

Bifurcation Stenting: Implications of the Nordic Study

Alan C. Yeung, MD

Li Ka Shing Professor of Medicine (Cardiology)

Director, Interventional Cardiology

Chief, Division of Cardiovascular Medicine

Stanford University Medical Center

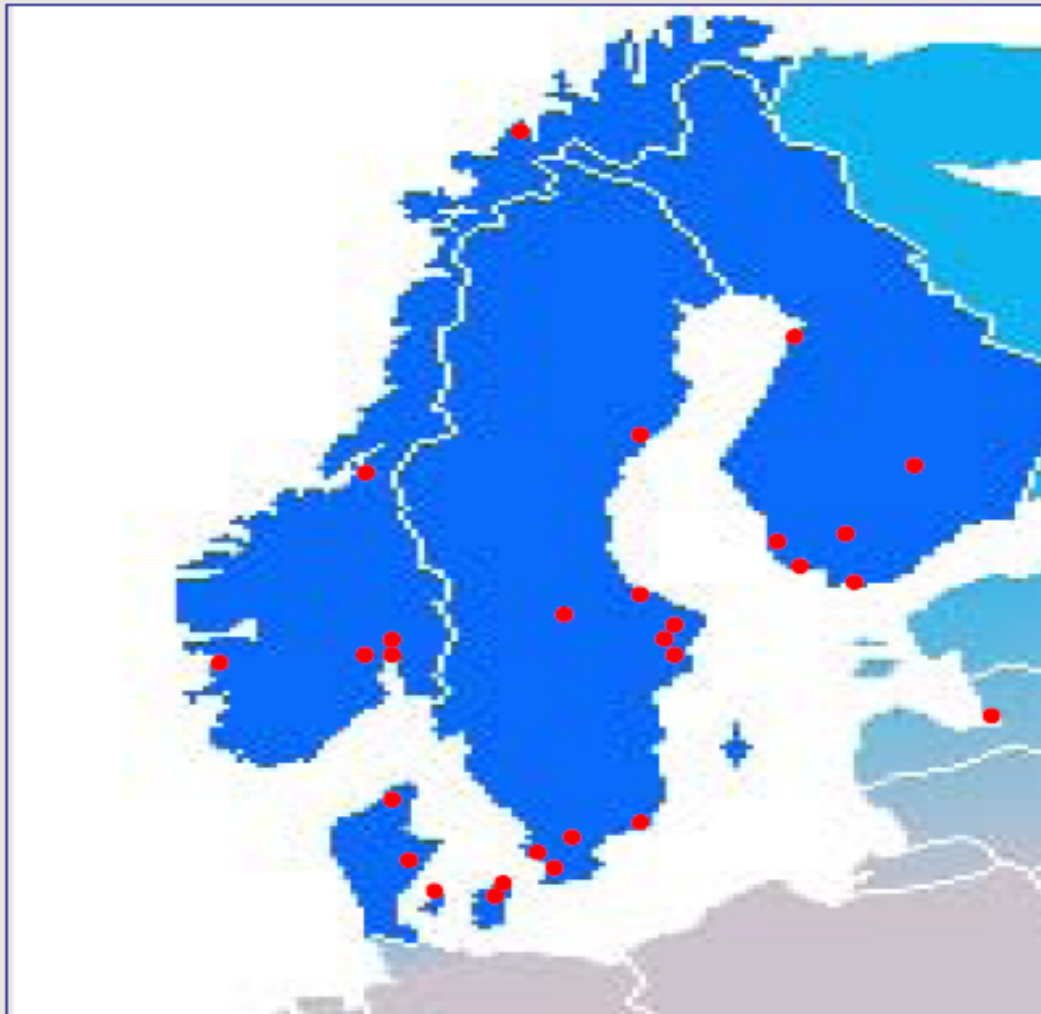


Bifurcation Restenosis Rate

- **Lefevre et al. JACC 2005; 46**
 - **Frontier (BMS) 44.8%**
- **Tannabe et al AJC 2004; 91**
 - **Two Cyphers: Various techniques 22.7%**
- **Colombo et al Circ 2004;109**
 - **1 vs 2 Cyphers 25.7%**

Nordic Bifurcation Study

28 Participating Centers – 5 EUROpean countries



A prospective, multicenter, large-scale randomized trial of single vs. multiple drug-eluting stents in bifurcation lesions

Purpose

To compare two stenting strategies in *de novo* bifurcation lesions using Sirolimus eluting stents:

- Stenting main vessel and optional stenting of side branch (MV)
- Stenting main vessel and side branch (MV+SB)

Main treatment principles

Optional stenting of side branch (MV)

- Stenting of main vessel
- Side branch balloon angioplasty if TIMI flow <3
- Side branch stenting if TIMI flow = 0 after balloon angioplasty

Main treatment principles

Stenting main vessel and side branch (MV+SB)

- Stenting of both vessels by “crush”, “culotte”, “T” or other techniques
- Procedure finalized by “kissing” balloon inflation

Inclusion criteria

- Stable or unstable AP or silent ischemia
- Bifurcation lesion of LAD/diagonal, Cx/obtuse marginal, RCA-PDA/posterolateral branch or LM/Cx/LAD in a right dominant system
- Diameter of main vessel by visual estimate **$\geq 2,5$ mm**
- Diameter of side branch by visual estimate **$\geq 2,0$ mm**

Randomization (n: 413)

Stenting main vessel only
(n: 207)

n: 413 (100%)

Stenting main vessel and side branch
(n: 206)

Clinical Follow-up, 6 months
(n: 207)

n: 413 (100%)

Clinical Follow-up, 6 months
(n: 206)

Stratification at randomization

Scheduled Angiographic Follow-up,
8 months
(n: 176)

n: 358 (100%)

Scheduled Angiographic Follow-up,
8 months
(n: 182)

Angiographic Follow-up available
(n: 151)

n: 307 (86%)

Angiographic Follow-up available
(n: 156)

