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Final kissing balloon inflation with non compliant balloons.

Is it better ? A pilot study.

European Bifurcation Club

EBC

Provisionnal T, Where are we?

- “Gold standard Approach”
- Need for SB stenting in all comers studies:

  5 to 40%

Background

NC balloons could be better than conventional balloons for final kissing balloon inflation

- Better proximal stent deployment
- Reduced balloon oversizing in SB

Design of the study

Prospective all comers study

2 centers (Massy and Toulouse)

Main exclusion criteria

- In stent restenosis
- Medina 0,0,1 lesions

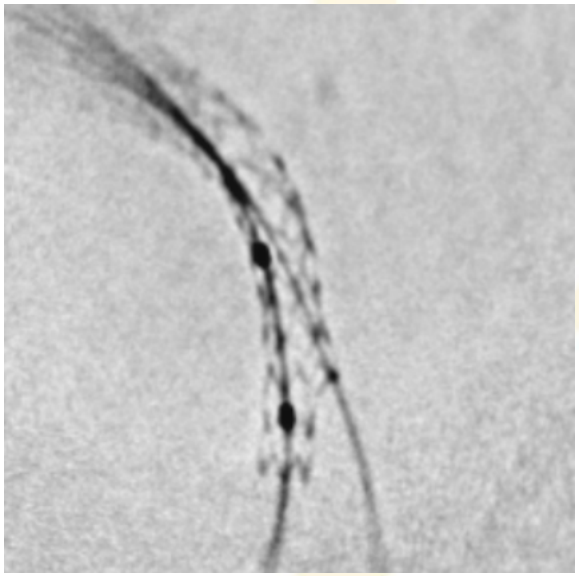
Design of the study (2)

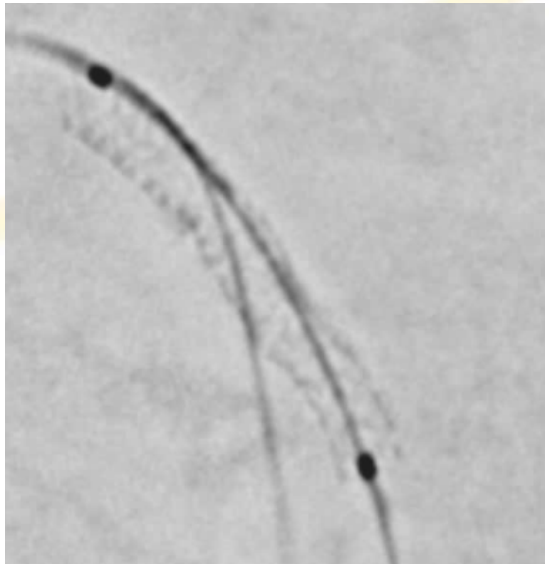
Default strategy:

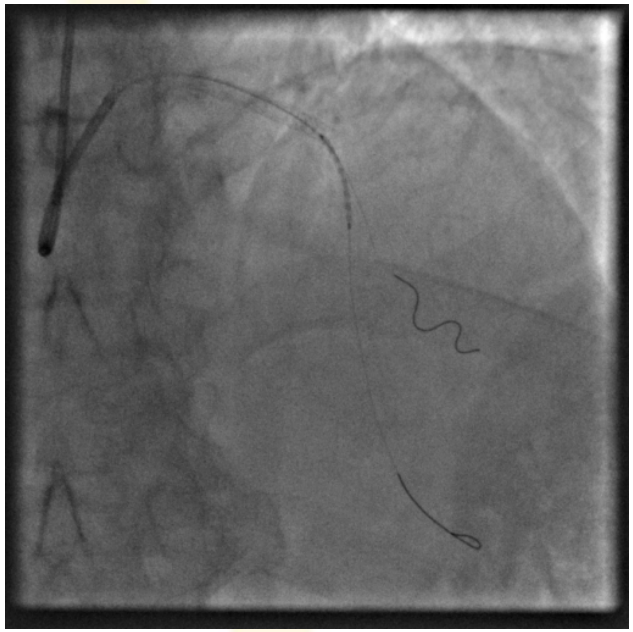
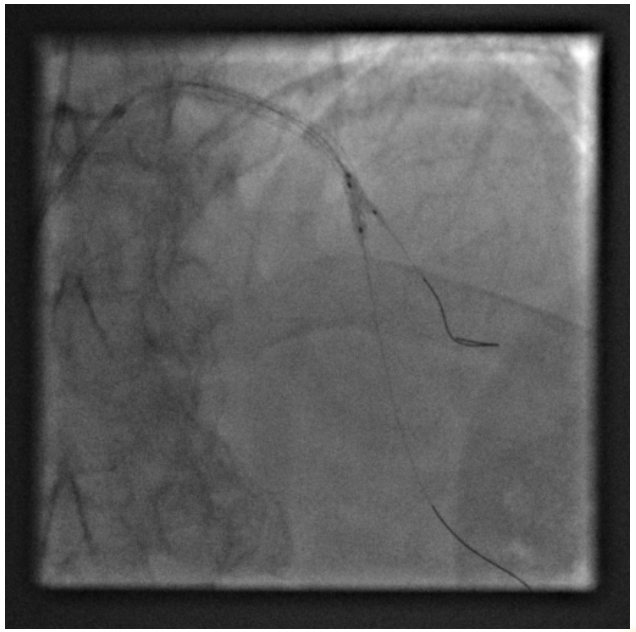
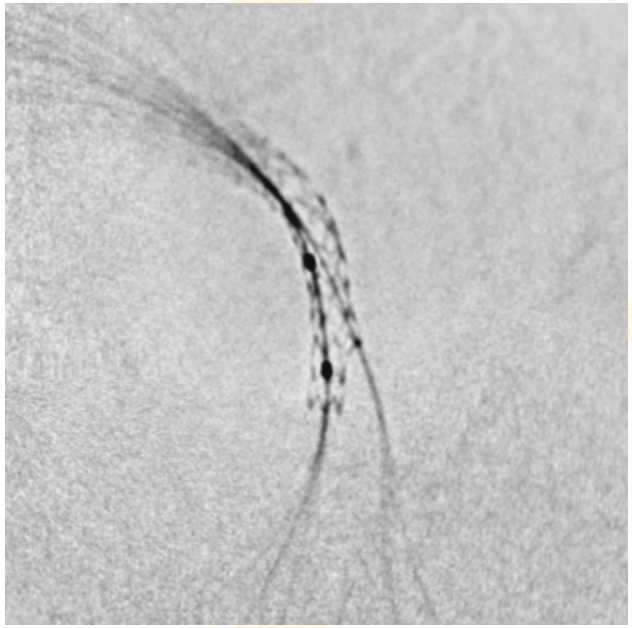
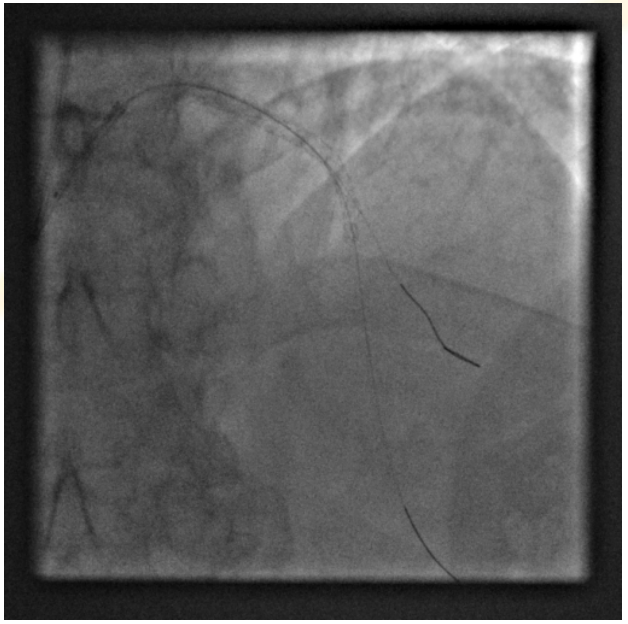
- MB stenting using Sirolimus, Everolimus or Paclitaxel drug eluting stents
- Provisional SB T-stenting using 6 Fr guiding catheter
- Systematic use of 2 wires at the beginning of the procedure
- No SB predilatation

