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Updated Thoughts on Left Main Bifurcation PCI: Simple (Provisional) vs Structured (2-Stent) Practical Approach

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What Is Provisional Stenting?

Provisional or conditional stenting should be **defined** as the use of **stents** limited to those conditions and cases in which the operator, despite an aggressive balloon angioplasty technique with large balloons and high pressure, has been unable to obtain a result that ensures optimal chances of early and late patency.

Technique vs Strategy/ Philosophy

Provisional Stenting

- Simple and Fast
- Excellent short term and long term results
- Reserves all other options in case of failure
- > 60% of patients with LM bifurcation can be treated using the provisional technique

Side Branch (SB) Stenting

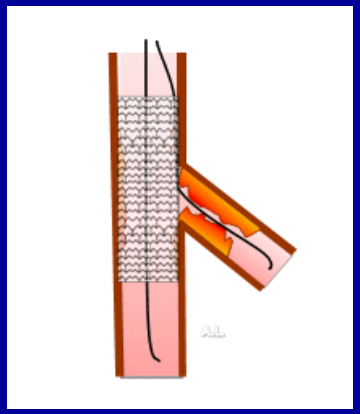
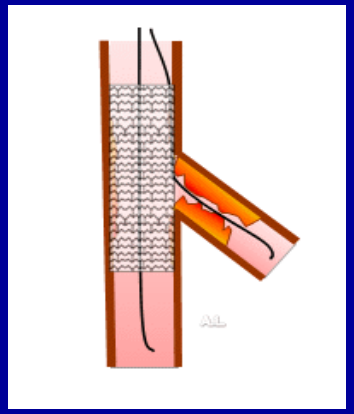
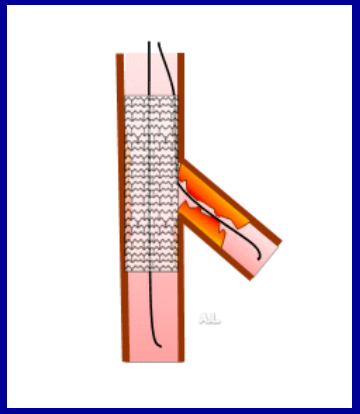
SB stenting should be considered when:

- there is significant SB flow impairment (Thrombolysis In Myocardial Infarction TIMI flow grade <3)
- in the presence of a major SB dissection
- when the SB is diseased and large enough to lead to significant residual ischemia
- when future access toward the SB may be important

EuroIntervention 2018; 13: 1540-1553

FJ Sawaya et al JACC CV Intv 2016; 18: 1861- 1878

Provisional Requiring A 2nd Stent - Bailout Options

	TAP	Reverse Crush	Culotte
			
Advantages	❑ Easy to perform ❑ No recrossing	❑ Complete coverage of ostium ❑ Any anatomy	❑ Complete coverage of ostium
Disadvantages	❑ Struts protruding into MB	❑ Recrossing into SB ❑ 3 layers of struts	❑ More difficult rewiring of both branches ❑ Double stent layer

Iakovou I et al JACC 2006; 46: 1446-1455

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What Are The Clinical Evidence For Left Main Provisional vs 2-Stent Strategies?

Left Main PCI: Provisional vs 2-Stent Strategies

ESC European Society of Cardiology
European Heart Journal (2021) 00, 1–11
doi:10.1093/eurheartj/ehab283

FASTTRACK CLINICAL RESEARCH
Clinical trials

The European bifurcation club Left Main Coronary Stent study: a randomized comparison of stepwise provisional vs. systematic dual stenting strategies (EBC MAIN)

David Hildick-Smith [1]*, Mohaned Egred [2], Adrian Banning [3], Philippe Brunel[4], Miroslaw Ferenc [5], Thomas Hovasse[6], Adrian Wlodarczak [7], Manuel Pan[8], Thomas Schmitz[9], Marc Silvestri[10], Andreis Erglis[11], Evgeny Kretov[12], Jens Flensted Lassen[13], Alaide Chieffo [14], Thierry Lefèvre[6], Francesco Burzotta [15], James Cockburn[1], Olivier Darremont[16], Goran Stankovic [17], Marie-Claude Morice[6], and Yves Louvard[6]

