Comparative Efficacy of Azilsartan and Telmisartan in Hypertensive Patients

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ABSTRACT

BACKGROUND

Hypertension is defined as an abnormally raised arterial blood pressure with the mean arterial pressure being more than 130 -140 mmHg and the diastolic pressure being more than 90 mmHg. It is a common and serious condition that may lead to morbidity and mortality and is a risk factor for stroke, MI, angina, heart failure, renal failure or death. So, as it is often called the "silent killer", as it has no symptoms and leads to serious complications. There are various causes of hypertension- alcohol consumption, smoking, excess salt intake, genetic predisposition, thyroid disease, kidney disease, and also with medications like oral contraceptives and some hormonal drugs, were as obesity, heredity and lifestyle play a major role in causing hypertension. We wanted to study the effects of Azilsartan and Telmisartan on hypertensive patients at Rama Hospital, Kanpur.

METHODS

This study was conducted in the Department of Pharmacology in association with Department of General Medicine in Rama Hospital and Research Centre, Mandhana, Kanpur, Uttar Pradesh.

RESULTS

In this study, a total of 50 patients was selected. Among them 31 were male and 19 were female. Age group was 30-70. In 30-40 years age group there were 10 patients, 41-50 years 15 patients, 51-60 years 20 patients and more than 60 there were 05 patients. After treatment with Azilsartan there is a reduction of mean systolic blood pressure from 152.51 ± 7.52 to 121.97 ± 3.34 mmHg and also reduction of mean diastolic blood pressure from 94.29 ± 3.5 to 82.00 ± 1.84 mmHg. In Telmisartan group, there is a reduction of mean systolic blood pressure from 159.66 ± 7.78 to 121.44 ± 2.34 mmHg and also reduction of mean diastolic blood pressure from 99.00 ± 4.60 to 85.76 ± 2.31 mmHg. Increased levels of sodium in the body may cause hypertension. After 3 months treatment with Azilsartan/Telmisartan, reduction of mean sodium levels in Group-A- 157.80 ± 140.40 mmol/dl to 140.40 ± 5.16 mmol/dl the mean difference is 170.40 ± 5.45 and in Group-B- 156.7 ± 4.18 mmol/dl to 140.40 ± 5.16 mmol/dl the mean difference is 16.32 ± 5.90 respectively. Also, there is a reduction of mean potassium levels in Group-A- 6.20 ± 1.14 to 4.28 ± 0.61 mmol/dl the mean difference is 1.92 ± 1.15 and in Group-B- 5.80 ± 0.55 to 4.07 ± 0.37 mmol/dl the mean difference is 1.72 ± 0.74 respectively.

CONCLUSIONS

Azilsartan is an effective blood pressure lowering drug with its safety and efficacy comparable to that of Telmisartan.

KEY WORDS

Hypertension, Azilsartan, telmisartan, Blood Pressure

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BACKGROUND

Hypertension is defined as an abnormally raised arterial blood pressure with the mean arterial pressure being more than 130-140 mmHg and diastolic pressure being more than 90 mmHg. It is a common and serious condition that may lead to morbidity and mortality and is a risk factor for stroke, MI, angina, heart failure, renal failure or death. It is often called as the "silent killer", [1] as it has no symptoms and develops in serious disease complication. Causes of hypertension include alcohol consumption, smoking, excess salt intake, genetic predisposition, thyroid disease, kidney disease and also with medications like oral contraceptives and some hormonal drugs, obesity and lifestyle.[2] Blood pressure is defined as an arterial pressure exerted by the blood on the walls of blood vessels. Normal BP= 120/80 mmHg.[3] There are different types of hypertension. 1. Primary hypertension and 2. Secondary hypertension. Primary hypertension- arterial blood pressure due to increased peripheral resistance, these are of two types.[4] a) Benign Hypertension: It is due to increase in systolic blood pressure of 200 mmHg and diastolic blood pressure 100 mmHg in at resting phase and during sleep. b) Malignant hypertension- blood pressure increases to systolic blood pressure 250 mmHg and diastolic blood pressure 150 mmHg. This raised blood pressure causes renal, retinal diseases and even may cause death.

We wanted to compare the effects of Azilsartan and Telmisartan on hypertensive patients at Rama Hospital, Kanpur.

METHODS

After obtaining ethical committee approval, a prospective, randomized control study was conducted in the Department of Pharmacology in association with the Department of General Medicine in Rama Hospital and Research Centre, Mandhana, Kanpur, Uttar Pradesh for a period of one year with a follow up period of three months. 50 hypertensive patients who attended OPD of the Department of General Medicine in Rama hospital, Mandhana, Kanpur were included in the study.

