Oral anticoagulants should be paused before transcatheter aortic valve implantation, researchers say

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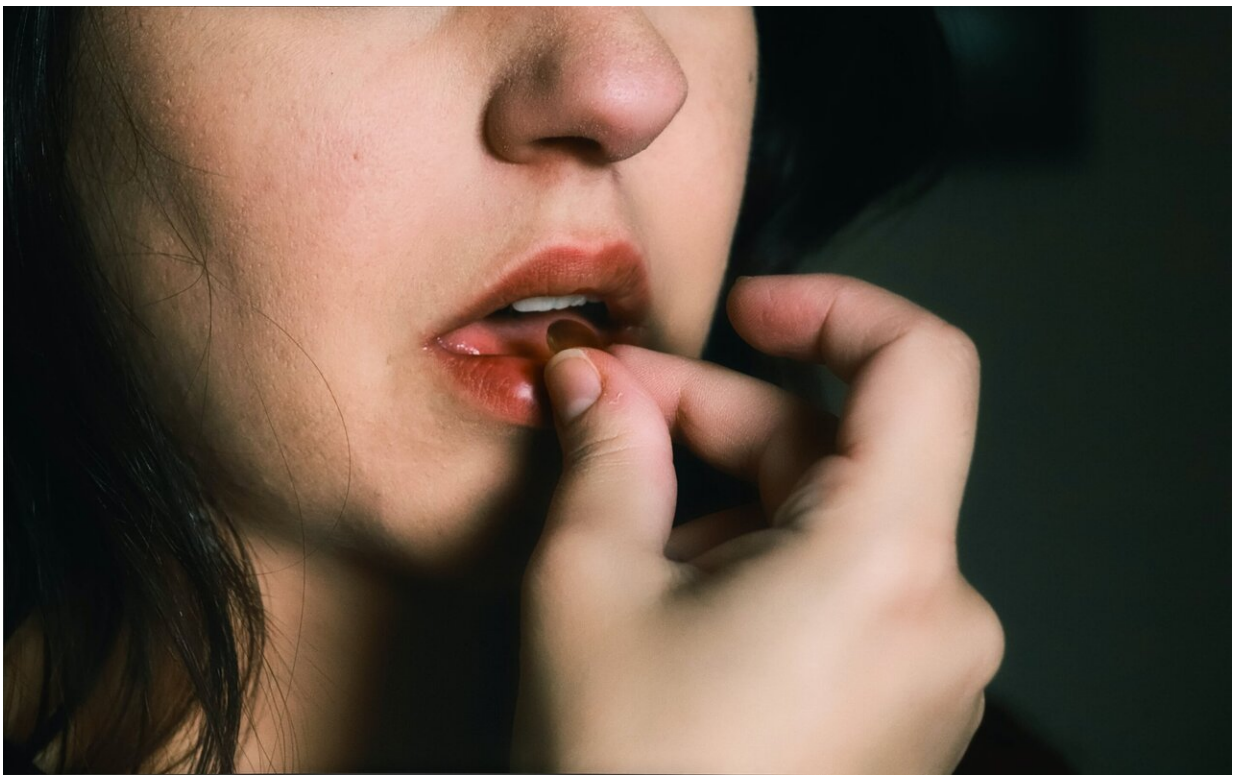

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There was no apparent benefit to continuing oral anticoagulants compared with interruption in patients undergoing transcatheter aortic valve implantation (TAVI), according to late-breaking research

presented in a Hot Line session today at ESC Congress 2024. The study is published in the *New England Journal of Medicine*.

"The optimal strategy for periprocedural anticoagulation management is not well studied in patients undergoing TAVI, who are often relatively elderly and have other health conditions. Whether oral anticoagulants (OACs) should be interrupted in patients with a long-term indication, such as those with atrial fibrillation (AF), was uncertain.

"Observational evidence suggests that continuation may decrease the risk of thromboembolic events, such as stroke, and does not increase the risk of bleeding. The randomized POPular PAUSE TAVI trial investigated continuing vs. interrupting OACs and in fact, we found the opposite: no sign of a reduction in thromboembolic events and more bleeding in the continued OAC group," explained Dr. Dirk Jan van Ginkel, coordinating investigator from the St Antonius Hospital, Nieuwegein, Netherlands.

POPular PAUSE TAVI was an open-label, investigator-initiated, non-inferiority trial in patients on OAC with planned TAVI. Patients at high risk for thromboembolism for whom interruption of OACs was not an option were excluded (i.e. those with a mechanical heart valve prosthesis, intracardiac thrombus, venous thromboembolism within 3 months before TAVI, or transient ischemic attack [TIA] or stroke in patients with AF within 6 months before TAVI).

Participants were randomized in a 1:1 ratio to continue OAC or to stop OAC at least 48 hours before TAVI. The primary endpoint was a composite of cardiovascular mortality, stroke of any cause, myocardial infarction, major vascular complications and major bleeding within 30 days after TAVI. Secondary endpoints included thromboembolic events (such as stroke, TIA, myocardial infarction or systemic embolism) and bleeding complications.

In total, 858 patients were randomized from 22 European sites. The mean age was 81 years and 34.5% were women. The mean CHA2DS2-VASC score was 4.5, indicating moderate-to-high risk of stroke. Over 80% were taking direct oral anticoagulants (81.9%), with the rest taking vitamin K antagonists (18.1%).

The primary composite endpoint occurred in 16.5% of patients in the continued OAC group and 14.8% in the interrupted OAC group (risk difference 1.7%; 95% confidence interval [CI] −3.1 to 6.6; p=0.18 for non-inferiority). The non-inferiority margin (4% for the absolute between-group difference) was not met and therefore the investigators were not able to state that continuation was non-inferior to interruption.

Any bleeding occurred in 31.1% of patients in the continued group and 21.3% in the interrupted group (risk difference 9.8; 95% CI 3.9 to 15.6). There was no difference in thromboembolic events with continued vs. interrupted OACs (8.8% vs. 8.2%; risk difference 0.6; 95% CI −3.1 to 4.4).

"We now have evidence from a randomized trial that continuing OAC provides no apparent benefit in terms of thromboembolic events. Given the higher incidence of bleeding, our data support interrupting OAC in patients undergoing TAVI," concluded Professor Jur ten Berg, principal investigator of the study.

More information: Dirk Jan van Ginkel et al, Continuation versus Interruption of Oral Anticoagulation during TAVI, *New England Journal of Medicine* (2024). DOI: 10.1056/NEJMoa2407794

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