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RESEARCH ARTICLE

A comparative study of efficacy of enalapril versus telmisartan in patients with diabetic nephropathy

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ABSTRACT

Background: Diabetic nephropathy (DN) is the leading cause of end-stage renal disease (ESRD) worldwide and is estimated that ~20% of type 2 diabetics develop ESRD during their lifetime. In type 2 diabetics with microalbuminuria, both enalapril and telmisartan have shown to reduce microalbuminuria, thereby delaying the progression of renal disease in diabetics. **Aim and Objective:** This study aims to evaluate the efficacy of enalapril versus telmisartan among patients with DN for 6 months. **Materials and Methods:** A prospective, open-labeled, randomized, comparative study was conducted involving 100 type 2 diabetics with mild hypertension and Grade I DN was divided randomly into two groups of 50 each, aged between 18 and 69 years with either sex, attending medicine outpatient department or admitted in medicine wards. One group received tab. enalapril maleate, 5–10 mg/day, while other group received tab. telmisartan, 40–80 mg/day, and were followed up once a month for 6 months. Efficacy was assessed using urine albumin, serum urea, serum creatinine, and blood pressure (BP). **Results:** Demographic and baseline urine albumin level, serum urea, serum creatinine, and BP were comparable between two groups. Early improvement in urine albumin and serum creatinine levels was seen with enalapril (at 2 months, urine albumin: $P = 0$; at 3 months, serum creatinine: $P = 0.007$). Reduction of BP was greater with telmisartan (systolic BP/diastolic BP (DBP): $P < 0.001$). In later phase, no significant difference was observed between two groups among the parameters such as urine albumin estimation ($P = 1$) and serum urea ($P = 0.286$). **Conclusion:** Both enalapril and telmisartan were equally efficacious in DN. However, enalapril had better response than telmisartan in our study.

KEY WORDS: Diabetic Nephropathy; Hypertension; Microalbuminuria; Enalapril Maleate; Telmisartan

INTRODUCTION

Diabetes mellitus (DM) is a group of metabolic disorder characterized by hyperglycemia, due to defect in insulin secretion, insulin action, or both. Chronic hyperglycemia of diabetes is associated with long-term damage, dysfunction, and failure of different organs, especially eyes, kidneys, nerves, heart, and blood vessels.[1]

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Over the past two decades, the worldwide prevalence of diabetes has risen dramatically, from an estimated 171 million in 2000 to 425 million in 2017 and is estimated to reach 629 million by 2045. India alone had 69.2 million people suffering from diabetes.[2] Projections from the Indian Council of Medical Research-India Diabetes study have shown that India has 62.4 million people suffering from diabetes, making diabetic nephropathy (DN) an important cause of renal failure. A study from India has shown that 31.3% of renal failure in India is caused by DN.[3]

DN develops in ~40% of diabetic patients and is the leading cause of end-stage renal disease (ESRD) worldwide. It is estimated that ~20% of type 2 diabetics reach ESRD during their lifetime. Renal disease in diabetics, clinically characterized by increasing rates of urinary albumin excretion, starting from normal albuminuria, which progresses to microalbuminuria, macroalbuminuria, and eventually to ESRD, is a major but under-recognized contributor to the global burden of disease. Metabolic changes associated with diabetes lead to glomerular hypertrophy, glomerulosclerosis, and tubulointerstitial inflammation and fibrosis.[4]

Persistent albuminuria in the range of 30–299 mg/24 h (microalbuminuria) is the earliest stage of DN in type 1 diabetes and is a marker for the development of nephropathy in type 2 diabetes. Patients with microalbuminuria who progress to macroalbuminuria (≥300 mg/24 h) are more likely to progress to ESRD over a period of few years.[5]

Hypertension occurs twice as commonly in diabetics than in comparable non-diabetics. Patients with both disorders have a markedly higher risk for premature microvascular and macrovascular complications. Aggressive control of blood pressure (BP) reduces both micro- and macrovascular complications.[6]

Over the past few years, several interventions were done using renin-angiotensin blocking drugs which demonstrated to reduce the risk and slow the progression of renal disease. In the treatment of both micro- and macroalbuminuria in diabetic patients, either angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs) are currently recommended by clinical guidelines.[7]

In patients with type 2 diabetes with microalbuminuria, both ACEIs like Enalapril and ARBs like telmisartan have shown to reduce microalbuminuria and thereby delay the progression of renal disease. Hence, ACEIs/ARBs shall be the first line drugs in the treatment of DN with hypertension.[8] Although many studies have compared the renoprotective effect of enalapril (ACEI) and telmisartan (ARB) monotherapy in DN patients, the advantage of one drug over the other in terms of renal protection in DN remains unsettled. Therefore, further investigations are required to examine the renal effectiveness of enalapril and telmisartan in DN patients.

