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Clinical and socio-demographic profile, drug sensitivity pattern and treatment outcome of drug resistant DR TB patients registered for treatment at a tertiary care centre in South India

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ABSTRACT

Background: Drug resistant tuberculosis is a major threat to TB elimination activities. In our study, we address the clinical, socio-demographic profile, drug sensitivity pattern and treatment outcome of drug resistant TB patients.

Materials and Methods : A record based cross sectional study was conducted in 77 Drug Resistant TB cases registered for standardized treatment at a tertiary care centre in South India from January 2012 to December 2019. The clinical, socio-demographic, radiological characteristics, drug sensitivity pattern and treatment outcome of these patients were recorded.

Results: 51 were males and 26 were females. 31 (40.3%) were diabetic, 30 (39%) were tobacco users, 12 (15.6%) were health care workers, 40 (52%) had low BMI and 4 (5.2%) were HIV-TB. 66 (85.7%) showed resistance to isoniazid, 62 (80.5%) to rifampicin, 8 (10.4%) to ethambutol, 9 (11.7%) to Fluoroquinolones, 2 (2.6%) to Second Line Injectables and 6 (7.8%) to Streptomycin. Treatment outcomes were as follows: cured 41 (61%), treatment completed 2 (2.6%), failure 2 (2.6%), lost to follow up 9 (11.7%), regimen changed 3 (3.9%), died 11 (14.3%), not evaluated 2 (2.6%) and treatment stopped due to adverse drug reactions 1 (1.3%). Unfavourable treatment outcomes were associated with low BMI, previous ATT and fluoroquinolone resistance.

Conclusion: More than half of the patients had favourable treatment outcomes. Low BMI, previous ATT and fluoroquinolone resistance were factors associated with poor outcomes.

1. Introduction

TB disease where the bacilli is resistant to one or more anti TB drugs is known as Drug Resistant TB (DR TB). According to the findings of the National Drug Resistance Survey in India, 2014-2016; any drug resistance among new patients is 22.54%, among previously treated patients is 36.82% and among all patients is 28.02%; any Isoniazid resistance (16% in all with 11.6% in new and 25.09% in previously treated patients) being the driver for Rifampicin resistance; almost all Rifampicin Resistant -TB patients are resistant to Isoniazid with/without other first or second-line drugs; Multidrug Resistant-TB is 6.19% in all patients (2.84% among new and 11.6% among previously treated patients).[1]

The programmatic management of DR TB has resulted in varying treatment outcomes; with treatment success rates varying from 40 to 70% among various centres.[2–4] Several socio-demographic and clinical factors may be responsible for the development of DR TB and poor treatment outcomes.

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U Venkatesh et al conducted a cross sectional study to assess the epidemiological profile of MDR TB patients from Gorakhpur division admitted at DR TB centre of a tertiary care hospital.[5] It was found that patients with previous history of irregular ATT, smoking and alcohol consumption and inadequate housing ventilation were associated with the development of drug resistant TB. Nearly 68.8% of patients were resistant to Isoniazid(H) and Rifampicin(R) and 18.5% were resistant to H, R and Streptomycin (S) followed by H, R and Ethambutol(E). Nearly 3.8% of patients were HIV positive and 7% had history of diabetes, 64.3% had low BMI.

In a study conducted in Western Maharashtra,[6] treatment outcome of the patients was as follows: treatment success in 84(58%), died 28(19%), 28(19%) defaulted and failure in 14(9%). The study identified three predictors for successful treatment outcome: urban residence, patients with chest x ray findings of moderately advanced disease and patients whose DR TB status diagnosed by CBNAAT.

Analysis of 63 patients of MDR TB on DOTS Plus regimen was done at LG Hospital, TB Unit, Ahmedabad to analyse demographic, clinical, radiological and bacteriological profile, drug sensitivity pattern, adverse drug reactions and treatment outcome.[7] Extensive lung lesions, cavitation, poor adherence to treatment, high initial bacterial load and BMI less than 18 were associated with poor outcome.

