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# Drug Utilisation Study in Paediatric Patients with Acute Exacerbation of Bronchial Asthma Hospitalised in a Tertiary Care Teaching Hospital

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## ABSTRACT

**Introduction:** Bronchial asthma is a heterogeneous disease in children. It often leads to acute exacerbations resulting in increased Emergency Department (ED) visits, hospital admissions and school absenteeism among them. Irrational prescribing practices are quite prevalent among children. This highlights the importance of Drug Utilisation Studies (DUS) that are essential to investigate the pattern of drug use, thereby ensuring cost-effective health care and rational use of drugs.

**Aim:** To evaluate drug utilisation pattern for the treatment of acute asthma exacerbations in children hospitalised in a tertiary care teaching hospital.

**Materials and Methods:** This cross-sectional, observational study was conducted in the in-patient, Department of Paediatrics for a period from December 2017 to March 2019. A total of 30 children aged 1-17 years of either sex hospitalised for acute asthma exacerbations were enrolled in the study. Parameters like demographic profile and pattern of drug use were assessed. The collected data was presented as percentages, SD and mean.

**Results:** Results revealed that most commonly affected age group was 1-5 years (43.33% of total subjects) with female predominance. 13.33% children presented a positive family history of asthma. To manage acute exacerbations of asthma, all the patients received anti-asthmatic drug combinations and inhalational route was preferred. Corticosteroids and Short Acting  $\beta_2$  Agonists (SABA) were the most commonly prescribed drug classes. SABA (Levosulbutamol) was prescribed mainly through inhaled route (66.66%). 90% children received inhaled budesonide while IV Hydrocortisone was used in 86.66% cases of exacerbation. Combination of inhaled SABA + Ipratropium bromide was given in 36.66% patients. Montelukast was prescribed in 33.33% children as an add-on therapy. Average duration of hospital stay for the present episode was  $3.96 \pm 1.04$  days. Average number of drugs per prescription was 10.13. None of the drug was prescribed by generic name and antibiotics were used in 96.66% patients.

**Conclusion:** The observed drug utilisation pattern in the present study does not completely comply with the recommendations of standard treatment guidelines for asthma. High prescribing of antibiotics, polypharmacy and prescribing by brands are issues that need to be addressed which will ensure rational use of drugs in future.

**Keywords:** Anti-asthmatic drugs,  $\beta_2$  agonists, Children, Corticosteroids, Prescription pattern

## INTRODUCTION

Bronchial asthma is a heterogeneous disease in children which typically presents with respiratory symptoms like wheezing, shortness of breath, chest tightness and cough and reversible airflow limitation [1]. In childhood, acute exacerbations of asthma occur frequently and often result in ED visits, hospitalisation and school absenteeism [2]. These are mainly characterised by deterioration of asthma symptoms and decrease in respiratory function that might demand change in therapy [3]. Current estimates suggest that across the globe, around 300 million people already suffer from asthma and the number is predicted to rise by 100 million by 2025 [4].

Though asthma is highly prevalent in high income countries but its mortality rate is comparatively higher in low-middle-income countries [4]. About 14% of the paediatric population across the globe suffer from asthma and the incidence is profound in urban areas [5]. Several studies in Indian children reported an asthma prevalence rate ranging between 2.2% to 22%, however, there is no data reporting prevalence of asthma exacerbations [5-11]. In 2009, the prevalence of asthma exacerbation in the United States was 4.2% accounting for 12.8 million people, out of which 4.0 million belonged to paediatric age group. From 2001-2009, the prevalence of asthma had increased at a steady rate of 1.2% per year, but prevalence of asthma exacerbations remained stable (3.9%-4.3%) from 1997-2009 [12].

