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Diagnosis of hepatitis C virus among hemodialysis patients—which is the ideal method?

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Abstract

Background: Globally, it was estimated that hemodialysis (HD) was required in 3.9 million persons with kidney failure in 2017. The global prevalence of Hepatitis C virus (HCV) in the general population is approximated at 0.7% worldwide, and it varies from 1% to 85% in different countries among patients undergoing hemodialysis (HD). This study highlights the diagnostic efficacy of Immunochromatography test (ICT), fourth generation Enzyme-linked immunosorbent assay (ELISA) which determines anti-HCV antibodies and HCV core antigen, Real-time polymerase chain reaction (RT-PCR) for diagnosis of HCV infection in chronic HD patients and also assesses the impact of other factors including age, sex, length of dialysis, number of blood transfusions, and serum transaminases levels. **Methods**: Seventy-five patients diagnosed with end-stage renal disease (ESRD), who had been receiving HD for more than six months, were included. Blood samples were collected and subsequently analyzed for the presence of anti-HCV antibodies using an ICT, a fourth-generation ELISA, and RT-PCR. **Results**: Of the 75 samples tested, ICT, fourth-generation ELISA and RT-PCR were positive in eight (11%), 12 (16%), and 22 (29%) respectively. **Conclusions**: Solely screening for HCV antibodies is often not sufficient to exclude HCV infection in HD patients. Furthermore, HD patients do not always have detectable HCV RNA. Hence, close monitoring and stringent infection control practices are imperative to mitigate the transmission of HCV.

Keywords: Enzyme-linked immunosorbent assay; Hemodialysis; Hepatitis C virus; Immunochromatography test; Reverse transcriptase polymerase chain reaction

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Introduction

Individuals suffering from end-stage renal disease (ESRD) frequently receive hemodialysis (HD) as a form of renal replacement therapy. HD was estimated to be necessary for 2.1 million patients globally in 2012, rising to 3.9 million in 2017, and this figure will probably increase by 7% yearly [1, 2]. The World Health Organization (WHO) reports that over 3% of the global population is infected with the Hepatitis C virus (HCV) [3]. The prevalence of HCV varies from 1% to 85% in different countries among patients undergoing HD due to underlying compromised cellular immunity, which makes them more vulnerable to infection [4]. The estimated prevalence of HCV in India ranges from 1% to 1.9% and, owing to the country's substantial population, it raises public health concerns. In India, acute viral hepatitis due to HCV accounts for up to 1.16–10.6% [5]. Globally, the WHO statistics indicate that 58 million individuals are affected with chronic hepatitis C infection [6]. Over 20 years, 10–20% of chronic HCV infection progressed to cirrhosis, which may further worsen to decompensated cirrhosis and hepatocellular carcinoma (HCC) in later life. Factors contributing to HCV infection include patient age, immune response, severity of hepatic inflammation, co-infection with human immunodeficiency virus (HIV) or hepatitis B virus (HBV), and lifestyle behaviours like consumption of alcohol [5]. Routinely HCV screening among HD patients is performed using an immunochromatography test (ICT) or third generation ELISA to detect anti-HCV antibodies. Due to the immunocompromised state in HD patients, the window period of HCV infection is prolonged compared to that of normal individuals, rendering high-false negative results. Real time polymerase chain reaction (RT-PCR) which is the gold standard test should be performed to confirm the infection [7]. This study highlights the diagnostic efficacy of immunochromatography test, fourth generation enzyme-linked immunosorbent assay (ELISA) which detects anti-HCV

antibody and HCV core antigen, real time polymerase chain reaction (RT-PCR) in diagnosing Hepatitis C infection among chronic HD patients and also assesses the impact of other factors including age, sex, length of dialysis, number of blood transfusions, and serum transaminases levels.

