

THE STUDY OF AN ADVERSE DRUG REACTION CAUSED BY FIRST LINE ANTI-TUBERCULAR DRUGS**Dr. Shaik Mohammed Sumeer*¹ and Dr. Noorush Shifa Nizami²**^{1,2*} Doctor of Pharmacy (PHARM-D) Intern, St. Paul's College of Pharmacy, Nagarjuna Sagar Road, Turkayamjal, Hyderabad, T.S – 501510.***Corresponding Author: Dr. Shaik Mohammed Sumeer**

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ABSTRACT

Development of drug resistance in the treatment of tuberculosis, especially multi-drug resistant TB (MDR-TB) had begun the Global public health issue in many countries. Drug resistance may be developed due to infection with the resistant strain or it may be a result of the insufficient treatment, usually when the patient is exposed to irregular drug supply, single drug, poor drug quality, selective drug intake or maybe the erratic absorption of medications, which is usually rare. We present a case in which the patient is already diagnosed with ATT drugs and came to the hospital with the adverse effects of the ATT drugs and the patient was presented with the complaints of vomiting, loose stools, burning micturition and epigastric burning sensation since two days and was diagnosed as drug – induced gastritis and was treated with antibiotics, proton pump inhibitors, acid blockers and the other supportive treatment was given.

KEYWORDS: ADRs, Anti Tubercular treatment, Mycobacterium, DOTS Therapy.**INTRODUCTION**

Tuberculosis (usually known as TB) it is the bacterial infection which is mainly caused by the organisms which belongs to the Mycobacterium tuberculosis.^[1] The WHO (World Health Organization) declared TB as a "Global emergency" in the year 1993.^[2] However, globally very few initiatives have been taken to fight tuberculosis and the most important being the DOTS (which is abbreviated as directly observed treatment, short course) strategy. DOTS is known as the methodology to make sure that all the patients with TB, who are on TB treatment gets the best chance to be cured. Patients should take their medicines everyday and remain under the direct observation of the healthcare professional. Treatment course will last from 6-8 months and that will be included in therapy with the drugs known as isoniazid, rifampicin, ethambutol, pyrazinamide and streptomycin.^[3]

The World Health Organization (WHO) has defined ADR as "A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function." Few common ADRs which occur due to the antitubercular drugs includes, visual disturbances, jaundice, peripheral neuropathy, pancreatitis, skin rashes, ototoxicity, hyperuricaemia and hypersensitivity reactions.^[4] Recent studies found that ADRs accounts for 5% of all hospital admissions and death in 0.1% of medical and 0.01% of

surgical cases.^[5] It is also found that 50% of the ADRs are usually preventable if detected early.^[6] Globally, many countries have started certain programs in order to monitor the adverse drug reactions, with varying degree of success.

REVIEW OF LITERATURE

1. The World Health Organization (WHO) has defined ADR as "A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function." Few of the common Adverse drug reactions occur due to the antitubercular drugs are peripheral neuropathy, visual disturbances, jaundice, pancreatitis, skin rashes, hypersensitivity reactions, hyperuricaemia and ototoxicity (Anupa Khatri Chhetri et al).
2. The incidence of ADRs commonly associated with DOTS therapy was low but is a serious problem in India due to the high TB burden on the country. Hence, monitoring for the possible ADRs, mainly in patients at increased risk of TB should be routinely done. The DOTS therapy is effective and also safe when compared to the daily treatment regimens, but the higher incidence of tuberculosis will increase the number of patients at the risk of the adverse events. Therefore the patients who are receiving the DOTS therapy may require the close monitoring for the adverse events and, hence a Pharmacovigilance

program should be added at national level in order to assess changes that are caused in the incidences of these adverse events (Faisal imam et al).

- In the study, performed by Sood A, Majority of the patients who were on DOTS plus therapy have been reported the ADRs after the chronic administration and hence it could be due to the toxic and the cumulative effect of drugs whereas the ADRs reported by patients on CAT1 ATT were constantly acute and sub-acute in onset and also majority of ADRs among both treatment schedules had no serious reactions and only few patients required hospitalizations in both the groups. No life threatening ADR and death was reported in either of the groups (Sood A et al).

PRESENTATION OF CASE

A 63 year old female weighing 70 kg was admitted to the hospital, a tertiary care center on 11th January 2021. Patient was presented with complaint of vomiting, loose stools, burning micturition and epigastric burning sensation for the past two days and was diagnosed as drug – induced gastritis and was treated with Antibiotics (clarithromycin and amoxicillin, proton pump inhibitors (omeprazole), acid blockers also called as histamine H-2 blockers to reduce the amount of acid release in the digestive tract. The patient had a history of hypertension, diabetes mellitus, hypothyroidism, urinary bladder koch's (biopsy proven) patient was already on ATT. On examination, CVS: S1S2 heard, no murmurs, CNS: NAD, B.P: 130/90 mmhg, Spo2: 98% @ RA. In this case, the patient was diagnosed with TB prior to hospital admission but due to ATT patient has experienced the above symptoms and managed accordingly.

DISCUSSION

Tuberculosis (TB) has always remained one of the most dangerous health problems and India has always been the highest TB burden country (accounting for one fifth of the global incidence) an estimated amount of 1.96 million cases annually.^[5] Nearly 2.9 million people usually die from Tuberculosis every year worldwide. About one-fifth of them are from India alone.^[6] Approximately 500,000 people die from the disease >1000/day.^[7] With this fast spreading Tuberculosis, India has enforced and adopted directly observed treatment known as short course (DOTS) strategy. The first-line medicines included under DOTS therapy are Isoniazid, Rifampicin, Pyrazinamide, Ethambutol, and Streptomycin that are known to cause the adverse effects such as gastritis which is being found in this case report and the other ADRs may also occur such as hepatotoxicity, visual disturbances and skin allergies. Hepatotoxicity is a serious adverse effect and the risk of hepatotoxicity is based on the data from few prospective Indian studies was 11.5% compared with 4.3% in the Western publications. Currently recommended anti-tuberculosis (ATT) regimen (DOTS) is mostly well tolerated. But some patients may also experience the problems usually because of bulk of the medicines, like a

single day's dose which consist of 6-7 tablets. Drug related side effects can be minor or major and sometimes it can also be life threatening. Hence, rather than concentrating only on treatment, the adverse effects of drugs should also be taken into the account for achieving the better patient compliance.

CONCLUSION

Adverse drug effects are mainly observed in the patients taking anti TB treatment, mostly the symptoms will be mild such as gastritis and the treatment approach to be followed is to treat the onset of symptoms along with the concurrent medication. There is no marked sign of hepatotoxicity in patient taking anti tubercular treatment. Interventions and correct knowledge to cure these kinds of mild adverse effects may lead to increased patient compliance and increased the quality of life of the patient and better outcome. Some studies have also reported that family plays the major and most important role in order to combat the illness. Family pressure have always played much important role in patient's compliance to the treatment.

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