

Comparative Evaluation of ICT and ELISA for Detection of Syphilis among Blood Donors

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Abstract:

Background: *Syphilis is a sexually transmitted disease (STD) caused by *Treponema pallidum* that represents a major public health problem worldwide. Blood transfusion is the one of the important routes for syphilis transmission.*

Objective: *The current study aimed to evaluate the specificity and sensitivity of ICT (Immune Chromatography Test) comparison with ELISA (Enzyme-linked Immune-Sorbent Assay) for the detection of *Treponema pallidum*.*

Methods: *The current descriptive, cross-sectional study conducted in Khartoum hospital from December 2014 to March 2015, Ninety blood donor's volunteers were selected randomly to participate in this study. A structured questionnaire was used to collect demographics and clinical data. ELISA and ICT were done to determine the presence of syphilis among the study population.*

The Results: *Of the 90 blood donor's enrolled in the study, 6 were positive by ICT and 4 positive by ELISA. The sensitivity of ICT in comparison to ELISA was 75.0% and the specificity was 97.7 %.*

Conclusion: *The present study revealed that ELISA was more accurate to evaluate the safety of blood donation in comparison to ICT.*

Key words: Blood donors, ELISA, ICT, Khartoum-Sudan, Syphilis

Introduction

Syphilis is a chronic systemic infection that is often categorized as a genital ulcerative disease which causes fetal and prenatal death in 40% of affected pregnancies and major anomalies among newborn survivors⁽¹⁾. It caused by the spirochete bacterium *Treponema pallidum*. Transmission of syphilis represents the most frequent infectious complication of blood transfusion in the developing world and a major cause of transfusion associated mortality. The reported frequency of contamination varies depending upon the nature of the period from transfusion to clinical presentation varies from 4 weeks to 5 months, averaging 9 - 10 weeks, and the infected recipient usually exhibits a typical secondary eruption. Donors at any stage of disease, including late, latent syphilis, can transmit the infection ⁽²⁾. The risk of transmission through the transfusion of blood and blood components stored below 20°C is very low. However, it was observed that many cases were associated with the appearance of a sore on the blood donor few days after the donation. Thus, syphilis can be transmitted from donors who are clinically and biologically negative. It is clear that medical selection and mainly information and questioning are essential to identify those who have been exposed to the infection two months prior to the donation of their blood ⁽¹⁾. Syphilis is believed to have infected 12 million additional people in 1999, with greater than 90% of cases in the developing world. Affects between 700,000 and 1.6 million pregnancies a year, resulting in spontaneous abortion, stillbirth, and congenital syphilis. During 2010 it caused about 113,000 deaths down from 202,000 in 1990. In Sub-Saharan Africa, syphilis contributes to approximately 20% of perinatal death ⁽³⁾. The objective of the current study was to evaluate the specificity and sensitivity of ICT (Immune Chromatography Test) comparison with ELISA (Enzyme-linked Immune-Sorbent Assay) for the detection of *Treponema pallidum*.

Methods

The current descriptive, cross-sectional study carried out between December 2014 and March 2015. Ninety blood donor's volunteers were selected randomly from Khartoum hospital - Sudan. This study was approved by Al-Neelain University ethical committee board and an informed consent was obtained from each participant before collecting the demographic and clinical data. Five-mL blood samples were obtained for serological analyses. Samples were centrifuged and sera were separated immediately. Sera were stored at -20°C , and tested for the presence of syphilis antibodies by using Immunochromatography Test (ICT) devices of Intec (ACON) company, and enzyme-linked immune-sorbent assay (ELISA) (BIOREX). The presence of Syphilis antibodies was considered as the evidence for exposure to syphilis (Recent or past infections). All collected data were analyzed using SPSS. Descriptive statistics were reported as the mean \pm SD for continuous variables and as the frequency (%) for dichotomous variables. To evaluate the relationship between different factors, we performed chi-square analysis. Quantitative variables were compared using independent t-test. P. values < 0.05 were considered statistically significant.

The results

All of the 90 blood donors attended Khartoum hospital between December 2014 and March 2015 were males. The majority of the participants 57 (63.3%) were married, while 33 (36.7%) were unmarried. The age range was between 20 and 39 and the median age was 29.8 years. More than half of the participants (54.4%) were from other states. All patients' blood samples were tested by ELISA and ICT for detection syphilis antibodies, 4 (4.4%) and 6 (6.7%) of those participants were positive respectively. As demonstrated in the table (1).

