Vascular Intervention // Coronary // **Orsiro**

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Long-term Outcomes with Biodegradable Polymer Sirolimus-eluting Stents versus Durable Polymer Everolimus-eluting Stents in ST-segment Elevation Myocardial Infarction (STEMI): 5-year follow-up of the BIOSTEMI randomized trial

Conclusions

- In patients with STEMI undergoing primary PCI, Orsiro is superior to Xience with respect to the rates of TLF at 5 years of follow-up, a difference driven by a numerically lower risk of clinically-indicated TLR.[1]

- Orsiro shows 31% significantly less target lesion failure at 5-year in STEMI patients: Orsiro DES: 7.7% vs. Xience DES: 11.1% (BIOSTEMI with historical information RR, 0,70; 95% BCI, 0.51-0.95, Bayesian posterior probability, 0.988)[1]

Study design

Investigator-initiated, prospective, multicentre, assessor-blinded, randomized (1:1), controlled, superiority trial comparing Orsiro and Xience in STEMI patients undergoing primary PCI.

Endpoints

Primary Endpoint for BIOSTEMI
Target Lesion Failure (TLF) at 12-month follow-up defined as the composite of:
- Cardiac Death
- Target Vessel-Myocardial Re-Infarction (TV-reMI)
- Clinically Indicated-Target Lesion Revascularization (CI-TLR)

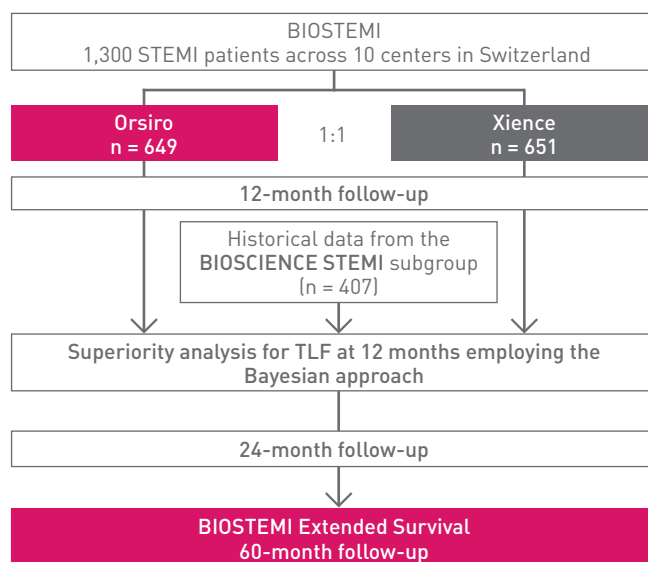### Primary Endpoint for BIOSTEMI Extended Survival
TLF at 60-month follow-up defined as the composite of:
- Cardiac Death
- TV-reMI
- CI-TLR

Selected Secondary Endpoints for both BIOSTEMI and BIOSTEMI ES
Individual components of the primary endpoint, All Cause Death, Target Vessel Revascularization (TVR), Target Vessel Failure (TVF), Definite Stent Thrombosis, Definite or Probable Stent Thrombosis (ST)

Patient characteristics[1]	Orsiro n = 649	Xience n = 651
Age, years*	62.2 ± 11.8	63.2 ± 11.8
Male	79%	73%
Active Smoker	46%	39%
Diabetes Mellitus	11%	13%
BMI [kg/m^2]*	26.9 ± 4.3	26.8 ± 4.3
Previous MI	4%	4%
Previous PCI	5%	5%
Previous CABG	0.3%	1%

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1,300 STEMI patients across 10 centers in Switzerland

Orsiro n = 649 — 1:1 — **Xience** n = 651

12-month follow-up

Historical data from the **BIOSCIENCE STEMI** subgroup (n = 407)

Superiority analysis for TLF at 12 months employing the Bayesian approach

24-month follow-up

BIOSTEMI Extended Survival 60-month follow-up

Angiographic and procedural characteristics[1]	Orsiro n = 816**	Xience n = 806**
Number of lesions/patient*	1.26 ± 0.57	1.24 ± 0.52
Total Occlusion	49%	55%
Thrombus Aspiration	30%	31%
Baseline TIMI flow		
0 or 1	55%	59%
2	13%	14%
3	31%	27%
Cardiogenic shock	3%	3%
Small vessel (minimum stent diameter ≤3.0 mm)	36%	40%
Bifurcation treatment (including left main coronary artery)	12%	14%
Long Lesions (total stent length ≥20 mm)	71%	71%

