

Original article |

SOCIO-EPIDEMIOLOGICAL PARAMETERS INFLUENCING THE TREATMENT OUTCOME IN NEWLY DIAGNOSED SMEAR POSITIVE CASES UNDER DOTS IN DISTRICT AMRITSAR

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ABSTRACT

Introduction: Tuberculosis has brought untold miseries to generations and even today, when newer modalities for diagnosis and treatment have made the disease curable, people are still suffering and dying from this disease. The present study is an attempt to know about the socio-epidemiological parameters affecting the treatment outcome in new smear positive patients under DOTS.**Methods:** The study was conducted on new smear positive patients registered under DOTS in two Treatment Units (TUs) present in Amritsar city. House to house visits were done and socio-epidemiological parameters were studied by completing a pre designed proforma evolved for this purpose.**Results:** Out of 250 patients, 149 (59.6%) were males and 101(40.4%) were females. 75.8% of the cases among males and 87.2% among females were in the age group of 15-45 years. Male preponderance, with male to female ratio of 1.5:1 was seen. Socio-demographic factors affecting the treatment outcome were age, sex and marital status.**Conclusion:** On statistical analysis, it was observed that favourable outcome was significantly associated with mean age of 29.2 ± 13.3 years ($p = 0.013$), female sex (OR = 2.19, $p = 0.04$) and unmarried cases ($\chi^2 = 7.186$, $p = 0.027$). Family size, literacy status and socio-economic status were not significantly associated with the treatment outcome.**Key words:** socio-epidemiological parameters, treatment outcome, DOTS

INTRODUCTION

Till date, tuberculosis (TB) caused by *Mycobacterium tuberculosis*, has remained a major health problem world over.¹ The disease has brought untold miseries to generations and even today, when newer modalities for diagnosis and treatment of tuberculosis have made the disease curable, people are still suffering and dying from this disease.² It retains its foothold among populations, especially those with weak immunity or those living in poor socio-economic status.

India is the highest tuberculosis burden country globally, accounting for 1/5th of the global incidence and 2/3rd of the cases in the south East Asia.³ Indian population is composed of people of diverse cultural, linguistic, biological, ethnic and genetic backgrounds, living in different socio-cultural and socio-economic settings.¹ Tuberculosis primarily affects people in their most productive years of life with important socio-economic consequences for the household.³ Several studies have explored reasons behind the gender bias in tuberculosis susceptibility and

found that fear and stigma associated with TB makes greater impact on women than on men. A study by *Joseph et al* revealed that favourable outcome was more in patients aged 30 years or less and in females, place of residence did not affect the outcome.¹⁰

The Revised National TB Control Programme (RNTCP) based on internationally recommended Directly Observed Treatment Short Course (DOTS) strategy, was launched in 1997 expanded across the country in a phased manner and covered the whole nation by March 2006.⁴ RNTCP was implemented in Amritsar since 1st January 2003. Poor treatment adherence leading to risk of drug resistance, treatment failure, relapse, death and persistent infectiousness remains an impediment to the tuberculosis control programmes. The objective of the study was to identify predictors of poor outcome among new smear positive TB patients registered for the treatment.

METHODS

The study was conducted on new smear positive patients registered under DOTS in two Treatment Units (TUs) present in Amritsar city. One TU is located in the Chest and TB Hospital, Amritsar and the other is located in the Civil Hospital, Amritsar. A pre designed and pre-tested proforma was administered to the subject after taking his or her consent. Approval of college ethical committee was granted at the time of submission of the plan of the study.

Sampling Technique: Based on the quarterly reports of both the TUs and by the expected incidence of new smear positive (NSP) cases in the northern zone of India which is 95/lac population/yr, a quota of 250 cases was affixed (As population covered under two TUs is approximately 11 lac, the expected NSP cases in a year comes around 1045 and expected cases in a quarterly cohort is around 250).

Study Sample: The study sample consisted of 250 new smear positive (NSP) cases that were enrolled from December 1, 2009 to February 28, 2010. The study period was extended till the projected number achieved.

Inclusion Criteria: New smear positive patients of >15 years of age were included in the study.

