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COMPARATIVE STUDY OF COMBINATION THERAPY OF TELMISARTAN + AMLODIPINE VS TELMISARTAN + CILNIDIPINE IN HYPERTENSIVE PATIENTS

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ABSTRACT

BACKGROUND :

Hypertension also known as high blood pressure, is a hidden global menace, and it is a major risk of other heart diseases. A crucial need for any combination is evidence that it reduces BP significantly more than monotherapy with its separate components.

METHOD:

A comparative observational study of combination therapy (Telmisartan + Amlodipine vs Telmisartan + Cilnidipine) in Hypertensive patients was conducted over 6 months in tertiary care hospital, a total of 108 cases were collected and patient's medical records were assessed.

RESULTS:

The results showed a considerable reduction in blood pressure among both the selected groups. There is a considerable reduction of blood pressure in the group A patients (of about 30mmHg systolic pressure decrease and 20mmHg diastolic pressure decrease) with an exception in some patients, with the incidences of side effects of unusual heart rate, and general puffiness.

Group B showed significant results in decreasing the BP levels and also maintaining stability after consecutive months. There is progressive reduction (of about 40mmHg systolic pressure and 20mmHg diastolic pressure decrease) without any substantial side effects.

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CONCLUSION:

The corresponding study concludes that blood pressure can be significantly decreased and maintained after the discharge of the patients with comparatively fewer incidences of side effects by the antihypertensive combination of Telmisartan + Cilnidipine compared to the combination of Telmisartan + Amlodipine which doesn't maintain the stable BP and has the incidence of side effects.

KEYWORDS:

combination therapy, comparative study, aggressive hypertension, cardiovascular endpoints, antihypertensive efficacy.

1. INTRODUCTION

1.1 HYPERTENSION

- Hypertension is defined as abnormally high blood pressure (more than 140/90 mmHg) in the arteries.[2]
- Hypertension is the most important preventable contributor to disease and death, leading to myocardial infarction, stroke, and renal failure when it is not detected early and treated appropriately[1]
- The Eighth Joint National Committee (JNC 8) recently released evidence-based recommendations on treatment thresholds, goals, and medications in the management of hypertension in adults.
- Usually, a mean arterial pressure greater than 110mmHg under resting conditions is considered to be hypertensive; this level normally occurs when the DBP is greater than 90 mm Hg and the systolic pressure is greater than about 135-140 mmHg.

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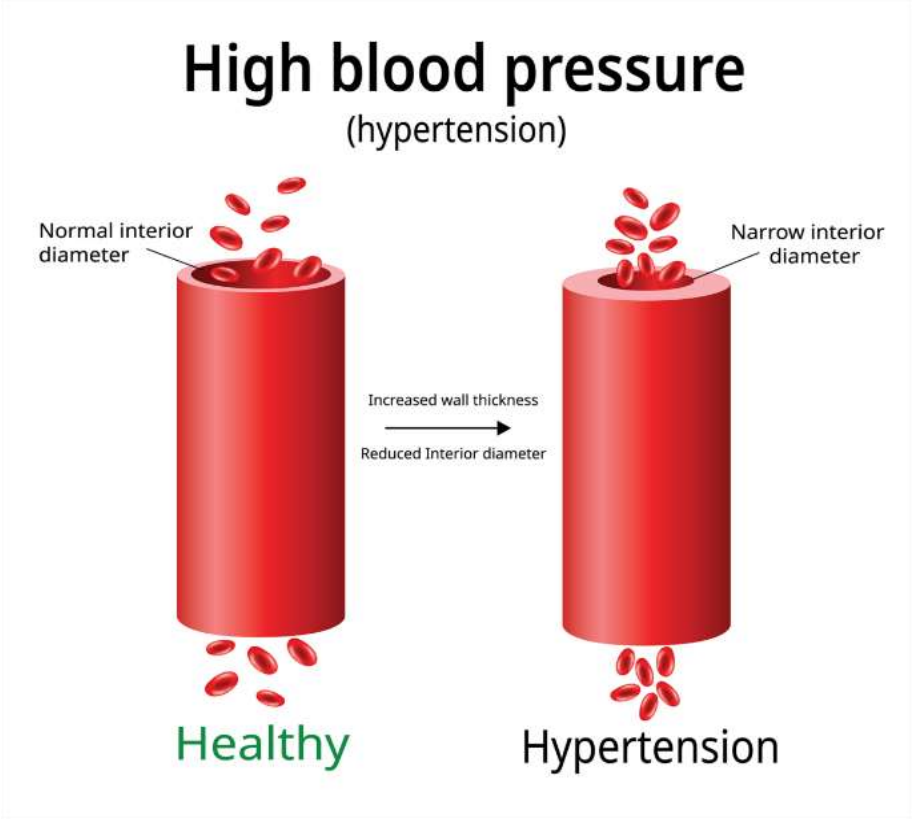

Figure 1: High Blood pressure

1.2 ETIOLOGY

- Factors increasing BP, include:
  - **i.** Sedentary lifestyle leads to obesity.
  - **ii.** Insulin resistance
  - **iii.** High alcohol intake
  - **iv.** High salt intake
  - **v.** Stress
  - **vi.** Low potassium intake, and calcium intake.[23]

- Medications that increase BP
  - **i.** The contraceptive pills
  - **ii.** Steroids
  - **iii.** {NSAIDS} - like ibuprofen and naproxen

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iv. Some over-the-counter cough and cold medications
v. Some herbal medications – particularly those containing liquorice
vi. Some recreational drugs – eg: cocaine amphetamines
vii. (SSNRI) antidepressant- is venlafaxine.

