



**COMPARATIVE STUDY OF SERUM CREATININE IN PATIENTS GOING
THROUGH HEMODIALYSIS WITH OR WITHOUT HEPATITIS C INFECTION**

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ABSTRACT

The most frequent cause of chronic viral liver disease in hemodialysis patients is hepatitis C. Hemodialysis patients continue to have a high prevalence of chronic Hepatitis C Virus (HCV) infection, which is a serious public health issue. Comparing serum creatinine levels in hemodialysis patients with and without HCV infection was the main goal of this study. From March to June 2023, a four-month cross-sectional study was carried out. Patients receiving hemodialysis at different dialysis facilities throughout Lahore had their blood samples taken. Alkhidmat Lab in Lahore handled the processing and analysis of these samples. Long-term dialysis patients were tested for the presence of HCV using the Enzyme-Linked Immunosorbent Assay (ELISA). 102 samples in all were analyzed. Of these, 63 patients had negative HCV tests and 39 had positive ones. A significant correlation between HCV infection and elevated serum creatinine levels in hemodialysis patients was found by statistical analysis, with a p-value of less than 0.05. Additionally, the data revealed that male patients had a higher prevalence of HCV infection (61.2%) than female patients (38.8%). According to the study's findings, patients undergoing long-term hemodialysis are still at serious risk from Hepatitis C. Additionally, the strong link between HCV infection and changed creatinine levels emphasizes the necessity of ongoing observation and early detection techniques to enhance patient outcomes and lessen the burden of disease in this susceptible group.

INTRODUCTION

In hemodialysis patients, the most common cause of viral liver disease is HCV infection (Knudsen et al., 1993) . Approximately, 170 million people have chronic HCV infection globally which can lead to liver cirrhosis and hepatocellular cancer and it is more common among those receiving hemodialysis treatment.(Alter, 2007)(Shepard et al., 2005). In certain countries, such as India, the incidence of HCV infection on dialysis patients was 83%. (Chandra et al., 2004) . Venezuela has 71%, UAE has 46%. and low predominance have been found in Switzerland (Couser et al., 2011). When HCV infection occurs in hemodialysis patients, it frequently causes chronic liver disease with cirrhosis and increases the risk of problems if those patients receive a kidney transplant because immunosuppressive medication is necessary to prevent rejection. (S0270929502700375, n.d.) . Kidney disease can be evaluated in terms of overall renal function (GFR) and various kidney damage markers (serum creatinine and blood urea)(Arora et al., 2020). Kidney receives blood supply of 1/5th of cardiac output essential for performing its principal function of filtering blood. The amount of liquid that passes through Bowman's sac per unit of time is called GFR (Webster et al., 2017).

A compromised filtration mechanism allows GFR to decrease significantly, and is clinically reported as proteinuria. (CKD) is considered to be 60 mL / min per 1.732 over period of 3 months (S0085253815524034, n.d.) . Primary disease process involves severe proteinuria and low

albumin levels in blood due to Nephrotic syndrome ("KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target,," 2007) . CKD is characterized as the existence of kidney injury, evidenced by excessive excretion of albumin or impaired bone function, quantified by GFR, which

occurs for more than three months(Levey et al., 2005) (Gansevoort et al., 2013) . Those with early CKD have higher risk of dying from end stage renal disease as their condition progresses (Go et al., 2004) .Obesity, cholesterol, hypertension, diabetes, smoking, and poor lifestyle choices all worsen the condition of dialysis individuals.(Cusumano et al., 2013).

End-stage renal disease (ESRD) patients have been treated with renal replacement therapy (RRT), which includes hemodialysis (HD), peritoneal dialysis (PD), and kidney transplantation globally since the 1940s. (Lysaght, 2001)(Helwig et al., n.d.) Patients on RRT have been constantly increasing, particularly in developing nations. (Moeller et al., 2002)(Grassmann et al., 2005) . Above one million patients are documented to be taking HD for extended periods of time and this number is rising substantially each year. (Scholar, n.d.) . Dialysis reduces a variety of clinical indications of kidney failure and prevents early death. Despite its effectiveness, HD patients experience poor quality of life, greater mortality rates and more hospital readmissions than the general population. (Fernandes et al., 2021).

