



Message and Lessons from Updated EURO CTO Trial

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Conflict of interest



- I, Gerald S. Werner, MD, have no conflict of interest to declare with regard to the following presentation



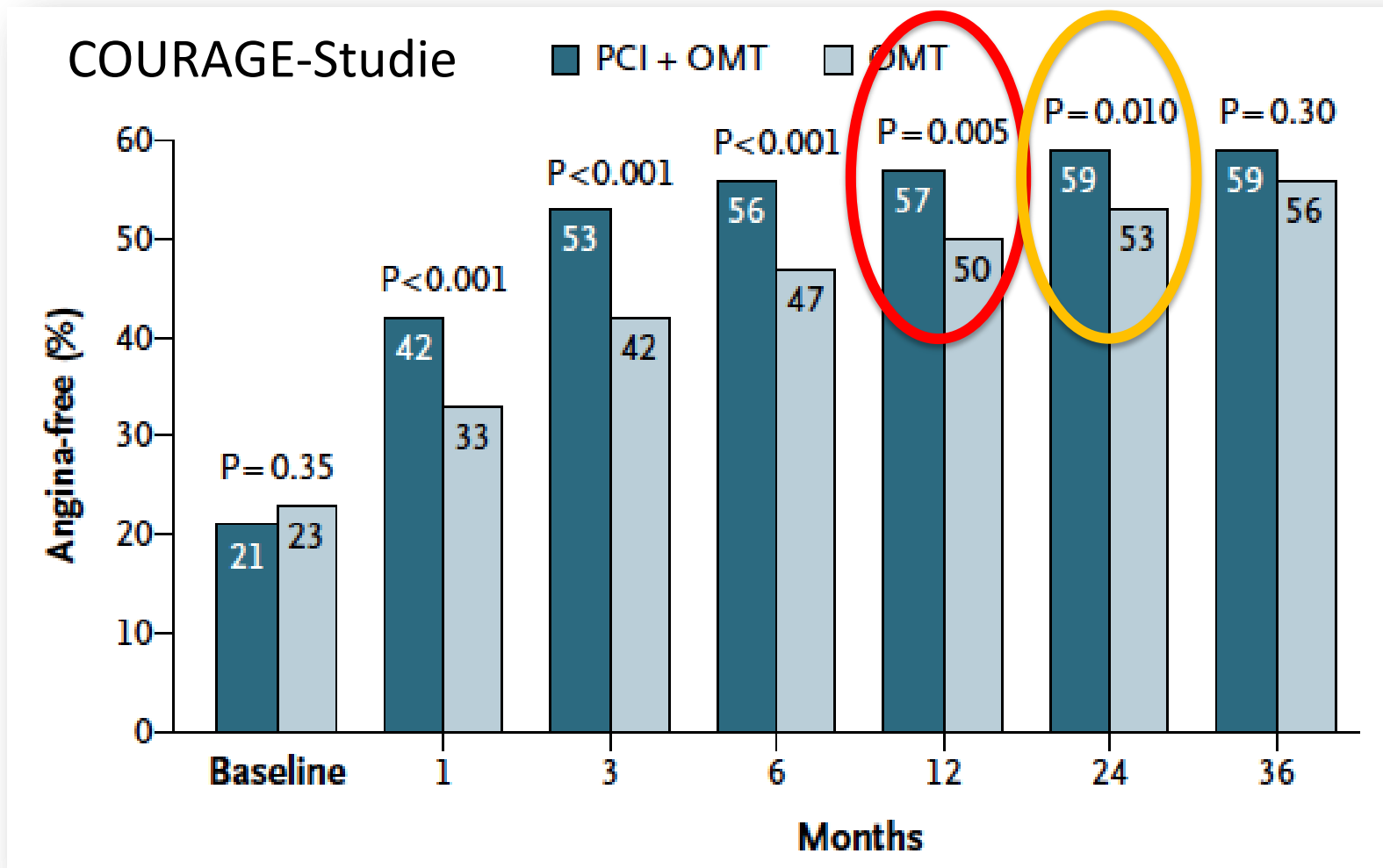
The problems of recruiting for PCI trials



- We must convince the patient that intervention is a good option
- And then again, maybe he does not need it
- Selection bias is an imminent problem whenever we compare PCI with medical therapy
 - Will you randomize your uncle with CCS 3 and a dominant RCA CTO to medical therapy ?



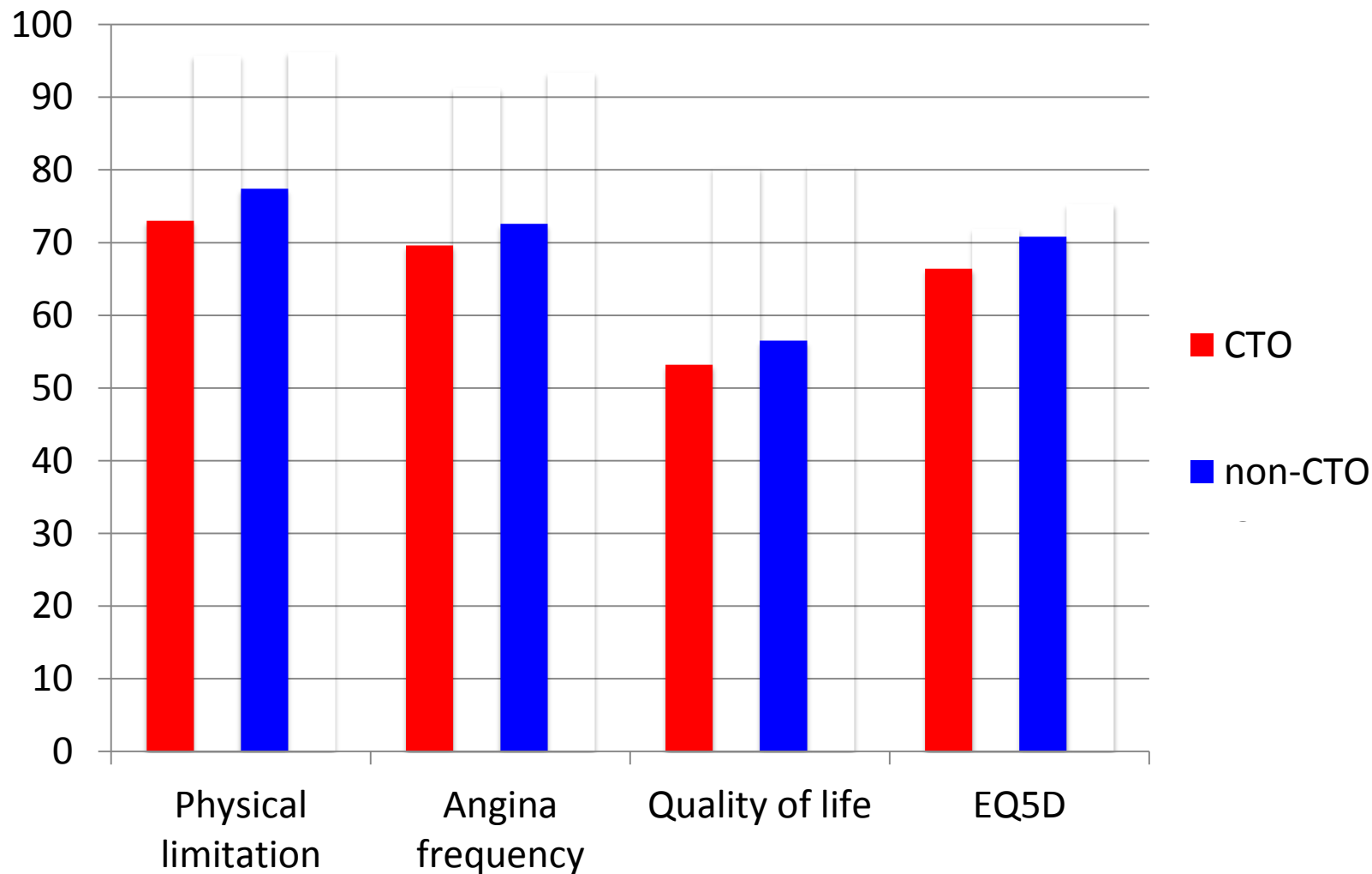
SAQ Improvement (Angina frequency) in COURAGE



