

“Study on Risk Factors and Its Assessment in Management of Systemic Hypertension”

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Abstract

Hypertension is one of the major chronic diseases resulting in high mortality and morbidity worldwide. It is a leading risk factor for coronary heart disease, stroke and chronic renal disease. There are many classes of antihypertensives available. Health care professionals need to utilise limited resources wisely in order to provide effective, safe and affordable antihypertensive therapy to the maximum number of patients. The objective of the study is to determine the risk factors in hypertension and appropriateness of antihypertensive drugs in the selected study population as per our inclusion criteria. The prospective observational study was conducted. The data were collected from regular ward rounds and they were analysed. The appropriateness was analysed using the JNC guidelines. A total of 75 patients were included in our study, their prescription were analyzed. The total number of inappropriate drugs were found to be 24 in which 11(45.83%) drugs of ACE inhibitors was found to be contraindicated with Renal failure, followed by 6(25%) Diuretics were contraindicated with dyslipidaemia, 6(25%) beta blockers were contraindicated with Asthma & COPD and 1(4.16%) ARBs were contraindicated with Renal failure & Hyperkalemia. The total numbers of antihypertensive prescribed drugs for the study population were found to be 156, where 138(88.46%) found to be rational and 18(11.54%) were irrational. A total of 8(44.44%) drugs prescribed from same class, was found to be irrational followed by 6(33.33%) increased frequency and 4(22.22%) over dose. The results revealed that continuous monitoring of the prescribing of antihypertensive agents by the clinical pharmacist is necessary to resolve the issues of inappropriateness and enhancement of rational prescribing. The clinical pharmacist has the greater responsibility in monitoring of hypertensive patients with other comorbid conditions.

Key Words: Hypertension, risk factors, drug therapy, rational prescribing.

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I. INTRODUCTION

In India, hypertension in the general population is largely undetected, and the available data and study on the topic is merely the tip on an iceberg. Pooling of epidemiological studies shows that hypertension is present in 25% urban and 10% rural subjects in India. At an underestimate, there are 31.5 million hypertensives in the rural and 34 million in the urban population. According to the recent review on the global burden of hypertension, the estimated prevalence of hypertension (in people aged 20 years and older) in India during 2000 was 20.6% among males and 20.9% among females and is projected to increase to 22.9% and 23.6% respectively by 2025. The estimated total number of people with hypertension in India during 2000 was 60.4 million males and 57.8 million females and projected to increase to 107.3 million and 106.2 million respectively in 2025.

As high blood pressure is the leading cause of stroke and a major risk factor for heart attacks, one of the most important aspects of preventive cardiology should be to identify as many people who have the disease as possible and to take steps to lower the blood pressure before it causes damage to the blood vessels, heart, kidneys and other organs. There are also several millions of others whose hypertension has been diagnosed but who are not being adequately treated to normal blood pressure levels.

There are many classes of antihypertensives available. Rational prescribing is essential as HTN is highly prevalent and therapy is chronic. Health care professionals need to utilise limited resources wisely in order to provide effective, safe and affordable antihypertensive therapy to the maximum number of patients.

Choice of an anti-hypertensive agent is influenced by age, concomitant risk factors, presence of target organ damage, other co-existing diseases, socioeconomic considerations, and availability of the drug and past experience of the physician.

Combining of low doses of two or more drugs having synergistic effect is likely to produce lesser side effects. In 60 – 70% of patients, goal blood pressure will be achieved with two or more agents only. Use of fixed dose formulations should be considered to improve compliance. Drugs with synergistic effects should be combined pertinently to enhance BP lowering effect as to achieve the target BP.

Use of long acting drugs provide 24 hour efficacy with once daily administration ensures smooth and sustained control of blood pressure which in turn is expected to provide greater protection against the risk of major cardiovascular events and target organ damage. Once daily administration also improves patient compliance.

