

Impact of Quality Control Measures in Prevention of HCV Seroconversion in Haemodialysis Patients.

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Abstract:

Background: HCV infection is very prevalent among the haemodialysis (HD) patients and constitutes a major cause of morbidity and mortality among these patients. This study is designed to reduce the HCV seroconversion rate among haemodialysis patients. **Methods:** A total number of 382 HD patients in King Fahad Kidney center (KFKC) were recruited in the study in a period of 2 years, from January, 2012 to December, 2013. The quality control measures were implemented effectively in March, 2013. HCV seroconversion rates were assessed every 3 months during the observation period. **Results:** The prevalence of HCV cases in the beginning of the study was 23.3%. After 1 year the prevalence of HCV cases increased to be 24.3% and HCV seroconversion

rate was 1% by the end of the 1st year. Outbreak of HCV infection occurred in the following 3 months and the prevalence increased to 25.1% and seroconversion rate recorded 0.78% in these 3 months only. After effective application of the quality control measures, no further HCV seroconversion were recorded in the following 9 months till the end of the study and the seroconversion rate was 0% (significant reduction, $\chi^2 = 8.3, P = 0.003$). **Conclusion:** Effective implementation of the quality control measures on the haemodialysis patients decreased the seroconversion rates of HCV as a blood borne disease among these patients.

Key words: quality control measures, haemodialysis, hepatitis C virus.

Introduction:

Hepatitis C virus (HCV) infection represents a big public health challenge in this millennium and the World Health Organization estimates that, until 1998, 170 million people carried the HCV worldwide and in recent years 200 million or 3% of the world population is infected with this virus⁽¹⁾.

The prevalence of HCV infection in patients undergoing dialysis is greater than that in the general population, suggesting that patients on dialysis may be at higher risk of acquiring HCV infection. This is predominantly because these patients are more exposed to risk factors for the acquisition of this infection and also because they are monitored monthly by laboratory examinations that permit an early diagnosis of the infection⁽²⁾. The prevalence of HCV infection in hemodialysis patients(HD) can vary from 7% up to 70% in some countries^(3,4).

In contrast with the hepatitis B virus (HBV), no vaccine is available for HCV⁽⁷⁾. Accurate testing for HCV is complicated by regional variation in the HCV genome and by variation

in screening tests⁽⁴⁻⁸⁾. Patients infected with HCV often have minimal clinical evidence of disease^(6,7,8). HCV infection in end-stage renal disease (ESRD) patients has been associated with greater morbidity and mortality^(6,10,11).

There are many quality control measures to minimize the transmission of blood-borne infections including HCV in patients with ESRD already on HD.

These measures include hand hygiene protocols, awareness programs, aseptic technique policies, using single dose vials of heparin instead of multiple dose vials, reduction of the use of the central line access, environmental planning, staff planning, controlling of HD center entrances, improving bed and machine conditions and using erythropoietin to reduce blood transfusion⁽¹²⁻¹⁵⁾.

Chronic hepatitis C virus infection is found with variable prevalence in dialysis populations in different parts of the world. Outbreaks of hepatitis C has been reported in King Fahad Kidney Center (KFKC) in Riyadh,

KSA. In 2012 four patients were seroconverted from anti-hepatitis C virus (HCV) antibodies negative to anti-HCV antibodies positive. On the other hand, in first quarter of 2013, the Prevention and Control of Infection Department reported three new cases were seroconverted to HCV positive among hemodialysis patients of the center.

This project is designed to prevent seroconversion of HCV in dialysis patients.

Patients & Methods:

A total number of 382 patients with ESRD already on HD at least for 6 months were followed up in KFKC for 2 years; from January 2012 to December 2013. Application of the standard quality control program measures for HD patients was effective starting March, 2013. Patients were checked for HCV antibodies & PCR, HBV screen also was performed. Patients who were reactive to HBV were excluded from the study. All other causes of liver dysfunction & treatment with interferon &/or ribavirin were excluded. A case of HCV was defined as a patient diagnosed before as having HCV or was HCV antibody-positive at the time of entry of the study. Serology for HCV was done for our studied patients every 3 months. HCV seroconversion was defined as any patient was HCV antibody negative at the entry of the study then became positive at any time during the study.

Quality Control Measures Of HD Patients:

The quality control measures of HD in KFKC includes the following items:

Awareness programs: Lecture hall policies and procedures & PPT (power point) presentation.

Demonstrate proper aseptic techniques: Aseptic techniques policy, education sessions, audit sheet.

