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PHARMACOVIGILANCE STUDY OF ANTIHYPERTENSIVE DRUGS AT A TERTIARY CARE CENTER AND MEDICAL COLLEGE

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ABSTRACT

Introduction: According to WHO's definition an Adverse Drug Reaction (ADR) is a response to a drug that is noxious and unintended and occurs at doses normally used in human for the prophylaxis, diagnosis, and treatment of disease, or for modification of physiological function. Adverse drug reactions (ADRs) are considered among the leading causes of morbidity and mortality if not addressed in time. Around 6% of hospital admissions are estimated to be due to ADRs and about 6-15% of hospitalized patients experience a serious ADRs. Hence, there is a need to monitor the safety profile of all the medications on continuous basis and to review their therapeutic rationale in case of chronic ailments such as hypertension. So, this study is planned "pharmacovigilance study of antihypertensive drugs at a tertiary care center and medical college" at MGM medical college Aurangabad, Maharashtra. **Methods:** An open labelled, non-comparative, observational study to monitor ADRs associated with antihypertensive medications at MGM Medical college, Aurangabad. Study was conducted in department Of Pharmacology, Pharmacovigilance Cell, MGM Medical College, Aurangabad. This study was completed in six months. **Results:** A total of 221 ADRs were reported in 1080 patients. The gender distribution among the patients, who experienced ADRs are mentioned in table below. In our study 119 males and 102 females had ADR. Our study found that Beta-blockers were most frequently associated with Adverse drug reactions followed by calcium channel blocker, angiotensin-converting enzyme inhibitors and Diuretics. **Conclusion:** The above study would be useful for the physicians in rational selection of drug therapy for treatment of hypertensive patients. Also Adverse drug reactions can be minimized with the evolving knowledge about the use of drugs judiciously.

INTRODUCTION

According to World Health Organizaion's definition an Adverse Drug Reaction (ADR) is a response to a drug that is noxious and unintended and occurs at doses normally used in human for the prophylaxis, diagnosis, and treatment of disease, or for modification of physiological function.[1,2] The factors such as polypharmacy, age, gender, race, genetics, multiple, and inter-current diseases can cause morbidity and mortality in many cases.

Adverse drug reactions (ADRs) are considered among the leading causes of morbidity and mortality if not addressed in time. Around 6% of hospital admissions are estimated to be due to ADRs and about 6-15% of hospitalized patients experience a serious ADR.[3] When the Food and Drug Administration (FDA) approves a new drug for marketing, data regarding the adverse advents profile may not be sufficient as they are observed in clinical trials. Clinical trials for new drugs are having short duration and are conducted in populations in smaller population as compared to post marketing studies. Thus most common dose related ADRs are usually detected in the pre-marketing phase while ADRs in post marketing surveillance are important from patient safety view.[4]

The study population in trials generally exclude the elderly, children, pregnant women, patients with multiple diseases, and those on medication suspected of interaction with the study drug,[5] Hence, there is a need to monitor the safety profile of all the medications on continuous basis and to review their therapeutic rationale in the light of add on information done by pharmacovigilance activities. Monitoring of ADRs important in case of chronic ailments such as hypertension. hypertension pharmacovigilance is important as it requires long term therapy predisposing to adverse drug events.[6]

Hence, there is a need to monitor the safety profile of all the medications on continuous basis and to review their therapeutic rationale in in case of chronic ailments such as hypertension. So, we planned "pharmacovigilance

study of antihypertensive drugs at a tertiary care center and medical college" at MGM medical college Aurangabad, Maharashtra.

AIM AND OBJECTIVES

AIM

To perform pharmacovigilance study of antihypertensive drugs at a tertiary care center and medical college.

