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Short Communication

STUDY ON PREVALENCE OF ADVERSE DRUG REACTIONS IN PATIENTS SUFFERING FROM TUBERCULOSIS IN A TERTIARY CARE HOSPITAL

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ABSTRACT

Objective: To study the prevalence of ADRs associated with the use of anti-tubercular drugs in patients with tuberculosis in a tertiary care hospital.

Methods: A prospective observational and active surveillance study was conducted in the department of pulmonology and DOTS Centre in Owaisi Hospital and Research Centre over a period of 6 mo after the study was approved by IRB. The patients who gave informed consent were included in the study and their information was analysed after being recorded in a data collection form.

Results: Descriptive statistical analysis was carried out to generate results, the continuous measurement being presented as mean standard deviation (min-max) and categorical measurement presented in number (%). The results showed the prevalence of ADRs to be 69%. The prevalence of ADRs was more in females (55%) than in males (45%) and 75.9% of them reporting more than 1 ADR. ADR's affecting the skin and appendages were high (23.56%) while ADR's affecting gastrointestinal system (19.28%), the hepatic system (4.28%), the musculoskeletal system (15.7%), Central and peripheral nervous system (7.85%), Vision (0.7%) were comparatively less.

Conclusion: The study highlighted the importance of developing strategies to ameliorate ADRs both to improve the quality of patient care and to control TB safely.

Keywords: Prevalence, Tuberculosis, Adverse Drug Reaction

Infectious diseases are the important leading causes of death (morbidity and mortality) among the people of Tuberculosis (TB), HIV/AIDS and with other chronic diseases [1]. Among various infectious diseases, TB is one of the leading contagious infection responsible for death which is affected by Mycobacterium tuberculosis [2].

In 1993, WHO declared TB as a global emergency and National Tuberculosis Programmes (NTPs) strategy was started all over the world to employ the daily regimens/Directly Observed Treatment-Short course (DOTS) of anti-TB drugs [3].

The long duration of TB treatment drugs like Isoniazid, Pyrazinamide, Rifampin, Ethambutol and Streptomycin–are potentially responsible to cause adverse drug reactions like hepatotoxicity, visual disturbance, arthralgia, headache, skin rashes etc. These Adverse reactions mostly observed/occur in the first three months of treatment. A large number of patients are exposed to anti-TB drugs at PHCs of RNTCP/DOTS, yet no such major findings were observed in monitoring/detecting of ADRs. The ADRs are one of the major reasons for patient default about their treatment [4].

The high prevalence of TB treatment highlight the need of the importance of the clinical pharmacist, for monitoring ADRs and to increase awareness of ADRs among the patients and health care professionals by reporting any suspected ADRs. This type of activity of the pharmacist will help in minimizing ADRs [5, 6].

The present study was conducted to evaluate the prevalence of adverse drug reactions in patients suffering from tuberculosis. As TB is a widespread disease in major parts of India several steps have been taken to eradicate the disease and programs such as RNTCP and DOTS were initiated. The occurrence of ADRs is one of the main reasons of non-compliance, by designing a prospective observational study we have targeted the TB affected patients. This study also gives us an idea on all the common ADRs that occur during the course of treatment intending to provide knowledge about the ADRs associated with anti-tubercular drugs.

A hospital based prospective observational study was conducted over a period of 6 mo (August 2014-February 2015) in Out Patient Department of Owaisi Hospital and Research Centre, Hyderabad, Telangana State, India after it was approved by Institutional Ethics Committee (IEC).

Patients of both genders willing to give verbal informed consent and above the age of 17, patients with family history of tuberculosis, patients on DOTS therapy and patients diagnosed with TB were included for the study whereas pregnant women, patients who were not willing to give verbal informed consent, in-patients or the hospitalized patients and patients who were not able to communicate or have a language problem were excluded for the study.

120 patients met the inclusion criteria and so were enrolled for the study after obtaining Informed consent either from patients or through a legally acceptable representative for documentation of any suspected ADRs.

The relevant details such as clinical presentation, date of starting and stopping of event, relevant laboratory investigations, other relevant history including pre-existing diseases, suspected medication (including dose, frequency, route of administration, dates and duration of administration and indications for use) and concomitant medicines (including self-medication and herbal remedies) of inpatients were recorded on a patient data collection form along with demographic details such as age, gender, weight, diagnosis and prescription details like date, DOTS therapy (Category I and Category II) given to the patient, duration of treatment.

