Long term clinical outcome of a Novel Abluminal Coated Sirolimus-eluting Coronary Stent in Diabetic patients: Insight from en-ABL e-Registry

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Potential conflicts of interest

Speaker's name: Bernardo Cortese

I have the following potential conflicts of interest to report (last 2 years):

Consultant: Aachen Resonance, Abbott Vascular, Astra Zeneca, Kardia, Innova, Stentys, Daiiki-Sankyo.

Honorarium: Hexacath, Amgen, Stentys, Sanofi, B.Braun.

Institutional grant/research support: AB Medica, St Jude, Abbott Vascular.

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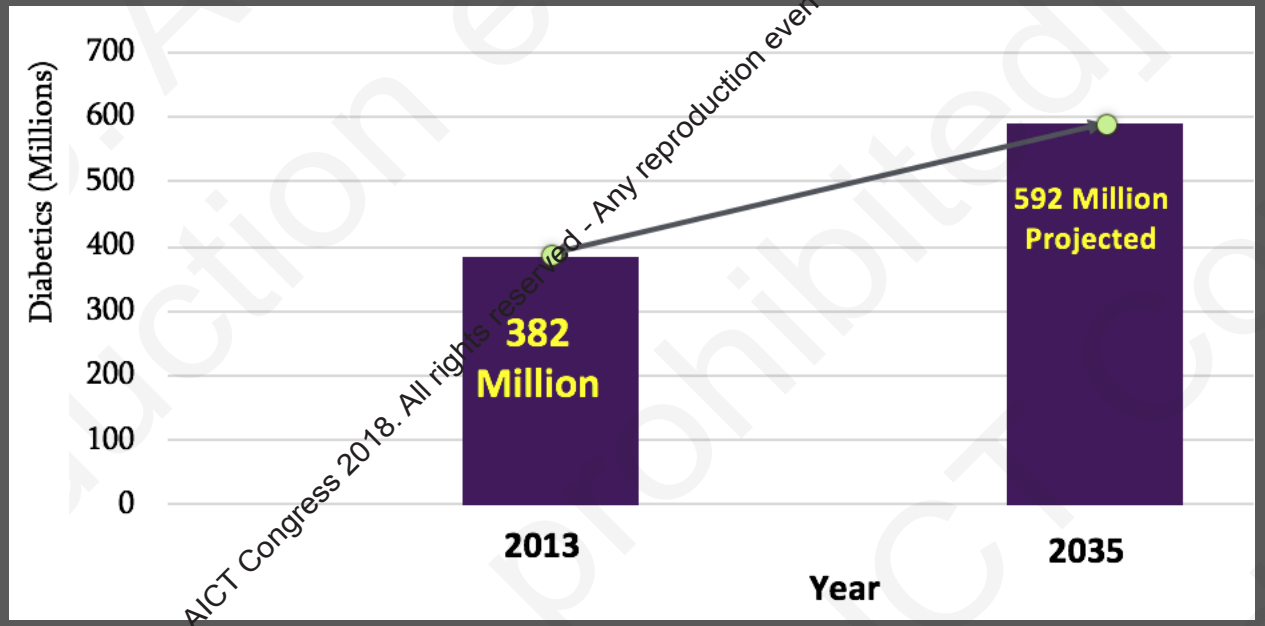
WHY A STUDY ON DIABETIC PATIENTS?



- CVD is a major complication of diabetes and the leading cause of early death in these subjects: approximately 65% of diabetic patients die from coronary or cerebral event.
- Overall 30% of patients undergoing PCI are diabetics and have poorer outcomes when compared to similar non-diabetic patients following PCI.

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Rev Endocr Metab Disord. 2010 March ; 11(1): 75–86
Cardiovascular Research (2008) 78, 563–571

Why are PCI Outcomes Worse in Diabetics?

