IJHOSCR

Original Article

International Journal of Hematology-Oncology and Stem Cell Research

Source Plasma Donation: The Experience of the Iranian Blood Transfusion Organization

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Received: 23, May, 2021
Accepted: 12, Aug, 2021

ABSTRACT

Background: A declining need for red blood cells coupled with strengthening demand for plasma-derived medicines has led to a strong focus on moving whole blood donors to plasmapheresis. The purpose of this study was to evaluate the four-year policies of the Iranian Blood Transfusion Organization (IBTO) in terms of plasmapheresis recruitment of first-time donors and its effect on plasmapheresis outcome.

Materials and Methods: Plasmapheresis data related to 16 centers from 2016 to 2019 was obtained from IBTO software. This information includes; (1) blood donation number, (2) plasmapheresis donation number, (3) number of plasmapheresis donors, (4) plasmapheresis donor demographic data, (5) plasmapheresis donor status, (6) frequency of plasma donation for each donor, (7) volume of plasma and (8) the prevalence of transfusion-transmissible infections (TTIs) in plasmapheresis donors.

Results: The result of this study demonstrated that plasmapheresis collection centers have recruited 85,515 (91%) first-time and 8,595(9%) regular and repeated donors from 2016 to 2019 years. Plasmapheresis to blood donation index was increased from 0.2% in 2016 to 4.9% in 2019. The mean donation number was 2 times per year. The trend of the yearly Whole Blood Donation (WBD) Index decreased from 26.69 to 24.11/1000 for the general population. The total volume of collected source plasma was 49,203 liters during this period. However, 46,000 liters of recovered plasma were decreased due to less WBD. Furthermore, the results indicated that the prevalence of HCV was significantly higher in first-time donors compared to repeated and regular donors (P = 0.000).

Conclusion: It is concluded that during four years, the net volume of plasma did not increase and plasmapheresis led to reducing WBD in our country. Moreover, first-time plasmapheresis donors can be associated with challenges such as increasing screening costs and compromising the safety of plasma resources. Therefore IBTO decided to stop the project and focus on its main role to prepare safe and sufficient blood components through WB collection and also single donor platelet and concurrent plasma by plateletpheresis.

Keywords: Donor recruitment; Plasmapheresis; Plasma fractionation

INTRODUCTION

Plasmapheresis is the removal of a weight-dependent volume of plasma and the return of cellular elements to the donor. This plasma is used to purify proteins such as clotting factors and intravenous immunoglobulin (IVIg) for medical use[1]. Therefore, the need for source plasma as starting material for manufacturing plasma derivatives is growing. Presently, several countries such as the United States, Germany, and Austria are self-sufficient in plasma-derived products[2]. These countries permit paid plasma collections. Other countries import plasma derivatives from countries that permit payment, especially the United States[3]. Approximately 89% of the world's plasma used in the manufacture of plasma derivatives comes from paid collections, with the U.S. alone contributing 70%[4].

Plasmapheresis donors can donate twice a week with at least a 48-hour interval between collections and a maximum of 36 times per year. The volume of plasma removed during plasmapheresis (625–800 ml) is expected to result in only minimal physiological changes due to hypovolemia[6]. However, due to the long draw time as well as the return of cellular components and anticoagulants, adverse events can occur to a greater degree of plasmapheresis donors compared to whole blood (WB) donors[7]. Routinely donors are only recruited if they have completed at least one WB donation without complication. This strategy is intended to increase donor safety. Furthermore, after a successful WB donation, the donor will likely be more confident to convert to a plasmapheresis donor.

Iran, a country with increasing demand for plasma-derived medicines, has considered plasmapheresis to produce sufficient quantities of plasma[5]. Although recovered plasma is provided by the Iranian Blood Transfusion Organization (IBTO) for tool fractionation and the private sector has its own source plasma collection centers, IBTO decided to set up plasmapheresis. In 2016, IBTO set up five plasmapheresis centers in different parts of Iran (Tehran, Shiraz, Tabriz, Zanjan, and Urmia). Between 2017 and 2018, seven centers began to collect plasma in other cities, including Esfahan, Karaj, Yazd, Kermanshah, Semnan, and Ahvaz, with a plan to expand to other parts of Iran. In 2019, four other centers opened in Tehran, the capital of Iran, due to a large number of blood donors. At the same time, policies focused on increasing plasma donation statistics for the increase of plasma-derived medicine products.

