

Diagnostic performance of the novel FujiLAM assay to detect tuberculosis in HIV-positive patients

Helena Huerga, Epicentre, France

Background

The novel urine-based point-of-care FujiLAM assay is a promising tool for tuberculosis (TB) diagnosis. We prospectively assessed the diagnostic accuracy of FujiLAM and we compared it to the WHO-recommended Abbott TB-LAM assay in people living with HIV (PLHIV) in Uganda, Kenya, Mozambique, and South Africa.

Methods

Diagnostic prospective study including ambulatory HIV-positive individuals (≥ 15 years) with signs or symptoms of TB irrespective of their CD4 count, and asymptomatic patients with advanced HIV disease. All patients received clinical examination, FujiLAM and Abbott TB-LAM, GeneXpert MTB/RIF Ultra (sputum or urine), culture (sputum) and chest X-ray. Accuracy of the assays was evaluated against a microbiologically reference standard (confirmed TB defined by any positive culture or Xpert Ultra result).

Findings

We included 1575 patients: 1031 Group 1 and 544 Group 2 with median CD4 count 528 cells/ μL [IQR: 272-770] and 128 cells/ μL [IQR: 66-181], and microbiologically confirmed TB in 12.4% (96/776) and 5.5% (18/330), respectively. The overall sensitivities of FujiLAM and Abbott TB-LAM were respectively, 59.6% (95%CI 50.1-68.7) and 40.4% (95CI 31.3-49.9), p -value <0.001 . FujiLAM sensitivity was higher than that of Abbott TB-LAM among patients with $\text{CD4}<200\text{cells}/\mu\text{L}$, 69.2% (95%CI 56.6-80.1%) and 52.3% (95CI 39.5-64.9), p -value=0.035, respectively, and among patients with $\text{CD4}\geq 200\text{cells}/\mu\text{L}$, 46.9% (95%CI 32.5-61.7) and 24.5% (95CI 13.3-38.9), p -value=0.019, respectively. The specificities of FujiLAM and Abbott TB-LAM were 86.6% (95%CI 84.3-88.7) and 86.4% (95%CI 84.1-88.5) respectively.

Interpretation

This large prospective study shows the higher sensitivity of FujiLAM compared to Abbott TB-LAM, and its potential significant benefit in rapid and simple TB diagnosis of PLHIV.