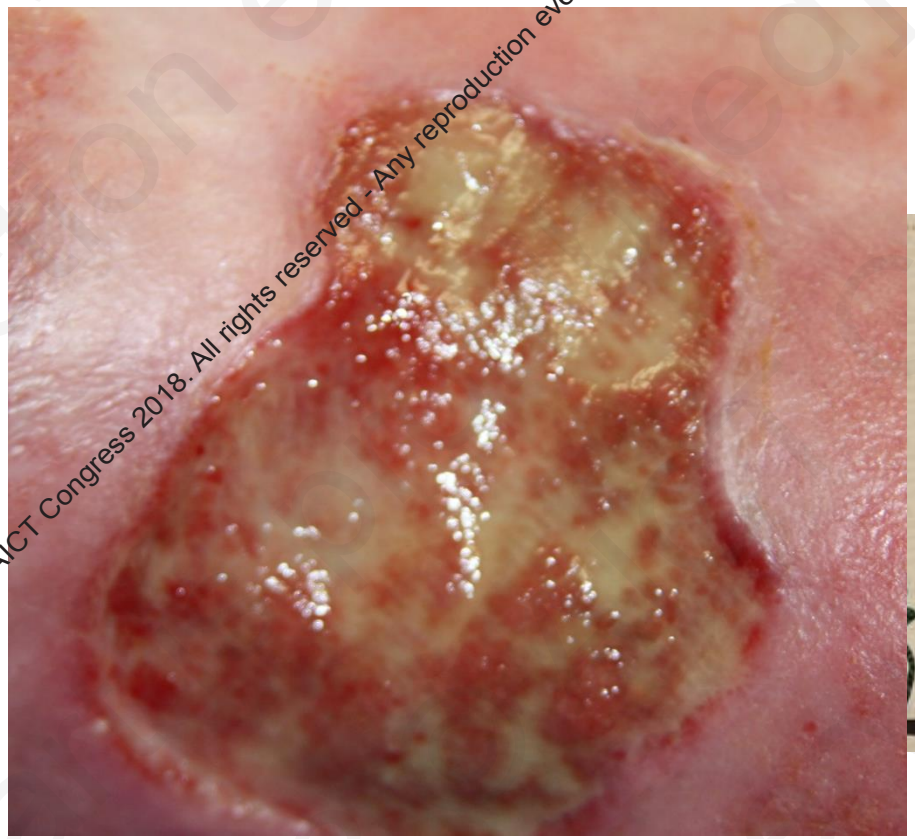
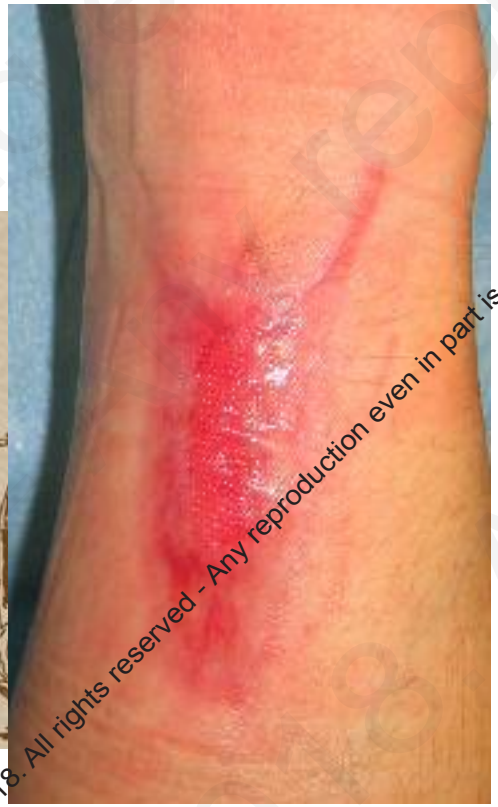
Can COMBO DAPT Flexibility Benefit Other Patients

Dr. Angus Shing Fung Chui
Associate Consultant
Queen Elizabeth Hospital
Hong Kong

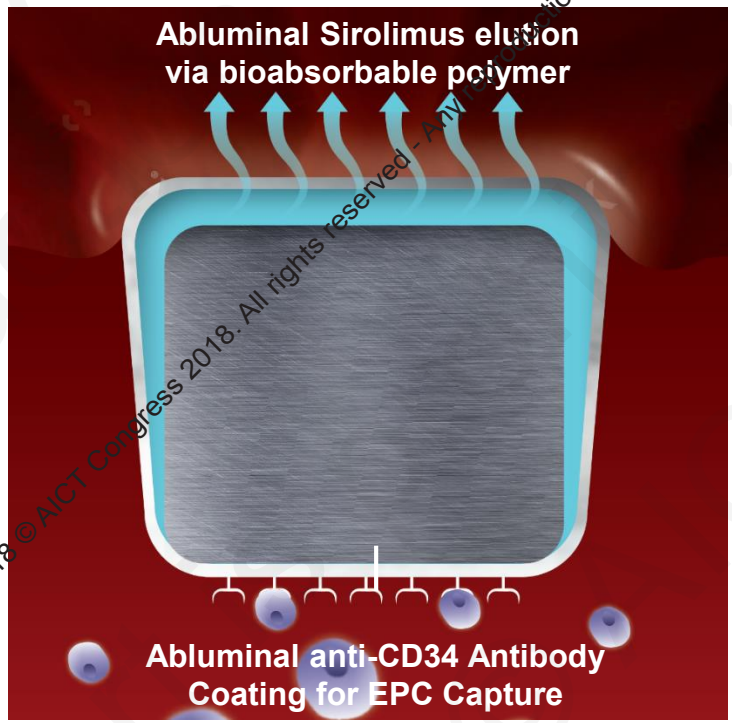
伊利沙伯醫院
QUEEN ELIZABETH HOSPITAL

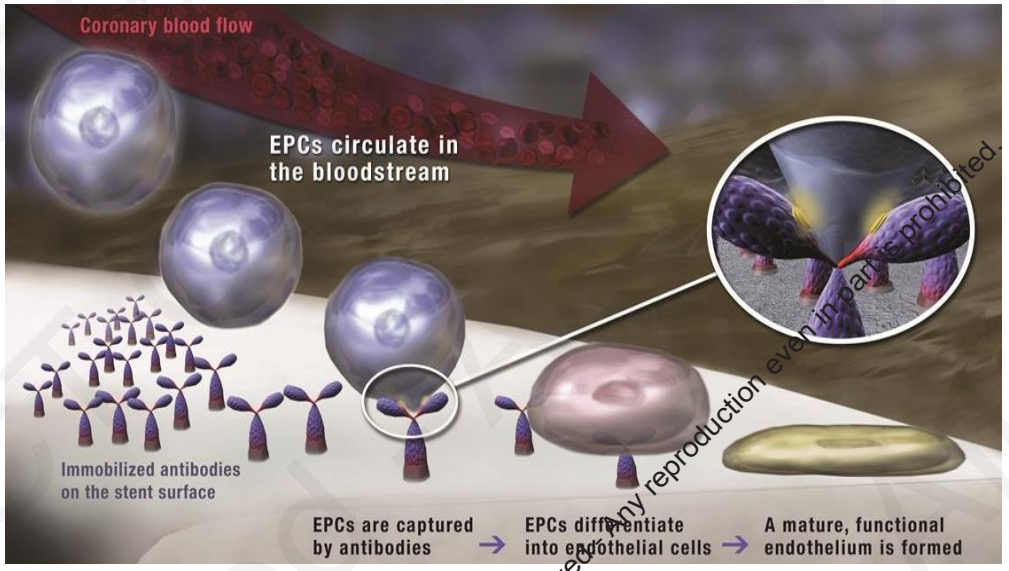
What is healing?