- More extensive atherosclerosis and diffuse multivessel disease
- Accelerated disease progression
- Increased comorbidity (prior MI, prior CHF, etc)
- Smaller vessels
- Longer lesions
- Higher incidence of left main disease
- DES fare worse in DM vs non-DM patients

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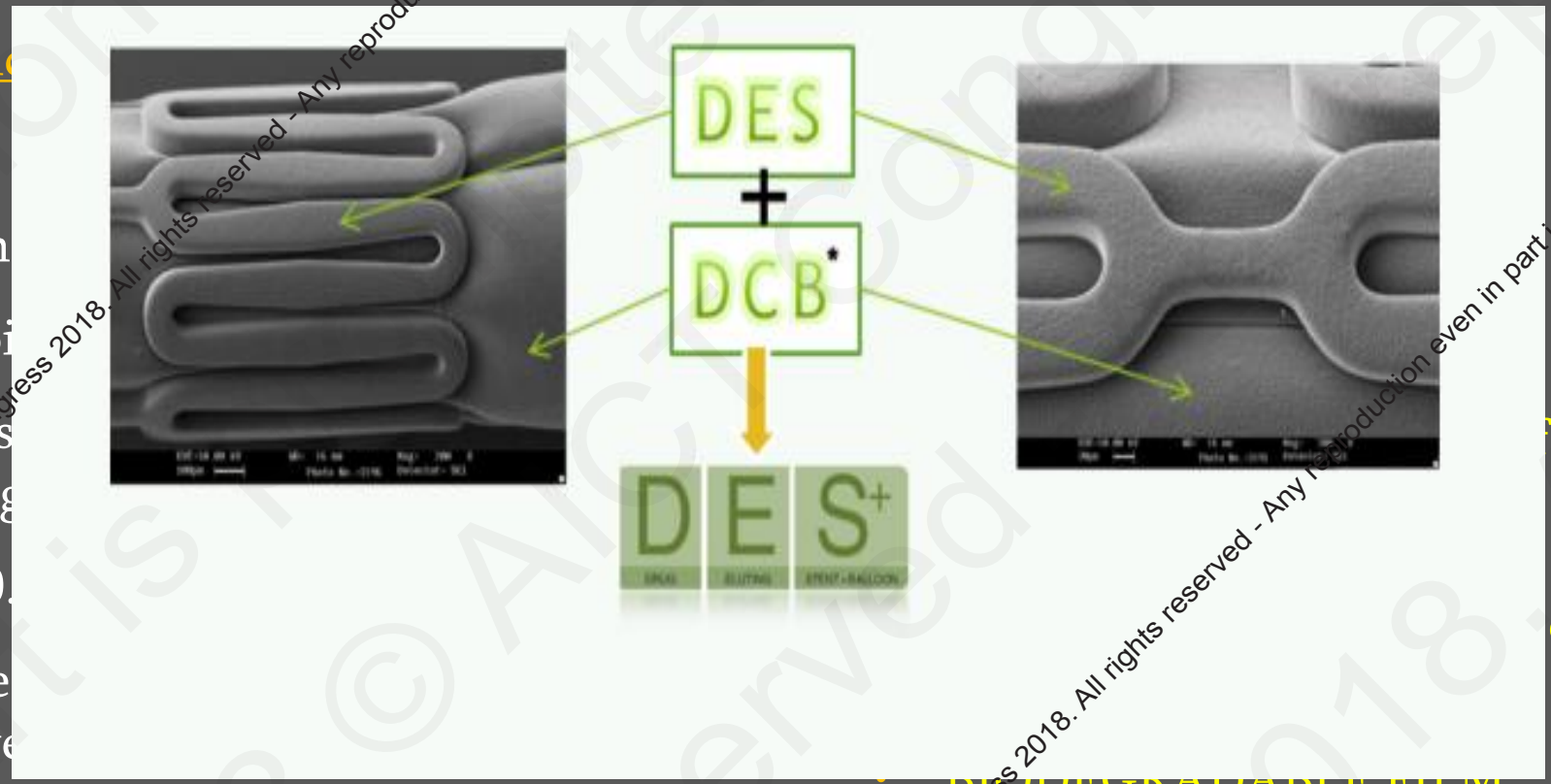
ABLUMINUS DES

