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Effect of Ticagrelor Monotherapy vs Ticagrelor with Aspirin on Major Bleeding and Cardiovascular Events in Patients with Acute Coronary Syndrome:

The TICO Randomized Clinical Trial

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Abstract

Importance:

Discontinuing aspirin after short-term dual antiplatelet therapy (DAPT) was evaluated as a bleeding reduction strategy. However, the strategy of ticagrelor monotherapy has not been exclusively evaluated in patients with acute coronary syndromes (ACS).

Objective:

To determine whether switching to ticagrelor monotherapy after 3 months of DAPT reduces net adverse clinical events compared with ticagrelor-based 12-month DAPT in patients with ACS treated with drug-eluting stents.

Design, setting, and participants:

A randomized multicenter trial was conducted in 3056 patients with ACS treated with drug-eluting stents between August 2015 and October 2018 at 38 centers in South Korea. Follow-up was completed in October 2019.

Interventions:

Patients were randomized to receive ticagrelor monotherapy (90 mg twice daily) after 3-month DAPT (n = 1527) or ticagrelor-based 12-month DAPT (n = 1529).

Main outcomes and measures: The primary outcome was a 1-year net adverse clinical event, defined as a composite of major bleeding and adverse cardiac and cerebrovascular events (death, myocardial infarction, stent thrombosis, stroke, or target-vessel revascularization). Prespecified secondary outcomes included major bleeding and major adverse cardiac and cerebrovascular events.

Results:

Among 3056 patients who were randomized (mean age, 61 years; 628 women [20%]; 36% ST-elevation myocardial infarction), 2978 patients (97.4%) completed the trial. The primary outcome occurred in 59 patients (3.9%) receiving ticagrelor monotherapy after 3-month DAPT and in 89 patients (5.9%) receiving ticagrelor-based 12-month DAPT (absolute difference, -1.98% [95% CI, -3.50% to -0.45%]; hazard ratio [HR], 0.66 [95% CI, 0.48 to 0.92]; P = .01). Of 10 prespecified secondary outcomes, 8 showed no significant difference. Major bleeding occurred

in 1.7% of patients with ticagrelor monotherapy after 3-month DAPT and in 3.0% of patients with ticagrelor-based 12-month DAPT (HR, 0.56 [95% CI, 0.34 to 0.91]; P = .02). The incidence of major adverse cardiac and cerebrovascular events was not significantly different between the ticagrelor monotherapy after 3-month DAPT group (2.3%) vs the ticagrelor-based 12-month DAPT group (3.4%) (HR, 0.69 [95% CI, 0.45 to 1.06]; P = .09).

Conclusions and relevance:

Among patients with acute coronary syndromes treated with drug-eluting stents, ticagrelor monotherapy after 3 months of dual antiplatelet therapy, compared with ticagrelor-based 12-month dual antiplatelet therapy, resulted in a modest but statistically significant reduction in a composite outcome of major bleeding and cardiovascular events at 1 year. The study population and lower than expected event rates should be considered in interpreting the trial.

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Randomized Controlled Trial

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