Symbiosis

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A Targeted Pharmacovigilance Study on Antitubercular Drugs in the Department of Pulmonary Medicine at Tertiary Care Teaching Hospital in Rural Area

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Abstract

[illegible] (TB) [illegible] mycobacterium tuberculosis [illegible] leading to increased morbidity and mortality. Adverse drug reactions (ADRs) are a global health problem [illegible] and a leading cause of [illegible]. [illegible] ADR reporting [illegible] and improve patient compliance [illegible] treatment outcome.

Keywords: [illegible]

Introduction

According to World health organisation, Tuberculosis is an infective bacterial disease caused by mycobacterium tuberculosis which most commonly affects the lungs. This is the second deadliest disease and it accounts up to [illegible]% of total yearly cases in the world and about [illegible] million die every year. There were an estimated [illegible] million new TB cases with [illegible] million TB deaths in [illegible] [illegible]. Most of the medicines used to treat TB today have been in the market for several decades [8]. Clinicians treating TB patients around the world know these medicines well, and are usually well aware of their associated ADRs. Antitubercular drugs also cause various types of ADRs and affects almost all the system of the body mainly the gastrointestinal, liver, skin, nervous system and skin [9, 10]. ADRs is defined as "Any response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the modification of physiological function". ADRs is considered to be the sixth leading cause of death [11]. The incidence rate estimates approximately [illegible]% of hospital admissions are due to ADRs. Drug attributed deaths are estimated to be [illegible]% in all medical inpatients [12]. About [illegible]% of ADRs identified were directly linked to high costs. ADRs not only increase the mortality and morbidity but also multiply the health care cost [13]. Post-marketing surveillance is also needed for these new drugs. ADRs are unfortunately burden of society both financially and in terms of human suffering. Systematic ADR monitoring and reporting helps physicians for rational prescribing of drugs [14-16].

Methodology

The prospective observational study was conducted in the Department of Pulmonary Medicine and Tuberculosis at Chhatrapati Shivaji Subharti Hospital (Meerut) and its Pharmacology Department. It is a [illegible] bedded tertiary care teaching hospital in rural area. This pharmacovigilance study has been approved by the institutional Ethics Committee. All the patients visiting the medicine for pulmonary dysfunction in outdoor patient department [illegible] and are taking anti-tubercular treatment were enrolled in the study. The patients diagnosed by pulmonologist [illegible] of these patients were recorded. Patient's demographic profile, their relevant disease particulars, treatments, outcomes and adverse effects were recorded. The ADRs were recorded in the specified Performa designed by the National Pharmacovigilance Programme for this purpose. All suspected ADRs were confirmed with the help of different investigations/tests that was depended on the type ADRs. The patients were followed up till the study completed and any new change in prescription and status of each ADR was recorded.

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Inclusion criteria

All patients of either sex aged 17 years and above who are under the treatment of tuberculosis with anti-tubercular drugs.

Exclusion criteria

1. Patients who are HIV Positive.

2. Patients with Chronic illness such as Cirrhosis, chronic hepatitis and acute viral hepatitis.

3. Patients who are unwilling to participate in the study.

Ethics

The patient's data were recorded and privacy of identity was maintained. The study was approved by the Institutional Ethics Committee of [illegible] Medical College and Hospital, file number [illegible].

Observations

There were ADRs in all the 22 cases to antitubercular drugs. But these were successfully managed by immediate measures taken. Symptomatic addition of adjuvant drugs for adverse conditions could relieve the adverse conditions. This helped in ensuring compliance with antitubercular drugs. No antitubercular drug had to be withdrawn as adverse effects could be managed with dose reduction or adjuvant treatment. The ADRs experienced by the tubercular patient were non-serious and for the management of these ADRs an adjuvant drug therapy was done and they responded [illegible] [illegible] (Table 2).

