Original Research Article

AN EFFECTIVENESS, SAFETY AND TOLERABILITY STUDY OF AZILSARTAN AND TELMISARTAN IN PATIENTS OF ESSENTIAL HYPERTENSION: A RANDOMIZED AND OPEN-LABEL STUDY

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ABSTRACT:

BACKGROUND: The aim of this study was to compare effectiveness, safety and tolerability of azilsartan and telmisartan in terms of their blood pressure lowering capacity, effect on hematological and biochemical profile and side effects respectively in patients of essential hypertension.

METHODS: This was an observational, prospective, open label, randomized, parallel study. The study was conducted after getting approval from the ethics committee at RIMS, Ranchi. Total sample size was 108. Blood pressure recordings, hematologic and biochemical investigations were done at the beginning of study and at every visit according to study design. The first group was prescribed tablet azilsartan 40mg once daily and the other tablet telmisartan 40 mg once daily at the beginning. Each patient was followed for 12 weeks and total study duration was 1 year.

RESULTS: The treatment arms showed significant reduction (p<0.05) in both systolic and diastolic blood pressure at the end of study period, although while doing inter-group comparison, the difference was not significant. Safety profile of both drugs was similar. Notable side-effects included fatigue and dizziness apart from headache.

CONCLUSION: Azilsartan and telmisartan reduced the blood pressure significantly in 12 weeks when compared from the baseline, but the reduction was similar when an intergroup comparison was done. The drugs did not adversely affect the haematologic and biochemical parameters. Few side-effects were reported but these were mild in nature and did not require any specific intervention.

Keywords: Angiotensin receptor blocker, Azilsartan, Effectiveness, Essential hypertension, Randomized, Safety, Telmisartan, Tolerability

INTRODUCTION

Hypertension is one of the significant contributory factor of wide array of cardiovascular diseases like congestive heart failure, myocardial infarction, coronary heart diseases, stroke, renal failure and many more, ultimately leading to morbidity and untimely death in majority of the affected population. [1,2]

Essential hypertension is defined as elevated blood pressure in which other causes of hypertension such as renovascular disease, renal failure, pheochromocytoma, aldosteronism, or other causes of secondary hypertension or mendelian forms (monogenic) can be ruled out. [3]

India launched the fourth National Family Health Survey (NFHS-4) in 2014-2015. This survey covered all the 29 states along with the 6 union territories. The data collected from this survey projected the mean prevalence of blood pressure to be 22.4%. Maximum number of people in the survey had their systolic blood pressure 140-159 mm of Hg and/or diastolic blood pressure 90-99 mm of Hg which is 6.7 % in case of women and 10.4% for men. [4]

The primary aim of initiating antihypertensive therapy is to de-escalate the incidence and prevalence of cardiovascular accidents such as coronary disease, stroke and heart failure. This decrease in the blood pressure prevents damage to blood vessels and reduces both morbidity and mortality in people suffering from hypertension.[5,6] A decrease in systolic blood pressure by 10 mm Hg and diastolic blood pressure by 5 mm Hg curtails the risk of stroke and coronary heart disease by 33-48% and 17-27% respectively.[7]

Angiotensin receptor blockers (ARBs) are antagonists of angiotensin II receptors (AT_1) receptor. According to JNC-8, it is now one of the first line drug in treatment of hypertension. These drugs have very high affinity for the AT_1 receptor. These drug acts by decreasing the total peripheral resistance (afterload) as well as cardiac venous return (preload). [8]

Azilsartan is the eighth and latest drug of the ARB group. Its prodrug is known as azilsartan-medoxomil and once

administered, it is hydrolysed rapidly to the active moiety azilsartan .The anti-hypertensive dose of azilsartan is 40-80 mg. The drug is started at a dose of 40 mg daily and then it is adjusted according to patient's response towards the drug. The peak plasma level is attained after 30 minutes to 1 hour of oral administration. [9,10,11,12] Telmisartan is a longer acting ARB having plasma half-life of ~24 hours,which reaches peak plasma level within 30 minutes to 1 hour of oral administration. Hepatic insufficiency compromises the clearance of the drug from the body. It is also given in doses of 40-80 mg daily.[9]

This study compares the effectiveness, safety and tolerability of azilsartan and telmisartan in context of blood pressure lowering effects, changes in hematological and biochemical parameters, and side-effect profile respectively. Hence, new drugs that are more efficacious and well tolerated could be effective in improving BP control in the hypertensive population.

