Analysis of reasons of blood donor deferral at a tertiary care institute in India and its reflections on community health status

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Abstract:

INTRODUCTION: Safe blood donors form the backbone of safe blood transfusion services. Donor eligibility policies are a critical layer of blood safety designed to ensure selection of healthy donors and to protect recipients from any harm. This study was planned to analyze the pattern of whole blood donor deferrals and its characteristics and reasons at a tertiary care institute in northern India, as the pattern varies according to epidemiology of diseases in different demographic areas.

MATERIALS AND METHODS: It was a cross-sectional study of 2 years’ duration from December 2015 to November 2017. The data of the potential donors who were deferred were recorded on a separate pro forma which included their demographic details, type of donation - voluntary donor and replacement donor; first time and repeat donor; type of deferrals (permanent and temporary); and the reasons of deferrals.

RESULTS: A total of 3133 donors (voluntary - 1446 and replacement - 1687) donated and 597 donors were deferred (deferral rate - 16%) during this period. Majority of the deferrals, i.e., 525 (88%) were temporary, while 72 (12%) were permanent. The most common reason of temporary deferral was anemia. The most common reason of permanent deferrals was a medical history of jaundice.

CONCLUSIONS: Our study results indicate that the blood donor deferral can have subtle variations based on regional aspects that should be considered when national policies are developed as pattern of deferral varies according to the epidemiology of diseases in different demographic areas.

Keywords: Blood donor deferral, permanent deferral, temporary deferral

Introduction

Safe blood donors form the backbone of safe blood transfusion services. The safety of the blood supply is ensured through several procedures from donor selection to testing of donated units. Donor selection is still emphasized even in the era of sensitive transfusion-transmitted infections (TTIs) screening techniques. Donor eligibility policies are a critical layer of blood safety designed to ensure selection of healthy donors and to protect recipients from any harm. This study was planned to analyze the pattern of whole blood donor deferrals and its characteristics and reasons at a tertiary care institute in northern India, as the pattern varies according to the epidemiology of diseases in different demographic areas. The reasons of deferral were evaluated with respect to the ethnic and regional differences.

Materials and Methods

It was a cross-sectional study of 2 years duration from December 2015 to November 2017. From the time of study initiation till...
May 2017, data were collected retrospectively, and from June 2017 to December 2017, deferred donors were followed prospectively. The data of the potential donors who were deferred were recorded on a separate pro forma which included their demographic details, type of donation - voluntary donor (VD) and replacement donor (RD); first time (FT) and repeat (RPT) donor; type of deferrals (permanent and temporary); and the reasons of deferrals. The blood donors were selected as per the norms laid down by the Drugs and Cosmetics Act and Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India.\cite{2,3} Individuals aged between 18 and 65 years were accepted for blood donation. Donors having weight of 45 kg or more and hemoglobin (Hb) of 12.5 g/dl or more were eligible for whole blood donation. Donors were screened for Hb by HemoCue Hb 301+ (HemoCue AB, Angelholm, Sweden). For the potential donors to be eligible for donation, interval between two donations was at least 3 months.

Descriptive analysis to investigate the characteristics and reasons of deferral among different demographic groups was done as gender, FT/RPT donors, VD/RD, and temporary/permanent deferrals. Donor deferral rates for various reasons were calculated in percentages. They were compared using Chi-square test. \( P < 0.05 \) was considered statistically significant. All statistical analyses were carried out with SPSS software (SPSS, Inc., Chicago, IL, USA).

**Results**

A total of 3730 potential donors were screened during the study period. 3133 donors (voluntary - 1446 and replacement - 1687) donated and 597 donors were deferred (deferral rate - 16%) during this period. Of these 597 deferred donors, 483 (80.9%) were males while 114 (19.1%) were females, (male: female = 4.2:1; \( P = 0.009 \)). The mean age of deferred donors was 28.6 ± 9.3 (range 18–47 years). The most common reason of deferral was anemia [169; males ‑ 90, females ‑ 79; \( P = 0.0001; \) Table 1], followed by drug intake (86), medical reasons (72); history of jaundice (36), alcohol intake (31), surgery/ear piercing/tattooing (23), high Hb (20), inadequate sleep (17); low weight (16), dog bite (11), recent blood donation (7); unwilling (5), poor venous access (4), underage (4), high-risk sexual behavior (3), and anxiety due to fear of needle prick (3). Majority of the deferrals, i.e., 525 (88%) were temporary, while 72 (12%) were permanent [Table 2]. The most common reason of permanent deferrals was a medical history of jaundice. On subgroup analysis, the frequency of deferral was 396 versus 201 in RD versus VD, respectively [\( P = 0.002 \)]. Similarly, it is much higher in FT donors compared to RPT donors (390 vs. 207, respectively). Deferrals due to

