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Epidemiological Profile of Hepatitis C Patients at India's New Hub –Haryana

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Abstract

Aims and objectives: The aim was to study Epidemiological profile in patients infected with Hepatitis C Virus and to assess the various risk factors, genotypes, viral load and geographic foci of the disease, if any.

Introduction: Hepatitis C virus (HCV) is a major cause of liver disease worldwide and a potential cause of substantial morbidity and mortality in the future. Professional blood donation continues to flourish despite a law condoning this. Another malaise in our health system is the reuse of improperly sterilized needles. Both these factors are potential sources for the spread of hepatitis C in India.

Results: Majority of the subjects (65%) were male.81% of the subjects came from rural residential areas. 84% of the subjects were married. The age distribution curve showed a sharp peak between the age group 20 to 35 years (38%). More than one third (37.37%) of the patients were from Kaithal alone. Kaithal and Fatehabad together made up 60% of the subjects. The districts bordering Punjab were having more prevalence in comparison to other parts. History of previous surgery and tattooing appeared as major risk factors. 60% of the patients were asymptomatic. Most of them were found to have HCV infection at screening camps followed by screening during preanaesthetic checkups and blood donation. Genotype 3 was the most common (58%) followed by genotype 4 (22%) and Genotype 1 (17.30%). Genotype 5 and 6 was seen only in 0.2% and 0.1% respectively. There was no case of genotype 2.

Keywords: Genotype; Recycled needles; Tattooing; Blood transfusion

Abbreviations: HCV: Hepatitis C virus; PCR: Polymerase Chain Reaction; CI: Confidence Intervals; LFTs: Liver function tests.

Introduction

Hepatitis C virus (HCV) is a major cause of liver disease worldwide and a potential cause of substantial morbidity and mortality in the future. The complexity and uncertainty related to the geographic distribution of HCV infection and chronic hepatitis C, determination of its associated risk factors, and evaluation of cofactors that accelerate its progression, underscore the difficulties in global prevention and control of HCV. It has been estimated that the global prevalence of Hepatitis C virus (HCV) infection is around 2%, with 170 million persons chronically infected with the virus and 3 to 4 million persons newly infected each year. Although HCV is endemic worldwide, there is a large degree of geographic variability in its distribution. Countries with the highest reported prevalence rates are located in Africa and Asia [1].

The impact of this infection is just emerging in India. The risk factors most frequently cited as accounting for the bulk of HCV transmission worldwide are blood transfusions from unscreened donors, injection drug use, unsafe therapeutic injections, and other health-care related procedures. Professional blood donation continues to flourish despite a law condoning this. Another malaise in our health system is the reuse of improperly sterilized needles. Both these factors are potential sources for the spread of hepatitis C in India. The worrying aspect of acute hepatitis C infection is that spontaneous viral clearance is unusual with nearly 54%-86% of the infected individuals progressing to chronic hepatitis [2-4]. Approximately a fifth of the patients with chronic hepatitis C progress to cirrhosis over a time spanning nearly a decade [5].

In this study the focus was on the epidemiological profile of the patients. We also tried to find the major risk factors associated with the disease in and around this area. The epidemiology of hepatitis C in India has not been studied systematically. The subjects of study were confirmed hepatitis C patients on Polymerase chain reaction (PCR) testing. The records of all these patients were meticulously maintained in the department. Since the patients visited the clinician every week under the treatment regime, contact with every patient and follow up was very convenient. The treatment was provided free for BPL/SC/ST and to rest on subsidized rates, as per Haryana government policy, therefore more people come forward to receive the treatment.

Review of Literature

The estimated global prevalence of HCV infection is 2.2%, corresponding to about 130 000 000 HCV-positive persons

worldwide [1]. Because many countries lack data, this estimate is based on weighted averages for regions rather than individual countries. Region-specific estimates range from < 1.0% in Northern Europe to > 2.9% in Northern Africa. The lowest prevalence (0.01%-0.1%) has been reported from countries in the United Kingdom and Scandinavia; the highest prevalence (15%-20%) has been reported from Egypt [2,3]. An estimated 27% of cirrhosis and 25% of HCC worldwide occur in HCV-infected people [4].

The epidemiology of hepatitis C in India has not been studied systematically. Most of the studies of the prevalence of hepatitis C have been based in blood banks with the assumption that the blood donors are a surrogate for the population at large. However, with the advent of professional donors this assumption may be a fallacy [6].

