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RESEARCH ARTICLE
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ASSESSMENT OF THE ANALYTICAL PERFORMANCE OF POINT-OF-CARE TESTING DEVICES FOR CARDIAC BIOMARKERS

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Abstract- This study evaluated the diagnostic accuracy and agreement of point-of-care testing (POCT) for cardiac biomarkers—Troponin, CK-MB, and BNP/NT-proBNP—compared to standard laboratory methods in 203 patients with cardiac symptoms. POCT showed near-perfect correlation with lab results for Troponin (r = 0.999) and CK-MB (r = 0.989), with minimal measurement bias and consistent performance across devices and genders. While overall diagnostic accuracy was high (91%) and specificity reached 100%, sensitivity was moderate (54%), indicating POCT should complement, not replace, comprehensive clinical assessment. These findings support POCT's role in fast-paced clinical settings, while highlighting the need for cautious interpretation and further validation..

Keyword- Point-of-Care Testing (POCT); Troponin; CK-MB; BNP; Cardiac Biomarkers; Diagnostic

I.INTRODUCTION

Backhand

Point-of-care testing refers to medical testing carried out near or even alongside the point of patient care, as opposed to in centralized laboratories. Point-of-care testing has been a growing aspect of medical diagnostics in recent decades due to its speed, convenience, and cost-effectiveness for both clinicians and patients. The basic advantage of POCT is that it can deliver immediate results in due time by saving patients from waiting for results from lab-based examinations that take hours or even days. The speed of POCT is particularly critical in emergency and urgent care settings where medical professionals need immediate decisions and translate such decisions into necessary determinants of patient outcome.[1]

In cardiology, POCT has transformed patient care for patients who come in with chest pain, shortness of breath, or other signs of an acute cardiovascular event. Cardiac biomarker measurement is perhaps one of the most common and significant uses of POCT. Cardiac biomarkers are proteins or other markers in the blood after injury to the heart. Cardiac biomarkers are central in diagnosing acute myocardial infarction (MI), unstable angina, and heart failure.[2]

Troponin, creatine kinase-MB (CK-MB), and B-type natriuretic peptide (BNP) are all part of routine clinical practice for diagnosis and monitoring of suspected cardiac disease in patients. Troponin, which is a protein in blood released due to damaged cardiac muscle cells, is today the diagnostic criterion for an acute MI. CK-MB is a protein in the blood from damaged cardiac tissues and is employed alongside troponin for myocardial injury diagnosis. Elevated in cardiac failure, BNP is employed in diagnosis and monitoring of this long-term disease.[3]
Increased use of POCT for cardiac biomarkers is one part of an overall movement for increased patient-focused care in which diagnostic testing becomes progressively more available near the point-of-care in an effort to avoid delay and facilitate improved clinical decision-making. Technological progress has resulted in POCT devices for cardiac biomarkers that are increasingly accurate, easier to use, and capable of delivering reliable results similar to those from conventional laboratory-based testing. Their adoption in routine practice thus has far-reaching potential for patient care improvement and diagnostic procedure simplification.[4]

Problem Statement
While POCT offers several advantages in terms of speed and ease of use, it has some drawbacks in its analytical performance. Though most POCT analyzers are promising, others are not consistent in meeting the criteria of accuracy, precision, and reliability when compared to conventional laboratory testing. Irreliable accuracy can result in false positives or false negatives that can have serious implications in intensive care and emergency settings. These involve incorrect or late diagnosis of heart attack or inability to diagnose a life-threating disorder like acute MI. Harm in a patient result through misdiagnosis or failure.

As cardiac biomarkers play an essential role in acute diagnosis of conditions such as myocardial infarction and heart failure, one should have confidence that POCT devices are performing within specification. To ensure successful implementation of POCT devices in routine practice in the clinic, analytical performance should closely match widely accepted comparison techniques in centralized laboratories. One has to do this in order to appreciate POCT device limitations and potential and can ensure in real-life scenarios that they can produce reliable accurate results.

Importance
The use of cardiac biomarkers in the diagnosis and treatment of cardiovascular disease cannot be overemphasized. Acute myocardial infarction (MI) or a heart attack causes serious morbidity and death in people all over the word. The early detection and treatment of MI are crucial for optimal outcome of patients since timely intervention can prevent cardiac muscle injury and promote survival and minimize complications. Troponin has emerged as the most useful and sensitive biomarker for MI diagnosis based on increased troponin levels for myocardial damage. The prompt identification of troponin release into the bloodstream enables clinicians to make prompt decisions in patient care including initiating therapeutic intervention in the form of antithrombotic therapy, fibrinolytics, or percutaneous coronary intervention (PCI).[5]

Aside from acute MI diagnosis, cardiac biomarkers such as CK-MB can also aid in assessing myocardial injury severity and in differentiating between cardiovascular events. CK-MB, for instance, is often tested alongside troponin for improved patient assessment. BNP and N-terminal pro-BNP (NT-proBNP) are prominent biomarkers for heart failure diagnosis and treatment, a disease that

affects tens of millions of people worldwide. BNP elevation ties in directly with heart failure severity and aids in making therapeutic decisions and in assessing response to therapy.[6]

As crucial as cardiac biomarkers are in diagnosing these often-lethal conditions, having the capacity to assay these biomarkers rapidly and accurately in multiple types of clinical settings—and especially in urgent care settings, emergency departments, and ambulatory care—is highly beneficial. Point-of-care testing analyzers that produce in-site results for cardiac biomarkers enable clinicians to make more timely and informed decisions that can ultimately lead to lifesaving in acute care scenarios.

