

Sero-prevalence of syphilis, risk factors and clinical characteristics among blood donors in a tertiary care hospital in Karachi, Pakistan

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ABSTRACT

Background: Transfusion poses a risk of transfusion-transmitted infections. Our aim is to evaluate blood donors who test positive for syphilis in order to confirm the diagnosis, assess clinical features and establish risk factors.

Material and Methods: A cross-sectional study was conducted from June to December 2024 at Sindh Institute of Urology and Transplantation (SIUT), Karachi. All blood donors who tested positive for treponemal antibodies by chemiluminescence immunoassay (TP-CMIA) were evaluated at the Infectious Diseases (ID) clinic between June to December 2024. History, examination and confirmatory testing with rapid plasma reagin (RPR) and *Treponema pallidum* hemagglutination (TPHA) tests were performed.

Results: A total of 20,685 donors were screened, and 374 (1.8%) tested positive on TP-CMIA. Of 374, 152 (40.6%) presented to the clinic of whom 91 (60%) were confirmed to have syphilis. Of these, 61(40%) were RPR negative but TPHA positive. Mean age was 33.5 ± 7.93 , and 150 (98.6%) were male. Pre-marital or extra-marital sexual relations were significantly associated with confirmed syphilis [OR 9.06, 95% CI (3.9-20.8)].

Conclusion: Sero-prevalence of syphilis in blood donors is 1.8% at our centre. It is of concern that 40 % of donors with confirmed syphilis were negative for RPR, as this is used for initial screening at many blood donation centres. Pre-marital and extra-marital high-risk sexual activities were highly associated with confirmed syphilis. A thorough and detailed history can effectively identify and exclude high-risk donors for blood donation, providing a cost-effective approach to screening.

Keywords: Syphilis, Screening, Blood donors

BACKGROUND

Transfusion poses a risk of transfusion-transmitted infections (TTIs)¹ Detecting TTIs, such as hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), and *Treponema pallidum* (TP), before transfusion is crucial to ensure safety.²

Globally, 118.2 million blood donations are collected, with 58% from low- and middle-income countries. According to the World Health Organization (WHO), safe blood transfusion is a universal human right. In Pakistan, it is estimated that 2.7 million blood donations

are collected annually from approximately 650 blood centres.³

According to a global report, Pakistan is considered a country with moderate prevalence of syphilis.⁴ Studies conducted in Pakistan suggest a sero-prevalence ranging from 2.5% to 3.9% among blood donors.⁵⁻⁸

Syphilis is a sexually transmitted disease caused by the spirochete *Treponema pallidum* (*T. pallidum*). It can also be transmitted through blood and blood products. Clinically, it has a protean presentation, ranging from painless genital ulcers to cardiac and neurological manifestations.⁹ Syphilis can be divided into various stages: primary, secondary, latent, and tertiary. Donors with latent infection can be asymptomatic and potentially transmit syphilis to blood recipients. Therefore, highly sensitive tests are recommended to screen donors for syphilis.¹⁰

Serologic tests for syphilis include non-treponemal tests such as the Venereal Disease Research Laboratory (VDRL) or the rapid plasma reagin (RPR) tests as well as treponemal tests such as the *Treponema pallidum* hemagglutination assay (TPHA), *Treponema pallidum* chemiluminescence immunoassay (TP-CMIA) as well

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This article can be cited as: Samar S, Dodani SK, Qureshi J, Badlani S, Moin H. Sero-prevalence of syphilis, risk factors and clinical characteristics among blood donors in a tertiary care hospital in Karachi, Pakistan. Infect Dis J Pak. 2025; 34(3): 164-169.

DOI: <https://doi.org/10.61529/idjp.v34i3.405>

Receiving date: 09 Jun 2025 Acceptance Date: 19 Aug 2025

Revision date: 08 Aug 2025 Publication Date: 30 Sep 2025



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as the fluorescent treponemal antibody absorption test (FTA-ABS).

