ORIGINAL ARTICLE

Comparative Evaluation of Efficacy, Safety and Tolerability of Azilsartan Versus Losartan in Patient Suffering from Hypertension

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Abstract:

*Background:*Losartan was launched in 1995 as first angiotensin receptor blocker and azilsartan was launched in India in 2011. Not much data was available in Indian population for comparing these two drugs, so this study was planned. *Objectives:*To evaluate the efficacy, safety and tolerability of azilsartan versus losartan in patients of hypertension. Material and *Methods:*A prospective open randomized parallel group comparative study was done to evaluate the efficacy, safety and tolerability of azilsartan (Group I) versus losartan (Group II) in patients of stage I hypertension. Effectiveness of the drugs was calculated in terms of fall in mean systolic and diastolic blood pressure over 24 weeks. Data was statistically analysed using appropriate tests. *Results:* No significant difference of distribution of sex, weight, SBP, DBP and pulse rate was observed in both groups at baseline. In group I, mean SBP at baseline was 162.60±3.92 which decreased to 129.20±2.94 at 24 weeks. In group II, mean SBP was 162.40 ± 3.42 at baseline which decreased to 130.00±3.54 at 24 weeks. In group I, mean DBP at baseline was 100.16±2.48 which decreased to 80.20±6.24 at 24 weeks. In group II mean DBP was 100.28±2.49 at baseline which decreased to 82.32 ±2.36 at 24 weeks. *Conclusion:*Both drugs were efficacious, safe and well tolerated in hypertensive patients. Azilsartan results in significant decrease in SBP as compared to losartan although the clinical difference between two was only of 1.20 mm of Hg at the end of 24 weeks.

Key words: Systolic blood pressure, diastolic blood pressure, azilsartan, angiotensin receptor blockers, responders

Introduction:

Hypertension is among the leading cause of morbidity across the globe. It is estimated that 1.28 billion adults aged 30-79 years worldwide have hypertension, most (two third) living in low- and middle-income countries. [1] It accounts for approximately 6% of deaths worldwide. Hypertension is frequently seen in individuals aged 40 years or above and affects about half of the population aged 60 years and above. [2] It doubles the risk of cardiovascular diseases that includes coronary heart disease, congestive heart failure, ischemic and haemorrhagic stroke, renal failure and peripheral arterial disease. [3] Both genetic and environmental factors contribute in causation of disease. Hypertension shows polygenic inheritance which in alliance with environmental factors lead to the pathological changes and end organ damage. Obesity, dyslipidaemia, insulin resistance, sedentary lifestyle, stress, alcohol, smoking, dietary habits are risk factors linked to hypertension. Clinically, hypertension may be defined as that level of blood pressure at which the institution of therapy reduces blood pressure related morbidity and mortality. Grade I hypertension is diagnosed when SBP is between 140-159 and DBP is between 90-99 mmHg and Grade II is diagnosed when SBP is ≥ 160 and DBP is ≥ 100 mmHg. [4] Non pharmacological measures are advised to all the patients irrespective of stage of hypertension which includes consumption of healthy diet, salt restriction, smoking cessation, regular physical activity etc. Angiotensin II plays a crucial role in pathophysiology of Hypertension. Angiotensin receptor blockers (ARBs) have become the first line drugs for management of HT surpassing ACE inhibitors due to adverse effects associated with the latter like cough. ARBs bind to AT1 receptors with high affinity and inhibit most of the biological effects of angiotensin II i.e vasoconstriction, stimulation of synthesis and release of aldosterone,cardiac

