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Title: Comparative analysis of detection of Mycobacterium tuberculosis and rifampin resistance determination through microbiological and molecular genetics methods for pulmonary tuberculosis patients with presence or absence of sputum

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Body: The majority of studies on diagnostics of pulmonary tuberculosis (PTB) used only sputum that appears at later stages of disease and don't use bronchoalveolar lavage (BAL) fluid obtained by bronchoscopes. At the same time these patients are epidemiologically dangerous even at the early stages of disease. The aim of our study was to compare the possibilities of microbiological and molecular genetics methods for Mycobacterium tuberculosis (MTB) detection and rifampin resistance identification (RIF-R) in new cases of PTB through sputum or BAL fluid examination. We conducted a double-blind randomized retrospective investigation. The aetiology of PTB has been proven by receiving the culture growth or histological examination of lung tissue with Ziehl-Neelsen staining. A total of 134 specimens (32 sputum and 102 BAL fluid) from 133 patients gave positive results by Real-Time PCR (kit “AmpliSenceMTB-FL”) and by sequencing of rpoB gene (kit “AmpliSenceMTB-Rif-seq”). We received growing of MTB culture in only 23 (74.2%) sputum and 56 (54.9%) BAL fluid compared to the molecular genetics investigations. We found RIF-R in 12 (38.7%) sputum and 37 (36.3%) BAL fluid by all methods. In addition to the culture method we managed to detect RIF-R in 5 sputum and 25 BAL fluid samples (plus one insignificant mutation). Due to the higher sensitivity of molecular genetics methods we not only found out MTB in proven cases of PTB more likely than culture method, but also higher level of RIF-R that did not demonstrate a difference between patients with presence or absence of sputum.