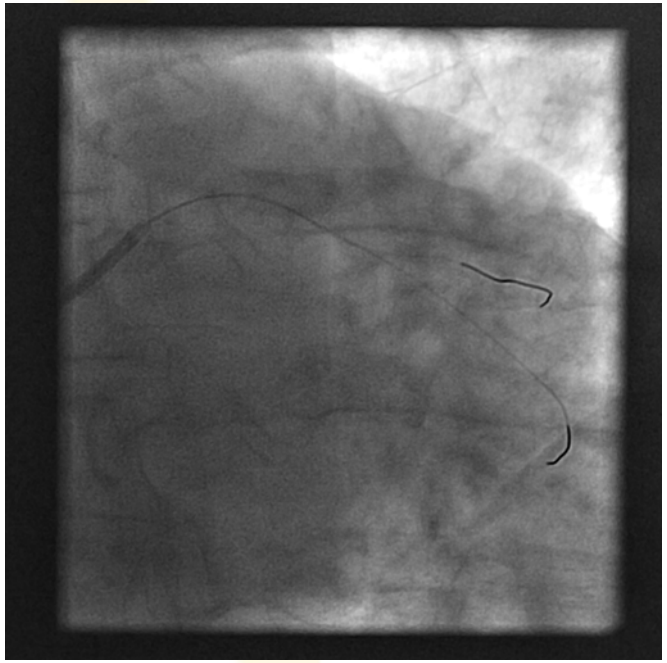
Design of the study (3)

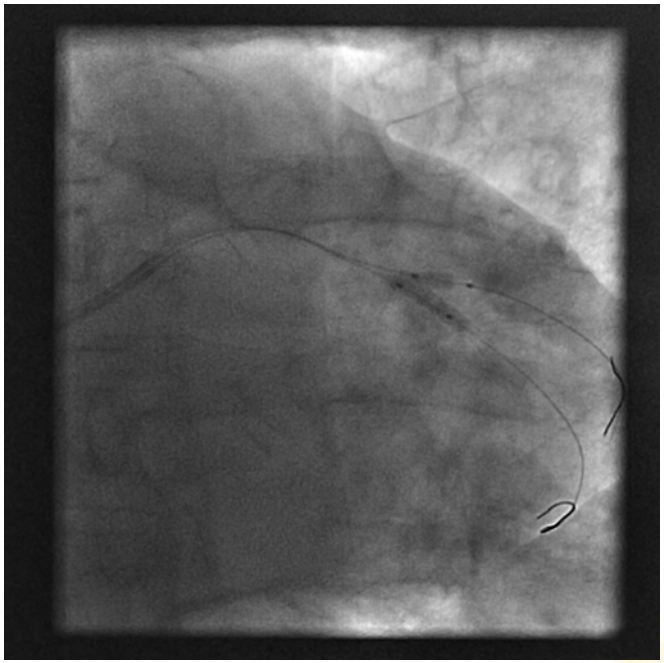
- Kissing with NC balloon (Hiryu, Terumo)
  - Pressure choosen by operator
- Systematic stent enhancement:
  - Using stentboost (Philips) or Stentviz (GE).
  - Visualization of metal projection

