

# A study of utility of mantoux test in the suspected cases of tuberculosis at a tertiary health care center

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## Abstract

**Background:** Tuberculosis (TB) in India accounts for the one-fourth of the global cases, adding almost 2.8 million cases annually. **Aims:** 1) To study the prevalence of tuberculin sensitivity among suspected tuberculosis patients, 2) To study various presentations of TB in Mantoux test positive patients, 3) To restudy the sensitivity and specificity of Mantoux test in tuberculosis in current scenario. **Methodology:** After approval from the institutional ethical committee this cross-sectional study in the suspected tuberculosis patients attending the OPD at the department of Respiratory medicine of a tertiary health care, SKNMC and GH, Narhe, Pune center during the Six month period i.e. Jan 2017 to June 2017. During Six month period there were 480 patients were referred to the pulmonology department. The analysis was done by *MEDCAL Software* and the sensitivity, specificity, positive predictive value, negative predictive value etc. was calculated. **Result:** In our study we have found that Overall induration 311 (64.79%) patients out of that 177 (36.88%) were Positive ( $\geq 15$  mm). So, prevalence of Mantoux test positive was 36.88% in the suspected patients. The majority of the Study participants were in the age group of  $>50$  were 122 (25.42%) followed by 21-30 were 98 (20.42%), 0-10 were 70 (14.58%), 11-20 were 64 (13.33%), 41-50 were 64 (13.33%). The majority of the suspected patients were Male i.e. 262 (54.58%) followed by Female i.e. 218 (45.42%). The most common etiology of Mantoux test positive patients was Pulmonary TB was 75 (42.37%) followed by Other were 62 (35.03%), followed by Lymph Node TB 24 (13.56%), Followed by Pleural effusion were 16 (9.04%). The Sensitivity of the Mantoux test was 95.86% with 95% C.I. (91.65% to 98.32%) and Specificity was 95.18% (92.17% to 97.28%), Positive Predictive Value was 91.53%, Negative Predictive Value was 97.69%. **Conclusion:** It can be concluded from our study that the Mantoux test is having very high diagnostic utility as high sensitivity and specificity so employed whenever there is confusion to the diagnosis of tuberculosis but the results below 15 mm should be cautiously interpreted.

**Key Words:** Tuberculosis (TB), Tuberculin Skin Test (TST), Mantoux test, Sensitivity and specificity of Mantoux test.

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## INTRODUCTION

Tuberculosis (TB) in India accounts for the one-fourth of the global cases, adding almost 2.8 million cases annually.<sup>1</sup> The Mantoux test was developed by Koch in 1890 but the intradermal technique currently in use was

described in 1912 by Charles Mantoux, a French physician who developed on the work of Koch and Clemens von Pirquet<sup>2</sup> to create his test in 1907. After such a long history it is surprising that the interpretation of the test remains controversial. The reaction to intracutaneously injected tuberculin is the classic example of a delayed (cellular) hypersensitivity reaction. T-cells sensitized by prior infection are recruited to the skin site where they release lymphokines. These lymphokines induce induration through local vasodilatation, edema, fibrin deposition, and recruitment of other inflammatory cells to the area. Features of the reaction include<sup>3</sup> its delayed course, reaching a peak more than 24 h after injection of the antigen;<sup>4</sup> its indurated character; and<sup>5</sup> its occasional vesiculation and necrosis. The Mantoux test does not measure immunity to TB but the degree of hypersensitivity to tuberculin. There is no correlation

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between the size of induration and likelihood of current active TB disease but the reaction size is correlated with the future risk of developing TB disease. The test has a poor positive predictive value for current active disease.<sup>6</sup> There is no correlation between the size of post-vaccination Mantoux reactions and protection against TB disease and routine post-BCG Mantoux testing serves no purpose. The results of this test must be interpreted carefully. The person's medical risk factors determine the size of induration the result is positive (5 mm, 10 mm, or 15 mm). A record should also be made of formation of vesicles, bullae, lymphangitis, ulceration and necrosis at the test site. The formation of vesicles, bullae or necrosis at the test site indicates high degree of tuberculin sensitivity and thus presence of infection with tubercle bacilli.<sup>7</sup>

**MATERIAL AND METHODS**

After approval from in institutional ethical committee this cross-sectional study in the suspected tuberculosis patients at the Department of Respiratory medicine of a tertiary health care center during the six month period i.e. Jan 2017 to June 2017. During the six month period there were 480 patients were referred to the pulmonology department. All details of the patients like age, sex was noted. A written and informed consent in all the patients was taken. All necessary investigations like X-ray chest, USG abdomen, FNAC and Histopathology and Culture with the respective samples was done. All the suspected patients undergone Mantoux test as per the Guidelines of Vineet K. Chadha *Indian J Pediatrics, 2001*<sup>14</sup>. A test more than 15 mm was considered positive in all the patients. The results of the Mantoux test were compared with Culture for mycobacteria . The analysis was done by *MEDCAL Software* and the sensitivity , specificity, positive predictive value, negative predictive value etc. was calculated.

