Final Three-Year Outcome of a Randomized Trial Comparing Second Generation Drug-eluting Stents Using Either Biodegradable Polymer or Durable Polymer

The NOBORI Biolimus-Eluting versus XIENCE/PROMUS Everolimus-eluting Stent Trial (NEXT)

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On behalf of the NEXT Investigators

Potential conflicts of interest

Speaker's name: Masahiro Natsuaki

☑ I do not have any potential conflict of interest

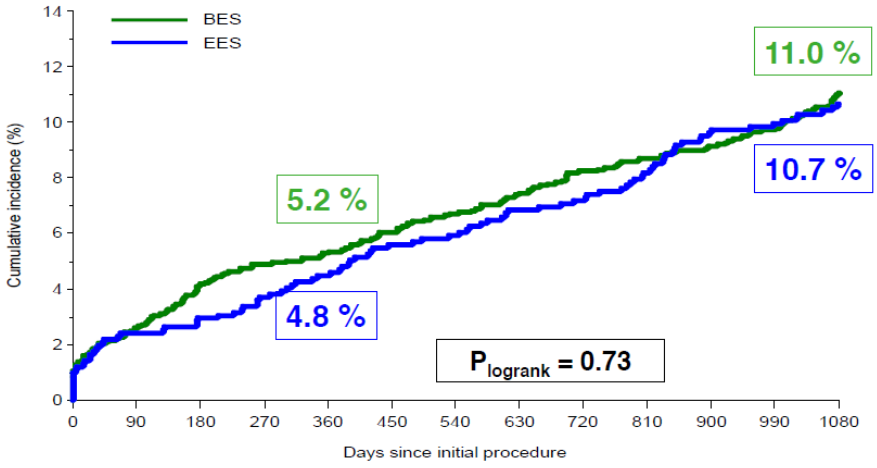
Study sponsor: Terumo Japan

Background

The advantage of coronary stent using biodegradable polymer could emerge beyond 1-year after stent implantation, when polymer has been fully degraded.

However, there are only a few randomized controlled trials other than the NEXT reporting the clinical outcomes beyond 1-year after biodegradable polymer biolimus-eluting stent (BP-BES) implantation as compared with durable polymer everolimus-eluting stent (DP-EES) implantation.

Therefore, we report the clinical outcomes of BP-BES compared with DP-EES through 3-year and beyond 1-year after stent implantation in the largest ever reported prospective multicenter randomized open label trial.

