



## ORIGINAL RESEARCH PAPER

## Microbiology

### Prevalence of Hepatitis C in chronic liver disease patients at a Tertiary Health Care Centre in Western Maharashtra

**KEY WORDS:** Chronic liver disease, Hepatocellular carcinoma, Immunochromatographic test

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#### ABSTRACT

Hepatitis C is an emerging infection in India. HCV causes life-long chronic infections of cirrhosis, chronic liver disease and hepatocellular carcinoma. Infection is currently defined by the presence of specific anti-HCV antibodies, with or without the presence of detectable viral RNA. Among the diagnostic modalities, tests that detect the anti-HCV antibodies are widely used in developing countries. Rapid tests have certain advantages over the others thus compelling their widespread use in resource limited settings.

The study was aimed to determine the seroprevalence of HCV among the chronic Liver disease patients at a tertiary health care centre in Solapur, Maharashtra.

**Results:** The anti HCV antibody seroprevalence was 227 (2.10%) by rapid anti-HCV antibody immunochromatographic test. The age group of 41-60 years was most commonly affected and males outnumbered the females with a male: female ratio of 1.76.

**Conclusion:** Rapid anti HCV antibody detection tests provides sensitive and specific results for high risk groups.

#### Introduction

Hepatitis, the inflammation of the liver tissue, is caused by viruses like Hepatitis A virus, Hepatitis E virus, Hepatitis B virus, Hepatitis D virus and Hepatitis C virus. Amongst these, Hepatitis C is an important health problem in many countries including India. Since its detection in the year 1989 using molecular biology techniques on serum from experimentally infected animals<sup>(1)</sup> its prevalence is on the verge of rise. According to a NCDC report the estimated burden of chronic hepatitis C infection in South Asia is 50 million and the population prevalence of HCV infection in India is 1 percent.<sup>(2)</sup> Over one lakh people get infected with HCV every year and about 12.2 million HCV infected are carriers in our country.<sup>(3)</sup> HCV is a RNA virus of the flaviviridae family and genus Hepaciviruses. It is heterogenous in nature and exists in 6 genotypes and many serotypes. Genotype 1 is most prevalent worldwide whereas both genotype 1 and 3 are predominant in India.<sup>(2,4)</sup> Although 15%- 45% of infected persons spontaneously clear the infection within 6 months without need of treatment, the remaining 55%-85% develop chronic infection with cirrhosis and hepatocellular carcinoma accounting for 27% and 25 % respectively.<sup>(5,6)</sup> It is one of the leading causes of liver transplantation and the most common chronic blood borne infection in many developed countries.<sup>(1)</sup> This makes the screening of HCV infection an essential in developed as well developing countries like India.<sup>(7)</sup>

Among the different modes of transmission of Hepatitis C infection are the blood transfusions, IV drug use, unsafe therapeutic injections, health care related procedures and rarely sexual transmission.<sup>(1,3)</sup> HCV Infection is currently defined by the presence of specific anti-HCV antibodies, with or without the presence of detectable viral RNA.<sup>(3)</sup> The detection of viral antigens by direct assay helps to diagnose active infection and also quantifies HCV- RNA. Indirect test like Enzyme immunoassay (EIA), Chemiluminiscent immunoassay (CLIA) are used to detect antibodies.<sup>(8)</sup> The testing for anti-HCV antibodies by EIA followed by nucleic acid testing of HCV RNA is the standard protocol in developed countries. But in resource limited countries like India the testing by such sophisticated modalities is difficult as they are expensive, requires continuous electric supply and trained personnel. The level of the HCV proteins in the serum is low well

than the detection limits. Thus the tools are mainly focused towards the detection of the host generated antibodies to HCV proteins.<sup>(5)</sup>

Since its detection in 1989, the diagnostic tools for Hepatitis C have undergone evolution. Recently, several commercially prepared rapid tests or point of care tests have been used and evaluated for detection of anti-HCV antibodies. These user-friendly assays have quick turnaround time, do not require sophisticated equipments, and allow testing of serum, plasma or whole blood at or near the patient and have high clinical sensitivity. Thus, such rapid tests are widely used in various set up of developing countries.<sup>(7)</sup>

The prevalence of HCV varies across different regions and populations. Since meager data is available on Hepatitis C from this region of Maharashtra, this study was carried out in a view to contribute to the existing prevalence of chronic hepatitis C in our country.

