Journal of the Turkish Academy of Dermatology

Research

An Investigation of Efficacy of Topical Niacinamide for the Treatment of Mild and Moderate Acne Vulgaris

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Published:
J Turk Acad Dermatol 2008; **2 (4)**:jtad82402a
This article is available from: http://www.jtad.org/2008/4/jtad82402a.pdf
Key Words: niacinamide, acne vulgaris, mild and moderate acne, treatment

Abstract

Objective: Niacinamide is a newly-approved anti-acne drug with a potent anti-inflammatory effect. In this study, safety and efficacy of topical 4% niacinamide gel in mild and moderate acne vulgaris was investigated.

Methods: Forty-one patients aged 18-25 (mean: 21.6±2.52) with mild and moderate acne vulgaris seen in dermatology outpatient clinic were enrolled in the study. All patients were treated with niacinamide 4% topical gel (*Vivatinell Acnecinamide* Gel) for eight weeks.

Results: 38 patients among 41 were able to complete the treatment. Decrease in the number of pustules comedones and papules were statistically significant at the end of the treatment compared to onset of treatment ($p<0.05$). Few side effects such as pruritus (n=1) and mild burning (n=3) were observed in very small percentage of patients.

Conclusions: Findings of this study indicate that 4% niacinamide containing gel is effective and safe in alleviating symptoms of mild to moderate acne, with earlier improvement in pustules.

Introduction

Acne, a chronic inflammatory disease of the pilosebaceous units of the face, neck, chest, and back, is the most common skin disorder occurring universally, with an estimated prevalence of 70-87% [1]. It is a pleomorphic disorder characterized by both non-inflammatory (comedones) and inflammatory (papules, pustules, nodules) lesions. Grading of acne is mandatory to determine the appropriate therapeutic strategy. Effective treatment can dramatically improve a person's quality of life [2].

The role of *Propionibacterium acnes* (*P. acnes*) in inflammatory acne is almost universally accepted [3]. Systemic antibiotics have been used for several years to reduce the population of *P. acnes*. During the last decade topical antibiotics have become more acceptable for treating inflammatory acne vulgaris because they have fewer side effects and interactions than oral antibiotics. But wide spread use of these agents is becoming increasingly associated with the emergence of resistant pathogens raising concerns about microorganism resistance and highlighting the need for alternative non-antimicrobial agents for the treatment of acne [4].

These findings indicate the need to develop strategies to minimize the use of antibiotics in acne therapy [5].

Table 1. Comparison of the Effect of Treatment Between Succeeding Months

Lesions	Groups Compared		
	0-1 Months z (p)	0-1 Months z (p)	(0-1 Months z (p)
Comedone	1.489 (0.137)	0.631 (0.528)	z:-2.041 p:0.041*
Papule	1.883 (0.060)	1.855 (0.064)	z:-2.575 p:0.010*
Pustule	z:-2.514 p:0.012*	z:3.025 p:0.002*	z:-4.044 p:0.000*

*: $p < 0.05$

Niacinamide is a newly-approved anti-acne drug with a potent anti-inflammatory effect. Reduction of inflammation is a major mechanism of anti-acne treatment. More recent studies have noted that topical niacinamide is extremely well tolerated by facial skin that this agent provides several beneficial effects in reducing sebum production [6, 7].

In this study, safety and efficacy of topical 4% niacinamide gel in mild and moderate acne vulgaris was investigated.

Materials and Methods

Forty-one patients aged 18-25 (mean: 21.6±2.5) with mild and moderate acne vulgaris seen in dermatology outpatient clinic were enrolled in the study. All patients were treated with niacinamide 4% topical gel (*Vivatinell Acnecinamide* Gel) for eight weeks. Mild acne was defined as the presence of comedones, and papules, moderate acne was defined as the presence of comedones, papules, and few pustules on the face [8]. Local ethical committee approved the study.

None of the patients had received any anti-acne therapy within the last 30 days and none of the married female patients received any oral contraceptive or were pregnant.

The efficacy of the drug was evaluated at two times in a every month by counting the acne lesions. The criterion for effectiveness of the treatment was the reduction of the number of lesions, at the end of eight weeks. Dermatological evaluation after the treatment was as follows:

0: ineffective,
1: mild healing,
2: moderate healing,
3: prominent healing,
4: complete healing.

