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Major article

An investigation of an outbreak of hepatitis C virus infections in a low-resourced hemodialysis unit in Vietnam

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Background: Hepatitis C virus (HCV) is a risk for all hemodialysis patients. Over a 2-month period in 2013, there were 11 HCV seroconversions at a satellite hemodialysis unit in Vietnam. We report the epidemiologic investigation of the transmission mode in the absence of unavailable phylogenetic analysis.
Methods: The outbreak occurred during a 2-year dynamic cohort study. All patients were tested every 2 months, and staff was tested annually for hepatitis B virus surface antigen and HCV core antigen. Cases were tested for viral genotypes to examine the genetic relationship. Direct observation of the patient care environment was performed, and infection control policy was reviewed for potential breaches. Data obtained during the cohort study were used to assess lifestyle and treatment-related risk factors for the incidence of HCV infection.
Results: All patients reused dialyzers and shared hemodialysis machines. One reprocessing system was used to rinse used dialyzers. The preparation area for parenteral medication and clean supplies was adjacent to the blood sample handling area and storage of reused dialyzers. HCV transmission through a shared machine was the likely mode of transmission in 1 of the 11 cases. Indirect contact transmission was the likely mode of HCV transmission for the remaining 10 cases.
Conclusions: Sharing hemodialysis machines was not the main risk factor for the outbreak, which was most likely caused by environmental contamination associated with infection control breaches. The outbreak highlights the importance of providing dedicated dialyzer reprocessing systems and strict adherence to infection control precautions to prevent HCV cross-contamination.

Hepatitis C virus (HCV) infection is common among the hemodialysis population both in developed and less-developed countries.[1] Even with specific infection control guidelines available for hemodialysis setting,[2,3] HCV outbreaks occur sporadically worldwide.[4,5] In Vietnam, satellite hemodialysis services have been developed to meet the increasing demand of end-stage renal disease patients. The challenge for decentralization will be the ability to fully implement standard precautions for the prevention of HCV and hepatitis B virus (HBV) infections.[6] We report an outbreak of HCV infection in the hemodialysis unit of District-6 Hospital, Ho Chi Minh City, Vietnam, over 2 months between September and November 2013. Current infection control practices at the unit and possible risk factors were examined to identify the source of infection.

METHODS

Study design

The outbreak was observed during a 2-year prospective cohort study which followed a dynamic population treated at the hemodialysis unit of District-6 Hospital between October 2012 and October 2014. The dynamic population was comprised of patients who entered and left the unit. During this 2-year period, all District-6 unit patients were recruited to participate in the study. Patients provided written informed consent to participate in the study. The study protocol was approved by the Human Research Ethics Committee University of New South Wales Australia (approval no. HC12363), Ho Chi Minh City Health Service (approval no. 3242/SYT-VP), and District-6 Hospital (approval no. 223/TB-BV) authorities.

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All of the ethics committees approved the consent procedure. During the 4 months from October 1, 2012-January 31, 2013, all patients aged ≥18 years were screened for hepatitis B virus surface antigen (HBsAg) and hepatitis C virus core antigen (HCV-coreAg). Only patients who were seronegative for HBsAg or HCV-coreAg were continuously recruited into the study. The recruitment rate for the cohort study was 100%. All patients consented to be screened for HBsAg and HCV-coreAg every 2 months, and testing continued until the study end point in October 2014 or until death, discharge, or the development of concurrent infection with HCV and HBV, whichever occurred first. Patients who seroconverted during this period were tested for viral genotyping. In accordance with our ethics approval, we reported all 2 month follow-up results to the director of the unit. In this article we report results for the 2 months prior and 2 months after the outbreak, from September 30, 2013-January 31, 2014, to illustrate the incidence of seroconversion before, during, and after the outbreak.

In the 2 months since the previous serology testing, between September and November 2013, when the outbreak of HCV occurred, there were 119 enrolled patients. Of these, 9 were HCV positive and 9 were HBV positive. These 18 patients were known to have acquired HCV or HBV infection since the previous follow-up in September 2013. All participants provided information on demographics, lifestyle, and treatment-related risk factors. Demographics included age and sex. Lifestyle risk factors included unprotected sexual contact, injecting drug use, shared use of razor blades, toothbrushes and nail clippers, piercing, tattooing, acupuncture, and having an HCV- or HBV-infected sexual partner or direct caregiver. Treatment-related risk factors included recent surgery, blood transfusion within the last 2 months, dialyzer reuse, hemodialysis session frequency (1-3 sessions per week), and attendance to different hemodialysis units. These data were reported every 2 months from a self-administered questionnaire and were crosschecked with the medical records. Information on the participants' HBV vaccination status, hemodialysis schedule (dates of hemodialysis), machine number, and treatment session (morning, noon, afternoon, or evening session) were obtained from their medical records. In accordance with the local guidelines there were dedicated machines that were only to be used by HCV-infected patients; therefore, inadvertent sharing of dedicated machines was examined as a potential risk factor for HCV.

