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Original Article

Factors Associated with Treatment Compliance of Extrapulmonary Tuberculosis Patients at the End of Intensive Phase

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Abstract

Introduction: *Tuberculosis (TB) remains a global health threat, with extrapulmonary tuberculosis (EPTB) posing particular challenges in diagnosis and treatment compliance. This study investigated factors affecting compliance among EPTB patients in Bangladesh, with a focus on those receiving treatment under the Directly Observed Treatment, Short-course (DOTS) strategy.*

Methodology: *A cross-sectional study was conducted, collecting data from 209 individuals with EPTB using a semi-structured questionnaire at 12 DOTS centers in the Dhaka division. Patients aged 18 and older, regardless of gender, with EPTB were included. Those who were being re-treated or had serious illnesses like human immunodeficiency virus (HIV), chronic kidney disease, stroke, cancer, or cardiovascular disease (CVD) were excluded. Treatment compliance was measured by adherence to prescribed treatment, including the avoidance of missing doses, at the end of the intensive phase. Those who complied with treatment were compared with those who did not comply.*

Results: *Of 209 respondents, the level of treatment compliance to EPTB treatment was 96% and cervical lymph node was found to be affected mostly (30%) by tuberculosis. Mean age, age group, belief about death that can result if not treated, and satisfaction from counseling by healthcare providers were significantly associated with treatment compliance ($p < 0.05$). On binary logistic regression analysis, joint family type (AOR = 65.802; 95%CI:.58-1865.504) was independently associated with treatment compliance.*

Conclusion: *The compliance among the extrapulmonary tuberculosis patients attending DOTS centers was 96%. The study found that mean age, age group, belief about EPTB that can result in death if not treated, satisfaction with counseling from the health care provider were associated with treatment compliance with anti-TB treatment among people with EPTB.*

Keywords: *DOTS, Compliance, EPTB, Tuberculosis.*

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Introduction

Despite substantial advances in diagnosis, treatment, and preventive measures over the past ten years, tuberculosis (TB) continues to be the leading cause of death from infectious diseases globally. The Mycobacterium tuberculosis complex (M. tuberculosis) of bacteria is the primary cause of this fatal infectious disease. The World Health Organization (WHO) estimates that 10 million new cases of tuberculosis were diagnosed globally in 2019, with an estimated 1.5 million deaths.[1] Depending on the site of infection and clinical manifestations, all forms of tuberculosis have an annual incidence rate of 221 per 100,000 people. TB can be classified as either pulmonary TB (PTB) or extrapulmonary TB (EPTB).[2]

South Asian countries with high TB incidence and prevalence include Pakistan, Afghanistan, India, and Bangladesh. For example; 3.4 million new cases of tuberculosis are reported annually throughout the continent, representing a 39% of global incidence rate.[3] Moreover, the prevalence of EPTB varies from 19% to 23% in South Asia with a predominance of females.[4] Prevention of the spread of EPTB in South Asia has been hindered by socioeconomic inequalities, poor healthcare systems, high illiteracy rates, and persistent economic challenges.[5]

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In Bangladesh, the scenario is also similar. In 2021, 221 cases of tuberculosis were anticipated per 100,000 people. A total of 307,561 cases were reported, accounting for 82% of all incidence cases. In 2020, 42,193 cases of extrapulmonary tuberculosis were reported. For patients with extrapulmonary tuberculosis, the treatment success rate was 91.65%. Throughout the course of medical treatment, 1,530 extra-pulmonary cases (3.63%) had died. Within the age group of five to forty-four, there were more female extrapulmonary tuberculosis cases than male cases. Furthermore, there were fewer male cases than female cases in all other age groups.[5]

However, EPTB receives less attention than pulmonary tuberculosis due to its relatively low infectious potential. However, because of challenges in diagnosing it and its tendency to end up in high rates of morbidity and mortality, it is regarded as a serious clinical concern.[7,8] Therefore, it's critical to assess treatment compliance to ensure reliable and efficient disease management. It remains unclear what constitutes satisfactory compliance with EPTB treatment.[9] Therefore, to achieve the government's goal of zero TB by 2035, special attention to controlling EPTB is also needed. This study aims to identify factors associated with treatment compliance among EPTB patients taking anti-tubercular drugs in Bangladesh.