Among HD treated people, the incidence of HCV infection is 3.4 to 32.1% which is really alarming. (Quiroga et al., 2006). Patients going for HD treatment are confronting certain risks of HCV procurement due to many factors i.e., reduced cellular immunity, frequent hospitalizations, regular exposure to bloods during transfusions and vascular access, different pre-existing diseases such as diabetes, high fat levels and long-term kidney failure. These factors increase the risk of exposure to nosocomial infections (Kishi et al., 2006) (Kumar et al., 2013) . Intravenous drug use, blood transfusions from unscreened donors, sharing and reuse of syringes, and other similar practices are the most common mode of acquiring HCV infection. (Hoenig & Zeidel, 2014) .The rationale for this study is based on

the need to investigate and understand the impact of hepatitis C infection on serum creatinine levels in ESRD patients undergoing hemodialysis. By conducting a comparative analysis, we aim to elucidate whether hepatitis C infection exacerbates renal dysfunction and affects serum creatinine levels, thereby influencing the clinical management and outcomes of these patients.

LITERATURE REVIEW

Chronic kidney disease (CKD) is one of the most pressing health concerns around the world, with more and more people progressing to end-stage renal disease (ESRD) which necessitates renal replacement therapy, including hemodialysis. Determining renal function by measuring serum creatinine levels is important in evaluating the renal function of patients and is often raised in those with ESRD. Nonetheless, serum creatinine levels are influenced by a myriad of factors such as muscle mass, nutrition, and infections such as hepatitis C virus (HCV).(Pol et al., 2019)

Patients on hemodialysis have a higher prevalence of HCV due to increased risks of vascular access, frequent transfusions, and long-term contact with the healthcare system. Prevalence of HCV in the hemodialysis population is reported to be between 10 to 60 percent depending on the region and the healthcare practices in place. The presence of HCV infection in patients with ESRD not only makes the clinical management more challenging, but also alters the biochemical profile of the patient, in particular serum creatinine.(Fabrizi et al., 2015)

Systemic effects caused by HCV infection go beyond organ damage and include changes to protein metabolism, nutrition, inflammation, and other processes which may influence serum creatinine levels. Some reports indicate that HCV patients undergoing hemodialysis may have lower serum creatinine compared to non-HCV hemodialysis patients, possibly because of muscle wasting from chronic liver disease

and inflammation.(Fabrizi et al., 2015; Pol et al., 2019)

On the other hand, some researchers have reported that serum creatinine concentrations in HCV-positive and HCV-negative dialysis patients did not differ significantly after adjusting for age, sex, dialysis adequacy, and other factors. These differing results highlight the urgent need for more thorough comparative research, especially in areas with high prevalence of HCV in dialysis populations, such as South Asia and the Middle East.(Corouge et al., 2016)

Moreover, the combination of liver and kidney dysfunction often creates specific difficulties in diagnosis and treatment. Because of diminished production of creatinine in patients with liver dysfunction, serum creatinine levels may not reflect renal function accurately. This makes the interpretation of creatinine levels in HCV-positive hemodialysis patients tricky.(Goldfarb-Rumyantzev et al., 2005)

Therefore, conducting a comparative study evaluating serum creatinine levels in hemodialysis patients with and without hepatitis C infection is important to assess whether HCV infection independently alters renal function markers and enhance renal function assessment in this population. Such information could be helpful regarding the prognosis and in refining the optimization of dialysis regimens.

METHODOLOGY

STUDY DESIGN AND DURATION:

A Cross-sectional study was carried out from March 2023 to June 2023, a total of four months. This study's main goal was to examine and contrast particular blood parameters between hemodialysis patients, with an emphasis on those who had or did not have an infection with the Hepatitis C virus (HCV). To get a representative and varied sample of hemodialysis patients, the study was conducted in several dialysis facilities located throughout the Pakistani city of Lahore.

