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Spacers versus Nebulizers in Treatment of Acute Asthma A Prospective Randomized Study in Preschool Children

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ABSTRACT

Background: Asthma affects approximately 14 million adult Americans and is responsible for over 450,000 hospitalizations each year. Every year, approximately 1.8 million asthma patients visit the emergency department. Aerosol delivery to mechanically ventilated patients utilizing nebulizers or metered dose inhalers (MDI) with spacers has been shown to be feasible and beneficial. **Aim and Objectives:** The goal of this study was to analyse MDI aerosol administration with spacer delivery and nebulizer among preschool kids.

Material and Methods: A randomized, double-blind medical experiment involving 200 preschool children were divided into 2 groups received active drug either by nebulizer (group 1=100 patients) or MDI-spacer (group 2=100 patients). Assessment was done including clinical history, medications history, height, weight and BMI. All of the following parameters were measured: heart rate, respiratory rate, and arterial oxygen saturation while the children were awake and breathing room air. FEV1 was calculated using a portable spirometer. These clinical and laboratory tests were performed 10, 20, and 40 minutes after using the nebulizer. **Results:** The mean age in months was 25.4 ± 12.7 among group 1 and 26.6 ± 11.6 among group 2. Group 1 included 43% males and 57% females while group 2 included 52% males and 48% females. The mean BMI for age z score in group 1 was 0.31 & 0.97 and 0.32 & 0.89 in group 2. There was a statistically substantial variation between the two groups in terms of FEV1. In terms of heart rate, respiratory rate oxygen saturation, or hospital stay duration, there was no statistically substantial variation between the two groups.

Conclusion: The MDI-spacer and the nebulizer both delivered salbutamol equally well aerosol therapy to preschool children suffering from wheezes and acute asthma exacerbations. The spacer had higher effect on FEV1 than nebulizer but there was no difference regarding oxygen saturation and hospital stay duration.

Key words: Metered dose inhaler, Spacers, nebulizers, Preschool children, Wheezes.

INTRODUCTION

Asthma affects approximately 14 million adult Americans and is responsible for over 450,000 hospitalizations each year. Every year, approximately 1.8 million asthma patients visit the emergency department (1). Exacerbations of pediatric asthma place a huge medical and financial strain on healthcare systems as well as society at large. Acute exacerbations and poor asthma control have been identified as the cause of approximately one-third of direct and virtually all indirect asthma expenditures, with asthma treatment costs tripling when an exacerbation occurs (2). Aerosol delivery to mechanically ventilated patients has been demonstrated to be feasible as well as nebulizers or metered doses inhalers (MDI) with spacers.

A variety of factors influence the inhaled dose and the aerodynamic properties of aerosol administration within the ventilation circuit. Nebulizers' effects on the aerodynamic properties of the dose emitted in a ventilation circuit have received a lot of attention. The impact of the location of the aerosol distribution mechanism position in various types of ventilation circuits has also been investigated [(3)]. Even the ventilator mode, as well as the effects of heat and humidity, have been studied. Many studies have recommended that vibrating mesh nebulizers must be used instead of jet nebulizers to reduce dose [(4)]. Because it delivers drugs directly to the target organ, inhaled bronchodilator therapy is the first and most important treatment for asthma exacerbations. Even after multiple doses or continuous treatment, lower doses can be used to achieve comparable efficacy while reducing side effects [(1)]. Albuterol, the most commonly used bronchodilator, was previously administered via nebulization (NEB) with compressed air/oxygen. However, metered dosage inhalers with a spacer (MDI+S) have been shown to be beneficial and achieved substantial popularity as an alternate route of albuterol administration [(5)].

Studies estimate that more than half of children who use MDIs without devices, such as a spacers and valved holding chambers (VHCs) with mouthpieces or masks, gain little to no clinical benefit from their medication due to incorrect inhaler technique [(6)].

