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ASIAN INTERVENTIONAL CARDIOVASCULAR THERAPEUTICS
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Controversy in PCI: When to perform CTO intervention- Don't over do it!

Dr. Sengottuvelu. G

Chennai, INDIA



Conflicts of Interest

Speaker's name : Gunasekaran, Sengottuvelu, Chennai

I do not have any potential conflict of interest

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CTO vs non CTO PCI

- Technical complexity
- Potential life threatening complications
- Prolonged fluoroscopy
- Higher contrast load

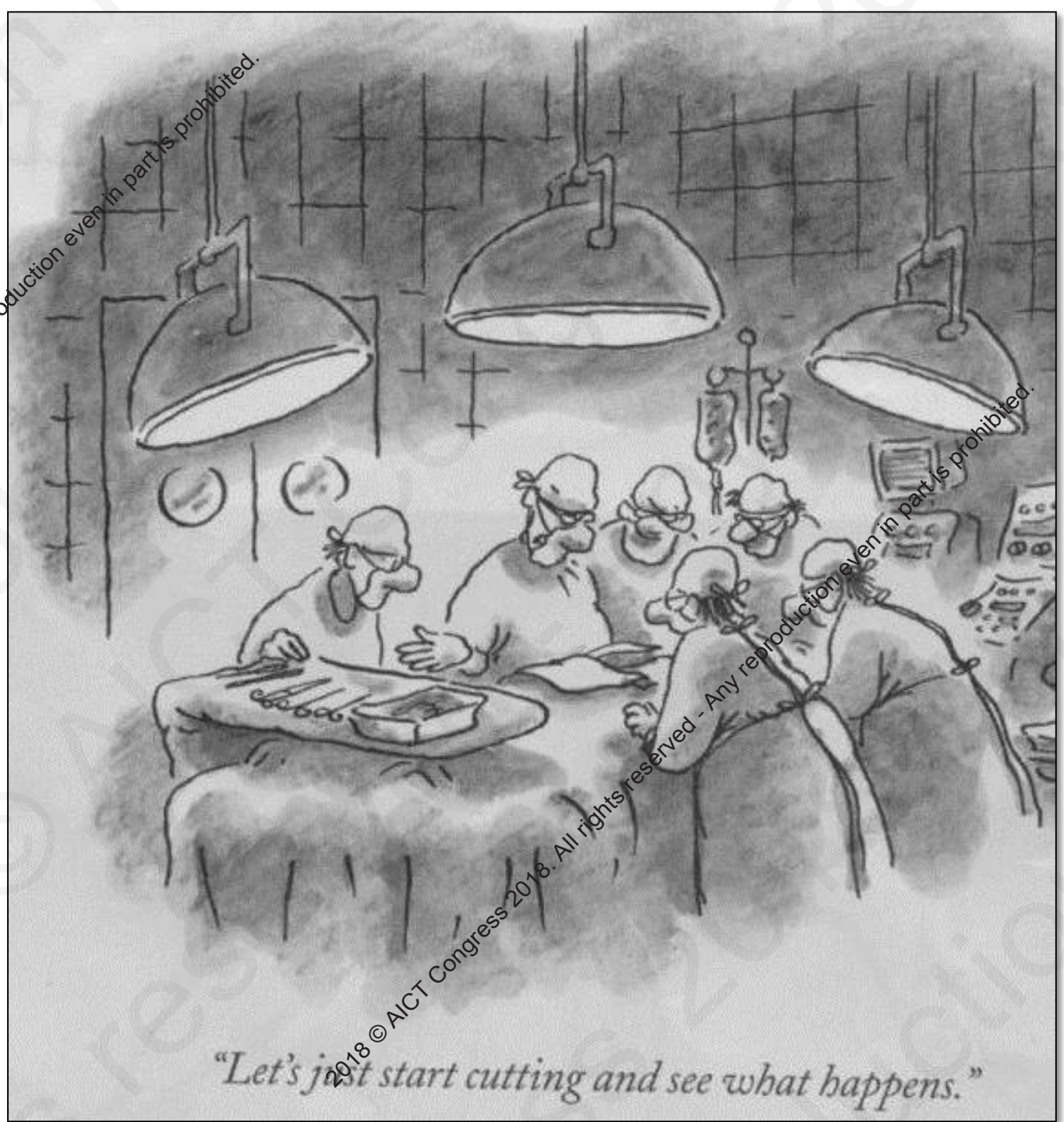
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*Many a times
capability to perform
CTO PCI is considered
rather than
appropriateness*

*Just because its easy
doesn't make it right!
Just because its hard
doesn't make it wrong!*



"Let's just start cutting and see what happens."



Aims of CTO PCI

QOL improvement

Symptom benefit

LV function improvement

Survival benefit

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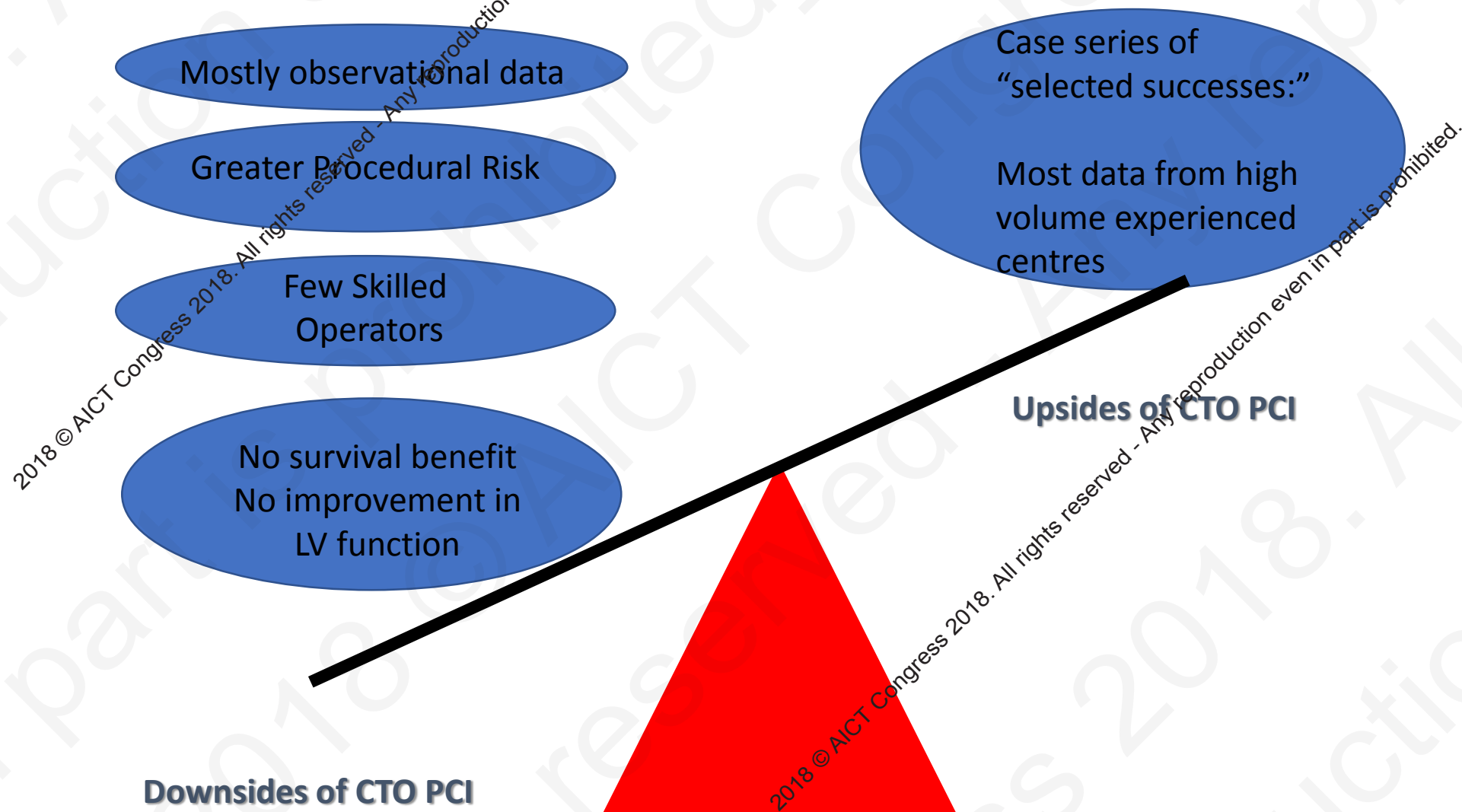
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Do we have evidence ?

