

DRUG UTILISATION STUDY IN THE TREATMENT OF HYPERTENSION IN A TERTIARY CARE HOSPITAL

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ABSTRACT

BACKGROUND

Hypertension, a common clinical problem is considered as an 'iceberg disease' because its unknown morbidity far exceeds the known morbidity. In terms of attributable deaths, it is one of the leading behavioural and physiological risk factors amounting to 13% of global deaths. Drug selection is based on efficacy in lowering BP (blood pressure) and in reducing Cardiovascular (CV) endpoints like stroke, myocardial infarction and heart failure. This study was carried out to evaluate the pattern, extent, rationality and frequency of the use of antihypertensive drugs in the treatment of hypertension.

The aim of the study is to analyse drug utilisation in the treatment of hypertension in a tertiary care hospital.

MATERIALS AND METHODS

This study was conducted during January 2014 to December 2015 in Medicine OPD (Outpatient Department) in a tertiary care hospital. The sample size was selected as per the WHO recommendations on conducting Drug Utilisation Studies (DUS).

Statistical Analysis- The collected data was numerically coded and entered in Microsoft Excel 2007 and analysed by SPSS version 16.

Settings and Design- Prospective, cross-sectional, observational study.

RESULTS

Out of 612 patients, 262 (42.81%) were in the age group of 60 and above. Considering gender distribution, 328 (53.59%) were males and 284 (46.41%) were females. Of these, 274 (44.78%) were prescribed monotherapy, 256 (41.83%) were prescribed two-drug therapy, 72 (11.76%) were prescribed three-drug therapy and 10 (1.63%) were prescribed four-drug therapy. Among 274 (44.78%) patients prescribed with monotherapy, 112 (40.87%) were prescribed with CCB (calcium channel blocker), 76 (27.73%) were given BB (B-blocker), 45 (16.42%) were prescribed ACEI (angiotensin converting enzyme inhibitor), 35 (12.77%) were prescribed with ARB (angiotensin receptor blocker) and 6 (2.18%) were prescribed with Diuretics (D). Of the total antihypertensive drugs prescribed, 68.30% were prescribed by generic name, while 25.98% were prescribed as FDCs (fixed drug combination) and 39.05% of antihypertensive drugs were from NLEM (national list of essential medicine). Average number of drugs prescribed per encounter in our study was 2.42, while number of antihypertensive drugs per encounter were 1.34.

CONCLUSION

The findings of our study suggest that majority of prescriptions had generic names of the drugs. Improving practitioners' knowledge and attitude in rational prescribing can prove to be a cornerstone in achieving rational use of antihypertensive drugs.

KEYWORDS

Antihypertensive Drugs, Drug Utilisation, Monotherapy, Polytherapy.

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BACKGROUND

Hypertension, a common clinical problem is considered as an 'iceberg' disease' because unknown morbidity far exceeds the known morbidity.^{1,2} In terms of attributable deaths, it is one of the leading behavioural and physiological risk factor amounting to 13% of global deaths. Hypertension is reported to be the fourth contributor to premature death in developed countries and the seventh in developing countries.^{3,4}

According to the report of the Joint National Committee (JNC) for detection, evaluation and treatment of high blood pressure, hypertension is defined as a clinical state where the systolic blood pressure is above 139 mm of Hg and the diastolic blood pressure above 89 mm of Hg persistently. In children and adolescents, hypertension generally is defined as systolic and/or diastolic blood pressure consistently >95th percentile for age, sex and height. Blood pressures between the 90th and 95th percentiles are considered prehypertensive and an indication for lifestyle interventions.⁵

Four classes of antihypertensive drugs namely Calcium Channel Blockers (CCBs), beta blockers (B-blockers), Angiotensin-Converting Enzyme inhibitors (ACE)/Angiotensin Receptor Blockers (ARB) and diuretics are the most prescribed antihypertensive drug classes in many parts of the world. Monotherapy for hypertension is desirable because of better patient compliance, lower cost and fewer adverse effects. However, it is observed that most patients with hypertension require two or more drugs acting by different mechanisms (polypharmacy). According to some estimates, up to 40% of patients may respond inadequately even to two agents and are considered to have "resistant hypertension."⁶ Drug selection is based on efficacy in lowering BP and in reducing cardiovascular endpoints like stroke, myocardial infarction and heart failure.⁷ One rationale for polypharmacy in hypertension is that most drugs evoke compensatory regulatory mechanisms for maintaining blood pressure, which may markedly limit their effect.⁸

