

Late Breaking Trial/First Report Investigation

Washington DC, September 25th 2010

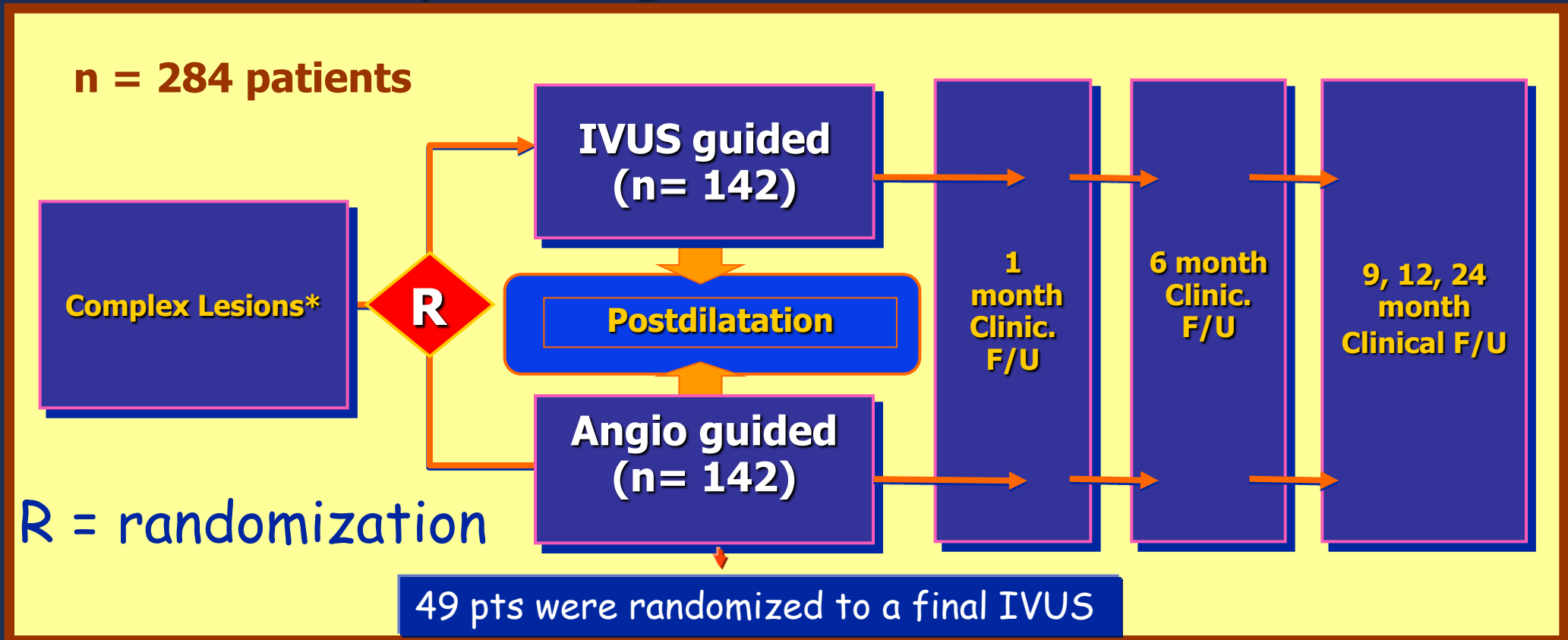


AVIO: A Prospective, Randomized Trial of Intravascular-Ultrasound Guided Compared to Angiography Guided Stent Implantation in Complex Coronary Lesions

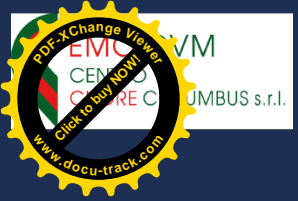
12:15pm-12:25pm

Antonio Colombo, MD
San Raffaele Scientific Institute and Columbus Hospital
Milan, Italy
On behalf of the AVIO Investigators

