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Original Research Article

Prevalence of hepatitis C in patients with chronic kidney disease at a tertiary care hospital in north India: a retrospective analysis

Amrit Dhar[1], Vijant S. Chandail[1]*, Viney Sambyal[1], Vinu Jamwal[2]

[1]Department of Internal Medicine, Government Medical College Jammu, Jammu and Kashmir, India
[2]Department of Internal Medicine, ASCOMS, Jammu, Jammu and Kashmir, India

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***Correspondence:**
Dr. Vijant S. Chandail,
E-mail: vijantchandail@yahoo.co.in

ABSTRACT

Background: Hepatitis C and chronic kidney disease (CKD) both present an unsolved public health problem Hepatitis C virus (HCV) is easily transmitted in haemodialysis units and by kidney transplantation. HCV leads to increased mortality and morbidity due to cirrhosis and hepatocellular carcinoma, while accelerating the progression of CKD. The aim of the study was to describe the demographic, clinical/biochemical profile and prevalence of patients with CKD who have HCV infection.
Methods: This was a retrospective analysis of patients with CKD who presented to out/in patient department of medicine in a tertiary care center in Jammu from a period of Feb 2016 to Nov 2018. Detailed clinical history along with previous lab reports were noted and tests for HCV infection were conducted in all patients. Diagnosis of HCV was made via HCV RNA(RT PCR) and positive Anti HCV IgG serology.
Results: Total 67 patients were included with median age of 54 years (range 43-72 years) with majority 76.1% being males, and 71.6% within 41-60 years age group. 31.4% were HCV positive out of which 81% were males. 7 patients were found to have co-infection with HIV and HBsAg. Genotype 1 (72%) was found to be more common than Genotype 3. Ultrasonography and Upper GI endoscopy showcased 57% with dilated spleenoportal axis and oesophageal varices respectively.
Conclusions: Prevalence of HCV infection in CKD patients is high with genotype 1 being commonest. False negative Anti HCV antibody is common hence screening with HCV RNA is recommended. Strict universal precautions should be employed in hospitals and dialysis units to prevent transmission.

Keywords: Chronic kidney disease, Haemodialysis, Hepatitis C, Prevalence

INTRODUCTION

Currently India harbours around 10-15 million infected people with Hepatitis C virus(HCV) with a prevalence of 0.5-1.5% of population.[1] Frequency of Hepatitis C in patients of Chronic Kidney Disease (CKD) on hemodialysis has always been found to be more than general population with reports suggesting prevalence between 5-60% in developed countries and more than 50% in developing countries.[2,3]

HCV is easily transmitted by kidney transplantation as well as in hemodialysis(HD) units due to breakdown of

universal precautionary procedures.[4] Wide variations has been shown to exist in prevalence of HCV infection in different dialysis units and countries as shown by Dialysis Outcomes and Practice Patterns Study (DOPPS). Mean HCV Facility prevalence was around 13.5% with variations ranging from 2.6% to 22.9% among countries (DOPPS).[5] Risk factors such as number of blood transfusions, duration of CKD, Hepatitis B/HIV co-infection, prior transplant have been identified.

There exists a strong causal association between Hepatitis C infection and kidney diseases of glomerular origin like mixed cryoglobinemia, membranous nephropathy, membranoproliferative glomerulonephritis and polyarteritis nodosa.[6,7] In addition, treatment of these patients with conventional therapy remains a big challenge due to differences in response rates compared to normal individuals.[8,9] Although many studies have been done on prevalence of HCV in CKD patients in India but the data on these patients remains scarce. The aim and objective of this study was to describe the demographic characteristics, clinical/biochemical profile of patients and prevalence of patients with CKD who have HCV infection presenting in a tertiary care centre in Jammu.

