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REVASC

ClinicalTrials.gov, Identifier: NCT01924962

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	Company
• Consulting Fees/Honoraria	Ashai Intecc, Boston, Medtronic, Teleflex, Cardinal Health, Abboth, Biotronik, Terumo, AstraZeneca, Daiichi Sankyo
• Grant/Research Support	REVASC was sponsored by Cordis

REVASC Trial

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

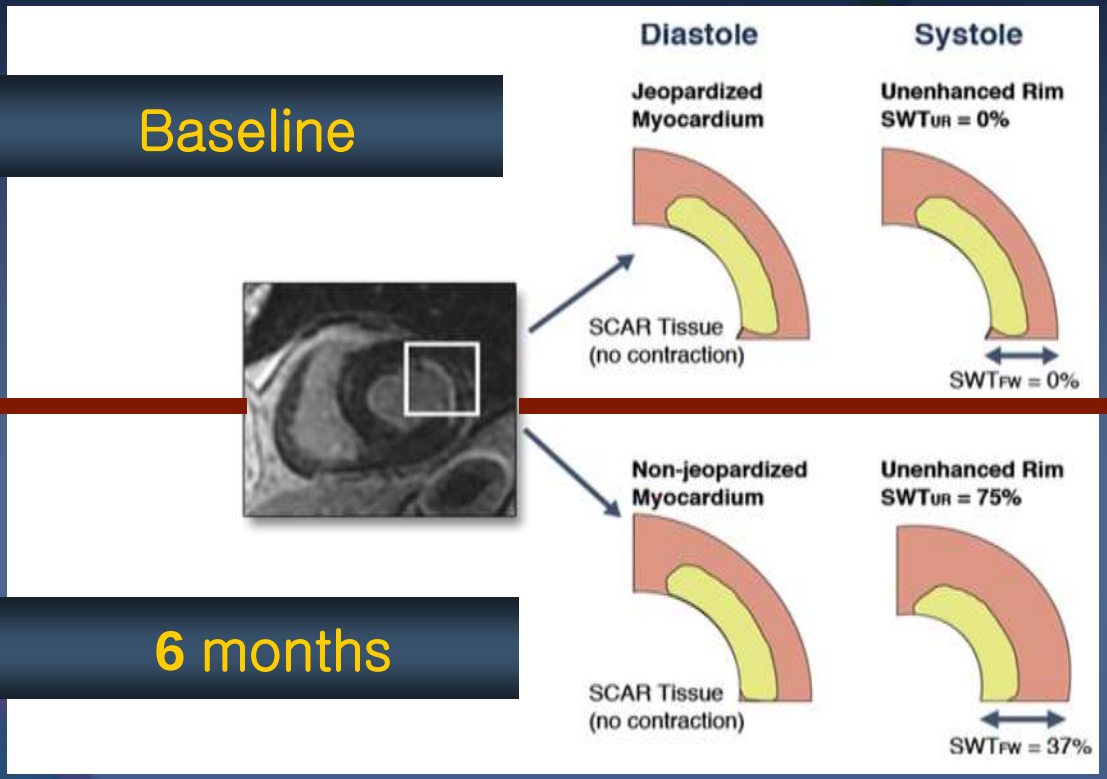
Background

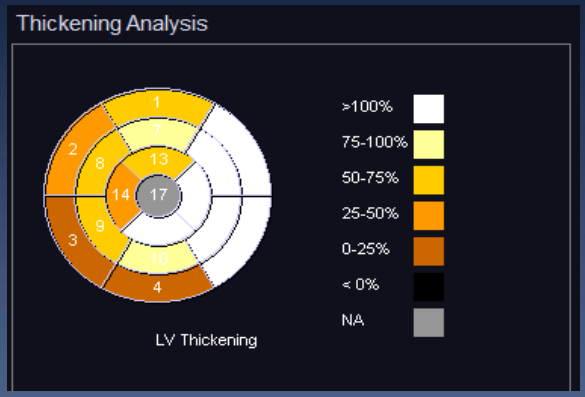
- Whether percutaneous coronary intervention (PCI) in chronic occluded coronary arteries (CTO) may improve outcomes compared to optimal medical therapy (OMT) is still controversial.

