

## EFFICACY, SAFETY, AND COST-EFFECTIVENESS OF TELMISARTAN AND CILNIDIPINE IN HYPERTENSIVE PATIENTS WITH CORONARY ARTERY DISEASE IN A TERTIARY CARE TEACHING HOSPITAL: A PROSPECTIVE COMPARATIVE STUDY

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### ABSTRACT

**Objectives:** The objective of the study is to evaluate and compare telmisartan with cilnidipine's cost-efficiency, safety, and effectiveness in hypertensive patients with coronary artery disease (CAD).

**Methods:** From January 2017 to June 2018, a non-randomized, open-labeled, comparative study was carried out in the SRM Medical College Hospital's Department of Cardiology. A total of 126 individuals with electrocardiogram-confirmed CAD and hypertension were divided into two groups, each consisting of 63 participants: Telmisartan (40 mg) and cilnidipine (10 mg). Blood pressure, renal function, electrolytes, adverse effects, and costs were measured at baseline, 12 weeks, and 24 weeks.

**Results:** At both 12 and 24 weeks, telmisartan reduced systolic blood pressure more than the other medication (mean difference at 24 weeks: 5.6 mmHg;  $p < 0.000$ ). Both drugs showed comparable diastolic blood pressure reductions. Although cilnidipine caused a significant drop in serum creatinine ( $p = 0.001$ ), renal parameters stayed constant. Telmisartan was better tolerated than cilnidipine, which had more side effects. The cost-effectiveness of cilnidipine was significantly higher (mean cost difference: Indian rupee 96.8;  $p < 0.000$ ).

**Conclusion:** Both drugs are effective antihypertensives for people with CAD. While cilnidipine is more affordable, telmisartan provides better blood pressure control and renal safety with acceptable tolerability.

**Keywords:** Hypertension, Telmisartan, Cilnidipine.

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### INTRODUCTION

Hypertension (HTN) is a major public health problem and a leading cause of cardiovascular morbidity and mortality worldwide. According to the global burden of disease study, it is the seventh leading cause of premature death in developing countries and the fourth most common cause in developed countries [1,2]. The risk of coronary artery disease (CAD), stroke, heart failure, and nephropathy is increased since HTN is often misdiagnosed due to its lack of symptoms, despite being avoidable and controlled [3,4]. To reduce cardiovascular events and improve mortality, proper management of HTN is crucial, particularly in patients with concurrent CAD [5]. Because of their efficacy and safety, calcium channel blockers (CCBs) like cilnidipine and angiotensin receptor blockers (ARBs) like telmisartan are highly recommended as first-line treatments among all antihypertensive classes [6]. In Indian patients with Stage-I HTN, the START ABPM trial (2023) showed that telmisartan outperformed cilnidipine in terms of blood pressure control over the course of a 24-h period, particularly during early morning surges [7]. Similarly, results from the TRANSCEND trial demonstrated that, in comparison to a placebo, telmisartan significantly decreased cardiovascular events and hospitalizations in high-risk CAD patients [8].

Despite the high frequency of prescriptions for both, there is scarce data on their relative cost-effectiveness, safety, and efficacy in patients with CAD and HTN. Hence, this study aims to evaluate the effectiveness, safety, and cost-effectiveness of telmisartan and cilnidipine in hypertensive patients with CAD in the outpatient Department of Cardiology in SRM Medical College Hospital and Research Centre.

### METHODS

From January 2017 to June 2018, the Department of Cardiology at SRM Medical College Hospital and Research Centre carried out this non-randomized, interventional, open-label, comparative study. A total of 126 HTN individuals with CAD were recruited and split into two parallel groups. Telmisartan 40 mg was given to Group A, and cilnidipine 10 mg was given to Group B. Each group consisted of 63 patients. The formula  $n = 2(\alpha + \beta)^2 \sigma^2 / (\mu_1 - \mu_2)^2$  was used to determine the sample size, where  $\alpha = 1.96$  (95% confidence level),  $\beta = 0.842$  (80% power),  $\sigma = 4$  (population variance), and  $(\mu_1 - \mu_2) = 2$  (effect size). Evaluations were conducted at baseline, 12 months, and 24 months during the patients' follow-up. Adults over 18, both sexes, newly diagnosed hypertensive patients with blood pressure  $\geq 140/90$  mmHg and  $\leq 180/110$  mmHg and not on treatment within 6 months, elderly hypertensive patients with uncontrolled blood pressure, patients with electrocardiogram-confirmed CAD, and those with other co-morbid conditions such as diabetes, dyslipidemia, or ischemic heart disease were all included in the study. Known sensitivity to ARBs or CCBs, pregnancy or lactation, hepatic impairment, angioedema, heart block, congestive heart failure, or uncontrolled blood pressure ( $>180/110$  mmHg) were among the exclusion criteria. Blood pressure, body mass index (BMI), renal function tests, electrolytes, side effects, and medication cost were among the clinical and biochemical data evaluated. Written informed consent was collected and ethical clearance (1076/Institutional Ethics Committee/2016) was obtained. Descriptive statistics, independent t-test, paired t-test, and Chi-square tests were used in the Statistical Package for the Social Sciences version 21.0 data analysis.