Materials and methods

This cross-sectional diagnostic accuracy study was undertaken in the Department of Microbiology, spanning from March to December 2023. The study included 75 individuals above 13 years of age with chronic renal disease who had been on HD for more than six months. A comprehensive proforma was used to collect sociodemographic information such as age and gender, duration of illness, previous occurrences of jaundice, a record of blood transfusions, and specific characteristics of co-morbid conditions. A distinct laboratory ID was given to every participant. 5 mL of venous blood were drawn using sterile aseptic procedures, and the serum was used for ELISA (TCG42206, Erbalisa HCV Gen 4 Antigen (Ag) + Antibody (Ab), TransAsia Bio-Medicals Ltd, Daman, India) and immuno-chromatography test (HCV Rapid Test, 9557TG, Bio line Diagnostics, Mumbai, India). An additional 5 mL of blood was collected into an Ethylenediaminetetraacetic Acid (EDTA) tube intended for HCV RNA PCR (MyLab Discovery solutions, Pune, India), and the samples were kept at −80 °C until the tests were conducted. The tests were performed in accordance with the manufacturer's specified protocols. Patients under HD for more than 6 months and aged over 13 years were included in the study. The patients previously positive for HCV or on empirical antiviral therapy and those with hepatitis B co-infection were not enrolled in the study.

The findings of the study outcome were statistically examined for accuracy, completeness, and consistency using metrics like mean and percentages. Three diagnostic techniques were compared for the degree of agreement, and a kappa value was produced. Statistical comparisons of the Rapid ICT, ELISA, and RT-PCR findings were performed using McNemar's χ^2 test. The Chi square test and student *t*-test were used to perform the statistical analyses. All statistical operations were conducted using IBM SPSS software, version 29.0 (IBM Corp., Armonk, NY, USA). Statistical significance was defined as a probability value (*p*-value) of less than 0.05.

Results

The study population consisted of 75 patients, comprising 42 (56%) males and 33 (44%) females. A significant statistical correlation was noted in this study between gender and HCV infection (Table 1). Among the 75 patients, 34 (45%) belonged to the age group of 21 to 40 years. All 75 patients were tested for HCV ICT, ELISA, and HCV RNA PCR. Among the 75 samples tested, 8 (11%), 12 (16%), and 22 (29%) were positive with ICT, ELISA, and HCV RNA PCR assays (Table 2). Of the 75 patients, 28 tested positive for HCV. Males showed the highest positivity of 21 (75%) compared to females, 7 (25%). The greatest proportion of positive cases 14 (50%) were found to be between the ages of 21 and 40, followed by 41–60 years with 10 (36%). The mean age of HCV-positive cases was 39.1 ± 13.2 years (Table 1). Comorbid conditions like hypertension alone in 12 (43%) and both diabetes and hypertension in eight (28%) were observed among the HCV-positive individuals. Among the positive cases, 14 (50%) had received dialysis for a period of 20 to 30 months, 18 (64%) underwent dialysis at multiple centers, and 12 (43%) of them received dialysis twice a week. Among individuals diagnosed with HCV, the average duration of HD was determined to be 21.32 ± 5.9 months. Of the HCV-positive cases, 5 (18%) had multiple blood transfusions, and 23 (82%) had elevated Aspartate aminotransferase (AST) >35 IU/mL and Alanine aminotransferase (ALT) levels >40 IU/mL (Table 1). When compared to RT-PCR, the rapid ICT demonstrated a sensitivity of 22.7%, a specificity of 94.3%, a positive predictive value (PPV) of 62.5%, and a negative predictive value (NPV) of 74.6% (Table 3). The Fourth Generation ELISA test, when compared to RT-PCR, also showed a sensitivity of 27.3% and a specificity of 88.7%, with a PPV of 50% and an NPV of 74.6% (Table 3). Furthermore, a direct comparison of ICT against the Fourth Generation ELISA in Table 4 shows that, the ICT had a sensitivity of 66.7% and a specificity of 100%. The kappa value measuring the degree of agreement between ICT and ELISA was 0.771 (p-value < 0.0001).

Discussion

After it enters the body, the virus may establish a latent phase, primarily due to suppression by the host immune system. But during the period of active viral replication, HCV replicates extremely quickly, and approximately 10^{12} virus particles are produced every day. It has been stated that only 10–15% of HCV-infected people exhibit symptoms. Spontaneous resolution is observed in 25–50% of symptomatic and 10–15% of asymptomatic individuals [5]. Hence, it is difficult to diagnose HCV among asymptomatic patients. Geographic differences in the HCV genome and variations in screening test create further chaos in accurate HCV testing [7]. The duration of the window period exhibits variability based on the serological assay generation utilized, ranging from 66 days for conventional serology tests to merely four days when nucleic acid testing (NAT) is employed [1]. The majority of the studies used anti-HCV antibodies as a diagnostic tool for HCV, which is unable to differentiate between resolved and active infections.

