

Prescription Pattern of Antituberculosis Drugs in Treatment of Tuberculosis at a Tertiary Care Hospital in Andhra Pradesh, a Cross-Sectional Study

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Abstract

The success of tuberculosis treatment is based upon the prescription pattern following Revised National Tuberculosis Control Programme/National Tuberculosis Elimination Program/World Health Organization guidelines, reflecting the burden of the disease which is increasing yearly. This implicates the variations in prescriptions advised in the treatment of tuberculosis. The present study was aimed to evaluate the prescription patterns of tuberculosis treatment in a tertiary hospital at Andhra Pradesh, India. Ninety-two patients were included in the study after obtaining ethical approval and informed consent. The prescription patterns were evaluated and compared to the standard guidelines. The mean age of the patients was 38.72 and showed male preponderance. Six regimens were used during the treatment. The patients showed good recovery which concludes that following the standard prescription pattern provides a good success rate in the treatment of tuberculosis.

Keywords: Anti-tuberculosis therapy; observational study, treatment regimens

Introduction

Tuberculosis in human is principally caused by *Mycobacterium tuberculosis* and it is a worldwide pandemic. Though newer modalities and treatments have evolved, still millions are being affected by this disease.¹

National Tuberculosis Elimination Program (NTEP) 2020 was introduced by the government of India with an aim

to cut the disease transmission chain and end tuberculosis (TB) disease in India by 2025.² In spite of diagnostic and treatment advancements, unfortunately, a large population is still affected from TB. Deaths due to TB were 2 million during 2013 and it has increased further during 2019.²

Adverse drug reactions (ADR) are a great burden to national anti-tuberculosis program.

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The prescription pattern can affect the compliance of treatment negatively, which results in MDR-TB indirectly.^{4,5} With this background, the present study was initiated to evaluate the prescription pattern in tuberculosis treatment.

Methods

This prospective cross-sectional, observational study was conducted in the pharmacology department and pulmonary medicine out-patient department at NRI Medical College and General Hospital, Andhra Pradesh. This study was conducted during January 2020 to July 2020 for a period of six months. All new cases prescribed for the treatment of tuberculosis were enrolled in the study after obtaining the institutional ethics approval (IEC NRIMC 128 dated 25 January 2020) and informed consent from the patient. Total of 92 patients were included in the study. The patients with age range of 15-80 years of either sex with active or inactive TB were included in the study. Patients not willing to participate or to provide consent were excluded from the study.

The prescriptions were obtained from the patients and the data was documented. The obtained data was compared with the standard Revised National Tuberculosis Control Programme (RNTCP)/NTEP 2020 guidelines of India. The sample size included all the new patients of tuberculosis treatment during the study period, willing to participate in the study as per inclusion criteria.

The prescriptions were also evaluated as per the recent WHO guidelines. The prescription was stated as correct if it includes the following criteria like at least 4 first-line anti TB drugs were prescribed, all doses adjusted as per weight, all patients were advised to take the daily dose of drugs at once or at the same time, no second-line drug since drug-

resistant TB patients were not included in the study.⁶

Statistical Analysis

Statistical analysis was done using GraphPad Prism online software. In the current study the data was expressed in n (%), mean and standard deviation (SD).

Results and Discussion

One-fifth of global TB cases are accounted from India.⁶ The Revised National TB Control Programme (RNTCP) which is directly observed treatment, short-course (DOTS) based has achieved a remarkable success rate of 85% cure.^{7,8} This prospective observational cross-sectional study included 92 patients out of 100 screened patients. Eight patients were excluded from the study as they were not willing to participate in the study.

The prescription patterns were observed and documented. The mean age of the patients was 38.72 years and the baseline mean BMI was 21.32 kg/m². The mean age is comparable with the previous study in India^{9,10} and similar BMI category was observed majorly in other studies.^{11,12} All the patients were smear-positive in pulmonary type or confirmed as positive TB of extra-pulmonary type and category I (no history of antituberculosis drug therapy). All the patients included in the study had completed follow-up for six months and with no dropouts.

The encounters were compared and analyzed with respect to prescription patterns and standard treatment following the RNTCP guidelines. Totally 276 encounters were analyzed for prescription pattern which included first visit and 2 follow-up visits of ninety-two patients after confirmed diagnosis. The demographic details of the patients were tabulated in Table 1. Male preponderance

was observed among the patients of this study, however the study sample was small to define the level of incidence. This preponderance was also reported by Rao S (2009).¹³ The patients were of category I defined as per RNTCP guidelines, including both pulmonary TB and extra-pulmonary TB cases. Among 92 patients, 3 female cases presented with extra-pulmonary TB.

