



## STUDY OF PRESCRIPTION PATTERN IN PAEDIATRIC PATIENTS OF BRONCHIAL ASTHMA ATTENDING OUTPATIENT DEPARTMENT IN A TERTIARY CARE TEACHING HOSPITAL

### Pharmacology

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### ABSTRACT

**Background of the study:** Paediatric bronchial asthma is a common chronic airway disorder which requires long term management. Globally, irrational prescribing poses a huge problem which increases the cost of treatment as well as incidence of adverse drug reactions. This emphasizes dire necessity for monitoring of prescriptions pattern. As such, this study was planned.

**Materials and Methods:** An observational, non-interventional, and cross-sectional study was conducted in a tertiary care teaching hospital in Aurangabad. All childhood asthma patients attending outpatient department were enrolled in the study in accordance with inclusion and exclusion criteria. Patient's demographic details, details of anti-asthmatic drugs, and all other drugs such as dose, duration, type of dosage form used, frequency of drug administration, etc. were recorded.

**Results:** Out of 300 children enrolled in the study, majority were males and belonged to the age group of 6-10 years. 43.67% patients received single anti-asthmatic drug whereas, 56.34% patients received multiple drug therapy. Average number of drugs per prescription was 2.89. Inhalational route was preferred and all the drugs were prescribed by their brand names. Short acting beta 2 agonists (85%) was prescribed the most followed by (47.66%) inhalational corticosteroids. Antibiotics were prescribed in 11.33% patients.

**Conclusion:** Prescribing trends in anti-asthmatic drugs were mainly in accordance with the standard treatment guidelines. However, all the drugs were prescribed by brand names. To overcome this, training should be provided to health care practitioners regarding WHO drug policies and significance of generic prescribing.

### KEYWORDS

Bronchial asthma, Prescription pattern, Anti asthmatic drugs

### INTRODUCTION

Bronchial asthma is a heterogenous disorder, mainly characterized by varying degrees of airway obstruction, bronchial hyper-responsiveness, and airway inflammation.<sup>[1]</sup> Clinically, it is presented by recurrent episodes of wheezing, shortness of breath, chest tightness and coughing. Being a chronic disorder, it has been known to increase frequency of hospital admissions as well as economic burden more in children as compared to adults.<sup>[2],[3]</sup>

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.<sup>[4]</sup> 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.<sup>[5]</sup> The prevalence of childhood bronchial asthma also 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.<sup>[6]</sup> According to several studies, the median prevalence of bronchial asthma in Indian children is estimated to be about 4.75%.<sup>[7]</sup> Also, prevalence rate of asthma in Indian children of age group of 5-11 years has been roughly estimated to be 10-15%.<sup>[8]</sup>

For the management of asthma, GINA guidelines have suggested various drugs like long and short acting  $\beta_2$  agonists (salbutamol, salmeterol, formoterol), corticosteroids (fluticasone, prednisolone, budesonide), xanthene derivatives (theophylline) and leukotriene receptor antagonists (montelukast). Either these drugs are used alone or in conjunction with other anti-asthmatic drugs.<sup>[9]</sup>

Irrational drug use increases the cost of treatment, higher incidence of adverse drug reaction, prolongation of illness and hospitalization.<sup>[10]</sup> Due to asthma, approximately 1.9 disability-adjusted life years (DALYs) per child are lost every year in Indian children below 15 years of age.<sup>[8]</sup> Moreover, inadequate prescriptions also affect quality

of life of asthma patients.<sup>[11]</sup> Monitoring of prescription pattern not only ensures rational prescribing but also creates awareness among prescribers regarding appropriate and safer use of drugs. Thus, prescribing of drugs requires continuous assessment.<sup>[12]</sup>

Keeping this in mind, this study was planned to observe the drug prescription pattern in treatment of paediatric bronchial asthma patients attending outpatient department at a tertiary care teaching hospital.

