Research Square

Preprints are preliminary reports that have not undergone peer review.
They should not be considered conclusive, used to inform clinical practice,
or referenced by the media as validated information.

Serum Samples Cannot Be Used for Fluorescence Immunoassay for detection of myocardial infarction triple

Wanju Xu
Shandong Qianfoshan Hospital
Zhonghua Gong
Shandong Qianfoshan Hospital
Yan Yan
Shandong Qianfoshan Hospital
Shiyu Lv (lvshiyu0726@sina.com)
Shandong Provincial Qianfoshan Hospital
Jiazheng Wang
Shandong Qianfoshan Hospital

Short report

Keywords: whole blood sample, serum sample, CTnI, Mb, CK-MB

Posted Date: July 29th, 2020

DOI: https://doi.org/10.21203/rs.3.rs-47551/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License.
Read Full License

Abstract

Background: Whole blood or plasma samples are recommended for use in triple-marker testing of myocardial infarction. Whether serum sample can be used for the diagnosis of myocardial infarction has not been compared and validated.

Methods: Whole blood samples and serum samples were detected with CTnI, Mb and CK-MB simultaneously by using immunofluorescence assay method.

Results: Both CK-MB and TNI detection results were highly consistent for whole blood samples vs. serum samples. However, when Mb is tested, the positive rate of serum samples is relatively low, and there will be more false negative results, resulting in missed diagnosis.

Conlusion: Serum samples cannot be used in replace of whole blood samples for triple-marker testing and diagnosis of myocardial infarction.

Background

Acute myocardial infarction is a clinically common critical illness caused by severe myocardial ischemia and myocardial necrosis caused by coronary artery disease [1]. Its testing and diagnosis are usually based on clinical symptoms, ECG findings and test results of triple-marker diagnosis of myocardial infarction [2]. Because some patients with AMI have no typical clinical manifestations in the early stage of the disease, such patients have no characteristic ST segment changes on the electrocardiogram. Therefore, at present, early diagnosis of AMI mainly relies on the test results of the triple-marker testing of myocardial infarction at clinical laboratory. CTnI, Mb, CK-MB are three specific biochemical markers of AMI [3–6]. The immunofluorescence assay for CTnI, Mb, CK-MB is a relatively advanced triple-marker testing method for myocardial infarction. Whole blood or plasma samples are recommended for use in triple-marker testing of myocardial infarction using certain matured commercial kits. Whether other samples can be used for the diagnosis of myocardial infarction by triple-marker testing indicators has not been compared and validated. In this study, we explored the possibility of triple-marker testing for myocardial infarction by replacing whole blood samples with serum samples based on the results of triple-marker testing for myocardial infarction with serum and whole blood samples.

Materials And Methods

1. Sample Collection

Whole blood samples and serum samples from a total of 30 patients who underwent triple-marker testing of myocardial infarction between July 24, 2018 and August 2, 2018 in Qianfoshan Hospital of Shandong Province were collected. CTnI, Mb and CK-MB were detected immediately after venous blood collection.

2. Assay method

Whole blood samples or serum samples were tested using myocardial infarction triple-marker test plates (Alere company). According to the instructions, blood samples or serum samples were added dropwise to the sample wells. After the sample has diffused to the frontmost mark line on the reagent cartridge, place the cartridge in a fluorescence reader to read the fluorescence values. All operations were carried out at room temperature.

3. Diagnostic thresholds

According to the instructions of Alere company kit, the sample can be diagnosed as CTnI positive when the test result is greater than 1.0 ng/mL, Mb positive when the test result is greater than 107 ng/mL, and CK-MB positive when the test result is greater than 4.3 ng/mL.

4. Statistical analysis

Student's *t*-test was further performed on the dataset using SPSS 19.0 software when a significant difference existed in the positive and negative results between whole blood samples and serum samples in the results of triple-marker testing for myocardial infarction of all the 30 cases.

