

THE DIVERGE Trial

*On Behalf of the DIVERGE
Investigators and Study Group*

Stefan Verheye, MD, PhD

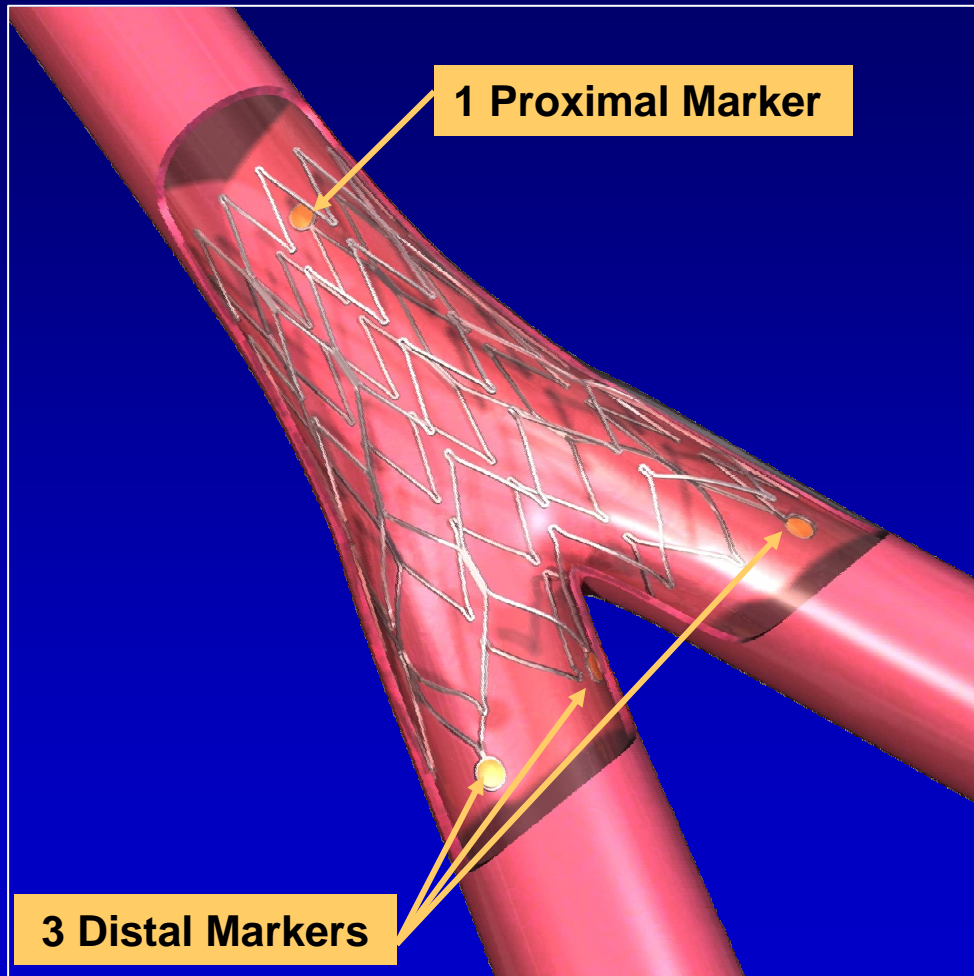
**Antwerp Cardiovascular Institute
ZNA Middelheim
Antwerp, Belgium**