METHODS

This was an observational, prospective, randomized, parallel, open label, comparative study. The study was conducted in the department of pharmacology & therapeutics and department of cardiology of Rajendra Institute of Medical Sciences, Ranchi after getting proper approval from the Institutional Ethics Committee.This study was conducted in accordance with the principles outlined in the Declaration of Helsinki (1964) and International Conference on Harmonisation(ICH) – Good Clinical Practices (GCP) guidelines.

The total study duration was of 12 months, from 1st April, 2018 to 31st March 2019. The patients were followed-up for 12 weeks from the date of enrollment following randomization. A sample size of 108 (54 per treatment group) was calculated as sufficient to have 80% power to detect a difference of 5 mm Hg in change from baseline DBP with a 5% level of significance , assuming a standard deviation of 8.5mm Hg and a 20 % dropout rate owing to loss to follow-up.

Inclusion criteria was patients aged 18 years and above of either sex, having essential hypertension with systolic blood pressure between 140-180 mm of Hg and diastolic blood pressure between 90-110 mm of Hg (Patients >60 years of age were recruited if the SBP was >150 mm of Hg). Newly diagnosed and untreated case or those who had discontinued antihypertensive medication voluntarily for more than 4 weeks were also included in the study.

The criteria for excluding the patients from this study were thoroughly observed and comprised of a history of intolerance to ARBs, severe hypertension i.e. SBP > 180

mm of Hg and DBP > 100 mm of Hg, Patients of secondary hypertension, Pregnant women and lactating mothers or women suffering from pregnancy induced hypertension, Clinically relevant or unstable cardiovascular diseases, presence of heapto-biliary or pancreatic disorders, impaired renal function. Those with history of stroke, TIA or MI within last 4 months or diagnosed with congestive cardiac failure were also excluded. Patients having any history of thyroid disorder or Type 1 or poorly controlled type 2 diabetes mellitus (HbA1c: ≥8%) were also deemed ineligible for the study. Patients in whom the blood pressure was not adequately controlled within 8 weeks of initiating the therapy were also excluded from the study including those with having prior non-compliance to the prescribed medication.

At the time of patient enrollment, freely given informed consent was obtained from each participant. Patients were randomized in two groups. Those assigned to "group 1" were treated with Azilsartan (started with 40 mg /day) and those assigned to "group 2" were treated with Telmisartan (starting with 40 mg/day). Those patients who failed to show satisfactory blood pressure reduction after 2 weeks of therapy were prescribed other/additional drugs for the same and excluded from the study.

The patients were examined by the consultant physician. Conventional sphygmomanometer was used for the blood pressure measurement. All recording were taken in both arm at initial visit in both supine and sitting position and in left arm (sitting only) on subsequent visit using a well calibrated sphygmomanometer. Auscultatory method of blood pressure measurement was used. Systolic blood pressure (SBP) was the point at which first two or more Korotkoff sound was heard and disappearance of Korotkoff sound was used to define diastolic blood pressure (DBP). Average of three consecutive measurements at intervals of 1 minute was recorded.

A comprehensive and detailed history was taken from each participant. After recording all the above information, a thorough physical examination was also conducted. Baseline parameters like height, weight, blood pressure etc along with blood investigations were entered in the predesigned case record form and were updated at each visit of the respective patient. The patients were followed up at 2nd, 4th, 8th and 12th week from the treatment initiation.

The investigations conducted for safety profile included Blood Count, Hemoglobin%, Fasting blood sugar & 2hr Post-prandial blood sugar, HbA1c, Liver function tests (Serum Bilirubin, SGOT, SGPT), Serum potassium, Serum sodium, Serum Creatinine & Uric Acid and Lipid Profile

(TC, TG, HDL, LDL, VLDL). The change in these parameters was assessed at the completion of study period. Drug tolerability was assessed in terms of side-effect encountered by the patient during the study period and was asked about in detail at each visit.

