

A COMPARATIVE STUDY OF PREVALENCE OF HCV BY RAPID DIAGNOSTIC TEST KIT AND ELISA IN A TERTIARY CARE HOSPITAL, ANDHRA PRADESH

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ABSTRACT

Objective: Hepatitis C Virus (HCV) is an enveloped single-stranded RNA virus transmitted through exposure to small quantities of blood and most commonly through blood transfusion. For diagnosing hepatitis C infection, serologic assays are the most important tools which detect the human antibodies generated as a response to hepatitis C virus. We aim to estimate the prevalence of HCV in a Tertiary care hospital.

To assess the Seroprevalence of HCV by Rapid Diagnostic Test (RDT). To assess the Seroprevalence of HCV by ELISA. To compare the Sensitivity and Specificity of RDT with ELISA.

Methods: A total of 360 serum samples were collected from patients attending outpatient departments over a period of 12 mo. These samples were tested for HCV antibody using a commercially available ELISA kit and Rapid Diagnostic Test (RDT) Kit according to the instructions provided in the manufacturer's manual.

Results: Among the 360 samples tested, 28 samples were positive by ELISA whereas only 20 were positive by Rapid Diagnostic test kit. Majority of the samples collected were in the age group of 21-30 yrs. Positive cases were almost equally distributed in all age groups.

Conclusion: The present study highlights current scenario of HCV infection in a tertiary care hospital. RDT, though showed 100% specificity, the sensitivity was only 71.43%. It missed 8 positive cases. Hence we cannot rely on rapid tests. But as they are simple to perform, rapid and cheap, their use can be restricted only to emergency situations.

Keywords: Prevalence of HCV, Rapid diagnostic test Kit

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INTRODUCTION

The hepatitis C virus (HCV) is an enveloped single-stranded RNA virus and classified as a separate genus (Hepacivirus) within the Flaviviridae family. About 170 million people worldwide are at risk of HCV, reported with a high incidence of chronic liver illness including cirrhosis and hepatocellular carcinoma [1]. In India, the estimated prevalence of HCV infection is about 1-1.9% [2].

The HCV is a blood-borne virus. The most common mode of infection is through exposure to small quantities of blood. This may happen through intravenous drug abuse, unsafe injection practices, transfusion of unscreened blood and blood products and sexual practices that leads to exposure of blood. Around 30% (15 - 45%) of infected HCV persons clear the virus within 6 mo without any treatment or medications. The remaining 70% (55 - 85%) of people develop chronic HCV infection, which may lead to cirrhosis of liver that ranges between 15% and 35% within 19 y [3].

For diagnosing hepatitis C infection, serologic assays are the most important tools which detect the human antibodies generated as a response to hepatitis C virus. Anti HCV antibody is typically identified by using Enzyme Linked Immuno Sorbent Assay (ELISA) and Chemiluminescent Micro-Particle Immunoassay (CMIA) [4]. The overall sensitivity of Rapid Diagnostic Test (RDT) Kit ranges from 86.3% to 99.4% [5].

They can also be identified by quantifying HCV RNA. Both the assays are done in order to minimize the false positive and false negative results. HCV RNA detection test by PCR is accepted globally as a gold standard procedure for the diagnosis of HCV infection.

Recently, detecting HCV core antigen has been an alternative for HCV RNA quantification as it rises early in the infection and correlates with RNA levels.

DBS (Dried Blood Spots) have been recently evaluated as an alternative for detecting HCV genotyping and RNA and it has been recommended in the recent WHO guidelines [6]. There are not many studies that researched DBS as a sample for the detection of HCV RNA in our country. Also, there is an influence of temperature of the Indian subcontinent on such samples.

The present study was conducted in a tertiary Care Hospital in Tirupati to detect the seroprevalence of hepatitis C virus using a RDT Kit and ELISA method.

MATERIALS AND METHODS

It was a cross-sectional study conducted in the Department of Microbiology, SV Medical College, Tirupati, Andhra Pradesh. A total of 360 samples were collected from patients attending outpatient departments of SVRRGGH over a period of 12 mo from April 2022 to March 2023.

About 2-3 ml of whole blood was collected through venipuncture. Serum was separated by centrifugation and tested for HCV antibody using a commercially available ELISA kit and Rapid Diagnostic Kit according to the instructions provided in the manufacturer's manual.

RESULTS

The present study was conducted in the Department of Microbiology, Sri Venkateswara Medical College, Tirupati. Among the total 360 blood samples collected, the study results were as follows:

DISCUSSION

This study was done to compare the seroprevalence of HCV by RDT and ELISA methods. A total of 360 samples were collected from different outpatient departments of SVRRGGH, Tirupati and tested by ELISA as well as RDT methods. The results of the present study were compared with other similar studies.

Table 1: HCV Seropositivity by RDT and ELISA

No. of samples tested	No. positive by RDT	No. positive by ELISA
360	20 (5.5%)	28 (5.8%)

Among the 360 samples tested, only 20 were positive by RDT, whereas 28 were positive by ELISA.

