

DOI: <https://dx.doi.org/10.18203/2319-2003.ijbcp20262869>

Original Research Article

Evaluation of rational use of drugs used in hypertension in a tertiary care hospital: a cross-sectional observational study

Suneel I. Majagi^{1*}, Devasena Manohar², Jagadeesh Gaddeppanavar³

¹Department of Pharmacology, Gadag Institute of Medical Sciences, Gadag, Karnataka, India

²Department of Pharmacology, Pondicherry Institute of Medical Sciences, Puducherry, India

³Department of General Medicine, Gadag Institute of Medical Sciences, Gadag, Karnataka, India

Received: 07 March 2026

Accepted: 06 August 2026

*Correspondence:

Dr. Suneel I. Majagi,

Email: suneelmajagi@yahoo.co.in

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ABSTRACT

Background: Hypertension is a major public health problem due to increased morbidity, mortality and cost to the public. Various group of antihypertensive drugs are used in the management of hypertension. Criteria like medications appropriate to the clinical needs, required individual doses, adequate period and lowest cost are considered during rational use of medicines. Irrational prescribing can cause increased morbidity, mortality, adverse drug reactions (ADRs), and economic burden. World Health Organization (WHO) stress the need to promote rational use of drugs. Hence the present study has been planned to evaluate rational use of antihypertensive drugs according to the WHO guidelines.

Methods: Present study design is a cross-sectional observational study. Data regarding antihypertensive drugs was collected as per WHO guidelines viz., details of prescriptions, patient counselling and drugs. Details of co-morbid illnesses, ADRs, precautions and contraindications were also noted. Standard statistical tests were used to analyse the data and the study was approved by the institutional ethics committee.

Results: Various criteria required for rational use of medicines in regard to prescription, patient counsel and drugs were followed in all (100%) the patients. Diuretics caused ADRs in a greater number of patients. More patients suffered from ADRs affecting central nervous system followed by gastro intestinal tract, and cardio vascular system. No precautions and contraindications were found for any of the prescribed drug.

Conclusions: WHO-rational use criteria and joint national committee (JNC) 8 guidelines were adhered. Medical council registration number and stamp have to be mentioned in the prescription. Prescriptions of generic name drugs must be promoted.

Keywords: Drugs, Hypertension, Rational

INTRODUCTION

Hypertension, two-thirds of cases which occur in low and middle-income countries, is a growing concern because of its association with morbidity, complications, mortality and costs.¹⁻⁴

Management of hypertension often involves use of different classes of drugs (e.g., beta-blockers, diuretics, and calcium channel blockers) and adherence to standard guidelines.⁵⁻⁷ Rational drug use includes use of appropriate

drugs, individualised doses, adequate period and lower cost.⁸ Conversely, irrational (under, over, incorrect, extravagant, or multiple use of drugs) prescribing exacerbates adverse outcomes and expenses.⁹⁻¹¹

World Health Organization (WHO) advocates rational drug use, but studies on rational antihypertensive drug use are scarce.¹² Hence the present study evaluates rational drug use in hypertensive patients as per WHO guidelines at a tertiary care hospital.

METHODS

Present cross sectional observational study was conducted over a period of two years during July 2022 to July 2024. Sample size (purposive sampling) consisted 1422 hypertensive patients, which was calculated based on a prevalence of previous study.³

Data, at a single point, was obtained from the hypertensive patients visiting outpatient department (OPD) of general medicine in the tertiary care hospital.¹³ Hypertensive patients of both the gender were included in the study. Patients below 18 years of age and pregnant women with hypertension were excluded from the study.

Data regarding rational use of antihypertensive drugs was collected as per WHO guidelines. Data was mainly collected in three categories.

Prescription's details

Details included designation of the prescriber and medical council registration number; patient information like name, gender, age and place; date of dispensing, diagnosis including comorbid condition, documentation of details of prescription, hospital name, signature of the prescriber, stamp, confirmation of dispensed drugs by the prescriber.

Details of patient counselling

Records were obtained under the headings like whether patient understood the instructions, patient's issues were clarified, storage instructions given and patient signature was obtained.

