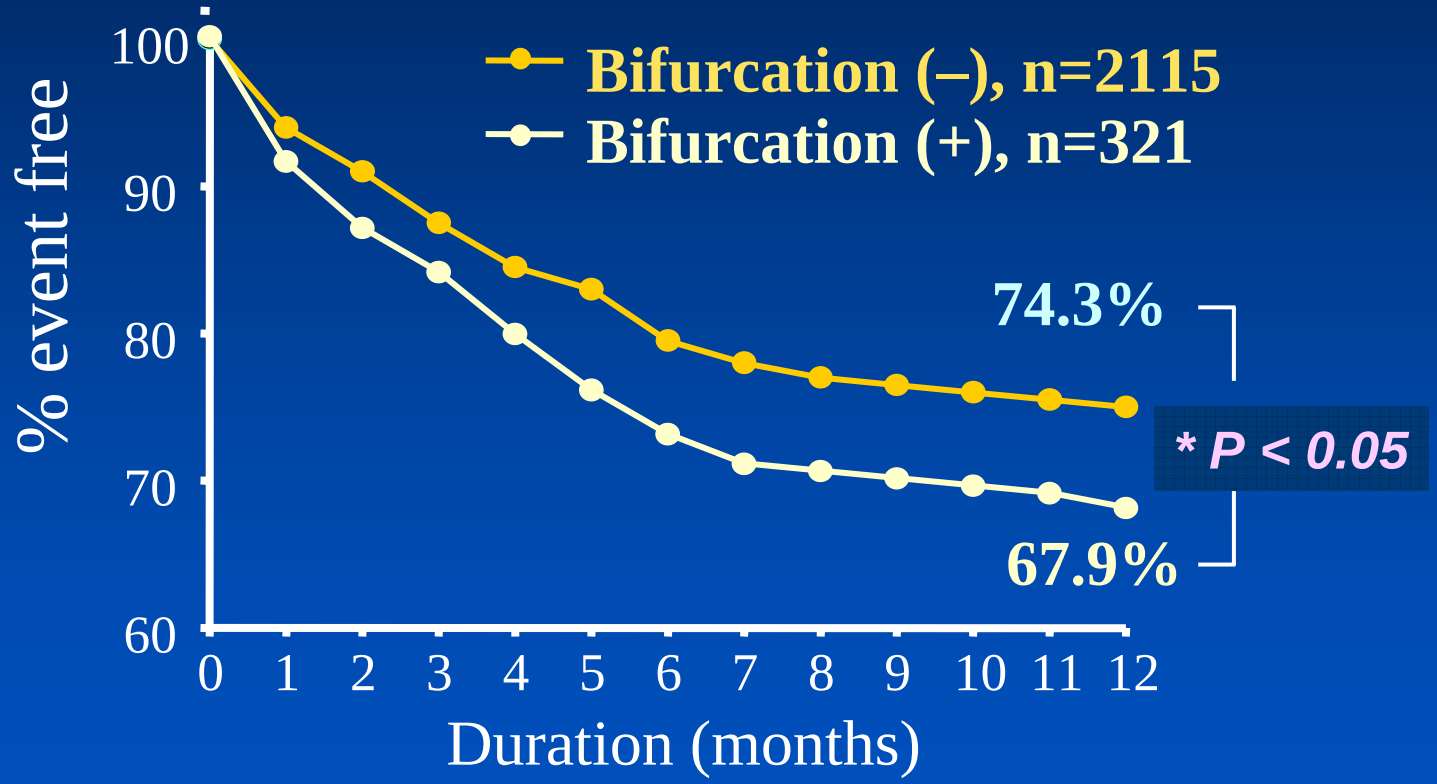
PCI for Bifurcation Lesions

Bifurcation lesion has been a predictor of worse prognosis of PCI.

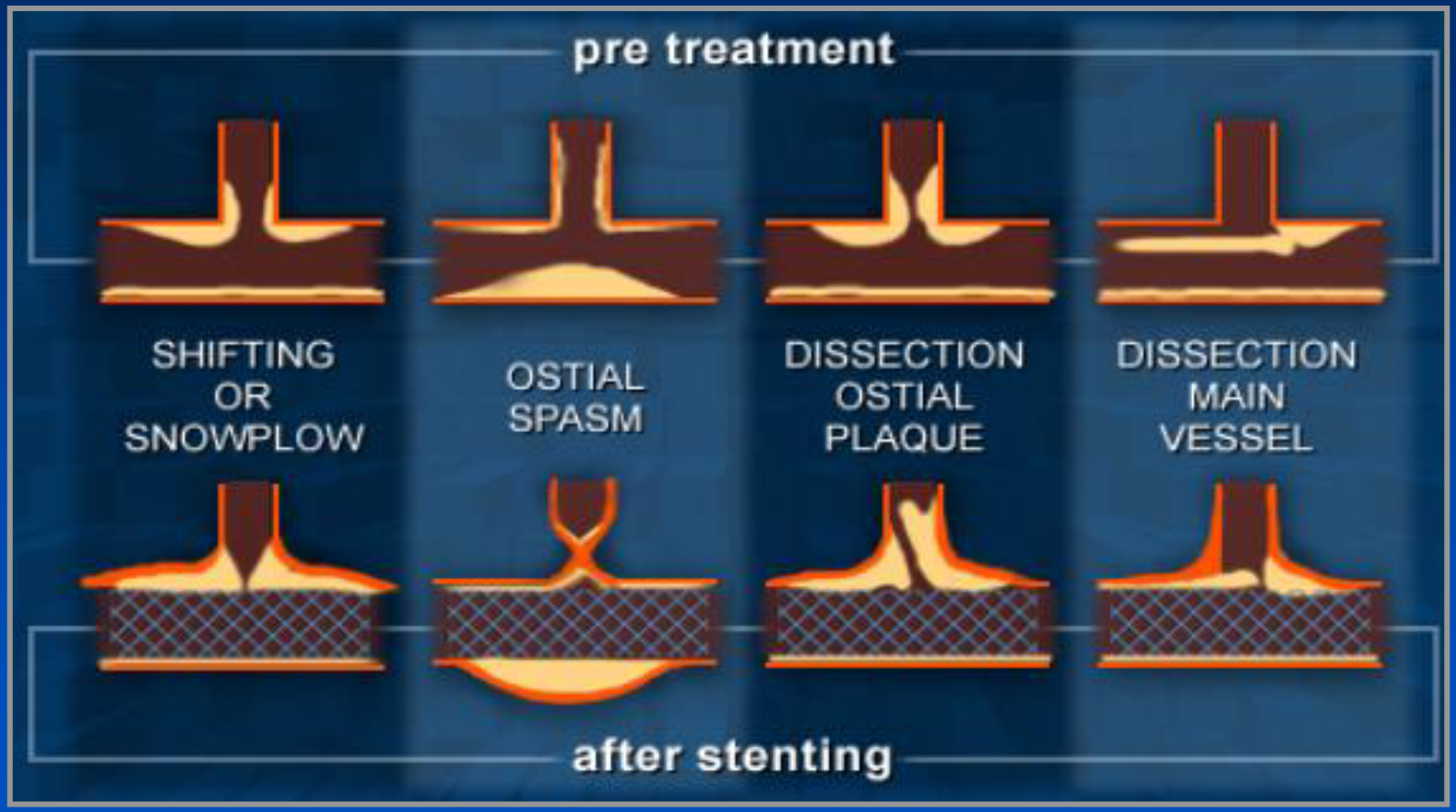
Event-free survival after BMS implantation in NHLBI Registry



Suwaidi J, et al. AJC 2001;87:1139-44

Side Branch Loss

Main Mechanism of Adverse Outcomes



Side Branch Loss in Bifurcation

Procedural and Angiographic Characteristics

	SB success (n=132)	SB failure (n= 26)	*p*
Vessel diameter	2.54 ± 0.55	2.29 ± 0.34	0.03
Initial % stenosis	35.9 ± 20.7	44.7 ± 22.4	0.05
Initial MLD	1.65 ± 0.69	1.28 ± 0.55	0.01
Final % stenosis	34.9 ± 0.55	81.4 ± 12.7	< 0.01
Final MLD	1.63 ± 0.62	0.43 ± 0.29	< 0.01
Thrombosis (%)	3.0	7.7	0.26
Lesion length (mm)	4.5 ± 2.6	4.0 ± 2.1	0.38

Chaudhry EC et al. *J Thrombo Thrombolysis* 2007

Independent Predictors of Side Branch Failure

	Odds ratio	95 % CI	*p*
Diabetes mellitus	2.55	1.01 – 6.43	0.047
β blocker pre PCI	0.28	0.10 – 0.79	0.02
Parent eccentricity	2.93	1.09 – 7.83	0.03
SB vessel diameter	0.16	0.04 – 0.61	< 0.01

** OR for SB diameter is based on a 1 mm increase, alternatively:

1 mm decrease	6.37	1.64 – 25.0
0.1 mm decrease	1.2	1.05 – 1.39

Chaudhry EC et al. *J Thrombo Thrombolysis* 2007

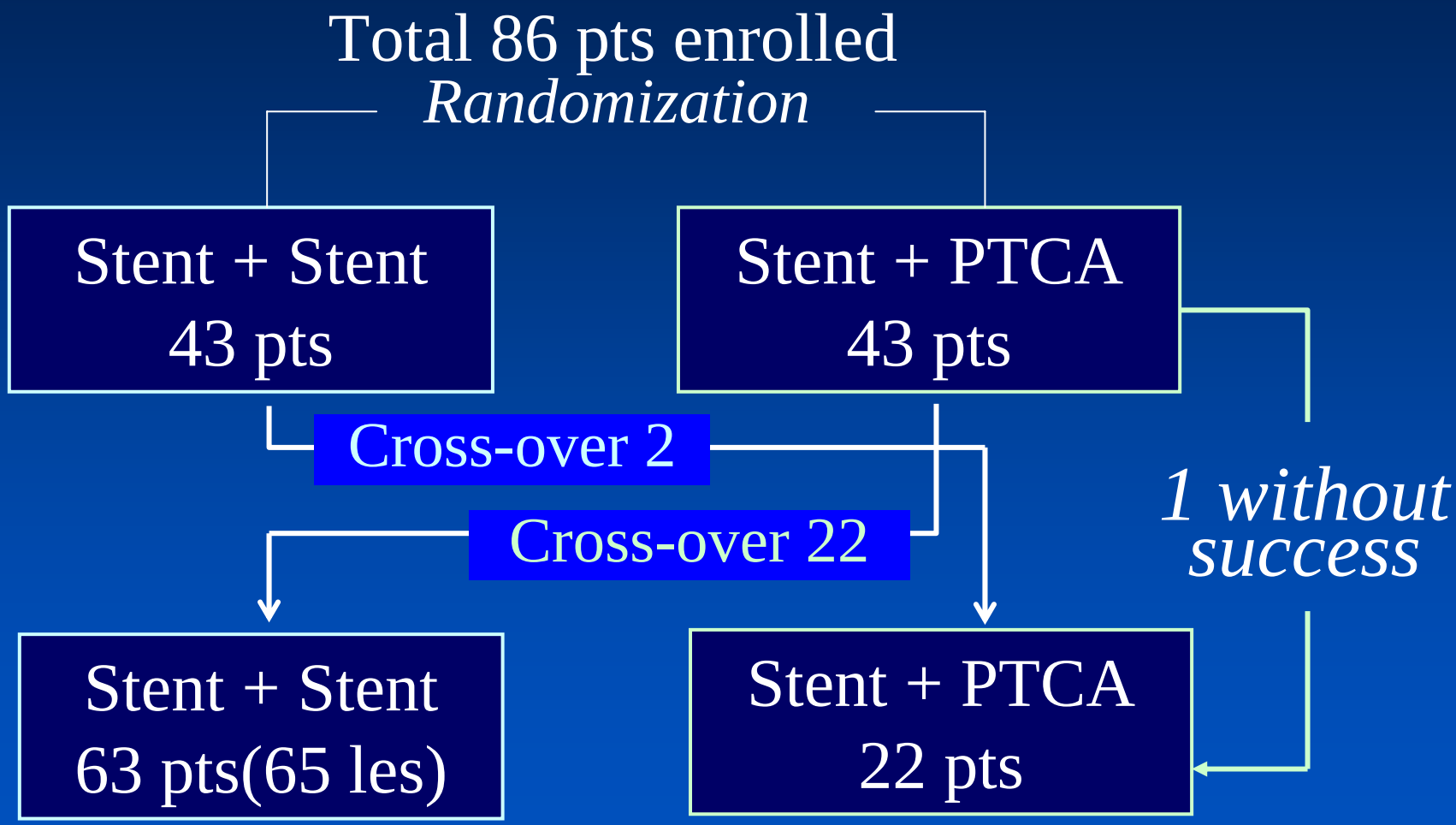
In the DES era
we have some questions.

1. Two stents better than one?
2. If using 2 stents, what's the best approach?
3. Dedicated bifurcation DES?

Is DES a final solution for bifurcation ?

SIRIUS Bifurcation Study

Sirolimus Eluting Stent



A Colombo, et al. Cir 2004;109:1244

Procedural Technique

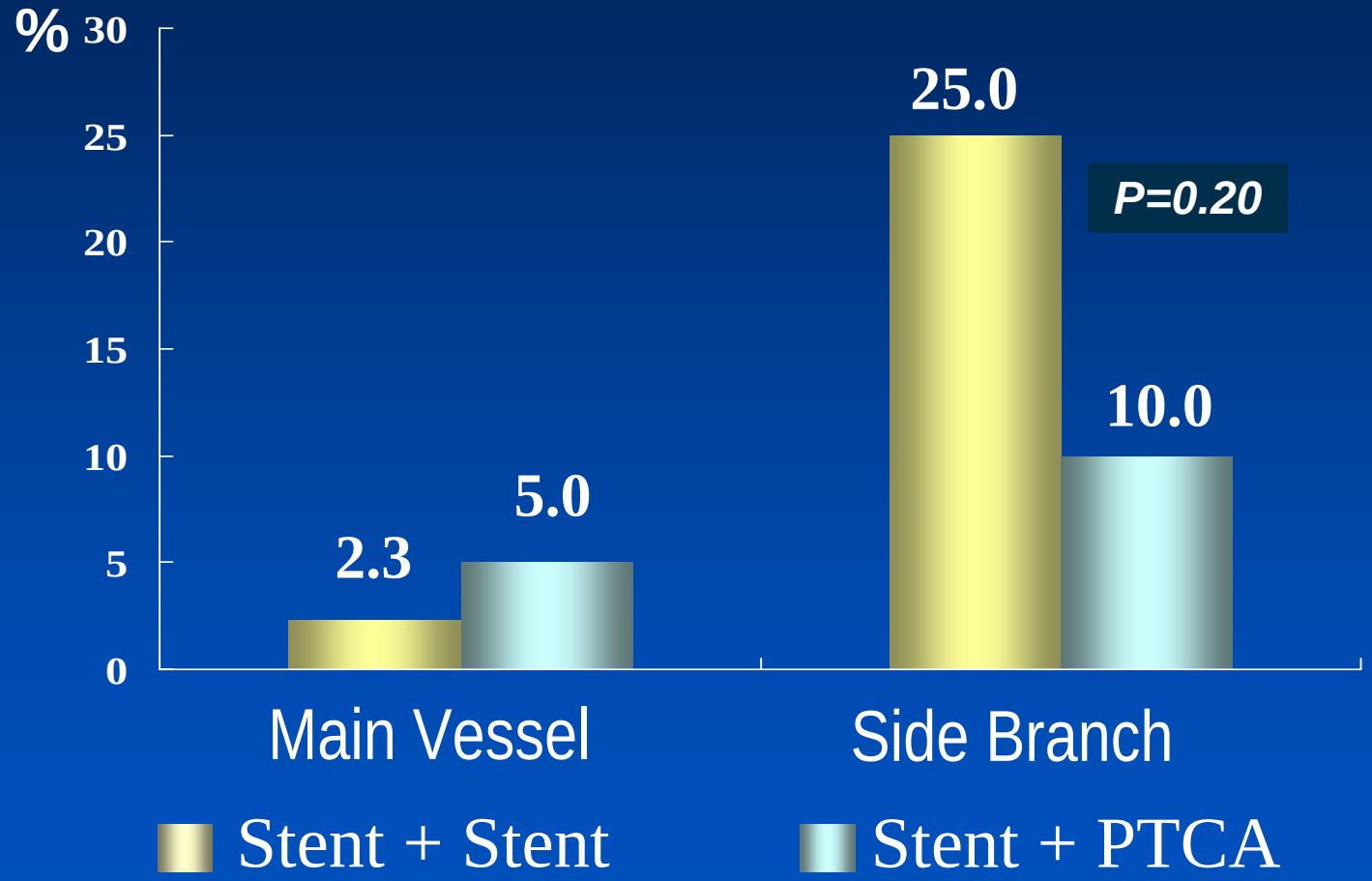
SIRIUS Bifurcation Study

Technique	Stent / Stent (n=63)	Stent / PTCA (n=22)
T- stenting	60	
Side branch first	40	
Main vessel first	20	
V- stenting	1	
Y- stenting	2	
Kissing balloon	60 (95%)	19 (86%)
GPIIb/IIIa inhibitor	27 (43%)	8 (37%)

A Colombo, et al. Cir 2004;109:1244

In-Segment Restenosis

SIRIUS Bifurcation Study



A Colombo, et al. Cir 2004;109:1244

DES is a solution for bifurcation ?

- **Main branch** — **Certainly, Yes**
- **Side branch** — **Not certain, yet**

We should focus on the treatment of side branch in bifurcation PCI with DES.

