

ORIGINAL RESEARCH

Appropriateness of Inhalational Therapy use among Children with Bronchial Asthma: Experience of a Tertiary Care Center

Dr. Punita Kumari¹, Dr. Chandan Kumar Singh^{2*}, Dr. (Prof) Hemant Kumar³

¹Medical Officer, Department of Pediatrics, P.M.C.H, Patna, Bihar, India

^{2*}Senior Resident, Department of Pediatrics, P.M.C.H, Patna, Bihar, India

³Professor, Department of Pediatrics, PMCH, Patna, Bihar, India.

Corresponding Author

Dr. Chandan Kumar Singh

Senior Resident, Department of Pediatrics, P.M.C.H, Patna, Bihar, India

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ABSTRACT

Background and Objectives: Inhalational therapy is beyond doubt the mainstay of treatment in children suffering from bronchial asthma. However, the use of inhalational therapy needs proper evaluation as poor handling of such devices and wrong inhalation technique are associated with decreased delivery of the drug and hence poor disease control. It is therefore important to study the drawbacks in inhalation technique and factors associated with incorrect usage of these medical devices by children or their caregivers. **Methods:** We conducted this prospective observational study over a period of 2 years from January 2022 to December 2023 at O.P.D and Emergency of Pediatrics deptt at P.M.C.H, Patna including children of age 5-16 years with Bronchial asthma who were using inhalational devices for atleast one month. **Result:** 197 children were enrolled over the 2-year study period. Mean age of the study population was 6.94 ± 2.53 years. Male: Female ratio was 1.3:1. Mean age at diagnosis was 6.27 ± 2.21 years. Mean duration of using the inhalational device was 6.13 ± 1.79 months. Overall, only 32% were getting inhalational therapy properly. MDI was the commonest device being used (61%) followed by nebulizer (22.8%). However, MDI was also the most commonly improperly used inhalational device (77.5%). Whereas, children receiving nebulization therapy were subjected to the least number of errors (44.4%). The most common error in MDI was failure to shake the MDI, in DPI/Rotahaler it was inadequate breath accentuation and in nebulization it was poor fitting of the mask. Rate of error was the least when the educator was a doctor ($n=77$, 62%) followed by nurses ($n=33$, 75%) and maximum with pharmacists ($n=24$, 82.7%). In univariate analysis, following were found to significantly increase the risk of erroneous use: atleast one parent being illiterate, low socioeconomic status, inhabitation in rural area, training about usage by personnel other than a Doctor and device usage for <3 months. **Conclusion:** Majority of the children (68%) were not correctly getting inhalational therapy properly. Proper education to patients/parents on correct usage may not only improve control of the symptoms of the disease but might also allow dose reduction in the long term.

Key words: Bronchial asthma, error, inhalational therapy, DPI/Rotahaler, MDI, nebulizer, spacer.

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INTRODUCTION

Children with reactive airway disease or bronchial asthma constitute a significant proportion of O.P.D/Emergency visits. Inhalation therapy remains the mainstay of treatment in such children both during exacerbation of their symptoms and during the maintenance phase of therapy due to the ease of administration, faster onset of action and lesser systemic effects.¹ Amount of the drug actually reaching the lungs and available for action(s) is largely influenced by the technique of inhalation, type of the device used and the fine particle dose of the

drug.² Types of inhalational devices available in the market include Metered Dose Inhaler (MDI), Dry Powder Inhaler (DPI), Metered Dose Inhaler with Spacer (MDI with Spacer), Breath actuated Metered Dose Inhaler (baMDI) and Nebulizer. Though MDIs are quite common mode of inhalational therapy, poor handling and wrong technique leads to decreased medication delivery and hence poor disease control.³ Review of patients' handling of their usual inhaler devices in actual primary care or pulmonary clinical practice setting has shown that only few of them correctly use their devices.⁴ The classic study on

inhaler techniques done by Mollimard et al. in over 3800 outpatients showed that around 50% of the subjects made at least one error when using a DPI.⁵ This erroneous use was even higher (76%) in case of MDI. Similar studies conducted in India and abroad have shown comparable high rates of error in use of such inhalation devices.^{6,7} It is therefore imperative on the part of the pediatricians and respiratory therapists to understand the issues related to correct usage of these devices and also to understand the difficulties faced by patients while using them. There is paucity of data from northern India on proper or improper use of MDI by children at homes, leading to incomplete understanding of the problem which makes the situation difficult to address. With this background and keeping in mind the burden of bronchial asthma in our children, we undertook this study to evaluate, analyze and address the issues related to improper usage of inhalational devices.

Aim & Objectives

Aim: To study the correctness and problems in technique used for inhalational therapy at home by children &/or their parents.