Details of drugs

Drugs details included information regarding total number of drugs, presence of appropriate indication for the drug, dose, frequency, duration of treatment, duplication of same drug or same class of drug, brand name, generic name, compliance issues, any allergy, any precautions, any contraindications, possible drug- drug interaction and cost.

Data regarding co-morbid illnesses, adverse drug reactions (ADRs), precautions and contraindications were also collected.

Data was analysed by using standard statistical tests by using statistical package for the social sciences (SPSS) software. Descriptive statistics like frequency, mean etc were used. Study was approved by the institutional ethics committee (IEC). Informed written consent was obtained from each patient before recruiting into the study.

RESULTS

Analysis of data regarding prescriptions revealed that each prescription of 1422 patients contained: designation of the prescriber; patient's information like name, gender, age

and place; date of dispensing; diagnosis; documentation of prescription; hospital name; signature of the prescriber; confirmation of the dispensed drugs by the prescriber. Details of co-morbid conditions were mentioned in all the 696 (100%) prescriptions. Medical council registration number and stamp was not found in any of the prescription.

Assessment of data regarding patient counselling revealed that each patient understood instructions regarding the drug dosage/frequency, route of administration as well as storage of the drugs. Each patient's issues/doubts were clarified. Signature was obtained from all the hypertensive patients regarding the same.

Analysis of data regarding drugs revealed that overall, a total of 2538 drugs and 1509 antihypertensive drugs were prescribed. Appropriate drug was chosen for the condition. Correct dose, frequency and duration of treatment were written for all the drugs (both for overall and antihypertensive drugs). Duplication of same drug or same class of drug was not found in any of the prescription. Precautions, contraindications, allergies and possible drug-drug interactions were not found for any of the drug in all the prescriptions. There were no compliance issues and all the drugs were supplied free of cost to the patients.

Among 2538 overall drugs, 1359 (53.54%) drugs were prescribed with brand name while 1179 (46.45%) drugs were prescribed with generic name. Whereas out of 1509 antihypertensive drugs, 1011 (66.99%) drugs were prescribed with brand name and 498 (33.00%) drugs were prescribed with generic name.

Blood pressure (BP) of 1422 hypertensive patients was measured and assigned into different BP category as per American Heart Association guidelines.³ A total of 28 (1.97%) patients belonged to normal category [systolic blood pressure (SBP) <120 mmHg and diastolic blood pressure (DBP) <80 mmHg], 14 (0.98%) patients belonged to elevated BP category (SBP=120-129 mmHg and DBP <80 mmHg), 80 (5.62%) patients belonged to stage 1 Hypertension category (SBP=130-139 mmHg or DBP=80-89 mmHg) and a total of 1300 (91.42%) patients belonged to stage 2 hypertension category (SBP ≥140 mmHg or DBP >90 mmHg). Out of 1422 hypertensive patients, a total of 696 patients had co-morbid conditions (Table 1). A total of 152 patients developed ADRs for different classes of antihypertensive drugs. Details of data regarding ADRs has been shown in Table 2. Details of systemwise distribution of ADRs to antihypertensive drugs is shown in Table 3. Outcome of treatment in hypertensive patients were evaluated as per joint national committee (JNC) 8 guidelines which was followed in the hospital for management of hypertension.¹⁴ Outcome of treatment in total hypertensive patients, without comorbid illnesses and with co-morbid illnesses has been shown in Figure 1. Outcome of treatment in individual comorbid illness have been evaluated (Table 4). Details of outcome of treatment in different gender and age groups was assessed (Figure 2).

Table 1: Details of comorbidities, precautions and contraindications in hypertensive patients.

