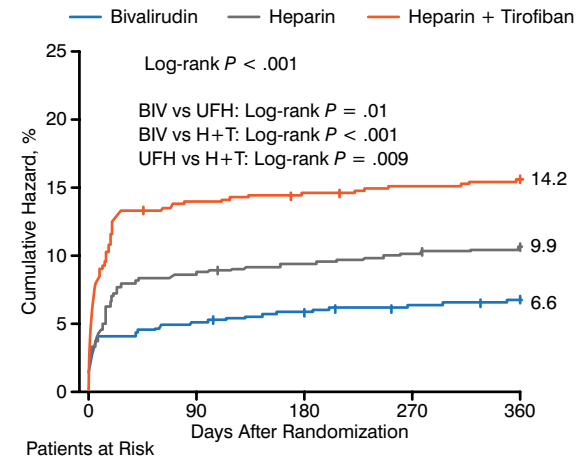
Figure 3. Treatment-Related Bleeding



Biv, bivalirudin; H + T, heparin plus tirofiban; UFH, unfractionated heparin.
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There were no significant differences as to major ischemic events at 1 year; however, bleeding risk favored bivalirudin (Figure 3).

The open-label trial design limits interpretation of these findings, as does the unequal number of STEMI and NSTEMI participants. In addition, Chinese domestic bivalirudin was used in this study. Prasugrel and ticagrelor were not used, as they were not available in China at the time of enrollment.

Six-Month DAPT Noninferior to 12-Month Regimen Following Stent Implantation

Written by Brian Hoyle

Results from the Second Generation Drug-Eluting Stents Implantation Followed by Six Versus Twelve Month Dual Antiplatelet Therapy trial [SECURITY; Colombo A et al. *J Am Coll Cardiol*. 2014. In press] have demonstrated the noninferiority of postprocedural dual antiplatelet therapy (DAPT) for 6 months as compared with 12 months in non-high-risk patients undergoing percutaneous coronary intervention (PCI) with a second-generation drug eluting stent (2G-DES). The trial findings were described by Antonio Colombo, MD, Centro Cuore Columbus, Milan, Italy.

The SECURITY trial was a prospective, randomized, non-inferiority, investigator-driven trial. The main inclusion criteria were the presence of coronary artery disease with stable angina, unstable angina or asymptomatic documented ischemia as clinical manifestations. Additional inclusion criteria were patient age over 18 years, no other DES implanted before the target procedure, and no bare metal stent implanted in the 3 months before the target procedure. The main exclusion criteria were history of treatment for venous or arterial graft lesions, in-stent restenosis, unprotected left main lesions, STEMI within 48 hours of surgery, non-STEMI in the prior 6 months. Additional exclusion criteria were left ventricular ejection fraction (LVEF) ≤ 30%; hypersensitivity or allergy to study drug or devices; chronic renal insufficiency; diagnosed life expectancy < 24 months; and current participation in another study involving a drug or device.

The primary end point was a composite of cardiac death, MI, stroke, stent thrombosis, or Bleeding Academic Consortium Criteria (BARC) type 3 or 5 bleeding at 12 months. Conversely, secondary end points included the composite of cardiac death, MI, stroke, definite/probable stent thrombosis or BARC type 2, 3, or 5 bleeding at 12 and 24 months, and the occurrence of MI, ischemia-driven revascularization (with PCI or coronary artery by-pass graft), all bleeding events, and all-cause mortality at 30 days and 6, 12, and 24 months.

The analysis was carried out according to the intention to treat principle. Additionally, it was prespecified as a per-protocol analysis including only patients fulfilling all major inclusion criteria and treated according to the assigned randomization arm.

Overall, 1399 patients were randomized to the 6-month (n = 682) or 12-month (n = 717) DAPT regimen. The randomization arms were well balanced in terms of baseline clinical and angiographic characteristics. Use of medication during the trial was similar at 6 months. Conversely, more than 30% of patients in the 6-month group were on DAPT regimen at 12 months.

