CTO PCI Should Be Very Selective

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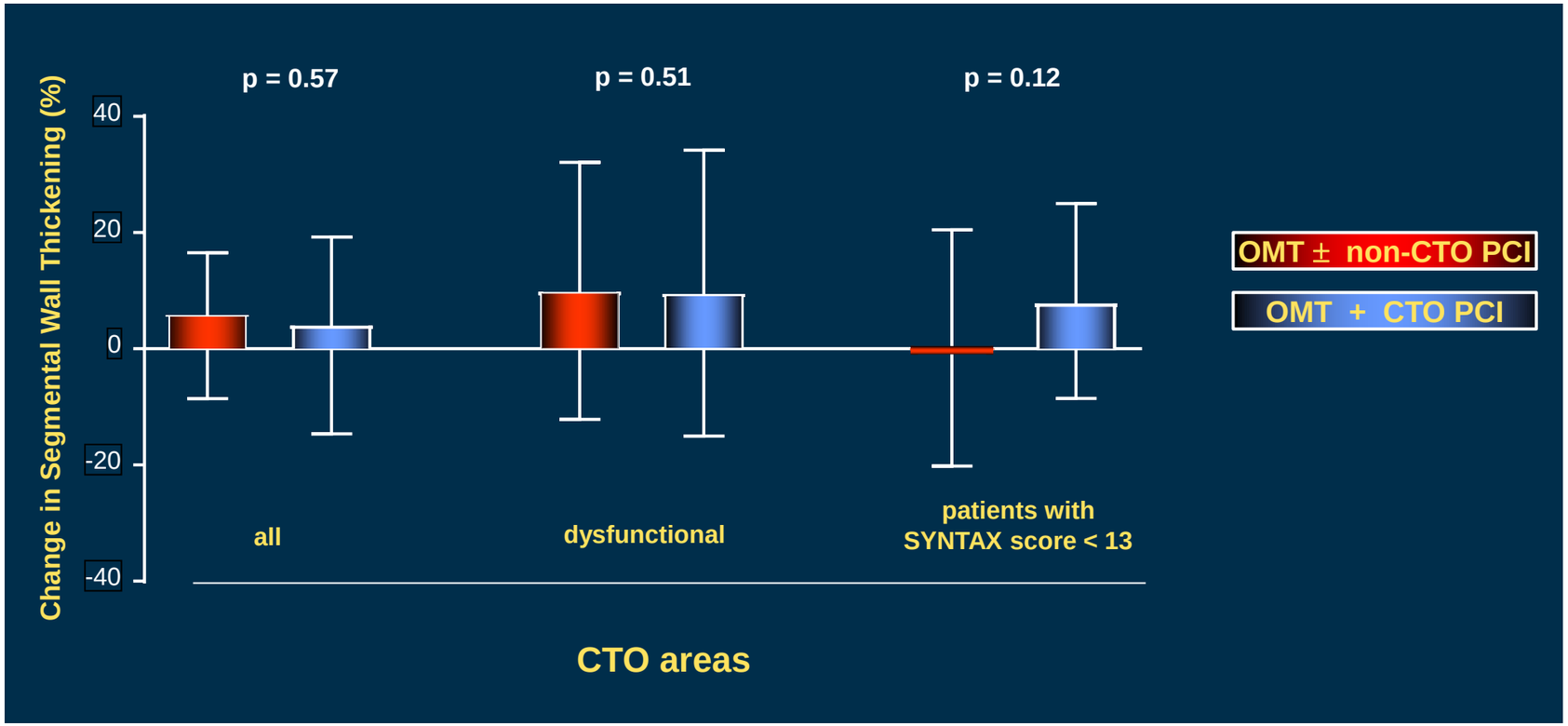
REVASC Primary Endpoint: Change in Segmental Wall Thickening at 6 Mo

205 CTO patients randomized to CTO PCI vs. no CTO PCI

(no CTO PCI group included 60% non-CTO PCI)

