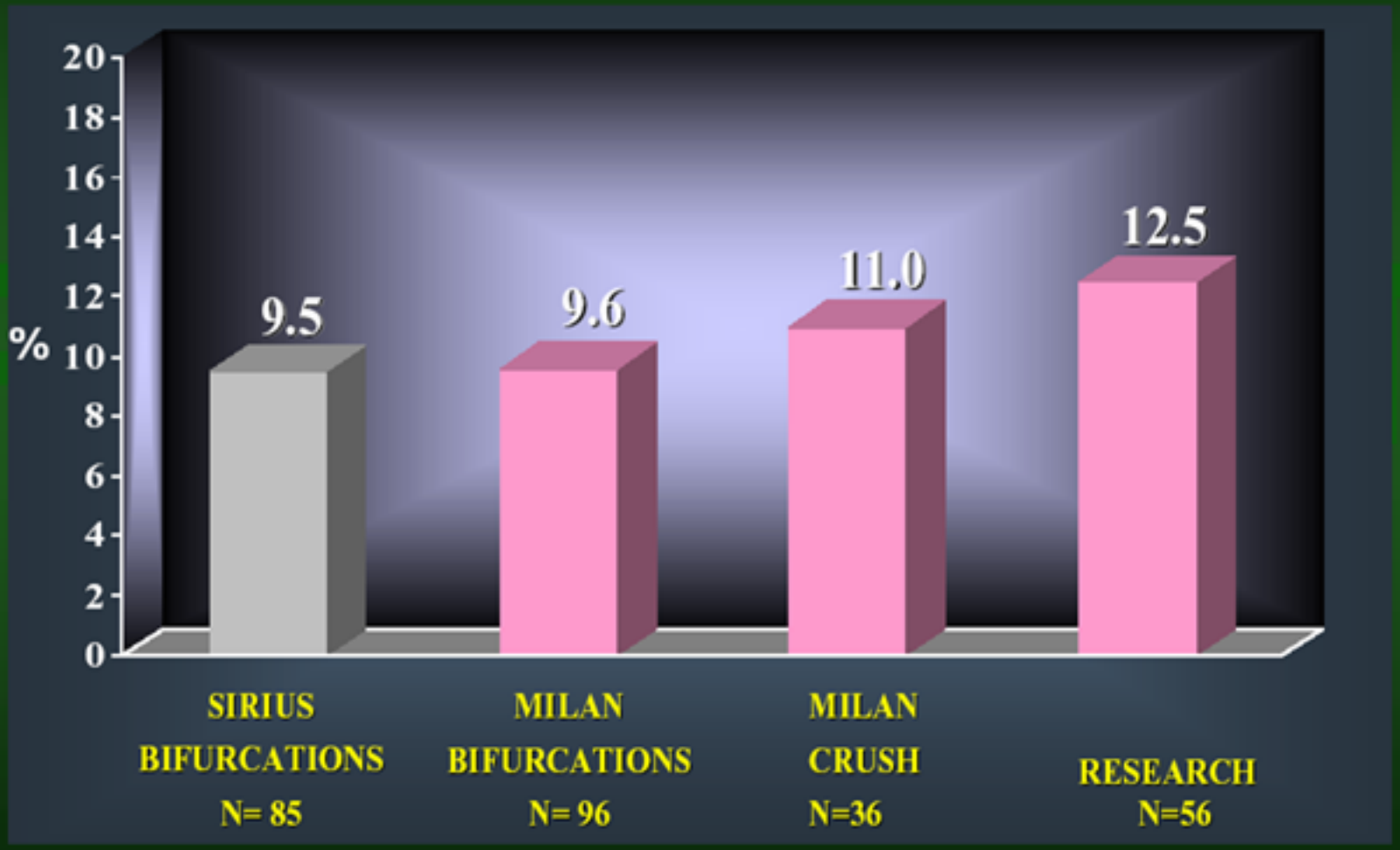
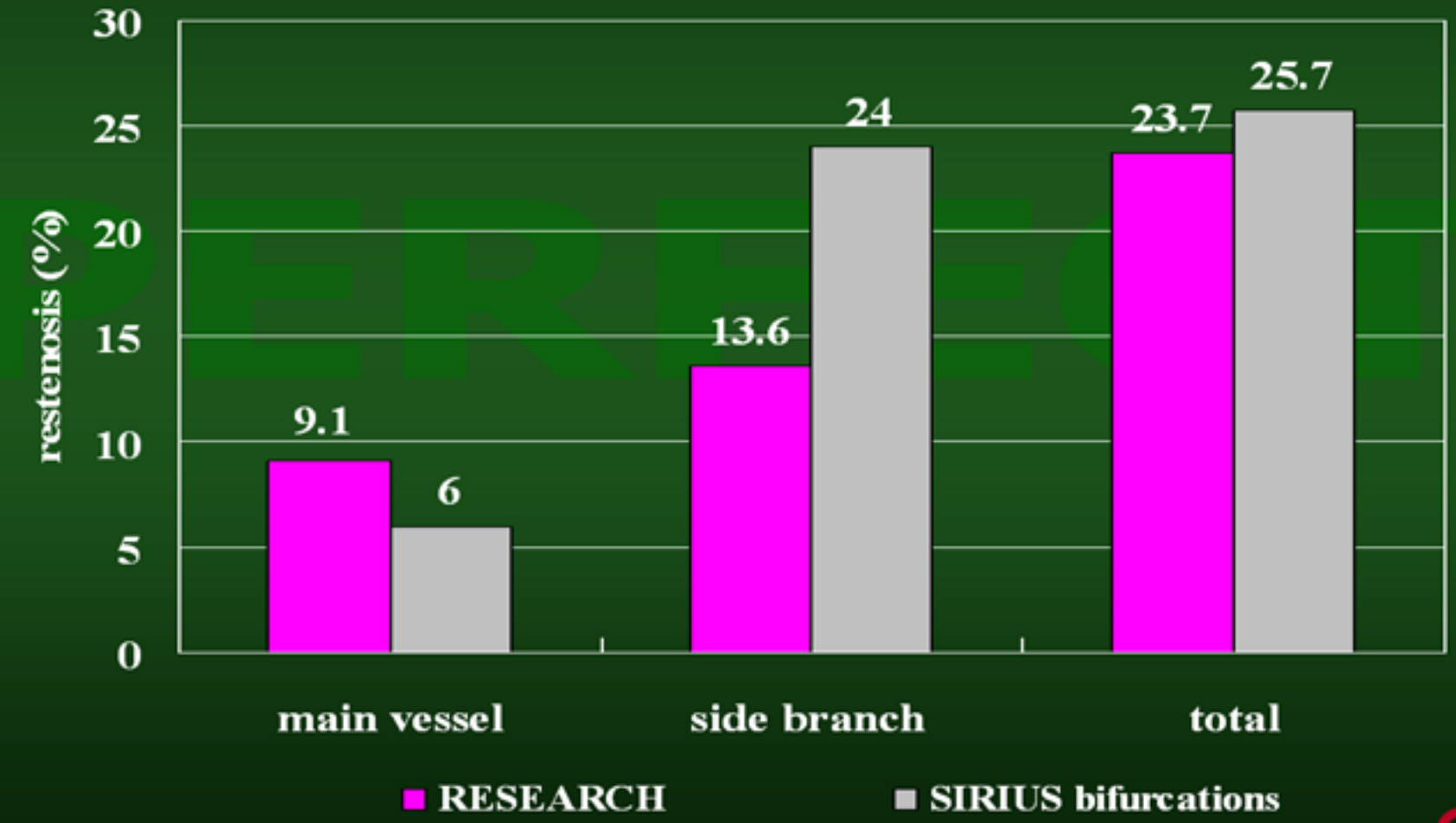
PrE Rapamycin Eluting Stent FlExi-CuT Registry (PERFECT Registry)

