Comparison of 2 Different Paclitaxel-coated Balloons in Coronary In-stent Restenosis

A RCT

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Presenter Disclosure Information

Presenter: Eun-Seok Shin, MD,PhD

Title: Comparison of 2 Different Paclitaxel-coated Balloons in Coronary In-stent Restenosis

No relationships to disclose

No industry sponsorship

Commercially Available DCBs

Drug and Device	Company	Additive	Substance Class	Dose (μg/mm²)	Approval
Paclitaxel					
Agent	Boston Scientific	Acetyl tributyl citrate	Plasticizer	2	CE certified
Elutax SV	Aachen Resonance	None		2.2	CE certified
Danubio	Minvasys	n-Butyryl tri-n-hexyl citrate	Plasticizer	2.5	CE certified
SeQuent Please	B. Braun	Iopromide	X-ray contrast medium	3	CE certified
Pantera Lux	Biotronik	n-Butyryl tri-n-hexyl citrate	Plasticizer	3	CE certified
RESTORE	Cardionovum	Shellac	Varnish	3	CE certified
AngioSculptX	Spectranetics	Nordihydroguaiaretic acid	Antioxidant	3	CE certified
Chocolate Touch	QT Vascular	Undisclosed		3	CE certified
Dior II, BioStream	Eurocor Biosensors	Shellac	Varnish	3	
Essential	iVascular	Undisclosed		3	CE certified
IN.PACT (Admiral, Pacific, Falcon)	Medtronic Vascular	Urea	Endogenous metabolite	3.5	CE certified, FDA approved (Admiral)
Sirolimus					
Selution	Med Alliance	Biodegradable polymer	Microreservoirs		
Virtue	Caliber Therapeutics	Biodegradable polyester-based polymers	Submicrometer nanoparticles		
Magic Touch	Concept Medical		Phospholipids		CE certified
Sequent Please SCB	B. Braun		Crystalline sirolimus	4	CE certified

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Genoss DCB vs. SeQuent Please

		Genoss DCB	Sequent Please
Manufacturer		GENOSS Co. / Korea	B.BRAUN / Germany
Drug		Paclitaxel	
		3μg/㎟	
		Crystalline	
Additive (Excipient)		Shellac + vitamin E	Iopromide
Coating thickness		23 μm	37 μm
Balloon	diameters	2.00/2.25/2.50/2.75/3.00/ 3.25/3.50/3.75/4.00	2.00/2.50/2.75/3.00/3.50/4.00
	lengths	10/15/18/20/23/25/30/35/40	10/15/17/20/26/30
	No. of folds	3 folds	4 folds
	Profile	0.81 mm	1.03 mm
	NP	8 atm	7 atm
	RBP	16 atm	14 atm

Aim

- To evaluate the angiographic efficacy and the clinical safety and effectiveness of the Genoss DCB in a randomized trial

Methods

- 7 cardiovascular centers in South Korea
- Patients ≥19 years of age with clinical evidence of stable or unstable angina or silent myocardial ischemia
- Inclusion criteria: lesions to be a Mehran Type I-III ISR with at least 50% DS, occurring >90 days after coronary stent implantation
- Exclusion criteria: infarct-related artery lesions in patients with acute myocardial infarction, restenosis lesions with thrombosis or in bypass grafts, target vessels with complete occlusion (Mehran type IV)
- Dual antiplatelet therapy for six months

