

# Evaluation of treatment pattern with Global Initiative for Asthma (GINA) guidelines in patients of bronchial asthma

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## Abstract

**Background:** Drugs play an important role in improving human health and promoting well-being. However, to produce the desired effect, they have to be safe, efficacious and have to be used rationally. **Aims and Objectives:** A Study of evaluation of treatment pattern with Global Initiative for Asthma (GINA) guidelines in patients of bronchial asthma. **Methodology:** The study was a prospective observational study for a period of one year from February 2015-January 2016. The study was conducted at outpatient and inpatient department of medicine and paediatrics in a tertiary care hospital. The study was approved by Institutional Ethics Committee of the Institution to which the study site is affiliated. Permission was acquired from the head of department of medicine and paediatrics for the study. **Results:** overall pattern of drug use in medicine patients.  $\beta_2$  agonists were the most common antiasthmatic drugs prescribed in all the patients followed by corticosteroids (92.57%) and methylxanthines (85.71%) respectively. The next common drug class prescribed was antimicrobial agents (65.14%). Oxygen was prescribed in 7.43% patients. Other drugs prescribed were antacids and antireflux agents (28.57%), antihistaminics (20%), vitamins and minerals (15.43%), antidiabetics (9.71%), antihypertensives (9.14%) and antipyretics and analgesics (3.43%). **Conclusion:** It was concluded from our study that Overall pattern of drug use showed that  $\beta_2$  agonists and corticosteroids were most common class of antiasthmatic drugs prescribed. A detailed drug utilization of antiasthmatic drugs indicated that the use of oral and nebulised salbutamol, injection hydrocortisone, nebulised budesonide and injection as well as oral theophylline was high in both IPD and OPD medicine patients. The use of oral and nebulised salbutamol, systemic steroids and nebulised budesonide was high only in paediatric IPD patients as compared to paediatric OPD patients.

**Key words:** Global Initiative for Asthma (GINA), Bronchial asthma(BA), Drug use pattern of Bronchial asthma.

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Received Date: 28/03/2019 Revised Date: 10/05/2019 Accepted Date: 02/06/2019

DOI: <https://doi.org/10.26611/10101032>

## Access this article online

Quick Response Code:



Website:

[www.medpulse.in](http://www.medpulse.in)

Accessed Date:  
22 June 2019

## INTRODUCTION

Drugs play an important role in improving human health and promoting well-being. However, to produce the desired effect, they have to be safe, efficacious and have to be used rationally. Drug use is a complex subject involving the prescriber, the patient and pharmaceutical institutions. It is influenced by factors such as drug availability, prescribers' experience, health budget, promotional activities of the pharmaceutical industry, cultural factors, communication system and the complex interaction between these factors.<sup>1</sup> Drug utilization has been defined by the World Health Organization (WHO)

**How to cite this article:** Shreyas Ramchandra Burute, Ruchi Doongarshi Shah, Ramchandra B. Burute, Sunita Jaiprakash Ramanand. Evaluation of treatment pattern with Global Initiative for Asthma (GINA) guidelines in patients of bronchial asthma. *MedPulse International Journal of Pharmacology*. June 2019; 10(3): 28-32. <https://www.medpulse.in/Pharmacology/>

in 1977 as “the marketing, distribution, prescription, and use of drugs in society, with special emphasis on the resulting medical, social, and economic consequences”.<sup>2</sup> The principal aim of drug utilization research is to facilitate the rational use of drugs in populations in terms of efficacy, safety and cost. Drug utilization studies are necessary for knowing extent of drug use, identifying variability in drug-use among different regions or within the region, identifying problems concerning inappropriate use of drugs, plan targeted interventions to improve drug use and to measure impact of these interventions.<sup>2</sup> Drug utilization studies are thus considered as the tool to evaluate health care system and are the need of the hour.<sup>3</sup> In the past drug utilization studies have been carried out either in outpatient or inpatient and in adults or children. However, to the best of our knowledge we have not come across any study in India which evaluates the pattern of drug utilization in bronchial asthma over its entire spectrum and varying severity and collates the treatment pattern with GINA guidelines. Keeping the above mentioned points in mind, the present study was therefore conducted to study drug utilization pattern in all bronchial asthma patients at the outpatient and inpatient department of medicine and paediatrics in a tertiary care hospital and to collate treatment pattern with GINA guidelines.