JACC
JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY

ORIGINAL INVESTIGATIONS

Double Kissing Crush Versus Provisional Stenting for Left Main Distal Bifurcation Lesions

DKCRUSH-V Randomized Trial

Shao-Liang Chen, MD,[a] Jue-Jie Zhang, PhD,[a] Yaling Han, MD,[b] Jing Kan, MBBS,[a] Lianglong Chen, MD,[c] Chunguang Qiu, MD,[d] Tiemin Jiang, MD,[e] Ling Tao, MD,[f] Hesong Zeng, MD,[g] Li Li, MD,[h] Yong Xia, MD,[i] Chuanyu Gao, MD,[j] Teguh Santoso, MD,[k] Chootopol Paiboon, MD,[l] Yan Wang, MD,[m] Tak W. Kwan, MD,[n] Fei Ye, MD,[o] Nailiang Tian, MD,[o] Zhizhong Liu, PhD,[a] Song Lin, MD,[o] Chengzhi Lu, MD,[p] Shangyu Wen, MD,[q] Lang Hong, MD,[r] Qi Zhang, MD,[s] Imad Sheiban, MD,[t] Yawei Xu, MD,[u] Lefeng Wang, MD,[v] Tanveer S. Rab, MD,[w] Zhanquan Li, MD,[x] Guanchang Cheng, MD,[y] Lianqun Cui, MD,[z] Martin B. Leon, MD,[aa] Gregg W. Stone, MD[aa]

Chieffo et al EuroInterv 2016; 12: 47-52
SL Chen et al J Am Coll Cardiol 2017; 70: 2605–17

