

Real-World Data on Widespread Use of DCB : Insights From the IRIS-DEB Registry

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Disclosure

- I, Do-Yoon Kang, DO NOT have any relevant financial relationships to disclose.
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Background

- Drug-coated balloon (DCB) is an attractive therapeutic strategy for coronary in-stent restenosis or de novo small vessel disease.
- DCBs are recommended as a class 1A for the treatment of in-stent restenosis in the 2018 ESC guideline.
- There is still limited data about long term efficacy and safety of paclitaxel-coated balloon angioplasty in large-scale, real-world registry.

IRIS-DEB Registry

- An investigator-initiated, prospective, multi-center, real-world registry.
- Recruiting all consecutive patients who received DCB treatment from 8 centers in Korea from March 2014.
- Annual clinical follow-up upto 5 years was planned.
- A total of 1176 patients were enrolled with median 36 (IQR 12-60) month FU.

Inclusion / Exclusion Criteria

INCLUSION

1. Men or women at least age ≥ 20 years.
2. Patients who had residual stenosis $\leq 30\%$ after pre-dilation, without flow-limiting coronary dissection.
3. Patients who received drug-coated balloon treatment for significant coronary artery disease.
4. The patient or guardian agreed to the study protocol and the schedule for clinical follow-up, and provided informed written consent, as approved by the appropriate IRB/Ethical Committee of the respective clinical site.

EXCLUSION

1. Patients with allergy to Paclitaxel or antiplatelet agents.
2. Patients with a history of significant adverse events with aspirin, P2Y12 inhibitor, or heparin.
3. Patients with bleeding tendency, coagulation disorder.
4. Life expectancy < 1 years for any non-cardiac or cardiac causes.

Study Outcomes

- **Primary Outcome**

- : **Target-lesion failure** (a composite of death from cardiac cause, target-vessel-MI, or target-lesion revascularization) at 1 year

- **Secondary Outcomes**

- : Target-lesion failure at 5 year,
Individual components of the primary outcome at 1 and 5 year,
Stent thrombosis at 1 and 5 year,
Procedural success

Baseline Characteristics

Characteristics	Total (N = 1000)	ISR (N = 589)	De novo (N = 411)	P value
Age	66.0 ± 10.7	66.7 ± 10.5	65.1 ± 10.8	0.02
Male	757 (75.7%)	457 (77.6%)	300 (73.0%)	0.10
Smoking (%)	191 (19.1%)	107 (18.2%)	84 (20.4%)	0.40
HTN (%)	713 (71.4%)	431 (73.3%)	282 (68.6%)	0.12
DM (%)	437 (43.7%)	267 (45.3%)	170 (41.4%)	0.20
Dyslipidemia	796 (79.7%)	481 (81.8%)	315 (76.6%)	0.06
Dialysis (%)	64 (6.4%)	38 (6.5%)	26 (6.3%)	>0.9
Previous MI (%)	211 (21.1%)	166 (28.2%)	45 (10.9%)	<0.01
Previous CABG (%)	33 (3.3%)	23 (3.9%)	10 (2.4%)	0.20
ACS presentation (%)	417 (41.7%)	238 (40.4%)	179 (43.6%)	0.30
LV Ejection fraction, %	57.3 ± 11.1	56.5 ± 11.6	58.2 ± 10.4	0.03
Total cholesterol, mg/dL	139.1 ± 37.7	134.0 ± 33.4	146.3 ± 42.1	<0.001
HDL cholesterol, mg/dL	44.4 ± 13.4	44.1 ± 12.0	44.8 ± 15.1	0.50
LDL cholesterol, mg/Dl	78.9 ± 31.3	74.3 ± 28.1	85.1 ± 34.2	<0.001

