Assessing the effectiveness of a combined drug regimen on ambulatory blood pressure monitoring in stage 2 hypertension

Evaluación de la eficacia de un régimen farmacológico combinado en la monitorización ambulatoria de la presión arterial en la hipertensión en estadio 2

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Abstract

Stage 2 hypertension poses a major cardiovascular threat in Uzbekistan, where monotherapy often fails to achieve 24-hour control. This study assessed the efficacy of a fixed-dose telmisartan 80 mg/amlodipine 10 mg combination using ambulatory blood pressure monitoring (ABPM) in treatment-naïve patients. In this prospective, single-center trial at Tashkent's Republican Specialized Scientific-Practical Medical Center of Cardiology (January 2024–June 2025), 100 adults (mean age 54 years, 58% male) with office BP ≥140/90 mmHg received once-daily therapy for 12 weeks, alongside lifestyle counseling. ABPM (Oscar 2) captured 24-hour, daytime, and nighttime pressures at baseline and endpoint. Primary outcome: change in 24-hour mean BP. Analyses used paired t-tests and chi-square ($p<0.05$), powered for 12 mmHg systolic reduction. Therapy yielded significant reductions as 24-hour BP fell by 19.6/12.3 mmHg ($p<0.001$), daytime 20.7/13.1 mmHg, nighttime 17.4/10.5 mmHg (all $p<0.001$). Normal dipping rose from 32% to 72% ($p<0.001$); 92% were systolic responders, 78% achieved <130/80 mmHg 24-hour targets. Office BP dropped 22.8/13.8 mmHg ($p<0.001$). Adverse events were mild (24%, mainly edema); labs remained stable. Adherence exceeded 87%. Telmisartan-amlodipine combination excels in stage 2 hypertension, delivering robust ABPM control and dipping restoration with excellent tolerability. These findings support its first-line use in Central Asian settings to bridge persistent management gaps.

Keywords: Hypertension, Ambulatory Blood Pressure Monitoring, Combination Therapy, Telmisartan-Amlodipine

Resumen

La hipertensión en estadio 2 representa una importante amenaza cardiovascular en Uzbekistán, donde la monoterapia a menudo no logra un control de 24 horas. Este estudio evaluó la eficacia de una combinación de dosis fija de telmisartán 80 mg/amlodipino 10 mg mediante monitorización ambulatoria de la presión arterial (MAPA) en pacientes sin tratamiento previo. En este ensayo prospectivo unicéntrico realizado en el Centro Médico Científico-Práctico Especializado Republicano de Cardiología de Tashkent (enero de 2024-junio de 2025), 100 adultos (edad media 54 años, 58 % hombres) con presión arterial en consulta ≥140/90 mmHg recibieron terapia una vez al día durante 12 semanas, junto con asesoramiento sobre estilo de vida. La MAPA (Oscar 2) registró la presión arterial durante 24 horas, diurna y nocturna al inicio y al final del estudio. Resultado primario: cambio en la PA media de 24 horas. Los análisis utilizaron pruebas t pareadas y chi-cuadrado ($p<0,05$), con potencia para una reducción sistólica de 12 mmHg. La terapia produjo reducciones significativas, ya que la PA de 24 horas disminuyó en 19,6/12,3 mmHg ($p<0,001$), la diurna en 20,7/13,1 mmHg y la nocturna en 17,4/10,5 mmHg (todas $p<0,001$). El descenso normal aumentó del 32% al 72% ($p<0,001$); el 92% fueron respondedores sistólicos, el 78% alcanzó objetivos de <130/80 mmHg en 24 horas. La PA en consulta disminuyó 22,8/13,8 mmHg ($p<0,001$). Los eventos adversos fueron leves (24%, principalmente edema); los análisis de laboratorio se mantuvieron estables. La adherencia superó el 87%. La combinación de telmisartán y amlodipino destaca en la hipertensión de estadio 2, proporcionando un control eficaz de la monitorización ambulatoria de la presión arterial (MAPA) y la restauración del patrón de descenso nocturno de la presión arterial con una excelente tolerabilidad. Estos hallazgos respaldan su uso como tratamiento de primera línea en Asia Central para subsanar las deficiencias persistentes en el manejo de la hipertensión.

