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Xpert MTB/RIF Assay for the Diagnosis of Pulmonary And Extra Pulmonary Tuberculosis

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Abstract
Detecting patients with active Tuberculosis (TB) disease is an important component of tuberculosis control programs, as early diagnosis and treatment of tuberculosis is essential in reducing the morbidity, mortality and the escalating costs associated with advanced disease. We conducted this study to access the usefulness of Gene Xpert MTB/RIF assay technique in the diagnosis of tuberculosis and rifampicin (Rif) resistance. We retrospectively reviewed the clinical records and rapid diagnostic results of all patients with suspected Tuberculosis who visited the pulmonary clinic of Government Rajaji Hospital (GRH), Madurai from January 2017 to June 2017. Various pulmonary and extra pulmonary specimens were collected under aseptic precautions. These Xpert MTB/RIF samples were processed according to the manufacturer's specifications. A total of 764 consecutive pulmonary and extra pulmonary clinical samples were included. Out of 764 samples, 136 (18%) tested positive for M.tuberculosis. Of these 136 positive samples, 124 (91.2%) were found to be Rif sensitive and 10 (7.4%) were found to be Rif resistant. Rif resistant cases were referred for initiation of MDR treatment. This study shows that GenXpert is useful in the early diagnosis of Rif resistance in both pulmonary and extrapulmonary specimens.

Keywords: *Gene-Xpert, tuberculosis, pulmonary, extrapulmonary*

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I. Introduction

Tuberculosis (TB) is the most common infectious diseaseworldwide caused by *Mycobacterium tuberculosis* (MTB).Detecting patients with active Tuberculosis (TB) disease is an important component of tuberculosis control programs, as early diagnosis and treatment of tuberculosis is essential in reducing the morbidity, mortality and the escalating costs associated with advanced disease. The Xpert[R] MTB/RIF assay (Cepheid Inc., CA, USA) marks an important development inthe field of rapid molecular TB diagnostics. This multifunctional diagnostic platform isan automated, closed system that performs real-time PCR and can be used by operators withminimal technical expertise, enabling diagnosis of TB and simultaneous assessment ofrifampicin resistance to be completed within 2 h. The Xpert MTB/RIF assay was rapidly endorsed by the WHO in December 2010 as a replacement for sputum smear microscopy, particularly in settings with high rates of HIV-associated TB and multidrug-resistant TB. More recently, evaluations of the assay have extended to a variety of nonrespiratory clinical samples from patients with EPTB. We conducted this study to access the usefulness of Gene Xpert MTB/RIF assay technique in the diagnosis of tuberculosis and rifampicin resistance.

II. Materials and methods

Study Design: Retrospective data record review.
Setting: Study was conducted in the Department of TB and Respiratory Diseases, Government Rajaji Hospital, Madurai Medical College, Madurai
Study Procedure: We retrospectively reviewed the clinical records and rapid diagnostic results of all patients with suspected Tuberculosis who visited the pulmonary clinic of Government Rajaji Hospital (GRH), Madurai from January 2017 to June 2017. The study was approved by the Hospital Ethics Committee. A waiver of consent was obtained due to the retrospective nature of the study. Various pulmonary and extra pulmonary specimens (ascitic fluid aspiration, cervical node aspiration, CSF sample, Fibre optic bronchoscopic samples, gastric juice aspirates from paediatric cases, peritoneal fluid, sputum, tracheal aspiration, urine, breast abscess

aspiration) were collected under aseptic precautions. These Xpert MTB/RIF samples were processed according to the manufacturer's specifications.

III. Results & Discussion

All the records were scrutinized, checked, and computerized by trained data entry operators. Data entry was done in Excel 2013 and analysis was performed using SPSS 20. Descriptive statistics were performed.

A total of 764 consecutive pulmonary and extra pulmonary clinical samples were included. These samples were obtained from 764 patients with a median age of 43 yrs. Most of them 314 (41.7%) were in the 41-60 age group and 483 (63.2%) were males (Table 1). Out of 764 samples, 136 (18%) tested positive for *M.tuberculosis.* Of these 136 positive samples, 124 (91.2%) were found to be Rif sensitive and 10 (7.4%) were found to be Rif resistant. Rif resistant cases were referred for initiation of MDR treatment.

IV. Conclusion

This study shows that GenXpert is useful in the early diagnosis of Rifamycin resistance in both pulmonary and extrapulmonary specimens

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Table 1: Clinical Characteristics and Xpert results of study patients

Variables	n (%)
Age (in yrs)	
Median (IQR)	43 (29, 54)
Age Group (in yrs)	
≤20	124 (16.5)
21 – 40	222 (29.5)
41 – 60	314 (41.7)
61 – 80	91 (12.1)
>80	2 (0.3)
Sex	
Male	483 (63.2)
Female	281 (36.8)
Case	
HIV	293 (38.4)
Extra Pulmonary	98 (12.8)
Pediatric Sample	85 (11.1)
Smear Negative PT	288 (37.7)
Type	
Ascitic fluid	6 (0.8)
Breast abscess	1 (0.1)
Cervical node	2 (0.3)
CSF	14 (1.8)
FOB	100 (13.1)
Gastric juice	53 (6.9)

Peritoneal abscess	1 (0.1)
Pleural fluid	50 (6.5)
Pneumothorax sample	1 (0.1)
Pyothorax	17 (2.2)
Sputum	512 (67.0)
Tracheal aspiration	1 (0.1)
Urine	6 (0.8)
Result	
Negative	618 (81.9)
Positive	136 (18.0)
Invalid	1 (0.1)
DST	
Sensitive	124 (91.2)
Resistant	10 (7.4)
Indeterminate	2 (1.5)

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