doi:10.36849/JDD.7067

BRIEF COMMUNICATION Journal of Drugs in Dermatology

An Investigator-Initiated Trial of a Polymeric Emulsion of Halobetasol Propionate and Tazarotene in the Treatment of Palmoplantar Psoriasis

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ABSTRACT

Background: Palmoplantar psoriasis is a chronic, difficult-to-treat localized variant of psoriasis that affects the palms and soles, significantly affecting patient's quality of life.

Objective: To evaluate the synergistic effect of a fixed-combination topical lotion composed of halobetasol propionate 0.01% and tazarotene 0.045% in the treatment of palmoplantar psoriasis.

Methods: This was an open-label investigator-initiated trial involving 21 patients with moderate-to-severe palmoplantar plaque-type psoriasis who underwent treatment with halobetasol propionate 0.01% and tazarotene 0.045%. Subjects were assessed for disease severity using the palmoplantar Physician Global Assessment and the mean difference over time was compared using the Wilcoxon signed-rank test.

Results: 5 patients (24%) achieved a palmoplantar Physician Global Assessment of 0 or 1 after week 24 or last observation carried forward. The mean palmoplantar Physician Global Assessment significantly decreased from baseline (3.57) to week 24/last observation carried forward (2.38) (P<0.001).

Discussion: Halobetasol propionate 0.01% and tazarotene 0.045% lotion demonstrated efficacy in adult patients with moderate-to-severe palmoplantar plaque-type psoriasis through significant improvement in palmoplantar Physician Global Assessment. The complementary mechanisms of action of the corticosteroid and tazarotene may be of benefit compared to monotherapeutic agents.

J Drugs Dermatol. 2023;22(2):218-220. doi:10.36849/JDD.7067

INTRODUCTION

Palmoplantar psoriasis is a chronic, localized form of psoriasis affecting the palms and soles and is prevalent in 3-4% of individuals with psoriasis.[1] Although there has been no standard therapeutic treatment, potent to super-potent topical corticosteroids, tazarotene (TAZ), and vitamin D analogues are commonly the first-line agents.[1,2] However, as monotherapy, these agents do not properly penetrate the thickened stratum corneum, often resulting in treatment failure.[2] As a result, the objective of this study was to evaluate the synergistic effect of an FDA approved fixed-combination topical lotion composed of the mid-to-high potency corticosteroid halobetasol propionate (HP) 0.01% and the retinoid TAZ 0.045% (HP/TAZ; Duobrii®) on improving the signs and symptoms of palmoplantar plaque type psoriasis.

MATERIALS AND METHODS

Patients aged 18 years or older with moderate-to-severe plaque-type psoriasis, as determined by a score of ≥3 on the palmoplantar Physician Global Assessment (ppPGA) scale were eligible to participate in this open-label study.[3] ppPGA scores include 0 (clear), 1 (almost clear/minimal), 2 (mild), 3 (moderate), 4 (marked/moderate-to-severe), and 5 (severe).[3]

Subjects applied a thin layer of HP/TAZ lotion once daily to affected areas for 24 weeks. Subjects were assessed for disease severity using the ppPGA at 0, 2, 8, 12, 16, and 24 weeks and treatment satisfaction using a previously published numerical rating scale.[4] Photography of the hands and/or feet were taken to assess for treatment response. Safety and treatment-related adverse events were evaluated throughout the study.

The difference between Baseline (week 0) and week 24/Last Observation Carried Forward (LOCF) was assessed with the Wilcoxon signed-rank test. Alpha risk was set to 5% ($\alpha = 0.05$). Statistical analysis was performed with EasyMedStat (version 3.14; www.easymedstat.com).

FIGURE 1. Progression of moderate-to-severe palmar psoriasis with once daily HP/TAZ treatment at week 0 (baseline) and at 12 weeks.

