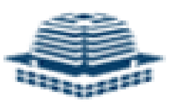

# *How Do We Manage Bifurcation Lesions While Waiting for the Dedicated Bifurcation Systems?*


**Ioannis Iakovou, MD, PhD**

*Onassis Cardiac Surgery Center, Athens, Greece*

# Disclosures

**I have no following financial relationships to disclose related to this presentation**

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# *How Do We Manage Bifurcation Lesions*

- One vs. Two Stents?
- If two stents, which technique best?
- Is a > 50% SB lesion usually significant?
- Is final kissing mandatory?

# Bifurcation Classification

PMB (Proximal), DMB (Distal), SB

0,1

0,1

0,1

1,1,1

1,1,0

1,0,1

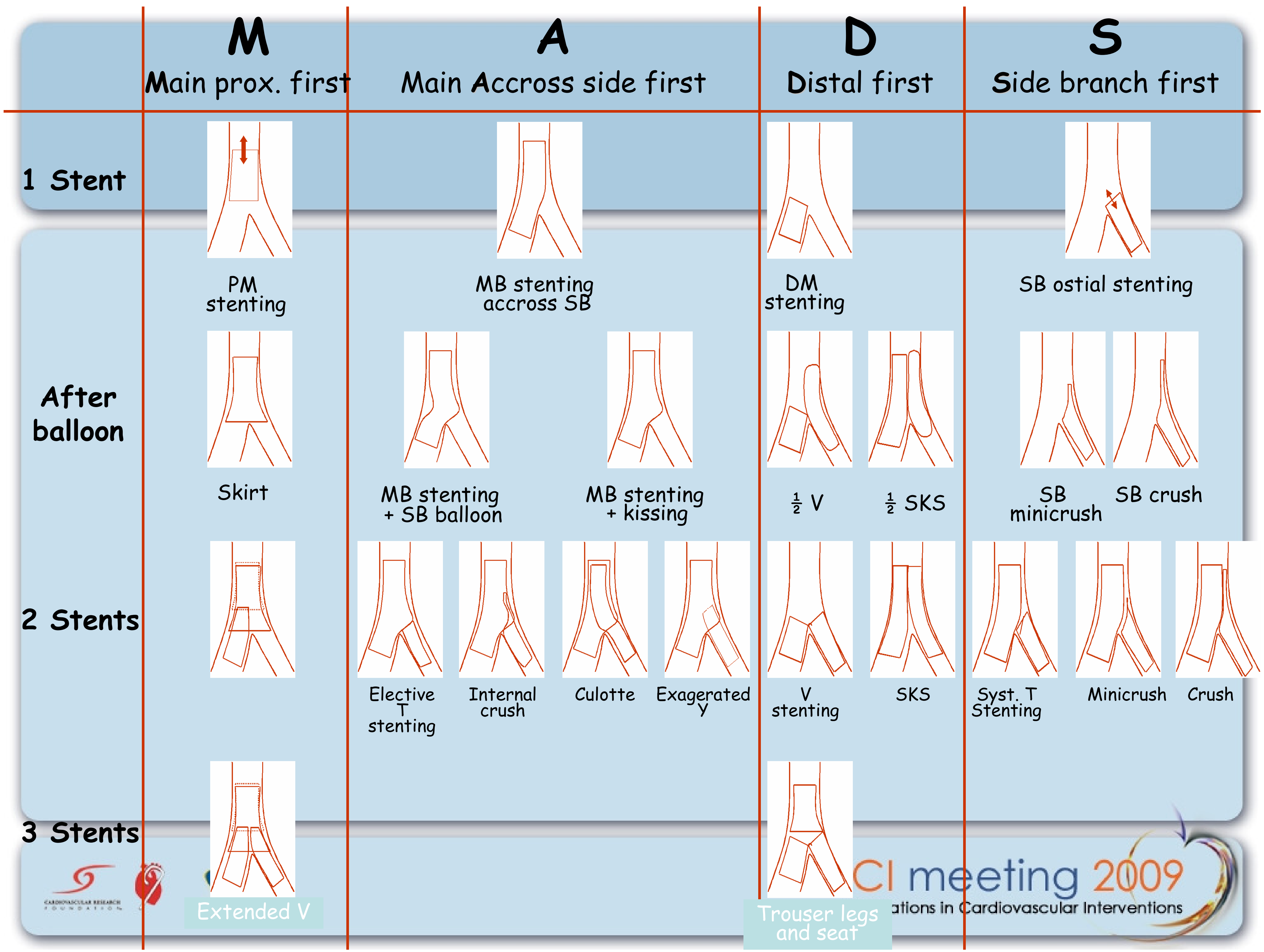
0,1,1

1,0,0

0,1,0

0,0,1

Medina A, et al. Rev Esp Cardiol. 2006;59:183


M
Main prox. first
A
Main Accross side first
D
Distal first
S
Side branch first
1 Stent
PM
stenting
MB stenting
accross SB
DM
stenting
SB ostial stenting
After
balloon
Skirt
MB stenting
+ SB balloon
MB stenting
+ kissing
½ V
½ SKS
SB
minicrush
SB crush
2 Stents
Elective
T
stenting
Internal
crush
Culotte
Exagerated
Y
V
stenting
SKS
Syst. T
Stenting
Minicrush
Crush
3 Stents
Extended V
Trouser legs
and seat
CI meeting 2009
ations in Cardiovascular Interventions

