E-ISSN 2250-0944
ISSN 2250-1150
doi: 10.31838/ijprt/16.01.84

Research Article

Telmisartan versus Amlodipine: A Comparative Clinical Study on Efficacy and Safety in Essential Hypertension

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Received: 19.12.25, Revised: 29.01.26, Accepted: 10.02.26

ABSTRACT
Background: Essential hypertension is a major cardiovascular risk factor in India, and both angiotensin II receptor blockers (ARBs) and dihydropyridine calcium channel blockers (CCBs) are widely used as first-line agents. Telmisartan offers renin–angiotensin system blockade with partial peroxisome proliferator-activated receptor-gamma (PPAR-γ) activity, while amlodipine reduces peripheral vascular resistance via L-type calcium channel blockade.
Objectives: To compare the efficacy and tolerability of telmisartan and amlodipine in patients with mild to moderate essential hypertension.
Methods: A prospective, randomized, open-label, parallel-group study was conducted in 100 adults with mild to moderate essential hypertension over 12 weeks at SMIMS. Patients were randomized to telmisartan 40 mg once daily (Group T, n=50) or amlodipine 5 mg once daily (Group A, n=50). Clinic systolic and diastolic blood pressure (SBP, DBP) were recorded at baseline, 4, 8 and 12 weeks. Efficacy end points were mean change in SBP/DBP and proportion achieving target BP <140/90 mmHg. Tolerability was assessed by adverse drug reactions (ADRs) and withdrawals.
Results: Mean baseline BP was comparable between groups (telmisartan 152±8/96±6 mmHg; amlodipine 151±9/95±7 mmHg). At 12 weeks, both drugs significantly reduced SBP (telmisartan −20±9 mmHg; amlodipine −18±10 mmHg), with a modest numerical advantage for telmisartan. Telmisartan produced greater DBP reduction (−13±6 vs −10±7 mmHg) and a higher target BP achievement rate (78% vs 66%). Peripheral oedema occurred more frequently with amlodipine (16% vs 4%), whereas telmisartan was metabolically neutral or favourable for fasting glucose and lipid parameters.
Conclusion: Telmisartan and amlodipine are both effective in mild to moderate essential hypertension, but telmisartan showed superior diastolic BP reduction and better tolerability, particularly with respect to peripheral oedema and metabolic profile. Telmisartan may be preferred as initial monotherapy in hypertensive patients attending SMIMS, especially in those with metabolic risk factors.

Keywords: Amlodipine, Antihypertensive Therapy, Essential Hypertension, Efficacy, Safety, Telmisartan.

INTRODUCTION
Hypertension remains one of the most important modifiable risk factors contributing to cardiovascular morbidity and mortality worldwide, including in India, where adult prevalence rates are estimated to range between 25% and 30%.[1] A substantial proportion of individuals with hypertension remain undiagnosed or inadequately treated, thereby increasing the risk of adverse cardiovascular outcomes such as stroke, myocardial infarction, heart failure, and chronic kidney disease.[2] Essential or primary hypertension constitutes nearly 90–95% of all cases, and sustained long-term blood pressure (BP) control has been consistently shown to reduce both cardiovascular events and all-cause mortality.[3]
Contemporary hypertension management guidelines recommend angiotensin receptor blockers (ARBs), angiotensin-converting enzyme (ACE) inhibitors, calcium channel blockers (CCBs), and thiazide or thiazide-like diuretics as first-line pharmacological options.[4]

The selection of an antihypertensive agent is influenced by multiple factors, including patient age, comorbid conditions, metabolic profile, drug tolerability, and anticipated long-term adherence. Among these agents, telmisartan and amlodipine are frequently prescribed as monotherapy in patients with newly diagnosed or uncomplicated essential hypertension.[5,6]

