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Research Article

TO MONITOR THE ADVERSE DRUG REACTIONS ASSOCIATED WITH THE USE OF ANTIHYPERTENSIVE AGENTS IN A TERTIARY CARE HOSPITAL IN CENTRAL KERALA

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ABSTRACT

Objective: The objective of the study is to monitor the adverse drug reactions (ADRs) due to anti-hypertensive drugs prescribed in a tertiary care hospital.

Methods: The study was conducted in the outpatient department of General Medicine of a tertiary care hospital in Kerala. The demographic details and suspected ADRs were collected from the patients and evaluated, and causality assessment was done.

Results: More women developed ADRs compared to men due to the anti-hypertensive drug. The occurrence of adverse reactions was seen to be more in older patients over 50 years of age compared to younger individuals. The occurrence of ADR was more in patients using a combination of drugs (74.3%) rather than monotherapy. Calcium channel blockers were associated with more number of adverse reactions (62.5%) with amlodipine showing the maximum ADRs (64.8). The commonly seen ADR was edema. When the causality assessment was done, most were probable/likely followed by possible.

Conclusion: This study shows that calcium channel blockers were the therapeutic class of drugs that caused the most number of ADRs, especially pedal edema; there was a higher frequency of ADRs to various antihypertensive drugs. Females and those more than 50 years old had shown a higher proportion of ADRs though not statistically significant. Furthermore, those individuals who took more drugs to treat hypertension also showed more ADRs. This study of adverse reactions toward antihypertensive medications will help physicians to choose a better option to treat their patients which will eventually help in patient satisfaction and medication safety.

Keywords: Adverse drug reactions, Antihypertensive agents, Edema.

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INTRODUCTION

Hypertension can be defined as a systolic blood pressure of 140 mmHg or greater or a diastolic pressure of 90 mmHg or greater [1]. The treatment of hypertension using various drugs has shown great applications in lowering blood pressure levels and also in the primacy prevention of morbidity and also mortality in various individuals with the illness [2,3].

According to the World Health Organization (WHO), "An adverse drug reaction (ADR) is any response to a drug which is noxious and unintended and occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or the modification of physiological function" [4-7]. The Food and Drug Administration has defined a serious adverse event as one in which the patient's outcome may be "death, or life-threatening, hospitalization, disability, congenital anomaly or required intervention to prevent permanent impairment or damage" [8].

ADRs are seen as one of the most leading reasons for morbidity and mortality among patients. It has been also found that 6% of hospital admissions are because of ADRs and about 6–15% of various hospitalized patients can also experience a serious ADR [9].

There is a great need to check the safety of the drugs prescribed on a constant basis and to corroborate the new facts and figures coming out of the various ongoing pharmacovigilance undertakings [10,11].

The WHO has defined pharmacovigilance as the "*science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems.*" [12].

Proper causality assessment becomes especially important as in most cases the ADRs are not very specific, the diagnostic tests may not be done, and doing a rechallenge is not ethical. Thus, the WHO-UMC system of causality assessment was applied in the study to get the correct picture of the ADRs [13,14].

There is also much scarcity in the amount of literature available on the ADRs to antihypertensive drugs available in this part of the country. This gap in knowledge prompted us to move forward with this study.

In an observational study conducted by Fowad Khurshid on the monitoring of 21 ADRs associated with the use of antihypertensive medicines in a hospital in New Delhi to 192 patients, the incidence of ADR was more in those individuals more than 40 years of age, most susceptible being age 40–50. Furthermore, ADRs were more among females. Combination therapy was more dangerous than monotherapy. In causality assessment, maximum was possible followed by probable and unlikely. Calcium channel blockers were found to develop a maximum number of ADRs followed by diuretics and beta-blockers. Among individual drugs, ADRs were most common for amlodipine followed by torasemide [15].

In another questionnaire-based study conducted by A Hussain on the monitoring of 34 ADRs associated with antihypertensive medications given in another hospital in South Delhi to 250 patients, the incidence of ADRs was found to be more in middle-aged patients most susceptible being the age group of 40–50 years and also more among female patients [11].

