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Association between early weight variation and treatment outcomes among extensively drug-resistant tuberculosis patients in Pakistan: a multicenter retrospective cohort study

Muhammad Abubakar,[1] Javeria Sehar,[2] Rimsha Mukhtar[3]

[1]Department of Pharmacy Practice, Faculty of Pharmacy, Salim Habib University, Korangi Creek, Karachi, Pakistan; [2]Department of Rehabilitation Medicine and Physical Therapy, Xuzhou Medical University, China; [3]Department of Pharmacy Practice, Faculty of Pharmacy, Hamdard University, Islamabad Campus, Islamabad, Pakistan

Correspondence: Rimsha Mukhtar, Department of Pharmacy Practice, Faculty of Pharmacy, Hamdard University, Islamabad Campus, Islamabad, Pakistan. E-mail: riamuk10@gmail.com

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Abstract

Tuberculosis (TB) is commonly associated with significant weight loss, and weight gain during treatment is often considered an indicator of treatment response. However, evidence regarding the association between weight change and treatment outcomes among patients with extensively drug-resistant TB (XDR-TB) remains limited. This study aimed to evaluate the relationship between weight change during treatment and treatment outcomes among XDR-TB patients in Pakistan. A multicenter retrospective cohort study was conducted using data from XDR-TB patients treated at 27 Programmatic Management of Drug-Resistant TB units across Pakistan between May 2010 and June 2019. Patient data were extracted from the Electronic Nominal Recording and Reporting System of the National Tuberculosis Control Program. Weight change was assessed at 2, 4, and 6 months of treatment and categorized as no weight gain, weight gain <4 kg, and ≥4 kg. Logistic regression analysis was performed to determine the association between weight gain and favorable treatment outcomes. A total of 255 XDR-TB patients were included in the final analysis. Among them, 54.9% were male, and the majority (52.2%) belonged to the 21-40 year age group. Overall, favorable treatment outcomes were observed in 54.9% of patients. In multivariate analysis, weight gain at the fourth month of treatment showed a statistically significant negative association with favorable treatment outcomes for both weight gain <4 kg (OR 0.343, p=0.039) and ≥4 kg (OR 0.370, p=0.020). No statistically significant association was observed between weight gain at two or six months and treatment outcomes. These findings suggest that weight gain during treatment may not be a reliable predictor of favorable treatment outcomes among XDR-TB patients, and additional clinical and microbiological indicators should be considered when monitoring treatment response.

Key words: XDR-TB, weight variation, Pakistan, treatment outcomes.

Introduction

Tuberculosis (TB) remains one of the leading causes of morbidity and mortality worldwide and continues to pose a major public health challenge, particularly in low- and middle-income countries [1]. According to recent global estimates, approximately 10.7 million people developed tuberculosis in 2024, and about 1.23 million deaths were attributed to the disease, making TB the leading cause of death from a single infectious agent globally [2]. Despite the availability of effective treatment, the global TB burden remains substantial, with the majority of cases occurring in a limited number of high-burden countries. Pakistan is among the countries contributing significantly to the global TB epidemic and accounts for a considerable proportion of worldwide cases [2,3]. The emergence and spread of drug-resistant tuberculosis (DR-TB) represent a major obstacle to TB control. Drug resistance frequently develops as a result of inadequate treatment regimens, poor adherence to therapy, interrupted treatment, or inappropriate use of anti-tuberculosis medications. Multidrug-resistant tuberculosis (MDR-TB) and extensively drug-resistant tuberculosis (XDR-TB) are particularly concerning due to limited treatment options, prolonged treatment duration, and lower treatment success rates compared with drug-susceptible TB. Patients with XDR-TB often experience severe disease and require complex treatment regimens that are associated with significant toxicity and suboptimal treatment outcomes [2,4,5].

