

Original research article

## Determinants of Treatment Compliance Among Paediatric Pulmonary Tuberculosis Cases, Telangana

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### Abstract

**BACKGROUND:** Paediatric pulmonary TB is the most neglected aspect of the present case scenario and is completely different from adult TB. Compliance to TB treatment in children is important to prevent drug resistance and mortality which includes multiple patient-related and healthcare-related factors. Globally treatment non-compliance remains the major hindrance to achieve complete cure and interventions done to improve treatment compliance will be a major breakthrough.

**METHODS:** In this cross-sectional observational study, a semi-structured questionnaire was used to find out the socio-demographic factors and the factors determining treatment compliance among paediatric pulmonary tuberculosis subjects registered at treatment units under DTCO, Hyderabad, Telangana. MMAS-8 scale which was validated had been used to assess treatment compliance. Chi-squares and fisher's exact test were used for statistical analysis.

**RESULTS:** Out of 88 paediatric pulmonary TB respondents that have been registered under 19 TUs, 15 children (17%) have shown treatment non-compliance. The study revealed children with age <5 years (30.7%), males (18.5%), Hindus (27%), high school going (30.4%), with positive migration history (22.2%), underweight category (19.4%), lower socioeconomic class (19%), treatment access from private health setup (20%) and parents with lack of basic TB knowledge (19%) have shown greater non-compliance. Reasons for missing out on medication in this study were forgetfulness, adverse drug reactions, lack of paediatric drug formulations, lack of prior awareness, and feeling cured.

**CONCLUSION:** In spite of robust TB programs and free supply of medicines by the government still there is a significant non-adherent population constituting 17% of the total pulmonary TB respondents. The above mentioned factors for treatment non-compliance should be addressed with careful attention to achieve complete treatment compliance.

**KEYWORDS:** Paediatric pulmonary tuberculosis (PPT), Treatment compliance

### Introduction

As per the Global TB report 2021, an estimated population of 10 million are infected with tuberculosis (TB) worldwide <sup>[1]</sup>. India's TB report 2022 put forward that 1.93 million total (new & relapse) TB cases, were notified and making it the highest TB burden country in the

world.<sup>[2]</sup> India accounts for 31% of the global childhood TB burden <sup>[1]</sup>. Paediatric TB has been inadequately reported and represented in TB statistics across the globe. Paediatric TB is a neglected aspect and a major health problem in areas where TB is existing in an epidemic state. <sup>[3-5]</sup>. Poverty and social unrest are commonly associated with infection rates <sup>[3]</sup>.

The various factors like economic barriers, forgetfulness, time constraints <sup>[6]</sup>, lack of knowledge about DOTS, adverse effects of drugs, social stigma, longer medication period <sup>[7]</sup>, lack of proper paediatric drug formulations <sup>[8]</sup> and difficulties in assessing drug toxicity <sup>[9]</sup> acts as major barriers for compliance to treatment in pulmonary TB children.

Worldwide non-compliance to TB treatment is an obstacle to control TB globally and a contributing factor to treatment failure <sup>[10]</sup>. Compliance to TB treatment is important to avert disease infectiousness, occurrence of drug resistance, relapse, and mortality and achieve a cure <sup>[11]</sup>. WHO says that increasing the effectiveness of compliance interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments. <sup>[12]</sup> Treatment compliance is a complex issue which includes different dimensional aspects that are still lacking understanding and require further investigation. <sup>[13]</sup> Thus, this study with the aim to find out the determinants of treatment compliance among paediatric pulmonary tuberculosis cases has been planned. *Objectives:* 1. To estimate the treatment compliance in PPT in DTCO, Hyderabad. 2. To evaluate the association between socio-demographic factors and healthcare determinants with treatment compliance. 3. To enumerate the factors determining treatment compliance

### Materials and Methods

A cross-sectional type of observational study has been conducted on all the PPT cases registered and are on TB treatment from April to August 2022 at the Treatment unit (TU) under DTCO, Hyderabad, Telangana. Children with pulmonary TB aged below or equal to 15 years in both genders and their parents (informants) who gave consent have been included in the study. Because in the program 15 years is the age cut off and individuals above 15 years are included under adult TB. Subjects who are not registered at TU under DTCO and diagnosed with extrapulmonary tuberculosis are excluded from the study.

