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Original Article

Prevalence of hepatitis B & C viruses among patients on hemodialysis in Lucknow, Uttar Pradesh

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ABSTRACT

Problem considered: Patients on hemodialysis (HD) are at high risk of viral hepatitis due to high number of blood transfusion sessions, prolonged vascular access, high exposure to infected patients and contaminated equipment, and cross contamination from the dialysis circuits. This study was done to determine the prevalence of Hepatitis B virus (HBV) & Hepatitis C virus (HCV), in patients on hemodialysis in Lucknow, Uttar Pradesh.

Methods: In a cross-sectional study, done at two different hemodialysis units in Lucknow, Uttar Pradesh, from October 2011 to June 2012, patients on HD were enrolled and clinical data such as age, gender, duration of dialysis, number of transfusions was collected from each patient. Serum sample was collected from each patient. Hepatitis B surface antigen (HBsAg) & anti HCV antibodies (Ab) were measured and lab diagnosis was further confirmed by a qualitative polymerase chain reaction (PCR) assay.

Results: Of 186 participants, anti HCV Ab was positive in 13 patients (6.99%), comprising 11 (84.61%) males and 2 (15.39%) females. Hepatitis C Virus nucleic acid was detected in all 13 enzyme linked immunosorbent assay (ELISA) positive patients. Six patients (3.23%) were positive for HBsAg, comprising 3 (50%) males and 3 (50%) females. Hepatitis B virus nucleic acid was also detected in all ELISA positive patients. One patient had coinfection of HBV & HCV, confirmed by both ELISA and PCR. Significant correlation was found between number of blood transfusion and anti HCV Ab and HBsAg positivity.

Conclusion: There is low prevalence of Hepatitis C Virus and Hepatitis B Virus in hemodialysis patients in this region.

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1. Introduction

Hemodialysis (HD) patients are at high risk for viral hepatitis due to the high number of blood transfusion session. These patients are often anemic, require prolonged vascular access, have high possibility of exposure to infected patients and contaminated equipment, and cross contamination from the dialysis circuits.^{1,2}

Hepatitis C virus (HCV) infection is the most common chronic blood borne infection in the world.³ HCV is a single stranded positive sense RNA virus belonging to the family flaviviridae and genus hepacivirus. It often causes lifelong persistent infection.⁴ Hepatitis B virus (HBV) is a partially double stranded DNA virus, belonging to family Hepadnaviridae and genus Orthohepadnavirus. Chronic infection and related liver diseases are common due to HBV infection.⁵ The majority of cases with chronic HBV and/or HCV infection develop complications i.e. 15%–40% may develop cirrhosis, liver failure and or hepatocellular carcinoma.⁶

HBV and HCV seroprevalence is high in some dialysis centers, sometimes with grave consequences. Studies from India have reported variable prevalence & incidence. Initial studies reported very high anti HCV positivity rates in HD patients, accounting for nearly 24–28% positivity.^{7,8} A large difference exists between HBV and HCV prevalence data in HD units from different regions of India ranging from 1.4 to 46%.^{9–11}

Present study reports the prevalence and the associated risk factors of Hepatitis B & Hepatitis C virus infection in patients on hemodialysis in two dialysis units in Lucknow, Uttar Pradesh, India.

2. Methods

In a cross-sectional study, done during October 2011 to June 2012, 186 patients on hemodialysis were recruited from two different hemodialysis units in Lucknow, Uttar Pradesh, India.

Ethical clearance was obtained from the intuitional ethics committee. All end stage kidney disease patients on hemodialysis with history of at least 10 dialyzes settings were recruited after obtaining a written informed consent from each patient. Both the dialysis units have dedicated dialysis machines for HCV and HBV positive patients. Both the centers use new disposable dialyzer sets every time for positive patients.