A II-gen. DES with unique coating technology

Technical Specifi

- CoCr L605
- 73 µm strut th
- Average Recoi
- Average Forces
  foreshortening
- Drug Dose- 0
- Biodegradable
  than 5 µm laye



f balloon is coated

ends of balloon is

BIODEGRADABLE FILM

Protective film upon inflation of stent system

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en-ABL e-Registry

Objective

Evaluate the safety and efficacy of Abluminus DES in real world-all comer patients

Design

Multicenter, prospective, all-comers registry in 31 centers in India

FU Interval

Ambulatory visits or telephone contact at 1 month, 9 months, 1 year and yearly afterwards up to 5 years after the index procedure.

Primary Endpoint

Major Adverse Cardiac Events (MACE) at 1-Year follow-up *

Secondary Endpoint

Stent Thrombosis (ST) according to the ARC definition calculated at any time point;
MACE assessed up to 3 years.

* MACE is composite of cardiac death, target vessel MI (TV-MI), Target Lesion Revascularization (TLR).

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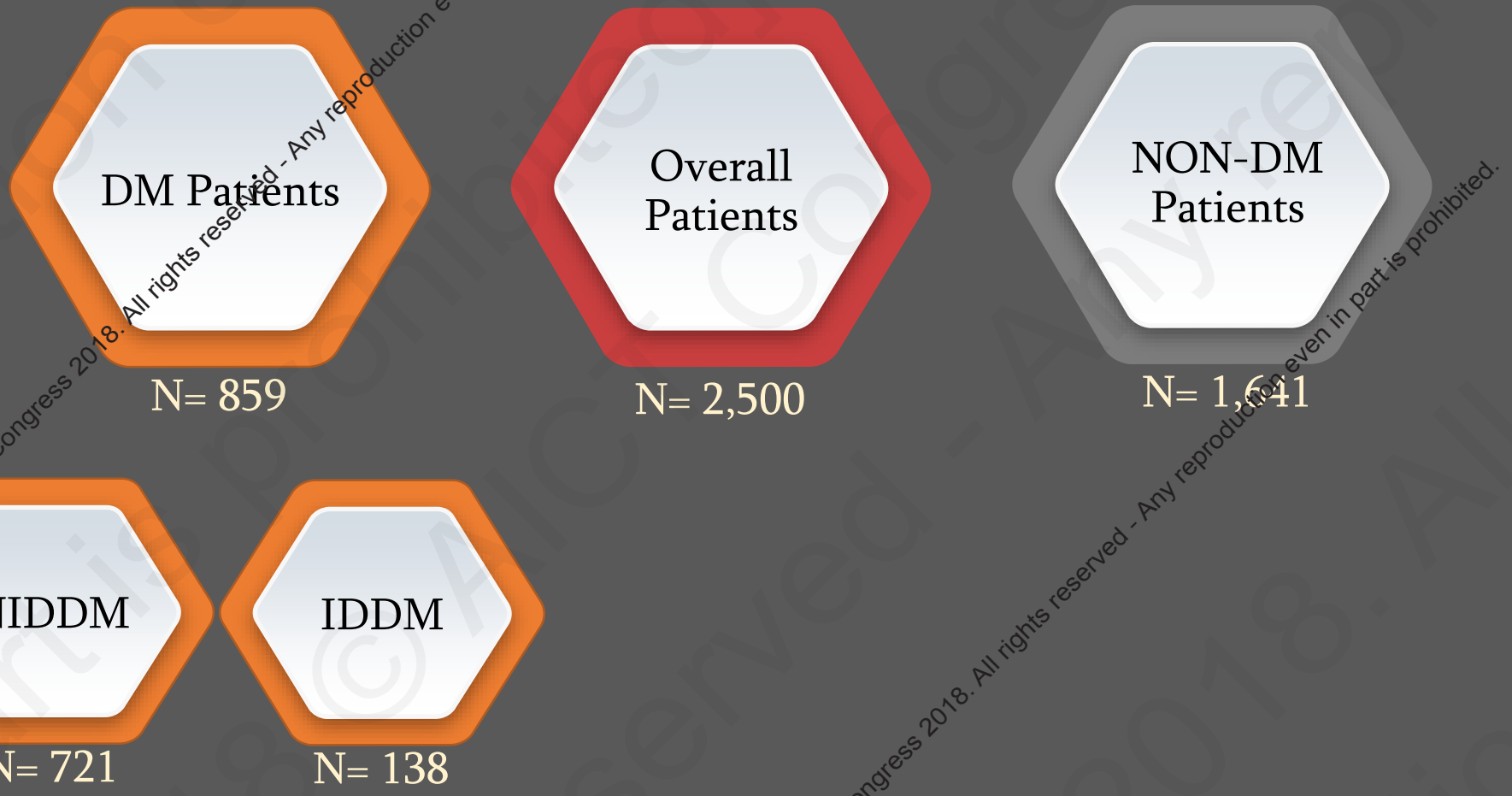
Diabetic patients pooled from en-ABL e-Registry