Sindh Institute of Urology and Transplantation (SIUT) blood bank uses the TP-CMIA test for screening of blood donors which is considered highly sensitive.¹²

This study aims to evaluate donors who test positive for syphilis in order to confirm the diagnosis, assess risk factors, and evaluate clinical features.

MATERIAL AND METHODS

A cross-sectional study was conducted from June to December 2024 at Sindh Institute of Urology and Transplantation (SIUT), Karachi. SIUT is a 750-bedded tertiary care center operating on a public-private partnership model. It houses the country's largest kidney transplantation unit and also provides services in nephrology, gastroenterology, liver transplantation, urology, and uro-oncology.

The blood bank follows basic screening guidelines recommended by the Association for the Advancement of Blood and Biotherapies. (13) Blood donations at SIUT are screened for a complete blood count, hepatitis B surface antigen, hepatitis C antibody, human immunodeficiency virus antibody, syphilis serology, and malaria antigen test. Syphilis screening is performed using the Abbott Architect system, which operates on the principle of chemiluminescence immunoassay (TP-CMIA). If a donor tests positive for any of these screening tests, they are not approved for donation and are referred to the Infectious Diseases (ID) clinic for further evaluation.

The estimated total population of blood donors in 6 months was calculated around 12000 subjects. Taking the prevalence of syphilis from previous studies as 3.91 with 2% margin of error and 95% confidence interval, a total of 351 was sample size for this study.

All blood donors registered at SIUT who tested positive for Treponemal antibodies by chemiluminescence immunoassay (TP-CMIA) and presented to the ID clinic were included in the study. Patients with indeterminate test results were excluded.

At the ID clinic, a detailed history was documented and data collected for demographics, history of pre-marital or extramarital sexual contact, men who have sex with men (MSM) or contact with female sex workers (FSW). Prior history of sexually transmitted infections (STIs), history of blood transfusions, and drug use was recorded. Physical examination was performed for

presence of genital lesions, urethral discharge, rash, lymphadenopathy, and neurological findings. Laboratory tests were performed for confirmation of the positive (TP-CMIA) including rapid plasma reagin (RPR) test and Treponema pallidum hemagglutination (TPHA) test.

The study was approved by the Ethical Review Committee of SIUT (ERC: 481)

Statistical analysis: The data was entered and analysed in SPSS version 22.0. Normally distributed continuous variables were expressed as mean \pm S.D. and non-normally distributed variables as median (IQR). Categorical variables were presented as counts and percentages. The univariate and bivariate analyses were performed separately for each of the variables using an unpaired "t" test or Chi-square test (Fisher's exact test where expected frequency was less than 5) as appropriate. P value < 0.05 was taken as statistically significant

Definitions:¹⁴

Confirmed syphilis: If TP-CMIA is positive and either RPR or TPHA or both are positive.

Syphilis negative: If TP-CMIA is positive and both RPR and TPHA are negative.

RESULTS

A total of 20,685 donors were screened during the study period. All of them were first-time donors that included predominantly replacement donors (family members of the patient who were requested to donate in order to replenish blood supplies reserved for the patient) and also voluntary donors.

A total of 374 (1.8%) tested positive on TP-CMIA. The prevalence of TP-CMIA positivity among blood donors at SIUT ranged from 1.2-2.15 % in 7 months (Figure-I). Out of 374 who tested positive for TP-CMIA, 152 (40.6%) kept their appointment to the ID clinic. Out of 152, 91 (60%) were confirmed to have syphilis of whom 61(40%) were RPR negative but TPHA positive. Figure-II.

The demographic characteristics of 152 donors are shown in Table-I. The mean age was 33.5 ± 7.93 ; there were 150 (98.6%) males. One (0.6%) patient was HBsAg positive, 1 (0.6%) was HCV antibody positive and 1(0.6%) tested positive for HIV antibodies.

Table-II shows a comparison of risk factors between confirmed syphilis positive and negative donors. A history of premarital or extramarital sexual relations

[OR 9.153 95% CI (4.083-20.541) p value <0.001] and a history of drug use [OR 1.744 95% CI (1.514 – 2.001)

p value 0.011] were found to be significantly associated with confirmed syphilis.

