

EDITORIAL COMMENT

Can Quality-of-Life Analysis Aid in Substantiating Simple Over Complex Strategies for Bifurcation Lesions?*

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The strategies for percutaneous coronary intervention involving major anatomic bifurcations have been the subject of long debate as to whether complex 2-stent techniques are required or should simple provisional stenting strategy suffice. However, the debate seems to have settled following results from several randomized trials and registry studies (1–4). Although there are no formal guidelines on the strategies for bifurcation lesions, the current consensus from the European Bifurcation Club is to consider provisional stenting for most bifurcations. However, 2-stenting strategy is reserved for complex bifurcations, which involves large side branch with ostial disease extending >5 mm from the carina and the side branch subtending a greater degree of the myocardium (5). All the studies that have compared these 2 bifurcation strategies have focused on outcomes

See page 139

measured as hard and soft endpoints, with additional angiographic outcomes in some studies (1,2). Although we make our decisions considering these endpoints, it may be important to view the strategies from the patient's perspective and the impact on their functional status. However, none of the randomized studies on bifurcation has addressed this issue until now. The investigators of the BBC ONE (British Bifurcation Coronary; Old, New, and Evolving Strategies) study (6). In this issue of *JACC: Cardiovascular Interventions* have tried to give an additional dimension to this debate by measuring the functional status of patients

recruited for their study. In the original trial, 500 patients with bifurcation lesions were randomized to either simple provisional stenting versus complex (crush or culotte) 2-stent strategies. The primary endpoint (composite of death, myocardial infarction, or target vessel failure) at 9-month follow-up occurred more frequently in the complex stenting group, driven principally by a greater number of periprocedural myocardial infarctions (1). Sirker et al. present the prospectively performed quality-of-life analysis on these patients before the procedure and at 9-month follow-up. The analysis was performed using a well-validated and widely used scoring system (Seattle Angina Questionnaire), which assesses the broader spectrum of the disease impact on the patient's quality of life (7). The Seattle Angina Questionnaire has 5-separate scales, with each scale based on a group of questionnaires that explore the angina burden on the patient's daily activities and the patient's perception of the disease and the treatment received. The score on each scale ranges from 0 to 100 with low scores reflecting poorer levels of function.

The baseline scores were identical in both the groups with the mean scores of >60 for angina frequency and physical limitation scales. This implies that some patients scored high on the scale, indicating that they may not have had symptoms significant enough to justify percutaneous coronary intervention. It may be possible, such patients have had significant ischemia burden on the noninvasive test. However, the criteria for patient's selection are not provided either in this paper or the originally published study.

The main findings from the study were the following. 1) There was significant improvement in all aspects of the scores following percutaneous coronary intervention, except for treatment satisfaction, which showed a nonsignificant trend toward improvement ($p = 0.22$). Improvement occurred irrespective of the bifurcation strategy. 2) There were no significant differences in the scores at 9-month follow-up between simple and complex treatment groups. Furthermore, the analysis of change in the scores between follow-up and baseline did not differ significantly between the 2 groups. 3) The number of patients who were free of angina at follow-up was not significantly different (65.1% in the simple treatment group vs. 59.7% in the complex group; $p = 0.23$). 4) The drop in antianginal medications was similar between the 2 groups.

These results also support the findings that, although carina and/or plaque shift makes the ostium of the side branch appear pinched, most of them are not hemodynamically significant (as shown in the study by Koo et al. [8]). These results have motivated Sirker et al. (6) to make the final statement: "The lack of difference in symptomatic and functional outcomes between simple and complex approaches strengthens the argument that a default simple strategy is preferable in most cases, given its other proven advantages (reduced procedural duration, radiation dose,

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equipment costs, and so on).” However, this statement is probably strong, given some limitations of the study. First, as recognized by the authors, the follow-up is quite short (9 months) to detect all significant restenosis-causing symptoms in either group. In the previous studies that have used the Seattle Angina Questionnaire (COURAGE [Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation] and SYNTAX [Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery]), the assessments have been made at various time intervals (1, 3, 6, 12, 34, and 36 months with COURAGE and 1, 6, and 12 months with SYNTAX), which give a trend in the scores and is more likely to identify the potential differences in the treatment modalities (9,10). Therefore, it is necessary to demonstrate an absence of any differences in the quality-of-life assessment with further longer follow-up, which may then substantiate provisional stenting for most bifurcation lesions. Moreover, results from the main study were published over 2 years ago and did not show any significant differences in the endpoints (out-of-hospital myocardial infarction and revascularization) except for periprocedural myocardial infarction (1). So, it is not a surprise to notice an absence of any differences in the quality-of-life assessment, which were performed at the same time (9-month follow-up). Although, the study had >80% of patients with true bifurcation (as per Medina classification), the terminology “true bifurcation” does not fully describe the actual complexity of bifurcation as it does not incorporate the size of