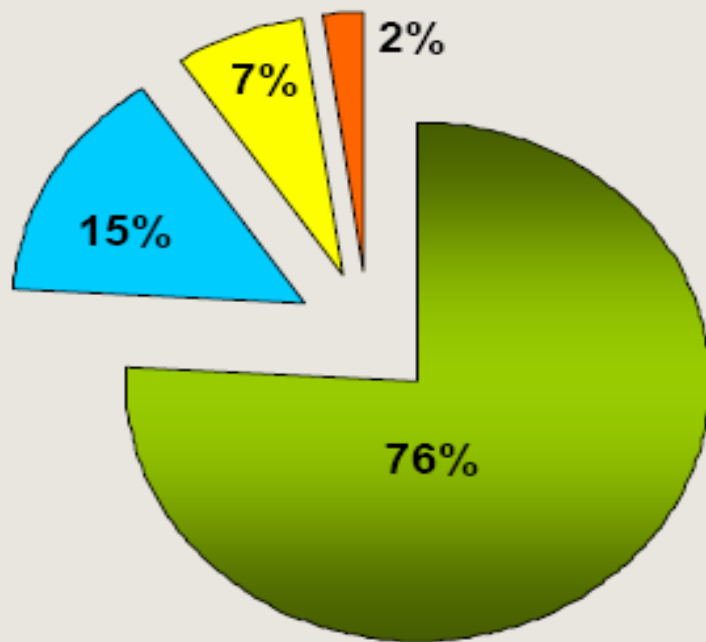
Angiographic end points

Eight months angiographic follow-up

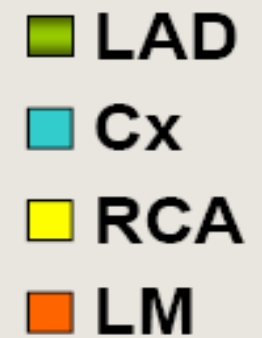
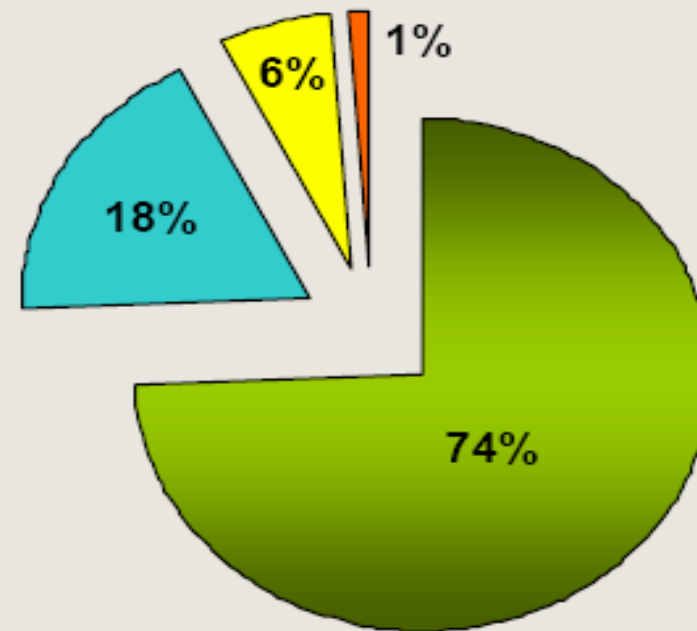
- In lesion >50% stenosis of MV +/- occlusion of SB
- Minimal luminal diameter (MLD) of MV and SB
- In lesion >50% stenosis in the entire bifurcation lesion
- In lesion >50% stenosis of MV
- In lesion >50% stenosis of SB

Vessels treated

MV



MV+SB



Procedural data

	MV (n=182)	MV+SB (n=176)	p-value
MV stented (%)	100	98.9	ns
SB stented (%)	2.7	95.5	<0.001
Kissing balloon (%)	34	74	<0.001
Tx successful (%)	98	95	ns

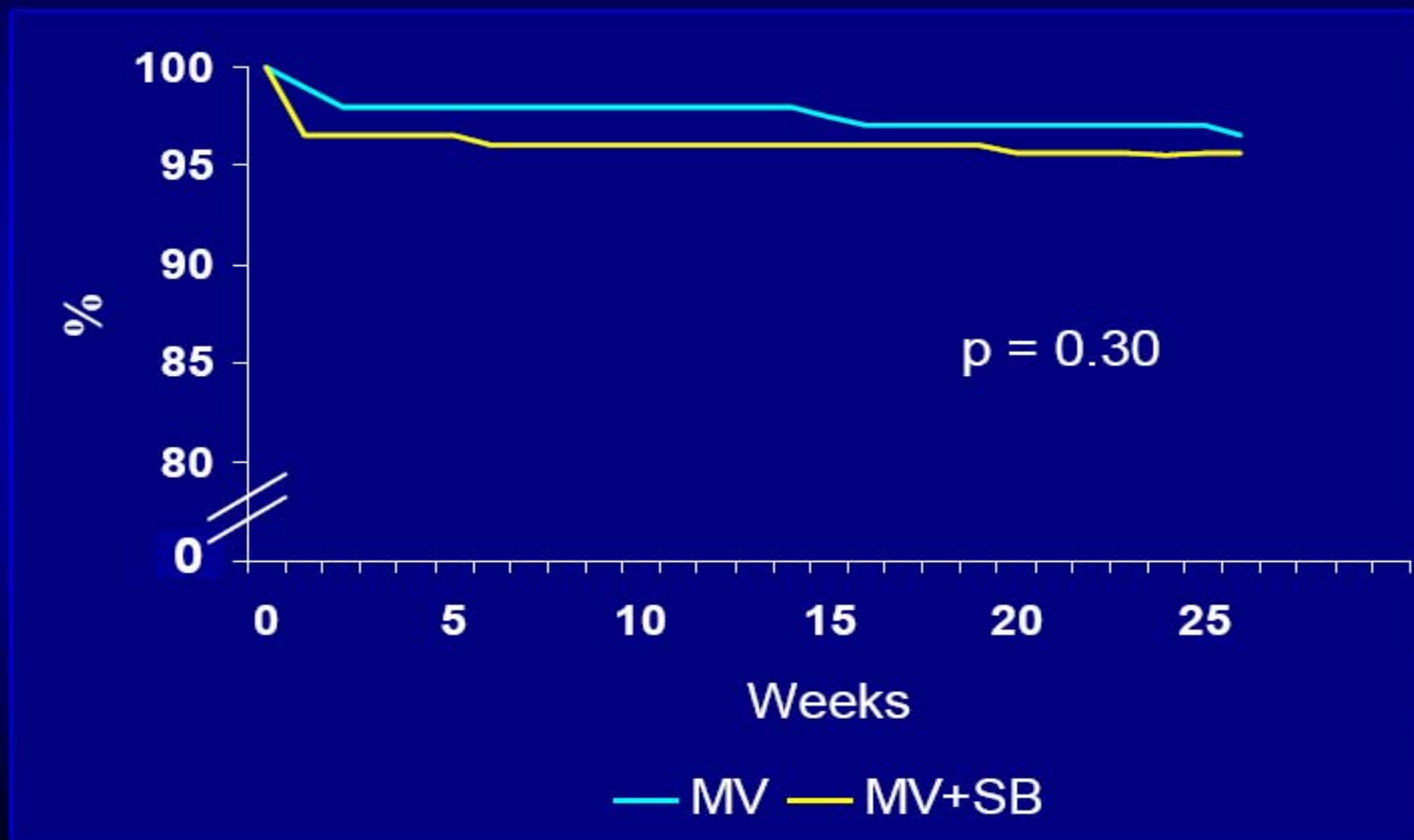
(Residual stenosis <30% of MV + TIMI flow III in SB)

Procedural data I

	MV (n=207)	MV+SB (n=206)	P-value
Aspirin Tx (%)	99.5	98.5	ns
Clopidogrel Tx (%)	100	99.5	ns
GPIIb/IIIa Tx (%)	51	51	ns
Procedure time (min)	59 ± 30	74 ± 30	< 0.001
Fluoro time (min)	15 ± 9	21 ± 10	< 0.001
Contrast (ml)	233 ± 93	283 ± 117	< 0.001

