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Magnitude and determinants of adverse treatment outcomes among tuberculosis patients registered under Revised National Tuberculosis Control Program in a Tuberculosis Unit, Wardha, Central India: A record-based cohort study

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ABSTRACT

Introduction: Deaths, defaults, relapses, and treatment failures have made the control of TB difficult across the globe.
Methodology: This study is a record-based follow-up of a cohort of patients registered under Revised National Tuberculosis Control Program in the year 2014 in Wardha Tuberculosis Unit, India. Data was collected from the records available at the District Tuberculosis Office.
Results: Data of 510 patients was analyzed. The sputum conversion rate was 88%. The overall treatment success rate was 81.9%, and rates of any adverse outcome, deaths, defaults, failure, and shift to Category IV regimen were 32.60/100 person years at risk (PYAR), 16.88/100 PYAR, 11.12/100 PYAR, 3.45/100 PYAR, and 1.15/100 PYAR, respectively. The median times for the above outcomes were 81 days, 110 days, 66 days, 118 days, and 237 days, respectively. The cumulative probability of occurrence at 6 months of any adverse outcome, deaths, default, failure, and shift to Category IV regimen was 0.145, 0.056, 0.088, 0.002, and 0.004, respectively. On multivariate analysis, the determinant of any adverse outcome was age >45 years, whereas extrapulmonary disease was protective. The hazard of defaulting was also significantly higher in male patients and those aged >45 years.
Conclusion: Appropriate interventions and program implementation to reduce the adverse treatment outcomes and interruptions will help in improving program performance.

1. Introduction

The number of tuberculosis (TB)-related deaths is unacceptably large in India as most of them are preventable only if access to health care is improved for diagnosis and appropriate treatment is provided [1]. In India, approximately 5–8% of TB patients die every year [2]. The Revised National Tuberculosis Control Program (RNTCP) was launched nationwide in 1997 to bring the disease under control by means of reliable diagnosis and free uninterrupted drug supply. The National Strategic Plan 2012–17 aims to achieve a 90% success rate in new cases and 85% in re-treatment cases [3].

The death rates are higher among re-treatment cases of TB. The failure rate is also high among re-treatment cases [2]. New cases have a higher survival rate than re-treatment cases by the time of treatment completion [4]. Defaulting from treatment is associated with drug resistance [5] which in turn is associated with lower treatment success rates (TSRs), higher adverse treatment outcomes [6], and higher mortality [7].

Despite the efforts of RNTCP, TSR still lags in the targets of National Strategic Plan. Thus, it becomes imperative to understand the magnitude and the determinants of adverse treatment outcomes so that appropriate corrective measures can be planned based on local epidemiology. Therefore, the present study was conducted to study the magnitude and determinants of adverse treatment outcome in TB patients treated under RNTCP in Wardha Tuberculosis Unit (TU), Central India.

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2. Methodology

2.1. Study setting

The present study was a record-based follow-up of a cohort of all the patients registered under RNTCP in 2014. The study was conducted in Wardha TU. Wardha is a district in Central India, with a population of about 1.3 million and 32% of its population residing in urban areas. It has a sex ratio of 946 females per 1000 males. The district has three TUs spanning across eight administrative blocks [8].

2.2. Data collection

We extracted the data of all the patients registered under RNTCP in 2014 from the District TB office. Along with Nikshay software, the TB register was also checked to fill any missing data. The data for each patient was recorded at the time of registration routinely under the program by the program staff. For patients who were registered more than once in the year for treatment due to default ($n = 3$), relapse ($n = 2$), or treatment failure ($n = 1$), only the first instance was considered, and the rest were excluded from the study to rule out the possibility of bias due to duplication of some of the baseline characteristics (Fig. 1). The treatment outcomes of patients and the time of treatment outcome were determined according to RNTCP definitions [9]. We classified the area of residence using census definitions [8].