Each participant's blood was drawn using standard venipuncture techniques, guaranteeing patient safety and appropriate aseptic techniques. Patients who voluntarily agreed to participate in the study and had been receiving hemodialysis for a minimum specified amount of time met the inclusion criteria. Patients with co-morbid conditions that could materially change laboratory results unrelated to dialysis or HCV status were excluded.

To guarantee sample integrity, the blood samples were transported under stringent cold chain conditions after collection. Following that, every specimen was processed and examined at Alkhidmat Laboratory, a respectable diagnostic center with a Lahore location that is well-known for its standardized procedures and quality control measures.

PATIENT POPULATION & GROUPS:

The study involved the enrollment of 102 patients in total. In order to ensure that the chosen cohort had enough exposure to the dialysis procedure for accurate biochemical analysis, all participants had been undergoing maintenance hemodialysis for at least six months.

The enrolled patients were divided into two groups according to their HCV status in order to evaluate the effect of HCV infection on kidney function indicators, particularly serum creatinine. Patients who tested positive for Hepatitis C virus infection by serology were included in Group A. The group of hemodialysis patients who also had an HCV infection was represented by these patients. However, hemodialysis patients who tested negative for HCV infection were included in Group B, which was used as the control group for comparison.

Serum creatinine, an important indicator of renal function and dialysis adequacy, was one of the biochemical differences that could be clearly and methodically investigated by splitting the patients into HCV-positive and HCV-negative groups. The study sought to

determine whether HCV infection significantly affects serum creatinine levels in patients receiving long-term hemodialysis by examining and contrasting these two groups. The results of this study could help develop better treatment plans for patients who have both an HCV infection and renal failure.

COLLECTION OF SAMPLES:

Properly trained technologist took the blood from patients in the vials which had had clot activator in it. For phlebotomy, sterile syringes served the purpose.

METHOD:

HCV test was carried out using serum.

STEPS:

As soon as the samples were loaded into the analyzer, they were carefully positioned inside the sample disk and scanned. This guaranteed precise sample identification and appropriate placement for further examination. Selecting the proper test protocols via the automated interface came next after the system verified that the samples had been loaded correctly.

The testing procedure was streamlined through automation, which reduced human error and increased productivity. The system started the automated analysis of the samples after setting the test parameters. In addition to improving workflow, automation preserved the accuracy and consistency of the results across several samples.

The system quickly generated and reported the results after the test cycles were finished. Depending on the reporting format chosen, the analyzer was configured to either display or print the results. Following that, these findings were examined and interpreted in accordance with accepted laboratory practices.

Crucially, quality control samples were used in every test. As internal checks to confirm the precision and accuracy of the test system, controls are crucial parts of laboratory testing. The laboratory made sure that the tests were

reliable and valid by using controls that are unique to each assay.

The standard operating procedures used in contemporary clinical laboratories are reflected in this methodical and controlled approach to sample handling, test automation, and result reporting. It emphasizes how important automation and quality control are to getting reliable diagnostic results.

Above 1.0 considered as reactive where below 1.0 considered as non-reactive so the cut-off value is 1.0.

CREATININE DETERMINATION

METHOD:

Normal range of creatinine level is 0.8-1.2mg/dl. Above 1.2 considered as kidney defect. Using a routine chemistry analyzer creatinine test was performed from serum samples.

STEPS:

1. We let the chemicals to come up to room temperature (18–30 °C).

2. One well was taken as control, one well as standard, and one well as a sample.

3. 400µl of R1 diluent was added into each well.

4. 100µl R2 was then added to each well.

5. 50µl of Standard was added into standard well, 50µl of control into control well.

6. 50µl of Sample was added into sample well. Plate reader were calibrated using blank well and absorbance was read at 450nm.

