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Left main bifurcation treatment: is one stent enough?

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This commentary refers to 'The European bifurcation club Left Main Coronary Stent study: a randomized comparison of stepwise provisional vs. systematic dual stenting strategies (EBC MAIN)', by D. Hildick-Smith *et al.*, https://doi.org/10.1093/eurheartj/ehab283 and the discussion piece 'The stepwise provisional approach to left main stem bifurcations in Europe', by D. Hildick-Smith, https://doi.org/10.1093/eurheartj/ehac080.

With much interest we read the article by Hildick-Smith *et al.*[1] concerning stepwise provisional stenting vs. systematic dual stenting in patients with significant distal left main disease, recently published in the *European Heart Journal*. Patients were randomized to a provisional one-stent or a planned two-stent strategy, which could either be Culotte, double kissing (DK)-mini crush, T stenting, or T and protrusion. The study was powered to show superiority for the one-stent (14%) over the two-stent technique (25%) for the 1-year primary composite endpoint of death, myocardial infarction and target lesion revascularization, corresponding to a relative risk reduction of 44% (25–14/25) and a hazard ratio of 0.56. The actual event rate in the control group turned out to be much lower than foreseen and the study did not meet its primary endpoint (14.7% for one-stent vs. 17.7% for two-stent; hazard ratio 0.8, 95% confidence interval 0.5–1.3; $P = 0.34$). Despite these findings, the authors nevertheless concluded that the provisional one-stent strategy could be deemed the preferred strategy for distal left main bifurcation treatment. Is this justified?

Due to the lower than expected event rate in the control group, the study arrived at an exceptionally broad 95% confidence interval of 0.5–1.3. In other words, the study cannot exclude a 50% reduction nor a 30% increase in MACE with a one-stent technique. Notably, the study was also unable to exclude the 44% relative risk reduction in which the authors were aiming for. The inconclusive study results warrant a more modest interpretation than provided by the authors. Although the authors acknowledge the fact that the study was underpowered, they still recommend the one-stent strategy.

Why was the study underpowered? Clearly, the anticipated primary endpoint rate in the two-stent group was overestimated. According to the rationale and design paper of the study, the event rate in the two-stent group was based upon three studies published between 2008 and 2010, two registries and a randomized trial evaluating coronary artery bypass or percutaneous coronary intervention for the treatment of significant left main disease.[2] However, the randomized DKCRUSH III study (preceding the publication of the EBC MAIN rationale and design paper) reported a major adverse cardiac event rate of 16.3% for the Culotte technique and 6.2% for the DKCRUSH technique for the treatment of significant distal left main stenosis at 1 year,[3] suggesting a much lower event rate for two-stent technique. Hildick-Smith *et al*. thus expected a higher incidence of the primary endpoint in the comparator strategy than reported in recent literature. Hence, a high relative risk reduction was anticipated, and the sample size could remain relatively small. However, the investigators also took the risk of failure to reach the study endpoint, and they should have accepted this by drawing the appropriate conclusion.

Until now, the best evidence emanates from the DKCRUSH V trial which supports the use of a planned two-stent strategy with a DKCRUSH technique for the treatment of significant distal left main disease.[4]

Conflict of interest: none declared.

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