

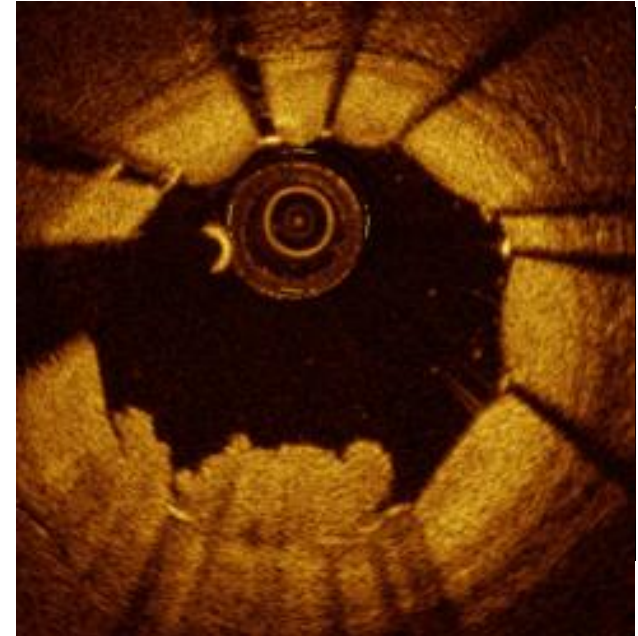
Building on early successes: one-year follow-up of the Stentys stent in STEMI patients (APPOSITION programme)

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On behalf of the APPOSITION investigators

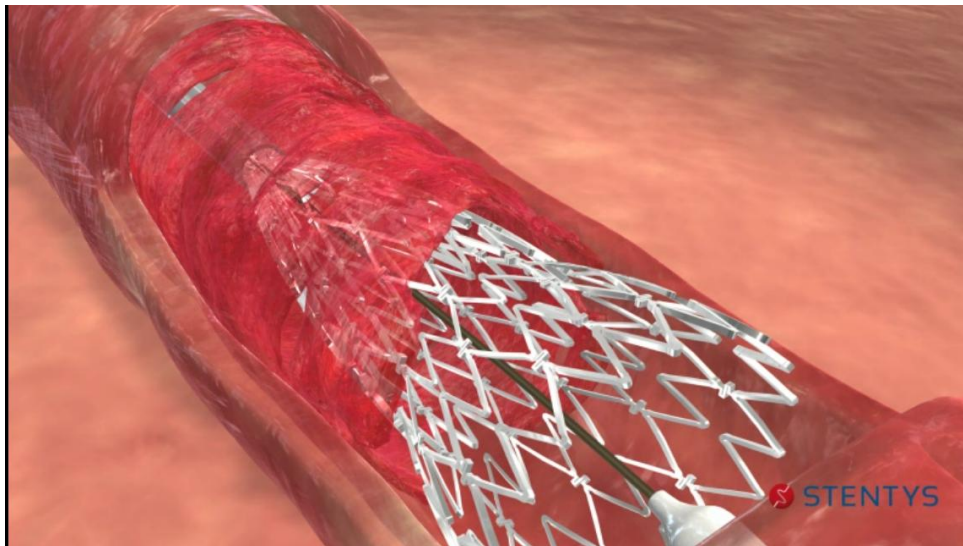
- Problems in AMI
 - Thrombus
 - Vasoconstriction
 - No-reflow
 - Late malapposition?
 - High rate of stent thrombosis
- Solution to these problems
 - Thrombo-aspiration, anti-platelet therapy, nitrates,
 - Oversizing?, High pressure stent implantation?
 - Assess the use of a self-expanding stent in AMI



Concept



- Self-expanding, Self apposing Nitinol stent which can increase in size after implantation
- Reduce acute and acquired malapposition
- Minimize embolization and no-reflow by avoiding aggressive postdilatation



