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Original Article

Interpretation and Clinical Correlation of Tuberculin Skin Test Results among Clinically Diagnosed Childhood Tuberculosis

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Abstract

Background: Diagnosing tuberculosis (TB) was still a worldwide big challenge in cases with negative reports of Xpert MTB/RIF, smear, and culture test of acid-fast bacilli (AFB). A single, direct Xpert MTB/RIF test identified 98.2% of the sputum smear-positive TB cases and 72.5% of those with sputum smear-negative TB. Such a diagnosis was often made based on the clinical criteria and other supportive findings like tuberculin skin test (TST).

Objective: Hence, this study was to help in the diagnosis and treatment of clinically diagnosed childhood TB, especially in the limited resource rural areas and developing countries.

Materials and Methods: Based on the WHO revised criteria of TB diagnosis, to include clinically diagnosed TB instead of smear-negative TB disease, an operational definition of clinically diagnosed TB for the selection of participants for TST was established for this study. Based on the recommendation of the CDC team at the Saskatchewan Lung Association, 2007-03-21 at the Wayback Machine, the TST results of the study were interpreted.

Results: Hence, in our study, the sensitivity of TST was 82.35% (≥10 mm) in the age group of 1–4 years and 60.16% (≥15 mm) in the age group of >4–12 years. However, this study shows that the positivity rate of TST was increased from 60.16% (≥15 mm) to 86.15% (≥10 mm), if the TST results≥10 mm were interpreted as positive even in this age group of >4 years–12 years.

Conclusion: In such very difficult situations of clinically diagnosed TB, this study observed that empiric anti-TB treatment may be started without microbiological confirmation to clinically diagnosed childhood TB patient with negative reports of Xpert MTB/RIF, smear, and culture test of AFB, presented with one or more of the following symptoms and signs of clinically diagnosed childhood TB: (1) Chronic anorexia, (2) ill health and fatigue, (3) weight loss of >5% during the past 3 months or documented failure to strive during the preceding 3 months, (4) night sweating and persistent fever >2 weeks, and (5) non-remitting cough >2 weeks but cannot be diagnosed clinically by any possible causes than TB, and positive TST report, in resource-limited rural areas anddeveloping countries.

Key words: Childhood tuberculosis, Diagnosis, Mantoux tuberculin test, Purified protein derivative, Tuberculin skin test

INTRODUCTION

Tuberculosis (TB) remains a leading cause of morbidity and mortality in the world, especially in developing countries.[1]

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The tuberculin skin test (TST) (also called a Mantoux tuberculin test) is one of the methods for detecting *Mycobacterium tuberculosis* infection in an individual and is used in the diagnosis of TB in individual patients, as well as in epidemiological settings, to measure the prevalence of TB infection in population.[1]

Best results of Ziehl–Neelsen stain are obtained in respiratory samples. Its sensitivity is variable. Sensitivity ranges from 46% to 78% and the specificity is virtually 100%. The sensitivity is grossly compromised when the bacterial load is <10,000 organisms/ml of sputum sample.[2,3]

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The TST is an imperfect marker of TB infection and previous reports indicate that 10–25% of persons with active TB disease have a negative TST result. However, little is known about the relationship between the TST result and the clinical presentation of TB disease.[4]

Recently, the WHO revised the criteria of TB diagnosis, to include clinically diagnosed TB instead of smear-negative TB.[5]

The children with clinically diagnosed TB disease may present one or more of the following symptoms and signs: (1) chronic anorexia, (2) ill health and fatigue, (3) weight loss of >5% during the past 3 months or documented failure to strive during the preceding 3 months, (4) night sweating and persistent fever >2 weeks, and (5) non-remitting cough >2 weeks.[5]

Diagnosing TB worldwide still consists of methods that are intended to isolate the pathogen, which is a major limitation when the mycobacterial load (paucibacillary disease) is low, or the site of infection is not easily accessible, or sampling error and technical problems are occurred. For these reasons, diagnosis of smear-negative TB is often delayed, and such a diagnosis is often made based on the clinical response to empiric anti-TB treatment (ATT) without microbiological confirmation.[6]

Hence, it is rational to take up this study to help in the diagnosis and treatment of childhood TB disease, especially in the limited resource rural areas and developing countries.

