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A STUDY ON ASSESSMENT OF ADVERSE DRUG REACTION MONITORING IN CARDIAC PATIENTS IN A TERTIARY CARE HOSPITAL

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Abstract
Cardiovascular disease describes coronary heart disease, cerebrovascular disease, peripheral arterial disease, rheumatic and congenital heart disease and venous thromboembolism. Collectively, cardiovascular disease is responsible for 17.9 million deaths per year globally 31% of all deaths, within which Ischaemic Heart disease accounts for the majority of mortality. The present study aimed to assess adverse drug reaction monitoring in cardiac patients in a tertiary care hospital. 31-40 years age patients were 56 (26.66%), 41-50 years age patients were more 56 (26.66%) as compared to other age groups. Calcium channel blockers patients were more 56 (26.66%), as compared to Beta blockers patients were 44 (20.95%), Nitrates patients were 54 (26.71%), Alpha blockers patients were 56 (26.66%), Carbonic anhydrase inhibitors patients were 56 (26.66%). Central nervous system affected patients were more (68%), as compared to Respiratory system affected patients were (56%), Gastrointestinal system affected patients were (39%), Cardiovascular system affected patients were (47%), Musculoskeletal system affected patients were (68%). Adverse drug reactions potential for a particular cardiovascular drug varies with the individual, the disease being treated, and the extent of exposure to other drugs. Knowledge of this complex interplay between patient, drug, and disease is a critical component of safe and effective cardiovascular disease management. The risk of Adverse drug reactions increased with the number of drugs in the prescription. Most of the Adverse drug reactions were mild in severity and were not preventable. The timely therapy adjustment can helps to optimize pharmacotherapy and reduce the severity of these reactions.

Keywords: Cardiovascular disease, Venous thromboembolism, Peripheral arterial disease, Prescription, cerebrovascular disease, Adverse drug reactions.

INTRODUCTION

Cardiovascular disease describes coronary heart disease, cerebrovascular disease, peripheral arterial disease, rheumatic and congenital heart disease and venous thromboembolism. Collectively, CVD is responsible for 17.9 million deaths per year globally 31% of all deaths, within which Ischaemic Heart disease (IHD) accounts for the majority of mortality. Despite a fall in the proportion of CVD related deaths over the last 40 years, the rate of decline is slowing while morbidity from CVD is rising. The financial implication of this on healthcare providers is substantial – it is estimated that CVD now costs NHS in the UK £9 billion a year and €210 billion across the European Union in combined direct and indirect costs. The ability to identify those at risk of CVD allows for risk factor modification through primary prevention. There are a number of factors that affect a person's risk of developing CVD including increasing age, gender, family history and ethnicity which are non-modifiable [1-3]. There are also a number of factors in terms of lifestyle and pharmacological interventions that have been demonstrated to affect CVD risk and are modifiable including hypertension, obesity, tobacco smoking, diet, exercise, cholesterol levels, alcohol intake and diabetes mellitus control. Contemporary guidelines targeting primary prevention of cardiovascular disease (CVD) were reviewed from the European Society of Cardiology (ESC), European Society of Hypertension (ESH) and American Heart Association (AHA)/American College of Cardiologists (ACC).In keeping with the previous review, common areas within these guidelines were noted and then a literature search was performed using the search terms Exercise, Diet, Weight, Weight loss, obesity, Smoking, tobacco, e-cigarette, electronic cigarette, alcohol, ethanol, lipids, cholesterol, HDL, LDL, triglycerides, hypertension, blood pressure, glucose, diabetes, polypill,

anti-platelets. Modification of cardiovascular risk is predicated upon the understanding of underlying individual risk burden [4-7]. Many of the interventions discussed below use risk stratification methods to guide their timing and intensity; as such, the use of validated risk assessment tools in primary prevention of CVD is vital and recognized in both European and American guidelines. The ESC guidelines recommend the use of the SCORE risk assessment tool, whilst the ACC guidelines recommend the use of the updated atherosclerotic cardiovascular disease (ASCVD) risk assessment tool both of which are available online as simple risk calculators for ease of use.

