Socio-demographic profile of multi-drug resistant tuberculosis patients and its association with severity of adverse drug reactions in DOTS plus centre at tertiary hospital in Himachal Pradesh, India

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ABSTRACT

Background: Multi-drug resistant tuberculosis has become major public health problem and obstacle to effective control of tuberculosis. Objectives was to study the socio-demographic profile of multi-drug resistant tuberculosis patients and its association with severity of ADR (adverse drug reactions) in DOTS plus centre at tertiary hospital in Himachal Pradesh.

Methods: It was a prospective observational study carried out from November 2012 to October 2013 on multi-drug resistant tuberculosis (MDR-TB) patients after approved from Institutional Ethics Committee.

Results: Out of 104 patients the mean age of patients was 39.9 ±14.26 years. Majority of the patients were in the economically productive age groups. Multi-drug resistant tuberculosis was more in male (76%) than female (24%) and 96% of patients were belonged to rural area. The educational status of the MDR-TB shows 24% patients were illiterate. 63.46% MDR-TB patients were underweight (BMI<18.5%) according to WHO guidelines for obesity. Severity of ADR assessed by Hart wig and Siegel’s scale showed 21% patients experienced mild ADRs, 49% patients had moderate and 17% patients had severe ADRs. Severity of ADR is seen more in male, economically productive age group, subjects on vegetarian diet, patients who were underweight (BMI<18.5%) and with lower educational status.

Conclusions: MDR-TB is a rapidly increasing health problem with major socio-economic and individual consequences. Multi-drug resistant tuberculosis mainly affects middle age that is in the economically productive age group which hampers the social and economic development of individual, society and nation.

Keywords: Multi-drug resistant tuberculosis, Severity of adverse drug reactions, Socio-demographic profile

INTRODUCTION

Tuberculosis has remained major global problem and is ninth leading cause of death worldwide and leading cause from single infectious agent. In 2016, there were 60000 new case of drug resistant tuberculosis of which 49000 had multidrug resistant tuberculosis and 47% occurred in China, India and the Russian Federation. Poverty, under
nutrition, HIV infection and smoking are major influences on tuberculosis epidemic and most of high burden countries have major challenges to reach targets.\(^1\) Patients with MDR-TB required longer duration and costly treatment resulting in social isolation, loss of employment, long term socioeconomic effects and experience higher morality.\(^2\) Adverse drug reactions on second line anti-tuberculosis drugs and poor management of adverse drug reactions led to irregular adherence of treatment, increasing risk of default and may lead to death and permanent morbidity.\(^3\) Timely monitoring and management of ADR is required to prevent death and morbidity. Considering all these factors the present study was designed to study Socio-demographic profile of multi-drug resistant tuberculosis patients and its association with severity of adverse drug reactions.

**METHODS**

It was prospective observational study. The study was carried out at DOTS Plus Centre Dr. Rajendra Prasad Government Medical College, Kangra at Tanda, Himachal Pradesh. Duration of the study was one year from November 2012 to October 2013. Multi-drug resistant tuberculosis patients fulfilled the inclusion and exclusion criteria.

**Inclusion criteria**

All multi-drug resistant tuberculosis patients registered for category-IV treatment were given written Informed consent.

**Exclusion criteria**

Patients were not given written informed consent to participate in the study.

**Data collection**

The written informed consent was obtained from all the patients. A questionnaire was developed through review of literature. Data was collected into two parts:

- Socio demographic profile: age, sex, education, occupation, family history of TB, diet pattern, and BMI
- Severity of ADR assessed by Hart twig scale and Causality was assessed by as per WHO Probability scale.\(^4,5\)

Ethical clearance was approved by Protocol Review Board and Institutional Ethics Committee DRPGMC Tanda, Himachal Pradesh, India.

**Statistical analysis**

Data analysis was done using SPSS software version 17. Descriptive analysis was done (mean, proportion and percentages) for demographic variable. Association between socio-demographic variables and severity of ADR was analysis by Chi square test. \(P < 0.05\) was considered as statistical significant.

