

Profile of multi drug resistant (MDR) and rifampicin resistant TB patients treated under category IV of RNTCP

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Received: 07 February 2017

Accepted: 06 March 2017

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ABSTRACT

Background: The emergence of resistance to drugs used to treat tuberculosis (TB) and particularly multidrug resistance TB (MDR-TB) has become a significant health problem and obstacle to effective TB control in India. Present study was conducted to study clinical and sociodemographic profile of MDR and rifampicin resistant TB patients registered for treatment under RNTCP in Yavatmal district of Maharashtra state.

Methods: All drug resistant (MDR and rifampicin resistant) TB patients residents of Yavatmal district, treated at DOTS plus site with Standardized Treatment Regimen (STR) from 1st quarter 2009 to 3rd quarter 2013 were included. Data was obtained from electronic treatment register maintained at DOTS Plus site.

Results: There were total 60 confirmed MDR and rifampicin resistant TB patients from Yavatmal district. Male patients (65.00%) were comparatively more than females (35.00%). Almost half (46.67%) of the patients belonged to the productive age group i.e. 30-45 years followed by another one third (35.00%) in the age group of 15-30 years. 93.33% patients were previously treated under RNTCP (under CAT II), out of them 48.51% were failure, 37.50% relapse and 14.29% defaulter.

Conclusions: Among MDR and rifampicin resistant TB patients, maximum patients were males, belonged to the social and productive age group, HIV negative and previously treated due to treatment failure.

Keywords: MDR-TB, Rifampicin resistant, RNTCP Category IV, STR

INTRODUCTION

The emergence of resistance to drugs used to treat tuberculosis (TB) and particularly multidrug resistance TB (MDR-TB) has become a significant health problem and obstacle to effective TB control in India¹. MDR-TB is defined as resistance to isoniazid and rifampicin with or without resistance to other drugs.¹

Prevalence of MDR TB in India is less than 1- 3% and around 12-17% among the new and retreatment cases respectively.^{2,3} Under revised national tuberculosis control program (RNTCP) both MDR and rifampicin resistant TB patients are suspected from Category I and II patients and diagnosed by sputum culture. They are

included under category IV and treated with Standardized Treatment Regimen (STR).

Present study was conducted to study clinical and sociodemographic profile of MDR and rifampicin resistant TB patients registered for treatment under RNTCP in Yavatmal district of Maharashtra state.

METHODS

Observational type of descriptive study was conducted at DOTS plus site at Akola (which caters five districts including Yavatmal) Maharashtra. All drug resistant (MDR and rifampicin resistant) TB patients treated with Standardized Treatment Regimen (STR) from 1st quarter 2009 to 3rd quarter 2013 were included. Data was

obtained from electronic treatment register maintained at DOTS Plus site. Data was analyzed with SPSS and epi-info software. Permission from institutional ethical committee was obtained before beginning of the study. Privacy and confidentiality of the data was strictly maintained.

Drug resistant suspects can be any of the following:

1. RNTCP category I and II failure patients.¹
2. RNTCP category II sputum smears positive TB patients at the end of four months or later.
3. Sputum smears positive close contacts of confirmed drug resistant TB patients.

Drug resistant suspects are confirmed by culture and sensitivity of their sputum samples. Line Probe Assay (LPA) method is used for culture of sputum and proportion method is used for drug sensitivity testing.

Confirmed patients of drug resistant TB are put in category IV under RNTCP and treated with standardized treatment regimen (STR) after pretreatment evaluation. STR comprises intensive phase of six months (extended upto nine months depending upon follow up sputum culture result) and continuation phase of eighteen months. Intensive phase consists of daily administration six drugs namely Kanamycin, Ofloxacin, Ethionamide, Cycloserine, Pyrazinamide and Ethambutol. Similarly continuation phase consists of daily administration four drugs namely Ofloxacin, Ethionamide, Cycloserine and Ethambutol.

RESULTS

There were total 60 confirmed MDR and rifampicin resistant TB patients from Yavatmal district were registered for category IV treatment under RNTCP and administered Standard Treatment Regimen (STR) for it.

Table 1: Type of drug resistance.

	No	%
Rifampicin Resistance	18	30.00
Multidrug Resistance (MDR)	42	70.00

Out of those 60 patients treated 70.00% patients had MDR TB (resistant to both isoniazid and rifampicin) and remaining 30.0% were resistant to rifampicin and sensitive to isoniazid.

Table 2: Year wise distribution of patients.

Year	No	%
2009	09	15.00
2010	12	20.00
2011	17	28.33
2012	22	36.67

There was gradual increase in number of patients treated from year 2009 (09) to year 2012 (22).

Table 3: Demographic profile of drug resistant TB patients.

