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Drug Utilization Pattern, Cost of Illness and Cost-Effective Analysis of Antihypertensive Drugs in a Tertiary Hospital- A Cross-Sectional Study

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Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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ABSTRACT

Background: Hypertension is a condition with a substantial public health burden and a high risk of cardiovascular disease. The increasing prevalence of hypertension requires the use of cost-effective treatment and effective management of a disease. Hence, this study aims to assess the cost-effectiveness of antihypertension drugs in patients with hypertension and other co- morbidities.
Methods: The study was designed as prospective and interventional, with objectives to evaluate the cost of illness, prescribing patterns of different classes of antihypertensive drugs alone or in combination, and cost-effectiveness evaluation of other groups of antihypertensive drugs prescribed. Provided About 40 patients were with antihypertensive drugs of various classes whose health scores were calculated using the EQ-5D-5L questionnaire and calculated the total cost of treatment. Also calculated Most common Prescribe antihypertensive medications and the cost-effectiveness of each drug.
Results: This study showed that 58% of patients received combination therapy, 42% received monotherapy. Metoprolol was most cost-effective, followed by Carvedilol, which was in the case of

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monotherapy. Concerning combination therapy, Amlodipine + Bisoprolol proved to be the most cost-effective. ARBs were the most commonly prescribed class of antihypertensive drugs.
Conclusion: The study provided significant improvement in the health score of patients concerning the cost-effective antihypertensive treatment, showing an effective reduction in BP/ Helped in the management of hypertension and helped reduce risk factors associated with various cardiovascular diseases.

Keywords: DUE: Drug utilization evaluation, HTN: hypertension, QOL: Quality of life, DALY: daily adjusted life in years, SBP: systolic blood pressure, DBP; Diastolic blood pressure.

1. INTRODUCTION

DUE is an ongoing authorized and systematic quality improvement process designed to review drug use and prescribe patterns. The DUE main aim of the study is to promote rational drug use by Reducing drug and health-related treatment costs & improve the quality of medical treatment & health-related quality of life improvement. Generally, two types of DUE studies are 1. Quantitative DUE studies 2. Qualitative studies.

Quantitative studies involve the collection, organization, and display of estimates or measurements of drug use. This type of data is often used for making purchasing decisions or other financial activities such as preparing drug budgets.

On the other hand, qualitative DUE studies are multidisciplinary operations that collect, organize, analyses and report information on actual drug use. They are usually a one-off examination of narrowly defined areas of drug use, typically specific drugs or specific conditions [1].

Hypertension is a leading public health challenge globally due to its high prevalence and related morbidity and mortality. An estimated 978 million adults / 28% of the world's adult population, had uncontrolled hypertension in 2008.

Hypertension has also unfolded as a leading risk factor for morbidity and mortality in developing regions, low and middle-income nations from two decades. The disease burden resulting from hypertension translates into a substantial economic payment. In China, the estimated annual direct medical costs of chronic diseases caused by/or related to hypertension were approximately three billion dollars in 2003 [2].

Prescription pattern/drug utilization research is an essential tool as it offers an unbiased evaluation of prescribing, dispensing, and distributing drugs. It also helps identify the profile and extent of drug use and trends and agrees with local and international treatment guidelines [3,4].

Drug utilization studies in hypertension provide insights into the current prescribing practices and help us facilitate the rational use of drugs. Evaluating antihypertensive drug utilization and assessing BP control of hypertensive patients helps to alleviate the burden of hypertension. Pharmacoeconomic evaluations can be applied to review the value of treatments, compare the medical cost and health outcomes associated with new medicines to the price, and determine the existing alternative treatment outcome. The different Pharmacoeconomic parameters for estimating are: - Direct Medical Costs - Drugs, medical supplies and devices, laboratory and diagnostic tests, attended, and physician visits.

Direct Nonmedical Costs - Transport to and from healthcare facilities, extra shifts to the emergency ward, child or family care expenses, special diets, and other out-of-pocket expenses. Indirect Nonmedical Costs; Loss of productivity. Mortality – Loss of years of service due to sudden death.

•Intangible Costs - Nonfinancial outcomes of disease and medical care such as pain, suffering, disturbance, and trouble.
•Opportunity Costs – Value of the alternative therapy that forwent.
•Incremental Costs - The extra costs required to procure an additional unit of effect [4,5].

The cost-effective analyses contain cost outcomes and costs contrast. The Cost-effectiveness is dependent on QALYs. Higher the QALYs better the cost-effectiveness, which directly affects the total cost, ultimately benefited patients and reduces therapy's overall economic burden [4-9].