The data was expressed as mean ± standard deviation (SD) and as percent (%) wherever applicable. For intra-group assessment, paired t-test was applied and for inter-group comparison, independent t-test was applied using IBM SPSS Statistics Version 20. A p-value of <0.05 was considered to be statistically significant. Any value above this was considered to be non-significant. The results were expressed in form of tables, chart, pie and bar graphs.

RESULTS

A total of 108 patients were enrolled in the study, 54 in each group. The total number of patients who completed the study was 100, 49 in group 1 and 51 in group 2. Out of 8 dropouts, 2 required additional therapy, 2 were withdrawn due to non-compliance to the treatment and 3 were lost during follow-up. Both the drugs were started at a dose of 40 mg/day. (Figure 1)
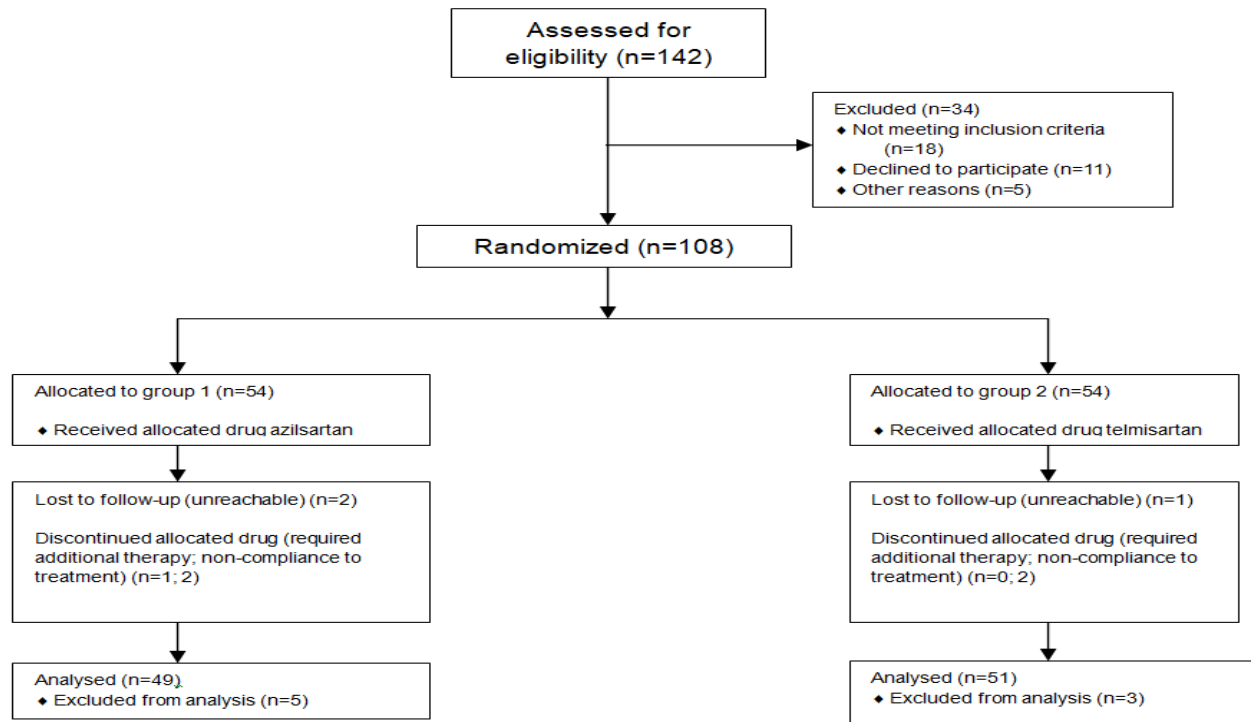
Figure 1: Consort diagram of the study

The two groups were analyzed for their demographic profile, hematological tests and biochemical investigation profile and it was seen that both the groups comparable in baseline demographic characteristics and systolic as well as diastolic blood pressure (Table 1,2). The age and sex distribution of the patients is depicted in the table 3.

