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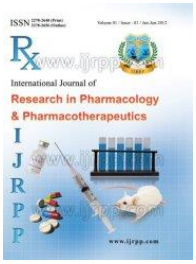

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A comparative study between efficacy and safety of telmisartan (ARB) and enlapril (ACEI) in hypertensive patients

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ABSTRACT

Background

Hypertension is the most common cardiovascular disease that affects about 1 billion individuals worldwide [1]. It is defined conventionally as sustained increase in blood pressure ≥ 140/90mmHg. In India the prevalence of hypertension is 25% in urban population and 10% in rural population The WHO reports that hypertension is responsible for 62% of cerebrovascular disease and 49% ischemic heart disease with little variation by sex.

Aims and objectives

To compare the efficacy and adverse effect profile of telmisartan and enalapril maleate in essential hypertensive patients. [2]. To compare the incidence of adverse effects in both telmisartan and enalapril groups.

Methods

This was a prospective, observational study conducted on outpatients attending Medicine OPD in SMC/GGH, Vijayawada. A total of 80 patients were recruited in the study and divided in to two groups with 40 patients in each group. The total period of the study was 3 months. Clinical examination findings, investigations and relevant history were obtained from studied patients and entered in the proforma. Periodic recording of blood pressure was done for every 2, 6 and 12weeks. Laboratory investigation were carried out before initiation of therapy and at the end of the study.

Results

Essential hypertension was more in the age group of 50-55 years accounting for n=24 followed by 40-44yrs which was n=20. After 12 weeks of therapy in essential hypertension group systolic blood pressure was reduction to normal level was 85% with telmisartan and 70% with Enalapril maleate. Diastolic B.P. reduction was 70% with telmisartan and 60% with Enalapril maleate treatment in patients after 12 weeks of treatment. Cough – 2.5% telmisartan group, 10% in Enalapril maleate group, between 10-12 weeks. Rash – observed equally 2.5% in telmisartan group.

Conclusion

In the present study both telmisartan and enalapril maleate reduced both systolic and diastolic blood pressures in both Groups at 2 weeks, 6 weeks and 12 weeks almost equally. But in terms of adverse effect profile, persistent dry cough was observed in 10% of enalapril maleate treated group and 2.5% in telmisartan treated group. Rash was observed 2.5% with both drugs. Telmisartan is effective and better tolerated than enalapril in the treatment hypertension.

Keywords: Enalapril, Telmisartan, Essential hypertension.

INTRODUCTION

Hypertension is the most common cardiovascular disease that affects about 1 billion individuals worldwide [1]. It is defined conventionally as sustained increase in blood pressure ≥ 140/90mmHg. In India the prevalence of hypertension is 25% in urban population and 10% in rural population (59.9 and 69.9 per 1000 in males and females respectively in the urban and 35.5 and 35.9 per 1000 males and females respectively in rural population[2]. The WHO reports that hypertension is responsible for 62% of cerebrovascular disease and 49% ischemic heart disease with little variation by sex. The hypertension is the number one attributable risk factor for death accounting 20% of all deaths worldwide (nearly 10 million). The risk of developing cardiovascular complications is higher when the individual combines hypertension with other risk factors like obesity, diabetes mellitus, hypercholesterolemia/ dyslipidemias or smoking [3].

According to BHS (British Hypertension Society) updated clinical guidelines in the management of hypertension are: 1) In hypertensive patients younger than 55 years, first choice therapy should be an ACE Inhibitor (ACEI) or an Angiotensin Receptor Blocker (ARB). 2) In hypertensive patients aged 55 years and over initial therapy should be either calcium channel blocker or a thiazide diuretic. 3) If initial therapy was with a calcium channel blocker or thiazide type diuretic and second drug is required add an ACE inhibitor or an ARB. Initial therapy was with an ACE inhibitor, add a calcium channel blocker or a thiazide type diuretic. 4) If the hypertension is not controllable with combinations of above groups of drugs, add further diuretic therapy or alpha blocker/beta blocker [4].

BLOOD PRESSURE CLASSIFICATION [5]

Blood Pressure Classification	Systolic, mmHg	Diastolic, mmHg
Normal	≤ 120	And ≤ 80
Prehypertension	120-139	Or 80-89
Stage 1 Hypertension	140-159	Or 90-99
Stage 2 Hypertension	≥ 160	Or ≥ 100
Isolated Systolic Hypertension	≥ 140	And ≤ 90

The antihypertensives of the 1980-90s are Angiotensin Converting Enzyme (ACE) Inhibitors and calcium channel blockers. Angiotensin II antagonists are the latest antihypertensives. With the development of many types of drugs, delineation of their long term benefits and complications, and understanding of the principles on which to combine them, hypertension can now be controlled in most cases with minimum discomfort [6]. Telmisartan is available as tablets for oral administration, containing 20 mg, 40 mg or 80 mg of telmisartan. Blockage of the angiotensin II receptor inhibits the negative regulatory feedback of angiotensin II on rennin secretion, but the resulting increased plasma renin activity and angiotensin II circulating levels do not overcome the effect of telmisartan on blood pressure [7].

