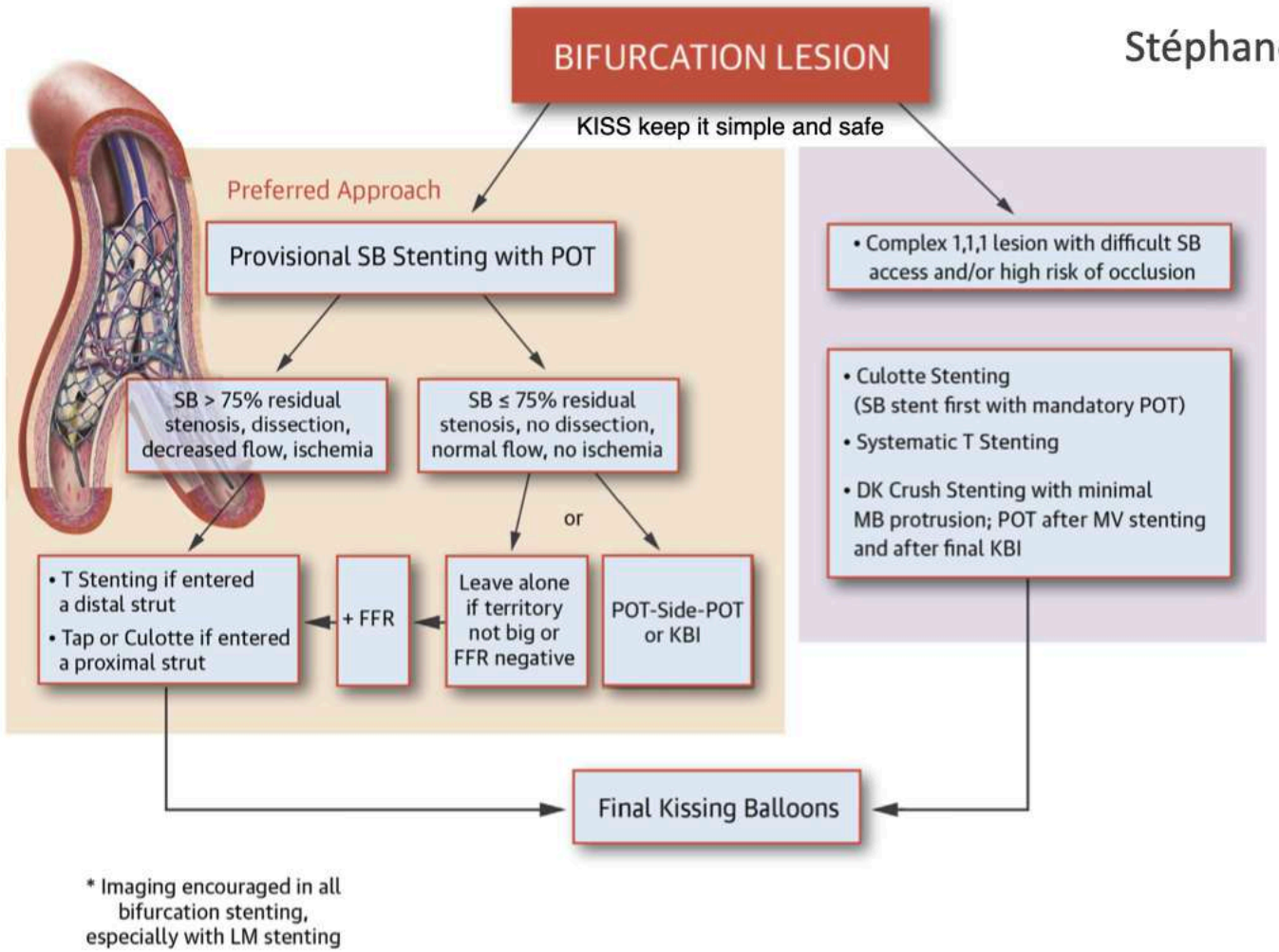
CE QUI POURRAIT CHANGER MA PRATIQUE EN 2022

1 ou 2 stents sur le TC (EBC Main)

Stéphane COOK (Fribourg, CH)



Sawaya, F.J. et al. J Am Coll Cardiol Intv. 2016;9(18):1861-78.

Stratégie à 1 stent

(conventionnel 9mo; TRYTON, Genereux et al., JACC 2015)

Plus facile/rapide & Meilleur suivi clinique

1Y, NORDIC III Spirit, Sawaya et al, JACC I, 2016
3 y; SMART-Strategy - Song et al. JACC 2016
5y; Nordic -Maeng et al, JACC, 2013
1 y; EBC 2 - Hildick-Smith et al., Circ CI, 2016
(5 y; DKCRUSH-II - Chen et al. Circ CI 2017)

Stratégie à 2 stents

Dommage, mais on fera avec

1 y; EBC 2 - Hildick-Smith et al., Circ CI, 2016
5 y; DKCRUSH-II - Chen et al. Circ CI 2017

Quel est l'angle entre les deux branches filles?

Angle droit (90°)

