

To Study the Blood Pressure Response to Azilsartan in Hypertension Patients

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ABSTRACT

Introduction: Hypertension is most important cause for morbidity and mortality world wide, and it is one of the leading cause of non communicable disease mortality. But most of the hypertension patients are not aware and they are not under control. So the study was done to analyse the clinical features of Hypertension and blood pressure response, side effects of patients treated with Azilsartan.

Material and methods: We retrospectively collected data of all patients presenting to outpatient department over 3 months, the parameters studied were Age, symptoms, signs, investigations if any, with main focus on patients with Hypertension (Diagnosed according to JNCVII guidelines) treated with Azilsartan 40 mg along with blood pressure response from day1, day 8 and day 30 were noted.

Results: Total number of patients were 22, with Male to Female ratio of 59%:41% and the age ranging from 35 years to 70 years with mean age of .51.72 years. The commonest symptom was headache in 41% followed by giddiness and body pains in 18.8%, neck pain in 13.63% and leg pains, weakness in 4.54%. Day 1 mean Systolic Blood pressure was 164.55 mm Hg and mean Diastolic Blood pressure was 98.54 mm Hg, after treatment with Azilsartan the mean Systolic Blood Pressure on day 8 was 141.66 mm Hg and mean Diastolic Blood pressure was 89.66 mm Hg, and day 30 mean systolic Blood pressure was 133.55 mm Hg and mean Diastolic Blood pressure was 88.83 mm Hg. 88.8 % patients reached target blood pressure, 12% did not reach the target, 2(9%) patients had giddiness.

Conclusion: Azilsartan has better Blood pressure lowering effects with good tolerance in hypertensive patients.

Keywords: Hypertension, Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), Azilsartan,

treated with Azilsartan, in Nizams Institute of Medical sciences hospital which is a multispecialty, tertiary care referral hospital were collected over a period of three months.

Inclusion criteria

1. All patients diagnosed with Hypertension treated with Azilsartan 40 mg.
2. Age above 18 years.

Exclusion criteria

1. Patients Age below 18 years .
2. Age more than 75 years.
3. Pregnant women.
4. Secondary Hypertension.

Information from out patient records of all patients recruited for analysis was reviewed. In the history, demographic details, symptoms with the duration, risk factors if any were noted.

Laboratory investigations

Hemogram, complete urine examination, Liver function test, Renal function test, Lipid profile Chest radiograph, Ultrasound Abdomen (carried with MYLAB60 model, eSaote company from Ahmedabad), Electrocardiography, 2D Echocardiography were done and noted.

Diagnosis

The diagnosis of Hypertension was done according to JNC VII th guidelines.⁴ Hypertension was diagnosed when Systolic Blood Pressure (SBP) was 140 mmHg and/or Diastolic Blood Pressure (DBP) 90 mmHg. Isolated systolic hypertension was defined as a Systolic Blood Pressure 140 mmHg and a Diastolic Blood Pressure <90 mmHg.⁴

Follow up

Those patients who were on Azilsartan 40 mg dose, and their initial Blood pressure on day 1 was noted, then subsequently the Blood pressure was noted on day 8 and day 30 were also noted, along with any side effects.

The above data from all the patients was tabulated and analysed retrospectively .with main focus on symptoms, Blood pressure response to Azilsartan 40 mg on day 8 and day 30 and any side effects were noted.

The study was retrospective audit with no patient direct identifiers, hence consent was not taken .Hospital ethics

INTRODUCTION

Hypertension is an important chronic disease which causes significant morbidity and mortality.¹ With prevalence of 33% in urban and 27% in rural India, among them 41% in urban and 25% patients are aware of the disease.² But only 37% in urban and 24% in rural are treated for hypertension. Among them only 20% in urban and 10% in rural are under control.² Since there are many groups of drugs to control blood pressure among them renin-angiotensin-aldosterone-system (RAAS) blockers are commonly chosen because of efficacy and low side effects.¹ The new RAAS blocker Azilsartan has demonstrated sustained antihypertensive efficacy³ and this drug has been in Indian market since few months, and there are hardly any studies among Indian patients regarding efficacy and side effects which made us to collect data on Azilsartan on blood pressure response and its side effects.

