

CLINICAL PROFILE, TREATMENT OUTCOMES, AND ADVERSE REACTIONS IN EXTRAPULMONARY TUBERCULOSIS: A PROSPECTIVE OBSERVATIONAL STUDY FROM A TERTIARY CARE CENTRE IN SOUTH INDIA

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ABSTRACT

Background: Extrapulmonary tuberculosis (EPTB) remains a significant diagnostic and therapeutic challenge due to its diverse clinical manifestations and paucibacillary nature. Data regarding the clinical spectrum and treatment outcomes of EPTB in South India remain limited. The Objective is to evaluate the clinical profile of patients with EPTB, assess treatment outcomes following anti-tubercular therapy (ATT), and analyses significant adverse reactions associated with treatment. **Materials and Methods:** A prospective observational study was conducted in the Department of General Medicine, Government Medical College, Kozhikode, Kerala, from October 2023 to October 2024. Fifty-four patients aged ≥ 12 years diagnosed with EPTB according to National Tuberculosis Elimination Programme (NTEP) guidelines were included. Patients with pulmonary tuberculosis and HIV infection were excluded. Demographic characteristics, clinical features, diagnostic modalities, treatment responses, and ATT-related adverse reactions were analysed. **Results:** The mean age of participants was 50.26 years, with males accounting for 61.1% of cases. As the study was done in an in patient setting of a tertiary care centre, the most common forms of EPTB were tuberculous meningitis/tuberculoma (20.4%) and skeletal tuberculosis (18.5%). Constitutional symptoms, particularly fever, weight loss, and loss of appetite, were observed in 72.2% of patients. Diabetes mellitus and hypertension were common comorbidities. Microbiological confirmation was achieved in only 38.9% of cases, whereas radiological and histopathological evidence played a major role in diagnosis. Treatment outcomes were favourable, with the majority of patients demonstrating symptomatic improvement at six months. ATT-induced hepatitis emerged as the most frequent adverse reaction. **Conclusion:** EPTB continues to pose substantial diagnostic challenges, necessitating a multidisciplinary diagnostic approach integrating clinical, radiological, microbiological, and histopathological evidence. Despite limited microbiological confirmation, treatment outcomes were generally favourable. Routine monitoring for ATT-induced hepatotoxicity is essential for improving patient safety.

INTRODUCTION

Tuberculosis remains one of the leading infectious causes of morbidity and mortality worldwide. While pulmonary tuberculosis receives greater attention because of its transmissibility, extrapulmonary tuberculosis (EPTB) contributes significantly to disease burden and frequently presents diagnostic difficulties. EPTB may involve virtually any organ system, resulting in varied and often non-specific clinical manifestations.^[1] The diagnosis of EPTB is

particularly challenging due to the low bacillary load in affected tissues, resulting in poor microbiological yield. Consequently, clinicians frequently depend on radiological findings, histopathological examination, and clinical judgement. Understanding the spectrum of EPTB and its treatment outcomes is essential for improving patient care and optimizing resource utilization in high-burden countries such as India.^[2] This study aimed to describe the clinical characteristics, diagnostic patterns, treatment responses, and adverse reactions among patients with

EPTB managed at a tertiary care teaching hospital in South India.

MATERIALS AND METHODS

Study Design and Setting: This prospective observational study was conducted in the Department of General Medicine, Government Medical College, Kozhikode, Kerala, over a one-year period from October 2023 to October 2024.

Study Population: Patients aged 12 years and above admitted in General Medicine wards with a diagnosis of extrapulmonary tuberculosis according to the National Tuberculosis Elimination Programme (NTEP) guidelines were included in the study. Patients with pulmonary tuberculosis and HIV infection were excluded. Consecutive eligible patients presenting during the study period were enrolled after obtaining informed consent.

Data Collection: Detailed demographic characteristics, clinical features, duration of symptoms, comorbid illnesses, laboratory investigations, radiological findings, microbiological evidence, histopathological findings, treatment responses, and adverse reactions related to anti-tubercular therapy were recorded using a structured proforma.

Outcome Measures

The primary outcome was assessment of the clinical profile of patients with extrapulmonary tuberculosis. Secondary outcomes included evaluation of treatment response following initiation of ATT and assessment of significant adverse reactions occurring during therapy. Patients were followed up at three and six months after initiation of treatment.