Table 1: Baseline patient characteristics: Demographic profile

Parameter	Azilsartan (n=49)	Temisartan (n=51)	p-value
Age (years)	54.55±7.86	54.61± 9.15	0.974
Sex - Male	29	27	-
Female	20	24	-
Height (m)	1.64±0.06	1.62±0.07	0.224
Weight (kg)	67.27±7.90	64.68±7.82	0.103
BMI	25.00±2.52	24.49±1.96	0.224
SBP (mm Hg)	150.37±6.19	149.57±5.88	0.510
DBP (mm Hg)	92.37±3.15	92.20±2.92	0.568

Values are expressed as Mean±SD (Standard Deviation); BMI = Body Mass Index ;SBP = Systolic Blood Pressure ; DBP = Diastolic Blood Pressure

Table 2: Baseline hematologic and biochemical profile of patients enrolled in the study

Parameter	Azilsartan (n=49)	Telmisartan (n=51)	p-value
TLC (10^9/L)	6.87±1.46	6.76±1.43	0.702
Pl (10^9/L)	293.57±70.23	292.78±69.87	0.955
RBC (10^{12}/L)	5.00±0.19	5.04±0.28	0.368
Hb (g/dl)	13.90±1.59	14.03±1.52	0.684
FBS (g/dl)	92.67±11.09	94.12±10.88	0.513
PPBS (g/dl)	135.78±16.43	136.94±15.37	0.715
HbA1c	6.21±0.38	6.27±0.37	0.408
Bil (T) (mg/dl)	0.82±0.20	0.85±0.20	0.504
ALT/SGPT (IU/L)	29.70±5.81	30.14±5.56	0.697
AST/SGOT (IU/L)	34.45±7.37	33.92±7.11	0.716
Sr. K (mmol/L)	4.18±0.35	4.16±0.34	0.762
Sr. Na (mmol/L)	141.04±2.89	140.90±2.56	0.800
Serum Creatinine (mg/dl)	0.89±0.14	0.90±0.13	0.595
Serum Uric Acid (mg/dl)	5.62±1.32	5.27±1.35	0.196
TC (mg/dl)	190.55±16.57	189.73±16.59	0.445
TG (mg/dl)	182.61±22.52	181.69±22.50	0.454
HDL-C (mg/dl)	45.88±11.90	46.56±10.98	0.906
LDL-C (mg/dl)	108.22±18.80	106.57±19.76	0.669
VLDL-C (mg/dl)	36.45±4.52	35.75±4.76	0.450

Values are expressed as Mean±SD (Standard Deviation); TLC= Total leucocyte count; Pl= Platelet; RBC= Red blood corpuscles; Hb= Haemoglobin; FBS = Fasting Blood Sugar ; PPBS = Post – prandial Blood sugar ; HbA1c = Glycosylated Haemoglobin; Bil(T)= Bilirubin total; ALT/SGPT = Alanine Aminotransferase/ Serum glutamic pyruvic transaminase; AST/SGOT = Aspartate aminotransferase / Serum glutamic oxaloacetic transaminase; Sr.K = Serum Potassium; Sr.Na = Serum Sodium; TC = Total cholesterol ; TG = Triglycerides ; HDL-C = High density lipoprotein – cholesterol ; LDL-C = Low density lipoprotein – cholesterol ; VLDL-C = Very low density lipoprotein – cholesterol

Table 3: Age and sex distribution in treatment arms

Age (years)	AZILSARTAN			TELMISARTAN		
	Male	**Female**	**Total**	**Male**	**Female**	**Total**
36-40	0	2	2 (4.08%)	1	1	2 (3.92%)
41-45	3	4	7 (14.29%)	4	3	7 (13.73%)
46-50	5	4	9 (18.37%)	2	9	11 (21.57%)
51-55	5	3	8 (16.33%)	8	3	11 (21.57%)
56-60	9	2	11 (22.45%)	6	1	7 (13.73%)
61-65	7	4	11 (22.45%)	1	3	4 (7.84%)
66-70	0	1	1 (2.04%)	5	4	9 (17.65%)
Total n(%)	**29**	**20**	**49 (100%)**	**27**	**24**	**51 (100%)**