- **DESIGN**
Prospective, non-randomized, single-arm, multi-center feasibility study
 - **OBJECTIVE**
To evaluate the safety and efficacy of the STENTYS® stent in AMI
 - **ENDPOINTS**
 - Stent apposition and expansion at 3 days
 - MACE at discharge and at 30 days
- Independent monitoring: Medpass*
Core lab: Cardialysis
Statistical analysis: INSERM U970 (Paris)
Prof. J.P. Tijssen (Amsterdam)

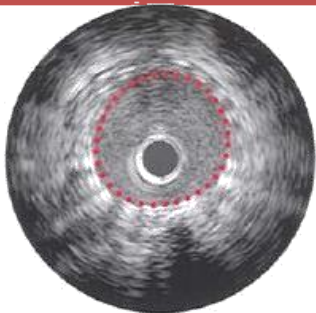
25 patients enrolled between March 2009 and October 2009 in 5 European clinical sites

25 patients with STENTYS® stent

IVUS at 0 and 3 days

Clinical follow-up at 30 days

Angiographic and IVUS follow-up at 6 months



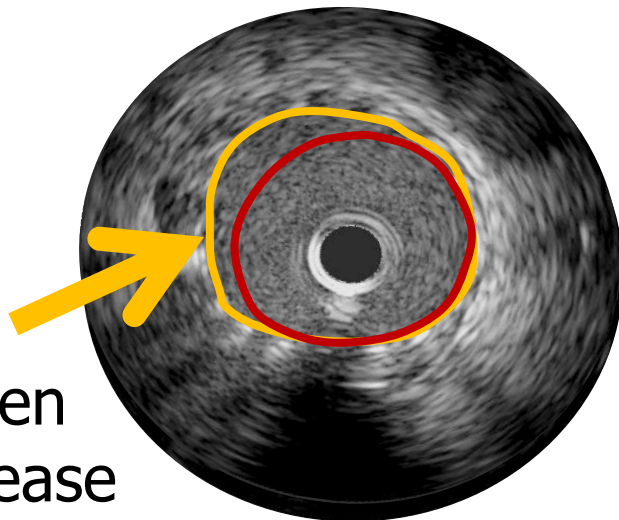
Post-PCI IVUS image of a STENTYS stent in AMI patient

IVUS image 3 days after procedure in this patient: 19% increase in reference lumen area

IVUS at baseline & 3 days

(paired; N=16)

	Baseline	3 day	Δ	p
Mean Reference Area (mm ²)				
Proximal	7.80 ± 2.33	8.21 ± 2.33	5%	NS
Distal	6.24 ± 2.05	7.41 ± 3.22	19%	p<0.02
Mean Lumen Area (mm ²)	7.55 ± 1.92	8.96 ± 2.27	19%	P<0.001
Mean Stent Area (mm ²)	7.60 ± 1.90	9.13 ± 2.41	20%	p=0.001
Minimum Lumen Area (mm ²)	5.19 ± 1.52	6.25 ± 1.61	20%	p=0.001



20% lumen
area increase

Mean Distal Reference
Area increase: 19%

At implantation
3 day follow-up

Adverse events (n=25)



	30 days	6 months	12 months
Cardiac death	0	0	0
Re- MI	0	0	0
Clinically driven TLR	0	3	4
Stent thrombosis	0	0	0
Total MACE	0	3	4

