

NEBULIZERS VS METERED DOSE INHALERS IN MILD TO MODERATE ASTHMA EXACERBATIONS IN CHILDREN

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ABSTRACT

Background: Despite the demonstrated equivalency, rapid delivery, and lesser use of personnel resources with the MDI/spacer combination, nebulized salbutamol remains the standard therapy for patients with acute asthma.²³ Patients' perception of the nebulizer being more effective, the lack of coordination between MDI actuation and inhalation when using an MDI/spacer during acute asthma, especially for first time users, and the notion that delivery with non-disposable commercial spacers is more expensive, has limited the use of spacers in the ED.²⁴ **Objective:** To compare the effectiveness of administration of salbutamol by metered-dose inhaler with spacer and administration of salbutamol by nebulizer to treat asthma exacerbation in children aged 1-5 years. **Methodology:** The study was a prospective Randomized controlled trial, conducted in the pediatric emergency department of a tertiary care government hospital. Subjects n₇₅ received salbutamol with a nebulizer and the spacer group n₇₅ received salbutamol by MDI/spacer, symptom scores were monitored in the two groups. **Results:** In the nebulizer group, 76%(57nos) patients had mild breathlessness, decrease in alertness, wheezing and mild suprasternal retractions and 24% (18nos) had moderate symptoms. After the therapy 76% were relieved from the symptoms and 24% had mild problems. In the MDI spacer group 92% (69nos) had mild symptoms and 8% (6nos) had moderate symptoms. After the therapy 92% were relieved of the symptom and 8% had mild problems.

Conclusion: It is concluded that MDI-spacer is as effective as a nebulizer for the aerosolized administration of salbutamol in an acute exacerbation of asthma in children. However, for developing countries, distinct advantages (economic and power requirement) argue strongly for utilization of MDI-spacer in preference to nebulizer.

Keywords: Spacer, Metered dose inhaler, MDI, asthma.

INTRODUCTION

Asthma is a chronic airway disorder that affects people of all ages throughout the world. It is a serious global health problem with an estimated 300 million affected individuals.¹ An additional 100 million may be diagnosed with asthma by 2025.² Asthma thus poses a significant burden in terms of health care cost and lost productivity.¹

In order to combat the problem of non delivery of the beta agonists to the peripheral airways for relief of bronchospasm, two different methods can be employed: wet nebulization and

metered-dose inhaler (MDI) with a spacer (holding chamber). Nebulization can be accomplished with room air or supplemental oxygen, and requires a supply of compressed gas or a power source. High doses of beta-agonist are put into the nebulization chamber (typical up to 25 times the dose from a MDI), but much of this dose is lost into the atmosphere and never reaches the patient's airways.

More recently, beta-agonists delivered via MDIs through a spacer have been used in acute asthma. The inhaler is actuated into the

chamber that is then emptied by the patient using either tidal breathing or single breaths⁵⁴. Inhaled β_2 -agonists are the drug of first choice for relieving bronchospasm in children too. Despite the demonstrated equivalency, rapid delivery, and lesser use of personnel resources with the MDI/spacer combination, nebulized salbutamol remains the standard therapy for patients with acute asthma.²³ Patients' perception of the nebulizer being more effective, the lack of coordination between MDI actuation and inhalation when using an MDI/spacer during acute asthma, especially for first time users, and the notion that delivery with non-disposable commercial spacers is more expensive, has limited the use of spacers in the ED.²⁴

This study hypothesized that Salbutamol delivered with a disposable spacer would be an efficient, alternative to nebulized Salbutamol treatment for children with mild to moderate asthma exacerbation presenting to the ED.

OBJECTIVE AND METHODOLOGY

OBJECTIVE

To compare the effectiveness of administration of salbutamol by metered-dose inhaler with spacer and administration of salbutamol by nebulizer to treat asthma exacerbation in children aged 1-5 years.

METHODOLOGY

The study was a Randomized controlled trial conducted at the Pediatric emergency department of Sree AVITTAM THIRUNAL HOSPITAL MEDICAL COLLEGE, TVPM for a period of SIX MONTHS (From the date of ethical committee approval). The inclusion criteria were children with diagnosed mild to moderate bronchial asthma exacerbation (according to GINA guideline) aged 1-5yrs. Children presenting with asthma exacerbation in the age group of 1 to 5 years at the pediatric casualty were identified. Informed written consent was obtained; asthma history and demographic data were collected. Demographic data included age and sex of patient. Baseline characteristics of Patients were evaluated on the basis of symptoms and signs that included breathlessness, alertness, and respiratory rate, use of accessory muscles, wheeze, and pulse/min. and noted.

For patients in the nebulizer group each treatment consisted of standard dose of 0.15mg/kg of salbutamol in 3ml of isotonic saline delivered by a oxygen driven nebulizer.

