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Original Research Article

A comparative study of Mantoux test and BCG test in diagnosis of childhood tuberculosis

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ABSTRACT

Background: India has one of the highest tuberculosis (TB) burdens globally. However, few studies have focused on TB in young children, a vulnerable population, where lack of early diagnosis results in poor outcomes.
Methods: The present study was undertaken to assess the sensitivity and specificity of tuberculin test (Mantoux) and BCG test in diagnosis of childhood tuberculosis and to compare above tests as a diagnostic tool and to assess the impact of factors affecting the test. Mantoux test was done with 1 TU contained in 0.1 ml of PPD R23 with tween 80 solution. BCG test was done using a heat stable freeze-dried vaccine, after fresh reconstitution and injected intradermally in left deltoid region with a tuberculin syringe and 27 G hypodermic needle.
Results: Tuberculous cases were more common in malnourished subjects more so with severe malnutrition. While maximum positivity 89% was obtained with BCG test, it was only 63% with Mantoux test, done with 5TU of PPD-RT-23. BCG was always positive whenever PPD was positive in any group of children. Sensitivity of Mantoux test was around 63% whereas that of BCG test was 89%. BCG test was more significantly associated with disease than tuberculin test ($p < 0.001$).
Conclusions: BCG test is a very sensitive and specific test for diagnosis of childhood tuberculosis. Mantoux test is affected by malnutrition and severity of disease whereas BCG test is affected only minimally. BCG test is more sensitive than Mantoux test (with 5TU PPD RT 23 Tween 80). A BCG induration of ≥10 mm or Mantoux induration ≥15 mm or an accelerated BCG test is indicative of active disease, irrespective of vaccination status of the patient.

Keywords: BCG test, Children, Diagnosis, Mantoux test, Tuberculosis

INTRODUCTION

India has one of the highest tuberculosis (TB) burdens globally. India accounts for one fourth of the global TB burden. In 2015, an estimated 28 lakh cases occurred and 4.8 lakh people died due to TB.[1,2] While the burden of childhood TB in India is not known, regional data from the World Health Organization (WHO) indicate that sputum microscopy smear-positive TB in children (<14 years old) accounts for 0.6%-3.6% of all reported cases.[3,4]

However, because the majority of children are sputum microscopy smear negative, these data underestimate the true burden of childhood TB.

It is estimated that childhood TB constitutes 10-20% of all TB in high-burden countries, accounting for 8-20% of TB-related deaths.[5-7] The epidemiology of TB in young children (<5 years old), a vulnerable population where diagnosis and treatment are most challenging, is not well understood, especially in countries with limited public health resources.

Diagnosis of tuberculosis in children is even more difficult than in adults. History of sickness is mostly vague; family history or history of contact is usually lacking, and clinical signs are not specific. The usual diagnostic criteria viz., tuberculin test, X-ray, sputum examinations have their own limitations. These limitations are even greater in paediatric practice.

Tuberculin test is very well known, helps to distinguish infected from non-infected individuals. But it is negative too frequently, particularly in severe disease or when associated with malnutrition etc to be very much a dependable test. Mass BCG vaccination also has added confusion to its interpretation and utility in clinical practice.

Considering the above facts there is a pressing need to rationalize diagnosis of tuberculosis, find out more sensitive and specific tests which can be done easily and formulate the exact reading of tuberculin as well as BCG test above which tuberculosis is most likely.

Thus, the present study was undertaken to assess the sensitivity and specificity of tuberculin test (Mantoux) and BCG test in diagnosis of childhood tuberculosis and to compare above tests as a diagnostic tool and to assess the impact of factors affecting the test.

METHODS

The study was taken up on the patients of tuberculosis attending paediatric OPD of a tertiary care teaching hospital, Haldia or admitted in paediatric wards and chest department. Children under 10 years of age were included in the study.

A total of 300 children were studied. Cases were selected with definitive evidence of tuberculosis of different types and healthy normal children were included as controls. All these children were grouped in the following categories:

Group I

200 healthy children were selected for control group. They were divided into 2 sub-groups of 100 each. First group had visible BCG scar and history of vaccination at birth/infancy (Group IA). The other group had no BCG scar on examination (Group IB).

Group II

100 children suffering from different types of tuberculosis constituted group II. Diagnosis of TB was based on clinical, radiological, biochemical and cytological parameters were made on the basis of scoring system suggested by Jones K et al.

