ADONIS-PCI Study overview

Submitted by KarolinaMosakowska on Wed, 08/23/2023 - 13:48

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More than 25% of patients referred for diagnostic coronary angiography and percutaneous coronary intervention (PCI) due to acute coronary syndrome (ACS) suffer from non-valvular atrial fibrillation (AF). In this particular setting, balancing between the prevention of thrombosis and the risk of bleeding remains challenging. Oral anticoagulation (OAC) prevents stroke and systemic embolism, but has not been shown to prevent stent thrombosis (ST). Dual antiplatelet therapy (DAPT) reduces the incidence of recurrent ischemic events and ST, but is less effective in reducing the incidence of cardioembolic stroke associated with AF. A common guideline-supported practice is to combine three drugs (OAC, aspirin and clopidogrel) in a triple therapy, which is associated with high annual risk (up to 25%) of major bleeding. Thus, new therapeutic strategies are urgently needed to maintain the efficacy while improving the safety of treatment in patients with AF and ACS undergoing PCI.

This is a prospective, randomized, open-label, blinded-endpoint, non-inferiority trial. 2230 patients with non-valvular AF that had undergone successful PCI due to an ACS within the previous 72 hours will be randomized in 1:1 ratio to receive one of the two treatments: dual therapy with dabigatran (150 mg twice daily or 110 mg twice daily) and ticagrelor (90 mg twice daily for 1 month, followed by 60 mg twice daily up to 12 months), or standard therapy according to current guidelines triple therapy with dabigatran (150 mg b.i.d. or 110 mg b.i.d.) plus clopidogrel (75 mg o.d.) plus aspirin (75 mg o.d.) followed by double therapy depending on the bleeding and ischaemic risk. Study treatment will be continued for 12 months. The primary study end-point is the first major or clinically relevant non-major bleeding event (per ISTH), in a time-to-event analysis. The main secondary end-point is a composite efficacy end-point of thromboembolic events (myocardial infarction, stroke, or systemic embolism), death, or unplanned revascularization (PCI or coronary artery bypass grafting) at 12 months.

We expect that dual antithrombotic therapy including reduced dose ticagrelor and dabigatran is at least non-inferior regarding bleeding risk and ischaemic protection, compared to the standard triple therapy in patients with AF and after ACS, treated with PCI.