International Journal of Pharmaceutical and Clinical Research 2022; 14(1);393-398

**Original Research Article** 

# A Hospital Based Cross Sectional Study to Evaluate the Clinic-Demographic Profile of Pediatric Tuberculosis Detected by CBNAAT

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Received: 01-11-2021 / Revised: 29-11-2021 / Accepted: 08-01-2021 Corresponding author: Dr. Amit Kumar Conflict of interest: Nil

#### Abstract

**Aim:** A cross sectional study of in-hospital cases of Pediatric Tuberculosis detected by CBNAAT at teaching hospital in Bihar region.

**Methods:** This observational cross-sectional study was carried out in the Department of Pediatrics, Darbhanga Medical College and Hospital, Laheriasarai, Darbhanga, Bihar, India, for 1 year, after taking the approval of the protocol review committee and institutional ethics committee. The study was carried out by analyzing the clinical & laboratory data of 100 patients treated with ATT.

**Results:** Data of a total of 100 patients were analyzed. Male: female ratio was almost equal i.e., 1:1 (Male-50, Female 50). 90 patients were below the poverty line. 65% of the patients were from rural areas. 82% of patients had a tubercular contact history in the family and almost the same percentage (83%) households had a history of smoking in family members. 72% had a reactive tuberculin test. All the patients were non-reactive on HIV Screening. In 26% of cases gastric aspirate was sampled and near about (11.53%) turned reactive for tuberculosis by CBNAAT. Out of 74 sputum samples from children more than five years of age. 40% of overall collected samples were reactive to CBNAAT testing for tuberculosis at this centre. None of the pediatric samples was positive for MDR TB. 57% of children completed treatment and 35% were declared cured.

**Conclusion:** This study concludes with 40% positivity after CBNAAT testing for tuberculosis infection in collected samples of sputum and gastric aspirate where only 11.53% yield in GA samples. Because of the WHO End TB strategy, there is a need to implement standard procedures for sampling methods to increase yield in collected samples for diagnosis of Pediatric tuberculosis and improve contact tracing with the available diagnostic tools.

Keywords: Pediatric TB, CBNAAT, Gastric aspirate, Sputum

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#### Introduction

Tuberculosis is an infectious disease that has plagued humans since the Neolithic times with the earliest reported case dating back to5000 B.C [1]. In the year 2016, there were an estimated 10.4 million new cases of TB which included 5.9 million men

and 3.5 million women and 1.0 million children with an estimated 14 lakh TB deaths [2]. In developing communities with a large proportion of the population younger than 15 years of age, a high disease incidence is observed in young children. In a study conducted at Tuberculosis Research Centre, Chennai over a 15-year period the annual risk of TB infection was seen to be 2% [3]. With an annual risk of infection of 2-3%, close to 40% of the population may be infected by the age of fifteen [4]. Children are poor producers of sputum and in children especially <7 years old, it is a challenge to obtain good smear samples for AFB. The co-infection of HIV and TB is difficult to treat and has high mortality and morbidity. The bacteriological diagnosis of active TB in adults is comparatively easier when compared to children due to its paucibacillary nature and symptoms in both differ creating difficulty in diagnosis. In 2013, WHO recommended the use of Gene Xpert MTB/RIF to diagnose Pediatric TB and Rifampicin resistance along with clinical profile for ease of diagnosis [5,7].

## Material and methods

This observational cross-sectional study was carried out in the Department of Pediatrics, Darbhanga medical college and Hospital, Laheriasarai, Darbhanga, Bihar, India, for 1 year, after taking the approval of the protocol review committee and institutional ethics committee. The study was carried out by analyzing the clinical & laboratory data of 100 patients treated with ATT.

## **Inclusion criteria**

Pediatric patients of age ranging from six months to 18 years who were diagnosed with Tuberculosis by Cartridge Based Nucleic Acid Amplification (CBNAAT) test done by GeneXpert (Cepheid-2013) and were treated with anti-tuberculosis therapy (ATT) at the study centre.

## **Exclusion criteria**

Patients out of age criteria and not registered for ATT in DTC Data were excluded.

## **Statistical Analysis**

Statistical analysis was done using a Microsoft Excel spreadsheet.

## Results

Data of a total of 100 patients were analyzed. Male: female ratio was almost equal i.e. 1:1 (Male-50, Female 50). 90 patients were below the poverty line. 65% of the patients were from rural areas. 82% of patients had a tubercular contact history in the family and almost the same percentage (83%) households had a history of smoking in family members. 72% had a reactive tuberculin test. All the patients were non-reactive on HIV Screening. (Table 1) In 26% of cases gastric aspirate was sampled and only (11.53%) turned reactive for tuberculosis by CBNAAT. Out of 74 sputum samples from children more than five years of age. 40% of overall collected samples were reactive to CBNAAT testing for tuberculosis at this centre. None of the pediatric samples was positive for MDR TB. 57% of children completed treatment and 35% were declared Age-wise cured. sampling distribution has been shown in Table-2

#### Table 1: Distribution of studied cases according to general profile, sampling and results

Parameters	No.	Percentage (n=100)			
Age-wise distribution					
6-12 months	5	5			
1-5 years	13	13			
5-10 years	13	13			

