

A Prospective, Randomized Open-Label Study for Assessment of Antihypertensive Effect of Telmisartan Versus Cilnidipine Using Ambulatory Blood Pressure Monitoring (START ABPM Study)

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Abstract

Background: The antihypertensive agent telmisartan is an angiotensin II receptor blocker with a terminal elimination half-life of 24 h and has a high lipophilicity, thereby enhancing its bioavailability. Another antihypertensive agent, cilnidipine is a calcium antagonist and has dual mode of action on the calcium channels. This study aimed at determining effect of these drugs on ambulatory blood pressure (BP) levels.

Methods: A randomized, open-label, single-center study was conducted during 2021 - 2022 on newly diagnosed adult patients with stage-I hypertension, in a mega city of India. Forty eligible patients were randomized to telmisartan (40 mg) and cilnidipine (10 mg) groups, with once daily dose administered for 56 consecutive days. Ambulatory blood pressure monitoring (ABPM) (24 h) was performed pre- and post-treatment, and the ABPM-derived parameters were compared statistically.

Results: Statistically significant mean reductions were observed in all BP endpoints in telmisartan group but only in 24-h systolic blood pressure (SBP), daytime and nighttime SBP, and manual SBP and diastolic blood pressure (DBP) in cilnidipine group. The mean change from baseline to day 56 between two treatment groups showed statistical significance in last 6-h SBP ($P = 0.01$) and DBP ($P = 0.014$), and morning SBP ($P = 0.019$) and DBP ($P = 0.028$). The percent nocturnal drop within and between groups was statistically nonsignificant. Also, the between group mean SBP and DBP smoothness index differed nonsignificantly.

Conclusions: Telmisartan and cilnidipine once daily were effective

and well tolerated in the treatment of newly diagnosed stage-I hypertension. Telmisartan provided sustained 24-h BP control and may offer advantages over cilnidipine in terms of BP reductions, particularly over the 18- to 24-h post-dose period or critical early morning hours.

Keywords: Ambulatory blood pressure; Nocturnal dip; Smoothness index; Hypertension

Introduction

Hypertension is a common non-communicable disease (NCD) and is of major public health concern accounting for 19% of all deaths globally [1]. Hypertension is defined as an office blood pressure (BP) reading of at least 130 mm Hg systolic and 80 mm Hg diastolic, with the corresponding 24-h ambulatory BP readings being 125 mm Hg systolic and 75 mm Hg diastolic [2]. Today, an estimated 1.28 billion adults in the age range of 30 - 79 years worldwide have hypertension and two-thirds of them are living in lower- to middle-income countries. Nearly 46% of adults with hypertension are unaware of the condition, while about 42% of the cases are diagnosed and treated. Only about 21% of the cases have hypertension under control [3]. In India, hypertension is diagnosed if office BP exceeds 140/90 mm Hg and ambulatory BP exceeds 130/80 mm Hg, as per Indian guidelines on hypertension-IV [4]. The asymptomatic nature of hypertension contributes to a lack of awareness of this condition, thus being labeled as a “silent killer disease”. It is an independent risk factor for coronary heart disease, stroke, myocardial infarction, heart failure, and chronic kidney disease. If hypertension remains undiagnosed or uncontrolled, it can cause mortality or permanent disability [5]. However, it is a modifiable risk factor with non-pharmacological and pharmacological measures providing a substantial reduction of these conditions. Hence, BP measurements are essential for the diagnosis and management of hypertension [6].

The office (clinic) BP measurements provide a snapshot of an individual's BP, which might be falsely elevated or falsely low [7]. Moreover, these measurements do not provide variations in BP during the day and the effect of antihypertensive

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treatment, which is essential for the management of hypertension. Ambulatory blood pressure monitoring (ABPM) allows the automatic reading of the circadian variation in BP and the evaluation of treatment efficacy throughout the dosing interval [8]. ABPM provides an effective prediction of cardiovascular risk and enables BP control at the time of heightened risk, thereby improving the long-term prognosis [9]. It helps in reducing the possible number of false readings and provides dynamic variations in BP [6].

To achieve effective control of BP, a long-acting antihypertensive agent is essential. Telmisartan is one of the angiotensin II receptor blockers (ARBs) with a terminal elimination half-life of 24 h and has a large volume of distribution due to its high lipophilicity [10]. This enhances its tissue penetration, intracellular absorption, and bioavailability. Telmisartan blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor in many tissues, such as vascular smooth muscle and the adrenal gland. Telmisartan does not bind to or block other hormone receptors or ion channels known to be important in cardiovascular regulation. The efficacy of telmisartan as monotherapy has been extensively studied using ABPM to demonstrate its BP control at the end of a once-daily dosing interval [11].

