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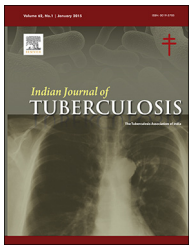

Original Article

Treatment outcome of extrapulmonary tuberculosis under Revised National Tuberculosis Control Programme

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ABSTRACT

Background: Extrapulmonary tuberculosis (EPTB) constitutes 15–20% of tuberculosis cases in India. Earlier studies have evaluated treatment outcomes of EPTB with little information on outcomes of individual site of EPTB.

Aims: The objective was to study the outcome of Directly Observed Treatment Short course (DOTS) treatment of EPTB in different organ systems under Revised National Tuberculosis Control Programme.

Methods: Multi-centric retrospectives record review was carried out in three states in India. Data were collected from TB registers and analysed.

Results: Of the total 2219 patients studied, there were more males in age group 15–45. The commonest sites of EPTB were lymph node (34.4%) and pleural effusion (25.2%) followed by abdominal (12.8%) and central nervous system (CNS) (9.4%). Lymph node involvement was more common in females (58%) and pleural effusion in males (70%). Overall treatment completion rate was 84% in EPTB patients. Treatment completion was 86% in HIV negative EPTB patients compared to 66% in HIV positive patients. Individually, treatment completion rate observed as follows: lymph node 90.9%, genitourinary 92.6%, bone and joint 86%, pleural effusion 84.7%, abdominal 76% and CNS (tuberculoma and meningitis) 63.7%. The site of EPTB was not recorded in 173 (7.8%) patients.

Conclusion: Treatment outcome of EPTB was poor in HIV infected patients and those with CNS tuberculosis. More efforts are needed to improve the treatment completion rates in these groups of patients.

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1. Introduction

Extrapulmonary tuberculosis (EPTB) constitutes 15–20% of all tuberculosis (TB) cases and in human immunodeficiency (HIV) positive patients, whereas EPTB accounts for more than 50% of all cases of TB.[1–3] According to cohort analysis by Central TB Division, Ministry of Health & Family Welfare, its prevalence in India varies between 8.3–13.1% in different districts.[4] There is a rise in incidence of EPTB in industrialised and developing countries.[5–7] due to increasing HIV prevalence, availability of better diagnostic imaging modalities, laboratory facilities and specialised medical personnel as found in studies conducted in the western world and by tertiary care hospitals in India.[8]

Revised National Tuberculosis Control Programme (RNTCP) through DOTS treatment, aimed at achieving 85% treatment success rate among those who have been treated at the time of study which is presently increased to 90%. Since management guidelines are mainly aimed at pulmonary TB, it is difficult to measure treatment outcome in EPTB, and hence most of the patients are labelled as 'treatment completed' unlike 'cure' in pulmonary TB.

EPTB, because of its low infectivity, has been given low priority in RNTCP. While DOTS regimens are widely used in treatment of pulmonary TB, it may not be the same with EPTB. Some of the reasons could be as follows: fear of disease not responding to intermittent regimens of shorter durations, non-sensitization of the physicians treating EPTB about DOTS and difficulties in monitoring response to treatment. The objective of this study was to evaluate the outcomes of DOTS treatment in different organ systems other than the lung. Earlier studies have evaluated treatment outcomes of EPTB as a whole with little information of outcomes in individual organ systems. Most studies have compared the outcomes of EPTB with outcomes of pulmonary TB.[4,7–9]

2. Materials and methods

2.1. Design and setting of study

This was a retrospective record review conducted in three districts of three states. Data were collected from selected tuberculosis units (TUs) of districts located in three Indian states for the period of January 2010–December 2012.

Target population: Patients with EPTB at the selected districts enrolled for RNTCP on DOTS regimens were included in the study. Patients of EPTB along with pulmonary TB who were registered under DOTS and patients in whom treatment outcome was unknown were excluded from the study.

Ethical issues: Ethical clearance was obtained from the Institutional Ethical Committee of each participating centre.

Data extraction: Data on patient's age, sex, type of patient, category of anti-tubercular treatment, HIV status, site of disease and treatment outcome were extracted from the records. Whenever data were not available in the records they were recorded as 'unknown'.

Data variables were defined as per the RNTCP Guidelines.[10,11] EPTB under RNTCP is referred to TB of organs other than the lungs including pleura, lymph node, abdomen, genitourinary tract, meningitis, tuberculoma etc.[12]

1. Type of patient.
   i. *New*: A TB patient who has never had treatment for TB or has taken anti-TB drugs for less than one month is considered as a new case.
   ii. *Transferred in*: A TB patient who has been received for treatment in a TU, after starting treatment in another TU where he has already been registered.
   iii. *Others*: A patient who does not fit in any of the above categories.
2. Category of treatment.
   Standardised intermittent thrice a week dosing regimens using streptomycin (S), isoniazid (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E) as follows: Category I: $2(HREZ)_3 + 4(HR)_3$, Category II: $2(SHREZ)_3 + 1(HREZ)_3 + 5(HRE)_3$ and Category III: $2(HRZ)_3 + 4(HR)_3$. (The number denotes the duration in months and subscript denotes the frequency of doses per week.)
3. Treatment outcome.
   1. *Treatment completed*: EPTB patient who has received full course of treatment and has not become smear positive during or at the end of treatment is declared as treatment completed.
   2. *Died*: Patient who died during the course of treatment regardless of cause.
   3. *Defaulted*: A patient after treatment initiation has interrupted treatment consecutively for two or more months.
   4. *Transferred out*: A patient who has been transferred to another TU/district/state and whose treatment outcome is not available is considered as 'Transferred Out'.
   5. *Treatment failure*: Any TB patient who is smear-positive at five months or more after initiation of the treatment and not put on MDR-TB treatment.
   6. *Switched over to MDR-TB treatment*: A patient who has been diagnosed as having MDRTB by an RNTCP accredited laboratory, prior to being declared as ''Failure'', and is placed on the RNTCP MDR-TB treatment regimen is said to have switched over to MDR TB treatment.
4. **HIV status** was recorded as positive, negative, or unknown (when data were not available).
5. **Site of EPTB**: Lymph node, pleura, bone and joint, genitourinary, CNS (TB meningitis and tuberculoma), Intestine or Others, which included sites other than the above such as eye, skin, military etc.

Data management: The data were pooled at the co-ordinating centre at the National Institute for Research In Reproductive Health, Mumbai. These were then captured and compiled in Epi Info™, version 7, and analysed for variable distribution and correlation between the variables.

3. Results

Data of 2219 EPTB patients were collected from the three selected districts. The patient characteristics are shown in Table 1. Of the 2219 cases, more than half of the patients (56%) were in the age group of 15–45 years. Overall prevalence of

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