Exclusion Criteria: Patients with extra pulmonary tuberculosis and smear negative tuberculosis patients were excluded.

The **possible outcomes** of the new smear positive patients under DOTS can be: **Cured, Treatment completed, Died, Failure, Defaulted or Transferred out.** House to house visits were done and socio-epidemiological parameters were studied by completing a pre designed proforma evolved for this purpose.

Statistical Analysis: Data management and analysis was done by using Microsoft excel and SPSS version 17.00. A Chi-square test was used to evaluate differences in categorical variables. Mantel Hanzel Odds Ratio (OR) and 95% CI were calculated for dichotomous variables. ANOVA test were used to compare quantitative variables.

RESULTS

The present study to assess the efficacy of DOTS was carried out on 250 newly diagnosed smear positive pulmonary tuberculosis cases registered under two Treatment Units present in Amritsar city. The total sample consisted of 149 (59.6%) males and 101(40.4%) females. Out of these 113(75.8%) males and 98(87.2%) females were in the age group of 15-44 years.

Table-I illustrates distribution of cases according to their socio-demographic profile. Out of the total 250 cases, 84.8% were native and 15.2% were migrant. More than half i.e. 53.2% were married, 45.6% were unmarried and 1.2% were bereaved (widow/widower). 59.2% were Hindus and 38.8% were Sikhs. Almost three fourth of the cases i.e. 73.6% belonged to lower caste. It was observed that 62% of cases belonged to joint families and more than half i.e. 54.4% had medium sized families having 5-8 members in the household. 41.6% of the cases were below matric and 32% were illiterate. There were only 26.4% cases who were matric or above matric. Income Generating Activity (IGA) group comprised of labourers (36%), service men (13.2%), working females (6%) and cultivators/businessmen (5.2%). Non IGA group comprised of housewives (25.2%), students (12.8%) and those doing no work (1.6%).

A perusal of Table-II shows that more than half of the cases were belonging to lower middle class (51.2%) and low class (6%). 40.8% were from upper middle class and only 2% were from high socio-economic status.

Table I: Distribution of cases according to the socio-demographic profile

Parameter	Cases (n = 250) (%)
Place of Residence	
Native	212 (84.8)
Migrant	38 (15.2)
Marital Status	
Married	133 (53.2)
Single	114 (45.6)
Widow/Widower	3 (1.2)
Religion	
Hindu	148 (59.2)
Sikh	97 (38.8)
Others	5 (2.0)
Caste	
Upper caste	43 (17.2)
Artisan caste	23 (9.2)
Lower caste	184 (73.6)
Family type	
Nuclear	95 (38)
Joint	155 (62)
Family size*	
Large	34 (13.6)
Medium	136 (54.4)
Small	80 (32.0)
Education	
Above Matric/Matric	66 (26.4)
Below Matric	104 (41.6)
No Schooling	80 (32.0)
Occupation	
IGA**	
Cultivator/Businessman	13 (5.2)
Service	33 (13.2)
Labourer	90 (36.0)
Working female	15 (6.0)
Non IGA	
Housewife	63 (25.2)
Student	32 (12.8)
No work	4 (1.6)

*According to the number of persons in the household: >8: large, 5-8: medium and 1-4: small; ** IGA-Income generating activity

Table II: Distribution of cases according to Socio-economic status

Socio-economic status*	Cases (n= 250) (%)
High	5 (2.0)
Upper middle	102 (40.8)
Lower middle	128 (51.2)
Low	15 (6.0)

*According to Modified Udai Pareekh Scale

Table III depicts that mean age of the cases who were cured was 29.2 ± 13.3 and of those who had failure as their outcome was 27.6 ± 8.7 . Mean age of cases with death as the outcome was 40.7 ± 17.5 . Relation of age with the outcome was found to be statistically significant ($F = 2.974$, $p = 0.013$).

