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Research Article

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Comparative precision analysis of cardiac Tropinin I (cTnI) on two immunoassay instruments, Roche Cobas e411 and Beckman Coulter Access 2

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Abstract *Background*: In recent years, exchanging from one company brand or technology to another, for In Vitro Diagnostics, is becoming an important concern for clinical laboratories, when providing services for cardiac biomarkers such as Troponins. *Aim:* In present study we demonstrated comparative analytical correlation precision compatibility of cTnI on two immunoassay instruments, Cobas e411 and Beckman Coulter Access 2. *Materials and Methods:* Blood samples were collected from 75 patients and 25 healthy individuals in heparinized tubes. The patients were divided into three groups with 25 patients in each group, according to severity of cardiac conditions. Plasma was separated and analyzed for cTnI on Cobas e411 using electro-chemiluminescence (ECLi) immunoassay technology (Roche Diagnostics, Basil) and Beckman Coulter Access 2 using chemiluminescence technology (Beckman, USA) and data were compared statistically by using SPSS ver 18.0 (USA), regression correlation analysis and considered significant when $P < 0.05$. *Results:* Analysis of samples data depicted compatible and appreciable precision amongst both instruments with regression R^2 ranging from 0.872 to 0.921, representing attuned accuracy of 92.1%, 89.5% and 87.2% for replicated run on two different instruments, in suspected cardiac cases, MI and cardiac myopathies and cardiac patients, respectively. *Conclusion:* Regression correlation assessment of data showed compatible linearity and accuracy of both assays with R^2 ranging from 0.872 to 0.921, which provided precision surety for exchanges or switching of instruments for an individual parameter.

Keywords Troponins, Troponin I, cTnI, immunoassays, chemiluminescence

Introduction

One of the very important cardiac biomarker, troponin (cTn) I is a troponin isoform which is unique to the cardiac myocyte. Its measurement is sensitive and specific for detecting cardiac injuries [1, 2]. Several analytical generations of cTn assays have been upgraded, well recognized by regulatory bodies over the years [1, 2]. The materialization and expansion of newer, faster, technical-friendly and financially feasible instruments for clinical medicine laboratories in last three decades, induced importance to manage, organize and ensure analytical precisions, quality and rapid turnaround time (TAT) for several biomarkers, including Troponin isoforms [3-5]. Within a span of last 10 years, advanced clinical practice has focused on improved cTn assays for rapid diagnosis of acute myocardial infarction (MI) and related cardiac anomalies [1,2,6]. This was also advocated by international task force guidance [5] including guidelines recommended by professional societies worldwide [1, 2, 6]. In recent years, introduction of further and farther sensitive cTn assays allowed earlier, more rapid MI detection, facilitating in identification of higher percentage of patients arriving in emergency wards with apparent chest pains and who actually are at risk of, seemingly, short-term major adverse cardiac events [1, 2 ,7, 8,9].

Moreover, in recent past, switching from one company brand or technology to another, whether reasoned as financially feasible or technology viable, is also became an important issue for clinical laboratories, when providing services for cardiac biomarkers such as Troponin or NT pro BNP [8, 9]. The end-user, as well as the service provider needed to sure about accuracy, precision and compatibility of technology, analytical principles and reference ranges amongst diagnostic instrument brands, if and when switching from one brand to another became a necessity.

In present study we demonstrated comparative analytical correlation precision compatibility of cTnI on two immunoassay instruments, Cobas e411 and Beckman Coulter Access 2.

Materials and Methods

Patients' selection and study protocol

Seventy five patients (males = 62; females = 13, age range = 36-82 yrs) with either chest pain, dysponea or with known history of Acute Coronary Syndrome (ACS), Ischemic stroke, ventricular dysfunction or myocardial infarction/ necrosis were included in this prospective study from June 2018 to Nov 2018. Sample collection were made from patients falling within the inclusion criteria of clinical symptoms or known history of ACS, Ischemic stroke, ventricular dysfunction or myocardial infarction and necrosis. The patients who are on steroid therapy, underwent surgery, suffering from renal impairment were excluded from the study. Twenty five samples were also taken from Age-gender matched individuals with no history of any adverse clinical condition.

Analytical Measurement of cardiac Troponin I on Immunoassay analyzers

Blood samples were collected from 75 patients and 25 healthy individuals in heparinized tubes. The patients were divided into three groups with 25 patients in each group, according to severity of cardiac conditions (Fig 2-4). Plasma was separated and analyzed for cTnI on Cobas e411 using electro-chemiluminescence (ECLi) immunoassay technology (Roche Diagnostics, Basil) and Beckman Coulter Access 2 using chemiluminescence technology (Beckman, USA). Normal reference range of cTnI = < 0.30 ng/ml. The data was compared statistically by using SPSS ver 18.0 (USA), regression correlation analysis and considered significant when $P < 0.05$.

