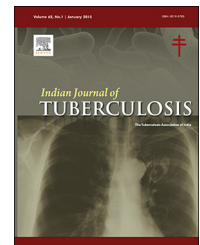




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Original article

Efficacy of alternate day Directly Observed Treatment Short-course (DOTS) in skeletal tuberculosis – A retrospective study

Rajat Chopra^{a,*}, Rama Bhatt^b, S.K. Biswas^c, R. Bhalla^d

^a Consultant Orthopaedics, Sir Ganga Ram Hospital, New Delhi 110060, India

^b District Tuberculosis Officer, Ramakrishna Mission Free TB Clinic, New Delhi 110005, India

^c Senior Chest and TB Specialist, Ramakrishna Mission Free TB Clinic, New Delhi 110005, India

^d Senior Consultant Orthopaedics, Sir Ganga Ram Hospital, New Delhi 110060, India

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ABSTRACT

Objective: To assess the efficacy of alternate day (thrice a week) Directly Observed Treatment Short-course (DOTS) regimen spanning six to nine months in providing sustained cure for skeletal tuberculosis (TB) under programmatic conditions.

Design: Retrospective cohort study.

Setting: An urban district tuberculosis centre in India under the Revised National Tuberculosis Programme.

Participants: A cohort of 218 patients treated with alternate day DOTS regimen for skeletal TB between 2007 and 2012.

Methods: All patients with the diagnosis of skeletal TB registered between 2007 and 2012 who successfully completed treatment were followed up for evidence of disease recurrence or relapse using structured interviews conducted between August 2013 and October 2015 after ensuring a minimum follow up of two years.

Results: Of the 200 patients eligible for follow up in this study, 117 (58.5%) had a minimum follow up of two years. The remaining 83 cases could not be traced. 105 (89.7%) of these 117 patients were symptom free for two years or more after the completion of treatment. There were four cases who had a relapse of the disease within two years of completion of treatment. Eight cases were administered further ATT soon after the completion of treatment under DOTS.

Conclusions: This study confirms the efficacy of the alternate day DOTS regimen in successfully treating all forms of skeletal TB, including spinal TB, with a success rate of 89.7%.

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* Corresponding author. Tel.: +91 8826178877.

E-mail address: choprarajat@hotmail.com (R. Chopra).

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1. Introduction

South East Asia Region (SEAR) accounts for nearly 40% of the global morbidity and mortality due to tuberculosis (TB) with 4.5 million prevalent cases and 440,000 deaths reported from the region in 2013.¹ India, with a population of 1.25 billion, in turn contributed to 24% of the estimated global incidence of TB cases and about 20% of global TB-related deaths for the same year.¹

India launched its Revised National Tuberculosis Control Programme (RNTCP) in 1997 to tackle the burgeoning TB menace and expanded it to cover the entire country by 2006.² Under this programme more than 650 TB suspects per 100,000 population were being examined and over 1.5 million TB patients started on the internationally recommended Directly Observed Treatment Short-course (DOTS) annually.³

The DOTS strategy was launched by WHO in 1995 for TB control and more than 180 countries around the world are currently implementing this programme.² Under DOTS, TB mortality in India has been reduced from 39 per 100,000 population in 1990 to 23 per 100,000 population in 2010 and the prevalence of TB brought down to 256 per 100,000 population in 2010 from 456 per 100,000 population in 1999.³

Skeletal TB accounts for approximately 2% of all TB cases and 11% of all extrapulmonary TB (EPTB) cases.⁴ Traditionally RNTCP has been asserting that "in the absence of neurological complications, skeletal TB can be effectively treated with 6 months of Short Course Chemotherapy (SCC). There is no role for surgery on a routine basis".⁴ A landmark 10 year follow up study by the Tuberculosis Research Centre (TRC) and Chennai Medical College established the efficacy of Short Course Chemotherapy (SCC, 6 months) in the treatment of spinal TB.⁵ Several other studies suggest that 6–9 months of chemotherapy should be adequate in treating most cases of spinal TB.^{6,7} Valsalan et al. recently reported that DOTS was comparable to other standard regimens in treatment of spinal TB with fewer side effects.⁸

However, many practicing orthopaedicians continue to employ longer (12 months or more) regimens especially in cases of spinal TB, as also for other forms of skeletal TB, and have remained sceptical about the alternate day DOTS regime of RNTCP.^{9,10} This has led to poor referrals to RNTCP, suboptimal utilization of DOTS services and prolonged treatment duration.

Given the aforesaid background, this study was planned to retrospectively review the efficacy of alternate-day DOTS in skeletal TB under programmatic conditions as per RNTCP guidelines.

2. Objective

To retrospectively assess the efficacy of alternate day (thrice a week) DOTS regimen spanning 6–9 months in providing sustained cure for skeletal TB (not requiring any further anti-tuberculous therapy for at least two years) under programmatic conditions at an urban district tuberculosis centre.

3. Methods

In this study we examined the treatment data of all the patients of skeletal TB treated by the DOTS regimen between 2007 and 2012 at Ramakrishna Mission Free TB Clinic, Karol Bagh, New Delhi, India. This Clinic has served as a District Tuberculosis Centre (DTC) right from the inception of RNTCP in 1998. Starting with a service population of approximately 500,000 in 1998, it was catering to a 700,000 population base through 18 DOTS centres and seven Designated Microscopy Centres (DMCs) in 2012. It is equipped to conduct basic diagnostic investigations (sputum microscopy and X-ray studies, besides FNAC at its attached Medical Centre). All residents of the area served by this Clinic wishing to be treated under RNTCP are registered at this DTC. The skeletal TB cases were either diagnosed at the Clinic by visiting orthopaedic surgeons or referred for treatment from other centres (both government and private) and were treated with alternate day DOTS as per standard RNTCP protocols (see [Annexure I](#)).

The electronic TB Programme Management System (e-TBPMS) maintained at the centre provided a list of all patients diagnosed with "Skeletal TB" between 2007 and 2012. The computerized registry as well as the manual record cards of these patients were reviewed for data on demographic profile, site of lesion(s), method of diagnosis, date and duration of treatment, category of DOTS therapy and treatment outcomes.

All patients with skeletal TB registered between 2007 and 2012 who successfully completed treatment were included for follow up in this study. Follow up interviews were conducted between August 2013 and October 2015 after ensuring that a minimum of two years had elapsed between the date of completion of treatment and the date of the follow up interview. The e-TBPMS co-ordinator attempted to contact all patients included in the study, first over phone and then by personal visits to patients at the addresses they provided while registering for treatment.

The interview focussed on the following questions:

- (1) Was the patient free from symptoms at the end of treatment?
- (2) Did the patient have to continue taking anti-TB therapy (ATT) after completion of DOTS?
- (3) Did the patient suffer a relapse of TB at the same or other site after completion of treatment as noted in their record at the centre? If yes, did they receive ATT?
- (4) Is the patient currently free of symptoms?

The data obtained from the interviews was correlated with the information available in the treatment records of the patients.

4. Results

During the six-year period under review (2007–2012), 11,274 patients received DOTS at the DOT centres under the DTC. This included 3086 patients (27.4%) treated for EPTB and 218 patients (1.93%) treated for skeletal TB. Of the 218 patients with skeletal TB considered for this study, 116 (53.2%) were

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