COMBO Dual Therapy Stent Design and Function

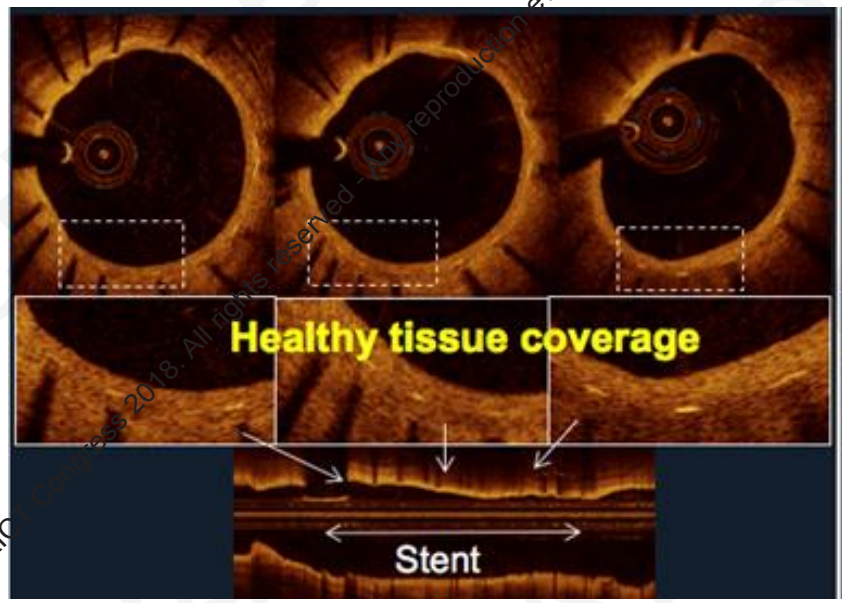




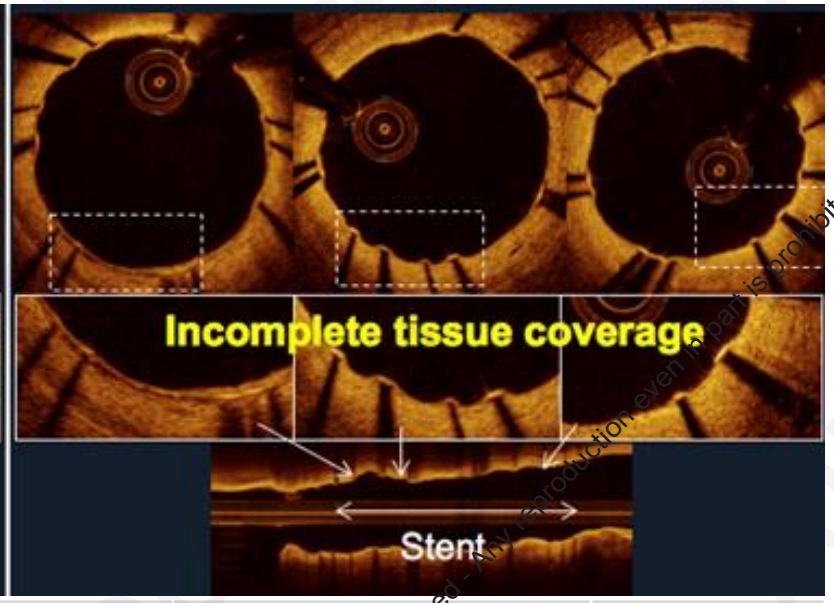
Early restoration of functional endothelium via rapid EPC capture may be beneficial under ACS