Simple vs. Complex Strategy

Stenting Technique

- **Simple stenting technique**

  DES implantation only at the main vessel with optional balloon angioplasty or stenting at the side branch

- **Complex stenting technique**

  DES implantation at the main vessel and the side branch

Simple Stenting Technique

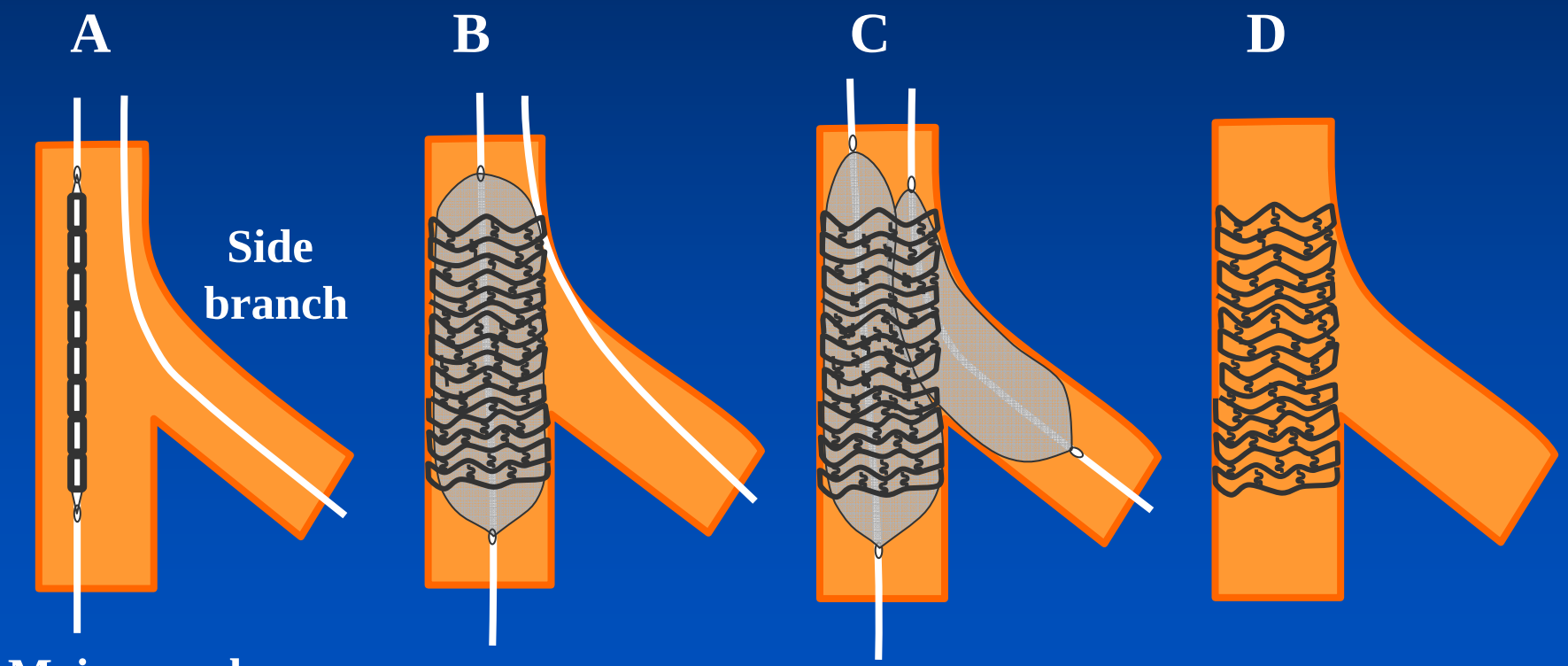
1. Stent placement in the main branch only

And

1) Optional kissing balloon inflation
2) Provisional T stenting
3) Provisional Reverse Crush technique

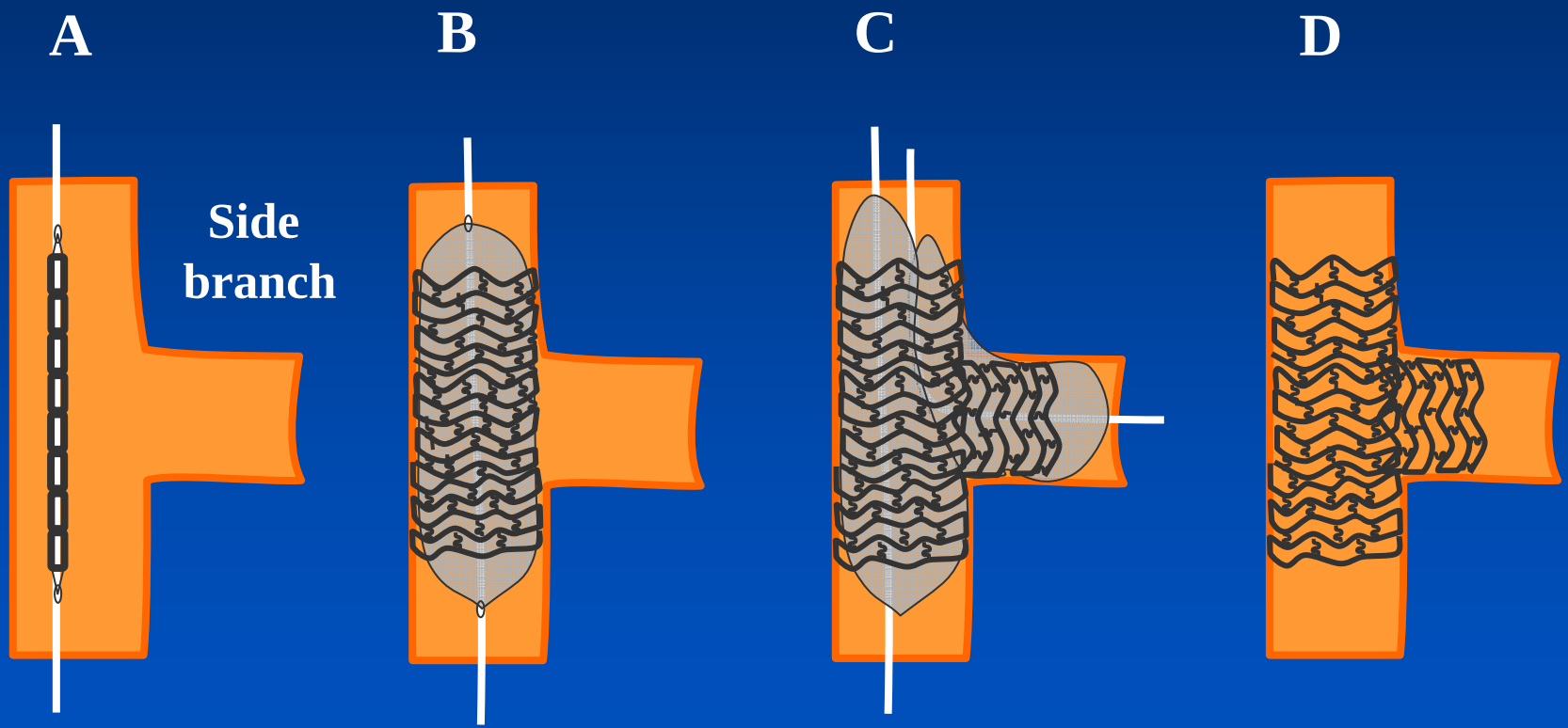
Stenting Crossing Side Branch With Optional Kissing Balloon Inflation

Normal or diminutive side branch ostium



Provisional T Stenting

In cases with significant narrowing of side branch after main branch stenting



Provisional T Stenting

- In extremely angulated lesions, it is difficult to place the second stent in the side branch.
- Deployment of side branch stent before final kissing inflation should be performed with high pressure (14-18atm) to achieve optimal scaffolding.
- Kissing balloon inflation during placement of the second stent in the side branch is very important to prevent distortion of the main branch stent.

Provisional T Stenting

- Optimal scaffolding of the side branch ostium was generally ensured when the stent strut opened towards the side branch is distal and closer to the carina.

- To achieve complete lesion coverage, put the second stent in the side branch slightly protruding to the main branch.

Provisional T Stenting with Cyphers

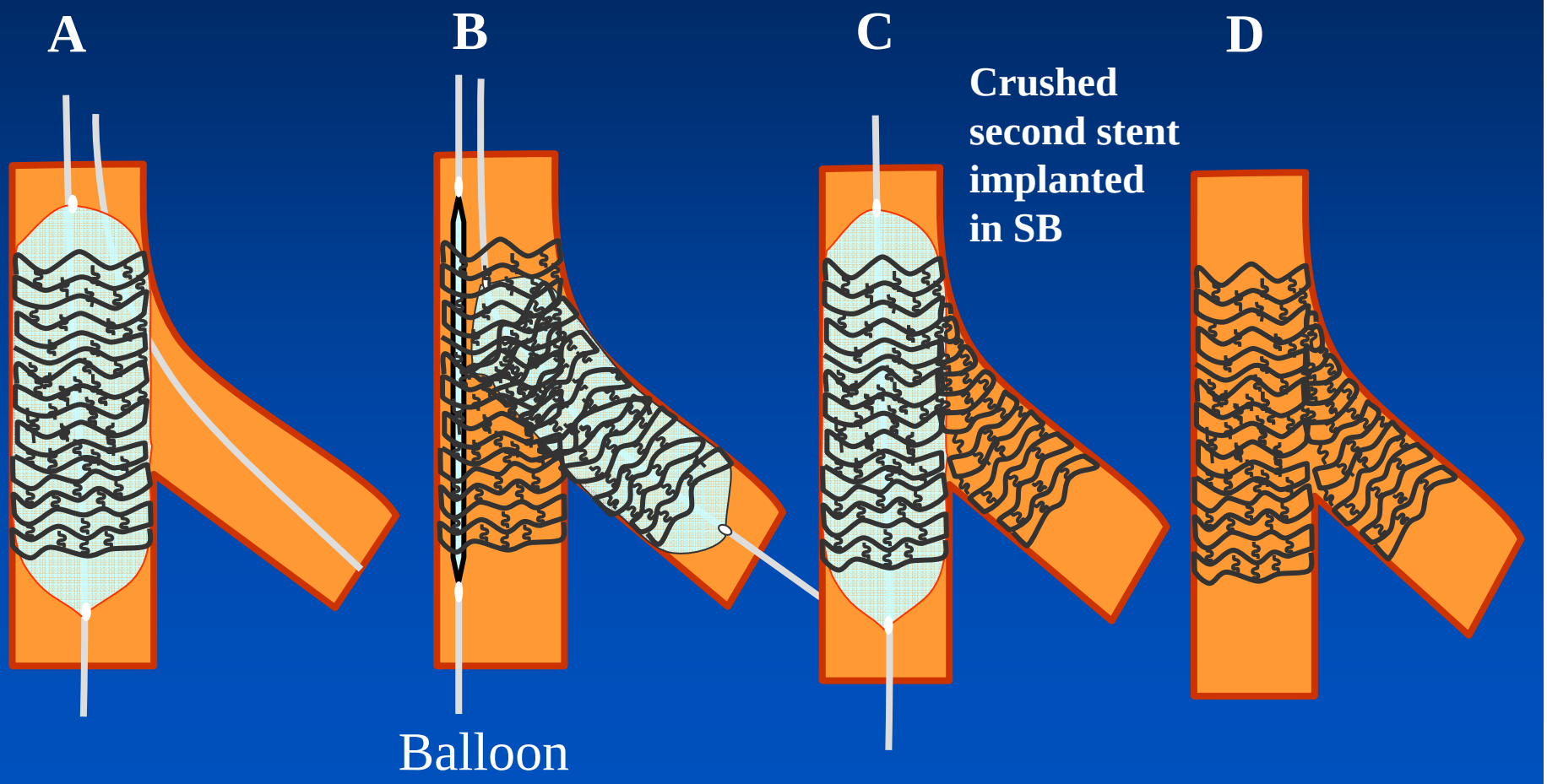
Single Center in France

- 252 patients
- Kissing balloon inflation in 97%
- Side branch stenting in 22.5%
- Angiographic success in 100% of MB and 98% in SB
- Follow-up at 7 months
  - No stent thrombosis
  - No death or MI
  - 2 TLR (2.5%)

Lefevre T et al. ACC 2005

“Internal” or “Reverse” Crush

allows provisional SB stenting with full ostial coverage



“Internal” or “Reverse” Crush

- This technique allows provisional stenting of the side-branch with a fall-back strategy that delivers coverage of the side-branch ostium without gaps.
- Final kissing balloon inflation may be difficult because a balloon should be crossed through the crushed stent segment in the side branch ostium.

Results of Simple vs. Complex

Randomized Study

Simple vs. Complex Stenting

Main vessel stenting vs. Both branch stenting using SES

	Simple (n=47)	Complex (n=44)
In-hospital outcomes		
Death	0	1 (2%)
Non-Q MI	2 (4%)	0
6-Month outcomes		
Death	1 (2%)	0
MI	0	0
TLR	1 (2%)	2 (5%)
Remote revascularization	2 (4%)	2 (4%)

Pan M, et al. Am Heart J 2004;148:857

Randomized Study

Angiographic Outcomes

	Simple (n=47)	Complex (n=44)
MLD of parent vessel, mm		
Baseline	0.74±0.50	0.76±0.38
Post-procedure	2.75±0.38	2.66±0.33
Follow-up	2.50±0.49	2.30±0.56
MLD of side branch, mm		
Baseline	0.93±0.44	0.85±0.43
Post-procedure	1.95±0.52	2.15±0.45
Follow-up	1.78±0.42	1.73±0.71
Restenosis (overall)	3 (7%)	8 (20%)
Main vessel restenosis	1 (2%)	2 (5%)
Side branch restenosis	2 (5%)	4 (10%)

All p=NS

Pan M, et al. Am Heart J 2004;148:857

Non-randomized Study

Simple vs. Complex Stenting

In Milan using SES

	Simple (n=58)	Complex (n=126)	p
Debulking			
Main branch	4 (7%)	16 (13%)	0.36
Side branch	2 (3%)	13 (10%)	0.20
Stenting technique			
Crushing		84 (67%)	
T stenting		30 (24%)	
V stenting		8 (6%)	
Culotte		4 (3%)	
Kissing balloon	25 (43%)	78 (62%)	0.03

Ge L, et al. Am J Cardiol 2005;95:757

Non-randomized Study

Procedural Outcomes

	Simple (n=58)	Complex (n=126)
Angiographic success	56 (98%)	117 (100%)
Procedural success	50 (88%)	112 (96%)
Cardiac death	0	1 (0.9%)
Q MI	0	1 (0.9%)
Non-Q MI	5 (8.8%)	10 (8.5%)
TLR	0	1 (0.8%)
TVR	0	1 (0.8%)
Intraprocedural thrombus	0	2 (1.7%)

All p=NS

Ge L, et al. Am J Cardiol 2005;95:757

Non-randomized Study

Nine-Month Outcomes

	Simple (n=37)	Complex (n=90)
Cardiac death	0	1 (1.1%)
Q MI	0	0
Non-Q MI	0	2 (2.2%)
TLR	2 (5.4%)	8 (8.9%)
TVR	2 (5.4%)	10 (11.1%)
MACE	7 (18.9%)	21 (23.3%)
Thrombosis		
Subacute	0	2 (2.0%)
Late	0	0

All p=NS

Ge L, et al. Am J Cardiol 2005;95:757

Non-randomized Study

Angiographic Outcomes

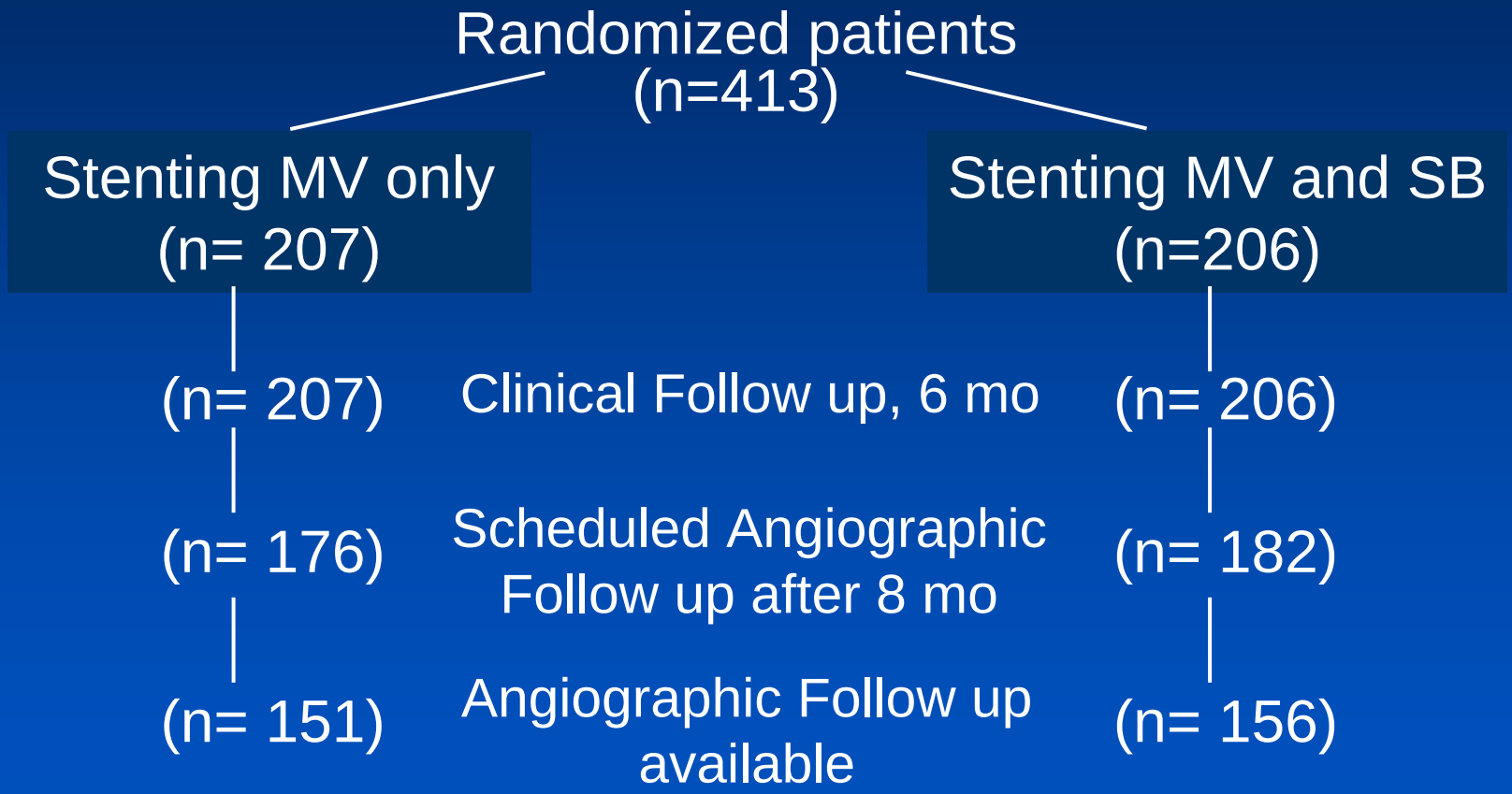
	Simple (n=37)	Complex (n=90)
MLD of parent vessel, mm		
Post-procedure	2.69±0.53 *	2.84±0.43
Follow-up	2.45±0.60	2.43±0.70
Late loss of parent vessel	0.26±0.37	0.32±0.47
MLD of side branch, mm		
Post-procedure	1.85±0.53 *	2.37±0.36
Follow-up	1.55±0.50	1.76±0.60
Late loss of side branch	0.34±0.20	0.53±0.58
Restenosis		
Main vessel restenosis	1/21 (4.8%)	5/52 (9.6%)
Side branch restenosis	1/21 (4.8%)	7/52 (13.5%)

*** p<0.05**

Ge L, et al. Am J Cardiol 2005;95:757

Nordic Bifurcation Study

Using Cypher-Select, randomized trial at 28 centers in Denmark, Sweden, Finland, Norway, and Lativa



