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**Research Article** 

# Assessment of Drug Utilization Pattern and Rational Use of Antihypertensive Therapy in Geriatric Patients: A Prospective Observational Study

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# Abstract



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Background: Hypertension is one of the most frequently occurring noncommunicable diseases, and it causes a variety of cardiovascular complications and mortality. Diagnosis and treatment in elderly patients are very difficult due to their changes in physiology and physiological responses to the therapy. Drug utilization studies are plausible instrument in the evaluation in health care practice. **Objective:** To assess drug utilization pattern and rational use of antihypertensive therapy in geriatric patients. Materials and methods: This is a prospective observational study that took place in 200 inpatients over the course of six months. The study includes subjects with age group of 65 years and above with all comorbidities. The collected data was statistically evaluated by appropriate descriptive statistical analysis. Here the prescription pattern and rationality were analysed. Results: In this study out of 200 patients, 53% of prescriptions contain combination therapy and remaining 47% contains mono therapy. Most commonly prescribed class as mono therapy was Calcium channel blockers 79. 00% (Amlodipine). Among two drug regimen Calcium channel blockers + Diuretics and the three-drug regimen Calcium channel blockers + Angiotensin Receptor Blocker + Diuretic combination are generally prescribed. Here the overall rate of adherence to JNC 8 is 95%. Conclusion: In this study by analysing prescription pattern, we concluded that most commonly prescribed drug class was Calcium channel blockers (Amlodipine). The present study results demonstrate that, most of the physicians are adherent to the JNC 8 recommendations.

*Keywords:* Antihypertensive drugs, Adherence to JNC 8, Rational use, Prescription patterns.

# **INTRODUCTION**

Hypertension is a paramount independent stake factor for a variety of diseases. It's linked to a lot of morbidity and mortality in diverse populations, which has a large economic impact. Antihypertensive agents are one of the widely used therapeutic agents due to increased prevalence of Hypertension and their heterogenic therapeutic efficacy. Most of the randomized controlled trials have concluded that early management of high blood pressure can significantly reduce the risk of coronary artery disease, end stage renal disease, CHF, stroke and gross morbidity. The guidelines by the JNC are still considered as gold standard. Each updated version of JNC guidelines concentrates on drug treatment threshold and drug choices. Geriatric patients are more vulnerable to drug related problems because of their agerelated changes in physical, physiological, and psychological aspects. A number of risk factors are assumed to increase the risk of drug related problem in geriatrics, such as over use of drugs, inappropriate use, medication errors, medication nonadherence etc. The literature reviews give confidence that the outcome of the study aspect definitely gives a positive impact on society and Healthcare professionals to take

necessary steps to prevent the drug related problems in the geriatric population. This study primarily focuses on the assessment of drug utilization patterns and rationally of prescribing antihypertensive agents in elder patients with co morbid conditions. It is very essential to study and rise a question on how the drugs are prescribed and what is the rationale behind the prescription.

# **MATERIALS AND METHODS**

*Study site:* Vivekananda General Hospital, Deshpande Nagar Hubballi.

Study design: This is a Prospective observational study.

*Study period:* This study was conducted for a period of 6 months.

*Study subjects:* This study included the in-patients admitted in Vivekananda hospital Hubbali.

*Ethical Approval:* Ethical clearance for this study was obtained from institutional ethical committee. (Ref. No. KLECOPH/IEC/2020-21/05)

*Study criteria:* The study includes geriatric population ( $\geq$ 65 years), patients of both the gender and patients with all comorbid conditions attending inpatient department. The study excludes patients who are attending outpatient department, patients with the age group of less than 65 years, patients with psychiatric disorders, patients admitted in ICU, patients with incomplete medical records and patients who are not willing to participate in the study.

*Data collection:* The data is collected with a suitable patient data collection form.

*Statistical method:* The data is statistically tested with the help of Descriptive analysis.

### **RESULTS**

### Distribution of demographic data of subjects

Out of 200 study populations 54.00% were females (n=108) and 46.00% were males (n=92). The mean age of the study participants was found to be  $69.7 \pm 7.66$ . The results shown that subjects of age group between 65 to 70 (74%) were most affected and 33% (n=66) subjects were smokers and 36.50% (n=73) were alcoholics. Among study population, 41.00% (n=82) subjects were under APL and 59.00% (n=118) were BPL and 34.50% (n=69) were literate and 65.50% (n=131) were Illiterate {Table No.1}.

