Χρόνιες Ολικές Αποφράξεις

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Α Καρδιολογική Κλινική Πανεπιστημίου Αθηνών
Ιπποκράτειο ΓΝΑ
No conflict of interest
CTO/ Definitions

- The presence of TIMI 0 flow within the occluded segment with an estimated occlusion duration of > 3 months

- Encountered in 15-30% of patients undergoing cor. Angio

- >50% are symptomatic

Definition

- CTO
- Chronic Total Occlusion
Chronic Total Occlusion (CTO)  
From Randomized Trials to Daily Practice

The single most common reason for a patient to be referred to surgery and not randomized was a CTO with low success rate of recanalization.

J Am Coll Cardiol. 2014;63(12_S). S0735-1097(14)61634-X

<table>
<thead>
<tr>
<th>TABLE 2</th>
<th>Completeness of Revascularization and CTOs in Multivessel Revascularization Trials and Registries</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trial, Years (Ref. #)</strong></td>
<td><strong>Patients, n</strong></td>
</tr>
<tr>
<td>CASS, 1974-1979 (28)</td>
<td>3,372</td>
</tr>
<tr>
<td>MASS-II, 1995-2000 (30,31)</td>
<td>611</td>
</tr>
<tr>
<td>BARI, 1988-1991 (32)</td>
<td>1,829</td>
</tr>
<tr>
<td>ERACI II, 1996-1998 (34)</td>
<td>450</td>
</tr>
<tr>
<td>SoS, 1996-1999 (35)</td>
<td>988</td>
</tr>
<tr>
<td>SYNTAX, 2005-2007 (37,39,40)</td>
<td>1,800</td>
</tr>
<tr>
<td>New York State PCI Reporting System, 1997-2000 (43)</td>
<td>21,945</td>
</tr>
</tbody>
</table>
CTO Surgical revascularization/ SYNTAX trial

CABG n=266
12 were not treated with CABG

CABG n=254

Not Bypassed n=81
Bypassed n=173

Reason not bypassed:
- Not intended to treat (n=12)
- Diseased (n=11)
- Inadequate conduit (n=2)
- Too small (n=19)
- Unable to find (n=1)
- Other (n=36)

Overall 68.1% of TO were successfully bypassed

ITT, Per Lesion
SYNTAX trial
Incomplete revascularization predicts adverse outcomes

Farooq V et al, Circulation. 2013
Complete vs Incomplete Revascularization

Table 2. Adjusted HR (IR and IR Subgroups vs. CR) and 95% CI for 18-Month Mortality and Mortality/Mi by Subgroups of IR

<table>
<thead>
<tr>
<th>Patient Group</th>
<th>No. of Cases</th>
<th>Mean Length of Follow-up (Months)</th>
<th>No. of Events</th>
<th>Adjusted HR* (95% CI)</th>
<th>p Value</th>
<th>No. of Events</th>
<th>Adjusted HR† (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CR</td>
<td>3,499</td>
<td>19.0</td>
<td>165</td>
<td>Reference</td>
<td></td>
<td>216</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>IR</td>
<td>7,795</td>
<td>18.9</td>
<td>551</td>
<td>1.23 (1.04–1.45)</td>
<td>0.01</td>
<td>736</td>
<td>1.27 (1.09–1.47)</td>
<td>0.002</td>
</tr>
<tr>
<td>Subgroups of IR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 IR vessel with no total occlusion</td>
<td>3,815</td>
<td>18.9</td>
<td>239</td>
<td>1.23 (1.02–1.48)</td>
<td>0.03</td>
<td>316</td>
<td>1.22 (1.04–1.44)</td>
<td>0.02</td>
</tr>
<tr>
<td>1 IR vessel with total occlusion</td>
<td>1,725</td>
<td>19.1</td>
<td>112</td>
<td>1.11 (0.87–1.42)</td>
<td>0.39</td>
<td>145</td>
<td>1.14 (0.92–1.41)</td>
<td>0.24</td>
</tr>
<tr>
<td>≥2 IR vessels with no total occlusion</td>
<td>1,233</td>
<td>19.1</td>
<td>92</td>
<td>1.18 (0.89–1.56)</td>
<td>0.26</td>
<td>132</td>
<td>1.34 (1.04–1.73)</td>
<td>0.03</td>
</tr>
<tr>
<td>≥2 IR vessels with total occlusion</td>
<td>1,022</td>
<td>18.4</td>
<td>108</td>
<td>1.44 (1.14–1.82)</td>
<td>0.002</td>
<td>143</td>
<td>1.50 (1.21–1.86)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

