

Sensitivity and Specificity of rapid HIV Testing of Pregnant Women in India

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Products Evaluated

Oraquick HIV-1/2 (Orasure Technologies Inc.)

Determine HIV-1/2 (Abbott Laboratories)

NEVA HIV-1/2 (Cadila)

This study took place between September 2000 and 1 October 2001, 1258 pregnant women were screened for HIV using the above rapid tests. The aim of the study was to provide data from India on the reliability of rapid HIV tests for screening of pregnant women.

Abstract

Objective: Efforts to prevent HIV transmission from mother to infants in settings like India may benefit from the availability of reliable methods for rapid and simple HIV screening. Data from India on the reliability of rapid HIV test kits are limited and there are no data on the use of rapid HIV tests for screening of pregnant women. **Methods:** Pregnant women attending an antenatal clinic and delivery room in Pune agreed to participate in an evaluation of five rapid HIV tests, including (a) a saliva brush test (Oraquick HIV-1/2, Orasure Technologies Inc.), (b) a rapid plasma test (Oraquick HIV-1/2) and (c) three rapid finger prick tests (Oraquick HIV-1/2; HIV-1/2 Determine, Abbott; NEVA HIV-1/2 Cadila). Results of the rapid tests were compared with three commercial plasma enzyme immunoassay (EIA) tests (Innotest HIV AB EIA, Lab systems/ELISCAN HIV AB EIA, UBI HIV Ab EIA). **Results:** Between September 2000 and October 1, 2001, 1258 pregnant women were screened for HIV using these rapid tests. Forty-four (3.49%) of the specimens were HIV-antibody-positive by at least two plasma EIA tests. All of the rapid HIV tests demonstrated excellent specificity (96± 100%). The sensitivity of the rapid tests ranged from 75± 94%. The combined sensitivity and specificity of a two-step algorithm for rapid HIV testing was excellent for a number of combinations of the five rapid finger stick tests. **Conclusion:** In this relatively low HIV prevalence population of pregnant women in India, the sensitivity of the rapid HIV tests varied, when compared to a dual EIA algorithm. In general, the specificity of all the rapid tests was excellent, with very few false positive HIV tests. Based upon these data, two different rapid HIV tests for screening pregnant women in India would be highly sensitive, with excellent specificity to reliably prevent inappropriate use of antiretroviral therapy for prevention of vertical HIV transmission.

Results

Below is a summary of the results from the paper, showing the sensitivity and specificity of rapid HIV tests in pregnant women in India.

Rapid Tests	n	Sensitivity*%, 95%CI	Specificity*%, 95%CI
Oraquick Saliva	1244	75.0	100
Oraquick Plasma	1250	86.4	99.9
Oraquick Finger Stick	1253	90.3	99.9
Abbott Determine Finger Stick	1013	88.6	99.9
Cadila Finger Stick	749	94.1	96.4

* Sensitivity and specificity of rapid tests compared with results of conventional HIV enzyme immunoassay (EIA) test.

Conclusions

The data identifies a number of two-step rapid HIV tests that would provide excellent sensitivity and specificity when detecting HIV in pregnant women in India.

“...results from two sequential rapid HIV tests would reliably prevent inappropriate use of antiretroviral therapy for prevention of vertical HIV transmission.”