Although antihypertensive therapy is generally lifelong, an effort to decrease the dosage and the number of antihypertensive drugs should be considered after effective control of hypertension. Pharmacists can have a significant role in monitoring blood pressure and managing the medication of patients with hypertension. As one of the most easily accessible health care professionals, pharmacists have the necessary tools and knowledge to implement timely screening and effective prevention initiatives. Those with prescriptive authority can modify antihypertensive regimens to better personalize a patient’s treatment. Actively involved in hypertension research, pharmacists also play an important role in updating and publishing annual evidence-based guidelines. Recognizing pharmacists as key members of hypertension management opens the door to increasing their involvement in several additional chronic health conditions.

As hypertension often exists with other comorbid conditions such as Diabetes mellitus, Myocardial infarction, Congestive cardiac failure (CHF) and Chronic kidney disease (CKD) the antihypertensive therapy should be chosen according to specific individual variables including the cardiovascular risk factor profile, the presence of coexisting disorders may either favour or limit the use of particular antihypertensive drugs. To treat hypertension associated with these comorbid conditions various guidelines are available. They are aimed to provide indications for clinical practice based on rigorous scientific evidence. Physicians are not completely adhering to standard guidelines while treating hypertension with comorbid conditions. 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 comorbidities .

Drug utilization studies are done to analyse prescribed drugs to patients, taking into account patient safety, clinical evidence, cost effectiveness and treatment efficacy and other factors. As well as hypertensive treatment is life long treatment, the prescription needs special emphasis of consideration of these factors.

OBJECTIVES OF THE STUDY

- To assess the prevalence of hypertension among various cardiovascular disorders in the study department.
- To assess the various risk factors associated with hypertension in study population.
- To document the treatment pattern of anti-hypertensives and blood pressure control among study subjects.

PLAN OF THE STUDY

The study is planned to be carried out in 3 phases

→PHASE I

- Literature survey
- Preparation of the protocol
- Designing of structured data entry format
- Obtaining consent from the hospital ethical committee

→PHASE II

- Data collection
- Documentation of collected data using the data entry format

→PHASE III

- Analysis of all the collected data
- Interpretation of the data
- Graphical representation of the data
- Preparation of the project report

The study protocol will be submitted and presented to get approval from the institutional ethical committee and ethical committee of the hospital. Patient’s case records which met the inclusion criteria were planned to be screened during the study. Literature review on all observational studies (e.g., cross-sectional, cohort, case-control studies, and case series), are to be screened. Studies that reported the use of anti-hypertensives and risk factors for hypertension were included as primary literature supporting the work.

Materials and methods:

- **Study site:** 1000 bedded, private tertiary care multi-specialty teaching hospital.
- **Study department:** Cardiology department of the study hospital.
- **Study duration:** 06 months
- **Study design:** Prospective, observational study.
- **Inclusion criteria:**
 - ✓ Patient case records with age greater than 18 years
 - ✓ Newly diagnosed and known case of hypertensive patients
 - ✓ Patients with confirmed diagnosis of hypertension
- **Exclusion criteria:**
 - ✓ Patients who are not willing to give consent
 - ✓ Case records where no anti-hypertensive medications are prescribed
- **Sample size :** 75 cases

Study Population: A number of 75 eligible patient’s case records will be analysed for the study based on the selection criteria.

Sample size derivation methodology:

$$\text{Sample size} = \frac{\frac{z^2 \times p(1-p)}{e^2}}{1 + \left(\frac{z^2 \times p(1-p)}{e^2 N} \right)}$$

For Confidence interval of 95%, the Z score is 1.96.

The Margin of error (e) is taken to be 5%

The population proportion (p) is taken as 20%

The total population size (N) is estimated to be 75.

PATIENT INFORMATION FORM

A patient information form has been prepared, to inform the patient or the care givers about the purpose and the necessity of the study. The patients were assured that the confidentiality will be strictly maintained.

PATIENT CONSENT FORM

A patient consent form has been prepared and written consent was obtained from the patient or from the caregivers. The format contains details like address, date, place, provision for signature of the patient or caregivers, investigator and supervisor. **DATA ENTRY FORMAT**

A specially designed data entry format was prepared and used to record the patient’s details. Data entry format has the provision to record patient details, laboratory investigations, Diagnosis, Drug chart etc.

