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## Impact of body mass index and lipid profile among hypertensive patients including Pharmacoeconomics analysis: An Indian study

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### Abstract

**Objective:** To find the prevalence of obesity and hyperlipidemia among hypertension patients and to analyze the prescription pattern and to study the cost analysis of antihypertensive therapy.

**Methods:** It was a Prospective observational cohort study done over a period of six months (Nov 2017 to April 2018) in a tertiary care teaching hospital in Chidambaram, Tamil Nadu. The patient demographics, BP, BMI, Lipid data were collected & recorded into data collection forms including patient's prescription

**Key findings:** Total of 70 subjects was enrolled in the study. The age distribution of study shows maximum number of patients being in 70-80 years (33%). Majority of hypertensive subjects come under stage II hypertension (74%) and are considered to be obese (42%). 70-80 year's age group are having the highest average mean for BP which is  $166.52 \pm 29.17/93.91 \pm 9.88$  mmHg. The highest average BP ( $166.55 \pm 28.44/96.55 \pm 13.69$  mmHg) was observed in obese patients. Furosemide (28%), Amlodipine (28%), Enalapril (28%) was most frequently prescribed drugs in monotherapy. Furosemide with Enalapril (36%) was most frequently prescribed drugs in double therapy. Furosemide with Enalapril with Amlodipine (45.40%) was most frequently prescribed drugs in triple therapy. Quadruple drug therapy was prescribed in accelerated hypertension cases.

**Conclusion:** The present study shows that blood pressure tends to increase as the age increases. Higher prevalence of BP was seen in obese patients. Hyperlipidemia was tending to be higher in Hypertensive crisis stage with increased BP. Mono therapy (45%) was highly preferred than combination therapies. Diuretics are more economical than ACE inhibitors, CCB and ARB. Prescription trend showed diuretics as first line treatment followed by ACE inhibitors, CCB and ARB which complies with AHA/ACC guidelines.

**Keywords:** Antihypertensive drug cost analysis, hyperlipidemia, hypertension, obesity, prescribing pattern

### Introduction

Hypertension [HTN], known as high blood pressure [BP], is a condition in which blood pressure is increased to the extent that blood pressure lowers the clinical benefit. It is considered to be a major public health problem in India by 2020 and a common lifestyle disease [12]. It was an important factor in determining the cardiovascular risk of an individual and its associated health burdens. In 2017, the new guidelines for hypertension was developed by American college of Cardiology (ACC) and American Heart Association (AHA) guidelines for the detection, prevention, management and treatment of high blood pressure after JNC 7 Hypertension guidelines. The guidelines eliminated the category of pre-hypertension, categorizing patients as having either Elevated (120-129 and less than 80) or Stage I hypertension (130-139 or 80-89) [10].

Hypertension is the most common morbidity identified in adults who are overweight and the leading mortality risk in adults, attributable to around 12.8% of deaths worldwide [6]. Hypertension is associated with both risks alone in the context of overweight and obesity. According to WHO, overweight and obesity are defined as abnormal or excessive fat accumulation that may impair health [11]. Overweight is a body mass index [BMI] greater than or equal to 25 kg/m<sup>2</sup> and obesity is a BMI greater than or equal to 30 kg/m<sup>2</sup>. Several studies have now examined secular BP trends with secular BMI trends. Overweight and obesity have grown rapidly over the past decades, parallel with BP's rise. Obviously, excess weight is responsible for a large number of cases of hypertension. Hypertension related factors are overweight with a family history of hypertension, low birth weight, non-white ethnicity,

sedentary behavior or Insufficient physical activity, and poor sleep quality are more likely to develop hypertension<sup>[6]</sup>.

The association between hypertension and hyperlipidemia is well established and both can contribute to increasing the susceptibility of patients to coronary heart disease (CHD) development. Serum lipid and lipoprotein (hyperlipidemia) abnormalities are recognized as major modified risk factors for cardiovascular disease and as independent risk factors for essential hypertension have been identified. Dyslipidemia is more common in hypertensives than normotensives, and as BP increases, lipid levels increases<sup>[7-9]</sup>.