stimulation, and renal reabsorption of sodium. ARB drugs include losartan, olmesartan, candesartan, valsartan, telmisartan and azilsartan. Losartan is the prototype drug of ARBs which was approved by USFDA in 1995 and Azilsartan was approved in 2011. Losartan has oral bioavailability of 33% and peak concentration of active metabolite is achieved in 3-4 hours whereas azilsartan is given as a prodrug azilsartan medoxomil which is hydrolysed to azilsartan in gastrointestinal tract during absorption. The bioavailability after oral dose is 60% and peak plasma concentration is reached in 1.5-3 hours. No dose adjustments are required with either of these drugs in elderly, patient with mild to moderate hepatic or renal dysfunction. Recommended dose of azilsartan is 40-80 mg/day and losartan is 50-100 mg/day. [5, 6] Sica [7], Bakris [8], White [9], Rakugi [10], Reddy [11], Zannad [12] conducted randomized controlled trials comparing azilsartan with other ARBs namely valsartan, olmesartan, candesartan and telmisartan and concluded that Azilsartan significantly improve systolic blood pressure at different time intervals. Smith [13], Oparil [14], Zhu [15] and Mujeeb [16] compared olmesartan, telmisartan and valsartan with losartan in different randomized control trials and found telmisartan and olmesartan more efficacious than losartan in reducing systolic and diastolic blood pressure. Elliott compared losartan with valsartan and concluded that both drugs are similarly effective in reducing blood pressure in mild to moderate hypertension. It was also found that there was a decrease in serum uric acid levels with losartan. [17] Since, there is scarcity of data available on comparison between losartan and azilsartan, so present study was planned to compare efficacy, safety and tolerability of these two drugs.

Material and Methods:

In this prospective, open, randomized, parallel group, comparative study, 100 patients of hypertension attending the outpatient department of medicine, PIMS, Jalandhar were included. The study was conducted over 24 weeks. The patients fulfilling the inclusion criteria and having none of the exclusion criteria were enrolled in the study after obtaining written informed consent. New patients with hypertension not on any antihypertensive therapy of age 18 years or more were included in the study. Patients who were excluded from the study were either already on anti-hypertensive or had hypersensitivity to azilsartan/losartan. Pregnant/lactating women/women planning to conceive were also excluded. Patients with hepatic insufficiencies, renal disorder, severe bradycardia, cardiogenic shock, heart block, sick sinus syndrome, decompensated heart failure, bronchial asthma, hypothyroidism, cerebrovascular accident, coronary artery disease, refractory hypertension, hypertensive urgency /emergency or other co- morbidities like hyperthyroidism, anxiety disorders or patients unwilling/unable to comply with the study proceedings were not included. All the patients and their relatives were informed about the trial in layman language and written consent was taken. Detailed history, clinical examination, biochemical investigation were done and patients were randomly divided into two groups of 50 each. Group I patients received azilsartan 40mg once daily and subsequent titration was carried up to maximum recommended dose of 80 mg depending upon the therapeutic response. Group II patients received losartan 50 mg once daily and subsequent titration was carried up to maximum dose of 100 mg depending upon the therapeutic response.Responders and non-responders were identified. Patients whose blood pressure did not reduce to <140/90 with maximum dose within one month were grouped as non-responders while others were classified as responders. Blood pressure was measured on day 0, 1st week, 2nd week, 4th week, 8th week, 16th week and then on 24th week in sitting position with the same sphygmomanometer on right arm after 10 minutes rest. Average of three blood pressure measurements were recorded at, five minutes interval after the patient was seated. Systolic BP was taken as appearance of korotkoff sounds (phase I) and diastolic end point was at the disappearance of korotkoff sounds (phase V).Following base line investigations were carried out at the commencement of treatment—hemoglobin (Hb), total leucocyte count (TLC), differential leucocyte count (DLC), fasting blood sugar (FBS), blood urea, uric acid, serum creatinine, serum electrolytes, liver function test (LFT), lipidogram, echocardiography (ECG) and urine routine examination (R/E). At the end of 24 weeks, the

