Alere Troponin at Three hours study (ATAT)
A diagnostic accuracy study of a point of care troponin I assay

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Background

Measuring cardiac troponin concentrations is central to the diagnosis of acute myocardial infarction (AMI) by the universal definition. However, the turnaround time of laboratory assays is 45-60 minutes, not including transport time. This is the niche that point of care (POC) troponin assays have sought to fill, aiming to rapidly rule out ACS thereby improving patient care and increase efficiencies in the acute care setting.

We aimed to evaluate the diagnostic accuracy of the Alere Triage Cardio3® POC cardiac troponin assay in patients presenting to the Emergency Department (ED) with suspected ACS, using cut-offs set at the limit of detection (LoD) and 99th centile upper reference limit (URL) of the assay.

Methods

This was a planned sub-study of the multi-centre prospective observational Bedside Evaluation of Sensitive Troponin (BEST) study. Patients were prospectively enrolled in 8 hospitals across England on presenting to the emergency departments with symptoms suggestive of an ACS. Patients were excluded if they had another medical condition requiring admission or the peak symptoms were >12 hours ago. Written consent was obtained for each patient and ethical approval from the Health Research Authority was obtained (14/NW/1344).

Blood samples were drawn at 0 and 3 hours, they were analysed with the Alere POC cardiac troponin I (cTnI) assay. The 99th centile is 0.022ng/ml and the LoD is 0.01ng/ml. The primary outcome was a diagnosis of AMI, adjudicated according to the third universal definition. Reference standard cardiac troponins measured at was used and measured at 0 and 3 to 6 hrs.

		cTnI timing			
		0hr		3hr	
		Sensitivity	NPV	Sensitivity	NPV
Threshold	LoD	0.839	0.967	0.949	0.989
	URL	0.790	0.959	0.881	0.975

Table 1 : Diagnostic accuracy for the detection of Acute Myocardial Infarction at limit of detection (LoD <0.01ng/ml) and Upper reference limit (URL <0.02 ng/ml).

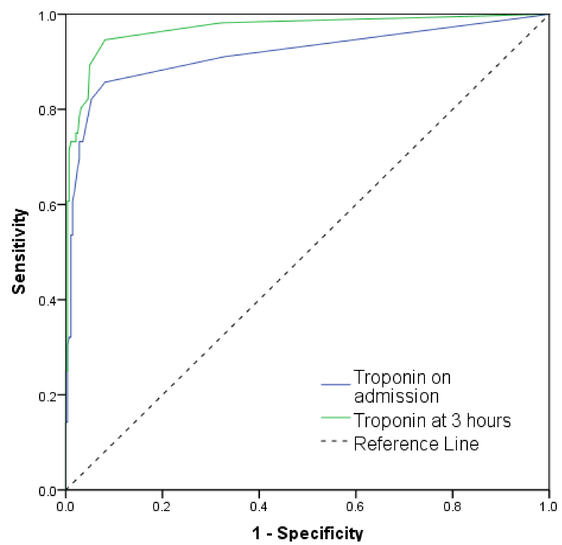

Figure 1 - Receiver operating characteristics curve for Alere 0 and 3 hour Troponin I in diagnosing Acute Myocardial Infarction, area under the curve 0.917 and 0.970

Results

We enrolled 500 patients, of which 432 had an admission sample (62 with AMI) and 382 (59 with AMI) had a 3-hour sample for analysis. Using the admission sample, POC cTnI had a sensitivity of 79.0% (95% CI 66.8 – 88.3%) and a specificity of 95.3% (92.4 – 97.4%) at the conventional 99th centile cut-off. Using the LoD as a cut-off yielded a sensitivity of 83.9% (72.3 – 92.0%) with specificity 91.9% (88.3 – 94.6%).

With the 3-hour sample, sensitivity at the 99th centile was 88.1% (77.1 – 95.1%) with specificity 94.9% (91.7 – 97.1%). At the LoD, the sensitivity was 94.9% (85.9 – 98.9%) with specificity 91.8% (88.1 – 94.7%).

The receiver operating characteristic curve clearly shows superiority to the 3 hour cTnI with an area under the curve of 0.970 compared to 0.917.

Conclusion

Our findings show that the Alere Triage Cardio3® POC cTnI assay has optimal sensitivity using the LoD cut-off with sampling 3 hours after arrival. However, as over 5% of AMIs would be missed, this strategy should not be used alone to 'rule out' AMI. Further research should focus on utilisation alongside validated decision aids.