Table-I: Characteristics of blood donors who have positive TP-CMIA test. n=152

Characteristics	n (%)
Age mean \pm SD	33.55 \pm 7.93
Male	150 (98)
History of pre-marital and/or extra marital sexual contact.	107 (70.4)
Drug use	9 (5.9)
Prior blood transfusion	6 (3.9)
Prior diagnosis of sexually transmitted infection	8 (5.3)
History of urethritis	6 (3.9%)
Condom Use	6 (3.9)
Men who have sex with men (MSM)	4 (2.6)
Contact with female sex workers	34 (22.4)
Clinical Findings:	
None significant:	144 (94.7)
Chancre	8 (5.3%)

Table-II: Association of clinical characteristics and risk factors between confirmed syphilis positive and syphilis negative donors. n=152

Characteristics	Syphilis positive n=91	Syphilis negative n=61	p-value	OR (95%CI)
Sexual contact				
Pre-marital and extra-marital	80 (87.9%)	27 (44.3 %)	<0.001	9.15 (4.083-20.541)
Men who have sex with men (MSM)	3/80 (3.8 %)	1/27 (3.7%)	0.991	1.01 (0.101-10.169)
Contact with Female sex workers (FSW)	26/80 (32.5%)	8/27 (29.6%)	0.782	1.14 (0.443-2.955)
Prior diagnosis of sexually transmitted infections	7 (7.7 %)	1 (1.6%)	0.145	5.00 (0.599 -41.711)
History of urethritis	6 (6.6%)	0 (0.0%)	0.082	1.71 (1.497 – 1.971)
History of prior blood transfusion	6 (6.6%)	0 (0.0)	0.082	1.71 (1.497 – 1.971)
Drug use	9 (9.9%)	0 (0.0%)	0.011	1.74 (1.514 – 2.001)
Chancre at presentation	6 (6.7%)	2 (3.2%)	0.476	2.08 (0.406 – 10.675)