Study Design and Time Frame



*Complex lesions were defined as Long lesions (>28mm), CTO, Bifurcations, Small vessels and Patients requiring 4 or more stents



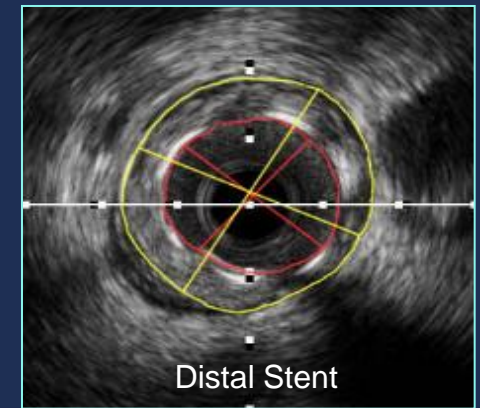
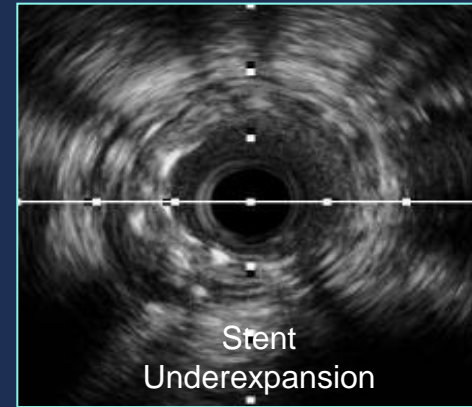
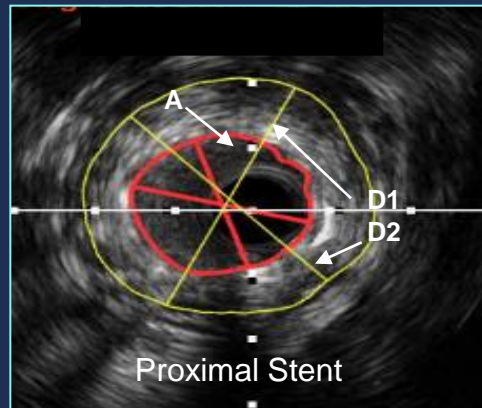
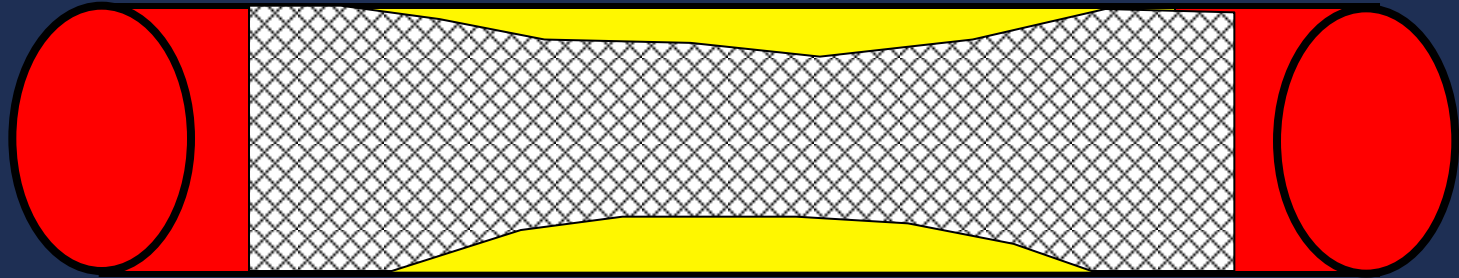
AVIO Criteria for optimal stent expansion:

70%±10% of the cross sectional area of the inflated balloon used to post-dilate the stent

The size of the NC balloon selected to post-dilate the stent is the average of the media to media diameters of the stented area measured proximally, medially and distally inside the stent.