## RESULTS

In both groups, the majority of individuals were between the ages of 41 and 60. There was no significant variation in the mean age ( $52.7 \pm 10.2$  vs.  $51.6 \pm 10.5$  years,  $p=0.56$ ). Although there was no statistically significant difference in the gender distribution ( $p=0.187$ ), males were more common in both groups (47% in telmisartan and 53% in cilnidipine) (Table 1).

BMI measurements showed a significant difference ( $26.3 \pm 1.8$  vs.  $25.5 \pm 1.8$ ,  $p=0.02$ ), suggesting that the telmisartan group had a higher baseline BMI. The distribution of BMI categories, however, fell short of statistical significance ( $p=0.07$ ). Personal habits including drinking and smoking were not statistically significant, and co-morbid diagnoses and CAD involvement were similar across groups (Table 1).

**Table 1: Background characteristics of the study participants (n=126)**

Background characteristics	Telmisartan (n=63)	Cilnidipine (n=63)	p-value
Age (mean $\pm$ SD)	52.7 $\pm$ 10.2	51.6 $\pm$ 10.5	0.56
Age group (%)			
<40 years	12 (52.2)	11 (47.8)	0.56
41–60 years	40 (52.6)	36 (47.4)	
>60 years	11 (40.7)	16 (59.3)	
Gender (n/%)			
Male	47 (47)	53 (53)	0.187
Female	16 (61.5)	10 (38.5)	
BMI (kg/m <sup>2</sup> ) (mean $\pm$ SD)	26.3 $\pm$ 1.8	25.5 $\pm$ 1.8	0.02
BMI group (%)			
Normal	0 (0)	4 (100)	0.07
Overweight	17 (44.7)	21 (55.3)	
Obesity	46 (54.8)	38 (45.2)	
CAD (%)			
Single vessel disease	21 (55.3)	17 (44.7)	0.69
Double vessel disease	17 (50)	17 (50)	
Triple vessel disease	25 (46.3)	29 (53.7)	
Diagnosis (%)			
HT and CAD	8 (61.5)	5 (38.5)	0.82
HT, CAD, and dyslipidemia	17 (47.2)	19 (52.8)	
HT, CAD, and DM	22 (51.2)	21 (48.8)	
HT, CAD, DM, and dyslipidemia	16 (47.1)	18 (52.9)	
Personal habits (%)			
None	12 (48)	13 (52)	0.18
Smoking	16 (43.2)	21 (56.8)	
Alcohol	21 (58.3)	15 (41.7)	
Smoking and alcohol	14 (51.9)	13 (48.1)	

BMI: Body mass index, HT: Hypertension, CAD: Coronary artery diseases, DM: Diabetes mellitus, SD: Standard deviation

Telmisartan significantly reduced systolic blood pressure (SBP) more after 12 weeks (mean difference [MD] 8 mmHg, 95% confidence interval [CI]: 5.6–10.5,  $p<0.000$ ) and 24 weeks (MD 5.6 mmHg, 95% CI: 2.9–8.4,  $p<0.000$ ). There were no significant variations in the diastolic blood pressure (DBP) drops between the groups at any time. Telmisartan demonstrated a pronounced reduction in mean artery pressure (MAP) at 12 weeks (MD 2.7 mmHg, 95% CI: 0.7–4.8,  $p=0.009$ ), but at 24 weeks, the differences were not statistically significant ( $p=0.39$ ), suggesting a potential convergence in long-term MAP control (Table 2).