Clinical data such as age, gender, duration of dialysis, previous status of Hepatitis B surface antigen (HBsAg) and anti HCV antibody (anti HCV Ab) and Liver Function Test (Total Bilirubin, Alanine transaminase (ALT), Aspartate transaminase (AST) and Alkaline phosphatase (ALP)) of participants were recorded, using a preformed questionnaire, at the time of enrollment. History of injection of intravenous drugs, having received blood and/or blood products, unsafe sexual practice, history of tattooing, body piercing, surgery and dental care were also recorded.

Approximately 3 ml of blood was collected from each subject and sera was tested for anti HCV antibodies (Erba-Transasia 3rd generation) and Hepatitis B surface antigen (HBsAg) (ErbaTransasia) by an enzyme linked immunosorbent assay (ELISA). Patients testing positive for antibodies against HCV and/or HBsAg were tested by real time polymerase chain reaction (Real Time PCR) (Genome Diagnostics) for detecting HCV nucleic acid and HBV nucleic acid to rule out false positives by ELISA. Statistical Analysis was done using SPSS version 16. *p* value <0.05 was considered statistically significant.

3. Results

Of 186 patients, 117 were males and 69 were females. The age group varied from 13 to 83 years with mean age of 45.11 ± 15.44 years. The number of hemodialysis sittings received by these patients ranged from 12 to 87 per patient. The major primary diseases causing end stage kidney disease

Table 1 – Comparison of demographic features and risk factors in patients on hemodialysis with and without HCV infection.

	HCV infected cases, <i>n</i> = 13 (6.99%)	HCV non-infected cases, <i>n</i> = 173 (93.01%)	<i>p</i> value
Male, <i>n</i> = 117 (62.9%)	11 (9.40%)	106 (90.60%)	0.06
Age (in years)			
<14, <i>n</i> = 1 (0.54%)	0 (0%)	1 (100%)	
≥14–60, <i>n</i> = 154 (82.80%)	12 (7.80%)	142 (92.20%)	
>60, <i>n</i> = 31 (16.70%)	1 (3.23%)	30 (96.77%)	
Total serum bilirubin (mean ± SD) mg/dl	0.38 ± 0.11	0.48 ± 0.42	0.3
Serum alkaline phosphatase (mean ± SD) IU/L	302 ± 173.1	186.43 ± 131.8	0.003
Serum Aspartate transaminase (mean ± SD) IU/L	50.8 ± 44.1	33.8 ± 25.64	0.03
Serum alanine transaminase (mean ± SD) IU/L	51 ± 66.9	35.35 ± 29.3	0.10
Duration of dialysis in months (mean ± SD)	17 ± 8	12 ± 7.53	0.02
Positive history of blood transfusion, <i>n</i> = 158 (84.95%)	11 (6.96%)	147 (93.04%)	0.30
History of ≥10 units of blood transfusion received, <i>n</i> = 35 (18.82%)	9 (25.71%)	26 (74.29%)	<0.05
Positive history of body piercing/tattooing, <i>n</i> = 77 (41.40%)	3 (3.90%)	74 (96.10%)	0.09
Positive history of drug addiction, <i>n</i> = 3 (1.61%)	1 (33.33%)	2 (66.67%)	0.18

(ESKD) included chronic nephritis (62, 33.33%), diabetes mellitus (46, 24.7%), hypertension (42, 22.58%), urological diseases (8, 4.3%), cystic renal diseases (6, 3.23%), systemic lupus erythematosus (1, 0.54%) and unknown etiology (21, 11.29%).

Of 186 participants, anti HCV antibody was positive in 13 (6.99%) patients. Total nine of them were known positive for anti HCV Ab at the time of enrollment while remaining was detected by us. All of them were positive for HCV nucleic acid. Six patients (3.23%) were positive for HBsAg, of which four were HBsAg positive at the time of enrollment and remaining were first time detected by us. HBV nucleic acid was positive in all HBsAg positive patients. One of the patients had coinfection of HBV & HCV.

