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Journal club

Innovative new diagnostic test to detect TB and rifampin resistance

Tuberculosis remains a major public health concern. Existing diagnostic tools are slow and result in delays initiating appropriate treatment. This is particularly a problem in patients with HIV, in whom sputum–smear analysis is frequently negative and those with multi-drug resistant strains.

In this study, the performance of an automated molecular assay for *Mycobacterium tuberculosis* (MTB) and resistance to rifampin (RIF) (Xpert MTB/RIF) was assessed. This test, through detection of an MTB-specific sequence of the *rpoB* gene and probing for rifampin-resistance determining region mutations, provides results within 2 h.

Three sputum samples were analysed from 1730 eligible patients with suspected tuberculosis in reference laboratories in Peru, Azerbaijan, South Africa and India. With a single test, 98.2% of patients with smear-positive, culture-positive tuberculosis were identified. Among those with smear-negative, culture-positive disease, the sensitivity of the assay was 72.5% with one test, 85.1% for two tests and 90.2% for three tests. The diagnostic specificity for tuberculosis was 99.2%. MTB/RIF testing correctly identified 97.6% of bacteria which had exhibited rifampin-resistance on phenotypic drug-susceptibility screening.

The MTB/RIF assay provides a prompt sensitive method of detection of tuberculosis and its potential resistance to rifampin. The benefit of a point-of-contact diagnostic test, with low man-power implications, sounds attractive for poorly funded healthcare systems. However, the authors admit several limitations to its uptake including high initial costs, rifampin-resistance testing only and a need to demonstrate similar efficacy in other healthcare settings.

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