In this study it was found that the subjects were diagnosed with hypertension mostly since 5 to 10 years (35%) {Fig.1}.

In the study it was found that out of the selected study population 36% (n=138) were diagnosed with type 2 DM followed by 15% (n=57) were diagnosed with CNS diseases.

Table No.1 Distribution of Demographic data		
Demographic Data	Percentage (N)	
Age		
65-70	74(148)	
71-75	12.5(25)	
76-80	7(14)	
81-85	6(12)	
>85	0.5(1)	
Gender		
Male	46(92)	
Female	54(108)	
Personal History		
Smoking	33(66)	
Non-smoking	67(134)	
Alcoholic	36(73)	
Non-alcoholic	64(127)	
Educational Status		
Literate	34(69)	
Illiterate	66(131)	
Economic Status		
APL	41(82)	
BPL	59(118)	

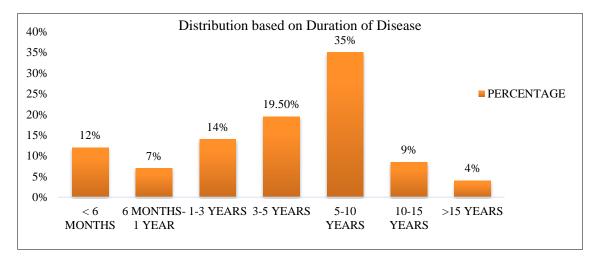


Figure 1: Distribution of subjects based on duration of disease.

#### **Prescription pattern analysis**

In the study it was found that the antihypertensive treatment given to the hypertensive patients were of 2 types, monotherapy 47.00% (n=94) and combination therapy 53.00% (n=106). In this study out of 23 combination

therapy with FDC, 91.30% (n=21) were combination therapy with one FDC and 8.70% (n=2) were combination therapy with two FDC {Table No.2}.

Table No.2 Distribution of subjects based on type of therapy, Combination therapy with FDCs			
Type of Therapy	Percentage(N)		
Monotherapy	47(94)		
Combination therapy	53(106)		
Combination Therapy with FDCs			
Combination therapy with 1 FDC	91.3(21)		
Combination therapy with 2 FDCs	8.7(2)		

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Among 93 monotherapies, CCBs were most commonly preferred class 79% (n=74). By analysing distribution of two drug combination therapy, out of 61, CCB + Loop Diuretic was the most routinely prescribed combination therapy 44.27% (n=27) {Table No.3}. Out of 34 three drug combination therapy, the most commonly prescribed combination was CCB+ Diuretic+ ARB 15% (n=5). By evaluating the distribution of 4 and 5 drug combination therapy, it was found that, 4 drug combination CCB+ Alpha Beta Blocker + ARB +Diuretic 18%(n=2) and 5 drug

Table 3: Distribution of Monotherapy and two drug combination therapy.				
Distribution of Monotherapy	Percentage (N)			
Thiazide diuretics	1.06(1)			
ACE Inhibitors	3.19(3)			
ARBs	7.44(7)			
Beta Blockers	8.51(8)			
Alpha and Beta Blocker	1.06(1)			
ССВ	79(74)			
Distribution of 2 Drug Therapy				
ACE Inhibitors+ Beta Blocker	1.64(1)			
ACE Inhibitors +Loop Diuretic	4.9(3)			
ARBs +Beta Blocker	4.92(3)			
ARBs+ Loop Diuretic	3.28(2)			
ARBs+ Thiazide Diuretic	3.28(2)			
CCB + ACE Inhibitors	1.64(1)			
CCB +Alpha Beta Blocker	6.56(4)			
CCB+ Alpha Agonist	3.28(2)			
CCB+ARBs	6.56(4)			
CCB+ Beta Blocker	11.48(7)			
CCB+ Loop Diuretic	44.27(27)			
Loop Diuretic + Loop Diuretic	1.64(1)			
Loop Diuretic+ Potassium Sparing Diuretic	1.64(1)			
Loop Diuretic +Beta Blocker	3.28(2)			
Potassium Sparing Diuretic+ Beta Blocker	1.64(1)			

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combination CCB+ Diuretic +Alpha Beta Blocker +Diuretic +Alpha Agonist 18% (n=2) were prescribed most {Table No.4}. In the study Amlodipine was prescribed more commonly (72%) compared to other drugs. Out of 26 prescribed antihypertensive agents, 24 drugs are given in the form of tablet. Amlodipine, belongs to the class of CCB, is the most commonly prescribed drug in the study population 49.48% (n=143). Only 2 antihypertensive drugs were prescribed as injection/infusion form. In that, Furosemide was the most commonly prescribed drug 82.61% (n=57).

