



Research Article

Profile of Adverse Drug Reactions in TB Patients Taking ATT

Authors

Dr Aashutosh Asati¹, Dr Manoj Indurkar²

Department of Pulmonary Medicine, S.S.M.C Rewa

ABSTRACT

INTRODUCTION- Tuberculosis treatment need more than one drug combination to eradicate tuberculosis bacteria.² The use of multidrug regimens has been associated with increased incidence of adverse drug reactions of anti-tubercular drugs. Hence, there is a need to monitor the adverse effects of antitubercular drugs in a hospital set up.

METHODOLOGY- Information on any past or current occurrence of adverse effects due to the ATT drugs being administered to the patients was collected. Frequency distribution tables were prepared from the collected data.

RESULTS AND DISCUSSION- In our study Gastrointestinal symptoms like Anorexia, Vomiting, Nausea, abdominal pain were the most commonly reported ADRs followed by headache and tingling and burning sensation in hands and feet. Similar adverse effects were reported in other studies. Adverse drug reactions were more frequently and more severely reported among females and elderly patients (>60yrs).

CONCLUSION- Adverse drug reactions among patients taking anti tubercular treatment is common, So identification of such adverse effect and prompt management will definitely be very helpful for a successful anti tubercular chemotherapy.

INTRODUCTION

India is the second-most populous country in the world one fourth of the global incident TB cases occur in India annually. As per WHO Global TB Report, 2015, out of the estimated global annual incidence of 9.6 million TB cases, 2.2 million were estimated to have occurred in India.¹ Tuberculosis treatment need more than one drug combination to eradicate tuberculosis bacteria. First line anti-tuberculosis drugs recommended by WHO are combination between isoniazid, rifampicin, pyrazinamide, ethambutol and streptomycin.² The use of multidrug regimens has been associated with increased incidence of adverse drug reactions of anti-tubercular drugs.³

Under RNTCP, the doses of first line anti-TB drugs (Isoniazid, Rifampicin, Pyrazinamide, Streptomycin and Ethambutol) were consistent on the basis of body weight and were given different regimens. In initial intensive phase combination of 4-5 drugs is used for 2-3 months, aimed to rapidly kill the TB bacilli, bring about sputum conversion and to get symptomatic relief. This is followed by a continuation phase lasting 4-6 months, during which the remaining bacilli are eliminated so that relapse does not occur.^{4,5} As the treatment of TB almost always involves combinations of drugs that are to be taken for a prolonged period of time, the occurrence of ADR is quite likely. Moreover, the adverse effect of one drug may be enhanced by

the associated drug used which is one of the major reasons for the faulty patient treatment. So, there is a need to monitor the side effects of anti tubercular drugs in a hospital set up.⁸

In the course of anti tubercular treatment some patients may experience problems, usually due to the bulk of the drugs, a single day's dose consisting of more than five drugs. Drug related side effects might be minor or major.⁶ In general, a patient who has minor side effects should be encouraged to continue the treatment with symptomatic measures such as antacids, anti histaminics, anti emetics, or analgesic. If major side effects occur, the regimen, or the offending drug, if identified, must be stopped. Further management depends on the nature of side effects and may have to be done in a hospital.⁷

These side effects are regarded as one of the major causes of non-adherence to anti-TB treatment.⁹ Hence, comprehensive understanding of the various ADRs along with their management is mandatory for effective TB management.¹⁰

METHODOLOGY

The study was done in SSMC Rewa. The target population was Tuberculosis patients undergoing anti tubercular treatment (ATT) with first line drugs. Any patient undergoing treatment at the time of study was included. Patients who were lost to follow up within one month, uncooperative or unwilling to be enrolled, or suffering from other co-morbidities were excluded. The study tool used was the Patient profile form which recorded all the information, such as name, age, sex, residence, life style factors and dietary factors. Information on any past or current occurrence of adverse effects due to the ATT drugs being administered to the patients was collected. Frequency distribution tables were prepared from the collected data.

