

HATTRICK-OCT Trial

Early neointimal coverage and vasodilator response following Orsiro vs. Resolute Integrity in patients with Acute Coronary Syndrome

Conclusions

- Orsiro® had a significantly lower percentage of uncovered struts compared with Resolute Integrity* at strut level (3.9% vs. 8.9%, p <0.001)
- No significant difference in vasodilator response was seen in both arms

Study design

Prospective, randomized, multi-center trial

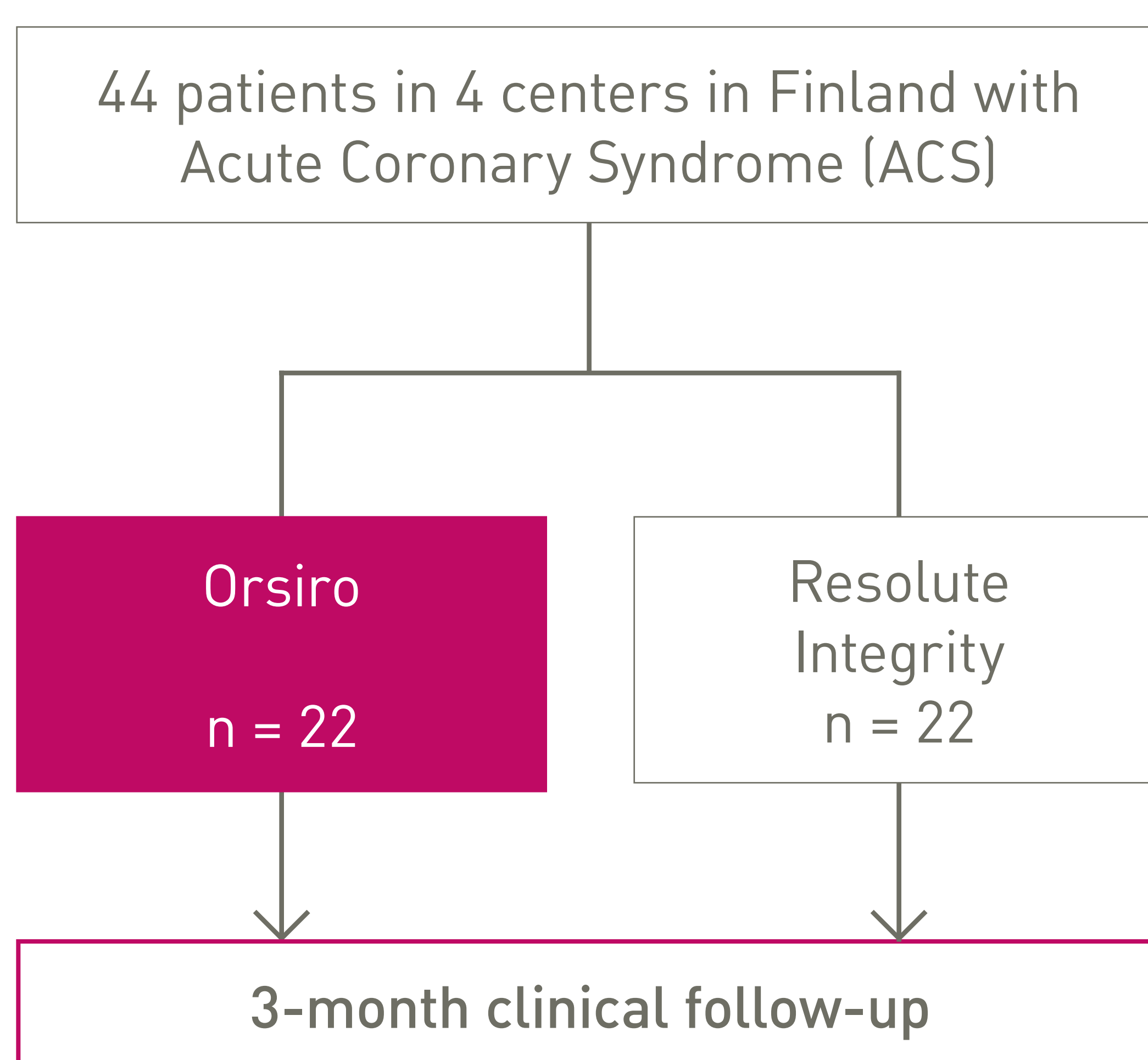
Endpoints

Primary safety endpoints

- Percent uncovered struts at 3-month follow-up

Secondary endpoints (selected)

- Malapposed struts at 3-months
- Coronary flow reserve (CFR) at 3-month follow-up



Patient characteristics	Orsiro n = 22	Resolute Integrity n = 22	p-value
Age (years)**	62.5 ± 9.7	62.0 ± 12.1	0.87
Male	81.1%	77.3%	0.72
Risk factors			
Hypertension	36.4%	27.3%	0.75
Hypercholesterolemia	31.8%	18.2%	0.49
Current smoking	22.7%	36.4%	0.51
Indication for PCI			
Unstable angina	4.5%	13.6%	0.61
NSTEMI	40.9%	36.4%	1.0
STEMI	54.5%	50.0%	1.0

Lesion characteristics	Orsiro n = 22	Resolute Integrity n = 22	p-value
Stent diameter (mm)**	3.2 ± 0.3	3.2 ± 0.3	0.71
Stent length (mm)**	18.0 ± 3.4	17.5 ± 3.2	0.65
Lesion type			0.50
A	15.8%	11.1%	
B1	52.6%	66.7%	
B2	31.6%	16.7%	
C	0.0%	5.6%	

Procedural characteristics	Orsiro n = 22	Resolute Integrity n = 22	p-value
Pre-dilatation	77.3%	82.66%	0.72
Post-dilatation	40.9%	78.3%	0.02

* Resolute Integrity is a registered trademark of Medtronic Vascular Inc.