The value is rounded to the lower .00 or 0.50 mm. For values 3.5 mm or above the operator can downsize as per judgment

Deploy Stent and Perform IVUS

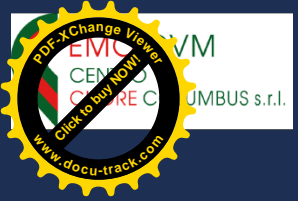


A in **RED** = Stent CSA 3.6 mm^2

D1 = Max vessel Diameter (3.3mm)

D2 = Min vessel Diameter (3.1mm)

Optimal balloon size 3mm, target 70%

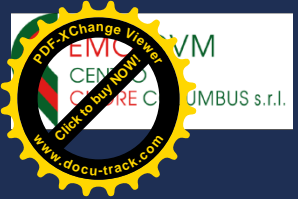


Study endpoints

Primary Endpoint: was post-procedure in lesion minimal lumen diameter (MLD) evaluated by corelab QCA

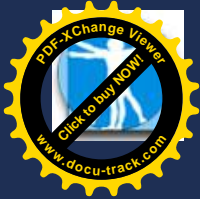
Secondary endpoints: TLR and composite of MACE (death, MI, TVR) at 9 months

Study hypothesis: MLD 2.9 ± 0.4 for IVUS vs. 2.7 ± 0.5 mm for angio guided DES post-dilatation .



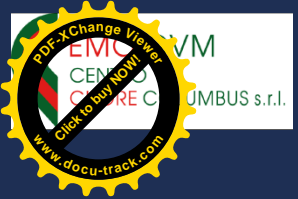
AVIO trial

Angiography Vs IVUS Optimization



Clinical Characteristics

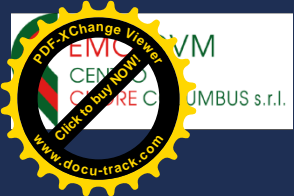
	IVUS (n=142)	Angio (n=142)
Age (years)	63.9±10.1	63.6±11.0
Gender (M/F)	117/25	109/33
Diabetes (%)	23.9	26.8
Hypercholesterolemia (%)	70.4	76.8
Hypertension (%)	70.4	66.9
Current smokers (%)	34.5	31.0
Unstable Angina (%)	29.6	26.1
LVEF (%)	55.3±8.5	55.9±8.6



Lesion Characteristics

	IVUS (n=182)	Angio (n=179)
CTO (%)	13.6	17.8
Bifurcations (%)	23.1	27.2
Long lesions (%)	62.1	58.0
Small Vessels (%)	21.9	23.7
LAD location (%)	53.3	48.6