- **DESIGN**

International, prospective, randomized, two-arm multi-center trial

- **OBJECTIVE**

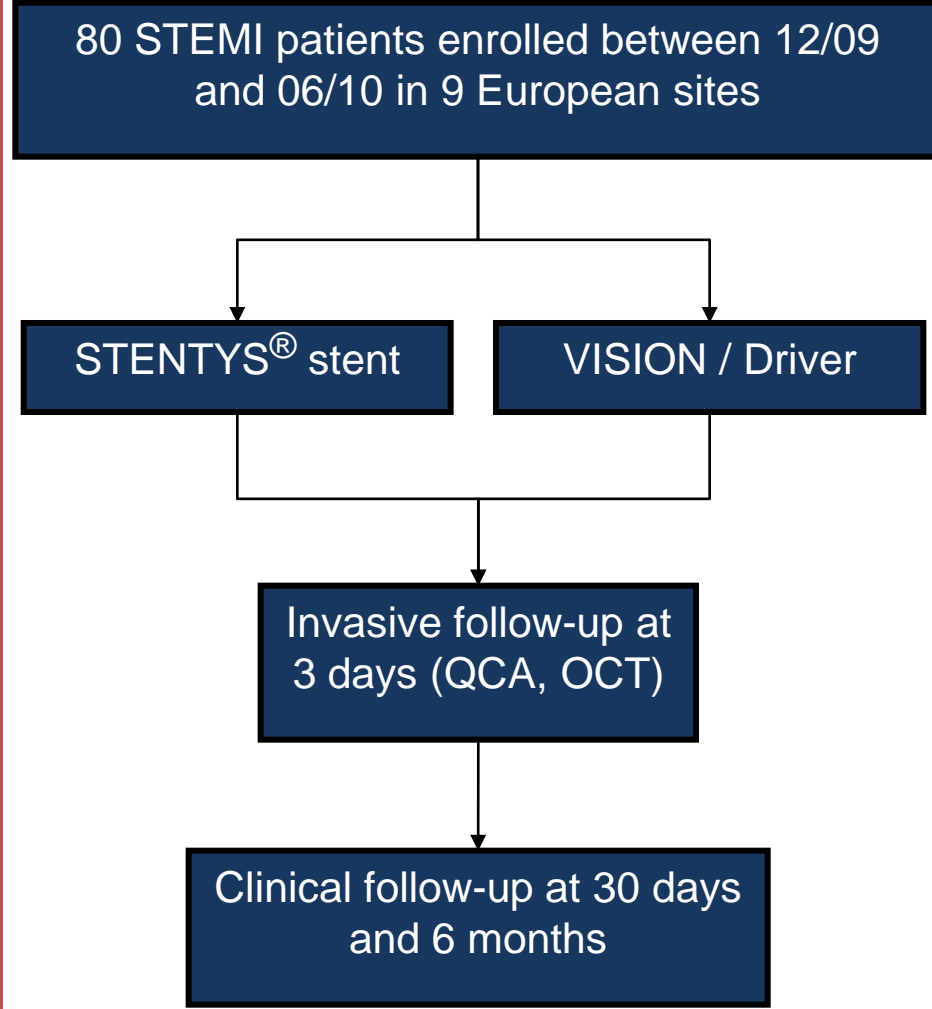
To compare the STENTYS® Stent with balloon-expandable stents in AMI

- **ENDPOINTS:**

- **Stent strut apposition** and expansion at 3 days (measured by OCT)
- MACE @30 days and 6 months