Both guidelines advise consideration of alternate risk calculators in specific populations with altered CVD risks; the ASCVD calculator is intended and validated only for use in patients aged between 40–79, whilst the SCORE risk chart was similarly derived from patients aged <80, and the online version and is intended for use in patients aged 40–65. There are now a variety of alternate risk assessment tools designed and validated for use in more narrowly defined population groups, including diabetic patients and the elderly, and it is important to remember to use the appropriate tool for the correct cohort. These tools all deliver a quantitated measure of risk for the physician, commonly in the form of 10-year CVD risk, or 10-years cardiovascular disease mortality [8-11].

METHODOLOGY

Study Design: It was Prospective observational study.

Study Period: The Present study was conducted for a period of six months.

Study Site: The Present study was conducted in a cardiology department in a tertiary care hospital.

Sample Size: It was 210 Patients.

Inclusion Criteria

- Patients who are willing to give consent.
- Patients with cardiac disease symptoms.
- Patients of either sex, diagnosed with cardiac disease.
- Patients receiving treatment for cardiac disease.

Exclusion Criteria

- Patients below 18 years.
- Patients who were not willing to join in the study.
- Patients who are not diagnosed with respiratory abnormalities.
- Special population including pregnant women and lactating women.
- Psychiatric abnormalities.

Institutional Ethics Committee (IEC) Consideration

The research protocol was submitted to ethical committee and ethical Committee was permitted to perform the research work in cardiology department.

Patient Data Collection and Management

The data collection form contains information regarding age, sex, diagnosis, past medical history, laboratory data, and diagnostic results.

Statistical Analysis

The data was represented as percentages. The $P<0.05$ was considered to indicate a statistically significant difference.

AIM

The present study aimed to assess adverse drug reaction monitoring in cardiac patients in a tertiary care hospital.

OBJECTIVES

- To study the demographic profile of cardiac disease patients.
- To study the adverse drug reactions among cardiac disease patients.

RESULTS

20-30 years age patients were 32 (15.23%), 31-40 years age patients were 56 (26.66%), 41-50 years age patients were 56 (26.66%), 51-60 years age patients were 66 (31.42%).

Table 01: Age wise distribution

S.No	Age	Total (N=210)	Percentage (%)
1	20-30	32	15.23
2	31-40	56	26.66
3	41-50	56	26.66
4	51-60	66	31.42
	Total	**210**	

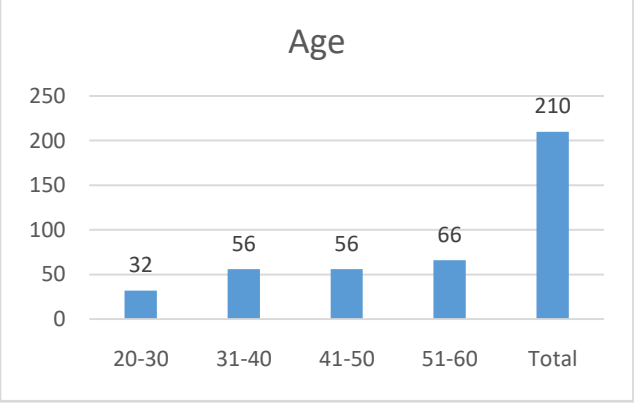

Fig 01: Age wise distribution

In our study male patients were 88 (41.90%), female patients were 122(58.09 %).

Table 02: Gender

S.No	Gender	Total (N=210)	Percentage (%)
1	Male	88	41.90
2	Female	122	58.09
	Total	**210**	

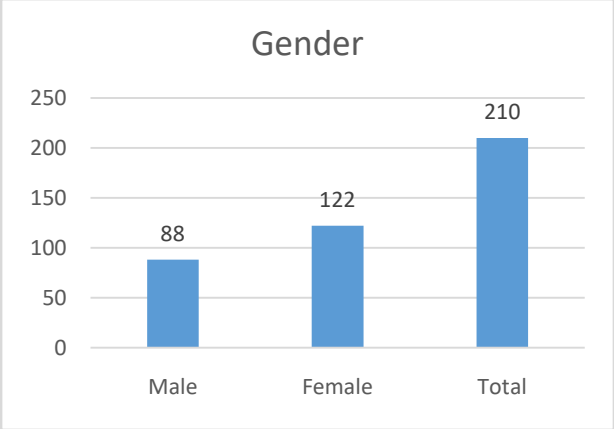

Fig 02: Gender

In our study Literate patients were 145 (69.04%), Illiterate patients were 65 (350.09%).