Another antihypertensive agent cilnidipine is a novel calcium antagonist due to its dual mode of action on the calcium channels. Cilnidipine blocks both the L-type and N-type calcium channels. Simultaneous blockade of the L-type and N-type calcium channels results in a significant reduction of BP without causing reflex tachycardia. It blocks the N-type channel at sympathetic nerve ending [12-14]. Thus, the dual mode of action of cilnidipine permits vasodilation and sympathetic blockade. Due to its lipophilic and avidly binding property, cilnidipine has shown prolonged and desirable antihypertensive effect [15].

Both telmisartan and cilnidipine are recommended as first-line drugs for hypertension control; however, the half-life of cilnidipine is shorter than telmisartan. Accordingly, a clinical trial was planned to evaluate if there is any difference in the 24-h antihypertensive efficacy of two drugs due to difference in half-lives, using ABPM. Moreover, the interest in the trial was to compare the safety and tolerability of telmisartan and cilnidipine administered to hypertensive patients.

Materials and Methods

Study design and participants

A prospective, randomized, open-label, single-center trial for assessing the 24-h antihypertensive efficacy of telmisartan versus cilnidipine was planned during the year 2021 - 2022. Newly diagnosed adult patients of either sex with stage-I hypertension and willing to participate in the trial were considered for screening. The demographics, vital signs, physical examination, and medical history were recorded for each participant. Moreover, blood samples were collected, and electrocardiogram (ECG) was recorded for each participant. Subjects

with systolic blood pressure (SBP) \geq 140 mm Hg and/or diastolic blood pressure (DBP) \geq 90 mm Hg by manual cuff sphygmomanometer in clinical setup, requiring initiation of antihypertensive medication with single-drug therapy, were included in the study. Those subjects with hepatic impairment, chronic renal failure, and coronary artery disease were excluded from the study. Furthermore, type 2 diabetes mellitus (DM) patients diagnosed for more than 2 years, type 1 DM patients, patients with a history of surgery or malignant hypertension, recent substance abuse, breast-feeding or pregnant females, patients with history of human immunodeficiency virus (HIV) infection, hepatitis B and C were excluded from the study.

Randomization and masking

Forty eligible subjects were equally assigned to two groups/arms using a unique randomization code sequentially through an interactive web response system (IWRS). Subjects received one of the two active study drugs (i.e., either telmisartan 40 mg tablet or cilnidipine 10 mg tablet) based on randomization. The study medications were labeled with a unique material code that was linked with the randomization scheme. Randomization codes assigned to subjects were available to the investigator(s) from the IWRS without revealing the treatment allocation.

Procedure and investigational product (IP) administration

The study protocol has been schematically shown in Figure 1. Proper instructions regarding the device handling were given to each subject. On day 1, (24 h post ABPM device attachment), the subject visited the site to return the device and the data were extracted from the machine and stored in the computer as the pre-treatment data. Before the start of dosing, trough manual BP was measured manually. The study drug was dispensed to the subjects after detaching the ABPM device. They were instructed about the timings of IP intake for the entire duration of the study until the next visit. Subjects were administered with tablet telmisartan 40 mg (80 mg if needed) orally once daily, or cilnidipine 10 mg (20 mg if needed) orally once daily for 56 consecutive days (8 weeks). No other antihypertensive medications, apart from study drugs, were allowed during the study period. Subjects were asked to visit the site for applying the ABPM device on day 56 (end of study (EOS)) after the treatment period. The manual trough BP was measured immediately before the subject takes medication on day 56. On day 57, the device was detached from each subject and the data were downloaded to the personal computer. The BP recording times were similar at both day 0 and day 56, to compare the effect of treatment within and between groups. The vital signs and lab investigations (hemoglobin A1c (HbA1c), creatinine, urea, complete blood count (CBC) and bicarbonate) were also performed on day 57. The subject's compliance, IP accountability, and assessment of adverse events (AEs) and serious adverse events (SAEs) were also done on day 57. Loss to follow-up was considered as subjects participating until the baseline