Steigen TK et al. Circulation 2006;114: 1955-1961

Six month MACEs

Nordic Bifurcation Study

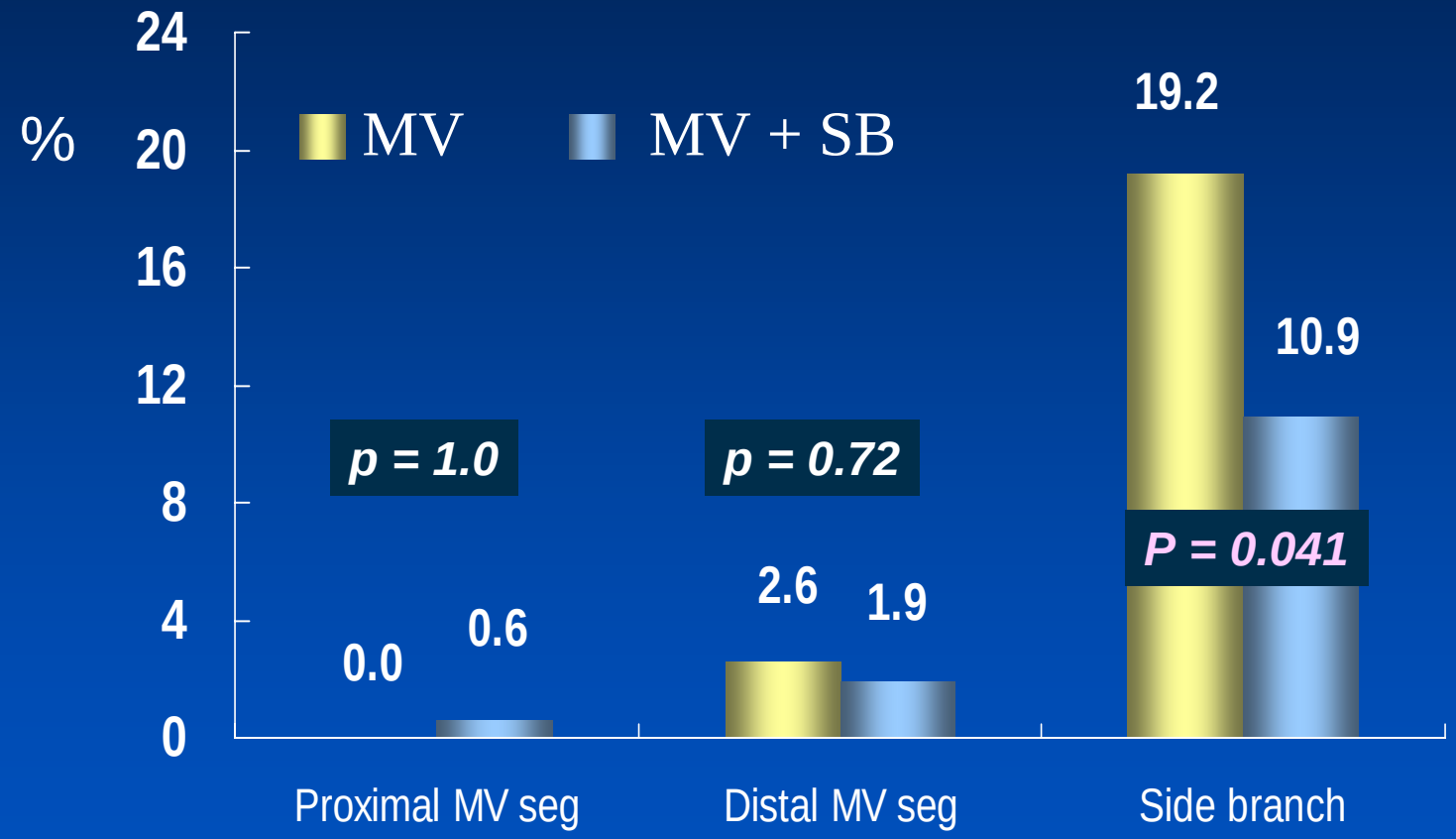
	MV (207)	MV+SB (206)	*p*
Cardiac death	2 (1.0)	2 (1.0)	1.00
Total death	2 (1.0)	3 (1.5)	0.61
MI	0 (0.0)	1 (0.5)	0.31
TVR	4 (1.9)	4 (1.9)	0.99
Stent thrombosis	1 (0.5)	0 (0.0)	0.31
TLR	4 (1.9)	2 (1.0)	0.36

*** MV = main vessel, SB = side branch, Values in n (%)**

Steigen TK et al. Circulation 2006;114: 1955-1961

Rate of stenosis at 8-months

Nordic Bifurcation Study



Steigen TK et al. Circulation 2006;114: 1955-1961

The Clinical Outcomes of PCI of bifurcation lesions with SES : Arterial Revascularization Therapies Study part II (ARTS II)

Non-bifurcation (n=283)	Vs.	Bifurcation (n=324)			
		True bifurcation	Partial bifurcation	One stent	Two stents
		210	114	263	61

Tsuchida K et al. *EHJ* 2007

One-year Outcomes in ART II

	One stent (n=263)	Two stent (n = 61)	*p*
CVA	2 (0.8)	1 (1.6)	0.47
Death	3 (1.1)	0 (0.0)	1.00
Nonfatal MI	16 (6.1)	3 (4.9)	1.00
PCI	22 (8.4)	3 (4.9)	0.32
CABG	5 (1.9)	0 (0.0)	0.59
MACCE	37 (14.1)	6 (9.8)	0.53
Stent thrombosis	4 (1.5)	1 (1.6)	1.00

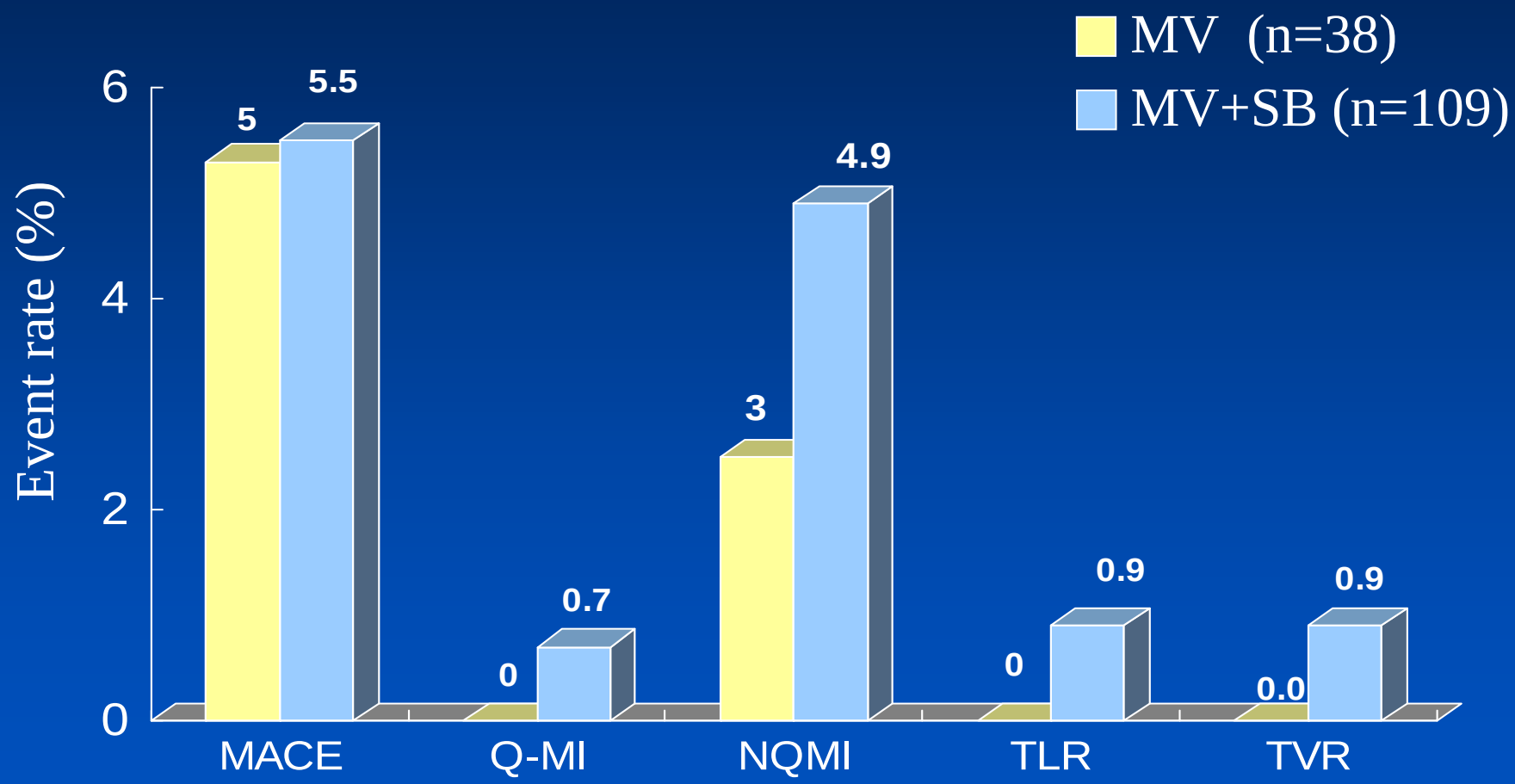
* MACCE = major adverse cardiac and cerebrovascular event

** Values in n (%)

Tsuchida K et al. EHJ 2007

PCI with PES in Bifurcation

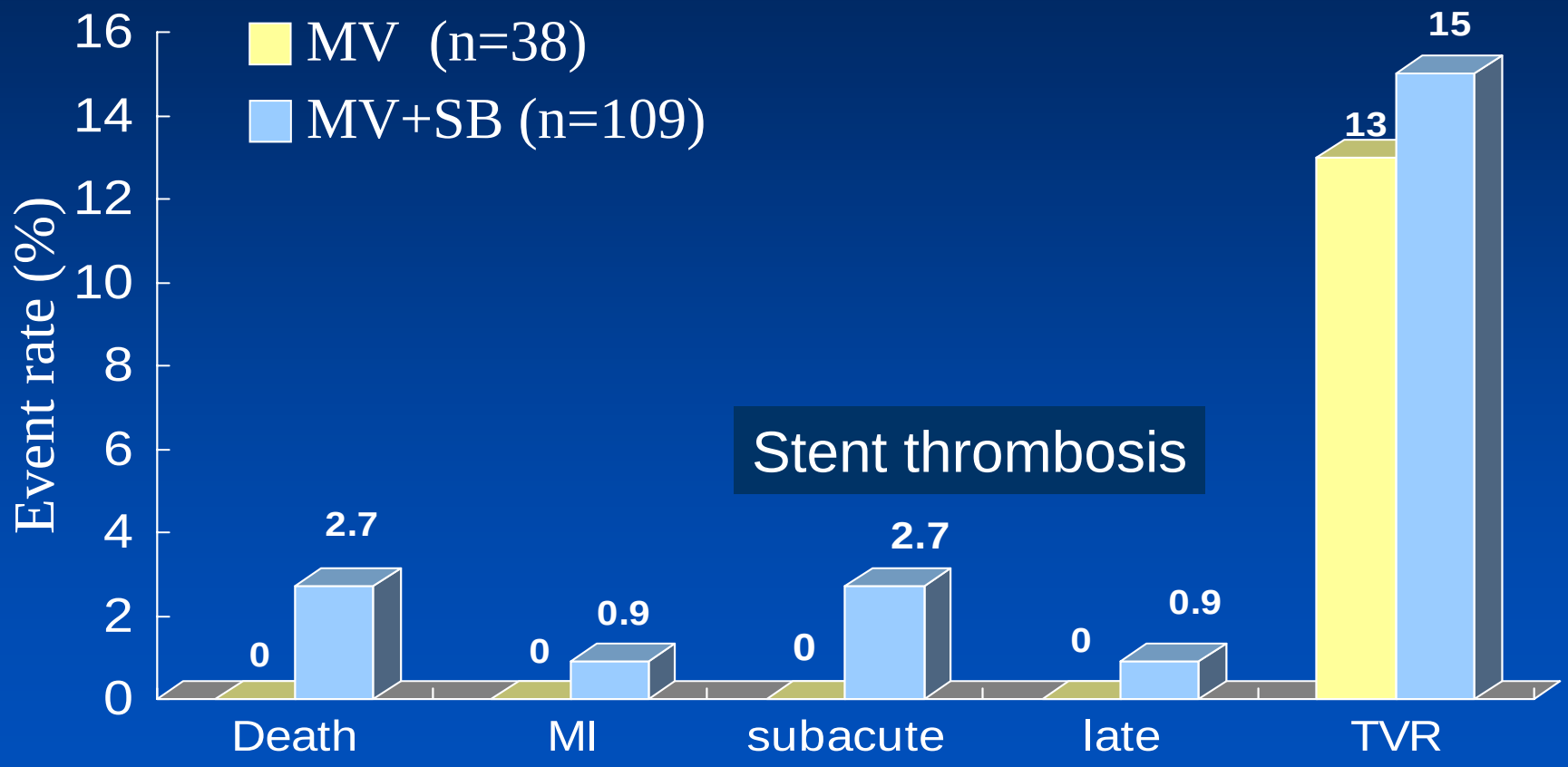
In-Hospital MACE



Di Mario et al. CCI 2007;69: 416-424

PCI with PES in Bifurcation

One-Year MACE



Di Mario et al. CCI 2007;69: 416-424

Non-randomized Study in AMC

Simple Strategy in 61%

Patients (n = 213) with de novo bifurcation lesions except LM (n =213)
[Jan 2003 ~ Dec 2004]

Complex Stenting
[Group A, n=60]

Simple stenting
[Group B, n=153]

Eligible Patients (n=167)
[Jan 2003 ~ Jul 2004]

Clinical (n=159) and Angiographic (n=112) Follow-up

Non-randomized Study in AMC

Baseline QCA Characteristics

	Complex (N=60)	Simple (N=153)	*P*
Reference diameter, mm			
MB	2.86 ± 0.43	2.92 ± 0.44	0.44
SB	2.35 ± 0.39	2.30 ± 0.42	0.49
MLD, mm			
MB	0.93 ± 0.52	0.87 ± 0.55	0.51
SB	0.91 ± 0.32	1.23 ± 0.72	0.004
Diameter stenosis, %			
MB	66.9 ± 16.8	70.8 ± 17.2	0.20
SB	56.9 ± 13.3	52.1 ± 27.4	0.52
Lesion length, mm			
MB	29.6 ± 16.6	26.0 ± 13.7	0.16
SB	15.3 ± 9.7	7.4 ± 4.4	<0.001

MB= Main Branch; SB= Side Branch

Non-randomized Study in AMC

Procedural Findings

	Complex (N=60)	Simple (N=153)	*P*
MB			
Balloon size, mm	3.84 ± 0.39	3.66 ± 0.51	0.09
Balloon/artery ratio	1.23 ± 0.23	1.20 ± 0.16	0.37
SB			
Balloon size, mm	3.07 ± 0.43	2.98 ± 0.32	0.42
Balloon/artery ratio	1.21 ± 0.26	1.19 ± 0.18	0.40
Success Rate*, %	99.2	94.3	0.75
Kissing balloon %	86.7	78.5	0.36

Non-randomized Study in AMC

QCA after Procedure

	Complex Stenting (N=60)	Simple Stenting (N=153)	*P*
MLD, mm			
MB	2.69 ± 0.36	2.73 ± 0.43	0.51
SB	2.27 ± 0.38	1.55 ± 0.53	<0.01
Diameter stenosis, %			
MB	3.9 ± 13.0	5.5 ± 12.6	0.48
SB	14.8 ± 15.6	31.5 ± 21.0	0.01
Acute gain, mm			
MB	1.73 ± 0.48	1.87 ± 0.58	0.18
SB	1.33 ± 0.43	0.78 ± 0.59	<0.01

Non-randomized Study in AMC

In-Hospital Outcomes

	Complex Stenting	Simple Stenting	P
Patients	60	153	
Cardiac death	0	0	…
MI			
Q MI	0	0	…
Non-Q MI	4 (6.7%)	6 (3.9%)	0.47
Stent thrombosis	0	0	…
TLR	0	0	1.0

Non-randomized Study in AMC

QCA at 6 Months

	Complex (N=49)	Simple (N=114)	*P*
Angiographic F/U rate	81.7%	74.5%	0.32
MLD, mm			
MB	2.25 ± 0.76	2.53 ± 0.60	0.71
SB	2.02 ± 0.68	1.52 ± 0.48	0.20
Late loss, mm			
MB	0.17 ± 0.67	0.09 ± 0.56	0.50
SB	0.36 ± 0.62	0.01 ± 0.50	0.03
Restenosis			
MB	7 (14.2%)	6 (5.3%)	0.40
SB	9 (18.4%)	2 (1.7%)	0.03
Overall	13 (26.5%)	6 (5.7%)	0.09

Non-randomized Study in AMC

Clinical Outcomes at 9 Months

	Complex Stenting (n=58)	Simple Stenting (n=145)	P
Cardiac death	0	0	...
MI	0	0	...
Stent thrombosis	0	0	...
TLR	4 (6.9%)	3 (2.1%)	0.46
MACE	4 (6.9%)	5 (3.4%)	0.43

Simple vs. Complex Stenting

- Simple stenting technique crossing the side branch should be preferred in bifurcation lesions with non-diseased side branch.
- Final kissing balloon dilatation improves immediate outcome of the side branch.
- Provisional T stenting can be used when the side branch narrowing was deteriorated after stenting in the main branch.

Simple Stenting vs. Complex Stenting

Make the procedure simple if possible !

Complex Stenting Techniques

Inevitable in certain cases..

