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Research Article

Comparative Study of Enzyme Linked Immunosorbent Assay (ElISA) and Rapid Test Screening Methods on HIV, HBsAg, HCV and Syphilis among Voluntary Donors in Owerri, Nigeria

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Abstract

A comparative study of Enzyme linked immunosorbent assay (ELISA) and rapid test screening method on HIV, HBV, HCV and syphilis among voluntary donors was investigated on 350 subjects in Owerri. They were 250 males and 100 females, all ranging from the age of 21-50 years. Transfusion transmissible infections (TTIS) are the major problem associated with blood transfusion. Accurate estimates of risk of TIIS are essential for monitoring the safety of blood supply and evaluating the efficacy of currently employed screening procedures for immunodeficiency virus (HIV 1 and 2) hepatitis B virus (HBV), hepatitis C virus (HVC) and syphilis using both enzyme linked immunosorbent assay (ELISA) and rapid test screening method. For HIV 1 & 2 screening test, the female donors shows significant increase ($P<0.05$) between the ELISA and Rapid test method while there is no significant increase ($P>0.05$) between the ELISA and rapid test method for male donors. Hepatitis B virus screening test shows a significant increase ($P<0.05$) between ELISA and rapid test method for female donors, while there is no significant increase ($P>0.05$) between the two methods for male donor. Also hepatitis C Virus screening test shows a significant increase ($P<0.05$) between the two methods for the female donors and shows no significant increase ($P>0.05$) for male donors. However, there is significant increase ($P<0.05$) between ELISA and rapid test method for syphilis screening test among female donors while there is no significant increase ($P>0.05$) for the male donors. This study shows that there is a difference between the two test method, hence indicated that 30(8.57%) infected units of blood would have been transfused due to false negative results with rapid test method. It was found in this study that prevalence of TTIs were high in females than the males.

Keywords: ELISA; Rapid test; HIV; Hepatitis; Syphilis; Blood transfusion

Introduction

Blood transfusion and component therapies are well established and essential medical practice. These therapies however are not without risk and may lead to the transmission of infectious agent from donor to recipient. The common infectious agent includes human immuno deficiency virus (HIV 1 and 2), hepatitis B virus (HBV), hepatitis C virus (HCV) and syphilis (Schreiber et al., 2008). In pursue of global blood safety, the world health organization (WHO) recommends that all blood donation should be screened for evidence of infection prior to the release of blood and blood products for clinical use WHO, [1]. According to WHO guidelines, the screening of all blood donations should be mandatory for IV 1 & 11, HBV, HCV and syphilis.

The prevalence of viral infection in blood donations can be used as a valuable indicator to assess the safety of blood supply and potential risk of TTIs.

The pre-donation screening of blood donors for TTIs is the practice by which a prospective donor is tested for the presence of one or more of the TTI agent by a single rapid or quick method and

donation is deferred if the test is reactive for any of the TIIs markers Bhawani et al. [2].

Universally, the normal procedure is to administer a standard questioner, measure the concentration of hemoglobin and weight of the donor. The donor is then bled if found fit based on the selection criteria and asked to leave after a period of rest. The donor blood units are then separated into various components and stored. The blood is then tested using Elisa assay technique. All those reactive for any of the TTRIs are appropriately discarded including their respective components. Those non reactive for viral markers are appropriately labeled and use for transfusion Lequim [3].

Human immune deficiency virus (HIV 1 & 2), HBV, HCV, and syphilis are the most important agents causing transfusion transmissible infectious (TIIs) and they constitute large health care burdens worldwide Kitchen et al. [4].

Transfusion of TIIs during serological negative window period still poses a threat to blood donor safety. Therefore, strict selection of blood donors and comprehensive screening of donor's blood using standard methods are highly recommended to ensure the safety of blood for recipient.

This study shows the importance of serological evidence of TTIS which may be obtained by testing for HIV 1 & 2 Ag-Ab, HBsAg, HCV antibody and syphilis antibody in serum individual of voluntary blood donor to reduce the window period and to increase the assay sensitivity.