#### Material and Methods:

The study is a retrospective analysis of the data available at the virology laboratory in department of Microbiology at Dr.V.M. G.M.C, Solapur, Maharashtra. Serum or plasma from patients presenting with symptoms of chronic liver disease were processed. About 2-3ml of whole blood was collected in clean test tubes from each patient and allowed to clot and retract. The serum thus separated was used for analysis. The duration of the study was around 2 years from January 2015 to January 2017. The demographic data were reviewed from the available records. A rapid immunochromatographic test (Aspen HCV kit) was done on the specimen (serum/plasma) for qualitative detection of the anti-HCV antibody. This rapid test utilizes a combination of protein A coated particles and recombinant HCV proteins to qualitatively detect the presence of anti-HCV antibody in serum or plasma. The recombinant proteins are encoded by the genes for both structural (nucleocapsid) and non-structural proteins.

#### Results:

A total 10,780 patients were evaluated for anti- HCV antibody of which 227 (2.10%) were positive by the rapid Hepatitis C virus

immunochromatographic test. The age group of 41-60 years was most commonly affected having 54.62% cases followed by 21-40 years (22.46%), >60 years (14.09%), and 0-20 years (8.81%). Among the positive cases, males (63.88%) outnumbered the females (36.12%) with a male: female ratio of 1.76. The age and sex distribution is shown in table 1.

**Table 1: Showing age and sex distribution of HCV positive patients**

Age group	Male	Female	Total
0-20 years	14 (70%)	6 (30%)	20 (8.81%)
21-40 years	31 (60%)	20 (40%)	51 (22.46%)
41-60 years	78 (62.90%)	46 (37.10%)	124 (54.62%)
>60 years	22 (68.75%)	10 (31.25%)	32 (14.09%)
Total	145 (63.88%)	82 (36.12%)	227

## Discussion:

The prevalence of HCV differs widely among the developed and developing countries. A study done by Petruziello et al<sup>(9)</sup> in Italy estimated the global prevalence of HCV by carrying out a systematic analysis of the published data between 2000 and 2015 that covered nearly 90% of global population as per the definition of Global burden of Disease project. This study states the global prevalence of 2.5% ranging from 2.9% in Africa and 1.3% in America. The study also highlights that the global prevalence has decreased from 2.8% (during 1990 to 2005 period) to 2.5% with a relevant decrease in the prevalence of high income zones especially western Europe. This could be attributed to the mandatory testing of the blood donors for the HCV as well the advent of the directly acting antiviral drugs (DAAs) for the treatment.<sup>(10)</sup> The prevalence of anti-HCV in the general population of the south Asia region which includes India along with Afghanistan, Bangladesh, and Pakistan, is 2.5%, ranging between 6.7% in Pakistan and 0.8% in India.<sup>(9)</sup>

The seroprevalence of anti-HCV antibodies at our tertiary health care centre is 2.10%. On evaluating the studies carried out near our region, the seroprevalence of HCV antibodies in a study done in Karad revealed a prevalence of 0.38%. Population based studies in rural Maharashtra stated the prevalence to be very negligible as low as 0.9%.<sup>(11,12)</sup> A study in AFMC Pune had zero prevalence of hepatitis C among the soldiers.<sup>(13)</sup> Thus on comparing with the available data from nearby regions, the prevalence of Hepatitis C is still high in our region.