S. no.	Co-morbidity conditions	Number of patients	Percentage I (%)	Percentage II (%)	Precautions	Contraindications
1	Diabetes mellitus	616	43.31	89.01	BB/diuretics	-
2	Ischemic heart disease	11	0.77	1.59	-	CCB except amlodipine
3	Headache	11	0.77	1.59	-	-
4	Knee pain	8	0.56	1.15	-	-
5	Upper respiratory tract infection	7	0.49	1.01	-	-
6	Dental caries	5	0.35	0.72	-	-
7	Bronchial asthma	4	0.28	0.58	-	BB/ACEI
8	Back pain	3	0.21	0.43	-	-
9	Psoriasis	3	0.21	0.43	-	-
10	Giddiness	3	0.21	0.43	-	-
11	Gastritis	3	0.21	0.43	-	-
12	Depression	2	0.14	0.29	BB	-
13	Fever	2	0.14	0.29	-	-
14	Myalgia	2	0.14	0.29	-	-
15	Urticaria	2	0.14	0.29	-	-
16	Thyroid disorder	2	0.14	0.29	-	-
17	Tenia corporis	2	0.14	0.29	-	-
18	Lower respiratory tract infection	1	0.07	0.14	-	BB/ACEI
19	Trigeminal neuralgia	1	0.07	0.14	-	-
20	Bursitis	1	0.07	0.14	-	-
21	Acute paronychia	1	0.07	0.14	-	-
22	Chronic eczema	1	0.07	0.14	-	-
23	Pterygium	1	0.07	0.14	-	-
24	Shoulder pain	1	0.07	0.14	-	-
25	Herpes	1	0.07	0.14	-	-
26	Chronic obstructive pulmonary disease	1	0.07	0.14	-	BB/ACEI
27	Chronic kidney disease	1	0.07	0.14	-	-
	Total	696	48.94	100	-	-

Percentage I is calculated as compared to total number of hypertensive patients (=1422), percentage II is calculated as compared to total number of comorbid patients (=696), CCB - calcium channel blockers, ARB - angiotensin receptor blockers, BB - beta blockers, ACEI - angiotensin converting enzyme inhibitors, ARNI - angiotensin receptor neprilysin inhibitor, C/I - contraindication

Table 2: Details of adverse drug reactions.

Class of anti-hypertensive drugs	Total no. of patients receiving the drugs	No. of patients experienced ADRs	Percentage I (%)	Percentage II (%)	Details of ADRs noted	No. of patients experienced ADRs	Percentage III (%)	Percentage IV (%)	Percentage V (%)
CCB	1099	75	5.27	6.82	Headache	25	1.75	2.27	33.33
					Pedal edema	15	1.05	1.36	20.00
					Cough	10	0.70	0.90	13.33
					Drowsiness	9	0.63	0.81	12.00
					Abdominal pain	9	0.63	0.81	12.00
					Vomiting	7	0.49	0.63	9.33
ARB	345	55	3.86	15.94	Headache	20	1.40	5.79	36.36
					Dizziness	20	1.40	5.79	36.36
					Drowsiness	15	1.05	4.34	27.27
Diuretics	13	11	0.77	84.61	Diarrhoea	3	0.21	23.07	27.27
					Itching	3	0.21	23.07	27.27
					Dizziness	2	0.14	15.38	18.18

Continued.

Class of anti-hypertensive drugs	Total no. of patients receiving the drugs	No. of patients experienced ADRs	Percentage I (%)	Percentage II (%)	Details of ADRs noted	No. of patients experienced ADRs	Percentage III (%)	Percentage IV (%)	Percentage V (%)
BB	49	10	0.70	20.40	Fatigue	2	0.14	15.38	18.18
					Difficulty in breathing	1	0.07	7.69	9.09
					Abdominal pain	5	0.35	10.20	50.00
					Diarrohea	2	0.14	4.08	20.00
					Vomiting	2	0.14	4.08	20.00
					Cough	1	0.07	2.04	10.00
ACEI	2	1	0.07	50	Cough	1	0.07	50	100
ARNI	1	-	-	-	-	-	-	-	-

Total antihypertensive drugs prescribed=1509, total number of patients experienced adverse drug reactions=152, percentage I is calculated as compared to total number of hypertensive patients (=1422), percentage II is calculated as compared to total number of patients receiving the respective class of drugs, percentage III is calculated as compared to total number of hypertensive patients (=1422), percentage IV is calculated as compared to total number of patients receiving the respective class of drugs, percentage V is calculated as patients experienced particular ADR as compared to total number of patients experienced ADR in the same class of drugs, ADR- adverse drug reaction, CCB- calcium channel blockers, ARB- angiotensin receptor blockers, BB- beta blockers

Table 3: System-wise distribution of ADRs to antihypertensive drugs.

