



How to Predict the Risk of Side Branch Occlusion during Bifurcation Intervention: From RESOLVE to CIT-RESOLVE Trial

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Provisional Stenting vs. 2-Stent Strategy

Nordic ¹ in 2006	413	Stenting MV+SB vs. Stenting MV only	A strategy of stenting the main vessel only, with optional stenting of the side branch is preferred.
BBK ² in 2008	101	Routine T-stenting vs. Provisional T-stenting	Routine T-stenting with SES did not improve the angiographic outcome.
Cactus ³ in 2009	350	Crush technique vs. Provisional SB stenting	A provisional strategy of stenting the main branch only is effective.
BBC-one ⁴ in 2010	500	Culotte or crush techniques vs. Stenting MV+KBD/T-tenting	The provisional technique should remain the preferred strategy in the majority of cases.
DKCRUSH-II ⁵ in 2011	370	DK crush vs. Provisional SB stenting	DK crush was associated with a significant reduction of TLR and TVR

MV=main vessel; SB=side branch;
KBD=kissing balloon dilatation

- 1.Circulation. 2006 Oct 31;114(18):1955-61.
- 2.Eur Heart J. 2008 Dec;29(23):2859-67.
- 3.Circulation. 2009 Jan 6;119(1):71-8.
- 4.Circulation. 2010 Mar 16;121(10):1235-43.
- 5.J Am Coll Cardiol. 2011 Feb 22;57(8):914-20.



Incidence of SBO in Provisional-stenting

- **Fuwai hospital: 7.37%¹**
- **Other centers : 8.4%-19.0%²⁻⁴**

Provisional stenting cannot fix all bifurcation lesions

1. JACC Cardiovasc Interv. 2015;8(1):39-46.
2. J Am Coll Cardiol. 2013;62:1654-1659.
3. Am Heart J. 2006;151:153-157.
4. Am J Cardiol. 1997;80:994-997.

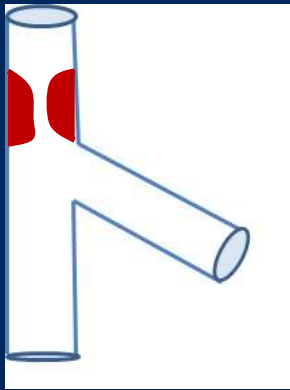
DEFINITION STUDY: Independent factors of MACE at 1yr in training group

	<i>P</i>	Sen (%)	Spe(%)
Major 1: LMd bif: SB-DS \geq 70%, SB lesion length \geq 10mm	<0.001	80	72
Major 2: Non-LMb: SB-DS\geq90%, SB lesion length \geq 10mm	<0.001	80	74
Minor 1: Moderate to severe calcification	0.002	64	65
Minor 2: Multiple lesions	0.007	68	60
Minor 3: Bifurcation angle $< 45^0$	0.004	64	53
Minor 4: Main vessel RVD < 2.5mm	0.010	69	58
Minor 5: Thrombus-containing lesions	0.002	66	64
Minor 6: MV lesion length ≥ 25 mm	0.010	57	66
Major 1 + any 2 Minor 1-6 = complex	-----	87	83
Major 2 + any 2 Minor 1-6 = complex	-----	88	83