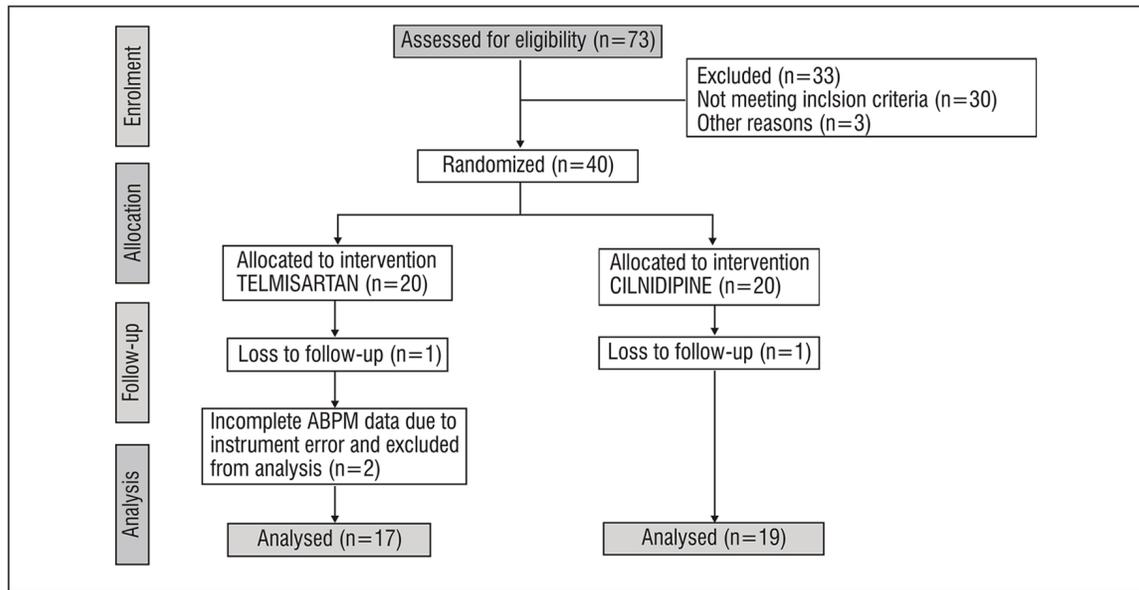


Figure 2. Sample flow diagram. ABPM: ambulatory blood pressure monitoring.

well as manual measurement data. For ABPM, a responder was defined as a subject with a mean 24-h DBP < 80 mm Hg or reduction in DBP at day 56 from baseline of $\geq 10\%$; and SBP < 130 mm Hg or reduction in SBP at day 56 from baseline of $\geq 10\%$. For manual measurement, the responder was defined as a subject with a mean DBP < 90 mm Hg or reduction in DBP at day 56 from baseline of $\geq 10\%$; and SBP < 140 mm Hg or reduction in SBP at day 56 from baseline of $\geq 10\%$. The distribution of responders and non-responders was compared between two groups using Pearson's Chi-square test.

Nocturnal dip

The systolic and diastolic nocturnal dips were obtained as the percentage drop in the mean BP from daytime to sleep periods. The comparison of nocturnal dips between baseline and day 56 in each group was performed using paired *t*-test, while the change in dip from baseline to day 56 between the two groups was compared using a *t*-test for independent samples.

SI

The systolic and diastolic SI was derived from the ABPM data for each patient referring to baseline and day 56 hourly values. For each patient, the continuous BP data at baseline and day 56, on systolic/diastolic parameters, were partitioned into four time zones, viz. morning, afternoon, evening, and night times. The mean BP values were obtained at baseline and day 56 according to time zones for each patient. The difference of means between baseline and day 56 for each time zone was obtained. The ratio of the mean of these differences and the SD of differences was referred to as the SI for the patient. Both

systolic and diastolic smoothness indices were obtained for each patient. Descriptive statistics like mean, SD, median and interquartile range for SI were obtained. The mean systolic/diastolic SI for both treatments was compared using a *t*-test for independent samples.

All the above analyses were performed using the R-programming tool (version 3.4.3) and SPSS, version 26.0 IBM Corp, USA, and the statistical significance was evaluated at 5% level.

Results

A total of 73 patients were screened, out of which 33 failed the inclusion criteria, thus leaving 40 patients for randomization. Twenty patients were randomized per group. During follow-up, one patient was lost in each group. Further, the continuous BP monitoring data for two patients in the telmisartan group were incomplete due to missing values, and hence were dropped from the analysis set. The final analysis was performed on 17 patients from the telmisartan and 19 patients from the cilnidipine group (Fig. 2). The per-protocol analysis was performed on the final data set. Table 1 provides descriptive statistics for demographic and anthropometric parameters of patients in two treatment groups. The mean age of patients in the telmisartan group was 41.88 (SD: 11.16) years, while that of the cilnidipine group was 41.47 (SD: 12.69) years, and the difference between the groups was statistically nonsignificant ($P = 0.651$). Further, the sex distribution, anthropometry, and clinical evaluations were also nonsignificantly different between the two at baseline (day 0). The ABPM data were obtained on these patients at baseline and day 56. Figure 3 provides the mean SBP and DBP profiles for 24-h duration at baseline and day 56 for both groups.

