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ORIGINAL ARTICLE

Assessment of adverse drug reactions in cardiology patients

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ABSTRACT:

Background: Adverse drug reactions (ADRs) refer to unintended and harmful reactions to medications that occur at doses used for prophylaxis, diagnosis, or therapy. The present study was conducted to assess adverse drug reactions in cardiology patients. **Materials & Methods:** 56 cardiology patients who developed ADRs of both genders were selected. They were categorized into mild, moderate, and severe ADRs, according to severity scale. The causality relationship between the drug and the effect was established using Naranjo's ADR probability scale. **Results:** Out of 56 patients, males were 32 and females were 24. Severity was mild in 12, moderate in 31 and severe in 13 cases. Adverse reactions were headache in 21, hypokalemia in 14, hyperkalemia in 5, heart block in 6, bradycardia in 17, hypothyroidism in 7, HSskin reactionin 9, and hypoglycemia in 15 patients. Drugs were nitrates in 12, β blockers in 7, diuretics in 22, combined β blockers and CCBs in 8, and digoxin in 7 patients. The difference was significant (P< 0.05). **Conclusion:** Most of the cardiology patients had moderate severity of ADR. In maximum cases, ADRs were related with diuretics.

Keywords: Adverse drug reactions, Cardiology, Hypokalemia

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INTRODUCTION

Adverse drug reactions (ADRs) refer to unintended and harmful reactions to medications that occur at doses used for prophylaxis, diagnosis, or therapy. These reactions can range from mild to severe and can occur with any type of medication, including prescription drugs, over-the-counter medications, herbal remedies, and supplements.[2]

Age, sex, genetics, underlying health conditions, and lifestyle factors can influence an individual's susceptibility to ADRs.[2]Dose, route of administration, duration of treatment, and drug interactions can affect the likelihood and severity of ADRs.Errors in prescribing, dispensing, or administering medications can increase the risk of ADRs.Globally, cardiovascular diseases (CVDs) continue to be the primary cause of morbidity and mortality. CVDs are responsible for around 30% of all annual deaths.[3] Because there are so many people with chronic illnesses, the amount of medications used annually is rather predictable, increasing the risk of adverse drug reactions.[4] Medication mistakes and adverse drug reactions (ADRs) have been linked to cardiovascular medications more than any other class of drugs. As such, it is important to periodically evaluate these prescriptions. The odds ratio (OR) of severe adverse drug events (ADEs) associated with cardiovascular medication was found to be 2.4 times higher than that of other medications, according to the adverse drug event prevention study group.[5]The present study was conducted to assess adverse drug reactions in cardiology patients.

MATERIALS & METHODS

The present study consisted of 56 cardiology patients who developed ADRs of both genders. All gave their written consent to participate in the study.

Data such as name, age, gender etc. was recorded. ADRs were characterized using Rawlins and Thompson classification. They were categorized into mild, moderate, and severe ADRs, according to severity scale. The causality relationship between the drug and the effect was established using Naranjo's ADR probability scale.Data thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

