BIOSTEMI

Biodegradable polymer sirolimus-eluting stent Orsiro® versus Durable Polymer everolimus-eluting stent Xience in patients with ST-segment Elevation Myocardial Infarction (STEMI) at 24 months

Conclusions

- At 24 months, Orsiro is superior to Xience in STEMI patients with respect to the primary endpoint of Target Lesion Failure (TLF) (5.1% vs. 8.1%, Rate Ratio (95% BCI**): 0.58 (0.40-0.84), Posterior Probability of Superiority: 99.8%)
- The difference in TLF rates remained statistically significant after the exclusion of historical information from the BIOSCIENCE trial (Rate Ratio (95% BCI**): 0.62 (0.40-0.96), Posterior Probability of Superiority: 98.5%)
- Clinically-indicated Target Lesion Revascularization (TLR) rate was significantly lower in Orsiro compared to Xience (2.5% vs. 5.1%, Rate Ratio (95% BCI**): 0.52 (0.30-0.87), Posterior Probability of Superiority: 99.3%)
- The significant difference at 24-m favoring the Orsiro vs. Xience DES might have clinically relevant implications for routine clinical practice.

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

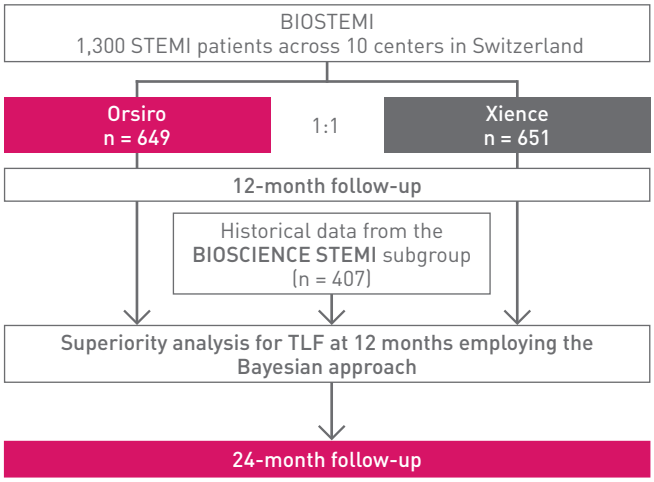
Primary Endpoint

Target Lesion Failure (TLF) at 12 months follow-up defined as the composite of:

- Cardiac Death,
- Target Vessel-Myocardial Reinfarction
- Clinically-indicated Target Lesion Revascularization (TLR)

Selected Secondary Endpoints

Individual components of the primary endpoint, All cause death, Target Vessel Revascularization (TVR), Target Vessel Failure (TVF), Definite Stent Thrombosis (Def ST), Definite or Probable Stent Thrombosis (Def/Prob 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%

* Xience is a trademark of Abbott Cardiovascular Systems Inc.
** Bayesian Credible Interval
‡ Data shown as mean ± SD
¤ Number of lesions

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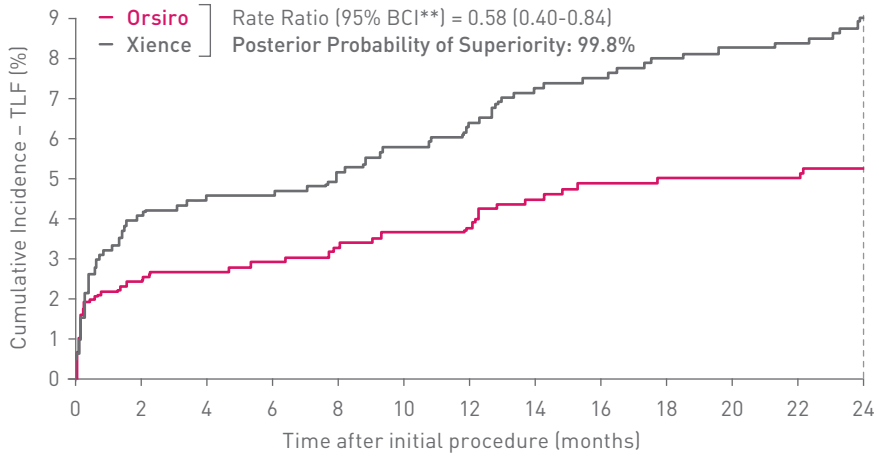
Primary Endpoint – TLF at 24 months[2]