J Am Coll Cardiol Intv 2009;2:17–25
Complete vs Incomplete Revascularization

U.K. Central Cardiac Audit Database for all CTO PCI compare outcomes of patients with successful versus unsuccessful PCI to a CTO
N=13,443

Success rate 70.6%

CTO Revascularization Decision

Am J Cardiol 2005; 95,1088-1091.
Complexicity

Clinical Justification
Angina

Dyspnea

Ischemia

Prognosis
Symptoms in CTO

• Angina (less prominent)
• Dyspnea
• Fatigue
• Patients minimize symptoms
• Often inappropriately labeled asymptomatic

EuroIntervention 2014;9:1165-1172
FACTOR Trial

SAQ Angina Frequency
- 9.5 (1.6, 17.5)

SAQ Physical Limitation
- 13.1 (5.1, 21.1)

SAQ Quality of Life
- 20.3 (11.9, 28.6)

Effect of Procedural Success

FACTOR Trial

Asymptomatic
- SAQ Angina Frequency: 4.3 (-5.4, 13.9)
- SAQ Physical Limitation: 6.3 (-5.0, 17.6)
- SAQ Quality of Life: 8.5 (-3.7, 20.7)

Symptomatic
- SAQ Angina Frequency: 10.3 (-0.8, 21.3)
- SAQ Physical Limitation: 15.9 (5.1, 26.7)
- SAQ Quality of Life: 27.3 (16.5, 38.0)

Effect of Procedural Success


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ERCTO Registry
Significant Improvement of Angina and Dyspnea

Galassi et al, JACC. 2015
Ischemia

- N=1697

The Canadian Multicenter Chronic Total Occlusions Registry

Collateral flow in CTO

European Heart Journal (2006) 27, 2406–2412
Coronary Collaterals

Rentrop Classification

Grades of collateral filling from the contralateral vessel

• Experimental data: 90% stenosis of an epicardial coronary artery
• Provides adequate LV contractility
• Provides adequate metabolic needs in hibernating myocardium

Specific pts
Specific cnd

0: none
1: filling of side branches of the artery to be dilated via collateral channels without visualization of the epicardial segment
2: partial filling of the epicardial segment via collateral channels;
3: complete filling of the epicardial segment of the artery being dilated via collateral channels.

Changes in Collateral Channel Filling Immediately After Controlled Coronary Artery Occlusion by an Angioplasty Balloon in Human Subjects

K. Peter Rentrop, MD, FACC, Marc Cohen, MD, FACC, Heiner Blanke, MD, Robert A. Phillips, MD, PhD
New York, New York

CLINICAL STUDIES

www.HCS.GR

70 ΧΡΟΝΙΑ ΚΑΡΔΙΟΛΟΓΙΑΣ (ΕΚΕ)
70 YEARS OF CARDIOLOGY (HSC)
38o ΠΑΝΕΛΛΗΝΙΟ ΕΠΕΤΕΙΑΚΟ ΣΥΝΕΔΡΙΟ
38th ANNIVERSARY PANHELLENIC CONGRESS
Ischemia LVEF improved 3 years after PCI at CTO

MRI N= 21
Before, 5m, 3yrs
2 viability indexes used transmural extent of infarction (TEI) and end-diastolic wall thickness

