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Treatment outcome on pulmonary tuberculosis and extra pulmonary tuberculosis in government general hospital, ongole

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Abstract

Background: Tuberculosis is a global disease leading to cause death worldwide. The Revised National Tuberculosis Control Programme (RNTCP), Directly Observed Treatment Short Course (DOTS), was launched to reduce tuberculosis mortality, improve patient adherence to treatment, and prevent the development of drug resistance. The aim of this study was treatment outcome of tuberculosis. Treatment outcome is an important indication of tuberculosis control programme. **Methodology:** An ambispective observational study was conducted in a government general hospital from August 2019 to January 2020 on the treatment outcomes of PTB and EPTB in the 15 years and older age group, both males and females, on category I regimens. Patients with comorbidities like HIV, diabetes, and social habits like smoking were included. Record based TB diagnosed data (August 2019 to January 2020) are taken and asses their treatment outcome after 6months of complete therapy. The recorded and collected data were analysed to evaluate the success rate of treatment outcomes for PTB and EPTB. **Results:** A total of 350 subjects were enrolled in the study, of which 311 are included and 39 are excluded due to incomplete data. The study with age group of 15 and above years where males 218(70.10%) and females 93(29.90%). Total pulmonary tuberculosis cases are 277 (89.07%), and extrapulmonary tuberculosis cases are 34 (10.93%). Subjects with HIV 48(15.43%), Diabetes 54(17.37%) and Tobacco smoking 85(27.33%). The treatment outcome was observed as follows: cured 144 (46.30%), treatment completed 98 (31.51%), transfer out 10 (3.21%), died 27 (8.69%), treatment failure 7 (2.26%), treatment lost to follow-up 14 (4.50%), and treatment regimen changed 11 (3.53%). At the end of the treatment, the success rate was found to be 78%. **Conclusion:** This study shows that the TB patients' treatment success rate was 78%, which is slightly less than the RNTCP norms. The died rate was 8% which is higher than national average. Perhaps the services need to improve tuberculosis case detection in HIV patients, while cure rates have to be improved in RNTCP. EPTB case enrolment is very low, whereas the referral system has to improve its services. So that EPTB cases enrolment may increase its number. The early detection may enhance the cure rates in patients.

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Introduction

Tuberculosis (TB) is one of the major health problems and leading causes of death worldwide; it kills around 1.7 million people each year [1]. In India, 2 million TB cases are noted each year. Effective treatment of TB requires adherence to a minimum of 6 months of treatment with multiple drugs [1]. It is estimated that about one-third of the world's population is infected with Mycobacterium tuberculosis. After a primary infection, TB may reactivate anytime and anywhere in the body. Clinical manifestations of TB are variable and depend on a number of factors that are related to the microbe, the host, and the environment.

Although TB is acquired by inhalation of contaminated droplets, it can produce disease in any organ system generally lungs is the initial site of infection the clinical manifestations of PTB is cough for 2 weeks associated with sputum production, fever, night sweats, chest pain, dyspnoea [2].

The term "EPTB," which encompasses all forms of TB other than pulmonary tuberculosis (PTB), can affect the lymph nodes, pleura, bones and joints, genitourinary tract, nervous system, intestines, etc. Clinical manifestations like enlarged lymph node, skeletal pain, urinary symptoms, abdominal swelling, abdominal pain, and headache. The diagnosis of some of the more severe forms of EPTB is a diagnostic challenge for physicians. EPTB hardly ever spreads the disease to others. If untreated TB leads to death within two to three years in at least half the patients, about 20 to 25% have natural healing, and the remaining 25% remain positive and continue to spread the disease in the community. Differences in the risk factors of extrapulmonary TB (EPTB) and pulmonary TB (PTB) are associated with gender, age, underlying diseases, geographical region, and degree of immune depression, prevailing socioeconomic conditions, and exposure to TB. Early detection is essential to interrupt transmission and reduce the death rate [2].

