Hepatitis C Virus Antibodies Among Hemodialysis Patients in Makka, Kingdom of Saudi Arabia

ABSTRACT

BACKGROUND: Hepatitis C virus (HCV) infection is the most common cause of chronic liver disease in the world and evaluation of the epidemiology of HCV infection was made possible by the development of a serological assay to detect antibodies to epitopes of HCV. Hemodialysis (HD) is considered to be one of the main risk factors of HCV transmission. The prevalence of antibodies to HCV (anti-HCV) in patients undergoing maintenance dialysis therapy (MDT) was found to be one of the highest among different risk groups and there is wide variation in the prevalence of HCV infection among different dialysis units and countries. Therefore, the prevalence of anti-HCV was studied in patients undergoing MDT.

MATERIALS AND METHODS: The current study is a cross-sectional one, where a sample of 361 HD patients were selected randomly from HD centers in three governmental hospitals in Makka city and they were subjected to assessment for the prevalence of anti-HCV by using questionnaire in addition to clinical measurements.

RESULTS: The overall prevalence of anti-HCV among HD patients was 49.9% according to clinical measurements and questionnaire.

CONCLUSION: The overall prevalence of anti-HCV among HD patients in Makka city (49.9%) was comparable to that reported from other parts of the Kingdom of Saudi Arabia (KSA) and it is almost similar to the already reported positivity rate of (45.2%) from the eastern region of KSA [1] and southern regions of KSA (45.5%), [2, 3] However, strict adherence to universal precautions as recommended by the Center for Diseases Control (CDC), meticulous regular disinfection of HD machines, strict isolation of HCV-positive patients, dedicated dialysis machines and nursing staff at new dialysis set-up could possibly be the reasons of relatively low anti-HCV positivity at the current study than that reported by Shaheen, et al [3, 4], from four centers in the western region of KSA, (72.3%) and that by Hurabi, et al [5] [6] in their multi-center study in KSA, (68%), as well as the mean national rate [3, 7]. On the other hand, the use of more sensitive third generation enzyme-linked immunosorbent assay (ELISA) technique, long duration on HD, multiple blood transfusions, patients with dialysis treatment in multi-centers, factors related to infrastructure, urbanization and operational system might be responsible for the high prevalence of anti-HCV found in this study than that reported earlier by Saeed, et al [8] from Riyadh and those observed in the central region of KSA [9] Although routes of transmission are still unclear, early detection of all infected patients is mandatory for HCV prophylaxis in HD patients. Furthermore, an intensive educational program for staff members, HD patients and proper evaluation of the HD situation are needed. Thus, observation of appropriate preventive measures by all HD-centers is paramount.

KEYWORDS

Hepatitis C Virus, Hemodialysis, Makka, Kingdom Of Saudi Arabia.

INTRODUCTION:

Hepatitis C virus (HCV) was first identified in 1989 by Choo et al. [10] HCV infection is a persistent public health concern in hemodialysis (HD) patients [11, 12] and is the most common cause of chronic liver disease among dialysis patients [13]. HD patients are vulnerable to HCV infection because of the risk for exposure to HCV associated with the dialysis procedure [15]. In contrast with the hepatitis B virus (HBV), no vaccine is available for HCV [16]. Accurate testing for HCV is complicated by regional variation in the HCV genome and by variation in screening tests [16-19]. Patients infected with HCV often have minimal clinical evidence of disease [16, 18, 20]. HCV infection in end-stage renal disease (ESRD) patients has been associated with greater morbidity and mortality [18, 21, 22]. HCV infection has also been associated with greater morbidity and mortality in ESRD patients after they have received a renal transplant [23-25] and is particularly highly prevalent in developing countries [26].

There is wide variation in the prevalence of HCV infection among different dialysis units and countries as shown by Dialysis Outcomes and Practice Patterns Study (DOPPS) [27].

Approximately 170 million people in the world are infected with HCV [28]. The reported prevalence of anti-HCV antibody world-wide among dialysis patients has ranged from 1.7% [29] to 55% [30], from 1.7 to 70% [31], from 2% in northwestern Europe to 76.3% in Indonesia [32, 33] and from 29.4% to 65% in Brazil [34-37].

