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A prospective drug utilization review of hypertension therapy as per JNC VII guidelines in a south India tertiary care hospital

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ABSTRACT

Objective

The main objective of our study is to analyze the prescription patterns of antihypertensive drugs and adherence to JNC VII guidelines in a South India tertiary care hospital.

Method

Drug utilization data of 280 hypertensive patients, attending medicine Out Patient Department of Employees' State Insurance Corporation Model Hospital from January 2014 to June 2014 was collected from 24 hour hospital pharmacy.

Results

280 patients were included in this study. Drug utilization rates in all study subjects till date stands at Diuretics (30.62%), Angiotensin receptor blockers (27.82%), β -Blockers (11.7%), Calcium channel blockers (13.5%), ACE Inhibitors (16.07%). The most frequently prescribed antihypertensive drugs were diuretics followed by ARBs, ACE inhibitors, Beta Blockers, and CCBs. As for individual medicines, hydrochlorothiazide were the most commonly prescribed antihypertensive drug followed by Telmisartan, amlodipine, atenolol, ramipril, Toramide, losartan and. 69.6% received mono therapy and 30.4% received combination therapy (including fixed drug combinations). The prescription pattern was found to be in accordance with JNC VII guidelines.

Conclusion

The general pattern of antihypertensive utilization seems to be in accordance with the JNC VII guidelines for management of hypertension.

INTRODUCTION

Drug utilization review (DUR) according to WHO (1997) is defined as "the marketing, distribution, prescription and use of drugs in the society, with

special emphasis on the resulting medical, social and economic consequences" [9].

Drug utilization review, sometimes referred to as Drug use evaluation, is a system of continuous, systematic, criteria-based drug evaluation that ensures

the appropriate use of drugs. It is a method of obtaining information to identify problems related to drug use and if properly developed, it also provides a means of correcting the problem and thereby contributes to rational drug therapy.

Hypertension is a public health problem that affects >25% of the adult population worldwide [4][10]. Prevalence increases with age, with a 90% residual life time risk in normotensive individuals aged 55 to 65 years [11]. Hypertension has been identified as the leading risk factor of mortality and third leading cause of disability –adjusted life years [12][13]. Despite of availability of numerous antihypertensive agents the diagnosis management of hypertension are far from ideal with control rates 6% to 30% in different communities worldwide [13]. Non adherence to antihypertensive treatment has been associated with lower rates of blood pressure control and higher rates of cardiovascular events [14] [15]. The greater number of daily dose prescribe, poorer the compliance [16].

Nowadays many antihypertensive drugs are available in market in which ARB (Angiotensin receptor blocker) and Calcium channel blocker are the most commonly used drugs for the treatment of uncomplicated hypertension in initial therapy either in mono therapy or with combination of diuretics.

Amlodipine is a long acting dihydropyridine calcium channel blocker that reversibly block cellular calcium L- type channel is largely used. its slow association and dissociation at the calcium binding site ensure a gradual onset and extended duration of pharmacodynamic activity[17]. The high oral bioavailability (60%-65%), long half life(35-50 hours), and low renal clearance(7 ml/min per mg) ensure a sustained antihypertensive effect for >24 hours after a single oral amlodipine dose^{[17][18][19]}. Amlodipine is highly bound (>95%) to plasma protein, is readily taken by hepatic tissue, and is solely redistributed into the systemic circulation [20].

Losartan is an Angiotensin II type 1 receptor antagonist .After oral dosing, plasma concentration peak at 1 hour, and the half life of elimination is only 2 hours. Despite this, single daily dose of losartan appear to lower the blood pressure through the day, perhaps owing to the formation of a more slowly excreted, active metabolite. Currently losartan is indicated for hypertension, although it may be useful in congestive heart failure as well [21].

Telmisartan is an angiotensin II receptor blocker that shows high affinity for the angiotensin II receptor type 1 (AT₁), with a binding affinity 3000 times greater for AT₁ than AT₂. It has the longest half-life of any ARB (24 hours) [21] [22] and the largest volume of distribution. In addition to blocking the RAs, telmisartan acts as a selective modulator of peroxisome proliferators-activated receptor gamma (PPAR- γ), a central regulator of insulin and glucose metabolism. It is believed that Telmisartan dual mode of action may provide protective benefits against the vascular and renal damage caused by diabetes and cardiovascular disease (CVD) [22].