# One vs. two stents

**No controversy!!!**

- In *most bifurcational lesions* one stent is the *treatment of choice!!!*

# ESC: Rome Concept: Clinical Strategies

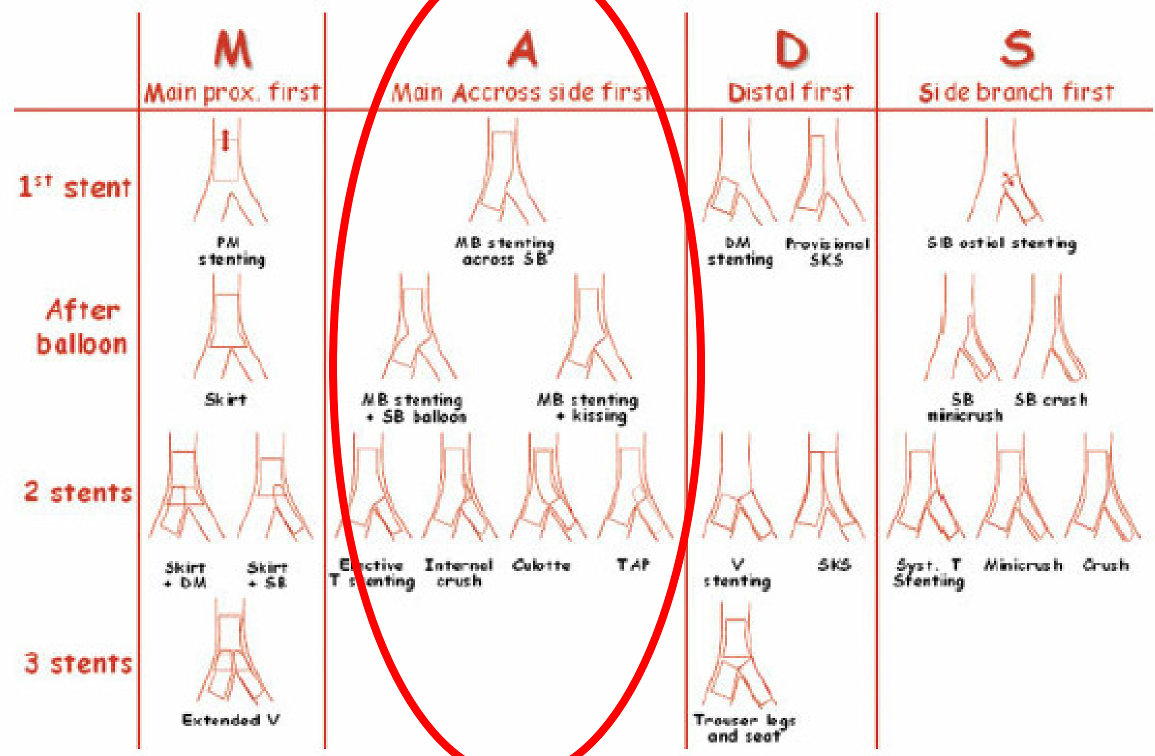
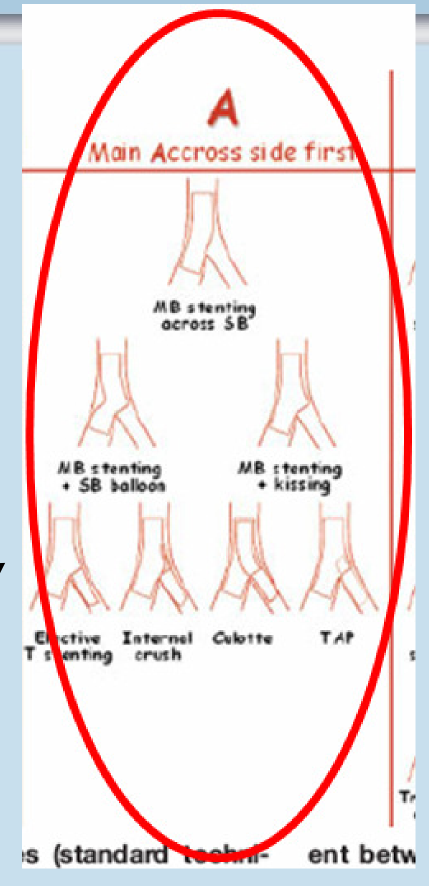



Fig. 3. MADS classification of techniques (standard techniques). In "M" family the "Skirt" technique was described with use of a stent manually crimped onto two balloons, but it is currently used with a dedicated stent (DEVAX). In the "A" family the T stenting technique seems similar to that of the "S" family, but here the MV stent is deployed first allowing provisional (Elective) and possibly better deployment of the SB stent. The internal Crush was named first Reverse Crush. The "TAP" stenting figure has also been named "Exaggerated Y" (Buchbinder). In the "S" family, though the intention is different between Minicrush and Modified T stenting described by Colombo, in practice when treating a patient it is very difficult to distinguish between the two stent figures (someone suggested that in modified T stenting the secondary access to the SB for kissing balloon inflation should be achieved through the lumen of the SB stent, instead of one of the most proximal stent cells, which is possible in a bench but hardly feasible in patients. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

# *Provisional stenting of Bifurcations: technique*

- Wire both vessels.
- Stent main vessel.
- Probably rewire sidebranch and kiss.
- Only treat “flow” in the sidebranch.
- If 2nd stent needed

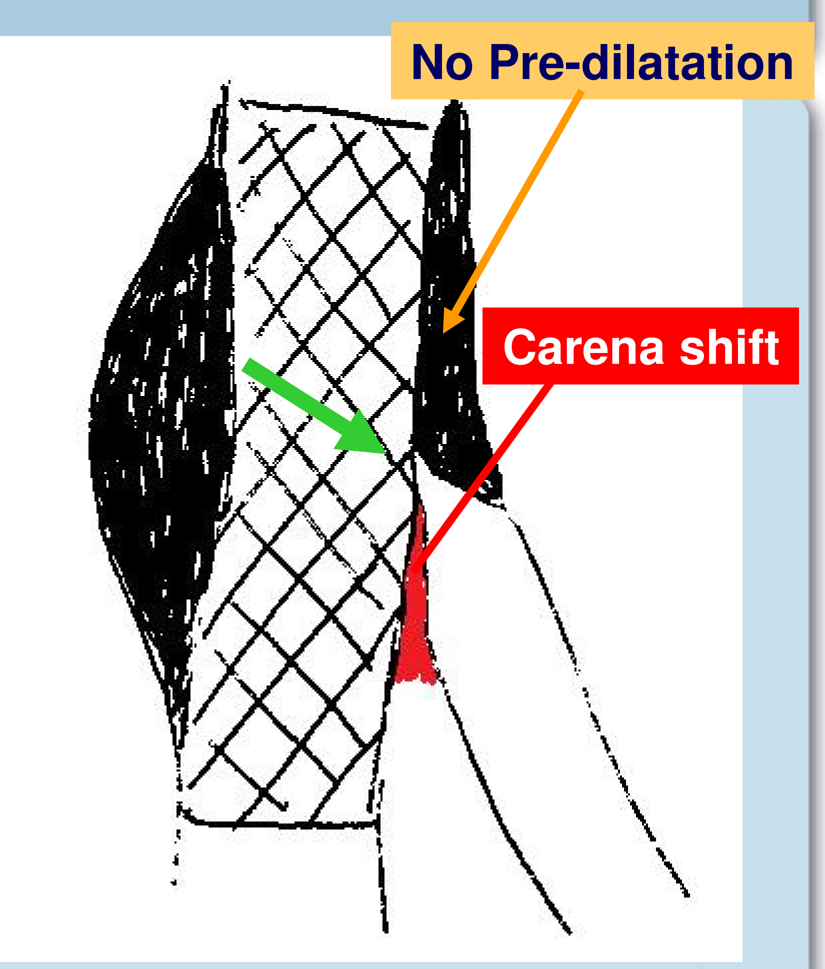


# Stenting MV across the SB. Distal wire cross creates better SB scaffolding than prox

| | Proximal cross | Distal cross |
|---|---|---|
| Single balloon SB dilatation | | |
| Kissing balloon post-dilatation | | |

# The case of true bifurcation (1,1,1)

- We should **avoid Side Branch pre-dilation** and **take advantage of the carena shift**
- the guidewire (GW) will cross the stent strut **exactly at the carina**



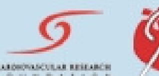

Post MB stenting

# Bifurcation Stenting in Pre-DES era: Restenosis Rates

## Non-Randomized studies with 6-Month Follow-Up

Angiographic Restenosis (%)

| Study | Stenting Both Vessels | Stenting Parent-Vessel Only |
|---|---|---|
| Saucedo[1] | 57 | 21 |
| Yamashiti[1] | 62 | 48 |
| Brunel[1] | 57 | 21 |
| Cervinka[1] | | 13 |
| Assali[2] | 41 | 11 |



[1] Melikian N., et al., *Minerva Cardioangiol* 2004; 52:365-78.
[2] Assali AR., et al., J Invasive Cardiol. 2004 Sep;16(9):447-50.