SES TLR in Bifurcations



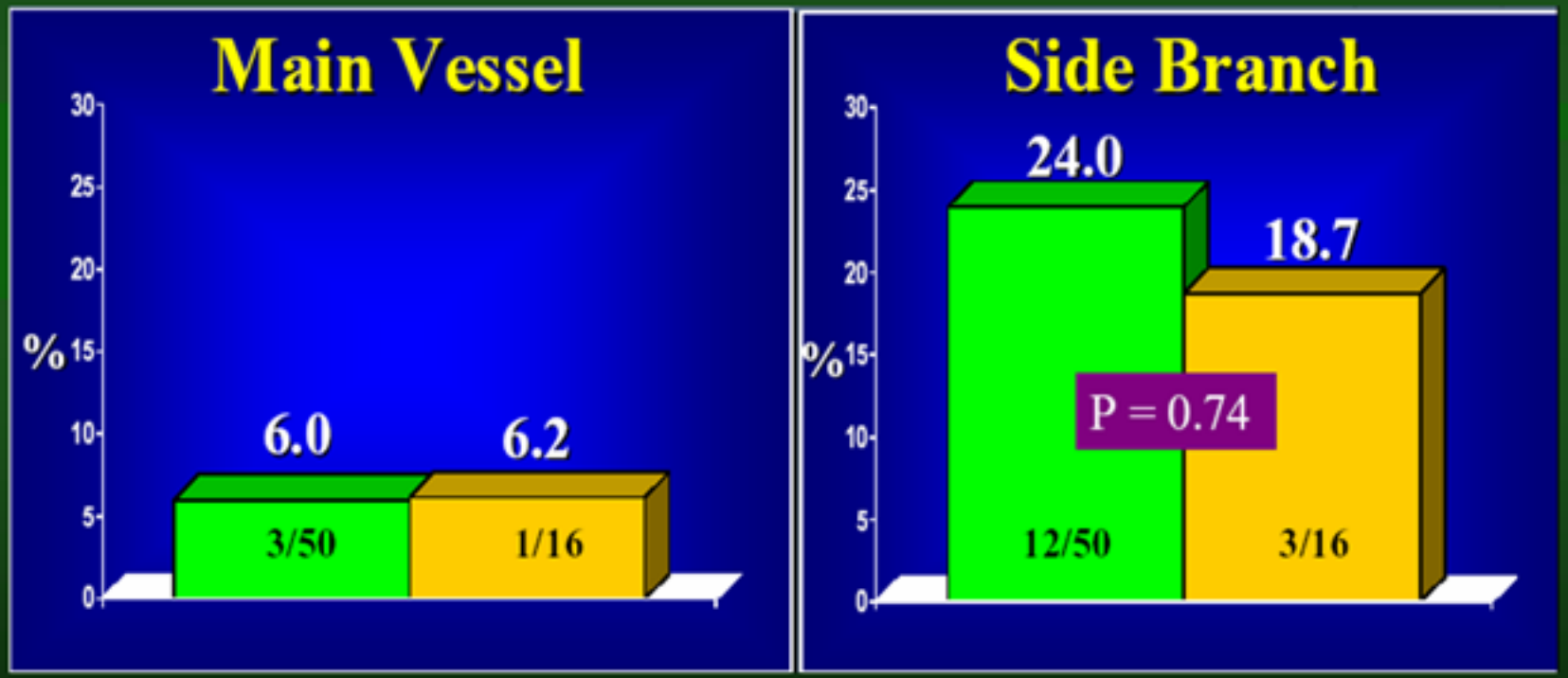
RESEACH Bifurcation Sub-study (n=58)
×
SIRIUS Bifurcations Study (n=55)



SIRIUS Bifurcations (n=66)
In Lesion Restenosis

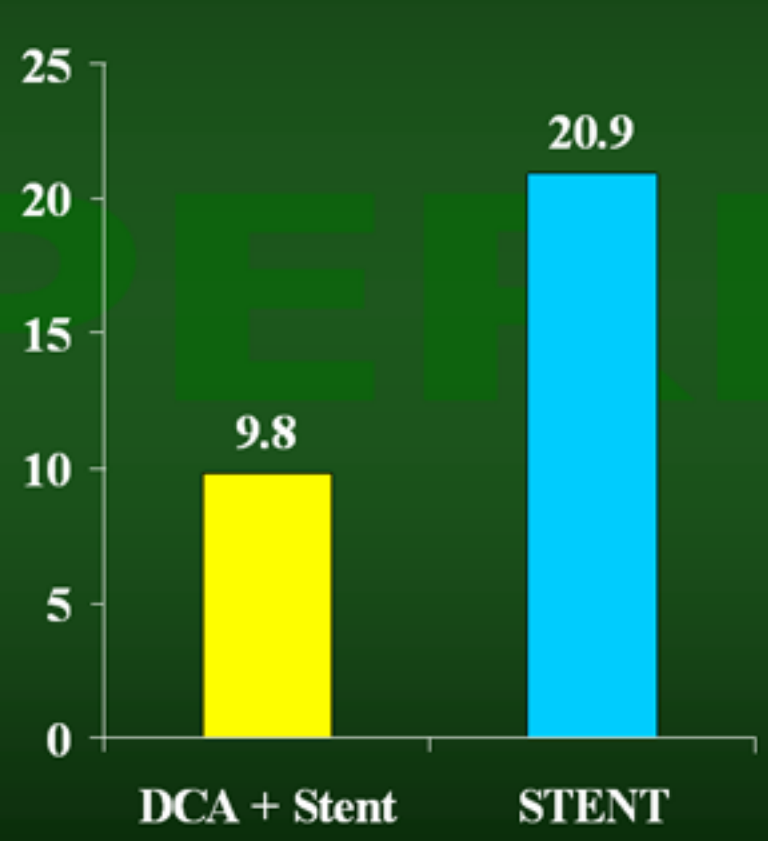
Total Restenosis (MV and/or SB) 25.7% (17/66)

