

## Original Research Article

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# Socio-demographic determinants of treatment outcome in multidrug resistant tuberculosis cases registered under Programmatic management of drug resistant tuberculosis services in Amritsar, Punjab

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## ABSTRACT

**Background:** Multidrug resistant tuberculosis (MDR-TB) has become a major public health problem. It is associated with significant morbidity and mortality. The treatment success rate worldwide is around 50%.

**Methods:** This cross-sectional study was conducted on all MDR-TB patients who were registered and being treated under PMDT services in Amritsar district from 1<sup>st</sup> April 2014 to 31<sup>st</sup> March 2015. The treatment outcome with their socio-demographic determinants was ascertained. Data management and analysis was done by using Microsoft excel and SPSS.

**Results:** Out of 87 MDR-TB patients, 57 (65.5%) were males and 30 (34.4%) were females. The various treatment outcomes observed were- 30 (34.5%) cured, 19 (21.8%) treatment completed, 18 (20.7%) died, 13 (14.9%) defaulted, 4 (4.6%) shifted to XDR TB regime and 3 (3.4%) failure.

**Conclusions:** On statistical analysis, it was observed that age (p=0.000), marital status (p=0.024), educational status (p=0.011) and occupation (p=0.002) were significantly associated with the treatment outcome. Other factors like sex, type of family and socio-economic status did not affect the treatment outcome.

**Keywords:** MDR-TB, Socio-demographic factors, Treatment outcomes, Amritsar

## INTRODUCTION

Drug resistant tuberculosis (DRTB) included both multi drug resistant (MDR) and extensively drug-resistant (XDR) TB; MDR-TB is defined as a disease caused by strains of *Mycobacterium tuberculosis* that are resistant to treatment with at least isoniazid (H) and rifampicin.<sup>1</sup> Worldwide, MDR-TB has become a major public health problem and is a great obstacle in the fulfillment of global End TB targets. India contributes one-fourth of the global burden of MDR-TB.<sup>2</sup> The WHO estimated that incidence of rifampicin (R) and MDR-TB in India is around 1,47,000. This means that there are around 11 patients per

1,00,000 population annually as per the Global TB report, 2017.<sup>3</sup> Although TB is a curable disease but the treatment success rate of MDR-TB worldwide has stagnated at around 50%. This low rate is due to many causes like demographic diversity, bacteriological and clinical backgrounds, factors related to health care delivery and financial situations.<sup>4</sup> MDR-TB is essentially a man-made phenomenon.<sup>5</sup> The prime culprits causing its occurrence are lack of awareness among treating physicians, improper treatment regimens and poor compliance. In addition, the treatment of MDR-TB is challenging due to its delayed diagnosis, long duration of treatment and drug toxicities. The disease is associated with significant

morbidity and mortality which can be prevented by early diagnosis, prompt institution of therapy, strict adherence to guidelines and management of adverse drug reactions.<sup>6</sup>

However, there is paucity of data available on the clinical profiles and treatment outcomes of MDR-TB patients enrolled under PMDT services. Hence, we conducted this study to analyse the treatment outcomes and their socio-demographic determinants in a cohort of pulmonary MDR-TB patients registered under PMDT services in our city with an intention of attaining a better understanding of this multifaceted disease.

## METHODS

The study was a cross-sectional study conducted on all MDR-TB patients registered and being treated with second line anti-tuberculosis drugs under PMDT services in Amritsar City.

### Study sample

All MDR-TB patients registered from 1<sup>st</sup> April 2014 to 31<sup>st</sup> March 2015.

### Inclusion criteria

All drug sensitivity tested (DST) confirmed MDR-TB cases who signed written informed consent.

### Exclusion criteria

Pregnant females and critically ill patients who needed management in an Intensive Care Unit (ICU).

### Data collection and analysis

A total of 87 patients registered with DTC (District Tuberculosis Centre) Amritsar and being treated with second line anti TB drugs were included in the study. A pre-designed and pre – tested proforma was administered to the subjects after taking his/her consent. Questionnaire included questions regarding the socio-demographic profile, past history, past duration of treatment, family history and occupational history of the patients. The possible outcomes of the MDR TB patients under DOTS can be: cured, treatment completed, died, failure, defaulted, lost to follow up or regimen changed/shifted to XDR.<sup>3</sup>

**Cured:** Treatment completed as recommended by the national policy without evidence of failure and three or more consecutive cultures taken at least 30 days apart during CP are negative including culture at the end of treatment.

