BIOFLOW-V

BIOTRONIK - A Prospective Randomized Multicenter Study to Assess the Sa**F**ety and Effectiveness of the Orsiro Siro**L**imus Eluting Coronary Stent System in the Treatment **O**f Subjects **W**ith up to Three De Novo or Restenotic Coronary Artery Lesions – **V (BIOFLOW-V)**

Conclusions

- In this 1,334 patient large, international, randomized, all-comers trial Orsiro demonstrated statistically significantly lower Target Lesion Failure (TLF) rates compared to Xience[1] at 12 months (Orsiro 6.2%, Xience 9.6%, p-value = 0.04)
- Procedure success was significantly higher with Orsiro (Orsiro 93.8%, Xience 90.1%, p-value = 0.02), mainly driven by a higher rate of in-hospital Myocardial Infarction (MI) associated with Xience (Orsiro 3.9%, Xience 6.7%, p-value = 0.03)
- Stent Thrombosis (ST) rate was numerically lower in the Orsiro cohort (Orsiro 0.5%, Xience 1.2%, p-value = 0.18)

Study design

Prospective, multi-center, 2:1 randomized controlled IDE (Investigational Device Exemption) trial to assess the safety and effectiveness of Orsiro in the treatment of patients with up to three de novo or restenotic lesions (standard PTCA only).

Principal investigators

- Dr. David Kandzari, Piedmont Heart Institute, Atlanta, US
- Dr. Jacques Koolen, Catharina Ziekenhuis, Eindhoven, Netherlands

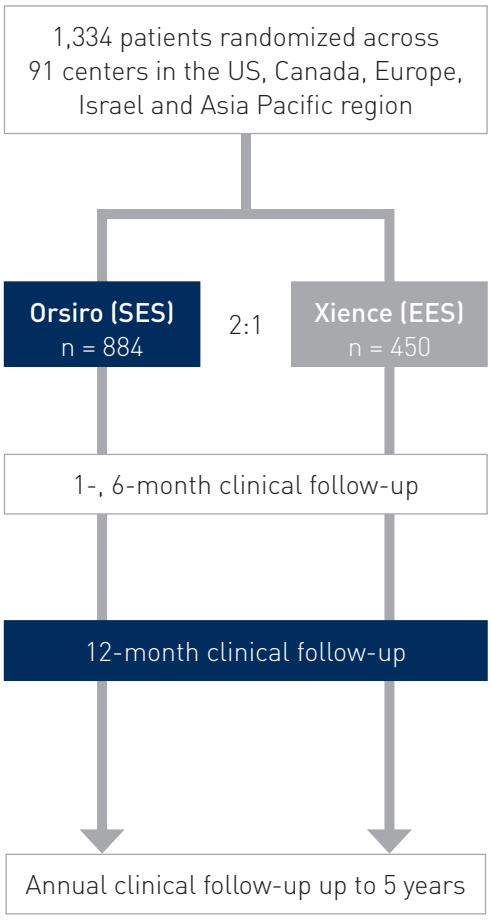
Endpoints

Primary endpoint

- TLF at 12 months defined as a composite of Cardiac Death (CD), Target-Vessel MI (TV-MI) or any clinically-driven Target Lesion Revascularization (cd-TLR)

Pre-specified secondary endpoints

- Components of the primary endpoint
- Target Vessel Failure (TVF) and individual TVF components
- Death
- MI and/or CD
- ST (all, definite, definite/probable, probable, possible ST)[2]
- Success rates (device, lesion and procedure)



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Baseline clinical, angiographic and procedural characteristics

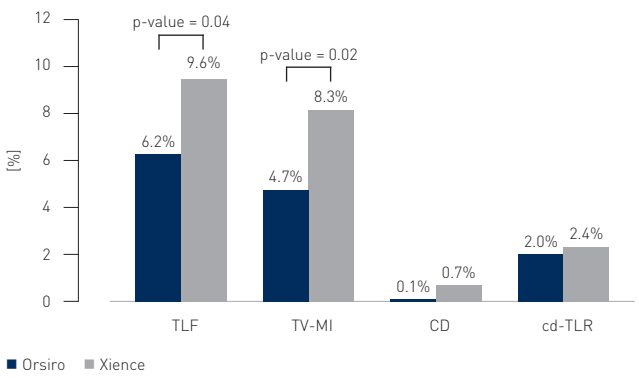
Number at risk	Orsiro n = 884	Xience n = 450
Female	224 (25.3%)	122 (27.1%)
Age [years]	64.5 ± 10.3	64.6 ± 10.7
Hypertension	696/873 (79.7%)	354/440 (80.5%)
Diabetes	299/883 (33.9%)	166/449 (37.0%)
Stable Angina	428/884 (48.4%)	213/449 (47.4%)
Unstable Angina	347/884 (39.3%)	175/449 (39.0%)
ACS	454/884 (51.4%)	223/450 (49.6%)
Previous PCI	323/877 (36.8%)	147/445 (33.0%)
Previous CABG	62/887 (7.1%)	23/445 (5.2%)
Reference Vessel Diameter [mm]	2.6 ± 0.5	2.6 ± 0.6