After going through all these, we wanted to see what are the patterns that are seen in our hospital. How there are variations in the occurrence of ADRs among various genders and age groups. Furthermore, wanted to see the various drug groups and individual drugs available for the treatment of hypertension showed ADRs after assessing their causality. There was a scarcity in the literature available from Kerala as far as we could find in this topic. This gap in knowledge prompted us to go with this study.

Aims and objectives

- To monitor the ADRs due to antihypertensive drugs prescribed in a tertiary care hospital in central Kerala
- To establish the causality relationship using standard WHO scale
- To categorize the adverse reactions into different organ systems involved in antihypertensive agents
- To use this information to educate the prescribing doctors about the importance of pharmacovigilance.

METHODS

Study design and participants

The work was an open, non-comparative, observational study to report the incidence of ADRs due to the antihypertensive medications prescribed to patients attending the outpatient department of General Medicine. Informed consent is taken from the patients and an interview is conducted to get the data needed to fill the standard ADR form as recommended by the central drug standard control organization, Government of India.

Data collection

A data collection team of three dedicated students of the college and a physician was set up after making them aware of the various aims and objectives of the study. Details of the patient such as initial, age, sex, height, and weight were collected. Details about the suspected adverse event such as the short description of the reaction occurred, the onset date and stop date of the occurrence of the event, various outcomes, and the treatments given. Furthermore, information about the suspected medications was also collected such as the name, indications, start date, stop date, dose, frequency, and route of administration of the drug. Past or present medical history, concomitant medications taken, relevant tests or laboratory data, and other relevant history were also taken including any pre-existing medical conditions if present. All this data collected was kept strictly confidential. All ADRs were evaluated using the "WHO Probability Assessment Scale" to establish the causal relationship which may be categorized into certain, probable, possible, unlikely, conditional, and unclassifiable with the help of a pharmacovigilance associate [13].

Study duration

The study was carried out over a period of 2 months from August 2022 to September 2022.

Study population

All hypertensive patients in a tertiary care hospital in south Kerala were treated with at least one antihypertensive drug.

Study settings

A tertiary care hospital in central Kerala.

Inclusion criteria

All the patients with hypertension without regard to their age and sex were treated with at least one antihypertensive drug.

Exclusion criteria

- Patients who were not undergoing treatment with antihypertensive medications
- Mentally retarded and unconscious patients (patients who are dependent on other people for administering their drugs).

Sample size

Considering 95% confidence interval and 5% absolute precision and based on the prevalence (10.93%) of ADR in hypertensive patients from a previous study [15], a minimum sample size of 150 was calculated using the following formula.

$$n = \frac{(z_{a/2})^2 \times pq}{d^2}$$

Where:

n = sample size

p = percentage

q = 1 - p

d = desired degree of precision

Z = standard normal value at the level of confidence desired.

Data sources

The filled ADR forms were collected and monitored to check the causality assessment and to analyze the various ADRs observed with different drugs given for the condition.

Data analysis

The data thus collected was entered into a Microsoft Excel sheet and analyzed with the help of a medical statistician. The categorical data such as gender and the presence of ADRs were presented as frequency and percentage and continuous data such as age as mean and standard deviation (SD). Age was then grouped into classes using a 10-year interval. The frequency of ADRs in the various therapeutic classes of antihypertensive drugs and the organ systems affected due to the ADRs and age, gender, and combination therapy was done using Chi-square/ Fisher's exact tests. A $p<0.05$ was considered statistically significant.

Ethical concerns

The study commenced after getting approval from the institutional ethics committee. Patients were included in the study after taking informed consent. They were fully free to withdraw their consent at any time. All the data thus collected shall be kept fully confidential. It shall not be used for anything other than the analysis of this study. No monetary or any other benefits were given to any participants of this study. All the hospital staff and statisticians helping in the data collection and analysis are rightly acknowledged.

OBSERVATIONS AND RESULTS

Data collected from hypertensive patients were analyzed and the results are presented in this section.

Age

The age of the patients ranged from 19 to 88 years with a mean (SD) of 61.1 (15.6) years.

The highest number of participants involved in the study was in the age group of 71–80 (n=40, 26.7%) followed by 61–70 (n=35, 23.3%) and 41–50 (n=24, 16.0%). The number and frequency of the individuals who participated in this study according to their age group are given in Table 1.