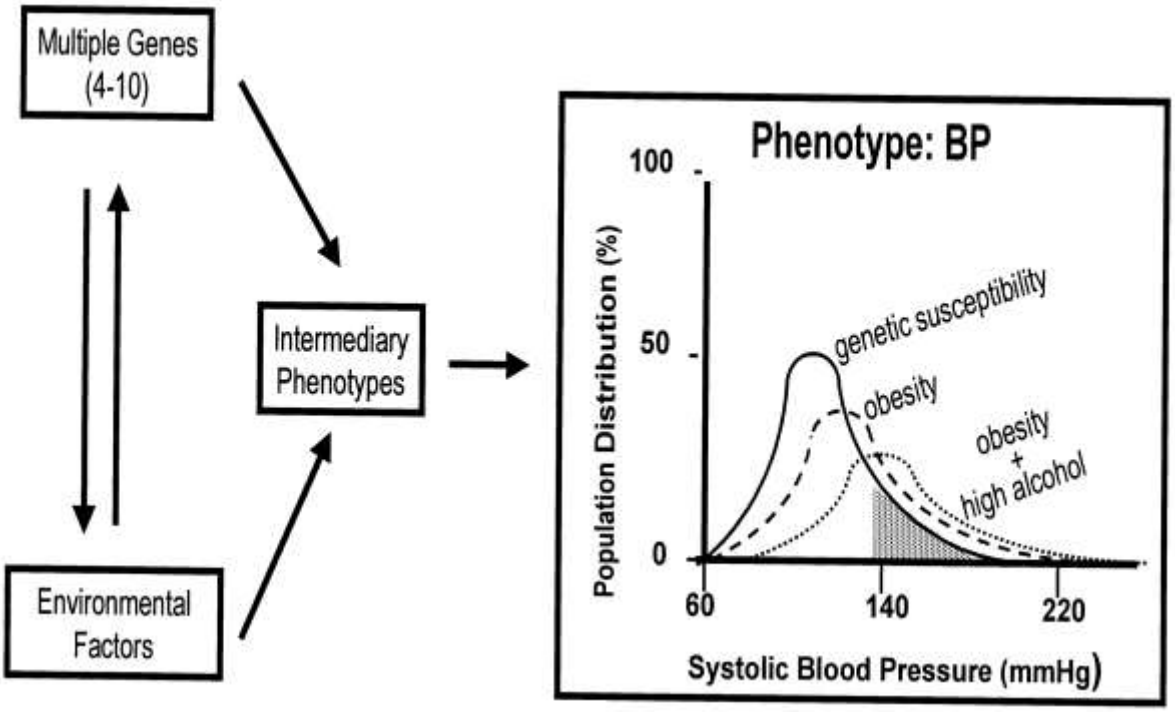

Figure 2 : Etiology of Hypertension

1.2 CLASSIFICATION (ACCORDING TO JNC 8)[6]

TABLE NO : 1

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BP CLASSIFICATION	SBP (mmHg)	DBP (mmHg)
Normal	<120	<80
Prehypertension	120-139	80-89
Stage 1	140-159	90-99
Stage 2	160	≥100
Hypertensive crisis	>180	>110

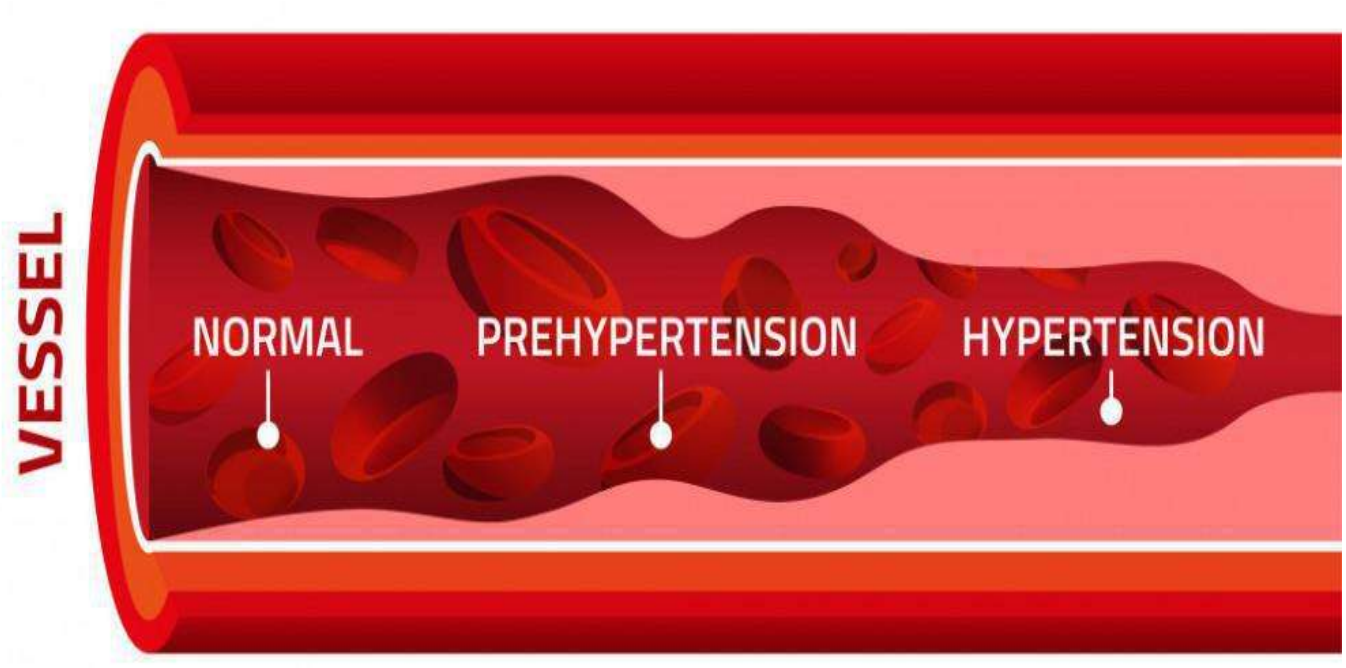

Figure 3: The thickness of the vessels

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1.4 PATHOPHYSIOLOGY

Both genetic and environmental factors contribute to the higher blood pressure. Both produce abnormalities in renal sodium motions in tubules, resulting in inadequate sodium excretion and salt and water retention. The retention of water and salt results in an increase in plasma and ECF volume, which influences cardiac output (increased). Another physiology is a functional vasoconstriction in the arteries, which result in an increment in TRP.

Defects in vascular smooth muscles may cause vascular wall thickness that leads to hypertension.[4]

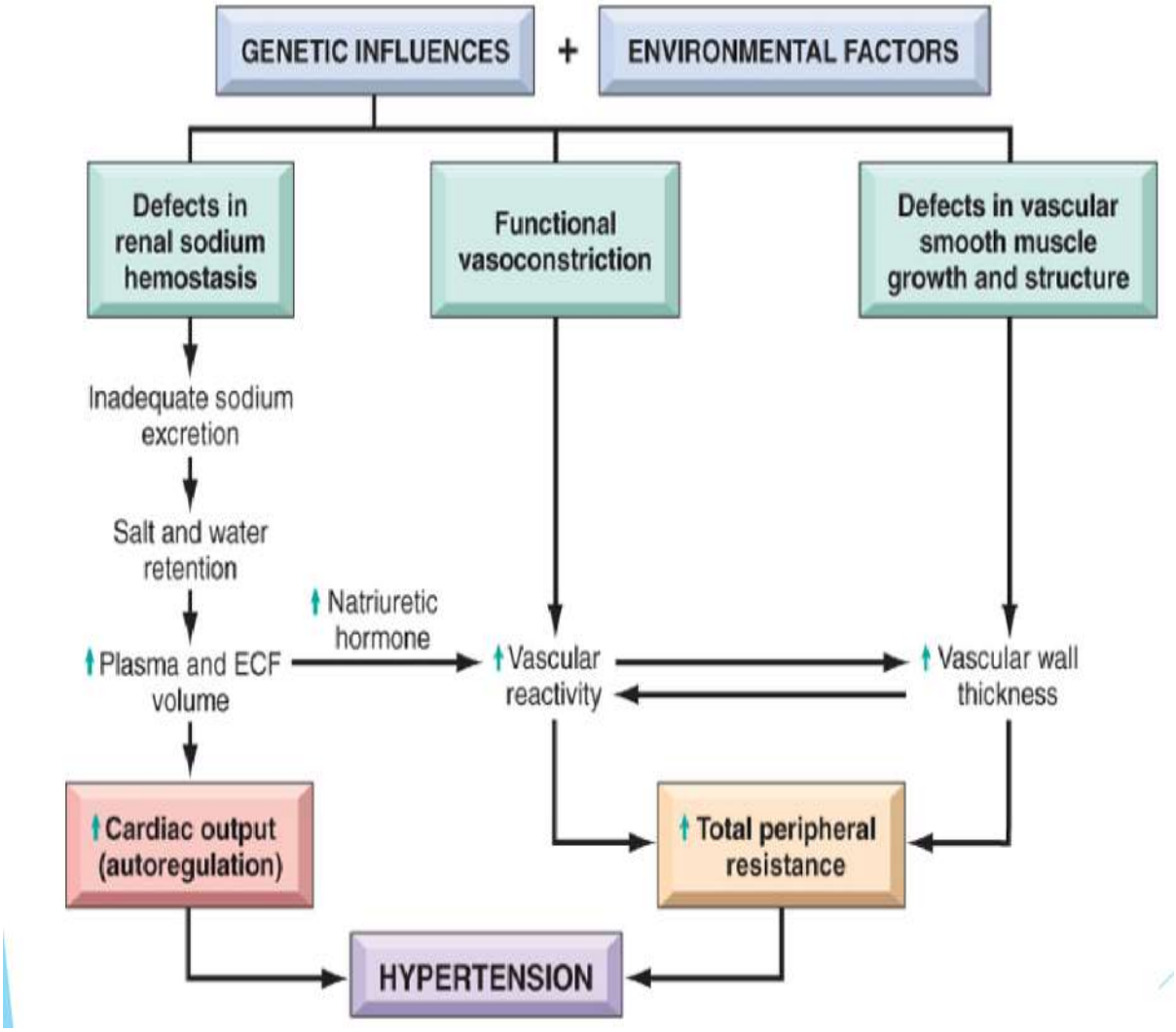

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Figure 4: Pathophysiology of Hypertension [4]