Independent monitoring: Genae

Core Lab: Cardialysis



Patient Characteristics



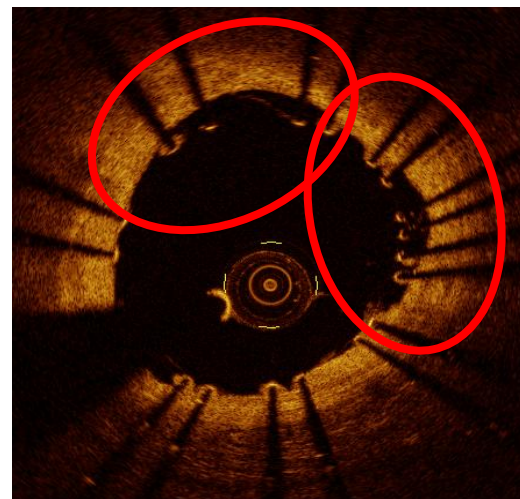
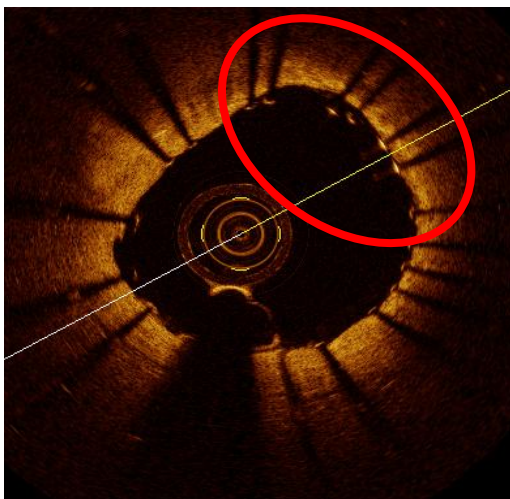
	STENTYS n=43	Control n=37	P Value
Age (mean)	61.7	59.3	NS
Male (%)	81.4	78.4	NS
Diabetes mellitus (%)	16.3	13.5	NS
Hypertension (%)	44.2	51.4	NS
Hypercholesterolemia (%)	44.2	51.4	NS
Smoking (current/previous)(%)	74.4	75.9	NS
Previous MI (%)	0.0	0.0	NA
Previous PCI (%)	0.0	0.0	NA
Target vessel LAD/LCX/RCA (%)	44 / 12 / 44	32 / 16 / 52	NS
Mean AMI time (hrs:min)	3:41	4:14	NS

Balloon vs Self-expanding

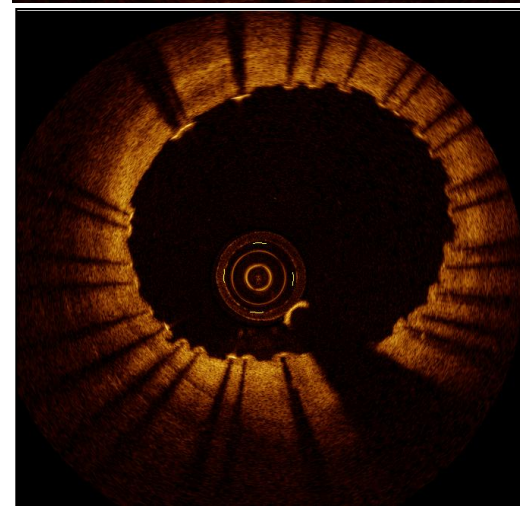
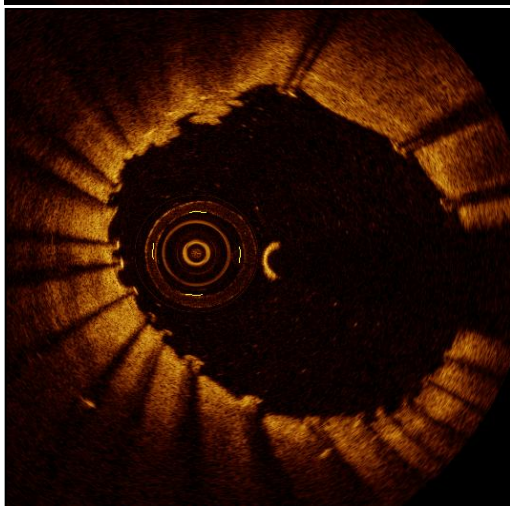
Day 0

Day 3

Balloon-
expandable
stent



STENTYS[®]
Coronary
Stent



Optical Coherence Tomography



	Stentys n=40	Control n=36	P Value
Post-PCI			
Mean Lumen area (mm ²)	7.88 ± 2.32	8.92 ± 2.22	NS
Mean Stent area (mm ²)	7.57 ± 2.29	8.95 ± 2.38	NS
Stent volume (mm ³)	191 ± 65	210 ± 83	NS
3 days follow-up			
Mean Lumen area (mm ²)	8.99 ± 2.39	8.81 ± 2.18	NS
Mean Stent area (mm ²)	9.02 ± 2.36	8.76 ± 2.26	NS
Stent volume (mm ³)	228 ± 72	206 ± 86	NS



