

Trial shows drug effective in nearly 80% of patients with hypertrophic cardiomyopathy

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Findings from a Cleveland Clinic-led clinical trial showed that the use of an experimental drug in severely symptomatic, hypertrophic cardiomyopathy patients significantly reduced the need for invasive

procedures.

The trial evaluated whether the drug, mavacamten, could be used as an alternative to [heart surgery](#) or alcohol septal ablation, therapies used to reduce thickening of the septum, the wall separating the right and left sides of the heart.

Findings from the "Valor-HCM Study: Myosin Inhibition as an Alternative to Surgical Myectomy or Alcohol Septal Ablation in Obstructive Hypertrophic Cardiomyopathy" were presented today during a Late Breaking Science Session at the *American College of Cardiology's* 71st Annual Scientific Session in Washington D.C.

Hypertrophic [cardiomyopathy](#) is a complex type of heart disease that causes thickening of the heart muscle, left ventricular stiffness and mitral valve changes. It affects an estimated 600,000 to 1.5 million Americans, or one in 500 people, but many of those patients go undiagnosed until the disease has progressed.

The cause of [hypertrophic cardiomyopathy](#) can be unknown or attributed to genetics, [high blood pressure](#) or aging, making it difficult to identify a high-risk population. Symptoms include chest pain, palpitations, shortness of breath, fatigue and syncope (fainting). Most people with hypertrophic cardiomyopathy have a low risk for sudden cardiac death. However, the condition is the most common cause of sudden cardiac death in people under age 30.

Medications such as beta-blockers, [calcium channel blockers](#) and antiarrhythmics are often prescribed to treat the symptoms of hypertrophic cardiomyopathy and prevent further complications. Patients with persistent symptoms may also undergo a septal myectomy, in which a surgeon removes a small amount of the thickened septal wall to widen the outflow tract (the path the blood takes) from the left

ventricle to the aorta. Another option is alcohol ablation, a cardiac catheterization procedure where a tiny amount of pure alcohol is injected into the septum, causing it to shrink back to a more normal size and widening the passage for [blood flow](#).

The Valor HCM phase 3 trial enrolled 112 symptomatic hypertrophic cardiomyopathy patients at 19 sites across the United States. All of the patients were referred to have surgical myectomy or alcohol ablation. They were randomized to an oral myosin inhibitor, mavacamten (5 to 15 mg daily) or placebo. Mavacamten works by reducing excessive contraction of the heart muscle, making it work more efficiently. It also reduces the stiffness of the [heart](#) muscle.

After 16 weeks, 43 of the 56 placebo-treated patients (76.8%) continued to meet guideline criteria for surgery or elected to undergo surgery compared with 10/56 (17.9%) mavacamten-treated patients. The study demonstrated significant reduction in left ventricular outflow tract pressure gradient in mavacamten-treated patients, along with improvements in quality-of-life measures. The long-term safety and outcomes of mavacamten will continue to be studied.

"These results could give what can be a very sick patient population a non-invasive therapy alternative," said Milind Desai, M.D., MBA, director of the Hypertrophic Cardiomyopathy Center and director of clinical operations in Cleveland Clinic's Heart Vascular & Thoracic Institute, and principal investigator of the trial. "There are few high-volume centers performing septal myectomy or alcohol ablations which may limit a patient's access to optimal results and patients may need repeat interventions. That is why it is vital to explore non-invasive options for these patients."

Steven E. Nissen, M.D., Chief Academic Officer of the Heart, Vascular & Thoracic Institute at Cleveland Clinic and the trials' senior author,

said, "The vast majority of the patients, even those in the [placebo group](#), chose to continue the drug after 16 weeks, suggesting a strong desire for this type of treatment option."

Provided by Cleveland Clinic

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