



Estimating the Adverse Reaction Among Iranian Blood Donors: The First National Report

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Abstract

Background: The aim of this study was to estimate the incidence of reactions caused by blood donations in Iran as well as exploring three potential scenarios of the worst, moderate, and the best situations for adverse reactions among Iranian blood donations by specifying the under-reporting rate.

Methods: There are two different designs; first, the ecological study was conducted to estimate the blood donation adverse effects by using the data registered in the donor vigilance part of Iranian Blood Transfusion Organization (IBTO). Second, the cross-sectional study was conducted to estimate under-reporting in the data. For the cross-sectional study, 2408 donors were selected randomly in three cities.

Results: In general, based on the estimations of this study, adverse reactions to blood donation in Iran is 2%(CI 95%, 1.4-2.6%). Local and systemic reactions estimated are 1.7%(CI 95%, 1.2-2.2) and 0.3%(0.1-0.5), respectively. Based on the national report, in general, adverse reactions to blood donation in Iran is 0.5(CI 95% 0.4-0.6). Local and systemic reactions estimated are 0.38%(CI 95% 0.28-0.48) and 0.03%(0.0-0.04), respectively.

Conclusion: Adverse reactions may vary from region to region in Iran, but in total, there is a lot of under-reporting in the incidence of adverse reactions to blood donation in Iran, most of which are related to local reactions.

Keywords: Blood safety, Hemovigilance, Adverse effect

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Introduction

According to the World Health Organization (WHO), approximately 112 million blood donations were collected worldwide in 2017 (1). These statistics indicate that blood transfusions require an organized system of care; however, many developing countries still face serious challenges in providing a healthy and adequate blood supply (2). The WHO has always emphasized that the Blood Transfusion Organization (BTO), as an important part of the health care system, must achieve self-sufficiency in the provision of healthy blood (3).

Out of all individuals qualified to donate blood, only 5% may contribute, and nearly 50% of them never return to donate again (4). Nowadays, due to lifestyle changes, increasing number of diseases, using new surgical methods, the expansion of healthcare centers and the raising of active hospital beds, the need for blood and its related products has been increased (4). Potential reasons such as anxiety, Adverse Reactions (AR) in blood donation, and a history of blood donation exemptions may cause blood donors not to return (4,5).

On the other hand, the most important factor in reducing the donor's desire to donate blood again is the occurrence of adverse reactions which is a barrier to have a healthy and sufficient blood supply. Therefore, eliminating or reducing these reactions might be a great help to achieve this goal (6).

The donor surveillance, which is known as Donor Vigilance, operates separately in the Iranian Blood Transfusion Organization (IBTO) (7). Given the importance of having healthy donors for the country's blood transfusion system, one of the most important priorities of the organization is to assure their health (8).

All adverse reactions which may occur after blood donation can be divided into two categories of local and systemic reactions (9). Hematoma, hemorrhage, bruising, and reactions associated with inflammation are considered as local reactions, reactions associated with dizziness, hyperventilation, pallor, and similar signs are systemic reactions (10). The most reactions resulting from blood donation have occurred among women and first donors (11,12).

In Iran, adverse reactions resulting from blood donation are recorded by Donor Vigilance members

in each province and are sent to the National BTO to prepare a national report. According to the literature, there is a high possibility of under-reporting among these reports. Hence, the aim of this study was the estimation of the incidence of reactions caused by blood donations in Iran as well as exploration of three potential scenarios of the worst, moderate, and the best situations for adverse reactions among Iranian blood donations by specifying the under-reporting rate.

Materials and Methods

Study design and Data collection

There are two different designs; first, the ecological study was conducted to estimate the blood donation adverse effects by using the data registered in the donor vigilance part of Iranian Blood Transfusion Organization (IBTO).

