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ORIGINAL ARTICLE

Trends in Seroprevalence of Hepatitis B, Hepatitis C, HIV, and Syphilis Infections in Iranian Blood Donors from 2003 to 2005

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Background and Aims: **To determine changes (trends) in infection rates of hepatitis B surface antigen (HBsAg), hepatitis C virus (HCV), human immunodeficiency virus (HIV), and syphilis in Iranian blood donor population.**
Methods: **Specimens of 1,004,889 volunteer blood donors in Tehran blood transfusion service from 2003 to 2005 were screened for HBsAg, anti-HCV, anti-HIV1/2, and VDRL (venereal disease research laboratory) reactivity in a cross-sectional survey. Reactive samples were verified using a recognized confirmatory test which consisted of a second independent HBsAg enzyme immunoassay (EIA), and neutralization assay; an additional independent anti-HCV EIA and HCV-RIBA assay; a second independent anti-HIV1/2 test, and HIV Western blot; and a confirmatory fluorescent Treponemal antibody absorbed (FTA-ABS) test, respectively.**
Results: **The seroprevalence of HBsAg, anti-HCV, HIV Ab1/2, and VDRL was 0.9%, 2.1%, 0.2%, and 0.04%, respectively, in all blood donors. Prevalence of confirmed positivity was 0.6%, for HBsAg, 0.1%, for HCV RNA, 0.004%, for HIV western blot and 0.004% for FTA-ABS. Between 2003 to 2005, a decreasing trend was observed in HBsAg frequency. HCV frequency decreased in 2005 compared to 2003. The trend of HIV infection frequency had no increasing or decreasing pattern, and was relatively stable while the trend of syphilis infection frequency increased.**
Conclusions: **Although the frequency of transfusion-transmitted infections is low, it is still far from ideal in the volunteer blood donors. Reduction of trends of infections could be achieved through more scrutiny in donor selection, improved sensitivity of serological tests, and re-evaluation of infection routes in donors.**
Keywords: **Seroprevalence, Hepatitis B, Hepatitis C, HIV, Syphilis**

Introduction

Evaluating trends in blood donor infectious disease rates is essential for monitoring blood supply safety and donor screening effectiveness. Monitoring the incidence of transfusion-transmission infections in blood donors is important for estimating the risk of transfusion and optimizing donor recruitment strategies to minimize transmission. The blood transfusion service of Islamic Republic of Iran requires that all donations of whole blood, plasma, and transfusable components for fractionation into injectable derivatives should take serologic tests for syphilis, hepatitis B surface antigen (HBsAg) by a sensitive and specific test, antibody to hepatitis C virus (anti-HCV), antibody to the human immunodeficiency virus (HIV-Ab), and VDRL. Collecting facilities are prepared to provide reported testing of all reactive tests for hepatitis, HIV, and syphilis infections. The samples are retested in duplicate in a single test run;

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using a test kit of the same type from the same manufacturer used for the initial test and then they are analyzed by a confirmatory test.

Receiving reports of the current prevalence and the incidence of infectious diseases, detecting new infected cases, estimate the risk of an undetected infectious donation entering the blood supply, health and economic impact of post transfusion hepatitis B, hepatitis C, HIV, and syphilis infections and cost-effectiveness of the analysis of expanded testing protocols for mentioned infections in blood donors. The findings may indicate that a substantial proportion of previously unrecognized asymptomatic cases with established chronic liver disease exist among blood donors. An improvement in the sensitivity of assays for mentioned infections would reveal the undiscovered patients, considering to perform liver biopsy to establish state of hepatitis, vaccination of newborns and health care personnel, and educating on the routes of preventing disease transmission to them. The aim of this study was to determine the trends in the seroprevalence of hepatitis B, hepatitis C, HIV, and syphilis infections in Iranian blood donor population from 2003 to 2005.