15% increase

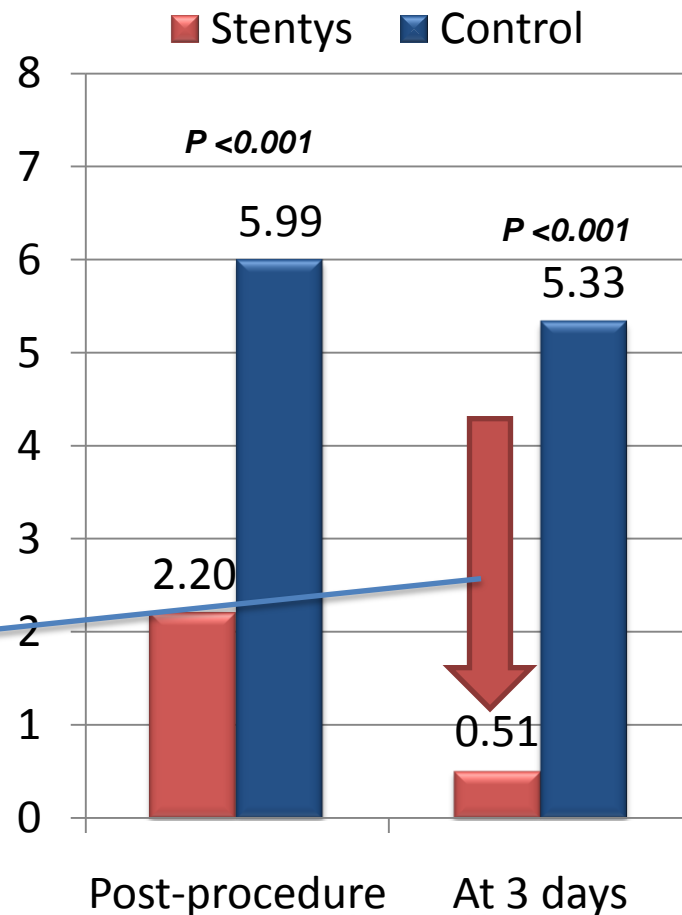
Primary study endpoint

Stent strut malapposition at 3 days



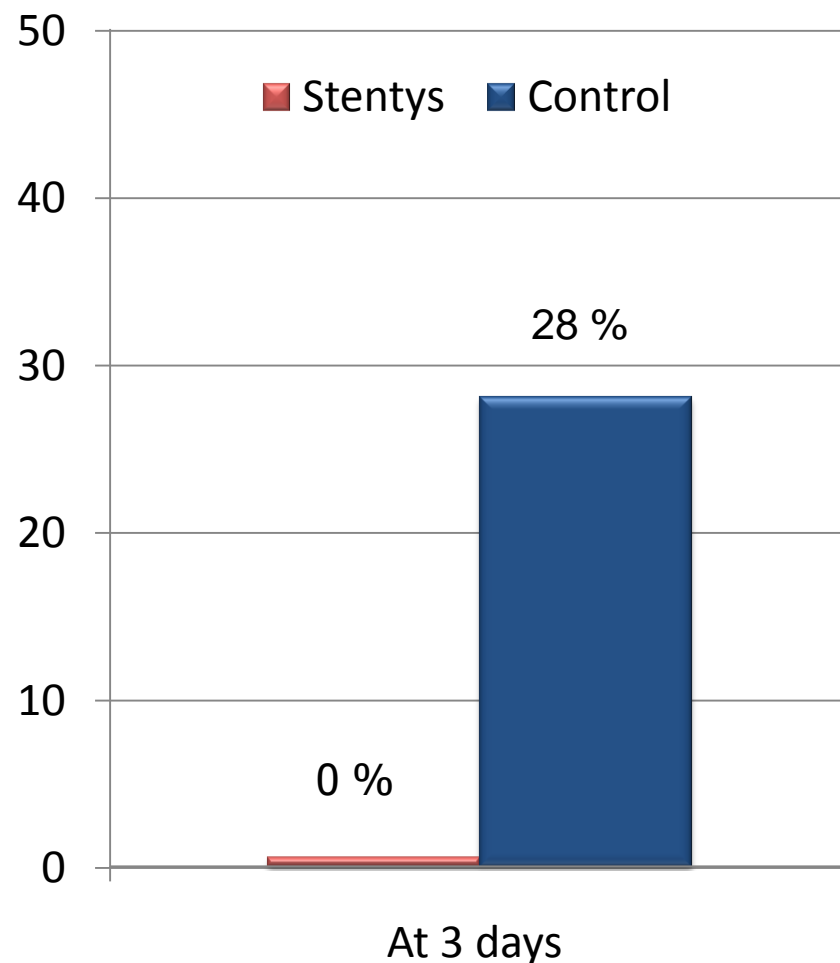
	STENTYS n = 40	Control n = 36	P Value
Post PCI	2.20%	5.99%	<0.05
3 days	0.51%	5.33%	<0.001