# Nordic I - Bifurcation Study

## Major Endpoints

Biomarker elevation >3x ULN (%)

| | Simple n=207 MV | Complex n=206 MV+SB |
|---|---|---|
| CKMB >3x ULN (In-hospital MI (%)) | 8,0 | 18,0 |

p=0.01

| 6 month MACE (%) | Simple n=207 MV | Complex n=206 MV+SB |
|---|---|---|
| Cardiac Death | 1,0 | 1,0 |
| MI | 0,0 | 1,0 |
| Stent thrombosis | 1,0 | 0,0 |
| TLR | 1,9 | 1,0 |
| TVR | 1,9 | 1,9 |
| MACE | 2,9 | 3,4 |

p=NS

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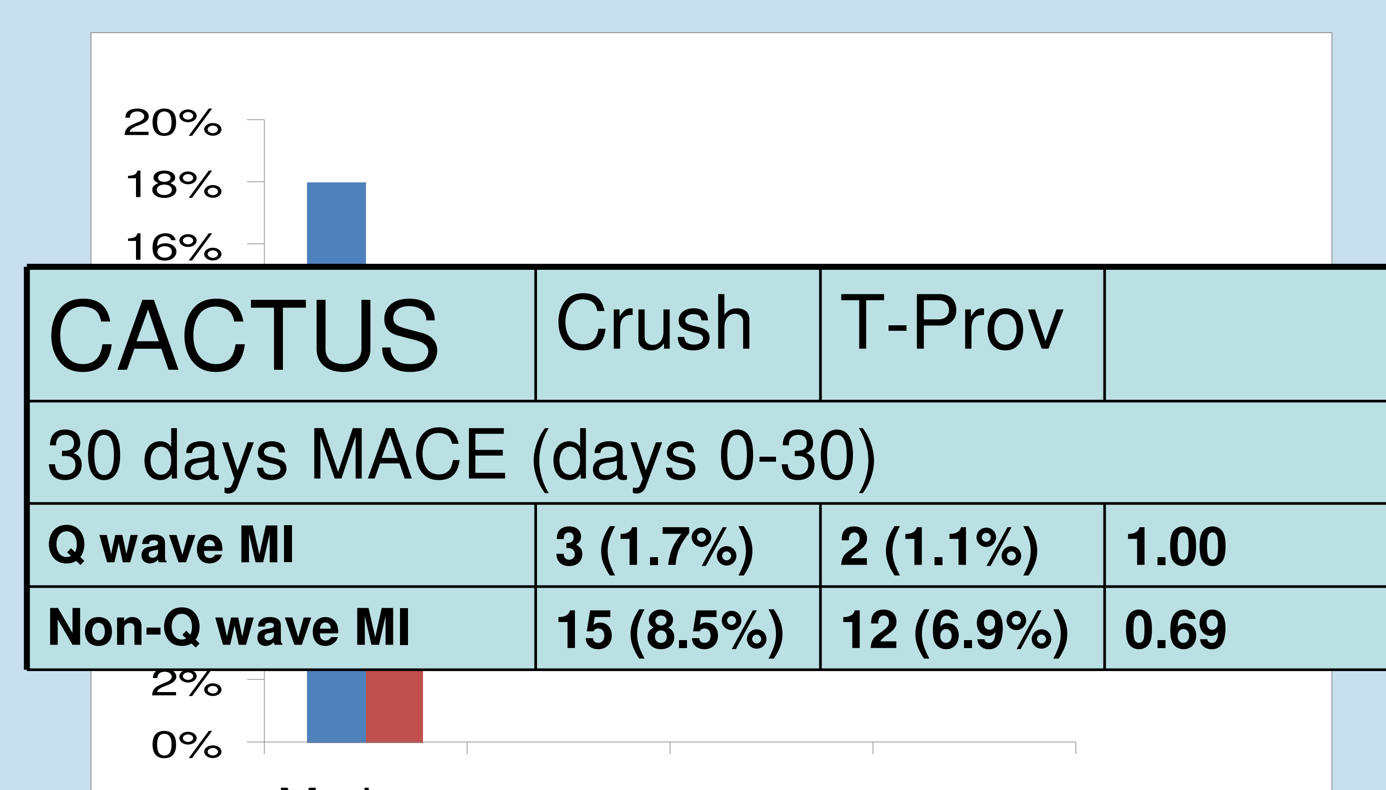
# Nordic: peri procedural MI




| CACTUS | Crush | T-Prov | |
|---|---|---|---|
| 30 days MACE (days 0-30) | | | |
| **Q wave MI** | **3 (1.7%)** | **2 (1.1%)** | **1.00** |
| **Non-Q wave MI** | **15 (8.5%)** | **12 (6.9%)** | **0.69** |

# BBC ONE

500

Provisional
250

Culotte or Crush
250

1 randomisation delay

1 withdrew consent,
1 no treatment attempted

Provisional
249

Culotte or Crush
248

# PRIMARY ENDPOINT, BBC 1

## Composite (9months) Death, MI, TVF

| | Complex | Simple | P value |
|---|---|---|---|
| Death | 2 (0.8%) | 1 (0.4%) | - |
| Myocardial infarction | 28 (11.2%) | 9 (3.6%) | - |
| Target vessel failure | 18 (7.2%) | 14 (5.6%) | - |
| Primary endpoint | 38 (15.2%) | 20 (8.0%) | 0.009 HR 2.0 (1.2 to 3.5) |

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# BBC-ONE angio results

| | Complex (n=250) | Simple (n=250) |
|---|---|---|
| **Side branch** | | |
| Stenosis pre-procedure (%) | 68 (29) | 63 (31) |
| Stenosis post-procedure (%) | 12 (24) | 37 (33) |

2/3 of the lesions on the SB had less than 70% residual stenosis at the end of the procedure

Less than 90% residual stenosis was acceptable and only 30% of the SB underwent additional procedure (27%B+3%S)

# Why 1 Stent probably is sufficient?

**SB Lesions are Usually Short!!!**

| | Bestent[1] | TULIPE[2] | Sirolimus[3] | Sirolimus[4] |
|---|---|---|---|---|
| Patients (n) | 105 | 187 | 85 | 47 |
| Reference (mm) | 2.7±0.4 | 2.3±0.5 | 2.1±0.3 | 2.1±0.5 |
| Lesion length (mm) | 5.6±4.2 | 3.7±3.3 | 5.3±4.2 | 4.5±3.0 |
| Stenosis SB (%) | 49±37 | 52±17 | 52±19 | 42±23 |