Lesion Characteristics

Characteristic	Total (Lesion N = 1085)	ISR (Lesion N = 639)	De novo (Lesion N = 446)	p-value
Number of disease extent (%)				0.09
One-vessel disease	477 (44.0%)	291 (45.5%)	186 (41.7%)	
Two-vessel disease	385 (35.5%)	231 (36.2%)	154 (34.5%)	
Three-vessel disease	223 (20.6%)	117 (18.3%)	106 (23.8%)	
MVD (%)	608 (56.0%)	348 (54.5%)	260 (58.3%)	0.20
Target lesion location (%)				<0.01
Left anterior descending artery	485 (44.7%)	315 (49.3%)	170 (38.1%)	
Left circumflex artery	276 (25.4%)	134 (21.0%)	142 (31.8%)	
Right coronary artery	280 (25.8%)	163 (25.5%)	117 (26.2%)	
Left main artery	40 (3.7%)	23 (3.6%)	17 (3.8%)	
Graft vessels	4 (0.4%)	4 (0.6%)	0 (0.0%)	
ACC/AHA lesion type B2C (%)	866 (79.8%)	509 (79.7%)	357 (80.0%)	>0.9
Calcification (%)	235 (21.7%)	131 (20.5%)	104 (23.3%)	0.30
Bifurcation (%)	269 (24.8%)	169 (26.4%)	100 (22.4%)	0.13
Chronic total occlusion (%)	111 (10.2%)	58 (9.1%)	53 (11.9%)	0.20