**RESULT**

**Table 1:** Prevalence of Mantoux test positive

Tuberculin	No	Percentage (%)
No induration	169	35.21
Induration		
≥5 mm	96	20.00
10-15 mm	38	7.92
≥ 15 mm	177	36.88
Total	311	64.79
<b>Grand Total</b>	<b>480</b>	<b>100.00</b>

Overall induration 64.79% patients out of that 36.88% were Positive (≥ 15 mm). So, prevalence of Mantoux test positive was 36.88% in the suspected patients.

**Table 2:** Distribution of the patients as per the age

Age group	No.	Percentage (%)
0-10	70	14.58
11-20	64	13.33
21-30	98	20.42
31-40	62	12.92
41-50	64	13.33
>50	122	25.42
<b>Total</b>	<b>480</b>	<b>100.00</b>

The majority of the Study participants were in the age group of >50 were 25.42% followed by 21-30 were 20.42%, 0-10 were 14.58%, 11-20 were 13.33%, 41-50 were 13.33%.

**Table 3:** Distribution of the patients as per the sex

Sex	No.	Percentage (%)
Male	262	54.58
Female	218	45.42
<b>Total</b>	<b>480</b>	<b>100</b>

The majority of the suspected patients were Male i.e. 54.58% followed by Female i.e. 45.42%.

**Table 4:** Distribution of the patients (Mantoux test positive) as per the etiology

Etiology	No.	Percentage (%)
Pulmonary TB	75	42.37
Pleural effusion	16	9.04
Lymph node	24	13.56
Other	62	35.03
<b>Total</b>	<b>177</b>	<b>100.00</b>

The most common etiology of Mantoux test positive patients was Pulmonary TB was 42.37% followed by Other were 35.03%, followed by Lymph Node TB 13.56%, followed by Pleural effusion were in 9.04%.

**Table 5:** Distribution of the patients as per the Sensitivity and specificity of the tuberculin test

Mantoux test	Culture		Total
	Positive	Negative	
Positive	162 (a)	15 (c)	177 (a+c)
Negative	7 (b)	296 (d)	303 (b+d)
<b>Total</b>	<b>169 (a+b)</b>	<b>311 (c+d)</b>	<b>480 (a+b+c+d)</b>

**Table 5a:** Analysis of Sensitivity and Specificity

Statistic	Formula	Value	95% CI
Sensitivity	$\frac{a}{a + b}$	95.86%	91.65% to 98.32%
Specificity	$\frac{d}{c + d}$	95.18 %	92.17% to 97.28%
Positive Likelihood Ratio	$\frac{Sensitivity}{1 - Specificity}$	19.87	12.12 to 32.59
F	$\frac{1 - Specificity}{Sensitivity}$	0.04	0.02 to 0.09
Positive Predictive Value	$\frac{a}{a + c}$	91.53%	86.82% to 94.66%
Negative Predictive Value	$\frac{d}{b + d}$	97.69 %	95.34% to 98.87%

From above table the Sensitivity of the Mantoux test was 95.86% with 95% C.I. (91.65% to 98.32%) and Specificity was 95.18 % (92.17% to 97.28%), Positive Predictive Value was 91.53%, Negative Predictive Value was 97.69 %.

## DISCUSSION

**The interpretation of the results are : Five mm or more is positive in :** HIV-positive person, Recent contacts of active tuberculosis cases, Persons with nodular or fibrotic changes on Chest X-ray consistent with old healed TB, Organ transplant recipients and other immunosuppressed patients who are on cytotoxic immune-suppressive agents such as cyclophosphamide or methotrexate. Patients on long term systemic corticosteroid therapy (> than six weeks) and those on a dose of prednisone  $\geq$  15 mg/day or equivalent. End stage renal disease.

