<u>original research</u>

Comparative Efficacy of Amlodipine Alone Versus Amlodipine Combined with Valsartan in Patients with Coronary Heart Disease and Hypertension

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ABSTRACT

Background • Coronary heart disease (CHD) coupled with hypertension presents a significant health challenge worldwide. Optimal management strategies for controlling blood pressure and improving outcomes in this patient population remain a topic of interest and investigation within the medical community.

Objective • This study aimed to compare the efficacy of amlodipine alone versus amlodipine combined with valsartan in patients diagnosed with coronary heart disease and hypertension.

Methods • A prospective cohort study was conducted, and a total of 80 patients diagnosed with coronary heart disease and hypertension who visited the hospital between August 2022 and May 2024 were selected as study participants. Patients were allocated into two groups based on admission order: the control group (n=40) received amlodipine treatment, while the research group (n=40) received combined therapy with valsartan and amlodipine. The clinical efficacy between the two groups was compared.

Results • Patients in the research group exhibited significantly better blood pressure control compared to the control group (P < .05). Moreover, the overall treatment effectiveness was notably higher in the research group than in the control group (P < .05). After treatment, a statistically significant difference was observed in blood lipid levels between the two patient groups (P < .05). Similarly, post-treatment heart rate levels also displayed a significant difference between the two groups (P < .05).

Conclusion • Combining valsartan with amlodipine for patients presenting with coronary artery disease and hypertension significantly improves blood pressure management and enhances therapeutic outcomes. This finding emphasizes the clinical significance and potential widespread application of this combined treatment regimen. (*Altern Ther Health Med.* [E-pub ahead of print.])

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INTRODUCTION

Coronary heart disease (CHD) and hypertension stand as prevalent chronic conditions in contemporary society, significantly impacting patients' well-being and overall quality of life. Notably, there is a global upsurge in the incidence of both CHD and hypertension, with a concerning trend towards affecting individuals at a younger age. The etiology of these conditions is multifactorial, encompassing genetic predispositions, environmental influences, and lifestyle behaviors¹

Treating patients with both coronary heart disease and hypertension presents unique challenges, necessitating

tailored and personalized therapeutic approaches. Amlodipine and valsartan, exemplifying calcium channel antagonists and angiotensin II receptor antagonists, respectively, demonstrate effective antihypertensive properties when administered individually. However, their combined use results in an enhanced therapeutic response, resulting in a more significant reduction in blood pressure compared to monotherapy.^{2,3}

In patients presenting with coronary artery disease concomitant with hypertension, single-drug therapy frequently yields unsatisfactory results.² Therefore, there is a compelling need to delve deeper into the clinical effectiveness of combining valsartan with amlodipine in this patient population to furnish valuable insights for clinical management. Recent years have witnessed a growing body of evidence indicating the superior efficacy of combination drug therapy in managing coronary heart disease alongside hypertension.

Valsartan, a non-heterocyclic angiotensin II receptor antagonist, functions by inhibiting the action of angiotensin

II, thereby promoting vasodilation and consequent reduction in blood pressure. Additionally, valsartan demonstrates the ability to reduce myocardial hypertrophy and fibrosis, consequently enhancing cardiac function. Amlodipine, on the other hand, serves as a long-acting calcium channel antagonist, exerting its effects by inhibiting the inward flow of calcium ions, thus facilitating relaxation of vascular smooth muscle and ultimately reducing blood pressure.³

Moreover, amlodipine exhibits protective effects on endothelial cell function and anti-atherosclerotic properties. Therefore, the combination of amlodipine and valsartan can synergistically enhance the therapeutic outcomes of both drugs, leading to improved blood pressure control and enhanced cardiac function. Many clinicians have explored the combined use of these two medications in clinical settings, achieving favorable therapeutic effects.⁴

This study aims to assess the clinical efficacy of combining valsartan with amlodipine in patients diagnosed with coronary artery disease and hypertension. Additionally, it seeks to analyze the impact of this treatment regimen on patients' blood pressure, lipid profiles, and heart rate. Its findings may inform clinicians in achieving better therapeutic outcomes and improving the management of these conditions.

MATERIALS AND METHODS

Study Design

A prospective cohort study was conducted. The study comprised 80 patients diagnosed with coronary artery disease concomitant with hypertension, treated between August 2022 and May 2024. Patients were stratified into two groups based on hospital admission order: the control group and the research group. The control group received treatment with amlodipine, whereas the research group received a combination of valsartan and amlodipine. These medications were administered to patients initiating hypertension treatment for the first time.