BL complexity score

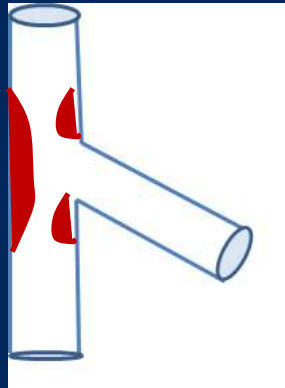
Lesion Morphology : 1,0,0

Lesion Score = 1



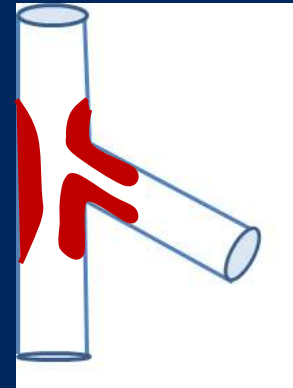
Lesion Morphology : 1,1,0

Lesion Score = 2



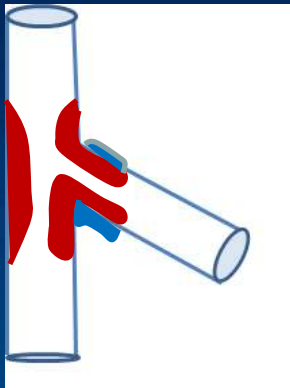
Lesion Morphology : 1,1,1

Lesion Score = 3



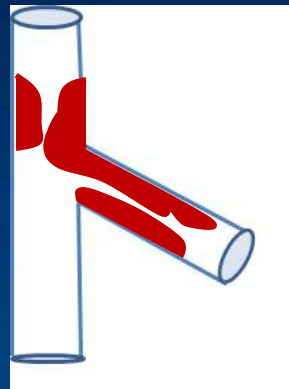
Lesion Morphology : 1,1,1C

Lesion Score = 4



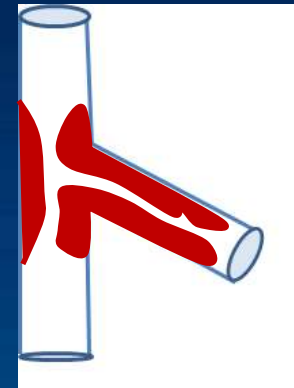
Lesion Morphology : 1,0,4

Lesion Score = 5



Lesion Morphology : 1,1,4

Lesion Score = 6



5/87



Current commonsense on risk factors of SBO

- True bifucation¹
- Diameter stenosis of MV and SB²
- Lesion length of SB³
- Lower bifurcation B angle⁴

1. Aliabadi D, et al. Am J Cardiol. 1997;15:80(8):994-7.

2. Steigen TK, et al. Circulation. 2006;114:1955-61.

3. Hahn JY, et al. J Am Coll Cardiol. 2013;62:1654-9.

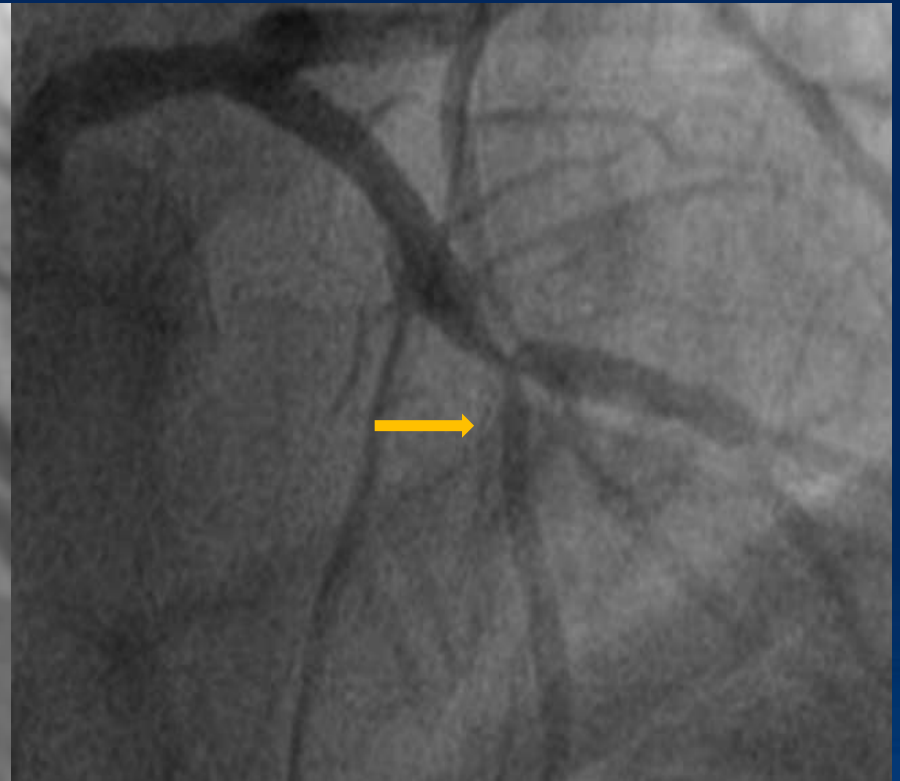
4. Kang SJ, et al. Circ Cardiovasc Interv. 2011;4(4):355-61.