Mean EF 54.7% vs. 59.6%

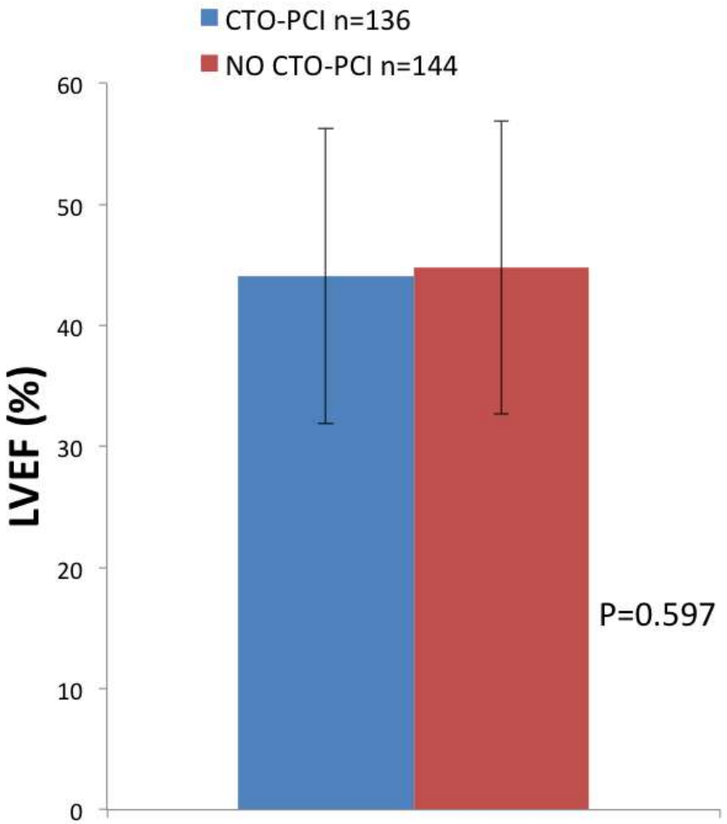
Baseline SYNTAX Score 14 vs. 16; rSS 2 vs. 11

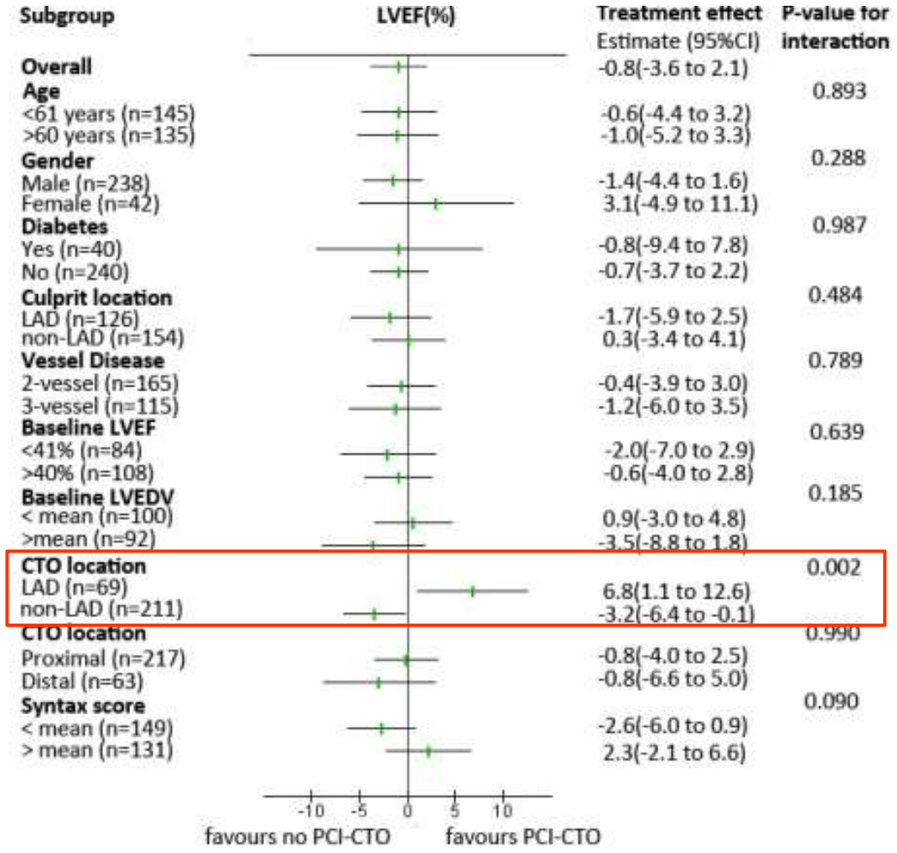


Mashayekhi et al, JACC CV Intv 2018

EXPLORE: MRI-Assessed LVEF at 4 months

280 STEMI pts with CTO randomized: CTO PCI (73% success) vs. no CTO PCI





	CTO-PCI (n=136)		No CTO-PCI (n=144)			Difference (95%CI)	p
LVEF (%)	44·1	(12·2)	44·8	(11·9)	-0·8	(-3·6 to 2·1)	0·597

Henriques et al, JACC 2016

DECISION-CTO

CTO Lesions - Eligible for PCI
(1 or 2 CTOs)

1:1 randomization

PCI for necessary Non-CTO lesions in MVD
and Guideline Directed Medical Treatment

CTO-PCI (n=642)	**No CTO-PCI (n=642)**
Treat CTO lesion	**Not Treat CTO lesion**

Clinical Outcomes at 3 years
(Composite of Death, MI, Stroke and any Revascularization)

