

# REVASC

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## Recovery of Left Ventricular Function in Coronary Chronic Total Occlusion

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# Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

## Affiliation/Financial Relationship

- Grant/Research Support
- Consulting Fees/Honoraria

## Company

- REVASC was sponsored by Cordis
- Ashai Intecc, Vascular Solutions, Cordis, Abboth, Biotronik, Terumo, AstraZeneca, Daiichi Sankyo

# Randomized Trials

<b>Trial</b>	<b>N</b>	<b>Study Type</b>	<b>Population</b>	<b>Primary Endpoints:</b>
<b>EXPLORE</b>	304	CTO PCI vs. no CTO PCI	STEMI with CTO	4-month: LVEF, LVEDV per MRI comparable in both groups
<b>DECISION-CTO</b>	834	CTO PCI + OMT vs. OMT	Stable Angina or ACS	3-year death, MI, stroke, or repeat revascularization comparable in both groups
<b>EURO-CTO</b>	396	CTO PCI + OMT vs. OMT	Stable angina	PCI group experienced lower angina frequency per SAQ

# REVASC Trial

## Recovery of Left Ventricular Function After Stent Implantation in Chronic Total Occlusion of Coronary Arteries :

### Background

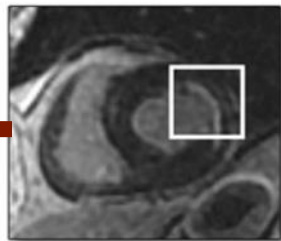
- Whether percutaneous coronary intervention (PCI) in chronic occluded coronary arteries (CTO) may improve outcomes compared to optimal medical therapy (OMT) is still controversial.

### Objective

- We evaluated whether PCI of CTO (CTO-PCI) improves left ventricular function in addition to PCI of relevant coexisting non-CTO vessels (no-CTO-PCI).

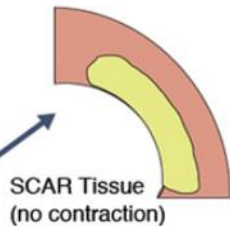
# Primary Endpoint: Segmental wall thickening (SWT) measured by cMRI after 6 months

**Baseline**



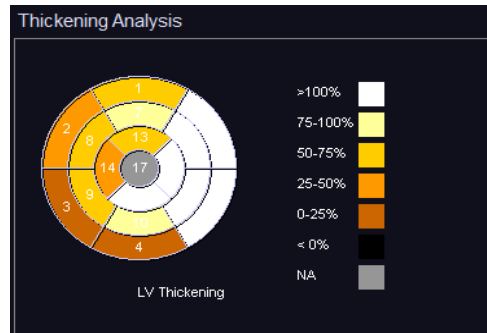
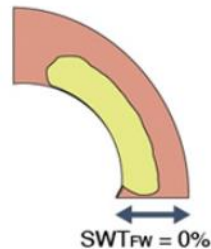
**Diastole**

**Jeopardized Myocardium**



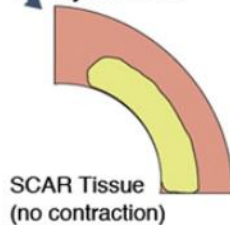
**Systole**

**Unenhanced Rim  
SWT<sub>UR</sub> = 0%**

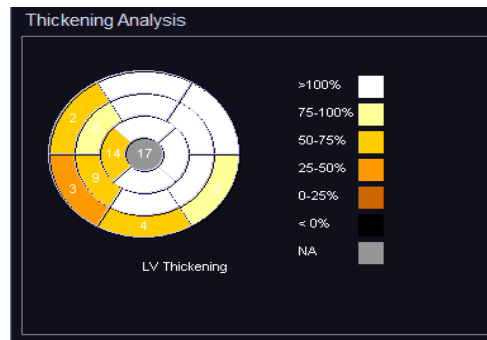
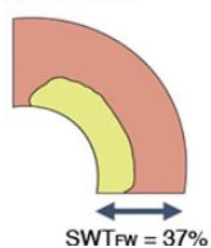