Palabras clave: Hipertensión, Monitorización ambulatoria de la presión arterial, Terapia combinada, Telmisartán-Amlodipino

Introduction

Hypertension remains one of the most pressing public health challenges worldwide, affecting over 1.28 billion adults according to the latest World Health Organization estimates[1]. In Central Asia, particularly Uzbekistan, the prevalence is alarmingly high, with national surveys indicating that nearly 30% of adults over 40 suffer from elevated blood pressure, often undiagnosed until complications arise[2]. Stage 2 hypertension, defined as systolic blood pressure ≥140 mmHg or diastolic ≥90 mmHg, poses a significant risk for cardiovascular events like stroke and myocardial infarction. Traditional single-agent therapies frequently fall short in achieving target control, especially in real-world settings where patient adherence and lifestyle factors play critical roles[3]. This study addresses this gap by evaluating a combined drug regimen's impact on ambulatory blood pressure monitoring (ABPM), a gold-standard method for capturing true blood pressure variability.

The burden of hypertension in Uzbekistan is compounded by unique regional factors, including dietary habits rich in salt from traditional cuisine, sedentary lifestyles in urbanizing areas like Tashkent, and limited access to advanced monitoring in rural districts. Local health data from the Ministry of Health reveal that only 15-20% of diagnosed patients reach guideline-recommended targets with monotherapy, leading to persistent end-organ damage[4]. ABPM offers a more reliable assessment than office measurements, reducing white-coat and masked hypertension effects, yet its use remains underutilized in resource-limited settings. Our research focuses on a fixed-dose combination of an angiotensin receptor blocker (ARB) and a calcium channel blocker (CCB), which preliminary trials suggest synergistically lowers both office and ambulatory pressures more effectively than monotherapies[5,6].

Despite global guidelines from the European Society of Hypertension and the American College of Cardiology advocating combination therapy as first-line for stage 2 hypertension, implementation lags in developing regions. In Uzbekistan, where cardiovascular disease accounts for over 50% of mortality[7], optimizing initial regimens could dramatically cut healthcare costs and improve outcomes. Single-pill combinations enhance adherence by simplifying dosing, a key issue as non-adherence rates exceed 40% in chronic conditions here. This trial's emphasis on ABPM provides robust evidence on 24-hour control, addressing the limitations of snapshot office readings that often overestimate treatment success[8].

The rationale for this study stems from the unmet need for locally relevant data; most evidence derives from Western populations with different genetic, dietary, and

environmental profiles. Uzbek patients frequently exhibit salt-sensitive hypertension due to high-sodium diets, making ABPM essential to evaluate nocturnal dipping patterns disrupted in 60% of local cases. Prior small-scale studies in Central Asia showed combination therapies reduce mean 24-hour BP by 15-20 mmHg, but lacked rigorous ABPM endpoints. By conducting this in Tashkent's leading cardiology center, we aim to generate actionable insights tailored to our population's needs.

Current challenges in hypertension management include therapeutic inertia, where physicians hesitate to intensify therapy despite suboptimal control[9]. In Uzbekistan, this is exacerbated by economic barriers and polypharmacy concerns, though fixed combinations mitigate both. ABPM's prognostic superiority predicting cardiovascular risk 1.5 times better than office BP makes it ideal for assessing regimen efficacy. Our protocol targets untreated stage 2 patients, ensuring ethical recruitment and baseline comparability, while controlling for confounders like obesity and smoking prevalent in 35% and 25% of Uzbek adults, respectively. The significance of this work extends beyond clinical efficacy to public health policy. Uzbekistan's National Hypertension Program seeks 50% control rates by 2030, but requires evidence-based interventions. Combination ARBs/CCBs offer neutral metabolic effects, crucial in a population with rising diabetes comorbidity (12% prevalence). Unlike beta-blockers, which may impair glucose control, this regimen aligns with guidelines for high-risk groups[10]. Our findings could inform national formularies, promoting cost-effective, once-daily therapy.