As the incidence of hypertension continues to rise over decades, there is a steady increase in treatment investment. In this regard, factors affecting prescribing trends have a significant impact on health economics. Drug costs have always been a barrier to effective therapy. The increasing prevalence of hypertension and increasing cost of its treatment affect the prescribing pattern among physicians and patient compliance<sup>[5-3]</sup>. The primary aim of hypertension therapy should be effective control of BP to prevent the progression of complications from reversing or delaying, thereby reducing an individual's overall risk without adversely affecting the quality of life. Hypertension patients are mostly treated with one or more antihypertensive medications. 2017AHA/ ACC hypertension guideline recommends thiazide diuretics as first line initiation therapy, followed by calcium channel blockers [CCBs], angiotensin II converting enzyme [ACE] inhibitors and Angiotensin receptor blockers [ARBs] for initiation anti-hypertensive therapy. Lifestyle measures, including reducing salt intake, stopping tobacco intake, and reducing body weight in obese patients, are part of all patients with hypertension management<sup>[10]</sup>.

The objective of the present study was to find the prevalence of obesity and dyslipidemia among hypertension patients and to analyze the prescription pattern of antihypertensive drugs and adherence to the guidelines of AHA/ACC hypertension guidelines 2017 as well as to study the cost analysis of antihypertensive therapy.

## Materials and Methods

It was a Prospective observational cohort study done over a period of six months (November 2017 to April 2018) in the Department of Medicine of a tertiary care teaching hospital in Chidambaram, Tamil Nadu. The study was approved by Institutional Human Ethics Committee (IHEC). All the patients provided written informed consent prior to the interview. Data was collected from the total of 70 patients, who visited the department of Medicine with Hypertension during the study period. The subjects taken for study are aged between more than 40 and less than 80 years old of both genders and diagnosed with hypertension; a systolic blood pressure reading  $\geq 140$  mm Hg and a diastolic blood pressure reading  $\geq 90$  mm Hg on at least two abnormal BP readings on different occasions and treated with anti-hypertensive medications.

The patient demographics, Blood Pressure data, BMI data, Lipid data were collected from patient case sheets and recorded into data collection forms. Patient prescriptions were studied to collect the anti-hypertensive drugs prescribed for the management of hypertension.

The height was calculated in centimeters (cm) by using height measuring tape & weight in kilograms (kg) was calculated by using weighing machine. By these data BMI was calculated using standard BMI formula. The patients were classified into

Stages of BMI (WHO revised Asian guidelines).  $BMI = \text{Weight (kg)} / \text{Height (m}^2\text{)}$ . The lipid data collected in data collection form was measured by doing Lipid profile test.

Each generic name (active ingredient) component of the drug was counted separately for brand name and combination antihypertensive agents from medication charts. Drugs cost were obtained from the Current Index of Medical Specialties (CIMS). The 2017 AHA/ACC hypertension guideline was used to classify the hypertension stages among patients. Patients receiving single antihypertensive medication were defined as receiving monotherapy; those who were receiving two antihypertensive medications were defined as receiving dual therapy; those receiving three antihypertensive medications are on triple therapy; and those getting four antihypertensive drugs are considered to be quadruple therapy.

The information extracted was entered in Microsoft Excel sheet and were analyzed as percentage and average.