The pharmacotherapy of asthma targets achievement and maintenance of clinical control. To manage asthma, the Global Initiative for Asthma (GINA) guidelines suggest use of different drugs such as inhaled and oral  $\beta_2$  agonists, inhaled and systemic corticosteroids, xanthine derivatives and Leukotriene Receptor Antagonists (LTRA) which are either used alone or in combination [13]. Irrational prescribing practices are quite prevalent among children [14]. The efficacy and safety of drugs marketed for paediatric age group are generally based on clinical trials for adults. Data from adults cannot be generalised in children due to difference in their Pharmacokinetic and Pharmacodynamic characteristics. This encourages increased use of off-label and unlicensed drugs in children, which in turn poses threat of Adverse Drug Reactions (ADR) among them [14]. This highlights the importance of drug Utilisation Studies (DUS). The World Health Organisation (WHO) defines DUS as "the marketing, distribution, prescription and use of drugs in a society with special emphasis on the resulting medical, social and economic consequences". DUS helps to evaluate and improve current prescribing trends and also promotes rational use of drugs in accordance with the available treatment guidelines [15]. Globally, studies describing drug utilisation of bronchial asthma in children have revealed non-adherence to current treatment guidelines and require emphasising rational prescribing [16,17]. The studies conducted in India also fall on the same lines with the prescribing practices demanding improvement and compliance to

current guidelines for management of bronchial asthma. to GINA recommendations [18,19]. Keeping this in the background, the present study was designed to evaluate pattern of drug in paediatric patients with acute exacerbation of bronchial asthma admitted in a tertiary care teaching hospital.

## MATERIALS AND METHODS

This was an observational, non-interventional cross-sectional study undertaken in paediatric in-patients of acute exacerbation of asthma from MGM Medical College and Hospital, Aurangabad. The study was carried out from December 2017 to March 2019 after taking approval from Institutional Ethics committee (MGM-ECRHS/2017/10).

**Inclusion criteria:** Children aged between 1-17 years, of either gender and diagnosed with asthma exacerbations defined as episodes of progressive increase in shortness of breath, cough, wheezing, or chest tightness, or some combination of these symptoms were included [20].

**Exclusion criteria:** Children with other systemic disorders, suppressed immunity, co-morbidities like TB, diabetes, renal disease, etc., and those unwilling to participate were excluded. Prescriptions that were not written legibly and in which drugs were not readable were also excluded.

Majority of the asthmatic patients that visited our tertiary care center were managed on Outpatient Department basis and only 30 children were hospitalised for asthmatic exacerbation during the above-mentioned period. After thorough explanation of the study, a written Informed consent form was obtained from parents/guardians of patients and additionally assent was obtained from children above 7 years of age.

Patient's demographic details (age, sex, family history, duration of hospitalisation) and details of prescribed drugs (name, dose, therapeutic class, dosage form, route of administration, dosing frequency, etc.) were retrieved from in-patient case files and recorded in a specially designed case record form. Details of standard intravenous fluids, oxygen, vaccines and blood transfusion were not recorded. Prescription pattern was assessed using WHO's core prescribing indicators mentioned as follows [21]:

1. Average number of drugs per encounter
2. Percentage of drugs prescribed by generic name
3. Percentage of encounters with an antibiotic prescribed
4. Percentage of encounters with an injection prescribed
5. Percentage of drugs prescribed from an Essential Drug List (EDL) or formulary

## STATISTICAL ANALYSIS

Data was compiled in a Microsoft excel spreadsheet and presented as mean, SD and percentage.

## RESULTS

A total of 30 children hospitalised for acute asthma exacerbation in the Paediatric Inpatient Department during the study period were studied for their prescription pattern. Demographic analysis revealed that there were 56.66% females and 43.34% males. Highest number of patients belonged to the age group of 1-5 years (43.33%) [Table/Fig-1].

Majority of the patients (60%) in the present study belonged to urban areas. It was also observed that 13.33 % children presented a positive family history of asthma. The average duration of hospitalisation for the current episode was 3.96±1.04 days [Table/Fig-1].

A total of 304 drugs were prescribed to the study population. Average number of drugs prescribed per patient was 10.13. All the drugs were prescribed by their brand names. Percentage of encounter with an antibiotic was 96.66%. All the patients in the

study received multiple anti-asthmatic drug therapy as compared with individual therapy [Table/Fig-2].

