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A PHARMACOVIGILANCE STUDY IN PATIENTS WITH BRONCHIAL ASTHMA IN A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT

Background:-Bronchial asthma is one of the most common chronic disease affecting about 345 million people. Bronchial asthma management includes multidrug therapy for long duration, and this therapy is associated with adverse drug reactions [ADRs]. So in this present study we planned to monitor & evaluate adverse drug reactions associated with anti-asthmatic drugs. **Objectives: -**The present study was conducted to evaluate the severity of adverse drug reactions associated with anti-asthmatic agents in a tertiary care hospital.

KEY WORDS: Aldehydes, Dihydropyramidinone derived Pyrazoles, Anti-inflammatory, Antimicrobial activities.

INTRODUCTION

Bronchial Asthma is termed as reversible airway obstruction of the lungs due to its hyper-responsiveness to external or internal allergen or nonspecific stimulus like exercise, cold and pathologically characterized by chronic inflammation of airways and clinically by cough, wheeze, chest tightness and dyspnoea.[1] The prevalence of asthma is about 4.5%[2,3] approximately. Across the world about 334 million patients affecting all age groups in patients with asthma. The prevalence of asthma has raised over the time and an additional 100 million people worldwide are expected to develop asthma held in the year 2025.[4]

In the Indian study on epidemiological study of asthma shows respiratory symptoms and chronic bronchitis in adults (INSEARCH), the prevalence of asthma in adults is about 2.05% with an estimated burden of 17.23 million.[5] A recent analysis using three different kinds of models (INSEARCH, GINA and WHO survey) reveals that the prevalence of asthma varies between 2.05-3.5% in India. Therefore further predicts said that prevalence rate of asthma will raised which can leads to an increase in the number of asthmatic patients.[6,7] ADR can be defined as the any responses to a drug which is noxious, unintended and which occur at doses used for prophylaxis, diagnosis and prevention of disease.[8] The WHO defined pharmacovigilance is a science and activities relating to the detection, assessment, understanding and prevention ofADR in the year 2004.[9] For monitoring of ADR parameters related to anti asthmatic agents in such cases we can use pharmacovigilance studies.[11] Most common adverse effects of anti-asthmatic agents such asOral thrush, tremor, palpitations, throat irritation and cough.[12]

MATERIALS AND METHODS

The study was conducted in outpatient and inpatient department of medicine in a tertiary hospital. A total 100 patients were interviewed it includes both male and female patients ageing above 18 years with bronchial asthma attending in outpatient and inpatient department of medicine in a tertiary care hospital during the time period of November 2016 to April 2017.Central Drugs Standard Control Organisation (CDSCO) ADR forms were filled. Causality categories were used for assessment of causality.[13] Severity of ADRs was assessed by using Hartwig and siegel scale.

RESULTS

A total 28 ADRs were reported in 18 patients out of 100 bronchial asthma patients. Among the 18 patients reportedwith ADRs 10(55.55%) were male while 8 (50.52%) were female. 4(22.24%) patients associated with ADRs observed in the age group of 41-50 years, followed by 4(22.64%) in age group 21-30 years, 3 (16.31%) in agegroup 31-40 years, 4 (22.01%) in age group 51- 60 and 3(16.66)in 61-70 each were observed.

Table 1: Distribution of ADRs among various age groups of asthmatic patients.

Age range	Male	Female	Total[%]
21-30	2	2	4(22.22%)
31-40	2	1	3(16. 56%)
41-50	2	2	4(22.26%)
51-60	3	1	4(22.32%)
61-70	1	2	3(16.67%)

Table 2: Types and number of ADR reactions.

Types of ADR reactions	Number of ADRs [%]
Oral trush	7(25%)
Palpitations	5(17.85%)
Sore throat	4(14.28%)
Running nose	3(10.71%)
Tremors	3(10.71%)
Dry mouth	2(7.15%)
GI distress, nausea	2(7.15%)
Bitter taste	1(3.57%)
Headache	1(3.57%)

Most common adverse drug reaction was occur with the use of anti-asthamatic agents is oral thrush (25%) followed by palpitation (17.85%), sore throat (14.28%), running nose (10.71%).

