DECISION - CTO

*D*rug-*E*luting stent Implantation *versus* optimal Medical Treatment in patients with *C*hron*I*c Total Occlu*SION*

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Study Back Ground

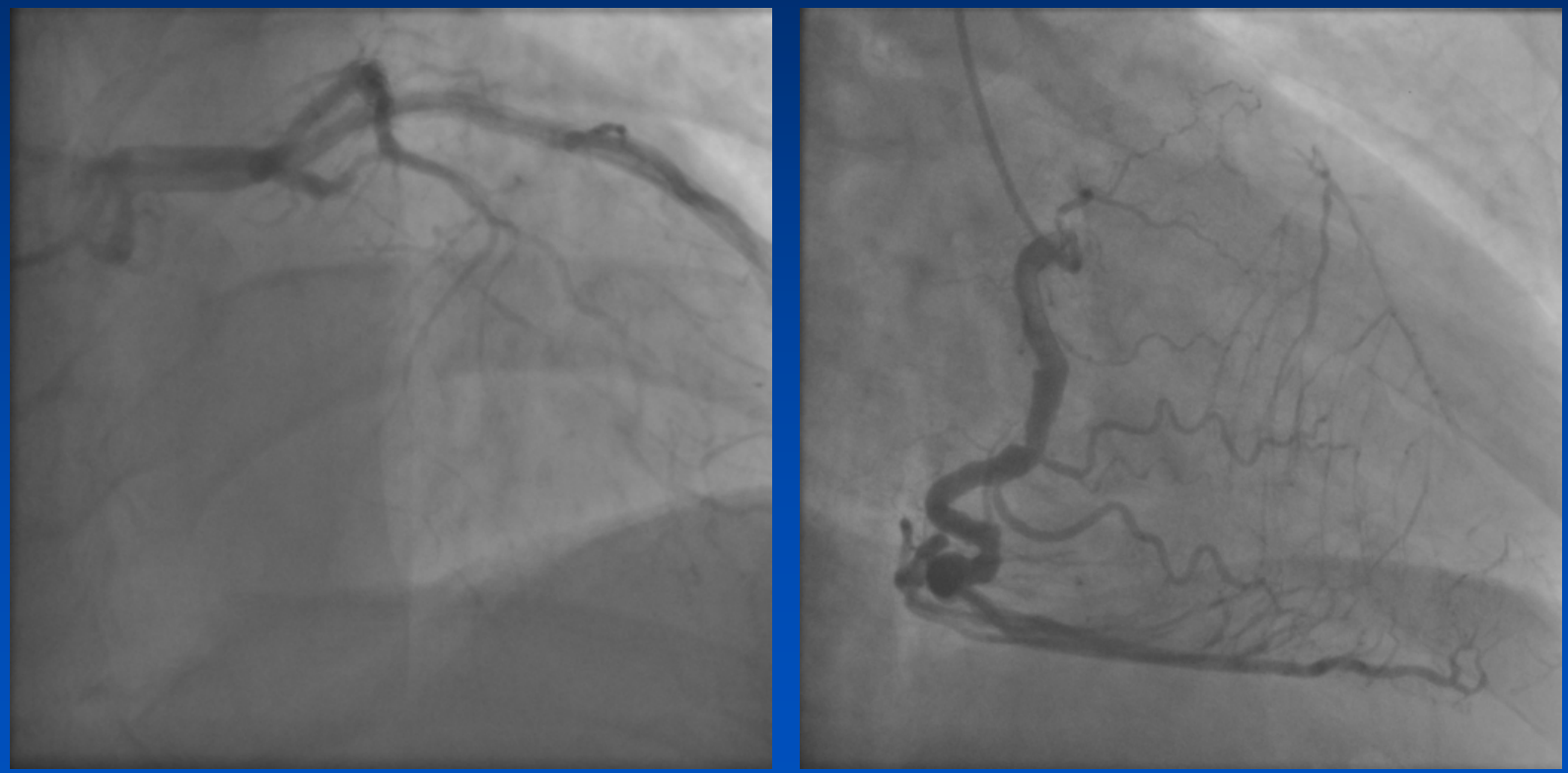
Current CTO intervention

- About 15% of all angioplasty procedures address chronic total occlusions.
- PCI success rate depends on the operator's skill and experience, usually around 70%.
- Although complication rate during CTO PCI is low, inevitable lethal complication may occur

