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Research Progress on the Treatment of Hypertension Combined with Coronary Heart Disease with Amlodipine and Atorvastatin Calcium Tablets

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Abstract: Hypertension combined with coronary heart disease, as a common chronic disease, often coexists, which has a significant impact on patients' health and quality of life. As a compound preparation, amlodipine and atorvastatin calcium tablets have shown significant efficacy in the treatment of hypertension combined with coronary heart disease in recent years. This study systematically analyzes the pharmacological characteristics, clinical treatment effect, and safety of amlodipine and atorvastatin calcium tablets. The research points out that this compound preparation can significantly regulate blood pressure, optimize myocardial blood supply, and thus effectively reduce the occurrence of adverse cardiovascular events.

Keywords: Amlodipine; Atorvastatin calcium tablets; Hypertension; Coronary heart disease

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1. Introduction

Hypertension and coronary heart disease are important cardiovascular diseases that affect people's lives and health globally, and their incidence and prevalence are increasing year by year. According to a WHO report, about 1.1 billion people worldwide suffer from hypertension, and a large number of new cases emerge every year. In China, the prevalence of hypertension remains high, with an estimated prevalence of about 27.9% among adults, affecting hundreds of millions of people [1]. Meanwhile, coronary heart disease cannot be ignored, as its mortality rate ranks among the highest among many diseases, making it a significant "killer" of the health of Chinese residents. Hypertension and coronary heart disease are closely related. As an independent risk factor for coronary heart disease, long-term elevated blood pressure can cause coronary endothelial injury, accelerate

the formation of atherosclerosis, and thus induce coronary heart disease. For people who have already developed coronary sclerosis, hypertension can further increase the heart's load, increasing the likelihood of severe cardiovascular events such as myocardial infarction and heart failure, affecting patients' quality of life and threatening their safety [2]. Amlodipine Atorvastatin Calcium Tablets are a combination of amlodipine, a dihydropyridine calcium channel blocker, and atorvastatin, a hydroxymethylglutaryl-CoA reductase inhibitor. Amlodipine can dilate blood vessels and lower blood pressure, while atorvastatin can lower blood lipids and stabilize plaques. The combination of the two complements each other and provides multiple functions such as lowering blood pressure, regulating blood lipids, and protecting blood vessels. Currently, through continuous clinical exploration, the medical community has confirmed the outstanding value of amlodipine atorvastatin calcium tablets in the comprehensive treatment of hypertension combined with coronary heart disease. With its significant therapeutic effect and high safety, this drug has gained high clinical recognition, opening up a new path for the treatment of hypertension combined with coronary heart disease and providing an effective reference.

2. Pharmacological effects of Amlodipine Atorvastatin Calcium Tablets

2.1. Amlodipine

Amlodipine is a third-generation dihydropyridine calcium channel blocker (CCB). Its positively charged side chain can specifically bind to the negatively charged regions of vascular smooth muscle cell membranes, continuously inhibiting the opening of L-type calcium channels and significantly reducing the influx of calcium ions. This mechanism promotes full relaxation of vascular smooth muscles and pronounced vasodilation, resulting in significant and sustained blood pressure-lowering effects, providing a reliable treatment option for hypertensive patients. Its mechanism of action lies in blocking vasoconstriction signal transmission, maintaining vasodilation, and achieving blood pressure control by improving hemodynamic parameters. Additionally, amlodipine can exert a certain blocking effect on N-type calcium channels. This action helps reduce the reflex sympathetic activation caused by vasodilation, prevents adverse reactions such as excessive heart rate, and also inhibits the increase in glomerular capsule pressure, protecting renal function [3].

As a complex drug molecule with both water and fat solubility, amlodipine consists of two enantiomers: racemic levorotatory and dextrorotatory forms. The racemic levorotatory form is the key active component that blocks calcium ion selective channels, exhibiting significant pharmacological efficacy. Although the dextrorotatory form has weaker pharmacological activity, it has significant advantages in scavenging oxidative stress damage and stimulating endogenous nitric oxide (NO) production, which helps improve the structural and functional integrity of vascular endothelial cells. The absorption process of this drug after oral administration is slow and complete, typically reaching peak blood concentration 6–12 hours after administration, with a stable blood concentration maintained at 8–12ng/ml. Its high bioavailability ranges from 64%–90%, and it is not affected by dietary factors, making it clinically convenient to administer [4].

