

EVALUATION OF PROPORTION AND RISK FACTOR ASSESMENT OF HYPERTENSION, RATIONALITY OF PRESCRIBING PATTERN OF ANTIHYPERTENSIVE DRUG IN CO MORBID CONDITION ACCORDING TO JOINT NATIONAL COMMITTEE(JNC) VII GUIDELINES.

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ABSTRACT

TITLE: Evaluation of proportion and risk factor assessment of hypertension, Rationality of prescribing pattern of antihypertensive drug in co morbid condition according to Joint National Committee VII guidelines in tertiary care hospital. **SCOPE OF THE EXPERIMENT:** Hypertension is the important public challenge in the world due to its high prevalence and strong association with cardiovascular disease and premature death. The guidelines that were prepared based on clinical trials, so by following this we would ensure the safety and efficacy of drugs in patients. **OBJECTIVE:** Proportion and risk factor assessment of Hypertension, Rationality of prescribing pattern of antihypertensive drugs. **METHODOLOGY:** The cases of

300 patients taking antihypertensive drugs were collected, only after the ethical committee approval. Patient who were willing to participate were included. Data were recorded and analyzed by Statistical Package for Social Science. **RESULT:** More than half of the patients, were female with age, 61-80 years. Most commonly observed risk factor was lack of physical exercise and the least were drugs. Most of the prescriptions were found to be irrational as per Joint National Committee VII guideline. **CONCLUSION:** Most patients were female with age, 61-80 yrs and common risk factor was lack of physical exercise. In patient with co morbidities, majority of the drug prescribed were irrational.

KEYWORDS: Hypertension, Rationality, Joint National Committee.

INTRODUCTION

In today's health world, the term silent killer that suits rightly to Hypertension, because of its nature. And it is the important public challenge in the world due to its high prevalence and strong association with cardiovascular disease and premature death. Hypertension is blood pressure elevated enough to perfuse tissues and organs.^[1]

It is estimated that approximately 30% of the population (50 million Americans) has high BP ($\geq 140/90$ mm Hg). Estimates from the National Health and Nutrition Examination Survey from 1999–2000 indicate that the prevalence is 30.1% and 27.1% among men and women, respectively. This represents a significant increase of 5.6% in women from 1988 to 2000, whereas the prevalence in men has remained unchanged. Prevalence rates are highest in non-Hispanic Blacks (33.5%), followed by non-Hispanic whites (28.9%) and Mexican-Americans (20.7%).^[5] BP values increase with age, and hypertension is very common in the elderly. The lifetime risk of developing hypertension among those 55 years of age and older who are normotensive is 90%. In the older population (age ≥ 60 years), the prevalence of hypertension is 65.4% (estimated in 2000), which is significantly higher than the 57.9% prevalence estimated in 1988.^[2]

In an analysis of world wide data for global burden of hypertension 20.6% Indian men and 20.9% of Indian women were suffering from hypertension in 2005. The percentage is grow up to 22.9 and 23.6 for Indian men and women, respectively by 2025. Recent studies from India have shown the prevalence of hypertension to be 25% in urban and 10% in rural people in India.^[12]

In integrated disease surveillance project in Kerala over all 9% respondents were found to have been diagnosed with hypertension by the health professional. In the urban area, the prevalence of hypertension was 10% with 9% among men and 11% among women. But in rural area hypertension is only 8%.^[13]

Hypertension is a heterogeneous medical condition. Hypertension is mainly primary and secondary.

Primary hypertension: In which no specific cause can be identified, constitutes greater than 90% of all cases of systemic hypertension. The average age of onset is about 35 years.

Predisposing factors

- a. Family history of essential hypertension, stroke, and premature cardiac disease
- b. Patient history of intermittent elevation of blood pressure
- c. Racial predisposition, more common in African Americans than whites
- d. Obesity
- e. Stress
- f. High dietary intake of saturated fat and sodium.
- g. Sedentary life style.

