



DRUG UTILIZATION PATTERN OF ANTI-ASTHMATIC DRUGS IN PAEDIATRIC PATIENTS IN PRIVATE HOSPITAL

Pharmacology

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ABSTRACT

Introduction: Pediatric asthma causes economic burden due to global trend of irrational prescribing patterns. Our study aimed to analyze prescription patterns of Anti-Asthmatic drugs at private hospital. **Materials and Methods:** The study was conducted at Yashoda Chest Clinic, Heera Patti at Azamgarh during October 2019 to February 2020. Patients attending OPD were included, their demographic details, details of anti-asthmatic drugs used were recorded along with adverse drug reactions. Collected data were statistically analyzed. **Results:** Our study results showed predominance of male over female and patient in the age group of 6-10 years were more, although, acute exacerbations were observed more in females of 1-5 years of age. Short acting beta agonists (SABA) were preferred followed by inhaled steroids & in acute states levosalbutamol and combination of levosalbutamol with ipratropium bromide were used. Encountered adverse drug reactions included palpitation, dryness of mouth, tachycardia, headache, sore throat, oral candidiasis diarrhoea etc. that occurred due to levosalbutamol, montelukast, budesonide and ipratropium bromide. **Conclusions:** Although drugs prescribed were in brand names both study centres exhibited comparable prescribing trends. This study highlights importance of ADR monitoring drugs causing so that they are used in caution in the vulnerable individuals.

KEYWORDS

INTRODUCTION

Bronchial asthma is a heterogenous disorder, mainly characterized by varying degrees of airway obstruction, bronchial hyper-responsiveness, and airway inflammation.¹ The main symptoms are presented by recurrent episodes of wheezing, shortness of breath, chest tightness and coughing.

According to World Health Organization (WHO) estimates, 300 million people suffered from asthma, which led to a death of 255,000 people in 2005 and over 80% of asthma deaths are reported from low and lower-middle income countries.² As per current Global Initiative for Asthma (GINA) guidelines, the global prevalence of asthma ranges from 1 to 16% of the population across the countries.³ Although, quality medications are easily available, still an upward trend has been shown in the prevalence and mortality due to asthma.⁴

The prevalence of childhood bronchial asthma varies widely from country to country. It ranges from 4 to 32% at the age of six to seven years, and the same range is applicable for ages 13 and 14. The highest prevalence of severe bronchial asthma in the world is in UK.⁵

The last two decades have witnessed a persistent increase in the prevalence of asthma globally as well as in India. The median prevalence of bronchial asthma in Indian children is estimated to be about 4.75% of the pediatric population.⁶ Also, prevalence rate of asthma in Indian children of age group of 5-11 years has been roughly estimated to be 10 -15%.⁷

The goal of asthma treatment is to achieve and maintain clinical control. For the management of asthma, Global Initiative for Asthma (GINA) guidelines has suggested various drugs like long and short acting β_2 agonists (salbutamol, salmeterol, formoterol), corticosteroids (fluticasone, prednisolone, budesonide), xanthine derivatives (theophylline) and leukotriene receptor antagonists (montelukast). Either these drugs can be used alone or in conjunction with other anti-asthmatic drugs.⁸ To decrease the mortality and morbidity of severe attacks, early recognition and timely intervention are crucial. Inhaled β_2 -agonists, corticosteroids and anti-cholinergic agents are first-line drugs for severe asthma exacerbation, whereas magnesium sulfate is effective for critically ill patients.⁹

Drug utilization study is one of the fundamental watchtowers for promoting rational use of drugs for treatment of various diseases, surveying the field of healthcare and thereby leading to a greater understanding of the development that underlies it.¹⁰ Drug Utilization Research (DUR) was defined by the WHO in 1977 as "The marketing,

distribution, prescription, and use of drugs in a society, with special emphasis on the resulting medical, social and economic implications".¹¹

Since treatment of Asthma requires long duration, adherence behaviour of patient is also an important factor which determines the outcome of the treatment.

