



ORIGINAL RESEARCH PAPER

Microbiology

HEPATITIS C VIRUS SEROPREVALNCE IN RENAL DISEASE PATIENTS AT SMS HOSPITAL AND ALLIED HOSPITALS

KEY WORDS: Hcv, Dialysis , Renal Failure, Renal Transplant, Rapid Test, Elisa.

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ABSTRACT

To assess the Seroprevalence of Hepatitis C virus in Renal Disease patients at SMS Hospital and Allied Hospitals. Various Renal disorders like ARF, CRF, Renal Failure Case without dialysis, Renal Failure Case with Maintenance Dialysis, Following Renal Transplant and Other Renal Diseases (with abnormal renal function test) cause multi organ failure leading to death. Infection with hepatitis C virus is a common nosocomial occurrence among hemodialysis (HD) patients (13). It is considered a cause of end-stage liver disease and contributes to high mortality and morbidity among patients on maintenance dialysis and following renal transplant cases (12).

BACKGROUND: Hepatitis C virus infection is highly prevalent among Various Renal disorders. The prevalence of HCV infection in HD patients varies markedly from country to country. The prevalence of HCV among dialysis patients in India is reported to range between 20 and 80%. (19) However, the prevalence of HCV infection in the western countries ranges between 4 and 23.3%. (21)

OBJECTIVES: To find out the seroprevalence of anti HCV antibodies in various categories of Renal Disease patients from different OPDS, wards and ICUs of SMS Hospital and J.K. Loan, Mahila Chikitsalaya and Zanana Hospital Jaipur etc. This study is conducted to aid in early detection & treatment & its prevention of HCV Virus infection in renal disease patients.

METHODOLOGY: The study is conducted in the clinical microbiology laboratory of the S.M.S. Medical College & Hospital, Jaipur from period of 1st January, 2007 to 13th November 2007 to evaluate the prevalence of anti HCV Antibody in symptomatic and asymptomatic individuals of 500 Renal disease patients. RAPID Test and ELISA TEST was done at clinical microbiology laboratory S.M.S. Medical College & Hospital, Jaipur.

RESULT: Total no. of anti HCV antibody positive cases in our study were very low 0.6% in Renal disease patients. Out of 500 sample tested for various renal diseases 3 (0.6%) were positive for anti HCV antibodies. HCV seroprevalence was maximum in following case of renal transplant (7.69%), followed by 0.93% in renal failure cases with maintenance dialysis HCV seroprevalence was seen maximum in 21 – 30 year age group (5.26%), followed by 0.8% in 41 – 50 year age groups and 0.55% in > 51 years age groups. Out of 356 males sample tested – 3 (0.8%) were positive for anti HCV antibodies and out of 144 females patients none were positive for anti HCV antibodies in 500 renal diseases patients. Comparison of studies conducted by other researchers showed slight variations in prevalence of HCV infection. There is a scarcity of information on HCV prevalence particularly in developing countries like India, hence present study was conducted for early detection & prevention in Renal disease patients.

INTRODUCTION:

The prevalence of hepatitis C virus antibody is high, between 3.4% and 32.1%, among hemodialysis patients and potential kidney transplant candidates. Hepatitis C is the main cause of chronic liver disease in patients with end-stage renal disease (ESRD) (7). Despite the decrease in the incidence of newly acquired HCV infections observed in recent years, which may be attributable to the efficient serologic HCV tests used in blood transfusions and to the use of erythropoietin to treat anemia, contamination by HCV still occurs in HD units (17). Patients infected with HCV who undergo renal transplantation show a higher risk for progression to severe liver disease, death, and graft failure after transplantation compared with anti-HCV negative recipients (6). HCV infection increases mortality rates in uremic patients, and cirrhosis and other liver-related deaths are more frequent in HCV-infected dialysis patients than in those without the virus (5).

Hepatitis C virus have main modes of transmission i.e., by blood and blood products mainly and also noticed in drug addicts. These viruses are highly infectious (About hundred times more than HIV virus) (10). Globally, HCV has infected more than 170 million people and thus represents a viral pandemic 7 times more widespread than HIV infection [1]. In India approx 1.8-2.5% of the population is presently infected by HCV [4] and 20 million are suffering from HCV infection & its complications [14]. Previously blood transfusion was a major mode of HCV transmission but now that donor blood is thoroughly screened, majority of cases are injectable drug users. HCV is also transmitted perinatally, by improperly

sterilized dialysis equipment (68% of cases) and by unprotected sex with infected partners and with other STDs and even patients with HIV [2].