Materials and Methods

Clinical and laboratory assessment

1,004,889 individuals from Tehran aged 18 to 68 years who came to Tehran blood transfusion center from 2003 to 2005 to donate blood were surveyed. All donations were tested according to the recognized screening test algorithms for hepatitis B surface antigen, anti-HCV, anti-HIV1/2, and VDRL (venereal disease research laboratory) reactivity for syphilis. Samples repeatedly reactive or indeterminate for HBsAg were further analyzed with a second independent HBsAg EIA, and if further reactive, tested using a neutralization assay. All reactive samples were verified through a recognized confirmatory test. Samples repeatedly reactive or indeterminate for anti-HCV were confirmed with an additional independent anti-HCV EIA and with a HCV-RIBA assay. Anti-HCV was tested by EIA, which is a qualitative enzyme immunoassay for detection of antibodies to hepatitis C virus in human serum or plasma and was confirmed by HCV RIBA 3.0. Samples repeatedly reactive or indeterminate for HIV were confirmed with a second independent anti-HIV1/2 test by EIA, and a HIV western blot. For syphilis infection, when the initial tests results (VDRL) were reactive, the donor was tested using fluorescent Treponemal Antibody Absorbed (FTA-ABS), a confirmatory Treponemal-based assay. The ethics committee of Baqiyatallah University of Medical Sciences approved the study proposal and protocol.

Statistical analysis

95% confidence intervals (CI) of the incidence rates were obtained by Poisson distribution [1], and positive predictive values were calculated by number of people with a positive confirmed test divided by number of people with a positive screening test.

Results

The results of serological screening tests for HBV, HCV, HIV, and syphilis infections performed by Tehran blood transfusion service between 2003 and 2005 showed that the seroprevalence was 8844 (0.9%) for HBsAg, 21390 (2.1%) for anti-HCV, 2509 (0.2%) for HIV Ab1/2, and 402 (0.04%) for VDRL in 1004889 subjects. The prevalence of confirmed HBsAg, HCV RNA, HIV western blot and FTA-ABS was 0.6%, 0.1%, 0.004%, and 0.004%, respectively. Between 2003 and 2005, a decreasing trend was observed in the frequency of HBsAg . The trend of HIV infection frequency had no increasing or decreasing pattern and was relatively stable. The trend of syphilis infection frequency was increasing in 2003 to 2005. The trend of HCV incidence rate was decreasing in 2003 but again became increasing in 2005. Tables 1 and 2 show the incidence rates (IR) per 100000 for HBV, HCV, HIV, and Syphilis for the years 2003 to 2005 by primary screening and confirmatory tests.

Table 1. Incidence rates (IR) per 100000 for HBV, HCV, HIV, and Syphilis by primary screening tests between 2003 and 2005, Iran.

Year		2003	2004	2005
No. of blood donors		329516	329961	345412
HBV	No. Positive	3761	2766	2317
	IR per 10^5 (CI 95%)	1141 (1105-1178)	838 (807-870)	671 (644-699)
HCV	No. Positive	9288	4903	7199
	IR per 10^5 (CI 95%)	2819 (2762-2877)	1486 (1445-1528)	2084 (2036-2133)
HIV	No. Positive	1141	425	943
	IR per 10^5 (CI 95%)	346 (327-367)	129 (117-142)	273 (256-291)
Syphilis	No. Positive	115	150	137
	IR per 10^5 (CI 95%)	35 (29-42)	45 (38-53)	40 (33-47)

Table 2. Incidence rates (IR) per 100000 for HBV, HCV, HIV, and syphilis by confirmatory tests between 2003 and 2005, Iran.

Year		2003	2004	2005
No. of blood donors		329516	329961	345412
HBV	No. Positive	2343	1949	1684
	IR per 10^5 (CI 95%)	711 (683-740)	591 (565-617)	488 (465-511)
HCV	No. Positive	462	225	276
	IR per 10^5 (CI 95%)	140 (128-154)	68 (60-78)	80 (71-90)
HIV	No. Positive	11	17	11
	IR per 10^5 (CI 95%)	3.3 (1.5-6.0)	5.2 (3.0-8.2)	3.2 (1.6-5.7)
Syphilis	No. Positive	7	12	19
	IR per 10^5 (CI 95%)	2.1 (0.9-4.3)	3.6 (1.9-6.4)	5.5 (3.3-8.6)

Comparing the results of primary screening and confirmatory tests showed that primary screening tests overestimated the frequencies. Positive predictive value of primary screening HBV, HCV, HIV, and syphilis tests in 2005 was 72.7, 3.8, 1.2, and 13.9, respectively.