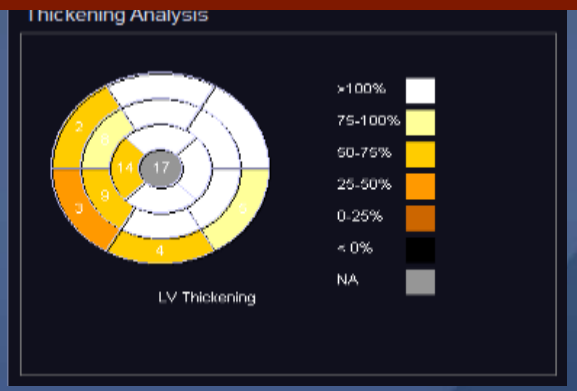
Objective

- We evaluated whether PCI of CTO (CTO-PCI) improves regional 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







Modified from Kirschbaum SW et al, JACC Cardiovasc Imaging. 2010 Jun;3(6):614-22

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.

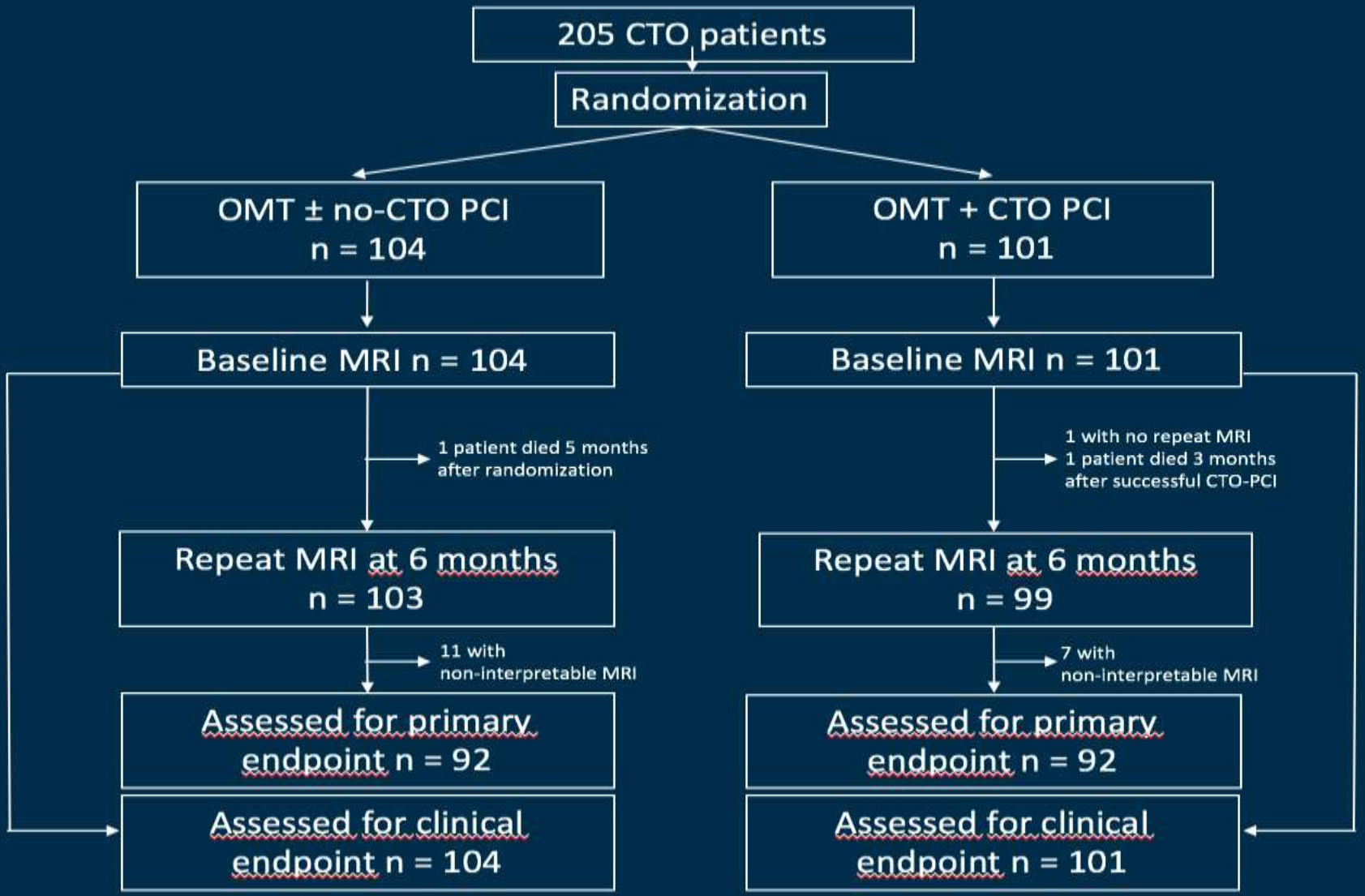
Patient selection

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

	no-CTO-PCI (n = 104)	CTO-PCI (n = 101)	p Value
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