Golden Rules of Bifurcation Stenting with DES

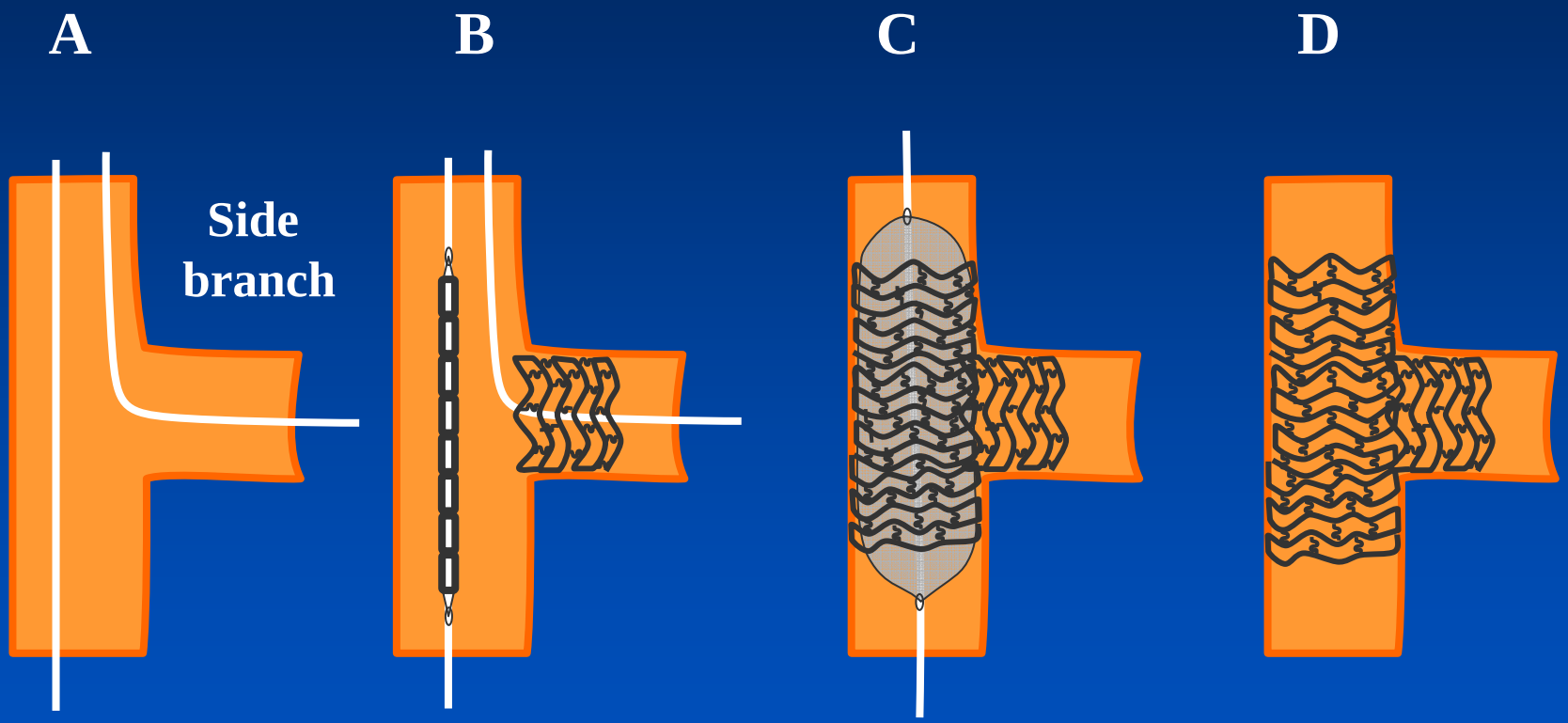
1. **Complete lesion coverage**
   - especially at the side branch ostium
2. **Optimal stent apposition**
   - all the stented segments in the main and side branch

Complex Stenting Techniques

that can fulfill two rules…

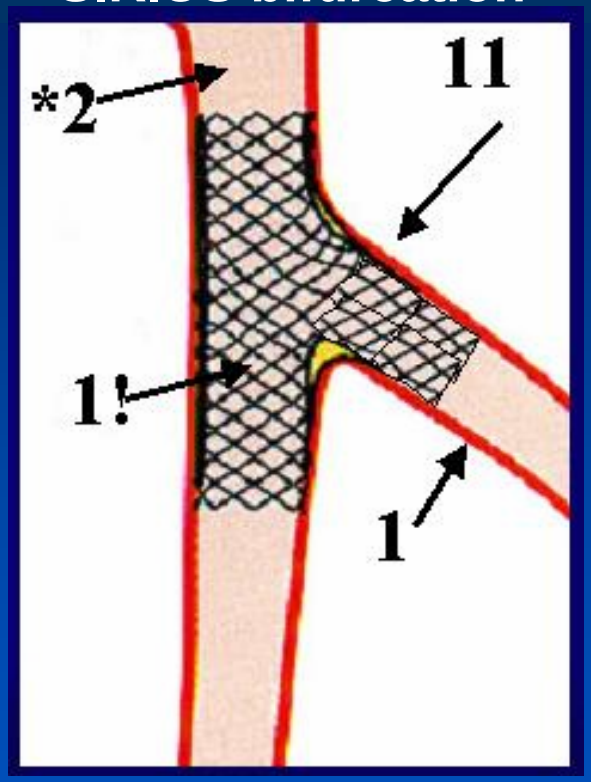
1. Modified T stenting
2. Crush technique
3. Y stenting
4. V stenting
5. Kissing stenting

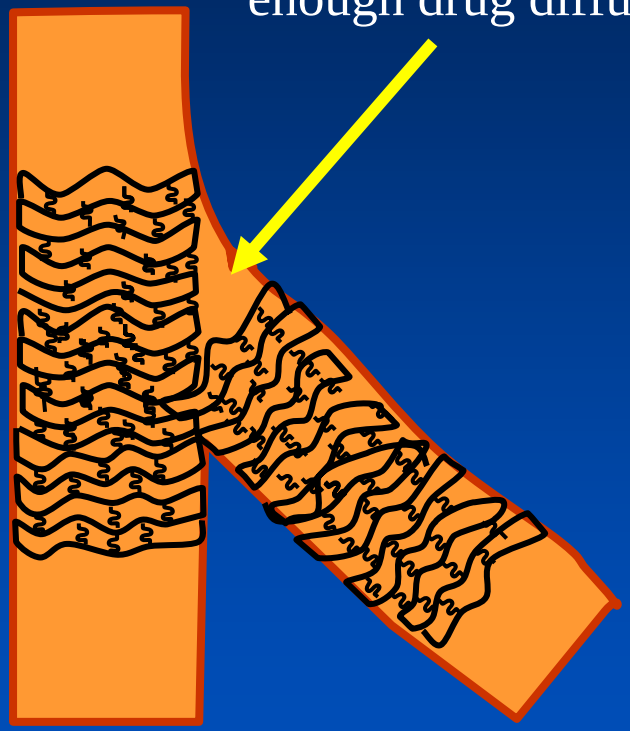
Modified T Stenting



Limitation of Modified T Stenting

Restenosis site of T stenting in SIRIUS bifurcation

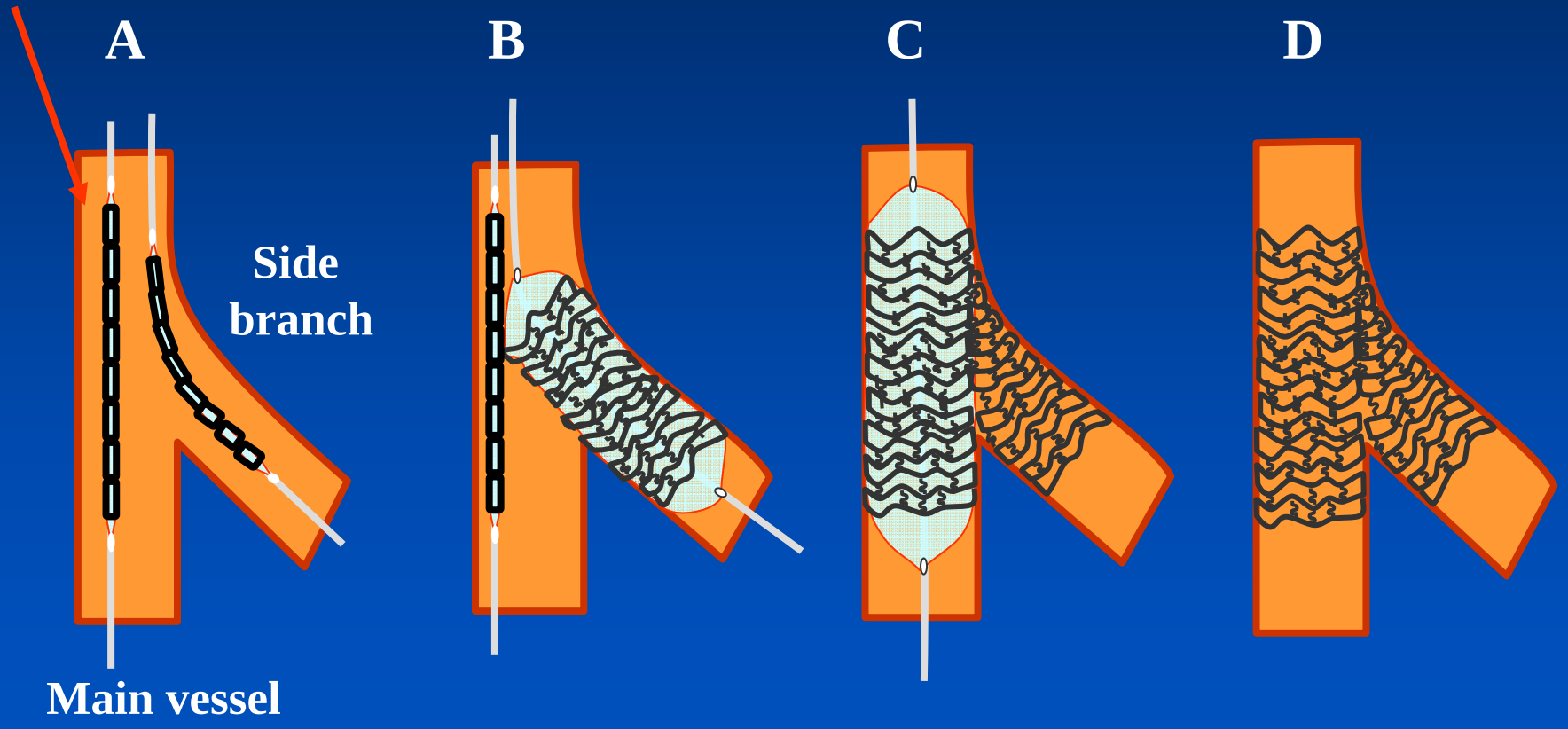




To prevent potential gap at the ostial side branch, the first stent should cover the entire surface of the side branch.

Crush Technique

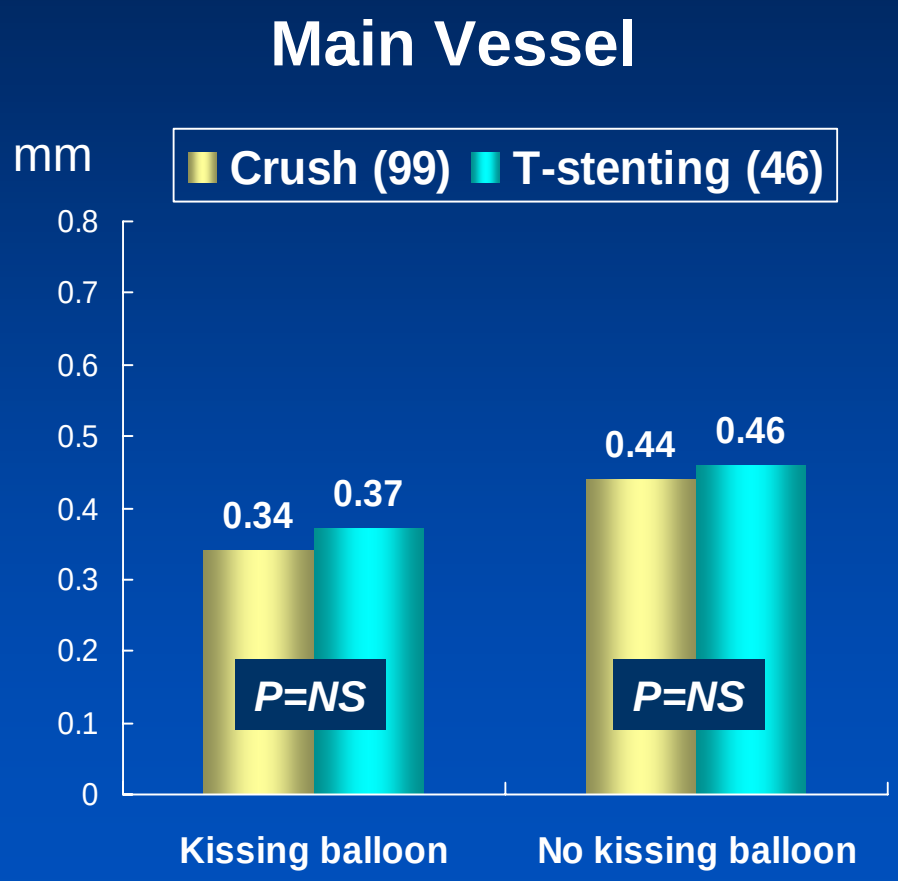
Proximal location of the stent in the main vessel

