Original Article

THE FATE OF TUBERCULOSIS CASES AFTER TWO YEARS OF DOTS CHEMOTHERAPY IN AURANGABAD CITY, MAHARASHTRA

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ABSTRACT

Background: Majority of relapses after Short Course of Chemotherapy (SCC) occur within two years after treatment initiation. Change in disease status over a period of time is termed as fate. During a non-intervention period, the fate of cases reflects the natural dynamics of the disease and to study this will likely provides an insight into the effectiveness of the control programme.

Objectives: The objective of this study was to assess the fate of TB cases after two years of Directly Observed Treatment Short Course Chemotherapy (DOTS).

Methodology: The present cross section study was carried out on TB cases which were registered for DOTS in 2006. The cases were distributed into various strata by Stratified Random Sampling method and to get the representation of each type of TB cases, cases were chosen by Systematic Random Sampling Method from each stratum. Out of 357, total 304 cases were contacted.

Results: Out of total 304, 254(83.55%) cases had favourable fate and 50(16.45%) unfavourable. Of 40 died cases, 12(30%) cases had died during DOTS and 28(70%) died within two years after completion of DOTS treatment. After two years of DOTS Chemotherapy, four cases found bacteriologically sputum positive and six previously sputum negative and extra-pulmonary cases had relapsed with clinical and histological evidence of current active TB. But primary outcome of four bacteriologically positive sputum cases was that two cases had cured, one TC and one defaulted. Thus the relapse rate was 0.99% (3/304). Total 8 (29.63%) cases were found on retreatment at the time of interview.

Conclusion: This study may add the knowledge on TB, time trend of mortality and natural dynamic of TB disease.

Key words: Fate, DOTS, Tuberculosis.

INTRODUCTION

Tuberculosis (TB) is an infectious disease caused by *Mycobacterium* TB.TB remains a world-wide public health problem despite the fact that the causative organism was discovered more than 100 years ago and highly effective drugs and vaccine are available making TB a preventable and curable disease.[1] It reduces the working capacity of infected persons and extracts a heavy toll from families and the country as a whole. Hence it is a disease with devastating social and economic costs.[2]

The emergence of drug resistant TB and particularly Multi-Drug Resistant TB (MDR-TB) has become a significant public health problem in a number of countries and an obstacle to effective TB control.[3]Relapse after treatment is a crucial determinant of relative merits of chemotherapeutic regimens. Majority of relapses after Short Course of Chemotherapy (SCC) occur within two years after treatment initiation.[4]Change in disease status over a period of time is termed as "fate". The disease status may have been classified as cure, continued to be suspect case, converted into bacillary cases and dead.[5] The fate may be favorable as free from disease and unfavourable as death / bacteriologically positive.[6]During a non-intervention period, the fate of cases reflects the natural dynamics of the disease and comparison of the same under control measures is likely to provide an insight into the effectiveness of the control programme.[7] The sociological

problems were faced by the cases following their treatment. It becomes necessary to investigate the behaviour of cases with respect to his efforts to cope with the changed situation following prolonged sufferings, as are the treatment results in terms of deaths, bacteriological conversion and emergence of drug resistance.[5]

There are very few studies regarding the fate or long-term follow up of TB cases after DOTS. Hence the present study regarding the fate of TB cases after two years of DOTS treatment was undertaken.

OBJECTIVES

The objective of this study was to assess the fate of TB cases after two years of Directly Observed Treatment Short Course Chemotherapy (DOTS).

MATERIAL AND METHODS

The present cross section study was carried out on TB cases which were registered for DOTS in 2006 to know their fate after two years of DOTS. The cases were interviewed at their residences after two years of getting the primary outcome like cure, default, failure etc. after DOTS treatment.The fate of symptomatic cases was evaluated bacteriologically. The lists of all TB cases registered in two Tuberculosis Units were obtained from City TB Officer (CTO). This study was conducted in Aurangabad city Municipal Corporation area during the period of October 2009 to September 2010.

