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**Research Article**

# Adverse Drug Reactions of Commonly Used Antifungal Drugs - A Pharmacovigilance Study

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**ABSTRACT**

Pharmacovigilance is mainly a study that involves safety of those drugs which are being marketed under the clinical use in practical conditions for larger communities. The aim of this pharmacovigilance study was to determine the adverse drug reactions (ADRs) of the antifungal drugs which are commonly being used at a tertiary health care hospital (Jaiprakash Hospital & Research Centre Pvt. Ltd.) at Rourkela. An observational, prospective type of examination of the ADRs has been conducted for a period of 1 month and 4 weeks (24th January, 2022 to 23rd March, 2022) in the OPD of the skin department of Jaiprakash Hospital & Research Centre Pvt. Ltd., Rourkela. During the study period, a total of 6 patients suffering from fungal infections have visited the OPD, and about 12 ADRs events were reported. Out of 12 ADRs which have been identified, a higher percentage of adverse drug reaction (ADRs) has been found in the males (66.67%) as compared to that in females (33.33%). Out of the 12 ADRs, higher number of ADRs has occurred in the age group of ≥ 43 years (83.33%) as compared to that of the age group of < 43 years (16.67%). On causality assessment, nearly 50% ADRs were considered as possible, about 41.67% ADRs were considered as probable, and about 16.67% ADRs were considered as definite. The present study is very much valuable in making the medicinal therapy rational and safer so as to improve the patients compliance.



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## INTRODUCTION:

Pharmacovigilance is mainly a study that involves safety of those drugs which are being marketed under the clinical use in practical conditions for larger communities. Adverse Drug Reactions (ADRs) is defined as an unpleasant type of reaction due to an intervention which is in relation with the use of a medicinal product at it's normal dosage level. It is categorized into six types from Type A to Type F[1].

Fungi are saprophytic, non-motile, chemo-organotrophic type of organisms. They can exhibit dynamic type of interactions with their environment of nutrition which can be exemplified by various changes in the morphology, depending upon the availability of nutrients[2,3]. The fungal infection spreads due to warm and humid conditions and also due to unhygienic lifestyle. The fungal cells can utilize varied range of nutrients and also equally employs diversed type of nutrient acquisition techniques. The treatment of fungal infections caused in the humans is one of the most challenging cases due to the resistance of the drugs and changes in the morphology of the fungi. The systemic antifungal chemotherapy development has made significant contribution in the field of treating majority of the fungal infections of the humans[4].

As the antifungal drugs are being used widely throughout the world for treating various types of fungal infections, so keeping it in consideration a pharamcovigilance study was being carried out for determining the possibility of occurrence of ADRs with the usage of this drugs. This pharmacovigilance study would help in providing a rational and safer treatment to the patients.

## MATERIALS AND METHODS:

The ADR monitoring study was observational, prospective type done from 24th January 2022 to 23rd March 2022 over one month and four weeks duration in the OPD of the skin department of tertiary health care hospital. The data of the ADR was collected and analyzed by using the Naranjo ADR scale method in the similar manner as per the process of Kumar BN et al[5]. and Murali M et al[6] .

### Inclusion criteria:

The inclusion criteria of this study involve all the suspected type of adverse drug reactions that may have been caused due to the medications, which have been prescribed to the patients. This data was ultimately reported, noted and analyzed.

### Exclusion criteria:

- Use of any kind of alternate type of system of medicines like Homeopathy, Ayurvedic, Unani, and etc.

- Patients taking more than 3 prescription drugs.
- All types of mentally retarded.
- All sorts of drug addicts.
- Excessive consumption, and over-dosage.
- Unconscious type of patients and those patients who cannot respond to the verbally asked questions have also been excluded from the study.

**Collection of data:**

The data was being collected by the preparation of the patient's profile forms. The forms which have been prepared mainly included the details like name of the patient, age, sex, weight, height, name of the drug, type of ADR, causality assessment, and route of administration. When an ADR was suspected, the data like the patient medication details, patient details, comprehensive type of adverse drug reactions, and the route and type of drug administered reports were collected.

Then the causality was assessed using the Naranjo causality assessment scale, as it is widely being used and is also very much simple to apply. All types of errors that occurred in the administration of the drugs, over-dosage, failure of therapy, and drug abuse were excluded from the study[7].

**Statistical Method:**

From the data which is being collected from the study, we calculated the mean, standard deviation, percentage, and the "Student's t- test" was being applied at 5% level of significance to determine the association between the ADR probability score of male and female route of administration.

**RESULTS:**

During the 1 month and 4 weeks study period (i.e., from 24th January 2022 to 23rd March 2022), there were total 12 ADRs related to the antifungal drugs reported. The data of sex wise ADRs has been shown in Table 1., age wise ADRs data has been illustrated in Table 2., causality assessment of ADRs has been shown in Table 3., and the ADRs associated with the route of administration has been illustrated in Table 4.