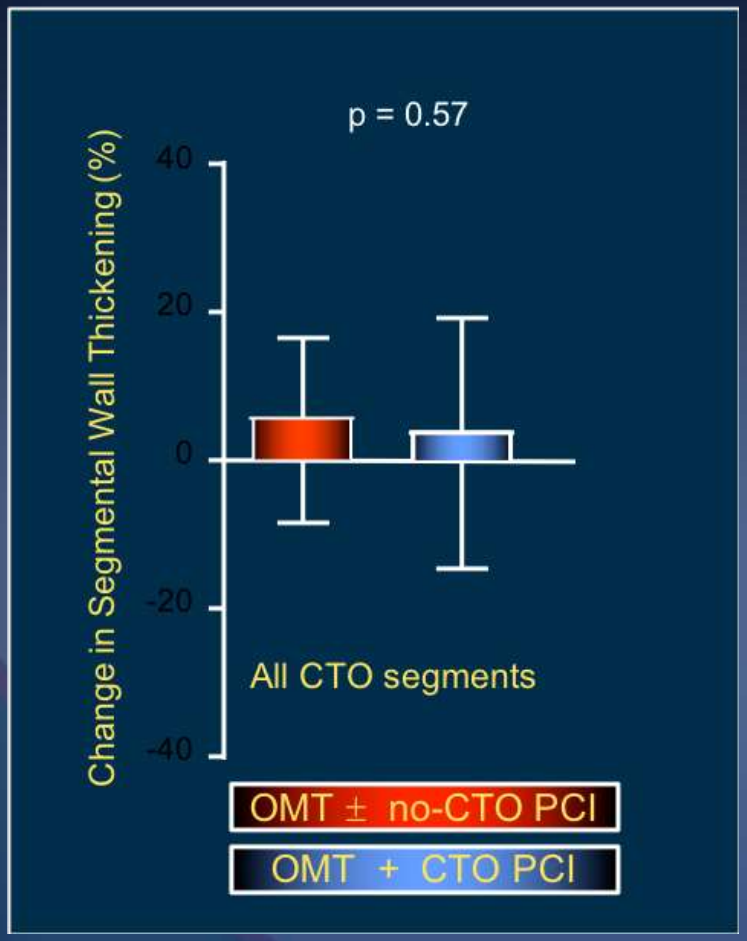
Angiographic characteristics

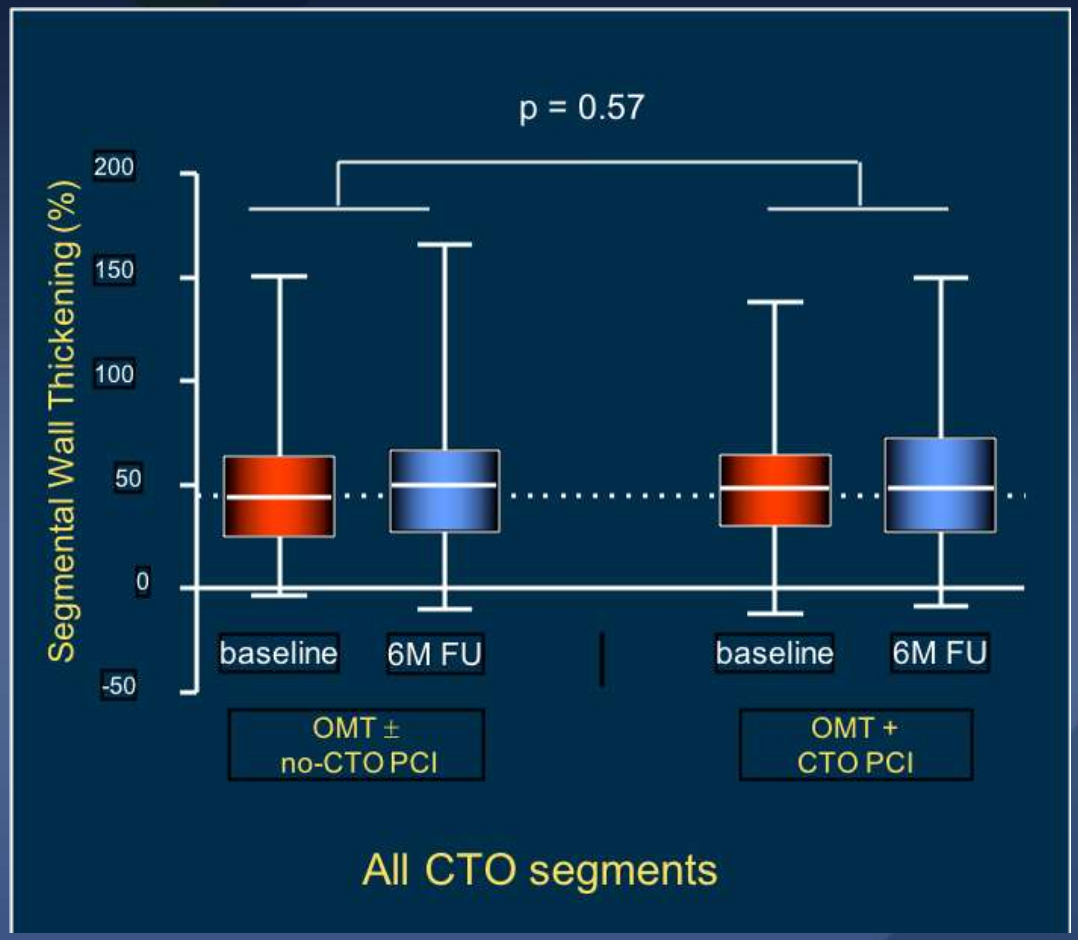
	no-CTO-PCI (n = 104)	CTO-PCI (n = 101)	p Value
Coronary artery disease 1-vessel disease 2,3-vessel disease	 10 (9.6) 94 (90.4)	 14 (13.9) 87 (86.1)	0.55
SYNTAX-Score	16 [11 - 21]	14 [9 - 22]	0.33
Residual SYNTAX-Score	11 [8 - 16]	2 [0 - 7]	<0.01
J-CTO Score	2 [1 - 2]	2 [1 – 3]	0.43
PROGRESS Score	0 [0 – 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 2nd attempts	100 (99.0)
Procedure time (minutes)	96 [65 – 149]
Fluoroscopy time (minutes)	37 [20 – 76]
Radiation dose (µGy*cm²)	10322 [5725 – 17539]
Contrast Volume (ml)	280 [200 – 400]

