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Research Article

Drug Utilization Pattern of Antiasthma Drugs in Children at Tertiary Care Teaching Hospital

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Abstract: ***Background:*** Bronchial asthma is known to be one of the major causes of morbidity and mortality in India. There is paucity of Indian data which evaluate the pattern of drug utilization in bronchial asthma over its entire spectrum and varying severity. ***Material and Methods:*** This is a Prospective, observational, non-interventional study of children who presented between February 2020 and November 2020. Study conducted at Department of Paediatric and Pharmacology. With a sample size of 90 patients who confirmed to the following predetermined inclusion and exclusion criteria. ***Result:*** The overall utilization of Anti-asthmatic drugs among paediatric asthma patients were found to be –short acting β2 Agonists (41.1%) long acting β2agonist (LABA) (10.0%), steroids (13.3%) and leukotriene modifiers (1.11%). Pattern of drug prescription in asthmatics showed the highest prevalence of β2 Agonists followed by corticosteroids and finally, the leukotriene modifiers. One additional antiasthmatic drug: anticholinergics were also used among patients. ***Conclusion:*** To conclude, this study provides few insights into the drug use patterns in a pediatric outpatient department of a tertiary care teaching hospital. The prescribing from NLEM was fair, the use of injections was low and there is a scope for improvement in case of medicines prescribed by generic name.

Keywords: Antiasthma drugs, Drug utilization studies, Paediatrics.

INTRODUCTION

Drug utilization studies (DUS) are necessary for knowing the extent of drug use, identifying variability in drug use among different regions or within the region, and developing interventions to improve rational drug use [1]. DUS are thus considered a tool to evaluate health-care system and are the need of the hour [2]. DUS are more importantly required in resource-poor countries like ours so as to ensure that the scarce resources are utilized effectively.

There are about 334 million patients with asthma affecting all age groups, across the world, and about 17–30 million patients suffer from asthma in India [3]. 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 pediatric population, and its prevalence varies from place to place [4]. As per the Global Initiative for Asthma guidelines, mainly two categories of drugs are used, namely controllers (inhaled and systemic glucocorticoids and inhaled long-acting beta-agonists [LABA] in combination used with inhaled corticosteroid (ICS), leukotriene modifiers, sustained–release theophylline, cromones, and anti-immunoglobulin E) and relievers (inhaled and oral beta-2 agonists, short-acting anticholinergics, and short-acting theophylline) [5-9]. These drugs can be used alone or in conjunction with other antiasthmatic drugs [10].

There is paucity of Indian data which evaluate the pattern of drug utilization in bronchial asthma over its entire spectrum and varying severity. Hence, the present study was conducted to assess the drug utilization pattern in all bronchial asthma patients at the outpatient department (OPD) and inpatient department (IPD) of medicine and pediatrics at a tertiary care hospital.

MATERIAL AND METHODS

This is a Prospective, observational, non-interventional study of children who presented between February 2020 and November 2020. Study conducted at Department of Paediatric and Pharmacology. With a sample size of 90 patients who confirmed to the following predetermined inclusion and exclusion criteria.

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Inclusion criteria

- Paediatric patients of bronchial asthma (both acute and chronic cases)
- Patients of either gender within the age limit of 1-13 years
- Who attended outpatient department (OPD) as well as in patient department (IPD),
- Willing to enrol in a study with informed consent forms was included in the study.

Exclusion criteria

- Patients who are <1 and >13 years,
- Patients with other co-morbid conditions like TB, Diabetes/renal failure
- Patients with other systemic disorders
- Patients who were immunocompromised were also excluded.

METHOD

Once their consultation with the paediatrician was over, the prescriptions were collected and necessary details were noted on the questionnaire. The patient's parents were also interviewed on the predesigned questionnaire. The details of the drugs prescribed were noted down. After noting down the required parameters, prescriptions were returned to the patients. After the completion of the study, the questionnaires were analysed to obtain the drug utilization pattern and from Current Index of Medical Specialties (CIMS) and Indian Pharmaceutical Guide. It also included the OPD number, demographical details, and patients name, age, sex. A brief questionnaire was designed specifically for the study is attached with case report form which chief complaints, and history of asthma, severity and the current status of asthma. The details of the drugs prescribed (dose, route, frequency, duration), the cost of therapy.

