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Original Research Article

Treatment outcome of tuberculosis patients treated under DOTS in Calicut

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ABSTRACT

Background: Tuberculosis remains a worldwide public health problem despite the fact that highly effective drugs are available making TB a curable disease. DOTS chemotherapy remains central to the public health approach to tuberculosis control under RNTCP. The present study is conducted to know the clinical profile and treatment outcome of TB patients registered under RNTCP in Mukkam CHC, Calicut. The study was conducted with the following objectives: 1) to study the treatment outcome of TB patients receiving DOTS, 2) to find the occurrence of pulmonary, extra-pulmonary and MDR TB and 3) to find out factors responsible for poor treatment outcome.
Methods: This record based study was conducted in Mukkam CHC. Details of patients who were enrolled under RNTCP in the year 2013 were collected from RNTCP records. Data was analyzed using SPSS version 16. Results are expressed in percentage. Statistical analysis used was Chi square test.
Results: Out of 289 patients studied, 66.78% were males and 33.22% were females. 69.5% of the patients were having pulmonary TB and 30.5% extrapulmonary TB. There were two cases of MDR TB. 58% of the patients with pulmonary TB were sputum positive and 42% were sputum negative. 87.8% were given Cat I treatment and 11.7% were given Cat II treatment. Only one patient was on Non DOTS regimen. 96.6% of the patients had completed DOTS. When treatment outcome was analyzed, the patients with treatment completed was 54%, cured 35%, defaults 4%, treatment failure 2% and transfer out 2% and 3% of patients died during the course of the treatment. 7.61% of patients had diabetes mellitus and only one case was reported HIV positive. Treatment outcome was significantly associated with type of patient and pulmonary TB sputum positivity.
Conclusions: The treatment success rate was 100% in 0-5 years and least in > 65years of age group. Further studies are required to find out the reasons for comparatively high proportion of sputum smear negative cases.

Keywords: Tuberculosis, DOTS, Treatment outcome

INTRODUCTION

Tuberculosis(TB) is a worldwide, chronic communicable bacterial disease which still continues to be a major public health problem even after its discovery a century back.[1] Of the 8.6million cases, 2.2million (25%) million cases occurred in India making India the world's highest TB burden country.[2] Effective drugs for tuberculosis have been available since the 1940s.[3] Directly observed treatment short course(DOTS) chemotherapy remains central to the public health approach to tuberculosis control under Revised National TB Control Programme (RNTCP).[4,5] DOTS is a strategy to ensure cure by providing the most effective medicine and confirming that it is taken.[4] The DOTS strategy has five components: political will, diagnosis by quality assured sputum smear microscopy, adequate supply of quality assured short course chemotherapy drugs, directly observed treatment and systematic monitoring.[1] RNTCP data on Tuberculosis is analyzed and published annually at country level,

which gives information on incidence, prevalence, and mortality rate and co infection with HIV.

Hence the present study was conducted to know the clinical profile and treatment outcome of TB patients receiving DOTS chemotherapy registered under RNTCP in Mukkam CHC, Calicut and to identify factors responsible for poor treatment outcome.

METHODS

A record based study was conducted in the Community Health Centre Mukkam in Calicut district. All patients suffering from TB registered for treatment under RNTCP in 2013 at CHC Mukkam were enrolled for study. Retrospective data collection was done using RNTCP records (treatment cards and TB registers) which are meticulously maintained in the CHC. Age, sex and religion of TB patients, type of TB for which the patient was treated, type of treatment offered to the patient, duration of therapy, documented treatment outcome, HIV and diabetes mellitus status of the enrolled patients were extracted from the RNTCP records. Data was entered in Microsoft excel spread sheet and analyzed using SPSS version 16. Chi-square test was used to find out the factors associated with poor treatment outcome.

Definitions of tuberculosis cases and treatment[4]

New case: A patient with sputum positive pulmonary TB who has never had treatment for TB or has taken anti-TB drugs for less than 4weeks.

Relapse: A patient who returns smear positive having previously been treated for TB and declared cured after the completion of his treatment.

Failure case: A patient who was initially smear positive who began treatment and who remained or became smear positive again at five months or later during the course of treatment.

Return after default: A patient who returns sputum smear positive, after having left treatment for at least two months.

Transfer in: A patient recorded in another administrative area register and transferred into another area to continue treatment.

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

There were total 289 patients registered under RNTCP for DOTS chemotherapy of which 66.78% were males and 33.22% were females. 13.8% patients belonged to the age group 0-5 years, 3.1% to 6-14 years, 12.45% to 15-24 years, 9.7% to 25-34 years, 13.14% to 35-44 years, 17.3% to 45-54 years, 17.9% to 55-64 years and 12.45% to >65 years. 134 (46.3%) patients belonged to Hindu religion, 117(40.4%) to Muslim and 38 (13.1%) to Christian religion.

Table 1: Demographic and clinical characteristics of study subjects (n=289).