SBO CASE



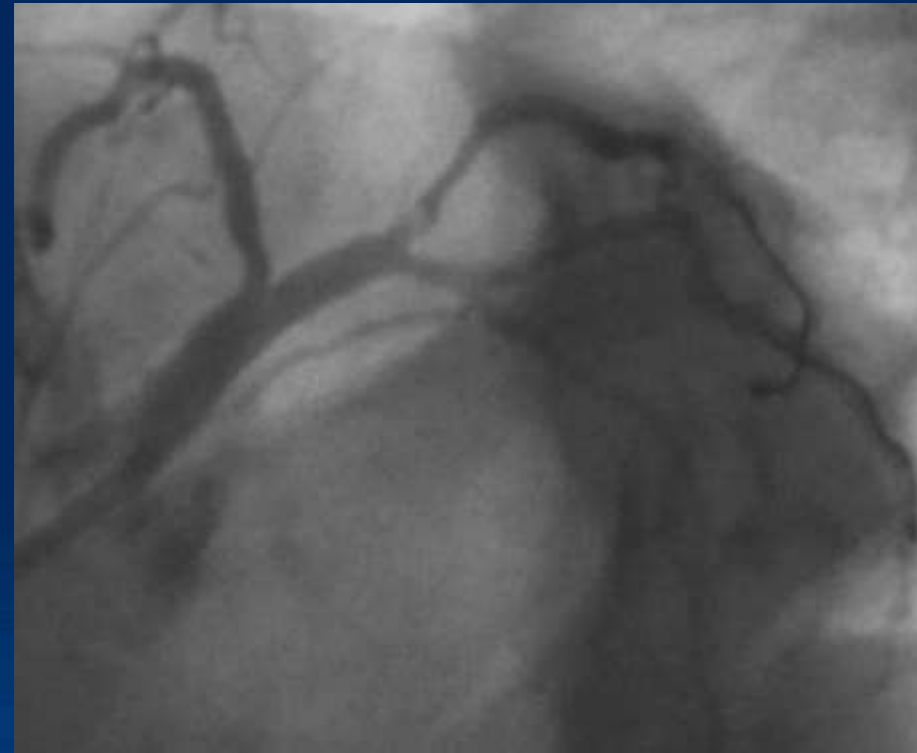
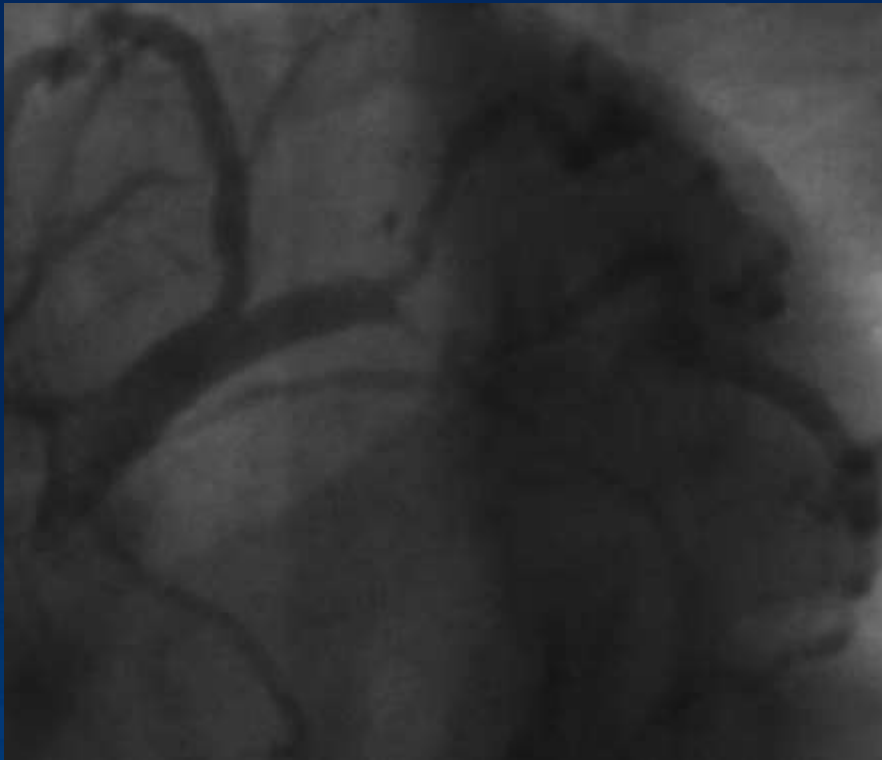