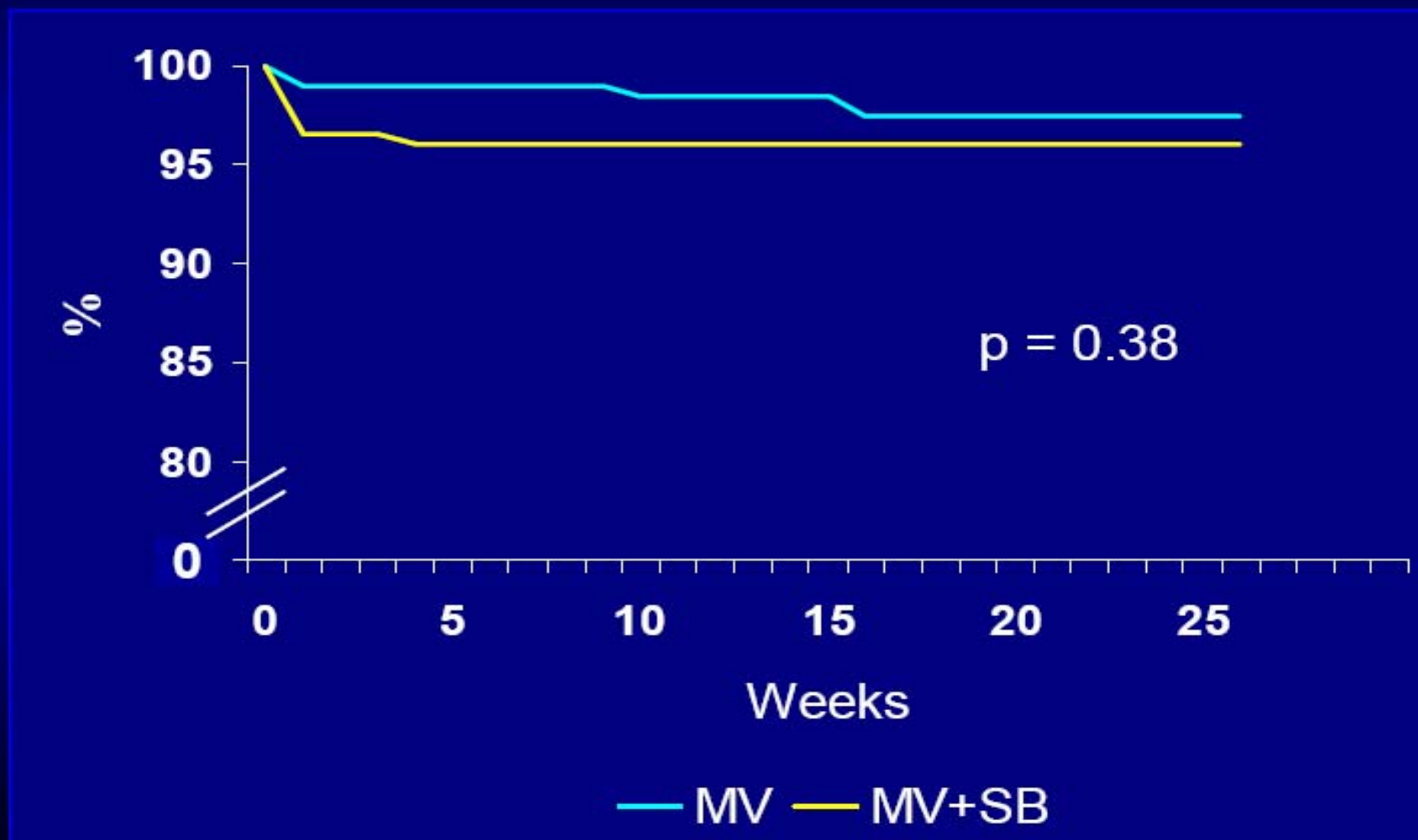
Event free survival

MACE (cardiac death, MI, TVR, stent thrombosis)



Event free survival

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



Individual end points after 6 months

	MV (n=207)	MV+SB (n=206)	P-value
Total death (%)	1.0	1.5	ns
Cardiac death (%)	1.0	1.0	ns
Myocardial infarction (%)	1.4	1.0	ns
Index lesion MI (%)	0.0	1.0	ns
TLR (%)	1.4	2.0	ns
TVR (%)	1.4	2.5	ns
Stent thrombosis (%)	1.0	0.0	ns

Biomarkers at the procedure

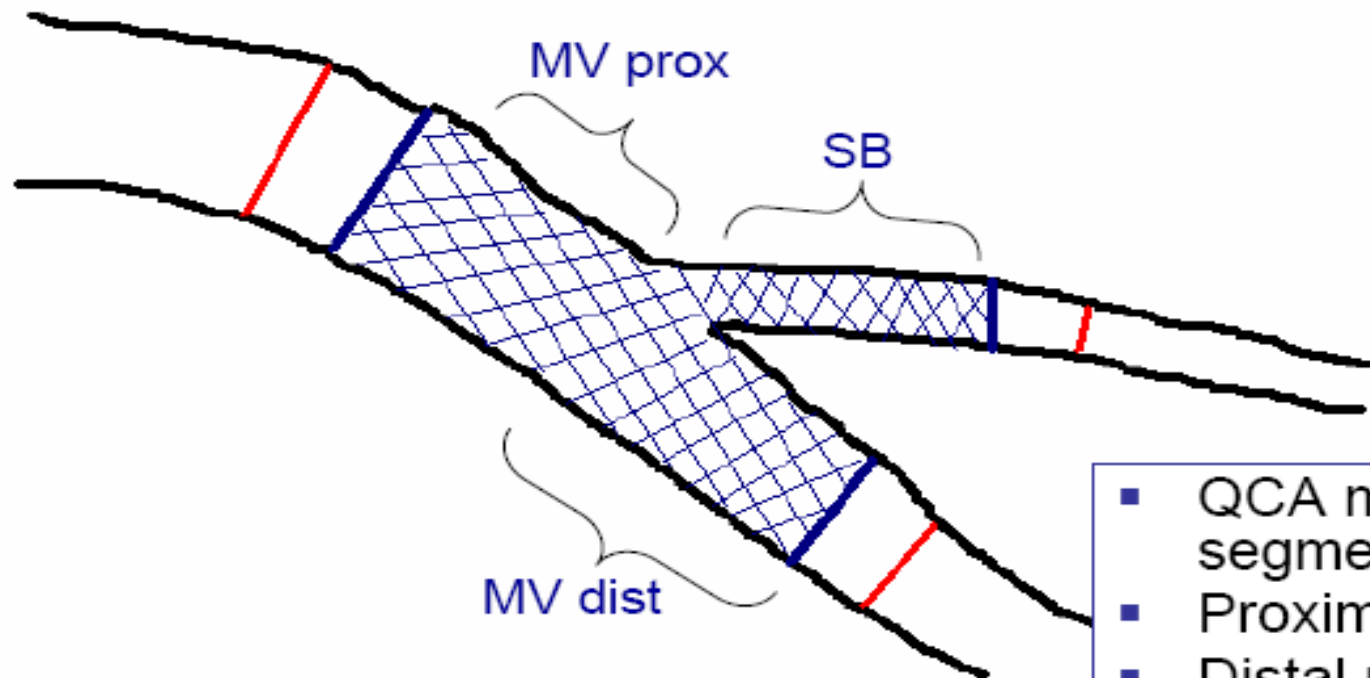
- CKMBmass, Troponin-T or Troponin-I was measured at the procedure and after 12-18 hours
- CKMBmass was used as primary marker, Troponin-T/I only if CKMBm was not available
- Only those with normal markers pre-PCI were included
- Patients with UAP were included, if pre and post procedure markers were normal
- Marker elevation x 3 ULN was considered significant

Procedure related biomarker elevation (279 patients)

