|| ISSN(online): 2589-8698 || ISSN(print): 2589-868X ||
International Journal of Medical and Biomedical Studies
Available Online at www.ijmbs.info
PubMed (National Library of Medicine ID: 101738825)
*Index Copernicus Value 2018: 75.71*
Original Research Article
Volume 4, Issue 3; March: 2020; Page No. 78-80

# STUDY OF EFFICACY OF METERED DOSE INHALER (MDI) AND DRY POWDER INHALER (DPI) FOR DELIVERY OF SALBUTAMOL IN TREATMENT OF ACUTE EXACERBATION OF ASTHMA IN PATIENTS, ATTENDING IN TERTIARY CARE HOSPITAL AT, PATNA

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**Article Info:** Received 14 February 2020; Accepted 11 March 2020
**DOI:** https://doi.org/10.32553/ijmbs.v4i3.1078
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**Conflict of interest:** No conflict of interest.

**Abstract**

Objective: Present study was undertaken to compare the efficacy of Metered dose inhaler (MDI) with spacer and with Dry powder inhaler (DPI) for delivery of salbutamol in acute exacerbation of bronchial asthma. It is a randomized controlled trial study.

Material and Methods: A total of 78 children in the age group of 6-14 years who presented with a mild or moderate acute exacerbation of asthma were included in the study. Salbutamol dose of 400µg were given to all the children's by either a MDI with spacer or a DPI in randomized pattern. All the changes in the wheezing and accessory muscle scores, Sa02, and PEFR were noted.

Results: Out of 78 children, 42 were assigned to the MDI spacer group and 36 to rotahaler (DPI) group. After receiving treatment, the PEFR improved by about 14% in both the groups. The oxygen saturation increased by 2.1% in both the groups. Within each group, the improvement in PEFR, Sa02, wheeze and accessory muscle score after the treatment was statistically significant.

Conclusion: Metered dose inhaler with spacer and Dry powder inhaler are equally effective in delivering salbutamol in therapy of mild to moderate acute exacerbations of bronchial asthma in children between 6-14 years of age

**Keyword:** DPI**,** Salbutamol, Treatment, Asthma, Children, MDI, PEFR

## Introduction

Asthma is a chronic inflammatory syndrome characterized by episodic airflow obstruction after inhalation of allergens or trigger agents resulting in tightness of chest, wheeze and dyspnea. Airways are hyper responsive to variety of agents [1, 2, 4]. Aerosol inhalation has long been recognized as the mainstay of treatment of asthma.

Salbutamol (Albuterol) is a highly selective $\beta_2$ agonist. Inhaled salbutamol delivered mostly from pressurized metered dose inhaler ($_P$MDI) Produces bronchodilation within 5 minutes and the action last for 2-4 hours. So that it is used to abort and terminate the attacks of asthma and not for prophylaxis [3, 5].

Now a day's most of the asthmatic patients are treated and maintained on inhaled medication only. Two types of aerosols are used. First use drug in solution i.e. Pressurized metered dose inhaler and deliver a specified dose of drug in spray form per actuation. Device are operated properly with deep inspiration, many patients are unable to operate the machine.

A large volume Spacer (chamber interposed between the inhaler and the patient's mouth) can be used to improve drug delivery by obviating the need for precise coordination [8]. Moreover, larger particles settle on the walls of the spacer reducing the fraction that deposits in the throat and is later swallowed. Oral complications like candidiasis with inhaled steroid as well as systemic involvement are reduced.

Jet nebulizers delivered drug solution in mist form in which pressurized air or oxygen which can be inhaled through a mouth piece, face mask or in a tent by. Ultrasonic nebulizers use electrically vibrated crystals, pressurized air or oxygen is not needed.

Metered dose inhalers are easy to use and devices can be carried along, while nebulizers are used at patient's bed side. Nebulizers are more effective for control of severe attacks of asthma for children as well as elderly, More than one drug can be nebulized simultaneously.

Dry powder inhalers (DPI) are also portable devices in which the capsule (rotacap) containing the drug is punctured or cut across and the powder are aerosolized by the inspiratory air flow of the patient. It requires high velocity inspiration which children, elderly and the very sick may not be capable of inspiration. Cough and

bronchoconstriction produced by dry powder due to irritation of the air passage.

Efficacy of aerosolized drug depends on the particle size: 1-5µ diameter particles deposit on the bronchioles and effectively deliver the drug. Larger particles settle on the oropharynx, while very fine particles do not settle anywhere and are exhaled out. On an average only 10% of the inhaled drug reaches the site of action. A considerable fraction is swallowed. So that to minimize systemic action,the drug should have low oral bioavailability.

Spacer devices improve inhaled to swallowed drug ratio. Efficacy of the inhaler also enhances after slow and deep breathing and holding the breath after inhalation. Increase ratio of smaller particles of 1-2 µm can be generated using the newer HFA propellant based pMDIs and improves delivery of the drug to the smaller bronchioles but from peripheral lungs systemic absorption is increases. Studies comparing the clinical efficacy of MDI and DPI in the treatment of asthma in children are limited especially so about comparison in acute exacerbations.

