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A SHORT TERM PROSPECTIVE, INTERVENTIONAL, COMPARATIVE CLINICAL STUDY FOR EVALUATION OF RAMIPRIL VERSUS TELMISARTAN IN HYPERTENSIVE PATIENTS WITH TYPE 2 DIABETES MELLITUS

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ABSTRACT: **Aim:** To comparatively evaluate the antihypertensive efficacy and tolerability of ramipril and telmisartan in stage 1 hypertensive diabetic patients. **Material and Methods:** This short term, prospective, randomized, interventional, comparative clinical study was conducted amongst 53 patients of stage 1 hypertension with type 2 diabetes (27 ramipril and 26 telmisartan patients), aged 30 years and above. Ramipril was administered 5 mg/day and telmisartan 40 mg/day respectively throughout the study period of 3 months. Blood pressure was measured using mercury sphygmomanometer. Paired and unpaired student t-test was applied. **Results:** Mean SBP was 153.2 and 154.52 mm Hg and mean DBP 87.6 and 87.57 mm Hg in ramipril and telmisartan group respectively. During follow-up the mean SBP and DBP consistently decreased. At 3 months the mean SBP was 124.72 and 123.83 mm Hg in ramipril and telmisartan group respectively. Similarly, the mean DBP at 3 months was 78.16 and 76.7 mm Hg in ramipril and telmisartan group respectively. Although the lowering of blood pressure (both systolic and diastolic) by ramipril or telmisartan individually was statistically significant yet comparatively reduction of BP between the two groups was not significant. **Conclusion:** Both regimens were equally effective and well tolerated with minimal incidence of adverse effects including cough.

INTRODUCTION: Hypertension is a multifactorial disease affecting one billion populations worldwide. It is most common, readily identifiable and reversible risk factor for myocardial infarction, stroke, heart failure, atrial fibrillation, aortic dissection and peripheral arterial disease.¹ Hypertension is extremely common comorbid condition in diabetes, affecting 20-60% patients with diabetes.² It substantially increases the risk of both macrovascular and microvascular complications including stroke, coronary artery disease, peripheral vascular disease, retinopathy, nephropathy and neuropathy.²

Antihypertensive agents such as calcium channel blockers, angiotensin I converting enzyme inhibitor (ACEi), angiotensin type-1 receptor blocker (ARB) and mineralocorticoid receptor blocker (MRB) are very useful in controlling hypertension of any cause in the clinical setting.^{3,4}

The renin angiotensin aldosterone system (RAAS) plays an important role in the pathogenesis of atherosclerosis and pathophysiology of cardiovascular disease. Therefore, despite a large number of antihypertensive agents, belonging to different pharmacological classes and modifying different physiological parameters, being currently available, yet in the present study only ramipril and telmisartan are selected because these agents not only are long acting but have shown clinically documented antihypertensive efficacy, better compliance and tolerability as well as prevented hypertension related end organ damage thus conferring cardiovascular protection.⁵ Moreover,

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telmisartan has been developed with twin objectives of improving blood pressure (BP) control as well as controlling early morning rise of BP thus offering cardiovascular protection both in uncomplicated and complicated hypertension and possesses favourable metabolic profile (particularly on insulin sensitivity).⁶ Further, angiotensin converting enzyme inhibitors trials have suggested that RAAS blockade to be among the most efficient cardio protective interventions. ACE inhibitors and angiotensin II receptor blockers (ARBs) have become keystones of therapy for hypertension in diabetes because of their broadly demonstrated favourable effects on diabetic nephropathy and cardiovascular disease outcomes, as well as their modest favourable effects on measures of glucose metabolism.⁷

Additionally, modulation of RAAS with angiotensin converting enzyme (ACE) inhibitor ramipril and angiotensin receptor blocker (ARB) telmisartan not only reduces a range of adverse cardiovascular outcomes but also affords renoprotection. It may be mentioned that goal of antihypertensive therapy is to prevent complications of hypertension with their superior efficacy, though Asian population respond less favorably to ACE inhibitors as compared to westerners.⁸ Renin-angiotensin system blockade delays or avoids the onset of type 2 diabetes and prevents cardiovascular and renal events in diabetic patients.⁹ There is a wealth of data supporting the use of ARBs in diabetic patients.¹⁰

The present study has been designed to compare the antihypertensive efficacy and tolerability of the two regimens in patients of hypertension with type 2 diabetes mellitus since the data on Asian population are scarce and comparative evaluation data in Indian population are few.

