TITLE

Clinical Characteristics and Treatment Outcomes of Patients with Tuberculosis in Northern State, Sudan: A Retrospective Observational Study

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Background

Tuberculosis (TB) remains one of the world's leading infectious diseases and continues to be a major cause of morbidity and mortality despite the availability of effective diagnostic methods and curative treatment. According to the World Health Organization (WHO), tuberculosis is among the top causes of death from a single infectious agent, particularly in low- and middle-income countries where healthcare systems face significant challenges. In 2023, an estimated 10.8 million people developed TB globally, highlighting the persistent public health burden of the disease.[1]

Tuberculosis is caused by Mycobacterium tuberculosis and is transmitted primarily through airborne droplets. Although pulmonary tuberculosis (PTB) is the most common form and the principal source of transmission, extrapulmonary tuberculosis (EPTB) also contributes substantially to morbidity and may affect almost any organ system. Early diagnosis and prompt initiation of appropriate anti-tuberculosis treatment are essential to improve patient outcomes, interrupt disease transmission, and prevent the emergence of drug-resistant tuberculosis.[2]

The African Region continues to carry a disproportionate share of the global tuberculosis burden due to factors such as poverty, malnutrition, HIV infection, limited access to healthcare services, delayed diagnosis, and inadequate treatment adherence. Sudan is recognized as one of the countries with a substantial TB burden, and tuberculosis remains a significant public health concern despite the implementation of the National Tuberculosis Control Programme (NTCP), which follows WHO-recommended strategies for diagnosis, treatment, and surveillance.[3]

Several demographic and clinical factors, including age, sex, residence, HIV co-infection, diabetes mellitus, smoking, previous tuberculosis treatment, and diagnostic delay, have been reported to influence treatment outcomes among patients with tuberculosis. Identifying these factors is essential for improving treatment success rates and reducing mortality, treatment failure, and loss to follow-up.[4]

Northern Sudan has unique geographical and healthcare characteristics that may influence tuberculosis diagnosis, clinical presentation, and treatment outcomes. However, there is limited published evidence describing the clinical characteristics of tuberculosis patients and evaluating treatment outcomes in this region. Most available studies have been conducted in other regions of Sudan, leaving an important gap in locally generated evidence for Northern Sudan.

Rationale

Understanding the clinical characteristics and treatment outcomes of tuberculosis patients in Northern Sudan is essential for evaluating the performance of tuberculosis control programmes and identifying areas that require improvement. This study will provide updated local evidence on patient characteristics, diagnostic practices, treatment outcomes, and factors associated with unsuccessful treatment outcomes.

The findings are expected to assist the National Tuberculosis Control Programme, healthcare providers, and public health authorities in strengthening tuberculosis prevention and control strategies, improving patient management, and optimizing resource allocation. Furthermore, this study will contribute to the existing literature on tuberculosis in Sudan and provide baseline data for future clinical and epidemiological research.

Problem Statement

Tuberculosis (TB) remains a major public health challenge worldwide, particularly in low- and middle-income countries, where it continues to cause significant morbidity and mortality despite the availability of effective diagnostic tools and standardized treatment regimens. Although the World Health Organization (WHO) and national tuberculosis control programmes have made considerable progress in expanding access to TB diagnosis and treatment, treatment outcomes remain suboptimal in many settings due to delayed diagnosis, comorbidities, poor treatment adherence, and health system challenges.

In Sudan, tuberculosis continues to represent a significant public health concern. The National Tuberculosis Control Programme (NTCP) has implemented WHO-recommended strategies for case detection and treatment; however, regional variations in disease burden, healthcare accessibility, patient characteristics, and treatment outcomes are not fully understood. These variations may influence the effectiveness of TB control interventions and highlight the need for region-specific evidence.

Despite the importance of Northern Sudan in the national healthcare system, there is limited published evidence describing the clinical characteristics of tuberculosis patients and evaluating their treatment outcomes in this region. Furthermore, data on factors associated with unsuccessful treatment outcomes remain scarce, limiting the ability of healthcare providers and policymakers to develop targeted interventions for improving tuberculosis care and control.

Therefore, this study aims to assess the clinical characteristics and treatment outcomes of patients with tuberculosis in Northern Sudan and to identify factors associated with unsuccessful treatment outcomes. The findings will provide locally relevant evidence to support clinical practice, strengthen the National Tuberculosis Control Programme, and contribute to future tuberculosis research in Sudan.