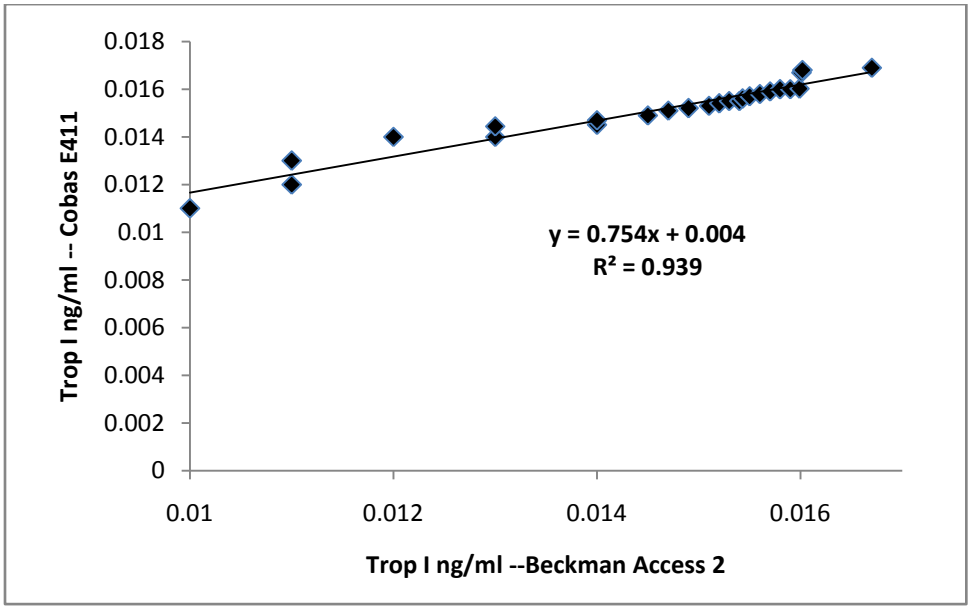

Figure 1: Comparative precision analysis of Trop I on Cobas e411 vs Beckman Access 2 for normal subjects

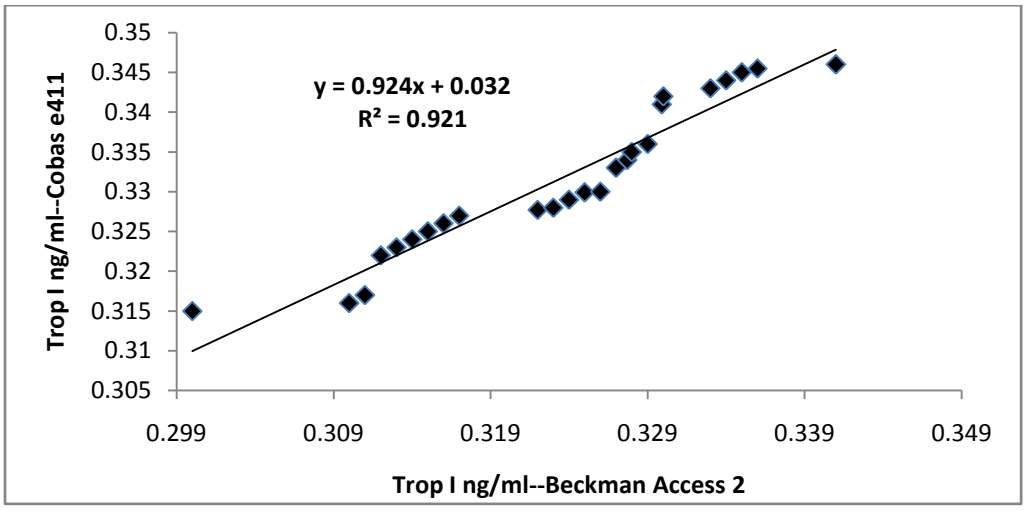

Figure 2: Comparative Precision analysis of Trop I on Cobas e411 vs Beckman Access 2 for suspected cardiac cases

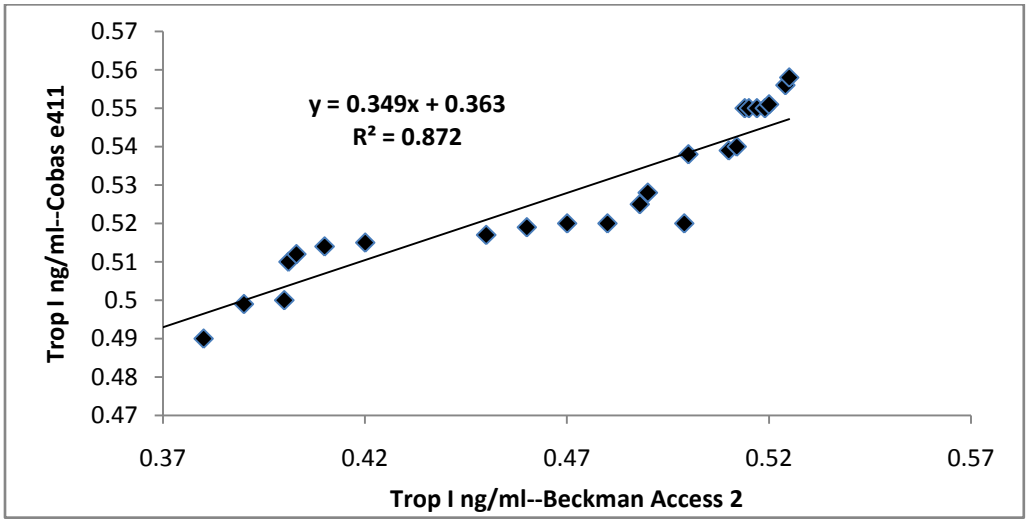

Figure 3: Comparative precision analysis of Trop I on Cobas e411 vs Beckman Access 2 for cardiac patients