Therefore, this study attempted to evaluate the four-year experience of IBTO in terms of plasmapheresis recruitment of first-time donors and its effect on plasmapheresis outcome.

MATERIALS AND METHODS

Data collection

This research was a retrospective cross-sectional study approved by the Ethics Committee of High Institute for Research and Education in Transfusion Medicine. Plasmapheresis data related to 16 centers was obtained from IBTO software from 2016 to 2019. This information includes (1) blood donation number, (2) plasmapheresis donation number, (3) number of plasmapheresis donors, (4) plasmapheresis donor's demographic data, (5) plasmapheresis donor's status, (6) frequency of plasma donation for each donor, (7) volume of plasma donation and (8) the prevalence of transfusion-transmissible infections (TTIs) in plasmapheresis donor's population.

The terms first-time, repeated, and regular donors are defined by IBTO. A first-time donor is a donor who succeeds in donating blood for the first time, a repeated donor is a donor who has donated blood in the past but not in the preceding 12 months, and the regular donor is a donor who has donated twice or more within 12 months.

As a routine program, all donors were checked for a health interview before donation. The individuals in the age range of 18 to 60 years, body weight greater than 50 kg, hemoglobin levels of ≥13 g/dL, no history of high-risk behavior such as sexual contact and tattoo, and serious illnesses such as an influenza-like symptom were considered as eligible donors. Those who were outside the range of inclusion criteria were excluded.

Statistical analysis

Statistical analyses were carried out using SPSS software [version 22]. The frequencies and percentages of demographic data were described. Data with normal distribution were analyzed by parametric test, and abnormal distribution was analyzed by nonparametric test. A p-value less than the significance level of 0.05 indicates there is a significant difference.

RESULTS

Results demonstrated that plasmapheresis centers (sixteen centers in eleven cities) recruited 85,515 (91%) first-time and 8,595(9%) regular and repeated donors over four years. Percentage comparison of plasmapheresis donations for each year showed that higher than 89% of donors were first-time donors (Figure1). Moreover, 78,152 units of plasma without obviously major events were collected. The plasma volume that was collected during this time was 49,203 Liter. During the same period, the total volume of recovered plasma decreased by about 46,000 liters due to 230,000 fewer WBDs (Figure 2). Demographic data showed that most plasmapheresis donors were male (P value = 0.043) with a mean age of 36.4 years. Individuals weighing more than 70 kg and less than70 kg donated 700 ml and 500 ml of plasma per session, respectively.

Furthermore, the results of TTI screening tests indicated that from 2016 to 2019, the overall positivity rate of hepatitis C virus (HCV) was 0.019% (18/94110), and all of them were first-time donors (P value = 0.000) (Figure 3).

The mean number of donations was two times for each donor per year. The percentage of plasmapheresis to blood donation increased from 0.2% in 2016 to 4.9% in 2019 (Table1).