1.28 lesions /patient were treated in IVUS vs 1.26 in Angio guided



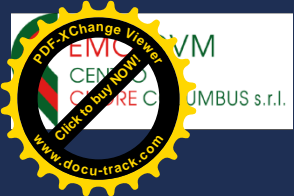
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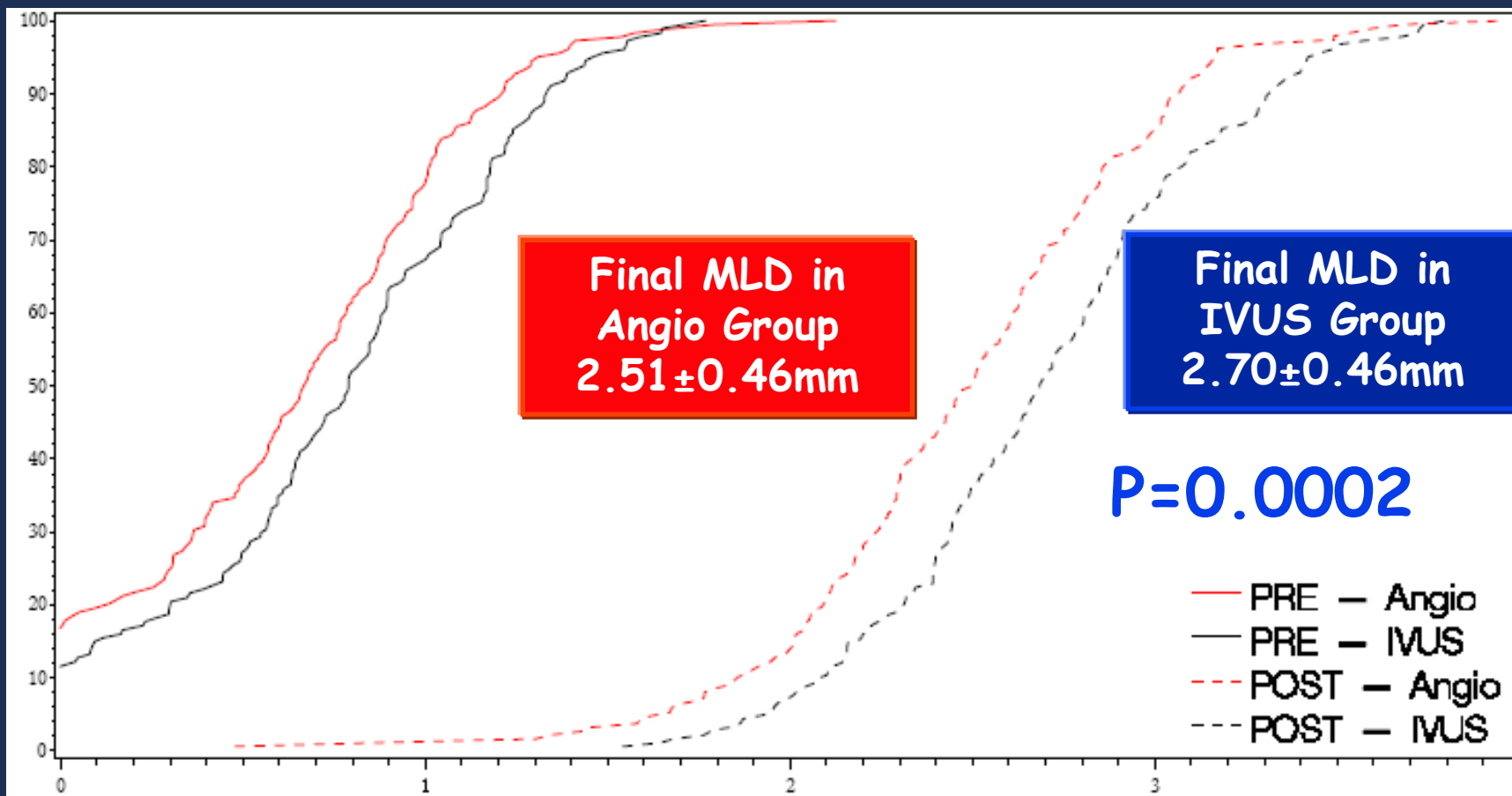
QCA measurements

	IVUS	Angio	P value
Baseline			
RVD (mm)	2.67 ± 0.46	2.62 ± 0.41	
Lesion length (mm)	27.4 ± 15.9	25.5 ± 15.0	
Baseline MLD (mm)	0.76 ± 0.46	0.65 ± 0.45	0.01
Baseline stenosis (%)	71.6 ± 15.8	75.5 ± 16.1	
In Lesion			
Final RVD (mm)	2.94 ± 0.42	2.81 ± 0.45	0.004
Final stenosis (%)	8.4 ± 7.9	10.5 ± 9.0	0.02
Final MLD (mm)	2.70 ± 0.46	2.51 ± 0.46	0.0002
In stent			
Final RVD (mm)	2.96 ± 0.46	2.83 ± 0.43	0.005
Final stenosis (%)	13.9 ± 7.3	15.5 ± 7.9	0.05
Final MLD (mm)	2.55 ± 0.46	2.39 ± 0.42	0.0006