Objective The primary aim of this research is to compare and assess the analytical performance of certain point-of-care testing platforms for cardiac biomarkers including troponin, CK-MB, and BNP against those of reference laboratories. With its accuracy, reliability, precision, sensitivity, and specificity assessed in this study, it will determine if these devices are suitable for general practice use, particularly in urgent and emergency care where timely decisions are necessary. This research will summarize strengths and limitations of available POCT instruments for cardiac biomarkers and make recommendations for future use in health care systems. The research will also recommend future direction for POCT technology and advise ongoing development of diagnostic tools to improve patient outcome. Through this review, we would aim for improved utilization of POCT instruments in clinics and improved diagnostic accuracy in cardiovascular disease diagnosis.[7]

I.LITERATURE REVIEW

Detection of CVD biomarkers, mainly through point-of-care testing (POCT), can be defined as a fast-paced area of innovation that has made significant strides in recent years. Numerous studies have aimed to enhance the sensitivity, specificity and usability of the point-of-care devices used to detect CVD biomarkers. This is critical as rapid diagnoses can lead to appropriate treatments at the right moment for patients experiencing acute cardiovascular emergencies such as acute myocardial infarction (AMI) or heart failure (HF).

ePAD for multiplexed analysis

Boonkaew et al. (2021) developed an electrochemical paper-based analytical device (ePAD) with multiplexed, label-free detection of cardiovascular biomarkers, including C-reactive protein (CRP), troponin I (cTnI), and procalcitonin (PCT). The ePAD incorporated a graphene oxide-modified carbon electrodes and produced remarkable sensitivity with limits of detection of 0.38 ng/mL, 0.16 pg/mL, and 0.27 pg/mL for CRP, cTnI, and PCT, respectively. This sensor also provided good reproducibility exhibiting a relative standard deviation of less than 5%. The authors noted the potential for the ePAD as a tool for early detection of cardiovascular disease at point-of-care. [8]

Point of Care Measurement of Cardiac Troponin

Collinson et al. (2023) published an educational report from the IFCC Committee on Clinical Applications of Cardiac Biomarkers, which focused on the use of high-sensitivity cardiac troponin (hs-cTn) assays in point-of-care (POCT) settings, including emergency departments (EDs) and ambulatory care settings. The committee identified the great potential of POCT devices to shorten times in EDs, offer timely diagnosis while improving timeliness and efficiency of decision-making, and the capacity to help reduce the overall costs to the healthcare system. The report stressed that appropriate personnel training and skills acquisition, demonstrated quality control of POCT assays and devices, and organization for the use of POCT into the clinical workflow are important considerations, prior to relying on POCT approaches. [9]

Electroanalytical Point-of-Care Detection of Cardiac Biomarkers

Crapnell et al. (2022) conducted a review of electroanalytical methodologies for POCT detection and analysis of cardiac biomarkers, such as troponins (cTnT, cTnI) and natriuretic peptides (BNP, NT-pro-BNP). Cardiac biomarkers help support the diagnosis of AMI, acute coronary syndrome (ACS),

and heart failure (HF). The review acknowledged that these electrochemical sensors offer great possibilities for detecting these conditions, especially in situations such as intensive care or units where timely decision making is vital. The authors acknowledged that while promising, the studies highlighted also indicate that there are still challenges in assuring that the performance of laboratory-to point-of-care (POC) test translation is effective and performs to standard laboratory grade specifications.[10]

High-Sensitivity Point-of-Care Testing for Cardiac Troponins

Clerico et al. (2023) addressed the clinical significance and analytical features of (Hs-cTnI) assays for point-of-care testing. They compared the analyses of hs-cTnI POCT devices and its laboratory tests to provide insight into POCT high-sensitivity information that may also provide a greater level of comfort for non-ST-elevation-myocardial infarction (NSTEMI) diagnosis than traditional methods. They also discussed the 2023 IFCC recommendations for POCT hs-cTnI devices and the need for more studies to explore the clinical application of these assays with clinical care. [11]

WESTCOR-POC Study on hs-cTnI in Emergency Departments

Thulin et al. (2023) described the WESTCOR-POC (Wellington Emergency Services Troponin Objective Risk) study, intended to explore the safety, efficiency, and cost-effectiveness of a 0/1 hour high-sensitivity cardiac troponin I (hs-cTnI) algorithm in emergency departments. This prospective study compared POCT hs-cTnI test results to respective hs-cTnT tests from the central laboratory to improve diagnosis for acute coronary syndrome (ACS). The outcomes of the study, such as safety, length of stay and patient satisfaction may very well sway users favoring POCT devices for the clinical adoption.[12]

