

Randomized Comparison of FFR-guided and Angiography-guided Provisional Stenting for True Coronary Bifurcation Lesions: The DKCRUSH-VI trial

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On Behalf of the DKCRUSH-VI Investigators

Disclosure statement of financial interest

Within the past 12 months, I or my spouse/partner have had no any financial interest/arrangement or affiliation with the organization(s).

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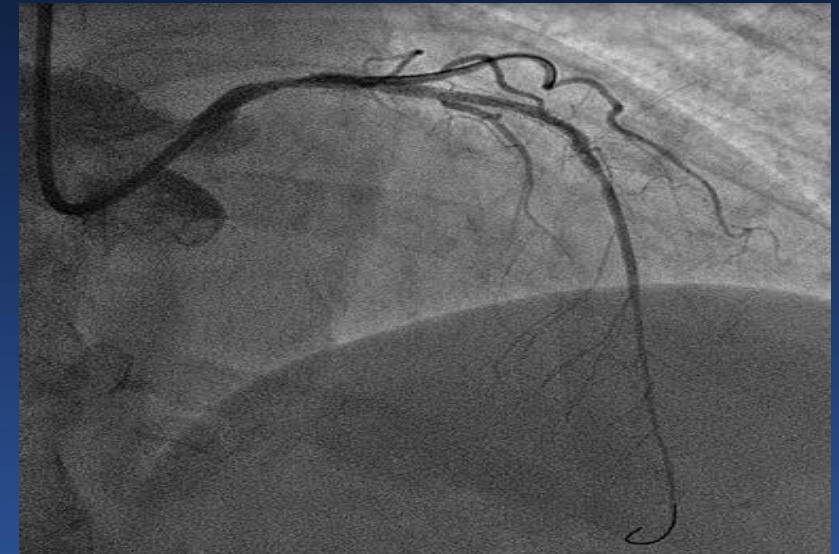
I, (Dr. Shao-Liang Chen) DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

Background

- ◇ **Angiography-guided provisional side branch (SB) stenting after main vessel stenting provides favorable outcomes for the majority of coronary bifurcation lesions.**
- ◇ **Fractional flow reserve (FFR) is the gold standard to assess functional ischemia of a coronary lesion**
- ◇ **Whether an FFR-guided provisional stenting approach is superior has not been studied.**

Objectives

To compare the outcomes of FFR-guided and angiography-guided provisional SB stenting (TAP technique) for true coronary bifurcation lesions



Study design

Medina 1,1,1/0,1,1 bifurcation lesions, SB \geq 2.5 mm

FFR group (n=160)

Angio group (n=160)

- DKCRUSH-VI study
- ChicTR-TRC-00000015
- PI: Dr. Shao-Liang Chen
- Dr. Gregg W Stone
- 8 centers
- Independent Committee
- Core Lab.: CCRF

Jailed wire, MV Stenting

SB FFR $<$ 0.8

Ostial SB: DS $>$ 70%, B/C dissection, TIMI $<$ 3

No

If yes, Kissing balloon inflation

No

If still yes, SB Stenting, FKBI

1-year clinical/13-m angio F/U

Major Inclusion criteria

- ◇ **Medina 1,1,1/0,1,1 bifurcation lesions**
- ◇ **Side branch ≥ 2.5 mm in diameter**
- ◇ **Lesion length in each branch could be covered by 2 DESs**

Exclusion criteria

- ◇ **MI <1 month** prior to PCI procedure;
- ◇ **LVEF <30%; eGFR <40 ml/min/1.73 m²;**
- ◇ **LMd bifurcation lesion with RCA-CTO not recanalized;**
- ◇ **Heavy calcification requiring rotational atherectomy;**
- ◇ **Previous CABG or PCI for the target vessel <6-m;**
 - ◇ **Planned surgical procedure during the first 6-m after enrollment;**
- ◇ **Stroke within 6 months;**
- ◇ **Contraindication or suspected intolerance to any study drug;**
- ◇ **Liver dysfunction; pregnancy; expected lifespan of <1 year**

