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Patterns of Drug Utilization in Children with Asthma



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ABSTRACT

This study aimed to investigate the prescription patterns of medicines in children with asthma. Asthma is a heterogeneous disease characterized by airway inflammation and it can lead to wheezing, dyspnea, tightness of the chest and cough, asthma affects millions of children globally. The study was conducted in a pediatric department of ESIC PGIMSR, Rajajinagar, Bengaluru, India. A total of 37 children with asthma were included in the study. The results showed that the prevalence of asthma was higher in boys than girls. The most common risk factors for asthma were family history of asthma and seasonal variation. The most common drugs used to manage asthma in children were salbutamol (bronchodilator), budesonide (corticosteroid), and prednisolone (corticosteroid). The least used drugs were adrenaline (sympathomimetic agent) and a combination of nasal decongestants, antihistamines, and antitussive. The most common route of drug administration was a nebulizer, followed by inhalation and oral. At the time of discharge, the most commonly prescribed medicines were budesonide, salbutamol, and prednisolone. The least prescribed drugs were a combination of nasal decongestants, antihistamines, and antitussive, and a combination of salmeterol and fluticasone propionate. The most common route of drug administration for discharge medicines was inhalation, followed by oral. The results of this study suggest that the prescription of medicines in children with asthma is by the standard treatment guidelines for asthma. However, it is important to educate patients and their parents about asthma, its preventive measures, and the importance of adherence to the treatment regimen and proper use of inhalers.

INTRODUCTION

The Global Initiative for Asthma (GINA) defines asthma as "It 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 limitation".^[1]

It is a long-term condition affecting people of all ages. The air passages in the lungs become narrow due to inflammation and tightening of the airway muscles.^[2] It causes wheezing, dyspnoea, chest tightness, and coughing at night or early in the morning. It can be managed by taking medicines and avoiding triggers causing the asthmatic attack.^[3]

According to the Global Burden of Disease Study 2015, asthma is among the top 20 causes of disability worldwide and ranks 23rd in terms of clinical burden when measured by disability-adjusted life years.^[4]

As per the Global Asthma Report 2018, it kills around 1000 people every day and affects as many as 339 million people. Its prevalence is rising among low-income and middle-income countries where they disproportionally suffer the most severe cases.^[5] Out of 1.31 billion people of India, about 6% of children and 2% of adults have asthma.^[6]

ETIOLOGY

Epidemiological studies support the idea that both genetics and the environment interact to cause asthma.^[7]

60 % to 80 % of vulnerability can be attributed to genetics. Asthma is an example of a complicated genetic condition because its phenotype is probably due to polygenic inheritance or a diverse combination of genes. Initially, researchers looked for connections between atopy (a genetic predisposition to extreme sensitivity to environmental allergens) and asthma.^[8]

Risk factors for early (less than 3 years of age) wheezing that is associated with viral infections include preterm birth, low birth weight, male gender, and parental smoking. Smaller airways are the cause of this early pattern.^[9]

The most significant cause of severe asthma in children is viral respiratory tract infections (RTI), and they are an important trigger in adults as well.^[10]

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ASTHMA SYMPTOMS IN INFANTS AND CHILDREN

Although the intensity and frequency of asthma symptoms might vary from person to person, they are mostly the same in children and adults.

However, compared to toddlers and young children (4 to 11), asthma symptoms are distinctively different in infants (under 1 year) and newborn (between 1 and 4). This is a result of the lung's general strength and capability, as well as variations in airway size.^[11]

Table 1: Symptoms of asthma in infants and children ^[11]			
Infants and Babies Toddlers and Young Chi			
Wheezing	Wheeze		
Dyspnea	Cough		
Cough	Dyspnea		
Frequent coughing	Chest tightness		
Exaggerated belly movements while breathing	Frequent coughing		
Sucking in of the ribs while inhaling	Attacks		
Interruption in laughing, crying or breathing	Delayed recovery from colds and other respiratory infections		
Fatigue and lethargy	Daytime fatigue and sleepiness		
Reduced activity	Interrupt in playing due to breathing difficulty		

Goal of the treatment – As per the GINA guidelines 2022, the long-term goals of asthma management are:^[1]

To maintain a normal level of activities and to achieve good control over symptoms.

To reduce the risk of asthma-related mortality, exacerbations, persistent airflow restriction, and side effects.

