

Evaluation of Sensitivity and Specificity of CK-MB against Cardiac Troponin I in Cardiac and Non-cardiac Patients

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ABSTRACT

Background: Ischemic heart disease (IHD) is most common cause of morbidity and mortality. The number is increasing day by day due to modern lifestyle. Early diagnosis of IHD is most important for which there is a need for specific and sensitive markers. Thus, the study was done through data analysis of the patient results of troponin I and creatine kinase-MB (CK-MB) which was asked by the Clinicians of Sir Takhtasinhji Hospital for different suspected clinical conditions. Data was taken of 2 months period from June 2024 to July 2024.

Materials and methods: Total 142 data were analyzed for serum troponin I and serum CK-MB, it is estimated on ABBOTT Architect c 8000 (fully automated chemistry analyzer) with immuno-inhibition method and serum cardiac troponin I is estimated on ABBOTT Architect i1000SR (fully automated immuno-analyzer) with chemiluminescent immunoassay (CLIA) method. Both the analyte estimations were done from serum samples simultaneously.

Results: Results concluded that:

- Out of 142 patients' data, 92 patients who have normal troponin I, 36 patients have CK-MB value under the reference range which indicates less sensitivity of CK-MB to detect cardiac disease.
- Out of 142 patients' data, 50 patients who have troponin I level higher than reference range, 43 patients have CK-MB value higher than the reference range which indicates specificity of CK-MB to detect cardiac disease is 86.0%.

Conclusion: For detection of cardiac disorders, tests with high sensitivity and specificity should be used. Detection technique of CK-MB by immuno-inhibition with limitation of instrument's photo detector, main reason for CK-MB very low sensitivity and specificity, in comparison to cardiac troponin I to evaluate cardiac condition.

Keywords: Acute myocardial infarction, Cardiac troponin I, Creatine Kinase-MB, Mortality, Sensitivity, Specificity.

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INTRODUCTION

Ischemic heart disease (IHD) is most prevalent cause of morbidity and mortality world-wide, and the numbers are increasing day by day due to modern lifestyle which is stressful, lack exercise and healthy diet. Early diagnosis of IHD is most important to reduce the morbidity and mortality of the patients. There are many tools for early diagnosis like electrocardiogram (ECG), echocardiography and biochemical markers like creatine kinase-MB (CK-MB), troponin I, troponin T, lactate dehydrogenase, serum glutamate oxaloacetate transaminase, etc. Initially CK-MB was widely used because of its cost-effectiveness, since the test could be performed on semi-auto-analyzers. It was considered the gold standard marker for myocardial necrosis.¹ Creatine kinase-MB predominantly located in myocardial cells and constitutes 1–3% of the total CK found in skeletal muscle and other tissues which limits its specificity. Nowadays, highly sensitive troponin I is considered as the best marker by the clinicians. But troponin I estimation requires costly instruments like enzyme-linked immunosorbent assay (ELISA) or fully automated chemiluminescence analyzers though it is considered more sensitive and specific compared to other markers. Due to special resource requirements to do cardiac troponin I, it is considered costly.²

AIM OF THE STUDY

- Compare the data of serum troponin I and serum CK-MB in patient's sample.

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- Determine sensitivity and specificity of serum CK-MB in comparison to serum troponin I.

MATERIALS AND METHODS

Clinical Biochemistry Laboratory provides laboratory services to the patients of the Sir Takhtasinhji Hospital, Bhavnagar, which is a Tertiary Care Public Health Hospital. This study is done through data analysis of the patient results of troponin I and CK-MB. Data was taken of 2 months period from June 2024 to July 2024. Total number of data analyzed is 142 which is of serum troponin I and serum CK-MB, which is asked through clinicians for different suspected clinical conditions.

Table 1: Sensitivity of CK-MB

Samples	No. of troponin I under reference range (less than 35 ng/mL)	No. of CK-MB under reference range (less than 25 IU/L)	No. of CK-MB higher than reference range (more than 25 IU/L)	False positive CK-MB	True negative CK-MB (sensitivity)
With normal troponin I	92	36	56	60.87%	39.13%

Table 2: Specificity of CK-MB

Samples	No. of troponin I above the reference range (greater than 35 ng/mL)	No. of CK-MB under the reference range (less than 25 IU/L)	No. of CK-MB higher than reference range (greater than 25 IU/L)	False negative CK-MB	True positive CK-MB (specificity)
With abnormal troponin I	50	07	43	14%	86%

Serum CK-MB is estimated on ABBOTT Architect c 8000 (fully automated chemistry analyzer) with immuno-inhibition method and serum cardiac troponin I is estimated on ABBOTT Architect i1000SR (fully automated immuno-analyzer) with chemiluminescent immunoassay (CLIA) method. Both the analyte estimations were done from serum sample simultaneously.

