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Heart attack risk increases with six-month dual antiplatelet therapy

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The combined rate of death from any cause, heart attack or stroke within 18 months was not significantly different in patients with acute coronary syndrome (ACS) who were randomly assigned to receive dual antiplatelet therapy (DAPT) for either six months or at least 12 months after receiving a drug-eluting stent. Patients who were given DAPT for only six months, however, had more than double the risk of a heart attack compared with those treated for at least 12 months, according to research presented at the American College of Cardiology's 67th Annual Scientific Session.

"Based on our findings, we can't say that short-term DAPT is safe in patients with ACS who have received drug-eluting stents," said Hyeon Cheol Gwon, MD, a professor in the Division of Cardiology at Sungkyunkwan University, director of the cardiac center at Samsung Medical Center in Seoul, South Korea, and principal investigator of the study. "We conclude that current guidelines that recommend prolonged DAPT in patients with ACS who are not at excessive risk for bleeding should continue to be followed."

ACS occurs when blood flow to the heart is suddenly blocked. It may take the form of a heart attack or unstable angina, chest pain that may signal an imminent heart attack. Patients who have had one episode of ACS are at elevated risk for another. ACS is often treated by inserting a small metal tube, or stent, into a blocked artery to keep the artery open, a procedure known as an angioplasty. A drug-eluting stent is a stent that has been coated with a drug to prevent scar tissue from forming inside

the artery.

Current guidelines published by the American College of Cardiology and the American Heart Association recommend that ACS patients not at excessive risk for bleeding should be treated with DAPT— aspirin plus clopidogrel or a similar drug such as ticagrelor—for at least 12 months after the implantation of a drug-eluting stent.

However, there is limited evidence that 12 months or more is the optimal duration for DAPT, Gwon said. Two recently reported studies suggested that six months of DAPT might offer similar benefits in terms of reducing patients' risk for death, heart attack or stroke, bleeding or other adverse events. These studies, however, had too few participants to provide definitive answers, he said.

"This is the largest trial to address the optimal duration of DAPT in patients with ACS," Gwon said.

The SMART-DATE trial enrolled a total of 2,712 Korean patients with ACS who were undergoing angioplasty. Their median age was 63 years, and 75 percent were male. Patients were randomly assigned to receive either DAPT for at least 12 months (DAPT-12) or DAPT for six months followed by aspirin alone for at least another six months (DAPT-6). The primary endpoint was the combined rate of death from any cause, heart attack or stroke within 18 months after stent insertion.

At 18 months, 63 patients (4.7 percent) in the DAPT-6 group and 56 patients (4.2 percent) in the DAPT-12 group had experienced at least one of the primary endpoint events. Thus, over the entire 18-month follow-up period, DAPT-6 was significantly not worse (or non-inferior) than DAPT-12, Gwon said. Rates of death from any cause were not significantly different in the two groups (2.6 percent in the DAPT-6 group vs 2.9 percent in the DAPT-12 group).

However, the risk of heart attack was 2.4-fold higher in the DAPT-6 group, with heart attacks occurring in 1.8 percent of DAPT-6 patients vs. 0.8 percent of DAPT-12 patients. Moreover, during the period between six and 18 months after stent insertion when patients in the DAPT-6 group were being treated with aspirin only, there was a 5.1-fold risk of having a heart attack in DAPT-6 patients compared with DAPT-12 patients. During this period, patients in the DAPT-6 group also had a 69 percent higher risk of dying from any cause or having a heart attack or stroke.

Limitations of the study, Gwon said, include the absence of blinding—that is, both patients and doctors knew whether a patient was in the DAPT-6 or the DAPT-12 group—and the absence of a group that was randomly assigned to receive a placebo. However, study statisticians and those whose role was to assess outcomes worked independently from those overseeing the trial, he said.

Patients in the trial will be followed for an additional 18 months, for a total of three years of follow-up, Gwon said.

This study was simultaneously published online in the *Lancet* at the time of presentation.

Provided by American College of Cardiology

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