Research Article

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Assessment of severity and patterns of adverse drug reactions of antitubercular drugs used in DOTS therapy

Shashi Marko* and JL Marko**
*Department of Pharmacology, Bundelkhand Medical College, Sagar, India.
**Department of Pharmacology, Pharmacology, Gandhi Medical College, Bhopal, India.

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Abstract: Adverse drug reactions (ADRs) are considered as one among the leading causes of morbidity and mortality. A general knowledge of the various ADRs and their management is essential for the effective management of Tuberculosis. This study was planned for assessment of severity and patterns of ADRs to Anti-tubercular drugs used in DOTS therapy in Hamidia Hospital, Bhopal and T.B. Hospital Idgah Hills, Bhopal. Information of the ADRs is data based collected from DOTS center with the help of treating physician and other health care professionals in a specialized Performa and the assessment of ADRs done with the help of various scales and investigations. Maximum numbers of ADR were reported among male population within 4 week of starting DOTS therapy. Gastrointestinal system (Gastritis) was the most common system affected followed by Skin (Rashes). Majority of ADRs 53.22% were moderate, and 46.77% were mild. No severe life threatening ADRs were observed during the study period. In our study, we found DOTS therapy safer, but regular monitoring is required for ADRs to prevent the ADRs at the initial stage.

Keywords: Adverse Drug Reactions (ADRs), Antitubercular drugs, DOTS therapy.

INTRODUCTION

WHO defines Adverse Drug Reaction (ADR) as "any response to the 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 modification of physiological function"[1].

Adverse Drug Reactions (ADRs) are considered as one among the leading causes of morbidity and mortality. Around 6% of hospital admissions are estimated to be due to ADRs and about 6–15% of hospitalised patients experience a serious ADR [2–4]. ADR reporting has become an important component of monitoring and evaluation activities performed in hospitals [5]. Depending upon the severity, ADRs were classified into mild, moderate and severe reactions using the criterion developed by Hartwig et al., for severity assessment [5].

The main objectives of the study is to

1. To assess and analyze the ADRs according to their demographic distribution, onset, reporting and presentations.
2. To classify the severity of ADRs to anti-tubercular Agents in to mild, moderate and severe based on the clinical feature and investigations.

MATERIAL AND METHODS

The present study was conducted in the department of Pharmacology Gandhi Medical College Bhopal and TB Hospital Idgah hills Bhopal from 15 April 2010 to 15 Dec. 2010. The cases were included all the patients visiting the DOTS Centre and those admitted in the medical wards in Hamidia Hospital and TB Hospital Idgah hills Bhopal with suspected ADRs due to antitubercular drugs.

- Information of the ADRs is data based collected from DOTS center with the help of treating physician and other health care professionals in a specialized Performa.
- The assessment of ADRs done with the help of following scales and investigations.

Assessment scale

a. WHO assessment scale [6]
b. Naranjo scale [7]
c. European A.B.O scale [8]

Investigations

- Liver Function Test.
- Routine haemogram
- Peripheral Blood smear
- Stool for occult blood,
- Urine routine and microscopy examination,
- Blood urea,
- Serum creatinine and
- Upper gastrointestinal endoscopy (in necessary cases).

***Corresponding Author:**
Dr. Shashi Marko,
Assistant Professor, Pharmacology,
Bundelkhand Medical College,
Sagar, India.

Inclusion Criteria

1. Patients of all the categories of TB with ADRs to Anti-tubercular agents visiting in the DOTS center.
2. Patients with ADRs to Anti-tubercular Agents in wards.
3. Patients above 12 years of Age.
4. Patients receiving minimum one Anti-tubercular Agents.

Exclusion Criteria

1. Patients below 12 years of age.
2. Patients who were HIV Positive.
3. Pregnancy.
4. Patients known case of Diabetes Mellitus.
5. Patients of MDR-TB and XDR-TB.

Observations

Total 820 patients who were taking DOTS therapy, included in this study out of which 720 patients from OPD and 100 patients from IPD. The most common age of patient was 21-30 years followed by 31-40 years. Total 62 ADRs detected in 62 patients, 2 patients were dropped out from DOTS therapy due to ADR (Table 1 & 2).