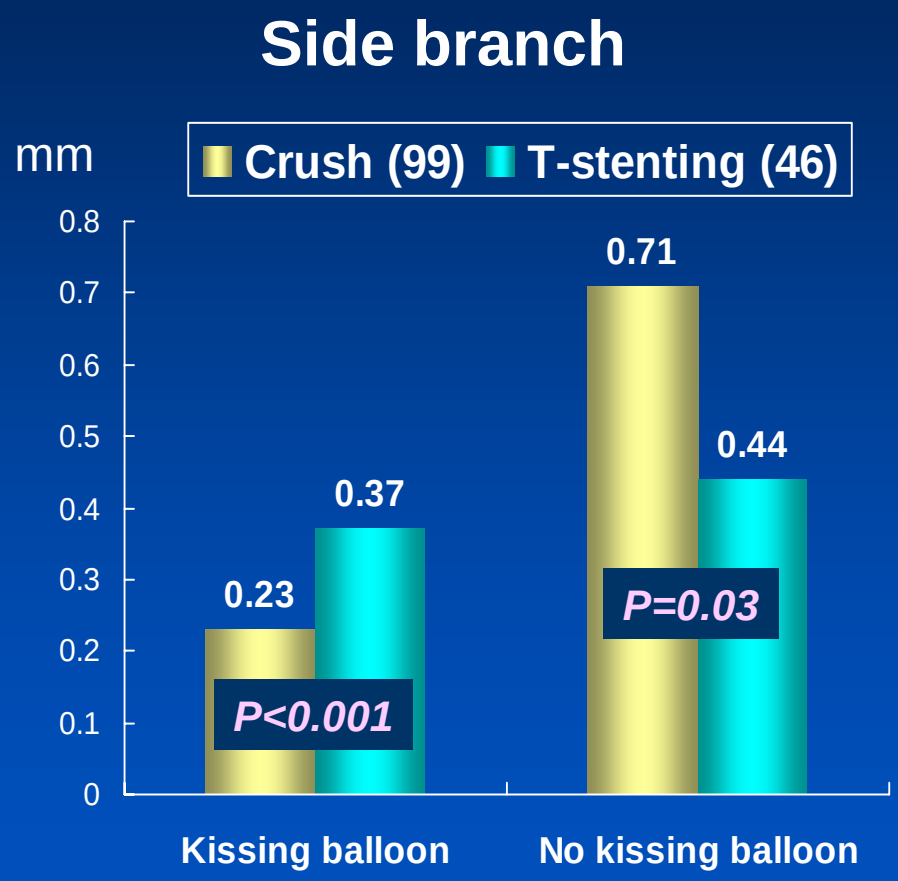


Non-randomized Registry in Milan

Crush vs. T-stenting

Late Loss





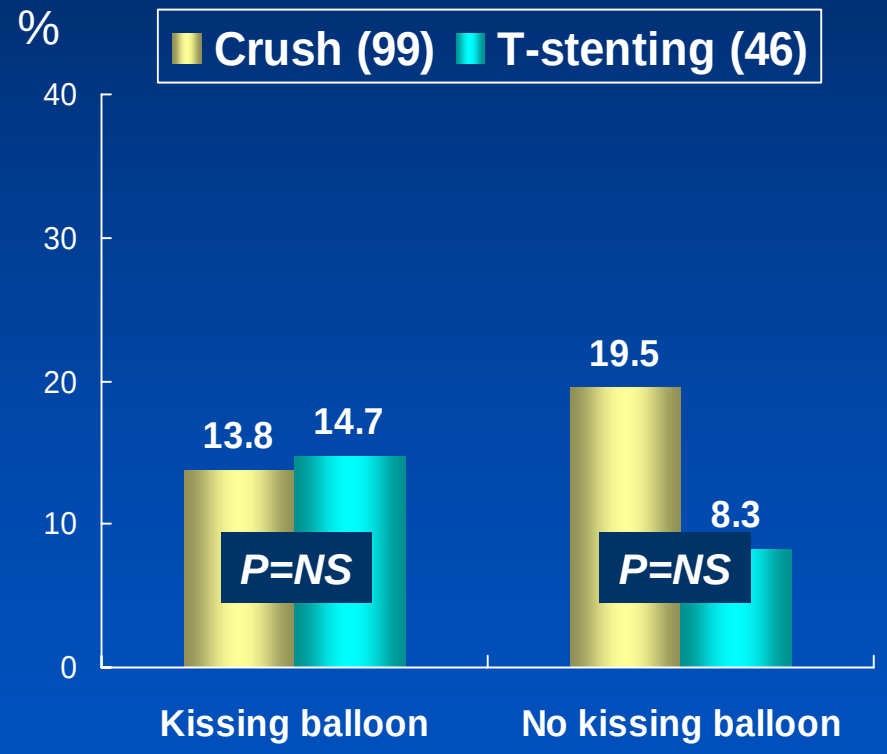
Ge L, et al. Heart 2006;92:371

Non-randomized Registry in Milan

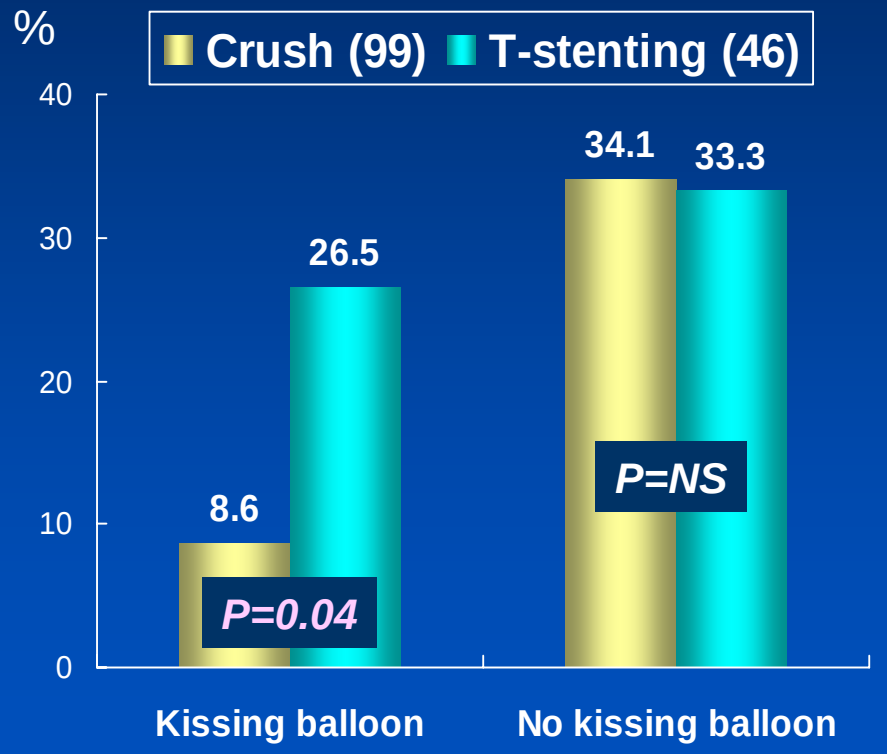
Crush vs. T-stenting

Restenosis Rate

Main Vessel



Side branch



Ge L, et al. Heart 2006;92:371

Non-randomized Registry in Milan

Crush vs. T-stenting

Clinical Outcomes at 1 Year

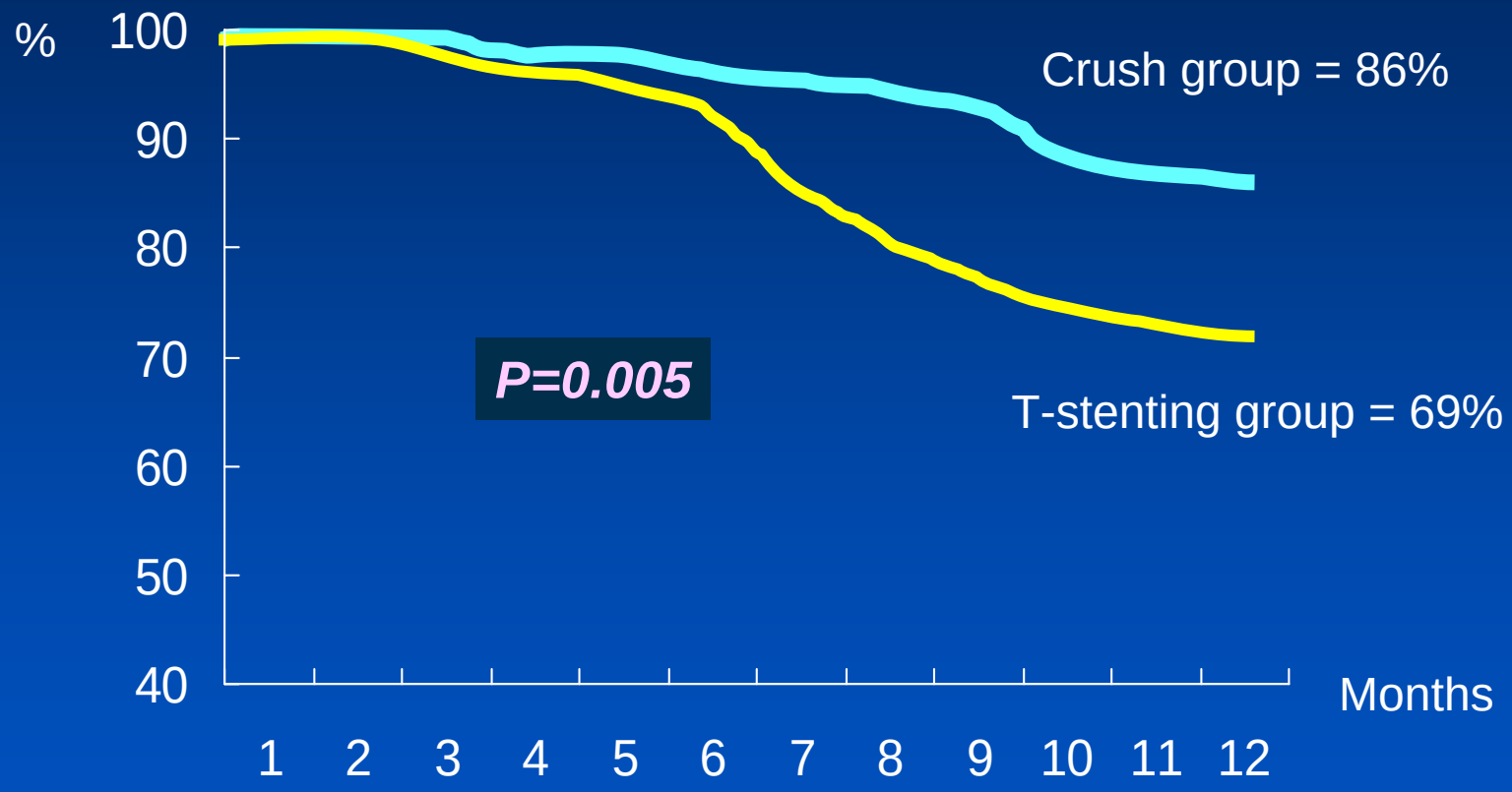
	Crush (n=121)	T-stent (n=61)	P value
Cardiac death	1 (0.8%)	0	0.73
AMI	12 (9.9%)	2 (3.3%)	0.20
Q-MI	2 (1.7%)	0	0.80
Non-Q-MI	10 (8.3%)	2 (3.3%)	0.34
TLR	17 (14.0%)	19 (31.1%)	0.01
TVR	20 (16.5%)	20 (32.8%)	0.02
MACE	32 (26.4%)	22 (36.1%)	0.23

Ge L, et al. Heart 2006;92:371

Non-randomized Registry in Milan

Crush vs. T-stenting

TLR-Free Survival at 1 Year



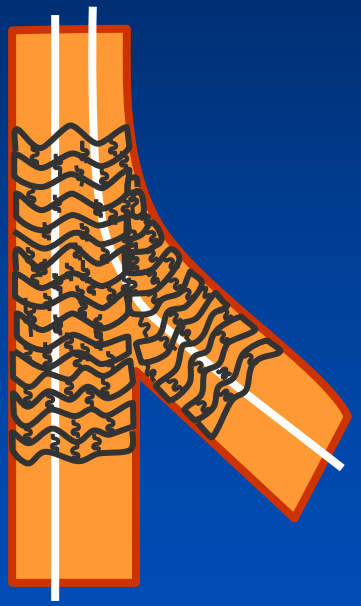
Ge L et al. Heart 2006;92:371

One More Step of Crush Technique

Final Kissing Balloon Dilatation

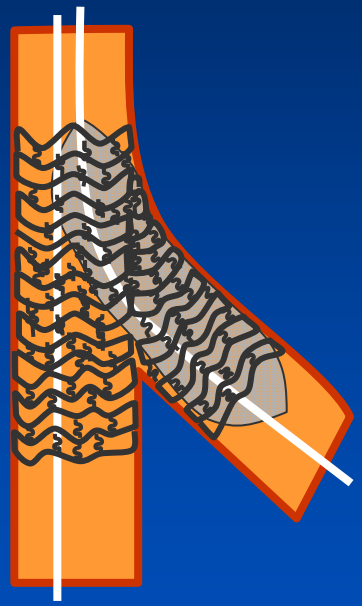
for side branch re-opening and stent optimization

E



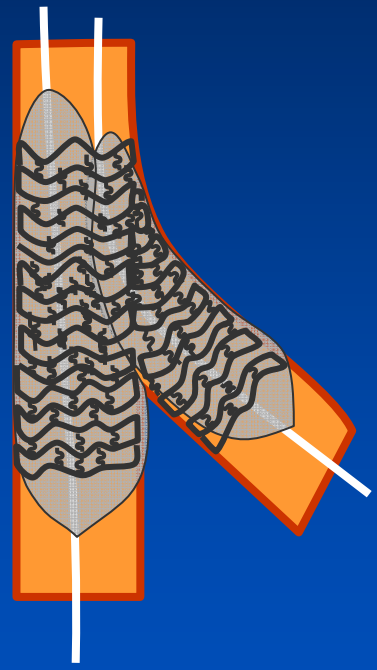
Re-advancement of wire into the side branch

F



Opening of the side branch ostium

G



Final kissing balloon inflation

Advantages of Final Kissing Balloon Inflation

- Fully expand the stent in the side-branch ostium.
- Wide the gaps between stent struts covering the side branch.
- Eliminate main branch distortion.

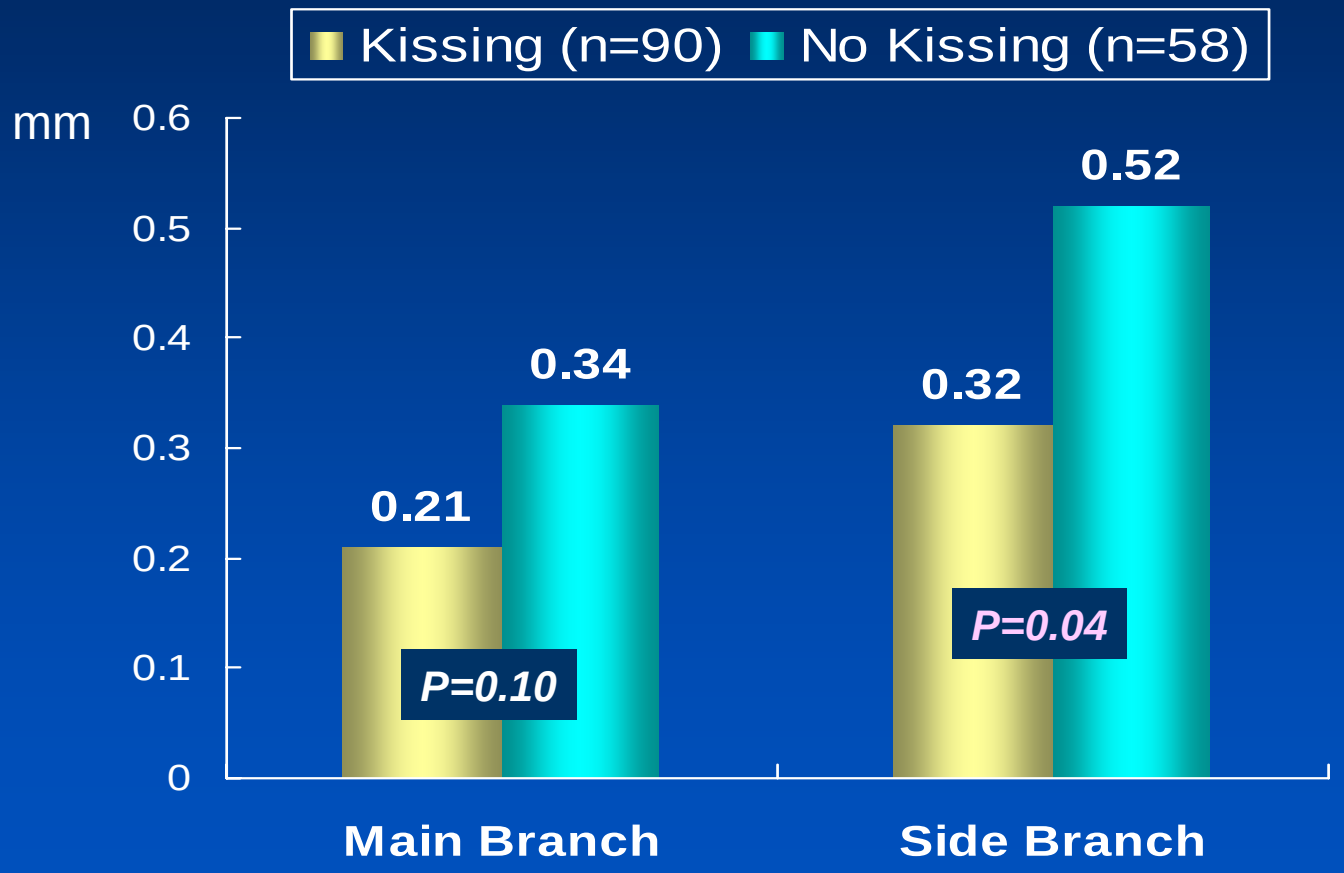
Tips of Final Kissing Ballooning

- Guiding catheter with good back-up support
- Use of hydrophilic wire
- Low profile balloon
- Crush the side branch stent completely by high pressure balloon dilatation of the main vessel stent before wire re-crossing
- Stepwise size increment of balloon from 1.5~2.0mm
- Postdilation of the main vessel with a balloon of narrower diameter than the deploying balloon caused main-branch stent distortion.

Non-randomized Registry in Milan

Final Kissing vs. No Kissing

Late Loss

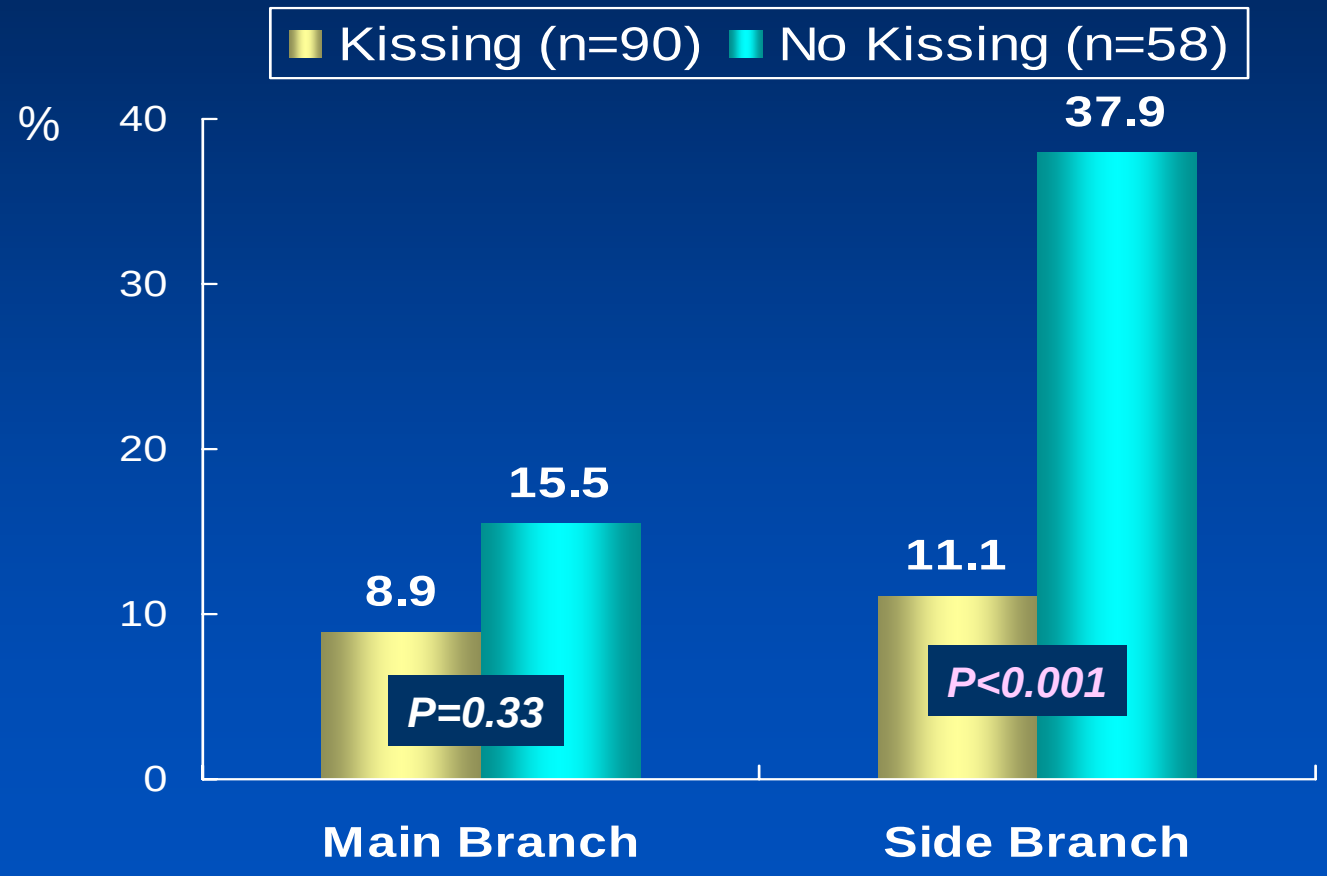


Ge L, et al. J Am Coll Cardiol 2005;46:613

Non-randomized Registry in Milan

Final Kissing vs. No Kissing

Restenosis Rate



Ge L, et al. J Am Coll Cardiol 2005;46:613

Non-randomized Registry in Milan

Final Kissing vs. No Kissing

Clinical Outcomes at 9 Months

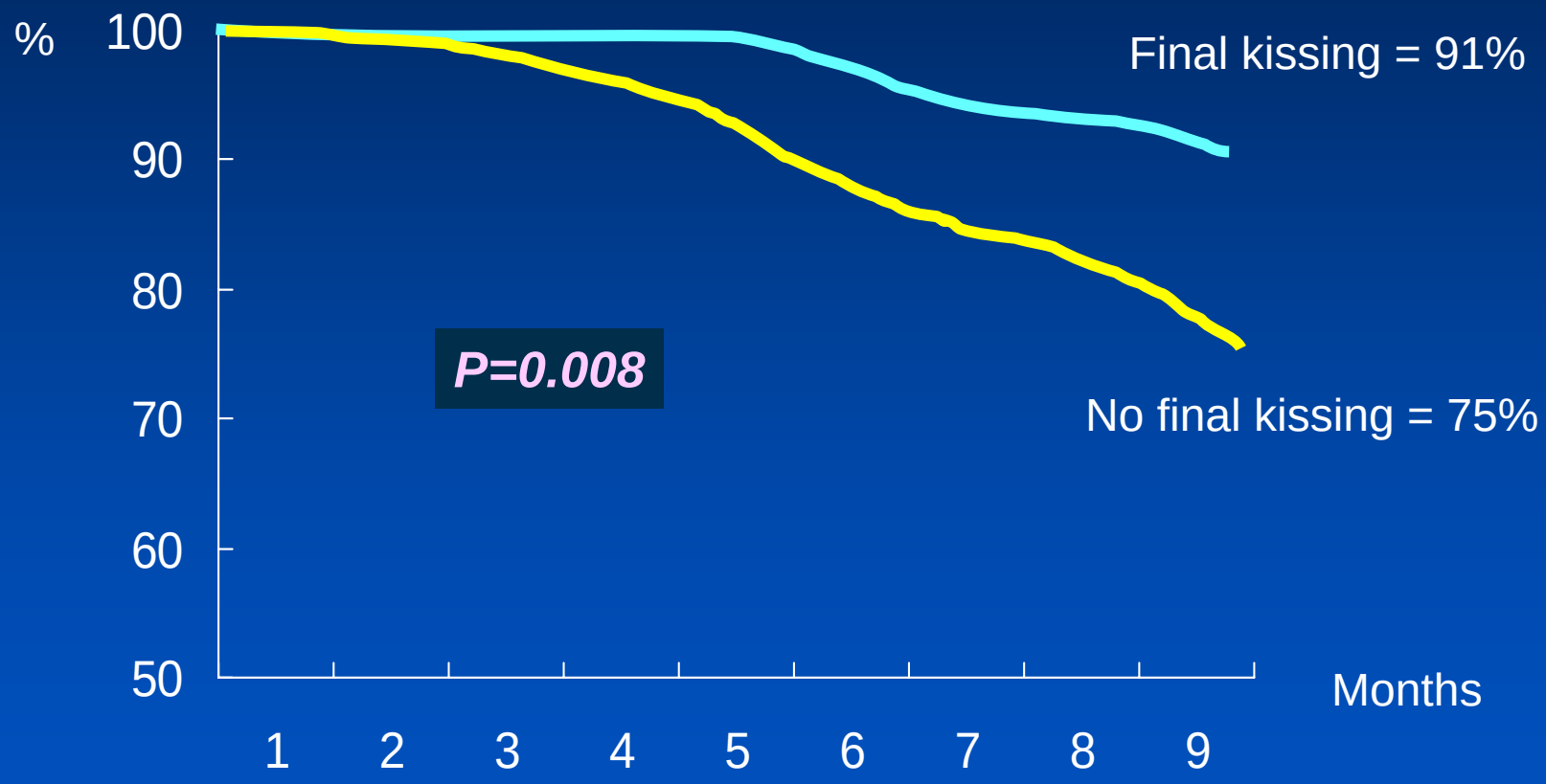
	Kissing (n=116)	No kissing (n=65)	P value
Cardiac death	2 (1.7%)	0	0.54
Q-MI	2 (1.7%)	4 (6.2%)	0.28
Non-Q-MI	10 (8.6%)	5 (7.7%)	0.95
TLR	11 (9.5%)	16 (24.6%)	0.008
TVR	12 (10.3%)	19 (29.2%)	0.002
MACE	23 (19.8%)	25 (38.5%)	0.008

Ge L, et al. J Am Coll Cardiol 2005;46:613

Non-randomized Registry in Milan

Final Kissing vs. No Kissing

TLR-Free Survival at 1 Year



Ge L et al. J Am Coll Cardiol 2005;46:613

Cypher for Bifurcation

Multicenter Registry in Asia

	Y-stenting	Single stenting	Crush-KB (+)	Crush-KB (-)
No of patients	102	70	75	45
Procedural success (%)	100	100	100	100
MACE at 30 days (%)	0	0	0	0
Restenosis rate (%)	**4.9**	**21.4**	**4.0**	**24.5**
Parent vessel	0	1.4	0	2.2
Side branch	4.9	21.4	4.0	22.2
TLR (%)	4.9	22.8	6.7	24.4

Nakamura S et al, ACC 2005

Optimal stent expansion is very important !

