

XV PROEDUCAR-SOLACI FELLOWS COURSE CHIP PCI - LEARNING CASES AND TECHNIQUE REVIEWS

11:10-11:30 Room B1 y B2

Learning Case and Technique Reviews - Non-LM Bifurcation Disease. Step-by-step

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I have the following financial relationships

Speaker's Bureau:

Medtronic

Terumo

Boston Scientific

Abbott Vascular





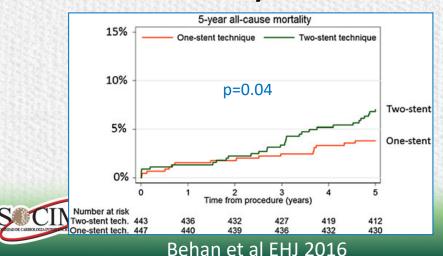


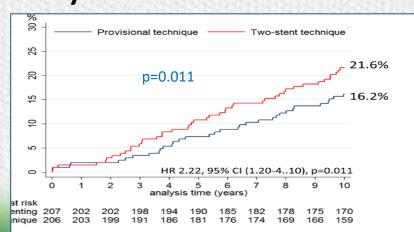


Background: 1 vs. 2-stents trials

- Many trials have shown lack of benefit associated with systematic two-stent strategies for bifurcations
 - NORDIC, BBC ONE, BBK, CACTUS etc....
- Even in patients with larger, true bifurcations
 - EBC TWO

Outcomes may be worse with systematic dual stenting:









Stepwise Provisional versus Systematic Culotte for true nonleft main bifurcation lesions: EBC TWO study

EBC TWO compared provisional and culotte strategies

Kissing balloon-inflation routine, T-stent if required

Second generation drug-eluting stents

SB diameter ≥2.5mm, SB lesion length ≥5mm

200 patients recruited in Europe from 2011-2014

16% side branch stenting in provisional cohort

Less procedural time, radiation and cost

12-month outcomes reported in 2016

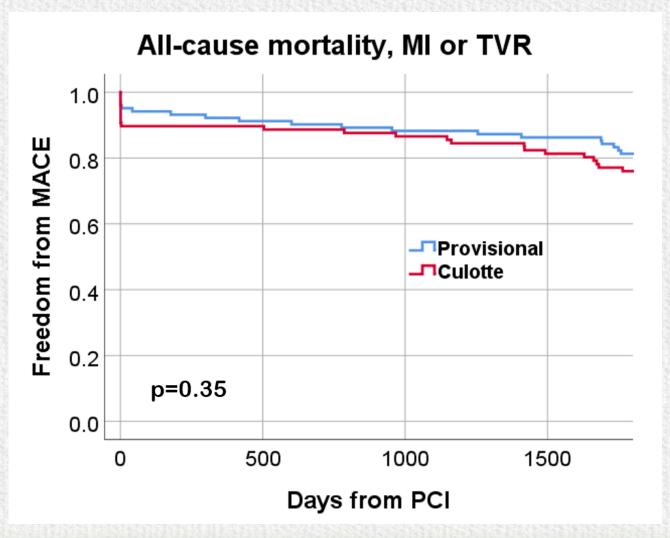
MACE not significantly different between provisional and culotte cohorts (7.7% vs 10.3%, p=0.53)







EBC TWO: 5-year follow-up



Provisional 18.4% vs Culotte 23.7% HR 0.75 (95% CI 0.41-1.38)

Routine culotte did not improve 5-year MACE beyond provisional stenting in non-left main true bifurcation lesions

Only 16% provisional patients required SB stent







The EBC Ethos of treatment for bifurcation

- Keep it simple and safe;
- Limit the numbers of stents;
- Respect the original bifurcation anatomy and try to reproduce it;
- Aim for well apposed and well expanded stents, with limited overlap;
- The *provisional SB stenting* strategy is the "standard" approach for treatment of the vast majority of bifurcation lesions, *including the left main*;