1.5 DIAGNOSIS

To assess target organ damage:

X-ray to measure heart size, ECG to detect LV hypertrophy and signs of IHD, Echocardiogram for LV systolic and diastolic functions, Urinalysis- proteinuria > 200 mg/day, and hematuria suggest renal involvement.[5]

To determine the cause of hypertension:

1. X-ray chest Rib notching indicates coarctation of the aorta, and Mediastinal widening suggests aortic dissection.

2. Imaging of the abdomen (Sonography, CT scan, MRI) To detect- kidney tumors, Renal calculi, Adrenal tumors, Pheochromocytoma, etc.

- Sphygmomanometer.

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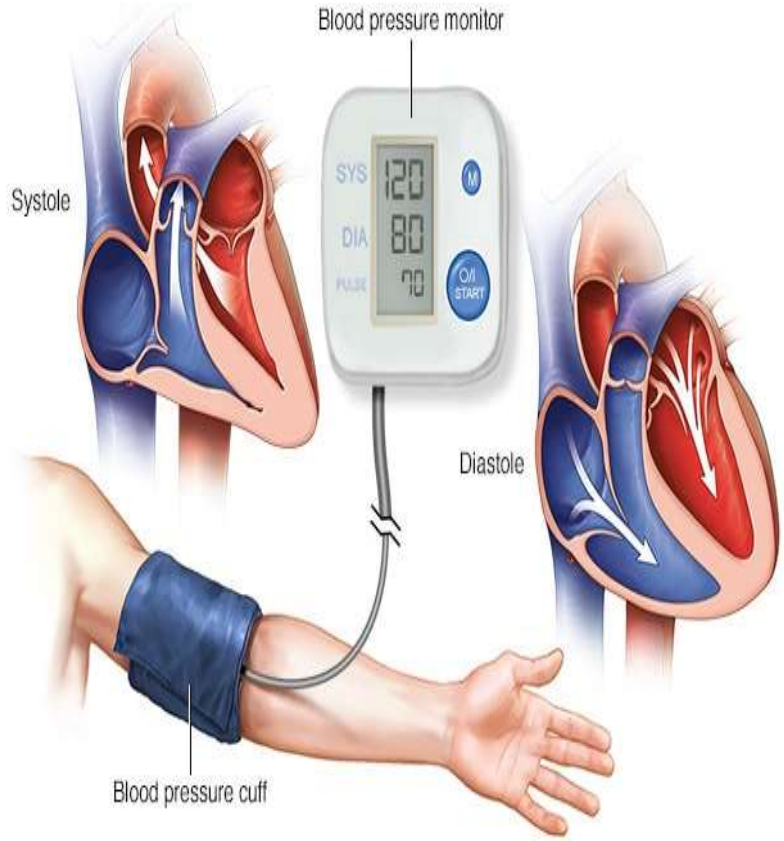

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Figure 5: Blood pressure monitoring [5]

1.6 TREATMENT

- When the SBP is equal to or greater than 150mmHg, or when the DBP is 90mmHg or higher, pharmacologic therapy should be commenced.

- If the blood pressure does not decline to the optimal value after starting therapy, the dosage should be modified or a second medicine added (thiazide diuretic, calcium channel blocker, ACE inhibitor, or ARB; do not combine an ACE inhibitor with an ARB).

- If the antihypertensive medications described above fail to achieve the desired blood pressure, antihypertensive drugs from other classes can be employed

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Hypertension Treatment

Compelling Indications	
Indication	**Treatment Choice**
Heart Failure	ACEI/ARB + BB + diuretic + spironolactone
Post –MI/Clinical CAD	ACEI/ARB AND BB
CAD	ACEI, BB, diuretic, CCB
Diabetes	ACEI/ARB, CCB, diuretic
CKD	ACEI/ARB
Recurrent stroke prevention	ACEI, diuretic
Pregnancy	labetolol (first line), nifedipine, methyldopa

Beta-1 Selective Beta-blockers – possibly safer in patients with COPD, asthma, diabetes, and peripheral vascular disease:
- metoprolol
- bisoprolol
- betaxolol
- acebutolol

Drug Class	Agents of Choice	Comments
Diuretics	HCTZ 12.5-50mg, chlorthalidone 12.5-25mg, indapamide 1.25-2.5mg triamterene 100mg *K+ sparing* – spironolactone 25-50mg, amiloride 5-10mg, triamterene 100mg furosemide 20-80mg twice daily, torsemide 10-40mg	Monitor for hypokalemia Most SE are metabolic in nature Most effective when combined w/ ACEI Stronger clinical evidence w/chlorthalidone Spironolactone - gynecomastia and hyperkalemia Loop diuretics may be needed when GFR <40mL/min
ACEI/ARB	*ACEI:* lisinopril, benazapril, fosinopril and quinapril 10-40mg, ramipril 5-10mg, trandolapril 2-8mg *ARB*: candesartan 8-32mg, valsartan 80-320mg, losartan 50-100mg, olmesartan 20-40mg, telmisartan 20-80mg	SE: Cough (ACEI only), angioedema (more with ACEI), hyperkalemia Losartan lowers uric acid levels; candesartan may prevent migraine headaches
Beta-Blockers	metoprolol succinate 50-100mg and tartrate 50-100mg twice daily, nebivolol 5-10mg, propranolol 40-120mg twice daily, carvedilol 6.25-25mg twice daily, bisoprolol 5-10mg, labetalol 100-300mg twice daily,	Not first line agents – reserve for post-MI/CHF Cause fatigue and decreased heart rate Adversely affect glucose; mask hypoglycemic awareness
Calcium channel blockers	*Dihydropyridines*: amlodipine 5-10mg, nifedipine ER 30-90mg, *Non-dihydropyridines*: diltiazem ER 180-360 mg, verapamil 80-120mg 3 times daily or ER 240-480mg	Cause edema; dihydropyridines may be safely combined w/ B-blocker Non-dihydropyridines reduce heart rate and proteinuria
Vasodilators	hydralazine 25-100mg twice daily, minoxidil 5-10mg terazosin 1-5mg, doxazosin 1-4mg given at bedtime	Hydralazine and minoxidil may cause reflex tachycardia and fluid retention – usually require diuretic + B-blocker Alpha-blockers may cause orthostatic hypotension
Centrally-acting Agents	clonidine 0.1-0.2mg twice daily, methyldopa 250-500mg twice daily guanfacine 1-3mg	Clonidine available in weekly patch formulation for resistant hypertension

Figure 6: Indications for treatment along JNC 8 Guidelines [6]