## Results

By applying inclusion and exclusion criteria total of 70 samples were enrolled into the study. The subjects are divided into four age trends. The age distribution of study shows that the maximum number of patients being in 70-80 years, accounting 33% of the total. The total number of male and female patients participated in the study were 40 (57%) males and 30 (43%) females. The subjects were classified in to BP classification, based on AHA/ACC guidelines, 2017. In the present study out of 70 subjects 52 (74%) come under stage II hypertension, 16 (23%) come under hypertensive crisis stage and only 2 (3%) come under stage I hypertension classification. The subjects are categorized into different classification of BMI, based on the revised consensus guidelines for Asian Indians. In the study population 41.5% are considered obese, 37% are considered overweight, and nearly 21.5 % are having normal BMI. The study shows majority of the hypertensive subjects are considered to be obese (42%) and overweight(37%), while 22% are accounting normal BMI. The average systolic and diastolic blood pressure was calculated to age trend wise. 70-80 years age group are having the highest average mean for BP which is  $166.52 \pm 29.17/93.91 \pm 9.88$  mmHg. The BP tends to increase as the age increases. The average systolic and diastolic blood pressure was calculated for subjects under BMI categories. The highest average BP ( $166.55 \pm 28.44/96.55 \pm 13.69$  mmHg) was observed in obese patients. The average systolic and diastolic blood pressure, total cholesterol, LDL-C, HDL-C, triglycerides, and BMI were calculated among hypertensive patients under BP classification. The lipid data was tending to be higher in Hypertensive crisis stage with increased BP.

The prescribing pattern of antihypertensive drug therapy was studied. Monotherapy was most preferred drug therapy. Out of 70 subjects, 32 subjects were given mono drug therapy. Mean cost per month was calculated. Diuretics, CCB and ACE inhibitors are most prescribed category of drugs. ACE inhibitor tends to show lowest mean cost/month and ARB shows the highest. Furosemide (28%), Amlodipine (28%), Enalapril (28%) were totally prescribed for 27 patients out of 32 patients in monotherapy. Out of 70, 25 subjects were prescribed with two antihypertension drugs. Mean cost per month was calculated. Diuretics + ACE inhibitors were prescribed mostly and the mean cost per month was INR 219. Furosemide with Enalapril (36%) was most frequently

prescribed drugs in double therapy. Triple drug therapy was prescribed for 11 subjects out of 70. Triple therapy was mostly prescribed in stage hypertensive crisis stage. Most combined antihypertensive drug given were Diuretics + ACE inhibitors + CCB and the mean cost was INR 474. Furosemide with Enalapril and with Amlodipine (45.40%) was most frequently prescribed drugs in triple therapy. Quadruple drug therapy was prescribed only for 2 subjects out of 70. Quadruple drug therapy was mainly prescribed in accelerated hypertension case.

## Discussion

BMI is closely associated with elevated BP and the risk of hypertension is high in obese population. The lipid data tend to be higher in Hypertensive crisis stage with increased BP. The patients were divided into four age trends 40 – 49 years (14%), 50 – 59 years (24%), 60 – 69 years (29%) and 70 – 80 years (33%). Most of the patients come under 70 – 80 years age where in Srinivas Pai K *et al.* (2014) [1] concluded that higher numbers of hypertensive patients were seen between age group 50-60 years (36%). The subjects were classified into categories of BP (AAC/AHA guidelines 2017). Stage 1 hypertension (130-139/80-89 mmHg) was diagnosed only in two subjects (3%), while most of them were diagnosed with Stage 2 hypertension ( $\geq 140/\geq 90$  mmHg) in 52 subjects (74%), majority of the patients were in this group, whereas 16 subjects (23%) of patients were observed in the hypertensive crisis ( $>180/>120$  mmHg) category. 70-80 years age group are having the highest average mean for BP which is  $166.52 \pm 29.17/93.91 \pm 9.88$  mmHg. The BP tends to increase as the age increases. In our study, the subjects are categorized into different classification of BMI, based on the revised consensus guidelines for Asian Indians. In this study population 41.5% are considered obese, 37% are considered overweight, and nearly 21.5 % are having normal BMI. The average BMI was calculated to age trend wise. BMI tend to be higher in age group of 50-59 years ( $25.29 \pm 1.87$  kg/m<sup>2</sup>). Higher prevalence of BP was seen in obese patients. The highest average BP ( $166.55 \pm 28.44/96.55 \pm 13.69$  mmHg) was observed in obese patients. Therefore, the risk of hypertension is high in obese population. In our study higher prevalence of Lipid data was seen in Hypertensive crisis category. In the present study the most used drug therapy for treatment of hypertension was mono therapy (45%), followed by double therapy (36%), triple therapy (16) and quadruple therapy (2%). In mono therapy, total 6 drugs were prescribed. Among this Furosemide (28%), Amlodipine (28%) and Enalapril (28%) were the most frequently prescribed drugs. In mono therapy, Telmisartan shows the highest mean cost per month of INR (425.4) and Nifedipine shows the lowest mean cost per month of INR (55.8). In double therapy, total 13 combinations were prescribed. Among this Enalapril + Furosemide (36%), followed by Furosemide + Amlodipine (16%) were the most frequently prescribed drugs. In dual therapy Enalapril + Cilnidipine shows the highest mean cost per month of INR (185.1) and Spirinolactone + Telmisartan shows the lowest mean cost per month of INR (486.9). In triple therapy, total 6 combinations were prescribed. Among this Furosemide + Enalapril + Amlodipine (45.4%) were the most frequently prescribed drugs. In triple therapy Ramipril + Carvedilol + Telmisartan shows the highest mean cost per month of INR (591.3) and Metoprolol + Furosemide + Verapamil shows the lowest mean cost per month of INR (271.5). In Quadruple therapy, total two combinations were

