Keratolytic Activity of a Novel Topical Dimethicone Formulation (PB/LO-112) Compared to 10% Salicylic Acid Oil in Patients with Psoriasis Capitis

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Background

Psoriasis is a common chronic inflammatory skin disease most commonly characterized by well-demarcated, erythematous plaques with silver scales and associated with a number of comorbidities. Globally, the prevalence of psoriasis reported in population-based studies in adults ranges from 1% to 8.5%, with differences based on geographic location.[1]

Many patients with psoriasis feel stigmatized and suffer from marked physical and psychological disease burden, contributing to significant reductions of quality of life (QoL). The scalp is one of the most common sites of psoriasis, affecting 50–80% of patients.[2] Treatment can be burdensome and includes keratolysis of plaques followed by anti-inflammatory measures. Keratolysis with salicylic acid in oily vehicles is effective but burdensome and inconvenient to many patients.

LOYON® (PB/LO-112) is a unique, patented combination of the dry emollient Cetiol® CC and the medical silicone oil dimethicone. The combination of the 2 substances gives LOYON® a low surface tension as well as high creep and spreading properties. The liquid is very easily applied and allows a gentle yet effective lifting of scales.

Objectives

The objective of this study was to evaluate the efficacy, safety, and patient acceptance for this novel topical formulation (PB/LO-112) compared to 10% salicylic acid (10-SA) for the removal of scaling in patients with chronic psoriasis capitis.

Methods

In this single-center, randomized, active-controlled, observer-blinded, parallel group trial, 90 patients with chronic psoriasis capitis were randomized equally into 2 groups: one receiving the dimethicone formulation LOYON® (test group) and the other receiving a topical 10% salicylic acid formulation (10-SA, standard group). Primary outcomes parameter was the improvement of scaling of the Psoriasis Scalp Severity Index (PSSI). Minimum clinical response was defined as at least 0.5 units improvement on the PSSI scaling score [0-4] at day 7 after daily application. Secondary outcomes were the Scalp Physician Global Assessment (sPGA), patient quality of life (DLQI) and patient acceptance and tolerability by PBI, EQ-5DVAS and EQ-5D. For control reasons, the overall PASI was assessed and a second observer-blinded analysis was conducted after photo documentation. The effectiveness of PB/LO-112 was statistically tested for non-inferiority to 10-SA.

Results

There was a statistically significant reduction of scaling score after 7 days in both treatment groups (PB-LO/112: baseline [mean±SD] 2.8±0.7, day 7=2.2±0.7, p<0.001; 10-SA: baseline [mean±SD] 2.9±0.8, day 7=2.1±0.8, p<0.001) in both groups and non-inferiority (p=0.91 for the intent to treat and p=0.83 for the per protocol population) for PB-LO/112 compared with 10-SA. For the secondary endpoint of Scalp Physician Global Assessment (sPGA), the response was equivalent in the 2 groups. However, the PBLO/112 group saw a faster onset of keratolytic effect than the 10-SA group.

EFFICACY (PSSI scaling score)

The primary endpoint analysis (improvement of ≥0.5 points in PSSI scaling scores) after 7 days demonstrated that the PB/LO-112 group was non-inferior to 10-SA group (p = 0.83 for the PP population), thereby providing evidence of equivalent efficacy of PB-LO/112. (Figure 1) PSSI erythema and infiltration scores showed highly significant improvement in both groups compared to baseline as well as the sPGA score (data not shown). Relative reduction of PSSI was in favor of PB-LO/112 after 3 treatment days (25% for PB-LO/112 vs.14% for 10-SA; and increased for PB-LO/112 to 38% after 7 days, while 10-SA remained on the initial level. (Figure 2)

Safety

For PB-LO/112 and 10-SA, in total 13 adverse events (AEs) in 10 patients were reported. Eight AEs were mild, 4 were moderate and 1 (i.e., an allergic reaction of severe intensity which appeared in the 10-SA group) was severe. The most frequently reported AEs were erythema (n=3) and itching (n=3). Two AEs led to premature discontinuation. the vast majority of patients (71 %) reported AEs only at day 7 or later. There were no serious AEs.

Patient Reported Outcomes

For patient benefit and quality of life determined with the PBI, DLQI and EQ-5D Questionnaire, an improvement from baseline to visit 3 (day 7) was observed in both groups. The difference in improvements between the 2 groups was not statistically significant. Compliance to treatment instructions was generally described as very good by physicians in both treatment groups.

Conclusion

PB/LO-112 and 10-SA show comparable efficacy with respect to desquamation of scalp psoriasis, with a time advantage for PB/LO-112. In the light of excellent safety and very good patient acceptance, this dimethicone formulation might be an alternative to conventional keratolytics

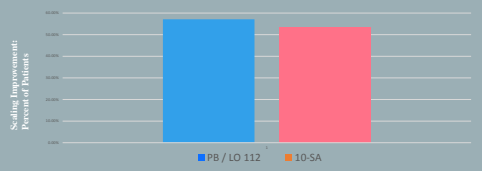

Figure 1. Improvement in Scaling after 7 Days

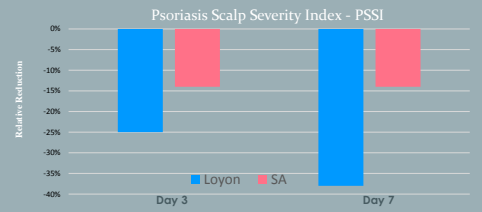

Figure 2. Psoriasis Scalp Severity Index (Relative Reduction)

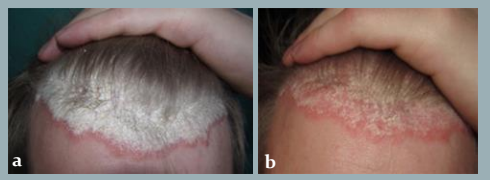

Figure 3. Photographs of the scalp of a 19-year-old patient with pronounced scalp psoriasis (a [left]) at baseline and (b [right]) after treatment with PB-LO/112 once daily for 7 days. A significant improvement of scaling is seen.

References

1.Michalek IM, Loring B, John SM. A systematic review of worldwide epidemiology of psoriasis J Eur Acad Dermatol Venereol. 2017;31(2):205.

2. Schön MP, Henning Boehncke W-H. Medical progress: Psoriasis. N Engl J Med 2005;352:1899-912.