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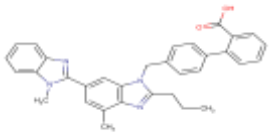
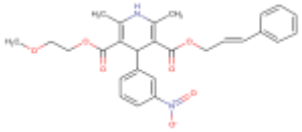
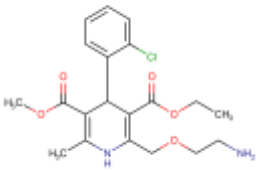
1.7 ABOUT THE DRUGS

TABLE NO. 2 DRUGS[24]

ABOUT THE DRUG	TELMISARTAN	CILNIDIPINE	AMLODIPINE
STRUCTURE			
DRUG CLASS	Angiotensin II receptor antagonists	Calcium channel blocker (L and N-type)	Calcium channel blocker (L-type)
DOSE	40mg	10mg	5mg
INDICATIONS	Used alone or in combination for treating hypertension	L-type CCB used to treat high BP	Treatment of conditions such as HTN ,coronary heart disease,etc
MOA	Inhibits the action of angiotensin II on vascular smooth muscles leading to a decrease in BP	Inhibits the influx of calcium ions into vascular and cardiac smooth muscle cells	Restricts the entry of ca^{2+} ions into excitable cells
ABSORPTION	The oral route is well absorbed	Peak plasma concentrations are achieved 6-12 hours after oral administration	Rapid absorption with a maximum peak concentration after 2 hours
VOLUME OF DISTRIBUTION	Approximately 500 L	21 L/kg	Has a large volume of distribution

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PROTEIN BINDING	Highly bound to plasma proteins	About 98%	Very high protein binding
HALF-LIFE	Approximately 24 hours	About 30–50 hours	About 20.4 min
SIDE EFFECTS	Vision changes, dizziness, fast heartbeat	Palpitation,flushing,excess of fall in BP	Pedal edema, a pounding heart beat

2. REVIEW OF LITERATURE :

1. C. Venkat S. Ram MD, et al, 2022 stated that ARB combined with CCB effectively reduced BP to below the new target <130/80mmHg and had positive effects on central hemodynamics. [7]

2. JH Jo, et al; 2021, stated that Drug T+CL works efficiently for HTN and its complications. It also provides cardioprotective effects, by elevating endothelial nitric oxide synthase. Similarly, shows vasoprotectiveness as a combination inhibits DNA synthesis for vascular injury. [8]

3. Guerrero – Garcia, 2018, stated that Globally 25% of HTN patients should take 2 or 3 antihypertensive drugs for decreasing BP <140/90mmHg. [9]

4. Bryan Williams et al, 2017, stated that response to combination therapy was uniform and at least 5mmHg more compared to monotherapy. [10]

5. R. Majul MD et al, 2015 stated T+AM gives a good reduction in DBP at the relevant doses. In a study, it is concluded that if 10 subjects are included, 9 of them showed a satisfactory response. [11]

6. Marcel Ruzicka, et al, 2012 stated that a better antihypertensive effect was observed for combination therapy. [12]

7. S Neldam, B Dahlöf, et al, 2013, stated that many hypertensive patients can achieve their BP targets, when on the drug T+AM while failing to do with monotherapy. Furthermore, <140/90mmHg reading of BP will be reached in less period unlike for monotherapy. [13]

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8. Samir. G Mallat, 2012, stated that Telmisartan as a long-acting ARB, which also has good Pd parameters makes it selected for the therapy for high BP. In other agents of the same class, several properties do not support considering them for the therapy. Hence, it is the best option for inclusion in treatment.

9. Arya M. Sharma, et al, 2011, stated that in a selected population of DM patients and HTN, T/A provided prompt and greater bp decrease compared with monotherapy, with a majority of them reaching <140/90mmHg reading. (14)

10. Debases Bisoi, et al, 2010, stated that there will be psychomotor functions and memory disturbances in newly diagnosed stage I essential HTN patients. Telmisartan shows more improving trends in memory in cilnidipine. Also, it is stated that improvement in psychomotor activities in cilnidipine patients was observed unlike for patients on telmisartan. (15)

11. Sanjay Kalra, et al, 2010, stated that it is very much important to control BP to a normal level for producing a reduced clinical CV endpoint, particularly in patients with DM where a more aggressive lowering of BP is required. In such cases, monotherapy is not successful but combination therapy shows a desired response. (16)

12. White, William B. Littlejohn et al, 2010 stated that T+AM gives 24-hr BP efficacy compared to patients on a single drug with stage 1 and 2 HTN.

13. Maurizio Cagnoni, et al, 2010, stated that when BP is uncontrolled by low-dose monotherapy, either a high dose of monotherapy drug or a Combination drug is required for the timely maintenance of BP.

14. M Destro, et al; 2008, stated that Amlodipine 10mg was not found to be effective in treating patients with higher levels of BP, especially in the cases known to be with stage 2 HTN. Valsartan 160mg was found to be effective. (17)

15. Ajinomoto Co, et al, 2007stated that cilnidipine combined with ARB controls BP without any adverse events and also cilnidipine successfully reduces increased heart rate.

16. Joel M. Neutel, 2007, stated that for the treatment of HTN major contributing factor is patient compliance with the ongoing therapy, it includes safety, convenience, polypharmacy, cost, and education in the selection of antihypertensive agents. According to new studies referred less dose of a combination drug is preferred to improve elevated bp. (18)

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17. **Joel M Nutel et al, 2007,** stated that ARB's have shown therapeutic advances in treating HTN. Telmisartan, which has a 24-hour duration of action or greater can be prescribed for once-daily dosing without compromising, for bp control. This drug has shown effective 24hr bp control including the early morning period which is critical.

18. Yuki Kaneshiro, et al, 2004 stated that the study that is conducted on T+CP has the factors for reducing and also inhibiting the various vascular complications such as blindness, heart attack, stroke, and others. ARB's have shown therapeutic advances in treating HTN. Telmisartan, that has a 24-hour duration of action or greater can be prescribed for once-daily dosing without compromising, for bp control. This drug has shown effective 24hr bp control including the early period which is critical.

19. S. Kojima, **et al, 2004,** stated that proteinuria in patients on amlodipine was observed at a little higher level. Whereas cilnidipine when studies showed a greater reduction in GFR in another group which includes patients with renal diseases. (19)

20. Reginald. H Smithwick , et al, 1956, stated the prognosis becomes worse as signs of cardiovascular renal damage increase and that within each of the groups, the prognosis for females with hypertensive cardiovascular disease is better than for males. (20)

3. NEED FOR STUDY:

- Hypertension is the major risk for both heart disease and stroke.
- Many guidelines have been implemented in reaching the targeted BP goals with Rational combination therapy is based on the deliberate coadministration of 2 or more carefully selected antihypertensive agents.
- There are seven classes of antihypertensives, the combination of angiotensin II receptor blockers (ARB'S) and calcium channel blockers (CCB'S) are much preferred for the treatment of recurrent or aggressive hypertension

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- A combination of Telmisartan40mg + Amlodipine 5mg vs Telmisartan 40mg + Cilnidipine10mg is taken for the study and examined for its safety, efficacy, anti hypertensive response and side effects.

4. AIM :

To observe the therapeutic response associated with the treatment of combination therapies of Telmisartan and Amlodipine with Telmisartan and Cilnidipine in hypertensive patients.

4.1 OBJECTIVES:

i. To observe the therapeutic response and adverse effects of drugs in patients with hypertension.

ii. To monitor hypertension levels.

iii. To estimate the fast recovery among 2 combination therapies given to the patients.