Demonstrate proper hand hygiene program: Hand hygiene policy, education sessions, audit sheet. Monitor staff performance regarding the aseptic techniques practice through conducting audit round by the multidisciplinary team. Conduct Hand Hygiene Campaign. Provision of hand out material to increase staff compliance to hand hygiene practice. Increase hand rub and hand washing stations.

Using Heparin single dose vial policy instead of multiple doses.

Reduction of using the central line access & provision of pre and post dialysis disposable procedure sets.

Improving the environmental cleaning: Conduct awareness sessions to patient about caring their central line access. Monitor nursing staff performance regarding the cleaning of particularly HD beds and machines and house keeper for cleaning the floors and walls. Update director of the HD center and director nursing to pre and post cleaning data sheet in regular bases. Train nursing staff and house keeper on the correct practice of HD machine disinfection and use the cleaning material. Increase distance between HD beds to be 1.5 meters.

Nursing manpower improvement plans: application of 2:1 patient –staff nurse ratio. Decrease shortage of staff.

Controlling the HD center entrances through security department improvement: Secured all KFKC facilities & increase security men.

Improving bed sharing & machine type for every patient: Standardized bed number and machine type to every patient, standardized fixed duty of nurses to patients on weekly bases.

Medical supply improvement: as changing the old HD machines by new version ones.

The quality control center in KFKC did a regular & continuous supervision & check up for all the parameters and the percentage of achievement of the targets of the quality control programs in HD units of KFKC.

A regular reporting to the quality control center from each HD unit including database & the cases of HCV including the seroconversion cases.

Statistics & Statistical Methods

The main item of our study was HCV cases as regards to the prevalence and seroconversion rates. The prevalence of HCV cases was studied as a cross sectional study of HCV cases among our HD patients. Seroconversion rates were checked every 3 months and were defined as any case with HCV antibodies negative at the entry of the study and changed at any time during the study into HCV antibodies positive. The seroconversion rates were represented as the number of the seroconversion cases per 100 patients every 3 months. Chi- square test was used to compare between the different groups. P was considered statistically significant if < 0.05 . SPSS software program (SPSS Inc., USA) was used.

Results:

The baseline clinical & demographic data of the studied patients are present in table 1. The number of patients was 382, 210 (55%) were males & 172 (45%) were females. The mean age of the patients was 55.6 years ±13.7 years. The mean duration of HD was 33.2±29.6 months. The numbers of each group of patients according to the etiology were; diabetic nephropathy: 152 (39.79%), hypertension nephropathy: 127(33.24%), primary glomerular disease: 29(7.59%), obstructive uropathy: 8 (2.1%), unknown disease: 33(8.63%), other causes: 33 (8.66%).

The duration of the study was 2 years (from January, 2012 to December, 2013). The number of HCV cases in our HD patients at the beginning of our study in January, 2012 was 89 (23.3%) patients, 4 cases were seroconverted by the end of 2012, so HCV cases were 93 (24.3%)&the seroconversion rate in 2012 was 1%. Outbreak of seroconversion of additional 3 cases were added in the first quarter in 2013. HCV cases were 96 (25.1%). The seroconversion rate in these 3 months only was 0.78%. After effective application of the HD quality control in March, 2013, no seroconverted cases were recorded till the end of the study in December, 2013. So, the seroconversion rate to HCV was 0% after effective application of the quality

control measures. These results showed significant reduction of the HCV seroconversion rate during the study ($\chi^2 = 8.3, P = 0.003$).

Quality Control Measures:

During the observation period, the attendance rate of the awareness programs was 92% & 80% of the staff were compliant to aseptic technique policy & 60 procedures were monitored per month. 70% of the staff were compliant to hand hygiene policy practice. There was 55% reduction in the rate of using central line in HD in 2013 & 90% of the KFKC staff attended the education sessions. Reduction of the shortage of the nursing staff to 10% by supporting 36 new staff. Adding 40 new HD beds & 78 new version of HD machines.

HCV Seroconversion Rates:

Outbreaks of hepatitis C has been reported in King Fahad Kidney Center. In 2012, 4 patients are seroconverting from anti-hepatitis C virus (HCV) negative to anti-HCV positive (the seroconversion rate was 1%) & 3 additional patients were seroconverted in the first quarter of 2013 among hemodialysis patients (the seroconversion rate in these 3 months only is very high ; 0.78%) . However application of the infection control program was done in March, 2013, the last 9 months of the observation study no cases of HCV seroconversion were recorded till the end of the study (in December, 2013).