Table 03: Education

S.No	Education	Total (N=210)	Percentage (%)
1	Literate	145	69.04
2	Illiterate	65	35.09
	Total	**210**	

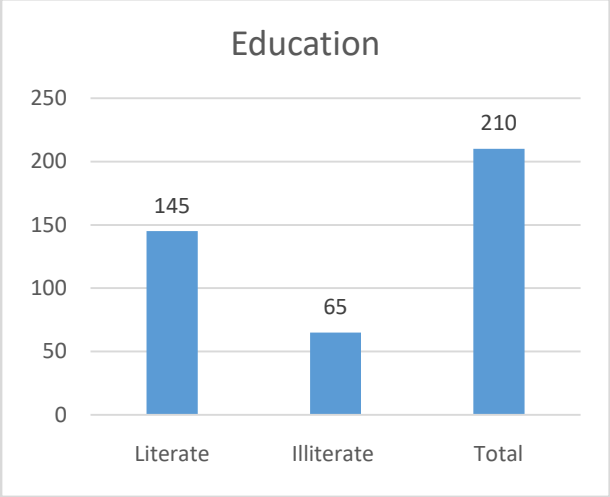

Fig 03: Education

In our study 1-6 days hospital admitted patients were 67 (31.09%), 7-14 days hospital admitted patients were 98 (46.66%), 15-25 days hospital admitted patients were 45 (21.42%).

Table 04: Hospital stays(days)

S.No	Hospital stay (days)	Total (N=210)	Percentage (%)
1	1--6 days	67	31.09
2	7--14 days	98	46.66
3	15--25 days	45	21.42
	Total	**210**	

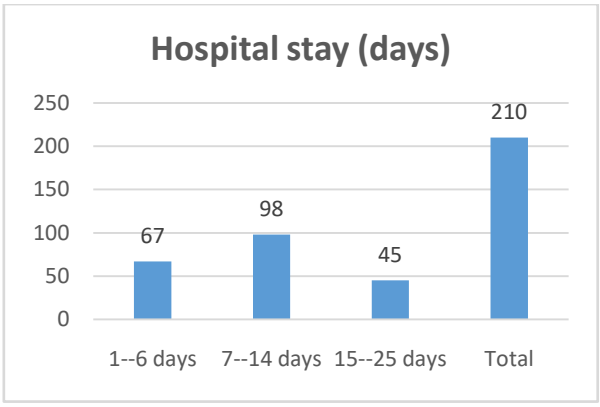

Fig 04: Hospital stay (days)

Calcium channel blockers patients were 56 (26.66%), Beta blockers patients were 44 (20.95%), Nitrates patients were 54 (26.71%), Alpha blockers patients were 56 (26.66%), Carbonic anhydrase inhibitors patients were 56 (26.66%).

Table 05: Suspected drugs causing ADRs in this study

S.No	Number of prescribed medications	Total (N=210)	Percentage (%)
1	Calcium channel blockers	56	26.66
2	Beta blockers	44	20.95
3	Nitrates	54	26.71
4	Alpha blockers	56	26.66
6	Carbonic anhydrase inhibitors	56	26.66
	Total	**210**	

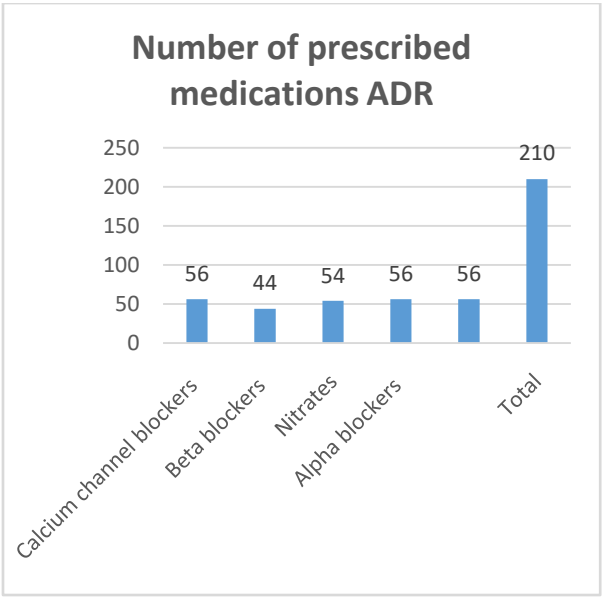

Fig 05: Number of prescribed medications

Central nervous system affected patients were (68%), Respiratory system affected patients were (56%), Gastrointestinal system affected patients were (39%), Cardiovascular system affected patients were (47%), Musculoskeletal system affected patients were (68%).

