

ABSTRACT

Tuberculosis (TB) is caused by a bacterium known as *Mycobacterium tubercle bacilli*. TB infection is a serious global public health concern ranked second among the leading causes of mortality associated with infectious diseases. The laboratory diagnosis of pulmonary tuberculosis (PTB) and smear-negative pulmonary tuberculosis (SNPT) in resource-limited countries are often based on X-ray and sputum smear microscopy. However, these diagnostic tools have long turnaround time, require experts to carry out diagnosis, have a problem in detecting resistance to TB drugs and also in detecting TB in Human immunodeficiency virus (HIV) infected individuals. Although there is recent development of GeneXpert® assay that has a short turnaround time and can detect resistance to rifampicin among TB patients, its reliability needs to be continuously evaluated. Thus this study investigated the comparative performance of smear microscopy and GeneXpert® assays relative to culture among suspected TB cases in Nyamira Referral Hospital among TB suspected patients. The specific case of HIV positive patients was also studied. A cross-sectional study was carried in Nyamira Referral Hospital among suspected TB cases aged two years and above. The results of this study show that among 682 participants, 182(26.69%) were diagnosed definite-TB (positive) with both GeneXpert® assay and culture while 500(73.31%) were non-definite TB. GeneXpert® had a higher sensitivity (100%) and specificity (99.4%). Smear microscopy revealed low sensitivity (26.4%) and a higher specificity (98.2%). The concordance test of smear microscopy and GeneXpert® revealed a significant ($p < 0.0001$) variation in agreement between the two assays 113.78% with a Cohen's kappa, 0.3181 (CI = 0.2424 - 0.3938). The results of this study indicate that 36 (5.28%) out of 682 enrolled patients showed resistance to either one of the first line TB drugs (rifampicin, isoniazid and Ethambutol) while none of the enrolled patients were resistant to streptomycin which is a second line TB drug. In conclusion GeneXpert® assay has high sensitivity and specificity in the detection of tuberculosis among suspected TB cases compared to smear microscopy. This study recommends procurement of more GeneXpert® machines to all diagnosis hospitals to help earlier detection of TB disease.