Moreover, TB often manifests as a wasting disease, leading to a decrease in body mass index (BMI) due to the loss of both fat-free mass and fat mass. Moderate-to-severe malnutrition, increase metabolic demand, chronic infectious nature have been identified as a critical risk factors for mortality during the initial weeks of TB treatment [6,7]. Along with this, weight loss has long been recognized as a common clinical feature of active TB. Conversely, weight gain during treatment is often interpreted as an indicator of clinical improvement and recovery [8,9]. Several studies have suggested that weight variation during treatment may serve as a predictor of treatment outcomes among patients with drug-sensitive TB and multidrug-resistant tuberculosis [9-12]. Additionally, longitudinal analysis has demonstrated that patients experiencing weight loss, particularly within the initial months of treatment, are at a higher risk of treatment failure or death [1]. Similarly, weight variation has been identified as a significant predictor of treatment outcome among MDR-TB patients, with diverging weight trends observed between those who were cured and those who died during therapy [12]. Previous studies found inconsistent associations between

BMI and TB outcomes. One study found that a higher BMI (per unit rise) was significantly related to a lower risk of death, while four studies found that a lower BMI was significantly associated with a higher risk of mortality among TB patients. Yet, two other investigations did not find any changes in mortality risk according to BMI (<18·5 vs. ≥18·5 kg/m2) [13].

However, evidence regarding the relationship between weight change and treatment outcomes among patients with XDR-TB remains limited. In particular, few studies have evaluated whether weight variation during the early phase of treatment can reliably predict treatment outcomes among XDR-TB patients [1,9,14]. Due to the high burden of DR-TB in Pakistan and the clinical importance of identifying simple indicators of treatment response, evaluating the role of weight variation in predicting treatment outcomes may provide valuable insights for clinicians and TB control programs. It is because, monitoring weight is an inexpensive way to get valuable information about how well someone is responding to treatment. This is especially important in places where resources limited. Therefore, the present study aimed to assess the association between weight change during treatment and treatment outcomes among XDR-TB patients treated at Programmatic Management of Drug-Resistant Tuberculosis (PMDT) units across Pakistan.

Materials and Methods

Study design

This retrospective cohort study analyzed electronic nominal recording and reporting system (ENRS) files of patients diagnosed with XDR-TB who initiated treatment between 1 May 2010 and 30 June 2019 across all active PMDT sites in Pakistan. This study was conducted and reported in accordance with the recommendations of the STROBE Initiative for observational studies.

Study setting

Data was collected from all 27 PMDT units operating under the National Tuberculosis Program (NTP) of Pakistan. These specialized units are responsible for diagnosing, treating, and monitoring drug-resistant tuberculosis cases nationwide.

Study participants

During the study period, 560 XDR-TB patients were enrolled for treatment at PMDT units. Patients who were still receiving treatment at the time of analysis (n=102) were excluded. In addition, 203 patients with incomplete weight records during the first six months of treatment (i.e., at least one missing weight measurement) were excluded. After applying these criteria, 255 patients with complete weight monitoring data were included in the final analysis. Due to the retrospective nature of the study, all eligible XDR-TB patients recorded during the study period with complete weight monitoring data were included in the final analysis. The patient selection process is summarized in Figure 1.

Data collection and variables

Data was collected about following variables such as sociodemographic microbiological, and clinical characteristics of study participants were obtained from the NTP database through an ENRS files. Extracted variables included age, gender, baseline microbiological status, treatment regimen, body weight measurements during treatment at least first 6 months of treatment and their treatment outcomes. Treatment outcomes were defined and categorized according to WHO guidelines and have been described in our previously published studies [1,15,16].

Weight gain define as "if a patient increases their weight from their baseline body weight at 2, 4 and 6 month of treatment were declared as weight gain patient. After that, patient is divided into three categories such as no weight gain, below 4-kilogram increase and 4 and more kilogram increases. These categories were used against the favorable treatment outcomes (both treatment completed and Cured patient) to earlier detection of successful treatment outcomes among XDR-TB patients. We used these categories to help understand recovery and its prognostic value. Patients were grouped this way because there is no agreed-upon cutoff for weight gain in patients with MDR/XDR-TB. These categories help distinguish between patients with no recovery some weight gain and significant weight gain. We also wanted to ensure we had patients in each group for regression analyses. Other studies have also found that weight gain is an indicator of how well patients with drug-resistant tuberculosis are responding to treatment [11,17-19].

