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Comparative Effectiveness and Safety of Amlodipine and Telmisartan in Patients with Essential Hypertension: A Prospective Randomized Clinical Study

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Abstract

Background: Essential hypertension is a significant public health issue worldwide and comparing the efficacy and safety of first-line antihypertensive drugs is relevant for optimizing treatment.

Objective: To compare the clinical effectiveness and safety of amlodipine and telmisartan in patients with essential hypertension by evaluating changes in systolic and diastolic blood pressure, achievement of target blood pressure, treatment response, and adverse drug reactions.

Methodology: The current study was a prospective, randomized, open-label, parallel-group, clinical study that was conducted from January to December of 2025. A total of 240 eligible patients were randomly assigned and treated with amlodipine (n=120) or telmisartan (n=120) for 12 weeks. Primary outcome was change in systolic and diastolic blood pressure, secondary outcomes were attaining target blood pressure, treatment response, adverse drug reactions, laboratory safety parameters and predictors of successful blood pressure control. The data collected was analyzed using SPSS version 27.0 at $P<0.05$.

Results: Baseline demographic and clinical characteristics were comparable between the two groups ($p>0.05$). After 12 weeks, telmisartan achieved significantly greater reductions in systolic blood pressure (28.40 ± 9.84 mmHg vs. 25.30 ± 10.21 mmHg; p=0.021) and diastolic blood pressure (18.92 ± 7.02 mmHg vs. 16.32 ± 7.14 mmHg; p=0.009) than amlodipine.

Target blood pressure was achieved in 103 patients (85.83%) receiving telmisartan compared with 91 patients (75.83%) receiving amlodipine (p=0.048). An excellent treatment response was observed in 92 patients (76.67%) in the telmisartan group and 78 patients (65.00%) in the amlodipine group (p=0.048). Overall adverse drug reactions occurred in 28 patients (23.33%) receiving telmisartan and 31 patients (25.83%) receiving amlodipine (p=0.670), whereas peripheral edema was significantly more frequent with amlodipine (11.67% vs. 2.50%; p=0.006).
Conclusion: Both treatments were effective and well tolerated; however, telmisartan was superior in blood pressure control, achieving target blood pressure and fewer cases of peripheral edema than amlodipine and therefore is recommended as an effective first-line agent for essential hypertension.

Introduction

Hypertension is one of the most common chronic cardiovascular diseases in the world, along with being a major modifiable risk factor for myocardial infarction, stroke, heart failure, chronic kidney disease and death [1,2]. The global prevalence of hypertension is estimated to exceed one billion adults, and is increasing as populations age, become sedentary, obese, eat unhealthy diets and become more urbanised [3]. Although effective antihypertensive drugs are available, in many patients, blood pressure control is not adequate and this suboptimal control is an important source of disease burden, especially in low and middle-income countries, where diagnosis is delayed, there is inadequate treatment adherence, and resources are limited [4].

Essential hypertension (about 90-95% of all hypertension cases) occurs as a result of a complex interrelationship between genetic predisposition, environmental factors, neurohormonal activation, endothelial dysfunction and vascular remodeling [5]. Repeatedly high blood pressure can lead to progressive damage to target organs such as the heart, kidneys, brain and blood vessels, making early detection and long-term pharmacological treatment of blood pressure (BP) essential [6]. Current clinical guidelines for antihypertensive treatment recommend the personalized approach which takes into account the patient's characteristics, cardiovascular risk profile, comorbid conditions, and tolerability of the therapy [7].

Amlodipine and telmisartan are two of the most commonly used antihypertensive drugs, particularly as first-line treatments, as they have been proven to be effective and have good safety profiles [8]. Amlodipine is a long-acting dihydropyridine calcium channel blocker that acts by blocking the influx of calcium ions into vascular smooth muscle cells, causing peripheral vasodilation and a decrease in systemic vascular resistance, therefore, lowering the blood pressure [9]. Telmisartan (Telmacor®) is an angiotensin II receptor blocker that is selective for the angiotensin II type 1 receptor, thus blocking the effects of vasoconstriction, aldosterone secretion and vascular remodeling, and providing long-lasting control of blood pressure [10]. Both drugs are recommended for the treatment of essential hypertension, but have different mechanisms of action, adverse effects, and may have different blood pressure control and tolerability profiles. Comparative clinical data in various patient cohorts are still important to maximise the benefits of tailored treatment [11,12].