**Ten mm or more is positive in:** Recent arrivals (less than five years) from high-prevalence countries, Injectable drug users, Residents and employees of high-risk congregate settings (e.g., prisons, nursing homes, hospitals, homeless shelters, etc.), Mycobacteriology lab personnel, Persons with clinical conditions that place them at high risk (e.g., diabetes, prolonged corticosteroid therapy, leukemia, end-stage renal disease, chronic malabsorption syndromes, low body weight, etc.), Children less than four years of age, or children and adolescents exposed to adults in high-risk categories, Infants, children, and adolescents exposed to adults in high-risk categories.

**Fifteen mm or more is positive in:** Persons with no known risk factors for TB Reactions larger than 15 mm are unlikely to be due to previous BCG vaccination or exposure to environmental mycobacteria.

**False-positive result:** Some persons may react to the TST even though they are not infected with *M. tuberculosis*. The causes of these false-positive reactions may include, but are not limited to, the following: Infection with non tuberculous mycobacteria, Previous BCG vaccination, Incorrect method of TST administration, Incorrect interpretation of reaction, Incorrect bottle of antigen used, Due to the test's low specificity, most positive reactions in low-risk individuals are false-positives.<sup>8</sup> A false-positive result may be caused by nontuberculous mycobacteria or previous administration of BCG vaccine. Prior vaccination with BCG may result in a false-positive result for many years later.<sup>9</sup>

**False-negative result:** A negative Mantoux result usually signifies that the individual has never been exposed to *M. tuberculosis*. However, there are factors that may cause a false-negative result or diminished ability to respond to

tuberculin<sup>10,11</sup> Cutaneous anergy (anergy is the inability to react to skin tests because of a weakened immune system), Recent TB infection (within 8-10 weeks of exposure), Very old TB infection (many years), Very young age (less than six months old) Recent live-virus vaccination (e.g., measles and smallpox), Overwhelming TB disease. Some viral illnesses (e.g., measles and chicken pox), Incorrect method of TST administration, Incorrect interpretation of reaction, insufficient dose and inadvertent subcutaneous injection. The absence of cell mediated immunity to tuberculin may be due to the lack of previous sensitization or due to a false-negative result for various reasons or due to anergy because of immune suppression. Most children with negative result have not been infected with *M. tuberculosis*. A small proportion of otherwise normal children with *M. tuberculosis* infection remain PPD-negative for unknown reasons. From the time of infection to the development of CMI there is a window period of some two to six weeks, when the Mantoux test would be negative. Those that are immunologically compromised, especially those with HIV and low CD4 T-cell counts, frequently show negative results from the PPD test. This is because the immune system needs to be functional to mount a response to the protein derivative injected under the skin. Negative tests can be interpreted to mean that the person has not been infected with the TB bacteria or that the person has been infected recently and not enough time has elapsed for the body to react to the skin test. A repeat test is not advocated before one week as the tuberculin injected for the first test has a booster effect on the subsequent dose. TST may convert to positive  $\leq$  eight weeks after Mycobacterium tuberculosis infection, an interval that is usually referred to as the "window period". A negative TST obtained < eight weeks before does not exclude infection, and a second test is recommended after eight weeks.<sup>12</sup> In our study we have found that Overall induration 64.79% patients out of that 36.88% were Positive ( $\geq$  15 mm). So, prevalence of Mantoux test positive was 36.88% in the suspected patients. The majority of the Study participants were in the age group of >50 were 25.42% followed by 21-30, Were 20.42 %, 0-10 were 14.58%, 11-20 were 13.33%, 41-50 were 13.33%. The majority of the suspected patients were Male i.e. 54.58% followed by Female i.e. 45.42%. The most common etiology of Mantoux test positive patients was Pulmonary TB was 42.37% followed by Other were 35.03%, Followed by Lymph Node TB 13.56%, followed by Pleural effusion were in 9.04%. The Sensitivity of the Mantoux test was 95.86% with 95% C.I. (91.65% to 98.32%) and Specificity was 95.18 % (92.17% to 97.28%), Positive Predictive Value was 91.53%, Negative Predictive Value was 97.69 %. This study

similar to Ji Eun Lee *et al*<sup>13</sup> they found Of the 143 patients included in the analysis, active TB was diagnosed in 100 (69.9%). There were 141 male patients, none of whom had immunosuppressive disease. The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of TST were 94% (95% CI, 87-98%), 88% (95% CI, 74-96%), 95% (95% CI, 88-98%), and 86% (95% CI, 72-94%), respectively.

## CONCLUSION

It can be concluded from our study that the Mantoux test is having very high diagnostic utility as high sensitivity and specificity so employed where ever there is confusion to the diagnosis of tuberculosis but the results below 15 mm should be cautiously interpreted.

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