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Original Research1 Article

A Comparative Study of Safety and Efficacy of Azilsartan and Telmisartan in Newly Diagnosed Hypertensive Patients.

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Abstract

Objectives: The antihypertensive medicine telmisartan and the angiotensin receptor blocker azilsartan are both frequently prescribed to people with hypertension. Azilsartan and Telmisartan were compared for their safety and effectiveness.

Materials and Methods: The participants in this prospective, randomized trial were patients at Rama Medical College Hospital & RC, Kanpur. Severe hypertension >180 mm of Hg, pregnant women, cardiac arrhythmias, smokers, and alcoholics were excluded from this study. Patients with newly diagnosed hypertension of either sex within the age range of 25-60 years with a blood pressure of >140/90 mm of Hg were included in the study. Two groups of patients are created, with group 1 receiving Azilsartan and group 2 receiving Telmisartan.

Results: 100 patients were randomly divided into two groups; of the 50 patients in each group, 1 received azilsartan, while the other 2 were lost to follow-up. Three of the 50 patients in group 2 who got telmisartan were unfollowable. Systolic and diastolic blood pressure were not significantly different between the two medications after 24 hours. Azilsartan decreased mean systolic and diastolic blood pressure more than Telmisartan.

Keywords: ARB- Angiotensin receptor blocker, ACE – Angiotensin-converting enzyme, BP-Blood pressure.

Background

Hypertension, or high blood pressure, is a chronic medical disorder marked by continuously raised blood pressure in the arteries. A key risk factor for dementia, peripheral vascular disease, vision loss, chronic renal disease, atrial fibrillation, and coronary artery disease is persistently high blood pressure.

Primary hypertension and secondary hypertension are the two main subtypes of hypertension [1]. The most prevalent type of hypertension, sometimes referred to as

essential hypertension or primary hypertension, has no single recognised cause. Genes, nutrition, and lifestyle all contribute to hypertension. A less frequent variation of the disease, secondary hypertension, develops as a result of a particular ailment. Hypertension can be a side consequence of conditions such as sleep apnea, tumours, and kidney failure.

Diastolic blood pressure is the lowest blood pressure between heartbeats while systolic blood pressure is the maximum blood pressure during one heartbeat.

In general, hypertension is referred to as a “silent killer” because most people with hypertension are unaware of the problem because it may have no warning signs or symptoms. For this reason, it is essential that blood pressure is measured regularly. When symptoms do occur, they can include early morning headaches, nosebleeds, irregular heart rhythms, vision changes, and buzzing in the ears. Severe hypertension can cause fatigue, nausea, vomiting, confusion, anxiety, chest pain, and muscle tremors [2].

Modifiable risk factors [3] for higher blood pressure include unhealthy diets (excessive salt consumption, a diet high in saturated fat and trans fats, low intake of fruits and vegetables), physical inactivity, consumption of tobacco and alcohol, and being overweight or obese. Non-modifiable risk factors include a family history of hypertension; age over 65 years and co-morbid diseases such as diabetes or kidney disease [4]. Reliable measurements of blood pressure depend on attention to the details of the technique and conditions of the measurement. Proper training for positioning of the patients and selection of cuff size are essential. Recent regulations prevent the use of mercury because of concerns about its potential toxicity, these instruments should be calibrated periodically and their accuracy confirmed. Before the blood pressure measurement is taken, the individual should be seated quietly in a chair with feet on the floor for 5 minutes quietly sitting at a comfortable room temperature. At least two measurements should be made Systolic blood pressure is the first of two regular "tapping" Korotkoff sounds and diastolic blood pressure at which the last regular Korotkoff sound is heard [5].

Recent studies from India have shown the prevalence of hypertension [6] to be 25% in urban and10% in rural adults in India. In India, by the end of 2025 the projected prevalence of Hypertension in men and women is 22.9% and 23.6 % as per the statistics of the directorate general of health services, ministry of health & family welfare, Government of India. The prevalence of overall hypertension in India by 2020 will be 159.45/1000 population.

Materials and Methods

The Prospective Randomized clinical study was conducted in Rama Medical College Hospital & RC, Kanpur.

Inclusion Criteria

Both Male and female newly diagnosed hypertensive patients aged between 25-60 years (SBP≥140mmHg and DBP ≥90mmHg) were included. Newly diagnosed Hypertensive patients, Patients who are ready to give informed consent to participate in the study.