In group 1(azilsartan), mean systolic blood pressure at 0 week was 150.37±6.19 mm Hg. At 2nd , 4th , 8th and 12th week the mean systolic blood pressure recorded were 145.35±6.37 mm Hg, 140.33±4.97 mm Hg, 136.29±5.51 mm Hg and 133.67±5.57 mm Hg respectively. The reduction of systolic blood pressure was statistically significant (<0.05) at 2nd, 4th, 8th and 12th week when

compared with the baseline systolic blood pressure. The mean systolic blood pressure was reduced by 11.09% at the end of the study period. (Table 4, Figure2)

In group 2(telmisartan), mean systolic blood pressure at 0 week was 149.57±5.88 mm Hg. At 2nd , 4th , 8th and 12th week the mean systolic blood pressure recorded were 144.94±6.35 mm Hg, 139.73±5.00 mm Hg, 136.16±5.44 mm Hg and 133.80±4.95 mm Hg respectively. The reductionof systolic blood pressure was statistically significant (<0.05) at 2nd, 4th, 8th and 12th week when compared with the baseline systolic blood pressure. The mean systolic blood pressure was reduced by 10.51% at the end of the study period. (Table 5, Figure 3)

In group 1(azilsartan), mean diastolic blood pressure at 0 week was 92.37±3.15 mm Hg. At 2nd , 4th , 8th and 12th week the mean diastolic blood pressure recorded were 90.53±3.31 mm Hg, 86.82±3.03 mm Hg, 83.84±2.67 mm Hg and 82.53±2.67 mm Hg respectively. The reduction of diastolic blood pressure was statistically significant (<0.05) at 2nd, 4th, 8th and 12th week when compared with the baseline diastolic blood pressure. The mean diastolic blood pressure was reduced by 10.59% at the end of the study period. (Table 4, Figure2)
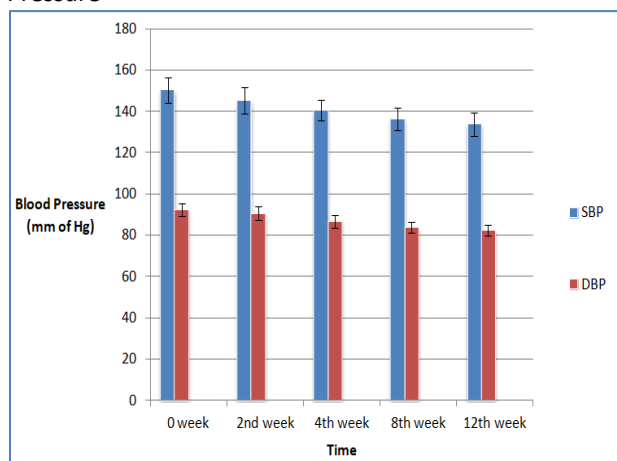
In group 2(telmisartan), mean diastolic blood pressure at 0 week was 92.20±2.92 mm Hg. At 2nd , 4th , 8th and 12th week the mean systolic blood pressure recorded were 90.55±3.21 mm Hg, 87.37±2.87 mm Hg, 84.51±2.65 mm Hg and 83.06±2.72 mm Hg respectively. The reduction of systolic blood pressure was statistically significant (<0.05) at 2nd, 4th, 8th and 12th week when compared with the baseline systolic blood pressure. The mean diastolic blood pressure was reduced by 9.86% at the end of the study period. (Table 5, Figure 3)

In both group 1 and group 2, significant reduction in systolic and diastolic blood pressure is seen at the end of study. Although there is no significant difference in between the two groups at 2nd, 4th, 8th and the end of study as far as changes in systolic and diastolic blood pressures is considered (p>0.05). (Table 6, Figure 4,5)

