



A STUDY ON ADVERSE DRUG REACTION TO ANTI-TUBERCULAR DRUGS ON PATIENTS TAKING DOTS THERAPY – A PROSPECTIVE STUDY

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ABSTRACT

Tuberculosis (TB) is an infectious disease caused by Mycobacterium Tuberculosis, is the second leading infectious cause of death in world. The aim of this study was to evaluate the ADRs to anti tubercular drugs in tuberculosis patients. It was prospective observational study 300 patients were included and were monitored for ADRs. Out of 300 patients, 110 (36.66%) developed ADR. The incidence of ADRs were found to be more in females (77.27%) as compared to males (22.72%). Incidence of ADRs were maximum in the age group 21-40 years (63.63%). Majority of ADRs were Increased liver enzyme transaminase (23.12%) and followed by gastritis (19.90%). As a pharmacist we have the liability to support the patients during the period of antitubercular treatment. These ADR may steer the patient to make a judgment for stopping the medications and finally the occurrence of drug resistance and an amplified health care cost. If a proper educational system is implemented, most of the patient may report their ADR and thereby we can improve the patient adherence and therapeutic outcome.

Keywords – Tuberculosis; Adverse drug reaction; Antitubercular drugs; Increased liver enzyme.

1. INTRODUCTION

Tuberculosis is a major public health problem in India. It is the second leading infectious causes of death in the world wide. The world health organization declared TB as a global health emergency in 1996¹. As per WHO estimate, nine million people globally develop active TB and 1.7 million die of it annually. In India it is estimated that nearly 2 million people develop active disease every year and about 0.5 million die from it².

The world adopts directly observed treatment short course (DOTS) for TB control thought the national TB control programs in different countries and is making good progress³. Pharmacovigilance activities can help in obtaining real information of safety and effectiveness of medicine when they are being used in the population⁴.

This study aims to explore and observe adverse drug reactions of antitubercular drugs in DOTS therapy. Good patient adherence to the treatment regimen is the foundation stone to effective antitubercular therapy. Noncompliance is cited as the major problem to the control of the tuberculosis at the level of public health and finally which escort to the drug resistance in case of TB^{5,6}.

2. MATERIALS AND METHODS

The study was carried out in the DOTS center in Coimbatore region. It was a prospective and observation study. The study was carried out from July 2015 to December 2016. The data such as demographic details, blood investigation, chest radiograph, ultrasound, computed tomogram, MRI, histopathological report was documented. Patient were categorized to receive category I DOTS for newly detected cases and category II DOTS for patients who were previously treated.

Statistical analysis:

The data was analyzed using SPSS version 20 software. chi-square test was used for compared proportions.

3. RESULTS AND DISCUSSION

A total of 300 patients were included in the study. The patients are divided in to four groups viz 0-20 years, 21-40 years, 41-60 years, and above 60 years. Majority of the cases (31.66%) belongs to the age groups of 21-40 years.

Table 1: Age wise distribution of patients

Sr. No.	Age group (Years)	No. of patients (N=300)	Percentage (%)
1	0-20	60	20.01
2	21-40	95	31.66
3	41-60	80	26.66
4	Above 60	65	21.66