	MV (n=153)	MV+SB (n=126)	P-value
>3 elevation (%)	8	18	0.011
>5 elevation (%)	4	13	0.008
>10 elevation (%)	3	5	ns

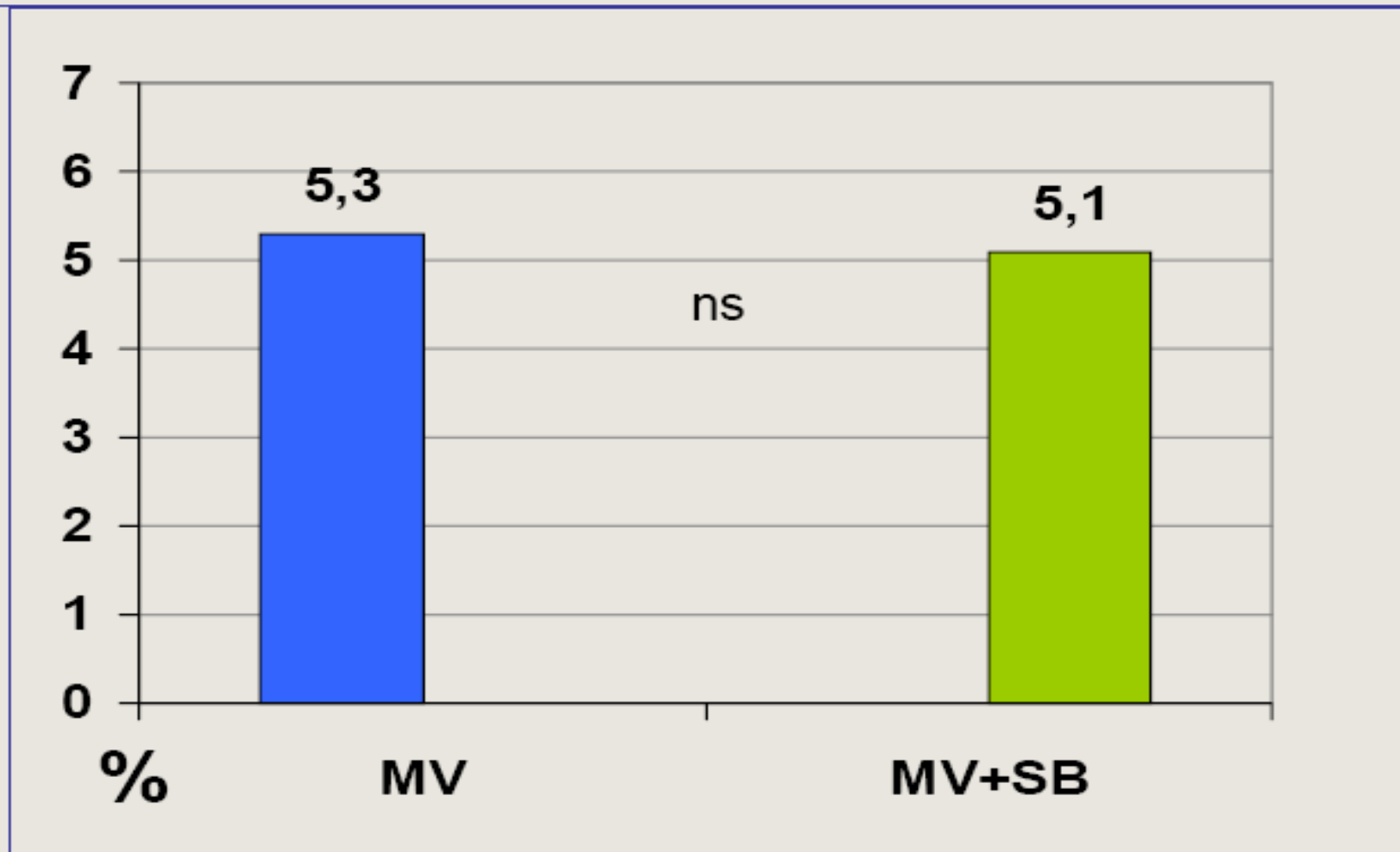
Angiographic follow-up after 8 months

Complete angiographic evaluation in 307 (86%) patients

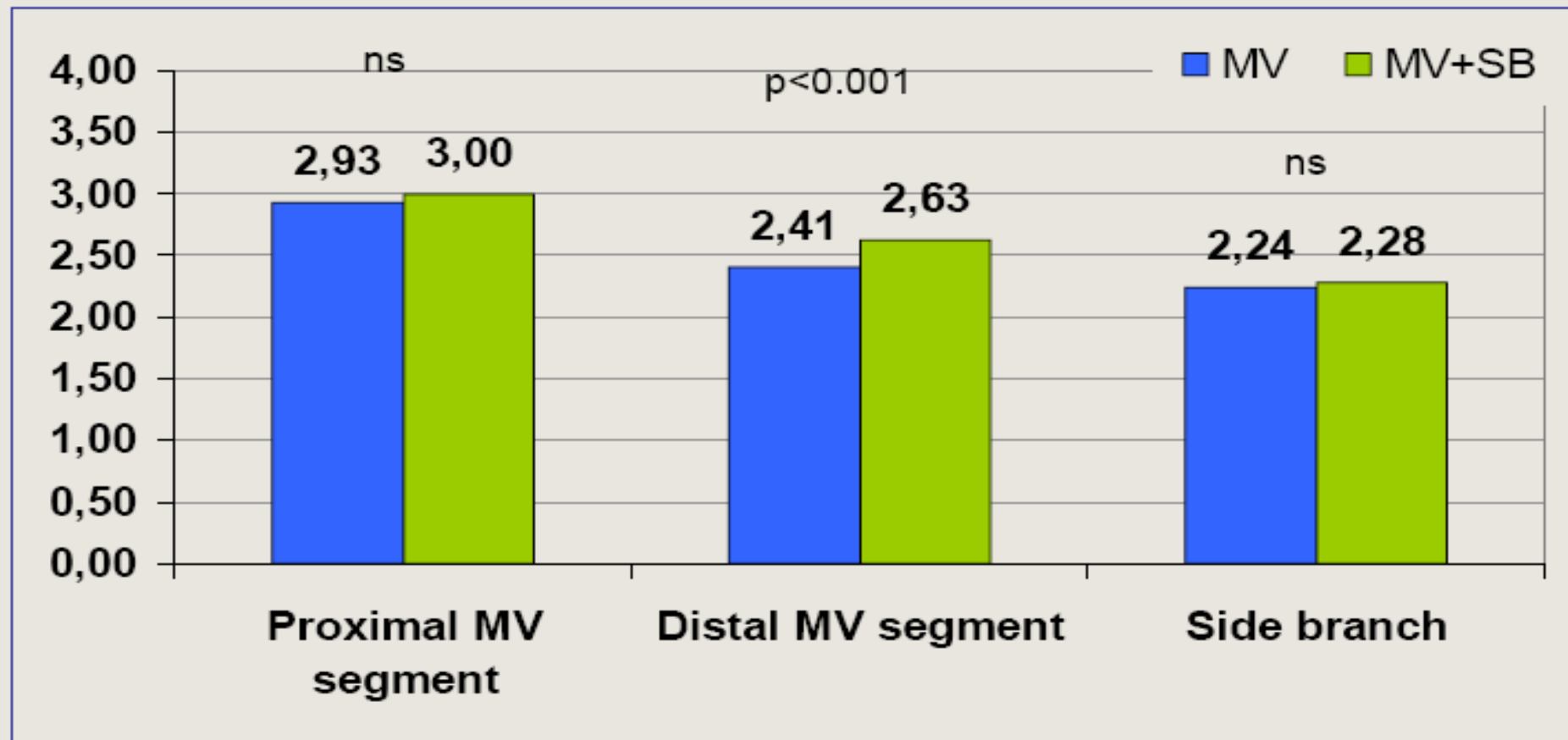


- QCA measurements in 3 segments
- Proximal main vessel
- Distal main vessel
- Side branch
- Edge (5 mm)

