Primary PCI – Current developments and implementation

SD Kristensen
MD, DMSc, FESC
Department of Cardiology
Aarhus University Hospital Skejby
Denmark
Conflicts of interest

- Lecture fees/advisory boards: AstraZeneca, Daiichi-Sankyo, Eli Lilly, The Medicines Company
ESC guidelines on STEMI 2008

PRIMARY PCI: IA

Preferred therapy if performed within 120 minutes

90 minutes for patients presenting within 2-3 hours
Talk overview

- Why 24/7 STEMI centres?
- Can we improve the outcome of primary PCI?
- Logistics – how can we shorten the time to reperfusion?
- Implementation of PPCI in Europe – Stent for life project
Transport time to cath lab > 2 hours
Thrombolysis (prehospital)
Rescue PCI if necessary

Transport time to cath lab > 2 hours

REACT Study
_N Engl J Med_ 2005
Antiplatelet and Fibrinolytic Treatment: CARESS-in-AMI

ASA 300-500 mg iv

UFH (40 U/kg (max 3000); 7 U/kg/h)

2 x 5 U bolus (30’) Reteplase

Abciximab 0.25 mg/kg bolus 0.125 μg/kg/min x 12 h

IMMEDIATE PCI n=294

MEDICAL TREATMENT + RESCUE n=298

C Di Mario et al Lancet 2008
Comb. Primary EP at 30 days

[Clinical graph showing the proportion of patients having an event over time. The graph compares Med. Treatment/Rescue (4.1%) vs. Immediate PCI (11.1%). The difference is statistically significant (P<0.001).]

C Di Mario et al, Lancet 2008
Rate of Ischemic Events at the Available Follow-up

<table>
<thead>
<tr>
<th>Study</th>
<th>Routine early PCI</th>
<th>Selective Invasive Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAPITAL-AMI (n=170)</td>
<td>11.6%</td>
<td>24.4%</td>
</tr>
<tr>
<td>CARESS-In-AMI (n=588)</td>
<td>4.4%</td>
<td>10.7%</td>
</tr>
<tr>
<td>SIAM-III (n=103)</td>
<td>25.6%</td>
<td>50.6%</td>
</tr>
<tr>
<td>TRANSFER-AMI (n=1089)</td>
<td>11.0%</td>
<td>17.1%</td>
</tr>
<tr>
<td>GRACIA-1 (n=409)</td>
<td>8.8%</td>
<td>20.3%</td>
</tr>
<tr>
<td>NORDISTEMI (n=208)</td>
<td>10.0%</td>
<td>21.0%</td>
</tr>
</tbody>
</table>

Time from Fibrinolysis to Routine Early PCI (hr):

- CAPITAL-AMI: 1.6
- CARESS-In-AMI: 2.3
- SIAM-III: 3.7
- TRANSFER-AMI: 3.9
- GRACIA-1: 16.7
- NORDISTEMI: 2.7
Early presenters

- CAPTIM substudy
- < 3 hours: room for prehospital thrombolysis?
STEMI ambulance patients presenting early, <3 h (n=2500)
Large amount of ischaemic but viable myocardium
and acceptable bleeding risk

STREAM: Study on a pharmaco-invasive strategy

TNK bolus
Aspirin
Clopidogrel
ENOX (EXTRACT)

Transfer
Immediate PCI only if failed thrombolysis (<50% ST resolution)
otherwise angiography 12–24 hours

Aspirin
Clopidogrel
Antithrombotic (left to investigator)

Transfer
PCI mandatory

Endpoints of interest:
death, recurrent MI, shock, CHF, stroke

TNK, tenecteplase; ENOX, enoxaparin
Late presenters

- >12 hours ongoing ischaemia (IIaC)
- 12-24 hour (stable) (IIbB)
- >24 hours occluded vessel (IIIb)
• BRAVE-2
• Reduction of infarct size in patients treated with PCI compared to medical therapy.

Schoemig et al JAMA 2005
Symptom duration > 12 hours

Infarct size and myocardial salvage after primary angioplasty in patients presenting with symptoms for <12 h vs. 12–72 h


1Department of Cardiology, Aarhus University Hospital, Skejby, Brendstrupgaardsvej 100, Aarhus 8200, Denmark; and 2Department of Nuclear Medicine, Aarhus University Hospital, Skejby, Aarhus, Denmark

Received 8 December 2008; revised 14 January 2009; accepted 4 March 2009
Salvage index

Linear regression:
- p=0.02
- $R^2=0.02$

69 % (45-92) vs. 53 % (27-89)
- p=0.06

(n=262)
Establish PCI centers with 24/7 service
Talk overview

• Why 24/7 STEMI centres?
• Can we improve the outcome of primary PCI?
• Implementation of PPCI in Europe
• Logistics – how can we shorten the time to reperfusion?
Microvascular Obstruction

