

ABSTRACTS OF E-POSTERS RESEARCH AND AUDITS CONTD.

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Evaluation of Point-of-Care Testing (POCT) Devices for Cardiac Troponin I in Screening Patients with Myocardial Infarction

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Introduction and Objectives

Cardiac troponin I (cTnI) is a crucial biomarker for diagnosing myocardial infarction (MI). However, many remote hospitals lack access to cTnI assessment facilities. This study investigates the feasibility of using Point-of-Care Testing (POCT) devices to triage MI patients in such settings, facilitating their transfer to tertiary care hospitals. Assessing the quality of POCT devices is essential for this purpose. This report outlines the assessment methodology of two POCT devices and presents the obtained results.

Methods

Two POCT devices, labelled X and Y, for measuring cTnI were compared against the Ortho-Vitros 3600, serving as the reference method, with optimum internal and external quality control measures. Basic specifications of the POCT devices and the comparator were obtained from their respective kit inserts. Routine patient samples were analyzed in singlicate using POCT devices and the reference method. Linear regression analysis was conducted, and correlation graphs were generated. Within-run precision was evaluated using a patient sample and imprecision (CV) was calculated for the POCT devices.

Results

The linearity ranges for cTnI measurement with POCT devices X and Y were 0.01–15 ng/mL and 0.03–30 ng/mL, respectively, with decision-making cutoff values for diagnosing MI established at 0.04 ng/mL and 0.5 ng/mL, respectively. Regression analysis demonstrated acceptable linearity for both POCT devices, with correlation of $R^2=0.7388$ for device X and $R^2=0.8881$ for device Y. However, higher imprecision was observed for both analyzers, with a CV of 26% for device X and 20% for device Y at decision-making cutoff levels.

Conclusions

This study highlights major challenges associated with the implementing POCT devices for cTnI assays in triage settings aimed at diagnosing MI in acute care. Specifically, the adoption of higher cutoff levels in the POCT devices, not aligned with the recommended 99th percentile for the healthy population, and the poor precision observed at these cutoff values emerge as significant hurdles.

Keywords

Cardiac troponin, Point-of-care-devices, Myocardial infarction, Correlation