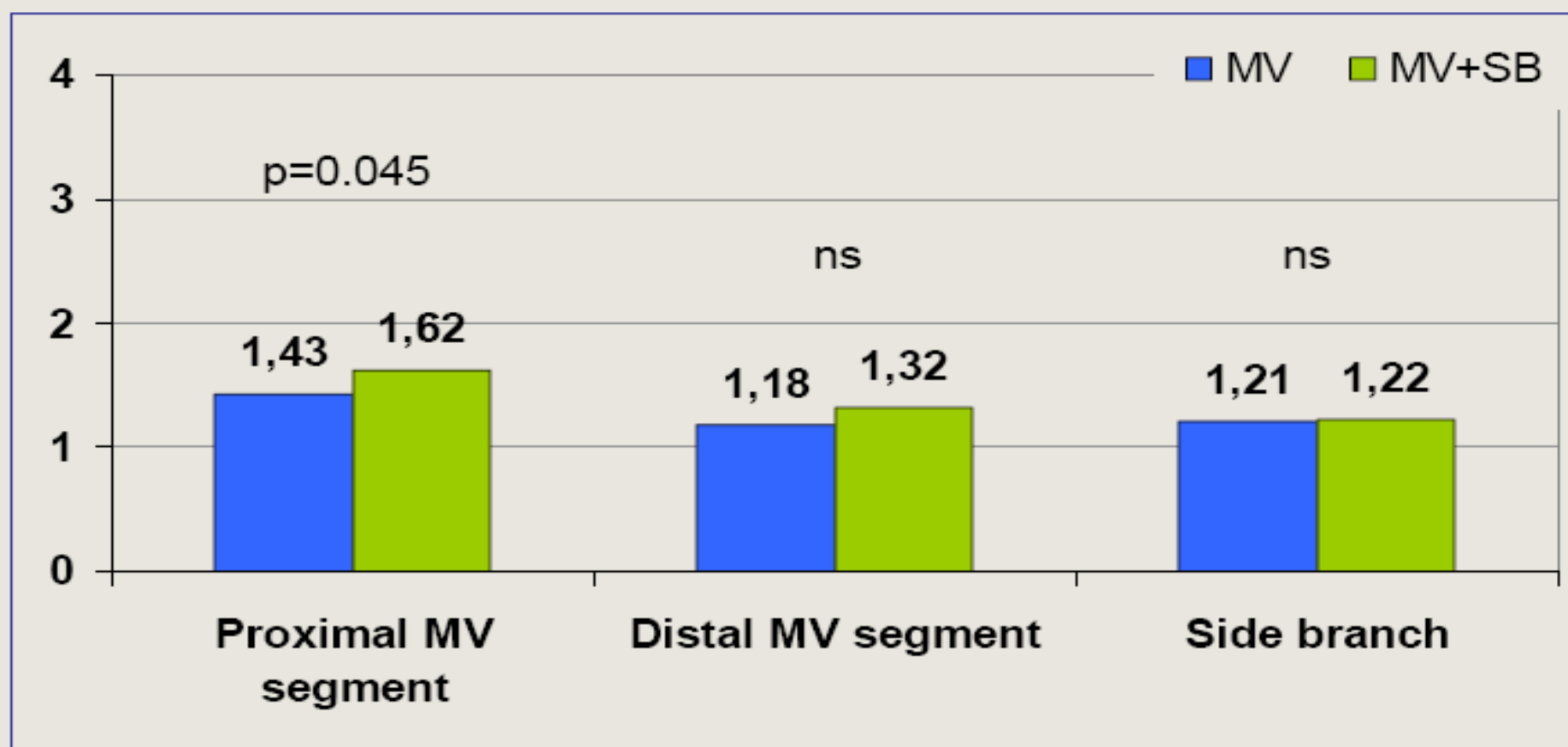
**Rate of main vessel in-lesion
diameter stenosis >50% and side branch
occlusion
after 8 months**



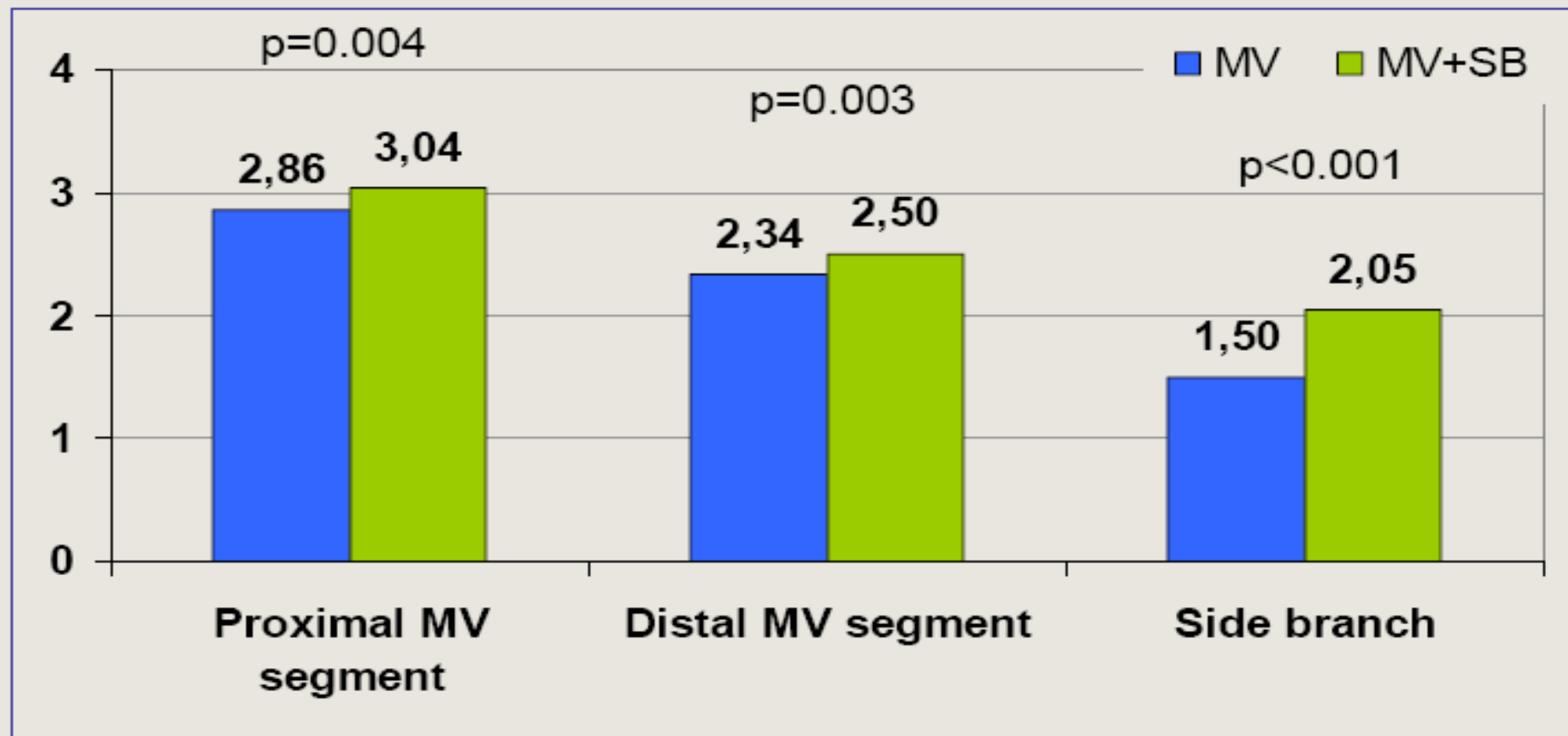
In-segment reference diameter (mm) before procedure