AIMS & OBJECTIVE:

To find out the Seroprevalence of hepatitis C virus among Renal Disease patients. To evaluate the frequency of HCV viremia and HCV infection increases mortality rates in uremic patients, and cirrhosis and other liver-related deaths are more frequent in After Renal transplant and HCV-infected dialysis patients than in those without the virus (5). Patients infected with HCV who undergo renal transplantation show a higher risk for progression to severe liver disease, death, and graft failure after transplantation compared with anti-HCV negative recipients (6). Hence a study has been conducted to detect the seroprevalence of HCV among patients with Renal Disease patients to aid in early detection, treatment and prevention in the community.

MATERIAL AND METHODS:

The study is conducted in the clinical microbiology laboratory of the S.M.S. Medical College & Hospital, Jaipur from period of 1st January, 2007 to 13th November 2007 to evaluate the prevalence of anti HCV Antibody in symptomatic and asymptomatic individuals of 500 Renal disease patients. Various categories were identified based on clinical evaluations & various investigations. The collected blood was allowed to clot & serum was separated. The sample were stored at 2-8°C & tested within 7 days of collection. Patients' serum samples were subjected to following tests for detection of Anti-HCV antibodies.

A- Rapid test:- DOT immunoassay for detection of Anti-HCV antibodies.[11,24]

B- ELISA test :- For Detection of Anti-HCV antibodies[8,26]

HCV MICROELISATEST:

The 3rd generation HCV Microlisa is an in vitro qualitative enzyme linked immunosorbent assay for the detection of antibodies against HCV (anti-HCVs) in human serum or plasma. The kit is basically intended to screen blood donations to identify and eliminate the infected units of blood and for clinical diagnostic testing. This kit is manufactured by J.Mitra& co.Pvt.Ltd.New Delhi,India.

Principle:- The 3rd generation HCV Microlisa is based on a highly sensitive technique, Enzyme Linked Immunosorbent Assay which detects antibodies against HCV in human serum and plasma. The HCV proteins are present in serum at levels well below the limits of detection. Thus, immunodiagnosis of HCV infection is based on detection of host generated antibodies (anti-HCVs) to viral proteins.The 3rd generation HCV Microlisa utilizes a combination of antigen with the sequence of both HCV structural and non-structural antigen i.e. CORE, E1, E2, NS3, NS4 and Ns5.

- The results were read on Microplate spectrophotometer at 450 nm.
- Cut off value was calculated as per the manufacturer's guidance and the results were interpreted accordingly.

Cut off value = 0.1xPCx+0.1

Pcx = Mean absorbance of positive control

- Interpretation :- According to their absorbance values, samples were interpreted as either reactive for HCV antibody (HCV positive) or non reactive for HCV antibody (HCV negative) if test specimens with absorbance value within 10% below the cutoff should be considered suspect for the presence of antibodies and should be retested in duplicate.
- Sample found to be reactive initially by HCV Microlisa test were again tested by visual rapid test which is HCV TRI-DOT test.

HCVTRI-DOT

The 4th Generation HCV TRI-DOT is a rapid, visual, sensitive and qualitative in vitro diagnostic test for the detection of antibodies to Hepatitis C Virus in human serum or plasma. The 4th Generation HCV TRI -DOT has been developed and designed with increased sensitivity for core and NS3 antibodies using a unique combination of modified HCV antigens. They are for the putative core (structural), protease/helicase NS3 (non-structural) NS4 (non-structural)

and replicase NS5 (non-structural), regions of the virus in the form of two test dots "T₁" & "T₂" to provide a highly sensitive and specific diagnostic test. This Kit is manufactures by J. Mitra& Co.Pvt.Ltd.New Delhi,India.

Principle:- 4th generation HCV TRI-DOT has been developed and designed using modified HCV antigens representing the immunodominant regions of HCV antigen. HCV antigens are immobilized on a porous immunofiltration membrane.

- Interpretation: - Results are noted as per manufactures guidelines and results were interpreted accordingly. If test dots T₁, & T₂, either both dark and light in colour (pink), result should be considered reactive for antibody to HCV. If only control dot appear it indicates that the sample is non-reactive for anti-body to HCV.
- Sample found to be positive for HCV antibodies by both HCV microlisa test & HCV TRI-DOT method would be further tested for hepatitis B Surface antigen by ELISA test.

RESULT:

Total no. of anti HCV antibody positive cases in our study were very low 0.6% in Renal disease patients. Out of 500 sample tested for various renal diseases 3 (0.6%) were positive for anti HCV antibodies.HCV seroprevalence was maximum in following case of renal transplant (7.69%), followed by 0.93% in renal failure cases with maintenance dialysis HCV seroprevalence was seen maximum in 21 – 30 year age group (5.26%), followed by 0.8% in 41 – 50 year age groups and 0.55% in > 51 years age groups. Out of 356 males sample tested-3 (0.8%) were positive for anti HCV antibodies and out of 144 females patients none were positive for anti HCV antibodies in 500 renal diseases patients.Comparison of studies conducted by other researchers showed slight variations in prevalence of HCV infection.