Concern for complications in patients who may not derive clinical benefit

- Most data is only from observational studies
- Most compare successful and failed CTO PCI
- Only some observational studies suggest improved survival
- Improvement in LV function is inconsistent
- Technical and procedural challenges
- Can lead to life threatening complications

CTO Revascularisation



POINT/COUNTERPOINT

Treat the Patient, Not the Angiogram

Opposing Viewpoint, see p 1385

J. Aaron Grantham, MD

Millions of people are living with refractory angina and ischemic pain despite maximal medical therapy and are told that they have no revascularization option. The most common reason patients are told that they have no option for revascularization is the presence of a coronary chronic total occlusion (CTO).¹ Although no rigorous data exist, anecdotally, the majority of CTOs are now approachable with percutaneous techniques using drug-eluting stents owing to advances in the techniques that have resulted in improved success rates regardless of anatomy (>85%) and significant relief of ischemic symptoms while maintaining adequate safety. However, attempt rates for CTO percutaneous coronary intervention (PCI) range from 0% to 16% between institutions.² The question then arises: Among patients with a good indication for revascularization (particularly those with refractory angina and a CTO), why are so many not offered revascularization options? Here, the Canadian Cardiovascular Society Task Force on Refractory Angina provides some insights: "...[T]he nonrevascularization status will be influenced by the local expertise and operator tolerance to risk."³

- **DECISION-CTO trial**
- **Explore trial**
- **EuroCTO trial**
- **Revasc trial**



EXPLORE: No LVEF Boost with Extra CTO Stents

JACC: Cardiovascular Intervention
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Successful Recanalization of Native Coronary Chronic Total Occlusion Is Not Associated With Improved Long-Term Survival

REVASC

ClinicalTrials.gov, Identifier: NCT01924962



Recovery of Left Ventricular Function in Coronary Chronic Total Occlusion

OBJECTIVES The purpose of this study was to evaluate long-term clinical outcomes after reported percutaneous coronary intervention (PCI) for native coronary total occlusion (CTO).

Coverage from the American College of Cardiology (ACC) 2017 Scientific Sessions

Perspective > Trials and Fibrillations with Dr. John Mandrolia

COMMENTARY

First Clinical Trial of CTO Procedures Failed to Deliver

John Mandrolia, MD
DISCLOSURES | March 19, 2017

(updated March 25, 2017) Dr. Seung-Jung Park from the Asan Medical Center in Seoul South Korea presented the DECISION-CTO trial at the American College of Cardiology (ACC) 2017 Scientific Sessions.^[1] It is the first randomized clinical trial of stenting vs optimal medical therapy for coronary chronic total occlusion (CTO).

Noting the absence of high-level evidence for this procedure, a panelist at the late-breaking clinical-trial sessions said this:

"It's a stake in the ground to see a randomized trial for percutaneous chronic

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NEWS - INTERVENTIONAL ACC 2017

DECISION-CTO: PCI Stumbles for Stable CAD Patients With Chronic Total Occlusions

In a blow to interventionalists, the results did not show a benefit of the procedure over medical therapy alone. But hope remains.

Will L. Maxwell | March 19, 2017



WASHINGTON, DC—The first and only randomized trial of chronic total occlusion (CTO) revascularization versus optimal medical therapy in stable patients has come up empty-handed for PCI, disappointing enthusiasts who had hoped the interventional approach would have the edge.

"This study suggested that optimal medical therapy could be a reasonable initial approach for coronary CTO compared with CTO PCI," Seung-Jung Park

Related

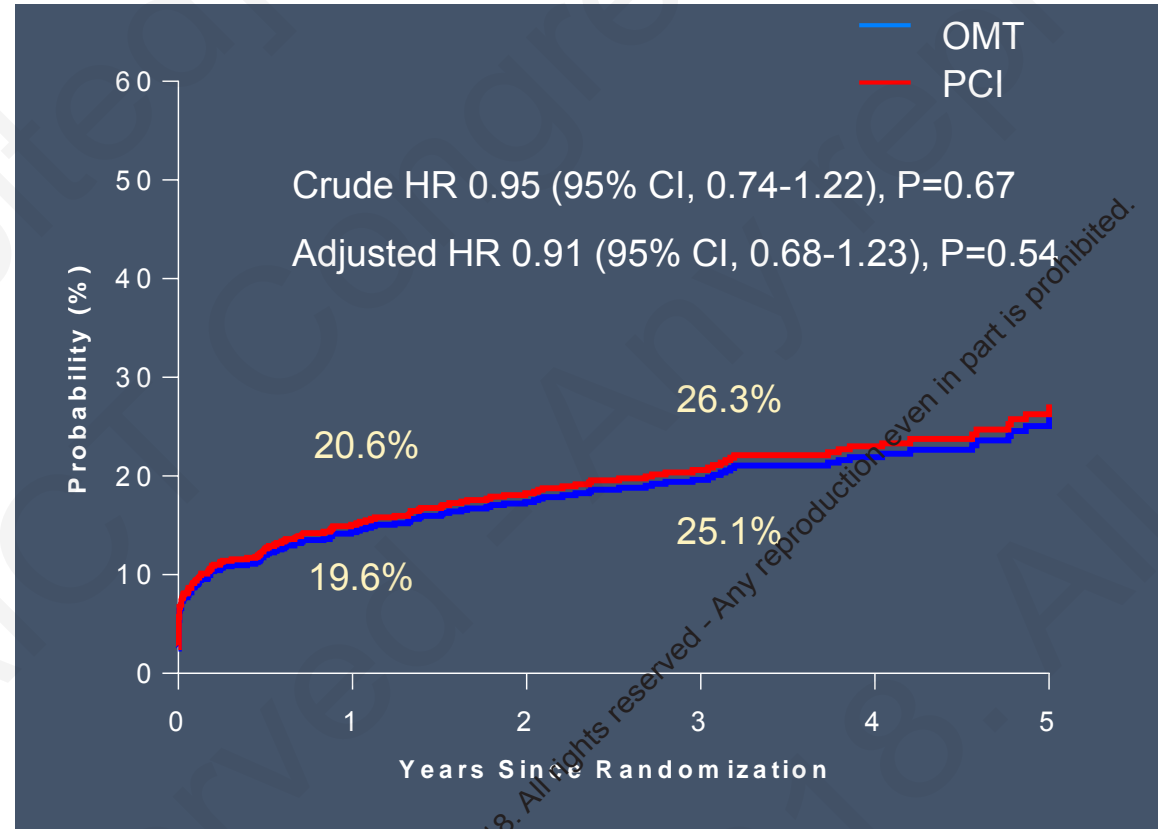
PRESENTATION ACC 2017
DECISION-CTO: Optimal Medical Therapy With or Without Stenting For Coronary Chronic Total Occlusion

