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ORIGINAL RESEARCH

Diagnostic Performance of Point-of-Care Troponin I and Laboratory Troponin T in Patients Presenting to the ED with Chest Pain: A Comparative Study

This article was published in the following Dove Press journal:
Open Access Emergency Medicine

Osama H Mohammad[1]
Vamanjore A Naushad[1]
Nishan K Purayil[1]
Laith Sinan[2]
Naseem Ambra[1]
Prem Chandra[3]
Firjeeth C Paramba[1]
Jassim Mohammad[4]
Sajid Chalihadan[1]
Irfan Varikkodan[1]
Azeez Palol[1]

[1]Department of General Internal Medicine, Hamad Medical Corporation, Doha, Qatar; [2]Glasgow Medical College, Glasgow, UK; [3]Medical Research Center, Hamad Medical Corporation, Doha, Qatar; [4]Accident & Emergency Department, Hamad Medical Corporation, Doha, Qatar

Background: Chest pain is a common symptom in patients visiting the emergency department (ED). Diagnosing acute coronary syndrome is a challenging task for emergency physicians. Evaluation of chest pain depends on clinical symptoms and signs, ECG, and cardiac enzymes. Here, we aimed to compare the diagnostic performance of the point-of-care troponin I assay with laboratory HsTnT assay in patients presenting to the ED with chest pain.

Methods: A prospective study was done at the ED of Alkhor Hospital, Hamad Medical Corporation, between March 2016 and December 2016. Patients more than 18 years old who presented to the ED with chest pain were enrolled. Patients with renal failure, initial ECG showing ST-elevation MI, or arrhythmias, and hemodynamically unstable patients were excluded. A blood sample was collected at 0 and 3 hours post-admission for POC TnI and laboratory HsTnT assay. The sensitivity, specificity, PPV, NPV, and AUC were determined and compared.

Results: Out of 313 patients enrolled, ten were excluded. At 0 hour, the POC TnI assay had a lower sensitivity (72.5% versus 97.5%) and had almost equal specificity (99.24% versus 93.2%) when compared to lab HsTnT assay. At 3 hours post-admission, the sensitivity increased to 95% versus 100%, and specificity was 100% versus 94.3% when compared to lab HsTnT. The POC TnI assay had a higher PPV than HsTnT, whereas both assays showed a high NPV at 0 and 3 hours.

Conclusion: Although the diagnostic performance of POC TnI was lower than that of Lab HsTnT at 0 hour, at 3 hours post-admission, the diagnostic performance was almost equal to that of HsTnT. Hence we conclude that chest pain in patients with a negative POC TnI at 3 hours post-admission is unlikely to be due to NSTEMI.

Keywords: point-of-care, POC, TnI, HsTnT, ED, chest pain, NSTEMI

What This Paper Adds

Section 1: What is already known on this subject

- Measurement of cardiac markers in the blood is key in the evaluation of patients presenting with chest pain to the ED.
- Most of the hospitals fail to meet the recommended turnaround time of less than 60 min from the time of blood drawn to the reporting of the final results.
- Recent research shows that troponin assays done within 3 h of arrival at the ED can rule out myocardial infarction.

Correspondence: Vamanjore A Naushad
Department of General Internal Medicine, Hamad Medical Corporation, Doha 3050, Qatar
Tel +974-55902242
Email nousha87@hotmail.com

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DovePress
http://doi.org/10.2147/OAEM.S259726

Section 2 : What this study adds

- The diagnostic performance of POC TnI was lower than that of Lab HsTnT at 0 hour.
- Chest pain in patients with a negative POC TnI assay at 3 h post admission to the ED is unlikely to be of NSTEMI .
- We recommend that in patients presenting to the ED with chest pain undergo a repeat POC TnI assay at 3 h post admission to rule out acute coronary syndrome.

