Efficacy and Tolerability of 5% 5-Fluorouracil Cream and 5% Imiquimod Cream in the Management of Actinic Keratoses on the Face and Scalp

Emil Tanghetti, MD1 and Phillip Werschler, MD2

1 University of California Davis, School of Medicine, Sacramento, CA
2 University of Washington School of Medicine, Seattle, WA

Abstract

Intervention: Actinic keratoses (AK) are common sun-induced skin lesions which have the potential to develop into squamous cell carcinoma. Treatment options for eradication of AKs include liquid nitrogen and topical therapies such as 5% fluorouracil (5-FU) and imiquimod. We conducted a study to compare the efficacy and tolerability of 5% 5-FU cream and imiquimod 5% cream in patients with AK on the face and scalp.

Methods: 36 patients (age range 18-64 years) with at least 4 AK on the face or scalp were randomized into two treatment groups in this investigator-blinded study. Group 1 (n=19 patients) applied 5% 5-FU cream to their AK lesions twice-daily for 4 weeks. Group 2 (n=17 patients) applied imiquimod 5% cream to all AK lesions twice-weekly overnight for 16 weeks. The study duration followed the FDA approved product labeling for each product. AK lesions were examined and evaluated at each visit. The percentage of patients with complete clearance of AKs two months post-therapy completion were compared between the two groups.

Results: After 4 weeks of treatment with 5% 5-FU and a 2-month follow-up, 94% of patients treated with 5% 5-FU had cleared. Following 16 weeks of treatment, 5% Imiquimod cream cleared AKs by 91% (p<0.01). Complete clearance occurred in 65% of patients with 5% 5-FU and 24% of patients with 5% Imiquimod applied 2-month post-therapy completion (p<0.05). The adverse event profile did not differ significantly between the two therapies. Adverse events reported by most patients in both groups included erythema, crusting, erosion and edema. These adverse events were transient in all cases.

Conclusion: In this study, topical 5% 5-FU cream applied for 4 weeks was shown to have superior efficacy to imiquimod 5% cream applied for 16 weeks. The two treatments did not differ significantly in adverse event profile.

Keywords: Actinic keratoses, 5% 5-fluorouracil cream, 5% imiquimod cream, topical immune response modifier, face, scalp.

Introduction

Actinic keratoses (AK) are common sun-induced skin lesions which have the potential to develop into squamous cell carcinoma. Treatment options for eradication of AKs include liquid nitrogen and topical therapies such as 5% fluorouracil (5-FU) and imiquimod. The topical immune response modifier imiquimod 5% cream has been utilized in the management of AKs. The topical immune response modifier 5% 5-FU cream and imiquimod 5% cream have been effective and safe alternatives in the treatment of AKs. The current study sought to compare the efficacy and tolerability of 5% 5-FU cream and imiquimod 5% cream in patients with facial and scalp AK.

Methods

Subjects: N=36 patients

Inclusion Criteria:
- Adults between 21 and 64 years old.
- Good health.
- A minimum of 4 AKs on the face or scalp.

Exclusion criteria:
- Immunosuppressed.
- Pregnancy.
- Known allergy to study medication.
- Topical medication use for AK within past 2 months.
- Liquid nitrogen treatment for AK within past 30 days.
- Facial laser treatment within past 6 months.
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Intervention:
- Group 1 (n=19 patients): 5% 5-FU cream (Fulex®, Valeant Pharmaceuticals International) was applied twice-daily to AK lesions for 4 weeks.
- Group 2 (n=17 patients): 5% imiquimod cream was applied twice-weekly to AK lesions overnight for 16 weeks.

Outcome measures:
- AK lesion counts were measured at baseline and months 1, 2, 3, 4, and 6 followed by long-term follow-up performed 1 year post-therapy completion.
- Percentage of patients with complete clearing of AKs.
- Physician global assessment of improvement.
- Patient tolerability and degree of erythema.

Results

- 63% of patients (12/19) achieved complete clearance of all AKs with 5% 5-FU compared to 24% of patients (4/17) with imiquimod, when measured 8-weeks post-therapy completion.
- Following 16 weeks of 5% imiquimod application and a 2-month follow-up, 66% of AKs had cleared (p<.01). Complete clearance occurred in 65% of patients treated with 5% 5-FU and 24% of patients treated with imiquimod 5% cream and this was statistically significant at week 16 (p<.05).

- Patients treated with 5% 5-FU for 4 weeks experienced a mean reduction in AK lesion counts of 88% at the 8-week visit and 91% at the 12-week visit (Figure 2, above).
- Patients treated with 5% Imiquimod for 16 weeks experienced a mean reduction in AK lesion counts of 66% at the 24-week visit (Figure 2, above).
- After 1 year of post-therapy follow-up, 87% of AKs were still cleared with 5% 5-FU whereas 75% of AKs were cleared with 5% imiquimod, indicating a low recurrence rate with both therapies.

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