Presenter: Seung-Jung Park | March 20, 2017

Prospective, open-label, randomized trial

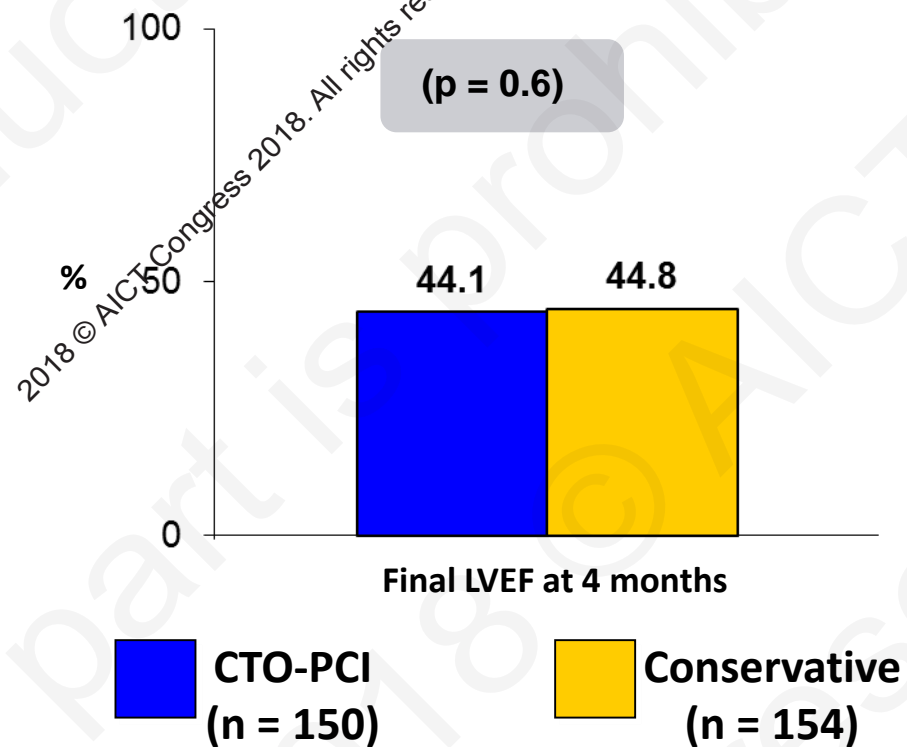
To compare outcomes of OMT alone with PCI coupled with OMT in patients with CTO.

- Over a 6-year period, 834 patients were randomized; 398 to optimal medical therapy and 417 to optimal medical therapy plus CTO PCI.
- OMT as an initial strategy was not different compared to PCI in terms of the composite of death, MI, stroke, or any revascularization at 3 years.
- There was no improvements in quality-of-life scores or angina.



Primary Endpoint: Composite of Death, MI, Stroke, and Any RR at 3 Years

Pts with STEMI treated with primary PCI and non-infarct artery CTO were randomized to CTO-PCI within 7 days or conservative management. All were followed for 4 months with CMR.



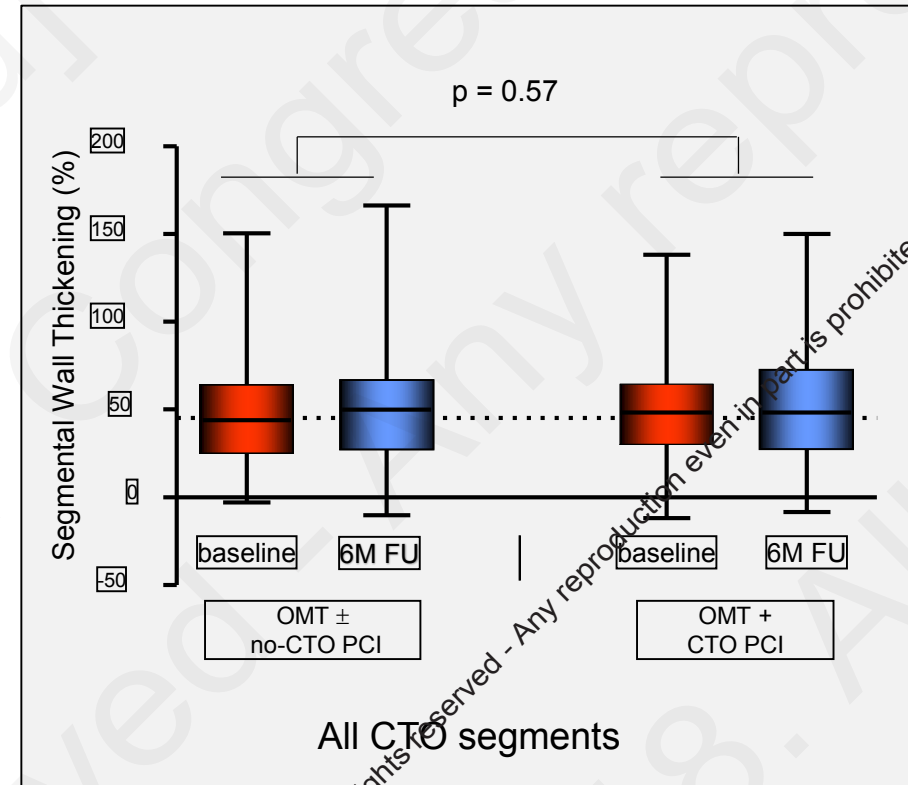
Results

- LVEF at 4 months: CTO-PCI vs. conservative: 44.1% vs. 44.8%, $p = 0.6$; LVEDV: 215.6 vs. 212.8 ml, $p = 0.70$
- MACE at 4 months: 5.4% vs. 2.6%, $p = 0.21$
- Periprocedural complications in CTO arm: Dissections: 13, tamponade 1, emergency CABG/ stroke/death: 0