Parents of eligible patients were contacted by phone or in person a paediatrician. Using a non-leading interview script, a standardised questionnaire was administered to identify any ADR-related drug cessation, reported spontaneously or after prompting, using three approaches. First, we enquired about the occurrence and reason for any asthma drug cessation. Second, we asked if the child had experienced an ADR to any asthma medication. Finally, a list of ADRs was read to parents to determine if any of them had ever occurred with any asthma drug. If an ADR was reported in any of these three questions, parents were asked to describe the type and onset of symptoms, circumstances related to the event, dose adjustments or drug discontinuation resulting from the ADR, and, when applicable, the evolution of the ADR after discontinuation of the drug (dechallenge) and after restarting the medication (rechallenge) [20].

ADR report to assess event severity, evolution and immutability using the Naranjo score [20], briefly, the Naranjo algorithm evaluates the drug causality for an adverse drug reaction based on 10 questions. Each answer is assigned a value (−1 to +2) for a maximum score of 12, with causality considered definite if the total score is ≥ 9, probable if 5–8, possible if 1–4 and doubtful if ≤ 0. Moreover, the severity of the reactions was analysed using modified Hartwig and Siegel's scale.

STATISTICAL ANALYSIS

The Data was entered into SPSS sheet and analysed. The data was presented using frequencies, percentages along with appropriate graphs and charts. The quantitative variables were presented using descriptive statistics such as mean, and Standard deviation. The Association between variables were tested using chi-square test. The level of significance was set at 0.05. All p values less than 0.05 are considered as significant.

RESULTS

During the study, 90 paediatric asthma patients' prescriptions were included for data analysis as per inclusion & exclusion criteria.

The various parameter analysed are as follows

Table-1: Age wise Distribution of Paediatric Patients

Age (in year)	No. of patients (n=90)	Percentage
1-4	9	10
5-8	47	52.2
9-13	34	37.7
Total	90	100

The paediatric group patients were divided into three classes as per the age-group. Most of the paediatric patients suffering from asthma 52.2% were found in the age group of 5-8 years followed by (10%) 1-4 years and 9-13 years (37.7%).

Table-2: Gender wise Distribution of Paediatric Patients

Gender	No. of patients	Percentage
Male	54	60
Female	36	40
Total	90	100

Demographic analysis of data revealed that there were 60% male and 40% female in the study.

Table-3: Grading of asthma severity (% of patients)

Grading	No. of patients	Percentage
Mild	30	33.3
Moderate	57	63.3
Severe	3	3.33
Total	90	100

Out of 90 Paediatric asthma patients, 33.3% were suffering from mild persistent and the remaining 63.3% were patients of moderate persistent and 3.33% are least one of severe asthma.

Table-4: Anti-asthmatic drug combinations

Drug therapy	No. of patients	Percentage
Monotherapy	60	66.6
Combination therapy	30	33.3
Total	90	100

The percentages of the patients who received either monotherapy or combination therapy, i.e., two, three, or four drug regimens, showed that 66.6 %, of all the patients were treated with a single anti-asthmatic drug (monotherapy) excluding other concomitant medications used together. 33.3 % children were treated with anti- asthmatic drug combinations. The results of this study showed that most of the patients received multiple drug therapy as compared to a single drug therapy. All the drugs were prescribed by their brand names.

Table-5: Drugs used in asthma

Drug class	No. of patients	Percentage
Short acting β2 -agonists	37	41.1
Long acting β2 -agonists	9	10.0
Steroids alone	13	13.3
Leukotriene Modifiers	1	1.11
Steroids + Beta-agonists	19	21.1
Anticholinergic+ Beta-agonists	11	12.2

The overall utilization of Anti-asthmatic drugs among paediatric asthma patients were found to be – short acting β2 Agonists (41.1%) long acting β2agonist (LABA) (10.0%), steroids (13.3%) and leukotriene modifiers (1.11%). Pattern of drug prescription in asthmatics showed the highest prevalence of β2 Agonists followed by corticosteroids and finally, the leukotriene modifiers. One additional antiasthmatic drug: anticholinergics were also used among patients.

Table-6: Distribution According to Class of Drugs Prescribed (Asthmatic Medication)

Drug	No. of patients	Percentage
Salbutamol	37	41.1
Salmeterol	9	10.0
Deflazacort	2	2.22
Budesonide	7	7.7
Prednisolone	4	5
Montelukast	1	1.11
Salmeterol+Fluticasone	19	21.1
Salbutamol+Ipratropium Bromide	11	12.2

Salbutamol is most commonly used short acting β2 Agonists, Salmeterol was most commonly used long acting β2 Agonists. Budesonide, Deflazacort & Fluticasone are most commonly used corticosteroids among children.