7. Then we read the absorbance urgently after adding the diluents.

ETHICAL APPROVAL:

An ethical approval was obtained from NUR International University, Lahore and Alkhidmat Lab Lahore under ethical letter number AKL-25-2023.

STATISTICAL ANALYSIS

Version 22 of the Statistical Package for the Social Sciences (SPSS) was used to carefully analyze the data gathered for the study. For performing statistical analysis in the social sciences, medical research, and other domains

involving quantitative data, this software is well-known and frequently utilized. It provides a wide range of tools that make statistical testing, data management, and result interpretation easier. SPSS version 22 was used in this study to guarantee precision, dependability, and effectiveness in managing all data variables.

Frequencies (numbers) and associated percentages were used to summarize and present categorical data, which are variables that represent discrete groups or categories as opposed to continuous values. The distribution and proportion of variables within the sample population can be better understood with this method, which improves the interpretability and informativeness of the results.

Furthermore, a P-value threshold of less than 0.05 was deemed significant in order to ascertain whether statistically significant relationships or differences between variables were present. Accordingly, any result with a P-value less than 0.05 was considered to have a statistically significant association, suggesting that the observed associations or differences were unlikely to have happened by accident. Since it represents a 95% confidence level in the findings, this significance level is typically chosen in scientific research. All things considered, this systematic approach to data analysis made sure that the study's conclusions were accurate, scientifically sound, and statistically valid.

RESULTS

The study participants' baseline clinical and demographic data are shown in Table 1. Middle-aged people were the most affected in this study population, as the majority of the patients were between the ages of 41 and 50. The complications of chronic kidney disease may become more noticeable in this age group, necessitating treatments like hemodialysis.

The distribution of participants by gender showed a clear male preponderance over females. This gender disparity could be due to

either a higher prevalence of end-stage renal disease (ESRD) in men or perhaps more males in the study area having access to or using hemodialysis services. To comprehend the fundamental causes of this discrepancy, more research would be necessary.

In terms of hemodialysis frequency, a sizable fraction of patients (47.1%) were receiving dialysis two or three times a month. This implies that many people were not getting dialysis as often as the recommended two to

three times a week. Financial limitations, restricted access to dialysis facilities, or cultural and personal factors that impact compliance are some of the possible causes of such infrequent dialysis sessions. Since infrequent dialysis is linked to insufficient toxin removal and fluid overload, which may result in subpar clinical outcomes, this lower-than-optimal frequency may have an impact on patient outcomes.

Table 1: Baseline Demographic and Clinical features of Subjects

Variables	N (%)
Age	
20-30	16(15.6)
31-40	21(20.5)
41-50	33(32.2)
51-60	18(17.6)
60 and above	14(13.7)
Gender	
Male	54(52.94)
Female	48(47.06)
Time Interval of Hemodialysis	
Twice a week	13(12.7)
2-3 times a month	48(47.1)
3-4 times a month	38(37.3)
3 times in a week	03(2.90)

The demographic distribution of hemodialysis patients who were positive for the Hepatitis C Virus (HCV) is shown in Table 2. A total of 102 patients undergoing routine hemodialysis were included in the study. 39 of these patients tested positive for HCV, making up a sizable portion of the study population.

The frequency of infection was significantly higher in male patients than in female patients, according to a gender distribution analysis of HCV-positive cases. This suggests that among the hemodialysis population being studied, there is a gender difference in the prevalence of HCV. The higher proportion of HCV-positive men raises the possibility of behavioral patterns or risk factors related to gender that could

increase the spread or vulnerability of HCV infection in this population.

Because hemodialysis patients are at a higher risk of blood-borne infections because of repeated vascular access and possible exposure to contaminated equipment or blood products, the results highlight the significance of routine HCV screening in dialysis facilities. The demographic information emphasizes the need for improved infection control procedures in dialysis facilities as well as gender-focused preventive strategies.

