Abstract: Performance of the ESC 0/1h- and 0/3h-algorithm for the early diagnosis of myocardial infarction in patients with diabetes mellitus

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On behalf: Biomarkers in Acute Cardiac Care study group

Topic(s):
Acute Coronary Syndromes: Biomarkers

Citation:

Background: Patients with diabetes mellitus (DM) may have elevated levels of high-sensitive cardiac troponin (hs-Tn) despite acute myocardial ischemia being present. However, it is unclear whether this constrains diagnostic strategies in patients with suspected acute myocardial infarction (MI).

Purpose: We aimed to assess the diagnostic performance of the European Society of Cardiology (ESC) 0/1 hour (h) and 0/3h-algorithms comparing patients with and without DM and to derive optimized cut-offs.

Methods: We prospectively enrolled patients with symptoms suggestive of MI in two large clinical cohorts and measured hs-TnI at admission (baseline) and 1 (cohort A) and 3h (cohort A+B) thereafter. Patients with ST-elevation MI were excluded. Patients were stratified based on a diagnosis of DM at baseline. Final diagnoses were adjudicated independently by two cardiologists using all clinically available information, including hs-TnT, but blinded to hs-TnI values. Our primary outcomes of interest were safety of rule-out (defined by sensitivity and negative predictive value [NPV]), accuracy of rule-in (defined by specificity and positive predictive value [PPV]) and the overall performance (% of patients adjudicated to either rule-out or -in). For optimized cut-offs, a NPV >99.0% and a PPV >75.0% were targeted.

Results: DM was prevalent in 563 (15.29%) of 3683 included patients. MI was more prevalent among patients with DM (137 [24.3 %] vs. 498 [16.0 %], p < 0.001). Using the ESC 0/1h-algorithm (Figure), rule-out was safe in diabetics (p for sensitivity = 1.00) with higher NPV in non-diabetics (p<0.001), while the proportion of patients ruled-out was smaller in diabetics (22.3 % vs. 41.8 %). Accuracy of rule-in was significantly lower in diabetics (specificity p = 0.0035, PPV p = 0.48), with a higher rule-in rate of patients with DM (29.5 % vs. 21.8 %). Using the ESC 0/3h-algorithm, safety of rule-out was lower in both groups compared to the ESC 0/1h-algorithm, with again higher NPV for non-DM (sensitivity p = 0.18, NPV p < 0.001) and a higher proportion of non-DM ruled-out (65.9 % vs. 75.2 %). Accuracy of rule-in was significantly lower for patients with DM (specificity p = 0.0094, PPV p = 0.87). Cut-off adjustment to yield pre-defined accuracy measures resulted in: 4ng/L at baseline or 6ng/L with a delta of 2ng/l for rule—out and 90ng/L or a delta of 10ng/L for rule-in with the ESC 0/1h algorithm; for the ESC 0/3h-algorithm cut-offs were 5ng/L with a delta of 20% for rule-out and 50ng/L with a delta of 20% for rule-in.

Conclusion: Application of the ESC 0/1h- and 0/3h-algorithms in diabetic patients provided reduced safety and accuracy for rule-out and rule-in of MI, respectively. Use of alternative cut-offs resulted in improved diagnostic safety and accuracy.
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