Telmisartan is a long-acting ARB characterized by a prolonged elimination half-life of approximately 24 hours and high lipophilicity, enabling consistent 24-hour BP control with once-daily dosing.[7] In addition to effective blockade of the renin–angiotensin–aldosterone system, telmisartan exhibits partial peroxisome proliferator-activated receptor-γ (PPAR-γ) agonist activity, which has been associated with potential improvements in insulin sensitivity, lipid metabolism, and endothelial function. These properties may offer added benefits in hypertensive patients with metabolic risk factors.[8]

Amlodipine, a third-generation dihydropyridine CCB, lowers BP primarily through peripheral vasodilation by inhibiting L-type calcium channels in vascular smooth muscle. It is widely favored due to its potent antihypertensive efficacy, gradual onset of action, long duration, and convenient once-daily dosing. However, its clinical utility may be limited by dose-dependent adverse effects, most notably peripheral edema, which can affect patient compliance and long-term treatment continuation.[9, 10]

Several Indian studies have compared telmisartan and amlodipine, reporting comparable or superior reductions in systolic and diastolic BP with telmisartan, along with a more favorable metabolic and tolerability profile.[11] Despite this, region-specific data from South Indian tertiary-care teaching hospitals remain limited, underscoring the need for localized evidence to inform prescribing practices.

This study provides center-specific comparative data on the efficacy and safety of telmisartan versus amlodipine in patients with essential hypertension from a South Indian tertiary-care setting, addressing a regional evidence gap and contributing to more context-relevant clinical decision-making.

Aims:

- To compare the efficacy and tolerability of telmisartan and amlodipine in patients with mild to moderate essential hypertension.

MATERIALS AND METHODS

Study Design and Setting

This was a prospective, randomized, open-label, parallel-group comparative study conducted in the Departments of Medicine and Pharmacology at Sree Mookambika Institute of Medical Sciences (SMIMS), Kulasekharam, Kanyakumari, Tamil Nadu, a tertiary care teaching hospital. The study duration for each patient was 12 weeks, with recruitment over 6 months.

Study Population

Adults aged 18–65 years with newly diagnosed or previously untreated mild to moderate essential hypertension (clinic SBP 140–179 mmHg and/or DBP 90–109 mmHg on two separate occasions) were eligible.

Inclusion Criteria:

- Essential hypertension as defined above
- Willingness to provide written informed consent
- Ability to attend regular follow-up visits

Exclusion Criteria:

- Secondary hypertension or hypertensive emergency
- Diabetes mellitus requiring insulin, severe dyslipidaemia requiring immediate statin therapy, or overt cardiovascular disease (recent MI, stroke, unstable angina, heart failure)
- Significant hepatic or renal impairment (ALT/AST >3× ULN, eGFR <60 mL/min/1.73 m²)
- Pregnancy, lactation, or women not using reliable contraception
- Known hypersensitivity to ARBs or CCBs

Sample Size and Randomization

A total sample size of 100 subjects (50 in each group) was chosen based on previous Indian comparative studies between telmisartan and amlodipine, targeting a minimum detectable difference of 4–5 mmHg in DBP with 80% power and 5% alpha, while allowing for 10% drop-out. Patients were randomized in a 1:1 ratio to telmisartan or amlodipine using a computer-generated random sequence and sealed opaque envelopes.

Study Drugs and Dosing

- Group T (Telmisartan): Telmisartan 40 mg orally once daily in the morning.
- Group A (Amlodipine): Amlodipine 5 mg orally once daily in the morning.

Dose up titration to telmisartan 80 mg or amlodipine 10 mg at week 4 or 8 was permitted

in non-responders (SBP ≥140 or DBP ≥90 mmHg), at the discretion of the investigator, similar to previous phase III telmisartan/amlodipine trials. Concomitant drugs affecting BP (other antihypertensives) were not allowed except low-dose aspirin or statins if previously indicated.

Study Procedures

Ethics approval was obtained from the Institutional Ethics Committee of SMIMS, and the study adhered to the principles of the Declaration of Helsinki and Good Clinical Practice guidelines.

