OBJECTIVES: The aim of the study was to investigate the relationship between bleeding within the 30 days after percutaneous coronary interventions (PCI) and 1-year mortality and to assess the appropriateness of inclusion of the periprocedural bleeding in a quadruple composite end point to assess PCI outcome. BACKGROUND: Periprocedural bleeding is one of the most frequent complications of PCI. METHODS: This study included 5,384 patients from 4 randomized placebo-controlled trials on the value of abciximab after pre-treatment with 600 mg of clopidogrel: ISAR-REACT, -SWEET, -SMART-2, and -REACT-2. Bleeding--defined according to the Thrombolysis In Myocardial Infarction criteria--included all bleeding events within 30 days after enrollment. The primary end point was 1-year mortality. RESULTS: In the 4 trials, within the first 30 days there were 42 deaths (0.8%), 314 myocardial infarctions (MIs) (5.8%), 52 urgent revascularizations (1.0%), and 215 bleeding complications (4.0%). Mortality at 1 year was 3.6% (n = 197). A Cox proportional hazards model revealed that the 30-day occurrence of bleeding (hazard ratio [HR] 2.96, 95% confidence interval [CI] 1.96 to 4.48; p < 0.001), MI (HR 2.29, 95% CI 1.52 to 3.46; p < 0.001) and urgent revascularization (HR 2.49, 95% CI 1.16 to 5.35; p = 0.019) independently
predicted 1-year mortality. The c statistic was 0.79 for bleeding, 0.78 for MI, and 0.78 for urgent revascularization, demonstrating a comparable discriminatory power of these adverse events for predicting 1-year mortality. CONCLUSIONS: Our study demonstrates a strong relationship between the 30-day frequency of bleeding and 1-year mortality after PCI and supports the inclusion of periprocedural bleeding in a 30-day quadruple end point for the assessment of outcome after PCI.