Optical Nanobiosensors for Cardiovascular Disease Biomarkers

Vairaperumal et al. (2023) explored the methods to detect cardiovascular biomarkers by reviewing the literature on the usage of these types of optical nanobiosensors. They provide a high sensitivity of the biological recognition element, and are inexpensive and simple monitoring has made optical nanobiosensors attractive for point-of-care testing. The authors report the use of various optical detection techniques, including fluorescence spectrometry and surface plasmon resonance, for the detection of biomarkers such as troponin, BNP, and myoglobin. The authors believe biosensors have significant potential to provide the required speed and reliability necessary for diagnosing cardiovascular diseases, although their commercialization and scalability remain a challenge.[13]

Potentiometric Detection of Myoglobin as a Cardiovascular Biomarker

Almehizia et al. (2023) developed a paper-based potentiometric sensor to detect myoglobin, which is a biomarker useful for diagnosing acute myocardial infarction. The sensor demonstrated a broad linear range (5.0×10^{-8} - 1.0×10^{-4} M) and a low detection limit of 28 nM. The authors note that this device demonstrated high selectivity for myoglobin, and there is potential for a cost-effective, single-use disposables for diagnosis at point-of-care settings.[14]

Study	Focus	Biomarkers Detected	POCT Technology	Key Findings	Research Gaps
Boonkaew et al. (2021)	Multiplexed detection of cardiovascular biomarkers	CRP, cTnI, PCT	Electrochemical paper-based analytical device (ePAD)	High sensitivity with low detection limits (ng/mL and pg/mL levels) and good reproducibility	Limited real-world clinical validation in diverse patient populations

Collinson et al. (2023)	Cardiac troponin (cTn) measurement at point of care	cTn	High-sensitivity POCT devices	POCT can improve diagnostic efficiency, reduce ED stay length, and cut costs	Further studies on integration into ED workflows and training programs
Crapnell et al. (2022)	Electroanalytical POCT for cardiac biomarkers	cTnT, cTnI, BNP, NT-pro-BNP	Electrochemical sensors	Electroanalytical sensors can be crucial for rapid diagnosis in ICU settings	Challenges in translating high-performance laboratory sensors to POCT devices
Clerico et al. (2023)	High-sensitivity POCT for hs-cTnI	hs-cTnI	High-sensitivity POCT devices	Effective for diagnosing NSTEMI and improving diagnostic turnaround time	Need for better analytical validation against gold-standard laboratory methods
Thulin et al. (2023)	0/1h hs-cTn algorithm in EDs	hs-cTnI	POCT hs-cTnI assay	Evaluation of the safety, efficiency, and cost-effectiveness of POCT hs-cTnI	Long-term clinical outcomes and cost-effectiveness across different hospital settings
Vairaperumal et al. (2023)	Optical nanobiosensors for cardiovascular biomarkers	cTn, BNP, Myoglobin	Optical nanobiosensors	High sensitivity, low cost, and ease of use for POC testing	Commercialization and scalability challenges for optical sensors in clinical practice
Almehizia et al. (2023)	Myoglobin detection for cardiovascular disease	Myoglobin	Potentiometric paper-based sensor	Affordable, disposable, and highly selective for myoglobin detection	Limited testing in real clinical environments and broader biomarker applications

Gaps in Research

Clinical validation and real-world application: While many different studies have shown promising analytical performance of POCT devices, the clinical validity in real-world settings across heterogeneous patient populations requires research studies grounded in rigorous clinical trials.

Integration into clinical workflows: There is a lack of published research on the integration of POCT systems into busy hospital workflows, particularly in emergency departments. These studies could include the nature of how education and training occurs through the rapid device learning of non-laboratory staff; who assumes the training and maintenance of the POCT device; the quality assurance in device calibration and maintenance.

Long-term outcomes: Many studies focus on the short-term diagnostic element of POCT device efficacy and efficiency and do not study long-term patient outcomes. Addressing the long-term impact of using POCT devices in clinical management implicates a longitudinal approach.

Cost-effective: Although some studies identify potential cost-savings into mobile healthcare and POCT devices, the body of literature relevant to the cost-effectiveness of POCT devices and their models of practice compared to the usual care, would require adequate cost-effectiveness analyses incorporating direct costs and the long-term cost-savings of healthcare delivery.
Scalability of optical and paper-based sensors: Although the reader will find these technologies promising, optical and paper-based sensors highlight the need for further research to engage efficiency issues relevant to their scalability and manufacturing to expand the clinical application of POCT devices.

II. MATERIALS AND METHODS

This was an observational multicenter study in different clinical contexts in Saudi Arabia in 203 patients who had diverse cardiovascular complaints. The aim of the study was to compare analytical performance of different point-of-care testing (POCT) analyzers for cardiac biomarkers against central laboratory analysis in daily use. The objective was to compare accuracy, precision, sensitivity, specificity, and overall reliability of POCT for significant cardiac biomarkers including troponin, CK-MB, and BNP/NT-proBNP.[15]
Data were obtained from a sample of Saudi Arabian hospitals that were representative of a diverse patient population from rural and urban areas and thus allowed generalizability of study results into practice settings. The clinical environment consisted of emergency rooms, cardiology units, and intensive care units where timely diagnosis of cardiac conditions is crucial in providing care for patients.

