



A COMPARATIVE ANALYSIS OF SEROPREVALENCE OF SYPHILIS DETECTED BY RAPID PLASMA REAGIN TEST AND ENZYME LINKED IMMUNOSORBENT ASSAY IN BLOOD DONORS ATTENDING A REGIONAL BLOOD TRANSFUSION CENTRE

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ABSTRACT **Background:** Syphilis screening methodology in all Government hospitals in state of Kerala was changed from the Rapid Plasma Reagin (RPR) method to Enzyme linked immune sorbent assay (ELISA) in August 2021. We compared the prevalences of syphilis in blood donors before and after this change in Government Medical College, Trivandrum. **Methods:** Samples positivity under RPR (2019 January to 2021 July) and ELISA (2021 August to 2022 December) screening were compared. **Results:** A total of 113059 donations were analysed. Seroprevalence in the RPR testing period was 106/78537 (1.4 %) and in ELISA was 74/34522 (2.1%) **Conclusions:** Frequency of seroreactive cases were significantly higher when tested with ELISA.

KEYWORDS :

INTRODUCTION

In India, Syphilis screening in blood banks were done conventionally with the Rapid Plasma Reagin (RPR), a nontreponemal test. Those tested seroreactive were referred for confirmatory testing. Treponemal tests are usually used to confirm such cases and start treatment. RPR titer correlates with disease activity and can be used to monitor treatment response also.^[1] Currently treponemal enzyme immunoassays are also widely employed for screening because they can be performed on an automated platform and facilitate high-throughput screening. Enzyme Immune Assays (EIA) for IgG antibodies detect both past and present infections efficiently.^[2]

In August 2021, most of the Govt Medical Colleges in Kerala changed from RPR to ELISA methodology for syphilis screening. Since no studies were done to compare the effect of this change, we conducted a retrospective study to compare seropositivity rates of syphilis before and after the change in technology.

METHODS

Study design – Retrospective

Study setting – Department of Transfusion Medicine, Govt Medical College Trivandrum

Study duration – Data of past 5 years was analysed.

Study population – Records of whole blood donor screening were utilised

We defined a screen positive sample on the basis of a reactive RPR during the RPR period (January 1, 2018–July 31, 2021). During the EIA period (August 1, 2021–Dec 31, 2022), a screen positive sample included a positive EIA above the cut off on duplicate testing ERBALISA SYPHILIS kits (Transasia Bio –medicals Ltd. India). Samples were defined as confirmed positive if the confirmatory test (TPHA) was positive.

Prevalence of samples remaining seroreactive after repeating in duplicate was calculated both in the RPR period and ELISA period.

Data was entered in excel sheet. Statistical analysis was also carried out in excel.

RESULT

A total of 113059 donations were analysed. Demographic and serological characteristics are summarised in Table 1.

Table 1 Demographic characteristics of the study population

	Time Period 1(RPR)	Time period 2(ELISA)
Males	76852	33900
Females	1685	622
Voluntary	71081	27119
Replacement	7799	9908
Seropositive for syphilis	106 (1.3%)	74 (2.1%)
Seronegative for syphilis	78431 (98.7%)	34448 (97.9%)

Most of the blood donors were males in both periods. A total of 110752 males (97.9%) and 2307 females (2.04%) donated in the 5 year period. 86.8% (98200) were voluntary blood donors. 5 year annual trend of blood donation is given in figure 1. Proportion of seropositivity in both periods are given in table 2. Prevalence of syphilis was higher in ELISA screened donors. The chi-square statistic 9.5082. The p-value is 0.02046. Significant at $p < .05$

DISCUSSION

Laboratories in many industrialized nations are increasingly using automated treponemal screening tests such as the EIA for the serological diagnosis of syphilis—primarily because of the ease in high-volume screening and to decrease subjectivity associated with visual reading of RPR. An Indian study by Sachdev et al found ELISA as equally sensitive (100%), more specific (56.3% vs. 0%), more accurate (83.7% vs. 62.7%), had better positive predictive value (79.4% vs. 62.8%) and negative predictive value (100% vs. 0%), and less biological false positivity (37.2% vs. 20.6%) when compared to RPR. They also suggested that The WHO recommendations of screening for syphilis in low prevalence population of blood donors using ELISA may be adopted for usage in transfusion services that have the facility of ELISA. Naidu et al also confirmed the utility of ELISA in screening for syphilis.

We observed an increase in the diagnosis of confirmed positive syphilis during the EIA period by approximately 3-fold compared with the RPR period, possibly because of EIA(+)/RPR(–) results predominantly. This may translate to increased detection of latent syphilis of unknown duration, prior treated syphilis, early syphilis, or nonsyphilitic treponemal disease. But it may also be due to the increased sensitivity of ELISA tests for screening syphilis which may be an advantage for blood safety including the identification of a small group of patients with infectious (transmissible) syphilis. A very recent Korean study⁵ had compared prevalences similarly and another study from Sudan found slightly higher seroprevalence with RPR. Seroprevalence of syphilis revealed from ELISA method was 7 (7.6 %), which was equal to ICT but was slightly increased in RPR group 6 (8.7%). Also in a study comparing 9 serological methods for syphilis testing, different variations of ELISA identified much higher

number of cases than RPR^[7]

Blood banks requiring a high volume of syphilis screening are moving from the conventional RPR to automated EIA treponemal screening tests. The study implies that, after introducing ELISA as the initial screening tool for syphilis, blood bankers should anticipate higher number of patients with EIA positive results alongside negative RPR and/or negative confirmatory test. Referral centres should be equipped for proper counselling and confirmatory testing RPR-negative latent syphilis of unknown duration is likely small, still that possibility also should be explored

Study also implies that change in screening methodology can significantly enhance detection of syphilis, leading to an increase in the diagnosis of latent syphilis of unknown duration or prior treated syphilis, and a small but notable increase in the detection of early syphilis. Further study should be initiated along with confirmatory testing in the same setting, to account for the potential false positives. On one hand, enhanced detection (and therefore treatment) of early syphilis may interrupt onward transmission and also serve as a surrogate marker of other sexually transmitted diseases like HIV also.

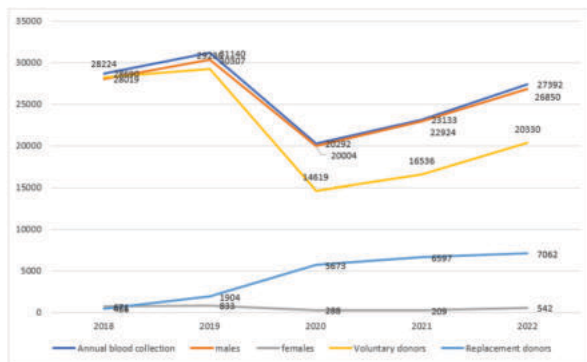


Figure 1. Five Year Trend of Annual Blood Collection

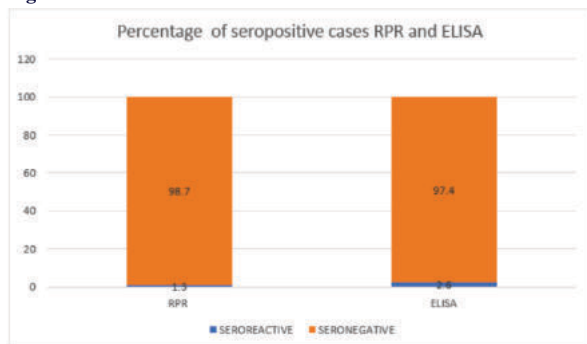


Figure 2. Proportion of Seropositive cases in RPR and ELISA

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