Analysis of clinical & risk factors in patients with HBV & HCV infection is shown in Tables 1 and 2. Positive history of blood transfusion (receiving >10 blood units) was found to be a significant ($p < 0.05$) risk factor for HBV and HCV infection. The average number of blood transfusion units received was 14 ± 9.29 in HCV positive and 5 ± 2.81 in HCV negative patients, while 11 ± 9.8 and 6 ± 4 in HBV positive and negative patients respectively. Duration of dialysis was significantly associated with risk of HCV infection. Aspartate transaminase (AST) and Alkaline phosphatase (ALP) level was significantly higher in HCV positive patients (Tables 1 and 2).

4. Discussion

The prevalence of viral hepatitis is greater in patients on hemodialysis than in the general population affecting quality of life and mortality. The results of this study showed that the prevalence of HBV and HCV infection was 3.23% and 6.99%, respectively in patients on hemodialysis. The prevalence of HCV antibodies in patients from nephrology units is high and has been reported to range from 5 to 54%.¹² HBV infection is less prevalent than HCV in hemodialysis units.¹³ The rate of serum HBsAg seropositivity on maintenance hemodialysis in the developed world is currently low (0–10%) but outbreaks of acute HBV infection continue to occur in this setting. The

prevalence of HBV infection within dialysis units in developing countries appears higher (2–20%) based on several reports.¹⁴ Studies carried out in various centers worldwide among dialysis patients have shown a prevalence of HCV as 8–36% in North America,^{15,16} 25–39% in South America,¹⁷ 1–36% in Europe,¹⁸ 17–51% in Asia,¹⁶ 1.2–10% in New Zealand and Australia,^{15,21,22,40} and 7–85% in South Africa.¹⁹ The HBV prevalence rate varies from one dialysis unit to another. The prevalence rate in Europe is reported to be 23–43%,²⁰ in USA 16–18%,¹⁵ in Tunisia 18%,²² in France 2.2%,¹⁵ in Russia 39–50%,²³ and in South Africa 17%.²¹ Generally, more than half of the infected patients on dialysis become persistent, symptomless hepatitis B surface antigen (HBsAg) carriers without biochemical evidence of hepatitis.²¹ In addition, the appearance of serological markers for HBV may be delayed by as long as 6–12 months. Some dialysis centers have reported outbreaks of fulminant HBV infection indicating that immunocompromised hosts, such as end stage kidney disease patients on dialysis, may develop severe disease from HBV infection.²⁴ In India, reported prevalence of HBV and HCV infection among hemodialysis patient is variable. Reddy et al have reported that among patients on hemodialysis 5.9% were HCV positive while 1.4% patients had HBV infection and 3.7% had coinfection with HBV and HCV.¹¹ Chandra et al have reported that among the patients of chronic kidney disease, renal transplant or hemodialysis, HBV, HCV and coinfection of both viruses were 7.46% and 37.10% respectively.¹⁰

Current serologic testing for hepatitis C antibody utilizes a third generation ELISA test. With a sensitivity of approximately 97% these tests have been configured to optimize sensitivity, in order to protect the blood supply. Specificity remains an issue, and false positivity may be a problem.²⁵ Hemodialysis patients, being immunosuppressed as a result of their renal impairment, may not mount an antibody response to hepatitis C virus with HCV infection and early studies have shown that ELISA anti HCV antibody negative dialysis patients may be HCV RNA positive.^{26–29} These early studies used first and second generation ELISA tests for anti HCV Ab with a lower sensitivity. Since then there have been

Table 2 – Comparison of demographic features and risk factors in patients on hemodialysis with and without HBV infection.

