International Journal of Clinical and Diagnostic Pathology

ISSN (P): 2617-7226
ISSN (E): 2617-7234
www.patholjournal.com
2019; 2(1): 22-24
Received: 11-11-2018
Accepted: 15-12-2018

Dr. Anand kanasagara
Tutor, GMERS Medical College, Himmatnagar, Gujarat, India

Dr. Nilay Shah
Assistant Professor, Department of pathology, GMERS Medical College, Himmatnagar, Gujarat, India

Dr. Krupal Hapani
Consulting Pathologist, Vision pathology laboratory, Bhavnagar, Gujarat, India

Dr. CK Shah
Professor & HOD, Department of Pathology, N.H.L. Medical College, Ahmedabad, Gujarat, India

Correspondence
Dr. Nilay Shah
Assistant Professor, Department of pathology, GMERS Medical College, Himmatnagar, Gujarat, India

Comparative study of rapid 3RD & 4TH generation Elisa in diagnosis of HIV in blood donors

Dr. Anand Kanasagara, Dr. Nilay Shah, Dr. Krupal Hapani and Dr. CK Shah

DOI: https://doi.org/10.33545/pathol.2019.v2.i1a.06

Abstract
Background: Blood is a life saving resource but at the same times however, blood transfusion can be a source of life threatening infections, if screening is not carried out properly [1]. It is also the most efficient vehicle for the transmission of human immunodeficiency virus (HIV). Hence there is a need for accurate screening of HIV among blood donors.
Material and method: The material for the study was collected from the 500 random donors coming to blood bank, N.H.L. Medical College, V.S. Hospital Ahmedabad affiliated with Gujarat University. Serum samples of donors were tested for HIV by rapid, 3rd generation ELISA & 4th generation ELISA.
Results: 500 blood donors were evaluated with rapid immune chromatography, 3rd generation Elisa & 4th generation Elisa. Among them 54 donors fall in age group of 20 years & below, 192 of them were from 21-30 years, 174 of them were from 31-40 years, 65 of them were from 41-50 years & 15 of them were from 51-60 years of age group. All were negative for HIV with all methods.
Conclusion: The rapid tests have advantages such as ease of use, minimal training required for the user, easy interpretation, and a long shelf life. These tests can be done with a short turnaround time, avoiding the delay incurred in batching. Thus, rapid tests can be used as an alternative to ELISAs in blood banks.

Keywords: HIV, Immunochromatography, 3rd generation ELISA & 4th generation ELISA

Introduction
Blood is a life saving resource but at the same times however, blood transfusion can be a source of life threatening infections, if screening is not carried out properly [1]. It is also the most efficient vehicle for the transmission of human immunodeficiency virus (HIV). Hence there is a need for accurate screening of HIV among blood donors. As per National Acquired immunodeficiency syndrome Control Organisation (NACO), the prevalence of human immunodeficiency virus (HIV) infection in adults in India is 0.27% [2]. There are many reports about the HIV prevalence among blood donors in India, the rate ranging between 0.084% to 3.87% [3-9]. Blood transfusion is an integral and life saving procedure of modern medicine, but simultaneously it carries the risk of transmitting the life-threatening transfusion-transmissible infectious agents such as human immunodeficiency virus (HIV). Thus ensuring the safety of blood is a major concern in transfusion therapy although the improved screening and testing of blood donors has significantly reduced transfusion-transmitted diseases.
In 1982, the Morbidity and Mortality Weekly Report from the Centres for Disease Control (CDC) provided information on possible transmission of acquired immunodeficiency syndrome (AIDS) by contaminated blood and blood product (Centre for Disease Control: Update on acquired immunodeficiency syndrome (AIDS) among patients with haemophilia A. MMWR. 1982; 31:644-51) Since then, public and private health institutions, blood banks and manufacturers of diagnostic tests have collaborated to develop a blood safety vigilance system to reduce transfusion-related human immunodeficiency virus (HIV) transmission.
In 1985, the first specific HIV type 1 (HIV-1) antibody test was licensed and blood donors then underwent double screening: a) an extensive pre-donation questionnaire to determine donor eligibility and b) post-donation HIV-1 antibody testing. The most commonly used method for detecting HIV antibodies (HIV Ab) has been enzymelinked immunosorbent assay (ELISA). The performance of HIV screening assays has improved substantially over the years.