Endpoint

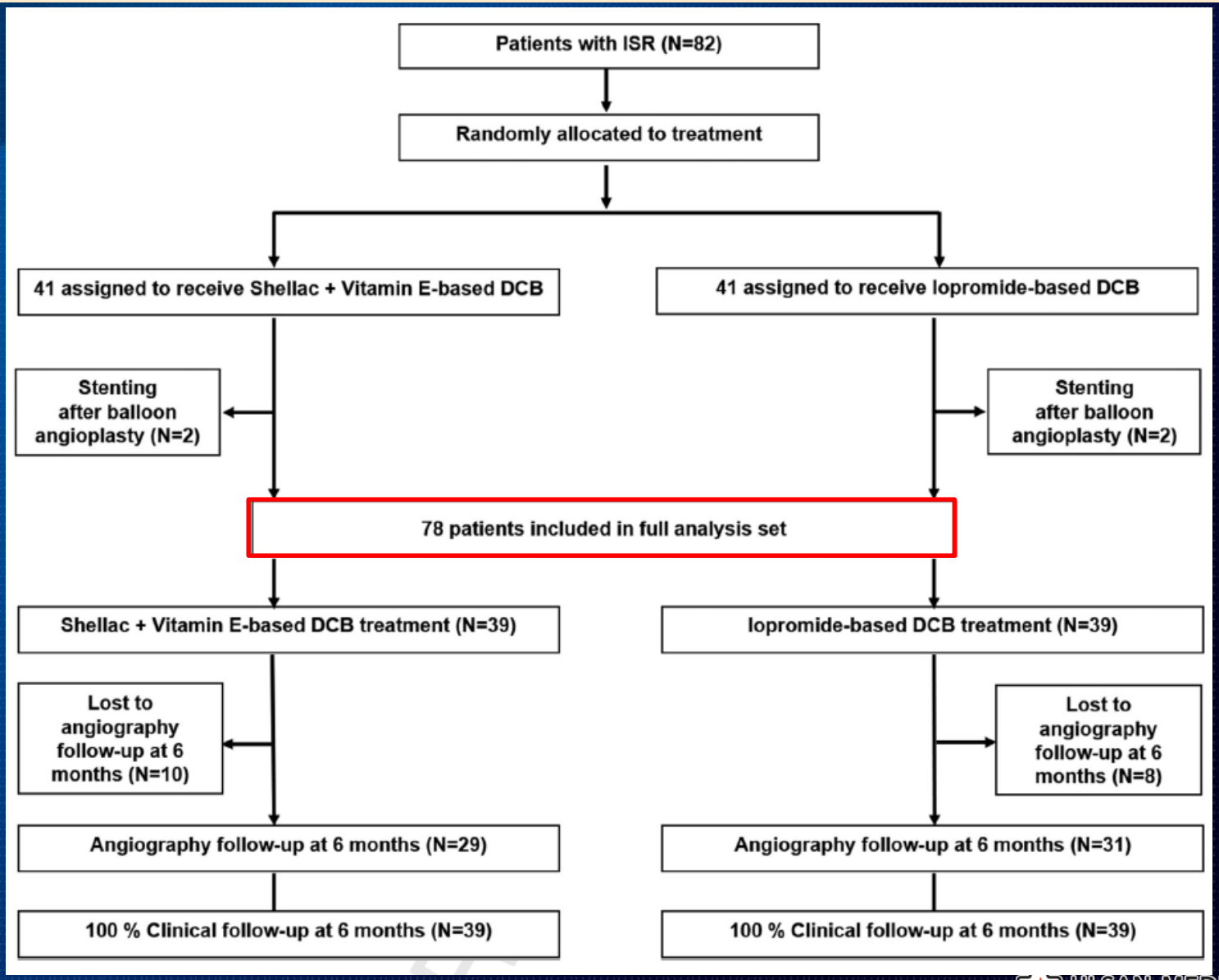
- Primary endpoint (intention to treat): Angiographic in-segment LLL at 6 months

- Secondary endpoint: MACE composed of occurrence of cardiac death, target lesion myocardial infarction, stent thrombosis, clinically driven TLR at 6 months

Results

November 2016 - July 2018

ClinicalTrials.gov (NCT04405063)



Clinical Baseline Characteristics

	Genoss DCB (n = 39)	SeQuent Please (n = 39)
Age, years	67.8 ± 11.2	65.2 ± 9.7
Male	33 (84.6)	29 (74.4)
Hypertension	32 (82.1)	30 (76.9)
Diabetes mellitus	21 (53.9)	24 (61.5)
Hyperlipidemia	12 (30.8)	12 (30.8)
Current smoking	5 (12.8)	8 (20.5)
Prior myocardial infarction	5 (12.8)	8 (20.5)
Prior CABG	1 (2.6)	0
Prior stroke	0	0
Stable angina pectoris status	31 (79.5)	29 (74.4)
Bare metal stent ISR	5	4
Drug-eluting stent ISR	34	35

Angiographic and Procedural Characteristics

	Genoss DCB	SeQuent Please
Multivessel disease	11 (28.2)	10 (25.6)
SYNTAX score	9.6 ± 7.2	8.9 ± 7.4
Target vessel location		
Left anterior descending artery	18 (46.2)	19 (48.7)
Left circumflex artery	10 (25.6)	9 (23.1)
Right coronary artery	11 (28.2)	11 (28.2)
Mehran type		
I	19 (48.7)	17 (43.6)
II	16 (41.0)	16 (41.0)
III	4 (10.3)	5 (12.8)
IV	0	1 (2.6)
Number of study balloon	1.0 ± 0.2 (40)	1.1 ± 0.3 (42)
Study balloon diameter, mm	3.0 ± 0.4	3.0 ± 0.4
Study balloon inflation time, second	54.6 ± 12.5	53.9 ± 12.3
Delivery time to target lesion, second	43.8 ± 39.1	42.5 ± 33.2
TIMI flow grade 3 at end of procedure	39 (100.0)	39 (100.0)
Bail-out strategy	0	0