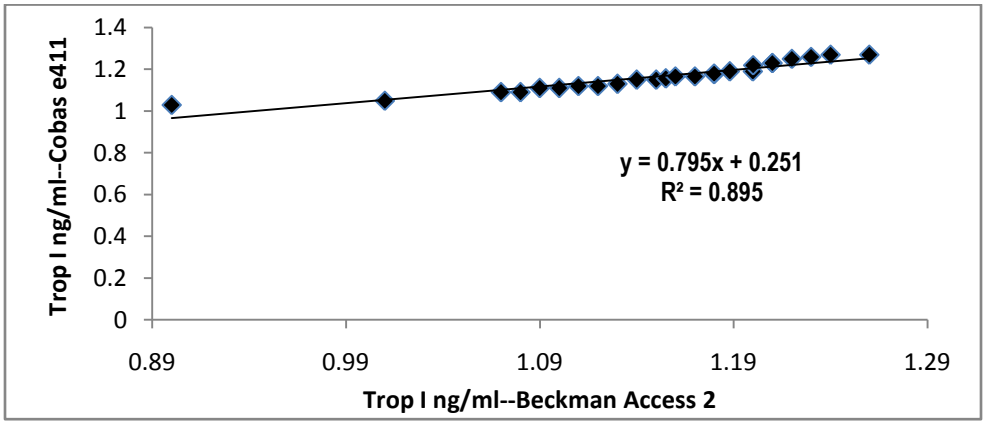

Figure 4: Comparative precision analysis of Trop I on Cobas e411 vs Bekman Access 2 for patietnts with Myocardial infarction and Cardiac myopathies

Results

Results are summarized in Fig 1 to 4. The patients were divided into three groups with 25 patients in each group, suspected cardiac cases (Fig 2), cardiac patients (Fig 3), and with MI and cardiac myopathies, accordingly (Fig 4). Samples were analyzed for cTnI on Cobas e411 using electro-chemiluminescence (ECLi) immunoassay technology (Roche Diagnostics, Basil) and Beckman Coulter Access 2 using chemiluminescence technology (Beckman, USA). Data were compared using SPSS ver 18 with regression correlation equations. Analysis of samples data depicted compatible and appreciable precision amongst both instruments with regression R^2 ranging from 0.872 (Fig 3) to 0.921 (Fig 2), representing attuned accuracy of 92.1% (Fig 2), 89.5% (Fig 4) and 87.2% (Fig 3) for replicated run on two different instruments, in suspected cardiac cases, MI and cardiac myopathies and cardiac patients, respectively.

Discussion

Analytical precision, compatibility, accuracy, reproducibility are some of the technical jargons that are very much interrelated and posses significant position for service providers in a medical or health care settings such as clinical laboratories [9-11]. Switching analytical instruments for reasons such as choice of advanced technology, better financial viability, accessibility or managing work load is now a routine in tertiary care hospitals or large-scale stand alone commercial clinical laboratories. To compare and evaluate diagnostic and analytical precision and accuracy of cTnI, several dozen studies were conducted and reported in last one decade [9-11]. The present study was also conducted to evaluate precision, accuracy and compatibility of cTnI assay on two different instruments and brands, Cobas Roche and Beckman Coulter Access 2. Due to high volume of samples for cTnI per 24 hours and being a tertiary care hospital, having backups is a necessity and possessing more than one IVD instruments for the same parameter is smart management. Analysis of patient's samples on both instruments depicted compatible and appreciable precision with regression R^2 ranging from 0.872 to 0.921, thus representing accuracy level of 87.2% to 92.1%, providing us analytical surety for switching instruments as per need and work-load without any significant deviation in results. Previous studies reported analytical comparison of even more than two instruments for cTnI and other cardiac biomarkers with mostly depicting sustainable accuracy and precision [9-11]. Interestingly exchanging or replacing normal cTnI with high sensitive cTnI is sometimes necessitates precision evaluation, even if it was done with the same brand of instruments [12, 13].

Conclusion

The present study described comparative precision analysis of cTnI on two immunoassay instruments. Regression correlation assessment of data showed compatible linearity and accuracy of both assays with R^2 ranging from 0.872 to 0.921, which provided surety for exchanges or switching of instruments for an individual parameter.

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