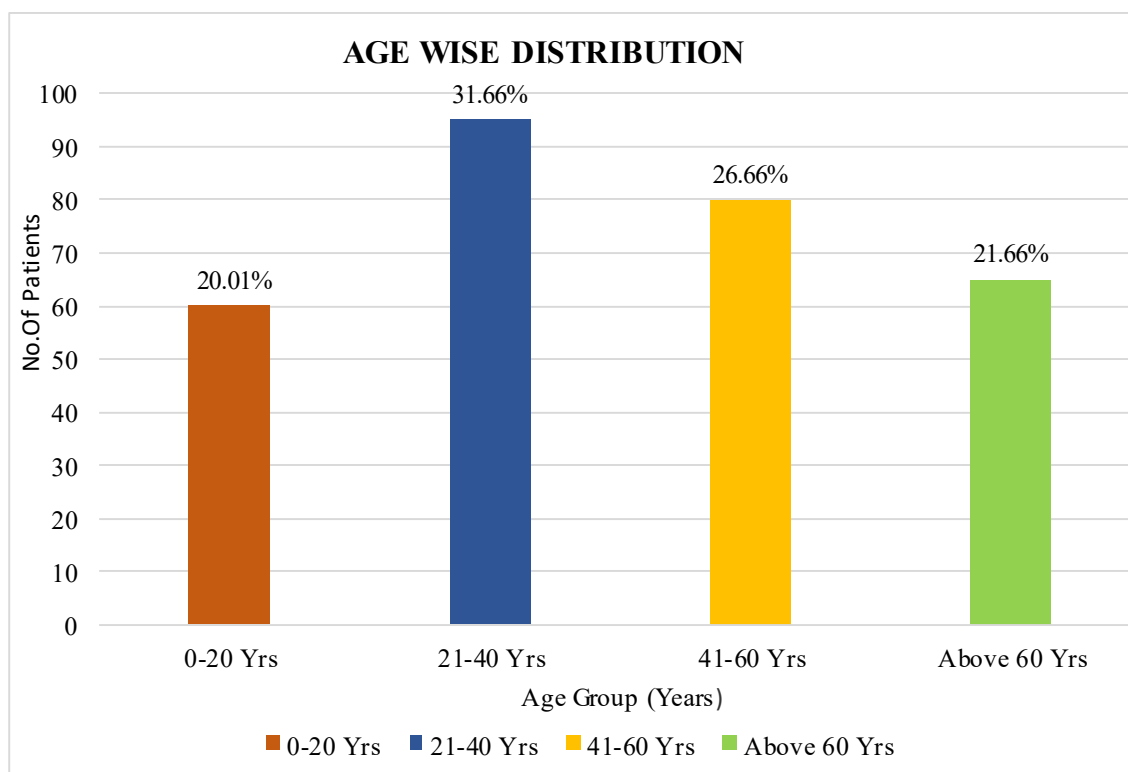


Fig. 1: Age wise distribution of patients

Table 2: Gender wise distribution of patients

Sr. No.	Gender	Number of Patients (60)
1	Males	155 (51.66%)
2	Females	145 (48.33%)

Out of total 300 patients, in which females 145 (48.33%) were found to be having a slightly lesser number of incidences than males 155 (51.66%) in the ratio of 1:1.06.

Table 3: Treatment Categories

Sr. No.	Treatment Categories	Number of Patients (N=300)	Percentage (%)
1	Cat I DOTS (HRZE)	240	80.00%
2	Cat II DOTS (HRZES)	60	20.00%

H- Isoniazid, R- Rifampicin, Z- Pyrazinamide, E- Ethambutol, S-Streptomycin

In present study, the majority of the cases belongs to category I DOTS (80%) and followed by category II DOTS (20%). It may be due to the fact that most of the patients were newly diagnosed.

Table 4 : Sex distribution of adverse drug reactions among TB patients

Sr. No.	Gender	Developed ADR (N=110)	Not Developed ADR (N=190)	P - Value
1	Males	25 (22.72%)	130(68.42%)	<0.001
2	Females	85 (77.27%)	60(31.57%)	

Out of 300 patients, 110 patients developed ADRs, the incidence of ADRs were more found in females (77.27%) compare to males (22.72%). And this difference was statistically significant (P<0.001).

Table 5 : Age distribution of ADR among TB patients

Sr. No.	Age groups (Years)	Developed ADR (N=110)	Not Developed ADR (N=190)	P - Value
1	0-20 Yrs	10 (9.09%)	50 (26.31%)	<0.001
2	21-40 Yrs	70 (63.63%)	25 (13.15%)	
3	41-60 Yrs	25 (22.72%)	55 (28.94%)	
4	61 Above	5 (4.54%)	60 (31.57%)	

Incidence of ADRs were maximum in the age group 21-40 years (63.63%) and followed by 41-60 years (22.72%).

Table 6 : Distribution of Adverse drug reactions

Sr. no.	Type of ADR	Number of Incidence (N=186)	Percentage (%)
1	Increased liver enzyme transaminase	43	23.12
2	Gastritis	37	19.90
3	Weakness or fatigue	30	16.13
4	Skin rash	27	14.52
5	Joint pain	18	09.68
6	Anorexia	15	08.06
7	Peripheral neuritis	06	03.23
8	Optic neuritis	05	02.69
9	Prolonged PT	05	02.69

Out of 186, most of ADRs was found to be as increased liver enzyme 43 (23.12%) followed by gastritis 37 (19.90), weakness or fatigue 30 (16.13%) and skin rash 27 (14.52%).