Secondary hypertension: Hypertension secondary to any disease and drugs

a) Disease

- Renal disease : Acute glomerulonephritis
Chronic renal disease
Micro albuminuria
Polycystic disease & Renin producing tumors
Renal artery stenosis & vasculitis
- Endocrine disease : Hyperaldosteronism
Acromegaly & Pheochromocytoma
Hyperthyroidism & Hypothyroidism
- Cardiovascular disease: coarctation of aorta
Myocardial infarction & Ischemic heart disease
Left ventricular hypertrophy & Heart failure
- Neurological disease : Psychogenic
Central sleep apnea
Increased intracranial pressure

b) Drugs

- NSAID, Corticosteroids
- ACTH, Estrogen
- Cyclosporine
- Antidepressant(especially Venlafaxine)
- Clonidine β blocker combination
- Cyclosporine and Tacrolimus^[1,2]

PATHOPHYSIOLOGY

The multiple mechanism of hypertension constitute aberrations of blood pressure. The blood pressure level is a complex trait that is determined by the interaction of multiple genetic environmental and demographic factors that influence 2 hemodynamic variables, cardiac output and peripheral resistance.

Blood pressure = cardiac Output x Total peripheral resistance

- **Sympathetic nervous system:** Baroreceptors in the carotids and aortic arch respond to changes in blood pressure and influence the arteriolar constriction and dilation. When stimulated to constriction, that increase the heart rate and peripheral resistance, thus increasing blood pressure.
- **Renin Angiotensin Aldosterone System:** Fall in blood pressure stimulate release of renin by kidney. Renin react with circulating substrate and angiotensinogen to produce angiotensin I. In the pulmonary endothelium is another enzyme called angiotensin converting enzyme, that convert angiotensin I to angiotensin II, potent vasoconstrictor. Angiotensin II stimulate the release of aldosterone from adrenal gland, which result in increased sodium reabsorption, fluid volume and blood pressure.
- **Fluid volume regulation:** Increased fluid volume increase venous system distension and venous return, affecting cardiac output and tissue perfusion. These changes alter the vascular resistance that increase the blood pressure Multiple factors are responsible for sustaining Hypertension. Potential defect in sodium transport, play a role in sustaining hypertension. Other factors include genetics, endothelial dysfunction and neurovascular anomalies. Other vasoactive substance involve are nitric oxide, endothelin, bradykinin, and atrial natriuretic peptide.^[1]

DIAGNOSIS

Hypertension is diagnosed by a simple test using sphygmomanometer. And it is measured at two end points, when the heart is most contracted at peak pressure (Systolic pressure) and then when the heart is most relaxed (Diastolic pressure). Elevated systemic blood pressure usually defined as a systolic reading ≥ 140 mmHg and a diastolic blood pressure ≥ 90 mmHg. According to seventh report of joint national committee on the Detection Evaluation and treatment of high blood pressure hypertension has 4 stages and it is illustrated as follows.^[4]

Table No: 1 JNC VII classification of Hypertension

Classification	Systolic hypertension	Diastolic hypertension
Normal	120mmHg	80mmHg
Prehypertension	120-139mmHg	80-89mmHg
Stage 1	140-159mmHg	90-99mmHg
Stage 2	≥160mmHg	≥100mmHg

If the clinic blood pressure is 140/90mmHg or higher conform the diagnosis of hypertension. When the ambulatory blood pressure monitoring is used then take at least two measurement per hour during the usual walking hours.^[7]

RISK FACTORS

Awareness about the risk factors for hypertension is required to decrease the double burden on the society.^[8] Obesity, Excess dietary sodium intake, reduced physical activity, inadequate intake of fruits and vegetables, excess alcohol intake, smoking, stress are the important risk factor for hypertension.^[4]

A large number of drugs are currently available for reducing blood pressure.

Classification

- Diuretics
- Aldosterone receptor blockers
- Beta blockers
- ACEIs
- ARBs
- CCBs
- Alpha-1 blockers
- Central alpha-2 agonists and centrally acting drugs
- Direct vasodilators

PRESCRIBING PATTERN OF ANTIHYPERTENSIVES

High BP can be treated using several classes of drugs. Joint National Committee (JNC) VII Guidelines recommending the use of antihypertensive drugs in hypertensive patients with compelling indications including Heart failure, Myocardial Infraction, Diabetes, Chronic Kidney Disease, Patient with High Coronary risk and those with Recurrent stroke^[4].

