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Abstract: Patients receiving oral anticoagulation (OAC) who undergo drug-eluting stent (DES) implantation require additional dual antiplatelet therapy with aspirin and clopidogrel. Such triple therapy confers an elevated bleeding risk, and its optimal duration is not known. The goal of this study was to evaluate whether shortening the duration of clopidogrel therapy from 6 months to 6 weeks after DES implantation was associated with a superior net clinical outcome in patients receiving concomitant aspirin and OAC. In this randomized, open-label trial, we enrolled patients receiving OAC who underwent DES implantation at 3 European centers between September 2008 and December 2013. A total of 614 patients receiving concomitant aspirin and OAC were randomized to either 6-week clopidogrel therapy (n=307) or 6-month clopidogrel therapy (n=307). The primary endpoint was a composite of death, myocardial infarction (MI), definite stent thrombosis, stroke, or Thrombolysis In Myocardial Infarction (TIMI) major bleeding at 9 months. The primary endpoint occurred in 30 patients (9.8%) in the 6-week group compared with 27 patients (8.8%) in the 6-month group (hazard ratio [HR]: 1.14; 95%...
CI: 0.68 to 1.91; p=0.63). There were no significant differences for the secondary combined ischemic endpoint of cardiac death, MI, definite stent thrombosis, and ischemic stroke (12 [4.0%] vs. 13 [4.3%]; HR: 0.93; 95% CI: 0.43 to 2.05; p=0.87) or the secondary bleeding endpoint of TIMI major bleeding (16 [5.3%] vs. 12 [4.0%]; HR: 1.35; 95% CI: 0.64 to 2.84; p=0.44). Six weeks of triple therapy was not superior to 6 months with respect to net clinical outcomes. These results suggest that physicians should weigh the trade-off between ischemic and bleeding risk when choosing the shorter or longer duration of triple therapy. (Triple Therapy in Patients on Oral Anticoagulation After Drug Eluting Stent Implantation [ISAR-TRIPLE]; NCT00776633).