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Defining the end point of drug therapy in tuberculosis of the spine

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ABSTRACT

Background: Tuberculosis (TB) of the spine (Pott's disease) remains one of the most common forms of skeletal tuberculosis and is an important cause of pain, neurological deficits, spinal deformity, and long-term disability, particularly in developing countries. Although antitubercular therapy (ATT) is the cornerstone of treatment, the optimal endpoint for discontinuing therapy remains controversial because clinical recovery, laboratory improvement, and radiological healing often occur at different stages. This study evaluated the clinical, laboratory, and radiological parameters used to determine the endpoint of ATT in patients with spinal TB.

Methods: A retrospective observational study was conducted in the Department of Orthopaedics at Padmini Care Hospital, Tangi, Cuttack, Odisha, India, between October 2022 and May 2024. Medical records of 50 patients with spinal TB who completed standard first-line ATT were reviewed. Clinical improvement, neurological status, inflammatory markers (erythrocyte sedimentation rate [ESR] and C-reactive protein [CRP]), and serial radiological findings were analyzed to identify reliable indicators for treatment completion. Statistical analysis was performed using paired Student's t-test and Chi-square test, with $p<0.05$ considered statistically significant.

Results: The mean age of the patients was 42.8±13.1 years, with males comprising 62.0% of the study population. Significant clinical improvement was observed during treatment, with mean visual analogue scale pain scores decreasing from 7.8±1.1 to 2.1±0.9 ($p<0.001$). Neurological improvement occurred in 75.0% of patients with baseline neurological deficits. Mean ESR decreased from 63.5±17.2 mm/hour to 18.9±8.4 mm/hour, and mean CRP declined from 31.4±11.8 mg/l to 5.8±3.1 mg/l (both $p<0.001$). Although complete radiological healing was observed in 38.0% of patients, 94.0% demonstrated radiological stability without disease progression. No clinical relapse was documented during follow-up after discontinuation of ATT.

Conclusions: Clinical recovery, normalization of inflammatory markers, and radiological stability together provide a practical and reliable basis for determining the endpoint of antitubercular therapy in spinal TB. Complete radiological resolution should not be considered mandatory before treatment discontinuation. A multidisciplinary assessment may help prevent unnecessary prolongation of therapy while maintaining favorable clinical outcomes.

Keywords: Spinal tuberculosis, Pott's disease, Antitubercular therapy, Treatment endpoint, Erythrocyte sedimentation rate, C-reactive protein, Radiological healing

INTRODUCTION

Tuberculosis (TB) is a significant public health challenge globally, especially in underdeveloped countries. Extrapulmonary TB constitutes a substantial percentage of cases, with spinal TB recognised as the most prevalent and potentially debilitating variant of skeletal TB.[1,2] If not treated properly, spinal involvement can cause vertebral destruction, deformity, neurological impairments, and persistent discomfort.[3]

Antitubercular therapy (ATT) remains the primary method for managing spinal TB. The optimal period of therapy for

spinal TB remains contentious, unlike pulmonary TB, which has a clearly defined treatment duration.[4,5] Recommendations vary considerably, ranging from 6 months to over 18 months, depending on the severity of the condition, the response to treatment, and institutional guidelines.[6]

One of the hardest parts of treating spinal TB is knowing when to stop giving drugs. Clinical recovery often occurs early, whereas radiological resolution may be much delayed.[7] Persistent radiological anomalies may be misinterpreted as active illness, leading to unnecessary prolongation of treatment.[8] Conversely, prematurely discontinuing treatment may result in relapse and disease advancement.

Several criteria have been proposed to influence the duration of treatment, including pain relief, neurological recovery, normalisation of inflammatory markers, and radiographic evidence of healing.[9-11] But not everyone has agreed on one standard. This uncertainty underscores the imperative for a comprehensive and pragmatic approach in defining treatment endpoints.

The present study aims to evaluate clinical, biochemical, and radiographic data in patients with spinal TB to identify reliable indicators for predicting the endpoint of antitubercular drug therapy.