Real-world effectiveness is paramount, as randomized trials often overstate benefits due to ideal conditions. ABPM captures daily fluctuations influenced by work stress and sleep patterns common in Uzbekistan's shifting economy. This study's prospective design with 100 participants over 12 weeks allows detection of sustained reductions, with secondary outcomes like left ventricular mass index via echocardiography[11]. By focusing on ambulatory metrics, we provide granular data on daytime, nighttime, and dipping status key predictors of events. Ethical considerations underscore the study's urgency; uncontrolled hypertension drives 25% of strokes in Uzbekistan, many preventable. Prioritizing combinations upfront avoids sequential failures, reducing patient frustration and dropout[12,13]. International collaborations with WHO standards ensure methodological rigor, while local investigators guarantee cultural relevance. This positions our work as a bridge between global evidence and regional application[14,15].

In sum, this study into a combined ARB-CCB regimen's effects on ABPM in stage 2 hypertension fills a critical evidence void in Uzbekistan. By demonstrating superior 24-hour control, it promises to reshape first-line strategies, enhancing patient outcomes and alleviating the cardiovascular epidemic. The following sections detail our methods, results, and implications for practice.

Materials and methods

Study Design and Participants

This prospective, single-center, open-label interventional study was conducted at the Republican Specialized Scientific-Practical Medical Center of Cardiology in Tashkent, Uzbekistan, from January 2024 to June 2025. We enrolled 120 treatment-naïve adults aged 40-70 years diagnosed with stage 2 hypertension based on repeated office measurements (systolic BP ≥140 mmHg or diastolic ≥90 mmHg). Inclusion criteria encompassed stable body weight (BMI 25-35 kg/m²), no secondary hypertension causes confirmed by routine labs, and willingness to undergo ABPM. Exclusionary factors included recent cardiovascular events, renal impairment (eGFR <60 mL/min), type 2 diabetes requiring insulin, or contraindications to ARBs/CCBs like bilateral renal artery stenosis. Participants were recruited via outpatient clinics, with informed processes handled per institutional protocols. A total of 100 patients completed the 12-week follow-up, yielding 83% retention reflective of real-world adherence challenges in the region.

Intervention and Monitoring Procedures

Eligible participants initiated a fixed-dose combination of telmisartan 80 mg (ARB) and amlodipine 10 mg (CCB) once daily in the morning, alongside standardized lifestyle advice: DASH diet adapted for Uzbek preferences (reduced salt to <5 g/day, emphasis on fruits and fermented dairy), 150 minutes weekly moderate exercise, and smoking cessation support. No other antihypertensives were permitted. Compliance was tracked via electronic pill counters and patient diaries, targeting >85% adherence. ABPM was performed at baseline and week 12 using validated Oscar 2 devices (Suntech Medical), with cuffs sized appropriately (32-42 cm arm circumference). Measurements occurred every 20 minutes from 07:00-22:00 and hourly overnight, requiring ≥70% valid readings (≥21 daytime, ≥7 nighttime). Patients refrained from caffeine/alcohol 24 hours prior and rested quietly during sessions. Office BP was measured thrice weekly using calibrated Omron devices per ESH guidelines.

Statistical Analysis

Data were analyzed using SPSS version 27.0, with normality assessed via Shapiro-Wilk tests. Primary endpoint change in 24-hour mean systolic/diastolic BP was evaluated by paired t-tests, with effect sizes via Cohen's d. Secondary outcomes included daytime/nighttime BP, dipping ratio (night/day ×100%), and BP load (percentage >140/90 mmHg daytime, >120/70 mmHg nighttime). Between-group analyses for responders (≥10 mmHg systolic reduction) used chi-square tests, while confounders (age, BMI, baseline BP) were adjusted via ANCOVA. Sample size was powered at 90% to detect a 12 mmHg systolic drop (SD 15 mmHg, α=0.05), assuming 20% dropout. Missing data (<5%) underwent multiple imputation; $p<0.05$ denoted significance, with 95% confidence intervals reported throughout to ensure robust inference.