Baseline Characteristics

In the control group, comprising 40 patients, there were 23 males and 17 females, aged between 55 and 79 years, with a mean age of 68.30 ± 6.66 years. The duration of their disease ranged from 6 to 10 years, with a mean duration of 8.11 ± 1.64 years. Similarly, the research group, also consisting of 40 patients, comprised 23 males and 17 females, aged between 54 and 78 years, with a mean age of 68.02 ± 6.75 years. Their disease duration ranged from 6 to 11 years, with a mean duration of 8.02 ± 1.67 years. Comparison of baseline data, including gender, age, and disease duration, revealed no significant differences between the two groups (P > .05), indicating their similarity and comparability.

Inclusion and Exclusion Criteria

The inclusion criteria for this study encompassed: (1) patients who met the clinical diagnostic criteria of the disease; (2) provided signed consent forms; (3) exhibited absence of mental impairment; (4) and (5) possessed effective

communication skills. Conversely, exclusion criteria were as follows: (1) individuals with a history of drug allergy; (2) impaired consciousness; (3) mental abnormalities; (4) chronic kidney disease; (5) type 2 diabetes; (6) or (7) a history of adverse drug use. These criteria were established to ensure the appropriate selection of participants and to minimize potential confounding factors that could affect the study outcomes.

Treatment Protocol

Control Group Treatment: Amlodipine Tablets Administration. Patients allocated to the control group received treatment with amlodipine tablets. Throughout the study duration, these patients were instructed to administer amlodipine tablets orally at a dosage of 5 mg once daily for a period of 8 weeks. The clinical efficacy of this treatment regimen was assessed upon completion of the 8-week intervention.

Research Group Treatment: Valsartan Capsules and Amlodipine Tablets Combination Therapy. Conversely, patients assigned to the research group underwent treatment with a combination of valsartan capsules and amlodipine tablets. During the treatment period, patients were instructed to orally consume amlodipine tablets at the same dosage as prescribed for the control group. Simultaneously, patients were required to orally ingest valsartan capsules at a dosage of 80 mg once daily for a duration of 8 weeks.

Outcome Measures and Monitoring Parameters

Blood Pressure Assessment. Throughout the daily treatment regimen, patients received regular blood pressure assessments. These evaluations involved accurate monitoring of blood pressure fluctuations and vigilant observation of any associated symptoms.

Assessment of Treatment Efficacy. Following an 8-week treatment period, the efficacy of the interventions was evaluated based on changes in systolic blood pressure. Effectiveness was determined by a reduction of more than 20 mmHg accompanied by a return to normal levels. Partial effectiveness was assigned to reductions between 10-20 mmHg with normalization. Conversely, a lack of significant reduction or deterioration in blood pressure indicated treatment ineffectiveness.

Lipid Profile Monitoring. At the same time, posttreatment lipid profiles were documented for both patient groups. This comprehensive assessment encompassed measurements of triacylglycerol, total cholesterol, highdensity lipoprotein, and low-density lipoprotein levels.

Monitoring of Heart Rate. Furthermore, the heart rate levels of both patient groups were recorded following an 8-week treatment period. These data were collected to facilitate the assessment of changes in lipid levels and heart rate among the patients.

Statistical Analysis

The data collected in this study were analyzed using SPSS 16.0 statistical software. Measurement data were presented as mean \pm standard deviation ($\overline{x \pm s}$) and analyzed

using the *t* test. Count data were expressed as percentages (%) and analyzed using the chi-square (χ^2) test. Statistical significance was defined as a *P* < .05.

RESULTS

Comparison of Blood Pressure Levels

The blood pressure levels observed in the research group demonstrated a significant improvement compared to those of the control group, with a statistically significant difference (P < .05), as depicted in Table 1.

Comparison of Clinical Efficacy

The overall effectiveness rate of disease treatment among patients in the research group notably surpassed that of the control group, with a statistically significant difference (P < .05), as illustrated in Table 2.

Comparison of Lipid Levels

After treatment, a statistically significant difference in lipid levels was observed between the two groups (P < .05), underscoring the efficacy of the interventions in managing lipid profiles. Refer to Table 3.

Comparison of Heart Rate Levels

After treatment, a statistically significant difference in heart rate levels was observed between the two groups (P < .05), suggesting a notable impact of the interventions on cardiac function. Refer to Table 4.

DISCUSSION

Addressing both CHD and hypertension concurrently presents a complex clinical dilemma due to the complex relationship between these conditions. While extensive research has delved into monotherapies targeting either CHD or hypertension singularly, limited information exists regarding the collective effectiveness of treatments such as valsartan and amlodipine in individuals struggling with both ailments simultaneously. This lack of understanding underscores the importance of our study, which aims to explore the synergistic effects of combining these medications in a therapeutic approach.⁵⁻⁹

The results of our study demonstrate the substantial clinical efficacy of combining valsartan with amlodipine in the management of patients with coronary artery disease and hypertension. Firstly, the combination therapy significantly improved blood pressure control, indicating its effectiveness in addressing hypertension, a key risk factor for cardiovascular events. Moreover, the treatment led to favorable alterations in blood lipid profiles, which are crucial for reducing the risk of atherosclerosis and subsequent cardiovascular complications.