METHODS

Study design and study setting

This was a retrospective observational study conducted in the Department of Orthopaedics at Padmini Care Hospital, Tangi, Cuttack, Odisha, India, over a period of 20 months from October 2022 to May 2024. The study was undertaken to evaluate the clinical, laboratory, and radiological parameters used to determine the endpoint of ATT in patients with spinal TB.

Study population

A total of 50 patients diagnosed with spinal TB who completed ATT during the study period were included in the study. Patient records were retrieved from the hospital medical record system and reviewed retrospectively. The diagnosis of spinal TB was established using a combination of clinical presentation, radiological findings, laboratory investigations, and microbiological or histopathological confirmation wherever available.

Inclusion criteria

Patients fulfilling all of the following criteria were included: age ≥18 years; diagnosis of spinal TB based on clinical, radiological, laboratory, and/or microbiological findings; completion of standard first-line ATT; and availability of complete clinical records and follow-up data.

Exclusion criteria

Patients were excluded if they had: multidrug-resistant (MDR) or extensively drug-resistant (XDR) TB, incomplete medical records or inadequate follow-up, previous treatment for spinal TB at another institution with unavailable treatment details, alternative spinal infections or spinal malignancies, and severe immunosuppressive disorders likely to influence treatment response independently.

Treatment protocol

All patients received standard first-line antitubercular therapy according to the National Tuberculosis Elimination Programme (NTEP) guidelines applicable during the study period. The duration of therapy was individualized based on serial clinical assessment, laboratory parameters, and radiological findings.

Patients with progressive neurological deficits, spinal instability, severe kyphotic deformity, large paravertebral abscesses, or failure of conservative management underwent appropriate surgical intervention, including decompression with or without spinal stabilization and fusion, according to the treating surgeon's clinical judgment.

Data collection

The following information was extracted from the medical records: demographic characteristics (age and sex), clinical presentation and neurological status, duration of symptoms, pain severity using the visual analogue scale (VAS), laboratory investigations including erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP), radiological findings from serial plain radiographs and computed tomography (CT) or magnetic resonance imaging (MRI) where available, duration of ATT, and clinical outcome at completion of treatment.

Outcome measures

The primary objective was to determine reliable indicators for defining the endpoint of ATT in spinal TB.

The following outcome measures were evaluated: clinical improvement based on pain relief and functional recovery, neurological improvement or stabilization, changes in ESR and CRP during treatment, radiological evidence of healing or disease stabilization, and clinical status at completion of therapy and during follow-up.

The endpoint of treatment was determined using a composite assessment consisting of sustained clinical improvement, normalization or significant reduction of inflammatory markers, and radiological stability without evidence of disease progression.

Statistical analysis

Data were entered into Microsoft Excel 2021 and analyzed using IBM statistical package for the social sciences (SPSS) statistics version 26.0 (IBM Corp., Armonk, NY, USA).

Continuous variables are presented as mean±standard deviation (SD), whereas categorical variables are expressed as frequencies and percentages.

Comparisons between baseline and post-treatment continuous variables were performed using the paired Student's t-test. Categorical variables were analyzed using the Chi-square test or Fisher's exact test, wherever appropriate.

A two-sided p value <0.05 was considered statistically significant.

RESULTS

Patient characteristics

A total of 50 patients diagnosed with spinal TB who completed ATT during the study period were included in the analysis. The mean age of the study population was 42.8±13.1 years (range: 19–71 years). There were 31 (62.0%) males and 19 (38.0%) females. Lumbar spine involvement was the most common site, followed by the thoracic and cervical regions. The mean duration of ATT was 11.4±2.3 months.

Table 1: Baseline demographic and clinical characteristics (n=50).

Variable	Value
Number of patients	50
Mean age (years)	42.8±13.1
Male	31 (62.0%)
Female	19 (38.0%)
Thoracic spine involvement	23 (46.0%)
Lumbar spine involvement	24 (48.0%)
Cervical spine involvement	3 (6.0%)
Mean duration of ATT (months)	11.4±2.3

Clinical outcome

Progressive clinical improvement was observed throughout treatment. The mean VAS pain score decreased significantly from 7.8±1.1 at baseline to 2.1±0.9 at completion of therapy (p<0.001). Among the 20 patients presenting with neurological deficits, 15 (75.0%) demonstrated neurological improvement, 4 (20.0%) remained neurologically stable, and 1 (5.0%) experienced persistent neurological deficit without further deterioration.