For administration of MDI, the investigator dispensed 1 puff of salbutamol into the spacer and held the mask on the child's face while the

child breathed for 5 to 6 times through the mask. This process was repeated for a total of 4-6 puffs per treatment if needed.

Patients were reassessed by physician at the end of the treatment in each group on the basis of improvement of symptoms and signs

Outcome was measured by relief of symptoms assessed by change in respiratory rate (number of respirations/minute) and pulse/minute. And alertness of child based on subjective findings (breathlessness, talk, use of accessory muscles and wheeze).

Sample size calculated after pilot study as n=75 in group A (nebulizer group) and n=75 in group B (MDI with Spacer group).

RESULTS

A total of 150 patients who satisfied the inclusion criteria were enrolled for the study. 75 patients were included in the nebulizer group and 75 patients in the MDI spacer group. The total 150 patients in the two groups constitute the main study group for statistical analysis.

Socio-demographic background

1. Comparison of sample based on age

Majority of patients in both groups lie within 1.0 to 2.9 years age groups. The average age is 2.5 and 2.7 respectively in nebulizer and MDI spacer group respectively. The Chi square statistics ($p > 0.05$) shows that the age distribution of patients in both the groups are more or less similar.

2. Comparison of sample based on sex

It was found that the number of male patients in the nebulizer group and MDI spacer group was 41(54.7%) and 34(45.3%) were female. Chi square statistics ($p = 1.00$) shows that sex distribution in both the groups are more or less similar. This shows that male patients are more prone to asthma exacerbations under the age of 5 years.

Effectiveness and comparison of treatment on various symptoms

1. Breathlessness

Comparison of effectiveness on breathlessness under different therapy

In the nebulizer group 100% (75nos) had grade 1 changes and nil had grade 2 changes. In the MDI spacer group also 100% had grade 1 changes and nil had grade 2 changes. Mann-Whitney U test was used to compare the effectiveness of both the therapies on breathlessness, $p > 0.05$ shows that effect of both the therapies on the symptom of breathlessness is more or less similar.

2. Wheezing

In the nebulizer group 100% patients showed grade 1 changes and nil showed grade 2 changes. In the MDI Spacer group also 100% patients showed grade 1 changes and nil showed grade 2 changes. Mann-Whiney U test was u test was used to compare the effect of both therapies on the symptom of wheezing, $p > 0.05$ shows that the effect of both therapies on the symptom is more or less similar. (Table 1).

3. Respiratory rate

In order to compare the effect of the two therapies in reducing respiratory rate, Student t statistics is used. The average percentage decrease in respiratory rate is 19.2 and 17.0 respectively in nebulizer and MDI Spacer group. The t statistics ($p > 0.05$) shows that the percentage change in respiratory rate is more or less similar in nature in both groups.

4. Pulse/min

In order to compare the effect of the two therapies in reducing pulse/minute, Student t statistics is used. The average percentage increase in pulse/minute is 1.57 and 1.07 respectively in nebulizer and MDI Spacer group. The t statistics ($p > 0.05$) shows that the percentage change in pulse/minute is more or less similar in nature in both groups. (Table 2 and Figure 1).

DISCUSSION

- Although the Measurment of spirometry /PEFR would have given better results of the study, and since the study was carried out in a tertiary care government hospital where most of the patients belong to low socioeconomic status, thus missing the true reflection of society yet it can be seen that in both groups 41(54.7%)patients were males, and 34(45.3%) patients were females.
- In the nebulizer group, 76%(57nos) patients had mild breathlessness, decrease in alertness, wheezing and mild

suprasternal retractions and 24% (18nos) had moderate symptoms .After the therapy 76% were relieved from the symptoms and 24%had mild problems. In the MDI spacer group 92%(69nos) had mild symptoms and 8% (6nos) had moderate symptoms. After the therapy 92% were relieved of the symptom and 8% had mild problems.

- In the nebulizer group 76% (57nos) had mild problems in talking and 24% (18nos) had moderate problems in talking, because of asthma exacerbation. After therapy 85.3%(64nos) were relieved of their symptoms and 14.7%(11nos) had mild problems. In the MDI spacer group 92% (69nos) had mild difficulty in talking and 8%(6nos) had moderate difficulty in talking because of asthma exacerbation .After therapy 97.3% (73nos) were relieved of symptom while 2.7% had mild problem.
- The average respiratory rate was 50.0/minute and 39.5/minute respectively before and after therapy in the nebulizer group, while it was 44.7/minute and 36.8/minute in the MDI spacer group before and after therapy.
- The average pulse /minute were 105.7 and 102.8 before and after therapy in the nebulizer group. While the average pulse /minute were 103.1 and 99.9 respectively before and after therapy in MDI Spacer group.

CONCLUSION

From the study it can be concluded that MDI-spacer is as effective as a nebulizer for the aerosolized administration of salbutamol in an acute exacerbation of asthma in children. However, for developing countries, distinct advantages (economic and power requirement) argue strongly for utilization of MDI-spacer in preference to nebulizer.