Prior research has defined correct inhaler technique based on a patient performing a series of steps, ranging from five to 14, which are necessary for the inhaled medication to be effectively deposited into the lungs. While MDIs allow for some forgiveness in medication delivery even when misused due to the fine particles they contain, inhaler misuse is cited as one of the key reasons for failure of inhaled therapies [(7)]. The implications of inhaler misuse are broad, not only for patients but also for health systems as a whole. Patients with incorrect inhaler technique are more likely to have poorly controlled asthma, which is associated with higher exacerbations and healthcare utilization. Individuals with inhaler misuse may also lose confidence in their treatment regimen and subsequently have poor adherence, thereby contributing to asthma morbidity [(8)].

This study aimed at comparing aerosol delivery from MDI with spacer and nebulizer among preschool children.

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MATERIALS AND METHODS

The research was conducted in the Pediatric Emergency Department in Tanta university, faculty of medicine

A convenience sample of asthmatic patients who visited the emergency room during the day while the investigator was present were enrolled. The study was conducted during the period between October 1, 2020 and October 1, 2021.

Ethical considerations:

The Faculty of medicine's Ethics Committee, Tanta university approved the research. All the patients were informed about the surgery and the auto transplantation technique, after learning about the benefits and possible problems, every patients signed informed written permission. This project was done in compliance with the Human Studies Code of Ethics of the World Medical Association (Declaration of Helsinki).

Inclusion criteria: The child had to be between the ages of 0 and 5, have at least two episodes of wheezing in the past, and be currently wheezing or experiencing an acute asthma exacerbation

Exclusion criteria: Other chronic illnesses, altered mental status, and an initial oxygen saturation of less than 90% while breathing room air. Respiratory insufficiency requiring mechanical ventilation. As number of cases admitted to pediatric emergency department complaining from wheezes or acute exacerbation of asthma is in average of 50 per months, so in 4 months the number would be 200 cases. The sample was calculated comprehensively to include all patients admitted to pediatric emergency department with wheezes or acute exacerbation of asthma.

Dosage and administration: A double-blind, double-dummy research was used in this study. Before receiving standard treatment, one of the researchers evaluated the children and assigned them to one of two treatment groups: nebulizer (group 1=100 patients) or MDI-spacer (group 2=100 patients). The children were given either 4 ml of inhaled beta-2-agonist salbutamol (Ventoline 5 mg/ml) through an oxygen-driven nebulizer (group 1) or 4 puffs (10 breathes/puff) of salbutamol MDI (Airomir 100 g/puff) with a spacer (Nebunette) Formalized paraphrase (group 2). The doses were determined by the patient's weight. The treatment was repeated three times at a 20-minute interval.

Assessment: Clinical history, medication history, height, weight, BMI, heart rate, respiratory rate, and arterial oxygen saturation are all factors to consider. While the children were awake and breathing room air, a pulse oximeter was used to measure oxygen saturation. FEV1 was calculated using a portable spirometer. These clinical and laboratory tests were performed 10, 20, and 40 minutes after using the nebulizer. Apart from salbutamol, no other medications were administered during the study period. The length of stay in the hospital was also evaluated.

Statistical analysis:

The data were loaded into a computer and statistical analysis was performed using SPSS version 26 (Statistical Package for Social Science). To check whether the data was regularly distributed, Shapiro Walk test was utilized. To depict qualitative data, we employed frequencies and relative percentages. The variance between the qualitative variables was calculated using the Chi square test (x^2), as illustrated. Quantitative data was expressed using the mean and standard deviation. The difference in quantitative variables in two groups was calculated using the Student t test. Statistical relevance was found in all two-tailed statistical comparisons. A substantial change is shown by a P-value of ≤ 0.05, whereas a non-significant difference is indicated by a $P > 0.05$.