Vigilant use of antihypertensive drugs is need of time for limiting the disease of hypertension and related complications. As defined by WHO in 1977 Drug Utilisation Research is "the marketing, distribution, prescription and use of drugs in a society with special emphasis on the resulting medical, social and economic consequences."⁹

Drug utilisation studies, which evaluate and analyse the medical, social and economic outcomes of the drug therapy are more meaningful where they observe the prescribing attitude of physicians with the aim to provide drug rationally. These studies are carried out for finding short comings in different parameters of health systems and building the bridges, filling the lacunae for benefit of patients and for improving the efficiency of health system.

As polypharmacy increases with coexisting diseases, so does drug-drug interactions, hence a strict vigilance needs to be maintained for the prescribed drugs and their effects. Therefore, it is need of the hour to carry out such drug utilisation studies from time to time, so that all people involved in irrational prescribing circuit are familiarised with their fallacies, its impact on healthcare, so that it can rectify them and thus help in reducing the cost and adverse effects due to such irregularities thereby increasing the efficacy of treatment of the disease.

Thus, the present study was carried out to evaluate the pattern, extent, rationality and frequency of the use of antihypertensive drugs in the treatment of hypertension.

Aims and Objectives

Aim- The aim of this study was to analyse drug utilisation in the treatment of hypertension in a tertiary care hospital.

Objectives- To assess pattern of prescriptions (both monotherapy and polytherapy) in patients with hypertension in a tertiary care hospital.

MATERIALS AND METHODS

Study Design- This was a prospective, cross-sectional observational study conducted during January 2014 to December 2015 in Medicine Outpatient Department in a tertiary care hospital. STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines were used in the preparation of protocol.¹⁰

As per the WHO recommendations on conducting drug utilisation study, at least 600 prescriptions has to be included in study. Hence, we included 612 patients in study.¹¹

Inclusion Criteria

1. New cases and old cases of hypertension.
2. Patients with age group above 30 years (NPCDCS- National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke).¹²
3. Patients willing to give written informed consent to participate in the study.

Exclusion Criteria

1. Patients not willing to give written informed consent to participate in the study.
2. Hypertension in pregnancy.
3. Patients who were advised admission.
4. Patients with antihypertensive medication for reasons other than hypertension, for e.g. anxiety, migraine.

Ethical Considerations- Ethical committee approval was obtained prior to the start of the study.

Study was conducted in four phases; namely, preparatory phase, phase of data collection, analysis and documentation. Analysis was done by calculating core indicators recommended by WHO.

The core indicators used were as follows-

- a. Average number of drugs prescribed per encounter.
- b. Average number of antihypertensive drugs prescribed per encounter.
- c. Percentage of antihypertensive drugs prescribed by generic name.
- d. Percentage of antihypertensive drugs prescribed from NEML (National List of Essential Medicines).

Percentage of encounters with injections prescribed is also a prescribing indicator. But, this study is performed in outpatient settings and most of the persons requiring injectable antihypertensive drugs are admitted in wards. Hence, this indicator was not used in our study.

Fixed Dose Combinations (FDCs)¹³ of antihypertensive drugs are rampantly used in treatment of hypertension. Hence, in addition to the above indicators, prescription pattern of monotherapy and fixed-dose combinations used to treat hypertension was also studied.

Statistical Analysis- The collected data was numerically coded and entered in Microsoft Excel 2007 and analysed by SPSS (Statistical Package for Social Sciences) version 16.

OBSERVATIONS AND RESULTS

Out of 612 patients, 262 (42.81%) were in the age group of 60 and above. The mean age of patients was found to be 55.29 ± 10.57 (mean ± SD). Considering gender distribution 328 (53.59%) were males and 284 (46.41%) were females.

