

# Efficacy of azilsartan and telmisartan in patients with type 2 diabetes and hypertension

## Abstract

Hypertension is defined as high blood pressure or a long term medical condition in which the arterial blood pressure is continuously elevated. It is also explained as sustained diastolic BP more than 90mmHG accompanied by the elevated systolic BP more than 140mmHg. Diabetes mellitus is a disorder related with a wide variety of disorders in metabolism, the principal feature is hyperglycaemia caused by inadequate insulin action. Azilsartan and Telmisartan are widely used to control hypertension in diabetes patients. This dissertation was designed to assess the efficacy of Azilsartan and Telmisartan.

**Material and methods:** Patients included in this study were diagnosed with Type 2 diabetes mellitus and Hypertension at least age of greater than or equal to 18yrs.

**Results:** From 305 subjects with diabetes hypertensive patients included in the study, 152 patients received Azilsartan and 153 patients were prescribed with Telmisartan.

**Conclusion:** Azilsartan 40mg and Telmisartan 40mg are proved to be efficacious in the patients with hypertension and T2DM, but Azilsartan 40mg has shown more efficacy than Telmisartan 40mg.

**Keywords:** type 2 diabetes, azilsartan, telmisartan, T2DM, BP, RAAS

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## Introduction

Hypertension is defined as high blood pressure or a long term medical condition in which the arterial blood pressure is continuously elevated.<sup>1</sup> It is also explained as sustained diastolic BP more than 90mmHG accompanied by the elevated systolic BP more than 140mmHg.<sup>2</sup> Diabetes mellitus is a disorder related with a wide variety of disorders in metabolism, the principal feature is hyperglycaemia caused by inadequate insulin action.<sup>3</sup> Most deaths (43%) fall out below 70 years of age. 422 million people across the globe in 2014 had diabetes with a 8.5% prevalence in adults. 1.5 million deaths in 2012 occurred due to diabetes. In 2012 among both genders it is the eighth major cause of death and fifth prime cause of death in woman. About 2,82,000 intensive care room visits for adult population aged 18 years and above encountered hypoglycaemia as an initial diagnosis and diabetes as secondary diagnosis in 2012.<sup>4</sup> In the past 30 years Diabetes prevalence consistently inclining and is increasing most rapidly in nations with low and middle income. Increasing concomitant risk factors like being overweight or obese are seen. Diabetes mellitus is a main reason for blindness and kidney failure, legs amputation and other chronic consequences that affect primarily on quality of life.<sup>5</sup>

## Relationship between hypertension and diabetes

In nephropathy, ECF or extra cellular fluid volume and whole body sodium (Na<sup>+</sup>) levels are increased. The action of the Renin Angiotensin Aldosterone System (RAAS) is decreased in these patients, and the high blood pressure is volume dependent, identical to other nephropathies. Other factors must play a vital role in the occurrence of high blood pressure in the non-existence of diabetic nephropathy. Both genetic and acquired factors are seen. Increased whole body sodium levels along with low or actual activity of the RAAS had been reported. People with high blood pressure have found with elevated insulin levels secondary to insulin resistance

and lowered insulin clearance. Elevated insulin levels may possibly be related with inclined renal sodium resorption and hyperactivity of sympathetic nervous system making way to hypertension in people with obesity and other insulin resistant conditions, such as type 2 diabetes. Insulin resistance is also linked to a decreased response of vasodilators to insulin and an elevated response for vasoconstrictors to various vasopressors. However, the action of insulin resistance in the etiology and pathogenesis related to hypertension is not clearly understood.<sup>6</sup>

The aim of our work is to compare Azilsartan and Telmisartan among Type 2 diabetes and hypertensive patients.

## Material and methods

Our citation was an observational research work carried out prospectively in Sri Bhadrakali Diabetic Clinic located at Hanamkonda, Warangal. Before initiation of our research, endorsement was sought and received from Institutional human ethics committee (IHEC) as (VCOP/PHARM.D/V/2018/018). Study population were selected by following inclusion and exclusion criteria's:

### Criteria for inclusion

All subjects diagnosed with Diabetes mellitus Type II and Hypertension with at least age greater than or equal to 18yrs.