In 1995, the World Health Organization (WHO) set up the Directly Observed Treatment Short Course (DOTS) strategy. It involves provision of stand courses of anti-tuberculosis drugs to patients under trained observers to prevent people from failing to complete their treatment. WHO has set a target level of 85% treatment success [3].

Under RNTCP (Revised National Tuberculosis Control Programs), the DOTS strategy is used to treat TB patients. Main Objectives of RNTCP are to achieve and maintain a cure rate of 85% among new sputum positive cases and to achieve and maintain case detection of 70% [3].

Treatment outcome is an important indicator of tuberculosis control programs, and monitoring and evaluating the treatment outcomes of tuberculosis patients is an integral part of the DOTS strategy.

Aim

The aim of this study was to evaluate the treatment outcomes of pulmonary tuberculosis (PTB) and extrapulmonary tuberculosis (EPTB).

Objectives

- To study the treatment outcomes among the new pulmonary tuberculosis and extrapulmonary tuberculosis patients.
- To study the sociodemographic profile of pulmonary tuberculosis and extrapulmonary tuberculosis.
- To assess the treatment outcome of tuberculosis patients under the revised national control programme.
- To achieve at least an 85% cure rate among new smear-positive cases.

Materials and Methods

Study Type

An ambispective observational study

Study Site

Department of TB, Government Hospital, Ongole, Andhra Pradesh, India.

Study Population

A total of 311 TB patients were included in the study.

Study Period

6 months [August 2019–January 2020]

Department

Department of TB, Government General Hospital

Study Criteria

The study will be carried out by considering the following criteria.

Inclusion criteria

- All age groups, i.e., 15 and older
- Gender specific [both males and females]

- Patients with comorbidities like HIV and diabetes
- Record-based TB diagnosis data (from August 2019 to January 2020) is taken and assessed for treatment outcome after 6 months of complete therapy
- Only the CAT-1 regimen is taken
- Social habits like tobacco

Exclusion criteria

- Pediatric patients are excluded (below 15 years)
- Patients with the CAT-II regimen
- Patients with incomplete data
- Patients with MDRTB and XDRTB
- Patients with monotherapy resistance and polytherapy resistance

Study Procedure

A record base tuberculosis diagnosed Patients' data is collected, and they are given treatment according to DOTS, i.e., each patient was treated with anti-tuberculosis treatment (ATT) over a scheduled period of time (6 months). Variables of interest were gender, age, type of TB (i.e., the record showed that the patients was either CBNATT/Smear positive PTB, Smear negative PTB, CXR positive, CXR negative and FNAC for EPTB as independent variables, whereas outcome variables were dependent variables treatment outcome (i.e., the record showed that the patient was either cured, treatment completed, died, treatment failure, treatment regimen changed, lost to follow up, and transfer out) and treatment success (i.e., the record showed that the patient was either and treatment completed).

Data Collection

Data was collected in both excel sheet as well as data collection form. For statistical analysis, the Student T-test was used by scoring based on diagnostic criteria for every two-month follow-up and calculating the overall p value in SPSS.

Results

In our study, we have collected data on 350 patients living with TB. 39 patients were excluded from the study due to incomplete data. 311 patients are included in the study who were diagnosed with TB and started the CAT I regimen of ATT under DOTS in RNTCP. Considering the socio demographic parameters, treatment outcome is majorly observed mostly among the people with age group 35-54 years (46.30%), followed by people with age group of 15-34 years (26.05%), 55-74 years (25.72%), >75years (1.93%).

AGE	NUMBER	PERCENTAGE
15-34 years	81	26.05
35-54 years	144	46.30
55-74 years	80	25.72
>75 years	6	1.93

Distribution According to Gender

Males (70.10%) experienced a higher percentage of treatment outcomes compared to females (29.90%).

GENDER	NUMBER	PERCENTAGE
Male	218	70.10
Female	93	29.90
Grand Total	311	100

Distribution According to Weight

In the category of weight, D2 (35–45 kg) (47.27%) is more frequently affected by tuberculosis when compared with other weight groups like D1 (25–35 kg), D3 (45–55 kg) (14.47%), and D4 (55 kg) (6.43%).