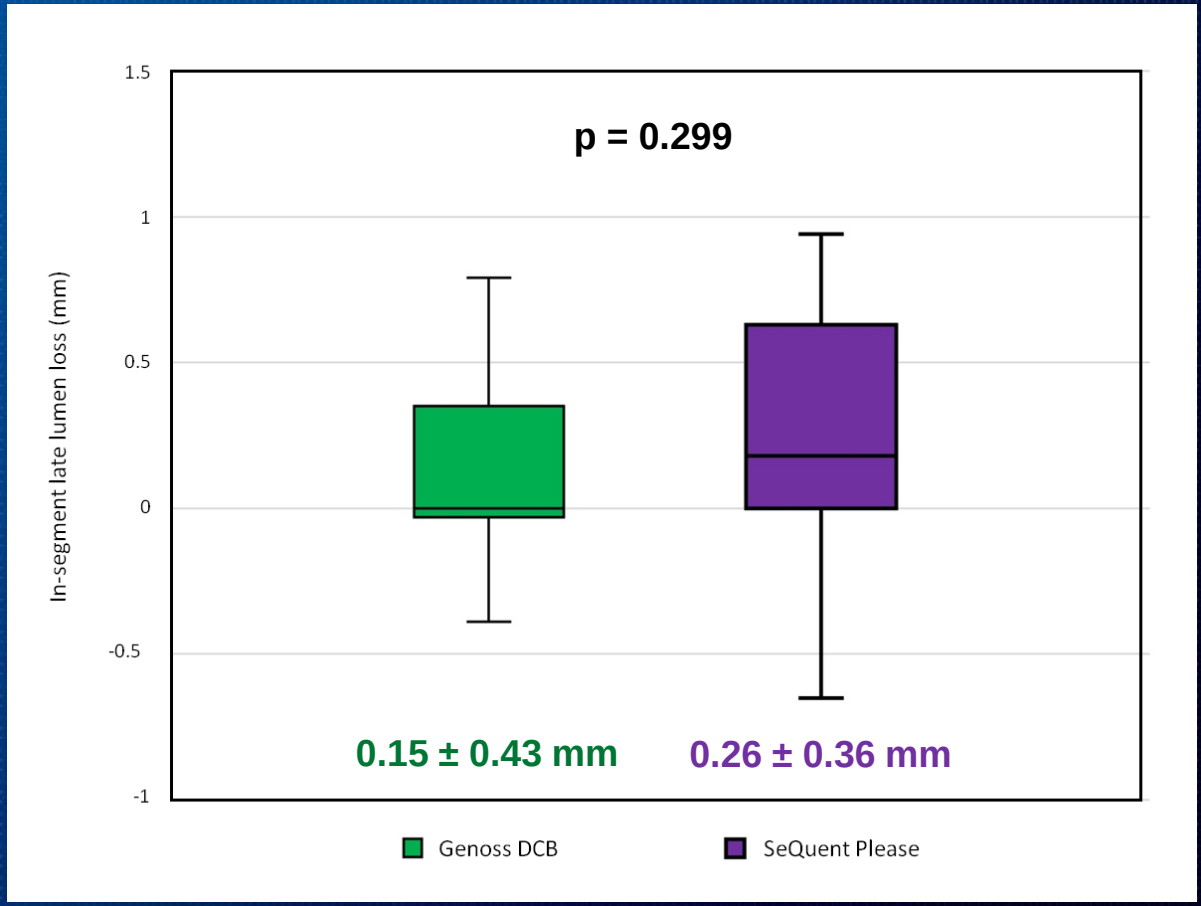
QCA Results I

	Genoss DCB	SeQuent Please	p Value
Pre-procedure	n = 39	n = 39	
Lesion length, mm	20.1 ± 6.0	21.7 ± 8.6	0.318
RVD, mm	2.4 ± 0.5	2.5 ± 0.5	0.466
MLD, mm	0.9 ± 0.3	0.9 ± 0.3	0.936
DS, %	62.2 ± 14.0	65.0 ± 10.7	0.331
Post-DCB	n = 39	n = 39	
RVD in-segment, mm	2.7 ± 0.5	2.8 ± 0.5	0.343
MLD in-segment, mm	2.1 ± 0.4	2.2 ± 0.4	0.220
DS in-segment, %	20.5 ± 8.8	19.5 ± 8.9	0.625
Acute lumen gain in-segment, mm	1.3 ± 0.4	1.4 ± 0.4	0.250

