PROFILE AND TREATMENT OUTCOME AMONG PULMONARY TUBERCULOSIS PATIENTS UNDER DOTS ATTENDING A TERTIARY CARE CENTRE IN DIBRUGARH DISTRICT, ASSAM

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ABSTRACT

BACKGROUND
Tuberculosis continues to be a major public health problem in India. The Revised National Tuberculosis Control Programme (RNTCP), an application of Directly Observed Treatment Short Course (DOTS) was launched in 1997 with a goal to reduce mortality and morbidity due to tuberculosis. DOTS Strategy aims to improve patient adherence to treatment and thereby prevents development of drug resistance. Treatment outcome is an important indicator of tuberculosis control programme.
Objective- To assess the profile and treatment outcome among pulmonary tuberculosis patients registered under DOTS in Assam Medical College and Hospital, Dibrugarh, Assam.

MATERIALS AND METHODS
A retrospective cross sectional study of patients diagnosed with Pulmonary Tuberculosis and enrolled under DOTS between February 2012 to January 2013 in Pulmonary Medicine Department of Assam Medical College and Hospital, Dibrugarh, Assam was carried out from March to August 2013. Analysis was done by using ratio, proportion, mean and standard deviation and chi-square test was used to see association.

RESULTS
Of the 661 patients registered, ratio of male and female was 2:1 and mean age of patients enrolled was 32.25 ± 15.12 years. Majority (63.2%) of patients were sputum smear-positive pulmonary tuberculosis followed by Re-treatment (18.8%) and sputum smear negative pulmonary tuberculosis (18%). Success rate was 85.4% whereas rate of default, failure, died and transferred out were 5.7%, 5%, 3%, and 0.8% respectively. Cure rate was found significantly highest in 21-30 years age group while default, failure and died rate was highest in >60 years age group. A significant association of unsuccessful treatment outcome was seen with older age group and male patients.

CONCLUSION
The study reveals high success rate (85.4%) which ensures that the DOTS therapy is highly effective and safe. Special emphasis should be put on sputum smear-positive pulmonary TB patients, older age group and male patients to decrease TB transmissions and unsuccessful treatment outcome.

KEYWORDS
RNTCP, DOTS, Pulmonary Tuberculosis, Dibrugarh.

BACKGROUND
Tuberculosis (TB) is the second most common infectious disease caused by Mycobacterium tuberculosis (Koch bacillus).[1] TB has re-emerged as a major global public health concern since the mid-1980s and also one of the important cause of morbidity and mortality. Globally, tuberculosis accounted for 1.2–1.5 million deaths with 85% of this occurring in developing countries.[2] In 2013, of the estimated global annual incidence of 9 million TB cases, 2.1 million were estimated to have occurred in India.[3]

India has the highest burden of tuberculosis in the world, accounting for approximately one fifth of the global incidence. Prevalence of tuberculosis in India is 256/100000 population and incidence of new sputum-positive pulmonary tuberculosis in India is 55/100000 population.[4]

Pulmonary TB (PTB) accounts for more than 85% of all cases[5] and is most likely a source of TB transmission in the community. A case of untreated smear-positive TB can infect up to 15 people annually and more than 20 people during the natural course of untreated disease.[6,7] Early diagnosis and adequate treatment of infectious patients with pulmonary TB are necessary to reduce transmission of M. tuberculosis and ultimately to achieve elimination of TB.[8,9]

The Revised National Tuberculosis Control Programme (RNTCP), an application of Directly Observed Treatment Short Course Chemotherapy (DOTS) was launched in India in 1977 with a goal to reduce mortality and morbidity due to tuberculosis. The DOTS strategy aims to improve patient adherence to treatment and thereby prevents development of drug resistance.[10] The national cure rate of 88% was documented by RNTCP in 2012 for the new smear-positive patients of pulmonary TB at the end of the treatment.[4]

Despite the implementation of effective control programme and high DOTS coverage, tuberculosis has remained a major cause of morbidity and mortality in all age groups. So, the present study was carried out to assess the profile and treatment outcome among pulmonary tuberculosis patients registered under DOTS in Assam Medical College and Hospital, Dibrugarh, Assam.