Stagnation thrombus

14 atm

Plaque rupture with atheromatous gruel

Embolisation

Microvascular Plugging

Microvascular Spasm or Edema

Platelet Aggregation

Collaterals ???
ESC STEMI Guidelines 2008

Adjunctive therapy: primary PCI

• Aspirin
  – A bolus of 150–325 mg (chewable) or 250–500 mg IV followed by lifelong therapy IB

• Clopidogrel
  – Bolus 300 mg or 600 mg IC

• Heparin
  – 100 U/kg (60 U/kg with GpIIb/IIIa) IC

Gp, glycoprotein; STEMI, ST-segment elevation myocardial infarction
ESC STEMI Guidelines 2008

- Abciximab IIa A
- Bivalirudin IIa B
- Thrombus aspiration IIb B
### Primary PCI: abciximab in cath lab

#### Death / MI / urg TVR at 30 days

<table>
<thead>
<tr>
<th>Study</th>
<th>Incidence (%)</th>
<th>Placebo ↓</th>
<th>ReoPro ↓</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>RAPPORT (n=483)</td>
<td>11.2</td>
<td>5.8</td>
<td>5.4</td>
<td>0.03</td>
</tr>
<tr>
<td>ISAR-2 (n=401)</td>
<td>10.5</td>
<td>5.0</td>
<td>5.5</td>
<td>0.04</td>
</tr>
<tr>
<td>ADMIRAL (n=300)</td>
<td>14.6</td>
<td>6.1</td>
<td>8.5</td>
<td>0.02</td>
</tr>
<tr>
<td>CADILLAC (n=2082)</td>
<td>6.7</td>
<td>4.3</td>
<td>2.4</td>
<td>0.01</td>
</tr>
<tr>
<td>ACE (n=400)</td>
<td>10.5</td>
<td>4.5</td>
<td>6.0</td>
<td>0.02</td>
</tr>
</tbody>
</table>

**Note:** Table shows the incidence of Death / MI / urgent TVR at 30 days for various studies with and without abciximab (ReoPro). The p-values indicate statistical significance of the differences between the placebo and ReoPro groups.
“Facilitated” PCI - still an option with thrombolytic agents/GP IIb/IIIa?
Adjunctive therapy: primary PCI

- Not recommended:
  Upstream therapy with GPI, fibrinolytics or the combination.
Prehospital initiation of tirofiban in patients with ST-elevation myocardial infarction undergoing primary angioplasty (On-TIME 2): a multicentre, double-blind, randomised controlled trial

Arnoud W J van’t Hof, Jurrien ten Berg, Ton Heestermans, Thorsten Dill, Reinhard C Funck, Wouter van Werkum, Jan-Henk E Dambrink, Harry Suryapranata, Gert van Houwelingen, Jan Paul Ottervanger, Pieter Stella, Evangelos Giannitsis, Christian Hamm, on behalf of the Ongoing Tirofiban In Myocardial infarction Evaluation (On-TIME) 2 study group*

Summary

Background The most effective magnitude and timing of antiplatelet therapy is important in patients with acute...
Acute myocardial infarction diagnosed in ambulance or referral center
ASA + 600 mg Clopidogrel + UFH

Placebo

Tirofiban *

Transportation

PCI center

PCI

Angiogram

Tirofiban provisional

Angiogram

Tirofiban cont’d

N=984

*Bolus: 25 µg/kg & 0.15 µg/kg/min infusion
Primary endpoint: residual ST Deviation one hour after PCI

- **Open Label**
  - Tirofiban: 3.9±6.5 mm, 18% normalized, 22% 1-3 mm, 22% 4-6 mm, 38% > 6 mm
  - no Tirofiban: 4.6±5.4 mm, 27% normalized, 18% 1-3 mm, 23% 4-6 mm, 33% > 6 mm
  - P-value: 0.097

- **Double Blind**
  - Tirofiban: 3.6±4.6 mm, 19% normalized, 19% 1-3 mm, 26% 4-6 mm, 36% > 6 mm
  - no Tirofiban: 4.8±6.3 mm, 25% normalized, 20% 1-3 mm, 26% 4-6 mm, 29% > 6 mm
  - P-value: 0.003
Survival free from Major Adverse Clinical Events

A. W. J. van 't Hof, NL, 975
ESC STEMI Guidelines 2008

- Abciximab IIa A
- Bivalirudin IIa B
- Thrombus aspiration IIb B
Harmonizing Outcomes with Revascularization and Stents in AMI

3602 pts with STEMI

Randomized

UFH + GP IIb/IIIa
N=1802

Bivalirudin Monotherapy
N=1800

R 1:1

30 day FU*

N=1778 (98.7%)

N=1777 (98.7%)

9 10

15 13

• • • Withdrew • • •

• • • Lost to FU • • •

ITT population

N=1802

N=1800

* Range ±7 days

Stone GW et al. NEJM 2008;358:2218-30
HORIZONS - bivalirudin: 30 Day Net Adverse Clinical Events