Primary endpoint:





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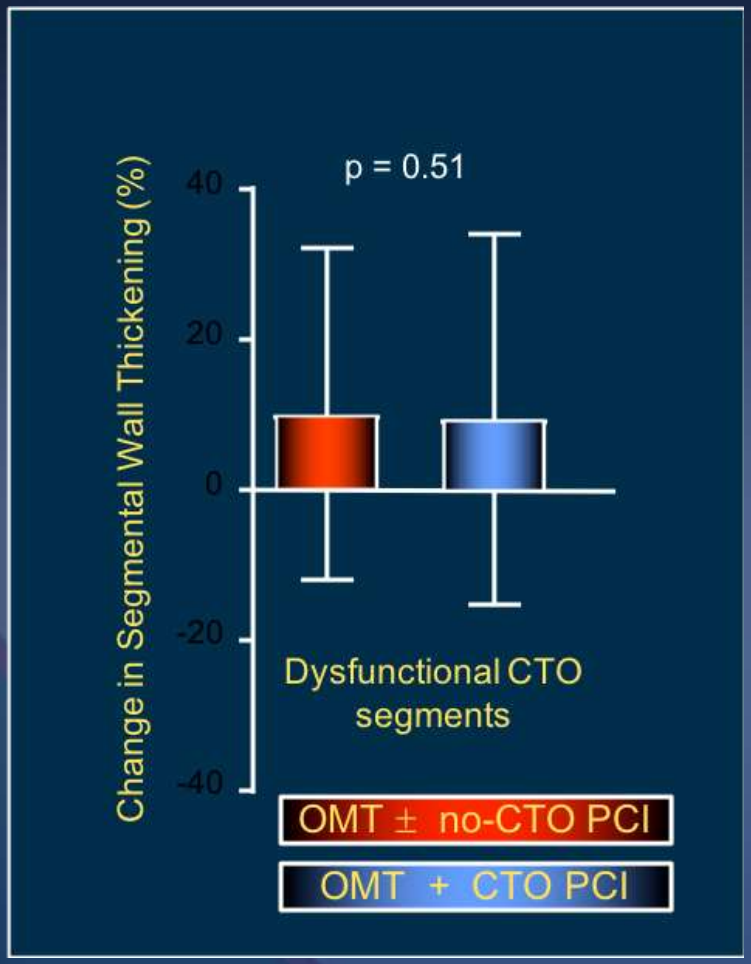

