

Effectiveness of confidential self-exclusion (CSE) and failed options on blood donation safety in Sari organization of blood transfusion, 2005

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Abstract

Background: Blood donation safety is one of the basic goals of the organization of blood transfusion in the world. Self-exclusion and failed options are additional screening tests to routine diagnostic tests which is performed to detect the transmitted infection through blood or blood products. The purpose of this study was to investigate the efficacy of these systems on the improvement of blood donation safety in Sari organization of blood transfusion.

Methods: A cross-sectional study was carried out using serologic results of donors who used confidential self-exclusion (CSE) and failed system and the results compared with usual donors (as control group). The donors were tested for hepatitis B surface antigen (HBs-Ag), hepatitis C Virus antibody (HCV-Ab) and human immunodeficiency virus (HIV-Ab). The information was obtained from the data bank of Sari organization of blood transfusion, 2005.

Results: The blood of 255 (1.5%) and 87 (0.5%) donors out of 17036 were excluded by failed and confidential self-exclusion methods respectively. The percentage of infection among the control group was 3% compared with 3.9% for the failed group and 9.2% for the self-exclusion donors.

Conclusion: The findings obtained from this study indicated that the confidential self-exclusion might be a suitable method to improve blood donation safety. It also revealed that it was possible to exclude infected donors at window period.

Key words: Blood Donation, Confidential Self-Exclusion, Failed, HBs-Ag, HCV, HIV.

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Blood donation safety is a basic policy of the organization of blood transfusion in the world. An important strategy is screening the donors with less exposure to blood transmitted infectious agents such as human immunodeficiency virus (HIV) or hepatitis B virus (1). However, the detection of healthy blood donors is the first and the most important step that warrant safety donation. Transmission of infectious diseases through blood or blood products may not be detected with routine diagnostic tests due to window period condition which is the risk of infection in spite of negative diagnostic results (2,3). Some blood donors either do not answer truthfully to the interviewers about the unhealthy condition of their blood or answer vaguely. Therefore, many countries have planned to legislate confidential self-exclusion (CSE) option to enhance transfusion safety (4). This way all blood taken from these donor's was discarded including the negative serologic tests. This helped the donors to know about their blood which was not suitable for transfusion. Failed option is only used by Iranian organization of blood transfusion based on the interviewer's opinion about donors. The method discards the donors blood without the existence of any criteria causing the rejection of donor. This is only performed when the interviewer presumes that some donors do not answer correctly about their lifestyle. The interview which is generally done before blood donation and is based on the organization of blood transfusion policy. These options have been used in Iran since 2003. However, their effectiveness is not evaluated clearly.

This study was conducted to assess the efficacy of CSE and failed options to improve blood donation safety by increasing the detection of unsafe donors.

Methods

A cross-sectional study was performed from March, 2005 to March, 2006. A total of 17,036 donors donated blood at Sari organization of blood transfusion. All blood donors were examined for HIV-Ab (Biorad), HCV-Ab (Avecina) and HBs-Ag (Diasorin) by ELISA test. All positive results were confirmed by Western blotting, HBcAb and RIBA (Recombinant Immunoblotting Assay) for HIV, Hepatitis B and Hepatitis C, respectively. The serologic results of all donors based on the data collected by the Data bank center were used. The process of donating was based on blood transfusion organization standards. A donor form which contains the demography and lifestyle information of the donor was filled up by the interviewer. These donors were divided into three groups as follows:

- 1) Usual donors (control group) are individuals whose blood was suitable for blood donation required by the Organization of Blood Transfusion standards.
- 2) CSE donors are individuals whose blood was confidentially excluded. In fact, the blood donors are not aware if their blood are safe or not. They informed the organization staff by writing the serial number of their donor

form on a separate paper and put it in the CSE- box. Like any usual donor, all tests were performed on their blood but the blood was excluded even if they were healthy.

3) Failed donors are individuals who did not have any clinical problem in donating blood but their blood was excluded based on the interviewer's opinion. Like any usual donors, all tests were performed on this blood, however, were excluded even if they are safe.

The data were analyzed using SPSS software with X^2 test and $p < 0.05$ was significant.

Results

The blood of 255 (1.5%) and 87 (0.5%) donors out of 17,036 were excluded by failed and CSE, respectively. The Elisa test was positive for 498 (2.93%) of control group compared with 10 (3.9%) in failed group and 8 (9.2%) of CSE group. The percentage of infection in CSE group was approximately 3 times more than the control group. The differences between these groups were significant ($p < 0.005$). The results obtained from Elisa test showed that the overall 130 (0.76%), 338 (1.98%) and 48 (0.28%) donors were positive for HBs-Ag, HCV-Ab and HIV-Ab, respectively. The percentage of HBs-Ag among CSE group was more than the other groups (Table 1). The HIV-Ab positive was only detected in control group by Elisa test, but only one of them was confirmed by Western blotting test (Table 1).

Table 1. Frequency of HBs-Ag, HCV-Ab and HIV-Ab positive among of CSE, Failed and Healthy donors obtained from ELISA and conformational tests. Sari, 2005.

Tested group	HBsAg		Anti HCV		Anti HIV		Total ELISA %	Total Conformational %
	Elisa N(%)	HBc-Ab N(%)	Elisa N(%)	Riba N(%)	Elisa N(%)	Western Blot N(%)		
Control (16694)	125(0.75)	95(0.57)	325(1.9)	15 ⁺ (0.09) 34 ^{IND} (0.2)	48(0/29)	1 ⁺ (0.006) 5 ^{IND} (0.03)	2.94	0.66
Failed (225)	1(0.4)	1(0.4)	9(4)	2(0.88)	-	-	4.4	1.28
CSE (87)	4(4.6)	4(4.6)	4(4.6)	1(1.1)	-	-	9.2	5.7

N.B: 6 donors have been positive for more than 1 infection obtained by Elisa test.

IND: Indeterminate

CSE: Confidential self exclusion

Discussion

The results obtained from this work indicated that the percentage of blood transmitted infection in CUE group was approximately three times more than the control group and failed. This finding was in agreement with the results obtained from other studies carried out in Iran and elsewhere (5-8). A study performed in Ghom Organization of blood transfusion demonstrated that the percentage of infection within the CSE group was higher than the control group (10.8% vs 3%) (5).

The results obtained from many studies showed that the prevalence of hepatitis B in donors who used CSE option was significantly higher than the control group (6-8). Peterson et al. reported that donors who confidentially excluded their blood from transfusion were 21 times more likely to have HIV antibody compared with the other donors (9). In contrast, study performed in Germany demonstrated that using CSE method might not increase blood donation safety (10). The failed method is only performed in Iran and there is no information about the effectiveness of this program. This method needs to be more investigated because of the direct impact of the interviewer's opinion on the process.

We therefore, conclude that the confidential self-exclusion is a suitable method for the improvement of Iranian blood donation safety. This program is more beneficial in a country where the individuals cannot avoid donating their blood in spite of their belief that their blood is not useful for transfusion.

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