RESULTS

Table I Distribution of patients

Total- 56		
Gender	**Male**	**Female**
Number	32	24

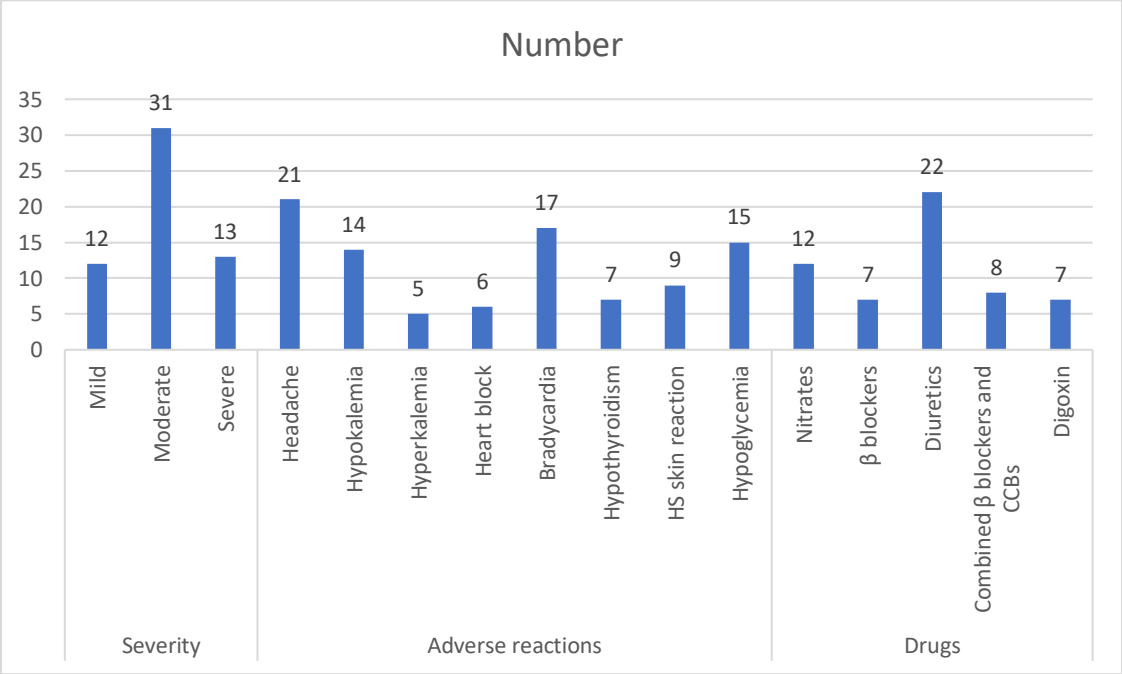
Table I shows that out of 56 patients, males were 32 and females were 24.

Table II Assessment of parameters

Parameters	Variables	Number	P value
Severity	Mild	12	0.02
	Moderate	31	
	Severe	13	
Adverse reactions	Headache	21	0.05
	Hypokalemia	14	
	Hyperkalemia	5	
	Heart block	6	
	Bradycardia	17	
	Hypothyroidism	7	
	HS skin reaction	9	
	Hypoglycemia	15	
Drugs	Nitrates	12	0.01
	β blockers	7	
	Diuretics	22	
	Combined β blockers and CCBs	8	
	Digoxin	7	

Table II, graph I shows that severity was mild in 12, moderate in 31 and severe in 13 cases. Adverse reactions were headache in 21, hypokalemia in 14, hyperkalemia in 5, heart block in 6, bradycardia in 17, hypothyroidism in 7, HS skin reaction in 9, and hypoglycemia in 15 patients. Drugs were nitrates in 12, β blockers in 7, diuretics in 22, combined β blockers and CCBs in 8, and digoxin in 7 patients. The difference was significant (P< 0.05).

Graph I Assessment of parameters



DISCUSSION

Pharmacovigilance has not picked up well in India and the subject is in its infancy. India rates below 1% in pharmacovigilance as against the world rate of 5%.[6,7] This is due to ignorance of the subject and also lack of training. India is the fourth largest producer of pharmaceuticals in the world. India is a vast country with more than 6 000 licensed drug manufacturers and more than 60 000 branded formulations.[8,9] It is also emerging as a clinical trials hub. Many new drugs are being introduced in the country, so there is an immense need to improve the pharmacovigilance system to protect the Indian population from potential harm that may be caused by some of the new drugs.[10,11]The present study was conducted to assess adverse drug reactions in cardiology patients.

We found that out of 56 patients, males were 32 and females were 24. Kaur et al[12] studied 966 indoor cardiology patients. A total of 208 ADRs were reported from 188 patients (19.5%). Of these 188 patients, 62 patients (33%) were hospitalized primarily due to the development of ADRs, while 126 (67%) patients developed ADRs during hospital stay. Nitrates were the most common offender drug group

(17.8%).Development of ADR in one of every five cardiac patient points toward a grave situation, but a higher incidence of Type A reactions in cardiology department means that these can be avoided.