Gender

In a total of 150 patients, 56% were males (n=84) and the rest were females.

Fig. 1 shows the gender distribution of participants.

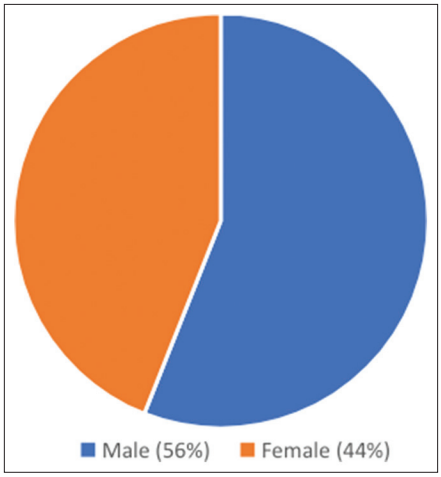

Fig. 1: Gender distribution of study subjects

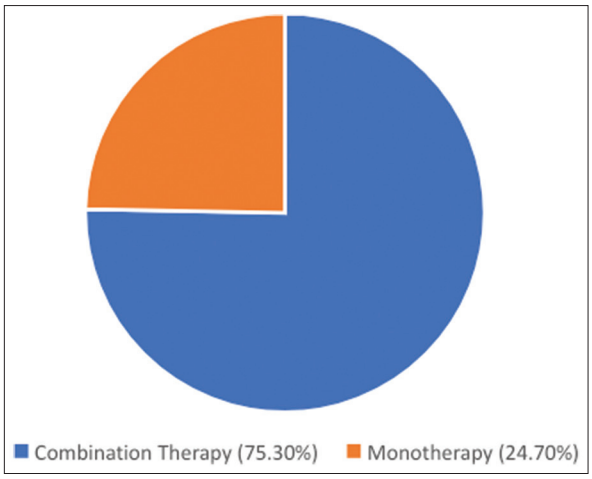

Fig. 2: Distribution of combination therapy

Combination therapy
The majority (75.3%) of the participants of the study had combination therapy whereas the rest were on monotherapy. This is shown in Fig. 2.

Number of combination drugs
Most of the participants were taking two drugs (n=108, 72.0%) and 5 (3.3%) individuals were taking three drugs as a part of their antihypertensive therapy. The number and frequency of the individuals who participated in this study according to the number of drugs taken are given in Table 2.

Total number of antihypertensive drugs taken by the 150 participants is 268.

Therapeutic class
The number of each therapeutic class of drug taken by individuals included in the study is noted. Calcium channel blockers (n=88, 32.8%) were the most commonly taken group of drugs followed by angiotensin II receptor blockers (n=76, 28.4%) and beta-blockers (n=62, 23.1%). The number and frequency of the various therapeutic classes of drugs taken in this study are given in Table 3.

Individual antihypertensive drugs
The number of each individual drug taken by the patients included in the study is noted. Metoprolol (n=57, 21.3%) was the most commonly taken group of drugs followed by amlodipine (n=54, 20.2%) and losartan (n=42, 15.7%). The number and frequency of the various drugs taken in this study are given in Table 4.

Table 1: Age distribution of study subjects

Age (years)	n (%)
11–20	2 (1.3)
21–30	3 (2.0)
31–40	13 (8.7)
41–50	24 (16.0)
51–60	22 (14.7)
61–70	35 (23.3)
71–80	40 (26.7)
81–90	11 (7.3)
Total	100 (100.0)

Table 2: Number of drugs taken in combination

Type of therapy	n (%)
Single drug	37 (24.7)
Two drug	108 (72.0)
Three drug	5 (3.3)
Total	150 (100.0)

Presence of ADR
The number of ADRs noted were 117 out of the the total 268 (43.7%) when we consider the number of drugs used. This is given in Fig. 3.

Type of ADR
The most common ADR noted was pedal edema (n=48, 43.3%) followed by postural hypotension (n=27, 24.3%) and hyperkalemia (n=20, 18.0%).

Distribution of types of ADRs
The most common ADR noted was pedal edema (n=48, 43.3%) followed by postural hypotension (n=27, 24.3%) and hyperkalemia (n=20, 18.0%) as given in Table 5.