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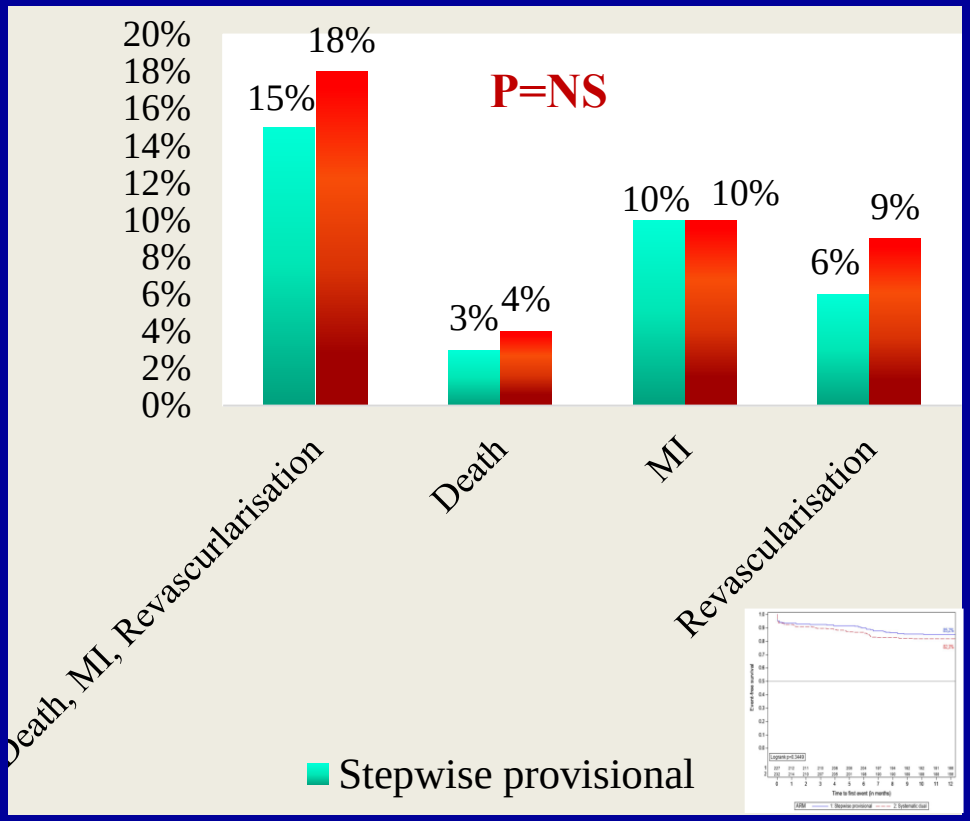
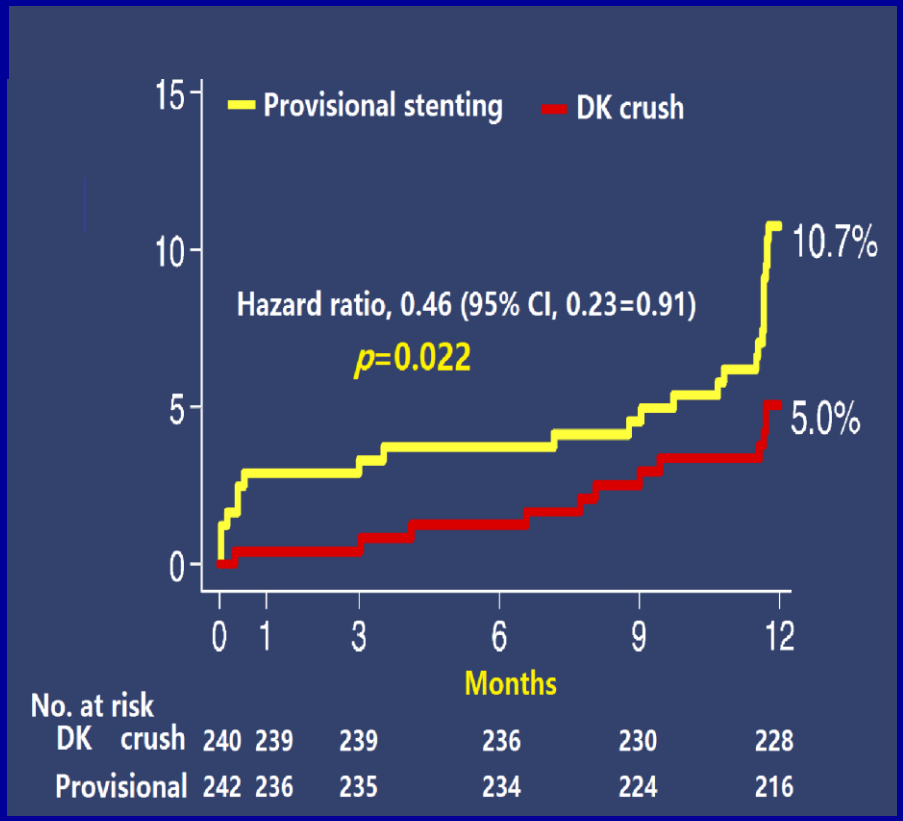
Provisional vs 2-Stent Strategies

EBC MAIN 1 Yr Results



DK CRUSH-V 1 Yr Target Lesion Failure



Chieffo et al EuroInterv 2016; 12: 47-52
SL Chen et al J Am Coll Cardiol 2017; 70: 2605–17

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Study Inclusion Criterias

	EBC Main	DK-CRUSH V
Primary endpoint at 1-year	Death, MI, TLR; Superiority design	Cardiac death, TVMI, TLR; Superiority design
Sample size	Estimated 450; Final 467	Estimated 484; Final 482
SYNTAX scores	<32 scores (23)	No limit (31)
AMI	>72 h	>24 h
CTO	Excluded	Included after successful PCI
Two-stent exact usage	Culotte 53%; TAP 33% DK Crush 5%	DK Crush 100%

