**Dissertation** at

DCDC Kidney Care, New Delhi



A Report on

# Study the Root Causes for Seroconversions at Different Dialysis Units of DCDC kidney care New Delhi

**BY: - Monica Shailesh** 



# **Acknowledgement**

I would like to express my special thanks to **Dr. SUMESH KUMAR** (Professor, IIHMR Delhi) and IIHMR, Delhi for giving me the golden opportunity to pursue my dissertation at DCDC Kidney Care, New Delhi.

Secondly I would also like to thank my parents and specially **Dr Sanjay Agrawal** sir who helped me a lot in being mentally strong and finalizing my projects within the limited time frame.

I am using this opportunity to express my gratitude to everyone who supported me throughout the course of my dissertation at DCDC Kidney Care, New Delhi.

I am highly thankful to **Dr Deepak Agrawal (VP –Clinical operations), And AVP Quality Mr Nooruddin**, for granting me the Opportunity for training and, for being helpful, supportive and receptive. His dynamic thinking, his broad and profound knowledge, his critical thinking has given me constant encouragement to achieve the task allotted and perform better.

Also, my successful completion of the projects would not have been possible without the helping deeds the entire clinical department of DCDC Kidney care and specially **Dr Rohit** as he is always being so cooperative and encouraging. Without their co-operation and warm attitude this project would have been a distant dream.

Speacial Regards to my mentor Dr Sumesh Kumar (Professor IIHMR Delhi) for his constant supervision and support in completing the projects.

Sr. No.	Table of Content	Page No.	
1.	Abbreviations	4	
2.	Organisational Profile	6	
3.	Introduction	8	
4.	Aim of Study	15	
5.	Review of literature	15	
6.	Objective	21	
7.	Methodology	21	
8	Statistical Analysis	22	
10	10 Discussion		
11	Recommendations	28	
12	Conclusion	29	
13	References	30	

# **List of Tables**

- Seroconversion data of first quarter (jan to april 20)
  Seroconversion data of quarter forth (nov 20, dec 20, january 21)

# **ABBREVIATIONS**

HD	HAEMODIALYSIS		
RO SYSTEM	REVERSE OSMOSIS SYSTEM		
ESRD	END STAGE RENAL DISEASE		
PPP	PUBLIC PRIVATE PARTNERSHIP		
PD	PERITONEAL DIALYSIS		
AKI	ACUTE KIDNEY INJURY		
CRF	CHRONIC RENAL FAILURE		
GFR	GLOMERULAR FILTRATION RATE		
HBV	HEPATITIS B VIRUS		
НСУ	HEPATITIS C VIRUS		
HIV	HUMAN IMMUNODEFICIENCY VIRUS		
HBsAg	HEPATITIS B SURFACE ANTIGEN		
ELISA	ENZYME LINKED IMMUNOSORBENT ASSAY		
ALT	ALANINE TRANSAMINASE		
PCR	POLYMERASE CHAIN REACTION		
LFT	LIVER FUNCTION TEST		
MRSA	METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS		
VRE	VANCOMYCIN RESISTANT ENTEROCOCCI		
ESBL	EXTENDED SPECTRUM BETA LACTAMASE		

# Section 1

**Organization Profile** 



# **ORGANISATION PROFILE**

About DCDC Kidney Care:

DCDC is one of the most trusted institutions in dialysis care delivery in Delhi / NCR and rapidly expanding to establish wide network in all formats.

As an epitome of trust and compassionate care, the chain of dialysis care always strives to excel with world class technology and expertise and aspires to bring to the community largest network of state of the art haemodialysis facilities, dialysis centres, under the banner of DCDC.

With standardized dialysis protocol, well trained renal professionals and backend technology procedures, 'DCDC' brings reliable, safe and effective dialysis with meticulously designed services.

Teamed with state of the art equipment, RO system and support on life style management, upkeeping the tradition of patient centricity and care, it provides quality treatment in shorter time without any compromises. Add to this a hygienic, homelike environment makes it the best in renal care.

Along with Dialysis, DCDC also endeavours to bring forward special services to support patients in organizing their lives better.

DCDC is the first dialysis institute in the country to offer home haemodialysis to patients at an affordable cost and with no initial investment. Evidence from well-planned research studies clearly proves that home haemodialysis patients live longer than patients treated in a dialysis centre. There is also good evidence that the quality of life of these patients is much better.

#### **Infrastructure:**

- 112 NUMBERS OF CENTERS
- 800+NUMBER OF MACHINES
- 6000+ NUMBERS OF HAPPY PATIENTS
- 500000+ TOTAL NUMBERS OF DIALYSIS DONE

#### **SERVICES**

- NEPHROLOGY CONSULTATIONS & TRANSPLANT CLINICS
- PREVENTIVE NEPHROLOGY: Early detection and determination of causes and timely treatment to prevent onset of ESRD.

- HOME COMFORT / DIALYSIS SPA: At DCDC we believe that our work begins from the moment the patient starts his journey from his home to the dialysis centre for his routine dialysis session
- INCENTRE HAEMODIALYSIS: Haemodialysis (HD) is one of the available treatments for ESRD that utilizes a dialysis machine to purify the blood. In Haemodialysis the blood flows through artificial kidney or dialyzer with the help of a dialysis machine that filters away the waste products.

DCDC is the leading provider of all round integrated dialysis and renal care services for patients all over India. DCDC is a rapidly expanding chain of soon to be more than 100 dialysis centres across India offering path breaking renal disease management services for Acute, Chronic, and End-Stage Renal Disease (ESRD). DCDC operates on an integrated 360 degree method of renal care with expertise in Nephrology & Dialysis, Psychology &Counselling, Nutrition & Diet, Rehabilitation & Lifestyle Management, Diagnostics, Urology, Surgeries including Fistulas & Grafts etc., and General Medicine.

DCDC has pioneered and launched a 'Partner of Choice' program for leading hospitals and medical facilities who wish to be associated with the leading renal care chain in India. We are currently associated with leading hospitals across the country. The scope of services varies from operative & management arrangements to the more popular Department In Hospitals.

Our 'Partner of Choice' program varies from hospital to hospital and is often customized according to the needs of the hospital, scope of services in hospitals and the infrastructure available. We are committed to providing quality care to patients and take away the headache of day to day running of the dialysis facility so that the hospital can focus on their core activities.

