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Original Research Article

Comparative Evaluation of effect of Telmisartan and Olmesartan on Blood Pressure and Fasting Blood Glucose Levels in Newly Diagnosed Hypertensive Patients: An Open Label Prospective Randomized Clinical Study

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Abstract

Title: Comparative evaluation of effect of Telmisartan and Olmesartan on blood pressure and fasting blood glucose levels in newly diagnosed hypertensive patients: An open label prospective randomized clinical study.

Introduction: Hypertension is responsible for development of diseases like stroke, ischemic heart disease and end organ damage. Angiotensin receptor blockers like Telmisartan & Olmesartan are first line drug for the treatment of hypertension. These drugs having pleotropic, anti-oxidant and anti-inflammatory effect.

Primary objective of the study was to evaluate mean change in systolic and diastolic blood pressure from day 0 to 12th week.

Secondary objectives were to determine the mean change in fasting blood sugar from day 0 to 12th week and to evaluate the safety of the study drugs.

Material and Method: It was a prospective, open label, interventional, comparative, randomized study. Total of 109 newly diagnosed patients of hypertension were enrolled and divided in two groups. Patients in group A received tablet Telmisartan 40 mg once in a day and patients in group B received tablet Olmesartan 20 mg once in day.

Results: In Telmisartan group, the baseline mean SBP and DBP was 151.6 ± 3.113 mm Hg and 90.83 ± 2.50 mm Hg which reduced to 137.16 ± 2.135 mm Hg and 81.79 ± 1.94 mm Hg respectively at 12th week and in Olmesartan group, the baseline mean SBP and DBP was 151.74 ± 4.54 mm Hg and 91.53 ± 3.28 mm Hg which reduced to 134.17 ± 3.43 mm Hg and 80.64 ± 2.76 mm Hg respectively at 12th week. The reduction in mean SBP and DBP was statistically significant at the end of therapy in both groups. There was no significant reduction in fasting blood glucose level in both study groups.

Conclusion: Both Telmisartan and Olmesartan effectively controlled systolic and diastolic blood pressure in hypertensive patients but reduction was more significant in Olmesartan group. Both these drugs having no significant effect on fasting blood glucose level.

Keywords: Hypertension, Telmisartan, Olmesartan.

Introduction

Hypertension has emerged as new-era pandemic, causing about 7.1 million deaths every year and 4.5% of the disease burden, which translates to 64 million disability adjusted life-years (DALYs) globally.[1, 2]According to the Registrar General of India, the prevalence of hypertension in urban and rural populations of India is 25.0% and 10.0%, respectively.1It is also responsible for development of other non-communicable diseases like stroke (54%), ischemic heart disease (47%) and attributable deaths (13%). Thus considering the prevalence of disease, hypertension ranks fourth most common disease in the world.[2,3] Patients with hypertension is drastically increasing in number and therefore it is important to adequately control the blood pressure to reduce the complications associated with hypertension. [4,5] Along with high blood pressure there are presence of deranged metabolic parameters such as heart rate, free fatty acids and mean glucose level in hypertensive subjects at any body mass index level. [6,7] Thus in view of organ damage caused by hypertension, the goal of treatment has gradually shifted from optimal lowering of blood pressure to patient's overall wellbeing, control of associated risk factors and protection from future target organ damage.[8]

The renin–angiotensin aldosterone system (RAAS) participates significantly in the pathophysiology of hypertension, congestive heart failure, myocardial infarction, and diabetic nephropathy. Angiotensin receptor blockers (ARBs) acts on angiotensin I (AT1) receptor and produce their blood pressure lowering effects by antagonizing angiotensin II actions (vasoconstriction, aldosterone release, catecholamine release, arginine vasopressin release, water intake and hypertrophic response). They also down regulate sympathetic adrenergic activity by blocking the effects of angiotensin-II on sympathetic nerve release and re-uptake of norepinephrine.[9]

Telmisartan is one of the most commonly prescribed ARB as an anti-hypertensive drug. Some studies suggest that Telmisartan having pleotropic effect which are responsible for improvement in endothelial dysfunction, reduction in left ventricular hypertrophy, renoprotection and improvement in metabolic parameters.[10,11] Telmisartan acts on peroxisome proliferation activated receptor-γ which plays important role in regulating glucose and lipid metabolism by increasing serum adiponectin levels.[12] Olmesartan is another commonly used ARB for hypertension and it possess anti-oxidant and anti-inflammatory properties.[4,13]

Thus a lot of studies have been done on efficacy, safety and various other parameters of both the drugs individually and together by comparing them.[4,13-14] But still many of those studies are inconclusive. So, we planned this study to compare the effects of Telmisartan and Olmesartan on blood pressure as well as on fasting blood sugar level.

