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A comparative study of Conventional methods and GeneXpert Mycobacterium tuberculosis Rifampicin (MTB/RIF) assay for diagnosis of childhood pulmonary tuberculosis

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Abstract

Background Diagnosis of childhood TB (tuberculosis) is challenging because its symptoms resemble other diseases, very few (less than five) mycobacteria are capable of causing the disease and children do not or rarely expectorate. These peculiar attributes make childhood TB different from adult TB but it is still not being dealt differently from adult TB .Despite evidences from national, international data and WHO recommendation for use of Gene expert/TB/RIF assay, decision to start the treatment is based mostly on Chest X ray, tuberculin skin test, history of contact and clinical sign and symptoms .Therefore, we planned this study to find best available choices of diagnostic tests for early case detection of childhood TB particularly MDR TB Methods: This comparative analytical study of 15 months was done at PHRC, SRCCH, NICH and Provincial TB Lab Ojha Institute of chest diseases Karachi. Our study population comprised of 143 probable cases of pulmonary TB below the age of 15 years. After taking written consent from parent/guardian, a Performa was filled with contact no, address, clinical history, scoring chart and diagnostic tests suggested by attending clinician. ZN staining for smear microscopy GeneXpert Mycobacterium tuberculosis Rifampicin (Xpert MTB/RIF) assay, Culture on Lowenstein–Jensen (L.J) media and Mycobacterium Growth Indicator Tube (MGIT) was done for every sample according to standard operating procedures of WHO and results were entered and analyzed on SPSS statistical package for social sciences. Results Out of 143 samples 7 (5%) were positive for MTB via Xpert MTB/RIF assay while 3(2.09) were positive through AFB microscopy, LJ culture and MGIT. When compared with gold standard blood culture sensitivity and negative predictive value of Xpert MTB/RIF were 100% and 97.14% while specificity and positive predictive value were 97.14% and 43% respectively. Conclusion Xpert MTB/RIF is a rapid test that can aid in timely diagnosis of peds TB, facilitating the timely treatment. However, specificity and PPV need to be taken into account. Key words: AFB microscopy, LJ and MGIT, Xpert MTB/RIF, Peds TB.

Background

Tuberculosis (TB) is among the major killer diseases in children. It is broadly categorized as pulmonary TB (Tuberculosis affecting the lungs) and extra pulmonary TB (TB involving body organs other than lungs). Most common symptoms of the child TB are cough, fever, anorexia, weight loss, sweating, breath difficulty, lymph adenopathy, wheezing ,it is mostly transmitted through adult contacts and can be investigated through contact screening but its diagnosis becomes challenge because children do not or rarely expectorate[1] .About one third of the world's population is infected with the TB disease, 95% of which are in the developing countries like Pakistan and 98% of all TB related deaths occur in these regions. New cases of TB were estimated to be 9.6 million , among them 1.0 million were below the age of 15 years and 3.2 million were women resulting into death of 890000 men,480000 women and 140000 children in 2014[2]. High incident rate of TB and low compliance rate with treatment even up-to 40% in developing countries is leading cause of treatment failure[4]. Early diagnosis and treatment is the main TB control strategy that seizes the disease by blocking its sources[2, 3].Multi drug resistance TB (MDR-TB) is defined as resistance to Isonoazid or Rifampicine with or without resistance to other first line drugs