Table 06: Systems affected by percentage of ADR

S.No	Systems involved	Total (N=210)	Percentage (%)
1	Central nervous system	68	32.38
2	Respiratory system	56	26.66
3	Gastrointestinal system	39	18.57
4	Cardiovascular system	47	22.16
5	Musculoskeletal system	68	32.38
	Total	**210**	

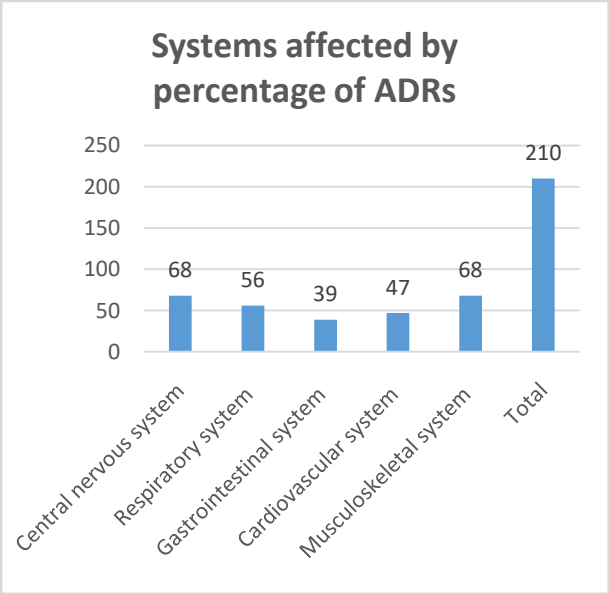

Fig 06: Systems affected by percentage of ADR

Severity of ADR includes Mild ADR 68 (30.95%), moderate ADR patients were 98 (46.66%), and Severe ADR patients were 44 (20.95%).

Table 07: Severity of ADR

S.No	Severity of ADR	Total (N=210)	Percentage (%)
1	Mild	68	30.95
2	Moderate	98	46.66
3	Severe	44	20.95
	Total	**210**	

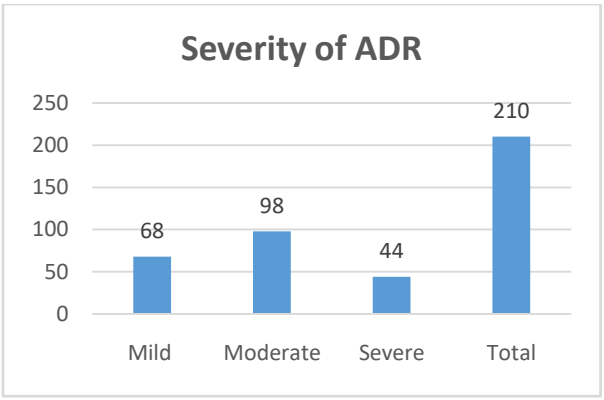

Fig 07: Severity of ADR

Hypotension ADR patients were 22 (10.47%), Constipation ADR patients were 34 (16.19%), Chest pain ADR patients were 56 (26.66%), Palpitation ADR patients were 22 (10.47%), Cough ADR patients were 37 (17.61%).

Table 08: Different ADRs induced by cardiovascular agents

S.No	Prescribed drugs	Total (N=210)	Percentage (%)
1	Hypotension	22	10.47
2	Constipation	34	16.19
3	Chest pain	56	26.66
4	Palpitation	22	10.47
5	Cough	37	17.61
	Total	**210**	

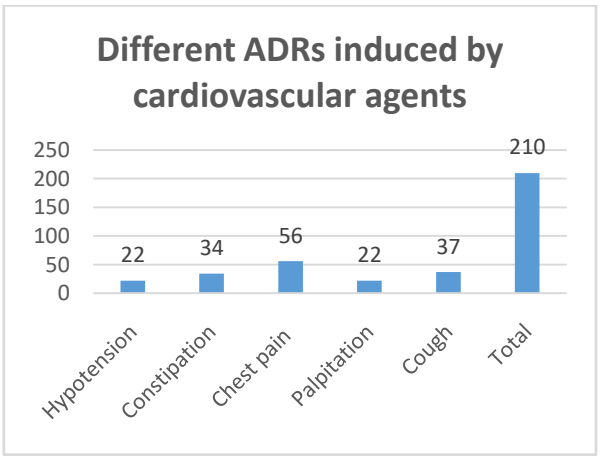

Fig 08: Documentation of DDIs

Unknown outcome patients were 34 (16.19%), Recovered outcome patients were 41 (19.52%), Not yet recovered outcome patients were 97 (46.19%), Hospitalization outcome patients were 38 (18.09%).

