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Original Research Article

Effectiveness of Dots Regimen in Management of Tubercular Spine

Prabhu Dayal Verma[1], Manoj Soni[2], Vipin Gupta[3]

[1]Assistant Professor, Department of Orthopaedics, Sardar Patel Medical College, Bikaner, Rajasthan, India

[2]Associate Professor, Department of Orthopaedics, Graphic Era Institute of Medical Sciences, Dehradun, UK, India

[3]Associate Professor, Central institute of Orthopaedics, Safdarjung Hospital, New Delhi, India

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Corresponding author: Dr. Prabhu Dayal Verma

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Abstract

Introduction: Spinal tuberculosis (Pott's spine) is a common form of extrapulmonary tuberculosis in developing countries and is associated with significant morbidity due to pain, deformity, and neurological deficits. Although the Directly Observed Treatment Short Course (DOTS) regimen is widely implemented under national tuberculosis control programs, limited data are available regarding its effectiveness in the management of spinal tuberculosis.

Objectives: To evaluate the effectiveness of the DOTS regimen in spinal tuberculosis with respect to clinical improvement, neurological recovery, laboratory and radiological healing, and the occurrence of adverse drug reactions.

Methods: A prospective observational study is conducted on 34 consecutive patients diagnosed with spinal tuberculosis and treated with Category I DOTS regimen in the Department of Orthopaedics, V.M.M.C. and Safdarjung Hospital, New Delhi, from October 2010 to February 2012. Four patients are lost to follow-up, and 30 patients are included in the final analysis. Diagnosis is based on clinical features, laboratory parameters, and radiological findings on X-ray and MRI. Patients are followed up periodically to assess symptom relief, neurological status, ESR levels, radiological resolution, and drug-related adverse effects.

Results: The majority of patients are in the 21–40 years age group (47%), with female predominance (60%). Thoracic spine involvement is the most common. All patients present with back pain, and 90% have constitutional symptoms. Motor weakness is observed in 70% of cases. Paradiscal type is the commonest form of spinal tuberculosis (90%). At 6 months of DOTS therapy, 90% of patients show complete resolution of back pain, with gradual normalization of ESR by the fifth month. MRI reveals complete or significant resolution of bone edema and abscesses in most patients. Neurological recovery is better in early stages of paraplegia, while advanced stages show partial recovery. Adverse drug reactions are mild and manageable, and no patient demonstrates drug resistance. A small proportion of patients require extension of DOTS therapy and surgical intervention.

Conclusion: DOTS regimen is an effective and safe treatment modality for spinal tuberculosis, resulting in favorable clinical, laboratory, radiological, and neurological outcomes in the majority of patients. Early diagnosis and strict compliance with therapy are crucial for optimal recovery, while advanced disease may require prolonged treatment and surgical management.

Keywords: Spinal tuberculosis, Pott's spine, DOTS regimen, Tubercular spondylitis, Neurological outcome.

Introduction

Spinal tuberculosis, also known as Pott's disease, is the most common form of skeletal tuberculosis and accounts for nearly half of all musculoskeletal tuberculosis cases [1]. Despite advances in diagnosis and chemotherapy, it continues to be a major health problem in developing countries, including India, due to high disease burden, delayed presentation, and socioeconomic factors [2]. The disease commonly affects the thoracic and lumbar spine and may result in severe complications such as spinal deformity, cold abscess formation, and neurological deficits if not treated appropriately [3]. The pathogenesis of spinal tuberculosis involves hematogenous spread of Mycobacterium tuberculosis from a primary focus, most often the lungs, leading to destruction of vertebral bodies, intervertebral disc involvement, and potential spinal cord compression [4]. Clinical presentation is often insidious, with persistent back pain, constitutional symptoms, and progressive neurological impairment

in advanced cases [5]. Early diagnosis and effective treatment are therefore essential to prevent permanent disability.

Antitubercular chemotherapy remains the cornerstone of management, with surgery reserved for selected cases such as progressive neurological deficit, spinal instability, severe deformity, or failure of medical treatment [6]. The Directly Observed Treatment Short Course (DOTS) regimen, recommended by the World Health Organization under national tuberculosis control programs, emphasizes standardized short-course chemotherapy with assured drug delivery and compliance [7]. While DOTS has proven efficacy in pulmonary and other forms of extrapulmonary tuberculosis, limited literature exists regarding its effectiveness specifically in spinal tuberculosis. This study is undertaken to evaluate the clinical, neurological, laboratory, and radiological outcomes of DOTS regimen in the management of spinal tuberculosis.

Aim and Objectives

Aim: To evaluate the effectiveness of the DOTS regimen in the management of tubercular spine.

Objectives:

1. To assess the clinical response to DOTS regimen in patients with spinal tuberculosis.
2. To evaluate neurological recovery following DOTS therapy in the tubercular spine.