Table III: Distribution of cases showing relation of age with the outcome

Outcome	Cases	Age (Mean \pm SD)
Cured	210	29.2 ± 13.3
Treatment completed	1	25.0
Failure	13	27.6 ± 8.7
Defaulted	12	36.0 ± 18.2
Transferred out	4	46.7 ± 30.7
Died	10	40.7 ± 17.5

ANOVA test: p - value 0.013

Above table shows that the favourable outcome in females was found to be significantly higher than in males ($p = 0.04$). The cure rate was 87.7% in those who were single, 81.9% in married and only 33.3% in bereaved. The relation of marital status with the treatment outcome was found to be statistically significant ($p = 0.027$). Other socio-demographic factors like nativity, family size, literacy and socio-economic status were not significantly associated with the outcome.

DISCUSSION

In the present study that 94.8% cases are from 15-59 years age group and only 5.2% are 60 years or above. The male female ratio was 1.5:1 approximately. This is in consonance with the findings of the study conducted by Mohrana *et al* (2009) in a tertiary level health facility of Orissa that 91.4% of the cases belonged to economically productive age group of 15-59 years.⁵ Pithadia PR *et al* (2012) in their study on evaluation of performance of RNTCP in Jamnagar district, Gujarat also revealed that about half (52.16%) of the patients belonged to productive age group with the male female ratio of 2.1:1.⁶ According to RNTCP status report 2012 also, TB primarily affects people in their most productive years of life.

The treatment outcome was categorized as *favourable* in cases of cure and treatment completed and as *unfavourable* in cases of failure, death, default and transfer out. Similar categorization (*favourable*, death and other unfavourable outcome) was done by Vasankari *et al* (2007) in their study on risk factors for poor treatment outcome in Finland⁷ and a study by Mukherjee *et al* (2009) on comparing outcomes in new pulmonary sputum positive and sputum negative cases under RNTCP in West Bengal, India.⁸ Also in line with the WHO criteria, a study by Berhe *et al* (2012) in Northern Ethiopia categorized the treatment outcome into Successful outcome (cured or treatment completed) and Unsuccessful outcome (failure, default or death).⁹

Table IV: Distribution of cases showing socio-demographic factors related to outcome

	Favorable Outcome		Unfavorable outcome				Significance*
	Cured (%)	Treatment Completed(%)	Failure (%)	Defaulted (%)	Transferred out (%)	Died (%)	
Sex							
Female (n = 101)	91 (90.2)	0 (0)	3 (3.0)	2 (1.9)	1 (0.9)	4 (4.0)	OR=2.19
Male (n = 149)	119 (79.9)	1 (0.7)	10 (6.7)	10 (6.7)	3 (2.0)	6 (4.0)	CI = 1.02-4.74 p = 0.04
Nativity							
Native (n = 212)	178 (83.9)	1 (0.5)	12 (5.7)	9 (4.3)	3 (1.4)	9 (4.2)	OR= 0.98
Migrant (n = 38)	32 (84.2)	0 (0)	1 (2.7)	3 (7.9)	1 (2.6)	1 (2.6)	CI= 0.38-2.53 p = 0.97
Marital status							
Married (n = 133)	109 (81.9)	1 (0.8)	8 (6.0)	6 (4.5)	3 (2.3)	6 (4.5)	$\chi^2 = 7.186$
Single (n = 114)	100 (87.7)	0 (0)	5 (4.4)	5 (4.4)	1 (0.9)	3 (2.6)	$df = 2,$
Widow/Widower (n=3)	1 (33.3)	0 (0)	0 (0)	1 (33.3)	0 (0)	1 (33.4)	p = 0.027
Family size							
Large (n = 34)	28 (82.4)	0 (0)	0 (0)	1 (2.9)	1 (2.9)	4 (11.8)	$\chi^2 = 0.602$
Medium (n = 136)	116 (85.3)	1 (0.7)	9 (6.6)	5 (3.8)	1 (0.7)	4 (2.9)	$df = 2$
Small (n = 80)	66 (82.5)	0 (0)	4 (5.0)	6 (7.5)	2 (2.5)	2 (2.5)	$p = 0.740$
Literacy							
Matric & Above (n=66)	59 (89.4)	0 (0)	2 (3.0)	3 (4.6)	1 (1.5)	1 (1.5)	$\chi^2 = 1.700$
Below Matric (n= 104)	85 (81.7)	1 (1.0)	5 (4.8)	6 (5.8)	2 (1.9)	5 (4.8)	$df = 2$
No schooling (n= 80)	66 (82.5)	0 (0)	6 (7.5)	3 (3.7)	1 (1.3)	4 (5.0)	$p = 0.427$
Socio-economic status							
High (n = 5)	5 (100.0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	$\chi^2 = 2.655$
Upper middle (n=102)	87 (85.3)	1 (1.0)	4 (3.9)	2 (1.9)	2 (1.9)	6 (6.0)	$df = 3,$
Lower middle (n= 128)	107 (83.5)	0 (0)	8 (6.3)	8 (6.3)	2 (1.6)	3 (2.3)	$p = 0.4480$
Low (n= 15)	11 (73.4)	0 (0)	1 (6.7)	2 (13.3)	0 (0)	1 (6.6)	