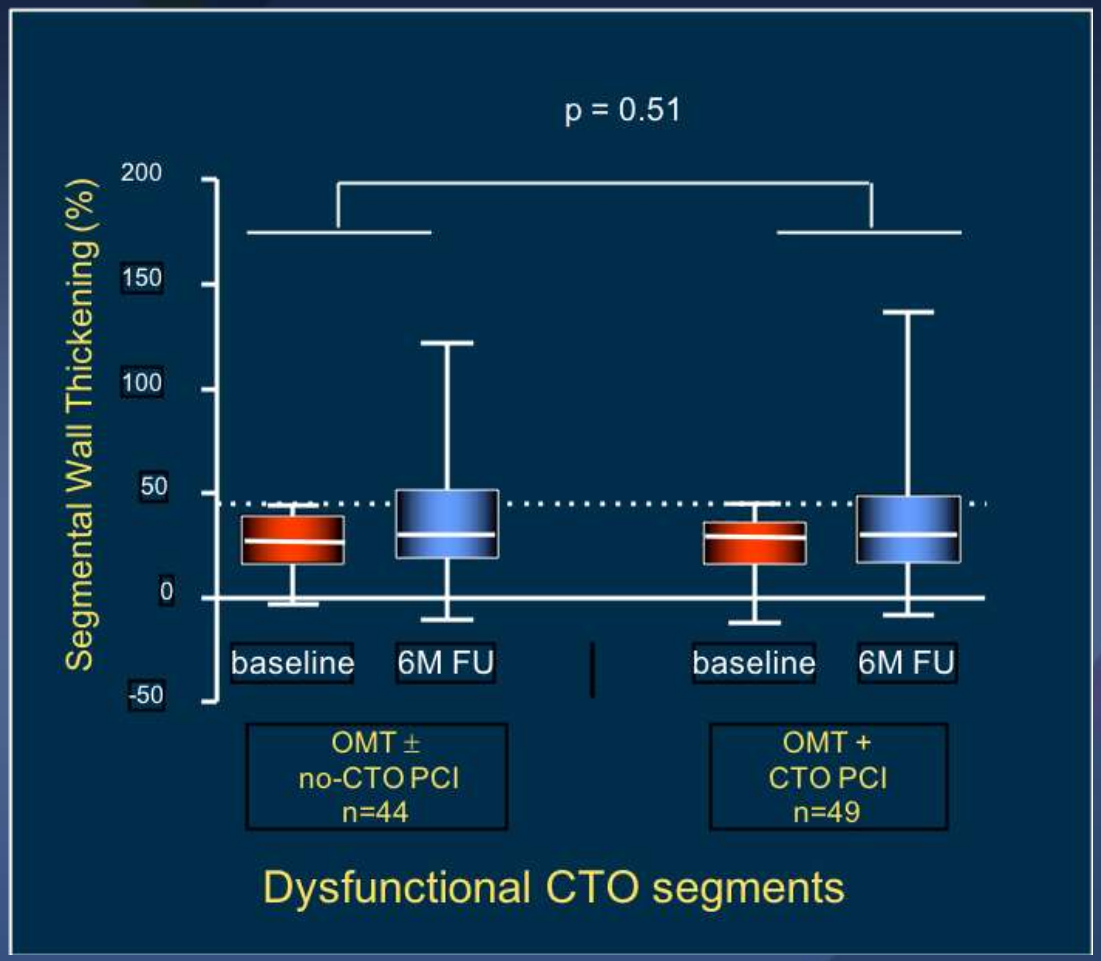

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