Assumptions and Lesion Characteristics

	EBC Main	DK CRUSH V
Lesion types	Medina 1,1,1/0,1,1	Medina 1,1,1/0,1,1
Primary endpoint at 1-year (stat assumption)	14% in provisional group 25% in two-stent group	14% in provisional group 6% in DK crush group
No. PCI yearly	>150 per operator	>300 per operator, ≥20 LM-PCI
SYNTAX scores	23	31
SB lesion length	7 mm	16 mm
Complexity	Not classified	Complex bifurcations in 31.5%

Procedures and Outcomes

		EBC Main		DK CRUSH V	
Cross-over to 2-stent		22%		47%	
Reasons for treating SB		TIMI<3, >A dissection, >90% compromise		TIMI <3, >A dissection, >75% compromise	
IVUS use		40%		41%	
Endpoints		Provisional	Two-stent	Provisional	DK Crush
Primary		14.7%	17.7%	10.7%	5.0%
Seondary	Death	3.0%	4.2%	CD:2.1%	1.2%
	MI	10.0%	10.1%	TVMI:2.9%	0.4%
	TLR	6.1%	9.3%	7.9%	3.8%
	ST	1.7%	1.3%	3.3%	0.4%

EBC MAIN: Limitations

- Designed to be superiority trial - not non-inferior

- Lower actual observed event rates of 14.7% (1-stent) vs 17.7% (2-stent) compared to assumed primary endpoint rates of 14% vs 25% at 1 year (? type 11 error)

- Non-uniformity in procedures: No POT in abt 15% in both gps, No KBT in PS (11%) even mandated.
  No second stent in 2-stent group (5%)
  Low operator experience in complex LM PCI.

- Only 85% of patients had appropriate cardiac enzyme measurement, which may impact on periprocedural MI rate

DK-CRUSH V: Limitations

- Under-powered study
- More complex procedures more time (16 more minutes or 19% more time) than provisional stenting
- **47%** 3 stent.

  Bail allenging
  d
  ST (6.1% vs 0.8%)

  Operators not familiar with ? TAP technique
- More attention paid to techniques in DK group (more POT and KBI)

Patient Selection Bias

Operator Performance Bias

Do Lesion Complexity Impact On Outcomes?

Early Recommendations of Provisional Stenting Based On Simple Lesions

	AMI	CTO	SB-D (mm)	SB-L (mm)	SB-DS (%)	D-Type
NORDIC-I	No	No	2.0	5	40	Simple
NORDIC-II	No	No	2.5	6	42	Simple
NORDIC-III	No	No	2.5	6	44	Simple
NORDIC-IV	No	No	2.75	6	40	Simple
CACTUS	No	No	2.5	5	62	Simple
BBC ONE	No	No	2.25	5	40	Simple

Recent Recommendations of Provisional Stenting Based On Complex Lesions

	AMI	CTO	SB-D (mm)	SB-L (mm)	SB-DS (%)	D-Type
DK-CRUSH-II	Yes	Yes	2.5	11	65	Complex
DK-CRUSH-III	Yes	Yes	>2.5	17	64	Complex
DK-CULOTTE-1	Yes	Yes	>2.5	14	78	Complex
DK-CRUSH-V			LCX			UPLMD
DEFINITION-II	Yes	No	>2.5	16	77	Complex