2.2. Atorvastatin

Atorvastatin, as a 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitor, plays a crucial role in lipid regulation in clinical practice. Through a highly competitive inhibitory mechanism, it directly targets HMG-CoA reductase, effectively blocking the biosynthetic pathway of cholesterol. This mechanism not only

significantly reduces the synthesis and storage of cholesterol in hepatocytes but also accelerates the metabolic clearance of low-density lipoprotein cholesterol (LDL-C). As a result, it causes a notable decrease in serum total cholesterol and LDL-C concentrations, with a reduction range of up to 30%–50% [5]. Additionally, atorvastatin exhibits multifaceted effects in regulating blood lipids, promoting the production of high-density lipoprotein cholesterol (HDL-C), and improving the lipid profile. Atorvastatin also effectively enhances the synthesis and release of nitric oxide (NO) by endothelial cells, thereby strengthening vasodilation and providing dynamic support to the vascular system. Furthermore, by inhibiting the proliferation and migration of vascular smooth muscle cells, it prevents the thickening of blood vessel walls and narrowing of lumens, ensuring the continuous patency of vascular channels. In the treatment of atherosclerosis (AS), atorvastatin stabilizes plaques, significantly reducing the risk of plaque rupture and providing robust protection to the vascular structure. Simultaneously, it suppresses local inflammatory responses, notably decreasing levels of inflammatory markers such as C-reactive protein and mitigating the destructive effects of inflammation on blood vessel walls. The absorption process of atorvastatin is rapid, reaching peak concentrations in the plasma within 1–2 hours after oral administration, allowing it to exert its therapeutic effects. Although the first-pass effect through the liver and intestine is significant, resulting in an absolute bioavailability of only 14% after a 10 mg oral dose, this efficiency is sufficient to ensure clinically significant results.

2.3. Combination therapy with amlodipine and atorvastatin

When amlodipine and atorvastatin are combined into a compound preparation, there is no significant difference in the absorption rate and extent (bioavailability) of the two component drugs compared to when they are administered separately. Although food does not significantly affect the absorption process of amlodipine, it can inhibit the absorption efficiency and extent of atorvastatin, resulting in a decrease in absorption rate by approximately 32% and a reduction in absorption degree by 11%. However, eating does not weaken the clinical efficacy of atorvastatin in reducing LDL-C. A study has shown that even when 10 mg of amlodipine and 80 mg of atorvastatin are administered together, the pharmacokinetic characteristics of amlodipine remain stable, while the peak concentration of atorvastatin is not affected. However, its area under the curve (AUC) increases by 18%, suggesting that the compound preparation may further enhance the efficacy of atorvastatin through synergistic effects [6]. The synergistic action of the two drugs allows for complementary advantages, enabling precise blood pressure control and optimized lipid metabolism. This significantly improves the state of vascular endothelium, effectively inhibits plaque development, and greatly reduces the incidence of cardiovascular adverse events, providing a more effective treatment strategy for patients with hypertension and coronary heart disease.

3. Clinical efficacy and safety of Amlodipine and Atorvastatin Calcium Tablets

3.1. Synergistic hypotension

Multiple clinical studies have clearly pointed out that amlodipine and atorvastatin calcium tablets have significant advantages in lowering blood pressure in combination therapy for hypertension with coronary heart disease [7]. Yu Peng et al. conducted a randomized controlled study that randomly divided 120 patients diagnosed with hypertension and coronary heart disease into two groups [8]. The experimental group was treated with oral amlodipine and atorvastatin calcium tablets (atorvastatin 20 mg, amlodipine 5 mg), once a