The satisfaction of the patients from the treatment was classified as follows:

0: not satisfied,
1: mildly satisfied,
2: moderately satisfied,
3: quite satisfied,
4: very satisfied.

All the side effects during treatment period were noted at each follow up examination.

Statistical Analysis

Comparison between pre and post treatment groups on continuous variables were conducted using *Wilcoxon* Signed Rank test. The significance level was set to 0.05. SPSS 15.0 evaluation version was used for statistical analysis.

Results

There were 33 female and eight male, totally 41 patients in our study. Among these patients 11 had mild and 30 had moderate degree of acne. The average ages of patients were 21.6+2.52 (between 15-25 years) and the disease duration was 48.37+37.47 months (between 1-120 months).

38 patients among 41 were able to complete the treatment. One patient was missed during treatment period and two other gave up using the drug as they thought that treatment is ineffective before the treatment period ended.

After the treatment three patients declared that they were not satisfied by the treatment; five said they are mildly satisfied; 14 said they are moderately satisfied; 11 said they are quite satisfied and five said they are very satisfied. After the evaluation of the treatment by dermatologist, treatment was found to be ineffective in two patients; there were mild improvement in 10 patients; moderate healing in 12 patients; prominent healing in nine patients and complete healing in five patients. The patients satisfied by the treatment said that treatment dried their skin and the newly erupting lesions healed more quickly. Unsatisfied patients

said that the treatment did not stop the eruption of new acnes.

Decrease in the number of pustules, comedones and papules was statistically significant at the end of the treatment compared to onset of treatment ($p<0.05$). However only the decrease in the number of pustules were statistically significant both in the first and second month of treatment compared to previous measures ($p<0.05$) (**Table 1**).

Few side effects such as pruritus (n=1) and mild burning (n=3) were observed. And none of these side effects were severe enough to necessitate withdraw of therapy.

Discussion

Niacinamide, is the pyridine-3-carboxylic acid amide form of niacin, a component of the vitamin B complex [**7**].

Niacinamide is beneficial because it results in the increased synthesis of proteins and keratin, stimulation of ceramide synthesis and acceleration of the differentiation of keratinocytes. These factors provide a stabilizing influence on epidermal barrier function and an improvement in the moisture content of the horny layer. On ageing skin, niacinamide improves the surface structure of the skin, shows a wrinkle-smoothing effect and has an inhibitory effect on photocarcinogenesis [**9**].

There are reports of topical niacinamide providing beneficial effects on reduction in acne severity. Topical niacinamide has marked anti-inflammatory properties [**10**]. Anti-inflammatory action affecting neutrophil chemotaxis has been reported for niacinamide. Niacinamide has been proved to inhibit histamine release and to suppress the lymphocyte transformation test. Additionally niacinamide has been shown to suppress cytokine-mediated induction of nitric oxide synthase in a number of cells, resulting in decreased inflammation [**11**]. *Draelos* et al showed that topical niacinamide is effective in lowering sebum excretion rate in facial skin [**7**].

Findings of this study indicate that 4% niacinamide containing gel is effective and safe in alleviating symptoms of mild to moderate acne, with earlier improvement in pustules.

There are few studies investigating effect of topical niacinamide on acne treatment [**8, 12**]. *Dos* et al, reported that clindamycin phosphate 1% and niacinamide gel 4% are equally and highly effective in the treatment of moderate acne either alone or combination [**8**].

A double-blind study was done by *Shalita* et al with topical niacinamide gel and topical clindamycin in the treatment of moderate acne. Seventy-six patients were randomly assigned to apply either niacinamide gel 4 % or clindamycin phosphate 1 % twice daily for 8 weeks. Both treatments produced a statistically similar reduction in the number of acne lesions and their severity[12]. They found an anti-inflammatory effect which could be clinically established by the reduction of inflammatory papules. In total, 82 % of those treated showed an improvement in only 68% of cases.

In another study *Sardesai* et al. compared of efficacy of topical clindamycin and niacinamide combination with plain clindamycin for the treatment of acne vulgaris and acne resistant to topical antibiotics. In contrast to our findings they showed that addition of niacinamide to clindamycin was of no added advantage [**13**].

Lack of control group is one of the limitations of this study. Another limitation of this study was that only 38 patient completed the treatment period. Larger samples could be more beneficial to explore the efficacy and safety of topical niacinamide in patients with acne.

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