substantial reduction in major bleeding. Prof. Steg concluded that these results support the use of bivalirudin for the prehospital management of STEMI prior to primary PCI.

Similar Outcomes With Two-Stent and Provisional Stenting Techniques in Large Side Branch Bifurcation Lesions

Written by Toni Rizzo

Bifurcation lesions occur at the point where one coronary artery branches from another. Currently, provisional side-branch stenting is the preferred strategy for treating most bifurcation lesions. This type of stenting involves stenting the main branch, reserving further stent placement in the side branch only if it is compromised. However, it is not known if provisional stenting provides the best outcomes in bifurcation lesions involving a large side branch.

The aim of the Nordic-Baltic Bifurcation Study IV [NCT01496638], presented by Indulis Kumsars, MD, Pauls Stradins Clinical University Hospital, Riga, Latvia, was to compare provisional stenting with a two-stent techniques for the treatment of true coronary bifurcation lesions involving a large side branch. The study investigators hypothesized that a two-stent technique would be superior to provisional stenting in this setting.

This open-label trial randomized 450 patients with bifurcation lesions involving a large side branch to either provisional stenting (n=221) or a two-stent technique (n=229). Patients with bifurcation stenosis involving both the main vessel and the side branch were eligible. The patients could have stable angina, unstable angina, or non-ST-segment elevation myocardial infarction (NSTEMI), but were excluded if they had STEMI, cardiogenic shock, other critical illnesses, or if the side branch lesion was >15 mm long. The first 225 patients were treated with a sirolimus-eluting stent and the last 225 patients received an everolimus-eluting stent. The primary endpoint was major adverse cardiac events (MACE), defined as the composite of cardiac death, non-index procedure-related MI, target lesion revascularization, and definite stent thrombosis.

Baseline demographics and clinical characteristics were well balanced between the two groups. Lesion characteristics were similar between the provisional stent and two-stent groups, with the exception of the main vessel reference diameter (3.5 vs 3.4 mm; p=0.04) and the side branch lesion length (7.4 vs 8.0 mm; p<0.0001; Table 1).

Of the 450 randomized patients, 220 in the provisional stent group and 227 in the two-stent group were stented and completed 6 months of follow-up. The side branch was dilated in 64.3% of the provisional group and in 78.0% of the two-stent group. Final kissing balloon stent dilation was performed in 36.1% of the provisional group and in 91.2% of the two-stent group. Side branch stenting was performed in 3.7% of the provisional group and 96.0% of the two-stent group. When defining success as residual stenosis of <30% in the main vessel plus TIMI Grade III flow in the side branch, 97.7% of the provisional group and 99.1% of the two-stent group had successful procedures.

Table 1. Lesion Characteristics

	Provisional (n=221)	Two-Stent (n=229)	p Value
LAD/diagonal(%)	74.1	76.7	ns
CX/obtuse marginal (%)	16.8	17.6	ns
RCA POA/PLA (%)	6.4	4.0	ns
LM/LAO/CX (%)	2.7	1.3	ns
Ref. diameter main vessel (mm)*	3.5	3.4	0.04
Ref. diameter side branch (mm)*	2.9	2.9	ns
Lesion length SB (mm)*	7.4	8.0	<0.0001
Angulation >60-70° (%)*	50.9	51.1	ns

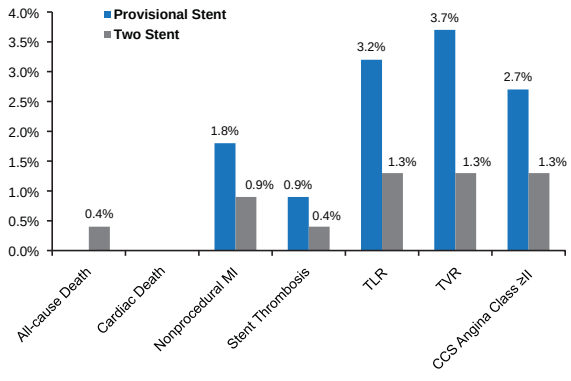
*visual estimation.

CX=circumflex; LAD=left anterior descending; LAO= left anterior oblique; LM=left main; POA=primitive olfactory artery; PLA=posterolateral artery; RCA=right coronary artery; SB=side branch.

At 6 months, the primary endpoint of MACE had occurred in 4.6% of patients in the provisional stent group compared with 1.8% of patients in the two-stent group (p=0.09).

No differences between the provisional stent group and the two-stent group achieved statistical significance for the following secondary endpoints (Figure 1).

Figure 1. Secondary Endpoints



CCS=Canadian Cardiovascular Society; MI=myocardial infarction; TLR=target lesion revascularization; TVR=target vessel revascularization.

At 6 months, there were no statistically significant differences in the rate of MACE between patients treated with provisional stenting and those treated with a two-stent technique for bifurcation lesions involving a large side

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

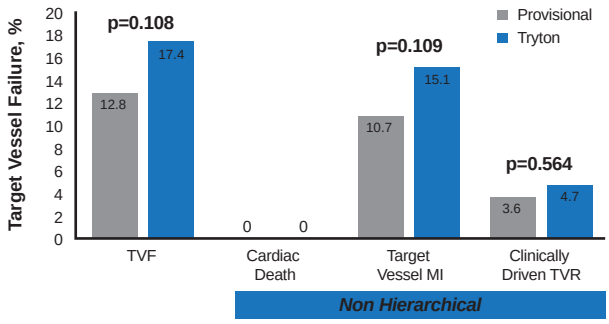
The Tryton stent is a cobalt alloy bare-metal stent. It is inserted in the proximal main vessel extending into the side branch, securing and protecting the side branch. A drug-eluting stent (DES) is placed in the main vessel through the Tryton stent. Finally, postdilation with a kissing balloon is performed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