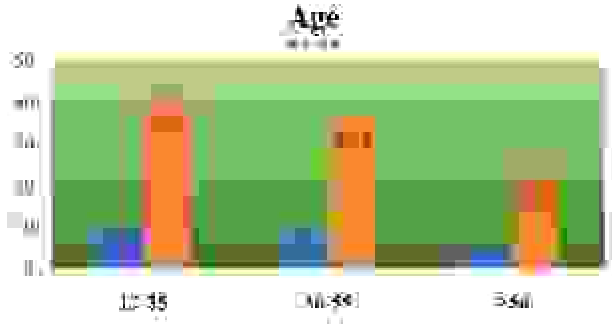


Figure 1: Age (in years) wise distribution of patients

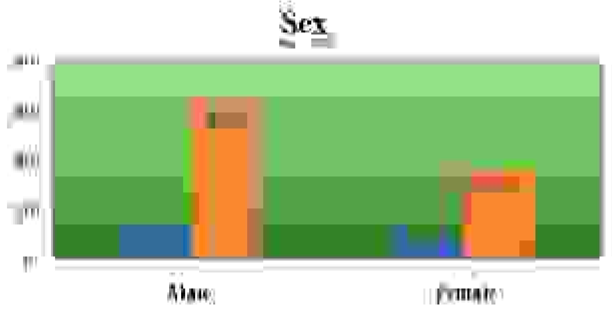


Figure 2: Sex (male, female) wise distribution of patients

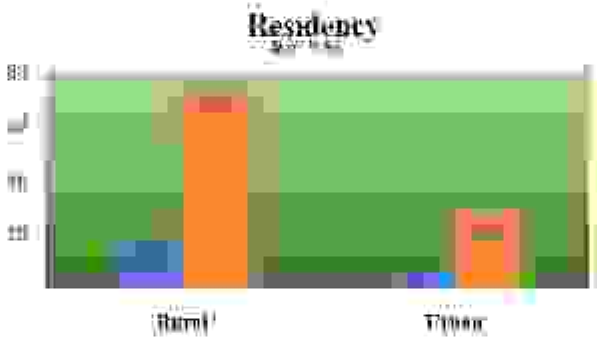
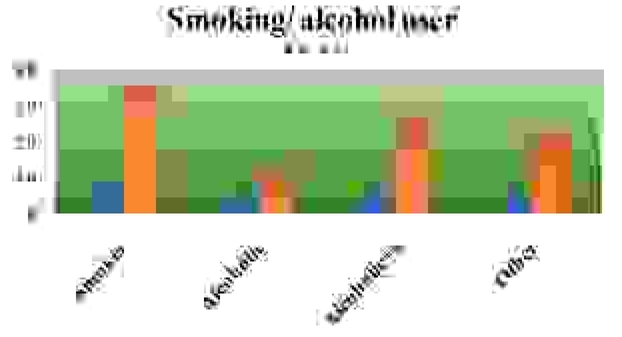


Figure 3: Residency (rural, urban) wise distribution of patients

Table 2: Antitubercular therapy used in 22 patients in department of pulmonary medicine and dose used [illegible].

S. No	Antitubercular drugs (combination dose and single dose)
1	Rifampicin+Isoniazid, Ethambutol, Pyrazinamide
2	Rifampicin+Isoniazid, Ethambutol, Streptomycin
3	Rifampicin+Isoniazid, Ethambutol, Streptomycin
4	Ethambutol, Rifampicin+Isoniazid
5	Rifampicin+Isoniazid, Ethambutol
6	Rifampicin+Isoniazid, Ethambutol
7	Streptomycin, Isoniazid+Rifampicin
8	Rifampicin+Isoniazid, Ethambutol, Pyrazinamide
9	Isoniazid+Rifampicin
10	Rifampicin+Isoniazid, Ethambutol
11	Rifampicin+Isoniazid, Ethambutol, Pyrazinamide
12	Pyrazinamide, Ethambutol+Isoniazid+Pyrazinamide+Rifampicin
13	Isoniazid+Ethambutol
14	Isoniazid+Rifampicin
15	Rifampicin+Isoniazid, Ethambutol
16	Rifampicin+Isoniazid, Pyrazinamide
17	Rifampicin+Isoniazid, Ethambutol, Pyrazinamide
18	Rifampicin+Isoniazid, Ethambutol
19	Rifampicin+Isoniazid, Ethambutol
20	Rifampicin+Isoniazid, Ethambutol
21	Ethambutol, Rifampicin+Isoniazid, Pyrazinamide
22	Rifampicin+Isoniazid, Ethambutol, Pyrazinamide



