

Original Research Article

Treatment outcome of the retreatment tuberculosis patients under RNTCP in eastern Uttar Pradesh

Praveen B. Gautam^{1*}, Ashwini Kumar Mishra¹, Santosh Kumar²

Department of TB and Chest, ¹BRD Medical College, Gorakhpur, ²SN Medical College, Agra, Uttar Pradesh, India

Received: 22 June 2017

Accepted: 07 July 2017

*Correspondence:

Dr. Praveen B. Gautam,

E-mail: pravingautom12@gmail.com

Copyright: © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

ABSTRACT

Background: India has the highest tuberculosis (TB) burden in the world. The directly observed treatment strategy is the most systemic and cost-effective approach to the disease. Furthermore, understanding the reasons for treatment outcome is important for the improvement of treatment systems. The objective was to study the treatment outcome of retreatment tuberculosis patients under RNTCP in eastern UP.

Methods: A longitudinal cohort study was undertaken among total 205 patients registered in category II under DOTS from June 2015 to May 2016. These patients were followed up to November 2016 till the completion of treatment. At the end of study period, treatment outcomes were analysed. The chi-square test was used to assess the statistical significance of each ratio. $P < 0.05$ was considered significant.

Results: Out of 205 re-treatment patients, 174 (84.4%) had pulmonary tuberculosis while 31 (15.1%) had extra-pulmonary TB. In the cohort of category II patients 93 (45.3%) were relapse, 58 (28.2%) belonged to others category, 31 (15.1%) were treatment after loss to follow-up and 23 (11.2%) were on treatment after failure. Maximum patients were male 133 (64.8%) and most of the patients were belonged to the age group of 20-40 years. Among retreatment cases the cure rate for relapse, treatment after failure, treatment after loss to follow-up and others cases were 74.1%, 60.8%, 35.4% and 55.1% respectively.

Conclusions: The relapse cases were the most commonly found in the re-treatment category however these patients were more likely to be cured with the category II regimen and treatment after loss to follow-up had high risk of retreatment failure. Continuous monitoring, adherence and treatment completion are essential for controlling the need of retreatment as well as improvement of tuberculosis control programme.

Keywords: Retreatment, Loss to follow-up, RNTCP, Tuberculosis, Outcome

INTRODUCTION

Tuberculosis is a major public health problem. Though India is the second most populous country in the world, one fourth of the global incident TB cases occur in India annually. As per WHO global TB report, 2015, out of the estimated global annual incidence of 9.6 million TB cases, 2.2 million were estimated to have occur in India.¹

Revised national tuberculosis control programme (RNTCP) was revised and intensified version of national

tuberculosis programme (NTCP) due to its failure and occurrence of multi-drug resistance.²

The directly observed therapy short course (DOTS) strategy is believed to be most valuable strategy for TB control. To combat this over-whelming problem, the government of India also piloted and then expanded the DOTS strategy under RNTCP.³ DOTS, which was launched in March 1997 and gradually covered the entire country of India by March 2006.

A key components of DOTS strategy is directly observed treatment, which aim to improve patient adherence to treatment and thus prevent the development of drug resistance.⁴

The present study was aimed to assess the treatment outcome of re-treatment tuberculosis patients under RNTCP in eastern U.P.

METHODS

The present prospective longitudinal cohort study was carried out in the department of Tuberculosis and Chest Diseases, BRD Medical College, Gorakhpur with attached Tuberculosis Unit from June 2015 to May 2016. Out of 610 patients who were registered during this period, only 205 patients were registered under category II, rest were registered under category I. Those patients, who were registered under category II were followed up to November 2016 till the completion of treatment. Both pulmonary and extra-pulmonary were enrolled, irrespective of the sputum status. Patients of category I, transferred out, transferred in during the period were excluded from the study. Informed consent was taken from the patients or guardians (in case of minors) and study was ethically approved by the Institutional ethical Committee. A detailed history of the patients regarding demography, educational and economic status and previous TB treatment were taken. These patients were followed up regularly and required laboratory investigations, chest x-rays and sputum smear examination were performed. At the end the study, treatment outcome of the re-treatment cases were evaluated.

Statistical analysis

All variables were described by proportions and differences between independent groups were compared using the chi-square test. $P < 0.05$ was considered as statistically significant.

Case definition

According to the world health organization (WHO), tuberculosis cases are classified into new and re-treatment (previously taken anti-TB drug for >1 month) TB cases. Re-treatment cases further classified as relapse, treatment after failure, treatment after loss to follow up and others.⁵ All re-treatment tuberculosis cases were treated by 8 months regimen of anti-TB drug under RNTCP guideline of TB treatment. Treatment outcome were defined as per WHO criteria.