OBJECTIVES

1) Our study is aimed to evaluate the incidence of ADRs in patients receiving anti-hypertensive agents in tertiary care center, MGM medical college & hospital, Aurangabad.
2) Analysis of ADR reported at MGM medical college primarily based on drug categories.
3) Classification of ADR based on sex, age have been included in our study to determine ADR severity based on age groups.
4) To reduce frequency of ADR and improving outcome with use of antihypertensives in MGM medical college, Aurangabad.

MATERIAL AND METHODS

Study Design- The present study was an open labelled, non-comparative, observational study to monitor ADRs associated with antihypertensive medications at MGM Medical college, Aurangabad.

Study center: Department Of Pharmacology, Pharmacovigilance Cell, MGM Medical College, Aurangabad.

Study period: Study was completed in six months.

Inclusion criteria

Newly diagnosed and elderly patients taking antihypertensive medication were divided for convenience in age groups < 40 years and > 40 years for analysis of ADR.

Exclusion criteria

• The use of alternative system of medicines like Ayurveda, Homeopathy, Unani, etc.
• Mentally retarded, those on antipsychotic medications
• Unconscious patients.

Data collection

The data was recorded on a questionnaire based Adverse Drug Reaction Monitoring (ADRM) form drafted according to WHO monitoring guidelines, which included data related to patient demographics (age, sex, height, weight, body mass index (BMI)), past medical history, present drug treatment, description, assessment and treatment of ADR.

Ethical approval

The study protocol was approved by institutional ethics committee of mgm medical college, Aurangabad. The study was conducted between February to July 2019 in patients attending the medicine OPD on a daily basis.

Statistical Analysis

Chi-Square test was used for analysis of our study. A 95% confidence interval and P <0.05 was used as a standard for testing the level of significance. Any value less than (P<0.05) is considered as significant. For expression of percentage value we have used MS-EXCEL SHEET.

RESULTS

Total no of prescription analyzed : 1080
Total no of ADR : 221

During the 6 months study duration, a total 1080 patients were treated for hypertension as per JNC VIII classification who visited the medicine OPD and also inpatients admitted for various co- morbidities. The demographic data is as follows among 1080 patients 432 patients were in age group of less than 40 years and 648 patients were in age group of more than 40 years (Table 1).

A total of 221 ADRs were reported in 1080 patients. The gender distribution among the patients, who experienced ADRs are mentioned in table below.

In our study 119 males and 102 females had ADR. Male had slightly more incidence of ADR as compared to female population.

Table 1: Demographic Data (Age And Sex Wise Distribution Of Antihypertensive Prescriptions).

