Abstract: **P961**

**Investigator versus Core Lab evaluation of coronary blood flow in PCI of patients in cardiogenic shock: a substudy of the CULPRIT-SHOCK trial.**

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**On behalf:** CULPRIT-SHOCK investigators.

**Topic(s):**
Coronary Angiography

**Citation:**
European Union Seventh Framework Program, the German Heart Research Foundation, German Cardiac Society.

**Background:** Thrombolysis In Myocardial Infarction (TIMI) flow is a prognostic factor which assessment is complex in life-threatening situations. Because TIMI flow evaluation by site investigator (SI) is subject to bias, independent Core-Laboratory (CL) adjudication is the reference standard in clinical trials.

**Purpose:** To evaluate the concordance between CL and SI in the evaluation of the culprit artery TIMI flow, and the associated prognosis in the CULPRIT-SHOCK trial.

**Methods:** All patients of the CULPRIT-SHOCK trial with CL adjudications were included in this analysis. CL adjudicators were blinded to patient’s characteristics and outcomes: pre and post-PCI TIMI flows were solely evaluated on the basis of coronary angiograms. SI determined the TIMI flow before and immediately after PCI of the culprit lesion. The concordance was determined by Cohen’s \(\kappa\) coefficient. A multivariate analysis was used to evaluate 1) factors of discordance 2) the association between each method of evaluation and the mortality at 30 days and 1 year.

**Results:** Among CULPRIT-SHOCK patients, 663 patients were eligible for this analysis. Of the 214 patients adjudicated TIMI flow 3 by CL before PCI, SI over-estimated the obstruction to TIMI flow 0-1-2 in 121 (56.5%). Of the 139 patients scored TIMI flow 0-1-2 by CL after PCI, SI over-graded their results to TIMI flow 3 in 79 (56.8%). Overall, the K coefficient of agreement was 0.44, 95%CI [0.36; 0.51] before PCI and 0.44, 95%CI [0.35; 0.53] after PCI. Mechanical circulatory support and culprit left main were the main factors of discordance of TIMI flow after PCI. The association between TIMI flow 0-1-2 after PCI and 30-days mortality was significant, whether adjudicated by SI or CL (figure). Post-PCI TIMI-flow 0-1-2 was associated to 1-year mortality only when evaluated by SI (figure).

**Conclusions:** In comparison to the independant CL evaluation, SI overestimated the severity of coronary slow flow before PCI, and the success of PCI in improving coronary flow. The level of agreement between CL and SI was moderate. While both evaluations predicted 30-days mortality, only SI scoring was associated to 1-year mortality.
Investigator versus Core Lab evaluation of coronary blood flow in PCI of patients in cardiogenic shock: a substudy of the CULPRIT-SHOCK trial.


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Association between TIMI flow evaluation by Core-lab or Site investigator and mortality

<table>
<thead>
<tr>
<th>TIMI 0-1-2</th>
<th>AdOR *</th>
<th>95 % CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>according to CL</td>
<td>1.73</td>
<td>[1.10; 2.71]</td>
<td>0.018</td>
</tr>
<tr>
<td>according to SI</td>
<td>2.41</td>
<td>[1.39; 4.20]</td>
<td>0.0018</td>
</tr>
<tr>
<td>according to CL</td>
<td>1.39</td>
<td>[0.87; 2.21]</td>
<td>0.17</td>
</tr>
<tr>
<td>according to SI</td>
<td>1.93</td>
<td>[1.09; 3.43]</td>
<td>0.025</td>
</tr>
</tbody>
</table>

* Adjusted OR
TIMI 3 according to CL or SI was the reference

Favors Mortality