Comparative study to evaluate efficacy & cost effectiveness of Olmesartan versus Telmisartan, in patients of stage I hypertension

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ABSTRACT

Background: *Hypertension is one of the most common diseases in the world. It is an important and independent risk factor for atherosclerosis, heart failure, renal disease, and peripheral arterial disease. It is directly responsible for 57% of all stroke deaths and 42% of coronary heart disease deaths in India*

Objectives: *To evaluate and compare efficacy and cost effectiveness in hypertensive patients receiving Olmesartan and Telmisartan in Stage I hypertension*

Material and methods: *The present study was an open, prospective, randomized, parallel group comparative study conducted in 60 patients of stage I hypertension over a period of 16 weeks. Patients were randomly allocated to two, age and sex, matched groups of 30 patients each. Group I patients were started on Olmesartan at a dose of 20 mg & Group II patients were put on Telmisartan at a dose of 40 mg. The BP lowering efficacy and cost effective analysis of Olmesartan versus Telmisartan was calculated & compared. The data was entered in Microsoft excel and compiled. Statistical analysis was done using various tests.*

Results: *Maximum patients in both the groups were in age group of 51-60 years. In group I there were 13 males and 17 females. In group II there were 14 males and 16 females. Both Olmesartan and Telmisartan are effective in lowering systolic & diastolic BP in supine & sitting positions & mean BP is also lowerer, more in Olmesartan group. By cost effective analysis Telmisartan was found more cost effective. Incremental cost effective ratio was found to be 218.35.*

Conclusion: *Both Olmesartan and Telmisartan belong to the same antihypertensive drug class, effectively reduce systolic and diastolic blood pressure at various visits. Taking into account Total cost Telmisartan was more cost effective than Olmesartan. ICER was found to be 218.35.*

Key Words: Olmesartan, telmisartan, cost effectiveness, hypertension, angiotensin receptor blockers

Introduction

Hypertension is one of the most common diseases in the world. Its origin dates back to 2600 BC when the ancient Chinese could only suspect hypertension by the quality of one's pulse and called it hard pulse disease & venesection & bleeding were recommended as the sole means of detecting hypertension. [1] The term "essentielle hypertonie", i.e. essential hypertension, was first quoted by the German physician Frank E in 1911 and continues to be used today. [2] It is defined as sustained increase in blood pressure ≥ 140/90 mmHg, a criterion that characterizes a group of patients whose risk of hypertension related cardiovascular disease is high enough to merit medical attention. [3] It is associated with marked morbidity, mortality & places a high burden on health care system. The risk of both macrovascular & microvascular complications including stroke, coronary artery disease, peripheral vascular disease, retinopathy, nephropathy & possibly neuropathy increases with hypertension.[4] A decrease of 2mmHg in BP can prevent 151,000 stroke and 153,000 coronary heart disease deaths in India. [5] As per the World Health Statistics 2012, of the estimated 57 million global deaths in 2008, 36 million (63%) were due to non communicable diseases (NCDs). The largest proportion of NCD deaths is

caused by cardiovascular diseases (48%). It is seen frequently in individuals aged 40 years and also affects about half of population aged 60 years and above. [6] In terms of attributable deaths, raised blood pressure is one of the leading behavioural and physiological risk factor to which 13% of global deaths are attributed. Nearly 1 billion adults had hypertension in 2000 & this is predicted to increase to 1.56 billion by 2025. [7] Pooled epidemiological studies show that the average prevalence of hypertension in India is 25% in urban and 10% in rural population. [8]

Treatment of hypertension

Healthy life style is mandatory. The life style modifications include weight reduction in overweight or obese patients (BMI<25kg/m^2), dietary salt restriction (<6g/d), adopting DASH (Dietary approaches to stop hypertension), eating plan which is rich in fruits, vegetables, low fat dietary products with reduced content of saturated and total fat, moderation in alcohol consumption and mental relaxation techniques, physical activity with brisk walk for 30 mins daily. [10]

