

Orsiro - BIOFLOW-III

Conclusions

- In this all-comers setting a low TLF rate of 5.1 % was observed within the first 12 months, which demonstrates safety and effectiveness of the Orsiro Hybrid Stent
- The results observed in this “real world” population demonstrate a low TLF rate comparable to other state of the art DES at 12 months
- In comparison with other published trials in patients with STEMI, Orsiro shows a low TLF rate

Study design

International, prospective, multi-center open-label, registry of the Orsiro drug-eluting stent in daily clinical practice.

Coordinating clinical investigator

- Prof. Johannes Waltenberger, M.D. Universitätsklinikum Münster, Germany

Primary endpoint

- Target Lesion Failure¹ (TLF) at 12 months

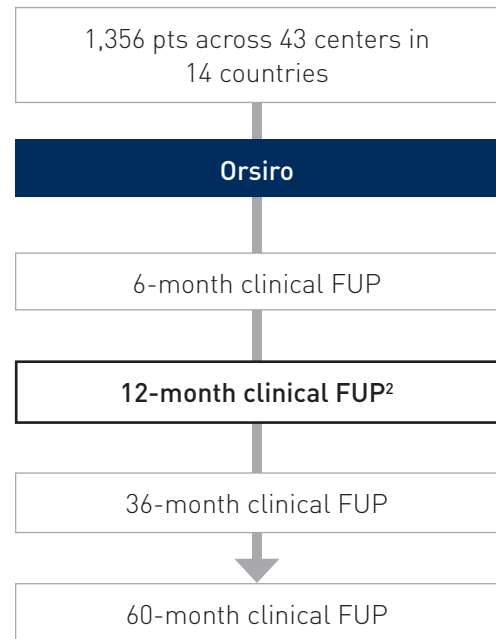
Subgroups

Pre-defined

- Diabetic patients
- Small vessels (≤ 2.75 mm)
- Chronic Total Occlusion
- Acute MI (STEMI and NSTEMI)

Post-hoc

- B2/C lesions
- Multivessel disease (MVD)
- STEMI vs NSTEMI



Patient and lesion characteristics

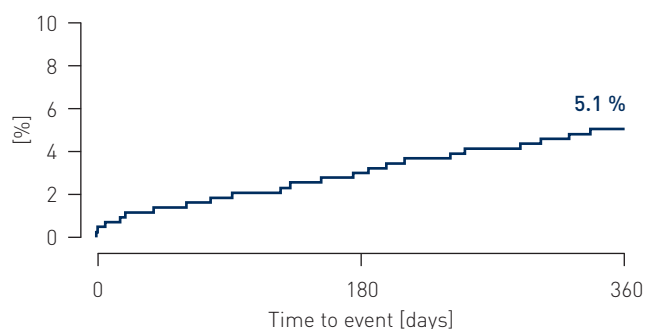
Patients	[n = 1,356]
Hypertension	76 % (1,029)
Hypercholesteremia	60 % (815)
Smoking	55 % (741)
Diabetes mellitus	30 % (402)
Acute MI	33 % (442)
Lesions	[n = 1,738]
Small vessels (≤ 2.75 mm)	48 % (828)
Chronic Total Occlusion	4 % (83)
Lesion characteristics	
Lesion length (mm \pm SD)	15.8 \pm 9.1
Ref. vess. diameter (mm \pm SD)	3.0 \pm 0.4
Diameter stenosis (% \pm SD)	86.3 \pm 11.1