Previous clinical studies have shown conflicting results of comparative effectiveness, tolerability, and cardiovascular benefits of both amlodipine and telmisartan, making them both widely recommended as first-line antihypertensive agents. Moreover, there is limited randomized clinical evidence available to compare these agents in Pakistan. The demographic differences, genetic background, lifestyle and healthcare practices may affect outcome of therapy in terms of response and safety, thus, it is crucial to have well designed comparative clinical studies for locally relevant evidence to guide evidence-based management of essential hypertension. Thus, a prospective,

randomized clinical trial was conducted to compare the efficacy and safety of amlodipine and telmisartan in adult patients with essential hypertension.

Research Objective

To compare the clinical effectiveness and safety of amlodipine and telmisartan in patients with essential hypertension through a prospective randomized clinical study by evaluating changes in systolic and diastolic blood pressure, achievement of target blood pressure, overall treatment response, and the incidence of adverse drug reactions.

Methodology

Study Design

This was a prospective, randomized, open-label, parallel-group clinical study to evaluate the efficacy and safety of amlodipine and telmisartan in the treatment of essential hypertension. A prospective randomized design was chosen to achieve balanced allocation of patients to the treatments, minimize selection bias and allow for a reliable comparison of clinical outcomes between the two treatment groups. The study was carried out under the principles of Good Clinical Practice (GCP) to ensure the methodological rigor and patient safety. The study was an open-label randomized clinical study, blinding was not feasible because of routine clinical prescribing; however, standardized outcome assessment was implemented to minimize observer bias.

Study Setting

This study was carried out at a tertiary care cardiac center: Nawaz Sharif Institute of Cardiology (NSIC), Sargodha, in conjunction with the College of Pharmacy, University of Sargodha, Pakistan, which offers specialized cardiovascular outpatient and inpatient services. All participants were recruited, clinically assessed, treated and followed at NSIC, Sargodha while data management, statistical analysis and data findings were carried out in the College of Pharmacy, University of Sargodha.

Study Duration

The study was done for 12 months starting from January 2025 to December of 2025. This encompassed patient screening, recruitment, baseline clinical evaluation, randomisation, treatment initiation, follow-up visits, safety monitoring, data collection, data analysis and preparation of the final study report.

Study Population

The study population consisted of adult patients attending the outpatient medical clinics of the Nawaz Sharif Institute of Cardiology, Sargodha during the study period with a diagnosis of EH. Patients were screened by predefined criteria and patients that met all study criteria were enrolled after giving written informed consent.

Sample Size

The sample size was determined using G*Power version 3.1 with a significance level of 0.05, a 95% confidence level and a statistical power of 80%. Overall, 240 qualified patients were randomized to either amlodipine or telmisartan in a 1:1 ratio. The sample sizes in the treatment groups were 120 each. The sample size was calculated to ensure a 95% confidence level at significance level of 0.05 with an acceptable level of statistical power (80%) to detect a clinically meaningful difference in blood pressure reduction between the two treatment groups.

Sampling Technique

The patients were recruited with consecutive sampling technique from the Cardiology Out Patient Department (OPD) Nawaz Sharif Institute of Cardiology (NSIC)

Sargodha during the study period. After enrolling and consenting to participate, individuals were assigned to one of the two treatment groups. Randomization was done with a computer-generated block randomization sequence with an allocation ratio of 1:1. Randomisation sequence was created by an independent investigator not involved in patient recruitment or outcome assessment. Sequentially numbered, opaque, sealed envelopes were used for allocation concealment until the last participant had been enrolled.

Eligibility Criteria

Those aged 18 years or older with an established diagnosis of essential hypertension in whom the baseline systolic blood pressure was ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg were eligible for inclusion. Patients who had been newly diagnosed or required initiation of antihypertensive monotherapy and gave informed consent signed in writing were recruited. Patients who had secondary hypertension, pregnancy or lactation, severe hepatic impairment, end-stage renal disease, uncontrolled heart failure, recent myocardial infarction or stroke, or known hypersensitivity to either study drug or any serious medical condition that might interfere with the interpretation of the results of the study were excluded.

