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A Study on Adverse Drug Reactions in Tuberculosis Patients Maintained on DOTS Protocol in Government Chest &TB Hospital Warangal District

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Abstract: *Tuberculosis (TB) was one of the top most causes of death worldwide in 2015 and was responsible for more deaths than Malaria and HIV. So, aggressive treatment of TB is the need of the hour. On the flip side, the TB drugs are known to cause several adverse drug reactions (ADRs).This study aims to document various ADRs in TB patients maintained on DOTS protocol with first line drugs.*

Methods: *A prospective observational study was carried out on 170 patients. The data was collected using a data collection form and the standard IPC-PvPI form prescribed by the WHO. The patients were also followed up on phone. Causality assessment was done by both WHO-UMC causality assessment scale, Naranjo algorithm and severity is assessed by Modified Hart Wig and Siegel scale.*

Results: *Total number of ADRs detected was 260.Gastrointestinal ADRs outnumbered other ADRs (38.07%), by a wide margin it was followed up by Central nervous system (28.84%),Dermatological(8.84%),Psychological(05%),ototoxicity(3.07%),visionimpairment(1.92%),Arthralgia (1.92%),Edema(8.07%) &others(3.46%).Further, patients kept on CAT II drugs were found to be more prone to ADRs (48.8%) than CAT I drugs (21.1%).*

Conclusion: *It's alarming that several adverse drug reactions were found to drugs prescribed to fight a major public health challenge being faced by the world in general and India in particular i.e., TB. Sufficient data on these ADRs will go a long way in helping the medical professionals to prescribe the drugs with least side effects and minimize the suffering of the patients.*

Keywords: *Tuberculosis, Adverse Drug Reactions, DOTSs, WHO-UMC Causality Scale, Naranjo Algorithm, Modified Hart Wig and Siegel Scale, Major Public Health Challenge*

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I. Introduction

Tuberculosis (TB) has become one of the biggest public health challenges in India currently. In 2015, 10.4 million new TB cases were reported worldwide [1].Sadly, India is one of the six countries which together constitute 60% of the world TB cases. Our nation which is home to around many HIV patients also cannot afford to have these many TB cases as most of the HIV patients die of tuberculosis. In 2016, 1 million people died of HIV globally [2]. TB is treated with drugs like Isoniazid, Rifampicin, which are known as first line of defense. However wrong and incomplete dosage have resulted in resistance to first line TB drugs, this is known as multidrug resistant TB. Mismanagement of MDR-TB has exacerbated the problem and led to XDR-TB. So, it's high time the world in general and India in particular made concerted efforts to end this madly. United Nations sustainable development goals also fix a target of this epidemic by 2030[3].However, adverse drug reactions to the TB drugs have become a major area of concern for the medical professionals and health authorities alike. Against this backdrop, this research paper tries to throw light on the extent and severity of adverse drug reactions on TB patients kept on DOTS protocol with first line drugs. ADRs are defined by the WHO as an unintended and noxious response to a drug that occurs at doses normally used for the prophylaxis, diagnosis, or therapy of diseases, or for the modification of physiological function [4].So, study of ADR's will go a long way in helping the healthcare professionals in treating TB with minimal side effects.