Pharmacotherapeutic measures include diuretics, beta blockers, calcium channel blockers, ACE inhibitors, calcium channel blockers, angiotensin receptor antagonists include losartan, Irbesartan, Candesartan, Valsartan, Telmisartan, Olmesartan. The various drugs differ with respect to dosing, metabolism, elimination, clinical efficacy and investigational applications

ARBs are well tolerated, side effects profiles are indistinguishable or even better than those of placebo. Unlike ACE inhibitors these do not induce cough. The efficacy and tolerability of ARBs, as well as other ancillary benefits, have led to their rapid uptake and widespread use. Angiotensin receptor blockers work by inhibiting the effects of a hormone called

angiotensin II, which produces a number of effects in the body. All the effects of Angiotensin II are mediated by angiotensin receptors. (AT)

Olmesartan medoxomil is a non peptide angiotensin II receptor antagonist. The drug acts by selectively blocking angiotensin II type 1 receptor sites in vascular smooth muscle, thereby inhibiting the vasoconstrictor effects of angiotensin II. [11] It is a pro-drug that is rapidly hydrolyzed into Olmesartan & absorbed from the gastrointestinal tract into the body. The peak plasma concentration reaches in 1to 2 hrs. Oral bioavailability is not affected by food.

Telmisartan angiotensin receptor blocker (ARB) shows high affinity for the angiotensin II type 1 (AT1) receptors. In addition to blocking these receptors, it acts as a selective modulator of peroxisome proliferator-activated receptor gamma (PPAR-γ), a central regulator of insulin and glucose metabolism. [12] Peak plasma levels are obtained 0.5-1 hour after oral administration and the plasma t1/2 is ~24 hours. Telmisartan is cleared from the circulation mainly by biliary secretion of intact drug. The plasma clearance of Telmisartan is affected by hepatic insufficiency.

Taking into account increasing prevalence of hypertension the present study aims to compare Olmesartan & Telmisartan, in efficacy & cost effectiveness in patients of Stage 1 Hypertension. Treatment of hypertension is lifelong & antihypertensive drug therapy is a common target of cost cutting efforts globally.

MATERIAL & METHODS

In this prospective open randomized parallel group comparative study 60 patients of hypertension attending the department of medicine Govt Medical

College & Rajindra Hospital, Patiala were included. The study was conducted over a period of 16 weeks and consisted of 8 follow up visits. The patients were well informed about the study procedure and written informed consent was taken. After taking a thorough history, clinical examination and biochemical investigations patients were randomly allocated to two age and sex matched groups of 30 cases each. Group I patients were started on Olmesartan (Olmezest 20) at a dose of 20mg/d. Group II patients were put on Telmisartan (Cresar 40) at a dose of 40 mg/d. Blood pressure was measured in supine and sitting positions at all the visits. For cost effective analysis ICER calculated i.e units of cost per benefits/effect unit. The patients fulfilling the inclusion criteria after verifying exclusion criteria were included. Inclusion and exclusion criteria were as follows:

Inclusion criteria:
- Patients with stage I hypertension.
- Adult male/ female aged 21 years or older and non pregnant females not planning for conception.
- Patient should not be on any other antihypertensive medication.

Exclusion criteria:
- Patient with history of hypersensitivity to Olmesartan or Telmisartan.
- Pregnant / lactating/ women planning to conceive.
- Patient with history of refractory, secondary or malignant hypertension.
- Patient with history of renal and hepatic disease.
- Patient unwilling or unable to comply with the study proceedings to give informed written consent.
- Patient with history of stroke, myocardial infarction, cerebral
- Haemorrhage and hypertensive encephalopathy

Blood pressure, both systolic and diastolic was recorded by mercury Sphygmomanometer and efficacy assessment was done by measuring blood pressure in supine and sitting positions on right arm after 10 min of rest. Blood pressure was measured at baseline and at every 2 weeks for 16 weeks. Cost-effectiveness analysis was done. The maximum retail price (MRP) of all the study drugs was noted. Mean cost of drugs for 16 weeks in both the treatment group was calculated.