Am J Cardiol 2008;101:179–185
Ischemia FFR@CTO

N=50/50

Catheterization and Cardiovascular Interventions 2014;83:9–16
FFR was similar in patients with poorly developed (CC 0), intermediate (CC 1), and well developed (CC 2) collaterals

Catheterization and Cardiovascular Interventions 2014;83:9–16
Ischemia FFR@CTO

Catheterization and Cardiovascular Interventions 2014;83:9–16
Prognostic Impact of CTO
SCAAR (Swedish Registry)

HR: 1.41 95% CI: 1.35-1.48
p-value: <0.001

Cumulative Mortality (%)

Time in years

Number at Risk

CTO
non CTO

0 1 2 3 4 5 6
14,269 11,009 9,015 7,163 5,447 3,797 1,773
74,373 58,408 47,639 37,365 28,218 19,270 9,204

Prognostic Impact of CTO in Ischemic HF
COMMIT-HF Registry

12-month mortality

p log rank < 0.001

Patients at risk:

- CTO: 278, 259, 246, 230, 224
- Non-CTO: 397, 378, 366, 360, 356

# CTO-PCI and Long-Term Survival Metanalysis

<table>
<thead>
<tr>
<th>Study</th>
<th>PCI success</th>
<th>PCI failure</th>
<th>Odds ratio [95%CI]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warren</td>
<td>0 26</td>
<td>0 18</td>
<td>* (excluded)</td>
</tr>
<tr>
<td>Ivanhoe</td>
<td>19 317</td>
<td>11 158</td>
<td>0.85 [0.37, 2.04]</td>
</tr>
<tr>
<td>Angioi</td>
<td>3 93</td>
<td>2 108</td>
<td>1.77 [0.20, 21.52]</td>
</tr>
<tr>
<td>Olivari</td>
<td>2 286</td>
<td>3 83</td>
<td>0.19 [0.02, 1.68]</td>
</tr>
<tr>
<td>Hoye</td>
<td>59 567</td>
<td>51 304</td>
<td>0.58 [0.38, 0.88]</td>
</tr>
<tr>
<td>Drozd</td>
<td>10 280</td>
<td>4 149</td>
<td>1.34 [0.38, 5.96]</td>
</tr>
<tr>
<td>Arslan</td>
<td>38 117</td>
<td>27 115</td>
<td>1.57 [0.85, 2.93]</td>
</tr>
<tr>
<td>Valent</td>
<td>3 344</td>
<td>0 142</td>
<td>2.92 [0.17, infinity]</td>
</tr>
<tr>
<td>Labriole</td>
<td>0 127</td>
<td>0 40</td>
<td>* (excluded)</td>
</tr>
<tr>
<td>Chen</td>
<td>4 132</td>
<td>3 20</td>
<td>0.18 [0.03, 1.34]</td>
</tr>
<tr>
<td>Lee</td>
<td>3 251</td>
<td>1 82</td>
<td>0.98 [0.08, 52.0]</td>
</tr>
<tr>
<td>Mehran</td>
<td>71 1226</td>
<td>30 565</td>
<td>1.10 [0.70, 1.76]</td>
</tr>
<tr>
<td>Jolicoeur</td>
<td>8 213</td>
<td>4 133</td>
<td>1.26 [0.33, 5.82]</td>
</tr>
<tr>
<td>Yang</td>
<td>1 87</td>
<td>0 49</td>
<td>1.72 [0.01, infinity]</td>
</tr>
<tr>
<td>Borgia</td>
<td>8 237</td>
<td>9 65</td>
<td>0.22 [0.07, 0.67]</td>
</tr>
<tr>
<td>Niccoli</td>
<td>2 196</td>
<td>5 121</td>
<td>0.24 [0.02, 1.50]</td>
</tr>
<tr>
<td>Yamamoto</td>
<td>30 1192</td>
<td>15 332</td>
<td>0.43 [0.23, 0.81]</td>
</tr>
<tr>
<td>Kim</td>
<td>9 2045</td>
<td>3 523</td>
<td>0.77 [0.19, 4.42]</td>
</tr>
<tr>
<td>TOTAL</td>
<td>270 7736</td>
<td>168 3007</td>
<td>0.73 [0.52, 1.03]</td>
</tr>
</tbody>
</table>