Hence, to answer the research question, an effort is being made to compare the efficacy of enalapril and telmisartan in patients with DN at tertiary care hospital, Vijayanagar Institute of Medical Sciences (VIMS), Bellary.

MATERIALS AND METHODS

The present study was a prospective, open-labeled, randomized, comparative study conducted during the period from January 2017 to June 2018. Ethics clearance (Reference Number: No. VIMS/STD.II/PG-EC/70/2016-17) from Institutional Ethics Committee of VIMS, Bellary, was obtained before the start of study.

A total of 100 patients previously diagnosed with type 2 DM, treated with diet plus oral hypoglycemic agents preferably metformin, with mild hypertension (systolic BP 140–159 mmHg and/or diastolic BP 90–99 mmHg), who present with features of Grade-I DN like presence of urine albumin (trace/+), in the age group of 18–69 years, attending the outpatient department or admitted to the medicine/nephrology wards in VIMS, Bellary, formed the population of our study. Inclusion and exclusion criteria were applied and having explained in detail about the study in patients' vernacular language, written informed consent was obtained from the patients included in our study.

All patients who refuse to give consent, patients with bilateral renal artery stenosis, advanced chronic kidney disease with hyperkalemia, who are intolerant to enalapril and telmisartan, pregnant women, and lactating women were excluded from the study.

Brief history of the patients including demographic data, medical history, and concomitant medications was documented and a general physical examination was performed to note relevant information and to exclude other comorbid conditions. A thorough clinical examination including recording of vital signs was done for all patients. Then, the selected patients were divided into two groups of 50 each, by block randomization method. One group received tablet enalapril maleate (ACEIs), 5–10 mg/day once daily, orally while the other group received tablet telmisartan (ARB), 40–80 mg/day once daily, orally and was followed up once a month for 6 months.

Periodic assessment for efficacy parameters of both the drugs was done at baseline and at each follow-up for 6 months. Efficacy was assessed by comparing any improvement in the clinical examination like BP and laboratory parameters such as urine albumin, serum urea, and serum creatinine.

Follow-up visits were at 1 month (visit 2), 2 months (visit 3), 3 months (visit 4), 4 months visit 5 5), 5 months (visit 6), and 6 months (visit 7) after administering the study drugs. A deviation of ± 2 days for the first follow-up and ± 1 week for subsequent follow-ups was accepted.

All patients included in the study were subjected to the following laboratory investigations and clinical examination for aiding the diagnosis and treatment, which includes testing of urine for the presence of albumin, serum urea, serum creatinine, glycated hemoglobin, and fundoscopy for diabetic retinopathy, clinical examination: BP, deep tendon reflexes, tuning fork test, and kidney biopsy (if required).

Measurement of BP was made using standard mercury sphygmomanometer after the patient had been supine for at least 5 min in a quiet room and the mean value was derived from two measurements taken at 2 min intervals (JNC 7).[9] DBP was defined by the total disappearance of sounds (Korotkoff Phase V).

Compliance to study medicines was measured by pill count during each follow-up.

Sample Size Calculation

Sample size was calculated based on the following formula

$N = 4pq/d^2$

and was found to be 50 in each group.

Statistical Analysis

The data were collected using a specially designed pro forma (case recording form) for the study and entered on a Microsoft Excel spreadsheet. Statistical analysis such as mean, standard deviation – for describing the data, Chi-square test – for comparing the proportions, and independent "*t*-test" – for comparing mean values was done using SPSS v20. $P < 0.05$ was considered statistically significant.

RESULTS

Baseline Demographic Characteristics

Table 1 represents the baseline demographic characteristics of the patients included in the study. Both enalapril and telmisartan groups were matched with respect to baseline demographic characteristics.

Evaluation of Efficacy Parameters

Urine albumin estimation

At baseline, in the enalapril group, urine albumin was + in 31 (62%) patients and trace in remaining 19 (38%) patients, whereas in the telmisartan group, it was + in 29 (58%) patients and trace in remaining 21 (42%) patients, which was not statistically significant ($P = 0.683$).

