

Introduction

- Palmoplantar psoriasis is related to a significantly decreased quality of life compared to generalized psoriasis^[1]
- However, therapeutic guidelines for palmoplantar psoriasis have not been established due to limited data^[2]
- Topical treatment is typically the first-line recommendation, but it is often ineffective in palmoplantar psoriasis, as standard preparations do not adequately penetrate the thickened stratum corneum of the palms and soles^[3]
- A novel polymeric emulsion lotion with a fixed combination of corticosteroid halobetasol propionate 0.01% and retinoid tazarotene 0.045% (HP/TAZ) may overcome this challenge, as it has demonstrated increased dermal penetration compared with conventional preparations of either ingredient^[4]
- In previous phase III trials, HP/TAZ significantly reduced psoriasis severity and affected surface area, but further analysis was not performed in palmoplantar areas^[5]
- The purpose of the current study is to examine the efficacy of the novel polymeric emulsion HP/TAZ in palmoplantar plaque-type psoriasis

Methods

- Open-label, investigator-initiated trial of 21 patients with moderate-to-severe palmoplantar psoriasis determined by the palmoplantar Physician Global Assessment (ppPGA)^[6]
- ppPGA scores include 0 (clear), 1 (almost clear/minimal), 2 (mild), 3 (moderate), 4 (marked/moderate-to-severe), and 5 (severe)^[6]
- Key Inclusion Criteria:
 - males and nonpregnant/willing-to-use contraception females, ages > 18 years
 - moderate-to-severe palmoplantar psoriasis (ppPGA score of > 3)
- Key Exclusion Criteria:
 - prohibited use of concomitant systemic or topical psoriasis treatments
 - failure to washout of any previous psoriasis treatment therapies
- Subjects applied HP/TAZ daily to affected areas for 24 weeks
- Assessment with ppPGA, photography, and treatment satisfaction was performed at procedure visits (baseline, weeks 2, 8, 12, 16, and 24)
- Efficacy assessment included percentage of patients achieving a ppPGA of 0 or 1 after 24 weeks of treatment
- Treatment satisfaction was assessed using a Numerical Rating Scale (NRS)
- Safety and treatment-related adverse events (AEs) were evaluated

Results

- 52% of patients failed previous monotherapy with Class I, II, and III topical corticosteroids
- Efficacy**
- Mean ppPGA significantly decreased from baseline (3.57) to week 24/Last Observation Carried Forward (LOCF) (2.38) ($p < 0.001$) (**Figure 1**)
 - 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]; $p < 0.001$) (**Figure 1**)
 - 5 (24%) achieved a ppPGA of 0 or 1 after 24 weeks/LOCF (**Figure 2**)
- Treatment Satisfaction**
- 57% of patients were moderately satisfied or very satisfied with HP/TAZ treatment

Figure 1. Mean ppPGA from Baseline to Week 24/LOCF

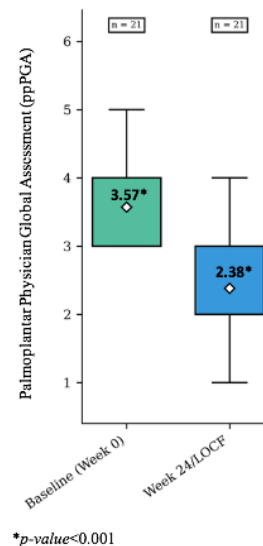


Figure 2. Progression of moderate-to-severe palmar psoriasis with once daily HP/TAZ treatment at week 0 and at end of treatment (EOT)



Safety

- Four participants reported treatment-related AEs with HP/TAZ
- All AEs were mild or moderate and transient in nature
- Most frequently reported treatment-related AEs were application site pruritis (14%), stinging (5%), and burning (10%) with none requiring discontinuation
- No serious AEs were reported

Conclusion

- Preliminary data with HP/TAZ indicates its potential in treating palmoplantar psoriasis
- Randomized, placebo-controlled studies with a larger sample size and follow-up post-treatment to monitor for recalcitrant disease may further demonstrate its efficacy

References

1. Chung, J., et al., *Palmoplantar psoriasis is associated with greater impairment of health-related quality of life compared with moderate to severe plaque psoriasis*. J Am Acad Dermatol. 2014. 71(4): p. 623-32.
2. Nair, L.V., *Management of recalcitrant palmoplantar psoriasis*. Journal of Skin and Sexually Transmitted Diseases, 2019. 1: p. 8-12.
3. Miceli A, S.G., ed. *Palmoplantar Psoriasis*. StatPearls. 2021, StatPearls Publishing: Treasure Island (FL).
4. Lebwohl, M.G., et al., *Fixed-Combination Halobetasol Propionate and Tazarotene in the Treatment of Psoriasis: Narrative Review of Mechanisms of Action and Therapeutic Benefits*. Dermatol Ther (Heidelb), 2021. 11(4): p. 1157-1174.
5. Lebwohl MG, S.J., Stein Gold L, Lin T, Israel R, *Efficacy, Safety, and Tolerability of a Halobetasol 0.01%/Tazarotene 0.045% Fixed Combination in the Treatment of Severe Localized Plaque Psoriasis: Post Hoc Analysis of Two Phase III Randomized Controlled Trials*. J Drugs Dermatol. 2019. 18(10): p. 1012-1018.
6. Gottlieb A, Sullivan J, van Doorn M, et al. *Secukinumab shows significant efficacy in palmoplantar psoriasis: Results from GESTURE, a randomized controlled trial*. J Am Acad Dermatol. 2017;76(1):70-80. doi:10.1016/j.jaad.2016.07.058.