Presence of ADR by therapeutic class
Among the various ADRs seen among each therapeutic class of drugs, the maximum number of ADRs were seen for calcium channel blockers (n=55, 62.5%) followed by angiotensin II receptor blockers (n=31, 40.8%) and alpha 2 agonists (n=19, 67.9%). The maximum proportion of ADRs was seen for alpha 2 agonists (67.9%) followed by calcium channel blockers (62.5%) and angiotensin II receptor blockers. Since $p<0.05$, there is a significant pattern seen. The number and frequency of the ADR caused by various individual drugs are as given in Table 6.

Presence of ADR by individual drugs
Among the various ADRs seen among each individual drug, the maximum number of ADRs were seen for amlodipine (n=35, 64.8%) followed by clonidine (n=19, 67.9%) and cilnidipine (n=17, 56.7%). There is a significant association seen between the presence of ADR and individual drugs ($p<0.001$). The number and frequency of the ADR caused by various therapeutic classes of drugs are as given in Table 7.

Distribution of ADR with respect to therapeutic class and individual drugs
Calcium channel blockers were observed to be the most common therapeutic class showing ADRs in this study. It was followed by angiotensin II receptor blockers, alpha 2 agonists, beta-blockers, and alpha-blockers. Amlodipine was seen as the most common individual drug showing the maximum number of ADRs among the individual drugs. The main complaints of the patient using this drug were conduction block, pedal edema, postural hypotension, and peripheral vascular occlusive disease. Clonidine (alpha 2 agonist) was the drug that was found to show the second most number of ADRs with postural hypotension being the chief complaint [Table 8].

Table 3: Distribution of study subjects by therapeutic class

Therapeutic class	Number of drugs (%)
Angiotensin II receptor blockers	76 (28.4)
Alpha-blockers	12 (4.5)
ACE inhibitors	2 (0.8)
Alpha 2 agonist	28 (10.4)
Beta-blockers	62 (23.1)
Calcium channel blockers	88 (32.8)
Total	268 (100)

Table 4: Distribution of study subjects by individual drugs

Individual drugs	Number of drugs (%)
Amlodipine	54 (20.2)
Cilinidipine	30 (11.2)
Clonidine	28 (10.4)
Enalapril	2 (0.7)
Losartan	42 (15.7)
Metoprolol	57 (21.3)
Nifedipine	3 (1.1)
Olmesartan	3 (1.1)
Prazosin	12 (4.5)
Telmisartan	31 (11.6)
Carvedilol	2 (0.7)
Propranolol	2 (0.7)
Benidipine	1 (0.4)
Atenolol	1 (0.4)
Total	268 (100)

Table 5: Distribution of study subjects by the type of adverse drug reaction

ADR type	Number of individuals (%)
Acute kidney injury	1 (0.9)
Bradycardia	3 (2.7)
Bronchial asthma	1 (0.9)
Conduction block	1 (0.9)
Hypotension	6 (5.4)
Hyperkalemia	20 (18.0)
Pedal edema	48 (43.3)
PE+PH	1 (0.9)
Peripheral gangrene	1 (0.9)
Postural hypotension	27 (24.3)
Peripheral vascular occlusive disease	2 (1.8)
Total	111 (100)

ADR: Adverse drug reaction

Table 6: Presence of adverse drug reaction by therapeutic class

Therapeutic class	ADR present, n (%)	ADR absent, n (%)	Total number of drugs
Angiotensin II receptor blockers	31 (40.8)	45 (59.2)	76
Alpha-blockers	3 (25)	9 (75)	12
ACE inhibitors	1 (50)	1 (50)	2
Alpha 2 agonist	19 (67.9)	9 (32.1)	28
Beta-blockers	8 (12.9)	54 (87.1)	62
Calcium channel blockers	55 (62.5)	33 (37.5)	88
Total	117	151	268

p=0.000 (Chi-square test). ADR: Adverse drug reaction

Causality assessment of ADRs

Most of the causality assessments of the ADRs showed probable/likely (n=64, 57.7%) in the WHO causality assessment scale followed by possible (n=44, 39.6%) and unlikely (n=2, 1.8%) [Table 9].