Study population: February 2001 was the first year of implementation of RNTCP in Aurangabad city and 682 TB cases were put on DOTS. Year by year more number of cases were put on DOTS and in 2006 year it reached to 1096. The TB cases registered for DOTS in year 2006 were taken as study population. The Cure rate of NSP cases was 86% and the success rate also 86 %.

Sampling technique: All 1096 cases were distributed into various strata by Stratified Random sampling method according to RNTCP guidelines such as 395(36.04%) New Sputum Positive (NSP), 177(16.15%) New Sputum Negative (NSN), 306(27.92%) New Extra pulmonary (NEP), 51(4.65%) Treatment after Default (TAD), 8(0.73%) Failure, 86 (7.85%) Relapse and 73 (6.66%) others. Out of 1096, the 32 cases were transferred out and would not be available for interview, hence excluded. Thus, the study population became 1064. Taking into consideration of feasibility and time required to gather data, it was decided to take 1/3rd of the study population. Further to get the representation of each type of TB cases, cases were chosen by Systematic Random Sampling Method from each stratum.

Sample size: The cases which were not found at their residence despite three visits were labelled as 'not traceable'. Out of 357, total 304 cases were contacted and remaining 53(14.85%) cases remained not traceable. So the sample size became 304.

Study Procedure: The investigator prepared an address list of the cases from TB Register. The investigator took the help of DOT providers to locate the houses of cases in the community. Prior sensitization regarding interview was done by DOTS providers such as the introduction of investigator and purpose of the study. The TB Cases were interviewed at their residence using a predesigned and pretested preformed. The data was collected after taking their written informed consent. The information regarding survival status of TB cases was collected. If TB cases found dead, time and cause of death was ascertained from relatives and/ or neighbourhood. The symptomatic cases were evaluated bacteriologically.

Fate of cases: The fate of TB cases was described in terms of favourable and unfavourable status. Bacteriologically negative and free from TB disease were labelled as favourable fate**.** The bacteriologically positive, other type and death cases were included in unfavourable fate.

Statistical analysis: Statistical analysis was performed using Epi-Info version 3.5.1 (Centers for Disease Control, Atlanta, GA, 2001). The information was interpreted in terms of percentages, Crude odds ratio (OR), 95% confidence intervals (CI) and Chi square tests. Statistical significance was set at P value of less than 0.05.

RESULTS

The primary outcome of 304 tuberculosis cases immediately after completion of DOTS treatment was that 129(42.43%) cases cured, 147(48.36%)treatment completed (TC), 14(4.61%)defaulted, 2(0.66%) failure and 12(3.95%) cases died. In the present study after two years of DOTS, out of total 304, 254(83.55%) cases had favourable fate and 50(16.45%) unfavourable. There were total 40 died cases, of which 12(30%) cases had died during DOTS and 28(70%) died within two years after completion of DOTS treatment.

Table 1: Fate of TB cases after two years of DOTS in terms of their primary outcome

Previous outcome	Unfavorable (n=50)			Favorable (n=254)
	Bact. Positive	Other *	Died	
Cured	2 (1.55)	2(1.55)	8 (6.20)	117 (90.70)
TC	1 (0.68)	4 (2.72)	15 (10.21)	127 (86.39)
Defaulted	1(7.15)	0(0)	5 (35.71)	8 (57.14)
Failure	0 (0)	0 (0)	0 (0)	2 (100)
Died	0 (0)	0(0)	12 (100)	0(0)
Total	4 (1.32)	6 (1.97)	40 (13.16)	254 (83.55)

*TB cases with sputum smear negative or extra-pulmonary had relapsed and were supported by clinical and histological evidence of current active TB.
Figure in parenthesis indicate percentage

In this study 27(9.25%) cases found symptomatic after two years of DOTS. Of these, 9 cases had persistence symptoms and in 2 cases symptoms reappeared. Among these, four cases found as bacteriologically sputum positive and six cases as clinical and histological evidence of current active tuberculosis. It was observed that the primary outcome of four bacteriologically positive sputum cases was two cases cured, one TC and one defaulted. Thus the relapse rate was 0.99% (3/304).Total 8 (29.63%) cases were found on retreatment at the time of interview.