DM: Diabetes Mellitus; IDDM: Insulin Dependent DM; NIDDM: Non-Insulin Dependent DM

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Patient Demographics

	Overall Patients N-2,500	DM N=859	NON-DM N=1,641	NIDDM N= 721	IDDM N= 138
Age, Years ± SD	57.0 ± 12.6	58.2 ± 12.9	56.9 ± 12.5	58.1 ± 13.1	59.1 ± 11.7
Male, %	78.9	76.0	80.4	76.8	71.7
Female, %	21.1	24.0	19.6	23.2	28.3
Previous CV History, %					
Previous MI	11.8	12.8	11.3	12.8	13.0
Previous PCI	5.9	8.1	4.8	7.6	10.9
Hypertension	42.2	59.6	33.2	58.9	63.0
Renal Failure	2.0	3.4	1.3	2.1	10.1
Clinical presentation, %					
Stable Angina	6.2	7.7	5.4	7.9	6.5
Inducible Ischemia	27.0	30.5	25.1	30.5	30.4
ACS	66.8	61.8	69.5	61.6	63.0
STEMI	42.8	37.0	45.9	36.3	40.6
NSTEMI	4.2	4.1	4.2	4.0	4.3
Unstable Angina	19.8	20.7	19.4	21.2	18.1
Extent of coronary artery disease, %					
1 -Vessel	83.2	81.1	84.3	81.1	81.2
2- Vessel	14.8	17.0	13.7	17.1	16.7
3-Vessel	1.9	1.9	2.0	1.8	2.2

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Lesion and Procedural Characteristics

	Overall Patients No. of lesions=2,969 No. of devices=3,287	DM No. of lesions=1,037 No. of devices=1,174	NON-DM No. of lesions= 1,932 No. of devices= 2,113	NIDDM No. of lesions= 870 No. of devices= 984	IDDM No. of lesions= 167 No. of devices= 190
No. of treated lesions	1.2	1.2	1.2	1.2	1.2
No. of stents per patient	1.3	1.4	1.3	1.4	1.4
Left Anterior Descending a.	48.9	44.3	51.3	44.0	45.5
Left Circumflex	21.2	23.4	19.9	23.2	24.5
Right Coronary artery	27.3	29.4	26.2	29.8	27.5
Lesion Details, %					
Small vessel (≤2.75mm)	47.2	58.9	40.8	58.5	61.1
Long lesions (≥28 mm)	55.2	55.6	55.0	55.4	56.9
Pre-dilatation	68.9	68.9	68.8	69.3	67.1
Post-dilatation	43.2	44.4	42.5	47.1	29.9
Procedure Success	99.2	98.9	99.3	99.2	97.8
Mean stent diameter	2.9 ± 0.4	2.8 ± 0.4	3.0 ± 0.4	2.8 ± 0.4	2.84± 0.4
Mean stent length	26.8 ± 8.8	26.5 ± 8.8	26.9 ± 8.8	26.5 ± 8.8	26.4 ± 8.8

