BIOFLOW-DAPT

Biodegradable-Polymer or Durable-Polymer Stents in Patients at High Bleeding Risk: A Randomized, Open-Label Clinical Trial

Conclusions

- Orsiro Mission DES showed safety and efficacy for short-DAPT in the BIOFLOW-DAPT trial.[1]
- Orsiro Mission DES is non-inferior to the Resolute Onyx DES for 1-month DAPT in HBR patients with regard to cardiac death, myocardial infarction or stent thrombosis (composite primary endpoint outcomes at 12-month: 3.6% vs 3.4%; p<0.0001).[1]

Study design

Prospective, multi-center, international, two-arm randomized controlled clinical study, including a total of 1,948 subjects. Subjects were randomized in a 1:1 ratio to receive either a Orsiro Mission or a Resolute Onyx stent.

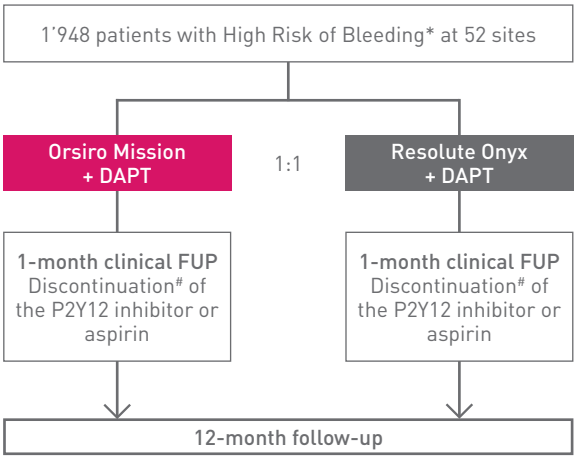
Endpoints

Primary endpoint at 1 year is a composite of:

- Cardiac death
- Myocardial Infarction (MI)
- Definite or probable stent thrombosis

Selected Secondary Endpoints

- Major Adverse Cardiac Events (MACE): defined as the composite of cardiac death, MI, and Target Vessel Revascularization (TVR)
- Target Vessel Failure (TVF), defined as the composite of clinically-driven TVR, cardiac death or TV-MI
- Target Lesion Failure (TLF), defined as the composite of clinically-driven TLR, cardiac death or TV-MI
- Rate of bleeding (BARC definition)



* meeting at least 1 of the pre-defined HBR criteria
\# Subjects not eligible for DAPT discontinuation not excluded from study

Baseline characteristics[1]	Orsiro Mission n = 969	Resolute Onyx n = 979
Gender male	67.9%	69.4%
Age, years, Mean ± SD	76.0 ± 8.5	75.6 ± 8.2
MI History	21.9%	23.9%
Hypertension	81.2%	82.1%
Hypercholesterolemia	68.0%	69.3%
Diabetes	31.1%	31.8%
Non-ST-elevation myocardial infarction	19.0%	18.5%
ST-elevation myocardial infarction	1.7%	1.7%
Most frequent high bleeding risk factors		
≥ 75 years of age	66.6%	66.3%
Moderate (estimated GFR 30-59 ml/min) or severe (estimated GFR < 30 ml/min) chronic kidney disease or failure (dialysis dependent)	28.5%	28.5%
History of stroke (ischemic or hemorrhagic) previous intracerebral hemorrhage or brain arteriovenous malformation	10.5%	11.5%
Clinical indication for chronic or life long oral anticoagulation	33.4%	37.8%
Anemia with hemoglobin <11.0 g/dL or requiring transfusion within 4 weeks before randomization	7.9%	8.0%
Cancer diagnosed or treated within previous 12 months or actively treated	7.4%	6.6%
History of hospitalization for bleeding within previous 12 months	2.6%	1.5%

	Orsiro Mission n = 969	Resolute Onyx n = 979
High bleeding risk criteria per participant		
One criterion	46.9%	46.3%
Two or more criteria	53.1%	53.7%
Lesion characteristics		
At least one B2/C lesion class	60.9%	63.5%
At least one lesion with moderate or severe calcification	35.3%	34.5%
At least one lesion with bifurcation	30.2%	31.7%

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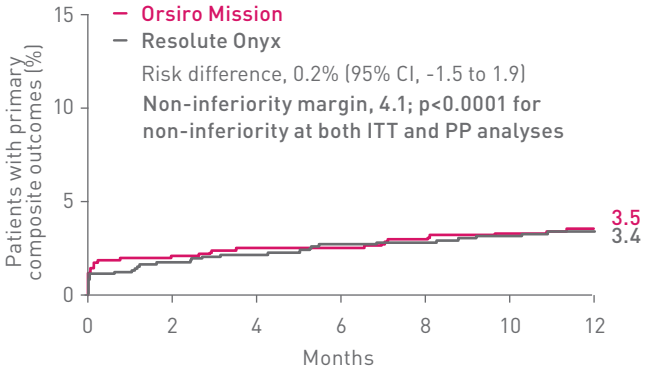
Primary endpoint: Cardiac death, Myocardial infarction, or Stent thrombosis

