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TRYTON STENT SYSTEM

TRYTON Dedicated Bifurcation Stent System for True Coronary Bifurcations in Large Side Branches

A review of the data on the performance of TRYTON compared to the current standard strategy of provisional stenting for these challenging clinical presentations.

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Bifurcation lesions are associated with lower procedural success rates and a higher risk of adverse cardiac events.[1,2] As numerous randomized controlled trials (RCTs) have suggested that patients with bifurcation lesions do not benefit from a two-stent strategy, provisional stenting (PS) has become widely accepted as the treatment strategy of choice for the majority of bifurcation lesions.[3-7] Indeed, the PS strategy has a number of advantages. Procedure-related myocardial infarctions and device-related clinical events at follow-up are decreased, which is not surprising given that the side branch (SB) is not intervened upon.[1] On the contrary, PS requires crossover to a second stent in more than one-third of cases,[5,8,9] with failure to deliver the SB stent in one out of 10 patients.[10] Moreover, the RCTs suggesting PS as the default strategy included all bifurcations irrespective of medina class, SB size, or myocardium at risk. In fact, several recent studies, including meta-analyses, have suggested that a dedicated two-stent strategy is associated with a lower need for revascularization in true bifurcation lesions compared with the PS technique.[1,11,12] Taken together, controversy remains regarding which patients benefit from a PS versus a two-stent strategy.

TRYTON BIFURCATION STENT SYSTEM

The TRYTON pivotal RCT compared the TRYTON dedicated bifurcation stent system (manufactured by Tryton Medical and distributed by Cordis, a Cardinal Health company), designed to specifically secure and treat the bifurcation SB, versus the PS strategy for the treatment of de novo true bifurcation lesions.[13] The TRYTON stent has a number of specific advantages. It is designed to be procedurally less complicated than performing more complicated two-stent strategies such as double-kissing crush or culotte, and moreover, the TRYTON stent is designed to significantly reduce the possibility of missing the SB ostium, which is the most common site of target lesion failure in two-stent bifurcation percutaneous coronary intervention (PCI).[13] Nonetheless, despite lower postprocedural and 9-month follow-up rates of percent diameter stenosis (DS) of the SB, the TRYTON pivotal RCT failed to show noninferiority to PS with regard to its primary endpoint, target vessel failure at 9 months.[13]

The failure was mainly driven by the unintentional enrollment of a large proportion of patients with SBs < 2.25 mm by quantitative coronary angiography (QCA) (those with the least to gain by a two-stent technique) and an increased incidence of periprocedural myocardial infarction (PPMI) using a clinically outdated definition (creatine kinase-MB ≥ 3× the upper limit of normal)[5,7] that has been superseded by the contemporary Society for Cardiovascular Angiography and Interventions (SCAI) definition of PPMI.[14] Indeed, a post hoc analysis of the intended population restricted to lesions involving SBs with a reference vessel diameter ≥ 2.25 mm demonstrated superior angiographic results, and subsequently, the TRYTON confirmatory study showed a reduction in PPMI prospectively in true bifurcations of this size.[15]

Although the trial failed to meet its primary noninferiority endpoint, it also failed to answer the clinical question relevant to practicing interventional cardiologists: Is the TRYTON dedicated SB system as good or better than PS in patients with true bifurcations with arteries large enough to gain a benefit? We recently

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set out to answer this question by performing a pooled analysis based on individual patient data of the safety and efficacy of the TRYTON dedicated bifurcation stent system for the treatment of true bifurcation lesions (Medina classification 1,1,1; 1,0,1; or 0,1,1)[16] with SBs ≥ 2.25 mm by QCA (analogous to 2.5 mm by visual estimation),[17] using the contemporary definition of SCAI PPMI[14] and analyzing the combined data from the TRYTON RCT and the TRYTON confirmatory study.[18]