Exclusion Criteria

Smokers/ alcoholics, Pregnant & lactating mothers, Patients on steroid therapy, history of long-term infections like TB, leprosy, recent trauma, or surgery, Patients with any co-morbid conditions like Liver, Kidney, Cardiac problems, and psychiatric illness, Resistant to participate or mental inability to take the drugs, Persons not willing to give informedconsent.

In the present study 100 patients who were willing to give informed consent and fulfilled inclusion and exclusion criteria were enrolled. Patients were randomly divided into two groups, Azilsartan gave group 1 40 to 80 mg daily, and group 2 was given Telmisartan 40-80 mg daily.

A sphygmomanometer was used for BP

measurement and the pressure at which the knockoff sounds were first heard was taken as the systolic blood pressure and the pressure at which the sounds disappeared was taken as the diastolic blood pressure. Two recordings of blood pressure were taken at an interval of 15 min in a sitting position.

After initial screening, the demographic data, past medical history, family history, findings of physical examination, and clinical examination were recorded in the case report form and following investigations were done. They were followed up at the end of 3 & 6 months.

Statistical Analysis

Data were entered in MS excel for normally distributed continuous data, comparisons for the significance of differences were done by using Student's paired t-test within-group before and after treatment. The student's unpaired t-test was used for comparison of normally distributed continuous data between the two treatment groups. P value<0.05 was considered statistically significant.

Results

This study was carried out on 100 patients who were randomized and divided into two groups of 50 each. Group 1 received 40 to 80 mg of Azilsartan and Group 2 received 40 to 80mg of Telmisartan.

Table 1: Comparison of systolic and diastolic blood pressure after given byAzilsartan

Group- I	Azilsartan	
	Systolic BP	Diastolic BP
Baseline	160.72±3.14	98.56±2.68
3 months	140.8±2.09	90.08±4.72
6 months	122.36±2.37	80.56±0.90

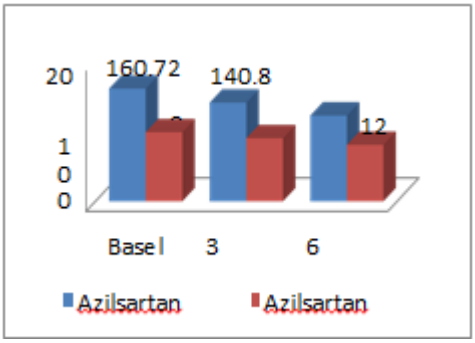

Figure 1: Comparison of Systolic and Diastolic blood pressure in group –I

Table 2: Comparison of mean difference of Systolic and Diastolic blood pressure in group-1 analyzed by paired t-test.

	Systolic BP		Diastolic BP	
	Mean Difference±SD	p-value	Mean Difference±SD	P- value
Baseline vs After 3 Months	19.92±1.05	P<0.001**	8.48±2.04	P<0.001**
Baseline vs. After 6 Months	38.36±0.77	P<0.001**	18.0±1.78	P<0.001**
3 months vs After 6 Months	18.44±0.28	P<0.001**	9.52±3.82	P<0.001**

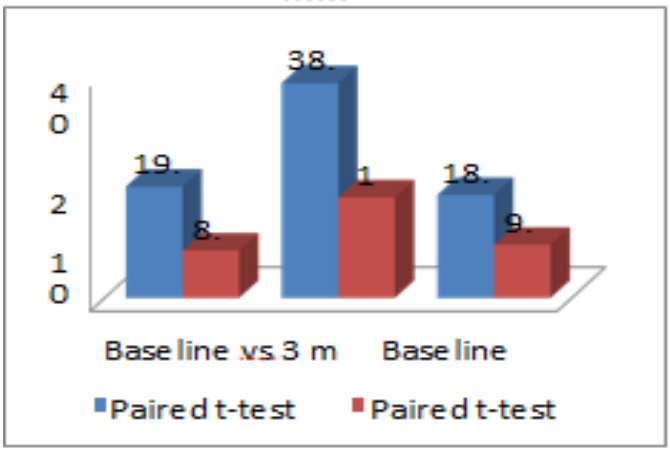

Figure 2: Comparison of Mean difference of systolic and diastolic blood pressure.

