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Post-donation telephonic interview of blood donors providing an insight into delayed adverse reactions: First attempt in India

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ABSTRACT

Background: Blood donor experiences both immediate adverse reactions (IAR) and delayed adverse reactions (DAR). With limited published data available on the incidence of DAR, a study was conducted to estimate incidence and profile of DAR through telephonic interview.
Materials and methods: Study was conducted over a 45-day period for consecutive volunteer whole blood donations at tertiary care hospital. Donors were divided into first-time, repeat and regular and were monitored for IAR. They were given written copy of post-donation advice. Donors were contacted telephonically three weeks post-donation and enquired about general wellbeing and specific DAR in accordance with a standard n international (International Society of Blood Transfusion) standard format.
Results: Donors participated in the study of which 1.6% donors experienced an IAR. Much larger number reported DAR (10.3% vs.1.6% $p < 0.0001$). Further, DAR was presented as a variegated profile with bruise, painful arms and fatigue being the commonest. DARs were more common in females than males (25% vs. 10.3%, $p < 0.02$). Localized DAR like bruise and painful arms were more common in younger donors (age <50 years) whereas systemic DAR like fatigue was common in older donors (>50 years). First time (12.3%) and repeat donors (13.5%) had similar frequency of DAR but were lower among regular donors (6.7%).
Conclusion: DARs are more common than IAR and are of different profile. Post-donation interview has provided an insight into donor experiences and can be used as a valuable tool in donor hemovigilance.

1. Introduction

A continuous and steady supply of blood components plays essential and important role in smooth functioning of the healthcare system. Blood transfusion services are continuously challenged to maintain a steady supply of the same by retaining of regular donors and recruitment of new donors. Blood donation is considered to be a safe procedure but a small number of donors may experience adverse reactions [1,2]. Multiple studies describe and report the immediate type of adverse reactions (IAR), since these reactions occur during or immediately after the blood donations and thus come to the attention of the donor center staff [1–6]. The most common reactions, which include vasovagal reaction and hematoma, can be managed by minimal medical assistance [1–6]. However, a donor can also experience a delayed adverse reaction (DAR) to blood donation just after leaving the donation center or may be much later [7–9]. Blood banks routinely encounter donors coming back with hematoma, fatigue or painful arm several days after the date of donation. This sporadic information is passive in nature and possibly 'tip of an iceberg'. This information and previous publication on DAR in Caucasians and African-Americans [7] prompted us to find the real numbers of DAR by actively conducting a telephonic interview three weeks after donation to estimate the incidence and profile of DAR and its comparison with IAR, in India.

Several published studies including few from India [1–6] report the incidence of IAR among blood donors. Recently a case report [10] on DAR was also published but no Indian study states the incidence of DAR experienced by the donors. The objective of the study was to find the incidence of DAR and factors affecting it.

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2. Materials and methods

2.1. Setting

The prospective study was conducted over a 45-day period from November to December 2013 for all consecutive volunteer whole blood donations at a tertiary care hospital-based blood bank in India.

2.2. Blood donor selection criteria

The donors were administered medical history questionnaire and underwent a physical examination before the actual donation. The selection criteria included age >18 years, weight >55 kg, hemoglobin ≥12.5 gm%, normal vitals including temperature <98.4 °F, pulse 60–100/min, systolic blood pressure 100–150 mm Hg, diastolic blood pressure 60–100 mm Hg and overall sense of well-being of the donor.

2.3. Donation process

Four hundred and fifty milliliter whole blood was collected by phlebotomy performed in the ante-cubital fossa of either right or left arm with a 16 gauge needle with donor lying in supine position. The donor was asked to rest on the donation couch for at-least 10 minutes post-donation. Only after the donor felt well, he was escorted for the post donation refreshment. The donor was also provided with printed copy of standard post-donation advice [11] at the time of leaving the premises. The total time duration of stay was usually 20–25 minutes after donation end-time. Any adverse reaction experienced by the donor after he/she had left the donor center premises was defined as DAR.

