The efficacy and safety of anti-bacterial/anti-inflammatory microneedle patch for the treatment of mild to moderate acne vulgaris: a randomized, double-blind study

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Introduction

Acne is a chronic inflammatory disorder of the pilosebaceous unit. Currently available products including astringents and benzoyl peroxide are minimally effective due to poor drug delivery. This poor drug delivery limits the efficacy of topical agents in spite of their excellent effect. The transdermal microneedle patch has been developed to overcome the stratum corneum barrier function and deliver an active ingredients to the pilosebaceous unit more effectively. In this study, we evaluated anti-inflammatory/anti-bacterial microneedle patches, which enables active ingredients for acne vulgaris to pass through the stratum corneum into the epidermal tissue more effectively and analyzed the efficacy and safety of microneedle patches in the treatment of acne vulgaris.

Materials and methods

This was a randomized, double-blinded, comparative study conducted at a single academic institution. Total 38 patients with mild to moderate acne vulgaris were randomly assigned to either microneedle patch group or controlled group. Microneedle patch group was instructed to attach study products which contain microneedles on the patch for the inflammatory and non-inflammatory papules. On the other hands, controlled group attached patch without microneedles containing the same active ingredients. In both groups, the test products were self-attached everyday to the inflammatory papules before sleep for 2 weeks and removed in the next morning. Final assessment was conducted 1 week and 2 weeks after the end of the treatment period. The number of papules were measured and Investigator Global Assessment score was assessed at each visit.

Table 1. The main ingredients of microneedle patch.

Components	Function
Hyaluronic acid	Microneedle
Aurein	Antimicrobial peptide
Niacinamide	Anti-inflammatory
Tea tree oil	Anti-inflammatory

Figure 1. Attachment skills of microneedle patch.

Results

The study population comprised 24 women (mean age: 25 years) and 14 men (mean age: 24.5 years). No patient was withdrawn because of an adverse event during the study. Accordingly, all patients completed the study period (2 weeks). The number of inflammatory papules showed significant difference between two groups (p value =0.034), especially at week 3.

Figure 2. Change of mean number of inflammatory papules.

The number of non-inflammatory papules were also counted. As in the inflammatory papules, microneedle patch group showed significant reduction in the number of non-inflammatory papules compared to control group at week 3 (p value =0.0408).

Figure 3. Change of mean number of non-inflammatory papules.

Figure 4. Baseline and 3 weeks after last treatment in microneedle patch group.

Figure 5. Baseline and 3 weeks after last treatment in controlled group.

Discussion

This study was conducted to the patients with mild to moderate acne vulgaris to evaluate the efficacy and safety of microneedle patch containing anti-inflammatory and antimicrobial components. Patches were applied to the both inflammatory and non-inflammatory papules on the face during 2 weeks. Effects and safety of study products were evaluated during first 2 weeks of attachment period and subsequent 2 weeks after the last treatment. 14 men and 24 women were included in the study, with mean age of 24.8 years. No patients had a history of systemic diseases or a history of taking medicine which can influence on the study results. The anti-inflammatory/antimicrobial microneedle patch group showed significant reduction rate of the number of both inflammatory and non-inflammatory papules compared to the controlled group. It seems that constant attachment of microneedle patches during first 2 weeks including new-onset acne papules might help consistent decrease in the number of acne papules. Investigator Global Assessment (IGA) score were decreased consistently at each visit in both two groups. Any side effects were reported during the study period such as erythema, burning sensation on the attachment sites.

We expect that microneedle patches can effectively deliver the active ingredients through the stratum corneum and can show effectiveness on the acne papules without any side-effects. This study has several limitations. The study population is small and the follow-up period was not long enough to evaluate long-term efficacy and safety of microneedle patch. Further systemic clinical study with large population and long treatment period is needed for product development.