Original Article

Treatment Outcomes and Factors Impacting Unsuccessful Outcome Among Extrapulmonary Tuberculosis Patients

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Abstract

Tuberculosis remains a significant public health challenge. The study aimed to identify factors influencing treatment outcomes for extrapulmonary tuberculosis (EPTB). From January 1, 2014, to December 31, 2018, a retrospective study was carried out at the District Headquarter (DHQ) Hospital Bannu in Khyber Pakhtunkhwa (KPK), Pakistan. There were 107 EPTB patients in all, aged 12-90 years, with 39.3% of them being female and 60.7% of them being male. With the assent of the patient, demographic information, smoking habits, and co-morbidities were noted. Logistic regression was used in SPSS 23.0 to analyse the data. The treatment success rate was 58.9% among new and relapsed EPTB patients and 24.3% among new smear-positive pulmonary tuberculosis (PTB) patients, with an overall success rate of 83.2%. The likelihood of unsuccessful treatment outcomes was higher among patients aged 36-45 years (AOR = 1.17 95% CL: .416-7.37) and patients with comorbidities (AOR = 2.66; 95% CL: .895-7.94). The patients having symptoms like sweating (AOR = 0.335; 95%CL .130-.863) and cough (AOR = 3.03; 95% CL: 1.35-6.76) were factors associated with the unsuccessful treatment. This study reveals that the ratio of unsuccessful treatment outcomes is still high. Unsuccessful treatment outcomes are due to patient's expiry, defaulter patients, treatment failure, and patient transfer. To reduce treatment interruptions, effective tracing strategies for patients who have been transferred and didn't complete treatment due to being defaulters should be devised and deployed. A follow-up plan should be tailored to each patient.

Keywords: Extra pulmonary tuberculosis, Unsuccessful treatment outcome, Successful treatment outcome, Pakistan

Introduction

Tuberculosis (TB) is an infectious disease caused by a bacteria named *Mycobacterium tuberculosis*. The disease usually affects the lungs (pulmonary tuberculosis), but it can also affect other body parts (extrapulmonary tuberculosis). After HIV infection, TB is the second greatest cause of death from an infectious disease worldwide [1]. According to WHO 2023 report, based on 2022 global data, a total of 7.5 million people were diagnosed and reported with a new episode of tuberculosis (including new and relapse cases). Among these, 83% had pulmonary TB, while 17% had extrapulmonary TB (EPTB) [1].

Globally, the number of EPTB patients has increased in recent years [1]. The EPTB accounted for 17% of the 7.5 million notified TB cases, with rates ranging from 8% in the Western Pacific region to 22% in the Eastern Mediterranean region [1]. Pakistan is ranked fifth among countries with the highest burden of tuberculosis (TB), with an estimated 510,000 new cases emerging annually and around 15,000 cases of drug-resistant TB developing each year. The country accounts for 61% of the TB burden in the WHO Eastern Mediterranean Region and is estimated to have the fourth highest prevalence of multidrug-resistant TB (MDR-TB) globally. Key factors contributing to the rise of drug-resistant TB include delays in diagnosis, unsupervised and inappropriate drug regimens, inadequate treatment, poor follow-up, and the lack of social support programs for high-risk populations [2]. National TB Control Program of Pakistan (NTP), data revealed the percentage of recorded cases of EPTB in the nation rose from 15.4% to 20% [3].

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Among the six WHO regions the Western Pacific Region, Southeast Asia Region, and Eastern Mediterranean Region had the highest treatment success rates. The African Region had a 79% treatment success rate, whereas the Americas and Europe Region had a 75% percent success rate [1, 4]. Few countries like India, Nigeria, and Ethiopia have reported inadequate levels of success while India (90.5%) reported optimal treatment outcomes [5-7]. It is reported somewhere else that the success rate for TB treatment was 94% [4]. The treatment success of EPTB patients in Pakistan is 60-88% [8, 9].

The analysis of TB treatment outcomes and the identification of related factors and predictors affecting the outcomes are necessary for the evaluation of NTP in Pakistan. NTP manages the availability of DOTs coverage for TB patients across the country. It also deals with the programmatic management of drug-resistant tuberculosis [9]. Despite all the efforts of NTP, EPTB cases have been mostly neglected.