5. ETHICAL COMMITTEE APPROVAL

The study was approved by the Institutional Human Ethical Committee (Ref no: GCPK/IEC/SEP 2022-2023/B01)

6. METHODOLOGY

6.1 STUDY SITE: The RVM Hospital, Laxmakkapally (V), Siddipet (D), Telangana,502279

6.2 STUDY DESIGN: An observational study

6.3 STUDY DURATION: Six months

6.4 STUDY SAMPLE SIZE: 108 patients, Group A Telmisartan 40mg + Amlodipine 5mg (n=54) in Group B Telmisartan 40mg + Cilnidipine10mg (n=54)

6.5 STUDY CRITERIA:

6.5.1 INCLUSION CRITERIA

- Patients who are diagnosed (old and new cases) with HYPERTENSION
- Patients with Bp: ≥160/90mmHg

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- Any gender of age 40-80 years
- Patients with other chronic diseases
- Patients who are previously on monotherapy are considered
- Patients on regular follow-ups
- Frequency of the combination drug: OD

6.5.2 EXCLUSION CRITERIA

- Patients who have not given consent
- Pregnant & lactating women
- Patients with diagnosis uncertainty
- Patients with allergic reactions

6.6 COLLECTION OF DATA

- Data is collected by taking a prescription. To collect the data, a carbon copy of the original prescription will be collected by the investigator.
- Patients with complaints of increased blood pressure will be completely evaluated by data collected through complete medical history, patient interaction, questionnaires, and telephonic follow-ups.

6.8 STATISTICAL ANALYSIS

Descriptive statistics presentation of data in a bar chart, pie chart values are expressed as frequency, percentage, mean, median, mode, SD, and SE. The student-independent two-sample t-test was used to find the statistical difference between study group variables and the association between the antihypertensive effect of combination drugs and side effects, all analysis $p > 0.05$ was considered to be significant. All statistical analysis was performed using SPSS statistical software, version 20.

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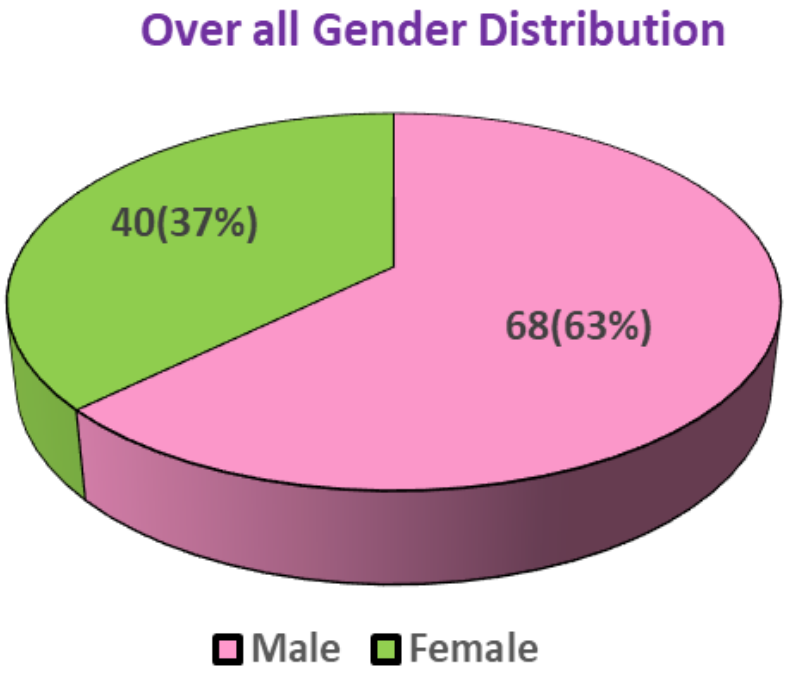
7. RESULTS

Table 3: Gender frequency and percentage calculation

Gender	Frequency	Percent
Male	68	63
Female	40	37
Total	108	100



Pie chart 1: Overall Gender Distribution

Table 4: Gender Distribution

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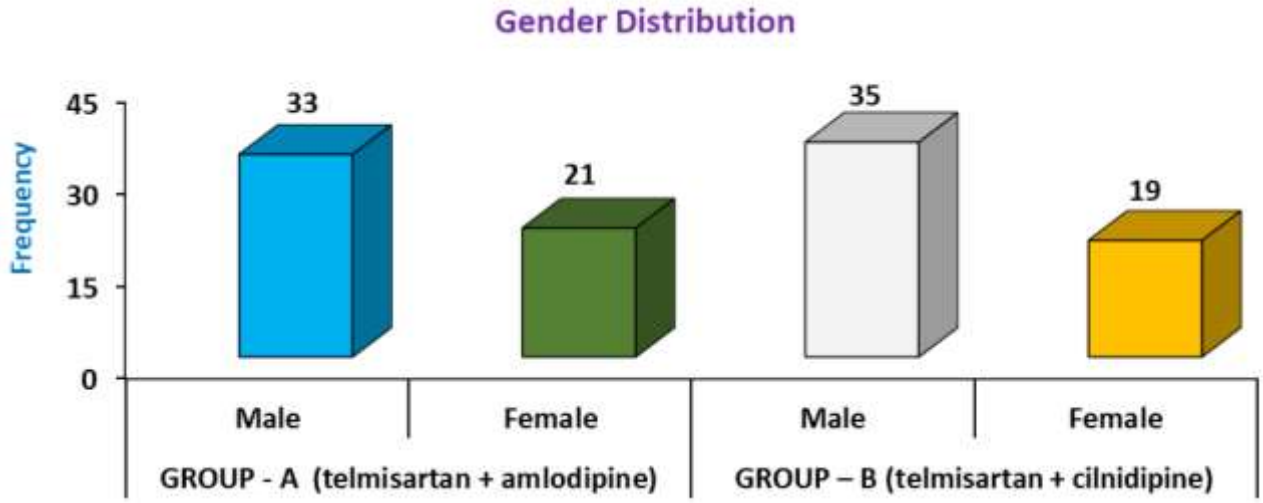
Group	Gender	Frequency	Percent
GROUP - A (Telmisartan + amlodipine)	Male	33	61.1
	Female	21	38.9
GROUP – B	Male	35	64.8



Graph 1: Gender Distribution for Group A and Group B

Table 5: Age-Wise Frequency and percentage calculation

Age (Years)	Frequency	Percent
40 to 50	20	18.5
51 to 60	36	33.3
61 to 70	38	35.2
71 to 80	11	10.2
More than 80	3	2.8

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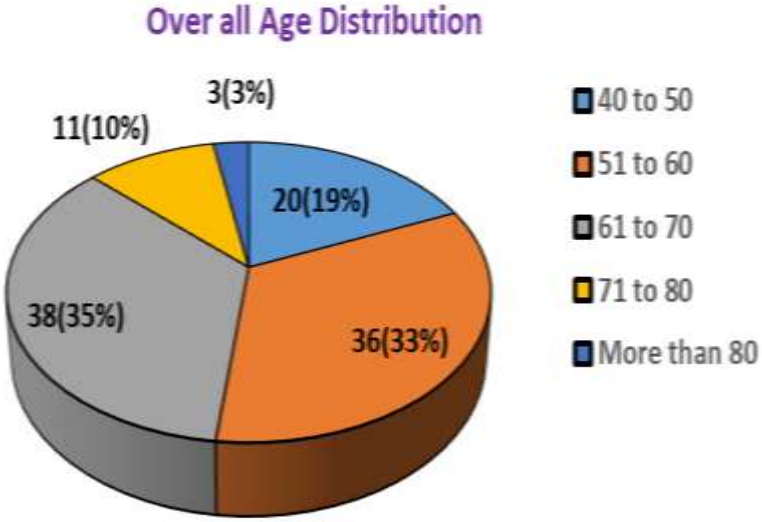
Total	108	100



			ercent
			20.4
			20.4
GROUP - A (Telmisartan + Amlodipine)	61 to 70	25	46.3
	71 to 80	7	13
	More than 80	0	0
GROUP – B (Telmisartan +	40 to 50	9	16.7

