Original Research Article

Prescribing pattern and adverse drug reactions of anti hypertensive drugs in Kishanganj hospital

Simar Deep Singh[1*], Jagmehak Kaur Satyal[2]

[1]Final Year PGT, [2]UG Student, Department of Medicine, M.G.M. Medical College and L.S.K. Hospital Kishanganj. Bihar, INDIA.
Email: simardeep17@gmail.com

Abstract

Irrational drug prescribing is a common practice globally; it results in increased morbidity, mortality and economic burden on society. Drug utilisation studies are an important tool to promote rational prescribing. **Methods:** The subjects' screening and recruitment was carried out at the Department of General Medicine, M.G.M Medical College and L.S.K Hospital, Kishanganj, Bihar. The entire study starting from patient recruitment, data collection, data analysis to reporting took about one year starting from 1st March 2015 to 31st February2016. The patients those are diagnosed as a newly hypertensive are entered in this study except those are matched with exclusion criteria. The treatment was started as per advice of the treating Physician. On next visit the other parameters like Lipid Profile, Blood Urea, Serum Creatinine, Thyroid function test, Blood Sugar, Uric Acid, ECG, Echo Cardiography, CBC, are also reviewed along with monitor of blood pressure. Total 500 randomly selected patients, aged from 18 to 69 yrs, those were attend in the outpatients Department of Medicine, during the study period, who are newly diagnosed as hypertensive or previously diagnosed hypertensive but not started the medication were included initially in my study. **Result:** Age and Sex wise distribution of the study population. Total 219 Patients were diagnosed with essential hypertension who were selected for my study. For each patient the age, gender, age at which hypertension was diagnosed; In our study 121(55.25%) patients were males and 98(44.75%) patients were females ratio was 1:0.80. distribution of mono therapy treatment of the study population. It observed, Patients those were under treatment of CCB -79 (55.24%), Diuretics - 41(28.68%), ACEI - 8 (5.59%), ARB – 8 (5.59%), and β- Blocker -7 (4.89%), out of 143 Patients. **Conclusion:** This prospective, observational study on assessment of prescribing pattern for hypertension confirmed that mono therapy was prescribed than the combination therapy. Specify with the guidelines, the most frequently prescribed drug class followed by CCB, diuretics, ARBs and ACEI, beta blockers. When considering combination therapy, two drug combination was prescribed. In two drug combination, CCB+Diuretics was mostly prescribed. Regarding the perception of physicians towards JNC 8 guidelines it was found that majority were following JNC 8 guidelines

Key Word: Prescribing pattern, adverse drug reactions.

Address for Correspondence
Dr. Simar Deep Singh Department of Medicine, M.G.M. Medical College and L.S.K. Hospital Kishanganj Bihar, INDIA.
Email: simardeep17@gmail.com
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INTRODUCTION

Hypertension is a major contributor to cardiovascular morbidity and mortality in India and worldwide[1]. The magnitude of the problem in industrialised and westernised population has been well investigated and documented. Blood pressure (BP) has been found to be increasing with age[2] the rise being steeper in men than women; after menopause women showing greater rise and reaching levels higher than men[1]. Alcohol intake, body mass index and social class all are important in this context[2]. In most non-industrialised populations rise of BP with increasing age is not an obligatory finding. A stable level of BP in adults is a common finding[5].

