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Drug utilization pattern and cost burden in hypertensive patients attending a North Indian tertiary care hospital

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Abstract

Background: Hypertension is a silent killer & global public health issue contributing significantly to cardiovascular disease, kidney failure, premature deaths and disabilities. Even modest increase in BP within normal ranges results in risk of cardiovascular disease. Pharmacotherapy of hypertension and the prescribing behavior have substantial economic implications for patients especially in a developing country like India. Therefore, it is important to analyze the prescription pattern of antihypertensive drugs and cost of the treatment.
Materials and methods: This was an observational cross-sectional study conducted on 200 primary hypertensive patients. Prescribing behavior was analyzed on the basis of core indicators mentioned in WHO document for Action Programme on Essential Drugs for four major classes of antihypertensive drugs. Cost analysis was done on the basis of total cost incurred in a month.
Results: Most commonly prescribed antihypertensive class was found to be Angiotensin Receptor Blockers (ARBs) followed by Calcium Channel Blockers (CCBs) and telmisartan was most frequently prescribed individual drug. The total cost of antihypertensive treatment was found maximally in high income group.
Conclusion: ARBs are the most commonly used antihypertensive drugs followed by CCBs, which is in accordance with JNC 8 guidelines. Cost incurred in the treatment is high in high income group.
Keywords: Hypertension, Angiotensin receptor blocker, Drug utilization, Cost burden.

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1. Introduction

Hypertension is a condition in which the blood pressure (BP) is persistently raised above the normal level. According to Joint National Committee (JNC) 7 guidelines, normal blood pressure for an adult ≥18 years is < 120/80 mmHg, pre-hypertension is 120-139/80-90 mmHg and hypertension is ≥140/90 mmHg [1]. The new American College of Cardiology/American Heart Association (ACC/AHA) guideline defines hypertension as blood pressure ≥130/80 mmHg [2]. It is a silent killer & global public health issue contributing significantly to cardiovascular disease, kidney failure, premature deaths and disabilities [3]. Globally, cardiovascular diseases account for approximately 17 million deaths per year, out of which 9.4 million deaths are because of hypertension [4-5]. It is responsible for at least 45% of deaths due to heart disease and 51% due to stroke [3]. An international survey (1990-2015)

showed that increase in systolic blood pressure from 110-115 mmHg to ≥140 mmHg resulted in substantial increased in Daily Adjusted Life Years (DALYs) and deaths [6]. In India, two recent studies revealed that the prevalence of hypertension is growing among younger age group. The National Family Health Survey-4 (NFHS-4) shows that the prevalence of hypertension in Indian younger men (15–54 years) and women (15–49 years) is 13.8% and 8.8% respectively, with an overall prevalence of 11.3%. Similarly, District Level Household Survey-4 (DLHS-4) has reported hypertension in 25.3% adults with a greater prevalence in men (27.4%) as compared to women (20.0%) [7]. Another study in India shows that 33% urban and 25% rural Indians are hypertensive; out of that 25% rural and 42% urban Indians are aware of their hypertensive status while 25% rural and 38% of urban Indians are being treated for hypertension [8]. Even modest increase in BP within normal ranges results in risk of cardiovascular disease. Cardiovascular risk starts at as low as 115 mmHg of systolic or 75 mmHg of diastolic pressure, although the conventional cut-off point for hypertension is 140/90 mmHg. It means in most countries of the world, more than 80% of adults are at risk from their blood pressure [9,10]. Over 80% of this burden occurs in low- and middle-income countries [11]. According to Registrar General of India, based on hospital records, cardiovascular diseases caused about 12-15% of all deaths in 1980s-1990s. Mortality due to cardiovascular diseases in between 2001-03 was 20.3% in males and 16.9% in females which increased in 2010-2013 to 25.1% and 20.8%, respectively. Among all leading causes of death, cardiovascular diseases retain the top position [12]. So, high blood pressure has a substantial impact on the burden of cardiovascular disease worldwide.

