Female sex independently predicts bleeding risk after percutaneous coronary intervention (PCI). Bivalirudin is safer than abciximab plus heparin in patients with non-ST-segment elevation myocardial infarction (NSTEMI). Thus, a greater benefit of bivalirudin in women would be expected. We performed a sex-based analysis of the patients with NSTEMI (n = 1,721, 399 women) enrolled in the ISAR-REACT 4 trial and randomized to receive bivalirudin or abciximab plus heparin. Main outcome was a 30-day composite of death, large recurrent myocardial infarction, urgent target vessel revascularization, or major bleeding. Secondary outcome was 1-year composite of death, myocardial infarction, or target vessel revascularization. No difference in the main outcome was observed in groups with bivalirudin or abciximab plus heparin: 12.6% versus 15.5% (hazard ratio [HR] 0.81, 95% CI 0.48-1.37) among women and 10.6% versus 9.5% (HR 1.12, 95% CI 0.77-1.64) among men. Major bleeding occurred in 4.5% in the bivalirudin group versus 7.5% in the abciximab plus heparin group (HR 0.60, 95% CI 0.26-1.39) among women and 2.0% versus 3.8% (HR 0.52, 0.27-1.02) among men. At 1 year, the secondary outcome was
observed in 24.1% in the bivalirudin group versus 28.7% in the abciximab plus heparin group among women, HR of 0.80 (95% CI 0.55-1.17), and in 20.6% and 19.0%, respectively, HR of 1.10 (95% CI 0.86-1.40) among men. Despite a higher peri-PCI bleeding risk in women, bivalirudin is as effective as and safer than abciximab plus heparin in women and men with NSTEMI undergoing PCI.