day, while the reference group only received oral amlodipine 5 mg treatment, once a day, with an intervention period of 12 weeks. The research data showed that the reductions in systolic and diastolic blood pressure in the experimental group were 22.5 mmHg and 12.3 mmHg, respectively, while the systolic and diastolic blood pressure in the reference group only decreased by 16.8 mmHg and 9.2 mmHg, respectively. The statistical difference between the two groups was significant ($P < 0.05$). In addition, the blood pressure compliance rate (systolic blood pressure <140 mmHg and diastolic blood pressure <90 mmHg) in the treatment group was as high as 88.3%, which was significantly higher than the 71.7% in the control group ($P < 0.05$). A large multicenter study by Hideaki involving 1000 patients confirmed that amlodipine and atorvastatin calcium tablets have a synergistic effect in lowering blood pressure [9]. In this study, patients were divided into single-drug amlodipine and atorvastatin groups and a combination treatment group. After 2 months of treatment, the blood pressure reduction in the combination group was increased by 6.2 mmHg (systolic blood pressure) and 3.5 mmHg (diastolic blood pressure) compared to the single-drug groups, respectively, and the blood pressure control rate reached 92%, which was also higher than the 78% and 80% in the single-drug groups. The mechanism may be related to the following synergistic blood pressure-lowering effects: (1) Improving endothelial function: Amlodipine lowers blood pressure by vasodilation, and atorvastatin reduces oxidative stress and protects endothelial cells. The combination of amlodipine and atorvastatin increases NO secretion, thereby lowering blood pressure; (2) Improving arterial compliance: Decreased arterial compliance is one of the important pathophysiological mechanisms of hypertension. The combination of amlodipine and atorvastatin can not only effectively improve arterial elasticity and delay the progression of atherosclerosis, but also significantly reduce blood pressure levels; (3) Regulation of neuroendocrine function: Hypertensive patients often exhibit hyperactivity of the sympathetic nervous system and increased activity of the renin-angiotensin-aldosterone system (RAAS). Amlodipine effectively inhibits sympathetic excitability by regulating calcium ion levels in vascular smooth muscle cells, while atorvastatin indirectly regulates the activity balance of the RAAS system by improving lipid metabolism. The combined use of these two drugs can intervene in neuroendocrine mechanisms synergistically, thereby promoting stable blood pressure control [10].

3.2. Synergistic lipid regulation

A study by MZG on patients with hyperlipidemia and hypertension showed that after 12 weeks of treatment, the level of low-density lipoprotein cholesterol (LDL-C) in the combination therapy group decreased by 42% compared to baseline, significantly higher than the 35% decrease in the atorvastatin monotherapy group ($P < 0.01$) [11]. Simultaneously, the high-density lipoprotein cholesterol (HDL-C) level in the combination therapy group increased by 12%, and the total cholesterol (TC)/HDL-C ratio decreased significantly. This indicates that the combination therapy not only effectively reduces “bad cholesterol” but also increases “good cholesterol” levels, optimizing the lipid profile. The mechanism of synergistic lipid regulation is analyzed as follows: (1) Inhibition of P-glycoprotein: Atorvastatin is a substrate of P-glycoprotein, while amlodipine, a calcium ion antagonist, can inhibit P-glycoprotein activity. This reduces the excretion of atorvastatin in the intestine and liver, increases the bioavailability of atorvastatin, and enhances its lipid-regulating efficacy. (2) Influence on cytochrome P450 enzymes: Atorvastatin is primarily metabolized by CYP3A4 enzymes, and amlodipine, as a CYP3A4 enzyme inhibitor, can reduce the metabolism rate of atorvastatin, prolong its duration of action, and enhance its lipid-regulating effect [12]. (3) Influence on gene expression: Amlodipine can induce the expression of LDL receptor genes, increase the number of LDL receptors on hepatocyte membranes, enhance the clearance

ability of LDL-C, and simultaneously inhibit the expression of HMG-CoA reductase genes, reducing cholesterol synthesis, thereby affecting lipid metabolism from multiple perspectives.

3.3. Safety evaluation

Amlodipine and atorvastatin calcium tablets are relatively safe in clinical applications. Numerous clinical trials have demonstrated that the combined use of these drugs has a similar incidence of adverse reactions compared to their use as single agents, with most reactions being mild to moderate and capable of resolving spontaneously or with symptomatic treatment.