Superior Healthy Tissue Coverage vs. EES

COMBO

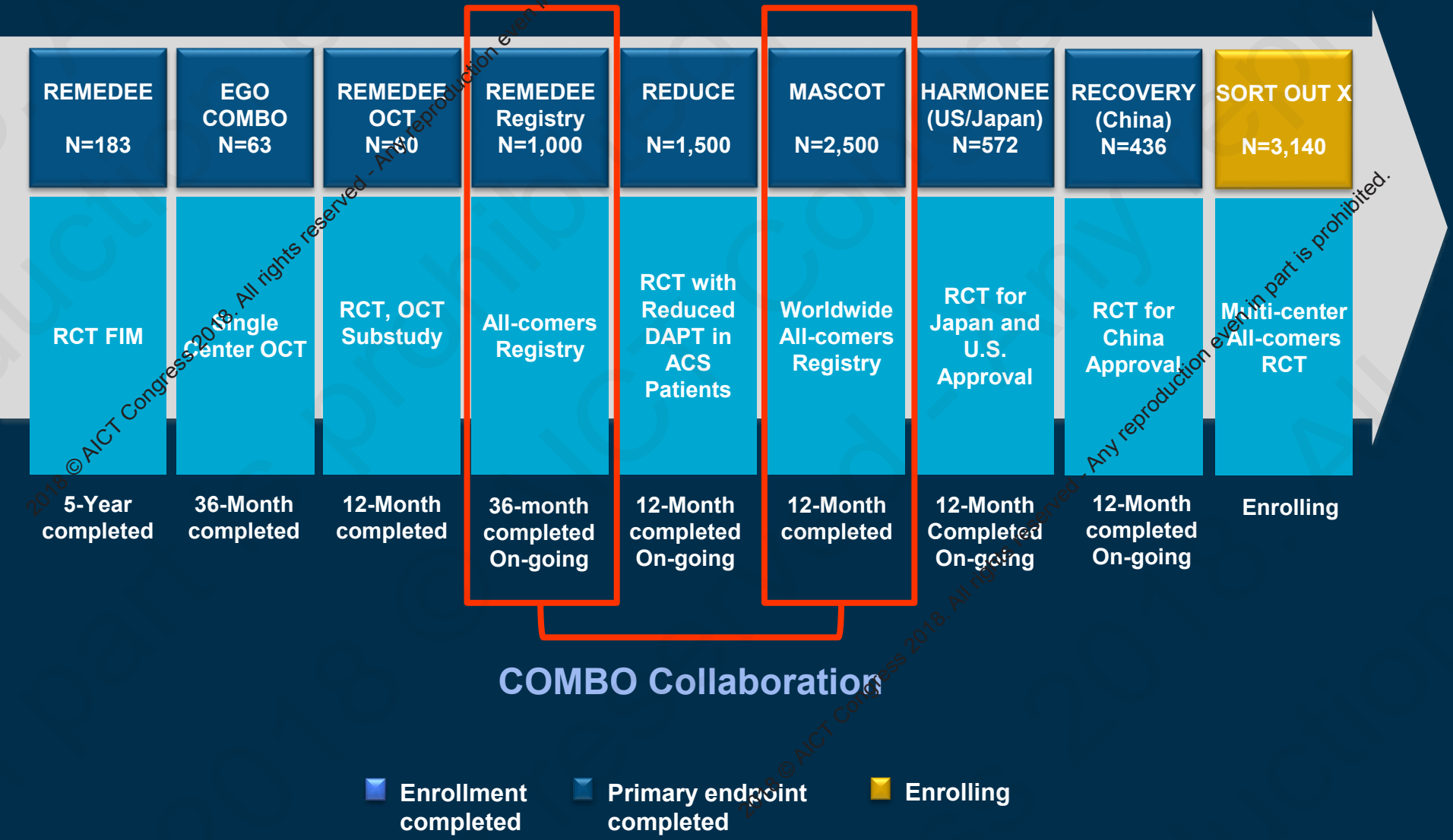


EES



	COMBO	**EES**	P-value
Number of lesion/patients	(69/61)	(64/60)	
(Mean %) [95% CI]	**91.56 [88.98, 94.13]**	**74.82 [70.02, 79.62]**	**<0.001**

Combo Clinical Trial Program



REMEDEE Registry

Primary objective:

- To evaluate the immediate and long term safety and performance of the abluminal sirolimus coated bio-engineered stent (COMBO) in routine clinical practice

Primary endpoint:

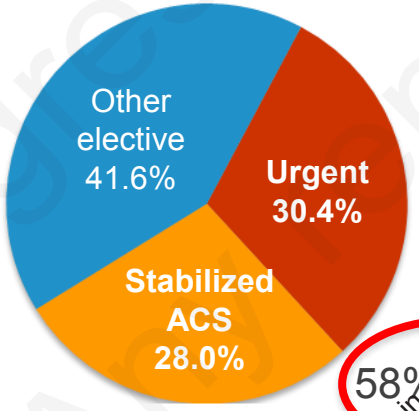
- Target Lesion Failure
  - Cardiac Death
  - Non-Fatal Target Vessel MI
  - Target Lesion Revascularization

REMEDEE registry

Patient Characteristics	N=1,000
Diabetes	18.4%
Insulin-dependent	6.4%
Hypertension	58.0%
Hypercholesterolemia	56.2%
Family history of CAD	45.5%
Prior PCI	30.1%

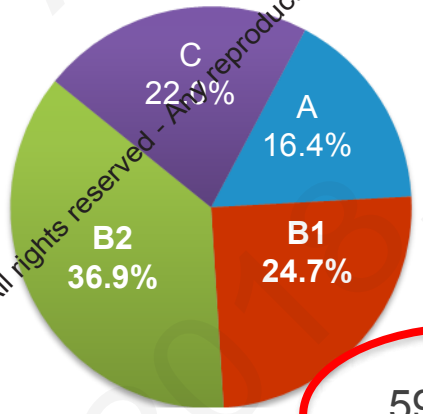
Lesion Characteristics	N=1,255
Length (mm)	15.0
RVD (mm)	3.0
Diameter stenosis	90.0%
Native coronary artery	95.4%
B2/C lesions	58.9%
Multi-vessel disease	10.5%

Indication for PCI



58% ACS

AHA/ACC Lesion Classification



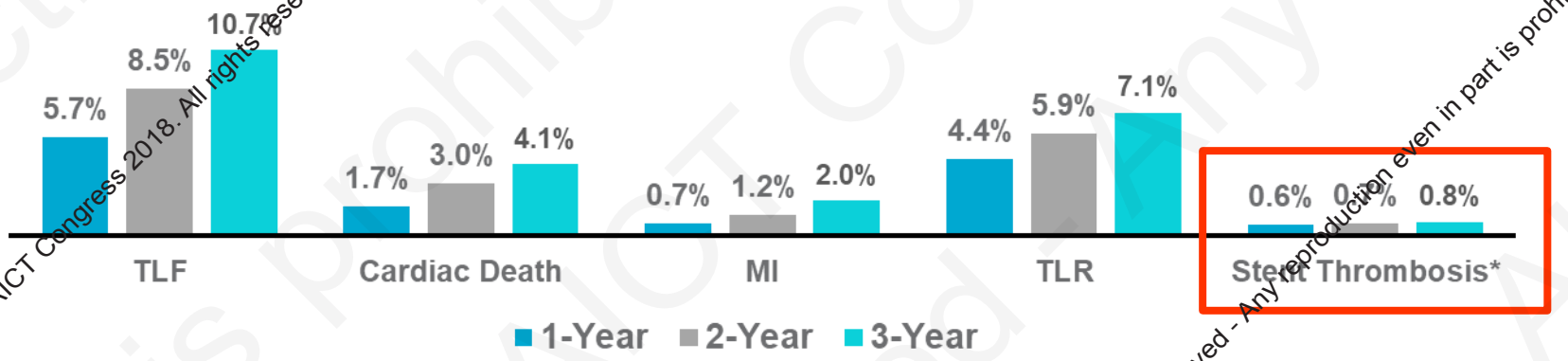
59% Type B2/C lesions

Source: P. Woudstra et al. J Am Coll Cardiol Intv. 2016; 9(11):1127-1134.