**6 months**

**Non-jeopardized Myocardium**



**Unenhanced Rim  
SWT<sub>UR</sub> = 75%**



# Study endpoints

- **Primary endpoint:**
  - **Change in segmental wall thickening (SWT) in the CTO territory according to the 17-segment model between baseline and follow-up at 6 months**
- **Secondary endpoints:**
  - **Changes in LV end-diastolic and end-systolic volume indices and left ventricular ejection fraction (LVEF)**
- **Clinical outcomes:**
  - **MACE at 12 months was defined as all-cause death, myocardial infarction and any clinically driven repeat revascularization.**

# Patient selection

## Major inclusion criteria

- CTO with an estimated reference vessel diameter of 2.5-4.0mm.
- Clinical symptoms or positive functional study for ischemia

## Exclusion criteria

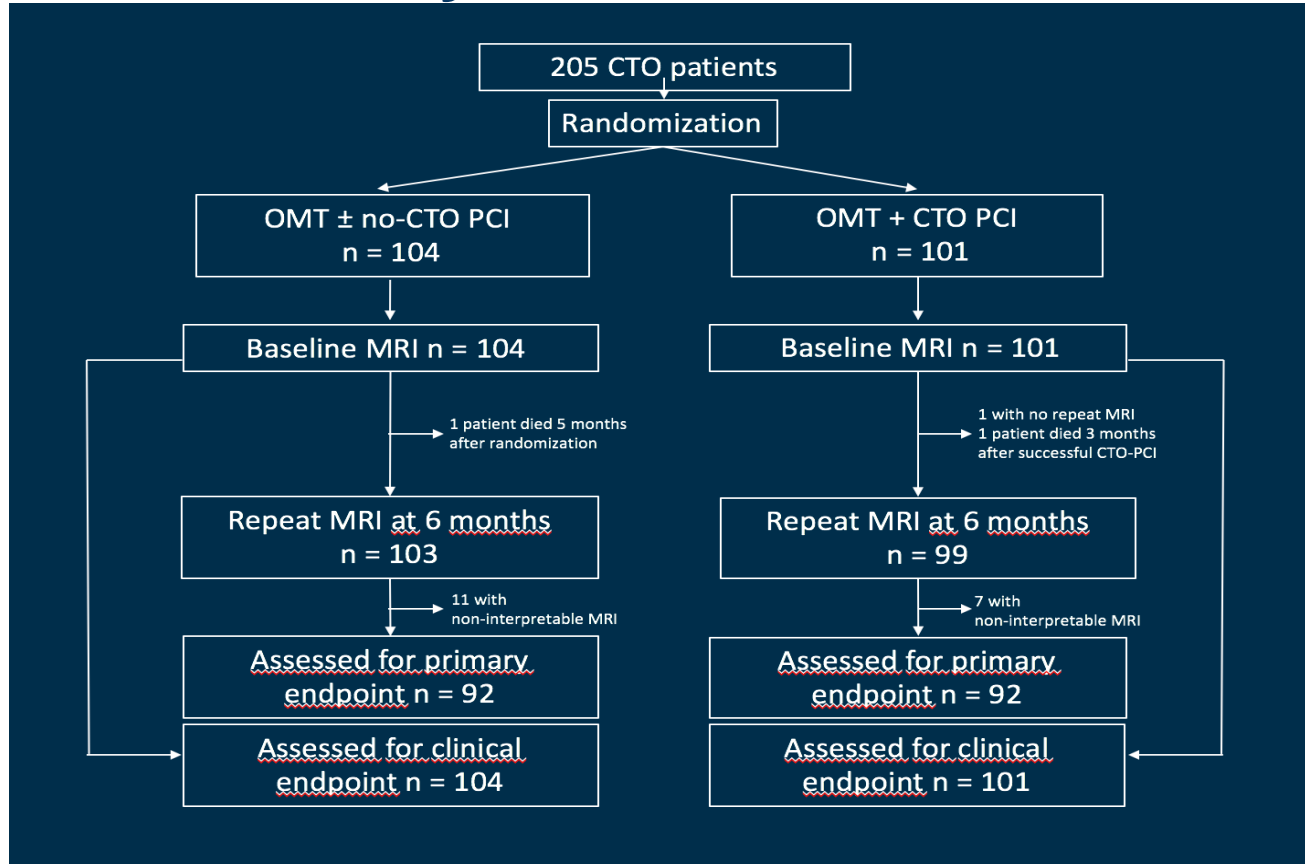
- Left ventricular ejection fraction < 25%
- Acute coronary syndrome < 72 hours preceding the index procedure
- Contraindications to cMRI