Introduction

Chest pain is one of the most common symptoms in patients visiting the emergency department (ED) worldwide. Chest pain accounts for 5–20% of all ED visits.[1] Causes of chest pain vary from non-significant musculoskeletal pain to life-threatening acute coronary syndrome (ACS) and pulmonary embolism, as examples. ACS consists of ST-elevation myocardial infarction (STEMI), non-ST elevation myocardial infarction (NSTEMI), and unstable angina (UA). Electrocardiogram (ECG) can differentiate between STEMI and NSTEMI, while cardiac troponin can differentiate between NSTEMI and UA when ECG is nonspecific or normal. Diagnosing ACS is a challenging task for ED physicians. Early diagnosis of ACS with early initiation of treatment leads to reduce mortality; hence appropriate risk stratification, triaging, and early treatment plan for chest pain is of utmost importance in the ED.

Evaluation and risk stratification of chest pain patients depends on clinical symptom and signs, ECG, and cardiac enzymes. Cardiac markers are important for identifying ACS in the absence of typical ECG changes in patients with chest pain.[2–5] In up to 50% of patients with non-diagnostic ECG, the diagnosis of acute MI depends on troponin tests.[6,7] Since cardiac markers are tested in a central laboratory, which is outside the ED, the diagnosis of ACS is delayed.[8,9]

Measurement of cardiac markers in the blood is key in the evaluation of patients presenting with chest pain to ED. However, most of the hospitals fail to meet the recommended turnaround time of less than 60 min from the time blood is drawn until the reporting of the final results.[10–13]

The advent of bedside tests, also called point-of-care (POC) tests, in which the blood tests are done near the patient location, has revolutionized the care provided to patients, especially in Eds. This has resulted in a significant reduction in the waiting time for laboratory test results or radiological department investigations, in turn decreasing the time in assessing and decision making of patients in the ED. In patients with suspected MI, POC testing has resulted in a decrease in waiting time for results by 1 hr[14] and length of stay (LOS) in the ED by 2 hrs,[15–17] and also a decreased time to treatment.[15,18,19]

Currently, the most sensitive and specific biochemical marker of myocardial necrosis is the detection of cardiac troponins in blood.[20] Recent research shows that troponin assays done within 3 hrs of arrival at the ED can rule out myocardial infarction (MI).[21,22]

Objective

Our research questions were:

1. Does the POC Troponin I (POC TnI) assay have better or equivalent sensitivity and specificity when compared to central laboratory high sensitive troponin T (lab HsTnT assay) in diagnosing or ruling out NSTEMI in patients with chest pain?
2. Does the repeat assay of POC TnI after 3 hours achieve a greater sensitivity/specificity than the first sample for diagnosing or ruling out NSTEMI in patients with chest pain?

Methods

Study Designs and Setting

A single-center prospective study was carried out in the emergency department of Alkhor hospital, Hamad medical corporation, Qatar, which is a secondary care hospital. The study was carried out from Mar 1, 2016 to Dec 31, 2016.

Study Population

Patients greater than 18 years old who presented to the ED with the chief complaint of chest pain were enrolled in the study. The patients with renal failure, initial ECG showing ST-elevation MI, or arrhythmias, hemodynamically unstable patients, and patients who refused to consent for participation were excluded from the study. Patients presenting with shortness of breath, palpitation, dizziness without chest pain were also excluded.

Study Protocol

Patients presenting with chest pain to the ED were triaged to the medical emergency room by the triage nurse, where the ED physician, who is the study investigator-assessed for the eligibility criteria. If eligible, informed consent was taken and enrolled in the study. A detailed history and

a physical examination were performed, and a 12-lead ECG was taken. A venous blood sample was drawn on arrival for the lab HsTnT assay, which is done in a central laboratory using the sandwich principle in Roche COBAS 600 e module with a cut-off value of 14 ng/l. The POC TnI assay was done at the bedside of the patient using one drop of blood from the same blood sample in an Abbott I –Stat cardiac reader, which has a reported detection limit of 0.02 ng/l and a cut off level of 0.08 ng/l. The POC test was carried out by the investigators who were trained in doing so. Both the blood assays and ECG were repeated after 3 hrs of first sampling. For I-Stat, the c Tn at 99th centile is 0.08 ng/L. The cTn at 20% CV is 0.07 ng/L. The cTn at 10% CV is 0.10 ng/L