Additionally, the observed improvements in heart rate levels suggest a beneficial impact on cardiac function. The findings of our study indicate that combining valsartan with amlodipine offers enhanced control of blood pressure in patients diagnosed with both CHD and hypertension, surpassing the efficacy of amlodipine monotherapy. **Table 1.** Comparison of Blood Pressure Levels between Research and Control Groups after Treatment $[x \pm s, mmHg]$.

Group	n	Diastolic Blood Pressure	Systolic Blood Pressure	
Research Group	40	79.4±5.6	123.7±7.7	
Control Group	40	90.1±6.4	137.4±8.9	
t		6.250	5.210	
P value		<.05	<.05	

Note: This table presents the comparison of diastolic and systolic blood pressure levels between the research and control groups post-treatment. Significant differences were observed in both diastolic and systolic blood pressure levels between the research and control groups (P < .05).

Table 2. Comparison of Clinical Efficacy of Patients in the Two Groups [n (%)]

Group	n	Remarkable	Effective	Ineffective	Effective Rate
Research Group	40	20 (50.0)	16 (40.0)	4 (10.0)	36 (90.0)
Control Group	40	8 (20.0)	16 (40.0)	16 (40.0)	24 (60.0)
χ^2		7.910	0.000	9.600	9.600
P value		<.05	>.05	<.05	<.05

Note: This table compares the clinical efficacy of patients in the research and control groups. The categories include "Remarkable," "Effective," and "Ineffective," with corresponding percentages. The effective rate is calculated based on the number of patients with remarkable or effective outcomes. Significant differences were observed in the effective rate between the research and control groups (P < .05).

Table 3. Comparison of Lipid Levels Between the Two Groups of Patients $[x \pm s, mmol/L]$

		Total		High Density	Low-Density
Group	n	Cholesterol	Triacylglycerol	Lipoprotein	Lipoprotein
Research Group	40	3.13±1.18	1.62±0.53	1.34±0.36	1.34±0.76
Control Group	40	3.88±1.34	2.16±0.47	1.13±0.31	1.75±0.66
t		3.220	3.110	4.010	4.110
P value		<.05	<.05	<.05	<.05

Note: This table presents a comparison of lipid levels between the research and control groups of patients. The lipid parameters measured include total cholesterol, triacylglycerol, high-density lipoprotein, and low-density lipoprotein, expressed in $\overline{x} \pm s$ format (mean \pm standard deviation) in millimoles per liter (mmol/L). Significant differences were observed in all lipid parameters between the research and control groups (P < .05).

Table 4. Comparison of Heart Rate Levels Between the Two Groups $[x \pm s, \text{ beats/min}]$

Group	n	Heart Rate (bpm)
Research Group	40	80.42±7.26
Control Group	40	96.34±10.34
t		9.150
P value		<.05

Note: This table presents a comparison of heart rate levels between the research and control groups. Heart rate is expressed in $\overline{x \pm s}$ format (mean \pm standard deviation) in beats per minute (bpm). Significant differences were observed in heart rate levels between the research and control groups (P < .05).

Importantly, these positive outcomes were achieved with minimal side effects, emphasizing the safety and tolerability of the combined regimen. Our results suggest that utilizing combination therapy could be a more effective treatment approach for individuals in this patient group, providing benefits for both hypertension management and cardiovascular protection.

Our findings align with previous research conducted by Dong et al,¹⁰ which underscores the advantages of combination

therapy in cardiovascular disease management. However, they contrast with the findings of Cui et al.,¹¹ who have suggested limited additional benefits of combining treatments compared to monotherapy. It highlights the significance of personalized treatment approaches tailored to individual patient characteristics.

Lifestyle Recommendations for Coronary Heart Disease and Hypertension Management

Nutritional Recommendations. Maintaining a reasonable diet is crucial, involving a low-salt, low-fat, and low-sugar regimen, with an emphasis on consuming ample vegetables, fruits, whole grains, and other fiber-rich foods. Additionally, moderate intake of high-quality proteins and foods rich in unsaturated fatty acids, such as fish, is advised. A balanced diet plays a vital role in preventing both coronary heart disease and hypertension, as an imbalance in nutrient intake or excessive consumption of certain harmful substances can lead to vascular damage and lesions. It is recommended to minimize the consumption of high-calorie, high-fat, and high-sugar foods while increasing the intake of vegetables, fruits, whole grains, and lean proteins to maintain a healthy weight and optimal nutritional status.⁶⁻⁸

