

## Original Research Article

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# A study of treatment outcome of paediatric tuberculosis patients in an urban city of central India

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## ABSTRACT

**Background:** It is an established fact that healthy children build healthy nation. Proper management of Paediatric Tuberculosis is very essential for the control of tuberculosis as children also act as a source of infection within a community. The objective of the study was to determine the treatment outcome of paediatric TB patients registered under RNTCP in Bhopal city and to determine the relationship of socio-demographic profile and other selected factors with treatment outcome in Paediatric TB patients registered under RNTCP in Bhopal city.

**Methods:** In this longitudinal study, data of all the paediatric TB patients (0 to 14 years of age group) diagnosed as TB and registered under R.N.T.C.P and fulfilling inclusion criteria during January 2013 to June 2013 were collected after obtaining informed consent from parents/guardians by using a structured questionnaire during their visit to designated microscopic centre (DMC) cum DOTS centre. The data was analysed on statistical software SPSS VS.20.

**Results:** In our study 93.33% of paediatric patients were treatment completed, 4.84% were declared cure and 0.60% patients each were transferred out, declared treatment failure and died respectively. Educational status of mothers of paediatric patients ( $X^2=40.569$  and  $p=0.019$ ,  $df=24$ ), BCG vaccination ( $X^2=11.299$  and  $p=0.023$ ,  $df=4$ ) and nutritional status of children ( $X^2=26.342$  and  $p=0.049$ ,  $df=16$ ) are significantly associated with treatment outcome.

**Conclusions:** Majority of paediatric patients were declared cured or treatment completed depending upon the result of sputum examination. In our study educational status of mothers of paediatric patients, BCG vaccination and nutritional status of children are significantly associated with treatment outcome. No association of treatment outcome was found with other selected factors such as age, gender, religion, type of family and socio economic status of paediatric patients.

**Keywords:** Paediatric tuberculosis, RNTCP, Treatment outcome

## INTRODUCTION

It is an established fact that healthy children build healthy nation. Despite effective chemotherapy, control has not been achieved due to poor therapeutic practices. RNTCP has evolved to take care of this problem by using DOTS strategy. The Indian program is the first program in the world to provide paediatric patient-wise boxes for childhood TB cases.<sup>1</sup> Proper management of paediatric

tuberculosis is very essential for the control of tuberculosis as children also act as a source of infection within a community.<sup>2</sup> Apart from monitoring and supervision of treatment, other factors also contributes in controlling the infection. This research study on treatment outcome of paediatric TB patients will definitely guide to prevent the spread of infection in the community through dedicated organised team of sincere social workers.

## Objectives

To determine the treatment outcome of paediatric TB patients registered under RNTCP in Bhopal city and to determine the relationship of socio-demographic profile and other selected factors with treatment outcome in Paediatric TB patients registered under RNTCP in Bhopal city.

## METHODS

There is one district tuberculosis centre for whole district. There were 3 TB units and 24 DOTS centre/microscopy centre in Bhopal city at the commencement of the study and this longitudinal study was conducted in all the three tuberculosis treatment units.

Data of all the paediatric TB patients (0 to 14 years of age group) diagnosed as TB and registered under R.N.T.C.P and fulfilling inclusion criteria during January 2013 to June 2013 were collected after obtaining informed consent from parents/guardians by using a structured questionnaire during their visit to designated microscopic centre (DMC) cum DOTS centre.

### Inclusion criteria

Inclusion criteria were age group of 0-14 years diagnosed as paediatric TB and registered under R.N.T.C.P. with parents consent.

### Exclusion criteria

Exclusion criteria were extremely ill patients – patients with severe complications like haemoptysis etc.; those patients whose parents did not give consent to participate in the study.

At the end of intensive phase information was obtained to know the response of treatment which is two months for category- I patients and three months for category- II patients and information was also obtained at the end of the treatment for treatment outcome which is six months for category- I patients and eight months for category- II patients as per RNTCP definition. The data was analysed on statistical software SPSS VS.20.