WEIGHT	NUMBER	PERCENTAGE
25-35 kg	99	31.83
35-45 kg	14	47.27
45-55kg	45	14.47
>55kg	20	6.43

Distribution According to Diagnostic tests

All patients were investigated, and specific tests like sputum/CBNAAT, X-ray, and FNAC were done to confirm the diagnosis. Out of 311 patients studied, sputum was performed in 65.28%, X-rays in 25.08%, and FNAC in 9.64%.

TYPE OF DIAGNOSTIC TEST	NUMBER	PERCENTAGE
SPUTUM/ CBNAAT	203	65.28
X-RAY	78	25.08
FNAC	30	9.64

Distribution according to type of TB

Patients with PTB and EPTB were 89.07% and 10.93%, respectively. Pulmonary tuberculosis is more common in males (73.29%) when compared to females. 26.71%. Females have a higher prevalence of EPTB (55.89%) than males (44.11%).

TYPE OF TB	NUMBER	PERCENTAGE

PTB	277	89.07
EPTB	34	10.93

Distribution According to co morbidities

Patients with co morbidities like HIV (15.43%) and diabetes (17.37%) In this study, males are more infected with TB with and without HIV and diabetes mellitus when compared to females.

Prevalence of TB with HIV and without HIV

Males were found to be more infected with TB and HIV (8.68%) than females (6.75%).TB with HIV, 15% and TB without HIV, 85%.

GENDER	TB WITH HIV		TB WITHOUT HIV	
	Number	Percentage	Number	Percentage
Males	27	8.68	191	61.41
Females	21	6.75	72	23.16
Total	48	15.43	263	84.57

Prevalence of TB with DM and without DM

In this study, males are more infected with TB with diabetes mellitus (14.47%) when compared to females (2.90%). TB with DM (17%) and TB without DM (83%).

GENDER	TB WITH DM		TB WITHOUT DM	
	Number	Percentage	Number	Percentage
Males	45	14.47	173	55.63
Females	9	2.90	84	27.0
Total	54	17.37	257	82.63

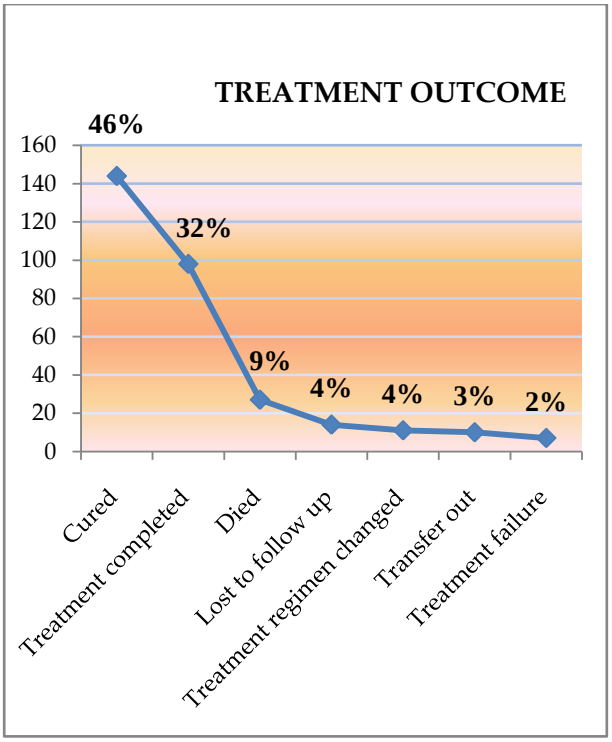
Prevalence of TB with Tobacco and without Tobacco

Social habits like tobacco males were more when compared to females as shown in table and TB with tobacco (27%) and TB without tobacco (73%)

GENDER	TB WITH TOBACCO		TB WITHOUT TOBACCO	
	Number	Percentage	Number	Percentage
Males	84	27.01	134	43.08
Females	1	0.32	92	29.59
Total	85	27.33	226	72.67

Distribution According to Treatment outcome:

Overall treatment outcomes were observed as follows: total cure rate (46.30%), total treatment completed (31.15%), total death rate (8.69%), total lost to follow-up (4.50%), total treatment regimen changed (3.53%), total transfer out (3.21%), and total treatment failure (2.26%).