10-fold reduction in malapposition



STENTYS n = 40	Control n = 36	P Value
0 %	28 %	<0.001

Definition malapposed stent¹:
≥ 5% malapposed struts



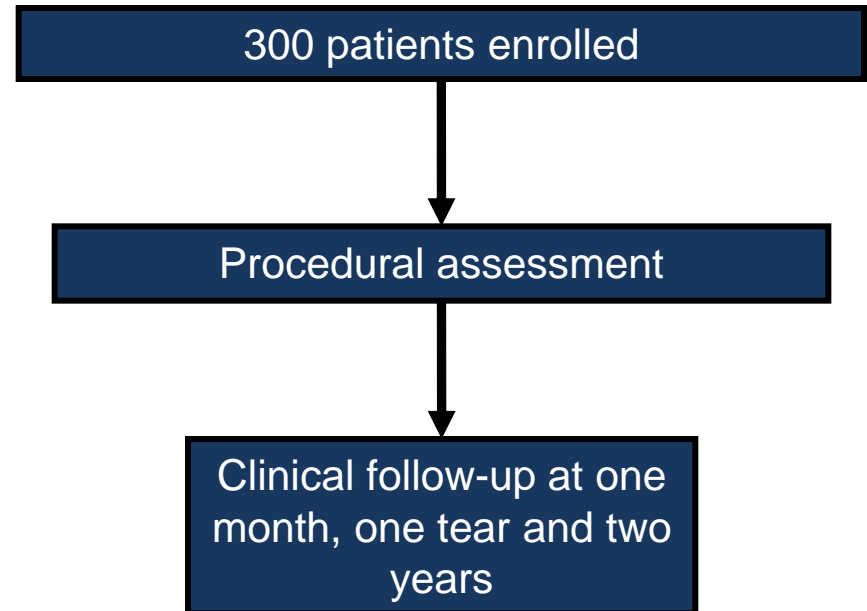
¹P. Barlis et al. *Eur Heart J* (2010) 31 (2): 165-176