The cross-sectional study was designed and conducted in three cities (as pilot places). To examine the difference between these cities, Chi square test was used. The sample size was estimated to be about 2180 donations. A total of 1,500 donors representing 2,408 donations (Kerman 800, Shahrekord 300 and Tehran 400 donors) were included in this study during 2018. Sample size was estimated by formula 1. in which p,q, and d are 0.007, 0.993, and 0.0035, respectively.

Formula 1.

$$\text{Sample Size} = \frac{Z^2 pq}{d^2}$$

Under-reporting estimation:

Data related to adverse reactions caused by blood donation are recorded in all Iranian provinces separately and sent to National BTO. The data registered in the National BTO was extracted and used as the gold standard. Incidence risk is calculated by dividing all adverse effects to all donations.

The results obtained from cross-sectional study provided an estimation for the standard incidence of adverse reactions to blood donation in Iran. This rate needed to be compared with national BTO data. In order to determine the percentage of under-reporting due to the adverse reactions to blood donation. The resulting number was expressed as a percentage showing the under-reporting percentage (Formula 2).

Formula 2.

Under-reporting=

$$\frac{\text{Reported adverse reactions from different phases} - \text{reported adverse reaction (BTO data)}}{\text{Reported adverse reactions from different phases}}$$

Sensitivity analysis to estimate the incidence of adverse reactions to blood donation in Iran

Several scenarios were considered in order to investigate the level of adverse reactions to blood donation in Iran based on the under-reporting rate in cross-sectional study. The highest under-reporting rate was regarded as the worst case; the next case was the base case under-reporting rate and finally, for the best case, the lowest under-reporting rate was considered as a parameter to estimate the incidence of adverse reactions to blood donation.

Geographical Distributaon of AR

Furthermore, a color spectrum based on quarters was used to determine the geographical distribution of AR in donors of each of the 31 provinces of Iran. The first quarter (Q1) indicates the lowest rate while the fourth quarter (Q4) has the highest rate in the provinces. This chart was created using the Arc Map GIS Ver. 10.2 software.

Ethics

The results of this study have extracted from the PhD thesis supported by Kerman University of Medical Sciences (IR.KMU.REC.1397.401).

Results

Results of cross-sectional study

In the retrospective study, we recruited 1500 donors, whose mean (SD) of age, height, and weight were 40.7±10.2, 175.9±8.7, and 87.3±14.1, respectively. About 20% of them have normal body mass index, about 50% were overweight and 28% were obese. Totally, 48 adverse reactions were occurred during their blood donations. The overall incidence of these reactions was 2% (95% CI: 1.4-2.6), the incidence of local reactions was 1.7% (95% CI: 1.2 ,2.2), and the incidence of systematic reactions was 0.3% (95% CI: 0.1 ,0.5) (Table 1).

National report and under-reporting estimation

According to the reports of the Donorvigilance Unit of National BTO in 2018, the incidence of adverse reactions to blood donation was approximately 0.5%. General and local reactions were reported to be 0.38% and 0.03%, respectively. Finally, an under-reporting percentage was calculated based on these reports and a comparison with the results obtained in descriptive study.

Table 1. Results of estimating the incidence of adverse reactions to blood donation in cross-sectional study

City	Number of donations (number of AR)	Adverse Reaction (95%CI)		
		Total	Systematic	Local
Kerman	1135 (20)	1.8 (1-2.5)	0.2 (0-0.4)	1.6 (1-2.5)
Shahrekord	463 (8)	1.8 (0.5-2.9)	0.2 (0-0.6)	1.7 (0.5-2.9)
Tehran	810 (20)	2.5 (1.4-3.5)	0.6 (0.07-1.2)	2.5 (1.4-3.5)
Total	2408 (48)	2 (1.4-2.6)	0.3 (0.1-0.5)	1.7 (1.2-2.2)

*There is no statistically significant difference between the three cities (p=0.49).

** Chi Square test was used.

AR—Adverse Reaction.