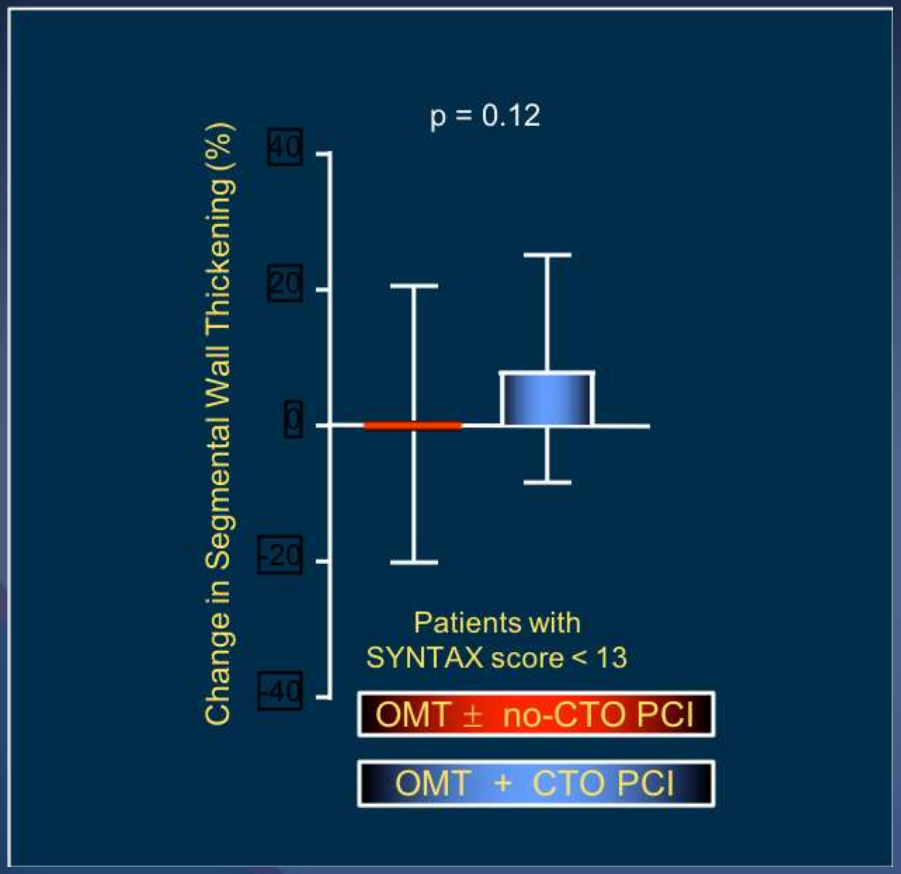
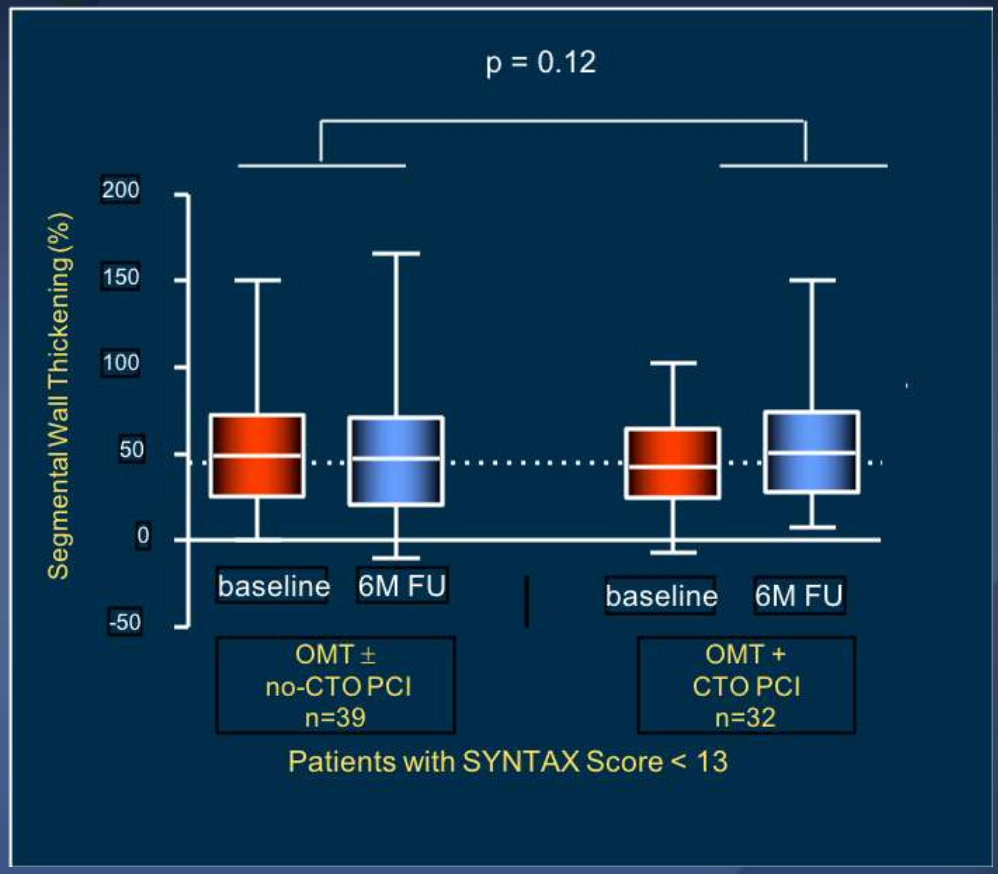