### MATERIALS AND METHODS

Following approval of Institution Ethics committee, an observational, non-interventional, and cross-sectional study was conducted from 21<sup>st</sup> November 2017 to 12<sup>th</sup> March 2019 in a tertiary care teaching hospital i.e. MGM Medical college & Hospital, Aurangabad. All childhood asthma patients (acute as well as chronic cases) between the age group of 1-17 years attending outpatient department (OPD) and willing to participate in the study with informed consent were enrolled in the study. Patients below 1 year of age, above 17 years of age, who were immunocompromised, or presented with other co-morbid conditions like TB, Diabetes/renal failure or other systemic disorders were excluded from the study.

All the patients were explained clearly about the purpose and nature of the study in the language they could understand. They were included in the study only after obtaining a written informed consent form (ICF) and Assent form (where applicable). Patient's demographic details, details of anti-asthmatic drugs, and all other drugs such as dose, duration, type of dosage form used, frequency of drug administration, etc. were recorded. After completion of the study, data was compiled and tabulated using Microsoft Excel. Data was presented in percentages. Also, SPSS software was used to analyse data using statistical tests like ANOVA. 'P' value  $\leq 0.05$  was considered as significant.

**RESULTS**

A total of 300 paediatric asthma patients were enrolled in the study. Demographic analysis revealed that 52.33% patients were males and 47.67% were females. Also, majority of asthma children belonged to the age group of 6 -10 years (Table-1) Associated comorbidities were observed in 32 patients. 6% of asthmatic children were obese, 3.33% suffered from allergic rhinitis and 1.33% had eczema. Only 10% children presented a positive family history of bronchial asthma.

**Table- 1: Demographic profile of patients**

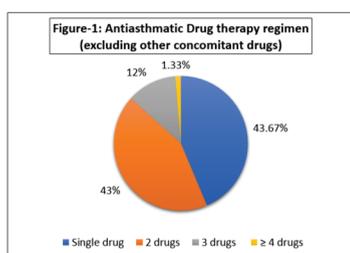
Demographic characteristics		Percentage
Gender	Male	52.33
	Female	47.67
Age group in years	1-5	35.66
	6 -10	47
	11-15	15
	16-17	2.3
Area of living	Urban	70.67
	Rural	29.33
Severity of Asthma	Intermittent	38.33
	Mild Persistent	30
	Moderate Persistent	19.33
	Severe Persistent	12.34
Control of Asthma	Well controlled	46.67
	Partly controlled	34.33
	Uncontrolled	21

Total 868 drugs were prescribed in 300 paediatric patients of asthma. Average number of drugs per prescription was 2.89. The minimum and maximum number of drugs per prescription was 1 and 7 respectively. All the drugs were prescribed by their brand names. Antibiotics (Azithromycin, Amoxicillin + Clavulanic acid, Cefixime, Cefpodoxime proxetil) were prescribed in only 11.33% asthmatic children. 43.67% patients were treated with single anti-asthmatic drug whereas 56.34% patients received multiple drug therapy as shown in Table-2.

**Table-2: Prescribing indicators**

Parameters	Details	
Total number of prescriptions	300	
Total no. of drugs prescribed	868	
Average drugs per prescriptions	2.89	
Encounter with Brand Names	100%	
Encounter with Antibiotics	11.33%	
Anti-asthmatic drugs prescribed (excluding other concomitant drugs)	Single drug therapy	43.67%
	Multiple drug therapy	56.34%

Prevalence of two drug combinations (43%) was the highest followed by three drug (12%) or ≥ four drug combinations (1.33%) as shown in Figure-1.



In this study, it was observed that 82.71% paediatric patients were prescribed inhalational anti-asthmatic drugs whereas only 17.28 % patients received oral formulations (Figure-2).