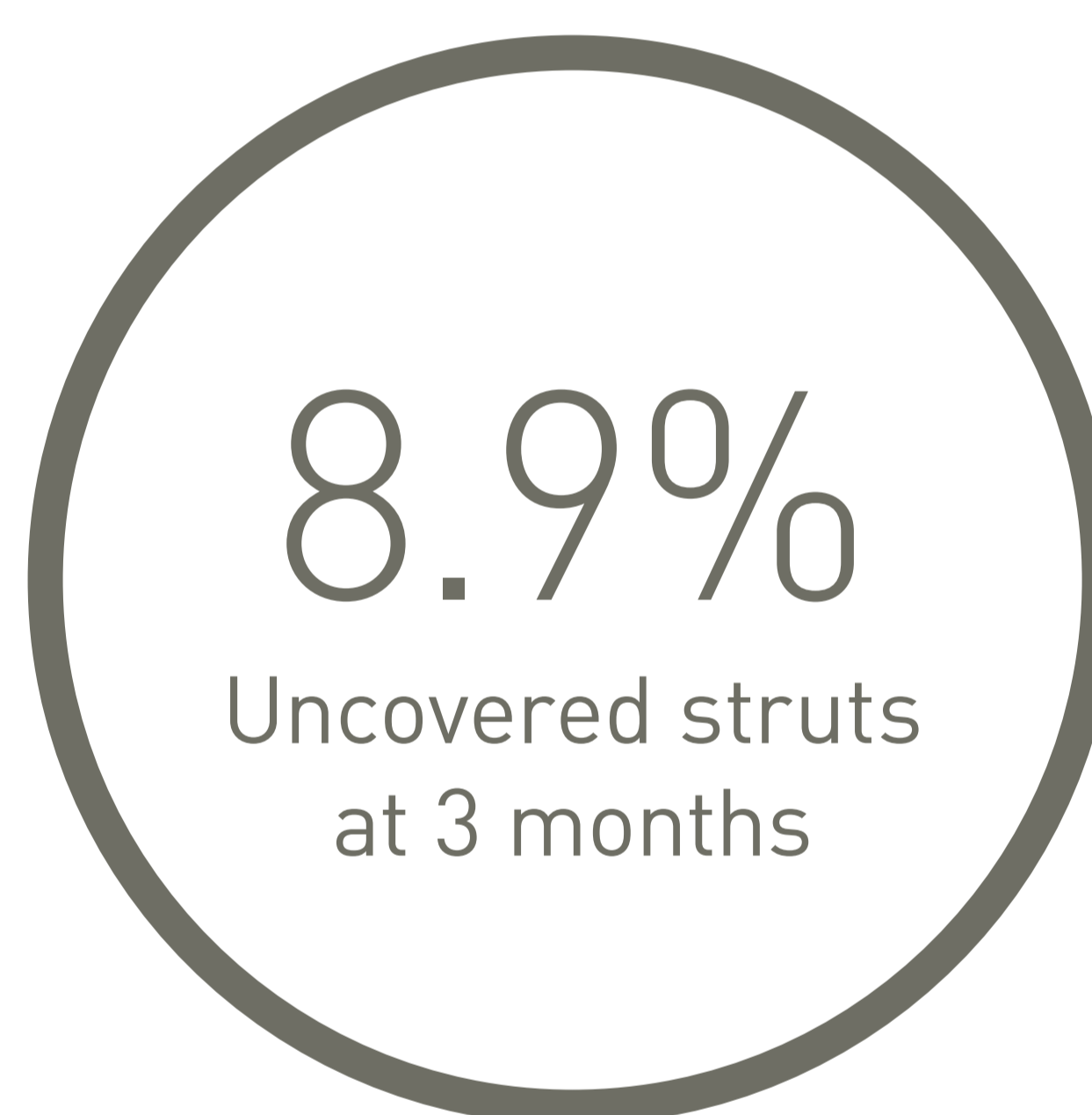
**Data given as mean ± SD



OCT at 3 months	Orsiro n = 22	Resolute Integrity n = 22	p-value
Strut level analysis			
Total number struts analyzed	4,897	5,467	0.13
Neointimal hyperplasi thickness (μm)**	69.1 \pm 58.2	76.5 \pm 82.9	0.15
Uncovered struts	3.9%	8.9%	<0.001
Malapposed struts	2.1%	5.3%	<0.001
Stent level analysis			
% Uncovered struts**	3.9 \pm 3.2	8.9 \pm 6.9	0.019
Stents with >5% uncovered struts	31.8%	63.6%	0.069
% Malapposed struts**	2.2 \pm 3.7	4.3 \pm 9.5	0.33
Intra-stent thrombus	9.1%	4.5%	1.0

**Data given as mean \pm SD

Key outcomes



Principal investigators

Dr. Tuomas Kiviniemi, Turku University Hospital, Turku, Finland

Dr. Pasi Karjalainen, Satakunta Hospital District, Pori, Finland

Karjalainen PP, Varho V, Nammass W, et al. Early neointimal coverage and vasodilator response following biodegradable polymer sirolimus-eluting vs. durable polymer zotarolimus-eluting stents in patients with acute coronary syndrome. *Circulation Journal*. 2015;79(2):360-7.

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

Orsiro is a trademark or registered trademark of the BIOTRONIK Group of Companies.