The increased interest in DUR has resulted due to recognition of the virtual explosion in the marketing of new drugs, the wide variations in the patterns of drug prescribing and consumption, and the increasing concern about the cost of drugs.¹¹ A prescription-based survey is considered to be one of the most effective and best methods to assess and evaluate the prescribing attitude of physicians and prescription based drug utilization studies are more meaningful to observe the prescribing attitude of physicians with an aim to provide drugs rationally. Irrational drug use increases the cost of treatment, incidence of adverse drug reaction (ADR) and hospitalization. ADRs are an unfortunate burden on the society, both financially as well as in terms of human suffering. They are associated with almost every drug and may range from mild to serious and even life threatening.

Prescribing of drugs requires continuous assessment because various factors like unethical drug promotion, lack of knowledge, unavailability of drugs, etc., have an impact on it, resulting in irrational trends in prescription. Since, rational prescribing will ensure enhancement of physician's knowledge and selection of most appropriate cost effective therapy, this study was planned to analyze prescription pattern of Anti-Asthmatic drugs in pediatric patients at private hospital in Northern India.

AIMS AND OBJECTIVE

The main objectives of the study were

1. To evaluate the demographic details in the enrolled patients.
2. To observe the pattern of Drug utilization in the Pharmacotherapy of Asthma.
3. To identify the occurrence of ADRs.
4. To observe for the practice of prescribing the medicine by their generic name and brand name.

MATERIAL AND METHODS

Study Site: This was prospective, observational study done at Yasodha Chest Clinic, Azamgarh (Private Set up) India after taking No Objection Certificate from Hospital Authorities. The duration of the study was 6 months from October 2019- February 2020 where 150 patients were enrolled as per inclusion and exclusion criteria.

Inclusion criteria

- Paediatric patients of either sex.
- Patients between age group of 1-17 years.
- Both acute and chronic cases of bronchial asthma.
- Patients who were willing to participate in the study with informed consent.

Exclusion criteria

- Patients who were less than 1 year of age and greater than 17 years of age.
- Patients who were immunocompromised.
- Patients with other co-morbid conditions like TB, Diabetes/renal failure.
- Patients with other systemic disorders.

Study Procedure:

The data was collected during regular visit to Out Patients Department (OPD) in the Department of TB & Chest, Yashoda Chest Clinic, Azamgarh. Standard data entry format was used to enter all the patient details collected during visit to OPD at the study site. The prescriptions were individually screened to assess the prescribing pattern of Anti-Asthmatic drugs. All this information was obtained from the patient's case files.

All the adverse drug reactions (ADRs) occurring during the therapy (either spontaneously reported or identified by the investigator) were noted in ADR reporting form. All the Patients were followed up following their enrollment till they were discharged. Based on the history and Pill count all the Participants were observed for the compliance of the therapy. A specially designed data entry format was used to enter all the information pertaining to the patient and drug therapy given were recorded in a Case Record Form (CRF), the information of which were obtained from Patient case files. During the course of the study the enrolled Patients were followed for occurrence of ADR and the same were reported to ADRs Monitoring centre. The collected data were thoroughly reviewed to maintain the quality of data. Transcribed data were also reviewed against data collection Performa to minimize transcription error's. After completion of the study, data were collected and analyzed using appropriate statistical tests.

RESULTS

On the basis of inclusion and exclusion criteria, 150 pediatric patients of bronchial asthma that attended OPD at Yasodha Chest Clinic, Azamgarh from October 2019 to February 2020 were enrolled in the study.

Table no 1: Distribution of pediatric patients based on Gender

Gender	Number of patients at Yasodha Chest Clinic
Male	76 (50.66)
Female	74 (49.33)
Total	150

Distribution of patients on the basis of gender revealed that 50.67% of the pediatric asthma patients were male and 49.33% were females as shown in Table 1.