Significant SB LL>3mm➔ 10-24%

[1] *Gobeil et al, Am J Cardiol 2001,*

[2] *Brunel et al Cathet Cardiovasc Intervent 68:67–73 (2006)*

[3] *Colombo et al, Circulation 2004; 109: 1244-9,*

[4] *Sengotuvel et al, JACC 2004 (abst.supp.)*

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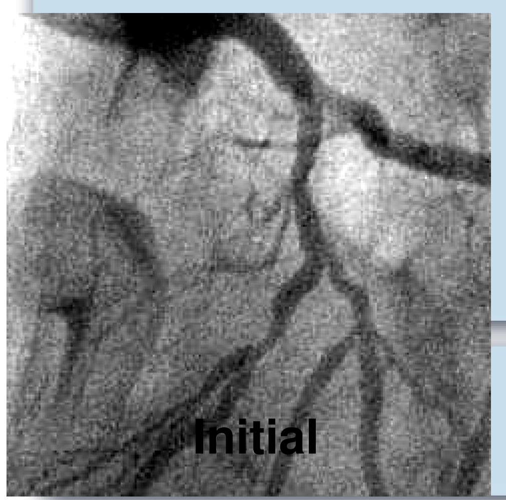
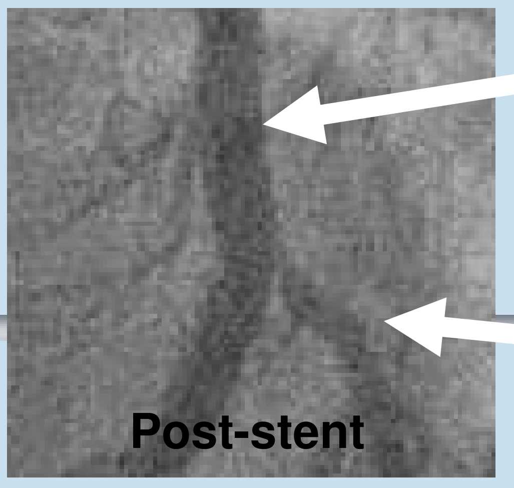
# Physiologic Assessment of Jailed Side Branch Lesions Using Fractional Flow Reserve

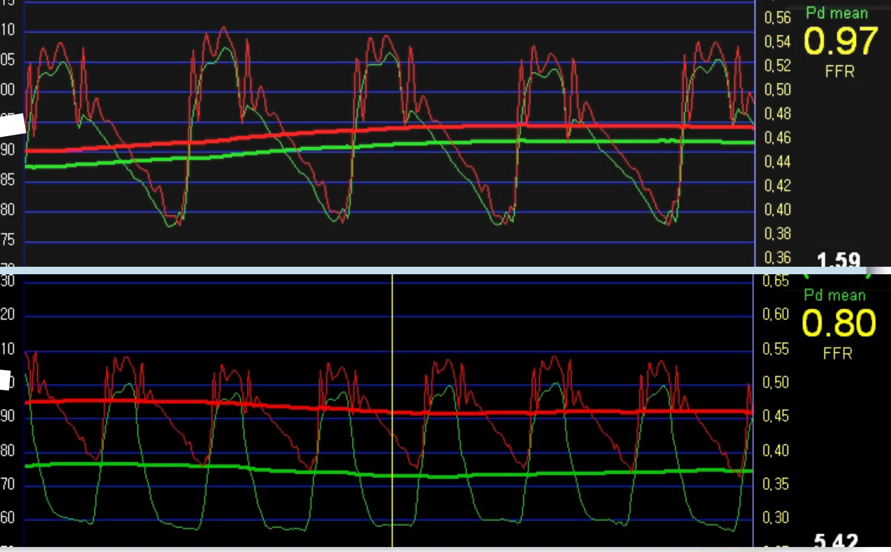
Bon-Kwon Koo, MD, PHD,* Hyun-Jai Kang, MD, PHD,* Tae-Jin Youn, MD, PHD,† In-Ho Chae, MD, PHD,† Dong-Joo Choi, MD, PHD,† Hyo-Soo Kim, MD, PHD,* Dae-Won Sohn, MD, PHD,* Byung-Hee Oh, MD, PHD, FACC,* Myoung-Mook Lee, MD, PHD, FACC,* Young-Bae Park, MD, PHD,* Yun-Shik Choi, MD, PHD,* Seung-Jae Tahk, MD, PHD‡

*Seoul, Seongnam, Gyeonggi-do, and Suwon, Republic of Korea*

***RADI pressure wire: Successful FFR measurement: 94/97 lesions (97%)***



# FFR-guided Jailed SB Intervention

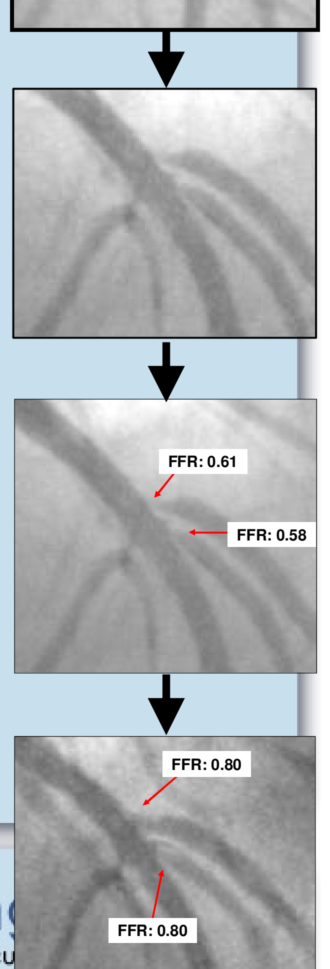
## *Conclusions*

- Stenting the main branch with DES
- Side branch intervention, when DS>75% or FFR<0.75

  - Kissing balloon technique with a *relatively small balloon at side branch*

  - If Stenosis > 75% or FFR < 0.75 after kissing balloon,

    → use larger balloon, or stent



# Treatment of Coronary Bifurcations

## When is a 2 stent strategy advisable?

- Problematic the treatment of “true” bifurcations (both branches have a stenosis) with 1 stent
- The advantage of 2 vs. 1 stent depends on:
  - *- size and distribution of the SB*
  - *- extent of the disease into the SB*

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# *Treatment of Coronary Bifurcations*

- In true bifurcations, with SB suitable for stenting and significantly diseased, the strategy of elective implantation of 2 stents may have the following advantages:
- *Lower risk of SB closure during MB stent implantation.*
- *Less difficulties in recrossing through stent struts with the second stent.*
- *Full lesion coverage (crush, culotte, V-stent, )*