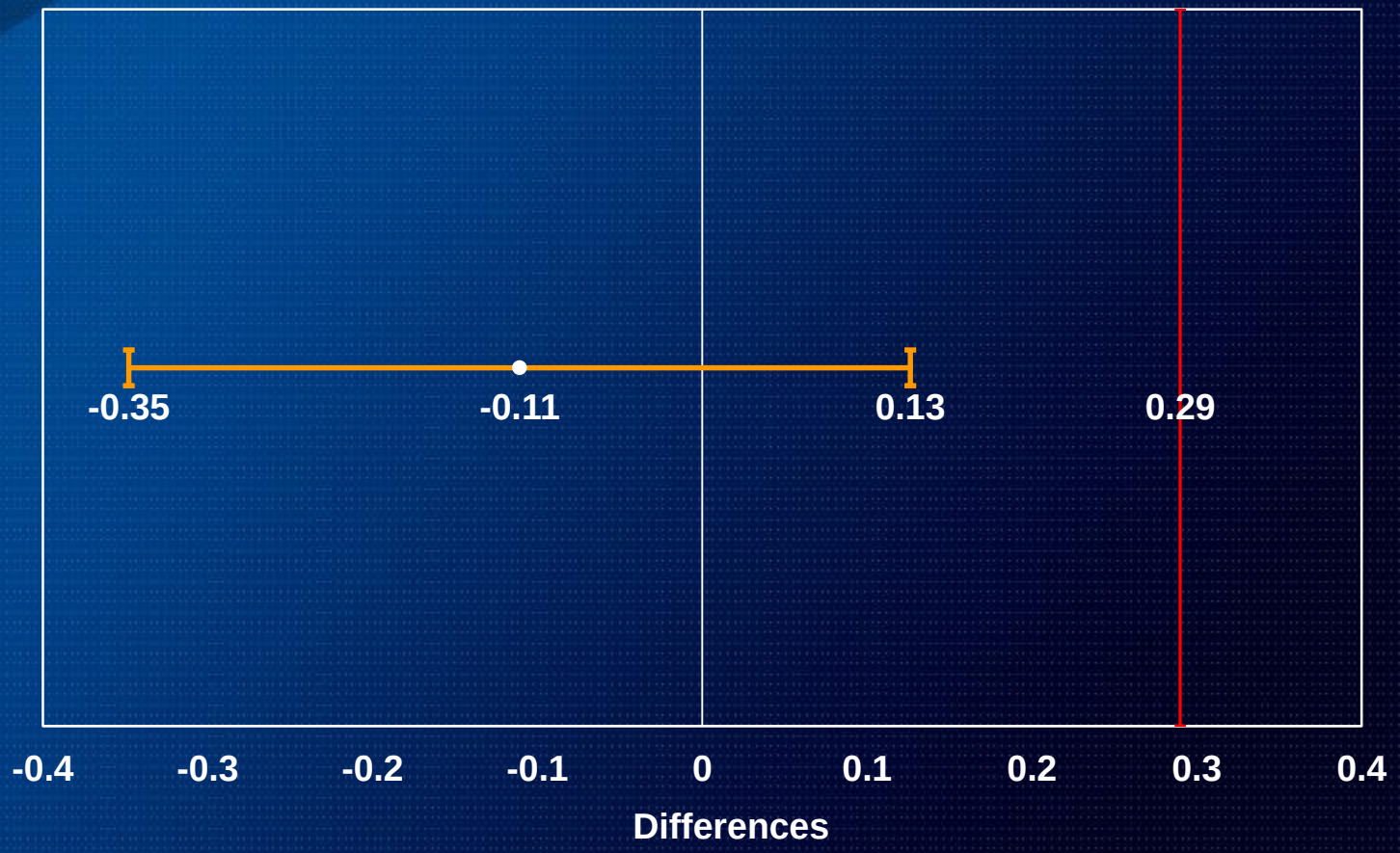
QCA Results II

	Genoss DCB	SeQuent Please	p Value
6-month follow-up	n = 29	n = 31	
Follow-up, days	184.0 ± 24.5	187.8 ± 20.3	0.299
RVD in-segment, mm	2.7 ± 0.5	2.7 ± 0.4	0.640
MLD in-segment, mm	2.1 ± 0.4	1.9 ± 0.6	0.196
DS in-segment, %	23.5 ± 10.9	30.4 ± 11.2	0.020
Late lumen loss in-segment, mm	**0.15 ± 0.43**	**0.24 ± 0.39**	**0.299**
Binary restenosis in-segment, %	0	2 (6.5)	0.164