Endpoints of the Study

▲ **Primary endpoint: composite major adverse cardiac event (MACE), including cardiac death, MI, and TVR**

▲ **Secondary endpoints:**

--- **cardiac death**

--- **MI: defined as CK-MB > 3-fold the 99% URN**

--- **TLR, CABG, TVR**

--- **restenosis**

--- **stent thrombosis**

Estimation of patient sample

- ◇ **We hypothesized that the rate of concurrent MACE:
5% in the FFR group
15% in the Angio group**
- ◇ **80% power (Type II error =0.20, $\alpha=0.05$, 2-sided tailed)**
- ◇ **A total sample size of 300 (150 patients/per group)**
- ◇ **5% (n=15) loss to follow-up**
- ◇ **Finally, 160 patients/per group.**

Results (1a): Baseline characteristics

	Angio group (n=160)	FFR group (n=160)	p
MI≥1-m, n (%)	25 (15.6)	28 (17.5)	0.64
Diabetes, n (%)	43 (26.9)	48 (30)	0.62
MVD, n (%)	110 (68.7)	112 (69.8)	0.82
LMd bif., n (%)	14 (8.8)	15 (9.4)	0.68
Medina 1,1,1, n (%)	139 (86.8)	132 (82.5)	0.30
CTO, n (%)			
MV	13 (8.1)	14 (8.8)	0.84
SB	6 (3.8)	3 (1.9)	0.50
TIMI <3, n (%)			
MV	21 (13.1)	20 (12.2)	0.54
SB	5 (3.1)	8 (5.0)	0.51

Results (1b): Baseline QCA

	Angio group (n=119)	FFR group (n=118)	p
Main vessel			
Bifurcation angle °	48.8 ± 18.8	52.5 ± 20.4	0.59
Lesion length, mm	31.0 ± 19.3	30.5 ± 15.5	0.82
RVD – prox, mm	2.94 ± 0.41	2.92 ± 0.41	0.69
DS% – prox	55.4 ± 5.3	56.1 ± 7.4	0.45
RVD – distal, mm	2.46 ± 0.36	2.48 ± 0.35	0.66
DS% – distal	55.9 ± 2.3	54.6 ± 2.2	0.67
Side branch			
Lesion length, mm	12.8 ± 8.4	11.9 ± 8.7	0.39
RVD, mm	2.28 ± 0.29	2.23 ± 0.30	0.21
DS%	57.8 ± 3.9	57.6 ± 4.4	0.08

Results (2): Procedural findings

FFR group (n=160)

Angio group (n=160)

Stenting MV(100%)

Measuring SB-FFR

SB stenting in 61 (38.1%) patients

Success (n=145, 90.6%)

Failure (n=15)

Success
(n=51, 83.6%)

Failure
(n=10, 16.4%)

FFR \geq 0.8
(n=70)

FFR<0.8
(n=75)

KBT

FFR \geq 0.8
(n=49)

FFR<0.8
(n=26)

KBI

FFR<0.8(n=4)

FFR \geq 0.8(n=8)

Failure(n=3)

Stenting SB (success in 22, 77.3%; failure in 8, 22.7%)