* Data shown as mean ± SD; ** Number of lesions
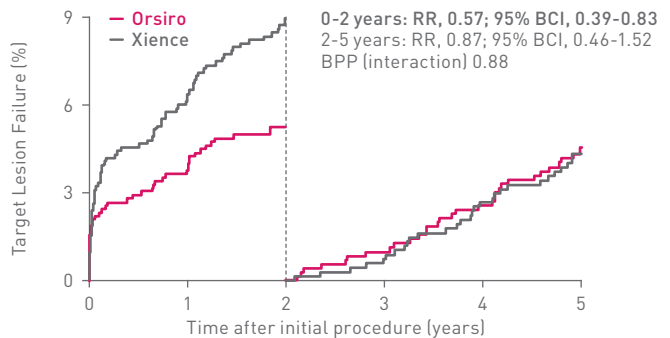
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Primary Endpoint – TLF at 5 years[1]

Orsiro – Proven safety and efficacy at short- and long-term follow-up with 31% significantly less TLF at 5-year in STEMI patients.[3]
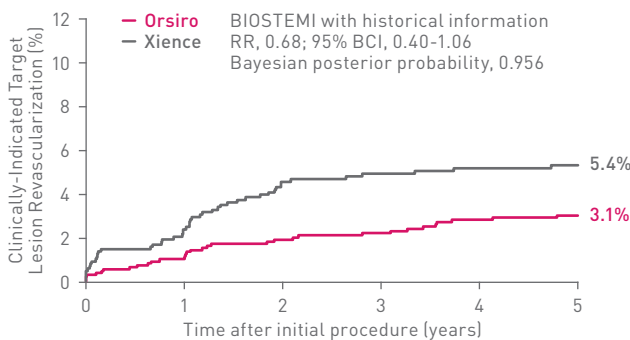
TLF at 5 years[1]

BIOSTEMI with historical information
RR, 0.70; 95% BCI, 0.51-0.95
Bayesian posterior probability, 0.988

TLF Landmark Analysis at 2 years[2]

0-2 years: RR, 0.57; 95% BCI, 0.39-0.83
2-5 years: RR, 0.87; 95% BCI, 0.46-1.52
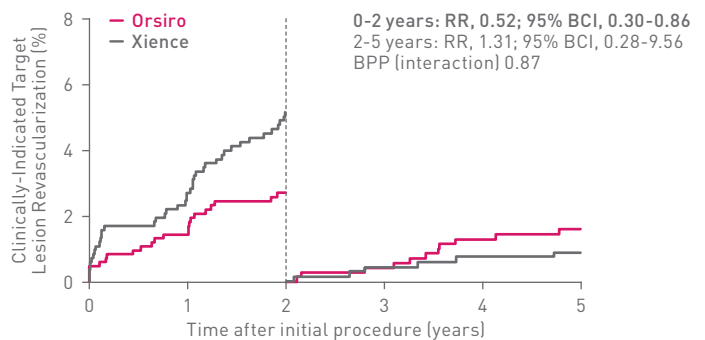BPP (interaction) 0.88
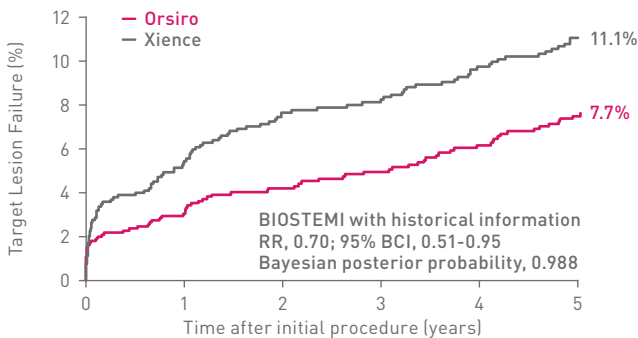
Selected Secondary Endpoints at 5 years

Orsiro is superior to Xience with respect to the rates of TLF at 5 years of follow-up, a difference driven by a numerically lower risk of clinically-indicated TLR.[3]

CI-TLR at 5 years[1]

BIOSTEMI with historical information
RR, 0.68; 95% BCI, 0.40-1.06
Bayesian posterior probability, 0.956

CI-TLR Landmark Analysis at 2 years[2]

