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Real-World Effectiveness and Safety of Telmisartan-Amlodipine Combination Therapy in Patients with Hypertension (Right Start Study)

Suresh V. Patted[1], Vikranth Reddy[2], Bhagyashree A. Mohod[*3], Mayur M. Mayabhate[3], Akhilesh D. Sharma

[1]Professor & Head, Department of Cardiology, Jawaharlal Nehru Medical College (JNMC), Belagavi, Karnataka, India
[2]Clinical Director & Senior Consultant – Nephrology, CARE Hospitals, Banjara Hills, Hyderabad, Telangana, India
[3]Medical Affairs Department, Alkem Laboratories Ltd., Mumbai, Maharashtra, India

Correspondence address: Dr. Bhagyashree Mohod

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ABSTRACT

Background: Hypertension remains a major contributor to cardiovascular morbidity and mortality, and achieving optimal blood pressure (BP) control in routine clinical practice remains challenging. Single-pill combinations (SPCs) comprising agents with complementary mechanisms of action are recommended by contemporary guidelines to improve BP control and treatment adherence. This study evaluated the effectiveness and safety of telmisartan–amlodipine SPC therapy in patients with hypertension managed in routine clinical practice in India.

Methods: This Study was a retrospective, multicenter, observational study conducted across tertiary care centers in India. Adult patients (≥18 years) with hypertension who received telmisartan–amlodipine SPC therapy for at least 3 months and had documented baseline and follow-up BP measurements were included. The primary outcome was change in systolic BP (SBP) and diastolic BP (DBP) from baseline to 3 months. Secondary outcomes included dose-wise effectiveness and incidence of adverse events (AEs).

Results: A total of 2,497 patients were included in the analysis; 61.9% were male, and the mean age was 56.95±11.20 years. The most frequently prescribed SPC was telmisartan/amlodipine 40/5 mg (81.2%). Mean SBP decreased significantly from 160.93 ± 18 mmHg at baseline to 135.82±14 mmHg at 3 months, corresponding to a mean reduction of 25.11 mmHg (15.6%; $p<0.001$). Mean DBP decreased from 106.86 ± 10 mmHg to 94.79 ± 8 mmHg, representing a mean reduction of 12.06 mmHg (11.3%; $p<0.001$). Significant BP reductions were observed across all dose groups ($p<0.001$). Adverse events were reported in 14 patients (0.56%).

Conclusion: In this large real-world cohort, telmisartan–amlodipine SPC therapy was associated with substantial reductions in both SBP and DBP across all evaluated dose strengths and demonstrated excellent tolerability. These findings support the effectiveness and safety of telmisartan–amlodipine SPC therapy for hypertension management in routine clinical practice.

Keywords: Hypertension, Telmisartan, Amlodipine, systolic blood pressure, diastolic blood pressure.

INTRODUCTION

Hypertension remains one of the leading modifiable risk factors for cardiovascular morbidity and mortality worldwide and continues to pose a substantial public health burden in India. Approximately 200 million individuals in India are estimated to have hypertension [1]. The ICMR-INDIAB study reported an overall weighted prevalence of hypertension of 35.5% among Indian adults [2]. Data from the National Noncommunicable Disease Monitoring Survey (NNMS 2017–2018) demonstrated that hypertension affects 28.5% of the adult population, while adequate blood pressure (BP) control is achieved in only a small proportion of patients [3]. Poorly controlled hypertension contributes significantly to cardiovascular and cerebrovascular disease burden and is associated with an increased risk of stroke, myocardial infarction, peripheral vascular disease, and coronary artery disease [4].

Despite the availability of multiple antihypertensive therapies, achieving recommended BP targets remains challenging in routine clinical practice [5,6]. Contemporary hypertension guidelines advocate the early use of combination therapy for most patients requiring pharmacological treatment [5-7]. The 2024 European Society of Cardiology guidelines recommend initiating treatment with a two-drug combination, preferably as a single-pill combination (SPC), in the majority of patients with hypertension [5]. Similarly, the 2023 and 2024 European Society of Hypertension guidelines emphasize the role of combination therapy and fixed-dose combinations in improving BP control and reducing therapeutic inertia [6,7]. Monotherapy may remain appropriate in selected patient populations, including frail or very elderly individuals [8].

