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Role of Rapid Test and ELISA in the Diagnosis of HCV in Haemodialysis Patients

Kanaga Priya Muthiah^{1*} and T. Susitha²

¹Department of Microbiology, Tirunelveli Medical College, Tirunelveli, India

²Department of Microbiology, KanyaKumari Government Medical College, Asaripallam, India

*Corresponding author

ABSTRACT

Keywords

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The usefulness of Rapid test and ELISA in the diagnosis of HCV in haemodialysis patients was analysed. In this study, Immuno Chromatography Test [ICT] rapid test was compared with ELISA for the effective detection of anti-HCV antibodies in patients on haemodialysis. A total of 106 blood samples, from chronic renal disease patients on haemodialysis were taken from the Department of Nephrology, Government Medical College Hospital, for a period of six months from July to December 2011. Sera were tested for anti HCV antibodies by rapid ICT and further tested by third generation ELISA. Anti-HCV antibodies were positive in 6 (5.66%) patients by ICT method while 7 (6.6%) patients were positive by ELISA method. The sensitivity and specificity of the ICT kit were 85.7% and 100% respectively whereas positive and negative predictive values were 100% and 99% respectively, which were significantly high and quite equivalent to the ELISA results. An ideal rapid test is a boon in time-saving situations like dialysis. Hence we conclude that HCV screening can be preferably done by a rapid test followed by a supplemental ELISA and polymerase chain reaction.

Introduction

Infection with Hepatitis C virus (HCV) has been identified as the major cause of post-transfusion non-A, non-B hepatitis (Capner *et al.*, 2007). The prevalence of HCV is consistently higher among haemodialysis patients than in general population and has been associated with greater morbidity and mortality (Natov *et al.*, 1996). The high prevalence of HCV infection in haemodialysis patients has been attributed not only to the frequency of blood transfusion but also to increasing years on dialysis suggesting that HCV may be transmitted among patients in

the dialysis unit, probably as a result of poor infection control practices (Quer *et al.*, 2005).

Laboratory diagnosis of HCV infection is usually based on the detection of circulating antibodies (Narayan *et al.*, 2001). The Immuno-chromatographic test (ICT) is rapid and simple and could be used in settings with limited facilities (Batool *et al.*, 2009). Enzyme-linked Immunosorbent Assay (ELISA) is widely used for anti-HCV antibody screening. A confirmatory test like radio-immunoassay or molecular technologies of higher specificity are recommended to test

all those samples found reactive by the screening test (WHO report, 2001). In this study, ICT is compared with ELISA for the effective detection of anti-HCV antibodies in patients on haemodialysis.

Chronic kidney disease (CKD) was included among Non –Communicable Diseases (NCD) in 2011 by World Health Organization. HCV is linked to CKD in several ways –some forms of renal disease are precipitated by HCV and ESRD patients are at rising risk of HCV acquisition. Nowadays, the spread of HCV among dialysis patients is declining but its prevalence remains high mainly in developing countries. Periodic screening of HCV infection is mandatory to prevent newer transmission and there is a need of effective diagnostic method in high resource regions. With this back-ground, this study entails in demonstrating the efficiency of ICT in comparison with ELISA in detection of HCV.

Materials and Methods

Sample size: A total of 106 blood samples, from patients on haemodialysis were collected

Place of study: Tirunelveli Medical College Hospital, Tirunelveli, Department of Nephrology.

Period of study: Six months from July to December 2011.

Inclusion criteria: The patients with chronic renal disease on haemodialysis of all age groups were included in the study.

Exclusion criteria: Pregnant women, acute renal failure cases were excluded.

Consent: An informed oral consent and a structured questionnaire were obtained from all patients.

Ethical clearance clearance: Ethical

clearance was also obtained from Institutional Ethical Committee.

Collection and transport of specimen

About 3-5 ml of blood was collected from the patients on haemodialysis and serum was separated by centrifugation. Sera were tested for anti HCV antibodies by rapid ICT immediately (Span Diagnostics Ltd. India). Sera were stored at -20°C and further tested by third generation ELISA (ERBA diagnostics Mannheim GmbH, Germany) as per the manufacturers' instructions.

Results and Discussion

A total of 106 blood samples from patients on haemodialysis were screened for anti-HCV antibody. Females constituted 31 (29.2%) of the study population whereas 75 (70.8%) were males. Both sexes were maximum in the age group of 40-59 years. The mean ages of males and females were 44.2 years and 41.2 years respectively. The difference of age between the gender was not statistically significant ($P>0.05$). (Table1)

Anti-HCV antibodies were positive in 6 (5.66%) patients by ICT method while 7 (6.6%) patients were positive by ELISA method. There was no statistical significance between ICT and ELISA methods for HCV detection. All the females were negative by both methods. Remaining 99 samples were negative by both ICT and ELISA methods. Anti –HCV antibodies were negative at extremes of age such as below 20 years and above 60 years. The prevalence of HCV infection among haemodialysis patients in this study was 6.6%.

