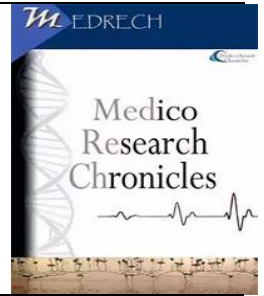




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Presumptive Tuberculosis In Children Below 12 Years At Tertiary Care Rural Hospital

Dr. Sakthi. D, Dr. Bhagyashree Bora, Dr. Jayashree Jadhav

1. Post Graduate, Department of Paediatrics, Pravara Institute of Medical Sciences, DU Loni.

2. Professor, Department of Paediatrics, Pravara Institute of Medical Sciences, DU Loni

3. Professor and HOD, Department of Paediatrics, Pravara Institute of Medical Sciences, DU Loni

ARTICLE INFO	ABSTRACT	ORIGINAL RESEARCH ARTICLE
Article History Received: November 2024 Accepted: January 2025 Key Words: Tuberculosis, Children, NTEP 2020, Malnutrition, Mantoux Test, CBNAAT, Rural Hospital, Clinical Profile	Background: Tuberculosis remains a significant public health challenge, particularly affecting children in India with an estimated 2.2 lakh cases annually. The clinical presentation of tuberculosis in pediatric populations differs markedly from adults, presenting unique diagnostic challenges. This study aimed to investigate presumptive tuberculosis in children below 12 years at a tertiary care rural hospital following the NTEP 2020 protocol. Objectives: 1. To diagnose tuberculosis according to NTEP 2020 protocol 2. To study the clinical profile and nutritional status of these patients 3. To identify confirmed cases of tuberculosis from presumptive cases Materials & Methods: We conducted an observational, descriptive cross-sectional study of 120 patients over two years (June 2022 - May 2024) at a tertiary care rural hospital. Children presenting with persistent fever or cough exceeding two weeks, significant weight loss, or contact history with pulmonary TB patients were enrolled. A standardized study proforma captured detailed clinical information. Comprehensive evaluation included anthropometric measurements, laboratory investigations, tuberculin testing, radiological assessment, and microbiological studies following NTEP 2020 guidelines. Results: Among 120 children with presumptive tuberculosis, 75 (62.5%) were confirmed cases. The majority (86.66%) of confirmed cases occurred in children under five years. Males showed higher prevalence (65.33%) compared to females. Persistent cough was the predominant symptom (82.66%), followed by fever (57.33%). Severe acute malnutrition was present in 46.77% of confirmed cases aged 6 months to 5 years. Hilar lymphadenopathy was the most common radiological finding (76%). Mantoux test positivity was observed in 33.33% of confirmed cases. Pulmonary tuberculosis constituted 94.66%	

Corresponding author
Dr. Sakthi D.*

of confirmed cases, while 5.33% presented with extrapulmonary manifestations.

Conclusion: Implementation of the NTEP 2020 protocol demonstrates effectiveness in early tuberculosis detection among children. The strong association between malnutrition and tuberculosis emphasizes the need for systematic TB screening in malnourished children. The study supports a comprehensive diagnostic approach combining clinical, radiological, and microbiological criteria, particularly focusing on children under five years who represent the most vulnerable group.

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INTRODUCTION

Tuberculosis (TB) remains a major global health challenge, particularly affecting children in developing countries. It is a chronic infectious disease that can involve any organ system, with an estimated 2.2 lakh children affected annually in India alone [1]. Despite significant advances in diagnosis and treatment, childhood tuberculosis continues to pose unique challenges due to its paucibacillary nature and non-specific clinical presentation [2,3].

The clinical manifestation of tuberculosis in children differs markedly from adults, making it particularly challenging to diagnose and manage. Children are more likely to develop extrapulmonary TB and severe disease forms, with shorter latency periods and a greater risk of disease progression following infection compared to adults [4]. The collection of diagnostic samples is often more difficult in children, and the disease tends to be paucibacillary, further complicating accurate diagnosis [5].

In India, the prevalence of primary tubercular infection in the pediatric population is concerning, with an annual risk of tubercular infection of 1.5%. By age 16, approximately 40% of children acquire infection, and nearly 10% of these eventually develop active disease [6]. Of particular concern is that 5% of infected children are expected to develop tuberculosis within the first two years of life, creating a substantial pool of infected children that ensures TB will

remain a significant public health challenge for the foreseeable future [7].