## RESULTS

In our study out of 165 paediatric tuberculosis patients who were registered for DOTS treatment under RNTCP from January 2013 to June 2013, 93.33% were treatment completed, 4.84% were declared cure and 0.60% patients each were transferred out, declared treatment failure and died respectively which is shown in Table 1. In RNTCP cured is defined only for sputum positive pulmonary patients and in our study most of the paediatric patients have sputum negative and extra pulmonary TB so the outcome of treatment was declared as treatment completed. Thus the treatment outcome of paediatric patients is in accordance with RNTCP objectives.

**Table 1: Distribution of patients according to treatment outcome.**

S.No.	Treatment outcome	Frequency	Percentage (%)
1.	Cured	08	4.84
2.	Treatment completed	154	93.33
3.	Defaulter	00	0
4.	Treatment failure	01	0.60
5.	Transferred out	01	0.60
6.	Died	01	0.60
	Total	165	100

**Table 2: Distribution of patients according to treatment outcome and type of TB.**

Treatment outcome	Pulmonary (%)	Extra pulmonary (%)	Total (%)
Cured	8 (100)	0 (00)	8 (4.84)
Treatment completed	84 (54.54)	70 (45.45)	154 (93.33)
Defaulter	0 (0)	0 (0)	0 (0)
Treatment failure	1 (100)	0 (0)	1 (0.60)
Transferred out	0 (0)	1 (100)	1 (0.60)
Died	0 (0)	1 (100)	1 (0.60)
Total	93 (56.36)	72 (43.63)	165 (100)

Table 2 shows that out of 165 paediatric patients, 154 i.e. 93.33% of patients were treatment completed in which 84 i.e. 54.54% were pulmonary cases and 70 i.e. 45.45% were extra pulmonary. One pulmonary patient was treatment failure while one extra pulmonary patient was transferred out and one died.

Association of treatment Outcome with the age, gender, religion, type of family and education of mother of paediatric TB patients were shown in Table 3-7 respectively. In our study maximum patients belongs to 1-10 years of age in which 96.33% of patients completed treatment and 2.75% were cured. There is no statistically significant association of age with treatment outcome. Similarly no statistically significant association was found between gender, religion, Type of family and treatment outcome. Though statistically significant association ( $\chi^2=40.569$  and  $p= 0.019$ ,  $df=24$ ) was found between education of mother and treatment outcome

Table 8 shows the association between treatment outcome and socio-economic status and it is observed that cure and treatment completion rate is constant in all socio economic classes. There is no statistically significant association between socio economic status and treatment outcome. This might be due to the fact that treatment under RNTCP is free of cost irrespective of socio economic status.

**Table 3: Association of treatment outcome with the age of paediatric TB patients.**

Age in years	Cured (%)	Treatment completed (%)	Defaulter (%)	Treatment failure (%)	Transferred out (%)	Died (%)	Total (%)
<b>&lt;1</b>	0 (00)	09 (100)	0 (0)	0 (0)	0 (0)	0 (0)	9 (100)
<b>1-10</b>	3 (2.75)	105 (96.33)	0 (0)	0 (0)	1 (0.91)	0 (0)	109 (100)
<b>11-14</b>	5 (10.63)	40 (85.10)	0 (0)	1 (2.12)	0 (0)	1 (2.12)	47 (100)
<b>Total</b>	8 (4.8)	154 (93.3)	0 (0)	1 (0.6)	1 (0.6)	1 (0.6)	165 (100)

$\chi^2=10.697$ ,  $p=0.219$ ,  $df=8$ .

**Table 4: Association of treatment outcome with gender of paediatric TB patients.**

Treatment outcome							
Gender	Cured (%)	Treatment completed (%)	Defaulter (%)	Treatment failure (%)	Transferred out (%)	Died (%)	Total (%)
<b>Female</b>	5 (5.2)	90 (92.8)	0 (0)	1 (1)	0 (0)	1 (01)	97 (100)
<b>Male</b>	3 (4.48)	64 (94.1)	0 (0)	0 (0)	1 (1.5)	0 (0)	68 (100)
<b>Total</b>	8 (4.8)	154 (93.3)	0 (0)	1 (0.6)	1 (0.6)	1 (0.6)	165 (100)

$\chi^2=2.882$ ,  $p=0.578$ ,  $df=4$ .

