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Research Article

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Precision, Accuracy and Regression Analysis of Cardiac Troponin I (cTnI) After Storage at Ambient Temperature for Different Time Intervals Using Cobas e801 iECL Immunoassay Analyzer

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Abstract Cardiac Troponin I (cTnI) is prescribed in many clinical conditions and therefore its accuracy, precision, collection, transport and storage conditions has been appropriately monitored and required to be followed as per international guidelines and clinical needs. Present study assessed the delays in analysis of cTnI for 9, 12 and 15 hours using sensitive total lab automation Cobas e801 system (Roche, Diagnostic) and regression analysis was performed to get percent correlation, accuracy and precision amongst analysis at zero hr (means within 30 min of collection) and several hours. Data of regression analysis revealed 94% accuracy at 9 hrs delay, 95% at 12 hrs and 98% at 15 hrs in comparison with cTnI analyzed. Data analyzed suggested that if the storage conditions, mainly tubes, area and temperature remains controlled, there will be no deviations in the analyzed cTnI even after 15 hrs. However, it doesn't meant that analysis of cTnI shall be hold for more than 1 to 2 hrs from collection to final report. It must be analyzed immediately as soon as sample received for timely clinical decisions and treatments.

Keywords: cardiac troponin I, cTnI, acute myocardial infarction, AMI, total lab automation

Introduction

Cardiac Troponin I (cTnI) is a cardiac marker, specific to validate presence of myocardial damages. It has been a successful biomarker to successfully detect acute myocardial infarction as per international and European medical associations and guidelines. Not only it detects Acute Myocardial Infarction (AMI), but also helpful in assessing cardiovascular injuries and suspected mortalities such as vascular surgery, non-cardiac surgeries, traumatic cardiac surgeries, or in cases of complicated pre-eclampsia [1-4]. Nonetheless, cTnI is prescribed in many clinical conditions and therefore its accuracy, precision, collection, transport and storage conditions has been appropriately monitored and required to be followed as per international guidelines and clinical needs [1-4].

As per manufacturer advise and international and European clinical guidelines, cTnI should be tested within two hours of collection for accurate clinical correlation and timely decisions. It is recommended that if this pre analytical

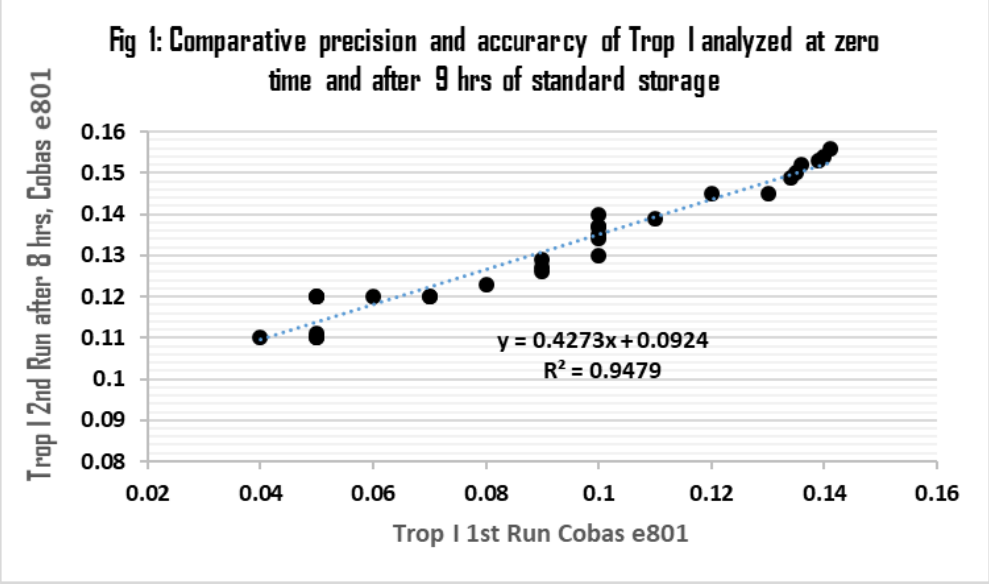
condition could not be followed, means sample not reached to clinical laboratories or not tested for two hours, than a second sample be collected for appropriate clinical correspondence and conclusions [1-4]. Another scenario is the delay in analysis, which is actually synonym with a pre-analytical phase error. Therefore, we assessed the delays in analysis of cTnI for 9, 12 and 15 hours using sensitive total lab automation Cobas e801 system (Roche, Diagnostic). Regression analysis was performed to get percent correlation, accuracy and precision amongst analysis at zero hr (means within 30 min of collection) and several hours.

