Original Article

Treatment outcomes of childhood tuberculosis with DOTS strategy in Kottayam, Kerala.

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Abstract

Background: Childhood tuberculosis is a reflection of sputum-positive pulmonary tuberculosis and extent of transmission of tuberculosis in the community. Children suffer from serious form of tuberculosis and are more likely to die if not treated at proper time. Paediatricians are reluctant to refer them to Directly Observed Treatment- Short course (DOTS) centres. Present study is conducted to know the clinical profile and treatment outcomes of childhood tuberculosis patients registered under Revised National Tuberculosis Control Program (RNTCP) in Kottayam, Kerala.

Methods: It was a record based cross-sectional study. Data was collected from RNTCP records from January to December 2009. Data was analysed using SPSS 16.0 and results were presented as proportions with 95% confidence limits. Chi-square test was used to find out the association.

Results: The total number of paediatric tuberculosis cases was 155. There were 84 (55.6%) males and 67(44.4%) females. 66 (43.7%) were less than 5 years of age. Out of 117 (77.5%) pulmonary tuberculosis cases, 8 (0.06%) were sputum smear-positive. Among extra-pulmonary TB cases, peripheral lymph node disease [25 (73.5%)] was most common. The treatment completion rate was 90.7% with cure rate of 100% among sputum smear positive cases. Chi-square test showed significant association between age and treatment outcome (p-value <0.0001).

Conclusions: Study showed that the RNTCP-DOTS is still the most effective strategy in treating childhood tuberculosis patients. Further studies are needed to assess the reasons for low proportion of smear positive and low TB meningitis cases.

Introduction:

Childhood tuberculosis is a reflection of prevalence of sputum smear positive pulmonary tuberculosis and transmission of tuberculosis infection in the community. It is estimated that globally 1.5 million new cases and 1, 30,000 deaths occur annually due to tuberculosis amongst children[1]. Because of less developed immune system, children are more prone to develop the disease[2].

Tuberculosis in children is mainly due to failure of tuberculosis control in adults. Childhood tuberculosis is always been a low priority in RNTCP as children rarely have sputum smear-positive tuberculosis. Moreover we don't have reliable data on incidence and prevalence of childhood tuberculosis due to lack of proper diagnostic facilities of tuberculosis in children.

To address the concern expressed by paediatric experts about the diagnosis and treatment practices for paediatric patients under RNTCP, in 2003 a consultation of experts on paediatrics and TB culminated in a national workshop on the 'Management of paediatric TB under RNTCP'. A major recommendation was that the drugs for paediatric TB cases should be supplied in patient-wise boxes (PWBs). It is planned to make these paediatric PWBs available for use in the programme from early 2006.

In Kerala, paediatric PWBs were introduced from 2008 but since then no studies have been conducted to assess the effectiveness of this DOTS strategy in treating childhood tuberculosis patients. Present study intends to find the treatment outcomes of childhood tuberculosis patients treated with DOTS strategy, under RNTCP.

Material and Methods:

A cross-sectional descriptive record based study was conducted in Kottayam district of Kerala. Kottayam district has 5 Tuberculosis Units. RNTCP records (Tuberculosis Register and Treatment Card) of all paediatric cases less than 15 years age from January2009-December2009 were reviewed. There were total 155 paediatric tuberculosis cases. Treatment

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outcomes details were not available for 4 children and were not included in the analysis. Variables studied were demographic (age and sex), clinical (disease classification, type of TB, site of extra-pulmonary TB) and treatment related (category, DOT provider, location, treatment outcomes). Data was entered in Excel spread sheet and analysis was done using SPSS 16.0 version. Results were summarised as proportions and 95% confidence limits.

Definitions of tuberculosis cases and treatment used in RNTCP

New: A TB patient who has never had treatment for TB or has taken anti-tuberculosis drugs for less than 1 month. A new case can be either sputum positive, sputum negative or extra-pulmonary.

Relapse: A TB patient who had been declared cured or whose treatment had been completed by a physician, but who reports back to the health service and is now found to be sputum smear-positive.

Treatment after default: A TB patient who received anti-tuberculosis treatment for at-least 1 month from any source and returns to treatment after having defaulted, i.e., not taken anti-tuberculosis drugs consecutively for at-least 2 months, and is found to be sputum smear-positive.