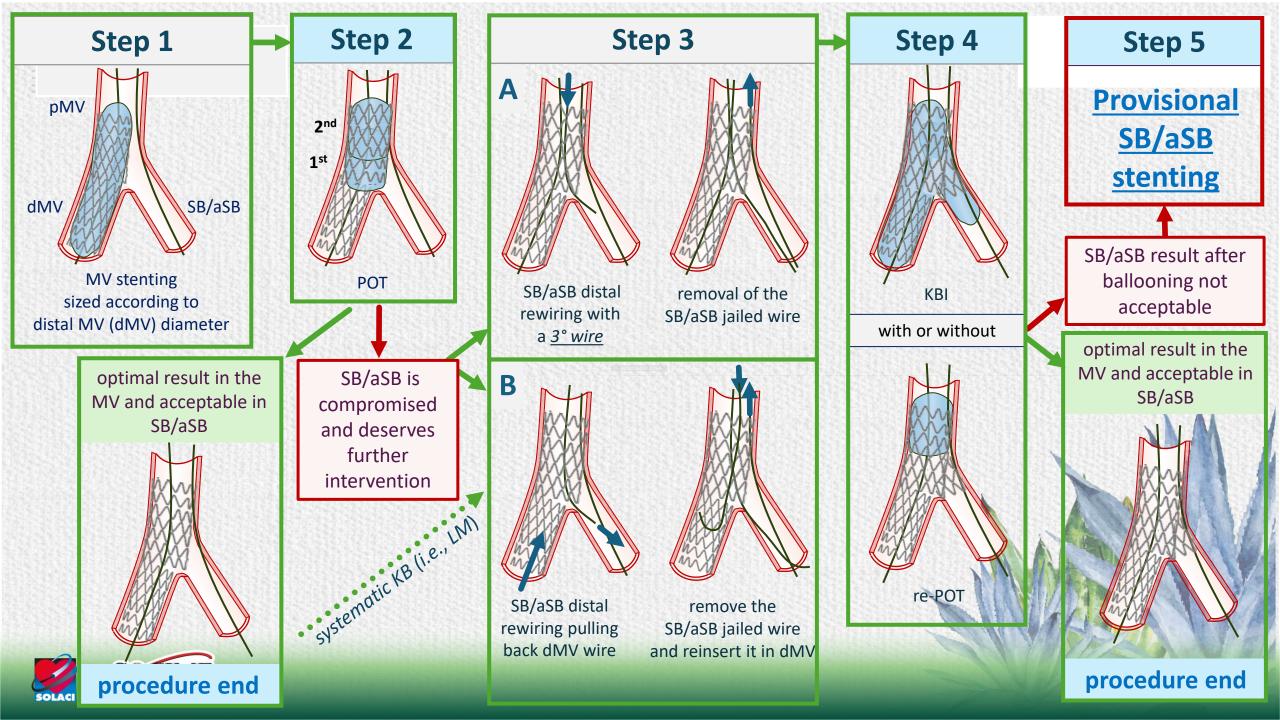


Stepwise provisional non-LM bifurcation PCI How it applies to everyday practice

- Wire both vessels
- Predilate the "main" branch
- Consider use of IVUS/OCT and cutting/scoring/rota/IVL
- Stent "main" vessel according to distal diameter
- POT in MV along stented length (mandatory step)
- Rewire SB
- Optional kiss for large SB (optional POT-KISS-POT)
 - If you need to do more...
- Optional 2nd stent (with mandatory kiss)

