



Monaldi Archives for Chest Disease

elSSN 2532-5264

https://www.monaldi-archives.org/

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Monaldi Arch Chest Dis 2025 [Online ahead of print]

To cite this Article:

Nyamagoud SB, Dsouza PD, Chitralu SPP, et al. **Impact of patient counseling on medication adherence and drug resistance patterns in tuberculosis patients**. *Monaldi Arch Chest Dis* doi: 10.4081/monaldi.2025.3434

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## Impact of patient counseling on medication adherence and drug resistance patterns in tuberculosis patients

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**Contributions**: all authors contributed equally to the study's conception, literature review, manuscript preparation, and revisions. The final version of the manuscript was thoroughly reviewed and approved by all authors, who collectively assume full responsibility for its accuracy and integrity.

**Conflict of interest**: the authors declare no conflicts of interest.

**Ethics approval and consent to participate**: the study's objectives were clearly explained to all participants and their families to ensure informed decision-making. Ethical approval was granted by the KLE College of Pharmacy Ethical Committee (IEC Reference Number: KLECOPH/IEC/2023-24/08).

**Informed consent**: written informed consent was obtained from each participant before enrollment.

**Patient consent for publication**: written informed consent was obtained from the patients for publication of this original article.

Availability of data and materials: all relevant data generated or analyzed during this study are included in this published article.

**Funding**: this research did not receive funding from any public, commercial, or not-for-profit organizations.

**Acknowledgments**: the authors extend their sincere gratitude to the KLE Academy of Higher Education and Research, Belagavi, as well as the patients, physicians, and hospital staff of Vivekanand General Hospital, Hubballi, for their invaluable support and cooperation. Their contributions were instrumental in the successful completion of this study.

### Abstract

Tuberculosis (TB) remains a primary global health concern, with non-adherence to anti-TB therapy contributing to prolonged infectiousness, treatment failure, and unfavorable outcomes. Despite established treatment protocols, adherence remains suboptimal due to patient-related, healthcare system, and socioeconomic barriers. This study aimed to identify key factors contributing to non-adherence and to evaluate the impact of structured patient counselling on treatment adherence. A cross-sectional observational study was conducted at Vivekananda General Hospital, Hubballi, India, involving 80 hospitalized TB patients. Data collection included demographic details and medication adherence scores, measured before and one month after counseling using the Medication Adherence Report Scale. Statistical analysis was performed using SPSS version 27.0, with Pearson's correlation applied to assess changes in adherence. The mean adherence scores significantly increased from 4.24±1.452 to 7.05±1.525 following counseling (p=0.006). The most commonly reported barriers to adherence included forgetfulness (62.5%), limited access to healthcare (50%), and poor communication with healthcare providers (47.75%). These findings highlight the effectiveness of structured counseling in improving adherence among TB patients. Addressing both individual and systemic barriers through targeted counseling interventions should be considered an integral component of TB care strategies.

**Key words:** tuberculosis, adherence, counselling, patient education, non-adherence, treatment outcomes.

#### Introduction

Tuberculosis (TB) remains a persistent global health concern, causing substantial morbidity and mortality, especially in low- and middle-income countries with high disease burdens [1]. Although anti-tubercular therapy (ATT) is effective when taken appropriately, non-adherence to treatment continues to compromise TB control efforts [2]. Poor adherence contributes to prolonged infectiousness, increased risk of relapse, and unfavorable treatment outcomes [3]. The World Health Organization (WHO) highlights that consistent adherence is essential for treatment success and preventing the spread of infection [4].

Multiple interrelated factors contribute to non-adherence. Patient-related factors such as forgetfulness, lack of awareness, stigma, fear of side effects, and cultural beliefs can influence treatment behaviour [5,6]. Healthcare system barriers like long wait times, inadequate patient-provider communication, and lack of follow-up can further discourage patients from completing therapy [7]. Socioeconomic constraints, including travel costs, wage loss, and limited access to healthcare services, also significantly impact adherence [8,9].

Despite the implementation of structured programs like Directly Observed Treatment, and Short-Course (DOTS), adherence remains suboptimal in many settings, indicating the need for supportive, patient-centered interventions [10]. Among such interventions, patient counselling has shown promise in enhancing treatment adherence. Counselling helps patients understand their disease, manage medication side effects, and recognize the importance of completing treatment, while also addressing psychological and social challenges [2,11,12].

