Management of ST-elevation myocardial infarction - Update 2009

Late comers: which options?

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Conflict of interests

NO POTENTIAL CONFLICTS OF INTERESTS TO BE DISCLOSED
Definition

“Late comers”: The current reperfusion paradigm in STEMI is that prompt reperfusion should be attempted within 12 hours of symptoms onset* → hence “late comers” are patients presenting >12 hours after symptom onset.

* Exceptions include stuttering chest pain, or shock.
Who are the Late Comers?

- **Timing**  
  12-72 h vs >72 h

- **Hemodynamics**  
  stable vs unstable

- **Symptoms**  
  angina/heart failure/none

- **Reperfusion**  
  complete/incomplete/none

- **IRA obstruction**  
  100% vs 70-99%
Who are the Late Comers?

A heterogenous group

No reperfusion /Occluded IRA
Shock -Arrhythmia
Heart failure

Stenotic IRA
Angina
Depressed LVEF

Patent IRA
Asymptomatic
Preserved LVEF

High risk

Low risk
High risk STEMI
Cardiogenic shock

Case #1: 45 yo F presenting with hypotension, requiring vasopressor/inotropes, chest discomfort ongoing for 14-16 hours, ECG shows ST elevation V1-V4

Question:
→ Should this patient be offered emergent angiogram and PCI/CABG?
High risk STEMI

Cardiogenic shock

The SHOCK trial (Hochman et al. NEJM 1999) included patients with STEMI and shock within 54 hours of presentation (median 11.5 hours).

Hochman et al. NEJM 1999

Reynold and Hochman. Circulation 2008
High risk STEMI

Cardiogenic shock

Case #1: 45 yo F presenting with hypotension, requiring vasopressor/inotropes, chest discomfort ongoing for 14-16 hours, ECG shows ST elevation V1-V4

Question:
Should this patient be offered emergent angiogram and PCI/CABG?

Definitely yes
The “not so late” late-comers

12 to 72 hours

Case #2: 65 yo M presenting with chest pain ongoing for 16 hours, ST elevation V1-V4

Options:
→ Fibrinolysis?
Fibrinolysis **12 to 24 hours**

→ Fibrinolysis? → not a viable option

Data from >2 RCT and a meta-analysis (FTT collaborative review - Lancet 1994) suggest that the benefit of fibrinolysis for pts presenting between 12-24 hours is minimal (35-day mortality 10.0% vs 10.5%, p=NS)
The “not so late” late-comers

12 to 72 hours

Case #2: 65 yo M presenting with chest pain ongoing for 16 hours, ST elevation V1-V4

Options:
→ Fibrinolysis? NO
→ Mechanical reperfusion?
Mechanical reperfusion
12 to 72 hours

→ PCI ? → conflicting results

The BRAVE-2 study (Schoemig et al. JAMA 2005)
- 365 pts (57% TIMI 0/1 flow, 23% TIMI 2 flow)
- 12-48 h (median 23 hours)
- invasive (PCI 95%) vs conservative strategy

→ 6.8% mean reduction in infarct size

→ 45% RRR for 4-year mortality (11 vs 20%)
  (Ndrepepa et al. JAMA 2009)
Mechanical reperfusion
12 to 72 hours

→ PCI? → conflicting results

A substudy of the OAT study (Menon et al. EHJ 2009)
- 331 pts (approx 15% of all OAT pts)
- 24-72 h (median 66 hours)
- PCI of occluded IRA vs conservative strategy (approx 20% had failed thrombolysis)

→ No difference in the Kaplan-Meyer 4-year mortality (8 vs 8%)
Mechanical reperfusion
12 to 72 hours

BRAVE-2
23 hours (12-48 hours)

OAT substudy
66 hours (24-72 hours)

11% vs 20%, p=0.04
4-year mortality
57%

8% vs 8%, p=0.84
TIMI 0/1 flow
99%
Mechanical reperfusion

12 to 72 hours

→ Which is the time frame for infarct salvage?