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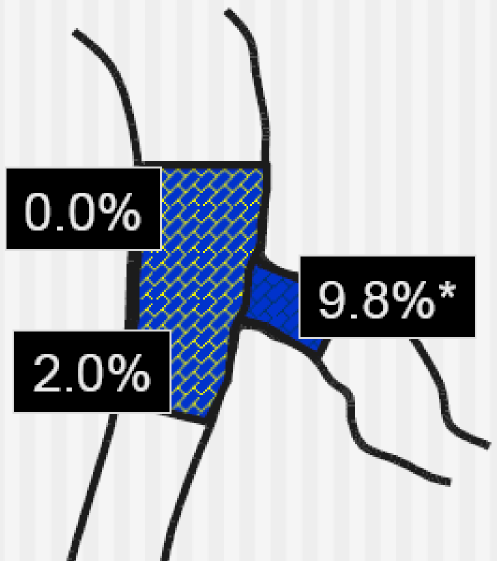
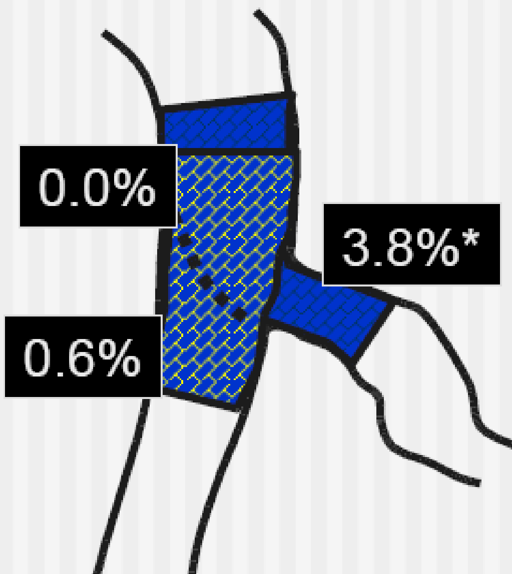
# NORDIC II

*There is a trend towards less restenosis of the entire bifurcation lesion because of significantly reduced SB in-stent restenosis in patients treated with the CULOTTE technique (Nordic II)*

CRUSH




CULOTTE



# NORDIC II: Procedure-related CK-elevation (n=296)

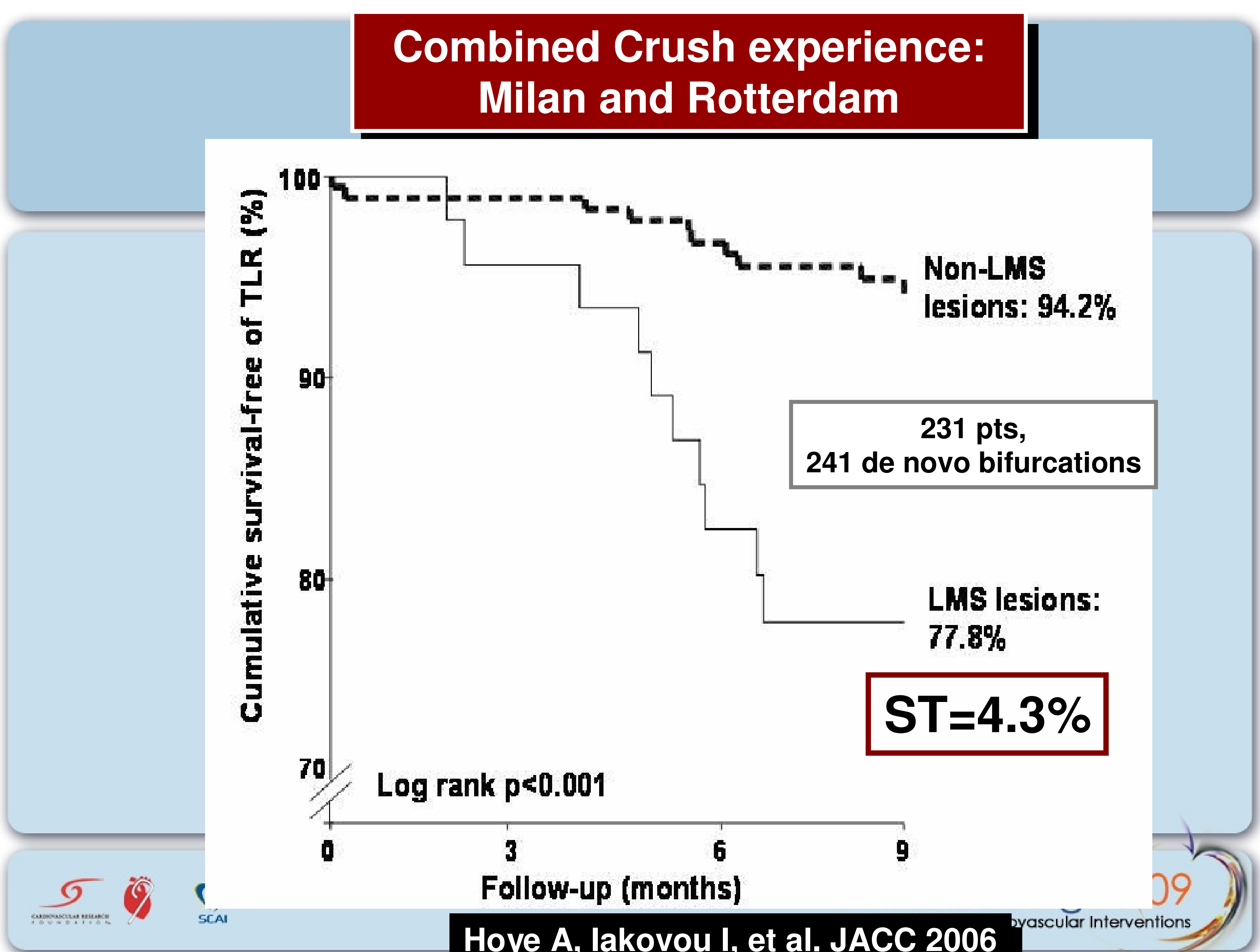
| | CRUSH (n=148) | CULOTTE (n=148) | P value |
|---|---|---|---|
| >3x elevation, % | 15.5 | 8.8 | 0.08 |

Niemela M, EBC 2007

# Influence of Bifurcation Angle on Outcome of Crush Technique

| | T-shape Bifurcation | Y-shape Bifurcation |
|---|---|---|
| T-stenting | +++ | ----- |
| Crush | ---- | +++ |
| Culotte | ---- | +++ |