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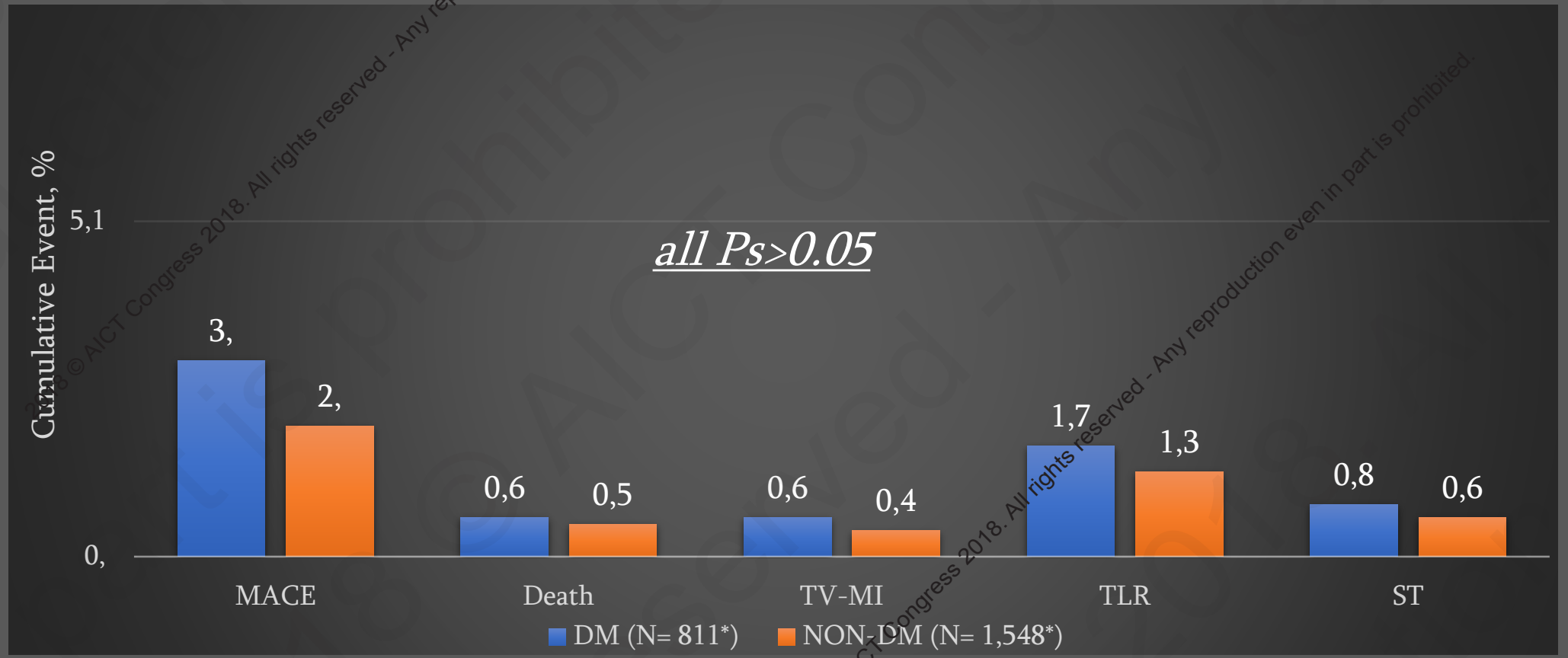
Clinical Outcomes by DM presentation