Busk et al (Eur Heart J 2009) looked at 247 pts with total occlusion undergoing PCI within 72 hours
The “not so late” late-comers

12 to 72 hours

Case #2: 65 yo M presenting with chest pain ongoing for 16 hours, ST elevation V1-V4

Options:

→ Fibrinolysis? NO

→ Mechanical reperfusion? Possibly
  → Within 24 hours Yes
  → 24-72 hours Yes/No
The “very late” late-comers

>72 hours

Case #3: 55 yo M on day 7 after non-reperfused anterior STEMI, asymptomatic (at rest)

Question:
→ Should he be offered a coronary angiogram and late revascularization?
The “very late” late-comers

>72 hours

GUSTO - I angiographic substudy
Modified from Puma et al. Am J Cardiol 1999

- *Independent of infarct size and ejection fraction*
The “very late” late-comers

>72 hours

TOSCA-2 trial
- OAT substudy (Dzavik et al. Circulation 2006)
- paired angiograms at baseline and 12 months

Irrespective of randomization arm,
- 54% had a patent IRA and 46% did not

"patients with a patent IRA at follow-up had a greater increase in LVEF than those with an occluded artery (absolute difference of 3.0%; \( p=0.003 \))." supporting Braunwald’s Open Artery Hypothesis
The “very late” late-comers
>72 hours

ALKK study (Zeymer et al. Circulation 2003)
- 300 patients
- 8-42 days after STEMI (median 23 days)
- 1-vessel CAD (30% had total occlusion)
→ 34% RRR in the composite endpoint (p=0.020)

SWISSI II study (Erne et al. JAMA 2007)
- 201 patients
- 3-58 days after STEMI (median 32 days)
- all with silent ischemia (30% had total occlusion)
→ 80% RRR in mortality at 10 years (p<0.001)
The “very late” late-comers

>72 hours

**DECOPI study** (Steg et al. Eur Heart J 2004)
- 212 patients
- >48 hours after STEMI (median 5 days)
- all with total (100%) IRA occlusion
→ No differences in outcome (but > LVEF increase with PCI)

**OAT study** (Hochman et al. N Engl J Med 2006)
- 2,166 patients
- 3-28 days after STEMI (median 8 days)
- all with total (100%) IRA occlusion (88% collaterals)
→ No differences in outcome (but ↓ angina with PCI and a trend in more favorable remodeling [TOSCA-2 substudy])
The “very late” late-comers

>72 hours

Case #3: 55 yo M on day 7 after non-reperfused anterior STEMI, asymptomatic (at rest).

Question:
→ Should he be offered a coronary angiogram and late revascularization?

CONFLICTING DATA FROM RCT
The “very late” late-comers

>72 hours

Better late than never?
Modified from Abbate et al. J Am Coll Cardiol 2008

- A meta-analysis of 10 studies \( \rightarrow \) 3,560 patients
- late PCI of the infarct-related artery \( >12h \) of AMI
- median 12 days (range 1-26 days) after AMI
- 10 studies \( \rightarrow \) over more than 15 years
- variable inclusion and exclusion criteria
- variable interventional and non-interventional tx
The “very late” late-comers

>72 hours

Better late than never?

Modified from Abbate et al. J Am Coll Cardiol 2008

<table>
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<th>95% CI</th>
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<td>TOPS</td>
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<tr>
<td>Total (95% CI)</td>
<td>0.51</td>
<td>[0.29, 0.91]</td>
</tr>
</tbody>
</table>

3 studies showed a mortality benefit

Median F/U: 2.8 years

\[ P = 0.03 \]

6.3% vs 8.4%

Favours PCI  
Favours medical Rx
The “very late” late-comers

>72 hours

Better late than never?
Modified from Abbate et al. J Am Coll Cardiol 2008

Late PCI lead also to:
- A greater increase in LVEF (+4.4%, p=0.009)
- A smaller increase in EDVi (-7.0 ml/m2, p=0.008)
- A smaller increase in ESVi (-7.5 ml/m2, p=0.004)

Even if analyzing the study with 100% IRA occlusion alone (Appleton et al. Cath Cardiovasc Int 2008):
LVEF (+3.0%, p<0.001), EDVi (-5.1 ml/m2, p=0.02), ESVi (-5.2 ml/m2, p<0.001)
The “very late” late-comers >72 hours
Better late than never?
Modified from Abbate et al. J Am Coll Cardiol 2008

A meta-regression analysis showed:
- Greater length of follow up predicted survival benefit and change in LVEF with PCI
- Studies enrolling also IRA 70-99% obstruction (representing 4 of the 10 studies, 16% of patients) more likely to be positive
- Studies that did not exclude patient with > moderate ischemia were also more likely to be positive
The “very late” late-comers

>72 hours

Case #3: 55 yo M on day 7 after non-reperfused anterior STEMI, asymptomatic (at rest).