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10-18 years	64	64					
Sex wise distribution							
Male	50	50					
Female	50	50					
Cast wise distribution							
General	7	7					
OBC	50	50					
SC	38	38					
ST	5	5					
Religion wise distribution							
Hindu	90	90					
Muslim	10	10					
Financial condition wise distribution							
APL	10	10					
BPL	90	90					
Area wise distribution							
Rural	65	65					
Urban	35	35					
Occupation wise distribution							
Labourer	67	67					
Farmer	28	28					
Service class	3	3					
Business	2	2					
Status of smoking in family							
Yes	83	83					
No	17	17					
History of contact							
Yes	82	82					
No	18	18					
HIV screening	100%	100%					
Mantoux test Reactive	74	74					
Type of sample							
Sputum	74	74					
Gastric aspirate	26	26					
CBNAAT results							
Reactive	40	40					
Test results							
Treatment completed	57	57					
Treatment after default	8	8					
Cured	35	35					

	6 to 12 months	>1 -5 years	>5-10 years	>10-18 years
Gastric aspirate	4	12	7	3
Sputum	00	00	10	64

 Table 2: Distribution of studied cases according to sampling results in different age groups.

# Discussion

This Record based study was undertaken to identify the epidemiology of tubercular infection in children diagnosed with a modern available modality like CBNAAT in the Datia district of central India.

During the study period, total tubercular patients notified were 46,00,811 in India and 3,59,284 in Madhya Pradesh alone, including both from the public as well as the private sector [8]. This study observed that 82% of children diagnosed with TB were having contact history in the family. About the above-mentioned data, Pediatric TB may have more hidden cases which are not reaching the health facility. In a recent study, TB screening for the child contacts of adult cases is not being done in the routine as a result many of the active TB cases in children may be missed. So, timely TB screening is imperative to reduce the burden of pediatric TB in India [9].

In a prospective study conducted on 223 Children with TB, they were found more likely to be HIV positive, TST positive, reside in rural areas, exposed to biomass cooking fuel, and have a mother with less than primary school education [10]. In our study we found none of the child with HIV infection on screening but 66% were from rural areas and 72% were tuberculin reactive. 83% of children diagnosed had exposure to smoke in the household. Other important contributing factors to the global resurgence of ΤB include poverty, overcrowding, increased travel. immigration, inadequate implementation of control programmes, multidrug-TB resistant TB (MDR TB) and incomplete treatment [11]. This study revealed that more than 90% patients were below the poverty line suggesting a direct relationship of TB with poor financial and poor hygienic conditions of the children in such families.

The most important and revolutionary development in TB diagnostics is the Xpert MTB/RIF assay. This is a fully automated real-time DNA based test that can detect both TB and resistance to rifampicin in less than 2 hours [7]. The revised National Programme Tuberculosis Control (RNTCP) which is now renamed as National Tuberculosis Elimination Programme (NTEP) has introduced Xpert facility at every district level of the country [8]. Xpert MTB/RIF has a high sensitivity of 95% and specificity of 99% for detecting MTB in pulmonary samples of patients with TB.

The sensitivity of Xpert MTB/RIF for detecting smear-negative, culture-positive samples is 78%; its sensitivity for detecting smear-positive, culture- positive samples is 99%. The sensitivity and specificity for detecting rifampicin resistance is 94% and 97% respectively concerning culture as the reference standard [12].

Whilst adult TB cases are often easily recognizable, due to typical radiological features and a positive sputum smear, childhood TB is frequently more difficult to diagnose. The clinical and radiological features of childhood TB are often nonspecific and subject to variable interpretation [13]. In primary care settings, microbiological confirmation of PTB is still rarely attempted in children.

This is due to the incorrect perception that respiratory specimens are difficult or impossible to obtain in children, the lack of infrastructure or trained staff to obtain such

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specimens and the lack of policy regarding microbiological confirmation in children. However, the yield of direct acid-fast smear microscopy is also very low since the disease is typically paucibacillary.14 A meta-analysis of 15 studies, including 3,640 children, demonstrated a sensitivity of Xpert for TB detection of 62% using expectorated or induced sputum, and a sensitivity of 66% using samples from gastric lavage [15]. This study result shows 74% yield from sputum samples but only 26% reactive from the gastric aspirate. Proper sampling technique, sample transportation and timely processing need to be evaluated separately. A study from Brazil also pointed out the need to standardize gastric lavage protocols for the diagnosis of pulmonary tuberculosis in children [16]. In a study carried out to assess the utility of Xpert assay, out of the 210 gastric aspirate samples, 34 (16.19%) were positive by Xpert assay. For a sample to be positive, 131 CFU/ml of bacilli is required by GeneXpert [17] There is importance of screening the samples by ZN staining and then confirming the diagnosis by culture, as GeneXpert cannot detect the Non-Tuberculous Mycobacteria (NTM) species which is needed to be evaluated further at study centre as it is observed that the overall yield of tubercular infection detected by Xpert is 42% including both sputum and GA samples but rest of the children were clinically diagnosed as tubercular and were treated accordingly.

## Conclusion

This study concludes with 40% positivity after CBNAAT testing for tuberculosis infection in collected samples of sputum and gastric aspirate where only 11.53% yield in GA samples. Because of the WHO End TB strategy, there is a need to implement standard procedures for sampling methods to increase yield in collected samples for diagnosis of Pediatric tuberculosis and improve contact tracing with the available diagnostic tools.

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