**Primary Endpoint**

Net adverse clinical events (%)*

<table>
<thead>
<tr>
<th>Time in Days</th>
<th>Heparin + GPIIb/IIIa inhibitor (n=1802)</th>
<th>Bivalirudin (n=1800)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>9.3%</td>
<td>12.2%</td>
</tr>
</tbody>
</table>

HR [95%CI] = 0.75 [0.62, 0.92]  

P=0.006

*MACE or major bleeding (non CABG)

R. Mehran, US, 977
1-Year All-Cause Mortality

Mehran, TCT 2008

<table>
<thead>
<tr>
<th></th>
<th>Bivalirudin alone (n=1800)</th>
<th>Heparin + GPIIb/IIIa (n=1802)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number at risk</td>
<td>1800</td>
<td>1802</td>
</tr>
<tr>
<td>Time in Months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>2.1%</td>
<td>1%</td>
</tr>
<tr>
<td>1</td>
<td>3.1%</td>
<td>2.1%</td>
</tr>
<tr>
<td>3</td>
<td>4.8%</td>
<td>3.4%</td>
</tr>
<tr>
<td>6</td>
<td>Diff [95%CI] = -1.5% [-2.8, -0.1]</td>
<td></td>
</tr>
<tr>
<td>HR [95%CI] = 0.69 [0.50, 0.97]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>P = 0.029</td>
<td>4.8%</td>
<td>3.4%</td>
</tr>
</tbody>
</table>

Δ = 1.0%  P = 0.049

Δ = 1.4%  P = 0.029
Bivalirudin prehospital in STEMI

EUROMAX trial
Distal protection - trombectomy
Interventional procedures – removal of embolic debris

Distal Microcirculatory Protection During Percutaneous Coronary Intervention in Acute ST-Segment Elevation Myocardial Infarction
A Randomized Controlled Trial

EMERALD, n=501

Rand
No effect

Randomized Evaluation of the Effects of Filter-Based Distal Protection on Myocardial Perfusion and Infarct Size After Primary Percutaneous Catheter Intervention in Myocardial Infarction With and Without ST-Segment Elevation

PROMISE

Rand
No effect

Distal Protection Improved Reperfusion and Reduced Left Ventricular Dysfunction in Patients With Acute Myocardial Infarction Who Had Angioscopically Defined Ruptured Plaque

Circulation 2004;110:1460

Non-rand
Effect ?
Angioscopic guidance
## Summary: Mechanical Devices to Remove Thrombus in AMI (13 RCTs)

<table>
<thead>
<tr>
<th></th>
<th>Thrombus aspiration</th>
<th>Thrombectomy</th>
<th>Distal protection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beneficial</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Harmful</td>
<td>1</td>
<td><strong>Kaltoft et al - largest</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 multicenter trials (100 – 501 pts) – 0 beneficial</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beneficial</td>
<td></td>
<td>±1</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Harmful</td>
<td></td>
<td><strong>AIMI - largest</strong></td>
<td></td>
</tr>
</tbody>
</table>
New evidence: Thrombus aspiration

- Thrombus aspiration during primary percutaneous coronary intervention.
- Cardiac death and reinfarction after 1 year in the Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS): a 1-year follow-up study.

TAPAS Primary endpoint: Myocardial blush grade

![Bar chart showing the comparison of Thrombus aspiration and Conventional PCI for patients' myocardial blush grade.](image)

- **Thrombus aspiration**
  - Grade 0/1: 17
  - Grade 2: 37
  - Grade 3: 46

- **Conventional PCI**
  - Grade 0/1: 26
  - Grade 2: 41
  - Grade 3: 32

*P < 0.001*
Mortality at 1 year

- Conventional PCI
- Thrombus-Aspiration

Log-Rank $p = 0.040$

*Unpublished results
Better ADP receptor-antagonist

- Prasugrel (TRITON TIMI 38)
- Ticagrelor (PLATO)
Prasugrel instead of clopidogrel in STEMI for 12 (15) months?

TRITON: STEMI cohort primary EP (CV death, MI and stroke at 15 months)

- **HR** = 0.79 (0.65–0.97)  \( \text{NNT} = 42 \)
- **RRR** = 21%  \( p = 0.02 \)
- Age-adjusted **HR** = 0.81 (0.66–0.99)

Montalescot et al. Lancet 2009
Ticagrelor versus Clopidogrel in Patients with Acute Coronary Syndromes

Lars Wallentin, M.D., Ph.D., Richard C. Becker, M.D., Andrzej Budaj, M.D., Ph.D., Christopher P. Cannon, M.D., Håkan Emanuelsson, M.D., Ph.D., Claes Held, M.D., Ph.D., Jay Horrow, M.D., Steen Husted, M.D., D.Sc., Stefan James, M.D., Ph.D., Hugo Katus, M.D., Kenneth W. Mahaffey, M.D., Benjamin M. Scirica, M.D., M.P.H., Allan Skene, Ph.D., Philippe Gabriel Steg, M.D., Robert F. Storey, M.D., D.M., and Robert A. Harrington, M.D., for the PLATO Investigators*
Ticagrelor vs Clopidogrel in STEMI