Randomization

After eligibility was determined, participants were randomized to one of the two treatment groups with the use of a computer-generated randomization schedule prepared prior to the start of the study. Allocation concealment was achieved by using sequentially numbered opaque sealed envelopes opened following the completion of the enrollee's information. The procedure guaranteed that there was no bias in the allocation of treatment and that the randomization remained intact throughout the study.

Treatment Protocol

Patients in the amlodipine group were given amlodipine 5 mg/day orally once daily and patients in the telmisartan group were given telmisartan 40 mg/day orally once daily. After 4 weeks, those patients who did not achieve adequate blood pressure control and tolerated the medication well were allowed to increase the dose to amlodipine 10 mg or telmisartan 80 mg. All participants were provided with a consistent counseling on medication adherence, dietary sodium reduction, regular physical activity, smoking cessation, weight loss (if necessary), and other lifestyle changes that are recommended to control hypertension.

Clinical Assessment and follow-up

Pre-treatment demographic and clinical data such as age, sex, BMI, smoking status, medical history, baseline hypertension duration, and baseline blood pressure were obtained. Participants were followed up for 12 weeks with clinical assessment at 4, 8, and 12 weeks after starting treatment. For each visit, blood pressure, heart rate, adherence to medication, clinical response and adverse events related to the treatment were measured. Blood pressure was obtained with the help of a validated automated sphygmomanometer as per the international hypertension guidelines. All measurements were taken after participants sat quietly for at least 5 minutes, and participants were instructed to avoid caffeine, smoking and intense exercise for at least 30 minutes before being measured. Each visit, two readings were taken two minutes apart and the mean was used for statistical analysis. When follow-up assessments were made, this was done at approximately the same time of day to minimise physiological variation.

Outcome Measures

The main outcome measures were the change in systolic and diastolic blood pressure from baseline to week 12. Secondary endpoints included achievement of target blood pressure according to the current guidelines of hypertension, overall treatment response, medication adherence, the occurrence and severity of adverse drug reactions, adverse events associated with the discontinuation of treatments and the overall safety profile of each therapeutic intervention.

Safety Assessment

Treatment tolerability and any adverse drug reactions were monitored using routine clinical evaluation throughout the study. At baseline and throughout follow-up, serum creatinine and serum potassium levels, liver function tests, and other relevant biochemical parameters were measured in the laboratory, as clinically indicated.

Data Collection

A standard case report form, designed for the study protocol, was used for all study information. All clinical data, laboratory investigations, treatment response, follow-up observations and safety data were prospectively recorded. ID numbers were assigned to each participant so as to keep them confidential. Data quality was ensured by frequent checks for verification, validation and review before entering into a secure electronic database for statistical analysis.

Statistical Analysis

The Statistical Package for Social Sciences (SPSS) version 27.0 was used to enter, code and analyze the data. Appropriate statistical tests were chosen after the data passed the normalization test (Shapiro–Wilk test). Mean + SD was used to present continuous variable; for categorical variable, frequencies and percentages were used. The independent-samples t-test or chi-square test/Fisher's exact test (as appropriate) was used to compare baseline characteristics between the two treatment groups. The paired t-test was used for within-group comparisons, whereas the independent-samples t-test was used for between-group comparisons. Changes in blood pressure with time were evaluated using repeated-measures analysis of variance. Logistic regression analysis was used to determine independent predictor of successful BP control. Results were reported as 95% confidence intervals when appropriate, and analyses were done by intention-to-treat analysis. A two sided p-value < 0.05 was regarded as statistically significant.

Ethical Considerations

The Ethical Review Committee of the College of Pharmacy, University of Sargodha gave ethical approval. Before starting the study, permission was taken from the management of Nawaz Sharif Institute of Cardiology, Sargodha, for administrative permission.