II. METHOD

Regular ward rounds was carried out in all the wards of department of cardiology. Each patient’s medication profile was reviewed. Patients who met the inclusion criteria were briefed on the project with the help of patient information form and if they are willing to participate in the study their consent were obtained. The data from medical chart were recorded in customized data entry form. The data were analyzed to describe the risk factors and appropriateness of anti hypertensive drugs in hypertensive patients with other comorbid diseases. The JNC guidelines were utilized to assess the appropriateness . The report on the study results were prepared and the same was submitted to the study department for their perusal and necessary modification on therapy considering the risk factors for a safe and effective patient care.

III. RESULTS AND DISCUSSION

The project work entitled “**Study on risk factors and its assessment in management of systemic hypertension.**” was a prospective observational study carried out in a 1000 bedded multispecialty private corporate hospital.

PREVALENCE OF HYPERTENSION

A total of 213 patients were admitted in the study site during the study period and 75 patients were found to be suffering from hypertension with other co-morbid diseases and were included in the study as per inclusion and

exclusion criteria. The percentage was found to be (35.21%) in the study site [Table No: 1] . A similar study conducted by Rama M P et al (2015) reported that hypertension prevalence were 37% in their study population.

TABLE NO.1 PREVALENCE OF HYPERTENSION

| Prevalence | No. of Patients (n=213) | Percentage |
|--------------------------|-------------------------|------------|
| Hypertensive patients | 75 | 35.21% |
| Nonhypertensive patients | 138 | 64.78% |

GENDER CATEGORIZATION

The total numbers of patients in study population were 75. Among them 49(65.33%) were males and 26(34.66%) were females. The study result reveals that prevalence rate of hypertension in female population was lower than that of male populations [Table No: 2]. A similar study conducted by Sai et al (2015) reported that prevalence of hypertension is more among males than females.

TABLE NO. 2 GENDER DISTRIBUTION OF STUDY POPULATION

| Gender | No of Patients (n=75) | Percentage % |
|--------|-----------------------|--------------|
| MALE | 49 | 65.33% |
| FEMALE | 26 | 34.66% |

AGE CATEGORIZATION

The age categorization of the patients was analysed. Majority of the patients 24 (32%) were in the age group of 50-59 years followed by 15 (20%) were in 40-49 years, 15 (20%) were in 60-69 years. Most of the studies were conducted and reported that the prevalence rates of hypertension among the people above 40 years of age has become increased. The similar results was observed in our study where majority of patients are 40 years and above.

The age categorization of the male patients was analysed and it was found that 17(34.69%) patients were in the age group of 50-59 years, 10 (20.40%) were in age group of 40-49 , 08(16.32%) were in age group of 60-69years, 08(16.32%) were in age group of 70-79 years.

The age categorization of the female patients was analysed and it was found that 07 (26.92%) were in the age group of 60-69 years, 07 (26.92%) were in age group of 50-59years, 04 (15.38%) were in age group of 70-79 years, 5 (19.23%) were in 40-49 years.

BMI RANGE ACCORDING TO INDIAN GUIDELINES

The weight and height of individual patients were also recorded in the study. From the weight and height data, the BMI (Body Mass Index) of all the 75 patients included in the study were calculated and categorized according to their respective values from the results it was observed many people of the study group were in over weight category 29(38.66%), followed by normal weight 18(24%), pre-obese 24(32%), underweight 3(4%) and obese 1(1.33%) [Table No:3]. A similar study conducted by Rebecca P Gelber et al (2007) reported that the maximum number of patients were in over weight category.

TABLE NO:3 BMI RANGE ACCORDING TO INDIAN GUIDELINES

| Category | BMI Range(kg/m2) | No. of Patients (n=75) | Percentage % |
|---------------|------------------|------------------------|--------------|
| Underweight | Less than 18 | 3 | 4 |
| Normal weight | 19 – 25 | 18 | 24 |
| Overweight | 25 – 30 | 29 | 38.66 |
| Pre – obese | 30 – 40 | 24 | 32 |
| Obese | Over 40 | 1 | 1.33 |

SOCIAL HISTORY

The analysis of hypertension risk factors among the study group risk shows that 31 (41.33%) patients were smokers, 26(34.66%) patients were alcoholic [Table No:4]. Similar study conducted by Mahantesh M Kurjogi et al (2021) reported that the prevalence of hypertension risk factors in the general population in which alcoholic and smoking were observed.

