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BIOSTEMI

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

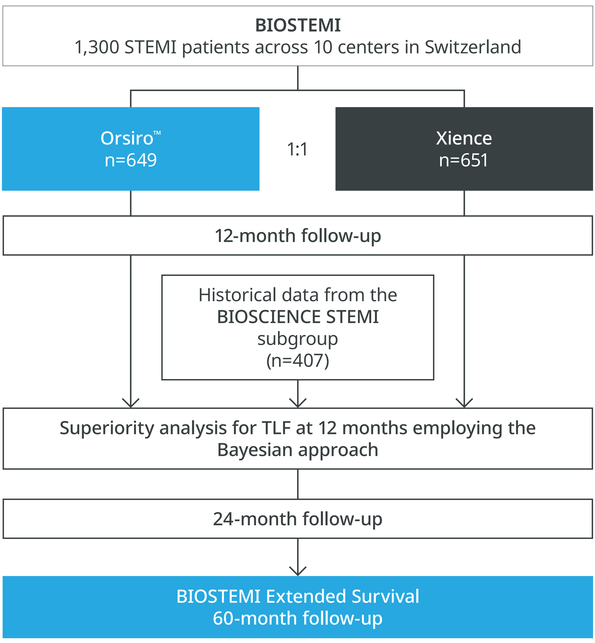
Target Lesion Failure (TLF) at 12-month follow-up defined as the composite of:
– Cardiac Death
– Target Vessel-Myocardial Re-Infarction (TV-reMI)
– Clinically Indicated-Target Lesion Revascularization (CI-TLR)

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/m²]*	26.9±4.3	26.8±4.3
Previous MI	4 %	4 %
Previous PCI	5 %	5 %
Previous CABG	0.3 %	1 %

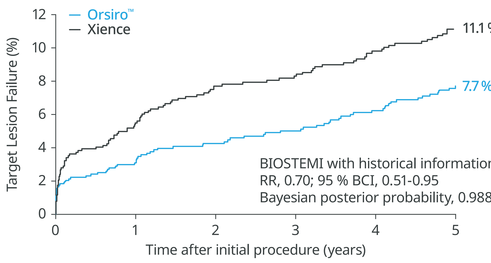
ANGIOGRAPHIC AND PROCEDURAL CHARACTERISTICS[1]	ORSIRO™ N=816**	XIENCE N=806**
Number of lesions/patient*	1.26±0.57	1.24±0.52
Total Occlusion	49 %	55 %
Thrombus Aspiration	30 %	31 %
Baseline TIMI flow		
0 or 1	55 %	59 %
2	13 %	14 %
3	31 %	27 %
Cardiogenic shock	3 %	3 %
Small vessel (minimum stent diameter ≤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*

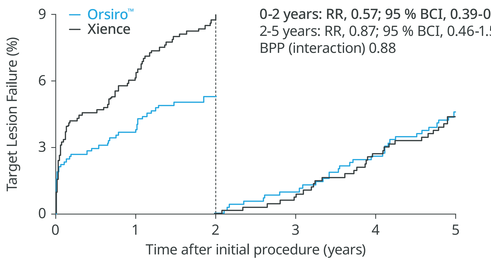
Primary endpoint – TLF at 5 years[1]

Orsiro™ DES – 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]



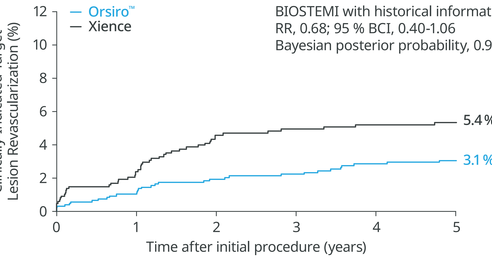
TLF Landmark Analysis at 2 years[2]



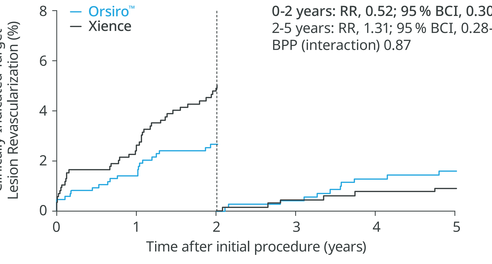
Selected secondary endpoints at 5 years

Orsiro™ DES 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]