Total MV 6.1% (4/66) **Total SB 22.7% (15/66)**

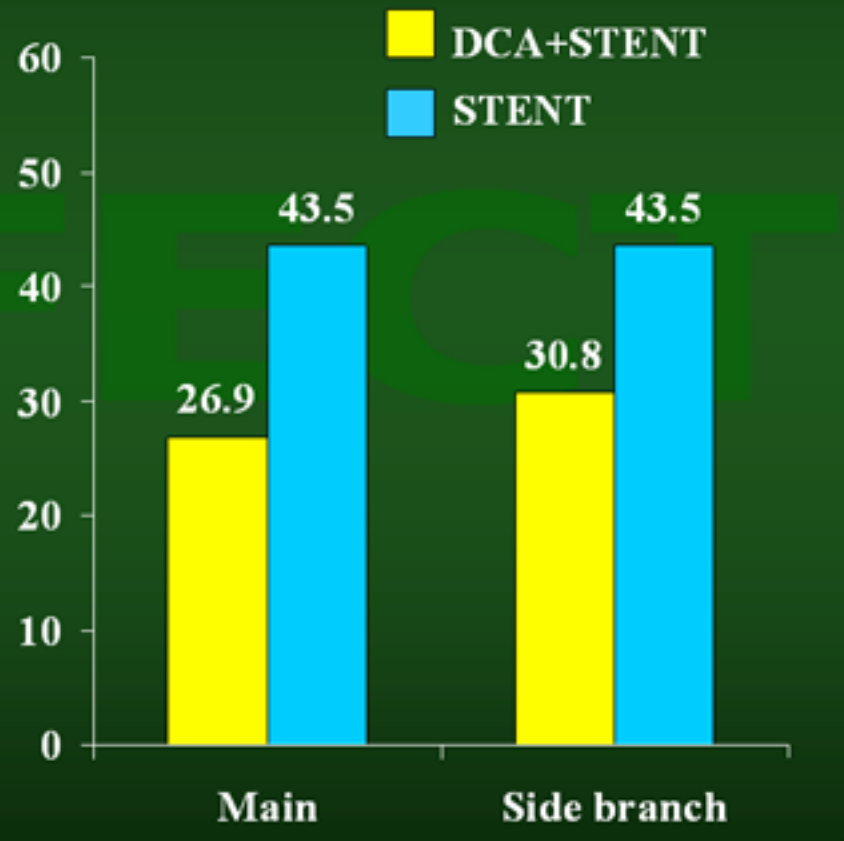


DCA/STENT in Bifurcation Lesions

AMIGO Trial



All *AMIGO* data



Milan Subgroup

Hypothesis & Objective

Hypothesis;

- Plaque removal by DCA prior to DES implantation for lesions located in bifurcation has the potential to reduce restenosis rate and improve long-term outcomes.

Objective;

- To evaluate the efficacy of pre DES plaque modification by DCA for ostial or bifurcated lesion

Study Design

- Multi-center non-randomized prospective registry
- DCA debulking prior to Cypher stenting for ostial or bifurcated lesion
- 9-month angiographic and clinical follow-up
- 15 Japanese centers

Inclusion Criteria

- Significant stenosis on located in distal LMT, ostium of LAD or LCx, or major bifurcation.
- De novo lesion
- Suitable morphology for DCA catheter delivery (no severe calc and acute proximal bending)
- Reference diameter > 2.5mm by visual estimate

Exclusion Criteria

- Bypass graft
- Bending > 60°
- Restenotic lesion
- Thrombotic lesion
- AMI (within 2 weeks) lesion

Endpoints

Primary endpoint

- **Angiographic restenosis (>50% DS) at 9 months**

Secondary endpoint

- **MACE, TLR, TVR by 9 months**

Patients Characteristics

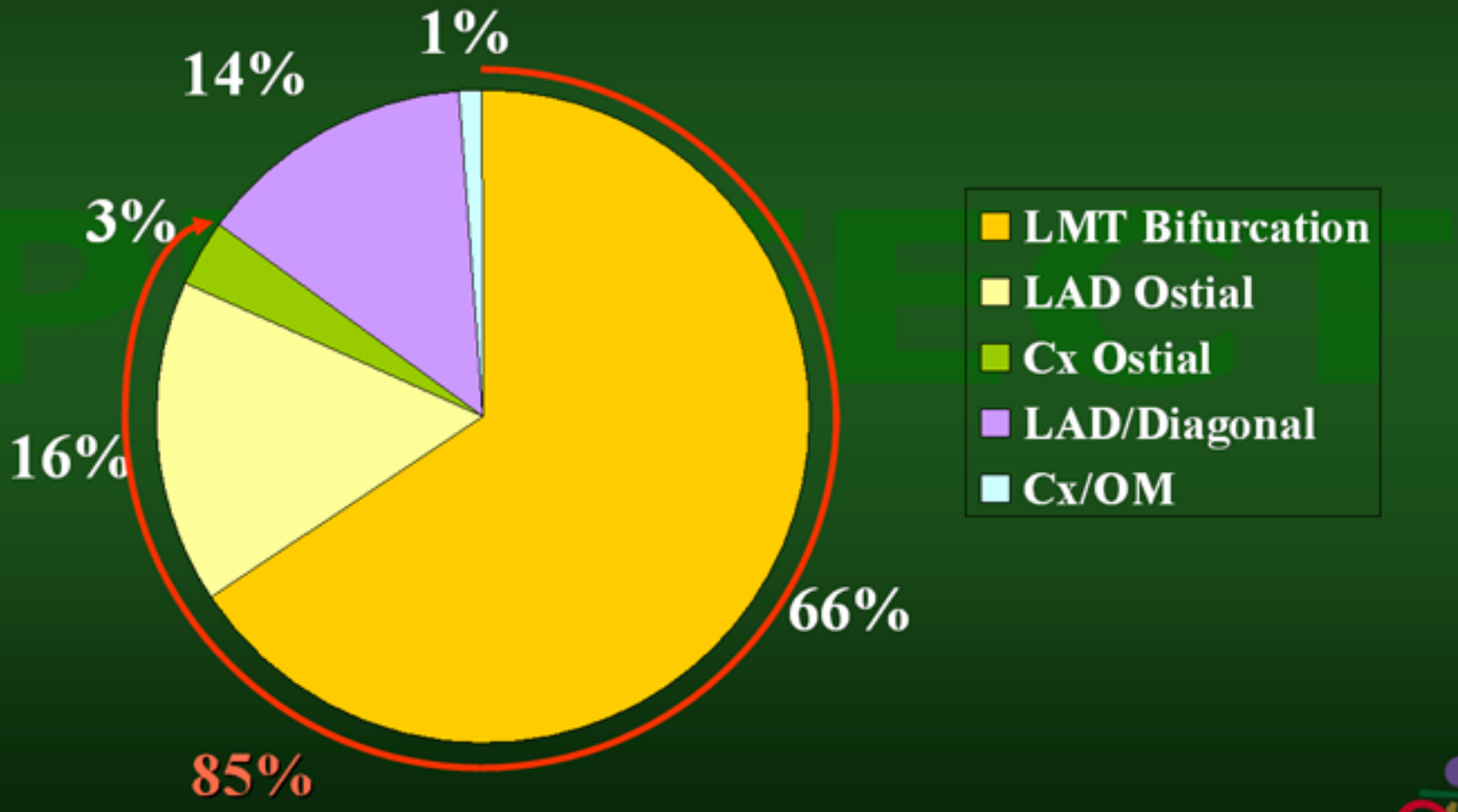
(Aug. 2004 ~ Oct. 2005)

Number	92
Male	78 (85%)
Age (y.o)	67 ±11
Prior MI	33 (36%)
Prior CABG	2 (2%)
UA	22 (24%)
HT	52 (57%)
DM	24 (26%)
HL	45 (49%)
H/O smoking	31 (34%)

PERFECT

Lesion Location

(n=92)