A combination of statins and antihypertensive drugs (diuretics, ACE inhibitors, CCB, beta-

blockers) will be used to avoid stroke in hypertensive's. Understanding the cost-effectiveness/ burden of therapy may become practical further [4-18].

Cost of illness analysis is used for measuring medical and other expenses. This study provides a general estimation of the direct and indirect costs of illness, and it also helps to Prevent. Early detection of complications helps reduce hospitalization and the number of drugs to break the direct medical and indirect costs [4-14].

The monitoring of hypertension management will help understand the practice, adopt an appropriate lifestyle, and also helps in cost minimization strategies [4-18]. Hence, this study was carried out to know the pattern of drug utilization in hypertensive patients.

Objectives: 1. To evaluate the prescribing pattern of antihypertensive drugs alone or in combination. **2.** To evaluate the most cost-effective therapy among the different groups of antihypertensive drugs prescribed

2. METHODOLOGY

Study Design: This study is the prospective observational study carried out in a tertiary care teaching hospital

Study setting & duration: The study was conducted in, Inpatient department for six months at the Cardiology/General Medicine Department at Sagar Hospitals, Kumarswamy Layout, Bengaluru. India

Study criteria: The patients were enrolled in the study as per the inclusion and exclusion criteria.

Inclusion criteria: The patient was treated with at least one antihypertensive drug.

Patients admitted as inpatients for antihypertensive treatment in the general ward, ICU, and emergency ward.

Exclusion criteria: Mentally disabled and unconscious patients, pregnant patients below 18 years & critically ill patients.

Sources of data: Sociodemographic Data, Previous medical and medication history, Treatment chart & interview with patient caretakers.

Study materials: Laboratory investigations, Information from the patient or patient's attendees, Case report of the patient, EQ-5D-5L Questionnaire

Study Procedure: The economic outcome, cost of illness, and cost-effectiveness analysis measured as QALY - quality-adjusted life years.

Sample size: Based on inclusion and exclusion criteria, fifty patients agreed and participated, but only 40 patients were presented until the completion of the study.

2.1 Methodology

After obtaining approval and clearance from Institutional Ethics Committee (IEC), the study was carried out in the Hospital for six months in the Out -Patient Department (IPD) of Sagar Hospitals, Bengaluru. Patients were selected based on inclusion and exclusion criteria. After taking the informed consent form from each patient, patient details include demographics, final diagnosis, laboratory data, and other Information collected from patients' records and documented in the designed data collection forms. Fifty patients' agreed and participated initially, but only 40 patients were presented until the completion of the study. The Questionnaire was provided to the patients in the Hospital and at discharge time, and even at the three follow-ups using a scale (Questionnaire: EuroQol group's EQ-5D 5LQuestionnaire).

Quality-Adjusted Life Year (QALY) is a generic measure of disease burden, including both quantity and quality of life lived. It is used in economic evaluation to assist the value of money of medical intervention. A QALY is a measure of health that functions the length of life and quality of life combined into a single index number.

To determine QALY, the single index number is multiplied by the utility value associated with the given state of health.

QALYs = one year life X one utility value
One QALY = one Year of a life lived in perfect health
As the individual patient study was conducted for three months, the QALY will be considered 0.25 instead of 1 (year of life lived in excellent health).

The utility value is determined by the visual analog scale (VAS) or EQ-5D Questionnaire.

A standard descriptive system such as the EuroQol group's EQ-5D 5L Questionnaire is used to detect the exact utility value.

After finding out the utility value, QALY is calculated by the given formula.

Cost-effectiveness = Average cost of treatment/QALYs

Cost-effectiveness is dependent on QALYs. Higher the QALYs better the cost-effectiveness, which directly affects the total cost, ultimately benefited patients and reduced the overall economic burden of therapy.

The collected data were subject to descriptive statistical analysis.

3. RESULTS

Among 50 patients enrolled, only 40 patients have completed the study. This study shows patients in which 55% were males and 45% were females. More no. of patients were from the age group of 60-69(12%) in this study. 70-79 patients were (10%), 80-89 were 6 %, 50-59 were 8 % 30-39 were 3 %, and least were from 40-49 were 1 %. In this study, 75% of patients were of normal weight, whereas 15% were underweight, 7 % were overweight, and 3% were obese. The marital status of the patients showed 97 % were married. The employment status of the patients showed. 68% were unemployed, and 32% were employed. In these studied patients 35% percent patients were housewife and the rest were bank employee 7.5%, businessman 10 %, Dhaba owner, ex-military 2.5 %, farmer 7.5 %, Govt. officer 10 %, manager 5%, supervisor2.5 %, teacher 12.5 %, technician 2.5 % respectively. The annual Income of the patients was a minimum of two lacks above. In this study, 75% of patients were literate, and 25% were illiterate. 10% of patients were having a smoking history only 10% of patients were alcoholics. In this study, 60% of patients stayed in for two days, 32% stayed for three days, and 8% stayed for four days.