Age	Male	Female
<40 yrs	276	156
>40 yrs	354	294

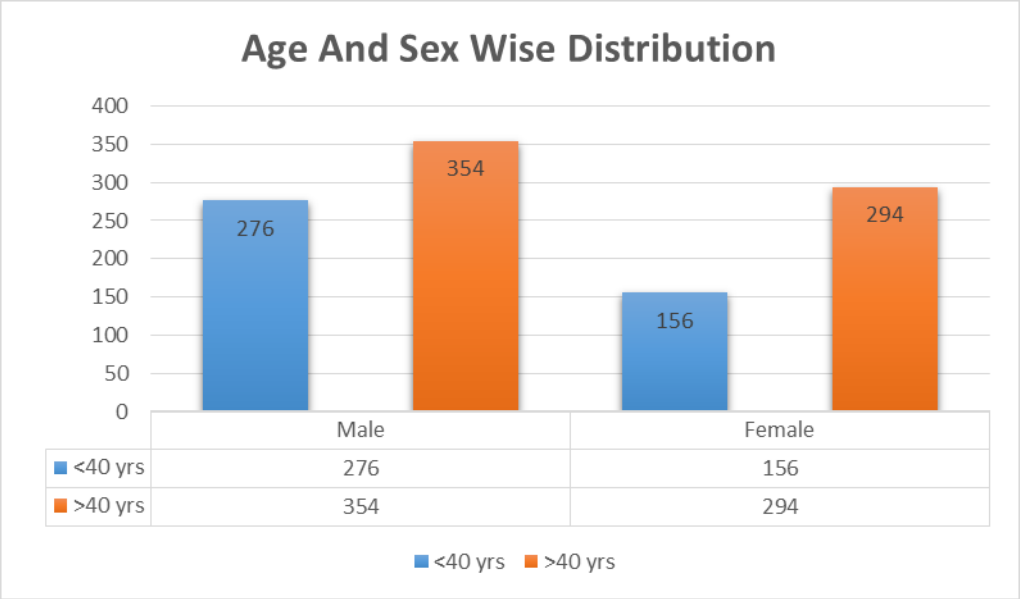

Figure 1: Demographic Data (Age And Sex Wise Distribution Of Antihypertensive Prescriptions)

Table 2: ADR related to age and sex wise distribution.

Age	Male	Female
<40 yrs	45	34
>40 yrs	74	68
Total	119	102

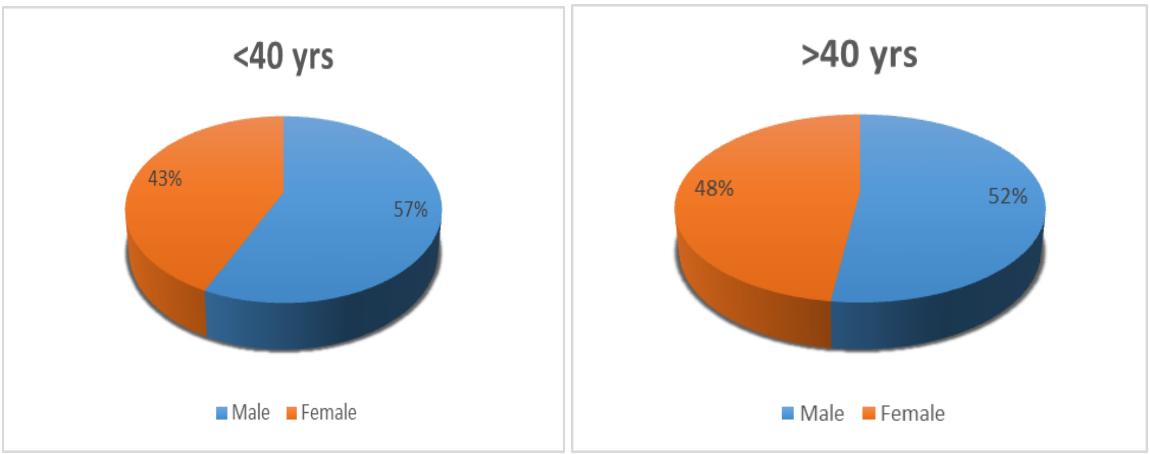

Figure 2: ADR related to age and sex wise distribution.

Table 3: Statistical Analysis of Adr Using Chi Square Test.

Age	Male	Female	Chi-Square / Significant / Non Significant (P<0.05)
<40 yrs	45	34	P= 0.006*(significant)
>40 yrs	74	68	P = 0.008*(significant)

Table 4: ADR Related To Systems Involved.

System	Total ADR	Percentage (%)
GIT	42	19
Skin	34	15.3
Respiratory system	36	16.28
CNS	38	17.19
Blood	5	2.26
Hepatobiliary system	10	4.52
Others / unclassifiable	56	25.3

The common gastrointestinal ADRs included gastritis, dysphasia followed by itching, rash and fluid filled lesions involving skin, respiratory ADRs included dyspnea, CNS ADRs included dizziness, headache.