	HBV infected cases, n = 6 (3.23%)	HBV non-infected cases, n = 180 (96.77%)	p value
Male, n = 117 (62.9%)	3 (2.56%)	114 (97.4%)	0.26
Age (in years)			
<14, n = 1 (0.54%)	0	1 (100%)	
≥14–60, n = 154 (82.80%)	5 (3.25%)	149 (96.75%)	
>60, n = 31 (16.70%)	1 (3.23%)	30 (96.77%)	
Total serum bilirubin (mean ± SD) mg/dl	0.48 ± 0.22	0.48 ± 0.42	0.99
Serum alkaline phosphatase (mean ± SD) IU/L	104 ± 15.7	191.6 ± 135.18	0.12
Serum aspartate transaminase (mean ± SD) IU/L	18 ± 14.24	34.66 ± 26.57	0.13
Serum alanine transaminase (mean ± SD) IU/L	21.75 ± 3.9	36.11 ± 31.03	0.26
Duration of dialysis in months (mean ± SD)	17 ± 5.8	13 ± 7.62	0.20
Positive history of blood transfusion, n = 158 (84.95%)	4 (2.53%)	154 (97.47%)	0.18
History of ≥10 units of blood transfusion received, n = 35 (18.82%)	3 (8.57%)	32 (91.43%)	<0.05
Positive history of body piercing/tattooing, n = 77 (41.40%)	4 (5.20%)	73 (94.80%)	0.15
Positive history of drug addiction, n = 3 (1.61%)	0	3 (100%)	

studies showing good correlation between HCV RNA and anti HCV Ab in hemodialysis patients.^{30–32} However even HCV viremia may be intermittently undetectable in clinically infected persons due to spontaneous fluctuations.³³ Currently, when using third generation ELISAs it is thought that, to use HCV RNA testing for routine screening is not necessary.³⁰ We have not done HCV nucleic acid detection in all the subjects, however, we have used 3rd generation ELISA for detecting anti HCV Ab. We may miss an occasional HCV-PCR positive & anti HCV Ab negative case. Looking at the relatively low specificity of 3rd generation ELISA we have confirmed all the anti HCV Ab positive cases with HCV nucleic acid positivity. As per WHO report, most of the kits of HBsAg has a sensitivity of more than 99% with slightly lower specificity,³⁴ hence, we did HBV-PCR for all the HBsAg positive cases for confirmation of the ELISA results.

Most studies concur that the duration of dialysis is closely related to a positive anti HCV rate.^{35–37} Our results emphasized that the longer dialysis duration was a significant risk factor for acquiring infection. Association of altered liver function test was significant with HCV infected patients. Patients with positive HCV antibody were found to have a significant relationship with frequency of blood transfusions ($p < 0.05$) as reported by Dussol et al.³⁸ Available data suggest that HCV has become the most common cause of acute hepatitis in dialysis patients and dialysis unit staff, following the implementation of infection control measures and vaccination for HBV.³⁹ Although we were unable to study the HBV vaccination/immunization status of our patient, the rate of HBV infection is low and of HCV infection (6.99%) is comparable with studies reported from other parts of the country. It should be noted that the prevalence of the hepatitis C virus in the country's general population is less than 1%⁴⁰ suggesting several fold increase in risk of HCV infection in hemodialysis patients. The HBV & HCV infection correlated with the frequency of blood transfusions and may, therefore, have been acquired through blood transfusion. Although blood for transfusion is screened for HBV and HCV, absence of HBsAg or anti HCV antibody does not therefore exclude the presence of HBV & HCV in blood donors always.¹³ It may be worth reporting here that both the units are attached to a blood bank within the hospital which does screening for both HBsAg and Anti HCV Ab by ELISA only. HBV and HCV nucleic acid has been detected in serum and peripheral blood mononuclear cells of HBsAg and HCV antibody negative hemodialysis patients and staff, and they are therefore potentially infectious to other patients and health personnel.¹³ Regular periodic screening for HBV & HCV markers in patients on dialysis is therefore important. There could be de novo infection secondary to the immunodeficient state in these patients, as has been reported.²¹ The prevalence of HBsAg in this patient population is almost same as that reported in the general population⁴¹ (as reviewed by Sibnarayan Datta), however, it should be noted that the dialysis population is highly selected and usually screened pre-dialysis.

This is a study covering only two dialysis units from one city, however, data shows low prevalence of HBV and HCV infections in hemodialysis centers in Lucknow, Uttar Pradesh. Since blood transfusion remains an important risk factor, screening of blood products for use in this population by Real Time PCR may be recommended.

Conflicts of interest

All authors have none to declare.

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