Remember:

Trial stopped early (834 patients)

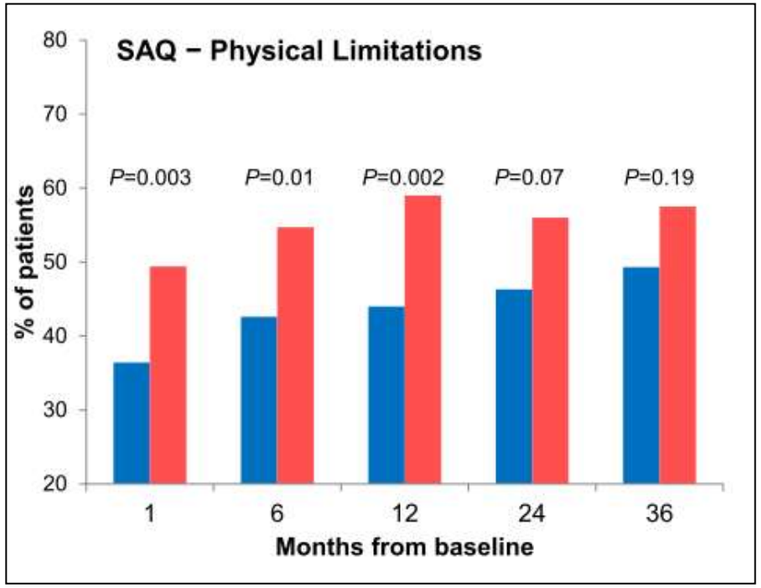
~Half got non-CTO PCI (introducing noise)

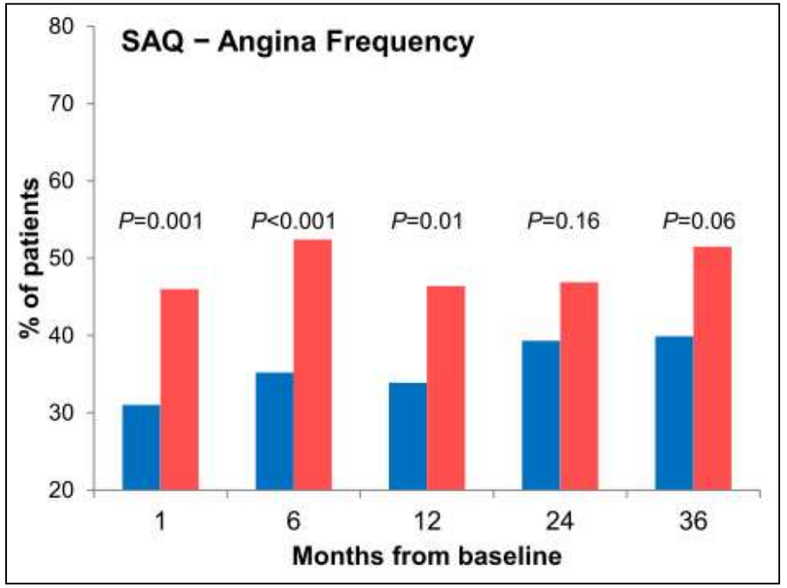
~20% crossover (immediate)

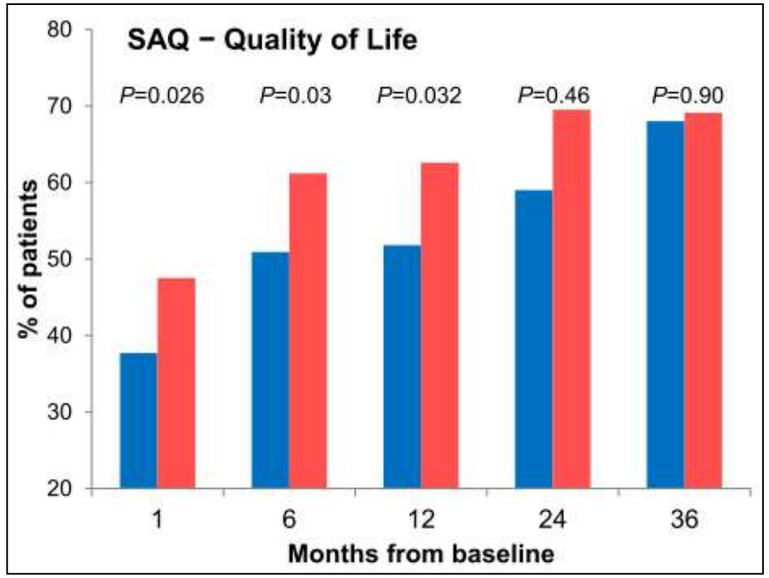
qMonth symptoms at baseline! (SAQ-AF ~80)