Objectives: - To study the types of inhalational devices used, their usage pattern, the errors committed while using such devices, nature of error observed and understanding the reason behind such errors

MATERIALS AND METHODS

Study Setting: O.P.D and Emergency area of Deptt of Pediatrics, P.M.C.H Patna.

Study duration: 2 years, from January 2022 to December 2023.

Study design: Prospective observational study.

Inclusion criteria: children from age group 5-16 years (both ages included) with Bronchial asthma who were using inhalational devices for relief &/or control of their disease for atleast one month who visited our O.P.D or ER for their primary disease or any other condition.

Exclusion criteria: Children with any condition or co-morbidity that could preclude the correct use of such devices (active T.B, musculoskeletal disease,

neurological disease, cleft lip/palate etc.) were excluded from the study.

Study technique: After obtaining written informed consent from the guardians, we enrolled potential candidates in this study. Information regarding baseline characteristics, relevant history, clinical examination, diagnosis, type of device used, frequency of administration and educator of the technique was recorded in a structured Performa. All enrolled subjects were interviewed and evaluated for proper inhalational therapy technique as described in the review by the European Respiratory Society.⁸ Furthermore, their administration technique during self-administration was closely observed and the findings recorded. At our institute, we assigned a single investigator trained in device use to carry all such interviews in order to eliminate inter observer variability. After this evaluation, proper demonstration and patient education regarding correct usage of inhalational therapy was explained and reinforced.

Statistical analysis: All information so obtained was first entered in Microsoft excel sheet and then analyzed by SPSS version 20 software. Results were presented as mean, standard deviation, percentage as appropriate. Dichotomous events were compared by Chi-Square test and continuous variables were compared by Student t-test. P value less than 0.05 was considered significant

RESULT

Over the two-year study period, 197 children with bronchial asthma were enrolled in this study who were prescribed inhalational therapy by their treating pediatrician. Mean age of the study population was 6.94 years (S. D= 2.53 years). 112 children were of male sex as compared to 85 females. Male: Female ratio was 1.32:1. Mean age at diagnosis was 6.27 years (S. D= 2.21 years). Mean duration of the inhalational device use was 6.13 months (S. D= 1.79 months). Table 1 shows general characteristics of the study participants.

Table 1: General characteristics of the participants

Characteristics	Number	Percentage/S.D
Gender:		
Males	112	56.9%
Females	85	43.1%
Place of habitation:		
Rural	103	52.3%
Urban	94	47.7%
Literacy status:		
Both parent literate	158	80.2%
Either parent illiterate	37	18.8%
Both parent illiterate	2	1.0%
Socioeconomic status:		
Lower	38	19.3%
Middle	91	46.2%
Upper	68	34.5%

Age at presentation (mean, SD) in years	6.94	2.53
Age at diagnosis (mean, SD) in years	6.27	2.21
Duration of therapy use (mean, SD) in months	6.2	1.77

Type of inhalational device & usage pattern: 69(35.1%) children were using MDI with spacer, 51 (25.9%) were using MDI with spacer & mask, 32(16.2%) were using DPI/Rotahaler and 45(22.8%) were using nebulization therapy. Most of the children were educated about using their device by a doctor (n=124, 62.9%) followed by trained nurses/hospital staffs (n= 44, 22.3%) and pharmacists (n=29, 14.7%). (refer Table 2).

Table 2: General characteristics of the different treatment groups

Characteristics	MDI+ spacer (n= 69)	MDI+spacer+Mask (n=51)	DPI/Rotahaler (n=32)	Nebuliser (n=45)
Age in years (mean± SD)	7.91±2.12	9.26±2.63	10.47±2.91	6.42±1.93
Male sex (n, %)	40 (57.9%)	28 (54.9%)	19 (59.4%)	25 (55.6%)
Duration of treatment in months (mean±SD)	6.51±1.94	6.13±1.28	8.26±2.73	4.95±1.89
EDUCATOR				
Pharmacist (n=29)	7	5	7	10
Nurse/trained staff (n=44)	8	7	13	16
Doctor (n=124)	54	39	12	19

Errors committed by children/caregivers while using their inhalation devices: Of the 197 children studied, 68% (n = 134) made one or more error whereas only 32% (n = 63) could use their device properly without any error. Most improperly used device was MDI with spacer and mask (n=54, 78.3%). followed by MDI with spacer (n=39, 76.5%) & DPI/Rotahaler (n=21, 65.6%). Whereas, the users of nebulizer committed the least number of errors (n=20, 44.4%). Rate of error was the least when the educator was a doctor (n=77, 62%) followed by nurses (n=33, 75%) and maximum with pharmacists (n=24, 82.7%).

Types of error observed

1. MDI with spacer users: The most common errors were: “inhaler not shaken” in 61.5%, “poor seal around mouth piece” in 53.8%, “no/short breath hold” in 43.6%% and “not exhaling to residual volume” in 35.9%.