| Reason for deferral | Total |
|---------------------|-------|
| Temporary deferral   |       |
| Age <18             | 4     |
| Alcohol             | 30    |
| Anxiety             | 3     |
| Blood donation <3 months | 7   |
| Medical causes      | 46    |
| Dog bite            | 11    |
| Surgery             | 23    |
| Fasting             | 1     |
| Drugs               | 80    |
| Menstruation        | 1     |
| Low Hb              | 169   |
| High Hb             | 20    |
| Infection           | 82    |
| Inadequate sleep    | 17    |
| Low weight          | 16    |
| Not willing         | 5     |
| Poor venous access  | 4     |
| Vaccination         | 6     |
| Total               | 525   |

| Permanent deferral   |       |
| Alcohol             | 1     |
| Medical causes      | 26    |
| Drugs               | 6     |
| High-risk behavior  | 3     |
| Jaundice            | 36    |
| Total               | 72    |

Hb=Hemoglobin. *indicates <0.05, **indicates <0.01
alcohol intake ($P = 0.008$), medical reasons ($P = 0.059$), drugs ($P = 0.028$), and infections ($P = 0.0001$) were significantly more in males than in females. However, in females, deferrals due to low weight were statistically significantly higher ($P = 0.0001$). Deferrals due to blood donation within the last 3 months were significant in RPT donors ($P = 0.009$), whereas in FT donors, low-weight deferrals were more ($P = 0.015$).

**Discussion**

Assessment of blood donor deferral in a demographic area gives us an insight of the regional aspects to be taken into consideration while formulating national policies. The donor deferral rate (16%) was low at our center and comparable to other centers in our country. Mangwana in a study on deferral of blood donors in a tertiary health care hospital in north India observed the deferral rate to be 17.88%.$^{[4]}$ Low Hb was the leading cause of total deferrals and in female donors (68.01% in female donors vs. 14.82% in male donors), followed by history of medication, hypertension, and alcohol consumption (common in men). Other studies from the same region have reported the deferral rate as 5.1% and 9%, respectively.$^{[6,9]}$ In a retrospective analysis of donor deferral by Sharma et al., the most common cause of deferral was low Hb (49.7%), followed by ongoing medications (11.8%), intake of alcohol within 24 h (8.6%), and fever and/or infection (5.5%). The most common cause of permanent deferral was hypertension and cardiovascular problems (3.8%), followed by history of jaundice/hepatitis B/C.$^{[3]}$ Another study from the same region quoted the donor deferral rate as 9%, with majority (91%) being deferred for temporary reasons. Anemia was the most common reason for temporary deferral, while hypertension was the major reason for permanent deferral.$^{[6]}$

A deferral rate in the range of 11%–33% has been quoted by various studies from western India.$^{[7-10]}$ In the study by Shrivastava et al., the donor deferral rate was 11.5%, with majority being temporary deferrals. History of jaundice was the most common cause of permanent deferral followed by high-risk behavior, while low Hb was the major reason for temporary deferral.$^{[7]}$ Another study from the nearby region quoted the donor deferral rate as 11.6%.$^{[8]}$ Low Hb followed by abnormal blood pressure (high or low) was the main reason of deferral. Another study observed the donor deferral rate as 25%, and low Hb (27.5%) was the most common cause of deferral followed by high blood pressure and intake of medicines. History of sexual exposure was observed as the most common cause of permanent deferral, although the author didn’t specify the details of the type of exposure (as with multiple sexual partners or with paid sex workers).$^{[9]}$ In the study by Shah et al. from western India, the blood donor deferral rate was found to be as high as 33%. Low Hb (78.3%) was the most common reason of temporary deferral, both in FT and repeat RPT donors (71%). The authors concluded that there is a need to increase the efforts to improve Hb in the RPT donors for donor retention and overall blood safety.$^{[10]}$

Studies from southern parts of India have reported the deferral rate of around 5%.$^{[11,12]}$ Sundar et al. in a retrospective analysis found that the three most common reasons for deferral in female were low Hb levels, low body weight, and hypotension. In males, the three most common reasons for deferral were hypertension, underweight, and low Hb levels.$^{[12]}$