The implementation of the National Tuberculosis Elimination Programme (NTEP) 2020 protocol has brought a structured approach to diagnosing presumptive TB in children. Under this protocol, presumptive TB refers to children suspected of having TB based on persistent fever for more than two weeks, cough lasting more than two weeks, significant weight loss ($\geq 5\%$ in three months), or failure to gain weight despite adequate nutrition [8,9].

Undernutrition serves as a serious comorbidity in patients with active TB in India, increasing the risk of severe disease, drug toxicity, drug malabsorption, and relapse after cure [10]. This relationship between nutritional status and TB creates a particularly challenging situation in rural settings, where both malnutrition and tuberculosis are often prevalent [11].

This study aims to investigate the clinical profile, nutritional status, and diagnostic aspects of presumptive tuberculosis in children below 12 years at a tertiary care rural hospital, following the NTEP 2020 protocol. Understanding these patterns and relationships is crucial for improving early detection and appropriate management of pediatric tuberculosis in rural settings, where resources may be limited and challenges in diagnosis and treatment are often magnified [12].

MATERIALS AND METHODS

Study Design and Setting

An observational, descriptive cross-sectional study was conducted at the Departments of Pediatrics and Pulmonology at a tertiary care rural hospital in Loni, Maharashtra, from June 2022 to May 2024. The study was approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants' guardians [13].

Study Population

Children below 12 years of age presenting with presumptive tuberculosis were enrolled based on the NTEP 2020 protocol criteria [14]. The inclusion criteria comprised:

- Persistent fever for more than 2 weeks
- Persistent cough for more than 2 weeks
- Weight loss of 5% in 3 months or no weight gain despite adequate nutrition
- History of contact with pulmonary tuberculosis patients

Children previously diagnosed with tuberculosis were excluded from the study to avoid confounding factors in the assessment.

Clinical Assessment

A detailed clinical history was obtained using a standardized proforma, including information about immunization status, socioeconomic background, and family history of tuberculosis [15]. Physical examination findings were systematically recorded, with particular attention to anthropometric measurements and the presence of lymphadenopathy.

Anthropometric Measurements

Height and weight measurements were performed by a single observer to ensure consistency. A stadiometer was used for measuring height in children older than 2 years, while an infantometer was used for those under 2 years. Weight was recorded using a calibrated electronic weighing machine [16]. Mid-upper arm circumference (MUAC) was measured for children aged 6 months to 5 years using standardized techniques [17].

Nutritional Assessment

Nutritional status was classified according to WHO criteria [18]. For children aged 6 months to 5 years, malnutrition was categorized as:

- Moderate Acute Malnutrition (MAM): MUAC 11.5-12.4 cm
- Severe Acute Malnutrition (SAM): MUAC <11.5 cm

For children aged 6-12 years, BMI-for-age percentiles were used to assess nutritional status [19].

Laboratory Investigations

Blood samples were analyzed for complete blood count, liver function tests, ESR, and CRP. HIV testing was performed after appropriate counseling. CSF examination, including gram staining and ZN staining, was conducted when clinically indicated [20].

Tuberculin Skin Testing

The Mantoux test was administered using 0.1 mL of purified protein derivative (PPD) injected intradermally into the volar surface of the forearm. The test was read after 48-72 hours, with induration ≥ 10 mm considered positive in normal nutritional status and >5 mm considered positive for SAM children [21].

Radiological Evaluation

Chest radiographs were obtained for all patients and independently evaluated by two expert radiologists. Additional imaging studies including ultrasonography and MRI were performed when clinically indicated [22].

Microbiological Testing

Samples for microbiological confirmation were collected as appropriate for each case. These included:

- Gastric lavage in children unable to expectorate
- Induced sputum in children over 5 years
- CBNAAT (Cartridge Based Nucleic Acid Amplification Test) testing on appropriate specimens [23]

Fine Needle Aspiration Cytology (FNAC) was performed in cases with significant lymphadenopathy, with samples processed for cytological examination and ZN staining [24].

