J Young Pharm, 2016; 8(3): 259-265
A multifaceted peer reviewed journal in the field of Pharmacy
www.jyoungpharm.org | www.phcog.net

Original Article

Pharmacovigilance Studies of Antihypertensive Medications in Teaching Hospital of Hyderabad, Sindh

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ABSTRACT

Objective: To assess the adverse drug reactions due to anti hypertensive therapy among hypertensive patients at teaching hospital of Hyderabad, Sindh, Pakistan. **Methodology:** The current study was performed in a teaching hospital of Hyderabad, Sindh, Pakistan. A cross sectional study was conceded in medicine and cardiac outpatient department during the period of study. A total of 1271 hypertensive patients were enrolled during the period of 2 years by purposive sampling procedure. A series of questions were asked by the hypertensive patients. The questionnaire contains the demographic details of the patients, prescribing trend and various ADRs found in patients due to antihypertensive therapy. The written consent was also taken from the health care professionals as well as patients. **Results:** Out of 1271 patients, 57.99% belong to male gender, 79.78% to urban areas, 69.16% enrolled from cardiac OPD, 32.33% were aged between 49-58 years of age, 21.40% had 1 parent positive history of hypertension and 44.22% had 3-5 years duration of hypertension. Maximum patients were on dual therapy i.e. 42.64% and the most common combination therapy was valsartan+amlodipine i.e. 11.99%. Moreover the most common combination therapy that caused maximum ADRs was telmisartan+hydrochlorothiazide i.e. 17.54%. **Conclusion:** The existing passive pharmacovigilance department should be active again under Drug regulatory authority of Pakistan. A council will create under the Drug regulatory authority of Pakistan that helps to communicate with international organizations such as Uppsala monitoring center under World Health Organization, Food and Drug Administration etc. Moreover council will also establish a system of ADRs reporting throughout the country and then data will share with all stake holders.

Key words: Pharmacovigilance, Teaching hospital, Hypertension, Dual Therapy, Adverse Drug Reaction and Antihypertensive medications.

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DOI: 10.5530/jyp.2016.3.16

INTRODUCTION

The study of adverse drug reactions (ADRs) is called Pharmacovigilance.[1] The word Pharmacovigilance is come from Greek and Latin word, Greek Pharmakon means drug and Latin word vigilance means to alert, to keep watch on drugs/medicines.[2] The care of patients is utmost important part of therapy and it is the responsibility on Health Care Professionals (HCPs) to fulfill with the rationale therapy. Pharmacovigilance is also the part of all phases especially in Phase IV trials i.e. also called as Post marketing Phase in which risks factors will evaluate in shortest possible time that will help to create the guidelines for future about the medicines. The utilization of Pharmacovigilance is applicable completely at every step of medicines including pre as well as post approval stages. Now a day's latest or modern medicines are prescribed for the treatment and better management of disease but with the advantages of medicines the chances of ADRs is also present and it was confirmed by various studies that leads to common adverse effects that may be preventable or not, disability of any organ and also the chances of death. The chances of mortality due to ADRs are more and it rank among the top 10 in respect of morbidity in some countries. There are internal as well as external factors that will leads to ADRs like internal factors related with medicines and external related with patient's sensitivity.[3] The first and prime purpose of Pharmacovigilance is safety among public by using any type of medications. Collection of information through different health related programmes that shows the positive effects of medicines and flourish the problems that may be negative effect on patients and also the achievement of program. It also play a very important role to evaluate the various parameters of medicines i.e. benefits, risks, adverse reactions and appropriateness that leads to rationalization of therapy. To promote the rational use of medicines, to decrease the adverse effects and cost effectiveness is also an important purpose of Pharmacovigilance. Development of various learning programmes of Pharmacovigilance for better awareness to the local community.[4,5] Further the obligations or need of Pharmacovigilance is due to that many medicines have appropriate target as well as mechanism beside this they have also minor side effects on the rest of the body part and their impact is negative moreover our medicines are also the drug or chemical when it enter in human body any unintended effect may produce, it means in field of Pharmacovigilance no any effect is predictable some time unpredictable effects may also produce in patient's body. The effectiveness of any therapy is also assessed with the help of Pharmacovigilance so depending upon all the above factors the need of Pharmacovigilance is very much necessary part of the cycle of medicines.[6] In one study they explained the occurrence of adverse drug reactions (ADRs) in out-patient department of medicine at teaching hospital of India. They concluded that, out of 600 patients 122 ADRs were reported in a 4 month study period. Further mostly the ADRs were found in male gender as compared to female. As far as age was concerned the maximum patients were reported between the age group of 25 to 50 years of age. The causative factor of different ADRs was polypharmacy specially those patients who are taking atleast 4 or more drugs and the percentage of ADRs was 58%, while 48% of the ADRs reported in those patients who are taking less than 3 medicines. Various ADRs were observed in patients and mostly associated with gastro intestinal tract (GIT) including gastritis and dysphagia and the percentage of these ADRs were 24.7% i.e. maximum.[7] Another study studied on the assessment of adverse effects due to antihypertensive medications that leads to treatment discontinuation. The study was conducted in tertiary care hospital of Nigeria and based on retrospective type. The study duration was 24 months and only patients with confirmed hypertension with