ACC/AHA lesion classification

A	B1	B2	C
12 %	36 %	32 %	20 %

Primary endpoint results

TLF rate out to 12 months



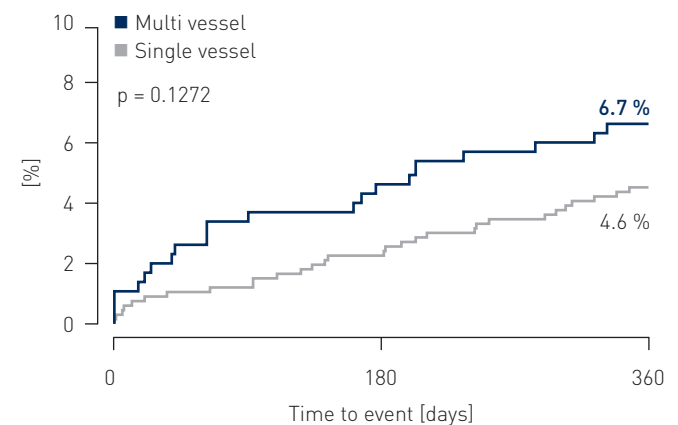
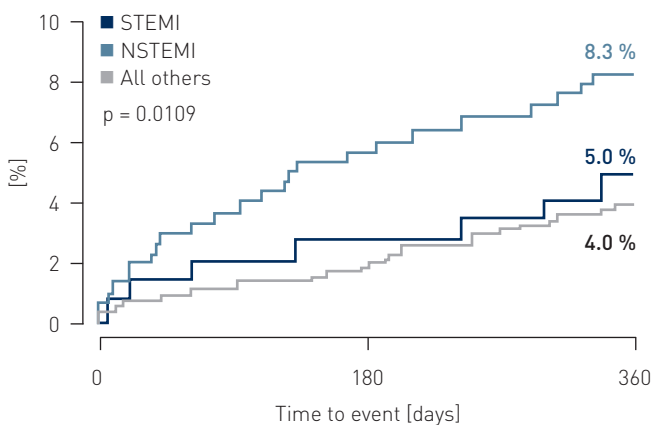
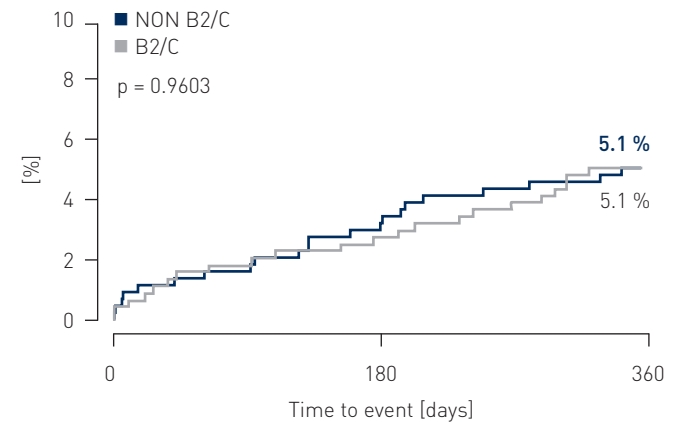
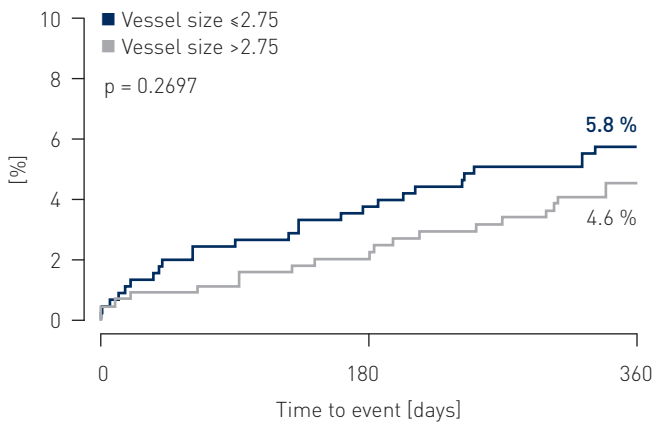
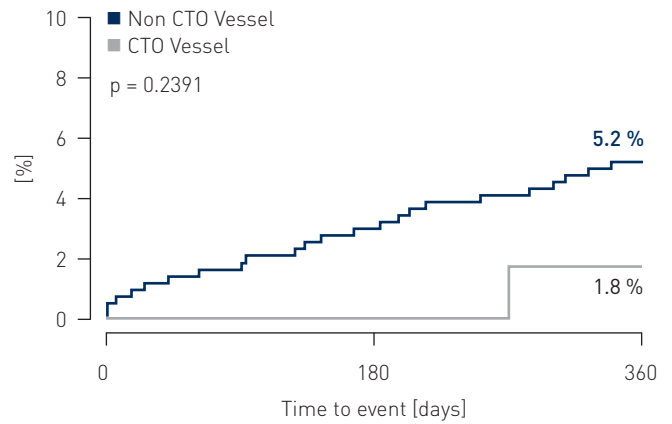
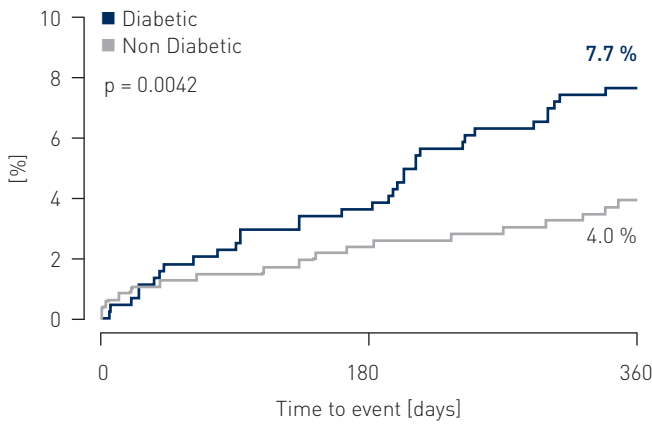
Target Lesion Failure – Composites [%]	Orsiro
Cardiac death	1.3
Target vessel MI	2.3
TLR (clinically driven)	3.0
CABG (emergent)	0.0

¹ Composite of cardiac death, target vessel Q-wave or non-Q wave Myocardial Infarction (MI), Emergent Coronary Artery Bypass Graft (CABG), clinically driven Target Lesion Revascularization (TLR)

² Follow-up compliance 95 %

Subgroup results

TLF rates out to 12 months



Major Secondary Endpoints: Device and Procedural Success

Devices	n = 1,738
Device success	98.8 %
Procedures	n = 1,356
Procedure success	98.2 %

Sources:

Presentation, Prof. Johannes Waltenberger, EuroPCR 2015

Presentation, Prof. Johannes Waltenberger, CRT 215

BIOTRONIK AG
 Ackerstrasse 6
 8180 Bülach · Switzerland
 Tel +41 (0)44 8645111
 Fax +41 (0)44 8645005
 info.vi@biotronik.com
 www.biotronik.com

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