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Original Research Article

Comparison of Efficacy and Safety of Azilsartan with Telmisartan in Patients with Hypertension

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Abstract:

Background: A sustained systolic blood pressure of more than 140 mm Hg or a sustained diastolic blood pressure of more than 90 mm Hg is considered to be hypertension. Heart disease and stroke, the two leading causes of mortality worldwide, can be caused by chronic hypertension. Compared to ACE inhibitors, angiotensin receptor blockers have the capacity to completely suppress angiotensin. They are more selective angiotensin blockers. The purpose of this study was to compare the safety and effectiveness of Telmisartan to the more recent ARB Azilsartan.

Methods: This Prospective, randomized open labelled parallel study was carried out at Department of Pharmacology and patients collected from outpatient and inpatient Department of Medicine, Jannayak Karpoori Thakur Medical College and Hopital, Madhepura, Bihar from March 2022 to August 2022. Participants in the trial had a blood pressure of ≥ 140/90 mmHg and had recently been diagnosed with stage I-II essential hypertension of either sex and were between the ages of 18 and 65. Pregnant women, history of drug or alcohol misuse, cardiac arrhythmias, severe hypertension >180/110 mm Hg, hypersensitivity to ARBs, secondary hypertension with any other origin, and severe hypertension were eliminated. Patients who agreed to participate in the trial were split into two groups at random and given azilsartan in group 1 and telmisartan in group 2, respectively. After starting treatment, a blood pressure of <140/90 mm Hg was considered the point of control.

Results: Two groups of 102 patients were randomly assigned. Azilsartan was administered to 52 individuals in group 1 of whom two were lost to follow-up. Six of the 50 patients in group 2 who got telmisartan were unfollowable. At 6 hours, 15 days, 1 month, and 3 months, there was no discernible difference between the two medications in either the mean systolic or diastolic blood pressure. Significantly, telmisartan reduced mean diastolic blood pressure more than azilsartan over the course of 24 hours. In the azilsartan group, 3% of patients experienced adverse symptoms linked to hypotension, but 8% of patients in the telmisartan group did.

Conclusion: Azilsartan is a blood pressure-lowering medication with similar safety and effectiveness to telmisartan.

Keywords: Blood Pressure, Azilsartan, Telmisartan.

Introduction

The Joint National Committee (JNC VIII) on hypertension defines hypertension as either a sustained systolic blood pressure of greater than 140 mm Hg or a sustained diastolic blood pressure of greater than 90 mm Hg. Despite the fact that many people may not have any symptoms, chronic hypertension can result in heart disease and stroke, the two leading causes of death worldwide. Another significant risk factor for the onset of chronic renal disease is hypertension.[1] To provide the greatest possible reduction in clinical cardiovascular events, blood pressure must be effectively controlled in patients with hypertension.2,3 BP values should be less than 140/90 mm Hg in patients who do not have target organ involvement, and less than 130/80 mm Hg in those who have diabetes mellitus, heart disease, or kidney disease.[4,5]. Both the pathogenesis of essential hypertension, arteriosclerosis-associated hypertension6, and insulin resistance7 appear to be heavily influenced by angiotensin II. In comparison to ACE medications, angiotensin receptor blockers are more selective angiotensin blockers and have the ability to completely suppress angiotensin[8]. The most frequently prescribed angiotensin receptor blocker (ARB) has a favorable pharmacokinetic profile, the longest plasma half-life. In 2018, the US Food and Drug Administration

(FDA) authorized azilsartan medoxomil as the eighth ARB for the treatment of hypertension following the initial launch of losartan in 1995.[9] By altering the tetrazole ring found in candesartan, azilsartan was created[10–11]. Azilsartan has been demonstrated to be effective in lowering blood pressure when given orally as the parent compound or as the ester prodrug azilsartan medoxomil[12–14].

Material and Methods

From March 2022 to August 2022, patients were recruited for this prospective, randomized, open-label parallel trial from the outpatient and inpatient departments of medicine at the Jannayak Karpoori Thakur Medical College and Hospital, Madhepura, Bihar. Participants in the trial had a blood pressure of ≥140/90 mmHg and had recently been diagnosed with stage I-II essential hypertension of either sex and were between the ages of 18 and 65. Both groups' maximum blood pressure readings were 180/110 mmHg. Only new hypertension patients who had not previously received antihypertensive therapy and who had no concomitant conditions were included.