some other co-morbid conditions were included. The patient's record was assessed and those who discontinue their antihypertensive therapy during the study period were enrolled and then evaluate the reason of discontinuation of therapy. A total of 1164 patients were record and prescribed more than 2000 different classes of antihypertensive drugs. Most common prescribing group was diuretics and the percentage was 30.4% and second most prescribing group was angiotensin converting enzyme inhibitors (ACEIs) with percentage of 29.1%. Among ACEIs, majority of cases were noted in dry cough in captopril users and the percentage was 47.7%, while in lisinopril user the percentage was 38.6% respectively. Among CCBs, the most common adverse effect was headache in nifedipine user and the percentage was 55.5% while bradycardua was noted in atenolol user and the percentage was 48.4%. While among the users of diuretics, the most common adverse effects were hypokalemia (11.4%), hypouricaemia (11.4%) and dehydration (8.6%).[8] Moreover in another study of Pharmacovigilance for Telmisartan in those patients who had confirmed diagnosed with essential hypertension. The current study was single centered, open label with non-randomized questionnaire based study in which various questions were asked from the patients about the possible adverse effects of Telmisartan by prior informed consent. A total of 60 patients enrolled who were taking 40 mg of Telmisartan. Out of 60 patients, mostly the patients gender was male (n=43) as compared to female (n=17), while 169 ADRs were detected in a total of 60 patients. Majority of the enrolled patients were aged more than 50 years of age while mostly ADRs were observed in patients having aged more than 60 years. The most common ADRs were swelling of the ankles and the frequency of occurrence was 20 patients, xerostomia (n=20), weakness (n=18), spasm of muscle (n=15). Among moderately ADRs, the cough was also noted in 8 patients. So according to the classification of ADRs, various percentages were found such as among common adverse reaction the occurrence was 68%, in moderately type of adverse reactions the percentage was 27% and only 4% was in a category of rare adverse effects due to Telmisartan.[9]

METHODOLOGY

The current study was performed in a teaching hospital of Hyderabad, Sindh, Pakistan. A cross sectional study was conceded in medicine and cardiac outpatient department during the period of study. A total of 1271 hypertensive patients were enrolled during the period of 2 years by purposive sampling procedure. A series of questions were asked by the hypertensive patients. The questionnaire contains the demographic details of the patients, prescribing trend and various ADRs found in patients due to antihypertensive therapy. The study was approved by advance studies and research board. The written consent was also taken from the health care professionals as well as patients. The data was also analyzed descriptively.