True bifurcations are different





Diameter stenosis always change





Data from subgroup analysis of RESOLVE study

Around 20% of 301 TBLs became non-TBLs

	Baseline DS (%)	DS after predilation(%)	p
Proximal MV	58.15 ± 26.13	43.17 ± 18.93	p<0.01
Bifurcation core	46.25 ± 28.02	32.83 ± 21.02	p<0.01
Distal MV	55.46 ± 23.89	42.70 ± 18.00	p<0.01
SB	53.65 ± 19.33	45.26 ± 21.49	p<0.01



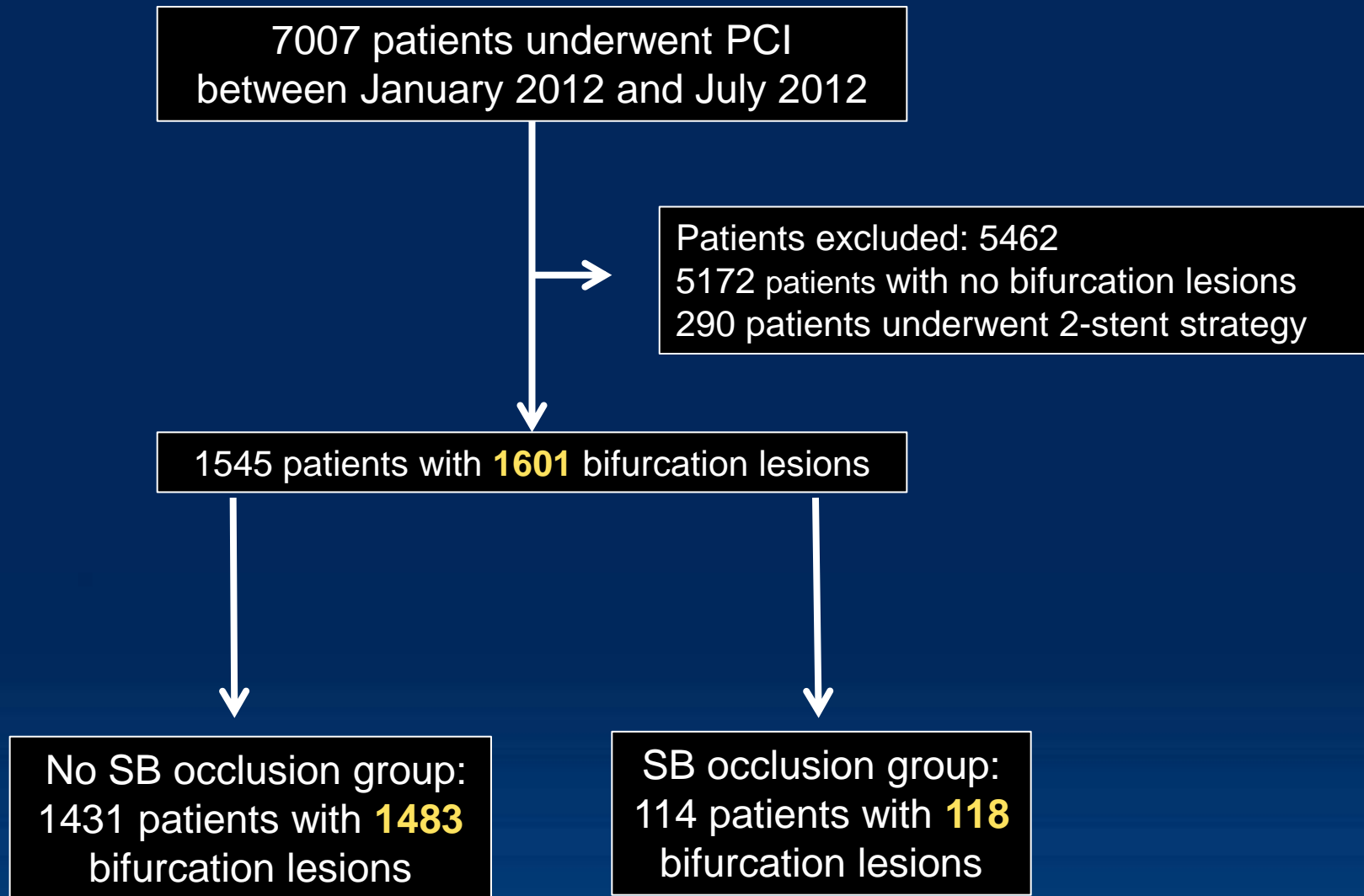
How bifurcation angle impact fate of SB?

