Thrombus Aspiration During Primary Percutaneous Coronary Intervention Improves Myocardial Reperfusion and Reduces Infarct Size: The EXPIRA (Thrombectomy With Export Catheter in Infarct-Related Artery During Primary Percutaneous Coronary Intervention) Prospective, Randomized Trial

Gennaro Sardella, Massimo Mancone, Chiara Bucciarelli-Ducci, Luciano Agati, Raffaele Scardala, Iacopo Carbone, Marco Francone, Angelo Di Roma, Giulia Benedetti, Giulia Conti, and Francesco Fedele

O.U. of Invasive Cardiology, Dept. of Cardiovascular Sciences
*Dept. of Radiology
Policlinico Umberto I - University “La Sapienza
ROME
GENNARO SARDELLA, MD;
MASSIMO MANCONE, MD;
RAFFAELE SCARDALA, MD;
CHIARA BUCCIARELLI DUCCI, MD;
ANGELO DI ROMA, MD;
IACOPO CARBONE, MD*;
GIULIA BENEDETTI MD,
GIULIA CONTI, MD;
FRANCESCO FEDELE, MD.

✓ No relationship to disclose
Background

Microembolization during Primary PCI

- In the AMI setting, the “no-flow” phenomenon is caused by the distal embolization after the IRA reopening.

- This common complication is associated with poor perfusion and high mortality.
Myocardial Perfusion After Primary PCI is Strongest Predictor of Mortality independently from IRA reopening

PPCI Hardest point

“Open Artery ...but Closed Myocardium !!

Background

Acute anterior MI post PCI

Microvascular obstruction valued by Ce-MRI predicts significantly increased rate of cardiovascular adverse events after AMI

Impact of Thrombectomy with EXPort catheter in Infarct Related Artery on procedural and clinical outcome in patients with AMI (EXPIRA Trial)

**Design**
Prospective, randomized, double-arm, mono-centric study.

**Pros**
- Principal investigator: G. Sardella MD
- 175 pts eligible for 1:1 randomization (Heparin 7500 U/I, GPIIb/IIIa, Aspirin, Clopidogrel 300 mg)
- Final MBG ≥ 2
- 90' ST resolution (> 70% decrease of ST segment after PCI)
- TIMI > 0-1
- TS < 3
- Cardiogenic shock
- 3- vessel / Left Main
- Contra to GPIIb/IIIa
- Contr to TCT 2007

**Secondary end-point:**
- MACE at 9 month clinical f-u (STEMI, at 6.8 ± 2.3 h from symptoms onset)

175 pts. randomized for 1:1 randomization

- 87 pts. randomized to Thrombectomy + PCI
- 88 pts. randomized to Standard PCI

- 81 pts. excluded:
  - Cardiogenic shock
  - 3-vessel / Left Main

- 9 months clinical f-u

**Secondary end-point:**
- MACE at 9 month clinical f-u

**256 pts.**
Impact of Thrombectomy with EXPort catheter in Infarct Related Artery on procedural and clinical outcome in patients with AMI (EXPIRA Trial).

Procedural Results

**MYOCARDIAL BLUSH GRADE**

*\[ p < 0.0001 \]*

<table>
<thead>
<tr>
<th>Basal</th>
<th>Post-POBA</th>
<th>Final</th>
<th>Basal</th>
<th>Post-Thr.</th>
<th>Final</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBG 3</td>
<td>28.7*</td>
<td>70.3*</td>
<td>39.5*</td>
<td>11.8*</td>
<td></td>
</tr>
<tr>
<td>MBG 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MBG 0/1</td>
<td></td>
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</table>

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(G.Sardella et al, TCT 2007)
Impact of Thrombectomy with EXPort catheter in Infarct Related Artery on procedural and clinical outcome in patients with AMI (EXPIRA Trial).

**90’ ST resolution after PCI (%)**

(> 70% decrease of ST segment)

\[ p = <0.01 \]

\[ \text{OR 6.36} \]

\[ (95\% \text{ CI 3.23-12.50}) \]

<table>
<thead>
<tr>
<th>%</th>
<th>CONVENTIONAL GROUP</th>
<th>EXPORT GROUP</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>37.5</td>
<td>80.0</td>
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</table>

*(G.Sardella et al, TCT 2007)*
Impact of Thrombectomy with EXPort catheter in Infarct Related Artery on procedural and clinical outcome in patients with AMI (EXPIRA Trial).

9 months Composite Cardiac Event Rates

- **DEATH**
  - CONTR. 4.6%
  - EXPORT 0%
  - p=0.059

- **MACE**
  - CONTR. 4.5%
  - EXPORT 10.3%
  - p=ns

(G.Sardella et al, TCT 2007)
We sought to evaluate the impact of thromboaspiration on procedural and long term outcomes in terms of microvascular damage and infarct size by contrast enhanced-MRI (ce-MRI) as compared to conventional primary PCI.

