



**Seroprevalence of HCV infection among patients at a tertiary care center in Eastern India- Urgent need to implement strategies to interrupt HCV transmission and develop HCV vaccine for the susceptible population.**

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**Abstract**

Since health-care workers (HCW) are exposed to occupational blood contact and subsequently are at risk to infection with blood borne pathogens from an infected patient, therefore, in a healthcare setup , a preliminary screening is done before performing any minor or major invasive procedure, to rule out the presence of HBV, HIV and HCV infection in patients. To protect a HCW in cases of accidental exposure to HIV positive sera, antiretroviral drugs given as post exposure prophylaxis (PEP) is available for HBV, a safe and effective vaccine is available but for HCV, no such vaccine is available till date. Since the transmission of HCV to HCW also depends on the seroprevalence of HCV infection in the local population, we decided to do a study to find the seroprevalence of HCV infection in patients attending various OPD and IPD of a tertiary care center of Eastern Bihar. A retrospective study from June 2017 to June 2018 was carried out in the virology lab of the tertiary care center of Eastern India in which records of all patients whose sera was screened for detection of Anti HCV antibody by Benesphera Microwell ELISA (IHF) were obtained and analyzed . A total of 37845 samples were screened during the above mentioned period out of which 142 (0.37% ) were found to be positive fo HCV

antibodies . Out of 142 seropositive patients, 65 ( 45.77 %) were male and 77 ( 54.22%) were females. The seroprevalence of HCV infection in this region of eastern India indicates an urgent need to implement strategies to interrupt HCV transmission and develop HCV vaccine for the susceptible population

**Keywords:** Seroprevalence , Hepatitis C Virus infection ( HCV ), HCV Vaccine, molecular methods, screening HCV

**Introduction**

Health-care workers are continuously at risk for occupational exposure and subsequently at risk to infection with bloodborne pathogens from an infected patient . Therefore, in a healthcare setup , a preliminary screening is done, before performing any minor or major invasive procedure, to rule out the presence of HBV, HIV and HCV infection in patients. For accidental exposure to HIV positive sera, ART is available and for HBV, a safe and effective vaccine is available but for HCV, no such vaccine is available till date.

Hepatitis C virus (HCV) infection of the liver can cause acute and chronic hepatitis. This is a blood borne viral infection that is transmitted most commonly by unsafe injection practices, inadequate sterilisation of medical equipments between procedures and the transfusion of

unscreened blood and blood products . It can also be transmitted less commonly by sexual route and also from the mother to her child (1 ). The global prevalence of people living with HCV is estimated to be between 130 and 150 million. Most of the infected people develop HCV related cirrhosis or liver cancer (2). HCV infection differs from other chronic viral infections, especially HIV infection, as it can be cured by treatment. Several treatment options are available and with the introduction of newer drugs, the cure rates have steadily improved .

There are six distinct HCV genotypes and the prevalence of HCV genotype infection in adults varies according to the geographical location. HCV genotype 1 ( subtypes 1a, and 1b) and genotype 2 ( subtypes 2a, 2b, and 2c ) are the most common variants found in the Western countries. HCV genotype 3 is found in South and East Asia (subtype 3a being the common variant among intravenous drug users of Europe). HCV genotype 4 is found in North Africa and the Middle East , genotype 5 is found in South Africa and genotype 6 is found in Asia.(3)

Generally , determination of HCV genotype and genotype 1 subtype (1a or 1b) is desirable prior to initiating treatment to choose appropriate therapy and its duration. But, now with the availability of pan-genotypic HCV drug regimens ( SOF – sofosbuvir, VEL- velpatasvir ; GLE- glecaprevir , PIB- pibrentasvir ; SOF – sofosbuvir, VEL- velpatasvir , VOX: voxilaprevir) treatment of infected individuals is possible without the need to identify the HCV genotype and subtype. This is especially useful in resource limited regions like India where virological tests are either not available or they are much more costly than the available antiviral treatment.