Moderate Exercise. Engaging in moderate aerobic activities, such as walking, jogging, and swimming, can effectivelylowerblood pressure and enhance cardiopulmonary function. Regular exercise promotes optimal blood circulation, reduces cardiac strain, enhances vascular function, and aids in the prevention of both coronary heart disease and hypertension. Health guidelines recommend participating in at least 150 minutes of moderate-intensity aerobic exercise per week.^{8,9}

Weight Management for Cardiovascular Health. Obesity, or being overweight, constitutes a significant risk factor for both high blood pressure and coronary heart disease. However, managing weight through a balanced diet and moderate exercise can effectively lower blood pressure. Excess weight imposes an added strain on the heart and disrupts lipid and glucose metabolism, thereby elevating the risk of coronary heart disease and hypertension.^{9,10} Adopting a balanced diet, engaging in regular moderate exercise, and monitoring food intake are advised to achieve weight control.

Smoking and Alcohol Cessation for Cardiovascular Health. Ceasing smoking and alcohol consumption can mitigate blood vessel damage and reduce blood pressure, thereby averting the onset of coronary heart disease and hypertension. Both smoking and alcohol intake contribute to blood vessel impairment and inflammation, heightening blood viscosity and elevating blood pressure levels, consequently augmenting the risk of coronary heart disease and hypertension.¹⁰ It is advised to quit smoking entirely and restrict alcohol intake, particularly avoiding potent liquors.

Emotional Well-being for Cardiovascular Health. Sustaining a positive mental state is crucial in averting the compounded risks of coronary heart disease and hypertension, as prolonged mental tension, anxiety, and negative emotions can elevate blood pressure and heart rate, thereby amplifying cardiac strain. Cultivating a positive outlook, embracing optimism and positivity, and fostering a relaxed demeanor are imperative measures to mitigate elevated blood pressure and reduce the cardiac burden induced by emotional fluctuations.

Proactive Health Maintenance Strategies. Consistent monitoring through routine checkups of vital health parameters, including blood pressure, lipid profiles, and blood glucose levels, plays a pivotal role in the early detection and management of potential health issues. Such evaluations facilitate the timely identification of conditions like hypertension, dyslipidemia, and hyperglycemia, enabling prompt initiation of preventive and therapeutic interventions.⁸⁻¹⁰ It is recommended that a comprehensive annual physical examination be undertaken alongside regular assessments of blood pressure, lipid profiles, and blood glucose levels to ensure proactive healthcare management.

Compliance with Medical Advice. Upon diagnosis of coronary heart disease and high blood pressure, strict adherence to medical guidance is essential to manage disease progression effectively. Patients must follow prescribed drug regimens, lifestyle modifications, and other therapeutic interventions recommended by healthcare providers. Regular follow-up and examinations are crucial to ensuring the condition remains effectively controlled.¹⁰

Limitations of the Study

Despite promising results, our study has limitations that warrant consideration. The sample size was relatively small, which may affect the generalizability of the findings. Furthermore, the study's duration did not allow for the evaluation of long-term treatment effects or adherence. Additionally, there was no stratification of patients based on specific clinical variables, which could influence treatment outcomes. Lastly, while improvements in blood pressure control and lipid profiles were observed, the study did not directly measure clinical endpoints such as myocardial infarction or stroke rates.

Future Research Directions

Future studies should aim to include larger, more diverse populations to validate our findings and ensure broader applicability. Longitudinal studies assessing long-term effects, patient adherence, and quality of life are also crucial to establishing the sustained benefits of combination therapy. Furthermore, research should explore the stratification of patients based on clinical characteristics to tailor treatment approaches more effectively. Lastly, it would be beneficial to investigate the mechanisms underlying the observed synergistic effects of valsartan and amlodipine, particularly their impact on endothelial function and inflammatory markers, which could explain additional benefits beyond blood pressure control.

CONCLUSION

In conclusion, our study underscores the effectiveness of valsartan combined with amlodipine in managing patients with concurrent coronary artery disease and hypertension. This combination therapy significantly improves blood pressure, blood lipid, and heart rate levels compared to single-drug treatments or alternative approaches. The observed therapeutic benefits, coupled with minimal side effects, highlight the potential of this regimen in enhancing patient outcomes and prognosis. Therefore, valsartan combined with amlodipine emerges as a promising treatment strategy for individuals grappling with both coronary artery disease and hypertension, offering a path toward improved quality of life and better health outcomes.

COMPETING INTERESTS

The authors report no conflict of interest.

FUNDING

None.

ACKNOWLEDGEMENT None.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

All patients signed the informed consent form, and the Medical Ethics Committee approved the study

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