	N	conclusion
Gil et al in 2009	92	Irrelevant
Kang et al in 2011	23	Smaller angle related to SBO
Gwon et al in 2012	44	Irrelevant
Hahn et al in 2013	2227	Irrelevant
Fujino et al in 2014	75	Smaller angle related to SBO
ZHANG et al in 2014	1200	Wider angle related to SBO

Before Strategy Selection.....

- More comprehensive and precious evaluation of SBO is needed
- Bifurcation should be classified as complex or simple, risky or non-risky

RESOLVE study



RESOLVE Score

Predictors	Level	Point	Predictors	Level	Point
1.Plaque distribution	opposite side of SB	0	4.Pre-procedural diameter stenosis of bifurcation core(%)	<50	0
	same side of SB	1		[50,70)	2
2.MV TIMI flow grade before stenting	TIMI III	0		≥70	3
	TIMI II	6	5.Bifurcation angle	<70	0
	TIMI I	11		[70,90)	4
	TIMI 0	17		≥90	6
3.Diameter ratio between MV/SB	<1.0	0	6.Diameter stenosis of SB before MV stenting (%)	<50	0
	[1.0,1.5)	2		[50,70)	4
	[1.5,2.0)	6		[70,90)	6
	≥2.0	9		≥90	7

Dou K, et al. JACC Cardiovasc Interv. 2015 8(1):39-46.

Zhang D, et al. CCI ,2015;85(1):705-716

Editorial Comment

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EDITORIAL COMMENT

When You Ask Yourself the Question “Should I Protect the Side Branch?”: The Answer Is “Yes”*



Antonio Colombo, MD,[†] Neil Ruparelia, DPM,[‡]

sequent stent implantation if required.

Although the risk score developed by the authors is interesting, we doubt that operators will try to calculate the specific score routinely prior to or during a procedure. However, further examination of the characteristics of the SB that occluded provides important information with regard to defining “high-risk” lesions and optimizing management strategy. The authors found that a high plaque burden (Medina classification 1 1 1) Thrombolysis In Myocardial

V-RESOLVE STUDY FLOWCHART

1601 bifurcation lesions enrolled in RESOLVE study



Visual estimation by independent observer who is blind to QCA analysis and incidence of SB occlusion