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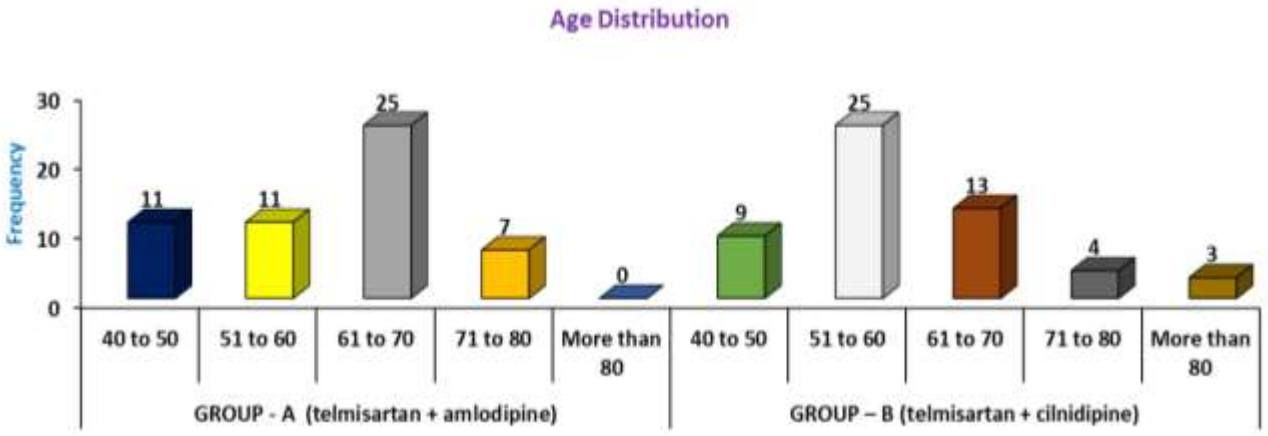
Cilnidipine)	51 to 60	25	46.3
	61 to 70	13	24.1
	71 to 80	4	7.4
	More than 80	3	5.6

Pie chart 2: Overall Age distribution

Group	Parameter	N	Minimum	Maximum	Mean	SD



Graph 2: Age distribution for Group A and Group B

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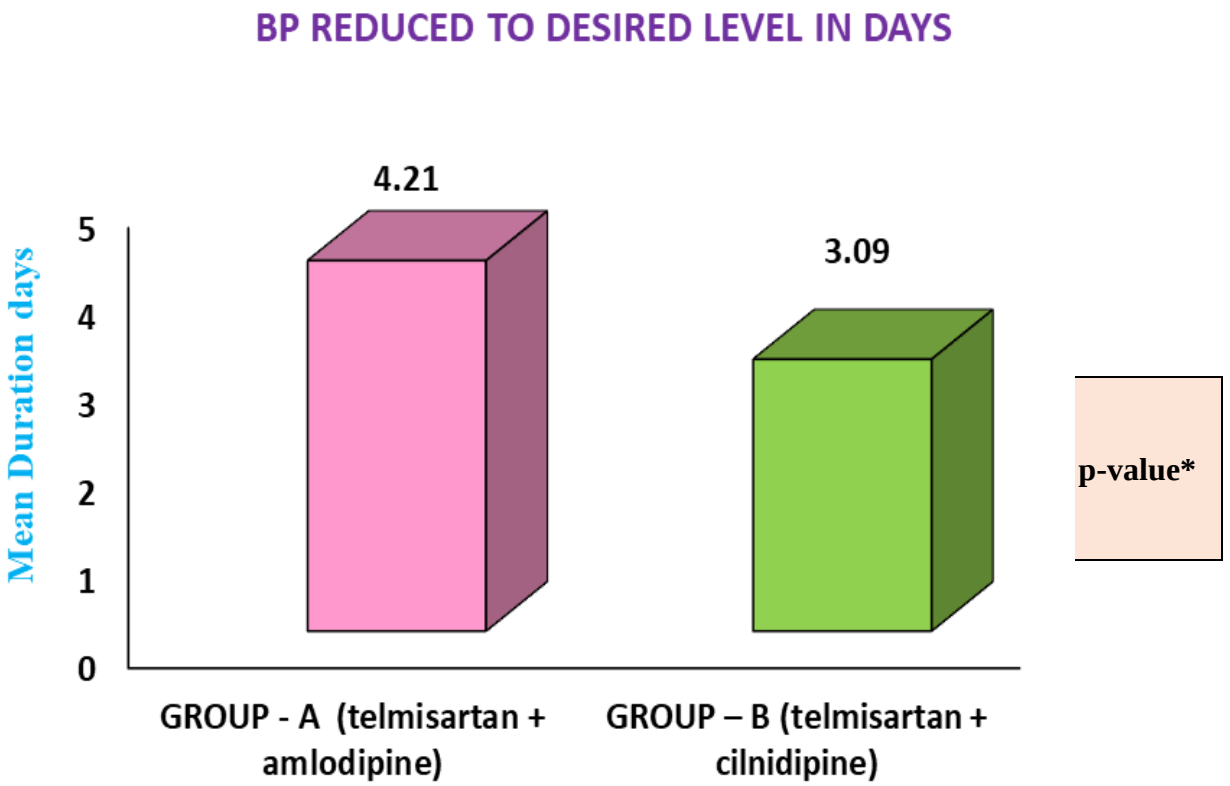
GROUP - A (Telmisartan +Amlodipine)	AGE (YRS)	54	42	80	61.67	9.28
	BP REDUCED TO DESIRED LEVEL IN DAYS	53	3	7	4.21	0.93
GROUP – B (Telmisartan + Cilnidipine)	AGE (YRS)	54	42	85	60.17	9.91
	BP REDUCED TO DESIRED LEVEL IN DAYS	53	1	5	3.09	0.93

Table 7: BP Reduced to the desired level in days (mean, SD calculations)

PARAMETER	GROUP - A (Telmisartan + Amlodipine)	GROUP – B (Telmisartan + Cilnidipine)	t-value	p-value*
BP REDUCED TO DESIRED LEVEL IN DAYS	4.21±0.93	3.09±0.92	6.18	0.0001 S

*- P<0.05 The mean comparison between groups using a t-test. NS: Non-significant S: Significant