Table No: 2 compelling indication

COMPELLING INDICATION*	RECOMMENDED DRUGS						CLINICAL TRIAL BASIS†
	DIURETIC	BB	ACEI	ARB	CCB	ALDOANT	
Heart failure	•	•	•	•		•	ACC/AHA Heart Failure Guideline, ¹³² MERIT-HF, ¹³³ COPERNICUS, ¹³⁴ CIBIS, ¹³⁵ SOLVD, ¹³⁶ AIRE, ¹³⁷ TRACE, ¹³⁸ ValHEFT, ¹³⁹ RALES, ¹⁴⁰ CHARM ¹⁴¹
Postmyocardial infarction		•	•			•	ACC/AHA Post-MI Guideline, ¹⁴² BHAT, ¹⁴³ SAVE, ¹⁴⁴ Capricorn, ¹⁴⁵ EPHEBUS ¹⁴⁶
High coronary disease risk	•	•	•			•	ALLHAT, ¹⁰⁹ HOPE, ¹¹⁰ ANBP2, ¹¹² LIFE, ¹⁰² CONVINCENCE, ¹⁰¹ EUROPA, ¹¹⁴ INVEST ¹⁴⁷
Diabetes	•	•	•	•	•		NKF-ADA Guideline, ^{88,89} UKPDS, ¹⁴⁸ ALLHAT ¹⁰⁹
Chronic kidney disease			•	•			NKF Guideline, ⁸⁹ Captopril Trial, ¹⁴⁹ RENAAL, ¹⁵⁰ IDNT, ¹⁵¹ REIN, ¹⁵² AASK ¹⁵³
Recurrent stroke prevention	•		•				PROGRESS ¹¹¹

Study of prescribing pattern is a component of medical audit to evaluate and monitoring the prescribing practices of prescribers for achieving the rational medical care for the hypertensive patients.^[11]

Hypertension in diabetes

Hypertension is common in type 2 diabetes, and antihypertensive treatment prevents macro vascular and micro vascular complications. In type 1 diabetes, hypertension usually indicates the presence of diabetic nephropathy. According to JNC VII patients with diabetes, the aim should be to maintain systolic pressure <130mmHg and diastolic pressure <80mmHg. But in some individuals, it may not be possible to achieve this level of control without appropriate therapy. Most patients require a combination of antihypertensive drugs. An ACE inhibitor (or an angiotensin-II receptor antagonist) may have a specific role in the management of diabetic nephropathy in patients with type 2 diabetes, an ACE inhibitor (or an angiotensin-II receptor antagonist) can delay progression of micro albuminuria to nephropathy.^[3]

Hypertension in CKD patients

Patient with hypertension develop Chronic Kidney Disease due to the damage of renal parenchyma and arteries. ACE inhibitors and ARBs reduce intraglomerular pressure which provide additional benefit for further reducing the renal function. So this is safest antihypertensive drug for controlling the BP in CKD patients. ACE inhibitors and ARBs combination is more effective than agent used alone, but routine use is controversial. Diuretics and third antihypertensive drug class (β blockers and CCB) is effective in these patients. ACE inhibitors is contraindicated in renal artery stenosis.^[2]

Hypertension in CVA patients

Attaining a BP goal who experience stroke is considered a primary modality to reduce the risk of secondary stroke. One clinical trial and Progress demonstrated that ACE inhibitor in combination with thiazide diuretics decrease the incidence of recurrent stroke in patient with history of stroke or TIA.^[4]

