Original Research Article

Comparative evaluation of Immunochromatographic Assay for screening Hepatitis C among blood donors in a rural teaching hospital, Sangareddy

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Abstract

Background: HCV is a blood borne virus. Mainly HCV infection attacks the liver and can cause chronic Hepatitis, liver cirrhosis (27%) and liver cancer (25%) and shows significant mortality and morbidity.

Aim: The present study was to assess ICT kit used in the preliminary screening process of HCV infection among blood donors in a rural teaching hospital, Sangareddy.

Materials and methods: In this study, 1050 number of blood units were collected from donors containing both voluntary and replacement donors for a period of one year from January 2015 to December 2015. 1050 donors were tested for HCV by using ICT kit and ELISA method.

Results: We found 4 out of 1050 subjects tested positive for HCV by using ICT kit and conformed by ELISA method.

Conclusion: The present study concluded that the overall performance of the rapid ICT kit for HCV was equally sensitive to ELISA and yet they were cheap and quicker. It can be recommended that ELISA comparable rapid devices may be allowed to be used for preliminary screening of Hepatitis C especially, in remote areas or where cost is an issue.

Key words

Hepatitis C virus (HCV), Immunochromatographic test kit (ICT), Transfusion Transmissible Infections (TTI's).

Introduction

Globally, Hepatitis C virus (HCV) infection became one of the major health problems [1]. Mainly HCV infection attacks the liver and can cause chronic Hepatitis, liver cirrhosis (27%) and liver cancer (25%) and shows significant mortality and morbidity. Worldwide, approximately 2-3% (around 170 millions) of population was chronically infected with HCV. Hence every year more than 5,00,000 people die with HCV related complications [2]. HCV is a blood borne virus. The transmission of HCV infection mainly occurs among drug users (sharing of injection equipment), reuse or inadequate sterilization of medical equipment like needles and syringes, transfusion of unscreened blood and blood products. HCV can also be transmitted by parental transmission (infected mother to child) and sexual contact; however these modes of transmission are much less common [3, 4].

Every year millions of lives are saved due to the blood transfusion and with every unit of blood there is 1% chance of Transfusion Transmissible Infections (TTI's). According to WHO, safe blood is a universal right, which means blood that is fully screened and harmless to the recipient and is not contaminated with any blood borne pathogenic diseases, such as HIV, HCV and HBV. So, WHO made mandatory to screen pre-transfusion blood for all blood transfusion associated diseases. In India screening of each and every blood units are mandatory and it is routinely done in blood banks. So, for screening and confirmation of HCV infection is based on advanced molecular and immunological techniques. For these screening techniques they required well established lab, expensive instruments and well trained technicians. Which are relatively expensive, for this reason, blood banks are using rapid immunochromatographic test (ICT) kits, to screen HCV in blood donors [5, 6].

The present study was to assess immunochromatographic test kits used in the screening of HCV among blood donors in a rural teaching hospital sangareddy.

Materials and methods

The present study was conducted at the blood bank of MNR Medical Collage and Hospital, Sangareddy and Telangana State, India (Catering to rural population). In this study, 1050 number of blood units were collected from donors containing both voluntary and replacement donors for a period of one year from January 2015 to December 2015. Blood donors were selected after taking detailed clinical history and brief medical examination. This study was approved by institutional ethical committee.

The fresh whole blood with a volume of 5 ml was collected from each donor in a sterile blood collection tube pre-treated with EDTA. Serum was obtained after centrifugation. The Serological test was performed according to WHO recommendation, involving rapid diagnostics assays and ELISA.

All the serum samples were tested by Immunochromatographic test kits (Genomix One step Hepatitis C antibody rapid test kit) and ELISA (HCV Microlisa (3rd generation), J. Mitra & Co. Pvt. Ltd, New Delhi, India) for HCV. The above investigations were carried out according to manufactures instructions.

Statistical analysis

Performance of rapid ICT kits was evaluated in terms of sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and efficiency which can be defined as follows: Sensitivity = [TP/ (TP+FN)] X 100, Specificity = [TN/ (TN+FP)] X 100, Positive Predictive Value (PPV) = [TP/ (TP+FP)] X 100, Negative Predictive Value (NPV) = [TN/ (TN+FN)] X 100, Efficiency = [(TP+TN)/ (TP+FN+TN+FP)] X 100].