investigations were repeated and compared with the baseline. Adverse effects as reported by patients were recorded and compared. The end point of the study was attainment of BP ≤ 140/90 mmHg for all patients. Patient was discontinued from the study at any stage if he/she developed life threatening symptoms like hypertensive encephalopathy, decompensated heart failure, and cardiogenic shock. Hundred patients were determined as sufficient to achieve at least 80% power to detect a difference of 4mm Hg between the azilsartan and losartan for the primary end point (SBP), with 95% confidence interval (assuming a 2-sided significance level of 5%), a standard deviation of 7.3 & 6.9 mm Hg in group 1 & 2 respectively. Considering a dropout rate of 5%, 55 patients in each group were recruited in the study. The study was approved by institutional ethics committee (PIMS/IEC/19/06) and clinical trial registry India (CTRI/2020/08/027209). The data obtained was put in tables and statistically analyzed by using SPSS software version 21. Unpaired t test was applied to compare the continuous data and Chi square was applied to compare the categorical data in both groups. The p value of < 0.05 was considered statistically significant.

Results:

Fifty-five patients were recruited in both groups, 5 patients from each group did not turn up at different time intervals and were not included in data analysis. Sociodemographic profile of patients at baseline in azilsartan (group I) and losartan group (group II) were comparable to each other. The mean age was 53.88±10.12 and 51.50±9.16 years in group I and group II respectively. No significant difference of distribution of sex, weight, SBP, DBP and pulse rate was observed in both groups at baseline (Table 1). In group I, mean SBP at baseline was 162.60±3.92 which decreased to 129.20±2.94 at 24 weeks. In group II, mean SBP was 162.40 ± 3.42 at baseline which decreased to 130.00±3.54 at 24 weeks. There was significant decrease in blood pressure at 2-week, 4-week, 8-week and at 16-weeks with mean difference of -3.36, -2.68, -3.44, -1.52 respectively. The reduction in SBP was similar in both groups at 24 weeks. (Fig.1, Table 2)In group I, mean DBP at baseline was 100.16±2.48 which decreased to 80.20±6.24 at 24 weeks. In group II mean DBP was 100.28±2.49 at baseline which decreased to 82.32 ±2.36 at 24 weeks. The mean difference of -0.36, 0.08, -0.64, -1.08, -1.20 was observed at 2-weeks, 4-weeks, 8- weeks, 16-weeks and at 24-weeks. The fall in DBP at 24 weeks was statistically significant (Fig.2,Table3)

Table 1: Comparison of baseline characteristics in azilsartanvs losartan group

	Group 1 A (n=50)	Group 2 L(n=50)	Mean difference	95% Confidence Interval of the Difference	
				Lower	Upper
Age (Years) (Mean±SD)	53.88±10.12	51.50±9.16	2.38	-1.45	6.21
Sex: n(%)	Male: 25(25%) Female:25(25%)	Male:16(16%) Female:34(34%)	-	-	-
Weight(Kg) (Mean±SD)	72.12±5.05	70.76±5.96	1.36	-0.83	3.55
Pulse Rate (Per minute)	76.20±5.90	77.58±6.63	-1.38	-1.38	1.11

There was no significant difference in levels of haemoglobin, TLC, DLC, FBS, blood urea, serum creatinine, serum uric acid, serum sodium, serum potassium, serum calcium, liver function tests and lipid profile in both groups at baseline and at 24 weeks. (Table 4,5) Dose was increased to 80mg once daily after 2 weeks of treatment in 12(24%) patients in group I and to 100mg once daily in 14(28%) patients in group II. All the patients were satisfied and responded to the treatment in both groups. No major adverse effect was reported in both groups. Azilsartan group reported 4.5% adverse effects while losartan group reported 4%. Four patients on

azilsartan reported dizziness, 3 fatigue and 2 reported headaches while 3 patients reported headache, 2 nausea, 1dizziness and 2 nausea with headache in losartan group.