**Treatment completed:** Treatment completed as recommended by the national policy without evidence of failure but no record that three or more consecutive

cultures taken at least 30 days apart are negative after the intensive phase.

**Failure:** Treatment terminated or need for permanent regimen change of at least two or more anti-TB drugs in CP because of lack of microbiological conversion by the end of the extended intensive phase or microbiological reversion in the continuation phase after conversion to negative or evidence of additional acquired resistance to FQ or SLI drugs or adverse drug reactions (ADR).

**Died:** A patient who dies for any reason during the course of treatment.

**Lost to follow-up:** A patient whose treatment was interrupted for one month or more for any reasons prior to being declared as failed.

**Regimen changed/shifted to XDR:** A TB patient's need for permanent regimen change of at least one or more anti-TB drugs prior to being declared as failed/A MDR-TB patient who is found to have XDR-TB by an RNTCP certified CDST laboratory and who has subsequently switched to a regimen for XDR-TB treatment initiation.

Outcomes were classified as Favourable outcome which includes cured and treatment completed patients and Unfavourable outcome that includes cases with outcome as treatment failure, died, defaulted and those who were shifted to XDR TB regime.

The socio-economic status was assessed by using Modified Udai Pareek Scale (MUP Score).<sup>7</sup> This Scale comprises of thirteen criteria in rural and twelve criteria in urban set up. These criteria include caste, education, occupation of husband and wife, type of family, size of family, house ownership, household assets, type of house, number of rooms and drinking water facility. In rural set up land holding and farm assets are included instead of house ownership. Each criterion has been assigned a specific number. Summation of these numbers is done with maximum and minimum scoring. Data analysis was done by SPSS version 20. Chi-square test was applied to prove their statistical significance and  $p < 0.05$  was considered to be significant.

### Ethics

The research proposal was approved by the college ethical committee at the time of commencement of the study.

## RESULTS

The present study was carried out on 87 MDR- TB cases registered under PMDT services in Amritsar city. The total sample consisted of 57 (65.5%) males and 30 (34.4%) females.

**Table 1- Distribution of cases according to their socio-demographic profile (n=87).**

	Number	Percentage (%)
<b>Age (yrs)</b>		
15-29	38	43.7
30-44	23	26.4
45-59	23	26.4
>60	3	3.4
<b>Sex</b>		
Male	57	65.5
Female	30	34.5
<b>Marital status</b>		
Married	50	57.5
Single	28	32.2
Widow	2	2.3
Widower	7	8.0
<b>Education</b>		
Above Matric	23	26.4
Matric	23	26.4
Below Matric	19	21.8
No Schooling	22	25.3
<b>Occupation*</b>		
IGA	63	72.4
Non IGA	24	27.6
<b>Family</b>		
Joint	28	32.2
Nuclear	59	67.8
<b>Socio-economic status</b>		
High	5	5.7
Upper middle	21	24.1
Lower middle	43	49.4
Low	18	20.7

\*IGA- Income generating activity; Non-IGA- Non income generating activity.

The perusal of above table shows that out of the total 87 patients, 38 (43.7%) were in the age group of 15-29 years. 23 (26.4%) were present in the age groups of 30-44 yrs and 45-59 yrs each. Only 3.4% were above 60 yrs. More than half i.e. 65.5% were males. 50 (57.5%) were married, 28 (32.2%) were single and 9 (10.3%) were widow/widower. As far as educational status is concerned, 23 (26.4%) each were in the category of above matric and matric. 19 (21.8%) were below matric and 22 (25.3%) were illiterate. Among the total, 63 (72.4%) were involved in income generating activity and 24 (27.6%) were not working. 59 (67.8%) cases belonged to joint families and 28 (32.2%) belonged to nuclear families. Out of the total 87 cases, almost half i.e. 43 (49.4%) were from lower middle class, 21 (24.1%) from upper middle class, 18 (20.7%) from lower class and only 5 (5.7%) belonged to high socio-economic status.

