



COMPARATIVE ANALYSIS OF RAPID IMMUNOCHROMATOGRAPHIC TEST (ICT) AND ENZYME LINKED IMMUNO SORBENT ASSAY (ELISA) TESTS TO DETECT ANTI-HCV ANTIBODY AMONG PATIENTS UNDERGOING HAEMODIALYSIS

Clinical Microbiology

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ABSTRACT

Introduction: Over the years HCV infection has proved to be one of the leading causes of public health issue as a result of high morbidity and mortality rate worldwide. Hence prevention or early detection has proved to be of great use to tackle the disease. Since the introduction of rapid screening assays, they have been used widely worldwide. Hence this study was conducted to compare rapid ICT test with ELISA for the effective detection of anti-HCV antibodies in patients on haemodialysis (HD). **Material and methods:** A total of 109 HD patients suffering from chronic kidney disease were recruited. This study was conducted from July 2019 to March 2022. Sera of all the patients was tested for anti HCV antibodies by rapid ICT and further tested by ELISA. **Results:** In our study results obtained show that the seroprevalence of anti-HCV was 26.6% i.e. 29 patients via rapid ICT and 35.8% i.e. 39 patients via ELISA depicting a significant difference of sensitivity and specificity of ELISA over ICT testing. **Conclusion:** The results indicated that the rapid ICT kits for HCV have a limited efficiency and should be backed by superior supplemental methods like ELISA and PCR where possible.

KEYWORDS

Anti-HCV antibody; ELISA; Hemodialysis; rapid ICT.

INTRODUCTION:

Hepatitis C virus (HCV) is a positive sense, ss-RNA virus, belonging to the family *Flaviviridae* and genus *Hepacivirus*. (1) HCV infection has emerged as a serious public health problem and one of the most crucial causes of liver disease in patients undergoing dialysis for a long duration.(2) Also HCV infection is seen to be the most significant cause of morbidity and mortality in patients undergoing HD.(3) Approximately 180 million individuals worldwide have been reported to be infected with HCV infection.(4) In India, nearly 13 million individuals are known to be suffering from chronic HCV infection.(5) Due to the highly asymptomatic nature of infection caused by HCV, mostly the patients remain undiagnosed.(6)

The seroprevalence of HCV in HD patients has been noted to range between 6%-60% in comparison to a seroprevalence of 4.3% to 45% shown in various studies conducted in India. (7)

As it is noted that in the dialysis units, hepatitis B and HCV viral infections are known to be crucial factors causing morbidity and mortality, management of these patients becomes complicated and cumbersome in lieu of these infections. (8)

Diagnosis of HCV infection done in a laboratory is usually based on the detection of circulating antibodies for which numerous immunoassays have been made available nowadays like ICT, ELISA and Enzyme Immunoassay. (9)

With this back-ground, this study entails in demonstrating the efficiency of ICT in comparison with ELISA for the effective detection of anti-HCV antibodies in patients on HD.

MATERIAL AND METHODS:

This study was conducted in the Department of Microbiology and associated hospitals in Western Rajasthan. The study participants included patients undergoing HD. The duration of the study was from July 2019 to March 2022. The number of samples included in this study was 109. An explained oral consent or a written consent in the form of designed questionnaire was obtained from all patients or their guardians.

Blood was drawn aseptically and serum was separated. Sera were tested for anti HCV antibodies by rapid ICT immediately Standard Diagnostics Biotline HCV Card Test) and further tested by ELISA (Merilisa from Meril Diagnostics). Patients' demographic details like age, gender, family history, duration of HD, blood transfusion history etc. details were noted.

Ethical Clearance:

Ethical clearance was obtained from Institutional Ethics Committee.

Statistical Analysis:

Statistical analysis was done with the help of IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp.

RESULTS AND OBSERVATIONS

The result deduced from this study reveals that total ICT positive samples were 29 whereas total ELISA positive samples were 39 clearly depicting a difference of 10 samples. Of these 29 ICT positive samples, one sample was detected to be ELISA negative. All the 10 ELISA positive samples were revealed to be ICT negative. (Table 1 & Table 2) In our study maximum positivity was noted in the age range of 31-60 years age group i.e. 46.9% in case of ELISA testing and 36.3% in case of ICT testing. (Table 3)

Our study reveals that among the total 64 males, 23 (36%) were positive with ELISA and 19 (29.7%) were positive with ICT testing, whereas among 45 females, 16 (35.6%) were positive with ELISA and 10 (22.2%) were positive with ICT testing. (Table 3) In our study positivity pattern noted showed that maximum positive patients i.e. 37.3% in case of ELISA testing and 29.4% in case of ICT testing were included in HD vintage of >1-3 years. (Table 3) It was observed that maximum positivity was noted in case of 1-10 units of blood transfused, for both ELISA and ICT testing i.e. 34.2% and 21.9% respectively. (Table 3)