ziekenhuisnetwerk
antwerpen

**cardio
middelheim**



AXXESS BA9 Eluting Stent

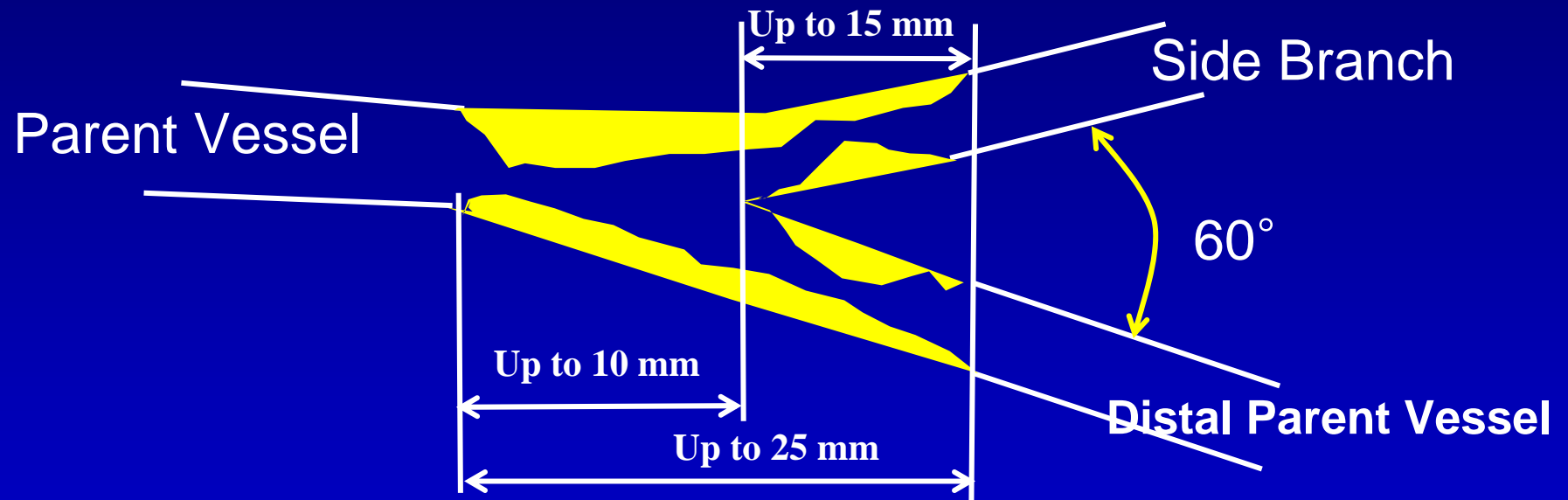


- Self expanding *Nickel-Titanium* stent placed at the level of the carina
- Elutes *Biolimus A9* (rapamycin analogue)
- Bioabsorbable polymer matrix
- Sizes
 - 3.0 and 3.5 mm in diameter
 - 10 and 14 mm in length

