An increasing number of patients undergoing coronary stenting need lifelong anticoagulation and therefore require a triple therapy typically consisting of aspirin, clopidogrel, and a vitamin K antagonist. Triple therapy confers an elevated bleeding risk as compared with dual therapy; however, omission of either antiplatelet or anticoagulation therapy might increase the risk of stent thrombosis or thrombembolic events. Although guidelines recommend a duration of dual antiplatelet therapy of 6 to 12 months after drug-eluting stent (DES) implantation, the optimal duration of dual antiplatelet therapy in patients receiving oral anticoagulation is not known. We postulate that 6-week clopidogrel therapy after DES implantation as compared with 6-month therapy is associated with improved clinical outcomes in patients undergoing DES implantation receiving concomitant aspirin and vitamin K antagonists. The ISAR-TRIPLE is a randomized, open-label trial that examines the restriction of clopidogrel therapy from 6 months to 6 weeks after DES implantation in the setting of concomitant aspirin and oral anticoagulant. Patients are
randomized in a 1:1 fashion to either 6-week or 6-month clopidogrel therapy. The primary end point is a composite of death, myocardial infarction, definite stent thrombosis, stroke, or major bleeding. The secondary end point comprises ischemic and bleeding complications. According to sample size calculations, a total of 600 patients are required to be enrolled. Clinical follow-up is scheduled at 6 weeks and at 6 and 9 months after randomization. There is clinical equipoise regarding the optimal duration of triple therapy after DES implantation in patients who need vitamin K antagonist therapy. The ISAR-TRIPLE trial aims to test the hypothesis that a 6-week triple therapy compared with a 6-month triple therapy improves net clinical outcomes.