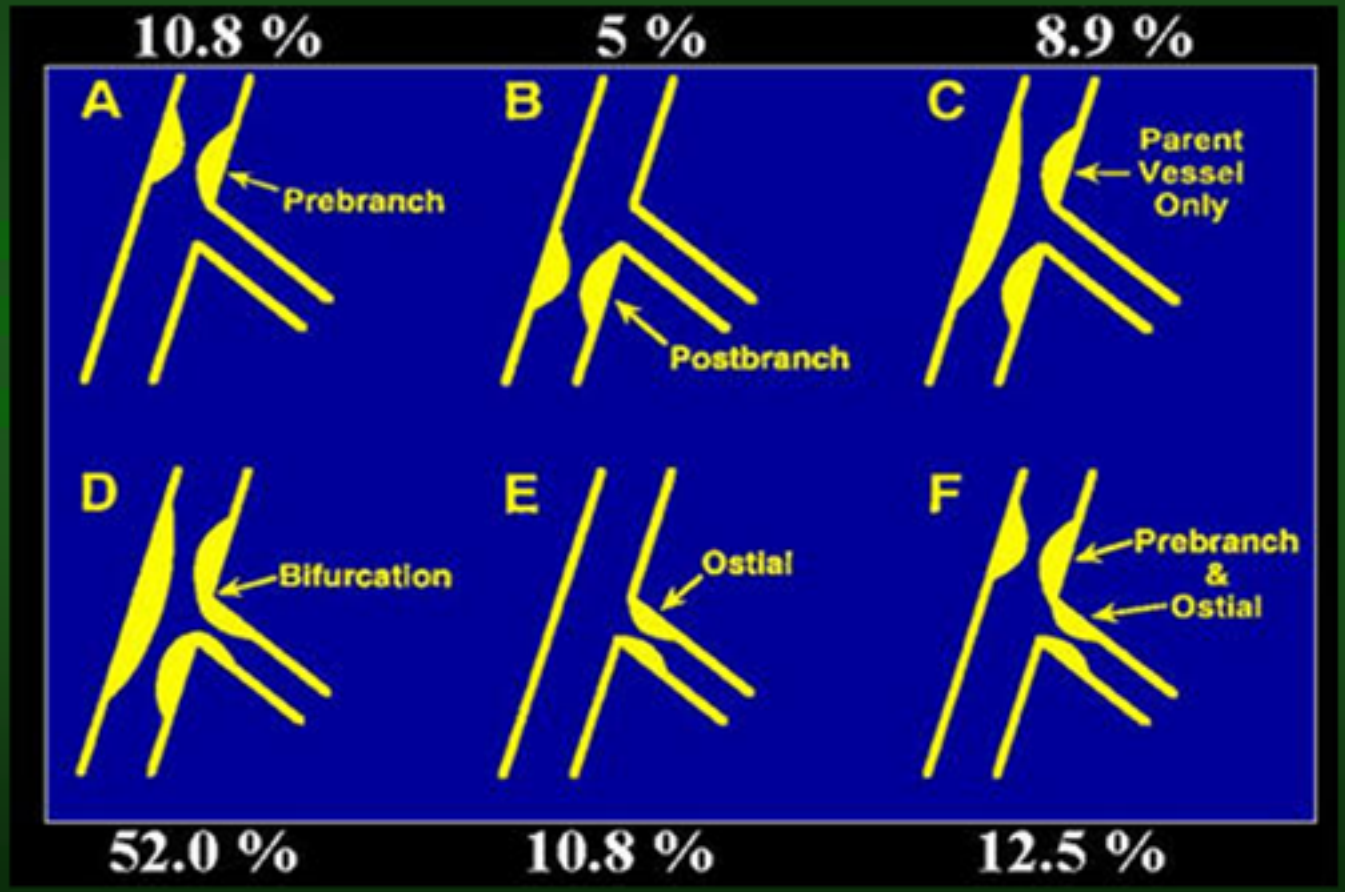


Classification of Bifurcation Lesions

Duke Classification

Bifurcation lesion classified into 6 types.

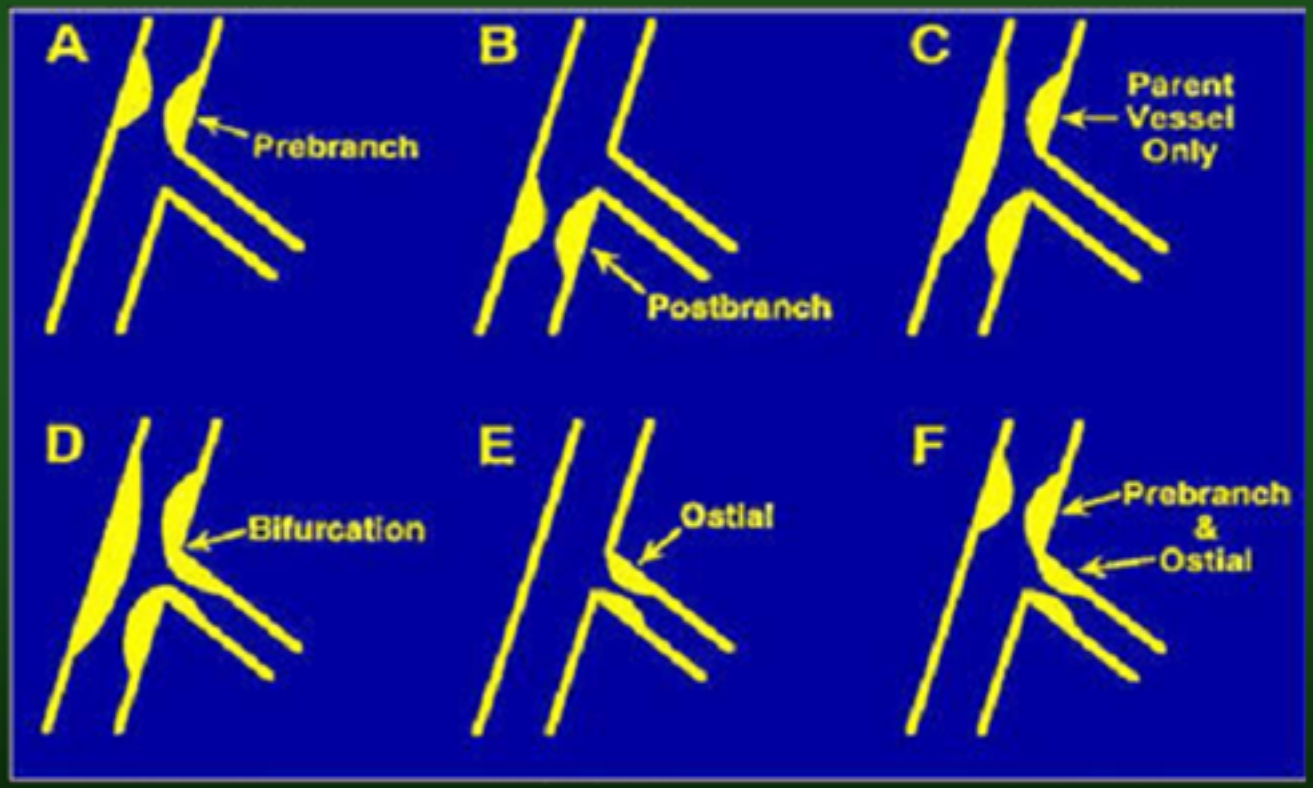
Type D lesion consists 52% of bifurcation lesion.