Table 2 reveals the distribution of cases according to their treatment outcomes. Out of the total 87 patients, 30 (34.5%) were cured, 19 (21.8%) were in the category of treatment completed, 18 (20.7%) died, 13 (14.9%) defaulted, 4 (4.6%) were shifted to XDR TB regime and 3 (3.4%) were failure.

**Table 2: Distribution of cases according to their treatment outcome.**

Treatment outcome	No.	Percentage (%)
<b>Cured</b>	30	34.5
<b>Treatment completed</b>	19	21.8
<b>Defaulted</b>	13	14.9
<b>Failure</b>	3	3.5
<b>Shifted to XDR</b>	4	4.6
<b>Died</b>	18	20.7
<b>Total</b>	87	100

**Table 3: Distribution of cases showing the socio-demographic factors affecting the treatment outcome.**

	Treatment outcome		Significance
	Favourable* (n=49)	Unfavourable** (n=38)	
<b>Age (yrs)</b>			
15-29 (n=38)	29 (76.3)	9 (23.7)	
30-44 (n=23)	15 (65.2)	8 (34.8)	$\chi^2=21.729$
45-59 (n=23)	4 (17.4)	19 (82.6)	df=3
>60 (n=3)	1 (33.3)	2 (66.7)	p=0.00
<b>Sex</b>			
Male (n=57)	30 (52.6)	27 (47.4)	$\chi^2=.915$
Female (n=30)	19 (63.3)	11 (36.7)	df=1 p=0.339
<b>Marital status</b>			
Married (n=50)	23 (46)	27 (54)	$\chi^2=5.0917$
Single/widow/widower (n=37)	26 (70.3)	11 (29.7)	df=1 p=0.024
<b>Education</b>			
Above matric (n=23)	15 (65.2)	8 (34.8)	$\chi^2=11.229$
Matric (n=23)	18 (78.3)	5 (21.7)	df=3
Below matric (n=19)	9 (47.4)	10 (52.6)	p=0.011
No Schooling (n=22)	7 (31.8)	15 (68.2)	

Continued.

	Treatment outcome		Significance
	Favourable* (n=49)	Unfavourable** (n=38)	
<b>Occupation</b>			
IGA (n=63)	42 (66.7)	21 (33.3)	$\chi^2=9.9347$
Non IGA (n=24)	7 (29.2)	17 (70.8)	df=1; p=0.002
<b>Family</b>			
Joint (n=28)	15 (53.6)	13 (46.4)	$\chi^2=0.127$
Nuclear (n=59)	34 (57.6)	25 (42.4)	df=1; p=0.722
<b>Socio-economic status</b>			
High (n=5)	4 (80)	1 (20)	$\chi^2=4.227$
Upper Middle (n=21)	11 (52.4)	10 (47.6)	df=3
Lower Middle (n=43)	27 (62.8)	16 (37.2)	p=0.238
Low (n=18)	7 (38.9)	11 (61.1)	

\*Favourable outcome included Cured and Treatment completed; \*\*Unfavourable outcome included Defaulted, Failure, Shifted to XDR and Died patients.

Table 3 depicts the socio-demographic factors affecting treatment outcome in MDR TB cases. It is evident from the above table that favourable outcome was seen in younger age group i.e. 15-44 yrs. 29 (76.3%) and 15 (65.2%) cases had favourable outcome in 15-29 yrs and 30-44 yrs age group respectively. Unfavourable outcome was seen in more cases in 45-59 yrs (82.6%) and >60yrs (66.7%) age group. The results were found to be highly significant (p=0.00). More than half cases among males i.e. 52.6% and 63.3% among females had favourable outcome. The results were not found significant. Regarding marital status, it was observed that favourable outcome was observed in those who were single/widow/widower (70.3%). 54% of the married cases were having unfavourable outcome. The results were found to be significant (p=0.024). As far as educational status is concerned, 65.2% of the cases above matric and 78.3% matriculate had favourable outcome while unfavourable outcome was more seen in below matric (52.6%) and illiterate (68.2%) cases respectively. The results were significant (p=0.011). Also favourable outcome was significantly higher (p=0.002) among those who were working i.e. IGA (66.7%) than those who were not working (33.3%). Type of family and socio-economic status were not significantly associated with treatment outcome.