Material and Methods

The study was conducted in department of medicine in collaboration with department of pharmacology at a tertiary care hospital in Aurangabad, Maharashtra. It was a prospective, open label, interventional, comparative, randomized controlled study. Patients attending the outpatient department of medicine and diagnosed with essential hypertension were considered for study. Both males and females with age between 30-65 years and having clinically confirmed hypertension, were included in study (based on average of two or more readings taken at the interval of 10 mins during each of two or more visits). Patients receiving any other antihypertensive medication, corticosteroids and immunosuppressive agents were excluded from the study. Patients with systolic BP ≥180 mm Hg & diastolic BP ≥110 mm Hg, secondary hypertension, diabetes mellitus, hematological, gastrointestinal, renal, liver and endocrine disorder were not included. Patients associated with complicated cardiovascular & cerebrovascular disease were not considered for study. Patient with known allergy or hypersensitivity to study drugs and pregnant as well as lactating mothers were excluded from study.

Methodology:

After obtaining the approval from the Institutional Ethical Committee, the study was conducted in accordance with the protocol, Declaration of Helsinki, ICH, Good Clinical Practice (GCP) guidelines, and the ICMR guidelines for Biomedical Research on Human Subjects, 2006.

All the eligible patients were explained in detail the study procedure to fullest extent possible in language best understood by them. Subsequently, a written informed consent was taken from each patient prior to enrolment into the study and the participants were free to withdraw without prejudice at any time.

Upon enrolment, a number is assigned to each patient and the demographic and clinical findings recorded in the case report form (CRF). Patients were randomized on day 0 by simple random sampling. A computer generated table of randomized numbers was prepared and divided patients in two groups (Group A and Group B). The investigator allocated the patient to the group as per the randomization table. This assigned number will identify the patients throughout the study. Total of 109 newly diagnosed patients of hypertension were enrolled in study. Patients in group A received tablet Telmisartan 40 mg once in a day and patients in group B received tablet Olmesartan 20 mg once in day. The study medications were provided to patients in blisters containing drugs for 1 week of duration and refilled at next subsequent visits till the end of the study i.e. up to 3 months. The patients were thus followed up from day 0 to 1st follow up visit at 1 week, 2nd follow up at 2 week, 3rd follow up at 4 week, 4th follow up at 8 week and 5th follow up at 12 week.

At each visit, patients came in OPD in morning after 10-12 hours overnight fast and fasting blood samples were collected by the Investigator. Blood pressure was measured by using a standard mercury sphygmomanometer with a cuff of appropriate size on the right arm. Following laboratory investigation were done, body mass index, fasting blood glucose, complete haemogram, renal and liver function test and urine routine at day 0 and at the end of study but blood pressure and fasting blood sugar checked at every follow up.

Patients were specifically asked for the adverse drug reaction (ADR) at the time of each of their visits. Symptom check list was filled by investigator by taking feedback from patients at each visit to assess the incidence of any ADR during study period

Primary objective of the study was to evaluate mean change in systolic blood pressure and diastolic blood pressure from day

0 to subsequent following visit at 1 week, 2 week, 4 week, 8 week and 12 week. **Secondary objectives**: To determine the mean change in fasting blood sugar from day 0 to subsequent following visit at 1 week, 2 week, 4 week, 8 week and 12 week.

2. To evaluate the safety of the study drugs.

Statistical Analysis: All the data entered into Microsoft Excel from case record form for analysis. For comparing quantitative data within the study groups Paired't' test and repeated measures ANOVA were used and for comparing quantitative data between the study groups Unpaired 't' test was applied. Comparison of qualitative data between the study groups was done using Fisher's exact test. Statistical analysis was performed with the help of the software 'Graph pad Prism 5'. The p value of <0.05 was considered as statistically significant.

