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Research Article

Diagnostic utility of point of care high sensitive troponin-i assay for early diagnosis of acute myocardial infarction in patients presenting with acute onset chest pain in emergency departments. The early heart study

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Keywords: Early heart study; High sensitive troponins; Acute myocardial infarction; Acute coronary syndrome; Early diagnosis of AMI; Point of care trop test

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Abstract

Background: An early diagnosis of myocardial infarction is highly important in the Emergency Department (ED). It facilitates rapid decision making and treatment and therefore improves the outcome in patients presenting with symptoms of chest pain.

Aims and objectives: To study diagnostic utility of new point of care high sensitive troponin-I assay in early diagnosis of acute myocardial infarction in patients presenting with acute chest pain.

Materials and methods: Forty six consecutive patients of acute onset chest pain who presented to our cardiac emergency department within three hours of symptom onset were enrolled for study. POC Hs Trop-I test was done on admission (0 hour), and after 3 hours if initial test result was negative. Quantitative troponin I (Q-Trop I) lab assay was done on admission (0 hour), 3 hours and 6 hours after admission. Six hour Q-Trop I assay was taken as gold standard for the initial diagnosis of AMI. The final adjudicated diagnosis of AMI was based on a composite of ECG changes (new ST segment or T wave changes, new onset LBBB), Troponin results, Echocardiography (new wall motion abnormality), angiographic findings (detection of a culprit lesion) and final chart review of observations made.

Results: Comparing the results of POC Hs Trop I results at 0 hour with the gold standard test we found the sensitivity of 97%, specificity of 100%, Positive Predictive Value (PPV) of 100% and Negative Predictive Value (NPV) of 92.3%. Sensitivity of POC Hs Trop I at 3 hours was better than POC Hs Trop I at 0 hour (97 vs. 100%) and equal to gold standard i.e. 100%. Specificity, PPV and NPV are 100% for POC Hs Trop I at 1 hour.

Conclusion: High sensitive Trop I test is rapid and reliable method to diagnose and exclude acute myocardial infarction in patients presenting with acute onset chest pain to our Emergency Departments.

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Introduction

The early diagnosis of Acute Myocardial Infarction (AMI) is highly important in the emergency department [1,2]. Patients with acute onset chest pain frequently present to the emergency cardiac services, while only 15–20% of all patients actually have acute myocardial injury [3]. The measurement of cardiac troponin is gold standard to distinguish between AMI and non-AMI patients. Current ESC guidelines recommend serial measurement of troponin after 1 or 3 hours, when using high-sensitivity assays [4]. The established diagnostic approach is based on the assay-specific 99th percentile in combination with an absolute or relative change of troponin concentration. Earlier studies reported an improved diagnostic performance for absolute changes [5,6]. Application of newer and more sensitive troponin assays enables the detection of much lower concentrations [7,8]. Using a high-sensitivity troponin I (Hs Trop I) assay, a 3 hour ESC algorithm based on the 99th percentile resulted in a high Positive Predictive Value (PPV) of 83.5% [9].

As per the third universal definition of myocardial infarction (2012), detection of a rise and/or fall of the measurements is essential to the diagnosis of acute MI [10]. An increased Cardiac Troponin (cTn) concentration is defined as a value exceeding the 99th percentile (with optimal precision defined by total Coefficient of Variation (CV <10%) of a normal reference population (URL).

Aims and objectives

To study the diagnostic utility of new Point of Care High Sensitive Troponin-I assay (POC Hs Trop-I) in early diagnosis of acute myocardial infarction in patients presenting as acute coronary syndrome.

Materials and methods

This study was conducted in the Department of Cardiology and Department of Clinical Biochemistry Batra Hospital and Medical Research Centre, New Delhi. Forty six (46) consecutive patients (>18 years of age) with acute onset chest pain (<3 hours) presenting to our cardiac Emergency Department as ACS were enrolled for the study. All patients were enrolled only after informed written consent were obtained.The principle of high sensitive troponin test assay is based on fluorescence immunoassay to be used in EDTA whole blood and plasma specimens. The test procedure involves the addition of several drops (0.5ml) of an EDTA anti-coagulated whole blood or plasma specimen to the sample port on the Test Device. After addition of the specimen, the whole blood cells are separated from the plasma using a filter contained in the test device. This specimen reacts with fluorescent antibody conjugates and flows through the test device by capillary action. Complexes of each fluorescent antibody conjugate are captured on discrete zones specific for each analyte. The test device is inserted into the Triage Meter. The meter is programmed to automatically perform the analysis after the sample has reacted with the reagents within the test device. The test results are ready within 10 to 15 minutes.