Variables	Categories	Children with acute exacerbation of asthma (N=30)
Age (in years)	1-5	13 (43.33%)
	6-10	10 (33.33%)
	11-15	6 (20%)
	16-17	1 (3.33%)
Gender	Male	13 (43.34%)
	Female	17 (56.66%)
Weight (Kg) (mean±SD)		24.58±17.36
Height (cm) (mean±SD)		116.23±25.53
Family history	Yes	4 (13.33%)
	No	26 (86.66%)
Area of living	Urban	18 (60%)
	Rural	12 (40%)
History of hospitalisation in the last 1 year due to asthma exacerbation		19 (63.33%)
Duration of hospital stay for the present episode (days, mean±SD)		3.96±1.04

**[Table/Fig-1]:** Characteristics of recruited paediatric patients with acute exacerbation of asthma.

Parameters		Details
Total number of prescriptions		30
Total number of drugs prescribed		304
WHO core indicators	Average number of drugs per encounter	10.13
	Percentage of drugs prescribed by generic name	0
	Percentage of encounter with an antibiotic	96.66%
	Percentage of encounter with an injection	100%
	Percentage of drugs prescribed from essential drug list*	74.34%
Number of anti-asthmatic drugs prescribed (excluding other concomitant drugs)	Single drug therapy	0
	Multiple drug therapy	30 (100%)
Number of anti-asthmatic drugs prescribed by injectable route		28 (23.93%)
Number of anti-asthmatic drugs prescribed by inhalational route		60 (51.28%)
Number of anti-asthmatic drugs prescribed by oral route		29 (24.78%)

**[Table/Fig-2]:** Prescribing indicators in paediatric IPD patients of asthma.

\*The Indian academy of Paediatrics Essential Drug List (EDL) for children of India, 2011 was considered

Among the children treated with multiple drug therapy, three drug combinations (43.33%) were most widely prescribed than four drug (40%) or ≥5 drug combinations (13.33%). In only 1 prescription, a combination of 2 asthmatic drugs was seen.

To manage paediatric patients with acute exacerbation of asthma in this study, highest number of anti-asthmatic drugs were given by inhalational route (51.28%) followed by oral (24.78%) and injectable (23.93%) [Table/Fig-2].

Among the concomitant medications, oral NSAIDs were preferred the most (86.66%) and paracetamol was mostly prescribed. A considerably high proportion of patients (76.66%) were prescribed antihistamines. Other frequently prescribed drugs were antireflux agents (63.33%), multivitamins and multimineral (50%), antiemetics (46.66%) and zinc supplements (33.33%) [Table/Fig-3].

[Table/Fig-4] describes the overall prescription pattern of anti-asthmatic drugs along with the route of administration. To manage asthma exacerbation in hospitalised children, the most commonly prescribed were corticosteroids (inhalational budesonide in 90% and intravenous hydrocortisone in 86.66% patients) and SABA

(inhalational levosalbutamol in 66.66% and its oral formulation in 43.33%). Frequency of prescription of other anti-asthmatic drugs was comparatively less.

Category according to treatment	Number of patients (N=30)
SABA (Levosalbutamol)	30 (100%)
Corticosteroids (Budesonide, hydrocortisone, dexamethasone, prednisolone)	30 (100%)
SABA + Anticholinergic (Levosalbutamol + Ipratropium bromide)	11 (36.66%)
LTRA (Montelukast)	10 (33.33%)
Anticholinergic (Ipratropium bromide)	2 (6.66%)
Magnesium sulfate	1 (3.33%)
Antibiotics (Amoxicillin+clavulanic acid, ceftriaxone, cefixime+clavulanic acid)	29 (96.66%)
NSAIDs (Paracetamol, ibuprofen, mefenamic acid)	26 (86.66%)
Antihistamines (Cetirizine, chlorpheniramine, phenylephrine)	23 (76.66%)
Antireflux-agents (Ranitidine)	19 (63.33%)
Multivitamins and Multimineral	15 (50%)
Anti-emetics (Ondansetron)	14 (46.66%)
Zinc supplements	10 (33.33%)
Others*	17 (56.66%)