Inclusion Criteria

- All the samples received from Sir Takhtasinhji Hospital, Bhavnagar for serum CK-MB and serum troponin I from intensive care unit (ICU), surgical ICU (SICU), medical wards, and emergency departments of Sir Takhtasinhji Hospital, Bhavnagar, Gujarat.
- All age groups and all genders were included.

Exclusion Criteria

- Rejected samples – hemolyzed, lipemic, and icteric.

RESULTS

The study included 142 patient samples in which serum troponin I and CK-MB were measured from various departments like ICU, medical wards, and emergency departments of Sir Takhtasinhji Hospital, Bhavnagar in the 2 months period from June 2024 to July 2024.

In these patients' data, following is observed:

- Of the 142 patients, 92 had troponin I levels below the reference limit (less than 35 ng/mL). Amongst those 92 patients' data,
 - No. of CK-MB value under the reference range (less than 25 IU/L) are: 36.
 - No. of CK-MB value higher than reference range (more than 25 IU/L) are: 56.
- Out of 142 total data, 50 patients' data have troponin I level higher than reference range (more than 35 ng/mL). Amongst those 50 samples data,
 - No. of CK-MB value under the reference range (less than 25 IU/L) are: 07.
 - No. of CK-MB value higher than reference range (more than 25 IU/L) are: 43.

Tables 1 and 2 shows the above-mentioned statistics.

Table 1 shows that:

- Out of 92 patients who have normal troponin I, 36 patients have CK-MB value under the reference range which indicates

specificity of CK-MB to detect cardiac disease is 39.13% (36/92) (true negative).

- And out of 92 patients who have normal troponin I, 56 patients have CK-MB value above the reference range which indicates that 60.87% of CK-MB value were false positive to detect cardiac disease.

Table 2 shows that:

- Out of 50 patients who have high troponin I value, 43 patients have CK-MB value higher than the reference range which indicates sensitivity of CK-MB to detect cardiac disease is 86.0% (43/50) (true positive).
- And out of 50 patients who have high troponin I, seven patients have CK-MB value under reference range. It indicates that 14% of CK-MB value were false negative to detect disease.

DISCUSSION

Creatine kinase-MB and cardiac troponin I is raised in almost similar clinical condition like angina, myocardial infarction, myocarditis, post-cardiopulmonary resuscitation (CPR), post defibrillator shock, etc. But there are some differences in relation to analysis. Which is as follows:

- Creatine kinase-MB is measured through immuno-inhibition method on either semi-auto chemistry analyzer or fully automated chemistry analyzer. These instruments use "kinetic method" of analysis and in relation to linear velocity curve of reaction, it derives delta OD of 60 seconds reaction curve. From derived delta OD, it derives concentration of CK-MB after multiplication with calibration factor. In general, calibration factor for CK-MB has remained between 4,000 and 6,000, so if there is change of 0.0001 delta OD (at 4th digit after decimal point), there will be a large change of CK-MB between 4 and 6.³
- In addition, in small laboratory, CK-MB is performed in semi-automated chemistry analyzer, which has its own insensitivity to measure OD at 4th digit after decimal point.
- Cardiac troponin I is measured through CLIA principle by fully automated immunology analyzer or POCT instrument, with same principle of CLIA. This technique is very precise and sensitive to measuring relative light units (RLU) for measurement of analyte. Hence, measurement of cardiac troponin I remain more sensitive, precise, and accurate.⁴
- Above mentioned both reasons, increase insensitivity, inaccuracy, and imprecision of CK-MB at lower range, especially at reference range.

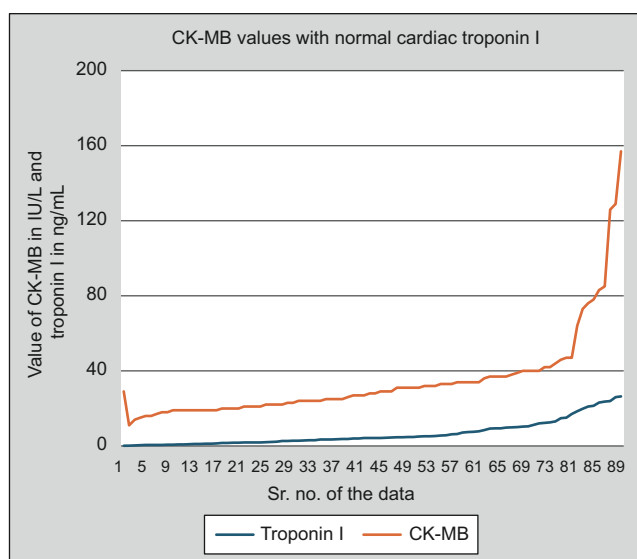


Fig. 1: The X-axis indicates the serial number of the data. The Y-axis indicates the value of CK-MB (IU/L) and value of troponin I (ng/mL). This figure shows that from total 92 data points with normal troponin I (gold standard test for cardiac disorders), only 36 data points of CK-MB were under the reference range, whereas 56 data points of CK-MB were drastically higher than the reference range. Which indicates that in borderline normal troponin I, CK-MB values are approximately 6–7 times the upper reference limit and were false-positive results

In this study, Table 1 shows that specificity of CK-MB was 39.13% (true-negative rate). This low sensitivity to detect negative results is already explained in the above-mentioned points 1 and 2.

