ejpmr, 2024, 11(7), 491-495

SJIF Impact Factor 7.065

EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Research Article

ISSN 2394-3211

EJPMR

ADVERSE EFFECTS OF SOME DRUGS FOR THE TREATMENT OF CARDIOVASCULAR DISEASES

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Article Received on 22/05/2024 **Article Revised on 12/06/2024** **Article Accepted on 02/07/2024**

ABSTRACT

The study is aim to assess the patient knowledge with the help of knowledge assessment questionnaire (KAQ) about the disease and detects the ADRs. This study was designed to compare adverse effects on cardiovascular drugs. Adverse drug reaction (ADRs) is a major cause of mortality worldwide. The objective of the present study were a) to find out the prevalence of adverse drug reaction (ADRs) in the hospitalized patient by active surveillance, b) to study the profile of ADRs detected and probable factors contributing to the same. This was a cross sectional study conducted at super specialty hospital Sri aurobindo medical college, Indore and high tech super specialty Indore, for four month study. Total number of patients taken for study was 50 in number. From many criteria's which was included firstly on the basis of gender were 25 males and 25 females. The patients were in age group more than 50 year was 25 and 35-50 were 14. drug used for their co morbidities to find out ADRs in which maximum ADRs found in chronic rheumatoid heart diseases, for this diseases patient took in two combination mainly Digoxin with Clopidogrel(47.36%) and another were with atorvastatin, spironolactone and warfarin (47.30 % ADRs) which was maximum in compare to other diseases. Adverse drug reactions on particular body system were mostly observed on CNS (32.14%ADRs). Also, Patient on combination therapy (Digoxin, furosemide, and spironolactone) had significantly more complaints regarding side effects than other category of drugs. The results obtained in some of previous studies in which digoxin and furosemide were well tolerated. The side effect experienced by spironolactone was swelling, hypotension, and systolic dysfunction. According to Naranjo naranjo causality assessment scale applied to this study illustrates that the maximum possible and probable adverse drug reaction were shown on Furosemide as well as for Digoxin and Spironolactone.

KEYWORDS: Adverse drug reaction, Pharmacovigilance, Prospective, observational, Cardiovascular.

INTRODUCTION

Drugs are double edge weapons while on one hand they can save lives, on the other hand they can cause adverse drug reaction (ADRs) which can be life threatening ADRs are a major cause of morbidity and mortality worldwide. Heart failure (HF) is a chronic disease characterized by the inability of the heart to pump an adequate amount of blood to achieve the demand of the different organ systems and/or doing so at increased filling pressures. The treatment and prevention of HF has become a burgeoning public health problem reaching epidemic levels especially for the elderly population. There are more than 20 million people affected worldwide and has a prevalence of 2% in developed countries. Pharmacovigilance has been defined as "The science and activities related to detection assessment understanding & prevention of Adverse reactions and any other drug-related problem. The thalidomide disaster in 1961 awakened a need to regulate pharmacovigilance not only by the national competent (regulatory) authorities but also over and above this at an international level. The Sixteenth World Health Assembly in 1963 adopted a resolution stressing the need for early action in regard to rapid dissemination of information on adverse drug reactions and led to initiation of the WHO Pilot Research Project form International Drug Monitoring in 1968. The purpose of this was to develop a system, applicable internationally, for detecting previously unknown or poorly understood adverse effects of medicines forming the basis of the practice and science of pharmacovigilance to improve the safe and cost effective use of medicines by avoiding further disasters in both developed and developing countries in the interests of improved public.

AIM AND OBJECTIVES

This study aim to reduce the intensity of undesirable effetcs produced by drug interaction as well as other negative responses related to the use of medicine through the marketing, distribution, prescription, distribution, and

use of medicine in hospital .objectives of this study was 1) to evaluate patient medication and find out our potential relavent ADRs 2)to estimate the rate and extent of potential ADRs in in-patient admitted during the study 3) to estimate the risk associated with potential ADRs 3) to identify the drug most commonly responsible for potential ADRs 4) to determine the cause including morbidity caused of this ADRs.