POC Hs Trop I was done on admission (0 hour) in all patients and after 3 hours if initial test was negative. Any value above 0.02 ng/ml is taken positive by Alere High sensitive Trop I diagnostics with a detection range of 0.02 to 10 ng/ml. Q-Trop I (lab assay) was done at 0 hour, 3 hours and 6 hours. Any value above 0.3ng/ml is considered positive by lab standards with a detection range of 0.3 to 50ng/ml. Six hour Q-Trop I assay was taken as gold standard for the initial diagnosis of AMI. The final adjudicated diagnosis of AMI was based on a composite of ECG changes (new ST segment or T wave changes, new onset LBBB), Troponin results (lab and bedside results), echocardiography (new wall motion abnormality), angiographic findings (detection of a culprit lesion).

Inclusion criteria

- ✓ Patients with age greater than 18 years.
- ✓ Patients with acute onset chest pain (<3 hours).
- ✓ Patients presenting with suspected ACS to the hospital.

Exclusion criteria

- ✓ Post CPR revived patients.
- ✓ Patients with acute Cerebrovascular event.
- ✓ Patients with multiple co-morbidities that may contribute to false readings like renal failure, sepsis and malignancy.
- ✓ Patients with history of chest trauma or major surgery in recent past.
- ✓ Patients on chemotherapy for malignancy.
- ✓ Lack of consent or patient not willing to give blood samples for study.

Statistical analysis

Data was tabulated in MS Office Excel worksheet. Descriptive statistics was computed for all the numerical data. Frequency tables were constructed for categorical data. Matrix plots, flow charts and figures were drawn as per need. Receiver Operating Characteristic curves (ROC curve) were constructed to demonstrate sensitivity and specificity of tests. The Area Under Curve (AUC) was calculated and analysed. Kappa statistics (Cohen's Kappa) was used to analyse the reliability of different tests against gold standard and final adjudicated diagnosis. For all the statistical analysis a P value ≤ .05 was considered to indicate as significant difference at 5% level of significance. All statistical analyses were performed by using SPSS version 16.0 and Stat Cal software. The results of Hs Trop I (0 and 1 hour) and Quantitative Trop I lab assay (0 and 3 hour) were analysed and compared with gold standard test (6 hour) and final adjudicated diagnosis for sensitivity, specificity, Positive Predictive Value (PPV) and Negative Predictive Value (NPV).

Results

Out of forty six patients of ACS studied; there were 39 (85

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Alere Triage Meter (Cardio 3 Panel) with testing cartridge.

%) males and 7 (15%) females. Point of care Hs Trop I test was done in all patients on admission (0 hour) and at 1 hour .Out of 46 patients of suspected ACS, 33 (71.7%) of patients had POC Hs Trop I positive at 0 hour and 13 (28.3%) had negative 0 hour test. At one hour out of 13 patients one was positive and 12 patients remained negative. Hence at one hour POC Hs Trop I showed a combined result of 34 (73.91%) positive and 12 (26.08%) negative test results. Conventional Q-Trop-I lab assay was done at 0 hr 3 hr and 6 hours. Six hour Q-Trop I was taken as gold standard for diagnosis of AMI. Q-Trop I was positive for 26 (56.5%) and negative in 20 (43.5%) at 0 hour and positive in 31 (67.4%) and negative in 15 (32.6%) at 3 hour. The gold standard 6 hour Q-Trop I test was positive in 34 (73.91%) and negative in 12 (26.08%).Comparing the POC Hs Trop I (0 hour) results with gold standard test we found the sensitivity of 97%, specificity of 100%, Positive Predictive Value (PPV) of 100% and Negative Predictive Value (NPV) of 92.3%. The area under ROC curve was 0.985 for POC Hs Trop I at 0 hours suggesting it as a very good test to diagnose AMI early in the course of chest pain. The reliability of Hs Trop I at 0 hour to diagnose AMI was compared with gold standard by Kappa statistics which showed a very good agreement (Cohen's kappa=0.945) and it suggested that POC Hs Trop I at 0 hour gives us excellent results to diagnose and exclude AMI in patients with chest pain. The sensitivity for Hs Trop I at 1 hour to diagnose AMI when compared with gold standard was better than Hs Trop I at 0 hour (97 vs. 100%) and equal to gold standard i.e. 100%. Specificity, PPV and NPV are 100% for Hs Trop I at 1 hour. The area under ROC curve for Hs Trop I at 1 hour was 1 suggesting the test is excellent to diagnose AMI with very high diagnostic accuracy. The reliability of Hs Trop I at 1hour was compared with gold standard to diagnose AMI by Kappa statistics which showed an excellent agreement (Cohen's kappa= 1) .This shows that Hs Trop I at 1 hour is excellent method to diagnose and exclude AMI. Results clearly indicate that POC Hs Trop I (0 hour and 1 hour) is better and reliable test to diagnose and exclude AMI when compared with Q-Trop I (0 hour and 3 hour) lab estimation test Study group included 39 (85%) males and 07 (15%) females (Table 1) (Figure 1).