Data Collection

The following data were collected: basic demographics, smoking history, comorbid conditions, family history of risk factors, physical findings, ECG findings, final diagnosis, and disposition. The laboratory data included POC TnI, Lab HsTnT, and renal function test results. The waiting time for the blood results from the time of drawing of blood until the availability of results for POC and Lab HsTnT was noted. The length of stay (LOS) was also recorded. The patients who were discharged from the ED were followed up for 1 month through their clinical information system for revisits to ED with cardiac symptoms.

Ethics

The study was approved by the Institutional review board of medical research center of Hamad Medical corporation, Doha Qatar (approval number 14229/14, JIRB 14–00150). The study was conducted in accordance with the ethical guidelines of the Medical Research Center including the Declaration of Helsinki.

Statistical Analysis

Descriptive statistics were used to summarize the demographic, clinical history, and other related characteristics of the participants. The normally distributed data and results were reported with mean and standard deviation (SD); the remaining results were presented with median and range. Categorical data were summarized using frequencies and percentages. Associations between two or more categories were assessed using Chi-square ($\chi 2$) test and/or Fisher Exact test, as appropriate. Continuous data between the two independent groups were analyzed using unpaired t or Mann Whitney U-test, as appropriate.

The focus of the data analysis was to determine the predictive accuracy of the iSTAT POC TnI in diagnosing NSTE in patients with chest pain. For this, the sensitivity, specificity, and positive and negative predictive values of these parameters were calculated, using final diagnosis (based on Coronary angiography, echocardiography, and cardiac enzymes) as the point of reference. A receiver operating characteristic (ROC) curve was calculated to derive the best suitable cut-off values and to assess model discrimination and predictive accuracy. The corresponding 95% CI was computed to measure the precision of the estimate. All p-values presented are two-tailed, and p-values < 0.05 were considered as statistically significant. All statistical analyses were performed using statistical packages SPSS 22.0 (SPSS Inc. Chicago, IL) and Epi-info (Centers for Disease Control and Prevention, Atlanta, GA) software.

Results

A total of 313 participants were enrolled, out of which ten were excluded leaving a final cohort of 303 patients for final analysis (Figure 1). The mean age was 44 years (range, 28–72 years), and 94% were males. The mean duration of chest pain was 46.13 min (SD ± 133.4). Hypertension was the most common risk factor observed. Fifty-one (16.9%) patients were diagnosed to have cardiac chest pain. Of the cardiac chest pain patients, five (1.7%) were diagnosed to have STEMI (their first ECG was normal and developed ECG changes while present in the ED), 35 (11.6%) NSTEMI, four (1.3%) unstable angina, and seven (2.3%) stable angina. The patients who were discharged from the ED were followed up for 1 month. Four patients returned to the emergency department during this period, and only one among them was readmitted with a cardiac complaint. The demographics and baseline characteristics are described in Tables 1 and 2.

Taking the manufacturer cut-off point for both the iSTAT POC TnI and the ROCHE Lab HsTnT, the sensitivity, specificity, positive predicted value (PPV), negative predicted value (NPV), diagnostic accuracy, and likelihood ratio of positive and negative results were calculated. The sensitivity of POC TnI for diagnosing NSTEMI at 0 h was 72.5% (95% CI; 57.2–83.9), which reached to 95% (95% CI; 83.5–98.6) after 3 h; whereas, for Lab HsTnT, it was found to be 97.5% (95% CI;87.1–99.5) and 100% (95% CI; 91.2–100), respectively. The POC TnI tests showed higher specificity both at 0 h (99.24%, 95% CI; 97.3–99.8 versus 93.2%, 95% CI; 89.-5–95.6) and after 3 h compared to Lab HsTnT (100%, 95%