Conclusions

Routine CTO-PCI performed within 1 week of primary PCI for STEMI does not result in improved LV function or clinical outcomes over an intermediate period of follow-up

- Revasc trial evaluated whether CTO-PCI improves LV function in addition to PCI of relevant coexisting non-CTO vessels.
- The change in segmental wall thickening measured by cardiac MRI (primary endpoint) was not improved in pts who underwent CTO PCI versus those who received OMT
- The trial was not powered for clinical outcomes



The initial plan was to enroll 1200 patients but because of slow enrollment, the study ended after randomizing only 407 patients 2:1 to CTO PCI and OMT or OMT alone.

QoL was the primary efficacy end point

7.3% of the OMT- only group crossed over to CTO PCI.

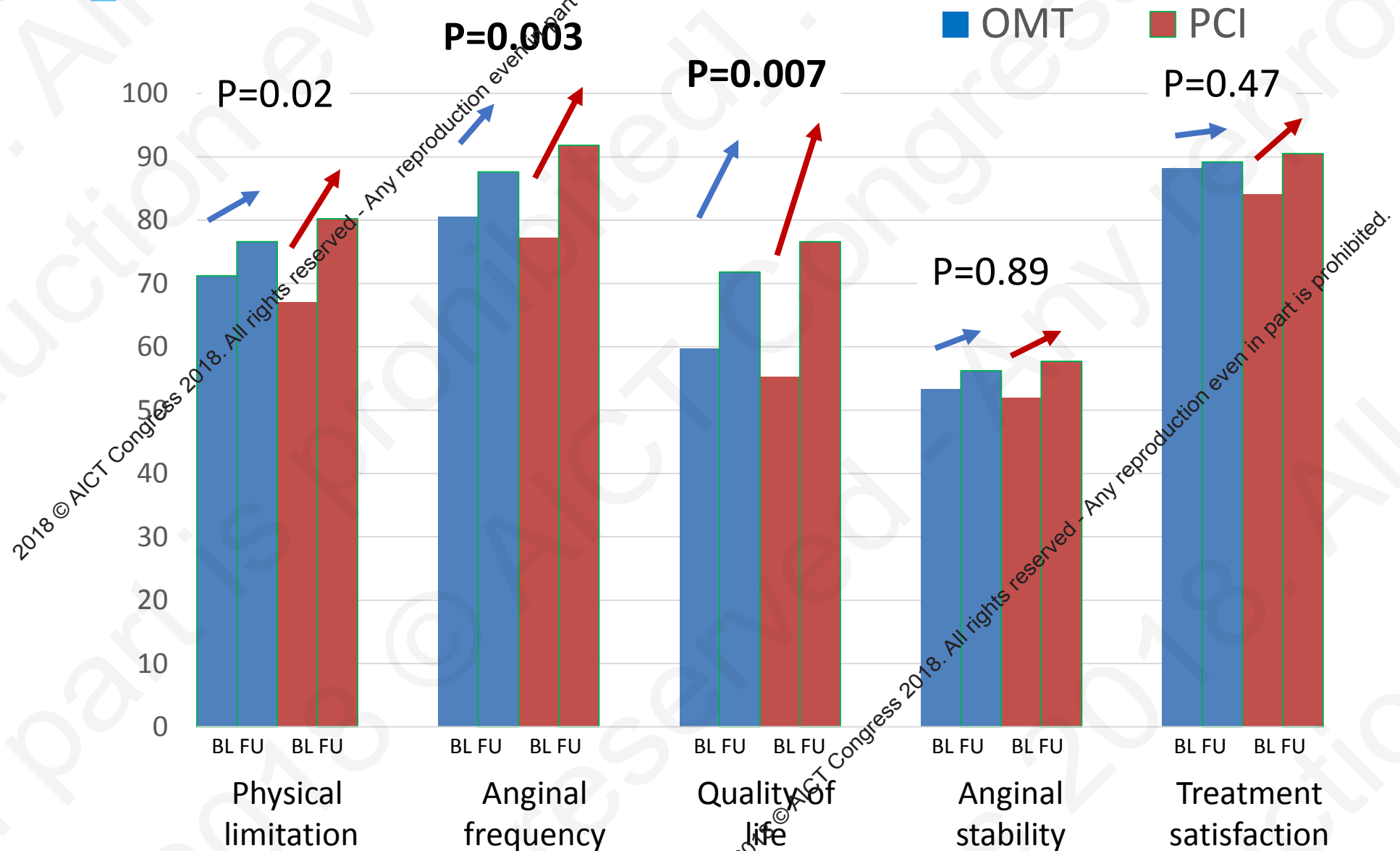
This study showed statistically significant improvement with CTO PCI in only few of the components of Seattle Angina Questionnaire (ie, angina frequency; P=0.009.)

Angina stability and treatment satisfaction were not significant.

No difference in MACE between the 2 groups at 12 months

	OMT (N=137)	PCI (N=259)	P value
Patients with any adverse event	9 (6.7)	13 (5.2)	0.52
All cause Death	0	2 (0.8)	0.55
Cardiac death	0	2 (0.8)	
Myocardial infarction	0	5 (1.9)	0.17
Non-Q-wave	0	4 (1.6)	
Q-wave	0	1 (0.4)	
Ischemia-driven revascularization	9 (6.7)	7 (2.9)	0.10
Cerebrovascular event	1 (0.7)	2 (0.8)	0.99
Stent thrombosis	0	1 (0.4)	0.99