Adhering to long-term therapies is a complex issue influenced by five sets of factors: social and economic factors, health care team and system-related factors, condition-related factors, therapy-related factors, and patient-related factors.[10] Factors that contribute to non-compliance in tuberculosis treatment include healthcare system issues, therapy-related issues, social and economic challenges, and client-related factors. In a study by Kandel, Mfenyana, Chandia, and Yogeswaran, researchers identified three primary reasons for non-compliance with TB treatment: poor communication between healthcare providers and patients, financial difficulties that limit access to healthcare facilities, and a lack of nutritious food necessary for effective TB treatment.[11] The National Institute of Health identifies illiteracy as a key reason for non-compliance with TB treatment, as patients may not fully understand written instructions about their treatment.[12] Other researchers suggest that TB may not be cured entirely through standard medical treatment, leading some patients to choose alternative methods.[13] The National Institute of Health report also indicates that substance abuse, being home-bound, stigma, and lack of trust in Western medicine are significant factors causing non-compliance with TB treatment.[13] According to McKinney, a straightforward approach should be taken to encourage compliance with TB treatment. This approach should include access to treatment, education on the importance of adhering to the treatment plan, and provision of convenient services that are culturally acceptable to patients.[14]

Materials & Methods

Study design

This cross-sectional study was conducted over one year from January 2023 to December 2023. It included individuals with EPTB who underwent treatment at selected DOTS centers for at least two months during this study period. The study was approved by the Institutional Review Board (IRB) of Bangabandhu Sheikh Mujib Medical University (Memo No. BSMMU/2023/9841, Date:19-07-2023).

Inclusion and exclusion criteria

Patients aged 18 and above, both male and female, with EPTB were included. Those having re-treatment and serious illness such as human immunodeficiency virus (HIV), chronic kidney disease, stroke, cancer, or cardiovascular disease (CVD), etc. were excluded were excluded.

Sample size determination and sampling procedure

The formula n= z2. [p*q]/d2 was used to calculate the sample size, where p is the proportion of compliance among tuberculosis patients attending DOTS regimen, q is 1-p, and d is the margin of error. As per[15] the proportion of compliance among tuberculosis patients attending DOTS regimen at 84% and considering an absolute error of 5%, the sample size came out as 206. A non-response rate of 10% was taken and the final sample size was 229. Due to time constrains, we were able to collect data from 209 people with EPTB. Enrolment of the patients was done using consecutive sampling until a sample size of 209 was achieved.

Study variables

Data was collected using a semi-structured questionnaire that included questions about the socio-demographic factors, patient related factors, socio-cultural factors and service provider related factors. Compliance for participants who had a history of EPTB and experience of EPTB treatment for at least two months and did not miss any dose of the DOTS regimen. The questionnaire was first prepared in English and then translated into Bangla. To assess the uniformity of responses and the clarity of the questions, the questionnaire was pretested. No modifications were needed before pretesting.

Operational definitions

Extrapulmonary tuberculosis:

According to the WHO, EPTB refers to any bacteriologically confirmed or clinically diagnosed case of TB involving organs other than the lungs, such as the pleura, lymph nodes, abdomen, genitourinary tract, skin, joints, and bones, as well as the meninges (NTP Annual Report, 2022).

Compliant patients: Compliant patients were termed participants who had a history of EPTB and experience of

EPTB treatment for at least two months and did not miss any dose of the DOTS regimen in this period.

