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High sensitive cardiac troponin i at admission and 30 minutes later to rule-in or rule-out acute myocardial infarction - Preliminary results from the RACING-MI trial

Authors:
C. Bang¹, C. Hansen¹, K. Glerup Lauridsen², C. Alcaraz Frederiksen³, M. Schmidt⁴, T. Jensen⁵, N. Hornung⁶, B. Løefgren², ¹Randers Regional Hospital, Clinical Research Unit - Randers - Denmark, ²Aarhus University Hospital, Research Center for Emergency Medicine - Aarhus - Denmark, ³Aarhus University Hospital, Department of Cardiology - Aarhus - Denmark, ⁴Regional Hospital West Jutland, Department of Cardiology - Herning - Denmark, ⁵Randers Regional Hospital, Department of Internal Medicine - Randers - Denmark, ⁶Region Hospital Herning, Department of Clinical Biochemistry - Herning - Denmark,

Topic(s):
Acute Coronary Syndromes: Biomarkers

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Introduction: Current ESC guidelines have introduced a 0h/1h algorithm for accelerated rule-in or rule-out of acute myocardial infarction (MI) when using assay specific high-sensitive cardiac troponin I (hs-cTnI). Several studies have investigated the diagnostic performance and safety of this approach using different hs-cTnI assays. However, little is known of the diagnostic performance of a 0h/30min algorithm.

Purpose: To evaluate the diagnostic accuracy of early rule-in or rule-out of MI after 30 minutes by applying assay specific hs-cTnI cut-off values from a recently validated 0h/1h algorithm.

Methods: We prospectively enrolled chest pain patients suggestive of MI admitted to the Emergency Department. Patients underwent serial hs-cTnI measurements at admission (0 hour) and after 3 hours according to clinical practice. In addition, hs-cTnI measurements were performed after 30 minutes. The assay specific cut-off values from the 0h/1h algorithm were applied to the 30 minute cohort (figure 1). Final diagnosis was adjudicated independently by two physicians.

Results: In total, 943 patients were included. MI was the final diagnosis in 67 (7.1%) patients. Overall, absolute hs-cTnI values after 30 minutes were significantly higher in the MI group than in the non-MI group (19.2 (Q1:Q3) 2.7–75.3) ng/L versus 0.1 (0.2–0.7) ng/L, p<0.001). When applying the assay-specific hs-cTnI cut-off values for the 0h/1h algorithm to the 30 minute patient cohort, 52.4% of patients were classified as rule-out with a negative predictive value of 100% (95% CI: 99.2–100). In total, 8.5% were classified as rule-in with a positive predictive value of 83.8% (95% CI: 74.2–90.3). Sensitivity was 100% (95% CI: 94.6–100) and specificity was 97.4% (95% CI: 95.7–98.6). Overall, 39.1% were assigned to the observational zone with a 3.5% prevalence of MI.

Conclusions: The use of assay specific hs-cTnI measurement at admission (0h) and 30 min later can be used to safely rule-out MI. This indicates that it might be safe to develop a 0h/30min algorithm and thereby reduce time to diagnosis even further. NCT03634384.
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1 Randers Regional Hospital, Clinical Research Unit - Randers - Denmark, 2 Aarhus University Hospital, Research Center for Emergency Medicine - Aarhus - Denmark, 3 Aarhus University Hospital, Department of Cardiology - Aarhus - Denmark, 4 Regional Hospital West Jutland, Department of Cardiology - Herning - Denmark, 5 Randers Regional Hospital, Department of Internal Medicine - Randers - Denmark, 6 Region Hospital Herning, Department of Clinical Biochemistry - Herning - Denmark

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Figure 1: Performance of the hs-cTnI 0h/30min algorithm when applying the validated 0h/1h hs-cTnI assay specific cut-off values.

**Suspected NSTEMI (30 min cohort) N = 943**

<table>
<thead>
<tr>
<th>Value</th>
<th>Rule-out (after 30 minutes)</th>
<th>Observe (after 30 minutes)</th>
<th>Rule-in (after 30 minutes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0h &lt; 3 ng/l</td>
<td>0h &lt; 6 ng/l AND Delta 1h &lt; 3 ng/l</td>
<td>n = 0 (MI) n = 494 (non-MI) N total = 494</td>
<td>Proportion: 52.4% NPV: 100% (99.2-100%) Sensitivity: 100% (94.6-100%)</td>
</tr>
<tr>
<td>6h &gt; 120 ng/l</td>
<td>OR Delta 1h &gt; 12 ng/l</td>
<td>n = 13 (MI) n = 356 (non-MI) N total = 369</td>
<td>Proportion: 39.1% Prevalence of NSTEMI 3.5%</td>
</tr>
<tr>
<td>Delta 1h &lt; 12 ng/l</td>
<td>OR Delta 1h &lt; 12 ng/l</td>
<td>n = 67 (MI) n = 13 (non-MI) N total = 80</td>
<td>Proportion: 8.5% PPV: 83.8% (74.2-90.3%) Specificity: 97.4% (95.7-98.6%)</td>
</tr>
</tbody>
</table>

Delta 1h indicates absolute change of hs-cTnI within 1 h; N: number; NSTEMI: non-ST-elevation myocardial infarction; MI: myocardial infarction; NPV: negative predictive value; PPV: positive predictive value.