Case definitions of re-treatment TB patients according to WHO

Relapse

Patients have previously been treated for TB, were declared cured or treatment completed at the end of their

most recent course of treatment and are now diagnosed with a recurrent episode of TB. (either a true relapse or a new episode of TB caused by reinfection)

Treatment after failure

Patients are those who have previously been treated for TB and whose treatment failed at the end of their most recent course of treatment.

Treatment after loss to follow-up

Patients have previously been treated for TB and were declared lost to follow-up at the end of their most recent course of treatment (these were previously known as treatment after default patients).

Others

Patients are those who have previously been treated for TB but whose outcome after their most recent course of treatment is unknown or undocumented

Definition of treatment outcome according to WHO

Cured

A pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment who was smear - or culture -negative in the last month of treatment and on at least one previous occasion.

Treatment completed

A TB patient who completed treatment without evidence of failure but with no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion were negative, either because tests were not done or because results are unavailable.

Treatment failed

A TB patient whose sputum smear or culture is positive at month 5 or later during treatment.

Died

A TB patient who dies for any reason before starting or during the course of treatment.

Lost to follow-up

A TB patient who did not start treatment or whose treatment was interrupted for two consecutive months or more.

Not evaluated

A TB patient for whom no treatment outcome is assigned. This includes cases "transferred out" to another treatment

unit as well as cases for which the treatment outcome is unknown to the reporting unit

Treatment success

The sum of cured and treatment completed.

RESULTS

In present study, 93 (45.3%) were relapse patients, 58 (28.2%) were belonged to others category, 31 (15.1%) were on treatment after loss to follow-up and 23 (11.2%) were treatment after failure.

Demographic characteristics

In Table 1, among 205 retreatment tuberculosis patients, 133 (64.8%) were male and 72 (35.1%) were female registered under category II of RNTCP, TU, BRD Medical college Gorakhpur. Among the male, 61 (45.8%)

were relapse, 14 (10.5%) were treatment after failure, 21 (15.7%) were treatment after loss to follow-up and others were 37 (27.8%). Among the female 32 (44.4%) belonged to relapse and 21 (29.1%) were other category.

Maximum patients belonged to age group of 20-40 years (42.9%). In this age group 41 (46.5%) were relapse cases, 23 (26.1%) were other category and thirteen patients (14.7%) were treatment after loss to follow-up.

In the present study, maximum patients were Hindu 99 (48.2%) while 74 (36.0%) were Muslim and 32 (15.6%) were Christian and Sikh. One forty two (69.2%) were married and 63 (30.7%) belonged to other (e.g. single, widow, widower).

Maximum patients were employed 69 (33.6%) followed by labourer 62 (30.2%), 51 (24.8%) were housewives and by education 153 (75.6%) were literate while 50 (24.3%) were illiterate.

Table 1: Socio-demographic profile with type of patients.