Hypertension in ischemic heart disease

Hypertensive patient are at increased risk for MI or other major coronary event and may be at higher risk of death at following acute MI unless contraindication pharmacotherapy should be initiated with β blockers. BB reduce the blood pressure, reduce symptoms of angina, improve mortality and reduces cardiac output, heart rate and AV conduction. Treatment also include smoking cessation, management of diabetes, lipid lowering, exercise training and weight reduction in obese patients. If β blockers is contraindicated in presence of severe airway reactive disease, high degree of AV block or sick sinus syndrome, either long acting Dihydropyridine or Nondihydropyridine type CCB may be used. CCB decrease the total peripheral resistance, which lead to reduction in blood pressure and in wall tension. Nondihydropyridine CCB in combination cause severe bradycardia or high degree of heart block. Therefore long acting dihydropyridine CCB are preferred for combination therapy with β blockers. If the blood pressure is not controlled by these drugs nitrates can be added. But they are used caution with patients taking Phosphodiesterase 5 inhibitor such as sildenafil.^[4]

Hypertension in heart failure

For hypertensive patients with heart failure five drug classes are listed as compiling indication for heart failure. The primary mechanism is decreased cardiac contractility. ACE inhibitors are recommended as the first drug of choice based on many numerous outcome studies showing decreased morbidity and mortality. β blockers is appropriate to further modify the disease in systolic heart failure. In patients with standard regimen of diuretics and ACE inhibitors β blockers produce reduction in morbidity and mortality. Early data suggest that ARBs may be better than ACE inhibitors in systolic heart failure. The addition of aldosterone antagonist can reduces morbidity and mortality of systolic heart failure. Eplerenone the newest aldosterone antagonist has been studied in patient with symptomatic systolic heart failure within 3-14 days. CCB are contraindicated in heart failure patients.

Hypertension in Left ventricular hypertrophy

LVH is an independent risk factor for CAD and is considered a cause of organ damage. LVH is occur in 50% of hypertensive patients. All classes of antihypertensive agent except vasodilators prevent LVH. ACE Inhibitors and ARBs are considered most effective agent for regressing LVH.

Hypertension in peripheral artery disease

Major risk factor for peripheral artery disease is hypertension, diabetes and smoking. Antihypertensive drug therapy is ineffective in relieving the symptoms of PAD. Vasodilator agent such as ACE inhibitors CCB, α -blockers and direct vasodilators do not improve walking distance or symptoms of claudication.^[4]

METHODOLOGY

STUDY DESIGN

It was a prospective observational study conducted in a tertiary care hospital in Trivandrum. This was a 6 month study conducted from October 2014 to March 2015.

SAMPLE SIZE

The sample size was calculated using the formula

$$N = \frac{Z_{\alpha}^2 p q}{D^2}$$

Where α - type 1 error or false positive error.

$$Z_{\alpha} = 1.96 = 2$$

P - Anticipated percentage of antihypertensive drug used among the patient admitted in cardiology hypertensive outpatient and hypertensive in patients.

$$q = 100 - p$$

d- Precision factor which is 20% of p

p- 30% (from pilot study conducted in cosmopolitan hospital private limited

Therefore d= 20% of 300. Hence total 300 patients were included in the study.

ENROLLMENT

- **INCLUSION CRITERIA**

All patients above age 18 years who were willing to participate in the study of both sex groups having hypertension was included in the study.

- **EXCLUSION CRITERIA**

Psychiatry patients, pregnant women and patient admitted for surgery and the patient who were not willing to participate in the study were excluded.

DATA COLLECTION

During the six months period, a total of 300 patients were enrolled in the study. The ethical approval for the study was granted by the Institutional Ethical Committee and Review Board after that we were started to collect cases for study. Written informed consent was taken from each patient before including in to the study. Identity of patient was kept confidential. The relevant data collected while accompanying the physician 6 days in a week and also from the inpatient medical records. Data was collected by using data collection form. Data like name, age, sex, general examination, vital signs, laboratory investigation, concurrent disease, risk factors, past medications and ongoing treatment including individual drugs collected from patient's case sheets. Also analysed to check the prevalence of hypertension (age, gender). Categorization of BP according to JNC VII is done by assessing the BP value from the patient BP chart and also directly taking the BP by using a mercury sphygmomanometer by using standard procedure.