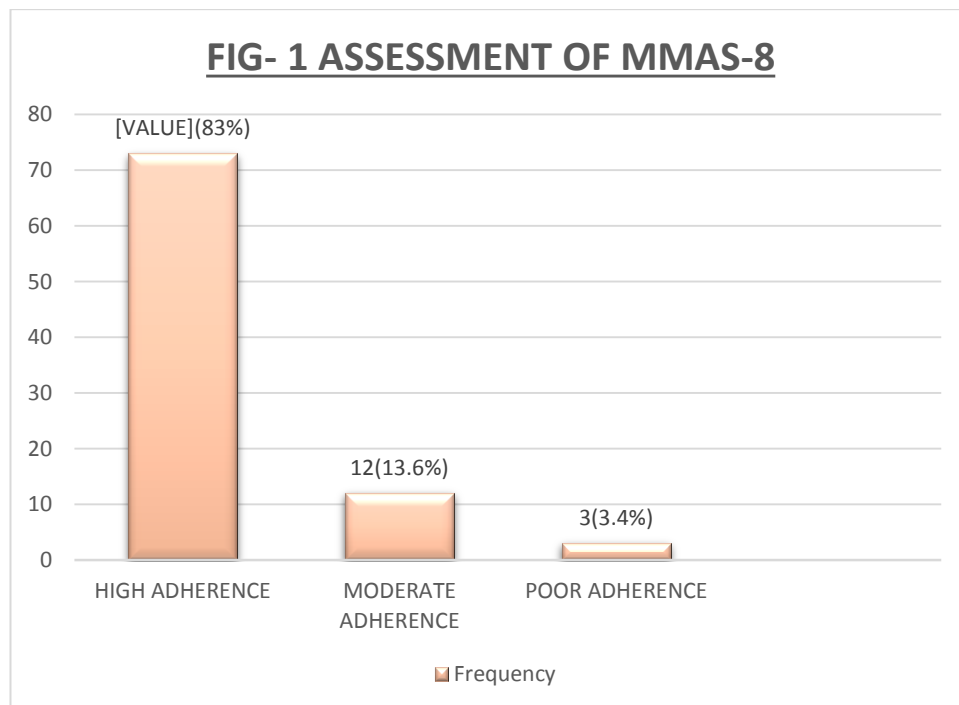
Data collection has been done after getting permission from the Institutional Ethical Committee. Necessary permission from the state TB officer and the district TB officer has been taken prior with regard to data collection. A written informed consent has been signed by all the informants of their respective children before proceeding with the study. Informants who have given consent to the study are interviewed with the semi-structured questionnaire having information about socio-demographic details, housing conditions, contact history, risk factors, basic knowledge about TB, paediatric pulmonary TB treatment profile, defaulters and Morisky Medication Compliance Scale (MMAS-8) which is a standard scale to measure compliance has been used.

Frequencies, percentages and chi-square tests have been used. Fisher's exact tests has been used wherever indicated. Social Package for Social Sciences (SPSS) software has been used for data analysis.

### RESULTS

A total of 109 paediatric pulmonary tuberculosis (PPT) cases that are registered in Hyderabad under 19 TUs have been approached, out of which 1 died, 1 migrated, 1 has been excluded because of age criteria, 1 has been registered in two TU's, 17 were non-respondents, 88 children's parents have consented for the study.