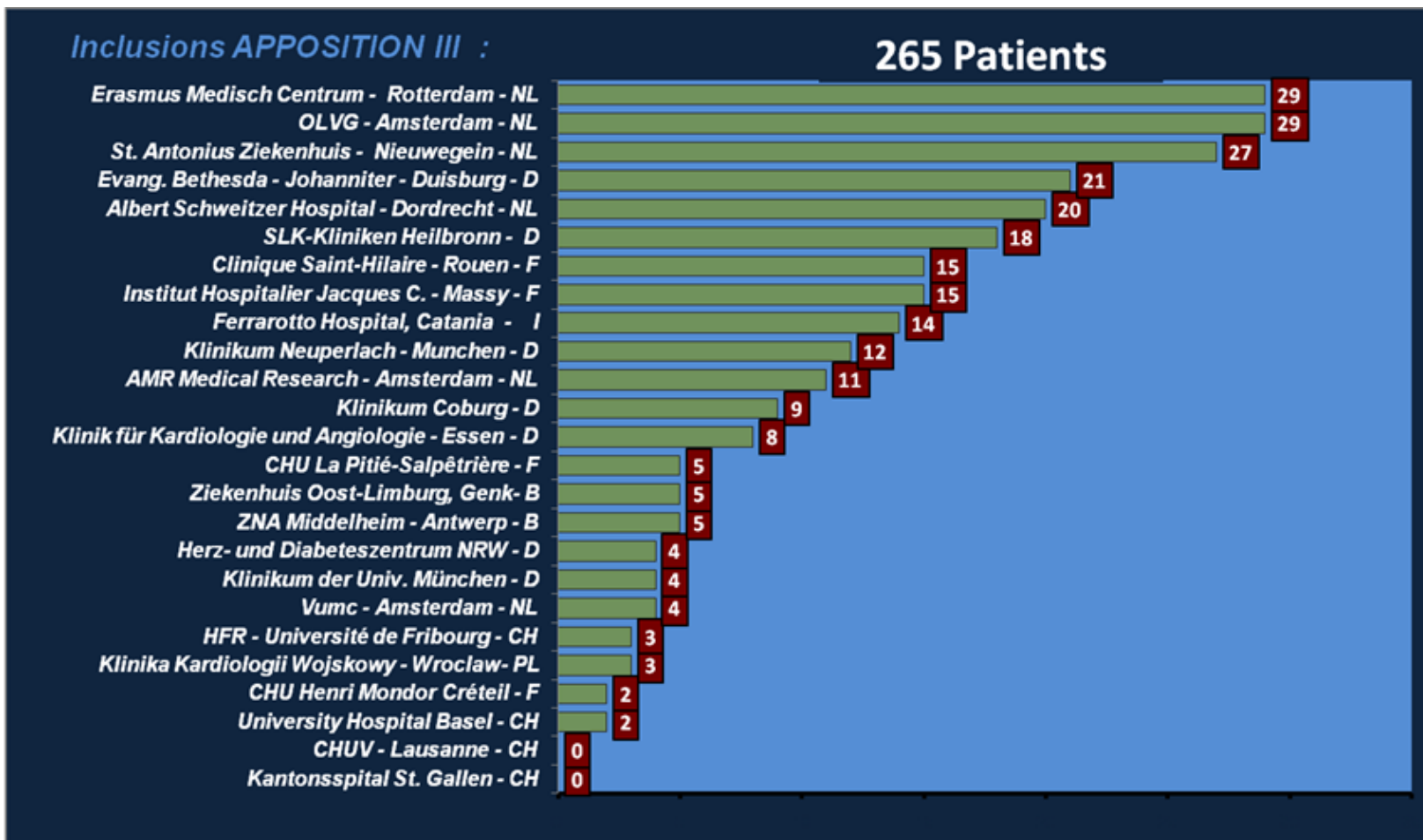
	STENTYS (n=43)	Control (n=37)
Cardiac Death	0	0
Re-Myocardial Infarction	0	0
Emergent Bypass Surgery	0	0
Clinically driven TLR	1	0
Stent thrombosis	0	0
Total MACE	1	0

All SAE's adjudicated by independent CEC

- **DESIGN**
Prospective, non-randomized, single-arm, real-life registry
- **OBJECTIVE**
To evaluate the long term safety of the STENTYS® stent in AMI
- **ENDPOINT**
 - MACE at one year

Independent monitoring
Independent CEC





STENTYS stent (N= 68)



Combined clinical outcome at 6 months

Cardiac Death	0
Re-Myocardial Infarction	0
Emergent Bypass Surgery	0
Clinically driven TLR	4
Stent thrombosis	0
Total MACE	4 (5.9%)