We found that severity was mild in 12, moderate in 31 and severe in 13 cases. Adverse reactions were headache in 21, hypokalemia in 14, hyperkalemia in 5, heart block in 6, bradycardia in17, hypothyroidismin 7, HS skin reactionin 9, and hypoglycemia in 15 patients. Drugs were nitrates in 12, β blockers in 7, diuretics in 22, combined β blockers and CCBs in 8, and digoxin in 7 patients. Jose et al[13] found that out of 408 patient population, the total incidence of ADR was determined to be 0.15%. A minimum of one adverse drug reaction (ADR) was documented in 1.14% of hospitalized patients and 0.012% of outpatients. The overall incidence of ADRs found in males and females did not differ significantly. Compared to other age groups, older adults and the elderly had a considerably greater incidence of ADRs (0.23%). The bulk of reports (72.5%) were type A responses, and more ADRs (43.4%) were classified as extremely common in the literature. Skin rash (10.5%) was the most commonly reported reaction, while the dermatological system (23.5%) was the most usually affected organ system. The medicine class most frequently implicated was antineoplastic drugs (21.8%), whereas phenytoin (7.8%) was the individual drug most frequently reported. The suspected drug was withdrawn for the management of the ADR in majority (56.6%) of the reports. In 74.8% of the reports the patient recovered from the reaction at the time of evaluation. Upon causality assessment, majority of the reports were rated as probable (53.7%). Mild and moderate reactions accounted for 50.5 and 43.9%, respectively. In 28.7% of the reports, the reaction was considered to be preventable. At least one predisposing factor was present in 79.9% of the reports and the most common predisposing factors associated were polypharmacy and multiple disease state.

Bates et al[14] found that electrolyte concentrates (odds ratio [OR], 1.7), diuretics (OR, 1.7), and medical admission (OR, 1.6) were independent correlates of ADEs. Independent correlates of preventable ADEs in the cohort analysis were low platelet count (OR, 4.5), antidepressants (OR, 3.3), antihypertensive agents (OR, 2.9), medical admission (OR, 2.2), and electrolyte concentrates (OR, 2.1). In the case-control analysis, exposure to psychoactive drugs (OR, 2.1) was an independent correlate of an ADE, and use of cardiovascular drugs (OR, 2.4) was independently correlated with severe ADEs. For preventable ADEs, no independent predictors were retained after multivariate analysis.

The limitation of the study is the small sample size.

CONCLUSION

Authors found that most of the cardiology patients had moderate severity of ADR. In maximum cases, ADRs were related with diuretics.

REFERENCES

1. LaPointe NM, Jollis JG. Medication errors in hospitalized cardiovascular patients. Arch Intern Med. 2003;163:1461–6.
2. Lesar TS, Lomaestro BM, Pohl H. Medication-prescribing errors in a teaching hospital: A nine year experience. Arch Intern Med. 1997;157:1569–76.
3. Prakash S. Pharmacovigilance in India. Indian J Pharmacol. 2007;39:123.
4. Biswas P, Biswas AK. Setting standards for proactive pharmacovigilance in India: The way forward. Indian J Pharmacol. 2007;39:124–8.
5. Camargo AL, Cardoso Ferreira MB, Heineck I. Adverse drug reactions: A cohort study in Internal Medicine units at a university hospital. Eur J Clin Pharmacol. 2006;62:143–9.
6. Suspected adverse drug reaction reporting form. Central drugs standard control organization. Available from: http://cdsco.nic.in/html/ADR_form_PDF_file.pdf[last accessed on 2009 Oct 25]
7. Rawlins MD, Thompson JW. Pathogenesis of adverse drug reactions. In: Davies DM, editor. Textbook of adverse drug reactions. Vol. 10. Oxford: Oxford University Press; 1977. p. 27.
8. Hartwig SC, Siegel J, Schneider PJ. Preventability in reporting adverse drug reactions. Am J Hosp Pharm. 1992;49:2229–32. [PubMed] [Google Scholar]
9. Naranjo CA, Busto U, Sellers EM, Sandor P, Ruiz I, Roberts EA, et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther. 1981;30:239–45.
10. Edwards IR, Aronson JK. Adverse drug reactions: Definition, diagnosis and management. Lancet. 2000;356:1255–9.
11. Koleva T, Madzharova IU, Baleva V, Dragoĭcheva TS, Stoĭkova K. Side effects of cardiovascular drugs [abstract] Vutr Boles. 1989;28:24–30.
12. Kaur S, Kapoor V, Mahajan R, Lal M, Gupta S. Monitoring of incidence, severity, and causality of adverse drug reactions in hospitalized patients with cardiovascular disease. Indian journal of pharmacology. 2011 Feb;43(1):22.
13. Jose J, Rao PG. Pattern of adverse drug reactions notified by spontaneous reporting in an Indian tertiary care teaching hospital. Pharmacol Res. 2006;54:226–33.
14. Bates DW, Miller EB, Cullen DJ, Burdick L, Williams L, Laird N, et al. Patient risk factors for adverse drug events in hospitalized patients. Arch Intern Med. 1999;159:2553–60.