PATIENT-LEVEL ANALYSIS OF THE TRYTON STENT SYSTEM

Of the 868 patients enrolled at 58 centers, 411 patients met the criteria for true bifurcation disease with SBs ≥ 2.25 mm. Of these, 287 patients were treated with the TRYTON stent and 124 patients were treated with PS. Procedural duration, fluoroscopy duration, and use of contrast media and lesion preparation were greater in the TRYTON group than in the PS group, as was procedural success (< 50% DS in SBs without in-hospital major adverse cardiovascular events [MACE] 95.4% vs 82.3%, respectively; $P < .0001$) with the TRYTON stent being delivered in 98% of cases. Target vessel failure at 1 year was 8.4% in the TRYTON group and 9.8% in PS group, which met the prespecified criteria of noninferiority ($P = .023$ for noninferiority). MACE rates were also not different between the groups (TRYTON arm, 10.9% vs PS, 9.7%; $P = .70$). At 9-month angiographic follow-up, SB DS was significantly lower in the TRYTON group (29.3% ± 21.9% vs 41.1% ± 17.5%; $P = .0008$) and binary restenosis (DS ≥ 50%) was higher in the PS group (19.0% vs 34.2%, respectively; $P = .052$).

LEARNING POINTS

So what did we learn that is relevant to the practicing interventional cardiologist?

- Bifurcation stenting using the TRYTON system was successful in 98% of bifurcation lesions attempted, with minimal increases in procedure duration, fluoroscopy, and contrast use.
- Despite tighter stenoses at baseline, the TRYTON stent system led to improved minimal lumen diameter, in-segment DS, device success, lesion success, and procedural success than PS immediately post-PCI in true bifurcation lesions.
- Target vessel failure, target lesion failure, and MACE between TRYTON and PS at either 30-day or 1-year clinical follow-up were not different.
- Angiographic assessment at 9 months identified a benefit for the TRYTON stent system compared to PS with respect to SB minimal lumen diameter, DS, and in-segment minimal lumen diameter.

Discussion

This debate exists because it is intuitive that revascularization of the SB would improve myocardial blood flow, which should, in turn, improve patient outcomes. Indeed, previous studies have shown that a 50% SB stenosis is associated with a positive fractional flow reserve in the SB.[19] However, bifurcation PCI is a balancing act. Vessel preparation with predilation, stenting, and postdilation of the SB inevitably lead to vascular injury, which can also lead to myocardial injury and PPMI. Of course, using the PS strategy, this is a nonissue as SB intervention is not mandated and, in most cases, is completely avoided. Thus, accepting the risk of vascular injury to the SB must be outweighed by the potential benefit (ie, the artery must be large enough and cover enough myocardium to provide benefit if revascularized). Using this rationale, the findings of the DKCRUSH-V study,[12] which compared a planned two-stent strategy to PS for the treatment of true left main bifurcations, resulted in a lower rate of target lesion failure at 1 year in the two-stents group.

Of course, within the context of scientific hygiene, our results must be taken in context. Despite representing the initial intended population of the TRYTON RCT, our analysis may be subject to selection bias by including a nonprespecified subgroup of the TRYTON RCT and the nonrandomized confirmatory study. Further, although it is widely accepted that visual assessment overestimates reference vessel diameter compared with QCA measurement, the inclusion of patients with SBs ≥ 2.25 mm by QCA is extrapolated to a visual estimation of ≥ 2.5 mm. Also, only focal lesions (< 5 mm) with 50% DS were enrolled in the TRYTON studies. The effects of using TRYTON for carina reconstruction in long or diffuse SB disease was not studied. Of course, the current version of the TRYTON stent is a bare-metal stent, and whether a drug-eluting version will increase the beneficial effect of the TRYTON stent in large SBs remains to be demonstrated, although this seems biologically plausible. Finally, the cost-effectiveness of TRYTON compared with the PS approach or other two-stent strategies, especially in light of procedure time, contrast use, and other resource utilization, remains to be determined.

CONCLUSION

Taking into account all of the RCT and observational data, bifurcation PCI remains a challenge due to its unpredictable nature. In this regard, the TRYTON stent system is clearly a major step forward. In situations where the operator, based on clinical judgement in the context of available data, has determined the need for a two-stent strategy, the TRYTON dedicated

bifurcation stent system is technically simplistic, safe, and efficacious. ■

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