Proximal LAD – CTO

53 aged male,

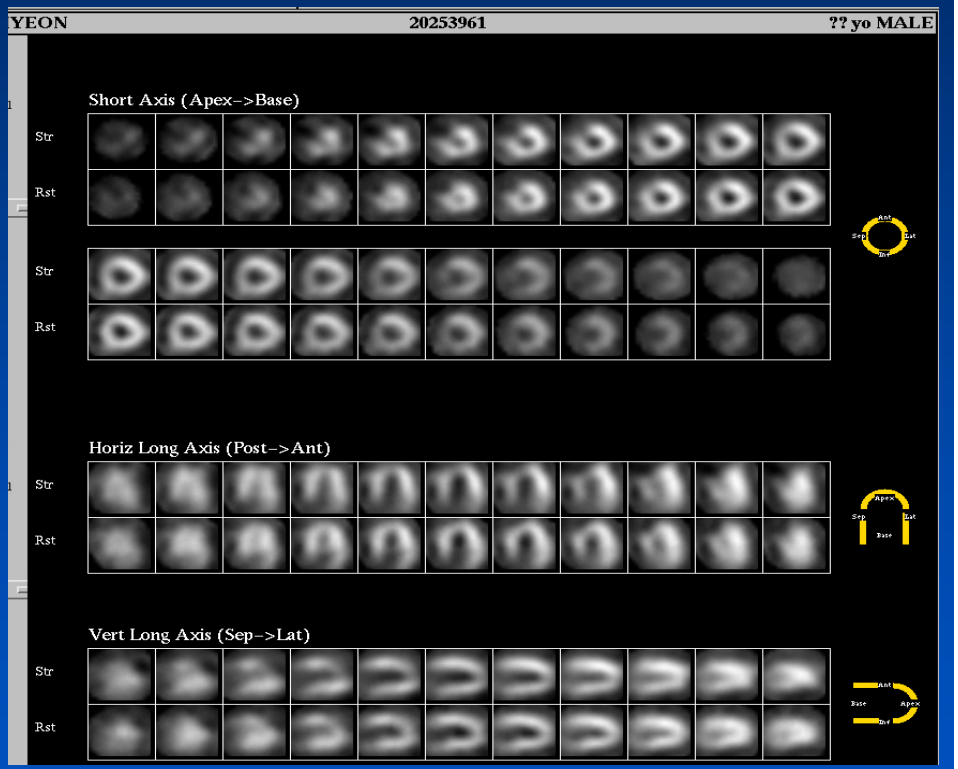
no symptom, good exercise performance



Proximal LAD - CTO

Negative TMT at stage 4

Small reversible defect in apex



Proximal LAD - CTO

53 aged male,
no symptom, good exercise performance
Negative TMT at stage 4
Small reversible thallium defect in apex

Followed the patients last 10 years
Quality of life is excellent with some medications.
(Aspirin 100mg,Tenormin 50 mg,Any-statin, QD)

Do you still want to do PCI ?

Conceptual Reasoning behind CTO intervention

Acute phase

- Relief of symptoms
- Avoid bypass surgery
- Safety margin in PCI of other vessel

