

Halobetasol 0.01% Lotion in the Treatment of Moderate-to-Severe Plaque Psoriasis of the Lower Extremities

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SYNOPSIS

- Psoriasis is a chronic, immune-mediated disease that varies widely in its clinical expression¹
- Topical corticosteroids are the mainstay of treatment in psoriasis, but long-term safety remains a concern, limiting use, and posttreatment flare-up is common²
- While psoriasis commonly affects lower extremities, treatment can be more problematic, and burden of disease heightened^{3,4}
- Recent phase 3 clinical data have demonstrated that halobetasol propionate (HP) 0.01% lotion (Byhali™ Ortho Dermatologics, Bridgewater, NJ) was significantly more effective than vehicle after 8 weeks of treatment in patients with moderate-to-severe localized plaque psoriasis,^{5,6} though efficacy in specific locations has not been reported

OBJECTIVE

- To investigate the efficacy of once-daily HP 0.01% lotion versus vehicle in patients with moderate-to-severe plaque psoriasis of the lower extremities

METHODS

Study Design

- Data from two phase 3, multicenter, randomized, double-blind studies of patients with moderate-to-severe psoriasis were pooled^{5,6}
- Participants were randomized (2:1) to receive HP 0.01% lotion or vehicle once-daily for 8 weeks, with a 4-week posttreatment follow-up
- At baseline, participants were required to have Investigator Global Assessment (IGA) score of 3 or 4 (5-point scale; 0=clear and 4=severe) and Body Surface Area (BSA) of 3% to 12%
- A post hoc analysis was conducted in a subset of patients with plaque psoriasis of the lower extremities, with a target lesion on the leg
 - For the target lesion, participants needed a score of ≥ 3 for at least 2 of 3 signs of psoriasis (erythema, plaque elevation, and scaling [5 point scale; 0=clear and 4=severe]), a sum of at least 8, and could not have a score of 0 or 1 in any one of the signs
 - Target could not be on areas covering bony prominences (ie, knees); however, overall psoriasis assessment (IGA and BSA) did not exclude the knees
- In these studies, CeraVe® hydrating cleanser and CeraVe® moisturizing lotion (L'Oréal, NY) were provided as needed for optimal moisturization/cleaning of the skin

Efficacy Assessments

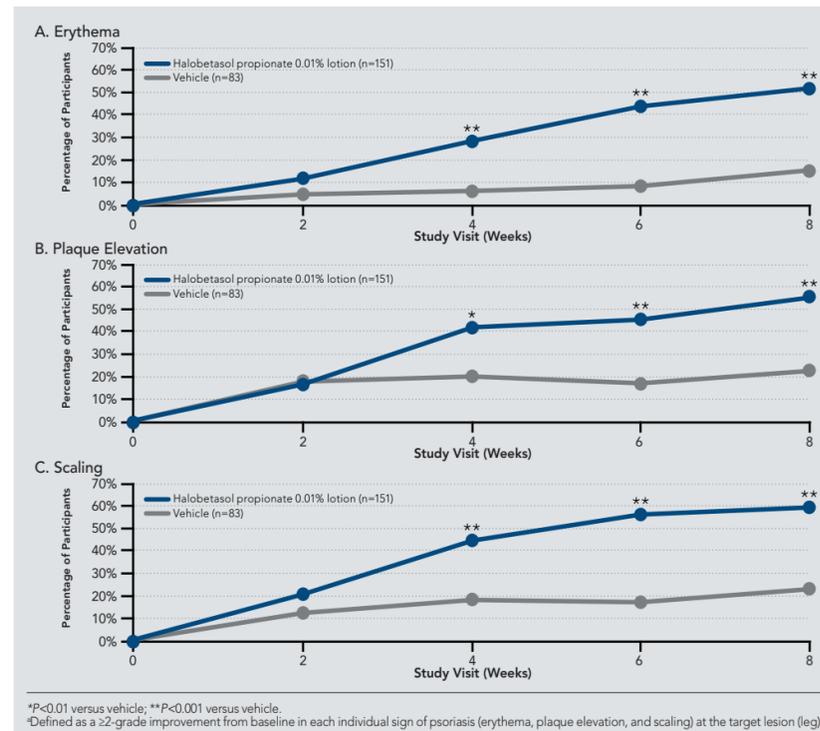
- Treatment success (≥ 2 -grade improvement from baseline) in each individual sign of psoriasis (erythema, plaque elevation, and scaling) at the target lesion (leg)
- Overall treatment success (≥ 2 -grade improvement from baseline in IGA score and a score of 'clear' or 'almost clear' [0 or 1])
- Improvements in overall mean BSA from baseline

- Reductions of $\geq 50\%$ and $\geq 75\%$ of overall IGxBSA from baseline (IGxBSA-50 and IGxBSA-75) at Week 8
- Quality of life (QoL) with 10 question Dermatology Life Quality Index (DLQI; 4-point scale; 0=not at all/not relevant and 3=very much)
 - Mean change in DLQI of 4 was considered a minimal clinically important difference (MCID)⁷