Data Analysis

Data were recorded in a pre-designed case proforma and analyzed using appropriate statistical tests. Categorical variables were expressed as frequencies and percentages, while continuous variables were expressed as mean $\pm$ standard deviation. Chi-square test was used for comparing categorical variables,

with $p < 0.05$ considered statistically significant [25].

The study followed the diagnostic algorithm for pediatric tuberculosis as per NTEP 2020 guidelines, ensuring a standardized approach to patient evaluation and diagnosis [26].

RESULTS

Demographic and Clinical Characteristics

Among 120 children with presumptive tuberculosis evaluated during the study period, 75 (62.5%) were confirmed to have tuberculosis, while 45 (37.5%) were not confirmed cases (Table 1).

Table 1: Distribution of Tuberculosis Cases

Category	Number	Percentage
Confirmed TB	75	62.5%
Not Confirmed	45	37.5%
Total	120	100%

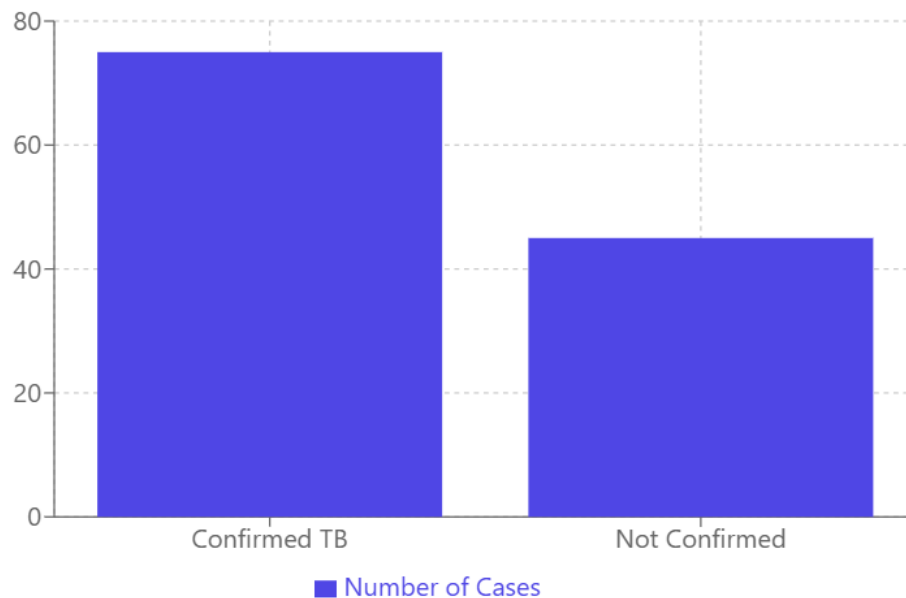


Fig 1: Distribution of confirmed vs not confirmed cases

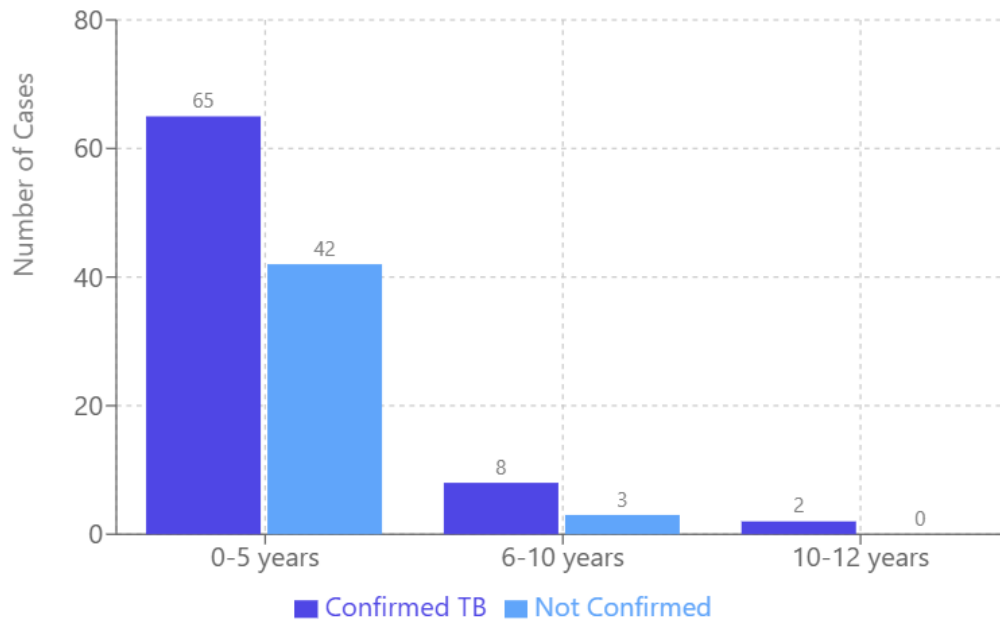
Age Distribution

The majority of cases (89.16%) were in the 0-5 years age group. In confirmed TB cases, 86.66% were aged 0-5 years, 10.66%

were 6-10 years, and 2.66% were 10-12 years. The age distribution showed no statistically significant difference between confirmed and unconfirmed cases ($p=0.4$) (Table 2).