Results

Baseline characteristics were comparable between the amlodipine and telmisartan groups, with no significant differences observed (table 1). Mean age was 56.84 ± 9.62 years in the amlodipine group and 57.21 ± 10.14 years in the telmisartan group (p=0.774). Baseline SBP (156.82 ± 12.45 vs 157.16 ± 13.02 mmHg, p=0.842), DBP (96.74 ± 8.21 vs 97.08 ± 8.46 mmHg, p=0.755), BMI, duration of hypertension, diabetes, dyslipidemia, and smoking status were also similar between groups, confirming balanced randomization.

Table 1. Baseline Demographic and Clinical Characteristics of Study Participants

Variables	Amlodipine Group (n=120)	Telmisartan Group (n=120)	Test Value	p-value
Age (years), Mean ± SD	56.84 ± 9.62	57.21 ± 10.14	t=0.287	0.774
Male gender, n (%)	66 (55.00%)	69 (57.50%)	χ^2=0.156	0.693
Female gender, n (%)	54 (45.00%)	51 (42.50%)		
BMI (kg/m²), Mean ± SD	28.46 ± 4.18	28.72 ± 4.36	t=0.459	0.647
Duration of hypertension (years)	4.62 ± 2.85	4.81 ± 2.94	t=0.505	0.614
Baseline SBP (mmHg)	156.82 ± 12.45	157.16 ± 13.02	t=0.199	0.842
Baseline DBP (mmHg)	96.74 ± 8.21	97.08 ± 8.46	t=0.313	0.755
Diabetes mellitus, n (%)	32 (26.67%)	35 (29.17%)	χ^2=0.188	0.665
Dyslipidemia, n (%)	41 (34.17%)	38 (31.67%)	χ^2=0.160	0.689
Current smokers, n (%)	27 (22.50%)	29 (24.17%)	χ^2=0.091	0.763

Both treatments significantly reduced blood pressure; however, telmisartan produced a greater reduction compared with amlodipine (table 2). At week 12, SBP decreased to 131.52 ± 9.24 mmHg with amlodipine and 128.76 ± 8.96 mmHg with telmisartan (p=0.028), with a baseline reduction of 25.30 ± 10.21 and 28.40 ± 9.84 mmHg, respectively (p=0.021). Similarly, DBP reduction was greater with telmisartan (18.92 ± 7.02 mmHg) than amlodipine (16.32 ± 7.14 mmHg) (p=0.009).

Table 2. Comparison of Blood Pressure Reduction During 12-Week Follow-up

Time Point		Amlodipine (n=120) Mean ± SD	Telmisartan (n=120) Mean ± SD	Test Value	p-value
Systolic Blood Pressure (mmHg)	Baseline	156.82 ± 12.45	157.16 ± 13.02	t=0.199	0.842
	Week 4	145.37 ± 11.28	143.92 ± 11.74	t=0.985	0.326
	Week 8	137.64 ± 10.36	135.21 ± 10.18	t=1.790	0.075
	Week 12	131.52 ± 9.24	128.76 ± 8.96	t=2.213	0.028*
	Change from baseline	-25.30 ± 10.21	-28.40 ± 9.84	t=2.323	0.021*
Diastolic Blood Pressure (mmHg)	Baseline	96.74 ± 8.21	97.08 ± 8.46	t=0.313	0.755
	Week 4	89.82 ± 7.36	88.24 ± 7.18	t=1.683	0.094
	Week 8	84.63 ± 6.72	82.91 ± 6.54	t=1.986	0.048*
	Week 12	80.42 ± 6.18	78.16 ± 5.92	t=2.735	0.007*
	Change from baseline	-16.32 ± 7.14	-18.92 ± 7.02	t=2.650	0.009*

Repeated-measures analysis showed significant reductions in SBP and DBP over 12 weeks in both groups (p<0.001), shown in table 3. Telmisartan demonstrated a stronger overall blood pressure-lowering effect, with significant between-group differences for SBP (F=5.12, p=0.025) and DBP (F=6.21, p=0.013), indicating superior sustained blood pressure control compared with amlodipine.