Primary endpoint: CV death, MI or stroke

HR: 0.85 (95% CI = 0.74–0.97), p=0.02
Should we use drug eluting stents in STEMI?
Four-year events in TYPHOON

<table>
<thead>
<tr>
<th>End point</th>
<th>Cypher (%)</th>
<th>Bare-metal stent (%)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>4.0</td>
<td>6.4</td>
<td>0.23</td>
</tr>
<tr>
<td>Cardiac death</td>
<td>3.2</td>
<td>4.8</td>
<td>0.37</td>
</tr>
<tr>
<td>MI</td>
<td>4.8</td>
<td>4.0</td>
<td>0.83</td>
</tr>
<tr>
<td>TLR</td>
<td>7.2</td>
<td>15.2</td>
<td>0.005</td>
</tr>
<tr>
<td>TVR</td>
<td>9.6</td>
<td>12.2</td>
<td>0.013</td>
</tr>
</tbody>
</table>

Spaulding C. EuroPCR 2009; May 19-22, 2009; Barcelona, Spain.
Transradial approach for STEMI?

- ACS and STEMI patients are frequently aggressively anti-coagulated with high rates of access site bleeding

- Access site bleeding is an independent predictor of mortality in ACS

- TRA lowers access site bleeding rates
Guidelines on myocardial revascularization

The Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Developed with the special contribution of the European Association for Percutaneous Cardiovascular Interventions (EAPCI)†

Authors/Task Force Members: William Wijns (Chairperson) (Belgium)*, Philippe Kolh (Chairperson) (Belgium)*, Nicolas Danchin (France), Carlo Di Mario (UK), Volkmar Falk (Switzerland), Thierry Folliguet (France), Scot Garg (The Netherlands), Kurt Huber (Austria), Stefan James (Sweden), Juhani Knuuti (Finland), Jose Lopez-Sendon (Spain), Jean Marco (France), Lorenzo Menicanti (Italy) Miodrag Ostojic (Serbia), Massimo F. Piepoli (Italy), Charles Pirlet (Belgium), Jose L. Pomar (Spain), Nicolaus Reifart (Germany), Flavio L. Ribichini (Italy), Martin J. Schalij (The Netherlands), Paul Sergeant (Belgium), Patrick W. Serruys (The Netherlands), Sigmund Silber (Germany), Miguel Sousa Uva (Portugal), David Taggart (UK)
STEMI Management

Flowchart:

1. Symptoms of STEMI
   - EMS
   - GP/cardiologist
   - Self-referral

   - Pre-hospital diagnosis & care
   - Ambulance to Cath

   - Primary PCI-capable centre

   - Primary PCI

   - Rescue PCI

   - Successful fibrinolysis?

   - Coronary angiography
     3–24 h after FMC
     Delayed PCI as required

   - Transfer to ICU
     of PCI-capable centre

   - Immediate fibrinolysis

   - Private transportation
     - Non-primary PCI-capable centre
     - PCI possible in <2 h

   - Immediate transfer to Cath Lab

   - YES
   - NO
# Table 36 Antithrombotic treatment options in myocardial revascularization

<table>
<thead>
<tr>
<th>STEMI</th>
<th>Antithrombotic Treatment</th>
<th>Level</th>
<th>Evidence</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Antiplatelet therapy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ASA</td>
<td>I</td>
<td>B</td>
<td>55, 94</td>
<td></td>
</tr>
<tr>
<td>Clopidogrel (with 600 mg loading dose as soon as possible)</td>
<td>I</td>
<td>C</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Prasugrel$^d$</td>
<td>I</td>
<td>B</td>
<td>246, 252</td>
<td></td>
</tr>
<tr>
<td>Ticagrelor$^d$</td>
<td>I</td>
<td>B</td>
<td>248, 253</td>
<td></td>
</tr>
<tr>
<td>+ GPIIb–IIa antagonists (in patients with evidence of high intracoronary thrombus burden)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abciximab</td>
<td>IIa</td>
<td>A</td>
<td>55, 94</td>
<td></td>
</tr>
<tr>
<td>Eptifibatide</td>
<td>IIa</td>
<td>B</td>
<td>259, 260</td>
<td></td>
</tr>
<tr>
<td>Tirofiban</td>
<td>IIb</td>
<td>B</td>
<td>55, 94</td>
<td></td>
</tr>
<tr>
<td>Upstream GPIIb–IIIa antagonists</td>
<td>III</td>
<td>B</td>
<td>86</td>
<td></td>
</tr>
<tr>
<td><strong>Anticoagulation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bivalirudin (monotherapy)</td>
<td>I</td>
<td>B</td>
<td>255</td>
<td></td>
</tr>
<tr>
<td>UFH</td>
<td>I</td>
<td>C</td>
<td>—</td>
<td></td>
</tr>
<tr>
<td>Fondaparinux</td>
<td>III</td>
<td>B</td>
<td>256</td>
<td></td>
</tr>
</tbody>
</table>
Earlier treatment => improved prognosis