CI-TLR Landmark Analysis at 2 years[2]



OTHER SECONDARY OUTCOMES[2]			BIOSTEMI WITH HISTORICAL INFORMATION FROM BIOSCIENCE	
	ORSIRO™ N=649	XIENCE N=651	RATE RATIO (95 % BCI)	BAYESIAN POSTERIOR PROBABILITY
Target Lesion Failure	8 %	11 %	0.70 (0.51-0.95)	0.988
Cardiac Death	5 %	6 %	0.81 (0.54-1.23)	0.839
TV-reMI	2 %	3 %	0.76 (0.41-1.34)	0.833
CI-TLR	3 %	5 %	0.68 (0.40-1.06)	0.956
Target Vessel Failure	10 %	13 %	0.74 (0.55-0.97)	0.984
CI-TVR	4 %	6 %	0.59 (0.34-0.98)	0.979
POCE	16 %	18 %	0.88 (0.66-1.14)	0.836
Definite Stent Thrombosis	2 %	3 %	0.58 (0.28-1.18)	0.933

OTHER SECONDARY OUTCOMES[2]			BIOSTEMI ONLY WITHOUT HISTORICAL INFORMATION FROM BIOSCIENCE	
	ORSIRO™ N=649	XIENCE N=651	RATE RATIO (95 % BCI)	BAYESIAN POSTERIOR PROBABILITY
Target Lesion Failure	8 %	11 %	0.68 (0.47-0.98)	0.981
Cardiac Death	5 %	6 %	0.89 (0.55-1.43)	0.677
TV-reMI	2 %	3 %	0.67 (0.32-1.35)	0.868
CI-TLR	3 %	5 %	0.56 (0.32-0.96)	0.982
Target Vessel Failure	10 %	13 %	0.71 (0.51-0.98)	0.982
CI-TVR	4 %	6 %	0.56 (0.34-0.92)	0.990
POCE	16 %	18 %	0.87 (0.67-1.13)	0.847
Definite Stent Thrombosis	2 %	3 %	0.59 (0.28-1.20)	0.927

Principal investigators:
Dr. J.F. Iglesias, Geneva University Hospital, Geneva, Switzerland
Dr. O. Muller, Lausanne University Hospital, Lausanne, Switzerland; Dr. T. Pilgrim, Bern University Hospital, Bern, Switzerland

References:
1 Iglesias, JF. Long-Term Outcomes with Biodegradable Polymer Sirolimus-Eluting Stents Versus Durable Polymer Everolimus-Eluting Stents in Patients With ST-Segment Elevation Myocardial Infarction: 5-Year Follow-up of the BIOSTEMI Randomized Trial, Presented at: TCT 2023; October 25, 2023; San Francisco, USA.
2 Iglesias, JF. et al. Long-term outcomes with biodegradable polymer sirolimus-eluting stents versus durable polymer everolimus-eluting stents in ST-segment elevation myocardial infarction: 5-year follow-up of the BIOSTEMI randomised superiority trial, Rounded outcomes from publications.
3 Based on TLF with Orsiro DES in comparison to Xience in STEMI patient.

BCI: Bayesian credible interval, BPP: Bayesian Posterior Probability, CABG: Coronary Artery By-Pass Graft, CI: Confidence Interval, PCI: Percutaneous Coronary Intervention, RR: Risk Ratio.

Clinical data collected with the Orsiro DES device within the Orsiro family clinical program. Clinical data conducted with Orsiro, Orsiro Mission's predecessor device can be used to illustrate Orsiro Mission clinical outcomes.

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South Africa Tel. +27 (0)11 807 4887 · assist.africa@teleflex.com

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BIOSTEMI

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

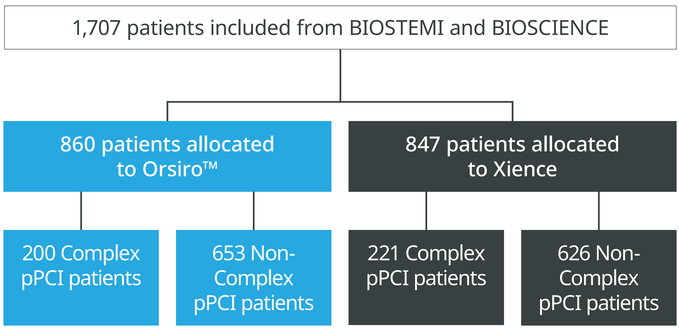
Subgroup analysis of complex vs. non-complex primary PCI Acute Coronary Syndrome (ACS) patients. From the BIOSTEMI trial, an investigator-initiated, prospective, multicenter, assessor-blinded, randomized (1:1), controlled, superiority trial comparing Orsiro™ and Xience in STEMI patients undergoing primary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