Hepatitis C is an emerging infection in India whose long term implications will be felt in the decades to come. It is a pathogen that is already responsible for a significant proportion of liver disease in various regions of India. The advent of the HIV epidemic may further add to the existing load of HCV infection in the country. Stringent blood banking laws need to be introduced and sterilization and reuse of needles discouraged. All this is not possible without increased public awareness of the magnitude and implications of this chronic infection and its mode of spread. Health authorities have to include hepatitis C on their radar as a disease which can result in significant morbidity and mortality in the years to come. 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.

Aim and Objectives

To study Epidemiological profile in patients infected with Hepatitis C Virus reporting to Hepatitis C nodal center in Haryana.

To assess the various risk factors in these patients.

To find out which genotypes are more common in these patients.

To find out viral load in the patients and its relation, if any to the genotype.

To find out the geographic foci of the disease, if any.

Materials and Methods

It was an epidemiology based, prospective study conducted at medical gastroenterology department of our institute over a period of four years. The record of each patient was meticulously maintained in the department. The proforma for hepatitis C patients was filled in each file. In this study the sample consisted of 1500 patients. The patients confirmed for hepatitis C infection by PCR analysis were included consecutively.

Data analysis

Collected data were entered in the MS Excel spreadsheet, coded appropriately and later cleaned for any possible errors. Analysis was carried out using SPSS (Statistical Package for Social Studies) for Windows version 20.0 and online Graph Pad software (Prism 5 for Windows) version 5.01. During data cleaning, more variables were created so as to facilitate association of variables. Clear values for various outcomes were determined before running frequency tests.

Pearson's chi-square test was used to evaluate differences between groups for categorized variables. "t" test was used to calculate difference of means for quantitative variables. Normally distributed data were presented as means and standard deviation, or 95% confidence intervals (CI) . All tests were performed at a 5% level of significance, thus an association was significant if the p value was less than 0.05.

Observations and results

In this study 1500 records were reviewed and the information mentioned in the attached proforma was analyzed. Majority of the subjects (65%) were male. Only 35% of the participants were females.81% of the subjects came from rural residential areas. 84% of the subjects were married. The age distribution curve shows a sharp peak between the age group 20 to 35 years. 38% patients lie in this age group. About one fourth (26.02%) of the patients lie in the age group 35 to 45 years. 3.32% patients belong to age group 11-20 yrs. and 1.03% of the patients are over 60 years of age. More than one third (37.37%) of the patients were from Kaithal alone. Kaithal and Fatehabad together made up 60% of the subjects attending the hepatitis C clinic in our sample. Patients from Karnal (10.6%), Jind (9.84%) and Panipat (8.08%) also have substantial representation in the sample. The districts bordering Punjab were having more prevalence in comparison to other parts. In our sample of patients history of previous surgery and tattooing appear as major risk factors. 31.73 % patients have a history of a major or a minor surgery and 31% of patients have history of tattooing. A substantial number (12%) of patients have history of receiving blood transfusion, 23.46% of the patients had a history of jaundice sometime in the past. Only 4.26% of the patients had a history of I.V drug abuse and 4% had a history of sexual relations with multiple partners. None of the patients in this sample had a history of dialysis. 60% of the patients were asymptomatic. Most of them were found to have HCV infection at screening camps followed by screening during preanaesthetic checkups and blood donation. Malaise (10.25%), pyrexia of unknown origin (7.25%), diffuse abdominal pain (5.75%) and joint pain (4.5%) were the major complaints in the symptomatic patients. 71% of the patients infected with genotype 4 showed a viral load more than 10 lakhs. While in the genotype 3, almost 50% and in genotype 1, 61% of the patients showed viral load more than 10 lakhs. In this study sample genotype 3 is the most common (58%). Curiously even genotype 4 (22%) and Genotype 1 (17.30%) has substantial presence. Genotype 5 and 6 was seen only in 0.2% and 0.1% respectively. There was no case of genotype 2. Genotype could not be determined in 2.40% patients due to low viral load.

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Alternate medication

957 (63.80%) patients out of cohort of 1500 patients had taken desi medication/ alternative medicines for treatment

Co infections

Eighteen patients (1.2%) in the sample were having HBsAg co infection.

Fifteen (1%) patients in this sample had HIV co infection.

Ultrasound findings

156 patients (10.4%) had varying stages of fatty liver.

75 patients (5%) had cirrhotic changes and out of them 50 patients were having decompensation in form of ascites.

Discussion

HCV infection has likely been endemic in many populations for centuries. However, the wave of increased HCV-related morbidity and mortality that we are now facing is the result of an unprecedented increase in the spread of HCV during the 20th century. Two 20th century events appear to be responsible for this increase; the widespread availability of injectable therapies and the illicit use of injectable drugs [6].

