PiCSO Reduces Infarct Size After primary PCI: A propensity-controlled matched study

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
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</thead>
<tbody>
<tr>
<td>• Grant/Research Support</td>
<td>• Miracor Medical Systems</td>
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<td>• Consulting Fees/Honoraria</td>
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<td>• Consulting Fees</td>
<td>• Boston Scientific</td>
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<td>• Medtronic</td>
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<td>• Consulting Fess</td>
<td>• Abbott</td>
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Background

- Infarct size (IS) predicts morbidity and mortality after STEMI
- Adjunctive strategies to limit infarct size (IS) may improve prognosis
- Pressure-controlled intermittent Coronary Sinus Occlusion intermittently increases average coronary sinus pressure and improves coronary perfusion in the ischemic zone and reduces infarct size
Pressure-controlled intermittent Coronary Sinus Occlusion (PiCSO)

- PiCSO increases average coronary sinus pressure and improves coronary perfusion in the ischemic zone.
- The mechanism of action is reduction of reperfusion injury through improved microvascular perfusion.
Materials & Methods

- 92 patients with a first anterior STEMI were enrolled in a prospective, parallel controlled study at 4 UK centers.
- Allocated to PiCSO or control based on availability of PiCSO trained physician or time of arrival at ER.
- PiCSO started after flow restoration, and before stenting.
- To avoid the potential influence of the non-randomised design of the study, a propensity score matched control cohort was selected from INFUSE-AMI patients with a 5-day cardiac MRI.
- We compared 20 patients treated with PiCSO device to 80 patients from INFUSE-AMI.
Results

- PiCSO treated patients were balanced on sex, age, pre PCI TIMI flow (0/1 vs 2/3), post PCI TIMI flow (2 vs 3), diabetes mellitus, culprit lesion location (proximal vs mid LAD), and symptom to balloon time between PiCSO and INFUSE-AMI patients with a propensity score.

- After propensity score matching 1 patient from the PiCSO study to a possible 3 patients from INFUSE-AMI, 15 PiCSO patients and 40 INFUSE-AMI remained.

- Baseline variables were well matched
## Results

<table>
<thead>
<tr>
<th></th>
<th>PiCSO</th>
<th>INFUSE-AMI</th>
<th>P-value</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (% male)</td>
<td>80.0</td>
<td>77.5</td>
<td>1.00</td>
<td>2.5%</td>
</tr>
<tr>
<td>Age (years)</td>
<td>58.3±11.1</td>
<td>59.1±11.3</td>
<td>0.83</td>
<td>-0.7</td>
</tr>
<tr>
<td>Diabetes Mellitus (%)</td>
<td>6.7</td>
<td>7.5</td>
<td>1.00</td>
<td>-0.8%</td>
</tr>
<tr>
<td>Proximal LAD (%)</td>
<td>60</td>
<td>67.5</td>
<td>0.60</td>
<td>-7.5%</td>
</tr>
<tr>
<td>Mid LAD (%)</td>
<td>40</td>
<td>32.5</td>
<td>0.60</td>
<td>7.5%</td>
</tr>
<tr>
<td>Pre PCI TIMI flow</td>
<td></td>
<td></td>
<td>0.14</td>
<td></td>
</tr>
<tr>
<td>0/1</td>
<td>60</td>
<td>70</td>
<td>0.53</td>
<td>-10.0%</td>
</tr>
<tr>
<td>2/3</td>
<td>40</td>
<td>30</td>
<td>0.53</td>
<td>10.0%</td>
</tr>
<tr>
<td>Final TIMI flow</td>
<td></td>
<td></td>
<td>0.14</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>13.3 %</td>
<td>15 %</td>
<td>1.00</td>
<td>-1.7%</td>
</tr>
<tr>
<td>3</td>
<td>86.7 %</td>
<td>85 %</td>
<td>1.00</td>
<td>1.7%</td>
</tr>
<tr>
<td>Symptom to balloon time (min.)</td>
<td>178.7±127.7</td>
<td>179.2±63.8</td>
<td>0.99</td>
<td>-0.5</td>
</tr>
<tr>
<td>Propensity score</td>
<td>0.76±0.16</td>
<td>0.80±0.13</td>
<td>0.35</td>
<td>-0.04</td>
</tr>
</tbody>
</table>
Results

- Mean infarct size (% total left ventricular mass) in PiCSO treated patients was **10.9%** (95% CI 5.1%, 16.8%), compared to **20.9%** (95% CI 17.33%, 24.48%) in the INFUSE-AMI control group; mean difference **-10.0%** (95% CI -16.8%, -3.2%), p-value = 0.004
Results

PiCSO – INFUSE-AMI (1:3)  
$p = 0.004$  
-9.99% (-16.84%, -3.15%)

PiCSO – INFUSE-AMI (1:2)  
$p = 0.012$  
-9.51% (-16.92%, -2.10%)

PiCSO – INFUSE-AMI (Regression)  
$p = 0.013$  
-8.02% (-14.31%, -1.73%)

Infarct Size (% of LV)  
-10% PiCSO better  
0% INFUSE-AMI better

Mean (95% CI)

LVEF

Ejection Fraction (%)

PiCSO better  
INFUSE-AMI better

INFUSE

MIRACOR

$p = 0.05$
Conclusions

- **PiCSO reduces Infarct Size in STEMI**
  - Initiation of PiCSO immediately after flow restoration but before stenting was associated with a **47% relative reduction** in 5-day infarct size in comparison to a propensity score matched control cohort taken from the INFUSE-AMI database.

- **PiCSO prevents deterioration of myocardial function after acute anterior STEMI**