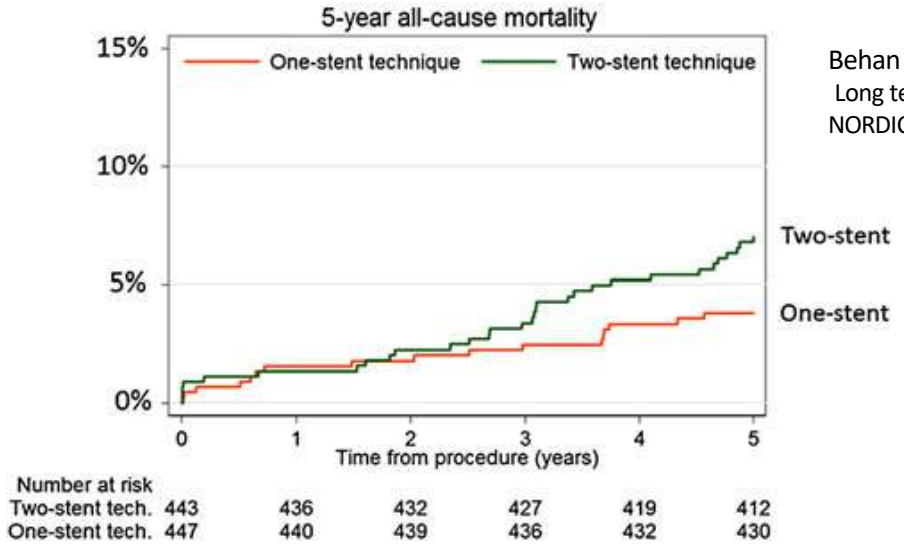
T-stenting systematique ou TAP

5y; BBK-1 (Ferenc et al. EIJ, 2015)

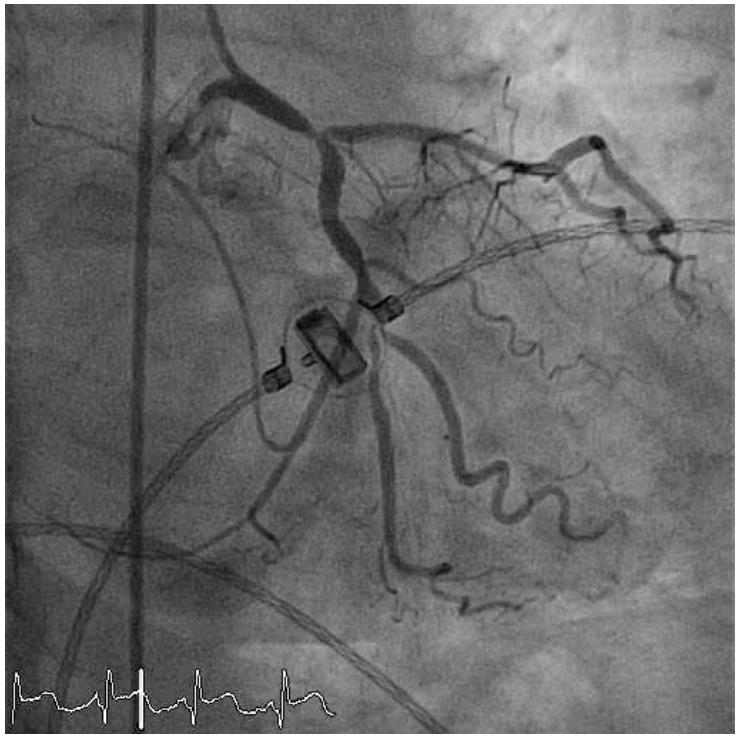
Angle aigu (70°)

DK-mini crush ou Culotte (ou V-stenting, Skirt, etc.)

1 & 3 y; DKCRUSH-III (Chen et al. JACC 2013; JACC CI 2015)
3y; Nordic (Kervinen et al., JACC CI, 2013)



Behan et al EHJ 2016
Long term follow-up of the NORDIC and BBC ONE trials



Différent pour le TC?

Résumé de l'épisode précédent (= évidence en 1 diapo)

