



## Interventional and Structural

### THREE-YEAR OUTCOME OF ALL-COMER PATIENTS TREATED WITH RESOLUTE ONYX ZOTAROLIMUS-ELUTING VERSUS ORSIRO SIROLIMUS-ELUTING STENTS IN THE RANDOMIZED BIONYX TRIAL

Poster Contributions  
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Authors: *Eline Ploumen, Paolo Zocca, Rosaly A. Buiten, C. Doggen, Adel Aminian, Carl Schotborgh, Gillian A. J. Jessurun, Ariel Roguin, Peter W. Danse, Edouard Benit, Clemens von Birgelen, Thoraxcentrum Twente, Medisch Spectrum Twente, Enschede, The Netherlands*

**Background:** The randomized BIONYX trial (ClinicalTrials.gov NCT02508714) established non-inferiority regarding safety and efficacy of the Resolute Onyx zotarolimus-eluting stent (RO-ZES) versus the Orsiro sirolimus-eluting stent (O-SES) at 1 year, and showed favorable 2-year outcomes for both stents. While both stents are used in routine clinical practice, for RO-ZES no clinical results have been published beyond 2 years.

**Methods:** We assessed in 2,488 all-comers the 3-year outcome after percutaneous coronary intervention with novel RO-ZES versus O-SES. The main endpoint target vessel failure (TVF) is a composite of cardiac death, target vessel myocardial infarction (MI), or target vessel revascularization. Time-to-endpoints was assessed by Kaplan-Meier methods, and between-group comparisons by log-rank tests.

**Results:** Three-year follow-up was available in 2,433/2,488 (97.8%) patients. There was no significant between-stent difference in TVF (RO-ZES 112/1,243 [9.2%] vs. O-SES 109/1,245 [8.9%],  $P = 0.85$ ) and its individual components (Table 1). The all-cause mortality rate was significantly lower in RO-ZES-treated patients (3.7% vs. 5.4%, HR 0.67, 95%-CI 0.46-0.97,  $P = 0.034$ ), but there was no significant difference in cardiac mortality (Table 1).

**Conclusion:** RO-ZES versus O-SES showed no difference in the main endpoint of safety and efficacy at 3-years. A lower rate of all-cause mortality in the RO-ZES group may most likely be a play of chance, yet long-term follow-up is of interest.

**Table 1. Three-Year Clinical Outcome**

	<b>Resolute Onyx n=1,243</b>	<b>Orsiro n=1,245</b>	<b>Hazard ratio (95% CI)</b>	<b>P<sub>log-rank</sub></b>
<b>Target vessel failure</b>	112 (9.2)	109 (8.9)	1.03 (0.79-1.34)	0.85
<b>Any death</b>	45 (3.7)	67 (5.4)	0.67 (0.46-0.97)	0.034
<b>Cardiac death</b>	13 (1.1)	23 (1.9)	0.56 (0.28-1.11)	0.09
<b>Target vessel myocardial infarction</b>	39 (3.2)	38 (3.1)	1.02 (0.65-1.60)	0.92
<b>Target vessel revascularization</b>	84 (6.9)	75 (6.2)	1.12 (0.82-1.52)	0.49
<b>Definite-or-probable stent thrombosis</b>	7 (0.6)	15 (1.2)	0.46 (0.19-1.14)	0.09