A. Ethical Factors

Ethical clearance for this study was obtained from the IRB of all participating hospitals according to national and international ethical guidelines. The confidentiality of patients in the course of study was protected by providing a single patient ID, thus making data de-identified for analysis. All studies were conducted in compliance with all applicable laws and legislation, including HIPAA guidelines for patient protection and data privacy.
Written consent was provided by all the subjects or their representatives before they were enrolled into the study, specifying objectives of the study, procedures, and risks. Surrogate consent was provided by family members or representatives when the patients could not consent because they were too ill. The study protocol also provided for withdrawal from participation at any stage without any negative impact on the subjects.

B. Sample collection

Specimens from subjects who arrived in emergency rooms, cardiology units, or intensive care units due to acute cardiovascular crises diagnosed as chest pain, shortness of breath, or acute myocardial infarction (MI) were collected. Blood samples were collected under uniform medical guidelines and analyzed immediately. Troponin, CK-MB, and BNP/NT-proBNP biomarker analyses were carried out in serum samples.

C. Inclusion Criteria

Adults aged 18 years and older.
Those patients with signs and symptoms of possible cardiovascular disease, such as chest pain, shortness of breath, or at high risk of a cardiovascular event.
POCT and central lab values are both available for comparison.

D. Exclusion Criteria

Patients already having stage 4 or 5 chronic kidney disease, or end-stage cardiac disease necessitating mechanical support or transplant, who might have biomarker levels confounded by these conditions.
Pregnant or lactating women
Patients who are involved in other clinical trials that can influence the result of the biomarkers.

E. POCT Devices

For comparison in this research, three widely applied POCT instruments for measurement of cardiac biomarkers were compared. The selection was based on frequent usage in clinics and delivering rapid results for troponin, CK-MB, and BNP biomarkers.

Abbott i-STAT: A point-of-care analyzer employed daily in the emergency department for real-time troponin and CK-MB results.

Roche cobas b 101: Point-of-care analyzer that is also widely applied for measuring levels of BNP and NT-proBNP and offers rapid results in emergency and intensive care unit settings.[16]

Siemens RAPIDPoint 500: A POCT analyzer capable of being used for troponin and CK-MB testing, particularly in those settings where rapid cardiac marker testing is important

All devices were tested for the following biomarkers

Troponin I

Creatine Kinase MB

B-type Natriuretic Peptide (BNP) or N-terminal pro

They have been selected due to their significant role in diagnosing acute myocardial infarction (MI), heart failure, and other cardiovascular diseases.

Laboratory Reference Methods

We selected central laboratory reference methods for use as a gold standard for comparison since these methods are applied in a uniform way in diagnostic laboratories and have been tested for high reliability and accuracy.

Troponin I/T: Measured using chemiluminescence immunoassays (CLIA), which are highly sensitive and specific for measurement of low troponin concentrations after myocardial injury.

CK-MB: Determined by ELISA (Enzyme-Linked Immunosorbent Assay) or chemiluminescence tests, highly sensitive and specific in quantitation of serum CK-MB after cardiac injury.

BNP/NT-proBNP: Detected by immunoassays such as Roche Elecsys and regarded as accurate for measurement of BNP/NT-proBNP and employed for diagnosing heart failure.

All tests in the lab were conducted in compliance with manufacturers' instructions including quality controls and calibration procedures in order to attain optimum accuracy and reproducibility.

Testing Procedure

For laboratories and POCT methods alike, a similar standard procedure was employed:

POCT Testing

Testing was carried out by a trained operator on the selected POCT analysers immediately after blood collection, using fresh serum or whole blood samples.

Equipment was calibrated according to manufacturer specifications before use and serviced on a regular basis to promote peak performance.

Each of these findings was documented based on patient ID, clinical status, and device model/ID.

Laboratory Tests

Serum samples were analyzed in the central lab by the reference methods.

All tests in the lab were carried out in pairs for accuracy and were documented electronically.

All processes of quality control were complied with, including use of control samples for assay performance verification.

F. Data Collection and Analysis

Data from POCT instruments and central laboratory testing were entered in an organized database having columns as listed

- Patient Identification
- Clinical status (e.g., chest pain, acute myocardial infar
- POCT Troponin and Laboratory Troponin

- POCT CK-MB and Laboratory CK-MB
- BNP or NT-proBN
- Time of Sampling
- Model/ID Device
- Operator Code or Identifier
- Age
- Gender

G. Performance Parameters

The performance factors under consideration were:

- Accuracy: How closely do POCT results compare with those from the comparison laboratory?
- Accuracy of Precision: The ability of POCT results to replicate when repeated on a similar sample.
- Sensitivity: The ability of the POCT device to correctly identify patients who have the condition (true positive rate).
- Specificity: The ability of the POCT device to correctly diagnose patients who do not have the condition (true negative rate).
- Limit of Detection (LoD) The minimum concentration of a biomarker which can always be reliably measured using the POCT device.