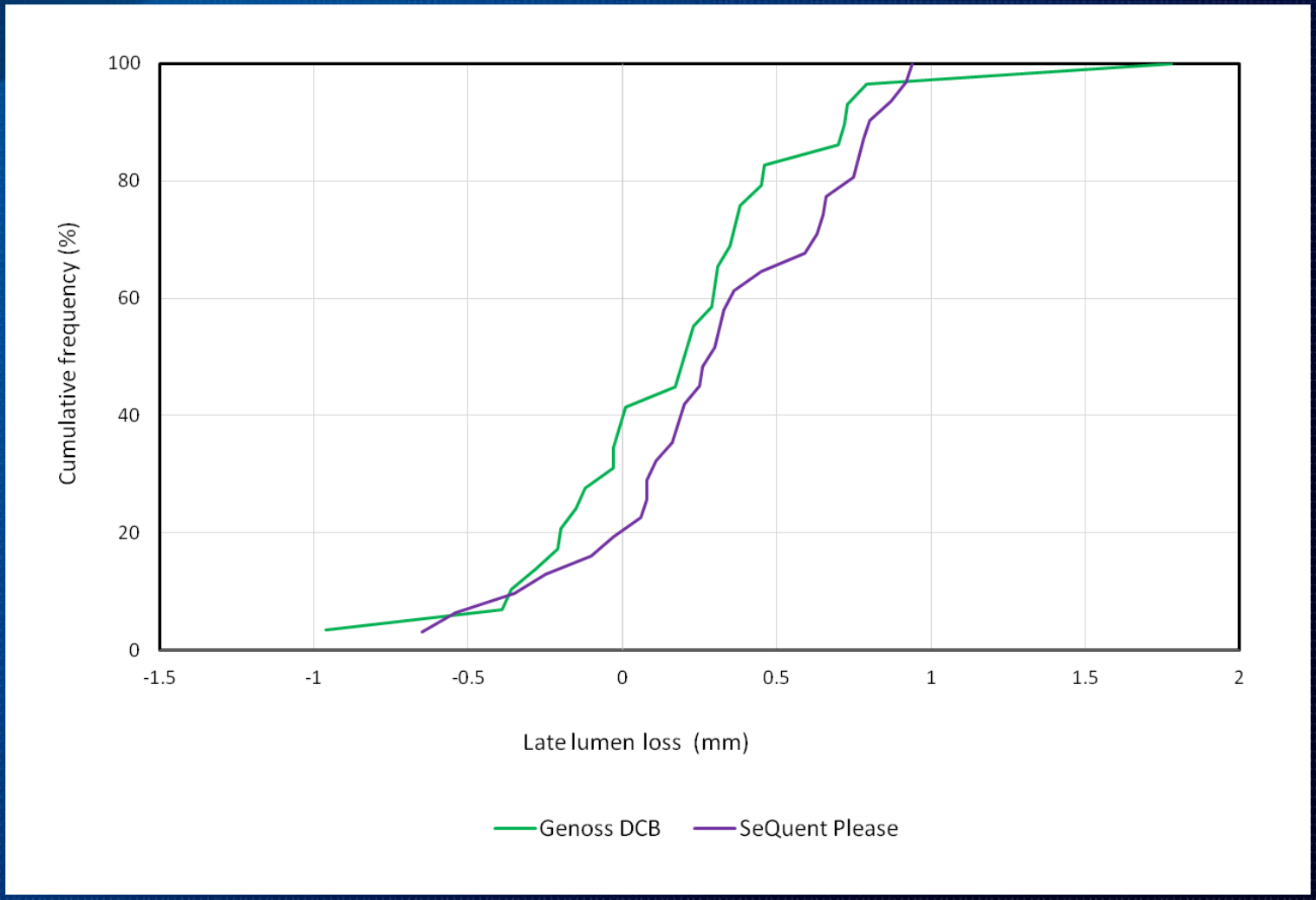
Primary endpoint: 6 months in-Segment LLL