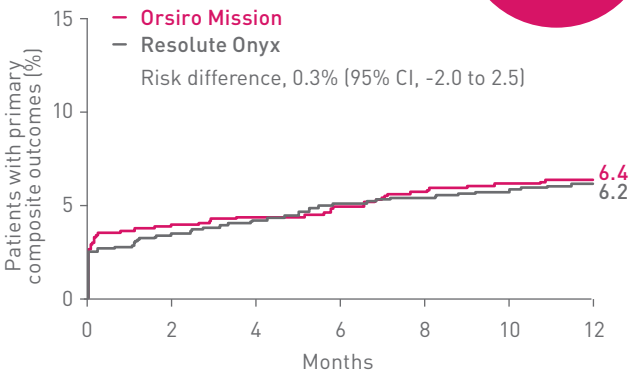
Orsiro Mission DES is non-inferior to the Resolute Onyx DES for short DAPT in HBR patients (risk difference: 0.2%, upper boundary of the one-sided 95% CI: 1.8, p<0.0001 for non-inferiority).[1]

Safe and effective with 1-month DAPT[1]

ARC-2 MI definition[2]



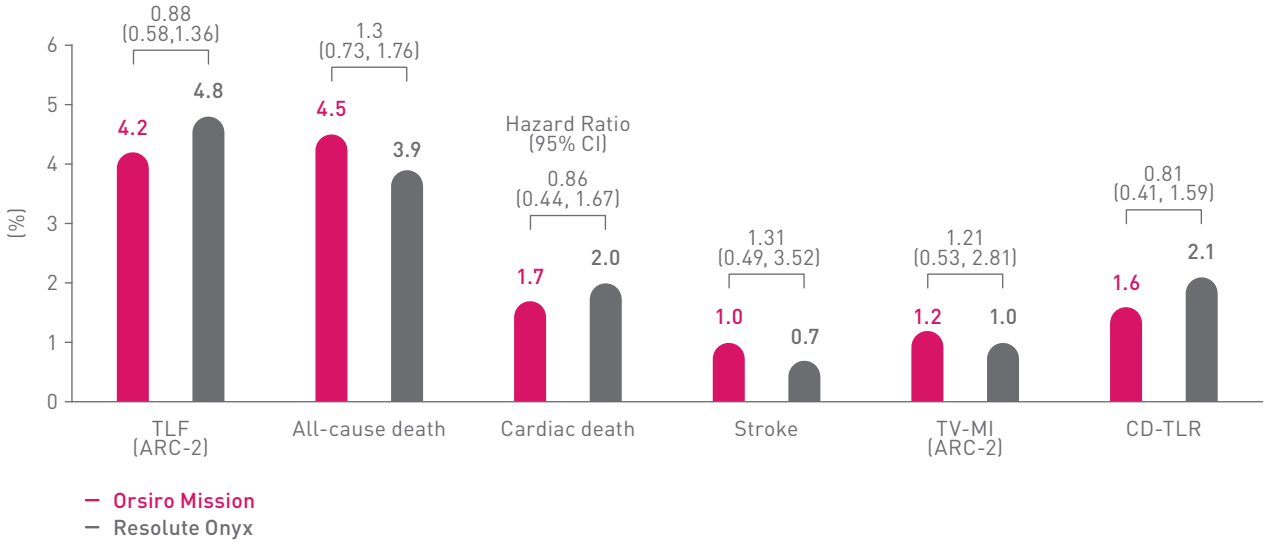
Third Universal MI definition[2]



Primary endpoint sub-components (ARC-2 definition)[1]

	Orsiro Mission n = 969		Resolute Onyx n = 979		Hazard ratio	
Cardiac death	16	1.7%	19	2.0%	0.86	95% CI 0.44-1.67
Myocardial infarction	12	1.2%	11	1.1%	1.11	95% CI 0.49-2.50
Stent thrombosis	8	0.8%	5	0.5%	1.64	95% CI 0.54-5.00

Secondary endpoints[1]



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1. Valgimigli M. et al. Biodegradable-polymer or durable-polymer stents in patients at high bleeding risk: A randomized, open-label clinical trial, Circulation, 2023; 2. Valgimigli M. Biodegradable-Polymer or Durable-Polymer Stents in Patients at High Bleeding Risk, Presented at ESC 2023, Amsterdam

Orsiro Mission DES is not indicated for one month of dual antiplatelet therapy (DAPT) in high bleeding risk (HBR) patients. Please refer to the IFU for indications and post-procedure antiplatelet therapy recommendations.

AHA / ACC: American Heart Association / American College of Cardiology, ARC: Academic Reserach Consortium, BARC: Bleeding Academic Research Consortium, CD-TLR: Clinically driven target lesion revascularization, CI: Confidence Interval, CTO: Chronic Total Occlusion, DAPT: Dual Antiplatelet Therapy, DES: Drug Eluting Stent, GFR: Glomerular Filtration Rate, HBR: High Bleeding Risk, ITT: Intention To Treat, MACE: Major Adverse Cardiac Events, MI: Myocardial Infarction, PP: Per protocol analysis, SD: Standard deviation, ST: ST segment (elevation myocardial infarction), TLF: Target Lesion Failure, TVF: Target Vessel Failure, TVR: Target Vessel Revascularization, TV-MI Target Vessel Myocardial Infarction

Clinical data collected with the Orsiro Mission DES device within the Orsiro family clinical program.

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