Evolocumab found to be safe and effective at reducing cholesterol in Chinese patients with type 2 diabetes

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Video Abstract

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Abstract

According to a new study, the cholesterol-reducing drug evolocumab plus a moderate-intensity statin dose was effective in Chinese patients with both type 2 diabetes and hyperlipidemia or mixed dyslipidemia. China has the highest diabetes burden of any country in the world. And as is the case for Western populations, diabetes is a major risk factor for cardiovascular disease in Asian adults. The primary target for treating such patients is reducing low-density lipoprotein, or LDL, cholesterol. While statin therapy is recommended globally, research suggests that statin-related adverse reactions occur at higher rates among Chinese patients. The inability to achieve the recommended LDL levels in Chinese patients might therefore be related to statin intolerance or underuse of statins due to the risk of adverse events. Now, a new study suggests that the drug evolocumab is safe and effective at reducing cholesterol for the high-risk group of Chinese patients with both type 2 diabetes and hyperlipidemia or mixed dyslipidemia. The double-blind, phase 3 trial was conducted in patients from 10 different countries over a treatment period of 12 weeks. Nearly half of the approximately 980 participants were from China. Patients were randomized to one of four subcutaneous treatments: 140 mg of evolocumab every 2 weeks, 420 mg of evolocumab monthly, or placebo at either of those frequencies. All patients received 20 mg of atorvastatin oral daily. Compared with baseline levels, evolocumab at either dose plus atorvastatin significantly reduced mean LDL cholesterol by 65 to 73%—a reduction of 75 to 85% compared to atorvastatin plus placebo. And more than 90% of Chinese patients who received evolocumab with background atorvastatin were able to achieve LDL cholesterol levels below 1.8 mmol/L, or 70 mg/dL. Additionally, the drug was well tolerated by patients, with most serious adverse events not considered related to the treatment. One important limitation of the study is the use of a low-intensity statin therapy regimen, 20 milligrams of atorvastatin, which is common in China but more conservative than in other regions. Another is the limited study duration and sample size. Despite these limitations, the results are consistent with those of evolocumab studies with longer durations and larger sample sizes. Altogether, they suggest that evolocumab is safe and well-tolerated among Chinese patients at high risk of developing cardiovascular disease, without affecting measures of glycemic control.