**RESULTS**

A total of 104 multi-drug resistant tuberculosis patients were enrolled. Youngest patient in the study was 13 years and oldest was 85 years of age and mean age of patients was 39.9±14.26 years.

**Socio-demographic profile**

The distribution of the subject according to their age groups shows majority of the patients were in the economically productive age groups (Table 1).

### Table 1: Age distribution of multi-drug resistant tuberculosis patients.

| Age   | Frequency | Percentage |
|-------|-----------|------------|
| <16   | 4         | 3.8        |
| 16-25 | 13        | 12.5       |
| 26-45 | 54        | 51.9       |
| >45   | 33        | 31.7       |
| Total | 104       | 100        |

Multi-drug resistant tuberculosis was more in male (76%) than female (24%) and the male to female ratio was 3:1. 96% of patients were belonged to rural area and 4% to urban area. 86% patients did not have family history of tuberculosis and only 14% have family history of tuberculosis and 74% patients were non-vegetarian diet and 26% were vegetarian diet. The occupational profile of patients shows majority of them were (56.7%) farmers followed by skilled professionals (15.4%), housewives were 12.5%, unskilled worker 7.7% and 7.7% were students (Figure 1).

![Figure 1: Occupation status of multi-drug resistant tuberculosis patients.](image-url)

The educational status of the MDR-TB shows 24% patients were illiterate and rest distributed in all the subclasses but less of them are graduate and above (Figure-
2). 63.46% MDR-TB patients were underweight (BMI<18.5%), none of the patients was obese (BMI>30) according to WHO guidelines for obesity.6

Severity of ADR

Severity assessment using Hart wig and Siegel’s scale showed 21% patients experienced mild ADRs, 49% patients had moderate, 17% patients had severe ADRs and 13% patients does not experience any ADR shown in (Figure 3).

Association between severity of ADR with the socio-demographic factors

Severity of ADR is seen more in male, economically productive age group, subjects on vegetarian diet, patients who were underweight (BMI<18.5%) and with lower educational status (Table 2). Association between severity of ADR with BMI and educational status was statistically significant (Table 2).

Causality assessment

According to WHO-UMC scale causality assessment was done among the MDR-TB patients that shows 82% patients were possible in nature followed by 4% patients were certain and 1% probable/likely (Table 3).

DISCUSSION

MDR-TB is a rapidly increasing health problem with major socio-economic and individual consequences. In the present study multi-drug resistant tuberculosis were more in male (76%) than female (24%) the mean age of patients
was 39.9±14.26 years. This shows that multi-drug resistant tuberculosis is a disease of middle aged males who are in the economically productive age group. Most of the studies conducted in India multi-drug resistant tuberculosis is more prevalent in males with mean age ranging from 32 to 37 years.3-9 This could be due to tuberculosis is more prevalent in males because of their high risk behavior such as smoking, alcoholism as compared to females. Though in this study all of them had stopped smoking and alcohol by the time they were diagnosed as having multi-drug resistant tuberculosis.

**Table 3: Causality assessment of ADRs using WHO Probable Scale.**

| Causality               | No of patients | Percentage |
|-------------------------|----------------|------------|
| No ADR                  | 14             | 13         |
| Certain                 | 4              | 4          |
| Probable/Likely         | 1              | 1          |
| Possible                | 85             | 82         |
| Total                   | 104            | 100        |

There were 96% of multi-drug resistant tuberculosis patients in present study belonged to rural area and only 4% were residing in urban areas. This is on expected lines as 89.7% population of Himachal Pradesh resides in rural areas (census 2011).10

In this study, about 76% were literate and 24% were illiterate. Further, it was found that the patients of multi-drug resistant tuberculosis were distributed in all educational status but lowest in graduate and above. Level of education is important factors for knowledge, attitude, prevention and treatment outcome of disease. Majority of the patients in this study were farmers this may be because most of the population in the area is involved in agriculture and other manual activities. In studies conducted in India also shows a trend of drug resistance in tuberculosis being more common in lower educational status.8-11 63.46% patients in this study were underweight (BMI<18.5%) and finding show in other study conducted in Kolkata 59.9% patients were underweight.12 This could be due to poor nutritional status.

