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ORIGINAL ARTICLE

A Comparative Study of Effects of Amlodipine and Telmisartan on Lipid Profile and Renal Function Tests in Uncomplicated Hypertensive Patients in a Tertiary Care Hospital in Chennai

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ABSTRACT
Compare the effects of Amlodipine and Telmisartan on Lipid profile and Renal function tests (Blood Urea and Serum Creatinine) among uncomplicated hypertensive patients. To compare the effects of Amlodipine and Telmisartan on serum lipid profile in patients with uncomplicated hypertension. To compare the effects of mlodipine and Telmisartan on Renal function tests (Blood Urea and Serum Creatinine) in patients with uncomplicated hypertension. To assess the effect of Amlodipine and Telmisartan on Blood pressure levels.
Keywords: Amlodipine, Telmisartan, Hypertension

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INTRODUCTION

Hypertension is a rapidly emerging non communicable disease worldwide. Essential hypertension is believed to be a result of complex interaction of genetic and environmental factors [1, 2]. An important characteristic of hypertension is that it exhibits iceberg phenomenon as many can be undetected and untreated. This poses another risk that most of such patients end up in complications before even beginning any specific therapy for hypertension. It is a chronic health condition of major concern due to its association with the causation of coronary heart disease, stroke and various other vascular complications. It poses a major challenge to healthcare policy makers and healthcare providers and impacts the people worldwide in socioeconomic and epidemiological change [3]. Many studies support the coexistence of hypertension with other comorbidities. The most common among them are abnormalities in lipid levels and renal parameters [4,5]. These conditions often go unnoticed by the treating physician. It can be detrimental and lead to complications like cardiovascular diseases, renal diseases and mortality. Hence early detection by screening and adequate pharmacotherapy is required to prevent onset of complications. Population wide preventive measures are the need of the hour across different countries [6]. Various choices of pharmacotherapy are available in the management of hypertensive patients. Non-Pharmacotherapeutic measures like prevention of obesity, reduction of salt intake, regular exercise and avoidance of excess alcohol intake and lifestyle modification also play a major role in control of hypertension [7]. Anti-hypertensive therapy is associated with reduction in incidence of stroke by 35% - 40%, myocardial infarction by 20% - 25% and heart failure by more than 50% [8]. Some of them, apart from just reducing blood pressure have additional benefits. For example anti-hypertensive classes like ACE inhibitors and ARBs prevent the progression of micro albuminuria to full-fledged proteinuria [9]. The Saga Telmisartan Aggressive Research (STAR) trial as well as many other studies, claimed that telmisartan also possesses lipid and also glucose lowering properties [10]. Amlodipine also has additional Low-density-Lipoprotein (LDL) lowering effect apart from being an efficient antihypertensive [11]. Some drugs have withstood the test of time and sufficient evidence of their benefits is available through several clinical trials worldwide involving a large group of genetically

diverse population, whereas some of them are newer ones with comparatively lesser clinical data for supporting their use. Selection of antihypertensive drugs should be based on the patient's background and clinical history with an eye on the side effect profile of the drug. Therefore, understanding the current situation of antihypertensive drug prescription is essential and will allow appropriate treatment for each patient and effective use of health resources. The initial antihypertensive agent should generally be selected from one of four drug classes shown to reduce cardiovascular events: Angiotensin- converting–enzyme (ACE) inhibitors, angiotensin - receptor blockers ARBs, calcium-channel blockers (CCB's), and thiazide-type diuretics [12]. According to recently published International Society of Hypertension guidelines (2020), ACE inhibitors /ARBs are first line therapy of hypertension. CCBs are another class of commonly used anti-hypertensive drugs [13]. In cases of mild to moderate hypertension, the initiation of drug treatment with a minimal dose of either CCBs or ARBs is recommended widely. Hence these two commonly used drugs for hypertension were chosen to study the additional benefits of lipid lowering and renal safety. With this background, our study was conducted to assess and compare the effects of Amlodipine and Telmisartan on the lipid profile, renal function and blood pressure.

MATERIAL AND METHODS

Study Design:

This is a Longitudinal type of observational study design, where uncomplicated hypertensive patients, attending Out - patient Department, department of General Medicine, Sree Balaji Medical College and Hospital, Chromepet, Chennai. The hypertensive patients who were already on either of the two drugs (Amlodipine or Telmisartan) for a duration of more than 6 months, were followed up for a duration of 6 months to compare the effect of these drugs on serum lipid prof ile, Renal function tests (Blood urea and serum creatinine) and Blood pressure.

Study Duration

Study was conducted for a duration of 1 year from January 2019 to December 2019.