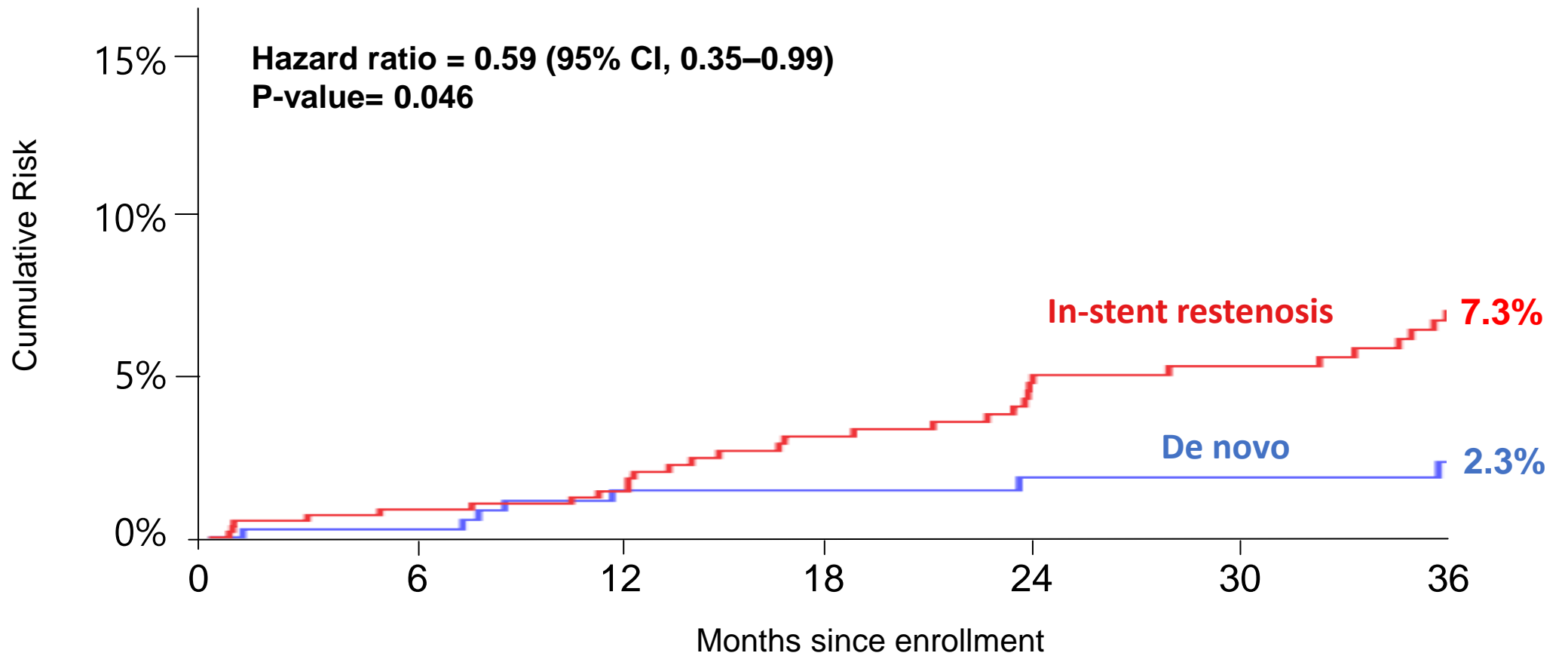
Procedural Characteristics

Characteristics	Total (Patient N = 1000) (Lesion N = 1085)	ISR (Patient N = 589) (Lesion N = 639)	De novo (Patient N = 411) (Lesion N = 446)	P value
DCB number for lesion	1.2 ± 0.5	1.2 ± 0.5	1.2 ± 0.4	0.20
DCB mean diameter, mm	2.9 ± 0.4	3.0 ± 0.4	2.6 ± 0.3	<0.01
DCB total length, mm	28.1 ± 19.0	28.5 ± 15.4	27.6 ± 23.3	0.40
Combine with DES (%)	101 (9.3%)	34 (5.3%)	67 (15.0%)	<0.01
IVUS during procedure (%)	426 (39.4%)	254 (39.7%)	172 (38.8%)	0.80
FFR during procedure (%)	115 (10.6%)	58 (9.1%)	57 (12.8%)	0.06
Discharge medication				
Aspirin at discharge (%)	969 (96.9%)	577 (98.0%)	392 (95.4%)	0.03
Clopidogrel at discharge (%)	872 (87.2%)	521 (88.5%)	351 (85.4%)	0.20
Ticagrelor at discharge (%)	68 (6.8%)	39 (6.6%)	29 (7.1%)	0.80
Statin at discharge (%)	947 (94.8%)	563 (95.7%)	384 (93.4%)	0.11

Clinical Outcomes

	Total (N = 1000)	ISR (N = 589)	De novo (N = 411)	P value
Clinical Outcomes at 1-year follow-up				
TLF (%)	31 (3.1%)	20 (3.4%)	11 (2.7%)	0.60
Cardiac death (%)	8 (0.8%)	6 (1.0%)	2 (0.5%)	0.50
TV-MI (%)	6 (0.6%)	2 (0.3%)	4 (1.0%)	0.20
TLR (%)	19 (1.9%)	13 (2.2%)	6 (1.5%)	0.50
Clinical Outcomes at 3-year follow-up				
TLF (%)	65 (6.5%)	49 (8.3%)	16 (3.9%)	0.006
Cardiac death (%)	13 (1.3%)	11 (1.9%)	2 (0.5%)	0.09
TV-MI (%)	17 (1.7%)	10 (1.7%)	7 (1.7%)	>0.99
TLR (%)	43 (4.3%)	34 (5.8%)	9 (2.2%)	0.007

Kaplan-Meier Estimates of Target Lesion Failure for 3-years



No. at risk

In-stent restenosis	589	560	506	434	399	345	325
De novo	411	373	301	262	245	225	205

Risk factors for TLF by Cox Proportional Hazards Models

Characteristic	Univariable	P value	Multivariable	p-value
Type of lesion-ISR	2.27 [1.23-3.61]	0.01	2.19 [1.37-3.50]	0.01
Male	0.77 [0.49-1.13]	0.16	0.76 [0.49-1.16]	0.20
Age	1.00 [0.98-1.02]	0.85	1.00 [0.98-1.02]	0.88
Current smoking	0.56 [0.31-1.01]	0.05	0.04 [0.57-1.04]	0.07
Hypertension	0.98 [0.64-1.49]	0.92		
Diabetes	1.52 [1.03-2.23]	0.03	1.52 [1.03-2.24]	0.04
CKD on dialysis	1.88 [0.98-3.61]	0.06		
Total cholesterol(mg/dL)	0.99 [0.99-1.00]	0.02		
LDL cholesterol (mg/dL)	0.99 [0.99-1.00]	0.05		
DCB number for lesion	1.68 [1.22-2.30]	<0.01	1.41 [1.01-1.92]	0.04
DCB mean diameter (mm)	2.15 [1.32-3.49]	<0.01		
DCB total length (mm)	1.91 [1.00-1.01]	0.05		
IVUS during procedure	1.66 [1.13-2.44]	0.01	1.56 [1.05-2.32]	0.03
FFR during procedure	0.85 [0.44-1.63]	0.62		
Combine with DES (%)	0.42 [0.15-1.13]	0.08		

Conclusion

- IRIS-DEB registry is an investigator-initiated, prospective, multi-center, real-world registry of the all-comer patients who received DCB treatment in South Korea.
- DCB angioplasty with paclitaxel coated balloon showed favorable 3-year clinical outcomes after treatment of coronary ISR or de novo small vessel disease.