Thiazide diuretics acts by Stimulating natriuresis (sodium excretion) is an important mechanism by which thiazide diuretics have their antihypertensive effects. Thiazides act on the distal tubule they directly inhibit the mechanism for transport of Na⁺ from the tubule lumen into the cells of the tubule wall, and hence enhance the amount of Na⁺ lost in the urine. Thiazides also cause loss of potassium and an increase in serum uric acid. Thiazides are often used to treat hypertension, but their hypotensive effects are not necessarily due to their diuretic activity. Thiazides have been shown to prevent hypertension-related morbidity and mortality although the mechanism is not fully understood. Thiazides cause vasodilation by activating calcium-activated potassium channels (large conductance) in vascular smooth muscles and inhibiting various carbonic anhydrases in vascular tissue. Absorption 50-60%, protein binding 67.9%, metabolism hydrochlorothiazide is not metabolized and half life 5.6 and 14.8 hours [8]

Ramiprilat, the principle active metabolite of ramipril, competes with ATI for binding to ACE and inhibits and enzymatic proteolysis of ATI to ATII. Decreasing ATII levels in the body decreases blood pressure by inhibiting the pressor effects of ATII. [23]

β -blockers Like metoprolol, atenolol competes with sympathomimetic neurotransmitters such as catecholamine for binding at beta(1)-adrenergic receptors in the heart and vascular smooth muscle, inhibiting sympathetic stimulation. This results in a reduction in resting heart rate, cardiac output, systolic and diastolic blood pressure, and reflex orthostatic hypotension. Higher doses of atenolol also competitively block beta (2)-adrenergic responses in the bronchial and vascular smooth muscles. [24]

Due to availability of various drugs it is, therefore, important to lay stress on the optimal management of

hypertension by making the best use of drugs available to us. It is therefore important to understand current antihypertensive medication utilization patterns and to study their impact on blood pressure control and hypertension-related clinical outcomes.

Drug utilization evaluation is a structural process used to assess the quality of drug therapy by engaging in the evaluation of the data on prescribing, dispensing and/or patient use in a given health care environment against predetermined, agreed upon criteria and standards. Drug utilization evaluation is a onetime study to assess appropriateness of drug therapy. The purpose is to identify if current patterns of prescribing, dispensing and use of drug therapy are consistent with criteria and standards. These criteria and standards demonstrate the drug therapy is effective, safe, appropriate, and cost effective and support optimal patient outcome.

Hence these Drug utilization studies which evaluate and analyze the drug therapy in hypertension and hypertension associated with diabetes mellitus is very essential from time to time to observe the prescribing attitude of physician with the aim of rational use of drugs and to minimize the adverse drug reaction (ADRs) [3].

DRUG UTILIZATION REVIEW

Drug utilization review (DUR) according to WHO (1997) is defined as “the marketing, distribution, prescription and use of drugs in the society, with special emphasis on the resulting medical, social and economic consequences”. [11]

Drug utilization review, sometimes referred to as Drug use evaluation, is a system of continuous, systematic, criteria-based drug evaluation that ensures the appropriate use of drugs. It is a method of obtaining information to identify problems related to drug use and if properly developed, it also provides a means of correcting the problem and thereby contributes to rational drug therapy.

The objective of drug used evaluation includes

- Ensuring the drug therapy meets current standard of care
- Controlling drug cost
- Preventing problems related to medication
- Evaluating the effectiveness of drug therapy

Identification of areas of practice that require further education of practitioners.

Drug use evaluation may be based on data collected

- Prospectively (as the drug is being dispensed or administered).
- Retrospectively (based on chart review or other data sources).
- Concurrent DUR (study evaluates dispensing, prescribing and/or patient use data at a point in time or intervals through acute or ongoing therapy and includes a timeframe from the onset).

METHODOLOGY

This prospective study was conducted in Out-patient Department of “Employee State Insurance Corporation” (ESIC), Model Hospital, Hyderabad from January 2014 to June 2014 for 6 months. In Employees’ State Insurance Corporation Model Hospital, Outpatient department is well established. There is well qualified train medical and paramedical staff.

Sample Size

A 280 prescription were reviewed which have complete information as per inclusion criteria.

Inclusion Criteria

The Patients profiles were collected from an Out-patient Department of “Employee State Insurance Corporation” (ESIC), Model Hospital, to determine the drug utilization pattern in outpatient department settings, whose profiles contains following criteria’s.

- Patients Aged above 18 years
- Patients Gender
- Drugs prescribed
- Dosage prescribed
- Routes of administration
- Comorbidity (Diabetes)

Exclusion Criteria

- Patients who are not receiving antihypertensive drug therapy.
- Patients with Tuberculosis were not included in this study.
- Patients with AIDS were not included in this study.