Inclusion Criteria

Patients of both sexes aged between 30 and 70 years with SBP between 140 mmHg and 170 mmHg were included in the study.

Exclusion Criteria

Pregnant women, diabetic and asthmatic patients suffering from hypertension, patients already on hypertensive therapy, patients with blood pressure more than 170 mmHg and patients more than 60 years of age were excluded from the study.

Detailed history is taken and routine laboratory investigations like estimation of Na + & K+ were done. The drugs were prescribed to the patients and the patients were followed for 3 months. The total duration of study is one year. 25 patients in group A received Azilsartan. 25 patients in group B received Telmisartan. The data is collected, entered in the MS Office Excel sheet and statistical analysis was done with SPSS software.

RESULTS

Figure 1. Graphical Representation of Genders

Figure 2. Graphically Representation of Age Groups

		Group A (Azilsartan)	Group B (Telmisartan)
Sl. No.	Parameters	Systolic Blood Pressure	Systolic Blood Pressure
1	Baseline	152.51 ± 7.52	159.66 ± 7.78
2	After 15 days	141.13 ± 6.59	151.93 ± 7.84
3	After 1 month	130.82 ± 5.14	145.48 ± 7.79
4	After 2 Months	126.15 ± 4.79	139.08 ± 6.74
5	After 3 months	121.97 ± 3.34	121.44 ± 2.34

Table 1. Tabular Representation of Systolic Blood Pressure of Azilsartan Group

		Group A (Azilsartan)	Group B (Telmisartan)
Sl. No.	Parameters	Diastolic Blood Pressure	Diastolic Blood Pressure
1	Baseline	94.29 ± 3.5	99.00 ± 4.60
4	After 15 days	90.22 ± 2.97	91.96 ± 3.54
5	After 1 month	87.53 ± 3.00	89.92 ± 2.99
6	After 2 Months	84.97 ± 2.35	87.8 ± 2.64
7	After 3 months	82.00 ± 1.84	85.76 ± 2.31

Table 2. Tabular Representation of Diastolic Blood Pressure of Azilsartan Group

Sl. No.	Para-meters	Group - A (Na+)	Group - A (K+)	Group-B (Na+)	Group-B (K+)
1.	Baseline	157.80 ± 140.40	6.20 ± 1.14	156.7 ± 4.18	5.80 ± 0.55
2.	Na+& K+ levels after 3 months	140.40 ± 5.16	4.28 ± 0.61	140.40 ± 5.16	4.07 ± 0.37
3.	Mean difference	170.40 ± 5.45	1.92 ± 1.15	16.32 ± 5.90	1.72 ± 0.74
4.	T-value	15.95	8.319	13.81	11.637
5.	p- Value	<0.05	<0.05	<0.05	<0.05

Table 3. Tabular Representation of Azilsartan and Telmisartan of Sodium Levels after 3 Months of Treatment

In this study, a total of 50 patients was selected. Among them 31 were male and 19 were female. Age group was 30-70. In 30-40 years age group there were 10 patients, 41-50 years 15 patients, 51-60 years 20 patients and more than 60 there were 05 patients. After treatment with Azilsartan there is a reduction of mean systolic blood pressure from 152.51 ± 7.52 to 121.97 ± 3.34 mmHg and also reduction of mean diastolic blood pressure from 94.29 ± 3.5 to 82.00 ± 1.84 mmHg. In Telmisartan group, there is a reduction of mean systolic blood pressure from 159.66 ± 7.78 to 121.44 ± 2.34 mmHg and also reduction of mean diastolic blood pressure from 99.00 ± 4.60 to 85.76 ± 2.31 mmHg. Increased levels of sodium in the body may cause hypertension. After 3 months treatment with Azilsartan/Telmisartan, reduction of mean sodium levels in Group-A- 157.80 ± 140.40 mmol/dl to 140.40 ± 5.16 mmol/dl the mean difference is 170.40 ± 5.45 and in Group-B- 156.7 ± 4.18 mmol/dl to 140.40 ± 5.16 mmol/dl the mean difference is 16.32 ± 5.90 respectively. Also, there is a reduction of mean potassium levels in Group-A- 6.20 ± 1.14 to 4.28 ± 0.61 mmol/dl the mean difference is 1.92 ± 1.15 and in Group-B- 5.80 ± 0.55 to 4.07 ± 0.37 mmol/dl the mean difference is 1.72 ± 0.74 respectively.

