Risk Factors for Treatment Failure Among Patients with Pulmonary Tuberculosis

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Abstract

Background: The treatment failure is a health and economic burden as the patient remains a source of infection in the community and it may lead to the development of multidrug resistance. **Aim:** To assess the risk factors associated with tuberculosis treatment failure among patients with pulmonary tuberculosis. **Research design:** Exploratory research was utilized. **Sample:** one hundred and ten adult male and female patients were diagnosed with treatment failure of pulmonary tuberculosis attend to the same setting and aged ranged from 20 to 65 years old. **Setting:** Chest diseases department & outpatient clinic at Assiut University hospital and chest hospital at Assiut city. **Tools:** Patient assessment sheet and Patient's Risk factors for treatment failure of pulmonary tuberculosis sheet. **Results:** show that majority of patient participants had poor knowledge about tuberculosis (86.4%), had inadequate nutrition (78.2%), poor adherence of oral medication (70%), and unsatisfied family support (54.5%) and poor health due to chronic disease (67.3%). **Conclusion:** Poor knowledge, oral medication adherence and family support are risk factors for treatment failure among patients with pulmonary tuberculosis. **Recommendations:** It is important to identify risk factors for treatment failure of pulmonary tuberculosis can be implemented and its preventive measures.

Keywords: Plumonary tuberculosis, Risk factors & Treatment failure.

Introduction

Pulmonary Tuberculosis is an acute or chronic infection caused by Mycobacterium tuberculosis. PTB is characterized by pulmonary infiltrates, the formation of granulomas with fibrosis and cavitation. The lungs are the most common site for the development of TB; 85% of patient diagnosed with TB present with pulmonary symptoms (Herchline et al., 2023).

People diagnosed with TB in most often by sputum smear and culture and when available by nucleic acid amplification test. The microbiological detection of TB is critical because it allows people to be correctly diagnosed. WHO-recommended bacteriological testing for TB confirmation of treatment failure. Sputum smear-negative TB cases with positive smear results at follow-up are the most prevalent ones (Abebe et al., 2019 & WHO, 2021).

One of the risks to TB control is treatment failure, which is defined as a patient who has a positive sputum smear or sputum culture five months or more after starting anti-TB treatment (**Charoensakulchai** et al., 2021).

The World Health Organization (WHO) recommends diagnosis of TB treatment failure in resource limited settings by sputum smear microscopy at 5 months or later during treatment. However, identification of those at risk of treatment failure is important before the 5 months in reducing TB spread, morbidity and mortality in affected individuals and may help in contributing to the achievement of the treatment targets. The ideal tool for this is frequent laboratory monitoring using sputum microscopy or culture (Asemahagn, 2021).

The most important causes of TB treatment failure of anti TB therapy is that the patient does not take the medication as prescribed and clinical improvement before completion of therapy (Endarti et al., 2018).

Positive HIV status, male, ethnicity, low body mass index (BMI), substance abuse, other co-morbidities (diabetes mellitus AND hypertension), prior treatment, DOTS clinics (directly observed treatments), drug resistance, low educational attainment, ignorance of treatment duration and importance, or failure to complete the 6-month course of anti-TB medications and lack of knowledge of the importance of sputum re-examinations, household income, medication side effects, lack of family support, and unsupervised treatment administration are some of the risk factors linked to TB treatment failure. (Shariff et al., 2019).

The current WHO guidelines for the treatment of drug-susceptible pulmonary TB have recommended a 6-month regimen comprising four first-line anti-TB drugs in the intensive phase (for 2 months) and two drugs in the continuation phase (for 4 months):2

of isoniazid/rifampicin/pyrazinamide/ months ethambutol and 4 months of isoniazid/rifampicin (2HRZE/4HR) Nurses play crucial roles in the management, care, and support of TB patients during the course of their treatment (Makhado, et al., 2018) and (Dartois, et al., 2022).

Operational definitions:

Risk factors: A variable linked to an elevated risk of illness or infection is known as a risk factor or determinant (parrtiz, et al., 2017).

Treatment failure: A person with treatment failure is defined as one whose treatment regimen needed to be terminated or permanently changed to a new regimen or treatment strategy. Reasons for such a change include no clinical or bacteriological response, adverse drug reactions (WHO, 2024).