Table 1: Results of ICT and ELISA test

TEST NAME	Total Positive	Total Negative	P-value
ICT	29	80	.143759
ELISA	39	70	

*p-value considered statistically significant at $\leq .05$

Table 2: Comparison of ICT and ELISA test results

Diagnostic Test	ICT positive (n=29)		ICT Negative (n=80)	
	ELISA Positive	ELISA Negative	ELISA Positive	ELISA Negative
Total	28	1	10	70
Diagnostic Test	ELISA positive (n=39)		ELISA Negative (n=70)	
	ICT Positive	ICT Negative	ICT Positive	ICT Negative
Total	28	11	1	69

Table 3: Baseline characteristics and clinical data of HCV among hemodialysis patients

Patient particulars	Anti-HCV positive Total=39		ICT positive Total=29		χ^2	p-value
Age group (years)	N	(%)	N	(%)		

≤30 (N=22)	4	18.2	2	9.1	0.234	.889
31-60 (N=66)	31	46.9	24	36.3		
>60 (N=21)	4	19	3	14.3		
Gender	N	(%)	N	(%)		
Male (N=64)	23	36	19	29.7	0.301	.582
Female (N=45)	16	35.6	10	22.2		
Duration of dialysis (years)	N	(%)	N	(%)		
≤1 (N=46)	8	17.4	3	6.5	1.345	.510
>1-3 (N=51)	19	37.3	15	29.4		
>3 (N=12)	12	100	11	91.7		
Number of blood units transfused	N	(%)	N	(%)		
0 (N=24)	11	45.8	10	41.7	0.564	.753
1-10 (N=73)	25	34.2	16	21.9		
>10 (N=12)	3	25	3	25		

*p-value considered statistically significant at ≤.05

DISCUSSION:

We observed that the patients' age range varied from 11-88 years in our centre. It is noted that in our study seropositivity in male population is higher as compared to female population. This pattern of positivity was also noted by Muthiah *et al.* (10) In our study seroprevalence of anti-HCV is noted to be maximum among 31-60 years age group which is similar to findings reported in middle-east countries. (11)

In our study, it was observed that anti-HCV seropositivity is in correlation with duration of dialysis. Our findings corroborate well with the observation of researchers worldwide (12) on the contrary studies in discordance to our finding have also been reported. (13)

In case of blood transfusion, in our study it was observed that maximum seropositive patients lied in the range of patients using 1 to 10 units. This is in correspondence with study conducted by Zamani *et al.* (14)

It has been established that differing degree of seroprevalence of anti-HCV antibodies varying from 1-84.6% in HD patients is prevalent worldwide. (15) Since the introduction of screening assays, it has been observed that the major concern in using rapid ICT is their variable degree of sensitivity and specificity. It has been established that an ideal rapid diagnostic test would have a high degree of PPV (positive predictive value) and low degree of false negative result. (16) As compared to ELISA, results of this study showed that the sensitivity of the rapid ICT kit was low i.e. 71.79% and the specificity was determined to be 98.57%. This observation shows similarity with the findings of Muthiah *et al.* (10) but shows disagreement with study performed by Khan *et al.* (16) In our study PPV and negative predictive value were calculated to be 96.55% and 86.25% respectively, which were noted to be significantly high in comparison to the findings of Khan *et al.* (16) Hence in our study on conducting comparative analysis via rapid ICT and ELISA it was noted that the seroprevalence of anti-HCV in our study was 26.6% and 35.8% respectively. The above results show discordance with findings of Hussain *et al.* (17)

We could not establish any statistically significant relationship between ICT and ELISA methods, which is in accordance with study performed by Muthiah *et al.* (10)

In our study additional positive samples were detected by ELISA, this fact can be attributed to the shorter incubation period in case of ICT employed in the study. Characteristically diagnostic tests with shorter incubation period are unable to detect low affinity or low concentration of antibodies in contrast to the classic and conventional type of immunoassays which include longer duration of incubation period allowing reaction to move forward to completion. Hence ICT tests may fail to detect HCV infection in patients with low affinity or low antibody titre. (16)

This study places emphasis on the fact that in serious or emergency situations like dialysis, an ideal rapid ICT is considered as a significant tool. Although an additional more specific test if available should be done, so as to help overcome the risk of nosocomial transmission of HCV infection with low antibody titre. (10) Further it is recommended that a positive screening test should be verified with test like RIA (radio-immunoassay) or PCR with high specificity. (18)

The results obtained in our study show similarity with the studies conducted in India where ELISA testing method has been proven to be more sensitive and specific in contrast to rapid ICT diagnostic test methods. (19) But still the studies relating to this comparison are much scarce as the trend is more towards the superior assays.

CONCLUSION:

Although ICT tests are known to be rapid, cost effective and require lesser man power, our study reveals that ELISA method is superior to rapid ICT tests as a result of higher sensitivity and specificity of ELISA.

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