There is a limited information on the clinical characteristics and epidemiology of extrapulmonary tuberculosis (EPTB). To date, information regarding the factors and predictors of unsuccessful treatment outcomes among EPTB patients in study setting area remains scarce. Hence, this study was conducted to examine treatment outcomes and identify the factors and predictors linked to unsuccessful outcomes in EPTB patients in Pakistan.

Materials and Methods

Study Design

A retrospective study was designed.

Study Setting

The current study was conducted in the District level refereal hospital of Bannu, Khyber Pakhtunkhwa (KPK), Pakistan from January 1st - 2014 to December 31st -2018. It is a 244-bedded hospital associated with Bannu Medical College. Data based on socio-demographics, clinical characteristics, Using NTP recommendations for Pakistan, microbiological and other laboratory data of TB cases were gathered from TB registrations, treatment cards, and TB medical personal files. Every month, NTP receives data from TB patients treated at DHQ Bannu using an electronic nominal recording and reporting system (ENRS). 'Assumed TB patients,' as proposed by the National Tuberculosis Program guidelines were identified based on the symptoms, microscopy, and chest x-ray. Confirmed EPTB patients were registered and provided free treatment in the respective hospitals.

Patients took EPTB treatment recommended by NTP and WHO. Patients were given a standard anti-TB regimen. Patients who discontinued treatment for more than four weeks were contacted by telephone and tracked down by a TB coordinator.

Participants

The study included all participants who were enrolled at cited Hospital.

Study Inclusion and Exclusion Criteria

All smear-positive and smear-negative extra pulmonary tuberculosis patients, new patients, and patients with relapse EPTB were included in the study. Patients who have PTB, females who were pregnant and children were excluded from the study.

Data Analysis

The data analysis tool used was the Statistical Package for Social Science (SPSS) (version 23, IBM Corp., Armonk, NY, USA). The relationship between patients' clinical, microbiological, and sociodemographic characteristics and unsatisfactory treatment outcomes was investigated using univariate analysis. Based on previously published research, their possible relationship to treatment outcomes, and suggestions from the clinical team and study supervisors, the independent variables for univariate analysis were chosen. Variables that were statistically significant in the univariate analysis were further examined using multiple logistic regression analysis to identify the final predictors of unsuccessful treatment outcomes. Variables with a p-value of <0.05 were considered statistically significant in the final model. Adjusted odds ratios (AOR), 95% confidence intervals (CI), and p-values were reported for each predictor.

Results and Discussion

Socio-Demographics and Clinical Characteristics

A total of 107 patients were registered for present study. EPTB patients were included in the study. The study included 65 (60.7%) males and 42 (39.3%) females. Out of 107 patients, the more cases of EPTB were among the age group 26-35 years 34 (31.8%) and the lowest 4 (3.7%) were of age 15 years or younger. People living in rural areas have a high percentage of EPTB (74.8%).

Around (39.3% of patients were smear-positive EPTB. The majority of patients showed high percentages of sputum (86.0%), profuse sweating (80.4%), LOW (73.8%), LOA (68.2%), and hemoptysis (72.9%). Around 20 patients were co-morbid. They had diabetes (8.4%), Hypertension (HTN) (1.9%), and COPD (3.7%), as indicated in **Table 1**.

Table 1. Socio-demographic characteristics Clinical Characteristics of new and relapsed Pulmonary Tuberculosis patients

Variables	Patients (%)
Gender	
Female	42 (39.3)
Male	65 (60.7)
Age (Years)	
≤ 15	4 (3.7)
16-25	9 (8.4)