Post-procedural IVUS after Crush

Final kissing balloon inflation in 92%

	Main vessel (n=5)	Side branch (n=5)	p
Reference EEM CSA, mm^2	13.9	8.6	
Reference lumen CSA, mm^2	9.0	5.9	
Stent CSA, mm^2	6.7±1.7	4.04±1.4	<0.001
Stent area <4 mm^2 (%)	8	20	
Stent area < 5 mm^2 (%)	44	76	
Stent expansion (%) (Stent CSA/reference lumen CSA)	89.3±18.4	78.0±16.1	0.01

Costa RA et al, J Am Coll Cardiol 2005;46:599

Crush and Kissing Balloon with Cypher in MATRIX Registry

108 patients, April 2003 ~ Nov. 2003

In- hospital events

- No death, MI, CABG, urgent TLR

30- day outcome

- No death
- Stent thrombosis 1.9 % (2/108)

Intermediate- term clinical outcome

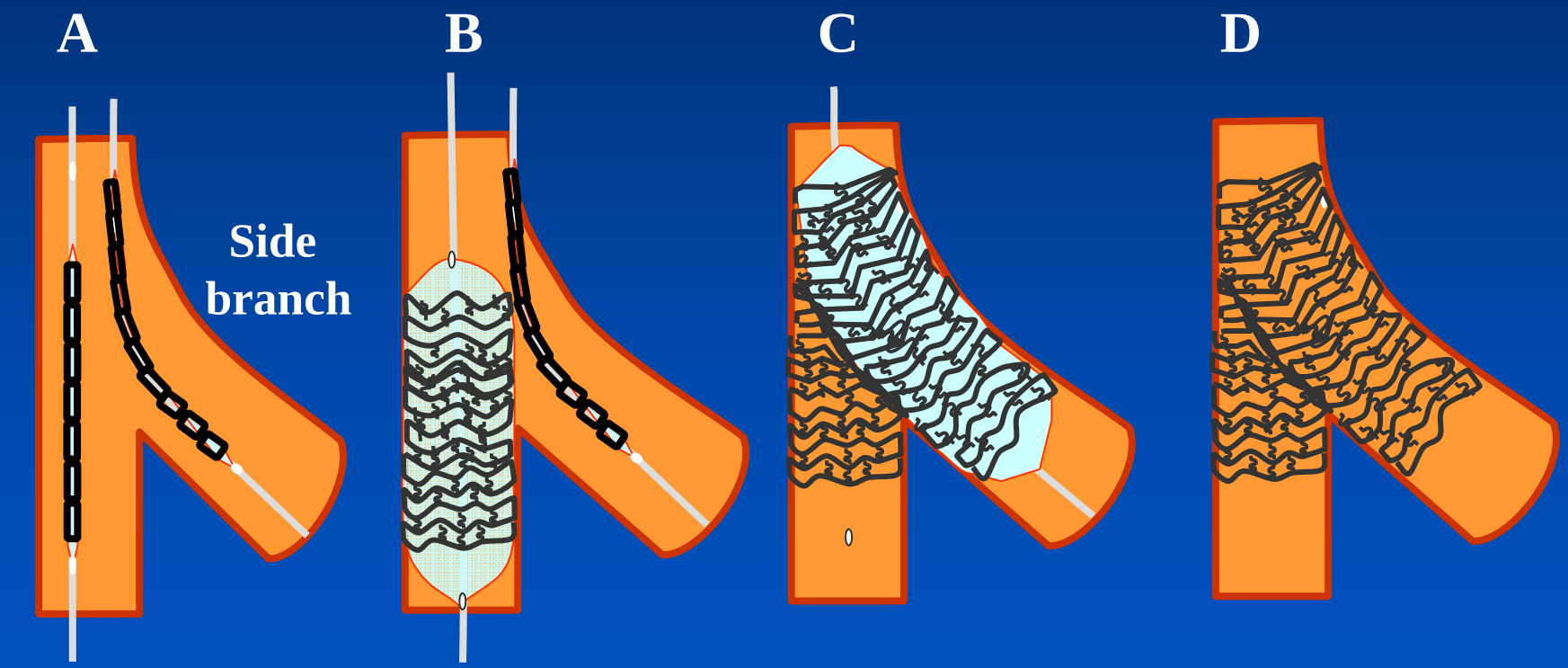
- No death, MI
- TLR 12 % (9/108)

I Moussa , ACC 2004

Inverted Crush

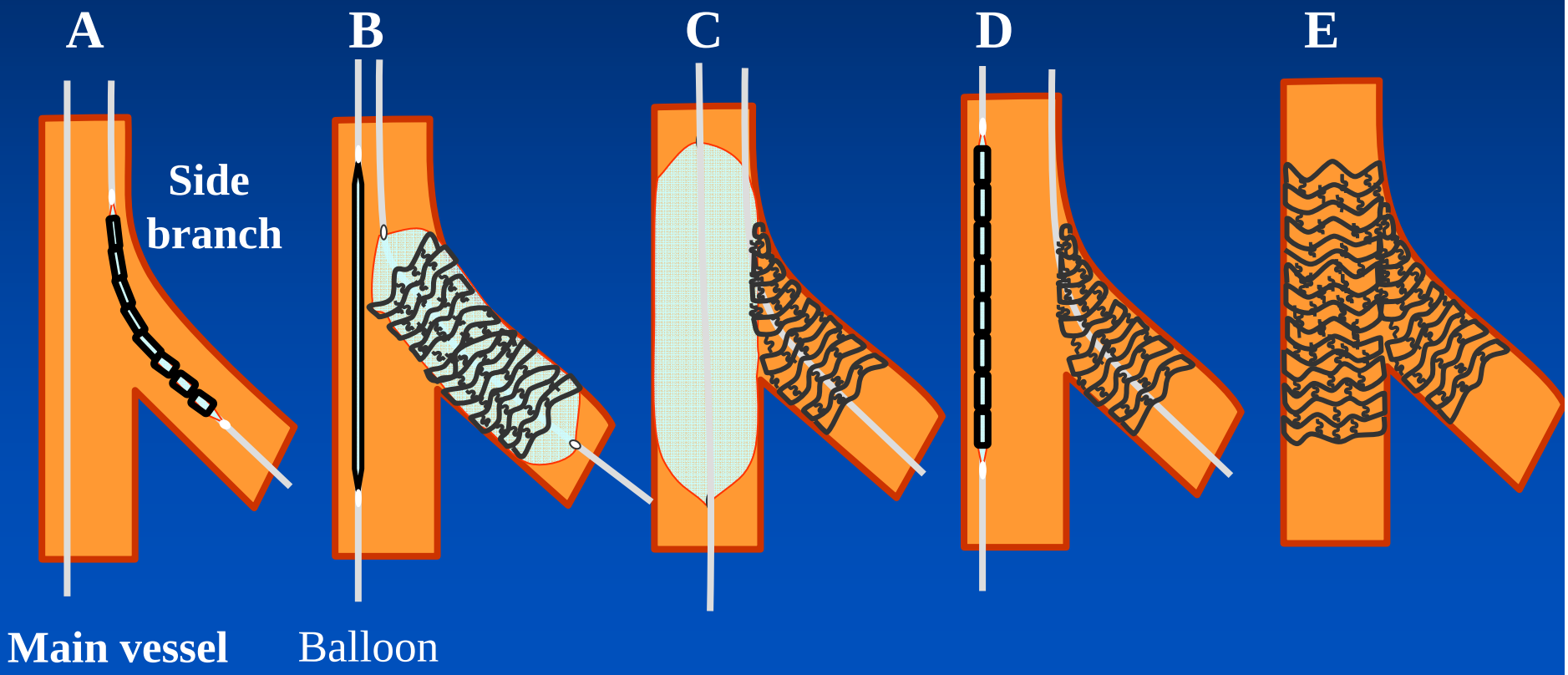
Modification in big side branch

Proximal location of the stent in the side branch



Mini-Crush Technique

1. Minor retraction of side br. Stent (1-2 mm)
2. Crushing with a balloon instead of main vessel stent
3. Final kissing ballooning

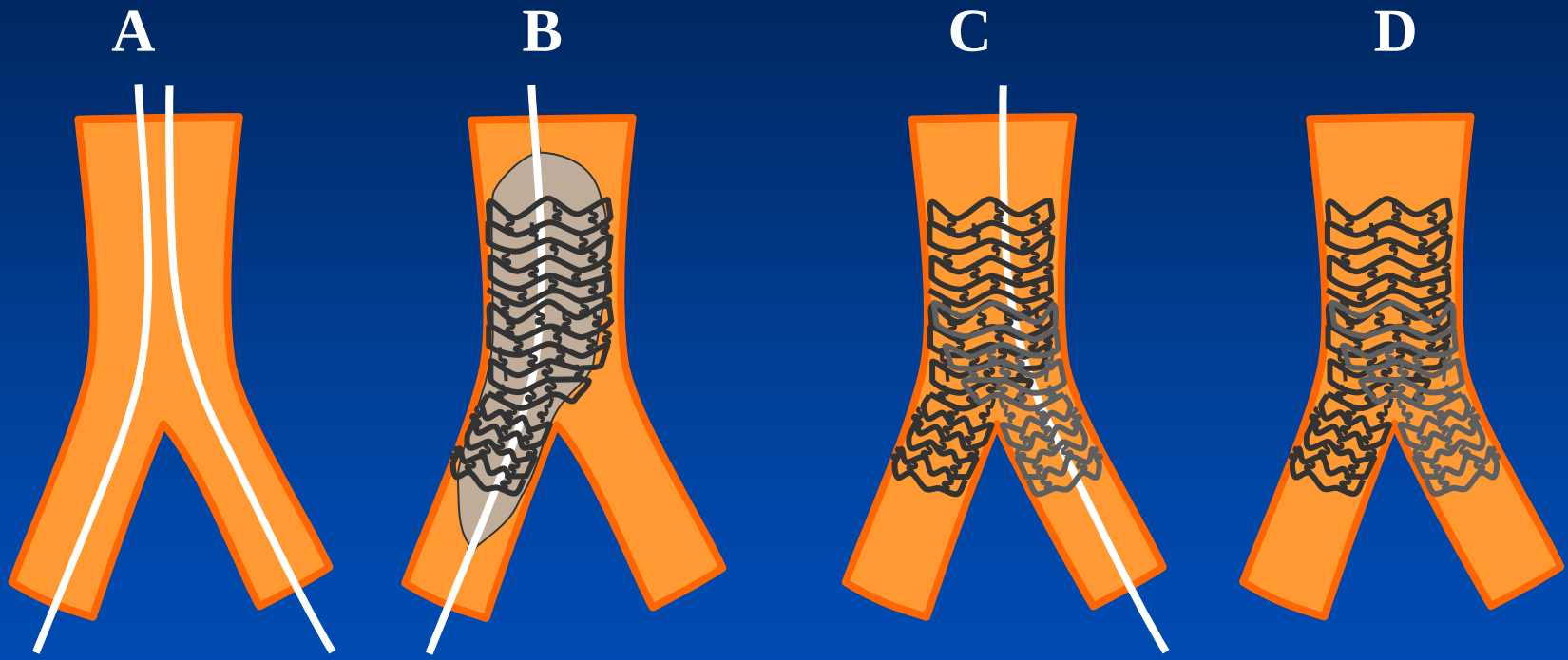


Comparison of Mini-crushing
with other techniques

	RVD, mm		Technque	Restenosis rate		
	Main	Side		Total (%)	Main (%)	Side (%)
Colombo	2.60±0.40	2.10±0.30	Provisional T-, V- and Crush	19 27.5	4.8 5.7	14.2 21.8
Tanabe.	2.64±N/A	1.99±N/A	T, Culotte, V, Crush	22.7	9.1	13.6
Ge et al.	2.81±0.58	2.44±0.58	Crush + kissing Crush - kissing	20 53.4	8.9 15.5	11.1 37.9
Galassi AR et al.	2.68±0.48	2.80±0.34	Mini-crush	14.2	12.2	2.0

Galassi AR et al, CCI 2007 ahead of printing

Y Stenting



- Complete lesion coverage
- Too much stent overlap at the proximal segment

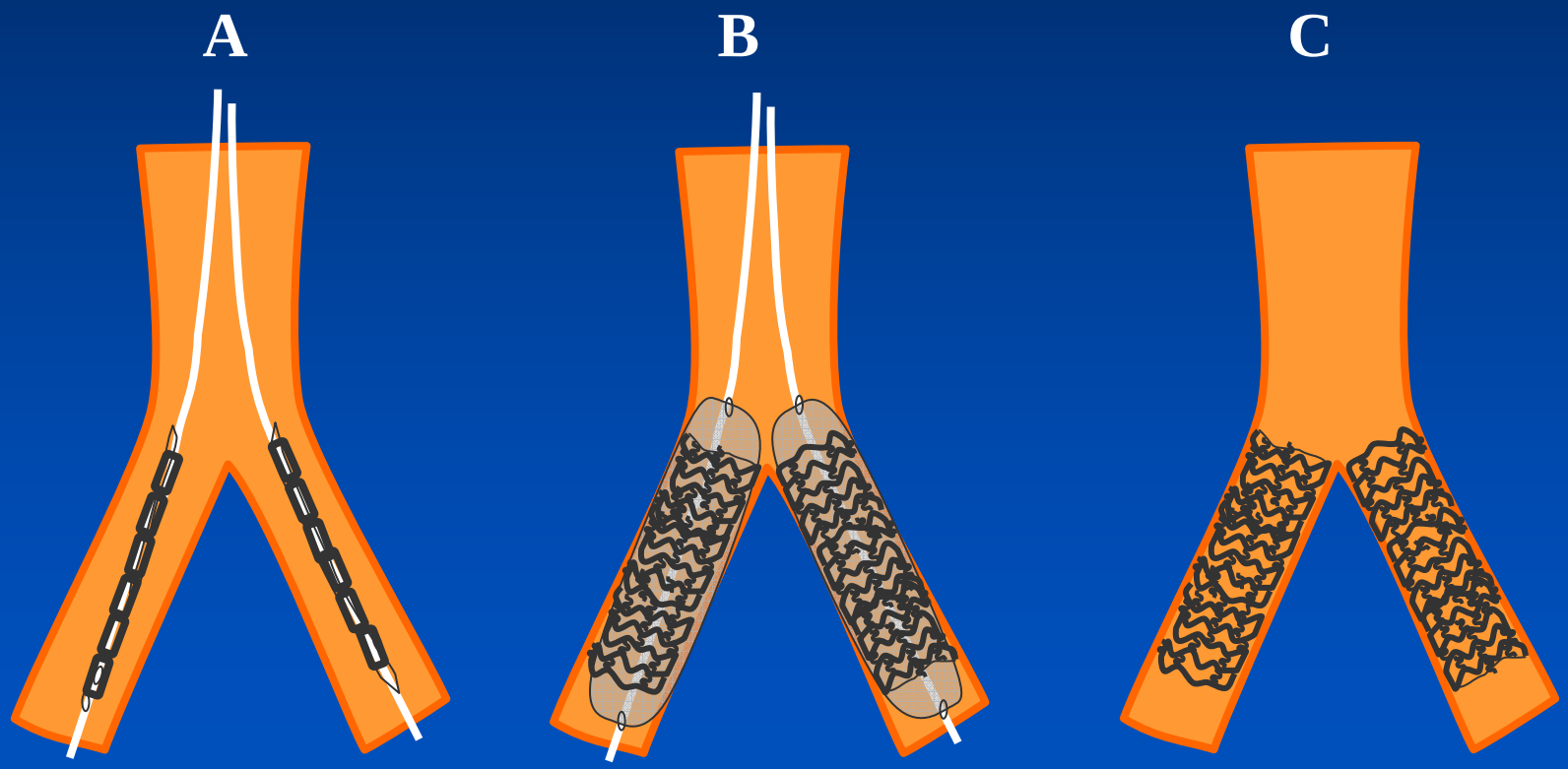
Cypher for Bifurcation
Multicenter Registry in Asia

	Y-stenting	Single stenting	Crush-KB (+)	Crush-KB (-)
No of patients	102	70	75	45
Procedural success (%)	100	100	100	100
MACE at 30 days (%)	0	0	0	0
Restenosis rate (%)	**4.9**	**21.4**	**4.0**	**24.5**
Parent vessel	0	1.4	0	2.2
Side branch	4.9	21.4	4.0	22.2
TLR (%)	4.9	22.8	6.7	24.4