Without a concerted effort addressing the prevention, diagnosis, treatment and control of hypertension, the pandemic of cardiovascular disease around the world will likely continue to grow. Hypertension awareness, lifestyle modification and drug treatment are the cornerstone of management of hypertension. There is a disparity in the interventions in low- and middle-income countries as compared to high-income countries. As revealed in a global study 2000-2010, the hypertension prevalence in high-income countries decreased by 2.6% and awareness, treatment and control improved substantially while low- and middle-income countries saw a 7.7% prevalence increase and there was little improvement in awareness, treatment and control [13]. According JNC 8, pharmacological treatment should be started when the blood pressure is ≥150/90 mmHg (in adults ≥60 yrs) and ≥140/90 mmHg (in younger patients <60 yrs, diabetic and chronic kidney disease patients). Target level blood pressure is <150/90 mmHg (for adult ≥60 yrs) and <140/90 mmHg (younger patients <60 yrs, diabetic and chronic kidney disease patients). The first line drug therapies for hypertension are Angiotensin Converting Enzyme Inhibitors (ACEIs) or Angiotensin Receptor Blockers (ARBs), Calcium Channel Blockers (CCBs) and Thiazide diuretics. Rest other drugs like selective β_1-blockers (e.g metoprolol), vasodilators (e.g hydralazine), aldosterone antagonists (e.g spironolactone), and central α_2-adrenergic agonists (e.g clonidine) etc. are used as add-on therapy when the first line therapy is ineffective. Usually monotherapy with the lowest effective dose and titrate-up it for maximum efficacy along with lifestyle changes are the initial strategy for intervention. When no effect is seen even after the highest tolerable dose another drug can be added from the same first line group drugs. Combination therapy can be started at the initiation of therapy. ACEIs or ARBs or combinations are the initial choices of intervention in Hypertension with chronic kidney disease. In blacks, therapy started with CCBs or thiazides or combination, while in non-blacks options are available from all four first line drugs [14].

The ultimate aim of antihypertensive drug therapy is to minimize or control the morbidity and mortality associated with persistent hypertension. With the establishment of efficacy of standard antihypertensive drugs in multi-centric clinical trials, selection of initial monotherapy and combination therapy (if required) is made possible. The effectiveness of an antihypertensive drug is also analyzed on the basis of patient's lifestyle and risk factors which are very important before considering any antihypertensive drug. Rational prescribing for antihypertensive drug in a patient must require four important considerations- drug efficacy profile, drug safety profile, suitability and affordability [15]. In developing nations (like India) as compared to developed nations, patients are usually not covered under any medical insurance schemes and pay out of their pockets for their healthcare needs. As antihypertensive therapy is a chronic therapy therefore, affordability (cost) is very important factor before considering any antihypertensive drug in patient of hypertension. This is also one of the important reasons for non-compliance and stopping the drug therapy [16]. In one study it was found that in developing nations most commonly prescribed antihypertensive is CCBs while in the same study the most cost-effective antihypertensive therapy was found to be the diuretics [17]. Another study from India revealed that monotherapy is the leading trend in antihypertensive therapy followed by fixed dose combinations (FDCs) and polytherapy. Among the different antihypertensive drug classes CCBs were the commonest drug class prescribed by the practitioners followed by beta-blockers. Diuretics were found to be the most cost-effective antihypertensive class followed by beta-blockers (BBs), CCBs, ARBs, ACEIs then

alpha-blockers [18]. Although JNC 8 has formulated the guidelines for rational & justified use of antihypertensive drugs, in developing nations like India abiding with guidelines is very difficult. The cost of medications has always been a barrier to effective treatment in developing countries (especially India). The rising cost of treatment continuously influences the prescribing pattern.

The current study was planned to analyze the prescription pattern of antihypertensive drugs, cost of the treatment and adherence to JNC 8 guidelines in a tertiary care hospital of India.

2. Materials and methods

This was an observational cross-sectional study conducted at a tertiary care hospital in North India over a period of one year. Prior to commencement, the study was approved by Institutional Ethics Committee (Vide Ref. No. IEC/2016/76-A/08) and only those patients volunteering to participate and provide written informed consent were included in the study. Participants were recruited as outpatients in the Medicine department.