26-35	34 (31.8)
36-45	20 (18.7)
46-55	24 (22.4)
56-65	10 (9.3)
≥ 66	6 (5.6)
Weight (kg)	
≤ 30	6 (5.6)
31-60	97 (90.7)
≥ 60	4 (3.7)
Residence	
Urban	27 (25.2)
Rural	80 (74.8)
Marital status	
Married	80 (74.8)
Unmarried	27 (25.2)
Smoking Habit	
Male	6 (5.6)
Female	1 (0.9)
Non-smoker	100 (93.5)
Snuff	
Male	13 (12.1)
Female	3 (2.8)
No	91 (85.0)
TB type	
Smear positive	42 (39.3)
Smear negative	65 (60.7)
Patient type	
New Patients	96 (89.7)
Relapse Patients	11 (10.3)
Chest X-ray	
Unknown	4 (3.7)
Clear	3 (2.8)
Lesion	100 (93.5)
Symptoms	
Sweat	
Yes	86 (80.4)
No	21 (19.6)
Cough	
Yes	63 (58.9)
No	44 (41.1)
Sputum	
Yes	92 (86.0)
No	15 (14.0)
Fever	
Yes	54 (50.5)
No	52 (48.6)
Shortness of Breath	
Unknown	5 (1.2)
Yes	92 (86.0)
No	15 (14.0)
Loss of Weight	
Yes	79 (73.8)
No	34 (31.8)
Loss of Appetite	
Yes	73 (68.2)
No	34 (31.4)
Hemoptysis	
Yes	78 (72.9)
No	29 (27.1)
Comorbidities	
TB only	87 (81.3)
Diabetes Miletus	9 (8.4)
Hypertension	2 (1.9)
Chronic obstructive pulmonary disease (COPD)	4 (3.7)
Hypertension and Diabetes Miletus	2 (1.9)
Other comorbidities	3 (2.8)

Treatment Outcome

Table 2 shows the percentage of patients in both successful and unsuccessful treatment outcome categories. The overall success rate for PTB treatment, including cured and treatment-completed cases, in district Bannu was 89 out of 107 patients (83.2%). Among the unsuccessfully treated patients, 2 (1.9%) patients expired, 7 (6.5%) patients transfer out and 9 (8.4%) patients were defaulters. Among all newly diagnosed smear-positive pulmonary tuberculosis (PTB) cases, 26 (24.3%) patients were cured and 63 (58.9%) patients completed the treatment.

Table 2. Treatment outcome of smear positive and smear negative Pulmonary Tuberculosis patients.

Variables	Patients (%)	Total
Treatment outcome		89 (83.2)
Successful treatment	63 (58.9)	
Cured	26 (24.3)	
Unsuccessful treatment		18 (16.8)
Treatment failure	0 (0.0)	
Patient Defaulter	9 (8.4)	
Transferred out	7 (6.5)	
Patient Expired	2 (1.9)	

Factors Associated with Unsuccessful Treatment Outcomes

Table 3 shows factors associated with unsuccessful TB treatment outcomes. Age, new TB patients, sweat, and cough were statistically significant related with the unsuccessful treatment outcome among EPTB patients. The odds of unsuccessful treatment outcomes were higher among patients with age group 36-45 years (AOR = 1.17 95% CL: .416-7.37) compared to the patients with another age group. This study also found that the odds of unsuccessful treatment were

higher among new EPTB patients (AOR = .180; 95%CL: .031-1.05) and the patients who showed symptoms of cough (AOR = 4.08; 95%CL: .867-19.24) and sweating (AOR = 0.335; 95%CL .130-.863).

Table 3. Unsuccessful treatment outcomes; Logistic regression.

Variables	Treatment outcome		Univariate analysis		Multivariate analysis	
Gender	**Success**	**Unsuccessful**	**OR (95%CL)**	**p-value**	**AOR (95%CL)**	**p-value**
Female	54 (50.5)	11 (10.3)				
Male	35 (32.7)	7 (6.5)	Referent 1.19 (.470-0.712)	0.712	-	-
Age (Years)						
≤ 15	4 (3.7)	0 (0.0)	Referent 0.000	0.999	-	-
16-25	8 (7.5)	1 (0.9)	Referent .320 (.037-2.74)	0.298	-	-
26-35	24 (22.4)	10 (9.3)	Referent .750 (.259-2.17)	0.59	-	-
36-45	16 (15.0)	4 (3.7)	Referent 3.05 (1.00-9.32)	**0.05**	Referent 1.17 (.416-7.37)	0.44
46-55	22 (20.6)	2 (1.9)	Referent 1.55 (.55-4.32)	0.397	-	-
56-65	9 (8.4)	1 (0.9)	Referent 0.667 (.129-3.44)	0.62	-	-
≥ 66	6 (5.6)	0 (0.0)	Referent 0.464 (0.52-4.17)	0.493	-	-
Weight (kg)						
≤ 30	5 (4.7)	1 (0.9)	0.000	0.99	-	-
31-60	81 (75.7)	16 (15.0)	Referent 3.12 (.365-26.76)	0.29	-	-
≥ 61	3 (2.8)	1 (0.9)	Referent 1.22 (.106-14.07)	0.87	-	-
Residence						
Urban	22 (24.7)	5 (4.7)	Referent 1.55 (.559-4.32)	0.39	-	-
Rural	67 (75.3)	13 (2.1)			-	-
Marital status						
Married	60 (56.1)	11 (10.3)	Referent 1.12 (.421-3.00)	0.814		
Unmarried	29 (27.1)	7 (6.5)			-	-
Smoking Habit						
Yes	4 (3.7)	3 (2.8)	Referent .514 (.279-.948)	0.03	-	-
No	85 (79.4)	15 (14.0)			-	-
Snuff						
Yes	14 (13.1)	2 (1.9)	Referent .800 (.079-8.16)	0.85	-	-
No	75 (70.1)	16 (15.0)			-	-
New TB case						
Yes	83 (77.6)	13 (12.1)	Referent .180 (.031-1.05)	**0.05**	Referent .297 (.023-3.33)	0.313
No	6 (5.6)	5 (4.7)				
Smear Type						
Positive						
Yes	33 (89.7)	9 (8.4)	0.000	0.999	-	-

