ISSN: 2577 - 8005

Research Article

Medical & Clinical Research

A Validation Study of an AFP Whole Blood One-Step Rapid Home Detection Kit in Screening for HCC

Wei Shen and Bing Ruan

State Key Laboratory for Diagnosis and Treatment of Infectious Diseases, National Clinical Research Center for Infectious Diseases, National Medical Center for Infectious Diseases, College of Medicine, Zhejiang University. Hangzhou, Zhejiang, 310003, China.

***Corresponding author**

Wei Shen, State Key Laboratory for Diagnosis and Treatment of Infectious Diseases, National Clinical Research Center for Infectious Diseases, National Medical Center for Infectious Diseases, College of Medicine, Zhejiang University. Hangzhou, Zhejiang, 310003, China.

Submitted: 26 April 2021; **Accepted**: 07 May 2021; **Published**: 14 May 2021

Citation: *Wei Shen, Bing Ruan (2021) A Validation Study of an AFP Whole Blood One-Step Rapid Home Detection Kit in Screening for HCC. Medical & Clinical Research 6(5): 524 - 526.*

Abstract

Hepatocellular carcinoma (HCC) is still a main cause of cancer-related death in China. Early detection and diagnosis may increase the likelihood of curing the HCC. Dynamic monitoring AFP levels can be a surveillance indicator to detect early-stage HCC. However, to our disappointment, most people with chronic liver diseases do not test AFP levels regularly for a variety of reasons. The AFP whole blood one-step rapid home detection kit, with a high sensetivity and specifitivity, can be used to test AFP levels periodically by community residents with chronic hepatitis B. This can make it possible to detect, diagnose and treat HCC much earlier. This research aimed to verify the previous studies on the kit's performance, characteristic, application and usage. The result was that the positive accordance rate and the negative accordance rate of the AFP whole blood one-step rapid home detection kit and ARCHITECT AFP were 96.77% (90/93) and 97.94% (95/97). The rapid home detection kit is introduced and popularized to apply into screening and diagnosing early-stage HCC in community individuals with chronic liver diseases, which is meaningful to achieving the goal of reducing mortality in patients with HCC to a great extent.

Keywords: AFP, Whole Blood One-Step Rapid Home Detection Kit, HCC, Early Detection, Early Diagnosis

Introduction

Hepatocellular carcinoma (HCC) is the most common type of primary liver cancer. In China, liver cancer is the second leading cause of cancer-related death and there were 326,000 new deaths (242,000 males and 84,000 females) in 2015. And it is reported that the new cases of liver cancer was 370,000, including 274,000 males and 96,000 females [1]. HCC occurs frequently in patients with chronic liver diseases, caused by HBV infection, HCV infection, alcohol abuse and metabolic associated fatty liver disease.

Studied as various biomarkers have been, Alpha-Fetoprotein (AFP) remains the most widely accepted and used in HCC. AFP, a glycoprotein, is produced by yolk sac and fetal liver. In other words, it cannot be detected in adult under normal circumstances. Up to now, huge numbers of clinical studies have confirmed that AFP is effectively used for clinical follow-up of patients with high risks of HCC and the early screening and diagnosis HCC [2].

Early diagnosis of HCC may increase the likelihood of cure, whereas early detection and diagnosis is still a challenging thing for doctors. AFP alone is not a perfect clinical indicator to identify the population with high HCC risks since elevated AFP levels can be detected in other liver diseases [3]. However, persistently elevated AFP levels have been confirmed that can be an independent risk factor to define the population which is at high-risk of HCC [4]. It seems advisable to apply values that are common practice (eg 20 ng/mL for HCC screening and diagnosis).

WHO estimates that in 2015, 257 million people were living with chronic hepatitis B infection (defined as hepatitis B surface antigen positive) [5]. Relevant studies show that the prevalence of HBsAg is estimated to be 6.1% in China in 2016. There are about 86 million people with chronic HBV infection, the diagnosis rate is 18.7%, and the treatment rate is 10.8% [6]. Most people with chronic liver diseases cannot detect AFP regularly. The reasons are as follows: First, they do not pay attention to the diseases which often lack of obvious clinical symptoms. Second, it is a time-consuming and laborious thing to see a doctor in a large hospital. Third, financial problem is also one of the main causes why symptomatic had not present clinical consultation. And the last, but not the least, discrimination against people with hepatitis B cannot be overlooked.