Discussion:

Azilsartan and losartan being angiotensin receptor blocker lowers blood pressure which in turns reduces the associated conditions like stroke, myocardial infarction and heart failure. Azilsartan has been compared with other ARBs like olmesartan, valsartan, candisartan but not with losartan. In this study azilsartan was compared to losartan at baseline and at 24 weeks. In both groups there was significant decrease in blood pressure from baseline at 24 weeks. There was significant decrease in SBP with azilsartan at 2, 4, 8 and at 16 weeks with mean difference

Table: 2 Comparison of systolic blood pressure at different time intervals in both groups

Systolic Blood Pressure	Group	Mean±SD	Mean difference	95% Confidence interval of the difference		p-value
				Lower	Upper	
0 week	AZL	162.60±3.92	0.20	-1.26	1.66	0.787
	Losartan	162.40±3.42				
2 weeks	AZL	140.68±3.53	-3.36	-4.87	-1.84	<0.001
	Losartan	144.04±4.07				
4 weeks	AZL	137.72±3.35	-2.68	-4.08	-1.27	<0.001
	Losartan	140.40±3.70				
8 weeks	AZL	133.52±3.99	-3.44	-5.07	-1.80	<0.001
	Losartan	136.96±4.22				
16 weeks	AZL	130.88±2.94	-1.52	-2.77	-0.26	0.180
	Losartan	132.40±3.38				
24 weeks	AZL	129.20±2.94	-0.80	-2.09	0.49	0.222
	Losartan	130.00±3.54				

Table:3 Comparison of diastolic blood pressure at different time intervals in both groups

Diastolic Blood Pressure	Group	Mean±SD	Mean difference	95% Confidence interval of the difference		p-value
				Lower	Upper	
0 week	AZL	100.16±2.48	-0.12	-1.10	0.86	0.810
	Losartan	100.28±2.49				
2 weeks	AZL	88.64±1.95	-0.36	-1.32	0.60	0.459
	Losartan	89.00±2.80				
4 weeks	AZL	85.24±2.35	0.08	-0.93	1.09	0.876
	Losartan	85.16±2.74				
8 weeks	AZL	83.36±2.95	-0.64	-1.81	0.53	0.283
	Losartan	84.00±2.96				
16 weeks	AZL	82.20±2.92	-1.08	-2.17	0.02	0.054
	Losartan	83.28±2.61				
24 weeks	AZL	80.20±6.24	-1.20	-2.25	-0.14	0.026
	Losartan	82.32±2.36				

Table 4: Comparison of fasting blood sugar, renal functions and electrolytes at 0 weeks and 24 weeks in both groups

	Group 1 Azilsartan	Group 2 Losartan	Mean Difference	95% confidence interval of the difference		p-value
	Mean± SD	Mean± SD		Lower	Upper	
Fasting blood sugar at 0 week (mg/dl)	98.340±9.928	98.540±11.498	-0.200	-4.463	4.063	0.364
Fasting blood sugar at 24 weeks (mg/dl)	93.300±8.160	92.36±9.021	0.940	-2.473	4.353	0.586
Blood Urea at 0 week	26.620±8.985	26.300±8.846	0.320	-3.218	3.858	0.858
Blood Urea at 24 weeks	20.920±6.812	21.620±6.269	-0.700	-3.298	1.898	0.594
Serum Creatinine at 0 week	0.840±0.213	0.792±0.188	0.048	-0.31	0.127	0.235
Serum Creatinine at 24 weeks	0.664±0.236	0.632±0.178	0.032	-0.05	0.114	0.446
Uric Acid at 0 week	5.110±0.925	5.076±0.925	0.034	-0.333	0.401	0.855
Uric Acid at 24 weeks	4.820±0.805	4.820±0.786	0.00	-0.315	0.315	1.000
Serum Sodium at 0 week	139.880±3.230	139.920±3.719	-0.040	-1.422	1.342	0.954
Serum Sodium at 24 weeks	140.060±2.668	140.260±2.693	-0.200	-1.264	0.864	0.710
Serum Potassium at 0 week	4.138±0.343	4.152±0.392	-0.014	-0.160	0.132	0.850
Serum Potassium at 24 weeks	4.060±0.188	4.056±0.244	0.004	-0.082	0.090	0.925
Serum Calcium at 0 week	9.168±0.369	9.268±0.420	-0.100	-0.257	0.057	0.209
Serum Calcium at 24 weeks	9.088±0.242	9.030±0.559	0.058	-0.113	0.229	0.503

