

Orsiro – SORT OUT VII

Conclusions

- One year data from large (n = 2,525) industry independent SORT OUT VII trial presented at EuroPCR 2015 demonstrate Orsiro is non-inferior to Nobori stent
- At one year, the primary endpoint target lesion failure (TLF) occurred in 3.8 % of Orsiro patients vs. 4.6 % of those treated with Nobori DES (p non-inferiority < 0.0001)
- Patients in the Orsiro arm demonstrated a significantly lower rate of definite stent thrombosis: only 0.4 % of Orsiro patients compared with 1.2 % of patients in the Nobori arm (p = 0.03)
- These highly encouraging results reconfirm those of BIOSCIENCE, the large independent comparison between Orsiro and Xience Prime presented at ESC 2014 and published in The Lancet

Study design

All-comers, multi-center, randomized, non-inferiority design

Principal Investigators

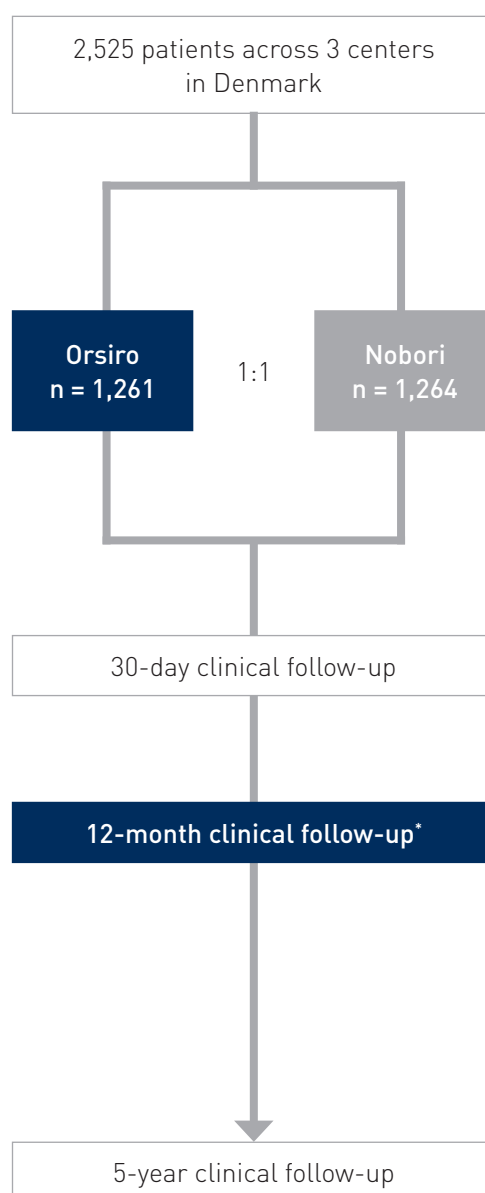
- Prof. Lisette Okkels Jensen, Odense, Denmark
- Dr. Per Thayssen, Odense, Denmark

Patient characteristics

Patients	Orsiro n = 1,261	Nobori n = 1,264
Diabetes	18.7 %	18.6 %
Indication for PCI		
Stable angina pectoris	44.3 %	43.9 %
NSTEMI/ unstable angina pectoris	30.7 %	32.6 %
STEMI	21.2 %	20.7 %
Other	3.7 %	2.8 %