Prescription pattern monitoring studies (PPMS) are drug utilization studies with the most deliberate prescribing, dispensing, and administering of medication. They facilitate the judicious use of regulated drugs as well as the minimization of drug abuse and misuse. The main aim of PPMS is to facilitate the rational use of medicines (RUM).^[12]

This study will establish the link between asthma prevalence, incidence, and treatment to improve the management of asthma in pediatric patients. The study is being undertaken to observe the anti-asthmatic drug prescribing trends in children, as well as to provide

healthcare professionals with an understanding of regularly used medicines in pediatric asthma, so that it can improve the prescription practice, improve the patient's condition and health-related quality of life.

Aim and objective of the study: This study aimed to analyze the prescribing pattern of medicines used in children with asthma, visiting pediatric department of a teaching hospital.

PATIENTS AND METHODS:

Study Design: This was an observational study.

Study Duration: 6 months of study, including planning, data collection, interpretation and thesis writing.

Study Centre: The study was conducted the department of Paediatrics at ESI PGIMSR, Rajajinagar, Bengaluru.

Study Population: The study was conducted in subjects drawn from the population admitted in pediatric ward at ESIC-MC & PGIMSR, Bengaluru, who had given informed consent and assent form.

Sample Size: The sample size was calculated using a prevalence of 11% in the Department of paediatrics and was estimated to be 37.

$$n = \frac{Z_{1-a_{/2}}^2 * p * (1-p)}{d^2}$$

INCLUSION CRITERIA:

- a. Subjects prescribed with anti-asthmatics admitted in department of pediatrics of ESIC hospital, Rajajinagar, Bangalore.
- b. Subjects below 18 years of age.
- c. Subjects of either gender.

EXCLUSION CRITERIA:

a. Subjects suffering with other disease conditions or severe chronic illnesses.

ETHICAL APPROVAL: This study was approved by ESIC-Medical College & PGIMSR (No.532/l/11/12/Ethics/ESICMC&PGIMSR/Estt. Vol.-IV).

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SOURCE OF DATA:

Patient profile and treatment details collected from patient's case sheets admitted in inpatient department of pediatrics.

STUDY TOOL:

Self-designed data collection form: A data collection form was designed to collect sample demographic aspects, chief complaints, history of present illness, medication history and medications.

STUDY PROCEDURE:

Subjects for the study were identified by the investigators during the ward visits based on the inclusion and exclusion criteria. The patients were explained the purpose of the study and informed consent and assent were obtained. Relevant data such as demographic details, medication chart, etc., was recorded. The data thus obtained was entered in a Microsoft Excel sheet and appropriate analysis was performed.

STATISTICAL ANALYSIS:

All recorded data were entered using MS Excel software and analyzed using MS Excel 2016. Descriptive statistics such as mean and standard deviation were computed for quantitative variables and frequencies and percentages were calculated for categorical variables. Histograms and pie charts were applied to find the nature of data distribution.

RESULTS

The study was conducted in subjects drawn from the population admitted in paediatric ward at ESIC-MC & PGIMSR, Bengaluru based on the inclusion criteria. A total of 37 study subjects were included in the study.

Table 2: Patients' Demographic Details (n=37)						
Gender distribution of patients						
Gender	Number of children	Percentage				
Female	11	30%				
Male	26	70%				
Age distribution of patients						
Age groups	Age	Number of Children	Percentage			
New-born	0 days - 1 month	0	0%			
Infant	1 month - 1 yrs.	0	0%			
Toddler	1-3 yrs.	4	11%			
Pre school	3-6 yrs.	7	19%			
School-age child	6-12 yrs.	15	40%			
Adolescent	12-18 yrs.	11	30%			

GENDER DISTRIBUTION

Out of 37 study subjects enrolled in the study, 26 (70%) were male and 11 (30%) were female as enlisted in figure 1.



Figure 1: Gender distribution of subjects

AGE DISTRIBUTION:

Out of 37 study subjects 15 (40%) of them belonged to School-age child (i.e., 6-12) years of age group, 11 (30%) of them were adolescents, 7 (19%) of them were pre-school and 4 (11%) of them were toddlers. The mean age of our study subject was found to be 9.3 years. Age distribution of the subjects are given in the figure 2.



Figure 2: Age distribution of patients (n=37)

RISK FACTOR

Out of 37 study subjects, 12 (32%) showed a family history of asthma, 8 (22%) of them had seasonal variation, and the rest of them had both dust and seasonal variation as the triggering factors for asthma, as enumerated in figure 3.



Figure 3: Risk factors among subjects

BASED ON TYPES OF DRUG THERAPY

Out of all the participants (n = 37), 23 subjects (62%) received poly drug therapy, 4 (11%) had received three-drug therapy, 7 (19%) of them had received two-drug therapy and only 3 (8%) had received one drug therapy as enumerated in the figure 4.