Export® aspiration catheter (Medtronic, Minneapolis, Minnesota)
Methods

**Design**

- Prospective, randomized, double-arm, mono-centric study.
- **End-points (MRI evaluation)**
  - Microvascular damage (grams/g) in terms of Hypoenhancement.
  - Infarct size (grams/g) in terms of Hyperenhancement.

75 patients eligible for 1:1 randomization (Anterior STEMI, at 6.8 + 2.3 h from symptoms onset)

- (Heparin 7,500 U/I, GPIIb/IIIa, Aspirin, Clopidogrel 300 mg)

37 pts randomized to Standard PCI

38 pts randomized to Thrombectomy + PCI

3 – 90 Day MRI follow-up

- Microvascular damage
- Infarct size
Methods

**Inclusion Criteria**
- Age >18 yrs
- STEMI within 9 hrs from symptoms onset
- “De novo" coronary artery lesions
- Native IRA ≥2.5 mm diameter
- Angiographically identifiable occlusive thrombus (TS grade ≥ 3)
- TIMI 0-1 at time of initial angiography

**Exclusion Criteria**
- Previous AMI or CABG
- Cardiogenic shock
- 3-vessel / Left Main CAD
- Severe valvular heart disease
- Unsuccessful PCI (no antegrade flow or 50% residual stenosis in the IRA)
- Rescue / Facilitaded PCI
- Contraindication to GP IIb/IIIa inhibitors
<table>
<thead>
<tr>
<th>Risk factors</th>
<th>Total Population (n=75)</th>
<th>Conventional Group (n=37)</th>
<th>Thrombectomy Group (n=38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yrs±SD</td>
<td>66.3±10.6</td>
<td>65.8±13.1</td>
<td>67.4±14.1</td>
</tr>
<tr>
<td>Males (%)</td>
<td>47 (62.7)</td>
<td>24 (64.7)</td>
<td>23 (60.5)</td>
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<tr>
<td>Hypertension (%)</td>
<td>43 (57.8)</td>
<td>24 (64.9)</td>
<td>19 (50.0)</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>17 (22.7)</td>
<td>9 (24.3)</td>
<td>8 (21.1)</td>
</tr>
<tr>
<td>Smoking (%)</td>
<td>26 (34.7)</td>
<td>11 (29.8)</td>
<td>15 (39.5)</td>
</tr>
<tr>
<td>Obesity (%)</td>
<td>2 (2.7)</td>
<td>2 (5.4)</td>
<td>0</td>
</tr>
<tr>
<td>Family History of CAD (%)</td>
<td>27 (36.0)</td>
<td>12 (32.4)</td>
<td>15 (39.5)</td>
</tr>
<tr>
<td>Cholesterol (mg/dl±SD)</td>
<td>164±13</td>
<td>165±10</td>
<td>163±11</td>
</tr>
<tr>
<td>Triglycerides (mg/dl±SD)</td>
<td>120±35</td>
<td>122±23</td>
<td>121±27</td>
</tr>
<tr>
<td>Renal Failure (%)</td>
<td>4 (5.3)</td>
<td>3 (8.1)</td>
<td>1 (2.6)</td>
</tr>
<tr>
<td>Killip class III (%)</td>
<td>19 (25.3)</td>
<td>12 (32.4)</td>
<td>7 (18.4)</td>
</tr>
<tr>
<td>Previous PCI (%)</td>
<td>10 (13.3)</td>
<td>4 (10.8)</td>
<td>6 (15.8)</td>
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<tr>
<td>Symptoms to balloon, (hrs±SD)</td>
<td>7.9±0.7</td>
<td>7.7±1.2</td>
<td>6.5±1.4</td>
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<tr>
<td>LVEF (%±SD)</td>
<td>43.1 ±12</td>
<td>40.8 ±7.5</td>
<td>41.9 ±0.9</td>
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</table>
### PROCEDURAL CHARACTERISTICS 1

<table>
<thead>
<tr>
<th></th>
<th>Total Population (n=75)</th>
<th>Conventional Group (n=37)</th>
<th>Thrombectomy Group (n=38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IABP (%)</td>
<td>7 (9.3)</td>
<td>4 (10.8)</td>
<td>3 (7.9)</td>
</tr>
<tr>
<td>Lesion length, mm±SD</td>
<td>13.8±5.7</td>
<td>14.1±5.6</td>
<td>14.9±4.9</td>
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<tr>
<td>Vessel size, mm±SD</td>
<td>2.9±0.6</td>
<td>2.8±0.5</td>
<td>2.9±0.6</td>
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<tr>
<td>MLD pre, mm±SD</td>
<td>0.8±0.4</td>
<td>0.9±0.4</td>
<td>0.7±0.3</td>
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<tr>
<td>GPIIb/IIIa Inhibitors</td>
<td>75 (100)</td>
<td>37 (100)</td>
<td>38 (100)</td>
</tr>
<tr>
<td>Direct stenting</td>
<td>32 (42.6)</td>
<td>2 (5.4)*§</td>
<td>28 (74.3)§</td>
</tr>
<tr>
<td>Post-dilatation</td>
<td>7 (9.3)</td>
<td>3 (8.1)</td>
<td>4 (10.5)</td>
</tr>
<tr>
<td>MLD post, mm±SD</td>
<td>2.9±0.7</td>
<td>2.8±0.5</td>
<td>2.9±0.3</td>
</tr>
<tr>
<td>Post-PCI diameter stenosis, (%±SD)</td>
<td>3.4±5.2</td>
<td>3.5±3.9</td>
<td>3.4±5.4</td>
</tr>
<tr>
<td>Stent Type (%)</td>
<td></td>
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<tr>
<td>Bare-metal Stent</td>
<td>29 (38.7)</td>
<td>17 (45.9)</td>
<td>12 (31.5)</td>
</tr>
<tr>
<td>Drug-eluting Stent</td>
<td>46 (61.3)</td>
<td>20 (54.0)</td>
<td>26 (68.4)</td>
</tr>
</tbody>
</table>