New screening test have been developed which simultaneously detect antigen and antibody WHO, [1].This research is carried out to ensure that TTIS are prevented by mandatory screening of donated blood before transfusion using a highly sensitive and specific test method (ELISA) to ensure the safety of blood for recipients. The purpose of this study was to compare the specificity and sensitivity of ELISA and rapid test screening method on HIV HBsAg, HCV and syphilis among voluntary blood donors in Owerri.

Materials and Method

This study was carried out in Owerri, Imo State Nigeria. The subjects were representative of only those residents in Owerri town.

Data was analyzed from 350 blood samples collected, 250 were males and 100 were female within the ages of 21-50 years. They were all voluntary donors in Owerri. Full industry and physical examination were performed and recorded for all volunteer blood donors to review their eligibility for donation, using the donor record form.

Blood samples were screened for the presence of HIV, HBsAg, HCV and syphilis using Enzyme linked immunosorbent assay (ELISA) and rapid test screening method. All data were evaluated using statistical software.

This study was a retrospective, descriptive and comparative study of ELISA and rapid test screening method for HIV, HBsAg, HCV and Syphilis among voluntary donor. 450ml of blood were collected into blood bag and after donation, a small quality of donated blood (3-5ml) each were put into the pilot bottles (commercially prepared EDTA). The samples were centrifuged, separated and stored at - 700C.

HIV 1 & 2, HBsAG, HCV and SYPHILIS TESTING Using the rapid test serum/plasma/whole blood

For the detection of HIV 1 & 2, the ultra Rapid test strip of determine and unigold was used to determine the presence of HIV 1 & 2 in the donor samples. ACON was used to determine the presence of HBsAg. While Diaspot rapid test strip was used to determine the presence of HCV and syphilis antibodies.

These are qualitative membrane strips based immunoassay for the detection of presence of HIV 1 & 2 antigen-antibody, HBsAg, HCV and syphilis (Trepemonapallidum) antibodies (lgA& M) in whole blood, serum or plasma.

All data were evaluated with SPSS (Statistical Package for Social Sciences) version 20.0. Statistical analysis included descriptive statistics of percentage and chi-square. A P value of <0.05 was considered significant.

Results

The experimental result (Table 2) shows the HIV status of the sampled population. From the result it can be seen that 5% of the female individuals tested positive to HIV using the ELISA screening technique while 1% tested positive with the Rapid method. However, 2% of the male individuals tested positive to HIV using ELISA screening method while 0.8% of the male individuals tested positive using Rapid method.

Table 1: Results of HIV, HBsAg, HCV and Syphilis using both ELISA and Rapid test methods among voluntary donors in Owerri. -ve Negative , + Ve Positive.

Donor		ELISA Method						Rapid Method									
Characteristics		HIV		HBV		HCV		SYPHILIS		HIV		HBV		HCV		SYPHILIS	
Gender	Total	-VE	+VE	-VE	+VE	-VE	+VE	-VE	+VE	-VE	+VE	-VE	+VE	-VE	+VE	-VE	+VE
Female	100	95	5	90	10	92	8	95	5	99	1	95	5	97	3	98	2
Male	250	245	5	241	9	240	10	244	6	248	2	245	5	244	6	246	4

Table 2: Prevalence of HIV according to gender of the donor using ELISA and Rapid test screening methods

Donor Characteristics		ELISA Method		Rapid Method	
Gender	**Total**	**No %**	**HIV +ve**	**No %**	**HIV +ve**
Female	100	5	5	1	1
Male	250	5	2	2	0.8
Chi square			2.16		0.45

Of the 350 samples tested, 10% of the female individuals tested positive to HBV with ELISA screening method while 5% of the female tested positive with rapid screening kit. On the other hand, 3.6% of male tested positive to HBV using ELISA method and 2% of the male individuals tested positive using Rapid method (Table 3).