A substantial proportion of patients require two or more antihypertensive agents to achieve BP targets [9,10]. Combining agents with complementary mechanisms of action provides greater BP reduction than monotherapy and may improve tolerability by minimizing dose-dependent adverse effects associated with individual drug classes [11]. Fixed-dose SPCs simplify treatment regimens, reduce pill burden, and may improve treatment adherence and persistence, thereby supporting long-term BP control [5–7].

Among the available antihypertensive combinations, the telmisartan–amlodipine SPC represents a rational therapeutic approach that combines blockade of the renin–angiotensin system with calcium channel inhibition. The complementary pharmacological actions of these agents provide effective and sustained BP reduction across a broad spectrum of patients with hypertension. Previous clinical studies have demonstrated the antihypertensive efficacy and favorable tolerability of telmisartan–amlodipine combination therapy [11]. In India, the TACT India study was designed to further evaluate the effectiveness and safety of this fixed-dose combination in routine clinical practice [12].

Although randomized clinical trials have established the efficacy of telmisartan–amlodipine therapy, evidence from routine clinical settings remains valuable for understanding treatment outcomes in diverse patient populations encountered in everyday practice. Real-world studies can complement clinical trial findings by providing insights into BP control and safety under routine care conditions. Therefore, the RIGHT START study was undertaken to evaluate the effectiveness and safety of telmisartan–amlodipine single-pill combination therapy in patients with hypertension managed in routine clinical practice in India

MATERIALS & METHODS

Study Design

This Study was a retrospective, multicentre, observational study conducted across tertiary care centres in India to evaluate the effectiveness and safety of the telmisartan–amlodipine single-pill combination (SPC) in patients with hypertension treated in routine clinical practice. Data were extracted from electronic medical records and institutional healthcare databases. Given the retrospective nature of the study and the use of anonymized patient data, individual informed consent was waived in accordance with applicable regulatory requirements. The study was conducted in compliance with the ethical principles outlined in the Indian Council of Medical Research (ICMR) Ethical Guidelines for Biomedical and Health Research Involving Human Participants. Ethics Committee approval was obtained prior to study initiation (approval number: ALK/IMP/HTN/003).

Study Objectives

The primary objective of the study was to evaluate the effectiveness of telmisartan–amlodipine SPC therapy in achieving blood pressure control among adult patients with hypertension. The secondary objectives were to assess the safety and tolerability of telmisartan–amlodipine SPC therapy by evaluating adverse events (AEs) and to determine the proportion of patients achieving predefined BP targets following treatment.

Study Population

Data were collected from adult patients (≥18 years) diagnosed with essential hypertension who received telmisartan–amlodipine SPC therapy for at least 3 months and had documented BP measurements available at baseline and at the end of follow-up. Patients with secondary hypertension, severe renal impairment, or incomplete clinical records, including missing baseline or follow-up BP measurements, were excluded from the analysis.

Outcome Measures

The primary effectiveness outcomes were changes in systolic blood pressure (SBP) and diastolic blood pressure (DBP) from baseline to 3 months after initiation of telmisartan–amlodipine SPC therapy. Secondary outcomes included the proportion of patients achieving BP targets during follow-up and the incidence of treatment-emergent adverse events reported during routine clinical care.

Data Collection

Data were extracted from medical records using a standardized data collection format. Collected variables included demographic characteristics (age, sex, and geographic region), clinical characteristics, relevant medical and family history, baseline comorbidities, BP measurements, treatment details, and documented adverse events. Information on cardiovascular risk factors and other clinically relevant variables available within the medical records was also collected.

Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA). Continuous variables were summarized as mean ± standard deviation (SD), whereas categorical variables were presented as frequencies and percentages. The distribution of continuous variables was assessed for normality prior to inferential analyses. Changes in SBP and DBP between baseline and 3-month follow-up were evaluated using the paired-samples t-test. Subgroup analyses were performed according to telmisartan–amlodipine SPC dose combinations to assess the consistency of treatment effectiveness across dosage regimens. A two-sided p-value <0.05 was considered statistically significant.