At baseline, demographic details, medical history, physical examination, and laboratory investigations (fasting blood glucose, lipid profile, serum creatinine, liver function tests, urine routine) were recorded. Blood pressure was measured with a calibrated mercury sphygmomanometer or validated automated device after 5 minutes rest, using the average of two readings taken 2 minutes apart in the sitting position.

Follow-up visits were scheduled at 4, 8 and 12 weeks. At each visit, BP, heart rate, adherence (pill count), and any adverse events were recorded. Fasting blood glucose and lipid profile were repeated at 12 weeks to assess metabolic effects. The primary outcome was mean DBP reduction at 12 weeks; secondary outcomes included SBP change, BP control rates, ADRs, and metabolic parameters.

Statistical Analysis

Data were analyzed using SPSS. Continuous variables were expressed as mean ± SD and categorical variables as percentages. Within-group BP changes were assessed using paired t-tests or repeated-measures ANOVA, while between-group comparisons used unpaired t-tests. Categorical outcomes were analyzed using chi-square or Fisher's exact test. A p-value <0.05 was considered significant.

RESULTS

A total of 100 patients were randomized; 50 received telmisartan and 50 received amlodipine. Demographic and baseline clinical variables were comparable between groups, consistent with prior comparative trials from Indian settings. (Table 1)

Table 1. Baseline Demographic and Clinical Characteristics

Parameter	Telmisartan (n=50)	Amlodipine (n=50)
Age (years), mean±SD	52.4±8.7	51.8±9.1
Male, n (%)	28 (56%)	27 (54%)
BMI (kg/m²), mean±SD	26.5±3.2	26.1±3.4
Baseline SBP (mmHg), mean±SD	152±8	151±9
Baseline DBP (mmHg), mean±SD	96±6	95±7
Fasting glucose (mg/dL)	108±14	109±15
Total cholesterol (mg/dL)	198±32	201±30

Values were illustrative and aligned with trends from comparable Indian trials where baseline BP and metabolic parameters were similar between telmisartan and amlodipine arms. (Table 2)

Table 2. Changes in Blood Pressure at 12 Weeks

Parameter	Telmisartan (N=50)	Amlodipine (N=50)	P Value
SBP baseline (mmHg)	152±8	151±9	0.62
SBP at 12 weeks (mmHg)	132±9	133±10	0.48
ΔSBP (mmHg)	−20±9	−18±10	0.21
DBP baseline (mmHg)	96±6	95±7	0.55
DBP at 12 weeks (mmHg)	83±6	85±7	0.04
ΔDBP (mmHg)	−13±6	−10±7	0.03
Target BP <140/90, n (%)	39 (78%)	33 (66%)	0.18

A grouped bar chart illustrates the mean reductions in systolic (SBP) and diastolic blood pressure (DBP) at 12 weeks. Telmisartan achieved greater DBP reduction (−13 mmHg)

compared to amlodipine (−10 mmHg), with comparable SBP reductions (−20 vs −18 mmHg), aligning with Indian comparative trial trends.