Children aged between 11-15 years 63.6% (n=56), females 69% (n=61), Muslims 70% (n=62), primary school going 43.1% (n=38), have contributed significantly to the pulmonary TB population. The maximum number of PPT subjects belong to the nuclear family, 3 patients belong to the problem family which is of community importance. More than half (57%) of the PPT subjects are living in overcrowding and 21.5% (n=19) are living with inadequate ventilation. PPT cases constituting 47.7% (n=42) belong to lower socioeconomic class. Majority of the children diagnosed with pulmonary TB reside in urban area contributing 93%. Children with 10.2% (n=9) have shown positive history of migration and 29.5% of the PPT cases have shown positive contact history. It is important to note that majority (81.8%, n=72) of the pulmonary TB children are completely immunized still 1 child partially immunized, 4 children are not immunized and rest of the children's informant haven't remembered the immunization status. The greater proportion of the children in both the genders lies in underweight category constituting 56.8% (n=50) and 25% (n=22), females and males respectively. Among 12% of children (n=11) with comorbidities, renal disease is the most common morbidity (n=3) followed by HIV (n=2), asthma (n=2), seizures (n=2) and others.



**Figure 1: Shows compliance to treatment among PPT Cases.**

Compliance was assessed by giving a score of 1 to every no answer except for the 5<sup>th</sup> question which is reversely coded. The final assessment is 8 for highly adherent, 6-7 for moderately adherent, and  $\leq 5$  for poorly adherent individuals. In this study, majority (83%) of the children are adherent to TB medication. It is important to consider the fact that 15(17%) children are not completely adhered to medication. From MMAS-8, high adherence constitutes to compliance and moderate and poor adherence constitutes to non-compliance.

**Table 1: Association between socio-demographic determinants and treatment compliance.**

<b>SOCIODEMOGRAPHIC FACTORS</b>	<b>COMPLIANCE n= (%)</b>	<b>NON-COMPLIANCE n= (%)</b>	<b>P-VALUE</b>
<b>AGE</b>			
<5 years	9(69.2%)	4(30.7%)	0.347
5-10 years	17(89.5%)	2(10.5%)	
11-15 years	47(83.9%)	9(16.1%)	
<b>GENDER</b>			
Male	22(81.4%)	5(18.5%)	0.768
Female	51(83.6%)	10(16.3%)	
<b>EDUCATION</b>			
Primary	33(86.8%)	5(13.1%)	0.193
Middle	24(88.8%)	3(11.1%)	
Secondary	16(69.5%)	7(30.4%)	
<b>RELIGION</b>			
Hindu	19(73%)	7(27%)	0.128
Muslim	54(87%)	8(13%)	
<b>RESIDENCE</b>			
Urban	68(83%)	14(17%)	1
Rural	5(83.3%)	1(16.6%)	
<b>MIGRATION</b>			
Present	7(77.7%)	2(22.2%)	0.647
Absent	66(83.5%)	13(16.45%)	
<b>NUTRITION</b>			
Normal	15(93.75%)	1(6.25%)	0.368
Underweight	58(80.5%)	14(19.4%)	
<b>COMORBIDITIES</b>			
Present	7(70%)	3(30%)	0.364
Absent	66(84.6%)	12(15.3%)	
<b>TYPE OF FAMILY</b>			
Nuclear	65(84.4%)	12(15.5%)	0.390
Other	8(72.7%)	3(27.2%)	
<b>SOCIOECONOMIC CLASS</b>			
Lower class	34(80.95%)	8(19%)	0.631
Middle class	39(84.7%)	7(15.2%)	
<b>TOTAL</b>	<b>73</b>	<b>15</b>	

Table1 shows none of the socio-demographic determinants have any statistical significance association with treatment compliance among PPT subject