![Odds ratio meta-analysis plot (random effects)](image-url)

*Favors success* vs *Favors failure*
Prognostic Impact of Successful CTO PCI Corean Registry

Death

- Log rank $P = 0.83$

Death or Q-wave myocardial infarction

- Log rank $P = 0.94$

<table>
<thead>
<tr>
<th>Years after PCI</th>
<th>No. of patients at risk</th>
<th>Success</th>
<th>Failure</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1004 891 763 638 543</td>
<td>169 147 139 126 111</td>
<td></td>
</tr>
</tbody>
</table>

Lee et al. J Am Coll Cardiol Intv. 2016
CTO in STEMI

Explore Trial Design

• **Patients**
  Patients with STEMI treated with pPCI and with a non-infarct related CTO.

• **Design**
  Global, multi-center, randomized, prospective two-arm trial with either PCI of the CTO or no CTO intervention after STEMI. Blinded evaluation of endpoints.

• **Objective**
  To determine whether PCI of the CTO within 7 days after STEMI results in a higher LVEF and a lower LVEDV assessed by MRI at 4 months.
## CTO-PCI treatment arm

<table>
<thead>
<tr>
<th>CTO-PCI (n=147)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of days from primary PCI to CTO PCI (mean, SD)</td>
<td>5 (±2)</td>
</tr>
<tr>
<td>Number of days from randomization to CTO PCI (mean, SD)</td>
<td>2 (±2)</td>
</tr>
<tr>
<td>Multiple CTO arteries treated</td>
<td>6 (4%)</td>
</tr>
<tr>
<td>Technique CTO procedure</td>
<td>Antegrade only</td>
</tr>
<tr>
<td></td>
<td>124 (84%)</td>
</tr>
<tr>
<td></td>
<td>Retrograde</td>
</tr>
<tr>
<td></td>
<td>23 (16%)</td>
</tr>
<tr>
<td></td>
<td>Crossboss/ Stingray</td>
</tr>
<tr>
<td></td>
<td>5 (3%)</td>
</tr>
<tr>
<td>PCI successful, self-reported</td>
<td>117 (80%)</td>
</tr>
<tr>
<td>PCI successful, corelab adjudicated</td>
<td>106 (72%)</td>
</tr>
<tr>
<td>Everolimus eluting stent</td>
<td>95 (90%)</td>
</tr>
<tr>
<td>Number of stents used (median, IQR)</td>
<td>2 (1-3)</td>
</tr>
</tbody>
</table>
Primary Endpoint #1 (LVEF @ 4m)

<table>
<thead>
<tr>
<th></th>
<th>CTO-PCI (n=136)</th>
<th>No CTO-PCI (n=144)</th>
<th>Difference (95%CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LVEF (%)</strong></td>
<td>44.1 (12.2)</td>
<td>44.8 (11.9)</td>
<td>-0.8 (-3.6 to 2.1)</td>
<td>0.597</td>
</tr>
</tbody>
</table>
Primary Endpoint #2 (LVEDV @ 4m)

<table>
<thead>
<tr>
<th></th>
<th>CTO-PCI (n=136)</th>
<th>No CTO-PCI (n=144)</th>
<th>Difference (95%CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>LVEDV (mL)</td>
<td>215.6 (62.5)</td>
<td>212.8 (60.3)</td>
<td>2.8 (-11.6 to 17.2)</td>
<td>0.703</td>
</tr>
</tbody>
</table>
LVEF – Subgroup analyses

The image shows a subgroup analysis of LVEF (%), treatment effect estimate, and p-value for interaction. The analysis includes subgroups such as Overall, Age (<61 years, >60 years), Gender (Male, Female), Diabetes (Yes, No), Culprit location (LAD, non-LAD), Vessel Disease (2-vessel, 3-vessel), Baseline LVEF (<41%, >40%), Baseline LVEDV (< mean, > mean), CTO location (LAD, non-LAD), CTO location (Proximal, Distal), Syntax score (< mean, > mean), and PCI-CTO (favors no PCI-CTO, favors PCI-CTO).