MATERIAL AND METHODS

This study was done in the Pharmacovigilance group belonging to the institution, department of cardiology at Sri Aurobindo Medical College, Indore & Mohak high tech superspeciality hospital Indore. This study protocol was approved by SAIMS Institutional Ethics Committee. Institution ethics committee reference no-14/03/24.

A prospective cross sectional study was conducted of patient aged between 14 to 70 year who presented for the treatment and care to the Sri Aurobindo Medical College & Hospital Indore and mohak high tech superspeciality hospital Indore over a period of four month study.

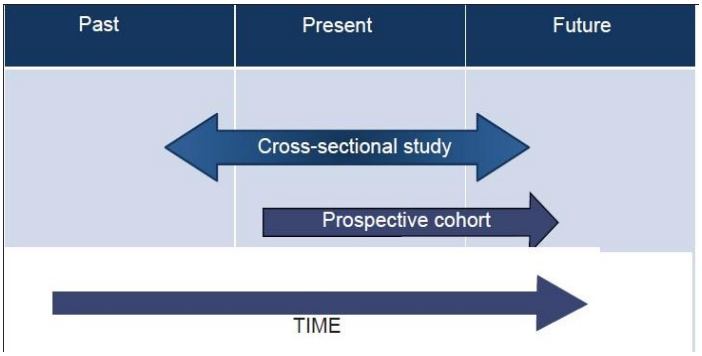


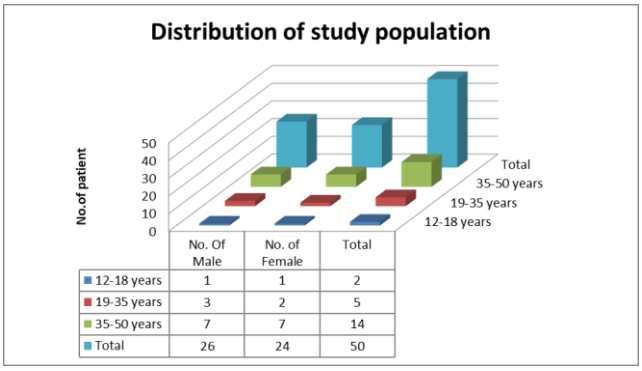
Figure No. 1: Design of present study- Prospective cross sectional study.

All the members of the families were first briefed about the project and verbal consent was obtained from each of the family member. Details of participants namely name, age, sex, residence, socio-economic status, consumption of drug, disease, laboratory values, status, co morbidities, eating habits, diagnostics value, medication chart, and previous detail adverse drug reaction if any were collected on a validated semi-structured questionnaire. (Past treatment & clinical details were obtained from the medical records), data on treatment employed and complaints presented by patients during hospitalization. This study was done for four months. Number of patient included in this study was 50.

Source: Patient attended in in-patient department of cardiology and admitted in different unit of department of medicine of SAIMS, Indore and mohak high tech hospital, Indore. All date collected were coded as per variables and data sheet and analyze. For the detection of possible ADRs the algorithm Naranjo et al.(1981) was used which involves the algorithm employs ten questions and yield a score for classification of causality of ADRs. Co morbidities were differentiating when there was a possible diagnosis in the patient charts.

RESULT AND DISCUSSION

Total number of patients taken for study was 50 in number. From many criteria's which was included firstly on the basis of gender were 25 males and 25 females. Second on the age group, more than 50 year was 25 and 35-50 were 14.



	No. Of Male	No. of Female	Total
12-18 years	1	1	2
19-35 years	3	2	5
35-50 years	7	7	14
Total	26	24	50

Figure No. 2: Showing distribution of study population.

The patients were looked upon for various comorbidities patients may have which may sensitize a patient and thus make prone towards the vicinity to face unpredictable ADRs occurring with the original ailment intended drugs. The distribution is thus helpful to indicate the

propensity of possible ADRs which should be consciously monitored in a Pharmacovigilance system.

Table No. 1: Distribution of subjects according to comorbidities.

S. no.	Diseases	No. of patient	Old	New
1	Chronic cardiac failure	4	2	2
2	Myocarditis	2	1	1
3	Chronic Rheumatoid Heart diseases	9	4	5
4	Ischemic heart diseases	6	2	4
5	Pericardial effusion	2	0	2
6	Hypertension	16	8	8
7	Hypocalcaemia	3	1	2
8	Coronary arterial diseases	8	2	6
	Total	50	30	20

On the basis of sex involved on maximum drug used were furosemide and spironolactone in female 5, in male 4.Digoxin, furosemide and spironolactone was about 70.58% of total ADRs attained from these combinations.