Treatment Success Rate

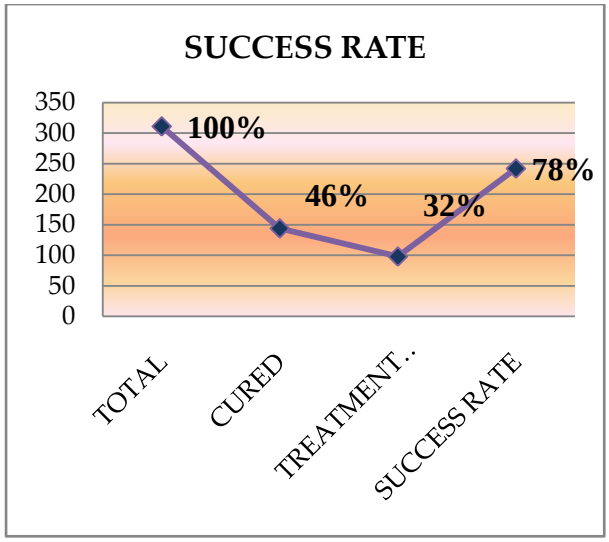
In our study, the success rate was assessed by two methods:

By statistical analysis using student T-tests in SPSS, we have observed that the P value is not significant based on scoring based on two-month follow-ups where the desired success rate is 85% according to RNTCP, whereas in our study the success rate was 78%, which is a significant value for treatment outcome but not up to standard.

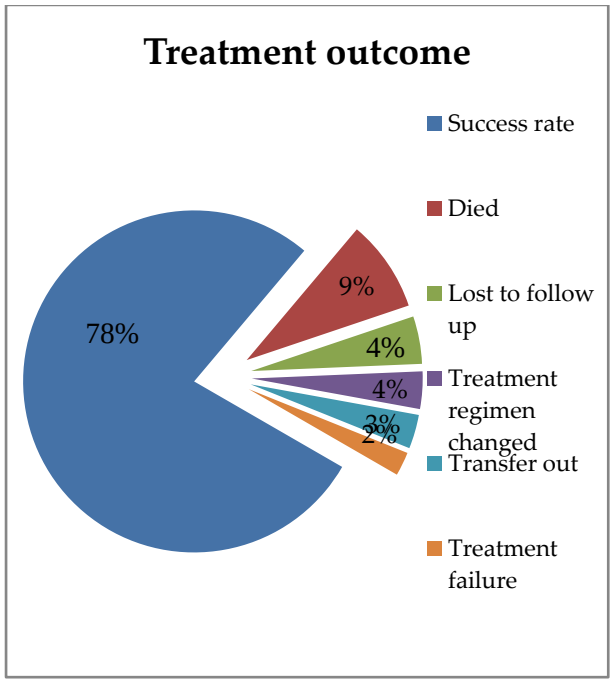
The TB Treatment Success Rate is calculated by dividing the number of new registered TB cases that were cured or completed a full course of treatment by the total number of new registered cases and multiplying by 100. The treatment success rate is calculated based on the treatment outcome for each patient.

Success Rate of TB Patients		
CURED	144	46%
TREATMENT COMPLETED	98	32%
CURED + TREATMENTCOMPLETED = SUCCESS RATE	242	78%

Success rate = cured + Treatment completed patients / Total no of new registered cases x 100



The treatment success rates are low, the cause of the problem can only be identified by determining the factors which are particularly high. Success rate is 78% lower than the target of 85% due to some factors like death ratet (8.69%) total lost to follow up (4.50%), total treatmentregimenchanged (3.53%), total transfer out (3.21%), total treatment failure(2.26%) as show in figure.