### Criteria for exclusion

Patient who were diagnosed with

- Secondary Hypertension due to an underlying cause
- Stage IV chronic kidney disease (GFR  $\geq$  30ml/mn)
- Type I Diabetes mellitus

## iv. Pregnancy and lactating mothers

## v. Cerebrovascular attack

Before initiation of any study processes oral and written informed consents were obtained and evaluated.

Subjects details of demographics and medical history were documented at base line. Prior to the initiation of therapy parameters were assessed from patient's records. Subjects received the drugs for 24weeks period and returned for final evaluation. Clinical and laboratory parameters include weight, Blood Pressure, Glycosylated Haemoglobin (HbA<sub>1c</sub>), Post Prandial Blood Glucose (PPBG), Fasting Blood Glucose (FBS), Serum Creatinine and Lipid Profiles.

### Measurements of treatment efficacy

Primary end point was change in blood pressures, HbA<sub>1c</sub>, FBS, PLBS levels at 3months as compared to the base line values in Azilsartan and Telmisartan groups. The secondary end point was change in lipid profile levels such as serum cholesterol, HDL, LDL, VLDL were measured at 3 months as compared to baseline values.

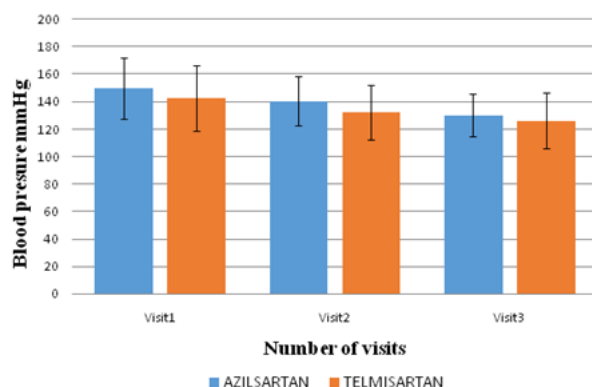
Statistical Analysis: Data was analysed by using graph pad prism software (version5). By using efficacy parameters, laboratory measures and vital signs, Mean and standard deviation were calculated. Difference between quantitative variables was evaluated by using paired t test. Statistical significance was recognised at  $p < 0.05$ .

## Results

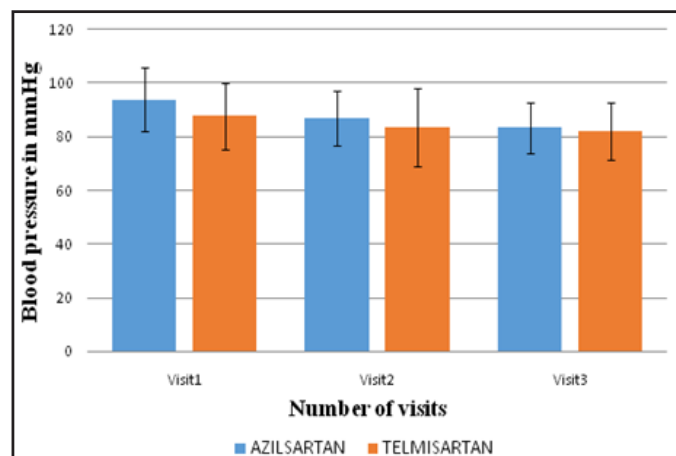
(Table 1) (Figures 1-5)

**Table 1** Demographic details of the study population

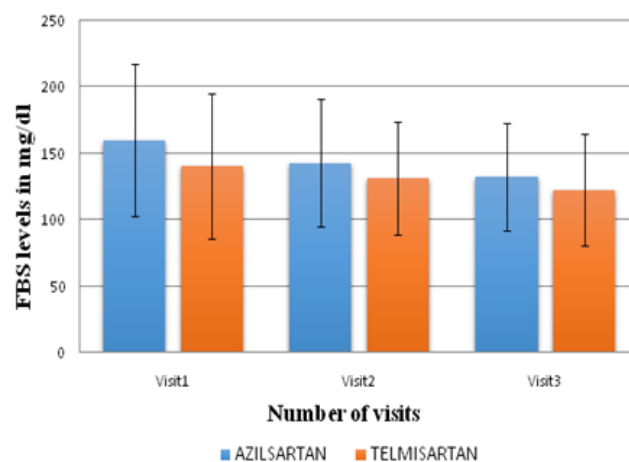
Characteristics	Values (Mean±SD)
Age (years)	54±10
Male n (%)	79 (43.6)
Female n (%)	102 (56.3)
Height (cm)	157.3±9.12
Weight (kg)	65.84±10.15
BMI (kg/m <sup>2</sup> )	26.64±3.82
Duration of diabetes (years)	8.11±5.45
Duration of hypertension	29.2±23.6