(FLD),estimated cases of multidrug resistance TB (MDR-TB) in 2014 were 480000 and countries using GenXpert MTB/RIF assay as essential diagnostic test have shown mark able increase in early case detection of MDR TB[1], besides this rapid detection of M. tuberculosis and rifampicin (RIF) resistance in infected patients is essential because TB is highly contagious disease .Although, Culture is the "gold standard" for final determination but it takes 2 to 8 weeks for positive and negative case identification respectively. Similarly, smear microscopy for acid-fast bacilli (AFB) is no doubt a rapid and inexpensive technique but poor sensitivity and poor positive predictive value (PPV) diminish its role. Rapid identification that is necessary for early start and positive response of treatment is mainly dependent on nucleic acid amplification techniques[4]. In this regard, Gene Xpert MTB/RIF assay is a novel device that performs both sample processing and hemi nested real-time PCR analysis in a single step for the diagnosis of tuberculosis and rapid detection of Rifampicin resistance in clinical specimens[5]. In this process 81-bp fragment of the M. tuberculosis rpoB gene is amplified and probed for mutations responsible for Rifampicin resistance. This whole process is completed in less than 2 hours[6] .A study conducted in Tunisia revealed that use Gene Xpert MTB/RIF dramatically improved the diagnosis of lymph node TB, according to this study, the sensitivity and specificity of the Xpert assay were 87.5% and 73.3%, respectively[7] .Similarly, a study conducted in Lahore endorsed the findings of above mentioned study for extra pulmonary TB[8] .Another study from Lahore revealed similar findings especially in smear negative pulmonary and extra pulmonary TB (EPTB) samples as compared to the conventional ZN staining. Among EPTB cases the highest yield of positivity was shown in Pus samples. Authors of this study suggested that use of TB Gene Xpert in endemic areas can serve well the purpose of correct diagnosis within minimal time .A study conducted in Turkey concluded that the Gene Xpert MTB/RIF test is such a simple method that routine staff with minimal training can perform it.results of the said study show that sensitivity of Gene Xpert equals with that of culture for smear-positive specimens but it was low in smear-negative pulmonary and extra pulmonary specimens because of less number of bacilli in these samples[10]. Lower positivity of both sputum smear (15 %) and culture (30-40%) make diagnosis of child TB a challenge [11]. In terms of time consumption ,Gene Xpert as it has been proved by a study from abbottabad takes just 2 hrs while LJ Culture takes 5 weeks and Zn smear takes 1-24. Thus, it can be precluded that use of MTB/RIF assay can detect not only the etiological agent but it will also detect MDR within two hours[12].these findings have also been endorsed by a study from New Delhi. Therefore, Gene Xpert helps well in detection of MTB and quicker evaluation of MDR that lead towards reduction in MDR and mortality associated with it[13].during literature search we found that studies available nationally or internationally have mostly been conducted on adults[4-16].**Rationale**: As early diagnosis and start of treatment play a vital role in success of TB treatment, wrong or late diagnosis may cause treatment failure and drug resistance. In case of childhood TB, diagnosis is challenge and treatment is often initiated on the basis of contact history, clinical sign and symptoms, chest x-ray (CXR) and TST (tuberculin skin test).Reasons for difficulty in diagnosing child TB may include resemblance of its symptoms with other diseases, Paucibacillary nature and very low /no expectoration by child patients .Therefore, it should be dealt differently from adult TB. Hence, we planned this study to determine the

utility of Xpert MTB/RIF assay in our settings. It is also expected that this study will help in early detection of MDR TB.

Methods

This comparative analytical study of 15 months was done at PHRC, SRCCH, NICH and Provincial TB Lab Ojha Institute of chest diseases Karachi. Convenient Sampling Technique was used to recruit the subjects

Inclusion Criteria: Probable cases of pulmonary TB suggested by multiple criteria like history of contact, ATT, radiological findings, immunological reaction, biopsy, sign and symptoms etc) having PPA score 4 or more than 4, age 15 or below 15 years were included in the study. **Exclusion Criteria:** All those patients who either refused to participate in the study or aged more than 15 years were excluded from the study

Study instrument: Structured Performa was used for data collection including demography, socio-economic status, clinical history, scoring chart and diagnostic tests (annexure-2).

Sample collection

Sputum samples were collected preferably outdoor in open air or in a separate ventilated room.

Patients were suggested to clean mouth with water rinse, Inhale and exhale for 2-3 time, keep both hands on hips, cough forcibly and collect sputum in the mouth, spit the sputum carefully into a wide-mouthed, unbreakable leak proof container and close the lid tightly to avoid spills or spilling outside the container.

Each specimen was labeled with the name of patient and local lab register number that matched with information on request form.

Gastric aspirates were collected by physician according to clinical laboratory standards institute (CLSI), National tuberculosis program (NTP) and WHO protocol. Patient was kept on fasting (NPO) at least for 6 hours .Details of the procedure was explained to the parents/caregiver and consent was obtained. After that, an appropriate sized feeding tube (10-12G) was inserted through one nostril till it reached the stomach. The position of tube was checked by insufflation of air into stomach. The contents of stomach were aspirated completely, kept in sterile container. Usual volume collected was around 10 ml. Samples were transported to laboratory for further processing within 1–2 h of sample collection.

<u>Storage/transport of specimen</u>

All specimens' were transported as soon as possible and were kept in cool temperature/refrigerator between collection and shipment.