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Migration studies have clearly documented rise of BP in populations who migrated from rural to urban areas. Various factors at play mediating rise of BP in urban setting are increased intake of calories, salt, animal proteins, saturated fat and alcohol and increased exposure to stressful events[2]. A meta-analysis of nine major observational studies involving 4,20,000 individuals free of cardiovascular and cerebrovascular diseases at baseline and followed up for 6 to 25 years showed a direct, continuous and apparently independent association of diastolic blood pressure (DBP) with both stroke and coronary arterial disease[3]. Pharmacological therapy to control BP was shown in a large number of randomized controlled trials to prevent cardiovascular and cerebrovascular events such as heart attacks and strokes[4,5]. Major classes of drugs used in pharmacotherapy of hypertension include, (1)Diuretics (2) Antiadrenergic Agents (3) Vasodilators (4) Angiotensin Converting Enzyme Inhibitors (5) Angiotensin Receptor Antagonists (6) Calcium Channel Blockers. Each class has its own efficacy profile as well as characteristic adverse drug reactions. Limitations of efficacy as well as unwanted side effects associated with each class of antihypertensives has led to almost non-stop search for new drugs to treat hypertension over last five decades. Before 1950, hardly any effective and well tolerated antihypertensive was available. Veratrum and Sodium thiocyanate though capable of lowering BP, were toxic and difficult to use. Ganglion blockers (Mecamylamine) introduced in mid-fifties had unacceptable severe side effects. Reserpine also enjoyed immense popularity in fifties and sixties but caused mental depression. In sixties and seventies alpha-methyldopa, alphablockers, diuretics and clonidine ruled as antihypertensives of choice. Beta-blockers came into widespread use from mid-seventies and are one of the most popular initial antihypertensives till now. In the eighties and nineties calcium channel blockers and angiotensin converting enzyme (ACE) inhibitors ruled the roost as antihypertensives. Angiotensin receptor antagonists and potassium channel openers are relatively recent introductions in the ever expanding armamenterium against elevated blood pressure.

METHODS

This prospective and comparative study was done to assess prescribing pattern and adverse drug reactions of anti hypertensive drugs in a tertiary care teaching hospital-Bihar. Apart from clinical efficacy, the coast effective and the safety profile of the prescribed medicine were also evaluated (ADR).

Settings

The subjects' screening and recruitment was carried out at the Department of General Medicine, M.G.M Medical College and L.S.K Hospital, Kishanganj, Bihar. The study was carried out to the Patients those are attending at OPD, Department of General Medicine,

Study period:

The entire study starting from patient recruitment, data collection, data analysis to reporting took about one year starting from 1st March 2015 to 31st February2016

Study design:

The current study had been designed as a post-registration, prospective, open label study. The patients those are diagnosed as a newly hypertensive are entered in this study except those are matched with exclusion criteria. The treatment was started as per advice of the treating Physician. On next visit the other parameters like Lipid Profile, Blood Urea, Serum Creatinine, Thyroid function test, Blood Sugar, Uric Acid, ECG, Echo Cardiography, CBC, are also reviewed along with monitor of blood pressure. In case adequate control of blood pressure i.e. sitting mean diastolic blood pressure (DBP) below 90 mm Hg, And Systolic blood pressure (<140 mm Hg) was not achieved with initial dose of the prescribed medicine, the dose was increased at subsequent follow up visits. If blood pressure was not controlled by the increased dose, the optimum dose of the initial medicine was advised on subsequent follow up visit. If blood pressure was not controlled with the optimum dose of the initial medicine the patients was advised to take more than one medicines MDT to control the blood pressure. In this study, some patients who were treated with ACEI complain dry cough, some patients presented with ankle oedema those were treated with CCB, some patients complaining weakness along with muscle cramping pain those were treated with Diuretics and one patients complaining about impotency who was treated with Diuretics (Thiazied Diuretics) the prescribed initial medicine was changed accordingly as per advise of treating physician. Moreover we also review the cost effective outcome of the treatment. As we know the hypertension is not a curable disease and regular medicine is needed for life long for controle the BP. The most of the patients those are attending at the OPD were belong to Below the Poverty level, cost of the medicine is one of the most important factor which will minimize the droop out form the treatment. It was a study of pharmaco economical study also.

Study population and patient selection:

Total **500** randomly selected patients, aged from 18 to 69 yrs, those were attend in the outpatients Department of Medicine, during the study period, who are newly diagnosed as hypertensive or previously diagnosed hypertensive but not started the medication were included

initially in my study. All the cases were diagnosed by the senior Professor of Medicine. Cases with diagnosed Hypertension were further evaluated on the basis of laboratory and radiological investigations for screening of Co-morbid diseases. Out of the study population, 219 patients, were selected on the basis of inclusion and exclusion criteria.