METHODS

This is a retrospective analysis of patients with chronic kidney disease who presented in out-patient department and in-patient department of medicine, in a tertiary care center in Jammu from a period of February 2016-November 2018 (i.e. over a period of 2 and half years). Informed consent from all the patients enrolled in the study was obtained. CKD cut-off of GFR (eGFR) less than 60 ml/min/1.73m^2 (GFR category G3a-G5) or persistent proteinuria by urinary dipstick for 3 months or more was set.[10] eGFR was calculated by CKD-EPI creatinine equation:

$141\times\min(SCr/\kappa,1)^{\alpha}\times\max(SCr/\kappa,1)^{-1.209}\times0.993^{Age}(\times1.018$ if female)($\times1.159$ if black).

where SCr is serum creatinine (in mg/dl), κ is 0.7 for females and 0.9 for males, α is -0.329 for females and -0.411 for males, min is the minimum of SCr/κ or 1, and max is the maximum of SCr/κ or 1.[10]

During the initial visit in OPD or Inpatient, detailed clinical history and physical examination was done, previous medical records and lab information was reviewed to obtain data on patient's age, sex, history of diabetes, hypertension, and other possible causes of CKD like glomerulonephritis, polycystic kidney disease etc. Tests were conducted for HCV along with screening for HBsAg and HIV to look for concomitant co-infection. HCV RNA quantitative by RT-PCR and HCV genotyping was also obtained whenever possible. Liver function tests (LFT) were obtained in HCV positive patients only. Total bilirubin, Serum albumin, AST, ALT, serum creatinine, platelet count, and INR was obtained. Ultrasonography and Upper GI endoscopy reports were also noted.

The diagnosis of HCV was made via HCV RNA (RT-PCR) and/or positive Anti HCV IgG serology (3rd Gen ELISA) and was done in all patients. Also, Patients who were Anti HCV IgG negative but HCV RNA positive (False negative) were included in the study and grouped under HCV Positive (Refer Table 1).

Patients who were HCV RNA negative were grouped under HCV Negative regardless of Anti HCV serology status.

Table 1: Data of patients included in HCV positive group.

Anti HCV	HCV RNA	HCV positive (n=21)
Positive	Positive	Included (19)
Negative	Positive	Included (2)
Positive	Negative[a]	Excluded(5) (under HCV Negative)
Negative	Negative	Excluded (under HCV Negative)

[a] HCV RNA negative on two occasions at three months interval in absence of treatment

Patients with acute renal failure, whose HCV RNA was negative on two occasions or those receiving treatment for HCV were excluded from the study.

Statistical analysis

Continuous parametric variables were reported as Mean±Standard deviation and categorical variables were expressed as percentages. Categorical variables were compared using chi-square test and Fischer's exact test and continuous variables were compared using students t-test. All analysis was performed using SPSS 20.0 software. For all tests, p values of <0.05 was considered significant.

RESULTS

A total of 67 patients were included in the study. The median age was 54 years with a range from 43-72 years. Mean age of patients was 55.32±7.98 (SD) years. Majority of the patients, 48 (71.6%) were included in the 41-60 age group (Table 2).

Table 2: Distribution of patients on the basis of age groups.

Age Groups	No. of Patients (n=67)	%
41- 50	19	28
51- 60	29	44
61-70	15	22
>70	4	6

Of all patients, 51 (76.1%) were males and 16 (23.9%) were females. Most common etiology of CKD was diabetes 36/67 (54%), followed by hypertension 27/67 (41%), while 4% (n=3) was due to glomerulonephritis. Etiology of rest 1% (n=1) was not specified or unknown. Mean Creatinine of patients was 5.88±2.67 mg/dl with a range of 1.8-15.4 mg/dl. Of all patients, 45 (67%) had stage V CKD, 16 (24%) had stage IV CKD, 4 (6%) had stage IIIb CKD and 2 (3%) had stage IIIa (KDIGO 2012).

Out of the 67 patients with CKD, 31.4% (n=21) were HCV positive and 68.6% (n=46) were HCV negative. Of those who were HCV positive, 81% (n=17) were males and 19% (n=4) were females. Also, 7 (33.3%) patients were found to have co-infection, 5 with HBV and 2 with HIV.

Mean AST was 90.23±105.39 IU/L and ALT was 74.52±85.98 IU/L, mean total bilirubin was 5.04±4.44, mean serum albumin was 3.42±0.78 mg/dl. In addition, Mean serum creatinine of HCV positive patients was 7.61±3.40 mg/dl (Table 3).

Genotyping was done on all the HCV positive patients and Genotype 1 was found to be more common than Genotype 3, with 72% (n=15) patients with genotype 1 and 18% (n= 6) with genotype 3.

There were 24 were Anti HCV positive of which 19 were HCV RNA positive as well while 5 were HCV RNA negative. 2 were HCV RNA positive but anti HCV negative. Sensitivity and specificity of Anti-HCV antibody test was thus found to be 90.5% and 89.1% respectively.