**[Table/Fig-3]:** Overall pattern of drug use in asthmatic children

\*appetite enhancers, cough suppressants, nutritional products, Vitamin D analogues, Calcium supplements

SABA: Short acting beta agonists; LTRA: Leukotriene receptor antagonists; NSAIDs: Non-steroidal anti-inflammatory drugs

Drug	Route of administration	Number of patients (N=30)
<b>SABA</b>		
Levosalbutamol	Oral	10 (43.33%)
	Inhalational	20 (66.66%)
<b>SABA + Anticholinergic</b>		
Levosalbutamol + Ipratropium Bromide	Inhalational	11 (36.66%)
<b>Anticholinergic</b>		
Ipratropium bromide	Inhalational	2 (6.66%)
<b>Corticosteroids</b>		
Budesonide	Inhalational	27 (90%)
Hydrocortisone	Injection (IV)	26 (86.66%)
Dexamethasone	Injection (IV)	1 (3.33%)
Prednisolone	Oral	6 (20%)
<b>LTRA</b>		
Montelukast	Oral	10 (33.33%)
Magnesium Sulphate	Injection (IV)	1 (3.33%)

**[Table/Fig-4]:** Overall prescription pattern of anti-asthmatic drugs in children hospitalised for acute exacerbation of asthma.

SABA: Short acting beta agonists; LTRA: Leukotriene receptor antagonists

In this study, the most commonly prescribed antibiotics in children were penicillins and cephalosporins. Parenteral Amoxicillin + clavulanic acid was prescribed in 13 (44.82%) patients whereas only 2 (6.89%) patients received its oral preparation. Parenteral Ceftriaxone was used in 13 (44.82%) asthmatic children. Only 1 (3.44%) child used oral preparation of Cefixime + clavulanic acid.

## DISCUSSION

Assessment of prescription pattern shows that average number of drugs per prescription was 10.13 which can be attributed to use

of multiple anti-asthmatic drugs and concomitants for inpatient management of acute exacerbation. Similarly, a higher value (13.25%) of indicator was reported in a study by Aleemudin NM et al., [22]. However, this does not comply with the WHO standards, hereby increasing the risk of adverse drug reactions, drug interactions, cost of hospitalisation and medication non-adherence in children [23].

All the drugs were prescribed by their brand names which is similar to a study conducted by Garje YA et al., [24]. Another study by Trivedi N et al., exhibited profound usage of brand names of drugs [25]. Deviation from generic prescribing is an irrational practice and indicates undue influence of promotional strategies by pharmaceutical companies.

In the present study, antibiotics were prescribed to a higher percentage (96.66%) of asthmatic children which suggests occurrence of some underlying upper or lower respiratory tract bacterial infection in them. The studies by Shah RD et al., and Karki S et al., also reported considerably high use of antibiotics i.e., 64% and 67%, respectively [19,26]. However, inappropriate and overuse of antibiotics in patients with asthma exacerbations needs to be discouraged as it lacks evidence of effectiveness and increases risk of bacterial resistance as well as antibiotic-related adverse effects [27]. To prevent their indiscriminate use, physicians should be educated to prescribe antibiotics only when truly necessary and all measures should be undertaken to confirm the type of antibiotic required. Also, antibiotic restriction policies formulated at hospital levels along with strict implementation of antibiotic usage protocol can address this issue effectively [28].

The percentage of encounter with an injection was 100% which was considerably higher than the range provided by WHO (13.4 - 24.1%) [29]. Similarly, few researchers also reported a higher value of this variable [19,30]. Possible reason for the high use of injections could be due to inclusion of inpatients.