The diagram highlights the subgroup analysis for CTO location, showing significant differences for CTO location LAD vs. non-LAD with a p-value of 0.002.
Ventricular Arrhythmias Among Implantable Cardioverter-Defibrillator Recipients for Primary Prevention Clinical Perspective (VACTO)

718 ICDs implantation

- 387 Non-ischaemic Patients
- 155 Secondary prevention
- 11 Primary prevention before 2002

165 Ischemic Patients

- 3 Coronary Angiogram information non-available

162 Patients included

71 CTO

- 0 lost to follow-up

71 Followed

91 No CTO

- 1 lost to follow-up

90 Followed

Kaplan-Meier survival curves for freedom from first appropriate device therapy in CTO and non-CTO populations.

Luis Nombela-Franco et al. Circ Arrhythm Electrophysiol. 2012;5:147-154
Optimal Medical Therapy With or Without Stenting For Coronary Chronic Total Occlusion

Seung-Jung Park, MD., PhD.

Heart Institute, University of Ulsan College of Medicine
Asan Medical Center, Seoul, Korea
Study Flow

834 patients randomized from 2010.3.22 to 2016.10.10

19 withdrew consents

398 allocated to OMT
- 310 treated with OMT
- 72 treated with PCI
- 5 treated with OMT after failed PCI
- 11 had incomplete data
  
  1-year FU
  348/357 (97.5%)
  
  3-year FU
  215/231 (93.1%)
  
  5-year FU
  87/99 (87.9%)

417 allocated to PCI
- 346 treated with PCI (success rate: 90.6%)
- 29 treated with OMT
- 36 treated with OMT after failed PCI
- 6 had incomplete data
  
  1-year FU
  344/354 (97.2%)
  
  3-year FU
  218/238 (91.6%)
  
  5-year FU
  85/102 (83.3%)
Primary End Point
(Death, MI, Stroke, Any Repeat Revascularization)

Crude HR 0.95 (95% CI, 0.74-1.22), P=0.67
Adjusted HR 0.91 (95% CI, 0.68-1.23), P=0.54
Death from any cause

Crude HR 1.50 (95% CI, 0.75-3.03), P=0.25

ITT Population

<table>
<thead>
<tr>
<th>Years since Randomization</th>
<th>OMT No. at Risk</th>
<th>PCI No. at Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>398</td>
<td>417</td>
</tr>
<tr>
<td>1</td>
<td>344</td>
<td>337</td>
</tr>
<tr>
<td>2</td>
<td>285</td>
<td>285</td>
</tr>
<tr>
<td>3</td>
<td>207</td>
<td>202</td>
</tr>
<tr>
<td>4</td>
<td>140</td>
<td>142</td>
</tr>
<tr>
<td>5</td>
<td>81</td>
<td>74</td>
</tr>
</tbody>
</table>
Death from any cause

![Graph showing the probability of cardiac death and non-cardiac death over years since randomization. The graph compares OMT and PCI groups.](chart.png)

**ITT Population**

<table>
<thead>
<tr>
<th></th>
<th>Cardiac Death</th>
<th>Non-CD</th>
</tr>
</thead>
<tbody>
<tr>
<td>OMT</td>
<td>P=0.22</td>
<td>P=0.31</td>
</tr>
<tr>
<td>PCI</td>
<td>3.6</td>
<td>1.6</td>
</tr>
<tr>
<td></td>
<td>1.9</td>
<td>1.2</td>
</tr>
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<td>81</td>
<td>74</td>
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</table>