Testing Tool

The Prescription indicator recommended by WHO were used as a tool to assess the drug utilization pattern. The standard DATA entry format was used as a instrument for the assessment of pattern of drug utilization.

DATA collection and analysis

The Prescription of the patient was observed and necessary information were collected. The data so obtained were analyzed for the calculation for drug used indicators which are described earlier.

Statistical consideration

The basic formula of average and percentage were used for determining the problem in drug use.

RESULTS

The objective of the study was to understand the drug utilization pattern of various classes of antihypertensive drugs as monotherapy and overall utilization in hypertensive patients. The findings of this study only included 280 prescriptions during the whole study period from January 2014 to June 2014 and observe the following observation.

Demographic profile of the study population.

Age

Patients were categorized into two groups. Patients of age group between 18-60 years were considered as adults and above 60 were geriatrics. In the present study 193 patients come under the category of adults and 87 patients were geriatric.

Table-1.Age of patients

Category	No. of patients
Adults (18-60)	193
Geriatric (> 60)	87

The study population comprised of 280 patients. We have divided the study population in the six age groups; they are follows 18-30 years, 31-40 years, 41-50 years, 51-60 years, 61-70 years and 71-80 years.

It was observed that 1.7% population belonged to age group 18-30 years which is followed by those between 31-40 years (2.8%), 41-50 years (21.4%), 51-60 years (42.8%), 61-70 years (27.8%) and 3.2%

from age group 71-80 years. Highest number of patients belongs to age group from 51-60 years which was 120 in numbers and constituting the 42.8% of the total study population. Secondly 78 patients belong to age group 61-70 and constituting 27.8% of the total study population.

Patient's age distribution with different age group and gender is presented in

Table-2 as shown below

Sl no.	Age group in years	Male	Female	Total
1	18-30	3	2	5
2	31-40	3	5	8
3	41-50	24	36	60
4	51-60	65	55	120
5	61-70	30	48	78
6	71-80	9	0	9
	Total	134	146	280

The patient's demographic characteristics can be represented by a graph indicating the size of male and female Population belonging to different age group.

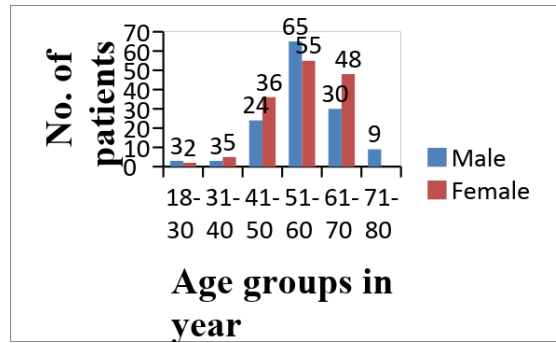


Figure-1

Gender and staging of hypertension

Sex had been a relevant factor in the clinical representation of hypertension. Out of 280 patients 134 were male and 146 were female. The study

finding indicates that hypertension was higher in females than males. Both stage I and stage II were higher in females than males

Table-3 Gender and staging of hypertension

Category	Stage- I (>140/90mmHg)	Stage - II (>160/100 mmHg)	Total
Male	88	36	124
Female	102	54	156
Total	190	90	280

Comorbidities

A total of 98 patients have concurrent diseases like Diabetes mellitus and Bronchial Asthma. 30.35 % population of the total study population possess DM and 4.64% population of the total study population

possess bronchial Asthma as a comorbidity factor. In Which 38 males and 47 females were having the DM and 6 males and 7 females were having the asthma. In diabetes associated hypertension the numbers of females was higher than the number of males.

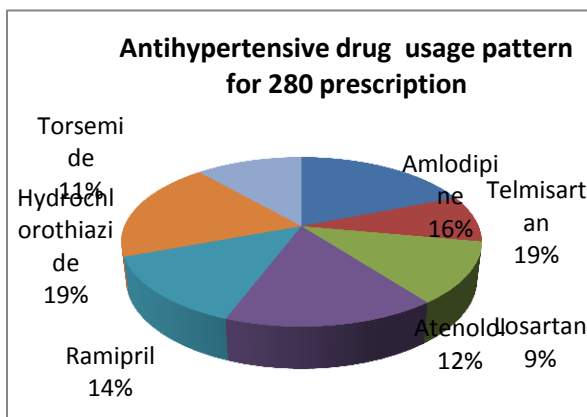
Table-4-Gender distribution of Diabetes and Asthma Associated Hypertension

Comorbidity	Male	Female	Total	Percentage
Diabetes mellitus	38	47	85	30.35%
Bronchial Asthma	6	7	13	4.64%

Prescribing Pattern for Hypertension

The study shows that the following proportions of hypertensive patients were used, Diuretics(30.62%), ARBs (27.82%), β -Blockers

(11.7%), CCBs (13.5%), ACEI (16.07%), Diuretics were most prescribed drugs followed by ARBs in the treatment of patients with early stage hypertension.