* 2 pts with recanalized IRA after guide-wire placement

§ p = <.0001
PROCEDURAL RESULTS 1

TIMI FLOW GRADE

\( p = 0.0005 \)

\( p = n.s. \)

<table>
<thead>
<tr>
<th>TIMI 0/1</th>
<th>TIMI 2</th>
<th>TIMI 3</th>
</tr>
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<tbody>
<tr>
<td><strong>Basal</strong></td>
<td><strong>Post POBA</strong></td>
<td><strong>Final</strong></td>
</tr>
<tr>
<td><strong>Basal</strong></td>
<td><strong>Post-Thromb</strong></td>
<td><strong>Final</strong></td>
</tr>
</tbody>
</table>

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PROCEDURAL RESULTS 2

MYOCARDIAL BLUSH GRADE

* p < 0.0001

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In-Hospital Outcome

90’ ST resolution after PCI
(> 70% decrease of ST segment)

\[ p = .0001 \]

OR 7.2
(95% CI 2.5-20.9)

CONVENTIONAL GROUP

40.5

THROMBECTOMY GROUP

84.2
<table>
<thead>
<tr>
<th></th>
<th>S-PCI (n=37)</th>
<th>EM-PCI (n=38)</th>
<th>P value</th>
<th>S-PCI (n=36)</th>
<th>EM-PCI (n=36)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Acute Phase 3 d</strong></td>
<td></td>
<td></td>
<td><strong>3-Month Follow-up</strong></td>
<td></td>
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</tr>
<tr>
<td>EDV (ml)</td>
<td>137.5±18.6</td>
<td>131.5±14.4</td>
<td>0.1</td>
<td>144.5±20.3</td>
<td>136.2±19.9</td>
<td>0.08</td>
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<tr>
<td>ESV (ml)</td>
<td>77.4±15.4</td>
<td>71.3±17.3</td>
<td>0.1</td>
<td>76.1±16.5</td>
<td>69.3±17.7</td>
<td>0.09</td>
</tr>
<tr>
<td>EF (%)</td>
<td>44.3±9.5</td>
<td>46.3±8.6 #</td>
<td>0.3</td>
<td>46.7±10.6</td>
<td>49.0±9.3 #</td>
<td>0.3</td>
</tr>
<tr>
<td>IS (%)</td>
<td>13±6.7</td>
<td>14±12 §</td>
<td>0.6</td>
<td>11±8.7</td>
<td>9±4.5§</td>
<td>0.2</td>
</tr>
<tr>
<td>IS (gr)</td>
<td>14±7.5</td>
<td>17±15*</td>
<td>0.2</td>
<td>13±12</td>
<td>11±8.7*</td>
<td>0.4</td>
</tr>
<tr>
<td>MVO(n)</td>
<td>27 (72.9%)</td>
<td>9 (31.5%)</td>
<td>0.0005</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>MVO (gr)</td>
<td>3.7±2.6</td>
<td>1.7±1.9</td>
<td>0.0003</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

#0.08; § p=0.001; *p=0.004; Yellow between groups, Red within groups
Microvascular evaluation (HPO) | Infarct size (HPR)

Pt 1: Control
Pt 2: Thrombectomy
Microvascular evaluation (HPO)  

Pt 1  
Microv. Damage  
5 sec 10 sec 15 sec  

Pt 2  
Improv. Microv. Function  
5 sec 10 sec 15 sec  

Infarct size (HPR)  

Pt 1  
Control  

Pt 2  
Thrombectomy  

Left Ventricular Motion
In this study Thrombectomy has been demonstrated to be safe and effective in AMI setting during Primary PCI.

Compared with conventional stenting, in patients with intracoronary visible and occlusive thrombus, pretreatment with manual aspiration thrombectomy during primary PCI improves acutely the parameters of myocardial tissue perfusion and ST resolution in a well selected population.

MRI long term evaluation showed a reduction of microvascular damage in the Thrombectomy group compared with the Control group.

In the Thrombectomy group setting resulted a reduction of microvascular damage and infarct size in long term compared with acute evaluation.