Table1: the basic demographic & clinical data of the studied patients

Variable item	Number
Total number of patients	382
Male (no, %)	210 (55%)
Female (no, %)	172 (45%)
Duration of the study (in years)	2
Duration of HD (in months)	33.2 ± 29.6
Age (no ± SD) years	55.6 ±13.7
Hypertension nephropathy (no,%)	127 (33.24 %)
Diabetic nephropathy (no,%)	152 (39.79 %)
Primary glomerulopathy (no,%)	29 (7.59%)
Idiopathic KD (no,%)	33 (8.63%)
Obstructive uropathy (no,%)	8 (2.09 %)
Other causes (no,%)	33 (8.66%).
HCV patients at the beginning of the study in Jan 2012 (no,%)	89 (23.3%)
HCV patients at the end of 2012 (no,%)	93 (24.3%)
No & % of seroconversion cases in 2012	4 (1%)
HCV patients at the end of March, 2013 (no& %)	96 (25.1%)
Seroconversion cases &rate from Jan to Mar,2013	3 (0.78%)
HCV cases by the end of 2013	96 (25.1%)
Seroconversion rate(from Mar to end 2013)(%)	0%

Figure 1

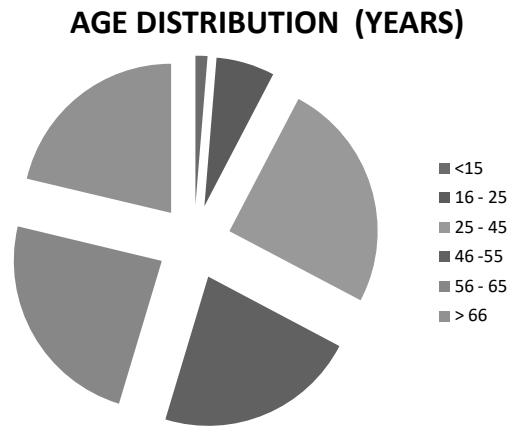


Figure 2

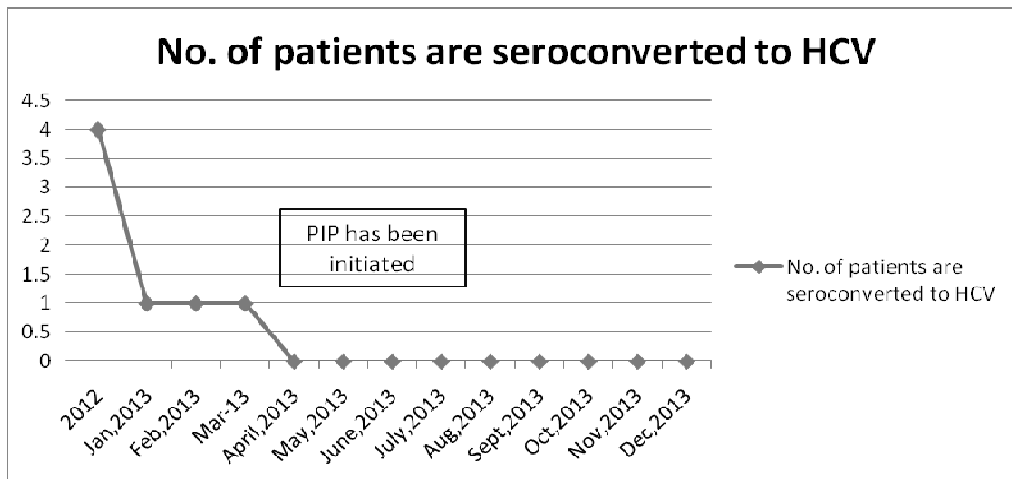


Figure 3

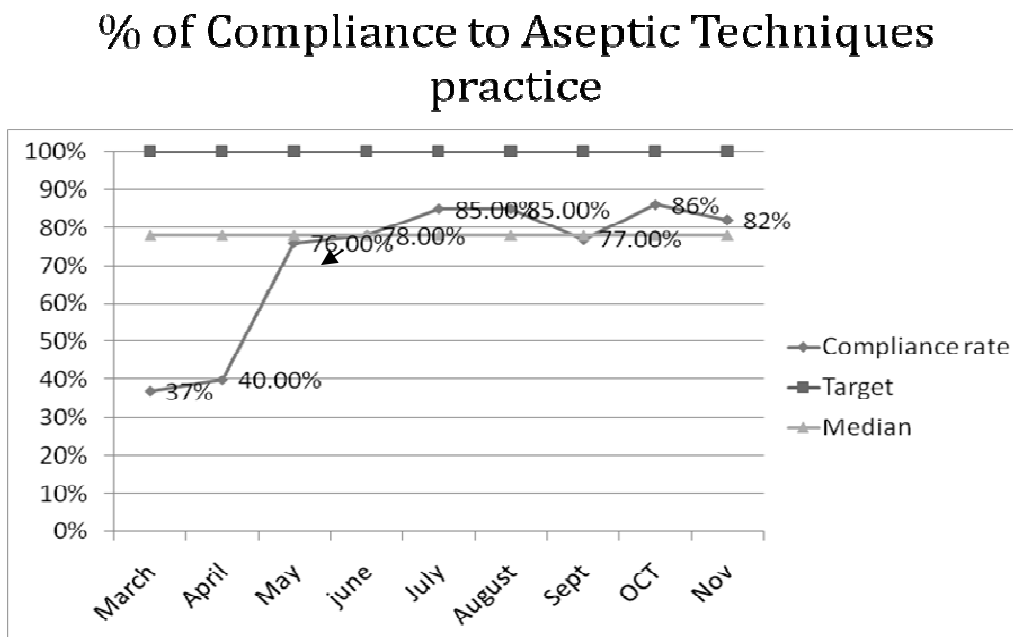
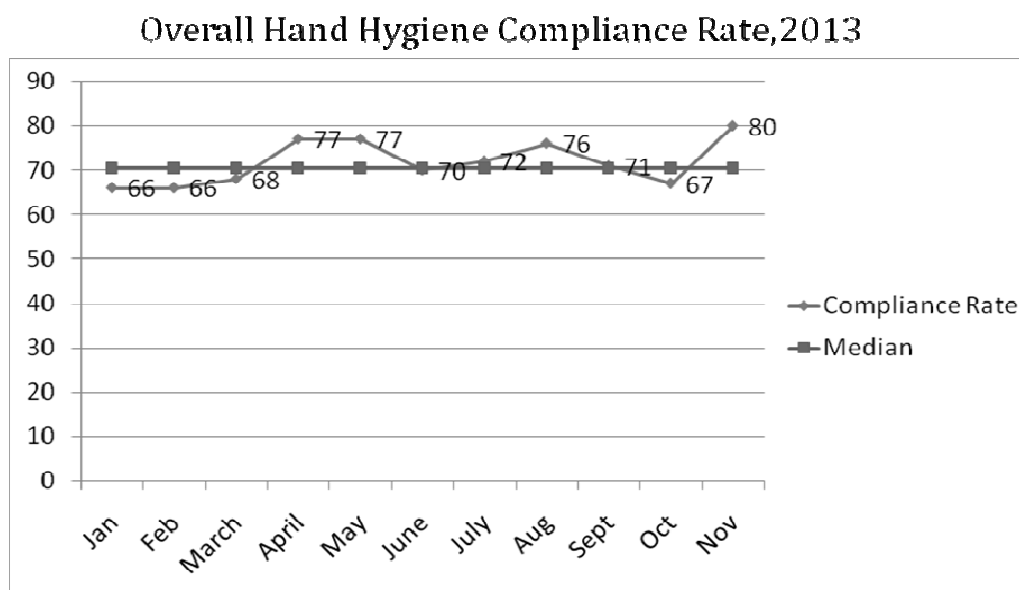


Figure 4:



Discussion:

More than 200 millions of the population (representing 3%) are infected by HCV according the WHO⁽¹⁾. The prevalence of HCV is much higher in haemodialysis patients than in the general population. Fabrizi confirmed that if the prevalence of HCV in the general population did not exceed 20% in endemic countries, it exceeds in chronic hemodialysis patients 80%⁽¹⁶⁾.