However, in Kingdom of Saudi Arabia (KSA), a positivity rate of HCV ranging between 14.5 and 94.7% has been reported [6]. Furthermore, studies from dialysis units in KSA have reported prevalence rates of 34.8% to 53.7%, 46.5%, 45.5% and 72.3% from the central [8, 38], eastern [39], southern [40], and western [3] regions, respectively. Other study conducted by Shaheen, et al [3] reported anti-HCV prevalence rate of 62.7% from Jeddah city and in a multi-center study of 22 HD units in KSA performed by Hurabi, et al [41] reported a prevalence rate ranging from 14.5 to 94.7% [4]. Patients on long-term HD are considered to be a population at risk for HCV infection and the prevalence of anti-HCV in patients undergoing maintenance dialysis therapy (MDT) was found to be one of the highest among different risk groups [42]. Chronic HD is associated with both endemic cases and, more rarely, sporadic outbreaks of HCV infection [43]. Therefore, the prevalence of antibodies to HCV (anti-HCV) was studied in patients undergoing MDT.

HCV infection is of great clinical importance since: (a) it is commonly associated with chronic liver disease and cirrhosis [15] [44] [45] [46]. (b) it can lead to the development of hepatocellular carcinoma [47] [48] (c) there is an increased risk of developing chronic liver disease in renal allograft recipients who are anti-HCV positive [49] [50] [51]. (d) till date, no vaccine has been developed for HCV. (e) there is an increased risk for development of chronic hepatitis in anti-HCV positive renal transplant recipients [52]. Although HCV-associated liver disease typically takes decades to become clinically manifest, a period of time much longer than the lifespan of most dialysis patients with a 5-yr survival of 60 to 70%, the liver disease-related complications seem the unlikely link to the high death risk [53]. However, the magnitude of HCV transmission within HD units is still unclear and therefore general recommendations for prevention have not been developed [12, 54, 55]. The Centre for Diseases Control (CDC) has made no recommendations for controlling HCV in HD units [12]. However, the natural course of HCV in HD patients is not well understood. It seems to differ from that in other HD patients [56]. Liver function tests are close to or near normal in many cases [57, 58] but the mortality of HCV infected HD patients seems to be enhanced compared with HCV negative HD patients in preliminary studies [59]. Thus, patients with HCV on chronic HD are at increased risk of death, which suggests that the focus should be directed more to identification and prevention of HCV infection in HD patients.

Despite the importance of this topic, there is remarkable paucity in the studies which identify prevalence of anti-HCV in HD patients in KSA. This paucity was detected after extensive search using the key words (Hepatitis C virus, Hemodialysis, Saudi Arabia) in both Pub Med and...
The aim of this study was to identify the prevalence of anti-HCV among HD patients at governmental kidney centers in Makkah city in KSA for the purpose of adopting practical measures to stop or minimize the spread of HCV infection among dialysis patients.

**MATERIALS AND METHODS:**

The current cross-sectional study was carried out in three HD centers at three major governmental hospitals in Makkah city which is located in the western region of KSA. The HD machines are always busy through the year with four shifts daily. Sometimes a fifth shift has to be arranged to overcome the heavy workload with large influx of patients during the Holy months of Ramadan and Hajj due to a large number of visitors from outside the city of Makkah and there is an arrangement for visitors who have ESRD and need dialysis to do it in governmental hospitals. Small HD units are also available in other governmental and private hospitals, which accommodate for only a small percentage of patients.

The study population represents patients registered in the three HD centers present in three major governmental hospitals in Makkah city. Their total number was estimated to be around 2000 patients at the time of the study; they included all patients with ESRD requiring HD and they are all registered in the HD units of kidney centers. Patients at the HD centers in the three hospitals undergo HD for an average of 3 times a week, with a small percentage undergoing HD only twice a week. The HD sessions usually take place in four shifts, from 7:30 A.M to 10:30 A.M, from 11:00 A.M to 2:00 P.M, from 2:30 P.M to 5:30 P.M and from 6:00 P.M to 9:00 P.M.