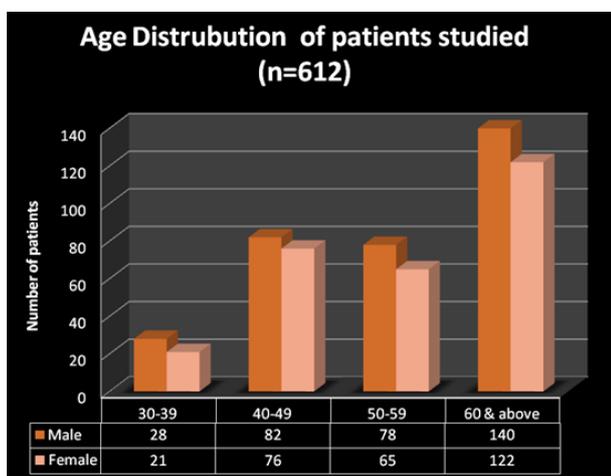


Figure 1. Age Wise Distribution of Hypertensive Patients (n=612)

Among 612 patients, 274 (44.78%) were prescribed with single antihypertensive (monotherapy), 256 (41.83%) were prescribed with two antihypertensive drugs (two-drug therapy), 72 (11.76%) were prescribed with three antihypertensive drugs (three-drug therapy) and 10 (1.63%) were prescribed with four antihypertensive drugs (four-drug therapy).

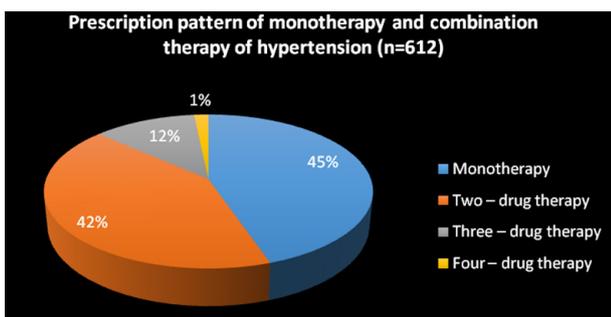


Figure 2. The Prescription Pattern of Monotherapy and Combination Therapy Used to Treat Hypertension

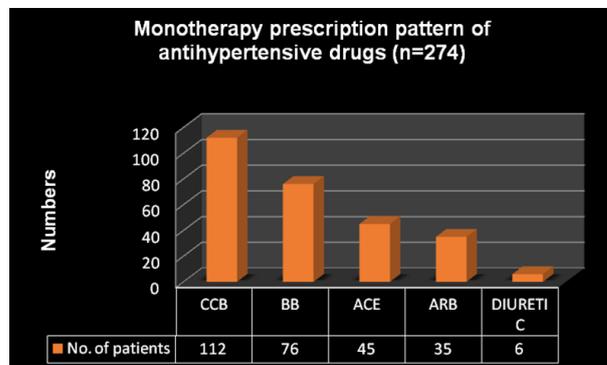


Figure 3. Monotherapy Prescription Pattern of Antihypertensive Drugs (n=274)

(CCB- Calcium channel blocker, BB- B blocker, ACE- Angiotensin-converting enzyme inhibitor, ARB- Angiotensin Receptor Blocker, D- Diuretic).

Out of 274 (44.78%) patients who were on monotherapy, 112 (40.87%) were prescribed CCB, 76 (27.73%) were given BB, 45 (16.42%) were prescribed ACEI, 35 (12.77%) were prescribed with ARB and 6 (2.18%) were prescribed Diuretics (D).

Of the 256 (41.83%) patients who received two-drug therapy, the commonest combination was BB+CCB 113 (44.14%) followed by BB+ACEI 66 (25.78%), CCB+ACEI 29 (11.32%), BB+ARB 25 (9.76%), ARB+D 16 (6.25%) and ACEI+D 7 (2.73%).

In our study, 72 (11.76%) patients were prescribed three-drug therapy. Various three drug combinations used were CCB+ACEI+BB 43 (59.72%), ARB+D+BB 22 (30.55%), BB+ARB+D 5 (6.94%) and ARB+D+CCB 2 (2.77%).

Only 10 (1.63%) patients received four-drug therapy out of which 7 (70%) were prescribed CCB+ACEI+ARB+BB and 3 (30%) were prescribed CCB+ACEI+BB+D.