The results of observations of individual patients were pooled for each group. Statistical analysis was performed using SPSS software version 20. All the analyses were performed on an intention to treat basis. For analysis of quantitative data, paired/unpaired t test was used.

Results

The Table 1, shows mean supine systolic blood pressure in Group I and Group II at baseline, 2, 4, 6, 8, 10, 12, 14 and 16 weeks. Mean diff at baseline was 1.33 ± 0.862 (p=0.092), at 2 weeks was 2.13 ± 0.39 (p=0.007) & was highly significant. Mean diff at 4 weeks was 0.93 ± 0.24 (p=0.064), at 6 weeks was 0.40 ± 0.374 (p=0.551), at 8weeks was 0.07 ± 0.34 (p=0.878), at 10 weeks was 0.20 ± 0.06 (p=0.678), at 12 weeks was 0.20 ± 0.556 (p=0.798), at 14 weeks was 1.2 ± 0.162 (p=0.162), at 16 weeks was 2.2 ± 0.149 (p= 0.080).

Table 2, shows mean supine diastolic blood pressure in group I and group II at baseline, 2, 4, 6, 8, 10, 12, 14 and 16 weeks. Mean Diff at baseline was 0.46 ± 0.20 (p=0.469), at 2 weeks was 3.33 ± 0.157 (p=0.031), at 4 weeks was 1.13 ± 0.035 (p=0.037), at 6 weeks was 1.13 ± 0.173 (p=0.056), at 8 weeks was 1.0 ± 0.237 (p=0.046), at 10 weeks was 1.2 ± 0.161 (p=0.041), at 12 weeks was 0.53 ± 0.491 (p=0.113), at 14 weeks was 1.0 ± 0.078 (p=0.085) and at 16 weeks was 1.0 ± 0.045 (p=0.093).

Table 1: Comparison of SBP supine at different visits in group I and group II

VISIT	GROUP I Mean ± SD	GROUP II Mean ± SD	Mean Diff ± SD	T test (p value)
Baseline	147.67± 3.407	149.00 ±2.545	1.33±0.862	0.092
2 weeks	141.60±2.749	143.73 ± 3.139	2.13±0.39	0.007**
4 weeks	135.87± 2.029	136.80 ± 1.789	0.93±0.24	0.064
6 weeks	134.47± 2.763	134.87 ± 2.389	0.40±0.374	0.551
8 weeks	131.60±1.923	131.67 ±1.583	0.07±0.34	0.878
10 weeks	129.13±1.871	129.33 ±1.844	0.20±0.027	0.678
12 weeks	127.93±2.993	127.73 ±3.050	0.20±0.06	0.798
14 weeks	125.27±2.993	126.47 ±3.549	1.20±0.556	0.162
16 weeks	124.80±4.715	127.00 ± 4.864	2.20±0.149	0.080

Table 2: Comparison of DBP supine at different visits in group I and group II

VISIT	GROUP I Mean ± SD	GROUP II Mean ± SD	Mean Diff± SD	T test (p value)
Baseline	92.07±2.545	92.53±2.345	0.46±0.20	0.469
2 weeks	86.60±2.415	89.93±2.258	3.33±0.157	0.031*
4 weeks	85.20±2.074	86.33±2.039	1.13±0.035	0.037*
6 weeks	83.00±2.334	84.13±2.161	1.13±0.173	0.056*
8 weeks	81.73±2.016	82.73±1.779	1.00±0.237	0.046*
10 weeks	81.00±2.149	82.20±2.310	1.20±0.161	0.041*
12 weeks	80.60±1.499	81.13±1.008	0.53± 0.491	0.113
14 weeks	80.60±2.175	81.60±2.253	1.00±0.078	0.085
16 weeks	80.33±2.294	81.33±2.249	1.00±0.045	0.093