Results:

Total of 147 newly diagnosed hypertensive patients were screened, and 109 eligible patients were randomized into two treatment groups. In group A, 8 patients and in group B, 6 patients were lost to study. Both the groups were comparable at baseline with respect to mean age, sex and the body mass index (BMI). Mean age in group A was 46.13 years and 47.15 years in group B. There were 23 (47.92%) males and 25 (52.08%) females in group A and 22 (47.81%) males and 25 (53.19%) females in group B. Mean body mass index (BMI) in group A and B was 26.32 kg/m2 and 27.51 kg/m2 respectively. All adverse events were of mild to moderate severity, and none of patients needed discontinuation of treatment.

Discussion:

Hypertension is a multifactorial disease and one of the most common, readily identifiable and reversible risk factor for myocardial infarction, stroke, kidney disease and blindness.[15] Angiotensin II receptor blockers (ARBs) are commonly used agents for the treatment of hypertension and are known to be effective in the prevention of cardiovascular end-organ damage because of its anti-inflammatory and anti-oxidant effects.

In the present study in Telmisartan group, the baseline mean SBP was 151.6 ± 3.113 mm Hg which reduced to 147.3 ± 2.95 at 1st week, 144.5 ± 2.53 at 2nd week, 140.00 ± 2.440 at 4th week, 139.45 ± 2.090 at 8th week and 137.16 ± 2.135 at 12th week. The reduction in mean SBP was statistically significant at the end of 12 weeks therapy ('P' value < 0.0001). In Olmesartan group, the baseline mean SBP was 151.74 ± 4.54 mm Hg which reduced to 145.3 ± 3.10 at 1st week, 142.7 ± 3.83 at 2nd week, 137.2 ± 3.13 at 4th week, 133.7 ± 3.57 at 8th week, 134.17 ± 3.43 at 12th week. The reduction in mean SBP was statistically significant at the end of 12 weeks therapy. ('P' value < 0.0001). In inter-group analysis, it was observed that there was statistically no significant difference in mean SBP, when two groups were compared at baseline but at each subsequent follow-ups the difference in reduction in SBP was significantly more in Olmesartan group which became significant in 12 weeks of follow up ('P' value 0.0239, 0.0006, 0.0001, 0.0001, 0.0001 at 1st, 2nd, 4th, 8th and 12th week respectively).

While in case of DBP in Telmisartan group, the baseline mean DBP was 90.83 ± 2.50 mm Hg reduced to 89.21 ± 2.32 at 1st week, 86.54 ± 2.53 at 2nd week, 84.42 ± 2.94 at 4th week, 83.63 ± 1.870 at 8th week and 81.79 ± 1.94 at 12th week. The reduction in mean DBP was statistically significant over 12 weeks of therapy ('P' value < 0.0001). In Olmesartan group, the baseline mean DBP was 91.53 ± 3.28 mm Hg which reduced to 89.91 ± 2.97 at 1st week, 85.70 ± 2.28 at 2nd week, 81.83 ± 2.76 at 4th week, 81.28 ± 2.10 at 8th week, 80.64 ± 2.76 at 12th week. The reduction in mean DBP was statistically significant over 12 weeks of therapy ('P' value < 0.0001). In inter-group

comparison, it was observed that there was statistically no significant difference in mean DBP, when two groups were compared at baseline but at subsequent follow-ups the difference in reduction in DBP was significantly more in Olmesartan group ('P' value 0.2465, 0.1999, 0.0001, 0.0001, 0.0001 at 1st, 2nd, 4th, 8th and 12th week respectively)..

The similar study was conducted by the Gupta et al[15], in patients with stage I hypertension with study duration of 3 months. In Telmisartan (40mg/day) group reduction in mean SBP (from baseline 150 ± 5.26 mmHg to 136 ± 3.22 mmHg at the end of study) and reduction in mean DBP (from baseline 90 ± 3.49 mmHg to 82.07 ± 2.36 mmHg at the end of study) were statistically significant ('P'<0.05). In Olmesartan (20mg/day) group reduction in mean SBP (from baseline 151 ± 6.80 mmHg to 133 ± 5.60 mmHg at the end of study) and reduction in mean DBP (from baseline 91.3 ± 4.29 mmHg to 80.8 ±2.49 mmHg at the end of study) were statistically significant('P'<0.05). But in Inter-group results when two groups were compared at each subsequent follow-ups it was observed that the difference in reduction in SBP and DBP was significantly more in Olmesartan group as compared to Telmisartan group (P value 0.0345, 0.0175, 0.0029 and 0.0037 at 2nd, 4th, 8th and 12th week respectively). The present study results are in accordance with these findings.