Chronic phase

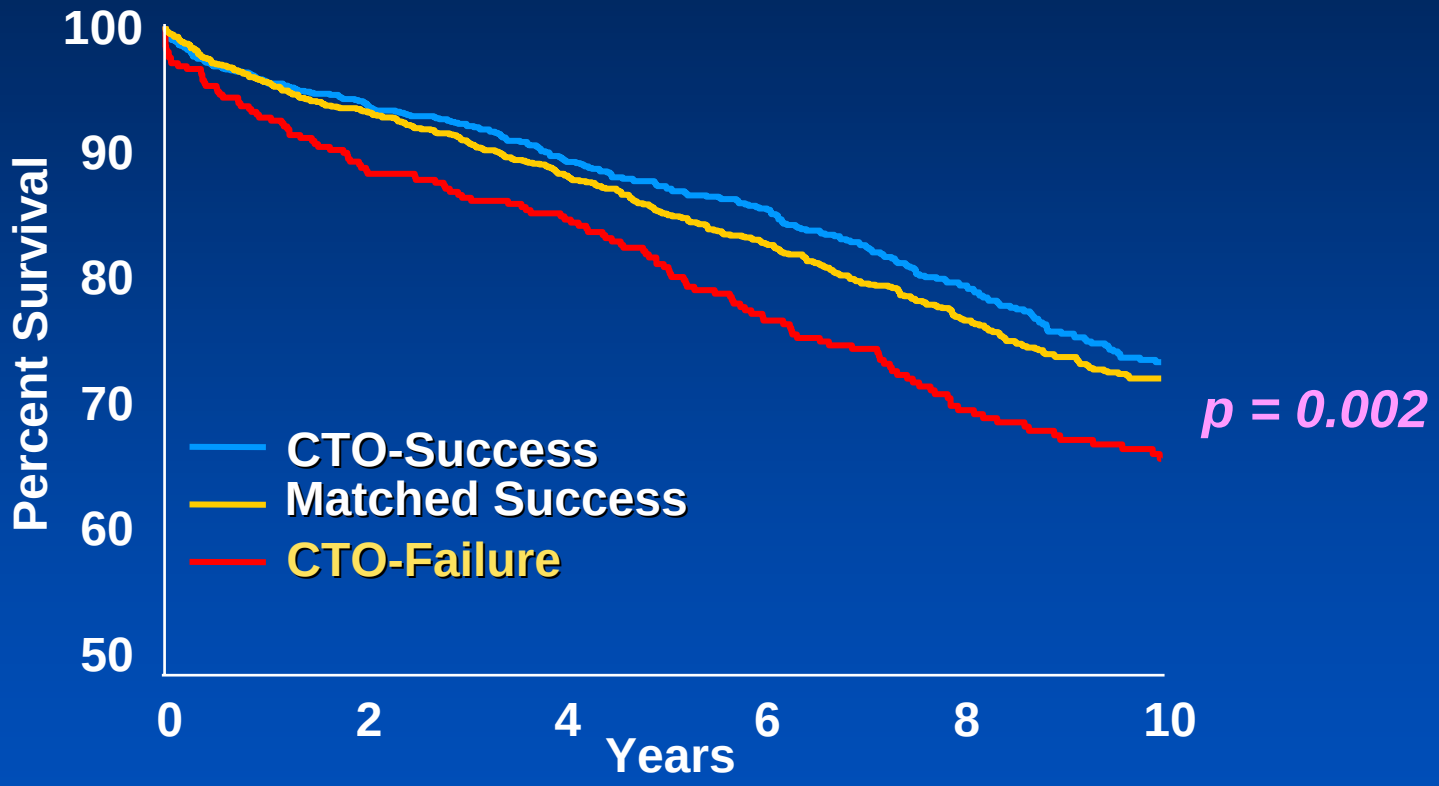
- Improvement of LV function
- Collateral for the future diseased vessel
- Improvement of long-term prognosis ?

Why
CTO intervention ?

Limited supporting data

Procedural Outcomes and Long-term Survival for PCI of CTO

Mid-America Heart Institute



CTO-Success %	93.9	89.4	85.5	79.3	73.5
CTO-Failure %	88.7	84.8	76.8	69.4	65.1
Matched-Success %	93.2	88.2	82.7	76.6	71.9

CardioVascular Research Foundation

Suero J et al. JACC 2001;38:409.

UNIVERSITY OF ULSAN COLLEGE MEDICINE

ASAN Medical Center

Long-term (4-year) Outcomes for CTO Revascularization

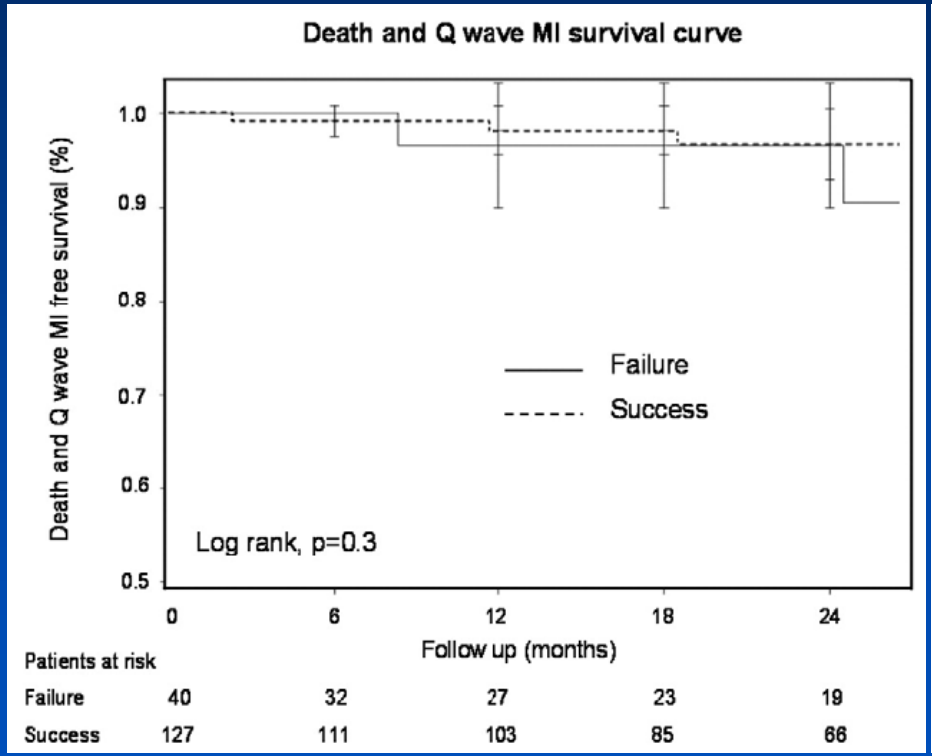
	Single vessel			Multivessel		
	CTO success (n = 261)	CTO failure (n = 99)	*P*	CTO success (n = 306)	CTO failure (n = 205)	*P*
Death (%)	97.3	99.0	0.3	92.5	86.3	0.02
Death or MI (%)	94.6	96.0	0.6	88.6	82.0	0.03
Death or CABG (%)	91.6	70.7	<0.001	86.9	61.5	<0.001
MACE (%)	72.0	47.5	<0.001	61.1	42.9	<0.001