Table 7: Presence of adverse drug reaction by individual drugs

Individual drugs	ADR present, n (%)	ADR absent, n (%)	Total number of drug
Amlodipine	35 (64.8)	19 (35.2)	54
Cilnidipine	17 (56.7)	13 (43.3)	30
Clonidine	19 (67.9)	9 (32.1)	28
Enalapril	1 (50.0)	1 (50.0)	2
Losartan	14 (33.3)	28 (66.7)	42
Metoprolol	7 (12.3)	50 (87.7)	57
Nifedipine	3 (100.0)	0	3
Olmesartan	2 (66.7)	1 (33.3)	3
Prazosin	3 (25)	9 (75)	12
Telmisartan	15 (48.4)	16 (51.6)	31
Carvedilol	0	2 (100)	2
Propranolol	1 (50.0)	1 (50.0)	2
Benidipine	0	1 (100.0)	1
Atenolol	0	1 (100.0)	1
Total	117	151	268

p=0.000 (Chi-square test). ADR: Adverse drug reaction

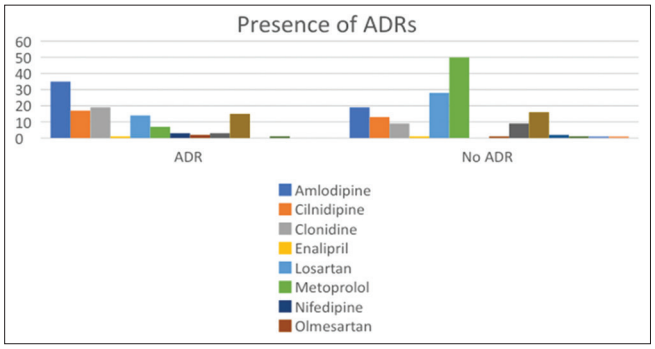

Fig. 3: Number of ADR events reported with inidvidual drugs

Organ system

The organ system which was mostly seen to be affected in the study by proportion was the general features such as pedal edema (n=49, 44.2%) followed by the Cardiovascular system (n=40, 36.0%) and the metabolic system (n=20, 18.0%) [Table 10].

Seriousness of ADR

All the ADRs in this study belonged to the moderate group. There were not any mild nor severe ADRs which required or prolonged hospital stay of the patient.

Association between the presence of ADR and age

The age group which developed the highest proportion of ADRs in this study was 31–40 years (84.6%) followed by 71–80 (n=31, 77.5%) and 61–70 years (n=27, 77.1%). The age group which developed the most number of ADRs in this study was 71–80 (n=31), followed by 61–70 (n=27), 41–50 (n=18) and 51–60 (n=15). It was also observed that most of the ADRs (n=80, 72.1%) occurred after the age of 50. No significant association was seen between the presence of ADR and age group (p=0.613). Table 11 gives the presence of ADR by age group.

Association between the presence of ADR and gender

Among 84 males, 70.2% had developed ADR whereas among the 66 females, it was 78.8%. The association between the presence of ADR and gender was not statistically significant (p=0.236). This data are shown in Table 12.

Association between the presence of ADR and combination therapy

Table 13 shows the association between the presence of ADR and combination therapy. Among 113 participants who had combination therapy, 84 (74.3%) developed ADR. Since p>0.05, there is no significant association between the presence of ADR and combination therapy.