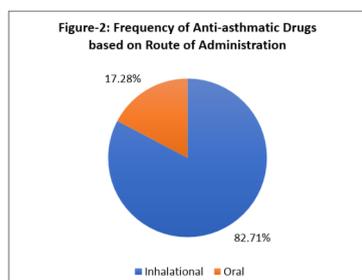
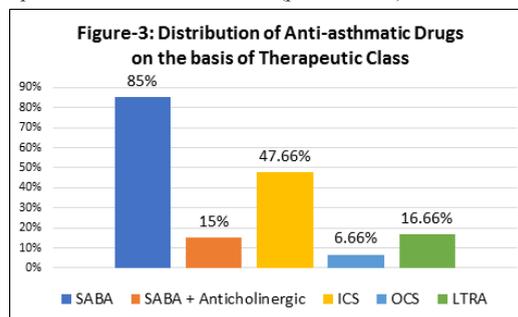


Figure-3 show prescription pattern of anti-asthmatic drugs according to therapeutic class. It was observed that short acting beta 2 agonist (SABA) was prescribed in 85% paediatric patients followed by inhalational corticosteroids in 47.66% patients. Prescription of leukotriene receptor antagonist (montelukast) and a short acting beta 2 agonist combined with anticholinergic (levosalbutamol + ipratropium bromide) was 16.66% and 15% respectively. Only 6.66% patients were prescribed oral corticosteroids (prednisolone).



Analysis of prescribing trends of anti-asthmatic drugs on the basis of severity of asthma (Table- 3) revealed that in patients of intermittent asthma, levosalbutamol was prescribed the most (78.26%) followed by montelukast (25.21%). In mild persistent asthma patients, frequency of prescription of levosalbutamol was the most (87.8%). On the other hand, in patients of moderate persistent asthma, budesonide (98.27%) and levosalbutamol (89.65) were prescribed the most. Similarly, in severe persistent asthma patients, budesonide (89.2%) and levosalbutamol (81.09%) were prescribed the most. It was observed that the difference in prescription of relievers like salbutamol or levosalbutamol in children with intermittent asthma and persistent asthma was not statistically significant. On the other hand, children with intermittent asthma were prescribed combination of levosalbutamol with ipratropium bromide more often as compared to the children of persistent asthma and the difference was statistically significant (p = 0.003). Budesonide was prescribed more in paediatric patients of persistent asthma as compared to intermittent asthma patients and difference was statistically significant (p =0.001). Montelukast was prescribed more often in paediatric patients of intermittent asthma as compared to persistent asthma and difference was statistically significant (p = 0.018). None of the patient in intermittent asthma received prednisolone. In comparison, patients of moderate and severe persistent asthma were prescribed prednisolone more and the difference was statistically significant (p=0.001).

**Table -3: Comparison of anti-asthmatic drugs according to severity of asthma**

Generic name of drug	Severity of Asthma				p-value
	Inter mittent N= 115	Mild Persistent N= 90	Moderate Persistent N= 58	Severe Persistent N= 37	
Salbutamol	1 (0.86)	2 (2.22)	-	1 (2.7)	0.570
Levosulbutamol	90 (78.26)	79 (87.8)	52 (89.65)	30 (81.09)	0.322
Levosulbutamol + Ipratropium bromide	27 (23.47)	9 (10)	2 (3.45)	7 (18.9)	0.003*
Budesonide	8 (6.95)	47 (52.2)	57 (98.27)	33 (89.2)	0.001*
Prednisolone	-	-	2 (3.45)	18 (51.42)	0.001*
Montelukast	29 (25.21)	10 (11.1)	6 (10.34)	5 (13.51)	0.018*

Values in parentheses depict percentage; \*statistically significant with p ≤ 0.05

NSAIDs (19%) were the most commonly prescribed concomitant medication. Other frequently prescribed drugs were antihistamines (18.66%), multivitamins and multimineral (15.33%), antibiotics (11.33%) and cough suppressants (6.66%).