Programmatic management of DR TB services have been rapidly scaled up across the country to achieve the targets of the End TB Strategy including reduction in TB deaths to 95% and TB incidence to 90% by the year 2025.[8] Early detection, immediate initiation of appropriate regimen and completion of treatment are vital for successful treatment outcomes. Treatment outcomes have been reported in only a few studies in India. Socio-demographic and clinical factors associated with treatment outcome have been inadequately studied.

Therefore, the objectives of the study were

1. To assess the clinical and sociodemographic profile of drug resistant TB cases registered for standardized treatment at a tertiary care centre in South India.
2. To identify their drug sensitivity pattern.
3. To analyse their treatment outcome.

2. Materials and Methods

A cross sectional study of drug resistant TB cases registered for standardized treatment at a tertiary care centre in South India was conducted. The DR TB cases were diagnosed from a RNTCP quality-assured Culture and DST laboratory by a RNTCP endorsed testing method. The DR TB cases registered for treatment between January 2012 to December 2019 were enrolled.

The patient data was collected from treatment register at the District TB Centre. Permission was obtained from District and State TB Officer. Ethical clearance was obtained from Institutional Ethical Committee, Government Medical College, Idukki.

The DR TB patients were classified according to the standard definition as:

Mono-resistance (MR): A TB patient, whose biological specimen is resistant to one first-line anti-TB drug only.

Poly-Drug Resistance (PDR): A TB patient, whose biological specimen is resistant to more than one first-line anti-TB drug, other than both Isoniazid (H) and Rifampicin (R).

Multi Drug Resistance (MDR): A TB patient, whose biological specimen is resistant to both Isoniazid and Rifampicin, with or without resistance to other first line drugs.

Rifampicin Resistance (RR): Resistance to Rifampicin detected; with or without resistance to other anti-TB drugs excluding H.

Extensive Drug Resistance (XDR): A MDR TB case whose biological specimen is additionally resistant to a fluoroquinolone and a second-line injectable anti TB drug.

The demographic details of the patients were collected. Socioeconomic status was assessed using Modified Kuppuswamy's scale.[9] Clinical, bacteriological and radiological characteristics of the patients were obtained. Chest radiographs of every patient were classified according to the National Tuberculosis Association of USA (1961).[10]

1. Minimal: Non cavitary lesions involving one or both lungs but the volume of involvement regardless of distribution less than or equal to one zone.
2. Moderately advanced: More advanced lesions than minimal but the total involvement not more than the volume of one lung. Cavities, if present, not to exceed a total diameter of 4 cm.
3. Far advanced (extensive): Any lesion more advanced than moderate.

The drug sensitivity pattern and treatment regimen were noted. Conventional MDR TB regimen was the standardized treatment regimen for MDR/RR patients prior to the Programmatic Management of Drug Resistant TB guidelines in 2019. Shorter MDR TB regimen is given to patient with MDR/RR pulmonary and extra pulmonary TB after excluding DST and non-DST based criteria. The All Oral longer MDR TB regimen is introduced in the guidelines for Programmatic Management of Drug Resistant TB under National Tuberculosis Elimination Programme (NTEP) in the year 2019. The All-Oral H mono/poly regimen is given in Isoniazid-resistant TB patients.

Any change in treatment regimen, extension or interruption of treatment were appended. The treatment

outcome as per standard definition as Cured, Treatment completed, Failure, Died, lost to follow up, Not evaluated and Regimen change were recorded.

The data obtained were entered into Microsoft Excel. Data were analysed with SPSS. Descriptive statistics was used to calculate the Mean+_ Standard Deviation, frequencies and percentage (%). For testing of the hypothesis, Chi square test was used. p value of 0.05 was considered statistically significant.

3. Results

During the study period, 77 DR TB patients were registered for standardized treatment. The median age was 42 years (range 9-81).

There were 51 (66.2%) males and 26 (33.8%) females with male: female being 2:1. Table 1 shows sociodemographic profile of these patients.

Other risk factor profile is as shown in Table 2.

Out of the 77 patients, 40 (51.9%) patients had a low BMI < 18 kg/m^2.

The most common symptom was cough in 70 (90.9%) patients. Figure 1 shows the symptom distribution among the DR TB patients. The mean duration of presenting symptoms was 2 months (range 1-4).

