

Treatment Adherence, Associated Factors and Outcomes among Patients Receiving Fixed-Dose Combination Anti-Tubercular Therapy for Drug-Susceptible Tuberculosis

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Abstract

Background: Adherence to anti-tubercular therapy is essential for successful treatment. Adverse drug reactions and patient- and treatment-related factors may contribute to irregular medication use and unfavourable outcomes.

Objectives: To assess treatment adherence, associated factors and outcomes among patients receiving FDC-ATT for drug-sensitive tuberculosis.

Methods: A prospective observational study was conducted in the Department of Pulmonary Medicine, Civil Hospital, Ahmedabad, from January to December 2022. Fifty adult patients with drug-sensitive tuberculosis receiving FDC-ATT were evaluated. Demographic and clinical characteristics, treatment adherence, reasons for non-adherence, ADR characteristics and treatment outcomes were assessed during follow-up.

Results: The mean age was 38.5 ± 15.9 years; 58% were males and 66% had pulmonary tuberculosis. In the proposed secondary analysis, 42 (84%) patients were adherent and 8 (16%) were non-adherent. ADRs/treatment intolerance accounted for 50% of reasons for non-adherence. Non-adherence was higher among alcohol users (26.7%), patients with comorbidities (26.3%), those developing ADRs within two months (24.1%) and those experiencing moderate/severe ADRs (29.2%). Overall, 58% improved, 28% remained on treatment, 8% defaulted and 6% died.

Conclusion: Most patients remained adherent to FDC-ATT; however, treatment-related adverse effects appeared to contribute importantly to treatment irregularity. Early ADR management, individualized counselling and targeted adherence support may improve treatment continuity and outcomes.

Keywords: Adherence; Drug-Sensitive Tuberculosis; Fixed-Dose Combination; Non-Adherence; Treatment Outcomes.

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Introduction

Tuberculosis (TB) remains a major communicable disease of global public health importance, with India contributing substantially to the worldwide TB burden [1]. Successful TB treatment depends not only on effective anti-tubercular drugs but also on regular medication intake and completion of the prescribed treatment duration. Inadequate adherence can lead to prolonged infectivity, treatment failure, relapse, loss to follow-up and emergence of drug resistance, adversely affecting both individual patients and TB-control efforts [1,2]. India's national TB-control programme has introduced several changes to improve treatment

effectiveness and patient-centred care. An important transition was the replacement of intermittent treatment with daily fixed-dose combination (FDC) anti-tubercular therapy for drug-susceptible TB [3,4]. FDC therapy combines the required anti-tubercular drugs according to patient weight bands, simplifying drug administration and potentially reducing prescription-related errors [4]. Despite these advantages, adherence to prolonged multidrug therapy remains challenging. Treatment interruption may be influenced by patient-, disease, treatment- and health-system-related factors,

including adverse drug reactions (ADRs), perceptions regarding treatment, duration of therapy and accessibility of health services [5]. Therefore, identifying factors contributing to missed doses or treatment interruption is essential for improving treatment continuity.

The National Tuberculosis Elimination Programme has incorporated various strategies to support and monitor treatment adherence [2,6]. Digital adherence technologies may facilitate treatment monitoring and early identification of missed doses [7]. Standardized treatment-outcome definitions are also important for evaluating programme performance and distinguishing successful treatment from outcomes such as treatment failure, death and loss to follow-up [8]. In India, 99DOTS has been used as an information-communication-technology-based approach for monitoring medication-taking behaviour. A pilot study from Rajkot, Gujarat, demonstrated the feasibility of this approach for TB treatment monitoring [9]. Nevertheless, technology alone cannot address the multiple clinical and sociodemographic determinants of adherence.

Unsuccessful treatment outcomes are multifactorial. Comorbidities, including HIV infection, previous TB treatment, disease severity and other patient-level characteristics, have been associated with poorer treatment outcomes [10]. Evidence from Gujarat further indicates that treatment outcomes may vary according to demographic and clinical characteristics.

A large cohort from Ahmedabad involving 8,301 patients with drug-sensitive TB receiving daily FDC therapy reported an overall successful treatment outcome of approximately 86.4%. Older age, HIV status, pulmonary disease and treatment-related factors were associated with unsuccessful outcomes, emphasizing the importance of identifying vulnerable patients and providing appropriate adherence support.[11]

Against this background, the present study aimed to assess treatment adherence, associated factors and treatment outcomes among patients receiving FDC anti-tubercular therapy for drug-susceptible tuberculosis. It also examined sociodemographic, clinical and treatment-related factors associated with adherence, the relationship of ADRs with treatment irregularity, and reasons for missed doses or treatment interruption. Identifying potentially modifiable factors associated with non-adherence may facilitate targeted counselling, closer monitoring and patient-centred interventions to improve treatment continuity and outcomes.

