

Ticagrelor alone, without aspirin, shows benefit in patients with diabetes

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Patients with diabetes who stopped taking aspirin three months after the insertion of a coronary stent and then took the anti-platelet medication ticagrelor alone for a year had fewer episodes of bleeding and no increase in heart attacks, stroke or other adverse events caused by blockages in the arteries, compared with patients who took both aspirin and ticagrelor for a year. The research was presented at the American College of Cardiology's Annual Scientific Session Together with World Congress of Cardiology (ACC.20/WCC).

"In patients with diabetes, treatment with ticagrelor alone significantly reduced clinically relevant bleeding compared with ticagrelor plus aspirin, without increasing the risk for additional [heart](#) attacks, strokes or death," said Dominick J. Angiolillo, MD, Ph.D., professor of medicine at the University of Florida College of Medicine in Jacksonville, Florida and first author of the study. The present study was a planned analysis of the TWILIGHT trial, he added, the results of which were published in the New England Journal of Medicine in November 2019. "These findings are consistent with the overall results of the TWILIGHT trial and were seen across all types of diabetes patients, irrespective of their clinical presentation and the treatment they were receiving for their diabetes."

Most heart attacks and strokes are caused by a blood clot in an artery that's been narrowed by a buildup of fatty deposits or plaque. Blood cells known as platelets help the blood to clot, and both ticagrelor and aspirin stop platelets from forming a clot that can block blood flow. Aspirin,

however, also heightens the risk of bleeding, particularly in the gastrointestinal tract. The TWILIGHT trial tested whether ticagrelor alone or ticagrelor plus aspirin more effectively reduced bleeding without increasing the risk for heart attacks, stroke, death or other adverse events caused by arterial blockages in patients who had received at least one stent and were at high risk for adverse events.

Stenting, also known as [coronary angioplasty](#) or percutaneous coronary intervention, is a minimally invasive procedure in which a flexible tube (catheter) is threaded through an artery under local anesthesia. At the site of the blockage, a tiny balloon at the tip of the catheter is inflated to unblock the artery and a stent, a tiny mesh tube coated with medication, is inserted to prop it open.

The TWILIGHT trial enrolled 9,006 patients at 187 medical centers in 11 countries, including the United States, Canada, the United Kingdom, India, Israel, China and five European countries, who had received at least one stent and were at high risk for bleeding or another arterial blockage. Results showed that ticagrelor alone reduced clinically relevant bleeding more than ticagrelor plus aspirin without increasing the risk of death, [heart attack](#) or stroke.

The current study looked just at the subgroup of randomly assigned patients in the TWILIGHT trial who had diabetes (2,620 patients or 37% of all the randomly assigned patients). In this subgroup, patients who received ticagrelor plus a placebo were less likely to have clinically significant bleeding compared with those who received ticagrelor plus aspirin, 4.5% vs. 6.7%, respectively.

On the secondary endpoint, 4.6% of the patients treated with ticagrelor plus a placebo died or had a heart attack or stroke, compared with 5.9% of those who received ticagrelor plus aspirin. Although this reduction was not statistically significant, it offered some reassurance that patients

were not harmed by the elimination of aspirin, Angiolillo said.

"Our primary goal was to ensure that dropping [aspirin](#) would reduce bleeding without increasing deaths, heart attacks or strokes," he said. "That goal was met."

The findings have some limitations. Patients' treating physicians made the diagnosis of diabetes, which was not confirmed by laboratory testing. Also, patients with the most severe type of heart attack, known as an ST-elevation myocardial infarction (STEMI), were excluded from the trial, so the results do not apply to them. In a STEMI heart attack, an artery to the heart is generally completely blocked, causing the death of some heart tissue. The patients enrolled in TWILIGHT had had either a non-ST-elevation [myocardial infarction](#) (NSTEMI) heart attack, in which a sudden arterial blockage due to [blood clots](#) partially stops blood flow to the heart, or stable angina, in which blood flow to the heart is interrupted by chronic [arterial blockages](#).

Further research is needed to identify the best treatment for patients like those treated in the TWILIGHT trial after they have completed a year on ticagrelor monotherapy, Angiolillo said.

"What should we do after one year? Should [patients](#) continue on a lower dose of ticagrelor?" he said. "This is currently an unanswered question."

Provided by American College of Cardiology

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