Material and methods

500 random blood donors of Vadilal Sarabhai Hospital were evaluated.

Selection of patients

Inclusion criteria: Total sample number included the number of blood donors donating blood only once during study period.

Exclusion criteria: Repeated donation of same donor during study period will be excluded & known seropositive donor for any infectious disease are excluded

Type of study: Cross sectional study

Samples & sampling technique

Serum Samples of blood donors are studied.

Total 500 donors are studied.

Prior to blood donation, donors were requested to answer the questionnaire to determine whether they were eligible for donation as per the criteria set by "NACO". Both the first time donors & repeated donors will be included in the study. 2 milliliters of each donor's blood are dispensed in a plain vacuatte labeled with sample number for mandatory screening for Transfusion Transmitted infections.

Serum samples were tested for HIV by rapid, 3rd generation Elisa & 4th generation Elisa.

Results

All serum sample of 500 random donors are tested with rapid method, 3rd and 4th generation ELISA for diagnosis of H.I.V. Standard Operative Procedures are following in each test.

Table 1: Results of each method

Name of test	No. of positive donors (out of 500)	No. of negative donors (out of 500)
3rd generation ELISA	0	500
4th generation ELISA	0	500
Rapid	0	500

Table 2: Age wise distribution of HIV BY rapid method

Name of test	Age	Total donors	No. of positive Donors	No. of negative Donors
Rapid	20 & below	54	0	54
Rapid	21-30	192	0	192
Rapid	31-40	174	0	174
Rapid	41-50	65	0	65
Rapid	51-60	15	0	15
Rapid	Total	500	0	500

Table 3: Age wise distribution of HIV by 3rd generation ELISA

Name of test	Age	Total donors	No. of positive Donors	No. of negative Donors
3rd generation ELISA	20 & below	54	0	54
3rd generation ELISA	21-30	192	0	192
3rd generation ELISA	31-40	174	0	174
3rd generation ELISA	41-50	65	0	65
3rd generation ELISA	51-60	15	0	15
3rd generation ELISA	Total	500	0	500

Table 4: Age wise distribution of HIV by 4th generation ELISA

Name of test	Age	Total donors	No. of positive Donors	No. of negative Donors
4th generation ELISA	20 & below	54	0	54
4th generation ELISA	21-30	192	0	192
4th generation ELISA	31-40	174	0	174
4th generation ELISA	41-50	65	0	65
4th generation ELISA	51-60	15	0	15
4th generation ELISA	Total	500	0	500

Table 5: Sex Wise Distribution of HIV

Sex	Total donors	No. of positive donors	No. of negative donors
Female	11	0	11
Male	489	0	491

Table 6: Type Wise Distribution of HIV

Type	Total donors	No. of positive donors	No, of negative donors
First time	480	0	480
Repeated	20	0	20

Discussion

Detection of HIV infections and diagnosis is mainly based on immunological assays among which ELISA and rapid tests are most common and widespread methods [10-12]. An important problem encountered at this point is the discordance between the results of two assays [13]. Which can be resolved depending on the availability of suitable kits. Hence, kit evaluation gains importance for determining the diagnostic kits of better performance. Though ELISA assay shows a high degree of sensitivity, it is costly and time taking, so rapid tests become a good alternative for ELISA in blood banks. Moreover, uses of synthetic antigens in some rapid kits have increased the specificity [virology 25]. Performance of rapid test is also satisfactory.

According VP torane *et al*. study in Mumbai rapid diagnostic kits are inferior compared to ELISA. So rapid kits are not be recommended at transfusion centre or blood bank for screening.

According to rajesh kannangai *et al* study they found rapid kits as satisfactory as ELISA in screening 7 other study as in our study.

According to harjeet kaur *et al* they found rapid kit is 100% specific for HIV detection but less sensitivity. So They haven't shown any promising results in their study.

From above results in our study it is clear there is no discordant in results between rapid, 3rd & 4th generation ELISA results. The accuracy of rapid test is concordant with 3rd & 4th generation ELISA.

