Diagnostic performance of lateral flow point-of-care HIV-Combo testing for detection of acute HIV infection in Eswatini

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Introduction

Acute HIV infection (AHI) is rarely diagnosed in resource-limited settings. Barriers to diagnosis include the high costs of viral load (VL)-based diagnostic testing algorithms and lack of availability of reliable point-of-care (POC) tests. We assessed the performance of a new POC test for the detection of AHI in Eswatini, Alere™ HIV-Combo.

Methods

Adult outpatients testing HIV-negative on Alere™ Determine through finger-prick testing by lay counsellors, or with discordant result (Alere™ Determine-positive and Uni-Gold™-negative) were enrolled at the Nhlangano Health Centre, between March 2019 and March 2020. Participants were then tested with the quantitative Xpert HIV-1 VL assay, used as the gold standard test for AHI. AHI was defined as a VL result ≥40 copies/mL. Leftover paired venous whole blood and plasma specimens were tested with the lateral flow fourth-generation antibody/p24 POC Alere™ HIV-Combo. Both Xpert and HIV-Combo tests were performed in the laboratory by a laboratory technician. A positive result for AHI using the HIV-Combo test was defined as reactivity on the p24 antigen and/or antibody bars. Diagnostic test characteristics were evaluated for plasma (HIV-Combo-plasma) and whole blood (HIV-Combo-wb), as compared with the results of Xpert testing.

Ethics

This study was approved by the MSF Ethics Review Board and the Eswatini Ethics Committee.

Results

A total of 745 (HIV-Combo-plasma/Xpert) and 429 (HIV-Combo-wb/Xpert) paired test results were available. 29/745 (3.9%) and 19/429 (4.4%) were AHI-positive based on the results of Xpert testing. 26/745 (3.5%) were reactive on HIV-Combo-plasma and 16 (3.7%) on HIV-Combo-wb. Most positive test results with HIV-Combo showed reactivity to antibodies only (76.9% HIV-Combo-plasma; 75.0% HIV-Combo-wb), and the remainder to p24 antigen (15.4%, 18.8%) only, or both p24 antigen and antibodies (7.7%, 6.3%). The area under the receiver operating characteristic curve was 0.93 for HIV-Combo-plasma and 0.89 for HIV-Combo-wb. Test sensitivity tended to be slightly higher for HIV-Combo-plasma (86.2%) as compared to HIV-Combo-wb (78.9%), and specificity was high for both tests (≥99.8%). The negative predictive value was above 99.0% for both tests, and positive predictive values were 93.8% for HIV-Combo-wb and 96.2% for HIV-Combo-plasma.

Conclusion

Lateral flow POC HIV-Combo testing in this setting was able to diagnose most cases of AHI, in comparison to the gold standard. This test therefore has potential for use in routine settings due to low cost and ease of use. However, further studies are needed to evaluate its performance when used in routine outpatient care settings by lay counsellors on finger-prick samples.

Conflicts of interest

None declared.

Bernhard Kerschberger

Bernhard is a medical doctor, who has worked as a public health practitioner in different positions within MSF since 2009. In recent years his focus has been on HIV and tuberculosis research, with a specific focus on expanding access to HIV treatment and earlier HIV diagnosis.