The blood pressure at different time intervals showed a decrease in the diastole and systolic pressures from the baseline to third follow-up.

Though P values may not show statically significant, the clinical condition of blood pressure showed trivial/sensible change from baseline to third follow up slightly in the systolic and diastolic due to Hypertension co-morbid conditions, which led there is a need for ongoing long term research studies to establish the significance both clinically & statistically. The slight change in the BP also showed a small improvement in EQ-5D domains.

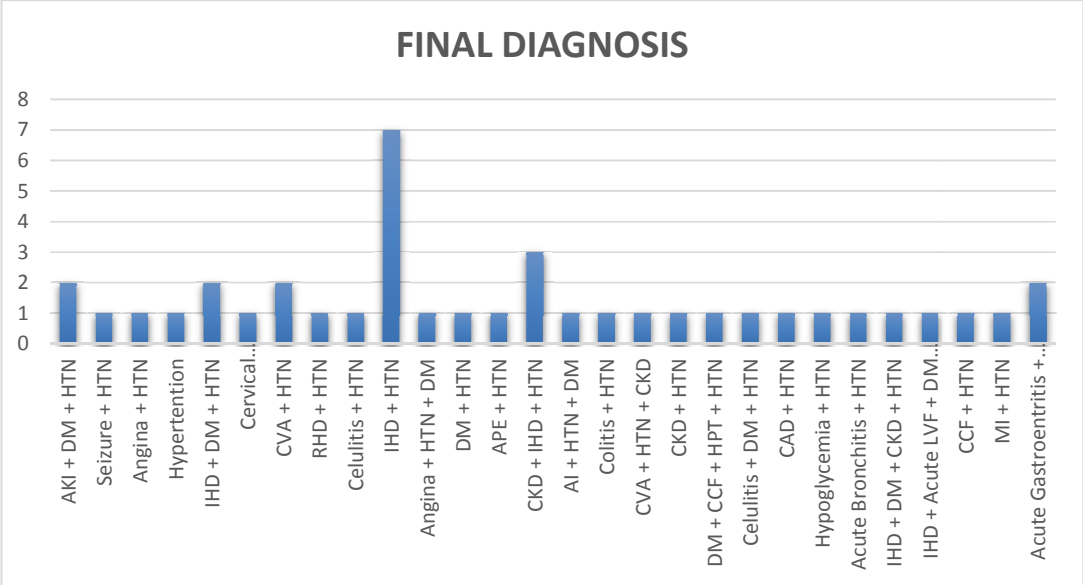

Fig. 1. Distribution of the final diagnosis

In this study majority of the patients were having Hypertension with co morbidities like IHD and DM.

Table 1. Distribution of blood pressure of patients

Blood Pressure at different time interval (mm Hg)	N	Mean	SD	P
Diastolic BP admission	40	87.17	9.044	0.12
Diastolic BP discharge		87.08	8.526	
Diastolic BP first follow		87.80	5.752	
Diastolic BP second follow		87.75	6.927	
Diastolic BP third follow		84.67	4.687	
Systolic BP admission		154.00	22.165	0.127
Systolic BP at discharge	40	148.13	13.760	
Systolic first follow-up		151.00	11.447	
Systolic second follow-up		151.13	13.610	
Systolic third follow-up		148.13	11.804	

Table 2. Distribution of patient's response/score to health questionnaire (Eq-5d 5l)

EQ5D 5L parameters	N	Mean	SD	P Value
Mobility in baseline	40	2.8750	0.33493	0.0067
Mobility in the first follow-up		2.3500	0.48305	
Mobility in the second follow-ups		1.9750	0.15811	
Mobility in the third follow-ups		1.4750	0.50574	
Self-care in the baseline	40	2.5000	0.50637	0.0001
Self-care in the first		2.1500	0.48305	
Self-care in the second		1.6250	0.49029	
Self-care in third		1.1500	0.36162	
Usual activities in the baseline	40	2.9000	0.30382	0.0001
Usual activities in the first		2.1000	0.30382	
Usual activities in second		1.7500	0.43853	
Usual activities third		1.1250	0.33493	
Pain at baseline	40	2.4250	0.50064	0.0001
Pain at first follow-up		2.0000	0.00000	
Pain at second follow-up		1.5000	0.50637	
Pain at third follow-up		1.1250	0.33493	
Anxiety depression baseline	40	1.5500	0.50383	0.0001
Anxiety depression First		1.1000	0.30382	
Anxiety depression second		1.0000	0.00000	
Anxiety depression third		1.0000	0.00000	