MATERIALS AND METHODS

This study was conducted in the Department of Pediatrics, JNIMS, over a period of 2 years from October 2016 to September 2018. The study was approved by the Institutional Ethical Committee of JNIMS. The purposive sampling method was used. Based on the WHO revised criteria of TB diagnosis, to include clinically diagnosed TB instead of smear-negative TB disease, an operational definition (OD) for the selection of participants for TST of the study was established. Hence, the child presented with one or more of the following symptoms and signs: (1) chronic anorexia, (2) ill health and fatigue, (3) weight loss of >5% during the past 3 months or documented failure to strive during the preceding 3 months, (4) night sweating and persistent fever >2 weeks, and (5) non-remitting cough>2 weeks but cannot be diagnosed clinically by any other possible causes than TB disease was selected for TST of the clinically diagnosed childhood TB in this study.

The following inclusion and exclusion criteria were used.

Inclusion Criteria

1. Those children presented with one or more of the above symptoms and signs of OD but cannot be diagnosed clinically by any other possible causes than TB disease were selected TST of the study.
2. Both male and female children from 1 year to 12 years of age and children with or without positive contact history of TB and Bacille Calmette–Guérin (BCG) vaccination but fulfilled the OD were included in the study.

Exclusion Criteria

The following patients were excluded from the study:

1. Those children presented with one or more of the symptoms and signs of OD but can be diagnosed clinically by any other possible causes than TB disease, were excluded from the study.
2. Have had a severe reaction to a TST in the past.
3. Those patients having any anaphylactic reaction in the past will be excluded from the study.
4. Have had TB in the past.
5. Have been treated with medicines, such as corticosteroids, that can affect the immune system.
6. Infected with HIV.
7. Have a skin rash that may make it hard to read the skin test.
8. Recent live virus vaccination (e.g., measles and smallpox).
9. Some viral illnesses (e.g., measles and chicken pox).
10. Incorrect method of TST administration.

The gender, caste, ethnicity, and race were not used as inclusion or exclusion criteria.

Those children fulfilled the OD of clinically diagnosed TB disease, but cannot be diagnosed clinically by any other possible causes than TB, were selected by the investigators for TST among the children in the OPD of Pediatrics Department, JNIMS. The selected children were sent to the OPD of Chest Department, JNIMS for TST. The person trained in TST performs the TST in Chest OPD, JNIMS. Five TU of tuberculin PPD RT23 is injected strictly intradermally on the volar aspect of the left forearm, which is the preferred site of the test, using 28 or 26-gauge needle and tuberculin syringe from which 0.1 ml can be delivered accurately. A discrete, pale elevation of the skin (a wheal) 6–10 mm in diameter should be produced when the injection is given correctly. If it is recognized that the first test was improperly administered, another test dose can be given at once, selecting a site several centimeters away from the original injection. A note in the record indicates the site chosen for the second test. The patient is instructed to keep the test site clean, uncovered, and not to scratch or rub the area. The reading of TST was done on 72 h after administration of TST, by the person trained in TST in the Chest OPD, JNIMS. The investigators obtain the informed consent from the parents/guardians. Then, only the

investigator enrolls the selected children for the study. The TST result and report were again checked by the investigator.

The recommendation of the CDC team at the Saskatchewan Lung Association, 2007-03-21 at the Wayback Machine, 5 mm or more of TST induration is positive in HIV-positive persons, persons with recent contacts with TB patients, persons with nodular or fibrotic changes on chest X-ray consistent with old healed TB, patients with organ transplants, and other immunosuppressed patients. 10 mm or more is positive in recent arrivals (<5 years) from high prevalence countries, injection drug users, residents and employees of high-risk congregate settings, mycobacteriology laboratory personals, persons with clinical conditions that place them at high risk, children <4 years of age, or children and adolescents exposed to adults in high-risk categories. 15 mm or more is positive in persons with no known risk factors for TB.[7]

Based on the above CDC recommendation, the TST indurations of ≥10 mm among the age group of 1–4 years and ≥15 mm among 4 years–12-year-old patients, with no known risk factors for TB were interpreted as positive TST in this study. Data were collected by the investigators. The TST reports and clinical findings of the children were collected in a pre-designed pro forma.

