A double-blind, prospective, randomized, vehicle-controlled efficacy assessment study of a skin care formulation for improvement of mild to moderately severe acne

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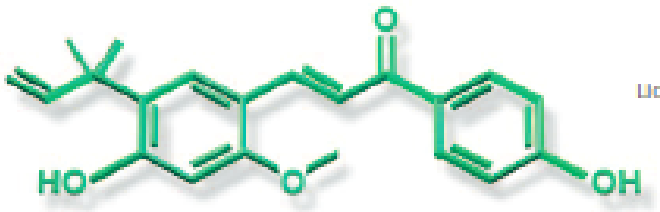
Abstract

Introduction and objective: Though the use of adjuvant skin care in the management of acne is widely recommended, so far there is limited evidence to support the efficacy of skin care alone for improvement of acne. We therefore performed an 8-week, double-blind, randomized, vehicle-controlled study to objectively assess the efficacy of a skin care formulation containing licochalcone A, carnitine and 1,2-decanediol in volunteers with mild to moderately severe acne.

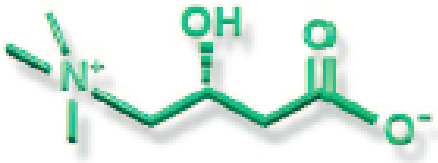
Material and methods: Sixty volunteers aged 14-40 years (40 female and 20 male, mean age 22.4 years) with mild to moderately severe papulopustular acne (10-25 inflammatory lesions) involving the face were included in the study. To minimize the effects of the individual cleansing routines, all participants were instructed to use the same cleansing products throughout the study and after wash-out period were randomized to receive either the formulation containing licochalcone A, carnitine and 1,2-decanediol or the vehicle alone to be applied twice daily on the face over 8 weeks. Reduction of the inflammatory lesions, *P. acnes* counts and skin surface lipid content assessed by minimally invasive skin bioengineering methods were defined as primary endpoints; the secondary outcomes included global improvement of the skin condition, Dermatology Quality of Life Index (DQLI), stratum corneum hydration and skin tolerability.

Results: Compared to baseline, at the end of the study there was significant reduction of the total lesion count ($p<0.05$), reduction of the papular and pustular lesions (for both, $p<0.05$) and significant reduction of skin surface lipid content assessed by both Sebumeter and Sebutapes (respectively, $p<0.01$ and $p<0.05$) in the group receiving the formulation containing licochalcone A, carnitine and 1,2-decanediol whereas at the same time no significant changes in the vehicle group were found. The application of the active ingredient formulation did not result in reduction of the stratum corneum hydration measured by capacitance and furthermore, was associated with more pronounced improvement of DQLI compared to the group receiving the vehicle alone.

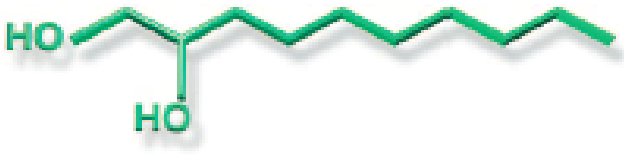
Conclusion: Our results provide evidence for the efficacy of the formulation containing licochalcone A, carnitine and 1,2-decanediol compared to only the vehicle and show that optimized skin care targeting inflammation, enhanced sebum production and *P. acnes* might alone offer benefit in the management of mild to moderately severe inflammatory forms acne.



Licochalcone A



L-carnitine



Decandiol

Background

Though the use of adjuvant skin care in the management of acne is widely recommended, so far there is limited evidence supporting the efficacy of skin care alone for improving the manifestations of mild to moderately severe acne.

Objectives

The aim of this double-blind, eight-week prospective randomized controlled study was to investigate the efficacy of a skin care formulation containing licochalcone A, carnitine and 1,2-decanediol compared to the vehicle alone in volunteers with mild to moderately severe acne involving the face.

Design and Participants

Sixty volunteers aged 14-40 years (40 female and 20 male, mean age 22.4 years) with mild to moderately severe papulopustular acne (10-25 inflammatory lesions) who were not receiving any topical or systemic acne medication were included in the study.

To minimize the effects of the individual cleansing routines, the volunteers were provided with the same cleansing products (a wash-gel and tonic) for the duration of the study.