The percentage of each drug type prescribed was depicted in Figure 1. The prognosis of patients did not necessitate the use of second-line drugs or injectables. The analysis of prescribed regimens suggested that the RNTCP guidelines 2018 were followed for the treatment of tuberculosis in all the patients. Total of 1246 drugs were prescribed in 276 encounters. The average number of drugs prescribed per encounter during the initiation of therapy was 6.85 ± 0.34 . The

average number of drugs prescribed per encounter during the first follow-up visit was 5.86 ± 0.34 .

The total number of regimens used was 6 (Table 2). Adjuvant treatment with Pyridoxine 10mg OD, Pantoprazole 40mg OD, Domperidone 10mg/Ondansetron 4mg OD was suggested to patients based on symptoms like polyneuropathy, abdominal pain or heart-burn, and nausea or vomiting respectively.¹⁴⁻¹⁶ The total number of doses of drugs prescribed to the patients during the entire course of treatment was 1246.

All the prescriptions evaluated in the study adhered to the guidelines. Due to the small sample size, the recovery rate did not correlate with that of previous studies showing up to 85% of recovery following the guidelines.^{17,18} This may be a limitation to the study.

Table 1: Patient Characteristics

No	Patient Characteristics	Mean \pm SD (n=92)
1	Gender (N)	
	Male	77
	Female	15
2	Age (Years)	38.72 ± 11.6
3	BMI (kg/m ²)	21.32 ± 1.8
4	Site of Disease (N)	
	Pulmonary	89
	Extra Pulmonary	3

n= number of patients

Table 2. Regimens Used in the Study

No	Regimen	N	N%
1	FDC-Isoniazid/Rifampicin/ Pyrazinamide/Ethambutol	52	56.2
2	FDC- Isoniazid/Rifampicin/ Ethambutol	52	56.2
3	Isoniazid, Rifampicin, Pyrazinamide, Ethambutol	35	38
4	Isoniazid, Rifampicin, Ethambutol	35	38
5	FDC- Isoniazid/pyridoxine, Rifampicin, Pyrazinamide, Ethambutol	5	5.43
6	FDC- Isoniazid/pyridoxine, Rifampicin, Ethambutol	5	5.43

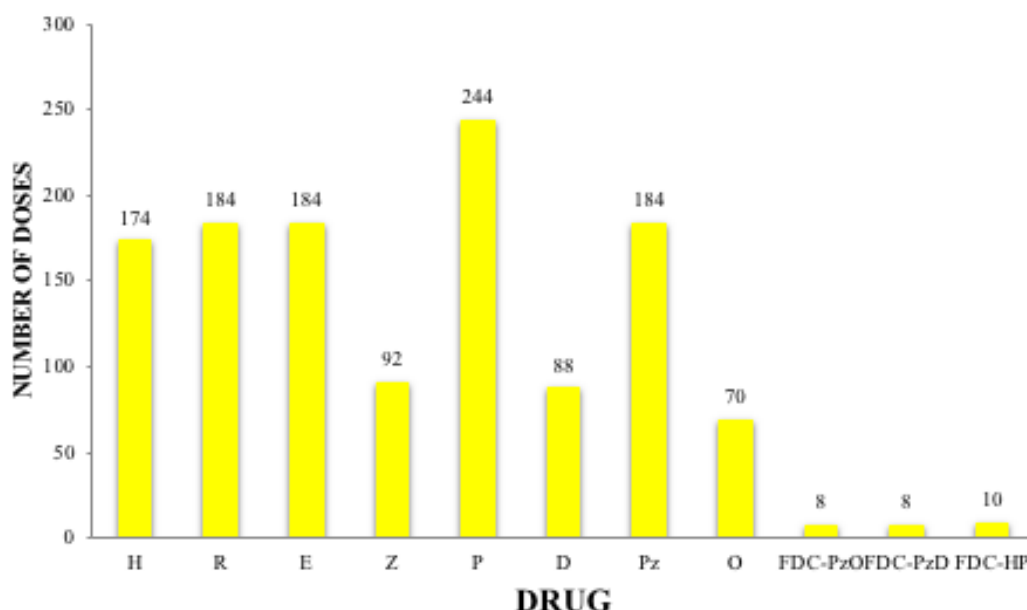


Figure 1. Drug dose frequencies used in the treatment of Tuberculosis. H-isoniazid, R-rifampicin, E-ethambutol, Z-pyrazinamide, P-pyridoxine, D-domperidone, Pz-pantaprazole, O- ondansetron, FDC- fixed dose combination

Conclusion

Though the study includes ninety-two patients, no requirement of further prescription with anti-tuberculosis drugs after 6 months suggests that following the standard prescription patterns and guidelines provided complete success rate in the treatment of tuberculosis.

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Conflict of Interest

None declared

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