Evaluations were done at the end of every 6 months and at the end of the study.

Data analysis was done by the statistician.

RESULTS

A total of 507 children of both sexes in the age group of 1 year–12 years were enrolled for TST of the study over the period of 2 years. The patients were divided into two groups. Of the total of 507 children, 153 children of both sexes were in the age group of 1 year–4 years and 354 children of both sexes were in the age group of above 4 years–12 years.

Table 1 shows that 126 (82.35%) of TST results (≥10 mm), of the total of 153 TST results, were found to be TST positive, in the age group of 1 year–4 years.

In this age group, 57.51% (88 of 153) of TST (10–<15 mm) results were found to be positive and 24.83% (38 of 153) of TST (≥15 mm) results were found to be positive.

Table 2 shows that 60.16% (213 of 354) of TST (≥15 mm) results were positive in the age group of >4 years–12 years.

Table 3 shows that 86.15% (305 of 354) of TST results were≥10 mm indurations, in the age group of >4 years–12 years. However, this study also shows that the positivity rate of TST was increased from 60.16% (≥15 mm) to 86.15% (≥10 mm), if the TST results ≥10 mm were interpreted as positive even in this age group of >4 years–12 years.

DISCUSSION

Culture remains the gold standard for laboratory confirmation of TB and is required for isolating bacteria for DST and genotyping.[8]

Diagnosing TB worldwide still consists of methods that are intended to isolate the pathogen, which is a major limitation when the mycobacterial load is low (paucibacillary disease), or the site of infection is not easily accessible, or sampling error and technical problems are occurred. For these reasons, diagnosis of smear-negative TB is often delayed, and such a diagnosis is often made based on the clinical response to empiric ATT without microbiological confirmation.[6]

Recently, the International Standards for TB Care recommended that Xpert MTB/RIF and/or sputum cultures should be performed in patients suspected of having pulmonary TB but that has negative sputum smears.[5]

In a recent study of the performance of Xpert MTB/RIF, among the 561 culture-positive patients (561/1730), a single, direct Xpert MTB/RIF test identified 98.2% (551 of 561) of the sputum smear-positive TB cases and 72.5% (124 of 171) of those with sputum smear-negative TB. The test was specific in 604 of 609 patients (99.2%) not affected by TB. The second Xpert MTB/RIF test among patients with sputum smear-negative and culture-positive

Table 1: Distribution of TST results and positivity rate of TST results, 10mm and above, in the age group of 1-4 years

Age in years	Total TST results	Total TST 0–<10 mm results	Total TST 10–<15 mm results	Total TST≥5 mm results	Total number of positive TST (≥10 mm) results
		(%)	(%)	(%)	(%)
1–4 years	- *n*=153	(27 of 153) *n*=27 (17.64%)	(88 of 153) *n*=88 (57.51%)	(38 of 153) *n*=38 (24.83%)	88+38=126 (126 of 153) *n*=126 (82.35%)

TST: Tuberculin skin test

Table 2: Distribution of TST results and positivity rate of TST results , 15 mm and above, in the age group of above 4 to 12 years

Age in years	Total TST results	Total TST 0–<10 mm results	Total TST 10–<15 mm results	Total TST≥15 mm results	Total positive TST≥15 mm results
		(%)	(%)	(%)	(%)
>4–12 years	*n*=354	(49 of 354) *n*=49 (13.84%)	(92 of 354) *n*=92 (25.98%)	(213 of 354) *n*=213 (60.16%)	(213 of 354) *n*=213 (60.16%)

TST: Tuberculin skin test

Table 3: Distribution of TST results and positivity rate of TST results ,10 mm and above,in the age group of above 4 to 12 years