Question:
→ Should he be offered a coronary angiogram and late revascularization?
→ If the IRA 70-99% stenosed → Yes
→ If angina/ischemia present → Yes
→ If no angina/IRA 100% → Yes/No
What do the ACC/AHA guidelines recommend?

**Beyond 24 hours**

- **NO REPERFUSION +**
  - Cardiogenic shock (class IIa)
  - Decomp CHF (class IIa)
  - Ventr arrhythmias (class IIa)

- **selected patients**

- Angiography

- **NO REPERFUSION +**
  - Late PCI >24h after AMI is not indicated
  - Class III for totally occluded artery
  - Class IIb for 70-99% stenosis

- **Conservative Management**

Focused update: Antman et al. J Am Coll Cardiol 2008
What do the ESC guidelines recommend?

**Beyond 12 hours**

12-24 hours
- Persistent pain (class IIa)
- Asymptomatic (class IIb)

>24 hours
- Stable patient
- Late PCI >24h after AMI is not indicated
  - Class III for totally occluded artery
  - No mention of IRA 70-99% stenosis

Angiography

Conservative Management

Van der Werf et al. Eur Heart J 2008
Conclusions

1) STEMI 'late comers' represents a heterogeneous group of patients

2) The benefits of late reperfusion are largely variable

3) A patient-tailored approach is preferable weighing risk/benefits, patients' preference, and physician judgment

4) To date <4,000 pts have been studied → calling for more RCT to address these questions
My approach

*This proposed approach may be in disagreement with current AHA/ACC or ESC guidelines*
For further slides on these topics please feel free to visit the metcardio.org website:

http://www.metcardio.org/slides.html
THE END
Who are the Late Comers?

- **12-72 hours**
  - No Reperfusion
  - Total IRA occlusion

- **>72 hours**
  - No Reperfusion
  - Partial Reperfusion

- **Reperfusion**
  - Critical IRA Stenosis (>70%)
The “very late” late-comers

>72 hours

What about the risk of recurrent AMI

Modified from Abbate et al. J Am Coll Cardiol 2008

**Review:** Late percutaneous coronary intervention for infarct-related artery occlusion

**Comparison:** Late percutaneous coronary intervention vs best medical therapy for infarct-related artery occlusion

**Outcome:** Non-fatal Myocardial infarction

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<th>Medical Rx n/N</th>
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<tbody>
<tr>
<td>ALKK</td>
<td>3/149</td>
<td>7/151</td>
<td>0.42 [0.11, 1.67]</td>
<td></td>
</tr>
<tr>
<td>BRAVE-2</td>
<td>5/182</td>
<td>4/183</td>
<td>1.26 [0.33, 4.78]</td>
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<tr>
<td>DECOPI</td>
<td>3/109</td>
<td>2/103</td>
<td>1.43 [0.23, 8.73]</td>
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<tr>
<td>Horie et al</td>
<td>3/44</td>
<td>7/39</td>
<td>0.33 [0.08, 1.40]</td>
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<tr>
<td>OAT</td>
<td>59/1082</td>
<td>44/1084</td>
<td>1.36 [0.91, 2.03]</td>
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</tr>
<tr>
<td>Silva et al</td>
<td>0/18</td>
<td>0/18</td>
<td>Not estimable</td>
<td></td>
</tr>
<tr>
<td>SWISSI II</td>
<td>11/96</td>
<td>40/105</td>
<td>0.21 [0.10, 0.44]</td>
<td></td>
</tr>
<tr>
<td>TOAT</td>
<td>3/32</td>
<td>1/34</td>
<td>3.41 [0.34, 34.65]</td>
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</tr>
<tr>
<td>TOMIIS</td>
<td>0/25</td>
<td>0/19</td>
<td>Not estimable</td>
<td></td>
</tr>
<tr>
<td>TOPS</td>
<td>5/42</td>
<td>0/45</td>
<td>13.35 [0.71, 249.24]</td>
<td></td>
</tr>
</tbody>
</table>

