HealthManagement.org
Promoting Management and Leadership

Dual antithrombotic therapy with dabigatran after PCI in atrial fibrillation

Triple antithrombotic therapy with warfarin plus two antiplatelet agents is the standard of care after percutaneous coronary intervention (PCI) for patients with atrial fibrillation (AFib), but this therapy is associated with a high risk of bleeding. Researchers conducted a randomised trial ("RE-DUAL PCI") to compare the use of two regimens of dual antithrombotic therapy that included dabigatran with the use of triple therapy that included warfarin among patients with AFib who had undergone PCI.

The RE-DUAL PCI trial shows that, among patients with AFib who had undergone PCI, the risk of bleeding was lower among those who received dual therapy with dabigatran and a P2Y12 inhibitor than among those who received triple therapy with warfarin, a P2Y12 inhibitor, and aspirin. In addition, dual therapy was noninferior to triple therapy with respect to the rate of thromboembolic events.

In this multicentre trial, researchers randomly assigned 2,725 patients with AFib who had undergone PCI to triple therapy with warfarin plus a P2Y12 inhibitor (clopidogrel or ticagrelor) and aspirin (for 1 to 3 months) (triple-therapy group) or dual therapy with dabigatran (110 mg or 150 mg twice daily) plus a P2Y12 inhibitor (clopidogrel or ticagrelor) and no aspirin (110-mg and 150-mg dual-therapy groups). Outside the United States, elderly patients (≥80 years of age; ≥70 years of age in Japan) were randomly assigned to the 110-mg dual-therapy group or the triple-therapy group.

The study's primary end point was a major or clinically relevant nonmajor bleeding event during follow-up (mean follow-up, 14 months). The trial also tested for the noninferiority of dual therapy with dabigatran (both doses combined) to triple therapy with warfarin with respect to the incidence of a composite efficacy end point of thromboembolic events (myocardial infarction, stroke, or systemic embolism), death, or unplanned revascularisation.

The research team reported these key findings:

- The incidence of the primary end point was 15.4% in the 110-mg dual-therapy group as compared with 26.9% in the triple-therapy group and 20.2% in the 150-mg dual-therapy group as compared with 25.7% in the corresponding triple-therapy group, which did not include elderly patients outside the U.S.
- The incidence of the composite efficacy end point was 13.7% in the two dual-therapy groups combined as compared with 13.4% in the triple-therapy group.
- The rate of serious adverse events did not differ significantly among the groups.

"In the dual-therapy regimens, each of the two doses of dabigatran led to a balance between the risk of bleeding

and the prevention of thromboembolic events, which offers clinicians two additional options for the treatment of patients with varying risks of thromboembolic events and bleeding," the authors write.

In choosing any antithrombotic regimen, it is necessary to balance the risk of bleeding with prevention of thromboembolic events. In recent years, clinical guidelines and consensus statements have evolved and now suggest that dual antithrombotic therapy is an option in this patient population (class IIb recommendation).

"Our findings in evaluating two regimens of dual therapy with dabigatran provide evidence that supports these changes in the guidelines for the treatment of this patient population," the authors add.

Source: The New England Journal of Medicine
Image Credit: Pixabay

Published on : Tue, 24 Oct 2017