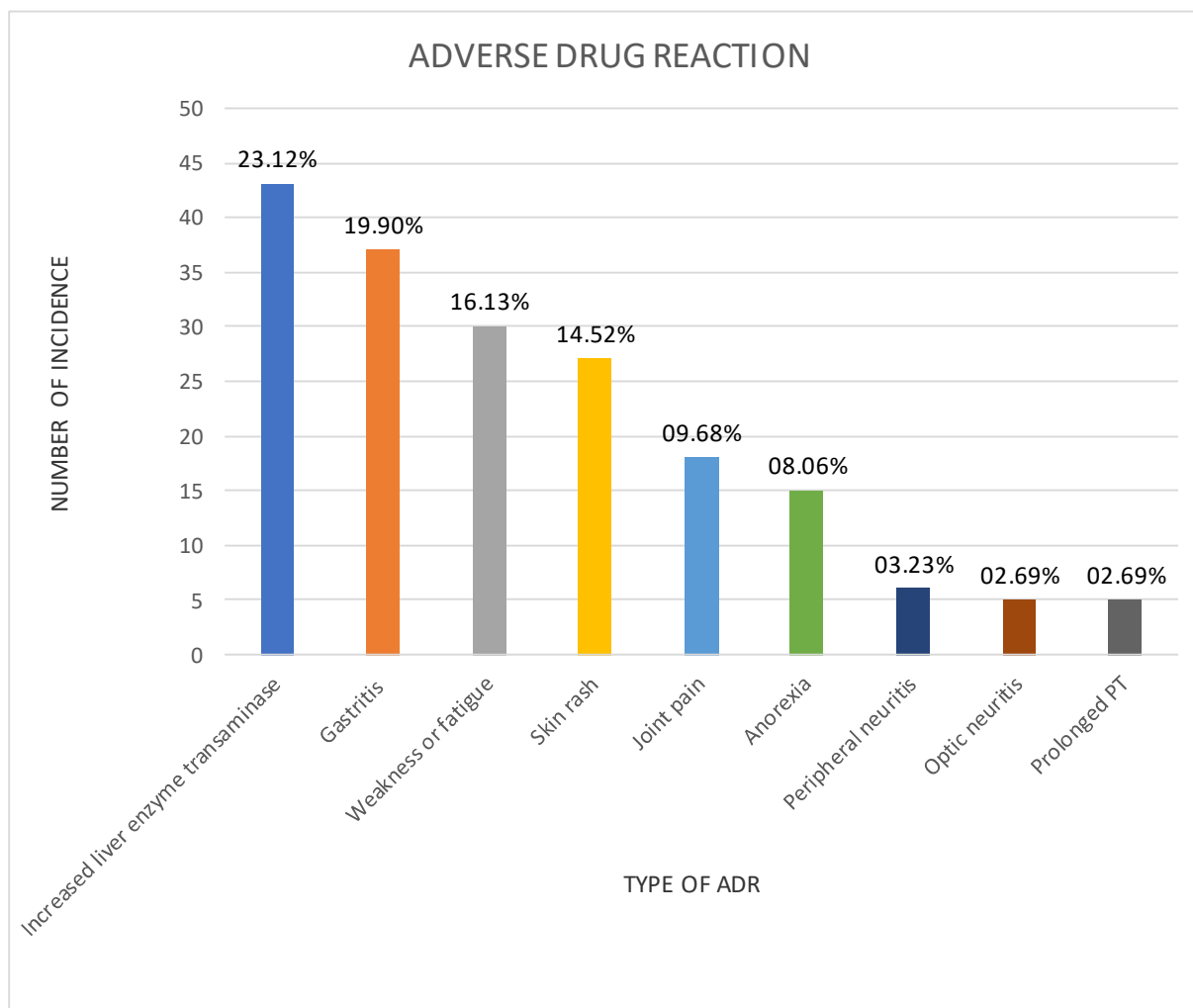


Fig. 2: Distribution of Adverse drug reactions

Tuberculosis requires prolonged treatment and some of the drugs may cause ADRs involving the liver, GIT, skin, nervous system, and eyes. Out of 300 patients included in our study (110) developed ADRs. 85 females and 25 males were developed ADRs. Most of the ADRs were in the age group of 21-40 years (63.63%). Increased liver enzyme was the most common ADR (23.12%), followed by gastritis (19.90%), weakness or fatigue (16.13%), and skin rash (14.52%). Reena varma et al, found that hepatitis and biliary dysfunction were most observed ADR ⁽⁶⁾. in our study 18 patients (9.68%) developed joint pain and anorexia were observed in 15 cases (8.06%). Only 6 patients had peripheral neuritis, 5 patients were optic neuritis and 5 patients were observed prolonged PT. All patients with ADR were managed symptomatically. The exact reason why females had more ADRs is not exactly known though some studies have shown increase incidence of hepatitis with elderly age, female sex, malnutrition, alcoholism, and low serum albumin levels ⁷.

4. CONCLUSION

Antitubercular drugs may cause ADRS just like other drugs used in management of other diseases. These reactions may lead to hospitalization, prolonged hospital stay and even death. People may develop more frequently severe adverse reactions such as

hepatitis, induced by this class of medicines. Regular monitoring of ADRS is essential for management of any diseases, especially tuberculosis where prolonged treatment is required. The activity of the pharmacovigilance needs to be strengthened.

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