

EDITORIAL COMMENT

Percutaneous Coronary Intervention Treatment of Bifurcation Lesions—A Work in Progress

The Importance of Single-Center Studies*

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Despite advances in interventional devices and techniques, bifurcation lesions continue to present a formidable challenge for the interventional cardiologist. Bifurcation lesions are frequently encountered and are associated with increased procedural time, risk, restenosis, and thrombosis (1–3). Furthermore, as the interventional community begins to focus on left main revascularization, the importance of treating bifurcation lesions will grow.

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The introduction of drug-eluting stents with its attendant restenosis reduction has led many investigators to reexamine stenting techniques for bifurcation lesions, many of which fell from favor in the bare-metal era. This has included re-examination of previously described techniques, such as, T stent, provisional T stent, culotte, and also has included the development of new “drug-eluting stent era” techniques, such as crush (and its variations) and simultaneous kissing stent/double barrel (4,5). The manuscript appearing in this edition of *JACC: Cardiovascular Interventions* from Galassi et al. (6), from Catania, Italy, presents their large, single center experience in the treatment of bifurcation lesions. As an active clinician, as well as someone involved in the development of a dedicated bifurcation stent who is planning a large randomized trial (7), this paper is of particular interest.

Galassi et al. (6) report outcomes in 369 consecutive patients with bifurcation lesions selected by the operator to

be treated with the “mini-crush” technique or a provisional treatment strategy. Six-month angiographic follow-up was obtained in nearly 80% of patients. All lesions were treated using drug-eluting stents (sirolimus [Cypher/Cypher Select Stent] or paclitaxel [Taxus Liberte Stent]) according to the strategy selected by the operator. The provisional strategy was selected in nearly half (47%) of patients followed by mini-crush in 37% of patients, with the remaining 16% receiving a mixture of other treatments (crush classic, culotte, and V stenting).

As would be anticipated, at baseline, patients in whom mini-crush was selected had higher risk angiographic characteristics, that is, Medina 1.1.1 and greater lesion length (in both main and side branch), than patients in whom a provisional strategy was selected. Both groups had similar procedural success rates. When the provisional strategy was selected, the side branch was stented 34% of the time. Despite having angiographic markers associated with poorer outcomes, patients treated with the mini-crush technique trended toward improved clinical outcomes and had improved angiographic outcomes with a 21% reduction in cumulative major adverse cardiac events (mini-crush: 20.6%, provisional: 26%, $p = \text{NS}$). Binary angiographic side branch restenosis was significantly reduced by 60% in the mini-crush group (8.5%) when compared with restenosis rates in patients treated with a provisional strategy (21.2%) ($p < 0.01$). With the increased complexity and cost of the mini-crush technique, one would expect that this technique would be reserved for higher risk patients

This investigation may be the largest series of its kind during the drug-eluting stent era and adds much to our understanding of the treatment of this difficult lesion subset. Rather than viewing this study as another inning in the ongoing rivalry between the provisional and mini-crush teams with a winner and loser, it might be more constructive to view these results as validating the ability of the operators in Catania, Italy, to select the correct treatment strategy for their patients.

When examining these data, it is important to highlight that this is not a randomized study. However, although randomized controlled trials remain a gold standard in clinical investigation, all too often data from single center series are inappropriately discounted. Large single center series such as the Catania series provide important information and help calibrate results from randomized studies evaluating treatments for bifurcation lesions, for example, Nordic (8), BBC ONE (British Bifurcation Coronary Study: Old, New, and Evolving Strategies) (9), and CACTUS (Coronary Bifurcation Application of the Crush Technique Using Sirolimus-Eluting Stents) (10) trials, by providing a glimpse into “real-world practice.”

Randomized trials comparing strategies for the treatment of bifurcation disease are particularly challenging. Angiographic tools for assessing bifurcation lesions are still evolv-

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ing. Though the Medina classification has provided a straightforward way to classify lesions, the reliability and prognostic capabilities of this tool have not been fully validated (11,12). Similarly, quantitative edge detection algorithms have recently been developed and are being assessed by leading core angiographic laboratories (12). The relatively small myocardial territory perfused by side branches make clinical events subtle and difficult to use as study end points. Finally, investigators are likely to be reluctant to enroll patients with a lesion when, in their personal judgments, there is not equipoise between the 2 test strategies, such as a Medina 1.1.1 lesion with a large side branch that is likely to require side branch stenting. The recently presented BBC ONE study (9) provides a good illustration. This large multicenter, randomized trial randomized 500 patients to a simple (stepwise T-provisional stenting) or a complex (crush or culotte) treatment strategy. Although the recruitment criteria were broad, both the long recruitment period (21 centers for 3 years) and the unexpectedly low use of side branch stent (2.8%) in patients assigned to the simple treatment strategy imply that these cases were highly selected. The concern is that patients with lesions at highest risk may not have been included (8).

For all these reasons, large series with angiographic follow-up as presented by the Catania group (6) contribute to our knowledge as we try to select the best therapy for our patients. Furthermore, these data highlight an important role for dedicated 2 stent strategies when treating high risk bifurcation lesions.

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