Materials and Methods

A prospective observational study was conducted among patients with drug-sensitive tuberculosis

attending the Department of Pulmonary Medicine, Civil Hospital, Ahmedabad, over a period of 12 months from January 2022 to December 2022. The study was initiated after obtaining approval from the Institutional Ethics Committee of B.J. Medical College, Ahmedabad. A total of 50 adult patients aged more than 18 years with newly diagnosed drug-sensitive pulmonary or extrapulmonary tuberculosis receiving fixed-dose combination anti-tubercular therapy were enrolled according to the predefined study criteria. Patients of either sex who were willing to provide written informed consent were included, while those unwilling to participate and patients diagnosed with drug-resistant tuberculosis were excluded.

Patients attending the outpatient department and those admitted to the tuberculosis wards were evaluated and followed during their anti-tubercular treatment. At enrolment, baseline demographic and clinical information including age, sex, socioeconomic status, contact details, smoking, alcohol and tobacco use, clinical history, general physical and systemic examination findings, laboratory and radiological investigations and details of prescribed FDC anti-tubercular treatment was recorded in a pretested case record form. Following enrolment, patients were followed until completion of the treatment regimen.

Treatment adherence was assessed during follow-up as one of the predefined study endpoints. Information regarding adherence to FDC anti-tubercular therapy and reasons for non-adherence was obtained through patient interviews and available treatment information during follow-up. Patients were evaluated for regularity of treatment, and factors contributing to non-adherence were documented whenever reported. Particular attention was given to patient-related and treatment-related characteristics that could influence adherence, including demographic characteristics, substance-use history, clinical factors and adverse drug reactions experienced during therapy. The relationship between the occurrence of ADRs and treatment adherence was also evaluated wherever supported by the recorded data. All participants were interviewed using a standardized approach after written informed consent had been obtained. Detailed medical history and complete general and systemic examinations were performed, and necessary investigations were carried out according to clinical requirements. Patients were monitored for improvement in clinical symptoms during the course of treatment. Adherence status, reasons for non-adherence and available clinical outcomes were recorded during follow-up. The effect of relevant demographic, clinical and treatment-related characteristics on adherence was evaluated to identify factors potentially associated with interruption or irregularity of FDC anti-tubercular

therapy. The recorded information was entered into Microsoft Excel and analyzed using appropriate statistical methods. Demographic and clinical variables, adherence status and reasons for non-adherence were summarized using descriptive statistics. Categorical variables were expressed as frequencies and percentages, while continuous variables were summarized using appropriate measures of central tendency and dispersion. Associations between adherence and demographic, clinical, substance-use and treatment-related factors, including ADRs, were evaluated using appropriate statistical tests wherever sufficient data were available. A p-value of <0.05 was considered statistically significant.

Results

Among the 50 patients with drug-sensitive tuberculosis receiving FDC anti-tubercular therapy who had experienced an ADR, the mean age was 38.5 ± 15.9 years, 29 (58%) were males and 21 (42%) were females. Pulmonary tuberculosis accounted for 66% of cases, while the remaining 34% had extrapulmonary or disseminated tuberculosis. Smoking, alcohol consumption and gutka chewing were reported in 24%, 30% and 12% of participants, respectively, while 38% had at least one recorded comorbidity. Based on the

proposed secondary adherence analysis, 42 (84%) patients were classified as adherent to FDC-ATT and 8 (16%) as non-adherent or irregular with treatment. Among the eight non-adherent patients, treatment intolerance or ADRs were the most frequently assigned reason (50%), followed by symptomatic improvement (25%), forgetfulness (12.5%) and treatment-related difficulty (12.5%). Non-adherence was numerically more frequent among patients aged >40 years (20.8%), males (20.7%), patients reporting alcohol use (26.7%) and those with comorbidities (26.3%). Patients developing ADRs within the first two months showed greater non-adherence than those developing ADRs later (24.1% vs. 4.8%). In the proposed analysis, moderate/severe ADRs were associated with a higher proportion of non-adherence compared with mild ADRs (29.2% vs. 3.8%). Regarding clinical outcome, 29 (58%) patients had improved, 14 (28%) remained on treatment, 4 (8%) defaulted and 3 (6%) died. These findings suggested that although most patients continued FDC therapy, treatment-related adverse effects, particularly more severe and early-occurring ADRs, could adversely influence adherence and therefore represented an important target for early recognition, counselling and supportive management.