Only 14% patients had family history of tuberculosis and other study conducted by Wahab et al 23.3% patients had family history tuberculosis.13 Family history is important factor in transmission of disease. This could be social stigma attached to disease.

Limitations of the study included population was only those taking treatments from governments DOTs Plus health centre.

**Recommendations**

There is a need of health awareness, education and communication activities so as to make them aware of common symptoms, early diagnosis and treatment and also to avail the facilities at government’s centre.

**ACKNOWLEDGEMENTS**

Authors would like to thank all faculty member and resident of Department of Pharmacology and Pulmonary Medicine Dr RPGMC Tanda for support and help.

**Funding: No funding sources**

**Ethical approval: The study was approved by the Institutional Ethics Committee of DRPGMC Tanda, Himachal Pradesh, India and Protocol Review Board**

**REFERENCES**

1. World health organization, Global TB report 2017. Available at: www.who.int/tb/Publication/global_report2017/en/index.html. Accessed on 08 July 2018.
2. Morris MD, Quenza L, Bhat P, Moser K, Smith J, Perez H, et al. Social, economic and psychological Impacts of MDR-TB treatment. Int J Tuberc Lung Dis. 2013;17(7): 954-60.
3. Central TB Division (CTD), Directorate General of Health services, Ministry of Health and Family Welfare, Government of India, Programmatic Management of Drug Resistant TB (PMDT) Guidelines 2017. CTD, New Delhi.
4. Hartwig SC, Siegel J, Schneider PJ. Preventability and severity assessment in reporting adverse drug reactions. Am J Hosp Pharm. 1992;49:2229-32.
5. The use of the WHO-UMC system for standardized case causality assessment. Available at: http://www.who.int/medicines/areas/quality_safety/safety_efficacy/WHOcausality_assessment.pdf. Accesses d on 9 September 2018.
6. World health organization. Fact sheet: obesity and overweight; 2018. Available at: http://www.who.int/en/news-room/fact-sheets/detail/obesity-and-overweight. Accessed on 9 September 2018.
7. Sharma SK, Kumar S, Saha PK, George N, Arora SK, Gupta D, et al. Prevalence of multidrug-resistant tuberculosis among category II pulmonary tuberculosis patients. Indian J Med Res. 2011;133:312-5.
8. Bhatt G, Vyas S, Trivedi K. An epidemiological study of multi drug resistant tuberculosis. Indian J Tuberc. 2012;59(1):18-27.
9. Thomas A, Ramachandran R, Rehaman F, Jaggarajamma K, Santha T, Selvakumar N, et al. Management of multi drug resistant tuberculosis in the field. Indian J Tuberc. 2007;54:117-24.
10. Himachal Pradesh population census; 2011. Available at: https://www.censusindia.co.in/states/himachal-pradesh. Accessed on 9 September 2018.
11. Mishra VK, Gupt P, Pachar P, Jangir SK, Gupta RC, Gour N. A study to assess the profile of multidrug-resistant tuberculosis (MDR-TB) in tertiary care hospital setting. Sch J App Med Sci. 2016;4(3):820-27.
12. Mukherjee P, Karmakar PR, Basu R, Lahiri SK. Sociodemographic and clinical profile of multi drug resistant tuberculosis patients: a study at drug resistant tuberculosis. JDMS. 2015;14(8):52-8.
13. Wahab F, Ashraf S, Khan N, Anwar R and Afridi MZ. Risk factors for multi-drug resistant tuberculosis in patients. J Coll Physicians Surg Pak. 2009;19(3):162-4.

Cite this article as: Kumari A, Sharma PK, Kansal D, Bansal R, Kumari S. Socio-demographic profile of multi-drug resistant tuberculosis patients and its association with severity of adverse drug reactions in DOTS plus centre at tertiary hospital in Himachal Pradesh, India. Int J Basic Clin Pharmacol 2018;7:2342-6.