The cilnidipine group experienced greater adverse medication events (38.1%) compared to the telmisartan group (22.2%). The most frequent side effect in both groups was headache (17.5% with cilnidipine and 12.7% with telmisartan). Cilnidipine was more likely to cause pedal edema, dizziness, flushing, palpitations, and nausea, all of which are documented adverse effects of dihydropyridine CCBs (Table 3).

Blood urea and creatinine levels did not differ statistically across groups at baseline or 24 weeks later. However, cilnidipine showed a significant drop in creatinine over time ( $p=0.001$ ), while telmisartan exhibited a non-significant trend toward improved renal parameters with a minor decrease in creatinine levels ( $p=0.56$ ). Over the course of 24 weeks, serum sodium levels remained constant in the telmisartan group ( $p=0.911$ ) but drastically dropped in the cilnidipine group ( $p=0.005$ ). Other electrolytes such as potassium, chloride, and bicarbonate showed no statistically significant intergroup differences (Table 4).

The cost of telmisartan was found to be higher than that of cilnidipine. A 6-month supply of telmisartan costs Indian rupee (INR) 1246.7 $\pm$ 126.4 on average, whereas cilnidipine costs INR 1149.9 $\pm$ 103.3 (Mean Difference INR 96.8, 95% Confidence Interval: 56.1–137.5,  $p<0.0001$ ) (Table 5).

## DISCUSSION

With mean ages of 52.7 years for the telmisartan group and 51.6 years for the cilnidipine group, the majority of the study population (76) was between the ages of 41 and 60. This age distribution is consistent with earlier findings by Shah *et al.* who found that people over 40 accounted for 84% of CAD cases [9]. Male predominance (telmisartan; 47% and cilnidipine; 53%) was detected in the sex distribution, which is in line with findings by Canto *et al.* that demonstrated myocardial infarction rates were greater in men, especially in younger age groups [10].

According to the BMI, almost all the patients (100% in telmisartan group and 93.7% in cilnidipine group) were overweight or obese. This is consistent with research conducted over a 12-year follow-up period by Stevens *et al.* which found a correlation between raised cardiovascular risk and higher body weight [11]. In the current study, there was no statistically significant difference in BMI between the two groups.

**Table 2: Systolic, diastolic, and mean arterial pressure among study participants at baseline, 12- and 24-week follow-up (n=126)**

Blood pressure	Paired t-test	Telmisartan	Cilnidipine	Independent t-test (mean difference from baseline with CI)	Mean difference (CI)	p-value
SBP (mean $\pm$ SD)	Baseline	149.7 $\pm$ 5.9	148.9 $\pm$ 6.6			
	12 weeks	130.5 $\pm$ 3.3	137.8 $\pm$ 5.2	12 weeks	8 (5.6–10.5)	0.00
	24 weeks	121.8 $\pm$ 3.5	126.7 $\pm$ 7.4	24 weeks	5.6 (2.9–8.4)	0.00
	p-value	0.00	0.00			
DBP (mean $\pm$ SD)	Baseline	98.1 $\pm$ 7.3	100.6 $\pm$ 6.3			
	12 weeks	83 $\pm$ 4.1	85.3 $\pm$ 5	12 weeks	–0.09 (–2.7–2.5)	0.94
	24 weeks	79.3 $\pm$ 3.5	81.6 $\pm$ 5.3	24 weeks	–0.13 (–2.9–2.7)	0.93
	p-value	0.00	0.00			
MAP (mean $\pm$ SD)	Baseline	114.8 $\pm$ 5.4	116.1 $\pm$ 5			
	12 weeks	98.6 $\pm$ 3.6	102.6 $\pm$ 3.9	12 weeks	2.7 (0.7–4.8)	0.009
	24 weeks	93.8 $\pm$ 3.9	96.2 $\pm$ 5.3	24 weeks	1.1 (–1.4–3.6)	0.39
	p-value	0.00	0.00			

SBP: Systolic blood pressure, DBP: Diastolic blood pressure, MAP: Mean arterial pressure, SD: Standard deviation, CI: Confidence interval

