

A Prospective Study of Evaluation of Medical Prescriptions And Drug Utilization For Bronchial Asthma Patients At A Tertiary Care Hospital

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Abstract: This study was conducted to assess medical prescriptions and prescribing pattern in patients of bronchial asthma in Chest – TB department. It was prospective, cross sectional, observational study. Data of first 200 eligible consecutive prescriptions during 3 months were considered. About 26% prescriptions were lacking patient's diagnosis so effort must be made to encourage writing complete prescription with diagnosis. Dose and duration were quoted in more than 90% of prescriptions as dose and duration of drug treatment is saved and auto-generated in HMIS system. Hence there are minimal chances of prescribing errors. Out of 200 patients, 54.5% were male and 45.5% were female. Majority of patients were from age group of 46 – 60 years. Allergy (53%) was most common precipitating factor followed by non-atopic (22%), infective (16.5%) and multifactorial (8.5%) of patients. Only 25.78% of drugs were prescribed by brand names. More than 99% drug prescriptions were from national list of essential medicines 2015. Most frequently prescribed anti-asthmatic drug was tablet salbutamol (87%) followed by tablet levocetirizine and methylxanthines. Polypharmacy was observed. Oral dosage form of B2 agonist was commonly prescribed in patients (87%). Inhalational therapy was prescribed to 13% of patients. Anti-asthmatic drugs given as inhalational therapy are more beneficial to the patients than systemic therapy. Hence, their maximum utilization in asthmatics will definitely reduce incidence of acute asthma as well as the adverse effects of anti-asthmatic drugs.

Keywords: Anti-asthmatic drugs, Drug utilization studies, Global Initiative for Asthma guidelines, Rational drug use, WHO drug use indicators.

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I. Introduction

Drug therapy plays a crucial role in improving human health by enhancing the quality of life and extending the life expectancy. A method to evaluate and improve drug use is by conducting Drug Utilization Studies (DUS). Drug Utilization is defined by the WHO (world health organization) as the marketing, distribution, prescription, and use of drugs in society with special emphasis on the resulting medical social and economic consequences [1]. The designed study involves a comprehensive review of patient's prescription and medication data in order to assure appropriate therapeutic decision making and positive patient outcomes. Globally asthma disease is one the most common chronic disease and currently affects approximately 300 million people in the world. Asthma is a chronic inflammatory disorder and it is characterized by bronchial hyper-responsiveness and airflow limitation [2, 3 and 4]. The symptoms of asthma include recurrent episodes of wheezing, breathlessness, chest tightness and cough [2, 3]. The characteristic pathophysiological changes in asthma involve several inflammatory cells and mediators that contribute to symptoms. Structural cells of the airways also produce inflammatory mediators, and contribute to the persistence of inflammation in various ways. Over 100 different mediators are now recognized to be involved in asthma and the key mediators are chemokines, leukotrienes, cytokines, histamine, nitric oxide and prostaglandins [2, 5, 6]. The goal of asthma treatment is to achieve and maintain clinical control. Clinical studies have shown that asthma can be effectively controlled by intervening to suppress and reverse the inflammation as well as treating the bronchoconstriction and related symptoms.

Medications to treat asthma can be classified as controllers or relievers. Controllers are medications taken daily on a long-term basis to keep asthma under clinical control chiefly through their anti-inflammatory effects. They include inhaled and systemic glucocorticoids, leukotriene receptor antagonists, long-acting inhaled β_2 -agonists in combination with inhaled glucocorticoids, sustained-release theophylline, cromones, anti-IgE, and other systemic steroid-sparing therapies [2, 7 and 8]. Inhaled glucocorticoids are the most effective controller medications currently available. Relievers are medications used on an as-needed basis that act quickly to reverse bronchoconstriction and relieve its symptoms. They include rapid-acting inhaled β_2 -agonists, inhaled anti-

cholinergics, short-acting theophylline, and short-acting oral β 2-agonists[2, 5]. Thus these medications that control and relieve asthma can be used for prophylaxis and treatment of acute episodes.

The various factors like boost in marketing of new drugs, wide variation in pattern of drug prescribing and consumption lead to polypharmacy. This type of prescribing behavior increases chances of adverse effects, drug – drug interaction, amplified cost of drugs. Present study is conducted to evaluate the drug pattern used in bronchial asthma and their rationality.