Packaging of specimen for transportation:

The basic packaging system for local surface transport of sputum specimens was considered as follows:

Primary receptacle- the specimen container

Secondary packaging zip lock vinyl bags (plastic bags) compatible to the size of specimen container so the vinyl bag could be sealed to avoid leakage and cross contamination.

Outer packaging- Transport box specimen container packed in vinyl bags were placed in transport box with suitable cushioning material.

Each transport box was placed inside with frozen ice packs for every shipment.

ZN staining for smear microscopy was done according to WHO recommended protocol[14].

Xpert MTB/RIF assay: Sample reagent was added in a 2:1 ratio to unprocessed specimen in 15 ml falcon tube and the tube was agitated twice during 15 minute incubation period at room temperature. Then 2 ml of the inactivated material was transferred to the test cartridge by a sterile disposable pipette (provided with kits). Cartridges were loaded into the Gene expert. The interpretation of data from TB/RIF test is software based[15]. **Culture on Lowenstein–Jensen (L.J) media**: After decontamination of the sputum samples they were inoculated on LJ media slopes.

MGIT: Added 0.8 mL of the supplements mixed above to each MGIT tube using a sterile pipette. Then, added 0.5 ml specimen to the appropriately labelled MGIT tube. Immediately recapped the MGIT tube tightly and mix well by inversion several times.

MGIT recorded the date the tube was flagged as positive and the number of days and hours taken to reach positivity (TTP = time to positive, also known as TTD = detection) [16].Taking LJ culture as Gold standard, sensitivity, specificity, positive predictive value and negative predictive values of Xpert assay were calculated by following formula.

Sensitivity:

$$\frac{\text{True positive (TP}}{\text{True positive (TP) + False negative (FN)}} \times 100$$

Specificity:

True negative (TN) _____x 100

True negative (TN) + False positive (FP)

Negative predictive value (NPV): True negative _____x 100

False Negative+ True negative

Positive predictive value (PPV): True positive (TP _____x 100

False positive+ True positive

Sample size: Sample size was 143 for the proposed study calculated on the basis of previous study; in that study, prevalence of TB among children was estimated to be 10.41% in developing countries including Pakistan2 .Sample size was calculated at 95% confidence interval with 5% precision using EPI info version 6.

Results

Out of 143 subjects 78(54.5%) were male while 65(45.4%) were female. Means of age, weight, Family size and Expenditures incurred were 6.14, 14.54, 6.056 and 30030 respectively (table-1).

Our results show that gender, type of specimen, vaccination status have no significance on results of geneXpert (P-Value >0.05) while Family history and history of contact have significant effect on genexpert results (P-value <0.05) (table-2).

Our study found that 7 (5%) samples were positive for MTB via Xpert MTB/RIF assay while 3(2.09%) were positive through AFB microscopy, LJ culture and MGIT (fig-1)

When compared with gold standard LJ culture sensitivity and negative predictive value of Xpert MTB/RIF were 100% and 97.14% while specificity and positive predictive value were 97.14% and 43% respectively. Genexpert not only detected all LJ culture positive samples but it also detected additional 4 samples from culture negative samples (table -3).

Discussion

Diagnosis of pediatric tuberculosis remains a challenge due to various factors including paucibacillary nature of its etiological agent, inability of children to expectorate, less mucoid specimens and resemblance of clinical symptoms of diseases with many other respiratory ailments[17].

In our study we tried to explore the various factors that may affect the outcome of GeneXpert results and also compared the ability of GeneXpert in detection of pediatric TB as compared to other methods including AFB smear, MGIT and LJ culture.

According to our results gender ,type of specimen, vaccination status of patients had no significance(P-Value <0.05) in outcome of GeneXpert results however, studies conducted at Bangladesh, Egypt and other regions have reported that gender difference has different prevalence of disease[18,19,20].

Although, we could not establish any association between specimen type and GeneXpert results but it has been reported by Zar HJ et al that induced sputum and Gastric aspirate specimens were positive in 54 (87%) and 40 (65%) respectively (P=0.018) [21].

Family history and history of contact have profound effect on disease transmission therefore it has been declared mandatory for national TB control programs by WHO to evaluate the contacts of index patients, add scores in TB score and give Isoniazid (INH) prophylaxis to peds contacts of adult patients .In this context our finding suggest significant association (P-Value=0.03 and 0.02) respectively between Family history, history of contact and GeneXpert results.