Sensitivity analysis to estimate AR in every Iran provinces

The results of under-reporting estimation of adverse reactions to blood donation reported to the donor vigilance unit showed that the under-reporting rate for systematic reactions ranged from 0 to 70% (with median underreporting rate of 35%), and for local reactions ranged from 67 to 98% (with the median

underreporting rate of 82%). In the case of total adverse reactions, underreporting rate ranged from 67 to 75%, with a median of 69%. After applying this rate on the reported number of adverse reactions from different provinces in Iran, the best, base and worst case scenarios were estimated for the whole country and also each province separately (Figures 1-3).

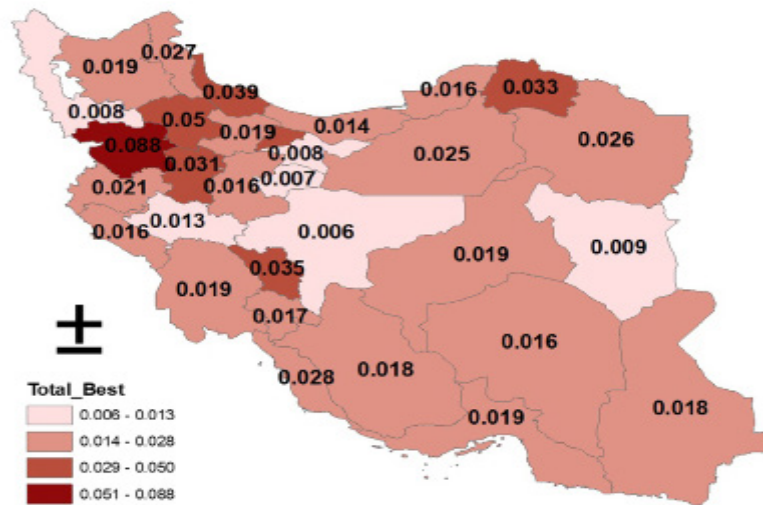


Figure 1. The best-case scenario of adverse reaction in Iranian blood donor (per 100 donations).

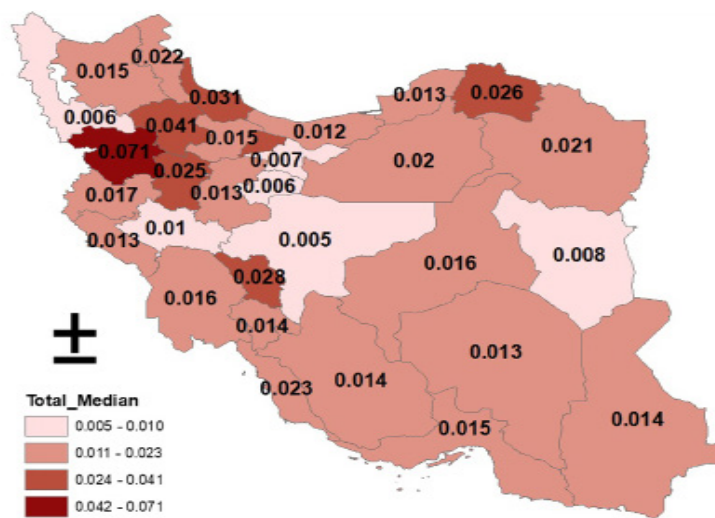


Figure 2. The base-case scenario of adverse reaction in Iranian blood donor (per 100 donations).