Nakamura S et al, ACC 2005

V Stenting

- **Bifurcation without stenosis proximal to the bifurcation**



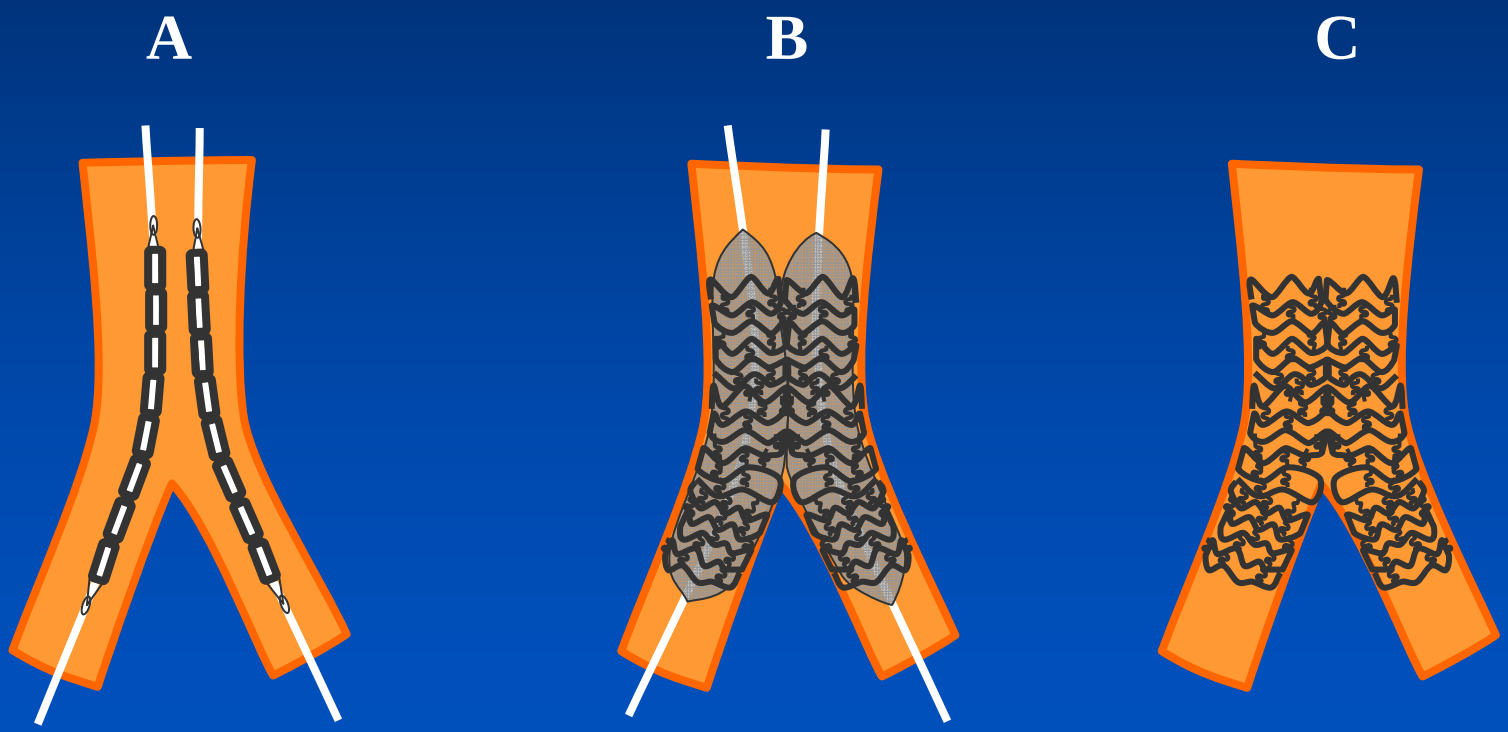
Crushing vs. V-stenting with Cypher
In Scripps Clinic

	Crushing	V	p
No of patients	111	58	
Final kissing, %	45	100	
In-hospital MACE	0	0	NS
TLR at 5 months	15.8	11.8	NS

Sawhney N et al, ACC 2005

Kissing Stenting

- Large proximal reference
- Bifurcation with stenosis proximal to the bifurcation



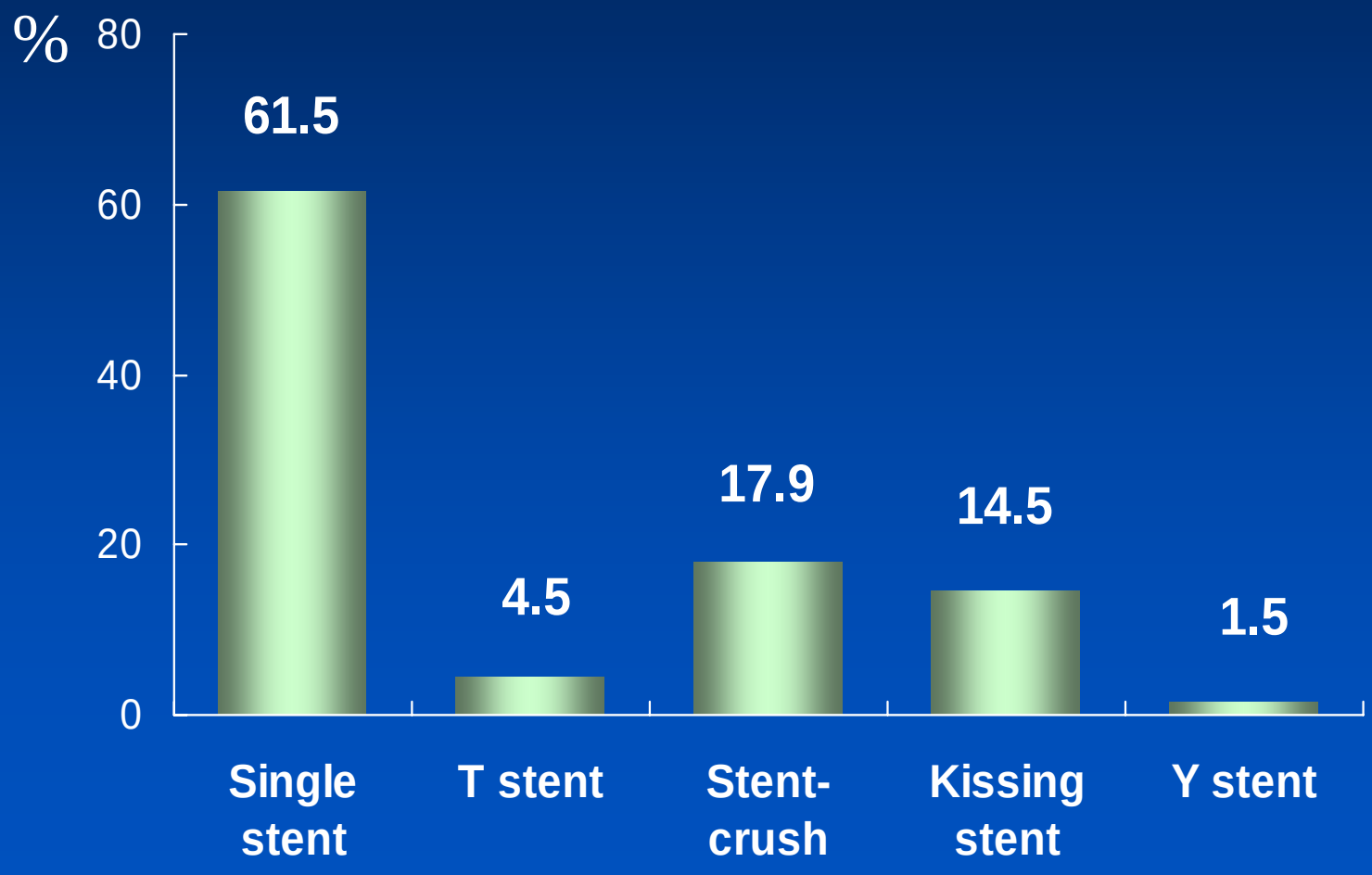
Kissing Stenting with SES

	N=116
Average F/U duration (months)	9 ± 2
Death (%)	2
MI (%)	4
Q-wave	1
Non-Q	3
Late stent thrombosis	0
TLR (%)	4
Main vessel only	1
Side branch only	3
Freedom from MACE (%)	91

Sharma SK. Cathet Cardiovasc Interv 2005;65:10

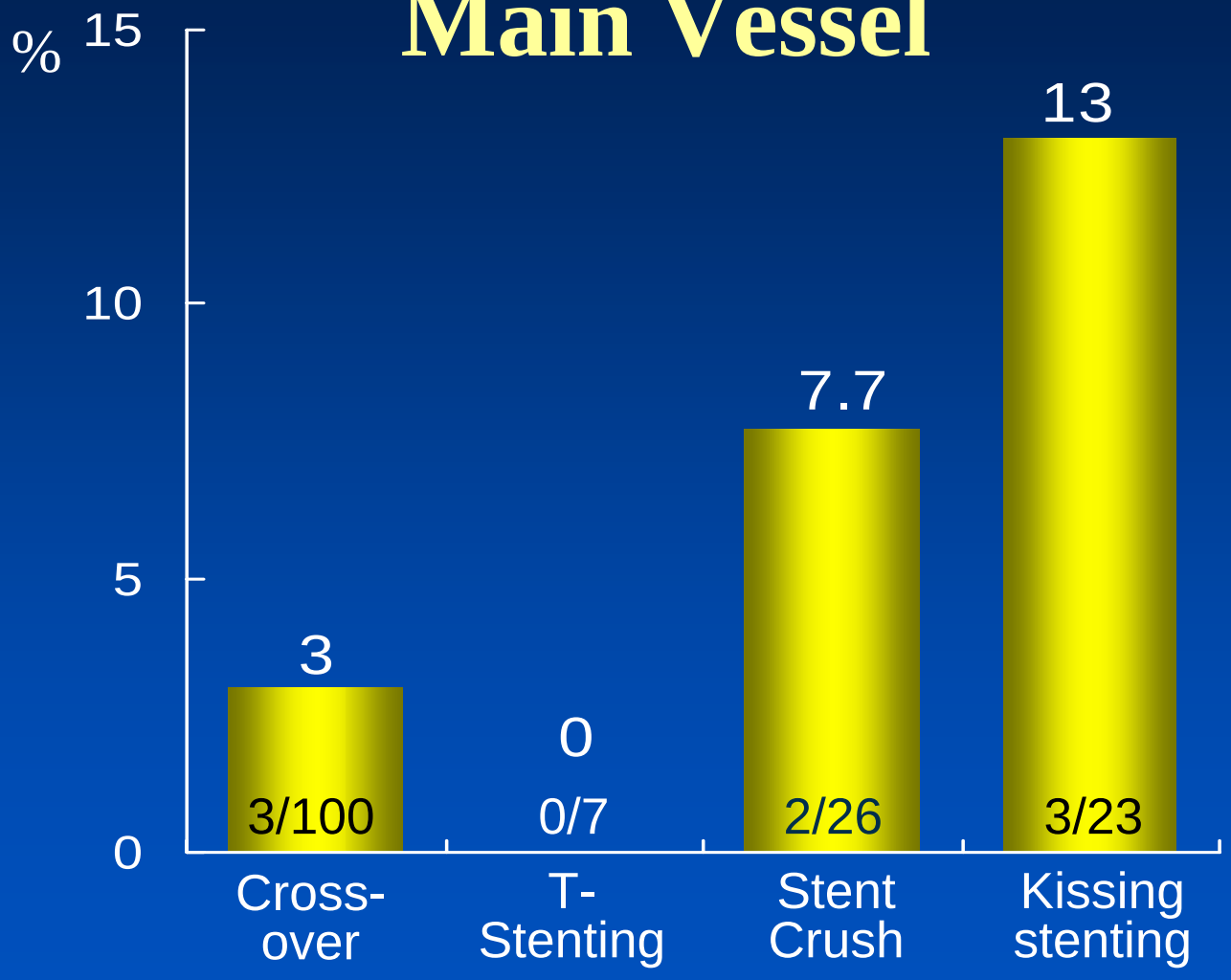
Bifurcation Lesions in AMC

Total 330 lesions with side branch ≥ 2.0mm



Restenosis Rate : 5.3 %

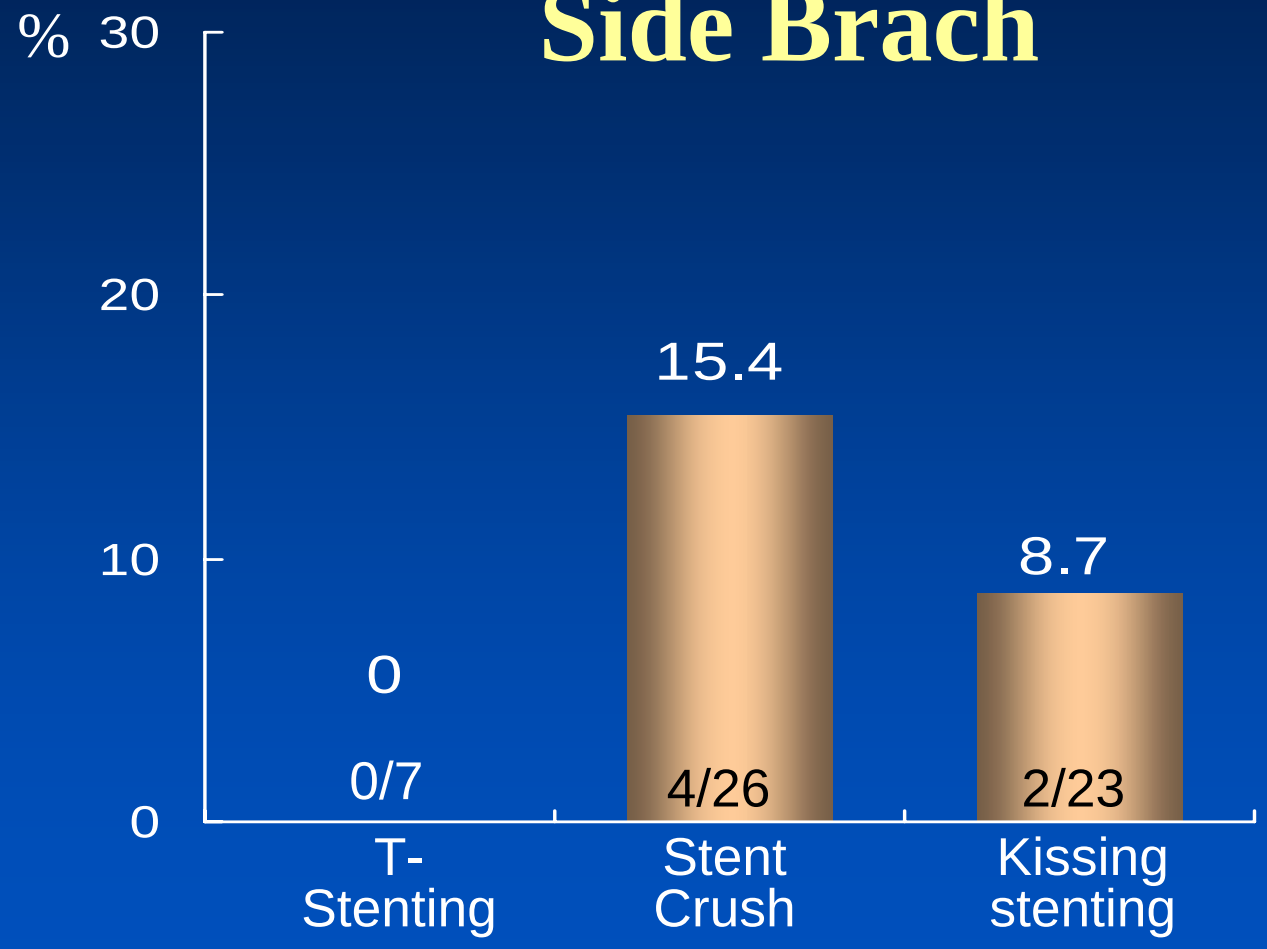
Main Vessel



* Bifurcation including LMCA

Restenosis Rate

Side Brach



* Bifurcation including LMCA

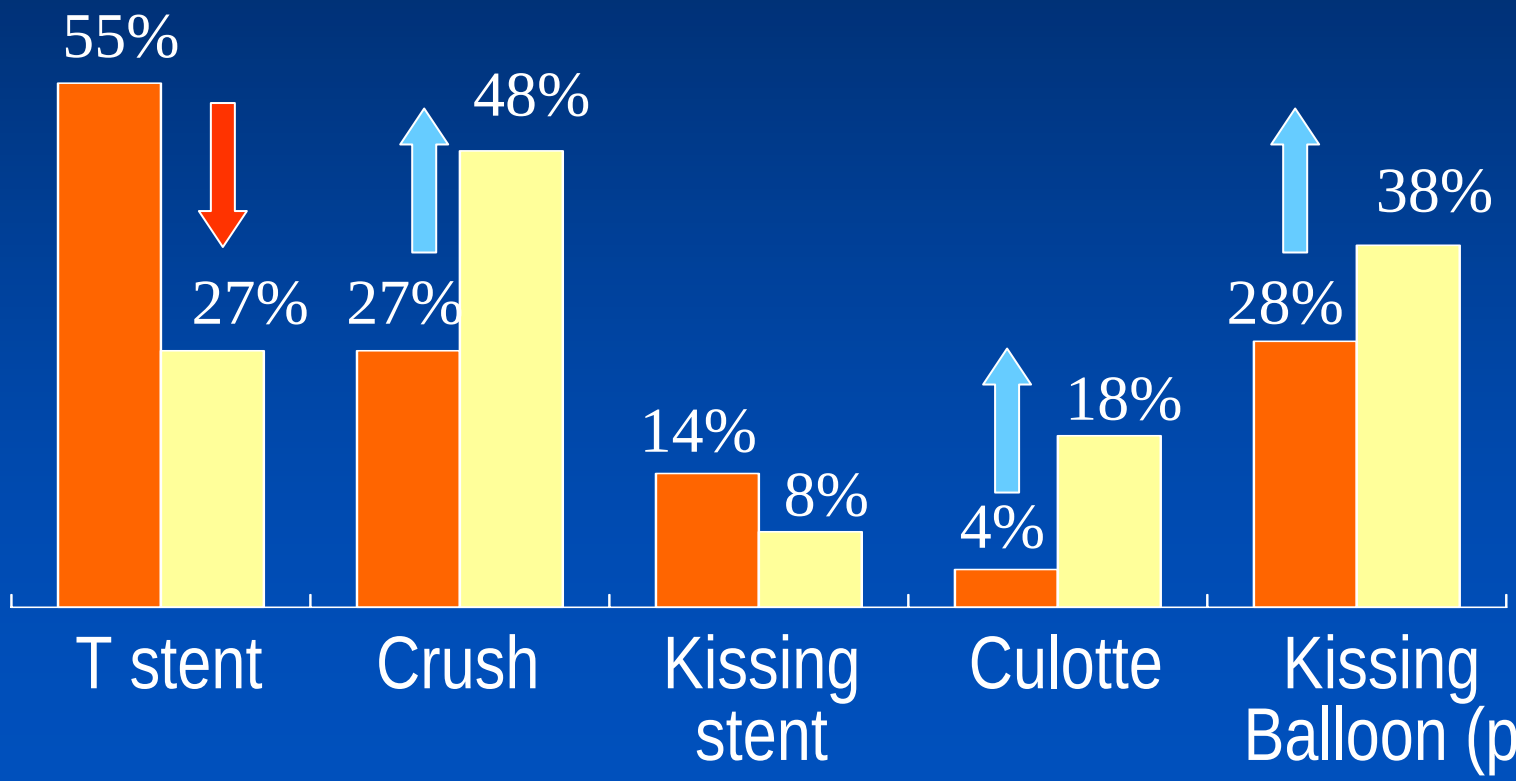
Cypher vs. Taxus

Stenting Technique Used

RESEARCH

CYPHER (n=144)
April 2002 ~ May 2003

TAXUS (n=104)
Mar. 2003~ Sep. 2003



Serruys PW et al, ACC 2005

Cypher vs. Taxus in RESEARCH

	Cypher (p=167)	Taxus (n=113)	P value
Main vessel			
Mean No of stents	1.56±0.84	1.48±0.67	0.4
Stent diameter, mm	2.85±0.23	2.93±0.34	0.007
Stent length, mm	30.35±17.68	30.32±17.78	1.0
Side branch			
Mean No of stents	1.11±0.36	1.13±0.39	0.8
Stent diameter, mm	2.53±0.29	2.60±0.35	0.06
Stent length, mm	14.05±7.61	18.76±10.45	0.0001
Kissing balloon inflation	47.3	45.1	0.9

Serruys PW et al, ACC 2005

Cypher vs. Taxus in RESEARCH

Patients with TLRs

- TLR was percutaneous in all cases
- TLR was for subacute stent thrombosis (2.4%) in 5 cases (2 Cypher and 3 Taxus)
- TLR was for restensis in 9 patients (2 Cypher and 7 Taxus)
- TLR for restenosis
  - Both branches: 2 patients (0.8%)
  - Main vessel: 4 patients (1.6%)
  - Side branch: 3 patients (1.2%)

Serruys PW et al, ACC 2005

Cypher vs. Taxus in RESEARCH

Determinants of MACE

	OR (95% CI)
Age	1.02 (1.01 – 1.05)
Previous CABG	2.75 (1.10 – 7.20)
Diabetes mellitus	2.15 (1.20 – 4.00)
Multivessel disease	1.36 (1.00 – 1.90)
Presentation with AMI	2.35 (1.10 – 5.00)
Use of Cypher	0.71 (0.40 – 1.00)

Stenting strategy was not associated with MACE.