ACUTE STEMI: early diagnosis

Immediate ECG – paramedics or doctors in the ambulance

• Telemedicine
• Prehospital thrombolysis
• Transferral for primary PCI
Pre-hospital ECG from a 56 year old male with chest pain

Example:

HR 53 bpm
PR 0.212 s
QRS 0.100 s

ST-elevation, overvej inferolateral myokardiebeskadigelse eller akut infarkt
Transmission of A 12-lead ECG To hospital.

Phone contact from hospital to patient and paramedic in the ambulance.
Organizational aspects: primary PCI

- Algorithms for transfer
- Training of ambulance staff
- Number of Centers
- Volume of PCI-centers
- Train more operators - a lot of night work
Operator based view on risk in P-PCI of STEMI
Operator based view on risk in P-PCI of STEMI
Operator based view on risk in P-PCI of STEMI
Stent for Life Initiative

Steen D. Kristensen, FESC
Chairman SFL,
Department of Cardiology
Aarhus University Hospital Skejby
Denmark
Stent for Life Initiative
European Executive Board
September 2010 - 2011

- Steen D. Kristensen/ SFL project co-chairman
- Jean Fajadet /SFL project co-chairman
- Nicolas Danchin
- Carlo Di Mario
- William Wijns
- Petr Widimsky
- Marielle de la Torre (EAPCI Executive Officer)
- Zuzana Kaifoszova (SFL Project Manager, Europe)
Stent for Life INITIATIVE

To improve the delivery and patient access to the life saving indications of PCI thereby reduce the mortality and morbidity of patients suffering from acute coronary syndromes.

www.stentforlife.com
Recommendations

• PPCI for STEMI (within 2 hours)
• Rescue PCI for failed fibrinolysis (within 12 hours)
• PCI for STEMI with shock and contraindications to fibrinolytic therapy irrespective of time delay
• Angiography and PCI after successful fibrinolysis (within 24 hours)
• Urgent PCI for hemodynamically unstable NSTE-ACS (within 2 hours)
• Early PCI for high-risk NSTE-ACS (within 72 hours)

ESC Guidelines

Stent for Life Initiative
Phase I
Situation Mapping & Data Collection
Reperfusion therapy for ST elevation acute myocardial infarction in Europe: description of the current situation in 30 countries

Petr Widimsky*, William Wijns, Jean Fajadet, Mark de Belder, Jiri Knot, Lars Aaberge, George Andrikopoulos, Jose Antonio Baz, Amadeo Betriu, Marc Claeyss, Nicholas Danchin, Slaveyko Djambazov, Paul Erne, Juha Hartikainen, Kurt Huber, Petr Kala, Milka Klinčeva, Steen Dalby Kristensen, Peter Ludman, Josephina Mauri Ferre, Bela Merkely, Davor Miličić, João Morais, Marko Noč, Grzegorz Opolski, Miodrag Ostojić, Dragana Radovanović, Stefano De Servi, Ulf Stenestrand, Martin Studenčan, Marco Tubaro, Zorana Vasiljević, Franz Weidinger, Adam Witkowski, and Uwe Zeymer on behalf of the European Association for Percutaneous Cardiovascular Interventions†

Cardiocenter, 3rd Faculty of Medicine, Charles University Prague, Czech Republic

Received 15 March 2009; revised 20 August 2009; accepted 5 October 2009
Annual incidence of hospital admissions for STEMI


82 / 100 000 inhabitants / year

(190 / 100 000 / year for all AMIs)
Reperfusion Therapies Differ in Countries

Annual Incidence of Primary PCIs

- ≥600 p-PCI / million / year
- 400-599 p-PCI / million / year
- 200-399 p-PCI / million / year
- <200 p-PCI / million / year
- Data not known
Primary PCI’s / million / year

Ø 378

PCI / million / year

CH DE PL CZ SE HU NO SLO DK IL A LIT IT SK
BE HR FR LAT PT ES SRB FIN UK BG GR TR RO

www.escardio.org/EAPCI
$\varnothing$ 20% of all PCIs are p-PCIs for STEMI
Mean population per one PCI center

Ø 518 698
Population per one primary PCI (24/7) center

Ø 917 614
Only 55% of all PCI centers offer non-stop 24/7 p-PCI service
Number of primary PCIs does not correlate to Countries’ GDP

R Sq Linear = 0.126
p=0.070
Only 51% STEMI patients arrive to the first hospital by EMS
STEMI Mortality per Treatment

- All STEMI: 9.1%
- Thrombolysis: 8.3%
- Primary PCI: 4.7%
Nationwide „thrombolytic strategy“ for STEMI results in 46% untreated patients

% from all STEMI

No reperfusion used

- Countries with p-PCI dominance
- Countries with thrombolysis dominance

www.escardio.org/EAPCI
Reperfusion Strategy Paradox

More patients receive reperfusion treatment in countries with low use of thrombolysis and high use of p-PCI
Summary

• Most North, West and Central European countries use p-PCI for the majority of their STEMI patients.

