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EDITORIAL COMMENT

# Treatment of Bifurcation Lesions

## Less Is More*

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The conventional approach to treating bifurcation lesions has involved either a provisional single-stent strategy or intentional stenting of both the main branch (MB) and the side branch (SB). Because neither the "simple" provisional strategy nor the "complex" multistent approach guarantees SB access or optimal SB scaffolding, dedicated bifurcation stents have been developed.

The Tryton Side Branch Stent (Tryton Medical, Inc., Durham, North Carolina) is a non-drug-eluting stent containing 3 zones designed to facilitate the treatment of bifurcation lesions: an SB zone that protrudes up to 6.5 mm into the SB, a transition zone to cover the carina, and an MB zone with limited scaffolding. Because this bifurcation stent requires recrossing into the MB to implant a drug-eluting stent and lock the device in place (1), its use falls into the "complex" category of approaches for treating bifurcation lesions.

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In this issue of the *Journal*, Généreux et al. (2) report the highly anticipated results of the TRYTON (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) bifurcation trial, which compared a dedicated bifurcation stent with provisional stenting for bifurcation lesions. The trial, which randomized 704 patients with true bifurcation lesions and used a noninferiority design, had disappointing results. At 9 months, the primary endpoint of target vessel failure (death, target vessel myocardial infarction [MI], or target vessel revascularization) was 17.4% in the bifurcation stent group compared with 12.8% in the provisional group, a difference that exceeded the pre-specified noninferiority margin of 5.5%. Moreover, procedures with the bifurcation stent were longer (71 ± 33 min vs. 57 ± 33 min) and required more contrast (261 ± 106 ml vs. 223 ± 93 ml) than those involving provisional stenting.

Favorable outcomes for the bifurcation stent included a lower in-segment diameter stenosis in the SB in the bifurcation stent group than in the provisional group (31.6% vs. 38.6%). This result may have occurred because 5.5 to 6.5 mm of the bifurcation stent extended into the SB and may have allowed more uniform strut apposition and carina support than provisional stenting (1). Despite this, no difference in binary restenosis rates was seen at 9 months (23% vs. 27%), and angiographic restenosis in either the MB or SB occurred at similar rates in the bifurcation stent and provisional groups (28% vs. 33%). The investigators discuss the limitations of using older technology based on a bare-metal platform and speculate whether a more contemporary design incorporating drug-eluting technology in the SB would have changed the results. Other analyses suggest that the planned use of a drug-eluting stent in the SB as part of a complex multistent approach lowers restenosis but increases the risk of stent thrombosis and MI (3).

When the TRYTON investigators planned the trial, they expected target vessel failure rates of 11% in the bifurcation stent group and 13% in the provisional group, but observed rates of 17.4% and 12.8%, respectively. A potential contributor to the worse than expected outcomes in the bifurcation stent group was the occurrence of more periprocedural MIs, probably because the bifurcation stent was used in smaller SBs than intended. The smallest version of the bifurcation stent used in the trial required an SB

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with a minimum diameter of 2.5 mm. Implantation of an SB stent in a smaller SB than intended may have led to dissection. Only 41% of the study population met the entry criteria based on SB diameter (≥2.25 mm by quantitative angiography and ≥2.50 mm by visual estimate). Future analyses could address the issues of MI definition and SB sizing.

Although most bifurcation lesions are straightforward to treat, it is sometimes difficult to predict which bifurcation lesions will be problematic. Patients with diffuse disease in the SB present a greater challenge than those with focal disease and have commonly been excluded from randomized controlled trials (4). The use of bailout SB stenting in the TRYTON study in 3% of the bifurcation stent group and in 8% of the provisional group (2) suggests, but does not prove, that patients with extensive and bulky SBs were not enrolled.

Because it is paramount to save the SB in every case, the search for dedicated bifurcation stent systems will continue. Other dedicated bifurcation stent systems, such as the "flower petal" technique (5), Axxess (Biosensors International Group Ltd., Singapore) (6), and Multi-Link Frontier (Guidant Corp., Santa Clara, California) (7), have the potential advantage of maintaining guidewire access to the SB throughout the procedure. The ultimate role of these and other dedicated bifurcation stents will require evidence from randomized controlled trials.

In summary, the TRYTON investigators (2) are commended for completing an important trial and for describing how the results should be translated into clinical practice. They state that provisional stenting remains the preferred approach for most bifurcation lesions. On the basis of these results, the flexibility of the provisional T-stent strategy or T-stenting with a small protrusion into the MB in the majority of bifurcation lesions will likely predominate in current practice over an approach using dedicated bifurcation stents or previous approaches using culotte, crush, or reverse-crush with multiple stents (8).

Treatment of all bifurcation lesions requires a minimum guide size of 6-F, even with the transradial approach. This allows both the MB and the SB to be wired and fully dilated, if necessary, before jailing the SB wire behind the MB stent. If the SB requires treatment for flow-limiting dissection or abnormal fractional flow reserve, the distal strut should be chosen for recrossing. Many excellent guidewires (e.g., the Choice PT Extra Support [Boston Scientific, Marlborough, Massachusetts], MiracleBros 3 [Abbott Vascular, Abbott Park, Illinois], and Hi-torque Whisper [Abbott Vascular]) have eliminated the difficulty of recrossing. Kissing balloon inflations are strongly recommended for 1-stent procedures and are mandatory for 2-stent procedures (8).

Stenting of bifurcation lesions requires prolonged dual antiplatelet therapy. In patients who cannot tolerate prolonged dual antiplatelet therapy or are likely to receive a bare-metal stent for a bifurcation lesion, the alternative of medical therapy or surgical revascularization should be recommended.

Much progress has been made, and more than 1,000 papers have been published on the treatment of bifurcation lesions since Colombo et al. (9) reported the use of kissing stents more than 20 years ago. New approaches that combine drug-eluting technology with flexibility in sizing and conformation—and a minimalist philosophy—are needed to improve the outcomes for bifurcation lesions.

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