Table 4: Effect of Azilsartan on systolic and diastolic blood pressure

Parameter (mm Hg)	Azilsartan (n=49)	p-value (0 vs 12 week)
SBP at 0 week	150.37±6.19	<0.05
SBP at 2nd week	145.35±6.37	
SBP at 4th week	140.33±4.97	
SBP at 8th week	136.29±5.51	
SBP at 12th week	133.67±5.57	
DBP at 0 week	92.37±3.15	<0.05
DBP at 2nd week	90.53±3.31	
DBP at 4th week	86.82±3.03	
DBP at 8th week	83.84±2.67	
DBP at 12th week	82.53±2.67	

Values are expressed as Mean±SD (Standard Deviation); SBP = Systolic Blood Pressure; DBP = Diastolic Blood Pressure
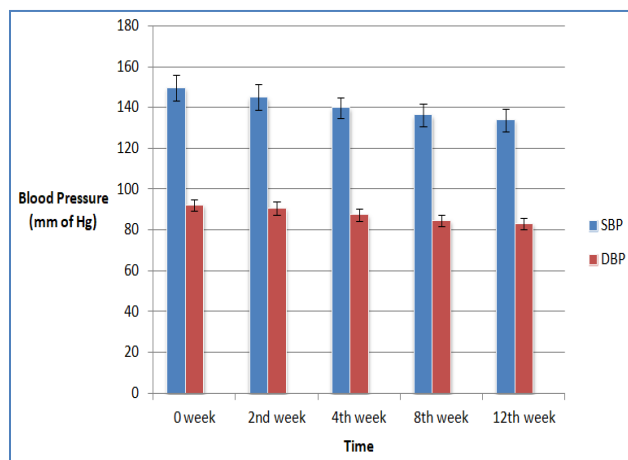

Figure 2: Bar graph describing changes in systolic blood pressure (SBP) and diastolic blood pressure (DBP) in group 1 (Azilsartan)

Table 5: Effect of Telmisartan on systolic and diastolic blood pressure

Parameter (mm Hg)	Telmisartan (n=51)	p-value (0 vs 12 week)
SBP at 0 week	149.57±5.88	<0.05
SBP at 2nd week	144.94±6.35	
SBP at 4th week	139.73±5.00	
SBP at 8th week	136.16±5.44	
SBP at 12th week	133.80±4.95	
DBP at 0 week	92.20±2.92	<0.05
DBP at 2nd week	90.55±3.21	
DBP at 4th week	87.37±2.87	
DBP at 8th week	84.51±2.65	
DBP at 12th week	83.06±2.72	

Values ar expressed as Mean±SD (Standard Deviation); SBP = Systolic Blood Pressure; DBP = Diastolic Blood Pressure


Figure 3: Bar graph describing changes in systolic blood pressure (SBP) and diastolic blood pressure (DBP) in group 2

Table 6: Comparison between Azilsartan and Telmisartan - Effect on Blood Pressure components

Parameter	Azilsartan (n=49)	Telmisartan (n=51)	p-value
SBP at 0 week	150.37±6.19	149.57±5.88	0.510
SBP at 2nd week	145.35±6.37	144.94±6.35	0.751
SBP at 4th week	140.33±4.97	139.73±5.00	0.548
SBP at 8th week	136.29±5.51	136.16±5.44	0.907
SBP at 12th week	133.67±5.57	133.80±4.95	0.902
DBP at 0 week	92.37±3.15	92.20±2.92	0.568
DBP at 2nd week	90.53±3.31	90.55±3.21	0.978
DBP at 4th week	86.82±3.03	87.37±2.87	0.348
DBP at 8th week	83.84±2.67	84.51±2.65	0.209
DBP at 12th week	82.53±2.67	83.06±2.72	0.330

