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ANALYSIS OF ADVERSE DRUG REACTIONS IN PATIENTS OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE: AN UNDER-GRADUATE MEDICAL STUDENT'S PERSPECTIVE

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ABSTRACT

Adverse drug reactions are under-reported by clinicians. Efforts are being done to improve the quality and quantity of reporting by incorporating the topic of pharmacovigilance and ADR reporting in curriculum of medical undergraduates. Chronic Obstructive Pulmonary Disease is a common clinical condition affecting approximately 10% of adult population of world. Drugs used for management of COPD usually produce a number of mild to moderately severe ADR which can be detected and evaluated by undergraduate medical students. In this research article we present the data of ADR detected in patients of COPD and discuss the impact of this strategy on academics and hospital services. Additionally, issues related with use of this strategy will also be discussed.

KEYWORDS: ADR's, Pharmacovigilance, COPD.

INTRODUCTION

Adverse drug reaction (ADR) are one of the major cause of morbidity and mortality globally. Over two million ADRs occur yearly that result in 5% fatality annually making ADR as the fourth leading cause of death in United States.[1] Similar epidemiology of ADR is seen in India also. Chronic Obstructive Pulmonary Disease (COPD) is one of the most common non-communicable disease affecting population. The global prevalence of COPD in adults aged ≥ 40 yr is approximately 9-10% while in India, the prevalence was found to be 3.49%in adults >35 yrs.[2,3]

Management of COPD includes smoking cessation and use of various medicines including bronchodilators (β agonists, anticholinergics, methylxanthines), corticosteroids (inhaled, systemic). These drugs are known to cause a number of adverse effects which can affect quality of life of patients and lead to burden on health care system. Patients are usually elderly, on multiple medicines and treatment is of a long duration so there are more occurrences of ADRs. The present study will help in generating background information about incidence of ADRs in COPD and inculcate a habit of reporting and analyzing ADRs among treating physicians.

MATERIAL AND METHODS

The study was conducted in already diagnosed patients of COPD visiting Pulmonary Medicine Out-patient Department at All India Institute of Medical Sciences, Rishikesh. All patients of COPD irrespective of disease status were included in the study.

Patients were screened for detecting ADRs to frequently used drugs using a check-list. If any ADR was reported, information about demography, disease activity and treatment history was collected in a customised Case Record Form (CRF). The information was used to identify factors possibly leading to adverse drug reactions andwas kept confidential. Patients were educated by treating physician regarding ADR and strategies to manage them. WHO Causality Assessment Scale was used for assessing causality of ADR.[4] The study protocol was approved by Institute Ethics Committee before enrolling patients. Informed Consent was obtained prior to conducting interview. Descriptive statistics was used for presenting results.

OBSERVATIONS AND RESULTS

The study was conducted from 01/07/2014 to 15/09/2014. 2513 patients reported to OPD in this period. 115 ADR were detected during this period in 37 patients.

1. Demography

Male: Female was 2.7:1. Alcoholism was rampant in patients reporting to OPD with median duration of alcoholism being more than 25 years. The demographic profile of patients who had ADR is described in Table 1.

2. Pharmacotherapy of COPD

All patients were on chronic treatment for COPD. On an average each patient who reported ADR was consuming more than 4 drugs (Range 1 – 8). Exertional dyspnoea, in the absence of nocturnal dyspnoea and dyspnoea at rest, was the commonest presenting complaint and was of such a grade that limited their daily activities.

Most of the patients on treatment were using fixed dose combination of formoterol with either tiotropium or budesonide. Details of drugs prescribed to patients reporting atleast one ADR is given in Table 2.

3. Adverse Drug Reactions

On an average one patient suffered from 4 different ADR. One patient on 7 drugs for COPD and hypertension had 13 ADR and another patient on oral steroids along with other drugs for COPD had 12 ADR. Figure 1 describe the frequency of each adverse effect. Only one caseof tachycardia, oral candidiasis, hirsutism, weight gain, chest pain, easy bruisability, buffalo hump, petechiae & insomnia was detected.

4. Causality Assessment of ADR

Most of the ADR reported in this study were categorized as 'probable'. Ankle edema in a patient of COPD not on drugs like calcium channel blockers or any other known pharmacological or medical reason to cause edema was classified as unlikely. Since re-challenge information was not available in any of the cases, none of the ADR was classified as certain. A description of categories of ADR is given in Table 3.