Shanghai Outdo Biotech Ltd successfully invented the first one-step AFP home detection product, fund by the National "12th Five-Year" Plan for Science & Technology Support, which only requires a drop of peripheral blood to detect the AFP level. The self-monitoring of AFP could be achieved anytime at home by it. The one-step AFP rapid detection kit had been verified that can screen for HCC in high-risk populations with high sensitivity and specificity [7].

Methods

Study Design, Setting, and Participants:

This study was conducted at the First Affiliated Hospital, College of Medicine, Zhejiang University, a teaching hospital in China. The study population comprised healthy controls taking a physical examination and hospitalized patients who were clinically diagnosed with HCC enrolled from August 2020 to January 2021. Patients who were aged less than 18 years were excluded. Ultimately, after screening based on the inclusion and exclusion criteria, 100 healthy persons and 225 patients were included in this prospective analysis.

Inclusion Criteria:

All patients were over 18 years old and clinically diagnosed as HCC.

Exclusion Criteria:

Other secondary liver cancer; gastrointestinal tumors with or without liver metastasis; during pregnancy; with ataxia telangiectasia; hereditary hypertyrosinemia; teratoma; embryonic tumor; with Benign liver diseases such as acute viral hepatitis, chronic active hepatitis, and cirrhosis has not yet developed into HCC; clinical data is incomplete.

Materials and Biological Principles:

Rapid test kit: AFP one-step rapid detection kit produced by Shanghai Outdo Biotech Co., ltd. ARCHITECT AFP: The ARCHITECT AFP assay is a two-step immunoassay for the quantitative measurement of AFP in human serum, plasma and amniotic fluid using CMIA technology, with flexible assay protocols, referred to as Chemiflex. In the first step, sample and anti-AFP coated paramagnetic microparticles are combined. AFP present in the sample binds to the anti-AFP coated microparticles. After washing, anti-AFP acridinium-labeled conjugate is added to create a reaction mixture in the second step. Following another wash cycle, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs). A direct relationship exists between the amount of AFP in the sample and the RLUs detected by the ARCHITECT i System optics.

All patients should be kept on an empty stomach when collected blood. Use a drop of the whole blood to test AFP strictly following the instructions, and the remaining specimens were used to detect AFP by Chemiluminescent Immunoassay.

It is a qualitative method for us to measure the AFP level by the kit. The positive result means that the value of AFP >= 20ug/L measured by the Chemiluminescent Immunoassay. The analysis method of accordance rate between AFP rapid test kit and the ARCHITECT AFP were shown in **Table 1.**

Table 1: The Comparison of Methods of AFP Rapid Test Kit and The ARCHITECT AFP

AFP one-step rapid home detection kit	ARCHITECT AFP		
	Positive	**Negative**	**Total**
Positive	90	2	92
Negative	3	192	195
Total	93	194	287

Results

Invalid Specimens

According to the product manual, we tested 325 specimens (225 HCC specimens and 100 health people specimens) in total. Among 225 HCC specimens, the test results of 35 samples are invalid (17 AFP positive and 18 AFP negative by ARCHITECT AFP test). There are 3 samples are invalid among 100 health people specimens.

Accordance Rate

Take the ARCHITECT AFP result as a standard, the results are as follows: There were 92 positive samples of AFP one-step rapid home detection kit, while 93 of ARCHITECT AFP test. There were 195 negative samples of the kit, while 194 of ARCHITECT AFP test. 90 specimens were positive detected by two different methods, and 192 specimens were negative (Table 1).

The accordance rate results are as follows:
Positive accordance rate: 90/93*100%=96.77%
Negative accordance rate: 192/194*100%=98.97%
Total accordance rate: (90+192)/287*100%=98.26%

Inconsistent Results Specimens

A total of 5 specimens showed different results in two methods. 2 out of 5 specimens were positive detected with the AFP one-step rapid home detection kit but negative by ARCHITECT AFP test. 3 specimens were negative with the kit but positive by ARCHITECT AFP test.

