

Hemetsberger et al.

Impact of Coronary Calcification on Clinical Outcomes after Implantation of Newer-Generation Drug-Eluting Stents: Comparison of 2-year outcomes of Orsiro™ DES vs Xience™ in patients with calcified lesions

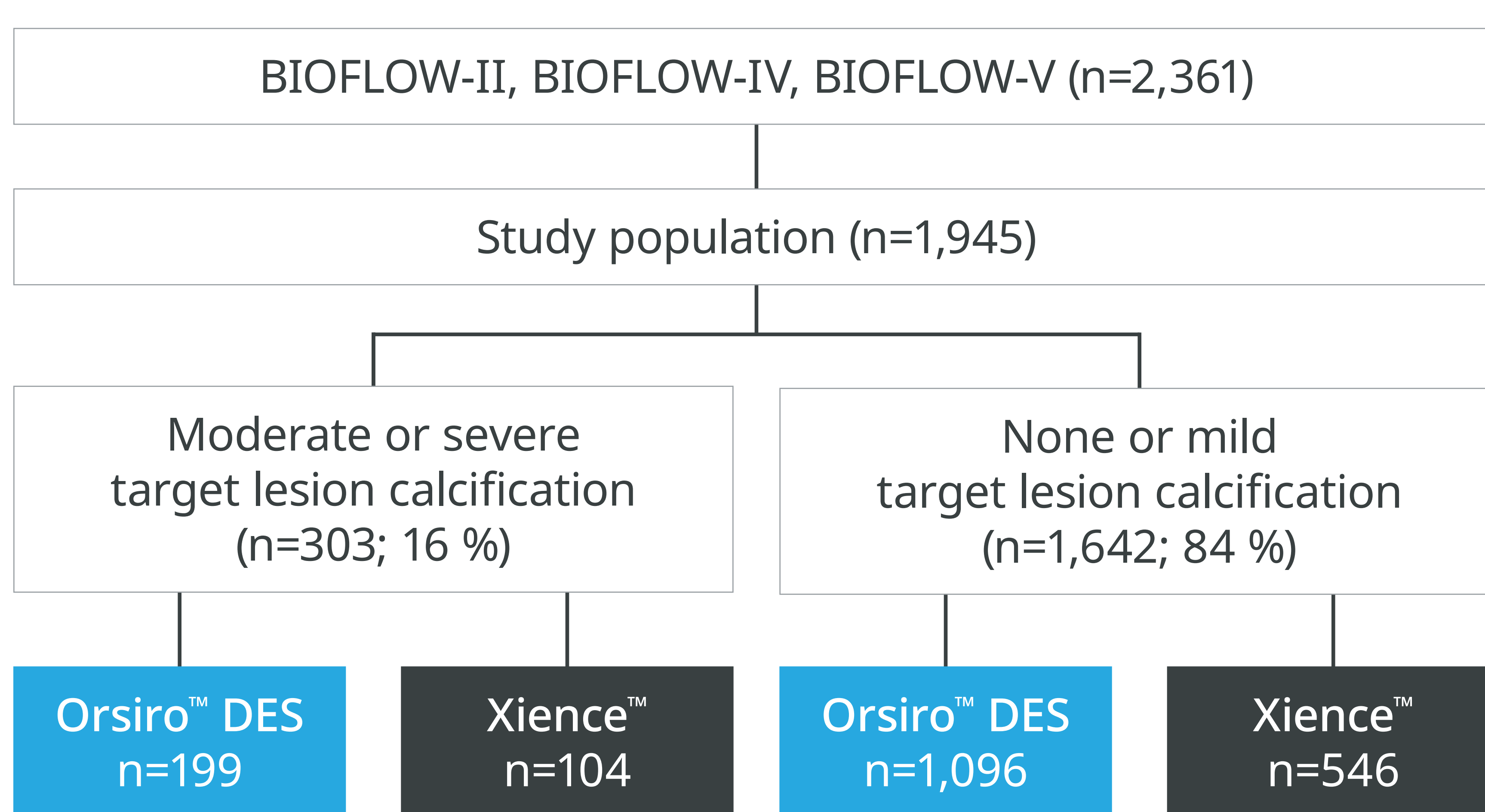
Conclusions

- At 2 years, Orsiro™ DES is proven to be safe and effective in moderate and severe lesion calcifications.*¹
- Orsiro™ DES shows a similar performance to Xience™ in calcified lesions and a significantly better performance in lesions without or with mild calcification (Target Lesion Failure: Non/Mild Calcification: 10.3 % (Xience™), 7.5 % (Orsiro™ DES), p-value=0.045).¹

Study design¹

Endpoints

- Target Lesion Failure (TLF) as composite of:
 - Cardiac Death
 - Target Vessel-Myocardial Infarction (TV-MI)
 - Target Lesion Revascularization (TLR)
- Probable/definite Stent Thrombosis (ST) at 2 years