#### Services offered:

- Outsourced Dialysis Services.
- Outsourced Nephrology and Acute Care
- Best in class clinical outcomes for dialysis.
- Staffing
- Consultancy and Investment in new Infrastructure
- Education & Training
  - Branding
  - Center of excellence

Now DCDC Health services is working in PPP MODE, **Public-private partnership** (**PPP**) is a funding **model** for a public infrastructure project such as a new telecommunications system, airport or power plant. The public partner is represented by the government at a local, state and/or national level

## <u>PROJECT REPORT: A study on the Root Causes for Seroconversions and</u> how to minimize it at Different Dialysis Units of DCDC kidney care Delhi

# **INTRODUCTION**

The kidneys are complex organs that are vital in maintaining normal body functions. The primary function of the kidney is to regulate the fluid and electrolyte and acid-base balances of the body to create a stable environment for tissue and cell metabolism. This life-sustaining function is accomplished by balancing solute and water transport, excreting metabolic waste products, conserving nutrients, and regulating acid-base balance in the body.

#### Major functions of the kidney

#### Excretory

- Maintains plasma osmology
- Maintains plasma pH
- Maintain the plasma concentration of electrolytes
- Excretes nitrogenous end products of protein metabolism

#### Nonexcretory

- Produces renin
- Produces erythropoietin
- Metabolizes vitamin D
- Degrades insulin
- Produces prostaglandin

#### ACUTE RENAL FAILURE

Acute renal failure is an acute loss of kidney function that occurs over days to weeks and results in an inability to appropriately excrete nitrogenous wastes and creatinine. Electrolyte disturbances and loss of fluid homeostasis may occur. Accepted diagnostic criteria include an increase in the serum creatinine level of 0.5 mg per dL (44.2  $\mu$ mol per L) or a 50 percent increase in the creatinine level above the baseline value, a 50 percent decrease in the baseline-calculated glomerular filtration rate (GFR), or the need for acute kidney replacement therapy.

#### **CHRONIC RENAL FAILURE**

Chronic renal failure (CRF) is a progressive deterioration of renal function that ends in uremia and its complications, which can lead to death unless dialysis is begun or a transplant is performed. Chronic renal failure develops in three major stages that progress from the decreased renal reserve, to renal insufficiency, and finally to irreversible renal failure.

#### COMPLICATIONS OF RENAL FAILURE

Patients with renal failure experience myriad complications related to almost all organ systems. They are also prone to a variety of disorders of fluid, electrolyte, mineral, and acid-base balance, depending upon the degree of renal failure and the cause of renal disease. Most problems arise with a severe decline in renal function.

- *Fluid and Electrolyte Disorders:* Most fluid and electrolyte disorders occur late in the course of renal failure when there has been a significant decline in GFR.
- Anemia
- Perforating Folliculitis
- Pericardial Tamponade
- Malnutrition
- Renal Osteodystrophy

#### **TREATMENT MODALITIES**

Dialysis and transplantation are life-prolonging therapies for many patients with renal insufficiency. Initially, patients with ESRD are managed with conservative therapy, but eventually, they require hemodialysis, peritoneal dialysis, and/or transplantation.

#### **HEMODIALYSIS**

Hemodialysis employs the process of diffusion across a semipermeable membrane to remove unwanted substances from the blood while adding desirable components. A constant flow of blood on one side of the membrane and a cleansing solution (dialysate).

#### PERITONEAL DIALYSIS

Peritoneal Dialysis like hemodialysis, may be performed in various settings and with several techniques. In patients with acute renal failure, intermittentPeritoneal Dialysis (IPD) has largely been replaced by CAVHD (Continuous arteriovenoushemodialysis). Chronic Peritoneal Dialysis was attempted in the late 1940s but was impractical until the development of a permanent peritoneal catheter, the Tenckhoff catheter.

#### TRANSPLANTATION

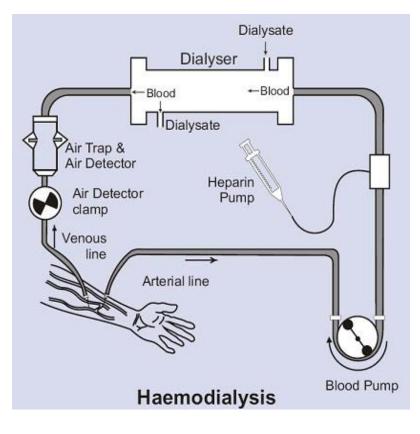
Transplantation of the human kidney is frequently the most effective treatment of advanced chronic renal failure. Worldwide, tens of thousands of such procedures have been performed. When azathioprine and prednisone were initially used as immunosuppressive drugs, the results with properly matched familial donors were superior to those with organs from cadaveric donors, namely, 75 to 90 percent compared with 50 to 60 percent graft survival rates at 1 year. During the 1970s and 1980s, the success rate at the 1-year mark for cadaveric transplants rose progressively.

#### DIALYSIS

Dialysis may seem complex, but it is based on simple scientific principles. This module will help you understand these principles and how they are used in dialysis.

Dialysis replaces three main kidney functions:

- 1. Removing wastes from the blood
- 2. Removing excess fluid from the blood
- 3. Keeping electrolytes (electrically charged particles) in balance



Haemodialysis

#### Scientific Principles Used in Dialysis

#### **Solutions**

A solution is a mixture of a solvent and a solute. The solvent is a fluid. The solute is any substance that can be dissolved into the solvent. So, in salt water, water is the solvent and salt is the solute. The dialysate is the solution that is used during dialysis. Water is the solvent. The solutes are electrolytes (e.g., potassium, calcium, sodium, magnesium, and chloride ions) and glucose (sugar). Electrolyte levels in dialysate closely match the levels in human blood. This reduces the loss of these electrolytes out of the blood and into the dialysate during dialysis. The patient's blood electrolyte levels can be controlled by

changing the dialysate. Adding an electrolyte to the dialysate at a level higher than in the blood will allow the electrolyte to enter the patient's blood during a treatment.

#### Semipermeable membrane

A semipermeable membrane is a type of thin, flexible filter—a barrier that allows only particles smaller than a certain size to pass through it. Think of the membrane as a strainer you might use to drain noodles. The water drains out, but the noodles are too big to pass through the holes. In dialysis, the semipermeable membrane's holes allow small molecules, such as water and urea, to pass through easily. Middle molecules can also pass through, but more slowly. The small size of the pores keeps larger molecules and blood cells from passing through the membrane.