*Dzavik et al AHJ 2006;152:762-9*



Combined Crush experience:
Milan and Rotterdam
Cumulative survival-free of TLR (%)
100
90
80
70
Non-LMS
lesions: 94.2%
231 pts,
241 de novo bifurcations
LMS lesions:
77.8%
ST=4.3%
Log rank p<0.001
0
3
6
9
Follow-up (months)
Hoye A, Iakovou I, et al. JACC 2006
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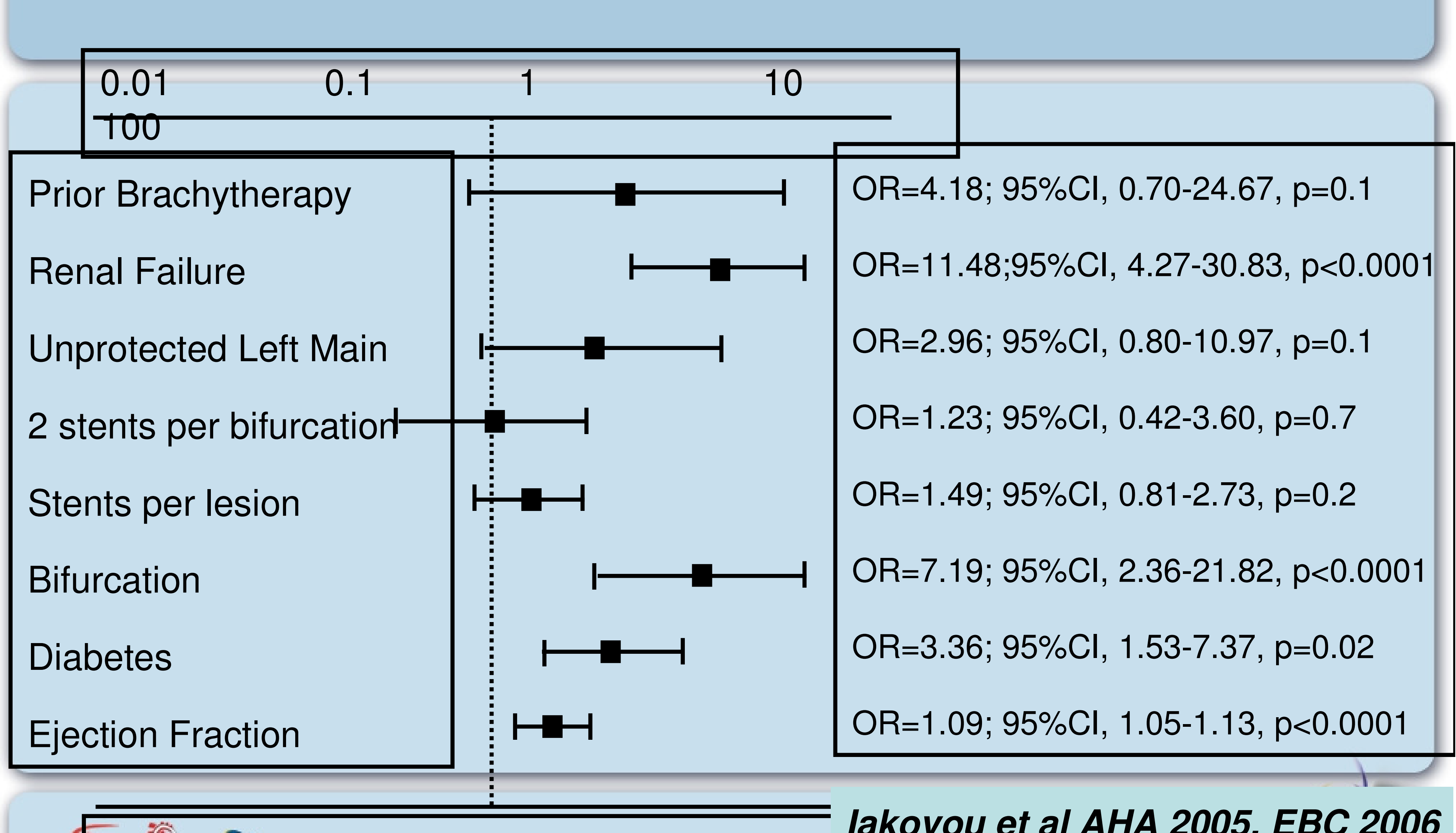
# Stent thrombosis in bifurcation stenting

## Bifurcation as independent risk factor for ST

| | n | RR | 95% CI | FU |
|---|---|---|---|---|
| **Iakovou et al** JAMA 2005 | 2229 | 5.96 | 1.90 - 18.68 | Subacute |
| | 2229 | 8.11 | 2.50 - 26.26 | Late |
| **Ong et al** JACC 2005 | 1017 | 3.00 | 1.30 - 6.80 | 6 mo |
| **Kuchulakanti et al** Circulation 2006 | 2974 | 4.40 | 1.96 - 10.00 | 12 mo |
| **French Registry** EBC 2007 | 2551 | 3.70 | 1.80 - 7.60 | |
| **Hwang + Koo** TCT 2006 | | 10.21 | 4.75 – 21.92 | Late |

# Predictors of stent thrombosis




***Iakovou et al AHA 2005, EBC 2006***

# CACTUS trial

Coronary Bifurcation Application of the Crush Technique Using Sirolimus-Eluting stents

## Procedural characteristics

| | Crush (n=177) | | Prov.-T (n=173) | |
|---|---|---|---|---|
| | MB | SB | MB | SB |
| Predilatation (%) | 89.8 | 89.8 | 90.8 | 90.8 |
| IVUS (%) | 3.4 | 2.8 | 4.1 | 2.3 |
| Total stent | | | ± 5.7* | 18.1 ± 6.2 (54 lesions) |
| Max pressu | | | ± 4.1 | 12.0 ± 2.4* |
| Final kissing (%) | 92.1 | | 90.2 | |
| IIb-IIIa GP inhibitors (%) | 22.6 | | 17.3 | |

NO final kissing inflation in
14 les in the CRUSH arm
17 les in the PROV-T arm

**31% (54/173) NEEDED PROVISIONAL STENTING IN THE SB**

** = p<0.05 for comparisons between crush and prov.-T*

**CACTUS trial**

**Coronary Bifurcation Application of the Crush Technique Using Sirolimus-Eluting stents**

# *Stent thrombosis*

| | Total | Acute (first day) | Subacute (days 2-30) | Late (days 31-180) |
|---|---|---|---|---|
| Crush (n=177) | **3 (1.7%)** | **1 (0.5%)** | **2* (1.1%)** | **0** |
| Prov.T (n=173) | **2 (1.1%)** | **0** | **1 (0.5%)** | **1 (0.5%) (definitive)** |

*p = 0.62 for comparisons between crush and prov.-T*

* *One patient did not take thienopyridine therapy after discharge*

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CACTUS trial

Coronary Bifurcation Application of the Crush Technique Using Sirolimus-Eluting stents

# Final kissing balloon inflation

| | YES | NO | P value |
|---|---|---|---|
| Myocardial infarctions | **7.5% (24/319)** | **29.0% (9/31)** | **<0.0001** |
| Stent thrombosis | **0.9% (3/319)** | **6.5% (2/31)** | **0.06** |