Tremors (each 10.71%), dry mouth(7.15%) GI distress (7.15%) bitter taste (3.57%) and headache (3.57%)among the patients of bronchial asthma receiving anti asthmatic agents (Table 2).

Table 3: Suspected drugs and their associated type of ADRS and number.

Antiasthamatic class	Drugs	No of ADRS/No of prescriptions	ADRS [No]
β_2 Agonist	Salbutamol	8/31	Palpitations(4) Bitter taste(2) Tremors(2)
	salmeterol	2/15	Headache(2)
Methyl xanthines	Theophylline	3/15	Palpitations(1) Bitter taste(1) Tremors(1)
Corticosteroids	Beclomethasone	4/18	Oral trush(3) Sore throat(1)
	Budesonide	6/8	Oral trush(3) Sore throat(3)
Anti cholinergic	Ipratropium	3/9	GI distress(1) Dry mouth(2)
Leukotrine antagonist	Montelukast	2/4	Running nose(2)

Most ADR was associated with inhalational Beclomathasone (22.22%) followed by inhalational budesonide (75%),montelukast (50%), salbutamol (25.8%), theophylline (20%), ipratropium (33.33%) and salmeterol (13.33%)

Table 4: Number of ADRS in patients receiving monotherapy and combination therapy.

Therapy	No of patients	No of ADRS	
Mono therapy	8	12	
Combination therapy	10	16	P > 0.05
Total	18	28	

Among the total 18patients, 8 were on monotherapy while 10 were on combination therapy. There was nosignificant difference in ADRs associated with monotherapy and combination therapy [Chi- square test (p> 0.05)

Table 5: casuality assessment of ADR according to WHOcategorie.

Assessment	No of ADRs	Percentage of ADRs
Certain	0	0
Probable	12	48.51
Possible	16	51.49
Unlikely	0	0
Conditional	0	0
Un conditional	0	0

In this we concluded that 48.49% ADRs were found to be probable while 51.51% were possible according to WHO-UMC category.

Table 6: ADR classification based on severity by Hartwing and Siegel Scale.

Severity	No of ADRs	Percentage of ADRs
Mild	16	57.14
Moderate	12	42.857
Severe	0	0

By using hartwig and siegel scale we can calculate highest percentage of ADRs (57.14%) were classified as

mild which included oralthrush, sore throat, running nose, dry mouth, GI distress, bitter taste, headache and were well tolerated by patients.While 42.85% were moderate which included palpitations and tremors, no severe reaction was observed

DISCUSSION

A total 28 ADRs were reported in 18 patients out of 100 bronchial asthma patients. Among the 18 patients 10(55.55%) were male while 8 (44.44%) were female. Most commonly observed adverse drug reaction is oral thrush and was observed in 7 patients out of 18 (25%) who received inhalational Beclomethasone and Budesonide corticosteroids, Most ADR (oral thrush) wasassociated with inhalational Beclomethasone in 7 out of 18 patients (22.22%). Risk of oral thrush may be reduced by using leansing mouth and brushing teeth after using the steroid inhaler. All 7 patients were not rinsing mouth or brushing teeth after use of inhalation. No prioradvice was given to patients regarding cleansing mouth after beclomethasone inhalation. High incidence of oralthrush in patients receiving inhalational beclomethasone is suggestive of need of counselling and advice to reducethe risk of oral thrush.[14,15,16,17,18] There was no significant difference in ADRs associated with monotherapy and combinationtherapy. Highest percentage of ADRs (57.14%) were classified as mild ADR on Hartwig and Siegel scale whichincluded oral thrush, sore throat, running nose, dry mouth, GI distress, bitter taste, headache and were well tolerated by patients. While (42.85%) were moderate which included palpitations and tremors.

CONCLUSION

Our study was concluded that the need of monitoring of ADRs with the use of anti-asthamatics in patients with asthma. Patients who are receiving inhalational steroids needs to be proper counselling for about cleansing mouth aftersteroid inhalation there by reducing the risk of oral thrush.

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