SBP was reduced more by telmisartan than by cilnidipine. In particular, after 24 weeks, SBP dropped by 27.9 (MD-5.6; CI-2.9–8.4) mmHg in telmisartan group and 22.28 (MD-8; CI-5.6–10.5) mmHg in cilnidipine group. The group's decreases in DBP were almost the same (18.83 mmHg for telmisartan and 18.95 mmHg for cilnidipine). In addition, the telmisartan group experienced a greater mean arterial pressure (MAP) drop (9.72 mmHg) than the cilnidipine group (2.92 mmHg) which is not statistically significant ( $p=0.39$ ). Lacourcière *et al.*'s findings, which showed that telmisartan considerably improved 24-h blood pressure control over amlodipine, corroborate these findings [12]. In addition, Gosse *et al.* found that telmisartan was more effective than ramipril at lowering SBP and DBP, especially at night and in the early morning [13]. Telmisartan demonstrated better SBP and MAP reductions, which are consistent with results from the START ABPM trial, which found that telmisartan performed better than cilnidipine in 24-h ambulatory blood pressure monitoring, especially in the early morning when cardiovascular risks are at their highest [7].

Studies by Makawana *et al.* and Manthri *et al.* validated the effectiveness of cilnidipine in decreasing blood pressure, particularly its capacity to avoid reflex tachycardia, which is frequently observed with other CCBs [14,15]. In contrast, a study by Kaur *et al.* demonstrated that both cilnidipine and telmisartan were equally effective in reducing blood pressure [16]. In addition, pharmacokinetic studies show that cilnidipine and telmisartan demonstrate better bioavailability [17,18].

Although the drop in blood pressure was similar, telmisartan showed a better renal profile. While the cilnidipine group showed a rise in serum creatinine levels (0.07 mg/dL), the telmisartan group showed a modest decrease in serum creatinine levels (0.06 mg/dL) and both are not statistically significant. This is consistent with research by Binqun *et al.* that found that cilnidipine gradually increased kidney parameters [19]. Telmisartan, on the other hand, was reported by

Minakshi *et al.* to be renal protective, with steady or marginally improved creatinine levels [20]. Although the differences were not statistically significant, blood urea levels in the telmisartan group slightly increased (1.14 mg/dL) while remaining unchanged in the cilnidipine group. These findings imply that patients with CAD and underlying renal impairment might benefit more from telmisartan.

The telmisartan group's serum sodium levels stayed rather constant, but the cilnidipine group's levels dropped considerably ( $p=0.005$ ). Although telmisartan is known to carry a risk of hyperkalemia, particularly in individuals with impaired renal function or those using potassium-sparing diuretics, potassium levels stayed constant in both groups. Although there were slight variations in blood bicarbonate and chloride levels with no discernible clinical consequences, Telmisartan did cause a rise in serum bicarbonate (1.37 mmol/L,  $p=0.25$ ), the clinical importance of which needs more research. This study's renal profile favored telmisartan, which is in line with previous research showing its renoprotective benefits, especially in CAD and diabetic patients [8]. Despite substantial creatinine reduction, other observational studies have shown that cilnidipine gradually deteriorates renal function in diabetics [19]. The population under study and the length of follow-up could be the cause of this discrepancy.

In both groups, adverse effects were often moderate and controllable. The most frequent adverse effect in both groups was headache (12.7% with telmisartan and 17.5% with cilnidipine). The prevalence of pedal edema, a typical dihydropyridine CCB side effect, was somewhat higher in the cilnidipine group (4.8%) compared to the telmisartan group (1.6%). These results support earlier research by Adake *et al.* and Dalvi *et al.* which found that cilnidipine decreased the incidence of edema when compared to amlodipine but not when compared to ARBs like telmisartan [21,22]. The tolerability profile of telmisartan was somewhat better than that of cilnidipine, as 77.8% of patients in the former group and 61.9% in the latter group reported no adverse effects.

**Table 3: Adverse effects among study participants (n=126)**

Adverse drug reaction	Telmisartan, n (%)	Cilnidipine, n (%)
Headache	8 (12.7)	11 (17.5)
Pedal edema	1 (1.6)	3 (4.8)
Dizziness	4 (6.3)	3 (4.8)
Flushing	1 (1.6)	3 (4.8)
Palpitation	-	2 (3.1)
Nausea	-	2 (3.1)
No adverse effects	49 (77.8)	39 (61.9)

Telmisartan therapy costs INR 1246.7 on average for 6 months, while cilnidipine costs INR 1149.91. The cost difference in favor of cilnidipine was statistically significant (MD-96.8; CI-[-56.1–137.5];  $p<0.0001$ ). However, patients with higher cardiovascular or renal risk may find that the slightly higher cost of telmisartan is justified due to its improved renal profile and more prominent blood pressure management. Cilnidipine was still much less expensive when compared to telmisartan, although this must be weighed against the latter's better blood pressure control and renal safety record. ARBs such as telmisartan were also shown to be cost-effective in the long run by a

