Original Research Article

Treatment outcome of tuberculosis patients in the directly observed treatment short course centres of Dibrugarh, Assam

Julee Rajkhowa*, Sultana J. Ahmed, Tulika G. Mahanta, Gourangie Gogoi

Department of Community Medicine, Assam Medical College and Hospital, Dibrugarh, Assam, India

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*Correspondence:
Dr. Julee Rajkhowa,
E-mail: jrajkhowa17@gmail.com

ABSTRACT

Background: Tuberculosis (TB), second leading cause of mortality in India. Despite of so many efforts of National Tuberculosis Elimination Programme (NTEP), tuberculosis is still prevalent. Therefore, this study was conducted to assess socio-demographic, clinical profile and treatment outcomes of patients on fixed drug combination (FDC) daily regimen.
Methods: Retrospective record-based study was conducted in two DOTS centres of Dibrugarh selected using simple random sampling. A total of 85 medical record were selected and reviewed. Information from treatment card were extracted using a pre-designed online format. Data collected were entered and analysed in SPSS version 25 software and presented using descriptive statistics.
Results: Total of 85 patients records were reviewed. Gender ratio was 54.1%: 45.9% for male:female. Majority 31.8% belonged to most productive age group of 25-34 years of age. Treatment completion rate was 80%, cured rate was 18.8% while 1.2% was died.
Conclusions: Male gender were reported with higher incidence of Tuberculosis. The low percentage of cure rate suggested the need for strengthening of TB services in the DOTs centres.

Keywords: Record review, Directly observed treatment short course, Treatment outcome

INTRODUCTION

Tuberculosis (TB) persists as a major public health challenge.[1-3] TB impacted the most economically productive age group leading to major socioeconomic hardship.[4] Many children and women experienced rejection from school and society due to their families diagnosed with TB.[4] In 2022, worldwide an estimated 10.6 million people fell ill with TB, comprising 5.8 million men, 3.5 million women and 1.3 million children.[5] While India notified 24.2 lakh TB (13% increase) compared to 2021, highest in the world.[6] In 2022, out of total TB cases notified, 61% were male, 39% were female, 5.6% were children <14 years and <1% were from other gender.[6] Treatment initiation rate among notified cases for 2022 was 95.5%.[6] In Assam, 78.4% TB cases were notified in 2022 and treatment success rate was 87.6% in males, 89.2% in female and 90.9% in transgender cases.[6] NTEP has consistently changed its programming to address the nation's tuberculosis control problems.[7] To meet National Strategic Plan (NSP) goals by 2025, newer interventions have been implemented, such as 99 DOTS (a creative and affordable intervention for ensuring medication adherence), Nikshay Poshan Yojana (financial assistance for nutritional support of the patient), universal drug sensitivity testing (DST), and strengthening adverse event surveillance and reporting.[7]

For early diagnosis, all persons with cough of ≥2 weeks should be referred for TB evaluation.[8] In Dibrugarh district of Assam, RNTCP (Revised National Tuberculosis Control Programme) was initially

introduced in 1998-1999 and has been implemented in all districts of Assam.[9,10] Present study was conducted to assess socio-demographic, clinical profile and treatment outcomes of patients on FDC daily regimen.

METHODS

Study setting and type

In 1998, NTEP was launched as a pilot project in Dibrugarh district of Assam.[11,12] Complete coverage of the state was attained in 2004 through phase-wise expansion.[12] This study was conducted in DOTs centres of a tertiary care teaching hospital and Rural Health Training Centre, Chabua of Dibrugarh district. This was an observational retrospective study based on medical records review.

Study participants and design

Out of 14 DOTs centres, 2 centres were selected by simple random sampling. In Dibrugarh district, there are total 6 Tuberculosis unit (TU) and 14 Designated Microscopy Centre (DMC).[10] Out of these 14 DMCs, 2 DMCs where the DOTs centre was present were selected by simple random sampling. The records of all the patients registered from the 1st April 2023- 1st July 2023 were extracted. Total of 85 records were reviewed and data were collected from the TB patient treatment card records at DOTs centre.

Data collection

Data was collected from TB treatment cards available at selected DOTs centres. For data extraction online formats were developed and utilized. This online format was first pretested by collecting data for 10% patients of sample size registered in another DOTs centre and was then modified to capture the necessary information depending on results of the pretest.