TLF rate at 24 months:

5.1% Orsiro | **8.1%** Xience

99.8% Posterior Probability of Superiority°

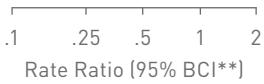
Orsiro is superior to Xience with respect to TLF at 24 months in STEMI patients. The effect was robust and maintained after the exclusion of historical information from the BIOSCIENCE trial.

Selected Secondary Endpoints at 24 months[2]

			BIOSTEMI with historical data from BIOSCIENCE		BIOSTEMI only	
	Orsiro n = 649	Xience n = 651	Rate Ratio (95% BCI**)	Bayesian Posterior Probability of Superiority	Ratio Ratio (95% BCI**)	Bayesian Posterior Probability of Superiority
Cardiac Death	2.9%	3.2%	0.77 (0.44–1.35)	82.3%	0.91 (0.49–1.69)	61.4%
TV-MI	1.5%	2.0%	0.67 (0.33–1.34)	87.5%	0.77 (0.33–1.75)	73.1%
Clinically-indicated TLR	2.5%	5.1%	0.52 (0.30–0.87)	**99.3%**	0.48 (0.26–0.86)	**99.3%**
TVF	6.0%	9.4%	0.61 (0.43–0.86)	**99.8%**	0.63 (0.42–0.94)	**98.8%**
Clinically-indicated TVR	3.1%	6.1%	0.56 (0.35–0.87)	**99.5%**	0.50 (0.29–0.84)	**99.6%**
Def ST	1.4%	1.8%	0.73 (0.30–1.69)	77.1%	0.76 (0.31–1.77)	73.9%
Def/Prob ST	2.0%	2.3%	0.72 (0.38–1.44)	83.7%	0.87 (0.41–1.84)	64.2%

Subgroup Analysis – TLF at 24 months[2]

		Orsiro	Xience	Rate Ratio (95% BCI**)	Favors Orsiro / Favors Xience	Bayesian Posterior Probability	Bayesian Posterior Probability (interaction)
Diabetes	no	27/575	43/569	0.59 (0.38-0.89)		0.994	0.774
	yes	5/73	10/82	0.43 (0.21-0.90)		0.986	
Small vessel	no	3/214	12/220	0.36 (0.11-0.85)		0.990	0.891
	yes	29/429	41/431	0.67 (0.42-1.06)		0.957	
Long lesion	no	6/139	10/152	0.69 (0.29-1.63)		0.799	0.658
	yes	26/504	43/499	0.56 (0.35-0.90)		0.992	
Multivessel	no	31/598	45/601	0.67 (0.45-0.99)		0.977	0.994
Disease	yes	2/50	8/50	0.08 (0.03-0.40)		0.999	



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** Bayesian Credible Interval; ° vs. Xience at 24-months in the BIOSTEMI trial, with respect to TLF, based on combined data set of BIOSTEMI and BIOSCIENCE STEMI groups.

1. Iglesias et al. Biodegradable polymer sirolimus-eluting stents versus durable polymer everolimus-eluting stents in patients with ST-segment elevation myocardial infarction (BIOSTEMI): a single-blind, prospective, randomised superiority trial; Lancet, September, 2019; 2. Pilgrim et al. Biodegradable – versus durable-polymer drug-eluting stents for STEMI. Final 2-year outcomes of the BIOSTEMI trial. J Am Coll Cardiol. Cardiovasc Interven. 2021, doi: 10.1016/j.jcin.2020.12.011.
For indications please see Instructions For Use.

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

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