──────── **Memorial Lecture by the Imamura Award Winner** ────────

RISK OF *MYCOBACTERIUM TUBERCULOSIS* INFECTION AMONG EMPLOYEES AT A GENERAL HOSPITAL WITHOUT WARDS FOR TUBERCULOSIS PATIENTS
── A Study of Interferon-Gamma Release Assay Positivity ──

Tatsuya ABE

Abstract [Objective] Risk of exposure to *Mycobacterium tuberculosis* among hospital workers was retrospectively evaluated using interferon-gamma release assay (IGRA) positivity as an indicator of exposure. We hypothesized that exposure to a hospital environment posed a risk of exposure to *M.tuberculosis*. [Subjects] The subjects were 870 employees who underwent IGRA from December 2010 to April 2012. They were divided into the following groups based on exposure in the hospital environment: 161 new employees who were evaluated at hiring (non-exposure group) and 709 existing employees including those who had undergone contact examinations (exposure group). [Methods] QuantiFERON-TB Gold®3G was used for IGRA. Logistic regression analysis was used to calculate the odds ratios for positivity in the exposure group compared to that in the non-exposure group. [Results] The overall positivity rate was 6.7%, with a significant difference between the groups (1.9% and 7.8% in the non-exposure and exposure groups, respectively) (P＝0.005). After adjusting for gender, years of employment, smoking history, and alcohol intake, the exposure group's odds ratio (95% confidence interval) for positivity compared to that in the non-exposure group was 4.1 (1.4−17.6) (P＝0.007). [Conclusion] These results suggest that exposure to a hospital working environment could present a risk of tuberculosis infection, regardless of years of employment.
Key words: Tuberculosis, Hospital-acquired infection, Contact examination, Interferon-gamma release assay, QuantiFERON

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EXTERNAL QUALITY ASSESSMENT OF ANTI-TUBERCULOSIS DRUG SUSCEPTIBILITY TESTING FOR DIAGNOSING EXTENSIVELY DRUG-RESISTANT *MYCOBACTERIUM TUBERCULOSIS*

Satoshi MITARAI

Abstract　[Objective] The infectious disease control law in Japan was amended in May 2015, and the category definition of *Mycobacterium tuberculosis* as an infectious pathogen has been changed, following the definition of extensively drug-resistant *M. tuberculosis* (XDR-TB) by the World Health Organisation. To assess the diagnostic capacity of XDR-TB, we conducted an external quality assessment (EQA) for anti-tuberculosis drug susceptibility testing (DST). [Method] A total of 10 *M. tuberculosis* strains with known drug susceptibilities were sent to each participating laboratory. The drugs assessed were isoniazid (INH), rifampicin (RFP), streptomycin (SM), ethambutol (EB), levofloxacin (LVFX), and kanamycin (KM). DST was performed using each routine method(s), and the results were compared with the judicial diagnoses. The sensitivity, specificity, overall agreement (efficiency) and kappa coefficient were calculated for each drug tested. In addition, the diagnostic accuracy of multidrug-resistant *M. tuberculosis* (MDR-TB) and XDR-TB was assessed. [Results] A total of 88 institutes including 67 hospitals, 16 commercial laboratories, and 5 public health laboratories participated in the EQA. With two laboratories submitting two sets of results, a total of 90 independent data sets were analyzed. For INH, RFP and LVFX, the efficiency was over 95%, but we found two strains each for SM, EB and KM with efficiencies less than 95%. In particular, strain 1 and strain 2 showed efficiencies of 72.2% and 71.1% for SM, respectively. This error was mainly found with one particular test kit. If we consider a passing score as showing $\geqq 95\%$ sensitivity and specificity both to INH and RFP, the diagnostic accuracy of MDR-TB was 92.2% (83/90) in this study. With the same criteria for INH, RFP, LVFX and KM, that of XDR-TB was 79.7% (63/79). [Discussion] The diagnostic capacity for XDR-TB was not sufficient in the current study. Good case management and pathogen control requires higher accuracy. The government may need to conduct a constant EQA and apply relevant remedial actions.
Key words: *Mycobacterium tuberculosis*, Drug susceptibility testing, External quality assessment, Extensively drug-resistant *Mycobacterium tuberculosis*