#### Diffusion

Diffusion is the process by which atoms, molecules, and/or other particles move from an area where they are in high concentration to an area where they are in low concentration. Diffusion can occur in solids, gases, or liquids, such as blood. Energy for the movement comes from the molecules themselves and does not depend on outside forces. In the body, substances move into and out of cells by diffusion through the cell membranes. In dialysis, diffusion occurs across an artificial semipermeable membrane. This is how wastes and fluid are removed from the patient's blood, and electrolytes are balanced. The following factors affect all diffusion—from tea bags to hemodialysis.

#### Osmosis

In diffusion, solutes move. In osmosis, the solvent moves across the membrane. Osmosis is the movement of a solvent through a semipermeable membrane from an area of lower solute concentration toward an area of higher solute concentration. The difference in concentration is called an osmotic pressure gradient. In both diffusion and osmosis, movement goes on until the concentration of molecules equilibrates (becomes equal) on both sides of the membrane.

#### **Filtration and Ultrafiltration**

Filtration is the movement of fluid through a filter as the result of hydraulic pressure. Fluid will always move from a higher pressure to a lower pressure. The filter traps any matter that is too large to pass through it. In dialysis, ultrafiltration (UF) water removal from blood due to a pressure gradient across a membrane (see Figure 4) is used to remove excess water that has built up. The filter used in UF is a semipermeable membrane.

#### DIALYSIS EQUIPMENT AND PROCEDURE

#### Dialyzers

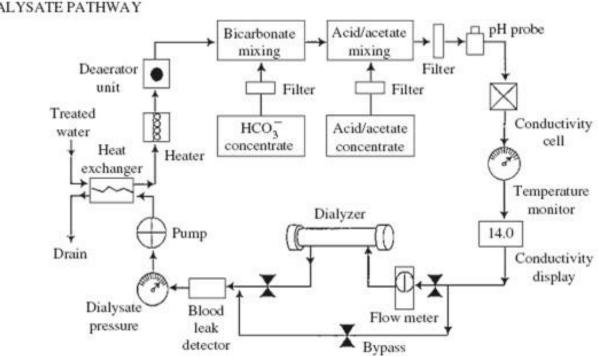
A dialyzer is an artificial kidney designed to provide controllable transfer of solutes and water across a semi permeable membrane separating flowing blood and dialysate streams. The transfer processes are diffusion (dialysis) and convection (ultrafiltration).

#### Dialysate

The goal of dialysis for patients with chronic renal failure is to restore the composition of the body's fluid environment towards normal. This is accomplished principally by formulating a dialysate whose constituent concentrations are set to approximate normal values in the body. Over time, by diffusional transfer along favorable concentration gradients, the concentrations of solutes that were initially increased or decreased tend to be corrected.

#### **Hemodialysis Delivery Systems**

A hemodialysis system and accessories is a device that is used as an artificial kidney system for the treatment of patients with renal failure or toxemic conditions and that consists of an extracorporeal blood system, a conventional dialyzer, a dialysate delivery system, and accessories. Blood from a patient flows through the tubing of the extracorporeal blood system and accessories to the blood compartment of the dialyzer, then returns through the further tubing of the extracorporeal blood system to the patient. The dialyzer has two compartments that are separated by a semipermeable membrane. While the blood is in the blood compartment, undesirable substances in the blood pass through the semipermeable membrane into the dialysate in the dialysate compartment. The dialysate delivery system controls and monitors the dialysate circulating through the dialysate compartment of the dialyzer. The extracorporeal blood system and accessories consist of tubing, pumps, pressure monitors, air foam or bubble detectors, and alarms to keep blood moving safely from the blood access device and accessories for hemodialysis to the blood compartment of the dialyzer and back to the patient.



#### DIALYSATE PATHWAY

# **SEROCONVERSION**

A change from a seronegative to a seropositive condition, changes from a seropositive to a seronegative condition, or change from a seropositive to another seropositive condition.

The development of detectable antibodies in the blood that are directed against an infectious agent (usually within a few weeks of infection).

Viral infection is a significant health concern in patients with Chronic Kidney disease on Maintenance Hemodialysis.

Injections, transfusion of blood product, organ transplantation, occupational exposure among health care workers, poor infection control practices, non-adherence to universal precautions etc. can lead to transmission of Viral infection.

Patients getting dialyzed at multiple dialysis centers with non-strict infection control practices may have exposure to viral infection and may spread it.

Although there are many viruses and diseases that can affect your health, the most important ones that you should be aware of while on hemodialysis are:

- Hepatitis B
- Hepatitis C
- HIV/AIDS

Most common seroconversions in a dialysis unit are Negative to Hepatitis-C or Hepatitis-B or HIV or Hepatitis-C to negative conversion.

#### Hepatitis-C or HCV

Hepatitis C is a liver infection that can lead to serious liver damage. It's caused by the hepatitis C virus. HCV infection is a significant cause of morbidity and mortality in hemodialysis (HD) patients and kidney transplant recipients. In developed countries, the prevalence of anti-HCV seropositivity among patients on maintenance HD ranges between 5% and 60%.

Many people with hepatitis C have no symptoms. But between 2 weeks and 6 months after the virus enters your bloodstream, you could notice Clay colored poop, Dark urine, Fever, Fatigue, Jaundice (a condition that causes yellow eyes and skin, as well as dark urine), Joint pain, Loss of appetite, Nausea, Stomach pain and Vomiting. These symptoms usually last for 2 to 12 weeks.

Hepatitis C spreads when blood contaminated with the hepatitis C virus gets into your bloodstream through contact with the blood or body fluids of an infected person.

You can be exposed to the virus from:

- Sharing injection drugs and needles
- Having sex, especially if you have an STD, an HIV infection, several partners, or have rough sex

- Being stuck by infected needles
- Birth -- a mother can pass it to a child
- Sharing personal care items like toothbrushes, razor blades, and nail clippers
- Getting a tattoo or piercing with unclean equipment

Hepatitis C Testing and Diagnosis-

Doctors will start by checking your blood for:

Anti-HCV antibodies: These are proteins your body makes when it finds the hep C virus in your blood. They usually show up about 12 weeks after infection.