Research Question

What are the clinical characteristics, treatment outcomes, and factors associated with unsuccessful treatment outcomes among patients with tuberculosis in Northern State, Sudan?

Objectives

General Objective

To assess the clinical characteristics, treatment outcomes, and factors associated with unsuccessful treatment outcomes among tuberculosis patients in Northern State, Sudan.

Specific Objectives

- Describe the socio-demographic characteristics of tuberculosis patients.
- Describe the clinical characteristics of tuberculosis patients.
- Determine the distribution of pulmonary and extrapulmonary tuberculosis.
- Describe the diagnostic methods used for tuberculosis diagnosis.
- Determine tuberculosis treatment outcomes.
- Identify factors associated with unsuccessful treatment outcomes.

Hypothesis

Null hypothesis (H_0):

There is no significant association between patients' characteristics and unsuccessful tuberculosis treatment outcomes.

Alternative hypothesis (H_1):

One or more patient characteristics are significantly associated with unsuccessful tuberculosis treatment outcomes.

Literature Review

Tuberculosis (TB) remains one of the leading causes of morbidity and mortality worldwide despite the availability of effective chemotherapy. Numerous studies have investigated the clinical characteristics of TB patients and evaluated treatment outcomes in different populations. Reviewing these studies provides valuable insight into disease patterns, determinants of treatment success, and existing knowledge gaps relevant to the present study.

Systematic Review:

In Sudan, Badawi et al. (2024) conducted a systematic review and meta-analysis to evaluate the epidemiology of tuberculosis across the country. The review included 26 published studies from different Sudanese states, including Northern State. The authors reported considerable regional variation in TB prevalence and identified male sex and rural residence as important factors associated with tuberculosis. They concluded that Sudan requires more comprehensive epidemiological studies to better understand tuberculosis distribution and improve control strategies. Although the review summarized available evidence, it did not specifically evaluate the clinical characteristics and treatment outcomes of patients in Northern State, highlighting an important knowledge gap.

International Studies

In **Singapore**, Low et al. conducted a retrospective cohort study evaluating tuberculosis treatment outcomes among adult patients receiving anti-tuberculosis therapy. The study demonstrated a high treatment success rate among patients who completed directly observed treatment, whereas advanced age, HIV infection, and multidrug-resistant tuberculosis were associated with poor outcomes. The authors emphasized the importance of early diagnosis and strict adherence to treatment protocols.

In Ethiopia, Tola et al. performed a. retrospective study among patients receiving tuberculosis treatment in public health facilities. The researchers reported an overall treatment success rate exceeding 85%. However, unsuccessful treatment outcomes were significantly associated with HIV co-infection, retreatment cases, and delayed diagnosis. The study recommended strengthening patient follow-up and adherence programs.

In China, Zhang et al. evaluated the clinical. characteristics and treatment outcomes of pulmonary tuberculosis patients in a tertiary hospital. Their findings showed that fever, persistent cough, weight loss, and hemoptysis were the most common presenting symptoms. Patients with diabetes mellitus and elderly patients experienced less favorable treatment outcomes compared with younger patients without comorbidities.

Literature Review

Regional Studies

In Ethiopia, Gebrezgabiher et al. assessed treatment outcomes among tuberculosis patients attending public hospitals. The investigators reported satisfactory treatment success rates but identified HIV infection, delayed treatment initiation, and poor treatment adherence as major predictors of unsuccessful outcomes.

In Egypt, El Mahallawy et al. evaluated the clinical presentation and treatment outcomes of pulmonary tuberculosis patients. The study found that chronic cough, fever, and weight loss were the predominant clinical manifestations. Most patients responded favorably to standard anti-tuberculosis therapy; however, patients with chronic diseases experienced relatively poorer treatment outcomes.

National Studies (Sudan)

In River Nile State, Elmadhoun et al. conducted a retrospective descriptive study involving tuberculosis patients registered in TB management centers. The study described patients' demographic and clinical characteristics and reported generally favorable treatment outcomes. Nevertheless, treatment interruption and loss to follow-up remained important challenges affecting overall treatment success.

In Khartoum State, Ali et al. investigated factors associated with treatment default among tuberculosis patients. The study demonstrated that poor treatment adherence was associated with socioeconomic difficulties, inadequate patient education, and limited access to healthcare services. The authors recommended strengthening patient counseling and follow-up systems.

Another study conducted in Khartoum State evaluated childhood tuberculosis and found that delayed diagnosis and extrapulmonary tuberculosis were common among pediatric patients. The authors emphasized the need for earlier diagnosis and improved clinical surveillance to reduce complications.