Materials and Methods

Study design and setting: Prospective observational longitudinal study conducted in the Department of Orthopaedics, V.M.M.C. and Safdarjung Hospital, New Delhi.

Study duration: October 2010 – February 2012.

Study population: The study population comprises patients diagnosed with spinal tuberculosis and treated with DOTS regimen during the study period. A total of 34 consecutive patients are included initially, out of which 4 patients are lost to follow-up. The final analysis includes 30 patients.

Inclusion Criteria

1. Newly diagnosed cases of spinal tuberculosis.
2. Patients of all age groups.
3. Patients with or without neurological deficit.
4. Patients willing to comply with DOTS regimen and follow-up schedule.

Exclusion Criteria

1. Spinal tuberculosis associated with HIV or other immunocompromised states.
2. Relapsed cases of spinal tuberculosis.
3. Defaulter cases of spinal tuberculosis.
4. Patients already on antitubercular therapy or on regimens other than DOTS.

Sampling Method: Consecutive sampling.

Study Tools: A predesigned and pretested semi-structured proforma is used to record patient details including demographic data, clinical presentation, neurological status, laboratory parameters, radiological findings, treatment details, adverse drug reactions, and follow-up outcomes.

Procedure of Sampling and Data Collection: All patients meeting the inclusion criteria are clinically evaluated at presentation. Detailed history regarding back pain, constitutional symptoms, and neurological deficits is obtained, followed by thorough general, spinal, and neurological examination. Routine hematological investigations including ESR and liver function tests are performed. Radiological evaluation includes X-ray and MRI of the involved spinal region. Where indicated, CT-guided needle biopsy, histopathology, culture, and RTPCR for Mycobacterium tuberculosis are performed.

All patients are started on Category I DOTS regimen after baseline investigations and ophthalmological evaluation. Patients are followed up monthly for the first two months and then every two months until completion of therapy. Clinical improvement, neurological status, laboratory parameters, radiological healing, and adverse drug reactions are documented during each follow-up. Patients showing inadequate response or deterioration are evaluated for surgical intervention and extension of therapy.

Ethics: Prior permission was obtained from the Institutional Ethical Committee before starting the study. Prior written informed consent was obtained from all patients or their guardians.

Data Analysis: Data collected was entered into Microsoft Excel and analyzed using SPSS software. Appropriate statistical methods are applied with a 95% confidence interval and a 5% level of significance.

Table 1: Sociodemographic Profile of Patients with Spinal Tuberculosis (n = 30)

Variable	Category	Frequency (n)	Percentage (%)
Age group (years)	0–20	10	33.0
	21–40	14	46.7
	41–60	3	10.0
	61–80	3	10.0
Gender	Male	12	40.0
	Female	18	60.0
Level of pott,s spine	Cervical	1	3.3
	Cervico-dorsal	1	3.3
	Upper thoracic	10	33.3
	Lower thoracic	7	23.3
	Thoraco-lumbar	3	10.0
	Lumbar	7	23.3
	Lumbo-sacral	1	3.3

Table 2: Clinical Presentation and Disease Characteristics (n = 30)

Variable	Category	Frequency (n)	Percentage (%)
Constitutional symptoms (Fever, Wt. Loss, Malaise, Loss of appetite)	Present	27	90.0
	Absent	3	10.0
Back pain	Present	30	100
	Absent	0	0.0
Motor weakness	Present	21	70.0
	Absent	9	30.0
Stage of paraplegia	Stage I	3	10.0
	Stage II	12	40.0
	Stage III	8	26.7
	Stage IV	1	3.3
	Not classified (lumbar involvement)	6	20.0
Type of spinal TB	Paradiscal	27	90.0
	Anterior	2	6.7
	Central	1	3.3
Stage of Tubercular Spondylitis	Pre-destructive	1	3.3
	Early destructive	18	60.0
	Mild angular kyphosis (10°–30°)	11	36.7
	Moderate/Severe kyphosis	0	0.0

Table 3: Radiological Findings, Treatment Outcome, and Adverse Drug Reactions

Variable	Category	Frequency (n)	Percentage (%)
MRI findings at presentation	Bone edema	30	100
	Prevertebral abscess	24	80.0
	Paravertebral abscess	22	73.3
	Epidural abscess	22	73.3
	Psoas abscess	14	46.7
Adverse drug reactions	Gastrointestinal symptoms	8	26.7
	Mild elevation of LFT	5	16.7
	Drug resistance	0	0
Outcome at 6 months of DOTS therapy	Complete resolution of back pain	27	90.0
	Partial resolution of pain	3	10.0
	Complete resolution of bone edema	24	80.0
	Significant reduction of bone edema	6	20.0
Complete Abscess resolution	Prevertebral (n=24)	22	91.7
	Paravertebral (n=22)	21	95.5
	Epidural (n=22)	19	86.4
	Psoas (n=14)	14	100