DECISION CTO: Responder Analyses

Clinically meaningful increases



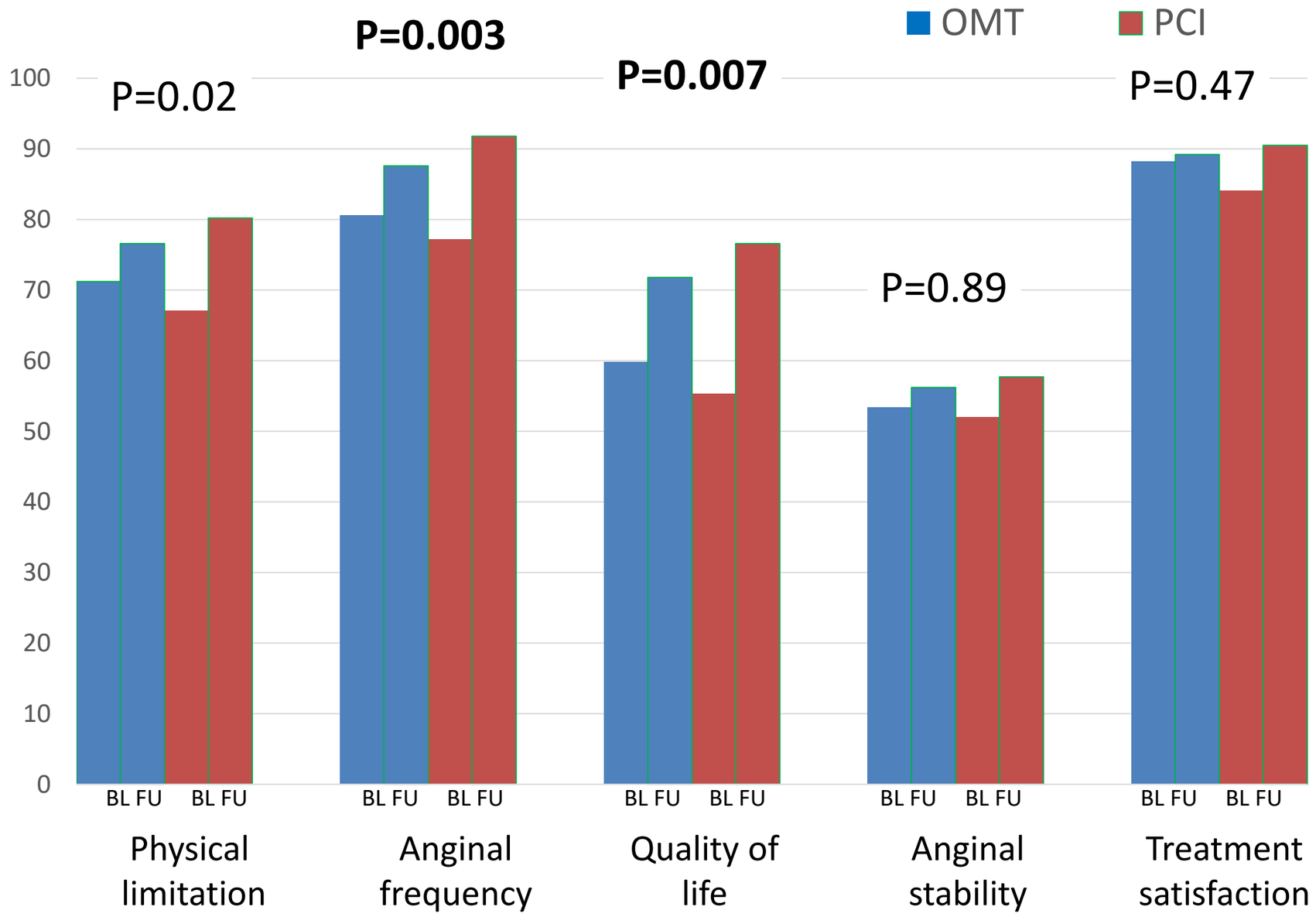




A change of ≥8, ≥20, and ≥16 points for the SAQ-physical limitation, angina frequency, and QOL domain, respectively, was considered clinically meaningful.