These pan-genotypic HCV drug regimens are IFN-free and ribavirin free. These can be offered to treatment-naive patients ( patients who have never been treated for their HCV infection) and treatment experienced patients ( patients who have previously been treated with either

pegylated IFN-a and ribavirin, or, pegylated IFN-a, ribavirin and sofosbuvir; or sofosbuvir and ribavirin), without cirrhosis or with compensated cirrhosis.( 4)

Treatment with antivirals can cure 90% of persons with HCV infection, but the access to diagnosis and treatment is limited especially in a resource limited country like India. Because of this reason, many people, despite being infected, are unaware of their infectious status . Moreover , assays meant to detect anti HCV antibodies may miss detecting infections in the acute stage and thus these infected individuals don't receive appropriate care ,and act as a potential source of infection to others. Transmission of HCV is a serious threat in developing countries , like India , where virological tests are either not available or they are much more costly.

With greater awareness of disease , its mode of transmission, access to sensitive diagnostic facilities and improved treatment regimens at affordable cost , the disease burden can be decreased , but for the total elimination of HCV infection , we need an effective prophylactic vaccine . HCV vaccine will help eliminate HCV infection by stopping HCV transmission to uninfected individuals and also cured individuals at risk for HCV re-exposure and persistence of infection (6).

Till date we do not have a HCV vaccine because of various obstacles including diversity of the virus, high rates of mutation leading to immune evasion ability of the virus in infected individuals and development of distinct but closely related HCV variants known as “quasispecies,” that can be present in a single individual (6,7,8). Despite these challenges, several investigators have claimed induction of immunity by candidate HCV vaccines but a properly designed clinical trials to confirm the definitive endpoints of safety and efficacy is still awaited (9). Since, there is no vaccine for hepatitis C till date, its control is difficult (1 ).

In May 2016 the World Health Assembly adopted the first global strategy for reducing the burden of HCV infection. The goal was to eliminate HCV infection as a public health concern by reducing 90% incident viral hepatitis infections and reducing 65% deaths due to viral hepatitis by 2030. Any country with the help of WHO can implement these strategies to eliminate HCV infection but for that purpose it has to have a detailed epidemiological seroprevalence data of HCV infection. (5)

Since the transmission of HCV depends on the seroprevalence of HCV infection in the local population, and such data is lacking in our state, we decided to do a study to find the seroprevalence of HCV infection in patients attending various OPD and IPD of a tertiary care center of Eastern Bihar.

## Methods

### Study area

The data was collected from the virology lab of a tertiary care center in Eastern India. It serves the need of people coming from local community as well as different regions of Bihar and other neighboring states.

### Study design

It was a retrospective, cross sectional observational study of records of all patients attending various OPD and IPD, whose sera was screened for detection of anti HCV antibody by Benesphera Microwell ELISA (IHF) from June 2017 to June 2018 at the virology lab of a tertiary care center in Eastern India.

### Study population

All patients from the local community, different regions of Bihar and other neighbouring states, attending various OPD and IPD of the tertiary care center of Eastern India constituted the study population.

### Study Method

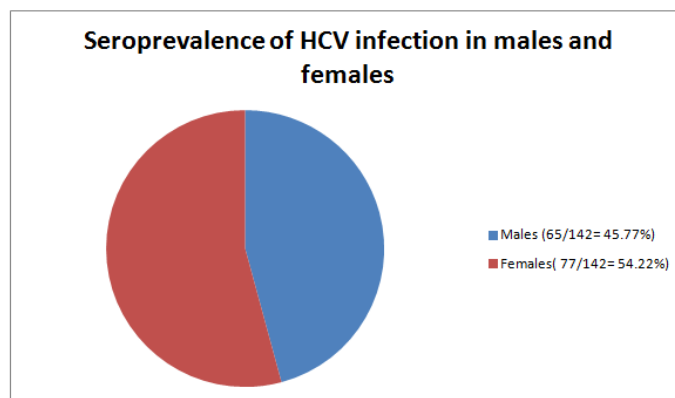
Records of blood samples screened for HCV infection in the IGIMS virology lab from June 2017 to June 2018 were obtained and analyzed. Benesphera Microwell

ELISA (IHF) was used for the screening of HCV antibodies, based on the ELISA principle for qualitative detection of antibodies specific to HCV in human plasma/serum, having the sensitivity of 99% and specificity 100%. All tests were done according to manufacturer instructions.

### Results:

A total of 37845 samples were screened during the above mentioned period out of which 142 (0.37%) were found to be positive for HCV antibodies. Out of 142 seropositive patients, 65 (45.77%) were male and 77 (54.22%) were females.