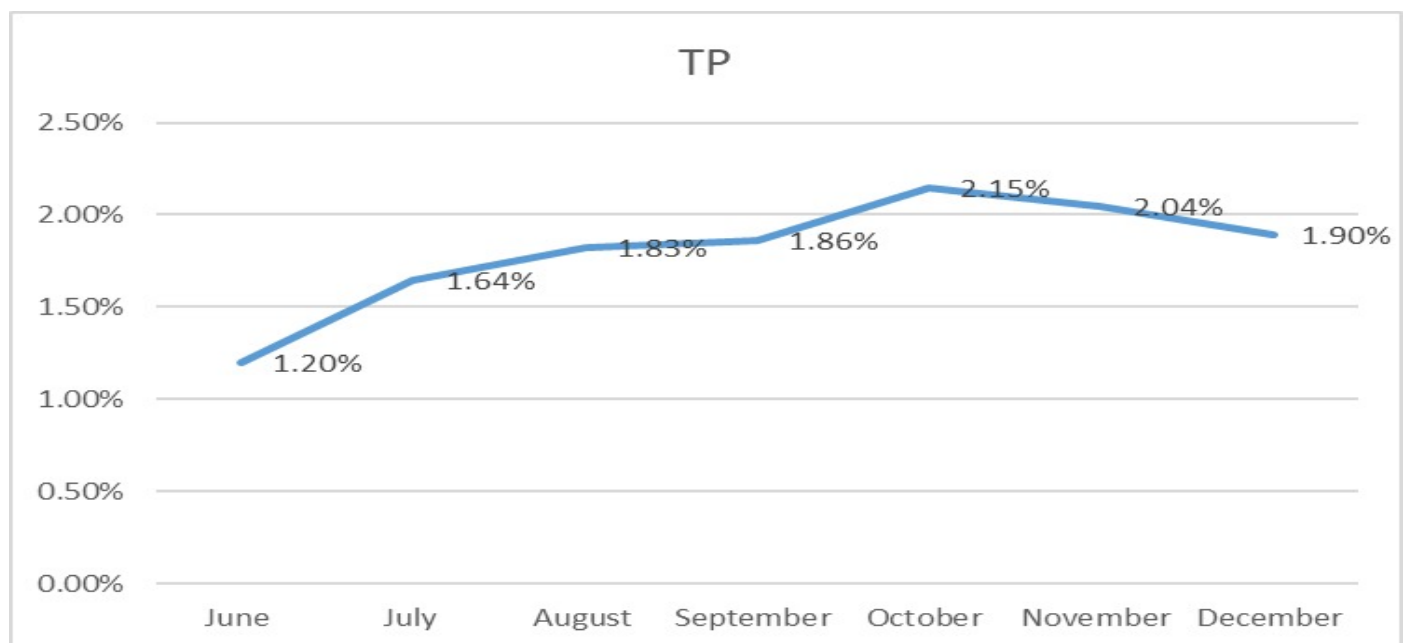


Figure-I: The prevalence of TP-CMIA positive test for syphilis among blood donors.

