Percutaneous Treatment of Coronary Bifurcation Lesions
Is Simplicity the Ultimate Sophistication?
Leonardo De Luca, MD, PhD, FESC

Coronary bifurcations remain one of the most challenging lesions in interventional cardiology in terms of procedural success rate and long-term adverse cardiovascular events. Although numerous techniques and devices have been proposed to address the treatment of bifurcation lesions, there are 2 primary interventional strategies commonly used: one is a more complex approach that implies the systematic implantation of a stent in both the main vessel and the side branch (SB), and the other is the provisional T-stent, consisting in stenting the main vessel only, with the option to place a stent in the SB, if necessary. Provisional stenting often results in worse angiographic performances, but it offers several advantages compared with other more complex techniques: it is simple to perform in most cases, and it is associated with a lower rate of acute and late complications, as well as costs. Therefore, in clinical practice, the provisional approach is widely accepted as the default technique in the majority of bifurcation lesions.

In this issue of the Circulation: Cardiovascular Interventions, Hildick-Smith et al report the highly anticipated results of the EBC TWO Study (European Bifurcation Coronary TWO), a prospective, randomized, multicentre trial conducted in 6 European countries. This trial included patients with true bifurcation lesions in which both the main vessel and SB reference diameters were ≥2.5 mm and SB ostial disease was ≥5 mm in length. In this context, the authors did not observe any difference in the composite end point of death, myocardial infarction, or target vessel revascularization at 12 months between a provisional approach and a systematic culotte stenting, a technique that has been favorably compared with other 2-stent strategies. Although the EBC TWO enrolled the population with most complex bifurcation lesions (ie, large SB and long SB proximal disease) that has been individually studied in randomized trials dedicated on bifurcations (Table), the rate of major adverse cardiovascular events observed in the provisional stenting arm was considerably lower compared with previous studies (Table). Notably, this low outcome rate (7.7%) made the study underpowered because the expected incidence of clinical events assumed for the calculation of the sample size was unintentionally overestimated (25%) considering the larger calibre of SB included. The excellent performance of the provisional strategy might be explained by the novel stent with biolimus A9 drug and biodegradable polymer that has been used, the high rate of procedural and kissing balloon success, the larger stents used per protocol or the increased experience of operators, as confirmed by the particularly low rate of crossover from provisional to a 2-stent strategy observed in the present study.

As in the vast majority of trials on coronary bifurcation lesions, in this study provisional stenting was associated with a lower rate of periprocedural myocardial infarction compared with the 2-stent strategy, reasonably because of repeat instrumentation and dilatation of vessels in the more complex procedure. Notably, the inclusion of periprocedural biomarker release in composite primary end points of trials on bifurcation lesions has been largely debated because it might favor provisional stenting (especially in studies with an open design and without a central core laboratory analysis validation) and in many cases, it do not have an independent prognostic significance. Indeed, a difference in mortality between the 2 treatment strategies has never been demonstrated, even for bifurcation lesions with large diameter and extension, as in the EBC TWO trial (2.0% versus 1.1%; P=0.59). Similarly, in the Nordic-Baltic Bifurcation Study IV (data presented at EuroPCR 2015) that randomized 450 patients with true bifurcation lesions involving a large SB (≥2.75 mm) to provisional stenting or a 2-stent strategy (using the culotte technique in
65.5% of cases), the rate of cardiac death (0.9% versus 0.9%; \( P=0.96 \)) and all-cause death (2.3% versus 2.2%; \( P=0.95 \)) at 2 year was similar between the 2 groups. This lack of mortality difference might be ascribed to the scarce impact of bifurcation procedures on prognosis, to the low residual risk of patients enrolled in bifurcation trials, to their relatively small sample sizes or to the short duration of follow-up. Accordingly, a recent pooled patient-level data analysis from 2 large bifurcation trials with similar methodology with a 5-year follow-up suggested that a provisional approach is associated with lower all-cause mortality than a systematic dual-stenting technique (3.8% versus 7.0%; \( P=0.04 \)).

In conclusion, what the EBC TWO trial results have added to the flourishing literature on treatment of bifurcation lesions? We can summarize that, to keep the procedure simple and safe, provisional T-stenting should continue to be the default approach in the vast majority of true coronary bifurcation lesions, even when a large SB is involved. At the end, as Leonardo da Vinci said “simplicity is the ultimate sophistication.” However, an upfront 2-stent strategy, if done properly, remains a reasonable option in ≈10% of cases not suitable for provisional stenting and when SB patency is deemed essential by the operator considering overall patient clinical presentation and conditions, rather than quantitative angiographic parameters.