Out of 46 patients 33 (71.7%) patients were positive and 13 (28.3%) were negative for POC Hs Trop I on admission (0 hour). All 13 negative patients were tested again at 1 hour out of these 12 were negative and one patient was detected positive (Table 2).

Out of 46 patients Quantitative Trop I was positive in 26 (56%) patients and negative in 20 (43%) patients at 0 hour. It was positive in 31 (67.4%) and negative in 15 (32.6%) at 3 hours after admission. At 6 hours Q-Trop was positive in 34 (73.9%) and negative in 12 (26.1%) patients (Table 3).

Turnaround time for POC Hs-Trop I was on average of 13.71 ± 1.91 minutes and for Q-Trop I it was 135.9 ± 18 minutes (Tables 4-7).

Discussion

The major limitation of standard cardiac troponin assays is their low sensitivity at the time of a patient's presentation, owing to a delayed increase in circulating levels of cardiac troponin. Recently, improvements in the technology of cardiac

Table 1: Gender distribution.

Gender	Total number of patients
Male	39
Female	07
Total	46

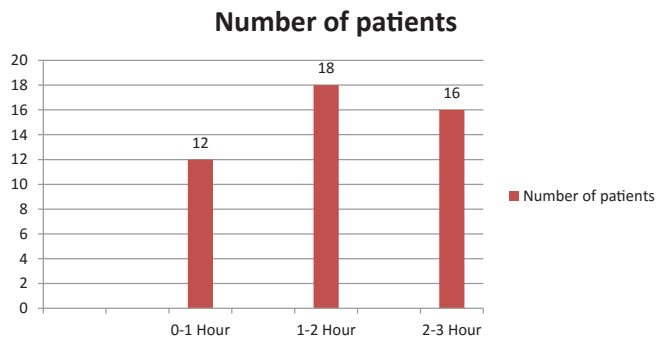

Figure 1: Presenting time to hospital (Duration of symptoms).

Table 2: POC Hs Trop I results at 0 hour and 1 hour.

Test	POSITIVE (%)	NEGATIVE (%)
Hs Trop at 0 hour (n= 46)	33 (71.7)	13 (28.3)
Hs Trop at 1 hour (n= 13)	1	12
Total (0 hour plus 1 hour)	34 (73.9%)	12 (26%)

Table 3: Quantitative Troponin results 0 hr, 3 hr and 6 hours.

Test	POSITIVE (%)	NEGATIVE (%)
Q Trop 0 hour (n= 46)	26 (56.5%)	20 (43.5)
Q Trop 3 hour n= 46	31 (67.4%)	15 (32.6)
Q Trop 6 hour (n= 46)	34 (73.9%)	12 (26.1)