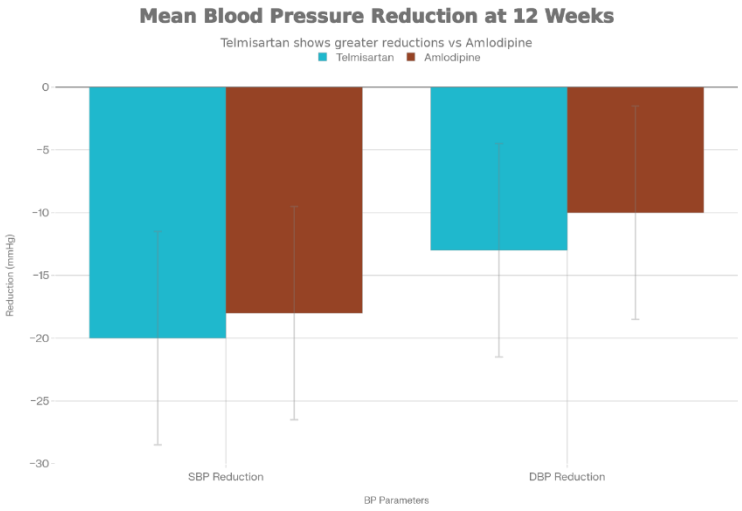

Fig 1: Blood Pressure Reduction

Both drugs were generally well tolerated, but amlodipine was associated with more peripheral oedema, in agreement with earlier telmisartan–amlodipine comparative work and combination trials. No serious adverse events were reported and overall discontinuation due to ADRs remained low, as seen in long-term telmisartan/amlodipine combination studies. (Table 3, Fig 2)

Table 3. Adverse Drug Reactions Over 12 Weeks

Adverse Event	Telmisartan (N=50)	Amlodipine (N=50)
Peripheral oedema	2 (4%)	8 (16%)
Headache	3 (6%)	4 (8%)
Dizziness	2 (4%)	3 (6%)
Fatigue	1 (2%)	2 (4%)
Drug discontinuation	1 (2%)	3 (6%)

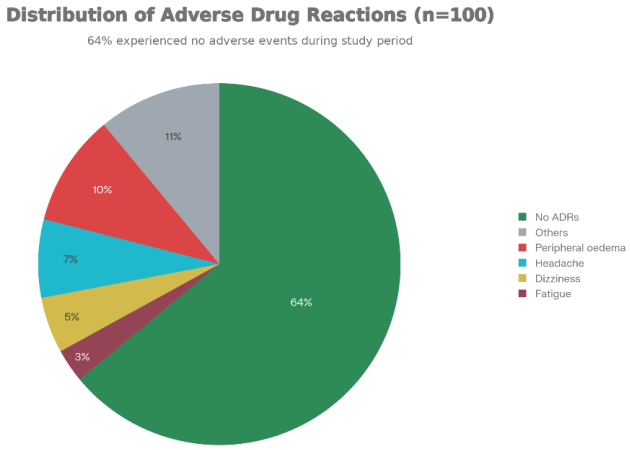

Fig 2: Distribution of Adverse Drug Reactions

Telmisartan showed slight improvements in fasting glucose and lipid profile, whereas amlodipine had neutral effects, in keeping with reports that telmisartan may confer metabolic benefits. (Table 4)

Table 4. Changes in Metabolic Parameters at 12 Weeks

Parameter	Telmisartan Baseline	Telmisartan 12 Weeks	Amlodipine Baseline	Amlodipine 12 Weeks
Fasting glucose (mg/dL)	108±14	103±13	109±15	110±16
Total cholesterol (mg/dL)	198±32	191±30	201±30	202±31
Triglycerides (mg/dL)	158±40	150±38	160±42	162±45

DISCUSSION

In this single-centre, randomized, open-label study conducted at SMIMS, both telmisartan and amlodipine produced significant and clinically meaningful reductions in systolic and diastolic blood pressure over a 12-week treatment period in patients with mild to moderate essential hypertension. Baseline demographic and clinical characteristics were well matched between groups, ensuring comparability and minimizing confounding, in line with previous Indian comparative trials evaluating ARBs and CCBs.

The magnitude of systolic blood pressure (SBP) reduction was comparable between the two treatment arms, with both agents achieving reductions consistent with earlier Indian and international studies. This finding reinforces current guideline recommendations that both ARBs and dihydropyridine CCBs are effective first-line antihypertensive agents for initial BP control. However, telmisartan demonstrated a statistically significant greater reduction in diastolic blood pressure (DBP) compared with amlodipine at 12 weeks, along with a numerically higher proportion of patients achieving target BP <140/90 mmHg. Although the difference in BP control rates did not reach statistical significance, the trend favors telmisartan and may be clinically relevant, particularly in patients with predominantly elevated DBP.