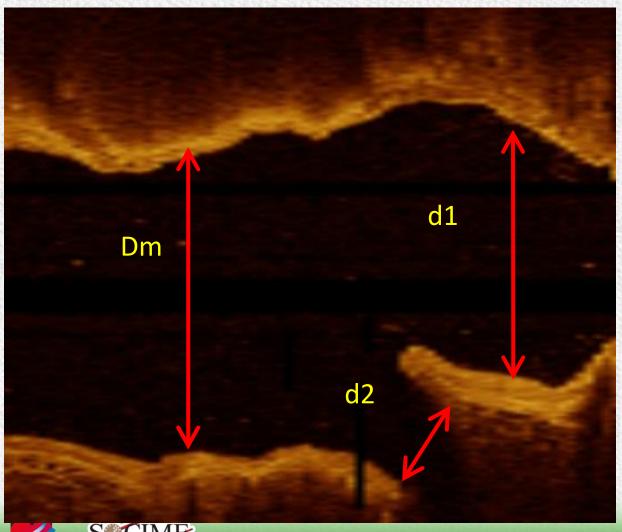


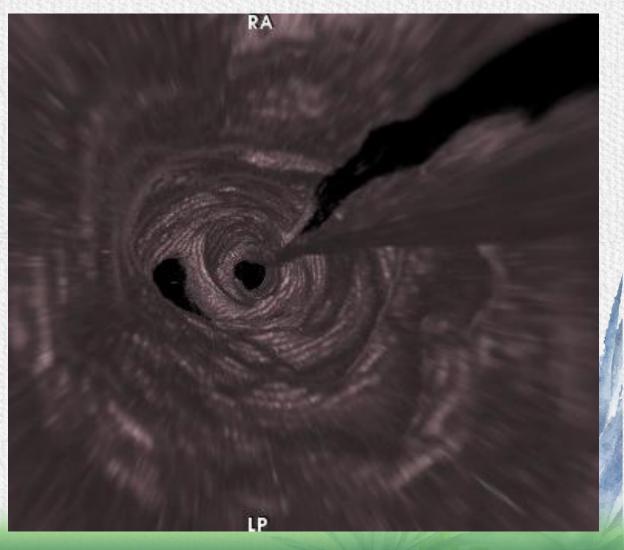






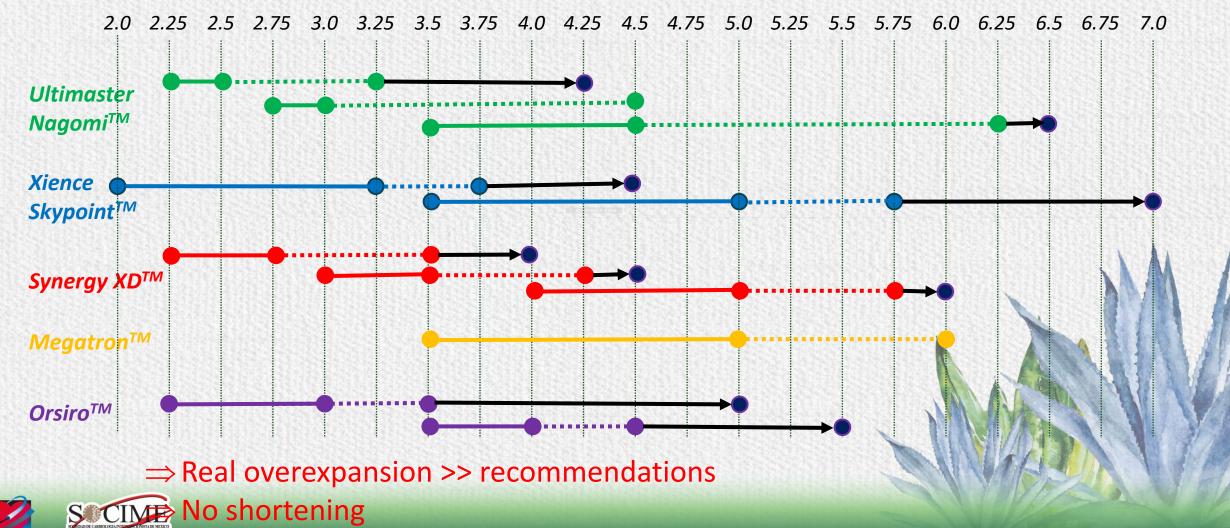
Main vessel caliber discrepancy: step down at bifurcation site