Table 2: Age Distribution of Cases

Age Group	Confirmed TB (n=75)	Not Confirmed TB (n=45)	Total (N=120)
0-5 years	65 (86.66%)	42 (93.33%)	107 (89.16%)
6-10 years	8 (10.66%)	3 (6.66%)	11 (9.16%)
10-12 years	2 (2.66%)	0	2 (1.66%)

**Fig 2:** age distribution between confirmed and not confirmed cases**Gender Distribution**

Males comprised 60.83% of total cases, with a higher proportion in confirmed TB (65.33%) compared to unconfirmed cases (53.33%). The gender difference was not statistically significant ($p=0.16$) (Table 3).

Clinical Manifestations

Among confirmed TB cases, cough >2 weeks was the most common symptom (82.66%), followed by fever >2 weeks (57.33%), and weight loss (9.33%). The difference in clinical manifestations between confirmed and unconfirmed cases was statistically significant ($p=0.004$) (Table 4).

Table 4: Clinical Manifestations

Symptoms	Confirmed TB (n=75)	Not Confirmed TB (n=45)	p-value
Cough >2 weeks	62 (82.66%)	25 (55.55%)	0.004
Fever >2 weeks	43 (57.33%)	29 (64.44%)	
Weight loss	7 (9.33%)	14 (31.11%)	

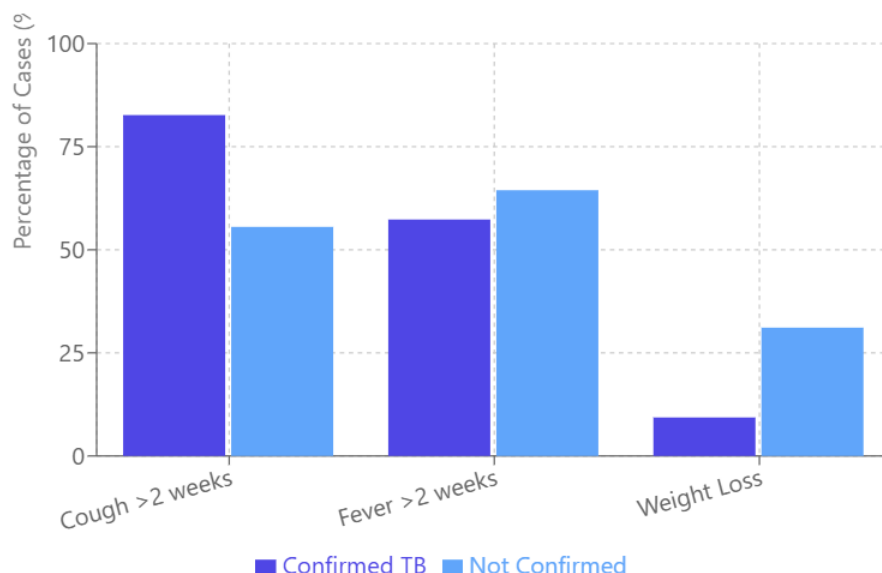


Fig 4: Clinical Manifestations in TB Cases

Nutritional Status

In the age group 6 months to 5 years, among confirmed TB cases:

- SAM: 46.77%
 - MAM: 30.64%
 - Normal: 22.59%
- The association between nutritional status and TB was statistically significant ($p=0.002$).