Enalapril maleate is the second Angiotensin converting enzyme inhibitor. It inhibits conversion of inactive angiotensin I to active angiotensin II. b) It is highly selective drug; does not interact directly with other components of rennin-angiotensin system. c) Enalapril maleate increase bradykinin levels and bradykinin stimulates prostaglandin biosynthesis.

Bradykinin and prostaglanding contribute to pharmacological effects of ACE Inhibitors [8].

AIMS AND OBJECTIVES

1. To compare the efficacy and adverse effect profile of telmisartan and enalapril maleate in essential hypertensive patients.
2. To compare the incidence of adverse effects in both telmisartan and enalapril groups.

MATERIALS AND METHODS

This was a prospective, observational study conducted on outpatients attending Medicine OPD in SMC/GGH, Vijayawada. The total period of the study was 3 months. The study protocol was approved by the Institutional Ethics Committee and written informed consent is taken from all patients enrolled in the study. A total of 80 patients with essential hypentension were recruited in the study and divided in to two groups with 40 patients in each group. Telmisartan Group received 40mg tab, Enalapril Group received 5mg tab. Clinical examination findings, investigations and relevant history were obtained from studied patients and entered in the proforma. Periodic recording of blood pressure was done for every two weeks. Laboratory investigation were carried out before initiation of therapy and at the end of the study. The Blood pressure was measured in right hand, in sitting posture with arm supported at heart level.

Inclusion criteria

1. Males and Females of age between 25 yrs – 55 yrs.
2. Mild and moderate essential hypertensive patients with Systolic B.P. between 130-169mm Hg and Diastolic BP between 90-109mm Hg.
3. Diabetic hypertensive patients who are under glycemic control receiving oral hypoglycaemic drugs.
4. Patients with history of hypertension without talking antihypertensive treatment for a period of one month.

Exclusion criteria

1. Males and Females age ≤ 25 yrs. and ≥ 55 yrs.
2. Pregnant & Lactating women
3. Patients already on other antihypertensive drugs.
4. IDDM patients receiving insulin
5. Patients with other conditions like – Severe hypertension, Hepatic failure, Respiratory failure, Renal failure, Congestive heart failure, Acute severe asthma, Secondary Hypertension, Chronic use of cortiscosteroids, NSAIDS and oral contraceptive pills.

Statistics

Data was analyzed using frequency & percentages. Data was described in form of tables. Data was entered in Microsoft excel 2007. IBM SPSS software version 21 is used for calculations. Paired and Unpaired 't' test is used for comparing attributes and variables of study. P <0.05 was considered as significant.

RESULT

A total of 80 patients with essential hypertension were recruited in the study and divided in to two groups with 40 patients in each group. Out of these 80 patients 46 were males and 34 were females. (Table.No:1)

Table.No:1 Gender Distribution of patients

S.No.	Gender	Essential hypertension	Percentage
1.	Male	46	57.2
2.	Female	34	44.8
	Total	80	

As per table no.2. Essential hypertension was more in the age group of 50-55 years accounting for n=24 followed by 40-44yrs which was n=20.

Table.No:2 Age-wise Distribution of patients

S.No.	Age Group	Essential hypertension	Total
1.	25-29	8	8
2.	30-34	8	8
3.	35-39	10	10
4.	40-44	20	20
5.	45-50	10	10
6.	50-55	24	24

After 2 weeks of therapy in essential hypertension Group Systolic Blood pressure reduction was normal in 60% with Telmisartan and with Enalapril maleate was 65%.

Table.No:3 After 2 weeks reduction in Systolic B.P

S.No.	Systolic B.P. reduction	Telmisartan	%	Enalapril	%
1.	Present	24	60%	26	65%
2.	Absent	16	40%	14	35%
	Total	40		40	

Reduction in Diastolic B.P after 2weeks therapy with telmisartan was 40% and Enalapril maleate was 15%.

Table.No:4 After 2 weeks reduction in Diastolic B.P.

S.No.	Systolic B.P. reduction	Telmisartan	%	Enalapril	%
1.	Present	8	40%	6	15%
2.	Absent	32	60%	34	85%
	Total	40		40	

After 6 weeks of therapy in essential hypertension group systolic blood pressure reduction to normal level was 75% with telmisartan and 65% with Enalapril maleate.

