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Cardiac multi-marker strategy for effective diagnosis of acute myocardial infarction

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ABSTRACT

Background: Heart-type fatty acid-binding protein (H-FABP) is a heart-specific and highly sensitive biomarker for early diagnosis of acute myocardial infarction (AMI). We investigated the effectiveness of H-FABP for diagnosis of AMI in patients with different ethnic background and different time from symptom onset.
Methods: Venous blood was withdrawn from consecutive patients with acute chest pain admitted to the First Affiliated Hospital of Xinjiang Medical University. The blood samples were used for measurement of creatine kinase MB (CK-MB) and cardiac troponin I (cTnI) using Beckman Coulter DC-800 analyzer, and detection of H-FABP using a one-step bedside immunotest.
Results: Two hundred and eighty-nine patients admitted within 12 h after the onset of symptoms were recruited in the study. The H-FABP immunotest was found to have higher diagnostic accuracy than cTnI and CK-MB in patients admitted within 3 h. The combination of H-FABP and cTnI was found to have the highest diagnostic accuracy (91%) among different cardiac markers and the other combinations. It gave the highest sensitivity [96% (95% CI: 91–98%)] and a comparable specificity [84% (95% CI: 76–89%)] to cTnI alone.
Conclusion: A cardiac panel consisting of H-FABP and troponin is recommended.
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1. Introduction

Cardiovascular disease causes a major burden in health care and is the single most costly disease for the health care system. It has been increasing in the past few decades in China, the largest and most populous developing country in the world. Acute myocardial infarction (AMI) is the leading cause of mortality among cardiovascular disease. The high mortality rate can be dramatically reduced by early diagnosis and effective coronary reperfusion.

From the ED perspective, it is important to expeditiously distinguish between AMI and non-AMI patients so as to be able to immediately start proper treatment. Although electrocardiogram (ECG) is a standard test to identify patients with AMI upon ED presentation, it still has relatively low sensitivity for detection of AMI (only 35–50%) [1]. Instead, plasma markers of myocardial injury ultimately show almost 100% sensitivity, dependent on the delay in their release into plasma.

Recently, a one-step bedside H-FABP immunotest so-called Cardio-Detect® designed to detect H-FABP in whole blood samples has become commercially available [2–6]. The test result is available within 15 min after addition of blood samples. It requires no sample pretreatment and, therefore, is suitable especially for application in an emergency situation. Many studies in the developed countries like Europe and Japan have demonstrated the superior performance of H-FABP for diagnosis of AMI in the early stage [7–12]. However, such information is still relatively insufficient in the developing countries with inconvenient traffic, low educational level, lack of hospital resources and comprehensive facilities. Study about the utility of H-FABP for diagnosis of AMI in China is also limited.

The prevalence of several chronic diseases in Xinjiang including myocardial infarction, diabetes, hypertension, and cancers is difference among different ethnic groups. Therefore, the present study aimed at investigating the effectiveness of the H-FABP immunotest compared to

Abbreviations: ACC, American College of Cardiology; AMI, acute myocardial infarction; cTnI, cardiac troponin I; ESC, European Society of Cardiology; H-FABP, heart-type fatty acid-binding protein; IQR, interquartile ranges; LR-, negative likelihood ratio; LR+, positive likelihood ratio; MYO, myoglobin; NPV, negative predictive value; PPV, positive predictive value; WHO, World Health Organization.

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current cardiac markers for diagnosis of AMI in patients with different ethnic background, different chronic diseases, different genders and different time from symptom onset in Xinjiang. Also, the diagnostic performance of different combinations of cardiac markers was compared. This study may act as a reference for those developing countries and the results can be compared to those studies conducted in developed countries to assess the universal applicability of the H-FABP immunotest for diagnosis of AMI. This study has been divided into two phases: Phase I has been implementing in Urumqi for 3 y; Phase II will be implemented in the southern, northern and eastern parts of Xinjiang for 4 y.

2. Methods

2.1. Study design and setting

According to the Declaration of Helsinki, the design of this study was to investigate the diagnostic accuracy of the H-FABP immunotest. This study was reviewed and approved by the ethical committee of the First Affiliated Hospital of Xinjiang Medical University in November 2007 with document number: No. 20071108. The First Affiliated Hospital of Xinjiang Medical University is a teaching hospital in the western border of area of Urumqi in Xinjiang. In 2007, there were 2332 visits for cardiovascular diseases to the Emergency Department (ED) of this hospital; 502 of them suffered from chest pain and 158 of these patients ultimately have been diagnosed as acute myocardial infarction (AMI) and 57 as angina pectoris.

This was a double-blind parallel study. Consecutive patients with acute chest pain admitted to the ED of the First Affiliated Hospital of Xinjiang Medical University were diagnosed according to the ESC/ACC guideline and the H-FABP immunotest. Fig. 1 showed the diagnostic pathway in this study.

