Study reveals best anti-clotting strategy after heart valve intervention

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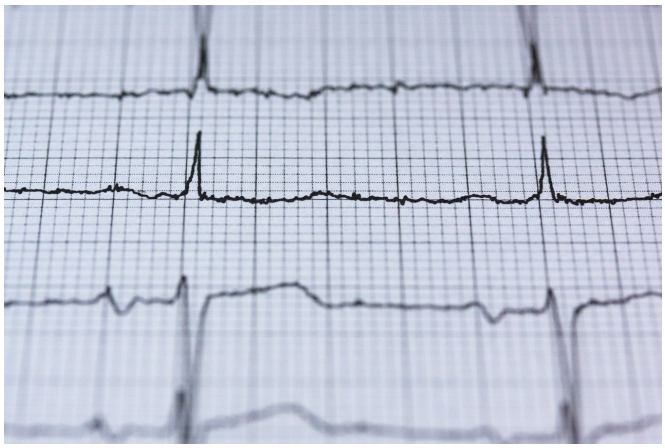

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The POPular TAVI trial has challenged current guideline recommendations on antiplatelet treatment after transcatheter aortic valve implantation (TAVI) in patients not taking oral anticoagulation. The findings are presented in a Hot Line session today at ESC Congress 2020.

"Aspirin alone as compared to aspirin with clopidogrel reduced the bleeding rate significantly, with an absolute reduction of more than 10%," said coordinating investigator Dr. Jorn Brouwer of St. Antonius Hospital, Nieuwegein, the Netherlands. "At the same time, aspirin alone compared to aspirin with clopidogrel did not result in an increase in thromboembolic events as captured in the secondary outcomes."

Aortic stenosis (narrowing of the aortic valve) is the most prevalent heart valve problem in Europe. TAVI is an established treatment for patients with severe symptomatic aortic stenosis. It is estimated that the annual number of procedures in Europe could reach 177,000.

Risks of bleeding and ischaemic complications after TAVI are relatively high and are associated with increased mortality. Guidelines recommend adding clopidogrel to aspirin therapy for three to six months after the procedure to reduce thromboembolic events. However, explorative studies have indicated that the temporary addition of clopidogrel is linked with a higher rate of major bleeding without a decrease in thromboembolic complications.

The POPular TAVI trial investigated the optimal antithrombotic therapy in two cohorts: patients not on oral anticoagulants (cohort A) and patients on chronic oral anticoagulation (cohort B). The results of cohort B have been published. Both cohorts were powered separately for the study outcomes.

The current study (cohort A) excluded patients who had undergone coronary artery stenting using a drug-eluting stent within three months or bare metal stent within one month prior to TAVI. A total of 665 patients without an indication for oral anticoagulation were randomly allocated to aspirin alone (331 patients) or aspirin with three months of clopidogrel (334 patients).

The study tested the hypothesis that aspirin alone compared to aspirin with clopidogrel for three months would reduce the rate of bleeding at one year. The co-primary outcomes were: 1) all bleeding (procedural and non-procedural) and 2) non-procedural bleeding.

In addition, the study tested the hypothesis that aspirin alone would be non-inferior to aspirin with clopidogrel with respect to two secondary outcomes at one year. The first examined bleeding and thromboembolic events and was a composite of cardiovascular mortality, non-procedural bleeding, all-cause stroke, or myocardial infarction. The second examined only thromboembolic events and was a combination of cardiovascular mortality, ischaemic stroke, or myocardial infarction.

Regarding the co-primary outcomes, aspirin alone resulted in a significantly lower incidence of bleeding compared to aspirin with clopidogrel at one year. All bleeding occurred in 50 patients (15.1%) receiving aspirin alone versus 89 (26.6%) patients receiving aspirin with clopidogrel (risk ratio [RR] 0.57; 95% confidence interval [CI] 0.42–0.77; p=0.001). Non-procedural bleeding occurred in 50 patients (15.1%) and 83 (24.9%), respectively (RR 0.61; 95% CI 0.44–0.83; p=0.005).

For the secondary outcome on bleeding and thromboembolic events, aspirin alone was superior compared to combined therapy. The outcome occurred in 76 patients (23.0%) receiving aspirin alone compared to 104 patients (31.1%) receiving aspirin with clopidogrel (difference -8.2 percentage points; 95% CI for noninferiority -14.9 to -1.5; p