Table 1. Adverse Outcomes in Dabigatran Versus Warfarin Treated Patients

	Population A		Population B		All patients	
	Dabigatran (n=133)	Warfarin (n=66)	Dabigatran (n=66)	Warfarin (n=18)	Dabigatran (n=168)	Warfarin (n=84)
Death, n (%)	1(1)	2(3)	0	0	1(1)	2(2)
Stroke, n(%)	9(7)	0	0	0	9(5)	0
Death/stroke/SE/MI, (n%)	11(8)	2(3)	2(6)	0	13(8)	2(2)
Death/stroke/TIA/SE/MI, n(%)	12(9)	4(6)	3(9)	0	15(9)	4(5)
Major bleeding, n(%)	7(5)	2(3)	0	0	7(4)	2(2)
Major bleeding with pericardial location, n(%)	7(5)	2(3)	0	0	7(4)	2(2)
Any bleeding, n(%)	35(26)	8(12)	10(29)	2(11)	45(27)	10(12)

MI=myocardial infarction; SE=systemic embolism; TIA=transcient ischemic attack.

RE-ALIGN showed that dabigatran was associated with significantly more bleeding and was less effective for preventing thromboembolic complications compared with warfarin in patients with mechanical heart valves. Prof. Van der Werf concluded that patients with mechanical heart valves should not be treated with dabigatran. The United States Food and Drug Administration and the European Medicines Agency have both already issued black box warnings for all novel oral anticoagulants that they should not be used off-label in patients with mechanical heart valves.

Thrombus Aspiration Fails to Improve Mortality Following STEMI

Written by Emma Hitt, PhD

Thrombus aspiration with percutaneous coronary intervention (PCI) did not improve mortality compared with PCI alone in patients with ST-elevation myocardial infarction (STEMI) in a large, randomized trial. Ole Fröbert, MD, PhD, Örebro University Hospital, Örebro, Sweden, presented data from the Thrombus Aspiration in ST-Elevation Myocardial Infarction in Scandinavia trial [TASTE; Fröbert O et al. *N Engl J Med* 2013].

Coronary artery thrombus aspiration performed in conjunction with PCI has been inconsistently demonstrated to improve blood flow and ST-segment elevation in patients with STEMI. The purpose of the TASTE trial was to evaluate the impact of thrombus aspiration in conjunction with PCI in patients with STEMI.

In the multicenter, prospective, registry-based TASTE trial, 7244 patients with STEMI were randomized to receive manual thrombus aspiration followed by PCI or PCI only. Patients with STEMI were eligible if they experienced symptoms for >30 minutes and <24 hours and STEMI or left bundle-branch block was confirmed on the electrocardiogram. Exclusion criteria were limited to age <18 years, previous randomization in the TASTE trial, and requirement for emergency coronary artery bypass grafting. The primary endpoint was time to all-cause mortality at Day 30. Secondary endpoints included time to rehospitalization with reinfarction at 30 days and time to stent thrombosis at 30 days. Prespecified analyses were performed in the intention-to-treat (ITT) population as well as a per-protocol population among those who received the actual treatment.

The time from symptom onset to PCI was similar among both treatment arms with a mean of ~180 minutes. In the PCI plus thrombus aspiration arm, the cumulative risk of all-cause mortality was 2.8% compared with 3.0% in the PCI-only arm (HR, 0.94; 95% CI, 0.72 to 1.22; p=0.63) in the ITT analysis and (HR, 0.88; 95% CI, 0.66 to 1.17; p=0.38) in the per-protocol analysis [Fröbert O et al. *N Engl J Med* 2013].

The cumulative risk of rehospitalization due to reinfarction was 0.5% in the PCI plus thrombus aspiration arm compared with 0.9% in the PCI-only arm (HR, 0.61; 95% CI, 0.34 to 1.07; p=0.09) [Fröbert O et al. *N Engl J Med* 2013]. In addition, 0.2% of patients that received thrombus aspiration experienced stent thrombosis, compared with 0.5% of patients that received PCI only (HR, 0.47; 95% CI, 0.20 to 1.02; p=0.06). The rates of stroke, neurologic complications, perforation, tamponade, heart failure, or left ventricular dysfunction at hospital discharge were similar among both treatment arms [Fröbert O et al. *N Engl J Med* 2013].

Prof. Fröbert stated that, in his opinion, the data from the TASTE trial indicate that thrombus aspiration plus PCI does not reduce number of deaths or rehospitalization in patients with STEMI compared with PCI only. Therefore, Prof. Fröbert suggested that there is likely no place for routine thrombus aspiration in conjunction with PCI in clinical practice.

Edoxaban Noninferior to Warfarin in Recurrent VTE and PE

Written by Emma Hitt, PhD

Edoxaban was noninferior to warfarin for prevention of recurrent venous thromboembolism (VTE) in patients with acute VTE who were initially treated with heparin. Harry R. Büller, MD, University of Amsterdam, Amsterdam, The Netherlands, presented data from the Comparative Investigation of Edoxaban Tosylate (DU176b) Versus Warfarin in the Treatment of Symptomatic Deep-Vein Clots and/or Lung Blood Clots trial [Edoxaban Hokusai-VTE Study; Büller HR et al. *N Engl J Med* 2013].