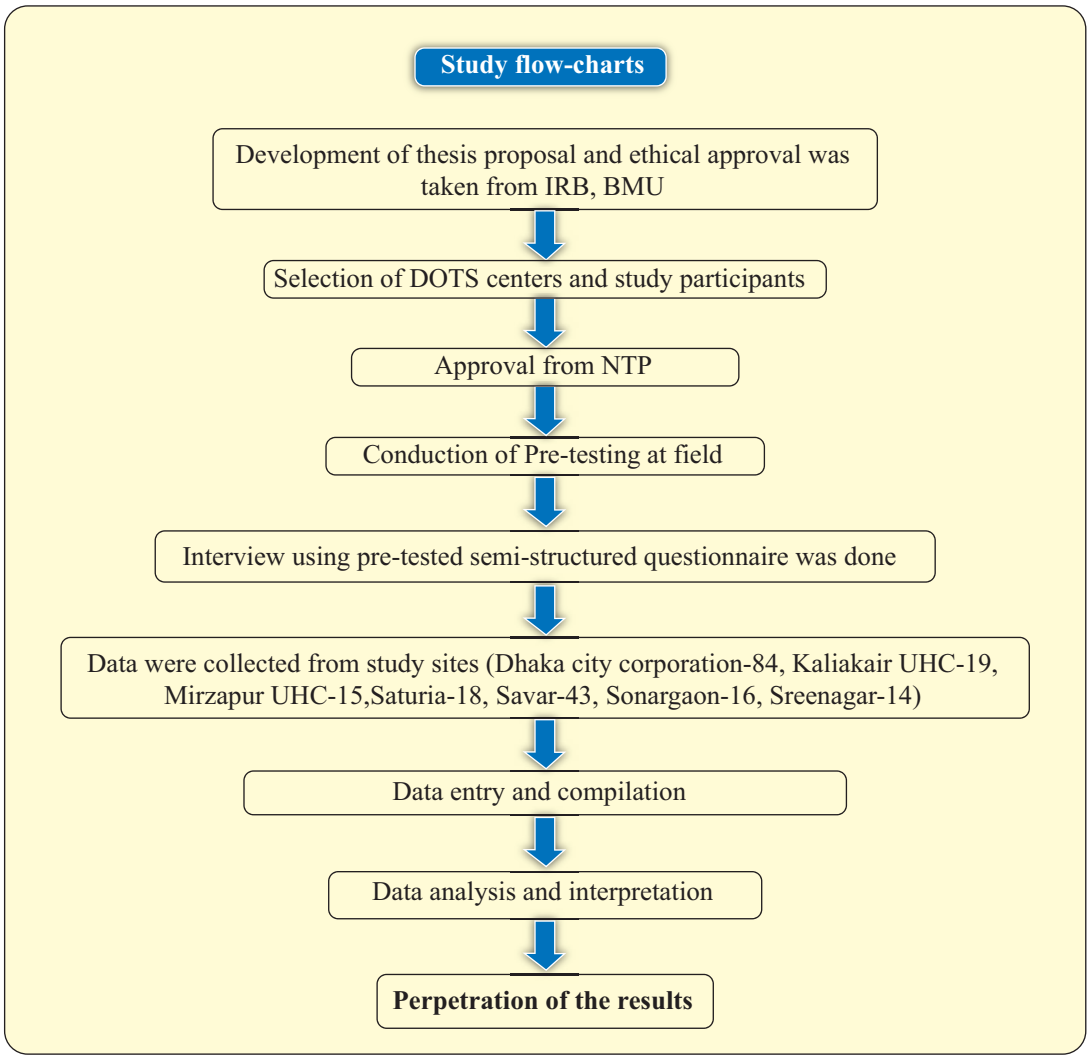
Non-compliant patients: Non-compliant participants were those who had a history of EPTB and experience of EPTB treatment for at least two months and missed any dose of the DOTS regimen. [16]

Data collection procedure

The participants were interviewed face-to-face at the DOTS center. Before the interview, written informed consent was obtained following an explanation of the study's purpose. Patients who gave consent were sent to a separate room and interviewed for around 20 minutes using a semi-structured questionnaire. The interview was carried out in Bangla. The patients' treatment cards contained information about their age, sex, occupation, type of EPTB, starting date of treatment, and medication schedule. We cross-checked the treatment card against the data provided by respondents regarding treatment compliance.

Data analysis and ethical considerations

A database in SPSS version 26 for Windows was developed according to the questionnaire. Data regarding all questions were entered into the developed database. Missing values were checked. Statistical analysis was done using SPSS 26. Frequency distribution and percentage of socio-demographic factors, patient-related factors, socio-cultural and service provider-related factors were compared between compliant and non-compliant people with EPTB. The continuous variables were expressed using mean (standard deviation). p-value was calculated by using chi-square for categorical (Fisher's exact test was done if any of cell had expected value less than 5) and t-test for quantitative variables. A p-value of less than 0.05 had been considered as statistically significant. The study was approved by the Institutional Review Board of Bangladesh Medical University before it started, and there was no physical harm to the study participants because there was no invasive technique. Confidentiality was preserved throughout the process.