RESULTS AND DISCUSSION

A total of 45 patients were included in the study. The demographic details of the patients receiving DOTS are shown in Table 1. 4 (9%) patients were less than 20 yrs of age, 31 (69%) individuals were

of age in between 20 to 60yrs, and 10 (22%) individuals age were 60yrs and above. Out of 45 patients, 29 (64) % were male and 16(36) % were female.

Out of 45 patients, 30 patients (66.6%) belonged to category I and 15 patients (33.3%) belonged to category II. The study showed that 89 % of the patients experienced adverse effects, among which 60% of the patients had multiple adverse drug reactions.

Table 2 shows the frequency distribution of adverse drug effects of ATT drugs in Category I and Category II TB patients. Among category I drug users 19 (64%) patients had anorexia/vomiting/ nausea, 6 (20%) patients had dermatological manifestations, 6 (20%) patients had joint pain, 15 (50%) patients had abdominal pain, 6 (20%) had burning sensation, 9 (30%) patients had headache, 3 (10 %) patients had no side effects.

Among category II drug users 08 (53%) patients had anorexia/vomiting/nausea; 06 (40%) patients had abdominal pain; 02 (12%) patients had dermatological manifestation, 4 (26%) got burning sensation, 03 (20 %) had joint pain. 1 (6%) patient reported no side effect.

Out of 16 female patients 15 (94%) female patients reported adverse effect, and most common were anorexia, nausea and vomiting. In age group > 60 years, 9 out of 10 (90%) patients had adverse drug effect.

Table 1: Demographic details of the patients receiving DOTS

Demographic variables		No. of patients	%
Age (in years)	<20	4	9%
	20-30	10	22%
	30-40	7	15%
	40-50	8	18%
	50-60	6	13%
	>60	10	22%
Sex	Male	29	64%
	Female	16	36%
Alcohol	Alcoholic	12	26%
	Non Alcoholic	33	74%
Smoking	Smoker	19	42%
	Non smoker	26	58%
Sputum smear	Positive	25	55%
	Negative	20	45%

Table 2: Frequency distribution of different categories of drug and its adverse effects

Adverse drug effect	CAT I		CAT II		Total	
	n	%	n	%	n	%
Anorexia/Vomiting/Nausea	19	63%	08	53%	27	60%
Abdominal pain	15	50%	06	40%	21	47%
Dermatologic manifestation	06	20%	02	12%	08	16%
Tingling and burning sensation on hands and feet	06	20%	04	26%	10	22%
Headache	09	30%	04	26%	13	29%
Joint pain	06	20%	03	20%	09	20%
Fever	07	23%	02	13%	09	20%
No adverse drug effect	03	10 %	01	6%	04	08 %

In our study Gastrointestinal symptoms like Anorexia, Vomiting, Nausea, abdominal pain were the most commonly reported ADRs followed by headache and tingling and burning sensation in hands and feet. Similar adverse effects were reported in other studies. As per study by Nishant P at al,¹¹ Gastrointestinal intolerance, arthralgia & itching with or without rashes were most common ADRs.

Adverse drug reactions were more frequently and more severely reported among females and elderly patients (>60yrs). Out of 16 female patients 15 (94%) female patients had adverse effect, and most common were anorexia, nausea and vomiting. In age group > 60 years, 9 out of 10 (90%) patients had adverse drug effect. As similar to our findings studies by Nishant P at al,¹¹ Yee et al¹² and Shakya et al^{13,14} showed that Female gender was found to be a significant risk factor for developing Adverse drug reaction. It might be because they pass through life stages like pregnancy, menarche, etc., which modify the drug response.¹⁵ Studies from the UK and Canada also reported females to have a significantly higher incidence of ADRs due to ATT drugs.¹² This suggests the need for special precautions while prescribing ATT drugs to females.

A study conducted by Daphne et al¹⁶ reported that most of the side effects occurred in patients above the age group of 60 years, same findings were noted in our study also.

CONCLUSION

Adverse drug reactions among patients taking anti tubercular treatment is common and these adverse

drug reactions contribute to non adherence of treatment that leads to treatment failure and drug resistance. So identification of such adverse effects and prompt management will definitely be very helpful for a successful anti tubercular chemotherapy.

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