Measurement of Blood Pressure

Guidelines from American Heart Association define proper procedures for measuring BP. These include the following:

- Allow the patient to sit quietly for 5 minutes before measuring BP.
- The patient should be seated comfortably with the back supported and the upper arm bared without constrictive clothing.
- The legs should not be crossed.
- The arm should be supported at heart level and the bladder of the cuff should be encircle at least 80% of the arm circumference. Larger or smaller cuffs must be used as needed.
- The mercury column should be deflated at 2 to 3 mm/sec, and the first and last audible sounds should be taken as systolic and diastolic pressure. The column should be read to the nearest 2 mmHg.
- Neither the patient nor the observer should talk during the measurement.

The measurement guideline recommend as the standard for measuring BP using Sphygmomanometer. And it was calibrated before for the study.

Analyse the major risk factors for hypertension by direct interview and from their case chart. Cohen perceived stress scale was used to assess the severity of stress. It contain 10 questions. PSS scores are obtained by reversing responses (e.g., 0 = 4, 1 = 3, 2 = 2, 3 = 1 & 4 = 0) to the four positively stated items (items 4, 5, 7, & 8) and then summing across all scale items. A short 4 item scale can be made from questions 2, 4, 5 and 10 of the PSS 10 item scale.^[17] BMI Categorization done by taking their weight and height and categorize it as underweight, normal, overweight and obese.

Data were analysed thoroughly and assess the rationality of prescribed antihypertensive drugs in co morbid condition according to JNC-VII guideline.^[4] For this assessment we divide the prescriptions into hypertension with single and multiple co morbidities.

STATISTICS

The data was then compiled, and subjected for statistical analysis. We used SPSS version for the statistical analysis.

RESULT

DEMOGRAPHIC DETAILS

Table No. 2: Frequency and percentage distribution of demographic variables of hypertensive patients.

Variables	Frequency	Percentage (%)
Age in years		
18-40	7	2.3%
41-60	98	32.7%
61-80	175	58.3%
Above 80	20	6.7%
Gender		
Male	138	46%
Female	162	54%

Data presented in Table shows that among 300 patients, more than half of the patients i.e. 175(58.3%) were in the age group of 61-80 years of age, more than one-fourth i.e. 98(32.7%) were in the age group 41-60 years of age, 20 (6.7%) were in the age group of above 80 and 7 (2.3%) were in the age group of 18-40 years of age. In the study conducted by Kothari et al, the most common age groups found was 59 years (68.52%).^[19] Most common age group of 60-69 years (34%) followed by 70-79 years (23%) and 40-49 years (22%) were found in study conducted by Pai et al.^[17] But in study conducted by Tiwari et al, the most common age group found that 50-59 years (33.3%) followed by 60-69 years and 40-49 years

(26.7%).^[18] In our study, female patients i.e. 162 (54%) outnumbered than male patients, 138 (46%). Similar result was observed in the study of Sandozi and Emani in which, 53% were female and 47% were male^[16]. Other study conducted in 2015 by Kothari et al, prevalence of HTN was 52.7% in males and 47.3% females.^[15]

BLOOD PRESSURE CATEGORIZATION

Figure below reveals that among 300 patients in the study, greater than half i.e. 159 (53%) of the patients have stage 1 hypertension, more than one fourth i.e. 90 (30%) have stage 2, less than one fourth i.e. 46(15.33%) have prehypertension and 5 (1.67%) have normal blood pressure. Similar result was found in the Study of Kaur S et al, were 37.2% patients had stage I HTN.^[19]

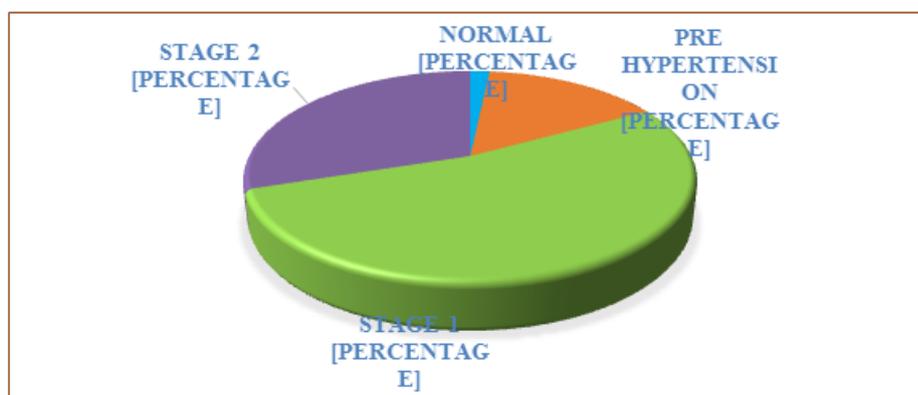


Figure. No: 1 Frequency and percentage of blood pressure categorization according to JNC VII guide line.