Pulmonary tuberculosis: Pulmonary tuberculosis is a bacterial infection due to Mycobacterium tuberculosis, spread from person to person through inhalation of infected respiratory droplets (WHO, 2018).

Significance of study

From researcher clinical experience as Head nurse in chest hospital at Assiut city for four years, it is observed most of hospitalized patients suffer from inadequate information about management of pulmonary TB and treatment failure .So the study will be conducted to describe risk factors associated with TB treatment failure among patients with pulmonary TB.

Aims of the study

The aims of this study were:

To assess the risk factors associated with TB treatment failure among patients with pulmonary TB. **Research** question

What are the risk factors associated with TB treatment failure among patients with pulmonary TB?

Patients and Method

Research design:

A descriptive exploratory research design was utilized to carry out this study. Descriptive exploratory research might use a variety of data collection methods with the most common being questionnaires and interviews. It was a useful approach in research that had clear benefits in helping to describe and explore variables and constructs of interest (Jain, 2021).

Setting:

This study was conducted in the chest diseases department & outpatient clinic at Assiut University hospital and chest hospital at Assiut city.

Sample:

Inclusion criteria:

(110) adult patients were diagnosed with treatment failure of pulmonary TB attend to the same setting and aged ranged from 20 to 65 years old.

Exclusion criteria:

New cases of pulmonary TB less than 6 months.

Tools of data collection:

Two tools were developed by researcher for collecting the necessary data for this study .It was conducted after reviewing national and international literature under guidance of supervisors (Shariff et al., 2019).

Tool (I): Patient assessment sheet: used to assess patient's demographic data and medical data, it was divided into 2 parts:

Part 1: Patient's Demographic Data: The purpose of this part was to assess the patient's demographic data, (e.g.; age, sex, marital status, residence, level of education and occupation).

Part 2: Patient medical data: It included; medical diagnosis, present medical history included symptoms and signs (chest pain, shortness of breath, cough, night sweating, hemoptysis, night fever and weight loss) .past health history, smoking status (smoker or nonsmoker, cigarettes or goza), smoking degree (mild, moderate, severe), and allergy to certain medications. Routine laboratory investigations included (CBC, INR, liver function, kidney function, chest X-ray and chest CT, ECG and sputum analysis)

Tool (II): Patient's Risk factors for treatment failure of pulmonary TB sheet:

It was developed by researcher after review of current literatures (Nugrahaeni et al., 2021) to identify the risk factors associated with TB treatment failure among patients with pulmonary TB based on (6) variables included:

- 1. Knowledge about disease: Assess patient's knowledge about pulmonary tuberculosis; (Definition, Mode of transmission, signs and symptoms, treatment of TB, importance to finish TB treatment, duration of treatment, recurrence of TB after treatment, check-up during TB treatment, problem with TB medicine ,prevention TB from spreading ,most susceptible to tuberculosis) which included (20) questions.
- 2. Nutritional status of patient: (number of meals, types of foods, current weight and dietary restrictions, amount of water drunk daily, recent changes of weight) which included (8) questions.
- 3. Oral medication adherence: (name of medications, time of medications, missing doses, challenges during taking medications, information about medications and Patient's strategies for taking medications) which included (8) questions.

- **4. Family support:** (aware of family about TB diagnosis, understanding of family about TB diagnosis and treatment, family support for patients with TB) which included (7) questions.
- **5.** Chronic disease: (chronic diseases, medications of chronic diseases and lifestyle changes to manage chronic health conditions) which included (10) questions.
- **6. TB treatment failure:** (symptoms during TB treatment ,previous treatment of TB, patient's information about drug-resistant TB, previous TB treatment failure ,treatment adherence and any changes in health status or side effects of TB treatment) which included (10) questions.

Scoring system:

Scoring system for risk factors for each item, a correct response was scored one grade and the incorrect scored zero. Risk factors were deemed unsatisfactory if the percent score was less than 60% and satisfactory if the percent score was 60% or more after the item scores were totaled and converted to percentages (Fayaz et al., 2014).

(Unsatisfactory score < 60%, Satisfactory score \geq 60%).

Methods:

Field work:

Tools development:

Data collection tools were developed based on reviewing the current, past, local, and international related literature in various aspects using books, articles, periodicals, magazines, and references (Asemahagn, 2021), (Charoensakulchai et al., 2021), (Dartois, et al., 2022), (Herchline et al., 2023),(WHO, 2021).