In cases positive of cardiac disease, CK-MB concentration will be on higher side, hence imprecision and inaccuracy get reduced as mentioned above in point 1 and 2. So, estimation of CK-MB to prove sensitivity to detect cardiac disease is up to 86.0% (true positive rate). But still there is imprecision at borderline high CK-MB, so it does not prove complete comparability with cardiac troponin I.⁵

With same reason of insensitivity at borderline result (near to reference range), CK-MB gave 60.87% of result false positive as well as 14% of result false negative to detect cardiac disease.

Figure 1 shows that in patients of borderline normal cardiac troponin I, there is exponential increase in CK-MB value by 6–7-fold of reference range. This clearly indicates insensitivity of CK-MB in comparison to cardiac troponin I.

It proves that even though estimation of CK-MB is specific marker of cardiac muscle, it is not very good at identifying true negative cases. This could lead to:

- Many individuals being incorrectly flagged as having cardiac disorder, though they are normal,
- Unnecessary follow-up tests, treatment, or interventions for the individuals, who do not have the condition,
- Increase burden on the health care system, and
- Undue stress, potential harm from certain procedures as well as loss of daily wages and decrease in the family income of the individual.⁶

If there is low specificity rate of the tests then there are chances that if the individuals are suffering from some real critical disorders,

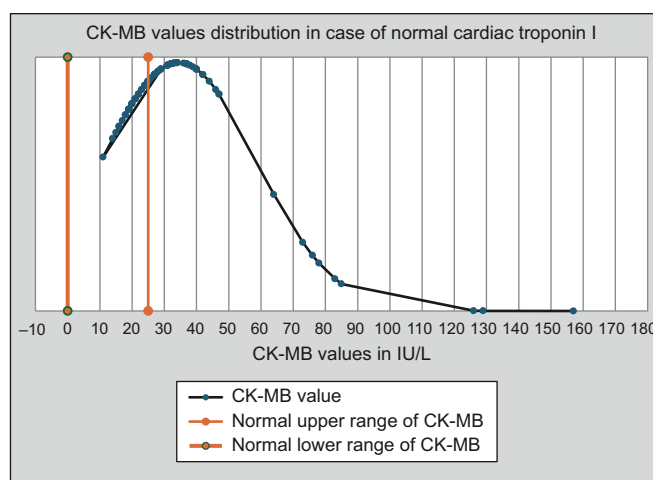


Fig. 2: The X-axis indicates the different CK-MB values in IU/L. The two vertical lines in the figure indicate the values of CK-MB in the lower reference range and higher reference range. When the level of troponin I was under the reference range, very few data values of CK-MB were in the reference range, and large number of the data values of CK-MB were higher than the reference range

it might be misclassified, and this would lead to undue health outcome and treatment decisions (Fig. 2).

Estimation of troponin I which is considered a gold standard test since it is more sensitive should be used to confirm the cases of cardiac disorders.

Limitations of the Study

Our present study has a few limitations. Study was limited to single center, limited sample size, variability in timing of sample collection.

CONCLUSION

In compared to cardiac troponin I, which is gold standard test to evaluate cardiac conditions,

- Creatine Kinase-MB is less sensitive (39.13%) especially at borderline normal reference range.
- Creatine Kinase-MB has specificity only (86.0%), which is relatively low for evaluating critical cardiac conditions.
- Detection technique of immuno-inhibition (CK-MB) with limitation of instrument's photo detector is main reason for CK-MB very low sensitivity and specificity, in comparison to cardiac troponin I to evaluate cardiac condition.⁷

Clinical Significance

Cost of CK-MB against troponin I is very less. Also CK-MB can be performed on cheap instruments like semi-auto analysers compared to Troponin I which is performed on costly Chemiluminescence analysers. Therefore cost of CK-MB is five times less compared to troponin I and it can be performed by any small laboratory located in the periphery of the city, thus helping the clinicians in the early diagnosis of cardiac as well as non-cardiac conditions.

Ethical Approval

Since the study was retrospective data analysis from the previous laboratory data where the sample identity was kept anonymous and no demographic details have been exposed therefore no ethical approval taken.

Data Availability Declaration

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Artificial Intelligence (AI) Disclosure

The authors acknowledge the use of ChatGPT for the purpose of grammar correction.

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AUTHORS' CONTRIBUTIONS

The author would like to thank the Mentor and guide, Piyush B Tailor who contributed to finalising the discussion and conclusion as per previous study and reference available. Jagruti D Dholakia contributed to data analysis and drafting the discussion. Arvi V Mehta and Jahanavi R Patil contributed to Data collection and segregation of the data as per study plan. Hetvi C Gajjar contributed to manuscript writing and statistical analysis.

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