

Seroprevalence of Hepatitis C Virus Infection among Blood Donors at Madhya Pradesh, India: A Retrospective Study-a Central State of India

Abstract:

Background:

Viral hepatitis is a global health problem with 170 million Hepatitis C Virus (HCV) carriers worldwide, and 12-13 million HCV carriers in India.

Unscreened blood and components play a significant role in transmission of HCV apart from reuse of injection needles, unsterilized surgical equipments and vertical transmission from mother to child. Unsafe blood transfusion not only poses a risk to patients, causing significant morbidity and mortality, but also adds to the economical burden on healthcare system.

Aims and Objectives:

Aim of this study is to estimate the sero-prevalence of HCV infection among the voluntary and relative donors over a period of 7 years at blood banks of Madhya Pradesh with collaboration of Madhya Pradesh State AIDS control Society (MPSACS) Bhopal, India from 2011 to 2017.

Materials and Methods:

This is a retrospective study of blood donation at blood banks, of Madhya Pradesh, India. Blood units were screened for TTIs from January 2011 To December 2017. Data was collected and compared statistically by frequency distribution and percentage proportion. Chi Square (χ^2) test was used to determine the significance of difference statistically.

Comment [OP1]: Type properly

Results: Out of the total 18,76,219 donors tested for TTIs over 7 years for HIV infection, 1980 (0.11%) were positive to anti-found to be HCV-reactive ($p = .000001$).

Conclusion: The prevalence of HCV infection was 0.11% among blood donors of Madhya Pradesh, India a Central State of India and showed variable incidence from 2011 to 2017.

Comment [OP2]: Check for typographical and grammatical errors.
2. Consider looking at probable factors associated with the infection.
3. Methodology not clear yet. Results very scanty.

Key Words: *Hepatitis C virus, Blood Donors, Transfusion Transmitted Infection; Retrospective study; India*

INTRODUCTION

Increasing incidence of viral hepatitis is posing a threat to healthcare in India, almost comparable to the three major communicable diseases i.e. HIV/AIDS, malaria and tuberculosis.¹ Out of the five hepatitis causing viruses, Hepatitis B virus (HBV) and Hepatitis C virus (HCV) have parenteral transmission and are known to cause chronic hepatitis, cirrhosis of liver and hepatocellular carcinoma (HCC). Hepatitis A virus (HAV) and Hepatitis E virus (HEV) are enterically transmitted and are responsible for both sporadic infections and epidemics of acute viral hepatitis. Around 400 million people all over the world suffer from chronic hepatitis and the Asia-Pacific region constitutes the epicenter of this epidemic.¹

The total global prevalence of HCV is estimated to be at an average of 1.6% (1.3-2.1%), corresponding to 115 (92-149) million viraemic infections [2]. In India, prevalence of HCV infection in the general population is estimated to be around 0.5%–1.5% [3]. Studies on blood donors have reported a prevalence of hepatitis C below 2% [4].

Comment [OP3]: Make sure your reference is current (2018-2019 study).

HCV is a single-stranded hepatotropic RNA virus of family Flaviviridae. HCV causes acute hepatitis which is mostly subclinical and gradually evolves into

chronic hepatitis in about 80% of those infected [5]. HCV has six major genotypes, with genotype 1 being the most prevalent genotype globally (46%), followed by genotype 3 in 22% and genotypes 2 and 4 in 13% each [6]. Overall, genotype 3 is the predominant genotype (63.85%) followed by genotype 1 (25.72%) in India [7].

Unscreened blood and components play a significant role in transmission of HCV apart from reuse of injection needles, unsterilized surgical equipments and vertical transmission from mother to child [8]. Unsafe blood transfusion not only poses a risk to patient, causing significant morbidity and mortality, but also adds to the economical burden on healthcare system. Thus, National AIDS Control organization (NACO) of India, mandates to screen every unit of blood and components for 5 transfusion transmitted infections (TTIs) i.e. HIV, HCV, HbsAg, Syphilis and Malaria [9]

The methods used to identify the presence of HCV employ the following screening targets:

1. Serological markers:
 - HCV antibody
 - HCV antigen
2. Viral nucleic acid:
 - HCV RNA.

HCV antibody and antigen: HCV antibody becomes detectable approximately 30 to 60 days after infection. Viral RNA appears followed by viral antigen between 0 and 20 days. Antibody can be detected between 10 and 40 days after antigen is first detected. The serology of HCV is still not fully understood. Serological screening has been highly effective in significantly reducing the transmission of HCV through the route of transfusion. However, HCV antigen can be detected in the

peripheral blood earlier than antibody in the course of early infection. HCV antigen assays, both antigen only and combined antigen-antibody, have been commercially available for a number of years. Hepatitis C virus RNA Viral RNA is normally detectable within a few weeks of infection and persists for 6–8 weeks prior to antibody seroconversion. The detection of HCV RNA may further reduce the risk of HCV transmission through the transfusion of infected blood donated during the window period of antigen and antibody assays. However, any benefit is dependent upon HCV incidence and the actual number of donations that may be collected in the window period [10].

Therefore WHO (World health organization) recommends to minimize the risk of HCV infection through the route of transfusion:

1. Screening should be performed using a highly sensitive and specific HCV antibody immunoassay or a combination HCV antigen-antibody immunoassay (EIA/CLIA). The assay should be capable of detecting genotypes specific to the country or region.
2. Screening using a highly sensitive and specific HCV antibody rapid assay may be performed in laboratories with small throughput, in remote areas or emergency situations [10].

Aim of this study is to estimate the sero-prevalence of HBV among the voluntary and relative donors over a period of 7 years at blood banks of Madhya Pradesh with support of Madhya Pradesh State AIDS control Society (MPSACS) Bhopal, India. The observations were also compared with the other relevant studies in India and abroad.

Comment [OP4]: Not logically organized. Remove any unnecessary statements. Make sure recent references/ studies are used. Check for typographical and grammatical errors.

MATERIALS AND METHODS

Present study was carried out at National AIDS Control Organization (NACO) supported blood bank and MPSACS (Madhya Pradesh State Aids Control Society) Bhopal, Madhya Pradesh, India. Donors were screened by trained personnel after satisfactory answering the donor's questionnaire, their physical examination and hemoglobin (Hb %) estimation. A total of 18,76,219 blood units from the selected donors were collected overall period of ten years (1st January 2011 to 31st December 2017). These were either Voluntary Donors (VD) and Replacement/relative Donors (RD). Replacement donors were those donors who donated blood for ailing patients and were family members, close relatives and friends of recipient. The voluntary donations were obtained from walk-in donors or in blood donation camps. Professional and paid donors were carefully eliminated. Written consent from the donor was taken before donation. 3 ml blood in plain vial and 2 ml blood in EDTA (ethylene diamine tetra acetic acid) vial taken from the satellite bag. All samples were screened for HCV and other transfusion transmitted diseases. Tests for HCV were performed with commercially available Enzyme immune assay kit (Merilisa HCV by Meril diagnostics) for antibodies against HCV. The HCV data of last ten years of Madhya Pradesh was collected, retrieved, tabulated, summarized and compared statistically by frequency distribution and percentage proportion. Chi Square (χ^2) test was used to determine the significance of difference statistically.

Comment [OP5]: Type properly.

Comment [OP6]: Advice to split heading to subheadings > Check for grammar and typo errors.

RESULTS

Blood from 18,76,219 apparently healthy donors aging 18 - 65 years was collected during the study period. Gender distribution, type of donation and HCV status of donors is depicted in Table 1.

Table 1

	Total Donation	HCV reactive	HCV non reactive	P value
Gender				
Male	1759893 (93.8%)	1864 (0.11%)	1758029 (99.9%)	
Female	116324 (6.2%)	116 (0.10%)	116208 (99.9%)	
Type of donation				
Voluntary	1637939 (87.3%)	1725 (0.10%)	1636214 (99.9%)	
Relative/Exchange	238278 (12.7 %)	255 (0.11%)	238023 (99.9%)	
HCV status of donors from 2011-2017				
	1871547 (100%)	1980 (0.11%)	1869567 (99.89%)	

Comment [OP7]: State the mean age of the population. Advice to describe all results here before putting and showing your tables/figures below.