**Table 4: Renal parameters and electrolytes values among study participants at baseline, 12- and 24-week follow-up (n=126)**

Parameters	Paired t-test	Telmisartan, mean±SD	Cilnidipine, mean±SD	Independent T-test (mean difference from baseline with CI)	CI	p-value
Urea	Baseline	26.8±9.5	25.9±8.6	-1.17	-3.3–0.99	0.29
	24 weeks	27.9±8.2	25.9±6.9			
p-value		0.18	0.96			
Creatinine	Baseline	0.94±0.75	0.93±0.16	-0.017	-0.22–0.18	0.86
	24 weeks	0.88±0.11	0.85±0.2			
p-value		0.56	0.001			
Sodium	Baseline	135.7±4.8	136±2.7	0.91	-0.35–2.2	0.15
	24 weeks	135.7±2.7	135.2±3.1			
p-value		0.911	0.005			
Potassium	Baseline	4.5±4.5	5.2±11.8	-0.88	-4.1–2.3	0.58
	24 weeks	3.9±0.6	3.7±0.32			
p-value		0.32	0.33			
Chloride	Baseline	101.1±4.7	99.4±11	0.85	-4.3–5.9	0.74
	24 weeks	99.7±12.3	98.8±13			
p-value		0.35	0.8			
Bicarbonate	Baseline	23.3±2.8	22.8±3	-0.56	-1.5–0.39	0.25
	24 weeks	24.7±3	23.6±3			
p-value		0.000	0.03			

SD: Standard deviation, CI: Confidence interval



Table 5: Cost-effective analysis of the drugs (n=126)

Group	Cost of the drug (180 tablets) (mean±SD)	Mean difference (CI)	p-value
Telmisartan	1246.7±126.4	96.8	0.000
Cilnidipine	1149.9±103.3	(56.1–137.5)	

SD: Standard deviation, CI: Confidence interval

2021 pharmacoeconomic evaluation, especially for patients with end-organ damage or cardiovascular risk factors [23]. The positive efficacy and tolerability profile of telmisartan in comparison to other ARBs and antihypertensives is further supported by real-world data from Korean Electronic Health Record-based cohort analyses and Indian Electronic Medical Record (EMR) studies [24,25].

The results of this study should be interpreted with a number of caveats in mind. First off, because the study is open-label and non-randomized, selection bias could occur. Furthermore, the generalized ability of the results to other contexts is constrained due to the study's single-center design and one tertiary care facility involvement. To draw conclusions regarding the intervention's long-term effects, the 24-week follow-up period might not be long enough to record long-term cardiovascular and renal outcomes. Furthermore, lifestyle factors that could have affected the results, such as medication adherence, physical activity, and food, were not evaluated in this study. Finally, the cost estimation was only limited to three drug brands, and generic substitutes and regional pricing variations were not taken into consideration, which could have an impact on the cost-effective analysis.

## CONCLUSION

In individuals with CAD, telmisartan and cilnidipine are both proven antihypertensive medications with almost similar safety records. However, cilnidipine provided a more advantage in cost profile and had reported fewer cases of hyperkalaemia. In terms of lowering SBP and preserving renal function, telmisartan fared slightly better. In light of these results, telmisartan might be the better option for hypertensive individuals who also have renal disease, whereas cilnidipine might be a viable option for young people, those who are wealthy or intolerant to ARBs. To validate the stability of blood pressure management and the influence on cardiovascular morbidity and mortality, more research is necessary, utilizing randomized controlled designs with bigger, multi-center populations and longer follow-up periods. To effectively guide treatment decisions in the real world, future research should incorporate patient-reported outcomes and adherence data.

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## AUTHOR'S CONTRIBUTION

The authors confirm their contribution to the paper as follows: Dr. Althab Begum Mohamed: Study concept and design, literature search, data acquisition, analysis, interpretation of results, manuscript preparation, and manuscript editing. Dr. Satyajit Mohapatra: Study concept and design, manuscript editing, and review. Dr. Jerin James: Literature search, data acquisition, analysis, interpretation of results, manuscript preparation. Dr. Janani L: Data analysis, interpretation of results, manuscript preparation.

## CONFLICT OF INTEREST

None.

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