- It usually takes a few days to a week to get results, though a rapid test is available in some places.
- The results can be:
  - Nonreactive, or negative:
    - That may mean you don't have hep C.
    - If you've been exposed in the last 6 months, you'll need to be retested.
  - Reactive, or positive:
    - That means you have hep C antibodies and you've been infected at some point.
    - You'll need another test to make sure.

If your antibody test is positive, you'll get this test:

HCV RNA: It measures the number of viral RNA (genetic material from the hepatitis virus) particles in your blood. They usually show up 1-2 weeks after you're infected.

- The results can be:
  - Negative: You don't have hep C.
  - Positive: You currently have hep C.

As part of the diagnosis process, you might also get:

Liver function tests: They measure proteins and enzyme levels, which usually rise 7 to 8 weeks after you're infected. As your liver gets damaged, enzymes leak into your bloodstream. But you can have normal enzyme levels and still have hepatitis C.

Treatment and Medication for Hepatitis C-

If you have acute hepatitis/ C, there is no recommended treatment. If your hepatitis C turns into a chronic hepatitis C infection, there are several medications available like Interferon, peginterferon, and ribavirin used to be the main treatments for hepatitis C.

Total time spent on dialysis is among the risk factors for the presence of anti-HCV antibodies and/or HCV RNA. HCV is the major etiologic agent of chronic hepatitis and possible liver cirrhosis and hepatocarcinoma.

#### Hepatitis B-

Hepatitis B is a virus infection that causes liver disease. Most people fight off this infection themselves, but some may progress to chronic liver disease and possibly liver cancer. Hepatitis B is spread by contact with the blood of an infected person.

You may have an increased chance of getting hepatitis B if you:

- Sex with an infected person
- Have been exposed to sharp instruments contaminated with infected blood, such as needles used for tattooing, body piercing and acupuncture
- Injection drug use that involves sharing needles, syringes, or drug-preparation equipment
- Passing from an infected mother to her baby during childbirth
- Contact with blood or open wounds or sores from an infected person
- Sharing of razors or toothbrushes from an infected person.

In the early years of dialysis, there was a danger of getting hepatitis B through exposure to the blood of an infected person at the dialysis unit. However, today the chance of getting hepatitis B through your treatment is very small because of two important advances. One of these advances is the use of strict infection control measures in dialysis units. The second improvement is the availability of a vaccination for hepatitis B.

#### HEPATITIS B SEROLOGIC MARKERS

Commonly used serological tests for HBV include those for HBsAg, antibody to HBsAg (anti-HBs), antibody to hepatitis B core antigen (anti-HBc) and viral DNA (HBV DNA) by polymerase chain reaction

The hepatitis B vaccine

A first-generation vaccine was subsequently developed, consisting of HBsAg extracted by plasmapheresis from HBV carriers, and then inactivated.

Modern 'second-generation' HBV vaccines are recombinant non-infectious subunit vaccines containing HBsAg.These are produced by the yeast *Saccharomyces cerevisiae* using recombinant DNA technology. There are two such HBV vaccine formulations available, Engerix B and Recombivax HB.

A third-generation vaccine has been produced from a mammalian cell line, although it is not yet in widespread use. It contains the pre-S1 and pre-S2 antigens that are present on the viral envelope. These antigens are more immunogenic than the HBsAg present in second-generation vaccines.

#### Drugs available for HBV infection

Available therapeutic options include interferon, the nucleoside analogues lamivudine and telbivudine, and the nucleotide analogues adefovir, tenofovir and entecavir. Interferon- $\alpha$  was the first available therapy for chronic HBV infection. Experience in dialysis patients comes from treatment of hepatitis C. In this group, it has been shown that renal failure greatly increases the half-life and area under the concentration–time curve. Side effects are therefore magnified and consist principally of influenza-like symptoms, myelosuppression and depression. Newer, pegylated interferon is no better tolerated in HD patients. There are no published series of HBV treatment with interferons in end-stage renal disease (ESRD). There is theoretical concern that they might be less effective given uremic immune hyporeactivity. Interferons are not recommended in dialysis patients with HBV infection. Tenofovir and entecavir are likely to be more effective, and tenofovir has been shown to be safe in HD patients, but neither drug has any significant evidence base from this patient group.

An effective vaccine has made a notable contribution to the protection of dialysis patients from the virus, although this is tempered by reduced potency and durability of the anti-HBs response in those with ESRD. The course of hepatitis B infection is different in patients with dialysis-dependent renal failure.

#### HIV

HIV (human immunodeficiency virus) is a virus that infects and damages your immune system. Your immune system helps your body defend itself against infection and other disease. HIV attacks and destroys the disease-fighting cells of your immune system and leaves your body weak against infection and cancer.

Having HIV may put you at risk for getting kidney disease. In fact, it is not unusual for people with HIV to develop kidney disease. This happens because:

- HIV can harm the nephrons (filters) in your kidneys. When this happens, the filters do not work as well as they should.
- HIV can infect the cells in your kidneys
- If not carefully monitored, some of the medicines used to treat HIV can harm the nephrons in your kidneys.

# Aim of the study

Determining the probable causes of seroconversion from negative to positive in HBV and HCV infection, as it is one of the important data to access the efficacy of infection control measures in a dialysis unit.

# LITERATURE REVIEW

## Incidence and Risk Factors for Hepatitis C Virus and Hepatitis B Virus Seroconversion in End-Stage Renal Failure Patients on Maintenance Haemodialysis

ManikKataruka\*ShefaliGupta<sup>†</sup>RajaRamchandran\*MiniSingh<sup>‡</sup>RadhakrishanDhiman<sup>§</sup>Kishanlal gupta\*

Renal replacement therapy in the form of either dialysis or transplantation is the only option for end-stage renal disease (ESRD). Blood-borne infections such as hepatitis B virus (HBV) and hepatitis C virus (HCV) are of special concern in these patients because of their high incidence. Although there are sufficient data from the developed world, there is scarcity of data from developing countries such as India.All newly diagnosed ESRD patients initiated on Haemodialysis after attending the Department of Nephrology, PGIMER, Chandigarh between January 2015 and October 2015 were included in the study. All the subjects were initially screened for HCV and HBV serology status and subsequent HCV and HBV status on follow-up at the end of 6 months and evaluated by standardized precoded questionnaires and biochemical examination.In a real-life scenario, HCV seroconversion is observed in 15% of the patients initiated on Haemodialysis. Isolation of both dialysis machine and personnel was associated with lower seroconversion.