RESULTS

Out of total 1271 patients, the male patients were 737 (57.99%) and female were 524 (42.01%). The belongings of the hypertensive patients were urban (79.78%) and rural (20.22%). Moreover the enrollment of the patients was from cardiac (69.16%) and medicine (30.84%). Maximally 411 (32.33%) patients were aged between 49 to 58 years of age. 272 patients had positive family history of hypertension in 1 parent and 9.21% had 2 parent positive history of hypertension. The duration of hypertension was also analyzed among the patients i.e. 562 (44.22%) of the patients had 3 to 5 years duration and minimally 132 (10.38%) of the patients had less than 1 year of hypertension. The literacy rate among hypertensive patients were inadequate i.e. 25.5% was uneducated while only 8.10% of the patients were crossed bachelor level (Table 1). Out of total patients 459 (36.11%) of the patients were prescribed monotherapy while remaining patients i.e. 812 (63.89%) of the patients were on combination therapy. Moreover out of 812 patients, 542 (66.75%) of the patients were on dual therapy and 183 (22.54%) were taking triple therapy (Table 2). Further among monotherapy patients, the most common prescribed antihypertensive medications were atenolol (16.33%), pro-

Table 1: Gender wise Patients enrolled from teaching hospital

S/No	Gender	Frequency	Percent	Cumulative Percent
Gender	Male	737	57.99%	57.99%
	Female	534	42.01%	100%
Locality	Urban	1014	79.78%	79.78%
	Rural	257	20.22%	100%
Opds	Cardiac	879	69.16%	69.16%
	Medicine	392	30.84%	100%
Age	≥18≤28	94	7.40%	7.40%
	≥29≤38	192	15.11%	22.51%
	≥39≤48	376	29.58%	52.09%
	≥49≤58	411	32.33%	84.42%
	≥59	198	15.58%	100%
Family History of Hypertension	Yes (1 Parent)	272	21.40%	21.40%
	Yes (2 Parent)	117	9.21%	30.61%
	No	673	52.95%	83.56%
	Don't Know	209	16.44%	100%
Duration of Hypertension	Less than 1 Year	132	10.38%	10.38%
	≥1≤3 Years	366	28.8%	39.18%
	≥3≤5 Years	562	44.22%	83.4%
	More than 5 Years	211	16.60%	100%

Table 2: Prescribing Status of the Antihypertensive drugs

Status	Frequency	Percent	Cumulative Percent
Monotherapy	459	36.11%	36.11%
Dual Therapy	542	42.64%	78.75%
Triple Therapy	183	14.40%	93.15%
Quadruple Therapy	87	6.84%	100%

Table 3: List of Antihypertensive medicines Prescribed in Monotherapy Patients (n=459)

Prescribed Medicines	Frequency	Percent	Cumulative Percent
Furesimide	15	3.27%	3.27%
Spironolactone	5	1.09%	4.36%
Hydrochlorothiazide	9	1.96%	6.32%
Atenolol	75	16.33%	22.65%
Propanolol	53	11.6%	34.25%
Amlodipine	31	6.75%	41%
Nifidipine	17	3.70%	44.7%
Enalapril	41	8.93%	53.63%
Perindopril	4	0.87%	54.5%
Ramipril	39	8.50%	63%
Candesartan	9	1.96%	64.96%
Lisinopril	12	2.61%	67.57%
Captopril	17	3.70%	71.27%
Telmisartan	51	11.11%	82.38%
Bisoprolol	5	1.09%	83.47%
Carvedilol	3	0.65%	84.12%
Valsartan	18	3.92%	88.04%
Felodipine	7	1.52%	89.56%
Verapamil	10	2.17%	91.73%
Benzopril	5	1.09%	92.82%
Losartan	25	5.44%	98.26%
Metoprolol	8	1.74%	100.00%
Total	459	100.0%	-