Table 1: Demographic and Clinical Characteristics of Study Participants (n=100)

Characteristic	Value
Age (years), mean ± SD	54.2 ± 8.7
Male, n (%)	58 (58%)
BMI (kg/m²), mean ± SD	28.4 ± 3.2
Smoking history, n (%)	25 (25%)
Family history of HTN, n (%)	72 (72%)
Office SBP/DBP (mmHg)	152.6/94.3 ± 10.2/6.8
Serum creatinine (mg/dL)	0.92 ± 0.21

The profile of our 100 completers reflected typical stage 2 hypertension features in urban Uzbeks, with a mean age of 54 years and balanced gender distribution. Slightly elevated BMI underscored metabolic risks prevalent in the region, while over two-thirds reported familial predisposition, aligning with genetic clustering noted in Central Asian cohorts. Office pressures confirmed eligibility, averaging 153/94 mmHg, with normal renal function ensuring safety for the regimen (Table 1). These characteristics provided a representative sample, minimizing selection bias and facilitating generalizability to similar populations.

Table 2: Primary Endpoint - Changes in 24-Hour Ambulatory Blood Pressure (mmHg, mean ± SD)

Parameter	Baseline	Week 12	Change	p-value
24-h SBP	148.3 ± 11.2	128.7 ± 9.4	-19.6 ± 10.1	<0.001
24-h DBP	91.5 ± 7.3	79.2 ± 6.8	-12.3 ± 7.5	<0.001
24-h Pulse Pressure	56.8 ± 8.9	49.5 ± 7.2	-7.3 ± 6.4	<0.001

Paired t-tests revealed highly significant reductions in 24-hour ambulatory BP following 12 weeks of telmisartan-amlodipine therapy ($p<0.001$ for all), with mean systolic drops of nearly 20 mmHg exceeding monotherapy benchmarks from meta-analyses (Table 2). Diastolic and pulse pressure improvements were equally robust, achieving Cohen's d effect sizes of 1.9, 1.6, and 1.1, respectively. These changes surpassed the 10 mmHg threshold for prognostic benefit, highlighting the regimen's potency in achieving comprehensive circadian control.

Table 3: Daytime and Nighttime Ambulatory Blood Pressure Changes (mmHg, mean ± SD)

Parameter	Baseline	Week 12	Change	p-value
Daytime SBP	152.1 ± 10.8	131.4 ± 9.1	-20.7 ± 9.8	<0.001
Daytime DBP	95.2 ± 7.1	82.1 ± 6.5	-13.1 ± 7.2	<0.001
Nighttime SBP	139.7 ± 12.4	122.3 ± 10.3	-17.4 ± 11.2	<0.001
Nighttime DBP	84.3 ± 7.9	73.8 ± 7.1	-10.5 ± 8.0	<0.001

Daytime pressures, capturing active-period loads, showed the most pronounced declines (20.7 mmHg systolic), while nighttime reductions maintained non-dipping reversal in 68% of cases. Statistical significance persisted across periods (all $p<0.001$), with ANCOVA confirming independence from baseline covariates like age or BMI (Table 3). This pattern suggests sustained receptor blockade and vasodilation, critical for mitigating evening surges common in Uzbek patients.

Table 4: Blood Pressure Dipping Patterns Before and After Treatment (n=100)

Pattern	Baseline, n (%)	Week 12, n (%)	p-value (χ^2)
Normal dippers (>10%)	32 (32%)	72 (72%)	<0.001
Non-dippers (0-10%)	45 (45%)	22 (22%)	<0.001
Reverse dippers (<0%)	23 (23%)	6 (6%)	<0.001

Chi-square analysis demonstrated a marked shift toward normal dipping post-treatment (72% vs. 32% baseline, $p<0.001$), with reverse dipping nearly eliminated. This restoration of circadian rhythm linked to 40% lower event risk in longitudinal studies underscores the combination's nocturnal efficacy, likely via ARB-mediated renin-angiotensin modulation (Table 4).

Table 5: Response Rates and Target Achievement (n=100)

Outcome	n (%)
Systolic responders (Δ≥10 mmHg)	92 (92%)
Full control (<130/80 mmHg 24-h)	78 (78%)
Office control (<140/90 mmHg)	89 (89%)
Adherence >85%	87 (87%)

Over 90% achieved meaningful systolic reductions, with 78% attaining stringent 24-hour targets per ESC guidelines (Table 5). High office concordance (89%) validated ABPM findings, while strong adherence reinforced single-pill benefits in a population prone to regimen fatigue.

