FFR- and Angiography-Guided Provisional Side Branch Stenting Offer Similar Benefits

Written by Maria Vinall

Results of the Comparison of FFR-guided and Angiography-guided Provisional Stenting for True Coronary Bifurcation Lesions: A Randomized, Multi-center Clinical Trial [DKCRUSH-VI] show that fractional flow reserve (FFR)-guided and angiography-guided provisional side branch (SB) stenting of true coronary bifurcation lesions are associated with similar rates of 1-year major adverse cardiac events (MACE). The DKCRUSH-VI trial is the first study to compare FFR-guided and angiography-guided stenting. The results were reported by Shao-Liang Chen, MD, Nanjing First Hospital, Lanzhou, China.

Angiographically guided provisional SB stenting after main vessel stenting is associated with favorable outcomes for the majority of coronary bifurcation lesions. FFR is the gold standard for the assessment of functional ischemia of a coronary lesion. The objective of DKCRUSH-VI was to compare the outcomes of FFR-guided and angiography-guided provisional SB stenting for true coronary bifurcation lesions.

The trial included 320 patients with true coronary bifurcation lesions (Medina 1,1,1, or 0,1,1), a SB ≥ 2.5 mm in diameter, and a lesion length in each branch that could be covered by 2 drug-eluting stents who were undergoing stenting with a provisional SB approach. Patients with a myocardial infarction (MI) < 1 month prior to the percutaneous coronary intervention (PCI) procedure and those with a left main disease bifurcation lesion with right coronary artery-chronic total occlusion not recanalized were ineligible for this study.

The primary end point was a composite of MACEs including cardiac death, MI, and target vessel revascularization (TVR). Secondary end points included cardiac death, MI, restenosis, stent thrombosis or target lesion revascularization (TLR), coronary artery bypass grafting (CABG), or TVR. Patients were randomly assigned 1:1 to an angiography-guided (n = 160) or an FFR-guided (n = 160) approach.

The proportions of patients with Medina 1,1,1 for the angiography and FFR groups were 86.8% and 82.5%, respectively. Baseline quantitative coronary arteriography (QCA) characteristics for the main vessel and SB were similar. Lesion length in the SB was shorter (nonsignificant) in the FFR group.

Side branch treatment (balloon or stenting) occurred in 56.3% of FFR cases vs 63.1% of angiography-guided cases ($P = .07$). Fewer stents were attempted in the FFR group (25.9% vs 38.1%; $P = .01$), but these were largely as successful as those in the angiography-guided group (77.3% vs 83.6%). There were no group differences for 1-year clinical outcomes for: cardiac death, MI, TLR, CABG, or TVR. The percentage of patients experiencing MACE was the same for both groups (18.1%). There were no significant differences in the Kaplan-Meier analysis of 1-year survival rates (Figure 1).

In a post hoc analysis, in-segment restenosis (defined as QCA distal segment [DS] > 50%) in the distal main vessel was significantly less frequent in the FFR group ($P = .01$; Table 1). However, in-segment restenosis in the side branch was significantly less frequent in the angiography group ($P = .037$; Table 1).

Limitations of the study include the use of an arbitrary FFR cutoff of < 0.80. In addition, the small difference in MACE between the 2 approaches cannot be excluded.