Results

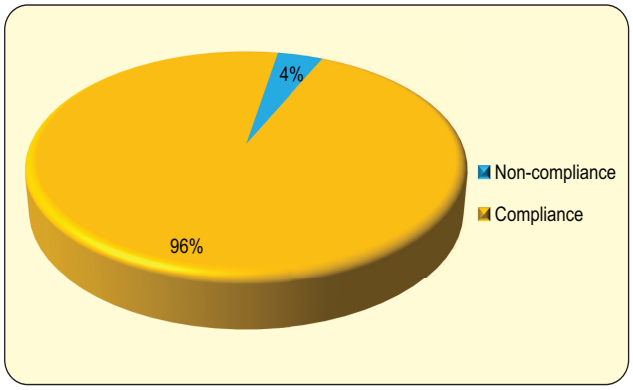


Figure 2: Distribution of treatment compliance to EPTB (N=209)

Out of the 209 participants analyzed, 200 (96%) were treatment compliant while nine (4%) were treatment non-compliant.

Among EPTB cases most had been suffering from cervical lymphadenitis which is 30%. Pleural and Abdominal Tuberculosis were in proportion of 19% and 11% respectively. Spine (7%), Supraclavicular lymph node (4%) and Breast TB (3%) were also common in people with EPTB. Besides these, numerous types of EPTB almost share a similar proportion (1-3%) (Figure 3).

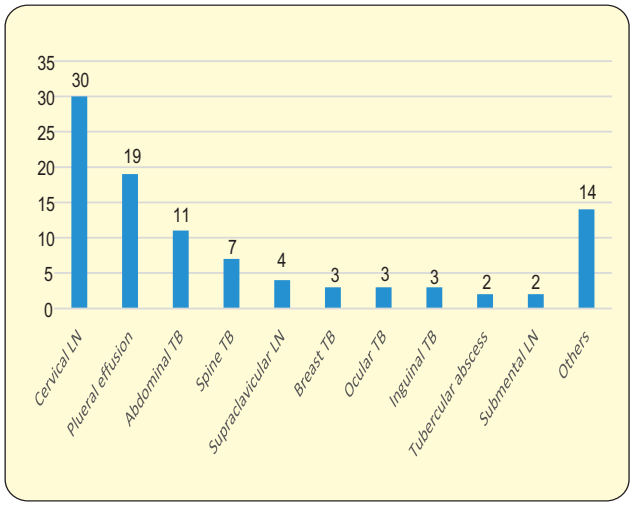


Figure 3: Distribution of different types of extrapulmonary tuberculosis (N=209)

Table 1 shows that the mean (SD) age of compliant respondents was 35 (14) years, while for non-compliant respondents, it was 26 (5) years; the difference was statistically significant (p = 0.04). Patients aged ≤35 years were significantly more likely to be compliant, with 100% of non-compliant patients being older than 35 years (p = 0.012). There was no significant difference in compliance rates between male and female patients (p = 0.739), as both

Table 1: Association of Socio-demographic Factors with Treatment Compliance among EPTB Patients on DOTS Regimen (N = 209)

Demographics		Total Number (N=209) (%)	Compliant (n=200)n (%)	Non-compliant (n=9)n (%)	OR (95%CI)	p-value
Age in years, Mean (SD)		35 (13)	35 (14)	26 (5)	9.31(0.38-18.20)	**0.041**
Age groups in years	≤35	126 (60)	117 (59)	9(100)		**0.012**
	>35	83 (40)	83 (41)	0 (0)		
Sex	Men	86 (41)	83 (42)	3 (33)		0.739
	Women	123 (59)	117 (58)	6 (67)	0.71 (0.17-2.90)	
Religion	Islam	197 (94)	189 (95)	8 (89)		0.419
	Other than Islam	12 (6)	11 (5)	1 (11)	0.47 (0.54-4.06)	
Marital Status	Married	167 (80)	162 (81)	5 (56)		0.082
	Single	42 (20)	38 (19)	4 (44)	0.29 (0.08-1.14)	
Educational Status	Non-formal/Primary	127(61)	124 (62)	3 (33)		0.159
	Secondary or above	82 (39)	76 (38)	6 (67)	0.31 (0.75-1.26)	
Occupation	Employed	95 (45)	92 (46)	3 (33)		0.515
	Unemployed/Housewife	114 (55)	108 (54)	6 (67)	0.58 (0.08-1.14)	
Family type	Nuclear	156 (75)	151 (75)	5 (56)		0.236
	Joint	53 (25)	49 (25)	4 (44)	2.46 (0.63-9.55)	
No. of family member	≤5	165 (89)	157 (79)	8 (79)		0.688
	>5	44 (21)	43 (21)	1 (21)	2.19 (0.67-18.00)	
Income	≤40,000 BDT	185 (89)	179 (90)	6 (67)		0.071
	>40,000 BDT	30 (11)	21 (10)	3 (33)	0.26 (0.56-1.00)	