Results

1. Test results of CK-MB

The CK-MB testing results of whole blood and serum samples showed a high consistency. Twenty-nine of the 30 samples showed consistent results. Among them, 28 were positive, and 1 was negative. Only one sample showed a positive result for serum test and a negative result for whole blood test. The consistency of CK-MB detection in whole blood and serum samples was 96.7% (29 / 30) (Table 1).

Table 1
Test results of CK-MB

Test results of whole blood samples	Test results of serum samples	
	+	-
+	1	0
-	1	28
2. Test results of Mb		

2. Test results of Mb

For Mb assay, the results of whole blood samples and serum samples were significantly different. Only 23 of the 30 samples showed consistent results, and the consistency was only 76.7% (23 / 30). Among them, 8 were positive for both types of samples, and 15 were negative for both typs of samples. Seven samples were positive in whole blood Mb assay, but negative in serum Mb detection (Table 2). Student's *t*-test on the data set showed that $p < 0.05$. The difference in the test results was statistically significant.

Table 2
Test results of Mb

Test results of whole blood samples	Test results of serum samples	
	+	-
+	8	7
-	0	15

3. Test results of TNI

For TNI assay, both the whole blood samples and the serum samples showed a negative test result. The consistency of TNI detection in whole blood and serum samples reached 100% (30 / 30) (Table 3).

Table 3
Test results of TNI

Test results of whole blood samples	Test results of serum samples	
	+	-
+	0	0
-	0	30

Conclusion

The results of this study showed that both CK-MB and TNI assay were highly consistent in the results of immunofluorescence assay of whole blood samples vs. serum samples. However, when Mb is tested, the positive rate of serum samples is relatively low, and there will be more false negative results, resulting in missed diagnosis. In summary, if the triple-marker testing of myocardial infarctionis performed

simultaneously, certain difference may present in the test results of serum samples and whole blood samples. Clinically, whole blood samples should still be recommended as diagnostic samples, and serum samples cannot be used in replace of whole blood samples for triple-marker testing and diagnosis of myocardial infarction.

Abbreviations

AMI: Acute Myocardial Infarction; CK-MB: Creatine Kinase-MB; CTnI: Cardiac Troponin I; ECG: Electrocardiograph; Mb: Myoglobin;

Declarations

Funding

Unfunded.

Availability of data and materials

The data supporting the conclusions are included in the article. Raw data are available upon request.

Ethics approval and consent to participate

Inform the patient in person and get consent.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

JZW conceived the research idea and designed this study with WJX, SYL. ZHG and YY performed the immunofluorescence assay. SYL analyzed the immunofluorescence results. WJX drafted the manuscript.

JZW revised the manuscript. All authors read and approved the final manuscript.

Acknowledgements

Thanks for ZHG and YY helping in detection of the immunofluorescence assay.

Especially thanks for WJX, she contributes to designing the project and drafting the manuscript.

References

[1] Mendis S, Thygesen K, Kuulasmaa K , et al. World Health Organization definition of myocardial infarction: 2008-09 revision [J]. International Journal of Epidemiology, 2011, 40(1):139.

[2] Thygesen K, Alpert J S, White H D. Universal definition of the myocardial infarction [J]. Harefuah, 2009, 148(1):47-62.

[3] Wu A H B , Panteghini M , Apple F S , et al. Biochemical markers of cardiac damage: From traditional enzymes to cardiac-specific proteins [J]. Scandinavian Journal of Clinical & Laboratory Investigation, 1999, 59(s230):74-82.

[4] Lee T H. Use of a Rapid Assay of Subforms of Creatine Kinase MB to Diagnose or Rule Out Acute Myocardial Infarction [J]. N.engl.j.med, 1995, 331(9):561-6.

[5] Junwei W, Feiyu W. The detection value of CK-MB, Myo and cTnI in Patients with AMI and HF [J]. Biomedical Research 2017; 28 (19): 8533-8536

[6] Cheng-Juan F, Yang-Ling O U, Shong-Di Y. Clinical application value of combined detection of serum Hs-CRP, CTnI, MYO and CK-MB for the diagnosis of acute myocardial infarction (AMI) [J]. China Journal of Modern Medicine, 2010.