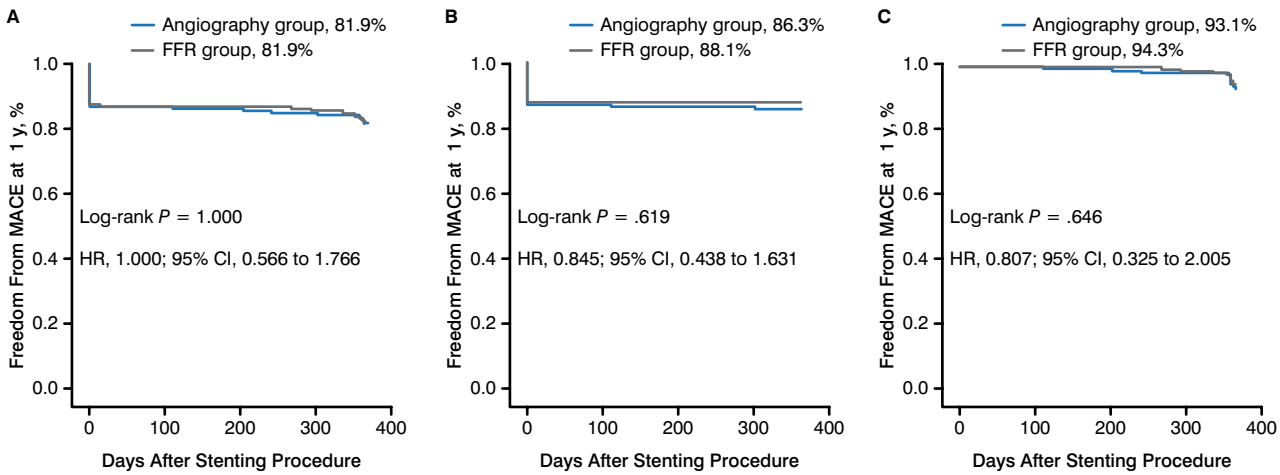
Prof Chen concluded that based on the results from the current multicenter randomized trial, FFR-guided and angiography-guided provisional stenting of true coronary bifurcation lesions are associated with similar rates of 1-year MACE, but FFR-guided SB lesion stenting holds the promise of fewer stents placement.

Peer-Reviewed Highlights From the

Transcatheter Cardiovascular Therapeutics Annual Meeting 2014

September 12–17, 2014
Washington, DC

Figure 1. Kaplan-Meier Analysis for 1-Year Survival



FFR, fractional flow reserve; MACE, major adverse cardiac events; TVR, transcatheter valve replacement.
A, Composite MACE. B, Myocardial infarction. C, TVR.
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Table 1. Distribution of Restenosis[a]

Location	Angiography Group	FFR Group	*P* Value
Proximal MV	4 (3.4)	2 (1.7)	.68
Distal MV	11 (9.2)	2 (1.7)	.01
Side branch	14 (11.8)	25 (21.2)	.037

FFR, fractional flow reserve; MV, main vessel.
[a]Using a post hoc definition.

Lower 30-Day Mortality After Early Stent Thrombosis With Bivalirudin vs Heparin

Written by Toni Rizzo

The risk of subacute (≤30 days) stent thrombosis (ST) is high after primary percutaneous intervention (PCI) for STEMI. HORIZONS-AMI [The Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction; Dangas GD et al. *Circulation.* 2011], EUROMAX [European Ambulance Acute Coronary Syndrome (ACS) Angiography Trial; Clemmensen P et al. *J Am Coll Cardiol.* 2014], and HEAT-PPCI [How Effective Are Antithrombotic Therapies in Primary Percutaneous Coronary Intervention; Shahzad A et al. *Lancet.* 2014] trials demonstrated an increased risk of acute ST (<24 hours) in patients treated with bivalirudin vs heparin with or without a platelet glycoprotein IIb/IIIa inhibitor (GPI).

George D. Dangas, MD, PhD, Mount Sinai Medical Center, New York, New York, USA, presented the results of a pooled analysis of the international, open-label HORIZONS-AMI and EUROMAX trials. The aim of the analysis was to determine the independent predictors for subacute ST and evaluate mortality after ST according to the antithrombotic therapy used for primary PCI. Patient data from both trials were pooled and analyzed. In both trials, patients were randomized to either bivalirudin or heparin ± GPI.

A total of 5800 patients with STEMI treated with primary PCI was included in the analysis. The baseline and procedural characteristics were similar in the bivalirudin and heparin ± GPI groups. Early ST occurred in 100 patients (1.7%), 20 (20%) of whom died within 30 days. A 1-day landmark analysis of early ST incidence (within 30 days) found an ST event rate of 1.3% in the bivalirudin group vs 0.2% in the heparin ± GPI group during the first 24 hours ($P < .0001$). There were no statistically significant differences in the incidence of ST after the first 24 hours up to 30 days in those patients treated with bivalirudin (0.9%) when compared with heparin ± GPI (1.2%; $P = .271$) groups.

A 4-hour landmark analysis demonstrated that the ST event rate was only significantly higher in the bivalirudin