Analyzing validity and variability between visual estimation and QCA analysis

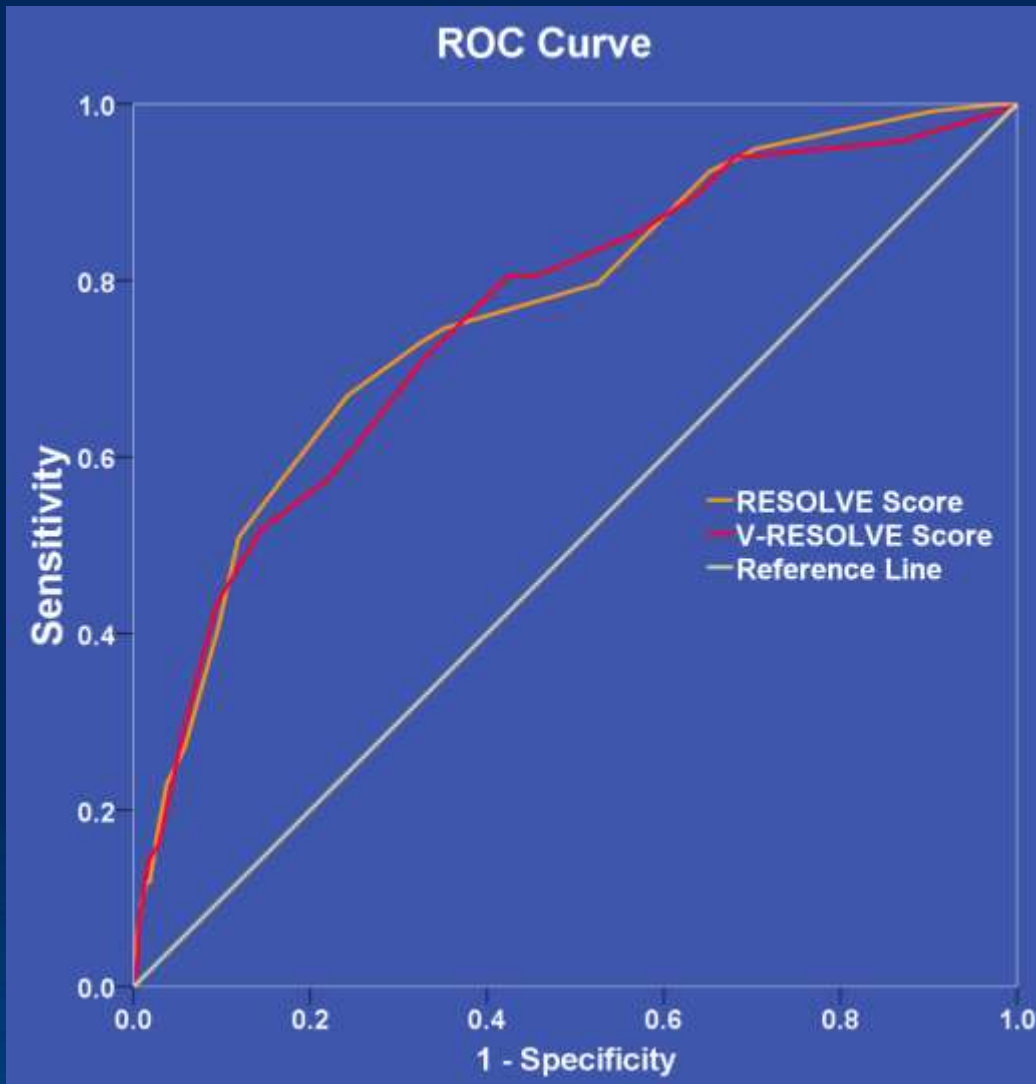


Rebuilt the RESOLVE score by all using visual estimation data



Test and validate the V-RESOLVE score

ROC Curve

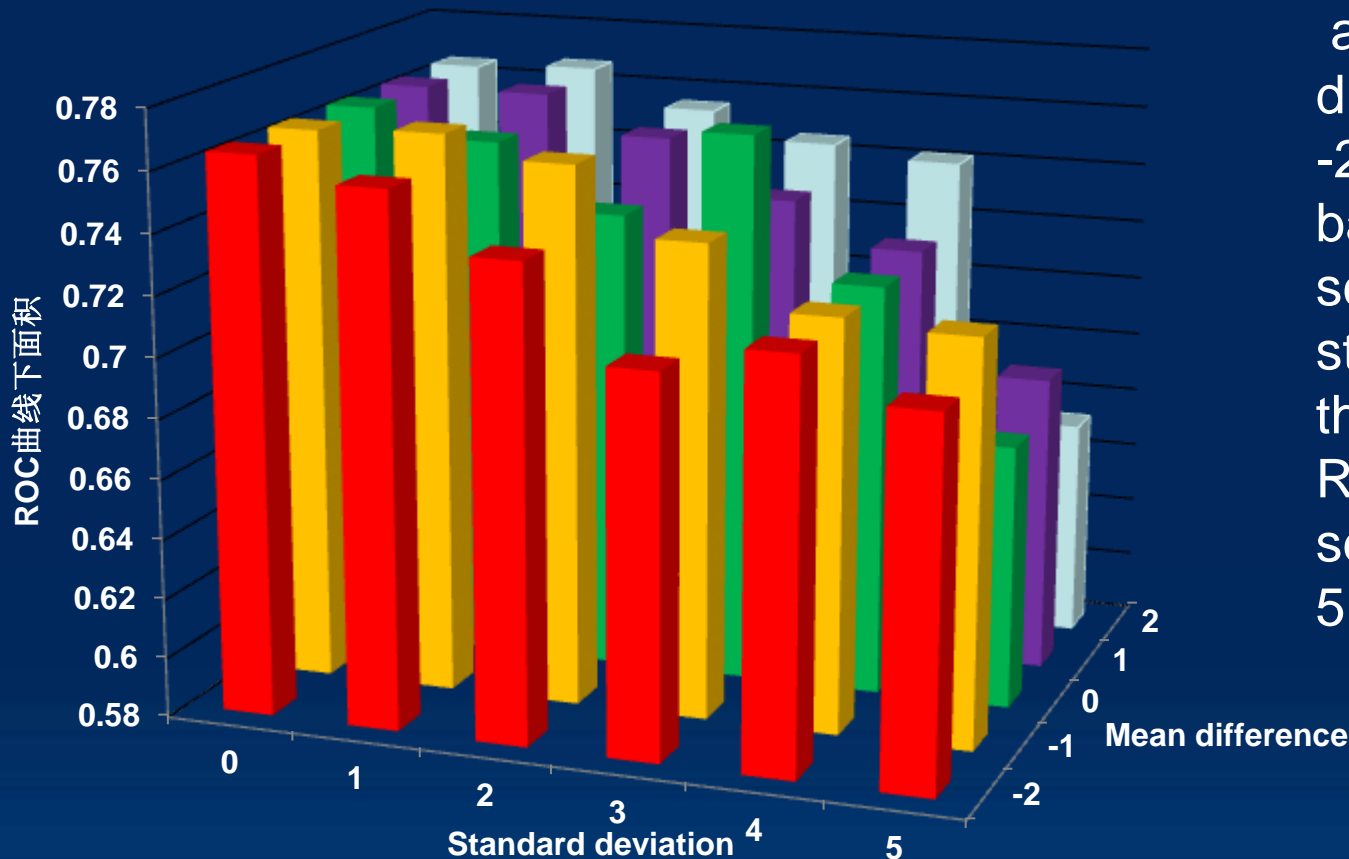


Area under curve (AUC) of RESOLVE score: **0.77**
(95% confidence interval [CI]: **0.72 to 0.81**)

AUC of V-RESOLVE score: **0.76** (95% CI: **0.71 to 0.80**)

	NRI or IDI	P value
NRI	-0.154	0.11
IDE	-0.009	0.42

Statistical simulation of 30 different observers