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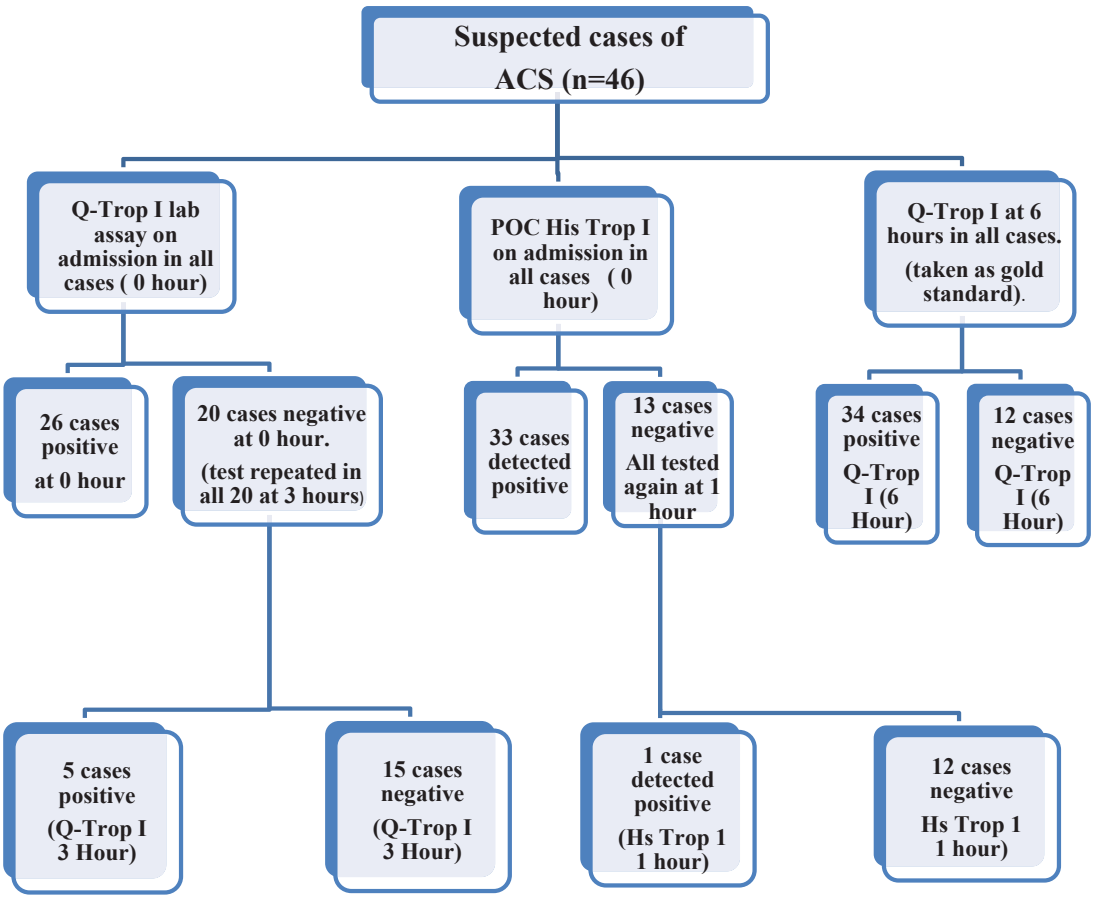
Troponin test results in our patients.



troponin assays have allowed manufacturers to provide fully automated assays with higher sensitivity than the previous assays and improved precision at the lower limit of detection (CV <10%) [11-13]. We enrolled adult patients who reported to our cardiac ED within three hours of onset of acute chest pain with high probability of acute coronary syndrome. Out of 46 patients studied 30 (65%) of patients were in the age group 40 to 60 years, 15 (32%) patients were above 65 years of age, mean age was 58.47 ± 11.83 years. These findings were similar when compared with results from Faizal P, et al. [14] (age group 55-74 years-60.87%), Mohanan PP, et al. [15], (51–70 years-57.2%) and Xavier D, et al. [16], (51-70 years-56.7%). Mean age of presentation was found to be 58.47 ± 11.83 years which is close to mean age reported by Xavier D, et al. [16], (57.5 ± 12.1), Gupta S, et al. [17], (58.32 ± 11.24), AlHabib KF, et al. [18], (58 ± 12.9).

Point of care high sensitive troponin I test gives us rapid results with very high diagnostic accuracy and essentially helps us to rule out cardiac chest pain. The test is very useful in terms of cost effectiveness and diagnostic utility when compared with Q-Trop I assay. Neumann JT, et al. [11], studied (Biomarkers in Acute Cardiac Care-BACC TRIAL) application of a high sensitivity troponin I assay in 3 cohorts of patients with acute chest pain. This study prospectively recruited 1040 patients who presented with acute chest pain and/or other symptoms suggestive of AMI. POC high sensitive troponin I test was done on admission (0 hour), 1 hour, and after 3 hours. With application of a low troponin I cut-off value of 6 ng/L, the rule-out algorithm showed a high negative predictive value of 99.8% (95% CI, 98.6%-100.0%) after 1 hour for non–ST-segment elevation MI type 1. The 1-hour approach was comparable to a 3-hour approach. Similarly, a rule-in algorithm based on troponin I levels provided a high positive predictive value with 82.8% (95% CI, 73.2%-90.0%).

This study concluded with a bottom line message that application of a 1-hour algorithm with a low high sensitive troponin I cut-off allows for accurate, rapid exclusion and identification of AMI. The 1 hour and 3 hour approaches yielded results those were not statistically different, whereas the 1-hour approach would allow faster diagnosis or discharge. A low cut-off performed significantly better than the 99th percentile as cut-off in view of follow-up mortality. The results for POC Hs Trop I in present study are pretty similar to results in BACC trial; we also had prespecified low cut-off (0.02 ng/ml) and we found similar sensitivity of POC Hs Trop I at 0 hour and 1 hour (97 and 100%) with a very high PPV and NPV for early diagnosis of AMI.

Present study also demonstrated results of 0 hour and 1 hour (97% and 100%) POC high sensitive troponin results

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Table 4: POC Hs Trop-I (0 hour) results in comparison to 6 hour Q-Trop I (Gold standard).