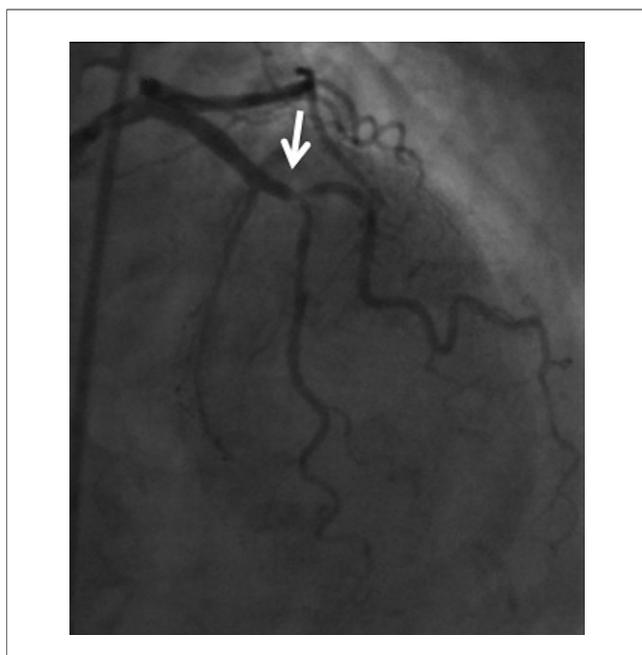


Figure 1. Simple True Bifurcation

Coronary angiography demonstrating simple true bifurcation (Medina class 111) with disease confined only to the ostium of the side branch (diagonal artery) (arrow).

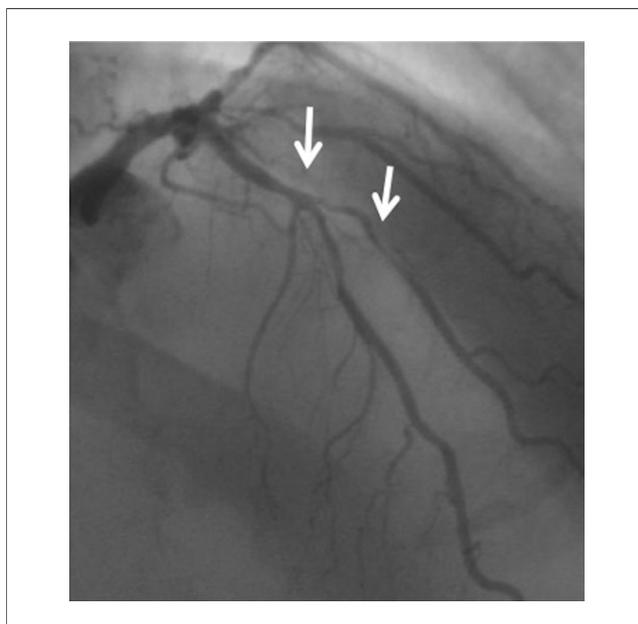


Figure 2. Complex True Bifurcation

Coronary angiography demonstrating complex true bifurcation (Medina class 111) with disease extending beyond the ostium into the side branch (arrows).

the side branch, extension of the lesion along the length of the side branch, and the degree of myocardial subtended (simple vs. complex true bifurcation, as demonstrated in Figs. 1 and 2). So, the representation of complex true bifurcation in the study is unknown, and probably such complex lesions are excluded from randomization inducing selection bias. The DKCRUSH-II (Double Kissing Crush Versus Provisional Stenting Technique for Treatment of Coronary Bifurcation Lesions) study probably had complex bifurcations as all lesions were true bifurcations with >80% in the Medina class 111. In addition, the mean length of side-branch lesions was approximately 15 mm in both groups, reflecting the complex true bifurcations. The results significantly favored 2-stent technique over provisional stenting, which indicated that 2-stent techniques are probably better in such complex bifurcations (11).

Although the results from the BBC ONE study claimed to substantiate provisional stenting strategy in most bifurcations, given its limitations, any additional value other than what is already known is debatable.

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