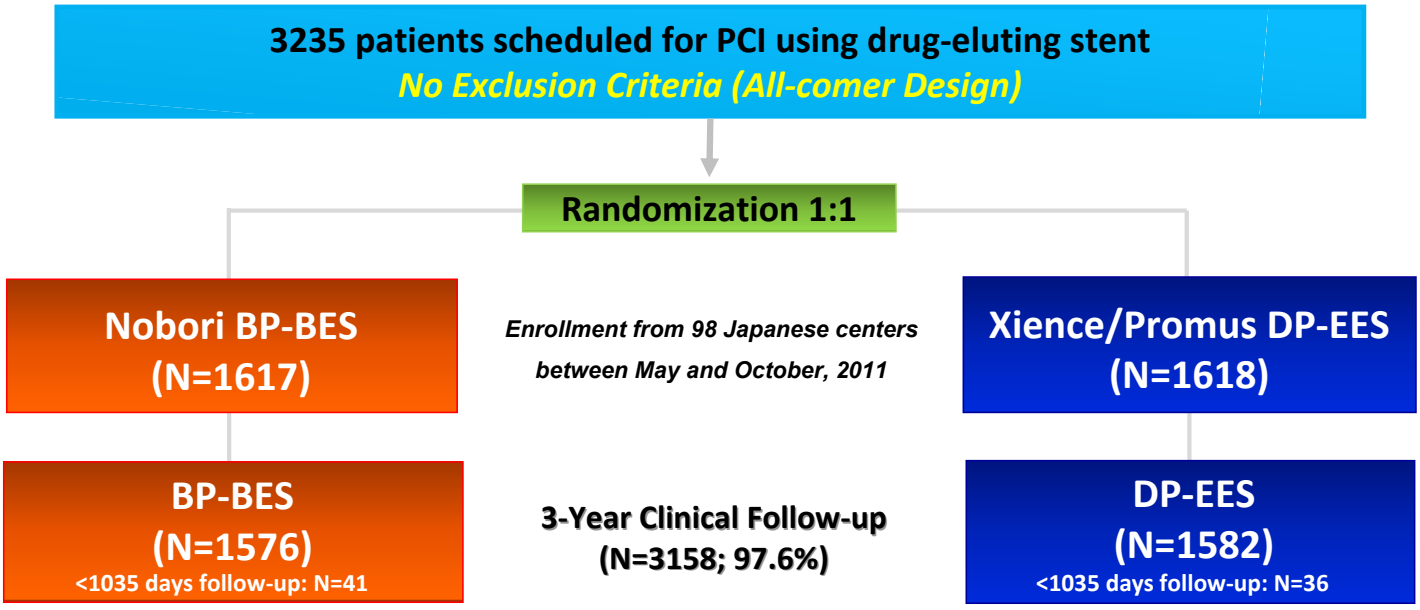


Smits P. EuroPCR 2014.

***COMPARE II** Cardiac death, myocardial infarction and TVR at 3-year*

NEXT Trial

Multicenter, randomized, non-inferiority trial comparing BP-BES with DP-EES



<Primary Endpoint>

Efficacy: Target lesion revascularization at 1-year

Safety: Death or Myocardial Infarction at 3-year

<Power Calculation>

3000 patients would yield 91% power to detect non-inferiority with the non-inferiority margin of 4.3% (True rate 12.2%)

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Baseline Characteristics

	BP-BES (1617)	DP-EES (1618)	P
Age (years)	69.1 ± 9.8	69.3 ± 9.8	0.49
Male gender	77 %	77 %	0.76
Diabetes	46 %	46 %	0.85
Hypertension	81 %	82 %	0.81
Prior PCI	50 %	51 %	0.9
Clinical diagnosis			0.62
Acute myocardial infarction	5.1 %	4.5 %	
Unstable angina	12 %	11 %	
Stable coronary artery disease	83 %	84 %	
Hemodialysis	6.5 %	5.2 %	0.11
Prior myocardial infarction	28 %	28 %	0.81
Prior stroke	10 %	11 %	0.43
Multivessel disease	51 %	51 %	0.9
SYNTAX score	10 (6-17)	10 (6-16)	0.17
No. of lesions treated per patient	1.27 ± 0.56	1.24 ± 0.51	0.1
No. of stents per patient	1.59 ± 0.84	1.6 ± 0.83	0.74
Total stent length per patient (mm)	33.0± 20.3	32.9 ± 20.7	0.87
Stent diameter (mm)	2.88 ± 0.67	2.87 ± 0.64	0.7
Multivessel treatment	13%	11%	0.21

Non-inferiority Assessment for the Primary Safety Endpoint

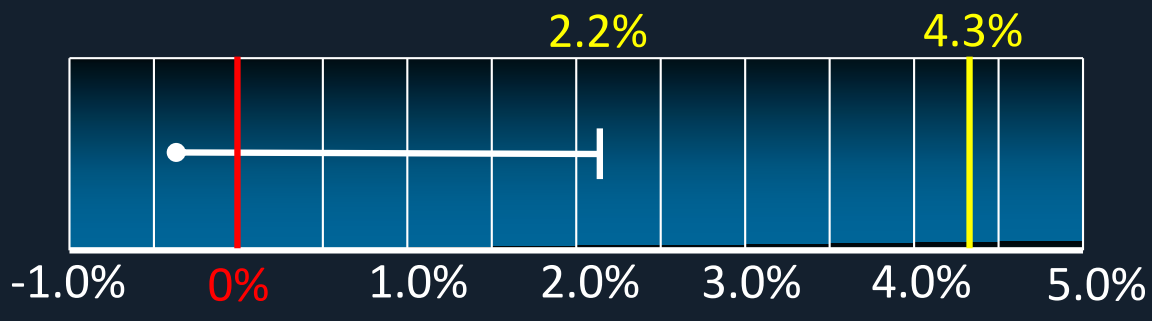
Death or Myocardial Infarction at 3-year