Overall, 46 (92.0%) patients achieved satisfactory clinical recovery by the end of treatment.

Table 2: Clinical outcomes following antitubercular therapy.

Clinical parameter	Baseline	End of treatment	P value
Mean VAS pain score	7.8±1.1	2.1±0.9	<0.001
Patients with neurological deficit	20	5	<0.001
Overall satisfactory clinical recovery	—	46 (92.0%)	—

Laboratory findings

Inflammatory markers showed progressive improvement during treatment. Mean ESR decreased from 63.5±17.2 mm/hour at diagnosis to 18.9±8.4 mm/hour at treatment completion (p<0.001). Similarly, mean CRP declined significantly from 31.4±11.8 mg/l to 5.8±3.1 mg/l (p<0.001).

Normalization of both ESR and CRP was achieved in 43 (86.0%) patients.

Table 3: Laboratory parameters before and after treatment.

Parameter	Baseline	End of treatment	P value
ESR (mm/hour)	63.5±17.2	18.9±8.4	<0.001
CRP (mg/l)	31.4±11.8	5.8±3.1	<0.001
Patients with normalized ESR and CRP	—	43 (86.0%)	—

Radiological outcome

Radiological evaluation demonstrated progressive healing in the majority of patients. Complete radiological healing was observed in 19 (38.0%) patients, whereas 28 (56.0%) showed radiological stability with evidence of healing but persistent residual vertebral changes. Only 3 (6.0%) patients demonstrated delayed radiological improvement without evidence of disease progression.

No patient showed radiological worsening after completion of therapy.

Determination of treatment endpoint

The decision to discontinue ATT was based on a composite assessment incorporating clinical recovery,

normalization of inflammatory markers, and radiological stability.

Among the study population: 46 (92.0%) patients demonstrated complete clinical recovery, 43 (86.0%) achieved normalization of ESR and CRP, and 47 (94.0%) showed radiological stability or healing without disease progression.

No patient developed clinical relapse during the follow-up period after discontinuation of therapy.

Table 4: Radiological outcome following treatment.

Radiological finding	Number (%)
Complete radiological healing	19 (38.0)
Stable healing with residual changes	28 (56.0)
Delayed radiological improvement	3 (6.0)
Radiological progression	0

Table 5: Indicators used for determining treatment endpoint.

Indicator	Patients (%)
Clinical recovery	46 (92.0)
ESR/CRP normalization	43 (86.0)
Radiological stability/healing	47 (94.0)
Clinical relapse during follow-up	0 (0.0)

Statistical analysis

Paired comparisons between baseline and post-treatment values demonstrated statistically significant improvements in pain score, ESR, and CRP (all $p<0.001$). Neurological improvement was significant (Chi-square test, $p=0.002$). Radiological stability at treatment completion was observed in 94.0% of patients. These findings indicate that clinical improvement and normalization of inflammatory markers generally preceded complete radiological healing and together provided reliable indicators for determining the endpoint of ATT.

DISCUSSION

The optimal duration of ATT for spinal TB remains a subject of ongoing debate because no single clinical, laboratory, or radiological parameter can reliably indicate complete disease resolution. Unlike pulmonary TB, spinal TB demonstrates variable rates of healing, with radiological recovery often continuing long after clinical improvement has occurred. Consequently, determining the appropriate endpoint of therapy requires a comprehensive assessment rather than reliance on a fixed treatment duration or a single investigation.[12]

In the present study involving 50 patients with spinal TB, the majority demonstrated marked clinical improvement during treatment. Pain scores decreased significantly from baseline, and more than 90% of patients achieved satisfactory clinical recovery by the completion of therapy. Neurological improvement was observed in three-fourths of patients who initially presented with neurological deficits, while no patient experienced neurological deterioration during follow-up. These findings are consistent with previous studies demonstrating that relief of pain and stabilization or improvement of neurological function are among the earliest and most reliable indicators of successful treatment response.[13]

