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Assessing the Oral Itraconazole-Induced Adverse Drug Reactions in Dermatophytosis.

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Abstract

Background: Dermatophytosis is a prevalent condition for which anti fungal Itraconazole is commonly prescribed. However, the adverse drug reactions associated with oral Itraconazole therapy remain a significant concern. The primary objective of this study was to assess the incidence, causality and severity of ADRs in patients with dermatophytosis treated with oral Itraconazole.

Matrials and Methods: This prospective observational study involved 81 patients from the Dermatology Outpatient Department of Santosh Medical College and Hospital. The WHO-UMC causality assessment scale and the Hartwig and Siegel severity assessment scale were used to evaluate ADRs.

Results: The study reported an ADR incidence of 23.14%, with higher prevalence observed in female patients and those aged 18-28. The severity of ADRs was mostly classified as mild 58.54% and moderate 41.46%, most frequently reported ADRs was abdominal discomfort, nausea, and headache. Notably No severe ADRs were reported.

Conclusion: Oral Itraconazole, an efficacious treatment for dermatophytosis, requires careful monitoring due to potential ADRs, particularly in young adults and females patients. The result highlight the need for vigilant patient management and set the way for further research focused on the reduction of ADRs in antifungal therapy.

Keywords: Itraconazole, dermatophytosis, Adverse Drug Reactions, Antifungal Therapy

Introduction

Dermatophytes are a group of closely related fungi belonging to three genera, Microsporum, Trichophyton, and Epidermophyton, of more than 40 different species, and only a few of these are common causes of human infections. Trichophyton fungi infect hair, skin, or nails, whereas Microsporum species only infect hair and skin. (1)

The prevalence of dermatophytosis in India has been reported to range from 36.6 to 78.4%. (2)

Itraconazole is a systemic antifungal drug that plays a crucial role in the treatment of superficial fungal infections. It has been associated with various adverse drug reactions that present challenges in clinical management. (3)

Triazoles mainly Itraconazole are used for oral therapy. Triazoles act on the cellular target, that is, the cell membrane Triazoles inhibit sterol 14-demethylase, the inhibition of enzymes leading to inhibition of ergosterol biosynthesis. (4)

The systematic collection and analysis of Adverse Drug Reaction (ADR) leads to the optimization of drug therapy, ensuring that it is not only safe and efficacious but also economically viable. This approach ultimately contributes to improving patient outcomes and the overall quality of healthcare services.

This research aim to investigate the incidence of adverse drug reactions associated with the use of itraconazole in patients with dermatophytosis.

Materials and Methods

This prospective observational study was conducted at the Dermatology Outpatient Department of Santosh Medical College Hospital. This study was approved by the Institutional Ethics Committee and included patients attending the Dermatology Outpatient Department of Santosh Medical College and Hospital. The inclusion criteria were newly diagnosed cases of dermatophytosis in patients aged 18 years or older at the commencement of the study. Patients diagnosed with dermatophytosis received itraconazole at a dose of 200 mg once daily for a duration of two weeks, after the drug received follow-ups, it was carried out for a duration of one month to assess the incidence of adverse drug reactions.

Statistical analysis

The Data was analysed through the calculation of percentages. The causality of adverse drug reactions (ADRs) was evaluated using the WHO-UMC causality assessment scale. Furthermore, the severity of any identified ADRs was assessed by the Hartwig and Siegel severity assessment scale.

Results

This study focused on a cohort of 121 patients diagnosed with dermatophytosis, selected according to specific inclusion criteria. Among the 69 patients, (57.02%) were identified as male and 52 (42.98 %) female. All participants were treated with itraconazole 200 mg daily for two weeks. Any adverse reactions to the medications were monitored through regular follow-ups in the outpatient department over a period of one month.