II. Materials And Methods

2.1 Study design: This was a prospective cross sectional observational study conducted at the tertiary care hospital of B. J. Government Medical College and Sassoon General Hospitals, Pune. Total 200 prescriptions from outdoor patients of Chest – TB department were collected for a period of 3 months, i.e. April 2017 to June 2017. The data was collected after getting permission from the respective head of the departments for analysing the prescriptions and after getting approval from the Institutional Ethics Committee. Strict confidentiality of the prescriber and patient was maintained during the study period. The number of drugs prescribed in each prescription was taken into account to calculate the incidence of polypharmacy.

2.2 Data collection: The data of first consecutive 200 eligible outdoor patients of Chest – TB department was obtained from case records. The inclusion and exclusion criteria were as follows-

Inclusion criteria

- 1) Outdoor patients visited Chest TB OPD from March 2017 to May 2017 and diagnosed as bronchial asthma
- 2) Patients of age more than 12 years of either sex
- 3) Patients with or without concomitant medical conditions like hypertension, diabetes mellitus
- 4) Patients taking concomitant medications like anti-hypertensive drugs, anti-diabetic drugs etc.

Exclusion criteria

- 1) Pregnant patients
- 2) Patients of age less than 12 years
- 3) Patients having other respiratory problems like Chronic obstructive pulmonary disease (COPD)

2.3 Prescription pattern: WHO guidelines were taken into consideration in evaluating the rationality of prescriptions [1]. Data and results were represented in suitable graphical and tabular forms. The data from the records were entered into a specially designed proforma. The following parameters were recorded for each prescription: patient's demographic profile, diagnosis, drug's name, route, frequency. The patients were categorized by sex and then divided into four age groups. The frequency of prescription was calculated for each age group and for males and females separately. Prescribing frequency was expressed as a percentage of the prescription of the individual drug/drug class in a particular age/sex category to the total number of patients in the particular age/sex category.

III. Results

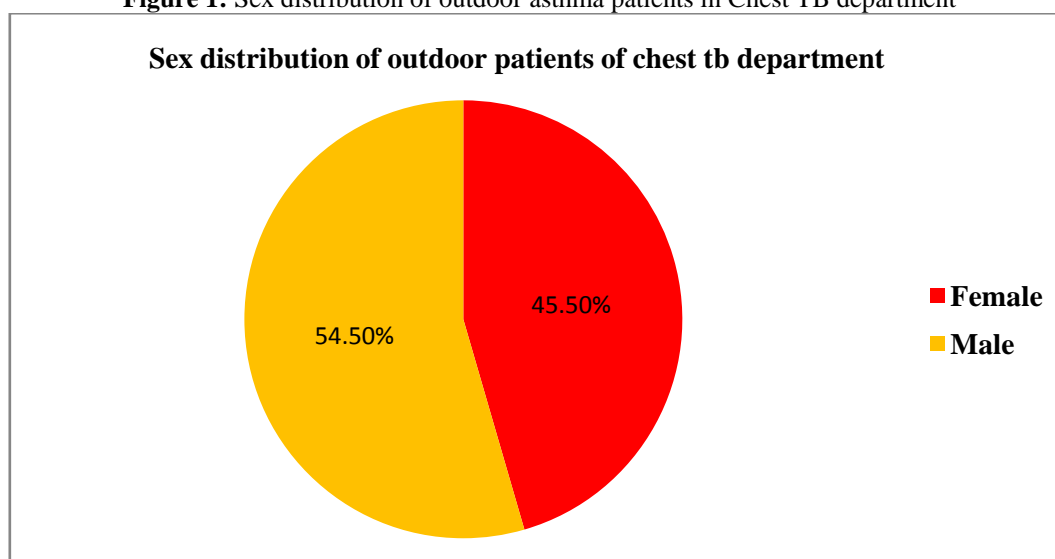
Total first 200 consecutive prescriptions of outdoor patients of asthma from Chest TB department were assessed. Out of 200 prescriptions, diagnosis was mentioned in 74% of prescriptions while it was not stated in 24% prescriptions. Otherwise dose and duration both were quoted in more than 90% of prescriptions. Almost 94% of prescriptions were relevant to the diagnosis (Table 1).

Table 1: Drug prescribing practices

		Number of prescriptions	Percentage
1) Diagnosis	Mentioned	148	74
	Not mentioned	52	26
2) Relevance of treatment of diagnosis	Full	188	94
	Partial	12	6
	Not relevant	0	0
3) Dose	Appropriate	186	93
	inappropriate	8	4
	Not mentioned	6	3
4) Duration of treatment	Appropriate	186	93
	inappropriate	8	4
	Not mentioned	6	3

Out of 200 bronchial asthma patients, 109 (54.5%) were male and 91 (45.5%) were female patients (Fig.1).