BP-BES 9.9% vs. DP-EES 10.3%

$P_{non\text{-}inferiority} < 0.0001$

Difference: -0.44%

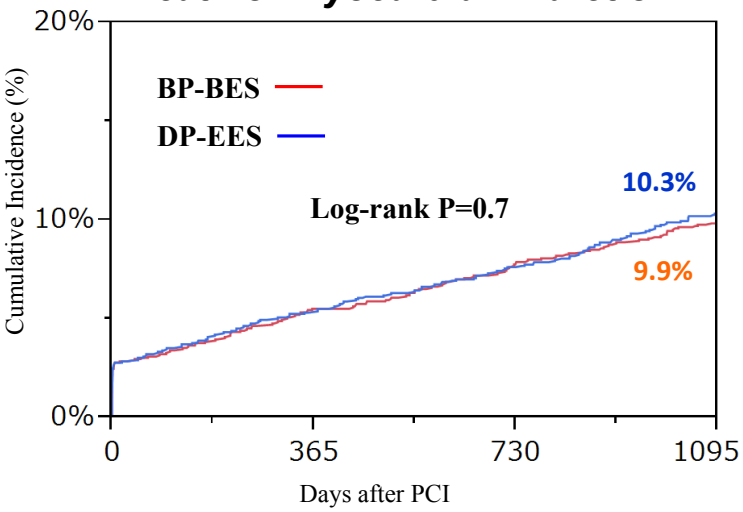
Upper one-sided 97.5% CI: 2.2%



Cumulative 3-year Incidence

Primary Safety Endpoint

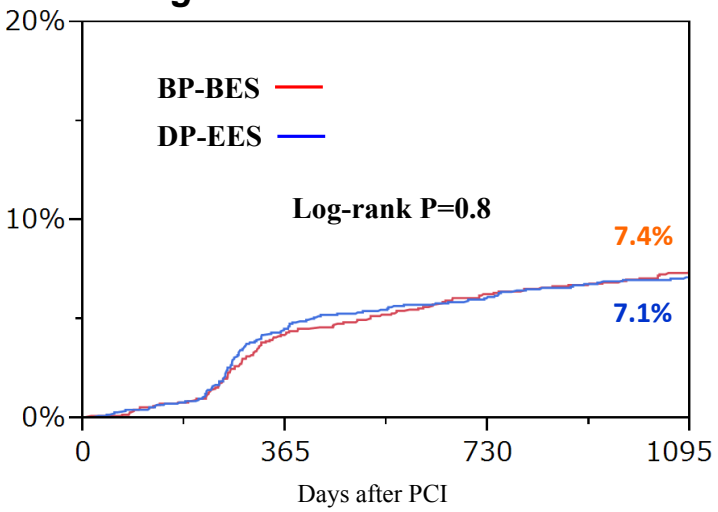
Death or Myocardial Infarction



Interval	0 day	365 days	730 days	1095 days
BP-BES group				
N of patients with at least 1 event		89	126	159
N of patients at risk	1617	1524	1478	1416
Cumulative Incidence		5.5%	7.8%	9.9%
DP-EES group				
N of patients with at least 1 event		87	124	166
N of patients at risk	1618	1529	1482	1413
Cumulative Incidence		5.4%	7.7%	10.3%

Primary Efficacy Endpoint

Target Lesion Revascularization



Interval	0 day	365 days	730 days	1095 days
BP-BES group				
N of patients with at least 1 event		68	99	116
N of patients at risk	1617	1506	1432	1353
Cumulative Incidence		4.3%	6.3%	7.4%
DP-EES group				
N of patients with at least 1 event		72	97	112
N of patients at risk	1618	1506	1440	1359
Cumulative Incidence		4.5%	6.1%	7.1%

