Side Branch Pre-dilation During Provisional Stenting of Coronary Bifurcation Lesions: A Randomized Controlled Trial

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The Effects of Side Branch Predilation During Provisional Stenting of Coronary Bifurcation Lesions: A Randomized Controlled Trial

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Potential conflicts of interest

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I have no potential conflicts of interest

Background

- Elective two-stent strategy is not superior to the provisional stenting.
- Jailed wire technique and pre-dilatation of the SB before MV stenting have been proposed to protect SB during provisional stenting.
- Not a precise conclusion from available, albeit rather insufficient data

COBIS registry

More common FKB and crossing-over

More common TVF and TVR in 21 mo

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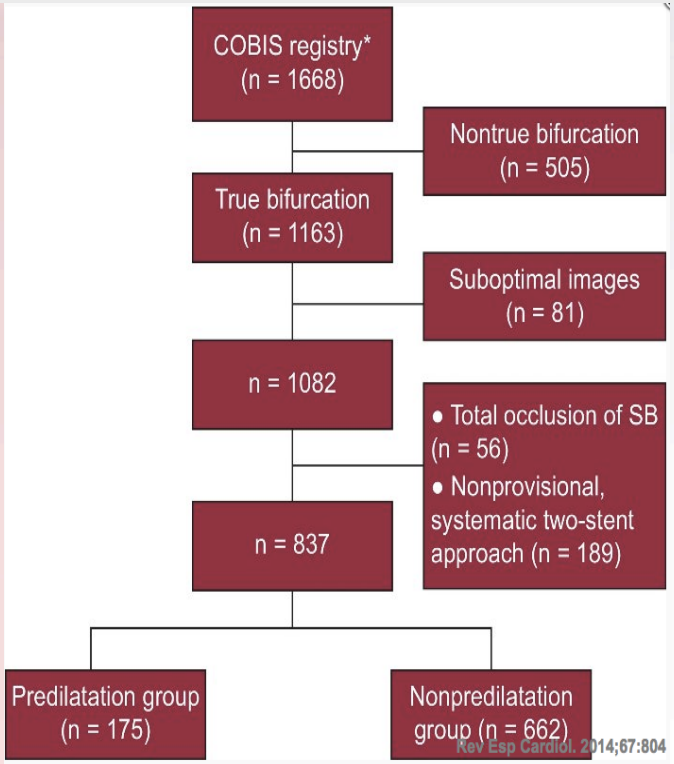

Pan et al

Lower rate of TIMI 0-1
Lower rate of TIMI<3
No change in access to the SB
Less need to treat SB
No change in clinical outcome in 1 and 6 mo

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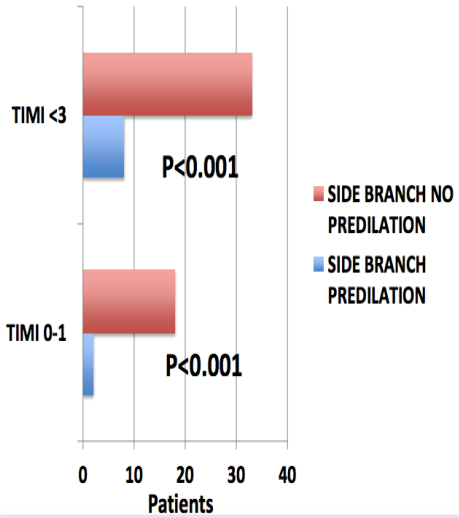
RESULTS (I): Primary end point (TIMI flow at side branch after main vessel stent)



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RESULTS (II): Secondary end points

	Side-Branch predilation (n=187)	Side-Branch no predilation (n=185)	p
Impossibility to re-cross (wire/balloon)	2 (1.5%) (n=127)	2 (1%)	0.62
Time of re-wiring (minutes)	2.2±6 (n=127)	3.2±7	0.20
Number of wires used in the re-wiring	1.1±0.4 (n=127)	1.3±0.6	0.023
Final % stenosis at side branch	16±17	15±16	0.59
Troponin post-procedure (IU/L)	2.9±7.2	2.8±6.2	0.87

