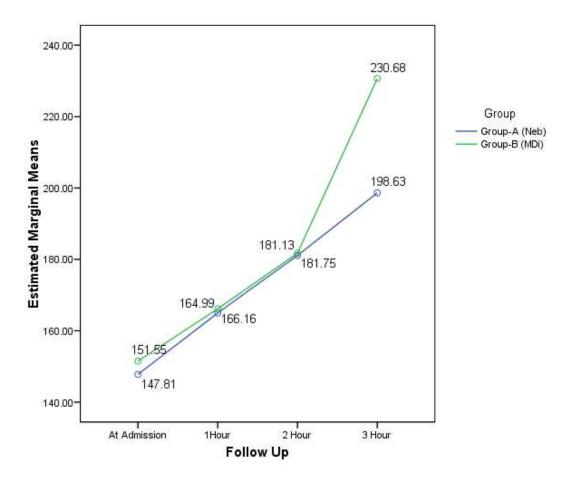




Group-A= Salbutamol+ 2ml of normal saline *Group-B*= Salbutamol inhaler with spacer

FIGURE-2

PEAK FLOW RATE IN TREATMENT GROUPS

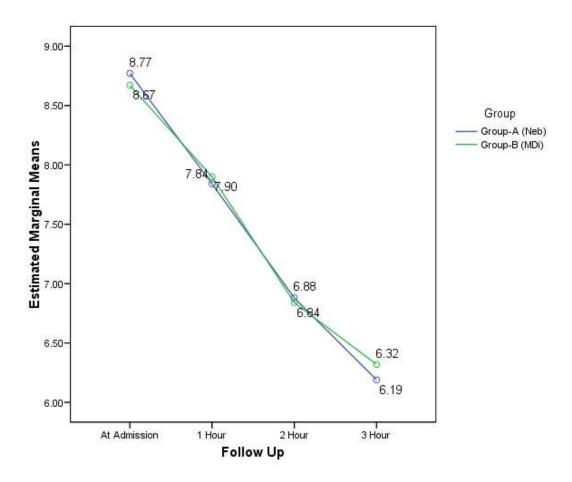


Group-A= Salbutamol+ 2ml of normal saline

Group-B=	Salbutamol	inhaler	with	spacer

FIGURE-3

MODIFIED PULMONARY INDEX SCORE (MPIS) IN TREATMENT GROUPS



Group-A= Salbutamol+ 2ml of normal saline *Group-B*= Salbutamol inhaler with spacer

DISCUSSION

Results of this study showed that salbutamol administered by metered dose inhaler (MDI) with a spacer device and by nebulizer both are effective in terms of modified pulmonary index score (MPIS) for the treatment of asthmatic children in emergency. Observed efficacy based on MPIS in GroupA was 91% and in Group-B it was 90%.Fayaz et all in his study didn't find any major difference between the two groups, moreover MDI+spacer was better than nebuliser for the treatment of severe acute asthma attack in children.¹³. Alhaider et all in his study the duration of treatment preparation and delivery was significantly lower in the MDI-spacer group (2 min reduction in preparation time and 5 min reduction in delivery time;p<0.01). Conversion to MDI-spacer for BDs and ICSs administration in hospitalized children improve hospital resource utilization.¹⁴ Jamalvi et all in his study reported that MDI/AD is an effective alternative to nebulizer for the treatment of children with acute asthma exacerbation in the ER.¹⁵

Fernandez et all in his study reported that administration of bronchodilators using a metereddose inhaler with spacer is an effective alternative to nebulizers for the treatment of children with acute asthma exacerbations in the emergency department.¹⁶ The use of a pMDI with a spacer (pMDI+S) is more effective than use of a nebulizer in young children in the emergency department setting.¹⁷⁻¹⁹

Studies have shown that in asthmatic children, use of MDI-spacers and nebulizers for bronchodilator administration in the emergency department have resulted in similar clinical responses, with shorter duration of stay, lower incidence of tachycardia, and even lower rate of admissions. In one study, 168 infants (aged 2-24 months) were randomized in a double blind trial comparing MDI-spacer- to nebulizer-administered albuterol for wheezing episodes in the emergency department.⁴ Patients in the spacer group had a significantly lower admission rate (5% versus 20% in the nebulizer group), received fewer treatments, had a lower mean increase in heart rate and were less likely to receive steroids. Lower admission rates in the spacer group were found primarily in children with more severe asthma exacerbation.⁴ Another randomized, doubleblind, placebo-controlled trial in an emergency department at a children's hospital included children 1-4 years of age with moderate to severe acute asthma. The spacer was as effective as the nebulizer in terms of

clinical score, respiratory rate, and oxygen saturation but produced a greater reduction in wheezing (p-value=0.03). Heart rate increased to a greater degree in the nebulizer group (11.0/ min vs. 0.17/min for spacer,p<0.01). Fewer children in the spacer group required admission (33% vs. 60% in the nebulizer group,PZ0.04, adjusted for sex). No differences were observed in rates of tremor or hyperactivity.²⁰ A report on US children's hospital's strategy to implement conversion to MDI-spacer showed increase spacer use from 25% to 77% among all non-intensive-care patients receiving albuterol and from 10% to 79% among patients with asthma (p<0.001).²⁰

This study confirms and adds to the previous evidence that MDI+spacer is as affective as a nebulizer in treating acute exacerbation of asthma in paediatrics.¹²⁶⁻¹²⁸ Reasons for this are that the child is used to it, so cooperates well (a new technique might be frightening); parents can help the child (a nurse can scare and upset a child);and some nebulizers are not O 2 driven, can interrupt high flow O2 for a considerable time in case of moderate to severe attack. There are many additional advantages for example to use a nebulizer, an experienced nurse should be available for 15–20 minutes which is quite difficult in busy emergency units. There are fewer side effects with spacers like tachycardia and that spacers are cheaper and portable.²¹

Furthermore, in third world countries commercially produced spacers are generally unavailable or too costly. Studies have tested the efficacy of home made spacers (500 ml plastic bottle and polystyrene cup) with conventional spacers for delivery of beta2 agonists via MDI in the management of acute exacerbation of asthma in children and concluded that both these devices are least as effective as a spacer. Children under 3 year of age were excluded for reasons documented earlier on, but studies have proved that MDI+spacer+mask are equivalent to or better than nebulizers in children as young as 6 months to 24 months.^{22,}

CONCLUSION

Both techniques showed that clinical efficacy measured as pulmonary index score < 9 and peak expiratory flow rate > 20% was achieved; hence both techniques were comparable and effective. Based on comparative efficacy, simplicity, convenience and financial advantages, meter dose inhalers with spacer can be utilized in children.

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