The Effect of Econazole Nitrate Topical Foam, 1% on Signs and Symptoms (Pruritus) of Interdigital Tinea Pedis

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ABSTRACT

Background: Tinea pedis is the most common dermatophyte infection. Treatment is critical in order to alleviate pruritic symptoms, to reduce the risk for secondary bacterial infection, and to limit the spread of infection to other body sites or other individuals. Topical antifungal foams are effective in treating interdigital tinea pedis, but little is known about how clinical efficacy of antifungal foams impact quality of life as compared to traditional antifungal creams.

Study Design: A single-center, investigator blinded, observational split body, pilot study was conducted to compare econazole nitrate topical foam, 1% to ketoconazole cream 2%. All 20 subjects received econazole nitrate topical foam, 1% and ketoconazole cream 2% to either right or left foot for 14 days. Improvements in patient quality of life and patient preference were measured using the pruritus visual analog scale 0/AS), Skindex-16, and patient preference questionnaires.

Results: Nineteen subjects completed the study and one subject was lost to follow-up. Both econazole nitrate topical foam, 1% and ketoconazole cream 2% were effective in reducing pruritic symptoms as measured by the pruritus VAS. The reductions in VAS exhibited by econazole nitrate topical foam, 1% were significantly greater than those exhibited by ketoconazole cream 2%. Patient symptom, emotional, functional and total scores from the Skindex-16 were significantly reduced by the final visit. Patients did not exhibit a significant preference for either econazole nitrate topical foam, 1% or ketoconazole cream 2% on patient preference questionnaires. One adverse event was reported with no further details provided.

Conclusion: While patient preference was equal for the two study medications, econazole nitrate topical foam, 1% had increased reductions in pruritus VAS scores compared to ketoconazole cream 2%. This suggests that econazole nitrate topical foam, 1% is both clinically effective and has meaningful improvements in patient quality of life.

INTRODUCTION

- Tinea pedis is the most common dermatophyte infection. Results from the National Ambulatory Medical Care Survey (NAMCS) and National Hospital Ambulatory Medical Care Survey (NHAMCS) (1995-2004) indicated an average of 4,124,038 annual visits for dermatophytoses during the study period with tinea pedis accounting for 18.8% (1).
- Treatment is critical in order to alleviate pruritic symptoms, to reduce the risk for secondary bacterial infection, and to limit the spread of infection to other body sites or other individuals (2, 3).
- Topical antifungal foams are effective in treating interdigital tinea pedis, but little is known about how clinical efficacy of antifungal foams impact quality of life as compared to traditional antifungal creams.

OBJECTIVE

- To compare the efficacy of and patient preference for econazole nitrate topical foam, 1% versus those of ketoconazole cream 2% on the signs and symptoms of interdigital tinea pedis.

SUBJECTS AND METHODS

Study Design

- Single-center, investigator blinded, observational, split body, pilot study
- All subjects applied econazole nitrate topical foam, 1% (Ecoza foam) and ketoconazole cream 2% (Nizoral Cream) to either the right or left foot. Study medication was applied twice daily; once in the morning, and once in the evening.
- The duration of the study was 14 days and consisted of a baseline visit and a final visit at the end of 14 days of treatment.

Subjects

- Male and female outpatients ≥18 years of age or older
- Pruritus visual analog scale (VAS) score >5
- Positive KOH preparation at baseline
- Able to understand study requirements and sign Informed Consent/HIPAA Authorization forms
- Female patients of child-bearing potential were required to have a negative urine pregnancy test and to practice a reliable method of contraception throughout the study.

ASSESSMENTS

Efficacy

- Pruritus VAS: at each study visit, subjects assessed the severity of pruritus using a 10-cm VAS with the left side of the scale anchored with "No Itch" and the right side of the scale anchored with "Worst imaginable itch".
- Skindex-16: subjects completed the Skindex-16 at baseline and the final study visit. The Skindex-16 is a short 16-item patient-completed assessment using numerical analogue scales (0 = never bothered to 6 = always bothered). Responses to the Skindex-16 are categorized into three subscales: symptom, emotional, and functional (4).

Treatment Preference

- Subjects also completed a treatment preference questionnaire at the end of the study.

Safety

- Subjects were monitored for signs and symptoms of adverse events (AEs) throughout the study.