Failure: Any TB patient who is smear-positive at 5 months after starting treatment. Failure also includes a patient who was treated with the Category III regimen but who becomes smear-positive during treatment.

Transferred in: A TB patient who has been received for treatment into a TB Unit after starting treatment in another unit where s/he had been registered.

Transfer out: A patient who has been transferred to another area register and treatment results are not known.

Cured: Initially smear positive patient who completed treatment and had negative smear result on at least two occasions (one at treatment completion).

Treatment completed: Initially smear negative patient who received full course of treatment or smear positive who completed treatment, with negative smear at the end of initial phase, but no or only one negative smear during continuation and none at treatment end.

Results:

Demographic and clinical characteristics[Table 1]

Of 155 children <15 years of age registered under RNTCP for treatment, complete details of treatment were available for 151 children and so other 4 patients were excluded from the analysis. There were more males (55.6%) than females. Majority 66 (43.7%) were under 5 years of age with 5 (3.3%) infants.

All 151 patients were categorised according to RNTCP guidelines. All patients were new cases (patients having received no anti TB treatment or anti TB treatment received for less than a month). More than three fourth 117 (77.5%) of the patients had pulmonary TB with 8 (5.3%) cases being pulmonary sputum smear positive. Rest 34 (22.5%) were extra-pulmonary TB patients.

Out of 34 extra-pulmonary TB (EPTB) cases, peripheral lymph node disease 25 (73.5%) was most common. Other EPTB cases included spine 5 (14.7%) and pleura 4 (11.7%).

Treatment outcomes at the end of the treatment [Table 2]

All patients were categorised and prescribed RNTCP standardised short course chemotherapy regimens. There were no retreatment patients. All were new cases with 96 (63.6%) patients belonging to Cat III and rest 55 (36.4%) to Cat 1.

Majority of the patients 73 (48.4%) were receiving DOTS from Government Health facility like Primary Health Centres, Government Medical college, District TB Centre (DTC), District Hospital. Majority of the patients 66 (43.7%) were from Kottayam TU and one third of them were taking treatment from DTC. The other major DOTS location was Anganwadi centres providing DOTS to 62 (41%) patients. There were very few community based DOTS delivery sites like Shops 9 (6%) and 7 (4.6%) patients were receiving DOTS from Neighbour's house.

Majority of the DOT provider were ASHAs 61 (40.4%). In Government Health Centres, the job was assigned to either Staff Nurses 47 (31.1%) or Pharmacists 11 (7.4%). Community Volunteers were giving DOTS to 32 (21.1%). Community volunteers included trusted person from a neighbour's family, TB Health visitors and Shop keepers

The proportion of patients with programme defined treatment completion rate was 85.4% (95% CI 78.5%-90.4%). 100% cure (8 patients) was achieved among sputum smear positive cases. Overall treatment completion rate (treatment completed and cured) was 90.7% (95% CI 86.1%-95.3%).

Since Kottayam is having tertiary care centre (Government Medical College), we expect referrals from the other neighbouring districts. There were total of 11 (7.3%) transferred out cases. Least proportion was of defaulter's i.e. 2%. No single case of death or failure was reported.

Table 1. Basic Demographic and clinical characteristics of study subjects N (151)

CHARACTERISTICS	No.	%
Sex		
Males	84	55.6
Females	67	44.4
Age-groups		
0-1 year	5	3.3
1-5 year	61	40.4
5-10 year	48	31.8
10-15 year	37	24.5
TB classification		
Pulmonary	117	77.5
Extra-pulmonary	34	22.5
Type of TB		
New smear negative pulmonary	109	72.2
New smear positive pulmonary	8	5.3
New extra pulmonary	34	22.5
Extra pulmonary TB type (n=34)		
Peripheral lymph nodes	25	73.5
Spine	5	14.7
Pluera	4	11.7

Table 2. Treatment characteristics and treatment outcomes of study subjects N (151)

CHARACTERISTICS	No.	%
Treatment category		
Cat-1	55	36.4
Cat-3	96	63.6
Cat-2	00	00.0
Dot center type		
Govt health facility(phc & others)	73	48.4
Anganwadi center	62	41.0
Shops	9	6.0
Neighour's house	7	4.6
Dot provider type		
Community volunteer	32	21.1
Asha	61	40.4
Staff nurse	47	31.1
Pharmacist	11	07.4
Treatment outcome		
Completed	129	85.4
Cured	8	5.3
Transfered out	11	7.3
Defaulted	3	2

Association between Demographic, Clinical variables and Treatment outcomes [Table 3]

To find out the association between various demographic and clinical variables and treatment outcome, we categorised treatment outcome into two categories. 'Treatment completed' which includes treatment completed patients and cured patients and the second category as 'Others' which includes transferred out and default.