There are both geographic and temporal differences in the patterns of HCV infection [4]. For example, vastly different countries, including the United States, Australia, Turkey, Spain, Italy, and Japan, belong to regions of the world with similar overall average prevalence of HCV infection (1.0%-1.9%), but have different patterns of age-specific prevalence. In the United States, prevalence is highest among persons 30-49 years old, who account for two-thirds of all infections, and lower than average among persons less than 20 and greater than 50 years old [5,7]. This pattern indicates that most HCV transmission occurred in the last 20-40 years, and primarily among young adults, a pattern similar to that observed in Australia [8]. In the United States [9,10], Australia [11], and countries in western and northern Europe with similar HCV epidemiology [12,13], the greatest variations in prevalence occur among persons with different risk factors for infection.

In contrast, the age-specific prevalence of HCV infection increases steadily with age in Turkey, Spain, Italy, Japan, and China [14-17]. In these countries, persons > 50 years old account for most infections, which suggest a cohort effect in which the risk for HCV infection was higher in the distant past, i.e., 40-60 years previously. In many countries with this pattern, the greatest variations in HCV prevalence occur geographically. In Italy, Japan and China, for example, there are hyper endemic areas of the country in which older persons have an HCV prevalence 20-fold greater than the average overall and 1.5-2-fold greater than the prevalence among older persons in other areas of the country [18-21].

In our study we found that infection is more prevalent in the young adults. There is a sharp peak in the age group 20 to 30 years and a substantial prevalence till 45 years of age. There are very few patients in the extremes of age groups that are less than 20 years and more than 60 years.

In a population based study from Ratia showed that the maximum number of hepatitis C cases, 486 (29.8 per cent), were in the age group 31–40 years and only 0.8 per cent of cases were in the 0–10 year age group [22].

The highest HCV prevalence in the world occurs in Egypt, where the prevalence of infection increases steadily with age, and high rates of infection are observed among persons in all age groups [2,23]. This pattern indicates an increased risk in the distant past followed by an ongoing high risk for acquiring HCV infection, although there are regional differences in average overall prevalence [3,24].

In our study we found that maximum cases were from Kaithal district of Haryana followed by patients from Fatehabad. We assume a temporal association between the risk factors such using unsterilized needles, syringes, and equipment and the high incidence of patients from these areas as compared to the others. Determining the incidence of HCV infection (i.e., the rate of newly acquired infections) is difficult because most acute infections are asymptomatic, available assays do not distinguish acute from chronic or resolved infection, and most countries do not systematically collect data on cases of acute disease. Even in countries with well-established surveillance systems, acute disease reporting systems underestimate the incidence of HCV infection [25-27].

The most efficient transmission of HCV is through large or repeated direct percutaneous exposures to blood (e.g., transfusion or transplantation from infectious donors, injecting drug use [10]. HCV is less efficiently transmitted by single small dose percutaneous exposures (e.g., accidental needle sticks) [10,28] or by mucosal exposures to blood or serum-derived fluids (e.g., birth to an infected mother, sex with an infected partner [10,29,30].

There is also evidence that the environment can serve as a reservoir for infectious virus. HCV transmission by in apparent percutaneous exposures has been caused by cross-contamination from reused needles and syringes, multiple-use medication vials, infusion bags, and injecting-drug use paraphernalia [31,32]. These epidemiologic data implicating transmission from environmental sources of HCV are supported by an experimental study that demonstrated the infectivity of HCV in blood after exposure to drying and storage at room temperature [7].

Because of the wide variety of human activities that involve the potential for percutaneous exposure to blood or blood-derived body fluids, there are numerous other biologically-plausible modes of transmission besides those with clearly-demonstrated epidemiologic associations with infection. These include cosmetic procedures (tattooing, body-piercing), intranasal drug use, and religious or cultural practices such as ritual scarification, circumcision, acupuncture, and cupping. In most regions of the world, there are insufficient data to determine whether these risk factors make any measurable contribution to overall HCV transmission. In those countries where adequate studies have been done, none of these activities have been consistently associated with HCV transmission [10,33].

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We found that tattooing and history of minor or major surgeries were the leading risk factors in the sample studied. We assume that percutaneous exposure through minor routes of transmission like multiple uses of unsafe injections and procedures by private practitioners and dental surgeons, respectively, sharing of shaving kits, and visiting roadside barbers have played an important role in HCV transmission in these areas.