1 stent vs. 2 stents dans le TC distal non protégé

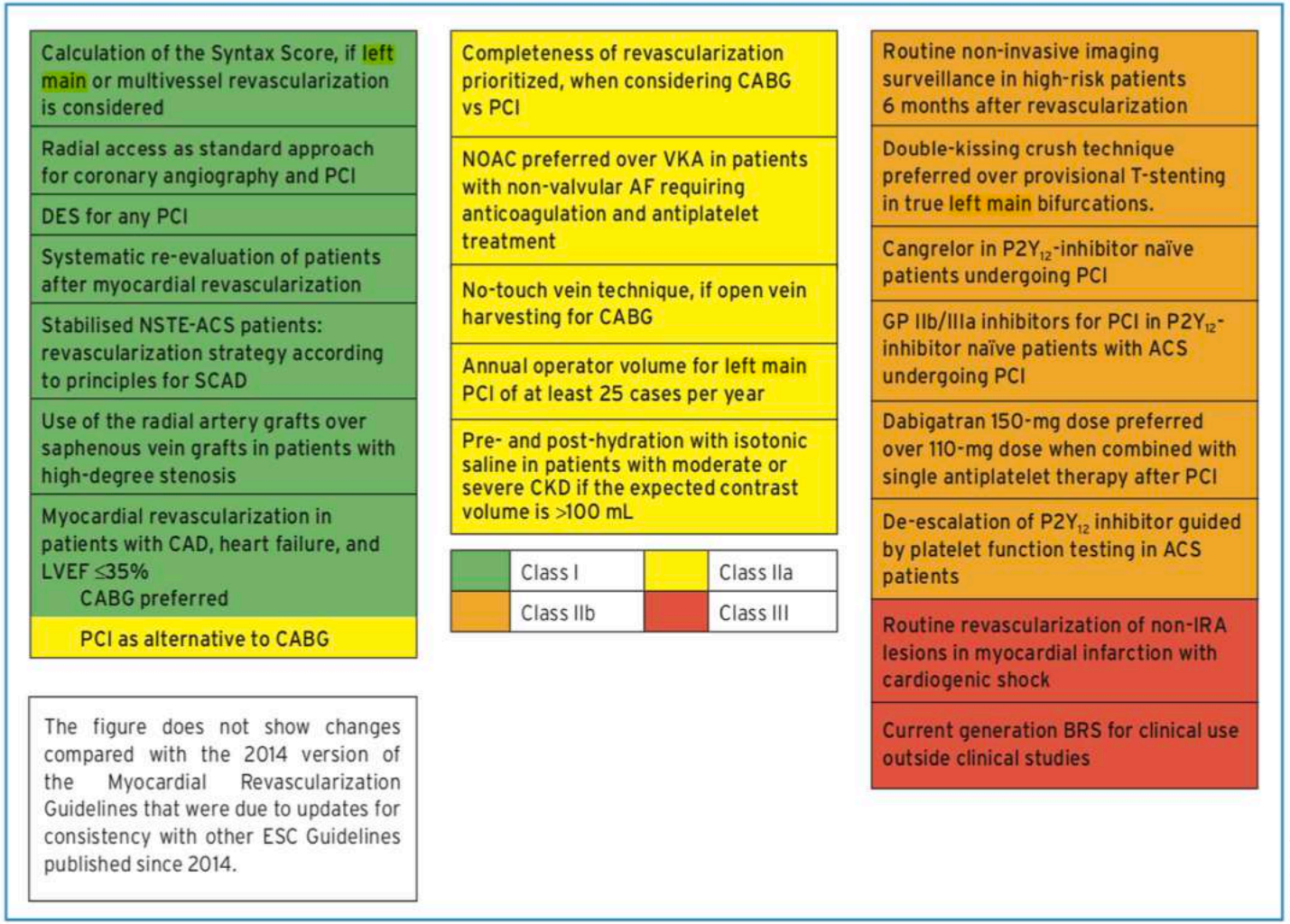
First Author	Publication year	1S	2S	Trial name	Control?	MACE	Cardiac death	TLR	MI	Definite/ probable ST
Chen et al.	2012	232	401	-	no	28.0 vs. 28.4	10.3 vs. 7.5%	12.9 vs. 17.2	10.5 vs. 5.5	3.4 vs. 2.0
Chen et al.	2014	36	66	DEFINITION	no	na.	na.	na.	na.	na.
Zhang et al.	2015	50	38	-	no	2 vs. 5.3	0 vs. 0	2 vs. 5.3	0 vs. 0	0 vs. 0
Gao et al.	2015	661	372	Fu Wai	no	9.2 vs. 11.6	4.4 vs. 3.5	6.7 vs. 8.6	6.8 vs. 8.6	2.5 vs. 1.6
Kandzari et al.	2018	344	185	EXCEL	no	14.1 vs. 20.7	3.3 vs. 8.3	7.2 vs. 16.3	7.7 vs. 12.8	1.5 vs 3.3
Kawamoto et al.	2018	216	161	FAILS-2	no	28.1 vs. 28.9	8.3 vs. 0.8	17.9 vs. 19.0	3.3 vs. 0	3.0 vs. 0
Ferenc et al.	2019	477	390	BBK-Left Main Registry	no	41.5 vs. 49.0	12.6 vs. 10.0	17.4 vs. 27.2	similar	5.9 vs. 4.6
Choi et al.	2020	682	253	COBIS III	no	10.6 vs. 17.4	1.8 vs. 4.5	5.5 vs. 15.3	2.7 vs. 2.7	na.
Lee et al.	2020	440	562	IRIS-DES &-MAIN	no	20.3 vs. 24.1	5.6 vs. 4.9	12.4 vs. 14.4	8.4 vs. 9.1	0.2 vs. 0.2
Wang et al.	2020	444	484	Fu Wai	no	12.4 vs. 10.5	4.9 vs. 1.9	3.0 vs. 3.7	7.5 vs. 5.8	3.5 vs. 1.5
Takagi et al	2020	608	329	Tokyo-Milano	PPS	29.6 vs. 38.3	8.6 vs. 5.5	15.8 vs 28	3.5 vs. 2.8	1.8 vs. 1.8
Nasir et al.	2020	73	30	Pakistan	no	4.1 vs. 16.7%	na	na	na	na
Chen et al.	2017	242	240	DKCRUSH-V	RCT	10.7 vs. 5.0	2.1 vs. 1.2	7.9 vs. 3.8	2.9 vs. 0.4	3.3 vs. 0.4

11 registres non controlés:
-6: aucune différence
-4: 1 S >> 2S
-0: 2S> 1 S

1 registre controlé:
1 S >> 2S

1 RCT: 2S >> 1S

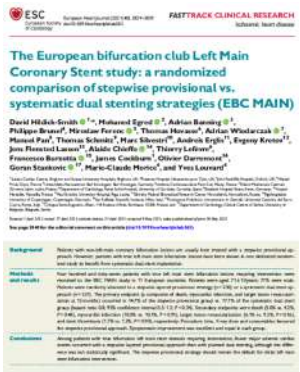
2.1 What is new in the 2018 Guidelines?



ACS = acute coronary syndromes; AF = atrial fibrillation; BRS = bioresorbable scaffolds; CABG = coronary artery bypass grafting; CAD = coronary artery disease; CKD = chronic kidney disease; DES = drug-eluting stents; FFR = fractional flow reserve; GP = glycoprotein; IRA = infarct-related artery; LVEF = left ventricular ejection fraction; NOAC = non-vitamin K oral anticoagulants; NSTEMI = non-ST-elevation; PCI = percutaneous coronary intervention; SCAD = stable coronary artery disease; VKA = vitamin K antagonists.