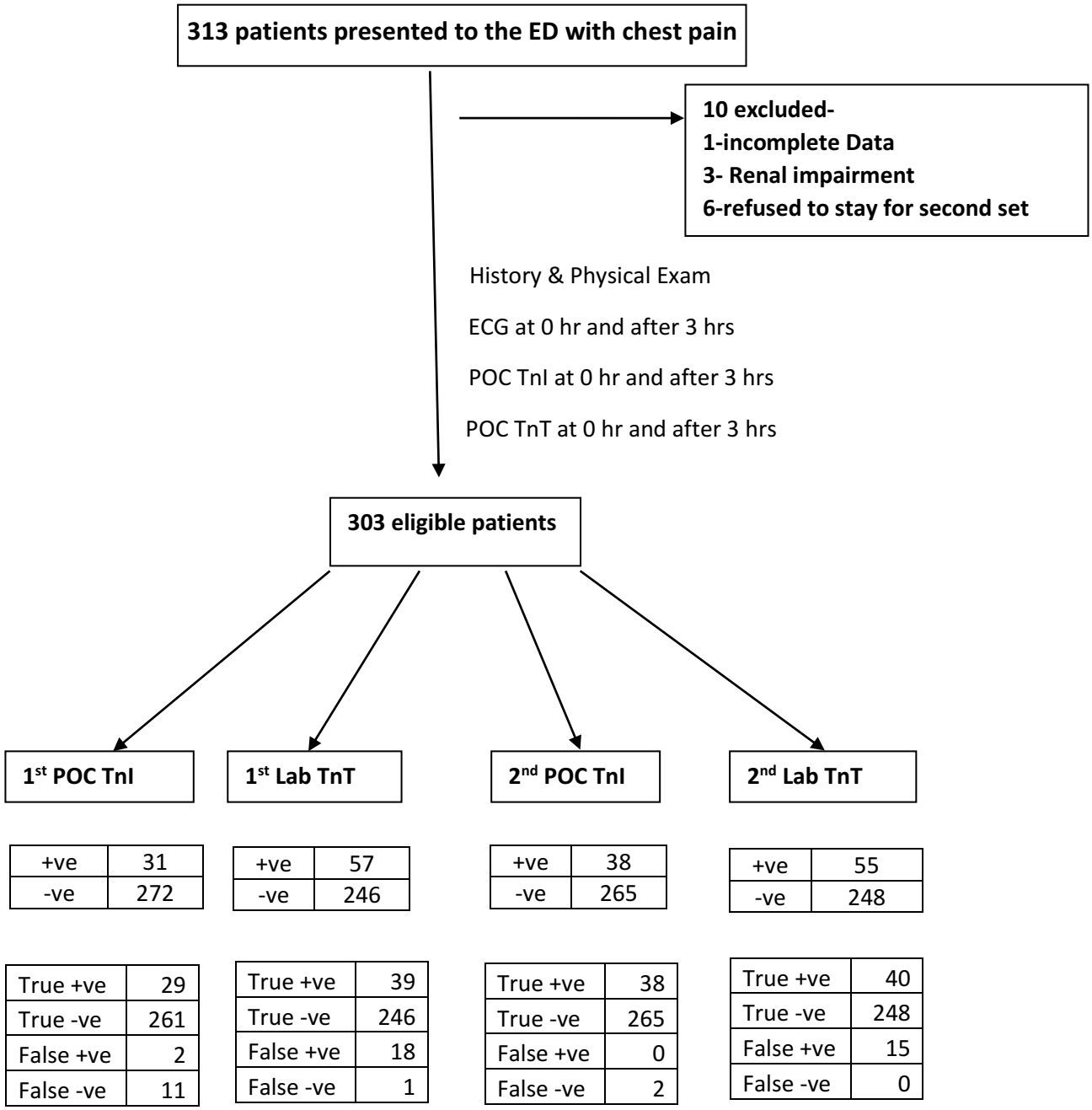


Figure 1 Flow chart showing patient enrollment.

