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Title: PCR based method for accurate diagnosis of mycobacterial disease and description of clinical profile of disease caused by non tuberculous mycobacteria

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Body: Introduction Sri Lanka uses direct microscopy to diagnose tuberculosis. This method has relatively low sensitivity of 70% and cannot differentiate Mycobacterium Tuberculosis Complex (MtbC) and Non-Tuberculous Mycobacteria (NTM). An accurate and rapid diagnosis of NTM could be made by Polymerase chain reaction. Objective To evaluate the use of PCR for accurate diagnosis and speciation of pulmonary disease caused by Mycobacteria and to describe clinical profile of disease caused by NTM. Method All patients diagnosed as pulmonary TB on the basis of positive sputum direct smear to acid fast bacilli during the 90 day period between 17-02-2009 to 19-05-2009 and placed on standard chemotherapy at a District TB clinic were included. Sputum of each patient was tested with 541-bp sequence of insertion element IS986 amplification. Samples which failed to amplify IS986 were analyzed by using 16S rRNA and six more gene loci, which are used as markers for identification of MtbC from NTM species. (Huard, et al. (2003) journal of clinical Microbiology; 41:1637-1650). Clinical profile and chest radiography of patients with NTM was recorded. Results Out of total study population of 44 patients 8 (18.18%) were confirmed to have disease due to NTM. Thirty six patients had disease due to mycobacterium tuberculosis. Out of 8 NTM patients one died. The other seven patients remained chronically ill. Conclusion PCR can rapidly and accurately differentiate NTM which causes a significant proportion of smear positive disease, who will remain chronically ill despite standard regime.