The lengthy serological window may also make it challenging to identify HCV infection by looking for anti-HCV antibodies, but viremia may develop even in the absence of HCV antibodies. Napoli *et al.* [8] suggested that early diagnosis of HCV during its acute phase is crucial. A recent global data study substantiates this recommendation to reduce disease burden [9].

Sravanthi K *et al.* [10] reported that HCV positive was noted in 41.6% by RT-PCR and 21.66% by ELISA. This current study investigated the prevalence of HCV by ICT, fourth-generation ELISA and HCV PCR, which were eight (11%), 12 (16%), and 22 (29%) respectively. In the present study, ICT showed only 66.7% sensitivity when compared with fourth-generation ELISA (Table 4). According to several studies, compared to NAT methods, HCV core antigen has

Table 1. Socio-demographic details of the study participants.

Categories	Variables	HCV-Positive (n = 28) (%)	HCV-Negative (n = 47)	*p*-value
Gender				
	Male	21 (75)	21	0.0105 Significant OR = 3.71
	Female	7 (25)	26	
Age in years				
	<20 yr	2 (7)	3	0.5929 Not Significant
	21–40 yr	14 (50)	20	
	41–60 yr	10 (36)	20	
	>61 yr	2 (7)	4	
	Mean age	39.1 ± 13.2	40.57 ± 13.0	
Co-morbidities				
	HTN	12 (43)	11	-
	DM	3 (12)	13	
	HTN with DM	8 (28)	6	
	Congenital/Obstruction	2 (7)	11	
	CIN	2 (7)	4	
	CGN	1 (3)	2	
Duration of HD (in mon)				
	<10	1 (4)	7	<0.001 Significant
	11–20	11 (39)	30	
	21–30	14 (50)	7	
	>31	2 (7)	3	
Number of dialysis centres				
	1	10 (36)	39	<0.001 Significant
	2	14 (50)	7	
	3	4 (14)	1	
Frequency of HD/wk				
	Once	6 (21)	15	0.9729 Not significant
	Twice	12 (43)	18	
	Thrice	10 (36)	14	
Blood Transfusion in times				
	<5	1 (3)	2	0.547 Not significant
	6–10	1 (3)	1	
	>11	3 (12)	3	
	Nil	23 (82)	41	
AST				
	Normal	5 (18)	42	<0.001 Significant
	Elevated	23 (82)	5	
ALT				
	Normal	5 (18)	42	<0.001 Significant
	Elevated	23 (82)	5	

HCV: Hepatitis C virus; OR: Odd's Ratio; HTN: Hypertension; DM: Diabetes Mellitus; CIN: Chronic Interstitial Nephritis; CGN: Chronic Glomerular Nephritis; HD: Hemodialysis; AST: Aspartate Aminotransferase; ALT: Alanine Aminotransferase.

Table 2. Distribution of assay positivity among the study participants.

Assays	Positives (n = 28)
Only ICT	0
Only ELISA	3
Only PCR	16
ICT & ELISA	3
ICT & RT-PCR	0
ELISA & RT-PCR	1
ICT + ELISA + RT-PCR	5

ICT: Immunochromatography test; ELISA: Enzyme-linked immunosorbent assay; PCR: polymerase chain reaction; RT-PCR: Real-time polymerase chain reaction.

Table 3. Evaluation of ICT and ELISA with gold standard test RT-PCR.

Assay	RT-PCR		Total
	Positive	Negative	
ICT			
Positive	5	3	8
Negative	17	50	67
Total	22	53	75
4th Gen ELISA			
Positive	6	6	12
Negative	16	47	63
Total	22	53	75
ICT & RT-PCR			
Sn: 5/22 (22.7%), Sp: 50/53 (94.3%), PPV: 5/8 (62.5%), NPV: 50/67 (74.6%)			
ELISA & RT-PCR			
Sn: 6/22 (27.3%), Sp: 47/53 (88.7%), PPV: 6/12 (50%), NPV: 47/63 (74.6%)			

ICT: Immunochromatographic test; ELISA: Enzyme-linked Immunosorbent Assay; RT-PCR: Reverse transcriptase polymerase chain reaction; Sn: Sensitivity; Sp: Specificity; PPV: Positive Predictive Value; NPV: Negative Predictive Value.