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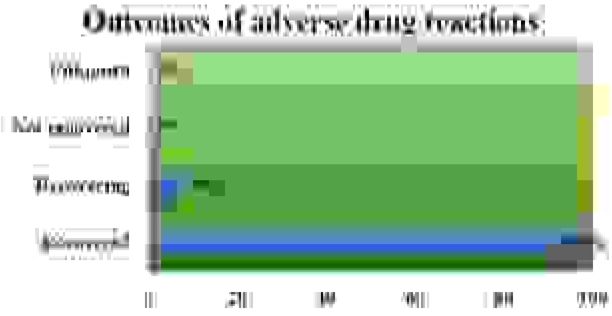

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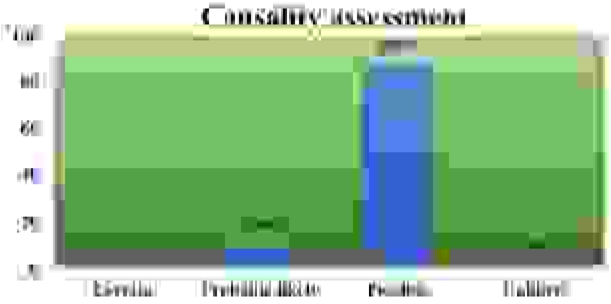

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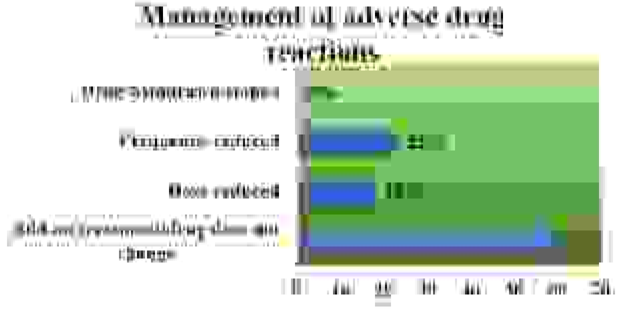

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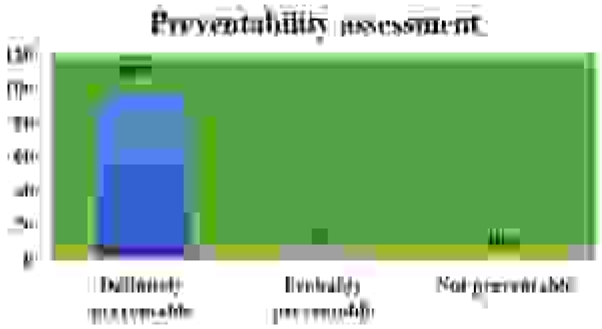

Figure 8: Preventability assessment of ADRs [illegible]

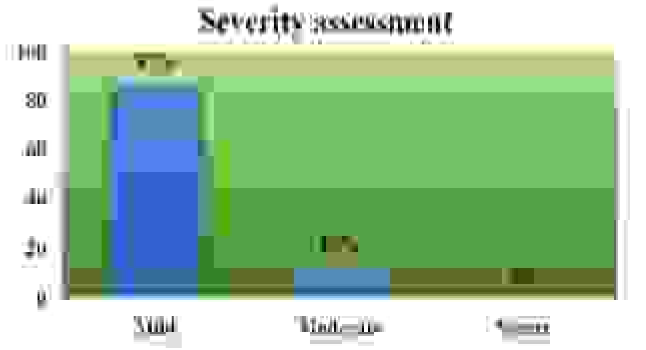

Figure 10: Severity assessment of ADRs by Hartwig and Siegel scale [20].