* p-value was calculated by using the chi-square test for categorical and the t-test for quantitative variables. is her's exact test was applied when expected cell counts were less than 5.
* In case of Age, Mean Difference at 95% CI

genders had similar compliance percentages (42% vs. 58%). Most compliant patients were Muslim (95%), and there was no significant difference in compliance between Muslim and non-muslim patients (p=0.419). While married patients had a slightly higher compliance rate, the association was not statistically significant (p = 0.082). Patients with secondary education or above had a lower rate of compliance (OR 0.31; 95% CI 0.75-1.26). The educational status was significantly associated with compliance (p=0.159). Compliance rates were similar between employed and unemployed/housewife patients (p=0.515). Most compliant patients (75%) lived in nuclear families, but no significant difference was found in compliance between nuclear and joint families (p=0.236). The number of family members had no significant effect on compliance (p = 0.688). Most of compliant patients earned ≤40,000 BDT, but the difference in compliance between the income groups was not statistically significant (p=0.071).)

Of the respondents who believed that EPTB can result death if not treated, 94% had never missed a dose of their TB drugs before and it was statistically associated with compliance to EPTB treatment (P=0.02) (Table 2).

Table 2: Association of Patient-Related Factors with Treatment Compliance among EPTB Patients on DOTS Regimen (N = 209)

Factors	Response	Compliant (n=200) n (%)	Non-compliant (n=9) n (%)	p-value
Belief about suffering from EPTB	Yes	200 (100)	9 (100)	-
Eased symptoms of EPTB after taking medication	Yes	188 (94)	8 (89)	0.446
Belief about EPTB that can result death if not treated	Yes	188 (94)	6 (67)	**0.019**
Perception about importance of taking EPTB treatment for the prescribed duration				
To prevent MDR-TB	Yes	24 (12)	0 (0)	0.602
To be cured	Yes	184 (92)	9 (100)	0.998
To prevent spread of tuberculosis	Yes	26 (13)	0 (0)	0.606
To prevent death	Yes	22 (11)	0 (0)	0.602
To protect family members	Yes	31 (16)	3 (33)	0.165
Belief about medicine provided within DOTS regimen can cure EPTB	Yes	194 (97)	8 (89)	0.269

* p-values were calculated using the chi-square test. Fisher's exact test was applied when expected cell counts were less than 5.

Table 3 shows that 95% of compliant patients reported having family support, and 100% of non-compliant patients received family support, with no significant difference in family support between the two groups (p = 0.998). Ninety-nine percent of both compliant and non-compliant patients received positive feedback from their family members, with no significant association (p = 0.998). Most compliant patients (98%) and non-compliant patients (100%) visited registered physicians, with no significant difference between the two groups (p = 0.998). Ninety-nine percent of both groups reported no cultural beliefs against DOTS treatment, with no statistically significant difference found (p = 0.998).

Table 3: Association of Socio-cultural Factors with Treatment Compliance among EPTB Patients on DOTS Regimen (N = 209)

Factors	Response	Compliant (n=200) n (%)	Non-compliant (n=9) n (%)	p-value
Support from family	Yes	190 (95)	9 (100)	0.998
Family members' positive opinion towards taking medication	Yes	199 (99)	9 (100)	0.998
Visited registered physicians only	Yes	197 (98)	9 (100)	0.998
Absence of cultural belief against DOTS regimen	Yes	199 (99)	9 (100)	0.998

* p-values were calculated using the chi-square test. Fisher's exact test was applied when expected cell counts were less than 5.

98% of compliant patients reported that the attitudes of healthcare providers were friendly, and 100% of non-compliant patients did the same. No significant difference was found between the groups (p = 0.998). Both compliant and non-compliant groups (100% vs 100%) had easy access, with no significant difference (p = 0.998). Ninety-nine percent of compliant patients found the operating times feasible, and 100% of non-compliant patients agreed (p = 0.998). 99% of compliant patients were satisfied, but only 78% of non-compliant patients were satisfied. The p-value (0.005) suggests a statistically significant difference. 86% of compliant patients found it convenient, compared to 78% of non-compliant patients with no statistically significant difference (p=0.620). Most compliant patients lived within 5 km of a DOTS center (92%), while 100% of non-compliant patients did (p=0.867). (Table 4).