Table 3: Prevalence of HBV according to gender of the donor using ELISA and Rapid test screening methods

Donor Characteristic		ELISA Method		Rapid Method	
Gender	**Total**	**No %**	**HIV +ve**	**No %**	**HIV +ve**
Female	100	10	10	5	5
Male	250	9	3.6	5	2
Chi square			4.98		2.16

Of the sampled population, 8% of the female individuals tested positive to HCV, and 4% of the male individuals tested positive to HCV with ELISA method while 3% of female and 2.4% of male tested positive to HCV using Rapid test method of blood screening (Table 4).

Table 4: Prevalence of HCV according to gender of the donor using ELISA and Rapid test screening method.

Donor Characteristics		ELISA Method		Rapid Method	
Gender	**Total**	**No %**	**HIV +ve**	**No %**	**HIV +ve**
Female	100	8	8	3	3
Male	250	10	4	6	2.4
Chi square			2.08		0.09

The percentage of female and male individuals that tested positive to syphilis using ELISA method of blood screening are 5% and 2.4% respectively while that of Rapid screening method are 2% of female and 1.6% of male donors (Table 5).

Table 5: Prevalence of SYPHILIS according to gender of the donor using ELISA and Rapid test screening method.

Donor Characteristics		ELISA Method		Rapid Method	
Gender	**Total**	**No %**	**syphilis +ve**	**No %**	**syphilis +ve**
Female	100	5	5	2	2
Male	250	6	2.4	4	1.6
Chi square			1.47		0.07

Discussion

HIV, HBV, HCV and Syphilis are the greatest threats to blood safety for transfusion recipients and pose a serious public health problem. HIV units are of major concern due to carrier state and complications associated with the infections.

On the evaluation of all the samples in the population, 5% and 2% of both female and male donors were found to be reactive to HIV with ELISA screening method as oppose to 1 % and 0.8% of female and male individuals with Rapid method. The inferior performance of Rapid method in comparison to ELISA has also been reported by Torane et al. [5] where both methods were used to screen blood donors for HIV infection and the RDT used missed some samples confirmed reactive by ELISA. This discordance may possibly be due to low antibody titres especially in recent infections where the levels may well be below the detection limit of RDTs but are picked up by the more sensitive enzyme immunoassay and its spectrophotometric format of result analysis.

In this study, 5% of female samples that initially tested negative with the rapid method, tested positive with ELISA technique for HBS. Similarly 1.6% of the male samples that tested negative with rapid method tested positive with ELISA method for HBS. This indicates that ELISA test is more sensitive and superior for the testing of blood donors for HBS.

The finding is consistent with previous report which indicated that ELISA technique is superior to rapid method in the diagnosis

of hepatitis B virus infection among blood donors. Failure of the rapid method to detect the presence of markers of infectious viral diseases may be due; inadequate coating of the antigen, nature of the antigen used and genetic heterogeneity of the virus Torane et al. [5].

It is observed that the high false negative results with the rapid method compared to ELISA in this work is in agreement with previous report Salawu et al. [6] which indicated that there is risk of donor blood containing HBV being transfused to patients due to suboptimal testing HBsAg using rapid kits only.

The rapid test method was found to have sensitivity, specificity, positive-predictive value and a negative predictive value of 3% and 2.4% for female and male individuals respectively in HCV. The samples that tested reactive to HCV by ELISA could not be detected by the rapid method. Failure of the rapid kits to detect HCV reactive samples may be due to inadequate coating of the antigens, nature of the antigens used or genetic heterogeneity of the virus.

Most of these rapid assays use recombinant proteins from the prototype virus alone. The variants of HCV may differ substantially in nucleotide sequence from one another and show varied geographical and epidemiological distributions Kaur et al. [7] and Robert et al. [8].

From the evaluation of the sample in the population, 5% and 2.4% of both female and male donors were reactive to syphilis infection using ELISA method as against 2% and 1.6% with rapid method. This could be the fact that ELISA test method is more sensitive to pick the lowest syphilis antibody titre than that of the rapid test method Pickening [9]. ELISA test are generally accurate test. They are considered highly sensitive and specific compared with rapid test methods. They have added advantage of not needing radioisotopes [10].

From the screening point of view, 30 (8.57%) infected units would have been transfused due to false negative result with the rapid test method.

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