Discussion

There are important potential public benefits to screen blood donors, early diagnosis and treatment of hepatitis B, C, HIV, and syphilis infections in asymptomatic subjects and modification of practices like alcohol consumption or prescription of hepatotoxic agents. In this study, a standard interview, physical exam and biochemical studies were conducted for each participant. We included volunteer blood donors and they were screened using a standard interview, physical exam, and history for high-risk behaviors. We did not use replacement or sold blood. The majority of donors were men.

The incidence of post-transfusion hepatitis C has decreased markedly since the implementation of donor screening for surrogate markers and antibodies to HCV. However, the current risk of post-transfusion hepatitis C is unknown. According to Donahue *et al.* [2] the risk of seroconversion in HCV is 3.84 percent per patient (0.45 percent per unit transfused) before donors are screened for surrogate markers which falls to 1.54 percent per patient (0.19 percent per unit) after screening. Since the addition of screening for antibodies to HCV in May 1990, the risk has been 0.57 percent per patient (0.03 percent per unit). Therefore, it is concluded that this decreasing trend achieved through increasingly stringent screening is statistically significant.

Relative importance of the two most common exposures associated with the transmission of HCV has changed over time [3]. Blood transfusions, which account for a substantial proportion of HCV infections which were acquired more than 10 years ago, account for only a small portion of recently acquired infections [3]. In contrast, injection drug use has accounted for a substantial portion of HCV infections during both the remote and recent past. Physicians need to be educated on the known and potential risks for HCV infection, the need to ascertain complete risk behavior histories from their patients, the appropriate evaluation of high-risk patients for evidence of infections.

Surgical operation, frequent dental therapy, dental extraction, multi-partner sex, and blood transmission are the main risk factors for HCV infection in Turkish community [4]. The rate of hepatitis C virus in index cases was 1.8% in their spouses and 1.2% in their children. The main route of HCV infection transmission in Mexico is blood transfusion and the highest incidence of chronic hepatitis C (CHC) has been found at fifth and sixth decade of life [5]. In Greece, although the prevalence of HCV in blood donors is low (0.2-0.4%), it is 1.25% in the general population. There was a trend of increasing prevalence with age. Increasing the prevalence with age and its association with parenteral exposure indicate that HCV infection can mainly be attributed to parenteral techniques in the past. The identification of a concrete rural area with particularly high seroprevalence needs further study of the whole population of the area [6]. Suboptimal decision making regarding treatment of chronic HCV patients would bring increasing opportunity costs for the health care system and society [7]. In the north of Mexico, the main route of transmission was blood transfusion and there is a marked decrease in the incidence of post-transfusion hepatitis since the introduction of anti-HCV antibody screening of blood donors (4.5%). Intravenous drugs use is now an important route of transmission [5].

In a study conducted by Polish blood transfusion service, serological tests were performed between 1994 and 2003 in 4233119 donors. RNA HCV was detected in 51 out of 2915299 (0.002%) anti-HCV negative plasma samples. The frequency of HCV infection markers was higher than that in most

European countries. However, a decreasing frequency of HCV markers detection, especially in repeat donors was observed [8].

The seroprevalence of HCV in consecutive blood donors tested at two blood banks in Karachi, Pakistan, between 1998 and 2002 was assessed. The overall seroprevalence of HCV in these blood donors was 1.8% (6349/351309). Trend analysis revealed a significant linear increase in proportions of HCV-seropositive donors from 1998 to 2002 [9]. Primary prevention programs focused on identified risk factors might help to curtail the spread of HCV infection in this community and in other similar settings in developing countries.

In a study [10] on 224000 blood donors tested for hepatitis C virus, the overall prevalence of confirmed positive donors was 0.04%. Findings indicated that a substantial proportion of previously unrecognized asymptomatic persons with established chronic hepatitis C existed among North Western blood donors of England.