TABLE NO:4 SOCIAL HISTORY

| Sl. No. | Risk Factor | No. of Patients (n=75) | Percentage % |
|---------|-------------------------|------------------------|--------------|
| 1 | Smoker | 31 | 41.33 |
| 2 | Alcoholic | 26 | 34.66 |
| 3 | Both alcoholic & smoker | 38 | 50.66 |
| 4 | None | 18 | 24 |

BLOOD PRESSURE CATEGORIZATION (SYSTOLIC BP)

The systolic blood pressure of patients were observed, 41(54.66%) patients were having systolic blood pressure >140mm/Hg followed by 16(21.33%) patients had systolic blood pressure of 130-140 mm/Hg.

CO-MORBIDITIES OF STUDY POPULATION

The co-morbidity of the hypertensive patients was analysed. The study reveals that 33(34.02%) of the study population was suffering from DM followed by 9(9.27%) CRF/ARF, 7(7.21%) Ischemic heart disease, 6(6.18%) Congestive heart failure, 4(4.12%) Hyperlipidemia other disorders [Table No:5]. A similar study conducted by **Nagaraj Desai (2022)** also reported that most common co-morbid condition among hypertensive population was diabetes. This report correlates with our study result.

TABLE NO:5 CO-MORBIDITIES

| Sl. No. | Co-Morbidities | No. of Co-Morbidities (n=97) | Percentage % |
|---------|-------------------|------------------------------|--------------|
| 1 | Diabetes | 33 | 34.02 |
| 2 | CRF/ARF | 09 | 9.27 |
| 3 | IHD | 07 | 7.21 |
| 4 | CHF | 06 | 6.18 |
| 5 | Hyperlipidaemia | 4 | 4.12 |
| 6 | Asthma/COPD | 4 | 4.12 |
| 7 | Angina | 4 | 4.12 |
| 8 | MI | 3 | 3.09 |
| 9 | Seizure disorders | 3 | 3.09 |
| 10 | Anaemia | 5 | 5.15 |
| 11 | LRTI | 4 | 4.12 |
| 12 | Ulcers | 8 | 8.24 |
| 13 | Other diseases | 7 | 7.21 |

PRESCRIBED DRUGS

The total numbers of prescribed drugs for the study population were found to be 691. A total of 126(18.23%) antihypertensive drugs were prescribed, followed by 61(8.82%) diuretics, 46(6.65%) antibiotic, 51(7.38%) antiulcer, 43(6.22%) NSAIDs, 40(5.78%) antihyperlipidemic, 61(8.82%) antidiabetic, 61(8.82%) antiplatelet agents, 53(7.67%) minerals and vitamins, 27(3.90%) anticoagulant, 12(1.73%) antianxiety, 12(1.73%) nitrites, 13(1.88%) antianginal, 14(2.02%) antiemetics. [Table No:6].

TABLE NO. 6 PRESCRIBED DRUGS

| S.No. | Drug class | No. of Drugs (n=691) | Percentage% |
|-------|-------------------|----------------------|-------------|
| 1 | Anti hypertensive | 126 | 18.23 |
| 2 | Diuretics | 61 | 8.82 |

| | | | |
|----|-----------------------|----|------|
| 3 | Antibiotic | 46 | 6.65 |
| 4 | Antiulcer | 51 | 7.38 |
| 5 | NSAIDs | 43 | 6.22 |
| 6 | Dyslipidaemia | 40 | 5.78 |
| 7 | Antidiabetic | 61 | 8.82 |
| 8 | Minerals and vitamins | 53 | 7.67 |
| 9 | Antiplatelet | 61 | 8.82 |
| 10 | Anticoagulant | 27 | 3.90 |
| 11 | Antianxiety | 12 | 1.73 |
| 12 | Nitrites | 12 | 1.73 |
| 13 | Antianginal | 13 | 1.88 |
| 14 | Antigout | 09 | 1.30 |
| 15 | Antiemetic | 14 | 2.02 |
| 16 | Antiasthma | 07 | 1.01 |
| 17 | Antiepileptic | 9 | 1.30 |
| 18 | Potassium Chloride | 8 | 1.15 |
| 19 | Antihistamine | 6 | 0.86 |
| 20 | Others | 32 | 4.63 |