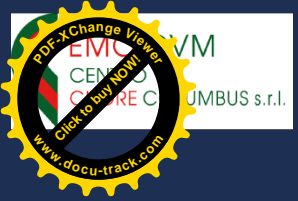


Primary Study End Point In lesion MLD

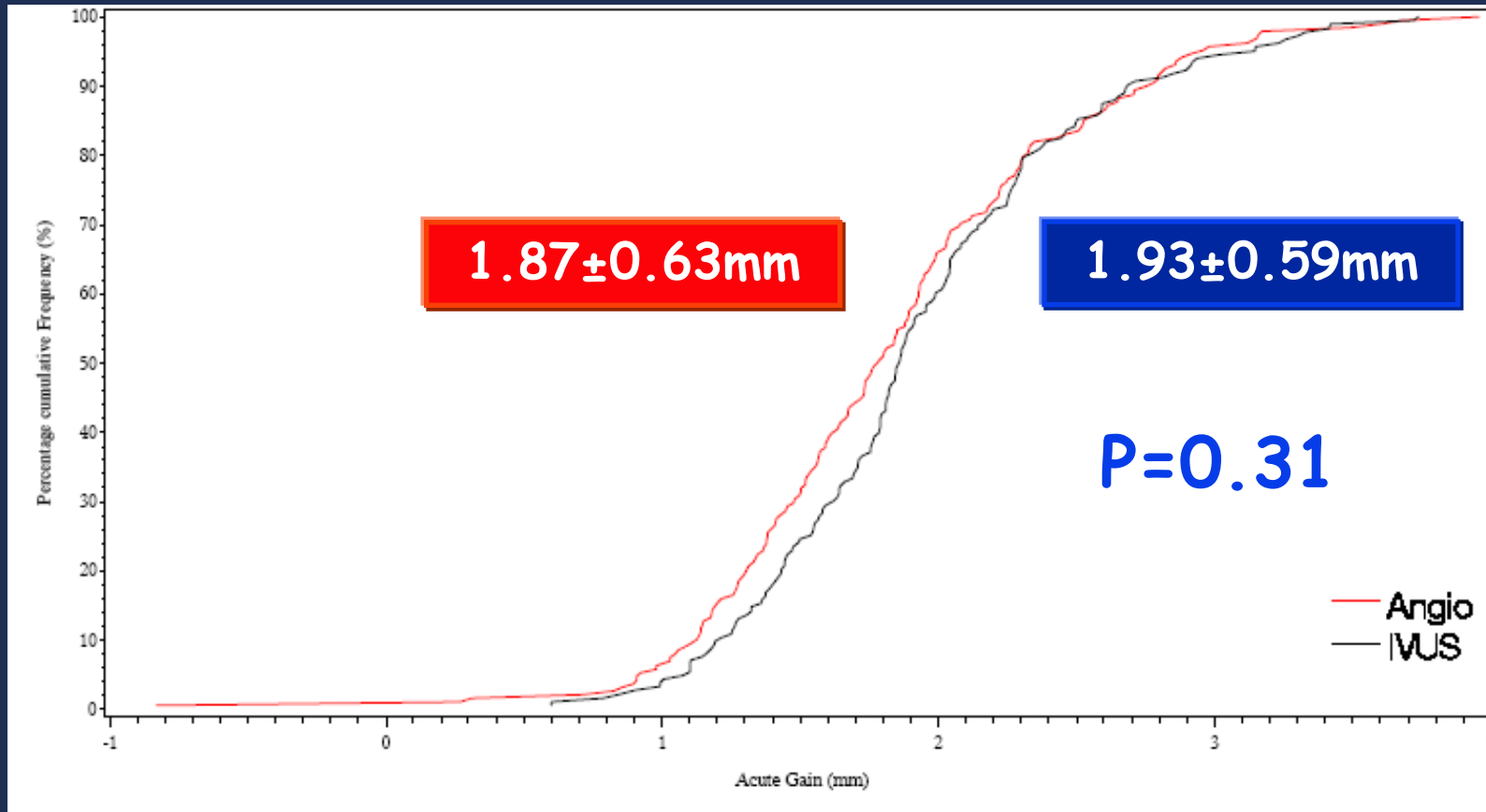
Cumulative Frequency %

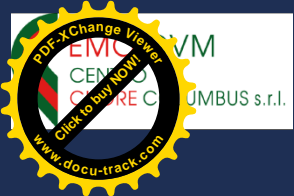


MLD (mm)