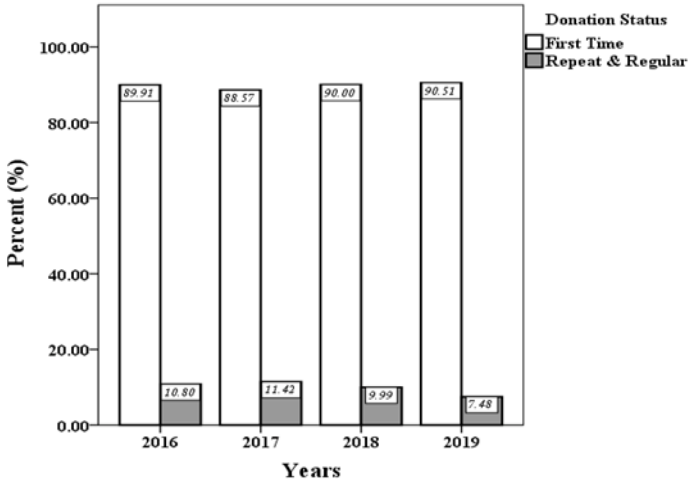


Figure1. Comparison of donation status percentage during four years

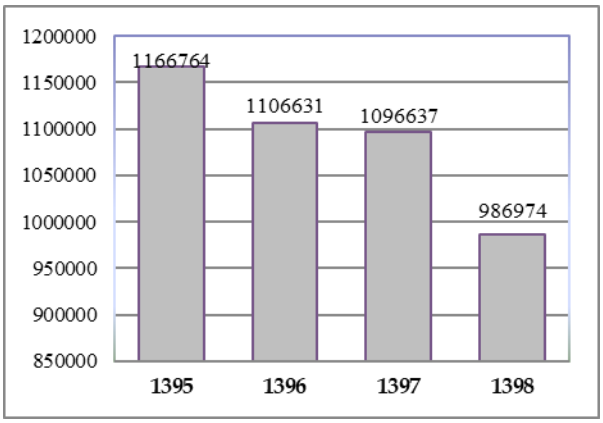
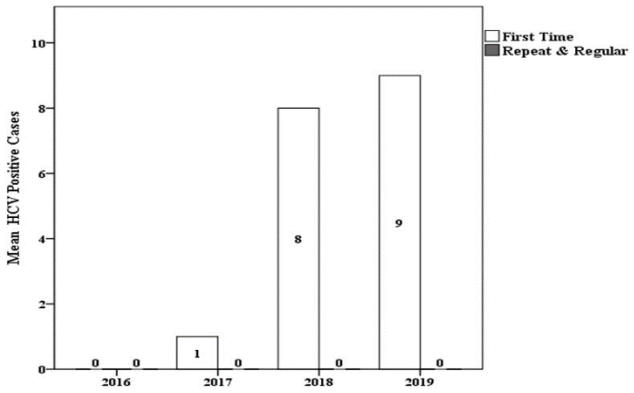


Figure 2. Total number of blood donations during four



Donation Status	HCV Positive Cases (Mean ± SD)	P Value
First Time	8 ± 2	0.000
Repeat & Regular	0 ± 0	

Figure 3. (A) Frequency of HCV positive cases during 4 years, (B) comparison of HCV prevalence indicate significant different between groups

Table1: Comparison of plasmapheresis variables during 4 years

Years		2016	2017	2018	2019	Total	P
Donation number	Blood donation	1156764	1106631	1096637	1039358	4399390	
	Plasmapheresis	2055	14389	38129	45061	99634	0.0001[a]
	Total	1158819	1121020	1134766	1084419	4499024	
Plasmapheresis/ Blood donation (%)		0.2	1.2	3.5	4.1	9	0.4[b]
Donation status	First time	1793	10975	33997	38750	85515	
(plasmapheresis)	Repeat & Regular	201	1415	3776	3203	8595	0.036[a]
	Total	1994	12390	37773	42811	94110	
Gender	Male	1958	11934	36471	41746	92127	
(plasmapheresis)	Female	36	456	1302	1065	2859	0.043[a]
	Total	1994	12390	37773	42811	94110	
Mean Age (plasmapheresis)		36.02	36.5	36.7	36.4	36.4	0.4[b]
Plasma donation (liter)		944	6443	19911	21905	49203	0.4[b]

a. Comparison between groups (Paired sample T-test)
b. Comparison of result during 4 years (Krus-kalwallis Test)

DISCUSSION

Our findings indicated that the net volume of plasma did not increase during four years. Moreover, plasmapheresis led to reduction of WBD in our country. Net plasma collection volume – considering the lost recovered plasma due to fewer WBDs- was less than 10000 liters during the same time.

To meet the demand for plasma-derived products, it is critically important that blood collection centers optimize the management of their plasmapheresis donor panels. However, only a small number (i.e., <5%) of the general public is active WB donors[8, 9] even fewer are active apheresis donors (i.e., donate plasma or platelets). For example, in Australia, only 2.41% of the population are active WB donors, and 0.13% are active apheresis donors[10]. Platelet and plasmapheresis donations contribute up to 4.6 % of the total annual donations in Malaysia, compared with Singapore where in 2012, apheresis donations made up approximately 8.4% of the total annual collections[11]. Similar ratios are reported by other countries where both WB and apheresis donation occurs in a voluntary, non-remunerated environment[12].