## DISCUSSION

Table 1 shows the distribution of cases according to their socio-demographic profile. It was observed in our study that out of the total 87 patients, 57 (65.5%) were males and 30 (34.5%) were females. Similar male preponderance was observed in the study by a study on MDR-TB patients in Cairo, Egypt and in Indonesia showing that out of the total, 72.9% and 68.6% were males respectively.<sup>8,9</sup>

In the present study it was observed that 52.8% were in the age group of 30-59 years of age i.e. economically productive years of life and only 3 patients were more than 60 years of age. Similarly, a prospective study by

Hire et al in Nagpur observed that out of the total 110 patients, 40 patients belonged to age group 40-49 years while two patients to age group 70-79 years.<sup>10</sup> Another study by Nair et al in Chennai showed that 70% were their in the age group of 15-44 yrs which is exactly similar to our findings where 70.1% cases are in 15-44yrs age group.<sup>11</sup> Our study revealed that 57.5% were married, 47.1% were below matric and 67.8% belonged to nuclear family. Majority of the cases i.e. 72.4% were working and belonged to lower middle class (49.4%) and lower class (20.7%). Somewhat similar findings were seen in a study by Bhatt et al in Ahmedabad city showing that 67.9% were married, literacy rate was 86.4% of which 61.4% had primary education, 65.4% belonged to nuclear family, majority were working and belonged to upper lower class.<sup>12</sup>

As is evident from table 2 that out of the total 87 patients, favourable outcome was present in 56.3% cases i.e. cured (34.5%) and treatment completed (21.8%) cases. Unfavourable outcome was seen in 43.7% cases comprising of defaulted (14.9%), failure (3.5%), shifted to XDR (4.6%) and died (20.7%) cases. Similarly, a study at a tertiary care centre in Mumbai showed that out of 194 patients, 48.4% (68 cured + 26 treatment completed) were successfully treated, 22 (11.3%) failed on therapy, 39 (20.15%) patients died, 23 (11.8%) defaulted, 26 (13.4%) completed treatment with outcomes unknown, 13 (6.7%) were transferred out and in 3 patients (1.5%) treatment was stopped. Another study in Karnataka showed that at the end of treatment, 19 (44.2%) were cured, 12 defaulted, 9 died, 1 failure and 2 were under XDR TB evaluation.<sup>6,13</sup> Other studies in Portugal and China showed the treatment success of 62% and 68.3% respectively.<sup>4,14</sup>

Table 3 shows the socio-demographic determinants of treatment outcome. Our study observed that favourable outcome was significantly higher among 15-44 yrs age group (p=0.000), those cases who were single/widow/widower (p=0.024), whose educational status was matriculate or above (p=0.011) and those who

were working i.e. IGA group ( $p=0.002$ ). Other factors like sex, type of family and socio-economic status did not affect the treatment outcome. Studies by Dengkui et al in Shanghai, Nair et al in Chennai and Gafar et al in South Africa on predictors of treatment outcome showed that unfavourable outcomes in MDR TB cases were significantly higher among cases  $>45$  years.<sup>11,15,16</sup> Chung Delgado et al in their study in Lima, Peru and Viana S et al in Brazil stated that education level was significantly associated with mortality among MDR-TB cases.<sup>17,18</sup> In a study on MRD-TB in South Africa in 2006, Holtz et al highlighted the lack of patient-provider interaction, drug use, and socioeconomic characteristics as the most significant factors associated with loss to follow-up.<sup>19</sup>

## CONCLUSION

MDR-TB treatment is a major challenge due to the chronic nature of disease, long duration of treatment and multiple drugs used in the regimen. The present study showed the favourable treatment outcome was present in 56.3% cases. 20.7% cases died during the treatment. The predictors of unfavourable outcome were age  $\geq 45$  years, unmarried/widow/widower (marital status), low educational status and not indulging in any income generating activity (IGA). Strategies should be designed to reduce the high rate of poor treatment outcomes.

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*Ethical approval: The study was approved by the Institutional Ethics Committee*

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