Distribution of 3 Drug Therapy		Percentage	
	(N	,	
Alpha Agonist + ARBs + Beta Blocker		[1]	
Alpha Beta Blocker +ARBs+ CCB		[1]	
CCB+ ACE Inhibitor +Beta Blocker		94(1)	
CCB+ Alpha Beta Blocker +ACE Inhibitor		[2]	
CCB+ Diuretics +ACE Inhibitor		94(1)	
CCB+ Diuretics + Alpha Agonist	3(	[1]	
CCB+ Diuretics +Alpha Beta Blocker	6(	[2]	
CCB+ Diuretics+ ARBs	15	5(5)	
CCB+ Diuretics+ Beta Blocker	12	2(4)	
CCB+ Diuretics +Nitrates	6(	[2]	
CCB+ Diuretics +Diuretics	3(	[1]	
Diuretics +ACE Inhibitor + Beta Blocker 3(1		[1]	
Diuretics +Alpha Beta Blocker+ ARBs 3(		[1]	
Diuretics + Alpha Beta Blocker +Nitrates 6(		[1]	
Diuretics +Diuretics +ARBs 12		2(4)	
Diuretics +Beta Blocker +Alpha Agonist 3(		[1]	
Diuretics + Diuretics + Beta Blocker 3(		[1]	
Diuretics + Diuretics + ACE Inhibitor 6(		[2]	
CCB+ACE Inhibitor +ACE Inhibitor 3(		[1]	
Distribution of 4 & 5 Drug Therapy			
CCB+ ACE Inhibitor + Alpha Beta Blocker + Beta Blocker		9.09(1)	
CCB+ Alpha Beta Blocker + ARBs +Diuretic		18(2)	
CCB + Diuretic+ Alpha Beta Blocker +ACE Inhibitor		9.09(1)	
Diuretic+ ACE Inhibitor +Beta Blocker +Diuretic		9.09(1)	
Diuretic+ ACE Inhibitor +Diuretic+ ARBs		9.09(1)	
Diuretic +Diuretic+ Alpha Beta Blocker +Nitrate		9.09(1)	
Diuretic +Diuretic +Beta Blocker + CCB		9.09(1)	
ARBs+ Beta Blocker +Diuretic+ Diuretic +CCB		9.09(1)	
CCB+ Diuretic +Alpha Beta Blocker +Diuretic+		18(2)	

### WHO Prescribing indicators?

The Drug utilization evaluation done by WHO prescribing indicators {Table No.5}.

Table 5: Drug utilization in the study asper WHO			
WHO Indicators	Encountered Values	Optimal range	
Average no of drugs per patient with active drugs in FDCs	1.825	1.6 - 1.8	
Percentage of drugs prescribed by generic names	34.50%	100%	
Percentage of encounters with injection prescribed	11.87%	13.4 - 24.1	
Percentage of drugs prescribed from NLEM	42.3%	100%	

In the present study 95% (n=190) of the prescriptions were following the JNC-8 guidelines for prescribing antihypertensive agents {Table No.6}.

Table 6: Distribution of Prescription based on Adherence to JNC-8.		
Adherence to JNC-8	Percentage (n)	
Prescriptions adhering to JNC-8	95(190)	
Prescriptions not adhering to JNC-8	5(10)	

In this study, the 9<sup>th</sup> recommendation (n=5) was found to be most violated among others {Fig.2}.

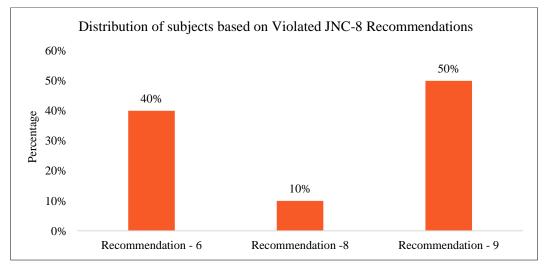


Figure 2: Distribution of subjects based on Violated JNC-8 Recommendations

## **DRP** analysis by PCNE

By evaluating the PROBLEM domain by PCNE, Treatment safety (P2) related problems were the most common type (74.52%) among others. By evaluating the CAUSES domain by PCNE classification, the most common cause for most of the DRP was found to be DRUG SELRCTION (C1) (63.06%). By evaluating the PLANNED INTERVENTION domain based on PCNE classification, most of the DRPs were not having interventions (58%). The remaining interventions are done mainly at patient level (22%) and Prescriber level (19%).