Table 1: Baseline demographic characteristics

Variables	Enalapril	Telmisartan	*P*-value
Age (years), Mean±SD	53.96±9.81	54.54±10.22	0.773
Gender – ***n*** (%)			
Male	34 (68)	33 (66)	1
Female	16 (32)	17 (34)	
BMI, Mean±SD	24.86±2.16	24.67±1.80	0.633
Duration of DM (years), Mean±SD	9.5±2.85	9.34±2.49	0.765

DM: Diabetes mellitus, SD: Standard deviation

At 1 month, in the enalapril group, 27 (54%) patients had + urine albumin and the remaining 23 (46%) patients had trace albumin, whereas in the telmisartan group, 28 (56%) patients had + urine albumin and the remaining 22 (44%) patients had trace albumin, which was not statistically significant ($P = 1$).

At 2 months, in the enalapril group, 35 (70%) patients had trace urine albumin and in the remaining 15 (30%) patients, no albumin was detected in urine, whereas in the telmisartan group, 12 (24%) patients had + urine albumin, 35 (70%) patients had trace urine albumin and in the remaining 3 (6%) patients, no albumin was detected in urine, which was statistically significant ($P = 0$).

At 3 months, in the enalapril group, 22 (44%) patients had trace urine albumin and in remaining 28 (56%) patients, no albumin was detected, whereas in the telmisartan group, 33 (66%) patients had trace urine albumin and in remaining 17 (34%) patients, no albumin was detected, which was statistically significant ($P = 0.027$).

At 4 months, in the enalapril group, 7 (14%) patients had trace urine albumin and in remaining 43 (86%) patients, no albumin was detected, whereas in the telmisartan group, 22 (44%) patients had trace urine albumin and in remaining 28 (56%) patients, no albumin was detected, which was statistically significant ($P = 0.001$).

At 5 months, in the enalapril group, no albumin was detected in the urine of all 50 (100%) patients, whereas in the telmisartan group, 12 (24%) patients had trace urine albumin and in remaining 38 (76%) patients, no albumin was detected, which was statistically significant ($P = 0$).

At 6 months, in the enalapril group, no albumin was detected in the urine of all 50 (100%) patients, whereas in the telmisartan group, only 1 (2%) patient had trace urine albumin and no albumin was detected in the urine of remaining 49 (98%) patients, which was not statistically significant ($P = 1$).

These observations are shown in Table 2.

Serum urea levels

The mean reduction in serum urea, in the enalapril group, from baseline (50.8 ± 15.7) to 3 months (37.1 ± 9.2) and 6 months (28.3 ± 7.6) was 13.7 (± 6.5) and 22.5 (± 8.1), respectively, whereas the mean reduction in the telmisartan group from baseline (49.8 ± 15.7) to 3 months (36.4 ± 11.7) and 6 months (26.6 ± 7.7) was 13.4 (± 4.0) and 23.2 (± 8.0), respectively.

Although the reduction of serum urea was more with telmisartan, there was no statistical significance ($P = 0.286$) between the two groups [Figure 1].

Serum creatinine levels

The mean reduction in serum creatinine in the enalapril group from baseline (1.9 ± 0.3) to 3 months (1.3 ± 0.2), 4 months (1.2 ± 0.2), 5 months (1.0 ± 0.2), and 6 months (0.9 ± 0.2) was 0.6 (± 0.1), 0.7 (± 0.1), 0.9 (± 0.1), and 1.0 (± 0.1), respectively, whereas the mean reduction in the telmisartan group from baseline (1.9 ± 0.2) to 3 months (1.4 ± 0.2), 4 months (1.3 ± 0.2), 5 months (1.1 ± 0.2), and 6 months (1.0 ± 0.2) was 0.5, 0.6, 0.8, and 0.9, respectively. Reduction of serum creatinine was more with enalapril, which was statistically significant at 3 (P = 0.007), 4 (P = 0.001), 5 (P = 0.002), and 6 months (P = 0.015) between the groups.

These observations are shown in Figure 2.

Systolic BP (SBP)

The mean reduction in SBP in the enalapril group from baseline (152 ± 8 mmHg) to 6 months (119 ± 5 mmHg) was 33 (± 3) mmHg, whereas the mean reduction in the telmisartan group from baseline (150 ± 8 mmHg) to 6 months (114 ± 5 mmHg) was 36 (± 3) mmHg. Statistically significant reduction in SBP was seen with telmisartan from 3 months (P = 0.048) to 6 months (P <0.001) between the groups [Table 3].