Table - 1: Hcv Seroprevalence Among Renal Disease Patients

Various Renal disease patients	Total No. of sample tested	Total No. of HCV (+) cases
Renal disease patients (RF, RF with dialysis RF without dialysis, Following Renal transplant)*	500	3 (0.6%)

* RF – Renal failure

The above table shows HCV seroprevalence among various Renal disease patients. In the present study a total no. of 500 samples were tested out of which 03 samples (0.6%) were positive for antibody to HCV.

Table - 2: Age Wise And Sex Wise Distribution Of Hcv Seroprevalence In Renal Disease Patients

Age in year	Male		Female		Percentage (%)
	Total no. of tested	Total no. of HCV Positive	Total no. of tested	Total no. of HCV Positive	
0-10 year	11	0	7	0	0/18 (0%)
11-20 year	8	0	10	0	0/18 (0%)
21-30 year	12	1 (8.3%)	7	0	1/19 (5.26%)
31-40 year	92	0	48	0	0/140 (0%)
41-50 year	84	1 (1.19%)	40	0	1/124 (0.8%)
>51 year	149	1 (0.67%)	32	0	1/181 (0.55%)
Total No. of Cases	356	3 (0.8%)	144	0	3/500 (0.6%)

Table shows that HCV seroprevalence was seen maximum in 21 – 30 year age group (5.26%), followed by 0.8% in 41 – 50 year age groups and 0.55% in > 51 years age groups.

Table also shows that out of 356 males sample tested – 3 (0.8%) were positive for anti HCV antibodies and out of 144 females patients none were positive for anti HCV antibodies in renal diseases patients.

Table - 3: Sexwise Distribution Of Hcv Seroprevalence In Various Types Of Renal Diseases

Type of Renal Disease	Male		Female		Percentage (%)
	Total no. of tested	Total no. of HCV Positive	Total no. of tested	Total no. of HCV Positive	
Renal Failure Case without dialysis	121	0	51	0	0/172 (0%)
Renal Failure Case with Maintenance Dialysis	153	2 (1.30 %)	61	0	2/214 (0.93 %)

Following Renal Transplant	13	1 (7.69 %)	0	0	1/13 (7.69 %)
Other Renal Disease	69	0	32	0	0/101 (0%)
Total No. of Tested	356	3 (0.8 %)	144	0	3/500 (0.6 %)

Table shows that out of 500 sample tested for various renal diseases 3 (0.6%) were positive for anti HCV antibodies.

Table also shows that HCV seroprevalence was maximum in following case of renal transplant (7.69%), followed by 0.93% in renal failure cases with maintenance dialysis

Table shows that HCV seroprevalence in males maximum was seen in following cases of renal transplants (7.69%), followed by 1.30% in renal failure cases with maintenance dialysis.

DISCUSSION:

Patients infected with HCV who undergo renal transplantation show a higher risk for progression to severe liver disease, death, and graft failure after transplantation compared with anti-HCV negative recipients (6). Frequency of HCV viremia and HCV infection increases mortality rates in uremic patients, and cirrhosis and other liver-related deaths are more frequent in After Renal transplant and HCV-infected dialysis patients than in those without the virus(5). Renal disorders caused by HCV have become a major public health problem throughout the world affecting millions of people. It is the cause of considerable morbidity & Mortality due to HCV infection is increasing at alarming rate, therefore detection of seroprevalence of HCV in Renal disorders is very essential[10].

Table-4: Comparative Study On Hcv Seroprevalance In Renal Disease Patients

S. No.	Authors & Year	Place	Prevalence of Anti HCV
1	Yapi et al 1991 (29)	Singapur	20%
2	Salunkhe et al 1992 (22)	India	45.2%
3	Sumathy et al 1993 (25)	South India	33.3%
4	Layjyn et al 1993 (16)	Korea	28%
5	Chanda MS et al 1993 (3)	Pune	12.1%
6	K.S. Shim et al 1994 (15)	Korea	13.9%
7	V.A. Arankalle et al 1995 (27)	West India	24.5%
8	Jaiswal et al 1996 (28)	Central India	41.90%
9	Gosvai et al 1997 (9)	Mumbai	27.8%
10	Pratima Gupta et al 2002 (20)	Uttranchal	9.6%
11	SS Sudan et al 2003 (23)	Jammu	8%
12	Present Study 2007	Jaipur	0.6%

Our findings are in accordance with various authors as above.