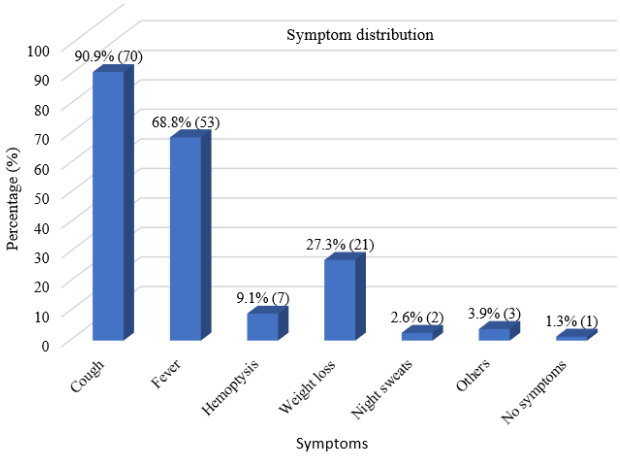

Fig. 1: Symptom distribution of the study population

The anatomical site of the disease was pulmonary in 74 (96.1%) and extrapulmonary in 3 (3.9%) patients.

The previous history of ATT and treatment outcome were as shown in Figures 2 and 3.

The mean duration of previous ATT was 5 months (range 1-27). Cartridge Based Nucleic Acid Amplification Test (CBNAAT) was done in 18/77 patients; with 9 patients showing MTB detected high; Rif resistance detected.

Figure 4 shows the resistance to individual drugs.

The drug resistance pattern is as shown in Figure 5.

Table 3 shows the drug resistance pattern among patients with previous history of ATT. 2 patients did not have history

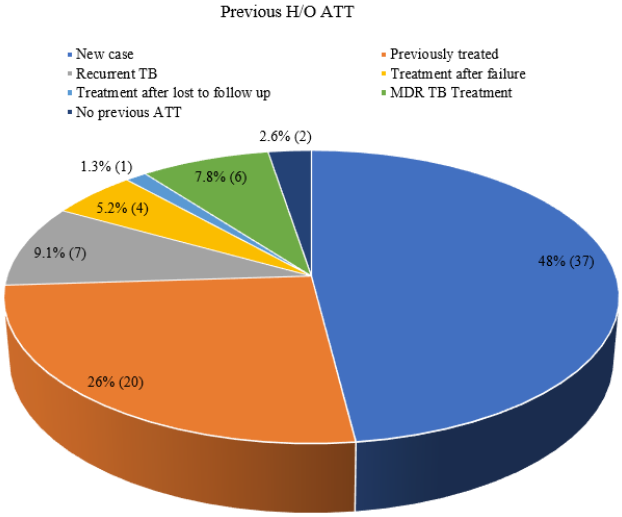

Fig. 2: Treatment history among previously treated patients.

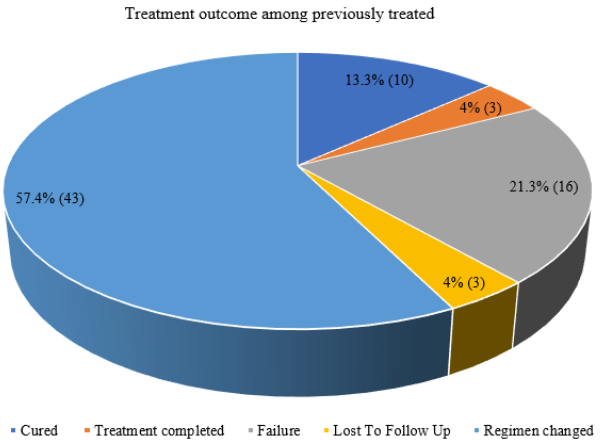

Fig. 3: Treatment outcome among previously treated patients.