In our study, Yield of genexpert in suspected (probable TB) cases was 5% while AFB smear, MGIT and LJ culture yielded <3%.Reasons may be the majority of specimens were gastric aspirates (75.5%) than sputum. Sputum gives better yield on LJ and AFB microscopy smear because its buoyant density, Instinct viscosity and residual debris content are high as compared GA samples thus our findings are consistent with previous studies .In our study, Sensitivity, and negative predictive value of Xpert MTB/RIF were 100% and 97.14% while specificity and positive predictive value were 97.14% and 43% respectively these values remained little bit low in a study conducted by Ghariani et al[22].Higher values of sensitivity, specificity and NPV endorse the capability of Xpert to 100% detect the disease in concerned population along with 100% efficiency in finding out the negative subjects. The low positive predictive value in our results may be due to the low frequency of the disease (<3%) in the population we studied. Other studies from India have reported sensitivity of Xpert MTB/RIF as 95.65% and 88.89% respectively but their positive predictive values were very high (84.21%)as compared to our results [23,24].

Similarly, studies conducted in Pakistan have shown high yield of Xpert as compared to AFB smear and LJ culture but their PPVs were quite high i.e. ≥ 70% as compared to our findings. Major difference in these studies as compared to our study could be the higher frequency of the disease in the population studied (43%) [25, 26, 27].

Limitations

Most of the previously conducted studies have been done on adults therefore; yield of Xpert MTB assay, AFB microscopy and LJ culture was low in our study because it was done on children.

Secondly our study was hospital based therefore results cannot be generalized over general population.

Conclusions

High sensitivity, specificity and negative predictive values of the Xpert assay endorse the utility of the test in detection of disease as well as ruling out the negative subjects, but low yield of all TB specific tests including Xpert assay still remains a challenge for the scientific community. Therefore, future research should focus on improvement of the diagnosis tests hence less reliance on clinical presentation to initiate the treatment.

Recommendations: All health facilities dealing with tuberculosis especially peds tuberculosis should have installed Xpert assay in their laboratories.

Abbreviations

1. Tuberculosis (TB)
2. Pulmonary TB(PTB)
3. Extra Pulmonary TB (EPTB)
4. Multi Drug Resistance TB (MDR-TB)
5. First Line Drugs (FLD),
6. Rifampicin (RIF)
7. Acid-Fast Bacilli (AFB)
8. Positive Predictive Value (PPV)
9. Negative predictive value (NPV)
10. Chest X-Ray (CXR)
11. TST (Tuberculin Skin Test
12. Clinical Laboratory Standards Institute (CLSI)
13. National Tuberculosis Program (NTP)
14. Lowenstein–Jensen (L.J)
15. Mycobacterium Growth Indicator Tube (MGIT)
16. Isoniazid (INH)

Declarations

Ethics approval and consent to Participate: Ethical Clearance was obtained from Institutional Ethical Review Board

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(Ref. no. 12/2017). Informed written consent was obtained from each individual for participation.

Consent to publish: Permission to publish was also sought.

Availability of data and materials: The datasets used and/or analyzed during the current study available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests.

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Authors' contributions: AR received grant for the study. AR, TML and MAM contributed to design, conducting of the study and preparation of the manuscript. TML, and YN, RB and ZA contributed to the data collection and supervision. All authors read and approved the final manuscript.

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Tables

Table-1 **Demographic features of the subjects**

Variable	Mean± S.D	Range
age	6.14 ±3.36	1-15
weight	14.54±7.53	2.5-34
Family size	6.056±2.062	3.14
Expenditures incurred	30030±42429	249700

Table -2 **Determinants of Probability of Gene Xpert Results**

Variable	Gene Xpert +ve N= (%)	Gene Xpert -ve N= (%)	Total	Percentage of N=143	P-Value
Gender					
Male	02 (2.56)	76 (97.43)	78	54.5	0.152
Female	05 (7.69)	60 (92.30)	65	45.4	
Type of Specimen					
Gastric aspirate	04 (3.7)	104 (96.29)	108	75.5	0.145
Sputum	03 (66.66)	32 (93.93)	35	24.47	
Vaccination status					
BCG vaccinated	01 (2.22)	44 (97.77)	45	31.46	0.292
BCG unvaccinated	06 (6.12)	92 (93.87)	98	68.53	
Family history of TB					
Patients with family history of TB	06 (9.37)	58 (90.60)	64	44.75	0.031*
Patients without family history of TB	01 (1.26)	78 (98.73)	79	55.25	
History of Contact					
Patients with history of contact	05 (11.62)	38 (88.37)	43	30.06	0.026*
Patients without history of contact	02 (2.00)	98 (98.00)	100	69.93	

