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*Original Research Article*

# Correlative Study of Elisa and Nuclic Acid Test in the Diagnosis of Transfusion Transmittable Viral Diseases

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## Abstract

*Introduction:* Blood transfusions are one of the major life saving procedures carried out to replace the host blood with that of donor to maintain the circulatory volume of blood. As most of the pathogenic microbes gets transmitted through haematogenous route. In order to provide a safe blood service in India, most sensitive and specific laboratory tests are the need of the hour even though the majority of the donations are through voluntary donations.

*Aims and Objectives:* To study the correlation of ELISA and nucleic acid test in transfusion transmittable viral diseases

*Material and Methods:* A two year study was carried out in Blood Bank of a tertiary health care centre in south central part of India for a duration of two years. All healthynon-remunerated voluntary blood donors were included in the study. Donors known positive for Human immunodeficiency virus (HIV), Hepatitis B or Hepatitis C infection were excluded from the study. ELISA test was performed at the same institution and ID-NAT tests were done at Molecular laboratory of state reference lab.

*Results:* A total of 16,286 voluntary blood donations were collected and tested for HIV, HBV, and HCV over a period of two years. Out of all healthy donors screened with standard operating protocol 13 cases were found to be positive for HIV, 136 cases for HBV and 16 cases for HCV in ELISA. NAT test done with the same donor's sample is found to be positive in 20 cases for HIV, 158 cases for HBV and 18 cases for HCV.

*Conclusion:* The screening method NAT for TTI is proved to be most effective method to detect TTI viruses than ELISA even in window period .

**Keywords:** Transfusion Transmittable Diseases; ELISA; NAT.

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## Introduction

Blood transfusions are one of the major life saving procedures carried out to replace the host blood with that of donor to maintain the circulatory volume of blood. As most of the pathogenic microbes gets transmitted through haematogenous route, maintenance of utmost standard of screening blood and blood products for transfusion transmittable infections (TTI) is need of the hour. Blood safety procedures and testing of blood and blood products, considerably reduces the risk, however, in current technology which is used still poses risk. There is higher risk of TTIs in patients receiving chronic and regular transfusions. The advent of TTIs has brought out revolutionary changes, research and developments in both testing of blood units and safety protocols in blood transfusion. According to the regulatory requirement of the Indian Drug and Cosmetics act of 1940, (1st Amendment rules 1992) it is compulsory to test each unit of blood donated for markers of HIV, HCV, HBV, malaria and syphilis [1,2]. High rate of morbidity and mortality of these TTIs could result in a massive burden on the health index and economy in a developing country like India. In order to provide a safe blood service in India, most sensitive and specific laboratory tests are the need of the hour even though the majority of the donations are through voluntary donations. The longer window period and inability of the conventional diagnostic methods to diagnose the infection in window period poses a considerable amount of TTI threat to the recipient. To reduce the residual risk to a larger extent sensitive screening tests such as Nucleic acid test (NAT) are needed as NAT has shown considerable results in developed countries like Europe since late 1990. Presently about 33 countries all over the world have implemented NAT [2,3].

The abilityof NAT in the diagnosis of infection in window period has reduced the residual risk of TTIs. In India,currently each blood units are screened for TTI markers using ELISA or rapid methods. [4,5,6] The NAT test are run on the principle of amplification of intended regions of nucleic acid of the virus such as HIV, HBV and HCV for detection. The present study is carried out to study the role of NAT in the diagnosis of TTI over conventional ELISA method in detection of HBV, HCV and HIV infections in window period [7,8].

*Aims and Objectives*

-Study the correlation of ELISA and nucleic acid test in transfusion transmittable viral diseases

## Material and Methods

A two year study was carried out in Blood Bank of a tertiary health care centre in south central part of India for a duration of two years. All healthynon-remunerated voluntary blood donors were included in the study. Donors known positive for Human immunodeficiency virus (HIV), Hepatitis B or Hepatitis C infection were excluded from the study. ELISA test was performed at the same institution and ID-NAT tests were done at Molecular laboratory of state reference lab.

The results of ELISA as well as NAT were collected and compiled together. The pattern of prevalence of Human immunodeficiency virus (HIV), Hepatitis B and Hepatitis C infection were studied.

## Results

A total of 16,286 voluntary blood donations were collected and tested for HIV, HBV, and HCV over a period of two years. Out of all healthy donors screened with standard operating protocol 13 cases were found to be positive for HIV, 136 cases for HBV and 16 cases for HCV in ELISA. NAT test done with the same donor's sample is found to be positive in 20 cases for HIV, 158 cases for HBV and 18 cases for HCV (Table 1).

**Table 1:** Table showing the number of seropositive donors by ELISA and NAT.

| | Positive in ELISA | Positive in NAT |
|---|---|---|
| HIV | 13 | 20 |
| HBV | 136 | 158 |
| HCV | 16 | 18 |

There was a significant percentage of donors found to be seropositive in NAT compared to that of ELISA. The percentage of missed seropositivity were 35%, 14% and 11% for HIV, HBV and HCV respectively (Table 2).

**Table 2:** Table showing percentage of seropositive donors diagnosed by NAT over and above ELISA.

| | Number of cases picked up by NAT over and above ELISA | Percentage of missed seropositivity |
|---|---|---|
| HIV | 07 | 35% |
| HBV | 22 | 14% |
| HCV | 02 | 11% |

A good statistical correlation was obtained between ELISA and NAT on student t test with a p value of $<0.01$.

The percentage of seropositivity missed in ELISA is highest in HIV infection i.e. 35% compared to HBV and HCV.

The percentage of seropositivity missed in ELISA were significantly high which might be due to longer window period of the viruses which delay in the formation of antibodied in the host which is the principle behind ELISA. Whereas in NAT nucleic acid of the virus will be picked up as a diagnostic indicator which appear as soon as the viral load increases in the host blood.

## Discussion

There is a significant improvement in Transfusion safety in recent past, blood transfusion was never so safe as it is nowadays. This significant improvement in blood safety has been reached through measures like stringent voluntary donor selection criteria, highly sensitive screening tests, high standards of quality in preparation of components and quality control of blood and blood components, and introduction of NAT testing as a routine screening procedure [7]. The major advantages of NAT screening is detection of virus as early as in carrier status with much higher sensitivity. Reports from developed countries displayed a limited value of NAT in enhancing blood safety. In contrast developing countries showed significant use [8].

NAT positivity study was done in different countries like Italy, Slovenia, Croatia etc. The yield of seropositivity is comparatively higher in all the studied in comparison to ELISA [10,11]. Studies conducted by Hourfar MK et al. reported that there was a good correlation of ELISA and NAT in the diagnosis of seropositivity with higher diagnostic accuracy of NAT over ELISA which is comparable to present study [12].

In a developing country like India transfusion transmittable diseases needs to checked with highest vigilance as awareness about HIV is very less when compared to developed countries with a high seropositivity in India. Not to take a further risk of TTI it is need of the hour to resort to NAT over ELISA for screening TTI viral infections.

## Conclusion

The screening method NAT for TTI is proved to be most effective method to detect TTI viruses than ELISA even in window period of the infection which is a boon to the recipient to combat the risk of TTI. NAT will help in improving the blood transfusion safety to a large extent which is need of the hour.

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*Conflicting Interest*

*(If present, give more details):* None.

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