

Original Research Article

FACTORS ASSOCIATED WITH SPUTUM CULTURE CONVERSION DURING THE INTENSIVE PHASE IN MULTIDRUG-RESISTANT TUBERCULOSIS PATIENTS RECEIVING A SHORTER REGIMEN

Rakesh Gattu¹, Prabhakar K², Shaik Umar Pasha³, Pramod Kumar T⁴

¹Assistant Professor, Department of Pulmonary Medicine, Surabhi Institute of Medical Sciences, Mittapally, Siddipet, Telangana, India.

²Assistant Professor, Department of Pulmonary medicine, Osmania Medical College/ Government General and Chest Hospital, Hyderabad, Telangana, India.

³Assistant Professor, Department of Respiratory Medicine, Government Medical College & General Hospital, Narsampet, Warangal, Telangana, India.

⁴Professor & HOD, Department of Pulmonary medicine, Osmania Medical College/ Government General and Chest Hospital, Hyderabad, Telangana, India.

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Corresponding Author:

Dr. Prabhakar K,
Assistant Professor, Department of
Pulmonary Medicine, Osmania Medical
College/Government General and
Chest Hospital, Koti, Hyderabad,
Telangana, India.
Email: prabhakar2kuruva@gmail.com

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ABSTRACT

Background: Mycobacterium tuberculosis, along with resistance to isoniazid and rifampicin, the two most important first-line anti-TB drugs, is responsible for causing multidrug-resistant tuberculosis (MDR-TB). Many investigations showed that, in comparison to drug-susceptible tuberculosis, culture conversion is delayed in the treatment of MDR-TB. Major risk factors for delayed culture conversion are smear-positive and the appearance of cavitary lung lesions, which are also indicators of severe pulmonary disease. The present study was undertaken to study factors associated with sputum culture conversion during the intensive phase in multidrug-resistant Tuberculosis patients receiving a shorter regimen.

Materials and Methods: This study was carried out at the Programmatic Management of Drug-Resistant TB (PMDT) centre at the National Institute of Tuberculosis and Respiratory Diseases (NITRD) and Nehru Nagar Drug-Resistant Tuberculosis (DRTB), New Delhi. All MDR-TB patients fulfilling the inclusion criteria for shorter regimen treatment and willing to give consent for participating in the study were enrolled in the study from July 2018 to December 2018. A total of 35 patients were enrolled during this. Sputum culture examination was done every two weeks in the first two months and then monthly till the completion of the intensive phase of treatment, and patients were followed with regular telephonic interviews of patient starting from the 1st week of initiation of treatment regularly and also on an as-needed basis.

Results: The male proportion in our study was 53.3%. Smokers in our study contributed to 23.3%. Twenty-two (73.3%) had having history of anti-tubercular treatment in the past. Culture conversion in the intensive phase was attained in 27 (90%) patients. Out of 27 patients, delayed culture conversion (>8 weeks) was found in 4 (14.8%) patients. On multiple logistic regression analysis, factors which were found to be independently and significantly associated with culture non-conversion were sputum grading 3+ (p=0.01019) and presence of clofazimine resistance (p=0.000494), delayed culture conversion was bilateral involvement on Chest x-ray (p=0.01163) and interruption in treatment (p=0.030681).

Conclusion: From our study, patients with far-advanced disease, bilateral chest x-ray involvement, cavities on chest x-ray, clofazimine resistance, higher sputum grade, and interruption in treatment were associated with poor outcomes in terms of sputum culture conversion.

Keywords: Multi-Drug Resistant Tuberculosis, Shorter Regimen, Sputum Culture Conversion, Risk Factors, Clofazimine Resistance, Bilateral Chest X-ray Involvement, Treatment Interruption.

INTRODUCTION

Mycobacterium tuberculosis is the bacterium that causes tuberculosis (TB), which is treatable and preventable. The condition continues to be a major cause of sickness and mortality. In 1993, tuberculosis was declared a worldwide epidemic by the World Health Organisation (WHO).^[1] Among them, 5.8 million were men, 3.2 million were women, and 1.0 million were children. In 2017, 1.3 million deaths (range, 1.2–1.4 million) occurred among Human Immunodeficiency Virus (HIV) negative people, and 300,000 deaths occurred from TB (range 266000–335000) among HIV-positive people. Global mortality due to TB in 2017, the proportion of people who died from the disease was 16%, down from 23% in 2000. Notifications have increased, but reporting of treatment outcomes has not kept pace.^[2]