Table 7: General & operation characteristics of ELISA & rapid method (guidelines from rapid HIV testing WHO 2005)

	ELISAs	**RAPID**
Detection (sample type/specimen)	HIV antibodies in plasma/serum	HIV antibodies in plasma/serum
Accuracy (sensitivity, specificity)	Varies with test, ELISAs & similar diagnostics performances	More sensitive than specific
Laboratory equipment	Micropipette, washer, incubator, spectrophotometer	None to minimal (micropipette)
Laboratory personnel	Skilled laboratory technician	Can be performed by any health care worker who has been adequately trained including counsellors
Time to perform	>2 hours	Mostly 10-30 minutes
Shelf life	Usually 12 months	Usually 12 months
Storage condition	2-8 ◦c	2-8 ◦c
Volume of tests	Mostly suitable for medium volume to large volume testing i.e.>40-90 samples per testing tray.	Most kits are suitable for small volume & large volume testing. i.e. 1-100 samples per day.

Conclusion

Purpose of our study is to estimate prevalence of HIV among blood donors, to see the distribution of HIV among male & female blood donors, to see age wise distribution & to see distribution among 1st time & repeated donors and to evaluate & compare the outcome of results with the 3rd generation ELISA other techniques such as 4th generation ELISA & rapid immunochromatographic kits.

The rapid tests have advantages such as ease of use, minimal training required for the user, easy interpretation, and a long shelf life. These tests can be done with a short turnaround time, avoiding the delay incurred in batching. Thus, rapid tests can be used as an alternative to ELISAs in blood banks. The disadvantages of the enzyme-linked immunosorbent assay (ELISA) are the need for well-trained technical manpower, appropriate equipment, and batch testing. In a developing country such as India, technical support is not available in most of the blood banks.

References

1. Dodd RY. Infectious disease testing. In: Hillyer CD, Silberstein LE, Ness PM, Anderson KC, editors. Blood banking and transfusion medicine basic principles and practice. 1st edition. Edinburgh: Churchill Livingstone, 2003.
2. Annual Report 2011-2012. National AIDS Control Organization, Department of AIDS Control, Ministry of Health and Family Welfare, Government of India. New Delhi: National AIDS Control Organization, 4-6.
3. Gupta N, Kumar V, Kaur A. Seroprevalence of HIV, HBV, HCV and syphilis in voluntary blood donors. Indian J Med Sci. 2004; 58:3067.
4. Singh B, Kataria SP, Gupta, R. Infectious markers in blood donors of East Delhi: prevalence and trends. Indian J Pathol Microbiol. 2004; 47:477-9.
5. Nanu A, Sharma SP, Chatterjee K, Jyoti P. Markers for transfusion-transmissible infection in north Indian voluntary and replacement blood donors: prevalence and trends 1989-1996. Vox Sang. 1997; 73:70-3.
6. Makroo RN, Salil P, Vashist RP, Lal S. Trends of HIV infection in blood donors of Delhi. Indian J Pathol Microbiol. 1996; 39:139-42.
7. Chattoraj A, Behl R, Kataria VK Infectious disease markers in Blood Donors. MJAFI. 2008; 64(8):33-5.
8. Shukla RS, Bhuyan KK. Can data on HIV Sero-reactivity among blood donors provide an insight into HIV prevalence in the general population? Indian J Public Health. 2007; 51:14-9.
9. Choudhury N, Ayagiri A, Ray VL. True HIV Seroprevalence in Indian blood donors. Transfus Med. 2000; 10:1-4.
10. Khan JK, Lone DS, Hameed A, Munim MR, Bhatti M, Khattak AA *et al*. Evaluation of the performance of two rapid immunochromatographic tests for detection of hepatitis B surface antigen and anti HCV antibodies using ELISA tested samples. Sp Ed Ann. 2010; 16:84-87.
11. Hussain T, Kulshreshtha KK, Sinha S, Yadav VS, Katoch VM. HIV, HBV, HCV, and syphilis co-infections among patients attending the STD clinics of district hospitals in Northern India. Int J Infect Dis. 2006; 10:358-363.
12. Iqbal HS, Solomon S, Murugavel KG, Solomon SS, Balakrishnan P. Evaluation and diagnostic usefulness of domestic and imported enzyme-linked immunosorbent assays for detection of Human Immunodeficiency Virus Type 1 antibody in India. Clin Diagn Lab Immunol. 2005, 12:1425-1428.