Mantoux test was done with 1 TU contained in 0.1 ml of PPD R23 with tween 80 solution obtained from BCG vaccine laboratory Guindy Madras (India). It was injected intradermally to the volar surface of left forearm with tubercular syringe and reaction was recorded as induration, after 72 hours and extent of induration was measured in transverse diameter with a ruler by PEN method and interpreted as: 0-5 mm negative, 6-9 mm doubtful and more than 10 mm positive. 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.[8,9]

BCG test was done using a heat stable freeze-dried vaccine, obtained from Japan BCG laboratory, stored at 2 to 8 degrees in refrigerator, after fresh reconstitution and injected intradermally in left deltoid region with a tuberculin syringe and 27 G hypodermic needle. Reaction was observed for one week especially 24-72 hours and again on 5^{th}-6^{th} day for maximum induration size and results were interpreted as: 0-5 mm negative, 5-10 mm mildly positive +, 10-20 mm moderately positive ++ and more than 20 mm strongly positive +++.[10] The readings of induration sizes were compared in symptomatic and control groups to establish diagnostic induration sizes of BCG test in previously vaccinated children. The results were also compared with Mantoux test.

RESULTS

A total of 300 cases were taken up in this study. Out of these 200 were selected randomly and were not suffering from any disease and constituted control group (Group I). Of these, 100 children had history of BCG vaccination in infancy or at birth and visible BCG scar over left deltoid (Group I A), and rest 100 had no history of vaccination as well as no BCG scar (Group I B). About 100 children of less than 10 years suffering from various types of TB constituted as study group (Group III). Tuberculin test with 5TU PPD-RT23 and BCG vaccine was given to all the children.

Out of 200 controls 100 (50%) had BCG scar and rest 100 (50%) had no scar. Table 1 shows almost equal male: female ratio in all groups. It was found that maximum number of patients was in class III and class IV (55%) socioeconomic status.

Table 2 shows pulmonary tuberculosis cases were maximum (56%). Tuberculous cases were more common in malnourished subjects more so with severe malnutrition. While maximum positivity 89% was obtained with BCG test, it was only 63% with Mantoux test, done with 5TU of PPD-RT-23.

Table 1: Age and gender distribution among participants.

Age (Year)	Group IA		Group IB		Total (%)	Group II	
	No.	%	No.	%		No.	%
< 1	5	5	5	5	5	6	6
1-3	30	30	35	35	32.5	34	34
>3	65	65	60	60	62.5	60	60
Female	48	48	46	46	94 (47)	44	44
Male	52	52	54	54	106 (53)	56	56

Table 2: Types of tuberculosis and nutritional status among study participants (n = 100).

Types	No.	%
Primary pulmonary tuberculosis	56	56
Military tuberculosis	10	10
Abdominal tuberculosis	10	10
CNS tuberculosis	12	12
Tuberculous lymphadenitis	12	12
Nutritional status		
Normal	25	25
Under-nutrition (Grade I and II)	35	35
Severe malnutrition	40	40

While frequency of BCG reaction was much higher than Mantoux test in all the types with p value less than 0.05, Mantoux was very low in military group (40%) and meningeal/CNS tuberculosis group (50%) as compared to other types of tuberculosis (Table 3).

Table 4 shows in tuberculous children the percentage of positivity with BCG and Mantoux are 89% and 63% respectively. It is noteworthy that percent positivity to BCG was significantly higher than to Mantoux test in the groups (I and II) but results within control group was not significant at all (p value > 0.05).

Table 3: Mantoux and BCG test in various types of tuberculosis.

Types of TB	Total no. of cases	Positive test	
		Mantoux test	BCG test
Primary pulmonary tuberculosis	56	37 (66.1%)	50 (89.2%)
Military tuberculosis	10	4 (40%)	8 (80%)
Abdominal tuberculosis	10	7 (70%)	9 (90%)
Meningeal/CNS tuberculosis	12	6 (50%)	10 (83.4%)
Tuberculous lymphadenitis	12	9 (75%)	12 (100%)

Table 4: Mantoux and BCG positivity in different groups.