**Table 5: Association between treatment outcome and religion.**

Treatment outcome							
Religion	Cured (%)	Treatment completed (%)	Defaulter (%)	Treatment failure (%)	Transferred out (%)	Died (%)	Total (%)
<b>Hindu</b>	6 (6.7)	82 (92.1)	0 (0)	1 (1)	0 (00)	0 (0)	89 (100)
<b>Muslim</b>	2 (2.7)	71 (94.1)	0 (0)	0 (0)	1 (1.3)	1 (1.3)	75 (100)
<b>Christian</b>	0 (00)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	01 (100)
<b>Total</b>	8 (4.8)	154 (93.3)	0 (0)	1 (0.6)	1 (0.6)	1 (0.6)	165 (100)

$\chi^2=4.729$ ,  $P=0.78$ ,  $df=4$ .

**Table 6: Association between treatment outcome and type of family.**

Treatment outcome							
Type of family	Cured (%)	Treatment completed (%)	Defaulter (%)	Treatment failure (%)	Transferred out (%)	Died (%)	Total
<b>Nuclear family</b>	07 (6.7)	95 (90.5)	0 (0)	1 (1)	1 (1)	1 (1)	105 (100)
<b>Joint family</b>	1 (5)	19 (95)	0 (0)	0 (0)	0 (0)	0 (0)	20 (100)
<b>Three generation family</b>	0 (0)	40 (100)	0 (00)	0 (0)	0 (0)	0 (0)	40 (100)
<b>Total</b>	8 (4.8)	154 (93.3)	0 (0)	1 (0.6)	1 (0.6)	1 (0.6)	165 (100)

$\chi^2=4.659$ ,  $p=0.793$ ,  $df=8$ .

**Table 7: Association of treatment outcome with education of mother.**

Educational status	Treatment outcome						
	Cured (%)	Treatment complete (%)	Defaulter (%)	Treatment failure (%)	Transferred out (%)	Died (%)	Total
<b>Illiterate</b>	1 (2.3)	43 (97.7)	0 (0)	0 (0)	0 (0)	0 (0)	44
<b>Primary school</b>	2 (10)	18 (90)	0 (0)	0 (0)	0 (0)	0 (0)	20
<b>Middle school</b>	3 (12)	21 (84)	0 (0)	0 (0)	0 (0)	1 (4)	25
<b>High school</b>	1 (1.9)	51 (96.2)	0 (0)	1 (1.9)	0 (0)	0 (0)	53
<b>Intermediate</b>	1 (7.1)	13 (92.9)	0 (0)	0 (0)	0 (0)	0 (0)	14
<b>Graduate</b>	0 (0)	05 (83.3)	0 (0)	0 (0)	1 (16.7)	0 (0)	6
<b>Postgraduate</b>	0 (0)	03 (100)	0 (0)	0 (0)	0 (0)	0 (0)	3
<b>Total</b>	8 (4.8)	154 (93.3)	0 (0)	1 (0.6)	1 (0.6)	1 (0.6)	165 (100)

$\chi^2=40.569$ ,  $P=0.019$ ,  $df=24$ .