**DISCUSSION**

Analysis of prescription pattern in paediatric bronchial asthma serves as an essential tool to evaluate current treatment trends for control of asthma in children.<sup>[13]</sup> Several international bodies have provided guidelines and clinical standards are also available for the management of asthma. This promotes rational prescribing among physicians, which in turn, ensures reduction in disease's burden and improvement of patient's quality of life.<sup>[14-16]</sup> In this study, the demographic

characteristics reveal that asthma was more prevalent the age group of 6-10 years. Male sex is a risk factor in paediatric asthma. In children below 14 years of age, prevalence of asthma is approximately twice as compared to females.<sup>[17]</sup> Demographic analysis of patients attending OPDs also showed that asthma was reported more in males as compared to females. Similar trend was observed in a study by Suman et al (2014)<sup>[18]</sup> that reported higher prevalence of asthma in male patients (64%) as compared to females (36%). A strong correlation has been observed between urbanization and asthma in children and various studies have demonstrated higher prevalence of asthma in urban areas as compared to rural. This can be attributed to poor quality of outdoor air because of rise in traffic and air pollution, exposure to indoor allergens and a stressful life in urban areas.<sup>[19]</sup> Likewise, in our study, maximum percentage of study population was urban constituting 70.67%. Analysis of occurrence of comorbidities in asthmatic children revealed that 6% were obese, 3.33% suffered from allergic rhinitis and 1.33% had eczema. These comorbidities not only increase the number of prescribed drugs but also increase the risk of drug interactions among them. Recognizing and treating these comorbid conditions significantly influence the pharmacotherapy of asthma and may improve asthma outcomes.<sup>[20]</sup> Association between parental asthma and childhood asthma has been observed in several studies.<sup>[21]</sup> In the present study, 10% presented a positive family history. Our findings are supported by a cross-sectional study from China by Xu D et al (2016) that reported a positive family history in 10.1% asthmatic children.<sup>[22]</sup> In this study, cases of intermittent asthma were more as compared to persistent asthma. However, in a study by Gupta S et al (2016) lesser percentage of intermittent asthma (35.2%) patients were reported in comparison with persistent asthma.<sup>[23]</sup>

Average number of drugs per prescription was 2.89. These findings somewhat correlate with a study conducted by Kumar et al (2015) and Karki S et al (2017) that reported a prescribing trend of an average of 3.5 and 2.9 drugs per prescription respectively.<sup>[24],[25]</sup> All the drugs were prescribed by their brand names. To overcome this, use of generic names should be promoted as an integral part of rational prescribing. In this study, 56.34% patients were on multi-drug therapy and 43.67% were on single drug therapy. This suggests awareness among physicians. Similar trend was observed in studies by Pandey et al (2010) and Shimpi et al (2012).<sup>[26],[27]</sup>

According to treatment guidelines, inhalational therapy should be the first choice of asthma treatment because it directly deposits drug into the lungs, thereby ensuring maximum therapeutic efficacy and less incidence of systemic side effects.<sup>[28],[29]</sup> Our study found that inhalational dosage formulations (82.71%) were preferred over oral dosage forms (17.28 %). Our finding correlates with a study done by Rafeeq et al (2017) in a tertiary care hospital in Saudi Arabia which reported inhalation route (61.3%) as the commonest followed by oral (34.8%).<sup>[30]</sup>

Over all anti-asthmatic drug utilization pattern showed that SABA (85%) was prescribed the most followed by inhalational corticosteroids. In comparison, usage of Leukotriene receptor antagonist, SABA combined with anticholinergic and oral corticosteroids was less. Our analysis indicates profound usage of relievers as compared to controllers and is in agreement with a study conducted by Patel et al (2012) in urban and rural areas of Saurashtra region in Gujarat.<sup>[31]</sup> Suman et al (2014)<sup>[18]</sup> also showed similar trend with SABA as the drug of maximum use category. Increased prescription of SABA is probably related to its quick onset of action and low cost.