RESULT

A total of 2,497 patients with physician-diagnosed hypertension who met the study eligibility criteria were included in the final

analysis. Baseline demographic and clinical characteristics are presented in Table 1. The mean age was 56.95 ± 11.20 years, and 61.9% of patients were male. Mean baseline SBP and DBP were 160.93 ± 18 mmHg and 106.86 ± 10 mmHg, respectively, indicating that the cohort represented patients with varying degrees of hypertension severity encountered in routine clinical practice. Lifestyle-related cardiovascular risk factors, including smoking, alcohol consumption, tobacco use, and excess body weight, were common within the study population.

Table 1. Baseline Demographic and Clinical Characteristics of the Study Population (N = 2,497)

Variable	n (%)
Age (years), Mean ± SD	56.95 ± 11.20
Gender	
Male (n %)	1546 (61.9)
Female (n %)	951 (38.1)
Weight (kg), Mean ± SD	72.42 ± 11.81
SBP (mmHg), Mean ± SD	160.93 ± 18
DBP (mmHg), Mean ± SD	106.86 ± 10
BMI Classification, n (%)	
Underweight (<18.5 kg/m²)	203 (8.1)
Normal BMI (18.5–22.9 kg/m²)	1048 (42.0)
Overweight (23.0–24.9 kg/m²)	1000 (40.0)
Obese (>25 kg/m²)	246 (9.9)
Active Smoker, n (%)	428 (17.1)
Alcohol Consumption, n (%)	586 (23.5)
Tobacco Use, n (%)	423 (16.9)
Family History of Dyslipidaemia, n (%)	802 (32.1)

Table 1 presents the baseline demographic and clinical characteristics of the study population. The cohort predominantly comprised middle-aged male patients with hypertension and a high prevalence of overweight/obesity and lifestyle-related cardiovascular risk factors. BMI: Body Mass Index; DBP: Diastolic Blood Pressure; SBP: Systolic Blood Pressure.

Comorbid Conditions

The baseline comorbidity profile of the study population is presented in Table 2. Diabetes mellitus was the most frequently reported comorbidity, affecting 1,570 (62.9%) patients. Heart failure was present in 570 (22.8%) patients, followed by chronic kidney disease in 531 (21.3%), prior myocardial infarction in 443 (17.7%), stroke in 380 (15.2%), and chronic liver disease in 308 (12.3%) patients.

Table 2. Baseline Comorbid Conditions in the Study Population (N = 2,497)

Comorbid Condition	n (%)
Diabetes Mellitus	1570 (62.9)
Heart Failure	570 (22.8)
Chronic Kidney Disease	531 (21.3)
Myocardial Infarction	443 (17.7)
Stroke	380 (15.2)
Chronic Liver Disease	308 (12.3)

Table 2 summarizes the baseline comorbidity profile of the study population, demonstrating a substantial burden of cardiometabolic diseases, with diabetes mellitus being the most frequently reported comorbidity.

Treatment Distribution and Blood Pressure Outcomes

Among the 2,497 patients included in the analysis, the most frequently prescribed telmisartan–amlodipine single-pill combination (SPC) was 40/5 mg, used by 2,027 (81.2%) patients. The 20/5 mg SPC was prescribed to 362 (14.5%) patients, whereas 108 (4.3%) patients received the 80/5 mg SPC regimen. A statistically

significant reduction in both systolic blood pressure (SBP) and diastolic blood pressure (DBP) was observed after 3 months of treatment **(Figure 1).**