Table 3: Comparison of systolic and diastolic blood pressure after given by Telmisartan

Group- I	**Telmisartan**	
	Systolic BP	Diastolic BP
Baseline	162.08±15.35	96.44±7.92
3 months	144.32±4.41	88.48±6.22
6 months	130.84±2.99	80.48±0.95

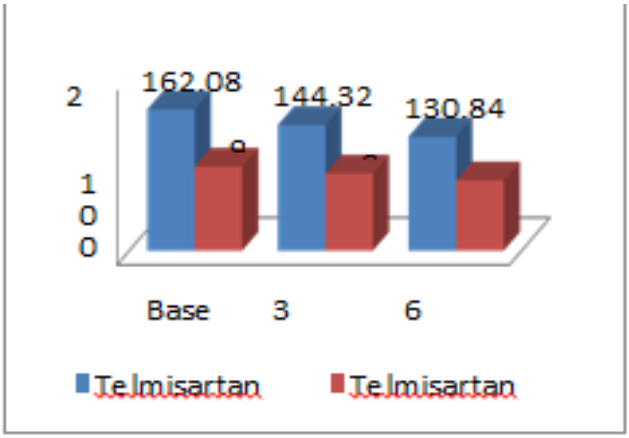

Figure 3: Comparison of Systolic and diastolic blood pressure given by Telmisartan.

Table 4: Comparison of mean difference of Systolic and Diastolic blood pressure in group-II analyzed by paired t-test.

	Systolic BP		**Diastolic BP**	
	Mean Difference±SD	p-value	Mean Difference±SD	P- value
Baseline vs After 3 Months	17.76±10.94	P<0.001**	7.96±1.7	P<0.001**
Baseline vs. After 6 Months	31.24±12.36	P<0.001**	15.96±6.97	P<0.001**
3 months Vs After 6 Months	13.48±1.42	P<0.001**	8.0±5.27	P<0.001**

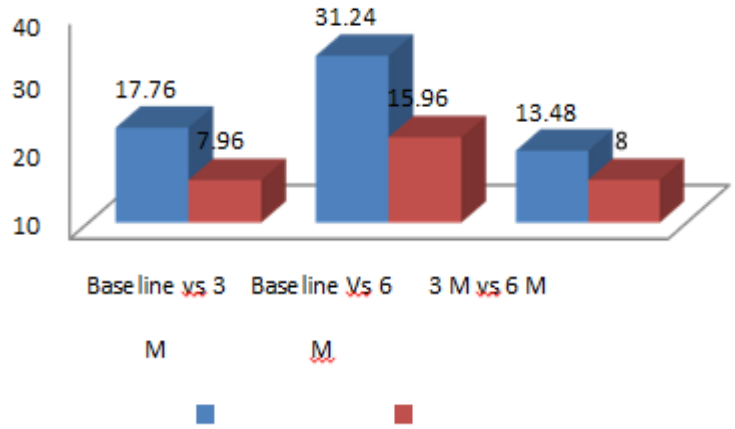

Figure 4: Comparison of Mean difference between systolic and diastolic blood pressure

Table 5: Comparison of Systolic and diastolic blood pressure of Azilsartan versus Telmisartan (Group-I vs Group-II) analyzed by unpaired t-test.

		Systolic BP	Diastolic BP
	Baseline	160.72	98.56
Azilsartan	3 months	140.8	90.08
	6 months	122.36	80.56
	Baseline	162.08	96.44
Telmisartan	3 months	144.32	88.48
	6 months	130.84	80.48