The format had information on socio-demographic characteristics of patients such as age, sex, occupation, family type, information on clinical variables such as type of patient, laboratory results such as smear microscopy, human immune deficiency virus (HIV) test results, anti-retroviral therapy (ART) and Isoniazid Preventive Therapy (IPT) enrolment of family members and information on TB treatment outcome. Operational definitions of standard TB treatment outcomes like "cured", "treatment completed", "treatment failure", "lost to follow up" and "died" were used.[13]

Statistical analysis

Data were entered and analyzed using SPSS version 25 software. Data was presented as frequencies and percentages. Odds ratio with 95% CI was applied to analyses the association of risk factors with treatment outcome.

RESULTS

Demographic and clinical characteristics of TB patients registered at DOTs centres of Dibrugarh

Total of 85 registered tuberculosis cases were reviewed registered in the selected DOTs centres. Mean age of cases was 33.91±13.84 years. Table 1 reveals most of the respondents, 27 (31.8%) belonged to the ages of 25-34 years. Greater proportion of the respondents 46 (54.1%) were males. Majority 74 (87.1%) belonged to nuclear family. 81 (95.3%) cases had pulmonary tuberculosis and 4 (3.7%) reported as extra-pulmonary tuberculosis. Out of 85 patients, 4 (4.7%) respondents were registered as diabetic and one (1.18%) was recorded as HIV positive. Mean weight of cases was 40.07±9.49 kg.

Table 1: Socio-demographic and clinical profile of tuberculosis patients registered at DOTs centres, Dibrugarh.

Variables		Number (%)
Age (years)	<15	2 (2.4)
	15-24	19 (22.4)
	25-34	27 (31.8)
	35-44	18 (21.2)
	45-54	11 (12.9)
	55-64	4 (4.7)
	>=65	4 (4.7)
Gender	Female	39 (45.9)
	Male	46 (54.1)
Family type	Nuclear	74 (87.1)
	Joint	11 (12.9)
Site of TB	Pulmonary	81 (95.3)
	Extra-pulmonary	4 (3.7)
DM-TB	Yes	4 (4.7)
	No	62 (72.94)
	NA*	19 (22.35)
HIV	Reactive	1 (1.18)
	Non-reactive	84 (98.82)
Weight (kg)	25-34	24 (28.2)
	35-49	47 (55.3)
	50-64	13 (15.3)
	65-75	1 (1.2)

*NA (not available): Result of Random Blood Sugar was not registered on the records reviewed, DM-TB: Diabetes Mellitus-Tuberculosis.

Treatment outcome among TB patients registered at DOTs centres of Dibrugarh

Figure 1 is showing the treatment outcome of TB patients at the end of continuation phase. The proportion of "successful" (cured and treatment completed) and "unsuccessful" (died, treatment failure, lost to follow-up) were 98.82% and 1.18% respectively. Out of 85 respondents, 68 (80%) were recorded as treatment

completed, 16 (18.8%) as cured and one (1.2%) was recorded died.

Determinants of treatment outcome in patients

Association of demographic and clinical factors with TB treatment outcome was assessed in Table 2. It was found that odds of successful treatment outcome were 3.98 times higher among the patients less than 35 years of age, 3.62 times higher in males than females and 2.13 times higher among the patients living in nuclear family than those living in joint family. Also, treatment success was negatively associated with HIV positive status, presence of diabetes mellitus and presence of alcohol intake history among the patients. None of the characteristics were found statistically significant.
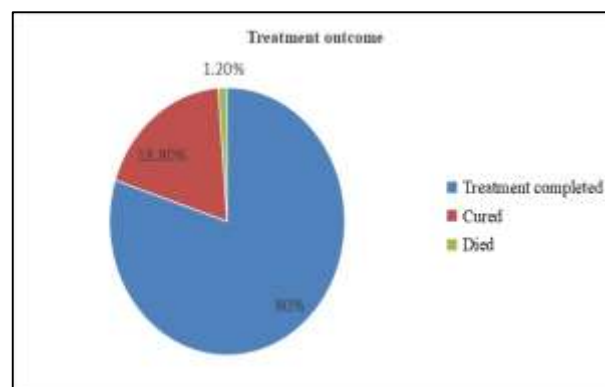

Figure 1: Treatment outcome among TB patients registered at DOTs centres of Dibrugarh.

Table 2: Association of demographic and clinical factors with TB treatment outcome.