Hepatitis C virus seroconversion in Haemodialysis units with a high prevalence of hepatitis C: do we need isolation?

#### Ahmed M Zahran MD

Nephrology Unit, Internal Medicine Department, Faculty of Medicine, Menoufia University, Menoufia, Egypt

The objective of this study was to determine whether the isolation of Haemodialysis patients with hepatitis C virus (HCV) in Haemodialysis units with a high prevalence of hepatitis C is necessary or not.

Patients with a long duration of dialysis were more liable to HCV seroconversion in dialysis units with a high prevalence rate of HCV infection, especially in developing countries. Good training on infection control measures with strict supervision of the dialysis staff is required. A controlled randomized study is needed to compare the isolation policy with no isolation of HCV patients on regular Haemodialysis in developing countries to determine whether there is any benefit of isolation.

#### Hepatitis B virus infection in dialysis patients.

Wong PN<sup>1</sup>, Fung TT, Mak SK, Lo KY, Tong GM, Wong Y, Loo CK, Lam EK, Wong AK.

Hepatitis B virus (HBV) infection remains a major issue among dialysis patients. It is associated with a high risk of hepatic complication. The liver disease runs a unique clinical course in dialysis patients, as it can progress with modest hepatic inflammation and prominent fibrosis. The conventional cut-off level of serum alanine aminotransferase (ALT) for commencing antiviral therapy may prove too high and inappropriate for dialysis patients, and liver biopsy appears to be the only definitive means to establish the activity of liver disease in dialysis patients. Liver biopsy should be considered in patients with a serum ALT level that is persistently greater than 30 IU/L, or 0.75-fold the upper limit of the normal level, and/or other clinical and laboratory findings that suggest active liver disease. For antiviral treatment, preliminary reports have shown that lamivudine is effective and well tolerated in dialysis patients. However, the long-term efficacy of lamivudine and its optimal effective dose in dialysis patients remain unknown. The prevention of nosocomial transmission among dialysis patients is also important. Universal precaution measures should be strictly observed and the segregation of hepatitis B surface antigen-positive Haemodialysis patients should be considered. For HBV non-immune patients, the importance of HBV vaccination should not be overemphasized. Until a new generation of highly immunogenic vaccines that are proven to be safe and effective in patients with end-stage renal disease becomes available, early vaccination before the development of end-stage renal failure remains the best way to secure immunological protection against HBV infection in dialysis patients.

# Prevalence, seroconversion and risk factors of hepatitis b and c infection in patients on maintenance haemodialysis

Vikas Makkar1, Dinesh Gupta2, Kanish Bansal3, N. S. Khaira4

HBV and HCV infections pose a great threat to patients on Haemodialysis and studies have been conducted regarding the prevalence and seroconversion rates. The present study was conducted to demonstrate the prevalence and seroconversion rate in patients with chronic Haemodialysis and also the incidence of liver function derangement in patients with Hepatitis B and C. This was one year prospective study done in patients of End Stage Renal Disease (ESRD) on Haemodialysis. All patients reporting to Nephrology Unit of a tertiary care centre irrespective of serological status were screened for inclusion in the study. The patients who were on Haemodialysis for a minimum period of 1 month and were likely to be available for follow-up for at least 6 months were included in the study. The patients were monitored for seroconversion every 3 months during their follow-up visits using HbsAg ELISA and Anti-HCV ELISA tests. Relatively high seroconversion rate of hepatitis B at centre was probably due to the fact that centre is a tertiary care referral centre and offers maintenance Haemodialysis as well. Many patients coming tocentre do not reveal the very fact that they are receiving/have received Haemodialysis sessions at other centers. Centers located in smaller cities many a times have one or two Haemodialysis machines and do not strictly follow isolation policies.Duration of Haemodialysis and number of Haemodialysis sessions were significant contributing factors towards development of hepatitis C infection . Number of blood transfusions significantly contributed to development of either hepatitis B or C whereas number and duration of haemodialysis and history of is drug were other significant risk factors for acquiring Hepatitis C in CRF patients on regular Haemodialysis.

# Prevalence and associations of hepatitis C viremia in Haemodialysis patients at a tertiary carehospital

S Jasuja<sup>1</sup>, AK Gupta<sup>1</sup>, R Choudhry<sup>2</sup>, V Kher<sup>3</sup>, DK Aggarwal<sup>1</sup>, A Mishra<sup>1</sup>, M Agarwal<sup>1</sup>, A Sarin<sup>1</sup>, MK Mishra<sup>1</sup>, V Raina<sup>4</sup>

Hepatitis C virus (HCV) infection in Haemodialysis (HD) is a significant problem. We evaluated the prevalence and associations of HCV viremia in our HD patients. All patients undergoing maintenance HD at our center were tested for HCV RNA by PCR after written informed consent. Detailed history regarding age, sex, and duration of dialysis, frequency of dialysis, blood transfusions in one year, number of dialysis centers, dialyzer reuse/fresh use, and recent laboratory data was recorded. A total of 119 patients (77 males and 42 females) were tested for HCV RNA. Thirty three (27.7%) tested positive. Duration of dialysis was significantly longer in HCV RNA positive group (P = 0.001). 45.2% of patients with duration of dialysis more than 16 months were HCV RNA positive while only 7.4% of patients with dialysis duration  $\leq$ 16 months were HCV RNA positive (*P* < 0.001). In univariate analysis, in HCV RNA group patients, ALT, AST, and GGTP were significantly elevated and albumin was significantly lower. 39% of patients who had dialysis at more than one center were HCV RNA positive as compared to 20% for patients undergoing dialysis at single center (P = 0.024). Binary logistic regression analysis showed albumin, duration of dialysis, and serum ALT to be significant variables. Sensitivity and specificity of anti-HCV ELISA was 72.7 and 97.7%, respectively. Prevalence of HCV RNA in the HD population is 27.7%. Duration of dialysis, getting dialysis at more than one center, elevated transaminase levels, and low serum albumin are important associations for HCV RNA positive.

# Consensus statement – 2001 recommendations for hepatitis b, c, g and hiv in maintenance dialysis patients a consensus statement produced for and by the dialysis and transplant subcommittee of the akf and the anzsn.