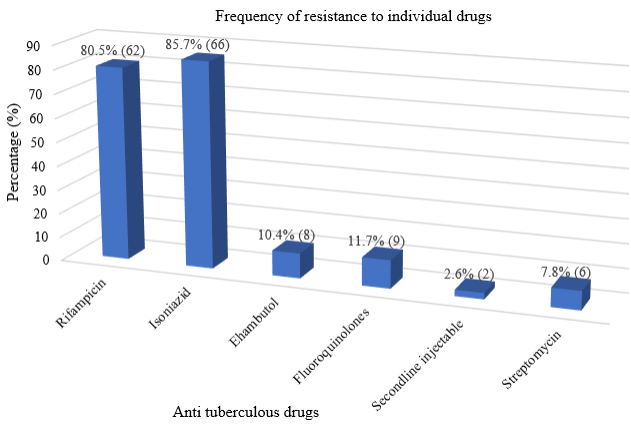

Fig. 4: Frequency of resistance to individual drugs

Table 1: Socio-demographic profile of the patients

Characteristics	Subcategory	Number	Percentage (%)
Age (years)	<20	5	6.5
	20-39	30	39
	40-59	31	40.2
	>=60	11	14.3
Education	Illiterate	1	1.3
	Primary school	16	20.8
	Middle school	15	19.5
	High school	21	27.3
	Intermediate/diploma	7	9.1
	Graduate	4	5.2
	Professional degree	13	16.9
Occupation	Unemployed	21	27.3
	Unskilled worker	20	26
	Semiskilled worker	7	9.1
	Skilled worker	11	14.3
	Clerical/shop/farm	6	7.8
	Semi professional	0	0
	Professional	12	15.6
Socioeconomic status	Lower	33	42.9
	Upper lower	15	19.5
	Lower middle	20	26
	Upper middle	3	3.9
	Upper	6	7.8

Table 2: Risk factor profile of the patients

Characteristics	Number	Percentage (%)
HIV TB	4	5.2
DM	31	40.3
Contact of DR TB	8	10.4
Tobacco user	30	39
Migrant	3	3.9
Healthcare worker	12	15.6
Alcohol use	31	40.3

Table 3: Drug resistance pattern among patients with previous h/o ATT

Previous ATT	Resistance pattern (No., %)							
	MR	PDR	MDR	RR	XDR	MDR+FQ	MDR+SLI	Total
New case	5	0	25	5	0	2	0	37
Previously treated	6	0	11	3	0	0	0	20
Recurrent TB case	2	1	3	0	1	0	0	7
Treatment after failure	0	0	2	0	2	0	0	4
Treatment after lost to follow up	0	0	0	0	1	0	0	1
MDR	0	0	0	1	0	4	1	6
Total	13	1	41	9	4	6	1	75

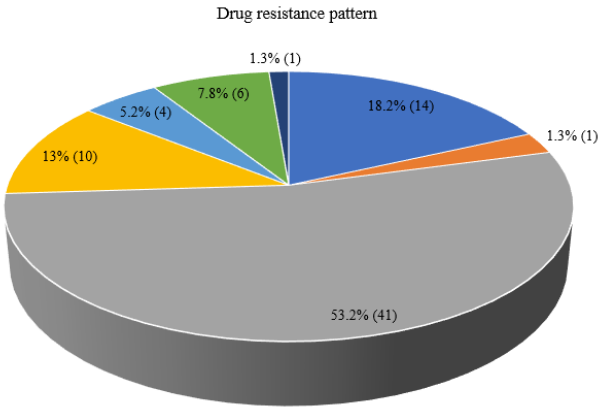

Fig. 5: Drug resistance pattern

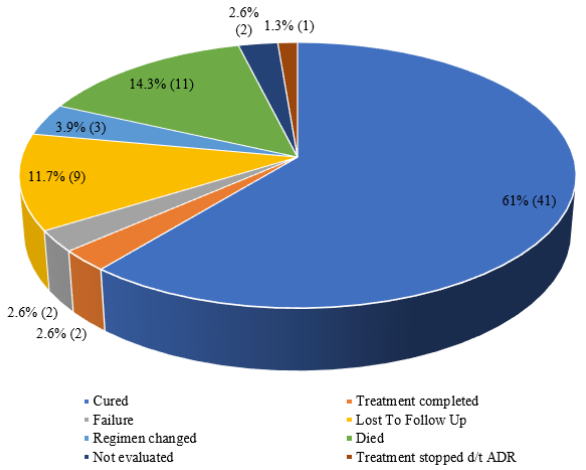

Fig. 7: Treatment outcome

of previous ATT.