Table 2 provides descriptive statistics for various ABPM-

Table 1. Baseline Characteristics of Subjects in Two Groups

Characteristics	Group		P value
	Telmisartan (n = 17)	Cilnidipine (n = 19)	
Age in years	41.88 (11.16); 36.15, 47.62	41.47 (12.69); 35.36, 47.59	0.651
Gender			
Female	7 (41.2)	11 (57.9)	0.317
Male	10 (58.8)	8 (42.1)	
Height (cm)	166.44 (6.79); 162.94, 169.93	165.15 (8.02); 161.29, 169.02	0.608
Weight (kg)	74.15 (12.91); 67.51, 80.78	70.32 (12.63); 64.24, 76.41	0.375
BMI (kg/m ²)	26.84 (5.15); 24.19, 29.49	25.78 (4.41); 23.65, 27.90	0.510
BP systolic (mm Hg)	154.53 (8.45); 150.45, 158.6	155.24(8.72); 151.27, 159.21	0.795
BP diastolic (mm Hg)	99.63 (6.61); 96.45, 102.82	102.38(10.17); 97.75, 107.01	0.323
Pulse rate (/min)	90.42 (9.14); 86.02, 94.82	88.76 (10.8); 83.84, 93.68	0.605
Respiratory rate (/min)	19.79 (1.72); 18.96, 20.62	19.71 (1.19); 19.17, 20.26	0.872
Temperature (°F)	97.28 (0.69); 96.95, 97.62	97.23 (0.78); 96.88, 97.58	0.812

Data are mean (SD), and 95% CI for mean for continuous variables, and number (%) for categorical variables. Percentages are based on the final analysis sample of the respective group. The P value for continuous variable is according to *t*-test for independent sample, while for categorical variable is using Pearson's Chi-square test. CI: confidence interval; BMI: body mass index; BP: blood pressure; SD: standard deviation.

derived variables and their comparison within the group. It also provides the change in variables from baseline to day 56 and the comparison of change between the two groups. In the telmisartan group, all the variables showed statistically significant mean differences, as indicated by P values < 0.05. In the cilnidipine group, systolic 24-h BP, systolic daytime BP, systolic nighttime BP, and manual systolic and diastolic measurements showed statistically significant mean differences with P values < 0.05. Further, the change in each variable from baseline to day 56 was compared between the two groups. The difference of means for systolic last 6 h (P = 0.010), diastolic last 6 h (P = 0.014), systolic morning (P = 0.019), and diastolic morning BP (P = 0.028), showed a statistically significant difference between the groups. The mean change in the telmisartan group was significantly higher than that in the cilnidipine group. The nocturnal dip was also analyzed for SBP and DBP on similar lines (Table 3). The change in the nocturnal dip from baseline to day 56 for SBP and DBP was statistically nonsignificant in both groups. Moreover, the difference in mean change in the nocturnal dip for systolic and diastolic BP was statistically nonsignificant between the two treatment groups. The SI was obtained for SBP and DBP and was summarized for each treatment group, as shown in Table 4. The mean systolic and diastolic SI was higher in the telmisartan group as compared to the cilnidipine group; however, the difference was statistically nonsignificant. The number of responders in two treatment arms according to ABPM and manual measurements is shown in Figure 4. Both ABPM and manual measurements showed a higher number of responders in the telmisartan group than in the cilnidipine group, although the difference was statistically nonsignificant.

Regarding safety, none of the patients reported any AE during the course of the study. The lab parameters showed statistically nonsignificant differences within and between groups.

Discussion

The present study aimed at determining the efficacy and safety of telmisartan versus cilnidipine using an ABPM device. The ABPM approach provided a dynamic viewpoint of BP trends over 24 h in patients in these two treatment groups. The effectiveness of the treatment over different time durations could be explored through continuous monitoring, which was the value addition of the study as compared to manual office measurements. The overall profile of BP in both treatment groups was similar to that reported by Plavnik et al in 2002 [16]. In general, both hypertensive and normotensive individuals have similar circadian variation in BP, with higher values during the daytime and lower during the night times [17]. In the morning period, the BP surges; however, the extent of the surge varies with the individuals, and some even display morning hypertension [18]. In our study, we also observed a rise in the BP level in the morning session with a peak reaching at mid-day, then declining till evening and reaching lowest during night times. The pattern was consistent before and after medication; however, there was a significant reduction post-treatment in both groups.