Statistical analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS), version 23. Descriptive statistics were used to summarize the sociodemographic, clinical and microbiological characteristics, and drug used among XDR-TB patients. Continuous variables were presented as mean ± standard deviation (SD), while categorical variables were expressed as frequencies and percentages. Linear logistic regression analysis was performed to find the association between weight gain at 2, 4 and 6 months of treatment with successful treatment outcomes. Those variables in linear regression having p-value <0.2 were moved forward into the multivariate binary logistic regression analysis to find the actual association of weight changes over treatment outcomes. Here p-value <0.05 was considered as statistically significant.

Ethical approval

Ethical approval and permission for the conduction of this study were granted by the Research and Ethics Committee of the Faculty of Pharmacy of Hamdard University, Islamabad (Ref no: HAM-PP/10/23). Furthermore, we confirm that all methods were performed in accordance with the relevant guidelines and regulations.

Results

Baseline characteristics of study participants

During the study period, a total of 255 XDR-TB patients met the inclusion criteria and were included in the final analysis. The majority of patients were male (54.9%), and more than half belonged to the 21-40-year age group (52.2%). Details of sociodemographic and microbiological characteristics of study participants are presented in Table 1.

Most patients (92.2%) had a previous history of tuberculosis treatment. Furthermore, 41.2% of patients were resistant to all first-line anti-tuberculosis drugs, and nearly half of the patients (48.2%) were resistant to a median of 7-8 anti-TB drugs. Detailed of baseline clinical characteristics are presented in Table 2.

Anti-tuberculosis drug utilization

Among the study population, the most frequently prescribed anti-tuberculosis drugs were pyrazinamide (99.6%), cycloserine (98.8%), ethionamide (98.4%), and para-aminosalicylic acid (92.9%). Other commonly used medications included linezolid (69.0%), moxifloxacin (71.0%), clofazimine (53.7%), and capreomycin (80.4%). Newer drugs such as bedaquiline and delamanid were used in a small proportion of patients (7.8% and 1.6%, respectively). Details of drug utilization among study participants are presented in Table 3.

Association between weight gain at 2, 4 and 6 months of treatment with favorable treatment outcomes

The association between weight gain during treatment and favorable treatment outcomes was evaluated by using logistic regression analysis. In multivariate binary logistic regression analysis, weight gain at 4 months was significant negative association with successful treatment outcomes (< 4kg; OR: 0.343; 95% CI: 0.124-0.946; p=0.039: and ≥4 kg; OR: 0.370; 95% CI: 0.160-0.856; p=0.020), compared with patients with no weight gain. However, weight gain at 2 months and 6 months was not significantly associated with favorable treatment outcomes in the multivariate analysis. Detailed results of the regression analyses are presented in Table 4.

Discussion

The present study evaluated weight variation over time among extensively drug-resistant tuberculosis (XDR-TB) patients and its association with final treatment outcomes. In this cohort, 54.9% of patients were male, and the majority belonged to the 21-40-year age group. Globally, tuberculosis (TB) demonstrates clear gender disparities, with men diagnosed more frequently than women, with an estimated ratio of approximately 1.6:1. These differences may be attributed to biological variations in disease presentation as well as disparities in access to healthcare in developing countries. In addition, men often exhibit greater exposure to TB risk factors, including smoking, alcohol consumption, HIV infection, lung cancer, and chronic obstructive pulmonary disease (COPD). Smoking, in particular, is a well-established risk factor for pulmonary tuberculosis, COPD, and lung cancer, and its higher prevalence among men contributes to the increased TB burden in this population [20].

In the present study, the majority of patients belonged to the economically productive age group of 21-40 years. Similar findings have been reported in studies conducted in other regions (1, 20). In developing countries such as Pakistan, individuals in this age group are often engaged in manual labor or migrate for employment opportunities, which may increase exposure to risk factors for tuberculosis infection and transmission [1,4].