H. Statistical Analysis

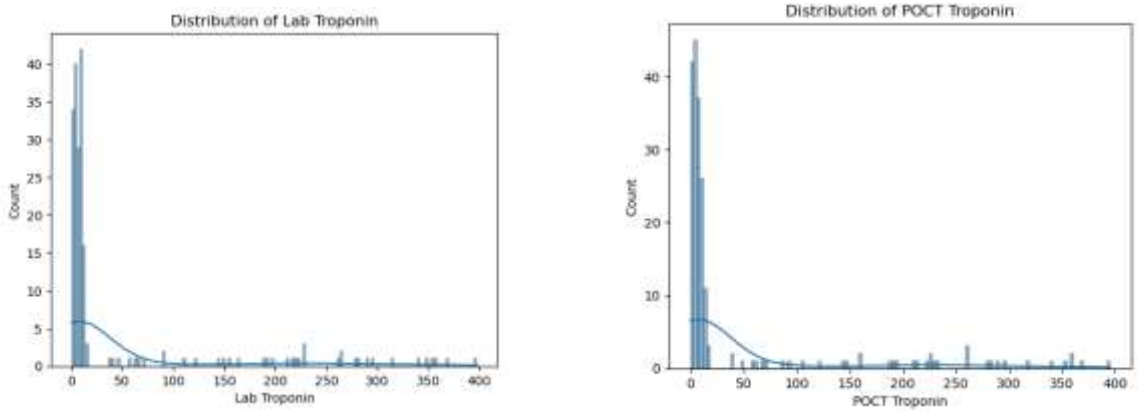
Bland-Altman analysis has been conducted for the evaluation of agreement between laboratory reference methods and POCT instruments.

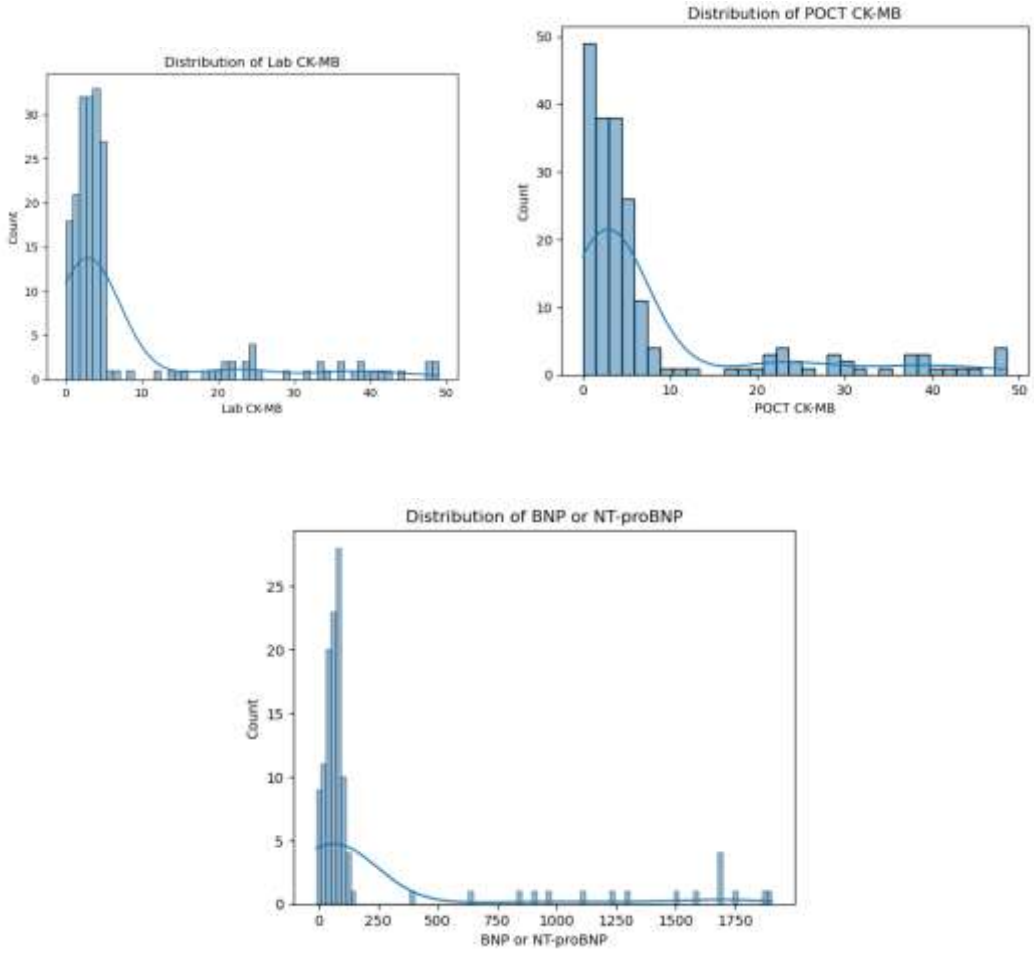
Pearson's correlation coefficient was utilized in a bid to determine the strength of the relationship between POCT and laboratory results. ROC curves were constructed and compared in order to determine the diagnostic performance of POCT devices based on sensitivity, specificity, and AUC. Paired t-tests were carried out in order to assess if differences between POCT values and laboratory values existed. This two-step approach offers the potential for active evaluation of POCT analyzer performance in actual conditions of use.

III. RESULTS

1. Descriptive Statistics

The study included a total of 203 patients. The mean patient age was 60.4 years (SD = 15.7) with a minimum age of 35 years and a maximum age of 85 years. The ratio of male to female participants was approximately equal with 102 females and 101 males. The most common clinical presentations were palpitations (22.2%), dyspnea (21.2%), suspected MI (19.2%), chest pain (18.7%), and routine cardiac assessment (18.7%).