Table 3: Biochemical parameters of HCV positive patients (n=21).

Parameters	Mean (SD)	Range	Unit
Bilirubin	5.04(4.44)	0.8-18	Mg/dl
Albumin	3.42(0.78)	2.1-4.3	Mg/dl
AST	90.23(105.39)	18-416	IU/L
ALT	74.52(85.98)	11-384	IU/L
Creatinine	7.61(3.40)	1.8-15.4	Mg/dl
Platelet count	1.70(1.03)	0.26-3.84	Lac/cu-mm
INR	1.41(0.44)	0.9-2.7	-

Characteristics of patients with and without HCV are compared in Table 4.

Ultrasonography was done in all the HCV positive patients (n=21), of which 12 (57%) patients showed coarse echopattern with dilated spleenoportal axis, out of which 3 were females and 9 were males.

Rest 9 (43%) had no to mild hepatomegaly seen on USG. Also, 5/12 (42%) had ascites. Hepatocellular carcinoma was not detected in any of the HCV positive patients.

UGI endoscopy was done in all the HCV positive patients and out of 21, only 12(57.14%) patients showed esophageal varices (grade III and IV) with portal hypertensive gastropathy. 3 out of 12 patients also showed evidence of Gastric antral vascular ectasia (GAVE).

Table 4: Comparison of Characteristics of HCV positive and HCV negative patients.

Characteristic	HCV positive N=21	HCV negative N=46	P value
Age	54.6±5.5	55.6±8.7	0.63(NS*)
Male	17 (81%)	34 (74%)	0.758 (NS†)
Female	4 (19%)	12 (26%)	
CKD stage			
IIIa	1 (5%)	1 (2%)	0.272(NS‡)
IIIb	1 (5%)	3 (6%)	
IV	2 (10%)	14 (31%)	
V	17 (80%)	28 (61%)	
Etiology			
Diabetes Mellitus	11 (52%)	25 (54%)	0.523 (NS‡)
Hypertension	10 (47%)	17 (37%)	
Glomerulonephritis	0 (0%)	3 (6%)	
Others	0 (0%)	1 (2%)	
Genotype			
1	15 (71%)	-	-
3	6 (29%)	-	

NS, not significant; CKD, chronic kidney disease, Data expressed as n(%) or mean ±standard deviation; various tests used for statistical significance($p<0.05$), *Students t-test; †Fischers exact test; ‡chi- Square test.

Table 5: Prevalence of HCV infection in CKD patients in various Indian studies.

Author	Place	Year	Total no. of patients	Patients with HCV infection(%)
Jaiswal SP[11]	Indore	1996	105	41.9%
Gosavi[12]	Mumbai	1997	72	27.8%
Chandra M[13]	Hyderabad	2004	256	46%
Reddy[14]	Hyderabad	2005	151	13.23%
Medhi[15]	Delhi	2008	250	17.2%
Jasuja[16]	Delhi	2009	119	27.7%

DISCUSSION

Many studies have been conducted from India about the prevalence of HCV infection in CKD patients on hemodialysis[11-16] (Table 5). All these studies cite high prevalence (10-40%) which corroborate with the prevalence of 31.4% in this study. Many such studies have been conducted in other countries as well. In a study in Pakistan, by Shafi et al, frequency of Hepatitis C in CKD patients was 27.2%.[17] In a study by Fabrizi et al, hepatitis C antibody was present in 20% of CKD patients.[18] Similarly the mean HCV prevalence was found to be 13.5% by Fissell et al, in a study across 7 countries (DOPPS).[5] Variations in results is most likely due to difference in prevalence of Hepatitis C in various geographical regions, different time periods of the studies, variations in methods of detecting Hepatitis C infection and practice of infection control measures in different countries. In addition, in Indian context the prevalence of Hepatitis C infection in CKD patients in our study is significantly higher than the general population (0.5-1.5%).[1]

Male predominance was seen in this study with 81% of HCV positive patients being males comparable to 69% males in another study by Arora et al, which can be associated due to higher incidence of CKD per se, and in males owing to higher incidence of diabetes and hypertension. Most common age group was 41-60 years, as in other studies ,again attributed to high incidence of CKD in this age group.[19]

In this study around 19% of HCV positive patients were females, this low number could be because there exists strong evidence in favour of higher HCV clearance rate in females compared with males.[20] Females with CKD have higher risk of accelerated disease progression and vascular and renal target organ damage than men.[21]