Table no 2: Distribution of pediatric patients based on Age group

Age group in years	Number of patients at Yasodha Chest Clinic
1-5	42 (28)
6 -10	82 (54.66)
11-15	23 (15.33)
16-17	3 (2)
Total	150

Out of 150 pediatric patients of bronchial asthma, that attended Yasodha Chest Clinic OPD, it was found that highest number of patients 82 (54.66%) belonged to the age group of 6-10 years followed by age group of 1-5 years accounting for 42 (28%) patients. 23 (15.33%) patients were enrolled from age group of 11-15 years whereas only 3(2%) belonged to age group of 16-17 years as shown in Table no 2.

Table no 3: Distribution of pediatric patients on the basis of**severity of Bronchial Asthma**

Type of Bronchial Asthma (N=150)	Number of patients at Yasodha Chest Clinic
Intermittent	65 (43.33)
Mild Persistent	25 (16.33)
Moderate Persistent	32 (21.33)
Severe Persistent	28 (18.66)
Total	150 (100)

Table 3 shows the distribution of patients on the basis of severity of bronchial asthma. Out of the 150 children enrolled at Yasodha Chest Clinic, 65 (43.33%) children had intermittent asthma and 25 (16.33%) cases of asthma were mild persistent, 32 (21.33%) moderate and 28 (18.66%) were severe persistent.

Table no 4: Distribution of pediatric patients on the basis of control of Bronchial Asthma

Severity of Bronchial Asthma	Number of patients at Yasodha Chest Clinic
Well controlled	44 (29.33)
Partly controlled	60 (40)
Uncontrolled	46 (30.66)
Total	150 (100)

Among the enrolled cases of pediatric asthma from OPD at Yasodha Chest Clinic, 60 (40%) children presented partly controlled asthma followed by 46 (30.66%) with uncontrolled asthma. Number of patients with well controlled asthma was the least i.e. 44 (29.33%) as shown in Table no 4.

Table no 5: Prescribing indicators in pediatric patients

Parameters		Details (Yasodha Chest Clinic)
Total number of prescriptions		150
Total no. of drugs prescribed		406
Average drugs per prescriptions		2.7
Encounter with Brand Names		100%
Encounter with Generic Names		0.00%
Anti-asthmatic drugs prescribed	Single drug therapy	51 (34 %)
	Multiple drug therapy	99 (66%)

In 150 patients enrolled at OPD, Yasodha Chest Clinic, total 406 drugs were prescribed. Average number of drugs per prescription was 2.7. The minimum and maximum number of drugs per prescription was 1 and 6 respectively. All the drugs were prescribed by their brand names. Analysis of prescription pattern in pediatric patients of bronchial asthma that attended OPD at Yasodha Chest Clinic revealed that 34% patients were treated with single anti-asthmatic drug whereas 66% patients received multiple drug therapy.

Table no 6: Distribution of anti-asthmatic drugs on the basis of route of administration

Route	Frequency (Yasodha Chest Clinic)
Inhalational	301 (74.13)
Oral	105 (25.86)
Total	406

In this study, it was observed that oral and inhalational dosage forms were prescribed for anti-asthmatic drugs in children that attended OPDs at Yasodha Chest Clinic. Frequencies of inhalational and oral dosage formulations of anti-asthmatic drugs were 74.13% and 25.86% respectively as shown in Table no 6.

Table no 7: Distribution of anti-asthmatic drugs according to therapeutic class

Therapeutic Class	Generic name of drug	Number of patients; Yasodha Chest Clinic
SABA	Salbutamol, Levosalbutamol	149 (36.69)
SABA + Anticholinergic	Levosolbutamol + Ipratropium Bromide	89 (21.92)

LABA + ICS	Salmeterol + Fluticasone	12 (2.95)
ICS	Budesonide	85 (20.93)
OCS	Prednisolone	30 (7.38)
LTRA	Montelukast	41 (10.09)
Total		406(100)