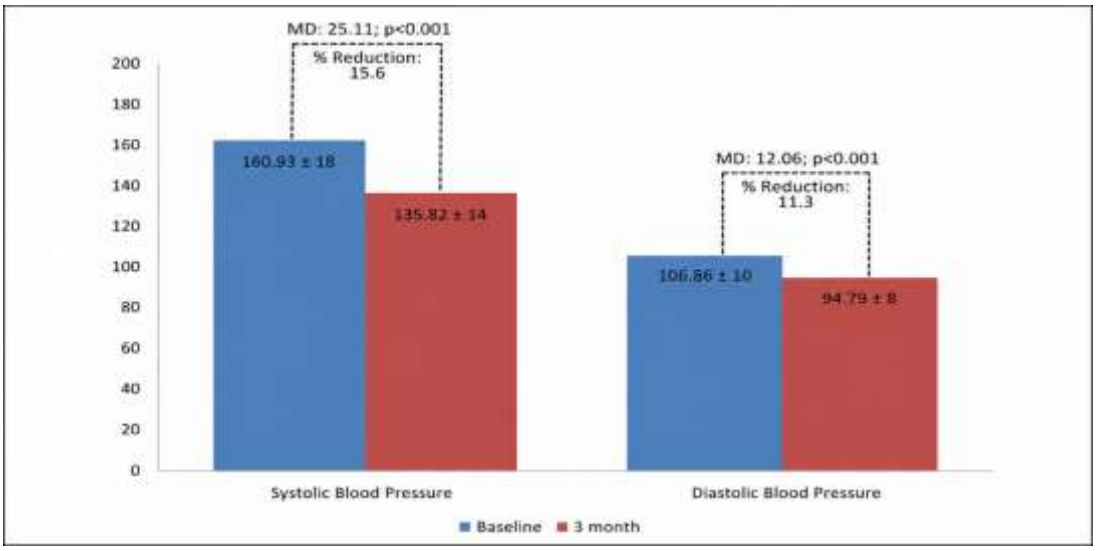

Figure 1. Changes in Mean Systolic and Diastolic Blood Pressure from Baseline to 3 Months.
Values are presented as mean ± standard deviation (SD). Percentage reduction was calculated relative to baseline values. Statistical significance was assessed using the paired-samples t-test. A p-value <0.05 was considered statistically significant.
DBP, diastolic blood pressure; MD, mean difference; SBP, systolic blood pressure.

Dose-wise Effectiveness and Safety Outcomes

Subgroup analysis demonstrated significant reductions in both systolic and diastolic blood pressure across all telmisartan–amlodipine dose groups (p<0.001 for all comparisons) (Table 3). The greatest reduction in BP was observed in the 20/5 mg group, with mean reductions of 39.63 mmHg in SBP and 20.81 mmHg in DBP. In the 40/5 mg group, mean SBP and DBP reductions were 22.59 mmHg and 10.46 mmHg, respectively. Corresponding reductions in the 80/5 mg group were 23.64 mmHg for SBP and 12.73 mmHg for DBP.
Adverse events were reported in 14 patients, corresponding to an incidence of 0.56% in the overall study population.

Table 3. Dose-wise Changes in Blood Pressure Following Telmisartan–Amlodipine Single-Pill Combination Therapy

Dose Group	n	Baseline SBP (mmHg), Mean ± SD	3-Month SBP (mmHg), Mean ± SD	Mean SBP Reduction (mmHg)	Baseline DBP (mmHg), Mean ± SD	3-Month DBP (mmHg), Mean ± SD	Mean DBP Reduction (mmHg)	p-value
Telmisartan/Amlodipine 20/5 mg	362	153.55 ± 16	113.92 ± 14	39.63	101.77 ± 8	80.95 ± 7	20.81	<0.001
Telmisartan/Amlodipine 40/5 mg	2027	161.91 ± 17	139.31 ± 13	22.59	107.56 ± 9	97.10 ± 8	10.46	<0.001
Telmisartan/Amlodipine 80/5 mg	108	167.36 ± 18	143.72 ± 15	23.64	110.69 ± 10	97.96 ± 8	12.73	<0.001

Table 3 summarizes the dose-wise effectiveness of telmisartan–amlodipine single-pill combination therapy. Significant reductions in both systolic and diastolic blood pressure were observed across all dose regimens, with the greatest absolute reduction noted in the 20/5 mg group (p<0.001 for all comparisons). DBP, diastolic blood pressure; SBP, systolic blood pressure; SD, standard deviation.

DISCUSSION

In this multicenter retrospective study involving 2,497 patients with hypertension, treatment with the telmisartan–amlodipine single-pill combination (SPC) was associated with significant reductions in both systolic and diastolic blood pressure over a 3-month follow-up period. The study population represented a relatively high-risk hypertensive cohort, with a substantial burden of cardiometabolic comorbidities, including diabetes mellitus, chronic kidney disease, heart failure, prior myocardial infarction, and stroke. Despite these clinical complexities, significant improvements in blood pressure control were observed, accompanied by a low incidence of reported adverse events.