L'étude

Patient Enrolment and Endpoints


ESC

FASTTRACK CLINICAL RESEARCH

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

EBC MAIN TRIAL

Randomised comparison of provisional strategy vs a systematic dual stent strategy for true bifurcation LM disease with Resolute Onyx™ DES

EBC MAIN

Stable or unstable angina patients with ULM bifurcation disease (type 1,1,1, or 0,1,1; both branches >2.75 mm) requiring PCI

Single-stent strategy
N=230

Dual-stent strategy
N=237

EBC Initiated
30 European Centers
Lead Investigator – David Hildick-Smith
Medtronic funded
Study Device: Resolute Onyx™ DES

6 mo | 12 mos | 3 yr | 5 yr

Primary endpoint:	**Composite of death, MI and TLR at 1 yr**
Secondary endpoints:	Death, MI, TLR each at 12 months Angina status, ST, death, MI, TLR at 3 and 5 years
Procedural endpoints:	Procedural and technical success Procedural and in-hospital MACE Procedure duration, fluoroscopy and cost

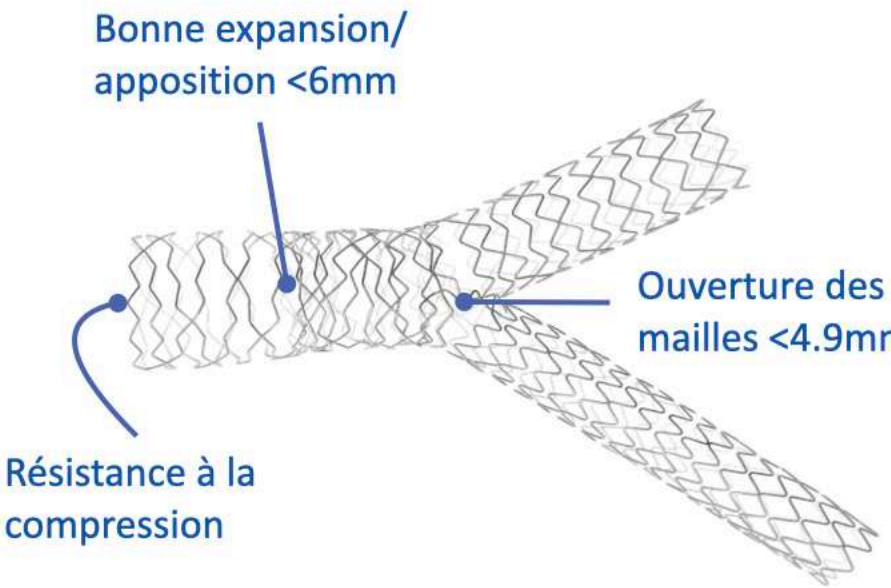
CERC Cardiovascular European Research Center

Choix du stent

DES Designs Overexpansion

Balloon Max Size		Synergy	Xpedition	Res. Onyx	Ultimaster	BioMatrix A	Orsiro
4.0	2.25	Small vessel (8 crowns, 2-4 connectors) *Expansion: 3.6mm*	Small vessel (6 crowns, 3 connectors) *Expansion: 4.1mm*	Small vessel workhorse (6.5 crowns, 2 connectors) *Expan: 3.3mm*	Small vessel (8 crowns, 2 connectors) *Expansion: 4.3mm*	Small vessel (6 crowns, 2 connectors) *Expansion: 4.1mm*	Small vessel (6 crowns, 3 connectors) *Expansion: 4.0mm*
	2.50						
5.0	2.75			Medium vessel workhorse (8.5 crowns, 2 connectors) *Expansion: 4.4mm*			
	3.00	Workhorse (8 crowns, 2-4 connectors) *Expansion: 4.2mm*					
	3.50		Large vessel (9 crowns, 3 connectors) *Expansion: 5.6mm*	Large vessel (9.5 crowns, 2.5 connectors) *Expansion: 5.6mm*	Large vessel (8 crowns, 2 connectors) *Expansion: 5.8mm*	Large vessel (9 crowns, 3 connectors) *Expansion: 5.9mm*	Large vessel (6 crowns, 3 connectors) *Expansion: 5.3mm*
6.0	4.00	Large vessel (10 crowns, 2-5 connectors) *Exp: 5.7mm*					
	4.50			Extra-Large vessel (10.5 crowns, 2.5 connectors) *Expansion: 6.0mm*			
	5.00						

- *Expansion : inner stent MLD excluding struts*
- *Max balloon size : Maverick 6.0mm at 14 ATM*

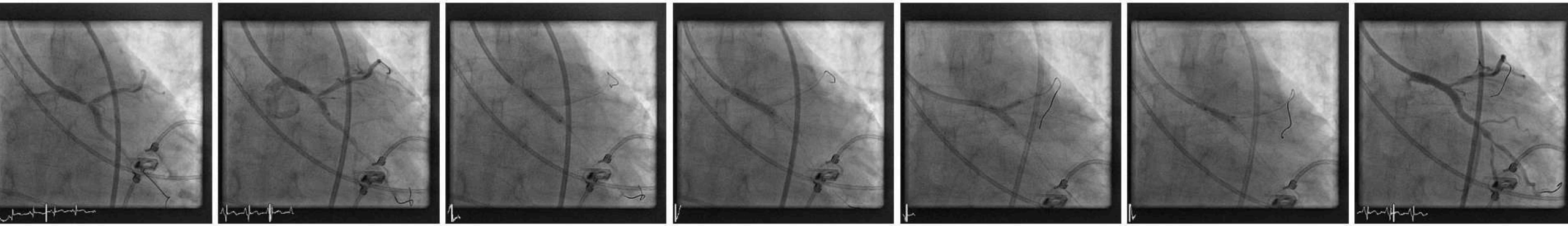


Resolute Onyx

- large matrice
- diamètres 4,5 mm et 5,0 mm extensibles jusqu'à 6,0 mm
- Résistance radiale et intégrité structurelle soutenues en cas de surexpansion
- Capacité d'adaptation aux diamètres de vaisseaux coniques
- *facilité à croiser* la SB

Choix de la technique

1 Préparation (minimale de la SB)
2.Stent LM-MB
3. POT
4. Rewirering distal strut
5. Kissing (alternate-HP/simultaneous-LP)
6. POT