32.6 % of patients in OMT finally were treated by PCI !!!

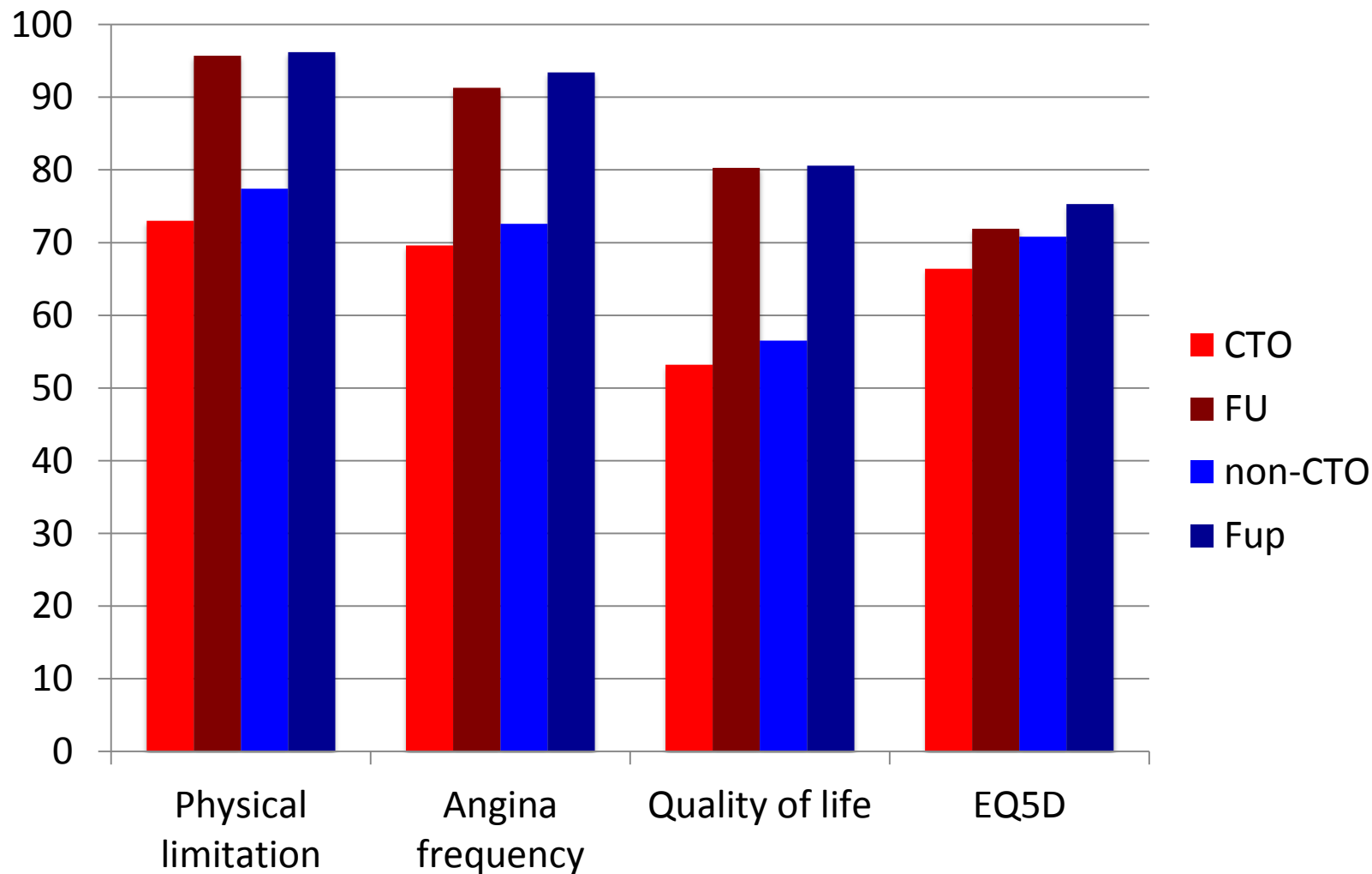


Quality of life in CAD



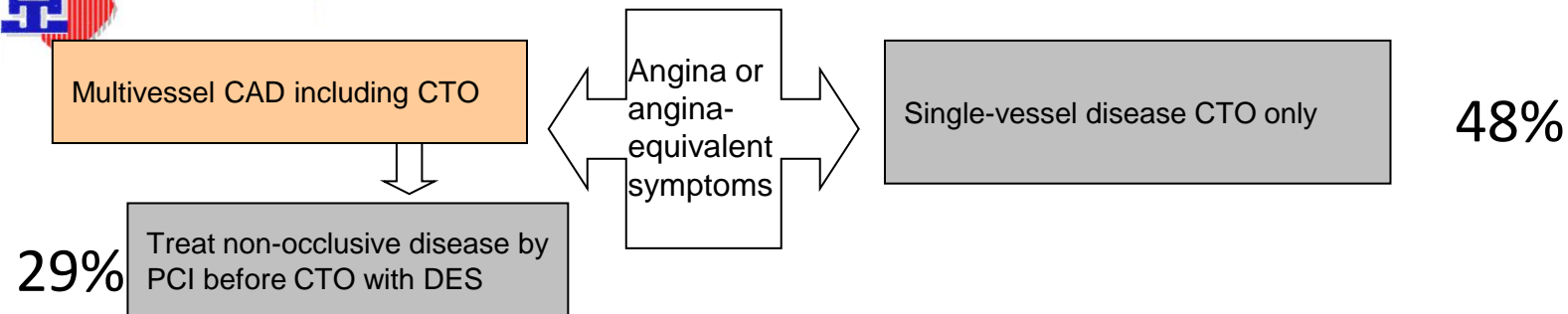


Quality of life in CAD





EURO-CTO Trial: Study flow chart





Major inclusion/exclusion criteria

- Patients with stable coronary artery disease and at least one CTO (TIMI 0, >3 months duration) with symptoms and/or ischemia and viability
- ***CTO location in a major artery (AHA 1-3, 6-7, 11) with a reference diameter $\geq 2.5\text{mm}$***
- Patients with multi-vessel disease should receive PCI to significant non-CTO lesions before randomisation; if the CTO needed treatment first, the patient was excluded

