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Short Communication

Clinical Efficacy and Skin Bioengineering Evaluations of a Semi-Occlusive Healing Ointment as an Adjuvant Therapy in Hand Eczema

Waranya Boonchai¹, Pichanee Chaweekulrat¹, Chutipon Pruksaeakanan¹, Supisara Wongdama¹, Janista Thumrongtharadol¹, Supenya Varothai^{1*}

¹Department of Dermatology, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand

***Corresponding Author:** Supenya Varothai, MD, Department of Dermatology, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand; E-mail: supenya.var@gmail.com

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Abstract

Background: Hand Eczema (HE) is the most common skin problem during SARS-CoV-2 pandemic which has impaired quality of life, impact work ability and cause hand dysfunction. The use of Topical Corticosteroid (TCS) alone can delay HE healing.

Objective: To determine the efficacy of a semi-occlusive ointment containing panthenol, glycerol and bisabolol as an adjuvant therapy to TCS in mild-to-moderate HE.

Methods: An open-label prospective study was conducted of 60 patients with mild-to-moderate HE. The tested product was applied to both hands, two or three times a day every 4 to 6 hours for 8 weeks. There was then a 4-week cessation period. Disease severity was assessed by physician/patient scoring systems, Corneometer, Tewameter and Visioscan that were collected at week 0, 2, 4, 8 and 12.

Results: Fifty-six patients completed the study. The patients had a mean age of 42.8 years and were mostly female. The median duration of HE was 12.0 years. The physician and patient global assessment scores of clinical severity; erythema, dryness, itching and functional impairment, were significantly reduced starting at week 2 compared with baseline. After the 4-week cessation of the tested product, patient lost the product efficacies. The proportion of

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patients who used TCS tended to decrease during the study period. Skin hydration was significantly improved at week 4. No unwanted effects found.

Conclusion: A semi-occlusive healing ointment with panthenol, glycerol and bisabolol was effective and safe for treating mild-to-moderate HE. Our study identified an adjuvant ointment choice for HE treatment other than TCS.

Keywords

Adjuvant Therapy; COVID-19 Hand Hygiene; Hand Eczema; Semi-Occlusive Ointment

Introduction

Hand Eczema (HE) is the most common skin problem during the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) pandemic, with a reported prevalence of 74.5% among health care workers [1]. The severity of HE can result in impaired quality of life, impact work ability and cause hand dysfunction [2]. Skin barrier defects, which play a central role in HE development, easily allow allergens and irritants to penetrate the epidermis [3]. Hand hygiene during the pandemic has increased the risk of hand dermatitis because of frequent hand washes, harsh hand sensitizers and the use of occlusive gloves, especially in people with an underlying atopic nature or an occupational risk.

Several barrier repair products with unique property compounds have been used to hasten the healing of impaired skin barriers and maintain a healthy barrier [4]. Additionally, the combination of moisturizers with Topical Corticosteroids (TCS) was more effective than TCS alone in eczema treatments [5]. Our study aimed to evaluate the efficacy of an ointment containing panthenol, glycerol and bisabolol as an adjuvant therapy to TCS in mild to moderate HE.

An open-label prospective study was performed at the Department of Dermatology, Faculty of Medicine Siriraj Hospital, Thailand, from September 2020 to September 2021. It was approved by the Siriraj Institutional Review Board (Si 798/2020) and registered with the Thai Clinical Trials Registry (TCTR20211130001). Sixty patients with mild to moderate HE lasting longer than 6 months and aged ≥ 18 years were enrolled. All the included patients provided written informed consent for participation. Any TCS prescribed before enrolment was allowed, but other skin-care products were prohibited. At first visit, an ointment containing panthenol, glycerol and bisabolol (Eucerin® Aquaphor soothing skin balm; Beiersdorf, Hamburg, Germany) was prescribed to each patient (full ingredients list of tested product: paraffinum liquidum, cera micro-cristallina, cersin, lanolin alcohol, panthenol, glycerol and bisabolol).

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One fingertip unit of the tested product was applied to both hands two or three times a day every 4 to 6 hours for 8 weeks. There was then a 4-week cessation period. Patients with a history of using systemic corticosteroids during the preceding two weeks, an allergy to any tested product ingredients, pregnancy, or lactation were excluded.

Assessments were made at baseline, week 2, week 4, week 8 and week 12 (after the 4-week cessation). They were performed by the following:

1. A physician using the Hand Eczema Severity Index (HECSI) scoring system (six clinical signs assessed were erythema, induration/papulation, vesicles, fissuring, scaling and edema) and a physician global assessment of clinical severity
2. A patient global assessment of overall severity and product satisfaction grading
3. Bioengineering measurements of skin hydration and transepidermal water loss using a Corneometer CM 825 and a Tewameter TM 300 (Courage + Khazaka electronic GmbH, Cologne, Germany), respectively. All parameters were measured in a room with temperature of 20-22°C and relative humidity of 40-60%
4. Clinical photography with a Visioscan (Courage + Khazaka Electronic, Cologne, Germany)

The patients had a mean age of 42.8 years and were mostly female (75.0%). Glove usage was found in 60.7% of the cohort; 12.5% had atopic dermatitis; and 42.8% were in high-risk jobs (healthcare workers, homemakers or agricultural workers). The median duration of HE was 12.0 years. Fifty-six patients (93.3%) completed the study. The median frequency of their TCS use was 0.5 days per week at baseline (week 0).