DEFINITION Study:
2-Stent Led to Lower Periprocedural MI & Cardiac Death

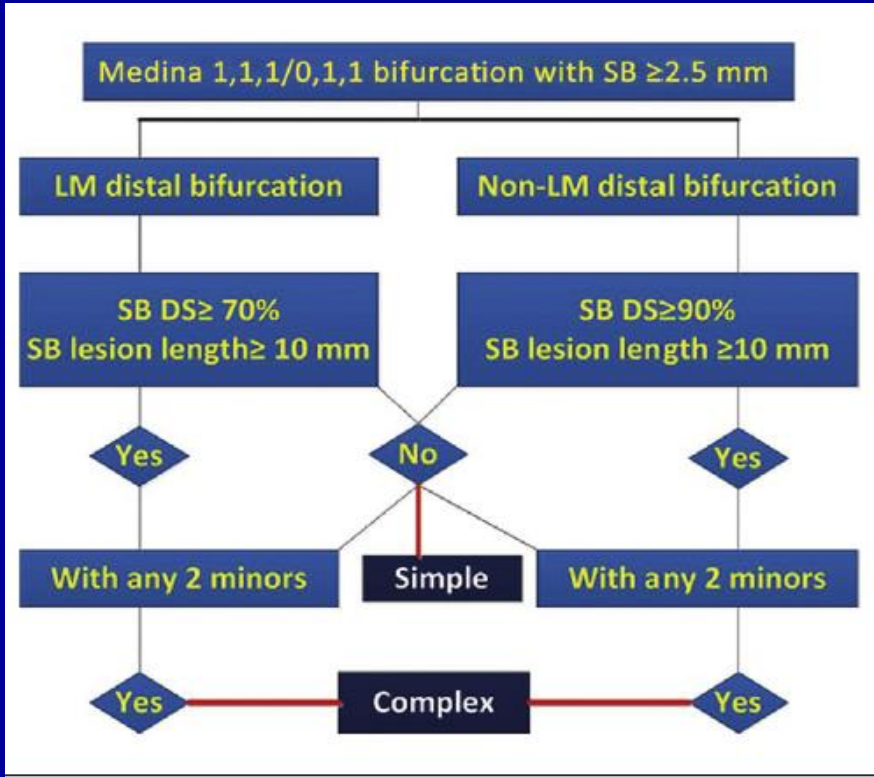


FIGURE 1 Description of Complex Bifurcation Lesion Definitions

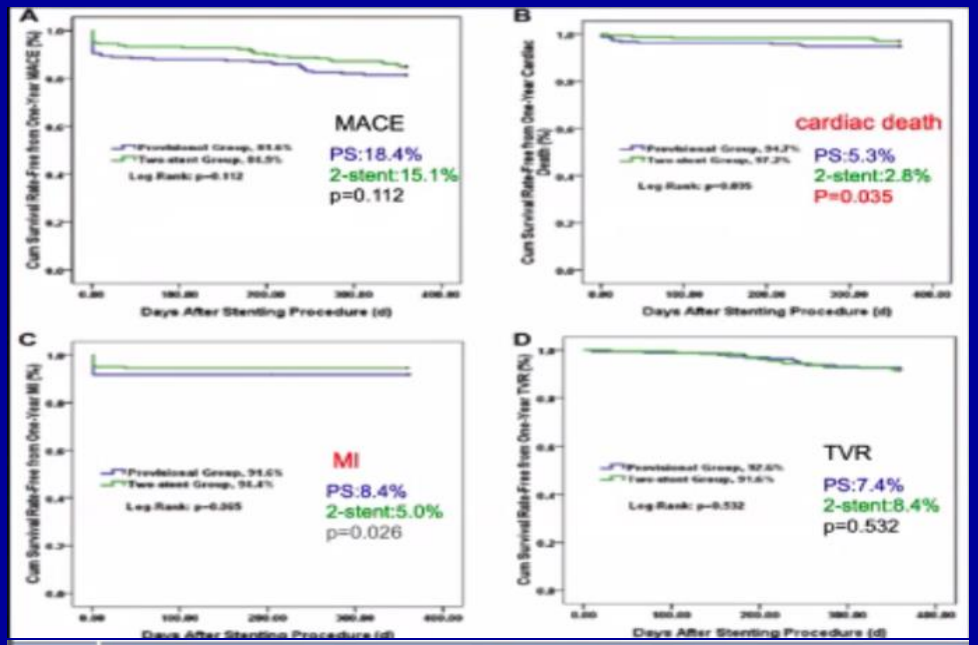
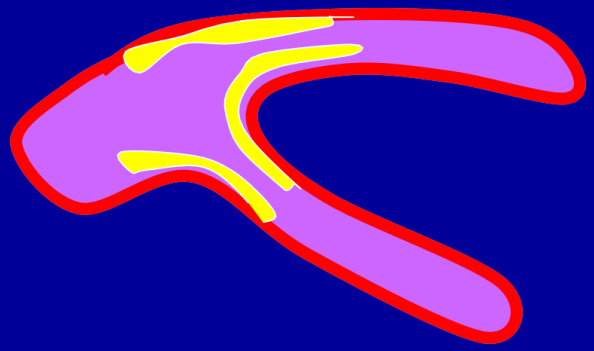