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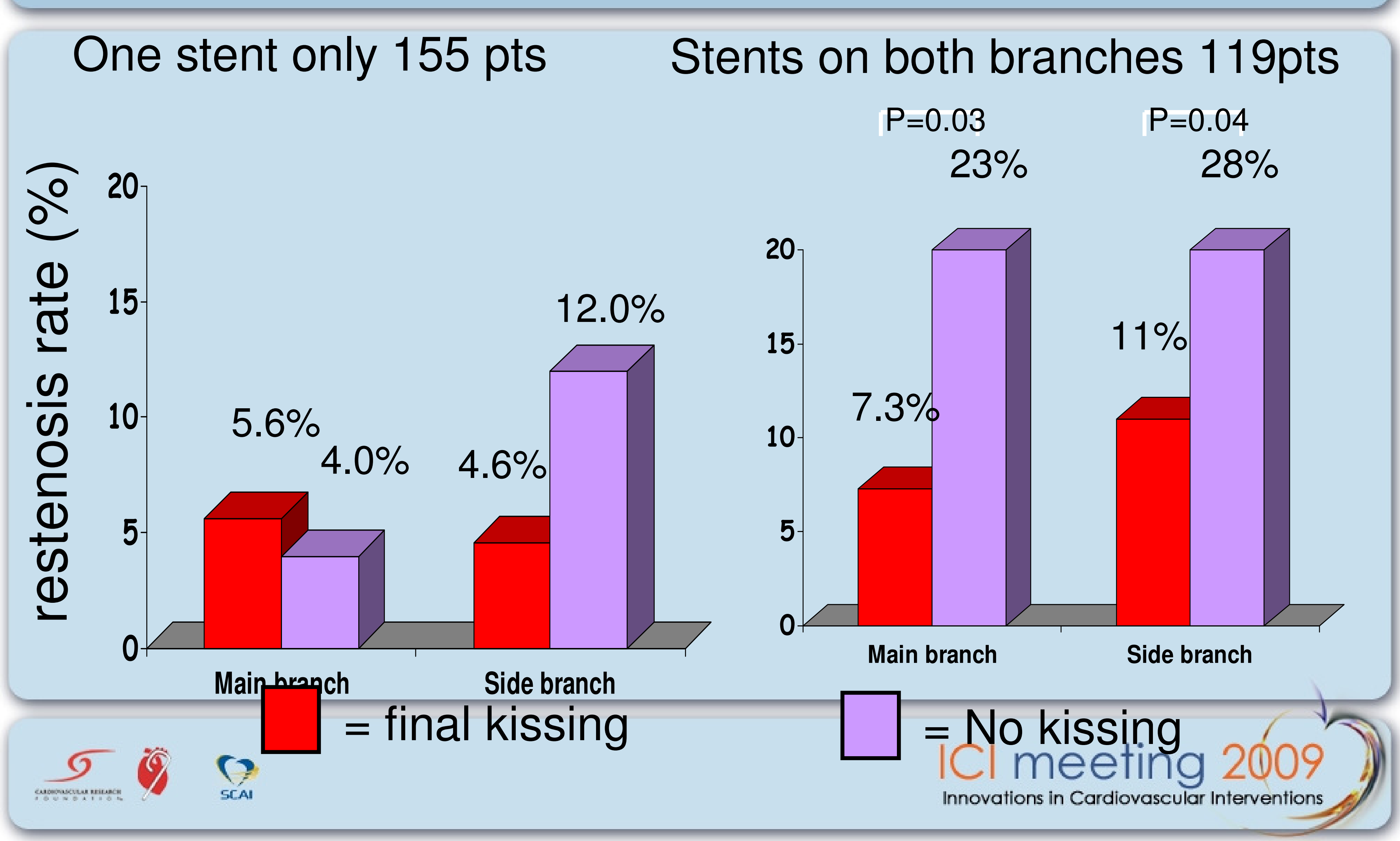
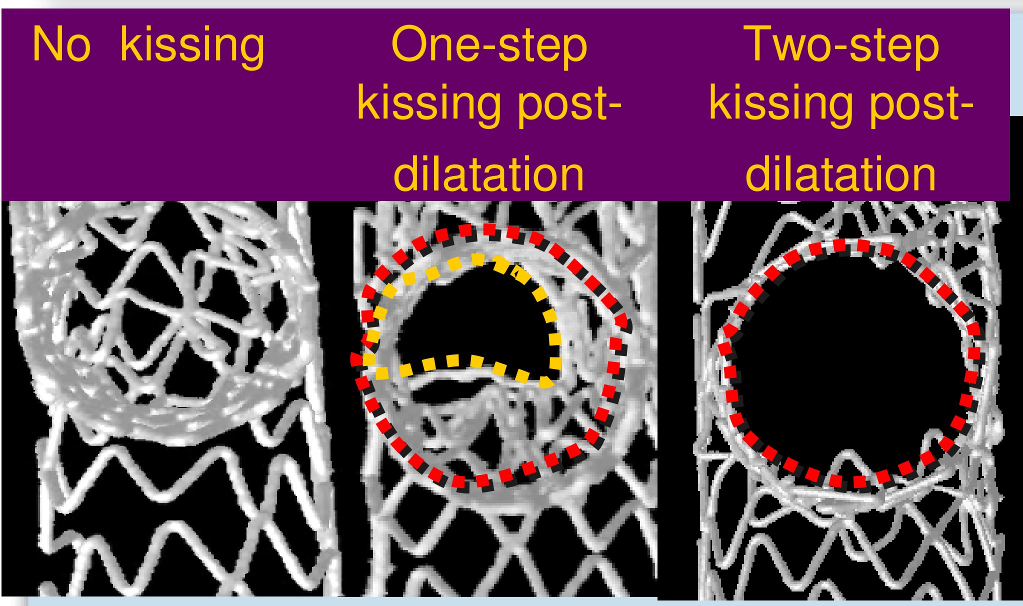
# DES in Bifurcation Lesions

## *Milan Experience*

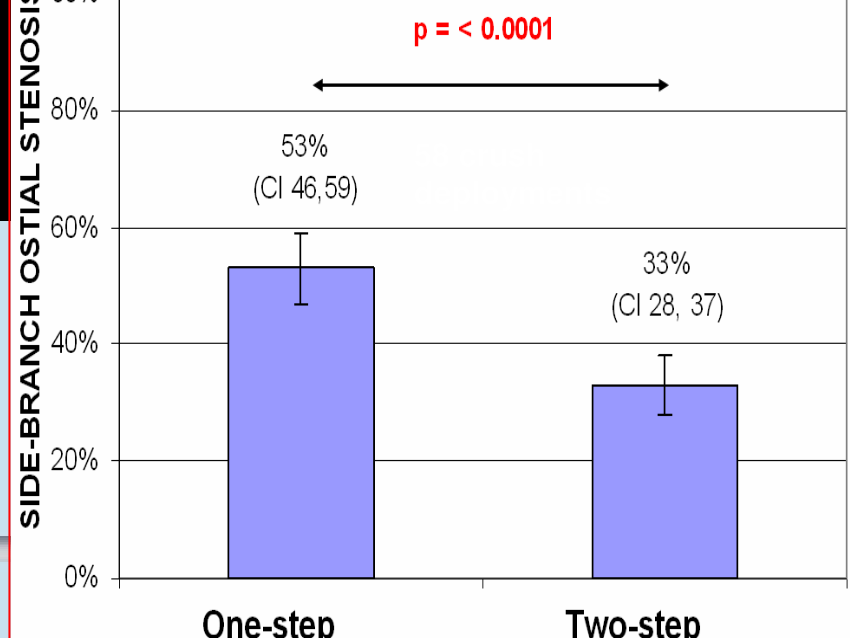


# We observed that two-step kissing was more effective than one-step kissing for improving metallic side-branch ostial area