What we know…

REMEDEE registry

Clinical Outcomes Out to 3 Years

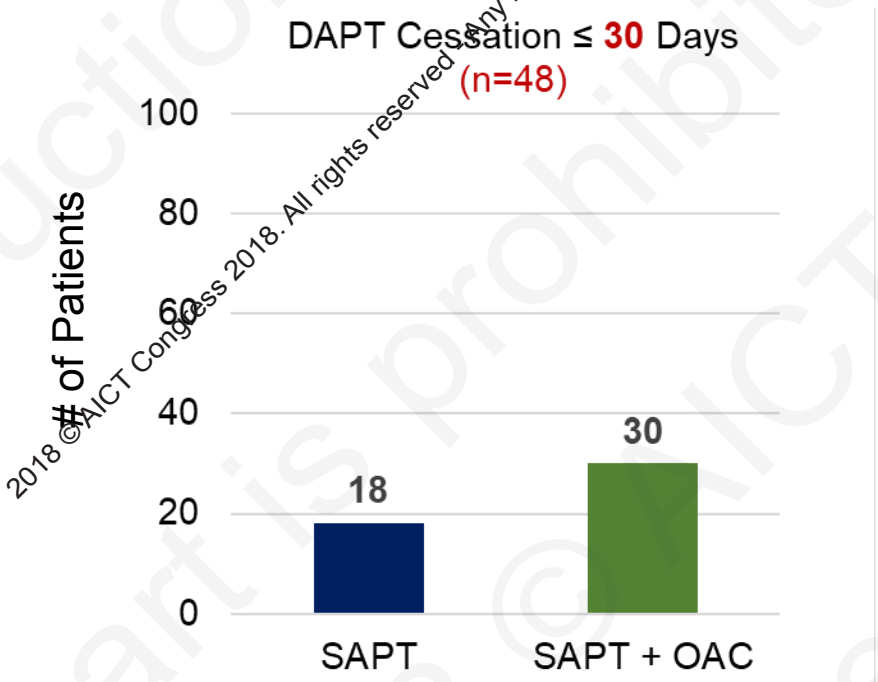


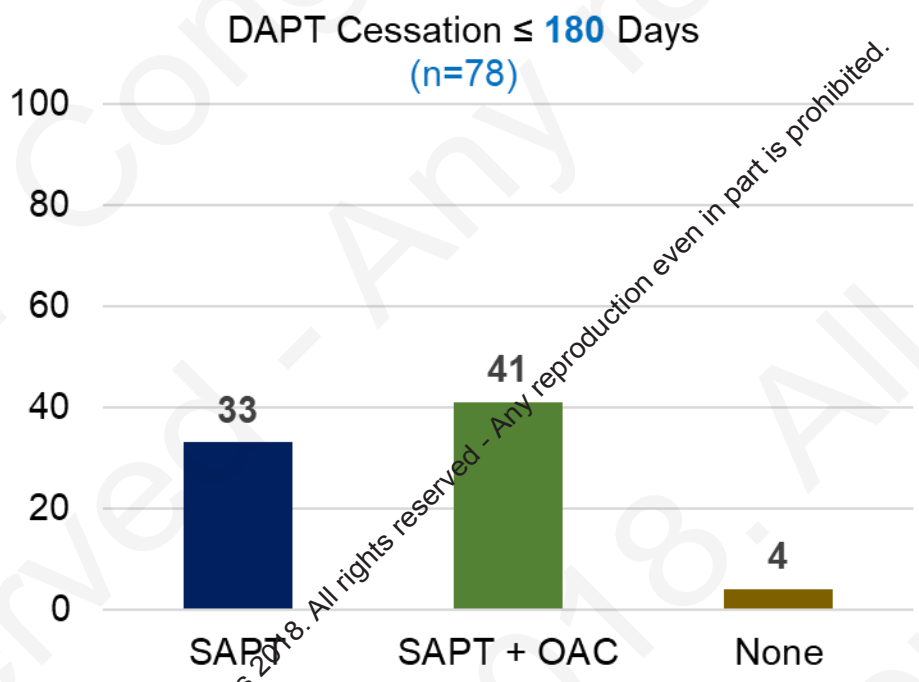
*1-Year: All 6 events (4 STEMI patients) within 9 days post procedure
2-Year: ACS patient at 380 days after DAPT cessation

- All ST at 1 year ≤ 9 days of PCI
- Only 1 VLST from 2 to 3 years

D. Kalkman, Oral Abstract Presentation, TCT 2017

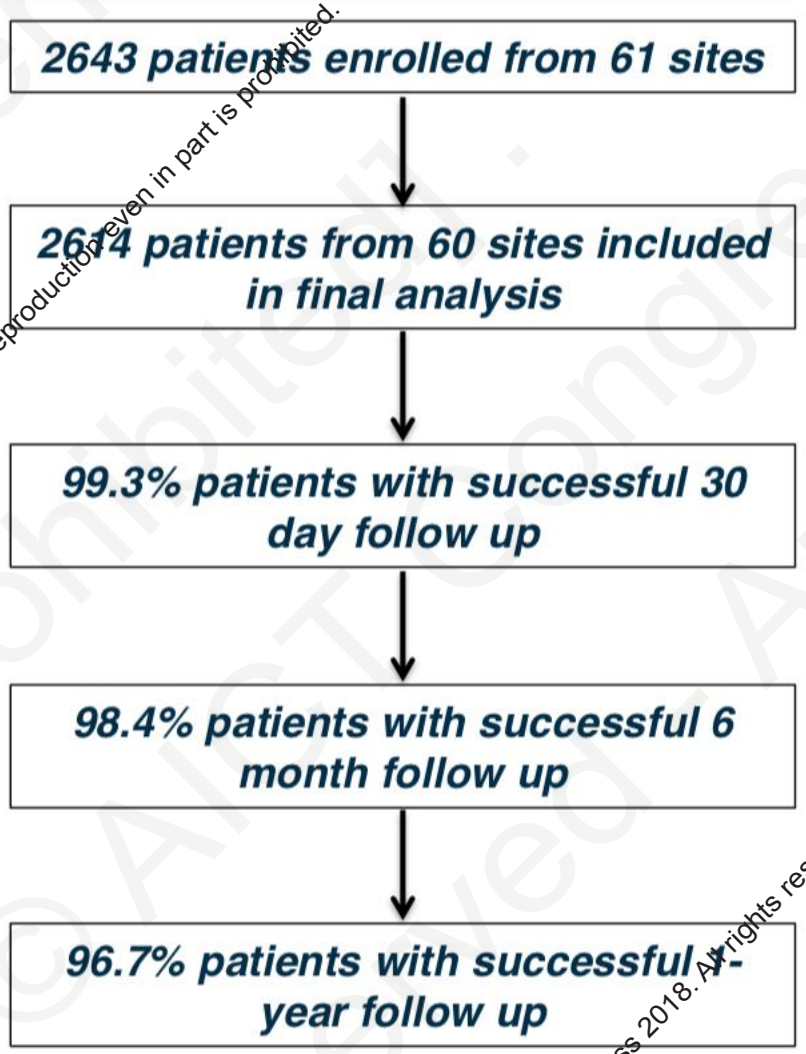
REMEDEE Registry Early DAPT Discontinuation