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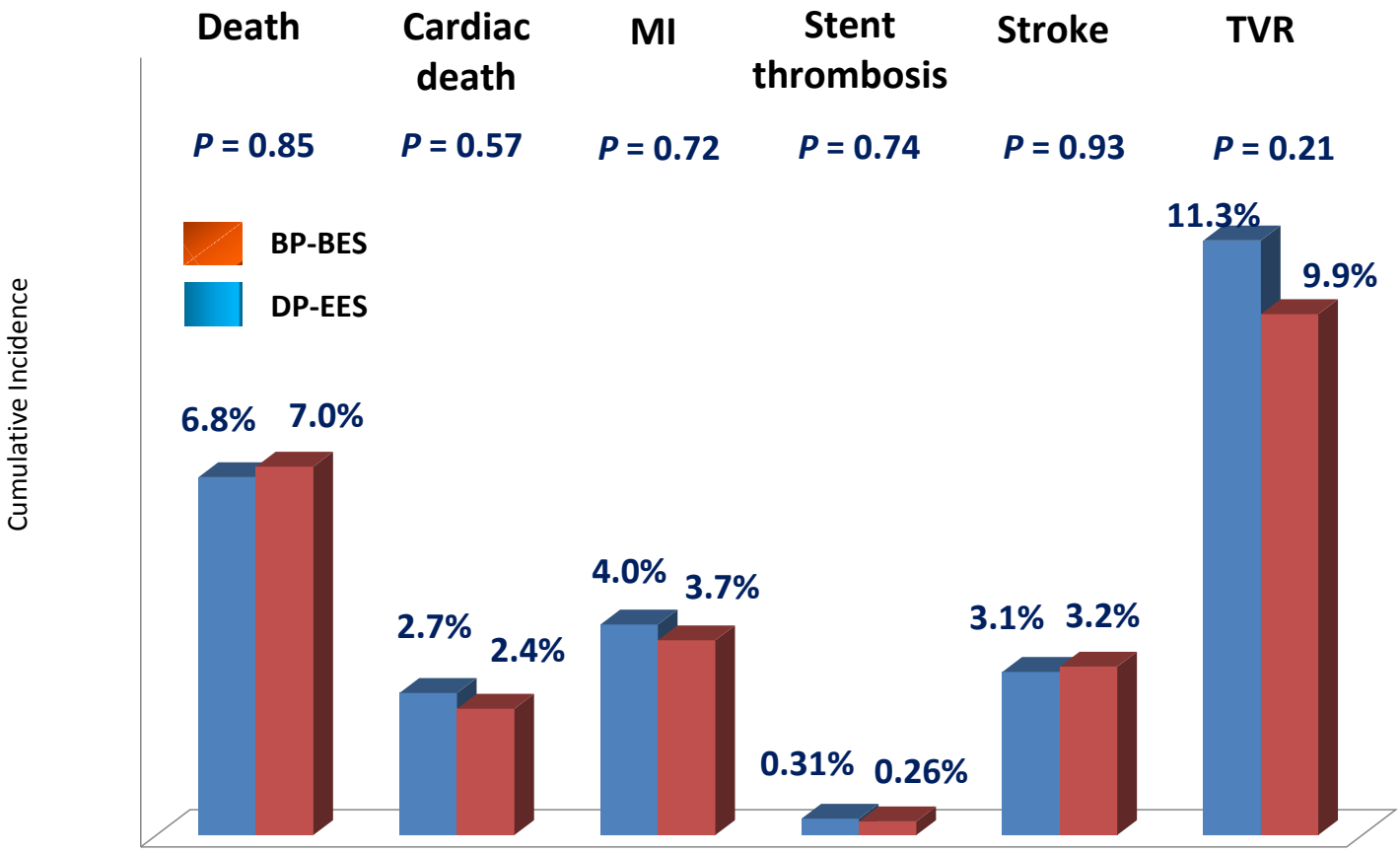
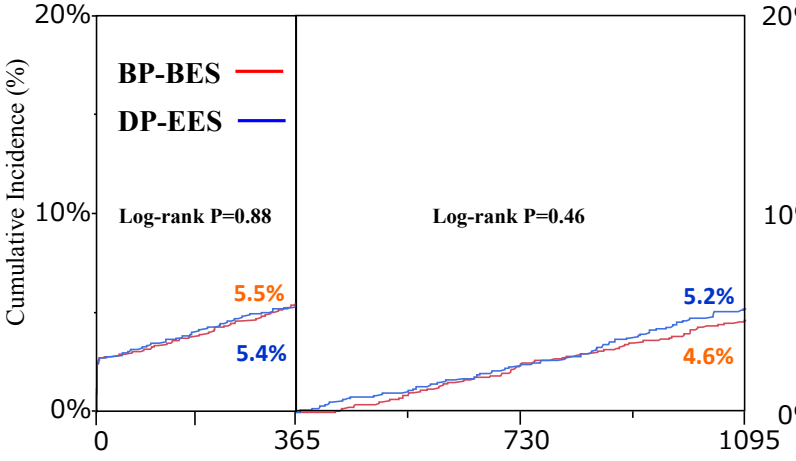
Clinical Outcomes at 3-Year