Regarding the antihypertensive effect, the ABPM-derived variables exhibited better improvement in both SBP and DBP in the telmisartan group as compared to the cilnidipine-treated group. There was a significant within-group reduction in 24-h SBP and DBP in the telmisartan group, unlike in cilnidipine group, where only 24-h SBP was reduced significantly. Overall, the reduction was prominent in SBP as compared to DBP in both the groups. The last 6-h SBP and DBP showed significant improvement in the telmisartan group, unlike in the cilnidipine group. The difference of change in these parameters from baseline to day 56 was also significantly better with telmisartan as compared to cilnidipine. Earlier, telmisartan 40

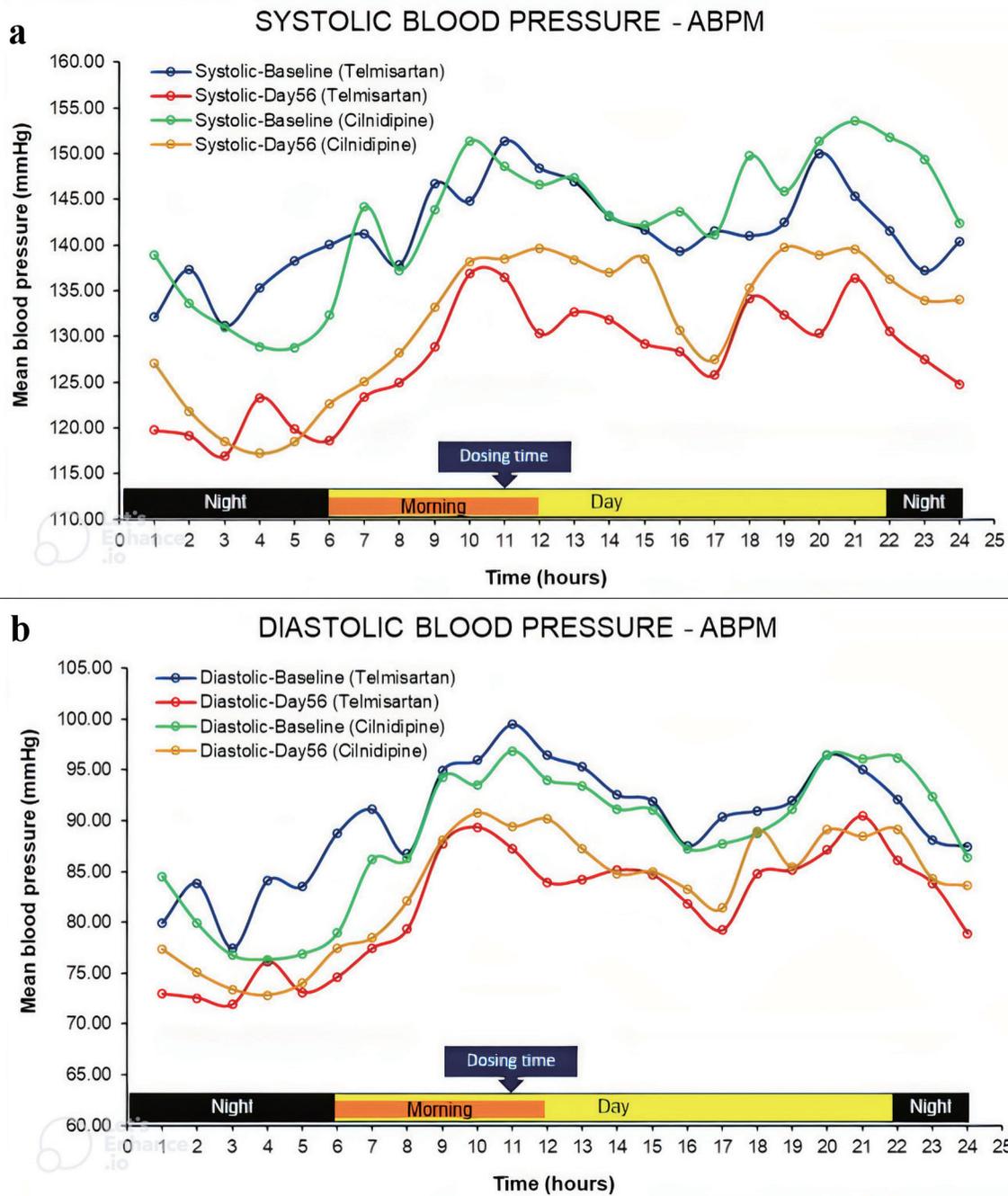


Figure 3. Profile of systolic and diastolic blood pressures during 24 h according to ABPM device. ABPM: ambulatory blood pressure monitoring.