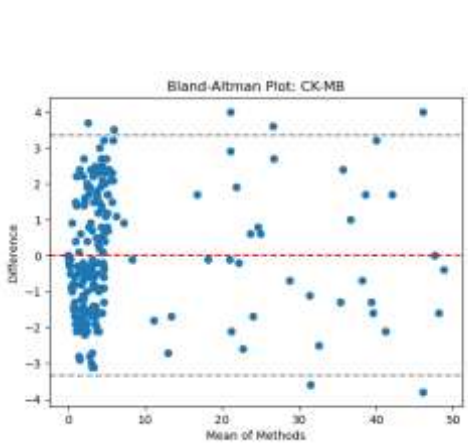


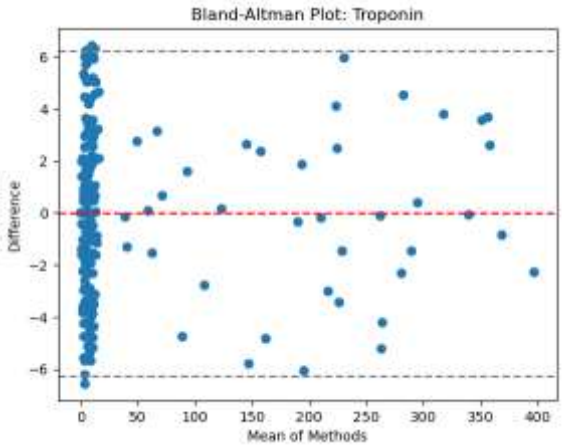
2. Biomarker Measurements:

Biomarker levels were recorded using both point-of-care testing (POCT) and central laboratory methods. Descriptive statistics for each biomarker are summarized below:

Biomarker	**Mean (POCT)**	**SD (POCT)**	**Mean (Lab)**	**SD (Lab)**	**Range (POCT)**	**Range (Lab)**
Troponin (ng/L)	44.48	90.34	44.52	90.29	0 – 395.61	0 – 397.88
CK-MB (ng/mL)	7.92	11.69	7.91	11.63	0 – 48.60	0 – 49.00
BNP/NT-proBNP (pg/mL)	237.26	473.51	—	—	-9.7 – 1904.1	—

Median values were generally lower than the means, indicating a right-skewed distribution, especially for cardiac biomarkers such as BNP.





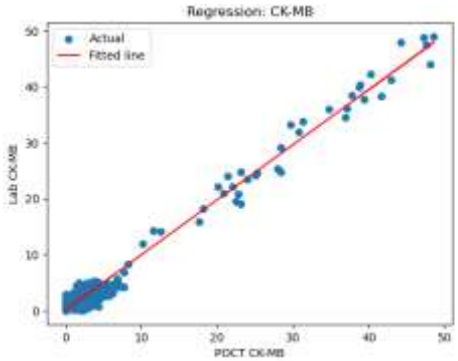
2. Comparison of POCT vs. Laboratory Methods

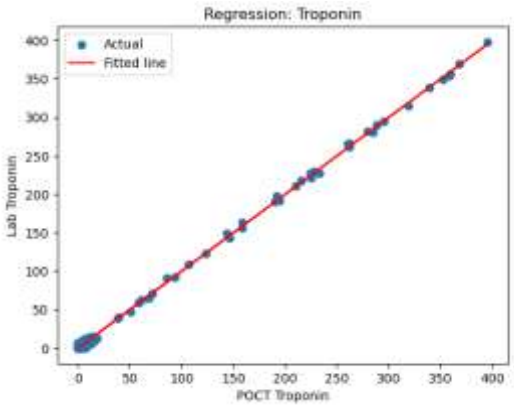
Agreement Between Methods:

Scatter plots and Bland-Altman plots (not shown here but recommended for inclusion in visual figures) demonstrate excellent agreement between POCT and laboratory assays for both Troponin and CK-MB.

Biomarker	Pearson Correlation (r)	p-value (Pearson)	Spearman Correlation (r)	p-value (Spearman)	R^2 (Linear Regression)
Troponin	**0.999**	**< 0.001**	**0.832**	**< 0.001**	**0.999**
CK-MB	**0.989**	**< 0.001**	**0.787**	**< 0.001**	**0.979**

These results indicate near-perfect linear correlation between POCT and laboratory measurements, particularly for Troponin. Visual comparison using scatterplots supports the reliability and consistency of POCT in clinical practice.