Table-7: Route of administration of Drugs

Route	No. of patients	Percentage
Inhalational	54	60.0
oral	36	40.0
Total	90	100

Different dosage forms used by asthmatic patient: The 61.6% of patients were given by inhalational route and remaining was given by oral route 38.3%.

Table-8: Gender of patients and adverse drug reaction (n = 7)

Gender	No. of patients		Total
	With ADR (%)	Without ADR (%)	
Male	4 (4.4%)	50 (55.5%)	54 (60.0%)
Female	3 (3.3%)	33 (36.6%)	36 (40.0%)
Total	7 (7.7%)	83 (92.2%)	90 (100%)

During the study period, a total of 7 ADRs were reported among 90 patients. The incidence rate of ADRs was found to be 7.7%. Our study revealed that out of 7 reported cases of ADR, 4 (4.4%) occurred in males and 3 (3.3%) in females as shown in Table 8.

Table-9: Percentage of various reported adverse drug reactions

ADR	No. of patients	Percentage
Palpitation	1	1.11
Dryness of mouth	2	2.22
Headache	1	1.11
Sore throat	1	1.11
Oral candidiasis	2	2.22
Total	7	7.7

The reported ADRs were 1.11% were headache, palpitation, dryness of mouth, sore throat, anorexia, and oral candidiasis, nausea/vomiting.

Table-10: Causality assessment of ADRs according to WHO-UMC scale

Type of reaction	No. of patients	Percentage
Certain	1	1.11
Probable	2	2.22
Possible	4	4.44

On causality assessment by WHO-UMC method, it was observed that 1 (1.11%) were certain, 2 (2.22%) were probable and maximum 4 (4.44%) was possible ADR.

Table-11: Severity of reported ADRs by modified by Hartwig and Siegel scale

Type of reaction	No. of patients	Percentage
Mild	2	2.22
Moderate	5	5.55
Severe	0	0

Assessment of severity of recorded adverse drug reactions with the help of Hartwig and Siegel scale showed that 2 (2.22%) accounted for mild reactions and 5 (5.55%) were moderate reactions. No severe ADR were recorded during the study period.

DISCUSSION

Asthma is a chronic inflammatory disease of airway. Number of patients suffering from asthma is increasing day by day. Treatment of asthma comprises of multiple therapeutic options. Drug utilization evaluation is most important for the promotion of rational uses of drug. Recommendation of various international bodies on asthma will help to improve prescribing practises of physician and make availability of standard guidelines. Irrational use of drug and inappropriate prescribing is the two-common phenomenon in the developing countries, which cause a big problem for providing the effective health care facilities [6]. Rational use of drug requires that patient receiving medications appropriate to their clinical needs in their individual required dose, for adequate period of time at lowest cost. This upsurges the need for pharmacotherapeutic studies.

The present study was thus conducted with a view to assess the drug usage pattern in paediatrics asthma patients attending the paediatrics department in a tertiary care hospital. The study included 90 asthma patients suffering from asthma with male preponderance. In this study, majority of prescriptions (60.0%) were for male children aged 5 years – 8 years (52.2%). This may be due to the fact that these age groups are more vulnerable and morbidities are commoner than older children and hence attendance to OPD is more. Proper health education is required to convince the patients.

Prescription pattern shows that maximum number of patients (41.1%) were prescribed beta-agonists, more specifically salbutamol, making it the preferred choice for asthma management. This finding is further reinforced by some previous studies in other countries [11]. It is from the group Short Acting Beta Agonist (henceforth SABA), and the main reason for its use is rapid onset and low cost. In addition, salbutamol does not increase exacerbation rates and provides instant symptomatic relief.

In our study, steroid consist the second largest prescribed drugs. This finding is reinforced by a similar study from India [12]. Corticosteroids (inhaled and oral) are one of the mainstay therapies for asthma. In addition to reduction of severity and exacerbation, they reduce airway hyper-responsiveness. They also help in reducing inflammation by inhibiting the activation and recruitment of T cells, macrophages, and dendritic cells, by decreasing mast cells survival, and by inhibiting the release of inflammatory mediators. [13] In addition, they reduce hospitalization, improve quality of life, and reduce overall mortality and morbidity [14].

