

TO ASSESS THE ADVERSE EFFECT PROFILE OF SECOND LINE DRUG IN TB PATIENTS

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Abstract

Background: A retrospective and prospective study including LPA /AFB CULTURE proven cases of MDR TB. Data will be collected from the patient attending the OPD & IPD in the Dept. of Respiratory Medicine Index Medical College, Indore.

Result: Out of 226 patients, 183 patients continue on treatment and 8 patients get cure and 12 patients dead and 12 patients defaulted the treatment.

Out of 226 patients, the present study shows that Gastrointestinal side effects are the most common 42.5%. 12 patients have renal toxicity and 8 patients have Arthralgia and 6 patients have cutaneous reactions and 14 patients developed hepatitis and 7 patients have some psychiatric illness and 7 patients developed hearing defect.

Conclusion: Overall, these findings emphasize the importance of continuing the systematic surveillance of M. tuberculosis isolates to monitor the trends of drug resistance in different patient categories as well as its association with HIV across the country to timely modify and strengthen the national programs in order to prevent the emergence of MDR-TB strains and avert the threat of XDR-TB.

Keywords: Profile, second Line Drug & TB.

INTRODUCTION

The emergence of resistance to drugs used to treat tuberculosis (TB), and particularly multidrug-resistant TB (MDR-TB), has become a significant public health problem in a number of countries and an obstacle to effective TB control.¹ In India, the available information from the several drug resistance surveillance studies conducted in the past suggest that the rate of MDR-TB is relatively low in India. However this translates into a large absolute number of cases and as yet the management of patients with MDR-TB is inadequate. Specific measures are being taken within the Revised National Tuberculosis Control Programme (RNTCP) to address the MDR-TB problem through appropriate management of patients and strategies to prevent the propagation and dissemination of MDR-TB.²

Management of treatment with second-line anti-TB drugs is complex. Most second-line drugs have a short shelf life, global production of quality-assured drugs is limited, and drug registration may be a lengthy and costly process that is not always attractive to drug manufacturers. In addition, drugs may need to be changed due to side effects, delayed

DST results, and poor response to treatment. To ensure uninterrupted drug supply, projected drug needs will be estimated as accurately as possible and procurement will begin well in advance of the anticipated need.³

Material & Method

This study will be done in the Dept. of Respiratory Medicine Index Medical College Hospital & Research Centre, Indore from April 2018 to March 2019.

- A retrospective and prospective study including LPA /AFB CULTURE proven cases of MDR TB.
- Data will be collected from the patient attending the OPD & IPD in the Dept. of Respiratory Medicine Index Medical College Hospital & Research Centre, Indore.

INCLUSION CRITERIA

1. Patient must be drug resistance case of TB of Dist. Indore.
2. Co morbid condition such as HTN, DM, IHD, liver failure, renal failure etc will be included.

EXCLUSION CRITERIA

1. Drug sensitive TB patient.
2. Non tubercular patient.

Results

Table 1: Showing Patients according to OUTCOME

Outcome	Frequency	Percent	Percent	Cumulative Percent
Cure	8	.9	.9	.9
Continue on treatment	192	80	2.7	3.5
Dead	12	11.5	11.5	15.0
Failed	2	.9	.9	15.9
Defaulted	12	5.3	5.3	21.2
Transfer out	1	.4	.4	21.7
Total	226	100.0	100.0	

Out of 226 patients, 183 patients continue on treatment and 8 patients get cure and 12 patients dead and 12 patients defaulted the treatment.

Table 2: Showing Patients according to ADVERSE EFFECT

Adverse Effect	Frequency	Percent	Valid Percent	Cumulative Percent
Gastrointestinal	96	42.5	42.5	42.5
Renal Toxicity	12	5.3	5.3	47.8
Arthrelgia	8	3.5	3.5	51.3
Cutenious ractions	6	2.7	2.7	54.0
Hepatitis	14	6.2	6.2	60.2
Psychiatric illness	7	3.1	3.1	63.3
Auditory	7	3.1	3.1	66.4
No adverse effect	76	33.6	33.6	100.0
Total	226	100.0	100.0	

Out of 226 patients, The present study shows that Gastrointestinal side effects are the most common 42.5%. 12 patients have renal toxicity and 8 patients have Arthalgia and 6 patients have cutaneous reactions and 14 patients developed hepatitis and 7 patients have some psychiatric illness and 7 patients developed hearing defect.

Discussion

Among patients with drug susceptible TB, the success rate of treatment with short-course chemotherapy is expected to be at least 85%. Patients showed good tolerance to the treatments and exhibited few side effects. However, MDR-TB therapy has a long treatment period (18–24 months) and the number of drugs used for treatment is relatively higher than for drug susceptible TB, and thus many side effects are known. In our study, we evaluated side effects observed during the treatment of MDR-TB.⁴

Most side effects occurred relatively infrequently in our study compared to that observed in previous reports. Furin JJ et al⁵ reported that 30% of patients had side effects requiring withdrawal of 1 or more TB medications. In our study, side effects were noted in

95 of the 256 patients (37.1%), and treatment had to be modified due to uncontrolled side effects in 54 patients (21.1%); this is lower than that observed in previous studies. The lower frequency of certain side effects and of the discontinuation of therapy may be attributable to a number of factors. First, almost all of the patients were treated for MDR-TB in the hospital. This permitted close monitoring of side effects and prompt implementation of management strategies designed to minimize these effects. Second, our team educated our patients regarding the severity of their disease and the absence of options for cure.⁶

The most common side effects were complaints of GI disturbance after MDR-TB treatment (18.4%). This is consistent with previous reports. GI disturbance was most pronounced after treatment with ethambutol and PAS. Most GI side effects can be managed without stopping the drug by escalating the dose, dividing the dose, or with the use of antiemetics. If the GI symptoms were not severe, we added H2 receptor blockers or antiemetic agents to the regimen. However, if symptoms such as nausea, vomiting, or loss of appetite were severe, PAS was withdrawn.⁷

Conclusion

Overall, these findings emphasize the importance of continuing the systematic surveillance of M. tuberculosis isolates to monitor the trends of drug resistance in different patient categories as well as its association with HIV across the country to timely modify and strengthen the national programs in order to prevent the emergence of MDR-TB strains and avert the threat of XDR-TB.

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