# Estimation of sample size

- **Hypothesis:** 15%-recovery of SWT with CTO-PCI versus a 2%-recovery with No-CTO-PCI at a common standard deviation of 30%.
- **Goal:** 80% power, level of significance 5%
- **Sample size:** 85 patients per study arm
- **Recruitment:** 200 patients  
(to account for losses to follow-up)



# Study flow of REVASC



# Baseline demographic and angiographic characteristics

	<b>no-CTO-PCI (n = 104)</b>	<b>CTO-PCI (n = 101)</b>	<b>p Value</b>
Age (years)	68 [61 - 74]	65 [57 - 72]	0.02
Male gender	90 (86.5)	91 (90.1)	0.43
Diabetes	31 (29.8)	32 (31.6)	0.77
LVEF (%)	59.6 [45.8 - 64.3]	54.7 [42.9 - 65.1]	0.48
Previous PCI	33 (31.7)	28 (27.7)	0.53
Previous myocardial infarction	38 (36.5)	39 (38.6)	0.76
Previous bypass operation	14 (13.5)	12 (11.9)	0.73

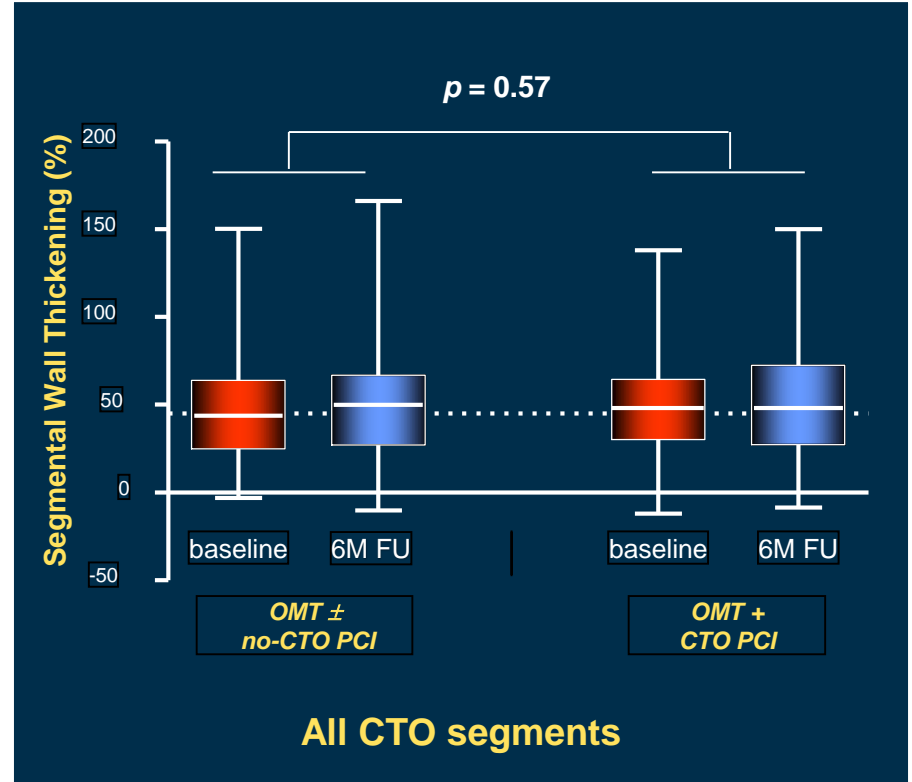
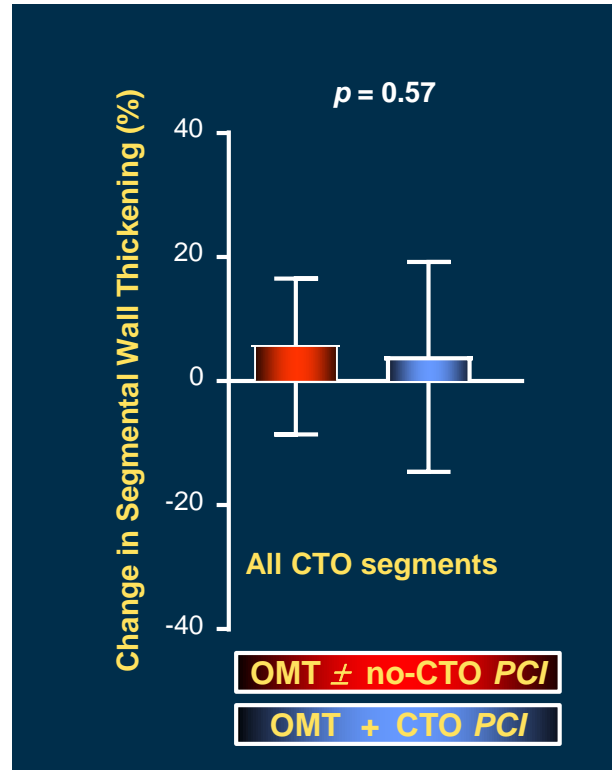
# Angiographic characteristics