The Global TB report 2017 states that the incidence of TB in India was approximately 28,00,000, accounting for about one-fourth of the world's TB cases. The timespan of the longer MDR-TB treatment regimens and the toxicity of certain agents lead to non-compliance with completing the treatment as intended. In addition, the high cost associated with the implementation of the regimens poses a significant challenge to health systems. Many attempts to decrease the length of treatment consisting of a combination of medicines, which are more tolerable, more effective and less expensive, have been ongoing for several years.^[3] A new, shorter regimen was assessed by six cohort studies conducted in Bangladesh. These studies showed promising results and offered the possibility of a more acceptable and more effective regimen than the one recommended by the World Health Organisation (WHO).⁴ Lately, a standardised treatment regimen lasting 9-12 months has been reported to give relapse-free cure in >85% of selected MDR-TB patients, with adverse reactions typical of those expected when using these second-line TB medicines.^[4,5]

Early conversion plays an important role in preventing transmission of MDR-TB, decreasing hospitalisation time, and decreasing the cost related to infection control measures.^[6] The important indicator of observing treatment outcome in MDR-TB patients is sputum culture conversion. Attaining more swift sputum culture conversion can increase patients' comfort by decreasing the duration of injectable drug use and simplifying a patient's therapy. An important infection control measure with regard to a public health point of view is decreasing the sputum culture conversion because patients with MDR-TB and positive sputum cultures are infectious and may spread the disease to other persons, family members, and health care providers. Several studies showed that culture conversion is delayed in the treatment of MDR-TB as compared to drug-susceptible tuberculosis. The indicators for

severe pulmonary disease are smear-positive and the appearance of cavitary lung lesions, which are also risk factors for delayed culture conversion following MDR-TB treatment. Patients' resistance to second-line anti-TB drugs shows slow culture conversion. Co-morbidities like low body weight and smoking have been linked to slow conversion.

Studies are sparse regarding the associations of the various factors for culture conversion in the MDR patients on a shorter regimen. Therefore, this study was conducted to determine the association of various factors with culture conversion among these patients.

MATERIALS AND METHODS

This study was carried out at the Programmatic Management of Drug-Resistant TB (PMDT) centre at the National Institute of Tuberculosis and Respiratory Diseases (NITRD) and Nehru Nagar Drug-Resistant Tuberculosis (DRTB), New Delhi. The study was undertaken after approval from the Institutional Ethical Committee.

Patients who were not willing to participate in the study, having evidence of Pre XDR-TB (Resistance to Rifampicin, INH and Fluoroquinolones or Injectable drug) Or XDR-TB (Resistance to Rifampicin, INH and Fluoroquinolones and Injectable drug), Pregnant and breast-feeding patients, Critically ill patient, Patients with Extra pulmonary disease, Exposure to more than one second-line medicines in the shorter MDR-TB regimen for more than one month, and those Intolerance to more than one medicine in the shorter MDR-TB regimen or risk of toxicity (e.g. drug-drug interactions) were excluded from the study. All MDR-TB patients willing to give consent for participating in the study and fulfilling the exclusion criteria for shorter regimen treatment were enrolled in the study from July 2018 to December 2018. 35 patients were enrolled during this time frame.

All enrolled patients were thoroughly examined. At first, a detailed history and clinical examination were conducted. Investigations such as Complete blood count, Random blood sugar, serum electrolytes & serum cholesterol, Liver function tests, Renal function tests and Sputum for AFB-direct smear (two samples) were noted. All the findings were entered in a Clinical Performance.

Chest X-rays (PA view) were carried out in all patients. Sputum culture examination was done every two weeks in the first two months and then monthly till the completion of the intensive phase of treatment, and patients were followed with regular telephonic interviews of patient starting from the 1st week of initiation of treatment on a regular basis and also on and when required basis. Time for smear conversion was defined as the duration between initiation of treatment and to first day of the two consecutive negative smear conversions 30 days apart. Time for Culture conversion was defined as

the duration between the initiation of treatment and to first day of the two negative consecutive culture conversions, 30 days apart. Accordingly, comparisons were done between culture converted and non-converted, and in culture converted patient's comparison was also done between those who achieved culture conversion either before, or by 8 weeks (early), with those that achieved conversion after 8 weeks (delayed) from the initiation of therapy. The data was entered into a Microsoft Excel sheet. After data collection, the data were cleaned before using Statistical Software (SPSS VERSION 23.0).

Statistical Analysis: The raw data were evaluated by using descriptive statistics. Appropriate statistical tests, like Fisher's Exact test, were used for qualitative data, and Spearman and Pearson

Correlation testing were used to derive correlations between various factors. P value <0.05 was taken to be significant.