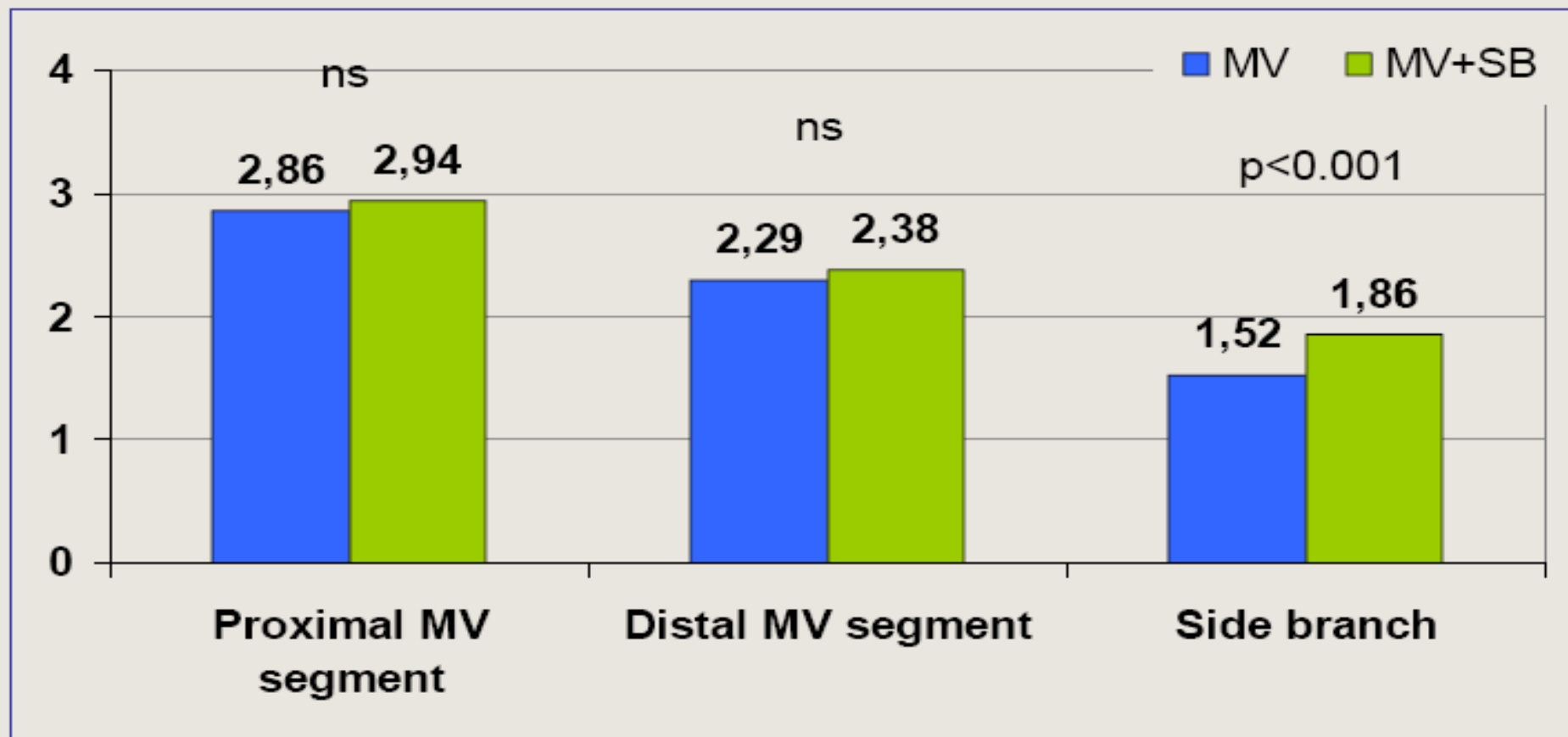
Minimal lumen diameter (mm) before procedure