RESULTS

Table 1: Age and Sex wise distribution of the study population

Age and Sex wise distribution of study population						
Age Distribution	Male	Percentage	Female	Percentage	Total	Percentage
>18-29	16	7.30%	12	5.48%	28	12.80%
30-39	47	21.47%	45	20.55%	92	42.00%
40-49	56	25.58%	40	18.27%	96	43.85%
50-59	1	0.45%	1	0.45%	2	0.90%
60-69	1	0.45%	0	0.0%	1	0.45%
Total	**121**	**55.25%**	**98**	**44.75%**	**219**	**100%**

Table 2: Age and Sex wise Distribution of the Study Population Diagnosed Stage I Hypertension

Age and Sex wise distribution of study population Diagnosed Stage I Hypertension						
Age Distribution	Male	Percentage	Female	Percentage	Total	Percentage
>18-29	14	8.43%	11	6.63%	25	15.07%
30-39	38	22.89%	36	21.68%	74	44.57%
40-49	34	20.48%	32	19.27%	66	39.75%
50-59	1	0.61%	0	0%	1	0.61%
60-69	0	0%	0	0%	0	0%
Total	**87**	**52.41%**	**79**	**47.58%**	**166**	**100%**

Table 3: Age and Sex wise Distribution of the Study Population Diagnosed Stage II Hypertension

Age and Sex wise distribution of study population Diagnosed Stage II Hypertension						
Age Distribution	Male	Percentage	Female	Percentage	Total	Percentage
>18-29	2	3.78%	1	1.88%	3	5.67%
30-39	9	16.98%	9	16.98%	18	33.96%
40-49	22	41.51%	8	15.09%	30	56.61%
50-59	0	0%	1	1.88%	1	1.88%
60-69	1	1.88%	0	0%	1	1.88%
Total	**34**	**64.15%**	**19**	**35.84%**	**53**	**100%**

Table 4: Sex wise distribution of Mono therapy treatment of the study population in different age group

Sex wise distribution of mono therapy of study population in different age group						
Age Distribution	Male	Percentage	Female	Percentage	Total	Percentage
>18-29	13	9.10%	10	6.99%	23	16.09%
30-39	29	20.28%	33	23.07%	62	43.36%
40-49	26	18.19%	30	20.98%	56	39.17%
50-59	1	0.69%	0	0%	1	0.69%
60-69	1	0.69%	0	0%	1	0.69%
Total	**70**	**48.95%**	**73**	**51.04%**	**143**	**100%**

Table 5: Age wise distribution of mono therapy treatment of the study population

Age	CCB	%	Diuretics	%	ACEI	%	ARB	%	β Blocker	%	Total	%
>18-29	15	10.48%	0	0%	1	0.69%	1	0.69%	6	4.19%	23	16.08%
30-39	37	25.88%	21	14.69%	0	0%	3	2.09%	1	0.69%	62	43.37%
40-49	25	17.49%	20	13.99%	7	4.89%	4	2.79%	0	0%	56	39.17%
50-59	1	0.69%	0	0%	0	0%	0	0%	0	0%	1	0.69%
60-69	1	0.69%	0	0%	0	0%	0	0%	0	0%	1	0.69%
Total	79	55.24%	41	28.68%	8	5.59%	8	5.59%	7	4.89%	143	100%

Table 6: Sex wise distribution of Multi Drug treatment of the study population in different age group

Sex wise distribution of Multi Drug treatment of the study population						
Age Distribution	Male	Percentage	Female	Percentage	Total	Percentage
>18-29	3	3.95%	2	2.63%	5	6.58%
30-39	18	23.68%	12	15.78%	30	39.47%
40-49	30	39.48%	10	13.16%	40	52.64%
50-59	0	0%	1	1.31%	1	1.31%
60-69	0	0%	0	0%	0	0%
Total	51	67.11%	25	32.88%	76	100%

