A Randomized Double-Blind Controlled Study on the Efficacy of a Repair Balm containing Prebiotic, Panthenol, and Madecassoside in Treating Skin Adverse Reactions Associated with EGFR Inhibitors and Capecitabine

[1]Xueqi Yan,[1]Yan Liang[1]Xiang Huang,[2]Yang Xu,[3]Zhong Shen,[3]Shangwen Sun,[3]Yijie Zheng,[4]Delphine Kerob,[1]Yongmei Yin

[1]Department of Oncology, The First Affiliated Hospital of Nanjing Medical University, Nanjing, CHINA.[2]Department of Dermatology, The First Affiliated Hospital of Nanjing Medical University, Nanjing, CHINA.[3]L'Oreal Dermatological Beauty, L'Oréal China, Shanghai, CHINA.
[4]La Roche-Posay Laboratoire Dermatologique, Levallois Perret, FRANCE.

Introduction

- Cutaneous adverse reactions (CARs) are frequent side effects of anticancer therapies that significantly impair patients' quality of life and may lead to serious complications if unmanaged[1,2].
- Restorative creams containing functional ingredients can help prevent and manage CARs by improving epidermal barrier integrity, promoting healing, and reducing inflammation[3].
- Although guidelines recommend their use[4,5], evidence on the efficacy of specific non-pharmaceutical skincare products, such as Cicaplast Baume B5+, for preventing and treating CARs induced by EGFR inhibitors and capecitabine remains limited, with no established clinical protocols.

Method

Study Design & Participants

- **This randomized, double-blind, controlled study enrolled 40 patients with cutaneous adverse reactions induced by EGFR inhibitors or capecitabine at The First Affiliated Hospital of Nanjing Medical University (Oct 2024 - Jun 2025).**

Participants（N=40）

Key Eligibility

- Aged 18-75 years.
- Pathologically confirmed malignant tumor.
- Current treatment with capecitabine or an EGFR inhibitor.
- Development of any cutaneous adverse reaction (e.g., rash, HFS) during therapy.
- Life expectancy >1 year and ECOG performance status of 0-1.

randomized 1:1

Intervention Group
Cicaplast Baume B5+ (La Roche-Posay) Repair Balm(Contains: Prebiotic, Panthenol, Madecassoside, etc.)
Application: Twice daily for 8 weeks.

Control Group
Silicone Ointment
Application: Twice daily for 8 weeks.

Assessment Timepoints:
Evaluations at baseline and weeks 2, 4, 6, and 8.

Efficacy Outcomes

- Clinician-Assessed (Primary Endpoint): Rash and HFS grade improvement in patients receiving EGFR inhibitors and capecitabine, respectively.
- Patient-Reported: Skin discomfort (VAS); Dermatology Life Quality Index (DLQI).

Safety Evaluation
Adverse events were monitored and recorded throughout the study.

Abbreviation: CARs, Cutaneous Adverse Reactions; DLQI, Dermatology Life Quality Index; ECOG PS, Eastern Cooperative Oncology Group Performance Status; EGFR, Epidermal Growth Factor Receptor; HFS, Hand-Foot Syndrome; VAS, Visual Analogue Scale

Results

Baseline Character

All 40 enrolled patients completed the study and were included in the analysis(Table 1). As detailed in Table 1, the intervention and control groups were well-balanced at baseline regarding demographic and clinical characteristics, including age, gender, ECOG performance status, systemic regimens, and baseline VAS and DLQI scores (all p > 0.05).

Table 1 Baseline and Characteristics

Characteristic	Intervention Group (N=20)	Control Group (N=20)
Age, years, median (range)	56.52 (34,71)	51.90 (39,73)
Female, n (%)	8 (40)	10 (50)
ECOG PS, n (%)		
0	6 (30.0)	7 (35.0)
1	14 (70.0)	13 (65.0)
Systemic Regimen, n (%)		
EGFR inhibitors	10 (50.0)	10 (50.0)
Capecitabine	10 (50.0)	10 (50.0)
VAS score, median(range)	5 (2,10)	5 (1,10)
DLQI score, median(range)	12 (2,19)	11 (3,8)