Study Sample Size

Sample size was calculated using the following formula (used for estimating a difference between means of two populations) and also by using the mean difference value in LDL based on a study by Tripathi N et al. 14

$n = (Z\alpha/2+Z\beta)2 *2*\sigma2 / d2$

where $Z\alpha/2$: for a confidence level of 95%, α is 0.05 and the critical value is 1.96

$Z\beta$: for a power of 80%, β is 0.2 and the critical value is 0.84 $\sigma2$ is the population variance, taken here as 17.632

d is the difference you would like to detect- 10%

Substituting the values in the formula, the sample size was calculated to be 49 in each group which was rounded off to 50. Total study sample was 100.

Sampling Method

Non-probable type of sampling method called purposive sampling method was utilized. The patients attending the out - patient department who satisfied the eligibility criteria and those who were available for follow-up were included in the study till the required sample size was achieved.

Study Procedure

After obtaining approval from the Institutional Ethics committee, the study was conducted in the out-patient department of General Medicine, Sree Balaji Medical College and Hospital. Hypertensive patients without any other complications who are satisfying the eligibility criteria were included in the study. A predesigned questionnaire was given to the subjects. Patient's voluntary informed written consent was obtained after explaining the risks and benefits to the patient in his/her own language. The patients who were taking the study drug Tablet Amlodipine 5mg once daily in the morning after breakfast and Tablet Telmisartan 40 mg once daily in the morning after breakfast were selected for the study. Recruitment was carried out until 50 patients in both study drug groups were reached. The patients were given assurance that any withdrawal from the study would not affect their future treatment in the same hospital. The blood pressure measurement and blood samples were collected for Renal function tests (Blood Urea, Serum Creatinine) and Lipid profile at baseline, 3 months and at 6 months of treatment. Contact numbers of the investigators and emergency physician were provided to all the study participants for any queries during the study period and for reporting of any adverse events. There were three scheduled visits during the study- baseline visit, 3rd month and 6th month.

Study Drug and Dosage

Patients taking Tablet Amlodipine 5mg once daily in the morning after breakfast and Tablet Telmisartan 40mg once daily in the morning after breakfast.

Statistical Analysis

The data was entered in Microsoft Excel (Annexure V- Master chart) and analysis was performed using IBM SPSS version 23. Results were reported as mean ± SD for parameters like blood pressure, serum lipid profile, blood urea and serum creatinine. Descriptive statistics and frequencies were used to describe socio-demographic variables. To compare the effect of study drugs (Amlodipine/Telmisartan) on study subjects with different duration of drug intake, the changes in parameters after the study subject has entered into study was only considered and analysed by Repeated measures ANOVA (Analysis of Variance) test. P value < 0.05 was considered as statistical significance at 95% confidence.

RESULTS

A total of 135 patients were screened for the study and 100 patients with Systemic Hypertension who fulfilled the eligibility criteria were included in the study. Initial recruitment was carried out for a period of 6 months from beginning of the study. New subjects were recruited in place of those subjects who were lost to follow-up and those who were withdrawn from the study. Three subjects dropped out from each study group after the end of recruitment period. The current study was done to measure the effect of Amlodipine and Telmisartan on lipid profile and renal function tests in uncomplicated hypertensive patients a longitudinal observational study. The socio-demographic features of the subjects who took part in this study and their statistical analyses are given.

Socio-Demographic Distribution of Study Participants

Age-wise distribution of study participants

The mean age of the study participants was 53.34 + 8.029 years. For statistical purpose the age-groups were divided into 4 groups with a class interval of 10 years. Age-wise distribution in two groups is depicted in Table 1. From this table it can be concluded that majority of the study participants were between 55 to 65 years. It can also be noticed that both groups had similar age distribution of study participants.

Table 1: Age-wise distribution of study participants (n=100)

Sl. No	Age groups	Amlodipine (50) n(%)	Telmisartan (50) n(%)	Total (100) n(%)
1	25 to 35	1	0	1
2	36 to 45	9	6	15
3	46 to 55	18	19	37
4	56 to 65	22	25	47

Table 2 depicts the variation in socio-demographic characteristics like gender, education, occupation and income between the amlodipine and telmisartan groups. It can be observed that, the two groups are similar in characteristics (p value not statistically significant) and they are comparable groups. Out of 50 subjects in each group, females were majority in number. Most of them had completed high school education and were either unemployed or retired currently. It can also be observed that most of them (65%) had an income of more than Rs. 10000 / month.