Test	Group I A		Group I B		Group II	
	No. tested	% +ve	No. tested	% +ve	No. tested	% +ve
Mantoux test	100	5	100	3	100	63
BCG test	100	10	100	7	100	89

BCG test was found to be positive in almost equal frequency in well-nourished as well as in mild grades of malnutrition. But in severe malnutrition BCG positivity was comparatively less 75%. Mantoux positivity was reduced sharply in severe malnourished (III and IV) patients 40% as compared to well-nourished and mildly (I and II) malnourished (77-80%) patients (p value <0.001). BCG test results showed 100% positivity in class I and II whereas in class V it was only 71.4%. This difference was statistically significant (p value <0.05). Interestedly, positive results of both Mantoux and BCG test were reduced as social class was lowered, but still, BCG test positivity in class V 71.4% was significantly higher than Mantoux test (42.9%).

Table 5: Relation with BCG vaccination at birth in control group.

	Group I A (with BCG scar)			Group I B (no BCG scar)		
	<1 year	1-3 years	>3 years	<1 year	1-3 years	>3 years
No. of subjects	5	30	65	5	35	60
Mantoux test	1 (20%)	4 (13.3%)	-	-	-	3 (5%)
BCG test	2 (40%)	5 (16.7%)	3 (4.6%)	-	1 (2.9%)	6 (10%)
Group II						
	< 1 year		**1-3 years**		**>3 years**	
No. of subjects	6		34		60	
Mantoux test	4 (66.7%)		21 (61.7%)		38 (63.3%)	
BCG test	5 (83.3%)		30 (88.3%)		54 (90%)	

Induration after 72 hours was found to be most constant in all the patients showing positive reaction. Approx. 97.8% of cases with positive BCG reaction had induration of 10 mm or more. Of 63 Mantoux positive cases 815 had induration of 15 mm or more. In group I higher positive results were obtained in group I A than group IB. Again, of those showing positive reaction in group I, 87.5% had Mantoux induration of 10-14 mm and 88.2% had BCG induration of 5-9 mm (Table 7).

Table 6: Significance of events of BCG test (n = 100).

No. of cases	3rd day	2 weeks	Later
50	Induration	Ulceration	Crust
28	Induration	Nodule	Nil
11	Induration	Nil	Nil
11		No reaction	

Table 7: Size of Mantoux and BCG test reaction in various groups.

Group	No. of +ve cases	5-9 mm		10-14 mm		15-19 mm		>20 mm	
		No.	%	No.	%	No.	%	No.	%
Mantoux reaction									
I A	5	-	-	4	80	1	20	-	-
I B	3	-	-	3	100	-	-	-	-
II	63	-	-	12	19	20	31.5	31	49.5
BCG reaction									
I A	10	9	90	1	10	-	-	-	-
I B	7	6	85.7	1	14.3	-	-	-	-
II	89	2	2.2	50	56.2	30	33.6	7	8

Table 8: Relative frequency of various types of BCG reaction.

Group	No. of +ve cases	Accelerated 6-12 hours		Classical 24-72 hours		Delayed after 72 hours	
		No.	%	No.	%	No.	%
I A	10	1	10	9	90	-	-
I B	7	1	14.3	5	71.4	1	14.3
II	89	48	53.9	33	37	8	9.1

Table 8 shows that most of the BCG positive subjects in control group I had classical reaction 82.2% and accelerated reaction was found in 11.8% (2 cases). In group II most frequent was accelerated reaction 53.9% and this is statistically significant over control group 11.8% (p value <0.001).

Table 9: Correlation between Mantoux and BCG vaccination.

Test	No. of subjects	Accelerated	Not accelerated
Mantoux + ve	63	46 (73%)	17 (27%)
Mantoux - ve	37	2 (5.4%)	35 (94.6%)

Table 10 shows correlation between BCG and Mantoux in TB and non-TB cases. BCG was always positive whenever PPD was positive in any group of children. Sensitivity of Mantoux test was around 63% whereas that of BCG test was 89%. BCG test was more significantly associated with disease than tuberculin test (p <0.001).

Table 10: Correlation between PPD and BCG tests.

Test		Accelerated	Not accelerated
Mantoux +ve	63	46 (73%)	17 (27%)
Mantoux -ve	37	2 (5.4%)	35 (94.6%)

Table 11: Comparison of specificity and sensitivity of BCG and Mantoux tests.