Hoye A et al, EHJ 2005;26:2630

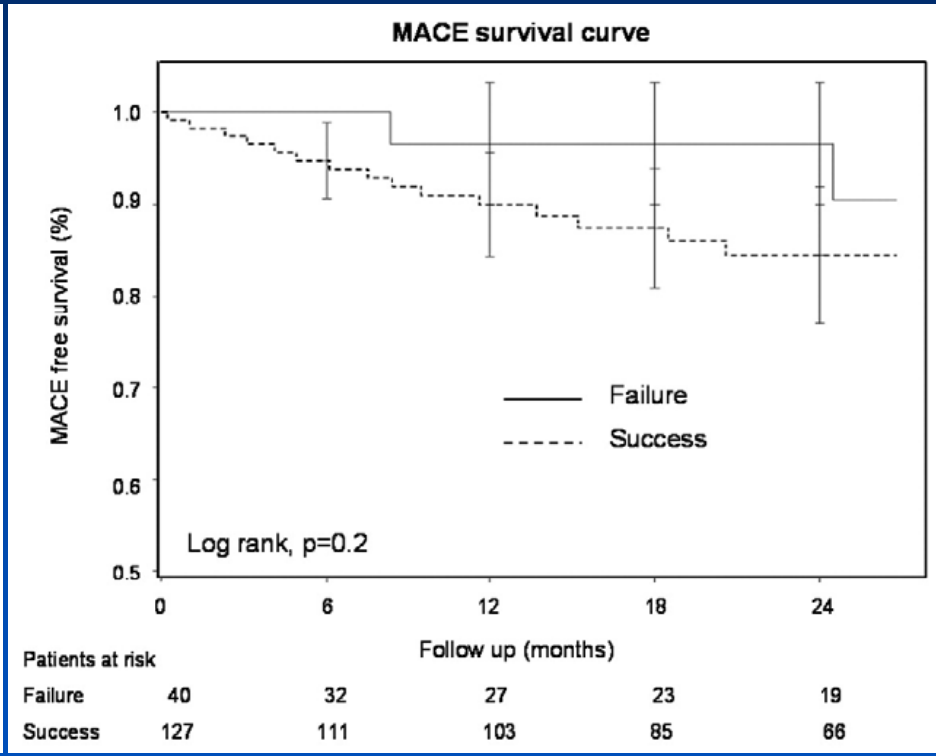
Long-term (2-year) Outcomes for CTO Revascularization

CTO Success (n=127) vs. Failure (n=45)