(SABA- Short acting beta 2 agonists, LABA- Long acting beta 2 agonists, ICS- Inhalational corticosteroids, OCS- Oral corticosteroids, LTRA- Leukotriene receptor antagonists)

Table no shows prescription pattern of anti-asthmatic drugs according to therapeutic class in paediatric asthma patients enrolled in Yasodha Chest Clinic where it was observed that short acting beta 2 agonist was prescribed in 149 (36.69%) paediatric patients followed by a short acting beta 2 agonist combined with anticholinergic in 89 (21.92%) paediatric patients, inhalational corticosteroids (Budesonide) in 85 (20.93%) patients. Prescription of leukotriene receptor antagonist 41 (10.09 %), oral corticosteroids in 30 (7.38 %) and only 12 (2.95%) patients were given a combination of long acting beta 2 agonist and inhalational corticosteroid (Salmeterol + Fluticasone).

Table no 8: Comparison of anti-asthmatic drugs according to severity of asthma

Generic name of drug	Severity of Asthma				P-value
	Intermittent N= 65	Mild Persistent N= 25	Moderate Persistent N= 32	Severe Persistent N= 28	
Salbutamol	16 (24.61)	16 (64)	14 (43.75)	12 (42.85)	0.294
Levosalbutamol	37 (56.92)	20 (80)	18 (56.25)	16 (57.14)	0.998
Levosalbutamol + Ipratropium bromide	36 (55.38)	15 (60)	16(50)	22 (78.57)	0.658
Salmeterol + Fluticasone	4 (3.07)	1(2.04)	4 (6.25)	3 (5.26)	0.60
Budesonide	2 (3.07)	12 (48)	29 (90.62)	42 (15)	0.001*
Prednisolone	1(1.53)	1(4)	2(6.25)	26 (92.85)	0.001*
Montelukast	22 (33.84)	5 (20)	4 (12.5)	10(35.71)	0.001*

*statistically significant difference

In pediatric patients enrolled at Yasodha Chest Clinic, prescribing trends of anti-asthmatic drugs on the basis of severity of asthma were analysed as shown in Table no 8. It was observed that in patients of intermittent asthma, levosalbutamol was prescribed the most (56.92%) followed levosalbutamol with ipratropium bromide (55.38%). In mild persistent asthma patients also levosalbutamol was most commonly prescribed 80%. In moderate persistent asthma patients, budesonide (90.92%) were prescribed the most while in severe persistent asthma patients, budesonide was most prescribed followed by Prednisolone.

Table no 9: Number and types of adverse drug reactions and their suspected drugs

Adverse drug reaction	Suspected Drugs	No. of patients reporting adverse drug reactions
Headache	Montelukast, Salmeterol	6 (4)
Sore throat	Budesonide, Fluticasone	6 (4)
Tachycardia	Salbutamol, Levosalbutamol, Salmeterol	5 (3.33)
Dryness of mouth	Ipratropium bromide	4 (2.66)
Cough	Levosalbutamol, Montelukast, Ipratropium bromide	4 (2.66)
Drowsiness	Phenylephrine, Levocetirizine	3 (2)
Oral candidiasis	Budesonide, Fluticasone	3 (2)
Tingling sensation	Salbutamol	2 (1.33)
Nausea/Vomiting	Levosalbutamol, Azithromycin	2 (1.33)
Diarrhoea	Azithromycin, Amoxicillin	2 (1.33)

Rhinitis	Levosalbutamol	1 (0.66)
Rash	Montelukast	1 (0.66)
Hoarseness	Fluticasone	1 (0.66)
Myalgia	Fluticasone	1 (0.66)

In pediatric patients enrolled at Yasodha Chest Clinic, on analyzing ADRs most common ADRs was headache followed by Sore throat as shown in Table no 9.

DISCUSSION

Pediatric bronchial asthma is a common chronic disorder of airways which requires long term management. This emphasizes dire necessity for monitoring of prescriptions pattern for the reduction of disease's burden and improvement of patient's quality of life.