- Some studies in India have documented the prevalence of Anti HCV (8% - 45.2%) in the chronic renal failure (CRF) patients on haemodialysis or in patients undergoing renal transplants. It was very surprisingly in present study it was only 0.6% this is probably the lowest rates of Anti HCV among CRF patients reported from India so far it may be due to all patients were screened before entering the haemodialysis programs.
- The prevalence of HCV among patient of renal disease patients varies widely in different centers of world and India. In our region it was very low 0.6% while it varied from 20% by Yapi et al 1991 (Singapur), to 45.2% by Salunkhe et al 1992 (North India), to 33.3% by Sumathy et al 1993 (South India), to 28% by Lau Jyn et al 1993 (Korea), to 12.1% Chanda MS et al 1993 (Pune), to 13.9% by K.Shim et al 1994 (Korea), to 24.5% by VA Arankalle et al 1995 (Westren India), to 41.90% by Jaiswal et al 1996 (Central India), to 27.8% by Gosvai et al 1997 (Mumbai), to 9.6% by Pratima Gupta et al 2002 (Uttranchal) and to 8% by SS Sudan et al 2003 (Jammu).
- All the studies clearly show that decreasing prevalence of HCV in renal disease patients with dialysis or post-renal

transplant patients because of all patients were screened before entering the haemodialysis programs and probably because currently we are using 4th generation anti-HCV kits which is the most sensitive technique detection of anti-HCV anti bodies than the past time.

SUMMARY AND CONCLUSION:

The present study was conducted in the Department of Microbiology & Immunology, SMS Medical College Jaipur. The object was assessing the seroprevalence of anti HCV antibodies in Renal Disease patients in SMS and Allied Hospital.

- The patients included in the study were of OPD and IPD from all associated hospitals of SMS Medical College reporting for diagnosis of anti HCV antibodies in Department of Microbiology from 1st January, 2007 to 30th November, 2007. The samples were collected and processed as per routine recommended methods of technical guidelines.
- In all, 500 patients were screened. The observations were made with reference to age sex, constitutional symptoms, various risk groups and investigations.
- The seroprevalence of HCV has declined since the screening of blood for donation in blood banks for anti HCV antibodies became mandatory in 1991 in some parts of the world and in India since 1997(10).
- HCV infection prevalence varies with geographical distribution and social characteristic of population groups(10).
- We observed Total no. of anti HCV antibody positive cases in our study were 0.6%. HCV seroprevalence was seen maximum in 21 – 30 year age group (5.26%), followed by 0.8% in 41 – 50 year age groups and 0.55% in > 51 years age groups. Out of 356 males sample tested – 3 (0.8%) were positive for anti HCV antibodies and out of 144 females patients none were positive for anti HCV antibodies in renal diseases patients.
- We also observed of anti HCV antibodies seroprevalence was maximum in following case of renal transplant (7.69%), followed by 0.93% in renal failure cases with maintenance dialysis.
- Our study is a step ahead in this direction with the purpose of providing authentic scientific data based on the affected population attending our hospital.
- The prevalence of hepatitis C virus antibody is high among hemodialysis patients and potential kidney transplant candidates. Hepatitis C is the main cause of chronic liver disease in patients with end-stage renal disease. HCV infection is the most important cause of renal diseases in several countries of the world. But at present no vaccine is available for it. Because of the increasing prevalence rate, this is necessary that medical personnel and health care workers must be educated and trained about the danger and consequences of HCV infection. All anti HCV antibody positive patients must be considered highly infectious and must be prohibited from donating blood, organ, tissues or semen. Therefore, routine screening of all the blood donors should be done in Blood Bank.
- We conclude that HCV prevalence particularly in developing countries like India, the present study and other similar studies by early detection of viral prevalence for in assessment of disease burden in community, in controlling the complications of viral infections in renal diseases and for effective implication of preventing and curative strategies. HCV directly affects epidemiology, morbidity, mortality, socioeconomic and preventive aspects. Infection with HCV is a growing health problem assuming epidemic proportion specially effecting young adults causing morbidity and mortality

resulting in loss of man power thus badly affecting the economy of countries. Routinely Ag-Ab detection tests and viral assays are done. It is very important that the priority for HCV control is concentrated on early detection and effective treatment of both HCV and HBV of which may offer the greater chance of prolonging the life of those suffering from HCV infection. It is suggested that education of public at large to increase the general awareness towards the transfusion transmitted diseases and how to prevent them. This calls for stringent screening measures for blood borne viruses at departmental laboratories and blood banks for all sera/blood processed. Health care workers, especially unsuspecting surgeons and nurse are at high risk of contracting such diseases from unscreened patients, reiterating the need for universal precautions to be followed at all times.

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