RISK FACTOR ASSESSMENT OF HYPERTENSION

Figure presented below shows that among 300 hypertensive patients in the study, more than half i.e. 239(79.6%) have the risk factor of lack of physical exercise followed by family history (55%), age (39.6%) and least risk factor observed for the risk factor of hypertension due to drugs i.e.2(0.67%). The study conducted by Kumar H et al identified that the major risk factors was family history (65.1%) and followed by alcoholism (38.1%), smoking (28.8%), age (27.3%).^[20]

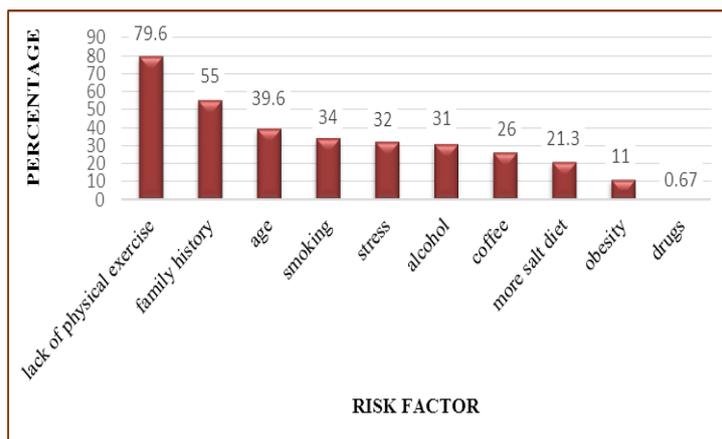


Figure No 2: Frequency and percentage of risk factor assessment of Hypertension

Figure below reveals that among 300 hypertensive patients enrolled in the study, more than half i.e. 203(67.7%) of the hypertensive patients have no stress, less than one fourth i.e. 59(19.7%) have high stress and more than one by eighth have moderate stress.

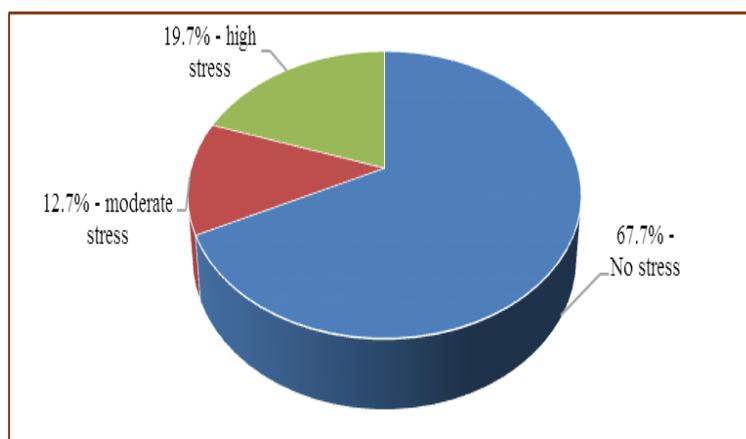


Figure No 3: Frequency and distribution of stress in hypertensive patients

Figure presented below reveals that among 300 hypertensive patients enrolled in the study, more than half i.e. 196 (65.3%) of the patients have normal body weight, one fourth i.e. 50(25%) have overweight, less than one by eighth i.e. 26(8.7%) were obese and 3(1%) were underweight. Similar results were found in a study conducted by Mbah B.O and Eme in which 70% normal weight, 17.5% overweight, 7.5% obese and 5% normal weight patients were found.^[21]