A large proportion of patients in this cohort (92.2%) had a previous history of tuberculosis treatment. The high level of drug resistance observed among these patients is therefore not unexpected. Previous TB disease and prior exposure to anti-tuberculosis therapy are recognized as major risk factors for the development of drug-resistant TB. These findings highlight the importance of early diagnosis, appropriate treatment regimens, and effective patient monitoring to prevent the emergence and transmission of multidrug-resistant tuberculosis (MDR-TB) [21].

Studies conducted in different settings have also reported a high degree of drug resistance among XDR-TB patients, with the median number of resistant drugs ranging from five to eleven [22-24]. The development of XDR-TB is frequently associated with inadequate or inappropriate TB treatment in the past Several factors may contribute to such inadequate treatment, including self-medication prior to diagnosis, delays in TB diagnosis and treatment initiation, irrational use of broad-spectrum antibiotics, inappropriate prescribing practices, availability of substandard anti-tuberculosis drugs, and poor patient adherence to treatment regimens [25,26].

In the present study, 41.2% of patients were resistant to all first-line anti-tuberculosis drugs. Comparable rates of resistance to all first-line drugs among XDR-TB patients have been reported in studies conducted in Korea (45.23%) and Argentina (100%) [14,27]. Among the three commonly evaluated first-line drugs--pyrazinamide, ethambutol, and streptomycin--the highest resistance rate was observed for ethambutol (74.1%), followed by pyrazinamide (70.2%) and streptomycin (60.8%). Previous studies have reported slightly lower rates of ethambutol resistance among XDR-TB patients, ranging from 41% to 68.8% [3,5].

Ethambutol acts as a bacteriostatic agent that inhibits the biosynthesis of arabinogalactan, an essential component of the mycobacterial cell wall [28].In the present study, pyrazinamide resistance was observed in 70.2% of patients, which is consistent with previously reported ranges of 66.8% to 88% among XDR-TB patients [3]. Pyrazinamide is a prodrug whose mechanism of action is not completely understood. When administered in combination with other anti-

tuberculosis drugs, it demonstrates strong bactericidal activity and contributes to improved treatment outcomes in drug-resistant TB regimens [29,30] .Resistance to pyrazinamide is commonly associated with mutations in the pncA gene . Despite the presence of resistance in some patients, treatment guidelines continue to recommend the use of pyrazinamide in selected cases due to the limited number of effective drugs available for XDR-TB treatment [31].

Body weight changes are frequently considered by both clinicians and patients as indicators of disease progression and treatment response in tuberculosis [11]. However, despite being a simple and easily measurable clinical parameter, weight variation has not been extensively evaluated as a predictor of treatment outcomes among XDR-TB patients. Previous studies have suggested that baseline body weight or body mass index may influence treatment outcomes. For example, one study reported a significant association between baseline body weight and mortality among XDR-TB patients, with individuals weighing less than 40 kg showing a higher risk of death compared with those weighing 40 kg or more [8] . Other studies have demonstrated gradual weight gain during tuberculosis treatment, indicating improvement in patient health status. For instance, research conducted in Houston, Texas reported a linear increase in body weight throughout the treatment period, emphasizing the benefits of uninterrupted therapy [32]. Similarly, Barnwal et al. reported significant weight gain among TB patients during treatment, with average weight increasing from 41.17±7.91 kg at baseline to 42.42 ± 7.58 kg at two months and 43.60 ± 8.78 kg at six months [33]. A study conducted in the Netherlands also observed that the majority of patients (85.4%) experienced stable or increasing body weight during treatment [9]. In contrast to these findings, the present study did not observe a positive association between weight variation and favorable treatment outcomes among XDR-TB patients. Weight variation was not found to be a reliable predictor of treatment success, as 47.4% of patients with weight variation experienced unfavorable outcomes. These findings suggest that body weight alone may not be a sufficient surrogate marker for predicting treatment outcomes in XDR-TB patients. Instead, clinical indicators such as sputum smear conversion, sputum culture conversion, and overall improvement in patient health status should be considered when evaluating treatment response.

