What Really Matters in Bifurcation PCI; Technique or Concept ?

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Bifurcation PCI How To Do ?

- Lots of bench tests and simulation studies generated lots of hypothesis and concerns.
- 2. Lots of different device and different technical Issues.
- 3. Why not more functional concept?







Non-LM Bifurcation PCI How To Do ?

1. 1 stent with provisional stenting
 2. 2 stent strategy







Meta-Analysis of 12 Major Studies, 6961 Pts 1 stent with provisional stenting is Better !

C

DES Thrombosis

Myocardial Infarction

n						5									
Study	Year	DDS	SDS	DDS better	SDS better	Weight*	RR (random) 95% Cl	Study	Year	DDS	SDS	DDS better	SDS better	Weight*	RR (random) 95% C
RANDOMIZE	D, CONT	ROLLED	TRIALS					RANDOMIZE	, CON	TROLLED	TRIALS				
NORDIC	2008	1/196	2/199		++-	5.37%	0.50 (0.04-5.55)	NORDIC	2008	39/196	20/199			16.86%	1.97 (1.19-3.26)
Ferenc et al.	2008	2/101	1/101	1		5.40%	2.00 (0.18-21.71)	Ferenc et al.	2008	2/101	1/101		+	1.80%	2.00 (0.18-21.71)
CACTUS	2009	3/177	2/173	_		9.73%	1.48 (0.24-8.66)	CACTUS	2009	19/177	15/173	-	-	13.48%	1.28 (0.65-2.35)
BC-ONE	2010	5/249	1/248			6.71%	4.97 (0.58-42.31)	BBC-ONE	2010	28/249	9/248		+	11.76%	3.09 (1.49-6.43)
K-CRUSH-II	2011	4/185	1/185			6.45%	4.00 (0.45-35.44)	DK-CRUSH-II	2011	6/185	4/185		-	5.59%	1.50 (0.43-5.22)
IETA-ANALY	SIS	15/908	7/906		+		2.01 (0.77-5.23)	META-ANALY	SIS	94/908	49/906		+		1.88 (1.35-2.62)
ochrane Q: 2.	48 (p: 0.6	51) P: 0%						Cochrane Q: 3.5	i9 (p: 0.	453) IP: 0%					
IONRANDO	WIZED, O	DBSERVA	TIONAL S	STUDIES				NONRANDON	AIZED,	DESERVA	TIONAL	TUDIES			
Ge et al.	2007	3/57	0/117			3.54%	14.24 (0.74-271.13)	Ge et al.	2007	13/57	5/117			8.04%	5.33 (1.99-14.24)
)i Mario et al.	2007	4/109	0/38		•	3.66%	3.19 (0.17-57.92)	Di Mario et al.	2007	7/109	2/38			4.01%	1.22 (0.26-5.62)
RTS II	2007	1/61	4/263		-	6.50%	1.07 (0.12-9.47)	ARTS II	2007	3/61	16/263	200	-	5.94%	0.80 (0.24-2.68)
OBIS	2010	2/292	9/1376	-	-	13.17%	1.04 (0.22-4.82)	COBIS	2010	5/292	15/1376		-	7.78%	1.57 (0.57-4.28)
-CYPHER	2011	3/263	10/1870		-	18.64%	2.13 (0.59-7.70)	J-CYPHER	2011	6/263	39/1870			9.77%	1.09 (0.46-2.55)
-PMS	2011	4/37	2/263			11.12%	14.21 (2.69-74.92)	J-PMS	2011	5/37	6/263			6.48%	5.92 (1.90-18.44)
ssali et al.	2011	2/141	3/260	-		9.72%	1.23 (0.21-7.27)	Assali et al.	2011	7/141	10/260	1	Contraction of the	8.49%	1 29 (0.50-3.32)
ETA-ANALY	SIS	19/960	27/4187		+		2.55 (1.13-5.78)	META-ANALY	SIS	43/960	93/4187			2010/20	1.85 (1.03-3.32)
ochrane Q: 8.	08 (p: 0.2	34) IP: 25.5	7%					Cochrane Q: 12	79 (p: 0	041) 12:53	11%		-		
META-ANALY	SIS	34/1868	35/5093		•	100%	2.31 (1.33-4.03)	META-ANALY	SIS	140/1727	142/5093		4	100%	1.86 (1.34-2.60)
Cochrane Q: 10.65 (p: 0.473) IP. 0%					Cochrane Q: 16	.34 (p: 0	129) P. 32	.69%		· · · ·					
				0.01 0.1	1 10 100	1000						0.01 0.1	1 10 100	1000	
				RR	LOG SCALE)							RR	LOG SCALE)		
		_									_				
	Si	nale	e-st	ent	Two	-ster	nt		(Sind	ale-	stent	Tw	o-ste	ent
				VII							MIV			\sim \circ \circ	7 116



Zimarino et al. J Am Coll Cardiol Intv 2013;6:687-95



Recent Meta-Analysis of 9 RCTs, 2569 Pts 2 Stent Techniques Are Also Good !