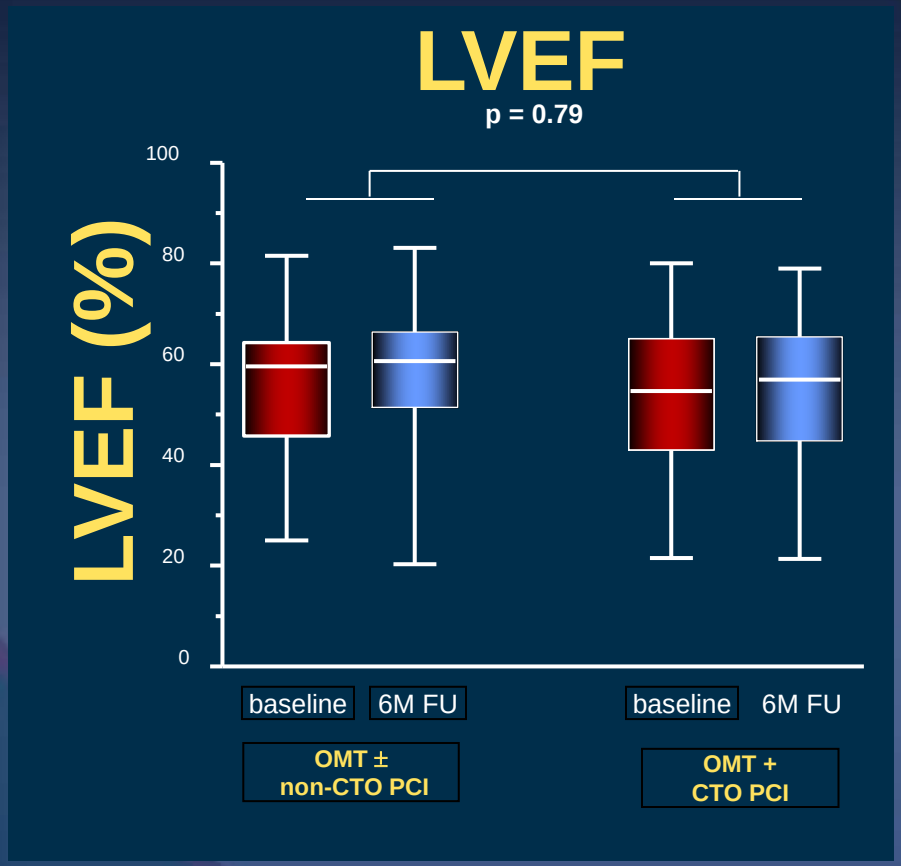
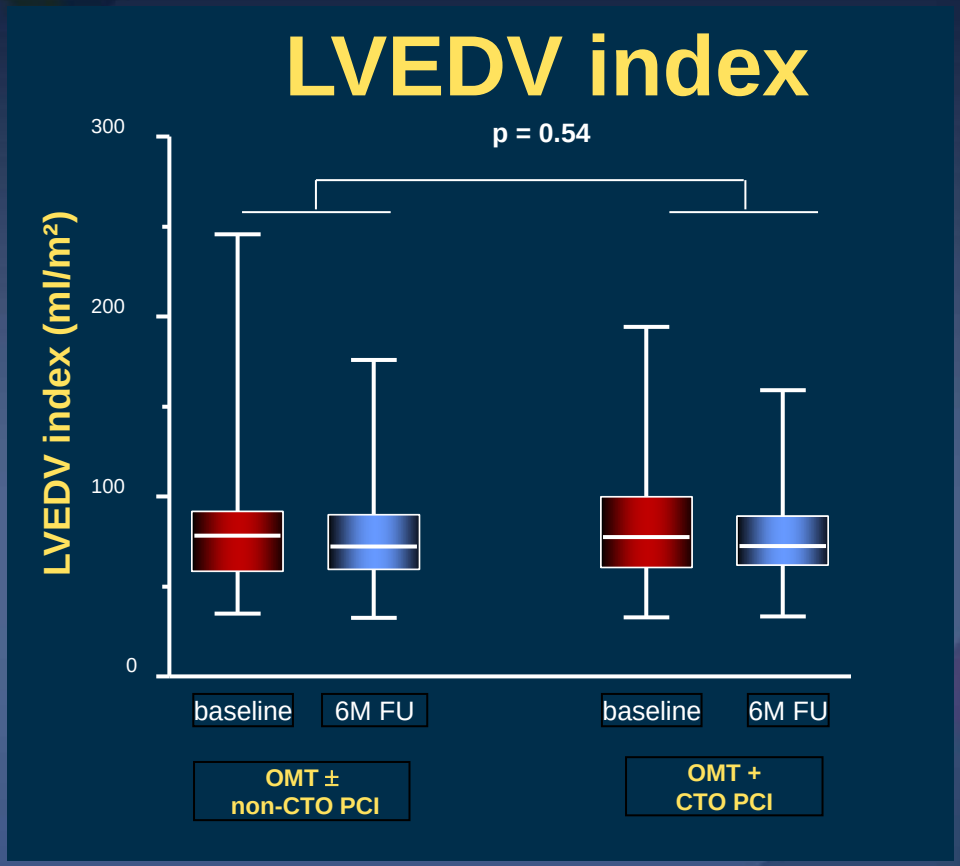