0% event rates of TLF, TV-MI and ST in patients with early DAPT discontinuation

Study Flow



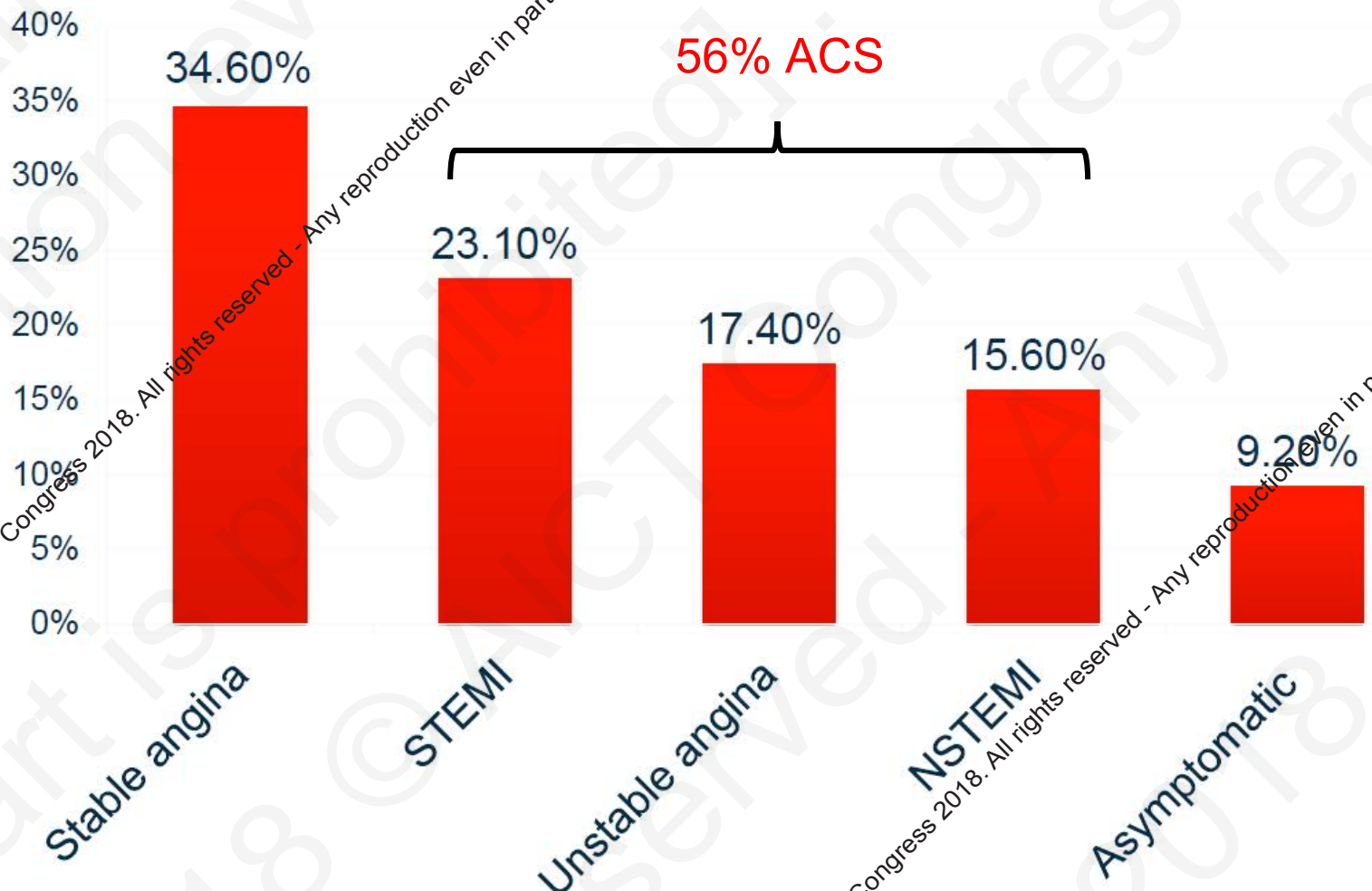
26 patients with delinquent data entry, 1 patient with duplicate data entry, 2 enrolled patients with exclusion criteria excluded

1 patient withdrew consent

Primary endpoint: 12 month Target lesion failure composite of cardiac death, non-fatal MI not clearly attributable to a non-target vessel or ischemia driven TLR

2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.
2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

CAD presentation



Clinical Outcomes at 1Year

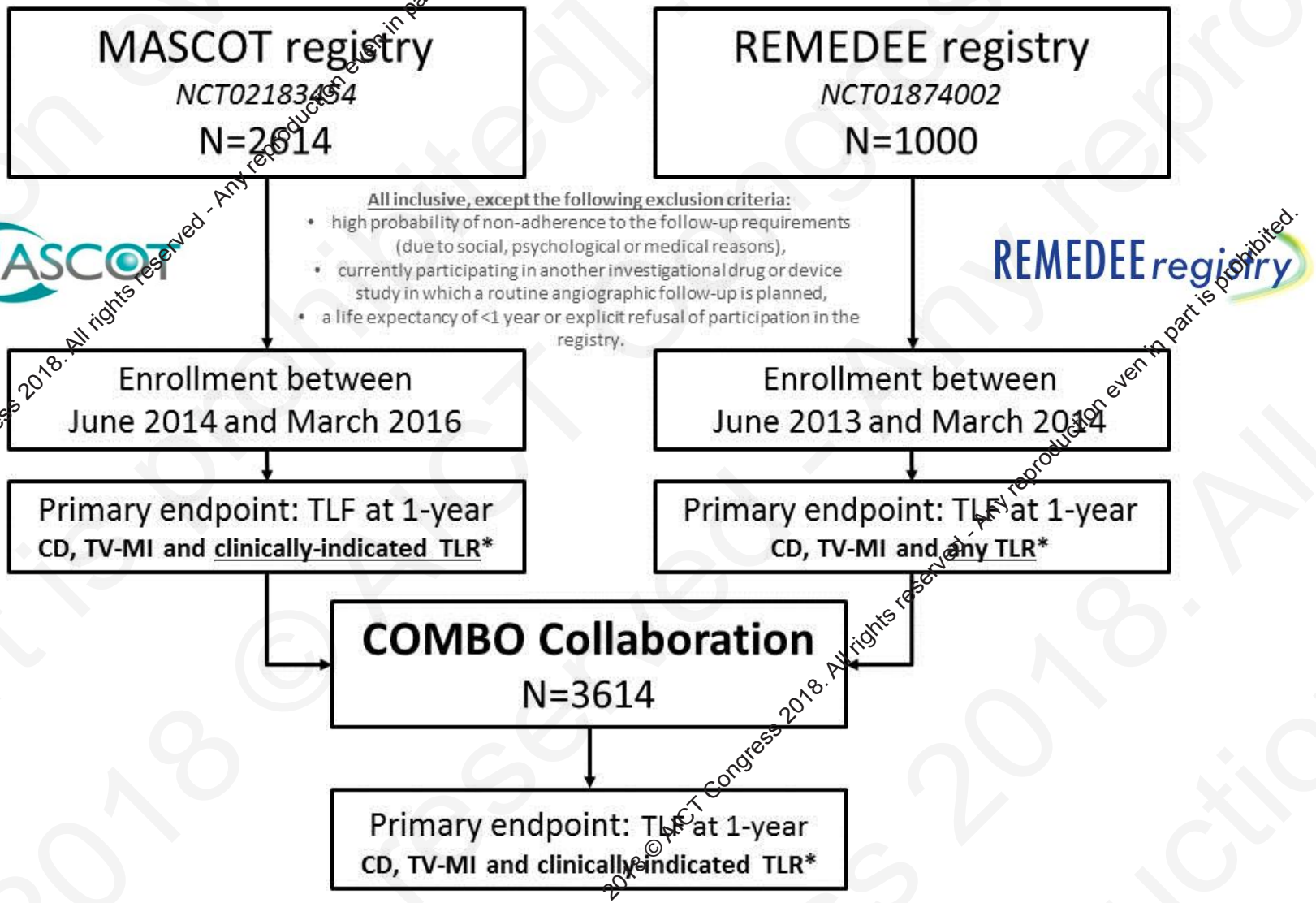
	N=2614
Primary endpoint: TLF	**88 (3.4%)**
All cause Death	53 (2.0%)
• Cardiac	36(1.4%)
• Non Cardiac	14 (0.5%)
• Cardiovascular	39 (1.5%)
Non-fatal MI	
• Not clearly attributed to a non-target vessel	36 (1.4%)
• Any	49 (1.9%)
Ischemia driven revascularization	
• TLR	37 (1.4%)
• TVR	12 (0.5%)
• NTVR	37 (1.4%)
• Any	72 (2.8%)