Atrial flutter, atrial fibrillation, ventricular tachycardia, severe hypertension >180/110 mm Hg, hypersensitivity to ARBs, secondary hypertension with any other etiology, history of drug or alcohol misuse Patients with asthma, sick sinus syndrome, Prinzmetal's angina, heart block, chronic heart failure, myocardial infarction, and peripheral vascular disease were also excluded, as were those with sinus bradycardia, sick sinus syndrome, myocardial infarction, sick sinus syndrome, sick sinus syndrome, myocardial infarction, and myocardial infarction. Patients with impaired kidney or liver function were also disqualified.

The study included 102 patients who met the inclusion and exclusion criteria, were willing to participate, provided informed consent, and were willing to participate. Computer generated numbers were used to divide the patients into two groups at random. Depending on the blood pressure, Group 1 received AZILSARTAN 40–80 mg daily, while Group 2 received TELMISARTAN 40–80 mg daily. The pressure at which the korotokoff noises were initially heard was taken as the systolic pressure, and the pressure at which the sounds faded was taken as the diastolic pressure, using a standard conventional sphygmomanometer. At intervals of 15 minutes, two readings of blood pressure were recorded while the subject was seated. Following initial screening, the case report form was used to record the demographic information, prior medical history, family history, physical examination findings, and clinical examination findings. Subsequent investigations were then carried out. ECG, serum creatinine, serum electrolytes, serum, CBP, and CUE.

Patients were only chosen if their blood pressure (BP) ranged from >140/90 mm Hg to <180/110 mm Hg (stage I and stage II hypertension). Depending on the blood pressure, Azilsartan was begun at a dose of 40 to 80 mg daily, whereas Telmisartan was started at a dose of 40 to 80 mg daily. After starting treatment, a blood pressure of <140/90 mm Hg was considered the point of control. After being initially informed of the probable ADR by doctors, the ADRs connected to Azilsartan and Telmisartan were observed and documented in appropriately constructed ADR documentation forms. Using Naranjo's Algorithm, the ADRs' causality was evaluated.The change from baseline in mean systolic and diastolic BP after 8 weeks of treatment served as the major end goal for evaluating efficacy.

In SPSS (version 22), statistical calculations were performed. 1) Student's paired t test for within group before and after treatment was used to compare for the significance of difference between groups of continuously distributed normally distributed data. 2) To compare normally distributed continuous data between the two treatment groups, the Student's unpaired t test was used. Statistical significance was defined as a P value <0.05.

Results

Two groups of 102 patients were randomly assigned to each other. Azilsartan 40 to 80 mg was given to group 1 while Telmisartan 40 to 80 mg was given to group 2. Azilsartan was administered to 52 individuals in group 1 of whom two were lost to follow-up. Six of the 50 patients in group 2 who got telmisartan were unfollowable.

Table 1: Effect of Telmisartan on Blood Pressure

Blood Pressure	Base line	At 6 hour	At 24 hour	At 15 days	At 1 month	At 2 months
SBP	157.15	143.06	136.02	133.86	130.11	128.63
DBP	95.0	90.68	87.27	86.25	84.54	83.18

Systolic blood pressure in the Telmisartan group decreased by 28.5±3.5 mm of Hg from baseline to study conclusion. At start, mean systolic blood pressure in this group was 157.15±11.83. Diastolic blood pressure declined by 11.11±2.058 mm of Hg, lowering the mean value from 95.0±83.18. Systolic and diastolic blood pressure both significantly decreased (P value< 0.001) (Table 1).

Table 2: Effect of Azilsartan on Blood Pressure

Blood Pressure	Base line	At 6 hour	At 24 hour	At 15 days	At 1 month	At 2 months

SBP	155.14	141.08	137.22	133.56	130.19	129.90
DBP	26.63	90.09	89.60	86.93	85.14	83.66

Systolic blood pressure in the Azilsartan group reduced by 25.24±3.45 mm of Hg from baseline to study conclusion, from 155.14±10.73 to 129.90±7.27 (systolic blood pressure was decreased by 25.24±3.45 mm of Hg). At the beginning of the trial, the mean diastolic blood pressure was 96.63±8.63, and at the conclusion, it was 83.66±5.42 (diastolic blood pressure fell by 3.208). The blood pressure was significantly lower. Table 2 shows that (P value 0.001).