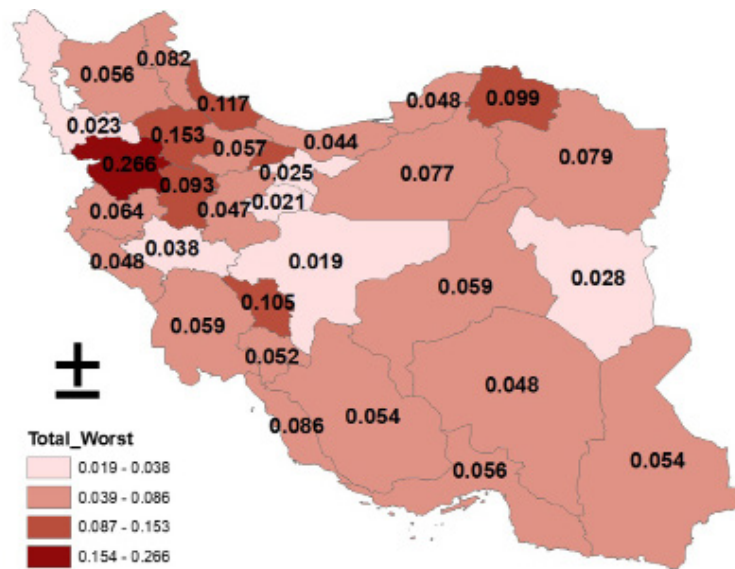


Figure 3. The worst-case scenario of adverse reaction in Iranian blood donor (per 100 donations).

Discussion

Based on the estimations of this study, in general, adverse reactions to blood donation in Iran vary between 1.5 to 2%. Local and systemic reactions were estimated between 0.09 to 1.5 and 0.38% to 1.26%, respectively.

According to the worst-case scenario, total adverse reactions for the whole country is estimated to be about 2%, which is consistent with the studies conducted in some other Iranian cities where adverse reactions to blood donations are reported up to about 2.5% (13). However, some other places have reported up to 27% of adverse reactions to blood donation, which seems to be very pessimistic since in the studies conducted in Iran, considering the worst case, 13.4% of the blood donors have experienced adverse reactions (14).

The results of studies on estimating general reactions showed that up to about 2% of blood donors have experienced general reactions (15). Considering the worst-case scenario for general reactions, these reactions were estimated to be about 1.5%. Broadly speaking, general reactions seem to occur in up to 2% of blood donors.

Systemic reaction in the worst-case scenario is estimated to be about 1.23% while it was estimated to be about 0.7% in another study conducted in Iran (13). Due to the wide range of mild to severe reactions in this type, it seems possible that this value reaches

around 1.23%.

Several studies have been published about the incidence of adverse reactions to blood donation in other countries and very different numbers are reported. In the United States of America, a study published in 2015 reported that 2.25% of blood donors experience adverse reactions, 0.3% of them were local reactions and 1.7% were systemic reactions (16).

According to a study conducted in 2012 in the Netherlands, as a European country, it was reported that 8.4% of blood donors had experienced adverse reactions to blood donation, out of which, 4.7% were local reactions and 3.7% were systemic reactions (17). The results of a study conducted in 2017 in India, one of the largest countries in Asia, demonstrated that adverse reactions to blood donation occurred among 10.2% of blood donors while 7.8% were local reactions and 1.5% were systemic reactions (18). In another study published in Nigeria as an African country, the results showed that 5% of people who donated blood experienced adverse reactions, of which 2.2% were local reactions and 2.8% of them were systemic reactions (19).

According to some studies conducted in neighboring countries of Iran like Pakistan, the results have shown about 1.3% of adverse reactions to blood donation among blood donors, and it was reported to be 11% in Saudi Arabia indicating that the incidence of adverse

reactions to blood donation is very different even in this region of Asia (12,20).

Due to various factors such as age, sex, height and weight of blood donors as well as other factors such as proper nutrition, adequate sleep, type of donation (first donation), stress, lack of drinking before donation, fear of donation and finally the volume of donated blood that may cause the occurrence of adverse reactions to blood donation (11,12,14,21-23), these differences in their incidence in different countries or even in different provinces of a country seems to be normal.

Limitations

In this research, we conducted a cross-sectional study on the databases of only three cities' which may be a limitation.

Conclusion

According to the results of this study, it seems that the incidence of adverse reactions to blood donation in Iran is between 1.5% and 2% while most of reactions

are local. Moreover, these reactions may vary from region to region in Iran, but in total, there is a lot of under-reporting in the incidence of adverse reactions to blood donation in Iran, most of which are related to local reactions.

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Conflict of Interest

None.

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Informed Consent

Informed signed written consent was taken from the patient involved.

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