**Table 8: Association between treatment outcome and socio-economic status.**

Socio economic status	Treatment outcome						Total (%)
	Cured (%)	Treatment completed (%)	Defaulter (%)	Treatment failure (%)	Transferred out (%)	Died (%)	
Upper class	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	00 (00)
Upper middle	0 (0)	3 (100)	0 (0)	0 (0)	0 (0)	0 (0)	03 (100)
Lower middle	0 (0)	9 (100)	0 (0)	0 (0)	0 (0)	0 (0)	09 (100)
Upper lower	5 (3.8)	123 (93.9)	0 (0)	1 (0.8)	1 (0.8)	1 (0.8)	131 (100)
Lower class	3 (13.6)	19 (86.4)	0 (0)	0 (0)	0 (0)	0 (0)	22 (100)
<b>Total</b>	<b>8 (4.8)</b>	<b>154 (93.3)</b>	<b>0(0)</b>	<b>1 (0.6)</b>	<b>1 (0.6)</b>	<b>1 (0.6)</b>	<b>165 (100)</b>

 $\chi^2=5.328$ , p=0.946, df=12.**Table 9: Association between treatment outcome and BCG.**

BCG	Treatment outcome						Total (%)
	N years	Cured (%)	Treatment completed (%)	Defaulter (%)	Treatment failure (%)	Transferred out (%)	
No	0 (0)	27 (93.10)	0 (0)	1 (3.44)	0 (0)	1 (3.44)	29 (100)
Yes	8 (5.88)	127 (93.38)	0 (0)	0 (0)	1 (0.73)	0 (0)	136 (100)
<b>Total</b>	<b>8 (4.8)</b>	<b>154 (93.3)</b>	<b>0 (0)</b>	<b>1 (0.6)</b>	<b>1 (0.6)</b>	<b>1 (0.6)</b>	<b>165 (100)</b>

 $\chi^2=11.299$ , p=0.023, df=4.**Table 10: Association between treatment outcome and nutritional status.**

PEM	Treatment outcome						Total (%)
	Cured (%)	Treatment completed (%)	Defaulter (%)	Treatment failure (%)	Transferred out (%)	Died (%)	
Grade-I	1 (3.22)	29 (93.54)	0 (0)	0 (0)	1 (3.22)	0 (0)	31 (100)
Grade-II	3 (6.38)	44 (93.61)	0 (0)	0 (0)	0 (0)	0 (0)	47 (100)
Grade-III	0 (0)	21 (100)	0 (0)	0 (0)	0 (0)	0 (0)	21(100)
Grade-IV	1 (6.66)	12 (80)	0 (0)	1 (6.66)	0 (0)	1 (6.66)	15 (100)
Normal	3 (5.88)	48 (94.11)	0 (0)	0 (0)	0 (0)	0 (0)	51 (100)
<b>Total</b>	<b>8 (4.8%)</b>	<b>154 (93.33)</b>	<b>0 (0)</b>	<b>1 (0.6)</b>	<b>1 (0.6)</b>	<b>1 (0.6)</b>	<b>165 (100)</b>

 $\chi^2=26.342$ , p=0.049, df=16.

In our study it is observed that those patients who are vaccinated with BCG have favourable results up to 100% than that those who are not vaccinated. Table 9 shows that there is statistically significant association ( $\chi^2=11.299$ , p=0.023, df=4) between BCG vaccination and treatment outcome. Association between treatment outcome and nutritional status is shown in Table 10 and it is observed that high cure rate and treatment complete was achieved in all grades of protein energy malnutrition and there is statistically significant association ( $\chi^2=26.342$ , p=0.049, df=16) between nutritional status of paediatric patients and treatment outcome.

## DISCUSSION

In the present study 93.33% of study population completed treatment, 4.84% was declared cure and 0.60% child died, 0.60% was declared treatment failure and 0.60% were transferred out. Similar findings were observed in the study of Kabra et al in which out of 459 patients were started on anti-tuberculosis drugs and were available for analysis 365 (80%) children completed the

treatment. Of these, 302 (82.7%) were cured with the primary regimen assigned to them in the beginning.<sup>3</sup> Sharma et al did a retrospective analysis of 1098 children at paediatric pulmonology department, TB, Institute, New Delhi. They observed a cure rate of 92.4% for new and 92% for retreatment cases. But the treatment completion rate was significantly higher for new cases (97%) than retreatment cases (53.6%). The overall success rate was 95.4% and 82.6% for new and retreatment cases respectively. Overall, the rate for default, failure and death were 3%, 1.95% and 1% respectively. They concluded that DOTS appears to be a highly efficacious treatment strategy.<sup>4</sup> In a study done by Sivanandan, retrospective review of records was done in 541 children (315 boys) suffering from tuberculosis, 459 (84.8%) children were cured and 82 (15.5%) had treatment failure.<sup>5</sup>