The fate of 129 primarily cured cases was as 117(90.70%) favourable fate and 12(19.30%) unfavourable fate. The unfavourable fate was found in 6 (42.86%) cases of total 14primarily defaulted cases. The fate of two primarily failure cases was as favourable.

In terms of survival status, 264(86.84%) cases were found survived after two years of DOTS. Out of 40 died cases, 12(30%) cases died during DOTS and 28(70%) died within two years after completion of DOTS treatment. Thus, there was 9.21 %(28/304) mortality within two years after completion DOTS.

The demography of cases was that 95(31.25%) cases had in age group of 15-24 years and only 10(03.29%) cases below 15 years of age. There were 175(57.57%) male participants and 129(42.43%) female. Nearly half cases were Hindu by religion i.e. 143(47.40%). Among the female cases, 51(39.53%) were Muslim.

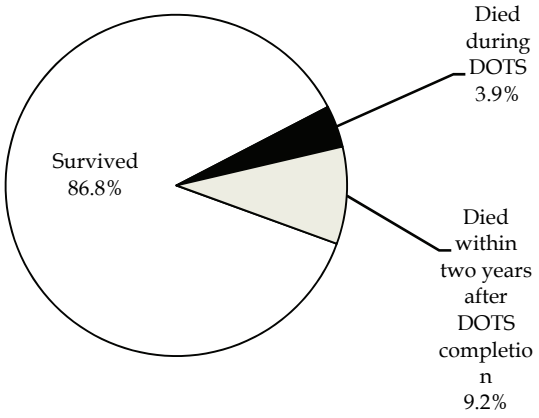

Figure No. 1. Survival status of TB cases after two years of DOTS treatment

Table 2: Fate of TB cases after two years of DOTS according to socio-demographic variables

Variables		Unfavourable (n=50)	Favourable (n=254)	OR (95% CI)	p value
Age (years)	Below 35	11 (6.08)	170 (93.92)	1	
	Above 35	39 (31.71)	84 (68.29)	0.14 (0.07- 0.29)	<0.05
Sex	Male	37 (21.14)	138 (78.86)	2.39 (1.21- 4.76)	0.01
	Female	13 (10.08)	116 (89.92)	1	
Religion	Hindu	25 (17.48)	118 (82.52)	1.15 (0.63-2.11)	0.65
	Other	25 (15.53)	136 (84.47)	1	
Marital status	Unmarried	4 (8.89)	41 (91.11)	1	
	Married	46 (17.76)	213 (82.24)	0.45 (0.15-1.32)	0.14
Education	Illiterate	27 (27.27)	72 (72.73)	2.97 (1.60- 5.51)	<0.05
	Literate	23 (11.22)	182 (88.78)	1	
Occupation	Unemployed	30 (18.75)	129 (80.63)	1.45 (0.78- 2.69)	0.23
	Employed	20 (13.79)	125 (86.21)	1	
Type of family	Nuclear	13 (13.27)	85 (86.73)	1	
	Other	37 (17.96)	169 (82.04)	0.70 (0.35-1.38)	0.30
Type of TB lesion	Pulmonary	39 (18.48)	172 (81.52)	1.69 (0.82- 3.47)	0.15
	EP	11 (11.83)	82 (88.17)	1	
Type of cases	New cases	38(15.70)	204(84.30)	1	
	Retreatment	12 (19.35)	50 (80.65)	0.78 (0.38-1.59)	0.49

The unfavourable fate was observed in 11(6.05%) cases with below 35 years of age group was while38(31.71%) cases in above 35 years of age. The number of females cases (116) had more significantly favourable fate than males (χ^2= 6.62, p<0.05).The unfavourable fate cases in Hindu religion were25 (17.48%), in Muslim 10 (10.53%) cases and 15 (23.08%) in Buddha religion. There was no significant diffrence in the fate of TB cases between religions (χ^2= 0.21, p >0.05).