While analysing previous ATT status, MDR TB was the most common resistance pattern among previously treated patients. Among the 41 patients diagnosed as MDR TB, the previous ATT received was as new case in 25, previously treated in 11, recurrent TB in 3 and treatment after failure in 2. There were 4 XDR TB cases, with 2 patients having received previous ATT as treatment after failure, 1 as recurrent TB and 1 as treatment after lost to follow up. Previous MDR TB patients developed additional resistance to FQ and SLI.

Figure 6 shows the radiological profile of these patients based on the standard classification.

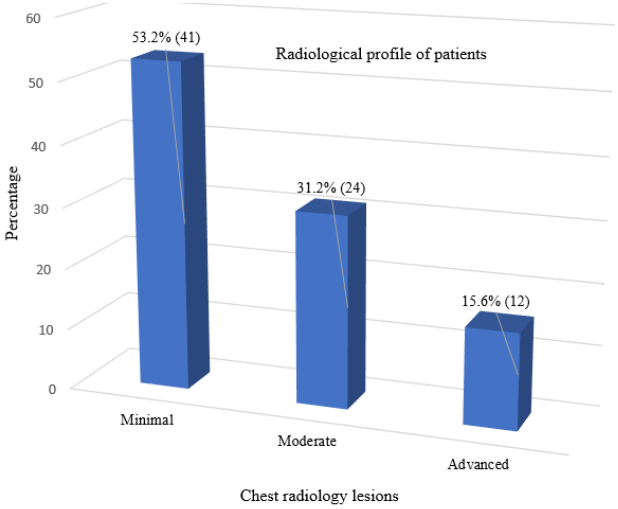

Fig. 6: Radiological profile of the patients

The treatment regimen for these DR TB patients is as shown in Table 4.

Conventional MDR TB regimen was the most common treatment regimen used in 44 (57.1%) of patients.

Treatment outcomes were as shown in Figure 7.

Majority of the patients had a favourable outcome as cured and treatment completed. Unfavourable outcomes were failure, lost to follow up, regimen changed, died and treatment stopped due to adverse drug reactions.

The treatment regimen had to be changed in 13 (16.9%) of the patients; the most common reason being adverse drug reactions followed by additional resistance. Treatment extension and interruptions were seen in 2 (2.6%) and 8 (10.4%) patients respectively.

Figure 8 shows the treatment outcome at the end of anti-tuberculous therapy based on the drug resistance pattern.

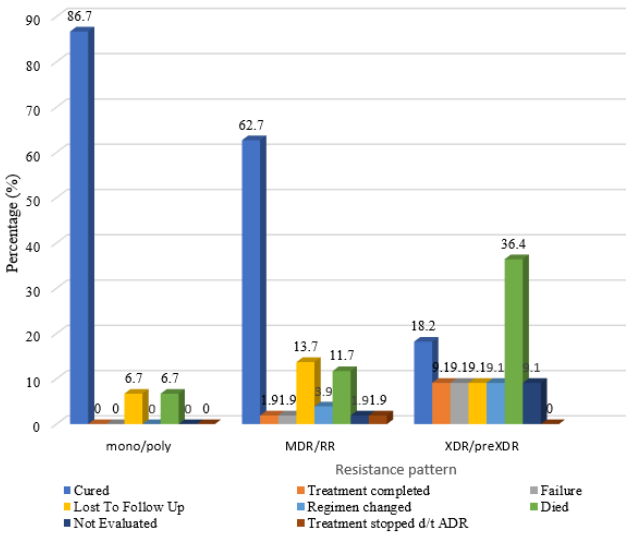

Fig. 8: Treatment outcome according to the drug resistance pattern

Cured as the treatment outcome was seen most commonly in 13/15 patients with mono/poly drug resistance pattern (86.7%), followed by 32/51 MDR/RR TB patients (62.7%). Patients with the XDR/pre-XDR resistance pattern