In this study, prescriptions of asthmatic children were studied and showed that asthma was reported more in males as compared to females which was in accordance with the study done by Suman et al¹² that reported higher prevalence of asthma in male patients. Our study results revealed that majority of the patients belonged to the age group of 6-10 years. Male sex is a risk factor in pediatric asthma. In children below 14 years of age, prevalence of asthma is approximately twice as compared to females.¹³

Our study results revealed that 65 (43.33%) children had intermittent asthma followed by 25 (16.33%) cases were mild persistent, 32 (21.33%) moderate and 28 (18.66%) were severe persistent. These findings were contradictory to a study done by Gupta S et al which reported lesser percentage (35.2%) of intermittent asthma patients in comparison with persistent asthma.¹⁴

Our study results revealed that 60 (40%) children presented partly controlled asthma followed by 46 (30.66%) with uncontrolled asthma. Number of patients with well controlled asthma was least i.e. 44 (29.33%). The choice of the anti-asthmatic drug depends on the severity of asthma as classified by GINA Guidelines. Not much of studies were found to classify asthma based on severity.

In our study average number of drugs per prescription for pediatric asthma patients was 2.7. These findings were contradictory to the study conducted by Kumar et al who reported a prescribing trend of an average of 3.5 drugs per prescription.¹⁵ All the drugs were prescribed by their brand names. Use of generic names should be promoted as an integral part of rational prescribing.

According to treatment guidelines, inhalational therapy is the mainstay of asthma treatment because it directly deposits drug into the lungs, thereby ensuring maximum therapeutic efficacy and less incidence of systemic side effects. Our study found that anti-asthmatic drugs were either administered by inhalational route or oral route in asthmatic children. 74.13% drugs were administered through inhalational route and 25.86% drugs were by oral route. These findings correlates with a study done by Rafeeq et al who reported inhalation route (61.3%) as the commonest followed by oral (34.8%).¹⁶

In our study on analyzing Anti-Asthmatic drugs based on therapeutic class SABA was maximum (36.69%) prescribed followed by SABA combined with anticholinergic. These findings were similar to study done by Suman et al¹² who showed similar trend with SABA as the drug of maximum used category. Increased prescription of SABA among asthma patients is probably related to its quick onset of action and low cost.

In our study prescribing trends of anti-asthmatic drugs on the basis of severity of asthma were analysed and observed that in patients of intermittent asthma, levosalbutamol was prescribed the most (56.92%) followed levosalbutamol with ipratropium bromide (55.38%). In mild persistent asthma patients also levosalbutamol was most commonly prescribed 80%. In moderate persistent asthma patients, budesonide (90.92%) were prescribed the most while in severe persistent asthma patients, budesonide was most prescribed followed by Prednisolone. This is in accordance with current GINA guidelines that promotes the use of daily controller in persistent asthma to prevent risk of exacerbations, hospitalizations and mortality.¹³ Use of montelukast is advocated in the management of pediatric intermittent asthma mainly due to its rapid onset of action and safety profile resulting in anti-inflammatory effect or bronchodilatation or combination of both.¹⁷ Our study results revealed that most common ADRs was headache

followed by Sore throat. Similar trend was observed in a study by Bhosale et al (2013).¹⁸

CONCLUSION

Through our study it was concluded that prescribing pattern were according to the indicators mentioned by WHO/INRUD except that very less drugs were prescribed by generic name. Evaluation of prescription pattern is considered as an important tool to assess and evaluate the rationality of the prescription. This minimizes incidence of adverse drug reactions in children as they are more susceptible and also ensures provision of cost-effective medical care. Additionally, health care professionals should be motivated to attend regular continuing medical education (CME) to update their knowledge regarding revised treatment guidelines. Impact of pharmaceutical companies and their representatives on trends in drug prescription should be checked on regular basis in hospitals. All these measures will ensure provision of safer and cost-effective medications to the patients.

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