Age in years	Total TST results	Total TST 0–<10 mm results	Total TST 10–<15 mm results	Total TST≥15 mm results	Total positive TST≥10 mm results
		(%)	(%)	(%)	(%)
>4–12 years	*n*=354	(49 of 354) *n*=49 (13.84%)	(92 of 354) *n*=92 (25.98%)	(213 of 354) *n*=213 (60.16%)	(305 of 354) *n*=305 (86.15%)

TST: Tuberculin skin test

TB increased detection sensitivity by 12.6% and the third by 5.1%, to reach 90.2%. When compared to phenotypic DST, the Xpert MTB/RIF assay correctly identified 97.6% (200 of 205) of patients harboring rifampicin-resistant strains and 98.1% (504 of 514) of those with rifampicin-susceptible strains.[9]

Recently, the WHO revised the TB definition to include clinically diagnosed TB instead of smear-negative TB. A clinically diagnosed TB case is one that does not fulfill the criteria for bacteriological confirmation but has been diagnosed with active TB by a clinician or other medical practitioners who have decided to give the patient a full course of TB treatment. Clinically diagnosed cases subse-Diagnosis of pulmonary TB http://dx.doi.org/10.4046/trd.2015.78.2.64 69 www.e-trd.orgquently found to be bacteriologically positive (before or after starting treatment) should be reclassified as bacteriologically confirmed.[5]

The present study shows that 82.35% (126 of 153) of TST (≥10 mm) results were positive, in the age group of 1–4 years and 60.16% (213 of 354) of TST (≥15 mm) results were also positive in the age group of >4 years–12 years. This study also shows that the positivity rate was increased from 60.16% (≥15 mm) to 86.15% (≥10 mm), if the TST results≥10 mm were interpreted as positive even in this age group of >4 years–12 years.

According to one study, sensitivity and specificity of Mantoux test in extrapulmonary TB has been reported as 47% and 86%, respectively.[10]

The findings of the present study were not comparable to this study. In their study, the TST sensitivity 47% was in extrapulmonary TB. In our study, the TST sensitivity was 82.35% (≥10 mm) in the age group of 1–4 years and 60.16% (≥15 mm) in the age group of >4–12 years. In this study, TST sensitivity was done among the clinically diagnosed childhood TB disease.

Ozuah *et al.* sought to determine the sensitivity, specificity, and predictive validity of a New York City Department of Health questionnaire in 2920 children. In all, 14% (413 of 2920) of children had at least one risk factor, and of these, 6% (23 of 413) had a positive TST (≥10 mm). In contrast, 0.16% (4 of 2507) of children without risk factors identified had a positive TST. The sensitivity of the questionnaire was 85% and the specificity was 86%.[11,12]

The above sensitivity of the questionnaire (85%) is comparable with the TST sensitivity of this study 82.35% (≥10 mm) in the age group of 1–4 years. This study shows that the positivity rate was increased from 60.16% (≥15 mm) to 86.15% (≥10 mm), if the TST results≥10 mm were interpreted as positive even in this age group of >4 years–12 years.

The past study conducted in Malaysia showed that the sensitivity of Mantoux test in active TB was 86%.[13]

This 86% sensitivity of TST in Malaysia was comparable with the TST sensitivity of this study. Our study showed that the sensitivity of TST was 82.35% (≥10 mm result) in the age group of 1 year–4 years and 60.16% (≥15 mm result) in the age group of >4 years and 12 years. This study shows that if the TST results≥10 mm were interpreted as positive TST, even in this age group of >4 years–12 years, the positivity rate was increased from 60.16% (≥15 mm result) to 86.15% (≥10 mm result).

One study reported that the false-negative rate among confirmed pulmonary TB was 20.5% and 11.7% in those with TB lymphadenitis.[14] The negative TST results of

this study were15% (≥10 mm result) in the age group of 1 year–4 years and 39.84% (≥15 mm result) in the age group of >4–12 years which were reduced to 13.85% if the TST results ≥10 mm were interpreted as positive TST, even in this age group of >4–12 years.