*= statistically significant

Table-3 Genexpert vs LJ Culture Results

		LJ Culture Results		
		+VE	-VE	Total
Genexpert Results	+VE	3	4	7
	-VE	0	136	136
Total		3	140	143

Figures

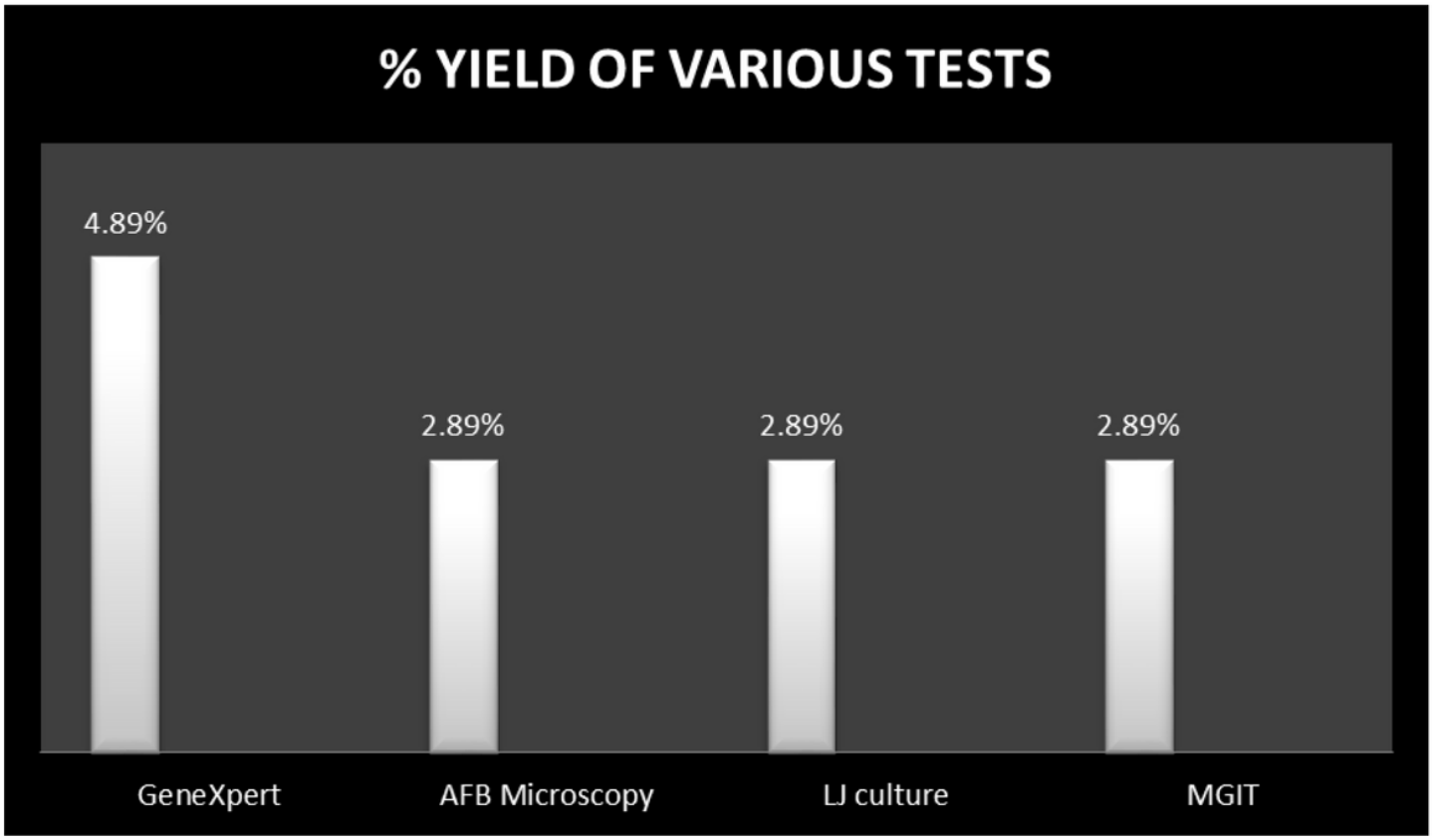


Figure 1

% yield of various tests