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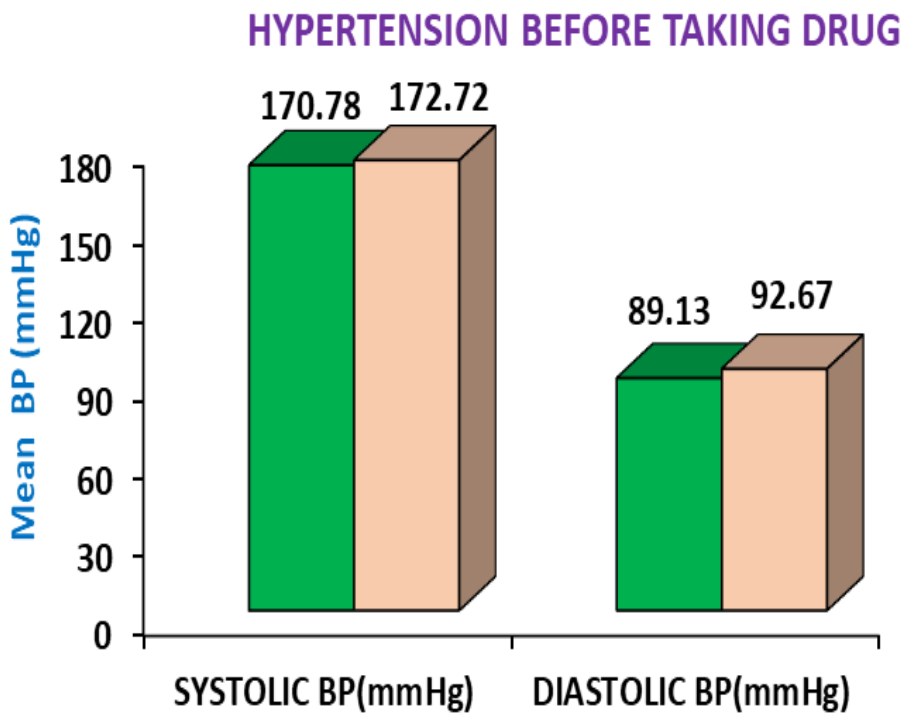
SYSTOLIC BP(mmHg) BEFORE TAKING DRUG	170.78±13.16	172.72±16.99	0.66	0.5080 NS
DIASTOLIC BP(mmHg) BEFORE TAKING DRUG	89.13±9.36	92.67±11.84	1.12	0.8800 NS

Graph 3. BP reduced to the desired level in days

Table 8. Systolic and Diastolic BP before taking the drug



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Graph 4: BP before taking drug

Table 9. Systolic and Diastolic BP after 5 days of taking the drug

PARAMETER	GROUP - A (Telmisartan + Amlodipine)	GROUP – B (Telmisartan + Cilnidipine)	t-value	p-value*
PARAMETER	(Telmisartan + Amlodipine)	(Telmisartan + Cilnidipine)	t-value	p-value*
AFTER TAKING HE DRUG SYSTOLIC BP(mHg) - MIN- 5 DAYS	129.85±10.45	125.93±9.82	2.01	0.0470 S
BP AFER TAKING I I	77.96±10.16	76.15±8.75	0.994	0.3212 S

HYPERTENSION AFTER 5 DAYS TAKING DRUG

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SYSTOLIC BP AFTER 2 MONTHS (REVIEW)mmHg	128.15±7.29	122.78±9.59	3.27	0.0010 S
DIASTOLIC BP AFTER 2 MONTHS (REVIEW) mmHg	79.07±9.37	77.41±9.15	0.935	0.352 NS

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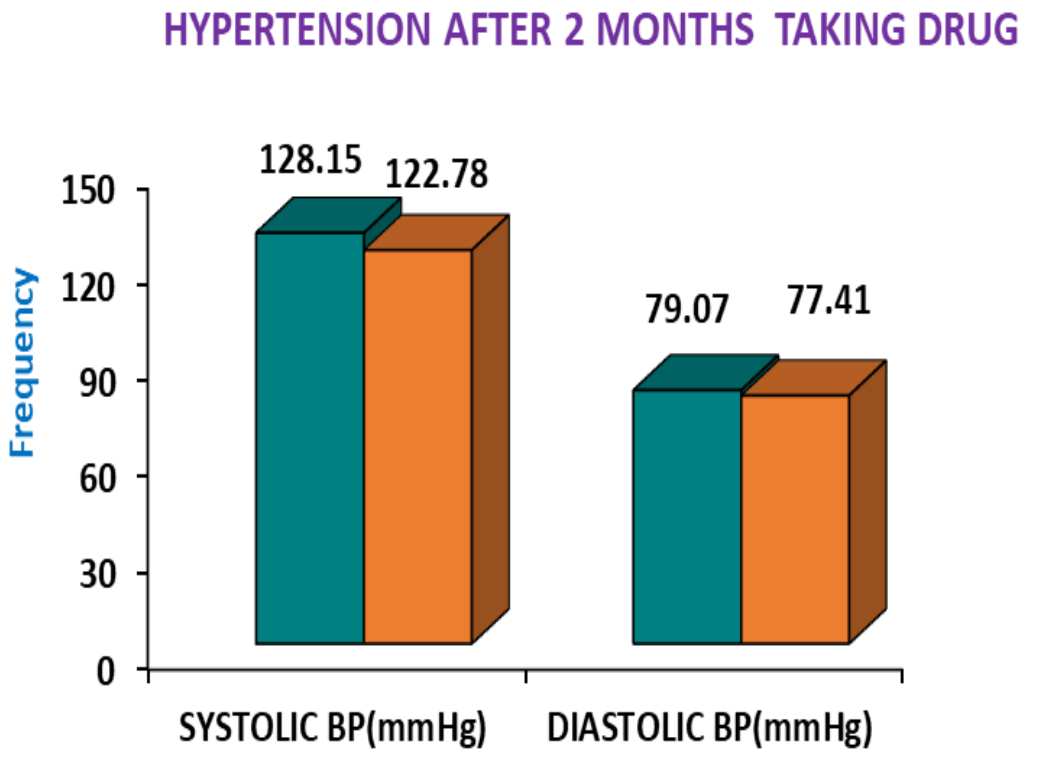

Graph 6: BP after 2 months of taking the drug

Table 11. The Antihypertensive effect of Group A and Group B drugs

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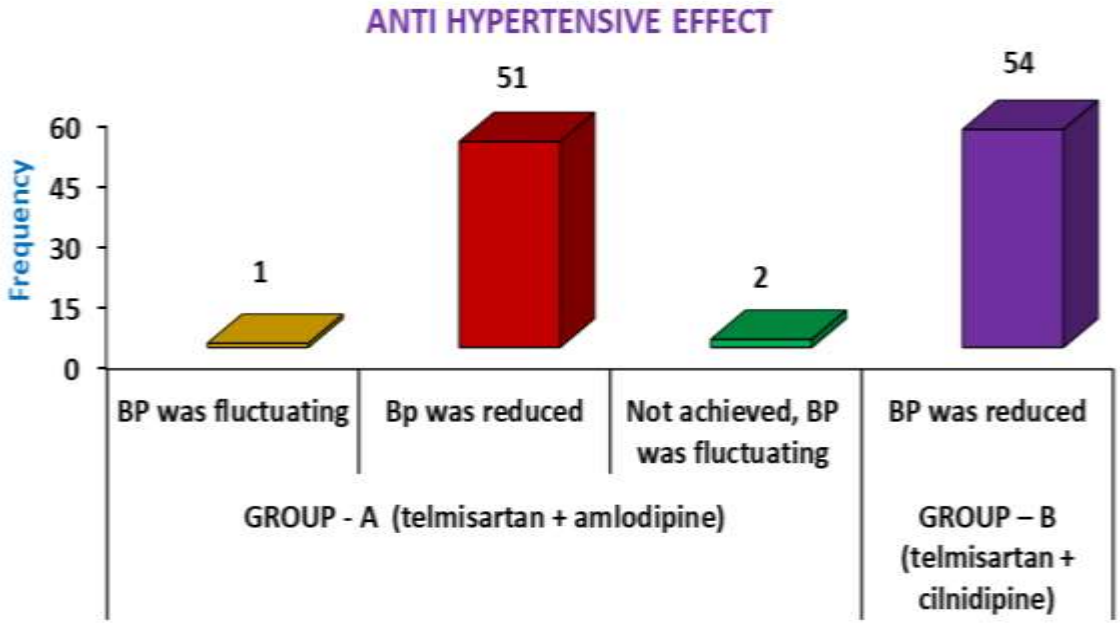