Classification of Bifurcation Lesions

Classification in PERFECT registry

7 (8 %) 29 (32 %) 23 (25 %)



28 (30 %) 0 (0 %) 5 (5 %)

DCA Procedural Results

(n=92)

1. FlexiCut size L/M: 91/1
2. Max. cutting pressure: 60.3 ± 35.0 psi
3. No of cut: 18.8 ± 12.5 cut
4. Vessels treated by DCA
   1) Main branch alone 89 (97%)
   2) Both main and side branch 3 (3%)

DCA Procedural Results

(n=92)

5. Complications during DCA

1) spasm	0%
2) side branch occlusion	0%
3) no flow	0%
4) perforation	0%

Stenting Procedural Results

(n=92)

1 STENT + KBT	53 %	48
1 STENT + Non KBT	25 %	23
Non crossover 1 STENT	16 %	15
1 STENT + SB-POBA	4 %	4
Crush STENT	0 %	0
T STENT	1 %	1
Culotte STENT	1 %	1

KBT: kissing balloon techique; SB: side branch

Stenting Procedural Results

Number	92
Delivery success	92 (100%)
Stent size	3.33 ±0.25 mm
Total length of stents	21.9 ±4.2 mm
Max. inflation pressure	17.2 ± 3.0 atm
No of STENT	1.36 ±0.62

In-Hospital Outcomes

(n=92)

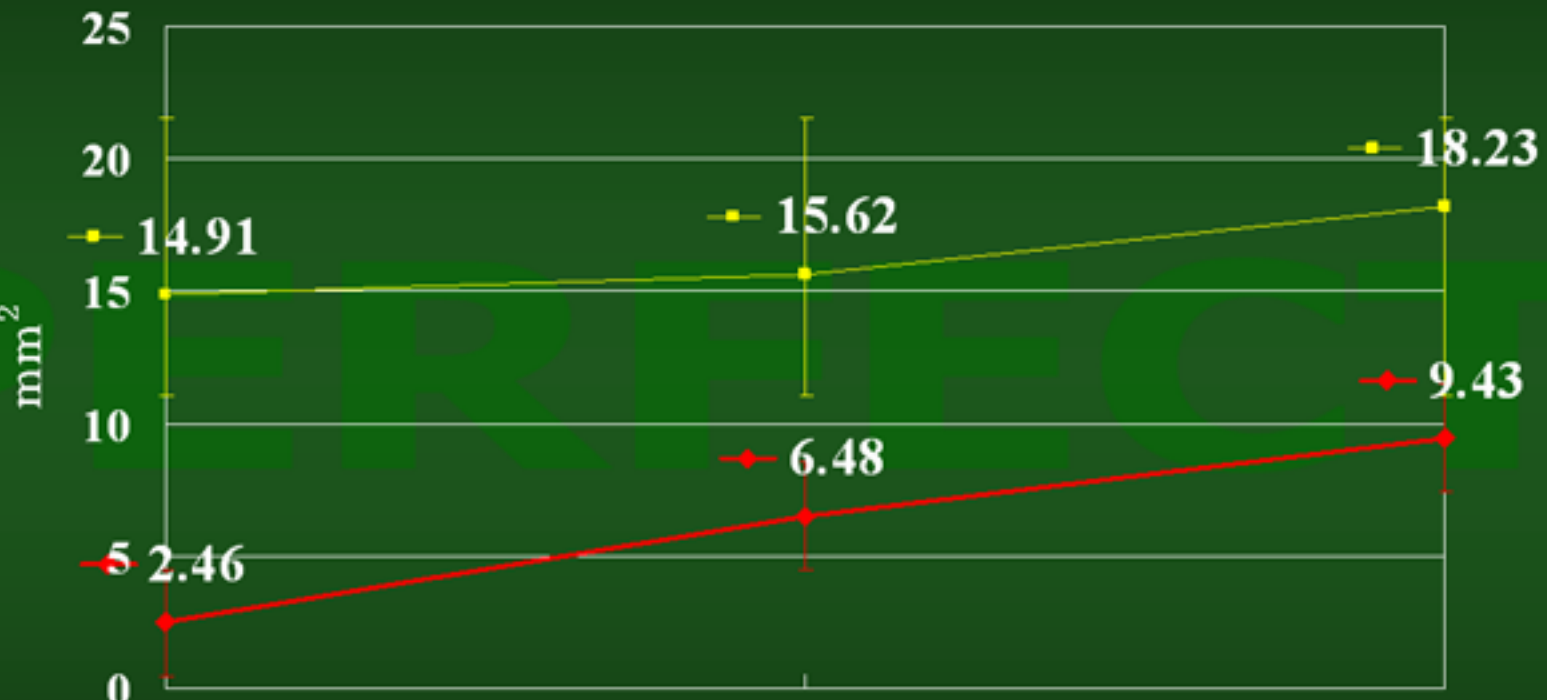
1) Death	0%
2) Em-CABG/TLR	0%
3) QMI	0%
4) Non-QMI	2%
5) Complication at access site	0%

QCA Analysis
Main Branch

Pre	**Lesion length**	**16.7 ± 8.3 mm**
	RVD	**3.33 ± 0.45 mm**
	MLD	**1.34 ± 0.37 mm**
	Percent DS	**59.9 ± 9.3 %**
Post	**RVD**	**3.83 ± 0.43 mm**
	MLD	**3.47 ± 0.65 mm**
	Percent DS	**9.4 ± 11.8 %**

QCU Analysis (Main Branch):

Vessel area, Lumen area, Area stenosis



AS	82.3%	59.9%	46.0%

9Mo Follow-up
Clinical Results

- Until Feb.2006, Fu CAG was performed in 42 patients. (46% Fu rate; Fu data collection is still on going.)
- No death, no CABG, no MI
- No TLR for the main branch
- TLR for the side branch in 1 patient (2.4%)

9Mo Follow-up
QCA Results

- Fu duration: 251 ± 66 days

Main Branch	reference	3.50 ± 0.43 mm
	MLD	3.13 ± 0.58 mm
	percent DS	10.7 ± 10.7 %
Side Branch	reference	2.50 ± 0.61 mm
	MLD	1.84 ± 0.56 mm
	percent DS	25.5 ± 17.4 %