TABLE 2: SOCIO-DEMOGRAPHIC DISTRIBUTION OF THE STUDY PARTICIPANTS (n=100)

S No	Parameter	Amlodipine (n=50)	Telmisartan (n=50)	Total	P Value
1	Sex Male Female	21(42%) 29(48%)	22(44%) 28(46%)	43(43%) 57(57%)	0.84
2	Education Illiterate Primary/Middle School High School Graduate/Professional	3(6%) 8(16%) 23(46%) 16(32%)	3(6%) 4(8%) 24(48%) 19(38%)	6 (6%) 12(12%) 47(47%) 35(35%)	0.64
3	Occupation Unemployed/Retired Employed	34(68%) 16(32%)	31(62%) 19(38%)	65(65%) 35(35%)	0.53
4	Income Upto Rs 10000/Month > Rs 10000/Month	19 (38%) 31 (62%)	16 (32%) 34 (68%)	35(35%) 65(65%)	0.52

Distribution of Other Hypertension Determinants among the Study Participants

Table 3 denotes the distribution of the factors which can influence the blood pressure control apart from the anti - hypertensive medications. These determinants can act as confounding factors. Hence the factors

were compared between two groups to rule out any confounding effect. It can be seen that these determinants are also distributed uniformly in both the amlodipine and telmisartan groups as p value is not statistically significant (not less than 0.05). Hence making both the groups comparable. 43 out of 100 subjects had family history of hypertension and 14 of them had a current history of smoking. 54 participants were not engaged in regular physical activity and 62 of them did not have salt restriction in their diet.

Table 3: Distribution of other determinants of blood pressure control among the hypertensive study participants (n=100)

S. No	Parameter	Amlodipine (N=50)	Telmisarta n (N=50)	Total	P Value
Family History					
1	Yes No	23(46%) 27(54%)	20(40%) 30(60%)	43(43%) 57(57%)	0.55
Current History					
2	Of Smoking Yes No	6(12%) 44(88%)	8(16%) 42(84%)	14(14%) 86(86%)	0.56
Physical					
3	Activity Yes No	18(36%) 32(64%)	28(56%) 22(44%)	46(46%) 54(54%)	0.05
Salt Restriction					
4	Yes	15(30%)	23(46%)	38(38%)	0.09
	No	35(70%)	27(54%)	62(62%)	

Table 4 shows BMI of study participants. It can be observed that majority of the study subjects were overweight (37) or Obese (40). Telmisartan group had majority of subjects in overweight criteria (54%) whereas amlodipine group had majority of subjects in obese (52%) criteria.

Table 4: Body Mass Index (BMI) of study participants (n=100)

S.No	BMI Classification	AMLODIPINE (n=50)	TELMISARTAN (n=50)	Total
1	Underweight	0	1(2%)	1(1%)
2	Normal	13(26%)	9(18%)	22(22%)
3	Overweight	11(22%)	26(54%)	37(37%)
4	Obese	26(52%)	14(28%)	40(40%)

Effect of Study Drugs on Blood Pressure (Bp) Control

The measured blood pressure was depicted as Mean ± Standard Deviation. Both Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) were depicted as Mean ± Standard Deviation along with the Confidence Interval (CI). The BP was measured at baseline, at 3 months and at 6 months in this study among all the study participants.

Effect of Amlodipine on Blood Pressure (mmHg)

The mean SBP value measured at baseline was 157+7.64. At 3 months of follow-up period, the mean SBP value reduced to 151+ 7.59 and after 6 months the mean SBP effectively reduced to 148+ 7.36 among the subjects in amlodipine group. Similarly, the mean DBP value measured at baseline was 92 + 4.8. At 3 months of follow-up period, the mean DBP value reduced to 88 + 4.2 and at 6 months the mean DBP effectively reduced to 85 + 3.7 among the subjects in amlodipine group. Table 5 also depicts that reduction in both SBP and DBP at 6 months of follow-up is statistically significant (p value<0.001). The confidence interval range also is narrow and significant.

Table 5: Effect of Amlodipine on Blood Pressure in mmHg(Mean+ Standard Deviation)

S.No	Parameter		Baseline (n=50)		At 3 months (n=50)		At 6 months (n=47)*		P Value
1	SBP	Mean+ SD	157+7.64		151+ 7.59		148+ 7.36		<0.001
		CI	154.5	158.7	148.8	153	146	150	
2	DBP	Mean+ SD	92 + 4.8		88 + 4.2		85 + 3.7		<0.001
		CI	90.6	94.3	86.6	89.6	83.9	86.0	

* 3 subjects excluded either due to loss to follow-up or withdrawal from study

Effect of Telmisartan on Blood Pressure

The mean SBP value measured at baseline was 158+6.87. At 3 months of follow-up, the mean SBP value reduced to 153+ 6.96 and after 6 months, the mean SBP effectively reduced to 141+ 6.15 among the subjects in telmisartan group. Similarly, the mean DBP value measured at baseline was 101 + 7.52. After 3 months, the mean DBP value reduced to 95 + 6.04 and after 6 months, the mean DBP effectively reduced to 84 + 3.41 among the subjects in telmisartan group. Table 6 also depicts that reduction in both SBP and DBP at 6 months is statistically significant (p value <0.001). The confidence interval range also is narrow and significant.