0-2 years: RR, 0.52; 95% BCI, 0.30-0.86
2-5 years: RR, 1.31; 95% BCI, 0.28-9.56
BPP (interaction) 0.87

Other secondary outcomes[2]

	Orsiro n = 649	Xience n = 651	BIOSTEMI with historical information from BIOSCIENCE Rate Ratio (95% BCI)	Bayesian Posterior Probability	BIOSTEMI only Without historical information from BIOSCIENCE Ratio Ratio (95% BCI)	Bayesian Posterior Probability
Target Lesion Failure	8%	11%	**0.70 (0.51-0.95)**	**0.988**	0.68 (0.47-0.98)	0.981
Cardiac Death	5%	6%	0.81 (0.54-1.23)	0.839	0.89 (0.55-1.43)	0.677
TV-reMI	2%	3%	0.76 (0.41-1.34)	0.833	0.67 (0.32-1.35)	0.868
CI-TLR	3%	5%	0.68 (0.40-1.06)	0.956	0.56 (0.32-0.96)	0.982
Target Vessel Failure	10%	13%	**0.74 (0.55-0.97)**	**0.984**	0.71 (0.51-0.98)	0.982
CI-TVR	4%	6%	**0.59 (0.34-0.98)**	**0.979**	0.56 (0.34-0.92)	0.990
POCE	16%	18%	0.88 (0.66-1.14)	0.836	0.87 (0.67-1.13)	0.847
Definite Stent Thrombosis	2%	3%	0.58 (0.28-1.18)	0.933	0.59 (0.28-1.20)	0.927

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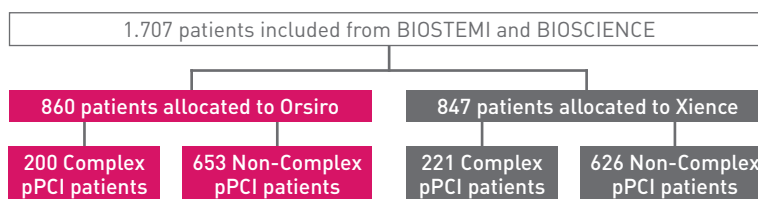Vascular Intervention // Coronary // **Orsiro**

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Complex Primary Percutaneous Coronary Intervention With Ultrathin Strut Biodegradable Versus Thin Strut Durable Polymer Drug-Eluting Stents In Patients With ST-segment Elevation Myocardial Infarction (STEMI): A Subgroup Analysis From The BIOSTEMI Randomized Trial[1]

Conclusions

- Orsiro outperforms Xience for the treatment of non-complex primary PCI STEMI patients at 2-year follow-up (Orsiro: 4.4% ; Xience: 8.2%, p=0,008) and numerically better outcomes in complex primary PCI STEMI patients.[1]
- Overall, as per investigator's interpretation, Orsiro was superior to Xience for stent-related outcomes at 2 years in primary PCI STEMI patients, irrespective of complexity.[1]

Study design

Subgroup analysis of complex vs. non-complex primary PCI Acute Coronary Syndrome (ACS) patients. From the BIOSTEMI trial, an investigator-initiated, prospective, multicenter, assessor-blinded, randomized (1:1), controlled, superiority trial comparing Orsiro and Xience in STEMI patients undergoing primary PCI.

1.707 patients included from BIOSTEMI and BIOSCIENCE

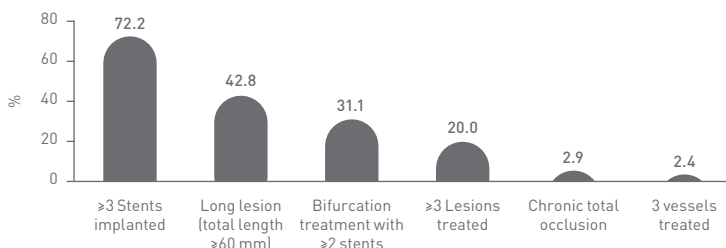| 860 patients allocated to Orsiro	847 patients allocated to Xience
200 Complex pPCI patients / 653 Non-Complex pPCI patients	221 Complex pPCI patients / 626 Non-Complex pPCI patients

Endpoints

Primary Endpoint

Target Lesion Failure (TLF) at 24-month follow-up defined as the composite of:
- Cardiac Death
- Target Vessel-Myocardial Re-Infarction (TV-reMI)
- Clinically Indicated-Target Lesion Revascularization (CI-TLR)

