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ANTICOAGULATION THERAPY

Otamixaban fails in NSTE-ACS

The findings of the TAO trial do not support the use of the novel factor Xa inhibitor otamixaban in patients with non-ST-segment elevation acute coronary syndromes (NSTE-ACS) undergoing an invasive procedure. Data from this trial were presented by investigator Philippe Gabriel Steg at the ESC Congress 2013, and simultaneously published in *JAMA*. Otamixaban was found not to be superior to unfractionated heparin (UFH) plus eptifibatide. In addition, "the risk of major or minor bleeding was approximately doubled with otamixaban across all patient subgroups, and a lower dose did not achieve better results," explained Professor Steg.

The TAO trial was conducted at 568 centres in 55 countries, and involved 13,229 patients with NSTE-ACS who were scheduled to undergo angiography or percutaneous coronary intervention (PCI). Participants were randomly allocated to receive a 60 IU/kg bolus of UFH followed by a 12 IU/kg/h infusion (plus eptifibatide if PCI was performed) or one of two otamixaban dosing strategies—0.080 mg/kg bolus followed by either 0.100 mg/kg/h or 0.140 mg/kg/h infusion. The 0.100 mg/kg/h approach was discontinued at the planned interim analysis owing to futility.

No difference was observed in the rate of the primary outcome (composite of cardiovascular death or myocardial infarction at 7 days) between otamixaban and UFH (5.5% vs 5.7%; adjusted relative risk [RR] 0.99, 95% CI 0.85–1.16, $P = 0.93$). The lack of superiority for otamixaban persisted at 30 days (RR 1.02, 95% CI 0.89–1.17, $P > 0.99$). In the safety analysis, otamixaban was associated with an increased rate of bleeding events compared with UFH (3.1% vs 1.5%; RR 2.13, 95% CI 1.63–2.78, $P < 0.001$). Sanofi have now discontinued the otamixaban development programme.

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Original article Steg, P. G. *et al.* Anticoagulation with otamixaban and ischemic events in non-ST-segment elevation acute coronary syndromes: the TAO randomized clinical trial. *JAMA* doi:10.1001/jama.2013.277165