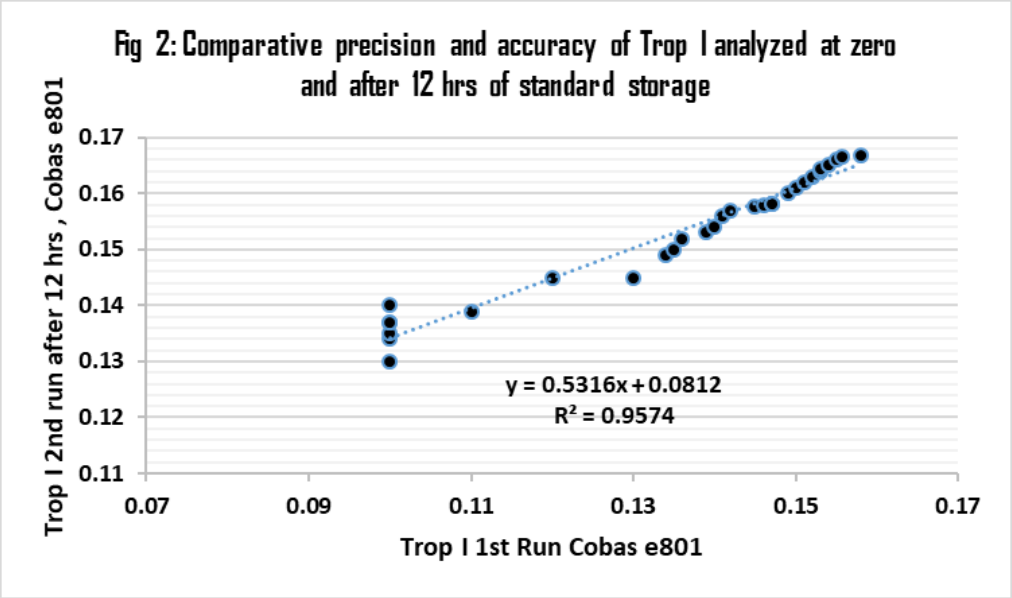
Material and Methods

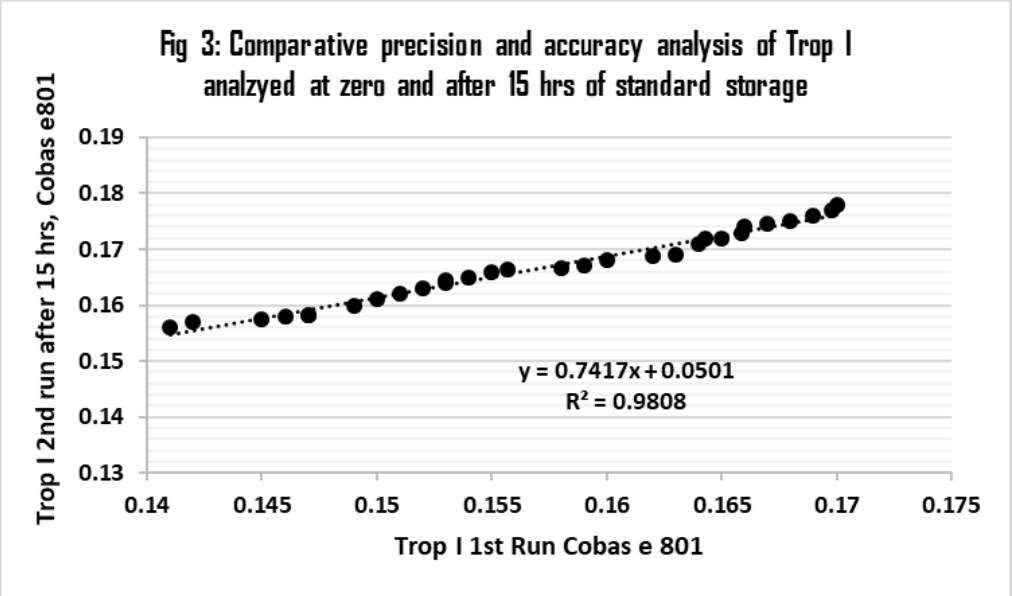
cTnI of patients, suspected of AMI or other cardiovascular anomalies (n = 30) were selected for this comparative, regression evaluated accuracy and precision valuation of delayed analysis, after 9 hrs., 12 hrs. and 15 hrs., storage at ambient temperature of 22-24OC. Samples were carefully analyzed at zero hrs (defined as analysis taken place within 30 minutes of blood collections and reported within 60 minutes) and then compared with storage at three time intervals, keeping the samples carefully sealed and stored as mentioned above. Data obtained were plot as regression analysis with Y intercept, and percent accuracy and precision was calculated via R2. Roche Cobas e801 (Total lab automation) integrated system iECL was used to analyses cTnI.