Figure 1: Sex distribution of outdoor asthma patients in Chest TB department



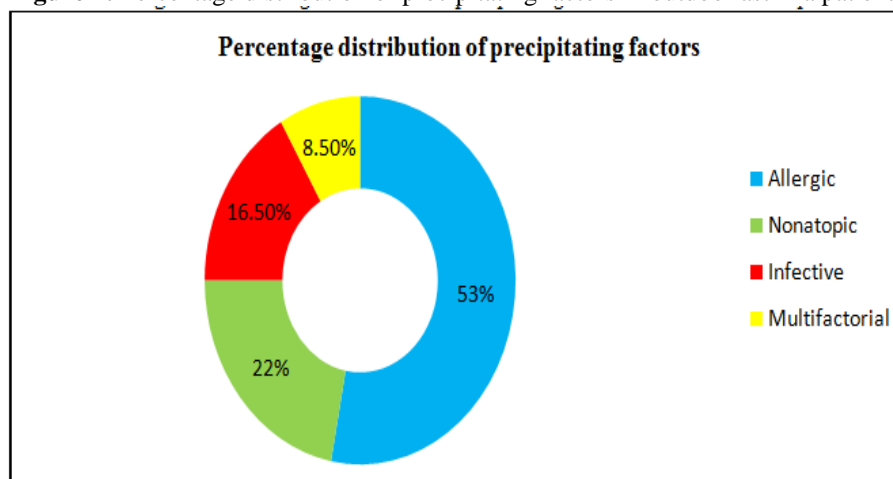
Out of 200 outdoor patients, majority of outdoor patients were from age group of 46 – 60years while only 12% patients belonged to 12 – 30 years age group. Rest were intermediate (Table 2).The men to women ratio was 1.2

Table 2: Age and sex distribution of outdoor patients in Chest – TB department

Age group	Outdoor patients		
	Male	Female	Total
12 – 30 years	8(7.34%)	4(4.40%)	12 (6%)
31 – 45 years	35(32.11%)	30(32.97%)	65(32.5%)
46 - 60 years	57(52.29%)	49(53.85%)	106(53%)
>60 years	9(8.26%)	8(8.79%)	17(8.5%)
Total	109(54.5%)	91(45.5%)	200

Out of 200 patients, it was observed that allergy (53%) was most common precipitating factor followed by non-atopic (22%), infective (16.5%) and multifactorial (8.5%) of patients [Fig. 2].

Figure 2: Percentage distribution of precipitating factors in outdoor asthma patients



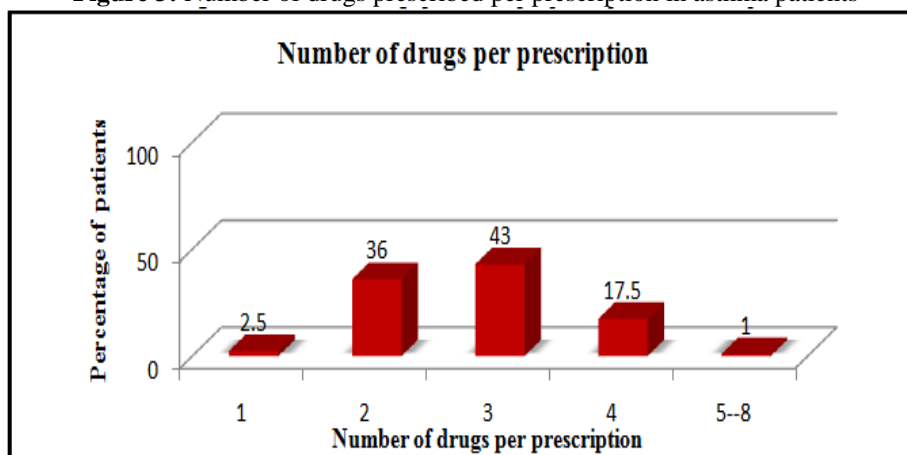
The Global Initiative for asthma (GINA) subdivided asthma by severity based on the level of symptoms, airflow limitation, and lung function variability into four categories: Mild intermittent, Mild persistent, Moderate Persistent, and Severe Persistent. In this study the severity of asthma was mild intermittent in 113 (56.5%) patients, mild persistent in 58 (29%), moderate persistent in 24 (12%) and severe persistent in only 5 (2.5%) of patients (Table 3).