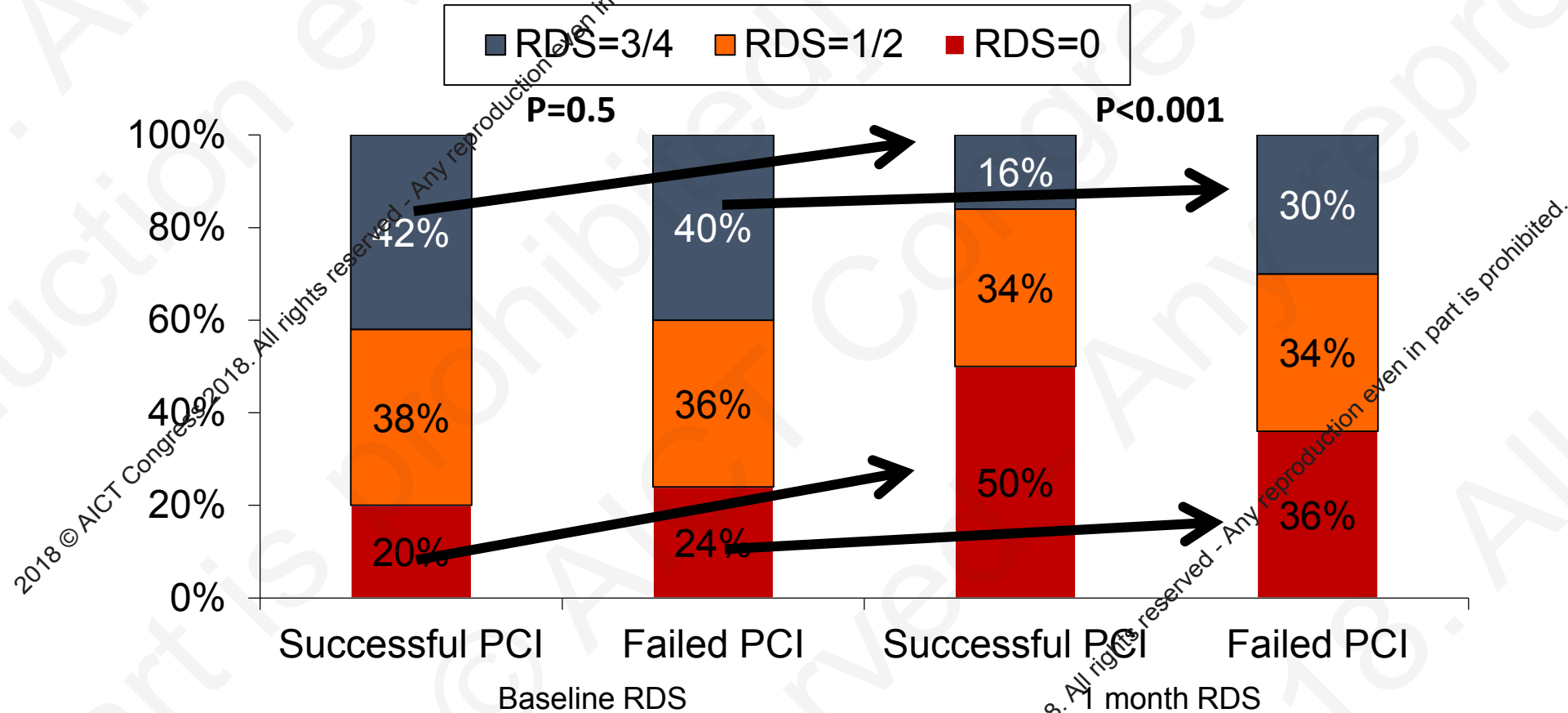
Primary Endpoint: SAQ health status (ITT)



For multiple testing the significance level is 0.01

OPEN CTO registry

80% reported dyspnea at baseline, 70% reported improved dyspnea



Improvement in dyspnea noted also in failed PCI group
 Improvement in depressive symptoms noted in PCI group – suggests possible placebo affect

THE LANCET

Volume 391 - Number 10115 - Pages 1-54 - January 6-12, 2018

Percutaneous coronary intervention in stable angina (ORBITA): a double-blind, randomised controlled trial

Rasha Al-Lamee, David Thompson, Hakim-Muhammad Dehbi, Sayan Sen, Kare Tang, John Davies, Thomas Keeble, Michael Mielewicz, Raffi Kaprielian, Iqbal S Malik, Sukhjinder Singh, Ricardo Petraco, Christopher Cook, Yousif Ahmad, James Howard, Christopher Baker, Andrew Sharp, Robert Gerber, Suneel Anwar, Ravi Assomull, Jamil Mayet, Roland Wensele, David Collier, Matthew Shun-Shin, Simon A Thom, Justin E Davies, Darrel P Francis on behalf of the ORBITA investigators

THE LANCET

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Volume 391, No. 10115, p3-4, 6 January 2018

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Comment

Last nail in the coffin for PCI in stable angina?

David L Brown, Rita F Redberg

Published: 02 November 2017

Placebo effect

Single center, double-blind, sham-controlled trial.

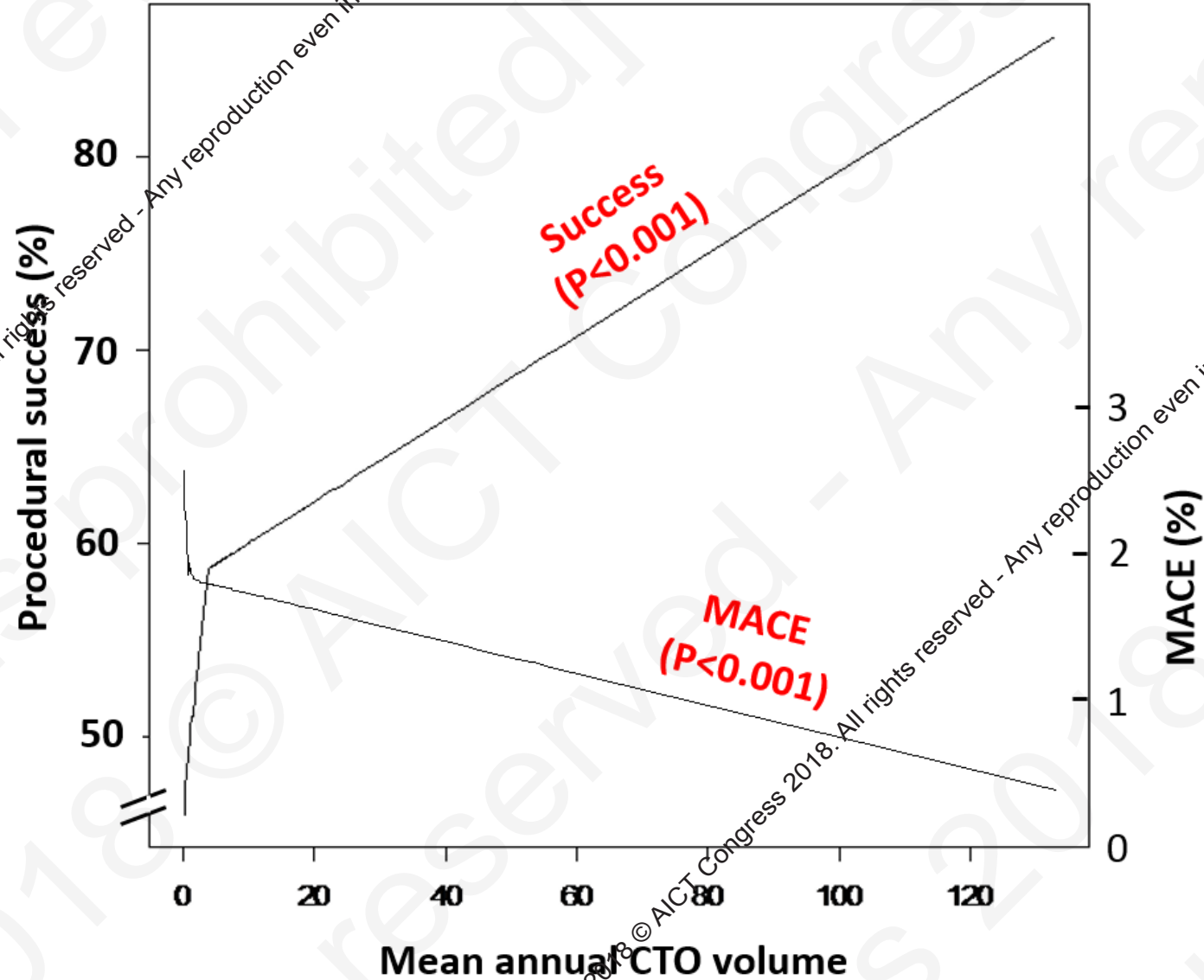
Randomize symptomatic CTO patients to CTO PCI or a sham procedure.