MATERIALS AND METHODS

Study Type
A Retrospective cross-sectional study.

Study Duration
Six months (March 2013 – August 2013).

Inclusion Criteria
All patients diagnosed with pulmonary tuberculosis and enrolled under DOTS during one year period (February 2012 to January 2013) in Pulmonary Medicine department of Assam Medical College and Hospital, Dibrugarh were included for study.

Data like Sociodemographic variables such as age and sex and category of TB at the start (new, Re-treatment) and treatment outcomes were collected from the DOTS registration book.

Ethical Consideration
Ethical clearance obtained from Institutional Ethics Committee and permission was taken from the Head of The Department of Pulmonary Medicine, Assam Medical College and Hospital, Dibrugarh prior to the study.

Case Definitions[11]

Pulmonary Tuberculosis, Smear Positive
Patient with at least one initial sputum smear examination (direct smear microscopy) positive for AFB.

Pulmonary Tuberculosis, Smear Negative
A patient with symptoms suggestive of tuberculosis with two smear examinations negative for AFB, with evidence of pulmonary TB by microbiological methods or Chest X ray.

New Cases
A patient who has never had treatment for tuberculosis or has taken antituberculosis drugs for less than one month.

Re-treatment
Patient who received 1 month or more of anti-TB drugs in the past.

Cured
Initially smear-positive patient who has completed treatment and had negative sputum smears, on at least two occasions, one of which was at completion of treatment.

Treatment Completed
Sputum smear-positive case who has completed treatment with negative smears at the end of the initial phase but none at the end of treatment

Or sputum smear-negative patient who has received a full course of treatment and has not become smear positive during or at the end of treatment.

Default
A patient who at any time after completion of 1 month of treatment has not taken anti-TB drugs for 2 months or more consecutively.

Failure
New smear-positive patient who is smear positive at 5 months or later after starting treatment.
Or a patient who was initially smear negative but becomes smear positive during treatment.

Transferred Out
A patient who has been transferred to another tuberculosis unit/District and his/her treatment results are not known.

Died
Patient who died during treatment, regardless of cause.

Successfully Treated
When a patient has cured or completed treatment.

Unsuccessful Treatment
It includes Default, Failure and patients who died. Transferred outpatients were excluded as their outcome of treatment is not known.

Statistical Analysis
Data was entered and analysed by SPSS V-14.0. Data were presented in ratio, proportion, mean and standard deviation. Association between different factors was seen by using Chi-square test.

RESULTS
A total of 661 patients diagnosed with pulmonary tuberculosis and enrolled under DOTS were identified. Of all patients, 456 (69%) were males and 205 (31%) were females. The male: female ratio was 2:1. The mean age of patients was 32.25 ± 15.12 years with majority (32.1%) were in 21-30 years age group followed by 18.3% in 31-40 years age group. (Table 1)

Variables		Number (%)
Age (years)	0-10	30 (4.5%)
	11-20	117 (17.7%)
	21-30	212 (32.1%)
	31-40	121 (18.3%)
	41-50	110 (16.7%)
	51-60	38 (5.7%)
	>60	33 (5%)
Sex	Male	456 (69%)
	Female	205 (31%)
Table 1. Demographic Characteristics of Pulmonary Tuberculosis Patients (n=661)		

About the profile of pulmonary tuberculosis, most (63.2%) were new sputum smear-positive pulmonary TB cases, followed by Re-treatment cases (18.8%) and new sputum smear negative (18%). (Table 2)

Profile of Pulmonary Tuberculosis Patients	Number	Percentages
New sputum smear positive	418	63.2%
New sputum smear negative	119	18%
Re-treatment	124	18.8%
Table 2. Profile of Pulmonary Tuberculosis Patients (n= 661)		