Concomitant Medications	Numbers	%
Vitamins	205	30.10%
Analgesics	141	21.30%
OHD	132	19.94%
Hypolipidaemics	82	12.39%
Antacids	52	7.85%
Insulin	39	5.89%
Anxiolytics	11	1.66%

Table 1. Distribution of Concomitant Medication Prescription Pattern with Antihypertensive Drugs (Multiple Responses)

Of the total antihypertensive drugs prescribed 68.30% were prescribed by generic name, while 25.98% were prescribed as FDCs and 39.05% of the drugs were from NEML.

Average number of drugs prescribed per encounter in our study was 2.42, while number of antihypertensive drugs per encounter were 1.34.

DISCUSSION

Of the total 612 patients, 262 (42.81%) were in the age group of 60 and above. It could be due to lack of awareness

and negligence in young individuals. This study implies that if hypertension is addressed at a younger age, then mortality and morbidity due to hypertension can be reduced to a great extent.

44.78% patients received monotherapy, while 55.22% were given combination therapy. These findings are similar to studies by Sharma AK et al,¹⁴ Kalabharathi H L et al,¹⁵ Jay Shah et al¹⁶ and Arief M et al.¹⁷ According to Flack et al,¹⁸ though combination therapy maybe logical especially when systolic blood pressure is greater than 15 mmHg and/or diastolic blood pressure is greater than 10 mmHg above targeted goal, care should be taken to avoid unnecessary combinations.

Though, diuretics are generally recommended as first line therapy for treatment of hypertension (JNC V and VII), CCBs were the most common drugs used as first line treatment in our study. Similar results were found by Sharma AK et al¹⁴, Karunakar Kota et al¹⁹ and Sagar JK et al.²⁰ Lower use of diuretics compared to ACEI and CCBs may be due to the deleterious effects of diuretics on glucose homeostasis and lipid profile.⁸

BB and CCBs were the commonest combination used in two-drug therapy. It is in accordance with the study done by Kasi JM et al²¹ and Dileep et al.²² Combination therapy besides offering greater control rates by increasing the efficacy of antihypertensive drugs by synergistic effects, also minimises adverse effects.

CCB+ACEI+BB was the most frequently used three-drug combination. Similar results were seen by Sharma AK et al,¹⁴ Kasi JM et al²¹ and Murti K et al.²³ Different results were found by Nwaka AL et al²⁴ and Mohd AH et al²⁵ in which telmisartan + hydrochlorothiazide + metoprolol (ACEI+D+BB) combination (33.33%) was mostly prescribed.

Angiotensin receptor blockers (ARB) + diuretics + β -blockers (44.44%) are mostly observed classes as three-drug therapy in hypertension alone grouped patients. Similar results were found in the study done by Etuk E et al²⁶ and Raikar SR et al.²⁷ The combination of ACEI/ARB + BB + diuretic is justified since diuretics produce potassium loss, while drugs interfering with RAS conserve potassium.

Among four-drug combinations, CCB+ACEI+ARB+BB was used most frequently, which is similar as shown by Dileep et al.²² Use of multiple drugs in combination is being increasingly recognised as critical to control hypertension in patients with diabetes. Several large clinical trials demonstrated that most patients with hypertension could achieve and sustain adequate blood pressure control only with the use of multiple drug therapy.

While analysing concomitant medications with antihypertensive drugs, we found that vitamins were most commonly prescribed. The reason maybe that they were freely and abundantly available in the government setup. Okonta JM et al²⁸ found that analgesics were the most commonly prescribed concomitant medications. Antidiabetics, antibiotics and multivitamins were the concomitant medications used in a study done by Mohammed et al.²⁹ In a study done by Mirza Atif Beg et al,³⁰

it was found that antidiabetic drugs were the most commonly prescribed. These concomitant medications play an important role in the actions of various antihypertensive drugs in controlling hypertension. These may affect different parameters of antihypertensive drugs and may attenuate their side effects. So, these drugs should be closely monitored.

As many as 68.30% of antihypertensive medicines were prescribed by their generic names. This is on higher side as compared to Jayanth et al,³¹ Mirza Atif Beg et al³⁰ and Raikar SR et al.²⁷ Difference may be attributed to the present study being done in a government setup and availability of generic drugs in stores. Prescriptions with generic drugs should be promoted. This will lead to uniformity in prescriptions; patients will get standard treatment at low costs, which will lead to increased patient compliance and will help in curbing mal practices in healthcare.