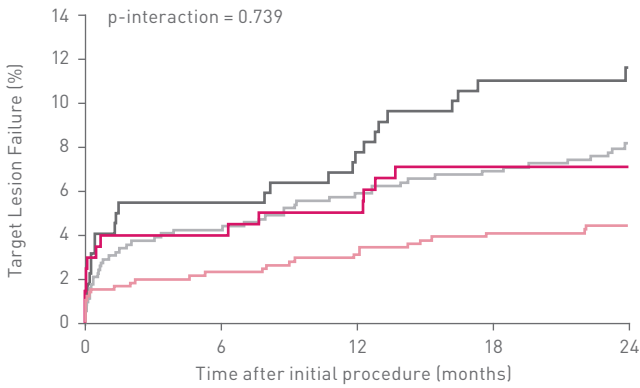## Characteristics of complex primary PCI patients

	%
≥3 Stents implanted	72.2
Long lesion (total length ≥60 mm)	42.8
Bifurcation treatment with ≥2 stents	31.1
≥3 Lesions treated	20.0
Chronic total occlusion	2.9
3 vessels treated	2.4

Baseline clinical characteristics

	Complex primary PCI		Non-complex primary PCI	
Patients	Orsiro n = 200	Xience n = 221	Orsiro n = 653	Xience n = 626
Age, years*	63.4 ± 11.7	64.4 ± 12.0	61.5 ± 12.0	62.3 ± 12.0
Male gender	80.5%%	74.2%	78.9%	74.1%
Body mass indey, kg/m²*	27.1 ± 4.7	27.3 ± 4.1	26.9 ± 4.2	26.7 ± 4.3
Diabetes mellitus	15.6%	11.8%	10.9%	13.3%
Hypertension	49.0%	51.8%	43.2%	45.0%
Hypercholesterolemia	55.3%	50.5%	46.8%	47.1%
Current smoker	44.1%	37.9%	46.6%	39.9%
Previous MI	2.5%	3.6%	4.6%	4.0%
Previous PCI	3.5%	4.1%	4.9%	5.3%
Previous CABG	1.5%	0.5%	0.6%	1.3%
Atrial fibrillation	4.0%	2.7%	1.5%	2.7%
Previous stroke or TIA	2.0%	1.8%	2.1%	2.9%
Left ventricular ejection fraction*	47.6 ± 11.3[a]	46.9 ± 11.0[b]	49.6 ± 10.8[c]	49.0 ± 11.2[d]
Multivessel disease	63.3%[e]	63.1%[f]	45.4%[g]	43.4%[h]

* Data shown as mean ± SD; [a] n = 155; [b] n = 180; [c] n = 403; [d] n = 381; [e] n = 147 ; [f] n = 160; [g] n = 496; [h] n = 491

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Clinical outcomes at 2 years[1]

TLF — p-interaction = 0.739
(Target Lesion Failure (%) vs Time after initial procedure (months))

Cardiac Death — p-interaction = 0.318
(Cardiac Death (%) vs Time after initial procedure (months))

Legend:
— Orsiro in Complex pPCI
— Orsiro in non-Complex pPCI
— Xience in Complex pPCI
— Xience in non-Complex pPCI

TV-MI — p-interaction = 0.120
(Target Vessel Q-wave or non-Q-wave Myocardial Infarction (%) vs Time after initial procedure (months))

CI-TLR — p-interaction = 0.781
(Clinically Indicated Target Lesion Revascularization (%) vs Time after initial procedure (months))
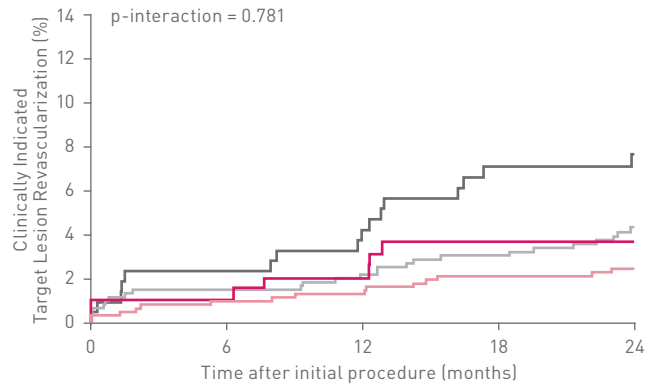
Orsiro outperforms Xience for the treatment of non-complex, and shows numerically better outcomes in complex primary PCI STEMI patients at 2 years.