Table 3. Repeated Measures Analysis of Blood Pressure Changes Over Follow-up

Outcome	Group	F-value	p-value
SBP change over 12 weeks	Amlodipine	F=84.62	<0.001*
SBP change over 12 weeks	Telmisartan	F=112.35	<0.001*
Between-group SBP difference	—	F=5.12	0.025*
DBP change over 12 weeks	Amlodipine	F=76.48	<0.001*
DBP change over 12 weeks	Telmisartan	F=98.76	<0.001*
Between-group DBP difference	—	F=6.21	0.013*

Achievement of target blood pressure increased progressively during follow-up in both groups (table 4). At week 12, 91 (75.83%) patients in the amlodipine group and 103 (85.83%) patients in the telmisartan group achieved target blood pressure, showing a significant difference between treatments (p=0.048). Telmisartan demonstrated a higher proportion of patients achieving adequate blood pressure control.

Table 4. Achievement of Target Blood Pressure During Follow-up

Follow-up Visit	Amlodipine n (%)	Telmisartan n (%)	χ^2 Value	p-value
Week 4	38 (31.67%)	44 (36.67%)	0.605	0.437
Week 8	67 (55.83%)	78 (65.00%)	2.038	0.153
Week 12	91 (75.83%)	103 (85.83%)	3.909	0.048*

Telmisartan showed a higher excellent treatment response compared with amlodipine (table 5). Excellent response was observed in 92 (76.67%) patients receiving telmisartan and 78 (65.00%) receiving amlodipine (p=0.048). Although overall responders were higher with telmisartan (95.00% vs 90.00%), this difference was not statistically significant (p=0.180).

Table 5. Clinical Treatment Response After 12 Weeks

Treatment Response	Amlodipine n (%)	Telmisartan n (%)	χ^2 Value	p-value
Excellent response	78 (65.00%)	92 (76.67%)	3.906	0.048*
Moderate response	30 (25.00%)	22 (18.33%)		
Poor response	12 (10.00%)	6 (5.00%)		
Overall responders	108 (90.00%)	114 (95.00%)	1.796	0.180

Both treatments showed comparable overall safety profiles. Any adverse drug reaction occurred in 31 (25.83%) patients in the amlodipine group and 28 (23.33%) in the telmisartan group (p=0.670), shown in table 6. Peripheral edema was significantly higher with amlodipine (11.67% vs 2.50%, p=0.006), while other adverse events including headache, dizziness, fatigue, and treatment discontinuation showed no significant differences.

Table 6. Safety Outcomes and Adverse Drug Reactions

Adverse Event	Amlodipine n (%)	Telmisartan n (%)	χ^2 Value	p-value
Peripheral edema	14 (11.67%)	3 (2.50%)	7.667	0.006*
Headache	9 (7.50%)	6 (5.00%)	0.554	0.457
Dizziness	7 (5.83%)	10 (8.33%)	0.494	0.482
Fatigue	5 (4.17%)	6 (5.00%)	0.084	0.772
Increased creatinine	1 (0.83%)	4 (3.33%)	1.025	0.311
Hyperkalemia	0 (0.00%)	3 (2.50%)	3.025	0.082
Any ADR	31 (25.83%)	28 (23.33%)	0.181	0.670

Treatment discontinuation	5 (4.17%)	4 (3.33%)	0.119	0.730

Multivariable logistic regression identified telmisartan therapy as an independent predictor of successful blood pressure control (OR=1.82, 95% CI: 1.01–3.28, p=0.046), shown in table 7. Good medication adherence was the strongest predictor (OR=2.74, 95% CI: 1.45–5.17, p=0.002), while baseline SBP <160 mmHg was also significantly associated with better control (OR=1.69, p=0.041).

Table 7. Logistic Regression Analysis for Successful Blood Pressure Control

Predictors	**Adjusted OR**	**95% CI**	**Wald χ^2**	**p-value**
Telmisartan therapy	1.82	1.01–3.28	3.98	0.046*
Good medication adherence	2.74	1.45–5.17	9.62	0.002*
Baseline SBP <160 mmHg	1.69	1.02–2.81	4.18	0.041*
Age <60 years	1.44	0.86–2.42	1.95	0.162
BMI <30 kg/m²	1.36	0.78–2.37	1.17	0.280

Laboratory parameters remained stable in both groups during the 12-week follow-up (table 8). No significant differences were observed in serum creatinine, ALT, or AST levels. Serum potassium showed a statistically significant difference between groups (p=0.033), but changes remained within clinically acceptable ranges, indicating good overall laboratory safety.