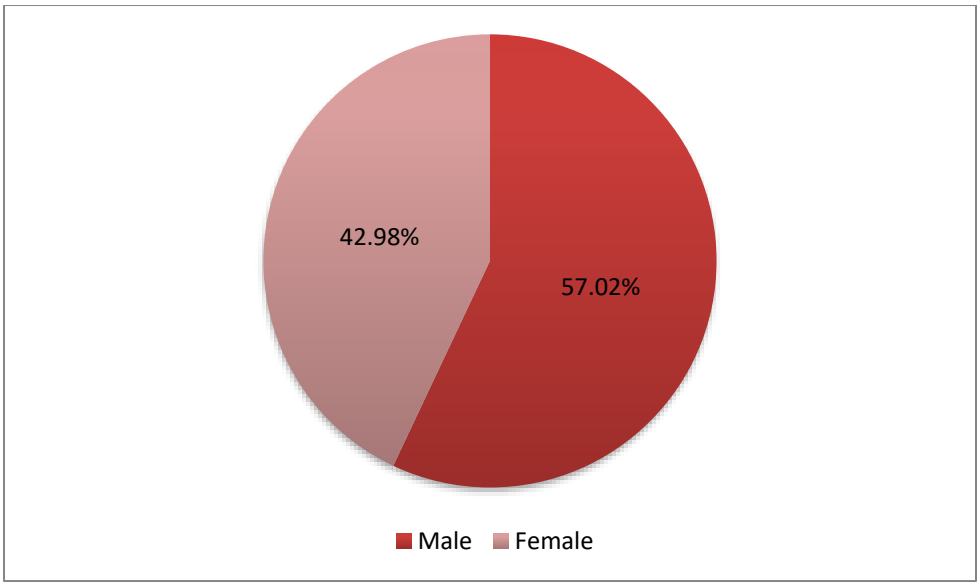

Figure 1: Gender distribution of Patients treated with Itraconazole

The number of individuals who experienced ADRs during the caused treatment was 28 (23.14%) of the total study population. The population consisting of 93 individuals (76.86%) did not exhibit any ADRs to treatment.

The gender-based analysis revealed a higher incidence of ADRs among female patients with 17 cases (60.71%) compared to 11 cases (39.29%) of male patients' examination based on age group, showing varying incidence rates of ADRs. The highest incidence was noted in the age group of 18-28 years accounting for 12 cases (42.86%) of the total ADRs. Within this group, 4 male patients (14.29%) and 8 female patients (28.57%) experienced ADRs. This was followed by the age group of 29-38 years with 8 cases (28.57%) consisting of 3 male patients (10.71%) and 5 female patients (17.86%). The age groups of 39-48 years there were 5 cases (17.86%), with 2 male patients (7.14%) and 3 female patients (10.71%). The age group of 49-58 years reported 2 cases (7.14%) equally distributed between 1 male (3.57%) and 1 female (3.57%), the age group of 59-68 years had the lowest incidence, with 1 case (3.57%), and all patients was 100% male.