Figure 4: Distribution of subjects based on types of drug therapy

TREATMENT OF PEDIATRIC ASTHMA DURING HOSPITAL STAY:

Out of all the medicines prescribed to the patients who were admitted during the study period, it was concluded that the most prescribed drug for managing asthma in subjects was salbutamol in 33 (89%), followed by budesonide in 30 (81%), prednisolone in 17 (46%), levosalbutamol and ipratropium bromide in 17 (46%), hydrocortisone in 8 (22%), Ambronite in 8 (22%), 3% NaCl in 5 (14%), oxygen in 4 (11%), levosalbutamol in 4 (11%), fluticasone in 3 (8%), cetirizine in 8 (3%), montelukast in 3 (8%), ipratropium in 2 (5%), combination of phenylephrine, chlorpheniramine maleate and dextromethorphan hydrobromide in 1 (3%), and adrenaline in 1 (3%).

The most common class of drug used to prescribe medicines were bronchodilator followed by corticosteroids, mucolytics, hypertonic saline, medical gas, antihistamines, LTRAs (Leukotriene Receptor Antagonists), combination of nasal decongestants, antihistamines and antitussives and the sympathomimetic agents.

The details of prescription patterns are enlisted in the table 3 and figure 5.

Table 3: Pattern of medications (and class of drug) used for managing asthma in children					
S. No	Class of drug	Medicines	Patient	Percentage	
1	Nasal decongestants+ Antihistamines+ Antitussives	Phenylephrine+ Chlorpheniramine maleate+ Dextromethorphan hydrobromide	1	3%	
2	Sympathomimetic agents	Adrenaline	1	3%	
3	Bronchodilator	Formoterol fumarate	1	3%	
		Ipratropium	2	5%	
		Salbutamol	33	89%	
		Levosalbutamol	4	11%	
		Levosalbutamol+ ipratropium bromide	17	46%	
4 Cort	Corticosteroids	Dexamethasone	1	3%	
		Fluticasone	3	8%	
		Hydrocortisone	8	22%	
		Prednisolone	17	46%	
		Budesonide	30	81%	
5	Hypertonic saline	3% NaCl	5	14%	
6	Medical gas	Oxygen	4	11%	
7	Antihistamines	Cetirizine	3	8%	
8	LTRAs	Montelukast	3	8%	
9	Mucolytics	Ambrolite	8	22%	

*PCM- Phenylephrine+ Chlorpheniramine maleate+ Dextromethorphan hydrobromide

*Duolin- Levosalbutamol and ipratropium bromide

*LTRAs- Leukotriene Receptor Antagonists



*PCM- Phenylephrine + Chlorpheniramine maleate + Dextromethorphan hydrobromide *Duolin- Levosalbutamol and ipratropium bromide

ROUTE OF DRUG ADMINISTRATION DURING HOSPITAL STAY

Nebulizer was the most preferred route of administration for the subjects admitted inside the hospital to manage the asthma followed by inhalation, oral and I.V. (injections) as shown in figure 6.



Figure 6: Route of drug administration (During hospital stay)

DISTRIBUTION OF MEDICATIONS AT THE TIME OF DISCHARGE:

At the time of discharge the most prescribed drug for managing asthma in subjects was Budesonide in 30 (81%), followed by salbutamol in 25 (68%), prednisolone in 10 (27%), fluticasone in 7 (19%), montelukast in 3 (8%), formoterol fumarate in 3 (8%), ambrolite in 2 (5%), cetirizine in 2 (5%), 3% NaCl in 2 (5%), a combination of salmeterol and fluticasone propionate in 1 (3%), the combination of phenylephrine, chlorpheniramine maleate and dextromethorphan hydrobromide in 1 (3%) and combination of levosalbutamol and ipratropium bromide in 1 (3%). The most common class of drug used were corticosteroid, bronchodilator, LTRAs (Leukotriene Receptor Antagonists), hypertonic saline, antihistamine, mucolytics, a combination of nasal decongestants, antihistamines and antitussives and a combination of LABA (Long Acting Beta Agonist) and corticosteroids. The detailed discharge medications are enlisted in the table 4 and figure 7. **Table 4:** Pattern of medications (and class of drug) used for managing asthma in children (at the time of discharge)

S. No	Class of drug	Medicines	Patient	Percentage
1	Nasal decongestants+ Antihistamines+ Antitussives	Phenylephrine+ Chlorpheniramine maleate+ Dextromethorphan hydrobromide	1	3%
2	Long-acting Beta agonist+ Corticosteroids	Salmeterol+ Fluticasone propionate	1	3%
3	Bronchodilator	Formoterol fumarate	3	8%
		Salbutamol	25	68%
		Levosalbutamol and ipratropium bromide	1	3%
4	Hypertonic saline	3% NaCl	2	5%
5	Corticosteroids	Fluticasone	7	19%
		Prednisolone	10	27%
		Budesonide	30	81%
6	Antihistamines	Cetirizine	2	5%
7	LTRAs	Montelukast	3	8%
8	Mucolytics	Ambrolite	2	5%





Figure 7: Pattern of medications used for managing asthma in children (at the time of discharge)

ROUTE OF ADMINISTRATION AT THE TIME OF DISCHARGE:

Most of the discharge medicines were advised to be taken through the inhalational route followed by oral route of drug administration, as shown in figure 8.