Characteristics	No.	Percentage
Sex		
Male	193	66.8
Female	96	33.2
Religion		
Hindu	134	46.4
Christian	38	13.1
Muslim	117	40.5
Disease classification		
Pulmonary TB	201	69.5
Extra pulmonary TB	88	30.5
Sputum examination		
Sputum positive pulmonary TB	116	57.7
Sputum negative pulmonary TB	85	42.3
Type of patients		
New	256	88.6
Treatment failure	6	2.1
Relapse	16	5.5
Default	2	0.7
Others	9	3.1
Category of dots		
Category i	254	87.8
Category ii	34	11.8
Non-dots	1	0.4
Treatment outcome		
Cure	101	35
Treatment completed	155	53.6
Treatment failure	6	2.1
Default	11	3.8
Deaths	10	3.4
Transfer out	6	2.1
Diabetes status		
Diabetic	22	7.6
Non diabetic	267	92.4
HIV status		
Positive	1	0.3
Negative	288	99.7

Table 2: Association between treatment outcome with demographic and clinical characteristics.

Characteristics	Treatment outcome			
	Treatment completion	Others	χ^2value	P-Value
Age				
<5	40	0	14.990	0.012
6-14	6	3		
15-24	33	3		
25-34	26	2		
35-44	35	3		
45-54	43	7		
55-64	45	7		
65&Above	27	9		
Disease classification				
Pulmonary TB	174	27	2.648	0.104
Extra Pulmonary TB	82	6		
Sputum examination				
Sputum Positive Pulmonary TB	94	22	7.221	0.007
Sputum Negative Pulmonary TB	80	5		
Diabetes melitus				
Diabetic	20	2	0.135	0.713
Non-Diabetic	236	31		
Type of patient				
New	229	27		
Treatment Failure	5	1		
Relapse	12	4	47.25	0.001
Default	1	1		
Others	9	0		

69.5% of the patients had pulmonary TB and 30.5% were had extrapulmonary TB, among the extrapulmonary cases, the most common site of involvement was cervical lymph nodes (68.1%), followed by pleura (13.6%), spine (5.6%), meninges (4.5%), abdomen (3.4%), skin (2.2%), genitourinary system (1.1%) and eyes (1.1%). There were two cases of MDR TB.

Out of 201 patients with pulmonary TB 57.7% were sputum positive and 42.2% were sputum negative pulmonary TB cases. 88.5% patients were new cases of TB, followed by 5.5% relapse, 2% treatment failure, 0.69% default and 3.1% others.

87.8% were given Cat I treatment and 11.7% were given Cat II treatment. Only one patient (0.34%) was on Non DOTS regimen. 96.6% of the patients completed DOTS (86.9% in Cat I and 9.7% in Cat II).

When treatment outcome was analyzed, the patients with treatment completed were 54%, cured 35%, defaults 4%, treatment failure 2% and transfer out 2%. 3% of patients died during the course of the treatment. Overall treatment completion rate was 89%. 7.61% of patients were having diabetes mellitus and only one case was reported HIV positive.

The treatment completion rate was more in age group <5years and it was statistically significant. Similarly treatment outcome showed statistically significant association with type of patient, and pulmonary sputum positivity. Other variables were not significantly associated with treatment outcome.

DISCUSSION

Our study showed 35.2% of patients in the age of 45-64(35.2%) with mean age 39 years. Tuberculosis was more common in males (66.8%) compared to females which was similar to the study conducted in Ludhiana.[6] 2/3rd of the patients in our study had pulmonary tuberculosis which was different from study of Getahun et al where it was 59.5%.[7] But some studies conducted in tertiary teaching hospitals in India showed similar results.[6]

In our study, out of the 201 pulmonary TB cases 57.7% were sputum positive which was much higher when compared to a study conducted in Ethiopia.[7] Among the extra-pulmonary cases the most common site of involvement was cervical lymph nodes and second most common site of involvement was pleura.

The overall treatment completion rate was 89% that includes treatment completed and cured patients which was consistent with the findings of study conducted by Getahun et al.[7]

Lastly we explored the relationship between treatment outcome with various demographic and clinical variables. Children below five years of age and adults in 45-64 ages had a better treatment outcome than with patients in other age category. The findings of better treatment outcome in younger children were consistent with the study finding of Ramesh et al.[8]

Treatment outcome also showed significant association with type of patient and sputum positivity. Patients who were a case of new sputum positive pulmonary TB showed a better treatment outcome. Diabetes status of the study subjects did not affected their treatment outcome. It shows that treatment of TB under DOTS is effective even in presence of metabolic derangement like diabetes. Some studies conducted in Kerala also showed similar results, but some other studies showed an inverse relationship.[9-11] Other variables like sex, religion, disease classification, and category of DOTS were not significantly associated with the treatment outcome.

CONCLUSION

The treatment success rate was 100% in 0-5 years and least in > 65years of age group. Sputum negative patients had successful outcome when compared with sputum positives which can be due to the low bacillary load in sputum negative cases. Further studies are required to find out the reasons for comparatively high proportion of sputum smear negative cases.

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