Table 1. Angiographic Results at 9 Months

	Follow-up (9 months)		
	Provisional (n=168)	Tryton (n=158)	p Value
Main Vessel			
RVD (mm)	2.88±0.32	2.95±0.35	0.050
MLD (mm)			
In-stent	2.44±0.43	2.47±0.54	0.581
In-segment	2.13±0.48	2.14±0.56	0.851
% DS			
In-stent	14.94±12.75	16.47±14.28	0.308
In-segment	26.02±14.01	27.77±15.87	0.292
Side Branch			
RVD (mm)	2.24±0.31	2.29±0.29	0.103
MLD (mm)			
In-stent	na	1.67±0.62	na
In-segment	*1.36±0.38*	*1.56±0.56*	*<0.001*
% DS			
In-stent	na	26.72±25.44	na
In-segment	*38.63±16.16*	*31.57±22.91*	*0.002*

DS=diameter stenosis; MLD=minimal luminal diameter; RVD=renovascular disease.

No Change in Thrombotic Risk With Short-Term DAPT After Stenting

Written by **Nicola Parry**

Fausto Feres, MD, PhD, Instituto Dante Pazzanese de Cardiologia, São Paulo, Brazil, presented the final results from the Optimized Duration of Clopidogrel Therapy Following Treatment With the Zotarolimus-Eluting Stent in Real-World Clinical Practice trial [OPTIMIZE; Feres F et al. *JAMA* 2013], demonstrating that in patients with coronary heart disease who received a drug-eluting stent (DES), cessation of dual antiplatelet therapy (DAPT) 3 or 12 months after implantation did not increase their risk of the composite endpoint of death, MI, stroke or major bleeding, or stent thrombosis at 1-year follow-up.

Although the optimal duration of DAPT following DES implantation remains uncertain, early discontinuation of DAPT is considered one of the most important predictors of thrombotic events after first-generation DES implantation [Bhatt DL et al. *N Engl J Med* 2006]. Current guidelines therefore recommend that patients receive long-term DAPT, for ≥12 months [Levine GN et al. *Circulation* 2011; Wijns W et al. *Eur Heart J* 2010].

OPTIMIZE, the largest prospective, multicenter, randomized controlled trial on this subject to date, was designed as a noninferiority trial to evaluate the safety and clinical impact of short-term DAPT in patients following DES implantation.

Patients were eligible to be included if they had symptoms of stable angina, silent ischemia, or a history of low-risk acute coronary syndrome (characterized by unstable angina or recent, but not acute, myocardial infarction [MI]). Exclusion criteria included primary or rescue percutaneous coronary intervention (PCI) for ST-segment elevation MI, previous treatment with any DES, and lesion located in a saphenous vein graft.

The primary endpoint of the study was net adverse clinical and cerebral events (NACCE) defined as a composite of all-cause death, MI, stroke, or major bleeding at 1 year. Secondary endpoints were major adverse cardiac events (MACE) defined as a composite of all-cause death, MI, emergent coronary artery bypass graft surgery, or target lesion revascularization and Academic Research Consortium (ARC) definite or probable stent thrombosis.

A total of 3119 patients were randomized 1:1 to either short-term (3 months; n=1563) or long-term (12 months; n=1556) DAPT following zotarolimus-eluting stent placement.

At 1-year follow-up, there was no significant difference between patients receiving 3 months and 12 months of DAPT following DES implantation in NACCE rates (6.0% vs 5.8%; risk difference, 0.17; 95% CI, –1.52 to 1.86; p=0.002 for noninferiority), MACE rates (8.3% vs 7.4%; p=0.36), or the occurrence of ARC definite or probable stent thrombosis (0.8% vs 0.8%; p=0.86).

Between 3 months and 1 year, there was no significant difference between short- and long-term DAPT groups in the occurrence of NACCE (2.6% vs 2.6%; risk difference 0.05; 95% CI, –1.06 to 1.17; p=0.91) or stent thrombosis (ARC definite or probable; 0.3% vs 0.1%; risk difference, 0.20; 95% CI, –0.09 to 0.48; p=0.18), for the short- versus long-term groups, respectively.

"Any bleeding" complications were reported in 80 patients up to 1 year, but only 23 cases (29%) were categorized as major bleeding events. Between 3 months and 1 year, although not statistically significant, there was a trend toward increased bleeding with prolonged DAPT, with a 2-fold higher rate in the long-term treatment group (major bleeding 0.4% vs 0.2%; p=0.31; any bleeding 1.0% vs 0.4%; p=0.07).

Prof. Feres concluded that, despite current guideline recommendations, data from the OPTIMIZE study demonstrate noninferiority of shorter-term DAPT in patients after DES implantation for the occurrence of death, MI, stroke, or major bleeding events, and without a significantly elevated risk of stent thrombosis. Long-term DAPT may therefore not always be necessary following second generation DES placement, and this may be particularly important for patients at high risk of bleeding following PCI.