Table 3: Severity grading of bronchial asthma patients on the basis of GINA

Global Initiative for asthma (GINA)		
Severity grading of bronchial asthma		
	Number of asthma patients	Percentage
Mild intermittent	113	56.50%
Mild persistent	58	29%
Moderate persistent	24	12%
Severe persistent	5	2.50%

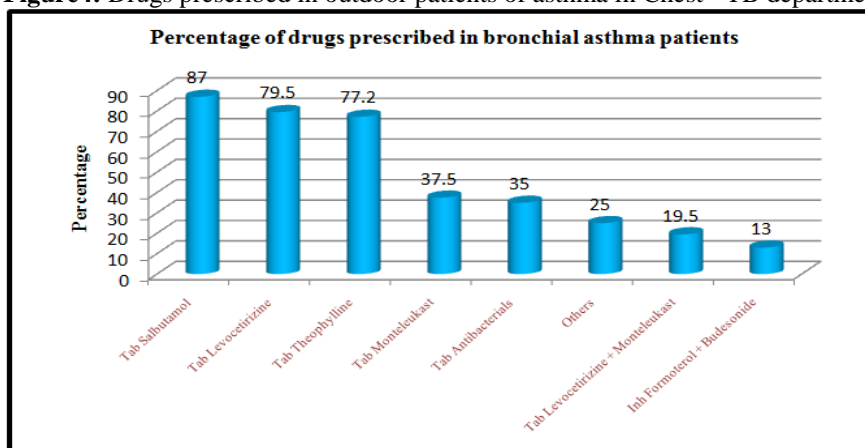
During the study period, 764 drugs were prescribed for 200 outdoor patients of asthma with or without co – morbidities (3.82 drugs per prescription). When assessed about the number of drugs per prescription, it was found that most commonly three drugs per prescription were prescribed in 43% of prescriptions and two drugs per prescription were prescribed in 36% of prescriptions in outdoor patients of asthma with or without co – morbidities (Fig 3).

Figure 3: Number of drugs prescribed per prescription in asthma patients



Drug utilization pattern in patients of asthma was studied separately. Number of drugs prescribed and frequency of their use in outdoor patients of asthma in Chest – TB departments was given in Fig 4. β_2 agonist (Tablet Salbutamol) was the most frequently prescribed group of anti-asthmatic drugs (87%) followed by anti-histaminic agent (Tablet Levocetirizine 79.5%) and Methyxanthines (77.2%) of patients. Inhaler of formoterol + Budesonide was prescribed in only 13% of patients. Co- medications like anti-hypertensive drugs, antidiabetics, vitamin supplements were prescribed in 25% of patients.

Figure 4: Drugs prescribed in outdoor patients of asthma in Chest - TB department



It was observed that, oral route of salbutamol was commonly preferred for in outdoor patients of asthma (87%) while only 13% patients received inhaler of β_2 agonist (Table 4).

Table 4: Dosage forms of drugs utilised in asthma patients in Chest - TB department

Dosage Form of β_2 agonist	Outdoor patients (%)
Oral	87
Inhaler	13

It was observed that 74.22% of the drugs were prescribed by generic names in outdoor patients of asthma. Prescriptions were further assessed for their consistency with national list of essential medicines 2015 (NLEM 2015) [9]. It was also observed 99.66% of drugs prescribed in outdoor patients were found to be from NLEM 2015. Among the different classes of drug combinations, tablet levocetirizine + montelukast (19.5%) and inhaler formoterol + budesonide (13%) remained the most frequently prescribed combinations asthma patients followed by [Fig. 4].

IV. Discussion

Prescription monitoring studies are important for obtaining data about the patterns and rationality of use, the determinants of drug use, and the outcomes of use. The WHO drug utilization indicators [1] are highly standardized and are recommended for inclusion in drug utilization studies. Average number of drugs per person is an important index of prescription audit. Mean number of drugs per prescription should be kept as low as possible. Irrational use of drug and inappropriate prescribing are the two common problems in the developing countries which cause a big hurdle for providing effective health care facilities [10]. Rational use of drug requires appropriate medications to their clinical needs in doses that meet their own requirements for adequate period of time and cost effective [11]. Thus, there is need for rational drug utilization studies. However, only a few studies have been conducted because of several constraints in India. A prescription-based survey is considered one of the scientific methods to assess and evaluate the rationality of the prescription. Now, recommendations of various international bodies on asthma which help improve prescribing practices of the physicians and ultimate clinical standard are available [5, 10]