MATERIALS AND METHODS:

This prospective, randomized, comparative clinical study of 3 months duration (July-September 2013) was carried out by the department of pharmacology in collaboration with department of medicine, Rohilkhand Medical College and Hospital, Bareilly. Ethical clearance from Institutional Ethical Committee has been obtained. Written

informed consent from all enrolled participants was undertaken.

A total of 53 newly diagnosed essential hypertension patients conforming to stage 1 (JNC - VII), who were 30 years and above and also suffering from type 2 diabetes were enrolled and constituted the sample size. For randomization all test subjects were allotted study numbers on first come first serve basis and subsequently odd numbers were allotted to ramipril group 5 mg per day and even study numbers to telmisartan group 40 mg per day throughout 3 months study period. The exclusion criteria included symptomatic heart failure, significant valvular heart disease, pericardial constriction or effusion, congenital heart disease, uncontrolled hypertension (BP >160/100 mm Hg), stroke due to subarachnoid hemorrhage, significant renal disease and known hypersensitivity or intolerance to ARB or ACE Inhibitor.

The study involved the use of a structured, pretested and predesigned questionnaire to collect the demographic informations, and blood pressure was measured with standardized calibrated mercury column type sphygmomanometer and stethoscope on two occasions at 5 min interval after the patient had rested for 15 min. Adverse effects, if any, were noted down for both regimens.

Patients under treatment were subsequently monitored and reassessed at 2 weeks (First follow up), 1 month (Second follow up), 2 month (third follow up) and 3 month (Fourth follow up) for evaluation of BP control and monitoring of adverse effects.

The data obtained were statistically analyzed using paired and unpaired student t-test using SPSS software version 17.

RESULTS & OBSERVATION: Out of a total of 53 enrolled patients, 27 patients were in ramipril group and 26 patients in telmisartan group. Five patients, 3 in ramipril group and 2 in telmisartan group dropped out during the study period. A higher prevalence of hypertension was noted in females compared to males. M: F ratio was 0.39:1. The urban – rural ratio was 0.65:1, **Table 1.**

TABLE 1: DISTRIBUTION OF MALE AND FEMALE IN RURAL AND URBAN POPULATION

Groups	Rural		Urban		Tot
	Male	Female	Male	Female	
RAMI	4	12	5	6	27
TELMI	5	11	4	6	26
TOT	9	23	9	12	53

Rami=Ramipril, Telmi=Telmisartan, Tot=Total

Table 2 depicts age and education wise distribution of patients. An increasing trend of hypertension was noted with increasing age though majority of patients belonged to 41-50 years age group. Educational status wise 18 (34%) hypertensive

diabetic patients are illiterate, 14 (26%) were less than high school pass, 11 (21%) were high school or more and 10 (19%) were graduate, post graduate and professionals.

TABLE 2: AGE DISTRIBUTION AND EDUCATIONAL STATUS IN THE TWO GROUPS OF PATIENTS.

Age group (years)	Groups		Tot (%)	Edu Stat	Groups		Tot (%)
	RAMI	TELMI			RAMI	TELMI	
Upto 40	3	3	6 (11%)	ILL	8	10	18(34%)
41-50	12	15	27(53%)	< HS	9	5	14(26%)
51-60	5	5	10(17%)	≥ HS	4	7	11(21%)
61-70	4	2	6(11%)	G	1	4	5(9.5%)
>70	3	1	4(8%)	PG	5	0	5(9.5%)
TOT	27	26	53 (100%)	TOT	27	26	53(100%)

EDU Stat=Educational Status, ILL=Illiterate, HS=High School, G=Graduate, PG=Post Graduate

Mean SBP at enrolment was 153.2 ± 1.65 and mean DBP was 87.6 ± 1.54 in ramipril group, **Table 3**. Similarly mean SBP at enrolment was 154.52 ± 3.02

and mean DBP was 87.57 ± 1.93 in telmisartan group, **Table 4**. Thus, mean SBP and mean DBP were comparable between the two groups.

