



ABSTRACT

Rapid and accurate diagnosis of Multi Drug Resistant (MDR) Tuberculosis (TB) is critical for improving patient care and decreasing TB transmission. Xpert MTB/RIF assay is an automated Nucleic acid amplification test that can detect both TB and Rifampicin (RIF) resistance in two hours with minimal biohazard. This study evaluates the diagnostic accuracy of Xpert MTB/RIF assay for pulmonary and extra-pulmonary MDR TB in comparison with reference methods. The population of 2023 MDR-TB suspects was included in this study. All were tested on Xpert MTB/RIF assay and sample size of 230 individuals which were found positive for MTB and rifampicin resistance on Xpert assay was further processed by Ziehl Neelsen (ZN) staining, Phenotypic culture and DST. That includes 225 pulmonary and 5 were extra-pulmonary samples. According to the results, Xpert MTB/RIF detected MTB in all the 225 (100%) cases while ZN smears were positive in 196 (96.4%) cases. Xpert MTB/RIF assay also observed increased case detection rate by 12.88% in smear negative cases and smear microscopy missed TB in 29 cases, out of these 22 later confirmed on culture. For extra-pulmonary samples, sensitivity for smear was calculated as 33% specificity and Positive Predictive Value (PPV) as 50% as compared to Xpert where both the sensitivity and PPV were calculated as 100%. In comparison with phenotypic Drug Susceptibility testing (DST), rifampicin resistance was detected in 99.1% (223 out of 225) pulmonary samples by Xpert assay while missed in only 2 samples thus sensitivity, PPV and diagnostic accuracy for Xpert assay were calculated as 99%, 91%, and 89.9%, respectively. For RIF resistance in extra-pulmonary samples, the sensitivity was found as 75%, PPV as 60% and diagnostic accuracy was 60%. This study revealed that out of 230 MDR cases, 122 were male and 108 were female with the mean age of 30.95 ± 12.67 years. This study further revealed that out of 205 culture confirmed cases, 5 (2.3%) were diagnosed as Extensively Drug Resistant (XDR) TB. The turnaround time of only 2 hours for Xpert assay was observed as compared to culture that took 3 to 8 weeks and ZN smear took 1 to 24 hours to give final diagnosis. Therefore based on results it is concluded that Xpert MTB/RIF assay is highly sensitive and specific test. Nevertheless, this test is not only valuable for rifampicin resistance detection but also in determining the patients MDR status in bringing to an end the spread of MDR-TB, XDR-TB and thus decreases mortality.