Original Article

Treatment outcomes of previously treated Tuberculosis cases in a tertiary care centre in Nagpur, India

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Abstract

Background:

Tuberculosis (TB) remains a public health problem in India and worldwide. The treatment success rate has been relatively less favourable among previously treated cases when compared to the treatment success rate among new smear positive TB cases.

Objective:

This study was undertaken to assess the characteristics and treatment outcomes in previously treated TB patients as per revised national TB control program Re treatment regimen.

Methods-Setting:

Indira Gandhi Government Medical College Nagpur serves as a Treatment centre (DOT centre) under Nagpur Municipal Corporation.

Study Design:

Retrospective record review of previously treated TB patients registered for treatment from December 2006 to June 2009 receiving short course chemotherapy as per RNTCP at DOTS centre of Indira Gandhi Government Medical College, Nagpur. Analysis was conducted using STATA.

Results:

Records of 105 previously treated TB cases were included in this document review. Majority 42(40%) were from 31-40 productive age group and were predominantly Males 74 (70%). Successfully treated cases included cured cases and those who had completed treatment. Among study group of the previously treated cases 74 (70.48%) completed treatment successfully. The outcome was unsuccessful in 31(29.52%) cases. Comparison of treatment outcomes within retreatment TB cases showed that the treatment success rate among Relapse cases was high (80%) as compared to Treatment after default (47%). Successful treatment outcomes were more frequent in females (80%) than males (66%) and Predominantly smear negative "Others cases" had slightly better outcome (71%) as compared to "Smear Positive previously treated cases" (70%).

Conclusion:

The results of this study show that Treatment success rate was poor among the previously treated male cases as compared to females and those returning for treatment after default. There is need of focusing attention to these cases with improved counselling support and care for the cases who had previously defaulted.

Keywords: Previously Treated TB, Treatment outcomes, Tertiary care centre, Default

Introduction:

Tuberculosis (TB) remains a public health problem in India and worldwide. India and China accounted for 39% of notified cases of TB worldwide in 2011. The notification rate of previously treated cases (retreatment cases) in India has increased by 40% over the past 12 years, from 18 per 100,000 population in 1999 to 25 per 100,000 population in 2011. The treatment success rate has been relatively less favourable among previously treatment cases when compared to the treatment success

rate among new smear positive TB cases. WHO surveillance data from 10 countries found the level of MDR to be 32% in patients returning after defaulting or relapsing and significantly higher (49%) in patients whose prior treatment has failed ² Drug Resistance Surveillance (DRS) of Gujarat, Maharashtra and Andhra Pradesh, estimated the prevalence of Multidrug Resistant TB (MDR-TB) to be about 12-17% in Previously Treated cases ³

Studies have been conducted previously regarding

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Retreatment outcomes⁴⁻⁹ but there are limited studies in India with previously treated tuberculosis cases at a tertiary care centre. The present study was conducted in a tertiary care centre DOT centre at Medical College in Nagpur city dominated by urban slum population. The present study was undertaken to assess the treatment success among previously treated TB cases treated as per revised national TB control program Re treatment regimen.

Material & Methods - Study Setting:

This study was conducted in Indira Gandhi Medical college(IGGMC), a public sector tertiary care centre which is having a DOT centre attached to Nagpur Municipal corporation. This tertiary care centre is serving as diagnostic centre and treatment centre(DOT Centre) for urban dominated and predominantly slum population.

Study Design and Study Population:

This was a retrospective record review of previously treated TB patients registered for treatment from December 2006 to June 2009 receiving short course chemotherapy as per RNTCP at DOTS centre of Indira Gandhi Government Medical College, Nagpur.Records of 105 previously treated TB cases were included in this document review

Case Definitions:

As per the Revised National TB control program guidelines.³

Type of previously treated TB cases - Relapse:

A TB patient who was declared cured or treatment completed by a physician and who reports back to the health facility and is now found to be sputum smear positive.