TABLE 3: COMPARATIVE FOLLOW UP VALUES OF SBP AND DBP WITH RAMIPRIL (N=24)

Systolic Blood Pressure				FU	Diastolic Blood Pressure			
Base Mean SBP±Sem	FU Mean SBP±Sem	T-Value	P-Value		Base Mean DBP±SEM	FU Mean DBP±SEM	t-value	p-value
153.2±1.65	135.36±1.7	8.611	< 0.05	1	87.6±1.54	84.84±1.33	1.162	> 0.05
153.2±1.65	130.16±1.05	14.993	< 0.05	2	87.6±1.54	80.56±1.12	4.055	< 0.05
153.2±1.65	126.24±0.83	15.631	< 0.05	3	87.6±1.54	80.56±1.0	3.656	< 0.05
153.2±1.65	124.72±0.94	17.131	< 0.05	4	87.6±1.54	78.16±0.89	5.316	< 0.05

SBP=Systolic Blood Pressure, DBP=Diastolic Blood Pressure, BASE=Baseline, FU=Follow Up, SEM=Standard Error of Mean

After therapy with ramipril in all the four follow ups the mean SBP and mean DBP were significantly reduced statistically ($p < 0.05$) as compared to baseline values, **Table 3**. Similarly,

following 3 months therapy with telmisartan in all the four follow-up the mean SBP and mean DBP were significantly reduced statistically ($p < 0.05$) when compared to baseline values, **Table 4**.

TABLE 4: COMPARATIVE FOLLOW UP VALUES OF SBP AND DBP WITH TELMISARTAN (N=24)

Systolic Blood Pressure				FU	Diastolic Blood Pressure			
BASE MEAN SBP±SEM	FU MEAN SBP±SEM	t-value	p-value		BASE MEAN DBP±SEM	FU MEAN DBP±SEM	t-value	p-value
154.52±3.02	135.39±2.16	7.589	< 0.05	1	87.57±1.93	82.57±1.85	2.604	< 0.05
154.52±3.02	130.7±1.3	8.279	< 0.05	2	87.57±1.93	79.48±1.15	4.089	< 0.05
154.52±3.02	126.43±1.04	9.626	< 0.05	3	87.57±1.93	79.04±1.22	4.851	< 0.05
154.52±3.02	123.83±0.81	10.741	< 0.05	4	87.57±1.93	76.7±0.66	5.954	< 0.05

SBP=Systolic Blood Pressure, DBP=Diastolic Blood Pressure, BASE=Baseline, FU=Follow Up, SEM=Standard Error Of Mean

Table 5 shows comparative evaluation of SBP & DBP following therapy with the two regimens. Although, SBP showed a significant reduction from baseline to the end of treatment, it may be noted SBP reduced at the end of treatment by 28.48 mm

of Hg in ramipril group and by 30.69 mm of Hg with telmisartan group. ($p < 0.05$ for both groups). However, the difference in mean reduction of SBP and DBP between the two groups was not statistically significant ($p > 0.05$).

TABLE 5: ANTIHYPERTENSIVE (SBP & DBP) EFFICACY OF RAMIPRIL (N=24) VERSUS TELMISARTAN (N=24)

Visits	Systolic blood pressure				Diastolic blood pressure			
	Rami Mean SBP±SEM	Telmi Mean SBP±SEM	t-value	p-value	Rami Mean DBP±SEM	Telmi Mean DBP±SEM	t-value	p-value
BASE	153.2±1.65	154.52±3.02	0.392	> 0.05	87.6±1.54	87.57±1.93	0.012	> 0.05
FU 1 (2 WKS)	135.36±1.7	135.39±2.16	0.011	> 0.05	84.84±1.33	82.57±1.85	0.788	> 0.05
FU 2 (1 M)	130.16±1.05	130.7±1.3	0.325	> 0.05	80.56±1.12	79.48±1.15	0.673	> 0.05
FU 3(2 M)	126.24±0.83	126.43±1.04	0.144	> 0.05	80.56±1.0	79.04±1.22	0.973	> 0.05
FU 4(3 M)	124.72±0.94	123.83±0.81	0.711	> 0.05	78.16±0.89	76.7±0.66	1.303	> 0.05