It was found that, one case was living separately far away from family members. The reason may be due to the stigma attached to the disease as family members did not allowed him to live with them. Of 259 married individual cases, the fate of 46 (17.76%) cases was unfavourable. In 12(3.95%) widowed individuals, the fate of 8(66.67%) was unfavourable. Also, 4(8.89%) unmarried individuals cases were found as unfavourable fate. A statistically significant difference was not observed between married and unmarried cases (χ^2= 2.20, p>0.05).The fate of 99 illiterate cases was unfavourable in 27(22.22%) cases. The proportion of unfavourable fate in illiterate cases was found significantly more than literate cases (χ^2 = 12.52, p <0.001).

The unfavourable fate of total 159 unemployed cases was found in 30(18.75%) cases. There was no significant difference in the fate of TB cases between employed and unemployment cases (χ^2= 1.421, p >0.05). Highest numbers of unfavourable cases were belonged to joint family (34) followed by nuclear (13) and only three cases from three generation family.

There was no significant difference in fate between nuclear and other type of families (χ^2= 1.07, p >0.05).

The unfavourable fate was found in 39(18.48%)cases with pulmonary type of lesion and in 11(11.83%)cases with extra-pulmonary lesion. The proportion of unfavourable fate in primarily retreatment type of cases was 19.35%.

Out of total 304study cases, 35(11.51%) cases had co-morbidity. All these co-morbidities were in singular forms. The fate of 14(40%) cases with co-morbidities was unfavourable. The significant difference was seen in the fate of TB cases with regards to their co-morbidities (χ^2= 15.97, p <0.05)

Table 3: Co-morbidities found among TB cases undergoing DOTS chemotherapy

Co-morbidities	Unfavourable (n=50)	Favourable (n=254)
Asthma	2(40)	3(60)
COPD	1(25)	3(75)
HIV	2(100)	0(00)
Liver disease	2(66.67)	1(33.33)
Renal	0(0)	2(100)
Diabetes	2(28.57)	5(71.43)
Hypertension	3(42.86)	4(57.14)
CAD	2(40)	3(60)
Subtotal	14 (40)	21(60)
No co-morbidities	36 (10.78)	233(89.22)

Figure in parenthesis indicate percentage

Table 4: Employment status after two years of DOTS in relation to primary outcome

Primary outcome	Employed at the time of diagnosis (n=143)			Unemployed at the time of diagnosis (n=161)	
	No Change (%)	Change (%)	Unemployed (%)	No change (%)	Employed (%)
Cured	55(42.64)	5(3.88)	3(2.33)	57(44.19)	9(6.98)
TC	54(36.73)	8(5.44)	1(0.68)	72(48.98)	12(8.16)
Defaulted	7(50.00)	2(14.29)	1(7.14)	1(7.14)	3(21.43)
Failure	1(100)	0(0.00)	1(50.00)	0(0.00)	0(0.00)
Died	4(33.33)	1(8.33)	0(0.0)	7(58.33)	0(0.0)
Total	121(39.80)	16(5.26)	6(1.97)	137(45.05)	24(7.89)

At the time of initiation of DOTS, 143(47.04%) cases had employment. Out of these, 121(84.61%) cases did not change their job, 16(11.29%) cases changed their job and 6 (4.20%) cases became unemployed. Among the unemployed cases at the time of initiation of DOTS, 137 (85.09%) did not change their job and 24 (14.90%) cases got new employment.