Serruys PW et al, ACC 2005

Cypher vs. Taxus
Crushing in Milan Registry

	Cypher	Taxus	p
No of patients	106	72	
Final kissing balloon, %	60	78	0.01
In-hospital thrombosis, %	1.9	4.2	0.7
Subacute stent thrombosis, %	0.9	0	1.0
Late stent thrombosis, %	0.9	4.2	0.3
TLR at 6 months, %	6.6	5.6	1.0
MACE at 6 months, %	18.9	16.7	0.8

Ge L et al, ACC 2005

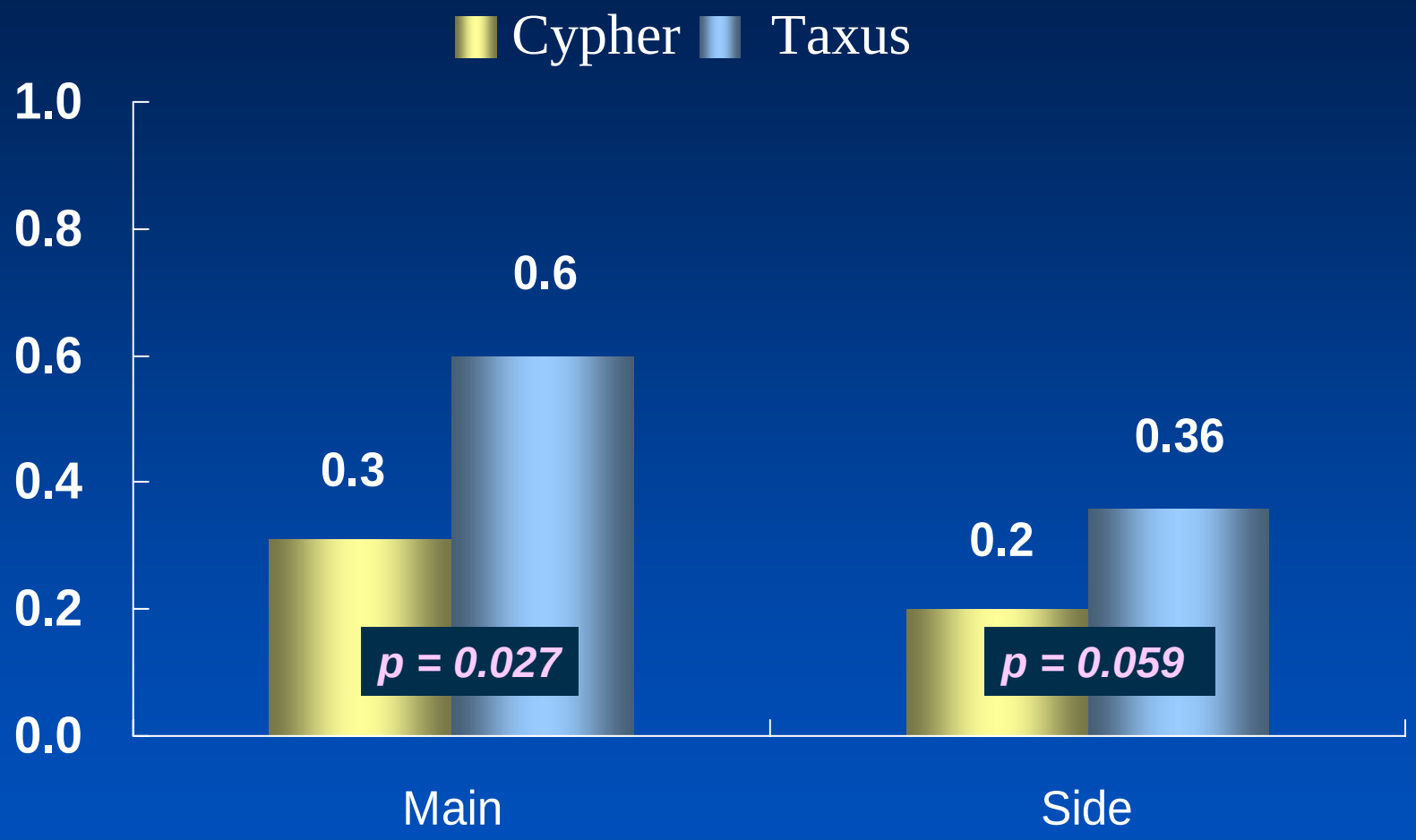
Cypher vs. Taxus

Random comparison

	SES	PES	p
No of patients	103	102	
Final kissing balloon, %	47	45	ns
In-hospital thrombosis, %	0	0	
Subacute stent thrombosis, %	0	0	
Late stent thrombosis, %	0	0.9	ns
Death at 24 months, %	2	3	ns
TLR at 24 months, %	4	13	0.021
Restenosis at 24 months, %	9	29	0.011

Pan et al, AHJ 2007;153:15.e1-15e7

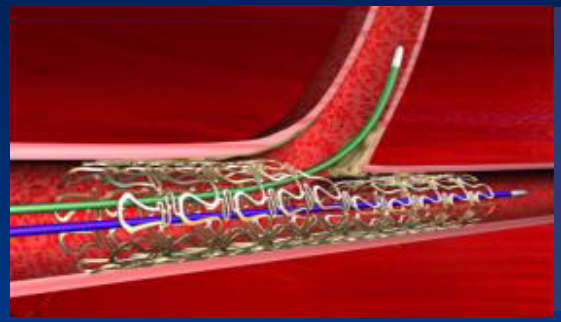
Late loss at 8-months



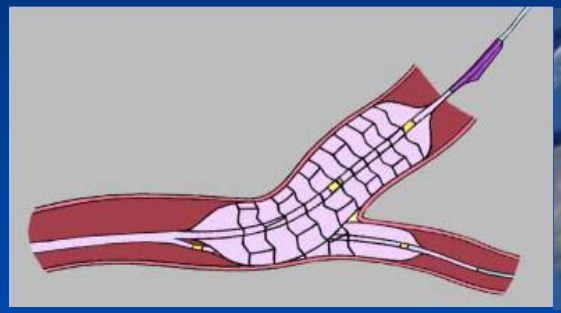
Pan et al, AHJ 2007;153:15.e1-15e7

Dedicated Bifurcation Stents

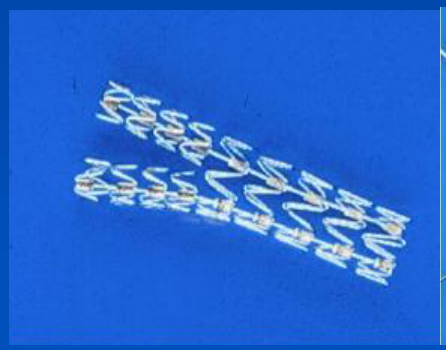
Bifurcated Stents



AST SLK-View Stent



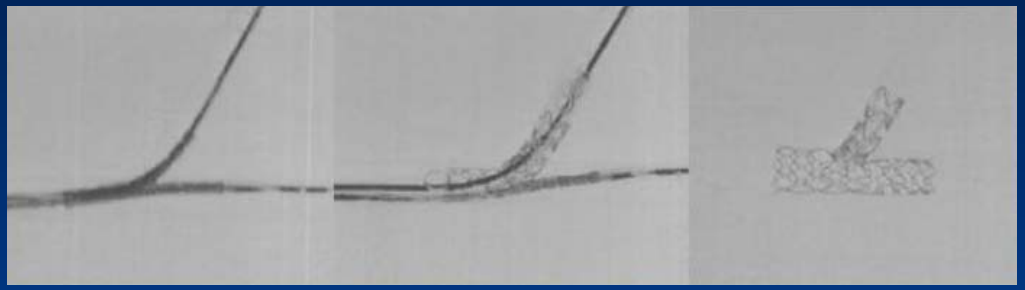
Guidant Frontier Stent



BARD Bifurcate XT

Bifurcated Stents

Cordis
DBS Stent



34 patients (mean 64 years)

- *Technical Success* *94%*
- *MACE @ 30 days* *0%*
- *Restenosis @ 6 Mo* *33%*
- *TLR* *19%*

Dibie A, et al. Am J Cardiol 2002;90:13H

Bifurcated Stents

AST SLK -View

Stent length = 17mm

Catheter length = 140 cm

Crossing profile = 0.055 IN

Available in two sizes

- **3.0mm with 2.5mm side hole**
- **3.5mm with 3.0mm side hole**

Ikeno F et al. Catheter Cardiovasc Interv 2006;67:198

SLK-View Stent Registry

Total 77 lesion (11 left main)	Main vessel	Side branch
Lesion length (mm)	10.7±4.5	7.4±4.2
Reference diameter (mm)	3.1±0.5	2.3±0.4
MLD before procedure (mm)	1.1±0.4	1.3±0.6
MLD after procedure (mm)	2.8±0.5	2.0±0.5
MLD at follow-up (mm)	1.6±0.7	1.2±0.7
Late loss (mm)	1.1±0.7	0.8±1.0
Restenosis, main vessel (%)	28.3	
Restenosis, side branch (%)		37.7
Restenosis, both branches (%)	15	15

Ikeno F et al. Catheter Cardiovasc Interv 2006;67:198

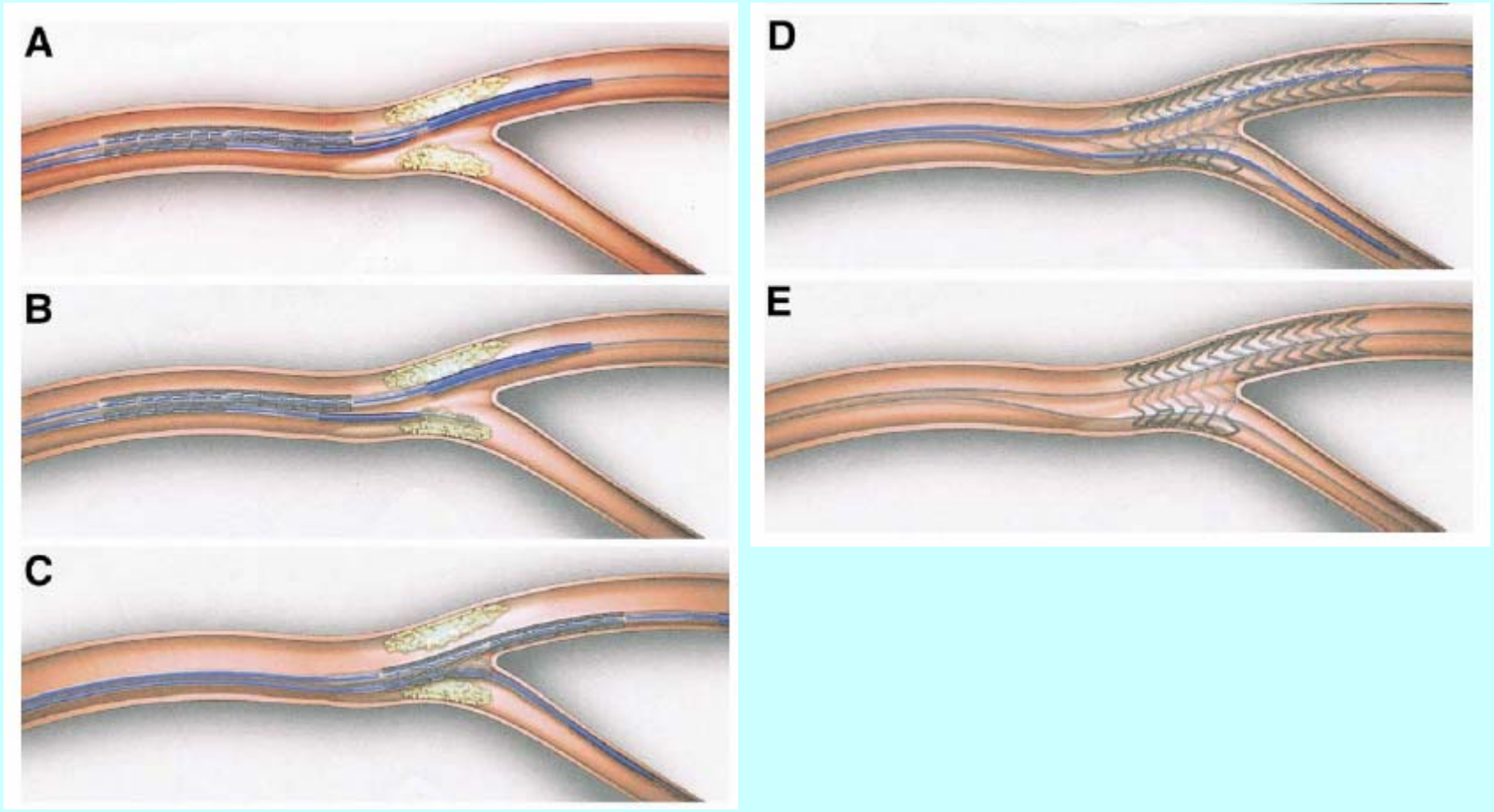
SLK-View Stent Registry

Clinical Findings

Total 80 patients	6 months
Death	1 (1.3%)
MI	2 (2.5%)
TLR	17 (21.3%)
CABG	5 (6.3%)
MACE	25 (31%)

Ikeno F et al. Catheter Cardiovasc Interv 2006;67:198

Frontier Stent



Lefevre T et al. J Am Coll Cardiol 2005;46:592

Frontier Stent Registry

Angiographic Findings

Total 96 patients	Main vessel	Side branch
Reference diameter (mm)	2.77±0.51	2.10±0.67
MLD before procedure (mm)	1.07±0.35	1.23±0.45
MLD after procedure (mm)	2.43±0.41	1.47±0.40
MLD at follow-up (mm)	1.59±0.56	1.13±0.47
In-segment restenosis (%)	29.9	29.1
In-stent restenosis (%)	25.3	-
Late lumen loss (mm)	0.84±0.55	0.34±0.45

Lefevre T et al. J Am Coll Cardiol 2005;46:592

Frontier Stent Registry

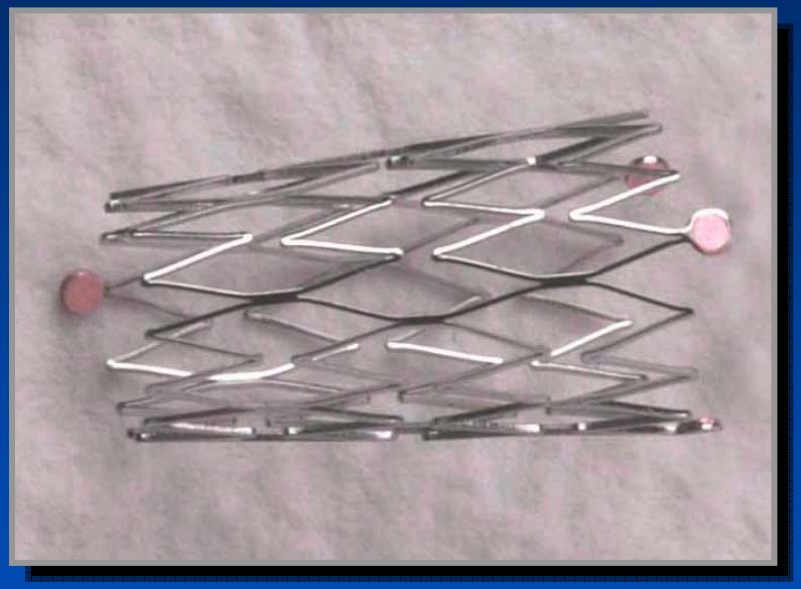
Clinical Findings

Total 105 patients	In-hospital	6 months
Death	0	0
Q-MI	1 (1.0%)	2 (1.9)
Non-Q MI	1 (1.0%)	2 (1.9%)
TLR	1 (1.0%)	14 (13.3%)
MACE	3 (2.9%)	18 (17.1%)
TVF	3 (2.9%)	24 (22.9%)
TVR excluding TLR	0	6 (5.7%)

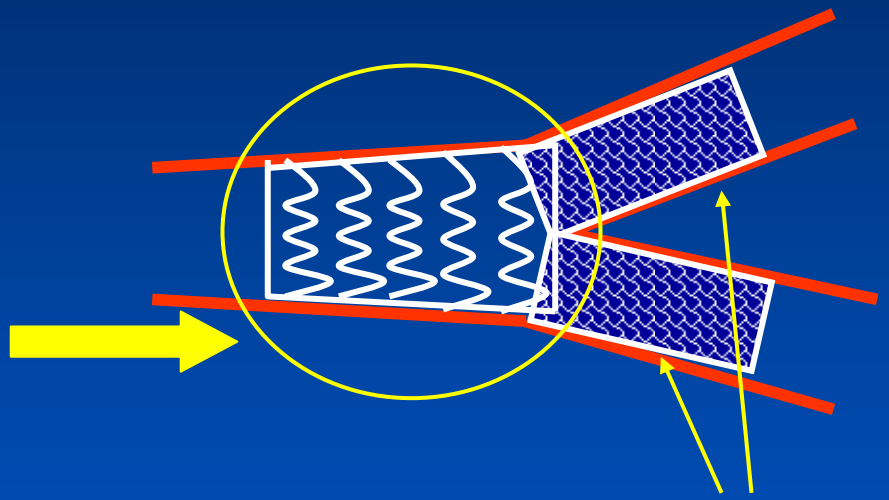
Lefevre T et al. J Am Coll Cardiol 2005;46:592

DES for Bifurcation Lesion

AXXESS Plus system



Biolimus A9 coated AXXESS stent



DES for Bifurcation Lesion

AXXESS Plus trial (n=136)

	Main vessel	Side branch	P value
Lesion length (mm)	17.3 ± 7.4	7.4 ± 3.6	<0.0001
Reference diameter (mm)	2.9 ± 0.4	2.4 ± 0.3	<0.0001
Preprocedure MLD (mm)	0.7 ± 0.3	0.9 ± 0.4	0.01
Final MLD (mm)	2.8 ± 0.5	2.4 ± 0.4	0.0005
Late loss (mm)	0.1 ± 0.6	0.7 ± 0.6	<0.0001
Restenosis (%)	5.7	8.3	0.64

Costa RA et al, AHA 2005

Conclusions

- DES implantation has dramatically improved long-term outcome of the main vessel in the bifurcation lesions.
- However, restenosis at the side branch remains a problem.
- Until now, no statement can be made regarding the most appropriate technique with DES for bifurcation lesions.
- Therefore, treatment decision should depends on each patient and each lesion.