	Mantoux 5 TU	BCG Test	Strength of association	P value
Sensitivity	63%	89%	0.0354	< 0.001
Specificity	96%	91.5%	0.0892	> 0.05

Sensitivity of BCG test was very much high (p value < 0.001) than Mantoux test. Specificity of the two tests was almost equal with no significant statistical difference. Again, highly significant strength of association was established statistically between the two tests.

DISCUSSION

A total of 300 children under 10 years of age were studied. Out of 200 healthy normal children those served as control, 100 children had BCG scar and 100 were not vaccinated.

One hundred children suffering from different types of tuberculosis constituted the study group. Each of these children was subjected to Mantoux test with 5TU PPD RT-23 with Tween 80 and BCG test with 0.1 ml of reconstituted BCG vaccine.

Maximum percentage of children from both control and study groups were of more than 3 years of age (60%). Slight male preponderance was found in both group I (53%) and group II (56%). Thus in 100 cases of tuberculosis percentage positivity with Mantoux test was 63% and that with BCG test was 89%. The high positivity rate of BCG test in comparison to Mantoux test has been observed by many workers in India (Udani et al, Desai et al, Lothe et al, Rupani et al, Aiyer et al, Choudhury et al, Dixit et al, Jaiswal et al, Bhambal et al and Kapoor RK et al.[11-20]

Severe types of tuberculosis i.e. military and meningeal type constituted 22% of cases. BCG test positivity was higher than Mantoux test in all types. The positivity of BCG test was significantly higher (p value <0.05) in 2 severe types of tuberculosis in comparison to Mantoux test positivity which was lesser than even other types of TB.

So, the real advantage of BCG test was seen in severe type of TB i.e. military and meningeal. BCG test was somewhat more sensitive in localized types of TB (than disseminated type, i.e. military and meningeal type) like, primary pulmonary TB, abdominal TB and tuberculous lymphadenitis. Advantage of BCG test in diagnosis of CNS tuberculosis has also been reported by many other workers (Udani, Parikh and Shah, Gupta and Agarwal, Choudhury, Singh and Verma, Dixit and Singh, Chandra et al.[11,13,16,17,21]

Among different types of tuberculosis in the present study, pulmonary tuberculosis was the most common among all age groups. Similar results were found in studies conducted by Rashid A (58%), Chandra (85%), Gh. Nabi (47.5%), and Bhandari et al (78%).[22,21,23,19] Many studies have demonstrated local impairment of afferent or sensitized limb of delayed hypersensitivity response in PEM.[24] The degree of immunological impairment parallels degree of PEM. Chandra has demonstrated numerical and functional deficiency of CD 4 and Helper cells in PEM which forms the basis of the clinical manifestations of PEM.[25] Hence children below 5 years of age, despite being vaccinated, on becoming malnourished and getting exposed to infectious cases, develop tuberculosis in a moderately severe form. In a hospital-based study, the authors have shown the result of BCG vaccination in malnourished children. Classical or generalized tubercular meningitis, miliary tuberculosis, disseminated form, and serious complications of primary go on occurring in malnourished BCG vaccinated children.[26] The present study also showed a much higher positivity of BCG test in children with TB (89%) as compared to Mantoux (63%) and it seemed that BCG test was more helpful in diagnosis than Mantoux test. It can be seen from our study results that BCG positivity also occurred in healthy controls (10% in group IA and 7% in group IB) with an overall 8.5% positivity. Comparative figures for Mantoux test were 5%, 3% and 4% respectively. A similar positivity rate of healthy control children has been reported by Mehta and Saini, Bhandari et al, Agarwal etc.[27,19,13] Hence these cannot be interpreted only as active infection. At best it can only serve as an indicator for present/prior tuberculosis infection.

In the present study around 50% of children below 10 years were vaccinated with BCG vaccine at birth or in infancy. It is possible that with expanded programme on immunization BCG coverage will increase to more than 90%. Hence, it is desirable to carry out studies to evaluate BCG and Mantoux test in vaccinated children.

In the control group with BCG scar had positive Mantoux and BCG reaction of 5% and 10% respectively as compared to 3% and 7% respectively in unvaccinated control group. There was an overall excess Mantoux and BCG reaction of 4% and 8.5% respectively. After 3 years none of the children were Mantoux positive whereas BCG positivity was seen in 4.6%. A similar picture has been put forward by a group of expert in TB prevention trial in 1979.[28] They have observed that cutaneous sensitivity induced by BCG vaccination waned after 2.5 years. So, from the result of present study it may be seen that amongst tuberculin positive cases 100% of Mantoux positivity and 70% of BCG positivity may be attributed to prior BCG vaccine.