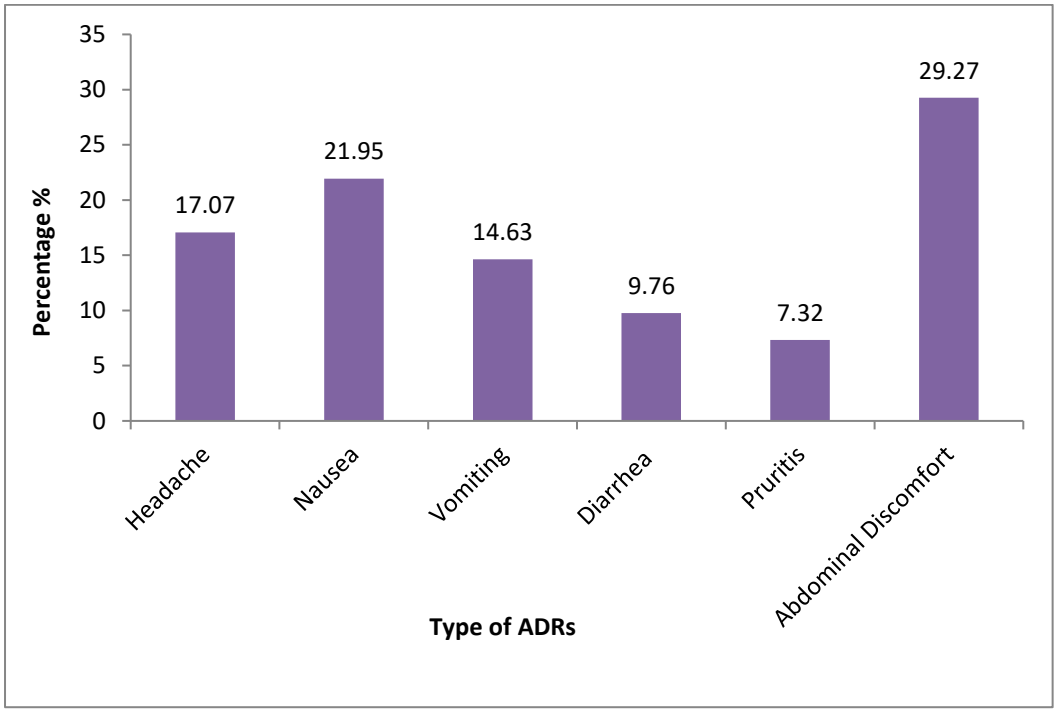

Figure 2: Incidence of Adverse Drug Reactions

A total of 41 ADRs were reported, of which abdominal discomfort was the most common ADR, affecting 12 patients (29.27 %), followed by nausea 9 cases (21.95 %), headache 7 patients, (17.07 %), vomiting 6 patients, (14.63%) diarrhea was observed in 4 patients (9.76 %), and pruritus 3 patients, (7.32 %).

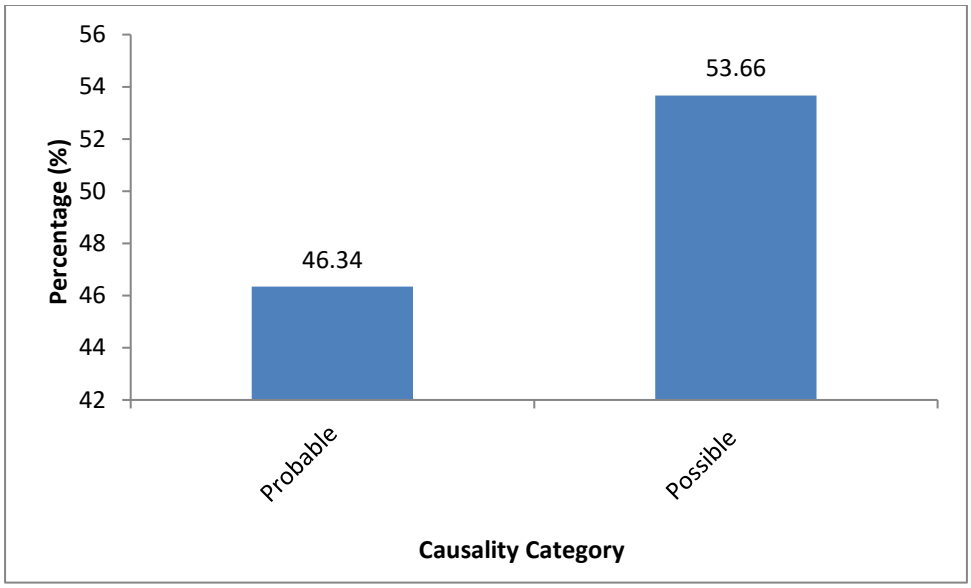

Figure 3: WHO Causality Assessment of ADRs

According to WHO causality scale ADRs associated with Itraconazole revels the following category out of 41 ADRs reported 22 (53.66%) ADRs were probable and 19 (46.34%) ADRs fall into the possible category.