Sham-procedure will undergo only bilateral arterial access without PCI

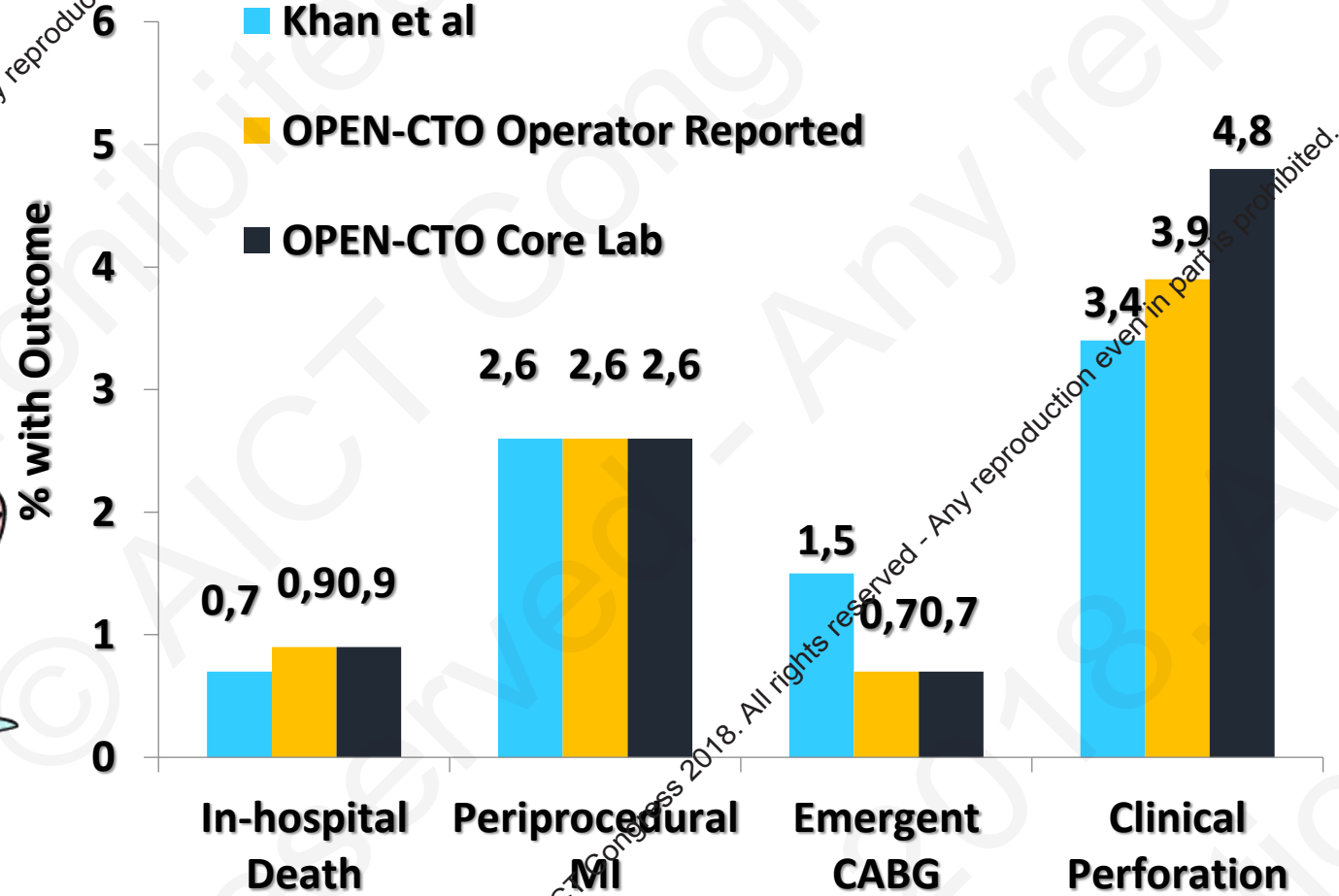
Improvement in SAQ-7 scores at 6 months

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CTO PCI - Is it worth the risk ? Complications are operator dependent



AICT Complications



Is the cancer risk real ?