Table 6: Effect of Telmisartan on Blood Pressure (Mean+ Standard Deviation)

S.No	Parameter		Baseline (n=50)		At 3 months (n=50)		At 6 months (n=47)*		P Value
1	SBP	Mean+SD	158+6.87		153+ 6.96		141+ 6.15		<0.001
		CI	156.3	160.5	150.9	155.1	139.3	143.2	
2	DBP	Mean+SD	101 + 7.52		95 + 6.04		84 + 3.41		<0.001
		CI	99.45	103.11	93.01	96.01	82.89	84.94	

* 3 subjects excluded either due to loss to follow -up or withdrawal from study

Effect of Study Drugs on Serum Lipid Profile of Study Participants (mg/dl)

Serum lipid profile was measured in five parameters. They are: Total Cholesterol (TC), Triglycerides (TG), High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL) and TC/HDL. All the values is expressed as mean + Standard Deviation along with confidence intervals.

Effect of Amlodipine on Serum Lipid Profile (mg/dl)

Mean serum Total cholesterol value at baseline was 170 + 25.07and at 3 months of follow up, it reduced to 169 +25.78. There was not any significant reduction after 6 months. Serum triglycerides values at baseline was 129+ 40.99. At 6 months, serum triglycerides remained almost unchanged. Serum HDL values at baseline value was 48+10.14. At 3 months, Serum HDL increased to 50+ 10.19. At 6 months, Serum HDL remained almost unchanged at 50+ 9.73. Serum LDL values at baseline value was 117+ 33.13. Serum LDL remained almost unchanged at 117+ 31.29. Serum TC/ HDL also remained almost unchanged at 3.48 +0.59.

From Table 7, it can be inferred that the amlodipine therapy after 6 months did not show much reduction in serum lipid profile values. Although there was slight reduction noticed, it was not statistically significant (p value >0.05).

Table 7: Effect of Amlodipine on Serum Lipid Profile (mg/dl) (Mean+ Standard Deviation)

S.No	**Parameter**		**Baseline (n=50)**		**At 3 months (n=50)**		**At 6 months (n=47)***		**P Value**
1	TC	Mean+ SD	170 + 25.07		169 +25.78		171 + 24.48		
		CI	161.7	177.6	161.7	177.2	163.5	178.8	
2	TG	Mean+ SD	129+ 40.99		128+41.55		128 + 40.61		
		CI	117.2	141.3	116.6	139.7	118.4	139.3	
3	HDL	Mean+ SD	48+10.14		50+ 10.19		50+ 9.73		
		CI	44.4	51.5	46.4	53	46.8	53.6	
4	LDL	Mean+ SD	117+ 33.13		116+33.32		117+ 31.29		
		CI	106.7	127.4	106.1	126.4	107.6	125.6	
5	TC/ HDL	Mean+ SD	3.63+0.68		3.48+0.63		3.48 +0.59		>0.05
		CI	3.24	4.03	3.24	3.73	3.27	3.69	

* 3 subjects excluded either due to loss to follow -up or withdrawal from study

Blood urea at baseline was 16.57+3.02. After 3 months of follow up it reduced to 15.62+2.82 and after 6 months again decreased to 14.79 +2.74. Treatment with Amlodipine showed decrease in blood urea compared to baseline value. Serum creatinine value at baseline was 0.85+0.12 and after 3 and 6 months of follow up, reduced to 0.81+0.13 and 0.77+0.17 respectively. Treatment with Amlodipine showed decrease in Serum creatinine compared to baseline values. Both reduction in blood urea and serum creatinine were statistically signifi cant (P<0.001).

Effect of Telmisartan on Serum Lipid Profile (mg/dl)

Mean Serum Total cholesterol value at baseline was 168+25.07. After 3 months of follow up therapy, it reduced to 152 + 27.39 and after 6 months, mean serum total cholesterol decreased to 129+ 27.97.