mg or 80 mg demonstrated better control of both SBP and DBP during the last 6 h of dosing interval as compared to losartan 50 mg [19]. Telmisartan 40 mg showed a reduction of 10.7/6.8 mm Hg for SBP/DBP in patients, which was significant ($P < 0.05$). Our study showed a higher reduction of 16.77/10.76 mm Hg with the same dose. In PROBE study with telmisartan 80 mg and valsartan 80 mg, a significant reduction was seen in the last 6 h in DBP in the telmisartan-treated group after 8 weeks [20]. In PRISMA study, the authors observed superior

reduction in SBP and DBP in the last 6 h with telmisartan 80 mg as compared to ramipril 10 mg after 14 weeks [21-23]. The evidence of telmisartan controlling the morning BP surge was also observed in MICCAT2 study [24]. Telmisartan 80 mg also proved to be more effective than ramipril 10 mg in reducing nighttime low and early morning mean SBP and DBP compared to baseline [25]. In our study, the nighttime improvement in SBP and DBP with telmisartan 40 mg was significantly better on day 56 as compared to baseline, while only

Table 2. Descriptive Statistics for Various ABPM-Derived Variables and Their Comparison Within Groups as Well as Comparison of Change From Baseline to Day 56 Between Groups

ABPM-derived variables (mm Hg)	Telmisartan (n = 17)				Cilnidipine (n = 19)				
	Baseline	Day 56	P value ^a	Change: Base-line to day 56	Baseline	Day 56	P value ^a	Change: Base-line to day 56	P value ^b
Systolic, 24 h	142.47 (10.55)	128.47 (11.61)	0.002	-14.00 (15.88)	140.44 (11.24)	132.83 (13.86)	0.007	-7.61 (10.51)	0.174
	126, 166	116, 156		-22.17, -5.83	123, 170	107, 174		-12.57, -2.65	
Diastolic, 24 h	91.18 (6.97)	82.91 (7.51)	0.012	-8.26 (12.03)	88.39 (10.4)	84.8 (9.21)	0.087	-3.59 (8.41)	0.196
	81.4, 102	74.6, 101		-14.45, -2.08	65.2, 113	65.9, 109		-7.55, 0.37	
Systolic, last 6 h	145.65 (13.09)	128.88 (12.41)	< 0.001	-16.77 (14.72)	139.48 (11.83)	135.2 (12.46)	0.148	-4.28 (12.01)	0.010
	125, 173.3	112.9, 165		-24.34, -9.2	117.8, 164.3	112.5, 162.3		-9.94, 1.37	
Diastolic, last 6 h	94.69 (10.05)	83.92 (8.35)	0.002	-10.76 (12.26)	87.79 (10.31)	86.53 (7.89)	0.521	-1.26 (8.15)	0.014
	77, 110.7	73.1, 111.3		-17.07, -4.46	69.6, 109.5	70.7, 101.6		-5.1, 2.58	
Systolic, morning	146.18 (13.08)	129.84 (11.54)	< 0.001	-16.34 (12.84)	141.95 (11.09)	136.21 (12.27)	0.058	-5.74 (12.07)	0.019
	125.8, 170.3	114.5, 161.7		-22.94, -9.74	126.3, 164.3	114.4, 161.8		-11.43, -0.04	
Diastolic, morning	94.66 (10.41)	84.82 (7.55)	0.002	-9.85 (10.95)	89.46 (9.93)	87.35 (7.56)	0.321	-2.11 (8.47)	0.028
	77.4, 112.4	74.7, 109.1		-15.48, -4.22	70, 109.5	72.3, 101.7		-6.09, 1.88	
Systolic, daytime	145.12 (10.89)	130.86 (11.35)	0.001	-14.26 (13.62)	144 (10.92)	136.95 (15.84)	0.011	-7.05 (10.62)	0.092
	129.1, 162.9	117.1, 155.7		-21.26, -7.25	129.5, 175.5	110.2, 188.1		-12.06, -2.04	
Diastolic, daytime	93.58 (8.01)	84.75 (7.29)	0.004	-8.84 (10.67)	90.78 (10.82)	87.41 (10.31)	0.126	-3.37 (8.89)	0.111
	81.8, 105.1	75.5, 103.3		-14.32, -3.35	65.3, 116.7	67.2, 117.5		-7.56, 0.82	
Systolic, night	137.95 (16.64)	121.85 (14.81)	0.011	-16.09 (23.17)	134.22 (14.37)	125.46 (12.62)	0.028	-8.76 (15.5)	0.263
	115.6, 178.5	106, 158.8		-28.01, -4.18	110.6, 166.1	100.1, 155.7		-16.06, -1.45	
Diastolic, night	85.74 (8.29)	74.68 (7.05)	0.004	-11.07 (12.8)	82.26 (11.27)	77.69 (8.03)	0.101	-4.57 (11.53)	0.128
	72.8, 105.9	66.4, 96.5		-17.47, -4.67	59.9, 100.7	61.8, 90.7		-10.12, 0.99	
Systolic, manual	155.18 (8.50)	137.07 (7.96)	< 0.001	-18.19 (11.97)	154.21 (8.22)	139.95 (9.49)	< 0.001	-14.26 (12.01)	0.104
	144, 166	123, 152		-24.56, -11.81	141, 170	119, 154		-20.05, -8.48	
Diastolic, manual	98.63 (6.52)	87.00 (7.26)	< 0.001	-11.63 (9.42)	101.37 (10.45)	85.63 (7.68)	< 0.001	-15.74 (14.32)	0.367
	87, 111	76, 101		-16.86, -7.13	77, 120	72, 97		-22.64, -8.83	