Patient characteristics¹

	MODERATE OR SEVERE CALCIFICATION N=303		NONE OR MILD CALCIFICATION N=1,612		P-VALUE
Age, yr	65.9 ± 9.2		63.9 ± 10.2		0.0019
BMI	24.2 ± 13.4		26.1 ± 10.5		0.0741
Women	29.4 %	89/303	23.9 %	392/1,642	0.0415
Hypertension	80.9 %	244/303	76.8 %	1,247/1,623	0.1237
Hyperlipidemia	80.5 %	244/303	73.4 %	1,202/1,637	0.0092
Diabetes mellitus	32.8 %	99/302	31.8 %	522/1,641	0.7393
Prior myocardial infarction	27.6 %	82/297	27.9 %	456/1,633	0.9114
Prior PCI/CABG	46.4 %	140/302	39.7 %	648/1,633	0.0301
Prior stroke or TIA	4.6 %	14/302	6.9 %	113/1,641	0.1459
Renal disease	5.6 %	17/303	8 %	132/1,641	0.1435
Cancer	9.9 %	30/303	8.1 %	133/1,640	0.3015
Clinical presentation					0.7125
Stable angina	54.1 %	164/303	54.2 %	889/1,641	
Documented silent ischemia	13.9 %	42/303	16.3 %	267/1,641	
Acute Coronary Syndrome	32.0 %	97/303	29.6 %	485/1,641	0.3907

Data are mean ±SD or percent (n/N).

Lesion characteristics¹

	MODERATE OR SEVERE CALCIFICATION N = 337		NONE OR MILD CALCIFICATION N = 1,915		P-VALUE
Multivessel treatment	16.6 %	503/302	10.2 %	167/1,641	0.0012
Complex lesion (B2/C)	90.5 %	305/337	46.3 %	877/1,896	<0.0001
Bifurcation lesion	10.7 %	36/337	10.1 %	193/1,915	0.7351
Thrombus	2.1 %	7/337	0.8 %	16/1,915	0.0366
Vessel tortuosity					<0.0001
None	41.2 %	139/337	70.6 %	1,352/1,915	
Moderate	38.6 %	130/337	16.3 %	313/1,915	
Severe	20.2 %	68/337	13.1 %	250/1,915	
Calcification					<0.0001
None/mild	-	-	100 %	1,915/1,915	
Moderate	76.0 %	256/337	-	-	
Severe	24.0 %	81/337	-	-	
Lesion length	14.94 ± 9.22		13.09 ± 6.49		0.0212
Long lesion >20 mm	24.6 %	83/337	14.3 %	272/1,903	<0.0001
RVD ≤2.75 mm	56.1 %	189/337	58.5 %	1,120/1,915	0.4097
Procedural characteristics					
Stent					0.3385
Orsiro™ DES	63.8 %	215/337	66.5 %	1,273/1,915	
Xience™	36.2 %	122/337	33.5 %	642/1,915	
Maximum stent implantation pressure (atm)	14.23 ± 2.91		14.00 ± 3.04		0.2311
Stent length (mm)	22.46 ± 7.44		20.35 ± 6.85		<0.0001
Overlapping stents	3.6 %	12/337	2.2 %	43/1,915	0.1491
Predilatation	96.4 %	324/336	86.1 %	1,619/1,881	<0.0001
Postdilatation	59.1 %	189/320	47.8 %	854/1,786	0.0002
Diameter stenosis at baseline	56.0 %	46.7-65.5	61.4 %	51.9-71.9	<0.0001
Diameter stenosis after procedure	8.9 %	3.0-15.2	6.9 %	1.7-12.1	<0.0001