Table 8: Adverse drug reactions and suspected antihypertensive medicines

Therapeutic class	Individual drugs	ADRs	Number of ADRs (%)
Angiotensin II receptor blockers (76)	Losartan (42)	Bronchial asthma	1 (2.4)
		Hyperkalemia	7 (16.6)
		Hypotension	1 (2.4)
		Pedal edema	2 (4.8)
		Peripheral gangrene	1 (2.4)
		Postural hypotension	2 (4.8)
	Total		14 (33.3)
	Olmesartan (3)	Acute kidney injury	1 (33.3)
		Postural hypotension	1 (33.3)
	Total		2 (66.6)
	Telmisartan (31)	Bradycardia	1 (3.2)
		Hypotension	3 (9.7)
		Hyperkalemia	10 (32.3)
		Postural hypotension	1 (3.2)
	Total		15 (48.4)
	Grand total		31 (40.8)
Alpha-blockers (12)	Prazosin (12)	Postural hypotension	3 (0.25)
	Grand total		3 (0.25)
ACE inhibitors (2)	Enalapril (2)	Hyperkalemia	1 (0.5)
	Grand total		1 (0.5)
Alpha 2 agonist (28)	Clonidine (28)	Postural hypotension	19 (67.8)
	Grand total		19 (67.8)
Beta-blockers (62)	Atenolol (1)	Postural hypotension	0
	Total		0
	Carvedilol (2)	Pedal edema	0
	Total		0
	Metoprolol (57)	Bradycardia	2 (3.5)
		Hypotension	1 (1.8)
		Hyperkalemia	1 (1.8)
		Pedal edema	1 (1.8)
		Peripheral vascular occlusive disease	2 (3.5)
	Total		7 (12.3)
	Propranolol (2)	Hyperkalemia	1 (50)
	Total		1 (50)
	Grand total		8 (12.9)
Calcium channel blockers (88)	Amlodipine (54)	Conduction block	1 (1.9)
		Pedal edema	31 (57.4)
		Postural hypotension	2 (3.7)
		Peripheral vascular occlusive disease	1 (1.9)
	Total		35 (64.9)
	Benidipine (1)	Postural hypotension	0
	Total		0
	Cilnidipine (30)	Hypotension	2 (6.7)
		Hyperkalemia	1 (3.3)
		Pedal edema	14 (46.7)
	Total		17 (56.7)
	Nifedipine (3)	Pedal edema	3 (100)
	Total		3 (100)
	Grand total		55 (62.5)

ADRs: Adverse drug reactions

Table 9: Distribution of causality assessment of adverse drug reactions

Causality assessment	n (%)
Probable/likely	64 (57.7)
Possible	44 (39.6)
Unlikely	2 (1.8)
Conditional/unclassified	1 (0.9)
Total	111 (100)

Table 10: Organ system distribution among adverse drug reactions

Organ system	n (%)
CVS	40 (36.0)
General	49 (44.2)
Metabolic	20 (18.0)
Respiratory system	1 (0.9)
Renal system	1 (0.9)
Total	111 (100)

CVS: Cardiovascular system

DISCUSSION

It is of great importance to have a clear profile of the various antihypertensive drugs which are prescribed in the hospital to find if there are any peculiarities in the patterns of ADRs which are seen in our locality. In the study, we observed that there was a higher frequency of ADRs to various antihypertensive drugs. There was also a scarcity of literature on this topic in our region as well that prompted us to go with this study.

Proportionately more women developed ADRs compared to men due to the antihypertensive drug they are taking even though it was not

Table 11: Presence of adverse drug reactions by age distribution of study subjects

Age (years)	Subjects with ADR, n (%)	Subjects without ADR, n (%)	Total number of subjects
11–20	1 (50.0)	1 (50.0)	2
21–30	1 (33.3)	2 (66.7)	3
31–40	11 (84.6)	2 (15.4)	13
41–50	18 (75.0)	6 (25.0)	24
51–60	15 (68.2)	7 (31.8)	22
61–70	27 (77.1)	8 (22.9)	35
71–80	31 (77.5)	9 (22.5)	40
81–90	7 (63.6)	4 (36.4)	11
Total	111 (74.0)	39 (26.0)	150

p=0.613 (Chi-square test). ADR: Adverse drug reaction

Table 12: Presence of adverse drug reaction by gender distribution of study subjects

Gender	Subjects with ADR, n (%)	Total number of subjects
Male	59 (70.2)	84
Female	52 (78.8)	66
Total	111 (74.0)	150

p=0.236 (Chi-square test). ADR: Adverse drug reaction

Table 13: Presence of adverse drug reactions with combination therapy

Combination therapy	Subjects with ADR, n (%)	Total number of subjects
Yes	84 (74.3)	113
No	27 (73.0)	37
Total	111 (74.0)	150

p=0.870 (Chi-square test). ADRs: Adverse drug reactions

statistically significant. It has been shown in studies that the female gender can be considered a risk factor for the production of ADRs, probably due to pharmacokinetic differences [15,16]. This might also be due to the higher emotional quotient in females leaving them much more sensitive to the pharmacological actions of the drug probably leading to more occurrence of ADRs in them [15].