Endpoints

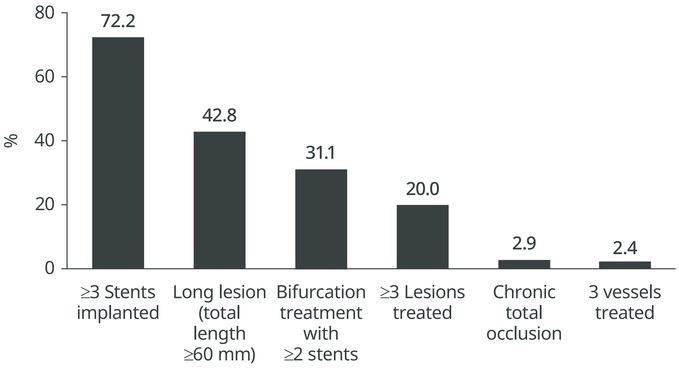
Primary endpoint

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

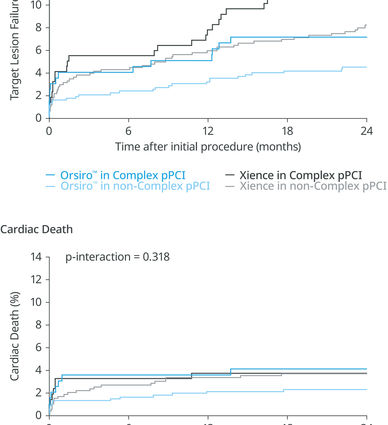


BASELINE CLINICAL CHARACTERISTICS	COMPLEX PRIMARY PCI		NON-COMPLEX PRIMARY PCI	
PATIENTS	ORSIRO™ N=200	XIENCE N=221	ORSIRO™ N=653	XIENCE N=626
Age, years*	63.4±11.7	64.4±12.0	61.5±12.0	62.3±12.0
Male gender	80.5 %	74.2 %	78.9 %	74.1 %
Body mass index, kg/m²*	27.1±4.7	27.3±4.1	26.9±4.2	26.7±4.3
Diabetes 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]

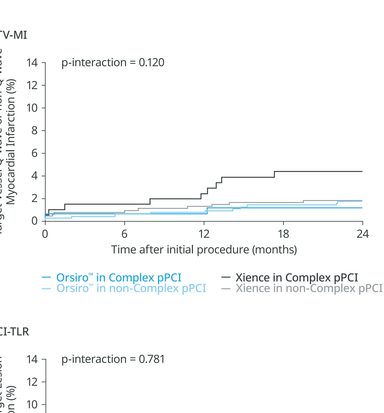
*Data shown as mean±SD [a]n=155 [b]n=180 [c]n=403 [d]n=381 [e]n=147 [f]n=160 [g]n=496 [h]n=491

Clinical outcomes at 2 years[1]