Treatment after default:

A patient, who has received treatment for TB for a month or more from any source and returns for treatment after having defaulted i.e., not taken anti-TB drugs consecutively for two months or more and found to be smear-positive

Treatment failure:

Any TB patient who is smear-positive at 5 months or more after initiation of treatment.

Others:

A patient who does not fit into the any of the types mentioned above.

Treatment outcome definitions - Cured:

Initially sputum smear positive patient who has completed treatment and had negative sputum smears on two

occasions, one of which was at the end of the treatment

Treatment completed:

Initially sputum smear positive patient who has completed treatment with negative smears at end of the intensive phase / two months in the continuation phase, but none at the end of the treatment is declared as treatment completed. Or Initially sputum smear negative patient who has received full course of treatment and has not become smear positive at the end of the treatment or Extra pulmonary TB patient who has received full course of treatment and has not become smear positive during or at the end of treatment

Died:

Patient who died during the course of treatment regardless of any cause

Failure:

Any TB patient who is smear positive at five months or more after initiation of the treatment and not put on MDR-TB treatment

Defaulted:

A Patient after treatment initiation has interrupted treatment consecutively for more than 2 months

Transferred out:

A patient who has been transferred to another TU and whose treatment outcome is still not available.

Switched over to MDR-TB Treatment:

A patient who has been diagnosed as having MDR-TB by an RNTCP accredited laboratory, prior to being declared as "Failure" and is placed on RNTCP MDRTB treatment regimen.

Data collection and data Variables.

Treatment card of previously treated cases was used as data collection tool. The variables documented for previously treated TB cases were those recorded on these treatment cards. The key variables included age, sex, type of Previously treated TB case, initial sputum result, follow-up sputum result and treatment outcomes. Variables were defined according to RNTCP definitions³. The data were collected in data documentation sheet by two independent investigators. Aggregated treatment outcomes of Treatment success includes cured and treatment completed. For the study unsuccessful outcome include died, defaulted and failure cases.

Data entry and Analysis:

Data entry operators conducted double data entry independently. All discrepancies in data entry were resolved through referral to the original data collection

tool and the data was finalized. Excel and Stata-64 software were used for data entry and analysis. Frequencies and proportions were calculated for all variables. Pearson's chi-square was used to compare proportions between different sub-groups.

Results:

In all 105 previously treated TB cases cards who had received treatment at IGGMC were available for study. Maximum cases were in the age group between 31-40yrs 40% (**Fig 1**)Previously treated cases were predominantly Males 74 (70%). The proportion of Relapse cases among males was 80% and others cases were 71% in the males. Males were out numbering the females. (**Fig 2**)

Out of 105 cases, sputum examination of 95 cases was done initially as 10 cases had no expectoration. Among these 61(64.21%) cases were found to be sputum positive. At the end of intensive phase of 3 months Sputum examination of 86 patients was done and 81(94.2%) were found to be sputum negative (**Table 1.**) Among study group of the previously treated cases 74 (70.48%) completed treatment successfully. The outcome was unsuccessful in 29.52% cases. (**Fig 3.**)

Table 1. Distribution of Previously Treated TB cases according to the result of sputum smears examination						
Result of sputum smear examination with Grades	Pre-treatment Sputum Exam Results	Follow up Sputum Results at 3 months				
3+	16 (15.24)	0 (0)				
2+	15 (14.29)	1 (0.97)				
1+	20 (19.05)	3 (2.91)				
Scanty	10 (9.52)	1 (0.97)				
Negative	34 (32.38)	81 (78.65)				
Not done	10 (9.52)	19(16.50)				
Total	105 (100)	105(100)				

The treatment success rate among Relapse cases was high(80%) as compared to Treatment after default (47%). (Table2) Successful treatment outcomes were more frequent in females (80%) than males (66%) and Predominantly smear negative "Others cases" had slightly

Table 2. Treatment Outcomes of Previously Treated TB cases, Nagpur							
Type of disease	Successful Treatment outcome (cured & treatment completed)	Unsuccessful Treatment outcome (defaulter, died and failure)	Total				
Relapse	32 (80)	8 (20)	40				
Treatment after default	10 (47.62)	11 (52.38)	21				
Others	30 (71.43)	12 (28.57)	42				
Failure	2 (100)	0 (0)	2				
Total	74 (70.48)	31 (29.52)	105				

better outcome(71%) as compared to "Smear Positive previously treated cases" (70%) (**Table 3**).