Dr Kathy Kociuba Staff Infectious Diseases Physician, SWSAHS, Sydney, Australia Dr Michael Suranyi, Staff Specialist Nephrologist, Director of Dialysis Services, Liverpool Health Service, Sydney, Australia

Outbreaks of viral infections, in particular hepatitis, have been reported in haemodialysis units since the introduction of haemodialysis therapy. Transmission of viral infections, including hepatitis in haemodialysis units, continues to occur and remains an important concern, as it is preventable. Viral transmission from infected patients can result in significant morbidity and mortality. Patients should be regularly screened for carriage of blood borne viruses, at regular intervals prior to and after commencement of dialysis. In particular patients should undergo Hepatitis B, Hepatitis C and HIV testing early in their management, when progressive renal failure can be predicted to inevitably progress to end stage renal failure and dialysis. Serology should be repeated just prior to starting dialysis to ensure results are available prior to instituting the procedure. The suggested frequency of subsequent testing is LFTs monthly, HbsAg/HbsAb 3-6 monthly, HCV Ab 3-6 monthly and HIV annually. Knowledge of the infective status of patients allows the implementation of measures to minimise the risk of cross-infection in the subsequent dialysis setting. Hepatitis B immunisation programs should be undertaken aggressively. Patients with chronic active viral infection should be referred for specialist review regarding potential anti-viral treatment. The risks and benefits of transplantation need to be carefully assessed prior to transplant waiting list enrolment in virally infected patients, and informed consent, regarding the risks versus the benefits, obtained prior to transplantation.

# **Objective of the study**

• To study the probable causes of seroconversion in a dialysis centers

# Methodology

The study was carried-out in Dialysis centers at DCDC KIDNEY CARE. It was a cross sectional descriptive study design and non-probability convenience sampling technique was used. The Study tool is existing serology and seroconversion data collected from 30 centers of DCDC kidney care of two quarters (april2020 & Jan'2021).All patients reporting to DCDC Dialysis Unit were screened for virology status before first dialysis and then in every quarter (Jan, April, July, Oct).

#### **Inclusion criteria**

The patients who were on Hemodialysis for a minimum period of 1 month before April 2020 and January 2021

#### Period of data collection

Two Quarter report (Quarter I- JAN TO APRIL 2020) & Quarter IV – (NOV 2020, DEC 2020 & JAN 2021) )

Sample size 30 DCDC Dialysis centers

#### **Data collection method**

Secondary data from seroconversion record of 30 centers Telephonic interview.

**Data analysis tool** Excel

# **Calculation of Seroconversion at each center**

Seroconversion Data april2020

Percentage Seroconversion= (No of Converted Patient/ Total No of Active Patients)\*100

**#Converted Patients**- Number of patients converted positive or negative **#Active Patients**- Number of patients on dialysis regularly as per their schedule

#### STATISTICAL ANALYSIS

TABLE 1: SEROCONVERSION DATA OF FIRST QUATER (JAN TO APRIL 2020)

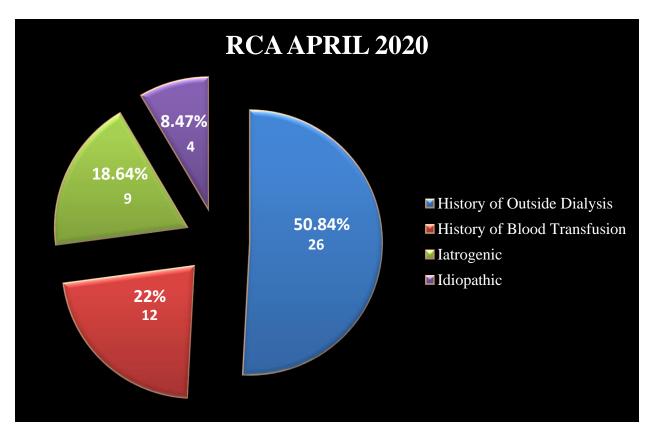
Sr No.	Name of Centre	Total active Patients	No. of Patient Converted	Percentage of Seroconversion(- ve) to (HCV+ve)	Percentage of ( ve) to (HBV +ve)	
1 Venkateshwar hospital		146	1	0.6%	0%	
2	Tarak hospital	14	2	8.7%	0%	
3	ESI Noida	24	2	8.3%	0%	
4	Civil Bahadurgarh	25	1	2%	0%	
5	DHAS	100	1	1%	0%	
6	Yatharth Hospital (UP)	108	3	2.7%	0%	
7	*Civil Raibareli	83	1	1.02%	0%	
8	Civil Amroha	44	4	9%	0%	
9	Civil Firozabad	85	1	1.17%	0%	
10	*Civil Gurugram(Haryana)	27	1	3.70%	0%	
11	Civil Sonepat	29	2	6.9%	0%	
12	Civil AmbalaCantt	82	5	4.87%1 pt hcv+ to -	0%	
13	Civil Jind	39	4	10.25%	0%	
14	*Civil Hisar	100	1	1%	0%	
15	*Civil Faridabad	47	1	2.17%	0%	
16	Civil Sirsa	37	4	10.08%	0%	
17	*Reg. Hosp.Bilaspur	117	3	2.25%	0%	
19	Sadar Hazaribagh	38	1	2.63%	0%	
20	RH. UNA	55	3	4.10%	0%	
21	Jagadhari	128	4	3.12%	0%	

TABLE 2- SEROCONVERSION DATA OF QUARTER FORTH (NOV 2020, DEC 2020, JAN21)

Sr No.	Name of Centre	Total Active Patient	No. of Patient Convert ed	Number of Patients converted (-ve) to (HCV+ve)%	Number of patients converted (-ve) to (HBV +ve)%	-	Total Percentage
1	Civil Ghaziabad	70	1	1%	0	0	1.42%
2	Civil Gurugram(Ha ryana)	51	2	3.21%	2	0	3.21%
3	Ambala Cantt	90	5	5.55%	0	1	5.55%
4	Jagatdhari	67	3	3.88%	0	0	3.88%
5	MAMC Agroha	36	1	2.77%	0	0	2.77%
6	RGSSH	227	3	1%	0	0	1.37%%
7	Civil Ambala Cantt	106	2	2%	0	0	2%
8	Civil Jind	63	2	3%	0	0	3.17%
9	Civil Palwal	25	1	4%	0	0	4.00%

Г

RCA for APRIL 2020



Total number of seroconversions- 51

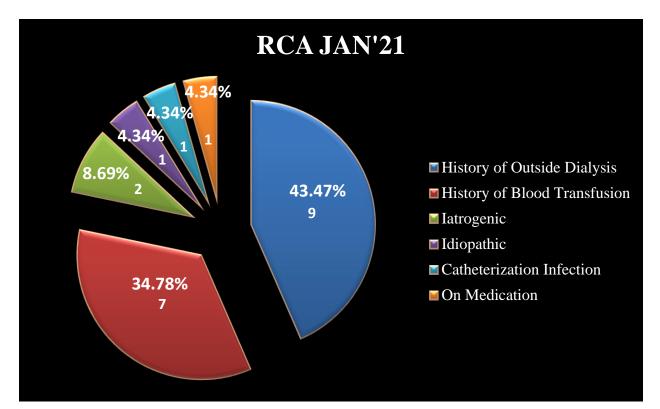
This pie chart depicts that the maximum seroconversion occurs in patients who get their dialysis at other units (50.84%) or irregular with their dialysis schedule.

