

## ORIGINAL RESEARCH ARTICLE

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# **Epidemiological Profile and Treatment Outcome of Childhood Tuberculosis Patients in Pune City**

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## **ABSTRACT**

**Background:** Tuberculosis (TB) is a major public health problem in India. According to the Global TB Control Report 2012, the incidence of childhood TB is estimated at 191 per 100 000 population. Childhood TB (for children aged <15 years) is generally considered to be a good marker of transmission in the community. The present study was undertaken to analyse the epidemiological and clinical characteristics of childhood TB patients and the interrelationship with the treatment outcome.

**Methodology:** This prospective study was carried out on 198 patients in the age group of 0-14 years registered in all the Tuberculosis units of Pune city. All clinical information was extracted from the treatment cards and TB registers.

**Results:** 39.4% were males, 40% were aged <5 years, 80 (40.4%) had extra-pulmonary involvement and the remaining 118 were pulmonary TB patients of whom 42 (35.6%) were smear positive. Overall cured and treatment completion rate was 185(93.5%). Poor treatment outcome was reported in 10(5%) patients.7 (3.5%) patients defaulted. 3 (1.5%) failure to treatment were reported.

**Conclusion:** Childhood TB in high burden countries requires far more attention from the researchers and TB control staff. The best means of preventing TB in childhood is by control of adult TB.

Key words: Childhood TB, treatment outcome, RNTCP

## **INTRODUCTION**

Tuberculosis (TB) remains the number one killer infectious disease in developing tries<sup>1,2</sup>. Childhood tuberculosis (TB) has traditionally had a lower priority than adult TB within National TB Programmes (NTPs), because it is largely non-infectious, cases have been thought to be few, and the assumption that effective control of adult TB could prevent childhood TB.3 In many countries with high TB incidence, however, childhood TB (i.e., TB among the population aged less than 14 years) constitutes a significant proportion (approximately 11-14%) of the TB case-load and under-5 mortality. Of the estimated 9.3 million annual incident TB cases in the world, at-least 1.5 million are estimated to be less than 14 years of age. 2,3

Children are susceptible to infection with *M. tuber-culosis* in the community, at greater risk of progressing to active disease when infected at a very young age and there are also well-documented cases of children acting as a source of infection within a community. These considerations justify a focus on the proper analysis of childhood TB programmes for the control of TB.WHO has recently called for more studies to define the global epidemiology of childhood TB, because the literature remains scant, dominated primarily by studies from industrialized countries and South Africa. Few epidemiologic studies of pediatric TB have been published from Asia.<sup>3</sup>

Routinely reported data do not capture comprehensive information on treatment outcomes and associated characteristics. This study was therefore undertaken to describe the profile of childhood TB cases registered under the RNTCP, their demographic and clinical characteristics and any associations between these characteristics with the treatment outcomes.

## **METHODOLOGY**

A prospective study was conducted in Pune which is the eighth largest metropolitian city located in western Maharashtra with a population of approximately 5,049,968 residing in an area of 450.69 sq. kms.

The Pune Corporation provides free health care services to its population. All TB Units are involved in follow-up and contact tracing and providing DOTS support. For children, the approach to case finding remains passive and follows WHO recommendations, using clinical examination, Mantoux test, sputum microscopy and chest X-ray for diagnosis. Based on the severity of the disease, cases are either treated by the Medical Officer of the facility or are referred to regional hospitals for specialist review and management. Treatment is in line with the 2010 WHO recommendations. Cases are then followed up by the respective treatment centres. The RNTCP in Pune city has followed the standardized online recording and reporting system since 2013.