Content validity and reliability:

Face validity was done by five specialists who evaluated the tools for clarity, relevance, applicability, and understanding, including four professors from the Medical-Surgical Nursing team and one professor from the chest Medicine department. Minor modifications were made, the necessary correction was done, and the tools were then designed in their final version and reliability tests were conducted.

Pilot study:

The pilot study included 10% of the study sample (11 patients) they were used to determine the tools' applicability and clarity as well to estimate time needed to fill in the data collection tools. The data from the pilot study were analyzed; no changes were made to the tools utilized, so the samples selected for the pilot study were involved in the study.

Reliability of the tool was measured by Cronbach's alpha coefficient (r-0.722).

Implementation:

- Permission was granted to proceed with the proposed study, the researcher-initiated data collection.
- The collection of data lasted over the period from June 2023 to March 2024.
- Data were obtained in three shifts(mooring , evening and night) from each patient undergoing were diagnosed with treatment failure of pulmonary TB attend to the chest diseases department & outpatient clinic at Assiut University hospital and chest hospital at Assiut city.
- During interview, the researcher introduced herself, described the study's goals, and received the patient's verbal consent to take part in the study on a voluntary basis.
- Each patient who participated in the study was interviewed individually, the questionnaire was filled by the researcher who asked the patients and documented their answer.

Ethical approval:

- Approval to conduct this study was given by the ethical committee (number 374) of the Assiut Faculty of Nursing at 24/3/2022.
- In order to obtain the required data, the Dean of the Faculty of Nursing sent a formal letter to the Head of the chest diseases Department and manager of chest hospital.
- Oral consent was gained from patients who were willing to participate after being informed about the study's nature and goals.
- The study sample was not in danger during the implementation of the research.
- The study adhered to standard ethical principles in clinical research. Anonymity and confidentiality were guaranteed.
- Patients had the right to decline from research participation at any time and/or withdraw from the study without giving a reason.

Statistically analysis:

The SPSS version 23 statistical software application was used to evaluate, code, analyze, and tabulate data. Frequencies and percentages were used as descriptive data. Qualitative data were reported as numbers and percentages (n, %). The mean and standard deviation (SD) of quantitative data were used. To analyze the association between two or more qualitative variables, the Chi square (χ 2) test was utilized. P-value ≤ 0.05 was established as the significant level.

Results

 Table (1): Frequency and distribution of the studied patients according to their demographic characteristics (n=110).

Variables	(N=110)	0/0	
Age			
Age 20-40yrs	56	50.9	
40-65yrs	54	49.1	
Means \pm SD	43.54 ± 13.69		
Gender			
Male	80	72.7	
Female	30	27.3	
Marital status			
Single	36	32.7	
Married	61	55.5	
Divorce	2	1.8	
Widow	11	10.0	
Educational level			
Illiterate	37	33.6	
Read and write	28	25.5	
Primary school	11	10.0	
Preparatory Secondary school	14	12.7	
Secondary school	13	11.8	
High educated	7	6.4	
Occupation			
Farmer	30	27.3	
Skilled worker	16	14.5	
Office	9	8.2	
Not working	23	20.9	
house work	15	13.6	
Student	1	.9	
Other	16	14.5	
Residence			
Rural	73	66.4	
Urban	37	33.6	

Table (2):Frequency and distribution of total patients risk factors for TB treatment failure (n=110).

Variables	(N=110)	%	
Patient's Knowledge			
Unsatisfactory knowledge	95	86.4	
Satisfactory knowledge	15	13.6	
Nutrition			
Unsatisfactory score $< 60\%$			
Satisfactory score $\geq 60\%$			
Inadequate	86	78.2	
Adequate	24	21.8	
Oral medication			
Unsatisfactory score $< 60\%$			
Satisfactory score $\geq 60\%$			
poor adherence	77	70.0	
good adherence	33	30.0	
Family support			
Unsatisfactory score < 60%			
Satisfactory score $\geq 60\%$			
Unsatisfied	60	54.5	
Satisfied	50	45.5	
Chronic disease			
Unsatisfactory score < 60%			
Satisfactory score $\geq 60\%$			
poor health	74	67.3	
good health	36	32.7	