Table 5: Comparison of lipid profile and liver functions at 0 weeks and 24 weeks in both groups

	Group 1 Azilsartan	Group 2 Losartan	Mean Difference	95% Confidence Interval of the Difference		p-value
	Mean± SD	Mean± SD		Lower	Upper	
Cholesterol at 0 week	161.000±21.914	165.980±26.582	-4.980	-14.648	4.688	0.309
Cholesterol at 24 weeks	158.480±18.737	161.620±20.989	-3.140	-11.036	4.756	0.432
LDL at 0 week	81.354±21.312	86.280±19.629	-4.926	-13.057	3.205	0.232
LDL at 24 weeks	80.764±19.735	83.660±16.175	-2.896	-10.057	4.265	0.424
HDL at 0 week	54.400±6.443	54.980±7.940	-0.580	-3.449	2.289	0.689
HDL at 24 weeks	54.220±6.453	55.340±5.791	-1.120	-3.553	1.313	0.363
Serum Triglyceride at 0 week	118.220±27.328	122.800±30.411	-4.580	-16.054	6.894	0.430
Serum Triglyceride at 24 weeks	110.520±25.844	118.320±26.469	-7.800	-18.182	2.582	0.139
Bilirubin at 0 week	0.566±0.236	0.584±0.234	-0.018	-0.111	0.075	0.703
Bilirubin at 24 weeks	0.644±0.177	0.600±0.156	0.044	-0.022	0.110	0.192
SGOT at 0 week	21.900±6.051	23.480±6.937	-1.580	-4.163	1.003	0.228
SGOT at 24 weeks	19.520±4.431	19.760±4.345	-0.240	-1.981	1.501	0.785
SGPT at 0 week	20.240±7.104	21.260±6.265	-1.020	-3.678	1.638	0.448
SGPT at 24 weeks	16.640±2.640	17.120±3.198	-0.480	-1.643	0.683	0.415
Alkaline Phosphatase at 0 week	80.280±22.964	81.080±23.292	-0.800	-9.979	8.379	0.863
Alkaline Phosphate at 24 weeks	67.358±23.289	71.480±19.973	-4.122	-12.732	4.488	0.344

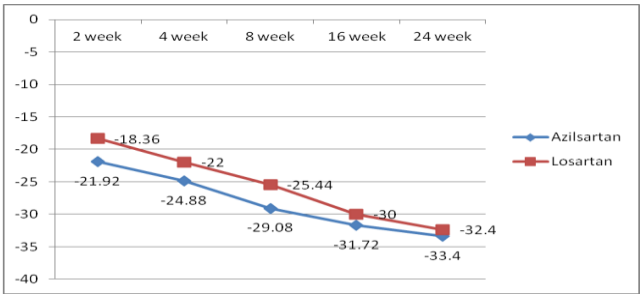

Fig. 1 Mean change in systolic blood pressure (mm of Hg) from baseline at different Time intervals in both groups

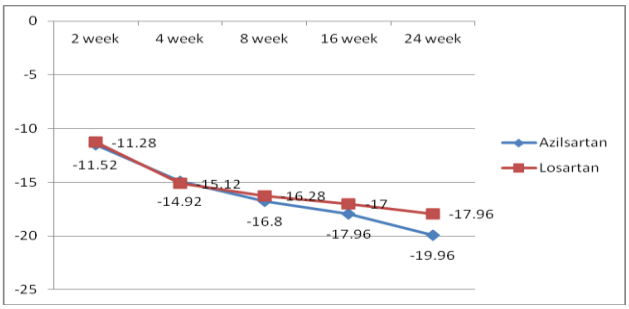

Fig. 2 Mean change in diastolic bloodpressure (mm of Hg) from baseline at different time intervals in both groups