No CTO-PCI strategy CTO-PCI strategy

EuroCTO Primary Endpoint: SAQ health status (ITT)

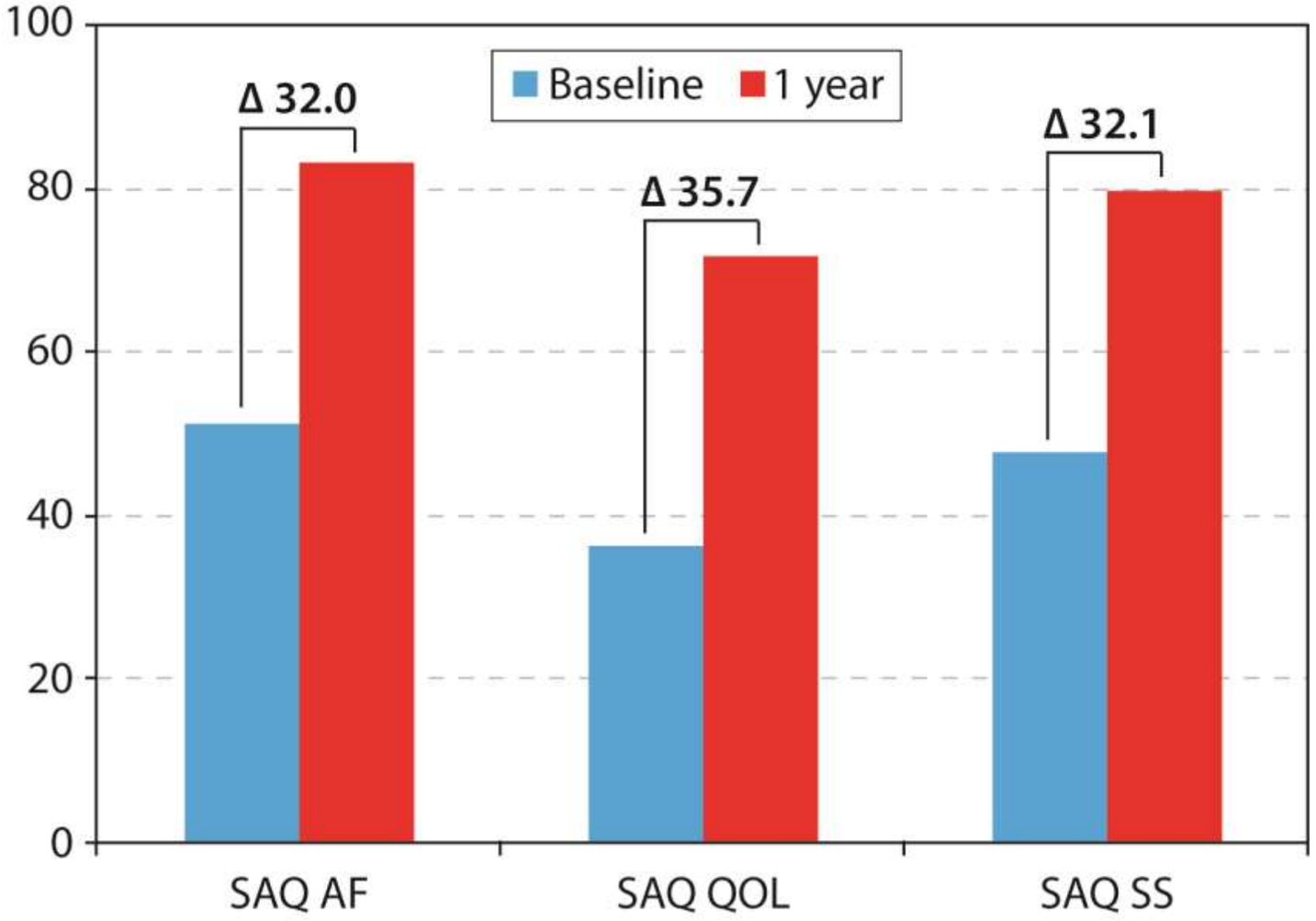


For multiple testing the significance level is 0.01

Werner et al, Eur Heart J 2018

QoL Improvements in Refractory Angina Patients

Refractory angina defined as angina despite 3+ meds (n=148, 14.8%)