an average absolute difference range from -2 to 2 with the QCA-based RESOLVE score, and the standard deviation of the calculated V-RESOLVE score was set to range from 0 to 5.

The c-statistic of the V-RESOLVE score ranged from 0.65 to 0.77, with all $p < 0.01$.

Risk groups compare with RESOLVE score

		V-RESOLVE score	RESOLVE score	P
Low and intermediate risk group	Range	0-11	0-9	
	Quartile	I II III	I II III	
	Rate of SB occlusion	4.32% (52/1205)	3.35% (39/1163)	0.22
High risk group	Range	12-43	10-43	
	Quartile	IV	IV	
	Rate of SB occlusion	16.67% (66/396)	18.04% (79/438)	0.60

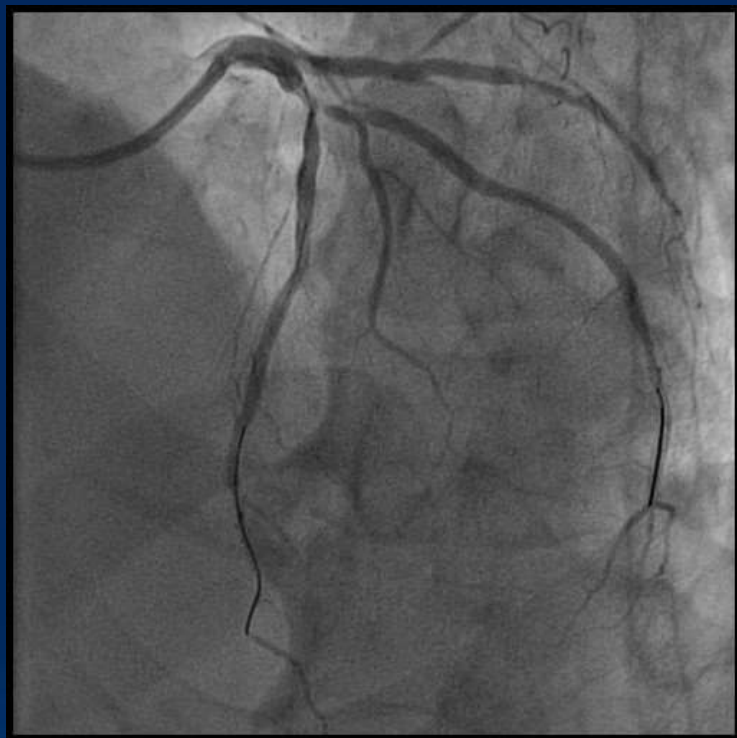
Dou KF, Zhang D, Xu B, et al. EuroInterv. 2016;11(14):1604-1611.

