Keratolytic activity of a novel topical dimeticone formulation (PB/LO-112) compared to 10% salicylic acid oil in patients with psoriasis capitis

Arnd Jacobi, Anke Mayer, Zografia Anastasiadou, Matthias Augustin

Institute for Health Services Research in Dermatology and Nursing, Psoriasis Center, University Medical Center Hamburg-Eppendorf, Germany.

BACKGROUND & OBJECTIVE

Many patients with psoriasis feel stigmatised 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. 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. For this, a new formulation of dimeticone for keratolysis of psoriatic plaques was developed in order to improve feasibility and patient acceptance. This compound was tested for the first time in this study to evaluate efficacy, safety and patient acceptance of the novel topical dimeticone formulation (LOYON®, PB/LO-112) compared to 10% salicylic acid (10-SA) in octyldodecanol with 15% Macrogol-4-laurylether for the removal of scaling in patients with chronic psoriasis capitis.

METHODS

Single-centre, randomised, active-controlled, observer-blinded, parallel group trial with n=90 patients randomised equally into two groups: I) topical dimeticone formulation PB/LO-112 (verum group) and II) topical 10% salicylic acid formulation (10-SA, standard group), for the removal of psoriatic plaques in patients with chronic psoriasis capitis. 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 of 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-5D-VAS and EQ-5D. For control reasons, the overall PASI was assessed and a second observer-blinded analysis after photo documentation was conducted. The effectiveness of PB/LO-112 was statistically tested for non-inferiority to 10-SA. Follow-ups between treatments were compared using the Wilcoxon signed-rank test. A chi-squared test was used to test for non-inferiority of PB-LO/112 compared to SA.

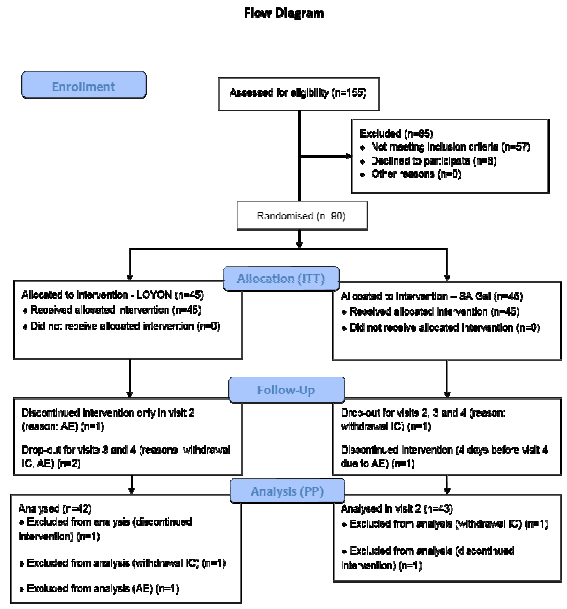


Figure 1: Flow diagram of study progressing referring to CONSORT 2010

RESULTS

There was a statistically significant reduction of scaling score after 7 days in both treatment groups (PB-LO/112: baseline [mean ±s tandard deviation] 2.8±0.7, day 7=2.2±0.7, p<0.001; 10-SA: baseline [mean ± standard deviation] 2.9±0.8, day 7=2.1±0.8, p<0.001) in both groups and non-inferiority (p=0.91 for the ITT and p=0.83 for the PP population) of PB-LO/112 compared with SA. The secondary endpoint of Scalp Physician Global Assessment (sPGA) also supports equivalent response to PB-LO/112 and SA. A faster onset of keratolytic effect was seen with PB-LO/112.

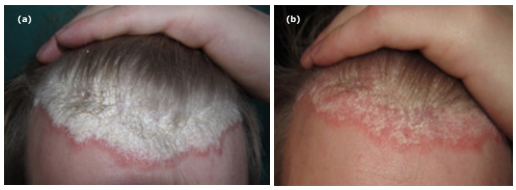
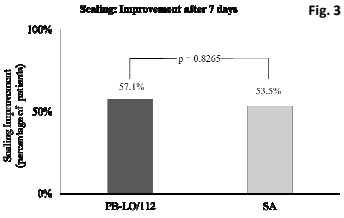
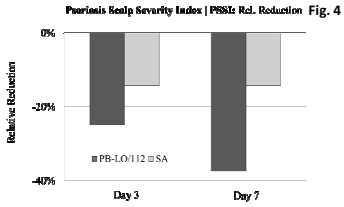


Figure 2: Photographs of the scalp of a 19-year-old patient with pronounced scalp psoriasis (a) at baseline and (b) after treatment with PB-LO/112 once daily for 7 days. A significant improvement of scaling is seen.

EFFICACY (PSSI scaling score)

Primary endpoint analysis (improvement of ≥0.5 points in PSSI scaling scores) after 7 days demonstrated that the verum 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 (Fig. 3). 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 favour of PB-LO/112 after 3 treatment days (25 % for PB-LO/112 vs. 14 % for SA; Fig. 4) and increased only for PB-LO/112 to 38 % after 7 days, while SA remained on the initial level.





TOLERABILITY

The tolerability of both test products was rated as “good” or “very good” by the majority of the patients and physicians. The patient acceptance was evidenced high as well as the satisfaction with the treatments.

SAFETY

For PB-LO/112 and 10-SA in total 13 adverse events (AEs) in ten patients were reported. Eight AEs were of mild, four of moderate and one (i.e. allergic reaction which appeared in the SA group) of severe intensity. 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, in both groups an improvement from baseline to visit 3 (day 7) was observed. Due to large variance, these improvements were not statistically significant between groups. Compliance to treatment instructions was mostly considered very good by the physicians in both treatment groups.

CONCLUSIONS

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 dimeticone formulation might be an alternative to conventional keratolytics

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Contact: Dr. Anke Mayer, Institute for Health Services Research in Dermatology and Nursing, Psoriasis Center, University Medical Center Hamburg-Eppendorf, Germany; a.mayer@uke.de