Not for sale in United States

Lesion Inclusion Criteria

Any Type Bifurcation
SB \geq 2.25 mm



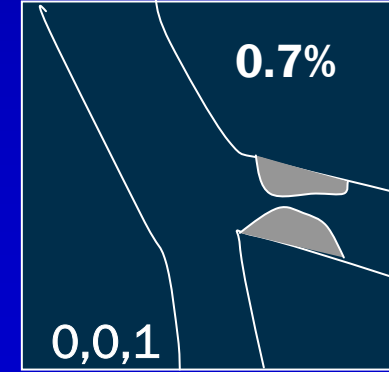
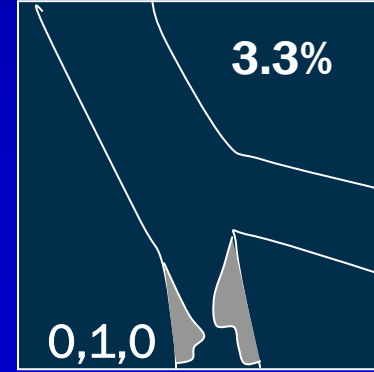
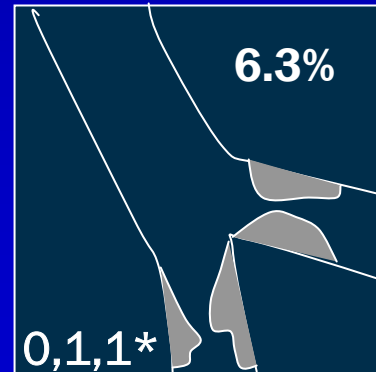
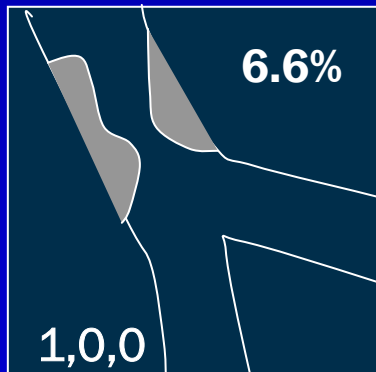
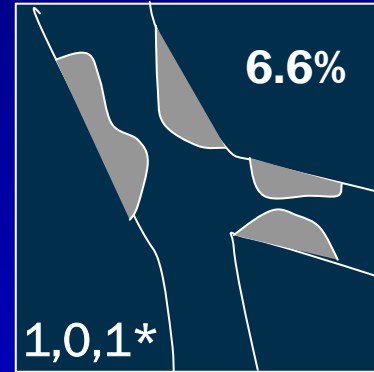
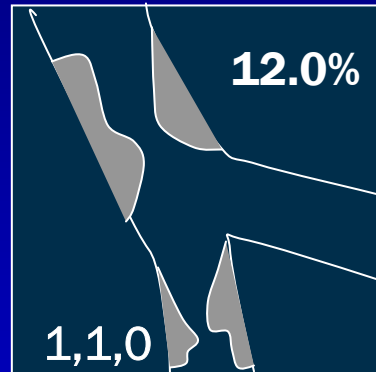
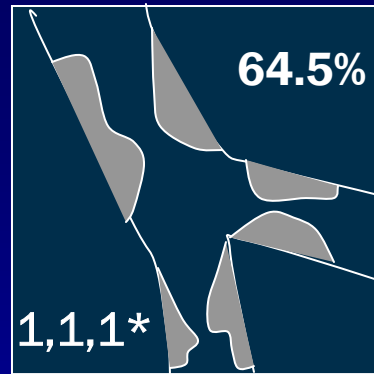
Stents:

Proximal = 10 or 14 mm AXXESS

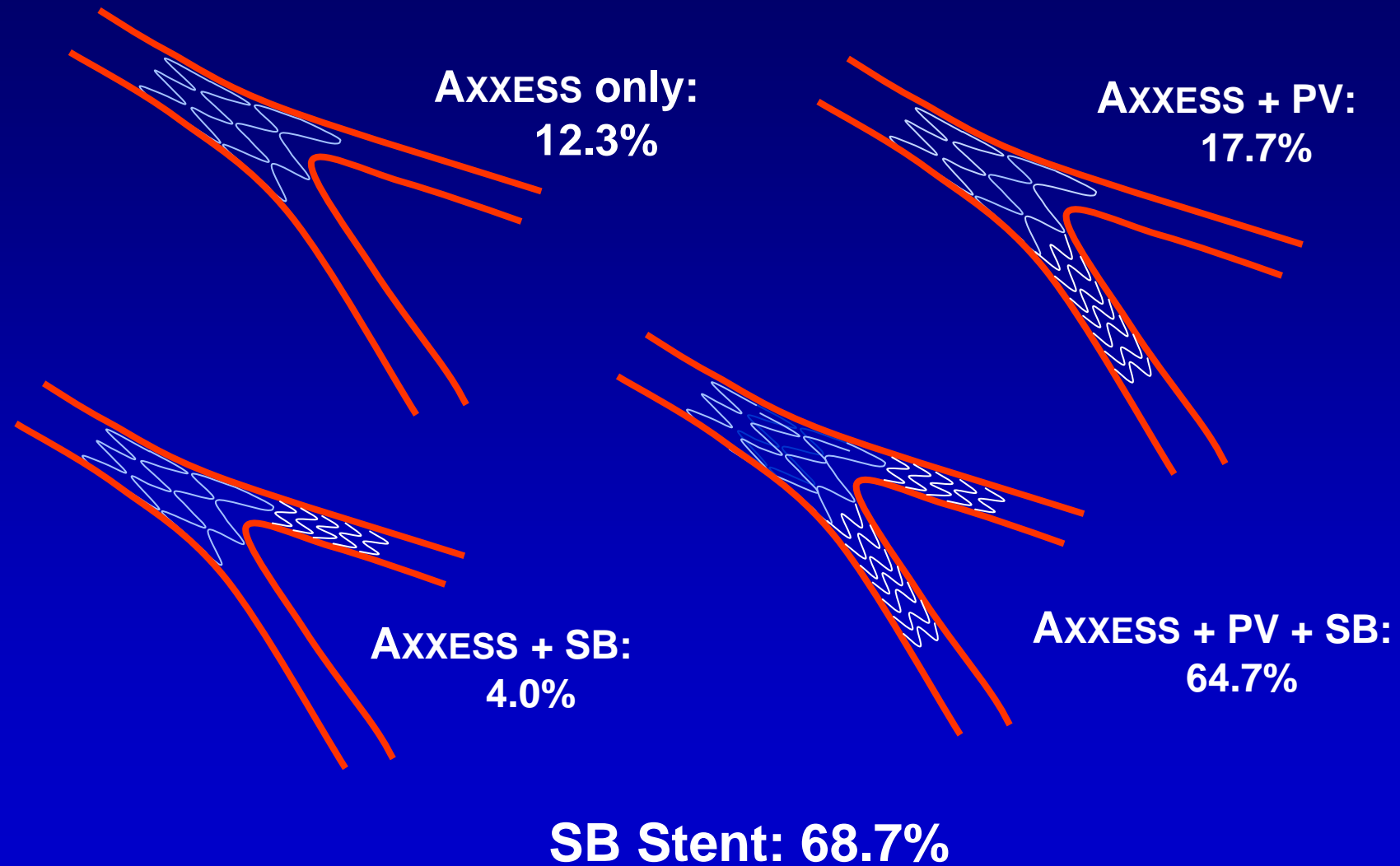
Distal PV or SB = add Cypher to fit

Medina Class All Patients

77.4%
True Bifurcation*



Stent Distribution Patterns



Clinical Results

In Hospital MACE

N (follow up)	100% (302)
All Cause MACE	3.0% (9/302)
<i>Death</i>	
Cardiac death	0.0% (0/302)
Non-cardiac death	0.0% (0/302)
<i>Myocardial Infarction</i>	
Q wave MI	0.0% (0/302)
Non-Q wave MI	3.0% (9/302)
<i>Target lesion revascularization</i>	0.0% (0/302)

*NQ MI is defined as CK >2x ULN and CKMB >ULN

Clinical Results

Cumulative 9 Month MACE

N completing follow up (%)	99.3% (300)
All-cause MACE	7.7%
<i>Any death</i>	0.7%
<i>Q wave MI</i>	1.0%
<i>Non-Q wave MI</i>	3.3%
<i>Ischemia-driven TLR - ALL BIFURCATION</i>	4.3%
<i>Exclusively side branch driven</i>	1.3%

Stent Thrombosis

	Protocol		ARC		
	Definite*	Probable	Definite*	Probable	Possible
Acute (In-hospital)	0	0	0	0	0
Subacute (to 30 days)	0.7%	0	0.7%	0	0
Late (30 days - 9 months)	0.7%	0	0.3%[§]	0	0

**All stent thrombosis in DIVERGE were confirmed with angiography.*

§ One case of asymptomatic chronic total occlusion is omitted in ARC classification but included in protocol definition.