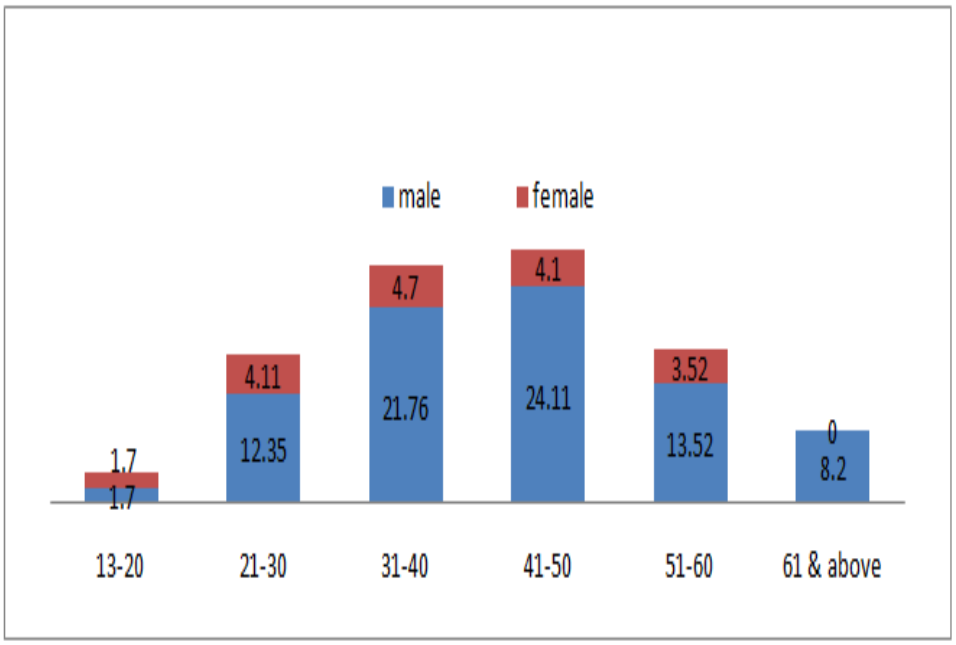
II. Materials and Methods

It is a prospective observational study conducted on 170 patients kept on Directly Observed Treatment Short course (DOTS) regimen at Regional Chest & TB Hospital in Warangal district of Telangana in India. The observational study was conducted for a period of 6 months from February to August 2017 after obtaining the requisite clearances from the Human Ethical Committee. All the TB patients who were on DOTS protocol and above the age of 13 years of both the sexes were studied. Some patients who were below 13 years of age or suffering from drug resistant TB or having a co-morbidity of HIV and Pregnant women were excluded from the study. A patient's data profile form was designed to keep a tab on their therapeutic profile. The causality assessment was done based on Naranjo's and WHO-UMC causality assessment scale and severity is assessed by Modified Hart Wig and Siegel scale.

III. Results and Discussion

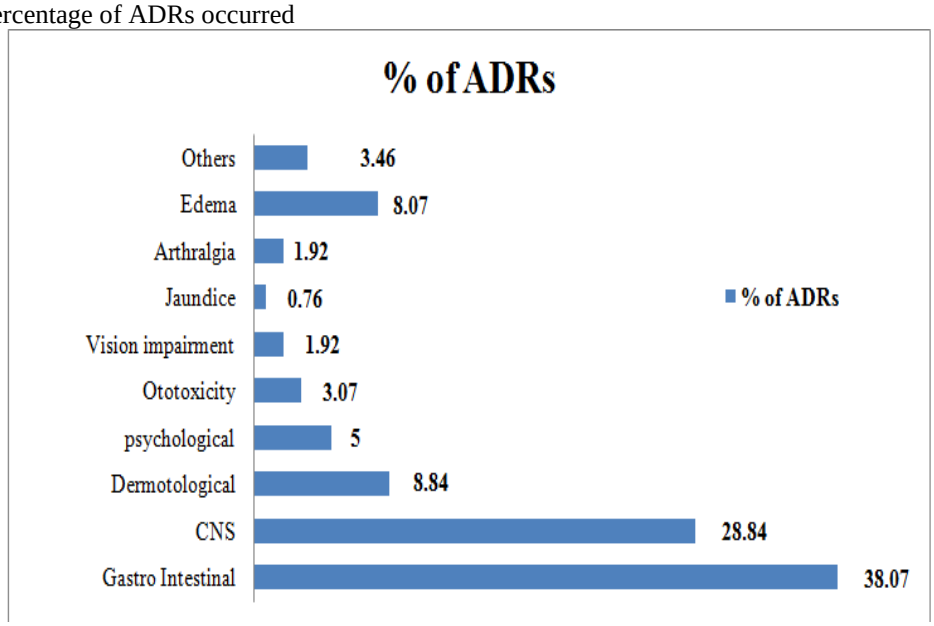
Anti TB drugs can have significant adverse drug reactions [5]. A whopping 119 patients out of the 170 patients studied showed one or more adverse drug reactions roughly translating to70% of the total study population. A total of 260 adverse drug reactions were detected during the course of the study.72.66% of males developed adverse drug reactions indicating that males are more prone to adverse drug reactions. Other such studies have also confirmed our research results [6, 7, and 8].Maximum number of patients were found in the age group of 41-50(28.21%), followed by 31-40(26.46%)**.**Our results indicate that productive age group populations are more susceptible to ADRs than too young or too old patients. Similar studies on adverse drug reactions in TB patients also corroborated with our results [9.]