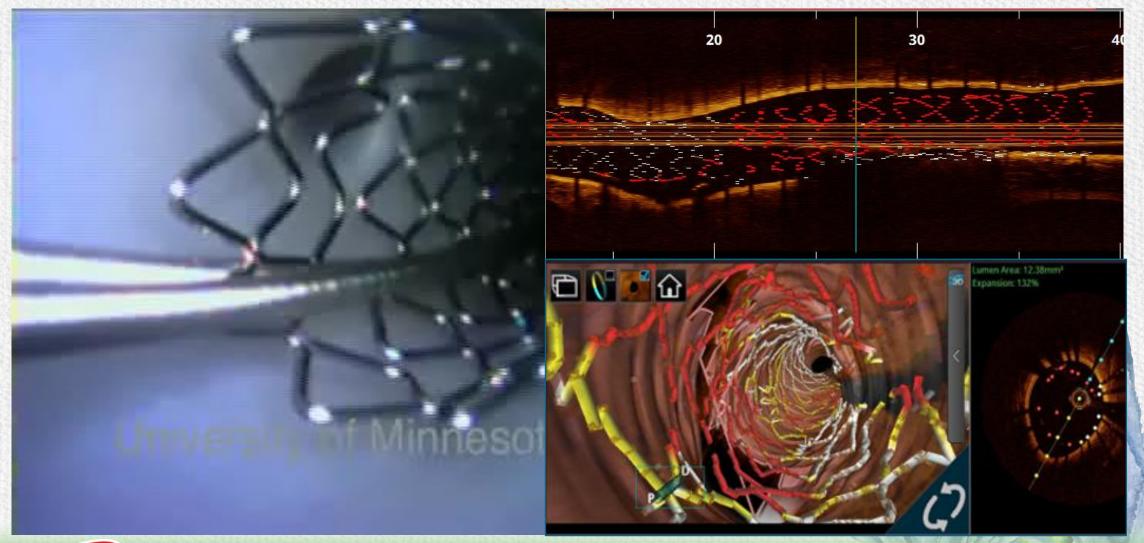


Stent size selection Maximal overexpansion: off label





The importance of POT



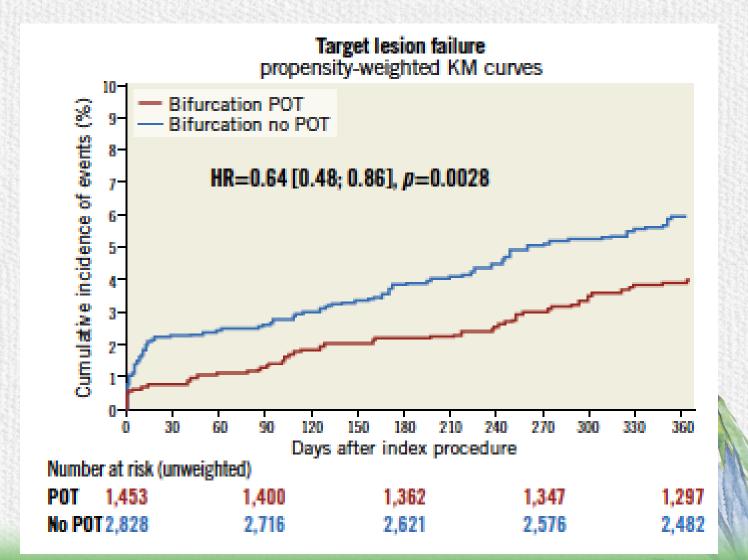






The impact of POT: Clinical evidence from e-Ultimaster registry











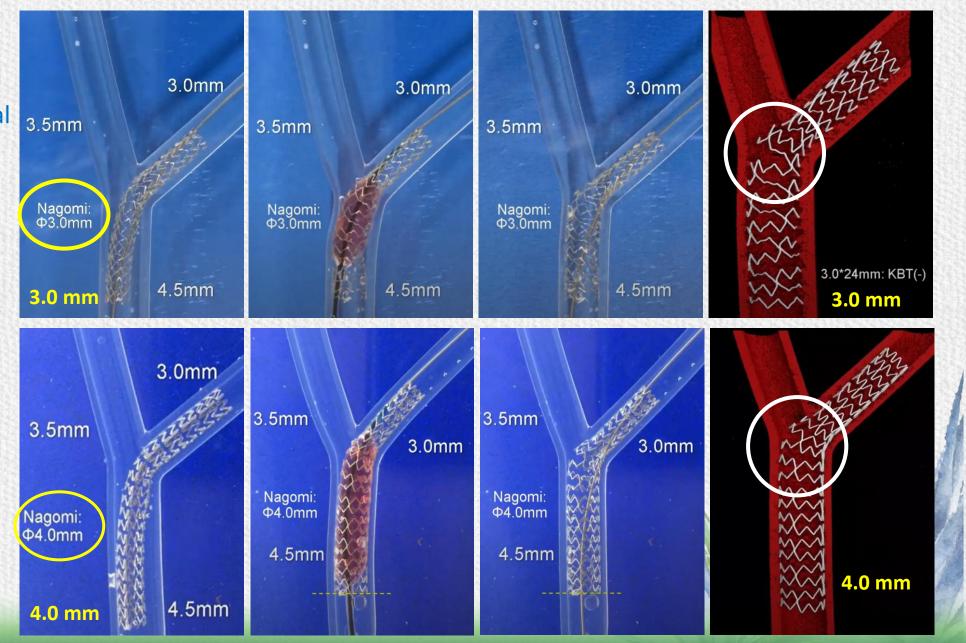
bifurcation stenting is the situation where the proximal and distal diameter difference is maximal



Crossover stentingand POT







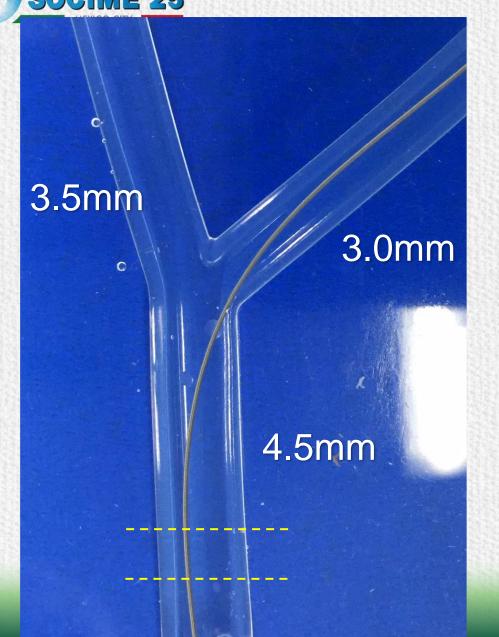


Optimal POT: should we start optimization from the carina site or from the proximal stent edge?