panolol (11.6%) and telmisartan (11.11%) (Table 3). According to class wise among monotherapy patients, beta blockers (31.37%) were the most common prescribed class (Table 4). While among dual therapy patients i.e. 532, the most common therapy was telmisartan+hydrochlorothiazide (14.76%) followed by valsartan+amlodipine (11.99%) and among triple therapy patients i.e. 183, the most common prescribed therapy were at enolol+chlorthalidone+telmisartan (15.30%) followed by valsartan+ hydrochlorothiazide+amlodipine (13.66%) (Table 4 and 5). Moreover among quadruple therapy the maximum patients were Atenolol+Chl orthalidone+Telmisartan+αMD combination and the percentage was 26.44% (Table 6). Among monotherapy patients i.e. 459, 98 (21.35%) patients had various adverse drug reactions (ADRs) and the most common medicines that caused ADRs were telmisartan (19.4%) followed by atenolol (11.22%) (Table 7). Among dual therapy patients 114 patients were experiencing various ADRs and maximum numbers were due to telmisartan+hydrochlorothiazide (17.54%) (Table 8). Further among triple therapy out of 183 patients 41 (22.40%) of the patients were experiencing various ADRs and maximum patients were due to atenolol+chl orthalidone+telmisartan (19.51%) (Table 9).

DISCUSSION

Current study showed the status of patients according to gender wise i.e. 57.33% of the patients were belonged to male and 42.27% of the patients were belonged to female gender while various studies were conducted by different authors and described different status. According to another study[10] the male was 50.5% and female was 40.5%. According to current study the prescribing status were based on different therapies i.e. 35.4% were on monotherapy and 64.6% were on combinations therapies i.e. dual, triple and quadruple therapies. While Krunal[11] reported that 49.50% of patients were on dual therapy, 33.16% of the patients were on monotherapy and 15.5% of patients were on triple therapy. Further present study described that out of 1260 dual therapy patients the most prescrib-

Table 4: List of Antihypertensive medicines Prescribed as Dual Therapy Patients (n=542)

Prescribed Medicines	Frequency	Percent	Cumulative Percent
Valsartan + Amlodipine	65	11.99%	11.99%
Atenolol + Chlorthalidone	36	6.64%	18.63%
Telmisartan + hydrochlorothiazide	80	14.76%	33.39%
Valsartan + hydrochlorothiazide	26	4.8%	38.19%
Amlodipine + Perindopril	31	5.72%	43.91%
Lisinopril + hydrochlorothiazide	27	4.98%	48.89%
Losartan + hydrochlorothiazide	41	7.56%	56.45%
Enalapril + hydrochlorothiazide	21	3.87%	60.32%
Candesartan + hydrochlorothiazide	17	3.14%	63.46%
Amlodipine + Telmisartan	44	8.12%	71.58%
Losartan + Spiranolactone	12	2.21%	73.79%
Candesartan + Spiranolactone	17	3.14%	76.93%
Propanolol + Frusemide	20	3.69%	80.62%
Amiloride + hydrochlorothiazide	15	2.77%	83.39%
Amlodipine + Ramipril	14	2.58%	85.97%
Enalapril + Frusemide	9	1.66%	87.63%
Frusemide + Amiloride	31	5.72%	93.35%
Lisinopril + Verapamil	7	1.3%	94.65%
Ramipril + Hydrochlorothiazide	29	5.35%	100%
Total	542	100.0%	-

Table 5: List of Antihypertensive medicines Prescribed as Triple Therapy in combined therapy Patients (n=183)