	No	%
Gender wise distribution of patients		
Male	39	65.00
Female	21	35.00
Age group wise distribution of patients		
<15 years	00	00.00
15-30 years	21	35.00
30-45 years	28	46.67
45-60 years	10	16.67
>60 years	01	1.66
Residence wise distribution of patients		
Urban	17	28.33
Rural	43	71.67

Male patients (65.00%) were comparatively more than females (35.00%). Almost half (46.67%) of the patients belonged to the productive age group i.e. 30-45 years followed by another one third (35.00%) in the age group of 15-30 years.

Age of the patients ranged from 15-62 years with mean 36.94 years and standard deviation 12.69years. Patients from the rural area (%) outnumbered those from urban area (%).

Table 4: HIV status of patients.

	No	%
HIV Positive	03	05.00
HIV Negative	57	95.00

Very few (only 3 out of 60 i.e.05.00%) patients were HIV positive and rest 95.00% were HIV negative.

Table 5: Previous RNTCP treatment category of patients.

	No	%
Previous RNTCP Treatment Category (n=60)		
Category I (New)	04	6.67
Category II (Previously Treated)	56	93.33
Previous RNTCP Treatment Outcome (n=56)		
Failure	27	48.21
Relapse	21	37.50
Defaulter	08	14.29

93.33% patients were previously treated under RNTCP (under CAT II); out of them 48.51% were failure, 37.50% relapse and 14.29% defaulter. Rest 6.67% patients were new (RNTCP category I).

DISCUSSION

As per the guidelines of RNTCP, both MDR (resistant to both and rifampicin resistant, TB patients are included under category IV and given STR after pre-treatment evaluation. Total such confirmed resistant TB patients from Yavatmal district were registered and treated at DOTS plus site Akola.

Out of those 60 patients treated, 42 (70.00%) had MDR TB (resistant to both isoniazid and rifampicin) and remaining 18 (30.0%) were resistant to only rifampicin and not to isoniazid. Similar findings were reported in a study by Kalpesh Jain et al where 93.00% patients had MDR TB and 7.00 % were resistant to only rifampicin.⁴ They also observed that the pattern of drug resistance was not significantly associated with the outcome of treatment with STR.

Total number of patients registered and treated at DOTS plus site went on gradually increasing from the year 2009, when that DOTS plus site was established, to the year 2013. It may be due to gradual intensifying case finding and case referral activities as well as enhancing capacity of the DOTS plus center. This trend is consistent with that revealed by Joint Monitoring Mission report which shows that in India only 1174 rifampicin resistant patients were put on treatment in the year 2009 which went increasing gradually year by year and in 2012, total 14117 patients were given treatment under category IV under RNTCP.⁵

Demographic profile of these patients showed that male (65.00%) patients outnumbered the female (35.00%) patients. Similar male dominance was also recorded in the various studies in India as well as Abroad.⁶⁻⁹ It may be the reflection of similar proportion of new(CAT-I) TB patients under RNTCP where among all patients treated from 1999 to year 2014, almost three fourth (74%) were males.⁵

Regarding the age group, except one, all patients were from productive age group i.e. 15-60 years and out of them half of them (46.67%) were from the age group of 30-45 years. Concentration of the patients in this most productive age group gives the idea regarding adverse social and economical consequences for their affected families, communities, states and country as a whole. Consistent findings were well documented in studies in India as well as from Abroad.^{4,6,8,9,10-12} Similar to male dominance, social and economic age group involvement among the drug resistant TB patients is similar to that observed among newly diagnosed TB patients.⁵

Among all 60 resistant TB patients, only 5.00% were HIV positive and rest 95.00% were HIV negative. Very less proportion of HIV positive patients among drug resistant TB patients is also recorded by Kapadia VK et al (1.2%), Bhatt G et al (6.34%), Ceatano Mota P et al (11%).^{7,10,13} Additionally all of them found no significant

statistical association between HIV status of patients and treatment outcome.

Only 4 out of 60 (i.e. 6.67%) drug resistant patients were from CAT I. Rest 93.33% patients were previously being treated under RNTCP (under CAT II) i.e. these patients were first treated under CAT I, but due to either failure or relapse or default, they were being retreated under CAT II. Out of these 56 patients, 48.51% were included under CAT II due to CAT I treatment failure, 37.50% due to relapse after successfully completing CAT I treatment and 14.29% due to defaulting CAT I treatment. Sharma S. K et al in their study reported that among previously treated drug resistant TB patients, maximum (75.00%) were of relapse followed by 16.8% defaulter and of failure (8.2%).⁶ In another study by Bhatt G et al revealed almost equal proportion of relapse (30.9%), defaulter (28.4%) and failure (27.2%) patients among previously treated drug resistant TB patients.¹⁴

Funding: No funding sources

Conflict of interest: None declared

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

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Cite this article as: Uike P, Hiwarkar P, Malkar V, Aswalle K. Profile of multi drug resistant (MDR) and rifampicin resistant TB patients treated under category IV of RNTCP. *Int J Basic Clin Pharmacol* 2017;6:784-7.