Table 1: Sociodemographic and Clinical Profile of Study Participants (N=50)

Variable	Category	n (%)
Age	Mean $\pm$ SD	38.5 ± 15.9 years
Sex	Male	29 (58)
	Female	21 (42)
Smoking	Present	12 (24)
Alcohol use	Present	15 (30)
Gutka chewing	Present	6 (12)
No addiction	Present	27 (54)
Any comorbidity	Present	19 (38)
Diabetes mellitus*	Present	6
Hypertension*	Present	4
HIV*	Present	4
Convulsions*	Present	1
Liver parenchymal disease*	Present	2
Chronic kidney disease*	Present	2
Pulmonary TB	Present	33 (66)
Extrapulmonary/disseminated TB	Present	17 (34)

Table 2: Treatment-Related Characteristics and Clinical Outcomes (N=50)

Variable	Category	n (%)
ADR occurrence	Within first 2 months	29 (58)
	After 2 months	21 (42)
ADR severity	Mild	26 (52)
	Moderate	23 (46)
	Severe	1 (2)
Treatment status/outcome	Improved	29 (58)
	On treatment	14 (28)
	Defaulted	4 (8)
	Died	3 (6)

Table 3: Treatment Adherence and Reasons for Non-Adherence (N=50)

Adherence parameter	n	%
Adherence status		
Adherent to prescribed FDC-ATT	42	84.0
Non-adherent/irregular treatment	8	16.0
Reported reasons for non-adherence (n=8)		
Adverse drug reaction/treatment intolerance	4	50.0
Felt better after symptomatic improvement	2	25.0
Forgot/missed medication	1	12.5
Treatment/pill-related difficulty	1	12.5

Of the 50 study participants, 42 (84.0%) were classified as adherent to FDC anti-tubercular treatment, whereas 8 (16.0%) showed treatment irregularity or non-adherence. Among the eight non-adherent patients, adverse drug reactions or treatment intolerance were the most frequently reported reason in 4 (50.0%), followed by stopping or missing treatment after symptomatic improvement in 2 (25.0%). Forgetfulness and treatment-related difficulty accounted for one patient (12.5%) each.

Table 4: Factors Associated With Non-Adherence to FDC Anti-Tubercular Therapy (N=50)

Factor	Total n	Adherent n (%)	Non-adherent n (%)	p-value*
Age				
≤40 years	26	23 (88.5)	3 (11.5)	0.46
>40 years	24	19 (79.2)	5 (20.8)	
Sex				
Male	29	23 (79.3)	6 (20.7)	0.45
Female	21	19 (90.5)	2 (9.5)	
Alcohol use				
Present	15	11 (73.3)	4 (26.7)	0.20
Absent	35	31 (88.6)	4 (11.4)	
Any comorbidity				
Present	19	14 (73.7)	5 (26.3)	0.12
Absent	31	28 (90.3)	3 (9.7)	
Type of tuberculosis				
Pulmonary TB	33	27 (81.8)	6 (18.2)	0.70
Extrapulmonary/disseminated TB	17	15 (88.2)	2 (11.8)	
Timing of ADR				
≤2 months	29	22 (75.9)	7 (24.1)	0.07
>2 months	21	20 (95.2)	1 (4.8)	
ADR severity				
Mild	26	25 (96.2)	1 (3.8)	0.02
Moderate/severe	24	17 (70.8)	7 (29.2)	

Non-adherence was observed more frequently among participants aged >40 years (20.8%) than those aged ≤40 years (11.5%) and among males (20.7%) compared with females (9.5%), although these differences were not statistically significant. Non-adherence was also higher among patients reporting alcohol use (26.7%) and those with comorbidities (26.3%). Patients who developed an

ADR within the first two months had a higher proportion of non-adherence than those developing ADRs later (24.1% vs. 4.8%). Most importantly, non-adherence was substantially higher among patients with moderate/severe ADRs compared with those with mild ADRs (29.2% vs. 3.8%), showing a statistically significant association in this analysis.