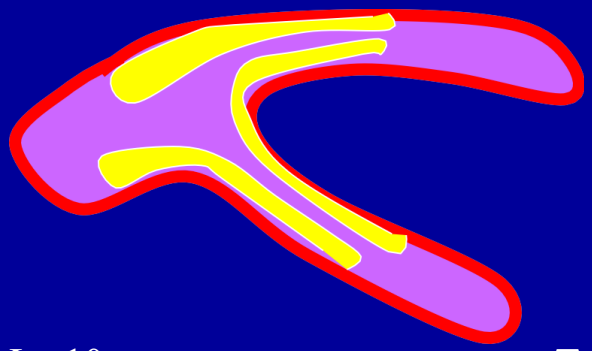
Table 1 Criteria of complex bifurcation lesions

Criteria	Lesion characteristics
Major 1	Distal LM bifurcation: SB-DS ≥70% and SB lesion length ≥10 mm
Major 2	Non-LM bifurcation: SB-DS ≥90% and SB lesion length ≥10 mm
Minor 1	Moderate to severe calcification
Minor 2	Multiple lesions
Minor 3	Bifurcation angle <45° or >70°
Minor 4	Main vessel RVD <2.5 mm
Minor 5	Thrombus-containing lesions
Minor 6	MV lesion length ≥25 mm
Major 1+any 2 minor 1–6=complex bifurcation lesion	

