HOST-IDEA – Stent Level Analysis

Biodegradable polymer vs. polymer-free ultrathin sirolimus-eluting stents

Conclusions

- The HOST-IDEA compares the **Orsiro®** with the Coroflex ISAR, two ultrathin strut DES. The trial was designed as a 2×2 factorial unrandomized study with both a DAPT and a DES arm.
- The **Orsiro** DES shows a 68% significantly lower 1-year TLF compared to Coroflex ISAR DES: **Orsiro** DES 1.1%; Coroflex ISAR DES 3.4%; HR 3.21 (95% CI 1.28 - 8.05), p = 0.011[1]
- The **Orsiro** DES shows a numerically lower major bleeding rate for both 3 and 12 months DAPT compared to Coroflex ISAR DES with an optimized 3 months DAPT.[2]
- Overall, **Orsiro** showed to be a better ultrathin strut DES compared to Coroflex ISAR.[1]

Study design

All-comers (no STEMI), multi-center, randomized controlled trial, non-inferiority trial. The HOST-IDEA trial was originally designed as a 2×2 factorial study, one arm comparing two DAPT durations and one arm comparing two ultrathin strut DES.

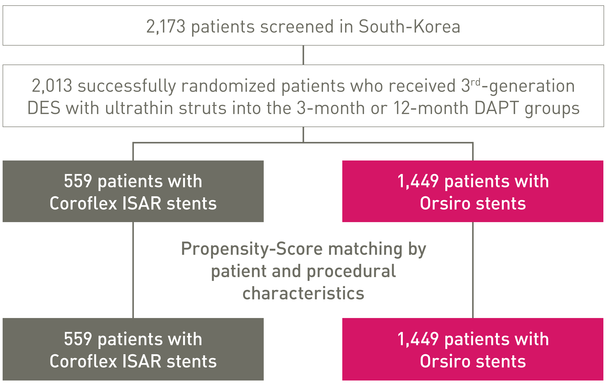
		Stent arm	
		Coroflex-ISAR	Orsiro
DAPT arm	3-month DAPT	n = 538	n = 538
		2x2 factorial design	
	12-month DAPT	n = 538	n = 538

Each arm led to a specific HOST-IDEA analysis, a DAPT-duration level analysis and a stent level analysis (presented in this clinical flyer).

Endpoints

Primary endpoint

- Target Lesion Failure (TLF)
  - Cardiac death
  - Target-vessel myocardial infarction
  - Clinically-driven target lesion revascularization

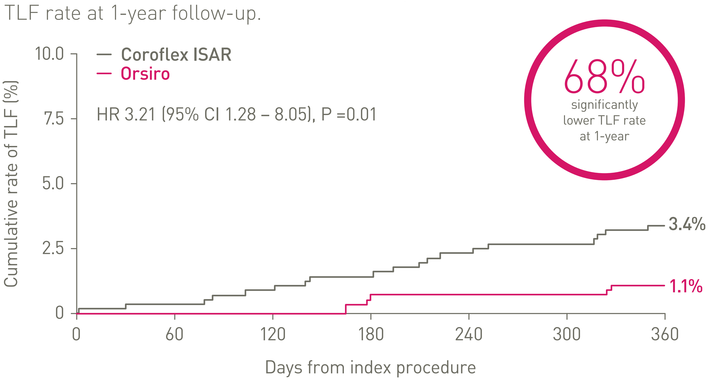


Baseline characteristics*	Coroflex ISAR n = 559	Orsiro n = 559	p-value
Clinical characteristics			
Mean age, years ± SD	65.0 ± 10.5	65.3 ± 10.2	0.68
Male	74.4%	72.8%	0.59
Diabetes	37.6%	40.6%	0.33
Hypertension	69.9%	70.7%	0.84
Dyslipidemia	80.5%	81.4%	0.76
Chronic kidney disease	9.5%	10.4%	0.69
Previous myocardial infarction	4.1%	4.3%	1.00
Previous revascularization	14.7%	17.0%	0.33
Previous cerebrovascular event	5.7%	7.2%	0.39
Peripheral vascular disease	1.6%	1.4%	1.00
Clinical diagnosis at the index PCI			0.65
Stable ischemic heart disease	49.4%	48.1%	
Unstable angina	34.5%	37.0%	
NSTEMI	16.1%	14.8%	
DAPT regimen			0.73
Aspirin + Clopidogrel	91.2%	92.3%	
Aspirin + Ticagrelor	5.7%	5.4%	
Aspirin + Prasugrel	3.0%	2.3%	
3-month DAPT group	47.9%	49.0%	0.77
Left main disease	5.4%	5.7%	0.90
Extent of coronary artery disease			0.99
One-vessel disease	53.3%	53.3%	
Two-vessel disease	26.5%	26.1%	
Three-vessel disease	20.2%	20.6%	
Mean diameter of stents mm ± SD	3.0 ± 0.4	3.0 ± 0.5	0.90
Total length of stents mm ± SD	25.7 ± 13.3	25.5 ± 12.1	0.88

*Propensity score-matched population

TLF in propensity score-matched population

Orsiro DES - Better ultrathin strut DES compared to Coroflex ISAR DES for TLF rate at 1-year follow-up.