Then the second most common contributing factor for seroconversion is patients getting blood transfusion that too other centers (22%).

Some other factors are Iatrogenic i.e. the mistakes or mishappens occur in our unit leading to seroconversion (18.64%).

There are also unknown factors for this conversion (8.47%).

RCA for Jan'21



# Total number of seroconversions-21

This pie chart depicts that the maximum seroconversion occurs in patients who get their dialysis at other units (43.47%) or irregular with their dialysis schedule.

Then the second most common contributing factor for seroconversion is patients getting blood transfusion that too other centers (34.78%).

Some other factors are Iatrogenic i.e. the mistakes or mishappens occur in our unit leading to seroconversion (8.69%).

There are some factors those are equally contributing for this seroconversion. Those are catheterization infection, unknown factors and patients on medication for treatment of HCV (4.34%).

# DISCUSSION

We can broadly classify the root causes in two parts-

a) External causes

- i. Outside dialysis
- ii. Outside Blood Transfusion /admission
- b) Iatrogenic causes
  - Same technicians working in both positive and negative area
  - Same mopping cloth for both positive and negative area
  - Unrestricted movement of staff in both the areas

After the analysis of two quarters the findings are-

- a) The most probable cause for seroconversion is "Patient getting dialysis at other unit."
- b) The second most common cause is "Patient getting admitted or blood transfusion in other centers/hospitals."

One of the treatments for chronic renal failure (CRF) is maintenance invasive Haemodialysis (HD) procedure. This procedure by itself affects innate immunity like changes in a chemotactic factor for leukocytes, the phagocytic function of neutrophils and monocytes and natural killer cell. Moreover, adaptive immunity is affected for example defect in the proliferation of T lymphocytes and down-regulation of phosphorylation pathways of lymphocytes. Therefore, HD patients are more susceptible to blood born viral infection like hepatitis B virus (HBV), hepatitis C virus (HCV) and Human immunodeficiency virus (HIV) due to the disturbance in the immune system . HBV and HCV infections are the important causes of morbidity and mortality among patients undergoing HD and impose problems in the management of patients in the dialysis units. Since patients with renal failure do not clear such viral infections efficiently, identifications of the potential risk factors and introduction of measures to address these factors are a priority in HD units.

This study is carried out to find out the probable causes of seroconversion so as to improve patient safety and staff safety. All patients reporting to DCDC Dialysis Unit were screened for virology status before first dialysis and then in every quarter (Jan, April, July, Oct). After analyzing the Quarter I(, jan To april) data comparatively with Quarter IV (nov to jan) 36% have increased rate of Seroconversion, 17% have decreased rate of Seroconversion , 50% centers have zero rate of Seroconversion.Out of 23 patients who got seroconverted in quarter 1, 61% are females and 31% are males , 26% are in the age group of 55-60 years followed by22% in the age group of 66-70 years , 17% in the age group of 46-50 years, 13% are in the age group of 51-55 years .Demographically seroconversion is more prevalent in the females predominantly in a age group of 55- 70 years. With respect to duration of dialysis and frequency of dialysis69% are on dialysis from 2-5 years and 22% from 5- 7 years , 9% are on dialysis since less than 2 years. And 65 % patients receive dialysis twice a week and 35% thrice a week.

Root cause analysis for seroconversion had been done with the help of center managers, dialysis technicians and infection control nurse. It had been done using telephonic media with center managers of each and every centers and taking the details regarding the patient's history, earlier serology record, and also patients who got seroconverted are telephonically interviewed for details regarding family history, history of blood transfusion. After root cause analysis for seroconversion, most common reasons arehistory of outside dialysis (46%), followed by history of blood transfusion (37%) and 17% other reasons such as catheterisation infection, improper dialyser processing, improper infection control.

Hepatitis B and C progress to liver cirrhosis and increase the morbidity and mortality on hemodialysis. In addition the staff of a dialysis unit are uniquely at risk of contracting these viral infections from contaminated blood and dialysate Preventing the transmission of infections involves several links in the chain involving the patients, the dialysis procedure and ancillary care, the staff of the unit and various administrative and waste disposal protocols. Hence, as the seroconversion occurs the action plan mentioned earlier is executed immediately, and all the corrective and preventive measures are adhered strictly .Following preventive actions are more strictly followed and routine checks are done : Hand hygiene, Complete Disinfection of hemodialysis machines, Dialysates- Liquid bicarbonate dialysate concentrate can support rapid bacterial proliferation, and hence it should not be used more than 24 hours after opening, When multiple dose medication vials (e.g., heparin, vials containing diluents) or solution bags are used for multiple patients, individual patient doses should be prepared in a clean, centralized area away from dialysis stations and delivered separately to each patient. All maintenance dialysis patients should be retested at regular every 6 months for HBV, HCV and HIV infection. Staff vaccination record is continuously monitored .All staff members should be vaccinated against hepatitis B, have their anti-HBs titer tested and be aware of their serostatus, i.e., whether or not they have titers >10 U/mlUnits with high (>20%) prevalence of HCV infection should strongly consider dialyzing HCV, HBV positive patients in a separate room. Where there are no isolation facilities, positive patients should be separated from susceptible patients (negative for HBsAg, anti-HBs, anti-HBc, anti-HCV, or anti-HIV), and undergo dialysis on dedicated machines .

Surveillance plan executed at all 9 centers in Presence of Center Manager& in my supervision through video call with the help of infection control nurse.