Laboratory Parameters

Mean hemoglobin levels were similar between confirmed (9.62 ± 2.39 g/dL) and unconfirmed cases (9.43 ± 2.09 g/dL). Total leukocyte count was higher in confirmed cases

($15.99 \pm 11.65 \times 10^3/\mu\text{L}$) compared to unconfirmed cases ($13.22 \pm 11.85 \times 10^3/\mu\text{L}$).

Radiological Findings Among confirmed cases:

- Hilar lymphadenopathy: 76%
 - Primary Ghon focus: 8%
 - HLN-doughnut sign: 6.66%
 - Miliary tuberculosis: 5.33%
 - Pleural effusion: 1.33%
- The radiological findings showed statistically significant differences between confirmed and unconfirmed cases ($p<0.001$).

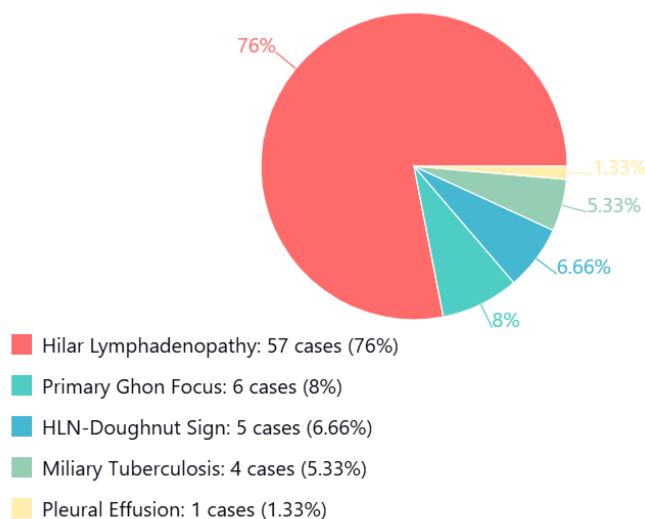


Fig 5: Distribution of Radiological Findings

Diagnostic Tests

- Mantoux test was positive in 33.33% of confirmed cases ($p < 0.01$)
- CBNAAT was positive in 10.6% of tested samples
- The positivity rate for gastric aspirate CBNAAT was statistically significant ($p = 0.03$)

Types of Tuberculosis Among confirmed cases:

- Pulmonary TB: 71 cases (94.66%)
- Extra-pulmonary TB: 4 cases (5.33%)
 - TB lymphadenitis: 2 cases
 - Tuberculous meningitis: 1 case
 - Tuberculous pleural effusion: 1 case

DISCUSSION

This study evaluated presumptive tuberculosis in children below 12 years at a tertiary care rural hospital, following the NTEP 2020 protocol. The study revealed several important findings that merit discussion in relation to existing evidence.

Diagnostic Yield and Age Distribution: Our study found a tuberculosis confirmation rate of 62.5% among presumptive cases, which is notably higher than rates reported by Moreto *et al.* (19%) [27] and Raizada *et al.* (12.8%) [28]. This higher yield might be attributed to our strict adherence to the NTEP 2020 diagnostic algorithm and the study's setting in a high-burden rural area. The predominance of cases in children under 5 years (86.66% of confirmed cases) aligns with findings by Verma *et al.* (77.9%) [29], reflecting the increased vulnerability of this age group to tuberculosis infection and disease progression.

Clinical Manifestations: Persistent cough exceeding two weeks was the most prevalent symptom (82.66%) in confirmed cases, consistent with findings by Bhanu *et al.* (72%) [30]. However, our observation of fever in 57.33% of cases was lower than reported by Tripathi *et al.* (85%) [31], possibly due to variations in case definitions and study

populations. The significant association between clinical manifestations and confirmed TB ($p = 0.004$) underscores the importance of systematic symptom screening in pediatric TB diagnosis.

Nutritional Status and TB: A striking finding was the high prevalence of severe acute malnutrition (46.77%) among confirmed TB cases aged 6 months to 5 years, with an additional 30.64% having moderate acute malnutrition. This association between malnutrition and TB is stronger than reported by Moreto *et al.* (59.3% SAM) [32] and confirms the bidirectional relationship between nutritional status and tuberculosis susceptibility described in previous studies [33, 34].