Comment [OP8]: Where are your P values?

Increasing trend in blood donation was reported from the year 2011 to 2017, depicted in Figure 1.

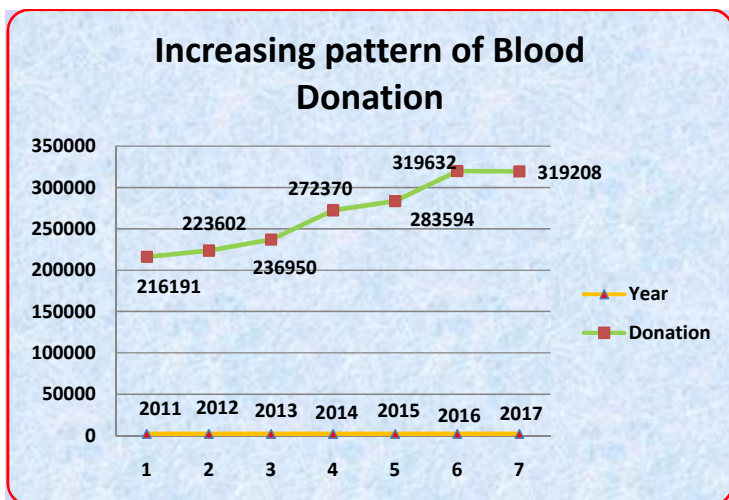


Figure No.1 : Trend of blood donation from 2011 to 2017

Comment [OP9]: Label your horizontal and vertical axis.

Table 2:- Yearly distribution of voluntary donation at

Year	Total donations	Voluntary Donation	Percentage (%)	P value
2011	216191	174033	80.5	P = 0.94
2012	223602	182906	81.8	
2013	236950	202118	85.3	
2014	272370	240230	88.2	
2015	283594	256085	90.3	
2016	319632	293102	91.7	
2017	319208	297821	93.3	
Total	1871547	1646295	87.3	

Table 3:- HCV reactivity in blood donors from 2011-2017

Year	Total donations	HCV reactive	HCV Prevalence (%)	p value
2011	216191	303	0.14	0.000001
2012	223602	294	0.13	0.000001
2013	236950	286	0.12	0.000001
2014	272370	292	0.11	0.000001
2015	283594	191	0.07	0.000001
2016	319632	272	0.09	0.000001
2017	319208	342	0.11	0.000001
Total	1871547	1980	0.105	0.000001

Geographical distribution in different areas and district was shown in Figure no. 2