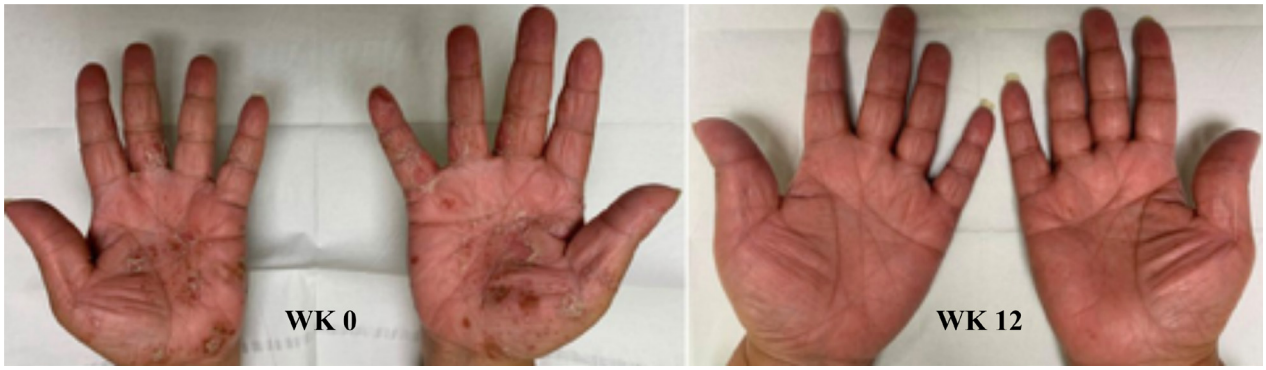
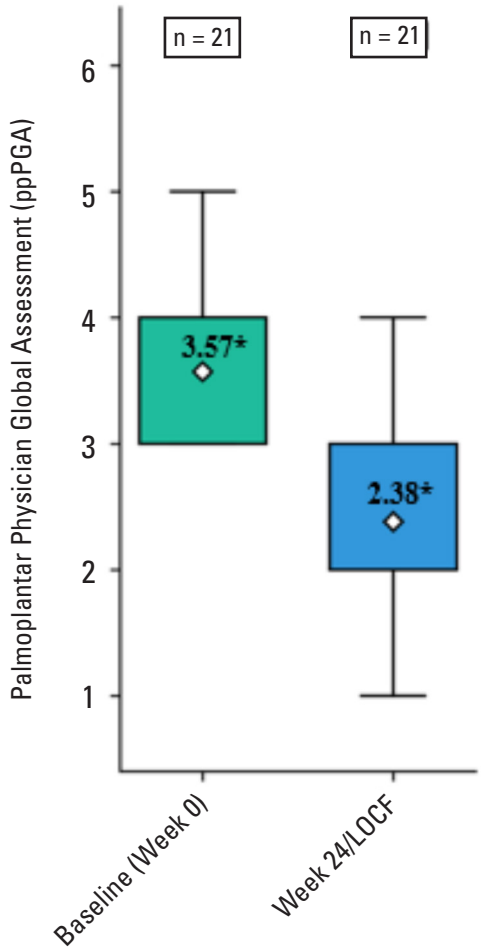


FIGURE 2. Mean ppPGA from baseline to week 24/LOCF.



*P-Value <0.001

TABLE 1.

Demographics and Baseline Disease Characteristics	
Characteristic	**No. (%)**
Sex	
Female	9 (42.9)
Male	12 (57.1)
Age, mean (range)	52.5 (27-72)
Race and ethnicity	
Black or African American	8 (38.1)
White	10 (47.6)
Asian	3 (14.3)
Disease duration since diagnosis, mean (SD)	7.57 years (8.2)

RESULTS

Demographic and baseline disease characteristics are shown in Table 1. A total of 21 patients aged 21 to 72 years received HP/TAZ; however, 57% of patients completed all 24 weeks of treatment. 52% of patients had failed monotherapy with Class I, II, and III topical corticosteroids. Among 21 patients, 5 (24%) achieved a ppPGA of 0 or 1 after 24 weeks or LOCF (primary endpoint). Figure 1 shows improvement of ppPGA following 12 weeks of treatment with HP/TAZ. The mean ppPGA significantly decreased from baseline (3.57) to week 24/LOCF (2.38) as shown in Figure 2 (P<0.001). Median ppPGA at baseline and week 24/LOCF were 3.0 (Interquartile Range [IQR] 1.0) and 2.0 (IQR 1.0), respectively, with a difference of 1.0 (IQR= 1.0; CI 95%= [1.0; 2.0]; P<.001). Overall, 62% were moderately or very satisfied with treatment (data not shown).

Most frequently reported treatment-related adverse events were application site pruritis (14%), stinging (5%), and burning (10%) with none requiring discontinuation. There were no serious adverse events reported.

DISCUSSION

HP/TAZ lotion significantly improved signs, symptoms, and severity of moderate-to-severe palmoplantar plaque-type

psoriasis in a proportion of patients based on improvement of ppPGA. Unlike other conventional monotherapeutic topical treatments, HP/TAZ's mechanism of action is uniquely formulated with a novel polymeric emulsion technology, allowing active ingredients to penetrate the thickened epidermal barrier of the hands and/or feet.[2] Topical treatment compliance tends to be poor amongst psoriasis patients.[5] However, HP/TAZ's optimal moisturizing capabilities and low irritative features have likely contributed to adequate patient adherence as evidenced by 62% of patients being moderately or very satisfied with treatment.

This study shows the positive response of treatment with HP/TAZ even in a population of patients with failure to mid-to-high potency topical corticosteroids.This is likely due to the synergistic anti-inflammatory and antiproliferative mechanisms of HP and TAZ.[2] Limitations to consider are the small sample size and lack of extensive follow-up time. Randomized, placebo-controlled studies with larger sample size and follow-up post-treatment to monitor for recalcitrant disease may be of beneficial use. The results of this study suggest that HP/TAZ lotion may be effective for adults with moderate-to-severe palmoplantar plaque-type psoriasis possibly through penetration of topically applied medications.

DISCLOSURES

Alice B. Gottlieb has received honoraria as an advisory board member and consultant for AnaptsysBio, Avotres Therapeutics, Amgen, Boehringer Ingelheim, Bristol-Myers Squibb Co., Incyte, Janssen, Eli Lilly, Novartis, Pfizer, Sun Pharmaceutical Industries, Inc., UCB, Dermavant, Sanofi, and Xbiotech. A.B. Gottlieb has received research/educational grants from Boehringer Ingelheim, Janssen, Ortho Dermatologics, Novartis, UCB, Xbiotech, and Sun Pharma. All funds go to Mount Sinai Icahn School of Medicine. Jenna Yousif, Folawiyo Babalola, Caroline Campbell, Jessica Vargas, and Krystal Mitchell have no conflicts of interest to disclose.

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