Def/Prob Stent Thrombosis	24 (0.9%)
• Def ST	12 (0.46%)
• Prob ST	12 (0.46%)
MACE	137 (5.2%)
Stroke	11(0.42%)
Bleeding	
• Major	46 (1.8%)
• Minor	63 (2.4%)
• Nuisance	20 (0.8%)
• Any	124 (4.8%)

- **56% ACS**
- **57% Type B2/C lesions**

A. Colombo, Oral Presentation, TCT 2017

COMBO Collaboration - Methods



R Mehran, Oral Presentation, EuroPCR 2018

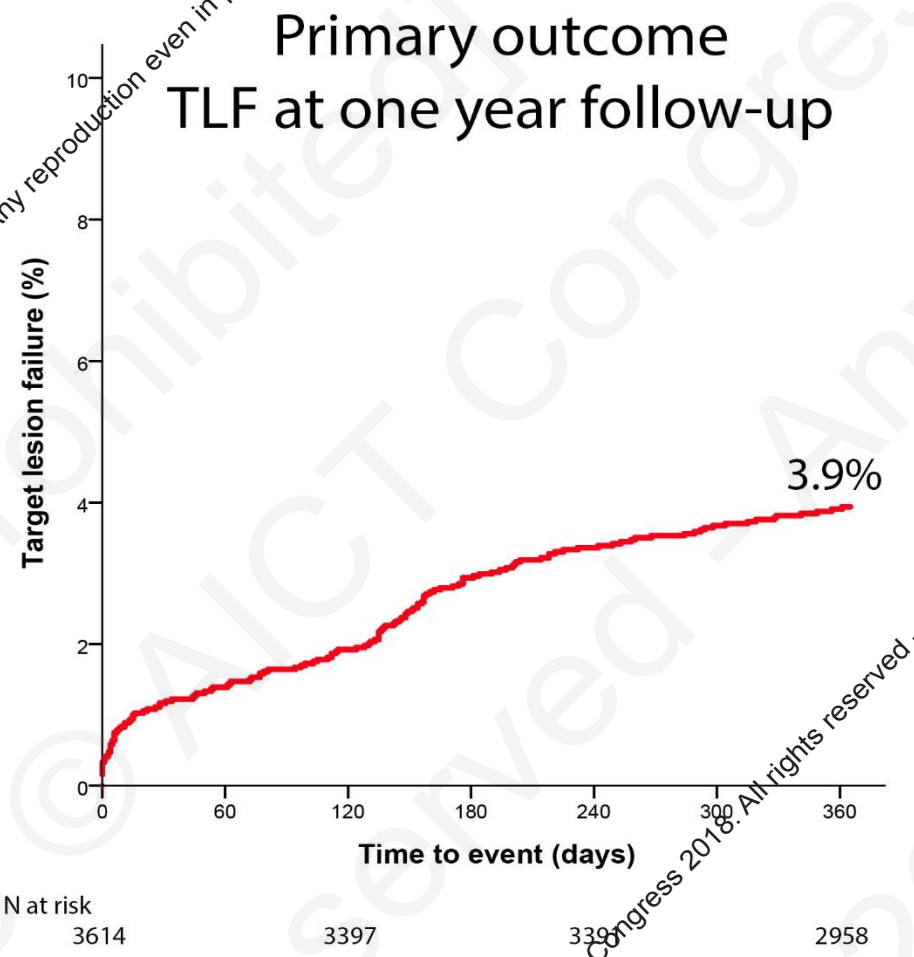
COMBO Collaboration - Patient Demographics

Age	63.5 ± 11.2	Prior MI	858 (23.7%)
Female	861 (23.8%)	Previous PCI	966 (26.7%)
Diabetes mellitus	1,050 (29.3%)	Previous CABG	206 (5.7%)
Insulin treatment	272 (7.5%)	Current smoker	1,009 (27.9%)
Hypertension	2,422 (67%)	Indication for PCI	
Hypercholesterolemia	2,101 (58.1%)	Asymptomatic	295 (8.2%)
Family History of CAD	1,107 (30.6%)	Stable angina	1,346 (37.2%)
Congestive heart failure	224 (6.2%)	STEMI	789 (21.8%)
Chronic renal failure	231 (6.4%)	NSTEMI	600 (16.6%)
Peripheral vascular disease	212 (5.9%)	Unstable angina	576 (15.9%)
Previous stroke	173 (4.8%)	Other	6 (0.2%)