There are many quality control measures were applied to reduce the rates of nosocomial infections in HD patients⁽¹²⁻¹⁵⁾. Our present study done in King Fahad Kidney Center (KFKC), from January, 2012 to December, 2013, was applied using these measures aiming to reduce the seroconversion rate of HCV as a nosocomial infection to 0%. The database of this study was assessed, supervised and reported by the quality control center of KFKC.

Outbreaks of hepatitis C has been reported in KFKC. In 2012 four patients (prevalence is 1%) were seroconverted from anti-hepatitis C virus (HCV) negative to anti-HCV positive. On the other hand, in first quarter of 2013, Prevention and Control of Infection Department in KFKC reported three new cases (prevalence in these 3 months only

is 0.78%) were seroconverted to HCV positive among hemodialysis patients, however, the last 9 months of the study no cases of HCV seroconversion were recorded.

So with implementation of the quality control measures to our patients in KFKC, the prevalence of HCV seroconversion dropped markedly from 1% at the start of the study in January, 2012 to 0% seroconversion at the end of the study in December, 2013. These results are consistent with other studies implementing the HD quality control measures to minimize HCV seroconversion in HD patients⁽¹⁷⁻²⁰⁾.

In conclusion of our present study, the implementation of the updated quality control measures to HD patients is highly effective in reduction of the HCV seroconversion rates as a blood borne virus.

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