No. at Risk

OMT  PCI

CardioVascular Research Foundation
Myocardial Infarction

Crude HR 0.77 (95% CI, 0.49-1.19), P=0.24

ITT Population

OMT

PCI

<table>
<thead>
<tr>
<th>Years since Randomization</th>
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<td>300</td>
</tr>
<tr>
<td>2</td>
<td>260</td>
<td>255</td>
</tr>
<tr>
<td>3</td>
<td>189</td>
<td>181</td>
</tr>
<tr>
<td>4</td>
<td>129</td>
<td>125</td>
</tr>
<tr>
<td>5</td>
<td>73</td>
<td>64</td>
</tr>
</tbody>
</table>
Myocardial Infarction

ITT Population

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</tbody>
</table>

Years since Randomization

Periprocedural

- OMT: 7.8%
- PCI: 9.7%
- P = 0.35

- OMT: 8.4%
- PCI: 10.7%

- OMT: 1.8%
- PCI: 1.8%
- P = 0.93

Spontaneous

- OMT: 9.4%
- PCI: 11.9%

P=0.35

P=0.93
Stroke

Crude HR 2.56 (95% CI, 0.80-8.17), P=0.11

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</tr>
<tr>
<td>5</td>
<td>77</td>
<td>74</td>
</tr>
</tbody>
</table>

OMT: Oral Medical Treatment
PCI: Percutaneous Coronary Intervention
Repeat Revascularization

Crude HR 0.81 (95% CI, 0.52-1.28), P=0.38
Repeat Revascularization

ITT Population

No. at Risk

<table>
<thead>
<tr>
<th></th>
<th>OMT</th>
<th>PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTO lesion</td>
<td>398</td>
<td>417</td>
</tr>
<tr>
<td>Non-CTO lesion</td>
<td>330</td>
<td>321</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Years since Randomization</th>
<th>OMT</th>
<th>PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>6.2</td>
<td>4.7</td>
</tr>
<tr>
<td>1</td>
<td>7.3</td>
<td>6.1</td>
</tr>
<tr>
<td>2</td>
<td>8.6%</td>
<td>14.0%</td>
</tr>
<tr>
<td>3</td>
<td>10.4%</td>
<td>11.8%</td>
</tr>
<tr>
<td>4</td>
<td>12.9%</td>
<td>15.7%</td>
</tr>
<tr>
<td>5</td>
<td>16.8%</td>
<td>18.6%</td>
</tr>
</tbody>
</table>