RESULTS

The mean age in months was 25.4 ± 12.7 among group 1 and 26.6 ± 11.6 among group 2. There were 43% males and 57% females in group 1. There were 52% males and 48% females in group 2. The mean BMI for age z score was 0.31 ± 0.97 among group 1 and 0.32 ± 0.89 among group 2. Regarding medications, there were 45% and 46% had beta 2 agonist, 42% and 40% had steroids and 3% and 4% had leukotrienes antagonist among group 1 respectively. In terms of sociodemographic data, there was no statistically substantial change between the two groups studied. (Table 1)

Table (1): Sociodemographic data among the two studied groups

Variable	Group 1	Group 2	P value
Age (months), Mean± SD	25.4± 12.7	26.6± 11.6	0.215
Gender Male n (%) Female n (%)	 43 (43) 57 (57)	 52 (52) 48 (48)	 0.711
BMI for age z score (Mean± SD)	0.31± 0.97	0.32± 0.89	0.900
Medications- Beta 2 agonist n (%) Steroids n (%) Leukotrienes antagonist n (%)	45 (45) 42 (42) 3 (3)	46 (46) 40 (40) 4 (4)	 0.812

Student t test; chi square test; *p is significant at <0.05, There was no statistically substantial change in heart rate between the two groups studied. (Table 2), respiratory rate (Table 3), and duration of hospital stay (Table 4).

Table (2): Heart rate between the two studied groups

Variable		Group 1 Mean± SD	Group 2 Mean± SD	P value
Heart rate	0m	145.1± 22.6	143.6± 20.9	0.619
	10 m	138.4± 19.2	140.3± 18.1	0.607
	20 m	132.5± 18.6	135.4± 17.4	0.511
	40 m	131.7± 17.9	133.3± 17.1	0.410

Student t test; *p is significant at <0.05

Table (3): Respiratory rate among the two studied groups

Variable		Group 1 Mean± SD	Group 2 Mean± SD	P value
Respiratory	0m	44.2± 12.6	40.9± 11.7	0.710
	10 m	43.7± 11.1	39.3± 11.6	0.616
	20 m	40.5± 8.6	39.1± 10.4	0.600
	40 m	38.3± 9.5	38.5± 9.1	0.801

Student t test; *p is substantial at <0.05

Table (4): Hospital stay between the two studied groups

Variable	Group 1	Group 2	P value
Hospital stay (minutes) Mean± SD	160.4± 76.5	172.8± 71.6	0.860

Student t test; *p is substantial at <0.05

The oxygen saturation was not statistically substantially different among group 2 and group 1 (Table 5).

Table (5): Oxygen saturation between the two studied groups

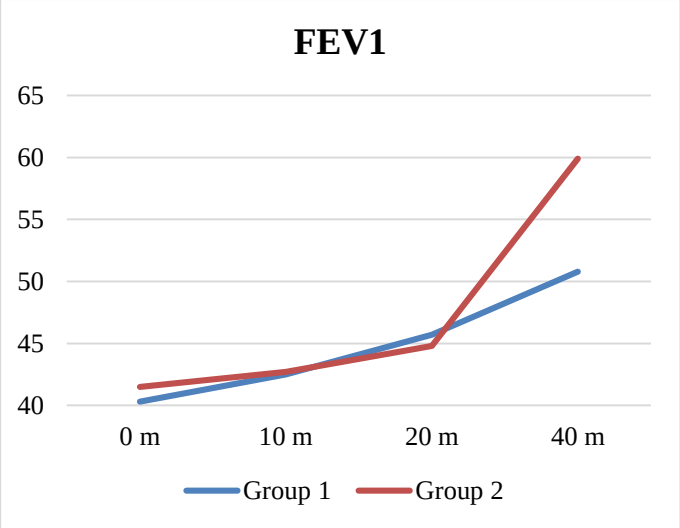
Variable		Group 1 Mean± SD	Group 2 Mean± SD	P value
Oxygen	0m	95.5± 2.4	95.3± 2.5	0.901
	10 m	95.0± 3.5	95.1± 3.3	0.700
	20 m	95.3± 2.6	96.0± 3.7	0.619
	40 m	95.4± 1.9	96.6± 1.8	0.056

Student t test; *p is significant at <0.05

The FEV1 was statistically significantly higher among group 2 than group 1 (Table 6 and Figure 1).