CI; 98.6–100% versus 94.3%, 95% CI; 90.8–96.5). The positive predictive value for POC TnI was significantly higher than that for Lab HsTnT at both 0 h (93.5%, 95% CI; 79.3–98.2 versus 68.4%, 95% CI; 55.5–79) and at 3 h (100%, 95% CI; 90.8–100 versus 72.7%, 95% CI; 59.7–-82.7). Both the tests had high negative predictive value at 0 as well as at 3 h (Table 3).

We performed a receiver operating characteristic (ROC) analysis to examine the sensitivity and specificity of POC TnI with Lab HsTnT cut off values at 0 and 3 h. Both tests showed a high AUC at 0 and 3 h. The AUC for POC TnI at 0 h was 0.978, while that for lab HsTnT was 0.993. At 3 h, the AUC for POC TnI was 0.999, and Lab HsTnT was 1.00. The AUC was higher for both assays in the second sample at 3 h than the first assay (Figure 2). The average turnaround time for POC TnI was 10 minutes, whereas that of lab HTnT was 60 minutes.

Table 1 Characteristics of Patients with Chest Pain

Variables		Number	Valid %
Age in years (mean)		44	
gender			
	Male	286	94.4
	Female	17	5.6
IHD Risk factors			
	Hypertension	89	30.0
	Cigarette smoking	77	25.8
	Family History of IHD	69	23.3
	Diabetes Mellitus	67	22.6
	Hyperlipidemia	36	12.2
Duration of chest pain (hours) Mean		46.13 ± 103.4	
Median		18	
Range		0.5–288	
ECG			
	Normal	227	75.7
	Abnormal	72	24.3
Disposition			
	ICU	43	14.0
	Discharge	258	86.0
Final Diagnosis			
	STEMI	5	1.7
	NSTEMI	35	11.6
	Unstable angina	4	1.3
	Stable angina	7	2.3
	non-Cardiac	252	83.2
Return to ED within one month			
	No	299	98.7
	Yes*	4	1.3

Notes: * From the patients discharged from ED, 4 returned back within one month: 1- NSTEMI -Admitted to ICU, 2-Non cardiac chest pain discharged from ED with normal Stress test,1 - intestinal obstruction- Admitted to surgery)

Discussion

The findings from this study suggest that the sensitivity of POC TnI at 0 h was lower than that of the central lab HsTnT in diagnosing NSTEMI in chest pain patients. Previous studies have reported similar results, with POC TnI showing a sensitivity of 63% when compared to central laboratory TNT that showed 88%, and the POC multi-marker panel that showed 83% for diagnosing acute myocardial infarction.[23] Another study by Petra Wilke et al compared the diagnostic performance of POC TnI, POC TNT, and central laboratory TNT based on renal function for prediction of MI. These authors reported a sensitivity of 83%, 80%, and 77% for POC TnI, POC TNT, and central lab TNT, respectively. They concluded that all three assays demonstrated equivalent diagnostic performance for diagnosing ACS in patients with normal renal function.[24] However, the main limitation of this study was that it was a retrospective study. Other studies also reported similar sensitivity to POC TnI.[25,26] Both the assays demonstrated a high specificity at 0 and 3 h with POC TnI having greater specificity than lab HsTnT. Past work by Elizabeth et al showed that the POC TnI was more specific (94%) than central lab TNT (87%).[23]

Table 2 Comparison of Risk Factors in Patients with Cardiac and Non-Cardiac Chest Pain