RESULTS

- This analysis included 234 patients where leg was identified as the target lesion (HP 0.01% lotion, n=151; vehicle, n=83)
- At the end of the 8-week treatment period, more than half of participants receiving HP 0.01% lotion achieved treatment success at the target lesion, with 52.1%, 55.5%, and 58.2% achieving ≥ 2 -grade reduction in erythema, plaque elevation, and scaling severity on the leg, compared with 15.7%, 22.9% and 22.2% of those treated with vehicle, respectively ($P < 0.001$ all; Figure 1)

FIGURE 1: Treatment Success^a in Psoriasis Signs of (A) Erythema, (B) Plaque Elevation, and (C) Scaling



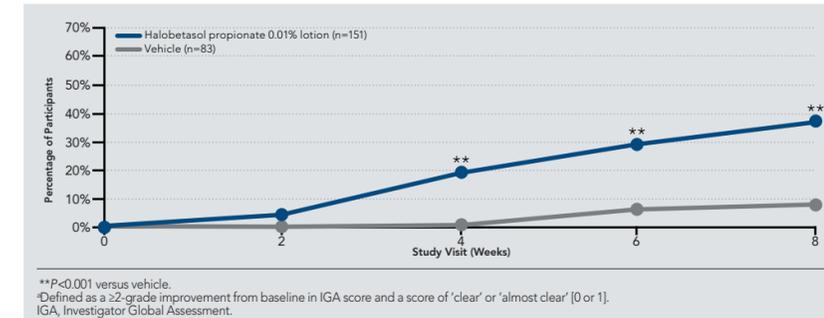
- Figure 2 illustrates treatment success with HP 0.01% lotion in the leg target lesion

FIGURE 2: Improvement of Psoriasis with Once-Daily Halobetasol Propionate 0.01% Lotion



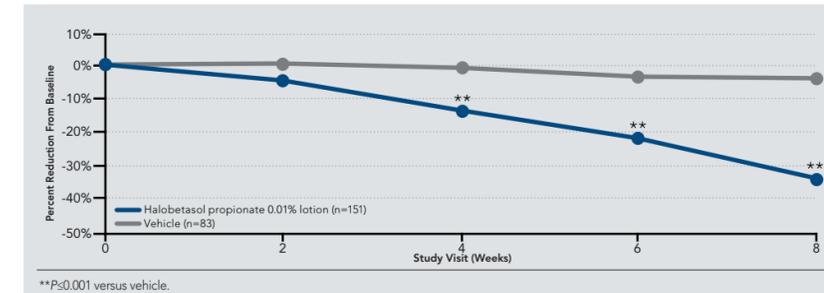
- Overall treatment success per IGA was achieved in 37.1% of participants treated with HP 0.01% lotion compared with 8.4% treated with vehicle ($P < 0.001$; Figure 3)

FIGURE 3: Overall Treatment Success^a on IGA Assessment of Disease Severity



- HP-treated patients had a 34.2% mean reduction from baseline in overall BSA compared with a 3.7% reduction in vehicle-treated patients ($P < 0.001$; Figure 4)

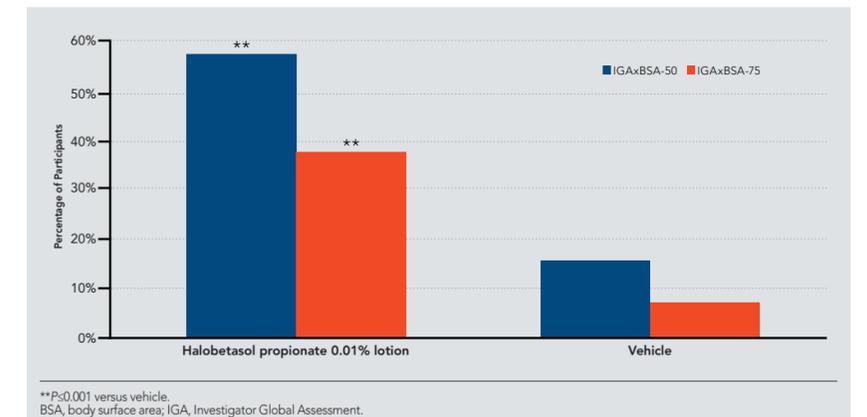
FIGURE 4: Mean Percent Reduction in Overall Body Surface Area (BSA)



- Mean percent reduction from baseline to Week 8 in IGxBSA score was also significantly greater with HP treatment (-50.5%) than with vehicle (-13.8%; $P < 0.001$)

- A clinically meaningful effect in overall psoriasis treatment (IGxBSA-75) was achieved by 37.7% of participants treated with HP 0.01% lotion compared with 7.2% treated with vehicle ($P < 0.001$; Figure 5)

FIGURE 5: Achievement of $\geq 50\%$ (IGxBSA-50) and $\geq 75\%$ (IGxBSA-75) Reduction in IGxBSA by Week 8



- A clinically relevant improvement in QoL was achieved by Week 4 with HP treatment (DLQI mean change of -4.5 vs -3.3; $P = 0.003$) and was maintained at Week 8 (DLQI mean change of -5.5 vs -3.8; $P < 0.001$ vs vehicle)

CONCLUSION

- Halobetasol propionate 0.01% lotion provided significant efficacy versus vehicle and clinically relevant improvements in QoL following 8 weeks of therapy in patients where the leg was identified as the target lesion

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AUTHOR DISCLOSURES

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