

Biodegradable Polymer Sirolimus-eluting Stent in Patients with Left Main Coronary Artery Disease: PRE-COMBAT-5 Trial

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Disclosure

- I, Jinho Lee, have NO conflict of interest related to this presentation.

Background

- In unprotected left main coronary artery (ULMCA)
 - second-generation DES showed a similar clinical outcome.
- Durable polymer (second-generation DES)
 - which potentially causing stent thrombosis and restenosis.
 - Biodegradable polymers has been introduced.
- Evaluate the safety and efficacy **biodegradable polymer sirolimus-eluting Orsiro stent (SES)** in the treatment of ULMCA stenosis

Method

- Multicenter, Investigator-initiated, Open label, Prospective Registry
- Patients were enrolled between March 2014 to July 2021
- Eligible patients with unprotected LMCA stenosis > 50%
- Treated with biodegradable polymer sirolimus-eluting stent
- Primary Outcome
 - 1-year rate of major adverse cardiac or cerebrovascular events (MACCE), defined as a composite of all-cause death, myocardial infarction, stroke, or target vessel revascularization

Statistics

- Baseline characteristics and Clinical outcomes were compared with the historical control from the PRECOMBAT-2 & 3 population, who were treated ULMCA with Everolimus-eluting stents (Xience V & Promus).
- Differences in clinical characteristics between two groups were adjusted with propensity-score matching methods.