Table 3: Comparison of SBP sitting at different visits in group I and group II

VISIT	GROUP I Mean ± SD	GROUP II Mean ± SD	Mean Diff ± SD	T test (p value)
Baseline	147.87±3.521	149.20±3.809	1.33±0.288	0.165
2 weeks	141.67±2.675	143.93±2.947	2.26±0.272	0.006**
4 weeks	136.07±1.856	137.00±1.640	0.93±0.216	0.044*
6 weeks	134.53±2.569	134.93±2.333	0.40±0.236	0.530
8 weeks	131.73±1.721	131.93±1.529	0.20±0.192	0.636
10 weeks	129.20±1.789	129.40±1.905	0.20±0.116	0.676
12 weeks	127.93±2.993	127.87±2.968	0.06±0.025	0.938
14 weeks	125.27±2.993	126.53±3.441	1.26±0.448	0.135
16 weeks	124.87±4.659	127.07±4.806	2.20±0.147	0.077

*significant (p<0.05) * *highly significant (p<0.01) *** very highly significant (p<0.001)

This table shows mean sitting systolic blood pressure in group I and group II at baseline 2, 4, 6, 8, 10, 12, 14 and 16 weeks. Mean Diff at baseline was 1.33±0.288 (p=0.165), at 2 weeks was 2.26±0.272 (p=0.006), at 4 weeks was 0.93± 0.216 (p=0.044), at 6 weeks was 0.40±0.236 (p=0.530), at 8 weeks was 0.20± 0.192 (p=0.636), at 10 weeks was 0.20±0.116 (p=0.676), at 12 weeks was 0.06±0.025 (p=0.938), at 14 weeks was 1.26±0.448 (p=0.135) and at 16 weeks was 2.2±0.147 (p= 0.077).

Table 4 shows mean sitting diastolic blood pressure in group I and group II at baseline 2, 4, 6, 8, 10, 12, 14 and 16 weeks. Mean Diff at baseline was 0.46±

0.294 (p=0.473), at 2 weeks was 1.26±0.293 (p=0.034*), at 4 weeks was 1.13±0.087 (p=0.027*), at 6 weeks was 1.13±0.024 (p=.045*), at 8 weeks was 1.13±0.092 (p= 0.016*), at 10 weeks was 1.2±0.185 (p=0.042*), at 12 weeks was 0.67±0.387 (p=0.054*), at 14 weeks was 1.07±0.119(p=0.068) and at 16 weeks was 1.0±0.015 (p=0.089).

This table shows MBP at baseline in Group I was 110.708 (2.87) & 95.188 (3.07) at 16 weeks. The MBP in Group II at baseline was 111.453 (2.85) & 96.588 (3.11) at 16 weeks. On comparing group I & group II, the mean difference was statistically significant. (p=0.05)

Table 4: Comparison of DBP sitting at different visits in group I and group II

VISIT	GROUP I Mean ± SD	GROUP II Mean ± SD	Mean Diff ± SD	T test (p value)
Baseline	92.27±2.612	92.73±2.318	0.46±0.294	0.473
2 weeks	88.87±2.389	90.13±2.096	1.26±0.293	0.034**
4 weeks	85.40±1.976	86.53±1.889	1.13±0.087	0.027*
6 weeks	83.07±2.148	84.20±2.124	1.13±0.024	0.045*
8 weeks	81.87±1.814	83.00±1.722	1.13±0.092	0.016*
10 weeks	81.07±2.148	82.27±2.333	1.20±0.185	0.042*
12 weeks	80.60±1.499	81.27±1.112	0.67±0.387	0.054*
14 weeks	80.60±2.175	81.67±2.294	1.07±0.119	0.068
16 weeks	80.40±2.253	81.40±2.238	1.00±0.015	0.089

Table 5: Comparison of mean blood pressure in group I and group II

	MBP± SD	MBP± SD	Mean difference± SD	t-test P value
GROUP I	110.708±2.87	95.188±3.07	15.520 ±0.20	0.05
GROUP II	111.453±2.85	96.588±3.11	14.865±0.26	

