DABIGATRAN VERSUS WARFARIN IN ATRIAL FIBRILLATION PATIENTS WITH LOW, MODERATE AND HIGH CHADS2 SCORE: A RE-LY SUBGROUP ANALYSIS

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Background: Patients with atrial fibrillation should be stratified for stroke risk and the CHADS2 is a widely accepted risk score. Warfarin reduces the risk of stroke in atrial fibrillation. In lower risk patients, e.g. CHADS2 score of 1, aspirin is often used instead of warfarin as the bleeding risk of warfarin can out-weigh the benefits. In the RE-LY trial, dabigatran 110 mg twice daily (D110) was non-inferior and 150 mg twice daily (D150) superior to warfarin for prevention of stroke or systemic embolism in atrial fibrillation patients.

Methods: RE-LY patients were low, moderate or high risk with CHADS2 score 0-1 (n=5,775); 2 (n=6,455) or 3-6 (n=5,882). We calculated relative risks (RR), 95 % confidence intervals and p-values for interaction.

Results: Annual rates of stroke or systemic embolism were 1.05%, 1.38% and 2.38% in low, moderate and high risk patients on warfarin. The RR for D110 vs. warfarin were 1.00 (0.65−1.55) in low; 1.04 (0.73−1.49) in moderate; and 0.79 (0.59−1.06) in high risk patients, p=0.4. The RR with D150 vs. warfarin were 0.62 (0.38−1.02) in low; 0.61 (0.40−0.92) in moderate; and 0.70 (0.52−0.95) in high risk patients, p=0.8. Annual major bleeding rates were 2.70 %, 3.14 % and 4.25 % in low, moderate and high risk patients on warfarin. The RR for major bleeding with D110 vs. warfarin was 0.67 (0.49−0.90) in low, 0.83 (0.65−1.07) in moderate, and 0.85 (0.67−1.06), p=0.4, in high risk patients; and with D150 vs. warfarin 0.73 (0.54−0.98) in low, 0.89 (0.69−1.14) in moderate, and 1.11 (0.89−1.37) in high risk patients, p=0.07.

Conclusion: In low risk patients both dabigatran doses have a favourable risk benefit profile compared to warfarin, with lower rates of stroke, systemic embolism and major bleeding. The benefit of D150 versus warfarin is consistent across risk groups; however the absolute reduction in stroke or systemic embolism with D150 is greatest in the highest risk group.