1-Year Follow-up (94.4% of patients)



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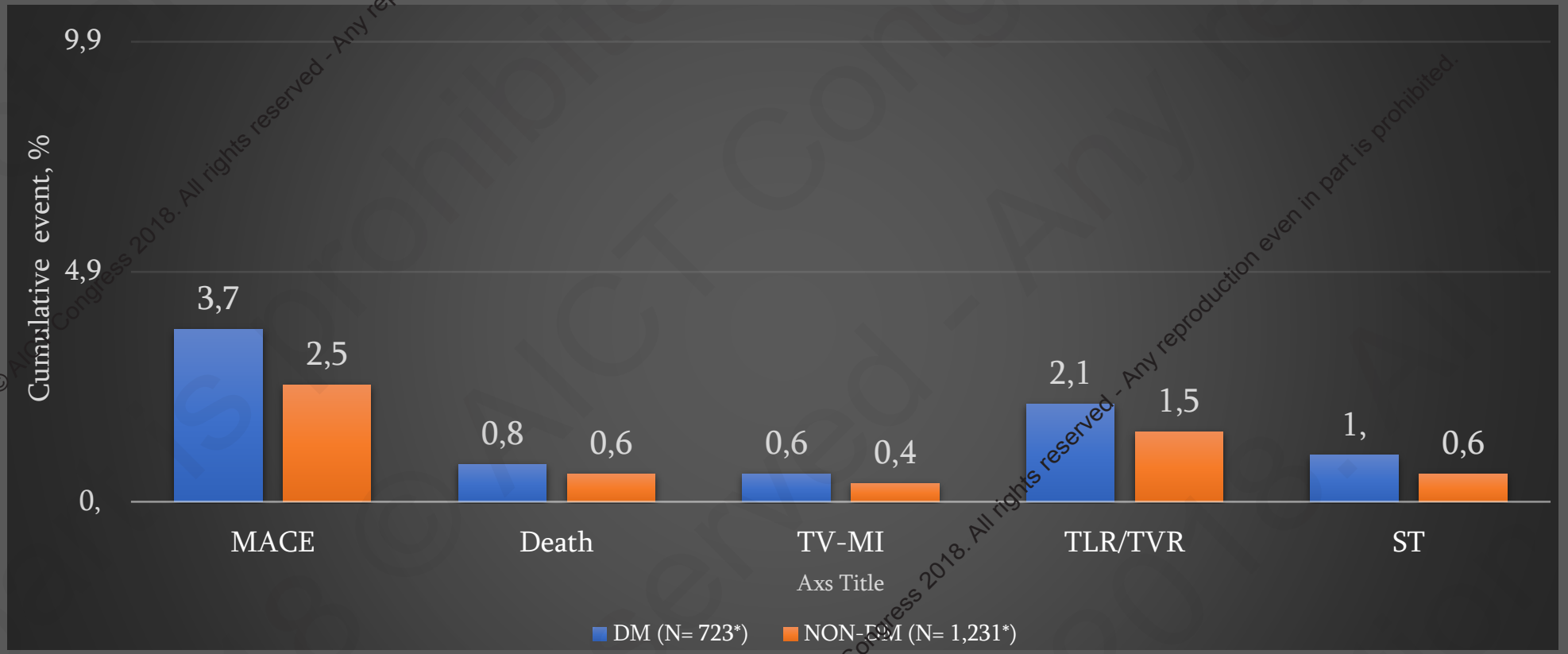
* No of patients completed 1-year clinical follow-up till August 2018. clinical follow-ups of remaining patient is ongoing.

Clinical Outcomes by DM presentation

2-Year Follow-up (76.3% of patients)



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* No of patients completed 1-year clinical follow-up till August 2018. clinical follow-ups of remaining patient is ongoing.