The strengths of this study include the large cohort of XDR-TB patients managed under standardized treatment protocols and the use of data obtained from the ENRS, which ensures consistency in data recording. However, several limitations should be acknowledged. First, the

retrospective design may introduce potential biases related to incomplete or missing data. Second, information regarding certain clinical variables, such as lung cavitation, BMI, HIV status, diabetes, socioeconomic factors, treatment adherence, adverse drug reactions, radiological disease severity, and other potential confounders that could influence both weight change and treatment outcomes was not available in the dataset, which may have influenced the interpretation of treatment outcomes. Lastly, we also discuss the possibility of residual confounding and selection bias arising from incomplete routine clinical records.

Conclusions

To conclude, in the current study showed that the change in weight during treatment did not correlate with the positive treatment results in XDR-TB patients. Though a lot of patients gained weight in therapy, even by the fourth month of the treatment, a weight gain was not a good indicator of how effective the treatment was. These results suggest that body weight cannot be a surrogate endpoint of successful treatment in XDR-TB management. Rather, clinicians ought to go by various signs of treatment response, such as sputum smear conversion, sputum culture conversion, and general clinical improvement in their assessment of patient response and subsequent treatment continuation or change.

Abbreviations:

TB: Tuberculosis

XDR-TB: Extensively Drug-Resistant tuberculosis

PMDT: Programmatic Management of Drug-resistant Tuberculosis

ENRS: Electronic Nominal Recording and Reporting System

NTP: National Tuberculosis Program

WHO: World Health Organization

ADRs: adverse drug reactions

BMI: body mass index

MDR-TB: Multidrug-resistant tuberculosis

FLDs: First Line Drugs

MTB: Mycobacterium Tuberculosis

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Table 1. Sociodemographic and microbiological characteristics of study participants.

Variable	Number (%)
Sex	
Female	115 (45.1)
Male	140 (54.9)
Age group (years)	
≤20	57 (22.4)
21–40	133 (52.2)
41–60	59 (23.1)
>60	6 (2.4)
Baseline weight category (kilogram)	
<40	79 (31.0)
≥40	176 (69.0)
Smoking status	
Non-smoker	241 (94.5)
Current or ex-smoker	14 (5.5)
Marital status	
Unmarried	82 (32.2)
Married	169 (66.3)
Widowed	4 (1.6)
Occupation	
Unemployed	161 (63.1)
Employed	94 (36.9)
Baseline sputum smear grading	
Negative	45 (17.6)
Scanty / +1	74 (29.0)
+2 / +3	128 (50.2)
Not available	8 (3.1)
Sputum culture conversion at 2 months	
No	160 (62.7)
Yes	95 (37.3)
Overall sputum culture conversion	
No	46 (18.0)
Yes	209 (82.0)

Scanty: 1–9 AFB (Acid fast bacilli)/100 HPF (High power field), +1: 10–99 AFB/100 HPF, +2: 1–9 AFB/HPF, +3: > 9 AFB/HPF

Table 2. Clinical characteristics and drug susceptibility pattern of XDR-TB patients.

Variable	Number (%)
Previous TB treatment history	
No	20 (7.8)
Yes	235 (92.2)
History of second-line drug use	
No	163 (63.9)
Yes	92 (36.1)
History of MDR-TB treatment	
No	170 (66.7)
Yes	85 (33.3)
Site of tuberculosis	
Pulmonary tuberculosis	250 (98.0)
Extra-pulmonary tuberculosis	5 (2.0)
Comorbidity	
No	213 (83.5)
Yes	42 (16.5)
Resistance to first-line anti-TB drugs	
Resistant to all five first-line drugs	105 (41.2)
Not resistant to all five	150 (58.8)
Drug resistance pattern	
Ethambutol resistant	189 (74.1)
Pyrazinamide resistant	179 (70.2)
Streptomycin resistant	155 (60.8)
Resistance to injectable drugs	
Resistant to all three injectable	116 (45.5)
Amikacin resistant	191 (74.9)
Capreomycin resistant	156 (61.2)
Kanamycin resistant	195 (76.5)
Ethionamide resistance	
Yes	23 (9.0)
No	232 (91.0)
Number of drugs resistant	
4–6 drugs	71 (27.8)
7–8 drugs	123 (48.2)
>8 drugs	61 (23.9)
Treatment outcome	
Favorable	140 (54.9)
Unfavorable	115 (45.1)

TB, tuberculosis; MDR-TB, multi drug resistance tuberculosis.