Data are mean (SD), and 95% CI for mean. ^aObtained using paired t-test. ^bObtained using paired t-test for independent samples. P values < 0.05 indicate statistical significance. Change in BP is calculated as baseline - day 56. CI: confidence interval; BP: blood pressure; SD: standard deviation; ABPM: ambulatory blood pressure monitoring.

Table 3. Descriptive Statistics for Nocturnal Dip and Its Comparison Within Group as Well as Comparison of Its Change From Baseline to Day 56 Between Two Groups

Nocturnal dip (%)	Group								P value ^b
	Telmisartan (n = 17)				Cilnidipine (n = 19)				
	Baseline	Day 56	Change: base-line to day 56	P value ^a	Baseline	Day 56	Change: base-line to day 56	P value ^a	
Systolic BP	4.93 (8.65); 0.48, 9.37	7.07 (4.45); 4.78, 9.36	2.14 (10.34); -3.17, 7.46	0.405	6.45 (6.4); 3.36, 9.53	7.69 (4.25); 5.64, 9.74	1.25 (8.00); -2.61, 5.11	0.505	0.771
Diastolic BP	9.05 (8.23); 4.82, 13.28	10.04 (5.38); 7.27, 12.81	0.99 (10.88); -4.60, 6.58	0.712	10.17 (7.42); 6.59, 13.74	10.21 (5.5); 7.56, 12.86	0.04 (10.01); -4.79, 4.87	0.986	0.787

Data are mean (SD); and 95% CI for mean. ^aObtained using paired t-test. ^bObtained using t-test for independent samples. Change in nocturnal dip is calculated as day 56 - baseline. CI: confidence interval; BP: blood pressure; SD: standard deviation

Table 4. Comparison of Smoothness Index Between Two Groups for Systolic and Diastolic BP

Smoothness index	Parameter	All patients		
		Group		P value ^a
		Telmisartan (n = 17)	Cilnidipine (n = 19)	
Systolic BP	Mean	1.79	1.38	0.601
	SD	1.52	2.82	
	Median	2.3	0.75	
	IQR	1.55	1.31	
Diastolic BP	Mean	1.44	0.68	0.167
	SD	1.6	1.54	
	Median	1.62	0.68	
	IQR	2.66	2.2	

^aObtained using t-test for independent samples. SD: standard deviation; BP: blood pressure; IQR: interquartile range.