		FINAL DIAGNOSIS (Q-Trop 6 Hours)		Total
		Positive	Negative	
Hs TROP 0 HRS	Positive	33	0	33
	Negative	1	12	13
Total		34	12	46

SENSITIVITY = TP / (TP + FN) = 33 / (33 + 1) = 97.06%
SPECIFICITY = TN / (TN + FP) = 12/ (12 + 0) = 100%
POSITIVE PREDICTIVE VALUE = TP / (TP + FP) = 33 / (33 + 0) = 100%
NEGATIVE PREDICTIVE VALUE = TN / (TN + FN) = 12 / (12 + 1) = 92.30%

Table 5: POC Hs Trop-I (1 Hour) results in comparison to 6 hour Q-Trop I (gold standard).

		FINAL DIAGNOSIS (Q-Trop 6 Hours)		Total
		Positive	Negative	
Hs TROP 1 HRS	Positive	34	0	34
	Negative	0	12	12
Total		34	12	46

SENSITIVITY = TP / (TP + FN) = 34 / (34 + 0) = 100%
SPECIFICITY = TN / (TN + FP) = 12 / (12 + 0) = 100%
POSITIVE PREDICTIVE VALUE = TP / (TP + FP) = 34 / (34 + 0) = 100%
NEGATIVE PREDICTIVE VALUE = TN / (TN + FN) = 12 / (12 + 0) = 100%

Table 6: Final adjucated diagnosis overall results for diagnosing AMI and ACS IN Hs Trop I (1 hour).

		FINAL DIAGNOSIS		Total
		Positive	Negative	
HS TROP 1 HRS	Positive	34	0	34
	Negative	7	5	12
Total		41	5	46

SENSITIVITY = TP / (TP + FN) = 34 / (34 + 7) = 82.93%
SPECIFICITY = TN / (TN + FP) = 5 / (5 + 0) = 100%
POSITIVE PREDICTIVE VALUE = TP / (TP + FP) = 34 / (34 + 0) = 100%
NEGATIVE PREDICTIVE VALUE = TN / (TN + FN) = 5 / (5 + 7) = 41.67%

Table 7: Turnaround time: POC High sensitive Troponin versus conventional Quantitative lab Troponin.

Turnaround time	Hs Trop I (Minutes)	Quant Trop I (Minutes)
Mean ± SD	13.71 ± 1.91	135.9 ± 18
Median	15	150
Min-Max	10-15	60-150

comparable to 3 hours and 6 hours (91.8% and 100%) Q-Trop I results for early diagnosis of AMI. Till Keller, et al., [19-21], studied high sensitive troponin I assay for the early diagnosis and risk stratification of myocardial infarction in a multicenter study that included 1818 consecutive patients with suspected acute myocardial infarction. The high sensitive cardiac troponin test was done on admission (0 hour), 3 hours and 6 hours after admission.The study showed high sensitive troponins are beneficial for early diagnosis of AMI.

The turnaround time of two tests was compared which was 13.71±1.91 minutes for POC Hs Trop I (0 and 1 hour) and 135.9±18 minutes for Q-Trop I. This is very important in emergency departments as rapid diagnosis of AMI helps us to implement early invasive strategy and to improve overall outcome of patients. This is an added advantage of POC Hs Trop I over Q-Trop I; rapid bedside results with high diagnostic accuracy in a very short span of time. POC Hs Trop I at 0 and 1 hours differ from each other by former being slightly less sensitive (97 vs. 100%) otherwise both tests proved to have equal specificity, NPV, PPV, and rapidity (very short turnaround time) of diagnosing and excluding AMI in patients presenting as acute onset chest pain. Q-Trop I lab assay are time consuming (median turnaround time of 135 minutes) and less sensitive (sensitivity= 91%) when compared with POC High sensitive troponin I at 0 hour (sensitivity= 97%) and 1 hour (sensitivity= 100%) for early diagnosis of AMI.

Conclusion

- POC High sensitive troponin-I test on admission and within 1to 3 hour of presentation is highly sensitive and specific for early diagnosis of AMI in patients presenting with suspected acute coronary syndrome.
- In addition POC High sensitive troponin I assay has very short turnaround time (13.7 ± 1.91 minutes) when compared with conventional Quantitative troponin I lab assay (135 ± 18 minutes), better diagnostic accuracy and provides rapid results with a scope to improve outcome in patients with AMI where early invasive management is needed.
- Patients with unstable angina have negative troponin results on admission and within 6 hours of presentation; they require additional tests to diagnose myocardial ischemia before being safely discharged from emergency departments.

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