54% ACS

R. Mehran, Oral Presentation, EuroPCR 2018

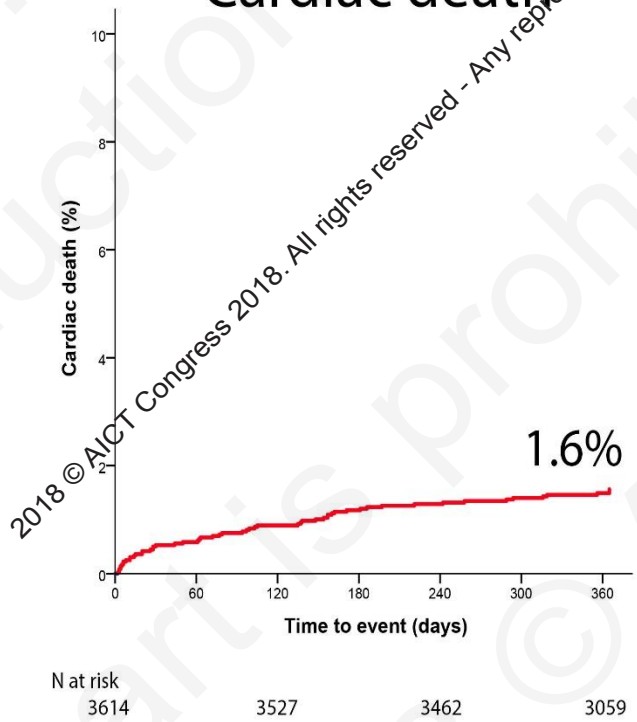
COMBO Collaboration Results
Primary endpoint

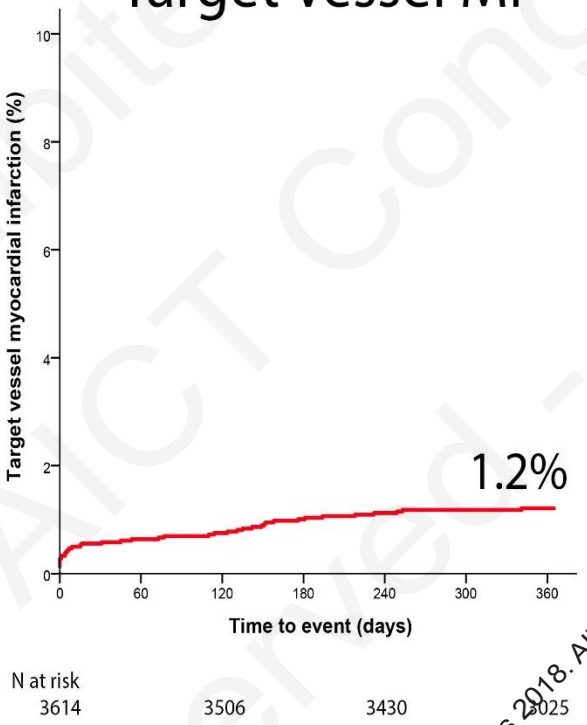


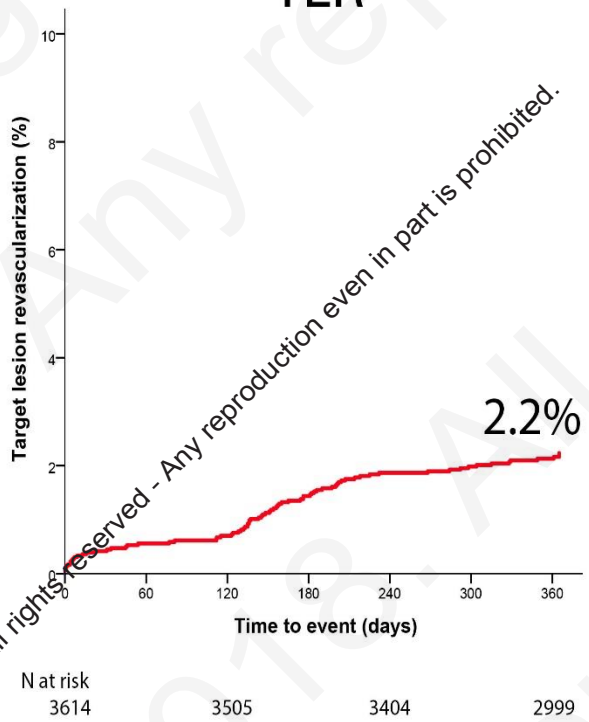
TLF at 1-year follow-up was observed in 140 patients (3.9%)

R. Mehran, Oral Presentation, EuroPCR 2018

COMBO Collaboration Results
Secondary endpoints





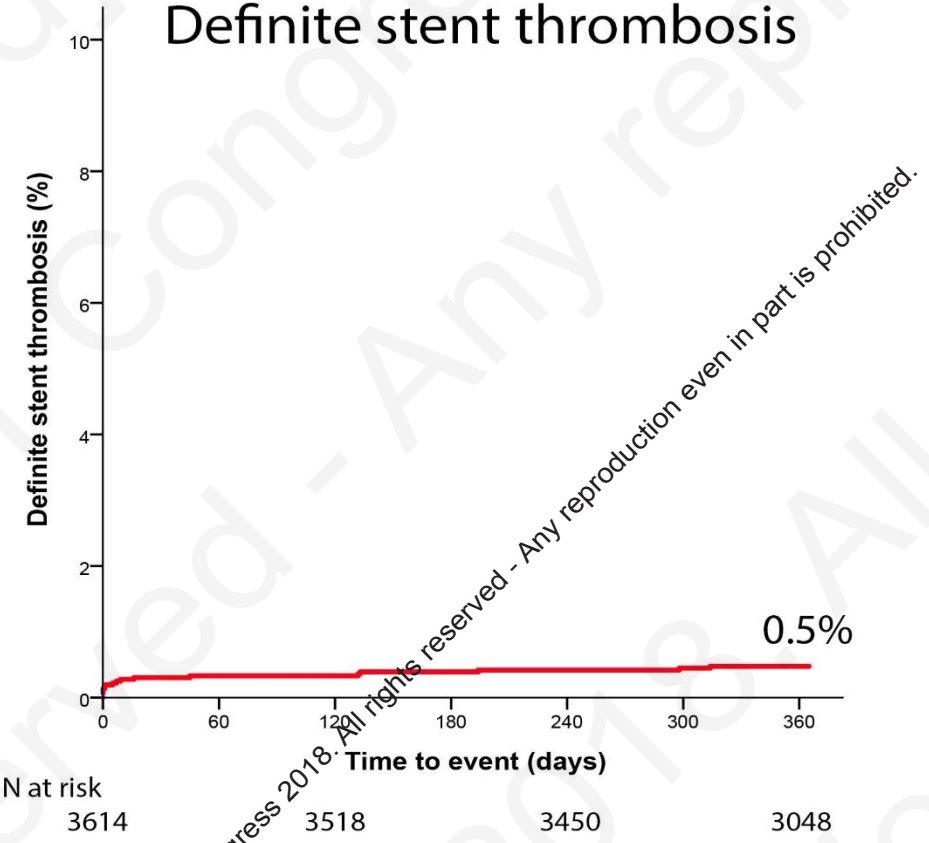


R. Mehran, Oral Presentation, EuroPCR 2018

COMBO Collaboration Results
Secondary endpoint

Very low definite ST rate:
0.5% (n=17) at 1 year FU

Definite/Probable ST rate:
0.8% (n=30) at 1 year FU



R. Mehran, Oral Presentation, EuroPCR 2018

COMBO under other indications
TAVI Patients

2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

UMC Utrecht

Clinical Performance of a Novel Bioengineered Drug-eluting Stent in TAVI-patients, First Results of the Combo-TAVI Registry