Treatment with Telmisartan showed decrease in Serum total cholesterol compared to baseline values and it was also statistically significant (P<0.001).
Serum triglycerides value at baseline was 135 + 42.13. After 3 months of follow up, TG reduced to 121+38.2 and to 102+30.81 at 6 months and was statistically significant (P<0.001). Serum HDL at baseline was 45+ 13.95. After 3 months of follow up, HDL increased to 51+ 12.57 and to 58+13.52 after 6 months. Treatment with Telmisartan showed an increase in Serum HDL compared to baseline values and with statistical significance. (P<0.001). Serum LDL value at baseline was 112+38.14. After 3 months of follow up, reduced to 100+36.59 and after 6 months reduced to 82+ 31.08. Treatment with telmisartan showed prominent decrease in Serum LDL compared to baseline values with statistical significance (P<0.001). Serum TC/ HDL value at baseline was 4.18+1.79 and after 3 and 6 months of follow up, values reduced to 3.18 +0.99 and 2.37+ 0.84 respectively and this reduction was statistically significant (P<0.001) (Table 8).

Table 8: Effect of Telmisartan on Serum Lipid Profile (mg/dl) (Mean+ Standard Deviation)

Parameter		**Baseline (n=50)**		**At 3 months (n=50)**		**At 6 months (n=47)***		**P Value**
TC	Mean+ SD	168+25.07		152 + 27.39		129+ 27.97		<0.001
	CI	159.9	175.7	144.6	159.9	121.6	136.8	
TG	Mean+ SD	135 + 42.13		121+38.29		102+30.81		
	CI	122.7	146.7	109.2	132.4	91.8	112.6	
HDL	Mean+ SD	45+ 13.95		51+ 12.57		58+13.52		
	CI	41	48	47.5	54.1	54.4	61.2	
LDL	Mean+ SD	112+38.14		100+36.59		82+ 31.08		
	CI	101.8	122.5	90.4	110.7	73.4	91.4	
TC/ HDL	Mean+ SD	4.18+1.79		3.18 +0.99		2.37+ 0.84		
	CI	3.79	4.58	2.94	3.42	2.16	2.58	

*3 subjects excluded either due to loss to follow -up or withdrawal from study

EFFECT OF STUDY DRUGS ON BLOOD UREA NITROGEN (BUN) AND SERUM CREATININE (SC) OF STUDY PARTICIPANTS

Effect of the study drugs on blood urea and serum creatinine were measured at baseline, 3 months and 6 months and expressed as mean + standard deviation in the following tables.

Effect of Telmisartan on Blood urea and Serum Creatinine

Blood urea value at baseline was 20 + 5.47. After 3 months of follow up, blood urea reduced to 21.26+5.24. But again, increased after 6 months. These changes were not statistically significant. Serum creatinine value at baseline was 0.82+0.14. After 3 months follow up, serum creatinine increased to 0.96+0.13 and after 6 months again increased to 1.12+0.13. Treatment with Telmisartan showed increase in Serum creatinine compared to baseline values and was statistically significant (P<0.001). However, the increase in values were within the normal range (Table 10).

Table 10: Effect of Telmisartan on Blood urea and serum creatinine (mg/dl)

S.No	**Parameter**		**Baseline (n=50)**		**At 3 months (n=50)**		**At 6 months (n=47)***		**P Value**
1	BUN	Mean+SD	20.02+5.47		21.26+5.24		24.32+5.89		0.09
		CI	18.7	21.3	20	22.5	22.9	25.7	
2	SC	Mean+SD	0.82+0.14		0.96+0.13		1.12+0.13		<0.001
		CI	0.78	0.86	0.92	1.00	1.08	1.17	

*3 subjects excluded either due to loss to follow -up or withdrawal from study

Comparison of Effect of Study Drugs on Various Measured Parameters of Study Participants at 6 Months Follow Up

The effects of study drugs Amlodipine and Telmisartan on blood pressure, serum lipid profile, blood urea and serum creatinine were compared using Repeated measures ANOVA statistical test and statistical significance given as p value. Comparison of effect of study drugs on blood pressure (Table 11)

From table 11, we can observe that in the Amlodipine group, the mean Systolic BP baseline value was 157+7.64, which reduced to 151+ 7.59 after 3 months and then to 148+ 7.36, after 6 months of the study. In the Telmisartan group, the baseline systolic Blood pressure baseline mean was 158+6.87, which reduced to 153+ 6.96 after 3 months of the study and was 141+ 6.15 at the end of 6 months of study. In

amlodipine group, the mean DBP value measured at baseline was 92 + 4.8. After 3 months of follow up, the value reduced to 88 + 4.2 and after 6 months of follow up, to 85 + 3.7 among the subjects. In the telmisartan group, the mean DBP value measured at baseline was 101 + 7.52. After 3 months of therapy, reduced to 95 + 6.04 and after 6 months, was 84 + 3.41 among the subjects in telmisartan group. It can be inferred that the reduction in Diastolic blood pressure in Amlodipine group after 6 months follow up, was more and statistically significant than the reduction in Telmisartan group (p value - <0.001). Comparison of SBP reduction was not statistically significant.