## METHODOLOGY

The study was a prospective observational study for a period of one year from February 2015-January 2016. The study was conducted at outpatient and inpatient department of medicine and paediatrics in a tertiary care hospital. The study was approved by Institutional Ethics Committee of the Institution to which the study site is affiliated. Permission was acquired from the head of department of medicine and paediatrics for the study. Confidentiality regarding patients information was maintained. A written informed consent was obtained from patients willing to take part in the study. A written informed consent of patients of either sex above age 5 years was obtained from parents/guardians and assent was obtained from children above age 7 years. Previously diagnosed patients of bronchial asthma of varied duration who visit the hospital outpatient department of medicine and paediatrics or are admitted in the inpatient department of medicine and paediatrics. Newly diagnosed patients of bronchial asthma by physicians either clinically, radiologically or by laboratory investigations were included into the study while Patients with coexistent respiratory disorders like bronchitis or emphysema (COPD), fibrosis and any other known lung disease. Patients who were not willing to give written informed consent were excluded from the study. Details of Age and Sex was asked Overall pattern of drug use in medicine patients, paediatric patients. The data was entered in excel sheet and analyzed by for excel software for windows 10.

## RESULT

**Table 1:** Distribution of the patients as per the Age and Sex

Characteristic	Age (in years)
Mean±SD	37.56±22.87
Range	6-83
Sex	No (%)
	Male 132(52.8%)
	Female 118(47.2%)

The average age of the Patients was 37.56±22.87 Yrs. (Range- 6-83), majority of the patients were Male -52.8% and Females were 47.2%.

**Table 2:** Overall pattern of drug use in medicine patients

Drug class	Number of Inpatients (%) (n=75)	Number of Outpatients (%) (n=100)	Total (%) (n=175)
<b>Antiasthmatic drugs</b>			
Beta-2(β2) agonists	75(100)	100(100)	175(100)
Corticosteroids	73(97.33)	89(89)	162(92.57)
Methylxanthines	73(97.33)	77(77)	150(85.71)
Anticholinergics	26(34.66)	22(22)	48(27.42)
Leukotriene inhibitors	2(2.66)	3(3)	5(2.86)
<b>Antimicrobial agents</b>	57(76)	57(57)	114(65.14)
<b>Antacids and antireflux agents</b>	44(58.66)	6(6)	50(28.57)
<b>Antihistaminics</b>	16(21.33)	19(19)	35(20)

<b>Vitamins and minerals</b>	17(22.66)	10(10)	27(15.43)
<b>Antidiabetics</b>	7(9.33)	10(10)	17(9.71)
<b>Antihypertensives</b>	8(10.66)	8(8)	16(9.14)
<b>Oxygen</b>	13(17.33)	0(0)	13(7.43)
<b>Antipyretics and Analgesics</b>	1(1.33)	5(5)	6(3.43)
<b>Drugs used for ischemic heart disease</b>	3(4)	0(0)	3(1.71)
<b>Antiemetics</b>	2(2.66)	0(0)	2(1.14)
<b>Antiparkinsonian drugs</b>	1(1.33)	0(0)	1(0.57)
<b>Others</b>	5(6.66)	0(0)	5(2.86)

Table 2 shows overall pattern of drug use in medicine patients.  $\beta_2$  agonists were the most common antiasthmatic drugs prescribed in all the patients followed by corticosteroids (92.57%) and methylxanthines (85.71%) respectively. The next common drug class prescribed was antimicrobial agents (65.14%). Oxygen was prescribed in 7.43% patients. Other drugs prescribed were antacids and antireflux agents (28.57%), antihistaminics (20%), vitamins and minerals (15.43%), antidiabetics (9.71%), antihypertensives (9.14%) and antipyretics and analgesics (3.43%).