The percentage of drugs prescribed from Essential Drug List (EDL) was found to be 74.34% which is lower than the standard (100%) [29]. This could be because of lack of awareness about EDL among the prescribers.

According to GINA and National Asthma Education and Prevention Program (NAEPP) Expert Panel Report 3 (EPR3) guidelines, patients presenting with acute asthma exacerbation require multiple anti-asthmatic drugs [3,31]. As per the present study data, all the children received multiple anti-asthmatic drugs. None of the patients was prescribed monotherapy. However, in other studies most of the patients received anti-asthmatic drugs combinations and very few were prescribed individual therapy [24,26,32-34]. A combination of three anti-asthmatic drugs was widely administered which is in line with studies by Garje YA et al., Karki S et al., and Arumugam V et al., [24,26,35].

Current treatment guidelines for asthma advocate the use of inhalational therapy as the first choice because of its local delivery of drug thereby decreasing dose as well as side effects [3,31]. In this study also, most of the anti-asthmatic drugs (51.28%) were prescribed via inhalational route. But in studies by Jayadeva BT et al., and Jyothi DB et al., nebulisation was the preferred route [32,33]. Some studies in the past also reported similar trend in preference of inhalational route [25,34,36]. In contrast, some researchers observed maximum prescription of oral dosage forms [24,26,37].

Overall drug use revealed that corticosteroids and  $\beta_2$  agonists were the most common therapeutic classes prescribed among children for the management of acute asthma exacerbations as shown in some studies [19,24,26,38]. Among the corticosteroids, inhalational route was preferred in 90% cases of exacerbation and all of them received budesonide. Parenteral corticosteroids such as IV Hydrocortisone and IV Dexamethasone were administered in 86.66% and 3.33% children respectively. In comparison, usage



of IV corticosteroid was in the range of 60-100% in some studies conducted in the past [32,33,38]. Oral corticosteroids (prednisolone) were prescribed in 20% children. Intravenous Magnesium sulfate is quite known in significantly reversing bronchospasm in children with acute asthmatic exacerbation not responding to conventional therapy [39]. Recently, analysis of several systematic reviews on treatment of acute paediatric asthma demonstrated its favourable effect on rates of hospital admissions as well as lung function parameters [39]. In this study, Magnesium sulfate was used in 3.33% cases of severe exacerbation. On the other hand, administration of oral prednisolone (65.45%) and Magnesium sulfate (43.64%) was very high in children in a study done by Shah RD et al., [19].

Many previous studies have reported the usage of SABA in the range of 40-80% [18,19,34,35,38,40]. In this study, SABA (Levosinbutamol) was prescribed more through inhaled route (66.66%) as compared to oral route (43.33%) while findings of another research report higher usage of oral SABA (77.2%) [18]. Combination of inhaled SABA + anticholinergic (Ipratropium bromide) was given in 36.66% patients, although few studies observed their higher use [25,32,33]. Another significant finding in the present study was usage of a leukotriene receptor antagonist (Montelukast) in 33.33% children as an add-on therapy. This is consistent with studies by Jayadeva BT et al., and Jyothi DB et al., that observed Montelukast use in 57% and 55% patients, respectively [32,33].

### Limitation(s)

As it was a single centre study with a limited sample size, the results might not represent general performance within a population. For higher precision and more robust assessments, a greater number of prescriptions should be included. Also, the study lacked follow-up and pharmaco-economic analysis.

### CONCLUSION(S)

This study evaluated the current prescription practices in paediatric patients of bronchial asthma at a tertiary care hospital. The observed pattern of drug use does not completely comply with the recommendations of standard guidelines. The issue of polypharmacy needs to be addressed as it is higher than standards. High prescribing of antibiotics is a matter of growing concern due to increased risk of antibiotic resistance, adverse effects and economic burdens for patients as well as the health care system. Generic prescribing is another element that needs to be worked upon. Also, asthma education campaigns, regular Continuing Medical educations and interventional programmes should be implemented at health care centres to improve asthma knowledge and increase awareness regarding current treatment practices among prescribers.

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