Variables		TB treatment failure	
	(N=110)	%	
Symptoms during TB treatment	102	02.6	
Persistent cough	103	93.6	
Hemoptysis (coughing up blood)	10	9.1	
Weight loss	77	70.0	
Fatigue	81	73.6	
Fever	43	39.1	
Others (please specify):	5	4.5	
Rate of overall health status currently			
Fair	92	83.6	
Poor	18	16.4	
Previously treated for tuberculosis	12	10.9	
If yes, complete the full course of treatment	10	9.1	
Informed about drug-resistant TB and its implications	2	1.8	
If yes, describe what you understood?	2	1.8	
Any previous TB treatment failure	6	5.5	
Become aware that you might be experiencing treatment failure?			
I noticed persistent or worsening symptoms.	38	34.5	
My healthcare provider informed me.	32	29.1	
I experienced side effects that were concerning.	4	3.6	
Results from sputum analysis showed concerns.	8	7.3	
I'm not sure.	28	25.5	
The period after starting TB treatment were informed about the possibility of treat	nent failure		
Within the first month	10	9.1	
Within the first six months	57	51.8	
After six months	9	8.2	
I'm not sure	34	30.9	
Tested for drug-resistant TB as part of current or previous treatment			
No	73	66.4	
Yes	5	4.5	
Not sure	32	29.1	
How comfortable he felt during discussing treatment adherence and any challenges with	healthcare pr		
Somewhat comfortable	20	18.2	
A little comfortable	85	77.3	
Not comfortable at all	5	4.5	
any changes in health status or experienced side effects to healthcare provider	104	94.5	
during TB treatment		2	

Table (3): Frequency and distribution of the studied patients TB treatment failure (n=110)

 Table (4): Relation between demographic data and patients risk factors for TB treatment failure(110)

Variables	Unsatisfacto	Unsatisfactory knowledge		Satisfactory knowledge	
	Ν	%	N	%	
Knowledge					
20-40yrs	44	40.0	12	10.9	X2:
40-65yrs	51	46.4	3	2.7	5.881 P=.024
Educational level					
Illiterate	32	29.1	5	4.5	
Read and write	26	23.6	2	1.8	
Primary school	8	7.3	3	2.7	X2:
Preparatory	14	12.7	0	0.0	26.855 P=.001
Secondary school	13	11.8	0	0.0	
High educated	2	1.8	5	4.5	
Occupation					
Farmer	28	25.5	2	1.8	X2: 20.987 P=.002**
Skilled worker	12	10.9	4	3.6	
Office	4	3.6	5	4.5	
Not working	22	20.0	1	0.9	
House work	15	13.6	0	0.0	
Student	1	0.9	0	0.0	
Other	13	11.8	3	2.7	

Table (1): Shows that the mean age of the studied patients was (43.54 ± 13.69) years. Most of the patients were males (72.7%); the majority of them were married, illiterate and lived in rural areas (55.5%, 33.7%) and 66.4%, respectively).

Table (2): Show that majority of patient participants had unsatisfactory knowledge about TB (86.4%), had inadequate nutrition (78.2%), poor adherence of oral medication (70%), and unsatisfied family support (54.5%) and poor health due to chronic disease (67.3%).

Table (3): Show that as regard the clinical presentation of symptoms during TB treatment failure, the majority of patients had a cough (93.6%), fatigue (73.6%) and weight loss (70%). The majority of them had expectoration (87.5%). And nearly (6%) had previous TB treatment failure. Half of them were informed about the possibility of treatment failure within the first six months after starting TB treatment. Majority of patient participants been tested for drug-resistant TB as part of your current or previous treatment and reported any changes in your health status (77.3%, 94.5% respectively).

Table (4): Shows that there was a statistically significant difference between and risk factors of TB treatment failure and demographic data.

Discussion

One of the leading causes of death in poor nations is tuberculosis. The complicated process of treating tuberculosis necessitates the six-month administration of a panel of at least four antimicrobial medications. A major medical issue arises when a conventional course of treatment is followed by treatment failure (**Mushtaq et al.**, **2023**).

Despite the existence of effective medications, pulmonary tuberculosis (PTB) remains a significant global public health concern, the evaluation and feedback of national TB control programs are crucial, requiring diligent monitoring of TB treatment outcomes and analysis of the factors influencing these outcomes. (Al Osaimi et al., 2024) Thus, the present study aimed to describe the risk factors for treatment failure among patients with pulmonary tuberculosis.