Seroprevalence of HCV infection during preoperative routine screening	
Seropositive sera	142 (0.37%)
Seronegative sera	37703
Total	37845



### Discussion

Keeping the safety concerns of HCW against possible infections in huge number of patients undergoing various minor and major invasive procedures in a healthcare setup, a preliminary screening is done before any such invasive procedure to rule out the presence of HBV, HIV and HCV infection. Since there is no vaccine for HCV infection and the transmission of HCV to HCW also depends on the seroprevalence of HCV infection in the local population, a retrospective, cross sectional observational study was

done from June 2017 to June 2018 at the virology lab of a tertiary care center in Eastern India. Records of all patients attending various OPD and IPD, whose sera was screened for detection of anti HCV antibody by Benesphera Microwell ELISA (IHF) was obtained and analyzed.

#### Strength of the study

To the best of our knowledge, very few studies have been done to evaluate the seroprevalence of HCV infections in this part of Bihar. In this context, the current study becomes highly relevant as it gives a platform for future investigation to ascertain seroprevalence of HCV infection at national level. It also provides a baseline information for considering introduction of molecular methods for determining the viral load of patients with seropositive sera and treat them accordingly in the designated centers.

#### Limitation of the study

The study was based on records of virology lab of IGIMS, Patna from June 2017 to June 2018. Confirmatory tests of seronegative sera and viral load determination and genotyping of HCV in seropositive cases was not done. The study population was only the patients attending various OPD and IPD, whose sera was screened before performing any invasive procedure for detection of anti HCV antibody. Thus, this study does not give the actual prevalence of the HCV infection in the population and regional variation inside the state could not be assessed.

In this study, it was found that, a total of 37845 samples were screened for HCV infection during the above mentioned period, out of which, 142 (0.37%) were found to be positive for HCV antibodies. The prevalence of HCV infection in this part of India is higher than the study done in Vellore, India, but lower than the studies done in other parts of the world. V Gowri, in a study in a tertiary care center in Vellore, have reported the

prevalence of 0.22% HCV infection which is lower than the prevalence found in our study. Jean Joel Bigna in their systematic review and meta-analysis of 31 studies including 36 407 individuals of Cameroon have reported an overall pooled prevalence of 6.5% HCV infection which is quite higher than our data. Though the prevalence rate of HCV is found to be low in our study, but, still, it is a warning sign as this data is representative of HCV infection only in unsuspected population who were detected to be seropositive in screening test before invasive procedure. Although population-based studies representative of an entire community are more useful, but most of the other HCV seroprevalence studies are typically cross-sectional study done in selected groups of populations—eg, blood donors or patients with chronic liver disease, and thus are not true representative of the HCV seroprevalence in their residential community or region. It indicates that the prevalence might be higher if studies are done on suspected cases of liver disease.

In our study, out of 142 seropositive patients, 65 (45.77%) were male and 77 (54.22%) were females indicating a higher seroprevalence of HCV infection in females in comparison to males.

#### Conclusion and Recommendations

The seroprevalence of HCV infection in this region of eastern India indicates the need for comprehensive and effective strategies to interrupt HCV transmission from infected population. Specific attention is needed to address the problem of transmission from patients having acute HCV infection with seronegative sera. Sensitive and affordable molecular methods need to be introduced in health care setups for the screening of HCV infections.

#### Implication of the study

Since data on seroprevalence of HCV infection is lacking in our state, this study could be a bench mark for the state. Similar studies can be undertaken at national level to know the actual burden of disease at country level so that

specific and effective strategies can be adopted to decrease and finally eliminate HCV infection.

The policy makers can formulate plans to introduce testing of all sera by sensitive and affordable molecular methods for confirmation of screening test results and also to determine viral load in patients with seropositive sera. Patients with true seropositive sera may be advised to seek further treatment at designated centers. This study can be used as a guiding tool for doctors and paramedics working in various health care set up of the state for prevention of transmission HCV infection to health care professionals in particular.

#### **Future Research**

More studies need to be undertaken at national level to obtain better knowledge of hepatitis C virus (HCV) seroprevalence so that government can implement specific strategies to eliminate the HCV infection and related burden in general population throughout the country.

#### **Author's contribution**

Dr Nidhi Prasad was the principal investigator and main author of this article.. Dr Neelima gave significant inputs in the development of this article by analyzing the data of virology lab and in completion of this manuscript.

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#### **Conflict of interests**

The authors declare that they have no conflict of interests.

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