Bifurcation QCA Methodology: Location Evaluation

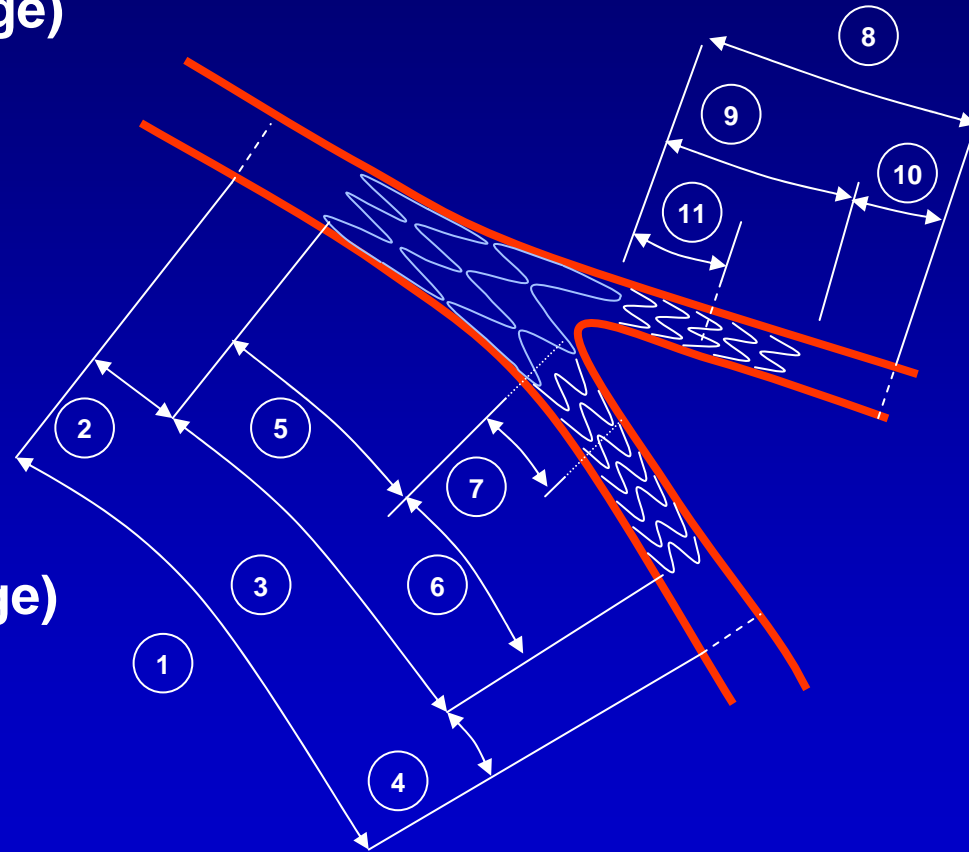
All bifurcation = PV, SB, and edges

Parent Vessel (edge to edge)

1. In-lesion
2. Proximal edge
3. In-stent
4. Distal edge
5. AXCESS stent
6. Distal stent
7. Ostial 5 mm

Side Branch (carina to edge)