The sample size needed for estimating prevalence of anti-HCV was calculated by using Epi-Info program version 6.04; the required sample size was 385 patients. The respondent who completed the participation accounted for 361; making a response rate of 93.8%. Inclusion criteria were any patient, conscious, understands, able to give an informed consent (if the patient was less than 18 years, the consent was taken from his parents) and regular on HD. Stratified sampling was conducted to ensure representativeness of male and female patients. Stratification was based on the available list of patients at each HD center in each hospital. This list cover patients from all wards, including male and female wards, the isolation section, both hepatitis C positive and negative patients and at different times of the day.

As the number of patients who were available at the time of the study accounted for 770 patients, an estimated sample size was 385 which represented one half of the patients; therefore, the estimation designated sample in each place was half of available listed patients as described in table one.

The allocation of patients from each list was done by systematic sampling selecting every second patient in each list. There were separate lists for males and females which facilitated allocation of the sample by gender.

Prevalence of anti-HCV in patients with ESRD was measured by a variety of methods. However, questionnaires and clinical measurements were used to measure prevalence of anti-HCV in HD patients.

A set of a structured questionnaire was developed by the researcher to ascertain information on patients' demographic characteristics and HCV status of patients and was translated into Arabic then it was back translated to ensure lexical equivalence. Additionally, it was subjected to validity testing after being translated into Arabic language and reviewed by consultant of family medicine, consultant of community medicine and nephrology consultant.

All patients underwent dialysis three times weekly. All units follow the same machine chemical disinfection protocols with no dialyzer reuse. The anti-HCV (Hepatitis C Virus Antibodies) assay was performed for every patient included in the study by using a third-generation enzyme - linked immunosorbent assay (ELISA) and for newly positive-case polymerase chain reaction (PCR) was performed for confirmation.

Dry weight (weight at the end of dialysis treatment) which is taken as the lowest tolerable weight at the end of dialysis treatment without the development of symptoms or hypotension, and the inter dialytic weight gain (IDWG) is calculated as the difference between the patient’s weight obtained at the onset of a dialysis treatment and the weight obtained at the end of the previous dialysis. The clinical measurements included biological measurements which included in addition to interdialytic weight gain (IDWG), biochemical markers which included pre-HD serum potassium or phosphorous levels and anti-HCV assay.

Upon arrival to the dialysis centers, the physicians in charge were contacted and the researcher used to present the study design and explain the purpose of the research to the HD staff. Information regarding the HD center was obtained from the chief HD nurse. According to selection and inclusion criteria, designated patients were invited to participate in the study after explaining to them the purpose of the study.

Medical files of the patient were examined to check the weight of patients pre hemodialysis, weight of patients post hemodialysis (dry weight), number of co-morbid diseases and the presence of chronic diseases (such as DM, HTN), psychiatric diseases, hospitalization history, kidney transplant history, causes of kidney failure, hepatitis profile, potassium and phosphorous level, for how long is he or she on dialysis, number of daily tablet, others... These information were available for every patient as they are doing a monthly blood test examination pre and post hemodialysis session to evaluate the level of potassium, phosphorus and others chemical indicators.

Weight for each patient was measured before and after each HD sessions by well-trained nurses. The patient's weight at the beginning of dialysis session was subtracted from the weight at the end of previous dialysis session (dry weight) to calculate the interdialytic weight gain (IDWG); then this IDWG is divided by weight at the end of previous dialysis session (dry weight) to get IDWG percentage. A standard electronic weighing chair was used to obtain the weight. The scale was placed on a hard floor surface. Participants were asked to remove their heavy outer garments; female patients were weighed with Abaya (ladies body cover), and Abaya was weighed and its weight was subtracted from the total. Weight was measured in all participants and taken to the nearest 0.1 kg using weighing scale. The scale was calibrated at the beginning and end of each examining day. The scale was checked using the standardized weights and calibration was corrected if the error was greater than 0.1 kg.

The pilot study was carried out in Jeddah kidney center at King Fahd general hospital (referral center for HD patients in Western province) on about 10% of our sample size who were not included in the main study.

Statistical Package for Social Science (SPSS) program, version 20 was used for statistical analysis of data. The level of statistical significance was set at $P<0.05$ throughout the study.