Results

Results are summarized in Figures 1 to 3. Regression analysis of cTnI regarding accuracy and precision valuation of delayed analysis, after 9 hrs., 12 hrs. and 15 hrs., storage at ambient temperature of 22-24OC was performed on Cobas e801 ECL analyzer. Samples were carefully analyzed at zero hrs (defined as analysis taken place within 30 minutes of blood collections and reported within 60 minutes) and then compared with storage at three-time intervals. Regression analysis revealed 94% accuracy at 9 hrs delay, 95% at 12 hrs and 98% at 15 hrs in comparison with cTnI analyzed. Regression analysis exhibited Y intercept at 9 hrs delay as 0.4273 x +0.0924, R2 0.9479 (Fig 1), Y = 0.5316 x + 0.0812, R2 0.9574 at 12 hrs (Fig 2) and Y = 0.7417 x + 0.0501, R2 0.9808 at 15 hrs (Fig 3) respectively. Data analyzed suggested that if the storage conditions, mainly tubes, area and temperature remains controlled, there will be no deviations in the analyzed cTnI even after 15 hrs. However, it doesn't meant that analysis of cTnI shall be hold for more than 1 to 2 hrs from collection to final report. It must be analyzed immediately as soon as sample received for timely clinical decisions and treatments.







Discussion

It has been reported that sample stability can be judged by periods of storage, from minutes to hours and days to weeks [5]. Short term stability are usually tested to establish reporting validity, accuracy and precision, whereas long term stability were used for standardization and storage protocols [1-5]. It has been reported that stability seems to be intact when cTnI analyzed within 30 to 60 minutes and storage at 4OC and if days then -20OC [5-8]. However it was also argued that analysis accuracy and precision also depends on analytical methods, instruments and pre-analytical steps. [6-8]. Moreover, many instruments doesn't show analytical stability for cTnI at room temperature and thus needed prompt analysis immediately after receiving the samples [6-8]. However many studies demonstrated that if samples stored at -70OC, analytical stability remains intact even after 5 years [9]. It was also imperative to collect blood within 3 to 6 hours, to corroborate AMI with cTnI results, thus timely orders to collect blood for the same is as important as timely analysis [8, 9].

Present study reported regression analysis of cTnI regarding accuracy and precision valuation of delayed analysis, after 9 hrs., 12 hrs, and 15 hrs., storage at ambient temperature of 22-24OC. Analysis was performed on Cobas e801 ECL analyzer. Samples were carefully analyzed at zero hrs (defined as analysis taken place within 30 minutes of blood collections and reported within 60 minutes) and then compared with storage at three time intervals. Regression analysis revealed 94% accuracy at 9 hrs delay, 95% at 12 hrs and 98% at 15 hrs in comparison with cTnI analyzed. Precision comparison showed considerable correlation and accuracy of cTnI analyzed at zero hr vs 9, 12 and 15 hrs. It is thus suggested that, although delays in testing doesn't affect the concentration of cTnI in our study, however consistency in timely analysis, gaps between collection and analysis and method validation are necessary tools and component to keep precision and accuracy intact for timely and proper clinical decisions.

Conclusion

Present study assessed the delays in analysis of cTnI for 9, 12 and 15 hours using sensitive total lab automation Cobas e801 system (Roche, Diagnostic). Regression analysis was performed to get percent correlation, accuracy and precision amongst analysis at zero hr (means within 30 min of collection) and several hours. Regression analysis revealed 94% accuracy at 9 hrs delay, 95% at 12 hrs and 98% at 15 hrs in comparison with cTnI analyzed. It is thus suggested that, although delays in testing doesn't affect the concentration of cTnI in our study, however consistency in timely analysis, gaps between collection and analysis and method validation are necessary tools and component to keep precision and accuracy intact for timely and proper clinical decisions.

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