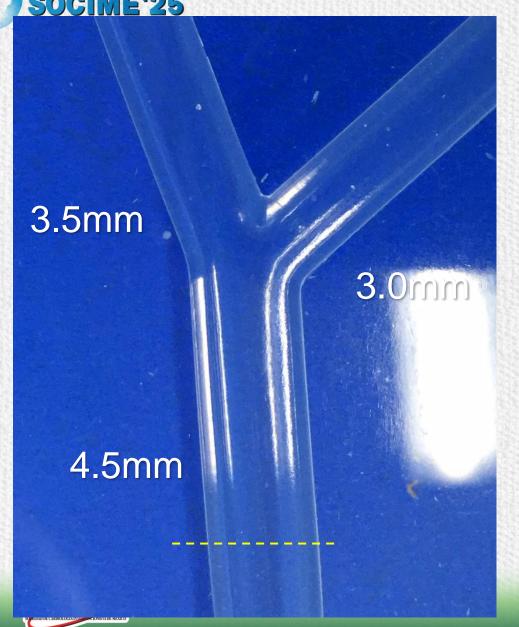
SOLACI POT: Expanding from the distal side using a short balloon SOCIME'25

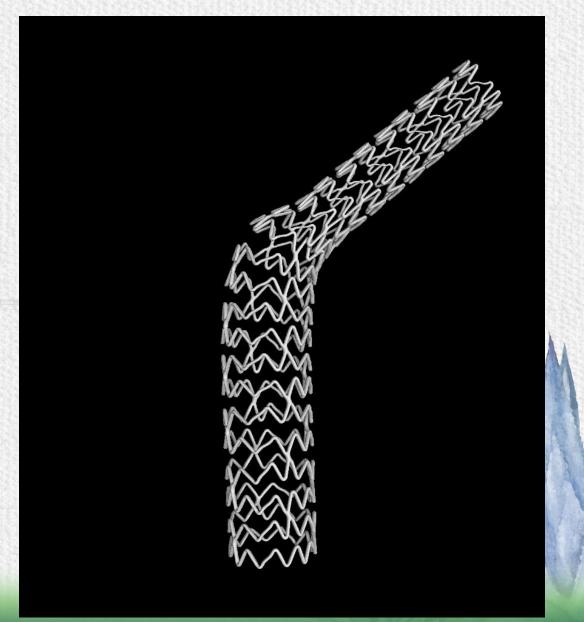






SOLACIPOT: Expanding from the proximal side using a short balloon SOCIME'25







How to size POT balloon:

Angio vs. Imaging:

Ref diam was limit for largest balloon

Largest balloon

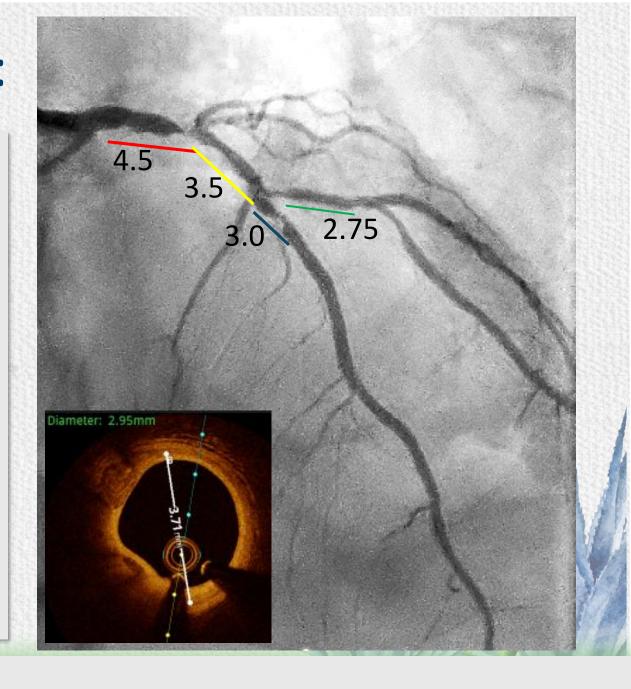
• OCT: 4.2±0.03mm

• Angio: 4.0±0.02mm

Perforations

• OCT: 0.8%

• Angio: 1.0%

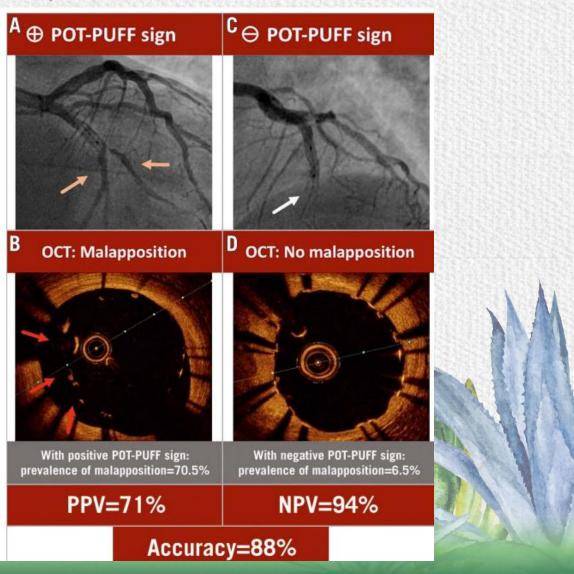




Stent apposition

The **POT-PUFF sign**: an angiographic mark of stent malapposition during proximal optimization







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KISS trial - Provisional stenting in bifurcation lesion: benefit of side branch intervention?