RESULTS (III): Major clinical events

	Side-Branch predilation (n=187)	Side-Branch no predilation (n=185)	p
1 MONTH			
- NSTEMI	3 (1.6%)	7 (3.7%)	0.23
- Death *	1 (0.5)	0	1
1-6 MONTHS			
- AMI	0	1 (0.5%)	1
- TLR	5 (2.7%)	5 (2.7%)	1
- Death *	1 (0.5%)	3 (1.6%)	0.37

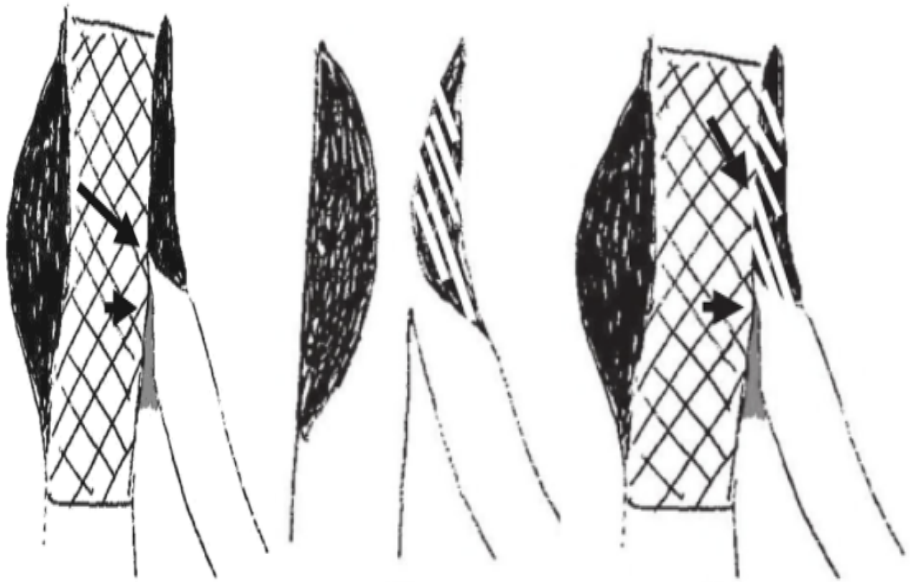
Am Heart J.2014;168:374-80

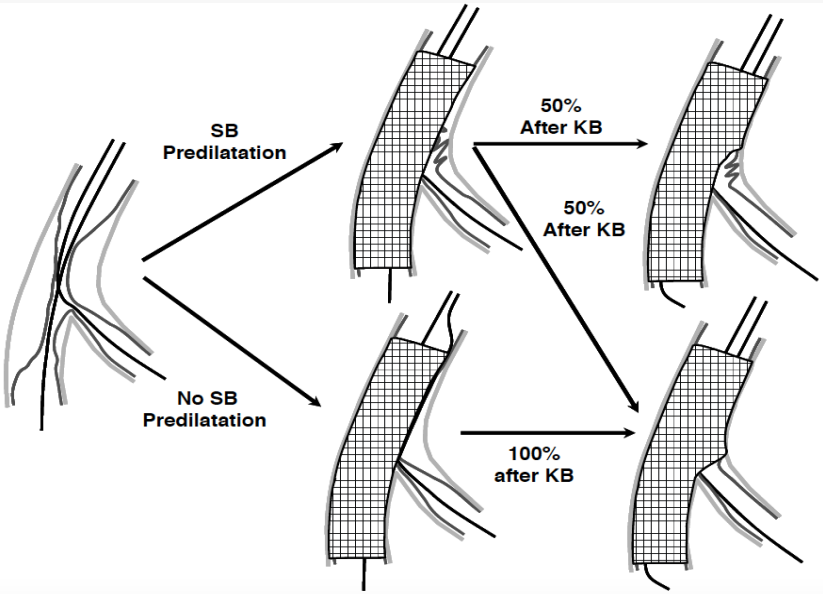
Pros:

- Potentially improves the SB-TIMI flow after MV stenting
- Potentially improves access to the SB after MV stenting
- Sometimes, no need for rewiring and post-dilation