The proportion of patients with treatment completion rate was more in under 5 year age (90.9%) compared to other age category and it was statistically significant with p value <0.0001. similarly Chi square test showed significant association between type of TB (Pulmonary, Extra pulmonary) & treatment outcome (p value <0.01) and site of TB and treatment outcome (p value <0.0001). Other variables were not significantly associated with treatment outcome.

Table 3. Association between demographic and clinical characteristics with treatment completion among study subjects N (151)

CHARACTERISTICS	TREATMENT OUTCOME@			
	Treatment completed n (%)	Others n (%)	Total	p-value
Sex				
Males	69 (82.1%)	15 (17.9%)	84	
Females	54 (80.5%)	13 (19.5%)	67	<0.80
Age				
<5 years	60 (90.9%)	6 (9.1%)	66	
5-10 years	42 (87.5%)	6 (12.5%)	48	<0.0001
10-15 years	21 (43.2%)	16 (56.8%)	37	
Type of TB				
Pulmonary	93 (79.4%)	24 (20.6%)	117	<0.20
Extra pulmonary	30 (88.2%)	4 (11.8%)	34	
Site of TB				
Peripheral Lymph node	24 (96%)	1 (4%)	25	<0.01
Others	5 (55.5%)	4 (45.5%)	9	
DOT centre				
Govt health facility	62 (84.9%)	11 (15.1%)	73	<0.28
Others	61 (78.2%)	17 (21.8%)	78	
Treatment category				
Cat 1	29 (52.7%)	26 (47.3%)	55	<0.0001
Cat 3	94 (97.9%)	2 (2.1%)	96	

Discussion:

There are very few studies that reports data on childhood TB and treatment outcome registered and treated under RNTCP in India. Such data definitely helps to understand the impact of our national programme in controlling childhood TB.

This study showed highest number of TB patients 61(40.7%) in 1-4 year age group which is similar to existing literature[2,3]. Children less than 5 years old are at greater risk of developing disease probably due to immature cellular immunity[4]. Some studies conducted in tertiary hospital of India also showed high proportion of patients in this age group[5].

Tuberculosis was more common in males 84 (55.6%) than females. A study conducted in North India in a tertiary care hospital by Garg P showed similar results[6]. According to World Health Organisation the ratio of pulmonary and extra pulmonary TB in children is usually around 1:3. In our study there was more number of pulmonary cases than extra pulmonary. But similar results are seen in study conducted by Garg P[6]. Among extra pulmonary cases the commonest was peripheral lymph node involvement which is consistent with the

results seen in most of the studies[1,2,4] and second common was pleural involvement. The only interesting part is the absence of TB meningitis cases. This may be because the Kottayam district is having Medical College and other private institutions and paediatricians treating them may not be referring the TB meningitis cases to RNTCP as they need extra care. Further studies are needed to explore these things.

The overall treatment completion rate was 90.7% that includes treatment completed and cured patients. These results are consistent with many studies conducted in India. A study conducted by Sharma S et al in Delhi and other studies showed similar overall treatment completion rate[7,8,9,10]. Among sputum positive cases, cure rate was 100%. But there were only 8 (5.8%) pulmonary sputum positive patients; this may be due to significant number of under 5 children who are not able to produce sputum effectively. Many children need naso-gastric aspiration to diagnose sputum positivity which is not readily available in either district hospitals or tuberculosis centres.

Lastly we explored relation between various clinico-demographic variables and treatment outcomes. Younger children registered better treatment outcome compared to older children. Other clinico-demographic variables were not significantly associated with treatment outcome.

Conclusions:

This study showed that the RNTCP DOTS is still the best strategy to tackle childhood TB as we saw more than 90% treatment completion rates. But we need more prospective studies to establish the effectiveness of DOTS in treating childhood TB.

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