Diastolic BP (DBP)

The mean reduction in DBP in the enalapril group from baseline (90 ± 6) to 6 months (75 ± 4) was 15 (± 2), whereas the mean reduction in the telmisartan group from baseline (90 ± 6) to 6 months (69 ± 5) was 21 (± 1). Statistically significant reduction in DBP was seen with telmisartan, from 1 month (P = 0.004) to 6 months (P < 0.001) between the groups [Table 4].

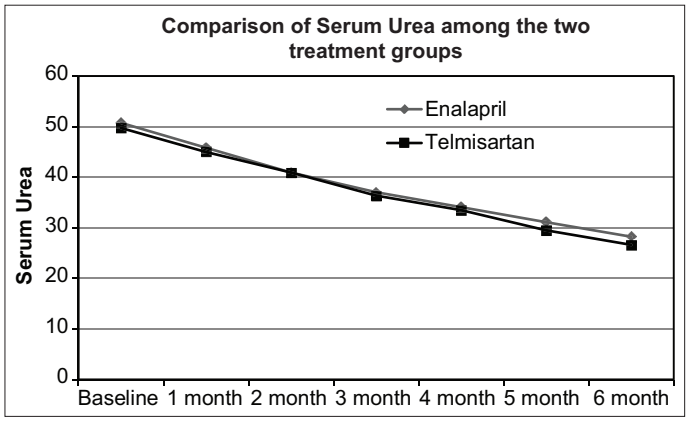

Figure 1: Comparison of serum urea

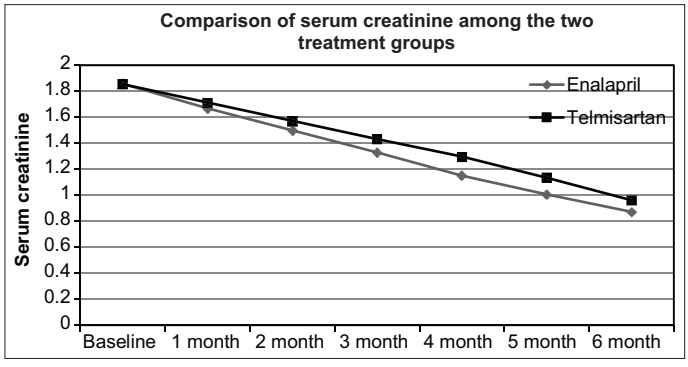

Figure 2: Comparison of serum creatinine

DISCUSSION

Diabetics with concurrent hypertension are at an increased risk of developing DN which is a major cause of illness and death in diabetes. It involves an increase in proteinuria and decline in glomerular filtration rate (GFR). The continuous kidney damage can lead to ESRD.[10]

Table 2: Comparison of urine albumin

Intervals	Enalapril		Telmisartan		*P*-value
	Frequency	Percent	Frequency	Percent	
Baseline					
+	31	62.0	29	58.0	0.683
Trace	19	38.0	21	42.0	
1 month					
+	27	54.0	28	56.0	1
Trace	23	46.0	22	44.0	
2 months					
+	0	0.0	12	24.0	0
Trace	35	70.0	35	70.0	
Nil	15	30.0	3	6.0	
3 months					
Trace	22	44.0	33	66.0	0.027
Nil	28	56.0	17	34.0	
4 months					
Trace	7	14.0	22	44.0	0.001
Nil	43	86.0	28	56.0	
5 months					
Trace	0	0.0	12	24.0	0
Nil	50	100.0	38	76.0	
6 months					
Trace	0	0.0	1	2.0	1
Nil	50	100.0	49	98.0	

Table 3: Comparison of SBP

Intervals	Enalapril		Telmisartan		*P*-value
	Mean	SD	Mean	SD	
Baseline	152.36	7.59	149.64	7.62	0.077
1 month	141.52	6.37	140.12	7.14	0.304
2 months	135.16	5.74	133.12	6.10	0.088
3 months	129.76	5.56	127.44	6.01	0.048
4 months	125.84	5.00	122.72	5.73	0.005
5 months	122.36	4.40	118.32	5.13	<0.001
6 months	118.56	5.19	114.28	5.36	<0.001

SBP: Systolic blood pressure

Table 4: Comparison of DBP

Intervals	Enalapril		Telmisartan		*P*-value
	Mean	SD	Mean	SD	
Baseline	90.44	5.70	89.88	6.15	0.33
1 month	85.28	4.67	82.20	5.57	0.004
2 months	82.08	4.83	78.68	5.02	0.001
3 months	79.72	4.28	75.76	4.79	<0.001
4 months	78.28	3.94	73.48	4.80	<0.001
5 months	76.64	3.67	71.36	4.82	<0.001
6 months	74.64	3.93	69.16	4.82	<0.001

DBP: Diastolic blood pressure

Drug therapy that focuses on tight glycemic control reduces the progression of nephropathy and cardiovascular complications.[11]

In diabetic hypertensives, both enalapril and telmisartan may have a beneficial effect on proteinuria and can effectively reduce the incidence of ESRD.[12] Till date, several studies have compared enalapril and telmisartan in terms of delaying or preventing the progression of DN. However, the advantage of one class of drug over the other remains unsettled.

