

Title: STOPDAPT-3: Prasugrel Monotherapy Without Aspirin in Acute Coronary Syndrome Patients

Participants: Dr Masahiro Natsuaki

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Dr Masahiro Natsuaki

"My name is Masashiro Natsaki from Saga University, Japan. I will present the results of STOPDAPT3 trial comparing the conventional DAPT strategy versus no aspirin strategy in patients with PCI.

Background of the Trial

DAPT is the standard strategy in patients undergoing PCI to prevent ischemic cardiovascular events, stent thrombosis in particular, at least one month after PCI. However, the incidence of major bleeding still remains high in patients with acute pulmonary syndrome or high bleeding risk. So in meta-analysis short durations of DAPT followed by a P2Y12 inhibitor monotherapy demonstrated 40% risk reduction in major bleeding events without increasing cardiovascular events. So the hypothesis of this study is that removing aspirin from DAPT regimen could reduce major bleeding events without increasing cardiovascular events in patients with ACS or HBR.

Study Design, Patient Population and Outcome Measures

66,000 patients with ACS or HBR undergoing PCI were randomly assigned to no aspirin group and DAPT group in one-to-one fashion.

Key Findings

The primary endpoint is bleeding and cardiovascular events. Regarding the Co-primary bleeding endpoint, cumulative one-month incidence was 1.5% in the no aspirin group and 4.7% in the DAPT group. Hazard ratio was 0.95, and p-value was 0.66, so no aspirin group was not superior to the DAPT group. Regarding the co-primary cardiovascular endpoint, evaluating the non-inferiority cumulative one-month incidence was 4.1% in

the no aspirin group and 3.7% in the DAPT group. Hazard ratio was 1.12, and upper 95% confidence interval was less than 1.5. So no aspirin group was non-inferior to the DAPT group. However, the rate of sub-acute, definite or probable stent thrombosis and unplanned coronary revascularization was higher in the no-aspirin group than in the DAPT group.

Applicability to Populations Outside of Japan

We should be careful in adapting this result to the population outside Japan. First, risk profile is different from Japanese and Westerns. Second, we used the low dose prasugrel in this study and this dose is one-third of the global dose of prasugrel. So we should be careful in adapting this result to the population outside Japan.

Take-Home Messages

In summary, aspirin-free strategy compared to the DAPT strategy failed to attest superiority for major bleeding event and was associated with a signal suggesting an excess of coronary events with no aspirin strategy. So DAPT with Aspirin and P2Y12 inhibitor would still remain the standard strategy in patients undergoing PCI at least within one month. Actually, the incidence of major bleeding was unacceptably high in this study, so further trials are needed. Exploring the strategy to reduce major bleeding events early after PCI in patients with ACS or HBR.”