P.R. Stella MD, PhD, Interventional Cardiologist

Department of Cardiology University Medical Center Utrecht

2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

Combo-TAVI registry

Aim: ***Assess clinical safety of Combo-DES in TAVI-patients***

FFR-guided PCI
with Combo stent
4 weeks DAPT

→ TAVI-Procedure → Clinical Outcomes

3 months DAPT

Stop dapt

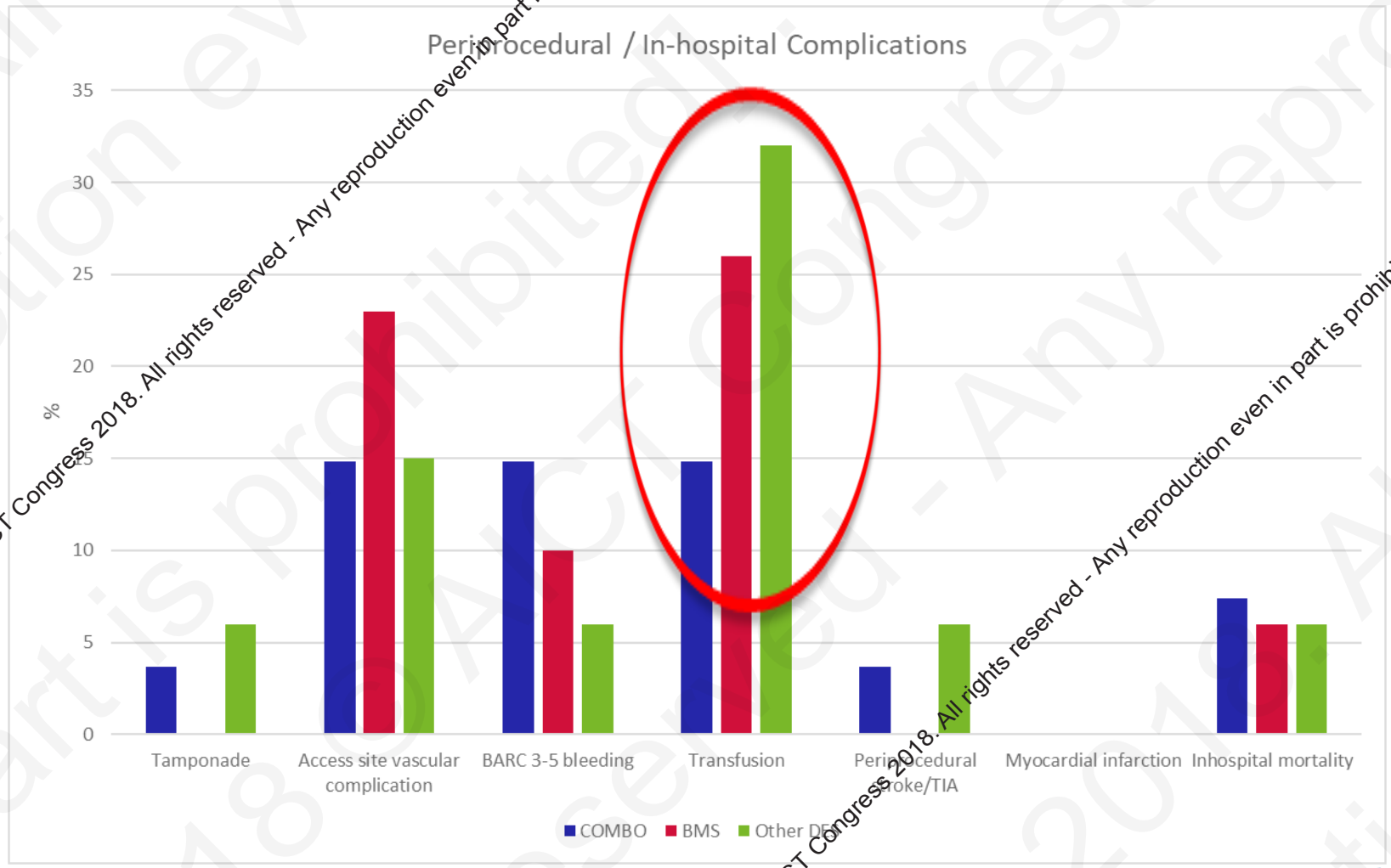
Courtesy of P. Stella, presented at TCT 2017

Combo TAVI Registry UMCU

BMS	• > 4 week before TAVI • DAPT 4 weeks + 3 mo after TAVI
DES	• > 4 week before TAVI • DAPT 6 months
Combo	• >4 weeks before TAVI • DAPT 4 weeks + 3 mo after

Courtesy of P. Stella, presented at TCT 2017

Combo TAVI Registry UMCU



Courtesy of P. Stella, presented at TCT 2017

Combo TAVI registry UMCU

Six months Outcome	COMBO (n = 40)	BMS (n = 40)	p-value	Other DES (n=44)	p-value
Lost to follow-up	1	2		3	
Average total duration of DAPT / Triple anticoagulation (month)*	3.4	3.7	0.76	5.7	0.03
6 months Death from any cause	0	0	1.0	2	0.56
Nonfatal spontaneous myocardial infarction	0	1	1.0	2	0.56
Major Bleeding	0%	7%	0.53	3%	1.0
Revascularization	1	1	1.0	1	1.0
Definite stent thrombosis	0	0	1.0	0	1.0
MACCE# or Bleeding	4%	10%	0.65	12%	0.41

Courtesy of P. Stella, presented at TCT 2017

Take Home Messages

- The COMBO stent with established pro-healing properties has demonstrated safety and efficacy in a sizeable population with a high percentage mix of patients with acute coronary syndrome and complex lesions
- From the REMEDEE Registry, early DAPT cessation was not associated with increase in adverse events
- Initial small sample study results in the COMBO TAVI Registry show the potential benefit of COMBO in patients with increased bleeding risks due to conjunctional use of DAPT and oral anti-coagulant agents
- The safety of COMBO in DAPT flexibility for both stable and urgent patients may potentially extend to other patients who do not tolerate prolonged DAPT

2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.
2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

Thank You

2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.

14th

AiCT

ASIAN INTERVENTIONAL CARDIOVASCULAR THERAPEUTICS

THE OFFICIAL CONGRESS OF APSIC

7 - 9th September 2018

Hong Kong

Convention and Exhibition Centre (HKCEC)

2018 © AICT Congress 2018. All rights reserved - Any reproduction even in part is prohibited.