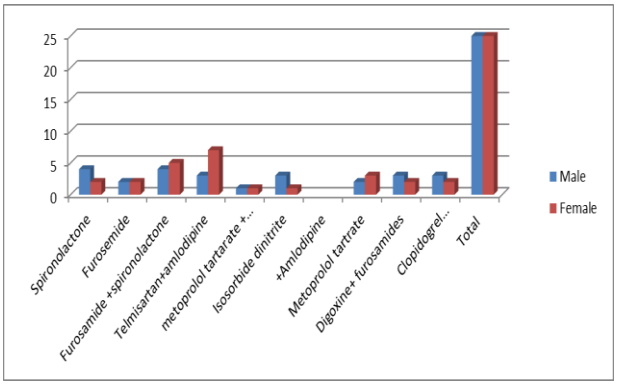


Figure No. 3: Drug administration in both sexes.

The distribution of ADRs depicting various social habits imparts the drug interaction feasibilities in patients with both alcohol and tobacco users was observed with the most ADRs (32.14%).

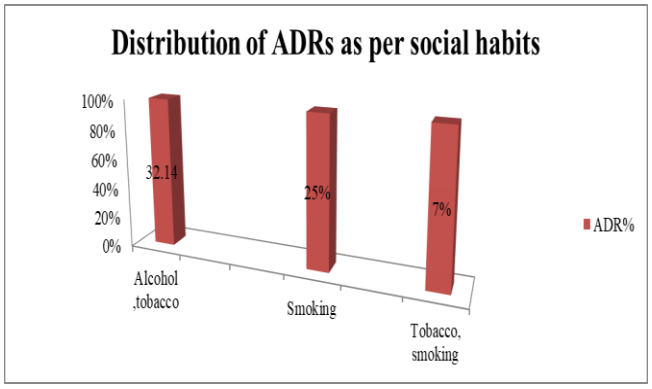


Figure 4: Distribution of ADRs as per social habits.

Another aspect on basis of adverse drug reactions on particular body system was the most on CNS. (32.14% ADRs) and next most common were on GIT Were 21.42% out of total ADRs.

Table No. 2: Distribution of ADRs according to cardiovascular drug therapy.

S. no	Drug	ADRs	ADRs%
1	Spironolactone	Swelling, Hypotension, Systolic dysfunction	17.64
2	Furosemide	Loss of appetite, Dizziness, insomnia	17.64
3	Furosemide +spironolactone	Hypotension, Electrolyte imbalance, Loss of appetite, Anxiety, both leg pain, Swelling in, stomach, appetite, chest, pain hypotension	58.82
4	Telmisartan+ Amlodipine	Headache, rashes, anxiety, dizziness loss of appetite,	47.05

		urinary tract, Infection, vomiting, constipation, insomnia	
5	Metoprolol tartrate + Amlodipine	Hypotension, chest pain	11.76
6	Isosorbide nitrite +Amlodipine	Hypertension, sleep disturbance. Anxiety,	17.64
7	Metoprolol tartrate	Stomach pain, swelling	19.45%
8	Digoxin+ furosamides+ spironolactone	Headache, swelling, fluid, disturbance, systolic dysfunction, chest pain, appetite hypotension, vomiting, difficulty in breathing, abdominal pain, nausea	70.58
9	Clopidogrel +aspirin+ atorvastatine	Anxiety, insomnia, hypertension, headache,	23.52
	Total		100

On the basis of disorders drug used for their co morbidities to find out ADRs in which maximum ADRs found in chronic rheumatoid heart diseases, for this diseases patient took in two combination mainly digoxin with clopidogrel (47.36%) and another were with atorvastatin, spironolactone and warfarin 47.30 % of adverse effects which was maximum in compare to other diseases. Patient on combination therapy (Digoxin, Furosemide, and Spironolactone) had significantly more complaints regarding side effects than other category of drugs. The risk of side effects associated with the combination of digoxin was six times higher than Metoprolol. The result obtained in some of previous studies in which Digoxin and Furosemide were well tolerated.