**Total (95% CI):**

PCI: 1779, Medical Rx: 1781

**Total events:** 92 (PCI), 105 (Medical Rx)

**Test for heterogeneity:** Chi² = 26.96, df = 7 (P = 0.0003), I² = 74.0%

**Test for overall effect:** Z = 0.36 (P = 0.72)

<table>
<thead>
<tr>
<th>Favours PCI</th>
<th>Favours medical Rx</th>
</tr>
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<tr>
<td>0.86 [0.38, 1.95]</td>
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</table>
The OAT in perspective

“We opened those patients that we thought should be opened and any patient left went to OAT”

Anonymous Investigator Quote
### OAT: Who Were They?

<table>
<thead>
<tr>
<th>Category</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>58</td>
</tr>
<tr>
<td>Class I</td>
<td>83%</td>
</tr>
<tr>
<td>Throm. Therapy</td>
<td>20%</td>
</tr>
<tr>
<td>Time from MI to Randomization</td>
<td>8 days</td>
</tr>
<tr>
<td>Stress test</td>
<td>27%</td>
</tr>
<tr>
<td>Ischemia mild/none</td>
<td>90%</td>
</tr>
<tr>
<td>SVD</td>
<td>82% (50% RCA)</td>
</tr>
</tbody>
</table>

Stable, untreated, non-ischemic, young, single vessel, 1 week out......
Who sees these???????
Coronary Intervention for Persistent Occlusion After Myocardial Infarction (OAT Trial)

Critical Review

1. Extraordinary amount of time to recruit
2. Study underpowered for endpoints
3. Represents a very small % of post-MI pts
4. Most had no viability in distribution of IRA
5. Only 8% had DES
6. No statistically significant difference in primary or secondary endpoints
7. 89% of stented pts had patent artery at 1 year
8. Long term F/U incomplete – only 44% to 3 years
9. Data meaningless in treating most post-MI pts
Mechanical reperfusion
12 to 72 hours

→ PCI? → clinical benefit? → BRAVE-2 study

90-day mortality

- Schoemig et al. JAMA 2005
  - 4% vs 6%, p=0.39

4-year mortality

- Ndrepepa et al. JAMA 2009
  - 11% vs 20%, p=0.04

Median time to randomization 23 hours (absolute range 12-48 hours)
Mechanical reperfusion

12 to 72 hours

→ PCI? → clinical benefit? → OAT substudy

4-year Kaplan-Meyer survival curve

8% vs 8%, p=0.88

Mean time 66 hours (range 24-72)

Menon et al. Eur Heart J 2009
Mechanical reperfusion 12 to 72 hours

→ Is there a Role for an Early Viability Study?

The VIAMI study (abstract presentation - Gruberg - 2006)
- 291 pts (approx 50% post-lytics)
- Low-dose dobutamine 48-72 h after MI
  → viability → randomized to PCI or cons tx
  → no viability → registry

→ In 'viable' pts, PCI lead to a reduction in events (D/MI/UA) (16% vs 7%, p=0.04)
→ The 'non-viable' pts had lowest rate (5%)
Variable risk / variable benefit

**ALKK**

**SWISSI 2**

**DECOPI**

**OAT**
The “very late” late-comers

>72 hours

The ALKK study (Zeymer et al. Circulation 2003)
randomized patients with 1-vessel CAD, 8-42 days after STEMI, to PCI vs conserv ther

Event rates 38% vs 25%, p=0.02 favoring PCI

Of note:
>70% pts had IRA stenosis <100%,
Pts with 100% IRA occlusion had less benefit
The “very late” late-comers

>72 hours

The SWISSI-2 study (Erne et al. JAMA 2007) randomized patients with 3-58 days after STEMI to PCI vs conservative therapy

