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FATAL BLEEDING, CASE-FATALITY RATE OF MAJOR BLEEDING AND ALL-CAUSE MORTALITY IN PATIENTS TAKING TARGET-SPECIFIC ORAL ANTICOAGULANT, A META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS

Moderated Poster Contributions Vascular Medicine Moderated Poster Theater, Poster Hall B1 Saturday, March 14, 2015, 4:00 p.m.-4:10 p.m.

Session Title: Pulmonary Emboli: Advances in Management Abstract Category: 46. Vascular Medicine: Venous Disease Presentation Number: 1169M-05

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Background: The impact of Target-specific oral anticoagulants (TSOACs) on mortality outcomes compared to warfarin remains unclear. The objective of this study was to estimate the rate of fatal bleeding, case-fatality rate of major bleeding and compare mortality outcomes in patients treated with TSOACs versus warfarin.

Methods: We searched for phase III, randomized controlled trails (RCTs) comparing TSOACs to warfarin (target international normalized ratio [INR], 2.0 to 3.0) in patients with atrial fibrillation or venous thromboembolism.

Results: Twelve RCTs involving 102 607 patients were included in the analysis. The case-fatality rate of major bleeding was 7.57% [95% CI, 6.53-8.68] in patients taking TSOACs and 11.0% [95% CI, 9.20-13.10] in patients taking warfarin. The rate of fatal bleeding in patients receiving TSOACs was 0.1 per 100 patient-years [95% CI, 0.13-0.27]. When compared with warfarin, TSOACs were associated with significant reduction in fatal bleeding (RR, 0.53 [95% CI, 0.43-0.64]; P<0.001; I2 = 0%), cardiovascular mortality (RR, 0.88 [95% CI, 0.82-0.94]; P=0.0002; I2 = 0%) and all-cause mortality, Figure 1 (RR, 0.91 [95% CI, 0.86-0.95]; P<0.001; I2 = 0%).

Conclusion: In a meta-analysis of RCTs, the use of TSOACs was associated with lower risk of case-fatality rate of major bleeding, fatal bleeding, cardiovascular mortality and all-cause mortality when compared to therapeutic warfarin (target INR between 2.0 to 3.0).

	TSOACs		VKAs		Risk Ratio		Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% Cl	M-H, Random, 95% Cl
J-ROCKET AF, 2012	7	637	5	637	0.2%	1.40 [0.45, 4.39]	
RE-MEDY, 2013	17	1430	19	1426	0.6%	0.89 [0.47, 1.71]	
RE-COVER, 2009	21	1274	21	1265	0.7%	0.99 [0.55, 1.81]	
RE-COVER II, 2014	25	1279	25	1289	0.8%	1.01 [0.58, 1.74]	
EINSTEIN-DVT, 2010	38	1731	42	1718	1.3%	0.90 [0.58, 1.39]	
AMPLIFY, 2013	41	2691	52	2704	1.5%	0.79 [0.53, 1.19]	
EINSTEIN-PE, 2012	58	2419	50	2413	1.7%	1.16 [0.80, 1.68]	
HOKUSAI-VTE, 2013	132	4118	126	4122	4.2%	1.05 [0.82, 1.33]	
ROCKET AF, 2011	208	7081	250	7090	7.4%	0.83 [0.70, 1.00]	
RE-LY, 2009	884	12091	487	6022	21.5%	0.90 [0.81, 1.01]	-
ARISTOTLE, 2011	603	9120	669	9081	21.6%	0.90 [0.81, 1.00]	-
ENGAGE-AF-TIMI-48, 2013	1510	14069	839	7036	38.5%	0.90 [0.83, 0.97]	=
Total (95% CI)		57940		44803	100.0%	0.91 [0.86, 0.95]	•
Total events	3544		2585				
Heterogeneity: Tau ² = 0.00; Chi ² = 5.17, df = 11 (P = 0.92); I ² = 0%							
Test for overall effect: Z = 3.96 (P < 0.0001) Favours [TSOACs] Favours [Vi/							