Adverse drug reactions related to anti-tubercular medications were listed out using Medscape and other related articles and journals. The adverse drug reaction caused by the individual drug was noted in the data collection form than were detected and brought to the notice of the medical officer for further evaluation. Details regarding the suspected drug, date of suspected drug started, date of onset of the reaction, a brief description of the reaction were documented and authenticated by the signature of the in charge medical officers and date of reporting.

The data analysis was done using Statistical Methods such as Descriptive statistical analysis using MS excel spreadsheet to generate graphs, tables etc., and results on continuous measurement were presented on mean standard deviation (min-max) and results on categorical measurement were presented in number (%) and were tabulated as follows:

Out of 120 patients enrolled in the study a total of 140 ADRs were reported by 83(69.16%) patients and 37 (30.84%) patients did not report any ADR.

The prevalence of ADRs in males and females was 45% and 55% respectively depicted in table 1

The patients who received Isoniazid, Rifampicin, Pyrazinamide and ethambutol were found with more number of ADRs i.e., 40 (75.5%) when compare with other combinations. ADRs were divided into 2 groups-single ADR and more than 1 ADR table 2

The percentage of patients with single and more than 1 ADR was 24.09% and 75.9% respectively.

Table 1: Demographic data (Gender)

Gender	No. of patients	% of patients
Male	54	45
Female	66	55
Total	120	100

Table 2: Adverse drug reactions

Adverse drug reactions	No. of patients	% of patients
Single adr	20	24.09
More than 1 adr	63	75.9
Total adr	83	99.99

The common adverse drug reactions related to individual drugs are shown in table 3

Table 3: Details on distribution of types of ADRs

ADR	No. of ADRs	% of ADRs
RIFAMPICIN		
Rash	10	7.14
hepatotoxicity	6	4.28
Orange urine	30	21.4
ISONIAZID		
Rash	23	16.42
Nausea & vomiting	11	7.85
Peripheral neuropathy	10	7.1
Loss of appetite	6	4.28
PYRAZINAMIDE	6	4.28
Anaemia		
Joint pain	20	14.2
Hyperuricemia	2	1.42
ETHAMBUTOL		
Anorexia	5	3.57
Stomach cramps	5	3.57
Headache	5	3.57
Optic neuritis	1	0.7

ADR's affecting the Skin and appendages were high, i.e., 33(23.56%), while ADR's affecting other systems were as follows gastrointestinal system 27 (19.28), i.e., hepatic system, i.e., 6 (4.28) musculoskeletal system, i.e., 22(15.7), central and peripheral nervous system, i.e., 15 (7.85)., Vision i.e., 1 (0.7). the most common adverse effect caused by rifampicin was orange colored urine, i.e., 30 (21.4%).

The common adverse drug reactions of Rifampicin were found to be orange colour urine 36% (n=30), hepatotoxicity 8% (n=6), and rash around 12% (n=10).

The common adverse drug reactions of Isoniazid were found to be rash and generalised itching 28% (n=23), nausea and vomiting 13% (n=11), peripheral neuropathy 12% (n=10) and loss of appetite 8% (n=6).

The common adverse drug reactions of Pyrazinamide were found to be joint pains 24% (n=20), anaemia 8% (n=6), hyperuricemia 3% (n=2).

The common adverse drug reactions of Ethambutol were found to be anorexia 12 % (n=10), stomach cramps 8% (n=6), headache 6% (n=5), and optic neuritis 2% (n=1).

However in our study it was found that the prevalence of TB was more in females than in males and most of the patients reported orange colour urine and the prevalence of Tuberculosis is more in females by 10% than in males(The percentage of females affected with tuberculosis is 55% and the percentage of males affected is 45%.)

Orange coloured urine was reported by most of the patients which was caused by rifampicin followed by rash and generalised itching caused by isoniazid.

The study showed that the prevalence of ADRs with anti-tubercular drugs was 69.16%. These ADRs had a substantial impact on TB control. Majority of the patients felt that after taking their treatment the condition worsened which was merely due to ADR of anti-tubercular therapy (ATT), which shows wrong conception about treatment. It was minimized by interviewing and patient counseling. Our study concludes that there is a need of a close monitoring system for proper detection of ADRs caused by anti-TB drugs. Counselling of patients for timely prevention, detection and management of ADRs will help in minimising the further occurrence

of ADR. Our study highlighted the importance of developing strategies to ameliorate ADRs both to improve the quality of patient care and to control TB safely.

The authors have no conflicts of interests to declare.

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CONFLICT OF INTERESTS

Declared none

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