Death/Q-MI free Survival



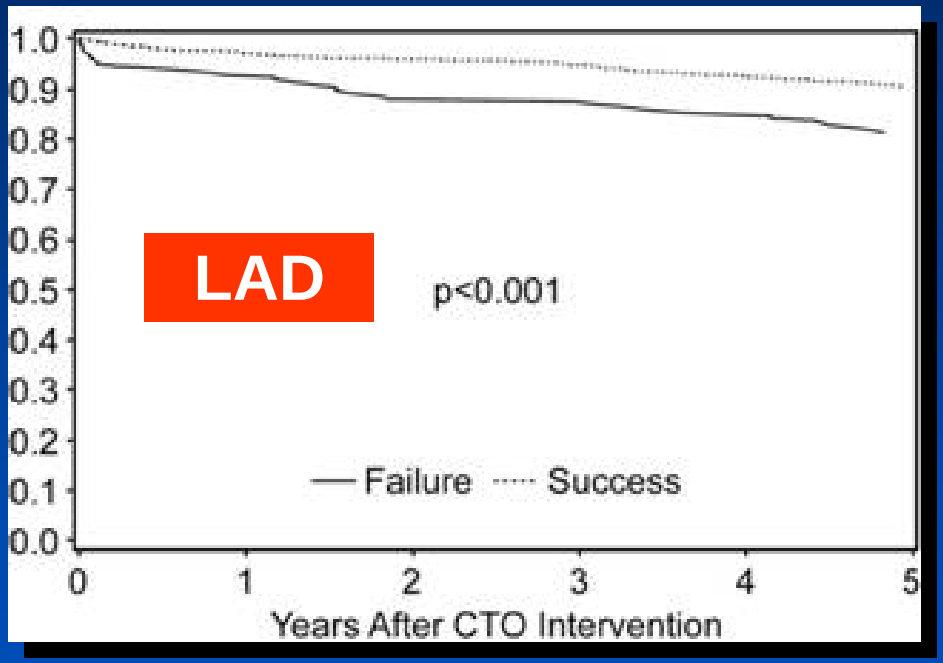
MACE free Survival

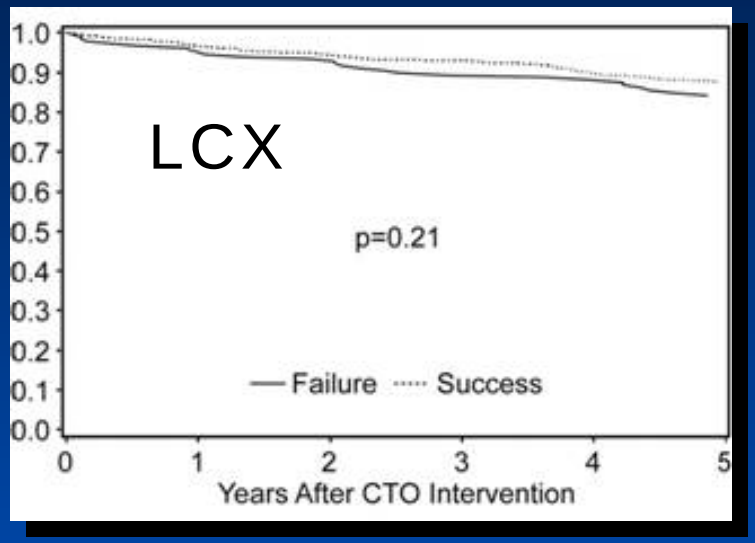


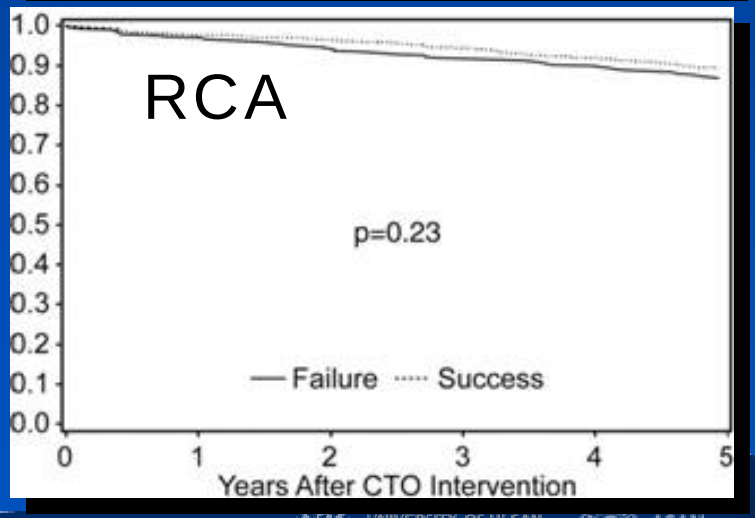
Labriolle A et al, Am J Cardiol 2008;102:1175-1181