Dou K, Zhang D, Xu B, et al. JACC Cardiovasc Interv. 2015;8(1):39-46

Case ---Baseline angiography



Case ---Angiography after pre-dilation



Plaque distribution---at the same side of SB:	1
MV TIMI flow grade---TIMI III:	0
Diameter stenosis of bifurcation core (%) --- $\geq 70\%$	3
Bifurcation angle- 70° - 90° :	4
Diameter ratio between MV/SB---[1-1.5):	2
Diameter stenosis of SB--- $\geq 90\%$:	7

Total score: 17---high risk of SB occlusion

Case ---Final result after crush stenting



A Randomized **C**omparison of **C**onventional
Versus **I**ntentional **S**tra**T**egy in Patients with
High **R**isk **P**re**D**iction of **S**ide Branch **O**cc**L**usion
in Coronary Bifurcation Inter**V**ention:
The **CIT-RESOLVE** trial
(NCT02644434)

Trial design

- Prospective
- Randomized
- Multi-center
- Single-blinded

Objectives

- To investigate whether **intentional strategy** is associated with significant reduction of side branch occlusion rate compared to **conventional strategy** in patients at high risk of side branch occlusion (**V-RESOLVE score ≥ 12**)

Study population

Inclusion criteria

- Subjects have coronary bifurcation lesions requiring PCI with stent implantation according to clinical guidelines and/or the operator's judgement;
- Visually estimated reference vessel diameter (RVD) of target main vessel ≥ 2.5 mm and ≤ 4.0 mm;
- Visually estimated RVD of target side branch ≥ 2.0 mm;
- Coronary anatomy is likely to allow delivery of a study device to the target lesion(s);
- V-RESOLVE score ≥ 12 points.

Exclusion criteria

- Left main lesions;
- In case of acute myocardial infarction (MI) of which the culprit vessel located at the left anterior descending coronary artery (LAD), the bifurcation lesion (LAD/diagonal branch [RVD >2.5 mm]) which is proximal to occluded LAD segment should be excluded.

Arms

- **Conventional strategy group:**
 - Provisional two-stent strategy
 - Jailed wire technique
- **Intentional strategy group:**
 - Primary two-stent strategy
 - Jailed balloon technique



Sample size Calculation

- 283 subjects in intentional strategy group and 283 in conventional strategy group, and the total number will be 566:
 - A 1:1 treatment allocation ratio of intentional strategy group and the conventional strategy group
 - A two-side significance level (alpha) of 0.05
 - 80% power to show differences in the rate of SB occlusion between intentional strategy group and conventional strategy group
 - The rate of SB occlusion in intentional strategy group: 4.0%
 - The rate of SB occlusion in conventional strategy group: 10.0%
 - The primary endpoint would be reached immediately after the main vessel stenting, therefore, the attrition rate is 0%
 - Sample size formula:

$$\frac{\left[\mu_{1-\alpha/2} \sqrt{2\bar{p}(1-\bar{p})} + \mu_{1-\beta} \sqrt{p_T(1-p_T) + p_C(1-p_C)} \right]^2}{(p_T - p_C)^2}$$

Endpoints

- Primary endpoint
 - Side branch occlusion after MV stenting
- Secondary endpoints
 - Elevation of biomarkers of peri-procedural myocardial injury (CK-MB and Troponin)
 - 12-month major adverse cardiac events

Thank you for
your attention!