SB PCI, any: 56.3%

SB stenting attempted: 25.9%

P=0.07

P=0.01

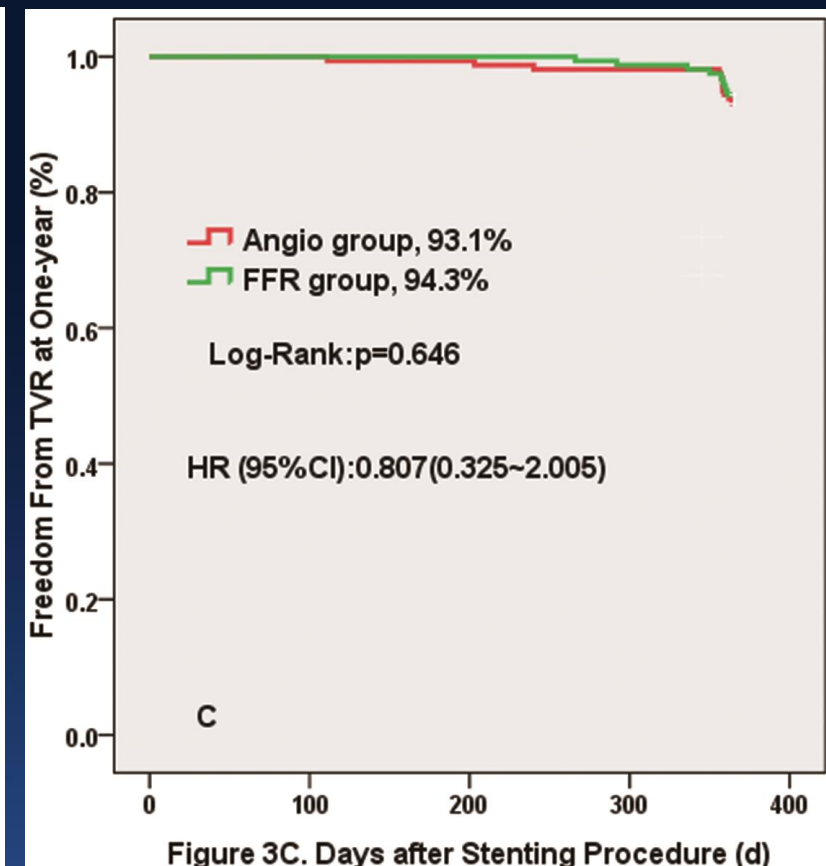
