Efficacy and safety of a cream containing octyl salicylic acid, salicylic acid, linoleic acid, nicotinamide, and piroctone olamine combined with 5% benzoyl peroxide in the treatment of acne vulgaris: a randomized controlled study

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To The Editor: Acne vulgaris is a chronic inflammatory skin disease involving the sebaceous glands. It has an incidence of approximately 9.4%, often occurring in adolescents.[1] The disease itself and the scars left after treatment can cause psychological stress in adolescents and seriously affect patients' quality of life.[2] At present, skin care products, either alone or in combination with medical drugs, have become important means for treating acne. This single-center, single-blind (clinician-blind), masculine-paralleled, randomized study (Registration number: ChiCTR2100051398) evaluated the efficacy and safety of a cream containing octyl salicylic acid, salicylic acid, linoleic acid, nicotinamide, and piroctone olamine (Duo+, La Roche-Posay, Paris, France) alone and in combination with benzoyl peroxide (BPO, Galderma, Paris, France) for the treatment of mild-to-moderate acne. The research was approved by the Ethics Committee of Shanghai Skin Disease Hospital, China (No. 2020-13 ke). All participants provided written informed consent.

Patients diagnosed with mild and moderate acne ranging in age from 18 to 35 years were recruited. In total, 67 patients were randomized into three groups: group A, treatment with Duo+; group B, treatment with Duo+ combined with BPO; and group C, treated with BPO (details of inclusion and exclusion criteria, blinding and randomization were described in Supplementary file 1, http://links.lww.com/CM9/B89). For the regimens, Duo+ was used twice a day, and BPO was used once per night. In group B, Duo+ was used 30 min before BPO. All patients used cleansing products (La Roche-Posay acne clearing cleansing gel), and they were followed up at baseline and on days 7, 14, 28, and day 56. A 3 cm × 3 cm area of facial skin with acne lesions was selected for analysis. Transepidermal water loss (TEWL), the erythema index (E), and the melanin index (M) were measured using Multi Probe Adapter 10 (Courage & Khazaka, Cologne, Germany). Repeated-measured analysis of variance was used to analyze continuous variables. The χ^2 test was used to compare qualitative variables. All data were analyzed using SPSS 21.0 software (IBM Corp., Armonk, NY, USA), and $P < 0.05$ was considered statistically significant.

We included 64 participants with an average age of 27.0 ± 4.1 years (7 men and 57 women) in the analysis. According to the different lesion patterns, we analyzed comedones and inflammatory papules (Supplementary Figure 1, http://links.lww.com/CM9/B90). There was no difference in the numbers of comedones and inflammatory papules among the three groups at baseline. Overall, the number of comedones in all groups displayed gradual decreases, with the fastest decline observed in group B on day 7. From day 28, patients in groups A and B exhibited better clearance of comedones than those in group C. There was no significant difference in terms of the comedo reduction between groups A and B until the last visit. In terms of inflammatory papules, the number tended to decrease gradually in all groups. The inflammatory papules in group A were significantly shrunken by day 28, whereas significant shrinkage was detected on day 14 in groups B and C. In terms of skin lesion clearance, group A had the slowest rate. We detected a difference versus baseline on day 14 in group A, versus day 7 in groups B and C. In addition, group A had a lower skin lesion clearance rate than groups B and C, and group B had the fastest skin lesion clearance rate. On day 56, the skin lesion clearance rate was satisfactory in all three groups,

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with group B having the highest rate. In terms of TEWL, no difference was observed in group A, whereas slight increases were detected in groups B and C that returned to normal in the second month. Concerning M, there were no differences among the treatment groups or time periods ($P = 0.72$ and $P = 0.81$, respectively). Regarding E, a gradual decline was noted in group A ($P < 0.05$).

The adverse reactions of the products were mild, mainly appearing within the first week after product use. There were two, four, and two cases of tingling in groups A, B, and C, respectively. Other adverse reactions were mild, including one case of pruritus each in groups B and C, one case of burning in group A, and two cases of burning in group B. In terms of erythema, there was one case each in groups A and B but none in group C, and there was no exudation in any group. By the second week, the adverse reactions had further resolved. At this point, there were no new cases of tingling, erythema, pruritus, and exudation. Only one patient in group C complained of pruritus. By weeks 4 and 8, no adverse reactions were reported.

Topical medication can be used to treat mild and moderate acne, especially inflammatory acne. BPO is a highly lipophilic oxidant that can sterilize and smooth skin. However, BPO can cause slight skin irritation and dry skin. In our study, adverse events were rare. The combined use of cosmetics can help relieve irritation or enhance efficacy.[3,4] This study revealed that after 56 days of treatment, the combination group had the highest rate of skin lesion clearance. In group A, patients had a gradual reduction in the number of comedones throughout the study. However, the decline started from day 14, suggesting that the effective time is at least 2 weeks. Meanwhile, in group A, a decrease in the number of papules was observed after 28 days of treatment. Thus, Duo+ is more effective in treating comedones than inflammatory papules. The use of Duo+ alone was less effective than combined use with BPO. Thus, in treating mild-to-moderate acne, the combined use of Duo + and BPO may be a more effective treatment option than the individual use of either product.

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Conflicts of interest

None.

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