	<b>no-CTO-PCI (n = 104)</b>	<b>CTO-PCI (n = 101)</b>	<b>p Value</b>
Coronary artery disease			0.55
1-vessel disease	10 (9.6)	14 (13.9)	
2,3-vessel disease	94 (90.4)	87 (86.1)	
SYNTAX-Score	16 [11 - 21]	14 [9 - 22]	0.33
Residual SYNTAX-Score	11 [8 - 16]	2 [0 - 7]	<0.01
J-CTO Score	2 [1 - 2]	2 [1 - 3]	0.43
PROGRESS Score	0 [0 - 1]	1 [0 - 1]	<0.01

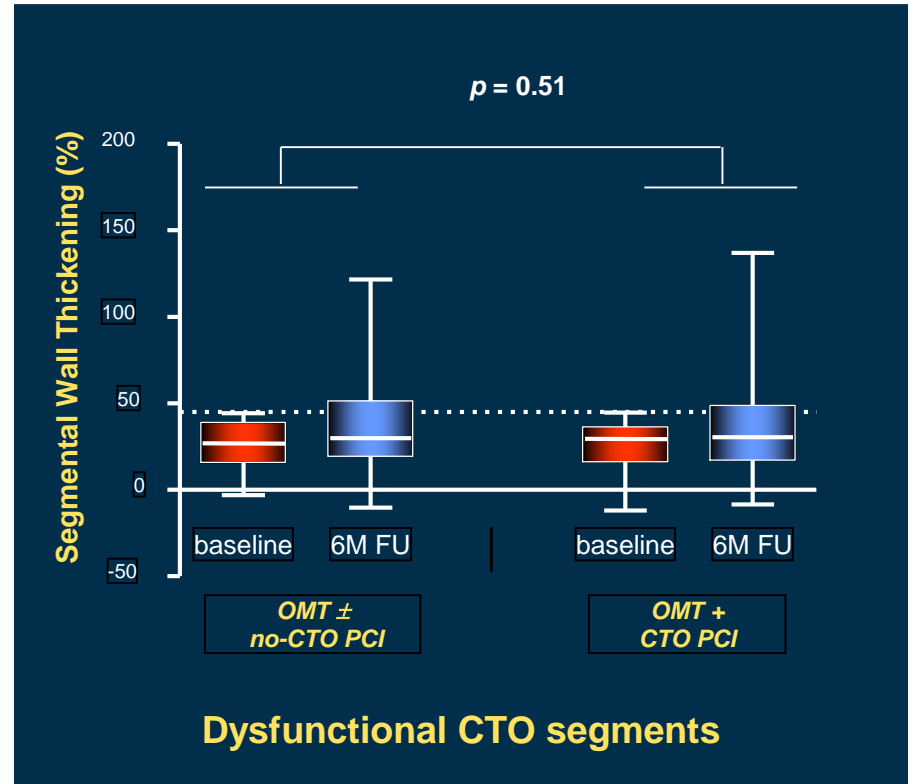
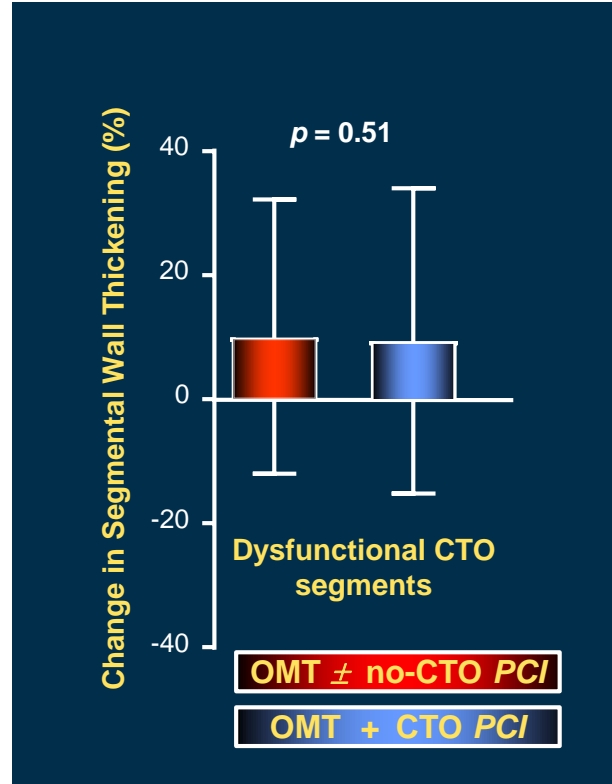
# Procedural CTO data

	CTO-PCI (n = 101)
CTO recanalization technique	
antegrade only	61 (60.4)
retrograde	40 (39.6)
Technical success on first attempt	87 (86.1)
Technical success including 2 <sup>nd</sup> attempts	100 (99.0)
Procedure time (minutes)	96 [65 – 149]
Fluoroscopy time (minutes)	37 [20 – 76]
Radiation dose ( $\mu\text{Gy} \cdot \text{cm}^2$ )	10322 [5725 – 17539]
Contrast Volume (ml)	280 [200 – 400]