Effective counselling fosters a trusting relationship between patients and healthcare providers, which can improve communication, dispel misconceptions, and reduce anxiety associated with treatment [13]. It is particularly valuable in low-resource settings, where barriers to adherence are multifactorial and individualized support is often lacking [14].

This study identifies key factors contributing to non-adherence and evaluates the effect of structured counselling on medication adherence among TB patients. By understanding these challenges and evaluating counselling as an intervention, the study seeks to inform the development of targeted, evidence-based strategies for improving TB treatment outcomes [15].

## Materials and Methods

## Study design

A cross-sectional observational study was conducted over six months from August 2024 to January 2025. A preliminary pilot study was carried out to determine the appropriate sample size. The final analysis included 80 inpatients diagnosed with tuberculosis and admitted to the TB ward of Vivekananda General Hospital (VGH), Hubballi, Karnataka, India.

## Study setting

The study was conducted in the Department of Tuberculosis at Vivekananda General Hospital, a tertiary care center in Hubballi, Karnataka.

## Study population

A total of 80 patients undergoing treatment for TB at VGH were included.

## Inclusion criteria

Patients aged 18 years and above, with a confirmed diagnosis of tuberculosis (pulmonary or extrapulmonary), receiving first-line anti-TB therapy, and with controlled comorbid conditions such as diabetes or hypertension. Patients with relapse after completing prior TB treatment were also eligible.

## Exclusion criteria

Patients from the outpatient department, those unwilling to provide informed consent, pregnant or lactating women, individuals with severe immunosuppressive conditions, active malignancies, or end-stage organ failure were excluded.

## Patient counselling

Structured, individualized counselling sessions were provided to each participant by trained healthcare professionals. The counselling focused on the importance of medication adherence, potential side effects, the need for consistent treatment, and managing psychosocial barriers. The sessions also aimed to clarify misconceptions, encourage communication, and improve patient motivation. A follow-up evaluation was conducted one month after the initial counselling session to assess changes in adherence.

## Data collection

Data included demographic details and medication adherence scores, measured using the Medication Adherence Report Scale (MARS-5) both before and one month after the counselling intervention.

## MARS-5 scale

The MARS-5 is a self-reported, validated tool that evaluates medication adherence using five items rated on a Likert scale. Scores range from 0 to 10, with scores below 6 indicating poor adherence and scores above 6 indicating good adherence. This scale was used to compare adherence pre- and post-counselling.

### Sample size calculation

The sample size was calculated based on the formula:

$$n = \frac{[Z_{1-\alpha_{/2}}]^2 p(1-p)}{d^2}$$

Where:

Z = 1.96 (for 95% confidence level)p = 0.5 (assumed proportion for maximum sample size) d = 0.11 (margin of error)  $\alpha = 0.05 \text{ (significance level)}$ 

Using these values, the estimated sample size was approximately 80 participants.

#### Statistical analysis

Data were analyzed using IBM SPSS Statistics version 27.0. Descriptive statistics were used for demographic and baseline variables. The effect of counselling on adherence was assessed using Pearson's correlation test to compare pre- and post-counselling MARS-5 scores. A p-value of <0.05 was considered statistically significant.

#### Results

#### Clinical profile of study participants

The demographic and clinical profiles of the 80 enrolled TB patients are detailed in Table 1. A higher proportion of females (58.75%) was observed compared to males (41.25%). The most common age group was 61–70 years (18.75%), followed closely by participants in the 21–30, 41–50, and 51–60-year age brackets, each comprising 17.5% of the sample. A significant majority of participants were rural residents (75%), and over half belonged to below-poverty-line (BPL) households (58.75%), while 26.25% were from above-poverty-line (APL) households and 15% from other income categories. Pulmonary TB (PTB) was the most frequently diagnosed form (42.5%), followed by old PTB (26.25%), miliary TB (12.5%), MDR TB (10%), and meningeal TB (8.75%). Comorbidities were present in the majority of patients, with hypertension (20%), anemia (16.25%), pneumonia (12.5%), lower respiratory tract infections (11.25%), and type 2 diabetes mellitus (11.25%) being most common; 8.75% of patients had no comorbidities. Treatment duration varied, with half (50%) of the patients receiving therapy for 12–24 months. The remaining patients were undergoing treatment for less than 3 months (6.25%), 3–6 months (7.5%), or more than 24 months (18.75%) (Table 1).