Death rate 3% vs 21%, p=0.01 favoring PCI

Of note:
>70% pts had IRA stenosis <100%,
All pts had inducible silent ischemia

>10-year F/U
The “very late” late-comers

>72 hours

A substudy of the SWISSI-2 study (Schoenenberger et al. Am J Cardiol 2009) looked at sudden death in PCI vs conservative therapy

Sudden Death 1% vs 11%, p=0.002 favoring PCI

Of note:
>70% pts had IRA stenosis <100%,
All pts had silent ischemia
The risk of sudden death was related to LVEF decline
The “very late” late-comers

>72 hours

The DECOPI study (Steg et al. Eur Heart J 2004) randomized patients with >48 hours after STEMI to PCI vs conservative therapy

No differences in outcome

>4-year F/U

Of note:
All pts had 100% IRA stenosis

PCI was associated with greater LVEF increase
The “very late” late-comers

>72 hours

The OAT study (Hochman et al. N Engl J Med 2006) is the largest (>2,000 pts) randomized trial of late PCI vs conservative therapy.

No differences in outcome

Of note:
All pts had 100% IRA stenosis

Median follow up <3 yrs
The "very late" late-comers

>72 hours

The OAT study (Hochman et al. N Engl J Med 2006) is the largest (>2,000 pts) randomized trial of late PCI vs conservative therapy

Fewer patients had angina w/ PCI up to 24 months

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<thead>
<tr>
<th></th>
<th>PCI</th>
<th>MED</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Num (%)</td>
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<td></td>
</tr>
<tr>
<td>Angina Pectoris</td>
<td></td>
<td></td>
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<tr>
<td>4-Month</td>
<td>190/1015 (18.7)</td>
<td>256/1026 (25.0)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>12-Month</td>
<td>158/964 (16.4)</td>
<td>211/958 (22.0)</td>
<td>0.002</td>
</tr>
<tr>
<td>24-Month</td>
<td>101/735 (13.7)</td>
<td>128/728 (17.6)</td>
<td>0.04</td>
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</table>
The “very late” late-comers

>72 hours

The TOSCA-2 trial is a substudy of the OAT (Dzavik et al. Circulation 2006) in which patients had paired angiograms at baseline and 12 months.

Patients in the PCI group tended to have a more favorable remodeling

17% of PCI group had late IRA occlusion
25% of MED had late IRA patency
The “very late” late-comers

>72 hours

Better late than never?

Modified from Abbate et al. J Am Coll Cardiol 2008

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<td>5/39</td>
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<td>0.18 [0.01, 3.99]</td>
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<td>22/105</td>
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<td>2.20 [0.19, 25.52]</td>
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<tr>
<td>TOMIIS</td>
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<td>1/19</td>
<td>0.75 [0.04, 12.82]</td>
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Total events: 112 (PCI), 149 (Medical Rx)
Test for heterogeneity: Chi² = 19.36, df = 8 (P = 0.01), I² = 58.7%
Test for overall effect: Z = 2.15 (P = 0.03)

Outcome: Death
Late presentation / No reperfusion

Better late than never?  
Modified by Abbate et al. J Am Coll Cardiol 2008

Meta-analysis of 3,560 patients from 10 different RCTs

Outcome: Death

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Outcome model

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Favour PCI  
Favours medical Rx

(NNT 48)
Why such a difference in outcome?