# Recommendations

- Strict adherence to the policies with respect to infection control
- Strict Surveillance of the dialysis unit with respect to infection control
- All units should develop methods to monitor, review and evaluate all infection data including-
  - Rates of infection with blood borne viruses and bacterial infections overall and individually
  - Results of serological testing for blood borne viruses.
  - They should calculate incidence and conversion rates for blood borne viruses.

• Unit in charge should regularly review adherence to infection control practices annually and more frequently if there is significant staff turnover.

- Continuous training of staff with respect to following:-
  - Appropriate use of personal protection equipment
  - Modes of transmission for BBV, pathogenic bacteria, and other microorganisms
  - Infection Control Precautions for Dialysis Units o Rationale for segregating patients
  - Correct techniques for initiation, care, and maintenance of dialysis access sites.

## Conclusion

The number of patients on maintenance hemodialysis is increasing rapidly in India. Chronic hemodialysis patients have an increased infection risk. HD facility is very conducive for transmission of infection since multiple patients receive dialysis concurrently. Transmission can occur directly or indirectly via contaminated devices, equipment and supplies, environmental surfaces, or hands of personnel. Even in the developed world, there are substantial deficiencies in infection control practices. These suggested reasons include lack of awareness of the practices and their importance, and lack of clarity of difference between universal precautions (recommended for all health-care settings) and the additional precautions necessary in the hemodialysis setting. The important infections that develop in these patients include viral infections such as hepatitis B and C, HIV and bacterial infections, especially those involving vascular access. The prevalence of antimicrobial-resistant bacteria has increased rapidly in health-care settings, including hemodialysis units in recent years. Antimicrobial use and direct contact transmission of resistant strains are the two main factors that have contributed to this significant increase. Infection control guidelines and surveillance system for infections in hemodialysis centers has been implemented in most advanced countries to cut down infection risk and to determine the frequency and risk factors for these complications. Units should establish written protocols for all procedures including cleaning and disinfecting surfaces and equipment in the dialysis unit.

# References

1. http://www.mmj.eg.net/article.asp?issn=1110-2098;year=2014;volume=27;issue=3;spage=551;epage=555;aulast=Zahran

Hepatitis C virus seroconversion in hemodialysis units with a high prevalence of hepatitis C:do we need isolation?

AhmedMZahran

MD

Nephrology Unit, Internal Medicine Department, Faculty of Medicine, Menoufia University, Menoufia, Egyp

2. https://www.hsd-fmsb.org/index.php/hsd/article/view/74

INCIDENCE AND POTENTIAL RISK FACTORS FOR SEROCONVERSION TO HEPATITIS C POSITIVITY IN PATIENTS ON MAINTENANCE HEMODIALYSIS IN SUB-SAHARAN AFRICA: A SINGLE CENTER STUDY

Gloria EnowAshuntantang, Richard Njouom, Andre PasalKengne, Antoine NyopeNgemhe, Francois FolefackKaze, Henry NnammeLuma, OudouNjoya

3. https://www.jcdr.net/article\_fulltext.asp?id=1476

Prevalence and Risk Factors of Hepatitis C among Maintenance Hemodialysis Patients at a Tertiary-Care Hospital in Coimbatore, India . Surendra Kumar P., Venu G., MadhusudhanaRao A., Balakrishnan N., Saravanan T., Sofia Rani A., SubbaRao T.M.

Department of Nephrology, Biochemistry & Clinical Pathology PSG Institute of Medical Sciences and Research (PSGIMS&R) Coimbatore - 614004 Tamilnadu, India.

4. https://jemds.com/latest-articles.php?at\_id=5524

PREVALENCE, SEROCONVERSION AND RISK FACTORS OF HEPATITIS B AND C INFECTION IN PATIENTS ON MAINTENANCE HEMODIALYSIS Vikas Makkar1, Dinesh Gupta2, Kanish Bansal3, N. S. Khaira4

5. http://clinicalestablishments.gov.in/WriteReadData/358.pdf.

STANDARD TREATMENT GUIDELINES HAEMODIALYSIS Ministry of Health & Family Welfare Govt. of India

6. https://bmcnephrol.biomedcentral.com/articles/10.1186/s12882-019-1529-1

Clinical practice guideline management of blood borne viruses within the haemodialysis unit

Elizabeth Garthwaite, VeenaReddy, SamDouthwaite, SimonLines, KayTyerman & James Eccles

7. http://www.ijstd.org/article.asp?issn=2589-0557;year=2019;volume=40;issue=2;spage=120;epage=125;aulast=Kansay

Seroprevalence of human immunodeficiency virus, hepatitis B virus, and hepatitis C virus among hemodialysis patients in a Tertiary Care Teaching Hospital in a developing country

Sonam Kansay<sup>1</sup>, Jannat Sekhon<sup>2</sup>, Saifi Rana<sup>2</sup>

 http://www.jcrsmed.org/article.asp?issn=2455-3069;year=2016;volume=2;issue=1;spage=20;epage=23;aulast=Perumal..Seroprevalence of hepatitis B and C in patients on haemodialysis and their antibody response to hepatitis B vaccination

Anandh Perumal<sup>1</sup>, Philip Vivian Joseph Ratnam<sup>1</sup>, Shashikala Nair<sup>1</sup>, Patricia Anitha<sup>1</sup>, Veerappan Illangovan<sup>2</sup>, Reba Kanungo<sup>1</sup> <sup>1</sup> Department of Microbiology, Pondicherry Institute of Medical Sciences, Puducherry, India

9. https://www.pjms.org.pk/index.php/pjms/article/view/366

Hepatitis-C and it's seroconversion in end stage kidney disease patients on maintenance hemodialysis and factors affecting it

Hepatitis-C in ESKD patients on maintenance hemodialysis

YasirHussain, AnjumShahza, Sidra Azam, NazishMunawar

10. <u>http://www.ijmm.org/article.asp?issn=0255-</u> 0857;year=2005;volume=23;issue=1;spage=41;epage=43;aulast=Reddy

Prevalence of HBV and HCV dual infection in patients on haemodialysis

GA Reddy<sup>1</sup>, KV Dakshinamurthy<sup>2</sup>, P Neelaprasad<sup>2</sup>, T Gangadhar<sup>2</sup>, V Lakshmi<sup>1</sup> <sup>1</sup> Department of Microbiology, Nizams Institute of Medical Sciences, Panjagutta, Hyderabad -500 082, Andhra Pradesh, India