System-wise distribution of ADRs	Central nervous system	Gastro intestinal system	Cardio vascular system	Respiratory system	Integumentary system	Musculo-skeletal system
Number of patients	91	28	15	13	3	2
Percentage I (%)	6.39	1.96	1.05	0.91	0.21	0.14
Percentage II (%)	59.86	18.42	9.86	8.55	1.97	1.31

Percentage I is calculated as compared to total number of hypertensive patients (=1422), percentage II is calculated as compared to total number of patients experienced ADRs (=152), ADR-adverse drug reaction

Table 4: Outcome of treatment in hypertensive patients with individual co-morbid illness.

Co-morbid illness (number of patients)	Target blood pressure*							
	Achieved		Not achieved					
			Only DBP un-achieved	%	Only SBP un-achieved	%	Both un-achieved	%
Diabetes mellitus (616)	188	30.51	17	2.75	293	31.33	118	19.15
Ischemic heart disease (11)	7	63.63	-	-	4	36.36	-	-
Headache (11)	4	36.36	-	-	6	54.54	1	9.09
Knee pain (8)	4	50	-	-	2	25	2	25
Upper respiratory tract infection (7)	3	42.85	-	-	2	28.57	2	28.57
Dental caries (5)	-	-	-	-	3	60	2	40
Bronchial asthma (4)	-	-	1	25	2	50	1	25
Back pain (3)	1	33.33	-	-	2	66.66	-	-
Psoriasis (3)	1	33.33	-	-	1	33.33	1	33.33
Giddiness (3)	3	100	-	-	-	-	-	-
Gastritis (3)	1	33.33	-	-	2	66.66	-	-
Depression (2)	2	100	-	-	-	-	-	-
Fever (2)	2	100	-	-	-	-	-	-
Myalgia (2)	2	100	-	-	-	-	-	-
Urticaria (2)	-	-	-	-	2	100	-	-
Thyroid disorder (2)	1	50	-	-	-	-	1	50
-----Tenia corporis (2)	-	-	-	-	-	-	2	100
Lower respiratory tract infection (1)	-	-	-	-	1	100	-	-
Trigeminal neuralgia (1)	1	100	-	-	-	-	-	-

Continued.

Co-morbid illness (number of patients)	Target blood pressure*							
	Achieved		Not achieved					
			Only DBP unachieved	%	Only SBP unachieved	%	Both unachieved	%
Bursitis (1)	-	-	-	-	1	100	-	-
Acute paronychia (1)	1	100	-	-	-	-	-	-
Chronic eczema (1)	-	-	-	-	1	100	-	-
Pterygium (1)	-	-	-	-	-	-	1	100
Shoulder pain (1)	-	-	-	-	1	100	-	-
Herpes (1)	-	-	-	-	-	-	1	100
Chronic obstructive pulmonary disease (1)	1	100	-	-	-	-	-	-
Chronic kidney disease (1)	-	-	-	-	-	-	1	100

Outcome (target BP) as per joint national committee 8 guidelines 14 viz., age ≥ 60 years [no diabetes or chronic kidney disease (CKD)]-BP goal $<150/90$ mmHg, age < 60 years [no diabetes or CKD]-BP goal $<140/90$ mmHg, all ages - diabetes present, no CKD- BP goal $<140/90$ mmHg, all ages and races - CKD present with or without diabetes - BP goal $<140/90$ mmHg, percentage is calculated as compared to total number of patients with co-morbid illness (=696), DBP - diastolic blood pressure, SBP - systolic blood pressure, BP - blood pressure