Variables		Treatment outcome		OR (95% CI)	P-value
		Successful	Unsuccessful		
		Number (%)	Number (%)		
Age (years)*	<35	48 (56.47)	-	3.98 (0.15 to 100.70)	0.40
	≥35	36 (42.35)	1 (1.18)	Reference	
Gender	Male	46 (54.12)	-	3.62 (0.14 to 91.50)	0.43
	Female	38 (44.70)	1 (1.18)	Reference	
Family type	Nuclear	73 (85.88)	1 (1.18)	2.13 (0.08 to 55.52)	0.64
	Joint	11 (12.94)	-	Reference	
HIV	Reactive	1 (1.18)	-	0.01 (0.0003 to 1.23)	0.06
	NR	84 (98.82)	-	Reference	
DM-TB*	Yes	4 (4.70)	-	Reference	
	No	61 (71.76)	1 (1.18)	0.87 (0.03 to 22.18)	0.93
	NA*	19 (22.35)	-	0.89 (0.03 to 22.81)	0.94
Alcohol	Yes	19 (22.35)	-	0.89 (0.03 to 22.81)	0.94
	No	65 (76.47)	1 (1.18)	Reference	
Tobacco	Yes	27 (31.76)	-	1.43 (0.05 to 36.37)	0.82
	No	57 (67.05)	1 (1.18)	Reference	

*Clubbing of age-group for particular analysis only, DM-TB: Diabetes mellitus-tuberculosis, NA (not available): Result of random blood sugar was not registered on the records reviewed

DISCUSSION

Most common age group affected was 15-34 years. Similar findings were reported by Mandolikar Y et al and by Bawri S et al.[14,15] This is suggestive of physical and economically active group was affected predominately, which may lead to increase in dependency, loss of income and thus poverty. Gender distribution in our study shows a higher prevalence of disease in males and similar male predominance was found by Awunor et al and Washington et al.[16,17] This may be because majority of females were homemakers and thus less exposed. Also, males tend to work outside and get more exposure to infectious agents than females. Nuclear family were more affected than joint and similar findings by Kamble et al.[18] This may be due to less than average living area per person and thus leading to overcrowding.

With regards to the HIV status of the patients, majority were HIV negative, and one was recorded as HIV positive. This is not consistent with results from a previous study carried by Ebuenyi et al reporting high number of HIV positive cases.[19] In our study treatment success was negatively associated with HIV positive status of the patients which is consistent with studies conducted by Alayu Alemu et.al and Fekadu et al.[20,21] They found that TB-HIV co-infected patients have lower treatment success rate. It is also in accordance with overall unsuccessful outcome in TB-HIV co-infection is high. Our study findings may not be conclusive or generalizable as we have not studied the HIV-TB patients exclusively.

DM-TB status of patients was found to be negatively influencing the treatment outcome. This is in accordance

that diabetes has been associated with increased risk of treatment failure, relapse and mortality in TB patients. Bagga et.al found unfavorable outcome amongst diabetics as compared to non-diabetics.[22] Statistically significant relationship was observed between diabetes and unfavorable treatment outcome. Dooley et al in Maryland, USA reported that diabetes was a relatively common morbidity and had a negative impact on treatment outcome.[23] Gupta et al in Manipal, India also reported that Diabetes mellitus was the most (30.9%) prevalent condition and significantly more common than other risk factors.[24]

High proportion of treatment completion rate was found in our study which is line with studies conducted by Kayina et al, Bagga et al and Tesema et al.[22,25,26] In our study, male gender, age <35 years and nuclear family type was found positively associated with successful treatment outcome although some studies have shown better outcomes in females while adverse outcome were seen in elderly.[27]

Limitation of our study was as it relied on secondary data and thus limited socio-demographic characteristics of the cases were obtained. Future follow up study may help in better evidence generation.

CONCLUSION

Low percentage of cure rate suggested the strengthening of TB diagnostic services in DOTs centres. High incidence of Tuberculosis amongst the male and the diabetic status of the study participants showed the requirement of targeted TB control measures to decrease poor TB treatment outcomes amongst high-risk patients. Furthermore, early identification of patients at high-risk of unsuccessful treatment outcome should be done and additional follow-up with combination of medical interventions and social support should be provided. Further research for effective implementation of existing/new interventions related to HIV and other social determinants should be done.

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