After a 7-day wash-out period the volunteers were randomized to receive either the active ingredient formulation containing licochalcone A, carnitine and 1,2-decanediol (verum) or the vehicle alone to be applied twice daily on the face over 8 weeks (Fig. 1).

Outcomes

- Reduction of the inflammatory lesions
- Global improvement of the skin condition
- Reduction of the skin surface lipids content
- Stratum corneum hydration
- Reduction of *P. acnes*
- Global photographs
- Dermatology Life Quality Index (DLQI)
- Skin tolerability

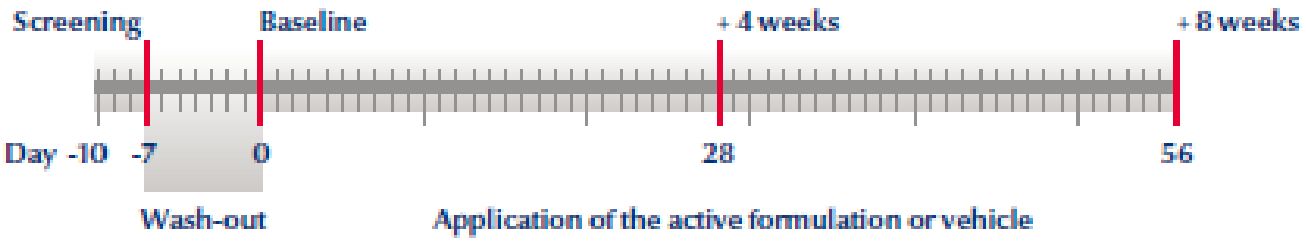
Results

The application of the formulation containing licochalcone A, carnitine and 1,2-decanediol resulted in significant reduction of the total lesion count (Fig. 2a), the papular and pustular lesions (Fig. 2b) as well as global improvement of the skin condition (Fig. 3) at the end of the study whereas no significant changes in the vehicle group were found.

Compared to baseline, at the end of the study there was significant reduction of the skin surface lipids content (sebum) in the verum group while the changes in the vehicle group were not significant (Fig. 4).

The application of the active ingredient formulation throughout the study did not induce skin dryness or reduction of the skin hydration measured by capacitance (Fig. 5).

Fig. 1. Investigation time points



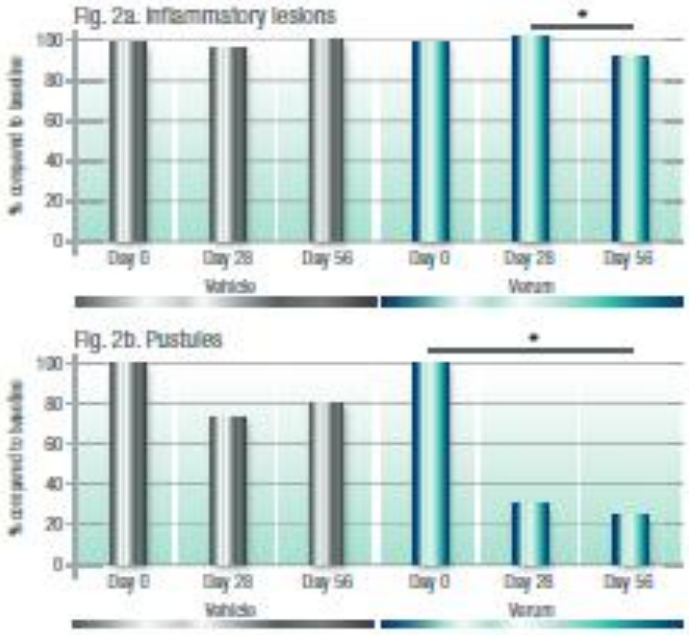


Fig. 2. Significant reduction of the total inflammatory lesion count (a) and pustules (b) in the verum group. Evaluation based on data from 25 volunteers for the verum, respectively 26 volunteers for the vehicle group. The results are presented as percentage compared to baseline; level of significance <0.05, *p<0.05.