2.1 Study design:

The primary hypertensive patients of 30-70 yrs age of either sex, who were on antihypertensive drug therapy and gave voluntary consent, were included in the study. Patients with secondary hypertension, post myocardial infarction, post stroke or any other co-morbidities were excluded from the study. A total of 200 patients were included in the study. Written informed consent was taken before including each patient in the study. A pilot study was carried out to validate the questionnaire. Patients were chosen randomly and their prescription was analyzed on the basis of core indicators mentioned in WHO document for Action Programme on Essential Drugs [19]. Primarily four major classes of antihypertensive drugs included in essential medicine list of hospital and their FDCs were analyzed. These four major classes of antihypertensive drugs were- ACEIs, ARBs, CCBs, diuretics and beta blockers (BBs).

2.2 Data collection:

Baseline demographic characteristics of the patients were recorded at the time of first contact. Patients were interviewed regarding duration of taking antihypertensive drugs and detail of adverse drug reaction (if developed). Following indicators were used for the analysis of prescribing behavior-

i. Frequency of antihypertensive administration with respect to gender, age, income groups and as monotherapy/combination therapy
ii. Cost of antihypertensive treatment in various income groups
iii. Utilization of various antihypertensive drugs

2.3 Safety & tolerability:

Treatment related adverse events during the study period were recorded and evaluated for their possible relationship to with the medications.

2.4 Statistical analysis:

Data were expressed as the real value or percentage on excel sheet.

3. Results

In the demographic data we found that out of 200 hypertensive patients, 70 (35%) patients were in the age group of 60-70years, which was maximum among all the age groups. This was followed by 40-49years age group (24.5%), 50-59years (23.5%) and then 30-39years (17%). [Table 1]

Table 1: Distribution of hypertensive patients in different age groups

Age groups (Years)	Number of patients	Percentage (%)
30-39	34	17.0
40-49	49	24.5
50-59	47	23.5
60-70	70	35.0
Total	200	100

In our study we found that among the attending 200 hypertensive patients, 113 (56.5%) patients were males while 87 (43.5%) were females. [Table 2]

Table 2: Gender wise distribution hypertensive patients

Gender	Number of patients	Percentage (%)
Female	87	43.5
Male	113	56.5
Total	200	-----

Among the total attending patients, we found 101 (50.5%) patients were non-smokers while 99 (49.5%) patients were smokers. Out of 200 patients 74 (37%) were male smokers while 25 (12.5%) were female smokers. [Table 3]

Table 3: Distribution of smokers and non-smokers among the patients

Gender	Number of smokers (%)	Number of non-smokers (%)
Male	74 (37)	39 (19.5)
Female	25 (12.5)	62 (31)
Total	99 (49.5)	101 (50.5)

We also found that 103 (51.5%) were in low income group, 82 (42%) were in middle income group and 13 (6.5%) were in high income group. Among the male patients, 62 (54.8%) were in low income, 42 (37.2%) in middle income and 9 (8%) in high income group. While among the female patients 41 (47.1%) were in high income, 42 (48.3%) in middle income and 4 (4.6%) in high income group. Maximum number of male patients was in low income groups while the female patients were almost equally divided in low- & -middle income groups. [Table 4]

Table 4: Income group wise distribution of patients

Income groups (INR/month)	Number of male patients	Number of female patients	Total
Low Income (10001 – 20000)	62 (54.8%)	41 (47.1%)	103 (51.5%)
Middle Income (20001 – 30000)	42 (37.2%)	42 (48.3%)	84 (42%)
High Income (30001 – 40000)	9 (8%)	4 (4.6%)	13 (6.5%)
Total	113	87	200

It was seen that ARBs 126 (63%) was the most commonly prescribed antihypertensive class, which was followed by CCBs 109 (54.5%), diuretics 82 (41%), BBs (8%) and ACEIs 6 (3%). Among the ARBs and all antihypertensive drugs, most commonly prescribed drug was telmisartan 120 (60%). This was followed by amlodipine 109 (54.5%), hydrochlorothiazide 72 (36%) and atenolol 14 (7%). Rest all drugs were prescribed in <5% of the patients. The individual drugs were prescribed in patients as monotherapy or as combination therapy. [Table 5]