Graph 7: Antihypertensive effect

Table 12. Frequency of side effects in Group A and Group B

Group	ANTI HYPERTENSIVE EFFECT	Frequency	Percent
GROUP - A (Telmisartan + Amlodipine)	BP was fluctuating	1	3.7
	Bp was reduced	51	1.9
	Not achieved, BP was fluctuating	2	94.4
GROUP – B (Telmisartan + Cilnidipine)	BP was reduced	54	100

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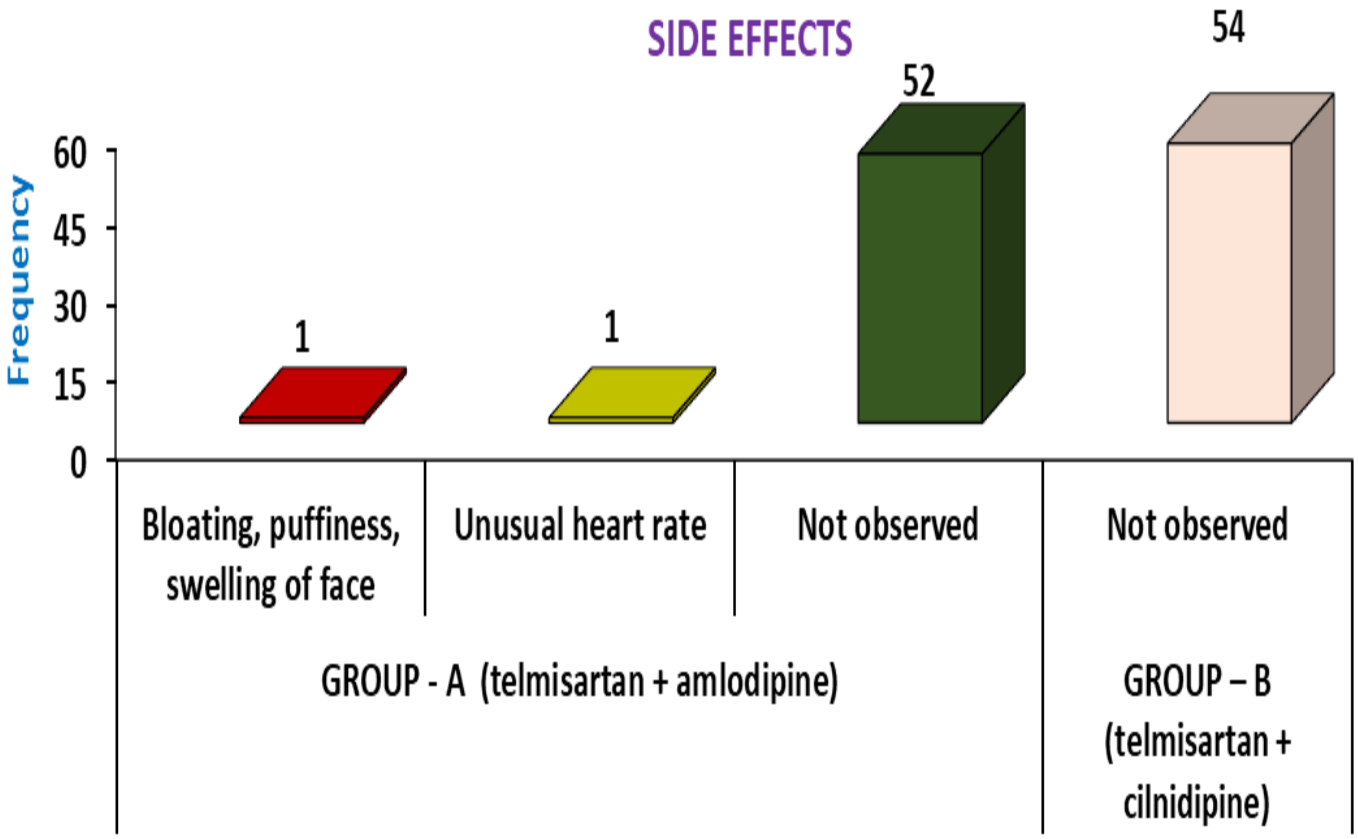

	Not observed	52	96.2
GROUP – B (Telmisartan + Cilnidipine)	Not observed	54	100

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Graph 8. Frequency of side effects

8. DISCUSSION

In this study, 108 patients attended the RVM hospital and are identified with high blood pressure.

Out of them, in Group A there were 33 males and 21 females, in Group B there were 35 males and 19 females, some with chief complaints of accelerated hypertension and others with accelerated hypertension associated with other comorbidities.

In Group A out of 54 patients, 11 patients were falling under the age group 40 to 50 years, 11 patients in 51 to 60 years, 25 in 61-70 years, and 7 in 71-80 years were recorded.

In Group B out of 54 patients, 9 patients were falling under the age group 40 to 50 years, 25 in 51 to 60 years, 13 in 61 to 70 years, 4 in 71 to 80 years, and 3 in greater than 80 years.

Tables 8 and 9 show a gradual decline in SBP from 170.78 ± 13.16 at the baseline to 128.15±7.29 after 8 weeks of treatment with telmisartan + amlodipine. statistical analysis using paired t-test was obtained which is statistically significant, P = 0.0010.

Tables 8 and 9 show a gradual decline in SBP from 172.72± 16.99 at the baseline to 125.93 ±9.82 after 8 weeks of treatment with telmisartan + cilnidipine. Statistical analysis using paired t-test was obtained which is statistically significant, P = 0.0010.

Tables 8 and 9 show a gradual decline in DBP from 89.13± 9.36 at the baseline to 77.96±10.16 after 8 weeks of treatment with telmisartan + amlodipine. Statistical analysis using paired t-test was obtained which is statistically significant, P = 0.0010.

Tables 8 and 9 show a gradual decline in DBP from 92.67± 11.84 at the baseline to 77.41±9.15 after 8 weeks of treatment with telmisartan + cilnidipine. Statistical analysis using paired t-test was obtained which is statistically significant, P = 0.0010.

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Application of the ANOVA test gives us P= 0.352. the difference between the 2 groups is statistically not significant but both drugs are equally efficacious in reducing SBP and DBP.

From table 11 it was observed that Group A, to 2 (3.7%) were showing fluctuation in BP,(1.9%) didn't show reductions in blood pressure and 51 (94.4%) showed a reduction in blood pressure levels. From the same table in Group B 54(100%) showed a reduction in BP.

From table 12 it was observed that in Group A, 1 (1.9%) were showing side effects of bloating, puffiness, and swelling of the face,1(1.9%) were showing unusual heart rate, 52(96%)of no side effects and in GroupB 54(100%) side effects were not observed.

9. CONCLUSION

As a result of this review, it was concluded that the combination of Telmisartan 40mg + cilnidipine 10mg was comparatively more preferred over Telmisartan 40mg + Amlodipine 5mg as it progressively reduces both SBP and DBP, maintains the stable hemodynamic parameters with fewer incidences of side effects than the latter which did not reach the desired antihypertensive effect and showed side effects in some patients such as general swelling, and facial puffiness.

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