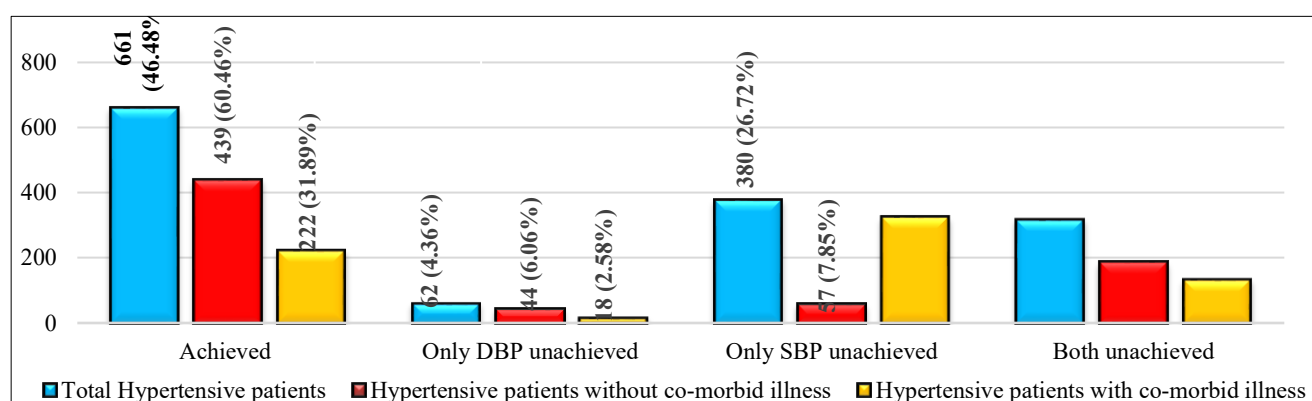


Figure 1: Outcome of treatment in hypertensive patients.

Outcome/target BP as per joint national committee 8 guidelines 14 viz., age ≥ 60 years [no diabetes or chronic kidney disease (CKD)]-BP goal $<150/90$ mmHg, age <60 years [no diabetes or CKD]-BP goal $<140/90$ mmHg, all ages - diabetes present, no CKD - BP goal $<140/90$ mmHg, all ages and races-CKD present with or without diabetes - BP goal $<140/90$ mmHg, total number of patients with hypertension, hypertension without comorbid illness and hypertension with comorbid illness were 1422,726 and 696 respectively, percentage were calculated as compared to total number of patients belonging to respective groups, DBP-diastolic blood pressure, SBP-systolic blood pressure, BP - blood pressure

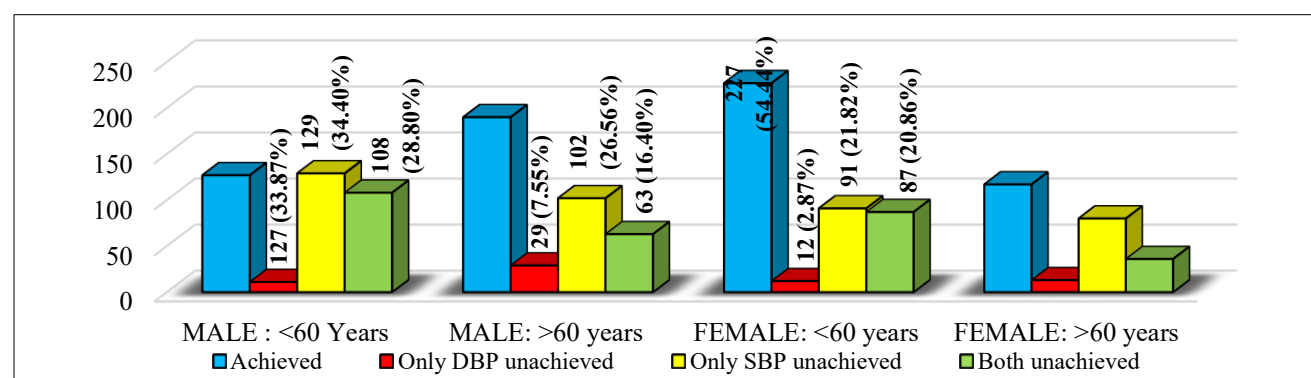


Figure 2: Outcome of treatment in hypertensive patients belonging to different age and gender (target blood pressure).

Outcome/target BP as per joint national committee 8 guidelines 14 viz., age ≥ 60 years [no diabetes or chronic kidney disease (CKD)]-BP goal $<150/90$ mmHg, age <60 years [no diabetes or CKD]-BP goal $<140/90$ mmHg, all ages- diabetes present, no CKD- BP goal $<140/90$ mmHg, all ages and races- CKD present with or without diabetes- BP goal $<140/90$ mmHg, percentage is calculated as compared to total number of patients belonging to respective groups, DBP - diastolic blood pressure, SBP - systolic blood pressure, BP - blood pressure

DISCUSSION

In the present study evaluation of rational use of drugs prescribed to hypertensive patients was carried out as per the WHO guidelines.⁸

Results of the present study indicate that each criteria of standard prescription writing like prescriber particulars, patient information etc, was followed for all the patients. But medical council registration number and stamps were missing. All criteria regarding counselling of patients like understanding of instructions, clarifying patients doubts/issues etc were fulfilled for each of the patient. Present study results regarding details of the drugs revealed that various norms regarding rational prescription of drug/s were followed. Literature review indicates a paucity of studies regarding the same.