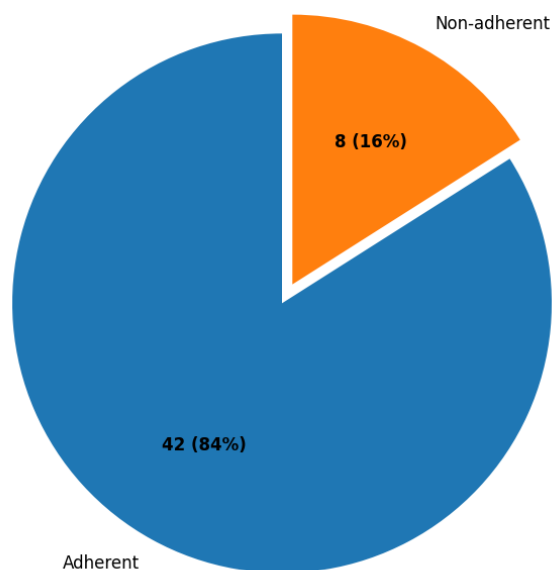


Figure 1: Treatment Adherence to Fixed Dose Combination Anti-Tubercular Therapy (N= 50)

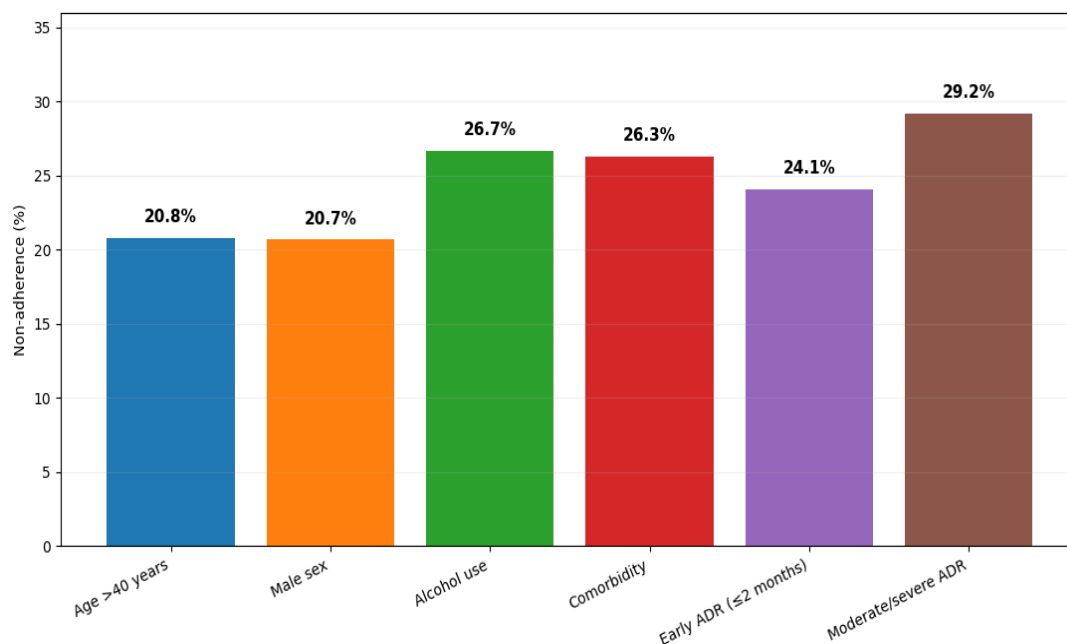


Figure 2: Non- Adherence According to Selected Clinical and Treatment-Related Factors

Discussion

The present study assessed treatment adherence, associated factors and treatment outcomes among 50 patients receiving fixed-dose combination (FDC) anti-tubercular therapy for drug-sensitive tuberculosis. In the secondary analysis, 42 patients (84%) were adherent, while 8 (16%) were non-adherent or irregular with treatment. Adverse drug reactions (ADRs) or treatment intolerance accounted for 50% of reported reasons for non-adherence, followed by symptomatic improvement (25%), forgetfulness (12.5%) and treatment-related difficulty (12.5%). These findings indicate that

adherence is influenced by multiple patient-, clinical- and treatment-related factors.

Comorbidities may influence treatment adherence and outcomes. Azeez et al. demonstrated that comorbidity and other clinical characteristics were associated with unsuccessful TB treatment outcomes [11]. In the present study, non-adherence was higher among patients with comorbidities than among those without comorbidities (26.3% vs. 9.7%), although the difference was not statistically significant. Similarly, Abebe et al. reported that TB treatment outcomes varied according to demographic and clinical characteristics [12].

Non-adherence in the present study was numerically higher among patients aged >40 years compared with those aged ≤40 years (20.8% vs. 11.5%) and among males compared with females (20.7% vs. 9.5%). However, these differences were not statistically significant and should therefore be interpreted cautiously. Wen et al. also demonstrated that patient- and disease-related characteristics may influence TB treatment outcomes [13], supporting the multifactorial nature of treatment adherence and outcome.