Survival Benefit in LAD - CTO intervention

but not in left circumflex and right coronary artery CTO interventions



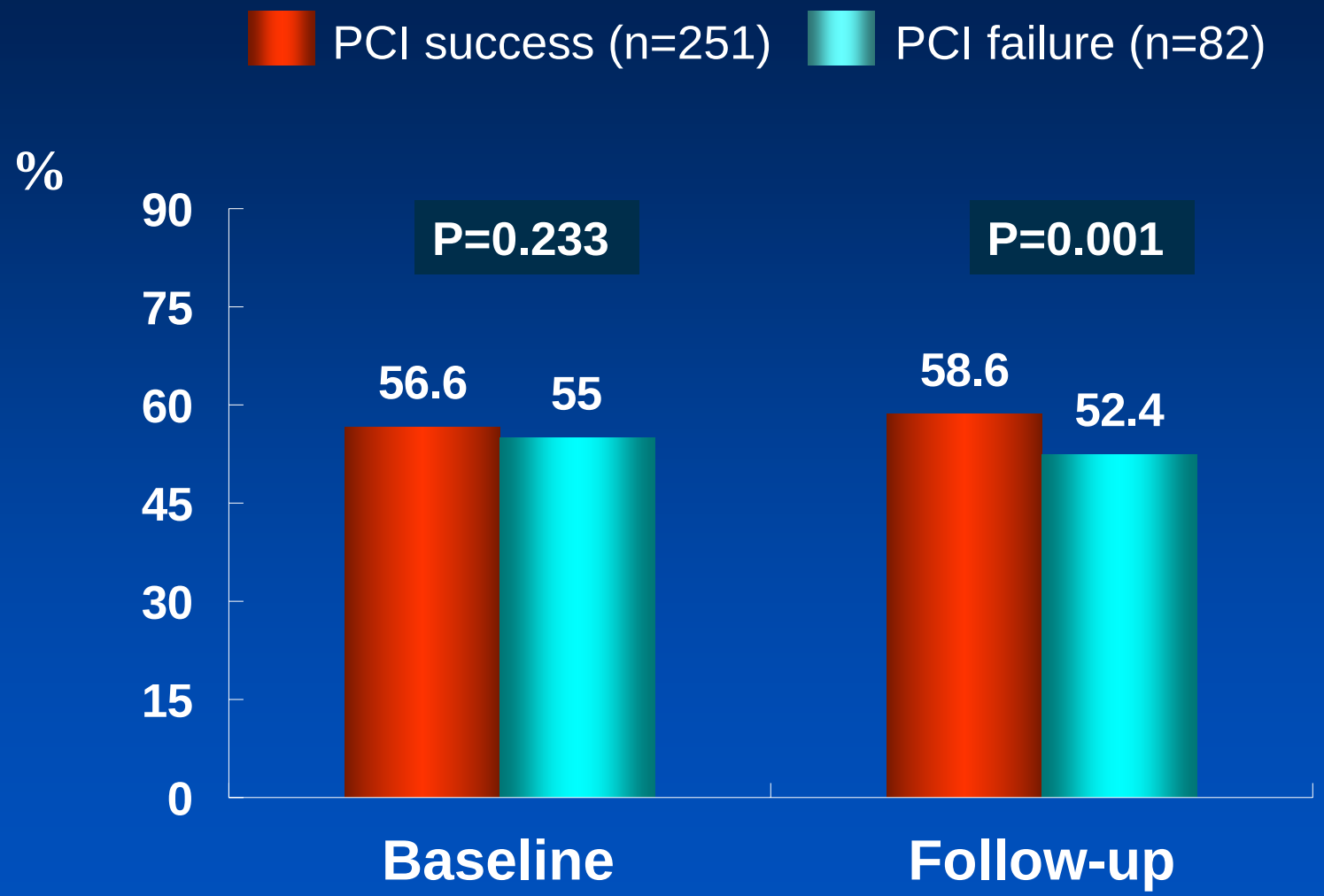




Safley, D. M. et al. JACC Intv 2008;1:295-302

AMC - CTO Registry Data, 2010

The change of LV function at 3 year follow up



Crude and Adjusted Hazard Ratios for **3-Year Clinical Outcomes**

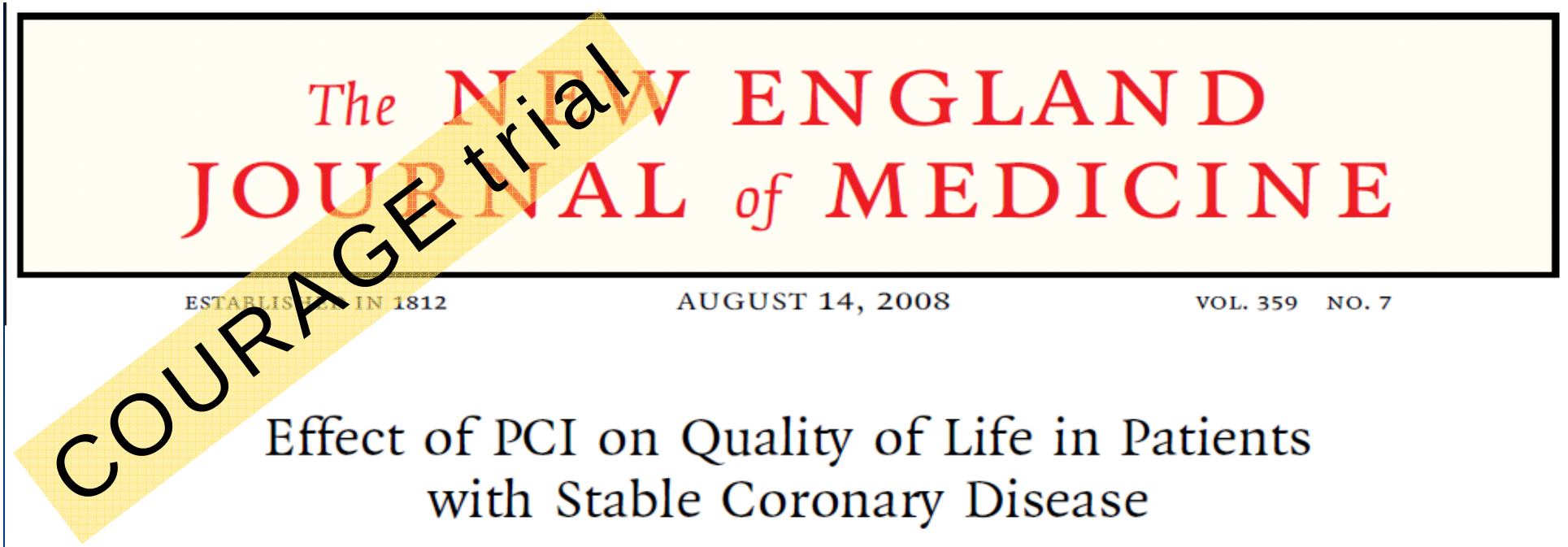
CTO success (n=251) vs. failure (n=82)

Outcome	Outcome rates (%)		Crude		Multivariable adjusted		Adjusted for propensity	
	Success	Failure	Hazard ratio (95% CI)	P-value	Hazard ratio (95% CI)	P-value	Hazard ratio (95% CI)	P-value
Death	3.8	7.1	0.491 (0.174-1.380)	0.168	1.003 (0.145-6.938)	0.998	1.070 (0.231-4.963)	0.931
MI	1.6	4.4	0.428 (0.096-1.913)	0.252	0.605 (0.076-4.827)	0.636	0.471 (0.045-5.032)	0.533
TVR	6.8	0	1.384 (0.502-3.812)	0.530	1.694 (0.481-5.964)	0.412	1.422 (0.313-6.457)	0.648
Death, or MI	5.4	12.5	0.426 (0.130-0.951)	0.039	0.810 (0.194-3.389)	0.773	0.843 (0.239-2.971)	0.791
Death, MI, or TVR	9.4	12.5	0.657 (0.348-1.239)	0.123	1.168 (0.473-2.886)	0.528	1.028 (0.349-3.028)	0.940
Death, MI, TVR or Re-hospitalization	9.4	22.3	0.380 (0.220-0.656)	<0.001	0.370 (0.203-0.677)	0.009	0.352 (0.163-0.759)	0.003

*Adjusted for age, sex, DM. HTN, smoking, hypercholesterolemia, previous PCI, previous MI, renal failure, ACS, multi-vessel disease, multiple CTOs, CTO vessel, CTO length, complete revascularization, EF

We still have Controversy
- Treat or Not treat -