9Mo Follow-up
QCA Results

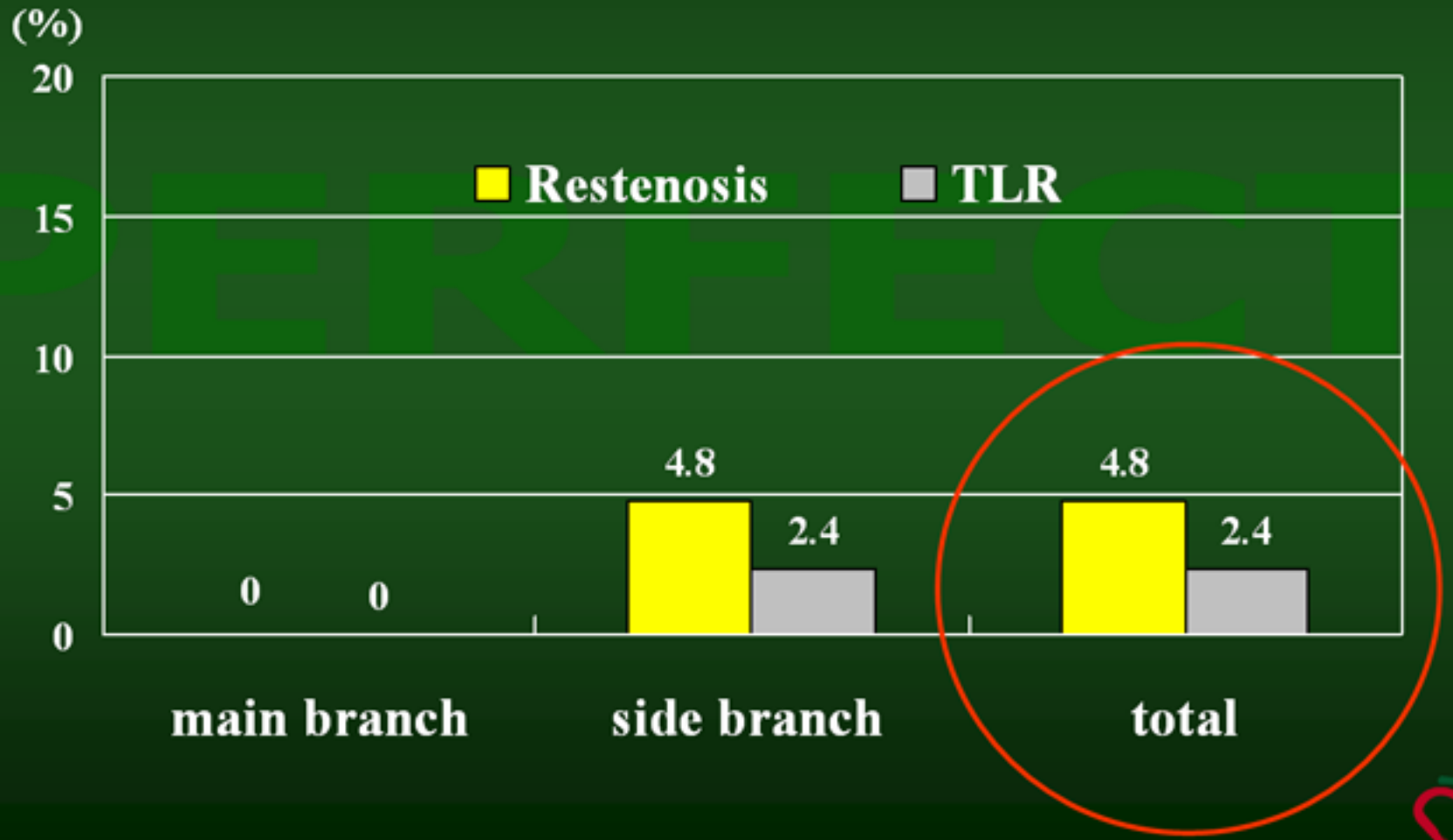
- Fu duration: 251±66 days

- Binary restenosis rate

  Main branch: 0%

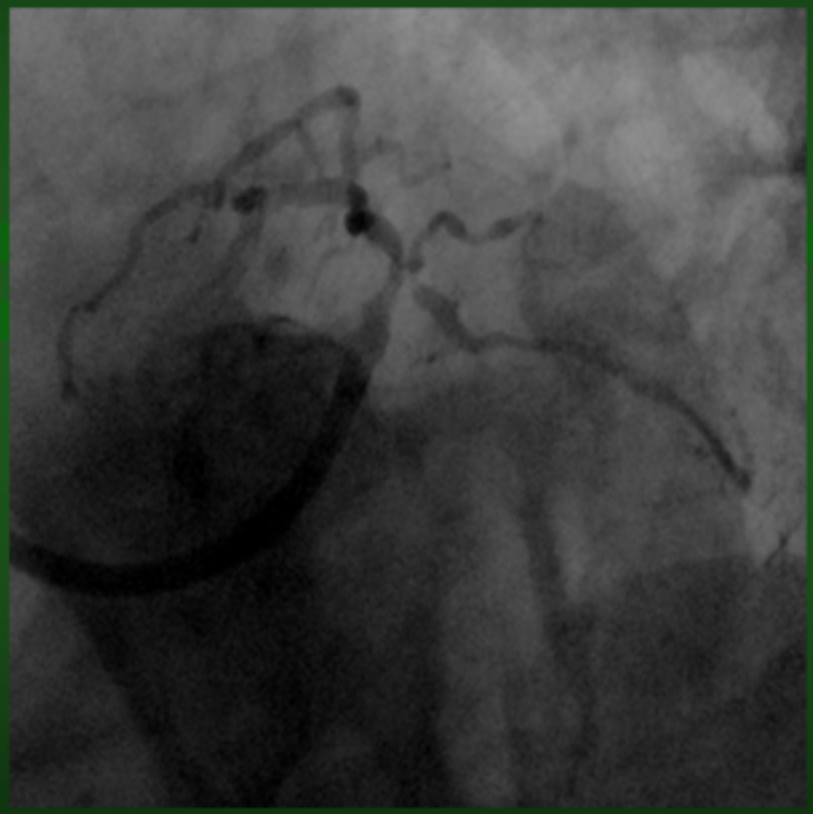
  Side branch: 4.8% (2/42)