Research Gap

The reviewed literature indicates that several international, regional, and Sudanese studies have investigated tuberculosis epidemiology and treatment outcomes. However, most Sudanese studies have focused on specific states such as River Nile and Khartoum or have addressed prevalence and risk factors rather than providing a comprehensive assessment of clinical characteristics and treatment outcomes. Furthermore, although the recent systematic review by Badawi et al. (2024) summarized tuberculosis research conducted in Sudan, it highlighted the need for additional studies to strengthen the available evidence.
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To the best of current knowledge, there is limited recent evidence specifically addressing the clinical characteristics and treatment outcomes of tuberculosis patients in Northern State, Sudan. Therefore, the present study aims to fill this gap by providing updated evidence that may support tuberculosis control programs and improve patient management within the state.

Study Justification

This study will provide updated evidence regarding the clinical characteristics and treatment outcomes of tuberculosis patients managed within routine NTCP services in Northern Sudan. Furthermore, identifying factors associated with unsuccessful treatment outcomes may contribute to improving patient management, strengthening TB control strategies, and supporting evidence-based decision-making by health authorities. The findings will also enrich the limited scientific literature on tuberculosis in Sudan and provide a foundation for future clinical and epidemiological research

Methodology

Study Design

This study will be a retrospective hospital-based observational study conducted using routinely collected tuberculosis records from participating tuberculosis diagnostic and treatment centres.

Study Area

The study will be conducted in Northern State, Sudan. Data will be collected from tuberculosis diagnostic and treatment centres operating under the National Tuberculosis Control Programme (NTCP), subject to the availability of eligible patient records.

Study Period

The study will include all eligible patient records available during a predefined study period. The exact start and end dates will be finalized after confirming the availability, completeness, and consistency of records across participating tuberculosis centres before data extraction.

Study Duration

The study is expected to be completed within approximately 11 weeks, including protocol development, ethical approval, data collection, data cleaning, statistical analysis, interpretation of findings, and report writing.

Study Population

The study population will comprise all patients diagnosed with tuberculosis and registered for anti-tuberculosis treatment at participating tuberculosis diagnostic and treatment centres under the National Tuberculosis Control Programme in Northern State during the predefined study period. Both pulmonary and extrapulmonary tuberculosis patients will be included

Methodology

Sample Size

A total enumeration (census sampling) approach will be used. All eligible tuberculosis patient records available during the predefined study period will be included in the study. The final sample size will be determined after assessing the availability and completeness of records. If the number of eligible records is found to be impractical for complete review, an appropriate sample size calculation and probability sampling technique will be considered before data collection begins.

Sampling Technique

Initially, a total enumeration (census sampling) technique will be employed whereby all eligible tuberculosis patient records within the predefined study period will be reviewed. If complete enumeration is not feasible after record assessment, the sampling technique will be revised accordingly with appropriate methodological justification.

Eligibility Criteria

Inclusion Criteria:

The study will include:

1. Patients diagnosed with pulmonary tuberculosis, extrapulmonary tuberculosis, or both according to the diagnostic criteria applied by the National Tuberculosis Control Programme.
2. Patients registered for anti-tuberculosis treatment at participating tuberculosis centres during the predefined study period.
3. Patients of all ages and both sexes.
4. Records containing sufficient information to confirm patient eligibility and determine the final treatment outcome

Exclusion Criteria:

The following records will be excluded:

Duplicate patient records.

Records that do not permit confirmation of tuberculosis diagnosis or registration for treatment.

Records with insufficient information to determine the final treatment outcome.

Illegible or severely incomplete records that prevent reliable data extraction.

Patients registered outside the predefined study period.

Methodology

Management of Missing Data

Records with missing information on non-essential variables will not be excluded from the study. Any unavailable or undocumented variable will be recorded as "Not recorded" or treated as missing data during statistical analysis. The extent of missing data will be reported where appropriate, and undocumented variables will not be assumed to be absent.

Time Table

The duration of the search will be about Six months, due to the conditions of the undergraduate exams for the Faculty of Medicine, Dongola University, pediatrics and internal medicine.

Phase	Estimated time
Proposal writing	month
Data collection	2 month
Data entry	month
Data analysis	month
Report writing	month

Budget Estimate

Items	Estimate Cost
Printing	600, 000
Transportation (internal-external)	1, 000,000
Living (outside state limits)	300,000
Communication (Internet - Calls)	150,000
Data Entry and Data analysis	300,000
Contingency	200,000
Total	**2,550, 000**