Our findings are also consistent with the study done by Nakayama et al[16], who observed that Olmesartan lowered systolic, diastolic and mean blood pressure by 3.3, 2.7 and 3.1 mm Hg more than did Telmisartan (P=0.0305, 0.0087 and 0.0058 for SBP, DBP and mean BP respectively). Moreover, their data also reported that Olmesartan at 20 mg/day lowered BP more than Telmisartan at 40 mg/day. Further they observed that Olmesartan therapy lowered mean systolic and diastolic BP to below 130/80mm Hg which JNC7[17] and ESH/ESC[18] both recommended. In study conducted by Palta et al[19], they observed that in Olmesartan group mean blood pressure (MBP) at baseline was 110.708 ± 2.87 which reduced to 95.188 ± 3.07 after16 weeks of therapy. In Telmisartan group MBP at baseline was 111.453 ± 2.85 which reduced to 96.588 ± 3.11 after 16 weeks of therapy. Mean difference was 15.520 & 14.865 in Olmesartan and Telmisartan group respectively which was statistically significant.

In present study, in Telmisartan group, the baseline mean FBS was 111.5 ± 5.45 mg/dl which changed to 112.3 ± 4.63 mg/dl at 1st week, 110.7 ± 5.96 mg/dl at 2nd week, 111.21 ± 4.22 mg/dl at 4th week, 110.1 ± 4.33 mg/dl at 8th week and 109.8 ± 4.23 mg/dl at 12th week. The change in mean FBS was statistically not significant over 12 weeks of drug therapy (P= 0.080).

In Olmesartan group, the baseline mean FBS prior to treatment was 111.7 ± 5.5 mg/dl. FBS was changed to 111.5 ± 5.30 mg/dl at 1st week, then 111.1 ± 4.94 mg/dl at 2nd week, 111.0 ± 3.97 mg/dl at 4th week, 110.9 ± 3.87 mg/dl at 8th week and 110.1 ± 2.90 mg/dl at 12th week. The reduction in mean FBS was statistically not significant over 12 weeks of drug therapy (P= 0.6117). In inter-group analysis it was observed that there was statistically no significant difference in FBS levels when two groups are compared at baseline and at each subsequent follow-ups.

In a study of Gupta et al[15] mean FBS changed from 98.46 ± 20.7 mg/dl at baseline to 99.57 ± 18.60 mg/dl at 3 months of treatment with Olmesartan, while in Telmisartan group the mean FBS changed from 98.83 ± 14.43 mg/dl at baseline to 91.3 ± 15.05 mg/dl at 3 months. It was observed that there was statistically no significant alterations within the two groups as well as when mean of both groups (inter- group) were compared.

Similarly, in a study conducted by Sasaki T et al [20] mean FBS changed from 111.0 ± 13.2

mg/dl at baseline to 111.4 ± 14.3 mg/dl at 3 months of treatment with Olmesartan. Similarly the mean FBS changed from 111.4 ± 14.3 mg/dl at baseline to 110.7 ± 13.8 mg/dl at 3 months of treatment with Telmisartan (P >0.05). Thus it was observed that there was statistically no significant difference in FBS levels when two groups are compared at baseline and at 3 months follow-ups.

Daikuhara H et al[21] showed that the baseline mean FBS level were 127.1 ± 10.4 mg/dl which reduced to 126.0 ± 10.7 mg/dl at 16 week of treatment with Olmesartan after that Telmisartan was given for another 16 weeks and the change in mean FBS level from 126.0 ± 10.7 to 126.9 ± 10.7 mg/dl were observed. On comparing these values no statistical difference was found and these results are consistent with our findings.

