



CODEN [USA]: IAJPBB

ISSN: 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES

<http://doi.org/10.5281/zenodo.821070>Available online at: <http://www.iajps.com>**Research Article**

**A PROSPECTIVE OBSERVATIONAL STUDY ON
PRESCRIPTION PATTERN, DRUG UTILIZATION AND AUDIT
FOR THE TREATMENT OF TUBERCULOSIS IN A TERTIARY
CARE HOSPITAL IN ANDHRA PRADESH**

K.P.R.Chowdary*, G Sumalatha, K. Sri Gouri and K.J.S.Dani

Department of Pharmacy Practice, Vikas Institute of Pharmaceutical Sciences,
Nidigatla, Rajahmundry, Pin: 533102.

Abstract:

Introduction: TB ranks as the second leading cause of death from an infectious disease worldwide, after the human immunodeficiency virus (HIV). Tuberculosis is caused by a bacteria called *Mycobacterium tuberculosis* that most often affects the lungs. Tuberculosis is a curable and preventable disease. Early diagnosis and adequate treatment of infectious patients with pulmonary TB are necessary to reduce transmission of tuberculosis and ultimately to achieve elimination of TB. If TB is detected early and properly treated using a combination of medicines for 6 to 9 months, the patients quickly become noninfectious and are eventually cured. **Objective:** The objective of the observational study is to evaluate the prescription pattern, drug utilization and the audit of anti-TB drugs usage in a tertiary care hospital in Rajahmundry, Andhra Pradesh. **Methodology:** The study design is a prospective observational study. A total of 80 cases related to treatment of TB were investigated. The inclusion and exclusion criteria include patients with pulmonary TB admitted as in patients in the hospital, patients with age group 15-80years of both men and women, patients with active or inactive TB taking anti-tubercular treatment and pregnant and lactating women. The data sources include patient case sheets, prescriptions issued and discharge medication sheet, WHO guidance on essential drugs and by interacting with physicians and patients. **Results and Conclusions:** Men are more prone(62.5%) to TB than women(37.5%). In all age groups men are more than females among the TB patients. Hypertension ,diabetes, COPD and thyroid are more prevalent co-morbid diseases in TB patients. 4-drug combinations consisting of rifampicin, isoniazid, ethambutol and pyrazinamide are most widely prescribed(86.25%). WHO suggested 7 essential drugs for TB out of which only 4 drugs were prescribed in the hospital. In most of the cases of mono drug therapy and combination therapy, the drugs are used at larger doses than the WHO suggested doses. Hence it is suggested that the WHO recommended all essential drugs may be used either alone or in combinations at the doses suggested.

Key Words: Prospective observational study, Prescription pattern, Drug utilization, Prescription audit, Anti tubercular drugs.

Corresponding author:

Prof. K. P. R. Chowdary,
Research Director,
Vikas Institute of Pharmaceutical Sciences,
Nidigatla, Rajahmundry-533102.
Mobile: 9866283578
E-mail: prof.kprchowdary@rediffmail.com.

QR code



Please cite this article in press as K. P. R. Chowdary *et al*, *A Prospective Observational Study on Prescription Pattern, Drug Utilization and Audit for the Treatment of Tuberculosis in a Tertiary Care Hospital in Andhra Pradesh*, *Indo Am. J. P. Sci.* 2017; 4(06).

INTRODUCTION:

Tuberculosis (TB) remains a major global health problem, responsible for ill health among millions of people each year. TB ranks as the second leading cause of death from an infectious disease worldwide, after the human immunodeficiency virus (HIV) [1]. The latest estimate reports that there were 9.0 million new TB cases in 2013 and 1.5 million TB deaths (1.1 million among

HIV negative people and 0.4 million among HIV-positive people). Tuberculosis is caused by bacteria called *Mycobacterium tuberculosis* that most often affects the lungs. Tuberculosis is a curable and preventable disease. It is transmitted from person to person via droplets from the throat and lungs of people with the active tuberculosis disease [2]. Early diagnosis and adequate treatment of infectious patients with pulmonary TB are necessary to reduce transmission of tuberculosis and ultimately to achieve elimination of TB. If TB is detected early and properly treated using a combination of medicines for 6 to 9 months, the patients quickly become noninfectious and are eventually cured [3]. The standard anti-TB therapy consists of four medications (rifampicin, ethambutol, isoniazid and pyrazinamide) and takes at least 6 to 9 months to complete, with serious risks of adverse reactions [4,5]. DOTS (directly observed treatment short course) is the internationally recommended control strategy for TB [6].