25.98% of antihypertensive drugs were prescribed as FDCs. Similar results were found by Mirza Atif Beg et al³⁰ 24.10% FDCs, Kasi JM et al²¹ 32.22% FDCs, and Shende et al³² 8.5% FDCs. However, Rathnakar UP et al³³ showed 63.8% of prescriptions with FDCs. Use of FDCs is on rise due to increased use of combination therapy as well as due to promotions by pharmaceutical industries. But, strict vigilance should be maintained on the sale of FDCs as it becomes difficult to monitor or adjust the doses of individual active drugs. Disadvantages of FDCs is that they add to the financial burden and cannot be titrated depending on the individual requirements.³⁴

39.05% of antihypertensive drugs were prescribed from NEML. Similar results were found by Mirza Atif Beg et al.³⁰ This was less as compared to study by Shankar R et al³⁵ and Shende et al³² who found that 45% and 52.2% drugs were prescribed from the National Essential Medicine List 2011, respectively. The practice of prescribing drugs from NEML needs to be encouraged.

It was found that the average number of drugs prescribed per prescription were 2.42 and average number of antihypertensive drugs prescribed per prescription were 1.34. So, it can be seen from the above data that the number of drugs prescribed were more compared to the number of drugs, which were required. This leads to polypharmacy, increasing cost and chances of ADRs. Similar results were obtained by Karunakar Kota et al,¹⁹ Mirza Atif Beg et al,³⁰ Raikar SR et al,²⁷ Okonta JM et al,²⁸ Shende et al,³² Sweileh WM et al³⁶ and Sandozi T et al.³⁷ The reasons for polypharmacy may be due to coexisting diseases, nonspecific complaints by the patients and low average consultation time given by practitioners.

JNC 7 has mentioned that most patients who are hypertensive will require two or more antihypertensive medications to achieve their BP goals. In our study, we found that out of 612 patients studied, 274 (44.78%) were prescribed with single antihypertensive (monotherapy) and 338 (55.22%) were prescribed with fixed-dose combination of antihypertensive drugs (either of 2, 3 or 4 drug combination).³⁸

Out of 274 patients who were on monotherapy, 112 were prescribed CCB, 76 were given BB, 45 were prescribed ACEI, 35 were prescribed with ARB and 6 were prescribed Diuretics (D) in our study. While JNC 7 has recommended that thiazide-type diuretics should be used as initial therapy for most patients with hypertension, either alone or in combination with one of the other classes. This may have been result of availability of drug in hospital setup physician preferences for other group of drugs.³⁸

JNC 8 has recommended that initial treatment shall include treatment with thiazide diuretics, calcium channel blocker, ACE inhibitors or angiotensin-receptor blockers. In our study, we found that most of the drugs prescribed as monotherapy follow these recommendations.³⁹

CONCLUSION

With regard to rise in prevalence of hypertension and increasing demand of antihypertensive drugs, regular audits, training and feedback need to be done and followed up. These will be important tools for checking irrational use of antihypertensive drugs. Improving patients' knowledge, attitude and compliance can prove to be a cornerstone in improving rational use of drugs. Prescribing drugs by generic names should be encouraged. Education of the prescriber is of utmost importance. Prescribers should be trained regarding correct diagnosis following STGs (standard treatment guidelines) and protocols. This will aid in improving antihypertensive drugs prescribing behaviour to a large extent.

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Recommendations

1. Prescribing medicines by generic names should be encouraged.
2. Physicians should be trained regarding correct diagnosis, STGs (Standard Treatment Guidelines) and treatment protocols.
3. Manufacturing and marketing of FDCs should be strictly monitored, so as to keep a check on irrational FDCs.
4. Limitation- In our study, patient follow up was not done due to which compliance could not be analysed.

Abbreviations

ACEI	Angiotensin-converting enzyme inhibitor
ARB	Angiotensin-receptor blocker
BB	B-blocker
CCB	Calcium channel blocker
D	Diuretic
DUS	Drug utilisation study
FDCs	Fixed-drug combination
NLEM	National list of essential medicines
OPD	Outpatient department

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