Table 1:

Grade change in Wheezing	Nebuliser		Metered doze		Mann-Whitney U	
	Count	Percent	Count	Percent	Z	p
Nil	0	0.0	0	0.0	0.00	$p > 0.05$
1	75	100.0	75	100.0		
2	0	0.0	0	0.0		

Table 2: Comparison of effectiveness on Pulse/min under different therapy

	Mean (% increase)	SD	N	t	p
Nebuliser	1.57	6.97	75	0.49	0.621
Metered doze	1.07	5.14	75		

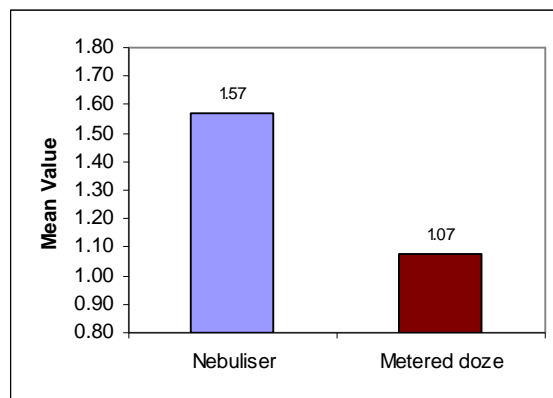


Fig. 1:

REFERENCES

- GINA. Global strategy for asthma management and prevention. National Institute of Health - National Heart, Lung and Blood Institute; Publication No 02-3659; 2008.
- Innes JA and Reid PT. Asthma. In: Boon NA, Colledge NR, Walker BR editors. Davidson's principle and practice of medicine. 20th ed. Edinburgh: Church Livingstone. 2006;670-8.
- Bedi RS. Patient education programme for asthmatics: Indian perspective. Indian J Chest Dis Allied Sci. 2007;49:93-8.
- Tavasoli S, Heidarnazhad H and Kazemnejad A. Factors affecting patients compliance to metered-dose inhaler drugs in two asthma clinics in Tehran, Iran. Iran J Allergy Asthma Immunol. 2006;5(4):187-93.
- Prabhakaran L, Lim G, Abisheganaden J, Chee CBE and Choo YM. Impact of an asthma education programme on patients knowledge, inhaler technique and compliance to treatment. Singapore Med J. 2006;47(3):225-31.
- Abdulwadud O, Abramson M, Forbes A, James A and Walters EH. Evaluation of a randomized controlled trial of adult asthma education in a hospital setting. Thorax. 1999;54:493-500.
- National Heart Lung Blood Institute Expert Panel Report 3: Guidelines for the diagnosis and management of asthma. NIH Publication. 2007;No. 07-4051.
- Kelly HW and Sorkness CA. Asthma. In: Dipiro JT, Talbert RL, Yee GC and Matzke GR. Pharmacotherapy, a pathophysiologic approach. 6th ed. Newyork: McGraw-Hill; 2008;503-35.
- Jindal SK, Gupta D, Aggarwal AN and Agarwal R. Guidelines for management of asthma at primary and secondary levels of health care in India. Indian J Chest Dis Allied Sci. 2005;47:309-43.
- Tsoukleris MG and Katona BG. Asthma and chronic obstructive pulmonary disease. In: Shargel L, Mutnick AH, Souney PF, Swanson LN, editors. Comprehensive pharmacy review. 5th ed. Philadelphia: Williams and Wilkins; 2004;956-79.
- Gibbs KP and Small Asthma M. In: Walker R and Edwards C. Clinical pharmacy and therapeutics. 3rd ed. Edinburg: Churchill Livingstone; 1994;375-95.
- Iafrate RP, Blake K. Asthma. In: Herfindal ET, Gourley DR and Hart LL. editors. Clinical pharmacy and therapeutics. 5th ed. Baltimore: Williams & Wilkins; 2000;547-69.
- Boulet LP, Becker A, Berube D, Beveridge R and Ernst P. Canadian asthma consensus report. CMAJ. 1999;161(11 Suppl).

14. Gross KM and Ponte CD. New strategies in the medical management of asthma. AAFP. 1998;58(1).
15. McFadden ER. Asthma. In: Kasper DL, Braunwald E, Fauci AS, Hauser SL, Longo DL and Jameson JL. Harrison's principles of internal medicine. 16th ed. New York: McGraw Hill, Health Professions Division. 2005;1508-16.
16. The National Asthma Education Prevention Program (NAEPP II) Guidelines for the Treatment of Asthma: Implications for the Pharmacist. 2000.
17. Liversha AM, Campanella SG and Aickin RP. Costs and effectiveness of spacer versus nebulizer in young children with moderate and severe acute asthma. J Pediatr. 2000;136:497-502.