

## Dropping aspirin for ticagrelor alone better in complex heart disease

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Patients with complex heart disease who stopped taking aspirin three months after the insertion of one or more coronary stents 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 over the same period. The research, a subanalysis of the TWILIGHT trial, was presented at the American College of Cardiology's Annual Scientific Session Together with World Congress of Cardiology (ACC.20/WCC).

"Among patients with complex coronary artery disease who completed three months of ticagrelor plus <u>aspirin</u>, ticagrelor monotherapy significantly reduced the incidence of clinically relevant bleeding without increasing the risk of additional heart attacks, strokes or death, compared with those who received ticagrelor plus aspirin," said George Dangas, MD, Ph.D., professor of medicine, cardiology and surgery at Mount Sinai School of Medicine in New York and lead author of the study.

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. 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 who had complex coronary artery disease (CAD; 2,342 patients or 33% of all the randomly assigned patients) and were at high risk for adverse events caused by arterial blockages. Patients were deemed to have complex CAD if they had blockages in three or more arteries or other complications that resulted in them receiving multiple stents. 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, 4.2% vs. 7.7%, respectively. Severe or fatal bleeding occurred in 1.1% of patients receiving ticagrelor monotherapy compared with 2.6% of those treated with ticagrelor plus aspirin.

"In this patient subset with complex heart disease, we found that it was



okay to withdraw aspirin and that doing so reduced bleeding without increasing heart attacks or other complications," Dangas said.

Rates of <u>stent thrombosis</u> (a blood clot inside a stent) were similar in the two groups of patients, Dangas said, which indicates that stopping aspirin did not cause an increase in this complication. While stent thrombosis is rare, he said, it is a complication that cardiologists worry about and do everything they can to avoid.

"It is reassuring that we saw no difference between the groups for this complication," he said.

A subanalysis of TWILIGHT patients with a type of heart disease known as acute coronary syndrome (ACS), presented at the American Heart Association annual scientific meeting in November 2019, also found that ticagrelor monotherapy lowered bleeding risk without increasing heart attacks, strokes or death, said Dangas. The current findings for patients with complex heart disease are consistent with those for patients with ACS, he said, indicating that in both subgroups of patients it is safe to withdraw aspirin after three months.

A limitation of the study is that patients with the most severe type of heart attack, known as ST-elevation <u>myocardial infarction</u> (STEMI), were excluded from the TWILIGHT 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 <u>patients</u> enrolled in TWILIGHT had either a non-ST-elevation myocardial infarction (NSTEMI) <u>heart attack</u>, in which a sudden arterial blockage due to <u>blood clots</u> more commonly partially stops blood flow to the heart, unstable angina or stable angina, in which blood flow to the <u>heart</u> is interrupted by chronic arterial blockages.



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