The study was conducted in all six Tuberculosis units of units of Pune city. All children registered in the age group of 0-14 years were included in the study. A total of 217 patients were registered. Consent was obtained in 198 patients.9 patients refused to give consent and the remaining 10 could not be traced to their households. Data on the total number of childhood TB cases registered was extracted from the TB treatment cards and TB registers into a structured data collection tool. The variables included: TB registration number, age, sex, type and category of TB, body weight at the initiation of treatment, treatment category and treatment outcome. Outcomes were categorized as favorable (cured and treatment completed) and unfavorable (died, failure). The parents of all these children in the age group of 0-14 years diagnosed and registered at the Tuberculosis units of Pune city were interviewed after informed consent was obtained. A follow up of all the subjects was done at the end of the intensive phase, at the end of 2 months after starting the continuation phase and at the completion of treatment short-course. All patients were also visited at their respective homes door to door to collect information on the housing standards, with the help of health visitor and stake holder in the community and relevant information about the socio-demographic characteristics of the subject.

Definitions of various clinical characteristics, categories and outcomes were followed as per the RNTCP guidelines.

Statistical analysis: Variables taken as independent variables to determine distribution of patients in each category include Age, Gender, Socioeconomic status, Parent's education, Occupation of the parents, Housing standards (i.e. ventilation and overcrowding), Type of TB, Category of TB, Sputum examination, HIV status, Treatment outcome as per RNTCP guidelines, etc.

Association of demographice (age and gender) and clinical characteristics (pulmonary and Extra pulmonary, type of TB, category of TB and treatment outcome) was determined with the treatment outcome using Odds ratio and Chi-square test.

Ethical clearance was obtained from the Research Ethics Board of the institute.

### **RESULTS**

Of the 198 childhood TB cases, Gender wise distribution revealed there were more female (60.6%) than male children (39.4%). Age wise distribution revealed, of the 198 patients majority were between the age group 11-14 i.e. 92(46.5%). Children less than 1 year comprised a meager of 9(4.5%). In the age groups 1-4 years 39(19.7%) children were registered. While between the age groups 4-7 years and 8-10 years 30(15.2%) and 28(14.1%) children suffered from tuberculosis respectively.

Table 1 Clinical characteristics of childhood TB patients (N=198)

| . ,                                |              |
|------------------------------------|--------------|
| Clinical Characteristics           | Patients (%) |
| Category (n=198)                   |              |
| Category I                         | 183 (92.4)   |
| Category II                        | 15 (7.6)     |
| Type of TB: Pulmonary (n=118)      |              |
| Smear Positive                     | 42 (35.6)    |
| Smear Negative                     | 76 (64.4)    |
| Type of TB: Extra Pulmonary (n=80) |              |
| Lymph node                         | 30 (37.5)    |
| Pleura                             | 19 (23.8)    |
| Abdomen                            | 8 (10)       |
| Meninges                           | 8 (10)       |
| Bones                              | 4 (5)        |
| Peritoneum                         | 1 (1.3)      |
| Miliary                            | 2 (2.5)      |
| Unknown                            | 8 (10)       |
| Treatment outcome (n=198)          |              |
| Cured                              | 37 (18.7)    |
| Treatment complete                 | 148 (74.7)   |
| Failure                            | 3 (1.5)      |
| Default                            | 7 (3.5)      |
| Transferred out                    | 3 (1.5)      |
| Death                              | 0 (0)        |

Table 2 Association of clinical characteristics and treatment outcome (N=198)

| Clinical characteristics | Good Outcome (n=185) (%) | Poor Outcome (n=13) (%) | Total | OR         | 95 % CI:    | P value  |
|--------------------------|--------------------------|-------------------------|-------|------------|-------------|----------|
| Age                      |                          |                         |       |            |             |          |
| ≤1                       | 8 (4.3)                  | 1 (7.7)                 | 9     | 1.84       | 0.2-15.9    | 0.397    |
| 1.01 - 14.00             | 177 (95.7)               | 12 (92.3)               | 189   |            |             |          |
| Gender                   |                          |                         |       |            |             |          |
| Male                     | 68 (36.8)                | 10 (76.9)               | 78    | 0.17       | 0.05-0.6    | 0.348    |
| Female                   | 117 (63.2)               | 3 (23.1)                | 120   |            |             |          |
| Type of TB               |                          |                         |       |            |             |          |
| Pulmonary                | 117 (63.2)               | 1 (7.7)                 | 118   | 20.64      | 2.6-162.2   | < 0.001  |
| Extra Pulmonary          | 68 (36.8)                | 12 (92.3)               | 80    |            |             |          |
| Category of TB           |                          |                         |       |            |             | < 0.0001 |
| I                        | 182 (98.4)               | 1 (7.7)                 | 183   | <b>728</b> | 70.3-7537.8 |          |
| II                       | 3 (1.6)                  | 12 (92.3)               | 15    |            |             |          |