Controllers (budesonide) were used more in paediatric patients of persistent asthma as compared to intermittent asthma patients. 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.<sup>[17]</sup> Montelukast was prescribed more often in paediatric patients of intermittent asthma. Use of montelukast is advocated in the management of paediatric intermittent asthma mainly due to its rapid onset of action and safety profile resulting in anti-inflammatory effect or bronchodilatation or combination of both.<sup>[32]</sup> As compared to anti-asthmatic drugs, usage of antihistamines, cough suppressants and antibiotics was less which suggests that health professionals are well versed with GINA guidelines for the management of asthma.

## CONCLUSION

Evaluation of prescription pattern is considered as an important tool to assess and evaluate the rationality of the prescription. This ensures provision of cost-effective medical care. This cross-sectional study has

effectively described the prescription pattern in paediatric patients of asthma attending outpatient in a tertiary care hospital. Through this study, we have concluded that prescribing trends in anti-asthmatic drugs are in accordance with the standard treatment guidelines. Only the matter of concern is prescription by brand names. To overcome this, training should be provided to health care practitioners regarding WHO drug policies and generic prescribing should be practiced to reduce economic burden as well as improve patient compliance. Prescription of inhalational corticosteroids as controllers shows awareness among prescribers. 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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## REFERENCES

- Herzog R, Rundles SC. Paediatric asthma: natural history, assessment and treatment. *Mt Sinai J Med.* 2011; 78(5): 645–660. doi:10.1002/msj.20285.
- Lee-Sarwar KA, Bacharier LB, Litonjua AA. Strategies to alter the natural history of childhood asthma. *Curr Opin Allergy Clin Immunol* 2017; 17:139-45.
- Bahadori K, Doyle-Waters MM, Marra C, Lynd L, Alasaly K, Swiston J, et al. Economic burden of asthma: a systematic review. *BMC Pulm Med* 2009; 9:24.
- Braman SS. The global burden of asthma. *Chest.* 2006; 130(1 Suppl):4S-12.
- Global Initiative for Asthma: Global strategy for asthma management and prevention. online appendix. 2018. <http://www.ginaasthma.com>
- International study of Bronchial Asthma and allergies in childhood (ISAAC). Worldwide variations in the prevalence of Bronchial Asthma symptoms. *Euro Respir J* 1998; 12:315-35.
- Pal R, Dahal S, Pal S. Prevalence of bronchial asthma in Indian children. *Indian J Community Med.* 2009; 34:310-6.
- Tundia MN, Thakrar DV. An epidemiological study of asthma and its risk factors in school going children in Bhavnagar city, Gujarat, India. *Int J Community Med Public Health.* 2018 Jun;5(6): 2317-2322.
- Sun HL, Kao YH, Chou MC, Lu TH, Lue KH. Differences in the prescription patterns of anti-asthmatic medications for children by paediatricians, family physicians and physicians of other specialties. *J Formos Med Assoc.* 2006 Apr; 105(4):277-83.
- Batta A, Madan N, Kalra BS, Arora S. Prescription Audit, Drug Utilization Pattern and Adverse Drug Reaction Monitoring in Outpatients of Orthopedics Department of Tertiary Care Teaching Hospital: A Pilot Study. *MAMC J Med Sci* 2019; 5:77-82.
- Spreight A, Lee D, Hey E. Under diagnosis and under treatment of asthma in childhood. *Br Med J* 1983; 286:1253-6.
- Karande S, Sankhe P, Kulkarni M. Patterns of prescription and drug dispensing. *Indian J Pediatr* 2005; 72:117-121.
- Sol IS, Kim YH, Kim SY, Choi SH, Kim JD, Kim BO, et al. Prescription patterns and burden of pediatric asthma in Korea. *Allergy Asthma Immunol Res* 2019; 11:280-290.