# DISCUSSION

According to this study the average age of patients was found to be  $69.7\pm7.66$  with female male ratio 27:23. Asper this study, hypertension is more prevalent in geriatric patients between the age group 65-70 (74.00%). This study result is contrast with the study conducted by **Romday R et al**, because in their study 40-60 age groups was the most common age group<sup>1</sup>.

In the current study majority of the co morbidities were T2DM (36%) followed by CNS diseases (15.0%), CVS diseases (13.70%). However, study conducted by **Nayaka et al**, had shown an inconsistent finding with the present study were majority of comorbidities were seen in RS diseases 66.67%, followed by endocrine diseases 35.33%, cardiovascular diseases 32.67%<sup>2</sup>. This discrepancy in the outcome may be assumed due to the study subjects enrolled and comorbidities included. The study by **Nayaka et al** included all geriatric patients irrespective of their co- morbid diseases<sup>2</sup>.

The 8th report of JNC on detection, evaluation, prevention and treatment recommends the use of ACEIs, ARBs, Thiazide diuretics and CCBs alone or in combination for the management of early-stage hypertension. The findings of this study show that, out of 200 prescriptions, 53% of prescriptions contains combination therapy (n=106) and remaining 47% (n=94) contains mono therapy. Similar study conducted by **Sharma JK et al** concluded that, monotherapy was prescribed in 48. 59% of total prescriptions and combination therapy was prescribed in 51.41% of total

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prescriptions<sup>3</sup>. In the 106 combination therapies, most of the physicians prescribed 2 drug regimens (57.54%). The most frequently prescribed class as mono therapy was Calcium channel blockers (CCB) 79. 00% (n=74). The study conducted by Malpani et al and Siva Reddy et al concluded the same<sup>4,5</sup>. However this result was not compactable with the study conducted by Narkar et al where ARB was the most frequently used class<sup>6</sup>. Amlodipine was the only CCB repeatedly prescribed in this study 71. 50% (n=143). Similarly, Paulose et al summarized that amlodipine was the most frequently used antihypertensive as mono therapy7. The second most commonly prescribed class as mono therapy was BB 8.51% (n=8). Among BB, metoprolol was the commonest 8.50% (n=17). These findings indicating disparities with study done by Sharma JK et al in small extent. In that BBs are the third most common class (5.48%) and atenolol was the commonest prescribed drug3. In antihypertensive multi drug regimen, two drugs regimen was the commonest in this study 57.54% (n=61). These findings are in consonance with other study performed by Sharma JK et al, 38.43% were two drug regimen therapy<sup>3</sup>. Among two drug regimen CCB+ Diuretics combination are generally prescribed. Similarly, Pandaya et al. found that the most generally prescribed two-drug combination was CCB+ Diuretic (12 percent and 37.8%, respectively)<sup>8</sup>. In this study, 32.07 percent (n=34) of the participants were administered a three-drug antihypertensive medication regimen. CCBs + ARBs + Diuretic was the most usually recommended threedrug combination. This is consistent with the findings of **Gupta et al.** who found that three medication combinations as antihypertensives were most commonly used: CCBs+ ACEIs/ARBs+ Diuretic<sup>9</sup>. In this study, 10.37% of prescriptions contain 4&5 drug antihypertensive regimen. Generally prescribed 4 drug combination is CCB+ Alpha Beta blockers + Diuretic +ARBs 18 %(n=2) and five drug combination is CCB+ Diuretic +Alpha Beta blockers +Diuretic + Alpha agonist 18%(n=2). Overall CCBs are commonly prescribed antihypertensive drugs followed by diuretic. JNC 8 recommends use of CCBs, Diuretic; ACEI/ARBs are preferred drug classes both in mono therapy and combination therapy.