2.4. Post-donation interview

All the whole blood donors, who donated during the study period, were telephonically contacted three weeks after donation by a single volunteer [7]. Volunteer was a qualified medical social worker who was trained in recognition and categorization of IAR, DAR and interview process by the medical director. Common standard written script was followed for conducting telephonic interview. The donors who could be contacted were called "respondents". The donor was explained about the survey and included in the study only after the donor verbally consented to it. At the outset, the donor was asked non-specific questions regarding general wellbeing and any unpleasant symptom during or after donation. Donors were then asked specific questions regarding any possible delayed adverse reactions experienced by them.

2.5. Interview script (Table 1)

Table 1
Telephonic interview script.

Interviewer: Good morning. How are you? I am calling from Blood Bank, Medanta Hospital.
Donor: . . .. . . (donor's response)
Interviewer: Is it good time to talk? Can I take 2–3 minutes of your time?
Donor: If No – Stop/If Yes – Proceed.
Interviewer: You had donated blood at our blood bank on . . . (date of donation). This call is regarding your feedback after blood donation. I will ask you some questions for which you may reply as "Yes" or "No". Do I have your consent for the same?
Donor: If No – Stop/If Yes – Proceed.
Interviewer: Did you feel any discomfort during or immediately after blood donation or in the refreshment area?
Donor: If Yes – Make note in case report form and proceed/If No – Proceed
Interviewer: Did you feel any discomfort after you left the blood center?
Donor: If Yes – Ask for description, make note in case report form and proceed/If No – Proceed to specific questions.
Interviewer: Did you experience any discomfort at the phlebotomy site?
Donor: If Yes – make note in case report form and proceed/If No- Proceed to thank
Interviewer: Was it –

- *Bleeding* (Delayed bleeding)
- *Bluish discoloration* (Bruise)
- *Bluish discoloration with swelling* (Hematoma)
- *Pain in the entire arm* (Painful arm)
- *Pain along the vein* (Thrombophlebitis)
- *Redness/itching* (Allergy)
- *Numbness/tingling* (Nerve irritation)
- *Fatigue* (*"Thakan"; common word in local vernacular parlance*)

Donor: . . ..
Interviewer: Are you all right now?
Donor: If Yes – Proceed to thank/If No – Book an appointment with blood bank physician and proceed to thank
Interviewer: Thank you for your valuable time. Please continue to donate blood.

2.6. Analysis of donor responses

Categorization of the donor responses from the case report form was independently performed by resident doctor and verified by consultant and medical director in a team based setting based on the standard for surveillance of complications related to blood donation by working party, ISBT [12].

2.7. Data analysis

For data analysis donors were classified into first-time (those donating for the first time), repeat (those who have donated at least once previously but not regularly) and regular (those who have donated at least once a year for last three consecutive years). Donors were also classified on the basis of their gender, age (<30 years, 31–50 years and >51 years), hemoglobin (< or >14.5gm/dl) and weight (< or >76 kg). Statistical analysis was done using the SPSS software (Version 22.0; IBM, Bengaluru, Karnataka, India).

2.8. Ethical approval

Blood donors sign a donor questionnaire cum consent form that allows the blood center to contact them. Institutional Review Board (IRB) approved the study. Owing to the observational nature of the study, IRB did not require separate informed consent.

3. Results

3.1. Demographics

Fig. 1 compares the demographics of total annual donors, total donors during the study period, respondents and non-respondents during the study period at the blood donation center (Fig. 1). A total of 1095 respondents participated in the study. Majority of the respondents were male (97.1%) and had donated at-least once previously (68%). The median age, weight and hemoglobin of the male respondents was 32.6 year, 77.7 kg, 14.5 gm/dl respectively. Similarly for the female respondents, age, weight and hemoglobin was 30.7 year, 66.7 kg, 13.1 mg/dl respectively (Table 2).

3.2. IAR vs. DAR

The incidence of IAR was 1.6% (n = 18; 95%CI = 0.86%–2.3%). The most common IAR observed was vasovagal reaction (83.3%) and hematoma formation (16.6%). In comparison to IAR (1.6%), a larger number of respondents had DAR (10.3%; 95%CI = 8.65%–12.26%). Eighty-three respondents observed single DAR (73.5%) whereas 30