DK CRUSH V: Target Lesion Failure at 1-Year

Simplex vs Complex Bifurcation Lesions



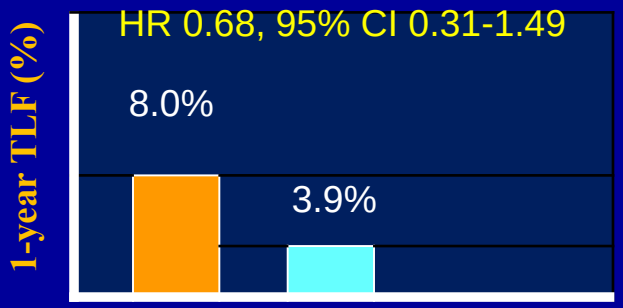


LCX-LL<10 mm
and/or os LCX DS <70%

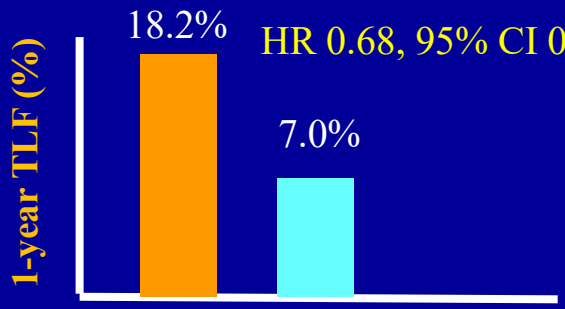
LCX-LL ≥10 mm
and os LCX DS ≥70%

Plus ≥2 of 6
minor criteria

Simple Lesions



Complex Lesions



Provisional DKCrush

Chen SL et al J Am Coll Cardiol 2017;70: 2605-2617

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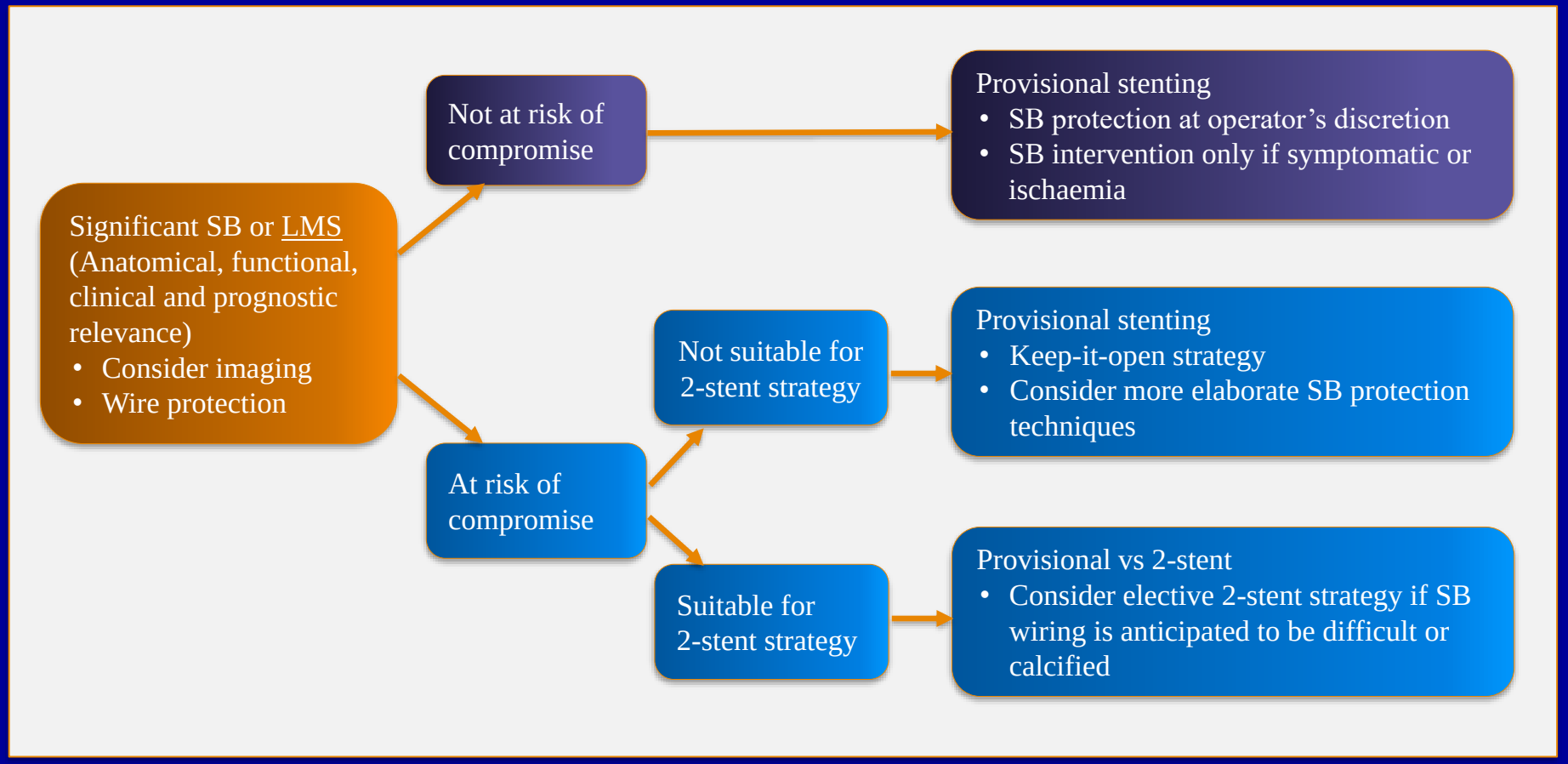
Asia Pacific Consensus Document On Coronary Bifurcation Interventions



PH Loh et al EuroIntervention 2020; 16:e706-e714 published online

Conclusions

- Stent treatment of true bifurcation left main stem coronary artery disease is safe (low ST) and effective
- Provisional vs 2-stent treatment strategy should be individualised according to lesion morphology (including complexity)
- Operator's knowledge, skills and experience/ judgement paramount