2.3. Data management and analysis

Data was analyzed using SPSS version 12.0 (IBM SPSS Inc., Chicago, IL, USA). The characteristics of patients were expressed as frequencies (%) and median [95% confidence interval (CI)]. Kaplan–Meier survival analysis was performed to estimate the survival probabilities of the patients. The end point studied was the adverse treatment outcomes (defaults, deaths, treatment failures, shift to Category IV) recorded under the RNTCP. Incidence rates, rate ratios, and their 95% CIs were calculated individually using OpenEPI version 3.01 (The OpenEpi project, Atlanta, Georgia) to evaluate the risk factors (age, sex, site of illness, category of treatment initiation, HIV, diabetes and area of residence). Multivariate analysis using the Cox proportional hazard regression models was performed to calculate hazard ratios (HRs) and their 95% CIs. All the variables were included in the model. Proportional hazards assumption was tested using log minus log plot, and the assumption of proportionality was met.

Ethical approval was obtained from the Institutional Ethics Committee, MGIMS, Sewagram before conducting the study (Approval No. MGIMS/IEC/COMMED/68/2014).

3. Results

A total of 516 patients were registered under RNTCP in 2014 in the TU. Six patients were excluded as they were registered twice in the program. Finally, 510 patients were included for analysis.

3.1. Study patients

The baseline characteristics of the patients are described in Table 1. About 37% patients were aged <30 years, and about 18% patients were aged ≥60 years. Also, 63% of the patients were men. Patients were approximately distributed equally across urban and rural areas. Furthermore, 77% patients had experienced TB for the first time. Of the remaining patients who had TB more than once, relapse and re-treatment others cases comprised about 10% each of the total patients, followed by a small proportion of treatment after default cases (2.4%) and treatment failure cases (0.2%). About 75% patients had pulmonary TB of which 233 (45.7%) patients were sputum positive. Additionally, 6.9% and 2.4% patients were known to be suffering from HIV and diabetes, respectively. Of the successfully treated patients, after excluding those whose regimens were prolonged due to smear positivity at the end of intensive phase (IP), we found that none of the patients completed their treatment on the expected date. In Category I, about 72.5%, 16.8%, and 10.7% patients completed their treatment between 24–28 weeks, 28–32 weeks, and after 32 weeks, respectively.

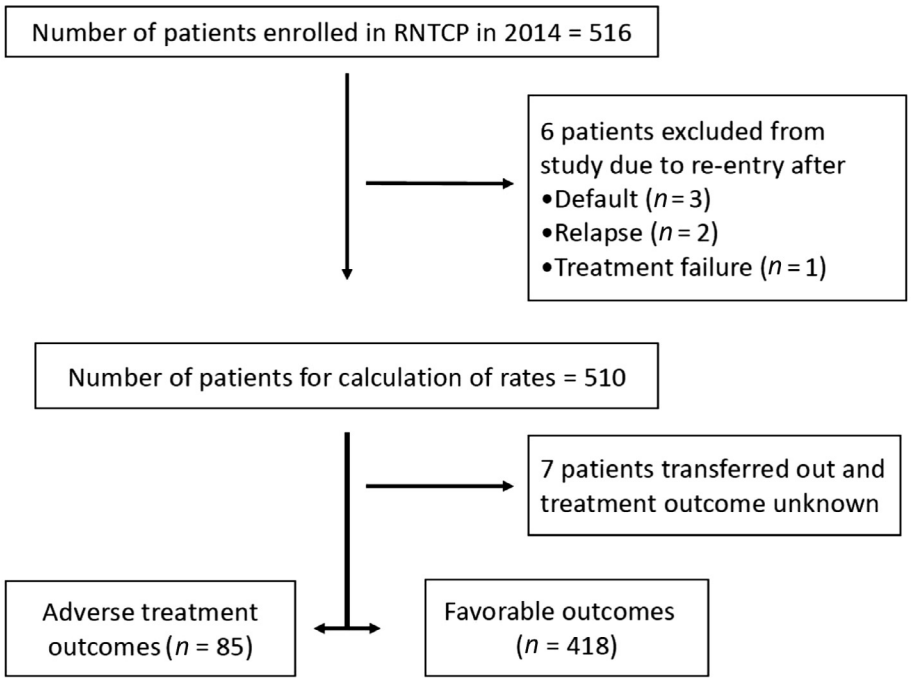

Fig. 1. A flowchart of study patients. RNTCP = Revised National Tuberculosis Control Program.