**Table 1** shows distribution of patients as per the clinical characteristics. The findings reveal, more number of children in category I, 183 (92.4%) as compared to 15 cases (7.6%) in category II. Distribution of patients according to type of TB shows that of the 198 patients, 118(59.6%) patients were diagnosed with pulmonary TB and the remaining 80(40.4%) patients were extra pulmonary involvement. 118 Pulmonary TB cases, 42 (35.6%) cases were sputum positive for Acid fast bacilli and 76 (64.4%) of pulmonary cases were sputum smear negative. The distribution of patients according to the site of extrapulmonary TB revealed that lymph node was the most common site of involvement 30 (37.5%). The programme-defined treatment outcomes among childhood Tuberculosis (TB) patients under the RNTCP across all groups notified under the RNTCP revealed an overall cured and treatment completion rate of 185(93.5%) of the total 198 patients treated according to RNTCP guidelines. Poor treatment outcome i.e default and failure was reported in 10(5%) patients.7 (3.5%) patients defaulted. 3 (1.5%) failure to treatment were reported. 3(1.5%) patients were transferred out. No case of death was reported.

Table No 2 shows the association between age, gender, type and category of TB with the treatment outcome. Outcomes were poor among extra pulmonary TB cases. The association between type of TB (p-value < 0.001 OR 20.64), category of TB (p-value < 0.0001, OR 728) with treatment outcome was statistically significant. Association of age, gender and treatment outcome was not significantly different among subgroups of patients according to pre-treatment demographic variables.

## **DISCUSSION**

This is a study from Pune describing the profile and treatment outcomes among childhood TB patients. The treatment success rates were very high across age groups, sex and type of TB, reflecting good programme performance. Outcomes were poor among retreatment and extra pulmonary TB cases, the associations were statistically significant. The case notification rate among children aged >5 years was higher than in those aged <1 year. This is consistent with the findings of other studies from North India, which have reported very low proportions of childhood TB cases in the 0-4 year age group4. This is possibly due to the presence of a dominant private health sector and the consequent under notification of TB cases to the RNTCP. The proportion of extra-pulmonary TB (EPTB) was almost 50%, with lymphadenitis accounting for over half of these cases and reported by Banu Rekha and Swaminathan S5. Association of age, gender and treatment outcome was not significantly different among subgroups of patients according to pre-treatment demographic variables. The findings of Srinath Satyanarayana, et al4 in 2010 in Delhi, Sharma et al in South Delhi<sup>6</sup> and Nelliyanil et al<sup>7</sup>were strikingly similar to our study. No significant association was found with age, gender and treatment outcome.

However studies outside India revealed different findings. Rangsima Lolekha et al<sup>8</sup> in 2008 in Thailand out of 279 children reported more defaults in the age group of 0-4yrs. (16/74, 22%) than in children aged 5-14yrs. (23/205, 11%), (p value <0.02). No deaths occurred in the 74 children aged 0-4, compared with 17 (8%) deaths in the 205 children aged 5-14 (p = 0.03). Harries et al<sup>9</sup> in 2002 in Malawi in their study findings revealed that outcome improved as age increased. With 25% of children aged less than 1 year completing treatment compared with 43% of those aged 1-4 years and 54% of those aged 5yrs and above (p<0.001). Death rates (p <0.001), default rates. (p<0.05) and unknown (p<0.05) also declined with advancing age. There was no difference with gender.