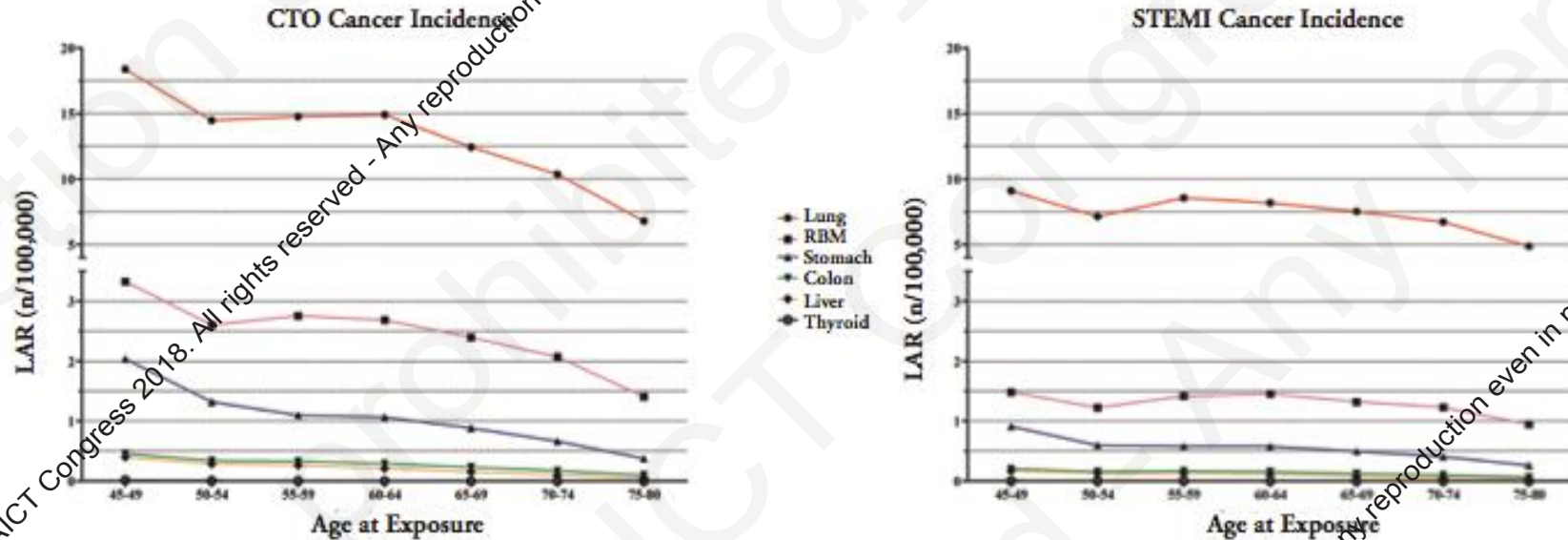


Figure 3. Estimated additional life attributable risk (LAR) of cancer incidence for individual organs following radiation exposure during percutaneous coronary intervention for chronic coronary total occlusion (CTO) and ST-elevation myocardial infarction (STEMI) patients.

Estimated additional cancer cases for individual organs was on average two times higher in patients treated with PCI for CTO compared to PCI for STEMI and the highest lifetime attributable risks were for lung and red bone marrow cancers. .



Appropriateness of CTO PCI in Patients With SIHD

Jan 30, 2018 | Rani Upadhyay, M.D.; Mir Babar Basir, DO; Khaldoun Alaswad, MD, FACC

Expert Analysis

Approximately 15.6 million Americans are affected by coronary artery disease, and it remains the most common cause of death in the United States.¹ Approximately 20% of such patients are known to have chronic total occlusions (CTO).² CTO lesions are commonly ischemic, and studies have shown that despite collateral circulation, normal coronary flow reserve is found in less than 10% of patients.³ The presence of CTO has been associated with worse cardiovascular outcomes and death in select patient populations.⁴⁻⁶ Despite the presence of symptoms and objective evidence of ischemia or viability in the CTO myocardial territory, revascularization rates for such patients remain low.¹ Here we will briefly review the improvements in current techniques, cardiovascular outcomes associated with successful CTO percutaneous coronary intervention (PCI), and discuss the current guidelines and appropriate use criteria for CTO PCI in stable ischemic heart disease (SIHD).

The ACC/AATS/AHA/ASE/ASNC/SCAI/SCCT/STS 2017 Appropriate Use Criteria for Coronary Revascularization in Patients With Stable Ischemic Heart Disease have eliminated the separate criteria for CTO lesions as was the case in the 2012 guidelines. Currently, indications for revascularization in SIHD are determined irrespective of whether the lesion is a CTO.²⁶ The indication for revascularization of a coronary artery lesion, whether CTO or severe stenosis, is based on symptoms, the extent of antianginal medications, and the risk of ischemia.

Conclusions

As adoption of CTO PCI becomes more common and as evidence of cardiovascular benefits continues to evolve, guidelines have favorably acknowledged the appropriateness of CTO PCI. **Currently, due to the lack of evidence from randomized control trials, routine use of CTO PCI is not recommended.** Patients who have symptoms of ischemia despite optimal medical therapy, those with moderate to large areas of myocardium at jeopardy, and patients with ischemic cardiomyopathies with viable myocardium are likely to gain the most benefit from CTO PCI. CTO PCI should be performed by operators who are well versed in CTO PCI techniques and management of associated complications. Most importantly, informed discussions with patients and providers emphasizing the risk and benefits associated with CTO PCI for a given patient's condition are the keys to providing patients with appropriate CTO PCI.

References

1. Mozaffarian D, Benjamin EJ, Go AS, et al. Executive Summary: Heart Disease and Stroke Statistics—2016 Update: A Report From the American Heart Association. *Circulation* 2016;133:447-54.
2. Azzalini L, Jolicoeur EM, Pighi M, et al. Epidemiology, Management Strategies, and Outcomes of Patients With Chronic Total Coronary Occlusion. *Am J Cardiol* 2016;118:1128-35.
3. Werner GS, Surber R, Ferrari M, Fritzenwanger M, Figulla HR. The functional reserve of collaterals supplying long-term chronic total coronary occlusions in patients without prior myocardial infarction. *Eur Heart J* 2006;27:2406-12.
4. Claessen BE, Dangas GD, Weisz G, et al. Prognostic impact of a chronic total occlusion of a non-infarct-related artery in patients with ST-segment elevation myocardial infarction: 3-year results from the HORIZONS-AMI trial. *Eur Heart J* 2015;33:768-75.

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Appropriateness of CTO PCI in Patients With SIHD

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26. AS, et al. Executive Summary: Heart Disease and Stroke Statistics—A Report From the American Heart Association. *Circulation* 2013;127:e67-122.

27. et al. Epidemiology, Management Strategies, and Prognosis of Chronic Total Coronary Occlusion. *Am J Cardiol* 2006;98:103-10.

28. Fritzenwanger M, Figulla HR. The functional significance of long-term chronic total coronary occlusions in patients with myocardial infarction. *Eur Heart J* 2006;27:2406-12.

29. G, et al. Prognostic impact of a chronic total coronary artery occlusion in patients with ST-segment elevation myocardial infarction: results from the HORIZONS-AMI trial. *Eur Heart J* 2013;34:103-10.

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Boukhris, Tomasello & Galassi

Should we give into temptation and attempt all chronic total occlusions?