Table 2: Age distribution of results by RDT and ELISA

Age distribution	RDT		ELISA	
	Negative	Positive	Negative	Positive
21-30	97	1	94	4
31-40	86	4	85	5
41-50	66	3	64	5
51-60	49	6	48	7
61-70	33	5	33	5
>70	9	1	8	2
Total	340	20	332	28

Majority of the samples collected were in the age group of 21-30 y followed by 31-40, 41-50, 51-60 and 61-70y. Positive cases were almost equally distributed in all age groups.

Table 3: Sex distribution of results by RDT and ELISA

Sex	Total	RDT		ELISA	
		Negative	Positive	Negative	Positive
Male	221	208	13	203	18
Female	139	132	7	129	10
Total	360	340	20	332	28

Among 360 samples collected 221 were males and 139 were females. Out of 20 positives by Rapid Diagnostic Test 13 were males and 7 were females. Out of 28 positives by ELISA 18 were males and 10 were females.

Table 4: Comparison of gender distribution of samples

S. No.	Study	Males (%)	Females (%)
1.	Manjunath P. Salmani <i>et al.</i> [7]	53.83%	46.17%
2.	Manoj Kumar <i>et al.</i> [8]	56.2%	43.8%
3.	Mahgoub A <i>et al.</i> [9]	60.05%	39.95%
4.	Mudasir Khan <i>et al.</i> [10]	58.83%	41.17%
5.	Present Study	61.39%	38.61%

In the present study, male predominance is observed i.e. 61.39% of males and 38.61% of females. The other studies are also showing male predominance similar to the present study.

Table 5: Comparison of age distribution of samples

S. No.	Study	Predominant age group (Years)	Percentage (%)
1.	Patil Satish R <i>et al.</i> [11]	20-40	58.75%
2.	Manoj Kumar <i>et al.</i> [8]	20-39	47%
3.	Rajani and Jais [12]	21-40	32.8%
4.	Singh R Metal. [13]	21-40	38.01%
5.	Present Study	18-40	52.22%

In all the above studies, including present study, the predominant age group is same i.e. around 20-40 y.

Table 6: Comparison of HCV Seroprevalence by RDT

S. No.	Study	Seroprevalence by RDT
1.	Arora SK <i>et al.</i> [14]	1.67%
2.	Singh RM <i>et al.</i> [13]	13.92%
3.	Barik G <i>et al.</i> [15]	30.1%
4.	El-Sokkary Rhetal [16]	37.7%
5.	Present study	5.55%

The seroprevalence of HCV by RDT is 5.55% in present study. In a study by Arora SK *et al.*, the seroprevalence of HCV by RDT is 1.67% lower than present study. In other studies by Singh RM *et al.*, Barik G *et al.*, and El-Sokkary Rh *et al.*, the seroprevalence of HCV by RDT is 13.92%, 30.1% and 37.7%, respectively, which is higher than present study.

Table 7: Comparison of HCV seroprevalence by ELISA

S. No.	Study	Seroprevalence by ELISA
1.	Arora SK <i>et al.</i> [14]	2.19%
2.	Singh RM <i>et al.</i> [13]	12.69%
3.	Barik G <i>et al.</i> [15]	32.04%
4.	El-Sokkary Rh <i>et al.</i> [16]	40.6%
5.	Present study	7.77%

The Seroprevalence of HCV by ELISA in the studies by Arora SK *et al.*, Singh RM *et al.*, closely resembling the present study, whereas the studies by Barik G *et al.*, El-Sokkary Rh *et al.*, are showing higher prevalence than the present study.

Table 8: Comparison of performance indicators

Performance indicators	RDT				ELISA			
	Sn(%)	Sp(%)	PPV(%)	NPV(%)	Sn(%)	Sp(%)	PPV(%)	NPV(%)
Singh RM <i>et al.</i> [13]	97.55	96.71	79.03	99.68	99.46	98.34	88.38	99.93
Present study	71.43	100	100	96.92	100	100	100	100

In a study by Singh RM *et al.*, RDT and ELISA were compared against PCR as gold standard, where the sensitivity and specificity of RDT were less when compared to ELISA. In Present study, as PCR was not done, the performance of RDT was compared with ELISA as standard and it was found that the sensitivity and specificity of RDT was less than ELISA.

CONCLUSION

The present study highlights current scenario of HCV infection in our hospital. Out of 360 samples, ELISA method detected 28 positives, whereas rapid test could detect only 20 positives. RDT though it showed 100% specificity when compared with ELISA, the sensitivity was only 71.43%. It missed 8 positive cases. Hence we cannot rely on rapid tests. But as they are simple to perform, rapid and cheap, their use can be restricted to emergency situations. But the result should be confirmed by ELISA or if available by PCR which is the gold standard for HCV diagnosis.

The general population should be educated about the virus and its modes of transmission and precaution should be taken. Prompt diagnosis using appropriate tools may prove useful in effective prevention and treatment in developing nations.