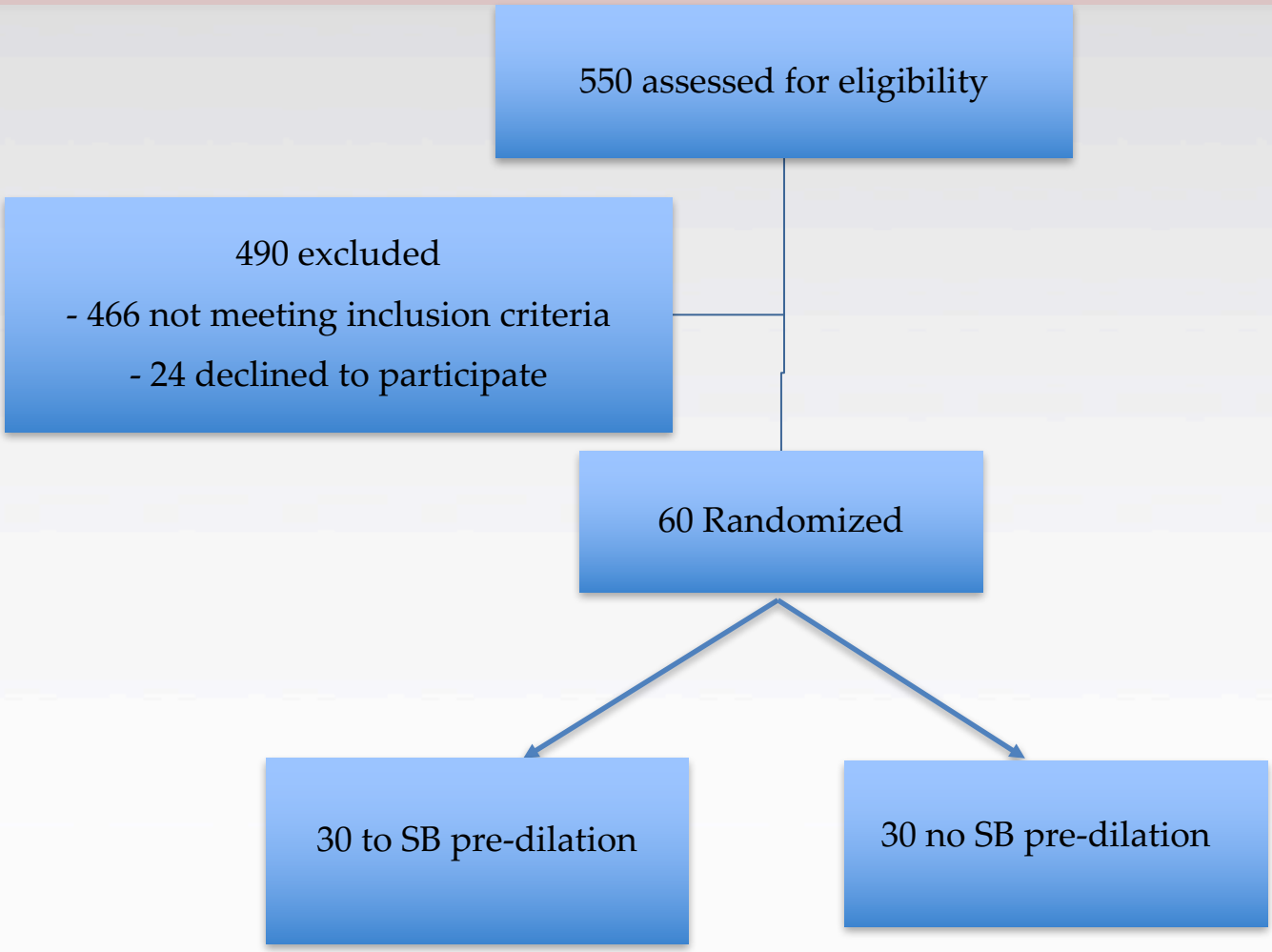
Cons:

- Possible dissection at the SB ostium, hampering access to the SB, more proximal cross
- No effect on clinical outcome





Study design



Inclusion criteria:

- *> 18 years of age*
- *CSA or non STE-ACS with an indication for CAG and PCI*
- *Having a true bifurcation lesion (Medina classification: [1,1,1], [1,0,1], [0,1,1])*
- *Undergoing single vessel PCI*
- *Diameter of the MV ≥ 2.5 mm*
- *Diameter of the SB ≥ 2 mm*
- *Length of stenosis in the SB ≤ 5 mm*

Exclusion criteria:

- *Inability to receive DAPT*
- *STEMI (<72h)*
- *Hemodynamic instability or cardiogenic shock*
- *Left main PCI*
- *Multivessel PCI*
- *Inability to access the SB*
- *Length of stenosis in the SB > 5 mm beyond the ostium*
- *Untreated major complications during the procedure*

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Primary endpoint:

- TIMI flow of the SB after MV stenting

Secondary endpoints:

- Severity of stenosis at the SB ostium
- The occurrence of dissection at the SB ostium
- Post-procedural cTnI rise
- Need for SB rewiring
- Time of rewiring
- Need for FKB and double stenting

Procedural Protocol and Follow-Up

- After wiring both the main and side branches, balloon angioplasty of the SB was performed in the predilation group using non-compliant balloons with the sizes similar to the SB reference size at a moderately high inflation pressures (14 - 18 atm).
- Pre-dilation of the MB was performed if required.
- The diameter of the MB stent was chosen according to the diameter of the distal segment after the origin of the SB.
- FKB dilation was considered in the presence of impaired SB flow (TIMI flow < 3) or SB ostial stenosis > 80%.
- In the case of continued impaired flow in the SB despite using FKB dilation, a double stenting technique was selected depending on the anatomy of the bifurcation lesion.

Results

Baseline characteristics

Baseline data	Predilation	Non-predilation	P value
Age (mean) y	58.9 ± 12.7	56.6 ± 9.4	0.42
Male Female	23 (76.7) 7 (23.3)	21 (70) 9 (30)	0.55
Smoking	7 (23.3)	7 (23.3)	0.9
HTN	8 (26.7)	17 (56.7)	0.01
DLP	12 (40)	11.(36.7)	0.31
DM	7 (23.3)	11 (36.7)	0.26
FHx	3 (10.3)	2 (6.7)	0.6
LVEF (%)	44.5 ± 9.41	45.19 ± 8.82	0.77
CSA NSTEMI UA	17 (56.6) 2 (6.7) 11 (36.7)	22 (73.3) 3 (10.3) 5 (17.2)	0.22 0.77 0.12
Preprocedural cTnI (μg/L)	0.19 ± 0.56	0.43 ± 1.62	0.44

Angiographic data	Predilation	Non-predilation	P value
Lesion location LAD-D LCX-OM Distal RCA	 24 (80) 5 (16.7) 1 (3.3)	 27 (90) 2 (6.7) 1(3.3)	0.48
Medina 1,1,1 1,0,1 0,1,1	 22 (73.3) 3 (10) 5 (16.7)	 21 (70) 3 (10) 6 (20)	0.94
Main vessel Lesion length (mm) Diameter (mm)	 24.60 ± 6.98 3.95 ± 1.23	 24.33 ± 7.80 3.27 ± 1.16	 0.88 0.29
Side branch Lesion length (mm) Diameter (mm)	 4.43 ± 1.74 2.33 ± 0.09	 3.67 ± 1.06 2.27 ± 0.13	 0.06 0.93

Procedural characteristics

Procedural data	Predilation	Non-predilation	P value
Type of stent			0.77
DES	30 (100)	29 (96.6)	
BMS	0	1 (3.3)	
Main vessel stent			
Length (mm)	28.53 ± 7.25	26.87 ± 7.86	0.32
Diameter (mm)	3.02 ± 0.33	2.96 ± 0.33	0.69
Side branch			
Dissection	5 (16.7)	0	0.07
TIMI flow< 3	3 (10)	1 (6.7)	0.34
Ostial stenosis >80%	4 (13.3)	8 (26.6)	0.17
Need to rewire	15 (50)	12 (40)	0.43
Rewiring time (mm), min	2.87 ± 1.69	3.08 ± 1.38	0.72
Final kissing inflation	14 (46.7)	11 (36.7)	0.43
Double stenting	4 (13.3)	0	0.11
cTnI level (μg/L)	0.75 ± 2.51	0.55 ± 1.12	0.69

Conclusions

- The study was not sufficiently powered because of the small number of the participants.

- Not statistically significant but from the clinical point of view, the results seem to be important and in accord with other studies.

- Side branch pre-dilation increases the possibility of dissection at the SB ostium and consequently the chance of crossing-over to two-stent strategy. On the other hand, pre-dilation does not facilitate SB access after MV stenting.

- It should be avoided as a routine strategy.