This study was undertaken to evaluate the rational use of drugs in bronchial asthma patients visiting OPD's of Chest – TB department of a tertiary level teaching hospital. Out of 200 prescriptions, diagnosis was mentioned in 74% of prescriptions. About 26% prescriptions were lacking patient's diagnosis so effort must be made to encourage writing complete prescription with diagnosis. Rational use of drug requires appropriate medications to their clinical needs in doses that meet their own requirements for adequate period of time and cost effective [12]. Dose and duration were quoted in more than 90% of prescriptions as dose and duration of drug treatment is saved and auto-generated in HMIS system. Hence there are minimal chances of prescribing errors.

The demographic results of patients revealed that number of male patients outnumbered female patients in Chest – TB department. This was comparable with Rajathilagam T et al study [2]. Rajathilagam T et al study found similar results about gender distribution as 57.29% males and 42.7% females. The reason for more male admissions in this study may be that female patients are reluctant to utilize health care facilities unless they are critically ill. The another reason for more male admissions in this study may be attributed to more male to female ratio in Maharashtra and in the Indian scenario. Majority of asthma patients were from age group of 46 – 60 years. Risk factors such as hypertension, diabetes mellitus and cerebrovascular events are more common after age of 45 years [10]. Michael B et al [13] in a study obtained similar results about age distribution of asthma patients of where

Allergic factors have been seen to be responsible for precipitating asthma in 53% of patients in this study and most of patients belong to mild intermittent grade of asthma (GINA). Similar results were attained in Rajathilagam T et al study [2]. In this study, the average number of drugs per prescription was 3.82 indicating polypharmacy. This result was comparable with study by Michael B et al. [13]. This prescribing trend may be attributed to the goals of asthma therapy to minimize chronic symptoms, to prevent recurrent exacerbations, to reduce the need for pulmonary function [3]. The pattern of drug utilization showed that drugs that provide symptom relief were prescribed more than the asthma controlling agents. Yet number of drugs per prescription should be kept low to prevent drug – drug interactions as well as to reduce hospital cost [10].

Analysis suggested that doctors preferred the oral formulations than the inhalational preparations. As inhalation preparations are costly so it is not feasible in government set-up to procure inhalational anti – asthmatics. Oral salbutamol was the most frequently prescribed anti – asthmatic drug. This may be because of easy availability and cheap anti – asthmatic medication with fewer adverse effects; hence oral salbutamol being prescribed more frequently in asthma OPD. This pattern has been seen in previous studies too [2, 13] but in contrast to analysis by Arumugam et al [14]. Short acting β_2 agonists relax airway smooth muscle and inhibit release of bronchoconstricting mediators from mast cells. They may also inhibit microvascular leakage and increase mucociliary transport by increasing ciliary activity. Even in recent times, short acting β_2 agonists are still highly preferred for asthma since they are the most effective bronchodilators which provide quick or “rescue” relief from acute asthma attacks [3, 15]. Other than short acting β_2 agonists, anti-histaminics (79.5%), methylxanthines (77.2%) leukotriene receptor antagonists (37.5%) were also prescribed frequently.

Methylxanthines represent a unique class of drugs for the treatment of asthma. They have demonstrated efficacy in attenuating the three cardinal features of asthma - reversible airflow obstruction, airway hyper-responsiveness, and airway inflammation. At lower serum concentrations, theophylline is a weak bronchodilator but retains its capacity as an immunomodulator, anti-inflammatory and broncho-protective drug. Hence theophylline's predominant role in asthma treatment is as a controller medication for chronic, persistent disease. Phosphodiesterase inhibition and adenosine receptor antagonism by methylxanthines have both been implicated in promoting airway smooth muscle relaxation and bronchodilation [16]. Theophylline serum concentrations need to be monitored closely owing to the drug's narrow toxic-therapeutic range, individual differences in metabolism and the effects of many factors on drug absorption and metabolism [16]. Many clinical studies have shown that theophylline decreases the frequency and severity of symptoms, including nocturnal exacerbations, and decreases the "as needed" use of inhaled beta-2 agonists. [17]. Second generation antihistaminic like levocetirizine was prescribed as an adjuvant drug in 38.4% patients. Cetirizine improves asthma symptoms, decreases rescue drug use and does not worsen pulmonary function parameters [16]. Montelukast, a leukotriene receptor antagonist which represents an important advance in asthma therapy was prescribed as a fixed dose combination with levocetirizine (19.5%) in this study. Histamine and leukotrienes are released in concert during the early and late phases of allergic reactions. Hence a combination of an antihistaminic and a leukotriene receptor antagonist has impressive additive inhibitory effects on both the early and late bronchoconstrictive reactions seen in bronchial asthma [17]. These leukotriene receptor antagonists are active over a wide range of asthma severity and have both an anti-inflammatory and a bronchodilator property [17]. They cause modest improvement in lung function, reduce asthma symptoms and lessen the need for β_2 agonist rescue therapy [3]. They are active orally, therefore overcoming the potential problems with compliance when using inhalers [18].