The results of the present study showed that plasmapheresis had an increasing trend from 2,055 to 45,061 during four years. In this regard, Germany and Italy have collected more than 300,000 donations by plasmapheresis. Sweden has collected more than 200,000, France 150,000, and Spain over 45000. Plasma collection centers in the united states have performed approximately 13 million plasmapheresis procedures annually for decades without obviously major events[13, 14].

In addition, our analysis showed that the mean number of the donation was two times for each donor per year, and individuals weighing more than 70 kg and less than 70 kg donated 700 ml and 500 ml of plasma per session, respectively, which seems not to be cost-effective. In a study conducted in Germany, 3000 donors were monitored over three years and concluded that all donors weighing 70 kg or more are safely able to donate 850 ml of plasma in each donation up to 60 times per year [15]. It should be noted that the challenges of plasma donation are more due to the length of the process, which can lead to the loss of donors and the occurrence of unwanted complications. Routinely after a successful WBD, the donor will be more likely to convert to plasma donation.[7,12] Low return rate of plasma donors in Iran may be related to the high rate of recruitment of first-time donors.

We found that the prevalence of HCV was 0.2% in first-time donors (18/85515), while all repeated/regular donors were negative for this infection. Retaining repeated donors is more cost-effective than recruiting new donors. Moreover, repeated donors have fewer health risks than first-time donors and are less likely to be deferred from donating[16]. Due to the increasing demand for plasma-derived products and the low proportion of individuals who are active plasmapheresis donors, the recruitment and retention of these donors via voluntary, non-remunerated donation is a challenge[17]. In Iran, similar to other countries such as Australia and the Netherlands, plasmapheresis donors are recruited from the WB donor panel. By targeting these donors, blood centers can identify eligible donors who can endure the apheresis procedure[18]. However, in Iran, due to the unwillingness of repeated or regular WBD for plasma donation, first- time donors were recruited for the process.

Despite the effectiveness of payment at increasing plasma collections, most countries have banned the practice of payment for plasma donation. The World Health Organization (WHO) urges member countries to adopt a voluntary, non-remunerated blood donation standard. The main reason offered against payment for plasma is worried about safety[19]. Canada has offered a unique opportunity to study the impact of paid plasma. It is not evident that the introduction of paid plasma has decreased blood donations in Canada. But, blood clinics have found a small but significant increase in blood donations, ranging from 8-10 additional blood donations per 100 additional plasma collections per city per month. Although some have hypothesized that decreased donations would be more prevalent among younger donors aged 17-24, they have found that paid plasma has no impact on blood donations among this age group[20]. In addition, the most paid plasma donors in the United States donate only 14–17 times per year, a frequency of collection far lower than the 104 maximum permitted by the FDA[21].

CONCLUSION

In conclusion, first-time plasmapheresis donors can be associated with challenges such as increasing screening costs and compromising the safety of plasma resources. Understanding the career path of plasmapheresis donors within none-remunerated or remunerated environments would be beneficial. It seems that involving the private sector to increase plasma donation statistics is helpful, while blood transfusion centers can focus on donor recruitment, inspection, and recovered plasma collection.

Despite the well-known advantages of apheresis collections, the cost of running an apheresis donation center is the main obstacle to expanding the program. We suggest that apheresis centers should develop strategies for the concurrent collection of plasma during plateletpheresis. New apheresis equipment, including the Haemonetics MCS plus (MCS+) and the Gambro Trima Accel (TA), enables the collection of various blood products in a single donation with few adverse events. The main advantage offered is reducing the costs to prepare the blood components and providing sufficient plasma and platelet in a situation of limited eligible donors. Therefore, we have plans to focus on this strategy from April 2021.

ACKNOWLEDGEMENTS

The authors acknowledge blood transfusion research center, High institute for research and Education in Transfusion Medicine, Tehran, Iran.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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