	Complex primary PCI				Non-complex primary PCI				
	Orsiro n = 200	Xience n = 221	HR (95% CI)	p-value	Orsiro n = 653	Xience n = 626	HR (95% CI)	p-value	p-value for interaction
Target Lesion Failure[a]	14 (7.1%)	25 (11.6%)	0.62 (0.32-1.19)	0.15	28 (4.4%)	49 (8.2%)	0.54 (0.34-0.86)	0.008	0.74
Cardiac Death	8 (4.0%)	8 (3.6%)	1.11 (0.41-2.95)	0.84	14 (2.2%)	22 (3.6%)	0.61 (0.31-1.19)	0.14	0.32
MI	5 (2.7%)	13 (6.2%)	0.42 (0.15-1.19)	0.09	23 (2.7%(	17 (2.9%)	1.29 (0.69-2.42)	0.43	0.06
TV-reMI	2 (1.0%)	9 (4.3%)	0.24 (0.05-1.13)	0.051	10 (1.6%)	10 (1.7%)	0.95 (0.39-2.28)	0.90	0.12
Cardiac death or any MI	12 (6.2%)	21 (9.6%)	0.63 (0.31-1.28)	0.20	36 (5.7%)	38 (6.3%)	0.90 (0.57-1.43)	0.66	0.40
Any Revascularization	11 (5.9%)	30 (14.3%)	0.39 (0.20-0.79)	0.006	40 (6.5%)	44 (7.5%)	0.86 (0.56-1.32)	0.50	0.056
Any TLR	7 (3.7%)	17 (8.2%)	0.45 (0.19-1.10)	0.07	17 (2.8%)	26 (4.5%)	0.62 (0.33-1.14)	0.12	0.58
CI-TLR	7 (3.7%)	16 (7.7%)	0.48 (0.20-1.18)	0.10	15 (2.4%)	25 (4.3%)	0.57 (0.30-1.07)	0.08	0.78
Any TVR	9 (4.8%)	24 (11.5%)	0.41 (0.19-0.88)	0.02	23 (3.7%)	30 (5.2%)	0.72 (0.42-1.25)	0.24	0.23
CI-TVR	9 (4.8%)	23 (11.0%)	0.43 (0.20-0.92)	0.03	21 (3.4%)	29 (5.0%)	0.68 (0.39-1.20)	0.18	0.33
Target Vessel Failure[b]	16 (8.2%)	32 (14.8%)	0.54 (0.30-0.99)	0.043	36 (5.7%)	54 (9.0%)	0.63 (0.41-0.96)	0.03	0.70
POCE[c]	25 (12.7%)	40 (18.3%)	0.67 (0.41-1.11)	0.12	64 (10.1%)	72 (11.8%)	0.86 (0.61-1.20)	0.36	0.44
Cerebrovascular event (any)	2 (1.1%)	5 (2.3%)	0.44 (0.09-2.28)	0.32	8 (1.3%)	10 (1.7%)	0.76 (0.30-1.93)	0.56	0.57
Def. Stent Thrombosis	2 (1.0%)	6 (2.8%)	0.37 (0.07-1.84)	0.21	8 (1.3%)	8 (1.3%)	0.95 (0.36-2.53)	0.92	0.32
Def./ Prob. Stent Thrombosis	4 (2.0%)	12 (5.5%)	0.37 (0.12-1.14)	0.07	12 (1.9%)	13 (2.2%)	0.87 (0.40-1.92)	0.74	0.21

a. Composite of cardiac death, target vessel myocardial reinfarction (Q-wave and non-Q-wave), and clinically indicated target lesion revascularization (primary endpoint); b. Composite of cardiac death, any myocardial reinfarction, or any target vessel revascularization; c. Composite of all cause death, any myocardial reinfarction, or any revascularization.

Principal investigators
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1. Iglesias et al. Complex primary percutaneous coronary intervention with ultrathin-strut biodegradable versus thin-strut durable polymer drug-eluting stents in patients with ST-segment elevation myocardial infarction: A subgroup analysis from the BIOSTEMI randomized trial, Catheter Cardiovasc. Interv., 2023.

Clinical data collected with the Orsiro DES device within the Orsiro family clinical program.

Nov_2023

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