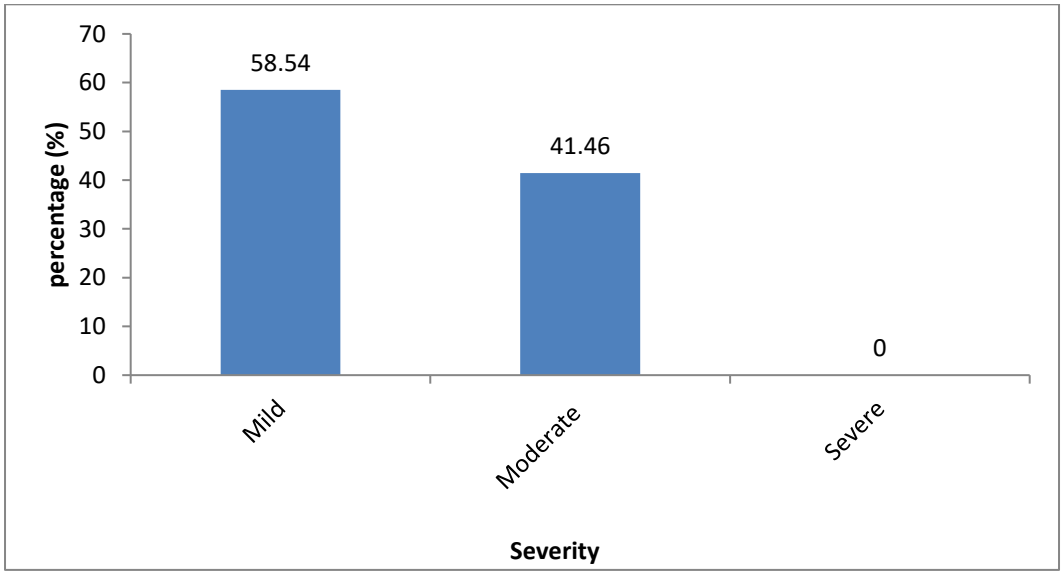

Figure 4: Severity Assessment of ADRs

The severity assessment of ADRs associated with itraconazole was conducted using the Hertwig and Siegel scale. The analysis revealed that 24 (58.54 %) ADRs were classified as mild and 17 (41.46%) were categorized as moderate.

None of reported ADRs were classified as severe based on severity assessment indicating that while the drug elicited adverse reactions, these did not escalate to severe levels in any of the observed cases.

Discussion

This study comprehensively evaluated the incidence and type of Adverse Drug Reactions in a cohort of 121 patients diagnosed with dermatophytosis who received itraconazole treatment. The demographic analysis revealed a higher proportion of male patients 57.02% compared to female patients 42.98%, which aligns with findings from previous research done by Noor et al., indicating a higher prevalence of dermatophytosis in males. (5)

In our study overall incidence of ADRs was 33.88% within the range reported in the literature, although our observed incidence rate is lower than the previous findings of Stein et al., who documented significantly higher incidence rate 35 % of ADRs. (6)

Notably, our study found a higher incidence of ADRs in females 60.71%, the previous by Zucker et al. shows the sex differences ADRs in women. (7) This discrepancy might be attributed to hormonal differences or other physiological factors.

The application of the WHO causality scale revealed that 53.66% of ADRs were probable and 46.34% were possible previous case report study by Vuono et al. who documented a probable association between Itraconazole and the skin rash. (8)

The current study indicates that the majority of adverse drug reactions (ADRs) associated with Itraconazole were mild in nature. Specifically, 58.54% of the ADRs were classified as mild. Furthermore, a significant portion was categorized as moderate. None of the reported ADRs reached a level of severity that would be classified as severe this is supported by previous study by Burden et al. Reported no severe or fatal cases. (9)

Conclusion

Itraconazole is effective for treating dermatophytosis and also possess the risk of adverse drug reactions particularly in female patients and individuals aged 18-28 years. The study observed 33.88% incidence rate of ADRs mostly mild-to-moderate in severity, our findings highlights the need for vigilant monitoring and personalized management in clinical settings. This study contributes valuable data to the understanding of Itraconazole-induced ADRs and underscores the importance of balancing treatment benefits with potential risks.

Conflict of Interest

Nil

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