As per Prescribing indicators by World Health Organization (WHO), the average number of drugs per patient was found to be 1.825, it was almost within in the optimal range (1.6-1.8). The percentage of encounters with injection was only 11.87%, this value was below to the optimal range. The percentage of medications prescribed by their generic name was 34.5% and percentage of medications prescribed from the NLEM -2021 was 42.3%. The both values suggesting that prescription writing using brand names were common and usage of drugs from NLEM was not optimal. Similar to the present study, WHO indicators for drug utilization was also used in the study conducted by Bhandary A et al, as per that average number of drugs per patient was 1.60 and the percentage of encounters with injection was only 2.21%<sup>10</sup>. The percentage of medications prescribed by generic names was 8.85% and percentage of medications prescribed from the essential drug list 2015 was only 32.30%.

In this study overall rate of adherence to JNC 8 is 95%(n=190). Complete adherence rate was observed among the patients of Hypertensive urgency and emergency with the JNC 8 guideline. This result was supported by Gupta et al and similar conclusion also reported in study conducted by **Ramday R et al**<sup>1</sup>. Remaining 5%(n=10) prescriptions are not adhere to JNC 8. The least adherence is to recommendation 6,8,9. According to JNC 8, the recommendation 6 explain about first line antihypertensive agents (Thiazide diuretic, CCB, ARBs, ACEI). The recommendation 8 explain about treatment specifications for CKD patients. Their treatment

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should include an ACEI or ARBs to improve kidney outcome. The recommendation 9 gives idea about combination therapy. If BP is failed to reach in a required goal using first line drugs, then titrate the dose at maximum again if it is not achieving the goal then go for combination therapy of first lines after that second line drugs.

In this study, a total of 157 DRPs are identified. By evaluating Problems based on PCNE, the most commonly encountered problems are treatment safety related problems 74% (n= 117). By assessing Causes as per PCNE, regarding drug choice problem, the results agree with studies conducted by **Redzuan AM et al**<sup>11</sup>. The current study indicating that, around 63%(n=99) of DRPs are associated with drug selection. The high frequency of drug selection issues indicated that pharmaceuticals should be prescribed with greater caution, particularly in elderly patients. By analysing planned interventions, most of the cases have no interventions. The majority of interventions accomplished at patient 22.00%(n=35) and prescriber 19.00%(n=29) level.

This study conducted was single centred and carried out only in inpatient department, therefore population was relatively homogenous. The sample size, which is included in the study was less. Due to this variableness and ambiguity should be considered as limitations. Despite these limitations the study revealed various significant features of the Drug utilization patterns and adherence of antihypertensive drugs to JNC 8 guidelines in diverse co-morbid conditions.

# **CONCLUSION**

In this study by analysing prescription pattern, we concluded that most commonly prescribed drug class was CCB (Amlodipine) followed by BB (Metoprolol). By analysing prescribing indicators by WHO revealed that, prescription writing using generic name and usage of drugs from NLEM need to be encouraged. Present study results demonstrating that, most of the physicians are adherent to the JNC 8 recommendations. But provider adherence in recommendations 6 and recommendation 9 has room for improvement. A regular monitoring of the prescription pattern and a new strategy of provider educational methods need to be promoted to keep a tab on the rational drug prescriptions for a better therapeutic outcome. Inclusion of clinical/hospital pharmacist in drug therapy monitoring and prescription analysis should enhance. This study disclosing that, treatment safety related problems were the most commonly observed DRP as per PCNE classification. By considering this, more interventions are essential to ensure the treatment safety and effectiveness in study population. In the current study population majority of them are illiterate and under below poverty level. Due to their illiteracy and financial instability, they are not adhering to the medication and they are at higher risk of morbidity and mortality.

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# **CONFLICTS OF INTEREST**

The authors conform that there are no conflicts of interest.

# **ABRIVATIONS**

ACE: Angiotensin Converting Enzyme ;**ARB**: Angiotensin Receptor Blocker ;**BB**: Beta Blocker ;**CCB**: Calcium Channel Blocker ;**CHF**: Congestive Heart Failure ;**CKD**: Chronic Kidney Disease ;**CNS**: Central Nervous System ;**CVS**: Cardiovascular System ;**DRP**: Drug Related Problems ;**FDC**: Fixed Dose

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Combination ;**JNC**: Joint National Committee ;**NLEM**: National List of Essential Medicine ;**PCNE**: Pharmaceutical Care Network of Europe ;**T2DM**: Type 2 Diabetes mellitus ;**WHO**: World Health Organization.

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