Risk factors such as blood transfusion were seen in 12% of the sample. Multiple sexual partners and i.v. drug abuse are not common in this sample. There is also some doubt about sexual transmission of this infection because the spouses of most of the chronic HCV infection patients were found to be negative for anti HCV antibodies on screening. In fact the extent to which HCV is transmitted by sexual activity and under what circumstances is one of the most controversial aspects of the epidemiology of hepatitis C. The results of different types of studies have been inconsistent. The strongest evidence for heterosexual activity as a risk factor for HCV infection came from case-control studies of persons with acute non-A, non-B hepatitis (now known as hepatitis C) in the United States during the 1970s and 1980s, which identified sex with an infected partner or with multiple partners as independently associated with acquiring disease [34,35].

In contrast, no association was found with male homosexual activity, and cross-sectional studies conducted since 1990 of men who have sex with men (MSM) and heterosexual persons in long term monogamous relationships with a partner with chronic HCV have found little evidence for sexual transmission of HCV [11]. One possible explanation for these apparent inconsistencies is that HCV is more likely to be transmitted by sexual intercourse when the infected partner is in the early phase of acute infection; virus concentration is high and there is no antibody to complex with antigen.

A higher rate of sexual transmission of HCV during the acute phase of infection in combination with a high proportion of persons having unsafe sex with multiple partners could explain the disproportionate amount of the HCV-related disease burden accounted for by sexual activity relative to the low efficiency by which the virus is transmitted by this mode, as well as the rare episodes of infection among partners of persons with chronic HCV. Thus, most of the HCV-related disease burden in developed countries has resulted from injection drug use, receipt of transfusions before donor screening, and high-risk sexual activity. In contrast, most of the disease burden in developing countries is related to receipt of unsafe therapeutic injections and contaminated blood, which is also true in our area. Characterizing the epidemiology of HCV infection in individual countries is crucial to developing and implementing effective preventive measures. In some, ensuring safe blood supplies and health-care related procedures are the highest priorities. In others, priorities need to focus on preventing injecting drug use, improving access to drug treatment, harm reduction counseling, and testing to identify HCV-infected persons for medical evaluation and management.

Larger differences have been noted in the HCV genome between strains from different geographical regions allowing the virus to be classified into six major genotypes [11]. Genotype of the virus does not appear to influence disease presentation or severity of disease but has been identified as a major predictor of response to antiviral therapy. Most of the reported studies from India seem to suggest a north south divide, where in genotype 3 predominates in the north, east and west India, whereas genotype 1 is commoner in south India [6,18].

Genotype 3 (58%) is the most common genotype in the sample studied. This data corresponds with the existing studies conducted in India. Surprisingly genotype 4 (22%) is the next most common genotype. Genotype 1 also had a significant incidence of 17.30%. We could not find any other reported study to compare the threat of the rising incidence of genotype 4 in Northern India. Hepatitis C virus (HCV) genotypes help to tailor the treatment response, but their influence on the disease severity and association with hepatic steatosis is not well understood.

In a study HCV-RNA and genotyping was carried out in 398 patients with chronic hepatitis C. It was found that Severe liver disease was present in 17 of 38 (45%) with genotype 1; in 1 of 3 (33%) with genotype 2; in 128 of 236 (54%) with genotype 3; 7 of 10 (70%) with genotype 4; and in 1 of 4 (25%) with mixed genotype.

In our study 71% of the patients infected with genotype 4 showed a viral load more than 10 lakhs. While in the genotype 3 infection almost 50% and in genotype 1, 61% of the patients show viral load more than 10 lakhs.

Both HIV and HCV infection share the same routes of transmission and it is not surprising that co-infection of these viruses is common. The prevalence of hepatitis C infection in patients with HIV infection has been very variable. Hepatitis C infection is expected to ride piggy-back on the HIV epidemic and is bound to be a significant cause of morbidity in India. Both HIV-HBV and HIV-HCV co infections increase morbidity and mortality beyond those caused by each disease alone and significantly complicates medical management and burden on health systems [8,9,11]. In our study 1.2% of the sample had HBV co infection whereas only 1% had HCV-HIV co infection. The main reason can be due to lesser number of patients had history of i.v. drug abuse or multiple sexual partners.

In comparison to Hepatitis C, epidemiological profile of hepatitis B is different in haryana. The patients suffering from hepatitis B are seen in both stages i.e. acute as well as chronic stage whereas patients suffering from hepatitis C are predominantly seen in chronic stage. Other difference noted is that patients of hepatitis C usually belong to younger age group, whereas Hepatitis B patients are seen at all ages. Hence, patients of hepatitis C belong to predominantly non-cirrhotic group whereas in hepatitis B belongs to both cirrhotic as well as non-cirrhotic group.