Hirai et al, Circ CV Intv 2019

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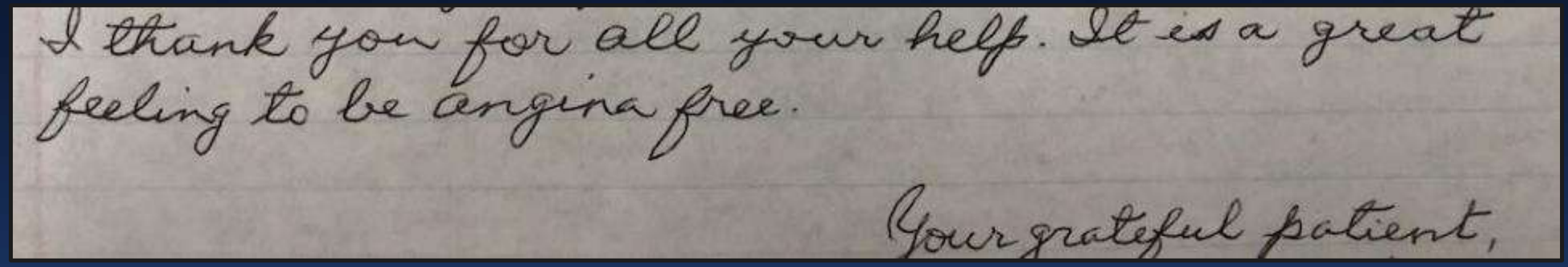
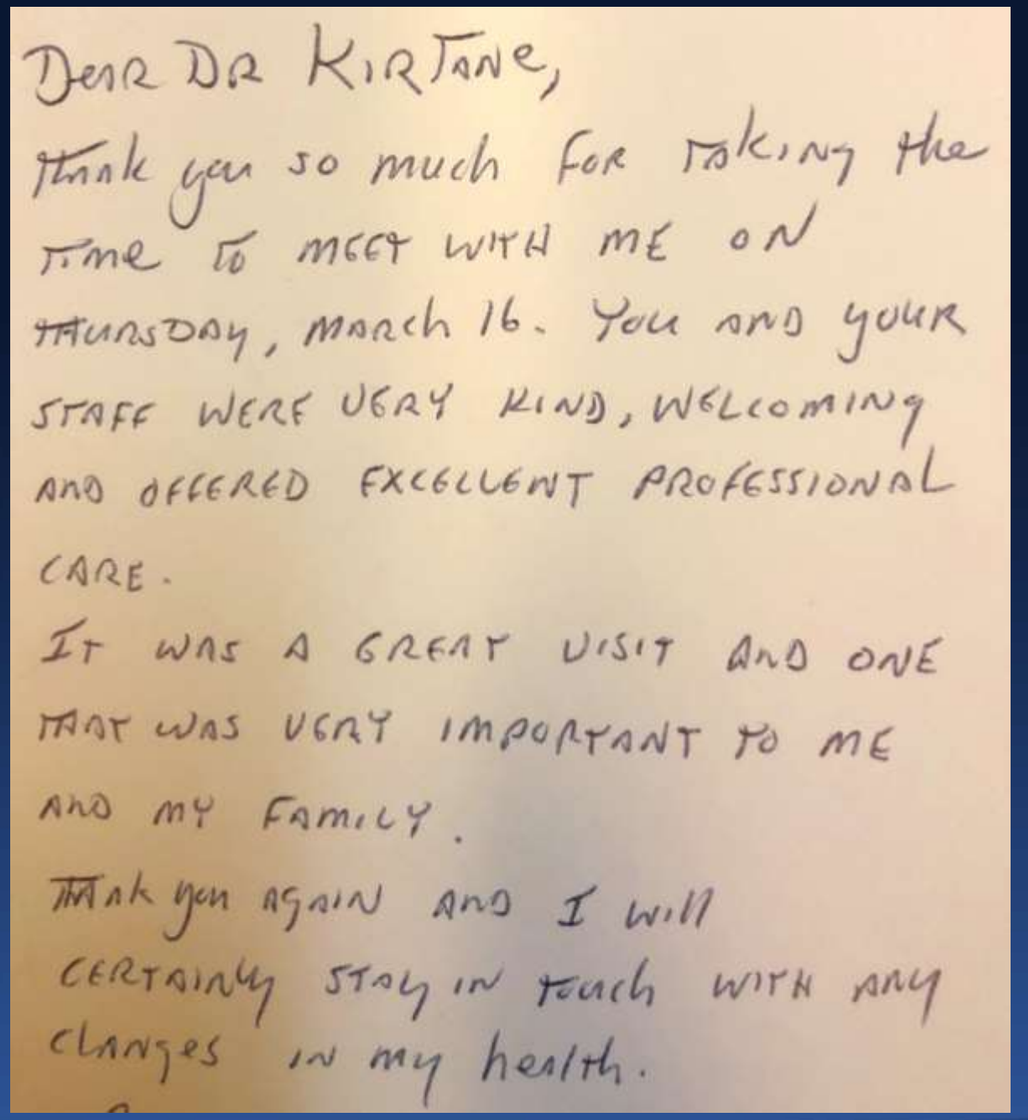
How Do Our Patients *with Real Symptoms* Actually Feel After Revascularization?


I thank you for all your help. It is a great feeling to be angina free.

Your grateful patient,

(and on less medication)

But Do We Need to Revascularize Everyone?



Dear Dr Kirtane,

Thank you so much for taking the time to meet with me on Thursday, March 16. You and your staff were very kind, welcoming and offered excellent professional care.

It was a great visit and one that was very important to me and my family.

Thank you again and I will certainly stay in touch with any changes in my health.