Table 11: Comparison of effects of study drugs on Blood Pressure after 6 months (mmHg)

S. No	Parameter		Amlodipine		Telmisartan		P value
1	SBP	Mean	148+ 7.36		141+ 6.15		0.48
		CI	146	150	139.27	143.19	
2	DBP	Mean	85 + 3.7		84 + 3.41		<0.001
		CI	83.9	86	82.89	84.94	

Comparison of effects of study drugs on Serum Lipid Profile

Table 12 indicates the comparison of effects of study drugs on serum lipid profile at 6 months follow-up. It can be inferred that the Telmisartan group showed significant reduction in serum total cholesterol (p value- <0.001) and Low-Density Lipoprotein (p value- <0.05). Although serum triglyceride was lesser in Telmisartan group, it was not statistically significant. There was higher level of HDL among participants of Telmisartan group after 6 months follow up when compared to Amlodipine group

Table 12: Comparison of effects of study drugs on Serum Lipid Profile after 6 months

S. No	Parameter		Amlodipine		Telmisartan		p-value
1	TC	Mean	171 + 24.48		129+ 27.97		
		CI	163.55	121.56	136.78	157.31	<0.001
2	TG	Mean	128 + 40.61		102+30.81		0.24
		CI	118.39	91.75	112.63	130.46	
3	HDL	Mean	50+ 9.73		58+13.52		0.46
		CI	46.76	54.35	61.18	54.37	
4	LDL	Mean	117+ 31.29		82+ 31.08		0.01
		CI	107.56	73.371	91.438	108.10	
5	TC/HDL	Mean	3.48 +0.59		2.37+ 0.84		0.13
		CI	3.27	2.16	2.58	3.51	

Comparison of effects of study drugs on Blood urea and Serum Creatinine

Table 13 depicts the comparison of effects of study drugs on blood urea and serum creatinine. It can be inferred that the Telmisartan group showed significantly higher level of blood urea and serum creatinine (p value- <0.001) when compared to Amlodipine group after 6 months follow up. But the values were within the normal range.

Table 13: Comparison of effects of study drugs on Blood urea and Serum Creatinine at 6 months follow-up

S. No	Parameter		Amlodipine		Telmisartan		P-value
1	B Urea	Mean	14.79 +2.74		24.32+5.89		
		CI	13.46	22.99	25.65	23.09	<0.001
2	Serum Creatinine	Mean	0.77+0.17		1.12+0.13		
		CI	0.77	1.08	1.17	1.00	<0.001

DISCUSSION

Hypertension is both a cause and effect of chronic kidney disease and contributes largely to its progression and morbidity with mortality of affected persons. This study was performed among uncomplicated hypertensive patients who were either on amlodipine or telmisartan treatment. 50 subjects were selected in each of amlodipine and telmisartan group. The primary aim was to compare the effects of Amlodipine and Telmisartan on serum lipid profile, blood urea and serum creatinine and also blood pressure values of study subjects at various intervals of follow-up. The study parameters were measured at baseline during recruitment, then at 3 months interval and at 6 months interval.

It is a well-known fact from previous research studies that these drugs as monotherapy or as combination with other antihypertensive drugs, when given in optimum dosages have been effective in controlling blood pressure values throughout the day. They are widely used in clinical practice as well. Additional

benefits are also available and these need to be proven to establish superiority of one drug over the other [14-17].

Pleotropic effects add to the value of a drug as well as help in reducing the cost incurred for the treatment of disease and prevention of complications. Adverse effects of drugs also need to be kept in mind while prescribing the drug to a patient. Telmisartan plus Amiodipine studies (TEAMSTA-5) that involved 1814 subjects who were administered telmisartan 40mg/ amlodipine 5mg or telmisartan 80mg, amlodipine 5 mg, TEAMSTA-10 telmisartan 40mg/ amlodipine 10mg or telmisartan 80mg amlodipine 10 mg. These 2 studies were designed for comparing Telmisartan / Amlodipine combination against Olmesartan / Hydrochlorothiazide combination. Safety and efficacy of the former combination was proved to be better than the latter. Although there is enormous evidence about the drugs amlodipine and telmisartan either studied as individual drugs or in combination, there are very few studies which compare their effects on lipid profile and blood urea and serum creatinine at follow-up intervals. Hence this study was carried out [17].