Figure 8: Route of drug administration (for discharge medicines)

DISCUSSION

This observational study was conducted to study the prescribing pattern of medicines used in children with asthma, in the Paediatric department of ESIC PGIMSR hospital, Rajajinagar, Bangalore.

A total of 37 subjects were enrolled in the study based on inclusion and exclusion criteria.

The subjects were categorized according to age and gender. Out of 37 subjects who were the part of study, most of them belonged to school age child group 6 to 12 years of age, 40% (n=15), and the number of males, 70% (n=26) were more than females 30% (n=11).

The mean length of hospital stay was 4.5 days, which is similar to the study conducted by *Hoskins et al. (2000)* 4.04 days.^[13]

In our study, it was found that asthma was more prevalent in males than females, and this result shows similarity to the study conducted by *Pandey A*, *Tripathi P et al.*, (2010) in which they analysed 100 cases of asthma and their study revealed that asthma was more prevalent in males than females.^[14]

The study showed that there was a relation between seasonal variation and asthma in children, especially during winter or cold (22%) when compared to the study carried out by *Chhabra S K et al.*, (1999) which showed that 2.4% children were getting asthma due to cold.^[15]

The study also showed that children who had family history of asthma were suffering with the condition (32%), which was similar to the study carried by *Deka H et al.*, (2022) in which it was found that children with a family history of allergy and asthma were at a very high risk of getting the disease.^[16]

Out of 37 patients, 23 (62%) have received a poly-drug therapy (i.e., more than three drugs) and only 3 patients (8%) received one drug therapy which was evident in the study carried out by *Fahmy SA et al.*, (2016) where 83 (54%) of the study participants have received multiple drug therapy and 71 (46%) participants with single drug therapy.^[17]

The most commonly prescribed drug to manage asthma in children was Salbutamol (89%) followed by Budesonide (81%) which comes under the class of Bronchodilators (SABA) and Corticosteroids (ICS) whereas the study conducted by *Gupta S, Awasthi S (2016)* showed that the study subjects received SABA through oral route (77.3%) which was preferred over inhalation (22.7%) and antitussives (52.1%) were prescribed in exacerbation.^[18]

During the hospital stay, a nebulizer was the most common route of administration (41.61%) followed by inhalation route (28.47%), oral (24.82%) and least used route of administration was injection (5.11%) whereas study conducted by *Kaur S et al.*, (2020) inhalation (81.23%) was the most common route followed by oral (18.76%) route.^[19]

At the time of discharge, Budesonide was most commonly prescribed (81%) followed by salbutamol (25%), which comes under the Corticosteroids (Inhaled Corticosteroids) and bronchodilator (Short Acting Beta Agonist) class of drug respectively.

The most preferred route of administration which was prescribed at the time of discharge for using asthma medicines was Inhalation (79.31%) followed by oral route (20.69%).

CONCLUSION

Asthma is one of the most frequent chronic childhood conditions affecting millions of children.

Our study concluded that male children were more prone to asthma when compared to female children. Based on age, the most number of children who were admitted due to asthma were 6-12 years and 12-18 years of age group.

Most of the patients had a family history of asthma which shows the evidence of genetic linkage to asthma in children.

From this study we concluded that the most commonly prescribed medication to manage asthma in children was salbutamol (a bronchodilator) followed by budesonide (a corticosteroid) and the most commonly preferred route of administration was nebulizer followed by inhalation during the hospital stay of the patients. At the time of discharge, most of the patients were discharged with budesonide (a corticosteroid) followed by salbutamol (a bronchodilator) and the most commonly preferred route was inhalation followed by oral.

It was also observed that the majority of the subjects have received a poly-drug therapy as required during the treatment period and few of them had received one drug therapy.

Prescription of medications in children with asthma was in accordance to the standard treatment guidelines for asthma. Patient and their parents should be educated regarding asthma, its preventive measures and also the importance of adherence towards treatment regimen and the use of inhalers.

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