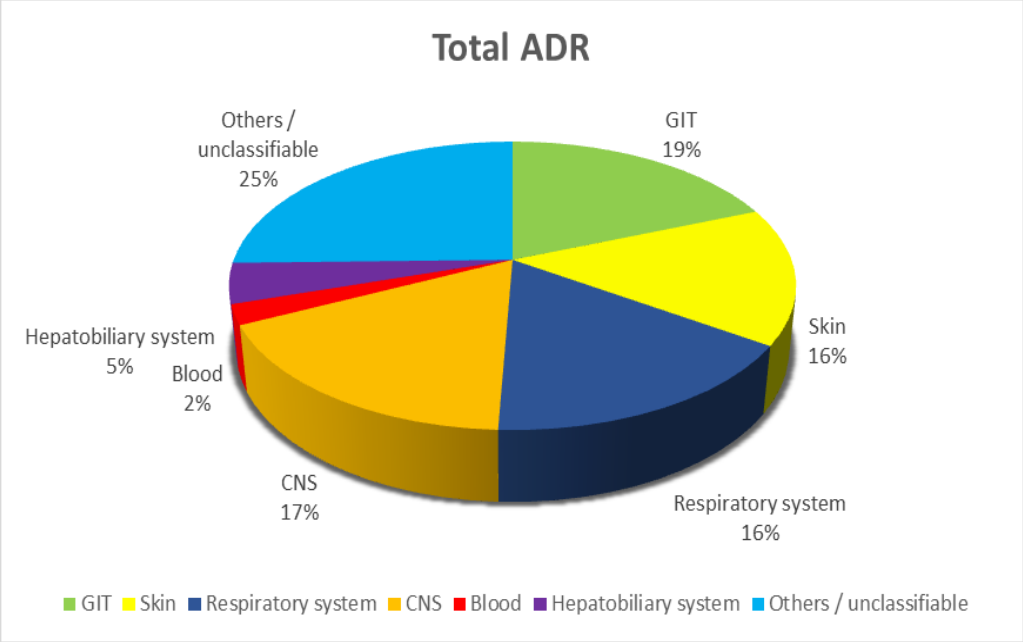

Figure 3: ADR Related To Systems Involved.

Table 5: Common classes of drugs involved in ADRs.

Drug Class	TOTAL ADR (%)
Beta Blockers	67 (30.3)
Calcium Channel Blockers	54(24.4)
ACE inhibitors	21(9.5)
ARB inhibitors	16 (7.23)
Diuretics	17(7.69)
Prazosin (alpha blockers)	10 (4.52)
Unclassified	36(16.30)

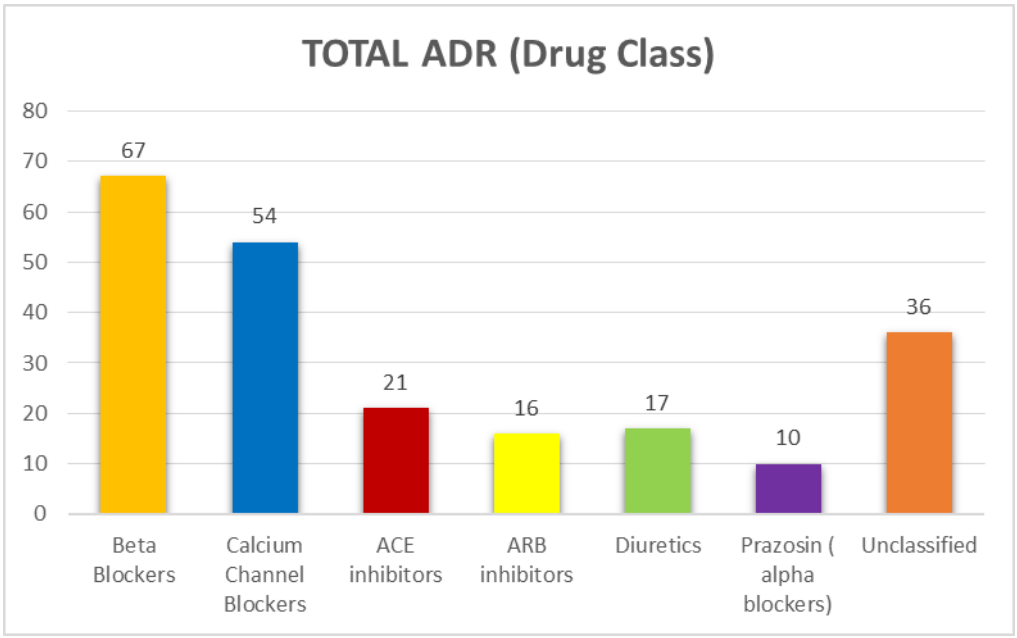

Figure 4: Common classes of drugs involved in ADRs.