DISCUSSION

Azilsartan a new RAAS blocker. This drug has been introduced in the Indian market and was approved by DCGI in December 2016 [5]. It is recommended for clinical use in hypertension by JNC 8. [6].

In our study the total samples size was 50 hypertensive patients. They are divided into two groups. Group A Azilsartan- 25 patients and in Group-B telmisartan- 25 patients among them 31 are male and 19 are female patients. This study considered with the study of Shetty, et. al. [7] in his study he among 22 hypertensive patients 59% were male and 41 % are female. In this study age group of between 51-60 there are 20 patients are hypertensive patients. After every 15 days blood pressure had been monitored after 3 month of drug treatment all the routine investigation had been done.

In Group-A (Azilsartan) the mean systolic blood pressure was 152.51 ± 7.52 after 15 days treatment with Azilsartan 40 mg the mean reduction in systolic blood pressure was 141.13 ± 6.59 after 1 month the mean reduction in blood pressure was 130.82 ± 5.14 , 2 months the mean reduction in blood pressure was 126.15 ± 4.79 , 3 months the mean reduction in blood pressure was 121.97 ± 3.34 , according Shetty, et. al. (2017) [7] in study on 22 hypertensive patients after giving Azilsartan systolic blood pressure at day 8 was 141.66 mmHg and at day 30 it reduces to 133.55 mmHg and diastolic blood pressure at day 8 was 89.66 mmHg after day 30 it reduces to 88.83 mmHg. He concluded that Azilsartan has better blood pressure lowering effects. And the mean diastolic blood pressure was 94.29 ± 3.5 after 15 days treatment with Azilsartan 40 mg the mean reduction in diastolic blood pressure was 90.22 ± 2.97 after 1 month the mean reduction in blood pressure was 87.53 ± 3.00 , 2 months the mean reduction in blood pressure was 84.97 ± 2.35 , 3 months the mean reduction in blood pressure was 82.00 ± 1.84 , according to Shetty, et. al. (2017) [7] in the study on 22 hypertensive patients after giving Azilsartan systolic blood pressure at day 8 was 141.66 mmHg and at day 30 it reduces to 133.55 mmHg and diastolic blood pressure at

day 8 was 89.66 mmHg after day 30 it reduces to 88.83 mmHg. He concluded that Azilsartan has better blood pressure lowering effects.

In Group-B (Telmisartan) the mean systolic blood pressure was 159.66 ± 7.78 after 15 days treatment with Telmisartan the mean reduction in systolic blood pressure was 151.93 ± 7.84 after 1 month the mean reduction in blood pressure was 145.48 ± 7.79 , 2 months the mean reduction in blood pressure was 139.08 ± 6.74 , 3 months the mean reduction in blood pressure was 121.44 ± 2.34 . And the mean diastolic blood pressure was 99.00 ± 4.60 after 15 days treatment with Telmisartan the mean reduction in diastolic blood pressure was 91.96 ± 3.54 after 1 month the mean reduction in blood pressure was 89.92 ± 2.99 , 2 months the mean reduction in blood pressure was 87.8 ± 2.64 , 3 months the mean reduction in blood pressure was 85.76 ± 2.31 showing statically significant. The baseline level of Na^+ of Group-A 157.80 ± 140.40 and in Group-B is 156.7 ± 4.18 after 3 months of treatment with Azilsartan and Telmisartan there is a decrease in the levels of Na^+ i.e. 140.40 ± 5.16 and 140.40 ± 5.20 which is statically significant and the mean difference of Group-A is 170.40 ± 5.45 and Group-B 16.32 ± 5.92 which shows statically significant. The baseline level of K^+ of Group-A 6.20 ± 1.14 and in Group-B is 5.80 ± 0.55 after 3 months of treatment with Azilsartan and Telmisartan there is a decrease in the levels of K^+ i.e. 4.28 ± 0.61 and 4.07 ± 0.37 which is statically significant and the mean difference of Group-A is 1.92 ± 1.15 and Group-B 1.72 ± 0.74 which shows statically significant. The baseline level of K^+ of Group-A 6.20 ± 1.14 and in Group-B is 5.80 ± 0.55 after 3 months of treatment with Azilsartan and Telmisartan there is a decrease in the levels of K^+ i.e. 4.28 ± 0.61 and 4.07 ± 0.37 which is statically significant and the mean difference of Group-A is 1.92 ± 1.15 and Group-B 1.72 ± 0.74 which shows statically significant.

CONCLUSIONS

Azilsartan is an effective blood pressure lowering drug with its safety and efficacy is comparable to that of Telmisartan.

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