Figur-2

195 patients received a single drug therapy i.e. 69.6% patients of the study population were treated with mono therapy while 85 patients i.e. 30.4%

patients were treated with two or more drugs (counting a fixed dose combination [FDC] with two ingredients as two drugs)

Table-5 list the drugs combination prescribed for hypertension in study population.

Sl.no	Drug Class	Drug	No. of Patients	% usage
1	Angiotensin(AT1) Antagonist	Telmisartan	53	18.9%
2	Angiotensin(AT1) Antagonist	Losartan	25	8.92%
3	Beta blockers	Atenolol	33	11.7%
4	Ace inhibitors	Ramipril	38	16.07%
5	Calcium channel blockers	Amlodipine	45	13.5%
6	Diuretics	Hydrochlorothiazide	54	19.2%
7	Diuretics	Torsemide	32	11.42%

Table-6-Patterns Of Use Of Antihypertensive Combination Therapy Among Hypertensive Patients

Two Drug Combination	No. of Prescription	Percentage
CCBs + β-Blockers	29	10.35%
ARBs + Diuretics	21	7.5%
CCBs + ARBs	9	3.21%
ACEI + Diuretics	14	3.92%
CCBs + ACEI	7	2.5%
CCBs + Atorvastatin	5	2.85%

It was observed that 6 drug combinations were prescribed for the treatment of hypertension. Maximum number of drug combination of Amlodipine (CCB) with Atenolol (β-blockers) was found in 29 patients constituting 10.35% of the total study population followed by Telmisartan and hydrochlorothiazide (Diuretic) drug combination found in 21 patients constituting 7.5% of population, Amlodipine with Telmisartan drug

combination was observed in 9 patients constituting 3.21%, Ramipril and hydrochlorothiazide (Diuretic) drug combination found in 14 patients constituting 3.92%, Amlodipine with Ramipril drug combination observed in 7 patient constituting 2.5% and Amlodipine with Atorvastatin drug combination was observed in 5 patients constituting 2.85% of the study population.

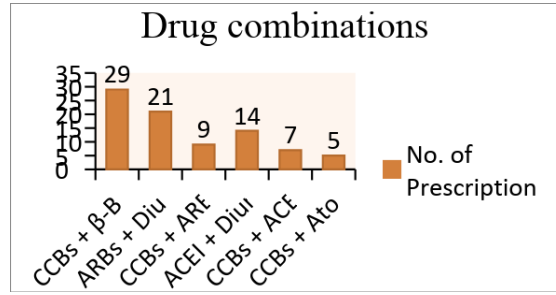


Figure-3-Graph.presenting Drug combination therapy

Prescribing Pattern for HTN associated Diabetes mellitus (DM)

There were 98 patients with coexistent hypertension-type 2 DM and hypertension- bronchial asthma. All patients received ARB and CCB. Here

Angiotensin (AT1) antagonists drugs are more frequently prescribed followed by Calcium channel blocker in treatment of diabetes and bronchial asthma associated hypertension.

Table-7-Treatment of Hypertension In Diabetics and Asthmatics

S.NO	Class	Drug	No Of Patients	Percentage
1	ARBs	Telmisartan	41	41.83%
2	ARBs	Losartan	11	11.22%
3	ACEI	Ramipril	19	19.38%
4	CCBs	Amlodipine	27	27.55%

Among the diabetes patient Telmisartan (ARB) and Amlodipine show maximum usage while losartan exhibits lesser usage pattern in the study population. Usage pattern for Telmisartan and Losartan was observed as 41% and 11.22% respectively. While usage pattern of Amlodipine

(CCB) and Ramipril (ACEI) was observed as 27.55%, 19.38% for diabetes associated hypertensive patients. Overall usage pattern of Angiotensin receptor blocker was higher than calcium channel blockers.