Bernard Chevalier on behalf of the KISS investigators

(Keep bifurcation stenting simple)







KISS trial design



Any de novo non-LM bifurcation lesion except 001 requiring a wire-based side branch protection

Side branch large enough to accomodate a coronary stent

Main branch stenting (Resolute Onyx) sized to distal reference diameter with a systematic proximal optimisation technique

Side branch patent with no flow reduction or any sign of ongoing ischemia



Randomisation (AFTER POT)



No side branch intervention

Side branch intervention
Kissing balloon technique
or POT/Side/POT







KISS trial endpoints



Primary endpoint: rate of periprocedural infarction/injury using ARC 2 definition within 48 hours Increase of 70 x troponine ULN of 35 x troponine ULN with additional criteria

Considering alpha=0.05 et Beta=0.8 with a rate of 15% in control group and a non-inferiority limit of 7.5%, 596 patients have to be randomized. Superiority will be tested if noninferiority is met.

Secondary procedural endpoints:

Technical success, Acute gain (QCA), Procedure time, Xray exposure (Air kerma, Fluoro time)

Secondary clinical endpoints @ 1 and 12 months:

TLF with its individual components, Def/probable stent thrombosis, Angina status

ITT analysis

304 vs 313 patients

Per Protocol analysis

268 vs 272 patients

(Cross over 2%vs 1,6%)







Procedural results

N patients	No SB intervention (303)	Control (314)	р
Technical success*	80,2%	82,1%	NS
Procedure time (median)	34 min	45 min	<0,001
Fluoro time (median)	10 min	13,2 min	<0,001
Air Kerma (median)	453 mGy	629 mGy	<0,001
Contrast volume (median)	130 ml	150 ml	<0,001
Acute gain in SB**	-0,04+-0,36 mm	0,10+-0,31 mm	<0,001

Reduction in procedure time(24%), contrast media volume(13%), X-ray exposure (28%)

^{*} Technical success: successful stenting with residual stenosis <20% by QCA & TIMI > I in SB ** by QCA analysis







What are the main results?

Primary endpoint	No SB intervention	Control	р
ITT (303/313)	4,1%	5,7% (3,4% P/S/P 8,9% KBT)	<0,001 NI 0,38 Sup <0,066
Per protocol (268/272)	4,1%	5,9%	<0,001 NI 0,34 Sup
AS treated (302/314)	4%	5.7%	<0,001 NI 0,38 Sup







One-year outcome

One-year clinical endpoints	No SB int	tervention	Cor	ntrol		р	
TLF	3.6%	<i>-</i> 5%	4.5%	6.4%	NS	NS	
Cardiac death	0.3%	0.3%	0%	0%	NS	NS	
TV MI	3.3%	4%	4.5%	4.8%	NS	NS	
CD-TLR	0.7%	1.3%	0%	1.9%	NS	NS	
Main branch CD-TLR	0.7%	1.3%	0%	1.9%	NS	NS	
Side branch CD-TLR	0.3%	0.7%	0%	0.3%	NS	NS	
Stent thrombosis (def/prob)	0.3%	0.7%	0.3%	0.6%	NS	NS	
TLF Kissing subgroup			8.9%	9.1%	N	S	
TLF SB ballooning			3.4%	4.6%	NS e		



Why is this study important

- Provisional stenting in routine non-LM bifurcation using Resolute Onyx DES is associated with a good short & mid-term outcome
- A no-touch strategy is non-inferior @ 30 days to systematic SB intervention and safe/efficient @ 1 year
- A further study in LM bifurcation would be useful

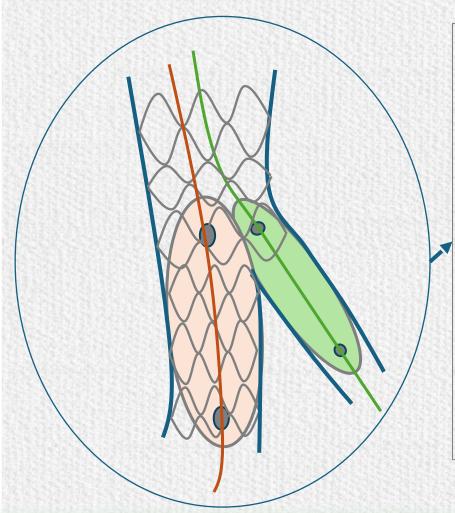






Final Kissing balloon inflation optional

When an important SB is jeopardized after MV stenting



- 2 NC balloons;
- Both sized according to the distal reference of the MB and the SB;
- Short proximal overlap (if longer proximal overlap, consider re-POT);
- Sequential balloon inflation (SB first)
 and simultaneous deflation;
- Keep balloons inflated 30 sec.