Values are expressed as Mean±SD (Standard Deviation); SBP = Systolic Blood Pressure (mm of Hg) ; DBP = Diastolic Blood Pressure (mm of Hg)
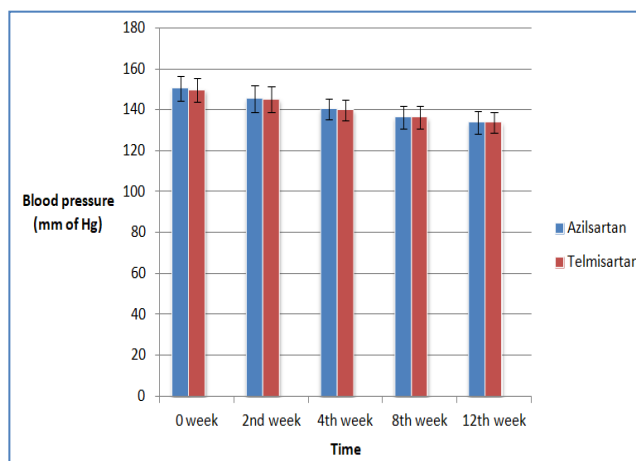
Figure 4: Bar chart showing changes in systolic blood pressure in group 1 (Azilsartan) and group 2 (Telmisartan) over the study period
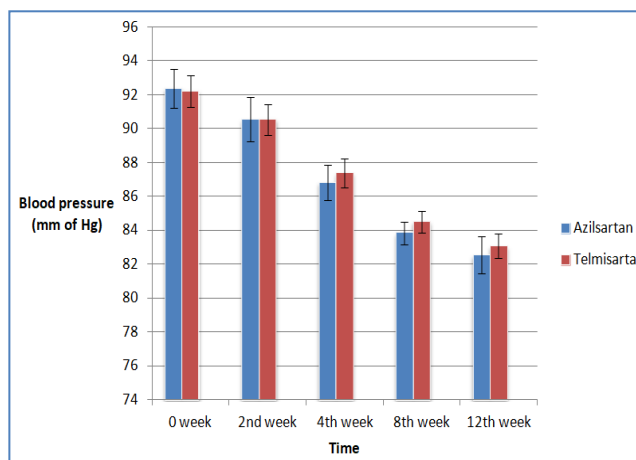
Figure 5: Bar chart showing changes in diastolic blood pressure in group 1 (Azilsartan) and group 2 (Telmisartan) over the study period

It was observed that at the end of study period there was no statistically significant difference in the various hematological and biochemical parameter after

treatment with azilsartan and telmisartan in the patients enrolled of the study. (Table 7)

Both the drugs were tolerated well with no report of any serious adverse event. The most common side-effect reported by group 1 patients was headache (6.12%) while that by group 2 was fatigue (3.92%). (Table 8)

Table 7: Comparison of changes in hematologic and biochemical parameters at the end of study period in both the treatment arms

Parameter	Azilsartan (n=49)	Telmisartan (n=51)	p-value
TLC (10^9/L)	6.92±1.30	6.82±1.28	0.701
Pl (10^9/L)	294.67±65.90	296.65±64.76	0.880
RBC (10^{12}/L)	5.02±0.20	5.06±0.27	0.395
Hb (g/dl)	13.95±1.44	14.08±1.35	0.618
FBS (g/dl)	93.22±9.38	94.71±9.13	0.425
PPBS (g/dl)	136.96±17.21	138.06±16.32	0.744
HbA1c	6.22±0.40	6.25±0.38	0.715
Bil (T) (mg/dl)	0.82±0.20	0.84±0.16	0.549
ALT/SGPT (IU/L)	29.51±6.31	30.00±6.41	0.701
AST/SGOT (IU/L)	34.71±5.95	33.78±5.57	0.422
Sr. K (mmol/L)	4.16±0.34	4.16±0.33	0.742
Sr. Na (mmol/L)	140.84±3.14	141.33±2.38	0.590
Serum Creatinine (mg/dl)	0.90±0.10	0.89±0.11	0.459
Serum Uric Acid (mg/dl)	5.70±1.33	5.27±1.33	0.194
TC (mg/dl)	188.61±16.02	186.73±17.13	0.571
TG (mg/dl)	180.29±23.25	177.41±23.70	0.542
HDL-C (mg/dl)	46.02±10.95	45.31±10.77	0.746
LDL-C (mg/dl)	106.55±19.26	105.90±20.33	0.870
VLDL-C (mg/dl)	36.04±4.64	35.51±4.70	0.571