Table 4: Service provider-related factors contributing to compliance of EPTB patients on DOTS regimen (N=209)

Factors	Response	Compliant (n=200) n (%)	Non-compliant (n=9) n (%)	p-value
Behavior of the health care provider	Friendly	197 (98)	9 (100)	0.998
	Compassionate	3 (1)	0 (0)	
	Rude	0 (0)	0 (0)	
	Not compassionate	0 (0)	0 (0)	
Easy access in getting appointments and medicine	Yes	200 (100)	9 (100)	0.998
Feasibility of operating times for the DOTS centers	Yes	198 (99)	9 (100)	0.998
Satisfied by counseling from health care providers	Yes	199 (99)	7 (78)	**0.005**
Convenience to visit DOTS centers on regular basis	Yes	172 (86)	7 (78)	0.620
Distance of residence from nearest DOTS center	<5 km	185 (92)	9 (100)	0.867
	5 -10 km	13 (6)	0 (0)	
	11-15 km	1 (1)	0 (0)	
	>15 km	1 (1)	0 (0)	

* p-values were calculated using the chi-square test. Fisher's exact test was applied when expected cell counts were less than 5.

Table 5: Binary Logistic Regression Analysis of Factors Independently Associated with Treatment Compliance (N=209)

Factors		Adjusted OR (95% CI)	p-value
Age in years, Mean (SD)		1.97 (0.79-4.84)	0.141
Age groups in years	>35	23935780.35 (0.00∞)	0.997
Sex			
Men (Reference)	Women	1.34 (0.09-20.36)	0.833
Religion	Other than Islam	0.0 (0.00∞)	0.998
Marital Status	Single	0.52 (0.04-6.66)	0.255
Educational status	Secondary or above	0.43 (0.02-6.57)	0.363
Occupation	Unemployed	0.13 (0.00-3.53)	0.223
Family type	Joint	65.80 (2.58-1865.504)	0.011
Income	>40,000 BDT	0.28 (0.00-3.54)	0.223
Eased symptoms of EPTB after taking medication	Yes	5.73 (0.00-5043.59)	0.613
Believe about EPTB can result death if not treated	Yes	65.80 (2.57-1685.506.58)	0.075
Support from family	Yes	2056.09 (0.00∞)	0.998
Family members' positive opinion towards taking medication	Yes	1.11e13 (0.00∞)	0.998
Visited registered physicians only	Yes	0.00 (0.00∞)	0.998
Absence of cultural belief against DOTS regimen	Yes	0.00 (0.59∞)	0.998
Satisfied by counseling from health care provider	Yes	11731953.11 (0.00∞)	0.998

In the binary logistic regression model, patients from joint families (AOR = 65.802; 95%CI:.58-1865.504) were found to be independently associated with compliance to EPTB treatment.

Discussion

The study examined compliance with anti-tuberculosis (TB) treatment under the DOTS strategy in Bangladesh, focusing on EPTB. It found a high compliance rate of 96%, consistent with the 91.65% treatment completion rate reported by the National Tuberculosis Control Program 2022[17] and in line with the anti-TB treatment compliance rates in Tanzania (95%)[18] and Uganda (92%).[19] However, this rate differed from the findings of Nigeria (50%)[20] and Pakistan (86%).[21] The government's extensive DOTS coverage and collaborative efforts with NGOs contributed to this success.