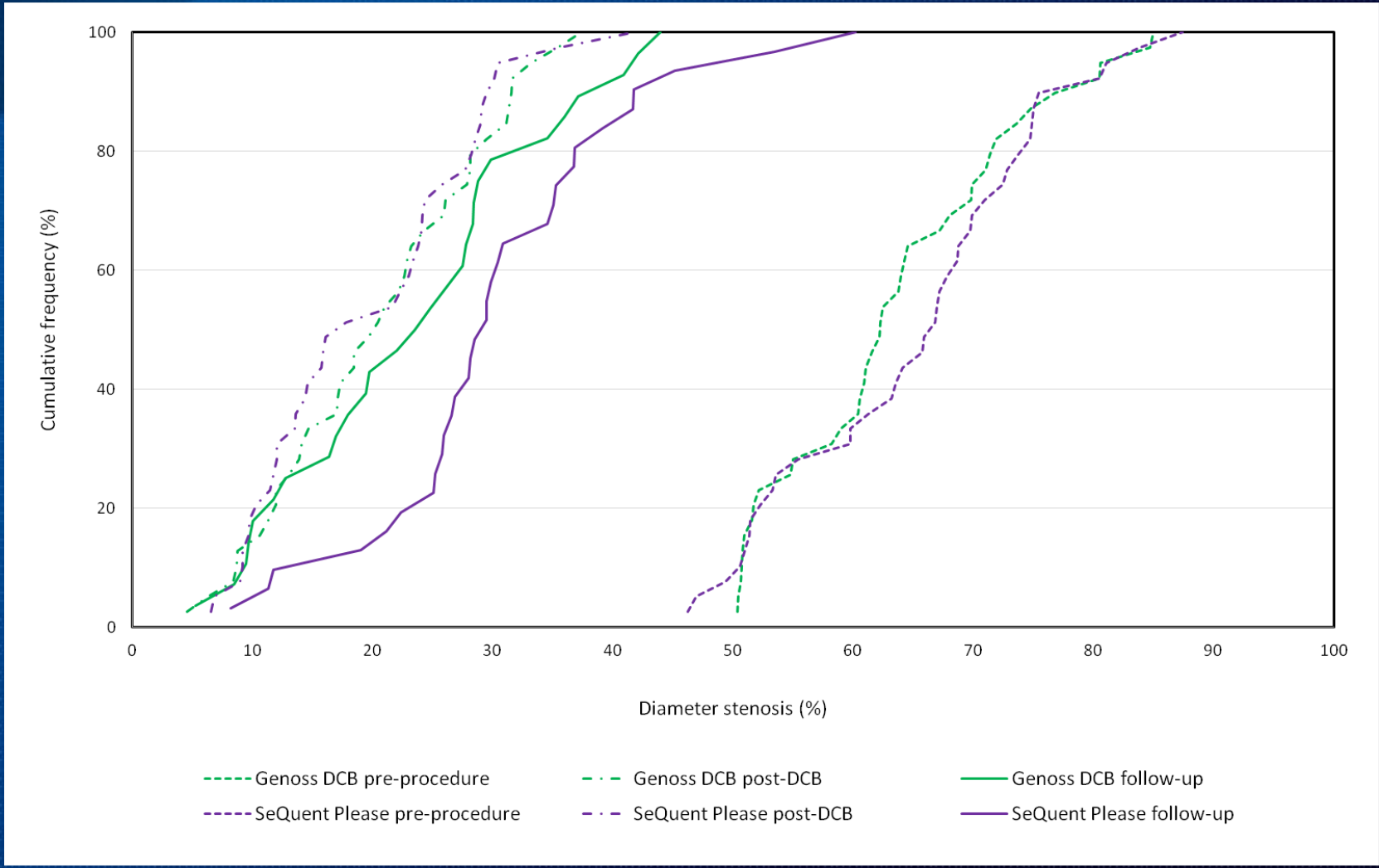
In-Segment LLL (p for non-inferiority = 0.001)