NUMBER OF ANTIHYPERTENSIVE AGENTS UTILIZED BY PATIENTS

The total number of antihypertensive agents utilized varies according to BP control achieved. The monotherapy was more widely used, 32(42.66%) patients were taking monotherapy, 28(37.33%) patients were taking dual drug therapy and 15(20%) patients were taking more than two drugs. **(Table No:7).**

TABLE NO. 7 TYPE OF THERAPY [ACCORDING TO NUMBER OF DRUGS PRESCRIBED]

| Type of therapy | No. of Patients (n=75) | % of patients |
|---------------------|------------------------|---------------|
| Mono therapy | 32 | 42.66 |
| Dual Therapy | 28 | 37.33 |
| More than two drugs | 15 | 20 |

CLASS OF ANTIHYPERTENSIVE AGENT

In this present study, β blockers 37(29.36%) were the most commonly prescribed antihypertensive agents followed by CCB 25(19.84%), Diuretics 17(13.49%), ARBs 15(11.90%), ACE inhibitors 31(24.60%) and α blockers 1(0.79%) **(Table No:8)**

. TABLE NO : 8 CLASS OF ANTIHYPERTENSIVE AGENTS

| Drug class | No. of Drugs (n=126) | Percentage % |
|-------------------|----------------------|--------------|
| β blockers | 37 | 29.36 |
| CCB | 25 | 19.84 |
| Diuretics | 17 | 13.49 |
| ARBs | 15 | 11.90 |
| ACE inhibitors | 31 | 24.60 |
| α blockers | 1 | 0.79 |

PRESCRIBING PATTERNS OF ANTIHYPERTENSIVE AGENTS

The total numbers of antihypertensive prescribed drugs for the study population were found to be 126 and the most commonly prescribed drugs are 15(11.90%) Amlodipine followed by 31(24.60%) Ramipril, 11(8.73%), Telmisartan, 18(14.28%) Metoprolol, 9(7.14%) Spironolactone, 9(7.14%) Nebivolol, 7(5.55%) Clinidipine, 8(6.34%) Hydrochlorothiazide, 6(4.76%) Atenolol, 1(0.79%) Prazosin. **(Table No:9)**

TABLE NO :9 PRESCRIBING PATTERNS OF ANTIHYPERTENSIVE AGENTS

| Class of drugs | Name of drugs | No. of Drugs (n=126) | Percentage % |
|------------------------------------------------|---------------------|----------------------|--------------|
| β Blockers | Metoprolol | 18 | 14.28 |
| | Nebivolol | 09 | 7.14 |
| | Atenolol | 6 | 4.76 |
| | Carvedilol | 2 | 1.58 |
| | Propranolol | 2 | 1.58 |
| CCB | Amlodipine | 15 | 11.90 |
| | Cilnidipine | 07 | 5.55 |
| | Diltiazem | 3 | 2.38 |
| Diuretics | Spironolactone | 09 | 7.14 |
| | Hydrochlorothiazide | 08 | 6.34 |
| Angiotensin II receptor blockers (ARBs) | Telmisartan | 11 | 8.73 |
| | Losartan | 3 | 2.38 |
| | Irbesartan | 1 | 0.79 |
| Angiotensin converting enzyme (ACE) inhibitors | Ramipril | 31 | 24.60 |
| α Blockers | Prazosin | 1 | 0.79 |

APPROPRIATENESS OF ANTI HYPERTENSIVE DRUGS

The total numbers of antihypertensive prescribed drugs for the study population were found to be 126, in which 102(80.95%) found to be appropriate and 24(19.04%) inappropriate (**Table No:10**).