Among 1080 prescriptions, The commonest ADRs associated with beta blockers were hypotension, giddiness, headache and bradycardia. Calcium channel blockers were associated with pedal edema, headache, swelling of the face and giddiness. ADRs associated with diuretics were muscle cramps, bradycardia, hypotension and vertigo. The only ADR associated with ACE inhibitors and ARBs was Dry cough. Followed by the ADR associated with alpha blocker was postural hypotension and headache.

DISCUSSION

In our study the antihypertensive medications were well tolerated in the age group less than 40 years in compare to the age group more than 40 years. No serious Adverse drug reactions were reported during our study period. More incidence of adverse effects were seen in the age group more than 40 years both in males and females as compared to age group less than 40 yrs.

Based on sex wise distribution male patients had slightly more incidence of Adverse drug reaction as compared to the female patients. Drug combinations were associated with higher number of Adverse drug reactions as compared to monotherapy.

The results of our study were similar to the study done by Hussain et al., where they have found that beta blockers had high incidence of Adverse drug reactions followed by CCBs, ACE inhibitors, ARBs, Diuretics and alpha blockers.[7] Our findings corroborate the results of previous studies which mention beta-blockers as the drug category most often implicated with ADRs.[8] Hence, while prescribing beta blockers monitoring of Adverse drug reactions must be made an essential part of treatment strategy.

The present work is a part of ongoing pharmacovigilance program at MGM medical college. Beta-blockers were most frequently associated with Adverse drug reactions followed by calcium channel blocker, angiotensin-converting enzyme inhibitors and Diuretics.

In conclusion, the above study would be useful for the physicians in rational selection of drug therapy for treatment of hypertensive patients. From our study data we can suggest that the Adverse drug reaction monitoring is essential for improving safety and efficacy of drug use. Also Adverse drug reactions can be minimized with the evolving knowledge about the use of drugs judiciously.

REFERENCES

1. World Health Organization International drug monitoring: The role of national centers. Tech Rep Ser WHO 1972, No. 498. Geneva: WHO.
2. Edwards IR, Aronson JK. Adverse drug reactions: Definitions, diagnosis, and management. Lancet, 2000; 356: 1255–9.
3. Jose J, Rao GM. Pattern of adverse drug reactions notified by spontaneous reporting in an Indian tertiary care teaching hospital. Pharmacol Res., 2006; 54: 226-33.
4. Upadhayai JB, Nangia AK, Mukhija RD, Misra M, Mohan L, Singh KK. Cutaneous reactions due to antihypertensive drugs. Indian J Dermatol, 2006; 51: 189-91.
5. Ahmad SR. Adverse drug event monitoring at the food and drug administration. J Gen Intern Med, 2003; 18: 57-60.
6. Goldberg AI, Dunley MC, Sweet CS. Safety and Tolarability of losartan potassium, an angiotensine II receptor antagonist compared with hydrochlorthiazide, atenolol, felodipine ER and angiotensin converting enzyme inhibitors for the treatment of systemic hypertension. Am J Cardiol, 1995; 75: 793-5.
7. Hussain A et al., A pharmacovigilance study for monitoring adverse drug reactions with antihypertensive agents at a South Delhi hospital. Int J Pharm Pract, 2006; 14: 311-3.
8. Tran C, Knowles SR, Liu BA, Shear NH. Gender differences in adverse drug reactions. J Clin Pharmacol, 1998; 38: 1003-9.