Table 09: Outcome of detected ADRs induced by cardiovascular agents

Prescribed drugs	Total (N=210)	Percentage (%)
Unknown outcome patients were	34	16.19
Recovered outcome patients were	41	19.52
Not yet recovered outcome patients were	97	46.19
Hospitalization outcome patients were	38	18.09
Total	**210**	

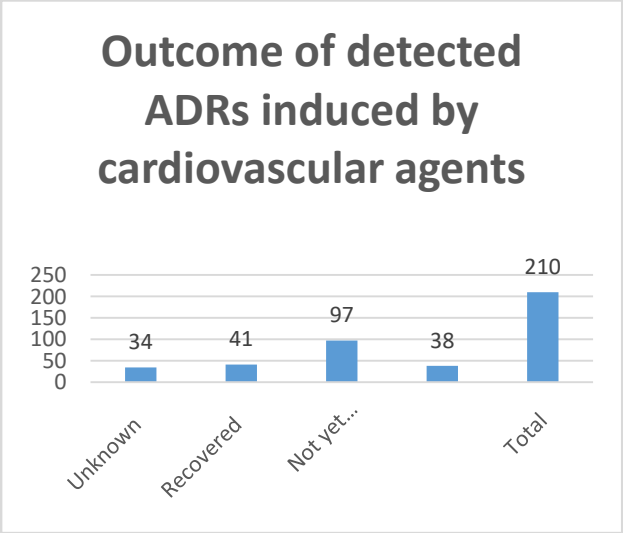

Fig 09: Outcome of detected ADRs induced by cardiovascular agents

DISCUSSION

- 31-40 years age patients were 56 (26.66%), 41-50 years age patients were more 56 (26.66%) as compared to other age groups.
- In our study female patients were more 122 (58.09 %) as compared to males 88 (41.90 %).
- In our study Literate patients were more 145 (69.04%), as compared to Illiterate patients were 65 (350.09%)12-17.
- 7-14 days hospital admitted patients were more 98 (46.66%), as compared to 15-25 days hospital admitted patients were 45 (21.42%).
- Calcium channel blockers patients were more 56 (26.66%), as compared to Beta blockers patients were 44 (20.95%), Nitrates patients were 54 (26.71%), Alpha blockers patients were 56 (26.66%), Carbonic anhydrase inhibitors patients were 56 (26.66%).
- Central nervous system affected patients were more (68%), as compared to Respiratory system affected patients were (56%), Gastrointestinal system affected patients were (39%), Cardiovascular system affected patients were (47%), Musculoskeletal system affected patients were (68%) [18-22].
- Moderate ADR patients were more 98 (46.66%) as compared to other ADR severities.
- Chest pain ADR patients were more 56 (26.66%) as compared to other ADR [23-25].
- Not yet recovered outcome patients were more 97 (46.19%), as compared to other prescribed drug outcomes [26-30].

CONCLUSION

Adverse drug reactions potential for a particular cardiovascular drug varies with the individual, the disease being treated, and the extent of exposure to other drugs. Knowledge of this complex interplay between patient, drug, and disease is a critical component of safe and effective cardiovascular disease management[26-28]. The majority of significant ADRs involving cardiovascular drugs are predictable and therefore preventable. Better patient education, avoidance of polypharmacy, and clear communication between physicians, pharmacists, and patients, particularly during the transition between the inpatient to outpatient settings, can substantially reduce ADR risk. Monitoring ADRs in patients using cardiovascular drugs is a matter of importance since this class of medicines is mostly used as multidrug therapy and always prone for ADRs[29-30]. The risk of ADR increased with the number of drugs in the prescription. Majority of the ADRs had a score of “possible” because of concomitant medications. Most of the ADRs were mild in severity and were not preventable. The timely medication therapy adjustments which help to optimize pharmacotherapy and reduce the severity of adverse drug reactions.

FUNDING

Nil

CONFLICT OF INTEREST

The author declares that there is no conflict of interest.

AUTHOR CONTRIBUTION

All authors are contributed equally.

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