Table 7: Age wise distribution of Multi Drug treatment of the study population

Age wise distribution of Multi Drug treatment of the study population									
Age	CCB + Diuretics		Diuretics with ACEI/ARB		CCB + β Blocker		CCB+ ARB /ACEI		Total Patients
>18-29	0	0%	0	0%	4	5.26%	1	1.31%	5 (6.57%)
30-39	12	15.79%	2	2.63%	8	10.52%	8	10.52%	30 (39.48%)
40-49	27	35.53%	5	6.57%	2	2.63%	6	7.89%	40 (52.64%)
50-59	1	1.31%	0	0%	0	0%	0	%	1(1.31%)
60-69	0	0%	0	0%	0	0%	0	%	0(0%)
Total	**40**	**52.63%**	**7**	**9.21%**	**14**	**18.42%**	**15**	**19.73%**	**76(100%)**

Adverse Drugs Reaction

All the patients started with mono therapy treatment during base line visit with different group of anti hypertensive drugs, 14 patients developed some ADR in subsequent visits.

- Patients treated with CCB(Amlodipin) presented with ankle oedema – No of patients were -9 (Nine)
- Patients treated with ACEI(Enalapril) complained with dry cough at night – No of patients were -02 (Two)
- Patients treated with Diuretics (Chlorthiadilone and Hydrochlorthiadilone) presented with un explained weakness and orthostatic hypotension–No of patients were-02 (Two) and 1(One) patient complained with erectile dysfunction.

This 14 patients were sifted to either mono therapy to other group of anti hypertensive drugs or multi drug treatment.

Table 8: Distribution of patients having ADR in respect of total number of study population

Total Number of Patient	Number of patient diagnosed with ADR	Percentage of patients with ADR	p Value
219	14	6.39%	0.000

Table 9: Distribution of patients developed ADR who received different group of anti hypertensive drugs

Total Number of Patients with ADR	No of patients developed ADR treated with CCB	Percentage of patients	No of patients developed ADR treated with ACEI	Percentage of patients	No of patients developed ADR treated with Diuretics	Percentage of patients
14	9	64.29%	2	14.28 %	3	21.43 %

Table 10: prescribing pattern of mono therapy treatment in my study population

Prescribing pattern of mono therapy treatment in my study population												
Age	CCB	%	Diuretics	%	ACEI	%	ARB	%	β Blocker	%	Total	%
Total	79	55%	41	29%	8	5%	8	6%	7	5%	143	100%

Table 11: Prescribing pattern of multi drug treatment in my study population

Prescribing pattern of multi drug treatment in my study population									
Age	CCB + Diuretics		Diuretics with ACEI/ARB		CCB + β Blocker		CCB+ ARB /ACEI		Total Patients
Total	40	53%	7	9%	14	18%	15	20%	76(100%)

DISCUSSION

Antihypertensive drugs are prescribed mainly to reduce the morbidity and mortality caused by hypertension and its complications. Many a time, patients require more than one drug for effective control of hypertension. Various classes of antihypertensive drugs like diuretics, inhibitors of the renin-angiotensin system, calcium channel blockers (CCB) and beta blockers (BB) have been shown to reduce complications of hypertension and may be used for initial drug therapy[7].