<table>
<thead>
<tr>
<th>Study</th>
<th>Patients</th>
<th>Two-Stent Strategy</th>
<th>Type of DES</th>
<th>Final KB</th>
<th>SB Diameter (Mean)</th>
<th>SB Lesion Length (Mean)</th>
<th>Follow-Up</th>
<th>MACE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pan et al2</td>
<td>91</td>
<td>T-stenting</td>
<td>SES</td>
<td>60% (P) vs 77% (2S)</td>
<td>2.5 mm (P) vs 2.5 mm (2S)</td>
<td>NA</td>
<td>6 mo</td>
<td>6.4% (P) vs 4.5% (2S); ( P=NS^* )</td>
</tr>
<tr>
<td>NORDIC3</td>
<td>413</td>
<td>Crush (50%), culotte (21%), other (29%)</td>
<td>SES</td>
<td>32% (P) vs 74% (2S)</td>
<td>2.6 mm (P) vs 2.6 mm (2S)</td>
<td>6.0 mm (P) vs 6.4 mm (2S)</td>
<td>6 mo</td>
<td>2.9% (P) vs 3.4% (2S); ( P=NS^* )</td>
</tr>
<tr>
<td>BBK4</td>
<td>202</td>
<td>T-stenting</td>
<td>SES</td>
<td>100% (P) vs 100% (2S)</td>
<td>2.4 mm (P) vs 2.4 mm (2S)</td>
<td>10.4 mm (P) vs 9.9 mm (2S)</td>
<td>12 mo</td>
<td>12.9% (P) vs 11.9% (2S); ( P=NS^* )</td>
</tr>
<tr>
<td>CACTUS4</td>
<td>350</td>
<td>Crush</td>
<td>SES</td>
<td>90% (P) vs 92% (2S)</td>
<td>2.2 mm (P) vs 2.3 mm (2S)</td>
<td>5.7 mm (P) vs 5.9 mm (2S)</td>
<td>6 mo</td>
<td>15.0% (P) vs 15.8% (2S); ( P=NS^* )</td>
</tr>
<tr>
<td>BBC ONE5</td>
<td>500</td>
<td>Crush (69%), culotte (31%)</td>
<td>PES</td>
<td>29% (P) vs 76% (2S)</td>
<td>NA</td>
<td>NA</td>
<td>9 mo</td>
<td>8.0% (P) vs 15.2% (2S); ( P=0.009^* )</td>
</tr>
<tr>
<td>DKCRUSH-II6</td>
<td>370</td>
<td>DK crush</td>
<td>SES</td>
<td>79% (P) vs 100% (2S)</td>
<td>2.3 mm (P) vs 2.4 mm (2S)</td>
<td>14.9 mm (P) vs 15.4 mm (2S)</td>
<td>12 mo</td>
<td>17.3% (P) vs 10.3% (2S); ( P=NS^* )</td>
</tr>
<tr>
<td>EBC TWO7</td>
<td>200</td>
<td>Culotte</td>
<td>BES</td>
<td>94% (P) vs 96% (2S)</td>
<td>2.6 mm (P) vs 2.7 mm (2S)</td>
<td></td>
<td></td>
<td>9.7 mm (P) vs 10.8 mm (2S)</td>
</tr>
</tbody>
</table>

BES indicates biolimus-eluting stent; BBC ONE, British Bifurcation Coronary Study: old, new and evolving strategies; BBK, Bifurcations Bad Krozingen; CACTUS, Coronary Bifurcations: Application of the Crushing Technique Using Sirolimus-Eluting Stents Study; DES, drug-eluting stent; DKCRUSH, double kissing crush; EBC, European Bifurcation Coronary; KB, kissing balloon; NA, not available; NS, not significant; PES, paclitaxel-eluting stent; SB, side branch; and SES, sirolimus-eluting stent.

*Death, emergency surgery, or acute myocardial infarction (MI).
†Cardiac death, MI, target vessel revascularization, and stent thrombosis.
‡Death, MI, and target lesion revascularization.
§Cardiac death, MI and target vessel revascularization.
║Stent diameter.
¶Death, MI, and target vessel failure.
#Death, MI, and target vessel revascularization.

References

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Key Words: Editorials • consensus • drug-eluting stent • myocardial infarction • percutaneous coronary intervention
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