- The benefit of successful CTO intervention compared to CTO failure (medical treatment) is still controversy. Furthermore, these small data were based on the retrospective registries.
- Evolving medical treatment and stent technology.
- Effect of optimal medical treatment may be underestimated in current practice.
- We need randomized controlled study.



Recent randomized controlled study in stable angina patients with non-CTO lesions did not show any benefits of revascularization in terms of angina symptom, events and survival

DECISION - CTO

*D*rug-*E*luting stent Implantation *versus* optimal Medical Treatment in patients with *C*hron*I*c Total Occlu*SION*

Objective

To compare the long-term (3-year) efficacy of drug-eluting stent implantation with optimal medical treatment for chronic total occlusion

* CTO: TIMI 0 flow and estimated duration ≥ 3 months

DECISION-CTO

CTO lesions - eligible for DES implantation
(Single CTO or MVD with 1 or 2 CTOs)

1:1 randomization
Randomization is stratified by CTO location (LAD vs. Non-LAD), DM and Involving center

DES (n=550)	**Medical Treatment (n=550)**
DES in non-CTO lesions, **Treat CTO lesions**	**DES in non-CTO lesions,** **Not treat CTO lesions**

Optimal Medical Treatment

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

Primary end-point: Composite of death, MI, stroke, and any revascularization
Secondary end-point: any revascularization, hospitalization due to acute coronary syndrome. death, MI, LVEF, and angina class, clinical outcomes at 5yr, 10yrs