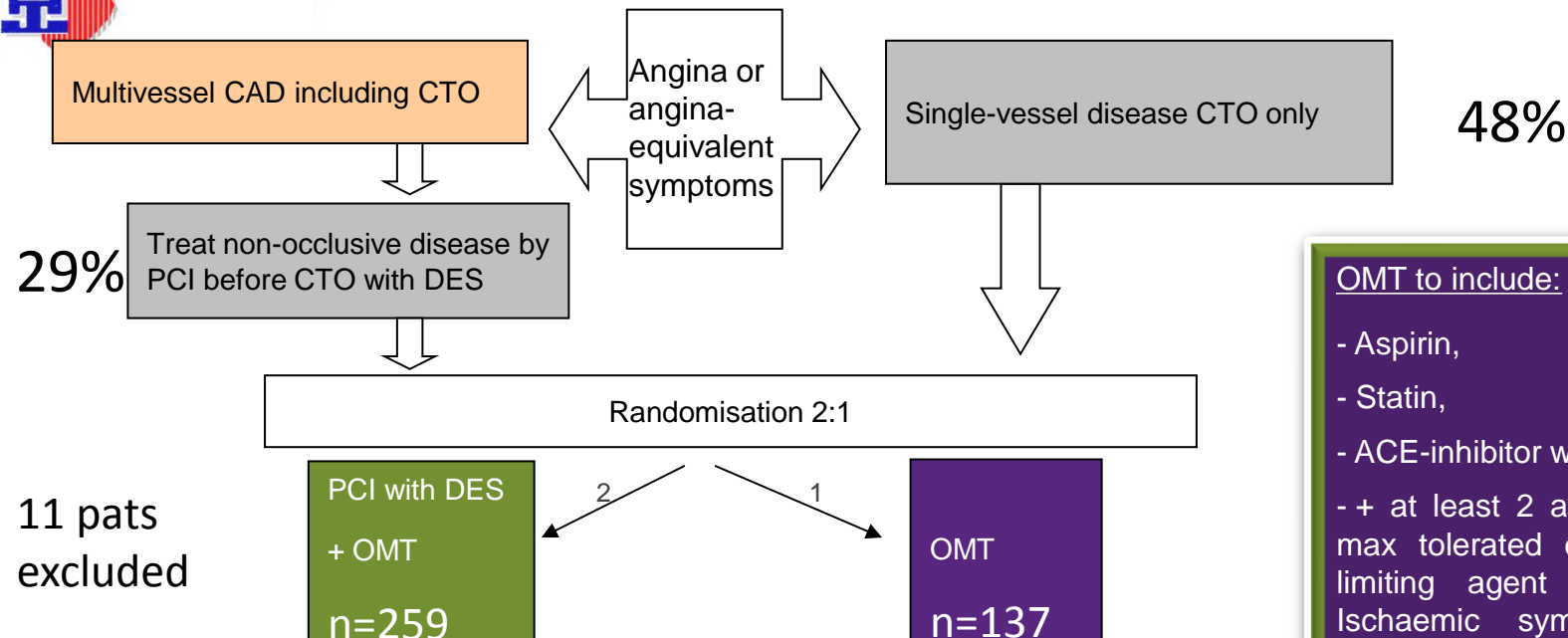


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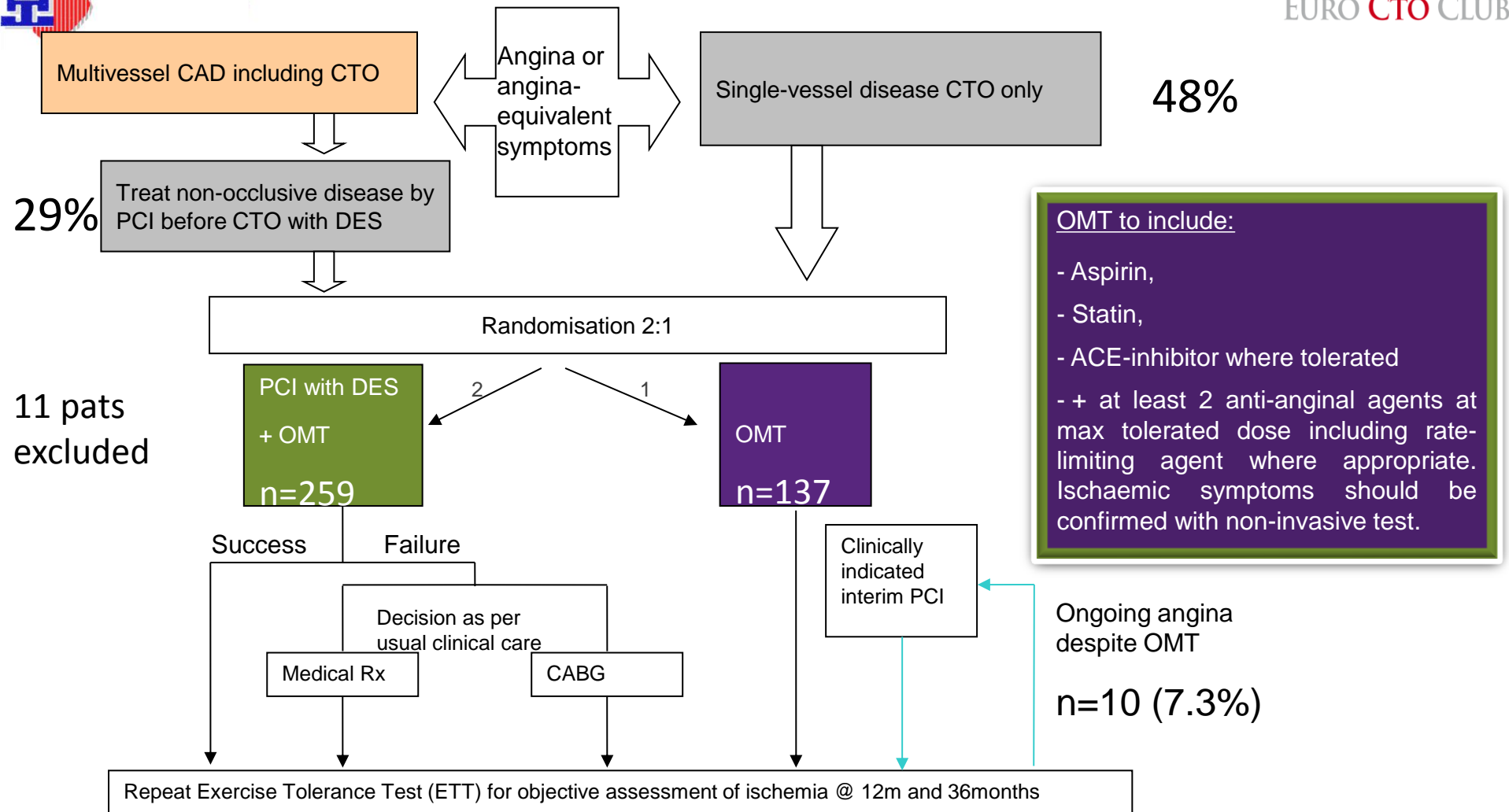
OMT to include:

- Aspirin,
- Statin,
- ACE-inhibitor where tolerated
- + at least 2 anti-anginal agents at max tolerated dose including rate-limiting agent where appropriate. Ischaemic symptoms should be confirmed with non-invasive test.

Efficacy: Health status @ 12 and 36 months
 Safety: Death, non-fatal myocardial infarction (ITT, PP) @ 36 months



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Patient characteristics



	OMT (N=137)	PCI (N=259)
Age (years)	64.7 ± 9.9	65.2 ± 9.7
Male (%)	86.1	83.0
BMI (kg/m ²)	28.3 ± 5.2	28.4 ± 4.9
Hypertension (%)	71.5	73.0
Diabetes mellitus	29.2	32.8
Previous MI (%)	18.3	22.8
Previous CABG (%)	7.3	13.1
Previous PCI (%)	51.8	56.0
PCI to facilitate study entry (%)	27.0	30.5
LVEF (%)	55.7 ± 10.8	54.5 ± 10.8



Lesion characteristics

	OMT (N=137)	PCI (N=259)
Target vessel		
RCA (%)	57.4	63.7
LAD (%)	27.0	25.5
LCX (%)	15.6	10.8
Reference diameter (mm)	3.0 ± 0.41	2.9 ± 0.44
Length of occlusion (mm)	26.5 ± 16.0	31.4 ± 20.5
Lesion calcifications (%)	36.1	37.3
Lesion tortuosity (%)	12.8	21.3
J-CTO score	1.67 ± 0.91	1.82 ± 1.07



PCI procedure in PCI group (n=255)

Radial approach for PCI (%)	34.3
Bilateral approach (%)	81.2
Retrograde approach (%)	35.8
Revascularisation successful (%)	86.3
Stents used	
Biomatrix (%)	91.1
Other DES (%)	8.9
Total length of stent used (mm)	65.9 ± 28.9
Width of largest stent (mm)	3.3 ± 2.49
Number of stents used	2.0 ± 1.32
Procedure duration (min)	118.1 ± 67.2
Fluoroscopy time (min)	48.8 ± 34.5



Procedural complications

Any complication N(%)	8 (2.9)
Death (%)	0
Q-wave MI (%)	0
Acute TVR/ emergency CABG (%)	0
Pericardial tamponade (%)	4 (1.5)
Vascular repair (%)	2 (0.7)
Blood transfusion (%)	2 (0.7)

- 6 post procedural CK >3 times ULN, including 2 CK > 5 times ULN,
- 4 troponine increase.
- None of the patients experienced pain or changes of the ECG and CEC did not adjudicate any of them as 4aMI (Universal definition)

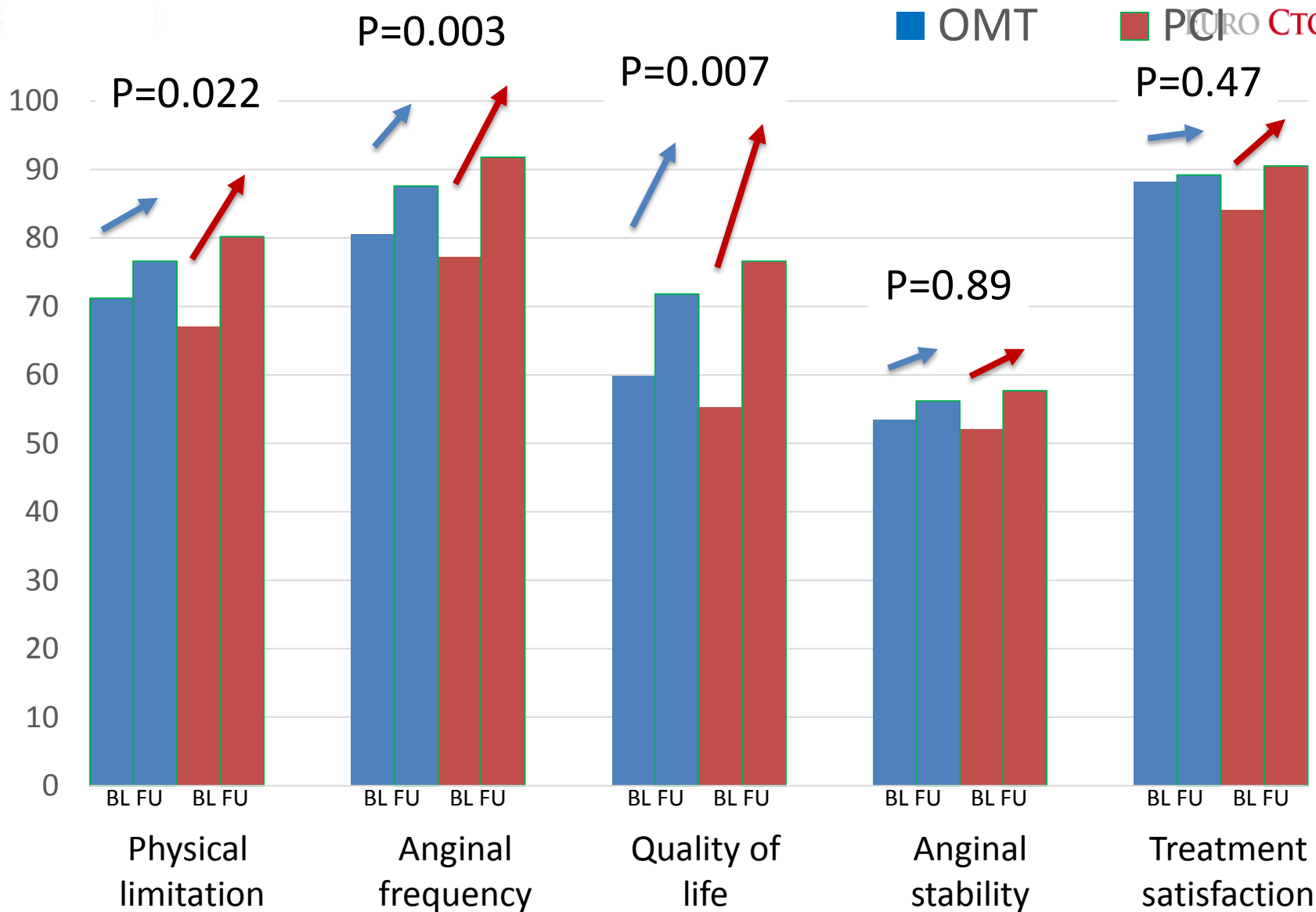


Primary Endpoint reached (ITT)