TABLE NO:10 APPROPRIATENESS OF ANTI HYPERTENSIVE DRUGS PRESCRIBED

| S.No. | Appropriateness | No. of Drugs (n=126) | Percentage% |
|-------|-----------------|----------------------|-------------|
| 1 | Appropriate | 102 | 80.95 |
| 2 | Inappropriate | 24 | 19.04 |

INAPPROPRIATE DRUG

The total number of inappropriate drugs for the study population were found to be 24 in which 11(45.83%) drugs of ACE inhibitors was found to be contraindicated with renal failure followed by 6(25%) drugs of Diuretics were contraindicated with dyslipidaemia, 6(25%) drugs of beta blockers were contraindicated with asthma & COPD and 1(4.16%) drugs of ARBs are contraindicated with renal failure & hyperkalemia. (**Table No:11**).

TABLE NO :11 INAPPROPRIATE DRUGS PRESCRIBED

| S.No | Class of inappropriate drugs | Drug contraindications | No. of Drugs (n=24) | Percentage% |
|------|------------------------------|------------------------|---------------------|-------------|
| 1 | ACEIs | Renal failure | 11 | 45.83 |

| | | | | |
|---|------------|------------------------------|---|------|
| 2 | Diuretics | Dyslipidaemia | 6 | 25 |
| 3 | β Blockers | Asthma & COPD | 6 | 25 |
| 4 | ARBs | Renal failure & Hyperkalemia | 1 | 4.16 |

DRUG INTERACTIONS

In the present study, only major drug interactions were documented. The total number of drug interactions included are 13. (Table No:12).

TABLE NO:12 DRUG INTERACTIONS

| S. No | Drugs | Interaction | Severity |
|-------|----------------------------------------------------|---------------------------------------------------------------------------------------------|----------|
| 1 | Ramipril + Telmisartan | Increase risk of adverse event (hypotension, change in renal function, acute renal failure) | Major |
| 2 | Digoxin + Spironolactone | May result in increased digoxin exposure | Major |
| 3 | Ramipril + Spironolactone | May result in hyperkalemia | Major |
| 4 | Aspirin + Spironolactone | Sodium exertion effect may be inhibited by aspirin | Major |
| 5 | Ramipril + Spironolactone | May result in hyperkalemia | Major |
| 6 | Spironolactone+Telmisartan | Life threatening hyperkalemia may occur. | Major |
| 7 | Metoprolol + Insulin | May increase risk of severity of hypoglycemia | Major |
| 8 | Ramipril + Kcl | May result in hyperkalemia | Major |
| 9 | Spironolactone + Kcl | May result in hyperkalemia | Major |
| 10 | Atenolol + Aspirin | May result in decreased antihypertensive effect | Major |
| 11 | Amlodipine + Clopidogrel | May result in decreased antiplatelet effect | Major |
| 12 | Atorvastatin + Diltiazem Hydrochloride | Increased risk of rhabdomyolysis | Major |
| 13 | Clopidogrel Hydrochloride+ Diltiazem Hydrochloride | Decreased antiplatelet effect and increased risk of thrombotic events. | Major |

IV. CONCLUSION

The study on drug use in hypertensive patients with other comorbid diseases was successfully carried out. The inappropriate drug use was found to be less prevalent. Majority of the patients under the study were receiving monotherapy for hypertension and major guidelines states the monotherapy is advisable for the people with hypertension including other comorbidities. Monotherapy will safeguard the patients from various adverse drug related events.

The results shows that β blockers are majorly prescribed at study site when compared with other class of antihypertensives. The β blockers are not the first drug of choice as per the guidelines and they involve risks associated with their use. The regular monitoring of the study population outweighs the risks associated with the β blockers and diuretics utilization.

The rational prescribing was observed in majority of cases, but still some irrational prescription of overdose and wrong frequency were identified. The continuous monitoring of the prescribing of antihypertensive agents by the clinical pharmacist can resolve the issues of inappropriateness and enhance the rational prescribing. The clinical pharmacist has the greater responsibility in monitoring hypertensive patients with other comorbid conditions.

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