of -3.36, -2.68, -3.44, -1.52 respectively. The decrease in DBP was observed in all weeks but it was statistically significant at 24 weeks with azilsartan although the clinical difference was only of 1.20 mm of Hg. Sicca et al [7] compared azilsartan and valsartan by ambulatory BP monitoring. It was observed that in the three treatment groups using valsartan 320 mg, azilsartan 40 mg and 80 mg, there is reduction of BP of -11.3mm, -14.9 mm and -15.3 mm of Hg at 24 weeks respectively. Bakris et al [8] compared azilsartanmedoxomil 40 mg with olmesartan 40 mg and concluded azilsartan to be more efficacious in reducing SBP by 2.1 mm of Hg and was well tolerated. White et al [9] concluded that azilsartan improved mean SBP better than olmesartan and valsartan in randomised controlled double blind trial at 80 mg dose by reduction of -14.5 mm of Hg. Rakugi et al [10] observed that azilsartanmedoxomil decreases both SBP and DBP significantly than candesartan at 16 weeks. The reduction with azilsartan was -12.4 mm of Hg and with candesartan was -9.8 for DBP and -21.8 vs -17.5 respectively for SBP. Reddy [11] compared the safety and efficacy of azilsartan with telmisartan and concluded that azilsartan was comparable to telmisartan clinically with significant reduction of 28.5± 3.5 mm of Hg in SBP and 11.11 ±2.058 mm of Hg in DBP. Zhu compared telmisartan with losartan and found thattelmisartan showed significant reduction of 12.5 mm of Hg in systolic blood pressure and reduction of 10.9 mm of Hg in diastolic blood pressure while losartan resulted in reduction of 9.4 mm of Hg in systolic blood pressure and 9.3 mm of Hg in diastolic blood pressure. [15] Mujeeb compared olmesartan with losartan and found that reduction in systolic blood pressure with mean difference of -13.5 mm of Hg and -11.4 mm of Hg in diastolic blood pressure is greater with olmesartan than losartan. [16] Elliott compared valsartan with losartan and found at 12 weeks both drugs decrease the systolic blood pressure significantly although between group difference is only 0.2 mm of Hg making both the drugs equally effective in patients of hypertension. [17] In our study azilsartan decreased systolic blood pressure by 21.92, 24.88, 29.08, 31.72 and 33.40 mm of Hg while losartan decreased it by 18.36, 22.0, 25.44, 30.0 and 32.40 mm of Hg at 2, 4, 8, 16, 24 weeks interval respectively from baseline. Similarly diastolic blood pressure was reduced by 11.52, 14.92, 16.80, 17.96 and 19.96 mm of Hg with azilsartan and by 11.28, 15.12, 16.28, 17.0 and 17.96 mm of Hg with losartan at 2, 4, 8, 16, 24 weeks respectively from baseline. Reddy reported in his study that 3% patients had to discontinue azilsartan because of complain of rashes while in this study no such hypersensitivity reaction or any serious adverse effect was observed. [11] Elliott reported rise in serum uric acid with valsartan [17] while in this study both losartan and azilsartan decreased serum uric acid though not significantly. No deleterious effect on lipid profile, blood counts, serum electrolytes, renal and liver functions was noted with azilsartan and losartan.

Conclusion:

Azilsartan and losartan were efficacious, safe and well tolerated in hypertensive patients. Azilsartan results in significant decrease in systolic blood pressure as compared to losartan although the clinical difference between two was only of 1.20 mm of Hg at the end of 24 weeks. The long-term benefit of losartan in reducing cardiovascular events has already been known whether azilsartan possesses the same has to be proven by planning long term studies.

Conflict of Interest - Nil

Sources of Support- Nil

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How to cite this article: Sunil Kumar Sharma, Baljit Jassal, Nipunjot Grewal, Rakesh Kumar and Jagminder Kaur Bajaj. Comparative Evaluation of Efficacy, Safety and Tolerability of Azilsartan Versus Losartan in Patient Suffering from Hypertension. Walawalkar International Medical Journal 2022; 9(2):1-7. http://www.wimjournal.com.

Received date: 25/07/2022 Reviseddate:02/09/2022 Accepted date: 05/09/2022