Table 4: Resolution of Disease Activity at the End of 6 Months of Dots Treatment

Tuberculous Paraplegia Staging	Total no of patients	Complete Resolution Of Disease	Partial Resolution Of Disease	No Resolution
Stage 1 (n=3)	3	3	0	0
Stage 2 (n=12)	12	11	0	1
Stage 3 (n=8)	8	4	4	0
Stage 4 (n=1)	1	0	1	0

Results

A total of 30 patients with spinal tuberculosis were Included in the study, The majority of patients belonged to the 21–40-year age group (46.7%), with a female predominance (60%), and a mean age of 28 years. Upper thoracic spine involvement was most common (33.3%), followed by lower thoracic (23.3%), lumbar (23.3%), thoracolumbar junction (10%), and cervical, cervicodorsal, and lumbosacral regions (3.3% each). Constitutional symptoms were present in 90% of patients, and all patients presented with back pain. The mean baseline ESR was 57 mm in the first hour (range 36–120 mm). Motor weakness was observed in 70% of cases, with paraplegia staged as Stage I in 10%, Stage II in 40%, Stage III in 26.7%, and Stage IV in 3.3%, while 20% could not be classified due to lumbar involvement without cord compression. Radiologically, most patients had paradiscal disease (90%), with early destructive stage seen in 60% and mild angular kyphosis in 36.7%; none had moderate or severe kyphosis. MRI at presentation showed bone edema in all patients, prevertebral abscess in 80%, paravertebral abscess in 73.3%, epidural abscess in 73.3%, and psoas abscess in 46.7%. All patients demonstrated resolution of constitutional symptoms by 3 months of DOTS therapy. At 6 months, complete resolution of back pain was noted in 90%, with partial relief in 10% due to persistent disease activity. ESR showed a gradual decline, stabilizing by the fifth month.

Adverse drug reactions were mild, with gastrointestinal symptoms in 26.7% and asymptomatic elevation of liver enzymes in 16.7%. Follow-up MRI at 6 months showed complete resolution of bone edema in 80% and significant reduction in 20%. Complete resolution of abscesses was observed in 91.7% of prevertebral, 95.5% of paravertebral, 86.4% of epidural, and 100% of psoas abscesses; patients with residual abscesses required extension of DOTS therapy.

Neurological recovery was best in early-stage disease, with 91.7% of Stage I and Stage II paraplegia showing complete recovery. In Stage III paraplegia, 50% achieved complete and 50% partial recovery, predominantly in upper dorsal (D2–D6) involvement with associated myelomalacia. The single Stage IV patient showed partial neurological and radiological recovery and required surgical intervention with extended chemotherapy. All patients with lumbar spine involvement without cord compression showed complete disease resolution at 6 months.

Discussion

This study showed that DOTS therapy demonstrated high effectiveness in managing spinal tuberculosis, with 80% of patients achieving complete resolution of disease at 6 months. The majority of patients were in the 21–40 years age group, and females predominated, consistent with demographic variations reported in previous studies by Rejith Valsalan et al.[8], S. Ramachandran et al.[9], and Oguz Karaeminogullari et al[10]. Thoracic and lumbar spine involvement was most common, aligning with prior literature, while cervical and lumbosacral involvement was rare. Back pain and constitutional symptoms were the most frequent presenting complaints, and significant improvement or complete resolution was observed in most patients after 6 months of DOTS therapy. Clinically evident abscesses, including prevertebral, paravertebral, epidural, and psoas abscesses, resolved in the majority, comparable to findings by Rejith Valsalan et al[8]. And Rani Balasubramanian et al.[11] Motor weakness was present in 70% of patients, with excellent neurological recovery in early-stage paraplegia (stages I–II), while advanced-stage cases (III–IV) had partial or delayed recovery, especially in upper dorsal spine involvement with compressive myelopathy. Adverse drug reactions were mild and manageable. Overall, our results support early initiation of DOTS therapy, which yields excellent radiological and neurological outcomes and reduces the need for routine surgical intervention, consistent with prior reports by J.H. Van Loenhout-Rooyackers et al.[12], Oguz Karaeminogullari et al.[10], and Rejith Valsalan et al.[8] The slightly lower complete resolution rate in our study (80%) compared to others may be attributed to shorter treatment duration (6 months), higher incidence of motor weakness, thoracic spine involvement, and MRI-documented abscesses.

Strengths and Limitations: The strengths of this study include its prospective design, uniform DOTS regimen, and comprehensive orthopedic assessment using clinical, neurological, and radiological parameters. Regular follow-up with MRI allows objective evaluation of healing. Limitations include the single-center nature of the study, small sample

size, and lack of long-term follow-up for late deformity progression and relapse.

Conclusion

DOTS regimen is an effective and safe treatment for spinal tuberculosis, providing good pain relief, radiological healing, and neurological recovery, especially in early-stage disease. Advanced cases with cord involvement may require extended therapy and surgical intervention.

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