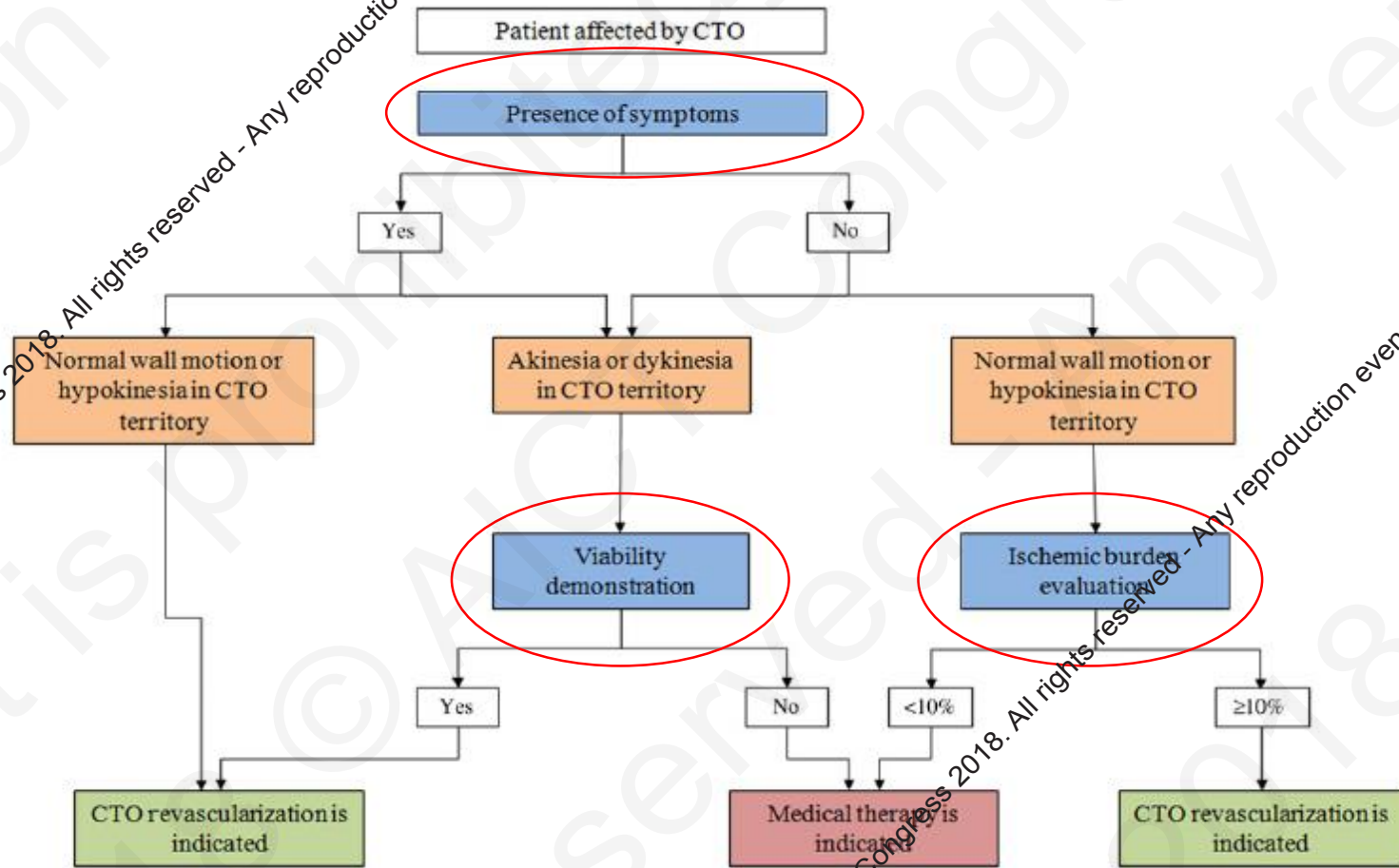
“The decision-making process of whom to undergo chronic total occlusion percutaneous coronary intervention, should pass through a rational analysis, taking into account clinical and anatomical factors and operator’s experience.”

Interv. Cardiol. (2014) 6(5), 399–401

Don't over do it – discuss pros & cons with your patient

Doubtful symptomatic benefit, No survival benefit, appx 3-5 % risk of complications, risk of malignancy

Appropriateness of percutaneous revascularization of coronary chronic total occlusions: an overview



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**Thank
You**

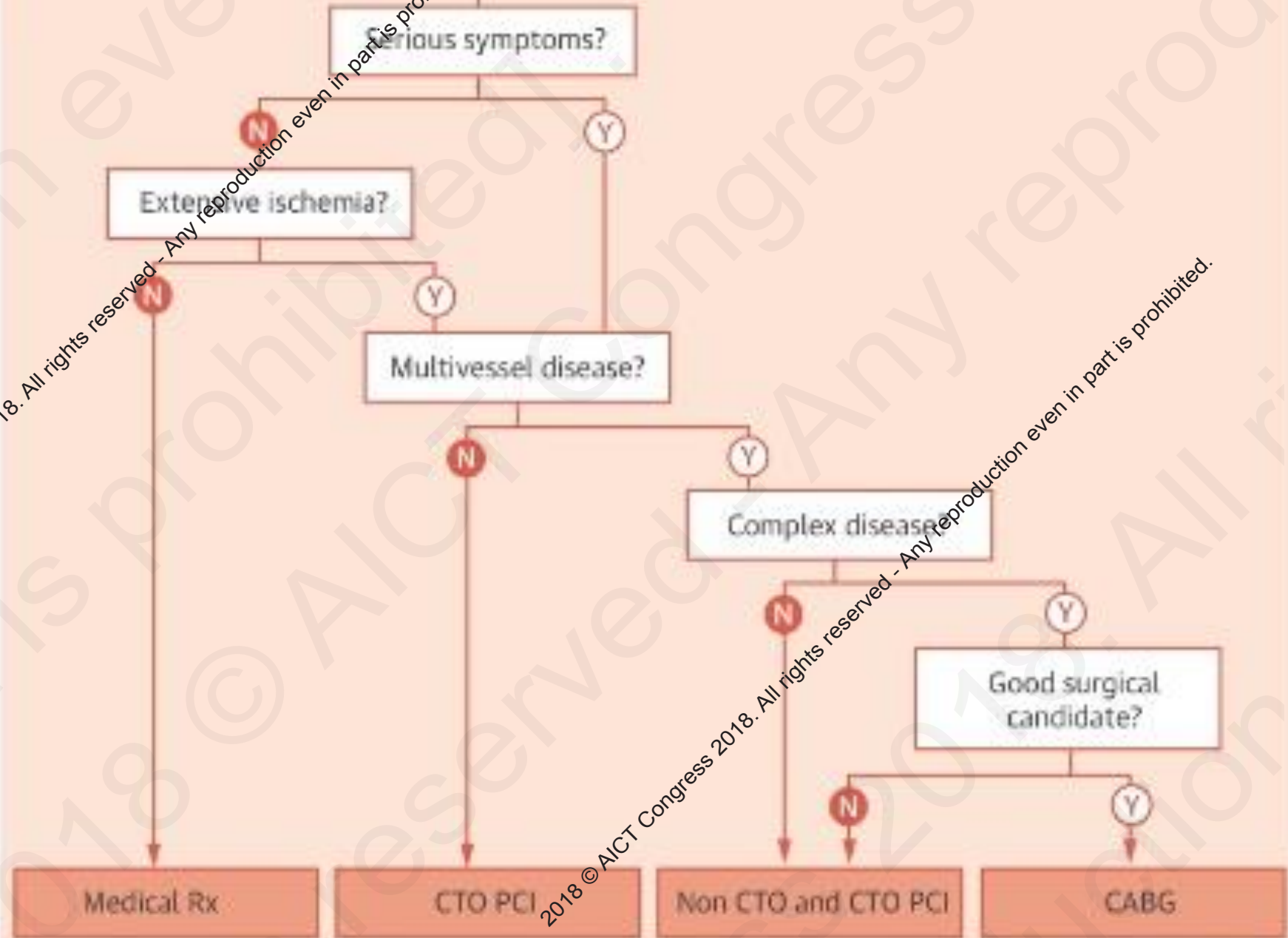
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Patients with coronary chronic total occlusions



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