In the present study, prescription of brand name drugs were more than the generic name drugs both in overall and antihypertensive drugs. Some studies have reported more and some studies have reported less percentage of generic drug prescription of antihypertensive drugs as compared to present study results of 33%.^{15,16} National medical council (NMC) has mandated to prescribe only generic drugs.¹⁷ Therefore prescription of generic drugs can be further promoted by organising awareness programs.

Details of comorbid condition/s was/were mentioned in the prescriptions of all patients suffering from other illnesses along with hypertension. There is a scarcity of reports regarding the same.

Results of the present study revealed that greater percentage of patients experienced ADRs who were prescribed Diuretics followed by angiotensin converting enzyme inhibitors (ACEIs), beta-blockers (BBs), angiotensin receptor blockers (ARBs) and calcium channel blockers (CCBs) in the decreasing order respectively. Other studies have reported different percentage of occurrence of ADRs associated with different antihypertensive drugs.^{18,19}

Headache and pedal edema were most common ADRs noted in patients receiving CCBs. Headache, dizziness and drowsiness were observed in patients receiving ARBs. diarrhea and itching were found to be frequent ADRs in patients receiving diuretics. Abdominal pain, diarrhea and vomiting were the more common ADRs seen in BBs prescribed patients. Among all the ADRs greater number of patients suffered from headache followed by drowsiness, dizziness, pedal edema, abdominal pain, cough etc in the decreasing order respectively.

Evaluation of system wise occurrence of ADRs to antihypertensive drugs indicate that greater number of patients suffered from ADRs affecting central nervous system (CNS) followed by gastrointestinal system, cardiovascular system (CVS), respiratory system, integumentary system (GIT) and musculoskeletal system

in the decreasing order. One study has reported that greater number of ADRs involved the CNS whereas another study has indicated involvement of CVS more than the other systems.^{18,20}

History of allergy, precautions, contraindications and possibility drug-drug interactions have to be considered while prescribing antihypertensive drugs to the patients suffering from hypertension alone or with different comorbid illnesses.^{21,22}

In the present study, factors regarding precautions, contraindications, allergy and possible drug-drug interactions were not detected. The JNC 8 hypertension guideline algorithm was followed for each patient/prescription. All the drugs with brand and generic names were supplied free of cost to the patients. There is a lack of comparative studies regarding the same.

Evaluation of effectiveness of management of hypertension indicated that 46.48% of patients achieved target blood pressure in which patients without comorbid illness were more in number than with comorbid illness patients. A study has reported similar outcomes.¹⁵

In the present study, female hypertensive patients showed good response to the treatment when compared with male hypertensive patients. Females below 60 years of age showed good response when compared to females aged more than 60 years. Whereas males above 60 years of age showed good response when compared to males aged less than 60 years. Literature review indicates a scarcity of reports in this regard.

Genetic factors can affect BP and can contribute to interindividual variability in response to antihypertensive treatment.²³ Genetic polymorphisms can influence drug response and genotype-based antihypertension therapies are the most effective.²³ In the present study, influence of genetic factors is not assessed.

CONCLUSION

In the present study, evaluation of rational use of drugs prescribed to hypertensive patients was conducted according to WHO guidelines in a tertiary care hospital. Various criteria required for rational use of medicines in regard to prescription, patient counsel and drugs were followed in all (100%) the patients. Diuretics caused ADRs in a greater number of patients. More patients suffered from ADRs affecting CNS followed by GIT, and CVS. There were no precautions and contraindications found for any of the prescribed drug. Medical council registration number and stamp must be mentioned in the prescription. Prescriptions of generic name drugs must be promoted.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Majagi SI, Manohar D, Gaddeppanavar J. Evaluation of rational use of drugs used in hypertension in a tertiary care hospital: a cross-sectional observational study. *Int J Basic Clin Pharmacol* 2026;15:974-80.