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New York State Database: CTO PCI

7/2009 – 6/2012: 4030 (3.1%) CTO PCI procedures with 61.3% success

	Estimate	Standard Error	Adjusted Odds Ratio (95% CI)	*P* Value
Intercept	2.5109	0.3317		<0.0001
Age by 10	–0.1098	0.0307	0.90 (0.84, 0.95)	0.0003
Ejection fraction <20%	–0.9714	0.3051	0.38 (0.21, 0.69)	0.0015
Previous PCIs	–0.2606	0.0712	0.77 (0.67, 0.89)	0.0003
Previous CABG surgery	–0.4488	0.0920	0.64 (0.53, 0.76)	<0.0001
Carotid/cerebrovascular disease	–0.2987	0.1215	0.74 (0.58, 0.94)	0.0140
CTO lesion location				
Right coronary artery	–0.4057	0.0814	0.67 (0.57, 0.78)	<0.0001
Left circumflex artery	–0.3480	0.0924	0.71 (0.59, 0.85)	0.0002
LAD artery and others*	…	…	Reference	…
CTO PCIs only	–0.5192	0.0707	0.59 (0.52, 0.68)	<0.0001
Operator CTO PCI volume per year (quartiles)				
Q1: <4	–0.8875	0.2657	0.41 (0.24, 0.69)	0.0008
Q2: 4–8	–0.6958	0.2720	0.50 (0.29, 0.85)	0.0106
Q3: 9–47	–0.4204	0.2852	0.66 (0.38, 1.15)	0.1405
Q4: ≥48	…	…	Reference	…

Highest volume quartile operators (48+) had >2X higher success than lowest 2 quartiles

Annual PCI volumes in the USA

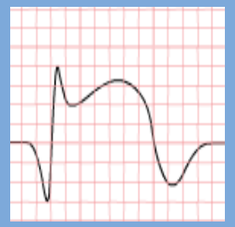
N=10,496 operators 2009-2015

44% Nearly half of operators performed fewer than 50 PCIs per year, the minimum number recommended by an ACC/AHA/SCAI scientific statement

Median operator volume was less than 50 in 9 states plus the District of Columbia

Compared with high-volume operators, **low-volume operators**:

Operated at **lower volume hospitals**

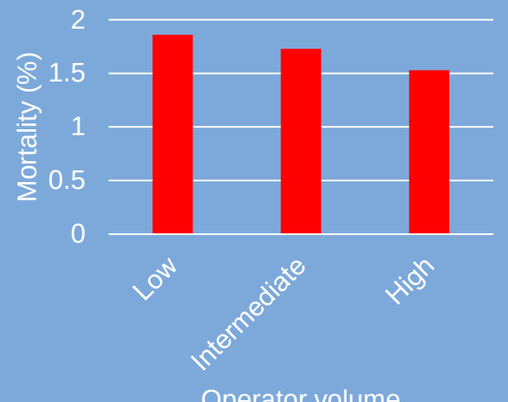


More frequently performed **emergency PCI** and PCI for **STEMI**

Less frequently used **radial access**

Used a greater volume of **contrast dye** and had longer **fluoroscopy times**

In-hospital mortality following PCI was **low**, but **higher for lower volume** operators



16% Risk-adjusted OR for mortality was 1.16 (95% CI 1.12-1.21) for low- versus high-volume operators

5% Risk-adjusted OR for mortality was 1.05 (95% CI 1.02-1.09) for intermediate- versus high-volume operators

Fanaroff A, et. al. JACC 2017

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OPEN CTO Registry

OPEN CTO
Outcomes, Patient health status, and Efficiency iN Chronic Total Occlusion hybrid procedures

1000 consecutive patients enrolled between Feb 2014 and July 2015 at 12 clinical sites in the US

Overall success: 89%; Success of 1st approach: 58%

In Hospital	Frequency
Death	0.9%
MI	2.4%
Emergent surgery	0.6%
Perforation	6.0%
Clinical perforation	4.9% (82%)
Bleeding Access	4.0%
Radiation injury	0.1%

30 Day	Frequency
Death	1.3%
Rehospitalization	14.7%
Unplanned	12.1%
Revascularization	2.6%
Planned	2.6%
PCI	2.3%
CABG	0.3%
Skin change	3.1%

Treatment of CTO

COR	LOE	Recommendation
2b	B-R	**In patients with suitable anatomy who have refractory angina on medical therapy, after treatment of non-CTO lesions, the benefit of PCI of a CTO to improve symptoms is uncertain.**