Clinical Outcomes in Complex cohort of patients along with Diabetes

	Diabetics with AMI N= 294	Diabetics with Small Vessel disease N=539	Diabetics with Long lesion N= 519	Diabetics with Long lesion in small vessel N=335
Patients with follow-up	265	507	486	312
MACE, %	2.6	3.7	3.5	3.8
Cardiac Death, %	0.8	0.8	0.8	1.0
TV-MI, %	1.1	0.6	0.2	0.3
TLR, %	0.8	2.4	2.5	2.6
Stent thrombosis, %	2.6	1.2	0.8	1.0

* No of patients completed 1-year clinical follow-up till August 2018. clinical follow-ups of remaining patient is ongoing.

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en-ABL e-Registry-LIMITATIONS

- Only one single population enrolled
- No centralized adverse events assessment
- No adverse events committee

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Ongoing Studies

ABILITY RCT

A Randomized clinical trial of Abluminus DES Sirolimus eluting stent versus Everolimus-eluting DES for Percutaneous Coronary Intervention in patients with Diabetes Mellitus: An Investigator-initiated pilot study.

Medical director : Prof. Antonio Colombo, Ospedale San Raffaele, Milano, Italy

Design:

Multi-centre, single-blinded, randomized, Investigator-initiated pilot clinical study.
A total of 165 patients with 110 in Abluminus DES group and 55 in the Everolimus Eluting DES group

Primary endpoint:

In-stent neo-intimal volume at 6-month follow-up, measured with optical coherence tomography (OCT) following PCI with Abluminus DES compared with in-stent neo-intimal volume following PCI with Everolimus-eluting DES

Secondary endpoint:

Neointimal area, calculated at the site of minimal lumen area at 6-month follow-up measured with OCT; Target Lesion Failure; Stent thrombosis; Cardiac death; Target vessel myocardial infarction; Target lesion revascularization at 12 months; Device success at 24 hours; Lesion success; Procedural success.

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Ongoing Studies

DEDICATE Clinical Registry

DRUG ELUTING STENT FOR DIABETIC PATIENTS IN CORONARY ARTERY DISEASE TREATMENT

A POST MARKET REGISTRY OF ABLUMINUS SIROLIMUS ELUTING CORONARY STENT SYSTEM FOR PERCUTANEOUS INTERVENTION IN PATIENTS WITH DIABETES MELLITUS

Principal Investigator: Dr. Luca Testa, IRCCS Policlinico S. Donato, San Donato M.ne, Milan, Italy

Design:
Prospective, Observational, Multi-center, Spontaneous ongoing clinical registry

Primary endpoint:
Target Lesion Failure (TLF) which is composite of cardiac death, target vessel myocardial infarction, and clinically indicated target lesion revascularization within 12-months

Secondary endpoint:
Stent thrombosis [Time Frame: 1 month, 12 months, yearly];
Cardiac death [Time Frame: 1 month, 12 months, yearly];
Target Vessel Myocardial infarction [Time Frame: 1 month, 12 months, yearly];
Target Lesion Revascularization [Time Frame: 1 month, 12 months, yearly];
Device Success at 24 hours;
Lesion Success at 24 hours; Procedural Success at 24 hours

200 Patients enrolled

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en-ABL e-Registry-CONCLUSIONS

- The results of this real-world multi-centre Registry show that Abluminus DES has good safety and efficacy profile in DM patients.
- The ABLUMINUS DES is the first DES to have consistent results in both diabetic and non diabetic patients.
- These initial promises of low MACE rates in complex patient subsets need to be validated further by ongoing and upcoming RCTs and real world data from other countries.