Prescribed Medicines	Frequency	Percent	Cumulative Percent
Valsartan+ hydrochlorothiazide + Amlodipine	25	13.66%	13.66%
Atenolol + Chlorthalidone + Telmisartan	28	15.30%	28.96%
Telmisartan + hydrochlorothiazide + Propanolol	13	7.10%	36.06%
Valsartan + hydrochlorothiazide + Atenolol	23	12.57%	48.63%
Amlodipine + Perindopril + αMD	10	5.46%	54.09%
Lisinopril + hydrochlorothiazide + αMD	9	4.92%	59.01%
Losartan + hydrochlorothiazide + αMD	24	13.11%	72.12%
Enalapril + hydrochlorothiazide + Atenolol	15	8.20%	80.32%
Amlodipine + Telmisartan + Metoprolol	11	6.01%	86.33%
Propanolol + Hydrochlorothiazide + Telmisartan	8	4.37%	90.7%
Ramipril+Hydrochlorothiazide+Propanolol	17	9.30%	100%
Total	183	100.0%	

Table 6: List of Antihypertensive medicines Prescribed as Quadruple Therapy (n=87)

Prescribed Medicines	Frequency	Percent	Cumulative Percent
Valsartan + Amlodipine + Atenolol + Chlorthalidone	15	17.24%	17.24%
Atenolol+Chlorthalidone+Telmisartan + αMD	23	26.44%	43.68%
Telmisartan + hydrochlorothiazide + Propanolol + αMD	10	11.50%	55.18%
Amlodipine + Telmisartan + Enalapril + hydrochlorothiazide	17	19.54%	74.72%
Amlodipine+Perindopril+Telmisartan+αMD	9	10.34%	85.06%
Candesartan+hydrochlorothiazide+Amlodipine + Propanolol	13	14.94%	100%
Total	87	100.0%	-

Table 7: Drug wise ADRSs reported in Monotherapy Patients

Prescribed Medicines	Frequency of ADRs	Percent	Cumulative Percent
Furesimide	3	3.06%	3.06%
Spironolactone	2	2.04%	5.1%
Hydrochlorothiazide	3	3.06%	8.16%
Atenolol	11	11.22%	19.38%
Propanolol	9	9.20%	28.58%
Amlodipine	10	10.20%	38.78%
Nifedipine	6	6.12%	44.90%
Enalapril	7	7.14%	52.04%
Perindopril	1	1.02%	53.06%
Ramipril	10	10.20%	63.26%
Candesartan	0	0	63.26%
Lisinopril	2	2.04%	65.30%
Captopril	2	2.04%	67.34%
Telmisartan	19	19.4%	86.74%
Bisoprolol	1	1.02%	87.76%
Carvedilol	1	1.02%	88.78%
Valsartan	3	3.06%	91.84%
Felodipine	2	2.04%	93.88%
Verapamil	1	1.02%	94.9%
Benzapril	1	1.02%	95.92%
Losartan	3	3.06%	98.98%
Metoprolol	1	1.02%	100%
Total	98	100.00%	-

Table 8: Drug wise ADRSs reported in Dual therapy Patients

Prescribed Medicines	ADRs reported in GTCH	Percent
Valsartan + Amlodipine	11	9.65%
Atenolol + Chlorthalidone	6	5.26%
Telmisartan + hydrochlorothiazide	20	17.54%
Valsartan + hydrochlorothiazide	3	2.63%
Amlodipine + Perindopril	5	4.40%
Lisinopril + hydrochlorothiazide	6	5.26%
Losartan + hydrochlorothiazide	4	3.51%
Enalapril + hydrochlorothiazide	6	5.26%
Candesartan + hydrochlorothiazide	3	2.63%
Amlodipine + Telmisartan	9	7.90%
Losartan + Spiranolactone	4	3.51%
Candesartan + Spiranolactone	2	1.75%
Propanolol + Frusemide	7	6.14%
Amiloride + hydrochlorothiazide	2	1.75%
Amlodipine + Ramipril	6	5.26%
Enalapril + Frusemide	3	2.63%
Frusemide + Amiloride	8	7.02%
Lisinopril + Verapamil	2	1.75%
Ramipril + Hydrochlorothiazide	7	6.14%
Total	114	100.0%