Since the need to improve the control of hypertension is well acknowledged, several guidelines on its classification and management have been developed. Some of the bodies which have developed guidelines are American Society of Hypertension/ International Society of hypertension (ASH/ISH), Joint National Committee (JNC) on Detection, Evaluation, and Treatment of High Blood Pressure, European Society of Hypertension (ESH)/European Society of Cardiology (ESC), National Institute for Health and Care Excellence (NICE) and Japanese Society of Hypertension. The JNC[8] guidelines published in 2014 are the most recent guidelines for the management of hypertension in different clinical settings. These guidelines were developed based on a systematic review of literature to help clinicians, especially the primary care physicians[6]. Despite these guidelines, and also evidence showing that hypertension is a major public health concern, many clinicians fail to assess BP routinely, and in those with a diagnosis of hypertension, do not start treatment or titrate the dosage of the drugs effectively[8]. The available guidelines recommend different goal BP levels and drug treatment options according to patients' individual clinical need Studies have shown that the application of guidelines to clinical practice improve the treatment outcomes. According to a retrospective study by Jackson *et al* . on 19,258 patients, applying JNC-7 guidelines to practice helped in achieving better BP control. Blood pressure control in the before-JNC 7 cohort was 40.8 % vs. 49.3 % in the after-JNC 7 cohort ($p < 0.0001$)[9]. The Table:1. shows Age and Sex wise distribution of the study population. Total 219 Patients were diagnosed with essential hypertension who were selected for my study. For each patient the age, gender, age at which hypertension was diagnosed; In our study 121(55.25%) patients were males and 98(44.75%) patients were females ratio was 1:0.80 The Table:2 Shows Age and Sex wise Distribution of the Study Population Diagnosed Stage I Hypertension at baseline visit, In our study 87(52.41%) patients were males and 79(47.58%) patients were females out of 166 patients, ratio was 1:0.90 The Table: 3 Shows Age and Sex wise Distribution of the Study Population Diagnosed Stage II Hypertension at baseline visit, In our study 34(64.15%) patients were males and 19(35.84%) patients were females out of 53 patients, ratio was 1:0.56 The Table: 4 shows Age and Sex wise distribution of the study population under mono therapy treatment. In our study 70(48.95%) patients were males and 73(51.04%) patients were females out of 143 patients, ratio was 1:1.04 The Table:5 Shows age wise distribution of mono therapy treatment of the study population. It observed, Patients those were under treatment of CCB -79 (55.24%), Diuretics - 41(28.68%), ACEI - 8 (5.59%), ARB –8 (5.59%), and β- Blocker-7 (4.89%), out of 143 Patients. The Table: 6 Shows age wise distribution of Multi Drug treatment of the study population. In our study 51(67.11%) patients were males and 25(32.88%) patients were females out of 76 patients, ratio was 1:0.49 The Table: 7 Shows age wise distribution of Multi Drug treatment of the study population. It observed, Patients those were under treatment of CCB+ Diuretics -40 (52.63%), Diuretics + ACEI/ARB - 7(9.21%), CCB + β-Blocker - 14(18.42%), CCB + ARB/ ACEI 15 (19.73%) out of 76 Patients. Table:8. 14 patients developed ADR during course of treatment among 219 patients. Table: 9. Among 14 patients who were developed ADR,[9] patients developed ADR due to CCB (Amlodipin), 2 patients developed ADR due to ACEI (Enalapril), 3 patients developed ADR due to Diuretics Table: 10 In my study it was observed that the commonly prescribing anti hypertensive drugs were CCB(55%) followed by diuratics (29%), ACEI (5%), ARB (6%) and β-Blocker (5%) Table:11 In my study, it was observed that the commonly prescribed multi drugs for the treatment of hypertensive patients were CCB+ Diuretics(53%) followed by CCB+ ARB/ACEI (20%), CCB + β-Blocker(18%), ACEI/ARB + Diuretics (9%). Evaluation of the parameters was done as per WHO indicator guideline for drugs prescribing for essential hypertension.(Stage I and Stage II).

CONCLUSION

This prospective, observational study on assessment of prescribing pattern for hypertension confirmed that mono therapy was prescribed than the combination therapy. Specify with the guidelines, the most frequently prescribed drug class followed by CCB, diuretics, ARBs and ACEI, beta blockers. When considering combination therapy, two drug combination was prescribed. In two drug combination, CCB + Diuretics was mostly prescribed. Regarding the perception of physicians towards JNC 8 guidelines it was found that majority were following JNC 8 guidelines. It was observed, during the study period, that the medicine (Amlodipin) which was mostly prescribed , very economical to the community participants and the medicine was very much potent anti hypertensive drug and well control the blood pressure

level. More over the medicines (Both mono therapy and MDT) which prescribed to the patients were available at pharmacy in M.G.M. Medical College, Kishanganj, Bihar. So patients complaints was very much satisfactory. The patients dropout was very much minimum because of availability of medicines at pharmacy counter. Which was also a major contributory part of my study to reduce the minimum patient's dropout.

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