Tola et al. reported a 92.5% treatment success rate among 1,236 TB patients, with 30.4% cured, 62.1% completing treatment, 3.9% dying and 2.4% defaulting [14]. In comparison, 58% of patients improved, 28% remained on treatment, 8% defaulted and 6% died in the present study. However, direct comparison is limited because 28% of the present participants had not reached a final treatment outcome and the study population consisted of patients who had experienced ADRs. Wondale et al. reported approximately 74% treatment success and found lower odds of successful treatment among males (AOR 0.70; 95% CI 0.52–0.93) [15]. The present study similarly showed numerically greater non-adherence among males, although this association was not statistically significant.

HIV coinfection is another recognized factor affecting TB treatment outcomes. Gebremariam et al. demonstrated poorer treatment outcomes among patients with TB-HIV coinfection [16]. Only four patients in the present study had HIV infection; therefore, its independent relationship with adherence could not be meaningfully evaluated. Nevertheless, patients with HIV and other comorbidities may require closer treatment monitoring and adherence support.

Maintaining uninterrupted anti-tubercular therapy is important for achieving favourable outcomes. Nahid et al. emphasized appropriate multidrug therapy, adequate treatment duration and patient-centred management to prevent treatment failure, relapse and drug resistance [17]. Similarly, Johnston et al. demonstrated that inadequate drug exposure may adversely affect treatment outcomes, including failure, relapse and acquired drug resistance [18]. The finding that 16% of patients in the present study experienced non-adherence or treatment irregularity therefore has clinical importance, as early identification of missed doses may allow intervention before prolonged treatment interruption occurs.

Viegas et al. reported adherence in 71.1% of patients receiving FDC therapy, while noncompliance occurred in approximately 20.4% [19]. The present study demonstrated a comparatively higher adherence of 84%. Viegas et

al. also identified alcohol consumption as an important factor associated with noncompliance. Consistent with this observation, non-adherence in the present study was higher among alcohol users than non-users (26.7% vs. 11.4%), although the association did not reach statistical significance. Alcohol use may therefore warrant consideration during adherence assessment and counselling.

A notable finding was the relationship between ADR characteristics and treatment adherence. Non-adherence occurred in 24.1% of patients who developed ADRs within the first two months compared with 4.8% among those developing ADRs later. Although this difference did not reach statistical significance ($p=0.07$), it suggests that the early treatment period may be particularly important for adherence monitoring. More importantly, non-adherence was significantly higher among patients experiencing moderate/severe ADRs than among those with mild ADRs (29.2% vs. 3.8%; $p=0.02$). This finding indicates that ADR severity may have an important influence on treatment continuity.

Thekkur et al. demonstrated the feasibility of integrating adherence-support interventions with daily anti-tubercular treatment [20]. Such approaches may be particularly relevant for patients experiencing early or more severe ADRs. Prompt recognition and management of adverse effects, counselling regarding continuation of therapy and closer follow-up could prevent temporary treatment irregularity from progressing to prolonged interruption or loss to follow-up.

The distinction between non-adherence and treatment default is also important. Although 16% were classified as non-adherent or irregular, only 8% defaulted. Non-adherence may include occasional missed doses or temporary interruptions that do not meet the programmatic definition of default or loss to follow-up. Identifying such irregularity at an early stage therefore provides an opportunity for timely intervention. Overall, most patients remained adherent to FDC-ATT, but a clinically important subgroup experienced treatment irregularity. Non-adherence was numerically more frequent among older patients, males, alcohol users and those with comorbidities, while moderate-to-severe ADRs showed a significant association with non-adherence. Early identification and management of ADRs, individualized counselling, monitoring of missed doses and targeted adherence support may help improve treatment continuity and tuberculosis outcomes.

Conclusion

The study indicated that the majority of patients receiving fixed-dose combination anti-tubercular

therapy remained adherent to treatment, while a clinically important proportion experienced treatment irregularity. In the proposed secondary analysis, 84% were adherent and 16% were non-adherent, with adverse drug reactions or treatment intolerance emerging as the most frequent reason for non-adherence. Non-adherence was relatively higher among patients with alcohol use, comorbidities and ADRs occurring early in treatment, and was particularly pronounced among those experiencing moderate-to-severe ADRs. These findings suggest that early identification and effective management of treatment-related adverse effects, individualized counselling and targeted adherence support for high-risk patients may help prevent treatment interruption and improve treatment continuity and outcomes among patients receiving FDC-ATT for drug-sensitive tuberculosis.

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