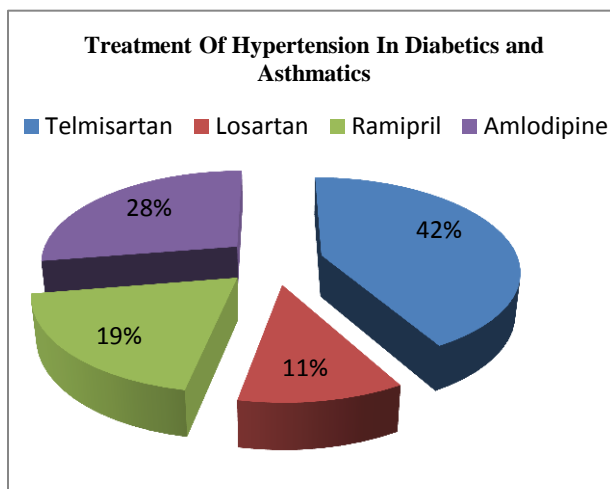


Figure-4- Overall drug usage pattern among diabetes and asthmatics

Drug prescribed by generic name

This study shows that not any drug is prescribed by generic names. All the drugs were prescribed by brand name or trade names which account 100% drugs prescribed by brand names.

The Dosage form usage pattern

Tablets were the dosage forms of the choice for antihypertensive drugs. It was prescribed for 100% prescription.

DISCUSSION

The need for blood pressure control has been suggested because blood pressure level $\leq 120/80$ mm Hg provide protection against Target organ damage and cardiovascular mortality. Currently available Calcium channel blockers (CCB), Angiotensin receptor blockers (ARB), ACE Inhibitors (ACEI), β -Blockers, Diuretics play an important role in hypertensive patients. All classes of drugs provide good tolerability and favorable metabolic profile. The benefits of blood pressure lowering with antihypertensive drugs has become increasingly evident with decrease in both all cause mortality and coronary artery disease.

This prospective observational study was conducted on 280 patients. The demographic profile shows higher females (52.2%) to males (47.8%) proportion in this study which indicates that females were predominantly coming than males for

consultation; the probable reason may be the sociological factors in this part of the country.

This study found that antihypertensive usage pattern among the study population was significantly higher for Diuretics than Angiotensin receptor blockers (ARB), β -blockers, CCBs, ACEI. Telmisartan, Losartan, Atenolol, Amlodipine, Ramipril, Toresmide, Hydrochlorothiazide, were the drugs prescribed to the patients. Overall drug usage pattern was higher for the Diuretics (30.62%), ARBs (27.82%), β -Blockers (11.7%), CCBs (13.5%), ACEI (16.07%).

In 35% of study population Diabetes and Bronchial asthma was present as comorbidity. ARBs (36.8%) were most frequently prescribed group in hypertensive diabetics and asthmatics as angiotensin antagonism is reported to decrease the onset and progress of micro vascular complications of hypertension and diabetes mellitus.

According to Americans diabetes associated guidelines that patient with diabetes mellitus should be treated with ARBs as a part of their initial regimen for the treatment of uncomplicated hypertension. In our study 30.35% of study populations with comorbidity Diabetes who have fulfill the rennin angiotensin blocker as a part of their initial therapy. So it's a good sign and showing the positive compliance of physician towards the clinical Guidelines.

In our study 30.35 % patients were treated by Drug combination or multidrug therapy (FDCs have also been used) in which CCBs and β -Blockers, ARB and diuretic, CCBs and ARBs, ACEI and Diuretics,

CCB and ACEI, CCBs and Atorvastatin are given in combination and 69% patient were treated with mono therapy. When mono therapy and poly therapy were considered together, ARBs were the most commonly prescribed antihypertensive drugs. Previous studies also supported that drug use pattern for ARB during period 1994-1999 was increased by 9%.

Previous study done by Sandozi Tasneem also supports our study and indicates 72% patients were on mono therapy and most prescribed drugs were from class ACE inhibitor & ARB followed by CCB.

This study also indicates that not any drug was prescribed by generic name all the drugs were prescribed by trade name or brand name which accounts for 100% drugs. Inclination towards the branded products stands true because of the belief that branded products have superior quality. Therefore it is important to build the confidence of prescriber towards the generic products as it will tend to decrease the cost of prescription. Some other reasons

like catchy names aggressive advertising and availability of drugs should also consider.

This study also indicates that tablets were a choice of dosage forms in patients. This leads to reduced cost of prescription. As socioeconomic patients coming to outpatient department was not so strong. Most of them were poor. This was excellent prescribing habit of physicians keeping in mind their financial conditions and concerned patients safety simultaneously.

CONCLUSION

The most frequently antihypertensive drugs were Diuretics followed by ARBs, β -Blockers, CCBs and ACE inhibitors. 69.6% received mono therapy and 30.4% received combination therapy counting fixed drug combinations. The prescription pattern was found to be in accordance with JNC VII guidelines.

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