Optimal Medical Treatment

- Beta-blocker, calcium channel blocker, and nitrate, alone or in combination, along with either ACEI or ARB as standard secondary prevention.
- LDL < 70 mg/dL. After correction of LDL, HDL> 40 mg/dL and TG < 150 mg/dL with exercise, extended-release niacin, or fibrates, alone or in combination.
- Blood pressure ≤ 140/90 (≤ 130/80 if renal failure or DM)
- DM, HBA1c < 7

Inclusion Criteria

Clinical

- Patients with angina and documented ischemia
- Age >18 years,
- Written informed consent

Angiographic

- *De novo* CTO lesion suitable for stent implantation
- Reference vessel size ≥ 2.5 mm by visual estimation
- Single CTO (at least proximal to mid portion epicardial a CTO)
- Two CTO (at least one CTO located in proximal to mid portion of epicardial artery)

Exclusion Criteria

- Contraindication to aspirin, clopidogrel or other commercial antiplatelet agent
- Three vessel CTO
- Left main disease,
- Graft vessel disease,
- In-stent total occlusion,
- Distal epicardial artery CTO
- LVEF<30%
- ST elevation AMI with other vessel CTO
- Hematological disease (WBC <3,000/mm3, platelet<100,000/mm3)
- Hepatic dysfunction (> 3 times normal)
- Renal dysfunction (Cr ≥2.0mg/dL)
- Inability to follow the protocol
- Sustained VT/VF
- Uncontrolled heart failure
- Limited life expectancy due to cancer or other end stage disease

Study Endpoint

- **Primary end-point:**
  - Composite of death, MI, stroke,
    and any revascularization (3-year)

- **Secondary end-point:**
  - Any revascularization,
  - CTO vessel related revascularization
  - Hospitalization due to acute coronary syndrome.
  - Death, MI, stroke
  - LVEF,
  - Angina class,
  - QOL.
  - 5-year &10-year clinical outcomes
  - Cost effectiveness

Seattle Angina Questionnaire

"19-Item Questionnaire"

- Physical Limitation
- Angina Stability
- Angina Frequency
- Treatment Satisfaction
- Quality of Life

Statistical analysis
Non-inferiority design

The non-inferiority margin was based on historical data, clinically acceptable relevance, and the feasibility of study recruitment. (Incidence of primary end point ; DES group 12% vs Medical group 17%)

For the non-inferiority testing with a noninferiority margin of 5% and a one-sided 5% significance level, 523 patients were needed to have 80% power to reject the null hypothesis if it was false.

Non-inferiority would be declared if the one-sided 95% upper confidence limit for the difference was not greater than 5%.

5% follow-up loss

Total : 1100 patients (550 patient/arm)

Sub-study

Baseline coronary CT (selected center)

- Usefulness during CTO intervention
- Predictor of successful intervention
- CT Characteristics of CTO lesions
- Predictor of future cardiac events ??

Follow-up Coronary angiography/coronary CT

- 3-Year angiographic and coronary CT FU in OMT group
- The natural change of collaterals in CTO lesions
- Change of CTO segment in coronary CT

TMT/Thallium SPECT

- Baseline and Yearly Functional status/ischemia burden
- Predictor of future cardiac events?

28 investigating centers are participating

1.	서울아산병원	박승정
2.	순천향대학교 천안병원	신원용
3.	충북대학교병원	배장환
4.	샘안양병원	서일우
5.	인제대학교 부산백병원	김동수/양태현
6.	고려대학교 구로병원	나승운
7.	울산대학교병원	이상곤
8.	순천향대학교부천병원	이내희/서존
9.	강릉아산병원	정상식
10.	부천성가병원	김희열
11.	서울보훈병원	이 근
12.	강원대학교병원	이봉기
13.	부산대학교 양산병원	김 준홍
14.	경상대학교병원	정영훈
15.	한림대학교 한강성심병원	김민규
16.	대전성모병원	허성호
17.	전북대학교 병원	체재건
18.	청주성모병원	양용모
19.	계명대학교동산병원	허승호

20	China	Peking University First Hospital	Yong Huo
21	China	Sir Run Run Shaw Hospital	Guo Sheng FU
22	India	Heart Care Clinic	Shirish Hiremath
23	Taiwan	National Taiwan University Hospital	Paul Hsien-Li Kao
24	Taiwan	Shin Kong Hospital	Jun-Jack Cheng
25	Taiwan	Taipei Veterans General Hospital	Chia-Yu Chou
26	Thailand	King Chulalongkorn Memorial Hospital	Wasan Udayachalerm
27	Thailand	Sirirai Hospital	Damras Tresukosol
28	Indonesia	Medistra Hospital	Teguh Santoso

Treat
or Not treat !

You can joint us if you mind !


Thank You !!
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