Table 6: Cost effectiveness analysis

Parameters	GROUP I	GROUP II	Difference in cost C1-C2	Difference in effectiveness E1-E2	ICER
Cost (Rs)	884.80 ±29.49	750.40 ±25.01	134.40± 4.48	0.655 ±0.06	218.35
Fall in mean MBP(mmHg)	15.520 ± 0.20	14.865 ± 0.26			

This table shows the cost effectiveness analysis of the Group I and Group II. Average cost of treatment of group I was Rs 884.80 ± 29.49 and group II was Rs 750.40± 25.01. Fall in MAP of group I was 15.520±0.20 mmHg and group II was 14.865±0.26 mm Hg. Difference in cost of treatment of both the group was Rs 134.40±4.48. Difference in the effectiveness in reduction of BP of both the group was0.655± 0.06.ICER was calculated by dividing the cost of treatment of both the groups to difference in effectiveness in reduction of blood pressure of both the groups. Its value comes out to be Rs 218.35 i.e In Olmesartan group to reduce the mean MBP by one mm Hg additional cost of Rs 218.35 have to be paid by the patient.

Discussion

Hypertension is a major contributor to cardiovascular disease and a leading cause of stroke, myocardial infarction, heart failure and kidney disease. Although benefits of blood pressure reduction have been well documented, the majority of patients remain undertreated and poorly controlled. Since hypertension is a chronic condition it is mandatory to ensure proper patient compliance to antihypertensive therapy. Medication costs, side effects of the drugs, poor quality of life are some of the main factors contributing to poor patient compliance.

EFFICACY

Systolic Blood Pressure In Supine Position: In the present study, systolic blood pressure in supine position fell from mean of 147.67 (3.407) at baseline to 124.80(4.715) mm Hg after 16 weeks of treatment in group I. There was lowering of BP on every visit & at 16 weeks there was a mean difference of 22.87mm Hg from baseline & this lowering was significant at 2 weeks (Table no. 1).In group II supine systolic blood pressure fell on each visit from mean 149(3.991) at baseline to 127(4.864) mm Hg after 16 weeks of treatment. At 16 weeks there was a mean difference of 22 mm Hg from baseline.

Diastolic Blood Pressure In Supine Position: In the present study, diastolic blood pressure in supine position fell from mean 92.07(2.545) at baseline to 80.33(2.294) mm Hg after 16 weeks of treatment in group I There was lowering of BP on every visit and was significant at 2,4,6,8& 10 weeks. (Table no.2).In group II supine diastolic blood pressure fell on each visit from mean of baseline 92.53(2.345) to 81.33(2.249) mm Hg after 16 weeks of treatment. At 16 weeks there was mean difference of 11.20 mm Hg from baseline.

Systolic Blood Pressure In Sitting Position: In the present study, systolic blood pressure in sitting position fell from mean 147.87(3.521) at baseline to 124.87(4.659) mm Hg after 16 weeks of treatment in group I. There was lowering of BP on every visit which was significant at 2, 4 weeks. (Table no.3) At 16 weeks there was mean difference of 23 mm Hg from baseline. In group II sitting systolic blood pressure fell on each visit from mean 149.20 (3.809) at baseline to 127.07 (4.806) mm Hg after 16 weeks of treatment. At 16 weeks there was mean difference of 22.13 mm Hg from baseline.

Diastolic Blood Pressure In Sitting Position: In the present study, diastolic blood pressure in sitting position fell from mean of 92.27(2.612) at baseline to 80.40(2.253) mm Hg after 16 weeks of treatment in group I. There was lowering of BP at every visit & was significant at 2, 4, 6, 8, & 10 weeks (Table 4). At 16 weeks there was mean difference of 11.87 mm Hg from baseline. In group II sitting diastolic blood pressure fell on every visit from mean 92.73(2.318) at baseline to 81.40(2.238) mmHg after 16 weeks of

treatment. At 16 weeks there was mean difference of 11.33 mm Hg from baseline.