■ OMT

■ PCI

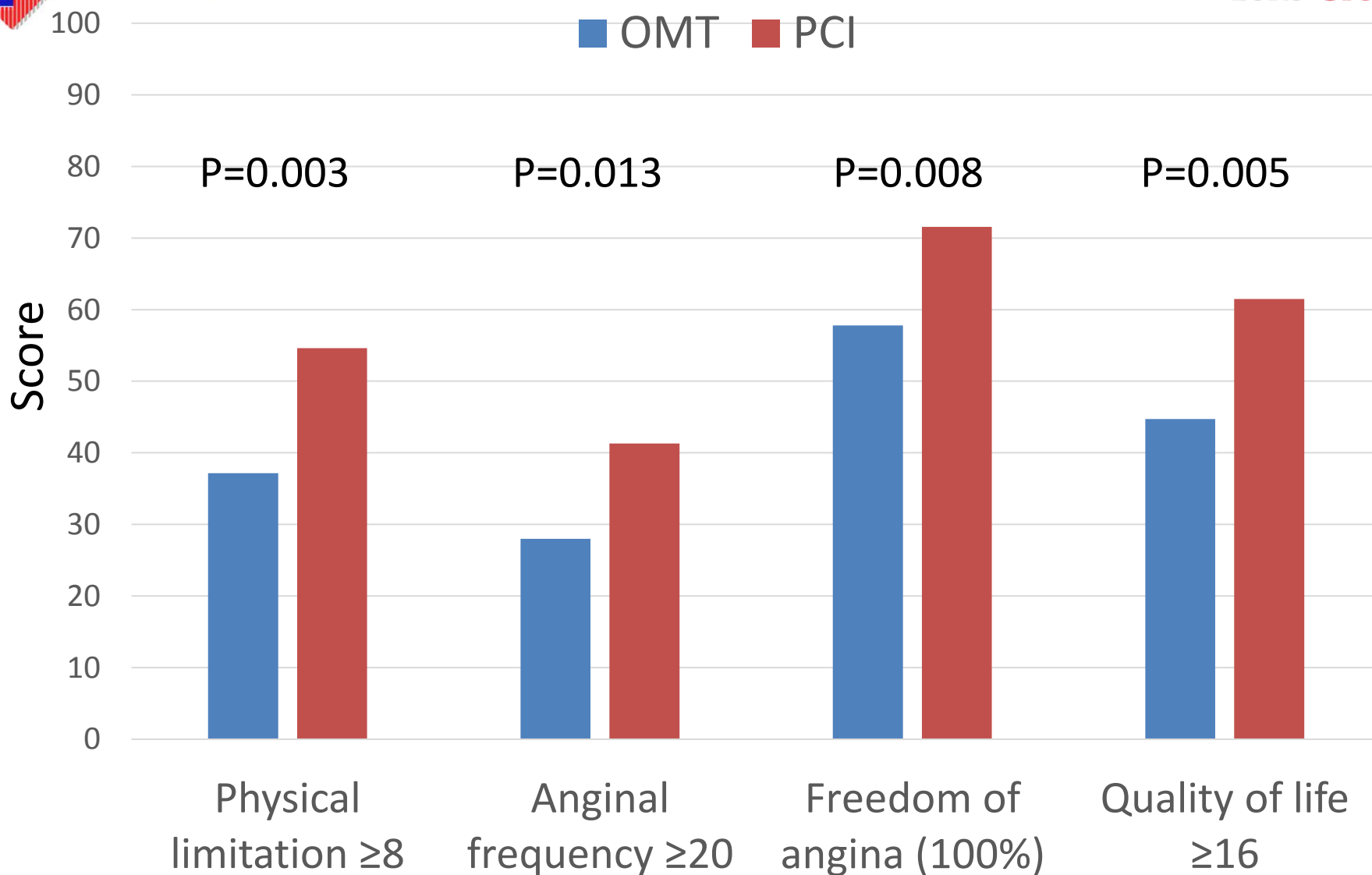


For multiple testing the significance level is 0.01

Eur Heart J 2018

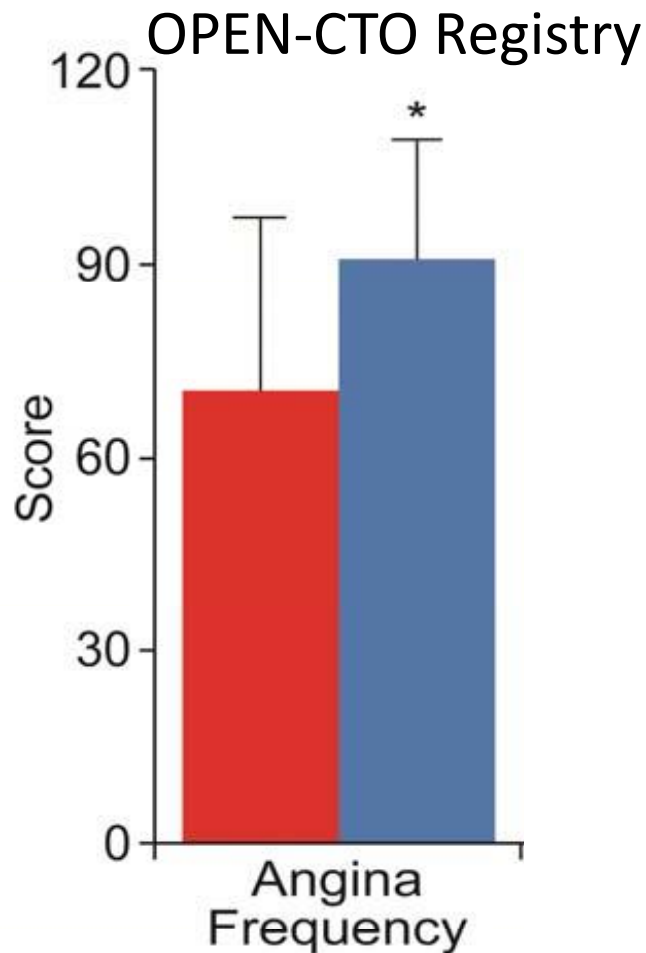
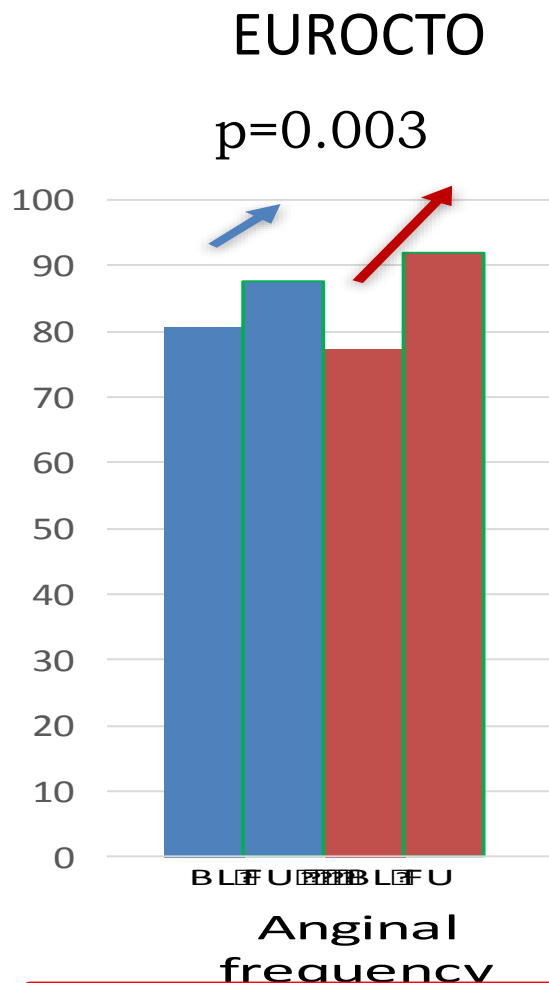