Cumulative Frequency Distribution of In-Segment LLL



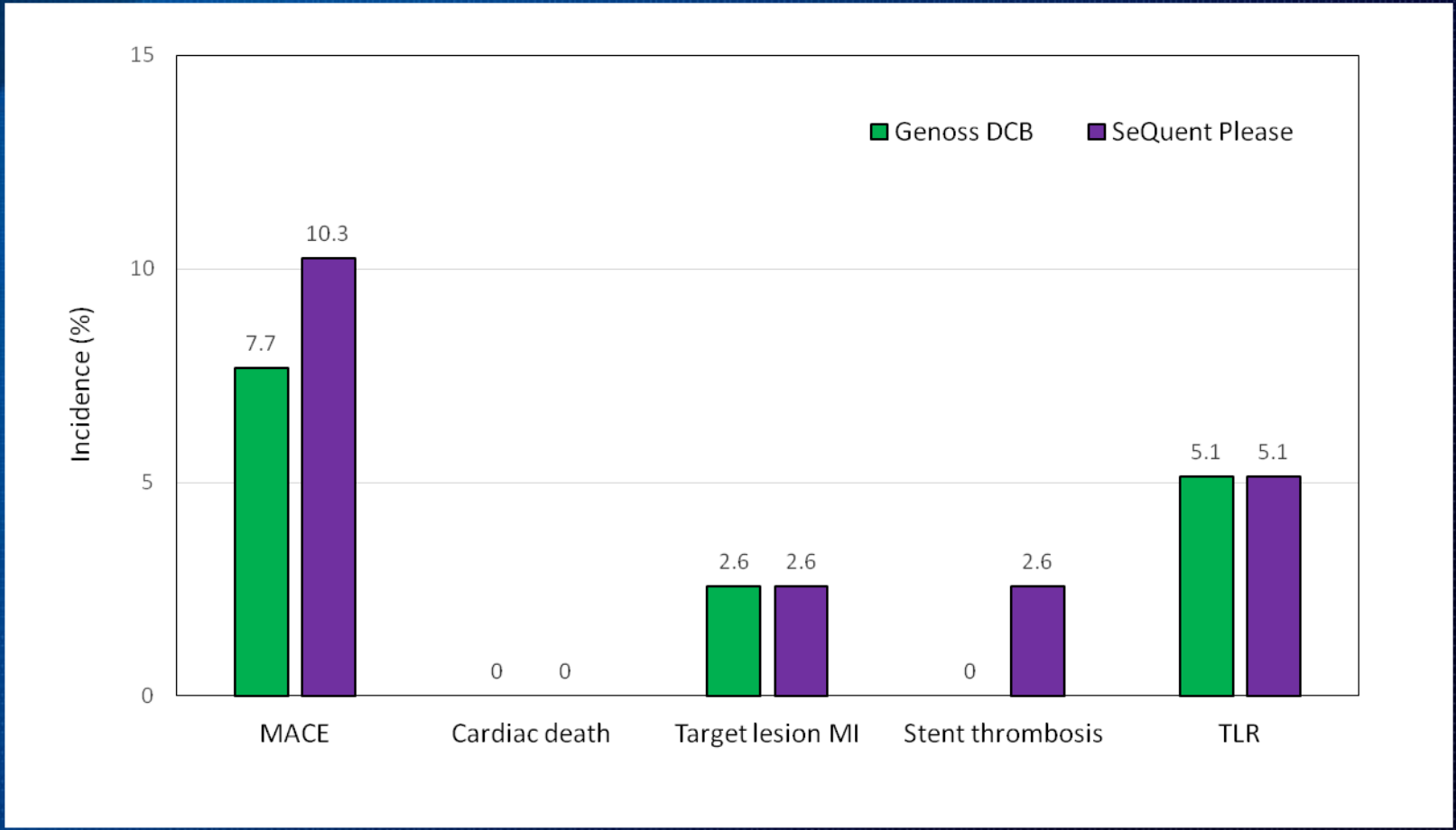
Cumulative Frequency Distribution of In-Segment DS



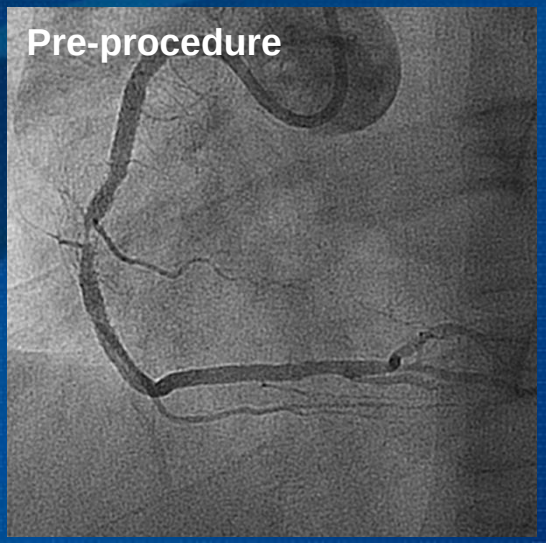
Clinical Follow-Up at Six Months

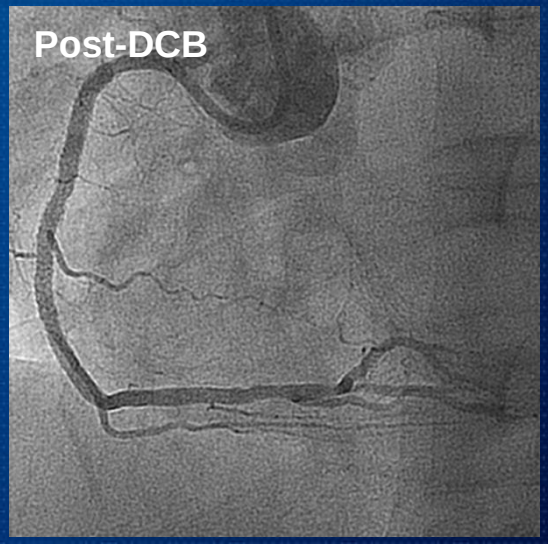
	Genoss DCB (n = 39)	SeQuent Please (n = 39)
MACE	3 (7.7)	4 (10.3)
Cardiac death	0	0
Myocardial infarction	1 (2.6)	1 (2.6)
Stent thrombosis	0	1 (2.6)
Target lesion revascularization	2 (5.1)	2 (5.1)
Target vessel revascularization	2 (5.1)	2 (5.1)
Stroke	0	0
New vessel revascularization	0	0

