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"SCREENING OF TRANSFUSION TRANSMISSIBLE INFECTIONS IN ENZYME LINKED IMMUNO SORBENT ASSAY NEGATIVE BLOOD DONORS USING NUCLEIC ACID TEST"

Pathology

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ABSTRACT

Introduction:- There is always possibilities of transmission of transfusion transmissible diseases. Blood transfusion can transmit Human immunodeficiency virus (HIV), hepatitis C virus (HCV), and hepatitis B virus (HBV), through infected blood. Even Routine serological screening test and ELISA [Enzyme-linked Immunosorbent Assay] can not detect all infected blood units. Hence, to overcome this drawback and to minimise the risk, NAT [Nucleic Acid Testing] provides additional protection with higher sensitivity and specificity. **Aim/Objective:-** Screening of transfusion transmissible infections {HIV, Hepatitis B &C} using NAT technique to determine occurrence of seropostive blood donors in ELISA negative individuals. **Methodology:-** An observational study was conducted in Department of Pathology Blood Bank, Gandhi Medical College and Associated Hospitals, Bhopal, where NAT investigation was conducted in all ELISA negative blood donors over the course of 1 year (04 Feb 21 to 04 Feb 22). **Statistical Analysis:-** 12- month data was compiled using Ms excel and analysed using Epi info 7.2. **Result:-** All the ELISA Negative(1271) blood units were tested by NAT. NAT was positive in 5 out of 1271 for HBV (0.4% cases). NAT was positive in 1 out of 1271 for HCV (0.1% cases).**Conclusion:-** Dual testing of blood and blood products using high sensitivity serological tests like NAT, aids in the detection of potentially infectious diseases in all stages of infection of HIV, HEPATITIS B and HEPATITIS C. In order to reduce overall treatment cost and boost effectiveness of healthcare system, it is advised to perform NAT in all ELISA negative blood donor samples.

KEYWORDS

NAT, ELISA, TRANSFUSION TRANSMISSIBLE DISEASES.

INTRODUCTION:-

Blood transfusion is a common medical procedure performed routinely for various conditions such as acute anemia due to hemorrhages, trauma, critical illness, sepsis or chronic anemias due to hepatic disorders, bleeding disorders, malignancies, or conditions associated with decreased erythropoiesis.[1] .

One of the common complication associated with blood transfusion is transfusion transmitted infections due to biological agents including hepatitis B virus, HIV, hepatitis C virus, etc.[4]

Thus, it is important to ensure the safety of the blood at the time of collection from voluntary donors, and screen the donated blood for viral markers with the help of highly sensitive screening tests.[2]

World Health Organization recommends screening of all the donated bloods for infections particularly for Hepatitis B, Hepatitis C, HIV and syphilis prior to its use.[5]

National Blood Policy was adopted by Government of India in 2002 as "An action plan for blood safety" to ensure the provision of safe blood supply. This policy recommends mandatory screening of donated blood for certain common transfusion transmitted infections including HIV, Hepatitis (B & C), syphilis and malaria.[6]

The prevalence of Transfusion transmitted HIV, HBV, HCV in high income countries is estimated to be 0.001%, 0.01%, 0.06% respectively according to WHO. However, the prevalence of transfusion transmitted HIV in low middle income countries is estimated to be 0.19% whereas that of HBV is 1.96%, HCV is 0.38%.[5]

Thus, the rate of TTI is considerably higher in low –middle income countries as compared to high income countries.[5]

Traditionally, serological testing or immunoassay Immunoassays (Ias):
Enzyme immunoassays (EIAs),Chemiluminescent immunoassays (CLIAs) ,Haemagglutination (HA)/particle agglutination (PA) assays ,Rapid/simple single-use assays (rapid tests) are methods for screening of donated blood for TTI's which are based upon the detection of antibodies to viral antigens or viruses. However, the major drawback of this method is it is not helpful in diagnosis or screening of infections during the window period i.e. an interval between exposure to virus and appearance of antibodies in the blood of donor.[8]

Thus transfusion of screened seronegative donations may be associated with transfusion transmitted infections and thus there was a need of sensitive screening test which helps in screening or detection of infection in donated blood even during the window period.

To overcome this issue, Nucleic Acid Testing (NAT) has been implemented with high success in Western countries.[9]

Though, NAT testing is initiated in few private institutions and certain state government, it is not mandatory to screen blood using NAT in India as its cost and requirement of the technical expertise limits its use in Indian setting.[9,10]

Nucleic acid testing (NAT) is the advance technique known to shorten or reduce the window period of the infections and thus helps in improving the safety of donated blood even in seronegative blood.[9] This technique is highly sensitive for detection of TTIs.