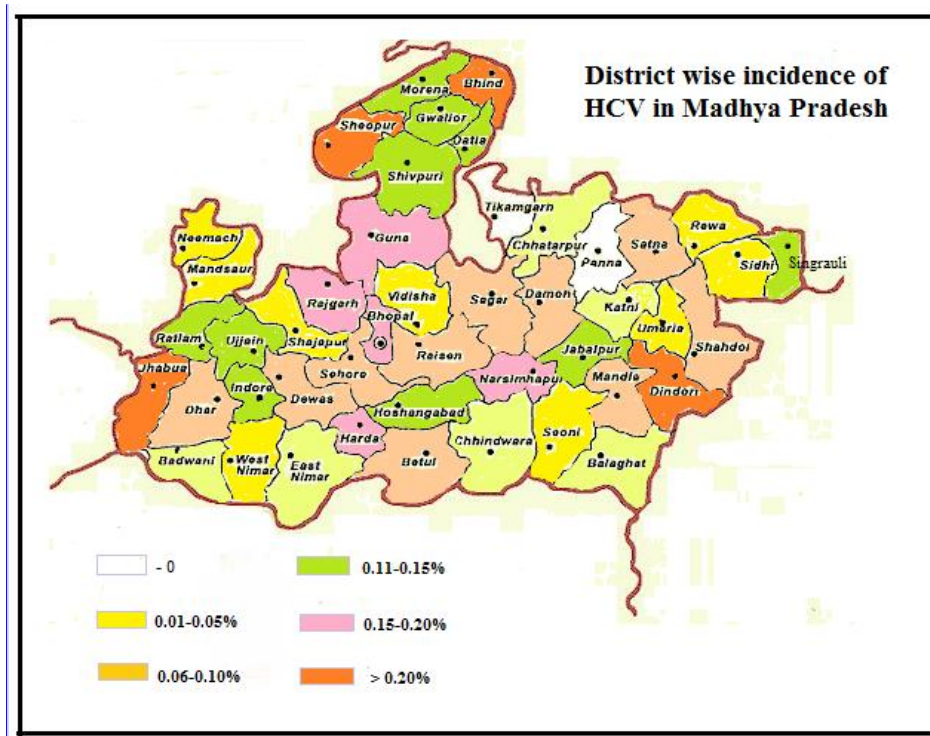


Figure No.2: District wise incidence of HCV in blood donors in Madhya Pradesh, India from year 2011 -2017

Comment [OP10]: Not clear. Present in table if you can.

Comment [OP11]: Adjust some tables/figures as commented. Advice to include more risk factors to make study robust.

DISCUSSION

The current study is conducted in sequence of a larger study conducted in 2018, elaborating the incidence of various transfusion transmitted [infections disease](#) (TTIs) in state of Madhya Pradesh.¹¹ A need of research upon individual TTIs i.e. HIV, HBV, HCV, syphilis and malaria arose which led to publication of trends of HIV and HBV in 2018, and continuing the process, the present study on HCV infection.

A slight difference was noted with respect to HCV reactivity in males and females. Males showed slightly higher HCV reactivity possibly attributed to more propensity for high risk behavior. However the difference was not found to be statistically significant similar to result of other study.¹² Voluntary blood donor showed slightly lesser HCV reactivity than relative/exchange donor because of VD are more likely to answer the questionnaire honestly in contrast to ED, who because of dire need and urgency of requirement of blood for the patient are more likely to hide the fact of high risk behavior. This has been advocated by WHO stating that “The safest blood donors are voluntary, non-remunerated blood donors from low-risk populations”.¹³

In the current study, we observed a steady increase in voluntary blood donation with an average of 87.3 % of total blood units generated by voluntary blood donation in 7 years. In the annual reports of Department of AIDS Control, Ministry of Health and Family Welfare, Government of India, in the data collected from NACO supported blood banks all over India, during the year 2010-11, the percentage of Voluntary blood donation was 79.4% against the target of 80% which steadily increased to 77% in 2016-2017.^{14,15} Prevalence of HCV in blood donors calculated in our study is found to be lower than most other incidence studies all over India (0.11 % vs. 2%).⁴ When analyzed year wise, a decrease in HCV reactivity among blood donors was reported from 2014 to 2015. This change was attributed to proper donor selection with counseling and filling up of questionnaire. In 2017 a slight increase was noted in HCV incidence which most likely occurred to introduction of advanced technique for detection which curtail the false negative results observed in the window period and increased sensitivity. In the 4 districts where HCV reactivity was reported to be more than 0.2%, it is possible due to prominent tribal rural population with limited health awareness.

Comment [OP12]: 1. Check for typographical and grammatical errors.
2. Check for unnecessary statements and expunge.
3. Discuss results sequentially as tables/figures are presented.
4. Use recent studies/references to justify or relate your study (2016-2019 literatures).

CONCLUSION

It can be concluded that there is an increasing trend in blood donations specifically voluntary blood donation with a male predominance. It can also be seen from the above data that there is a strategically fall in the prevalence of HCV infection from 2008-2017 which is due to the various awareness, educational programs and campaigns run by the Government of India and more work has yet to be done in this field.

Comment [OP13]: Reorganize your statements. Recommend way forward and limitations of your study.

ETHICAL APPROVAL

All author(s) hereby declare that all procedure have been examined and approved by the appropriate ethics committee of MPSACS, Bhopal, India and research have therefore been performed in accordance with the ethical standards laid down in the 1964 declaration of Helsinki.

Comment [OP14]: State ethical registration number given.

UNDER PEER REVIEW

References

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Comment [OP15]: 1. Make use of recent references (2016-2019).
2. Arrange references based on Journal's guidelines.
3. Advice to add more references for such study.