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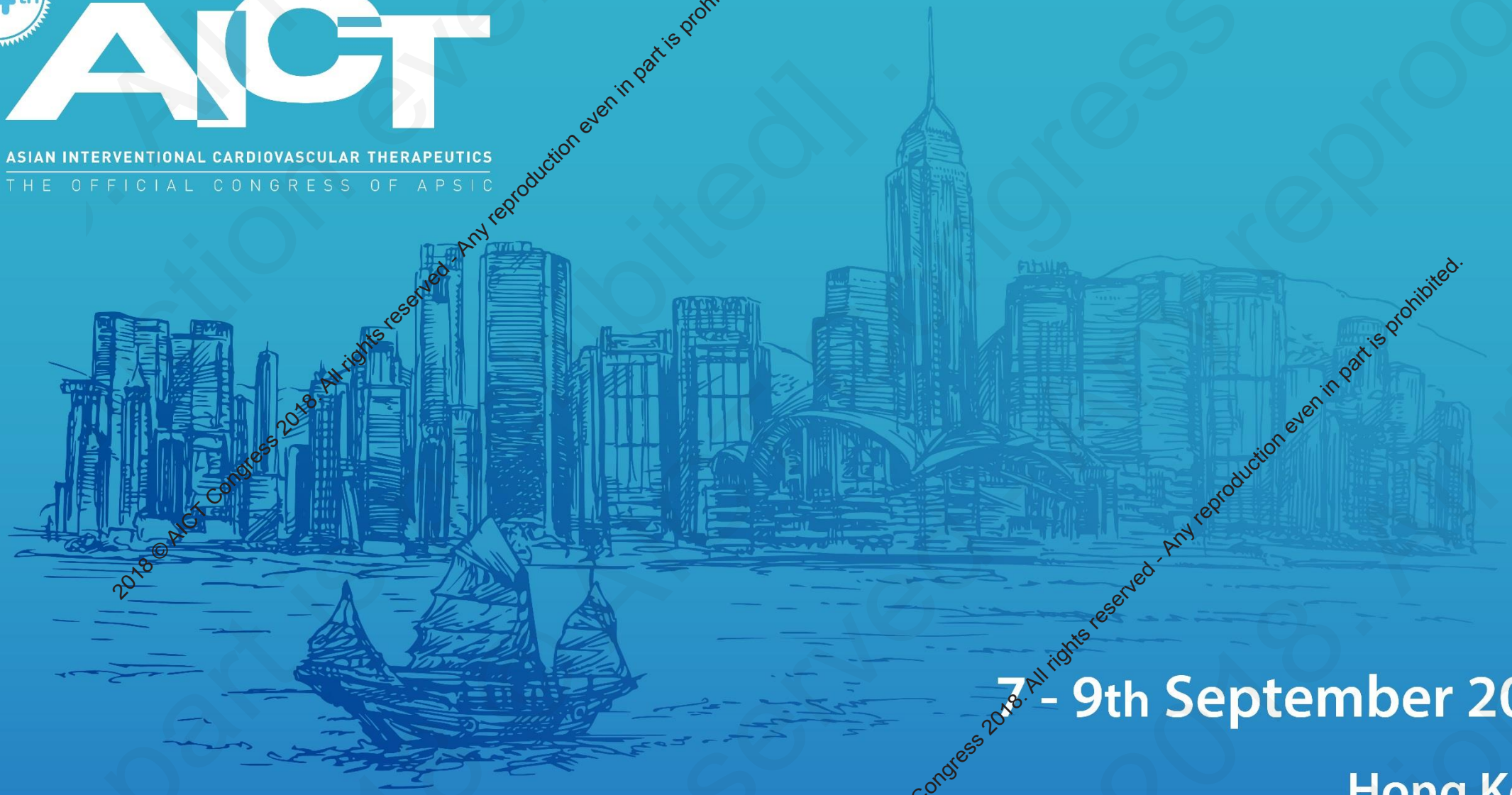
ASIAN INTERVENTIONAL CARDIOVASCULAR THERAPEUTICS

THE OFFICIAL CONGRESS OF APSIC



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