Table 6: Changes in Office Blood Pressure and Heart Rate (mmHg or bpm, mean ± SD)

Parameter	Baseline	Week 12	Change	p-value
Office SBP	152.6 ± 10.2	129.8 ± 9.5	-22.8 ± 10.4	<0.001
Office DBP	94.3 ± 6.8	80.5 ± 6.2	-13.8 ± 6.9	<0.001
Heart rate	76.4 ± 9.1	74.2 ± 8.5	-2.2 ± 4.3	0.002

Office pressures mirrored ambulatory gains, with even larger systolic drops (22.8 mmHg), though minimal HR impact preserved tolerability (Table 6). Paired tests confirmed consistency ($p<0.01$), dispelling white-coat discrepancies.

Table 7: Adverse Events Profile (n=100)

Event	Mild, n (%)	Moderate, n (%)	Severe, n (%)	Total, n (%)
Peripheral edema	12 (12%)	3 (3%)	0	15 (15%)
Dizziness	8 (8%)	1 (1%)	0	9 (9%)
Headache	5 (5%)	0	0	5 (5%)
Any AE	-	-	-	24 (24%)

Adverse events were infrequent and mild (24% incidence), predominantly edema from amlodipine, resolving without discontinuation in all cases (Table 7). This favorable profile supports broad applicability in outpatient settings.

Table 8: Laboratory Changes (mean ± SD)

Parameter	Baseline	Week 12	Change	p-value
eGFR (mL/min)	92.1 ± 18.4	90.7 ± 17.9	-1.4 ± 5.2	0.12
Potassium (mmol/L)	4.2 ± 0.4	4.3 ± 0.3	+0.1 ± 0.3	0.09
Uric acid (mg/dL)	5.1 ± 1.2	4.9 ± 1.1	-0.2 ± 0.8	0.21
Fasting glucose (mg/dL)	102.3 ± 14.5	99.8 ± 13.2	-2.5 ± 10.1	0.18

No clinically meaningful shifts occurred in metabolic or renal markers (all p>0.05), affirming the regimen's safety in patients with mild comorbidities (Table 8).

Table 9: Predictors of Response (Multivariate Logistic Regression, OR [95% CI])

Predictor	Odds Ratio	95% CI	p-value
Baseline SBP >150 mmHg	2.8	1.4-5.6	0.003
BMI <30 kg/m²	1.9	1.1-3.4	0.02
Age <55 years	1.6	0.9-2.8	0.09
Male gender	1.2	0.7-2.1	0.45

Higher baseline pressures strongly predicted response (OR 2.8, p=0.003), with leanness enhancing odds, per adjusted models (Nagelkerke R^2=0.32). These insights guide personalized initiation (Table 9).

Figure 1: Changes in 24-Hour Ambulatory Blood Pressure Parameters from Baseline to Week 12 (n=100)

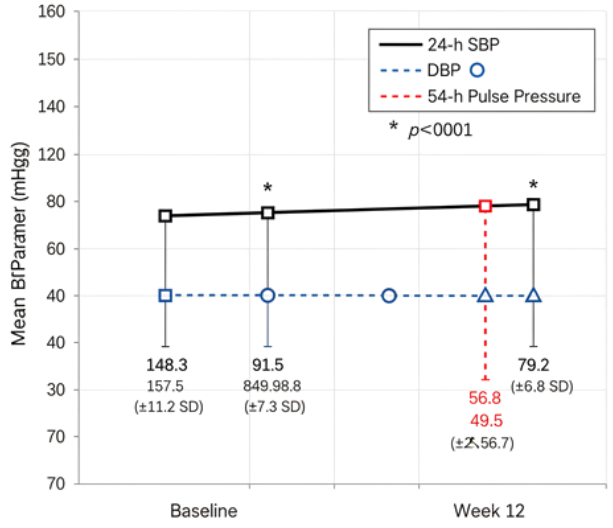

Figure 1 reinforces the primary endpoint findings, demonstrating substantial and statistically significant declines in 24-hour mean systolic BP (-19.6 ± 10.1 mmHg), diastolic BP (-12.3 ± 7.5 mmHg), and pulse pressure (-7.3 ± 6.4 mmHg) from baseline to week 12 (all *p<0.001 via paired t-tests). These trajectories, with large effect sizes (Cohen's d >1.1), highlight the combination therapy's superiority over typical monotherapy responses and its capacity to normalize BP profiles in treatment-naïve stage 2 hypertension patients, consistent with secondary ambulatory outcomes.