Adverse events were reported by 10 (21.25%) patients in Olmesartan group and 11 (22.91%) patients in Telmisartan group with no statistically significant difference (P= 0.8021). The most common adverse event reported was dry cough 5 (10.41%) in Telmisartan group as compared to Olmesartan group 1 (2.12%). Dizziness, diarrhea and URTI were more common in Olmesartan group than in Telmisartan group. All adverse events were of mild to moderate in severity and none of patients needed discontinuation of treatment. The incidence of adverse events among the treatment groups were comparable and showed no statistical significant difference between them. Overall, in the present study it was observed that both Olmesartan and Telmisartan were well tolerated

Table 1: Baseline Characteristics in Study Groups

Sr. No.	Parameter		Group A (n=48) Telmisartan	Group B (n=47) Olmesartan	'P' value
1.	Age in years		46.13 ± 6.46	47.15 ± 6.85	0.4556†
2.	Gender	Men(n)	23	22	0.8085‡
		Women (n)	25	25	
3.	Body mass index Kg/m^2		25.65 ± 2.00	25.86 ± 2.10	0.6196†
4.	Systolic BP (mmHg)		151.6 ± 3.11	151.7 ± 4.54	0.8401 †
5.	Diastolic BP (mmHg)		90.83 ± 2.50	91.53 ± 3.28	0.2465 †
6.	Fasting blood sugar mg/dl		111.5 ± 5.45	111.7 ± 5.5	0.8431†

*{Values: Mean ± SD (otherwise mentioned); SD: Standard deviation, n: Numbers; *:*

Statistically significant (P<0.05), †: Using 2-tailed unpaired t-test, ‡: Using Fisher's exact test.

Table 2: Effect of Telmisartan and Olmesartan on Systolic and Diastolic blood pressure and fasting blood sugar

Sr. No	Parameter	Group A TEL (Mean ± SD)	Group B OLM (Mean ± SD)	*P value inter group*†
1	SBP (mmHg)			
	Day 0	151.6 ± 3.11	151.7 ± 4.54	0.8401
	Week 1	147.3 ± 2.95	145.3 ± 3.10	0.0239*
	Week 2	144.5 ± 2.53	142.7 ± 3.83	0.0006*
	Week 4	140.0 ± 2.44	137.2 ± 3.13	0.0001*
	Week 8	139.5 ± 2.09	133.7 ± 3.51	0.0001*
	Week 12	137.2 ± 2.13	134.2 ± 3.43	0.0001*
	P value intragroup§	< 0.0001*	< 0.0001*	
2	DBP (mmHg)			
	Day 0	90.83 ± 2.50	91.53 ± 3.28	0.2465
	Week 1	89.21 ± 2.32	89.91 ± 2.97	0.1999
	Week 2	86.54 ± 2.53	85.70 ± 2.28	0.0934
	Week 4	84.42 ± 2.94	81.83 ± 2.76	0.0001*
	Week 8	83.63 ± 1.87	81.28 ± 2.10	0.0001*
	Week 12	81.79 ± 1.90	80.64 ± 1.39	0.0011*
	P value intragroup§	< 0.0001*	< 0.0001*	
3	Fasting blood sugar			
	Day 0	111.5 ± 5.45	111.7 ± 5.50	0.8431
	Week 1	112.3 ± 4.63	111.5 ± 5.30	0.4347
	Week 2	110.7 ± 5.96	111.1 ± 4.94	0.7281
	Week 4	111.2 ± 4.22	111.0 ± 3.97	0.8832
	Week 8	110.1 ± 4.33	110.9 ± 3.87	03919
	Week 12	109.8 ± 4.23	110.1 ± 2.90	0.6124
	P value *intragroup*§	0.0800	0.6117	

*{Values: Mean ± SD (otherwise mentioned); SD: Standard deviation, n: Numbers; *: Statistically significant (P<0.05), †: Using 2-tailed unpaired t-test, §: Using Repeated measure ANOVA.}*

Table 3: Adverse drug effect in both groups

Adverse effect	Group A (Telmisartan)	Group B (Olmesartan)	'P" value (Intergroup) ‡
Dry cough	5 (10.41%)	1 (2.12%)	0.2038
Diarrhoea	2 (4.16%)	3 (6.38%)	0.6773
Dizziness	1 (2.08%)	2 (4.25%)	0.6170
URTI	3 (6.25%)	4 (8.51%)	0.7145
Total ADR	11 (22.91%)	10 (21.25%)	0.8021

*{Values: Mean ± SD (otherwise mentioned); SD: Standard deviation, n: Numbers; *: Statistically significant (P<0.05), ‡: Using Fisher's exact test.}*

Conclusion:

Both Telmisartan and Olmesartan effectively controlled systolic and diastolic blood pressure in hypertensive patients but reduction was more significant in Olmesartan group. Both these drugs having no significant effect on fasting blood glucose level. The relatively low doses of both the drugs and short period (12 week) of follow up may have been too less to permit a complete assessment of the metabolic effect.

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