**Table 1: Demographic data of the patients who had ADRs**

| Sex wise ADRs | |
|---|---|
| **Sex** | **Number of ADRs (%)** |
| Male | 8 (66.67%) |
| Female | 4 (33.33%) |
| Total ADRs | 12 |

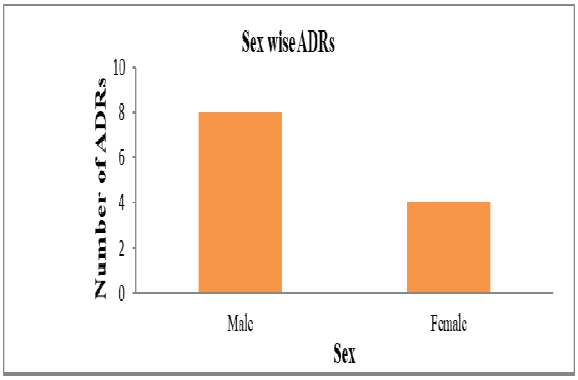


**Figure 1: Sex wise ADRs of the patients**

**Table 2: Patient demographics as per age group**

| Age wise ADRs | |
|---|---|
| **Age** | **Number of ADRs (%)** |
| < 43 years | 2 (16.67%) |
| ≥ 43 years | 10 (83.33%) |
| Total ADRs | 12 |

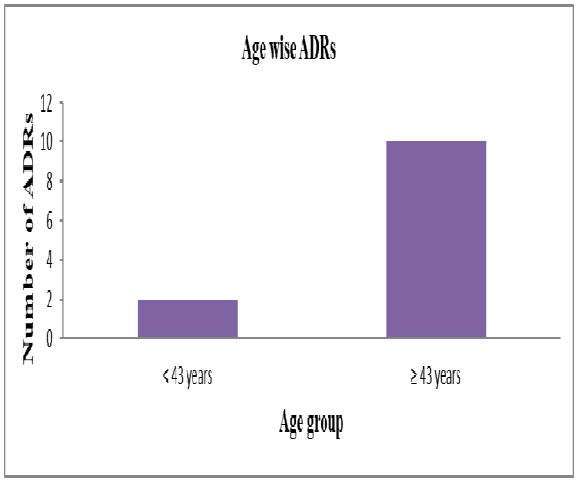


**Figure 2: Age wise ADRs of the patients**

**Table 3: Causality assessment of ADRs**

| Probability Scale | Number of ADRs (%) |
|---|---|
| Possible | 6 (50%) |
| Probable | 5 (41.67%) |
| Definite | 1 (16.67%) |
| Total ADRs | 12 |

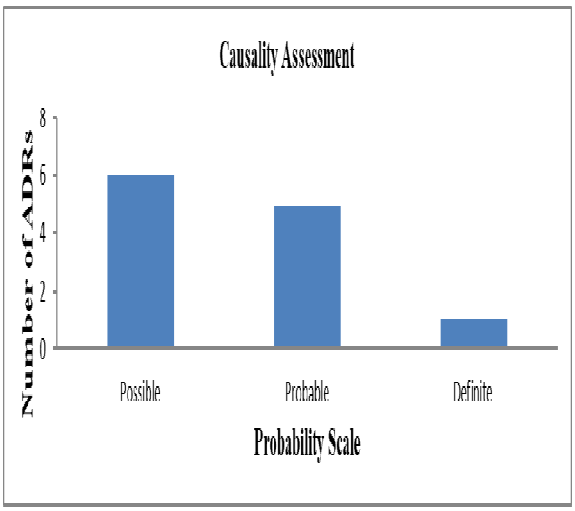


**Figure 3: Causality Assessment of the ADRs of the patients**

**Table 4: ADRs on the basis of route of drug administration**

| Route of administration | Number of ADR score (%) |
|---|---|
| Oral | 30 (51.72%) |
| Topical | 28 (48.28%) |
| Total ADR score | 58 |

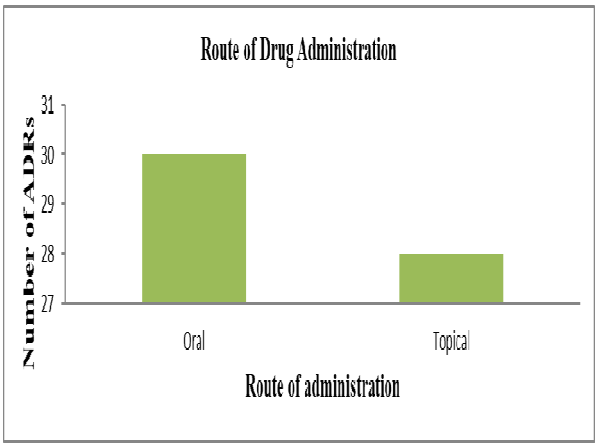


**Figure 4: ADRs on the basis of route of drug administration**

## CONCLUSIONS

From Table 1 data, it was found that out of 12 ADRs, 8 ADRs (66.67%) have occurred in males and 4 ADRs (33.33%) have occurred in the females. It indicated that the ADR associated with anti-fungal drugs is at higher percentage of occurrence in the males as compared to that in females. From Table 2, it can be determined that the anti-fungal drugs have caused ADR among the patient belonging to the age group of ≥ 43 years at higher percentage as compared to that in the age group of < 43 years. The data from Table 3, revealed that greater percentage of possible type of ADR has occurred in the patients, as compared to that of probable and definite type of ADRs. From the Table 4, as per the Naranjo scale causality assessment score, a higher percentage of ADR is associated with the administration of anti-fungal drugs from the oral route as compared to that of the topical route. Further, statistical analysis was being done using "Student's t – test" at 5% level of significance and it has been found that the calculated t-value (0.677) is less than the tabulated t-value (2.776), due to which the Null hypothesis is passed and accepted.

## CONFLICT OF INTEREST:

There is no such conflict of interest related to this investigation.

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