The presence of BCG vaccination is not a factor influencing tuberculin reactivity. It was earlier believed that previous BCG vaccination can account for PPD positivity depending on the interval between BCG and TST administration. Community-based studies, however, have shown that tuberculin reactivity was similar among those vaccinated in infancy and those who were never vaccinated. The same findings were noted in the study of Gonzales where no association was noted between BCG and tuberculin reactivity.[15] The same observations were noted in this study.

Nadal concluded that several diagnostic tests have been developed to aid in the detection of TB infection and disease. Nucleic acid amplification techniques (e.g., polymerase chain reaction [PCR]), serodiagnostic methods (e.g., ELISA kits), and T-cell-based assays (e.g., interferon-gamma assay) have been introduced but are not recommended for routine diagnosis of pulmonary TB in children due to its various limitations. These include its high cost, limited local availability (for PCR), and low sensitivity (for ELISA), with only a few studies involving children. Thus, the TST cannot be replaced just yet by these assays.[16] This present study also recommended that the TST cannot be replaced just yet by these assays, especially in resource-limited rural areas and developing countries.

This present study was in accordance with the studies of Colebunders *et al.* and Siddiqi *et al.* who concluded that a diagnostic approach to an acid-fast bacilli (AFB) smear-negative patient with possible TB includes, where available, a detailed medical history and clinical examination as well as radiological, microbiological, molecular, and histological investigations.[6,17]

Stuart *et al.* concluded that in contrast, Mantoux testing remains to be a readily available procedure in the detection of TB infection and is widely used in epidemiologic surveys, evaluation of contacts of patient with active TB, selection of persons for chemoprophylaxis, and surveillance of health care workers for TB infection. Unfortunately, the TST is dependent on many variables which may affect its interpretation and result.[18]

The present study observed that variables which may affect its interpretation and result of TST can be minimized. In this study, the criteria of the selection of patients for TST were the symptoms and signs of clinically diagnosed TB disease.

Fourie PB *et al.* had observed that not one of the clinical manifestations of the study participants was found to be a factor influencing tuberculin reactivity although the previous studies have shown that persistent cough, history of contact with a case of TB, low weight for age, and prolonged fever (in addition to a positive TST) were the most relevant predictors of disease in children.[19]

Our findings were in contrast to the findings of Fourie *et al.* The present study was supportive to the results of previous studies which have shown that persistent cough, history of contact with a case of TB, low weight for age, and prolonged fever (in addition to a positive TST) were the most relevant predictors of disease in children.

Tanchuan *et al.* had revealed that 52.1% of children in contact with sputum positive cases and 43.1% of those exposed to chest X-ray positive cases were positive PPD reactors.[20]

The positivity rate of TST in the present study was higher than the previous studies. It is due to the difference in the mode of the selection of patients for TST. In this study, the criteria of selection for TST were the symptoms and signs of clinically diagnosed TB disease.

CONCLUSION

Diagnosing TB was still a worldwide big challenge in cases of Xpert MTB/RIF and culture test reports were negative due to the major limitations when the mycobacterial load (paucibacillary disease) is low, or the site of infection is not easily accessible, or sampling error and technical problems were occurred.

In such very difficult situations, this study observed that empiric ATT may be started without microbiological confirmation to clinically diagnosed childhood TB patient with negative reports of Xpert MTB/RIF, smear, and culture test of AFB, presented with one or more of the following symptoms and signs of clinically diagnosed childhood TB: (1) chronic anorexia, (2) ill health and fatigue, (3) weight loss of >5% during the past 3 months or documented failure to strive during the preceding 3 months, (4) night sweating and persistent fever >2 weeks, and (5) non-remitting cough >2 weeks but cannot be diagnosed clinically by any possible causes than TB, and positive TST report, in resource-limited rural areas and developing countries.

In this study, TST was done only in the clinically diagnosed childhood TB. Hence, in our study, the TST sensitivity was 82.35% (≥10 mm) in the age group of 1–4 years and 60.16% (≥15 mm) in the age group of >4–12 years. However, this study shows that the TST positivity rate was

increased from 60.16% (≥15 mm) to 86.15% (≥10 mm), if the TST results ≥10 mm were interpreted as positive even in this age group of >4–12 years.

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