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Research Article

Comparative study of rotahaler with metered dose inhaler in administering salbutamol in children with bronchial asthma

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ABSTRACT

Background: It is estimated that around 300 million people suffer from asthma and the burden of this disease to families and patients is increasing worldwide. Reliver inhalations are the mode of management in acute exacerbation of asthma. Children of age 6-12 years can use both rotahaler and metered dose inhalers. This study compares the effectiveness of these two modalities in administration of salbutamol in acute exacerbation of asthma.
Methods: A prospective study among 200 children with acute exacerbation of bronchial asthma in children in 6 to 12 years of age having mild to moderate persistent asthma. Acute exacerbation was defined as PEFR of <80% of the predicted value, children were randomly allotted to two groups and were administered salbutamol either by rotahaler or by metered dose inhaler. PEFR was measured before and after administration of 200 µg of salbutamol and reversibility of bronchoconstriction was statistically analyzed.
Results: Mean increase in percentage of PEFR value after giving therapy was found to be 19.82 with SD -3.42, 21.9 with SD - 5.99, 20.61 with SD - 3.43, 21.31 with SD - 3.5 in rotahaler (Mild) group, rotahaler (Moderate) group, metered dose inhaler (Mild) group, Metered Dose Inhaler (Moderate) group respectively There was no statistically significant advantage of one modality over the other.
Conclusions: Rapid relief of airway obstruction can be achieved in acute exacerbation of asthma by both the devices namely rotahaler and metered dose inhaler.

Keywords: PEFR, MDI, Rotahaler, Acute Exacerbation, Asthma

INTRODUCTION

Asthma is a major cause of chronic morbidity and mortality throughout the world and there is evidence that its prevalence has increased considerably over the past 20 years, especially in children.[1] It is now estimated that as many as 300 million people of all ages and all ethnic backgrounds, suffer from asthma and the burden of this disease to health care systems, families and patients is increasing worldwide.[2] There is a rapid rise in incidence of asthma from 1980-1990.[3,4] Though genetic predisposition is one of the factors in children for the increased prevalence - urbanisation, air pollution and environmental tobacco smoke contribute significantly.[4] India has an estimated 15 - 20 million asthmatics. Rough estimates indicate a prevalence of between 11 and 34% in old Indian children.[4] One recent study in Delhi found that 16% of school children had asthma. School children suffer absenteeism, which hinders education as well as the child's participation in other school activities.[4]

As per GINA guidelines 2015,[5] asthma is a heterogeneous disease, usually characterized by chronic airway inflammation. It is defined by the history of respiratory symptoms such as wheeze, shortness of breath, chest tightness and cough that vary over time and

in intensity, together with variable expiratory airflow, repeated exacerbations and persistent uncontrolled asthma may per se cause permanent airway remodeling. Repeated life threatening asthma episodes affect their scholastic performance, sports activities and even day to day activities.

Recent advances in understanding the diseases, and the development of newer drugs & delivery systems, have made asthma control, better and easier. Asthma management should be aggressive and include anti-inflammatory medications, avoidance of known asthma triggers, and objective measurement of lung function. In particular, home peak expiratory flow rate (PEFR) monitoring is recommended for many patients with asthma. Asthma experts claim that home PEFR monitoring can help both the patient and the physician assess the severity of asthma, monitor the course of treatment, determine when emergency medical care is needed, and recognize diurnal variations of PEFR.

Asthma medications are used as "Reliever" or "Rescue" medication; it may also be used for long term prophylaxis or "Controller" medication. Quick relief medications like inhaled β_2 agonists, anticholinergics & short course systemic glucocorticoids are used in the management of acute episodes of bronchospasm. Given their rapid onset of action, effectiveness, and 4-6 hour duration of action, inhaled short acting β agonists are the drugs of choice for acute episodes of bronchospasm. They produce dilatation of the bronchi by inducing airway smooth muscle relaxation, reducing vascular permeability, airways edema and improving mucociliary clearance.

Inhaled therapy constitutes the cornerstone of asthma treatment in children 12 years and younger. A pressurized metered dose inhaler (MDI) with a spacer (with or without a face mask, depending on the child's age) is most widely prescribed and most widely improperly used instrument in asthma therapy. Since the drug released from the MDI travels at a high speed (110 km/hr) children may find difficult to synchronize the act of inspiration with MDI actuation. Improper technique may reduce intrapulmonary deposition, as the fast moving drug particles may get deposited in the oropharyngeal wall resulting in cold Frion effect and reflux bronchoconstriction. MDI are handy, portable, patient can own, nosocomial infections are less and good aerosol delivery in the shortest time. Moreover it is difficult to use in acute severe episode of asthma. To a certain extent this can be overcome by a spacer and a mask. Spacer allows the children to breathe few seconds later thereby obviating the respiratory obviating the respiratory coordination. The evaporation of propellant surrounding the drug particle decreases intrapulmonary deposition and avoids cold Freon deposition (eight folds) and prevents oropharyngeal candidiasis.