RESULTS

A total of 35 patients were enrolled during the defined period. Among these, 1 patient expired and 4 patients were lost to follow-up. Thus, for the current study, 30 patients were enrolled and analysed. Accordingly, comparisons were done between culture converted and non-converted, and in culture converted patient's comparison was also done between those who achieved culture conversion either before or by 8 weeks (early) with those who achieved conversion after 8 weeks (delayed) from the initiation of therapy.

Table 1: Culture-converted and culture non-converted patients from the initiation of therapy in the intensive phase

Factors		Culture-converted patients	Culture not converted patients	P Value
Age (years)	≤40	19 (70.37%)	3 (100%)	0.5548
	>40	8 (29.63%)	0 (0%)	
Gender	Male	14(51.85)	2(66.66)	1
	Female	13 (48.15%)	1 (33.33%)	
Socioeconomic status	Upper class & Upper middle	17 (62.96%)	1 (33.33%)	0.54
	Lower middle & upper lower	10 (37.04%)	2 (66.66%)	
BMI	Underweight (BMI<18.5)	8 (29.62%)	3 (100%)	0.04
	Non-underweight (BMI≥18.5)	19 (70.38%)	0 (0%)	
History of Smoking	Present	6 (22.22%)	1 (33.33%)	0.56
	Absent	21 (77.78%)	2 (66.66%)	
History of DM	Diabetes	5 (18.5%)	0 (0%)	1
	Non-diabetes	22 (81.5%)	3 (100%)	
History of Hypertension	Present	3 (11.11%)	0 (0%)	1
	Absent	24 (88.88%)	3 (100%)	
HIV Status	HIV reactive	1 (3.7%)	1 (3.7%)	1
	HIV Non-Reactive	26 (96.3%)	26 (96.3%)	
Past History of ATT	Present	19 (70.37%)	3 (100%)	0.54
	Absent	8 (29.63%)	0 (0%)	
History of TB contact	Present	7 (25.9%)	0 (0%)	1
	Absent	20 (74.1%)	3 (100%)	
Number of times ATT taken	One time	15 (78.94%)	2 (66.66%)	0.56
	More than once time	4 (21.06%)	1 (33.33%)	
Duration of ATT taken	≤6 months	15 (78.94%)	2 (66.66%)	0.56
	>6 months	4 (21.06%)	1 (33.33%)	
Source of ATT	Private	7 (36.85%)	1 (33.33%)	1
	Public	12 (63.15%)	2 (66.66%)	
Chest X-ray involvement	Bilateral	6 (22.22%)	3 (100%)	0.02
	Unilateral	21 (77.77%)	0 (0%)	
Cavity on X-ray	Present	8 (29.62%)	3 (100%)	0.04
	Absent	19 (60.38%)	0 (0%)	
Severity of chest X-ray	Far advanced disease	5 (18.51%)	3 (100%)	0.01
	Minimal & moderate disease	22 (81.49%)	0 (0%)	
Initial sputum grading	1+ and 2+	21 (77.77%)	0 (0%)	0.02
	3+	6 (22.22%)	3 (100%)	
DST pattern	RMP & INH both resistance	23 (85.18%)	3 (100%)	1
	RMP resistance only	4 (14.82%)	0 (0%)	
Clofazimine resistance	Present	1 (3.7%)	2 (66.66%)	0.02
	Absent	26 (96.3%)	1 (33.33%)	
Interruptions in Treatment	Present	6 (22.22%)	2 (66.66%)	0.16
	Absent	21 (77.77%)	1 (33.33%)	
Total		27 (100%)	3 (100%)	

In our study, a total of 27 patients achieved culture conversion in the intensive phase, and 3 patients didn't achieve culture conversion in the intensive phase. Above [Table 1]: Distribution and comparison of different factors among culture-

converted and culture non-converted patients from the initiation of therapy in the intensive phase. It can be seen that factors such as Body Mass index (low), Chest X ray findings (Chest X ray involvement, cavitation, severity), Initial Sputum grading and

clofazimine resistance were found to be significantly associated with culture non-conversion

Table 2: Culture conversion either before or by 8 weeks (early) with those that achieved conversion after 8 weeks (delayed) from the initiation of therapy