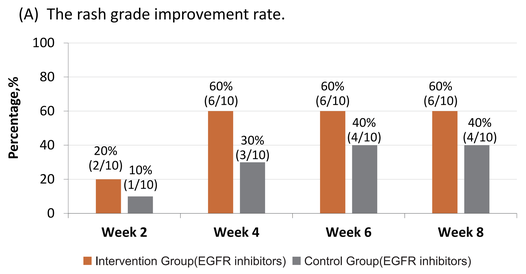
Efficacy Outcomes by Clinician-Assessed

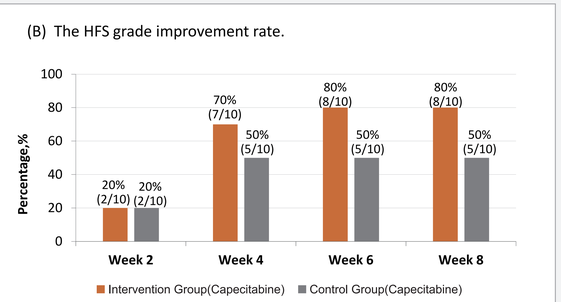
The improvement rates for both rash and HFS were consistently higher in the intervention group compared to the control group throughout the 8-week study period (Figure 1).

For rash grade improvement, the rate in the intervention group increased from 20.0% (2/10) at Week 2 to 60.0% (6/10) at Week 4, maintaining this level through Week 8. In contrast, the control group showed a slower and more modest improvement, from 10.0% (1/10) at Week 2 to 40.0% (4/10) at Week 8.

A similar trend was observed for HFS grade improvement. The intervention group's rate rose sharply from 20.0% (2/10) at Week 2 to 80.0% (8/10) at Week 6, while the control group's improvement plateaued at 50.0% (5/10) after Week 4.

Figure 1. Improvement Rates Over the Treatment Period. (A) Rash Grade Improvement Rate. (B) Hand-Foot Syndrome (HFS) Grade Improvement Rate



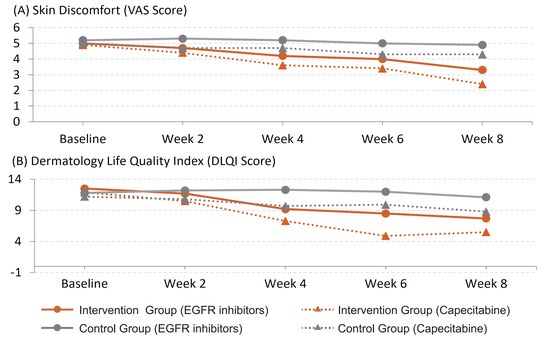


Patient-Reported Outcomes by Systemic Therapy

Improvements in patient-reported outcomes were consistent across different anticancer regimens. As shown in Figure 2, patients in the intervention group demonstrated rapid and sustained reductions in both skin discomfort (VAS) and dermatology-related quality of life impact (DLQI), irrespective of whether they were treated with EGFR inhibitors or capecitabine.

In contrast, the control group showed minimal improvement over the 8-week period. The VAS and DLQI scores in both control subgroups remained markedly higher than those in their corresponding intervention subgroups from Week 4 onward.

Figure 2. Longitudinal Changes in Patient-Reported Outcomes by Systemic Treatment Regimen. (A) Skin Discomfort (VAS Score) ; (B) Dermatology Life Quality Index (DLQI Score) .



Representative Clinical Cases

The clinical efficacy was further illustrated by representative case photographs (Figure 3), which showcase improvement in adverse reactions caused by different classes of anticancer drugs.

For chemotherapy-induced HFS (Figure 3A), associated with capecitabine, the patient exhibited substantial resolution of palmar hyperkeratosis and fissures after 8 weeks of treatment.

For targeted therapy-induced facial skin reaction (Figure 3B), associated with EGFR inhibitors, a notable attenuation in the severity of lesions, including a reduction in erythema and crusting, was observed post-treatment.

Figure 3. Representative Clinical Photographs Demonstrating Improvement in Anticancer Therapy-Induced Cutaneous Adverse Reactions. (A) Improvement of chemotherapy-induced hand-foot syndrome (HFS) in a patient treated with capecitabine. (B) Improvement of targeted therapy-induced papulopustular rash in a patient treated with EGFR inhibitors. Photographs show marked reduction in skin lesions after 8-week intervention with Cicaplast Baume B5+ repair balm. (A) HFS lesions demonstrate substantial resolution of hyperkeratosis and fissures. (B) Facial rash shows attenuation of erythema and crusted lesions.



Conclusions

Cicaplast Baume B5+ was superior to control in managing cutaneous adverse reactions from both chemotherapy and targeted therapy, providing greater clinical improvement, symptom relief, and quality of life benefit, suggesting its potential role in oncology supportive care.

Acknowledgment

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Contact
Yongmei Yin
Email: ymyin@njmu.edu.cn
Phone: 021-2601 8730

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