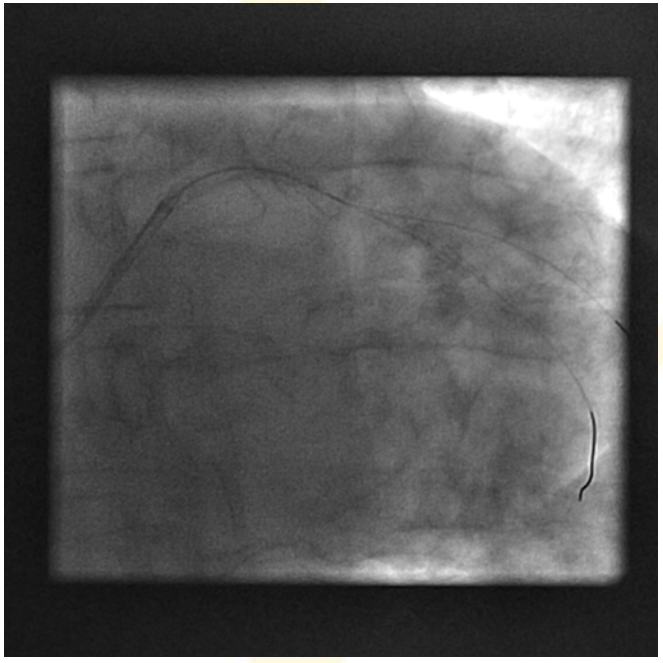


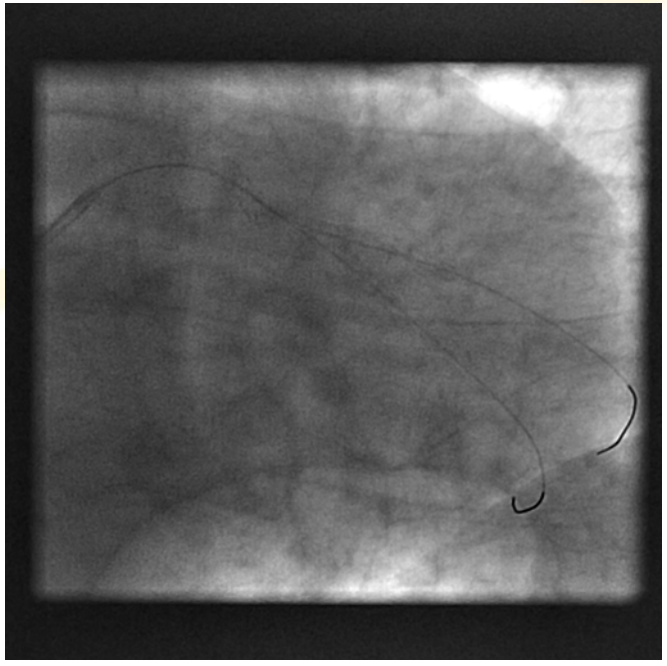










Main clinical characteristics (n=72)

Age (mean [SD / range])	66.4 ± 11.2
Male (%)	82.2
Risk factors (%)	
Diabetes	18.8
Hypertension	47.8
Hypercholesterolemia	56.5
Current Smoker	36.8
Previous CABG (%)	4.3
Indication for intervention (%)	
Stable Angina	32.9
Unstable Angina	30.0
Acute STEMI	11.4
Silent Ischemia	25.7
LV Ejection Fraction % (mean [SD])	54.6±13.0

Main angiographic characteristics (n=74)

Lesion Location	%
Distal LM	20.2
LAD / Diagonal	48.6
Circumflex / marginal	16.2
PDA / PLV	10.8
Other	4.2
Lesion Type	**%**
Medina 1,1,1	35.6
Medina 1,0,1	1.4
Medina 1,1,0	27.0
Medina 1,0,0	16.7
Medina 0,1,1	5.4
Medina 0,1,0	14.9

Main angiographic characteristics (2) (n=74)

Main branch	
Reference diameter (mm)	3.13±0.49
Lesion length (mm)	16.5±7.1
Stenosis (%)	77.6±14.3
Side Branch	
Reference diameter (mm)	2.27±0.41
Lesion length (mm	2.0±3.0
Stenosis (%)	26.1±33.0

Procedural characteristics

Main branch predilatation (%)	49.3
Stent type (%)	
Sirolimus	35.0
Paclitaxel	25.3
Everolimus	30.6
Other	8.1
Stent Diameter (mm)	3.14±4.05
Stent length (mm)	21.5±5.9
Pressure (atm.)	12.3±1.0

Final kissing balloon inflation

Need for SB predilatation (%)	8.1
MB NC balloon	
Diameter (mm)	3.01±0.32
Length (mm)	11.9±2.4
Pressure (atm.)	12.6±2.6
SB NC ballon	
Diameter (mm)	2.63±0.31
Length (mm)	11.9±2.4
Pressure (atm.)	13.4±2.4

Main Results

- Feasibility of the final kissing with NCB without SB opening: 91.9%
- Metal projection in Side branch: 86.1%
- Side branch dissection: 13.5%
- Need for SB stenting: 8.1%

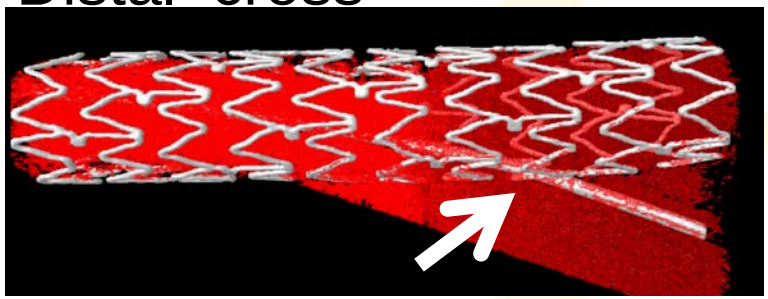
Main Results (2)