Table 3. Demographic and Smear characteristics of Treatment Outcomes of Previously Treated TB cases, Nagpur									
	characteristi	cs	Successful outcome	Unsuccessful outcome	total	P Value			
sex			,						
	Male		50	25	75				
	Female		24	6	30	0.092			
Туре			,						
	Previously treated smea positive	ır	44	19	63				
	Others		30	12	42	0.4345			

Discussion:

In the present study majority 42(40%) were from 31-40 years age group which is considered as productive age group. Previously treated cases were predominantly Males 74 (70%). This suggests that productive age group and males who is bread winner for the family are affected.

Out of 105 cases, sputum examination of 95 cases was done and 61(64.21%) cases were found to be sputum positive initially. At the end of intensive phase, Sputum examination of 86 patients was done and 81(94.2%) were found to be sputum negative. In a descriptive study conducted by Joseph N et al (2011) in Mangalore, South India, of the 74 study participants on retreatment regimen, 53 (72%) were in age group of 21 to 50 years. There were 86.5% males and 13.5% females on retreatment regimen. Sputum conversion rate at 3 months and 5 months of treatment was 73 and 78% respectively.⁴

In Present study, the success rate of treatment in previously treated cases was 74%.

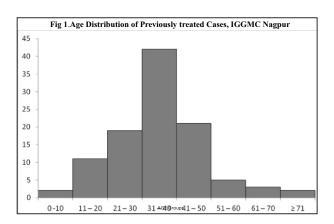
The findings were similar to study conducted by T. Sevim et al in Istanbul, Turkey, of the 57 male patients 37 (64.9%) were relapse cases and 20 (35.1%) patients were defaulters. The treatment success rate was 71.9% (68.4% cure rate and 3.5% completion rate) and failure was encountered in 22.8% of the patients.⁵

Successful treatment outcomes were more frequent in females (80%) than males (66%) and Predominantly smear negative "Others cases" had slightly better outcome(71%) as compared to "Smear Positive previously treated cases" (70%).

Similar findings were reported in study conducted in Andrapradesh, India by S.Srinath et al where outcomes in 'retreatment others' were significantly better with treatment success (83%) than all other types of retreatment cases. Success rate among females was 84% and better than males in this study.

The success of treatment was higher in relapse cases (80%) and others (71%) where as it was very low in treatment after default cases in present study. These findings correlate with an eleven year follow up study conducted by Mehra RK, of the 5576 patients registered for category I treatment there were 190 (3.4%) cases of failure and 442 (9%) cases of relapse. and when treated with retreatment regimen, favourable outcome was 76.4% cases of relapse.⁷

The results of the present study specifically point out towards the poor treatment outcomes among the "Treatment after Default" type of previously treated cases which may be risk for development of drug resistance as poor treatment, poor drugs and poor adherence lead to the development of Multi-drug resistant TB. ¹⁰



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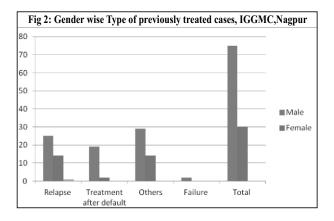
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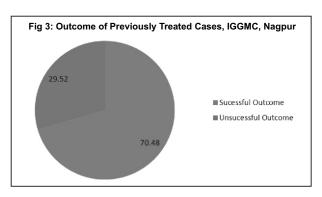
Conclusion:

The results of this study show that treatment success rate was poor among the previously treated male cases as compared to females and those returning for treatment after default. There is need of focusing attention to these cases with improved counselling support and care for the cases who had previously defaulted. Further studies especially qualitative research is needed to understand the reasons for poor outcomes in" treatment after default" cases.

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