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A Study of Outcome of Shorter MDR-TB Treatment Regimen on Multidrug Resistant Tuberculosis Patients under RNTCP

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Abstract: ***Background: Shorter MDR-TB (Multi Drug Resistant) Regimen is widely used for Pulmonary MDR Tuberculosis patients and there is much less data regarding the outcome of this regimen. Material and Method: The study is record based. The study enrolled 50 MDR PTB patients started on shorter MDR-TB regimen at department of Respiratory Medicine, Sir T Hospital, Bhavnagar from April 2018 to December 2018. Data regarding follow up sputum smear, sputum culture and outcome of patients started on shorter MDR regimen was collected from DTC Bhavnagar. Observation: Out of 50 patients enrolled in the study, 52% (26/50) patients completed the regimen, 26%(13/50) patients defaulted the treatment and 22%(11/50) died during the study. 23% (6/26) had positive end IP culture and 77% (20/26) had negative end IP culture. 23% (6/26) had positive end CP culture, 58% (15/26)had negative end CP culture and end CP culture were not sent in 19% due to change of regimen. 19% (5/26) reported FQ resistance, 4% (1/26) reported SLID resistance. 30% (15/50) patients were cured, 12% (6/50) had treatment failure, 10% (5/50) were put on newer regimen. Conclusion: Even though Shorter MDR regimen is cost effective and of short (9-11 months) duration, outcome of Shorter MDR regimen depends on patient's compliance and pattern of resistance to second line drugs.***

Keywords: Multi Drug Resistant Tuberculosis, Shorter Regimen, End IP Culture, End CP Culture

1. Introduction

MDR-TB is defined as resistance to at least rifampicin and isoniazid, the two most effective anti-TB drugs, while XDR-TB is a more severe form of MDR-TB with additional resistance to any fluoroquinolone and to injectable second-line drugs (amikacin, capreomycin, kanamycin) [1-3]. The 2011 WHO guidelines recommended an intensive treatment phase of 8 months and total treatment duration of 20 months for MDR TB patients[2]. In view of the lack of an effective standardized regimen that is appropriate for resource-poor settings, Van Deun and colleagues conducted observational cohort studies in Bangladesh to evaluate several regimens for multidrug-resistant tuberculosis in patients who had not received previous treatment with second-line drugs. The sixth regimen, administered to 206 participants for 9 to 11 months, yielded encouraging results, with relapse-free cure occurring in 87.9%Recent evidence suggests that a 9 to 12-month regimen (known as the 'Bangladesh regimen') may be effective in treating MDR-TB cases[4]. Shorter MDR-TB (Multi Drug Resistant) Regimen is widely used for Pulmonary MDR Tuberculosis patients and there is much less data regarding the outcome of this regimen. This study describes the follow-up evaluation of MDR TB patients started on 'Shorter MDR regimen' and cure rate and efficacy of shorter MDR-TB regimen.

2. Material and Methods

This retrospective study was carried out on all MDR-PTB patients initiated on Shorter MDR regimen at District Tuberculosis Centre, Bhavnagar, Gujarat, under RNTCP, from April, 2018 to December, 2018.

Study design: Retrospective study.
Study location: Department of Respiratory Medicine, Sir T. Hospital, Bhavnagar, Gujarat.
Study duration: April, 2018 to December, 2018.
Sample size: 50 patients
Sampling and recruitment: All MDR-PTB patients initiated on Shorter MDR regimen at District Tuberculosis Centre, Bhavnagar, Gujarat, under RNTCP, from April, 2018 to December, 2018 were consecutively included in the study.

Inclusion criteria:
- Multi Drug Resistant Pulmonary Tuberculosis (MDR-PTB) patients (Rifampicin Resistant).
- Second Line Injectable Drugs (SLID) and Fluoroquinolones (FQ) sensitive patients.
- Patients on Shorter MDR regimen.

Exclusion criteria:
- Extra pulmonary MDR TB patients.
- Patient with incomplete data/ missing data.
- Patient on shorter MDR regimen transferred out to other district/state.

Procedure and Methodology: All data was collected from PMDT register at District Tuberculosis Centre, Bhavnagar, with permission of District TB Officer (DTO), Bhavnagar. The study was conducted at department of Respiratory Medicine, Sir T Hospital, Bhavnagar. The data regarding F0 culture, follow-up sputum and culture was obtained and analyzed to see the final outcome of the patients started on Shorter MDR regimen with reference to follow-up sputum smear and culture results during the treatment.

3. Result

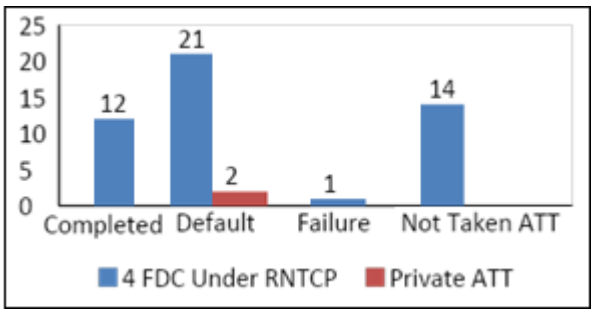
Out of 50 patients included in the study, 36 had past history of ATT, of which 02 patients took private ATT which they had default, 34 took 4FDC ATT under RNTCP. Out of these 34 patients, 12 completed ATT, 21 defaulted ATT and 1

patient had treatment failure.

Table 1 shows the Patients with past history of anti-tubercular treatment (ATT).