BASE=Baseline, FU=follow up, WKS=weeks, M=month

It was also observed that both regimens decreased DBP though telmisartan was found to be more efficacious in reducing DBP (10.87 mm Hg in telmisartan group versus 9.44 mm Hg in ramipril group). However, no statistically significant difference in DBP reduction was noted on comparing the results of two regimens, ($p > 0.05$) at the baseline and each of follow up visits and at final follow up. Thus, the difference in the mean reduction of DBP between the two groups was not statistically significant ($p > 0.05$).

The most common adverse effect seen with ramipril was dry cough (4%), whereas no adverse effect was seen with telmisartan in prescribed dosages.

DISCUSSION: Affecting one billion people world over, hypertension remains one of the leading causes of death worldwide and making it a public health problems. Recent reports indicate that nearly 1 billion adults (more than a quarter of the world's population) had hypertension in 2000, and this is predicted to increase to 1.56 billion by 2025.¹¹ The evidence has shown that the humoral system (RAAS) plays a key role in the development and progression of hypertension and hypertension related end organ damage as well as constitutes an important target for pharmacological intervention.⁵ Besides, the rennin angiotensin system (RAS) plays a pivotal role in the regulation of cardiovascular function, with angiotensin II being involved in hemodynamic and non-hemodynamic mechanisms

in the pathophysiology of cardiovascular disease.⁹ Further, using either an ACE inhibitors or angiotensin receptor blocker (ARB) confers cardiovascular protection.⁵ Increased levels of bradykinin also contribute to the positive effects of ACE inhibitors since activation of β_2 receptor leads to release of inducible nitric oxide and prostaglandin I_2 , with vasodilatory and tissue protective results.¹²

Redon et al¹³ have observed that compared with nondiabetic patients, diabetic patients had a significantly higher risk for cardiovascular death, myocardial infarction, stroke or hospitalization for congestive heart failure. The cardio vascular risk has been significantly higher in diabetics than in nondiabetic patients.

Thus, in the present study the two chosen agents for comparative evaluation basically modify RAAS for control of hypertension and have proven efficacy. Moreover, in the doses applied these agents cause minimal adverse effects profile and are well tolerated. The study was conducted to verify these observations.

Out of a total 53 enrolled patients, 5 patients (3 in ACE inhibitors and 2 patients in ARB group) dropped out during the short span of 3 months probably because of poor compliance owing to increased cost of medicine on prolonged administration, loss of follow up, adverse effects and more importantly due to poor awareness that

despite an adequate control of blood pressure one has to take medicine almost throughout his/her life over and above their antidiabetic drug dose.

In the present study, the females predominate over males and M: F ratio is 0.51:1. This is consistent with the observations reported in the serial epidemiological studies conducted in Jaipur by Gupta et al^{14, 15} where the prevalence of hypertension was lower (30% and 36% respectively) among males as compared to (34% and 38% respectively) in females. Other workers have also mentioned a similar larger involvement of females as compared to males.

The incidence of hypertension in diabetic individuals has been observed less in urban population, the urban-rural ratio 0.65:1. A lesser involvement of urban population is probably due to the fact that mostly poor villagers and rural population attend to our OPD, besides their shattered economy and poverty leading to stressful life thus contributing to hypertension. However, contrasting trend of larger involvement of urban population in hypertension has been reported by earlier workers in the field.^{16, 17}

In the present study increasing age is associated with increased prevalence of hypertension as well as diabetes. Thus, majority of newly diagnosed patients of hypertension 27 (53%) belonged to 41-50 years age group. Dubey et al¹⁸ has also reported the highest incidence of hypertension 44% (275/623) in the age group of 41 to 60 years, followed by 30 to 40 years 31% (193/623). Thus, our observations are in line with those of other workers.¹⁹⁻²¹ Rising atherosclerotic changes in vascular system with increasing age may probably be the prime cause. Moreover, presence of type 2 diabetes usually associated with altered lipid profile may also contribute towards hypertension. Further, in type 2 diabetes both telmisartan and ramipril increased nitric oxide activity of the renal endothelium significantly, which in turn may support the preservation of cardiovascular and renal function.²²

