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COMPARATIVE ASSESSMENT OF SAFETY AND EFFICACY OF TOPICAL KETOCONAZOLE AND TOPICAL LULICONAZOLE IN CASE OF DERMATOPHYTOSIS AT A TERTIARY CARE HOSPITAL IN JAIPUR

Pharmacology

Parth B Trivedi* B. Pharm, M. Phram, Msc medical pharmacology Department of Pharmacology, National Institute of medical sciences & Research, NIMS University, Jaipur (INDIA). *Corresponding Author

Dr. Manjula Bhargav M.B.B.S, MD Pharmacology Professor & Head ,Department of Pharmacology National Institute of medical sciences & Research,NIMS University, Jaipur (INDIA)

ABSTRACT

This comparative group study was done to evaluate the efficacy and safety of topical ketoconazole with topical luliconazole during a period of 4 weeks. 100 patients of dermatophytosis were selected from the skin department & were divided into two groups, each group consist of 50 patients. The patients in Group A were administered topical ketoconazole of 2% cream, and in Group B patients, topical luliconazole of 1% cream was applied topically. Diagnosis was confirmed by microscopic potassium hydroxide (KOH) examination. Global assessment was done at the end of treatment with mycological reduction in signs and symptoms (pruritus, erythema and desquamation) of tinea infections as compared to baseline by microscopic potassium hydroxide (KOH) examination.

KEYWORDS

Introduction:

Dermatophytosis (tinea) infections are fungal infections caused by dermatophytes (a group of fungi that invade and grow on dead keratin).[1] However in India, the most commonly occurring clinical type of dermatophytosis for adults includes, tineacorporis (58.84%) and tineacruris (12.3%).[2] A topical agents(Topical Ketoconazole & Topical Luliconazole) used for superficial fungal infections has to have broad-spectrum activity, high mycological cure rate, convenient dosing, low incidence of side effects and low cost.[3]Some of the newer agents (Luliconazole) required only once-daily application and shorter courses of treatment, and are associated with lower relapse rate.[4]

Materials and methods:

Out of 115 patients15 patients dropped out from the study and thus 100 patients completed the study. Patients with other body site involvement, patients who had received topical antimycotic therapy two weeks and four weeks, respectively, prior to initiation of the study were excluded. Participants with known history of hypersensitivity to study drugs, or with superadded bacterial infection, or pregnant and lactating female, or immune compromised patient and chronically ill patients were also not recruited. Participants were randomized with the help of table of random numbers in two groups containing 50 participants each. Group A received Ketoconazole 2% cream applied twice daily for four weeks; while group B received luliconazole 1% cream applied once daily for four weeks. The study medication was dispensed to the subject following randomization technique, provided all inclusion and exclusion criteria were satisfied.

Inclusion criteria: New patients of Dermatophytosis, Lesion covering small body surface area, Both sexes, Age: 21-50 years.

Exclusion criteria: Old patients of Dermatophytosis, Lesion covering large body surface area, Hypersensitivity to allylamine /benzylamine agents

Patients were followed up at monthly intervals for 6 week from the start of the study. At the end of treatment with mycological reduction in signs and symptoms (pruritus, erythema and desquamation) of tinea infections as compared to baseline by microscopic potassium hydroxide (KOH) examination.

Result :

100 patients were taken for study, 50 patients in Group A (given topical Ketoconazole 2% cream) and 50 patients in Group B (Given topical Luliconazole 1% cream) completed the study after 4 week. At end of treatment, the resolution of pruritus, erythema and Desquamation were seen as 52%,48% and 64% patient in Group A and 90%,72 % and 92% patient in Group B, respectively, however complete resolution of pruritus, erythema and Desquamation were occurred in group B but not in Group A at the end of follow up phase up to 6 week.

TABLE : Mean scores & p value of Group A (treated with ketoconazole) and Group B (treated with luliconazole) patients with treatment over baseline,2nd week and 4th weeks.

Week	GROUP A (TREATED WITH KETOCONAZOLE) MEAN±SD	GROUP B (TREATED WITH LULICONAZOLE)MEAN±SD	p-value
Base line	36.07±28.22	60.04±30.22	0.163
2nd Week	34.08±27.63	56.82±32.88	0.063
4th Weeks	30.08±27.63	50.82±32.88	0.013

Show that the patients in group A and group B started improving significantly with treatment by 4thweeks.Comparison between two groups showed that there was no statistically significant difference between two groups at 2nd week (P = 0.063). However, at 4th weeks the improvement in luliconazole treated group was better than in the ketoconazole treated group (P = 0.013), which is statistically significant. A difference was considered as significant if the P value was less than 0.05.

Discussion:

In the present study, Two drugs showed reduction in signs and symptoms (pruritus, erythema and desquamation) of tinea infections as compared to baseline. Luliconazole was found to be more effective than ketoconazole. The efficacy was higher in luliconazole group (p=0.013) than ketoconazole group.

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