The objective of the study is to evaluate the prescription pattern, drug utilization and audit for the treatment of TB in a tertiary care hospital in Rajahmundry, Andhra Pradesh.

METHODOLOGY:

The study design is a prospective observational study. A total of 80 cases related to treatment of TB were investigated in a tertiary care chest hospital in Rajahmundry, AP. The study is conducted during January 2017 to April 2017.

Inclusion and Exclusion Criteria:

1. Patients with pulmonary TB admitted as in patients in the hospital are enrolled.
2. Patients with age group 15-80 years of both men and women are included.
3. Patients with active or inactive TB taking anti-tubercular treatment.
4. Pregnant and lactating women are excluded from the study.

Sources of Data:

The data sources include patient case sheets, prescriptions issued and discharge medication sheet, WHO guidance on essential drugs and by interacting with physicians and patients.

Institutional Ethics Committee (IEC) approved the protocols of the study.

RESULTS AND DISCUSSION:

The objective of the observational study is to evaluate the prescription pattern, drug utilization and audit of anti-TB drugs usage in a tertiary care hospital in Rajahmundry, Andhra Pradesh. Audit is a review and the evaluation of the healthcare procedures and documentation for the purpose of comparing the quality of care which is provided with the accepted standards. Prescription audit consists of monitoring, evaluating and if necessary, suggesting modifications in the prescribing practices of medical practitioners.⁷

Data on prescription pattern and drug utilization on 80 TB patients are collected in a tertiary care chest hospital in Rajahmundry. Demographic details and past medical history related to co-morbid diseases are given in Table 1. The data indicated that men are more prone (62.5%) to TB than women (37.5%). People in the age group 31-45 years are more prone to TB (35%). In this group men are more (20%) than women (15%). In all other age groups also men are more than females among the TB patients. Among the various co-morbid diseases the more prevalent ones are hypertension (28.75%), diabetes (26.25%), COPD (12.5%) and thyroid (7.5%). In each case men are more in numbers than females except thyroid.

A study of prescription pattern given in Table 2 indicated that four drug combinations are most widely prescribed (86.25%). There are three 4-drug combinations utilized. The four drug combinations consist of rifampicin, isoniazid, ethambutol and pyrazinamide in different doses (Table 2). The same four drug combination is recommended by WHO in its list of essential drugs for TB. A comparison of WHO essential drugs and drugs prescribed for TB is given in Table 3. A 2-drug combination consisting of pyrazinamide and ethambutol is also prescribed (10%) though it is not included as a 2-drug combination in WHO list of essential drugs. The mono drug therapy consisting of pyrazinamide in different doses is also prescribed in a few cases (3.75%). In majority of the cases the dosage used is much larger than the dose suggested by WHO. For example, in the case of pyrazinamide the WHO suggested a dose of 400mg but it is used in doses 750-1000mg. In the case of ethambutol WHO suggested 100-400mg, but it is prescribed in 1000mg doses. WHO suggested seven (7) essential drugs for TB to be used either alone or in combination. Whereas in the tertiary care hospital where the study was conducted only four (4) antitubercular drugs

were used. In majority of the cases the drugs are used at larger doses than suggested by WHO. Prescribing drugs at doses higher than the doses recommended by the WHO may result in drug wastage, resistance development and further

complications due to excessive drug usage. Hence it is suggested that the WHO recommended all essential drugs may be used either alone or in combinations at the doses suggested.

Table 1: Demography and past medical history of the patients participated

Sex	Male	62.5%		
	Female	37.5%		
Age (years)	15-30	22.5%	M	F
			10%	12.5%
	31-45	35%	20%	15%
	46-60	20%	15%	5%
	61-80	22.5%	17.5%	5%
Social history	Smoking	22.5%		
	Alcoholic	25%		
Co-morbid diseases	Hypertension	28.75%	M	F
			16.25%	12.5%
	Diabetes mellitus	26.25%	13.75%	12.5%
	Thyroid	7.5%	-	7.5%
	COPD	12.5%	10%	2.5%