Table 4: Treatment regimen given to the patients

Characteristics	Subcategory	Number	Percentage (%)
Treatment regimen	All oral H mono-poly DR TB regimen	14	18.2
	Conventional MDR TB regimen	44	57.1
	Shorter MDR TB regimen	7	9.1
	All oral longer MDR TB regimen	3	3.9
	Modified regimen for MDR/RR TB+FQ/SLI resistance	3	3.9
	Regimen for XDR TB	5	6.5
	Regimen with new drug for MDR TB+FQ/SLI resistance	1	1.3

had treatment outcome as cured in only 2/11 (18.2%). Unfavourable outcomes such as died were highest in the XDR/pre-XDR TB resistance pattern 4/11 (36.4%). In the mono/poly and MDR/RR TB resistance pattern, 1/15 (6.7%) and 6/51 (11.7%) patients died respectively. Lost to follow up as treatment outcome was seen in 7/51 (13.7%) in MDR/RR TB patients, 1/11 (9.1%) in XDR/pre-XDR TB patients and 1/15 (6.7%) in mono/poly resistance.

The association of the clinical, demographic and bacteriological variables with favourable and unfavourable treatment outcomes were studied.

4. Discussion

This is the first study done in Idukki district to estimate the sociodemographic profile, drug sensitivity pattern and treatment outcome in DR TB patients. Most of the cases of DR TB were in the 20-39 and 40-59 year age group. These are usually the earning members of the family. The reason may be increased exposure at workplaces. Other similar studies reported DR TB cases predominantly in the 21-45 years age group.[11]

Our study shows more DR TB cases in males than females. The reasons may be increased exposure at workplaces and reduced adherence to treatment among males. This is in contrast to other similar studies where female gender was associated with DR TB; the reasons for which are not yet clear.[12,13]

Low income and poor education are factors associated with the development of DR TB.[14] Our study had more DR TB cases among the lower socioeconomic strata. Improved access to health services to the economically backward sections of the society may result in decrease in DR TB cases. Most of the cases were among educated people (high school and intermediate/diploma). This may be attributed to the high literacy rate in Kerala.

In a retrospective study conducted at a PMDT site of a tertiary care hospital in Mumbai,[15] the comorbidities associated with pulmonary DR TB patients were diabetes mellitus (32.8%), GERD (40.2%), anaemia (13.4%) and HIV infection (8.8%). Out of the 77 patients in our study population, 31(40.3%) were diabetic and 4 (5.2%) had HIV infection. DM and HIV seropositivity are immunocompromising conditions leading to increased chances of developing DR TB. 30(39%) and 31(40.3%) patients were addicted to tobacco and alcohol respectively.

A retrospective multi-centre investigation in China was conducted by Tang et al to analyse the risk factors for poor outcomes in MDR and XDR TB.[16] Poor outcomes were associated with a BMI<18.5 kg/m^2. In our study, 52% of patients were underweight (BMI<18 kg/m^2) with worse treatment outcome.

96% of patients had pulmonary TB in our study. In the profile of drug resistant tuberculosis by More et al,[17] all the patients had pulmonary TB. Similarly, 98.8% patients had pulmonary TB in the study by Bhatt et al at Ahmedabad.[18]

75/77 of the patients in our study had a previous history of anti-tuberculous therapy. This is almost similar to a study in Bangladesh on sociodemographic profile and drug sensitivity pattern of DR TB,[19] where all the MDR TB patients had previous history of ATT. MDR TB and mono resistant TB were the most common resistance pattern in patients with previous ATT. The previous ATT was as new case more commonly followed by previously treated >= 1 month. This can be either due to inadequate regimen or genetic susceptibility leading to decreased response to ATT. Proper education and counselling to ensure adherence to treatment and/or genetic analysis to understand the molecular abnormalities is of importance.

MDR TB was the most common resistance pattern seen in 41 (53%) of all DR TB patients in our study. More et al[17] on the profile of drug resistant tuberculosis in Western Maharashtra found that 73.95% of cases were MDR TB and 26.05% were Rifampicin resistant. In our study, 14 (18.2%) patients had mono resistance to Isoniazid and 10 (13%) patients were Rifampicin resistant.