**Table 3: Overall pattern of drug use in paediatric patients (n=75)**

<b>Drug class</b>	<b>Number of Inpatients (%) (n=75)</b>	<b>Number of Outpatients (%) (n=100)</b>	<b>Total (%) (n=175)</b>
<b>Antiasthmatic drugs</b>			
Beta-2( $\beta_2$ ) agonists	55(100)	18(90)	73(97.33)
Corticosteroids	55(100)	16(80)	71(94.66)
Methylxanthines	33(60)	11(55)	44(58.66)
Anticholinergics	24(43.63)	0(0)	24(32)
Leukotriene inhibitors	4(7.27)	0(0)	4(5.33)
<b>Antimicrobial agents</b>	31(56.36)	17(85)	48(64)
<b>Expectorants</b>	15(27.27)	8(40)	23(30.66)
<b>Antipyretics and analgesics</b>	11(20)	7(35)	18(24)
<b>Antacids and antireflux agents</b>	17(30.90)	0(0)	17(22.66)
<b>Oxygen</b>	14(25.45)	0(0)	14(18.67)
<b>Antihistaminics</b>	9(16.36)	4(20)	13(17.33)
<b>Others</b>	26(47.27)	0(0)	26(34.67)

Table 3 shows overall pattern of drug use in paediatric patients.  $\beta_2$  agonists were the most common antiasthmatic drugs prescribed in 97.33% patients followed by corticosteroids (94.66%) and anticholinergics (58.66%) respectively. Magnesium sulphate was prescribed to inpatients only (24%). The next common drug class prescribed was antimicrobial agents (64%). Oxygen was prescribed in 18.67% patients. Other drugs prescribed were expectorants (30.66%), antipyretics and analgesics (24%), antacids and antireflux agents (22.66%) and antihistaminics (17.33%).

## DISCUSSION

Conducting periodic studies of pattern of drug use in various hospital settings or patient populations is essential to critically analyze the current hospital drug policies and to make recommendations based on various guidelines to improve upon the current drug usage pattern in the future, if needed. It is more importantly required in resource poor countries like ours so as to ensure that the scarce

resources are utilized in the best possible manner. There is always a variation in drug utilization among different countries and even among health institutions within a country and sometimes within the same institute at different point of time probably because of changing disease trends over a period of time.<sup>4</sup> Asthma 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<sup>5</sup>. There are about 334 million patients with asthma affecting all age groups, across the world<sup>6</sup>. A recent analysis using three different estimate models: Indian study on Epidemiology of Asthma, Respiratory symptoms and Chronic bronchitis (INSEARCH), Global Initiative for Asthma (GINA) and WHO survey suggests that 17-30 million patients suffer from asthma in India<sup>7</sup>. Asthma is known to be one of the major causes of morbidity and mortality in India, comprising 3-11% of

adults and 3-5% of paediatric population<sup>8</sup> and its prevalence varies from place to place<sup>9</sup>. Global Initiative for Asthma (GINA) guidelines are the international guidelines available for the management of asthma. As per GINA guidelines, mainly two categories of drugs are used namely controllers (inhaled and systemic glucocorticoids and inhaled long acting beta agonists in combination used with inhaled corticosteroid, leukotriene modifiers, sustained-release theophylline, cromones, anti-IgE) and relievers (inhaled and oral beta-2 agonists, short acting anticholinergics, short acting theophylline). These drugs can be used alone or in conjunction with other antiasthmatic drugs<sup>5</sup>. Asthma cannot be cured, but clinical episodes can largely be prevented and controlled by proper management<sup>10</sup>. The goal of treatment as per GINA guidelines is to achieve good symptom control and to minimize future risk of exacerbations, fixed airflow limitation and side effects of treatment. It also identifies that fixed international guidelines may not work in many locations and hence it recommends that these guidelines be adapted according to local needs and availability of resources<sup>5</sup>. For effective implementation of any guideline it is important first to assess the current status of asthma care in the target region and this can be achieved by doing drug utilization study. This will help not only to understand the current prescribing trends but also to assess other factors like availability of preventive, diagnostic and curative resources and also affordability, compliance and knowledge of patients<sup>11</sup>. Drug utilization research can thus be used to compare the observed patterns of drug use for the treatment of certain disease with current recommendations or guidelines.<sup>12</sup> In our study we have seen that Table 2 shows overall pattern of drug use in medicine patients.  $\beta_2$ -agonists were the most common antiasthmatic drugs prescribed in all the patients followed by corticosteroids (92.57%) and methylxanthines (85.71%) respectively. The next common drug class prescribed was antimicrobial agents (65.14%). Oxygen was prescribed in 7.43% patients. Other drugs prescribed were antacids and antireflux agents (28.57%), antihistaminics (20%), vitamins and minerals (15.43%), antidiabetics (9.71%), antihypertensives (9.14%) and antipyretics and analgesics (3.43%). The use of  $\beta_2$  agonists is in accordance with other studies by Kamath *et al*<sup>13</sup> (100%), Pinal Patel *et al*<sup>8</sup> (90% in urban patients and 84% in rural patients), Arumugam *et al*<sup>101</sup> (66%). Other studies by Pandey *et al*<sup>102</sup> (40%). Similar observations were seen in a study by Michael *et al*<sup>16</sup> (antacids-33.33%, multivitamins-24.83%) and Kamath *et al*<sup>13</sup> (antireflux agents-26%, antihistaminics-30%, antidiabetics-15%, antihypertensives-12.5%). Table 3 shows overall pattern