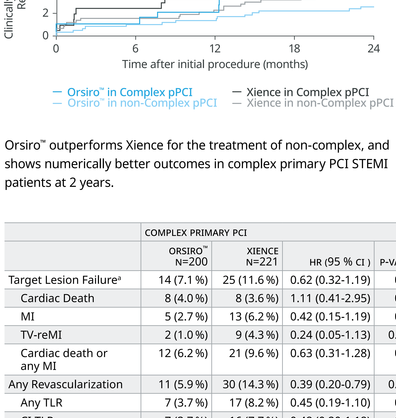
TLF



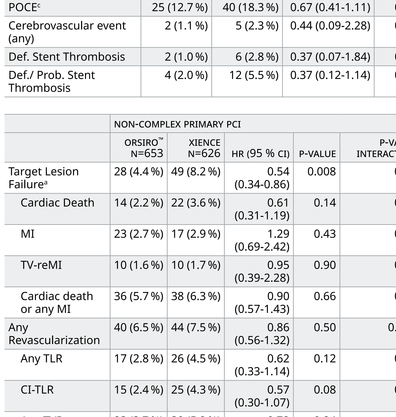
Cardiac Death



TV-MI



CI-TLR



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			
	ORSIRO™ N=200	XIENCE N=221	HR (95 % CI)	P-VALUE
Target Lesion Failure[a]	14 (7.1 %)	25 (11.6 %)	0.62 (0.32-1.19)	0.15
Cardiac Death	8 (4.0 %)	8 (3.6 %)	1.11 (0.41-2.95)	0.84
MI	5 (2.7 %)	13 (6.2 %)	0.42 (0.15-1.19)	0.09
TV-reMI	2 (1.0 %)	9 (4.3 %)	0.24 (0.05-1.13)	0.051
Cardiac death or any MI	12 (6.2 %)	21 (9.6 %)	0.63 (0.31-1.28)	0.20
Any Revascularization	11 (5.9 %)	30 (14.3 %)	0.39 (0.20-0.79)	0.006
Any TLR	7 (3.7 %)	17 (8.2 %)	0.45 (0.19-1.10)	0.07
CI-TLR	7 (3.7 %)	16 (7.7 %)	0.48 (0.20-1.18)	0.10
Any TVR	9 (4.8 %)	24 (11.5 %)	0.41 (0.19-0.88)	0.02
CI-TVR	9 (4.8 %)	23 (11.0 %)	0.43 (0.20-0.92)	0.03
Target Vessel Failure[b]	16 (8.2 %)	32 (14.8 %)	0.54 (0.30-0.99)	0.043
POCE[c]	25 (12.7 %)	40 (18.3 %)	0.67 (0.41-1.11)	0.12
Cerebrovascular event (any)	2 (1.1 %)	5 (2.3 %)	0.44 (0.09-2.28)	0.32
Def. Stent Thrombosis	2 (1.0 %)	6 (2.8 %)	0.37 (0.07-1.84)	0.21
Def./ Prob. Stent Thrombosis	4 (2.0 %)	12 (5.5 %)	0.37 (0.12-1.14)	0.07

	NON-COMPLEX PRIMARY PCI				
	ORSIRO™ N=653	XIENCE N=626	HR (95 % CI)	P-VALUE	P-VALUE INTERACTION
Target Lesion Failure[a]	28 (4.4 %)	49 (8.2 %)	0.54 (0.34-0.86)	0.008	0.74
Cardiac Death	14 (2.2 %)	22 (3.6 %)	0.61 (0.31-1.19)	0.14	0.32
MI	23 (2.7 %)	17 (2.9 %)	1.29 (0.69-2.42)	0.43	0.06
TV-reMI	10 (1.6 %)	10 (1.7 %)	0.95 (0.39-2.28)	0.90	0.12
Cardiac death or any MI	36 (5.7 %)	38 (6.3 %)	0.90 (0.57-1.43)	0.66	0.40
Any Revascularization	40 (6.5 %)	44 (7.5 %)	0.86 (0.56-1.32)	0.50	0.056
Any TLR	17 (2.8 %)	26 (4.5 %)	0.62 (0.33-1.14)	0.12	0.58
CI-TLR	15 (2.4 %)	25 (4.3 %)	0.57 (0.30-1.07)	0.08	0.78
Any TVR	23 (3.7 %)	30 (5.2 %)	0.72 (0.42-1.25)	0.24	0.23
CI-TVR	21 (3.4 %)	29 (5.0 %)	0.68 (0.39-1.20)	0.18	0.33
Target Vessel Failure[b]	36 (5.7 %)	54 (9.0 %)	0.63 (0.41-0.96)	0.03	0.70
POCE[c]	64 (10.1 %)	72 (11.8 %)	0.86 (0.61-1.20)	0.36	0.44
Cerebrovascular event (any)	8 (1.3 %)	10 (1.7 %)	0.76 (0.30-1.93)	0.56	0.57
Def. Stent Thrombosis	8 (1.3 %)	8 (1.3 %)	0.95 (0.36-2.53)	0.92	0.32
Def./ Prob. Stent Thrombosis	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:
Dr. J.F. Iglesias, Geneva University Hospital, Geneva, Switzerland
Dr. O. Muller, Lausanne University Hospital, Lausanne, Switzerland

References:
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. Clinical data conducted with Orsiro, Orsiro Mission's predecessor device can be used to illustrate Orsiro Mission clinical outcomes.

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