Final POT to correct deformation after KBI

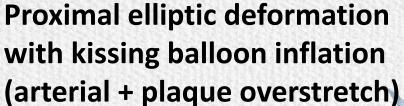


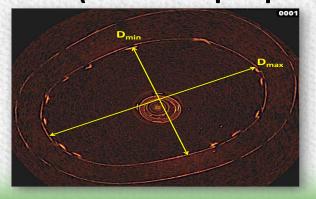
Bottle neck effect



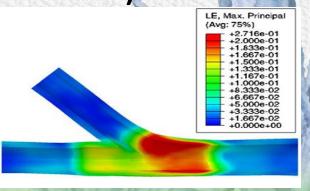
Foin et al. EuroIntervention 2011.





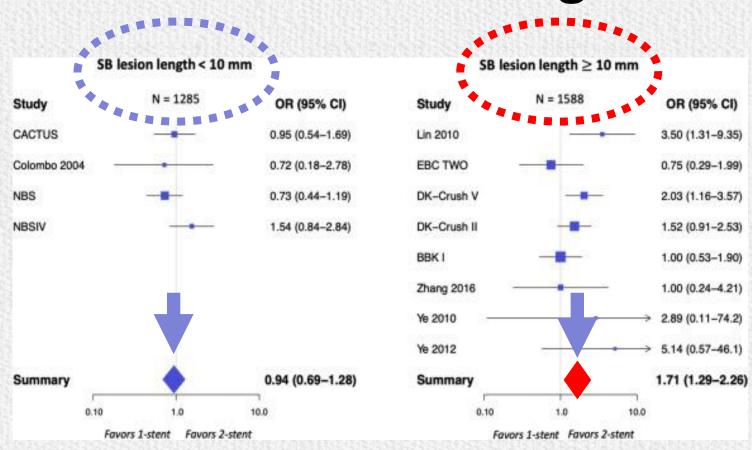


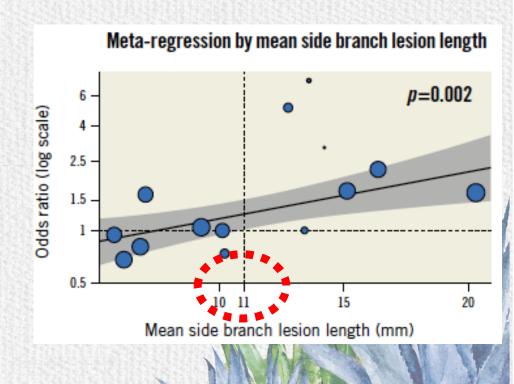
Mortier P et al. JACC CI 2014



Foin et al. JACC CI 2012

2-stents provide better outcomes if SB length ≥10mm











Elective two-stent strategies

- Elective 2-stent strategies may be considered for *long SB lesions, high risk of SB compromise or difficult access*;
- When a planned two stent strategy is used, this should be done in a provisional stepwise approach to the lesion, finalizing the procedure using a T/TAP or a culotte technique (as a part of provisional);
- For operators with appropriate experience, DK-Crush is a valuable option for complex bifurcation lesions;