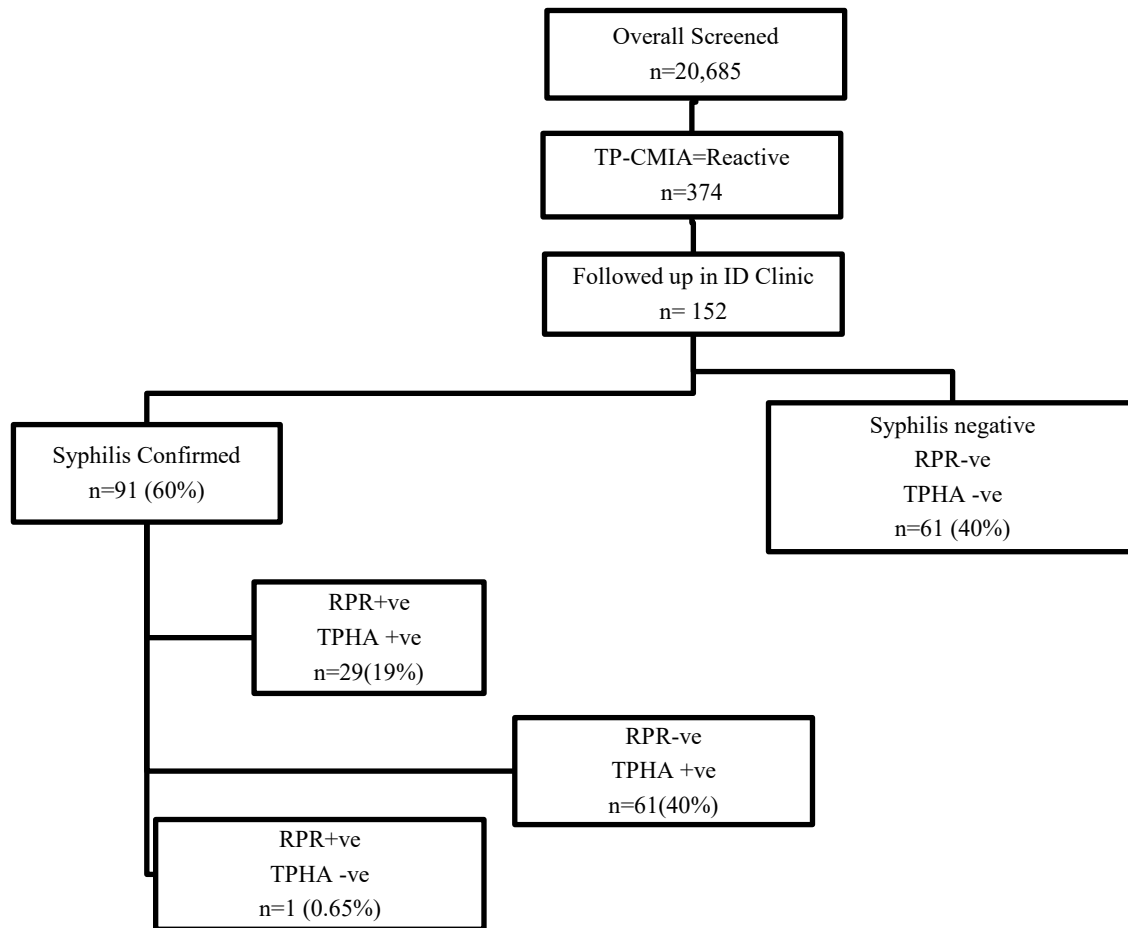


Figure-II: Pattern of post screening syphilis serological testing in blood donors

DISCUSSION

The prevalence of syphilis among blood donors in our study is 1.8% and is comparable to regional blood centres in Sindh province that reported an overall prevalence of 2.5%, with a rate of 1.5% specifically in Karachi.⁶ Another study from a bone marrow transplant centre in Karachi reported a similar rate of 2.1% among blood donors.⁷ However, blood centres from the province of Punjab reported a higher prevalence of 3.91%.⁸

We observed that over half of syphilis positive blood donors who were referred to the ID clinic did not keep their appointments. This issue has been reported globally, with Hojnosi *et al.* from the United States noting similar high dropout rates among military blood donors.¹⁵ Similarly, a 17-year retrospective study from India found a follow-up rate of only 45%.¹⁶ Another study from India reported that social stigma and lack of knowledge hindered donors' ability to follow up and return for further testing.¹⁷ Since the majority of donors in our study were asymptomatic, they may not have found it convenient to return for further testing.

Increasing awareness, such as involving social workers for counselling, can help convince these asymptomatic individuals to come back for evaluation and treatment. In our study, 40% of individuals who tested positive for TP-CMIA in the blood bank were subsequently found to be RPR-negative but TPHA-positive. The treponemal antibody test offers advantages for syphilis screening in blood donation due to its ability to detect syphilis in patients who are asymptomatic with latent infection. Our study found that TP-CMIA has a high false positivity rate of 40%. Ghafoor *et al* also reported a false positivity of 55.6% in a study from Northern Pakistan.¹⁰ The high false positivity rate may be attributed to the lower prevalence of syphilis in our population. High-volume blood banks may benefit from the TP-CMIA test, a machine-based, highly sensitive method that can effectively screen asymptomatic syphilis-positive donors.

When examining risk factors, donors with confirmed syphilis had a significant history of high-risk sexual contact. A thorough and detailed history can effectively identify and exclude high-risk donors for blood

donation, providing a cost-effective approach to screening.

LIMITATIONS

Our study's limitations include a large donor dropout rate. Additionally, we were unable to screen partners due to the fact that the majority of donors came from remote areas of Sindh, making it difficult for them to bring their partners along.

CONCLUSION

The prevalence rate of syphilis in blood donors at SIUT is comparable to that found elsewhere in Sindh. The donors were mostly young males providing replacement donation and the majority were asymptomatic. It is of concern that patients with confirmed syphilis were found to be negative for the non-treponema test RPR as this is a methodology most often used for initial screening in many centres. Pre-marital and extra-marital high-risk sexual activities were highly associated with syphilis positivity hence thorough and detailed history can effectively identify and exclude high-risk donors for blood donation, providing a cost-effective approach to screening.

CONFLICT OF INTEREST

None

GRANT SUPPORT & FINANCIAL DISCLOSURE

Declared none

AUTHOR CONTRIBUTION

Rohama Samar: Study design, manuscript drafting, final approval, accountable for all aspects of publication.

Sunil Kumar Dodani Reviewing it critical for important intellectual content, final approval, accountable for all aspects of publication.: Data analysis, final approval, accountable for all aspects of publication.

Javeria Qureshi: Acquisition of data, final approval, accountable for all aspects of publication.

Sanjay Badlani: Revisions, final approval of the version to be published, final approval, accountable for all aspects of publication.

Hira Moin: Data collection, final approval, accountable for all aspects of publication

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