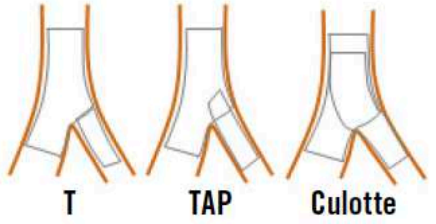


Olivier Darremond

John Ormiston

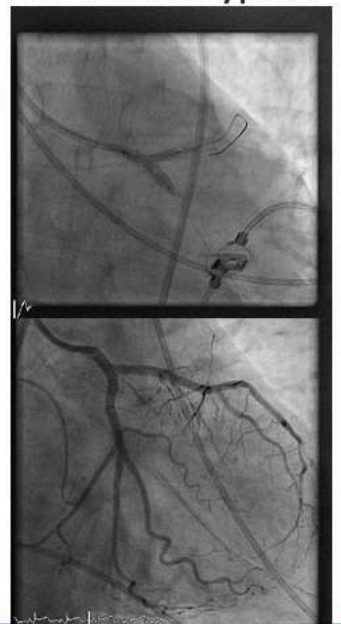
Bernhard Meier

Bernard Chevalier



Re-POT
Re-KISS

SB stent if
<TIMI 3 flow
>90% ostial
pinching
dissection >type A



Population

	Stepwise provisional ($n = 230$)	Systematic dual ($n = 237$)
Age (years), mean (SD)	70.8 (10.1)	71.4 (9.8)
Male sex (%)	182 (79%)	177 (74%)
Ischaemic symptoms	223 (97%)	224 (95%)
+ve non-invasive imaging	91 (40%)	100 (42%)
+ve FFR	47 (20%)	47 (20%)
IVUS <6 mm^2	77 (34%)	72 (30%)
BMI (kg/m^2), mean (SD)	28.6 (5.5)	28.4 (5.5)
Diabetes	66 (29%)	62 (27%)
Hypertension	180 (79%)	190 (82%)
Hypercholesterolaemia	158 (70%)	166 (72%)
Current smoker	36 (16%)	30 (13%)
Family history	74 (33%)	75 (33%)
Previous MI	60 (26%)	66 (28%)
Previous PCI	93 (41%)	99 (43%)
Previous stroke	16 (7%)	17 (7%)
Peripheral vascular disease	31 (14%)	37 (16%)
Renal failure[a]	12 (5%)	9 (4%)
Left ventricular function		
Good (EF > 50%)	143 (63%)	142 (62%)
Moderate (30–50%)	45 (20%)	54 (23%)
Poor (<30%)	9 (4%)	9 (4%)
Unknown	30 (13%)	27 (11%)

Présentation

	Stepwise provisional ($n = 230$)	Systematic dual ($n = 237$)
Presentation		
Stable coronary disease	149 (66%)	139 (60%)
CCS 0	25	32
CCS 1	31	19
CCS 2	49	42
CCS 3	35	38
CCS 4	8	7
Acute coronary syndrome	78 (33%)	93 (40%)

Lésions

SYNTAX score, mean (SD)	22.6 (5.9)	23.2 (6.0)
0–22	72 (30%)	62 (26%)
22–32	132 (56%)	134 (57%)
Missing	36 (15%)	40 (17%)
Medina classification		
1,1,1	204 (90%)	206 (89%)
0,1,1	23 (10%)	25 (11%)
Adverse lesion features		
Trifurcation	13 (5%)	10 (4%)
Calcification ≥moderate	101 (44%)	125 (54%)
Tortuosity ≥moderate	43 (19%)	56 (24%)
Angle between LAD and Cx	80.4 (20.1)	82.3 (22.8)

Technique

Stepwise provisional single stent group

The protocol specified the procedural steps for this group of patients. Coronary guide wires were passed to the left anterior descending (LAD) and circumflex (Cx)/intermediate arteries, respectively. One was designated the main vessel and one the side vessel. Lesion preparation was undertaken as required but side vessel predilatation was discouraged unless considered essential by the operator, to reduce the risk of an unsecured dissection. Stenting of the main vessel was undertaken with a wire jailed in the side vessel to preserve side vessel flow and access. Stent diameter was chosen according to the diameter of the main vessel immediately distal to the bifurcation. Following stenting of the left main into the main vessel, the left main stent was dilated to the carina with a short non-compliant balloon of appropriate size for the left main stem (proximal optimization technique, POT). Following this, the side vessel was rewired through a distal stent strut where possible, and a kissing balloon inflation was undertaken. Kissing balloon sizes were chosen according to the diameter of the distal main and side vessel respectively, with individual higher pressure inflation followed by a final lower pressure kiss dilatation. The left main stent was then dilated using either low pressure dilatation of the kissing balloon pair or a separate individual balloon. For these dilatations, non-compliant balloons were preferred to limit the risk of dissection through uneven expansion. Following kissing dilatation, the side vessel was not to be treated further unless there was one of the following: <TIMI 3 flow in the side vessel, severe (>90%) ostial pinching of the side vessel, threatened side-vessel closure or side-vessel dissection >type A. Under these circumstances, the operator could choose to implant a side vessel stent in a manner of their choosing (e.g. T, TAP, culotte). Following implantation of a second stent, repeat POT followed by recrossing and repeat kissing balloon inflation was mandatory, again using non-compliant balloons as above, with individual very high pressure inflations at the stent bifurcations followed by final kissing balloons at lower pressures. Further treatment to proximal or distal aspects of the main vessel or side vessel could be continued at the discretion of the operator in the event of, for example, proximal or distal dissections.