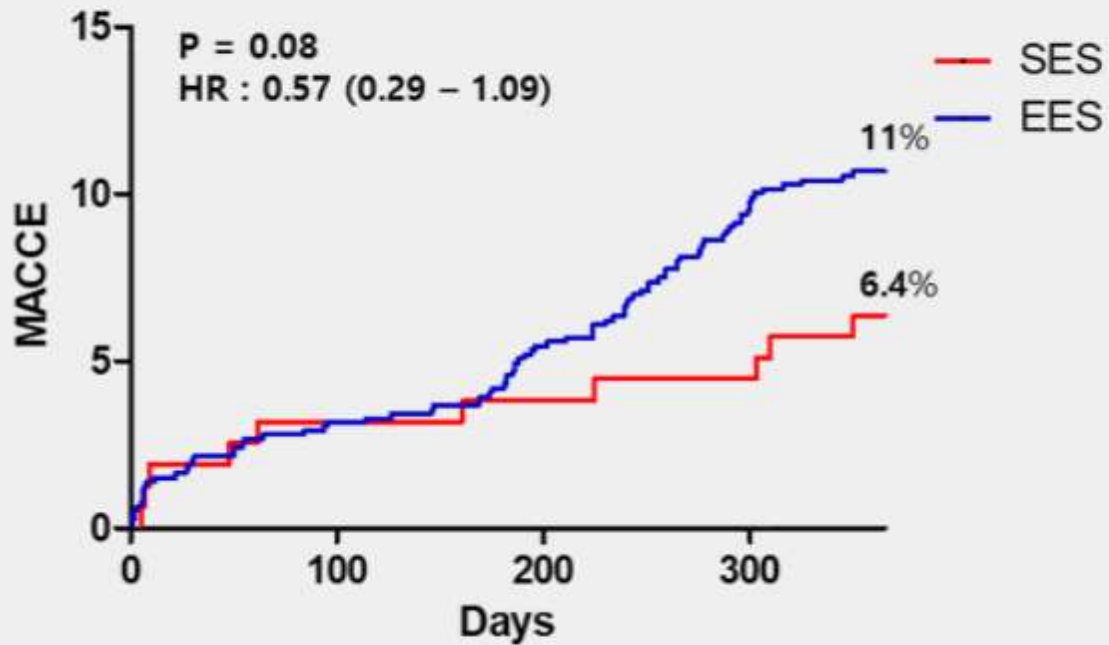
Result

- Baseline characteristics

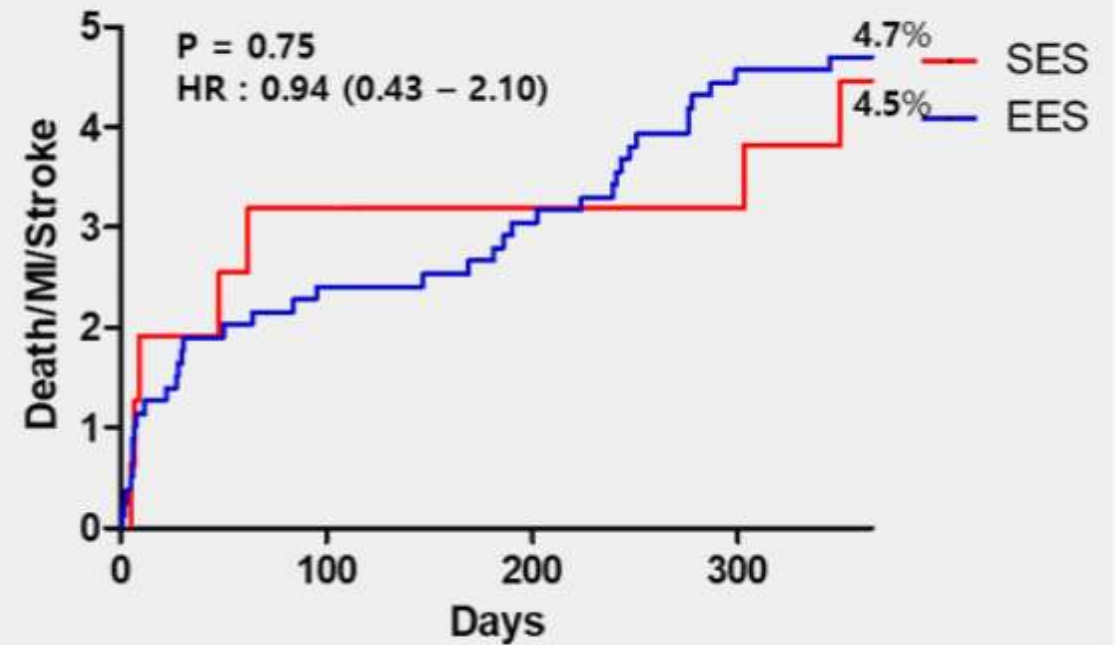
Characteristics	SES (N = 157)	EES (N = 791)	P-Value
Age (years)	65.5 ± 9.5	63.3 ± 9.7	0.01
Male sex	129 (82.2%)	566 (71.6%)	0.008
Hypertension	102 (65.0%)	488 (61.7%)	0.50
Diabetes mellitus	61 (38.9%)	302 (38.2%)	0.95
Current smoker	34 (21.7%)	191 (24.1%)	0.57
Dyslipidemia	115 (73.2%)	381 (48.2%)	<0.001
History of MI	7 (4.5%)	42 (5.3%)	0.81
Previous PCI	25 (15.9%)	76 (9.6%)	0.028
History of stroke	12 (7.6%)	37 (8.0%)	>0.99
Peripheral artery disease	1 (0.6%)	31 (3.9%)	0.07
Chronic renal disease	12 (7.6%)	9 (1.1%)	<0.001
Chronic lung disease	2 (1.3%)	15 (1.9%)	0.84
Acute coronary syndrome	87 (55.4%)	400 (50.6%)	0.31

Result

(A) MACCE



(B) Death/MI/Stroke



Result

- Clinical outcomes and hazard ratio at 1-year

Clinical Outcomes	SES (N = 157)	EES (N = 791)	Unadjusted Hazard Ratio (95% Confidence Interval)	P-Value
MACCE	10 (6.4%)	87 (11.0%)	0.57 (0.29 – 1.09)	0.08
Composite of death, MI, or Stroke	7 (4.5%)	37 (4.7%)	0.94 (0.43 – 2.10)	0.75
Death	4 (2.5%)	20 (2.5%)	1.01 (0.35 – 2.96)	>0.99
MI	4 (2.5%)	18 (2.3%)	1.11 (0.38 – 3.28)	0.85
Stroke	0 (0%)	8 (10.1%)	-	0.21
TVR	6 (3.8%)	57 (7.3%)	0.51 (0.22-1.19)	0.12

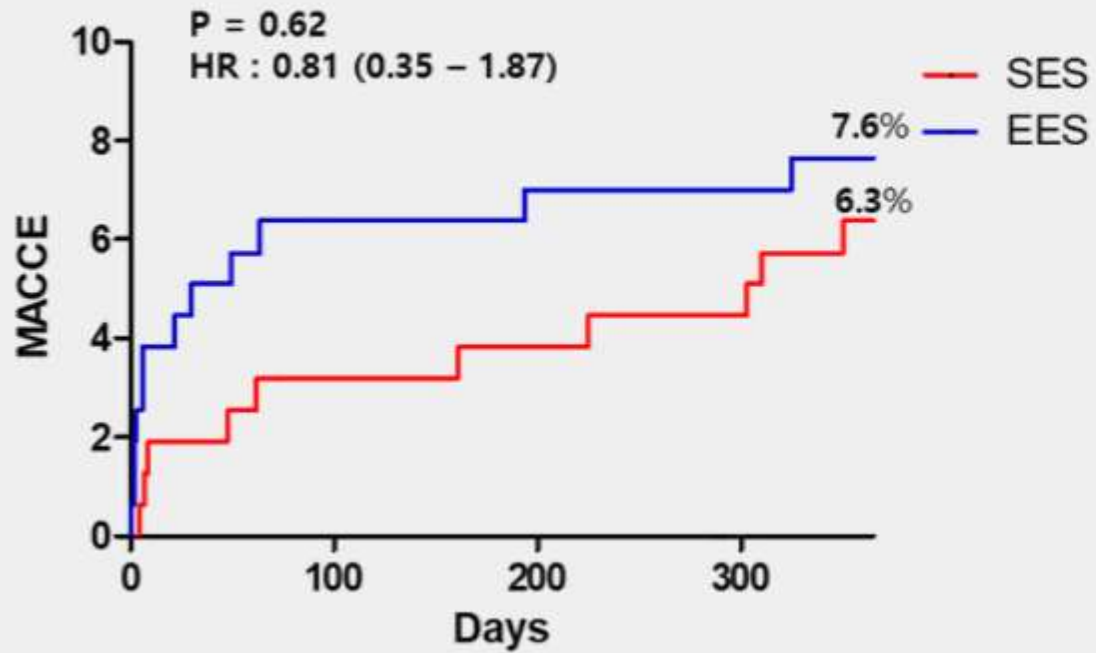
Result

- Baseline characteristics (PS Matched)