Minimal lumen diameter (mm) after procedure

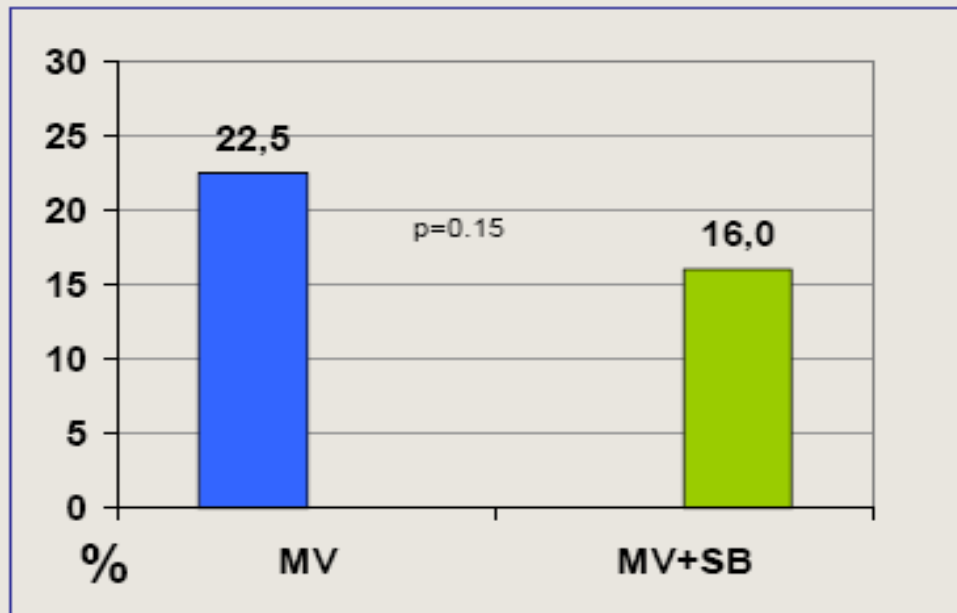


Minimal lumen diameter (mm) at 8 mo follow-up

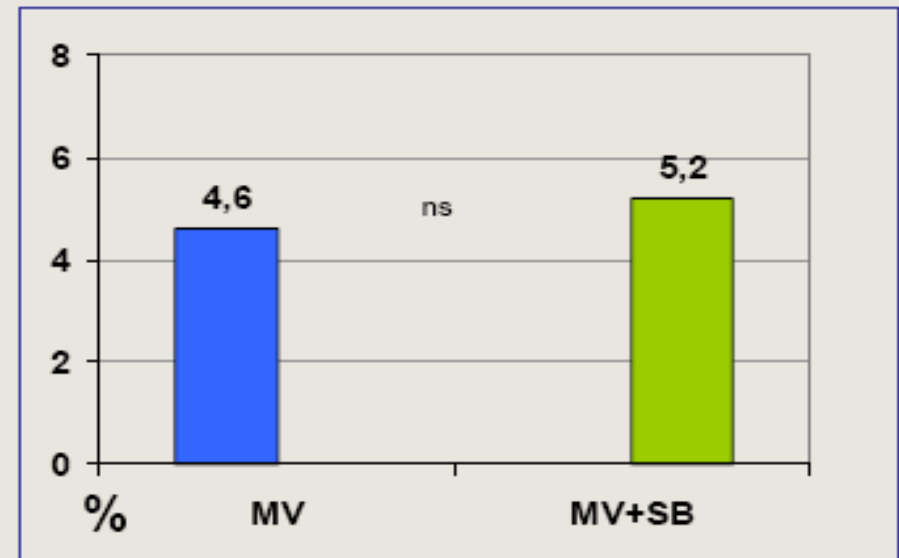


Angiographic Results after 8 months

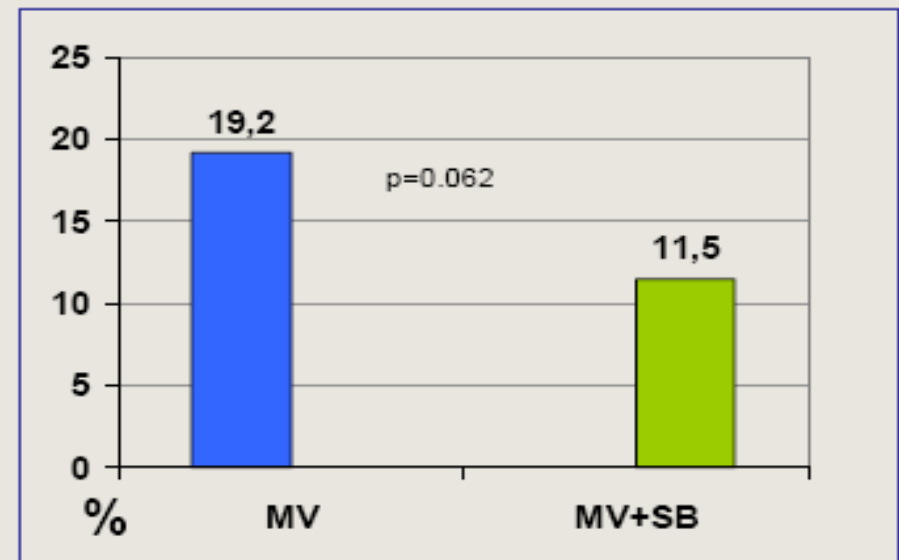
Entire bifurcation lesion diameter stenosis >50%



Main vessel diameter stenosis >50%



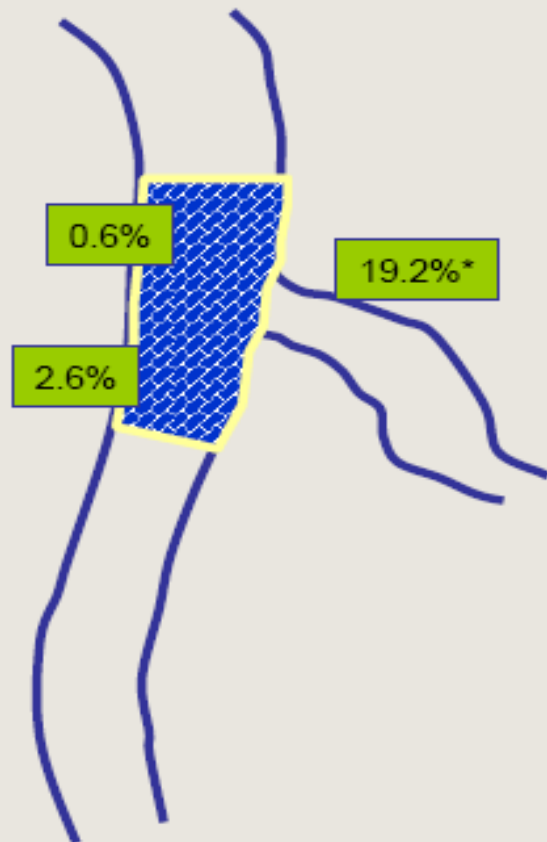
Side branch diameter stenosis >50%



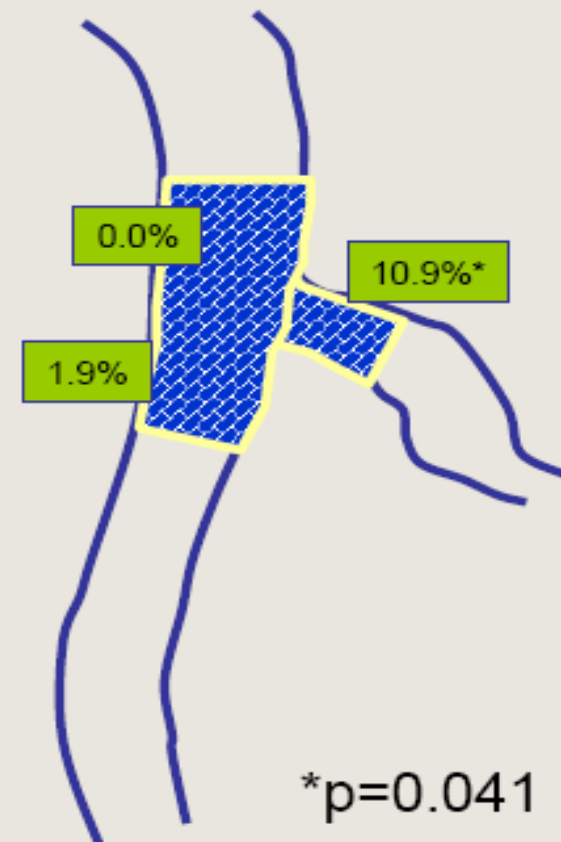
Angiographic follow-up after 8 months

Localization of >50% stenosis (in-stent and side branch)