Effect of study drugs on blood pressure

In this study, both the study drugs showed a significant (p value-<0.001) reduction in blood pressure values (both SBP and DBP) in the 6 months follow-up period indicating that both drugs are effective in control of blood pressure. When the reduction in mean BP by both drugs were compared by repeated measures ANOVA test, Amlodipine showed an edge over Telmisartan in reduction of Diastolic Blood Pressure values (p value-<0.001) after 6months of therapy. The difference was statistically significant. Whereas reduction in SBP was there but not statistically significant [18,19].

Effect of study drugs on serum lipid profile:

In our study treatment with Telmisartan showed significant decrease in Serum total cholesterol, LDL and serum triglycerides after 6 months of therapy (p value - <0.001). HDL also was significantly increased (p value - <0.001) compared to baseline values. Whereas treatment with amlodipine did not show much changes in serum lipid profile after the follow-up period. Although telmisartan showed significant reduction in lipid profile values when compared to amlodipine, it was statistically significant for total cholesterol (p value - <0.001) and LDL (p value - <0.01) fractions. There was also increase in HDL values of telmisartan group but it was not statistically significant. As per the study done by Tripathi N et al [20], Telmisartan reduced Total cholesterol, LDL and triglycerides significantly, compared to amlodipine group.

Effect of study drugs on blood urea and serum creatinine

In our study, Amlodipine group showed significant reduction in blood urea and serum creatinine after 6 months of therapy (p value - <0.001). Telmisartan group showed an increase in blood urea and serum creatinine where only increase in serum creatinine was statistically significant (p value -<0.001). Although telmisartan showed an increasing trend in blood urea and serum creatinine, the values were within normal range. When the changes in blood urea and creatinine values were compared in both groups, significant reduction was observed in amlodipine group; whereas telmisartan group showed increase in these values [21].

A study involving 92 subjects, showed that Telmisartan reduced blood Pressure and reversed proteinuria in Diabetic and Non diabetic / hypertensive patients who had Chronic kidney disease who already had proteinuria and with mild to moderate renal failure. This is in contradiction to our present study which showed increase in Renal function parameters with telmisartan. The small sample size and presence of pre-existing complications (micro-albuminuria) in the subjects could have been a factor influencing the study outcome, regardless of the treatment benefits [21].

Another study showed that in a group of 132 patients with diabetes, stage I hypertension, Telmisartan reduced both systolic and Diastolic BP in both groups, those without complications of Diabetes as well as with complications of Diabetes.

CONCLUSION

Amlodipine seems to reduce Diastolic blood pressure more effectively than Telmisartan in this study population. However, Telmisartan was found to have an advantage over Amlodipine when Lipid profile was concerned. Blood Urea, serum Creatinine values were found to increase in the Telmisartan group, when compared to Amlodipine group but within the normal range for an individual. From these results it can be inferred that in patients with associated conditions like Dyslipidemia and Cardiovascular diseases Telmisartan could have an additional benefit on lipid lowering in addition to its antihypertensive property; when it is prescribed with drugs like statins and other medications. This study also points out the importance of constant monitoring of Renal parameters in patients receiving ACE inhibitors, ARBs etc to look for elevated values including Potassium and sodium levels.