DATA ANALYSIS

- All analyses were conducted on an intent-to-treat population that included all subjects who were enrolled and received study medication.
- Descriptive statistics (mean, standard deviation, etc.) were provided for all continuous variables and frequencies for all categorical variables.
- Differences between study treatments were evaluated using analyses of covariance (ANCOVA) with baseline values for variables measured as covariates.
- All statistical tests were two-sided and interpreted at a 5% significance level.

RESULTS

SUBJECTS

- Twenty subjects (11 males, 9 females; 16 white, 4 black; age 46 ± 16 years [range = 18-68 years]) were enrolled.
- Ten subjects were randomly assigned to econazole nitrate topical foam, 1% on the left foot and ketoconazole cream 2% on the right foot; and 10 were randomized to receive econazole nitrate topical foam, 1% on the right foot and ketoconazole cream 2% on the left foot.
- One subject was lost to follow-up and all efficacy analyses were based on results for 19 subjects.

EFFICACY

Pruritus VAS

- There were substantial reductions from baseline in pruritus VAS scores for both econazole nitrate topical foam, 1% (P=0.0001) and ketoconazole cream 2% (P=0.001) (**Figure 1**).
- The mean reduction observed for the feet treated with econazole nitrate topical foam, 1% was significantly greater than mean reduction observed for the feet treated with ketoconazole cream 2% (P=0.006) (**Figure 1**).

Skindex-16

- There were significant decreases in the Skindex-16 domain scores from baseline to the final visit (all P<0.01) (**Figure 2**).
- It should be noted that no econazole nitrate topical foam, 1% vs ketoconazole cream 2% comparisons were possible for the Skindex-16 data, since all patients received both medications and the questions of the Skindex-16 were not medication-specific.

Figure 1. Results for Pruritus VAS

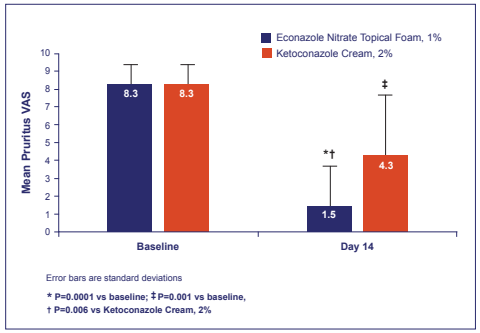
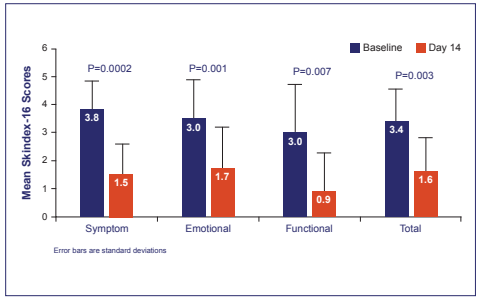


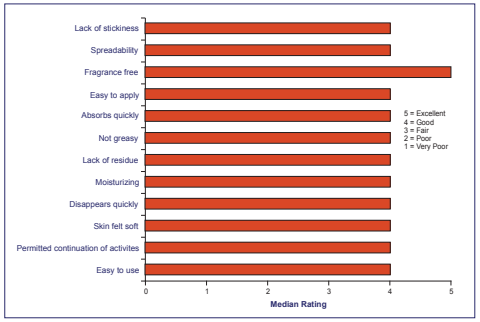
Figure 2. Results for Skindex-16



Subject Ratings

- There were no significant differences in patient preference on any item of the questionnaire between econazole nitrate topical foam, 1% and ketoconazole cream 2% (all P>0.05).
- Econazole nitrate topical foam, 1% had median ratings of good or excellent on all measures assessed (**Figure 3**).

Figure 3. Subject ratings of econazole nitrate topical foam, 1%



SAFETY

- One AE was noted, but no further details were provided.

CONCLUSIONS

- Econazole nitrate topical foam, 1% was significantly superior to ketoconazole cream 2% for decreasing pruritus VAS scores over 2 weeks of treatment in patients with tinea pedis.
- Treatment also significantly decreased Skindex-16 total scores and scores for all domains comprising this measure.
- Subject rated econazole nitrate topical foam, 1% as good or excellent for all properties evaluated.
- All of these results support the conclusion that econazole nitrate topical foam, 1% is clinically effective, easy to use, and provides meaningful improvements in patient quality of life.

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