Present study was conducted to know the effectiveness of salbutamol inhalation delivered by metered dose inhaler with MDI and rotahaler (DPI) in children suffering from mild or moderate acute exacerbation of asthma.

**Material and Methods**

Present study was conducted in the Department of Pharmacology, Patna Medical College, Patna, Bihar, with the help of Department of Pediatrics, Medicine and Radiology during the period of January 2016 to July 2017. A total of 78 children in the age group of 6-14 years presented with mild or moderate acute exacerbation of asthma were included in the study. Mild exacerbation was defined as presence of cough, moderate wheeze( i.e. found only at the end of expiration), breathlessness while walking, talks in sentences, has increased respiratory rate, with PEFR $\geq$ 70% of predicted and absence of cyanosis. Moderate exacerbation was defined as loud wheeze (i.e. present throughout exhalation), breathlessness while at rest, talks in phrases, has increased respiratory rate, with PEFR 40-69% of predicted and absence of cyanosis.

Children with features of severe acute exacerbation or PEFR less than 40% of the predicted value or a lower respiratory tract infection or taking bronchodilator within the last 6 hours of presentation were excluded from the study. Informed consent was taken from all the parents of study group.

The children were then randomized to receive salbutamol by either a MDI with spacer or DPI. Children were examined to record the wheezing and accessory muscle scores, oxygen saturation (Sa02) and PEFR using Wright's mini peak flow meter.[6,10 ] Children were then administered 400 µg of salbutamol by either a MDI with spacer or DPI (Rotahaler). Children of MDI group received four 100 µg puffs of salbutamol using a 750 ml commercially available spacer with valve (Tran's spacer, Lupin). It was ensured that each puff was administered with regular breathing for about 30 sec or 5-10 breaths and a tight seal was maintained.

Children with rotahaler (supplied by Cipla, Mumbai, India) groups received 2 rotacaps (supplied by Cipla, Mumbai, India) each of 200 µg salbutamol and do 5 maximum inspiratory maneuvers after each dose. Thirty minute after treatment, the children were reevaluated. Baseline parameters were compared for the two groups. The changes in the wheezing and accessory muscle scores, Sa02, and PEFR were recorded.

**Results**

Out of 78 children 42 children were assigned to the MDI spacer group and 32 to Rotahaler group. The proportion of boys was significantly more in the MDI spacer group. PEFR in both the groups were same. Children in the MDI spacer group had a higher accessory muscle use score than DPI group. After receiving treatment, the PEFR improved by about 14% in each of the groups. The oxygen saturation increased by 2.1% in both the groups. Wheeze scores within each group, the improvement in PEFR, Sa02 wheeze and accessory muscle score after the treatment were statistically significant. In both the groups the children cooperated equally well.

**Discussion**

Delivery of the drugs as aerosols, particularly via metered dose inhalers, has been a major breakthrough in the treatment of asthma, as it allows adequate drug deposition in the lower respiratory tract. However, despite adequate counseling many patients are unable to use a pressurized inhaler efficiently, especially children. Failure to co-ordinate inhaler actuation with inspiration is the most important drawback. Use of spacer device causes no need for any breath hand co-ordination. But the side effects of propellants and lubricants are not eliminated [9].

Dry powder inhalers (DPIs) were a good formulation for drug delivery to the airways without the attendant help of MDIs and are bioequivalent to them [14]. There is no need for any breath hand actuation.But minimum level of inspiratory flow for a DPI to be useful. In our study shows that efficacy of salbutamol in mild or moderate acute exacerbation of asthma was similar when the drug is delivered by MDI spacer or a dry powder inhaler. The increase in PEFR in the two groups was approximately 14%.

In MDI group accessory muscle scores were higher than Rotahaler group at baseline, while other parameters to assess severity were comparable. There was significant

improvement in the scores in both the groups, however the difference between two groups persisted. This discrepancy may be avoided by use of composite scores for assessment of severity. Another studies have been done to compare the efficacy of the many inhalational systems available among adults, Most of them have shown that salbutamol administered by aDPI is as efficacious as that by MDI [7].

There are very few studies to show the clinical efficacy of rotahaler in children with acute exacerbations of asthma. In a study on 44 children, Bronksy, et al. [6] observed that the two devices (rotahaler and MDI) were equally efficacious in delivering salbutamol in exercise-induced asthma. Alwarez, et al, [11] in an analysis of 100 cases observed that in stable asthma in children, salbutamol administered via MDIs is as effective as DPIs. No any extra clinical benefit was found in either case.

Singh and Kumar [13] compared the clinical efficacy of a transparent, DPI (transparent Rotahaler) with MDI and spacer in moderate persistent childhood asthma. Both the groups of children given both inhaled steroids and bronchodilators through either of the devices for 6 weeks and then were crossed over to the other group. PEFR at interval visits, PEFR variability, and extra bronchodilator use and on weekly symptom scores in acute exacerbations of asthma did not reveal any statistically significant differences during the two treatment periods [15].

**Conclusion**

The effectiveness of Metered dose inhaler with spacer and Dry powder inhaler are same in treatment of mild to moderate acute exacerbations of bronchial asthma in children in delivering salbutamol.

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