Achieving and maintaining recommended blood pressure targets remains a major challenge in routine clinical practice. Contemporary hypertension guidelines advocate the early use of combination therapy, preferably as a single-pill combination, to facilitate more rapid and sustained BP control while minimizing treatment complexity and therapeutic inertia [5–7]. The present findings support this treatment strategy and demonstrate the effectiveness of telmisartan–amlodipine SPC therapy in a real-world clinical setting.

The observed reduction in BP is consistent with findings from previous clinical trials evaluating ARB–CCB combination therapy. In a randomized study comparing valsartan–amlodipine combination therapy with amlodipine monotherapy, combination therapy achieved significantly greater reductions in BP while maintaining favorable tolerability [13]. Similarly, the TEAMSTA-5 study demonstrated that telmisartan–amlodipine SPC therapy produced significantly greater reductions in BP and superior BP control rates compared with amlodipine monotherapy in patients with uncontrolled hypertension [14]. Littlejohn et al. further reported that telmisartan–amlodipine combinations provided significantly greater antihypertensive efficacy than either component administered alone across multiple dose combinations [15]. The magnitude of BP reduction observed in the present study is therefore broadly aligned with previously published evidence supporting the effectiveness of ARB–CCB combination therapy.

Subgroup analyses demonstrated significant BP reductions across all evaluated dose regimens. Although the greatest absolute reductions in SBP and DBP were observed in patients receiving the 20/5 mg SPC, these findings should be interpreted cautiously because treatment allocation was not randomized and baseline clinical characteristics may have differed among dose groups. Nevertheless, consistent reductions in BP across all dose strengths support the effectiveness of telmisartan–amlodipine SPC therapy in routine clinical practice.

The findings of the present study are further supported by evidence from real-world clinical investigations. In the TACT-India study, telmisartan–amlodipine fixed-dose combination therapy was associated with significant reductions in both systolic and diastolic BP, with approximately 70% of patients achieving target BP levels after treatment [16]. Similarly, data from the NOVEL study demonstrated favorable antihypertensive effectiveness and tolerability of telmisartan plus S-amlodipine SPC therapy in a large nationwide hypertensive population [17]. Collectively, these findings reinforce the effectiveness of telmisartan–amlodipine SPC therapy across both controlled clinical trial settings and routine clinical practice.

The favorable safety profile observed in the present study is noteworthy. Adverse events were reported in only 0.56% of patients during the observation period, suggesting good tolerability of the treatment regimen. Fixed-dose combinations of ARBs and CCBs are recognized for providing effective BP control while maintaining a favorable safety profile and improving treatment adherence [18]. Previous evidence has also suggested that ARB–CCB combinations

may reduce the incidence of peripheral edema commonly associated with calcium channel blocker therapy [19]. The low incidence of adverse events observed in the present study is consistent with the established safety profile of telmisartan–amlodipine combination therapy.

The benefits of fixed-dose combination therapy extend beyond BP reduction alone. By simplifying treatment regimens and reducing pill burden, single-pill combinations may improve adherence and persistence with antihypertensive therapy, both of which are important determinants of long-term BP control [18]. Such strategies are particularly relevant in routine clinical practice, where inadequate adherence remains a major contributor to poor BP control. The findings of this study should be interpreted in light of several limitations. The retrospective design limits causal inference, and variations across centers in measurement and clinical practice may have influenced outcomes. Data on medication adherence, lifestyle factors, and some concomitant therapies were not consistently available, and changes in treatment during follow-up could not be fully accounted for. Residual confounding cannot be excluded, and the 3-month follow-up limits assessment of long-term outcomes.

CONCLUSION

In this large multicentre real-world study, telmisartan–amlodipine single-pill combination therapy was associated with significant reductions in both systolic and diastolic blood pressure over a 3-month follow-up period, with consistent effectiveness observed across all evaluated dose regimens. The treatment demonstrated a favourable safety profile, with a very low incidence of adverse events despite the inclusion of a high-risk hypertensive population with substantial cardiometabolic comorbidities. These findings support the effectiveness and tolerability of telmisartan–amlodipine single-pill combination therapy as a practical strategy for improving blood pressure control in routine clinical practice and reinforce its role as a guideline-concordant option for patients requiring combination antihypertensive therapy.

Declaration by Authors

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