• The lack of organised p-PCI networks is associated with fewer patients overall receiving some form of reperfusion therapy.
Stent for Life Initiative

Objectives

1. Define regions/countries with an unmet medical need in the optimal treatment of ACS.

2. Implement an action program to increase patient access to primary PCI where indicated:
   - To increase the use of primary PCI to more than 70% among all ST segment elevation myocardial infarction patients,
   - To achieve primary PCI rates of more than 600 per one million inhabitants per year,
   - To offer 24/7 service for primary PCI procedures at all invasive facilities to cover the country STEMI population need.
Stent for Life Initiative
Phase II
Learning the experience from the best practice countries
How to set up an effective national primary angioplasty network: lessons learned from five European countries

Jiri Knot1*, MD; Petr Widimsky1, MD, DrSc, FESC; William Wijns2, MD, PhD, FESC; Ulf Stenestrand3, MD, PhD; Steen Dalby Kristensen4, MD, PhD, FESC; Arnoud van’t Hof5, MD, PhD; Franz Weidinger6, MD, PhD, FESC; Magnus Jansson3, MD, PhD; Bjarne Linde Nørgaard7, MD, PhD; Jacob Thorsted Soerensen4, MD; Henri van de Wetering8, MA, ANP; Kristian Thygesen9, MD, DMSc, FESC; Per-Adolf Bergsten10, MD; Christofer Digerfeldt11, MD; Adriaan Potgieter12, MD; Nadav Tomer13, BSc, MBA; Jean Fajadet14, MD, PhD, FESC on behalf of the “Stent for Life” Initiative

1. Cardiocenter, Department of Cardiology, 3rd Faculty of Medicine Charles University and University Hospital Kralovske Vinohrady, Prague, Czech Republic; 2. Cardiovascular Center Aalst, Aalst, Belgium; 3. Department of Cardiology, University Hospital, Linköping, Sweden; 4. Department of Cardiology, Aarhus University Hospital Skejby, Århus, Denmark; 5. Department of Cardiology, Isala Klinieken, locatie Wezenlanden, Zwolle, The Netherlands; 6. Department of Medicine II, Hospital Rudolfstiftung, Vienna, Austria; 7. Department of Cardiology, Vejle Hospital, Vejle, Denmark; 8. Department of Cardiology, Isala Klinieken and Regionale Ambulance Voorziening IJsselland, Zwolle, The Netherlands; 9. Department of Medicine and Cardiology, Aarhus University Hospital, Aarhus C, Denmark; 10. Medical Officer EMS, Östergötland, Linköping, Sweden; 11. Department of Internal Medicine, Vinnevi Hospital, Norrköping, Sweden; 12. Abbott Vascular, Brussels, Belgium; 13. Cordis EMEA, Johnson & Johnson, Waterloo Belgium; 14. Department of Cardiology, Clinique Pasteur, Toulouse, France

# “Stent for Life” Initiative is a project jointly organised by the European Association of Percutaneous Cardiovascular Interventions (EAPCI) and EuroPCR, supported by EUCOMED and the ESC Working Group on Acute Cardiac Care. Project Steering Committee: Petr Widimsky, Jean Fajadet, Adriaan Potgieter, Nadav Tomer, William Wijns and Nicolas Danchin.
The authors have no conflict of interest to declare.

www.escardio.org/EAPCI
How Can We Improve Networks and Infrastructure

• Regional network (EMS, non-PCI hospitals and PCI centers) should cover an area with a population around 0.5 million (cca 0.3 – 1 million).

• Respect the right of local hospitals to take care for the patients after primary PCI is completed and the patient is stabilized (tertiary transport to the local hospital nearest to patient’s home).

• All PCI centers should provide non-stop (24/7) services for primary PCI. PCI hospitals, which are not able to provide non-stop (24/7) primary PCI services, should not be part of the network.

J.Knot: How to set up an effective national primary angioplasty network: lessons learned from five European countries (EuroIntervention, August 2009).
How Can We Improve Emergency Medical Services (EMS)

- EMS staff **training** is more important than the EMS staff **structure** (trained nurses suitable for the triage and transport of AMI patients)
- EMS ambulances: **equipped** by resuscitation facilities and by a portable 12-leads ECG.
- **ECG teletransmission** (to the PCI center) can be left on the local decision, is not mandatory.
- **Road transport is preferred** (air transport takes usually more time).
- **Helicopter transport** is generally faster in mountainous, islandic or very scarcely populated regions.