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AUTHORS CONTRIBUTIONS

All authors have contributed equally

CONFLICT OF INTERESTS

Declared none

REFERENCES

- Aceijas C, Rhodes T. Global estimates of prevalence of HCV infection among injecting drug users. *Int J Drug Policy*. 2007;18(5):352-8. doi: [10.1016/j.drugpo.2007.04.004](https://doi.org/10.1016/j.drugpo.2007.04.004), PMID 17854722.
- Shekhar S. Hepatitis C virus infection in the Indian sub-continent. In: *Hepatitis C in developing countries*. Amsterdam: Elsevier; 2018. p. 83-95. doi: [10.1016/B978-0-12-803233-6.00008-4](https://doi.org/10.1016/B978-0-12-803233-6.00008-4).
- Papatheodoridis GV, Tsochatzis E, Hardtke S, Wedemeyer H. Barriers to care and treatment for patients with chronic viral hepatitis in Europe: a systematic review. *Liver Int*. 2014;34(10):1452-63. doi: [10.1111/liv.12565](https://doi.org/10.1111/liv.12565), PMID 24750532.
- Hedskog C, Parhy B, Chang S, Zeuzem S, Moreno C, Shafran SD. Identification of 19 novel hepatitis C virus subtypes further expanding HCV classification. *Open Forum Infect Dis*. 2019 Feb 22;6(3):ofz076. doi: [10.1093/ofid/ofz076](https://doi.org/10.1093/ofid/ofz076), PMID 30949527.
- Kim MH, Kang SY, Lee WI. Evaluation of a new rapid test kit to detect hepatitis C virus infection. *J Virol Methods*. 2013;193(2):379-82. doi: [10.1016/j.jviromet.2013.07.005](https://doi.org/10.1016/j.jviromet.2013.07.005), PMID 23871756.
- Cloherly GA, Young TP, Lucic D, Steinhart C, Letendre S. Dried blood spots (DBS) for hepatitis C (HCV) molecular diagnostic testing. *J Hepat Res*. 2014;1(3):1017.
- Salmanni MP, Peerapur BV. Seroprevalence of hepatitis C among hospital-based general population in Bijapur Karnataka India. *Int J Biopharm Res*. 2014;3(3):204-6.
- Kumar M, Verma RK, Singh M, Nirjhar S, Chaudhary R. Seroprevalence of HCV infection at a Tertiary Care Hospital Western Uttar Pradesh, India. *Int J Res Rev*. 2019;6(4):1-5.
- Mahgoub A, El Imad T, Al Moussawi H, Daneshvar D, Haddad FG, Saabiye J. Hepatitis C infection patterns at a Tertiary Care Center in New York: a cross-sectional study. *Cureus*. 2018;10(2):e2225. doi: [10.7759/cureus.2225](https://doi.org/10.7759/cureus.2225), PMID 29713570.
- Khan M, Khan S, Haider S, Jalil F, Jamal M, Ahmad A. Prevalence and risk factors of hepatitis C virus (HCV) in Tehsil Batkhela District Malakand, KPK, Pakistan. *Int J Cont Res Rev*. 2018;9(6):20251-6. doi: [10.15520/ijcrr/2018/9/06/525](https://doi.org/10.15520/ijcrr/2018/9/06/525).
- Patil SR, Ghorpade MV. Seroprevalence of antibodies to the hepatitis C virus in a hospital-based population: a study from western Maharashtra, India. *Int J Collab Res Intern Med Public Health*. 2014;6(4):102-8.
- Rajani M, Jais M. Age-wise seroprevalence of hepatitis C virus infection in clinically suspected infectious hepatitis patients attending a Tertiary Care Hospital in Delhi. *Int J Med Public Health*. 2014;4(1):78-81. doi: [10.4103/2230-8598.127163](https://doi.org/10.4103/2230-8598.127163).
- Singh RM, Huidrom S, Dutta S, Sadhukhan PC, Singh KL. Comparative evaluation of three diagnostic tools for the detection of hepatitis C virus among high-risk individuals in a Tertiary Care Centre of Northeast India. *J Clin Diagn Res*. 2022;16(7):DC13-DC17. doi: [10.7860/JCDR/2022/56521.16610](https://doi.org/10.7860/JCDR/2022/56521.16610).
- Arora SK, Chhabra M, Anuradha A, Achra A, Duggal N. Comparison of fourth generation elisa and rapid diagnostic test for diagnosis of hepatitis c virus(HCV) infection in a Tertiary Care Hospital. *PIJR*. 2021;15-7. doi: [10.36106/2000717](https://doi.org/10.36106/2000717).
- Barik G, Acharya S, Sen Gupta Manideepa, Sadhukhan PC, Aich I, Chakraborty A. Comparison of HCV TRI-DOT with RNA PCR for confirmation of ELISA positive results and evaluation of a combination of ELISA and HCV TRI-DOT assay for diagnosis of HCV infection. *IOSR J Den Med Sci*. 2019;18(6):85-8.
- El Sokkary RH, Tash RM, Meawed TE, El Seifi OS, Mortada EM. Detection of hepatitis C virus (HCV) among health care providers in an Egyptian university hospital: different diagnostic modalities. *Infect Drug Resist*. 2017 Oct 17;10:357-64. doi: [10.2147/IDR.S145844](https://doi.org/10.2147/IDR.S145844), PMID 29270026.