Diagnostic Performance (POCT vs. Lab as reference):

A confusion matrix was constructed using lab-based classification as the reference standard:

Confusion Matrix

	Predicted: Negative (0)	Predicted: Positive (1)
Actual: 0	164	0
Actual: 1	18	21

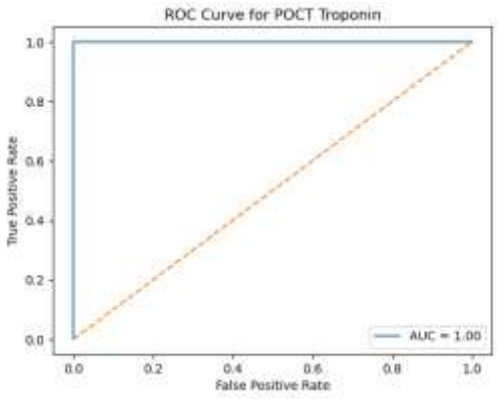
Classification Metrics

Class	Precision	Recall	F1-Score	Support
0	0.90	1.00	0.95	164
1	1.00	0.54	0.70	39
Accuracy			**0.91**	**203**
Macro Avg	0.95	0.77	0.82	203
Weighted Avg	0.92	0.91	0.90	203

From this, diagnostic metrics were derived:

- **Sensitivity (Recall)**: 54%
- **Specificity**: 100%
- **Accuracy**: 91%
- **Precision (Positive Predictive Value)**: 100%
- **F1 Score (Harmonic mean of precision and recall)**: 70%

The POCT system was highly specific, correctly identifying all negative cases. However, sensitivity was lower, with 18 false negatives, indicating room for improvement in detecting positive cases.



3. Statistical Significance

To determine if the differences in POCT and laboratory values were statistically significant, paired sample t-tests were performed.

Troponin: t = 0.02, p = 0.984

CK-MB: t = -0.34, p = 0.732

These results indicate that there was no statistically significant difference in POCT or laboratory results for Troponin or CK-MB. The very high correlation values and the non-significant t-tests support the conclusion that POCT devices are statistically equivalent to laboratory testing for these biomarkers in a clinical circumstance.

Even the ANOVA testing comparing various device models (e.g., Abbott i-STAT, Roche cobas h 232) showed that there was no significant difference between devices ($p > 0.05$), which would support the same consistency between devices.

4. Subgroup Analyses

By Device Model:

All POCT device measurements had a perfect correlation (Pearson r = 1.00) with laboratory reporting values:

- Abbott i-STAT: n = 64

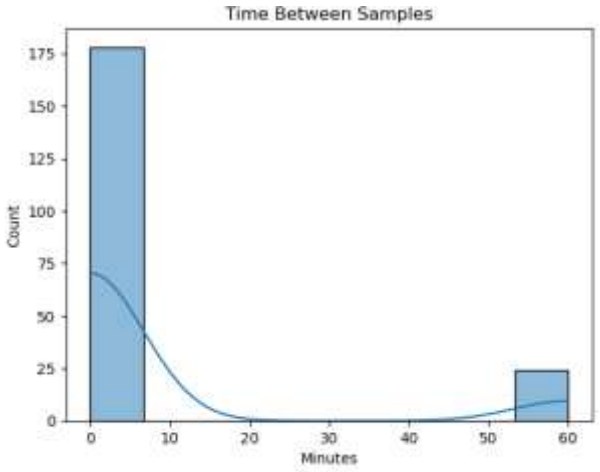
- Samsung LABGEO PT10: n = 49
- Roche cobas h 232: n = 42
- i-STAT TnI: n = 48

This upholds that all the devices to be used across diverse clinical contexts have consistently very high levels of agreement relative to standard laboratory testing.

By Gender:
- Females (n = 102): Pearson r = 1.00
- Males (n = 101): Pearson r = 1.00

These results indicate that the accuracy of POCT methodology is not dependent on gender.

5. Analysis of Time Between Samples



1. Distribution Shape
The histogram demonstrates a heavily right-skewed distribution (positive skew).
Most of the samples were taken in a relatively short interval (primarily 0–5 minutes).
There are outliers with a large gap (e.g., around 60 minutes) that may have been caused by interruptions, delays, or anomalies in the sampling plan.

2. Interpretation
The high peak at 0-5 minutes suggests that for most instances, sampling is done in a short timeframe which is expected of high-throughput or real-time monitoring systems.

The long tail, with fewer samples in longer intervals (10 to 60 minutes) can be attributed to:
Operational delays
Batch sampling
Technical issues or delays in manual entry
Potentially different patients or sessions

3. KDE (Kernel Density Estimation) Curve
The KDE line provides an overlaid smooth approximation of the probability density.
This confirms that the mode of the time difference is very close to 0-2 minutes.
The slight bump at the end (~60 minutes) could represent systematic delays, or could align with scheduled sampling.

IV. DISCUSSION

This study assessed the analytical performance and clinical reliability of point-of-care testing (POCT) for cardiac biomarkers, specifically Troponin, CK-MB, and BNP/NT-proBNP by comparing POCT to routine laboratory tests on 203 patients presenting with cardiac symptoms. The results show high agreement between POCT and laboratory results, thereby supporting the clinical application of POCT in emergency or routine cardiovascular contexts.

Agreement Between POCT and Laboratory Tests

The agreement between POCT and laboratory results was excellent with Troponin (Pearson's $r = 0.999$) and CK-MB ($r = 0.989$). The almost perfect linear relationship noted with R^2 values of 0.999 and 0.979, respectively, further supports the analytical quality of POCT testing platform's ability to accurately measure biomarkers of interest across the clinically relevant concentration range. Also importantly, the paired t-tests showed no significant differences between POCT and laboratory results ($p > 0.7$ for both biomarkers) demonstrating that the POCT biomarkers in this population are statistically identical to the laboratory assay results.