Values are expressed as Mean±SD (Standard Deviation); TLC= Total leucocyte count; Pl= Platelet; RBC= Red blood corpuscles; Hb= Haemoglobin; FBS = Fasting Blood Sugar ; PPBS = Post – prandial Blood sugar ; HbA1c = Glycosylated Haemoglobin; Bil(T)= Bilirubin total; ALT/SGPT = Alanine Aminotransferase/ Serum glutamic pyruvic transaminase ; AST/SGOT = Aspartate aminotransferase / Serum glutamic oxaloacetic transaminase; Sr.K = Serum Potassium; Sr.Na = Serum Sodium; TC = Total cholesterol ; TG = Triglycerides ; HDL-C = High density lipoprotein – cholesterol ; LDL-C = Low density lipoprotein – cholesterol ; VLDL-C = Very low density lipoprotein – cholesterol

Table 8: Incidence of side effects in treatment groups

Side effect	Azilsartan (n=49)	Telmisartan (n=51)
Headache	3 (6.12%)	1 (1.96%)
Dizziness	2 (4.08%)	1 (1.96%)
Fatigue	1 (2.04%)	2 (3.92%)
Gastrointestinal symptoms	0	0
Sweating	0	1 (1.96%)
Upper respiratory tract infection	0	1 (1.96%)
Urinary tract infection	1 (2.04%)	0
Back pain	0	0
Any serious side effects	0	0
Total n(%)	**7 (14.29%)**	**6 (11.76%)**

DISCUSSION

The incidence of hypertension is on a rise worldwide owing to modern lifestyle habits and the geriatric population, and is estimated to affect 1.5 billion persons—one third of the world's population—by 2025. The new cases of people suffering from hypertension mostly belong to developing countries which can be attributed to poor quality of hypertension treatment and control. High blood pressure leads to cerebrovascular accidents and ischemic heart diseases, leading to 9.4 million deaths every year. Half of these diseases in seen in people having blood pressure of ≥140/90 mm Hg and the rest half in people with lesser levels of elevated blood pressure.[13]

Many cogent drugs are available which can effectively lower the elevated blood pressure thereby reducing the mortality and morbidity in hypertensive patients. Knowledge of their antihypertensive mechanisms and sites of action allows accurate prediction of efficacy and toxicity. The rational use of antihypertensives, alone or in combination, can effectively decrease the blood pressure with minimum incidence of adverse events in the patients. [14]

Azilsartan is structurally similar to candesartan with the difference of an oxa-oxadiazole ring instead of tetrazole ring of candesartan. After giving the drug orally, the prodrug azilsartan medoxomil is rapidly converted into its active form azilsartan which blocks angiotensin induced AT1 receptor activation in insurmountable fashion.[15]

In the present study which was conducted as monotherapy with Azilsartan and Telmisartan in patients of essential hypertension, it was observed that both the drugs were effective in reducing both the systolic as well as diastolic blood pressure during the 12-weeks study period. When the drugs were compared for their effectiveness, it was seen that both azilsartan and telmisartan are equally effective in reducing the systolic and diastolic blood pressure. Other studies have shown a similar result in reducing blood pressure by azilsartan and telmisartan, although telmisartan has showed a slightly more reduction in diastolic blood pressure when compared to azilsartan.[16]

At the end of this study, there was no statistically significant change in any hematological or biochemical parameter. Although there was a slight decrease of serum potassium and serum sodium in the patients treated with azilsartan and similarly both the drugs decreased the levels of total cholesterol and total triglycerides at end of study, but these changes were statistically insignificant.

This study like any other study has its fair share of limitations. Firstly, to evaluate the effectiveness of the drug as an anti-hypertensive, usage of ambulatory blood pressure monitoring would have resulted in a better and more reliable data when compared to office blood pressure reading. Secondly, a bigger sample size could have lead to a better significance determination in both the treatment arms. Lastly, a crossover study design would have been used to decrease the influence of confounding factors, but this has its own disadvantages.

CONCLUSION

This is a study comparing the antihypertensive effects of two drugs, azilsartan and telmisartan. The study shows that both the ARBs, namely azilsartan and telmisartan are equally efficacious in reducing the blood pressure to target level (SBP<140 mm of Hg and DBP<90 mm of Hg) in patients of essential hypertension and that these drugs are equally safe in terms of tolerability and safety.

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