Bhandari et al (1984)[19] in a study of 600 healthy control children found that accelerated BCG was positive in 6.5% and tuberculin test was positive in 2.83%. Thus, accelerated BCG reaction was found in little more percentage of children than positive tuberculin reaction. Agarwal (1973)[13] found that in asymptomatic control children BCG was accelerated or positive in 5.88% while tuberculin test was positive in 3.29%. These studies have been evaluated statistically and it was emphasized that direct BCG with accelerated response does not give false positive reactions i.e. does not produce positive BCG reaction in non-infected children. In a series of 100 children with non-tuberculous illness Jaiswal and Bhandari (1976)[18] found that TT was positive in 11% and negative in 89% while BCG was positive in 22.2%. This again points out that in some of this non-tuberculous illness, BCG test is likely to bring out more cases of tuberculous infection which may need further studies to decide whether the later is active or quiescent. Desai et al[12] reported that 72 out of 450 (16%) normal children had positive BCG test, while Aiyer et al[15] had positive BCG test in 25% of non-tuberculous healthy control.

In the present study, 17 (8.5%) of 200 non-tuberclous children had a positive BCG test. Comparable figure for Mantoux test was 8 (4%). This finding suggests the fact

that a positive BCG test indicates a prior tuberculous infection and not necessarily active disease. In tuberculous children out of 89 BCG positive cases 2 (2.2%) had induration of 5-9 mm and 87 (97.8%) had induration of 10 mm or more. In a similar study in two groups of children, Study found that BCG produced a significantly larger induration (14 mm or more) in tuberculin reactors than in non-reactors. In tuberculous children out of 63 Mantoux positive cases, 12 (19%) had induration of 10-14 mm and 41 (81%) had induration of 15 mm or more.[29] Various workers while reporting on size of induration related to active infection observed that 80% of cases of active tuberculosis are associated with TT reaction of 15 mm or more (Medical Research Council 1949-50).

So it seem probable that, though ≥5 mm BCG or ≥10 mm Mantoux are taken as positive criteria for tuberculosis, large BCG reaction (≥ 10 mm) and Mantoux reaction (≥15 mm) are more significantly related to active infection (BCG 97.8% of cases as against 11.8% of controls and Mantoux 81% of cases as against 12.5% of controls (p value <0.001). Present study showed that BCG test to be more sensitive in tuberculosis diagnosis as compared to Mantoux test (p <0.001).

Again, specificity of two tests was same practically and both the tests were significantly associated with diagnosis of childhood tuberculosis (strength of association 0.0354 and 0.0892 for sensitivity and specificity respectively). So, BCG test was established as a much superior test over Mantoux test. Although some studies reported BCG test as less specific (Aiyer et al, Jaiswal et al), most of the workers have established that BCG test is as specific as Mantoux test (5 TU) and at the same time more sensitive in diagnosis of tuberculosis (Udani; Desai et al, Lothe et al; Dixit et al, Chandra et al, Narain R et al; Datta et al) which is in conformity of our findings.[15,18,30,12,13,17,21,31,32]

CONCLUSION

The present study was undertaken to compare the utility of BCG and Mantoux in the diagnosis of tuberculosis. Tuberculosis was found to be more commonly associated with malnutrition of different grades than with children with normal nutritional status. It was found to be more common in lower socio-economic class.

Mantoux test was positive in 63% of cases as against 89% positivity with BCG test. So, BCG was found to be superior than Mantoux test (p value <0.001; strength of association 0.354). BCG test was found to be more significant in the diagnosis of all the different types of tuberculosis than Mantoux test. But it was highly positive in military and meningeal disease as compared to other types of tuberculosis. BCG test is a very sensitive and specific test for diagnosis of childhood tuberculosis. Mantoux test is affected by malnutrition and severity of disease whereas BCG test is affected only minimally. BCG test is more sensitive than Mantoux test (with 5TU PPD RT 23 Tween 80). A BCG induration of ≥10 mm or Mantoux induration ≥15 mm or an accelerated BCG test is indicative of active disease, irrespective of vaccination status of the patient.

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