

Prevalence of HCV Infection among Patients of Medical College in NCR, Meerut, India

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Abstract: *Background:* Hepatitis C virus is a small, enveloped, positive-sense single-stranded RNA virus that causes hepatocellular carcinoma and lymphomas. *Aim of study:* To study the spectrum of presentation of HCV infection in the patients brought in the Medical college Hospital for a period of three months. *Methods:* A cross sectional study of 200 blood samples with no known history of hemodialysis, blood transfusion or needle injury brought for Testing HCV in a period of three months. Their serum is tested for HCV Abs by rapid immunochromatography, Enzyme Linked ImmunoSorbent Assay (ELISA). *Results:* Out of 200 samples, 56 of male (28%) and 144 (72%) of female patients were screened. 14 samples of patients were detected positive (07%). 05 male patients (8.92%), 09 female patients (6.25%) found positive. 100% patient from ICU was positive. 28.57% from Medicine department, 17.39% from Surgery, 10.52% from Gynecology department, 2.44% from OPD were detected positive for HCV. The patients from Ortho, Pediatrics and ENT were found Non -Reactive to the HCV test. *Conclusions:* 14 (7%) patients samples were found positive to HCV, higher than that of earlier studies. Age group of 21- 40 years were found worst affected in the study (71.42%). The present study clearly indicates that a preventive screening of population at large in a well-defined manner is required in India.

Keywords: Hepatitis C virus (HCV), CDC (Center for Disease Control), ELISA (enzyme-linked ImmunoSorbent assay)

1. Objective

To study the spectrum of presentation of HCV infection in the patients brought in the medical college hospital for a period of three months. The samples received in Microbiology lab drawn from different specialty departments and OPD were tested for HCV.

The main objective of this study is to know prevalence of HCV infection in the patients who have come to OPD and other specialty departments with various types of complaints for better awareness of HCV and early detection of the disease. Early diagnosis and curative treatment of HCV infection can reduce the risk of liver-related morbidity and mortality and also serve to prevent transmission of new infections.

2. Introduction

Hepatitis C is an emerging infection in India and an important pathogen causing liver disease in India. The high risk of chronicity of this blood-borne infection and its association with hepatocellular carcinoma underscores its public health importance. Blood transfusion and unsafe therapeutic interventions by infected needles are two preventable modalities of spread of hepatitis C infection. In addition, risk factor modification by reducing the number of intravenous drug users will help curtail the prevalence of this infection.¹

An estimated 3% of the world population is infected with Hepatitis C virus (HCV).² India is estimated to have about six million HCV infected individuals, most of whom are unaware of their infection status. The major modes of transmission of the virus include injection drug use, unsafe injection practices, blood transfusion etc. HCV causes acute hepatitis which is mostly subclinical, but which gradually evolves into chronic hepatitis in about 80% of those infected. HCV infected people are at risk for developing

chronic liver disease (CLD), cirrhosis, and primary hepatocellular carcinoma (HCC). It has been estimated that HCV accounts for 27% of cirrhosis and 25% of HCC worldwide. The US Center for Disease Control and Prevention (CDC) recommends screening all individuals with risk factors for HCV infection for antibodies to HCV (anti-HCV).^{3,4}

HCV was discovered in 1989 and established as an important etiological agent of transfusion associated hepatitis. HCV is a RNA virus belonging to the family Flaviviridae, genus Hepacivirus. positive sense single-stranded RNA genome. An important feature of the HCV genome is its high degree of genetic variability. HCV has been classified into six genotypes [1,2,3,4,5,6] with multiple subtypes. Genotyping is recognized as the primary tool for assessing the course of infection and determining treatment duration and response.^{5,6}

There is paucity of large-scale prevalence studies on hepatitis C in the general population of India. According to four large population based studies, the prevalence rates is varying from 0.09%–2.02%.⁷

The other major study estimated prevalence of hepatitis C virus (HCV) infection in India is between 0.5 and 1.5% with hotspots showing much higher prevalence in some areas of northeast India, in some tribal populations and in certain parts of Punjab. Genotype 3 is the most prevalent type of infection. Recent years have seen development of a large number of new molecules that are revolutionizing the treatment of hepatitis C.⁸