Fig No.1:% Age distribution among Males and Females



Gastrointestinal adverse drug reactions topped the list with 38.07%persons showing one or the other form of GIT ADRs like nausea, vomiting etc. It was followed by CNS ADRs accounting for 28.84%of the total. Dermatological ADRs like pruritis, rashes etc., and constituted 8.84%of the total.5% of patients reported Psychological manifestations like psychosis, behavioral changes etc.3.07% of the patients developed Ototoxicity while a meager 1.92% people had Vision impairment and an equal number of patients 1.92% reported Arthralgia. Edema was another major ADRs noticed among the patients with 8.07% of them developing edema of face, lower limbs etc., the other ADRs like Glossitis, Injection site pain etc., accounted for 3.46%.

Fig No.2: Percentage of ADRs occurred



Details of adverse drug reactions organ system wise are provide in table1:

Table no.1:

Adverse drug reactions	**No. of ADRs n=260(%)**	**No. of patients n=170(%)**
Nausea	18(6.92)	18(10.58)
Vomiting	33(12.6)	33(19.41)
Abdominal cramps	15(5.76)	15(8.82)
Epigastric burning	05(1.92)	05(2.94)
Diarrhea	13(5.0)	13(7.64)
Abdominal distension	02(0.76)	02(1.17)
Dysphasia	13(5.0)	13(7.64)
Headache	28(10.76)	28(16.47)
Dizziness	02(0.76)	02(1.17)
Drowsiness	16(6.15)	16(9.41)
Giddiness	11(4.23)	11(6.47)
Numbness	10(3.84)	10(5.88)
Paraesthesia	4(1.53)	04(2.35)
Vertigo	02(0.76)	02(1.17)
Fatigue	02(0.76)	02(1.17)
Pruritis	14(5.38)	14(8.23)
Rashes	09(3.46)	09(5.29)
Psychosis	04(1.53)	04(2.35)
Behavioral changes	08(3.07)	08(4.70)
Insomnia	01(0.38)	01(0.58)
Ototoxicity	08(3.07)	08(4.70)
Vision impairment	05(1.92)	05(2.94)
Jaundice	02(0.76)	02(1.17)
Edema	21(8.07)	21(12.3)
Arthralgia	05(1.92)	05(2.94)
Glossitis	06(2.3)	06(3.52)
Inj. Site swelling	02(0.76)	02(1.17)
Lymphadenitis	01(0.38)	01(0.58)

Results of the study showed that overwhelmingly high number of patients treated with CAT II drugs developed ADRs compared to CAT I drugs, showed in fig 3.
Causality assessment of various ADRs using Naranjo, WHO-UMC Scale and severity is assessed by Hart Wig & Siegel's scale is shown in the fig 4.