Characteristics	Relapse (n=93)	Treatment after failure (n=23)	Loss to follow up (n=31)	Others (n=58)	Total (n=205)	P value
Age (in years)						
<20 (%)	5 (50)	1 (10)	2 (20)	2 (20)	10 (4.8)	p≥0.05
20-40 (%)	41 (40.5)	11 (12.5)	13 (14.7)	23 (26.1)	88 (42.9)	
40-60 (%)	28 (45.1)	7 (11.2)	9 (14.5)	18 (29.0)	62 (30.2)	
>60 (%)	19 (42.2)	4 (8.8)	7 (15.5)	15 (33.3)	45 (21.9)	
Sex						
Male (%)	62 (45.8)	14 (10.5)	21 (15.7)	37 (27.8)	133 (64.8)	p≤0.05
Female (%)	32 (44.4)	9 (12.5)	10 (13.8)	21 (29.1)	72 (35.1)	
Religion						
Hindu (%)	48 (48.4)	9 (9.0)	14 (14.1)	28 (28.2)	99 (48.2)	p≥0.05
Muslim (%)	32 (43.2)	10 (13.5)	10 (13.5)	22 (29.7)	74 (36.0)	
Other	13 (40.6)	4 (12.5)	7 (21.8)	8 (25.0)	32 (15.6)	
Marital status						
Married (%)	65 (45.7)	17 (11.9)	22 (15.4)	38 (26.7)	142 (69.2)	p≥0.05
Other (single/widow) (%)	28 (44.4)	6 (9.5)	9 (14.2)	20 (31.7)	63 (30.7)	
Occupation						
Employed (%)	33 (47.8)	9 (13.0)	7 (10.1)	20 (28.9)	69 (33.6)	p≥0.05
Labourer (%)	29 (46.7)	7 (11.2)	14 (22.5)	12 (19.3)	62 (30.2)	
Housewife (%)	22 (43.1)	5 (9.8)	6 (11.7)	18 (35.2)	51 (24.8)	
Unemployed (%)	9 (39.1)	2 (8.6)	4 (17.3)	8 (34.7)	23 (11.2)	
Education						
Literate (%)	73 (47.0)	16 (10.3)	22 (14.1)	44 (28.3)	155 (75.6)	p≤0.05
Illiterate (%)	20 (40.0)	7 (14.0)	9 (18.0)	14 (28.8)	50 (24.3)	
Alcoholism						
Non-alcoholic (%)	78 (45.0)	21 (12.1)	22 (12.7)	52 (30.0)	173 (48.3)	p≥0.05
Alcoholic (%)	15 (46.8)	2 (6.2)	9 (28.1)	6 (18.7)	32 (15.6)	
Type of disease						
Pulmonary (%)	78 (44.8)	16 (9.1)	22 (12.6)	58 (33.3)	174 (84.8)	p≥0.05
Extra-pulmonary (%)	12 (38.7)	7 (22.5)	9 (29.0)	3 (9.6)	31 (15.1)	
HIV status						
Nonreactive (%)	89 (45.8)	23 (11.8)	29 (14.9)	53 (27.3)	194 (94.6)	p≤0.05
Reactive (%)	4 (36.3)	1 (9.0)	2 (18.1)	4 (36.3)	11 (5.3)	

Table 2: Treatment outcomes of the retreated TB patients.

Retreatment TB patients	Treatment success (%)					Total (%)
	Cured (%)	Completed (%)	Failure (%)	Loss to follow-up (%)	Died (%)	
Relapse (n=93)	69 (74.1)	9 (9.6)	4 (4.3)	6 (6.4)	5 (5.3)	93 (45.3)
Treatment after failure (n=23)	14 (60.8)	3 (13.0)	3 (13.0)	2 (8.6)	1 (4.3)	23 (11.2)
Treatment after loss to follow-up (n=31)	11 (35.4)	6 (19.3)	7 (22.5)	4 (12.9)	3 (9.6)	31 (15.1)
Others (n=58)	32 (55.5)	17 (29.3)	2 (3.4)	4 (6.8)	3 (5.1)	58 (28.2)
Total	126 (61.4)	35 (17.0)	16 (7.8)	16 (7.8)	12 (5.8)	205 (100)

Chi square = 29.245, p= 0.003 (significant <0.05).

In present study, 174 (84.8%) patients were having pulmonary while 31 (15.1%) were extra-pulmonary TB and 32 (15.6%) were alcoholic and 11 (5.3%) were HIV positive.

Treatment outcome

In Table 2, cure rate was maximum 69 (74.1%) in the patients belonging to relapse category followed by other category 32 (55.1%) while cure rate among treatment after failure and treatment after loss to follow-up were 14 (60.8%) and 11 (35.4%) respectively.

Maximum number of death and failure were observed in treatment after loss to follow-up category which were 7 (22.5%) and 3 (9.6%) respectively.

DISCUSSION

In present study, maximum retreatment patients were male 133 (64.8%) while female were 72 (35.1%). Similar study was conducted by Jha et al with 1198 (70.0%) male and 514 (30.0%) female in the study on retreatment TB cases.⁶

In present study, maximum retreatment patients belonged to the age group of 20-40 years (42.9%). Similar trend have been observed by Kaur et al.⁷

In present study, Hindu 99 (48.2%) were observed in retreatment cases while Muslim and other (Christian, Sikh) were 36.0% and 15.6% respectively. However there is no predilection of TB towards any religion.

In our study, 142 (69.2%) were married retreatment TB cases while Sophia et al, reported 59.4% married TB patients.⁸

In present study, 50 (24.3%) patients were illiterate which was similar to the study conducted by Sophia et al.⁸

In present study, 174 (84.8%) were pulmonary and 31 (15.1%) were extra-pulmonary which was in accordance to the study conducted by Karanjekar et al and 11 (5.3%)

were HIV positive, which was similar study conducted by Srinath et al.^{9,10}

The present study analysed the outcome of anti-tuberculosis treatment of patients who underwent the category II regimen.

