ABSTRACT

OBJECTIVE: To determine the diagnostic accuracy of tuberculosis (TB) nucleic acid amplification tests (NAATs) in urine samples for individuals with active pulmonary tuberculosis (PTB). DESIGN: Systematic review and meta-analysis. Electronic databases and reference lists were searched without age or setting restrictions up to May 2015. Eligible articles examined Mycobacterium tuberculosis NAATs in urine samples for PTB diagnosis in patients with sputum culture as the reference standard, and reported sufficient data to separately calculate sensitivity or specificity. RESULTS: Eight studies, including 1212 participants from seven countries with a mean age ranging from 28 to 48 years, were included. Polymerase chain reaction (PCR) with insertion sequence (IS) 6110, rpoB or cfp32/hf6 as gene targets was used for NAATs. The pooled sensitivity and specificity was respectively 0.55 (95%CI 0.36-0.72) and 0.94 (95%CI 0.78-0.99), with slightly higher sensitivity in human immunodeficiency virus positive individuals, at 0.59 (95%CI 0.20-0.89). Sensitivity was higher in sputum microscopy-positive than -negative individuals. Storage temperatures below -70°C, centrifuge speed <5000 rpm and IS6110 increased sensitivity on meta-regression. CONCLUSIONS: Urine M. tuberculosis PCR for active PTB diagnosis had high specificity but modest sensitivity (55%). Optimizing specimen handling, gene targets or PCR techniques may improve diagnostic accuracy. Reproducibility data are needed.