In this study the incidence of hypertension is more (66 %) in literate individuals as compared to illiterate. This is probably attributable to greater

awareness towards hypertension and diabetes among literate persons in recent times, and because of more stressful professional life, whereas illiterate are usually more involved with more physical work and farming activities to earn their livelihood.

Currently, the diagnosis and treatment of hypertension is based on the blood pressure values recorded at the office and the therapies designed to lower BP values have been found to have a positive impact on micro – and macro vascular end points in diabetes.²³ In the present study, the blood pressure was recorded in office settings and the two groups are well balanced with respect to initial systolic and diastolic blood pressures. Besides, other baseline characteristics are also comparable in the ramipril and telmisartan groups for proper comparative evaluation. Although office blood pressure recordings are quite convenient yet recent studies have demonstrated that ambulatory blood pressure monitoring is better correlated to end organ damage and cardiovascular morbidity from hypertension.^{24, 25}

In another short term (12 weeks) randomized, comparative, study between telmisartan versus ramipril in essential hypertension, Soni et al²⁶ have observed that telmisartan (40mg once daily) is as effective as ramipril (10mg once daily) in lowering SBP but produces a greater reduction in DBP than Ramipril. Further, in one meta-analysis of 28 randomized controlled trials involving 5157 patients, telmisartan had a superior blood pressure control over different ACE inhibitors (enalapril, ramipril and perindopril), fewer drug related adverse events, and better tolerability in hypertensive patients.²⁷ In contrast, we have observed that both ramipril and telmisartan are equally efficacious in lowering systolic as well as diastolic blood pressure.

Following treatment with either drugs the mean systolic and diastolic blood pressure consistently decreased significantly in all the four follow-ups when compared to baseline values ($p < 0.05$). Other workers in the field have also observed a similar statistically significant reduction in blood pressure (both systolic and diastolic) with ACE inhibitors and ARBs. Williams et al²⁸ while

observing the antihypertensive efficacy of telmisartan (80mg) Vs ramipril (5 or 10 mg), over the 24 hour dosing period including the critical early morning hours using ambulatory blood pressure monitoring, noted that the baseline mean ambulatory systolic and diastolic blood pressure (approximately 148/93 mm Hg) has been decreased. Moreover, PRISMA – 1 and 11 (Prospective, Randomized Investigation of the safety and efficacy of Micardis Vs ramipril) also observed that after 14 weeks, telmisartan was found to be more effective than ramipril in controlling blood pressure throughout the 24 hour period and during early morning period (mean systolic/diastolic – 4.1/-3.0 mm Hg, $p < 0.0001$). These results may be attributable to the long duration of telmisartan, which is sustained throughout the 24 hour dosing period.

The superior antihypertensive effect of telmisartan over ramipril in the above noted studies are in contrast to our observations as we observed that both these agents are almost equally effective antihypertensive agents; though we cannot comment on the effect of telmisartan over early morning rise of blood pressure. RAAS blockers in particular may be superior to other agents because they can prevent the onset of diabetes mellitus and protect against Cardio-vascular complications.²⁹

CONCLUSION: It is observed that both ramipril and telmisartan are almost equally effective as antihypertensive agents in causing lowering of blood pressure. Both treatments are well tolerated and adverse events including cough are less common with telmisartan. Further, studies with large number of patients with longer duration of follow-up are required to validate these observations.

In short, the prevalence of adverse effect as well as treatment discontinuation with telmisartan is low as compared to ramipril. Moreover, hypotension, angioedema and hyperkalemia were not observed in any of treated patient in the present study. Absence of cough and angioedema are notably the major advantages of ARB over ACE inhibitors. Limitations of study included short span of therapy, small sample size, as well as test subjects were not

matched on the risk factor history between two groups.

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