Table 1: Past history of ATT among study subjects

	4 FDC Under RNTCP	Private ATT
Completed	12	--
Default	21	02
Failure	1	--
Not Taken ATT	14	00

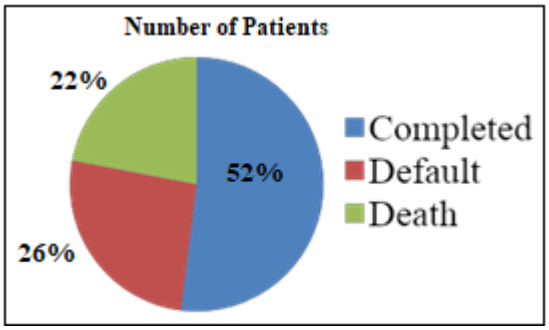


Out of 50 patients enrolled in the study, 52% (26/50) patients completed the regimen, 26%(13/50) patients defaulted the treatment and 22%(11/50) died during the study.

Table 2 shows the proportion of patients who completed the treatment, default the treatment and failed the treatment.

Table 2: Proportion of patients who completed the treatment, default the treatment and failed the treatment

Outcome	Number of Patients
Completed	26
Default	13
Death	11
Total	50

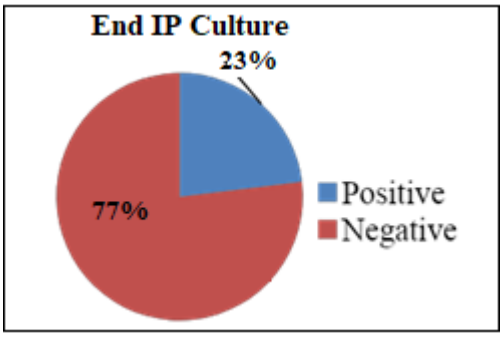


Out of remaining 26 patients, 6 patients had positive end IP culture (23%) and 20 patients had negative end IP culture (77%).

Table 3 shows proportion of sputum conversion at the end of Intensive Phase.

Table 3: Proportion of patients with positive and negative End IP culture

End IP Culture	
Positive	6
Negative	20

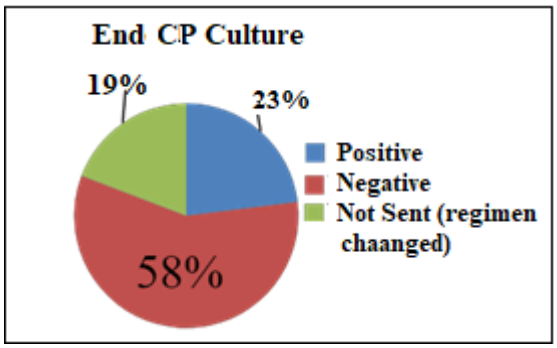


Out of 26 patients, 6 patients had positive End CP culture (23%), 15 patients had negative End CP culture(58%) and End CP culture were not sent in 5 patients due to change of regimen(19%).

Table 4 shows proportion of patients with positive and negative End CP cultures.

Table 4: Proportion of patients with positive and negative End CP cultures

End CP culture	
Positive	6
Negative	15
Not sent due to change of regimen	5



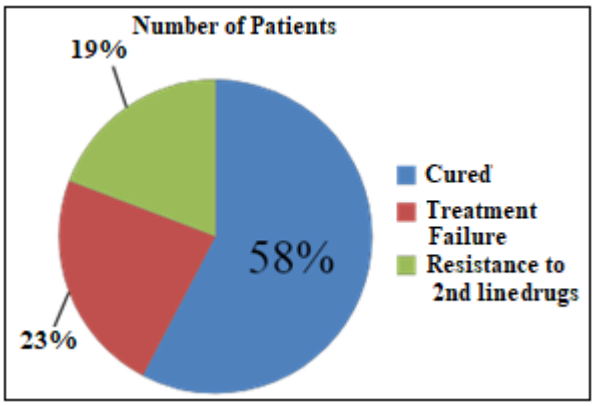
Out of 50 subjects included in the study, 09 developed resistance to 2nd line drugs, out of which 03 patients died. Out of remaining 06 patients, 05 were resistant to FQ and 01 was resistant to SLID. Out of 05 patients with FQ resistance, 04 were started on Bedaquiline regimen and 01 patient continued the same regimen, who was cured. 01 patient who was resistant to SLID was started on DST guided regimen.

Out of 26 patients, 15 patients were cured (58%), 6 patients had treatment failure (23%) and 5 patients developed resistance to 2nd line drugs (19%).

Table 5 shows final outcome of patients.

Table 5: Final Outcome of patients

Final Outcome	
Cured	15
Treatment failure	6
Resistance to 2nd line drugs and change of regimen	5



4. Discussion

1) Out of 50 patients enrolled in the study, 52% (26/50) patients completed the regimen, 26%(13/50) patients defaulted the treatment and 22%(11/50) died during the study.
2) 23% (6/26) had positive end IP culture and 77% (20/26) had negative end IP culture.
3) 23% (6/26) had positive end CP culture, 58% (15/26)had negative end CP culture and end CP culture were not sent in 19% due to change of regimen.
4) 19% (5/26) reported FQ resistance, 4% (1/26) reported SLID resistance.
5) 30% (15/50) patients were cured, 12% (6/50) had treatment failure, 10% (5/50) were put on newer regimen.

5. Conclusion

Even though Shorter MDR regimen is cost effective and of short (9-11month) duration, outcome of Shorter MDR regimen depends on patients compliance and pattern of resistance to second line drugs.

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