9Mo Follow-up
Binary restenosis / TLR rate



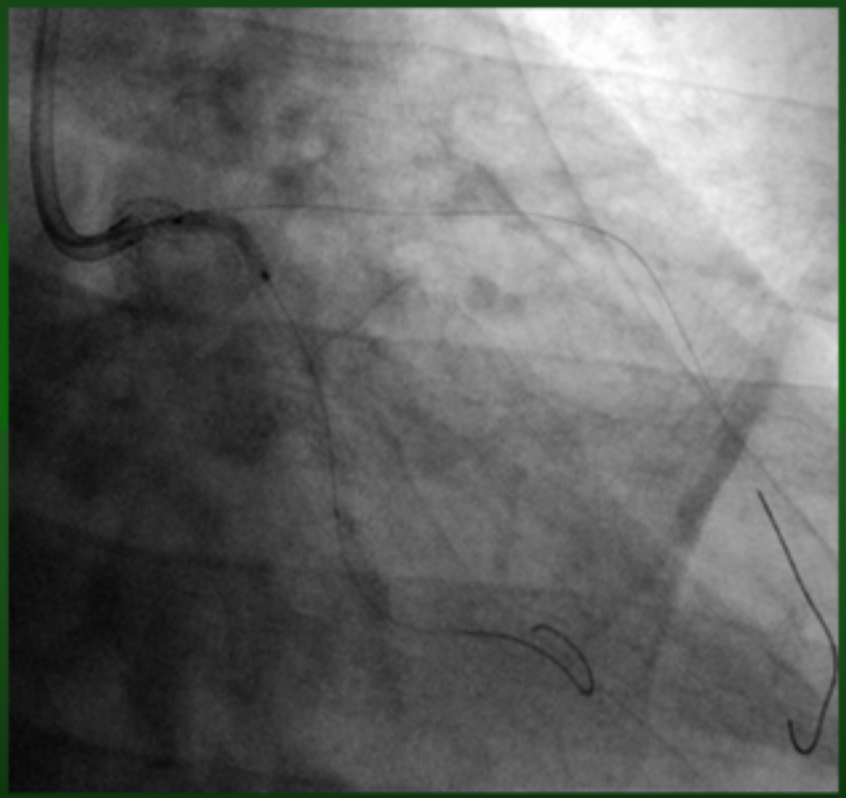
PERFECT Case

Pre PCI

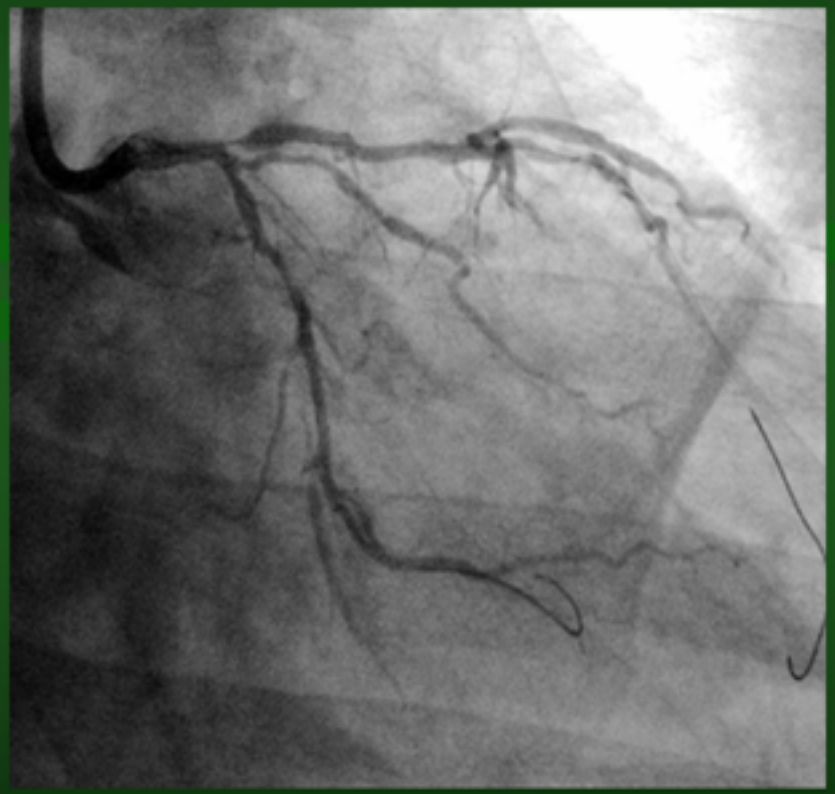


Type D bifurcation

PERFECT Case

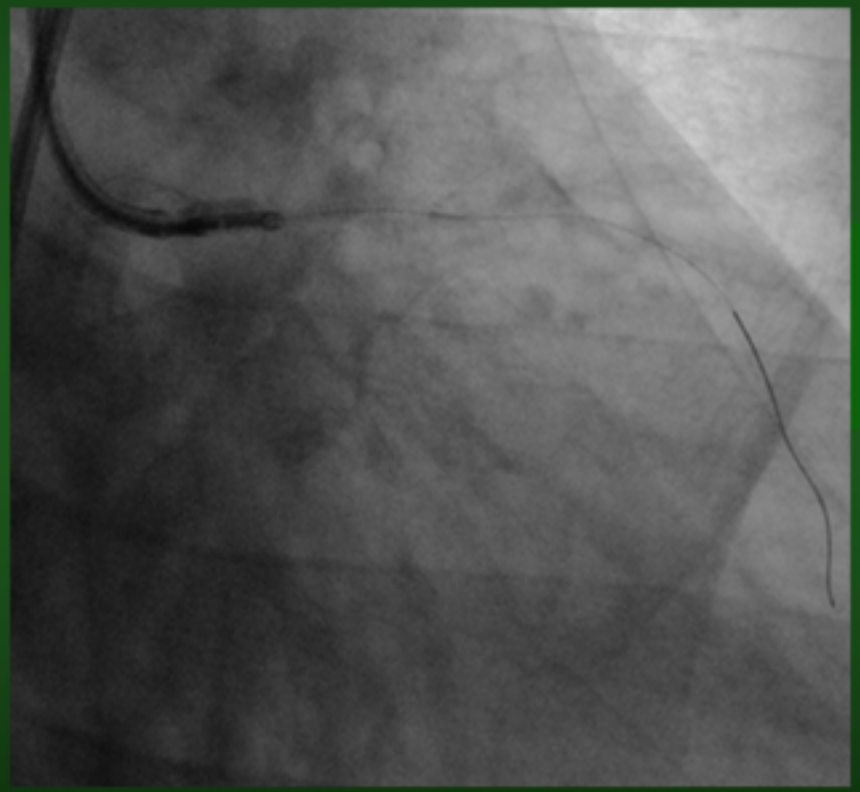


Cx POBA



Post Cx POBA

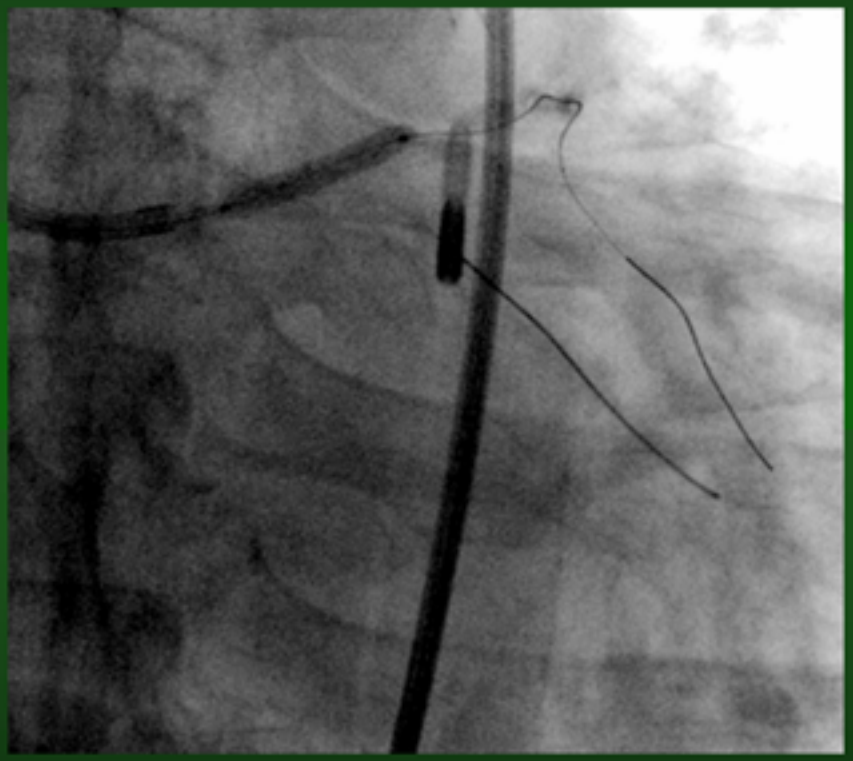
PERFECT Case



Flexi- Cut 70psi 28cut

Post DCA

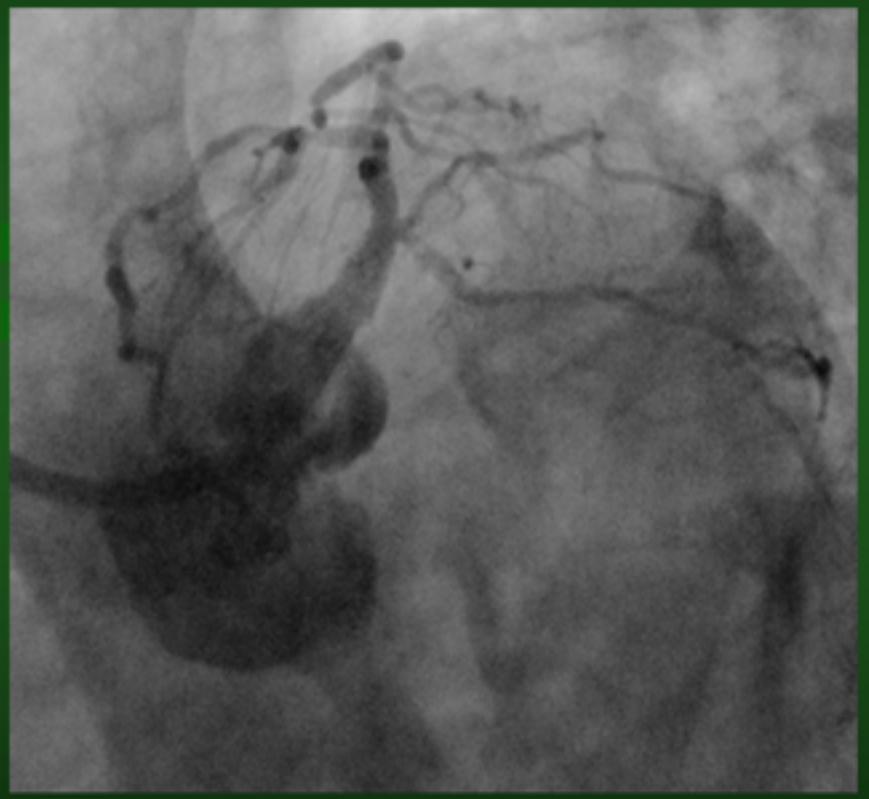
PERFECT Case



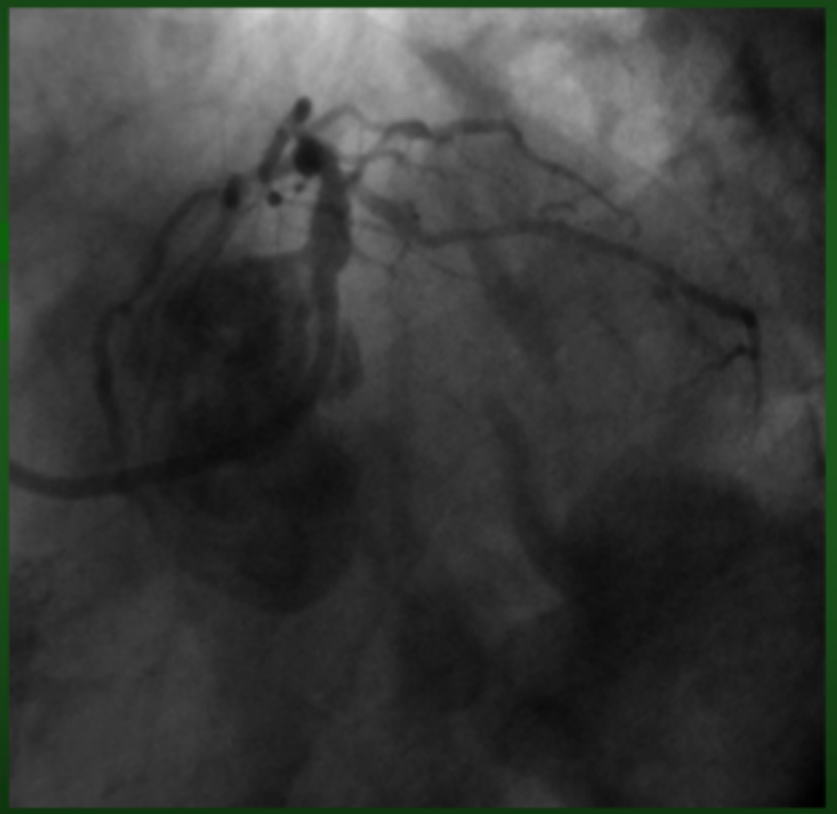
Cypher 3.0x18

KBT

PERFECT Case
Post Procedure

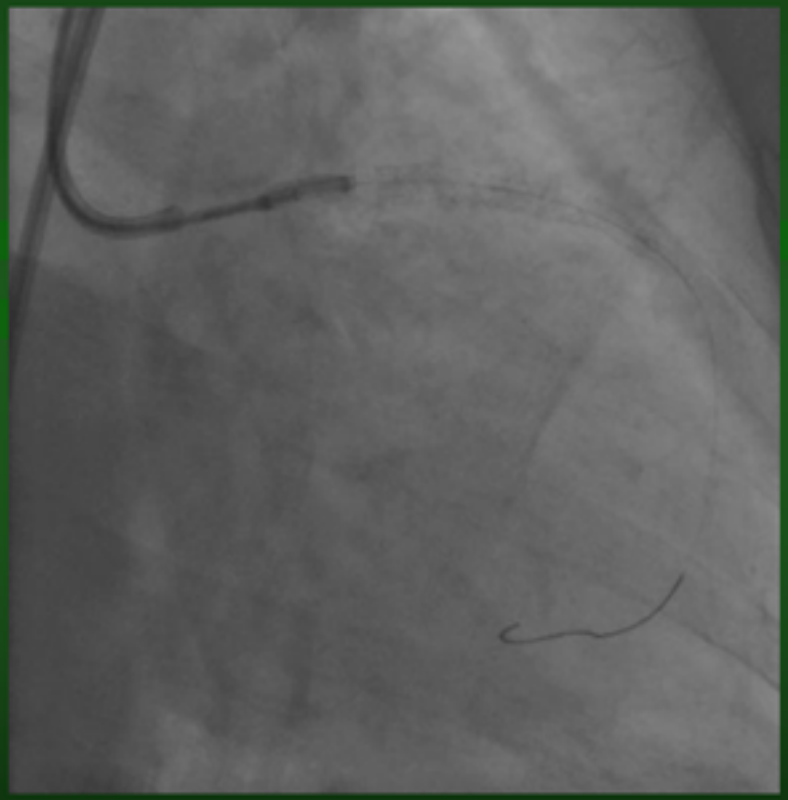


PERFECT Case
9Mo Follow-up



Restenosis and TLR Case for side branch

Type B bifurcation