A prospective study done by Indumathi et al evaluated intermittent short course chemotherapy for Paediatric tuberculosis. The overall cure rate was 95%. There were 02 failures among 34 PTB. There was no mortality. All

cases of disseminated, abdominal and lymph node TB responded with a 100% cure rate.<sup>6</sup> Sharma et al in their study observed a high treatment completion rate of 94.9% with 0.3% death rate, 2.2% default rate and 2.5% failure rate.<sup>7</sup>

In a study of Ruchi et al, Out of 1016 registered childhood TB cases; treatment result of 907 children was provided as 109 children were on treatment during the time of data collection. Out of these 907 children, 95% were cured or had completed the treatment; only 4% had defaulted; four (0.4%) died and there were 4 (0.4%) of treatment failure.<sup>8</sup> In a record based study conducted by Puwar et al in Ahmedabad city, out of total 382 paediatric patients, 83% percent of the children were completed treatment and 6% cases declared as cured while 1.3% of children died during treatment. Analysis of records suggests high treatment completion rate amongst RNTCP paediatric TB patients.<sup>9</sup>

In a study of Ramesh et al, the treatment completion rate was 90.7% with cure rate of 100% among sputum smear positive patients.<sup>10</sup> In a study of Nelliyanil et al, 94.7% of the patients completed treatment.<sup>11</sup>

In a five years retrospective study of Hailu et al, 41,254 TB patients were registered, of whom 2708 were children. Treatment outcomes were documented for 95.2% of children of whom 85.5% were successfully treated while rates of mortality and defaulting from treatment were 3.3% and 3.8%, respectively.<sup>12</sup> A retrospective record based study of cases registered between January 2008 and December 2011, at the Amdanga TB unit (TU), West Bengal was conducted by Mukherjee et al. Overall favourable outcomes (cured and treatment completed taken together) were 81.8% in children.<sup>13</sup>

As far as association between treatment outcome and socio demographic, nutritional status and other clinical variables is concerned, our study shows that educational status of mothers of paediatric patients, BCG vaccination and nutritional status of children are significantly associated with treatment outcome. In a study of Sivanandan the non-receipt of BCG vaccination during infancy were associated with treatment failure.<sup>5</sup> One possible explanation offered by the authors was that BCG might have limited the hematogenous spread, thus facilitating cure. Studies in mice indicate that prior immunization enhances macrophage phagocytosis and CD4 T-helper cell activity to contain mycobacterial dissemination.<sup>14</sup>

In our study no association of treatment outcome was found with age of paediatric patients. This is in contrast with the study of Ramesh et al in which there was significant association between age and treatment outcome.<sup>10</sup>

In our study there was no association between treatment outcome and gender of paediatric patients. Similar findings were observed in the study of Ramesh et al.<sup>10</sup>

In our study no association of treatment outcome was found with socio economic status of paediatric patients. This might be due to the fact that the treatment is free of cost irrespective of the socioeconomic status of the family. Secondly in our study all the patients belong to low socio economic status. Our observation is in contrast with the study of Djibuti et al in which low household income was remained statistically significantly associated with poor TB treatment outcome.<sup>15</sup>

## CONCLUSION

As far as treatment outcome of paediatric patients is concerned majority of paediatric patients were declared cured or treatment completed depending upon the result of sputum examination. In our study educational status of mothers of paediatric patients, BCG vaccination and nutritional status of children are significantly associated with treatment outcome. No association of treatment outcome was found with other selected factors such as age, gender, religion, type of family and socio economic status of paediatric patients. The RNTCP DOTS strategy is an effective treatment modality for TB in children achieving a high treatment completion rate and low death rate.

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