Fluoroquinolones (FQ) are the major group of drugs in the management of drug resistant tuberculosis. High degree of fluoroquinolone resistance was found in New Delhi.[20] 27.3% among MDR TB isolates had additional fluoroquinolone resistance. Indiscriminate use of

Table 5: Summary of statistically significant association between patient characteristics and treatment outcome

Variables		Favourable outcome	Unfavourable outcome	P value
Education	Illiterate	0 (0%)	1 (100%)	
	Primary school	10 (62.5%)	6 (37.5%)	
	Middle school	6 (40%)	9 (60%)	
	High school	16 (76.2%)	5 (23.8%)	0.029
	Intermediate/diploma	7 (100%)	0 (0%)	
	Graduate	3 (75%)	1 (25%)	
	Professional degree	7 (53.8%)	6 (46.2%)	
Occupation	Unemployed	14 (66.7%)	7 (33.3%)	
	Unskilled worker	10 (50%)	10 (50%)	
	Semiskilled	3 (42.9%)	4 (57.1%)	0.024
	Skilled	11 (100%)	0 (0%)	
	Clerical/shop/farm	4 (66.7%)	2 (33.3%)	
	Professional	7 (58.3%)	5 (41.7%)	
BMI	Low	57.5%	42.5%	
	Normal	64.5%	35.5%	0.04
	High	100%	0%	
Previous H/O ATT	New case	75.7%	24.3%	
	Previously treated	65%	35%	
	Recurrent TB	57.1%	42.9%	0.004
	Tx after failure	50%	50%	
	Tx after LTFU	0%	100%	
	MDR TB Tx	0%	100%	

Table 6: Summary of statistically significant association between resistance and treatment regime with outcome

Variables		Favourable outcome	Unfavourable outcome	P value
Rif resistance	Rif resistant	58.1%	**41.9%**	0.028
	Rif not resistant	86.7%	13.3%	
FQ resistance	FQ resistant	33.3%	66.7%	0.049
	FQ not resistant	67.6%	32.4%	
Drug resistance pattern	Mono/poly	86.7%	13.3%	
	MDR/RR	64.7%	35.3%	0.007
	XDR/pre-XDR	27.3%	72.7%	
Treatment regimen	Change	30.8%	69.2%	0.008
	Interruption	25%	75%	0.018

fluoroquinolones may lead to the increased emergence of isolates resistant to FQs. In our study, FQ resistance was seen in 11.7% patients, comparatively less than in other similar studies. Baseline second line DST is invaluable in their early detection and appropriate management.

Favourable treatment outcome (cured/treatment completed) was seen in 63.6% patients and unfavourable treatment outcomes (died/lost to follow up/regimen changed/failure/stopped due to ADR) seen in 36.4% patients in our study. A retrospective cohort study described similar treatment outcomes in the MDR TB patients treated.[21] In our study, unfavourable treatment outcomes were associated with low BMI (<18 kg/m^2) and previous ATT as treatment after failure, treatment after Lost to follow up and previous MDR TB treatment. Rifampicin and Fluoroquinolone resistance were associated with unfavourable treatment outcomes.

While analysing our data, it was found mortality was highest in the XDR/pre-XDR TB group (36.4 %). Lost to follow up was seen in 17.1 % of MDR TB and 9.1% of XDR/pre-XDR patients. This may be because most of the MDR TB patients in our study group were treated with Conventional MDR TB regimen of 22-27 months duration. Long treatment durations may be responsible for these patients being lost to follow up. Thus, shorter duration of treatment may be more effective and may potentially lead to better outcomes.

5. Conclusions

In our study, we observed more favourable outcome in patients treated for DR TB. Poor treatment outcomes were seen in patients with low BMI, previous ATT history and fluoroquinolone resistance. Thus, proper nutrition, education and counselling regarding treatment adherence and avoidance of irrational use of fluoroquinolones are vital. Longer duration of treatment and injectables may be obstacles in the management of these patients; that may be overcome by shorter regimes.

6. Source of Funding

None.

7. Conflict of Interest

The authors declare that there are no potential conflicts of interest for the authorship and publication of the article.

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