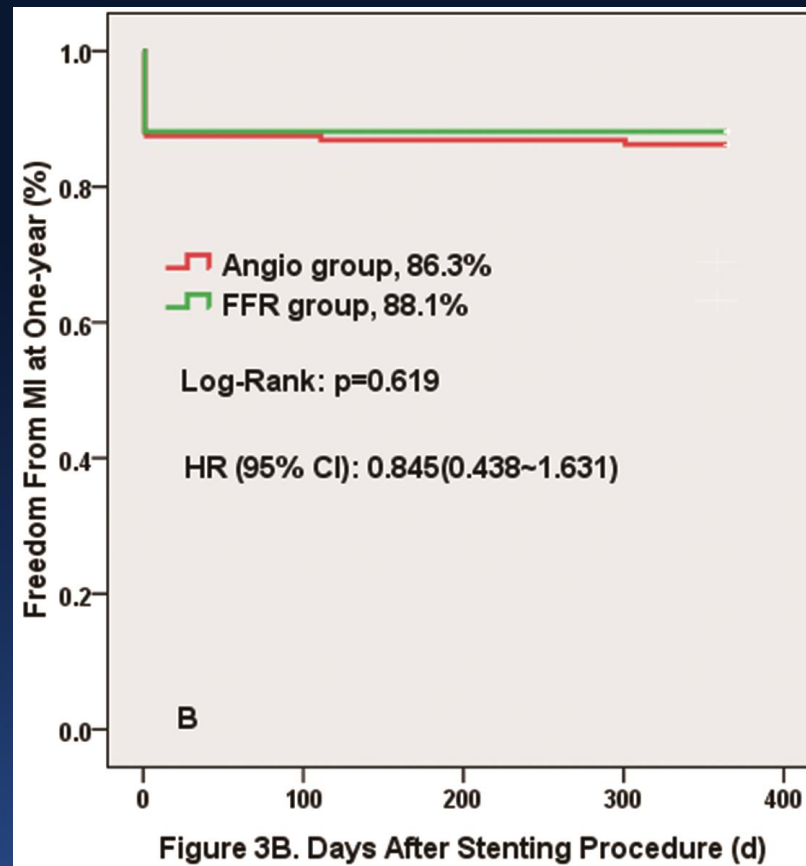
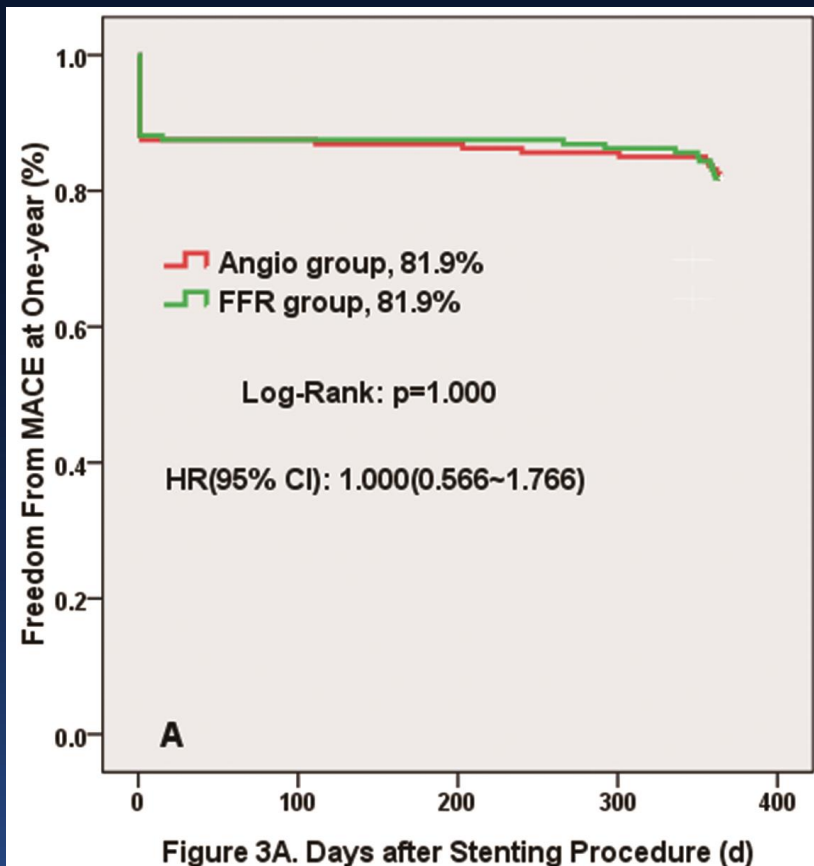
SB PCI, any: 63.1%

