Utility of a rapid point of care test for screening of syphilis among high-risk and low-risk population at a tertiary care hospital

Sir,

Syphilis, a disease rampant in the preantibiotic era, has been again on the rise since the advent of the 21st century after an interim downturn. With an existing worldwide burden of 17.7 million and 5.6 million, new syphilis infections added to the global pool per year, syphilis still institutes a diagnostic predicament.[1] As per the WHO (World Health Organization) estimate in 2012, 5.6 million new cases have been reported among adolescents and adults within the age group of 15–49 years. Most of these cases have been documented in low- and middle-income countries owing to the low rates of prenatal screening, which in turn result in higher rates of stillbirths and congenital syphilis, ensuing in an ever accruing burden of syphilis.[2]

The widely used nontreponemal and treponemal tests such as the Venereal Diseases Research Laboratory, macroscopic rapid plasma regain (RPR) tests and *Treponema pallidum* particle agglutination assay, fluorescent treponemal antibody absorbed tests, respectively, incur limitations such as the need for centrifuge, electricity, trained personnel, refrigeration facilities, etc., which often deter their use as screening tools at most peripheral centers. Thus, the sheer volume of patients to be screened and widespread availability of newer specific enzyme immunoassay-based treponemal tests are increasingly coercing laboratories to adopt automated testing

Table 1: Comparison of performance of the rapid diagnostic kit among different sub-populations

Attribute	Total population (*n*=80)	High risk population (*n*=56) (ART=24, STI=18, GYNE OPD=14)	Low risk population (*n*=24) (ANC=24)
Sensitivity (%)	100	100	*
Specificity (%)	98.68	98.08	100
Positive predictive value (%)	83.33	83.33	*
Negative predictive value (%)	100	100	100

*Since there were no patients from ante-natal clinics who tested positive for syphilis, the sensitivity and positive predictive value could not be calculated. ART=Anti-retroviral therapy clinic attendees; STI=Sexually transmitted infection clinic attendees; GYNE OPD=Gynecology outpatient department; ANC=Antenatal clinic attendees

modalities for diagnosing syphilis. The relative ease, high throughput, potential for automation, and objective interpretation of these newer immunoassay-based tests enable them to be used as "rapid point of care tests (POCTs)." The WHO and National Institute of Health are increasingly encouraging the development of newer POCTs, to be incorporated into screening programmes, to curtail disease burden.[3] Consequently, the "Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free, and Deliverable to those who need them" criteria was developed as a framework for all new POCTs.[4] In light of the limitations of traditional tests and widespread availability of rapid POCTs, the validation of the latter as "screening test" becomes indispensable. The present study attempts to evaluate one such candidate for screening syphilis.

Serum samples from 80 consecutive patients from various departments were evaluated to assess the performance of the "Is it syphilis test device" (Medsource Ozone Biomedicals Pvt. Ltd.). Two separate microbiologists, blinded to each others' findings, independently assessed the serum samples. Test results of RPR followed by reflex testing by *T. pallidum* Hemagglutination Assay (TPHA) was considered as the gold standard for calculating sensitivity, specificity, and positive and negative predictive values. Upon screening of 80 patients for syphilis, using RPR followed by reflex TPHA testing for samples reactive by RPR, five (6.2%) patients were found to harbor active syphilis infection, whereas six (7.5%) patients tested reactive by the "Is it syphilis test device"(Medsource Ozone Biomedicals Pvt. Ltd.). The sensitivity, specificity, positive predictive value, and negative predictive value of "Is it syphilis test device" were 100%, 98.68%, 83.33%, and 100%, respectively. Among the 80 patients who were screened for syphilis, 56 (70%) patients belonged to high-risk groups (gynecology outpatient department, anti-retroviral therapy, and sexually transmitted infection clinic attendees). Table 1 depicts the comparison of the performance of the "Is it syphilis test device" (Medsource Ozone Biomedicals Pvt. Ltd.) among the two subgroups.

The high sensitivity and specificity of the "Is it syphilis test device" reinforces its utility as a rapid on-site diagnostic tool for syphilis and an alternative to conventional RPR and TPHA for diagnosing syphilis in resource-poor conditions. An ideal screening test would yield a positive result only if the subject harbors the disease and vice versa. However, majority of the screening tests fall short of these ideal standards. The "Is it syphilis test device" (Medsource Ozone Biomedicals Pvt. Ltd.) evaluated in the present study was found to be 100% sensitive and 98.68% specific for the screening of syphilis in the entire study population. Resonating with the above findings, several studies conducted upon rapid POCTs for syphilis from Tanzania, Brazil, China, and Haiti among populations at moderate-to-high risk of syphilis revealed a specificity of >95%.[5] In addition, the test performed with a sensitivity and positive predictive value of 100% and 83.33%, respectively, among the high-risk sub-population similar to a study from Bengaluru, India, conducted among female sex workers comparing the performance of "SyphiCheck" test device as a POCT. The high specificity of the rapid tests with excellent positive likelihood ratios and median specificity similar to traditional nontreponemal test enables them to be used as efficient screening tools.[6]

Despite their simplicity, rapid turnaround, and cost-effectiveness, these POCTs cannot redress the limitations arising from inadequate syphilis testing facilities in many low-income countries. However, these new tests can strengthen and expand the reach of screening efforts once effectively incorporated in the control programs. Thus, exhaustive operational research encompassing point of care syphilis tests is imperative for expanding the reach and impact of control strategies of this age old disease, especially in resource-limited settings.

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Conflicts of interest
There are no conflicts of interest.

Bineeta Kashyap, Rituparna Saha, Vikas Saini, Chander Grover[1], Narendra Pal Singh
Departments of Microbiology and [1]Dermatology, University College of Medical Sciences, Guru Teg Bahadur Hospital, Delhi, India

Address for correspondence:
Dr. Bineeta Kashyap,
Department of Microbiology,
University College of Medical Sciences,
Guru Teg Bahadur Hospital, Delhi, India.
E-mail: dr_bineetakashyap@yahoo.co.in

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