Table (1): Demographic and clinical data

Characteristic	No.	%
Study group	90	100
Gender		
Male	90	100
Female	0	0
Family Status		
Married	57	63.3
Single	33	36.7
Age (Years)		
20 – 24	12	13.3
25 – 29	34	37.8
30 - 34	26	28.9
35 – 29	18	20.0
Residence		
Khartoum State	41	45.6
Other States	49	54.4
ELISA Results		
Positive	04	04.4
Negative	86	95.6
ICT Results		
Positive	06	06.7
Negative	84	93.3

ELISA test showed that 4 donors were syphilis positive, whereas ICT test showed that 6 donors were syphilis positive. The ICT test detected 2 donors were false positive and 1 donor was false negative when compared with ELISA (Table 2). The Sensitivity of ICT in comparison to ELISA was 75 % and the specificity was 97.7%

Table (2): The relationship between ELISA and ICT results

		ELISA		Total: No (%)
		Positive	Negative	
ICT	Positive	03	03	06 (06.7)
	Negative	01	83	84 (93.3)
Total: No (%)		04 (04.4)	86 (95.6)	100 (100)

Discussion

Strategies for blood safety were proposed and modified during the years until the adoption in 1987 by the WHO of a common international strategy. The general recommendations focus on

the control of the bacterial dissemination of the disease through blood transfusion by the selection of low risk blood donors and the screening of the disease by efficient lab tests ⁽⁴⁾. Blood donors with high-risk sexual behavior and other risk factors may be infected with syphilis and compromise the safety of blood used for transfusion. The medical selection of the blood donors consists of information of the donor, the finding of the risk factors in the behaviors and the medical history using a questionnaire, and the physical examination in order to find clinical signs of the infection. Donor deferral follows the identification of any risk. Medical selection is crucial because it could permit to defer more than half of infected donors, especially the ones in the early period of infection where laboratory tests are not efficient ^(5,6).

In laboratories; screening with both VDRL or RPR and TPHA has been common practice for many years as it provides sensitive and specific screening for all stages of syphilis, but it is more labor intensive than ICT and ELISA test, requires subjective interpretation, and cannot readily be automated. With these practical disadvantages, and with the recent commercial availability of ELISA and ICT, the VDRL or RPR and TPHA combination for screening is being widely replaced by the use of ELISA tests and ICT that detect treponemal IgG or IgM. The advantages of the ELISA format include high sensitivity and specificity the production of objective results, minimize subjective interpretations and facilitate automation. ICT is rapid, simple and cheap test but, it is less sensitive than ELISA and TPHA.

The prevalence of syphilis is still high in Sudan. The prevalence is however very variable from one area to another and from a country to another. In the present study, 4.4 % of blood donors were positive for syphilis. A prevalence of syphilis among blood donors was reported 3.5% ⁽⁷⁾ and 15% in Sudan ⁽⁸⁾, 17.4% in Cameroon ⁽⁹⁾, 12.8% in Ethiopia ⁽¹⁰⁾, 12.7% in Tanzania ⁽¹¹⁾, 7.5% in Ghana ⁽¹²⁾, 1.2% in Kenya ⁽¹³⁾, 1.1% in Nigeria ⁽¹⁴⁾,

and 0.49% in Eritrea⁽¹⁵⁾. These wide differences in the prevalence of syphilis infection among the blood donors may be due to the differences in geographical area, sample size, the time of the study, socio-cultural practices such as sexual behavior, marriage practices and laboratory technique used.

The current study revealed that ELISA was more accurate to evaluate the safety of blood donation in comparison to ICT. Strict selection of blood donors and comprehensive screening of blood using standard methods are highly recommended to ensure the safety of blood transfusion for recipients.

In the current study the sensitivity of ICT in comparison to ELISA was 75 % and the specificity was 97.7%, this is similar to study done in Sudan in (2012) by Elagib and Abdelmagid; 76.8% and 100%, respectively, and also similar to study done in Mozambique by Pablo et al (2006) ⁽¹⁶⁾, and study in Cuba done by Isaly et al (2002) ⁽¹⁷⁾.

Conclusion

The current study revealed that ELISA was more accurate to evaluate the safety of blood donation in comparison to ICT. Strict selection of blood donors and comprehensive screening of blood using standard methods are highly recommended to ensure the safety of blood transfusion for recipients.

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