Two steps:
1) Inflate at high pressure only the SB balloon
2) Perform kissing inflation

SB ostial stenosis (%) with one step vs. two step kissing



Ormiston

# Final Kissing: Yes or No?
# *Nordic Baltic Bifurcartion Study III*

Bifurcation patients with successful MV stenting
n: 477

No Kissing balloon
n: 239

Kissing balloon
n: 238

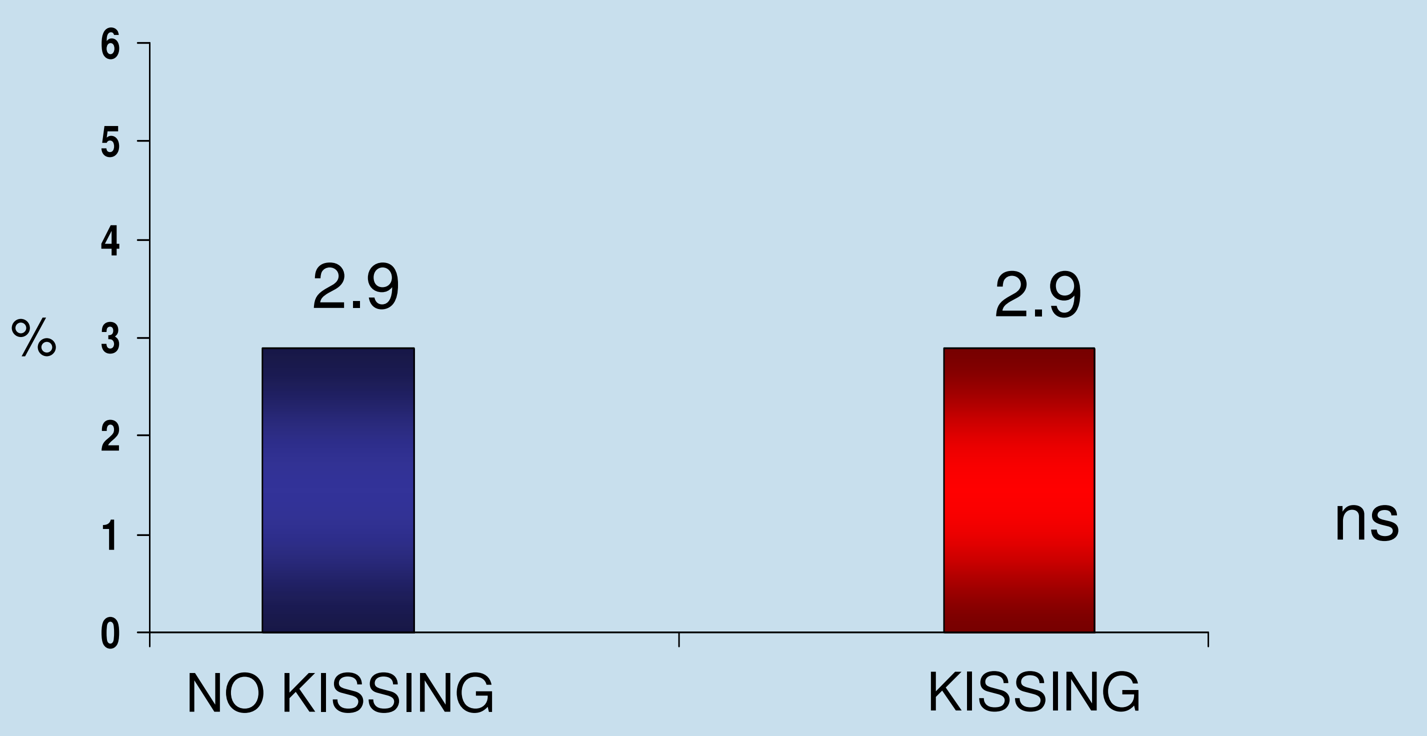
Clinical follow-up after 1 and 6 months
n: 477 (100%)

# Procedure data I

| | No kissing n=239 | Kissing n=238 | p-value |
|---|---|---|---|
| **Aspirin Tx (%)** | **99.6** | **100.0** | **ns** |
| **Clopidogrel Tx (%)** | **98.7** | **99.2** | **ns** |
| **GPIIb/IIIa Tx (%)** | **28.9** | **29.1** | **ns** |
| **Bivalirudin Tx (%)** | **20.9** | **26.2** | **ns** |
| **Procedure time (min)** | **47 ± 22** | **61 ± 28** | **0.0001** |
| **Fluorosc. time (min)** | **11 ± 10** | **16 ± 12** | **0.0001** |
| **Contrast (ml)** | **200 ± 92** | **235 ± 97** | **0.0001** |

# Primary end point

MACE (cardiac death, index lesion MI, TLR, stent thrombosis) after 6 months



# Open issues with bifurcations

- Technically demanding
- Time consuming
- Too much operator dependent
- Off the-shelf standard stents don't fit bifurcations
- Long term outcome?

**⇒ Is dedicated bifurcation stent the answer?**

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# *How Do We Manage Bifurcation Lesions*

- **One vs. Two Stents?**

  Answer: One Best

  But Two is OK if Needed

- **If two stents, which technique best?**

  Answer: Uncertain, probable the A techniques have an edge

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## *How Do We Manage Bifurcation Lesions*

- **Is a > 50% SB lesion usually signficant?**

  Answer: Often No

- **What's the key to bifurcations?**

  Answer: The Side Branch
  Size, Length, Location, Complexity and
  Angulation Ultimately Determine
  Optimal Bifurcation Therapy

# *How Do We Manage Bifurcation Lesions*

- **Is final kissing mandatory?**

  Answer: in 2 stent techniques  yes (maybe not in provisional)

- **Will dedicated stents be the answer to the problem?**

  Answer: Promising but uncertain

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# *Take Home Message:*

- Try to use 1 stent, allways focused in MV, but…..
- Don´t compromise in a bad angiographic result in SB, if needed….
- Use 2 stents no penalties for patients
- All techniques have pros and cons

**If the result is optimal the FU will be favorable**

A.Colombo

SCAI

Thank you!

Email: **iako@hol.gr**

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