More patients were free of angina, had better quality of life and improved physical capacity





Higher baseline scores (less symptoms) in RCTs vs. registry data



Baseline	81 vs 77	71	69 (failed)
FUP	87 vs 92 Δ 6 vs 15	92 Δ 21	84 Δ 15



Single Vessel Analysis

	OMT	PCI
Physical Limitation	N	118
	Mean (StdErr)	69.1 (2.19)
	N	109
	Mean (StdErr)	82.6 (2.10)
Angina Frequency	N	127
	Mean (StdErr)	78.4 (2.00)
	N	119
	Mean (StdErr)	92.2 (1.51)

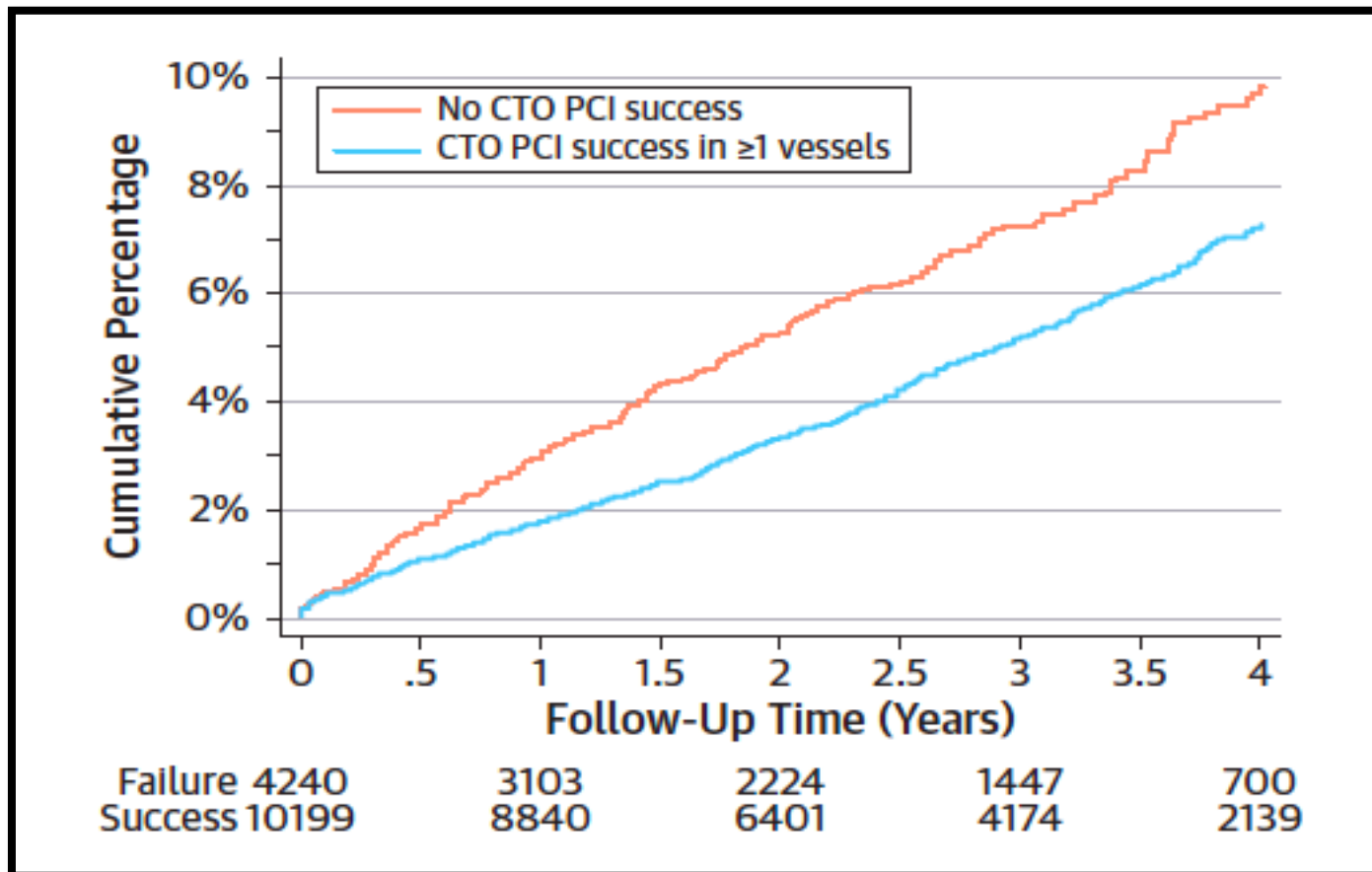


Angina Frequency

	OMT	PCI	
Multivessel	N	73	127
	Mean (StdErr)	78.9 (2.95)	76.0 (2.22)
	N	70	113
	Mean (StdErr)	85.7 (2.32)	91.3 (1.53)
Single vessel	N	60	127
	Mean (StdErr)	82.7 (2.98)	78.4 (2.00)
	N	58	119
	Mean (StdErr)	89.8 (2.33)	92.2 (1.51)