In this study, co-infection was seen in 33.3% patients though in some studies it is seen to be quite high (up to 50%).[13,22] This is of importance because patients co-infected with HIV have been reported to have an increased mortality and worse prognosis. Thus, it is recommended that all patients be screened for co-infection (HIV 1 and 2, HBsAg).[23,24]

In this study, most of the HCV patients were symptomatic for liver disease, with elevated ALT, AST and serum bilirubin levels. Therefore screening at regular intervals (ALT, AST every month, HCV RNA every 6 months) is recommended in CKD patients who are on Hemodialysis where HCV prevalence is quite high. Recently defined upper limit of ALT (30 and 19 IU/L for males and females respectively) might help in picking more patients with HCV infection but may lead to unwanted testing as most of them may not have HCV.[25] On the other hand, 42% of HCV positive patients with USG determined dilated spleenoportal axis had ascites with signs of portal hypertension suggesting imminent liver failure in future with a need of simultaneous liver-kidney transplant rather than kidney transplant alone which adds to the burden of the patient.

In this study, we found genotype 1 (71%) being more common among patients than genotype 3 which is overall the more common genotype be found among the Indian population. Our findings are similar to findings from other studies from India who also reported genotype 1 to be more prevalent among CKD patients, reasons for which are unclear.[26,27] Genotype 2 and other genotypes are infrequent.

In this study, 9.5% had false negative anti HCV antibodies, while HCV RNA was positive in the same. We performed both HCV RNA PCR and Anti HCV antibody (ELISA) for all patients. Sensitivity and specificity of Anti HCV Antibody test was found to be 90.5% and 89.1% respectively. Weinstein et al., reported 94% sensitivity and 91% specificity of 3rd generation microparticle immunoassay in identifying HCV RNA positivity.[28] Anti HCV essays come under two categories: enzyme immunoassay (EIA) and recombinant immunoblotting assay (RIBA). EIA is used most often due to its low cost. Currently, Third generation Anti HCV EIA (ELISA) is used as a screening tool for diagnosis of HCV infection as it has shown better performance than the previous two generations with improved sensitivity and specificity.[29,30] HCV RNA detection by reverse transcriptase PCR (RT-PCR) is used as a gold standard to identify HCV infection as it can detect HCV RNA before the appearance of Anti HCV antibodies or elevation of ALT levels.[31,32] The PCR assays are considered the most sensitive test for

diagnosing HCV infection. Since, this study had a false negative of around 9.5% in Anti HCV antibody test, coupled with the fact that antibody response in patients on chronic hemodialysis and after renal transplantation is poor, therefore it can recommend that HCV RNA should be obtained in CKD patients if HCV is suspected.[33,34]

HCV infection has been associated with greater risk of development and progression of CKD, as well as decreased graft and patient survival in patients who eventually undergo kidney transplantation.[35,36] Thus, it is of utmost importance that strict universal precautions should be employed in dialysis centres and hospital wards where CKD patients are admitted to prevent transmission of infection to other patients and health care workers.

In addition, it can be argued that it might be useful to study HCV infection in pre-dialysis CKD patients due to following: 1) HCV can accelerate the progression of CKD towards final stages of renal disease; 2) dialysis patients with HCV infection have greater risk of mortality comapared to HCV negative dialysis patients.[37] Therefore, identification and treatment of hepatitis C in CKD patients at an early stage may ameliorate progression of CKD, though further studies are required to verify.

This study had several limitations.

- This is a retrospective, single center study with limited sample size thus, no specific risk factors for hepatitis C infection in CKD patients could be found
- Liver function tests were done only in HCV positive patients, thus no comparisons between the status of liver functioning in HCV positive and HCV negative patients could be done. Thus, no conclusion regarding the pre-existing liver diseases in CKD patients could be made
- Long term follow-up after treatment and discharge of in-patient is not available.

CONCLUSION

In conclusion, the prevalence of HCV infection in CKD patients is high (31.4%), with genotype 1(71%) being the most prevalent. False negative anti HCV antibody is also common thus, screening with HCV RNA is recommended. Also, HCV detection in pre-dialysis patients along with strict universal precautions in hospitals and dialysis center can be recommended. Further studies are needed to see whether identification and treatment of hepatitis C in CKD patients will improve mortality .

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