Treatment Outcome	Total	Percentages
Cured	410	62
Treatment completed	155	23.4
Default	38	5.7
Failure	33	5
Transferred out	5	0.8
Died	20	3
Table 3. Treatment Outcome among Pulmonary Tuberculosis Patients (n=661)		

Regarding the outcome of treatment of pulmonary tuberculosis, success rate (cure and treatment completed) was 85.4%. Proportion of default, failure, died and transferred out among pulmonary tuberculosis patient were 5.7%, 5%, 3% and 0.8% respectively. (Table 3)

Treatment outcome in respect to age group, cure rate was significantly highest (65.3%) in 31-40 years age group followed by 64.5% in 41-50 years age group. Rate of Default, died and transferred out were found to be significantly highest in >60 years age group followed by 51-60 years group. (Table 4).

Age Group (years)	Cured	Treatment Completed	Default	Failure	Died	Transferred Out	Total	p value
0-10	13 43.3%)	12 (40%)	0 (0%)	3 (10%)	2 (6.7%)	0 (0%)	30	
11-20	74 (63.2%)	33 (28.2%)	5 (4.3%)	2 (1.7%)	2 (1.7%)	1 (0.9%)	117	
21-30	144 (67.9%)	33 (15.6%)	15 (7.1%)	16 (7.5%)	4 (1.9%)	0 (0%)	212	
31-40	82 (67.8%)	31 (25.6%)	5 (4.1%)	3 (2.5%)	0 (0%)	0 (0%)	121	<0.001
41-50	72 (65.5%)	25 (22.7%)	5 (4.5%)	2 (1.8%)	6 (5.5%)	0 (0%)	110	
51-60	23 (60.5%)	6 (15.8%)	2 (5.3%)	4 (10.5%)	2 (5.3%)	1 (2.6%)	38	
>60	2 (6.1%)	15 (45.5%)	4 (12.1%)	3 (9.1%)	4 (12.1)	3 (9.1%)	33	
Table 4. Treatment Outcome of Pulmonary Tuberculosis Patients in Respect to Age (n=661)								

p value <0.05 is significant at 95% confidence interval.
Unsuccessful treatment outcome was found to be significantly associated with older age group and male patients. In >60 years and male patients, the unsuccessful rate was highest i,e 43.3 % and 15.9% respectively while lowest in 31-40 years age group (6.6%) and female patients (9.4%). (Table 5)

Demographic characteristics	Treatment outcome			p value
	Unsuccessful	Successful	Total	
Sex				
Female	19 (9.4%)	184 (90.6%)	203	>0.05
Male	72 (15.9%)	381 (84.1%)	453	
Age (Years)				
0-10	5 (16.7%)	25 (83.3%)	30	
11-20	9 (7.8%)	107 (92.2%)	116	
21-30	35 (16.5%)	177 (83.5%)	212	
31-40	8 (6.6%)	113 (93.4%)	121	<0.001
41-50	13 (11.8%)	97 (88.2%)	110	
51-60	8 (21.6%)	29 (78.4%)	37	
>60	13 (43.3%)	17 (56.7%)	30	
Table 5. Association of Treatment Outcomes with Demographic Characteristics among Pulmonary Tuberculosis Patients (n=656)				

p value <0.05 is considered significant at 95% CI.

DISCUSSION

Routine recording and reporting of the numbers of TB cases diagnosed and treated by Revised National TB Control Programmes (RNTCPs) and monitoring of the outcomes of treatment was one of the five elements of TB control emphasized in the DOTS strategy, and remains one of the core elements of the stop TB strategy.[12] So, assessment of antituberculosis treatment outcome as well as analysis of factors responsible for poor treatment outcome is one of the major indicators for the evaluation of the performance of a Revised National Tuberculosis Control Program (RNTCP).