In lesion Acute Gain





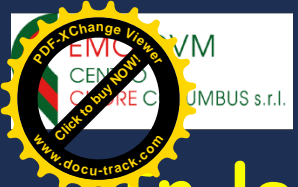
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QCA measurements in IVUS-optimized subgroup

	IVUS-AVIO criteria met	Angio	P value
Baseline	N-75 lesions	N-179 lesions	
MLD (mm)	0.79 ± 0.50	0.65 ± 0.45	0.03
Final In Lesion (Obstruction)			
MLD (mm)	2.86 ± 0.46*	2.51 ± 0.46	<0.0001
Acute gain	2.07 ± 0.59*	1.87 ± 0.63	0.02
Final In Stent			
MLD (mm)	2.68 ± 0.50*	2.39 ± 0.42	<0.0001
	IVUS-AVIO criteria not met	Angio	P value
Baseline	N-81	N-179	
MLD (mm)	0.76 ± 0.43	0.65 ± 0.45	0.054
Final In Lesion (Obstruction)			
MLD (mm)	2.6 ± 0.38*	2.51 ± 0.46	0.15
Acute gain	1.84 ± 0.52*	1.87 ± 0.63	0.7
Final In Stent			
MLD (mm)	2.51 ± 0.40*	2.39 ± 0.42	0.03