	Stepwise provisional ($n = 230$)	Systematic dual ($n = 237$)
Access site		
Femoral	64 (28%)	68 (29%)
Radial	161 (71%)	160 (70%)
Antiplatelets	230 (100%)	237 (100%)
Aspirin	216 (95%)	222 (96%)
Clopidogrel	147 (66%)	155 (67%)
Ticagrelor	48 (22%)	47 (20%)
Prasugrel	11 (5%)	13 (6%)
Glycoprotein inhibitor use	11 (5%)	9 (4%)
Main vessel LMS/LAD	174 (77%)	176 (77%)
Main vessel LMS/Cx	53 (23%)	54 (23%)
Preparation of main vessel	199 (88%)	204 (88%)
Balloon	147 (65%)	163 (69%)
Cutting balloon	25 (12%)	22 (10%)
Rotablation	28 (13%)	27 (12%)
Lithotripsy	4 (2%)	0 (0%)
Preparation of side vessel	112 (49%)	190 (83%)
Balloon	96 (43%)	159 (69%)
Cutting balloon	12 (6%)	18 (8%)
Rotablation	11 (6%)	16 (7%)
Lithotripsy	1 (0%)	0 (0%)
Vessel stented first		
Main	226 (100%)	119 (51%)
Side	0 (0%)	110 (49%)
Stent to main/first vessel	226 (99%)	229 (99%)
Stent diameter main/first vessel,	3.8 (0.5)	3.6 (0.6)
Stent length to main/first vessel,	22.1 (7.0)	21.8 (7.0)
Implantation technique		
Stepwise provisional	226 (99%)	12 (5%)
Culotte	—	121 (53%)
Crush (DK)	—	11 (5%)
T or TAP	—	76 (32%)
Unstated	—	10 (4%)
Proximal optimization after first stent	194 (85%)	199 (87%)
Kissing balloons after first stent		
Yes	202 (89%)	15 (6%)
Stent to side/second vessel		
Yes	51 (22%)	217 (94%)
Second stent implantation technique		
Culotte	26 (11%)	121 (53%)
Crush (DK)	0 (0%)	11 (5%)
T or TAP	24 (11%)	76 (33%)
Not applicable	176 (78%)	22 (10%)
Missing data	3	7
Reason for second stent		
Dissection	22 (10%)	—
Residual stenosis	26 (12%)	—
Impaired flow	1 (1%)	—
Other	2 (1%)	—
Stent diameter side/second vessel, mm (SD)	3.5 (0.6)	3.6 (0.6)
Stent length to side/second vessel, mm (SD)	17.6 (6.9)	19.3 (6.7)
Kissing balloon inflations after 2nd stent?		
Yes	51 (22%)	217 (93%)
Final POT		
Yes	184 (81%)	192 (84%)

Systematic planned two-stent group

The protocol specified the procedural steps for this group of patients. Coronary guide wires were passed to the LAD and Cx/intermediate arteries, respectively. One was designated the main vessel and one the side vessel. Lesion preparation was undertaken as considered necessary in both limbs. The stent technique was at the discretion of the operator but could be one of culotte, DK-minicrush, T or TAP. Stent diameter was made according to the diameter of the vessel immediately distal to the bifurcation. Specific practical steps varied according to the technique chosen. In the culotte strategy, after the first stent was implanted and POT done, the second vessel was rewired (ideally distally), predilated and a stent placed with a short overlap only to the main vessel stent. A second POT was made and the main vessel rewired. A final kiss was made with high pressure individual dilatations at the bifurcation of the stents followed by a lower pressure kiss at the neocarina. A final POT or low-pressure inflation of the two kissing balloons was made back to the proximal edge of the left main stem stent to ensure full apposition. Similar procedural steps, with appropriate variations, were required for the T, TAP, and DK-minicrush procedures, according to the principles laid out in previous European Bifurcation Club recommendations.[12,13] Further treatment to the proximal or distal aspects of the main vessel or side vessel could be made at the discretion of the operator. At any stage, proximal or distal dissections could be treated as required with further stent implantations.