2. MDI with spacer and mask users: The most common errors were: “inhaler not shaken” in 75.9%, “poor seal around mouth piece” in 68.5%, “not keeping the system in situ for few seconds post pressing the MDI” in 61.1%.

3. DPI/Rotahaler users: The most common errors were: “Insufficient acceleration” in 66.6%, “not inhaling deeply enough” in 52.4%, “poor seal around mouth-piece in 28.6%, “Long delay before inhalation (23.8%)” and “Stopping inhalation as device is fired (23.8%)”.

4. Nebulizer users: The commonest errors were: “poor fitting of the mask” in 75%, “no deep breathing throughout the treatment” in 60%, and “incorrect dose of medication” in 45%.

Factors contributing to error: Univariate analysis of probable demographic and treatment related factors was done. It was found that there was a statistically significant increase in occurrence of error in the presence of following factors: atleast one parent being illiterate (p=0.312), belonging to rural area (p=0.36), low socioeconomic status (p=0.244), educator not being a doctor (p=0.014) and device use for <3 months (p=0.097).

DISCUSSION

The present study was intended to know the problem statement, pattern of wrong usage and reasons for improper use of inhalation devices so as to address the reasons behind the same. Our study found that using inhalational devices correctly is really a challenging task in Indian patients due to their educational and socio-economic background. Out of the 197 children studied, only 32% could use their device properly. In our study, though male: female ratio was 1.31:1, this difference wasn't statistically significant. Mean age of the study population was 6.94 years (S. D= 2.53 years) which can be attributed to the higher

prevalence of reactive airway disease in younger children. Mean duration of device use was 6.1 months which indicates that the condition has a chronic pathology and hence treatment runs for months to years. We also found that the major chunk of such children came from rural background (52%) and approx. two-thirds (66%) of total children belonged to low socioeconomic strata of the society. This reflects that our hospital, being a tertiary care centre caters not only to urban children but also to children from nearby rural regions. Overall, MDI was the commonest device being used (61%) followed by nebulizer (22.8%). However, MDI was also the most

commonly improperly used inhalational device (77.5%). Whereas, children receiving nebulization therapy had the least number of errors (44.4%). The most common error in MDI was failure to shake the MDI, in DPI/Rotahaler it was inadequate breath accentuation and in nebulization it was poor fitting of the mask. Our results are comparable with the findings of Flor et al.⁹ Other authors have also shown that the rate of error in using inhalational therapy decreases when devices other than MDIs are used.¹⁰ However, if the technique is correct, drug delivery and clinical benefit is the same regardless of the device used.¹¹ In univariate analysis, we found a higher risk of improper use of inhalational therapy in the presence of: at least one parent being illiterate, low socioeconomic class, rural inhabitation, usage trained by personnel other than a Doctor and use of device for <3 months. Melani S et al.¹² and Ana Carlo Carvalho et al.¹³ found higher error rates in patients with low education levels and low socioeconomic status, which is similar to our finding. However, Hesselink et al.¹⁴ found no significant association between errors committed by the patients and their socio-economic status. As almost 50% of our cases came from rural background with a low level of education and socioeconomic status, the rate of erroneous use of devices was high in our study. Comparison of duration of device usage and errors committed showed a steep decrease in number of errors in the group using a device for more than 3 months. Elif sen et al.¹⁵ found that a longer duration of therapy was associated with a proper inhaler technique (p value <0.05). Gracia-Antequera et al.¹⁶ have also found that parents/ children receiving instructions more than once over a period of time tend to improve their performance of handling inhaler devices. The percentage of error was considerably higher when the educator was a pharmacist (82.7%) or nurses/hospital staff (75%). Fink and Rubin¹⁷ in their comprehensive study also found maximum error rate among self-educated and least among individuals educated by doctor. However, such high rate of failure to correctly use their inhalational devices also points to the fact that the training provided to the patients/caregivers probably was not sufficient. Deficient knowledge on the part of the training provider might also have contributed, as observed in a study conducted in Spain¹⁸ which showed only 14% physicians knew how to properly use MDI. Few other researchers have also shown that many healthcare professionals lack proper skill for teaching the correct use of inhalation devices.¹⁹ Nevertheless, patients' understanding of inhalation technique and difficulties faced while using them might have contributed to the ineffective patient training.

CONCLUSION

Majority of the children (68%) were not correctly using their inhalational devices. Proper education about device usage is crucial in ensuring adequate

delivery of drugs to lungs. Whatever be the chosen device, education from health caregivers has a major role in improving technique and compliance. Complete inhalation instructions and monitoring at each visit are crucial to ensure correct usage of inhalational devices by such children.

Limitations

First limitation is inherent in the study design that this is a single centre study. Second, long term follow up of these neonates was not done. Third, impact of re-education on the correct usage of inhalational devices was not studied.

Conflict of Interest: None

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