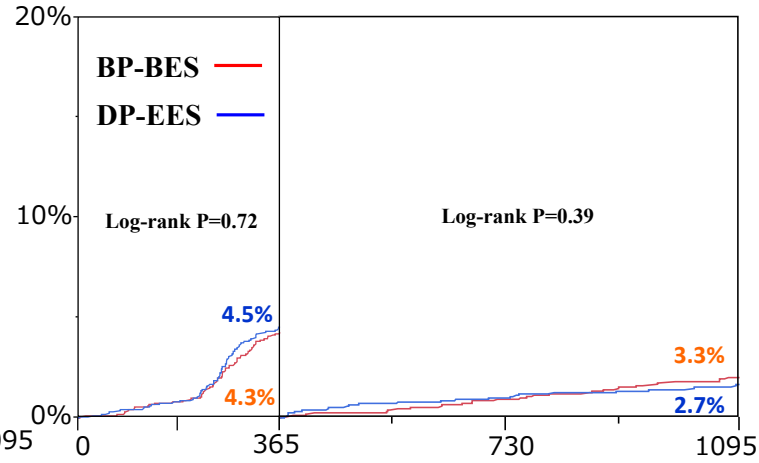


Landmark Analysis at 1-year

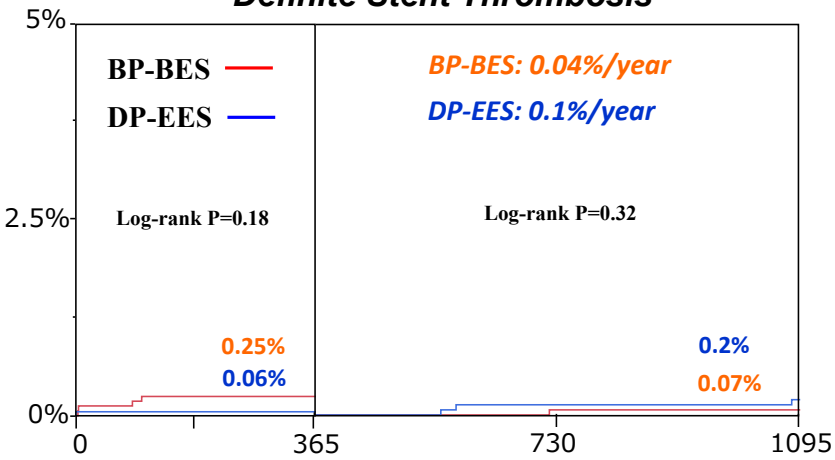
Primary Safety Endpoint
Death or Myocardial Infarction



Primary Efficacy Endpoint
Target Lesion Revascularization



Definite Stent Thrombosis



Conclusions

- *The safety and efficacy outcomes of BP-BES remained comparable to those of DP-EES through 3-year and beyond 1-year after stent implantation.*
- *There was no apparent signal suggesting either improvement or impairment of clinical outcomes with BP-BES compared with DP-EES.*
- *Longer-term follow-up is mandatory to fully understand whether BP-BES could provide any long-term benefit over DP-EES.*