Furthermore, knowing the demographics of those impacted can help legislators and medical professionals create focused monitoring, education, and treatment initiatives. In order to lower transmission rates and enhance patient outcomes in this susceptible group, early

detection and treatment of HCV-positive patients are essential.

Table 2: Demographic Profile of HCV Positivity in Hemodialysis Patient

Variable	N (%)
Frequency of HCV in Hemodialysis Patients	
Positive	39(38.2)
Negative	63(61.8)
Gender Distribution of HCV Positive Patients	
Male	24(61.2)
Female	15(38.8)

A thorough analysis of serum creatinine levels in hemodialysis patients, with an emphasis on those with Hepatitis C Virus (HCV) infection, is given in Table 3. Particularly when it comes to elevated creatinine levels, the data shows a noteworthy trend among patients with HCV. The table shows that serum creatinine levels above 6.0 mg/dL were present in a significant majority of HCV-infected patients undergoing treatment. In particular, 27 of the 39 HCV-positive patients (69.2% of the group) had creatinine levels higher than 6.0 mg/dL. This demonstrates unequivocally a strong correlation between these patients' advanced renal impairment and HCV infection.

A significant percentage of HCV-infected patients were in the moderate range of serum creatinine values, which ranged from 1.4 to 6.0 mg/dL, in addition to the highest creatinine

bracket. Twelve of the 39 patients in this category were documented, making up roughly 23.07% of the entire HCV-positive population. Even though they aren't mentioned in the data summary, the remaining patients might have lower creatinine levels or other clinical considerations.

These results highlight the seriousness of kidney damage in patients who are receiving hemodialysis and having an HCV infection at the same time. The significance of careful renal monitoring and possibly more forceful clinical intervention in this subgroup is highlighted by the high proportion of people with critically elevated creatinine levels. Additionally, it raises the possibility that an HCV infection could worsen underlying renal pathology or affect how well dialysis maintains ideal biochemical parameters.

Table 3: Comparison of Creatinine levels in HCV Positive and HCV Negative Hemodialysis Patients

	Creatinine Above 1.6-6.0 mg/dl	Creatinine Above 6.0 mg/dl	p-value
HCV Positive	12(11.8)	27	<0.001
HCV Negative	52	09	<0.001

DISCUSSION

The main objective of this study is to compare serum creatinine in patients undergoing hemodialysis with or without Hepatitis C infection. In current study, findings which is 39(38.2%) were recognized as positive for HCV and the remaining which included 63(61.7%) were negative. Out of all the total positive cases, males were more prone to get infected as the results elaborates a staggering number of 24 (61.53%) positivity in contrast to females with only 15 (38.4%) cases. In current study, ages between 41 to 50 were highly prevalent age group with percentages of (32.2%) and lowest category can be seen among ages 60 above with only (13.7%) cases.

The rate of frequency of HCV infection in current research was being recognized as extremes even by comparing with another research. Patient who are taking the aid of hemodialysis are being treated to have elevated hazards of getting infected by HCV in contrasts to those who are getting less treatments in current research. In relation to gender distribution and age wise data that current study showed, the probability of males getting infection is very much true as the same results were produced Zarkoon et al.,(121-126-1-PB, n.d.)

Similar research performed by Bdour S in Jordan in 2002 recorded that 34.6 percent of patients with hemodialysis were HCV infection positive, which is close to current figures(Bdour, 2002)

Compared to other related study's findings, inappropriate blood sample before to transfusions, needless exposure to blood and blood products, and a lack of knowledge about how HCV is delivered are all factors that contributed to the significantly increased rates of incidence and death in this population. The difference of results can be also due to factors of different protocols for screening, sanitation implementation and contrasting facilities. Contamination of dialysis instruments, improper sanitization and cleaning of exterior surfaces, inadequate contact with healthcare workers, appliances and patients, and poor treatment of

parenteral medications are the most significant errors in healthcare quality in hemodialysis centers(Bianco et al., 2013).