of drug use in paediatric patients.  $\beta_2$  agonists were the most common antiasthmatic drugs prescribed in 97.33% patients followed by corticosteroids (94.66%) and anticholinergics (58.66%) respectively. Magnesium sulphate was prescribed to inpatients only (24%). The next common drug class prescribed was antimicrobial agents (64%). Oxygen was prescribed in 18.67% patients. Other drugs prescribed were expectorants (30.66%), antipyretics and analgesics (24%), antacids and antireflux agents (22.66%) and antihistaminics (17.33%). The most common antiasthmatic drugs prescribed in paediatric patients were  $\beta_2$  agonists (97.33%) followed by corticosteroids (94.66%). This finding is consistent with previous studies like Sayedda *et al*<sup>18</sup> ( $\beta_2$  agonists- 100% in exacerbations, corticosteroids- 100% in persistent asthma), Garje *et al*<sup>197</sup> ( $\beta_2$  agonists- 81%, corticosteroids- 93%) and Kumar *et al*<sup>20</sup> ( $\beta_2$  agonists- 83.6%, corticosteroids- 40.98%). Higher percentage of paediatric patients were prescribed anticholinergics (58.66%) (Table 3) as compared to medicine patients (Table 2) and this was mainly ipratropium bromide in combination with salbutamol. A significantly different finding from medicine patients was use of magnesium sulphate in 43.64% patients in paediatric IPD. It is recommended that magnesium sulphate may be used parenterally in severe exacerbations of asthma not responding to initial treatment<sup>5</sup> thus indicating that these patients may be suffering from severe exacerbations. In a study done by Sayedda *et al*<sup>17</sup>, prescription of anticholinergics (32.4%) and magnesium sulphate (1.6%) was seen to be less as compared to the present study. This discrepancy could be because another bronchodilator aminophylline was also prescribed in their study. Aminophylline was not prescribed in paediatric patients of the present study. Similar to the results seen in medicine patients (Table 3), the use of leukotriene<sup>19</sup> Inhibitors is minimal (5.33%) and consistent to results observed by Pandey *et al* 102(4.4%). Antimicrobial agents were prescribed to higher percentage (64%) of paediatric patients in present study which is again similar to the medicine patients (Table 3). Garje *et al*<sup>17</sup> observed antibiotic prescription in 19% and Kumar *et al*<sup>196</sup> observed it in 36.06% of paediatric patients. The higher use of antimicrobials may be due to the inadequate control of asthma symptoms predisposing the patients to infection and exacerbation. The other classes of drugs were expectorants (30.66%) which were prescribed to only paediatric patients in this study and antihistaminics (17.33%). This observation was in accordance with Kumar *et al*<sup>20</sup> (antitussives -39.34%, antihistaminics -21.31%). Many expectorants contain terbutaline which is a  $\beta_2$  agonist and hence it reflects increased prescription of drugs being used for bronchodilatation.

## CONCLUSION

It was concluded from our study that Overall pattern of drug use showed that  $\beta_2$  agonists and corticosteroids were most common class of antiasthmatic drugs prescribed. A detailed drug utilization of antiasthmatic drugs indicated that the use of oral and nebulised salbutamol, injection hydrocortisone, nebulised budesonide and injection as well as oral theophylline was high in both IPD and OPD medicine patients. The use of oral and nebulised salbutamol, systemic steroids and nebulised budesonide was high only in paediatric IPD patients as compared to paediatric OPD patients. The use of theophylline was only in medicine patients while magnesium sulphate was prescribed to only paediatric patients.

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Source of Support: None Declared  
Conflict of Interest: None Declared