SB stenting attempted: 38.1%

Results (3): One-year clinical outcomes

	Angio group (n=160)	FFR group (n=160)	p
Cardiac death, n(%)	1 (0.6)	2 (1.3)	0.56
MI, n(%)	22 (13.8)	19 (11.9)	0.74
TLR, n(%)	8 (5.0)	5 (3.1)	0.57
CABG, n(%)	0	0	-----
TVR, n(%)	11 (6.9)	9 (5.6)	0.82
MACE, n(%)	29 (18.1)	29 (18.1)	1.00
ST-def/prob, n(%)	2 (1.3)	1 (0.6)	0.56

One-year Survival rate by Kaplan Meier analysis



Composite MACE

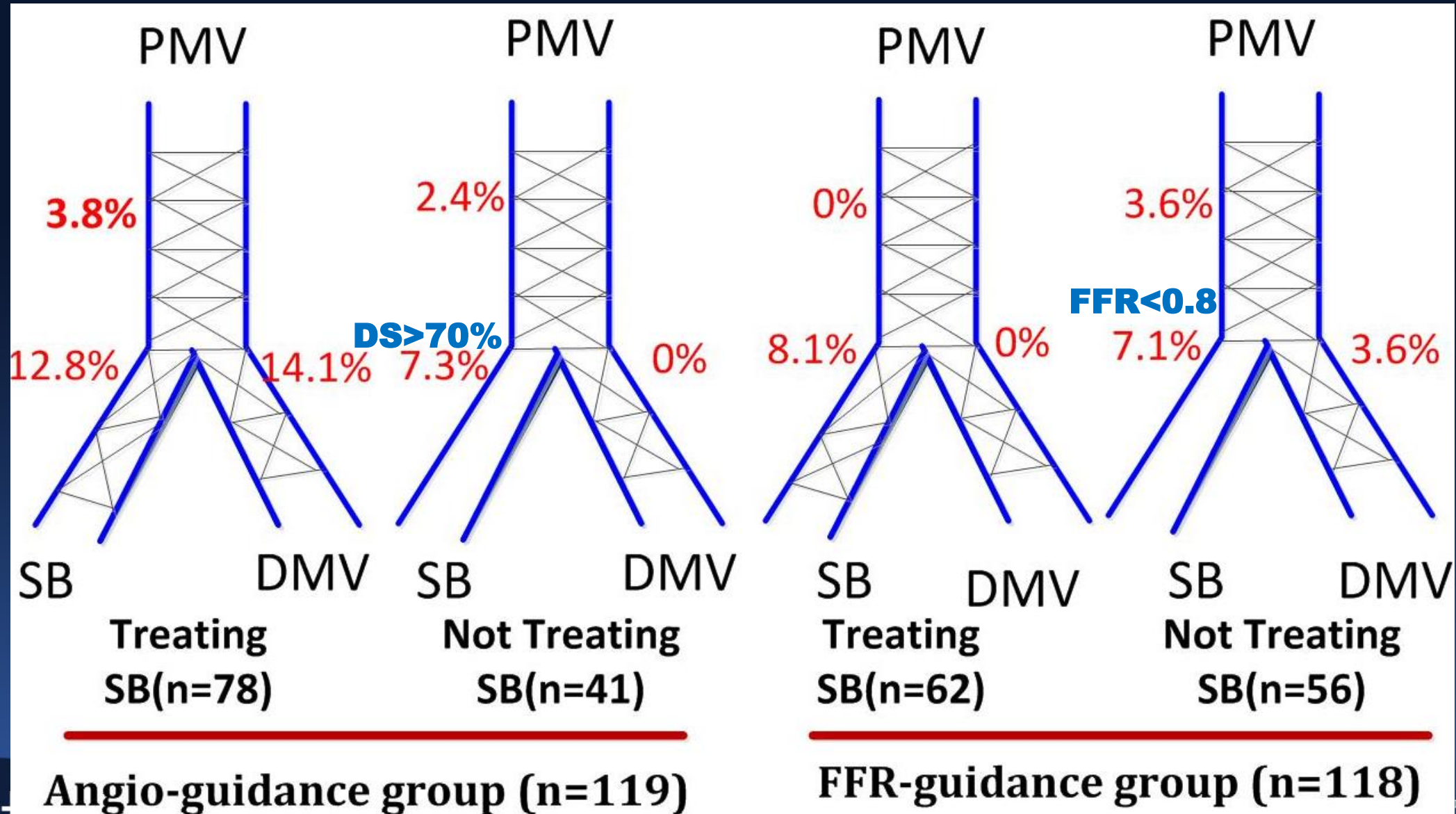
Myocardial Infarction

TVR

Results (4): Definition and distribution of restenosis

- ◇ In both the Angio and FFR groups, ISR in the PMV, DMV and stented SB was defined as a QCA DS $>50\%$;
- ◇ In the Angio group, ISR in a non-stented SB was defined as a QCA DS $>70\%$;
- ◇ In the FFR group, restenosis in a non-stented SB was defined as follow-up FFR <0.80 (i.e. **FFR-restenosis**).
- ◇ In a post hoc analysis for all SB lesions, restenosis was defined as a QCA DS $>50\%$.

Distribution of restenosis: Pre-specified definition



Distribution of restenosis: Post hoc definition

Post hoc analysis of in-segment restenosis*

Location	Angio group	FFR group	<i>p</i>
Proximal MV	4 (3.4)	2 (1.7)	0.68
Distal MV	11 (9.2)	2 (1.7)	0.01
Side branch	14 (11.8)	25 (21.2)	0.037

* defined as a QCA DS>50%; Segment=stented+P/D 5-mm MV, main vessel

Limitations

- ◇ **FFR cutoff of ≤ 0.80 was somewhat arbitrarily chosen**
- ◇ **Small difference in MACE between the 2 approaches cannot be excluded**
- ◇ **Further study is required in very complex bifurcations**

In conclusion

- ◇ **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**
- ◇ **Side branch is happy because of not owning stock of FFR**

Thanks for your attention !