Discussion

In the present study, out of 350 patients, 311 were included, and 39 were excluded because of incomplete data. TB treatment outcomes were classified as cured (46%), completed (32%), died (9%), failed (2%), lost follow-up (4%), transferred out (4%), and not evaluated (3%). It was observed according to the treatment outcome process. In a similar study, Sudipta Panda [4–5] found that the treatment success rate reduced from 90% to 76% due to default rates, and the failure rate increased from 7% to 10% and from 3% to 10%, respectively. Our findings were consistent with those of S.L. Chandha and R.P. Bhagi **[6]**, as well as Yatin Dholkia et al **[7]**. One of the five elements of TB control was routine recording, reporting, the number of TB cases diagnosed, treated by RNTCP, and monitoring of treatment outcomes.

The age distribution shows that treatment outcomes are most common among people aged 35-54 years (46.30%), followed by people aged 15-34 years (26.05%), 55-74 years (25.72%), and >75 years (1.93%). According to another study **[8]** nearly 70% of TB patients are between the ages of 15 and 54. The gender-wise distribution shows that males (70.10%) experienced a higher percentage of treatment outcomes compared to females (29.90%), similar to the previous report in Ethiopia **[9]**.(67.4% vs. 32.3%; 71.7% vs. 28.3%) and Hong Kong (16 vs. 77.8%) **[10]**. in the category of weight, D2 (35-45Kg) (47.27%) is more frequently affected by tuberculosis when compared with other weight groups like D1 (25-35Kg), D3 (45-55Kg) (14.47%), and D4 (55Kg) (6.43%) in another study [11]. Diagnostic tests like Sputumwas performed in (65.28%), X-ray in (25.08%) and FNAC IN (9.64%). 94% of new pulmonary tuberculosis cases and 6% of extrapulmonary tuberculosis cases were discovered. It was found to be between 0.4% and 20.1% in North India **[12]**. However, the prevalence was 3.2% in 1991, which increased to 20.1% in 1996 in South India **[13]**. The observed treatment success rate (78%) and cure rate (46%), both high [14-15], Compared to treatment-completed patients observed in this study, 58.61% were observed, while 50.39%, 41.90%, and 51.50% were observed in different studies done at Nagpur, Aurangabad, and by Jemal M et al**. [16–18]** The overall death rate in our study was 9%, compared to 4.17% in other studies, and 2.86%, 2.80%, 0.93%, and 0.78% in different studies in Aurangabad, Jemal M et al., Delhi, and Nagpur [18]. According to the WHO Global TB Report 2013, treatment success rate under RNTCP was 90% in 2011. In our study, the treatment success rate was 78%, showing the treatment outcome rate to be within the expected norms of RNTCP, which showed that the implementations of RNTCP in the study have not achieved the prescribed goal. Comparable to the study by Ajay Kumar Varma et al. Where the cure rate was 34.04% and the treatment success rate was 72.33% under RNTCP, the treatment success rate among retreated cases in 2011 was 75% which is more than in our study[19-20].

Conclusion

In summary, this study shows that TB patients' treatment success rate is 78%, which is slightly less and not significantly less than the desired rate as per RNTCP norms because of the influence of other reasons on treatment outcome, as follows: lost follow-up (4.5%), treatment regimen change (3.5%), transfer out (3.2%), treatment failure (2.2%), and death rate (8.8%), which is higher than the national average. Perhaps the services need to improve tuberculosis case detection in HIV patients, whereas cure rates have to be improved in RNTCP. EPTB case enrolment is very low; the referral system has to improve its services. As a result, the number of EPTB cases may increase. Early detection may improve cure rates in elderly patients.

Limitations

The recorded data details of socio-cultural and socio-economic factors such as education, occupation, housing, and income that can affect the outcome of patients on treatment were not documented in the record used for this study.

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Conflict of Interest

Authors declared no conflict of interest

Author Contribution

All authors contributed equally

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