		Early Culture converted patients (≤ 8weeks)	Delayed Culture converted patients (> 8weeks)	P Value
Age (years)	≤40	16(69.5%)	3(75%)	1
	>40	7(30.5%)	1(25%)	
Gender	Male	12(47.8%)	2(50%)	1
	Female	11(52.2%)	2(50%)	
Socioeconomic status	Upper class & Upper middle	15(65.3%)	2(50%)	0.61
	Lower middle & upper lower	8(34.7%)	2(50%)	
BMI	Underweight (BMI<18.5)	5(21.7%)	3(75%)	0.06
	Non-underweight (BMI≥18.5)	18(78.3%)	1(25%)	
History of DM	Diabetes	4(17.3%)	1(25%)	1
	Non-diabetes	19(78.7%)	3(75%)	
History of Smoking	Present	5(21.7%)	1(25%)	1
	Absent	18(78.3%)	3(75%)	
History of Hypertension	Present	2(8.7%)	1(25%)	0.39
	Absent	21(91.3%)	3(75%)	
HIV Status	HIV reactive	1(4.4%)	0(0%)	1
	HIV Non-Reactive	22(95.6%)	4(100%)	
Past History of ATT	Present	16(69.5%)	3(75%)	1
	Absent	7(30.5%)	1(25%)	
History of TB contact	Present	5(21.7%)	2(50%)	0.26
	Absent	18(78.3%)	2(50%)	
Number of times ATT taken	One time	12(75%)	3(100%)	1
	More than once time	4(25%)	0(0%)	
Duration of ATT taken	≤6 months	12(75%)	3(100%)	1
	>6 months	4(25%)	0(0%)	
Source of ATT	Private	7(43.75%)	0(0%)	0.26
	Public	9(56.25%)	3(100%)	
Chest X-ray involvement	Bilateral	2(8.8%)	4(100%)	0.0009
	Unilateral	21(91.2%)	0(0%)	
Cavity on X-ray	Present	4(17.4%)	4(100%)	0.004
	Absent	19(82.6%)	0(0%)	
Severity of chest X-ray	Far advanced disease	2(8.7%)	3(75%)	0.01
	Minimal & moderate disease	21(91.3%)	1(25%)	
Initial sputum grading	1+ and 2+	19(82.6%)	2(50%)	0.20
	3+	4(17.4%)	2(50%)	
DST pattern	RMP & INH both resistance	20(86.9%)	3(75%)	0.49
	RMP resistance only	3(13.1%)	1(25%)	
Clofazimine resistance	Present	0(0%)	1(25%)	0.14
	Absent	23(100%)	3(75%)	
Interruptions in Treatment	Present	3(13.04%)	3(75%)	0.02
	Absent	20(86.96%)	1(25%)	
Total		23 (100%)	4 (100%)	

In this study, a total of 23 patients achieved culture conversion before or by 8 weeks (early), and 4 patients achieved culture conversion after 8 weeks (delayed). Above [Table 2] Distribution and comparison of different factors among Culture conversion either before, or by 8 weeks (early), with

those that achieved conversion after 8 weeks (delayed) from the initiation of therapy. Factors such as Chest X-ray findings (Chest X-ray involvement, cavitation and severity) and Interruption in Treatment were found to be significantly associated with delayed culture conversion.

Table 3: Multivariate logistic regression analysis (culture on-conversion)

Parameter	Odds ratio	Multivariate analysis
Sputum grading (3+ Vs 1+ and 2+)	23.15(1.05-509)	p=0.01019
Clofazimine resistance (Present Vs Absent)	52.0(2.29-1180.82)	p=0.000494

[Table 3] indicates factors which were found to be independently and significantly associated with culture non-conversion were sputum grading 3+

(p=0.01019) and clofazimine resistance (p=0.000494).

Table 4: Multivariate logistic regression analysis (delayed culture conversion)

Parameter	Odds ratio (95% CI)	Multivariate analysis
Chest X-ray involvement (Bilateral vs Unilateral)	77.4 (3.14-1902)	P=0.01163
Interruption in treatment (Present Vs Absent)	20.0(1.53-260.8)	P=0.030681

[Table 4] indicates factors which were found to be independently and significantly associated with delayed culture conversion: Chest X-ray

involvement($p=0.01163$) and interruption in treatment ($p=0.030681$).

Table 5: Factors correlated with time to culture conversion

SN	Variables	Correlation Coefficient ρ	P Value
1	BMI (<18.5 Vs ≥ 18.5)	-0.4265*	0.026
2	Cavity (Present Vs Absent)	0.67958	0.0001
3	Sputum Grading (+3 Vs +1 and +2)	0.53545	0.004
4	Severity of Chest X-ray (Far advanced Vs Minimal and Moderately)	0.57944	0.001
5	Chest X-ray involvement (Bilateral Vs Unilateral)	0.5771	0.001
6	Interruption in treatment (Present Vs Absent)	0.39478	0.04

In our study [Table 5], factors such as cavities on chest x-ray, bilateral X-ray, far advanced disease interruption in treatment, and higher sputum grading were positively correlated with an increase in time to culture conversion. Conversely, BMI was negatively correlated with time to culture conversion, implying that low BMI was associated with an increase in time to culture conversion.