J.Knot: How to set up an effective national primary angioplasty network: lessons learned from five European countries (EuroIntervention, August 2009).
How Can We Improve Transport & Time Delays

*Primary transport* should *bypass the nearest non-PCI hospital and the Emergency Room or Intensive Care Unit of the PCI center.*

- Immediately diagnostic ECG call to cathlab and start transfer. The ECG – cathlab time <90 minutes can be achieved in vast majority of patients.

- Admission to Emergency Room (or ICU) in the PCI center delays reperfusion by at least 20-40 minutes.

- Admission to non-PCI hospital followed by the *“secondary transport”* to PCI center delays reperfusion by at least 30-60 minutes.

J.Knot: How to set up an effective national primary angioplasty network: lessons learned from five European countries (EuroIntervention, August 2009).
What can we learn from the best practice countries?

- Involvement of all stakeholders is necessary (professional societies, government, patients)
- Building 24/7 PPCI network to cover STEMI population is needed
- Launch transportation protocol; bypass the nearest hospital without cath lab
- Data collection/registry to analyze progress
- Education campaign to cardiologists, EMS, patients.
Implementation of PPCI
Stent for Life Initiative
Phase III
Implementation in Countries
Turkey (78 p-PCI / mil. / yr.)

Greece (95 p-PCI / mil. / yr.)

Bulgaria (130 p-PCI / mil. / yr.)

Serbia (157 p-PCI / mil. / yr.)

Spain (165 p-PCI / mil. / yr.)

France (231 p-PCI / mil. / yr.)
Declaration Signature Ceremony
EAPCI General Assembly at ESC September 2010

- Egypt
- Italy (415 p-PCI / mil./ yr.)
- Romania (20 p-PCI / mil./ yr.)
SFL Implementation in Countries

Objectives

- Finalize the national SFL structure.
- Develop local action plan and secure SFL budget.
- Hire a local project coordinator.
- Write, present (at the national cardiology congress) and publish (in the national cardiology journal) a "country mapping manuscript" (analyzing the AMI treatment and proposing solutions).
- Review country action plan with SFL Steering Committee.
- Present country progress at EuroPCR & ESC Congress
- Involve the public and media; education program.

www.escardio.org/EAPCI
How to improve current practice?
Example from Spain: “Codi infart”
Network in Catalunya
Ricard Tresserras, EuroPCR. Paris, May 25th 2010
1. “Codi infart” Network in Catalunya
Secure government agreement
2. “Codi infart” Network in Catalunya
Set regional PPCI network with 24/7 services to cover the population need
3. “Codi infart” Network in Catalunya

Gather data - AMIEST Registry
Monitor and evaluate quality and progress

| Full de recollida de dades de pacients ateses per |
| Codi IAM |

<table>
<thead>
<tr>
<th>Identificació del pacient</th>
</tr>
</thead>
<tbody>
<tr>
<td>CQP:</td>
</tr>
<tr>
<td>Data:</td>
</tr>
<tr>
<td>Major direct:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Activació</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demanda d'atenció: [ ] Al capdeu</td>
</tr>
<tr>
<td>[ ] Cèntric</td>
</tr>
<tr>
<td>[ ] Centralitzat</td>
</tr>
<tr>
<td>[ ] Atenció</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Primera atenció</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eix externs activats: [ ] OSM</td>
</tr>
<tr>
<td>[ ] CAMP</td>
</tr>
<tr>
<td>[ ] ICAB</td>
</tr>
<tr>
<td>[ ] SCP</td>
</tr>
<tr>
<td>Valora: [ ] Cèntric</td>
</tr>
<tr>
<td>[ ] Centralitzat</td>
</tr>
<tr>
<td>[ ] Interconectado</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Decisió/terapèutica</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Hidratació</td>
</tr>
<tr>
<td>[ ] [ ]</td>
</tr>
<tr>
<td>[ ] [ ]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Complicacions</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] [ ]</td>
</tr>
<tr>
<td>[ ] [ ]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Atenció a l'hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] [ ]</td>
</tr>
<tr>
<td>[ ] [ ]</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Seguiment</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] [ ]</td>
</tr>
</tbody>
</table>
Number of PPCI/million inhabitants/year after the Codi Infart implementation
Catalunya, Spain

Codi Infart

112%
Spanish 2009 Survey on PCI

www.hemodinamica.com

Primary PCIs / million / year

Catalunya: 472
SFL Spain
Key developments

• Based on the experience from Progaliam, Baleares, Murcia, Navarra and Catalonia a set of recommendations is under development. **EMS geographical transportation protocols** set up is key.

• 3 regions were identified for SFL phase I implementation:
  - Andalucía
  - Castilla La Mancha
  - Extremadura.