Fig 3: DOTS Categorization

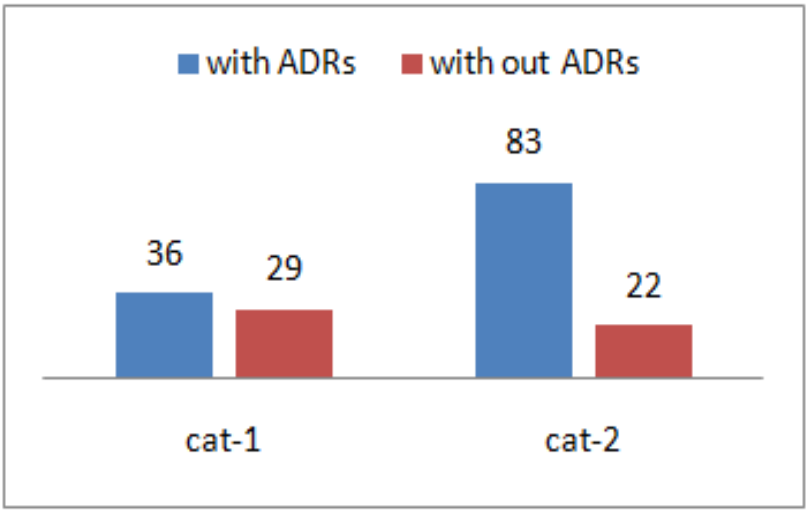
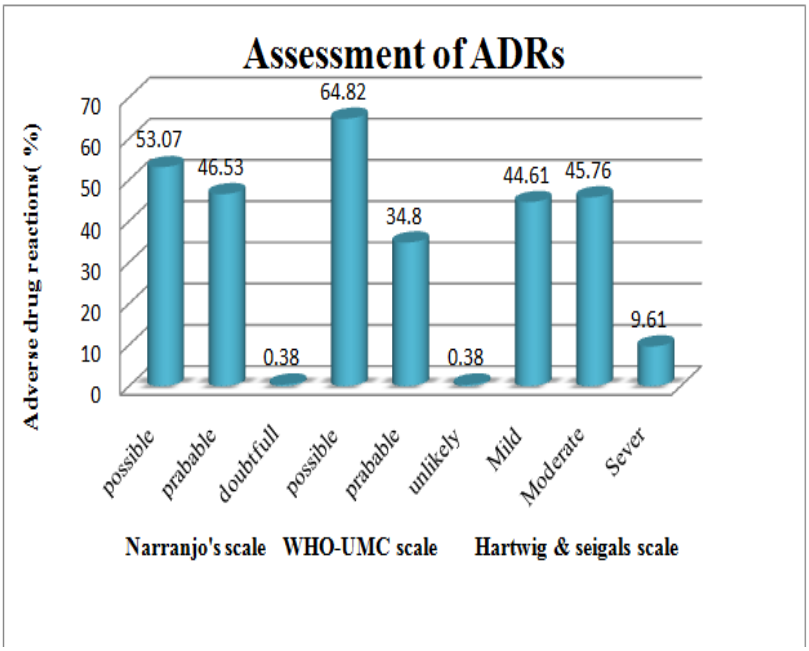


Fig No.4: Causality Assessment Scale



IV. Conclusion

Lately, tuberculosis has emerged as a major public health challenge for developing countries like India. Like the dreaded HIV/AIDS, this changes its nucleic acid most frequently making treatment difficult. TB has also become a big conundrum for the medical health professionals with the emergence of drug resistance. MDR-TB & XDR-TB are rearing their ugly heads making the treatment very difficult. In just 2015 alone 4, 80,000 patients were diagnosed by MDR-XDR. New drugs and newer treatment protocols are foraying into the market at an alarming interval to fight drug resistant tuberculosis patients. But, sadly most of the TB drugs have been triggering one or the other adverse drug reactions. Against this grim backdrop it becomes extremely necessary to keep the health professionals sufficiently informed about the adverse drug reactions to the TB drugs so that they can combat this killer disease more effectively with least side effects. This research paper will go a long way in informing the health professionals across the globe in general and in South India in particular, where significant number of cases are reported annually, about the possible ADRs to TB drugs.

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