Table (6): FEV1 among the two studied groups

Variable		Group 1 Mean± SD	Group 2 Mean± SD	P value
FEV1	0m	40.3± 10.7	41.5± 10.6	>0.999
	10 m	42.5± 12.3	42.7± 11.5	0.900
	20 m	45.7± 10.9	44.8± 9.9	0.811
	40 m	50.8± 10.5	59.9± 10.3	**0.041***



Student t test; *p is significant at <0.05

Figure (1): Comparison of the two studied groups regarding FEV1

DISCUSSION

Asthma is a prominent source of morbidity in newborns and young children, as well as a common cause of emergency department visits and hospitalization. Bronchodilators are often used to treat reactive airway disease in newborns. However, due to the large number of patients in crowded emergency rooms and the limited availability of oxygen ports, administering bronchodilators via nebulizer is frequently difficult [(5)]. Metered-dose inhalers have made it easier and aerosolized bronchodilators are less It is costly to administer asthma treatment to older children and adults. In contrast, younger patients frequently fail to coordinate inspiration with MDI activation, restricting how much medicine is inhaled [(4)]. The use of spacer devices has aided in the resolution of this problem. The spacer allows the patient to take normal breaths while receiving inhaled medications through a face mask or mouthpiece. By holding medication in a chamber. Spacers have been shown to deliver aerosolized salbutamol as well as, if not better than, nebulizers in children with wheezing [(2)].

Only a few trials have been undertaken to determine the efficacy of MDIs with spacers in giving albuterol to infants aged 2 and under. There was no controlled environment in these studies (double-blind design) and did not compare the efficacy of a spacer-equipped MDI to that of a nebulizer [(9)].

This study aimed at comparing aerosol delivery from MDI with spacer and nebulizer among 200 preschool children. We found no difference between the spacer and the nebulizer in treatment of asthma exacerbations and wheezes. In this study, there was no statistically substantial variation in heart rate between the two groups. Similarly , **Deerojanawong *et al.*** [(7)] in a prospective-randomised double-blind placebo-controlled trial in children as young as 5 years old with acute wheezing, they discovered that there was no statistically substantial variation between the two groups. In a controversial study, **Vilarinho and**

colleagues [10] compared the response to albuterol delivered via nebulization (NEB) to albuterol delivered via MDI + S in paediatric asthma exacerbations. The increase in HR was significantly lower (better; MD -6.47; 95 percent CI, -11.69 to -1.25; I2 = 0%; p =.02) when albuterol was administered via MDI + S than when administered via NEB. The variation in respiratory rate between the spacer and nebulizer groups was not statistically substantial in our research. 123 outpatients (1–24 months of age) with "moderate to severe" wheeze were seen in the emergency department in a single-blind, prospective trial. In this trial, there was no substantial distinction in oxygen saturation between the spacer and nebulizer groups. Furthermore, **Deerojanawong *et al.*** [7] There was no statistically significant difference in oxygen saturation between the two groups. Additionally, **Vilarinho *et al.*** [10] In terms of oxygen saturation, the spacer was shown to be equally as effective as the nebulizer.

In this study, there was a statistically substantial variation between the two groups. As spacers affect FEV1 and became higher than group 2 with nebulizers. Similarly, **Dahiya *et al.*** [9] In a study of 150 children aged 5 to 14 years with persistent asthma presenting with peak expiratory flow, researchers compared the effectiveness of all types of spacers commonly used by children in India (PEF). They found that after inhaling a bronchodilator through each of the spacers, PEF and FEV1 improved significantly.

CONCLUSION

Both the MDI-spacer and the nebulizer were equally effective in providing salbutamol aerosol therapy to preschool children with wheezes and acute asthma exacerbations. The spacer had higher effect on FEV1 than nebulizer but there was difference no effect regarding oxygen saturation and hospital stay duration.

Declarations:

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