Dry powder inhalers (DPI) are breath activated devices, which produce fine particles of medications by scraping or milling of the aerosolized powder. Lactose acts as a carrier and aids dispersion. Advantages are no need for hand- lung coordination, user friendly portable, simple, economical easy to assemble, use and clean, CFC free and ozone friendly. Disadvantages are requires good inspiratory effort > 60 l/min and cannot be used in young children, not useful in acute asthma, may produce cough and less dispersible in humid conditions.

Goals of asthma therapy are,[5] a normal life, including full participation in community and school activities like sports and exercises, sleep uninterrupted by asthma symptoms, optimal lung function as measured by pulmonary function tests and home peak flow meters. No hospitalizations or visits to the emergency department, use of rescue inhaler once a day less, if possible, freedom from medication side effects, no school absenteeism due to asthma.

It is recommended that "clinicians consider initiating home PEFR monitoring with patients who have mild and moderate asthma. The definition of moderate asthma includes patients who have symptoms more than two per week, that affect sleep and activity level, and who require occasional emergency care. A substantial amount of evidence indicates, however, that patients and their physicians always accurately estimate the severity of asthma.[5] In one straightforward clinical study, 255 patients with asthma were asked to estimate the severity of their asthma on a visual analog scale while they concomitantly measured the PEFR.[6] In 60% of these patients, no significant correlation was noted between their perceived severity of asthma and the actual PEFR measurement. A study of 12 boys with asthma attending a boarding school showed that daily PEFR monitoring detected only 32 to 40% of the asthma exacerbations detected by spirometry.[7] Another study that compared diaries of symptoms with diaries of PEFR monitoring showed that symptoms preceded a decrease in PEFR for most asthma exacerbations.[8]

PEFR readings should also theoretically be helpful to guide patients in their home management of acute exacerbations, and in indicating when they should seek emergency medical treatment. An early uncontrolled study by Beasly[9] showed that PEFR based self-management plans resulted in improved outcomes. Following this, data from 2 community based studies[10,11] in the U.K showed that patient PEFR self-monitoring and management was not useful in improving outcomes, especially in mild asthmatics. Others[12-15] reported improved outcomes in patients who were given either symptom or PEFR guided asthma self-management plans; most of these studies revealed that symptoms - guided management plans were as effective as PEFR guided plans.[12-14] It is undoubtedly clear that PEFR monitoring and early rescue therapy is the key for asthma management in mild and moderate persistent asthma .

Considering the above facts, this study aims at comparing the efficacy of the above two delivery systems with PEFR monitoring as an assessment tool in children of 6-12 years age group.

METHODS

We conducted a prospective study among 200 children with acute exacerbation of bronchial asthma in children in 6 to 12 years of age having mild to moderate persistent asthma who attended our tertiary care teaching and referral hospital, between January 2014 to February 2015. Informed consent was taken from the parents. Materials used for the study are peak expiratory flow meter (Wrights), salbutamol metered dose inhaler with spacer (100 µg/puff), rotahaler and salbutomal rotocaps (200µg/cap). Acute exacerbation was defined as PEFR of < 80% of the predicted value calculated by the formula (height in cm - 100) x 5 + 100.[16] These children qualifying with acute exacerbations were randomly assigned either salbutamol.

MDI with spacer (or) salbutamol rotacaps with rotahaler was given to the patient by the nursing staff. PEFR was checked by attending paediatrician in both study groups for comparison before and after administration of 200 µg of the drug at an interval of 20 minutes. It was recorded during entire stay in the hospital every 6 hours.

Those children of the age group 0-6 years, severe persistent asthma, acute exacerbations with life threatening features were excluded from study.

RESULTS

Among 100 children who used MDI with spacer, 55 had mild and 45 had moderate persistent asthma. In the rotahaler group, it was 60 and 40 respectively. Majority of children in the rotahaler group belong to the age group 6-9 years (80%) and children who were administered MDI with spacer the pattern was almost the same with 79% falling in age group 6-9 years sex wise distribution was predominantly male in the study group (126), when taken group wise, in all four categories males constituted 65% and this distribution was statistically insignificant. Majority of children had a height of 110-130 cm in all the four groups. It was observed that almost 25% of children were having positive family history of asthma.

On comparing the Mean PEFR before giving rotahaler (Mild) group found to be 141 L/min with SD - 27.16 and that of rotahaler (Mod) group found to be 143.25 L/min with SD - 30.75. Mean PEFR before giving MDI with spacer (Mild) group found to be 138.36 L/min with SD - 27.74 and that in MDI with spacer (Mod) group found to be 144 L/min with SD - 31.43.

In both groups (Rotahaler and MDI) of mild persistent asthma, average PEFR before giving the intervention was similar as per the non-significant analysis of variance (ANOVA) results. One way ANOVA applied to moderate persistent asthma group who underwent the two different interventions also had similar PEFR.