A comprehensive study design and accurate data collection were relied on a well-organized preliminary study. The preliminary study was implemented from September 2007 to November 2007 and 40 consecutive patients were recruited. The study protocol were revised and finalized after the preliminary study. All the patients in the preliminary study were not included in the current study.

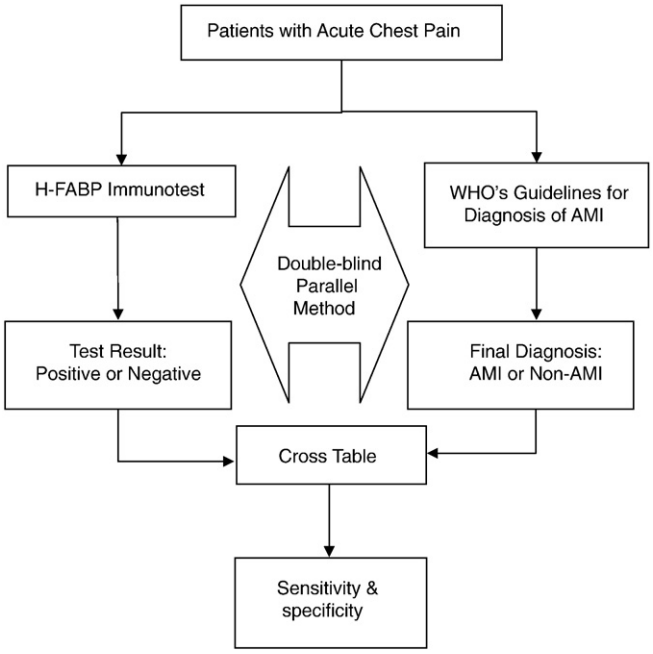

Fig. 1. Diagnostic pathway of the study.

2.2. Inclusion and exclusion criteria

Patients were included in this study if (i) they aged ≥18 y, (ii) chest pain suggestive of coronary origin at the discretion of an ED physician's assessment, (iii) and onset of chest pain <12 h prior to enrollment. Patients were excluded if (i) they were unable to give consent or unwilling to join the study; (ii) they had chronic renal injury (creatinine in serum >100 mol/l or >1.5 mg/dl); (iii) they had intention neuralgia or recent pain related to thoracic trauma within 3 days; (iv) they had severe skeletal muscle injury.

2.3. Patient assessments and investigations

According to the ESC/ACC guideline [13,14], patients were confirmed as AMI patients if they had (i) typical acute chest pain; (ii) abnormal 12-lead ECG defined as pathologic Q waves of >40 ms, ST-segment elevation or depression of >1 mm or abnormal T wave morphology; (iii) the cTnI concentration above the 99th percentile cutoff with a CV <10%.

The onset time of symptoms was critical in this study. The time was based on the subjective reports of the patients about the onset of chest pain. In order to minimize the variation, the medical doctors asked the patients and their relatives twice respectively. The ECG was examined by 2 internal medicine specialists and the final result was reported by the Vice Director at the ED.

2.4. Laboratory analysis

Venous blood was withdrawn from patients suspected of AMI at admission. The blood samples were used for detection of CK-MB, cTnI and H-FABP. The concentrations of CK-MB and cTnI were determined by using Beckman Coulter DC-800 chemistry analyzer. The cut-off values for CK-MB and cTnI were set at 25 U/l and 0.03 μg/l respectively. The final report was approved by a senior medical doctor in the Department of Laboratory Medicine. The measurement of all the cardiac markers using the analyzer in each sample was completed within 30–50 min. The final diagnosis was made by the Director at CCU and the Director at ED who were blinded to the H-FABP results.

All patients were also tested with CardioDetect® H-FABP immunotest (Fig. 2). It is a rapid chromatographic immunoassay designed for

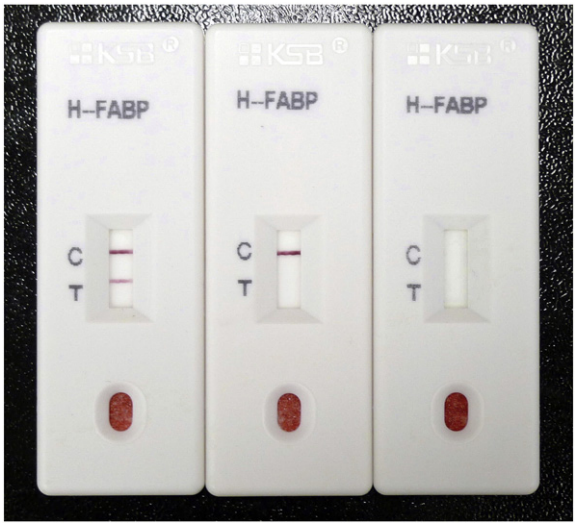

Fig. 2. CardioDetect®: a chromatographic immunotest for qualitative detection of H-FABP. The test result was positive if two red lines were visible (left). The result was negative if only one red line was visible at the control zone (middle). The test was invalid if no control line was visible (right).

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