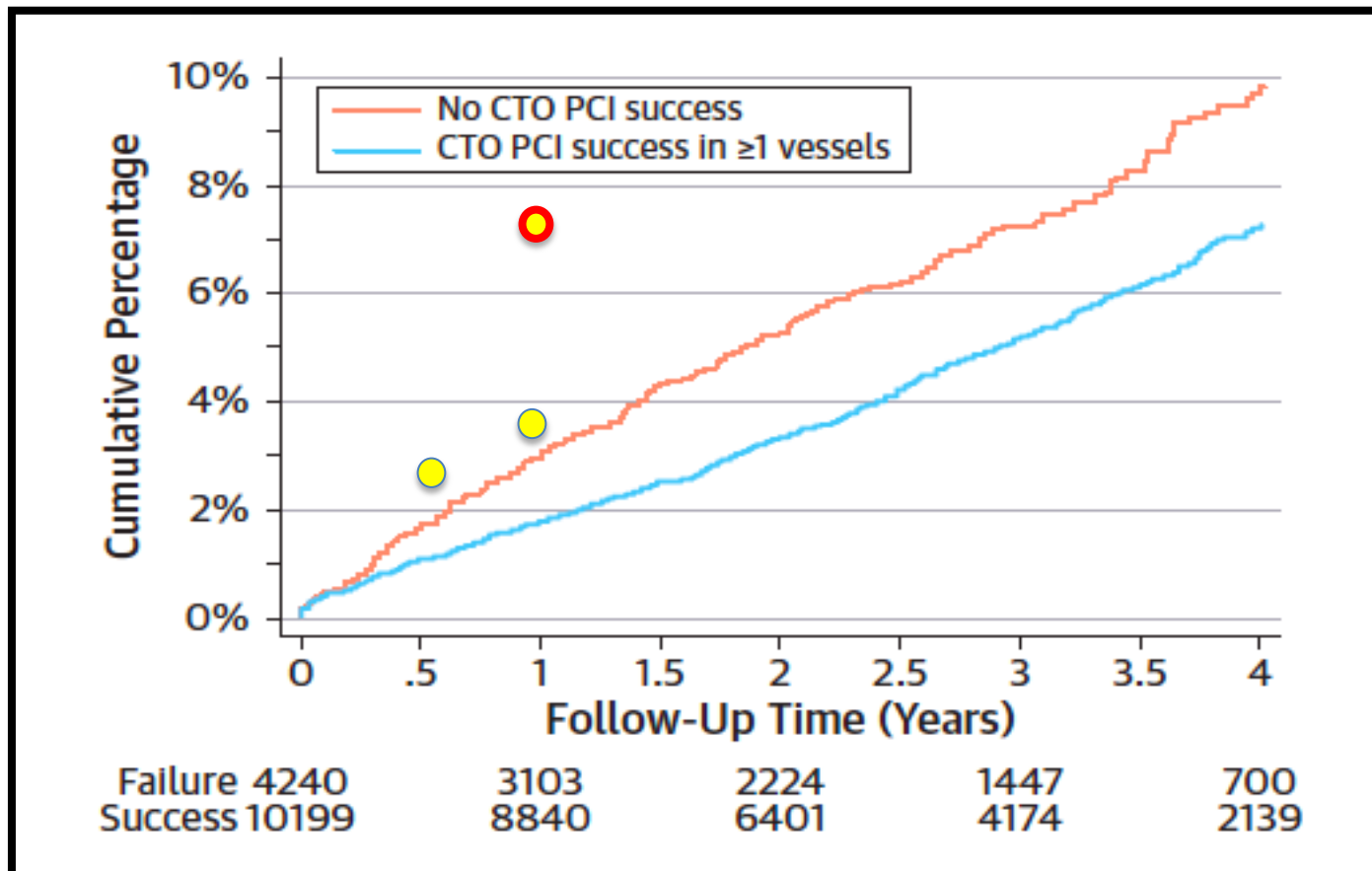


Mortality and CTO-PCI: BCIS



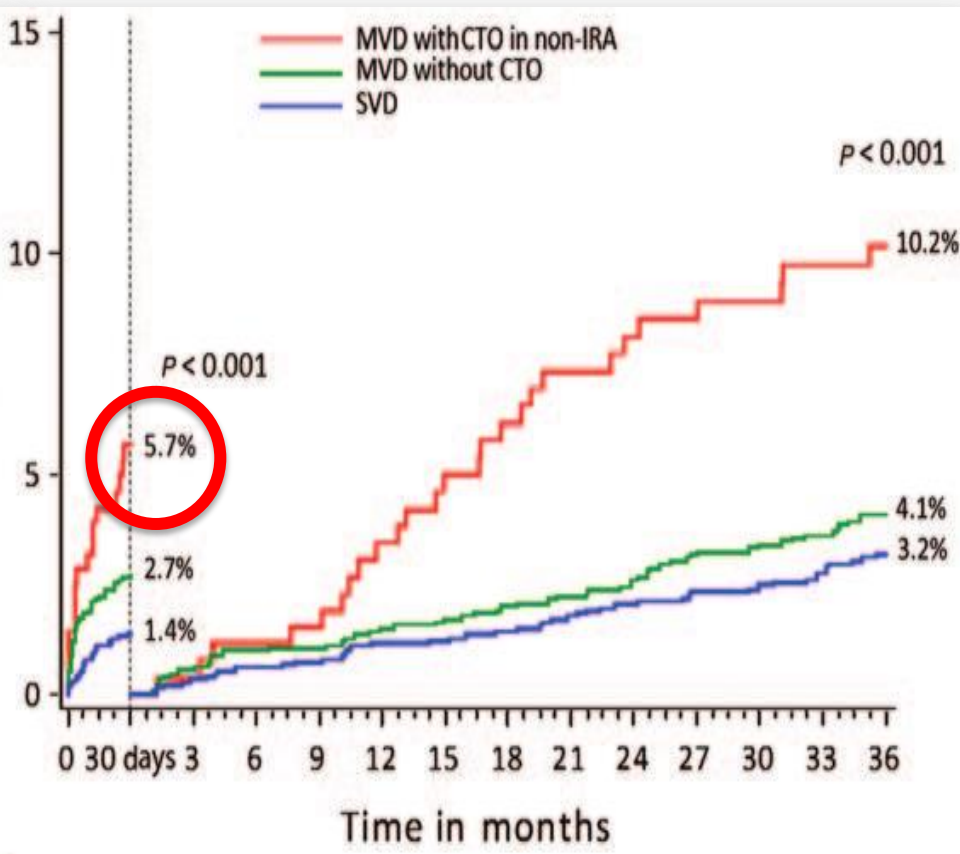
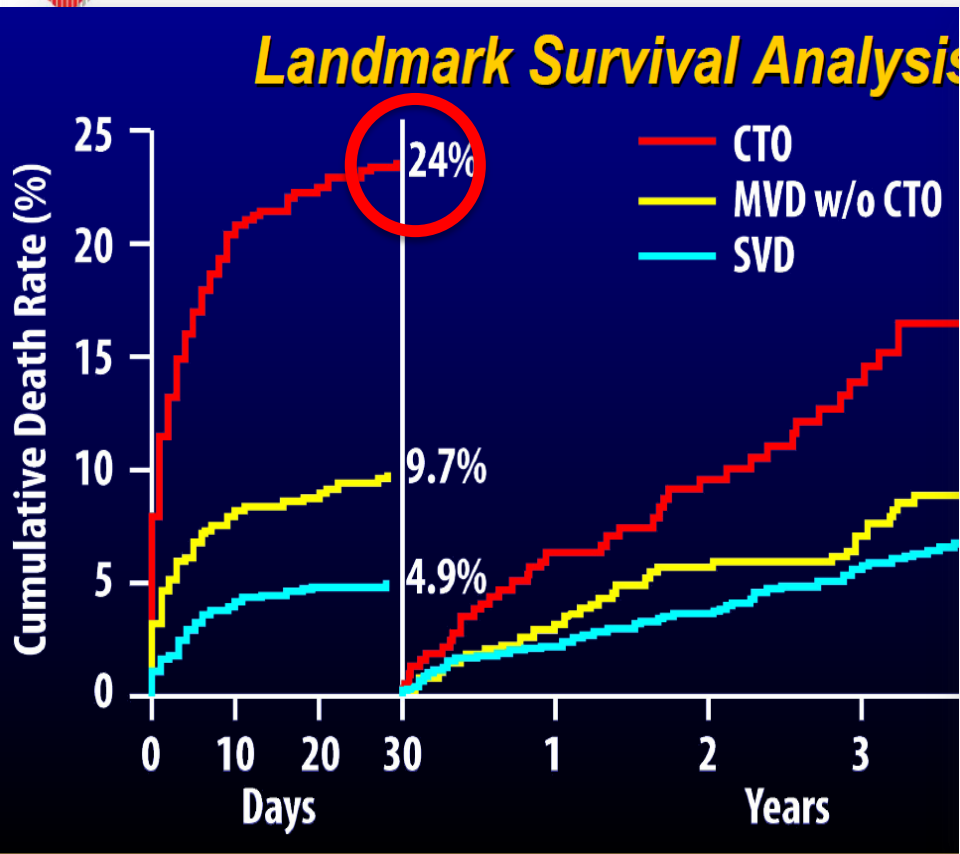