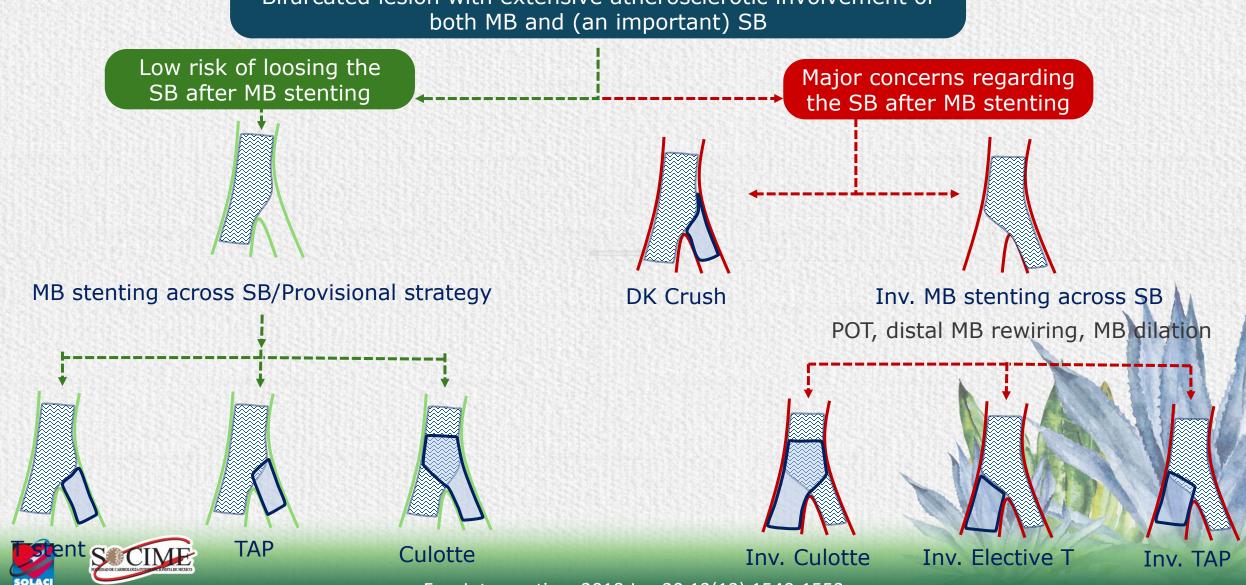






Elective two-stent strategies

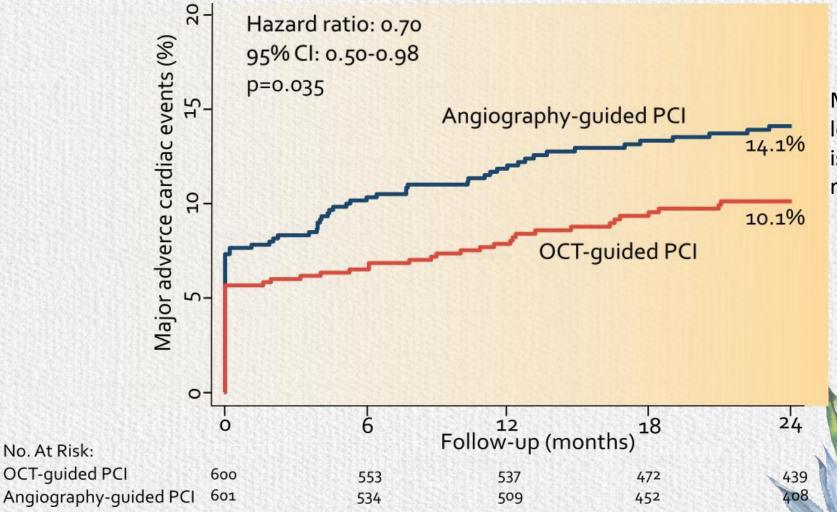
Bifurcated lesion with extensive atherosclerotic involvement of both MB and (an important) SB



EuroIntervention. 2018 Jan 20;13(13):1540-1553



OCTOBER Trial: Primary endpoint



MACE: cardiac death, target lesion myocardial infarction, ischemia-driven target lesion revascularization



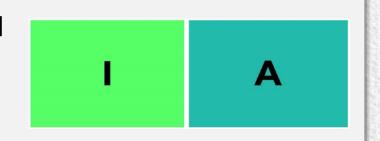




ICI Class I in LM and bifurcation PCI

2024 ESC Guidelines on Chronic Coronary Syndrome

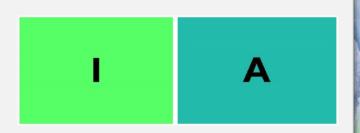
 Intracoronary imaging guidance by IVUS or OCT is recommended for performing PCI on anatomically complex lesions, in particular left main stem, true bifurcations and long lesions.



European Heart Journal 2024

2025 ACC/AHA/ACEP/NAEMSP/SCAI Guidelines on Acute Coronary Syndrome

In patients with ACS undergoing coronary stent implantation in left main artery or in complex lesions, intracoronary imaging with intravascular ultrasound (IVUS) or optical coherence tomography (OCT) is recommended for procedural guidance to reduce ischemic events.









Conclusions

- Stepwise provisional is logical, straightforward, reproducible, and versatile and remains the strategy of choice for most non-LM bifurcation lesions;
- Elective two-stent strategies may be considered for important SB with complex/extensive stenoses (the Definition II study criteria), difficult SB access or high risk of SB compromise;
- Use of imaging and physiology strongly encouraged to decide the appropriate stenting strategy and optimize the result of PCI.









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