Common adverse reactions primarily include headache, facial flushing, lower extremity edema, and gastrointestinal discomfort. The incidence of these reactions increases slightly with higher dosages, but remains relatively low overall. In a long-term follow-up study by Lu Xiangyang involving 2000 patients, the incidence of lower extremity edema in the combination therapy group was 8.5%, which was not significantly different from the 9.2% incidence in the amlodipine monotherapy group ($P > 0.05$) [13]. Atorvastatin monotherapy may cause a slight increase in transaminase levels, but combination therapy does not significantly increase this risk. The aforementioned long-term follow-up study showed that the incidence of elevated alanine aminotransferase (ALT) in the combination therapy group was only 1.2%, which was similar to the monotherapy group. When statin drugs are used alone or in combination with other drugs, a very small number of patients may experience myalgia, myositis, or even rhabdomyolysis.

However, the combination of amlodipine and atorvastatin does not significantly increase the risk of myopathy. A meta-analysis showed no significant difference in the incidence of myopathy between the combination therapy group and the monotherapy group (OR=1.05, 95% CI: 0.87–1.26) [14]. Long-term use of statin drugs may slightly increase the probability of developing diabetes, but this risk is far outweighed by the significant benefits of cardiovascular protection. The addition of amlodipine does not alter this risk profile, and the incidence of new-onset diabetes in the combination therapy group is similar to that in the monotherapy group.

3.4. Application in special populations

Amlodipine and atorvastatin calcium tablets have demonstrated good efficacy and safety in special populations such as the elderly, diabetics, and patients with renal insufficiency. In elderly patients with hypertension and coronary heart disease, combination therapy can significantly reduce the risk of cardiovascular events, and the incidence of adverse reactions is not significantly different from that of younger patients. For diabetic patients, combination therapy not only effectively controls blood pressure and blood lipids but also improves insulin resistance, with no adverse effects on blood glucose metabolism. In patients with renal insufficiency, amlodipine is primarily metabolized through the liver, and atorvastatin dose adjustment is relatively simple, making combination therapy a safe and effective treatment option.

4. The impact of amlodipine and atorvastatin calcium tablets on endpoint events

Liu Bing studied and analyzed the application of amlodipine and atorvastatin calcium tablets in patients with hypertension and coronary heart disease [15]. The study included 560 patients aged between 50–85 years old, diagnosed with hypertension and stable coronary heart disease. They were randomly assigned to the amlodipine

and atorvastatin calcium tablet group (amlodipine 5–10 mg/d combined with atorvastatin 20–40 mg/d) or the conventional treatment group (receiving only antihypertensive drugs and basic treatment for coronary heart disease). After a 3-year follow-up observation, the results showed that the amlodipine and atorvastatin calcium tablet group had a significantly lower incidence of major cardiovascular endpoint events (including myocardial infarction, rehospitalization for unstable angina, cardiac death, and stroke) compared to the conventional treatment group, with a relative risk reduction of 23% (P=0.018). In terms of myocardial infarction, the incidence in the amlodipine and atorvastatin calcium tablet group was reduced by 28% compared to the control group (P=0.032), demonstrating the significant advantage of this combination therapy in preventing acute coronary events.

Additionally, according to the research conducted by Leng Defeng et al., in a 5-year follow-up study of hypertensive patients taking amlodipine and atorvastatin calcium tablets, there was a significant optimization in the estimated 10-year cardiovascular risk based on the Framingham Risk Scoring System [16]. The risk decreased significantly from a baseline level of 18.5% to 10.2% ($P < 0.001$). This clinical benefit was not a short-term effect but gradually emerged 24 months after the initiation of treatment and showed a continuously increasing dose-dependent characteristic with prolonged medication use. This evidence not only clearly demonstrates that amlodipine and atorvastatin calcium tablets can serve as an effective primary prevention strategy for cardiovascular disease but also suggests that immediate initiation of continuous treatment has an irreplaceable clinical value for improving the long-term prognosis of patients with coronary heart disease.

5. Conclusion

In summary, amlodipine and atorvastatin calcium tablets exhibit significant synergistic effects in lowering blood pressure and regulating lipids in the treatment of hypertension with coronary heart disease through their unique pharmacological mechanisms of action, while also demonstrating good safety and tolerability. This compound preparation not only effectively controls blood pressure and lipid levels but also improves endothelial function, stabilizes atherosclerotic plaques, and reduces the risk of cardiovascular events, providing patients with a more comprehensive and effective treatment plan.

Disclosure statement

The authors declare no conflict of interest.

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