In our study poor treatment outcome was seen in patients with extra pulmonary TB than with pulmonary TB. Treatment completion and Cure rate out of 118 was 117(99.2%) for pulmonary TB as compared to 68(85%) for extra pulmonary TB out

of 80 cases. Poor treatment outcome for pulmonary TB was 1(0.8%) as compared to extra pulmonary involvement. A study in New Delhi observed factors associated with poor treatment outcome in children with tuberculosis<sup>4</sup>. They concluded that AFB positivity at the time of diagnosis, non-receipt of BCG vaccination and extra pulmonary tuberculosis as the major risk factors associated for poor treatment outcome. Extra pulmonary tuberculosis was the only major contributor for poor treatment outcome.

Harries and Sindhu et al9, 10 in 2002 in their independent studies on association of type of TB and treatment outcome observed that best outcome was seen in children with smear positive pulmonary tuberculosis with treatment completion rates of 76%. The worst treatment outcomes were for patients with smear negative pulmonary tuberculosis, while those with extra-pulmonary tuberculosis had an intermediate result. In these children with extra-pulmonary manifestations the proportion of those who completed treatment was 56% of those with TB Lymphadenitis, 55% with spinal disease, 48% with pleural effusion, 47% with pericardial effusion, 50% with miliary disease, 45% with ascites and 23% with meningitis. The treatment outcome improved with increasing age for each type of TB.

Studies conducted previously in India, China and Bhutan show an overall treatment completion rate (treatment completed and cured) of more than 90.7% <sup>11-15</sup> and the cure rate was 100% among sputum smear positive cases. There was significant association with the type and site of TB with 88.2% treatment completion rate for pulmonary and 79.2% for extra pulmonary TB. Similar observations were made by Sindhu et al <sup>10</sup> who reported, lymph node TB treatment completion rates of 96% as against 55.5% in extra pulmonary TB. A study in China <sup>10</sup> reported children with extra pulmonary TB were more likely to have poor treatment outcomes (failed to improve or died).

The strength of this study was that it covered health facilities throughout the city. In addition, data were collected from individual treatment cards, which meant that numbers and most data were accurate. Our study had some limitations. First, there was no information to confirm the validity of this diagnosis. A weakness of the study was poor documentation of the results of diagnostic investigations. A study from Malawi found that the practice of TB diagnosis in children was poor. A review of diagnostic procedures of childhood TB is therefore deemed essential to understand current practices and further improve diagnosis and management. Secondly, sites of extra-pulmonary involvement were not recorded for 10% EPTB cases. These deficiencies in the recording system need

to be addressed by training and supportive supervision of the health care staff at the TB centres which can be attributed to programme related low notification rate as observed by Mukherjee et al in their study findings.<sup>16</sup>.

This study highlights childhood TB as a problem in Pune and shows good treatment outcomes. It will hopefully serve to facilitate planning and policy development for better management of childhood TB. We hereby propose a further study to emphasize the need for the implementation of a well-managed national TB programme, and the association of socioeconomic status and treatment outcome <sup>17-18</sup>.

### CONCLUSION

On analyzing the epidemiological variables the gender wise distribution revealed that out of the 198 patients there were more female than male children (39.4%). Lymph node involvement 30(37.5%) was the most common manifestation in Extra-pulmonary TB patients. Overall cured and treatment completion rate was 185(93.5%).7 (3.5%) patients defaulted. 3 (1.5%) failure to treatment were reported .3(1.5%) patients were transferred to higher tertiary center for further treatment. No case of death was reported. Association of age, gender and treatment outcome was not significantly different among subgroups of patients according to pre-treatment demographic variables. However, the association was statistically significant with type of TB and category of TB.

Childhood TB in high burden countries requires far more attention from the researchers and TB control staff. There is little doubt that the best means of preventing TB in childhood is by control of adult TB. It is also important to improve diagnostic and case detection in childhood.

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