Gao et al. EuroIntervention. 2014;10(5):561-9

Recent Randomized Study CROSS and PERFECT (n=920) 1 or 2 Stent Technique Are Both Good !



CROSS and PERFECT Studies (n=920)

Kim YH, Park SJ, et al. JACC Interv. 2015 April 20;8(4):550-60



Non-LM Bifurcation PCI How To Do ?

- Both strategy, (1 or any 2 stent techniques) would be good in clinical outcomes in the era of 2nd DES.
- But, Less is More ! Less invasive (one stent) strategy would be preferred.





Side Branch Jailing After Main Branch Stenting Do you want to treat ?









Mechanism of Jailing Side Branch Discrete, Focal !



CardioVascStorkNational University Hospital

Courtesy of Koo BK

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Side Branch Jailing After Main Branch Stenting Do you want to treat ?



Side Branch FFR After Main Vessel Stenting (n=232)

SB FFR Post-stentin



Ahn JM et al, JACC Cardiovasc Interv. 2011 Feb;5(2):155-61



Serial SB FFR

Routine Kissing Balloon Inflation Can Not Make An Any Difference!



CardioVascular Research Foundation

SNUH registry and Nordic-Baltic bifurcation study Lee JM, Koo BK, et al. Eurointervention 2015 Leave It Alone; Why Is It OK ?

Negative FFR means *Excellent Prognosis (0.6%/year, Cardiac Death and MI)*, even in the presence of any angiographically proven disease.
 Routine Kissing Balloon Inflation Is Not Always Good.

Shaw LJ, J Nucl Cardiol 2004;11:171-85 ,Prognostic value of gated myocardial perfusion SPECT. Very large meta-analysis (n=39,173)



When ? 2 Stents Are Needed

<i>1 Stent</i>	Normal Side Branch, Whatever Size Is,
Provisional	(Medina 1.1.0., 1.0.0), or
(>70%)	Focal Diseased Side Branch
2 Stent Technique	Large SB (≥ 2.5 mm) → Large amount of myocardium Diffusely Diseased Side Branch (Medina 1.1.1., 1.0.1)



Many Factors Influencing 2 Stent Techniques

MB and SB size

- Bifurcation angle
- Plaque distribution and location
- Operator experience and expertise (most comfortable techniques)







Many Different 2 Stent Techniques

- T-stent, modified T-stent or TAP
- Mini-crush (or step crush), DKCRUSH
- Culotte
- V-stent
- Y-stent (SKS-simultaneous kissing stents)
- Dedicated Bifurcation Stent



Why Not, Any Different Outcomes ? with Different 2 Stent Techniques

- Different Indications,
- Very Limited Data,
- Small Ischemic Myocardium of SB Can Not Make an Any Hard Endpoint Difference (Death and MI). Only Difference would be in Soft End Point (TLR).





Survival Benefit of Revascularization, Side Branch PCI



Total Myocardium Ischemic Burden (%)

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Hachamovitch R, Circulation. 2003;107:2900-2906

What Really Matters in Non-LM Bifurcation PCI ? Conceptual Key Message

FFR Guided or FFR-Trained Concept Is Crucial for Bifurcation PCI !

by the Status of MB rather than Angiographic Appearance of the SB.







LM Bifurcation PCI How To Do ?

1. 1 stent with provisional stenting
 2. 2 stent strategy







LM PCI Many Issues,

Why FFR ? Why IVUS ? Which One ?







Significant Stenosis

Negative FFR

47/M Stable Angina



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Insignificant Stenosis

Positive FFR

62/F Stable Angina







Many Mismatches Ovarall, Intermediate LM Disease





Hamilos M et al. *Circulation 2009;120:1505-1512*



FFR is Crucial,

For the Decision Making to Treat or Not To Treat.







