18th ISSTDR, London, 2009

Abstract

Review of the performance of commercially available Herpes Simplex Virus type-2 tests among African populations

Samuel Biraro[1, 2], Helen Weiss[2], Philippe Mayaud[2], Heiner Grosskurth[1]

[1] *Medical Research Council (MRC)/Uganda Virus Research Institute (UVRI) Uganda Research Unit on AIDS, Entebbe, Uganda*
[2] *London School of Hygiene and Tropical Medicine, London, UK*

Background There are several commercially available type-specific serologic tests for Herpes Simplex Virus type 2 (HSV-2). These tests act by detecting the HSV-2 specific glycoprotein, gG-2, and therefore can distinguish between HSV-1 and HSV-2, and are easier, faster, and cheaper to perform than Western Blot. However, poor performance of the tests on samples from Africa has been reported.

Methods We searched the PubMed database for papers from sub-Saharan Africa reporting performance of commercially available HSV-2 tests against a gold standard (Western Blot or monoclonal antibody EIA). We summarise the performance of the two most commonly evaluated tests: Kalon gG2 ELISA (Kalon Biologicals, Guilford, UK) and Focus HerpeSelect HSV-2 ELISA (Focus Technologies, Cypress, CA).

Results We identified 13 studies evaluating the performance of Focus, and 7 of Kalon. Using the manufacturer's cut-off (index value = 1.1), Focus had a very high sensitivity (median 100%, range 98–100%) but variable specificity (median 88%, range 22–93%). Kalon had slightly lower sensitivity (median 92%, range 88–95%) but higher and less variable specificity (median 88%, range 79–100%). Performance varied by geographical location, type of study population, and HIV status, with generally lower specificity among HIV seropositive individuals. Four studies evaluated a higher cut-off of 3.5 for Focus, which improved test performance substantially (median 85%; range 80–87%).

Conclusion Sensitivity and specificity of HSV2 tests used in sub-Saharan Africa varied by setting, and were lower than reported from studies in the USA and Europe. Further research is needed to elucidate possible explanations for this. Differences in local strains or cross-reactivity with unidentified proteins may play a role. Evaluation of test performance prior to widespread use may help in deciding which test is most appropriate in given settings.