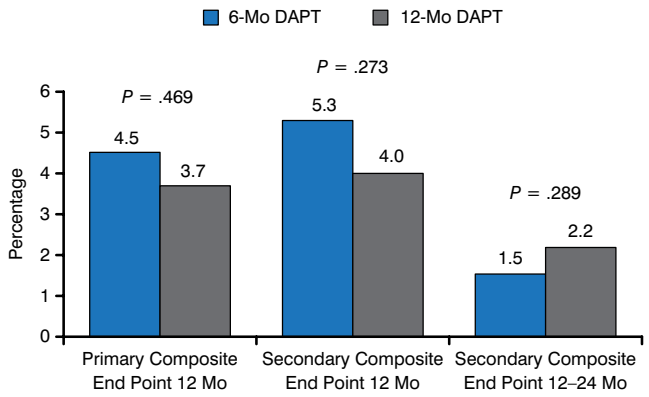
There were no statistically significant differences between the 6- and 12-month regimens concerning the primary and secondary composite end points at 12 months (Figure 1).

Moreover, no differences in the secondary end points incidence at 24 months were observed between the study groups.

Rates of the single end points are reported in Table 1. Again, no differences were observed across the different outcomes between 6- and 12-month regimens. Of note, only 6 cases of definite/probable stent thrombosis occurred at follow-up.

Multivariable analysis revealed a significant association between the primary end point and age, type of

Figure 1. Primary and Secondary Composite End Points



DAPT, dual antiplatelet therapy.

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Table 1. Secondary End Points

	6-Month DAPT (n = 682)	12-Month DAPT (n = 717)	*P* Value
Cardiac mortality, %			
12 Months	0.7	0.4	.435
24 Months	0.9	0.8	.931
BARC bleeding, 3 or 5, %			
12 Months	0.6	1.1	.283
24 Months	0.7	1.1	.455
Myocardial infarction, %			
12 Months	2.3	2.1	.747
24 Months	3.1	2.6	.630
Stroke, %			
12 Months	0.9	0.3	.136
24 Months	0.9	0.4	.280
Definite/probable ST, %			
12 Months	0.3	0.4	.694
24 Months	0.4	0.4	.951
Possible ST, %			
12 Months	0.0	0.0	NS
24 Months	0.0	0.0	NS

BARC, Bleeding Academic Consortium Criteria; DAPT, dual antiplatelet therapy; NS, nonsignificant; ST, stent thrombosis.

Source: Colombo A et al. *JACC* 2014.

Table 2. Predictors of the Primary End Point

Variables in the Model	HR	95% CI	*P* Value
Age ≥75 years	2.211	1.234 to 3.962	.007
Stent type			.019
Endeavor Resolute vs Biomatrix/Xience/Promus	2.336	1.051 to 5.190	
Mean number of stents (for each unit increase)	1.410	1.128 to 1.741	.002
Mean stents length (for each 5 units increase)	1.383	1.135 to 1.685	.001
Mean stent size (for each 2.5 units increase)	1.326	1.106 to 1.590	.002
Diabetes mellitus			.069
NIDDM vs none	0.895	0.464 to 1.729	
IDDM vs none	2.349	1.080 to 5.106	
DAPT 6- vs 12-month	1.272	0.754 to 2.145	.367
Female sex	1.596	0.897 to 2.838	.111

DAPT, dual antiplatelet therapy; IDDM, insulin-dependent diabetes mellitus; NIDDM, non-insulin-dependent diabetes mellitus.

Source: Colombo A et al. *JACC* 2014.

stent implanted and stent number/length/size (Table 2). Interestingly, diabetes mellitus was only of borderline statistical significance in this trial.

Despite several study limitations, such as the lower than expected primary end point incidence and statistical power, Dr Colombo concluded that the 6-month DAPT is noninferior to the 12-month regimen in low-risk patients undergoing PCI with a 2G-DES.

RSD Effective in Some Patients With Mildly Elevated BP

Written by Brian Hoyle

A small randomized study failed to demonstrate the superiority of renal sympathetic denervation (RSD) compared with medical therapy in achieving lowered blood pressure (BP). However, while systolic BP was decreased 6 months post denervation in all patients, the decrease was significant only for the per-protocol cohort. The findings, which are provocative rather than definitive, were reported by Steffen Desch, MD, University of Lübeck, Lübeck, Germany.

While percutaneous RSD might be effective in lowering BP in patients with severe resistant hypertension, the applicability when BP is only slightly elevated is unclear.