No	56 (30.8)	9 (8.4)				
Chest X-ray						
Lesion						
Yes	83 (77.6)	17 (15.9)	0.000	0.999	-	-
No	6 (5.6)	1 (0.9)				
Symptoms						
Sweat						
Yes	71 (66.4)	15 (14.0)	Referent 4.08 (.867-19.24)	**0.07**	Referent 4.29 (.676-27.25)	0.123
No	18 (16.8)	3 (2.8)				
Cough						
Yes	51 (47.7)	12 (11.2)	Referent 0.335 (.130-.863)	**0.02**	Referent .434 (.143-1.31)	0.140
No	38 (35.5)	6 (5.6)				
Sputum						
Yes	77 (72.0)	15 (14.0)	Referent 2.26 (.460-11.13)	0.31	-	-
No	12 (11.2)	3 (2.8)				
Fever						
Yes	44 (41.1)	10 (9.3)	Referent 1.28 (.514-3.20)	0.59	-	-
No	45	8				
Shortness of Breath						
Yes	22 (20.6)	4 (3.7)	Referent .455 (.137-1.50)	0.197	-	-
No	67	14				
Loss of Weight						
Yes	66 (61.7)	13 (12.1)	Referent 0.703 (.255-1.94)	0.46	-	-
No	23 (21.5)	5 (4.7)				
Loss of Appetite						
Yes	60 (56.1)	13 (12.1)	Referent .879 (.334-2.31)	0.79	-	-
No	29 (27.1)	5 (4.7)				
Hemoptysis						
Yes	65 (60.7)	13 (12.1)	Referent 1.33 (.460-3.86)	0.59	-	-
No	24 (22.4)	5 (4.7)				
Comorbidities						
TB only	72 (67.3)	15 (14.0)	Referent 2.66 (.895-7.94)	**0.07**	0.391 (.139-1.1**)**	**0.075**
Diabetes Miletus	7 (6.5)	2 (1.9)	Referent .375 (.022-6.34)	0.49		
Hypertension	2 (1.9)	0 (0.00)	0.000	0.99	-	-
Chronic obstructive pulmonary disease (COPD)	4 (3.7)	0 (0.00)	1.5 (.055-40.63)	0.810	-	-
Hypertension and Diabetes Miletus	1 (0.9)	1 (0.9)	0.000	0.99	-	-
Other comorbidities	3 (2.8)	0 (0.00)	0.000	0.99	-	-

In current study, the rate of unsuccessful treatment was 16.8%, while the success rate for EPTB treatment stood at 83.2%. This indicates a suboptimal treatment success rate among EPTB patients in Pakistan. Our findings align with success rates reported in other regions, such as 86% in Bénin [10], 85.2% in southern Ethiopia [11], and 83% in Uzbekistan [12]. Whereas, study conducted in Ghana, argumented that extrapulmonary success rate was lower due to some condition like geriatric [13]. However, contrasting our results, a higher treatment success rate has been reported in China [14, 15]. In

our study, the overall treatment success rate for EPTB patients was less than the 90% WHO target. Comparably, success rates have also been reported by other countries with large tuberculosis burdens, including as Pakistan (71.1%) [16], India (74%) [17], and Somalia (81.8%) [18]. Variations in treatment outcomes can be attributed to factors such as sample size, study settings, patient facilities, adherence to medication, and local beliefs among EPTB patients.