In our study, the rate of relapse, treatment after failure, loss to follow-up and other cases were 45.3%, 11.2%, 15.1%, 28.2% respectively. Chandrasekaran et al, have also found higher relapse in their study.¹¹

In our study, cure rate was highest in the relapse group i.e. 74.1% while in treatment after failure and other category cure rate was 60.8% and 55.5% respectively. Similar trend was seen by Mukherjee et al.¹²

In the present study, failure rate was highest among in the subcategory of treatment after loss to follow-up which was 22.5% and death rate was also high in loss to follow up category. The overall failure rate in this study was 7.8% which could be possible due to drug resistant tuberculosis.

The successful completion of treatment was seen in the present study is near to objective of success rate for retreatment RNTCP guideline.¹³

Limitation of this study was the treatment after loss to follow-up patients during treatment, who did not visit to find out reason and also no attempt was made to visit the patients who did not turn-up for re-starting treatment. Another limitation was that the analysis is based on self-reporting patients who were re-registered in the same tuberculosis unit (TU), but did not cover patients who have reported to any other TU or private sector.

CONCLUSION

Patients presenting for TB retreatment, those with relapse, treatment after failure or treatment after loss to follow up are often group together and treated with a standard category II regimen. However, this group have distinct demographic and clinical characteristics and important difference in retreatment outcome. Retreatment

cases represent a serious threat to TB control in many setting and could significantly undermine the overall success of the DOTS strategy. Hence RNTCP should be strengthened to combat resurgence of re-treatment cases and to improve the treatment outcome among retreatment cases.

ACKNOWLEDGEMENTS

We are thankful to entire staff of RNTCP for providing data and their valuable co-operation.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee of BRD Medical College, Gorakhpur

REFERENCES

- Central TB Division, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi. TB India 2016, Revised National TB Control Programme, annual status report 2016.
- Revised National Tuberculosis Control Programme (RNTCP) problem statement of TB in India. Available at: <http://gmchgov.in/e-study/lectures/community/medicine/RNTCP.pdf>. Accessed on 4 April 2017.
- Khatri GR, Frieden TR. Rapid DOTS expansion in India. Bull World Health Organ. 2002;80:457-63.
- Trebuq A, Reider HL. Two excellent management tool for National Tuberculosis Programme, history of prior treatment and sputum status at two month. Int J Tuberc Lung Dis. 1998;2:184-6.
- World Health Organization. Treatment of Tuberculosis Guidelines. 4th ed. World Health Organization; 2010. Available at: <http://www.who.int/publication/2010>. Accessed on 5 April 2017.
- Jha UM, Satyanarayana S, Dewan PK, Chanda S, Wares F, Sahu S, et al. Risk factors for treatment default among re-treatment tuberculosis patients in India, 2006. PLOS ONE. 2010;5(1):e8873.
- Kaur G, Goel NK, Kumar D, Janmeja AK, Swami HM, Kalia M. Treatment outcome of patients placed on treatment under directly observed therapy short course. Lung India, 2008;25(2):75-7.
- Sophia V, Balasangameshwara VH, Jagannath PS, Saroja VN, Kumar P. Treatment outcome and two and half year follow up of new smear positive patients under RNTCP. Indian J Tuberc, 2004;51:199-208.
- Karanjekar VD, Lokare PO, Gaikwad AV, Doibale MK, Gujrathi VV, Kulkarni AP. Treatment outcome and follow-up of tuberculosis patients put on Directly Observed Treatment Short-Course under rural health training center, Parthan, Aurangabad, India. Ann Med Health Sci Res, 2014;4:222-6.
- Srinath S, Sharath B, Santosh K, Chadha SS, Roopa S, Chander K, et al. Tuberculosis "retreatment others" profile and treatment outcome in the state of Andhra Pradesh, India. Int J Tuberc Lung Dis. 2011;15(1):105-9.
- Chandrasekaran V, Gopi PG, Santha T, Subramani R, Narayanan PR. Status of re-registered patients for tuberculosis treatment under DOTS programme. Indian J Tuberc. 2007;54:12-6.
- Mukherjee A, Sarkar A, Saha I, Biswas B and Bhattacharyya PS. Outcome of different subgroup of smear positive retreatment patients under RNTCP in rural West Bengal, India. Rural Remote Health. 2009;9:926.
- Revised National TB Control Programme, Technical and operational guidelines for tuberculosis control in India, 2016.

Cite this article as: Gautam PB, Mishra AK, Kumar S. Treatment outcome of the retreatment tuberculosis patients under RNTCP in eastern Uttar Pradesh. Int J Community Med Public Health 2017;4:2701-5.