Results

The present study was envisaged to study pattern of pulmonary medicine and tuberculosis cases, treatment given and assess the ADRs to first line antitubercular drugs prescribed to tuberculosis patients attending outpatient of department of pulmonary medicine and tuberculosis of a tertiary care teaching hospital. It was observed in this study total 22 ADRs were reported. The study was conducted in pulmonary medicine and tuberculosis department of [illegible] hospital ([illegible]) which is a [illegible] bedded tertiary care teaching hospital in rural area. In this observational study we found that the age of patients ranged from 15 to 65 years. That there were more male 63.6% patients as compared to female 36.4%. More than 77% patients were smokers or consumed alcohol. Whereas a less number of patients 23% were neither smoker nor consumed alcohol. Male predominance and a more number of smokers are in agreement with aetiology of respiratory diseases. Smoking and alcohol consumption are risk factors for respiratory diseases. There were adverse events in all the 22 cases of antitubercular drugs, but these were successfully managed by symptomatic measures either. Symptomatic addition of adjuvant drugs for adverse symptoms could relieve the adverse symptoms. This helped in ensuring compliance with antitubercular drugs. No antitubercular drug had to be withdrawn as adverse effects could be managed with dose reduction or adjuvant treatment. Total 22 ADRs were reported in 22 patients who experienced the ADR in outpatient department of pulmonary medicine and tuberculosis. The majority of cases of the adverse drug reactions were related to the central nervous system such as sedation, vertigo, severe headache and sleeping disturbance it happened in 27% mostly due to the first line antitubercular drug like rifampicin, isoniazid, ethambutol and pyrazinamide followed by gastrointestinal reaction such as nausea, vomiting, gastritis and abdominal pain 23%, skin reaction such as erythematous rash, urticaria and itching was 18%, cardiovascular such as palpitation and increased heart rate 9% and other adverse drug reaction were reported 18%. The adverse drug reactions experienced by the outpatient patient were non-serious and all were managed by the add-on drug therapy, for the basis of the risk benefit ratio of the drug therapy in treatment of tuberculosis drug withdrawal of the suspected drug was not required.

However the management of the adverse drug reaction occurrence in outpatient patient were done with add-on therapy 58%, then followed by drug permanently withdrawn, the dose reduced 18%, frequency of dose schedule reduced [illegible]. The causality of each ADR was assessed by using WHO-UMC causality assessment scale. On the basis of scale nearly [illegible] of the ADR were classified as certain, 17% probable, 38% possible and 8% of the ADR were unlikely. The severity assessment of each ADR was assessed by the modified Hartwig and Siegel scale as per this assessment highest number of ADR i.e. 87% of the ADR comes on the level 1-2 and classified mild ADR, 13% of the ADRs were on level 3-4 moderate ADR and there was no any ADR were come on the level 5 and above i.e. severe ADR. For the preventability assessment of each ADR Schumock and Thornton scale was used, and showed that 98% of the ADRs were definitely preventable, 2% of ADRs are probably preventable and no any ADRs are come under the not preventable class.

Conclusion

The present evaluation has revealed opportunities for interventions especially of avoidable ADRs which will help in promoting safer drug use. Information to the healthcare professionals improve the quality of patient care and outcome of disease treatment. The adverse drug reaction monitoring and reporting programmes in pharmacovigilance programme aims to identify the risks associated with the use of the drugs. This information may be useful in planning and to minimize the preventable ADRs. Many times the patients discontinue their treatment because of the suffering of the adverse drug reaction. Some time it may be very dangerous for the patient as well as society e.g. if the patient discontinues their antitubercular therapy the risk of the failure of the tubercular treatment increased and it may be the chance of resistance tuberculosis. So now the time has come to aware the general public too for the reporting the adverse drug reaction to nearest hospital or ADR monitoring centre or to the healthcare professionals. They may directly report the ADR through government Toll-free number 1800180 3024, ADR application in android and other media like social media [22-25].

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