Table 2: Prescription Pattern and Drugs Used

Prescription type	Drugs used and dose	Percentage usage
Monotherapy	Pyzina 750 (pyrazinamide)	1.25%
	Pyzina1000 (pyrazinamide 1000 mg)	2.5%
2- combination	Pyzina 750(pyrazinamide) Combutil 1000 (ethambutol)	10%
4- combination	Akurit 4 (Ethambutol 275mg Rifampicin 150mg Isoniazid 75mg Pyrazinamide 400mg)	15%
	Forecox (Rifampicin 225mg Isoniazid 150mg Pyrazinamide 750mg Ethambutol 400mg)	62.5%
	Macox plus 600+pyzina750+combutil 1000 (Rifampicin 600mg and Isoniazid 300mg)+ Pyrazinamide750mg+ Ethambutol 1000mg)	8.75%
Other drugs used along with anti-TB drugs	Amikacin (antibiotic)	77.5%
	Ciprofloxacin (antimicrobial)	77.5%
	Rehepatin (liver protectant)	67.5%
	Salbair-I nebulizer (anti-asthmatic)	37.5%
	Nimesulide (NSAID)	57.5%

Table 3: WHO Essential Drugs⁸ and Drugs Prescribed for TB - A Comparison

Combinations	WHO essential drugs with dose	Drugs prescribed with dose
MONOTHERAPY	Ethambutol 100-400mg	--
	Isoniazid 100-300mg tablet and 50mg scored tablet	--
	Pyrazinamide 400mg tablet 150mg dispersible and scored tablet	Pyrazinamide 750mg;1000mg
	Rifabutin 150mg capsule	--
	Rifampicin 20mg/ml;150mg 300mg tablets	--
	Rifapentine 150mg	--
	Streptomycin 1g in vial (powder for injection)	--
2-DRUG COMBINATIONS	Ethambutol 400mg +isoniazid 150mg	--
	Isoniazid +rifampicin (75+150mg);	--
	Isoniazid +rifampicin (150+300mg)	--
	Isoniazid +rifampicin (60+60mg)for intermittent use 3 times weekly	--
	Isoniazid +rifampicin (150mg+150mg) for intermittent use 3 times weekly	--
	--	Pyzina 750(pyrazinamide)+ Combutol 1000 (ethambutol)
3-DRUG COMBINATIONS	Ethambutol +isoniazid +rifampicin (275mg+75mg+150mg)	--
	Isoniazid + pyrazinamide +rifampicin (75mg +400mg+150mg);	--
	Isoniazid + pyrazinamide +rifampicin (150mg+500mg+150mg)for intermittent use 3 times weekly	--
4-DRUG COMBINATIONS	Ethambutol+ isoniazid +pyrazinamide +rifampicin (275mg+75mg+400mg+150mg)	Akurit 4 (Ethambutol 275mg Rifampicin 150mg Isoniazid 75mg Pyrazinamide 400mg)
	--	Forecox (Rifampicin 225mg Isoniazid 150mg Pyrazinamide 750mg Ethambutol 400mg)
	--	Macox plus 600 +pyzina750 +combutol 1000 (Rifampicin 600mg and Isoniazid 300mg)+ Pyrazinamide750mg+ Ethambutol 1000mg)

CONCLUSIONS:

1. Men are more prone(62.5%)to TB than women(37.5%).
2. In all age groups men are more than females among the TB patients.
3. Hypertension, diabetes, COPD and thyroid are more prevalent co-morbid diseases in TB patients.
- 4.4-drug combinations consisting of rifampicin, isoniazid, ethambutol and pyrazinamide are most widely prescribed (86.25%).
5. WHO suggested 7 essential drugs for TB out of which only 4 drugs were prescribed in the hospital.
6. In most of the cases of mono drug therapy and combination therapy, the drugs are used at larger doses than the WHO suggested doses.
7. Hence it is suggested that the WHO recommended all essential drugs may be used either alone or in combinations at the doses suggested.

ACKNOWLEDGEMENTS

It is a pleasure and privilege to express our deep sense of thanks and indebtedness to the management of Vikas Institute of Pharmaceutical Sciences, Principal Dr. T.V. Narayana and Vice-Principal Dr. G. Sumalatha and Dr. G. Srinivas, Vijaya Bharathi Chest Institute, Rajahmundry for giving their consent and facilities to carry out the present work.

CONFLICT OF INTEREST

Authors declared there is no conflict of interest.

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