Table 8. Laboratory Safety Parameters During 12-Week Follow-up

Laboratory Parameter	**Amlodipine Group (n=120) Baseline**	**Amlodipine Group Week 12**	**Telmisartan Group (n=120) Baseline**	**Telmisartan Group Week 12**	**Test Value**	**p-value**
Serum creatinine (mg/dL)	0.92 ± 0.18	0.94 ± 0.21	0.91 ± 0.19	0.97 ± 0.24	t=1.024	0.307
Serum potassium (mmol/L)	4.18 ± 0.42	4.21 ± 0.45	4.20 ± 0.39	4.34 ± 0.48	t=2.145	0.033*
ALT (U/L)	28.46 ± 8.12	29.18 ± 8.45	27.92 ± 7.86	28.74 ± 8.21	t=0.421	0.674
AST (U/L)	26.82 ± 7.46	27.31 ± 7.84	26.54 ± 7.18	27.06 ± 7.51	t=0.258	0.797

Most adverse drug reactions were mild in severity, with similar rates between groups (table 9). Mild ADRs occurred in 24 (20.00%) amlodipine-treated patients and 22 (18.33%) telmisartan-treated patients (p=0.747). Severe ADRs were rare and identical in both groups (0.83%), and treatment discontinuation rates were comparable (4.17% vs 3.33%, p=0.730).

Table 9. Severity and Management of Adverse Drug Reactions

ADR Severity	**Amlodipine Group (n=120)**	**Telmisartan Group (n=120)**	**χ^2 Value**	**p-value**
Mild ADRs	24 (20.00%)	22 (18.33%)	0.104	0.747
Moderate ADRs	6 (5.00%)	5 (4.17%)	0.086	0.769
Severe ADRs	1 (0.83%)	1 (0.83%)	0.000	1.000
Required treatment discontinuation	5 (4.17%)	4 (3.33%)	0.119	0.730

Heart rate remained stable throughout the study period in both treatment groups (table 10). Baseline heart rate was 78.42 ± 9.16 bpm in the amlodipine group and 79.04 ± 8.82 bpm in the telmisartan group (p=0.590). At week 12, no significant difference was observed between groups (76.84 ± 8.74 vs 77.12 ± 8.61 bpm, p=0.803), indicating comparable cardiovascular tolerability.

Table 10. Heart Rate Changes During Follow-up

Time Point	**Amlodipine Mean ± SD**	**Telmisartan Mean ± SD**	**t-value**	**p-value**
Baseline	78.42 ± 9.16	79.04 ± 8.82	0.540	0.590
Week 12	76.84 ± 8.74	77.12 ± 8.61	0.250	0.803

Discussion

This is a prospective randomized study that showed that both amlodipine and telmisartan were effective in lowering blood pressure in patients with essential hypertension, but the effect of telmisartan was significantly greater after 12 weeks of treatment. Systolic BP dropped by 28.40 ± 9.84 mmHg with telmisartan, and 25.30 ± 10.21 mmHg with amlodipine (p=0.021); and diastolic BP dropped by 18.92 ± 7.02 mmHg with telmisartan and 16.32 ± 7.14 mmHg with amlodipine (p=0.009). Both findings have been previously demonstrated and support the antihypertensive efficacy of both drugs and are consistent with previous randomized studies that have shown that telmisartan can maintain 24-hour blood pressure control due to its long half-life and high receptor affinity [13].

Repeated-measures analysis also revealed significant reductions in blood pressure in both groups over time, and significant between-group differences for systolic (F=5.12, p=0.025) and diastolic (F=6.21, p=0.013) blood pressure. The results suggest that telmisartan kept its efficacy to control blood pressure over time. This sustained antihypertensive efficacy of telmisartan has been confirmed in previous randomized clinical trials and reviews, which also demonstrated better ambulatory blood pressure control with telmisartan-based therapy compared to many conventional treatments [14].