8. In-lesion
9. In-stent
10. Distal SB edge
11. Ostial 5 mm

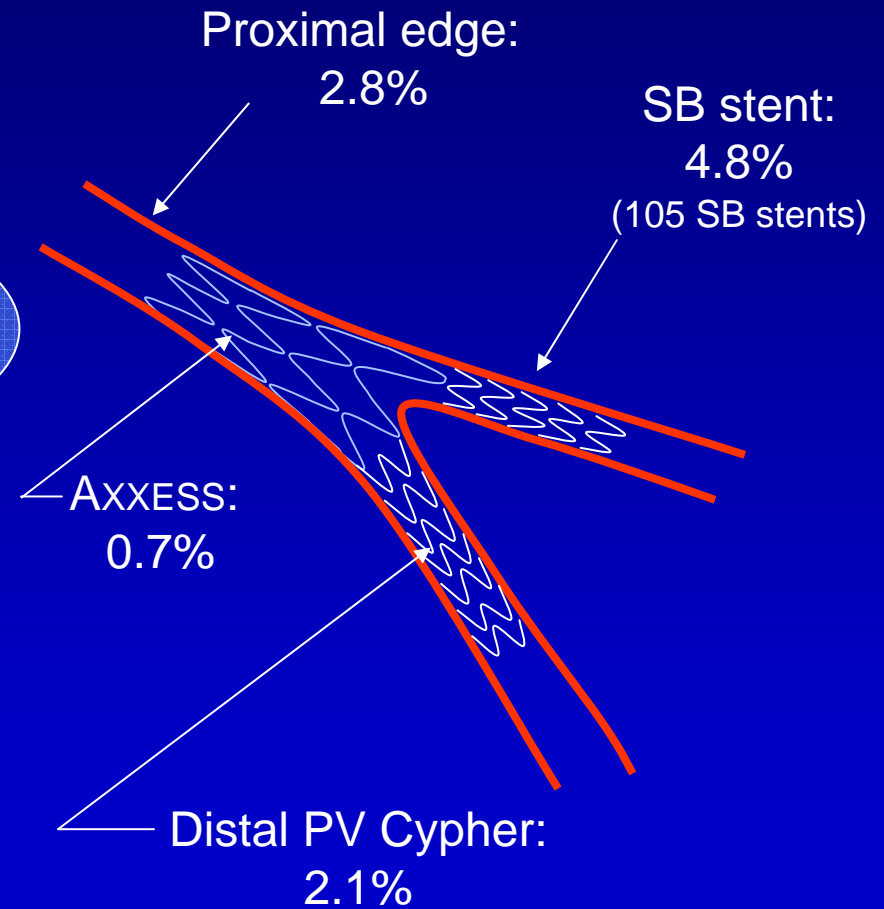
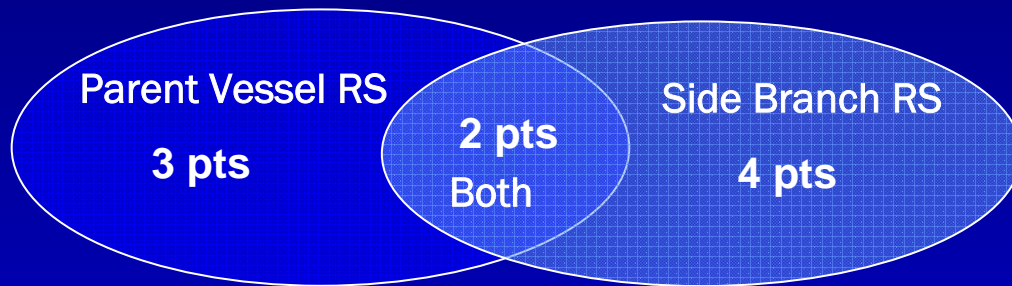


9 Month QCA Results

At Follow Up		Parent Vessel (N=140)	Side Branch (N=140)
Late Loss (mm)	In-stent LL (AXXESS only)	0.18 ± 0.49	-
	In-stent LL (all stents)	0.29 ± 0.50	0.29 ± 0.45
	In-lesion LL	0.20 ± 0.41	0.17 ± 0.34
Restenosis <i>Per Vessel</i>	In-stent - AXXESS Only	0.7%	--
	In-stent - Cypher	2.3%	4.8%
	In-lesion restenosis (all stents + edges)	3.6%	4.3%
Overall Bifurcation Restenosis	In-stent - PV + SB	5.0% (7/140)	
	In-stent or edges, within PV + SB	6.4% (9/140)	