This study also showed that antibiotics and multivitamins were prescribed as adjuvant therapy (25%). Antibiotics are highly effective against respiratory infections were commonly prescribed. These antibiotics favourably affect the bronchial hyper-responsiveness found in asthma and they also helped to improve the breathing and lung function in asthmatic patients with underlying respiratory infection [3, 16].

Inhalational form is the most safe and targeted therapy in bronchial asthma. The advantages being smaller dose, targeted delivery, rapid action and minimal systemic side effects [16]. But in this study also only 13% of patients received inhalation therapy. This could be attributed to high cost inhalational formulation than oral formulation. It is not feasible in government set-up to procure inhalational formulations of anti-asthmatics. Fixed dose inhalational therapy with a long-acting beta2 agonist and corticosteroids was prescribed in this study. Long-acting beta2 agonists should always be used in combination with inhaled corticosteroids as they alone do not treat the underlying chronic inflammation. In combination with corticosteroids they improve symptom scores, decrease nocturnal asthma, improve lung function, decrease the use of rapid-acting inhaled β_2 -agonists, reduce the number of exacerbations and achieve more rapid clinical control of asthma [16]. This greater efficacy has led to the development of fixed combination inhalers of corticosteroids and long-acting β_2 -agonist which are more convenient for patients and also increase patient compliance [5].

In this study, it was observed that, most of the drugs were prescribed by generic names. Some other study done in South India also confirmed that the tendency of physicians to prescribe drugs by generic names was less at tertiary care centres and out-patient clinics [19]. Prescribing drugs by brand names increase economic burden of the patients as they are costlier than the generic versions available in the market.

About 99.66% of the prescribed drugs were from the NLEM 2015 [9] in patients respectively. Hence these study reflecting a better level of adherence to prescribing from NLEM 2015.

The present study had certain limitations. The study was carried out over a three month period only. Only first consecutive 200 prescriptions were considered for analysis, and these may not have been representative of the patient population. Moreover, the depth and quality of data available at health facilities influenced the variables that could be studied. Variables such as diagnostic tests performed and their outcomes, signs of infection, patient load, previous treatment, concurrent medications and drug-drug interaction etc. may influence anti-asthmatic drug prescribing behaviour. However, these variables were not considered in this study. The patient's knowledge of the duration of treatment, proper time to take the medication was not assessed too. Further studies over longer period of time with a large sample size in various prescribing setup will give us better insight regarding prescription writing practices. Such type of studies provides necessary feedback to prescribers and may prove useful to formulate guidelines to policy makers. However, this study has dealt basic concept and identified key areas which require modifications for rational drug use.

V. Conclusion

Drug prescriptions for asthma patients were rational regarding their duration of administration, route, and the indication but some of them were devoid of diagnosis. The efforts must be made to encourage writing complete prescription. The patient's load is very high at government hospitals; yet, necessary information regarding patients, diagnosis and treatment schedule should be included in prescription for each and every

patient. Since resident doctors are future prescribers, there is need to sensitize an issue of prescribing skills in them to promote judicious use of different classes of drugs to avoid un-necessary use as well as drug interactions. Based on the results, it was observed that the incidence of asthma was more common in males when compared to females. Majority of the patients were from the age group of 46-60 years. Most of the patients were prescribed with multiple drug therapy out of which oral route was the most preferred one. Most frequently prescribed anti-asthmatic drug was oral salbutamol. Inhalational therapy was used in few patients. Anti-asthmatic drugs given as inhalational therapy are more beneficial to the patients than systemic therapy. Hence, their maximum utilization in asthmatics will definitely reduce incidence of acute asthma as well as the adverse effects of anti-asthmatic drugs. In this study, drug – drug interaction was not considered in this study. The comparative drug utilization studies can be planned in different set – ups to assess rational prescribing of anti -asthmatics.

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