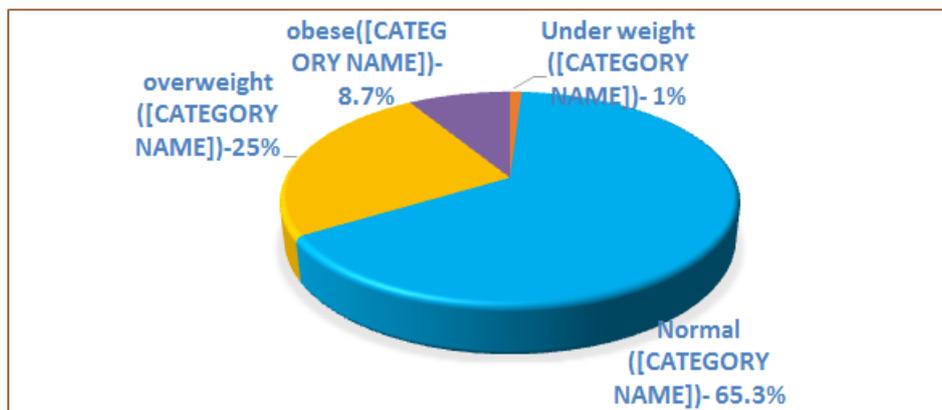


Figure No 4: Frequency and distribution of BMI grade in hypertensive patients

RATIONALITY

Figure presented below shows that, in 175 prescription of hypertensive patients with DM less than half i.e.65 were rational and remaining i.e.110 was irrational. In 30 prescriptions of hypertensive patients with CKD, 12 prescriptions were rational and remaining 18 were irrational. In a total of 25 prescriptions of hypertensive patients with CVA, less than one half i.e. 10 were rational and 15 were irrational. Out of 40 prescriptions of HTN with IHD, 11 were found to be rational. In other co morbidities with hypertension such as LVH and HF, most of the prescriptions were found to be irrational except PAD. Whereas in the study of Kothari *et al*, out of 566 hypertensive patients with DM, 549 were rational and out of 119 Hypertension with IHD prescription, 86 were rational. In 47 hypertension with CHF prescription, 44 were rational, Out of 30 hypertension with CKD prescription, 10 were found to be rational.^[15]

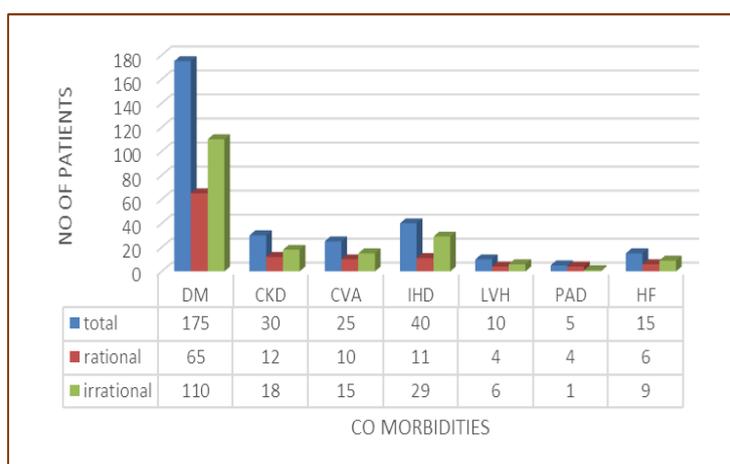


Figure No: 5 Frequency and distribution of rationality of antihypertensive drugs in single co morbid conditions.

CONCLUSION

The present study helped to identify the prevalence of HTN, JNC VII Blood categorization and risk factors of HTN. Prevalence was more among the age group of 61- 80yrs and was more in females. Study reveals that in patients with co morbidities, majority of the drug prescribed were irrational according to JNC VII guideline. It is evident that prescribing guidelines should be followed for better health outcome and improvement in quality of life of patients suffering from hypertension with co-morbidities because these guidelines are based on various clinical trials. Most of the hypertensive patients suffering from other co morbid conditions. So for the rational prescribing of antihypertensive drugs it is better to consider the co morbid conditions of each patients. There by reduce its progression to further complication and decrease the mortality rate of the patients.

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