Table 5: Distribution of prescribed antihypertensive classes and individual drugs

Drug classes	Individual drugs	Number of Prescriptions	Percentage (%)	Total Prescriptions
Diuretics	Hydrochlorothiazide	72	36	82 (41%)
	Chlorthalidone	6	3	
	Furosemide	2	1	
	Spironolactone	2	1	
ARBs	Losartan	4	2	126 (63%)
	Telmisartan	120	60	
	Olmesartan	2	1	
ACEIs	Lisinopril	4	2	6 (3%)
	Ramipril	2	1	
CCBs	Amlodipine	109	54.5	109 (54.5%)
BBs	Atenolol	14	7	16 (8%)
	Metoprolol	2	1	

ACEIs- Angiotensin Converting Enzyme Inhibitors, ARBs- Angiotensin Receptor Blockers, CCBs- Calcium Channel Blockers, BBs- Beta blockers

In gender specific distribution of drugs, we found that among all 87 male patients ARBs (80.5%) & CCBs (80.5%) were the most commonly prescribed drugs which were followed by diuretics (55.1%), BBs (11.5%) and ACEIs (3.4%). Among the females (113) ARBs were prescribed in 49.6% which was followed by CCBs (34.5%), diuretics (30%), BBs (5.3%) and ACEIs (2.6%). Overall most commonly prescribed group drugs were ARBs followed by CCBs, Diuretics, BBs and ACEIs. [Table 6]

Table 6: Gender-wise distribution of antihypertensive drugs in study population

Drug classes	Prescribed to male patients		Prescribed to females patients		Total
	Number	Percentage among males (%)	Number	Percentage among females (%)	
ACEIs	3	3.4	3	2.6	6 (3%)
ARBs	70	80.5	56	49.6	126 (63%)
CCBs	70	80.5	39	34.5	109 (54.5%)
Diuretics	48	55.1	34	30.0	82 (41%)
BBs	10	11.5	6	5.3	16 (8%)

ACEIs- Angiotensin Converting Enzyme Inhibitors, ARBs- Angiotensin Receptor Blockers, CCBs- Calcium Channel Blockers, BBs- Beta blockers

In age distributed prescriptions, we found that among all age groups ARBs were prescribed to maximum number of patients which was followed by CCBs, diuretics, BBs and ACEIs. Within the age group of 60-70yrs patients, ARBs (65.7%) were the most prescribed antihypertensive drugs which were followed by CCBs (58.6%), diuretics (41.4%), BBs (7.1%) and ACEIs (5.7%). Same trend of prescribing was also seen in other age group patients except in 50-59yrs age group where no ACEIs were prescribed, while in 30-39yrs age group patients ACEIs and BBs were prescribed equally. Among the different classes of antihypertensive drugs, ACEIs were prescribed maximally in 60-70yrs age group (5.7%) while no any prescription of 50-59yrs of age group patient had ACEI. ARBs were prescribed maximally in 60-70yrs age group patients (65.7%) followed by 50-59yrs (63.8%), 40-49yrs (61.2%) and 30-39yrs (58.8%). CCBs were included maximally in the prescriptions of age group 60-70yrs (58.6%) followed by 40-49yrs (57.1%), 30-39yrs (52.9%) and 50-59yrs (46.8%). Diuretics were almost equally prescribed in the age groups of 40-49yrs (44.9%) and 30-39yrs (44.1%). This was followed by 60-70yrs age group (41.4%) and 50-59yrs (34%). BBs were prescribed in < 15% of the patients in while ACEIs in almost < 5% of the patients among all age groups. [Table 7]

Table 7: Age wise distribution of different antihypertensive class prescribed to the study population

Drug classes	30-39 years (Out of 34)	40-49 years (Out of 49)	50-59 years (Out of 47)	60-70 years (Out of 70)	Total (Out of 200)
ACEIs	1 (2.9%)	1 (2%)	0 (0%)	4 (5.7%)	6 (3%)
ARBs	20 (58.8%)	30 (61.2%)	30 (63.8%)	46 (65.7%)	126 (63%)
CCBs	18 (52.9%)	28 (57.1%)	22 (46.8%)	41 (58.6%)	109 (54.5%)
Diuretics	15 (44.1%)	22 (44.9%)	16 (34%)	29 (41.4%)	82 (41%)
BBs	1 (2.9%)	6 (12.2%)	4 (8.5%)	5 (7.1%)	16 (8%)

