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EDITORIAL COMMENT

Challenging the "Provisional" Technique for Coronary Bifurcation Lesions*

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Despite considerable progress in the field of interventional cardiology, percutaneous treatment of coronary bifurcations continues to be associated with a lower procedural success rate and a higher incidence of complications, target lesion revascularization, and stent thrombosis (1). Excluding the 15% to 30% of lesions where stenting on both branches is clearly required from the beginning of the procedure (relatively large side branch [SB] with severe disease extending well beyond the ostium or with an unfavorable anatomy for SB rewiring), the provisional approach has become widely accepted as the default technique in the majority of bifurcations. Provisional consists in stenting the main branch (MB) with the option to rewire the SB, to perform kissing balloon inflation and if necessary to place a stent in the SB (1).

Because the provisional strategy and the more complex 2-stent approach demand SB reaccess, that can be difficult and may yield a suboptimal final result, multiple dedicated bifurcations devices have been developed over the last decade, with the goal to simplify treatment and improve outcomes. The Tryton Side Branch Stent (Tryton Medical, Inc., Durham, North Carolina) is a non-drug-eluting stent (DES) designed to facilitate a culotte technique in which the SB is treated first. The stent is mounted on a stepped balloon with different proximal and distal diameters, obeying the fractal geometry of the coronary tree. Furthermore, the special design of the stent with a minimal amount of metal with large cells in the (proximal) MB zone allows easy delivery of a DES in the MB.

The TRYTON Pivotal randomized controlled trial failed to show noninferiority of this approach versus the provisional technique in regard to its primary endpoint of target vessel failure (TVF) (death, target vessel myocardial infarction, or target vessel revascularization), despite superior angiographic results (lower diameter stenosis) at 9 months (2). The failure to meet the primary endpoint was mainly due to an increased incidence of periprocedural myocardial infarction (PPMI) in the Tryton stent group, probably because the bifurcation stent was used in smaller SBs than intended. Indeed, the study population was specified as patients with bifurcations involving large SBs (>2.5 mm by visual assessment); however, more than one-half on the enrolled lesions had diameter <2.25 mm by quantitative coronary angiography (QCA), corresponding to a lesion <2.5 mm by visual assessment. As the smallest version of the Tryton stent required a SB with a minimum diameter of 2.5 mm, many patients assigned to the Tryton group were treated with a stent mounted on an oversized balloon that may have led to dissection with consequent higher PPMI rate. A post hoc analysis of the treated lesions restricted to the ones involving SBs with a reference vessel diameter >2.25 mm demonstrated superior angiographic results and a numerical reduction in TVF within the noninferiority margin (3), justifying a follow-up prospective single arm study including only bifurcations with large SBs.

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In this issue of the *Journal*, Généreux et al. (4) report the results of the TRYTON Confirmatory Study, designed to support the results seen in the intended population of the TRYTON Pivotal trial (patients with a reference diameter >2.25 mm).

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This was a prospective single-arm extension of the TRYTON Pivotal trial enrolling an additional 133 patients with true bifurcation lesions treated with the Tryton Side Branch Stent, which were compared with the provisional approach arm of the TRYTON Pivotal trial (n = 143). Only patients with SBs >2.25 mm by QCA were included. Moreover, the lesion length in the SB had to be shorter than 5 mm, making this trial a comparison of lesions that most operators would almost always treat with the provisional approach. The Investigators selected PPMI (creatinine kinase-MB 3× upper limit of normal) as primary endpoint because the original Pivotal study demonstrated a higher occurrence of this complication in the Tryton group. PPMI occurred in 10.5% of the patients, being numerically lower than the provisional group in the TRYTON Pivotal study (11.9%) and therefore met the noninferiority primary endpoint.

What is the take home message that we can derive from TRYTON Confirmatory and Pivotal studies? We could state that implanting a Tryton stent in a bifurcation involving a large SB seems to be noninferior, as far as PPMI, compared to the provisional technique. Having said that, do we really need dedicated devices to facilitate the provisional approach? Although SB recrossing can sometimes be challenging and time consuming, several technical strategies may increase the possibility of rapid success. The choice of guide wire and utilization of the proximal optimization technique are of paramount importance (5,6). There are circumstances where, despite successful wire recrossing, the balloon has difficulties to advance into the SB. Repeated inflations of the balloon engaged toward the SB are frequently helpful maneuvers to gain the desirable distal position (5). The need for an additional stent in the SB in the provisional arm approach of the TRYTON Confirmatory trial was very low (5.6%), confirming that the bifurcation lesions included had focal SB stenosis, allowing an acceptable result with the simplest 1-stent approach. Moreover, procedures with Tryton Side Branch Stent required more time, and a higher amount of contrast was used compared to the provisional approach.

Do we see any hidden advantage in using the Tryton Side Branch Stent? A lower in-segment diameter stenosis in the SB was observed with the bifurcation stent compared to the provisional treatment both post-procedure (11.3% vs. 30.9%) and at 9-month follow-up (31.6% vs. 38.6%) in the TRYTON Confirmatory and Pivotal studies, respectively. These superior angiographic results may translate into favorable clinical endpoints when evaluating a large number of patients. Moreover, these differences may further magnify if we assume that future iterations of the Tryton stent may become drug eluting.

In addition, a longer "Tryton drug-eluting stent" may be implanted to treat bifurcation lesions involving SBs with long lesions, thus simplifying the procedure when a 2-stent strategy is required as intention to treat.

These results and these considerations mean that the game is not completely over. While the provisional approach reigns supreme, we are discovering subsets of bifurcation lesions such as the ones with long lesions in a large SB where a dedicated 2-stent approach may prove advantageous.

Specific devices facilitating a 2-stent strategy should be compared with a 2-stent approach using contemporary DES in complex bifurcation lesions in which an a priori 2-stent approach is the appropriate treatment. On the other side we are not completely sure if there is room to compete with the provisional approach for most of the bifurcation lesions appearing suitable for 1-stent approach.

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