Literature suggest that NAT reduce the window period of HBV, HCV and HIV to 10.34, 1.34 and 2.93 days respectively.[11]

The NAT technique has been introduced recently at tertiary care centre in Bhopal for screening of HIV, HBV and HCV in donated blood before transfusion. At our institute, mandatory screening using serological tests (ELISA) is routinely done and recently the screening is done with NAT also. The present study was therefore conducted at tertiary care center to analyze the efficacy of NAT testing as additional donor screening programme, detect the seroprevalence of transfusion transmitted infections (TTI) and to determine its role in improving blood safety.

MATERIALS AND METHODS-

After obtaining ethical clearance from Institute's ethical committee, all the cases fulfilling the inclusion criteria were enrolled.

An observational study was conducted in Department of Pathology Blood Bank, Gandhi Medical College and Associated Hospitals, Bhopal, where NAT investigation was conducted in all ELISA negative blood donors over the course of 1 year (04 Feb 21 to 04 Feb 22).

12- month data was compiled using MS excel and analysed using Epi info 7.2. Detailed data regarding sociodemographic variable such as name, age, gender, occupation, education, residence and contact number was obtained and entered in proforma.

Their relevant clinical history, presence of comorbid conditions, previous transfusion, drug history, family history, menstrual history (female donors) was obtained and documented. Weight, hemoglobin and blood group was recorded for all the patients to assess their eligibility of blood donation.

Exclusion Criterion:

1. ELISA positive donor (HIV 1 AND 2, hepatitis B AND C)
2. VDRL positive, Malaria positive donor

Ethical Approved:

Approved by institutional ethics committee Gandhi Medical College Bhopal.

RESULTS-

- The present study entitled "SCREENING OF TRANSFUSION TRANSMISSIBLE INFECTIONS IN ENZYME LINKED IMMUNO SORBENT ASSAY NEGATIVE BLOOD DONORS USING NUCLEIC ACID TEST" was conducted on a total of 1271 ELISA negative blood samples received at our blood centre over the course of 1 year (04 Feb 21 to 04 Feb 22).

- All the samples were screened for TTI {HIV, Hepatitis B and C} by nucleic acid test. The findings of our study are described as under-

Distribution according to findings of NAT :

All the ELISA negative(1271) blood units were tested by NAT.NAT was positive in 5 out of 1271 for HBV (0.4% cases). NAT was positive in 1 out of 1271 for HCV (0.1% cases).

DISCUSSION-

Though we preliminary screened all the donated blood samples with ELISA, however, this method may not be able to screen the TTI's during the 'window period' i.e. time between infection and appearance of antibodies. Thus, the donor is infective during this stage, but it might be missed by ELISA.

To overcome this issue, testing of blood by NAT have been recommended, which is based upon the technique of direct amplification and detection of nucleic acid component of the viruses rather than antibodies and hence, NAT may have beneficial role in detecting the infection during the window period.[17]

We screened all the ELISA negative blood donors for viral testing. Though we observed no case of HIV in ELISA negative blood samples, HBV and HCV were detected in 0.4% and 0.1% cases respectively.

In our study, the yield of NAT was 0.5% in addition to ELISA, i.e. out of 1271 ELISA negative samples, 6 donations (0.5%) were found to be in window period, 5 for HBV and 1 for HCV.

Our study findings were supported by the findings of **Chaithanya K et al (2018)**, in which, the yield of NAT was 0.11% i.e. combined NAT yield was documented to be 1 in 893 cases.[16] **Pathak S et al (2013)** in their study documented the NAT positivity in 3 cases out of 6587 negative samples and all were found to be HBV positive.[18]

- In another study by **Jain R et al (2012)**, the authors identified 8 NAT positive HBV cases in total sample with yield of 1 in 2972 cases.[13]
- **Agarwal N et al (2013)** in their study documented higher yield of NAT as compared to our study, i.e. they documented NAT positivity in 1 in 610 cases, of them, 73 were HBV, 37 were HCV and 1 was HIV.[14]
- In contrast to our study, **Makroo RN et al (2008)** documented NAT positivity of 1 in 1528 cases attributing to 0.065% with 6 HBV, 1 HCV and 1 HIV case.[10]
- **Chatterjee K et al (2012)** in their study documented the yield of NAT as 1 in 2622 donations attributing to 0.038%.[12] On the other hand, **Chigurupati P et al (2015),** the yield of NAT was 1 in 2000 i.e. 4 in 8000 were NAT positive among ELISA negative samples.[15] **Mahapatra S et al (2019)** documented the NAT positivity in 53 out of 57,289 sero-negative donors (0.092 %) yielding to 1 in 1078 cases.[8]

CONCLUSION

NAT can effectively detect HBV and HCV in ELISA negative sample. Implementation of NAT in the blood banks must be made mandatory as NAT can identify the viral nucleic acid way early before the serological tests i.e. in the window period.

Donors must be counselled before donation about the risk of transmitting infection during the window period.

NAT can be complementary to ELISA and its incorporation as a routine screening method in blood banks can be an effective method for safeguarding the blood supply.

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