Table 3: Distribution of ADRs according to body system.

S. no.	Body System	ADRs	ADRs %
1	CNS	Vomiting, Nausea, dizziness, insomnia, vomiting, headache, anxiety, sleep disturbance	32.14
2	G.I.T	Dyspepsia, Stomach pain, loss of appetite, Difficulty in motion pass, Abdominal pain. constipation	21.42
3	Urinary System	Urinary tract infection, swelling	7.14
4	Respiratory System	Difficulty in breathing, cough,	7.14
5	Excretory System	fluid, disturbance, electrolyte imbalance	7.14
6	C.V.S.	Chest, pain, hypertension, hypotension, Systolic dysfunction.	14.28
7	Others	Skin rushes, Swelling,leg pain	10.71
		Total	100%

But there are some variations in the results which show there are some new outcomes in comparisons of the previous data. The most important reason behind these variation does not mean that the some contradiction in previous studies but indirectly they are in quite support for my study. The side effect experienced by Spironolactone was swelling, hypotension, and systolic dysfunction. Lastly just after the analysis of all result this was the outcome of whole study was seen according to Naranjo scale we found that the maximum possible and probable adverse drug reaction were shown on Furosemide as well as for Digoxin, Spironolactone too.

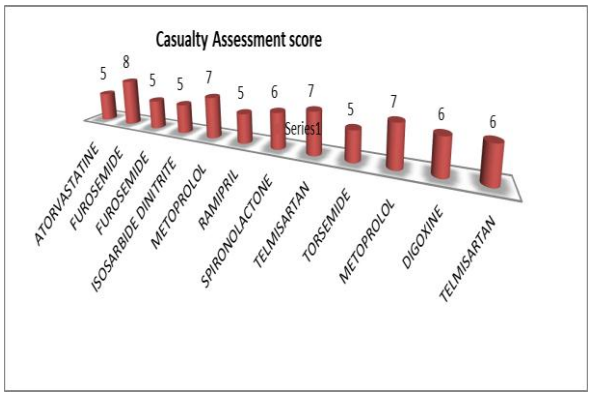


Figure No. 5: ADR distribution in the preview of Naranjo causality assessment scale.

CONCLUSION AND PERSPECTIVES

It may be concluded that although all the three drugs were well tolerated, more side effects were seen in the case of Furosemide, Spironolactone, and Digoxine. ADRs are a common contributor to illness in the older person, when assessing in older person. This is indeed required to look on more consciously on these ADRs and providing better intervention shall definitely

potentiate the patient and drug compliance thereof. This study therefore has provided baseline data for further larger studies and has ascertained the importance of prospective ADRs monitoring in Pharmacovigilance study.

REFERENCES

1. Chouhan A. S., PURANIK B. S., "A Pharmacovigilance analysis of antihypertensive drugs in essential hypertension patient in tertiary care hospital" IJARIIE-ISSN(0)-2395-4396, 2022.
2. Chawan S, Shaikh A, 'et al. "Pharmacovigilance study of antihypertensive drug at a tertiary care centre & medical college" European journal of pharmaceutical & medical research, 2021; 8(2): 457-461.
3. Evan L T, Paul M, 'et al'. "claim based algorithms for identifying Medicare beneficiaries at high estimated risk for coronary heart diseases events: a cross-sectional study". BMC health service research, 2014; 14, 195: 2-10.
4. Mande A, Pallavi K, John Wesley K, 'et al'. "clinical study on the therapeutic management of angina pectoris and to study the impact of patient councelling". IJP, 2013; 4(1): 1-7.
5. Romula Moreira dos S, Ivana Maria Fechine S, 'et al'. "drug use by elderly inpatient of a philanthropic hospital". BJPS, 2011; 47: 391-397.
6. Shrestha RK, Khan GM, 'et al'. "study of the side effects profile of different antihypertensive drugs among the hypertensive patient". Nepalese heart journal, 9: 26-36.
7. Brent T, Sebastiana K, 'et al', the burden and risk factors for adverse drug events in older patients- a prospective cross-sectional study. SAMJ, 2006; 96: 1255-1259.