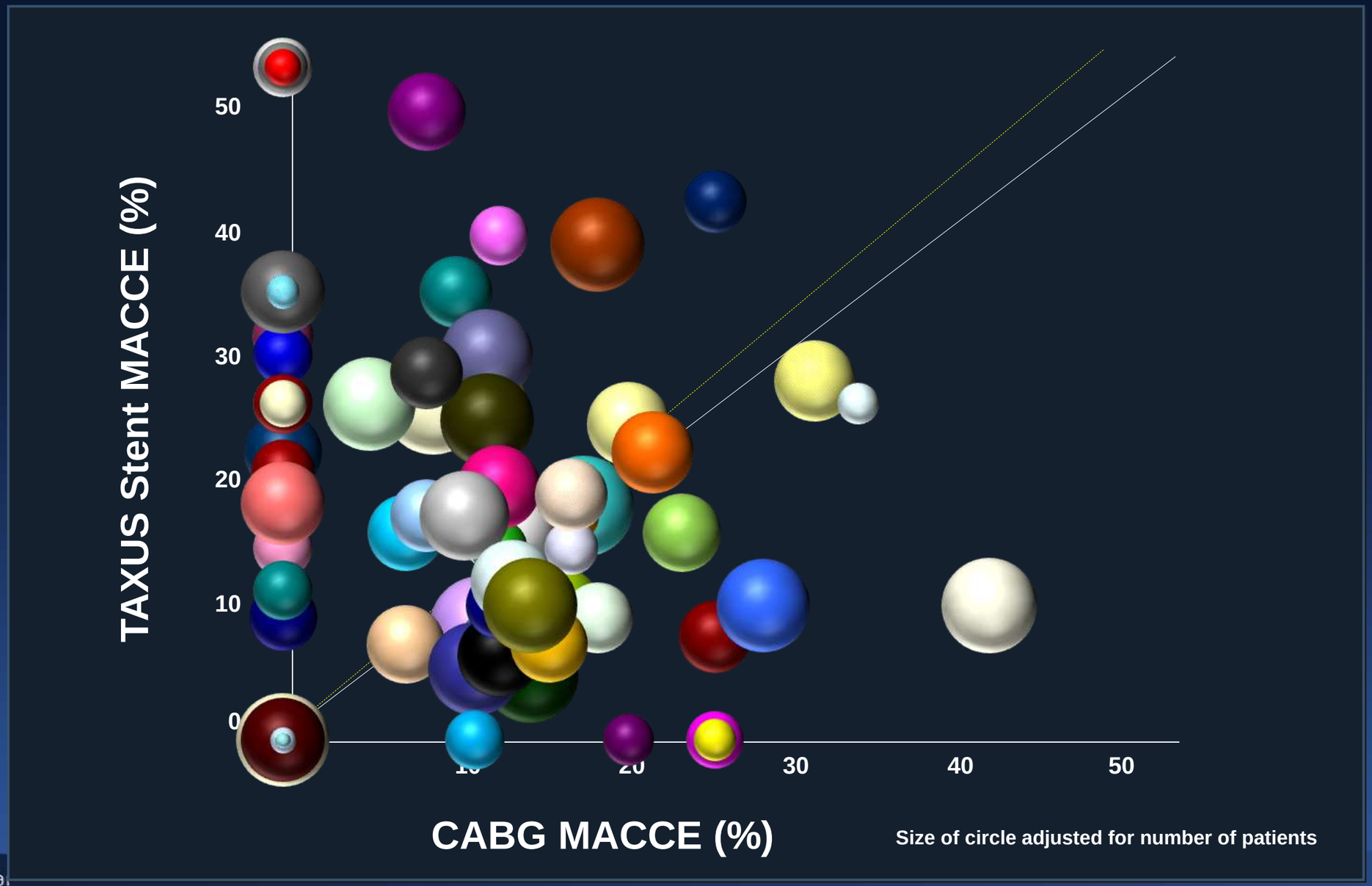
"Enthusiasm for treating these lesions was fueled by retrospective data suggesting improved outcomes for those patients who underwent successful recanalization compared with those who had failed. However, RCTs have not demonstrated improved function and have been equivocal w/regard to symptoms. For this reason, shared decision-making should inform treatment of patients with refractory angina despite GDMT w/remaining CTO coronary lesion, with careful discussions of the limitations of treating these lesions, as well as the potential benefits."

Ideal Components of the Informed Consent Process

Spend sufficient time to engage in shared decision-making; allow for a second opinion
Use plain language, avoiding jargon, and adopt the patient's words; integrate pictures to teach
Document teach-back of patient's knowledge and understanding
Conduct conversations with a trained interpreter, as needed
Provide patient-specific short- and long-term risks, benefits, and alternative treatments
Provide unbiased, evidence-based, reliable, accessible, and relevant information to patient
Discuss specific risks and benefits with regard to survival, relief of angina, quality of life, and potential additional intervention, as well as uncertainties associated with different treatment strategies
Provide patient time to reflect on the trade-offs imposed by the outcome estimates
Provide information on the level of operator expertise, volume of the facility, and local results in the performance of coronary revascularization options
Clearly inform of the need for continued medical therapy and lifestyle modifications

Adapted from Lawton et al, JACC 2021

Variability in Practice Should be Taken into Account: The SYNTAX Trial



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