P = 0.93

P = 0.33
Quality of Life Measures Over Time

(A) EQ-5D Visual Analogue Scale

- Baseline: 303, 309
- 1 Mon: 284, 277
- 6 Mon: 244, 242
- 12 Mon: 231, 222

P-values:
- Baseline: P=0.58
- 1 Mon: P=0.94
- 6 Mon: P=0.29
- 12 Mon: P=0.74

(B) SAQ, Physical Limitation

- Baseline: 305, 313
- 1 Mon: 265, 276
- 6 Mon: 244, 242
- 12 Mon: 231, 222

P-values:
- Baseline: P=0.05
- 1 Mon: P=0.52
- 6 Mon: P=0.80
- 12 Mon: P=0.75

(C) SAQ, Angina Stability

- Baseline: 304, 312
- 1 Mon: 265, 276
- 6 Mon: 244, 242
- 12 Mon: 231, 222

P-values:
- Baseline: P=0.17
- 1 Mon: P=0.24
- 6 Mon: P=0.15
- 12 Mon: P=0.35

(D) SAQ, Angina Frequency

- Baseline: 304, 313
- 1 Mon: 265, 276
- 6 Mon: 244, 242
- 12 Mon: 231, 222

P-values:
- Baseline: P=0.001
- 1 Mon: P=0.26
- 6 Mon: P=0.62
- 12 Mon: P=0.86

(E) SAQ, Treatment Satisfaction

- Baseline: 304, 313
- 1 Mon: 265, 276
- 6 Mon: 244, 242
- 12 Mon: 231, 222

P-values:
- Baseline: P=0.25
- 1 Mon: P=0.06
- 6 Mon: P=0.96
- 12 Mon: P=0.89

(F) SAQ, Quality of Life

- Baseline: 304, 313
- 1 Mon: 265, 276
- 6 Mon: 244, 242
- 12 Mon: 231, 222

P-values:
- Baseline: P=0.81
- 1 Mon: P=0.28
- 6 Mon: P=0.06
- 12 Mon: P=0.90
EUROCTO TRIAL

Study flow chart

- Multivessel CAD including CTO
  - Treat non-occlusive disease by PCI before CTO with DES
  - Randomisation 2:1
  - PCI with DES + OMT (n=259)
  - OMT (n=137)
  - Success
    - Decision as per usual clinical care
      - Medical Rx
      - CABG
  - Failure
    - Clinically indicated interim PCI
    - Ongoing angina despite OMT (n=10, 7.3%)

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

- Physical limitation: P=0.022
- Anginal frequency: P=0.009
- Quality of life: P=0.049
- Anginal stability: P=0.89
- Treatment satisfaction: P=0.47

For multiple testing the significance level is 0.01

EURO CTO trial investigators

70 YEARS OF CARDIOLOGY (HSC)
38th ANNIVERSARY PANHELLENIC CONGRESS
Changes in CCS class during follow-up

P<0.001

OMT
Baseline: CCS 1, 2, 3, 4
Follow-up: CCS 1, 2, 3, 4

PCI
Baseline: CCS 1, 2, 3, 4
Follow-up: CCS 1, 2, 3, 4

EURO CTO trial investigators
OPEN CTO
Outcomes, Patient health status, and Efficiency in Chronic Total Occlusion hybrid procedures

- Co PIs: James Sapontis, Bill Lombardi
- Manager: Karen Nugent
- Statistician: Kensey Gosch
- Core Lab: Federico Gallegos
- Publications: Spertus, Cohen, Marso, Yeh, Nicholson, Federici, McCabe, Karpmpalitis, and Grantham

Define success rate, safety, health status outcomes and costs of CTO PCI
OPEN-CTO: Strategy Success

1,000 consecutive patients undergoing CTO PCI by Hybrid approach

First Strategy

- AWE: 54.7%
- ADR: 13.9%
- RD: 18.1%
- RWE: 13.3%

Second Strategy

- AWE: 11.7%
- ADR: 44%
- RD: 23.7%
- RWE: 20.6%

Successful Strategy

- AWE: 40.8%
- ADR: 24.3%
- RD: 24.6%
- RWE: 10.3%

Overall Technical Success: 86.2% (corelab) vs. 90.0% (physician)
First strategy successful 56.1% with 30.5 min switch time
QoL Improvements in Refractory Angina Patients

Refractory angina defined as angina despite 3+ medications (n=148)

Baseline | 1 year
---|---
SAQ AF | Δ 32.0
SAQ QOL | Δ 35.7
SAQ SS | Δ 32.1

Hirai et al, unpublished
OPEN-CTO: Complications

- Khan et al
- OPEN-CTO Operator Reported
- OPEN-CTO Core Lab

% with Outcome

- In-hospital Death: 0.7, 0.9, 0.9
- Periprocedural MI: 2.6, 2.6, 2.6
- Emergent CABG: 1.5, 0.7, 0.7
- Clinical Perforation: 3.4, 3.9, 4.8