#### Impact of counselling on medication adherence in tuberculosis patients

The impact of counselling on medication adherence was evaluated using MARS-5 scores before and after counselling. The average adherence score improved markedly, rising from  $4.24 \pm 1.452$  before counselling to  $7.05 \pm 1.525$  post-counselling. Pearson's correlation analysis demonstrated a weak to moderately positive relationship (r = 0.303) between pre- and post-counselling scores, with the change being statistically significant (p = 0.006). This suggests that patient counselling significantly enhanced medication adherence among TB patients, despite variability in baseline adherence levels (Table 2).

#### Factors contributing to non-adherence in tuberculosis patients

Non-adherence factors were categorized into three domains: patient-related, healthcare system-related, and socioeconomic. Patient-related factors were most prevalent and reported by 75.75% (n=62) of patients, including forgetfulness, adverse drug effects, stigma, and personal or cultural beliefs. Healthcare system-related challenges were cited by 60% (n=48), involving regimen complexity, difficulty accessing care, and poor communication with healthcare providers. Socioeconomic barriers, particularly financial limitations, were reported by 27.5% (n=22). Specific causes of non-adherence included forgetting to take medications (62.5%, n=50), inability to obtain medications (50%, n=40), poor communication with providers (47.75%, n=38), regimen complexity (42.5%, n=34), perception of unnecessary treatment (31.25%, n=25), financial constraints (27.5%, n=22), adverse effects (15%, n=12), and cultural or religious stigma (10%, n=8) (Table 3).

#### Analysis of drug resistance patterns in tuberculosis patients

Drug resistance analysis revealed Isoniazid resistance in over half of the patients (52.5%, n=42), making it the most affected first-line drug. Ethambutol resistance followed at 43.75% (n=35), with Rifampicin resistance—critical in the context of MDR TB—seen in 32.5% (n=26). Pyrazinamide resistance was detected in 22.5% (n=18), and Amikacin resistance, a second-line injectable agent, in 15% (n=12). Ofloxacin, a fluoroquinolone used in resistant TB cases, showed the lowest resistance at 7.5% (n=6). These findings underscore the importance of early drug susceptibility testing and the need for personalized treatment protocols (Table 4).

#### Graphical representation of non-adherence factors

The contributing factors to non-adherence are graphically represented in Figure 1. The most common reason was forgetfulness (62.5%), followed by medication access issues (50%), inadequate communication with providers (47.75%), and regimen complexity (42.5%). Other significant causes included the belief that medication was unnecessary (31.25%), financial

barriers (27.5%), side effects (15%), and cultural or religious stigma (10%). These insights emphasize the need for improved patient-provider interactions, access facilitation, and robust patient education programs (Figure 1).

#### Patterns of drug resistance in tuberculosis patients

In terms of drug resistance classification, single-drug resistance was the most commonly observed pattern, affecting 16.25% (n=13) of patients. Triple drug resistance was documented in 20% (n=16), highlighting resistance to three anti-TB agents. Multi-drug-resistant TB (MDR-TB), defined by resistance to both Isoniazid and Rifampicin, was identified in 10% (n=8). Dual drug resistance was found in 6.25% (n=5) of patients. These findings reinforce the urgent need for early identification and individualized management strategies for drug-resistant TB cases (Figure 2).

#### Discussion

This study aimed to evaluate the impact of structured patient counselling on medication adherence in tuberculosis (TB) patients, along with an assessment of their demographic and clinical characteristics. The findings reveal that non-adherence remains a significant challenge in TB management, especially among socioeconomically disadvantaged populations.

The demographic data indicated that a majority of patients were female (58.75%), residing in rural areas (75%), and classified as below the poverty line (58.75%). These findings are consistent with existing literature that highlights the disproportionate TB burden among economically and socially vulnerable populations, where limited healthcare access and financial constraints often compromise adherence and treatment outcomes [16].

The most noteworthy finding of the study was the significant improvement in medication adherence following counselling. The mean adherence score increased from  $4.24 \pm 1.452$  before counselling to  $7.05 \pm 1.525$  post-counselling, with a statistically significant p-value of 0.006. The weak to moderate positive correlation (r = 0.303) between pre- and post-counselling scores suggests that counselling had a positive impact, although other variables may also influence adherence. These results are supported by prior studies, which demonstrated that structured counselling improves knowledge, corrects misconceptions, reduces fear of side effects, and encourages continued medication use—all of which are essential for successful TB treatment [17].