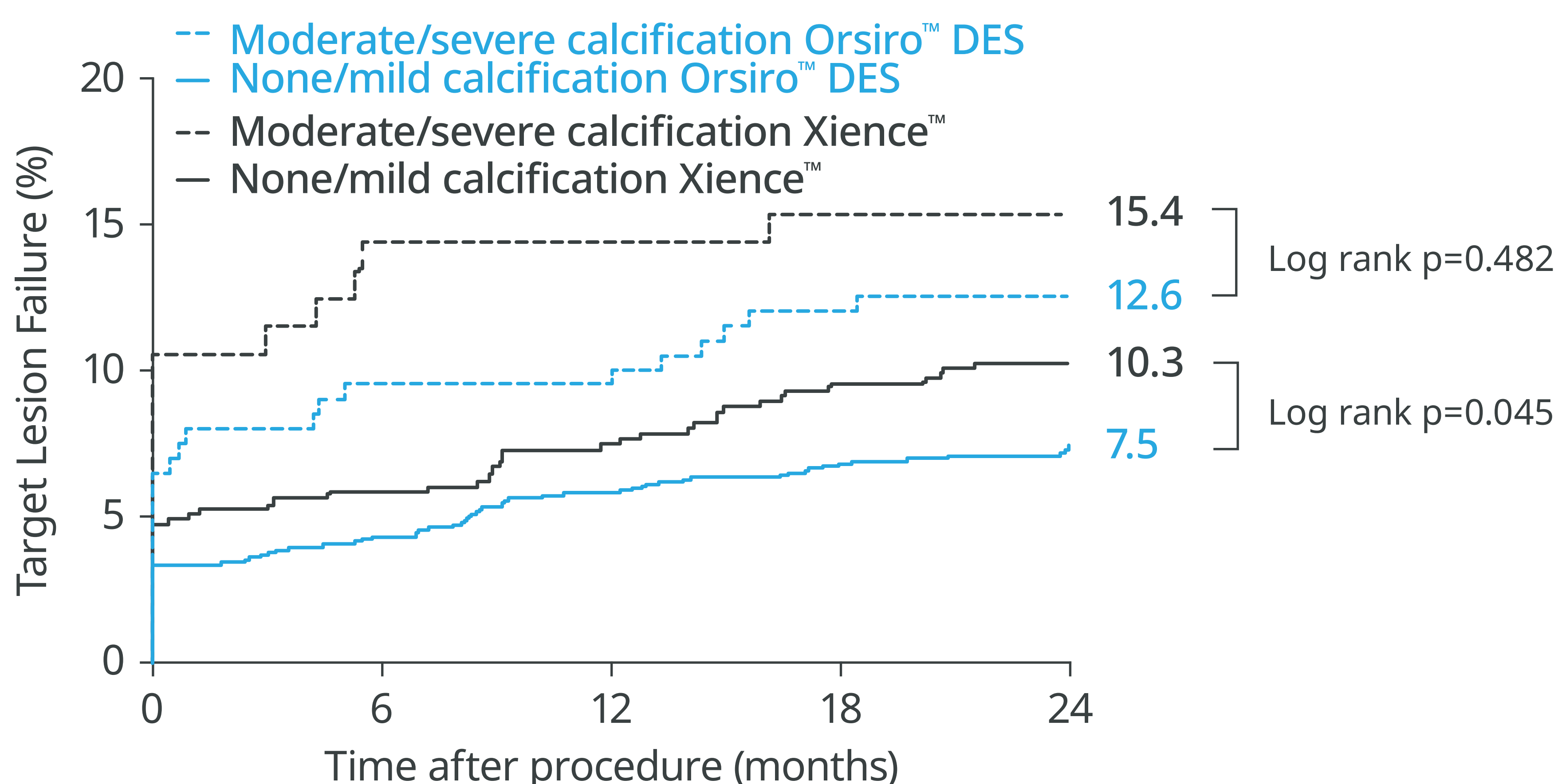
[§]Number of lesions





Target Lesion Failure at 2 years¹

Orsiro™ DES proven to be safe and effective in moderate and severe lesion calcifications.*



NUMBER AT RISK					
None/mild calcification – Xience™	546	514	505	494	357
None/mild calcification – Orsiro™ DES	1,096	1,048	1,032	1,021	717
Moderate/Severe Calcification – Xience™	104	89	89	88	64
Moderate/Severe Calcification – Orsiro™ DES	199	180	180	175	125

Probable or Definite Stent Thrombosis at 2 years¹

	MODERATE/SEVERE CALCIFICATION		NONE/MILD CALCIFICATION		P-VALUE
Definite/probable ST at 1 year	7/370	1.9 %	3/1,812	0.2 %	<0.0001
Definite/probable ST at 2 years	8/303	2.6 %	4/1,642	0.2 %	<0.0001

	MODERATE/SEVERE CALCIFICATION – ORSIRO™ DES		MODERATE/SEVERE CALCIFICATION – XIENCE™		P-VALUE
Definite/probable ST at 1 year	6/236	2.5 %	1/134	0.7 %	0.2229
Definite/probable ST at 2 years	6/199	3.0 %	2/104	1.9 %	0.5735

	NONE/MILD CALCIFICATION – ORSIRO™ DES		NONE /MILD CALCIFICATION – XIENCE™		P-VALUE
Definite/probable ST at 1 year	1/1,212	0.1 %	2/600	0.3 %	0.2165
Definite/probable ST at 2 years	1/1,096	0.1 %	3/546	0.5 %	0.0760

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Reference:

¹ Hemetsberger R. et al. Impact of Coronary Calcification on Clinical Outcomes After Implantation of Newer-Generation Drug-Eluting Stents, JAHA, 2021, BMI: Body Mass Index. Target Lesion Failure (TLF); Target-Vessel Myocardial Infarction (TV-MI), Target Lesion Revascularization (TLR). Probable/ definite Stent Thrombosis (ST).

*Based on 2-year TLF and definite/probable ST from Hemetsberger et al., 2021 (TLF-Mod/Severe Calcification: 15.4 % (Xience), 12.6 % (Orsiro), p=0.482) (Definite/probable ST-Mod/Severe Calcification: 2.0 % (Xience), 3.0 % (Orsiro), p=0.572).

Clinical data conducted with Orsiro, Orsiro Mission's predecessor device can be used to illustrate Orsiro Mission clinical outcomes.

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