prescribed. Enalapril + Furosemide + Carvedilol + Spirinolactone show the mean cost per month of INR (507.6) and Telmisartan + Amlodipine + Metoprolol + Cilnidipine shows the mean cost per month of INR (997.5). Quadruple drug therapy was mainly prescribed in accelerated hypertension cases. J. Joel *et al.*, (2015) [4] shows most of the patients has received monotherapy (75%). Diuretics showed to be more economical than other antihypertensive categories drugs. J. Joel *et al.*, (2015) [4] study showed diuretics and beta-blockers to be more economical than other antihypertensive categories. As per study reports, hypertension pharmacotherapeutic management costs were to be high. This enhanced price may be due to two or more combination of antihypertensive drugs treatment. Monotherapy treatment has costed low. Rachana Pr *et al.*, (2014) [3] study showed the most frequent prescribed drugs were CCBs followed by beta blockers and the diuretics were most cost-effective. In our study the most frequent prescribed drugs were diuretics followed by ACE inhibitors, CCB and ARB which complied with AHA/ACC hypertension guidelines where the first line treatment includes drug class diuretics followed by ACE inhibitors, ARB and CCB. The second line treatment includes drug class diuretics followed by beta-blockers.

## Conclusion

The present study shows that blood pressure tends to increase as the age increases. Majority of the hypertensive subjects are considered to be obese (42%). Higher prevalence of BP was seen in obese patients. Higher prevalence of Lipid profile was seen in Hypertensive crisis category. Lipid data was tend to be higher in Hypertensive crisis stage with increased BP. Mono therapy (45%) was highly preferred rather than combination therapies. Among the monotherapy majority of the patients were treated with Diuretics. Among combination therapy, Furosemide + Enalapril combination was highly prescribed. Diuretics are considered to be more economical than ACE inhibitors, CCB and ARB. Study cost assessment advices using generic medicines instead of branded medicines can reduce the patient's financial strain. Further modification of Drug Price Control Order 2013 is proposed to achieve patients' optimal health care and society benefits. Prescription trend showed diuretics as first line treatment followed by ACE inhibitors, CCB and ARB which complies with AHA/ACC guidelines.

## Contribution of Works

Dr. S. Parimalakrishnan conceived the idea. Dr. R. Umarani modified & developed the idea. Irfana, Suwitha, Jency compiled the idea into theory, proposed the protocol and carried out the experiment. Suwitha and Jency contributed in collecting subject details. Irfana contributed to the interpretation of results. All authors discussed the results and contributed to the final manuscript.

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