	Cardiac		Non-Cardiac		
Risk Factors	no.	%	no.	%	P value*
HTN	20	40.8	69	27.8	0.07
DM	14	28	53	21.4	0.313
CAD	5	10.2	26	10.5	0.946
Dyslipidemia	6	12.2	30	12.1	0.985
Smoking	23	46	54	21.7	0.000
Family History of CAD	16	31.3	53	21.6	0.134

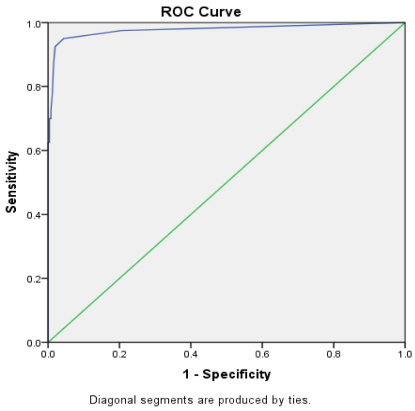
We also analyzed whether repeat testing of both assays 3 h after admission had any benefit in the diagnostic performance from the first assay. We found that sensitivity for POC TnI significantly increased after 3 h compared to the first assay, which was statistically significant. There was no significant difference between the sensitivity rates of POC TnI and lab HsTnT assays after 3 h. Kenichirouki Suzuki et al [27] compared the sensitivity and specificity of POC troponin I and T using different cut-off values for patients sampled at less than 3 h or more than 3 h after the onset of symptoms for diagnosing ACS. Their results showed sensitivity of POC TnI was significantly higher in patients sampled more than 3 h after the onset of symptoms (83.3%) than those sampled at less than 3 h (58.8%). The main difference between their study and ours was that it was a retrospective study, and they included trauma patients also.

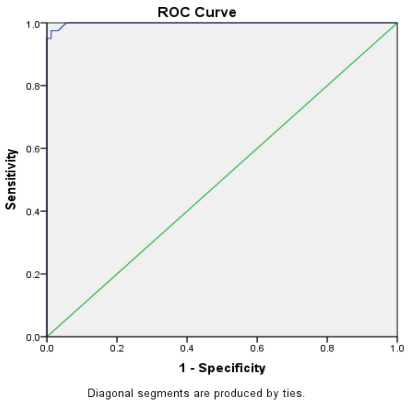
Both the assays showed a high negative predictive value at 0 as well as at 3 h. The high negative predictive value of POC TnI at 3 h has clinical ramifications in the management of chest pain patients in the ED. Past studies have shown that a cardiovascular cause may be present in

Table 3 Diagnostic Performance of POC TNI and Lab HTNT Assays

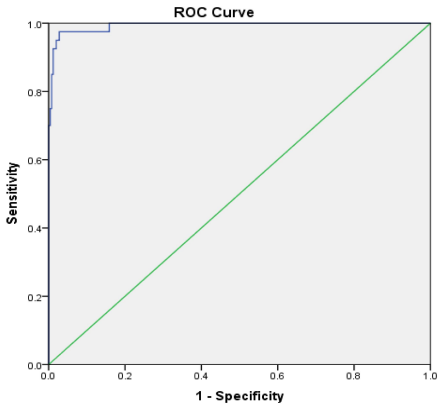
	POC TNI First Test (Zero Hour)	POC TNI Second Test (After 3 Hours)	HTNT – First Test (Zero Hour)	HTNT – Second Test (After 3 hrs)
Sensitivity (95% CI)	72.5 (57.2–83.9)	95 (83.5–98.6)	97.5 (87.1–99.5)	100 (91.2–100)
Specificity (95% CI)	99.24 (97.3–99.8)	100 (98.6–100%)	93.2 (89.5–95.6)	94.3 (90.8–96.5)
PPV (95% CI)	93.5 (79.3–98.2)	100 (90.8–100)	68.4 (55.5–79)	72.7 (59.7–82.7)
NPV (95% CI)	95.96 (92.9–97.7)	99.2 (97.3–99.8)	99.6 (97.7–99.9)	100 (98.5–100)
Diagnostic accuracy (%)	95.7 (92.8–97.5)	99.3 (97.6–99.8)	93.7 (90.4–95.9	95 (91.9–96.9)
Likelihood ratio of a positive test	95.3 (34.8–260.6)	undefined	14.3 (12.8–15.9)	17.53 (15.4–19.9)
Likelihood ratio of a negative test	0.27(0.23–0.33)	0.05 (0.01–0.13)	0.02 (0.00–0.19)	0.0