DISCUSSION

Survival status of TB cases: In the present study, total 86.84% cases were survived and 9.21% died within two years after completion of DOTS. Jagota P et al reported that, 91.51% survived and 8.48% died in 2 years follow-up.[8] Overall mortality rate was 14.2%. Dholakia Y et al reported that, 92.40% survived, 5.76% died during treatment and 1.83% died during follow-up after two years of DOTS.[9] Overall death rate was 7.60%. Sadacharam K et al reported that 85% survived and 15% death sat 2-3 years after initiation of treatment under a DOTS programme.[10]In the present study overall mortality within two years after DOTS was13.16%.Prasad R et al reported 3.38% and Verma SK et al reported 5.3% mortality after two years of DOTS.[11, 12]

Symptomatic status of TB cases: In our study 27 (9.25%) cases found symptomatic after two years of DOTS. At the time of interview, 9 (2.96%) cases were found persistence of symptoms and in 2 (0.66%) cases symptoms reappeared. Further, 8 (29.63%) cases had taken retreatment. Dholakia Y et al reported that after two years of DOTS, 17.32% cases were symptomatic and three cases were on retreatment.[9] Balasangameshwar VH et al reported that after 5 years of follow up 21.3% cases were persistent symptoms and 21% cases had received retreatment.[13]Mahadev B et al reported 40% had persistent cough.[14]

Fate of TB cases in relation to primary Treatment outcome: In the present study, the fate of 129 primarily cured cases was favourable in 117 (90.70%). Among 12 unfavourable fate cases, 2 (1.55%) were bacteriologically positive, 2 (1.55%) were other type case and 8 (6.20%) dead. The fate of 14 primarily defaulted cases was unfavourable in 6(42.86%) cases. The fate of two primarily failure cases was favourable. Jagota P et al followed up 130 cases after 5 years of SCC and reported that 25(19.2%) had unfavourable fate. The fate of 90 TC cases of previous outcome was that 12(13.3%) cases unfavourable of which, 9 died and 3 were bacteriologically positive. The fate of 40 previous defaulted cases was favourable in 27(67.5%). Of 13 (32.5% unfavourable fate cases, 7 died and 6 were bacteriologically positive.[6]

Fate of TB cases in relation to socio-demographic characteristic: In the present study 80.92% cases were married, 14.80% were unmarried, 3.95% widowed and one case was living separately far away from his family. Sophia Vijay et al reported that, 51.4% were married and 48.6% unmarried.[15]Our study observed that 32.57% cases were illiterate. Sophia Vijay et al had shown that, total 29.15% were illiterate.[15]Gurpreet Kaur et al reported that 36.9% cases were illiterate.[16] Our study had shown total 51.32% unemployed cases. Sophia Vijay et al reported that, 51.3% cases were employed and 48.71%unemployed.[15] Our study showed that84.61% did not change their job, 11.29% changed job and 4.20% were unemployed. Jagota P et al reported that no change in employment status in 77.7%

of the cases, 14.3% changed their job and 8% unemployed. [6]

Co-morbidities found in TB cases: The co-morbidities found in present study were as 11.63% asthma, 9.30% COPD, 4.65% HIV, 6.98% liver disease, 4.65% renal disease and20% each from diabetes, hypertension and Coronary Artery Disease. Sudheendra Ghosh et al reported co-morbidities among cases undergone Category I treatment as20.00%Asthma, 15.00% COPD, 24.66% Diabetes, 5.66% Renal Disease, 2.33%Liver Disease, 11.53%Coronary Artery Disease and 20.33% Hypertension.[17]Dasgupta et al reported that 26.54% asthma, 12.18% COPD and7.16% infective problems.[18]

CONCLUSION

This study may add the knowledge on tuberculosis disease, time trend of mortality and natural dynamics of tuberculosis disease. The efforts on identifying the probable fate could be applied to intensify the management of tuberculosis cases. More inputs should be provided for motivating the cases and their families regarding to strengthen their hold on DOTS chemotherapy and to prevent morbidity and mortality.

Limitations of the study: The time of initiation of DOTS was different for all cases. Since it was not possible to get interview on the exact date after two years of DOTS, this lacuna remained while conducting the study. Cases with TB disease were more than two years ago and also those died, cause of death ascertained through family members by verbal autopsy. These recall bias exits which could not be removed. The non-traceable cases were 14.85%. Therefore, the major limitations of this study were recall bias and around 15% non-traceable rate and.

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