PCI complexes

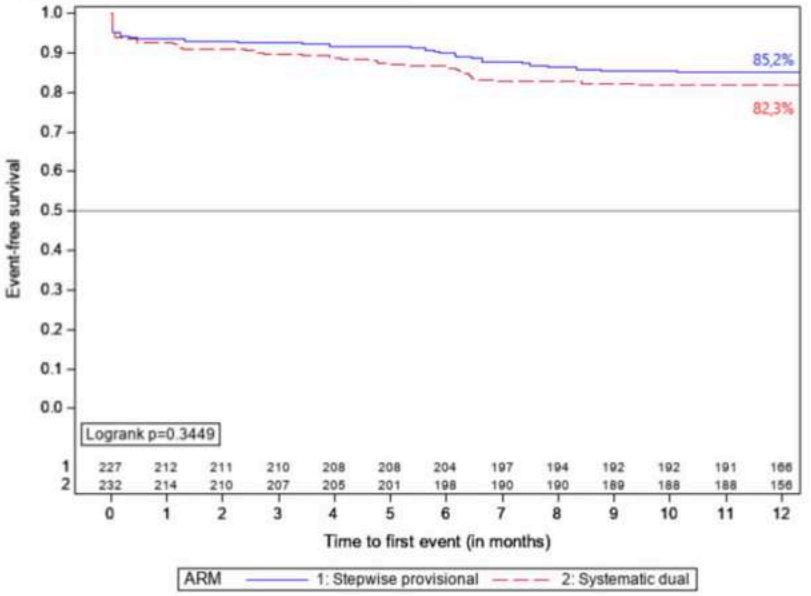
Procédure

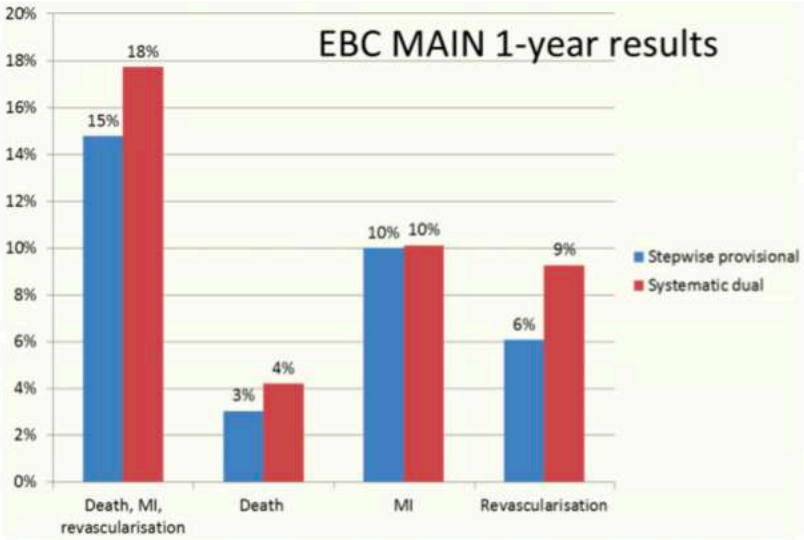
	Stepwise prov	Systematic	*P*-values
No. guide catheters used	1.2 (0.5)	1.2 (0.6)	*P* = 0.4
No. guidewires used	3.0 (1.4)	3.2 (1.5)	*P* = 0.07
No. balloons used	4.9 (2.1)	5.4 (2.2)	*P* = 0.004
No. stents deployed at bifurcation	1.6 (1.1)	2.3 (0.8)	*P* < 0.001
IVUS	81 (36%)	71 (31%)	*P* = 0.3
Single vessel	46 (20%)	19 (8%)	
Both vessels	35 (15%)	52 (19%)	
Reintervention resulting	28 (12%)	14 (6%)	
OCT	11 (4%)	17 (7%)	*P* = 0.3
FFR	12 (4%)	2 (1%)	*P* = 0.006
Stented length (mm)	25.4 (13)	31.7 (18)	*P* = <0.001
Additional vessels stented	103 (45%)	118 (51%)	*P* = 0.3
LAD	61	80	
Cx	29	22	
RCA	13	16	
Additional stents	1.6 (1.1)	1.7 (1.1)	*P* = 0.4
Total no. stents implanted	2.9 (1.3)	3.7 (1.1)	*P* < 0.001
Procedure duration, min (SD)	74 (35)	80 (39)	*P* = 0.049
Fluoroscopy duration, min (SD)	21 (12)	24 (16)	*P* = 0.02
X-ray dose (cGy.cm^2)	7060 (7320)	7470 (6560)	*P* = 0.02
Air Kerma (Gy)	0.70 (1.30)	0.82 (1.34)	*P* = 0.02
Contrast volume (mLs, SD)	215 (92)	225 (96)	*P* = 0.3
Technical success	202 (88%)	211 (89%)	*P* = 0.5
Procedural success	224 (97%)	219 (92%)	*P* = 0.8

Suivi clinique

	Stepwise provisional ($n = 230$)	Systematic dual ($n = 237$)	Hazard ratio (95% CI) and *P*-value
Primary endpoint			
Death, myocardial infarction or target lesion revascularization at 12 months	34 (14.7%)	42 (17.7%)	HR 0.8 (0.5–1.3), $P = 0.34$
Secondary endpoints			
Death	7 (3.0%)	10 (4.2%)	HR 0.7 (0.3–1.9), $P = 0.48$
Myocardial infarction	23 (10.0%)	24 (10.1%)	
Peri-procedural	9 (4%)	11 (5%)	HR 0.9 (0.5–1.7), $P = 0.9$
Subsequent	12 (5%)	13 (6%)	
Target lesion revascularization	14 (6.1%)	22 (9.3%)	
PCI	13	19	HR 0.6 (0.3–1.2), $P = 0.16$
CABG	1	3	
Stent thrombosis (definite/probable)	4 (1.7%)	3 (1.3%)	
Acute	1	0	
Subacute	1	1	HR 0.9 (0.4–1.9), $P = 0.9$
Late	2	2	

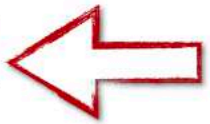
1° Endpoint

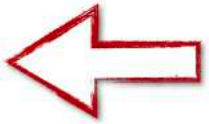




DK-Crush V vs. EBC Main

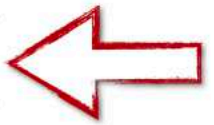
	DK-Crush V study		EBC Main	
	Prov Stent (DK) 240	DK Crush 242	Prov Stent 230	Systematic 237
Transradial	181 (75)	187 (78)	161 (71)	160 (70)
Aspirin	240 (100)	242 (100)	216 (95)	222 (96)
Clopidogrel	**240 (100)**	**242 (100)**	**147 (66)**	**155(67)**
Ticagrelor or Prasugrel	0 (0)	0 (0)	59 (27)	60 (26)
Pre-dilatation				
.MB	203 (84)	181 (75)	199 (88)	204 (88)
.SB	96 (40)	164 (68)	112 (49)	190 (83)
Nb Stent MB	**1.60 ± 0.6**	**1.58 ±0.69**	**1**	**1**
Diameter Stent MB, mm	**3.29±0.38**	**3.32±0.37**	**3.8±0.5**	**3.6±0.6**
Total MB length, mm	**48.2±18.4**	**49.3±19.1**	**22.1±7.0**	**21.8±7.0**
Side branch stent	**114 (47)**	**242 (100)**	**51 (22)**	**217 (94)**
Diameter Stent SB, mm	**2.97±0.38**	**2.92±0.35**	**3.5±0.6**	**3.6±0.6**
Total SB length, mm	**28.33±9.10**	**32.44±10.51**	**17.6±6.9**	**19.3±6.7**
POT performed	239 (98.8)	238 (99.2)	184 (81)	192 (84)
Final Kissing	191 (78.9)	239 (99.6)	51 (22)	217 (93)
Procedural IVUS/OCT use	98 (40.5)	103 (42.9)	92 (40)	88 (38)
Procedural duration	66±34	82±37	74±35	80±39
Technical success	235 (97)	236 (98)	202 (88)	211 (89)