MATERIAL AND METHODS

Out patient records of patients with diagnosis of Hypertension

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committee was informed of the study.

STATISTICAL ANALYSIS

Microsoft office 2007 was used for the statistical analysis. Descriptive statistics like mean and percentages were used to interpret the data.

RESULTS

Total 22 patients (Table-1) data was collected with age ranging from 35 years to 70 years, with mean age being 51.72 years, Male to Female ratio of 13:9 (59%:41%). The commonest symptom being headache in 41%, next symptom was giddiness, body pains in 18.8%, neck pains in 13.63%, leg pains in 4.54% and weakness in 4.54%.

Total 22 patients of Hypertension who received Azilsartan 40 mg and who came for review on day 8 and day 30 were included. The maximum systolic blood pressure (Table-2) noted on day 1 was 190 mm of Hg with mean systolic blood pressure of 164.55 mm of Hg, and maximum Diastolic blood pressure on day 1 was 108 mm of Hg, with mean diastolic blood pressure of 98.54 mm Hg. All the patients received Azilsartan 40 mg, after 8 days the mean systolic blood pressure was 141.66 mm Hg and mean diastolic blood pressure was 89.16 mm Hg. On follow up on day 30 (Figure-1) the mean systolic blood pressure was 133.55 mm Hg, and mean diastolic blood pressure was 88.83 mm Hg. 20 (90.9%), That is on day 8 and day 30 Mean systolic Blood pressure came down by -23.9 mmHg and 31 mmHg respectively and mean Diastolic blood pressure came down by day 8 by -9.4 and by day 30 -10.4 mm Hg from day 1 blood pressure reading. All patients reached the goal blood pressure of <140mm of Hg systolic and <90 mm Hg diastolic blood pressure, except 3 (13.63%) patients, who required Azilsartan 80mg to control the blood pressure. The side effects of giddiness was seen in 2 (9.09%) patients.

DISCUSSION

Hypertension is one of the leading risk factor of non-communicable diseases in south asia⁵, and leading cause of stroke deaths and coronary heart disease deaths in India.⁶ In our study we had 22 patients of Hypertension who were treated with Azilsartan 40mg. Among them 13(59%) were male and 9(41%) were female. which is similarly reported by M K singh⁷ et al 51% to 49%, Sathya et al⁸ 50.7% to 50.3% and William⁹ et al reported 54% to 46%. The age of the patients was 35 years to 70 years with Mean Age of 51, 72 years but M K singh et al⁷ had patients age ranging from 20 years to >70 years. But William et al⁹ had Mean age of 56 years in there study group.

The commonest symptom of presentation was headache in 41% patients followed by giddiness, body pains in 18.8%, neck pains in 13.6% and leg pains, weakness in 4.5% patients, which are nonspecific but have been reported similarly by Willam et al. ⁹ The Mean Systolic blood pressure at presentation was 164.55 mm Hg and Mean Diastolic blood pressure was 98.54 mm of Hg, which is more than reported by Gupta et al¹⁰ of systolic blood pressure of 128.8+ 17 mm Hg, but similar to Yugoslavian cohort¹¹ a baseline systolic BP of 144.2±23.7 mmHg. After these patients were treated with daily Azilsartan 40 mg the Mean systolic Blood pressure on day 8 was 141.66 mm Hg and Mean Diastolic Blood pressure was 89.16mm Hg. And on day 30 the Mean Systolic Blood pressure was 133.55 mm Hg and

	Numbers (%)
Total patients	22
Age	35 to70 years Mean age-51.72 years
Sex Male : Female	13:9 (59% : 41%)
Symptoms	
Head ache	9 (41%)
Giddiness	4 (18.18%)
Neck pain	3 (13.63%)
Body pains	4 (18.18%)
Leg pains	1 (4.54%)
Weakness	1 (4.54%)
Side effects while on Azilsartan	Giddiness 2(9.09%)