WHO website depicts update on HCV- Injection safety is improving but more action needed- 3 September 2019– A new journal article states that injection safety is improving, along with reduction in unnecessary injections. However, more action is needed in countries, particularly in the African and the Eastern Mediterranean regions, where a substantial number of unsafe injections are

still occurring. The study shows that over 96% of injections in 40 reporting countries were using new safer injection devices in 2011-2015. On average, women received more injections per year (1.85) than men (1.41). Improved injection safety helps to reduce transmission of blood borne infections such as hepatitis B, C and HIV in health clinics.⁹

3. Methods

Virological Tools for Diagnosis-

Indirect tests- serologic assays detecting specific antibody to HCV (anti-HCV)

Direct tests- Assays that can detect, quantify, or characterize the components of HCV viral particles, such as HCV RNA and core antigen.^{10,4} Direct and indirect virological tests play a key role in the diagnosis of infection, therapeutic decision-making, and assessment of virological response to therapy.

Anti-HCV Antibodies

The “serologic window” between HCV infection and the detection of specific antibodies varies from patient to patient. With current assays, sero conversion occurs on an average at 6-8 weeks after the onset of infection. In patients with spontaneously resolving infection, anti-HCV may persist throughout life, or decrease slightly while remaining detectable, or gradually disappear after several years.¹¹ Anti-HCV persists indefinitely in patients who develop chronic infection, although antibodies may become undetectable in hemodialysis patients or in cases of profound immunosuppression.⁴

Anti-HCV detection

Serological assays for detecting anti-HCV were developed and improved following the initial discovery of the virus because of the urgent need to screen blood donors and prevent transmission. Anti-HCV is typically identified by using enzyme-linked ImmunoSorbent assay (ELISA).

Principle of the Assay

- 1) HCV antigens are immobilized on a porous immunofiltration membrane. Sample and the reagents pass through the membrane and are absorbed into the underlying absorbent pad.
- 2) As the patient's sample passes through the membrane, HCV antibodies if present in serum/plasma, bind to the immobilized antigens. In the subsequent washing step, unbound serum/plasma proteins are removed.
- 3) In the next step, the protein-A conjugate is added which binds to the Fc portion of the HCV antibodies to give distinct pinkish purple dot against a white background at the test region (“T1” &/ or “T2”). At the control region (“C”) a “Built-in Quality Control Dot” has been devised to confirm the proper functioning of the device, reagent and correct procedural application.^{12,13,14}

HCV core antigen (HCV Ag) detection

During the past decade, several assays for the detection of the core antigen of HCV by ELISA or CLIA have been developed.¹⁴ These assays were envisioned as alternatives to NAT to be used in resource-limited settings, where

molecular laboratory services are either not available or not widely utilized owing to cost issues. Since these assays are either ELISA or CLIA based, they are user friendly, require less technical expertise and are less expensive compared to molecular techniques. Evaluations in transfusion settings have shown that the HCVcore Ag assay detects HCV infection as effective as NAT, about 40-50 days earlier than the current third generation anti-HCV screening assays. HCV core antigen levels closely follow HCV RNA dynamics, and allow clinical monitoring of a patient's therapy, independently of HCV genotype.^{15,16,17}

Analysis of study on Different parameters

Table 1: Analysis of HCV positive samples

Total No. of patient's sample	HCV + VE (No.)	HCV -VE (No.)	% HCV + VE samples	% HCV - VE samples
200	14	186	7.00%	93%

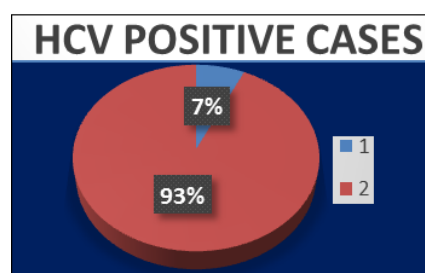


Table 2: Gender wise classification of patients under HCV Screening

Total No. of patients screened	Male sample No.	Male sample %	Female sample No.	Female sample %
200	56	28%	144	72%