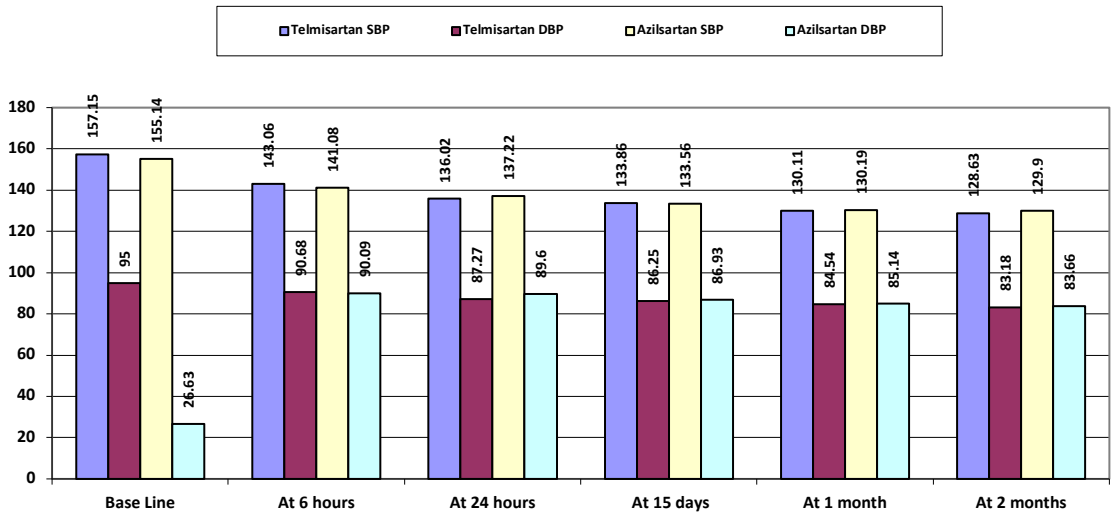

Figure 1: Comparison between the two drugs

Telmisartan 40–80 mg/day has been compared to azilsartan 40–80 mg/day for monotherapy. At 6 hours, 15 days, 1 month, and 3 months, there was no discernible difference between the two medications in either the mean systolic or diastolic blood pressure. It was statistically significant that telmisartan reduced mean diastolic blood pressure more than azilsartan over the course of 24 hours (P value=0.011) (Figure-1). Rashes and hypotension-related events (dizziness, postural dizziness, syncope, vertigo, and positional vertigo) were the two most frequent side effects in the Azilsartan group, which affected 3% of patients each. In contrast, the Telmisartan group experienced dizziness, postural syncope, and vertigo in nearly 8% of patients.

Discussion

In both preclinical and clinical studies, the newer angiotensin receptor blocker azilsartan has demonstrated cardiovascular advantages by reducing blood pressure. These advantages are brought about by its strong affinity for and gradual dissociation from AT1R. Antihypertensive medication has been linked in clinical trials with decreases in 1) stroke incidence, averaged at 35–40%; 2) myocardial infarction (MI), averaged at 20–25%; and 3) heart failure (HF), averaged at >50%.[15] Azilsartan has been shown to drop 24-hour blood pressure in hypertensive patients by a significant amount more than the highest approved dose of olmesartan medoxomil, the latter of which is thought by some to be one of the most effective ARBs for lowering blood pressure[16–18].

In the present trial, we discovered that azilsartan monotherapy is just as successful in lowering mean blood pressure as telmisartan given once daily when using mean systolic and mean diastolic blood pressure monitoring at 8 weeks as the major effectiveness end objective. Telmisartan displayed a somewhat greater reduction in diastolic blood pressure after 24 hours.

Azilsartan has been shown in other studies to be more effective and safe than commonly used ARBs, although we have shown that 3% of patients who reported rashes needed to stop taking the medication. Laboratory test results, vital signs, body weight, and 12-lead electrocardiogram data did not reveal any noteworthy clinically significant findings.

Conclusion

Azilsartan, a more recent angiotensin receptor blocker, lowers blood pressure effectively and safely. Its effectiveness is comparable to that of telmisartan with the added bonus of having fewer adverse effects, making it safe for usage in all patients.

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