Regarding demographic characteristics of patients with TB failure, this study revealed that the mean age of the studied patients was (43.54 ± 13.69) years, the majority of them were males, married, illiterate and lived in rural areas .These findings are congruent with (**Arsad et al., 2022**) who found that the mean age was 42.84 ± 16.579 and most of the patients were males. Additionally (**Neves et al., 2022**) who reported that the more than half of patients with treatment failure were males and their ages between 25 to 44 yrs old. Also (**Tok et al.**, **2020**) who reported that Unsuccessful TB treatment outcomes were founded to be associated with older age, males, & lower education levels (illiterate). Also Egyptian survey of (**Hammouda et al., 2023**) reported that highest percentage were males , married and illiterate.

From researcher points' of view, These results can be explained as weakened immune systems, agerelated comorbidities in older age, lack awareness about TB, its transmission, or the importance of strict adherence to treatment protocols in illiterate & behavioral factors like greater engagement in highrisk activities, which impair treatment success and increase treatment failure in these groups. This highlight the importance of targeted interventions to improve TB treatment outcomes in these vulnerable groups.

On the contrary of **Teferi et al.**, (2021) who reported high percent of treatment failure was between females, age of 25-34yrs and urban. This might be due to difference between the current study and (**Teferi et al.**, 2021) in study place and geographical area.

Concerning Previous TB treatment failure, the current study revealed that few number that had previous TB treatment failure, half of them were informed about the possibility of treatment failure with in the first six months after starting TB treatment and the majority of patients have been tested for drug-resistant TB as part of current or previous treatment and reported any changes in their health status. This is in contrary with (Gilmour et al., 2022) who reported that a history of TB treatment failure was a significant risk factor of TB treatment failure.

Regarding patient knowledge about TB, the current study revealed that majority of patient participants had unsatisfactory knowledge about TB. This result is in the same line with (AlOsaimi et al., 2024) who reported that, patients with treatment failure often unsatisfactory knowledge about TB, which can contribute to poor adherence and outcomes, highlighting the need for enhanced education and support during treatment. Also (Nugrahaeni et al., 2021) who reported that unsatisfactory patient knowledge about tuberculosis significantly correlates with treatment failure, as patients lacking understanding of medication and disease management are at a higher risk of non-compliance and poor outcomes. Also in the same line with (Purgiantari et al., 2022) who reported that satisfactory knowledge levels about tuberculosis significantly correlate with better compliance to treatment, potentially reducing the risk of treatment failure among patients.

This result can be explained as patients had unsatisfactory knowledge about the importance of completing the full course of TB treatment, they may prematurely discontinue their medication once they feel better, leading to incomplete treatment and potential drug resistance. This, in turn, increases the likelihood of treatment failure.

Regarding the relation between demographic data and patient knowledge regarding TB, there was a statistically significant between patient knowledge regarding TB and educational level, occupation. This result agree with (Muttagin et al., 2023) who found significant correlations exist between knowledge levels about TB and demographic factors such as gender, age, occupation, and education. Also supported with (Maharani et al., 2022) who reported that, demographic factors like employment status and family income influence knowledge about TB, with higher education correlating to better understanding, thereby reducing the risk of pulmonary TB treatment failure. Furthermore (Boah et al., 2021) reported that age, gender, education, place of residence, and occupation significantly correlate with knowledge regarding TB transmission and cure, influencing awareness and misconceptions among the population.

Conclusions:

According to the results of this present study, regarding risk factors of studied patients; the majority of studied patients had unsatisfactory level of knowledge about TB, had inadequate nutrition, poor adherence of oral medication, unsatisfied family support and poor health due to chronic disease.

Regarding risk factors of the studied patients; most risk factors for treatment failure for TB were unsatisfactory level of knowledge, oral medication adherence and family support.

Recommendation:

In the light of the findings of the current study the following recommendation were suggested:-

- 1. Educational programs for promoting awareness of patients with Pulmonary Tuberculosis about importance of adequate nutrition, adherence to oral medication &family support.
- 2. Continues educational guidelines and health education programs for nurses and medical teams who work with TB patients to improve patient self-care and self-efficacy and decrease the burden level of the disease.

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