Clot-busting drug benefits intermediate-risk patients with pulmonary embolism

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The clot-busting drug tenecteplase prevents death or circulatory collapse in a subgroup of patients with a blood clot in the lungs and appears to be especially useful in patients younger than 75, according to research presented today at the American College of Cardiology's 62nd Annual Scientific Session.

Pulmonary embolism occurs when part of a blood clot in a vein breaks off and travels to the lungs. It is fatal about 10 percent of the time, killing between 60,000 and 100,000 Americans each year. The most common cause of death is progressive failure of the heart's right ventricle, which sends blood to the lungs to pick up oxygen. Right ventricle failure leads to hemodynamic collapse, which means blood no longer circulates properly. Blood pressure suddenly drops or disappears altogether, and the risk of death is high.

Heparin is the current standard therapy for most patients, including a subgroup of patients that is said to have submassive or intermediate-risk pulmonary embolism: that is, they have normal blood pressure but dysfunction of the heart's right ventricle, which can be seen on an echocardiogram or CT scan. Blood tests also can help to identify these patients.

The Pulmonary Embolism Thrombolysis Study (PEITHO) tested the addition of a clot-busting (thrombolytic) drug, tenecteplase, to standard treatment with heparin. Tenecteplase dissolves blood clots rapidly but carries a known risk of bleeding in the brain. The double-blind study included 1,006 patients in 13 countries. They were randomized to heparin plus placebo or heparin plus tenecteplase.

The combined primary endpoint was death from any cause or circulatory system (hemodynamic) collapse after seven days. Hemodynamic collapse was defined as at least one of the following: needing CPR due to a loss of blood pressure; systolic blood pressure of less than 90 mm Hg or a drop of more than 40 mm Hg for at least 15 minutes; or the need for drugs called catecholamines, which boost circulation.

The primary endpoint was reduced by 56 percent in patients treated with tenecteplase and heparin, compared with the heparin-only group.

"In patients with intermediate-risk pulmonary embolism, thrombolytic treatment significantly reduced the primary endpoint," said Stavros Konstantinides, MD, PhD, professor for clinical trials at the Center for Thrombosis and Hemostasis, University of Mainz, Germany, and the study's co-principal investigator. "Overall, the study strongly supports the concept that risk stratification of patients makes sense and that these patients need something to prevent deterioration."

There was a significant reduction in hemodynamic collapse: it occurred in 1.6 percent of patients receiving tenecteplase versus 5 percent receiving placebo. Actual death rates were low and not significantly different between groups: 1.2 percent in the tenecteplase group versus 1.8 percent in the placebo group.

Major bleeding was significantly increased with tenecteplase: 6.3 vs. 1.5 percent in the placebo group. There were 10 hemorrhagic strokes in the tenecteplase group and one in the placebo group.

"This is more or less the rate that we have seen in previous thrombolytic trials," Dr. Konstantinides said. "Patients who were less than 75 years old had most of the benefit and a tendency toward fewer hemorrhagic strokes. Our future priorities are now to refine our risk stratification concept even further, to better identify those patients who will benefit most with less risk of bleeding. Also, the dose of the drug that we used could be lowered in older patients, and alternative methods of delivering

thrombolytics could be explored."

More information: Dr. Konstantinides will present "Single-bolus Tenecteplase Plus Heparin Compared With Heparin Alone for Normotensive Patients With Acute Pulmonary Embolism Who Have Evidence of Right Ventricular Dysfunction and Myocardial Injury: The Pulmonary Embolism Thrombolysis (PEITHO) Study" on Monday, March 11, at 11:45 a.m., in Moscone Center, South, Esplanade Ballroom.

Provided by American College of Cardiology

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