9 Month Restenosis

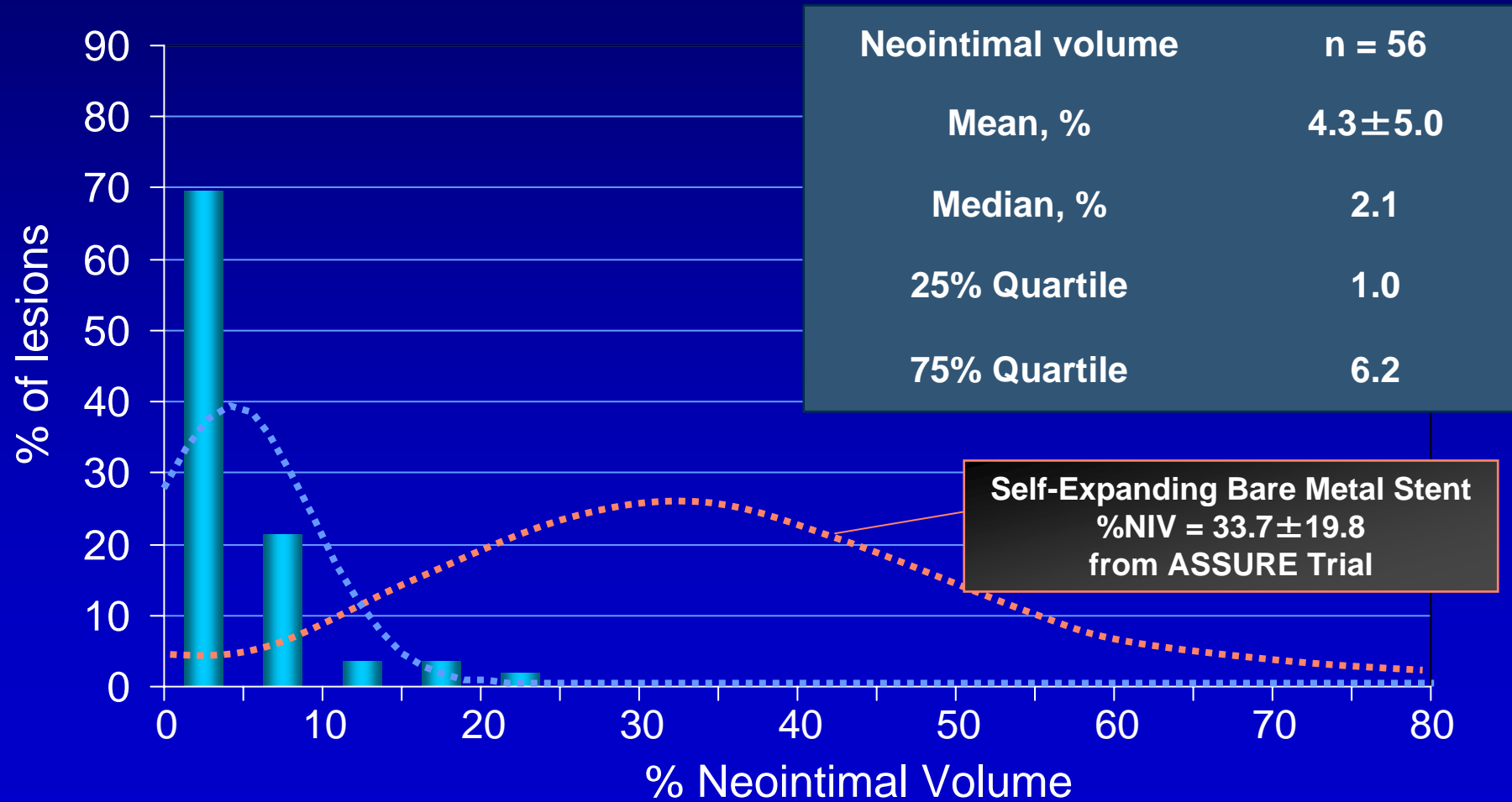
**Any in-bifurcation restenosis:
6.4% (9/140 at 9 months)**



Quantitative IVUS Analysis

Follow-up 3D IVUS analysis: n=56

AXXESS stent segment % NIV



Conclusions

- The use of AXXESS Biolimus A9 eluting stent for the treatment of complex bifurcation lesions resulted in:
 - A high procedure success rate (97%)
 - A low all-cause cumulative 9 month MACE rate (7.7%)
 - A low 9 month ischemic TLR rate (4.3%)
- Systematic angiographic follow up of 150 patients revealed an overall restenosis rate of 6.4% *inclusive* of both bifurcation branches. IVUS analysis showed suppression of neointimal hyperplasia within the stent.
- The clinical and angiographic benefit extends to patients with significant SB disease when treated with the AXXESS stent approach.