Number at risk	Orsiro n = 884	Xience n = 450
Lesion length [mm]	13.3 ± 7.6	13.2 ± 7.7
Bifurcation lesion	156/1051 (14.8%)	84/561 (15%)
Calcification, Moderate/severe	252/1051 (24.0%)	150/561 (26.7%)
Lesion Class B2/C	763/1051 (72.6%)	426/561 (75.9%)
Minimal Luminal Diameter (pre-procedural in-lesion) [mm]	1.1 ± 0.4	1.1 ± 0.4
Diameter Stenosis (pre-procedural in-lesion) [%]	55.4 ± 13.3	55.9 ± 13.5
Total stent length [mm]	26.8 ± 14.7	29.5 ± 17.5

p>0.05 (exception Total stent length p = 0.006)

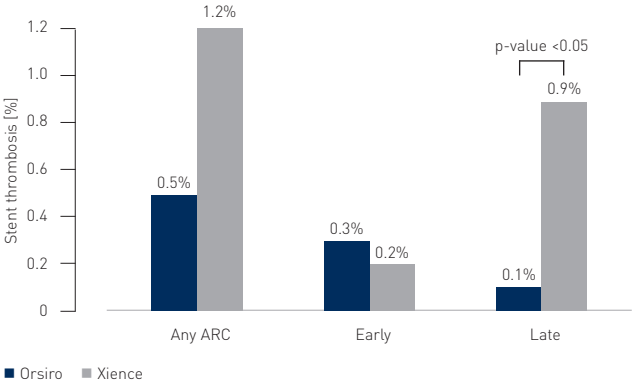
Clinical results

Primary endpoint and composits at 12 months



Stent thrombosis

Secondary endpoint – 12-month Academic Research Consortium (ARC) ST[2]



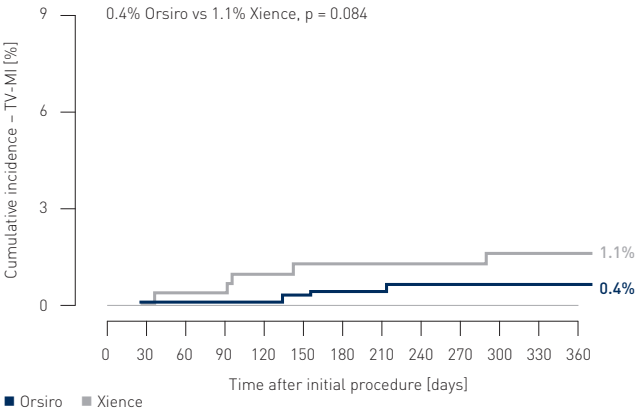
Clinical results

Analysis of interaction by groups and subgroups TLF at 12 months

Subgroups	Favors Orsiro	Favors Xience	HR and 95% CI	p-value for interaction
Vessel size				0.37
⩽2.75 mm			0.71 (0.45, 1.13)	
>2.75 mm			0.45 (0.18, 1.10)	
Age				0.16
>75			1.20 (0.45, 3.21)	
⩽75			0.56 (0.35, 0.88)	
Gender				0.61
Male			0.69 (0.42, 1.11)	
Female			0.54 (0.25, 1.16)	
Diabetes				0.91
Diabetic			0.66 (0.33, 1.31)	
Non-diabetic			0.63 (0.38, 1.05)	
Lesion length				0.25
>26 mm			0.31 (0.09, 1.11)	
⩽26 mm			0.69 (0.45, 1.07)	
ACS				0.24
ACS			0.50 (0.28, 0.89)	
Non-ACS			0.82 (0.45, 1.48)	

Kaplan-Meier estimate

Landmark Analysis TV-MI[3]



1 Xience is a registered trademark of Abbott Cardiovascular Systems Inc.; 2 according to Academic Research Consortium (ARC) criteria for acute, subacute, late, very late and cumulative stent thrombosis; 3 Kandzari D. BIOFLOW-V: A Prospective Randomized Multicenter Study to Assess the SaFety and Effectiveness of the Orsiro SiroLimus Eluting Coronary Stent System in the Treatment Of Subjects With up to Three De Novo or Restenotic Coronary Artery Lesions Science. Presentation at ESC 2017. Source: Kandzari D. et al., Ultrathin Bioresorbable Polymer Sirolimus-Eluting Stents versus Thin Durable Polymer Everolimus-Eluting Stents in Patients Undergoing Coronary Revascularisation (BIOFLOW-V): a randomised trial, 2017, The Lancet

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