All SAE's adjudicated by independent CEC



Design

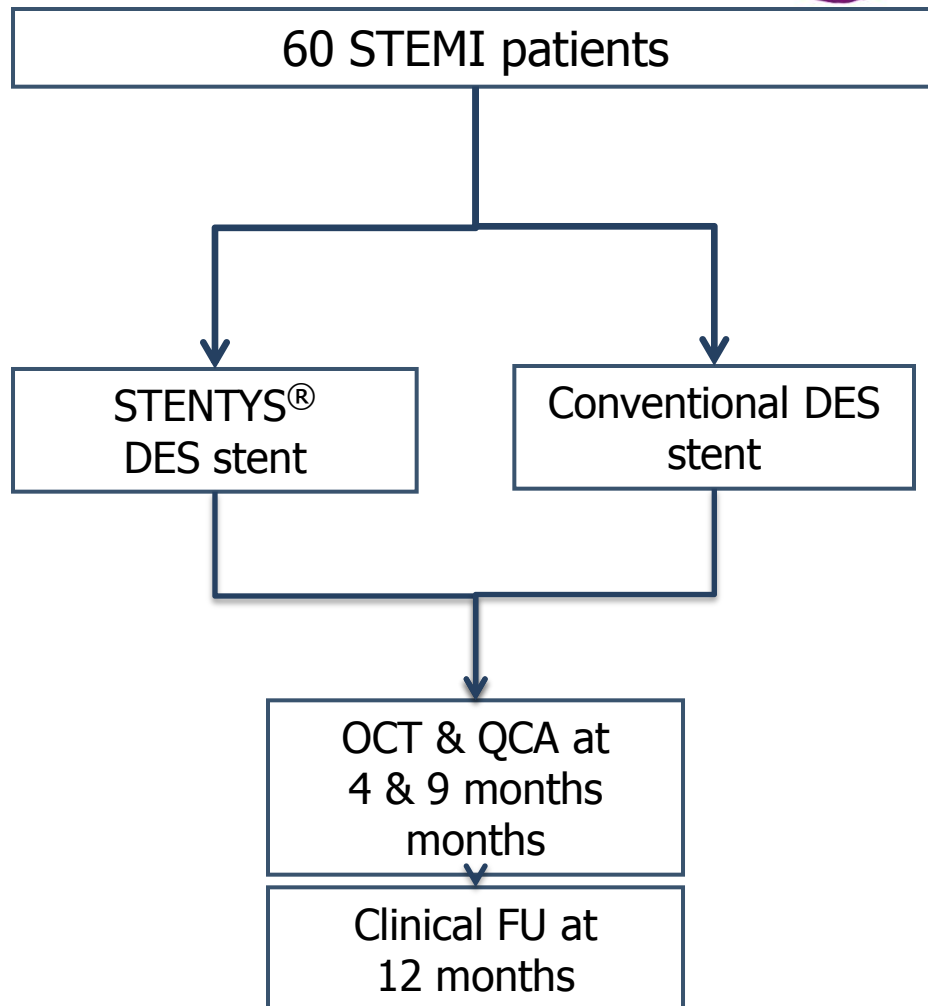
DESIGN Prospective, randomized, two-arm multi-center study

OBJECTIVE

To compare the **endothelization of the STENTYS® DES** with a balloon-expandable DES in AMI

ENDPOINTS

- % of uncovered struts at 4 & 9 months
- MACE up to 12 months



Conclusions



- APPOSITION I showed that vasodilation following PPCI can represent an increase of 19% of vessel area
- APPOSITION II showed that 28% of balloon-expandable stents are malapposed and that the STENTYS stent eliminates malapposition (0% at 3 days)
- At 6 month and 12 month, clinical results show a good efficacy of the STENTYS BMS
- APPOSITION III will evaluate the clinical benefits on improved stent apposition
- APPOSITION IV will study malapposition of DES version