The data in our study showed wide variation on comparing with the data of other regions of India. The anti HCV seroprevalence among the acute hepatitis and chronic liver disease patients in a study of Central India was 4.85% and 25.4% respectively.<sup>(14)</sup> A higher seroprevalence of 13% was recorded in a study in Amritsar.<sup>(15)</sup> A study carried in AIIMS Delhi recorded a prevalence of anti HCV antibodies as 13.83 in Chronic liver disease, 9% in Acute hepatitis and 1.85% among blood donors.<sup>(16)</sup> In the studies from south India, higher prevalence of 26%<sup>(17)</sup> and 43%<sup>(18)</sup> of anti HCV antibodies has been reported, whereas a prevalence as low as 0.68%<sup>(19)</sup> was recorded in a study of Tamilnadu in the year 2014. Such vast variation in the prevalence of HCV in different regions of our country could be explained by the different cultural factors and social habits that influence the transmission of HCV.

Parenteral transmission through blood transfusion remains the major and a significant mode of transmission of Hepatitis C as large amount of infective virions are transmitted to the susceptible recipient. To reduce the mortality and morbidity thus caused by blood transfusion, the screening of Hepatitis C was made mandatory in India from the year 2002.<sup>(20)</sup> Since then the prevalence of Hepatitis C is on a decline in many parts of India but the burden of this dreadful disease still prevails. A study illustrates that the percentage of seroprevalence of anti HCV antibodies among voluntary blood donors was more than one before the year 2000 and it has reduced to less than one thereafter. Not much data is available from the area near our region. So for comparing we used the data from the Blood bank at our tertiary care centre. The

seroprevalence of Hepatitis C among the voluntary blood donors tested at our tertiary care hospital during the same study period was 0.39% (32/8108). This is comparable to the other studies.<sup>(21,22)</sup> A prevalence as low as 0.14 % and as high as 0.74% has been reported from studies in Maharashtra.<sup>(23)</sup> A lowest prevalence of 0.13%<sup>(21)</sup> is reported from Vellore whereas a high prevalence of 0.44% from Chandigarh.<sup>(21,24)</sup>

The male gender and adult age group most commonly affected in our study could be related with the fact that they are exposed more to and involved in various risk behaviors. Our findings are in concordance with the other studies.<sup>(19,25,26)</sup> The low prevalence in the older age group could be attributed to the seroconversion and loss of carrier state. A study in Rwanda has correlated the lower incidence in females to the occurrence of certain genetic factors that cause spontaneous clearance of acute infection.<sup>(27)</sup>

In our study, due to non availability of sophisticated instruments like EIA and CLIA, the detection of anti HCV antibody was done by using rapid Immunochromatographic assay. Many studies have been conducted to evaluate screening tests for detection of HCV antibodies.<sup>(28,29,30)</sup> A study done by Smith et al<sup>(31)</sup> evaluated three rapid screening tests and concluded that the sensitivity of these tests ranges from 86% to 99% with higher specificity of 99.5%. The rapid test used in our study has a reported sensitivity of 99.6% and specificity of 99.8% compared with leading commercial HCV EIA test. Thus, rapid anti HCV tests provide sensitive and specific results for high risk groups with less probability of false positive and false negative results. However, their use in HIV/AIDS patient to evaluate HIV/HCV co- infection is questionable due to false negative results owing to impaired HCV antibody response in such patients. Also, to avoid the problem of false positive results, the rapid tests must be supplemented with ELISA or PCR to determine the exact seroprevalence.

## Conclusion

The prevalence of this infection is showing a downward trend, but the fact that it is not completely eliminated, should not be neglected and thus the screening of this infection in the blood banks and in risk populations should be continued to prevent transmission and ensure safety of mankind. Though the rapid anti-HCV detection tests show low proportion of false negative and false positive results have sensitivity and specificity closely comparable with the efficient screening tests like ELISA, their beneficial characteristics allow for the easy diagnosis and treatment of cases than the laboratory based tests and also are a great choice in resource limited settings. However, the results of these screening tests must be evaluated by confirmatory methods.

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