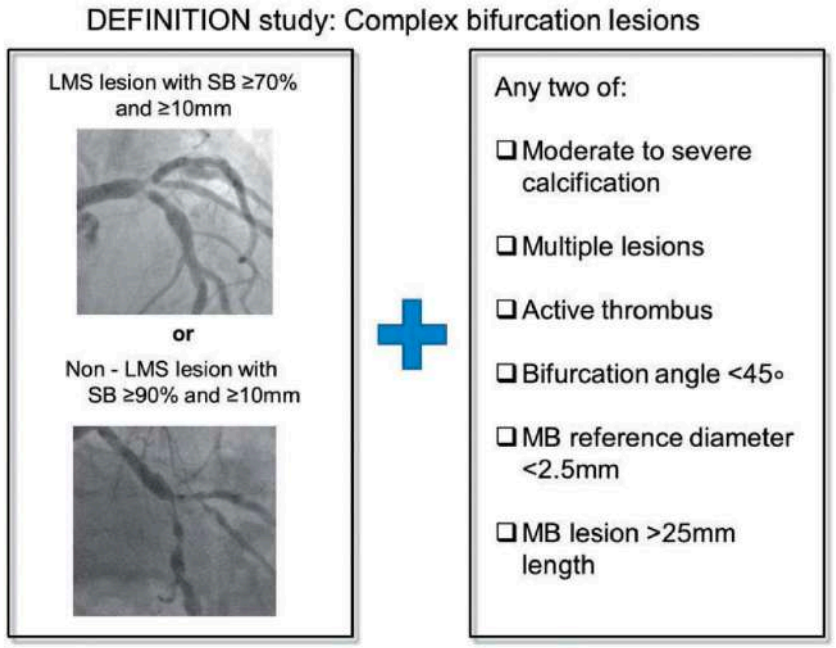
DK-Crush V vs. EBC Main

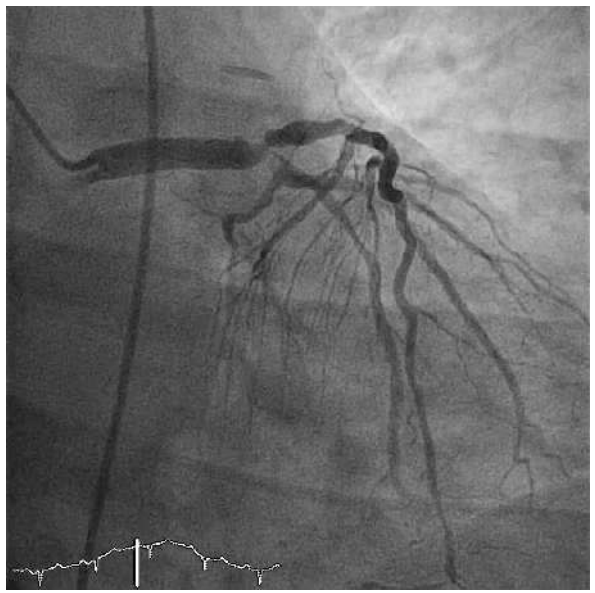
	DK-Crush V study		EBC Main	
	Prov Stent (DK) 240	DK Crush 242	Prov Stent 230	Systematic 237
All-cause death	5 (2.1)	7 (2.9)	7 (3.0%)	10 (4.2%)
All-cause MI			23 (10.0%)	24 (10.1%)
Target vessel MI	7 (2.9)	1 (0.4)		
Target lesion revascularizat	19 (7.9)	9 (3.8)	14 (6.1%)	22 (9.3%)
PCI	17 (7.1)	8 (3.4)	13 (5.7)	19 (8.0)
CABG	2 (0.8)	1 (0.4)	1 (0.4)	3 (1.3)
Stent thrombosis, definiti	8 (3.3)	1 (0.4)	4 (1.7%)	3 (1.3%)

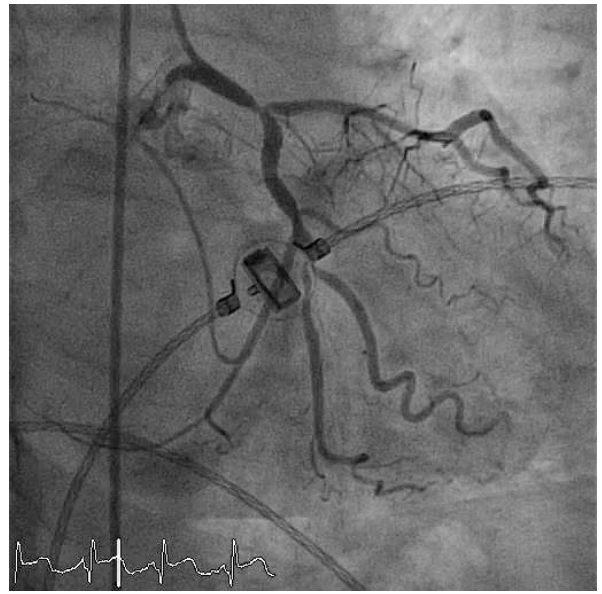


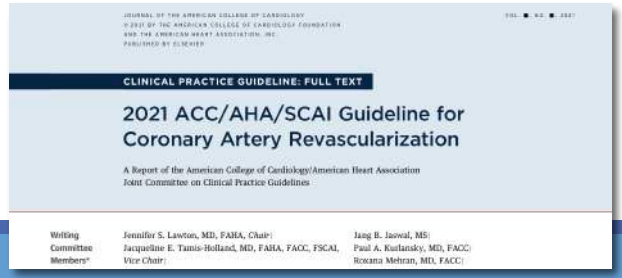
Conclusions EBC

- En utilisant une technique stricte, le nombre d'événements secondaires graves est inférieur avec l'approche provisoire par étapes.
- La durée de l'intervention, la dose de rayons X et les consommables sont moindres.
- Seul un cinquième des patients nécessite un deuxième stent.
- Il n'est pas nécessaire de " préjuger du résultat" et de commencer par une stratégie à deux stents.









EST-CE QUE CELA CHANGERA VOTRE PRATIQUE EN 2022?