ACEIs- Angiotensin Converting Enzyme Inhibitors, ARBs- Angiotensin Receptor Blockers, CCBs- Calcium Channel Blockers, BBs- Beta blockers

In our study we found that combination therapy was prescribed in maximum number of patients 63 (31.5%) in age group 60-70yrs while it was least preferred in age group 30-39yrs as prescribed in only 2 (1%) patients. Monotherapy was preferred therapy in patients of age group 30-39yrs, prescribed in 32 (16%) patients while least number of patients 7 (3.5%) in age group 60-70yrs. Overall combination therapy was prescribed in maximum number of patients 119 (59.5%) as compared to monotherapy 81 (40.5%). [Table 8]

Table 8: Prescription of monotherapy or combination therapy in different age group study population

Age groups (Years)	Number of patients on monotherapy	Number of patients on combination therapy
30-39	32 (16%)	2 (1%)
40-49	28 (14%)	21 (10.5%)
50-59	14 (7%)	33 (16.5%)
60-70	7 (3.5%)	63 (31.5%)
Total (%)	81 (40.5%)	119 (59.5%)

In our study we found that in low income group, ACEIs (83%) were the most preferred antihypertensive drug which was followed by BBs (62.5%), CCBs (56%), diuretics (53.6%) and ARBs (50.8%). In middle income group, the most preferred antihypertensive class was ARBs (40.5%) followed by CCBs (38.5%), Diuretics (33%), BBs (31.2%) and ACEIs (17%). While in case of high-income group patient's diuretics (13.4%) were the most commonly prescribed antihypertensive class followed by ARBs (8.7%), BBs (6.3%) and CCBs (5.5%). [Table 9]

Table 9: Distribution of antihypertensive drug classes among the different income groups

Income groups (INR/month)	ACEIs	ARBs	CCBs	Diuretics	BBs
Low Income (10001 – 20000)	5 (83%)	64 (50.8%)	61 (56%)	44 (53.6%)	10 (62.5%)
Middle Income (20001 – 30000)	1 (17%)	51 (40.5%)	42 (38.5%)	27 (33%)	5 (31.2%)
High Income (30001 – 40000)	0 (0)	11 (8.7%)	6 (5.5%)	11 (13.4%)	1 (6.3%)
Total	6	126	109	82	16

ACEIs- Angiotensin Converting Enzyme Inhibitors, ARBs- Angiotensin Receptor Blockers, CCBs- Calcium Channel Blockers, BBs- Beta blockers

In cost analysis of antihypertensive drugs, we tried to find out the monthly expenditure in different income groups. We found that average cost of antihypertensive treatment was INR 277.05/month. Among the different income groups, we found that the maximum cost of treatment was in high income group (INR 364.80) followed by low income group (INR 266.10) and middle-income group (INR 266.10). [Table 10]

Table 10: Monthly expenditure of antihypertensive drugs in income group patients

Income groups (INR/month)	Gender	Number of patients	Average cost (INR/month)	Average cost of in each income group (INR/month)
Low Income (10001 – 20000)	Male	62	266.70	266.10
	Female	41	265.50	
Middle Income (20001 – 30000)	Male	42	228.60	200.25
	Female	42	171.90	
High Income (30001 – 40000)	Male	9	408.60	364.80
	Female	4	321.00	
Total		200	277.05	277.05

In our results when we analyzed the adverse drug reactions reported by the patients for different antihypertensive class, we found most common adverse reaction with ACEIs was fatigue reported in 3 patients followed by headache (2 patients) and dizziness (1 patient). In case of ARBs 42 patients reported headache followed by body ache in 20 and dizziness in 18 patients. CCBs caused drowsiness in 32 patients; 15 patients reported headache and 4 patients' constipation. Diuretics caused nausea (30 patients) and weakness (14 patients); while patients who were on BBs reported fatigue (3 patients), dizziness (3 patients), rashes (3 patients) and headache (2 patients). [Table 11]