Table 3. Distribution of patient's total health scores

Total Health score (EQ5D5L)	N	Mean	SD	P-vale
Health score baseline		51.4250	8.56914	0.0001
Health score first	40	68.8250	7.97396	
Health scores second		80.1000	6.70935	
Health score Third		94.0500	6.22217	

The patient health score comparison from baseline to third follow-ups showed improved pharmacist involvement in the health monitoring.

This study showed 58% gave combination therapy, and 42% gave monotherapy among all the patients. In the monotherapy of antihypertensive drugs, the drug utilization pattern was as: 41% gave Angiotensin receptor blocker, 29% gave Calcium channel blocker, 18% were Alpha-blocker, and 12% were Beta-blocker.

In the combination therapy of antihypertensive drugs, the drug utilization pattern showed: 23% were given Beta blocker + ARB, 18% were given Beta blocker + CCB, 14% were given Beta blocker + ACE inhibitor, 14% were given CCB + ARB, 14% were given ARB + CCB + Beta blocker, 9% were given CCB + Beta blocker, 4%

were given Beta blocker + Alpha blocker and 4% were given ARB + Alpha blocker + Beta blocker.

According to this study, Metoprolol was the most cost-effective drug among all antihypertensive medications prescribed.

The cost-effective analysis (CEA) enlighten in the monotherapy drugs like Metoprolol and Carvidalol, and Amlodipine was observing, in that Metoprolol was the primary one. Whereas in the combination therapy Amlodipine+ Bisaprolaol, Telmisartan+Metaprolol followed by Atenalol+Losartan. Both monotherapy and combination therapy showed 100 percent clinical outcomes and improved total health (EQ5DL) domains.

4. DISCUSSION

The study was carried to assess the cost-effective analysis of antihypertensive drug-using QALY with the help of the EQ-5D-5L questionnaire. Out of 50 patients enrolled initially, Only 40 patients were completed due to the COVID-19 situation from October 2019 to March 2020.

Table 4. Distribution of different costs involved in the treatment

Different cost s (INR)	Mean ± SD(INR)
Hepatology cost	2457.00 ± 861.70
Hematology cost	760.00 ± 187.39
Biochemistry cost	1782.50 ± 446.57
Urine analysis cost	831.25 ± 204.96
Blood sugar test cost	206.50 ± 100.193
Total lab cost	7536.20 ± 2788.94
Total cost per day	645.629 ± 1021.11
Hospital charges cost	9442.50 ± 4490.15
Other cost	10.00 ± 63.24
Total direct cost	18284.94 ± 6818.87
Travel cost	650.00 ± 288.23
Special food cost	92.50 ± 157.52
Take career cost	490.00 ± 100.76
Total cost	1237.50 ± 336.41

Table 5. Distribution of the cost of illness

Costs	N	Mean	SD
Direct medical cost		18284.9457	6818.87359
Direct non-medical cost	40	1237.5000	336.41206
Total cost		19521.9857	6841.87902

Table 6. Cost effective analysis of different antihypertensive drugs

Antihypertensive Drugs	No. of Patients Prescribed	Avg. Treatment Cost	Avg. Utility Value	Avg. QALY	CEA
Metoprolol	17	519.6	91	22.75	22.83
Carvedilol	2	588.6	96.5	24.12	24.4
Amlodipine + Bisoprolol	1	580.5	95	23.75	24.44
Losartan	1	582.5	93	23.25	25.05
Nefidipine	1	577.8	87	21.75	26.56
Telmisartan	13	695.25	92	23	30.22
Amlodipine	20	703.78	89	22.25	31.63
Telmisartan + Metoprolol	3	1173.98	97.6	24.4	48.11
Olmesartan	4	1592.77	91.7	22.92	69.49
Atenolol + Losartan	1	2142	95	23.75	90.18
Prozosin	3	2145.6	91	22.75	94.31
Ramipril	5	2307.6	96.5	24.12	95.67

Age to be an essential risk factor for hypertension. The age of the subjects ranges from 35 to 86 average age being 67 years, among which 45% were females, and 55% were males. About 3% of patients were obese, 15% were underweight, and the rest all had normal BMI.

The economic burden of all the patients under this study was carried out, including their whole treatment cost. Hence we found out all the detailed information of patients under this study.