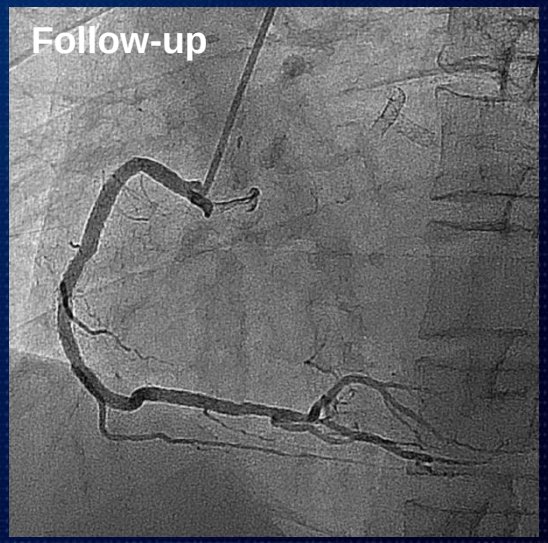
Major Adverse Cardiac Events



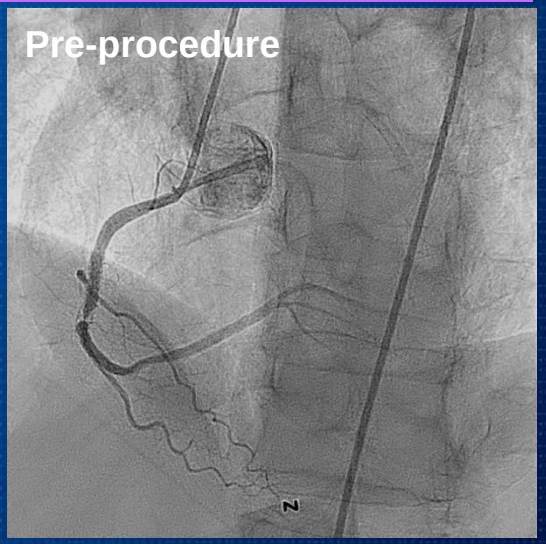
Genoss DCB treatment

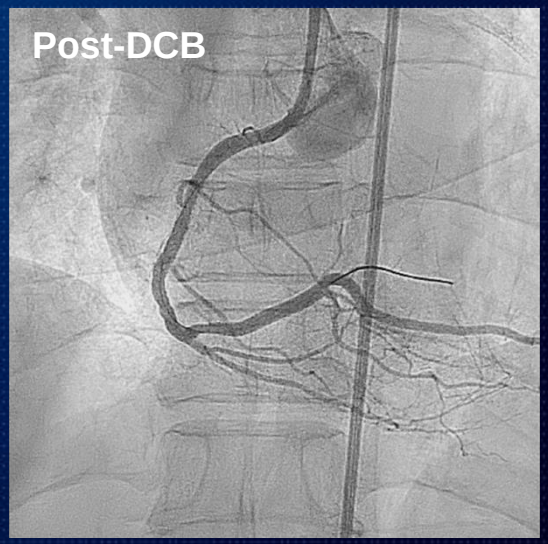


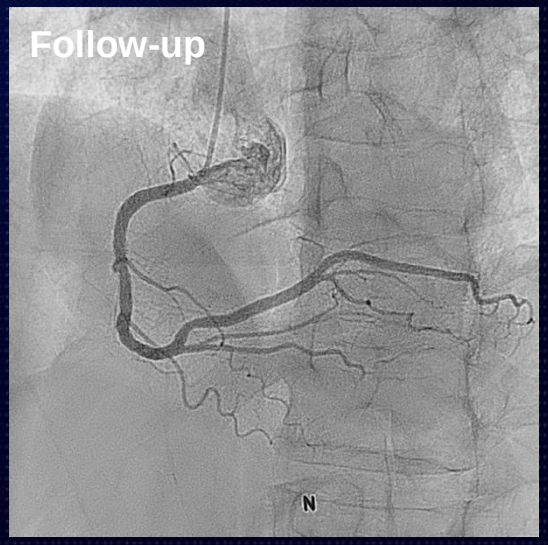




SeQuent Please treatment







Conclusions

- The Genoss DCB is a new paclitaxel-coated balloon with shellac plus vitamin E excipient.
- In this multicenter, head-to-head, first-in-man randomized trial, the Genoss DCB was non-inferior to the reference SeQuent Please for the primary endpoint of 6-month in-segment LLL.
- This study provided evidence for the efficacy and safety of the Genoss DCB treatment in treating coronary ISR lesions.
- However, longer-term follow-up and large-scale studies are needed to evaluate the clinical outcomes with the Genoss DCB in the treatment of coronary ISR.
- Furthermore, this Genoss DCB should also be investigated in de novo lesions.

Thank you for your attention!