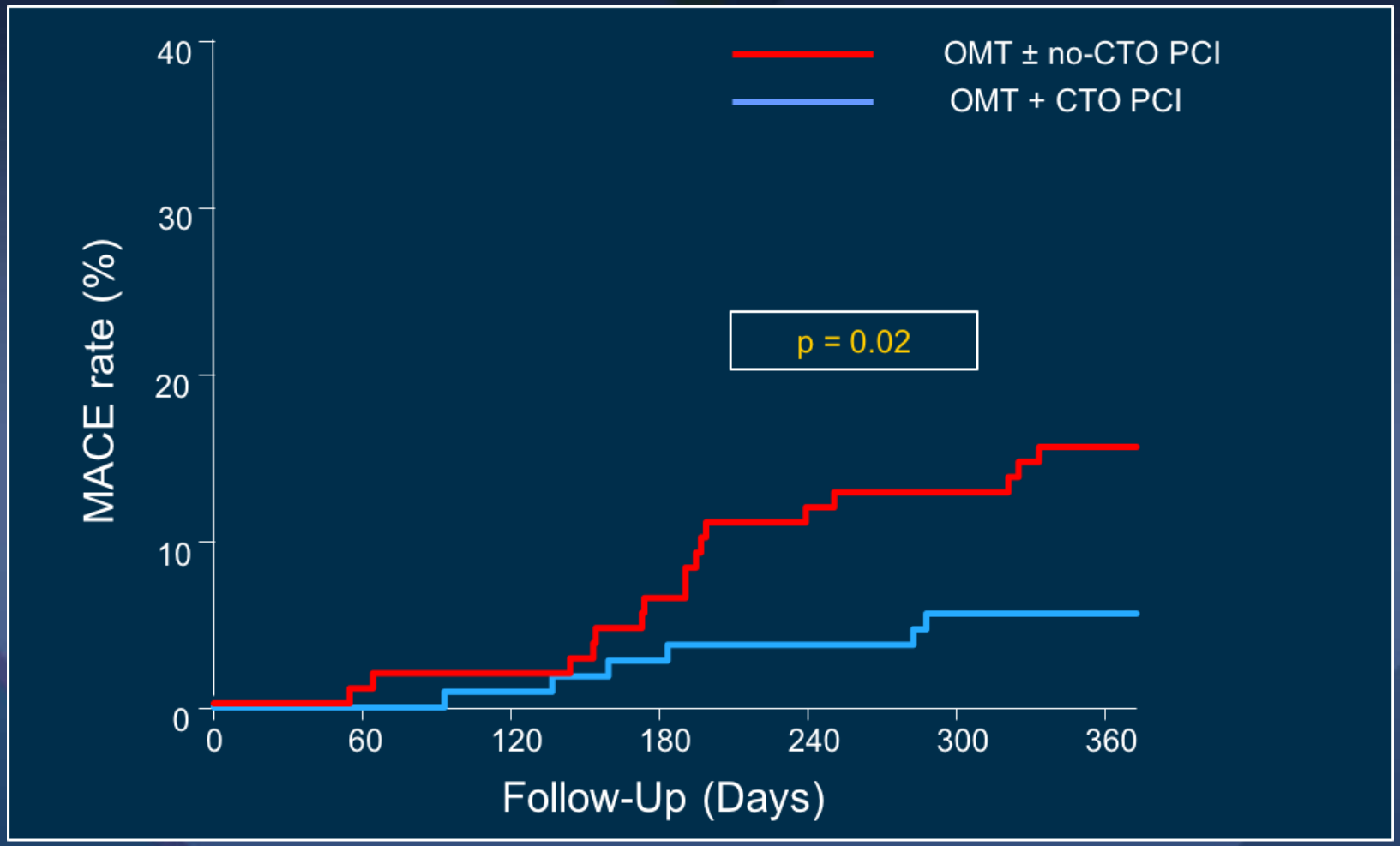


Secondary endpoint:





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.