The renal abnormalities are linked with younger age may result from the liver's high metabolic activity and the body's high immune response to viral infection, both of which place a burden on the kidney and produce an increase in creatinine level. Who reveals that the liver biopsy provides important information on the severity of HCV-related hepatic illness, but caution is needed in patients with CKD due to the likely reduced risk of blood involvement. After the initial HCV infection, the internal kidney inflammation known as glomerulonephritis may take years or even decades to develop(Galli et al., 1995)

A study confirms that the presence of anti-HCV Ig is associated with the progression of kidney disease, with a greater average of (+) anti-HCV in patients with more severe CKD(Lee et al., 2010).The variation in renal disease based on several variables, such as the association between HCV infection or non-HCV infection, and compare it to (variation in gender, age group, normal and abnormal of creatinine). In above table patient who tests positive for HCV in the kidney defect group, which consists of (39 patients with HCV infection and 63 HCV non-infected individuals). Current study provided information on the significance of hemodialysis treatment for the spread of HCV infection in Lahore and significant comparison creatinine levels in patients who have HCV infection vs those who do not have HCV.

CONCLUSION

According to the study's findings, the hemodialysis population is still at serious risk from Hepatitis C Virus (HCV), especially in developing nations like Pakistan where the prevalence of HCV infections is still startlingly high. 38.2% of the total hemodialysis patients evaluated tested positive for HCV infection, according to the study's findings. This significant percentage emphasizes how urgently

dialysis units and other healthcare facilities in the area need to implement efficient infection control procedures and awareness campaigns.

A more thorough examination of the demographic information revealed that men made up 61.2% of the infected cases and the majority of HCV-positive patients. Numerous socio-behavioral and clinical factors, including increased exposure to risky environments, a higher frequency of invasive procedures, or ignorance of the routes of transmission, could be responsible for this gender disparity. Additionally, a significant percentage of HCV-positive people (about 38.8%) were between the ages of 41 and 50. This middle-aged group might be a cohort that has had dialysis for a long time or has accumulated risk factors over time.

The link between HCV infection and serum creatinine levels in hemodialysis patients was one of the study's key clinical findings. Serum creatinine levels were found to be noticeably higher in HCV-infected people than in non-infected people. Increased levels of serum creatinine in patients with HCV may indicate either more severe stages of renal impairment or additional hepatic-renal interactions that are contributing to worsening health conditions. Elevated serum creatinine is typically a sign of decreased kidney function. In order to prevent further complications, this finding highlights the need for ongoing monitoring and customized management plans for dialysis patients with HCV.

Multiple blood transfusions were also found to be a significant risk factor for HCV transmission among hemodialysis patients. Frequent transfusion recipients were found to be more susceptible to HCV infection. This reaffirms how important it is to conduct thorough blood product screening, follow sterilization guidelines, and enforce stringent infection control procedures in medical facilities. Even with improvements in transfusion safety, HCV can still spread due to poor infection control procedures,

particularly in healthcare settings with limited resources.

The study also found that repeated blood transfusions are a significant risk factor for HCV transmission among hemodialysis patients. It was found that patients with a history of frequent transfusions were more likely to get HCV. This reaffirms how important it is to conduct thorough blood product screening, follow sterilization guidelines, and enforce stringent infection control procedures in healthcare facilities. Even with improvements in transfusion safety, HCV can spread due to poor infection control procedures, particularly in healthcare settings with limited resources.

In conclusion, the study highlights the seriousness of HCV infection among hemodialysis patients in Pakistan and clarifies its high prevalence, particularly among men and those between the ages of 41 and 50. Furthermore, the association between HCV infection and higher serum creatinine levels indicates that the virus significantly affects the clinical state of those infected. More stringent preventive measures are required, as multiple blood transfusions were found to be a significant contributing factor to the increased risk of infection. These results highlight the need for immediate measures to lower the prevalence of HCV in the hemodialysis population through improved screening, patient education, and preventative measures.

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