Longer follow up \(\rightarrow\) greater benefit

### Review
Late percutaneous coronary intervention for infarct-related artery occlusion

### Comparison
Late percutaneous coronary intervention vs best medical therapy for infarct-related artery occlusion

### Outcome
Death

<table>
<thead>
<tr>
<th>Study or sub-category</th>
<th>PCI n/N</th>
<th>Medical Rx n/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALKK</td>
<td>6/149</td>
<td>17/151</td>
</tr>
<tr>
<td>BRAVE-2</td>
<td>4/18</td>
<td>8/183</td>
</tr>
<tr>
<td>DECOPI</td>
<td>8/109</td>
<td>9/103</td>
</tr>
<tr>
<td>Horie et al</td>
<td>1/44</td>
<td>5/39</td>
</tr>
<tr>
<td>OAT</td>
<td>87/1</td>
<td>84/1084</td>
</tr>
<tr>
<td>Silva et al</td>
<td>0/1</td>
<td>2/18</td>
</tr>
<tr>
<td>SWISSI II</td>
<td>3/</td>
<td>22/105</td>
</tr>
<tr>
<td>TOAT</td>
<td>2/32</td>
<td>1/34</td>
</tr>
<tr>
<td>TOMIIS</td>
<td>1/2</td>
<td></td>
</tr>
<tr>
<td>TOPS</td>
<td>0/42</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td>1779</td>
<td>1781</td>
</tr>
<tr>
<td><strong>Total events:</strong> 112 (PCI), 149 (Medical Rx)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for heterogeneity:</strong> (\chi^2 = 19.36, \text{df} = 8) ((P = 0.01))</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for overall effect:</strong> (Z = 2.15) ((P = 0.03))</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Data from the recent BRAVE-2 publication not included
Why such a difference in outcome?

Presence of ischemia and/or suboccluded IRA → greater benefit

Review: Late percutaneous coronary intervention for infarct-related artery occlusion

Comparison: Late percutaneous coronary intervention vs best medical therapy for infarct-related artery occlusion

Outcome: Death

<table>
<thead>
<tr>
<th>Study or sub-category</th>
<th>PCI</th>
<th>Medical Rx</th>
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</thead>
<tbody>
<tr>
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<td>3/</td>
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<td>2/32</td>
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</tr>
<tr>
<td>TOMIIS</td>
<td>1/2</td>
<td></td>
</tr>
<tr>
<td>TOPS</td>
<td>0/42</td>
<td></td>
</tr>
</tbody>
</table>

Total (95% CI) 1779 1781
Total events: 112 (PCI), 149 (Medical Rx)
Test for heterogeneity: Chi² = 19.36, df = 8 (P = 0.01), I² = 58.7%
Test for overall effect: Z = 2.15 (P = 0.03)

Outcome: Death (NNT 48)

<table>
<thead>
<tr>
<th>Study or sub-category</th>
<th>OR (random)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALKK</td>
<td>0.33</td>
<td>[0.13, 0.86]</td>
</tr>
<tr>
<td>BRAVE-2</td>
<td>0.49</td>
<td>[0.15, 1.66]</td>
</tr>
<tr>
<td>DECOPI</td>
<td>0.83</td>
<td>[0.31, 2.23]</td>
</tr>
<tr>
<td>Horie et al</td>
<td>0.16</td>
<td>[0.02, 1.42]</td>
</tr>
<tr>
<td>OAT</td>
<td>1.04</td>
<td>[0.76, 1.42]</td>
</tr>
<tr>
<td>Silva et al</td>
<td>0.18</td>
<td>[0.01, 3.99]</td>
</tr>
<tr>
<td>SWISSII</td>
<td>0.75</td>
<td>[0.04, 12.82]</td>
</tr>
<tr>
<td>TOAT</td>
<td>2.20</td>
<td>[0.19, 25.52]</td>
</tr>
<tr>
<td>TOMIIS</td>
<td>0.49</td>
<td>[0.04, 12.82]</td>
</tr>
<tr>
<td>TOPS</td>
<td>Not estimable</td>
<td></td>
</tr>
</tbody>
</table>

0.49 [0.26, 0.94]
Five-year Kaplan-Meier actuarial cardiac survival and event-free curves for the PTCA (n=44) and no-PTCA (n=39) groups. With regard to cardiac survival, no significant difference was observed between the 2 groups. However, the no-PTCA group had worse prognosis. With regard to cardiac events (including cardiac death, nonfatal reoccurrence of MI, and development of CHF), the PTCA group had better prognosis than the no-PTCA group during the 5-year period.
Mechanical reperfusion
12 to 72 hours

→ Is there a Role for an Early Viability Study?

The VIAMI study (abstract presentation - Gruberg - 2006)
- 291 pts (approx 50% post-lytics) 48-72 h after MI
- Low-dose dobutamine
  → viability → randomized to PCI or cons tx
  → no viability → registry

→ In ‘viable’ pts, PCI lead to a reduction in events (D/MI/UA) (16% vs 7%, p=0.04)
→ The ‘non-viable’ pts had lowest event rate