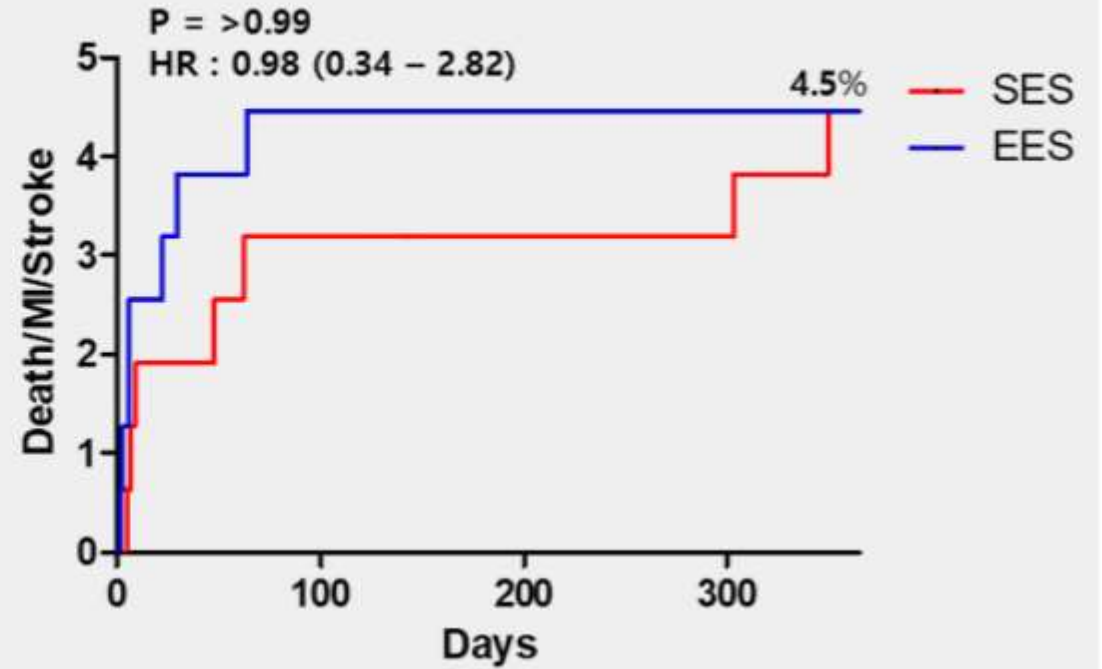
Characteristics	SES (N = 157)	EES (N = 157)	P-Value
Age (years)	65.5 ± 9.5	65.5 ± 9.5	>0.99
Male sex	129 (82.2%)	114 (72.6%)	0.059
Hypertension	102 (65.0%)	101 (64.3%)	>0.99
Diabetes mellitus	61 (38.9%)	59 (37.6%)	0.91
Current smoker	34 (21.7%)	28 (17.8%)	0.48
Dyslipidemia	115 (73.2%)	113 (72.0%)	0.90
History of MI	7 (4.5%)	5 (3.2%)	0.77
Previous PCI	25 (15.9%)	25 (15.9%)	>0.99
History of stroke	12 (7.6%)	9 (5.7%)	0.65
Peripheral artery disease	1 (0.6%)	1 (0.6%)	>0.99
Chronic renal disease	12 (7.6%)	8 (5.1%)	0.49
Chronic lung disease	2 (1.3%)	2 (1.3%)	>0.99
Acute coronary syndrome	87 (55.4%)	89 (56.7%)	0.91

Result

(A) MACCE



(B) Death/MI/Stroke



Result

- Clinical outcomes and Hazard ratio in Matched Population

Clinical Outcomes	SES (N = 157)	EES (N = 791)	Adjusted Hazard Ratio (95% Confidence Interval)	P-Value
MACCE	10 (6.3%)	12 (7.6%)	0.81 (0.35 – 1.87)	0.62
Composite of death, MI, or Stroke	7 (4.5%)	7 (4.5%)	0.98 (0.34 – 2.82)	>0.99
Death	4 (2.5%)	2 (1.3%)	1.96 (0.39 – 9.73)	0.41
MI	4 (2.5%)	4 (2.5%)	0.98 (0.24 – 3.94)	>0.99
Stroke	0 (0.0%)	3 (1.9%)	0.13 (0.01 – 1.29)	0.08
TVR	6 (3.8%)	8 (5.1%)	0.73 (0.25 – 2.08)	0.60

Limitation

- Single arm registry
- Small number
- Time difference with the control group
- No comparison of procedural details

Conclusion

- In the multi-center, prospective, real-world, PRECOMBAT-5 registry, SES with biodegradable polymer (Orsiro) showed a comparable 1-year risk of MACCE for ULMCA PCI with second-generation EES

Thank you for your attention