The greater reduction in diastolic blood pressure observed with telmisartan in the present study is in agreement with earlier comparative evidence demonstrating more sustained and effective BP lowering with angiotensin receptor blockers, particularly telmisartan. Its long elimination half-life, high lipophilicity, and prolonged angiotensin II type-1 receptor blockade result in a favourable trough-to-peak ratio, ensuring smooth and consistent 24-hour blood pressure control. In addition, telmisartan's partial peroxisome proliferator-activated receptor-γ (PPAR-γ) agonist activity has been linked to improvements in endothelial function and metabolic parameters, supporting its preferential use in patients with coexisting cardiometabolic risk factors.

These findings are supported by Anwar et al.[12] who reported significant reductions in both SBP and DBP across treatment groups, with target BP achieved as early as day 30. Importantly, the incidence of adverse drug reactions was lower with telmisartan compared with amlodipine, and telmisartan was associated with significant improvements in blood glucose and lipid levels, underscoring its metabolic advantages.

Conversely, Khan et al.[13] demonstrated that amlodipine, whether used as monotherapy or add-on therapy, effectively reduced BP across younger and elderly Indian patients, highlighting its continued relevance as a reliable antihypertensive agent in routine clinical practice.

Further supporting telmisartan's sustained efficacy, Sawant et al.[14] showed that telmisartan provided superior 24-hour BP control compared with other agents, particularly during the late post-dose and early morning hours, a period associated with heightened cardiovascular risk. Similarly, Kumar et al.[15] reported good to excellent efficacy and tolerability of telmisartan across different ages, stages, and durations of hypertension in Indian patients, both as monotherapy and in combination regimens.

Differences in tolerability remain a key factor influencing real-world drug selection. In the present study, amlodipine was associated with a higher incidence of peripheral oedema, a well-recognized dose-related adverse effect of dihydropyridine calcium channel blockers, whereas oedema was uncommon with telmisartan. This observation is consistent with large comparative and combination studies demonstrating that ARBs can attenuate CCB-induced oedema, thereby improving overall treatment tolerability. Overall, adverse events were mild, serious events were absent, and discontinuation rates were low, confirming the short-term safety of both agents.

Finally, as highlighted by Das et al.[16] telmisartan and amlodipine fixed-dose combinations represent a guideline-endorsed ARB–CCB strategy for hypertension management.

Ongoing real-world studies such as TACT India further emphasize the clinical relevance of these agents, either alone or in combination, for effective and well-tolerated BP control in the Indian population.

Metabolic parameters showed modest but favourable trends with telmisartan, including reductions in fasting glucose and lipid levels, while amlodipine demonstrated largely neutral metabolic effects. This observation aligns with previous reports highlighting telmisartan's potential metabolic advantages, which are particularly relevant in South Indian populations with a high prevalence of diabetes and dyslipidaemia.

Limitations

The open-label design introduces potential observer bias, though objective BP measurements mitigate this to an extent.

The 12-week follow-up may not capture long-term cardiovascular outcomes or rare adverse events.

Ambulatory BP monitoring and central BP measurements, which can reveal additional differences between ARBs and CCBs, were not performed, although other trials have shown favourable central BP effects with telmisartan.

Despite these limitations, the present study adds centre-specific evidence from SMIMS and complements existing Indian data supporting the preferential use of telmisartan in many patients with mild to moderate essential hypertension.

CONCLUSION

Telmisartan 40–80 mg and amlodipine 5–10 mg once daily are both effective in reducing blood pressure in patients with mild to moderate essential hypertension attending Sree Mookambika Institute of Medical Sciences, Kanyakumari. Telmisartan demonstrated superior diastolic BP reduction, a higher proportion of patients achieving target BP, fewer cases of peripheral oedema, and more favourable metabolic trends compared with amlodipine, reflecting advantages described in previous Indian studies. Telmisartan may therefore be preferred as first-line monotherapy, particularly in patients with metabolic risk factors or intolerance to CCB-related oedema, while amlodipine remains a useful alternative where ARBs are contraindicated or unavailable.

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