The occurrence of adverse reactions was seen to be more in older patients over 50 years of age compared to younger individuals lower than 50 years old similar to most studies on this topic [15]. This variation may be due to either the compromise of the functioning of the various organ systems, concomitant diseases suffered by the patient, the various drug therapies that the patient takes, and the decreased basal metabolic rate of the patient [15].

As expected, it was seen that patients who were taking combinations of drugs to treat hypertension showed more ADRs compared to those on monotherapy. This was consistent with various epidemiological studies that were done to look into the risk factors for the development of ADRs [17-19]. Thus, combination therapy must not be used unnecessarily as potential drug interactions may increase the chances of the development of ADRs. Only the essential drugs need to be used in the treatment of hypertension.

Calcium channel blockers were the therapeutic class of drugs that were affected with the most number of ADRs. This finding is consistent with various other studies as well which shows the class to show the maximum ADRs [19,20]. The second most number of ADRs were shown by angiotensin II receptor blockers which has also shown a higher proportion of ADR compared to the number of the drug given [20].

Among the various individual drugs given, amlodipine had shown the maximum number of ADRs, the most common complaint being edema. Edema has also been reported as one of the most common ADRs associated with amlodipine [19] and also in a study in Belgium on 57 patients [21]. The second most number of ADRs were seen among clonidine (an alpha 2 agonist) with postural hypotension being the adverse effect seen. The adverse reactions seen with other drugs are consistent with their respective pharmacological profiles as well.

When the causality assessment was done most were probable/likely followed by possible. This is also similar to various other studies where possible and probable were most frequently reported though some ADRs were classified as unlikely and unconditional according to the WHO causality assessment scale [11,15]. This scale has helped to improve the ability to establish a relationship between the drug and the ADR. However, it is important to report all cases even if the causality is not certain since the data will help to expand the database and can be used for future research and other study purposes [22].

The various effects of ADRs on different organ systems were checked and proved based on the symptoms provided by the patients. The most number of ADRs were seen causing general effects such as pedal edema followed by cardiovascular effects. This is consistent with various other studies which showed edema and other cardiovascular manifestations as the main adverse effects seen in their study populations [11,15]. When compared to their severity, they were found to be moderate whereas mild and severe cases were not reported. Severe cases including deaths, hospitalization, or disabilities were not reported in other studies as well [23].

All the ADRs collected were reported to the monitoring center to be uploaded to the software as a part of post-marketing surveillance and pharmacovigilance. This could be used to check the safety of the drugs on a bigger level. Efforts to involve health-care workers such as physicians in ADR reporting helped to educate and promote pharmacovigilance among them.

CONCLUSION

From this pharmacovigilance study, we found out that calcium channel blockers were the therapeutic class of drugs that caused the most number of ADRs, especially pedal edema. This was followed by angiotensin II receptor blockers which mainly caused hyperkalemia, alpha 2 agonists which mainly caused postural hypotension, beta-blockers, alpha-blockers which caused postural hypotension and ACE inhibitors. There was a higher frequency of ADRs to various antihypertensive drugs. Females and those more than 50 years old had shown a higher proportion of ADRs though not statistically significant. Furthermore, those individuals who took more drugs to treat hypertension also showed more ADRs. Causality assessment showed most ADRs to be probable/likely followed by possible. Organ system distribution of ADRs showed a general system, followed by the cardiovascular system. ADRs reported were of moderate severity and none caused any severe reaction in the patient.

Thus, since this study involves the monitoring of the ADRs of the various antihypertensive medications prescribed in our hospital, it may be used to help the treating physicians to choose the appropriate drugs which are safe for the patient. This would eventually lead to better patient satisfaction, decrease the chances of the patient discontinuing the therapy due to the adverse effects, and also reduce the financial burden of treating these adverse effects as well. Further studies are required to properly characterize these effects and to check into the ADR patterns seen in our area at regular intervals involving the participation of more health-care workers who are made more aware of the ADR reporting system in the country.

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CONFLICTS OF INTEREST

The authors does not have any conflict of interest

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