Table-1: Shows clinical findings

Blood pressure Day 1	Blood Pressure in mm Hg	Mean change in Blood pressure in mm Hg
Systolic Blood pressure	Mean--164.55	-
Diastolic Blood pressure	Mean--98.54	-
Day 8 on Azilsartan 40mg		
Systolic Blood pressure	Mean-141.66	-23.9 mm
Diastolic Blood pressure	Mean--89.16	-9.4
Day 30 on Azilsartan 40 mg		
Systolic Blood pressure	Mean-133.55	-31
Diastolic Blood pressure	Mean--88.83	-10.4
Not reaching target Blood pressure by day 30	3(13.63%)	

Table-2: Showing Blood Pressure response to Azilsartan 40mg

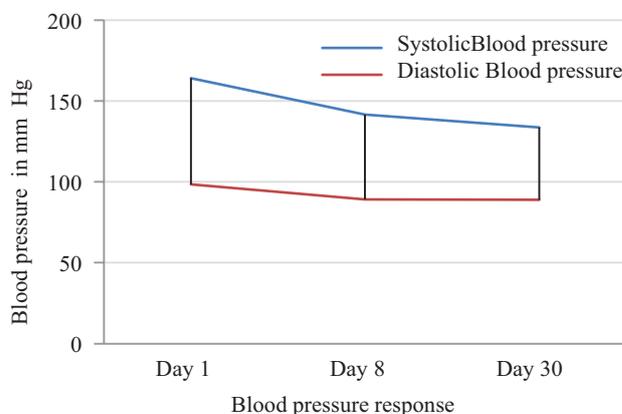


Figure-1: Showing Blood pressure response to Azilsartan

Mean Diastolic Blood pressure was 88.83 mm Hg. That is on day 8 and day 30 Mean systolic Blood pressure came down by -23.9 mmHg and -31 mmHg respectively and mean Diastolic blood pressure came down by day 7 by -9.4 and by day 30 -10.4mm Hg. Similarly but Bakris¹² et al reported Systolic blood pressure reduction by -13.5mm Hg by 6 weeks, White et al⁹ reported -14.3 mmHg by 6 weeks, Rakugi et al¹³ reported reduction of SBP -21.8 mm Hg and DBP of -12.4 mm Hg at 16 weeks and Sicca et al¹⁴ of SBP of -14.9 mm Hg and DBP of -11.3 mmHg at 24 weeks, Bonner et al¹⁵ reported SBP reduction of -20.6 mm Hg and DBP of -10.2mm Hg at 24 weeks. Kipnes et al¹⁶ reported reduction of SBP of -23mm Hg and DBP of -16 mm Hg.

The mean SBP and mean DBP reduction with Azilsartan 40 mg is -31 mm Hg and -10.4 mmHg in our study, which is better than Candesartan 8-12mg its SBP reduction is -17.5 mm Hg and DBP -9.8 mm Hg in Rakugi¹³ et al study, Bonner¹⁵ et al reported Azilsartan SBP reduction of -20.6 compared to Ramipril SBP reduction of -12.2 mmHg. Sica¹⁴ et al reported of SBP reduction of 11.3 mm Hg with valsartan 320mg and Bakris¹² et al showed SBP response to olmesartan 40 mg was -12.6 mm Hg which is less compared to our study .

Total 87.3% patients reached target blood pressure which is similarly reported by White⁹ et al and Bakris¹² et al.

The major side effects was giddiness in 2 (9.09%) patients which is similarly reported by Kipnes¹⁶ et al. (8.9%).

Thus Azilsartan has better Blood pressure reduction compared to candesartan, valsartan, olmesartan and Ramipril.

Limitations

This study has very small sample size, it's a retrospective study, other parameters like benefits on Heart, Vascular system, Brain, Kidney, Liver, Lipids and other systems have not been included in the the study.

CONCLUSION

Azilasartan a new angiotensin receptor (ARB) blocker has better clinical Blood pressure lowering effects compared to other ARBs with good tolerance. We expect more patients will have Blood pressure controlled, which will help in reducing risk for cardiovascular events. Hence Azilasartan is more efficient and effective in Blood pressure control in the Hypertension population.

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To my Wife Keerthi, Daughter Saanvi, My patients.

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