**p≤0.05 for comparison of IVUS lesions meeting AVIO criteria vs. lesions not meeting criteria

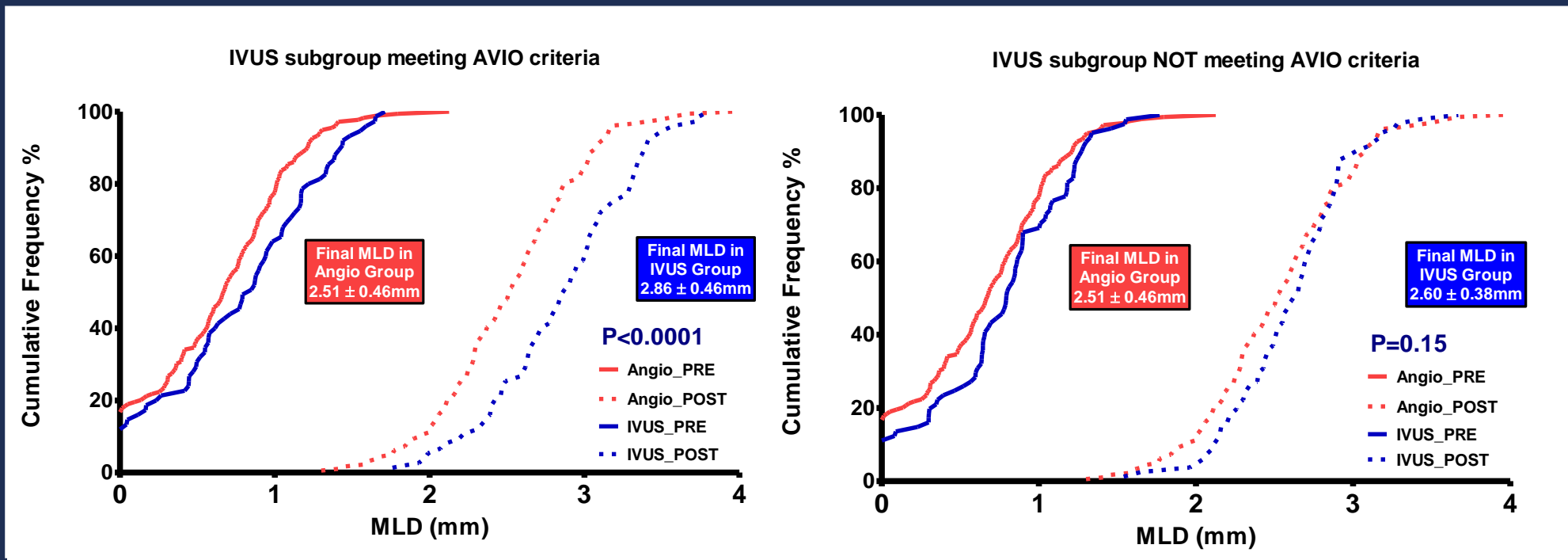


Primary Study End Point

In lesion MLD in lesion which met and did not meet AVIO criteria

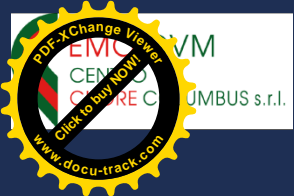
N= 75

N= 81



Criteria met

Criteria not met



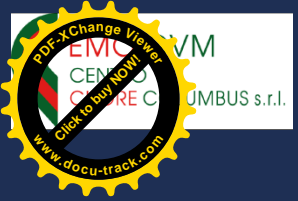
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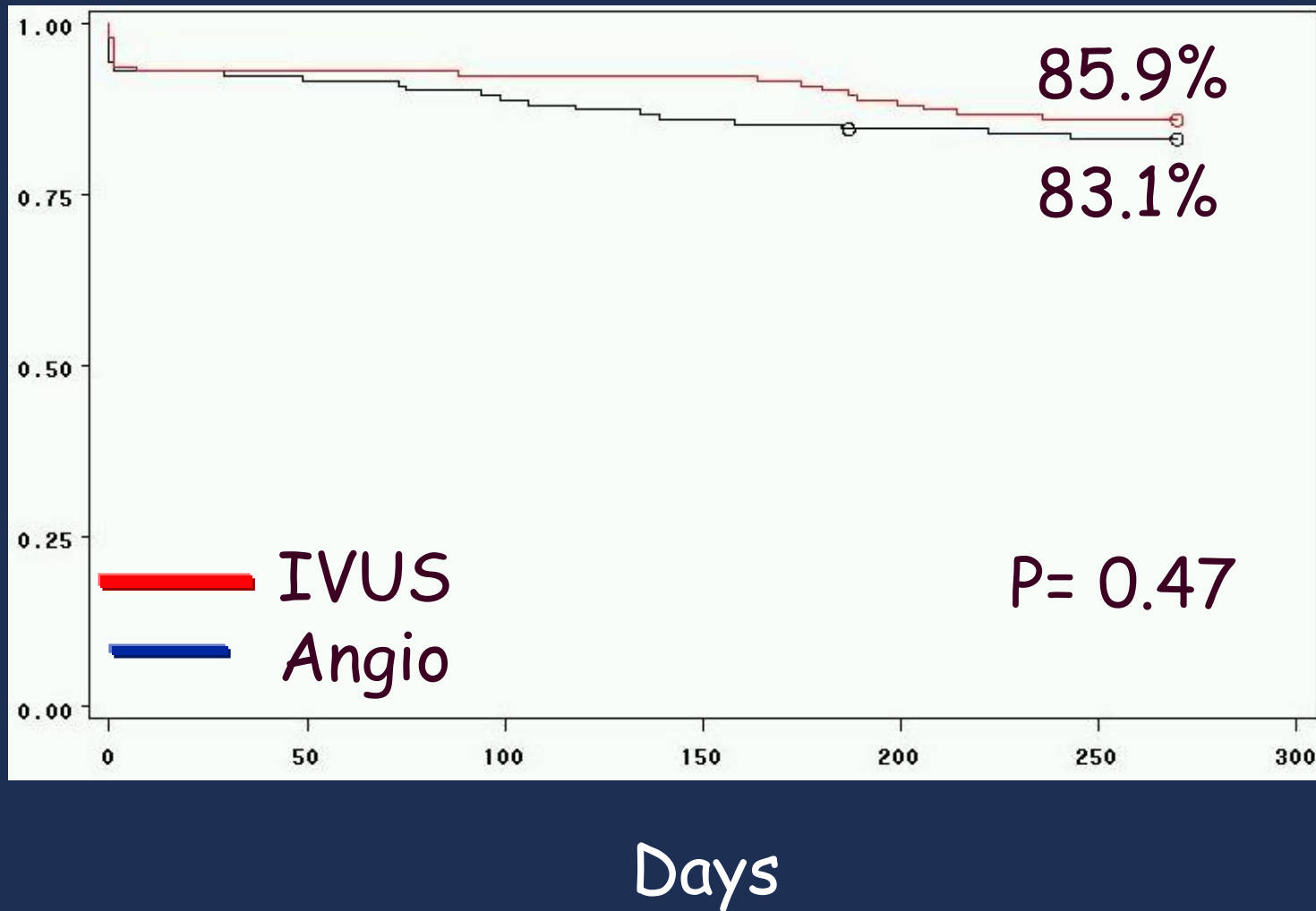