Table: 1. Demographic profile of patients

S. No	Characteristic (n = 37)	Value
1	Age (Mean ± SD)	57.5 ± 11.9
2	Gender (Male / Female)	27 / 10
3	Systolic Blood Pressure (mm Hg)(Mean ± SD)	127.0 ± 14.2
4	Diastolic Blood Pressure (mm Hg) (Mean ± SD)	77.8 ± 9.1
5	Pulse Rate (per minute) (Mean ± SD)	80.6 ± 11.8
6	Respiratory Rate (per minute) (Mean ± SD)	20.9 ± 4.0
7	Duration of Smoking (Years)	27.3
8	Duration of quitting (Months)	106.72
9	Duration of alcoholism (Years)	26.8
10	Duration since diagnosis (Months)	37.5 ± 60.6
11	Presence of exertional dyspnea (n / 37)	34 / 37
12	Presence of nocturnal dyspnea (n /37)	17 / 37
13	Inability to do daily activities (n / 37)	24 / 37

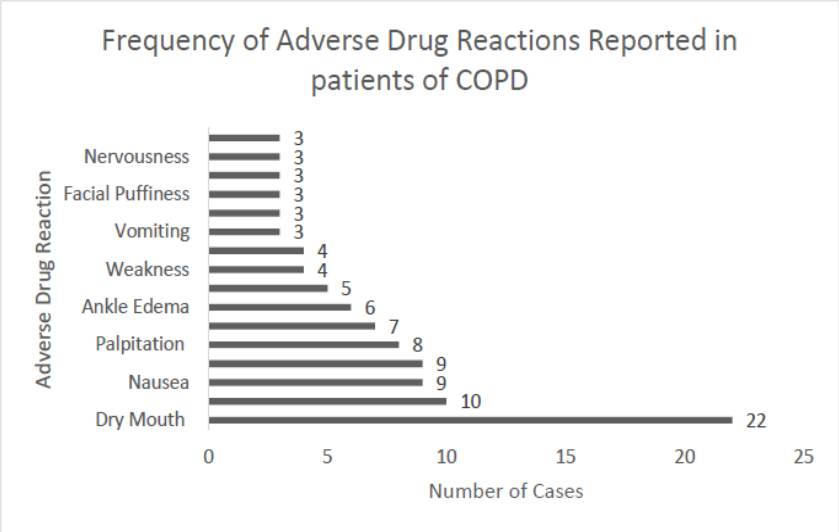
Table 2: Drugs prescribed for managing COPD

S. No	Drug	No of patients	Dose (Mean ± SD)	Median Duration of Use (months)
1	Formoterol	28	333.3 ± 82.97 ug	10.8
2	Salbutamol	SOS	SOS	
3	Deriphylline	22	475 ± 191.95mg	9.9
4	Budesonide	19	389.4 ± 45.9ug	5.6
5	Tiotropium	14	16.6 ± 3.26ug	4.7
6	Oral Steroids	5	6 mg	.5

Table: 3. Categories of ADR on the basis of WHO Causality Assessment Scale

ADR category	No of ADR
Certain	0
Probable	64
Possible	50
Unlikely	1
Unclassified	0
Unclassifiable	0

Figure 1. Description of adverse drug reactions detected in the study



DISCUSSION

The present study generated information about the incidence of ADR inpatients of COPD. Detection of 115 ADR in 37 patients of COPD during a period of more than two months in an OPD with foot fall of 2513 patients gives us an indication of under-reporting of ADR. Formoterol was the most commonly used drug in this study while dry mouth was most commonly reported ADR. This finding is most likely because of use of fixed dose combination of formoterol + tiotropium inhaler. Additionally, salbutamol in combination with ipratropium bromide or alone was prescribed for SOS use only. This is also evident from

the low frequency of sympathomimetic ADR seen in this study. As expected, polypharmacy and use of corticosteroids is associated with more ADR as seen in this study.

Causality assessment of ADR in OPD settings using WHO causality assessment scale and freely available information is likely to categorise ADR as possible and probable in most of the situations.[5,6] Many well documented ADR in light of lack of re-challenge information will also fall in this category which is one of the limitations of scales used. This aspect needs to be explored further in future.

Conflicts of Interest: None

ACKNOWLEDGEMENTS: None

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