Table 11: Adverse drug reactions reported by the patients

Adverse drug reactions (ADRs)	ACEIs	ARBs	CCBs	Diuretics	Beta blockers
Headache	2	42	15	0	2
Dizziness	1	18	0	0	3
Fatigue	3	0	0	0	10
Body ache	3	20	0	0	0
Drowsiness	0	0	32	0	0
Constipation	0	0	4	0	0
Rashes	0	0	0	0	3
Weakness	0	0	0	14	0
Nausea	0	0	0	30	0

4. Discussion

It has been well established that hypertension, chronic disease, is one of the serious health issues globally. This may require long-term therapy, even lifelong along with other modes of treatment. Appropriate and rational anti-hypertensive drug therapy is important to curb the increasing prevalence of the disease [7]. JNC 8 guidelines put forward the steps for management of hypertension based on efficacy, safety, affordability and cost. The deviation from this may result in bad outcome in the patient either in form of efficacy, safety or cost [14, 20].

In our study we found the prevalence of hypertension was 1.3 times more in males as compared to females. This finding is in accordance with some of the previous studies [7, 21, 22].

We also found that out of the total hypertensive patients, prevalence was maximum in the age group 60-70 years (35%) and least in 30-39 years age group (17%). There was increase in prevalence as advancing age. These results are in accordance with the earlier studies [23, 24]. So, this could be inferred that the advancing age is an important risk factor for hypertension which has been already established.

Our results also showed that among the male patients almost 50% were smokers and 50% were non-smokers. This is similar to the study done by Li G *et al*. [25].

It was found that out of total study patients, more than 50% were in low income group and around 6.5% in high income group; the rest were in the middle-income group category. Sabri S *et al*. also found similar results in their study [26]. The reason for this differential association may be due to poor lifestyle and inability to afford healthcare facilities.

This study revealed the various aspects of prescribing pattern for hypertension in our hospital. We found that most commonly prescribed antihypertensive class among our patients was angiotensin receptor blocker which was followed by calcium channel blockers and diuretics. Least preferred drug classes were beta blockers and angiotensin convertase enzyme inhibitors. This is in accordance with the JNC 8 guidelines which mentioned that starting therapy should be monotherapy with angiotensin receptor blocker or calcium channel blockers or thiazide diuretics or angiotensin convertase enzyme inhibitor.[14] Although, angiotensin receptor blockers are slightly costlier than angiotensin convertase enzyme inhibitors but they have better safety and tolerability profile. This is the reason for maximum number of prescriptions having angiotensin receptor blockers (telmisartan > losartan > olmesartan) either alone or in combination therapy.

Next most common drug prescribed was calcium channel blocker (amlodipine) which was prescribed to maximum number of patients of age group 60-70 yrs. This is also in accordance with the JNC 8 guidelines and previous studies [14, 27].

In age group-wise distribution it was found that ARBs were almost equally (62.4 ± 3.6%) prescribed in all age groups, CCBs more commonly prescribed in 60-70 years & 40-49 years age group. Diuretics were also almost equally prescribed in 30-39, 40-49- and 60-70-years' age groups.

Our results also showed that prescribing monotherapy was the main line of treatment in early age groups and combination therapy increasing with advancing age. This signifies that in higher age group patients, for adequate control of hypertension patient requires combination therapy instead of monotherapy.

In our cost analysis data, we found that in low income group and middle-income group average cost per month is almost similar but in high income group the average was higher.

In safety profile of different drug groups, it was found that common adverse effects encountered during therapy were headache, body ache, nausea and drowsiness. No serious reactions were encountered during therapy.

4. Conclusion

ARBs are the most commonly prescribed antihypertensive class in this study, followed by CCBs. Among the individual drugs, telmisartan was the most commonly prescribed antihypertensive agent followed by amlodipine. This pattern of prescribing behavior is in accordance with JNC 8 guidelines. Average monthly expenditure of antihypertensive drugs was found to be maximum in high income group while lowest in middle income group patients as the prescribing pattern varied according to the patient's income group.

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