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Incidence of clinically significant antibodies in patients and healthy blood donors: A prospective cross-sectional study from a tertiary healthcare center in India

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ABSTRACT

Introduction: Since there is scarce data available on incidence and type of irregular antibodies in patients and donors in India, a study was undertaken to find the incidence of irregular antibodies in patients and irregular antibodies and a positive Direct Antiglobulin Test (DAT) in blood donors.
Materials and methods: Antibody screening was performed using commercial pooled "O" cells and three-cell panel for donors and patients respectively and an 11-cell panel for identification using Column Agglutination Technology (CAT) with Low-Ionic-Strength Saline–Indirect Antiglobulin Test (LISS–IAT) technique (Ortho Clinical Diagnostics, Johnson & Johnson, USA). The cassettes used were Anti-human Globulin (AHG) type. DAT on donors was also performed using the AHG cassettes.
Results: Cumulative incidence of irregular antibodies amongst patients (n = 32,560) and donors (n = 31,367) were 0.12–0.009%, respectively. In patients, the commonest antibodies were from Rh system with anti-D being the most common antibody type (14/40; 35%) while in donors it was the MNS system with anti M (2/3) being the most common. Incidence of a positive DAT amongst the healthy blood donors was 0.04% (n = 13/32,560).
Discussion: Incidence of irregular antibodies in patients at 0.12% was slightly lower than published reports and could be because of the fact that the patient population studied comprised largely of surgical patients many of whom have never received blood transfusion. This data could also be more representative since the number of patients studied was much higher as compared to the previous Indian studies (32,560 vs. 531–2026). The report on incidence of irregular antibodies and DAT (0.009–0.04%) in blood donors was first such attempt in India.

1. Introduction

To make blood component transfusions safer for patients, increasingly large number of blood centers routinely performs patients' and donors' irregular antibody screening. It is desirable to use two or more reagent cells for antibody screen in patients, while a less sensitive method may be employed for donor antibody screening. If a patient has a clinically significant antibody, it is important to identify the antibody and provide the corresponding antigen negative red-cell component to the patient. This antigen-negative red-cell component is cross-matched by

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Anti-Human Globulin (AHG) technique to ensure that safest possible red-cell component is provided to the patient. Like-wise, if there is a clinically significant irregular antibody in a donor, plasma-containing component (Fresh Frozen Plasma, Platelet Concentrate) made from his/her donation may not be suitable for transfusion and has to be discarded. However, in India, there is scarce data available on incidence and type of clinically significant irregular antibodies in patients and donors.

Direct Anti-globulin Test (DAT) may be positive in a small percentage of otherwise healthy donors [1]. Here again, there is no data on DAT positivity in Indian blood donors.

The purpose of this study was, therefore to find the incidence of irregular antibodies in patients and irregular antibodies & DAT in donors. This cross-sectional designed study also analyzed various types of antibodies that were identified in these two populations.

2. Materials and methods

2.1. Place and Duration of Study

This prospective study was carried out at the department of Transfusion Medicine in a tertiary healthcare centre in the national capital region of India from April 2011 to June 2012 (15 months) for all consecutive patients and donors.

2.2. Sample type

EDTA (ethylenediaminetetraacetic acid) tubes were used for antibody screening, identification and DAT in blood donors and patients.

2.3. Technology, technique and equipment

All tests (antibody screening, identification and DAT) were done using Column Agglutination Technology (CAT) using Anti-Human Globulin (AHG) cassettes. The technique was Low-Ionic-Strength Saline–Indirect Anti-globulin Test (LISS–IAT) technique. While antibody screening and DAT was done on the automated equipment AutoVue Innova (Ortho Clinical Diagnostics, Johnson & Johnson, USA), antibody identification was done on semi-automated platform BioVue (Ortho Clinical Diagnostics, Johnson & Johnson, USA). All tests were performed according to the departmental Standard Operating Procedure (SOP) and as per manufacturer's instructions.

2.4. Antibody Screen

Antibody screening of blood donors were performed using commercially available pooled 'O' cells (Ortho Clinical Diagnostics, Johnson & Johnson, USA) and antibody screening of patients was performed using commercially available 3-cell panel (Surgiscreen from Ortho Clinical Diagnostics, Johnson & Johnson, USA)

2.5. Antibody identification

Antibody identification was done using 11-cell panel (Resolve Panel A from Ortho Clinical Diagnostics, Johnson & Johnson, USA) for both patients and donors.

2.6. Categorization of clinical disciplines

The clinical disciplines were categorized into two groups depending on presumed previous transfusion history. Group 1 with larger number of patients with presumed previous transfusion history constituted of Oncology & Hematology, Nephrology & Urology and Gastroenterology & Gastro-surgery.

While group 2 with fewer numbers of patients with presumed previous transfusion history comprised of Orthopedics, Hepatology, Cardiology & Cardio-thorasic Surgery and Others.

2.7. Transfusion policy

The hospital transfusion policy is to issue ABO RhD matched red cells after Anti-Human Globulin (AHG) Cross-match only.

2.8. Statistical analysis

Percentages, mean values and student 't' test were done using SAS (statistical analysis software) 9.1.3.

3. Results

During the period of study, a total of 32,560 patients and 31,367 donors were evaluated for clinically significant irregular antibodies. The demographic data of patients and donors is described in Tables 1 and 2, respectively. Amongst the total of 32 560 patients most were adults with age group of 18– >60 years (94.25%; $n = 30{,}685$) and majority were male (68.99%; $n = 22{,}466$). Amongst the total of 31,367 blood donors majority were male (95.6%; $n = 29{,}979$) between 31–65 years of age (82.5%; $n = 25{,}874$).

As depicted in Table 4, the cumulative incidence of irregular antibodies amongst the patients and donors were found as 0.12% (40/32,560) and 0.009% (3/31,367), respectively. The incidence (0.09%) of Rh antibodies was found to be highest among the clinically significant antibodies (29/40; 72.5%). Anti-D antibody was the commonest antibody in Rh blood group system (14/29; 48.3%). In present study, the second most common blood group associated with the relatively higher rate of antibody incidence was MNS blood group system (5/40; 12.5%). In two cases (5%) we could not identify the antibody in the patients and this was labeled as 'inconclusive'. However, amongst the blood donors the commonest blood group system associated with highest incidence of clinically significant antibody was MNS (2/3). Detailed incidence and type of clinically significant antibodies are depicted in Tables 3 and 4 .

The incidence of DAT amongst the healthy blood donors was 0.04% ($n = 13$).