### Predictors of Complications

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (per +10y)</td>
<td>1.31 (1.07, 1.60)</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>1.44 (0.83, 2.50)</td>
</tr>
<tr>
<td>BMI (per +5kg/m²)</td>
<td>0.83 (0.70, 0.99)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>0.94 (0.63, 1.41)</td>
</tr>
<tr>
<td>Current smoker</td>
<td>1.06 (0.87, 1.30)</td>
</tr>
<tr>
<td>Prior revascularization</td>
<td>1.08 (0.88, 1.30)</td>
</tr>
<tr>
<td>Chronic heart failure</td>
<td>0.83 (0.51, 1.35)</td>
</tr>
<tr>
<td>Prior stroke/TIA</td>
<td>1.20 (0.61, 2.34)</td>
</tr>
<tr>
<td>Peripheral arterial disease</td>
<td>0.91 (0.56, 1.48)</td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>1.57 (0.96, 2.59)</td>
</tr>
<tr>
<td>LV systolic dysfunction</td>
<td>0.90 (0.59, 1.37)</td>
</tr>
<tr>
<td>High-risk on non-invasive test</td>
<td>1.15 (0.73, 1.83)</td>
</tr>
<tr>
<td>Hemodynamic support pre-PCI</td>
<td>2.20 (0.45, 10.70)</td>
</tr>
<tr>
<td>Any retrograde approach</td>
<td>2.02 (1.33, 3.05)</td>
</tr>
<tr>
<td>J-CTO Score (per +1pt)</td>
<td>1.20 (1.03, 1.41)</td>
</tr>
<tr>
<td>Any radial access</td>
<td>1.11 (0.63, 1.94)</td>
</tr>
<tr>
<td>Any non-CTO lesion treated</td>
<td>1.04 (0.59, 1.84)</td>
</tr>
<tr>
<td>Deviation from hybrid algorithm</td>
<td>0.88 (0.37, 2.07)</td>
</tr>
</tbody>
</table>

**Age**

Retrograde approach

**J-CTO score**

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**tct2017**

Riley et al. Eurointervention, in press

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70 ΧΡΟΝΙΑ ΚΑΡΔΙΟΛΟΓΙΑΣ (ΕΚΕ)
70 YEARS OF CARDIOLOGY (HSC)

70th ANNIVERSARY PANHELLENIC CONGRESS
In-hospital MACE: components

MACE 3%

- MI 1%
- Tamponade requiring pericardiocentesis 0.9%
- Death 0.8%
- Re-PCI 0.3%
- Emergent CABG 0.2%
- Stroke 0.2%

NCT02061436
Mortality
(0.8%)

Causes of death

- Perforation/tamponade (6)
- Cardiogenic shock (4)
- Other cardiovascular (2)
- Unspecified (2)
- MI (1)
- Stroke (1)
- Multiple organ failure (1)
- Hemorrhagic shock (1)
- Respiratory failure (1)

Most common cause of death is perforation/tamponade.
Patient affected by CTO

Presence of symptoms

Yes

Normal wall motion or hypokinesia in CTO territory

CTO revascularization is indicated

No

Akinesia or dykinesia in CTO territory

Viability demonstration

Yes

No

<10%

Medical therapy is indicated

≥10%

Ischemic burden evaluation

CTO revascularization is indicated

Galassi et al. EHJ 2016
Hybrid approach

1. Dual injection
   - 1. Ambiguous proximal cap
   - 2. Poor distal target
   - 3. Appropriate "interventional" collaterals

   - no
     - Antegrade
       - 3. Lesion length < 20 mm
         - yes
           - Antegrade wiring
         - no
           - Antegrade dissection and reentry
             - Controlled (Stingray)
             - Wire based (LaST)

   - yes
     - Retrograde
       - 6. Retrograde true lumen puncture
       - Retrograde dissection and reentry

7. Switch Strategy
Proximal anchoring distal trapping technique in a chronic total occlusion unable to cross
Retrograde externalization of a Floppy RotaWire in a chronic total occlusion.

Synetos, Toutouzas,.. Bompotis .Int J Cardiol. 2015 Dec 15;201:160-1