FFR vs. IVUS MLA

Can LM IVUS MLA, Predict Functional Significance of Stenosis ?







Non-LM, IVUS MLA Matched with FFR Meta-analysis, 11 Clinical Trials 1759 pts



	Sensitivity (95% CI)						
01	0,92	(0,62 - 1,00					
12	0,68	(0.48 - 0.84					
	0,69	(0.54 - 0.80					
	0,71	(0,49 - 0,87					
	0.83	(0,78 - 0,88					
	0,90	(0,78 - 0,97					
	0,69	(0,59 - 0,79					
9	0,84	(0,64 - 0,95					
	0,87	(0,72 - 0,96					

Specificity (95% CI)

(0.37 - 0.69

(0.45 - 0.80

(0.63 - 0.78)

(0.55 - 0.78)

(0.59 - 0.67)

(0.52 - 0.67

(0.57 - 0.72)

(0.75 - 0.99)

(0.66 - 0.88)

0.54

0,64

0.71

0.68

0.63

0.60

0.65

0.92

0.79

Pooled Sensitivity = 0,79 (0,76 to 0,83) Chi-square = 20,55; df = 8 (p = 0,0085) Inconsistency (I-square) = 61,1 %



Ischemic Threshold IVUS MLA 2.61mm²

Pooled Sensitivity 79% Pooled Specificity 65%

Nascimento et al. Catheter Cardiovasc Interv 2013



Can IVUS MLA Predict Functional Significance of Non-LM Stenosis ?





Kang et al. Am J Cardiol 2012;109:947-53



MLA < 6.0 mm² matched FFR <0.75 (n=55, LM disease)



Jasti V et al. Circulation 2004;110:2831-6



MLA < 4.5 mm² matched FFR <0.80 (n=112, Os and Shaft LM disease)



$Cut-off = 4.5 mm^2$

79%
80%
83%
76%
80%

Park SJ et al. JACC Interv, 2014;7(8):868-874



Can IVUS MLA (4.5 mm²) Predict Functional Significance of LM Stenosis ?



Yes !

$Cut-off = 4.5 mm^2$

Sensitivity79%Specificity80%PPV83%NPV76%Accuracy80%

Park SJ et al. JACC Interv, 2014;7(8):868-874



How do I Implement ?

Ostial and Shaft LM Disease



Bifurcation with Down Stream Disease

4.5~6.0 mm² **Consider FFR !**

< 4.5 mm² Positive FFR

> 6.0 mm²
Negative FFR





Case 1, 55/M Effort Chest Pain



Is the Lesion Functionally Significant? How to Treat?







IVUS





5.3 mm²





ASAN Medical Center

IVUS vs. FFR



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How To Treat ? 1 or 2 Stent ?









Single Stent Crossover



XIENCE Alpine 4.0mm x 30mm







Final Angiogram









Any Jailing Morphology Cannot Predict Functional Significance of Jailed LCX

Jailing LCX After Stent Cross-Over







Mechanism of LCX Jailing After Stent Cross-Over



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Kang et al. Circ Cardiovasc Interv 2011;4:355-61



Functionally Significant LCX Jailing After Stent Crossover for LM Bifurcation



Kang SJ, Catheterization and Cardiovascular Interventions. 2014;83(4):545-52.

Death or MI at 2 Years Jailing LCX Defer Is Safe and Good !





AMC Data, 2016



1 or 2 Stents ?







2 Stent Techniques

- T-stent, modified T-stent or TAP
- Mini-crush (or step crush)
- Culotte
- V-stent
- Y-stent (SKS-simultaneous kissing stents)







Restenosis at 2 year LM PCI Using SES (n=423)



Kang et al. Circ Cardiovasc Interv 2011;4:1168-74

Effective Stent Area (Rule of 5,6,7,8 mm²) Restenosis Rate < 5% and TLR < 2%



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Kang et al. Circ Cardiovasc Interv 2011;4:1168-74





LM Bifurcation PCI How To Do ?

- Both strategy (1 or any 2 stent techniques) would be OK in the era of 2nd DES. Side branch treatment with FFR guided or FFR trained concept can make a good clinical outcomes.
- Whatever you used 2 stent technique, IVUS optimization (effective stent area, 5.6.7.8 mm²) can make a good clinical outcomes.





What Really Matters in Bifurcation PCI ?

It's a Matter of Concept rather than Technique !