Conclusion

The burden of hepatitis C infection is more in the males especially in the rural areas. The reason for this could be lack of awareness, hygiene and shortage of health facilities.

The young adults are the most affected. To tackle this problem

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from increasing further it is very important to organize public awareness and health education campaigns targeting healthcare providers, private practitioners, and the public. We also need to develop a national curriculum: a general curriculum in schools and colleges to explain and avoid exposure to HCV; and a professional curriculum to upgrade knowledge about prevention of HCV transmission among medical, dental and other health care professionals.

In order of the prevalence of disease we can formulate strategies and prioritize the districts that is Kaithal, Fatehabad, Karnal, Jind, Panipat, Sonepat etc. according to the decreasing incidence

The most important risk factors are use of unsterilized needles and other equipment. Tattooing has emerged as a major player here. It is a common practice and it is imperative to make people aware of the risks associated with it.

Genotype 3 is the most prevalent. But genotype 4 is also emerging.

Summary/Suggestions

This study was done to understand the epidemiological profile of hepatitis C patients attending the hepatitis C clinic at our institute. The main assumption as discussed above is that the local medical practioners and dentists were using unsterilized needles, syringes, and equipment which have led tothe dispersion of infection in this area. It was found that along with genotype 3 of the virus, which is common in north and central India, there is a high incidence of genotype 4.

Our suggestion would be

- Diagnostic tests for HCV are recommended in anyone presenting with suspected acute hepatitis, and in those with symptoms or signs of chronic liver disease, or abnormal liver function tests (LFTs) consistent with acute or chronic hepatitis.
- HCV transmission is likely to persist in areas with limited access to antiviral drugs and poor needle injection and blood product hygiene. It has been estimated that fewer than 50% of HCV-infected persons are diagnosed in most developed countries and the proportion of patients who access and complete treatment remains low. The numbers of patients aware of and accessing care are substantially lower in less developed countries. For these reasons as well as the cost of therapy, HCV therapy may not have a significant impact on the disease in many parts of the world and may have minimal impact in blocking the spread of infection within the human population. Therefore, development of a vaccine to prevent chronic HCV infection, if not to prevent infection altogether, is essential for control of HCV disease. Till then maximum thrust should be on prevention, followed by early recognition and treatment of the affected group.
- The burden of hepatitis C infection is more in the males especially in the rural areas. The reason for this could be lack of awareness, hygiene and shortage of health facilities.
- The young adults are the most affected. To tackle this problem from increasing further it is very important to organize public awareness and health education campaigns targeting healthcare providers, private practitioners, and the public. We also need to develop a national curriculum: a general curriculum in schools and colleges to explain and avoid exposure to HCV; and a professional curriculum to upgrade knowledge about prevention of HCV transmission among medical, dental and other health care professionals.
- In order of the prevalence of disease we can formulate strategies and prioritize the districts that is Kaithal, Fatehabad, Karnal, Jind, Panipat, Sonepat etc. according to the decreasing incidence
- The most important risk factors are use of unsterilized needles and other equipment. Tattooing has emerged as a major player here. It is a common practice and it is imperative to make people aware of the risks associated with it.
- Genotype 3 is the most prevalent. But genotype 4 is also emerging.
- The burden of hepatitis C infection is more in the males especially in the rural areas. The reason for this could be lack of awareness, hygiene and shortage of health facilities.
- The young adults are the most affected. To tackle this problem from increasing further it is very important to organize public awareness and health education campaigns targeting healthcare providers, private practitioners, and the public. We also need to develop a national curriculum: a general curriculum in schools andcolleges to explain and avoid exposure to HCV; and a professional curriculum to upgrade knowledge about prevention of HCV transmission among medical, dental and other health care professionals.
- In order of the prevalence of disease we can formulate strategies and prioritize the districts that is Kaithal, Fatehabad, Karnal, Jind, Panipat, Sonepat etc. according to the decreasing incidence
- The most important risk factors are use of unsterilized needles and other equipment. Tattooing has emerged as a major player here. It is a common practice and it is imperative to make people aware of the risks associated with it.
- Genotype 3 is the most prevalent. But genotype 4 is also emerging.

Limitations

1. In the present study, majority of patients belonged to non-cirrhotic group, hence more number of cirrhotic patients are required in future studies for better assessment in the latter group.
2. The prevalence of chronic hepatitis C is expected to be

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much higher in haryana, hence a larger group of such patients is required for better understanding.

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