This is especially relevant in clinical settings where the rapid access to test results are imperative: namely, emergency departments, ambulatory care settings, and in resource-limited settings where access to central laboratories could be delayed. The clear agreement between the POCT and laboratory results further validate the use of POCT in assessing cardiac risk stratification, and ruling out acute coronary syndrome (ACS).

Diagnostic Performance and Limitations

The diagnostic performance of POCT for positive cases has an accuracy of 91%, a specificity of 100%, and a sensitivity of 54%. While high specificity means false positives are very unlikely to occur – an important consideration given the risk of unnecessary hospitalizations and actions – the moderate sensitivity, evidenced by 18 false negatives, is concerning. As a caution, clinicians often require confirmation from additional blood work to rule out myocardial infarction or other serious conditions when POCT results are borderline or on the early side of injury.

There are a number of possibilities for why the sensitivity is limited:

Detection thresholds - POCT detection limits may be slightly higher than high-sensitivity lab assays

Sample handling - much of the previous day has been spent collecting samples, the environmental conditions in the field which may impact accuracy in POCT.

Timing of testing - it may be below the detection thresholds, in early phases of myocardial injury no matter the mode of testing.

However, if all of this is taken into account, the diminished sensitivity may still be counterbalanced with the increased negative predictive value, and POCT can remain as a frontline approach when combining the tool with clinically-directed judgement and repeat testing protocols with accepted or acceptable timelines.

Device and Subgroup Consistency

One of the notable strengths of the study was the use of multiple POCT platforms: Abbott i-STAT, Roche cobas h 232, Samsung LABGEO PT10, and the i-STAT TnI. All devices evidenced perfect Pearson correlations ($r = 1.00$) with lab values in their respective subgroups, demonstrating consistency and reliability of lab correlate values among manufacturers and technologies, which is important for scalability, as institutions often have a mix of POCT devices to choose from (procurement and supply chain) based on clinician preference.

Gender analysis yielded no differences in total measurement accuracy or strength of correlation, again supporting the feasibility of using POCT with diverse patient populations, involving both men and women. The limited distribution of gender (102 females, 101 males) similarly supports our conclusion.

BNP and NT-proBNP Variability

For BNP/NT-proBNP, data were only available for a subset of patients (123) and did not have correlating lab-based data for statistical correlation; however, descriptive analysis produced an impressive high typed variability (SD = 473.5) and a broad range of values (-9.7 to 1904.1 pg/mL)—the broad variability in biomarker values is quite indicative of using such biomarkers in a heart failure population. The negative minimum value also raised concern for a possible artifact in measurement or data entry that could be investigated in future studies. In light of BNP's use (standard use) in diagnosing and monitoring of patients with heart failure, further comparative studies should be undertaken to assess POCT BNP accuracy and reproducibility .

Clinical Implications

We found that POCT for cardiac biomarkers is clinically valid, with high level of agreement with laboratory results and low inter device and inter gender variability. These characteristics allow POCT to be potentially efficacious for:

- Rapid triage in an emergency clinical environment, where early rule-in/rule-out data about MI has an impact on clinical decision-making, patient wait times, patient flow, and yield in patient management.
- Remote or rural environments, where access to a central laboratory pathologist, troponin and/or CK-MB testing may be limited or non-existent.
- Bedside clinical monitoring, so as to limit time delay from specimen collection to clinical decision making.

While these are all advantages of POCT biomarkers, the finding that POCT and laboratory tests reach similar proportions of patients with MI proves that the moderate sensitivity of POCT requires that POCT and laboratory tests together form part of a coherent approach to diagnostics for patients at high risk or those patients with clinical presentations that cannot be ruled in or out for MI.

Limitations

While the results of this study are encouraging, there are several limitations:

No serial sampling Troponin and CK-MB concentrations can change with time in the setting of MI, and only one point comparison of specimens was made.

No formal gold-standard adjudication of MI While the authors stated we inferred the accuracy of the tests with laboratory results as our reference, we did not link either POCT and laboratory testing to final adjudication of clinical MI.

Limited BNP data Limited BNP data precluded the authors from being able to analyse the accuracy of BNP POCT testing with a laboratory comparator.

V.CONCLUSION

This study thoroughly examined the diagnostic accuracy and analytical agreement of point-of-care testing (POCT) for cardiac biomarkers - Troponin, CK-MB, and BNP/NT pro BNP -as compared to accepted reference laboratory methods in an actual clinical practice setting. Our results show very close agreement between POCT and laboratory tests, particularly for Troponin (Pearson’s r = 0.999) and CK-MB (r = 0.989) with strong statistical agreement with no difference in the pair-wise tests. Subgroup analyses based on devices or gender produced consistent reliability regardless of platform or other indications for patient care. The POCT investigations produced only moderate sensitivity (54%) despite high specificity and accuracy, and should not be used as a stand-alone definitively diagnosis. In early or borderline cases of myocardial infarction the moderate sensitivity presents limitations, however as demonstrated in our findings, POCT is useful adjunct to confirmation diagnoses, especially in the emergency, rural or time-critical clinical settings wherein timely decisions would be expected based on immediate diagnostic tools.

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