About 97% of patients were married; among all the patients, about 68% were unemployed, and 32% were employed, which was contradictory to the study conducted by Limaye D et al. The majority of patients had 3-6 lakhs as their annual income [11].

The distribution of smoking history among patients was not very prevalent, as only 10% were smokers. It was found that most of the patients were non-alcoholic.

The majority of patients stayed only 2-3 days in the hospital, but regular follow-up was conducted every month for three consecutive times, respectively.

The blood pressure of patients, being the essential factor in the study, showed an average systolic BP of 87.17mmhg with an SD of 9.04. Whereas systolic BP of 154mmhg with SD of 22.16 on admission, as demonstrated in Tab. 1, in our study. In a similar survey conducted by ARP et al. & Ramadhani DI et al. [16,17], There was a drastic reduction in BP by the follow-up, showing an average systolic BP of 84.46mmhg with SD 4.68 and systolic BP of 148.13mmhg with SD 11.8. shows the effectiveness of antihypertensive drugs during the study.

The cost of illness. Evaluated to know the expenses incurred in the treatment. We were able to find out that total direct medical costs with an average of 18284.84 ± 6818.87 and total indirect medical costs giving an average of 1237.5 ± 336.4. By knowing these values, we found the total cost of illness, which provided an average of 19521.98 with an SD of 6841.87, as shown in Tab. 5, similar to the study conducted by Zahara Eslampanah et al. [15].

The study conducted by Roobena Parveen et al. [16] prescribed various antihypertensive drugs to the patients under study also shows similar to our study results. The most common classes of antihypertensives that were prescribed are as follows: ARBs (41%), CCBs (29%), Alpha-blockers (18%), and Beta-blockers (12%), provided as monotherapy. In the case of combination therapy, the most commonly prescribed class of drugs were Beta-blocker + ARB (22%), Beta-blocker + CCB (17%), Beta + ACE inhibitor (13%), CCB + ARB (13%), a triple combination drug therapy commonly prescribed were ARB + CCB + Beta-blocker (13%).

The prescribing pattern was established, which was needed to find out cost-effective analysis of antihypertensive drugs which come under these classes—evaluated by using the help of the EQ-5D-5L questionnaire, which gave us the patient's response score, which provided us with a utility value required for, calculation of QALY. After conducting the statistical analysis, we found the cost-effectiveness of each antihypertensive drug prescribed. Tab. 6 showed, the medicines which were most cost-effective in the treatment were Metoprolol (22.83), Carvedilol (24.4), Losartan (25.05), Telmisartan (30.22), Amlodipine (31.63) which were given as monotherapy—in the case of combination therapy of drugs, Amlodipine + Bisoprolol (24.44), Telmisartan + Metoprolol (48.11), which were the drugs that were administered, showing the best cost-effectiveness among the patients under this study.

5. CONCLUSION

Hypertension is a severe global health problem, accounting for 10% of India's deaths and leading non-communicable diseases. The antihypertensive treatment effectively reduces hypertension-related morbidity and mortality. The increasing prevalence of disease requires cost-effective treatment. Hence did an economic evaluation of treatment accordingly.

The antihypertensive medications commonly prescribed are; ARBs were highest in number, followed by calcium channel blockers (CCBs), Alpha-blockers, and Beta-blockers respectively, in descending order, a case monotherapy. Concerning combination therapy, Beta-blocker + ARB and Beta-blocker + CCB were most commonly prescribed.

During the evaluation of the result, more commonly prescribed combination therapy was (58%) compared to monotherapy.

Cost-effective analysis showed the generic drugs yielding the most cost-effective treatment given, as Metoprolol being the most cost-effective drug, including Carvedilol, Losartan, Telmisartan, Amlodipine in case of monotherapy and Amplodipine + Bisoprolol was most cost-effective drug combination therapy followed by Telmisartan + Metoprolol.

The interventional study involved only a small group of patients. Having a bigger sample size to the study can provide us with an elaborate explanation about the best cost-effective treatment for the prevalence of hypertension.

LIMITATION OF THE STUDY

- This study was conducted only for six months
- Due to covid pandemic & drop out conditions, the sample size was minimal,

Future directions: This type of study can carry for an extended period and different hospital setups.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT

As per international standard or university standard, patients' written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

The study was prepared and submitted to the College of Pharmaceutical Sciences, Dayananda Sagar University Ethics Committee on human subject research for ethical clearance. Institutional Ethics Committee approved the study (Ethical Clearance Number: -DSCP/P-D/IHEC/2019-20/0006)

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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