Previous studies reported equivocal results regarding comparative efficacy of different steroids by various route of administration, as discussed below. Budesonide has shown better pharmacological profile as compared to prednisolone, however, prednisolone is cheap and available for oral administration [15]. Another study documented the preference of budesonide over prednisolone in pediatric acute moderate asthmatic attacks [16]. However, a study by volovitz *et al*. reported comparable efficacy for budesonide and prednisolone [17].

Our results indicated that a small fraction of patients was prescribed montelukast, a leukotriene receptor antagonist as compared to other previous studies. It may be partially explained by a better asthma control with already prescribed ICS and SABA. Another reason may be a slightly higher cost. Montelukast improves PEF, FEV1, and other parameters, reduces nocturnal symptoms, and may decrease the concomitant doses of ICS and SABA/LABA [18].

There are equivocal results regarding the route of administration for steroids, for example, prednisolone oral versus hydrocortisone intravenous showed similar efficacy [19]. However, a trial studying comparison of sequential therapy discovered that PEF, FEV1, and asthma scores are far better in the group prescribed IV methylprednisolone after oral methylprednisolone compared to the group given IV hydrocortisone after oral methylprednisolone [20]. In another study, oral prednisolone and IV methylprednisolone were found equally efficacious in children [21].

There are also well-established reports concerning the superiority of combination of Inhalational Corticosteroids (henceforth ICS) and Long Acting Beta Agonist (hereafter LABA) against individual therapy. A study in Brazil concluded that a combination of budesonide + salbutamol is better than oral prednisolone [23]. Cochrane review database also supports these reports [22]. However, mutual comparison between different ICS and LABA combinations revealed equivocal results [24].

Recently introduced SMART (Single Inhaler Maintenance and Reliever Therapy) or SiT (Single Inhaler Therapy) approach has produced good results

regarding the quality of life and dose reduction of both ICS and LABA as compared to ICS alone, however, there are few incidences of flare ups in children; hence, a controversy is ongoing regarding the long-term benefits, especially in pediatric age group [25]. However, a systematic review found fewer exacerbations but associated poor symptom control, which was supported by two other studies advocating its use based on cost effectiveness and achievement of greater asthma control [26]. Still trials are going on to establish the superiority of single inhaler treatment on "as needed" basis [27]. In our study, most of the patients were on more than two drugs but subanalysis revealed that ICS+LABA SiT were restricted to few and that too mainly in adult population. This is in accordance with recent updates.

Inhalational route is the choice for asthmatic patients as it delivers the maximum amount of drug with minimal systemic side effects. A previous study showed similar percentage [28]. However, medication by oral route becomes essential in case of inability to use the inhaler efficiently in an appropriate manner, especially in pediatric and geriatric population. They may not be able to coordinate the inspiration timing with inhaler puff. One solution is provided by nebulization that does not require coordination and works with normal tidal respiration but it is needs longer periods and mainly used in emergency for termination of acute attack. Oral medications do not depend on the technique, and a study reported a higher compliance of tablets than inhaled medications for asthma [29]. IV route also produces quick relief with 100% bioavailability and less airway irritation. Few studies have compared the efficacy of these regimens; however, there is a need for well-designed studies to explore the issue of route further [30].

Limitations of the study could be that it was conducted in a single center and results may not be applicable to general population. Also, study evaluated drug use pattern in only patients attending OPDs and prescription pattern will definitely vary among inpatient population. Seven-point criteria used for assessing rationality of FDCs cannot be regarded as the sole measure of rationality. WHO core drug prescribing indicators only indicate quantity of drugs prescribed but cannot determine accuracy of diagnosis or adequacy of drug choices. Furthermore, patient care indicators and facility indicators were not included as this was a prescription-based study. However, it provides useful baseline data over which future studies can be built upon.

CONCLUSION

Asthma, a common chronic disease has multiple therapeutic options. Guidelines like Global Initiative for Asthma (GINA) have enlightened physicians about the rational prescribing in asthmatic patients. The usage pattern as assessed in our study was in conformation to GINA guidelines. Various asthma education programs would benefit to improve knowledge and increase awareness regarding current asthma management paradigms in the medical community. Effective patient education measures and awareness campaigns in the community can also help in achieving better outcomes.

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