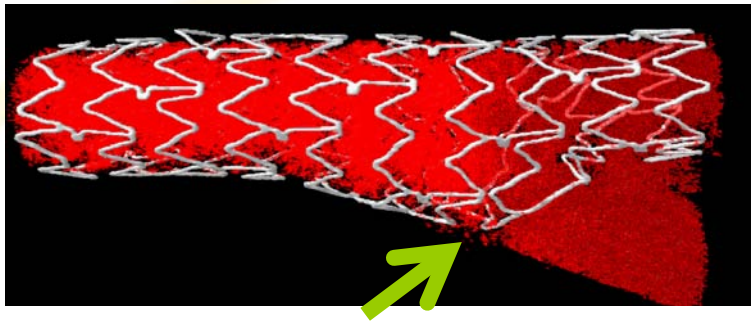
	Kissing without SB opening	Need for SB opening	P value
SB metal projection (%)	89.7	33.3	<0.001
SB dissection (%)	8.8	75.0	<0.001
SB stenting (%)	5.9	50.0	<0.001

Hypothesis

- Importance of the distal strut:
  - Among the 10 bifurcations without metal projection:
    - 5 present SB dissection
    - 4 needed SB stent

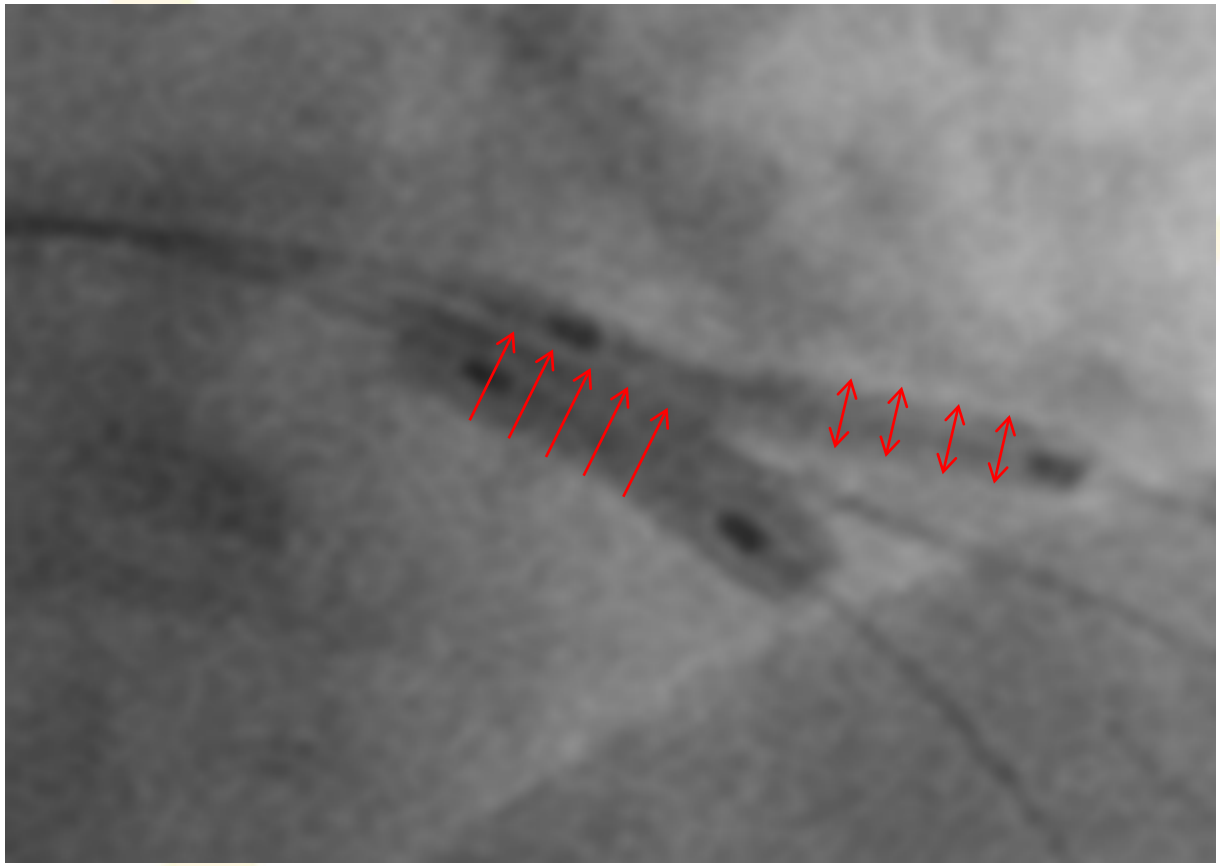
Distal cross





Hypothesis (2)

- Oversizing of the SB Balloon due to the pressure in the MB:



Conclusion

- Treatment of bifurcation lesions trought 6F guiding catheter using NC balloons:
  - Is feasible
  - Associated with excellent immediate results
  - And a low need of SB stent