The physician and patient global assessment scores of clinical severity were significantly reduced at week 4 compared with baseline (Fig. 1). The total HECSI score significantly improved after 2 weeks compared with baseline ($P < 0.001$; Fig. 1). The HECSI improvements mainly occurred in erythema and scaling, with infiltration/papulation showing a significant reduction from week 4 ($P < 0.001$). After the 4-week cessation of the tested product, the physician global assessment score and total HECSI score significantly reverted to baseline levels. Patients reported significant improvements in erythema, dryness, itching and functional impairment of their hands at week 2 compared with baseline (Fig. 1). Most patients strongly agreed that the tested product caused no irritation and relieved skin dryness but was greasy. Even though the proportion of patients who used TCS tended to decrease during the study period, no significant difference was observed ($P = 0.558$; Fig. 1). Skin hydration was significantly improved at week 4, but there was no change in transepidermal water loss compared with baseline (Fig. 1). Sample clinical photographs and Visioscan photographic images are shown in Fig. 2.

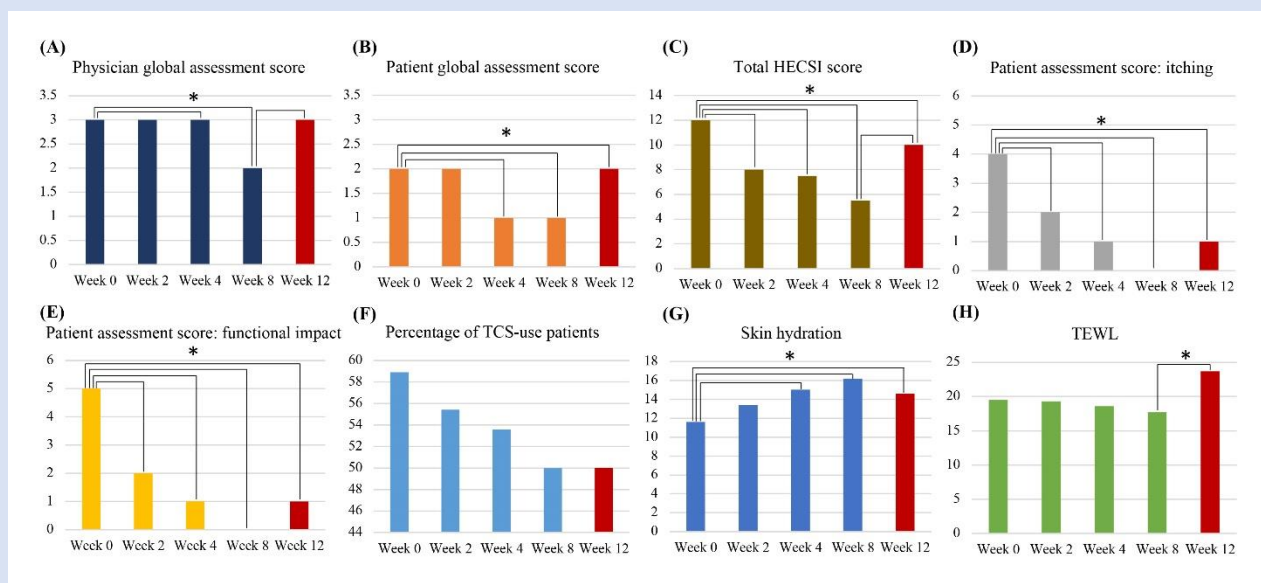


Figure 1: Comparison of parameters at baseline with different periods of the study and to week 12 after discontinuing the tested product. TEWL, transepidermal water loss; * $P < 0.05$ compared with baseline.