Discussion

Previously, a study, completed by Shanghai Outdo Biotech Co., ltd. and Qidong Liver Cancer Institute, showed that the kit had a high accordance rate with ELISA kit. The overall diagnostic accuracy,

sensitivity and specificity were gratifying. So, to further verify the ability of the kit in screening for HCC, our study enrolled 100 healthy persons and 225 HCC patients (110 AFP positive and 115 AFP negative by ARCHITECT AFP test).

For the blood samples of AFP-negative liver cancer patients, the results of the kits are highly consistent with ARCHITECT AFP test. But obviously, both methods have inherent shortcomings. How to detect AFP-negative liver cancer patients earlier is still an important research direction.

Our results further demonstrated the superior performance of the AFP one-step rapid home detection kit, which has a good consistency, sensitivity and specificity. Besides, the kit is simple, easy to use, the result of automation, using only a drop of whole blood. Thus, the AFP one-step rapid home detection kit is perfectly fit for screening and early diagnosis of HCC in community population.

China is one of the countries with the most liver disease patients in the world, including hepatitis virus infection, various types of hepatitis, liver cirrhosis and hepatocellular carcinoma. The economic burdens of liver diseases are enormous, especially liver cancer. However, early detection, diagnosis and treatment can greatly reduce the cost of liver cancer in high risk population in community.

At present, screening for liver cancer has not been widely popularized in most communities of China. The reason for this the limited medical resources intrinsic motivation is, out in a number of factors are the shacckles of early detection and treatment for HCC. Therefore, the AFP one-step rapid home detection kit with such features as easy to operate, no limit of time and space, fast results, low cost, high sensitivity and specificity must be the preferred method to monitor the level of AFP within the communities.

Once the kit shows positive result used at home, patients should go for further medical examination in hospital as early as possible. According to the related Meta-analysis, ultrasound alone has a low sensitivity to detect early stage HCC. However, ultrasound with AFP measurement can significantly increase sensitivity of early HCC detecion in patients with high-risks [8]. Certainly, liver biopsy still plays a very important role in the diagnosis and prognosis of HCC. Thereby many more patients with early-stage HCC can be diagnosed in time. The AFP one-step rapid home detection kit will greatly benefit the community with preexisting liver disease and in a high-risk state of suffering from HCC. The kit not only makes self-monitoring possible but also potentially improves compliance. From economics perspective, it reduces the cost of inpatients, the excessive consumption of medical resources and public finance expenditure. From the medical angle, this technique provides community individuals a new method of dynamic monitoring of AFP and early detection of HCC at home.

References

1. An L, Zeng HM, Zheng RS (2019) Liver cancer epidemiology in China, 2015. Chinese Journal of Oncology 41: 721-727.
2. Terentiev AA, Moldogazieva NT (2013) Alpha-fetoprotein: a renaissance. Tumour Biol 34: 2075-2091.
3. Sterling RK, Wright EC, Morgan TR (2012) Frequency of elevated hepatocellular carcinoma (HCC) biomarkers in patients with advanced hepatitis C. Am J Gastroenterol 107: 64-74.
4. Black AP, Mehta AS (2018) The search for biomarkers of hepatocellular carcinoma and the impact on patient outcome. Curr Opin Pharmacol 41: 74-78.
5. World Health Organization. Hepatitis B (2020) http://www.who.int/mediacentre/factsheets/fs204/en/.
6. Polaris Observatory Collaborators (2018) Global prevalence, treatment, and prevention of hepatitis B virus infection in 2016: a modelling study. Lancet Gastroenterol Hepatol 3: 383-403.
7. Jin J, Zhang XY, Shi JL (2017) Application of AFP whole blood one-step rapid detection kit in screening for HCC in Qidong. Am J Cancer Res 7: 1384-1388.
8. Tzartzeva K, Obi J, Rich NE (2018) Surveillance imaging and alpha fetoprotein for early detection of hepatocellular carcinoma in patients with cirrhosis: a meta-analysis. Gastroenterology 154: 1706-1718.e1701.