• Supplement in the Revista Española de Cardiología is in preparation. Deadline September 2010.

• Meeting in the Casa del Corazón (Madrid, June 2010) with heads of PCI centers and EMS will be followed by meeting with 17 regional government representatives in October 2010.
SFL Bulgaria
Key Developments

• PPCI BG map – new Cath Labs only at sites with 24/7 coverage (Ministry of Health)

• Modification of current DRG for STEMI

• Prehospital fibrinolysis only in districts without PCI facilities.

• Reduction of current minimal length of stay at primary hospitals

• New STEMI transportation

• List of SFL hospitals without Cath Labs sent to the EMSs by Ministry of Health
Bulgaria

Population ~ 260000
Distance to Cath Lab 210 км
3h drive on the average

Population > 420000

Transport

24/7 coverage

www.escardio.org/EAPCI
Bulgaria
No. of PPCI 3 years objectives

Data from the NHIF 2007-2009
• Five departments were identified as primary SFL pilot centres.

• **Prospective 1 month registry** will start in Oct/Nov in all centres of each department with ICU. All consecutive AMI patients hospitalized within 48 hours after onset will be enrolled. Data analysis will follow in December 2010.

• **Action plan** will be developed to improve the management of AMI based on the results of the analysis:
  - Public campaigns
  - Improvement of delay
  - Increase the transfer to PCI centres

• **Data reevaluation after action plan implementation in 2011.** Roll out in other regions based on best practice sharing.
SFL France – pilot regions

- Nord
- Essonne
- Côte d’Or
- Haute Savoie
- Haute Garonne

[Map of France with highlighted regions]
For 90% of the Greek population distance to cath lab covered in less than 2-3 hours
SFL Greece
Key Developments

National PPCI/STEMI Registry
- System is already in place but it is not obligatory to fill the data.
- Negotiation with government and insurance company is ongoing for issuing the directive to report all PPCI/STEMI as a base for reimbursement.

Physicians/nurses & technicians remuneration for 24/7 service
Negotiation with Ministry of Health and insurance companies started to reallocate funds to PPCI hospitals.

PPCI Cath Lab standard /Physicians license?
- PPCI cath labs should be equipped with the standard and PPCI specialized materials (i.e. thromboaspiration devices, stents, wires etc)
- PPCI trained staff (licence?)
SFL Serbia
Key developments

• President Tadic became a SFL Honorary Chairman.

• Action plan for Prevention and Control of Cardiovascular Disease in Serbia until 2020 was developed and has been accepted by the government and published in the Official paper in February 2010.

  Benchmark: Hungary
  
  Key focus on:
  - decentralization of the interventional cardiology services
  - patients’ education
  - emergency services training/unique phone number

• Project on Equal distribution of ACS and AMI treatment in the territory of Belgrade is in a final stage and will be discussed shortly in a City council.

• Call for SFL implementation in country has been launched. Request for funding submitted.
SFL Serbia – PPCI coverage

Estimated population of Serbia: 7.9 million

Number of Cath Labs: 17

ICVD Sremska Kamenica (2)
Clinical Center Zvezdara (1)
Clinical Center of Serbia (2+1)
Clinical Center Zemun (1)
Military Academy (1+1)
Clinical Center of Kragujevac (1)
Clinical Center of Nis (2)

ICVD Dedinje (2+1)
Clinical Center Bezanijska Kosa (1+1)

www.escardio.org/EAPCI
SFL Serbia
Increasing number of PPCI

Number of pPCI/1,000,000

Estimated population of Serbia: 7.9 million

- 2005: 19
- 2006: 78
- 2007: 147
- 2008: 213
- 2009: 311
- 2010: 439

Increase 40% predicted
SFL Turkey: key Developments

- SFL Country Champion appointed as Ministry of Health advisor.

- 18 pilot cities were chosen; total 36 PCI centers started perform PPCI as part of SFL; each city has at least two PCI centers with 24/7 PPCI service.

- 112 Ambulance brings the STEMI patient directly to the PPCI centers bypassing the hospital w/o PPCI facilities.

- Education of ambulance and emergency doctors started locally by local experienced cardiologists.

- Cardiology Simulation Center has been established in Istanbul and course for ACS started on a monthly basis (accredited by UEMS).
SFL Turkey
Pilot cities
SFL Initiative
3 years perspective

• Country tools “How to set up an effective PPCI network” will be developed and should serve for other countries as a best practice manual.

• Educational campaign will be launched in 2011 in all SFL countries to increase ACS disease awareness among public.

• European Survey will be launched in 2011 and results will be presented at EuroPCR 2012.
SFL Initiative
3 years perspective

• Country tools “How to set up an effective PPCI network” will be developed and should serve for other countries as a best practice manual.

• Educational campaign will be launched in 2011 in all SFL countries to increase ACS disease awareness among public.

• European Survey will be launched in 2011 and results will be presented at EuroPCR 2012.

Thank you very much!