After giving β_2 agonist with rotahaler for the mild group, mean PEFR was found to be 169.5 L/min with SD - 36 and for the moderate group was 172.25 L/min with SD - 41.38. Average PEFR after giving β_2 agonist MDI with spacer (Mild) group found to be mean 167 L/min with SD - 35.1 and that for moderate group found to be mean 174.88 L/min with SD - 39.52.

There was significant increase in PEFR after giving therapy (>13%) in all the four groups as expected. This was a clear evidence of reversibility of bronchoconstriction by the β_2 agonist administered in correct method and appropriate dosage.[5]

One way ANOVA was applied to compare the four categories of children. Non - significant ANOVA results indicates that mean PEFR value was similar for all categories. It ensures that after intervention their level of lung capacities gets was similar for all categories.

Increase in percentage of PEFR value after giving therapy found to be mean of 19.82 with SD - 3.42 in case of rotahaler (Mild) group category.

Increase in percentage of PEFR value after giving therapy found to be mean of 21.9 with SD - 5.99 in case of rotahaler (Mod) group category.

Increase in percentage of PEFR value after giving therapy found to be mean of 20.61 with SD - 3.43 in case of MDI with spacer (mild) group.

Increase in percentage of PEFR value after giving therapy found to be mean of 21.31 with SD - 3.5 in case of MDI with spacer (Mod) group.

One way ANOVA was applied to compare the four groups especially the effect of the two modalities of administrating the drug in mild persistent asthma and that in moderate persistent asthma. Non - significant ANOVA results indicates that mean increase in PEFR value was almost similar for all categories of children in this study. One way ANOVA was applied to compare increase in percentage of PEFR in the four groups. Non - significant ANOVA results indicates that increase in mean PEFR percentage was almost similar for all categories of children in this study.

Table 1: Mean and SD of PEFR before, after & increase in % (ml) group wise.

	A_1 rotahaler (mild)		A_2 rotahaler (mod)		B_1 MDI with spacer (mild)		B_2 MDI with spacer (mod)		"F" Ratio	"P" Value
	Mean	SD	Mean	SD	Mean	SD	Mean	SD		
PEFR (Before)	141	27.16	143.25	30.75	138.36	27.74	144	31.43	0.378	0.769
PEFR- A (After)	169.5	36	175.25	41.38	167	35.1	174.88	39.52	0.556	0.645
Increase percentage	19.82	3.42	21.9	5.99	20.6	3.43	21.31	3.59	2.356	0.073

DISCUSSION

In our study we have taken a population of children who were classified according to GINA guidelines[5] into two groups mild and moderate persistent asthma.

Peak expiratory flow is a simple quantitative and reproducible measure of resistance and severity of airflow obstruction and it can be used for short term monitoring and managing exacerbations. The patient's measured personal best is the most appropriate reference value for PEFR but in office practice, the assessment of a patient's appropriate peak expiratory flow rate, can be done using the formula PEFR = (Height – 100) × 5 + 100, which was compared in a study[16] with three other nomograms[17-19] and was found to be comparable and easier. There was not much difference in fall in PEFR between the two groups i.e. mild and moderate persistent asthma group. This can be explained by the fact that the study population had better accessibility to emergency management and also presented early during exacerbations.

A number of studies have been done to compare the efficacy of different inhalation systems for management of acute exacerbation of asthma in adults but studies are limited in children in the age group 6-12 years. Children of this age group in comparison to younger age group can use both rotahaler and MDI as their coordination is good.

In our study, the baseline characteristic of the two groups, rotahaler group and MDI group were similar and when statistically analysed were not significant. The fall in PEFR before intervention was significant in both the groups (less than 80 % of the predicted value proving the bronchoconstriction).

After the intervention the increase in percentage of PEFR was compared between the two groups (rotahaler and MDI). The increase in percentage of PEFR was significant in both the groups but inter group analysis showed that both devices were equally effective in delivering β_2 agonist in the management of acute exacerbation of asthma. This is in accordance with two previous studies[20,21] but a study done by Golish J[22] showed results contrary to this. More acceptability of DPI in paediatric population was shown by a study[23] even though clinical efficacy of both the devices was same.

The equal effectiveness of the two devices were reported with delivery of salbutamol in exercise induced asthma 24 which substantiates our results to a certain extent.

The primary outcome (decrease in percentage of PEFR) was compared according to the severity of asthma and was found to be statistically non-significant. Same effect was noted in a similar study done in Bangladesh.[25]

In this study only one primary outcome variable was assessed namely PEFR, it would have been better if clinical parameters like respiratory distress score, acceptability by the children, side effects if any were assessed.

CONCLUSION

Rapid relief of airway obstruction can be achieved in acute exacerbation of asthma by both the devices namely rotahaler and MDI. Both were equally effective. The choice between the two devices is to be decided by the treating physician considering the acceptability and financial background of the family.

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