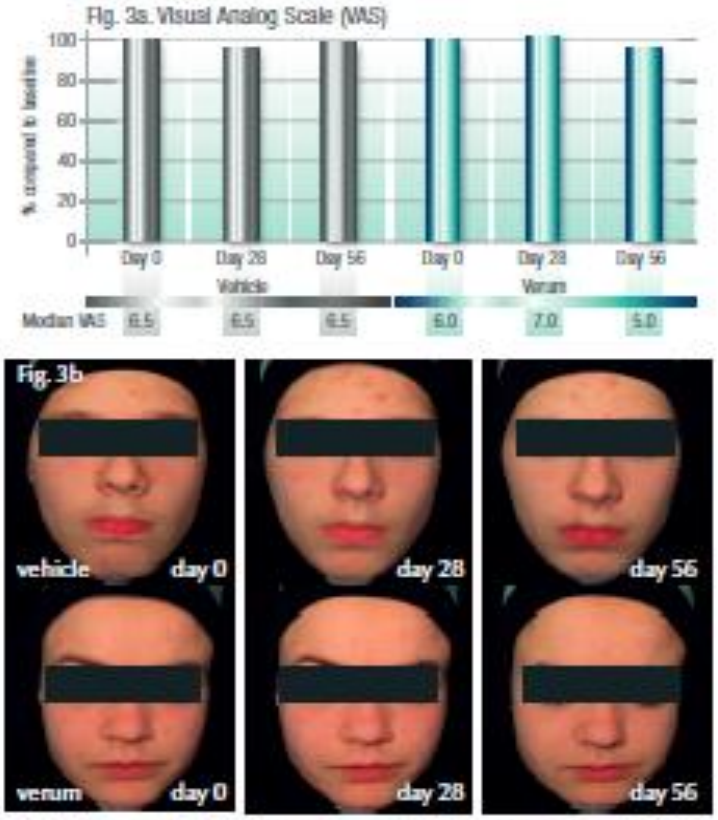


Fig. 3. Global improvement of the skin condition assessed by the investigator by means of a visual analog scale from 0 to 10 (a) and standardized photographs (b)

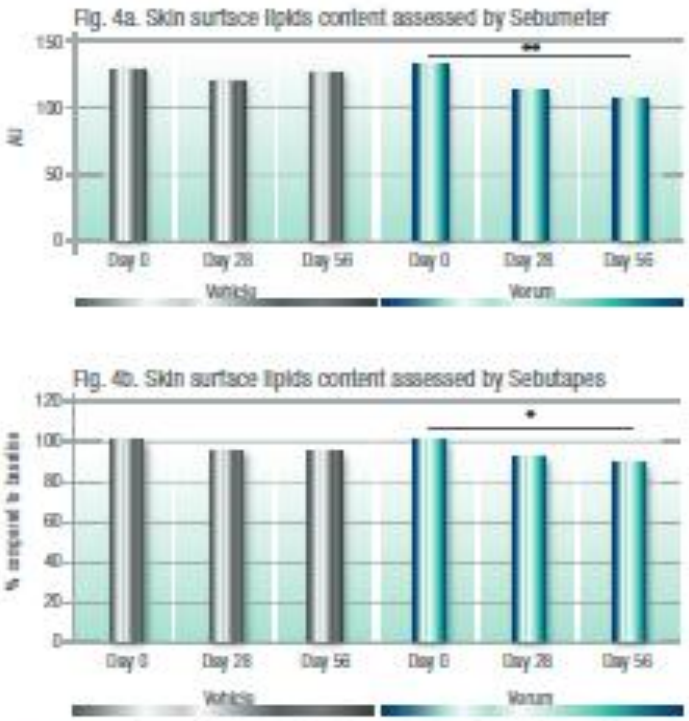


Fig. 4. Significant reduction of the skin surface lipids (sebum) in the group receiving the active ingredient formulation assessed by Sebumeter (a) and Sebutapes™ (b). Mean ± SEM, evaluation based on data from 25 volunteers for the verum and 26 volunteers for the vehicle group; level of significance <0.05, **p<0.01, *p<0.05.