Table 3: Gender wise Analysis of HCV positive samples

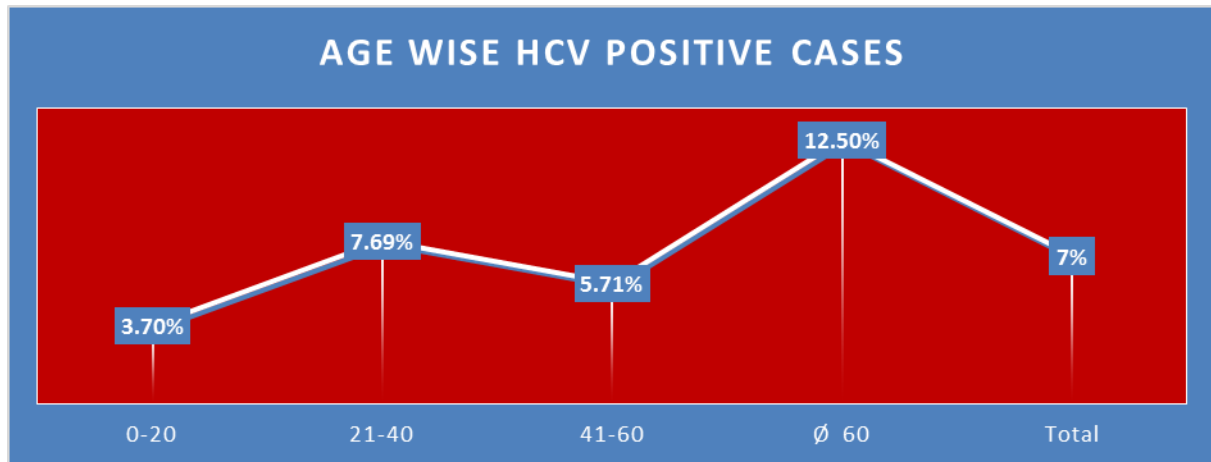
Gender	Total No. of sample	Sample found Reactive (+ve HCV) No.	HCV +VE Sample %
Male	56	05	8.92%
Female	144	09	6.25%

Table 4: Department wise Analysis of HCV positive cases

Department	Samples for HCV (No.)	% of samples (%)	HCV +VE (NO.)	HCV +VE %
Gynecology	38	19%	4	10.52%
Medicine	7	3.50%	2	28.57%
Surgery	23	11.50%	4	17.39%
OPD	123	61.50%	3	2.44%
Ortho	5	2.50%	0	0
ENT	2	1.00%	0	0
ICU	1	0.50%	1	100.00%
Paediatrics	1	0.50%	0	0
Total sample	200	100%	14	7%

Table 5: Age wise Analysis of samples on HCV positive cases

Age group (yrs)	Total sample (No.)	Total sample (%)	HCV +VE (No.)	HCV +VE (%)
0-20	27	13.50%	1	3.70%
21-40	130	65%	10	7.69%
41-60	35	18%	2	5.71%
≥ 60	8	4.00%	1	12.50%
Total	200	100.00%	14	7%



4. Results

In the study carried out for three months duration in Microbiology Lab at Medical college, the patients based on clinical examination by various specialties and OPD, total 200 blood samples were examined for HCV infection by ELISA Test for qualitative examination. 14 samples were detected positive out of 200 samples (7%) and 186 patients (93%) were found non-reactive to the test (Table 1). Out of 200 patients 56 male (28%) and 144 (72%) female patients samples were put to HCV test (Table 2).

05 male patients (8.92%) samples out of 56 patients were found Reactive to the test. 09 female samples (6.25%) out of 144 female patients were positive to the test (Table 3). 01 out of 01 (100%) patient from ICU was found positive. 02 out of 07 (28.57%) from Medicine department, 04 out of 23 (17.39%) from Surgery, 04 out of 38 (10.52%) from Gynecology department, 03 out of 123 (2.44%) from OPD were detected positive for HCV. The samples from Ortho, Pediatrics and ENT were found Non-Reactive to the HCV test (Table 4). The samples of patients above 60 years age was maximum (12.5%) positive followed by 7.69% in the age group of 21-40 years. 5.71% samples of patients in age group of 41-60 years were positive to the test. The lowest 3.70% samples were from the age group less than 20 years of patients in the present study (Table 5).

5. Conclusions

In the sample size of 200 patients 14 (7%) patients were positive to HCV. HCV infection is found slightly more in male patients than female patients. Maximum number (10) of patients in the age group of 21-40 years were positive (71.42%). The ratio of positive HCV cases (7%) is recorded substantially more in this study comparing the previous one study where the ratio ranges from 0.09%–2.02%¹⁴ and in other major study (based on which Govt. of India formulated guidelines), the ratio ranges from 0.5% to 1.5%¹⁵. One fact of higher ratio of positive HCV is that the HCV screening were made of the samples which have been referred with wide range of symptoms. But it is also a fact that there was no known history of blood transfusion, hemodialysis, needle injury or like. This study further strengthens the recommendation that HCV infection is substantially

increasing in India and it needs a preventive screening of population at large with a well-defined systematic approach.

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