The treatment failure rate in this study is 16.8%. Cases of patient noncompliance accounted for a significant portion of the unsuccessful outcomes, aligning with findings from parallel studies in Ukraine and Serbia [19, 20]. In this study, the main explanation for the unsuccessful treatment rate is patient default, a loss to follow-up due to transferring out, and patient expiry. Moreover, literature consistently reported on follow-up loss in tuberculosis patients with comorbid condition, adverse drug reactions, drug addiction, smoking, poor adherence are contributing factors towards poor treatment outcomes [21-26]. Additionally, the increased rate of loss to follow-up among TB patients may have led to the development of more complex and drug-resistant TB strains, ultimately resulting in higher mortality.

The majority of the EPTB patients were males (60.7%) which was consistent with other studies Uganda [27], and Ethiopia [11], Somalia [17], Ukrain [18], and Denmark [25]. The reason could be that men might be placed in social networks in such a way that they interact with a greater number of people or social groupings. The greater prevalence in males could also be attributable to biological processes that create differential susceptibility to TB.

A notable link was found between age, TB cases, symptoms, and co-morbidities. The prevalence of co-morbidities was higher in males; out of 107 patients in the study, 21 had various co-morbidities, with EPTB-DM and EPTB-COPD being the most common. Additionally, 2.8% of patients had EPTB-HEPATITIS, and 1.9% had EPTB-HTN. Diabetes was a major condition alongside PTB in our study. It has been reported that patients with diabetes-related co-morbidities faced a greater risk of poor outcomes and mortality [28]. In South-Eastern Iran, smoking, hepatitis, diabetes, anemia, and drug misuse were identified as predictors of TB mortality. These results suggest that TB programs should prioritize identifying high-risk groups for TB-related diseases and developing appropriate treatments to enhance treatment outcomes [29]. According to a real-world study, TB, smoking, COPD, and HIV have both detrimental and synergistic effects [30, 31].

The coexistence of TB and a baseline condition may promote disease progression and raise the risk of drug-drug interactions or side effects. Comorbidities were linked to a 1.9-fold increased chance of treatment failure, highlighting the need of identifying, monitoring, and treating comorbidities in patients getting TB treatment [22, 24, 25, 28, 31-33].

Multivariate analysis revealed that factors statistically linked to unsuccessful treatment outcomes included being in the 36-45 year age group, having new EPTB cases, and experiencing severe night sweating and cough. Patients aged 36-45 years had higher odds of unsuccessful treatment outcomes (AOR = 1.17, 95% CI: 0.416–7.37) compared to those in other age groups. This finding contrasts with study from Southern Ethiopia, where most patients were of working age (15-55 years). Although older patients in our study had lower treatment success rates than younger ones, this may be because treatment is often more complex and challenging in older EPTB patients. Additionally, cough and sweating were associated with unsuccessful treatment outcomes [34]. Patients aged less than 18 years were more likely to develop fever, night sweats, and hemoptysis, according to some studies [35, 36]. Dyspnea and weight loss may have been linked to a later stage of the disease, which has been impacted more by diagnostic delays, as well as poorer clinical outcomes.

Conclusion

This study highlights that the rate of unsuccessful treatment outcomes remains high, with an observed treatment success rate of 83.2%. By 2035, the WHO expects a 100% treatment success rate for EPTB patients in Pakistan. The current unsuccessful outcomes are attributed to factors such as loss to follow-up, defaulting, treatment failure, and mortality. A significant number of patients were lost to follow-up or died during therapy, raising serious concerns and calling for immediate action. In order to minimise treatment interruptions and trace patients who are lost to follow-up, effective tracing procedures should be established. To enhance their results, patients who are more likely to experience treatment failure should also have more oversight and monitoring.

These findings may not be fully applicable to the entire EPTB patient population across the country, given the unique demographics of DHQ Bannu, which serves TB patients from remote and rural regions. Due to the nature of the study and its methodological limitations, detailed clinical variables, drug side effects, and factors influencing loss to follow-up and mortality rates were not thoroughly examined.

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