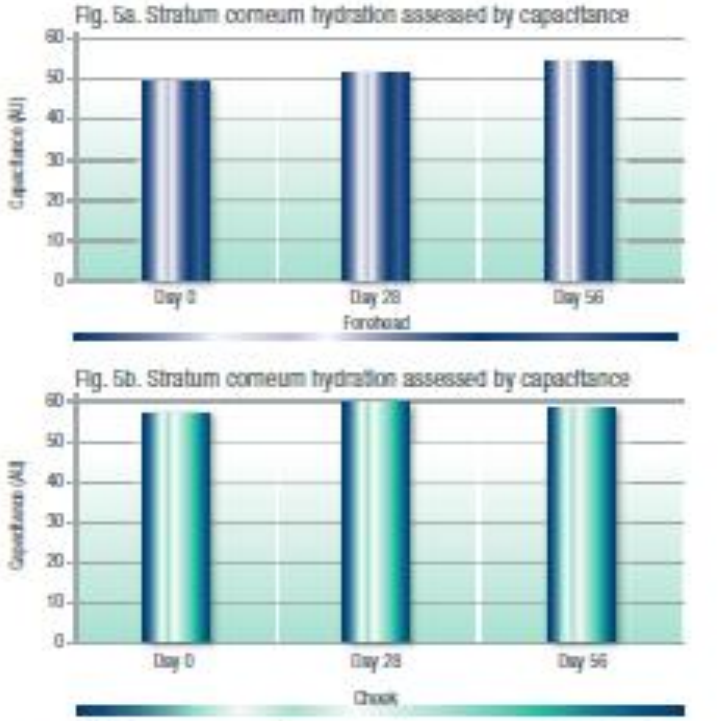


Fig. 5. Skin hydration assessed by measuring capacitance on the forehead (a) and cheek (b) (verum group). Mean ± SEM (n=25); AU-arbitrary units

Fig. 6a. Skin tolerability

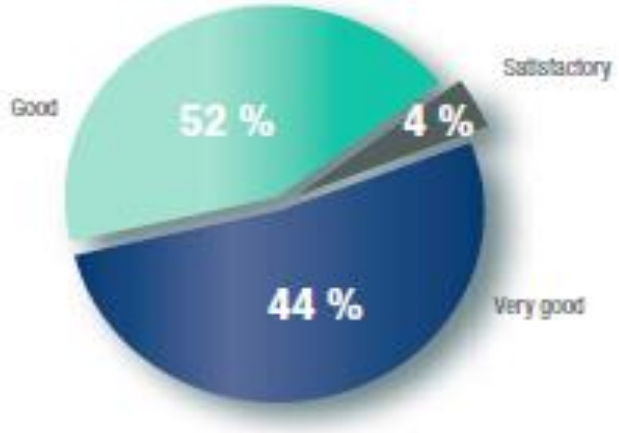
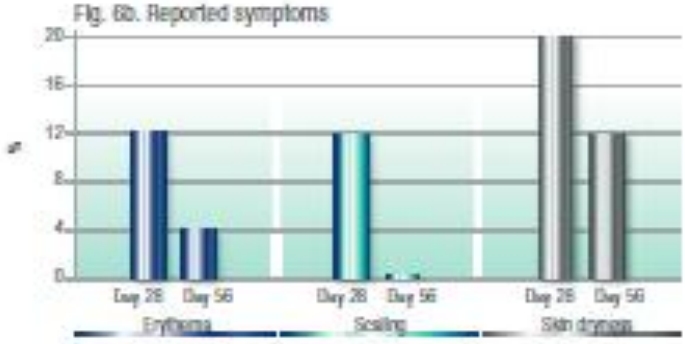


Fig. 6b. Reported symptoms



Compared to the group receiving the vehicle alone, the application of the active ingredient formulation resulted in more pronounced improvement of DLQI at the end of the study (reduction compared to baseline in the verum and vehicle group respectively, -23.1% and -6.4%). The active ingredient formulation was well-tolerated (Fig. 6); the reported subjective symptoms were mild and tended to decrease by the end of the study.

Conclusion

Our results provide evidence for the efficacy of the formulation containing licochalcone A, carnitine and 1,2-decanediol compared to only the vehicle and show that optimized skin care targeting inflammation, enhanced sebum production and *P. acnes* might alone offer benefit in the management of mild to moderately severe inflammatory forms acne.