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The effect of sex on the efficacy and safety of dabigatran dual therapy in atrial fibrillation after PCI: a subgroup analysis from the RE-DUAL PCI trial

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Background

The RE-DUAL PCI study (NCT02164864) compared dabigatran dual antithrombotic therapy (D-DAT) with warfarin triple antithrombotic therapy (W-TAT) in patients with atrial fibrillation (AF) undergoing percutaneous coronary intervention (PCI). As previously reported D-DAT reduced bleeding compared with W-TAT and was non-inferior with regard to thromboembolic events.

Aim

The aim of this subgroup analysis of RE-DUAL was to assess the relationship between sex and treatment effects of D-DAT and W-TAT on bleeding and thromboembolic outcomes.

Methods

Patients were randomized to receive W-TAT (warfarin, clopidogrel or ticagrelor, and aspirin) or D-DAT (dabigatran 110 or 150 mg twice daily with clopidogrel or ticagrelor; D110- or D150-DAT). Younger patients (aged < 80 yrs. [≤ 70 yrs. in Japan]) and US patients irrespective of age received D110-DAT, D150-DAT or W-TAT; older patients (aged ≥ 80 yrs. in non-US countries [= 70 yrs. in Japan]) received only D110-DAT or W-TAT. Bleeding and thromboembolic outcomes were assessed according to treatment group and by sex (female vs. male).

Results

A total of 2725 patients were randomized; 2070 patients were male (76.0%) and 655 (24.0%) were female. Overall females were older at time of PCI than males (73.2 ± 7.9 vs. 70.0 ± 8.8 years). The mean CHA2DS2-VASc and modified HAS-BLED scores were higher in women at 4.5 and 2.8, respectively, than in men at 3.3 and 2.7, respectively.
For the primary endpoint of major bleeding events or clinically relevant non-major bleeding events, treatment effects of D110-DAT vs. W-TAT were consistent for female and male patients (females: HR 0.69, 95% CI 0.47-1.01, males HR 0.46, 95%CI 0.37-0.59, interaction p-value 0.084). Similarly, consistent treatment effects were seen for the primary endpoint with D150-DAT vs W-TAT in female and male patients (females HR 0.74, 95% CI 0.48-1.16, males HR 0.71, 95% CI 0.56-0.90, interaction p value 0.83).

No interaction between sex and treatment was observed for D110- or D150-DAT vs W-TAT with regard to the composite efficacy endpoint of death, thromboembolic events or unplanned revascularization (interaction p values 0.73 and 0.72, respectively) (figure).

Conclusion

The treatment effect of dabigatran 110 mg and 150 mg dual therapy vs warfarin triple therapy was consistent across sex groups. This suggests that female and male patients with AF undergoing PCI should be treated equally in terms of the dosage of dabigatran selected for dual therapy strategies.