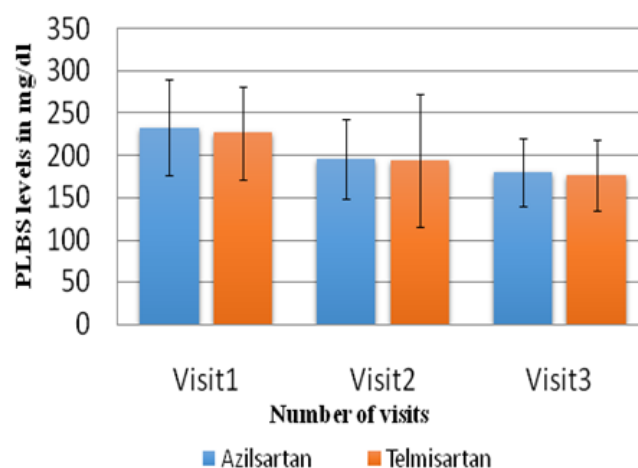
**Figure 1** Changes in systolic blood pressure.



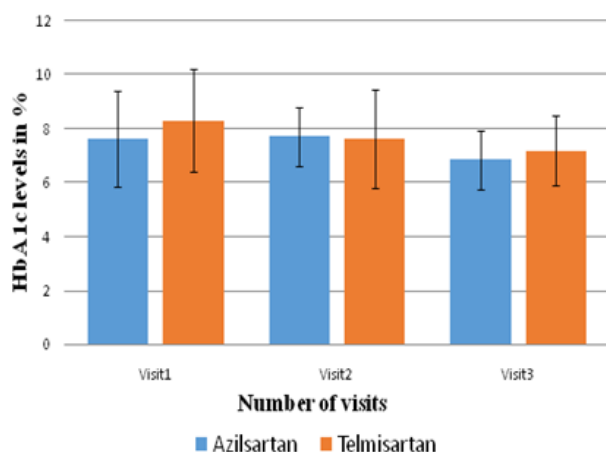
**Figure 2** Changes in diastolic blood pressure.



**Figure 3** Changes in fasting blood sugar levels.



**Figure 4** Changes in post lunch blood sugar levels.



**Figure 5** Changes in HbA1c levels.

## Discussion

Azilsartan provides greater SBP reduction in subjects with T2DM and Hypertension when compared to Telmisartan. It has expected pleiotropic benefits like improving insulin sensitivity, anti proteinuric effects, anti inflammatory effects, inhibits vascular cell proliferation

and endothelial dysfunction and attenuates cardiac remodelling after MI.

In the current analysis, there was a greater reduction in the SBP levels of Azilsartan group when compared to Telmisartan group. A small but significantly greater decrease in fasting blood glucose, post lunch blood glucose, HBA<sub>1c</sub> with Azilsartan 40mg noted compared to Telmisartan 40mg. Research studies pointed out before converge in the stimulation of Peroxisome Proliferating Activated Receptor-gamma (PPAR $\gamma$ ) pathway from Azilsartan as feasible favourable mechanism of patho physiology on the vital Angiotensin-1 receptors (AT<sub>1</sub>) inhibition through improving lipid profile.<sup>7</sup> Similar effect of Azilsartan is observed in our study reducing the lipid levels more than Telmisartan group. In our study we observed that efficacy of Azilsartan and Telmisartan was good reducing the blood pressure but Azilsartan shown greater reducing the systolic blood pressure in the patients T2DM and Hypertension. Our results were similar study conducted in china in which Azilsartan shows reduction of blood pressure levels in T2DM and Hypertensive patients.<sup>8</sup> In a study undertaken at Japan Azilsartan had been documented to have enhanced antihypertensive effects in reducing SBP in patients with Hypertension or Pre-diabetes mellitus and T2DM and serum creatinine levels in individuals using Azilsartan significantly increased after patients changed from their past ARBs. When compared to our analysis there was no significance observed in serum creatinine of Azilsartan group and Telmisartan group.<sup>9</sup>