Table 3. Anti-tuberculosis drug utilization among XDR-TB patients (n=255).

Drug	Yes n (%)	No n (%)
Cycloserine	252 (98.8)	3 (1.2)
Pyrazinamide	254 (99.6)	1 (0.4)
Para-aminosalicylic acid	237 (92.9)	18 (7.1)
Clarithromycin	155 (60.8)	100 (39.2)
Augmentin	168 (65.9)	87 (34.1)
Delamanid	4 (1.6)	251 (98.4)
Bedaquiline	20 (7.8)	235 (92.2)
Clofazimine	137 (53.7)	118 (46.3)
Linezolid	176 (69.0)	79 (31.0)
Levofloxacin	72 (28.2)	183 (71.8)
Moxifloxacin	181 (71.0)	74 (29.0)
Kanamycin	3 (1.2)	252 (98.8)
Amikacin	41 (16.1)	214 (83.9)
Capreomycin	205 (80.4)	50 (19.6)
Ethambutol	47 (18.4)	208 (81.6)
Ethionamide	251 (98.4)	4 (1.6)

Table 4. Association between weight gain and favorable treatment outcomes among XDR-TB patients.

Weight gain category	Good outcomes n (%)	Univariate analysis OR (95% CI)	p	Multivariate analysis OR (95% CI)	p
Weight gain at 2 months					
No weight gain	71 (27.8)	Reference		Reference	
<4 kg	48 (18.8)	0.320 (0.128–0.799)	0.015	0.651 (0.211–2.007)	0.455
≥4 kg	21 (8.2)	0.471 (0.180–1.231)	0.124	0.808 (0.273–2.388)	0.700
Weight gain at 4 months					
No weight gain	52 (20.4)	Reference		Reference	
<4 kg	45 (17.6)	0.292 (0.144–0.594)	<0.001	0.343 (0.124–0.946)	0.039
≥4 kg	43 (16.9)	0.341 (0.164–0.710)	0.004	0.370 (0.160–0.856)	0.020
Weight gain at 6 months					
No weight gain	55 (21.6)	Reference		Reference	
<4 kg	36 (14.1)	0.551 (0.304–0.999)	0.049	1.097 (0.487–2.467)	0.824
≥4 kg	49 (19.2)	0.686 (0.351–1.341)	0.270	1.037 (0.494–2.175)	0.924

OR, odds ratio; CI, confidence interval; kg, kilogram.

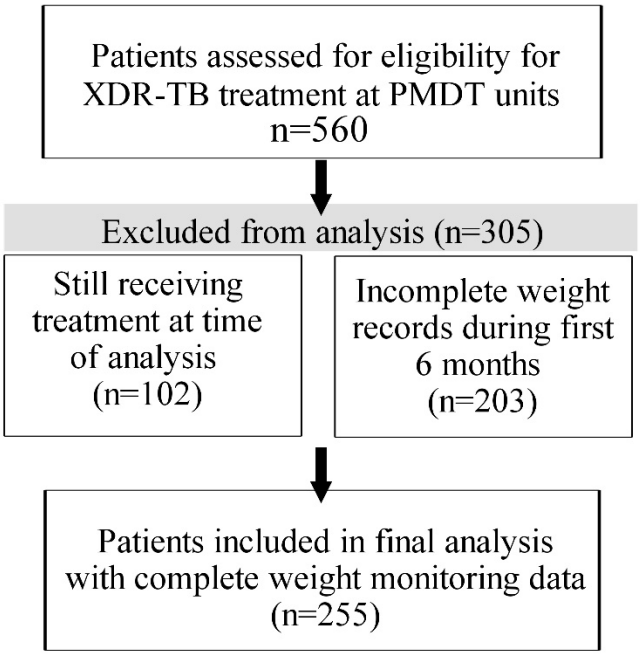

Figure 1. Flow diagram of patient selection for the retrospective XDR-TB cohort study.