Data was obtained after applying for ethical approval from the Ministry of Health & General Directorate of Health Affairs in Makkah city.

| Table 1: Description of samples and responses from each hospital according to gender: |
|-----------------|-----------------|-----------------|-----------------|
|                 | Al-Noor Specialist Hospital (ANSH) | King Abdul-Aziz Hospital (KAH) | King Faisal Hospital (KFH) |
| Available patients | 518              | 162             | 90              |
| Gender          | Male Female     | Male Female     | Male Female     |
| Available patients according to gender | 266 252        | 74 88           | 28 62           |
| Required sample of patients | 133 126        | 37 44           | 14 31           |
| Responded patients | 125 118        | 34 41           | 13 30           |
RESULTS:

The current study included 361 patients. Table 2 demonstrates that the majority of patients (78.9%) aged <65 years, with a mean age of 50.1±15.8 years. There was almost equal distribution of males and females with an overwhelming majority of Saudis (93.9%). About two thirds of them were married (62.3%) and around one third (31.3%) were illiterate. The great majorities (88.9%) were unemployed and almost two thirds of the patients (60.1%) had monthly income between 1000 and 3000 SAR (Saudi Arabian Riyals). Table 3 shows that the most commonly identified causes of renal failure were diabetes mellitus (23%) and hypertension (21.9%). On the same line, it was found that the overwhelming majorities of the patients (93.9%) were currently hypertensive and a considerable proportion (39.6%) were currently diabetic. One half of the patients (50.3%) were on dialysis for 60 months or more and the majority (77%) had previous history of hospitalization. Clinically, the average number of co-morbidities accounted for 3.0 diseases; the median interdialytic weight gain was 2.0 Kg; the average number of daily tablet(s) taken by patients was 5.0.

The mean levels of pre- hemodialysis serum potassium (K+) and phosphorus (po4) were 5.1(0.9) mmol/L and 5.3(1.8) mg/dl; the average number of daily tablet(s) taken by patients was 5.0. The mean levels of pre- hemodialysis serum potassium (K+) and phosphorus (po4) were 5.1(0.9) mmol/L and 5.3(1.8) mg/dl; the average number of daily tablet(s) taken by patients was 5.0.

Hospitalization history

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<th>Number of daily tablets</th>
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<th>Pre-hemodialysis serum phosphorus</th>
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<tr>
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<td>5.3(1.8) mg/dl</td>
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Table 4: Prevalence of HCV infection (n=361):

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<td>Negative</td>
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<td>50.1</td>
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DISCUSSION:

HD patients are at high risk for hepatitis viral infections especially for HCV infection,[60] which has been reported from different parts of the world as a common infection, have a high prevalence rate and now recognized as the principal cause of liver disease among HD patients. [61][28]

Prevalence of HBV and HCV in HD patients were reported by several authors ranging between 0.9% to 21.6% for HBV[62, 63] and 3.4% to 65.8% for HCV.[64-66] There is a wide range in prevalence rates of HCV infection among HD patients in different regions of the world, ranging from 1% in the UK to more than 90% in Eastern Europe.[14, 67-74]

In the current study, we observed a high prevalence of HCV antibody among patients undergoing HD at different centers in Makah city. The overall anti-HCV prevalence among HD patients in Makah city (49.9%) was comparable to that reported from other parts of KSA. It is almost similar to the already reported positivity rate of (43.2%) from the eastern region of KSA [1] and southern regions of KSA (45.5%)[2, 3].It is much lower than that reported from other centers in KSA. It is lower than that reported by Shaheen, et al [3, 4], from four centers in the western region of KSA,[72,3]% and that by Huraib, et al [5][6] in their multi-center study in KSA, (68%) as well as the mean national rate[3, 7] However, this value is higher than those observed in the central region of KSA.[9]

Strict adherence to universal precautions as recommended by the CDC and meticulous regular disinfection of HD machines, Strict isolation of HCV- positive patients, dedicated dialysis machines and nursing staff at new dialysis set-up could possibly be the reasons of relatively low anti-HCV positivity at the current study.