MV



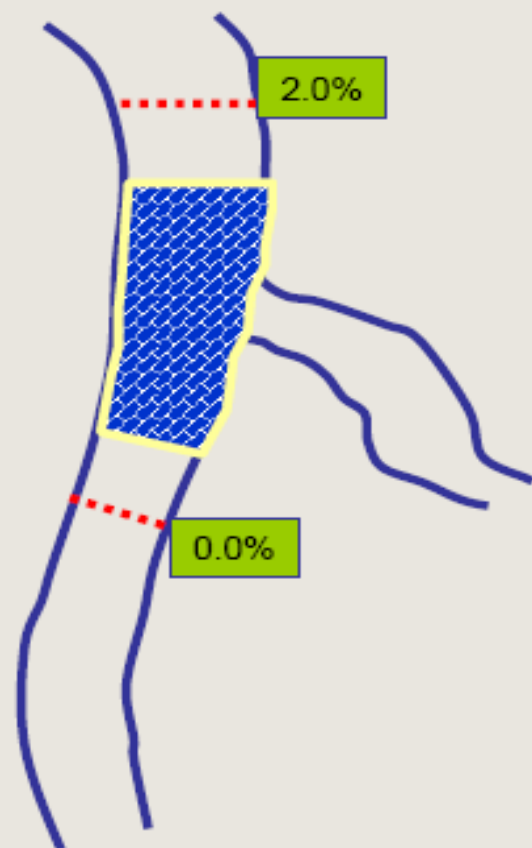
MV+SB



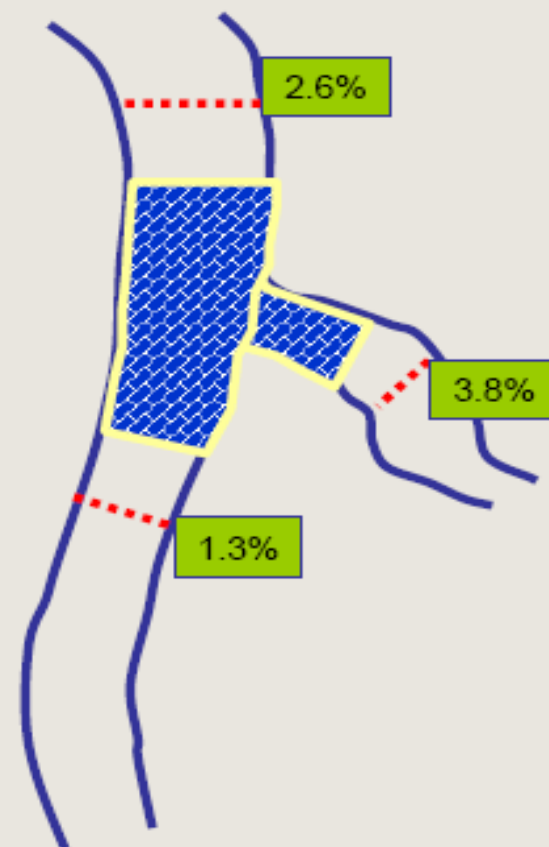
Angiographic follow-up after 8 months

Localization of >50% stenosis (edge)

MV



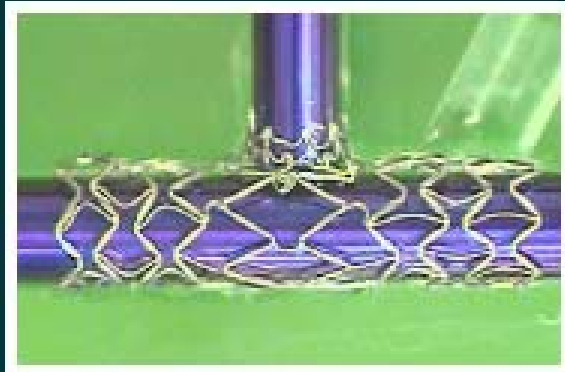
MV+SB



True Bifurcation Continues to be a Problem

- Provisional stenting technique (stenting of side branch if necessary) can be used to treat a majority of the patients. Faster and cheaper.
- True bifurcation (e.g. left main) with equally important side branch may not have been enrolled (not all comers !)
- Heavily calcified, long and tortuous SB lesions may not be possible to be treated by provisional stent.
- True bifurcation stent is needed for left main and those lesions with equally large side branch.

Dedicated Bifurcation Stents



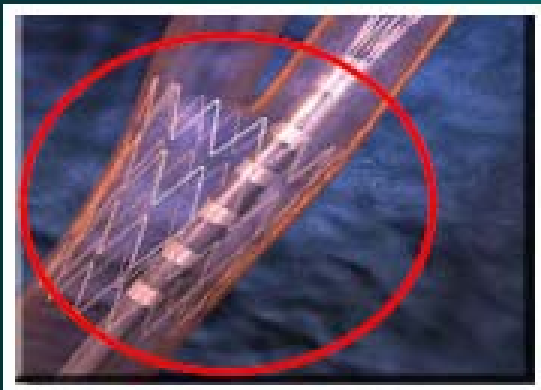
AST petal



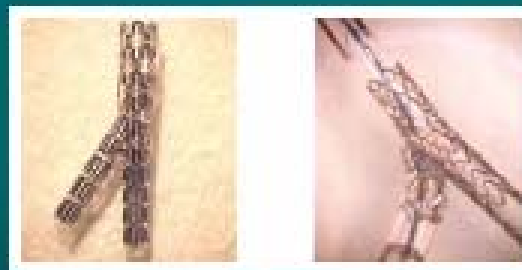
Guidant frontier



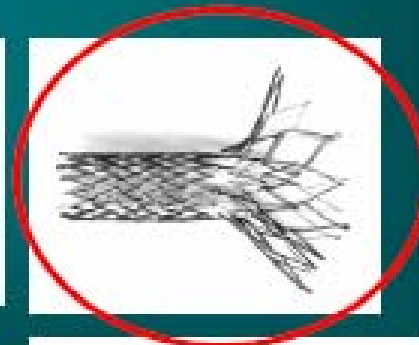
YMed sidekick



Devax (+ BA9)



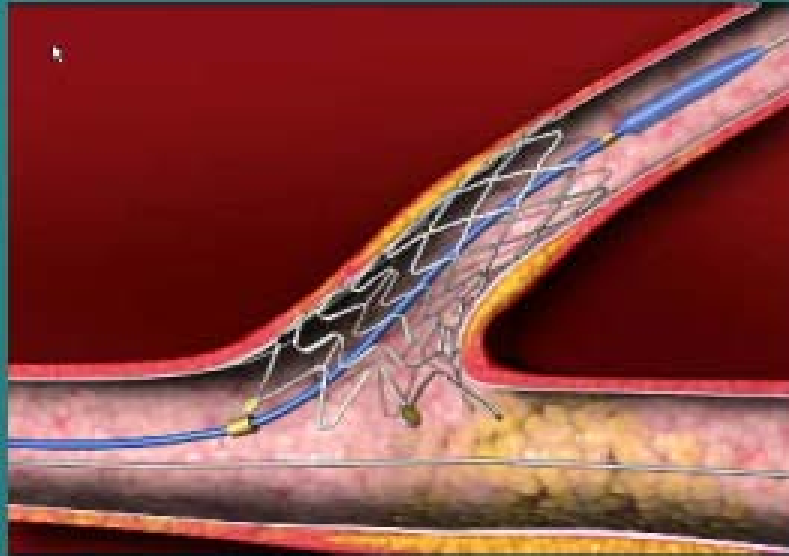
"true" bifurcation designs



sidebranch designs



Dedicated Sidebranch Stents



Cappella
(Facilitated T-stent)



Tryton
(Facilitated culotte stent)

Dedicated Bifurcation Stents

	Axxess	BSC-AST	Frontier	Ymed	Capella	Tryton
DES Program	Y	Y	Y	N	N	N
FIM/Randomized	Y/Y	Y-P/P	Y/N	Y/N	Y/N	Y/N
Side Branch Angle	Dep	Indep	Dep	Dep	Dep	Indep
Overlap Struts (M/S)	Main	Side	Main	Main	Main	Main
New Carina	Y	N	Y	N	N	N
Marker Bands Align.	Y	Y	N	N	Y	Y
Accuracy	Y	Y	?	?	?	Y