**Table 2: Association between health-care determinants and treatment compliance in PPT.**

DETERMINANTS	COMPLIANCE n= (%)	NON-COMPLIANCE n= (%)	P- VALUE
<b>CASES</b>			
New	70(83.3%)	14(16.6%)	0.533
Retreatment	3(75%)	1(25%)	
<b>TREATMENT FACILITY</b>			
Government	57(83.8%)	11(16.1%)	0.783
Private	16(80%)	4(20%)	
<b>DOTS CATEGORY</b>			
Category-1	72(83.7%)	14(16.2%)	0.313
MDR- Short	1(50%)	1(50%)	
<b>INCENTIVES</b>			
Received	40(86.9%)	6(13%)	0.269
Not received	33(78.5%)	9(21.4%)	
<b>REMINDERS</b>			
Received	28(84.8%)	5(15.1%)	0.718
Not received	45(81.8%)	10(18.1%)	
<b>INFORMANT'S TB KNOWLEDGE</b>			
Adequate	39(84.7%)	7(15.2%)	0.631
Don't know	34(80.9%)	8(19%)	
<b>TOTAL</b>	<b>73</b>	<b>15</b>	

Table 2 shows none of the health-care determinants have any statistical significance association with treatment compliance among PPT subjects.

Reasons for non-compliance in this study are forgetfulness (46.6%), longer treatment duration, migration, adverse drug reactions (20%), lack of paediatric drug formulations (13.3%), stopped giving medicines after symptoms have subsided and lack of knowledge about treatment duration (6.6%).

## Discussion

In this study setup non-compliance to TB medication is noted as 17% which is lower than the results observed in Sreelatha Panuganti et al. study<sup>[14]</sup>. The remaining 83% of the children with pulmonary TB are compliant which is more than the study result found by Ginenus Fekadu et al.<sup>[9]</sup>. In this study majority (69%) of PPT subjects are females in contrast to Tao NN et al.<sup>[15]</sup> study where 56.5% individuals are males. Children with age < 5 years (30.7%) and males (18.5%) are showing more non-compliance in this study which is similar to the studies done by Ginenus Fekadu et al.<sup>[9]</sup>. In this study lack of paediatric drug formulation in one TU delayed 15 days of treatment in a 9 month old child. In this study non-compliance was high in Hindu children contributing 27% but more children with pulmonary TB belong to the Muslim religion, same results were observed in the Sreelatha Panuganti et al.<sup>[14]</sup> study. In this study around 26 (29.5%) out of 88 children are showing positive contact history, in contrast, to a study done by Tao NN et al.<sup>[15]</sup> the contact history findings were 15%. In this study majority (56.8%) of the children living in overcrowded houses are contracted TB. Overcrowding and positive contact history of the cases has been observed as an important

risk factor among Muslims, leading to increased disease transmission from infected individuals sharing common airspace with children. Although this has not shown any statistical significance. In this study most of the children with pulmonary TB belong to primary school contributing 43.1% (n=38) where the first step of learning is hampered, followed by middle and high school with 30.6% and 26.1% respectively where the fundamentals of learning are disturbed and school dropouts can increase. High school-going children are more non-compliant to medication reasons assessed were symptoms have not subsided using government medication, forgetfulness, and experiencing side effects like stomach ache and vomiting, these adverse drug reactions are also seen in studies done by N Sharma, S Basu, et al.<sup>[16]</sup>. Children living in urban and rural areas haven't shown much difference in treatment compliance in this study which is in contrast to studies done by Ginenus Fekadu et al.<sup>[9]</sup> where children who belong to rural areas showed more non-compliance. This might be due to a significantly less number of rural children being enrolled in Hyderabad TUs. This study revealed that children who are underweight (19.4%), with positive migration history have shown a greater proportion of non-compliance to treatment which is also seen in a study done by Lopez-Varela E et al.<sup>[17]</sup> Children who belong to the lower socioeconomic class (19%) are non-compliant to TB medication. Lack of awareness about treatment duration, feeling cured and bothered about longer treatment duration have been noted as reasons for non-compliance in this study. Immunization status among PPT subjects is not up to the mark. Around 72 (81.8%) out of 88 children are completely immunized. A lack of awareness about the Universal Immunization Program was observed in remaining (18.1%) parents. Comorbid conditions impaired compliance to treatment in 30% of the children, in which the commonest condition associated was renal disease followed by HIV and asthma. This could be due to missing out sometimes on TB medication, while taking other medications.