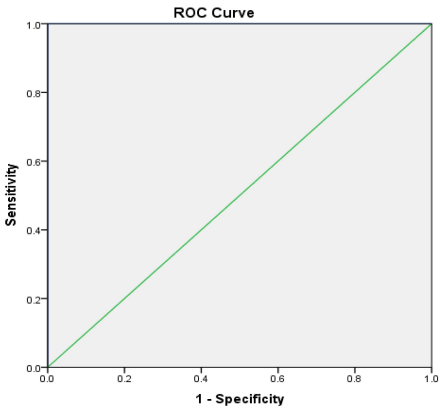
up to 20% of patients with chest pain. However, only 5.5% of these patients have a life-threatening condition, with the majority being diagnosed as non-cardiac chest pain.[28] Hence when evaluating a chest pain patient in ED failure to do an accurate triaging and risk stratification resulting in early discharge of an ACS patient from ED can increase





The POC TnI test at 0 hour* **(**The area under the curve is .978(95%CI of 0.95-1.00))
The POC TnI test at 3 hours* (The area under the curve (AUC) .999 (95 %CI 0.99-1.00))





The Lab TnT test at 0 hour* **(**The area under the curve (AUC) .993 (95 %CI 0.98-1.00))
The Lab TnT test at 3 hours***** **(**The area under the curve (AUC) 1.00 (95 %CI 0.99-1.00))

* The Unstable and stable angina has been excluded from the POC curve for accuracy of the data.

Figure 2 The ROC Curves of the POC TNI and the Lab HTnT at 0 hour and 3 hours.

the mortality, whereas over the investigation of low-risk non-cardiac chest pain patients will add up to the burden on already overcrowded ED. Our results show that a patient with negative POC TnI 3 h after admission is unlikely to have a life-threatening ACS.

In our study, the mean turnaround time for POC TnI was significantly less than that for lab HTnT. Chest pain is one of the most common complaints in acute care/primary case settings, and ruling out life-threatening ACS is a daunting task; failing to do so may lead to fatal complications. In resource hit third world countries with poor health infrastructure laboratory, cardiac enzymes are available only in urban hospitals. We believe that POC TnI testing can be used as an alternative to Lab cardiac markers in such situations for triaging and further appropriate referral of patients with chest pain.

Limitations

The main limitation of our study was the possible lack of accuracy in estimating the duration of onset of chest pain before presenting to the ED, which might have influenced the assay results. To overcome this, we chose the second sampling of blood at 3 h post-admission to the ED, irrespective of the duration of the chest pain. Secondly, the majority of our study subjects were males. This is due to the fact that our hospital is situated in the northern area of the country, which has a majority population of expatriate male workers.

Conclusions

The present study shows that POC TnI has a higher specificity and PPV than Lab HsTnT at both 0 and 3 h, while its sensitivity is equivalent to Lab HsTnT at 3 h but not at 0 h. However, the negative predictive value was high for both assays. We conclude that in patients with a negative POC TnI assay after 3 h of presentation to the ED, chest pain is unlikely to be due to NSTEMI, and they can be safely discharged from the ED.

Acknowledgments

The authors would like to thank all the nursing staff of the emergency department of Alkhor hospital for their support and contribution throughout the study.

Funding

This study was funded by the medical research center of the institution. There was no external funding for this study.

Disclosure

The authors report no conflicts of interest for this work.

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