	IVUS (n= 142)	Angio* (n= 142)
30 days MACE (days 0-30)		
Q wave MI	0 (0%)	0 (0%)
Non-Q wave MI	10 (7.0%)	10 (7.0%)
TLR	1 (0.7%)	0 (0%)
TVR (including TLR)	1 (0.7%)	0 (0%)
Cardiac Death	0	1 (0.7%)
Cumulative at 9-month MACE (days 0-270)		
MI	10 (7.0%)	12 (8.5%)
TLR	10 (7.0%)	7 (5.0%)
TVR (including TLR)	11 (7.8%)	10 (7.8%)
Cardiac Death	0	2 (1.4%)

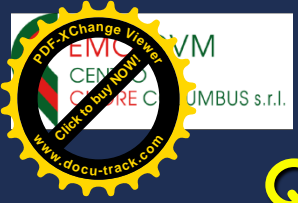
*One pt in the angio group was lost to follow-up at 9 months



Freedom from Cumulative MACE at 9 Months



1 definite stent thrombosis by ARC in IVUS group



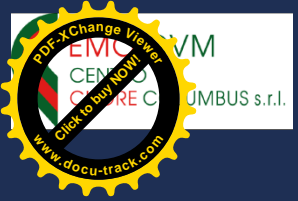
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QCA measurements at FU (9 months): 39% angio FU

	IVUS	Angio	P value
FU	Lesions=82 Patients=75	Lesions=67 Patients=52	
In Lesion (Obstruction)			
RVD (mm)	2.70 ± 0.46	2.65 ± 0.39	0.51
Stenosis (%)	13.0 ± 17.5	17.6 ± 20	0.14
MLD (mm)	2.56 ± 0.75	2.30 ± 0.68	0.03
Late loss	0.19 ± 0.58	0.30 ± 0.54	0.27
*Angiographic Restenosis			
-In-stent	7 (8.5%)	6 (9.0%)	0.93
-In-segment	16 (19.3%)	13 (18.8%)	0.95



Conclusions

- Our study demonstrated that a larger final MLD in lesion was obtained with IVUS guided DES post-dilatation (Primary Study End-Point)
- IVUS guided post-dilatation is safe procedure (no difference in 30 days MACE)
- No difference in cumulative 9-months MACE between IVUS and angio guided procedures
- Angiographic follow-up incomplete in order to make a statement regarding restenosis