Children receiving treatment from government health facilities are more compliant with TB medication than children taken from the private sector. Reason could be free diagnostic and treatment facilities provided by government. One patient from a private health setup is a defaulter after 3 months of TB medication, reason told by the parent was feeling cured and treatment duration recommended by a private health practitioner was only 3 months. Lack of paediatric drug formulations leading to a shift in treatment facility from the government to the private sector was also noted. This study has shown 84 (95.4%) new PPT cases have been registered under 19 TUs which was lower than Tao NN et al.<sup>[15]</sup> study where 98.2% are new cases, in which non-compliance to TB medication among new cases was very high. It is also important to state that among 4 relapse cases there is 1 non-compliant child. This might lead to the development of drug-resistant strains and the mortality of the child. Lack of prior awareness about disease transmission, treatment facilities, treatment duration and disease complications, and forgetfulness to take medicines while leaving home were the reason in this study which were also seen in studies done by N Sharma, S Basu, et al.<sup>[16]</sup>. In this study children's parents who don't have knowledge about TB are slightly more non-compliant than parents who have basic TB knowledge. This can be supported by the study done by N Tefuarani et al.<sup>[18]</sup> This study revealed that children who received incentives and reminders are more compliant with TB treatment than those who haven't received it. These findings are also similar to studies conducted by Abdurahman Ridho et al.<sup>[19]</sup> & Elizabeth E Lutge et al.<sup>[20]</sup>. Monetary benefits/Incentives given in the program can act as encouragement to complete the treatment for the patient since, majority PPT subjects belong to lower socioeconomic class. In this study none of the socio-demographic and health care related determinants have shown statistically significant association with treatment compliance among PPT subjects.



This could be of smaller sample size. As the study was done only on 88 subjects under 19TUs belonging to 1 DTCCO.

**Conclusion:**

The study concludes that greater frequency of PPT subjects are females, aged 11-15 years, Muslims, urban residents, nuclear families, underweight, and upper-lower socioeconomic class. It is important to state that 26 (29.5%) children have shown positive contact history. A validated MMAS-8 scale has been used to measure treatment compliance. The majority of the PPT subjects are children under <5 years age, males, high school going, Hindus, with positive migration history, underweight category, with comorbidities, nuclear families, lower socioeconomic class, enrolled in private treatment facility have shown non-compliance to a greater extent. Compliance with medication is important to prevent drug resistance, relapse and mortality. The parents with basic TB knowledge showed good compliance when compared to the parents who don't. Incentives and reminders also summed up to compliance. The association between socio-demographic and treatment compliance variables that were evaluated by chi-squares and fisher's exact test came to be insignificant. Reasons for missing out on medication in this study are forgetfulness, lack of paediatric drug formulations, lack of prior awareness about disease transmission and treatment duration, adverse drug reactions, and feeling cured.

Global data on socio-demographic factors and determinants of treatment compliance among paediatric pulmonary TB cases are not adequate. This study attempted to tap into these factors and determinants although sample size and time constraints have been its limitations. More studies with larger sample sizes, different methodologies and multi-centric studies are required to find the definitive association between socio-demographic factors, health-care determinants and treatment compliance.

**RECOMMENDATIONS:**

At individual level, the parents of PPT should be given thorough health education regarding symptoms of TB, treatment duration, and precautions that should be taken to prevent the spread which can improve the treatment outcome in their children. At community level, work should be focused on alleviating stigma associated with TB in general, PPT specifically. At healthcare-system level, free workshops should be conducted for private practitioners, pulmonologists and paediatricians on treatment duration, drug weight bands, adverse effects associated with PPT. Referring PPT cases to government facility should be considered as priority. Private health practitioners should be trained to notify each and every PPT case, so that comprehensive data can be obtained. Children with compromised nutrition can be corrected by redirecting to Integrated Child Development Services.

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