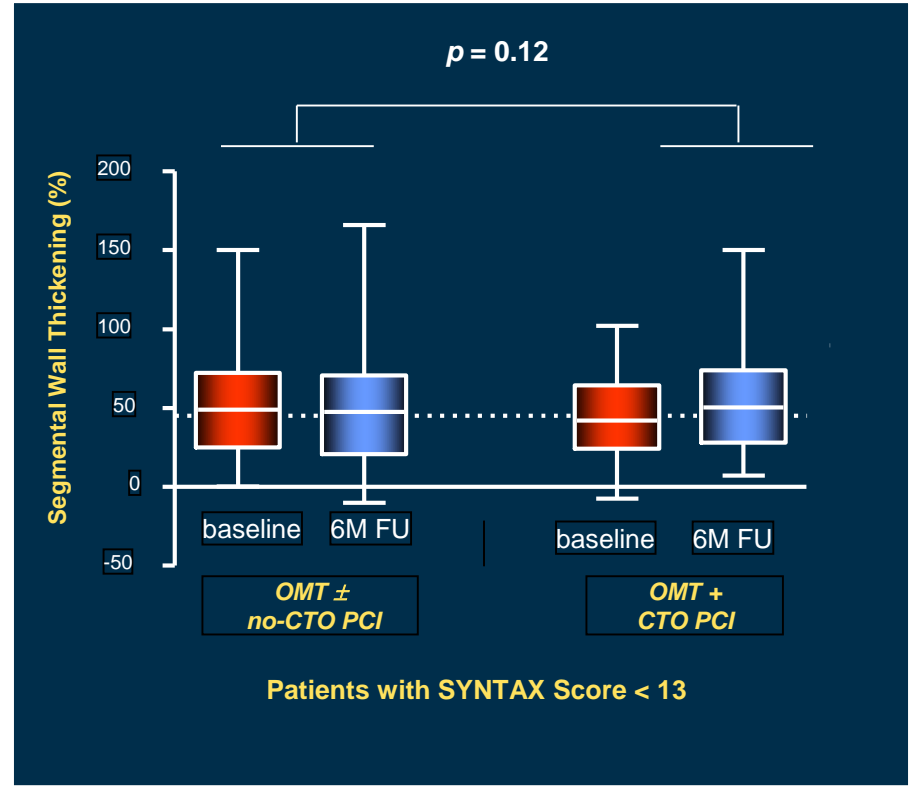
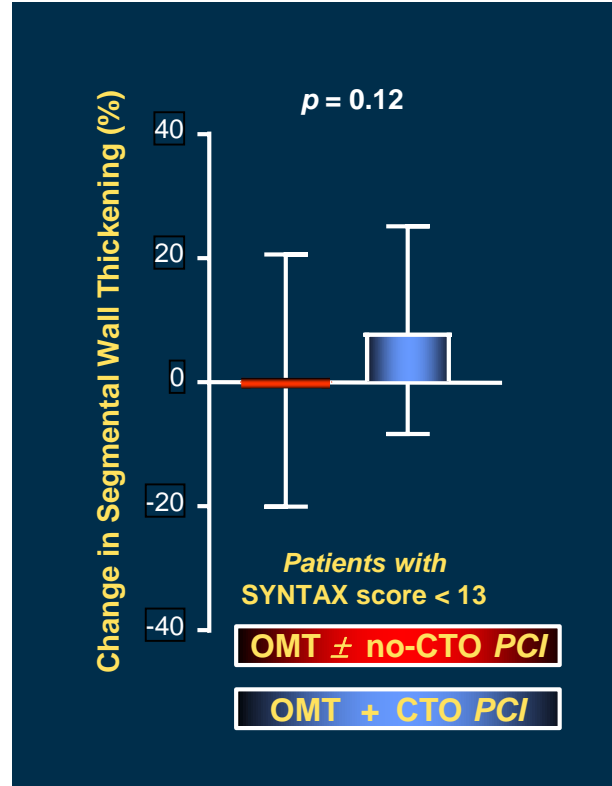
# Primary endpoint:



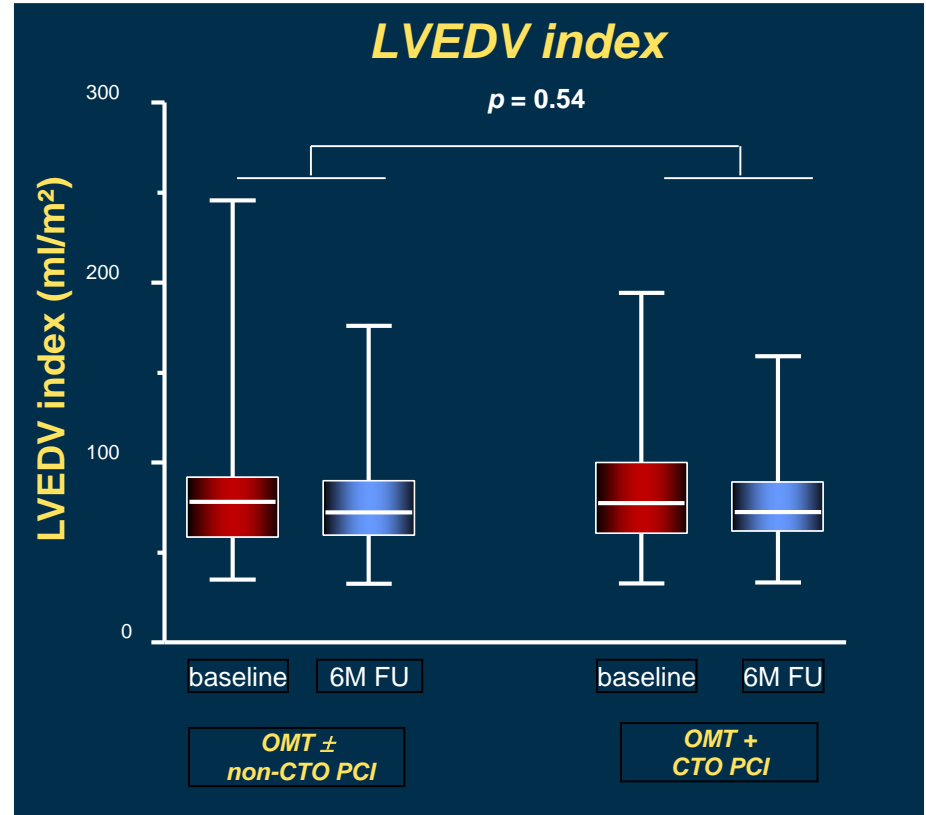
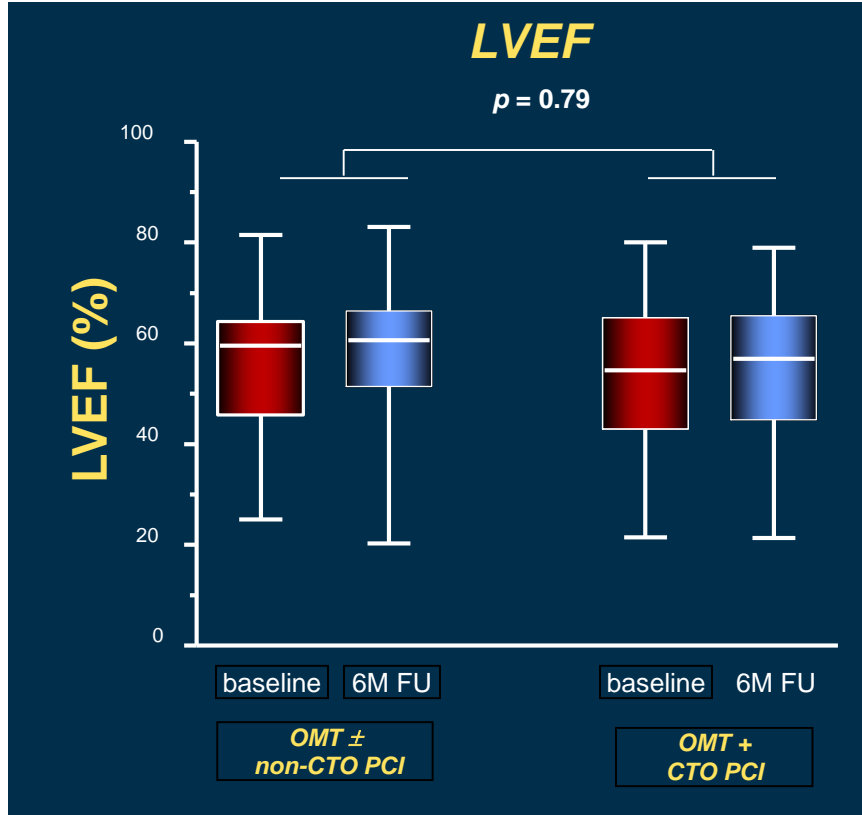
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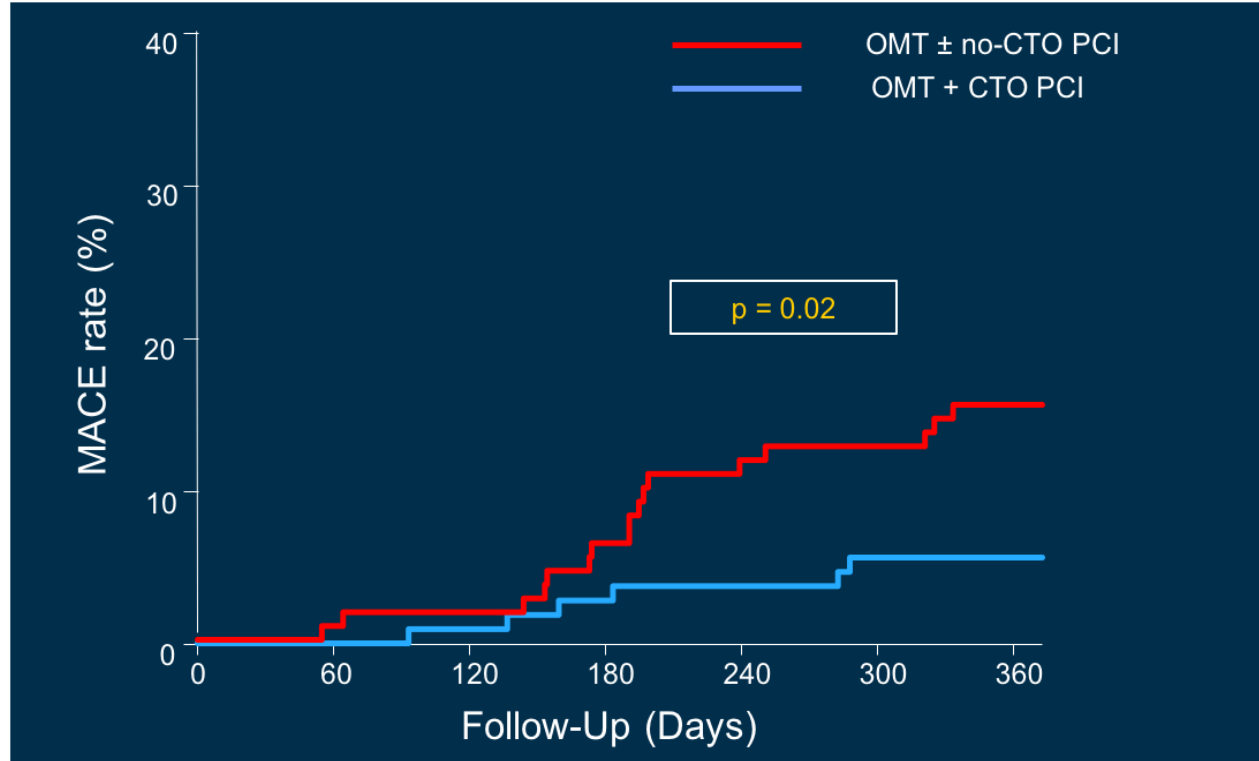


# Secondary endpoint:





# Major adverse cardiac events at 12 months (death, infarction, any revascularization)



# Major adverse cardiac events at 12 months

	no-CTO-PCI (n = 104)	CTO-PCI (n = 101)
MACE	17 (18.2)	6 (5.9)
Death of any cause at 12 months	2 (2.0)	1 (1.0)
Acute myocardial infarction	1 (1.0)	0 (0.0)
Clinically driven repeat revascularization at 12 months:	16 (15.4)	5 (5.0)
CTO vessel	14 (13.5)	3 (3.0)

# Conclusion

- **In the entire cohort, CTO-PCI did not improve regional or global left ventricular function over no-CTO PCI.**
- **In the subset of patients without major non-CTO lesions, CTO-PCI was associated with a trend towards larger improvement in segmental wall thickening than no-CTO-PCI.**
- **In the entire cohort, CTO-PCI resulted in clinical benefit over no CTO-PCI as evidenced by reduced MACE rates at 12 months.**

# Primary endpoint: Change of SWT in %