Gender differences suggested that treatment non-compliance was more frequent among women, attributed to social stigma and family obligations. This contrasts with findings from Ethiopia and Kenya, where men showed higher default rates due to time and work constraints.[22,23] **The age group most related to compliance was those aged over 35, aligning with Chowdhury et al.[16] who found higher adherence among** economically stable and active older participants. In contrast, studies from Pakistan found an association between higher non-compliance and participants aged 35–59, linked to workload.[21] Older adults often possess better health literacy due to their extensive experience with healthcare systems. This experience makes them more aware of the importance of completing their treatment. They are more likely to follow medical advice because they understand the potential consequences of not doing so, such as worsening health or death. This is especially true for diseases like EPTB, where completing treatment is crucial to prevent relapse or drug resistance. Older patients usually process and understand medical information better and have more opportunities to engage with the healthcare system throughout their lives. In contrast, younger individuals may not have the same level of health literacy. They might not recognize the long-term benefits of following a treatment plan, particularly if the disease has no symptoms or if they feel better early on. As a result, younger patients might stop their medication too soon. This can happen either because they don't fully understand the importance of their treatment or because they believe they have recovered before finishing the prescribed course. Older patients generally trust the healthcare system more, especially if they have had good experiences with treatments over the years. This trust often leads to higher compliance. Older individuals typically follow medical advice closely, believing it will help them maintain their health. Moreover, older adults tend to be more connected to healthcare systems, which gives them consistent follow-up and support.

Marital status also played a role, with married individuals showing a higher rate of compliance (81%) than singles (19%). Support from spouses and family likely contributed to adherence, as demonstrated by.[24] This finding contrasts with Nigerian studies, where singles showed a higher adherence rate to anti-TB medication due to fewer family-related responsibilities.[20] A difference in occupations was significantly associated with treatment compliance, with housewives showing the highest adherence and unemployed individuals showing the lowest adherence. The rapport between female DOTS providers and housewives may explain this, as suggested by Gad et al.[25] Conversely, the unemployed participants may have faced barriers such as transportation costs and psychological stress. Findings from India showed the opposite, with higher non-compliance among employed participants.[26]

Those with secondary education or higher showed the highest compliance level, with the highest proportion of non-compliant participants also coming from this group, indicating an ambiguous influence of education. Because a few of them are still students with attendant issues of youthful exuberance, for some, work-related distractions and other personal indulgences may be contributing factors to non-compliance. These results contradict those of Pandit & Choudhary[27] who found in their Indian study that compliance was lowest among graduates and highest among those with only a primary education. Although **sex, religion, and income had an insignificant role in treatment compliance in this study, compliance was higher among patients who knew that EPTB could result in death if not treated (94%) compared to patients who were not aware that EPTB could result in** death if not treated (6%). Similar results were found by Gad et al.[25] which perhaps emphasizes the role of fear-management theory. In our study, seven of the nine non-compliant individuals with EPTB were not satisfied with the healthcare provider's counseling, while 199 of the 200 compliant participants expressed satisfaction. That difference was statistically linked to EPTB treatment compliance (P=0.005). We found similar findings from another study of Tesfahuneygn et al.[22] They showed that there were nearly five times more odds of being non-adherent to the DOTS regimen when healthcare providers never counseled compared to the patients who were advised on each visit. In another study, good counseling and good communication between the patient and health professionals was linked to have positive effect on patients' adherence to their anti-TB medication regimen Bello & Itiola[28] also poor Communication between patients and health care staff and lack of proper information on TB and its treatment resulted in default from anti-TB therapy in another study conducted in Uzbekistan.[29]

Key barriers like family support and stigma had limited impact due to the Bangladeshi government's prioritization of TB education. However, dissatisfaction with healthcare counseling emerged as a critical factor, with seven of nine non-compliant participants expressing dissatisfaction. Good counseling practices significantly boosted adherence, as demonstrated by Tesfahuneygn et al.[22] and Bello & Itiola.[28]

Limitations

The study results may not be generalizable to the entire country. Still, they can be generalized to individuals similar to our study participants and from settings comparable to those of our study participants in Bangladesh or elsewhere in the world. We purposively selected DOTS centers with the highest number of EPTB cases for the availability of people with EPTB. Data collection from six upazila health complexes and DOTS centers in Dhaka City during the political unrest posed a significant challenge. As potential recall bias is an inherent characteristic of cross-sectional studies, our study may also be susceptible to this bias. The small number of non-compliant patients limits generalizability and statistical power. Time limitation was a significant factor in conducting the study. Prospective studies are needed to use repeated measures to monitor the treatment compliance of EPTB patients.

Recommendations

This study suggests that special attention should be given and strategies should be adopted according to age groups and occupation of people with EPTB while treating them under DOTS regimen. The role of healthcare provider is essential to focus more on monitoring and implementing standard therapy according to SOP for persistent and sustainable treatment compliance to EPTB. Patient education programs about the fatal consequences of EPTB should be conducted more than before to attain the Government's 'End TB Strategy' by 2035.

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