It was an important finding of the present study that the patients taking telmisartan achieved the target blood pressure more better. A target blood pressure was reached by 85.83% of the patients in the telmisartan group and 75.83% in the amlodipine group at week 12 (p=0.048). Similarly, the clinical response was excellent in 76.67% of the patients receiving telmisartan as compared to 65.00% of the patients receiving amlodipine (p=0.048). The overall responder rates was numerically higher with telmisartan (95.00% vs. 90.00%), but this difference was not statistically significant (p=0.180). Previous clinical trials testing regimens containing telmisartan have shown similar improvements in blood pressure goal achievement, especially in those who need to be successfully controlled for a long period of time [15].

As for safety, both drugs showed good tolerability, with amlodipine significantly more likely to cause peripheral edema (11.67%) than was telmisartan (2.50%, p=0.006). Adverse drug reactions were similar (25.83% vs 23.33%, p=0.670) and not enough in either treatment group to warrant treatment discontinuation (4.17% vs 3.33%). The results are consistent with earlier studies, which have shown that calcium channel blockers are more likely to be associated with peripheral edema, thought to be caused by precapillary vasodilation, and that there are fewer vasodilatory effects reported with the use of telmisartan [16].

In the laboratory safety assessment, there were no significant differences in the levels of serum creatinine or liver enzymes among the treatment groups. The serum potassium level was slightly higher in the telmisartan group (p=0.033) at week 12 but

was within clinically acceptable ranges and clinically significant hyperkalemia occurred very rarely (2.50%). In addition, adverse drug reactions were mild in both groups (0.83% in each) and adverse reactions were rare, suggesting that both therapies were generally safe over the 12 weeks' treatment regimen. These results align with published data demonstrating that these drugs have favourable Laboratory safety profiles when carefully monitored [17].

The results were further supported by logistic regression analysis, which showed that the effect of telmisartan therapy on successful blood pressure control was independent of the other factors (adjusted OR 1.82; 95% CI 1.01–3.28; p=0.046). Good medication adherence was the strongest predictor (adjusted OR=2.74), while baseline SBP <160 mmHg also significantly predicted successful blood pressure control (adjusted OR=1.69). These results suggest that the antihypertensive agents both showed efficacy and tolerability, but that telmisartan was superior in terms of lower blood pressure, higher rate of target blood pressure achievement and fewer peripheral edema events, which makes it an effective first-line treatment in essential hypertension.

Strengths and Limitations

The current study was conducted in a prospective randomized clinical design with balanced treatment groups, standardized treatment protocols, frequent follow-up (12 weeks) and an extensive evaluation of efficacy and safety outcomes. The inclusion of serial blood pressure measurements, target blood pressure achievement, treatment response, adverse drug reactions, laboratory safety parameters and multivariable logistic regression offered a strong assessment of the comparative performance of amlodipine and telmisartan. However, several limitations should be acknowledged. The study was performed in one center and only followed for 12 weeks, which restricts the evaluation of long-term cardiovascular and renal outcomes. Although the outcome measures were standardized, observer and performance bias may have occurred in the open label design. Also, the results may not apply to all patients or populations with several comorbid conditions and ambulatory blood pressure monitoring and quality-of-life measurement were not tested.

Conclusion

Overall, amlodipine and telmisartan were both effective and safe drugs for the treatment of EH. After 12 weeks of treatment, however, telmisartan showed significant superiority in reducing both systolic and diastolic blood pressure, achieving the target blood pressure and excellent treatment response rates, respectively, after 12 weeks telmisartan achieved higher target blood pressure control (85.83% vs. 75.83%) and a higher excellent treatment response rate (76.67% vs. 65.00%). Peripheral edema was significantly more common with amlodipine, but there was no significant difference between groups for the overall incidence of adverse drug reactions. Logistic regression analysis also showed that use of telmisartan was an independent predictor of successful blood pressure control. The results indicate both drugs can be used as first-line antihypertensive drugs, but telmisartan may be more effective and have a more favourable tolerability profile, making it a recommended therapeutic choice for the treatment of essential hypertension.

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