REFERENCES

1. Ehret G.B., Munroe P.B., Rice K.M., Bochud M, Johnson A.D., Chasman DI, et al. (2011). Genetic variants in novel pathways influence blood pressure and cardiovascular disease risk. Nature. Sep 11 ; 478(7367): 103 – 9.
2. Lifton R.P., Gharavi A.G., Geller D.S. (2001) Molecular mechanisms of human hypertension. Cell. Feb 23; 104(4): 545 – 56 .
3. Park K. Park' s Text Book Of Preventive And Social Medicine : 25 th Edition. Bhanot; 403 p.
4. Adamu U.G., Okuku G.A., Oladele C.O., Abdullahi A., Oduh J.I. (2013). Fasae AJ. Serum lipid profile and correlates in newly presenting Nigerians with arterial hypertension. Vasc Health Risk Manag [Internet]. 9:763 – 8. / pmc/ articles/ PMC3857265 /
5. Choudhury K.N., Mainuddin A., Wahiduzzaman M., Islam SMS.(2014). Serum l ipid profile and its association with hypertension in Bangladesh. Vasc Health Risk Manag [Internet]. 10:327 – 32.
6. Lloyd- Jones Donald M., Evans Jane C., Larson Martin G., Levy Daniel.(2002) Treatment and Control of Hypertension in the Community. Hypertension [Internet]. 40 (5): 640 – 6.
7. Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: Executive Summary: A Report of the American College of Cardiology/ American Heart Association Task Force on Clinical Practice Guidelines. Hypertens Dallas Tex 1979;2018 ; 71(6): 1269 – 324 .
8. Chobanian AV., Bakris G.L., Black H.R., Cushman W.C., Green L.A., Izzo J.L., et al. (2003) Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. Hypertens Dallas Tex 1979. Dec; 42 (6): 1206 – 52.
9. Ohishi M., Yoshida T., Oh A., Hiroi S., Takeshima T., Otsuka Y., et al.(2019). Analysis of antihypertensive treatment using real - world Japanese data- the retrospective study of antihypertensives for lowering blood pressure (REAL) study. Hypertens Res Off J Jpn Soc Hypertens. ; 42(7): 1057 – 67.
10. Lewington S., Li L., Sherliker P., Guo Y., Millwood I., Bian Z., et al. (2012). Seasonal variation in blood pressure and its relationship with outdoor temperature in 10 diverse regions of China: the China Kadoorie Biobank. J Hypertens. ; 30 (7): 1383 – 91.
11. Inoue T., Morooka T., Moroe K., Ikeda H., Node K. (2007). Effect of telmisartan on cholesterol levels in patients with hypertension - Saga Telmisartan Aggressive Research (STAR). Horm Metab Res Horm Stoffwechselforschung Horm Metab. May; 39 (5): 372 – 6.
12. Arslan Z., Ay S.A., Karaman M., Cakar M., Celik T., Balta S., et al. (2013). An additional LDL- lowering effect of amlodipine; not only an antihypertensive? Clin Exp Hypertens N Y N 1993. 35(6): 449 – 53 .
13. Barnett A.H., Bain S.C., Bouter P., Karlberg B., Madsbad S., Jervell J., et al. (2004). Angiotensin- Receptor Blockade versus Converting– Enzyme Inhibition in Type 2 Diabetes and Nephropathy. N Engl J Med [Internet]. 351 (19): 1952 – 61.
14. Unger T., Borghi C., Charchar F., Khan N.A., Poulter N.R., Prabhakaran D., et al. (2020). International Society of Hypertension Global Hypertension Practice Guidelines. Hypertens Dallas Tex 1979. 75(6): 1334 – 57 .
15. Williams B., Mancia G., Spiering W., Agabiti Rosei E., Azizi M., Burnier M., et al. (2018) ESC/ ESH Guidelines for the management of arterial hypertension The Task Force for the management of arterial hypertension of the European Society of Cardiology (ESC) and the European Society of Hypertension (ESH). Eur Heart J [Internet]. 2018 Sep 1 [cited 2020 Oct 22]; 39(33): 3021 – 104.Available from: https:// academic. oup. com/ eurheartj/ article/ 39/ 33 / 3021/ 5079119
16. Stergiou G.S., Palatini P., Asmar R., Bilo G., de la Sierra A., Head G., et al. (2018). Blood pressure monitoring: theory and practice. European Society of Hypertension Working Group on Blood Pressure Monitoring and Cardiovascular Variability Teaching Course Proceedings. Blood Press Monit. 23 (1): 1 – 8 .
17. Muntner P., Einhorn P.T., Cushman W.C., Whelton P.K., Bello N.A., Drawz P.E., et al. (2019). Blood Pressure Assessment in Adults in Clinical Practice and Clinic- Based Research: JACC Scientific Expert Panel. J Am Coll Cardiol. 2019 29; 73 (3): 317 – 35.
18. O' Brien E., Parati G., Stergiou G., Asmar R., Beilin L., Bilo G., et al. (2013). European Society of Hypertension position paper on ambulatory blood pressure monitoring. J Hypertens. ; 31(9): 1731 – 68.
19. Parati G., Stergiou G.S., Asmar R., Bilo G., de Leeuw P., Imai Y., et al. (2008). European Society of Hypertension guidelines fo r blood pressure monitoring at home: a summary report of the Second International Consensus Conference on Home Blood Pressure Monitoring. J Hypertens. ; 26(8): 1505 – 26.
20. Tripathi N., Bohara S., Singh R.R., Kumar A., Dhoan P., Uraiya D. (2016). Comparative study of telmisartan and amlodipine to assess the effect on blood pressure, lipid profile and blood glucose level in Indian hypertensive patients. Int J Med Res Rev; 4 (9): 1693 – 701.
21. Stergiou G.S., Palatini P., Modesti P.A., Asayama K., Asmar R., Bilo G., et al. (2020). Seasonal variation in blood pressure: Evidence, consensus and recommendations for clinical practice. Consensus statement by the European Society of Hypertension Working Group on Blood Pressure Monitoring and Cardiovascular Variability. J Hypertens. ; 38 (7): 1235 – 43.