Table.No:5 After 6 weeks reduction in Systolic B.P.

S.No.	Systolic B.P. reduction	Telmisartan	%	Enalapril	%
1.	Present	30	75%	26%	65%
2.	Absent	10	25%	14%	35%
	Total	40		40	

As per table no 6 a total of 20 patients achieved a reduction in Diastolic B.P with telmisartan and 14 patients in Enalapril group after 6 weeks of therapy.

Table.No:6 After 6 weeks reduction in Diastolic B.P.

S.No.	Systolic B.P. reduction	Telmisartan	%	Enalapril	%
1.	Present	20	50%	14	35%
2.	Absent	20	50%	26	65%
	Total	40		40	

After 12 weeks of therapy in essential hypertension group systolic blood pressure was reduction to normal level was 85% with telmisartan and 70% with Enalapril maleate.

Table.No:7 After 12 weeks reduction in Systolic B.P.

S.No.	Systolic B.P. reduction	Telmisartan	%	Enalapril	%
1.	Present	34	85%	28	70%
2.	Absent	6	15%	12	30%
	Total	40		40	

Diastolic B.P. reduction was 70% with telmisartan and 60% with Enalapril maleate treatment in patients after 12 weeks of treatment.

Table.No:8 After 12 weeks reduction in Diastolic B.P.

S.No.	Systolic B.P. reduction	Telmisartan	%	Enalapril	%
1.	Present	28	70%	24	60%
2.	Absent	12	30%	16	40%
	Total	40		40	

ADVERSE EFFECTS

Cough – 2.5% termisartan group, 10% in Enalapril maleate group, between 10-12 weeks. Rash – observed equally 2.5% in telmisartan group. There are no significant changes in the results of biochemical and pathological investigations carried before and after completion of the study. Fundus examination was normal in all cases before and after the study.

Table.No:9 Adverse Effects

S.No.	ADR	Telmisartan	Enalapril	Total
1.	Cough	2 (2.5%)	4 (10%)	6
2.	Rash	2 (2.5%)	2 (2.5%)	4
	Total	4	6	10

DISCUSSION

Hypertension is the most common cardiovascular disease that affects about 1 billion individuals worldwide. The WHO reports that hypertension is responsible for 62% of cerebrovascular disease and 49% ischemic heart disease with little variation by sex. The hypertension is the number one attributable risk factor for death accounting 20% of all deaths worldwide (nearly 10 million). So the present study was aimed to estimate the efficacy and tolerability of telmisartan in comparison with enalapril maleate in patients of hypertension. Many studies indicated similar efficacy profile for telmisartan and enalapril. More adverse effect profile was observed with enalapril maleate in comparison with telmisartan. This could be due to selective AT1 receptor blockade.

According to Zouz, Xi Gel Y nam HB, Zhou Of et al, 28 randomized control trial involving 5157 patients out of 721 studies on telmisartan have greater diastolic reduction than enalapril, (weighed mean difference 1.82, 95% confidence interval 0.66 to 2.99). Telmisartan showed greater diastolic B.P. reduction than enalapril. Relative risk (1.15, 95% c.i. 1.05 to 1.26). Telmisartan had fewer drug related adverse events than enalapril (RR – 0.57 c.u.i. 0.74). The meta analysis indicates that telmisartan provides a superior B.P. control to enalapril and better tolerability in hypertensive patients [9].

JH Chen studied 147 patients of Taiwanese, mild to moderate essential hypertensives on Telmisartan 40 mg, Enalapril – 10mg once daily. Treatment period 6 weeks. Telmisartan produced significant greater reduction from baseline in the primary end point diastolic BP compared with enalapril – 10mg. (11.7 Vs 8.7mm Hg respectively, p = 0.02) reduction from baseline SBP, DBP is more than 20mm Hg. Incidence of cough 8.5% with telmisartan and 18.4% with enalapril [10]. According to US FDS study and Boehringer Ingelheim Pharmaceuticals, angiotensin II antagonist appeared to be as effective as ACE

Inhibitors in delaying the progression of renal injury in animal models of diabetes.

CONCLUSION

In the present study both telmisartan and enalapril maleate reduced both systolic and diastolic blood pressures in both Groups at 2 weeks, 6 weeks and 12 weeks almost equally. But in terms of adverse effect profile, persistent dry cough was observed in 10% of enalapril maleate treated group and 2.5% in telmisartan treated group. Rash was observed 2.5% with both drugs. Hence, telmisartan offers advantages and represents an important new treatment option for hypertension patients. Telmisartan is effective and better tolerated than enalapril in the treatment hypertension.

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