Original Investigation

ONLINE FIRST

April 17, 2024

Extended Clopidogrel Monotherapy vs DAPT in Patients With Acute Coronary Syndromes at High Ischemic and Bleeding Risk

The OPT-BIRISK Randomized Clinical Trial

Yi Li, MD[1]; Jing Li, MD[1]; Bin Wang, MD[1]; et al

» Author Affiliations

JAMA Cardiol. Published online April 17, 2024. doi:10.1001/jamacardio.2024.0534

Visual Abstract

Editorial Comment

Key Points

Question What is the optimal antiplatelet regimen in patients with acute coronary syndromes (ACS) undergoing percutaneous coronary interventions (PCIs) who are at both high bleeding and ischemic risks (birisk)?

Findings In this double-blind, randomized clinical trial including 7758 PCI-treated birisk patients with ACS who completed 9 to 12 months of dual antiplatelet therapy (DAPT) after PCI, clopidogrel monotherapy for an additional 9 months resulted in a 25% reduction in the risk of Bleeding Academic Research Consortium types 2, 3, or 5 bleeding compared with clopidogrel plus aspirin.

Meaning Among birisk patients with ACS who completed 9 to 12 months of DAPT after PCI, subsequent treatment with clopidogrel was superior to continuing DAPT with aspirin and clopidogrel in reducing clinically relevant bleeding.

Abstract

Importance Purinergic receptor P2Y12 (P2Y12) inhibitor monotherapy after a certain period of dual antiplatelet therapy (DAPT) may be an attractive option of maintenance antiplatelet treatment for pa-

tients undergoing percutaneous coronary intervention (PCI) who are at both high bleeding and ischemic risk (birisk).

Objective To determine if extended P2Y12 inhibitor monotherapy with clopidogrel is superior to ongoing DAPT with aspirin and clopidogrel after 9 to 12 months of DAPT after PCI in birisk patients with acute coronary syndromes (ACS).

Design, Setting, and Participants This was a multicenter, double-blind, placebo-controlled, randomized clinical trial including birisk patients with ACS who had completed 9 to 12 months of DAPT after drug-eluting stent implantation and were free from adverse events for at least 6 months at 101 China centers between February 2018 and December 2020. Study data were analyzed from April 2023 to May 2023.

Interventions Patients were randomized either to clopidogrel plus placebo or clopidogrel plus aspirin for an additional 9 months.

Main Outcomes and Measures The primary end point was Bleeding Academic Research Consortium (BARC) types 2, 3, or 5 bleeding 9 months after randomization. The key secondary end point was major adverse cardiac and cerebral events (MACCE; the composite of all-cause death, myocardial infarction, stroke or clinically driven revascularization). The primary end point was tested for superiority, and the MACCE end point was tested for sequential noninferiority and superiority.

Results A total of 7758 patients (mean [SD] age, 64.8 [9.0] years; 4575 male [59.0%]) were included in this study. The primary end point of BARC types 2, 3, or 5 bleeding occurred in 95 of 3873 patients (2.5%) assigned to clopidogrel plus placebo and 127 of 3885 patients (3.3%) assigned to clopidogrel plus aspirin (hazard ratio [HR], 0.75; 95% CI, 0.57-0.97; difference, −0.8%; 95% CI, −1.6% to −0.1%; P = .03). The incidence of MACCE was 2.6% (101 of 3873 patients) in the clopidogrel plus placebo group and 3.5% (136 of 3885 patients) in the clopidogrel plus aspirin group (HR, 0.74; 95% CI, 0.57-0.96; difference, −0.9%; 95% CI, −1.7% to −0.1%; P < .001 for noninferiority; P = .02 for superiority).

Conclusions and Relevance Among birisk patients with ACS who completed 9 to 12 months of DAPT after drug-eluting stent implantation and were free from adverse events for at least 6 months before randomization, an extended 9-month clopidogrel monotherapy regimen was superior to continuing DAPT with clopidogrel in reducing clinically relevant bleeding without increasing ischemic events.

Trial Registration ClinicalTrials.gov Identifier: NCT03431142

Invited Commentary
Clopidogrel Monotherapy for Double-Risk Acute Coronary Syndrome
JAMA Cardiology

Read More About

Acute Coronary Syndromes | Cardiology | Ischemic Heart Disease | Clinical Pharmacy and Pharmacology | Emergency Medicine | Bleeding and Transfusion | Percutaneous Coronary Intervention

Trending

Research

Dual Antiplatelet Therapy De-Escalation After Myocardial Infarction With High Ischemic Risk

December 20, 2023

Select Your Interests

Others Also Liked

De-escalation of dual antiplatelet therapy for patients with acute coronary syndrome after percutaneous coronary intervention: a systematic review and network meta-analysis

Ovidio De Filippo et al., Evid Based Med, 2024

Real-world bleeding in patients with acute coronary syndrome (ACS) undergoing percutaneous coronary intervention (PCI) and prescribed different combinations of dual antiplatelet therapy (DAPT) in England: a population-based cohort study emulating a 'target trial'

Maria Pufulete et al., Open Heart, 2022

Precision antiplatelet therapy for the prevention of ischaemic stroke

David Wang, Stroke and Vascular Neurology, 2022

Trending

Nurse Practitioner Care and End-of-Life Outcomes for Nursing Home Residents With Dementia

JAMA Health Forum | *Research* | *May 10, 2024*

Anticoagulation for Atrial Cardiopathy in Cryptogenic Stroke

JAMA | *Opinion* |

February 7, 2024

Potentially Avoidable Hospitalizations Among Historically Marginalized Nursing Home Residents

JAMA Network Open | *Research* | *May 2, 2024*