**Table 2** It explains the effects of Azilsartan and Telmisartan on Blood pressure, Blood glucose, Lipid profile and Serum creatinine values

Characteristics	Effects of Azilsartan				Effects of Telmisartan			
	Visit1	Visit2	Visit3	P value	Visit1	Visit2	Visit3	P value
Systolic blood pressure (mmHg)	150.01±22.16	140.53±17.95	130.03±4.21	0.04	142.3±23.84	132.39±19.87	126.24±20.57	0.04
Diastolic blood pressure (mmHg)	94±11.92	87.03±10.26	83.35±9.46	0.05	87.73±12.43	83.49±14.5	81.92±10.6	0.05
Fasting blood glucose (mg/dl)	159.89±57.21	142.98±47.81	132.61±40.23	0.02	140.23±54.71	131.46±42.4	122.64±42	0.02
Post prandial blood glucose (mg/dl)	232.19±57.21	195.89±47.81	180.78±40.23	0.04	226.5±54.71	194.28±42	180.78±40.23	0.04
HbA1c	7.64±1.77	7.72±1.09	6.86±1.09	0.15	8.31±1.88	7.69±1.82	7.18±1.29	0.15
Triglycerides (mg/dl)	152.26±62.24	143.77±55.08	134.05±50.05	0.007	159.47±73.46	154.47±66.83	142.29±43.26	0.007
Total cholesterol(mg/dl)	163.3±43.04	156.46±44.46	149.61±42.31	0.3	156.14±35.3	156.11±26.09	155.75±27.87	0.3
High density lipoprotein (mg/dl)	41.08±12.15	39.54±8.59	39±7.87	0.05	37.99±9.6	37.29±7.19	36.87±10.25	0.05
Low density lipoprotein (mg/dl)	95.15±26.84	88.67±26.71	88.1±22.81	0.15	96.06±28.89	100.32±85.99	89.43±27	0.15
Very low density lipoprotein (mg/dl)	32.94±14.11	31.94±14.07	31.34±14.65	0.02	31.47±10.06	28.52±8.72	27.67±12.68	0.02
Serum creatinine (mg/dl)	1.05±0.68	1.02±0.23	1.08±0.24	0.1	1.03±0.28	1.02±0.29	0.98±0.3	0.1

## Conclusion

The results of present study reveal that the all the two groups showed an improvement in hypertension symptoms after 6 months of follow up. All evaluated efficacy parameters showed statistically significant.

From this study we conclude that both the drugs Azilsartan 40mg and Telmisartan 40mg are proved to be efficacious in the patients with hypertension and T2DM, but Azilsartan 40mg has shown more efficacy than Telmisartan 40mg. Azilsartan 40mg has shown more efficacy in reducing the SBP and DBP levels, blood glucose levels when compared to Telmisartan 40mg. Azilsartan a new Angiotensin

receptor blocker has shown superior BP lowering effects when compared with Telmisartan and is well tolerated in patients with Hypertension on the basis of this data we could expect that Azilsartan leads to enhanced BP control in patients with stage I and stage II Hypertension. Our findings represent a substantial improvement over the past but still leaves half of the hypertensive population at risk of cardiovascular events. Further studies must be carried out in order to improve the reliability of this drug, further comparative evidences are required using comparator agents, and increased understanding of pharmacodynamic behaviours of both can be demonstrated excellently. The patients must be educated about measuring BP using semi-automated device by which a permanent record of BP values can be drawn and helps the physician to suggest the doses required and minimise the risk of cardiovascular events in-patients with Hypertension & T2DM.

## Acknowledgements

None.

## Conflict of interest

The authors declare that there is no conflict of interest.

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