branch. In contrast with previous studies, the longer and more complex two-stent procedures did not result in more procedure-related MIs. Prof. Kumsars concluded that longer-term follow-up is needed before the optimal treatment strategy for this type of lesion can be recommended.

Tryton Two-Stent Strategy Safe, but Did Not Meet Noninferiority Endpoint

Written by Toni Rizzo

The current recommended treatment for patients with coronary bifurcation lesions is main branch stenting with provisional side branch stenting. This approach can lead to suboptimal results in the side branch of true bifurcation lesions, in which disease affects the origin of both branches. The objective of the Prospective Single Blind, Randomized Controlled Study to Evaluate the Safety & Effectiveness of the Tryton Side Branch Stent Used With DES in Treatment of de Novo Bifurcation Lesions in the Main Branch & Side Branch in Native Coronaries [TRYTON; NCT01258972] was to compare clinical and angiographic outcomes of the provisional one-stent strategy with the Tryton bifurcation two-stent approach in patients with true bifurcation lesions. Martin B. Leon, MD, Columbia University Medical Center, New York, New York, USA, presented the results of this study

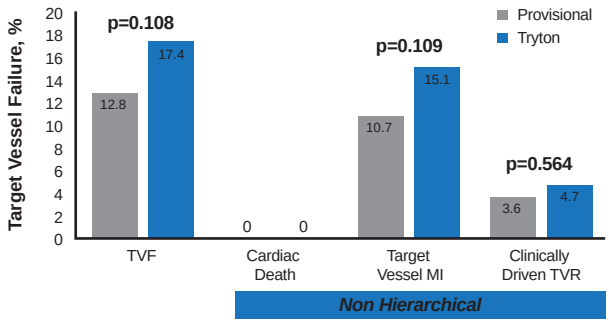
The Tryton stent is a cobalt alloy bare-metal stent. It is inserted in the proximal main vessel extending into the side branch, securing and protecting the side branch. A drug-eluting stent (DES) is placed in the main vessel through the Tryton stent. Finally, postdilation with a kissing balloon is performed to ensure complete lesion and ostium coverage of the side branch.

In the TRYTON study, 704 patients with true bifurcation lesions were randomized to treatment with the Tryton side branch stent and a DES main vessel stent (n=355) or a DES main vessel stent and provisional side branch stent (n=349). The trial was designed as a noninferiority trial with noninferiority margin of 5.5%. The primary endpoint (noninferiority) was target vessel failure (TVF) at 9 months, which was defined as a composite of cardiac death, periprocedural target vessel myocardial infarction (MI; defined as a creatine kinase [CK]-MB >3x upper limit of normal), or target vessel revascularization (TVR). The secondary endpoint (superiority) was the percent diameter stenosis (%DS) of the side branch at 9 months in the cohort who underwent followup angiography.

Patient demographics and clinical characteristics were similar between the two treatment groups. The Tryton stent was successfully implanted in 96.1% of patients in the Tryton group and 0.6% in the provisional group. Additional side branch stents were placed in 2.9% of the Tryton group and 8.0% of the provisional group.

While the rate of TVF was numerically higher in the Tryton arm than the provisional arm, the difference did not achieve statistical significance (17.4% vs 12.8%; p=0.108; Figure 1). The difference in the incidence of the primary endpoint was 4.6% between the two arms and the primary noninferiority margin was not met (upper 1-sided 95% CI, 10.3%; p=0.42 for noninferiority). Analysis of the components of the primary endpoint showed no statistically significant differences between the two arms. There were no cardiac deaths in either arm and >90% of the target vessel MIs were periprocedural.

Figure 1. Primary Endpoint: Target Vessel Failure and Components at 9 Months



MI=myocardial infarction; TVF=target vessel failure; TVR=target vessel revascularization.

Angiography showed that the secondary endpoint of side branch in-segment %DS was significantly lower in the Tryton arm (31.6%) compared with the provisional arm (38.6%; p=0.002; Table 1). The side branch in-segment minimal luminal diameter was significantly higher in the Tryton arm (1.56 mm) versus the provisional arm (1.36 mm; p<0.001). Angiography results for the main vessel showed no significant differences between the groups. Stent thrombosis was rare, with an overall rate of 0.4% (0.6% in the Tryton arm vs 0.3% in the provisional arm; p=1.00). There were no significant differences in restenosis rates between the two groups.

In this study, the Tryton two-stent strategy, when compared with a strategy of provisional stenting, did not meet the noninferiority clinical endpoint. This was largely due to a higher rate of small periprocedural CK-MB elevations in the patients treated with the Tryton stent; however, in side branches >2.25 mm, a Tryton two-stent strategy resulted in better angiographic results in the cohort of patients who underwent follow-up angiography.

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.