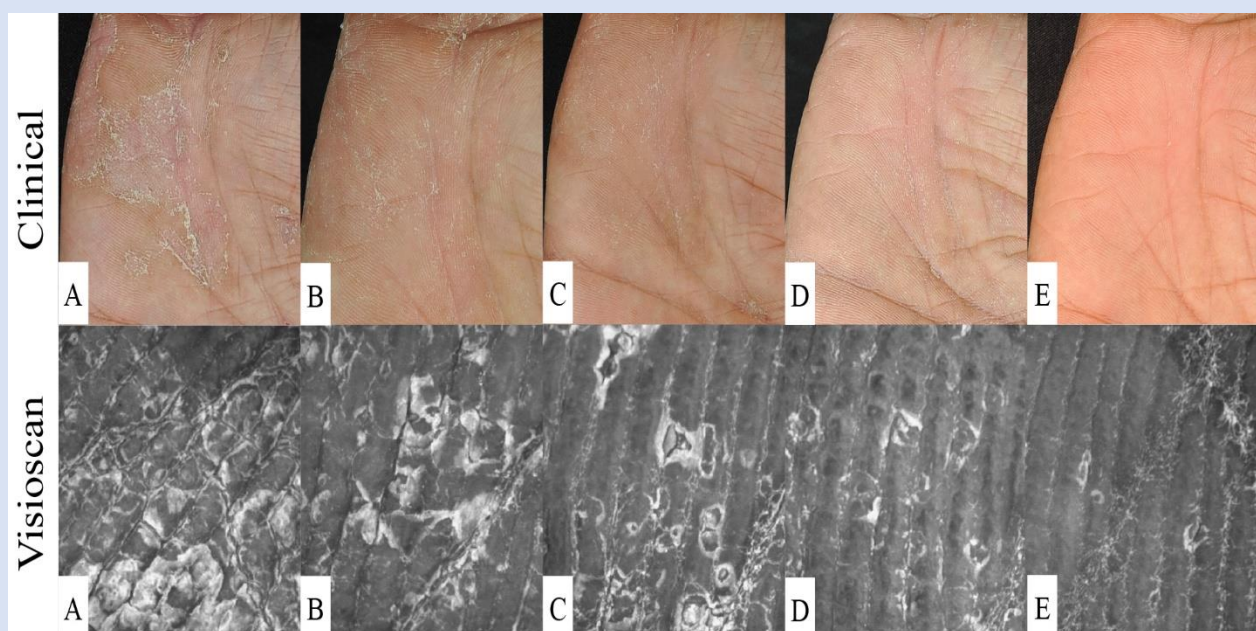


Figure 2: Representative clinical photographs and photographic images of Visioscan of a patient with moderate chronic hand eczema at the left palm at each follow-up visit; A) baseline, B) week 2, C) week 4, D) week 8 and E) week 12.

Comments

Prolongation of the SARS-CoV-2 pandemic over almost 3 years has accelerated HE occurrence [6]. Epidermal barrier impairment is the main pathology of HE. Restoration of the structural and functional integrity of the stratum corneum is essential to reverse the clinical signs and symptoms of the disorder [7]. TCS is a mainstay treatment that aims to reduce inflammation; however, prolonged TCS use affects stratum corneum lipids and increases skin barrier permeability, resulting in delayed healing [8]. Therefore, any adjuvant therapy that can reduce corticosteroid use should be considered [9].

Recently, the trends of moisturizers have shifted toward improving skin hydration, replenishing intercellular lipid lamella and adding various ingredients with anti-inflammatory, antioxidant and microbiome-modulating effects [10]. Moisturizers with unique properties as an adjunct to TCS therapy in HE have been successful [11].

The studied product is an ointment containing panthenol, glycerol, bisabolol and petrolatum. Panthenol has a moisturizing effect on the skin and enhances skin barrier reparation and regeneration, stimulating wound healing [12]. Glycerol is the most effective humectant. Bisabolol, extracted from chamomile, has anti-inflammatory and skin healing effects and can ameliorate pruritus. These positive attributes were confirmed by patients reporting that itch improved after 2 weeks of use [4,13,14]. Moreover, all assessments obtained with the 4 methodologies itemized above worsened after discontinuing the studied product, which proves its efficacy.

The proportion of our patients using TCS showed a declining trend during the study period. Because our baseline frequency of TCS use was minimal, the studied product could be used alone to treat mild HE due to its moisturizing, barrier-repairing and anti-inflammatory effects. To reduce the chance of developing allergic contact dermatitis, the studied product is free of fragrances and preservatives, both of which are common contact allergens. The benefit of this approach was supported by our study findings that the patients tolerated the ointment well and that there were no signs of irritation. However, there was a report of bisabolol allergic contact dermatitis [15]. Greasiness was the only complaint about the studied product, which has an ointment base. All patients had good compliance, which was assessed by the ointment consumed.

The limitation of the study is its open-label design without randomization and comparison. A 6.6% drop-off rate resulted from hospital evasion caused by the SARS-CoV-2 pandemic. The results of all assessment parameters may be better if we study the product under normal circumstances without SARS-CoV-2 preventive measures. Concomitant use of TCS during the study period might have interfered with interpretations, but the research was conducted in a real-world situation. However, in patients with previous TCS use, the continued use of that

TCS would not account for a change in assessment results. Any improvement in the results would be directly attributable to the tested product.

In conclusion, this study demonstrated the efficacy and safety of a semi-occlusive healing ointment containing panthenol, glycerol and bisabolol for treating mild to moderate HE. Our study identified an adjuvant ointment choice for HE treatment other than TCS.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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