The use of more sensitive third generation ELISA technique in our study could partially explain our higher prevalence rate than that reported earlier by Saeed, et al [8] from Riyadh. Factors related to infrastructure and operational system might be responsible for the very high prevalence of anti-HVC found in this study.

Dialysis treatment could be a specific independent risk factor for HCV transmission as cross infection and could be responsible for high prevalence of anti-HCV positivity in HD patients in the current study. The reported annual seroconversion rate of 7-9% among HD patients of KSA.[75]

The positive correlation of anti-HCV positivity with duration on HD coupled with 4.8% positivity among patients who had never been transfused, indicate strong possibility of nosocomial transmission of HCV, these observations have been reported from multiple HD centers. [14, 76, 77] Hence, the importance of strict adherence to universal infection control precautions should be emphasized in all the HD centers.

Blood transfusions could be responsible for the high prevalence of...
anti-HCV found in the current study. Blood transfusions can be a source for anti-HCV positivity according to reports [78] [79] though reports to the contrary also exist [80]. However, data on correlation between anti-HCV positivity and history of blood transfusion in dialysis patients is conflicting. Whereas, some workers reported positive correlation [3, 41, 72, 79] others found none.[81, 82] Nevertheless, HCV transmission through blood transfusion should be considered since the reported prevalence of anti-HCV antibody in healthy donors varies from 0.42% in Germany [83] up to 6.6% in China [84]. The overall prevalence of anti-HCV among voluntary blood donors in KSA is about 2.2% [85]. Thus, screening of blood donors for anti-HCV would be important to prevent HCV transmission.

But duration of HD in patients with or without blood transfusions is also an independent risk factor.[73, 81, 86, 88] Thus patient to patient transmission during HD has been suggested.[89-93] Patient to patient transmission was prospectively proved in several incidence studies in HD patients.[91-93] Repeated blood transfusions is a risk factor for HCV transmission. However, data on correlation between HCV positivity and number of blood transfusions is inconclusive. In some studies, a positive correlation with blood transfusion has been reported [72, 94] while others have refuted this possibility. [81, 82] An increased prevalence of anti-HCV positivity among patients on HD for longer periods of time has been reported.[95, 96]

Cross-infection could be responsible for the high prevalence of anti-HCV in HD patients in this study. Hence, the dialysis staff should observe all necessary precautions to prevent this. The allocation of separate HD machines for the anti-HCV positive patients could pose a real problem because of the large number of these patients. Since machine to patient transmission is not very well documented up to now, machine isolation may not be justified at the moment.

While the exact mode of HCV transmission through dialysis remains to be elucidated, it is reasonable to designate separate dialysis machines for anti-HCV positive patients. It would be of interest to follow-up the seronegative patients to see the impact of their isolation on seroconversion rate.

Nosocomial transmission of HCV and HBV is an important contributing factor to the spread of these viruses.[97, 98] Despite various infection control procedures in HD patient, prevalence and incidence rates of HBV and HCV are still significant. [99, 100] Studies have shown that strict aseptic measures can virtually eliminate transmission of HCV in units with a high prevalence of HCV infection.[101] It is known that different methods of control, cleaning and disinfection of the HD membranes, machines, instruments and environmental surfaces may interfere with determined prevalence.[97]

Although the route of HCV transmission in HD patients is not yet fully elucidated, previous studies suggest that dialytic age and number of blood transfusions are closely associated with HCV seropositivity. [102] Patients with dialysis treatment in multi-centers are also more prone to acquiring HCV infection.[103] Contaminated HD-machines, dialyzers, bloodline surfaces and hands of the caring staff and possibly, sharing of multi-dose heparin vials, are the possible factors that can contribute to the transmission of HCV among the multi-center visitors.