Results

In the present study, out of 1050 blood donors, 1018 (96.95%) were males and 32 (3.05%) were females. In our study, replacement donors were 785 (74.76%) and voluntary donors were 265 (25.24%) as per **Table – 1**. The recorded age range was 18- 50 years old and the age frequency distribution of infection was as per **Table - 2**. Results showed that seroprevalence of HCV infection was 2 in the age group 21 – 30 years. Lowest prevalence was recorded in the 18-20 and 31- 40 age group. Out of 1050 samples, 4 were reactive; while the others were nonreactive for HCV as per **Table - 3**. The entire reactive specimens were observed among the males donors and none of the female donors were non reactive for HCV infection as per **Table - 2**.

Table - 1: Month-wise distribution of blood donors according to Gender, Replacement and Voluntary donor.

Month wise	Total Donors (%)	Donor Type		Gender	
		Replacement donors (%)	Voluntary donors (%)	Male Donors (%)	Female Donors (%)
January	80 (7.61%)	52	26	78	02
February	103 (9.80%)	66	31	97	06
March	97 (9.23%)	59	37	96	01
April	107 (10.20%)	70	33	103	04
May	96 (9.14%)	71	23	94	02
June	76 (7.23%)	62	12	74	02
July	65 (6.20%)	53	10	63	02
August	95 (9.04%)	84	08	92	03
September	79 (7.52%)	66	10	76	03
October	81 (7.71%)	60	19	79	02
November	101 (9.61%)	82	17	99	02
December	70 (6.66%)	60	07	67	03
Total	1050 (100%)	785 (74.76%)	265 (25.24%)	1018 (96.95%)	32 (3.05%)

Table - 2: Distribution of blood donors with Hepatitis C infections according to age group.

Age (years)	Hepatitis C (HCV) Reactive	
	Male	**Female**
18-20	01	00
21-30	02	00
31-40	01	00
41-50	00	00
Total	**04 (0.38%)**	00

Discussion

In the present study, the number of male donors 1018 (96.95%) were more than the number of female donors 32 (3.05%). Similar findings were observed by Rose, et al. [7] and Singh K, et al. [8]. The present study showing that majority of donors were replacement donors 785 (74.76%), while voluntary donors were 265 (25.24%). which is similar to the other studies done by Singh K, et al. (84.43%) [8] and Arora D, et al. (68.6%) [9], In India replacement donors constitute a major group of blood donors which is reflecting the lack of awareness in the general population [4].

Table - 3: Evaluation of HCV rapid ICT kit with ELISA.

	Total samples	**Reactive**	**Non-Reactive**	**True Positive (TP)**	**True Negative (TN)**	**False Positive (FP)**	**False Negative (FN)**
Rapid ICT assay	1050	04	1046	04	1046	00	00
ELISA	1050	04	1046	04	1046	00	00

Globally, detection and diagnosis of HCV infection are mainly based on immunological assays among which rapid ICT kit and ELISA are most common and widespread methods [10]. An important problem encountered at this point is the conflict between the results of two assays. This can be resolved depending on the availability of suitable kits. Generally, the sensitivity of the ELISA kits was good when compared to the rapid immunochromatographic test (ICT) kits. In terms of price, the cost of ELISA kit was very high whereas the cost of ICT kit for HCV antibody detection was very cheap. The time taking for ELISA assay was more whereas by using ICT kits the screening of the specimens was done within 10 to 15 minutes only. So, because of this less expensive and easy to handle and rapid screening nature the rapid ICT test kits became an alternative for ELISA in blood banks [11]. Moreover now a day's majority of the ICT manufacturing companies are using disease specific recombinant antigenic protein that helps in increasing the specificity and sensitivity of the ICT Kits.

In the present study, the rapid ICT kit was compared with the standard ELISA assay for screening of Hepatitis C infection. Results of the present study showed that the sensitivity and NPV of ICT kits used for HCV infection screening were significantly equal to the ELISA results. On the other hand, PPV and specificity of rapid ICT kits were equal to ELISA tests. Overall the efficiency for both rapid ICT kits and ELISA were equal, as per **Table – 3** and **Table - 4**.

Table - 4: Comparison of parameters between rapid ICT and ELISA.

Parameters	**ELISA**	**Rapid ICT**
Sensitivity %	100%	100%
Specificity %	100%	100%
PPV	100%	100%
NPV	100%	100%
Efficiency	100%	100%

Conclusion

The present study concluded that the overall performance of the rapid ICT kit for HCV was equally sensitive to ELISA and yet they were cheap and quicker. It can be recommended that ELISA comparable rapid devices may be allowed to be used for preliminary screening of Hepatitis C infection especially, in remote areas or where cost is an issue.

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