Table 4. Correlation between rapid ICT and 4th Gen ELISA in HCV detection.

Assay	4th Gen ELISA		Total
	Positive	Negative	
ICT			
Positive	8	0	8
Negative	4	63	67
Total	12	63	75
Sn: 8/12(66.7%), Sp: 63/63 (100%), PPV: 8/8 (100%), NPV: 63/67 (94%), Kappa value: 0.771, $p < 0.0001$			

Sn: Sensitivity; Sp: Specificity; PPV: Positive Predictive Value; NPV: Negative Predictive Value; ICT: Immunochromatographic test; ELISA: Enzyme-linked Immunosorbent Assay.

demonstrated superior sensitivity and specificity, suggesting its potential as an alternative diagnostic approach in resource-limited settings [8]. Hence, all HD patients should be monitored and screened for HCV ideally by HCV PCR. A study mentioned that among anti-HCV positive donors, undetectable HCV RNA was observed in 30% of the individuals from Australia. Hence, post-seroconversion or in states of remission, viral loads demonstrate extensive fluctuation and a notable decrease [11]. Research indicates that HCV viremia is typically lower in HD patients than in infected individuals not on dialysis, potentially due to the degradation of viral particles during HD [12]. Dharmesti *et al.* [13] stated that seroconversion to HCV antibodies is not universally observed among HD patients.

While increased transaminase levels are commonly observed in HCV infection, this pattern is not consistently

evident in chronic HD patients presenting with viral hepatitis. Hence, a modest increase in AST could serve as an early indicator of HCV seroconversion [1]. Blood transfusions are a recognized mode of HCV transmission among CRF patients on HD.

Nosocomial transmission is attributable to inadequately sterilized medical equipment, including endoscopic devices, colonoscopy, angiographic and surgical instruments, which can increase the risk for HCV [14]. This study identified the duration of dialysis and attendance at multiple dialysis centers as significant risk factors for HCV infection. HCV infection raises the mortality rate for HD patients with ESRD, lowers life expectancy, leads to renal allograft rejection and diminishes quality of life.

The low sensitivities and specificities of the rapid kits may be attributed to the low-level antibodies in the circulation, or the patients may be in the early stage of the infection, or may have low viral load [15]. The prevalence of an infection affects the predictive values of the diagnostic assays. The PPV increases while the NPV decreases with an increase in the prevalence of an infection. As the prevalence of HCV varies within the country, it may influence the difference in the testing accuracy of both ICT and ELISA [16].

Among the various immunoassays available, this study employed only the fourth-generation ELISA and did not include the third-generation ELISA for the detection of anti-HCV antibodies. As a result, a direct comparison of the sensitivity and specificity between the third- and fourth-generation ELISA assays could not be performed. Additionally, although qualitative PCR testing was conducted to confirm the presence of HCV RNA, genotyping of the virus was not carried out. The absence of comparative ELISA analysis and viral genotyping represents important methodological limitations of the study.

Conclusions

ICT assays are less sensitive, 5/22 (23%), than fourth-generation ELISA 6/22 (27%) when compared with the gold standard RT-PCR method. Hence, screening for HCV antibodies alone is insufficient to definitely rule out HCV infection in HD patients. In addition, HD patients do not always have detectable HCV RNA. Further, there may not be an elevated transaminase level. Close monitoring and rigorous infection prevention and control measures must be implemented to mitigate the transmission of HCV.

Availability of data and materials

The data are contained within this article.

Author contributions

RST and PSK—designed the research study, wrote the manuscript and analysed the data. SK—wrote the manuscript. PR—provided help and advice on the preparation of the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study was conducted after obtaining written informed consent from all participants, utilizing a form approved by the Institutional Ethics Committee-Certificate of registration and ethical approval by Institutional Research Ethics Committee-Tirunelveli Medical College (TIREC ID: 20222440).

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Conflict of interest

The authors declare no conflict of interest.

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