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ASSESSMENT OF DRUG-DRUG INTERACTION AMONG TUBERCULOSIS PATIENTS IN PKTB HOSPITAL, MYSURU, KARNATAKA

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INTRODUCTION

Tuberculosis is caused by bacteria (Mycobacterium tuberculosis) that most often affect the lungs. Tuberculosis is curable and preventable. Tuberculosis is spread from person to person through air .When people with lung TB cough, sneeze, or split they propel the TB germs into the air. A person needs to inhale only a few these germs to become infected. About one –quarter of the world's population has latent TB, which means people have been infected by TB bacteria but are not (yet) ill with the diseases and cannot transmit the diseases. People infected with TB bacteria have a 5-15% lifetime risk of falling ill with TB.[1]

Anti-TB treatment aims to cure the patient, prevent complications and death, avoid relapses, reduce the transmission potential to susceptible individuals, and limit the emergence and spread of drug-resistant strains. For all these reasons, the therapeutic approach to TB requires the use of multiple drugs.[2] Treatment should include an intensive phase aimed at markedly decreasing the bacterial burden, followed by a 'sterilizing' consolidation phase, with an overall duration of at least 6 months.

The first-line standard regimen that is currently recommended for drug-susceptible TB is based on a 2-month intensive phase with four drugs (isoniazid, rifampicin, pyrazinamide and ethambutol; HRZE) followed by a 4-month consolidation phase with two drugs (isoniazid and rifampicin; HR). Dose adjustment is required for children according to body weight, but the regimen composition remains the same. Comorbidities do not justify any changes in the therapeutic approach to TB, although potential drug–drug interactions should be carefully evaluated and managed if necessary. Optimal adherence throughout the whole duration of treatment is crucial, as poor compliance is among the major causes of treatment failure, being associated with a high risk of resistance selection.

A drug interaction is defined as a pharmacokinetic or pharmacodynamic influence of drugs on each other which may result in desired in reduced efficacy and effectiveness or increased toxicity. DDI may lead to adverse drug reactions that can be severe enough to necessitate hospitalization. Studies have shown that DDI may cause up to 3% hospitalization. Drug interactions can reduce or increase the action of a medicine or cause adverse (unwanted) side effects. A drug interaction can decrease or increase the action of a drug or cause unwanted side effects.[3]

MATERIAL AND METHODS

A hospital based prospective and observational study was carried out in Princess Krishnarajendramani Tuberculosis Hospital, Mysuru. Which is associated with Mysore Medical College and Research Institute, Mysuru Karnataka. The study was performed for period of 6 months on in-patients of tuberculosis.

Assessment of results

A cross sectional study was performed on drug-drug interactions under sub categories of mechanism of drug-drug interactions, per person drug drug-interactions, and management requirement in drug-drug interactions. Relevant data of the enrolled patients including demographic details like age, gender, body weight, clinical data such as diagnosis, laboratory data, past medication history ,past history of non- medication adherence and interventions made ,co-morbidities, allergy status ,therapeutic data such as name of the drug, dose, frequency, route and duration of administration, concurrent medications, health care costs, factors influencing noncompliance was collected from various data sources and documented in a suitably designed data collection form. Data collection form designed and piloted for this study was used.

RESULTS AND DISCUSSION

Total number of 203 patients met the inclusion criteria, among those patients 187(92.1%) were male and 16(7.9%) were female. In the study population more number of 189(93%) patients comes from rural area and only 14(7%) from urban area. Large number of study population 70(34.8%) are unemployed. Whereas 116(57.1%) were engaged in small scale sales and service work. Very few are businessmen and some are farmer.

Demographic, Co-morbidities and treatment characteristics of tuberculosis patients.

S no.	Characteristics	Particular No. (%)
1.	**Gender** Men Women	 187 (92.1%) 16 (7.9%)
2	**Occupation** Unemployed Business Farmers Sales and service (small scale)	 70 (34.8%) 4 (2.0%) 23 (11.1%) 116 (57.1%)
3.	**Area of living** Rural Urban	 189 (93%) 14 (7%)
4.	**Co- morbidities** Hypertension Hyperlipidemia Cardiac disease Visual problems Nerve problem Sexual dysfunction Peripheral vascular disease Renal problem	 12 (4.66%) 17(6.61%) 21(8.17%) 38(14.78%) 53(20.62%) 11(4.28%) 57(22.17%) 48(18.67%)

The total drug-drug interactions among 203 study population are categories based on its mechanism. 76(51.1%) patients shows pharmacokinetic drug interactions, whereas 43(28.8%) patients shows pharmacokinetic drug interactions and 30(20.1%) patients shows unknown mechanism of drug interaction.

Severity of drug- drug interaction are very important to handle any situation, according to severity categorization result shows that 55(36.9%) had major drug-drug interactions 69(46.3%) have moderate drug-drug interactions, where only 25(16.8%) shows minor drug-drug interactions in the study.

Patients affected by number of drug interactions shows that 160 patients suffered 71 (47.6%) drug-drug interactions by 2-5 drugs. 37 patients have 75(50.3%) drug interactions due to 6-10 drugs, similarly more than 10 drugs were responsible for 3(2%) drug interactions in 6 individual.

Management can prevent some drug interactions so we categories some types of required management given in table.

Categorization of drug-drug interactions based on mechanism

MECHANISM	No: OF INTERACTIONS (n=149)	PERCENTAGE (%)
Pharmacokinetic Drug-Drug interactions	76	51
Pharmacodynamic Drug-Drug interactions	43	28.8
Unknown mechanism	30	20.1

Severity categorization of drug-drug interactions

SEVERITY	No: DRUG INTERACTIONS (n=149)
MAJOR	55 (36.9%)
MODERATE	69 (46.3%)
MINOR	25 (16.8%)

Number of drug interaction per patient

No: OF DRUGS	No: OF PATIENTS (n=203)	No: OF DRUG INTERACTIONS (n=149)
2-5	160	71 (47.6%)
6-10	37	75 (50.3%)
>10	6	3 (2.1%)

Management requirement s for the drug-drug interaction documented

MANAGEMENT	NUMBER OF D-D INTERACTION(n=149)
DOSAGE ADJUSTMENT	63 (42.2%)
NO MANAGEMENT REQUIRED	45 (30.2%)
MONITOR FOR SIGNS AND SYMPTOMS	17 (11.4%)
MONITOR FOR DRUG LEVELS	2 (1.4%)
MONITOR FOR BIOCHEMICAL PARAMETERS	2 (1.4%)
CHANGE DOSING INTERVAL	20 (13.4%)

CONCLUSION

It is establish fact that several challenges are posed by humans in dealing with disease that require a variety of treatment. Hence polypharmacy (use of more than one drug) may be necessity to produce desirable effect. Tuberculosis is one of kind disease that treats with a group of drugs. Tuberculosis is also having some co-morbidities and treatment of it may lead drug interactions. Drug interactions may be pharmacokinetic or pharmacodynamic. If any type of drug interaction in therapy of tuberculosis it is necessary to make changes on it. If needed modify the medication by dose adjustment, by measuring of signs and symptoms, discontinuation of drugs or replacement with 2nd drug of choice drugs. First line drugs also called CAT 1 drugs shows significant drug interaction including pharmacokinetic and pharmacodynamic.

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