Non-uniform adherence to the universal precautions and disinfection procedures in different centers as well as practice of dialyzing both HCV positive and negative patients in the same room, with or without separate machines, might be the underlying reasons to make these patients more prone to acquire HCV. However, dialysis of HCV positive patients in a separate designated room is not recommended by the CDC.[104] Multivariate analysis has revealed that seropositivity of HCV increases with the increased dialytic age of the patient and the number of blood transfusions. However, reports to the contrary have also been published regarding the association of blood transfusion and HCV transmission.[105, 106] Increased nosocomial transmission due either to prolonged immunocompromized state or breaches in the universal infection control measures during dialytic age, may be the factors responsible for this. Recently, nosocomial transmission of HCV among HD patients has been documented by the molecular analysis.[107, 108] which raises the question of how HCV-positive patients should be handled in dialysis units. Although, it has been showed that 50-70% of HCV-positive patients progress, over a period of 10-40 years, to chronic hepatitis with increased risk of cirrhosis, liver failure and liver cancer.[48] the longterm outcome of untreated patients chronic HCV infection having normal or elevated liver enzymes is still unknown.

CONCLUSION:
In conclusion, this cross-sectional study was designed to identify the prevalence of anti-HCV among HD patients in Makkah city since they are at high risk for HCV infection. The overall prevalence of anti-HCV among HD patients in Makkah city (49.9%) was comparable to that reported by Shalheen et al [1] and it is almost similar to the already reported positivity rate of (43.2%) from the eastern region of KSA [1] and southern regions of KSA (45.5%).[2, 3] However, Strict adherence to universal precautions as recommended by the CDC, meticulous regular disinfection of HD, machines, strict isolation of HCV-positive patients, dedicated dialysis machines and nursing staff at new dialysis set-up could possibly be the reasons of relatively low anti-HCV prevalence at the current study than that reported by Shalheen et al [3, 4] from four centers in the Western region of KSA, (72.3%) and that by Hurabi, et al.[5, 6] in their multi-center study in KSA, (68%) as well as the mean national rate.[3, 7] On the other hand, the use of more sensitive third generation ELISA technique, long duration on HD, multiple blood transfusions, patients with dialysis treatment in multi-centers, factors related to infrastructure, environment and operational system might be responsible for the high prevalence of anti-HCV found in this study than that reported earlier by Saeed, et al [8] from Riyadh and those observed in the central region of KSA.[9]

RECOMMENDATIONS:
This study recommends health leaders to improve the economic status of HD patients who need that support because almost two thirds of the patients (60.1%) had monthly income between 1000 and 3000 SAR. Since the great majorities (88.9%) of HD patients at the HD centers are unemployed, a subsidized support system must be initiated to support these patients; Social agencies and charitable organizations can collaborate with HD centers in this effort.

As the current study showed a high prevalence of anti-HCV among HD patients [almost one half (49.9%) of them were anti-HCV positive] in Makkah city, frequent measurement of prevalence of anti-HCV for them should be carried out in all HD centers in Makkah city and other parts of KSA.

Further qualitative and quantitative researches into effective ways are needed by using different research designs to identify the prevalence of anti-HCV among HD patients in Makkah city and other parts of KSA. The results of these researches are better to be compared with results of this study. These researches must continue in order to improve outcomes among HD patients.

Efforts should be done to identify factors associated with HCV infection in Makkah city and other parts of KSA in order to decrease them as these factors constitutes a major health problem for HD patients. However, in most European countries, consistent reinforcement of hygienic precautions and/or isolation strategies in HD units has resulted in a substantial decrease of both the incidence and prevalence of HCV infection in HD units.[109] So, we must concentrate more on those factors in addition to factors related to infrastructure, environment and operational system.

More detailed studies are required to know the exact mode of spread of HCV so that appropriate measures may be taken to prevent this serious disease from spreading. However, an intensive educational program for staff members and proper evaluation of the HD situation are needed. Thus, observation of appropriate preventive measures by all the HD-centers is paramount.

Strict adherence to the universal precautions combined with proper disinfection procedures and raising awareness among the HD staff and patients may reduce the spread of HCV infection in the dialysis units. Furthermore, as routes of transmission are still unclear, early detection of all infected patients is mandatory for HCV prophylaxis in HD units. Hence, the dialysis staff should recognize these patients as those factors constitute a major health problem for HD patients. However, in most European countries, consistent reinforcement of hygienic precautions and/or isolation strategies in HD units has resulted in a substantial decrease of both the incidence and prevalence of HCV infection in HD units. It is known that different methods of control, cleaning and disinfection of the HD membranes, machines, instruments and environmental surfaces may interfere with determined prevalence. [97]
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