In Switzerland [11], the reported incidence rates per 100000 between 1996 and 2003 were as follows: HIV: 95%, CI: 1.35 (0.62-2.57), HCV: 95%, CI: 1.50 (0.72-2.75), and HBV: 95%, CI: 5.36 (3.00-8.85) ;while they were 1.35 (95% CI: 0.62- 2.57) for HIV, 1.5 (95% CI: 0.72- 2.75) for HCV, and 5.36 (95% CI: 3- 8.88) for HBV between 1996 and 2003 [11]. In our study, the incidence rate per 100,000 in 345,412 blood donors in 2005 was 3.2 (95%CI: 1.6- 5.7) for HIV, 80 (95% CI: 71-90) for HCV, 488 (95% CI: 465- 511) for HBV, and 5.5 (95% CI: 3.3- 8.6) for syphilis. The number of confirmed cases in the whole 345412 donors was 11, 80, 1648 and 19 for HIV, HCV, HBV, and syphilis, respectively. In comparison to the reports from other countries mentioned above, our incidence rates are significantly higher especially for HBV and HCV. The declining prevalence of HBV infections from 2003 to 2005 among blood donors in Tehran indicates a significant progress in the recruitment of a safer donor population. Recommending routine HBV vaccination and re-evaluation of routes of infection in donors is mandatory.

In Jakarta, the seroprevalence is 4% for HBsAg and 3.9% for anti-HCV. Hepatitis B transmission is associated with low socioeconomic status, Chinese ethnic group and large family size, while hepatitis C is associated with an older age and a history of transfusions [12].

Following the immunization strategies and Expanded Program on Immunization, the incidence and prevalence of chronic HBV infection have reduced. In a study in Indonesia, the overall reduction in the prevalence of HBsAg among fully vaccinated children under than 4 years of age fell from 6.2% to 1.9%, for a reduction of 70% [13]. Another study recommended that students at secondary educational institutions in Hong Kong should be offered serologic screening and vaccination for hepatitis B [14].

A total of 52500 blood units collected from volunteer and replacement blood donors was screened for HBsAg, anti HIV 1,2 and VDRL reactivity over a period of 3 years from 1997 to 1999 in East Delhi [15]. Seropositivity was 471 (0.8%) for anti HIV 1/2, 963 (1.8%) for HBsAg, 1449 (2.76%) for VDRL, and 64 (0.5%) for anti HCV. Volunteer donors were comparatively safe. The seropositivity for HIV showed an increasing trend between1997 to1999. In our transfusion centers, only subjects positive in primary screening tests are re-tested according to the confirmatory test algorithms because of its cost-effectiveness. According to our study, primary screening tests for HCV and HIV show a lot of false positive results, and discarding samples with positive primary tests needs to be re-evaluated. We recommend using more sensitive serological confirmatory tests for estimating the prevalence and incidence rates of transfusion-transmitted infections.

HIV prevalence declined from 4.04% to 0.38% among blood donors in two large blood banks in northern Thailand from 1990 through 2001 [16] which indicates a significant progress toward the recruitment of a safer donor population in a developing country despite a major HIV and AIDS epidemic in the general population.

Data analysis between 1989 and 2003 in Greece suggested an increasing trend in HIV-seropositivity in migrants during recent years. It was recommended that group-based interventions, better access to health care and a comprehensive public approach should be applied to migrants [17-20].

Conclusions

Between 2003 and 2005, a decreasing trend in HBsAg frequency was observed in Iran. The trend of HIV infection frequency had no increasing or decreasing pattern, and was relatively stable. HCV frequency decreased in 2005 compared to 2003. The trend of syphilis infection frequency was increasing from 2003 to 2005. Although the frequency of transfusion-transmitted infections is low, it is still far from ideal in volunteer blood donors in Iran. Planning additional strategies to reduce the risk of transfusion- transmitted

infections, more scrutiny in donor selection, improved sensitivity of serological tests, and re-evaluation of routes of infection in donors are needed to reduce trends of infections.

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