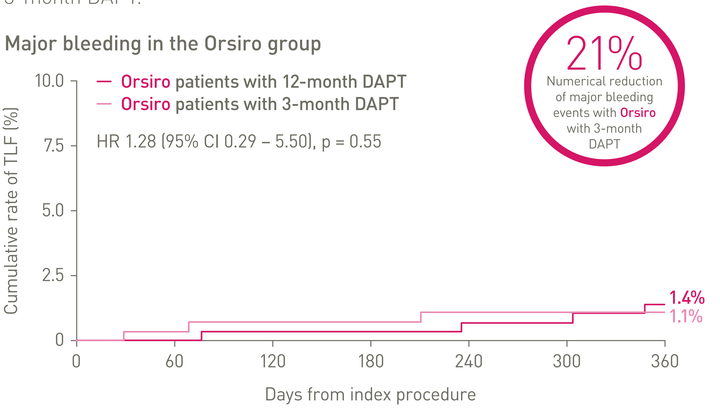
Other results in propensity score-matched population

	Coroflex ISAR n = 559	Orsiro n = 559	Hazard ratio (95% CI)	p-value
Target lesion failure	3.4%	1.1%	3.21 (1.28-8.05)	0.01
Cardiac death	0.9%	0.4%	2.51 (0.49-13.0)	0.27
Target-vessel myocardial infarction	0.9%	0.4%	2.53 (0.49-13.0)	0.27
Clinically-driven target lesion revascularization	2.6%	0.5%	4.75 (1.37-16.5)	0.01
Target vessel failure	4.0%	1.6%	2.48 (1.14-5.39)	0.02
NACE (TLF + stent thrombosis + major bleeding)	4.9%	2.3%	2.11 (1.09-4.08)	0.03
All cause death	1.3%	1.1%	1.17 (0.39-3.49)	0.77
Myocardial infarction	0.9%	0.9%	1.01 (0.29-3.48)	0.99
Any revascularization	4.4%	3.8%	1.15 (0.64-2.06)	0.64
Stent thrombosis (definite or probable)	0.2%	0.0%	n.a.	0.32
Major bleeding (BARC type 3 or 5)	2.0%	1.3%	1.58 (0.61-4.08)	0.34
Any bleeding (BARC type 2, 3 or 5)	5.1%	6.0%	0.85 (0.51-1.40)	0.52

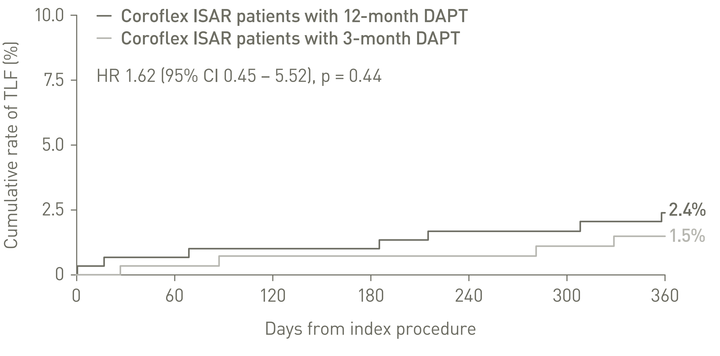
Major bleeding according to DAPT duration (BARC type 3 or 5)

Orsiro DES shows a numerically lower major bleeding rate for both 3- and 12-month DAPT compared to Coroflex ISAR DES with an optimized 3-month DAPT.[2]

Major bleeding in the Orsiro group



Major bleeding in the Coroflex ISAR group



Principal investigator

Dr. Hyo-Soo Kim - Seoul National University College of Medicine, Seoul, Republic of Korea

BARC: Bleeding Academic Research Consortium, CI: Confidence Interval, DAPT: Dual Antiplatelet Therapy, DES: Drug Eluting Stent, HR: Hazard ratio, NACE: Net Adverse Clinical Event, NSTEMI: Non-ST segment Elevation Myocardial Infarction, PS-matched: Propensity Score-matched, SES: Sirolimus Eluting Stent, STEMI: ST segment Elevation Myocardial Infarction, TLF: Target Lesion Failure

1. Calculation by Biotronik, from the 1:1 propensity score population of Kim H.-S. et al., HOST-IDEA Trial, EuroPCR, Paris, May 2023; 2. At 1 year, Kim H.-S. et al.; HOST-IDEA Trial, EuroPCR, Paris, May 2023.

BIOTRONIK AG
Ackerstrasse 6
8180 Bülach,
Switzerland

Tel +41 (0) 44 8645111
Fax +41 (0) 44 8645005
info.vi@biotronik.com
www.biotronik.com

BIOTRONIK
excellence for life