Mortality and CTO-PCI: BCIS



Mortality in
OPEN CTO

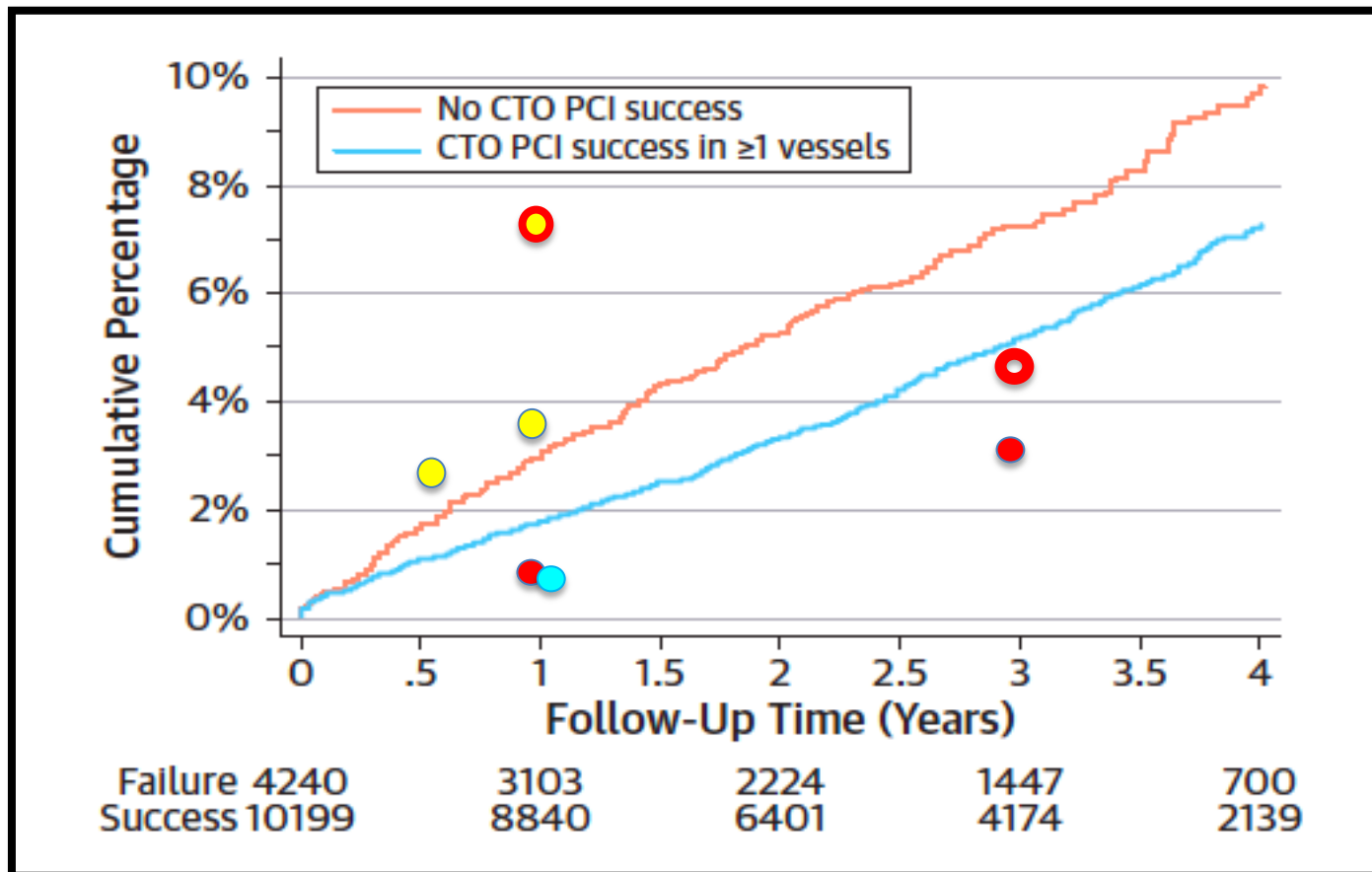
Selection bias: STEMI registry vs RCT



Same effect of the presence of a CTO on survival with STEMI,
But on a much lower level



Mortality and CTO-PCI: BCIS



Mortality in
OPEN CTO
DECISION CTO
EURO CTO



Lessons from the EURO-CTO Trial



- Due to slow recruitment the number of patients in this study is below the preplanned number, but still the power is 81%.
- The primary endpoint was met: PCI for CTO improved the health status regarding angina frequency, quality of

PCI should be the preferred treatment of patients with a CTO and clinical symptoms

but the long-term safety remains to be evaluated at 36 months (Primary safety endpoint)