Radiological Patterns: The predominance of hilar lymphadenopathy (76%) in our confirmed cases significantly exceeds rates reported by Lopez *et al.* (17.1%) [35] and Tripathi *et al.* (17.5%) [31]. This higher detection rate might be attributed to our use of standardized radiological interpretation criteria and the involvement of multiple expert readers. The observation of miliary pattern in 5.33% of cases is comparable to previous studies and represents the more severe end of the disease spectrum.

Diagnostic Modalities: The Mantoux test positivity of 33.33% in confirmed cases is lower than reported by Anuradha *et al.* (68.5%) [36], possibly reflecting the high proportion of malnourished children in our study population, as malnutrition can suppress tuberculin reactivity. The CBNAAT positivity rate of 10.6% aligns with the known paucibacillary nature of pediatric TB but is higher than reported by Tripathi *et al.* (6.2%) [31], suggesting improved sampling techniques.

Disease Pattern: The predominance of pulmonary TB (94.66%) in our study differs markedly from previous reports by Verma *et al.* [29] and Tripathi *et al.* [31], who found

higher proportions of extra-pulmonary TB. This variation might reflect differences in referral patterns and diagnostic approaches, though our finding emphasizes the importance of thorough pulmonary evaluation in presumptive TB cases.

Contact History and Transmission: History of TB contact was present in 28% of confirmed cases, comparable to findings by Malik *et al.* (26.6%) [37] but lower than reported by Moreto *et al.* (51.9%) [32]. This reinforces the challenge of establishing definitive exposure history in pediatric TB and suggests the possibility of unidentified community transmission.

Laboratory Parameters: The high prevalence of anemia (mean Hb 9.62 g/dL) in confirmed cases aligns with findings from Shelke *et al.* [38] and underscores the importance of considering TB in the differential diagnosis of unexplained anemia in children from endemic areas.

Study Limitations and Strengths: The single-center nature of our study might limit its generalizability, though the rural setting and comprehensive evaluation protocol provide valuable insights into TB diagnosis in resource-limited settings. The prospective design and standardized diagnostic approach according to NTEP 2020 guidelines strengthen the validity of our findings.

CONCLUSION

The implementation of the NTEP 2020 protocol proves to be an effective framework for early detection of tuberculosis in children, with our study demonstrating a significant diagnostic yield of 62.5% among presumptive cases. This underscores the protocol's value in resource-limited rural settings.

A crucial finding is the strong association between malnutrition and tuberculosis, with over three-quarters of confirmed cases in children aged 6 months to 5 years showing either moderate or severe acute malnutrition. This highlights the critical need for integrating nutritional assessment and

support into pediatric TB management programs.

The predominance of pulmonary tuberculosis (94.66%) in our study population emphasizes the importance of thorough respiratory evaluation in presumptive cases. The high prevalence of hilar lymphadenopathy (76%) on chest radiography reinforces the value of systematic radiological assessment in pediatric TB diagnosis.

Clinical manifestations, particularly persistent cough exceeding two weeks, prove to be reliable indicators for tuberculosis screening. However, the relatively low sensitivity of individual diagnostic tests, including Mantoux (33.33%) and CBNAAT (10.6%), reinforces the necessity of a comprehensive diagnostic approach rather than relying on single parameters.

The significant burden of disease in children under five years (86.66% of confirmed cases) calls for intensified case finding and preventive strategies targeting this vulnerable age group. This becomes particularly relevant in rural settings where early diagnosis may be challenging.

Our findings strongly support three key recommendations:

1. Every malnourished child should be systematically screened for tuberculosis, regardless of their presenting symptoms.
2. The combination of clinical, radiological, and microbiological criteria, as outlined in the NTEP 2020 protocol, should be consistently applied to optimize diagnostic accuracy in pediatric TB.
3. Early intervention strategies should be prioritized, particularly focusing on children under five years and those with compromised nutritional status.

These conclusions contribute to the growing body of evidence supporting structured approaches to pediatric TB diagnosis and highlight the continuing

challenges in detecting and managing tuberculosis in children, particularly in rural settings. The findings emphasize the need for sustained efforts to strengthen pediatric TB control programs while maintaining a high index of suspicion for TB in malnourished children.

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