In the 20-39 years age group, 4 (14.3%) were positive by ICT and 5 (11.9%) were positive by ELISA while among 40- 59 years, 2 (5.9%) were positive by both methods.(Table

2). The sensitivity and specificity of the ICT kit were 85.7% and 100% respectively whereas positive and negative predictive values were 100% and 99% respectively. (Table 3)

It is well known that haemodialysis patients are at high risk for development of HCV infection. The prevalence of HCV infection varies greatly among various patients on haemodialysis from different geographic regions. However, the data on the prevalence of anti-HCV among Indian haemodialysis patients remains scanty. In the present study, the prevalence of HCV infection among haemodialysis patients was found to be 6.6%. This is in accordance with (Reddy *et al.*, 2005), where the prevalence of HCV was 5.9% and (Almari *et al.*, 2005), where the prevalence was 6.1%. This is in contrast to the high prevalence rate by (Telaku *et al.*, 2009), (43%) and (Bdour *et al.*, 2002) (34.6%).

Since the introduction of screening assays for HCV antibodies, major efforts had been made to increase the diagnostic accuracy of the assays. The major concern in using rapid ICT is their variable degree of sensitivity and specificity. An ideal rapid test would have a high degree of positive predictive value and low degree of false negative result. (Khan *et al.*, 2010). Out of the 106 samples, 6 (5.66%) were detected by the rapid ICT for anti-HCV antibodies. In the present study, ELISA was considered as the gold standard to document HCV infection. Results of this study showed that the sensitivity of the rapid ICT kit was low (85.7%) compared to the specificity (100%), positive predictive value (100%) and negative predictive value (99%) which were significantly high. The results of the study by (Khan *et al.*, 2010) showed that the sensitivity of the rapid test was 45% only for HCV detection.

An additional positive sample detected by ELISA for HCV antibodies in the present study could be due to the short incubation period of the ICT. Characteristically short incubation tests, do not detect low affinity or low concentration of antibodies as compared to the classic type of immunoassays which employ longer incubation time allowing reaction to proceed to completion. (Khan *et al.*, 2010) the study by (Daniel *et al.*, 2005) showed a similar result, where one sample was negative by rapid test among ELISA tested positive samples for HCV detection.

In this study, all the positive samples belonged to male gender. It is thought that females had delayed health seeking behaviour. This is similar to the study by (Khan *et al.*, 2011) where higher prevalence was seen among males but the study by (Hamissi *et al.*, 2011) found almost equal prevalence between males (8.8%) and females (10.5%).

In the present study, ELISA detected 7 (6.6%) out of 106 samples for anti-HCV antibodies. Negative serology in spite of HCV viremia has been documented in haemodialysis patients. HCV viremia in the absence of anti-HCV may occur in the viremic stage early in acute infection. The antibody response in chronic haemodialysis tends to be poor and ELISA may underestimate the problem (Mukophadhya, 2008).

It has been documented that among immune compromised populations, the proportion of false positive results with the third generation ELISA averages 15%. Therefore one should not rely exclusively on a positive anti-HCV screening test to determine whether a person is infected with HCV. A positive screening test should be verified with an independent supplemental test like radio-immunoassay or polymerase chain reaction with high specificity (CDC & P, MMWR report 2003).

Table.1 Demographic status among haemodialysis patients

Age group (years)	Male		Female	
	No	%	No	%
Less than 20	2	2.7	2	6.5
20-39	28	37.3	13	41.9
40-59	34	45.3	13	41.9
60 and above	11	14.7	3	9.7
Total	75	100.0	31	100.0
Mean + S.D	44.2± 13.8		41.2 ± 13.9	
Significance	't'= 1.03 d.f = 104 p > 0.05			

d.f- degrees of freedom

Table.2 Age wise distribution among HCV positives by ICT and ELISA

Age group (years)	ICT		ELISA		'Z'	p Value
	Positive	%	Positive	%		
20-39 (n=28)	4	14.3	5	17.9	0.367	p> 0.05
40-59 (n=34)	2	5.9	2	5.9	0.0	p=1.00
Total (n=62)	6	9.7	7	11.3	0.291	p> 0.05

Table.3 Comparison of ICT with ELISA

		ELISA n=106		Z ² and χ^2	Significance
		+	-		
ICT n=106	+	6	0	0.0	p=1.00
	-	1	99		

Since immunization against HCV is not yet available, identification and isolation of infected HCV patients may minimize its spread in dialysis units.(Weinstein *et al.*, 2001). This study highlights that an ideal rapid ICT is a valuable tool in emergency situations like dialysis. An additional test if available can detect HCV infection and helps to avoid nosocomial transmission of HCV infection among patients on haemodialysis with low antibody titre.

In conclusion, in the present study the sensitivity of the rapid ICT was 85.7% and a 100% specificity (100%), positive predictive value (100%) and negative predictive value (99%) which were significantly high and quite equivalent to the ELISA results. An

ideal rapid test is a boon in time-saving situations like dialysis. Since HCV screening by a rapid test is easier, time saving, can be easily performed by any trained health care worker, at any time of need, it can definitely be preferred as a screening test not only before haemodialysis but also for any other emergency surgery. It is cost effective also. Hence we conclude that HCV screening can be preferably done by a rapid test followed by a supplemental ELISA and polymerase chain reaction.

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