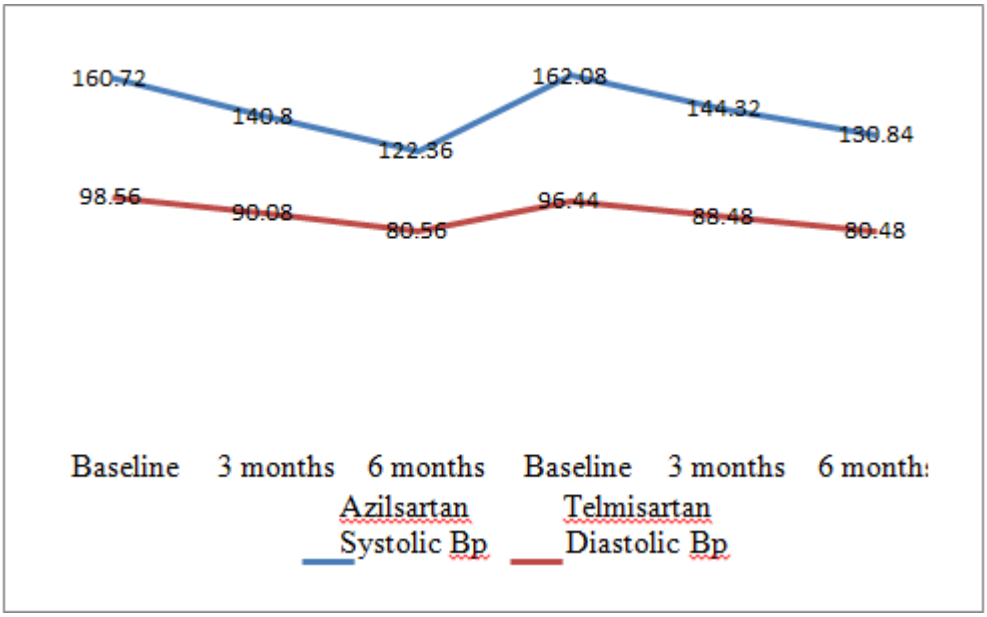

Figure 6: Comparison of Graphical presentation of systolic and diastolic blood pressure ofAzilsartan vs Telmisartan

In Goup-I after giving Azilsartan, mean systolic blood pressure at baseline was 160.72±3.14, after 6 months of the study mean systolic blood pressure was 122.36±2.37 systolic blood pressure was decreased by 38.36±0.77 mm of Hg). Mean diastolic blood pressure at baseline was 98.56±2.68 and mean diastolic blood

pressure after 6 months of the study was 80.56±0.90 (diastolic blood pressure decreased by 18.0±1.78). There was a significant reduction in blood pressure. (P value<0.001) (Bar Chart no-2).

In Group-II after giving Telmisartan mean systolic blood pressure at baseline was 162.08±15.35, after 6 months of the study mean systolic blood pressure was 130.84±2.99 (systolic blood pressure was decreased by 31.24±12.36 mm of Hg). Mean diastolic blood pressure at baseline was 96.44±7.92 and mean diastolic blood pressure after 6 months of the study was 80.48±0.95 (Diastolic pressure decreased by 15.96±6.97). There was a significant reduction in blood pressure. (P value<0.001) (Bar Chart no-4).

Monotherapy with azilsartan 40mg, to 80mg daily has been compared with telmisartan40mg to 80mg daily. There was no significant difference between the two drugs in both mean systolic and diastolic blood pressure of 3 months. Mean Systolic

A significant difference was observed. The mean difference between systolic and diastolic blood pressure at baseline versus 3 months, baseline versus 6 months, and 3 months versus 6 months were found to be statistically significant (P<0.001) (Table no- 2).

Yan Zang *et al*., (2019) **[9]** found after 6 months of Azilsartan mean systolic blood pressure 31.72±4.6 mm of Hg and mean diastolic blood pressure 16.8±2.3 mm of Hg were found to be statistically significant. Azilsartan effectively reduces blood pressure levels in hypertensive patients.

In the present study Telmisartan group was found after 6 months of Telmisartan mean Systolic blood pressure 31.24±12.36; mean diastolic blood pressure 15.96±6.97 significant difference was observed. The mean difference between systolic and diastolic blood pressure at baseline versus 3 months, baseline versus 6 months, and 3 months versus 6 months were found to be and Diastolic blood pressure at 6 months was reduced more with Azilsartan compared to Telmisartan (P value=0.001) which was statistically significant (Graph-1).

Discussion

Azilsartan selectively binds to angiotensin II type-1 receptor (AT1) as an antagonist, blocking vasoconstrictor and aldosterone-secreting effects of angiotensin II. Azilsartan has more than a 10,000-fold greater affinity for the AT1 receptor than for the AT2 receptor [7], which is predominantly involved in cardiovascular homeostasis. Azilsartan appears to dissociate from AT1 receptors much more slowly than other ARBs, which explains its longer duration of action when compared to other ARBs [8]**.**

In the present study, Azilsartan group after 6 months of treatment with Azilsartan mean Systolic blood pressure was 38.36±0.77; the mean diastolic blood pressure was 18.0±1.78

statistically significant (P<0.001). (Table no-3) Chiang *et al*., (1996) [10] foundafter 6 months of Telmisartan mean systolic blood pressure 31.8±3.2 mm of Hg and mean diastolic blood pressure 16.6±1.5 mm of Hg were found to be statistically significant (P<0.001).

Conclusion

Comparison of the groups using Telmisartan and Azilsartan Systolic and diastolic blood pressure are reduced by the Azilsartan group of drugs. When compared to Telmisartan, Azilsartan is a more effective and safe medication.

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