All 12 nurses working at the study clinic consented to HCV-coreAg and HBsAg testing in October 2012 and then in November 2013.

Laboratory tests

The ARCHITECT HCV Ag assay and ARCHITECT HBsAg assay (Abbott Laboratories, Chicago, IL), which are chemiluminescent microparticle immunoassays, were used to detect in blood samples the presence of HCV-coreAg and HBsAg, respectively. Positive samples were subsequently tested for the HCV and HBV genotype by the TRUGENE HCV 5′NC Genotyping kit and TRUGENE HBV Genotyping kit (Siemens, Munich, Germany). Details of the performance of these tests have been outlined elsewhere.[6] The viral genotyping was used to match HCV incident patients in the outbreak with known HCV prevalent patients who acquired HCV infection prior to September 2013.

Statistical analysis

SPSS version 20 (IBM, Armonk, NY) was used to manage the study database and test summary statistics for categorical variables, including numbers and percentages, whereas continuous variables were tested for means and SDs. The α was set at the 5% level. A Mann-Whitney test was used for continuous data. Inferential statistics including the crude odd ratio (OR) and Fisher exact test were used to analyze categorical data. The OR estimates for any subsequent follow-up period were not adjusted for risk factors if none were present during the previous follow-up.

Review of current infection control policy of the unit

We compared the infection control procedures with international recommendations[2,3,7] to identify risk factors for HCV cross-transmission. Direct observation of the patient-care environment at the unit was made between November 2013 and January 2014 for infection control resources and procedures.

RESULTS

HCV and HBV seroconversion of patients and nurses

During the September 2013 follow-up there were 114 patients in the cohort study of whom 1 new HCV-infected patient was detected. One patient was lost to follow-up caused by death, whereas 6 patients were newly recruited into the study, leaving 119 participants to be screened at the subsequent 2 month follow-up in November 2013. Of these 119 patients, 11 patients were diagnosed as new HCV-infected cases. At the subsequent follow-up in January 2014, 11 patients were censored (1 was referred, 9 died, and 1 developed concurrent infection) and 9 patients were newly recruited, leaving 117 patients in the cohort of whom 1 new HCV-infected case was detected. Analysis of HBV serology testing at the September 2013, November 2013, and January 2014 follow-ups identified 2 out of 114, 0 out of 119, and 1 out of 117 new infected cases respectively. The flowchart of enrollment is shown in Figure 1.

Between September and November 2013, the 119 patient cohort was tested, and an outbreak of 11 new HCV-infected cases was identified. The mean age of these new HCV-infected cases was 58 ± 16 years (range, 29-79 years), and the female-to-male ratio was 1:1.7. The frequency of hemodialysis sessions of the 11 cases ranged from 16-24 sessions (mean ± SD, 20 ± 4 sessions). Potential treatment-related risks for HCV infection included blood transfusion (1/11) and attendance to different hemodialysis units (5/11).

In October 2012, all of the nurses were HCV-coreAg negative. All but 1 nurse tested negative for HBsAg. The HBsAg-positive nurse had been previously diagnosed as a HBV inactive carrier prior to employment at the District-6 unit. By November 2013, HCV and HBV infection status among all nurses had not changed.

Risk factors for HCV infection

There was no significant association between HCV seroconversion and blood transfusion (OR = 0.6; 95% confidence interval [CI], 0.1-5.2; $P > .99$), attendance to different hemodialysis units (OR = 1.5; 95% CI, 0.4-5.1; $P = .50$), and frequency of hemodialysis sessions (20 ± 4 vs 19 ± 7; $P = .90$). The OR estimates were not adjusted for lifestyle risk factors and surgery because none of these factors was present during the previous follow-up.

Evaluation of current infection control practices at the unit

The infection control policy at the unit originally concurred with the guidelines developed nationally,[8] by the Renal Association (United Kingdom),[2] and by the Centers for Disease Control and Prevention (United States).[3] Major modifications because of limited financial and human resources included (1) omission of HBV vaccination for patients, (2) failure to maintain dedicated machines and treatment