Lesion characteristics

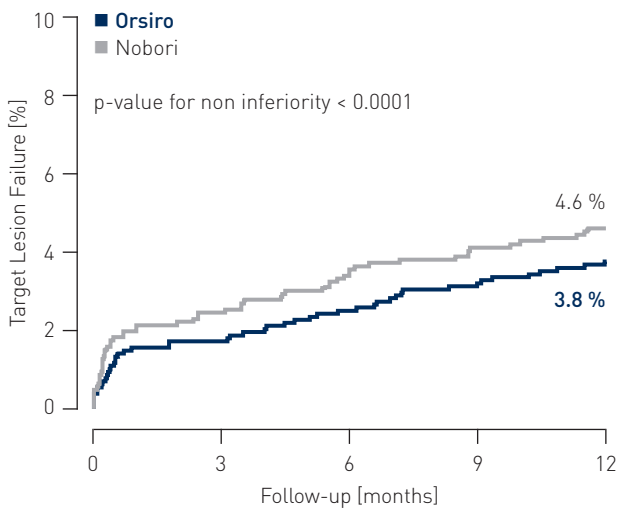
Lesions	Orsiro n = 1,590	Nobori n = 1,588
Left main artery	1.1 %	0.8 %
Left anterior descending artery	43.1 %	42.3 %
Left circumflex artery	21.3 %	22.0 %
Right coronary artery	33.1 %	33.7 %
Saphenous vein graft	1.4 %	1.2 %
Lesion type B2/C	56.6 %	56.2 %
Reference vessel size (mm)	3.2 ± 0.6	3.1 ± 0.5



* Primary endpoint: Target Lesion Failure composite of cardiac death, myocardial infarction or target lesion revascularization

Primary endpoint results

Target lesion failure at 12 months

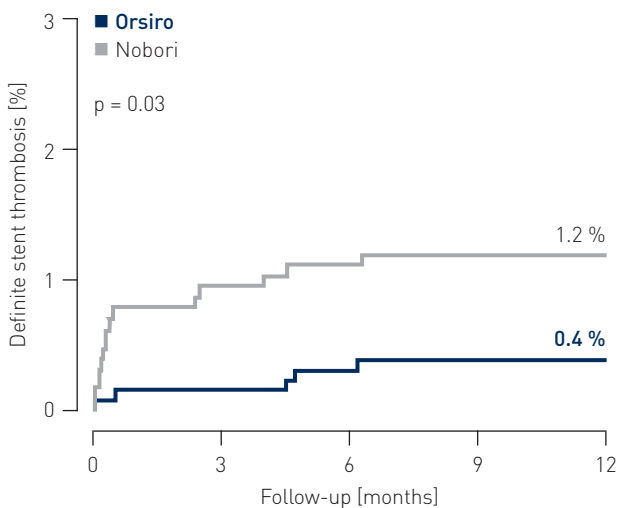


Components of primary endpoint at 12 months

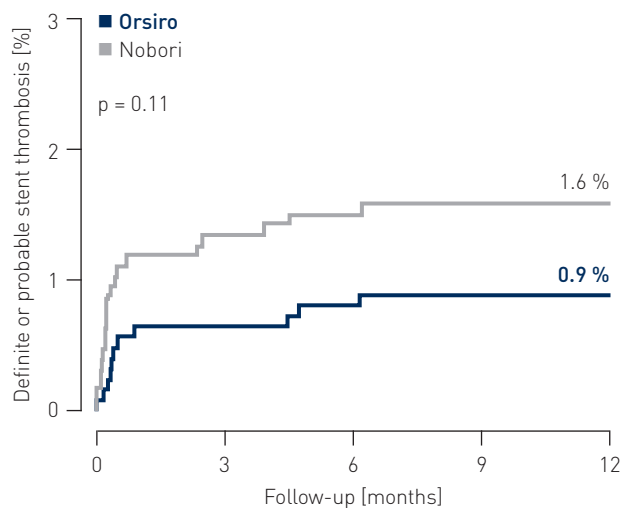
Target Lesion Failure Composites (%)	Orsiro n = 1,261	Nobori n = 1,264	p-value
Cardiac Death	1.3	1.4	ns
Myocardial Infarction	1.6	2.4	ns
TLR	2.0	2.9	ns
TVR	4.1	5.2	ns

Stent thrombosis* results at 12 months

Definite stent thrombosis



Definite or probable stent thrombosis



Source: Presentation, Lisette Okkels Jensen, EuroPCR 2015

* Definite and probable stent thrombosis according to ARC definition and adjudicated by independent clinical events committee
Not currently available in the United States