Our study was undertaken with an aim to study and compare the efficacy of enalapril maleate versus telmisartan in DN patients.

A total of 100 patients included in our study who were randomized to two groups of 50 each were comparable with respect to demographic characteristics such as age, gender, BMI, and duration of DM. Hence, the probable role of these contributing to the development of DN as a confounding factor in the study has been ruled out.

Most of the diabetics in our study are aged between 45 and 65 years which is comparable with the study conducted by Unnikrishnan *et al*.[4] Male preponderance was observed in our study which was consistent with the study conducted by Gall *et al*.[13] A study conducted by Tapp *et al*. indicated that obesity is one of the modifiable risk factors for DN.[14] In our study, comparison of BMI showed that there was no significant difference between the two groups.

A short-term clinical study conducted by Lacourciere *et al*.,[15] which directly compared the effect of an ARB (losartan) with that of an ACEI (enalapril) in type 2 diabetics with early nephropathy indicated that both drugs reduced urinary albumin excretion with no significant difference between their efficacy. In the DETAIL trial, 250 type 2 DM patients with early DN were randomly assigned to enalapril or telmisartan. This trial indicated that telmisartan was not inferior to enalapril in reducing a decline in GFR over 5 years.[16] In the present study, all patients included had albuminuria (+/trace). Although enalapril significantly decreased the urine albumin levels at 2, 3, 4, and 5 months, when compared to telmisartan, at 6 months, no significant difference was observed in both the groups, indicating that the rate of urine albumin reduction did not differ significantly in both the groups which is comparable with the above-mentioned studies.

In the present study, there was no significant difference in the mean reduction in serum urea between both the groups. However, both the groups showed statistically significant difference in the mean reduction in serum creatinine levels starting from 2 months to 6 months. The levels of serum creatinine are also an indicator of renal function and the serum creatinine value of <1.4 has been considered normal in our study. Few studies have shown that ARBs as well as ACEIs tend to reduce the risk of doubling of serum creatinine levels.[17,18] A study conducted by Brenner *et al*.[17] showed that the risk of doubling of serum creatinine concentration was 25% lower in the losartan group than in the placebo group.

Apart from albumin and creatinine levels, BP also plays an important role in delaying the progression of DN. Hannedouche *et al*. and Alcocer *et al*. showed that there was a greater reduction in both DBP and SBP with the use of telmisartan as compared with enalapril.[19,20] In the present study, there was a significant reduction in the SBP in the telmisartan group at 5 and 6 months ($P < 0.001$), compared to enalapril group. However, there was a gradual reduction in DBP with telmisartan, starting from the 1st month and this reduction was statistically significant when compared to that of enalapril. Findings in our study are comparable with the above-mentioned studies. Although telmisartan decreased BP greatly, when compared to enalapril, none of the patients in the study presented with hypotension.

Strengths of the study are the patients in both the groups which were matched to rule out confounding factors, our study is one among the few studies evaluating the efficacy of enalapril and telmisartan in Indian population, patient retention rate was good. There were no drop outs in our study.

Limitations of the study are that the study was a short-term study; hence, a long-term efficacy of enalapril and telmisartan could not be assessed. The sample size in our study was small, 50 patients in each group. Hence, the results cannot be generalized for population from which patients were selected.

However, the present study results can be further elucidated by conducting multicentric, randomized controlled trials, with a larger sample size and a longer duration of study.

CONCLUSION

The study concluded that the reduction in urine albumin levels and serum creatinine was greater with enalapril when

compared to telmisartan, during the early phase of study, indicating that enalapril has faster onset of action. Telmisartan is more efficacious in decreasing BP when compared to enalapril. Overall, efficacy when explained in terms of urine albumin estimation, serum urea, serum creatinine, and BP, later phase of the study indicates that both drugs had equal efficacy in providing renoprotection in early DN.

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