- National Heart, Lung, and Blood Institute, National Institutes of Health. International Consensus Report on the Diagnosis and Treatment of Asthma. Bethesda: National Heart, Lung, and Blood Institute, National Institutes of Health, March 1992. Publication no. 92-3091.
- NIH. Guidelines for the Diagnosis and Management of Asthma. Bethesda: National Institutes of Health (NIH), May 1997. p. 41 Publication no. 97-4051 A.
- National Heart, Lung and Blood Institute, WHO. Global Strategy for Asthma Management and Prevention. Bethesda: NHLBI/WHO workshop, 1997. NIH Publication no. 974051.
- GINA Reports - Global Initiative for Asthma - GINA [Internet]. Global Initiative for Asthma - GINA. 2019 Available from: <https://ginasthma.org/gina-reports/>
- Garje YA, Suman RK, Kumar R, Deshmukh YA, Patra V. Prescribing patterns and pharmaco-economic analysis of drugs used in paediatric asthma patients at tertiary care hospital. *World J of pharm pharmaceutical sci.* 2014; 3(6), 1448-1465.
- Gupta MK, Patodia J, Chaudhary P, Kakkur M. The rising trend of asthma prevalence in urban school children of Jaipur: A questionnaire-based study. *Indian J Allergy Asthma Immunol* 2018; 32:10-4.
- Gershon AS, Wang C, Guan J, To T. Burden of comorbidity in individuals with asthma. *Thorax.* 2010;65(7):612-618.
- Valerio MA, Andreski PM, Schoeni RF, McGonagle KA. Examining the association between childhood asthma and parent and grandparent asthma status: implications for practice. *Clin Pediatr (Phila).* 2010; 49(6):535-541.
- Xu D, Wang Y, Chen Z, et al. Prevalence and risk factors for asthma among children aged 0-14 years in Hangzhou: a cross-sectional survey. *Respir Res.* 2016; 17(1):122.
- Gupta S, Awasthi S. Assessment of treatment pattern of childhood asthma reporting to outpatients' facility of a tertiary care hospital in Lucknow, North India: A cross-sectional study. *Clinical Epidemiology and Global Health.* 2016; 4: S6-S11.
- Kumar V, Thankachan T, Amanapu A, Chandra D, Krishnan S. Study of Prescribing Pattern and Impact of Pharmaceutical Care in Bronchial Asthmatic Paediatric Patients in a Tertiary Care Teaching Hospital. *Indian Journal of Pharmacy Practice.* 2015; 8(1):42-48.
- Karki S, Mohanty I R, Potdar PV, Deshmukh YA, Shah RC, Pokhrel BR. Assessment of prescribing patterns of drugs used in adult asthma patients at a tertiary care hospital. *Int. J. Curr. Res. Med. Sci.* 2017; 3(6): 169-175.
- Pandey A, Tripathi P, Pandey R. Prescription pattern in asthma therapy at Gorakhpur hospitals. *Lung India.* 2010;27(1):8.
- Shimpi RD, Bavaskar R, Laddha GP, Kalam A, Patel K. Drug utilization evaluation and prescription monitoring in asthmatic patients. *Int J Pharm Bio Sci.* 2012; 2:117-22.
- Prasad A, Pradhan S, Datta P, Samajdar S, Panda P. Drug prescription pattern for bronchial asthma in a tertiary-care hospital in Eastern India. *National Journal of Physiology, Pharmacy and Pharmacology.* 2015; 5(3): 263.
- NAEPP Expert Panel Report: guidelines for the diagnosis and management of asthma updates on selected topics 2007. Available from: <http://www.nhlbi.nih.gov/guidelines/asthma>
- Rafeeq MM, Murad H. Evaluation of drug utilization pattern for patients of bronchial asthma in a government hospital of Saudi Arabia. *Niger J Clin Pract.* 2017; 20:1098-105.
- Patel Pinal D, Patel RK, Patel NJ. Analysis of Prescription Pattern and Drug Utilization in asthma Therapy; *International Research Journal of Pharmacy.* 2012; 257-260.
- Robertson C, Price D, Henry R, Mellis C, Glasgow N, Fitzgerald D et al. Short-Course Montelukast for Intermittent Asthma in Children. *American Journal of Respiratory and Critical Care Medicine.* 2007; 175(4):323-329.