The study also examined the various factors contributing to non-adherence, which were grouped into patient-related (e.g., forgetfulness, stigma, perceived lack of necessity), healthcare system-related (e.g., poor communication with providers, regimen complexity), and socioeconomic factors (e.g., cost, accessibility). These categories reflect the multifactorial

nature of non-adherence, a pattern consistently reported in TB adherence literature. For instance, a systematic review emphasized the importance of addressing these overlapping barriers through patient-centered care models that integrate psychosocial support and healthcare access improvements [18]. Similarly, a study conducted in Kerala underscored the significance of individualized interventions tailored to both patient needs and healthcare system capabilities [19].

The present findings highlight the critical role of counselling in improving adherence, particularly when delivered in a structured, empathetic, and accessible manner [20]. Incorporating regular counselling sessions into routine TB care, especially in high-burden, resource-limited settings could meaningfully enhance adherence and improve treatment outcomes [21].

## Limitations

Despite the encouraging findings, this study has several limitations. First, it was conducted at a single center with a relatively small sample size, which may limit the generalizability of the results. Second, the follow-up period was restricted to one month post-intervention, precluding assessment of the long-term sustainability of the counselling effect. Adherence levels may diminish over time due to treatment fatigue, emerging barriers, or changing personal circumstances.

Third, the study did not explore the psychological, environmental, or broader health system factors that may influence adherence, thereby limiting a more comprehensive understanding of adherence challenges. Additionally, potential selection bias cannot be excluded, as participants who consented to the study may have been inherently more motivated than the general TB population. Finally, the use of the self-reported MARS-5 adherence scale introduces the possibility of reporting bias, which could have influenced the accuracy of adherence measurements.

## Conclusions

This study highlights the effectiveness of structured counselling in significantly improving medication adherence among tuberculosis patients. By addressing both patient-level and healthcare system-related barriers, counselling serves as a valuable tool in bridging critical gaps in TB care. Integrating patient-centred counselling and engagement strategies into routine treatment protocols may enhance therapeutic outcomes and reduce the risk of drug resistance. Future research should focus on multi-center studies with larger sample sizes and extended follow-up periods to evaluate the long-term impact of counselling and to explore additional factors that influence adherence.

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SI. No	Categories	Frequency (N)		
1	Gender			
	Male	33	41.25	
	Female	47	58.75	
2	Age			
	20	6	7.5	
	21-30	14	17.5	
	31-40	12	15	
	41-50	14	17.5	
	51-60	14	17.5	
	61-70	15	18.75	
	71	5	6.25	
3	Residence			
	Rural	60	75	
	Urban	20	25	
4	Income	1	1	
	APL	21	26.25	
	Others	12	15	
	BPL	47	58.75	
5	Diagnosis			
	MDR TB	8	10	
	Meningeal TB	7	8.75	
	Miliary TB	10	12.5	
	Old PTB	21	26.25	
	РТВ	34	42.5	
6	Comorbidities			
	2° infection	8	10	
	Anemia	13	16.25	
	Anemia with type 2 DM	3	3.75	
	HTN	16	20	
	LRTI	9	11.25	
	No comorbidities	7	8.75	
	Pneumonia	10	12.5	
	Type 2 DM	9	11.25	
	URTI	5	6.25	
7	Treatment duration			
	Less than 3 months	5	6.25	
	3-6 months	6	7.5	
	6-12 months	14	17.5	
	12-24 months	40	50	
	24 months and above	15	18.75	

Table 1. Study participants clinical and demographic features.

# Table 2. Impact of counseling on TB patients.

Sl.no	Medication adherence	Mean ± SD	р
1	Pre counselling	4.24±1.452	0.006*
2	Post counseling	7.05±1.525	0.000

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\*statistically significant p<0.05.

Reason	Frequency(n)	Percentage (%)
	Trequency(II)	Fercentage (70)
Patient-related (forgetfulness, side effects, cultural /	62	75.75
religious beliefs, or social stigma)	02	/ 3./ 3
Healthcare system-related (complexity of regimen,		
access issues, poor communication with healthcare	48	60.00
providers)		
Socioeconomic factors (cost)	22	27.5

## Table 3. Factors contributing to non-adherence and their frequency distribution.

#### Table 4. Drug resistance in TB patients.

Drugs	Frequency (n)	Percentage (%)	
Isoniazid	42	52.5	
Rifampicin	26	32.5	
Ethambutol	35	43.75	
Amikacin	12	15	
Pyrazinamide	18	22.5	
Ofloxacin	6	7.5	



Figure 1. Multiple reasons for non-adherence to TB drugs.



Figure 2. Type of drug resistance in TB patients.