Literature from across the world has shown the donor deferral rate in the range of 10%–30%. Two studies from Iran reported it to be as 25.6% and 30.9%, respectively.$^{[11,13]}$ Ngoma et al. observed the donor deferral rate of 14% on retrospectively analysis in Japan.$^{[14]}$ If the rate of donor deferral is high at any center, it points toward a deficiency in the donor awareness and donor education material. In addition, if the reasons of deferral are not explained properly to the donors, it can have a negative impact on donor’s psychology leading to loss of the donors.$^{[10]}$ Our study shows that the FT donors accounted for 65% of deferrals compared to 35% in RPT donors, a finding consistent with other studies.$^{[1,13,14]}$ These studies concluded that FT donors are more frequently deferred as compared to the RPT donors. These FT, young donors are the future prospective blood donors who have the potential to increase the donor pool. However, temporary deferral may have a negative impact on donor’s psychology which can discourage them to return for subsequent donations. A study by Hillgrove et al. found that 21% of FT donors with low Hb returned as compared to 70% return in donors who were not deferred.$^{[15]}$ Hence, it is highly essential to clearly explain the cause of deferral with relevance to their safety as well as the patient’s safety and to motivate them to return for donation after the expiry of the deferral period.$^{[14-16]}$ According to a study, a successful donor is 29% more likely to return as compared to a deferred donor.$^{[17]}$

In our study, majority of deferrals were temporary (88%) deferrals. These were seen mostly among replacement (66%) donors, and male donors (80.9%). There was a significant difference of deferral in replacement versus voluntary ($P = 0.002$) and in males versus females ($P = 0.009$). Main reasons of deferral were anemia (28%), medication intake (14%), infections (13%), and medical reasons such as cardiac disease, blood transfusion <3 months back, uncontrolled hypertension or diabetes, and history of stroke (12%). In a study by Ngoma et al., temporary causes accounted for 99% of deferrals, out of which 50% were due to low Hb.$^{[14]}$ A
A study from India reported that 91% of deferrals were due to temporary reasons and anemia was the most frequent reason for donor rejection (32.8%).

Hence, this group needs to be addressed properly as it leads to apparent permanent deferral in otherwise willing donors. Donors deferred for low Hb are much less likely to return for future donations than the donors that are not deferred. A review by Alan et al. stated that low Hb deferral occurs in 10% of blood donor deferrals. The author has discussed programs that can be implemented to decrease anemia in regular donors as iron tablets and hematinsics, prolong donation interval, and monitor ferritin levels.

Our analysis suggested that there is high prevalence of anemia even in FT male donors. A total of 90 males (53% of anemic donors and 15% of total deferred donors), as compared to 79 females, were deferred due to anemia, out of which 56 were FT donors. Anemia in females is explainable which may be related to physiological conditions as menstrual loss and pregnancies. However, anemia in FT male donors may relate to unrecognized medical illnesses, occult gastrointestinal bleed, Vitamin B12 deficiency, and hyperthyroidism. Apart from iron supplementation, the donors from this region may be advised for regular de worming as it may be related to worm (hookworm) infestation in this demographic region. In addition, they should be advised medical consultation to rule out any underlying illness. Annen et al. in a study assessing the implications of low Hb deficiency in infrequent donors suggested that donors deferred for low Hb should be provided health information to seek diagnosis and treatment for their anemia.

Another unusual group of deferrals seen in our analysis was due to high Hb that is Hb >18 g%, observed in 3% of deferred donors. Secondary polycythemia is quite common in people residing in higher altitudes to compensate for less ambient oxygen and inadequate tissue oxygenation. As there are differences in Hb reference ranges for various ethnic groups, more demographic studies should be conducted to get epidemiologic evidence to know the extent of low and high Hb in males in this region and hence may warrant a revision of donor acceptance criteria. Some of the deferrals such as due to alcohol intake, inadequate sleep, anxiety, and fasting are totally avoidable if we strengthen our donor education and counseling strategies. Jashnani and Patil postulated that blood donor deferrals will surely decrease if the blood bank officials conduct sessions regarding donor acceptance criteria with the organizing team of the blood donation camps as a routine practice.

Among permanent deferrals, the main causes of deferral were jaundice (50%) followed by medical reasons (36%). Majority of deferred donors due to jaundice were FT male donors (male: female - 34:2) with a mean age of 33.1 ± 11.2 years (range 19–52 years). Certain conditions such as poor veins were categorized as permanent deferrals. Sometimes, blood bank professionals face a difficulty in distinguishing these conditions as permanent or temporary deferrals and also in justification to the donors. Hence, these entities should be included in the donor deferral criteria by the policy makers. Our primary goal is to recruit safe nonremunerated donors through stringent donor questionnaire. Improving donor awareness through education and predonation counseling by providing information, education, and counseling are some suggestions to pave a way to reduce donors with permanent deferrals. In addition, blood donors should be encouraged to avoid high risk behavior, adopt a healthy lifestyle and donate regularly.

Conclusions

Our study results indicate that the blood donor deferral can have subtle variations based on regional aspects that should be considered when national policies are developed as pattern of deferral varies according to the epidemiology of diseases in different demographic areas. Similar studies should be conducted in other centers of the region to gather more evidence so that the results can be generalized.

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Conflicts of interest

There are no conflicts of interest.

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