Serial evaluation of inflammatory markers also showed significant improvement throughout treatment. Both ESR and CRP decreased substantially from baseline values, with normalization occurring in most patients by the end of therapy. Although these biomarkers lack specificity for spinal TB, they provide useful objective measures of treatment response when interpreted alongside clinical findings. Previous investigators have similarly reported that declining ESR and CRP levels correlate well with disease resolution, although persistent mild elevation may occasionally occur because of factors unrelated to active spinal infection.[14]

An important observation of the present study was the difference between clinical recovery and radiological healing. While most patients became clinically asymptomatic with normalization of inflammatory markers, complete radiological healing was observed in only a minority of cases at the end of treatment. More than half of the patients demonstrated residual vertebral deformity or structural changes despite radiological stability and absence of disease progression. These findings are consistent with previous reports indicating that vertebral remodeling and bone healing continue for months after eradication of active infection, and therefore persistent radiological abnormalities should not necessarily be interpreted as ongoing disease activity.[15-17]

The present findings reinforce the limitations of relying exclusively on imaging studies to determine treatment completion. Persistent vertebral collapse, sclerosis, kyphotic deformity, or residual marrow signal changes may represent healing rather than active infection. Extending ATT solely because of incomplete radiological resolution may unnecessarily increase cumulative drug exposure, treatment costs, adverse drug reactions, and the likelihood of poor patient adherence without improving long-term outcomes.[18,19]

Based on our findings, a composite approach incorporating sustained clinical recovery, neurological stability or improvement, normalization of inflammatory markers, and radiological stability appears to provide a practical and reliable method for determining the endpoint of ATT. In the present study, 92% of patients achieved satisfactory clinical recovery, 86% demonstrated normalization of inflammatory markers, and 94% showed radiological stability without evidence of disease progression.

Furthermore, no clinical relapse was observed during the follow-up period after discontinuation of therapy. These observations support current recommendations that emphasize individualized treatment decisions based on overall disease response rather than complete radiological resolution alone.[20-24]

The strengths of this study include evaluation of multiple complementary parameters for assessing treatment response and inclusion of patients managed according to routine clinical practice. Simultaneous assessment of clinical improvement, laboratory markers, and imaging findings provides a comprehensive understanding of disease progression and supports a pragmatic approach to determining treatment endpoints.

Overall, the findings of the present study suggest that successful completion of ATT in spinal TB should be determined using an integrated assessment of clinical improvement, inflammatory marker normalization, and radiological stability rather than complete radiological healing alone. This multidimensional strategy may help avoid unnecessary prolongation of therapy while maintaining favorable clinical outcomes. Future multicenter prospective studies with larger patient populations are warranted to establish standardized evidence-based criteria for defining the endpoint of treatment in spinal TB.[25]

Limitations

Nevertheless, several limitations should be acknowledged. This was a single-center observational study with a relatively modest sample size, which may limit the generalizability of the findings. The retrospective design may also have introduced selection and information bias because data were obtained from existing medical records. Additionally, advanced imaging modalities such as serial magnetic resonance imaging were not uniformly available for all patients during follow-up. Longer post-treatment surveillance would also be valuable to assess late relapse and long-term functional outcomes.

CONCLUSION

Determining the endpoint of antitubercular therapy in spinal TB requires a comprehensive assessment rather than reliance on a single clinical or radiological parameter. In the present study, most patients demonstrated significant clinical improvement, normalization of inflammatory markers, and radiological stability by the completion of treatment, whereas complete radiological healing was observed in only a proportion of cases. These findings indicate that clinical recovery combined with normalization of laboratory parameters and the absence of radiological disease progression provides a practical and reliable basis for discontinuing ATT. Reliance solely on persistent radiological abnormalities may unnecessarily prolong treatment without improving patient outcomes. An individualized, multidisciplinary approach incorporating clinical, laboratory, and imaging findings is therefore recommended to optimize treatment duration while minimizing drug-related adverse effects and improving patient compliance. Further prospective multicenter studies with larger sample sizes and longer follow-up are warranted to establish standardized evidence-based criteria for defining the endpoint of therapy in spinal TB.

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