Statistical Analysis

Data were entered into Microsoft Excel and analysed using Statistical Package for Social Sciences (SPSS) software. Continuous variables were expressed as mean $\pm$ standard deviation and categorical variables as frequencies and percentages. Associations between categorical variables were assessed using Chi-square test or Fisher's exact test wherever appropriate. A p-value less than 0.05 was considered statistically significant.

RESULTS

A total of 54 patients diagnosed with extrapulmonary tuberculosis were included in the study. The mean age of the study population was 50.26 years. Males constituted 61.1% of cases

Table 1

Age Group	Frequency (n)	Percentage (%)
14–30 years	6	11.1
31–45 years	11	20.4
46–60 years	22	40.7
61–80 years	15	27.8
Total	54	100.0

Constitutional symptoms such as fever, weight loss, and loss of appetite were observed in 72.2% of patients and represented the most common presenting manifestations. Diabetes mellitus was the most common comorbidity, followed by hypertension. Tuberculous meningitis/tuberculoma was the most common form of EPTB (20.4%), followed by skeletal tuberculosis (18.5%). Other manifestations included abdominal tuberculosis, pleural tuberculosis, lymphadenitis, genitourinary tuberculosis, pericardial tuberculosis, and choroidal tuberculosis. Number of pleural effusion and lymphadenitis were low because of the patient selection. Most of those patients were managed on an OPD basis of from department of Pulmonology.

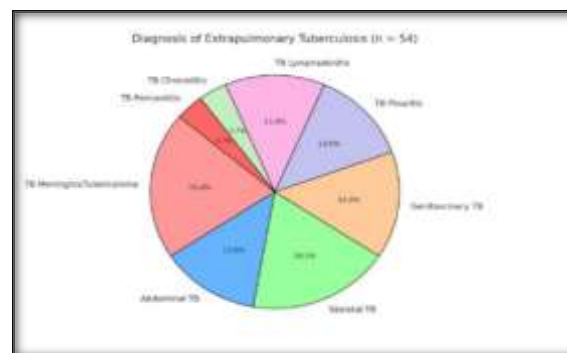


Figure 1

Microbiological confirmation was achieved in only 38.9% of cases. In the remaining patients, diagnosis was established through a combination of clinical findings, radiological evidence, and histopathological examination, highlighting the diagnostic challenges associated with the paucibacillary nature of EPTB.



Figure 2

Table 2: Distribution of Patients According to Clinical Outcome and Complications

Microbiological Evidence	Treatment Responses at 6 Months		Total (n)	OR (95% CI)	Chi-square	p-value
	Symptoms Present	Resolution of Symptoms				
Yes	2 (11.1%)	16 (88.9%)	18	1.375	0.110	0.740
No	3 (8.3%)	33 (91.7%)	36	(0.209–9.067)		

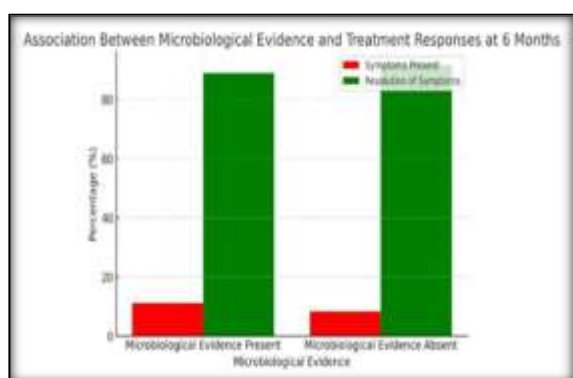


Figure 3

Significant adverse reactions were observed in 44.4% of patients during the first three months of treatment. Among the 54 study participants, significant adverse reactions requiring modification or interruption of anti-tubercular therapy (ATT) were observed in 24 patients (44.4%) at 3 months of follow-up. ATT-induced hepatitis was the predominant adverse reaction, occurring in 22 (91.6%) of the 24 patients who developed significant adverse reactions. Visual disturbances were reported in 6 patients (25.0%); of these, 4 had isolated visual disturbances, while 2 had concomitant ATT-induced hepatitis. Thus, the overall incidence of ATT-induced hepatitis at 3 months was 22/54 (40.7%), while visual disturbances occurred in 6/54 (11.1%) patients.