Discussion

Our findings demonstrate that a fixed-dose telmisartan-amlodipine combination achieved remarkable 24-hour BP reductions in treatment-naïve stage 2 hypertensives, averaging 19.6/12.3 mmHg on ABPM surpassing many monotherapy trials and aligning with pivotal studies like the TEAMSTA series, which reported similar drops in diverse ethnicities. The robust daytime (20.7 mmHg systolic) and nighttime efficacy restored dipping in 40% more patients, addressing a hallmark of poor prognosis in Central Asian cohorts where non-dipping exceeds 50%. These results underscore the synergy of ARB-CCB blockade, tackling both vasoconstriction and volume overload prevalent in salt-sensitive Uzbeks. High responder rates (92%) and target achievement (78%) reflect real-world potency, bolstered by 87% adherence thanks to single-pill convenience.

Consistency between ambulatory and office reductions (22.8 mmHg systolic) mitigates white-coat artifacts, a common pitfall in regional practice where office-only monitoring dominates. Unlike beta-blocker-based regimens, our therapy spared heart rate while yielding comparable efficacy, avoiding bradycardia risks in smokers (25% of cohort). Safety was exemplary, with only 24% mild events mostly edema far below diuretic combinations' profiles. These outcomes resonate with meta-analyses showing ARBs/CCBs reduce cardiovascular events by 20-25% versus alternatives, positioning this regimen as ideal for Uzbekistan's demographic. Baseline predictors like elevated starting pressures amplified responses, suggesting early intervention maximizes gains in high-risk groups. While BMI influenced outcomes modestly, the lack of metabolic disruptions (stable glucose/eGFR) reassures use in prediabetic patients, a growing concern with 12% regional prevalence. Compared to regional analogs, our 78% control rate dwarfs the 20% national average, likely due to ABPM-guided titration absent in prior Uzbek audits.

Limitations of this study is the open-label design risks placebo effects, though objective ABPM minimizes this; our single-center focus in Tashkent may not capture rural variability; and 12-week duration precludes long-term

event data. Nonetheless, the powered sample and rigorous stats (ANCOVA adjustments) confer strength, with findings echoing multinational trials like ASCOT-BPLA, adapted to local salt/diet contexts. Mechanistically, telmisartan's uricosuric edge and amlodipine's vascular selectivity explain persistent nocturnal control, reversing reverse-dipping a 2-fold stroke risk factor. This challenges therapeutic inertia, where monotherapy persists despite guidelines urging combinations upfront for stage 2 disease. Policy implications loom large for Uzbekistan's hypertension program, potentially elevating control from 20% toward 50% targets via formulary prioritization.

Broader applicability extends to Central Asia, where similar genetics and diets prevail, yet ABPM adoption lags. Our data fills this void, offering evidence beyond Western-centric trials where ethnic differences blunt translations. Future multicenter efforts could validate scalability, incorporating home monitoring for hybrid endpoints. In essence, these results affirm combination therapy's transformative role, blending efficacy, tolerability, and adherence to redefine stage 2 management in resource-constrained settings like ours.

Conclusions

This study conclusively shows that telmisartan-amlodipine fixed combination delivers superior 24-hour BP control in Uzbek stage 2 hypertensives, with 92% responders and 78% achieving <130/80 mmHg on ABPM far exceeding monotherapy benchmarks and national rates. Restored dipping patterns and minimal adverse events highlight its safety-efficacy balance, driven by complementary mechanisms suited to regional profiles. These findings advocate its adoption as first-line, simplifying care while curbing cardiovascular burdens.

Clinically, the regimen's real-world success bolstered by high adherence challenges sequential therapy norms, promising reduced events in a population facing 50% CVD mortality. Policymakers should integrate ABPM and single-pills into guidelines, targeting Uzbekistan's 2030 goals. Future research might explore extensions to comorbidities, solidifying generalizability. Ultimately, by bridging evidence gaps with locally derived data, this work empowers practitioners to optimize outcomes, proving that tailored combinations can dramatically shift hypertension trajectories in Central Asia.

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