*For statistical analysis, outcomes were divided in two categories: Favourable Outcome (F.O.) - include cured and treatment completed & Unfavourable Outcome (U.O.) - include failure, defaulted, transferred out and died.

Table III shows that mean age of the cases is significantly related to the treatment outcome ($F = 2.974, p = 0.013$). Treatment success was more in the younger age group (mean age 29.2 ± 13.3) and as the age advances the outcome is poor i.e. defaulted and died. Findings in the present study are concurrent with the findings of the treatment outcome study conducted by Joseph *et al* (2011) among new smear positive and retreatment cases of tuberculosis in Mangalore, South India. A favourable outcome in Category I was significantly more in patients aged 30 years or less.¹⁰ Another study done by Gaur *et al* (2004) in elderly tuberculosis patients taking DOTS in Delhi reported that case fatality and failure rate were higher in the age group > 65 years.¹¹

A perusal of **table IV** shows the relation of socio-demographic profile of the cases with the treatment outcomes. The cure rate is significantly higher in females (90.2%) than males (79.9%) ($p = 0.04$). Unfavourable outcome including failure rate and defaulter rate are more in males as compared to females. The findings in the present study are supported by Ahmed *et al* (2009) in their study in Karnataka showing that treatment outcomes were poorer among males with higher

proportion of initial defaulters.¹² Another study carried out by Lienhardt *et al* (1998) on factors determining the treatment outcome of adult smear positive cases in Gambia reported that female tuberculosis patients were more likely to achieve cure than males.¹³

It is observed in the present study that cure rate is almost same in natives as well as migrants. Default rate was somewhat more in migrants (7.9%) as compared to natives (4.3%). Nativity was not significantly associated with the outcome. In the study conducted by Jaggarjama *et al* (2007) on the reasons for non-compliance among patients treated under RNTCP in Tiruvallur district, South India, migration was stated as the reason for default in 31% of the cases by the DOT providers though the results were not found to be statistically significant¹⁴. Similarly, Joseph *et al* (2011) in a descriptive study on tuberculosis cases in Mangalore reported that place of residence did not have a significant influence on the treatment outcomes among NSP patients.¹⁰

The cure rate was higher in the unmarried cases (87.7%) as compared to those who are married (81.9%). This may be due to the reason that 94.7%

of the cases that were unmarried were in the comparatively younger age group of 15-29 years with more favourable outcome. The cure rate was 33.3% in those who were bereaved i.e. widows and widowers. This could be because of their psychological status resulting in poor compliance. The effect on the outcome was statistically significant ($p = 0.027$).

The present study reveals that family size, literacy status and socio-economic status were not significantly associated with the treatment outcome. A study by Pandit and Choudhary (2006) in Gujarat, India reported that socio-demographic factors like education, occupation and socio-economic status were not significantly associated with the treatment compliance¹⁵.

CONCLUSION

From our study we conclude that younger age, female sex and single marital status were significantly associated with the favourable treatment outcome while socio-demographic factors like family size, education, occupation and socio-economic status did not affect the treatment outcome. So, there is need to make health services available to the male working population and married people who are short of time at convenient hours and also to be more vigilant to screen persons with pulmonary symptoms among the elderly. If due importance would not be given to above stated points, it may lead to reversal of the gain achieved.

Acknowledgement

We are thankful to District TB Officer, Amritsar and staff at TB hospital and Civil hospital for helping us during the study. Also we are grateful to all the patients, for their kind and affectionate attitude and cooperation.

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