Between 3 and 6 months of follow-up, significant adverse reactions were observed in only 5 patients (9.3%), representing a substantial reduction compared with the 3-month assessment. Among these 5 patients, ATT-induced hepatitis remained the most frequent adverse reaction, occurring in 4 (80.0%) patients, while visual disturbance was observed in 1 (20.0%) patient.

Overall, the findings demonstrate that significant adverse reactions to ATT were considerably more frequent during the first 3 months of treatment and decreased substantially during the subsequent 3 months. Although minor gastrointestinal symptoms,

Treatment outcomes were favourable. Most patients showed symptomatic improvement at three months, with further clinical improvement and symptom resolution observed at six months following initiation of ATT. No statistically significant association was found between microbiological confirmation and treatment response.

including nausea, vomiting, and dyspepsia, were reported by approximately 62% of participants, these were not considered significant adverse reactions unless they necessitated a change in ATT. Other adverse reactions, including peripheral neuropathy, skin rashes, and thrombocytopenia, were not observed in the study population.

Regarding treatment outcomes, at the end of the 6-month follow-up period, 52 of the 54 participants (96.3%) remained alive, while 2 patients (3.7%) had died. Thus, despite the occurrence of significant ATT-related adverse reactions, particularly hepatotoxicity during the early phase of treatment, the overall 6-month survival in the study population was good, with the vast majority of patients completing follow-up.

Patients with microbiological confirmation had a lower incidence of adverse reactions compared with those without microbiological evidence. However, this association was not statistically significant.

DISCUSSION

The present study evaluated the clinical profile, treatment outcomes, and adverse reactions among patients with extrapulmonary tuberculosis managed at a tertiary care centre in South India.

The mean age of 50.26 years and male predominance observed in our study are comparable to findings reported in previous Indian studies. Tuberculous meningitis/tuberculoma was the most common form of EPTB, followed by skeletal tuberculosis. As we took only hospitalised patients, number of TB Lymphadenitis would have been under-estimated as most of lymphadenitis are treated on OPD basis. The predominance of neurological and skeletal tuberculosis may reflect referral patterns to tertiary care institutions where more severe and complicated cases are commonly managed.^[3,5]

Constitutional symptoms such as fever, weight loss, and anorexia were highly prevalent among study participants, reflecting the systemic nature of

tuberculosis. Diabetes mellitus and hypertension were frequently encountered comorbidities, emphasizing the importance of screening high-risk populations.

A major finding of this study was the low rate of microbiological confirmation. Only 38.9% of patients had definitive microbiological evidence of disease. This observation is consistent with previous studies and highlights the diagnostic limitations encountered in EPTB. Consequently, diagnosis often depends on a multidisciplinary approach incorporating clinical assessment, imaging studies, histopathology, and therapeutic response.

Treatment outcomes were generally favourable, with most patients demonstrating significant clinical improvement following initiation of ATT. The patients diagnosed through clinical, radiological, and histopathological criteria can achieve outcomes comparable to those with microbiologically confirmed disease.^[3]

ATT-induced hepatitis emerged as the most important adverse reaction encountered during follow-up. Hepatotoxicity remains a major challenge during anti-tubercular treatment and emphasizes the need for baseline and periodic liver function monitoring. Early recognition and appropriate management are essential to prevent treatment interruption and improve outcomes.^[4]

Although patients with microbiological confirmation demonstrated a lower incidence of adverse reactions, the association did not achieve statistical significance. Further studies involving larger patient populations are necessary to clarify this relationship. The strengths of the present study include its prospective design and systematic follow-up of patients. However, the relatively small sample size, single-centre nature of the study, and limited duration of follow-up restrict the generalizability of the findings. Long-term outcomes and relapse rates were not evaluated.

CONCLUSION

Extrapulmonary tuberculosis remains a significant diagnostic challenge because of its diverse clinical manifestations and low rates of microbiological confirmation. Only 38.9% of cases achieved microbiological confirmation, emphasizing the continued reliance on clinical, radiological, and histopathological evidence for diagnosis.

Despite these diagnostic challenges, treatment outcomes following anti-tubercular therapy were favourable in the majority of patients. ATT-induced hepatitis was the most frequent significant adverse reaction, underscoring the importance of routine liver function monitoring. A multidisciplinary diagnostic strategy integrating clinical, radiological, microbiological, and histopathological evidence remains essential for optimal management of extrapulmonary tuberculosis.

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