The present study revealed that among the Pulmonary TB patients registered within 1 year period, the proportions of the male were twice than female. Mekonnen D et al[13] in their study also reported similar findings. The possible reason might be related with lower rates of notification of TB among women than men due to low health seeking behaviour, lack of financial control and stigma associated with being TB positive.[14]

Patients who were mostly affected were within the age range group of 21-30 years (32.1%) and 31-40 years (18.3%). This agreed with findings reported in different

studies[15,16,13] which indicated that TB mainly affects the reproductive segment of the population. The age groups most affected from this work also conform to global trend in which the middle age groups are most at risk of being infected with tuberculosis. The reasons might be due to high prevalence of HIV, drug abuse, alcoholism, smoking in these age group and added factors like poor living conditions occasioned by unemployment and poverty thus portending grave danger to the society.[17,13]

The TB profile data showed that high proportions of TB patients were new sputum smear positive (63.2%) followed by Re-treatment (18.8%) and new sputum smear negative (18%) which is comparable with reports of WHO 2014.[15]

DOTS is a highly effective and efficient means of managing tuberculosis. In our study, the treatment success rate of Pulmonary tuberculosis cases was 85.4% which has achieved the target level set by the WHO for successful outcomes of 85% and the RNTCP[10] target of 85%. This may be due to full supervision of DOTS Strategy[10] in the treatment centres for 2 months on Category 1 and 3 months for Category 2 during the intensive phase while patients are expected to collect their drugs on monthly basis during the continuation phase. However, the study also documented unfavourable treatment outcome of 5.7% default, 5% treatment failure, 3% death, and 0.8% transferring out.

Age factor played a significant role in the outcome of antituberculosis treatment. Likewise, as the age of TB patients increased, defaulting rate of the patients was increased from 0% in the age group of 0-10 years to 12.1% in the age group of >60 years. This is in agreement with a study conducted in Northeast Ethiopia.[17] Higher age has been identified as a risk factor for default.

As the age of TB patients increased, the death rate of TB patients was raised and highest (12.1%) in geriatric age group. This is in line with studies conducted in Northeast Ethiopia[17] which showed old age as a risk factor for death.

Regarding the role of different sociodemographic characteristics as determinant in successful antituberculosis treatment outcome, it was observed that the success rate was more among female (90.6%) than male (84.1%). But the association was not found to be significant. Malede A et al [17]in their study also reported that females had more successful treatment outcomes than male. As the females are not exposed to various crowded social and environmental settings, so it may affect the outcome of successful treatment. [17] As the age of TB patients increased, the success rate is also decreased. The success rate is highest in 31-40 years followed by 11-20 years age group and lowest in geriatric age group (>60 years) followed by 51-60 years age group. This is in agreement with study done in Ethiopia [17] which reported old age increases the risk of poor treatment outcome. Older age groups have often co infections and physiological upset with age, less able to reach health institutions and are also poorer than the younger population. [17]

CONCLUSION
In summary, treatment success rate (85.4%) among Pulmonary TB patients in this study has met the target of RNTCP i.e. 85% which is very encouraging for TB control through DOTS strategy. The proportions of smear-positive PTB were higher than smear negative PTB cases and Re-treatment cases. Moreover, older age and male sex were found to be at risk of poor treatment outcome. There is a need for targeted medical interventions for the patients who are at high risk of unfavourable treatment outcomes. Correspondingly, those who attend health centres especially sputum smear-positive pulmonary TB patients, older age groups and male TB patients should be encouraged to decrease TB transmissions and successful treatment outcome. Generally, to reduce poor treatment outcome, patients should be strictly followed by health extension workers or trained community health workers.

DOTS is a highly effective and efficient means of managing TB. Efforts should be made to increase treatment centres so as to make them available to patients in developing countries that bear a large burden of the disease. Use of a comprehensive approach, which may include the provision of incentives, transportation, feeding, and others, will go a long way in enhancing DOTS.

Limitation of Study
The recorded data lack detailed clinical profile like CD4 count and other comorbidities. Also, other sociocultural factors and socioeconomic factors such as education, occupation, housing, and income that can affect the outcome of patients on treatment were not documented in the record used for this study.

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