Mean blood Pressure: In group I mean MBP at baseline was 110.708 (2.87) & at 16 weeks was 95.188 (3.07). In group II mean MBP at baseline was 111.453 (2.85) & at 16 weeks was 96.588 (3.11). Mean diff in group was 15.520 in group I & 14.865 in group II. However on comparing the two groups the difference was found to be statistically significant (p=0.05). There was more lowering of blood pressure in group I (olmesartan group)

Cost effectiveness

The daily cost with Olmesartan (Olmezest 20) was Rs 7.9 & Rs 884.8 for 16 weeks and Telmisartan (Cresar 40) daily cost was Rs 6.7 & Rs 750.4 for 16 weeks. For Yearly treatment Olmesartan cost Rs 2812.4 & Telmisartan costs Rs 2385.2.The cost effectiveness analysis of the Group I and Group II was done. Average cost of treatment of group I was Rs 884.80 ± 29.49 and group II was Rs 750.40± 25.01. Fall in MAP of group I was15.520±0.20mmHg and group II was 14.865±0.26mm Hg. ICER was calculated comes out to be Rs 218.35 i.e In Olmesartan group to reduce the mean MBP by one mm Hg additional cost of Rs 218.35 have to be paid by the patient. Brunner [13] in 2004 conducted a study,patients were randomized to Olmesartan (2.5-80 mg) or placebo once daily. It was found that Olmesartan produced a dose dependent decrease in diastolic & systolic blood pressures as compared to placebo which is consistent with our study. Nakayama et al[14] in 2007conducted a study to compare the effects of Olmesartan and Telmisartan on blood pressure, & concluded that Olmesartan lowered mean systolic and diastolic blood pressure more significantly than did Telmisartan which is also consistent with our study. In Jadhav et al [15] study Patients were randomized to

either olmesartan or telmisartan monotherapy, Olmesartan showed a Significant lowering of average 24hrs SBP as compared to telmisartan which is also consistent with our study Sasaki et al [16]evaluated the effects of telmisartan and olmesartan &concluded that telmisartan is more beneficial than olmesartan in reducing blood pressure in the early morning in patients with hypertension which is not consistent with our study. Arao et al [17] conducted a crossover study in hypertensive patients with type 2 diabetes, & concluded that there is no significant difference in blood pressure reduction rate between Olmesartan & Telmisartan treatment groups. This is also not consistent with our study.

COST EFFECTIVENESS

Difference in cost of treatment of both the groups was Rs134.40±4.48. Difference in the effectiveness in reduction of BP of both the group was 0.655± 0.06. ICER value comes out to be Rs 218.35 .Telmisartan was found to be cost effective. There was no study published that compares costeffectiveness of Olmesartan & Telmisartan. But Borsema et al [18]conducted a study to evaluate cost effectiveness, showed that treatment with olmesartan versus losartan, valsartan, and irbesartan resulted in a significantly larger decrease in BP (11.5 vs 8.2, 7.9and 9.9 mmHg [p < 0.05], respectively) and consequently more complications averted. Cost effectiveness for olmesartan, losartan, valsartan, and irbesartanwas estimated at euro 39100, euro77100, euro70700, and euro50,900 percardiovascular complication averted, respectively. The incremental cost effectiveness analysis indicated the most favorable cost-effectivenes soutcome for olmesartan, with lower costs and less cardiovascular complications for

olmesartan compared with the other three ARBs.

Both Olmesartan and Telmisartan effectively lowered systolic and diastolic blood pressure in supine and sitting positions, Olmesartan lowers Blood pressure more than Telmisartan. Taking into account cost Telmisartan is more cost effective. The limitation of our study was that sample size is less & can be increased to increase reliability and blinding can be done.

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Cite this article as: Palta S, Sehgal VK, Gupta AK, Singh H. Comparative study to evaluate efficacy & cost effectiveness of Olmesartan versus Telmisartan, in patients of stage I hypertension. Int J Med and Dent Sci 2015; 4(1):568-576.

Source of Support: Nil
Conflict of Interest: No