DISCUSSION

This is a prospective study to first evaluate the association of factors with culture conversion in MDR patients receiving a shorter regimen when compared to other studies. This study was conducted on 30 MDR TB patients and was followed till the intensive phase.

In our study, older age was not found to be significantly associated with both non-culture conversion and delayed culture conversion when compared to Akinsola et al,^[7] the median age of the study was 36.8 $\pm$ 12.7 years, and older age (>40 years) was found to be significantly associated with non-culture conversion. Similarly, in another study by E. V. Kurbatova et al,^[8] median age was 37 years, and sputum culture conversion rates were found to be declining with increasing age who received longer MDR regimens. Studies on shorter regimen,^[4] revealed that older age is a risk factor for poor outcome. The findings in our study were in contrast to other studies, probably because the majority of patients were in the younger age groups. Literature has shown that older age is a risk factor for delayed culture conversion. Frequency of adverse events may lead to frequent interruptions in the older age group and may lead to delayed or non-culture conversion.

In our study, no gender was found to be significantly associated with non-culture conversion and delayed conversion. This could be due to the small number of patients in the study group, differences in biology or social behaviour patterns and different regimens in the studies when compared to studies conducted by Kurbatova et al,^[9] A. Putri et al,^[10] reported that successful culture conversion was more common among females in MDR TB patients who received a longer regimen. No studies of shorter regimen discussed the impact of factors such as low BMI, Diabetes, Smoking,

Hypertension, HIV, ATT history, Association of bilateral disease, and cavitation on culture conversion, whereas our study includes all the factors.

Gender was found to be not significantly associated with non-culture conversion and delayed conversion. This could be due to the small number of patients in the study group, differences in biology or social behaviour patterns and different regimens in the studies. Whereas Mota et al,^[11] reported that males had delayed sputum culture conversion, Kurbatova et al⁹ reported that successful culture conversion was more common among females in MDR TB patients who received a longer regimen.

Low BMI is found to be significantly associated with non-culture conversion when compared to a study conducted by F. A. Putri et al,^[10] in 212 MDR enrolled patients, severely underweight patients (BMI <16 kg/m²) had longer time to initial conversion and a lower probability of sputum culture conversion within 4 months, Study conducted by A. Piubello et al,^[12] in MDR TB patients who received shorter regimen found low BMI as a predictor for poor outcome.

Diabetes was not statistically significant with non-conversion and delayed conversion of sputum. This could be due to small number of patients in the study group and differences in regimen whereas in study conducted by Akinsola OJ, et al,^[7] in 413 MDR PTB patients who received longer regimen, median time of culture conversion was more in diabetic than non-diabetic.

Smoking was not statistically significant with non-conversion and delayed conversion of sputum, whereas in a study conducted by Qiao Liu et al,^[13] in 139 MDR patients who received a longer regimen, they found smoking was associated with a reduced rate of culture conversion in univariate and multivariate analysis.

Hypertension was not significantly associated with delayed culture conversion. HIV was not statistically significant with non-conversion and delayed conversion of sputum. This could be due to only one patient in the study group, whereas a study conducted by Agumas Shibabaw et al,^[14] in 234 mono-resistant (RR) or MDR-TB patients receiving a longer regimen, the median time to culture conversion among HIV positive patients was significantly shorter at 67 days.

In our study, previous ATT history was not statistically significant with non-conversion or delayed conversion of sputum when compared to a study conducted by E.V.Kurbatova et al,^[12] in MDR patients receiving a longer regimen, which found that patients had poor outcomes who had been previously treated for TB or MDR-TB. Bilateral chest X-ray involvement was significantly associated with non-culture conversion ($p=0.02$) and delayed culture conversion ($p=0.0009$). Cavitation on chest x-ray was significantly associated with non-culture conversion ($p=0.04$) and delayed culture conversion ($p=0.004$). In a multicentre retrospective study conducted by Temesgen Yihunie Akalu et al,^[15] in 392 MDR patients on a longer MDR regimen found that cavitation delayed the time to sputum culture conversion.

CONCLUSION

From our study, patients with far-advanced disease, bilateral chest x-ray involvement, cavities on chest x-ray, clofazimine resistance, higher sputum grade, and interruption in treatment were associated with poor outcomes in terms of sputum culture conversion. Knowledge of factors known to be associated with non-conversion or delayed culture conversion on shorter regimen may help in early referral of such patients to higher centres and planning measures to take care of such factors.

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