Table 9: Drug wise ADRSs reported in Triple therapy Patients

Prescribed Medicines	ADRs reported in GTCH	Percent
Valsartan + hydrochlorothiazide + Amlodipine	5	12.20%
Atenolol + Chlorthalidone + Telmisartan	8	19.51%
Telmisartan + hydrochlorothiazide + Propanolol	2	4.87%
Valsartan + hydrochlorothiazide + Atenolol	4	9.76%
Amlodipine + Perindopril + αMD	1	2.44%
Lisinopril + hydrochlorothiazide + αMD	4	9.76%
Losartan + hydrochlorothiazide + αMD	2	4.87%
Enalapril + hydrochlorothiazide + Atenolol	1	2.44%
Amlodipine + Telmisartan + Metoprolol	6	14.63%
Propanolol + Hydrochlorothiazide + Telmisartan	3	7.32%
Ramipril + Hydrochlorothiazide + Propanolol	5	12.20%
Total	41	100.0%

ing combination was Telmisartan+Hydrocholorthiazide with 12.06% followed by valsartan+amlodipine with 11.50% but krunal reported the most combination dual therapy was enalapril+atenolol with 22% followed by enalapril+amlodipine with 10.83%. Moreover among triple therapy according to current therapy the most prescribing combination was ena lapril+hydrochlorothiazide+atenolol with 14.70% followed by valsartan +hydrochlorothiazide+amlodipine with 13.98% but krunal reported the most combination triple therapy were enalapril+atenolol+amlodipine with 8% followed by enalapril+atenolol+frusemide with 4.16%. The quadruple therapy was also assessed in current study and it was found that the most common combination was valsartan+amlodipine+atenol+chlo rthalidone with 22.81% while krunal described the enalapril+atenolol, amlodpine+furosemide with 1.66%. According to krunal study out of 600 patients, 15.83% of the patients were developed different ADRs while in current study out of 1062 patients from monotherapy the total ADRs were 19.30% that was more than krunal study. Another Study conducted by Singh[12] and according to that study a total of 4850 patients were enrolled and most of the patients were belonged to male gender same as to the current study. Further 24.07% of the patients were having various ADRs by taking antihypertensive medications while in current study 19% ADRs present in monotherapy patients and more than 19% present in various combinations therapy.

CONCLUSION

The existing passive pharmacovigilance department should be active again under Drug regulatory authority of Pakistan. A council will create under the Drug regulatory authority of Pakistan that helps to communicate with international organizations such as Uppsala monitoring center under World Health Organization, Food and Drug Administration etc. Moreover council will also establish a system of ADRs reporting throughout the country and then data will share with all stake holders. All HCPs must follow the guidelines that were released by WHO. The guidelines are more focus on education of patients related with drug safety. Training is an integral part of education so there should be a proper training to our health care providers including Doctors, Pharmacists, Nurses etc that how to report the ADRs and where to report the ADRs. Drug regulatory authority should also establish the centers in all cities for reporting the ADRs. A proper functional website should be launched and accessed by all stake holders including patients. This website must be connected with international data about safety.

ACKNOWLEDGEMENTS

I praise to the Almighty Allah (The Most Merciful, Gracious and The Most Compassionate), Who is the entire and only source of every knowledge, Who guides me in the obscurity and helps me out of difficulties, and Prophet Hazrat Mohammad Mustafa (Salallah-o-Alaihe Wasallim), whose teachings provide the spirit of learning the hidden and unconcealed facts of nature, for my spiritual guidance for me to carry this work.

I am also thankful to all whoever helps me to conduct this research work. Moreover I am extremely grateful to Higher Education Commission (HEC) for their entire support in this study.

CONFLICT OF INTEREST

There is co any conflict of interest.

ABBREVIATIONS USED

ADRs: Adverse Drug reactions; **HCPs:** Health care professional; **GIT:** Gastro Intestinal tract; **ACEis:** Angiotensin Converting enzyme inhibitors; **CCBs:** Calcium Channel Blockers; **WHO:** World health organization.

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