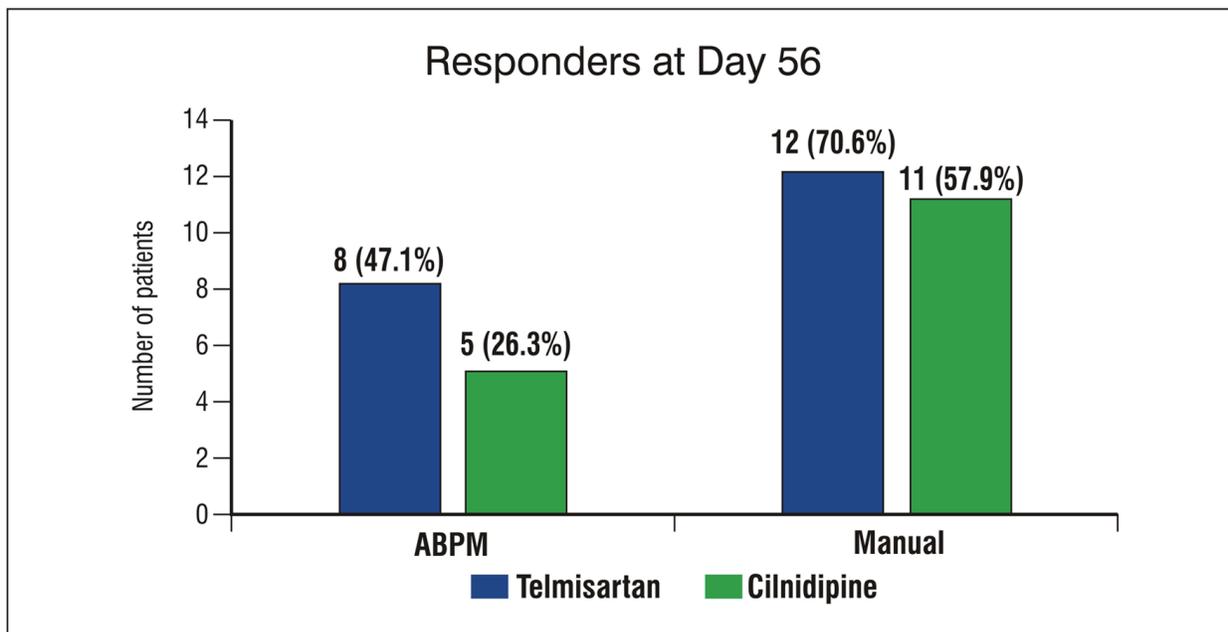


Figure 4. Column chart showing number of responders at day 56 in two groups for ABPM and manual BP measurement. ABPM: ambulatory blood pressure monitoring; BP: blood pressure.

SBP showed significant improvement with cilnidipine 10 mg. The reason for the superior effectiveness of telmisartan in the above studies could be that among all the ARBs, telmisartan has the longest half-life of about 24 h [26, 27]. This ensures its long duration of action and thereby effective control throughout the once-daily dose interval. Due to its lipophilic property, we observed a significant improvement in some of the ABPM-derived variables with cilnidipine; however, the effect was better with telmisartan than with cilnidipine.

The responder rate in the telmisartan group was higher (47.1%) than that in cilnidipine group (26.3%) based on ABPM data. The reported responder rate for ARBs ranges between 33-79%, while for calcium-channel blockers it ranges between 43-95% [28]. For telmisartan, the rate was within the reported range, while for cilnidipine, it was much below the observed rates. Another efficacy indicator nocturnal dip showed a higher percent increase for SBP and DBP in the telmisartan group than the cilnidipine group, although the change was statistically nonsignificant. Furthermore, the mean SI for SBP and DBP in the telmisartan group was higher than that in cilnidipine group for the study sample, although the difference in means was statistically nonsignificant. The higher index values in patients treated with telmisartan suggest better homogeneity or smoothing of BP reduction for the treatment [29]. There were no reported AEs during the study period in both the treatment groups and any deviations in laboratory parameters with respect to baseline values, thereby ensuring the safety of both the antihypertensive drugs. The smaller sample size is a limitation of the study, which may not allow generalization of the results to a larger population.

Conclusions

The efficacy and safety assessment of telmisartan 40 mg versus cilnidipine 10 mg using ABPM indicated the superiority of telmisartan over cilnidipine as regards last 6 h and morning time SBP as well as DBP. Telmisartan, with its longest half-life among ARBs, has the potential to reduce early morning BP, which has been demonstrated through numerous studies. Although cilnidipine showed improvement in the ABPM parameters, the effect was prominent in the telmisartan group. Both the drugs were well tolerated; however, considering the effective control of the morning BP surge, telmisartan can be a better choice for the management of mild to moderate hypertension.

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Financial Disclosure

Investigator (Dr. Rahul Sawant) initiated the study.

Conflict of Interest

The authors declare that they have no conflict of interest.

Informed Consent

All the subjects provided written informed consent.

Author Contributions

Rahul Sawant was involved in conceptualization, study design and manuscript review. Sachin Suryawanshi and Hanmant Barkate reviewed and approved the manuscript. Mayur Jadhav and Sumit Bhushan performed statistical analysis, contributed to manuscript writing and proof reading. Tanmay Rane did final proof reading and approval for publication.

Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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