Flexi-Cut 45psi 15cut

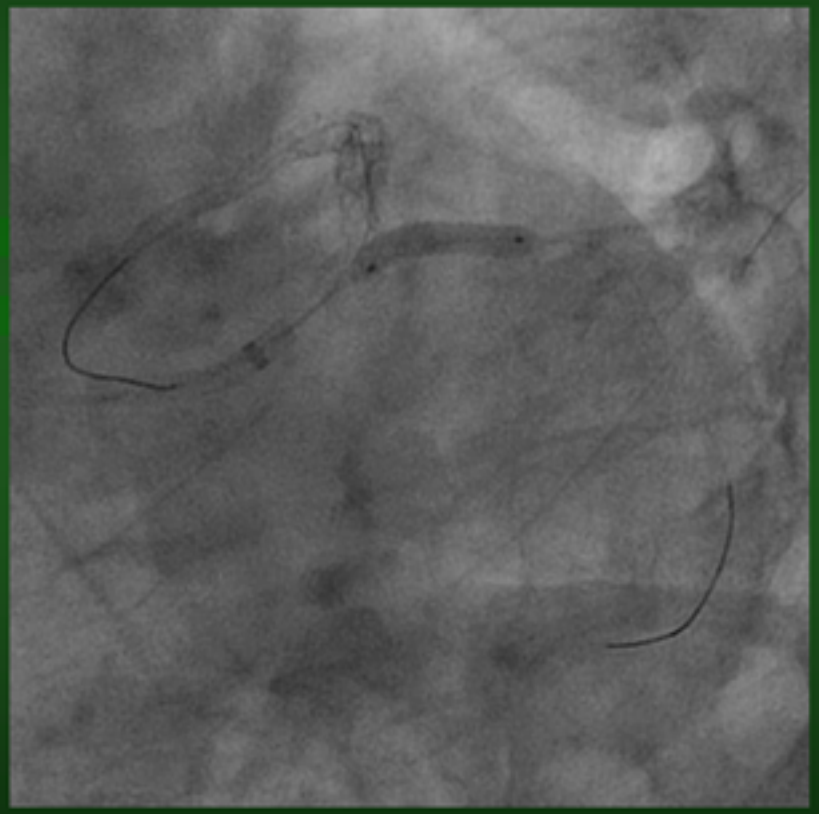
Restenosis and TLR Case for side branch

Cypher 3.5 × 23mm KBT

Post Procedure

Restenosis and TLR Case for side branch

9Mo Follow-up



Re-PCI as T-Stenting

Study Limitations

- Lesion selection bias (DCA catheter applicable)
- Small number patient enrolled
- Non-randomized fashion

Conclusions

- DCA prior to DES stenting is safe and makes it possible to avoid complex stenting in lesions located at bifurcation.
- The interim Fu data looks **PERFECT** for main vessel and almost **PERFECT** for side branch.
- This strategy warrants further evaluation.