Table 1: Patients Treated With Antitubercular Drugs

Age Group	Male	Female	Total	Percentage
12-20	85	65	140	17%
21-30	90	70	160	19%
31-40	90	80	170	21%
41-50	90	80	170	21%
51-60	85	65	150	18%
> 60	20	10	30	4%
Total	460(56%)	360(46%)	820	100%

Table 2: Age & Sex Wise Distribution Of ADRs

Age Group	Male	Female	Total	Percentage
12-20	6	5	11	17.74%
21-30	10	7	17	27.41%
31-40	8	7	15	24.19%
41-50	10	4	14	22.58%
51-60	4	1	5	8.06%
> 60	0	0	0	0
Total	38 (61%)	24 (39%)	62	100%

Table 3: Opd And Ipd Wise Distributions Of ADRs

ADRs	OPD	IPD	Total
GIT	24	4	28
Skin	10	2	12
Musculo	4	2	6
Hepatobiliary	2	2	4
CNS	3	1	4
Other	5	3	8
Total	48 (77.41%)	14 (22.58%)	62 (100%)

The majority of ADR were moderate 33 (53%) and mild 29 (47%) and no severe ADR were reported. The mild ADRs required no treatment or simply modification in the doses of suspected drug while moderate ADRs were required discontinuation of suspected drug and switch over to other antitubercular drug or symptomatic treatment of ADRs (Table 4).

TABLE. 4: Severity Of Adr In Different Age Groups

Age Group	Mild	Moderate	Severe	Total	Percentage
12-20	8	3	0	11	18%
21-30	8	9	0	17	27%
31-40	7	8	0	15	24%
41-50	5	9	0	14	23%
51-60	1	4	0	5	8%
Total	29(46.77%)	33(53.22%)	0	62	100%

Maximum number of ADRs detected were of gastritis 28 (45%) followed by 12 (19%) of rash, 6 (10%) of arthralgia, 4 (6%) of hepatitis, 2 (3%) of peripheral neuropathy, 2 (3%) of flu like syndrome, 6 (10%) of vertigo, 2 (3%) were of psychosis (Table 5).

Table 5: Severity Of ADR Involvement Of Different System

S. No.	ADR	Mild	Mod.	Severe	Total	Percentage
1	GIT (GASTRITIS)	2	8		10	16.12%
	Vomiting	4	10	0	14	22.58%
	Abdominal cramps	2	2		4	6.45%
	Diarrhea					
2	Skin Itching	6	2	0	8	12.90%
	Rashes	3	1		4	6.45%
3	Musculoskeletal Arthralgia	3	3	0	6	9.67%
4	Ototoxicity					
	Vestibular Symptoms	1	3	0	4	6.45%
	Auditory Symptoms	1	1		2	3.22%
5	Hepatobiliary Hepatitis	3	1	0	4	6.45%
6	CNS Periph. Neuropathy				2	3.22%
	Psychosis	2	2	0	2	3.22%
7	Others flu like syndrome	2		0		
	Total	**29(47%)**	**33(53%)**	**0**	**62**	**100%**

DISCUSSION AND CONCLUSION

Since there can be no hope of eliminating all the adverse effects of drugs it is necessary to evaluate pattern of adverse reactions [9]. There is a special need for systemic collection of information on ADRs in India due to wide variation in genetic, nutritional, environmental and disease patterns [10]. Therefore, better approaches must be devised for reporting assessment and management of individuals who present with drug induced disease [11].

This study was planned for assessment of severity and patterns of ADRs to Anti-tubercular drugs used in DOTS therapy in Hamidia Hospital, Bhopal and T.B. Hospital Idgah Hills, Bhopal.

Maximum numbers of ADR were reported among male population. Majority of ADRs (53.22%) were moderate, and 46.77% were mild. No severe life threatening ADRs were observed during the study period. In our study, we found DOTS therapy safer, but regular monitoring is required for ADRs to prevent the ADRs at the initial stage.

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