Original Research Article

Efficacy of 0.1% adapalene gel in reducing sebum secretion in patients with mild to moderate acne vulgaris

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Abstract

Background: Acne vulgaris is a chronic skin disease characterized by comedones, papules, and pustules. Adapalene treatment is found to beto be safe and effective in treating acne vulgaris, reducing inflammatory and noninflammatory lesions. **Aim:** To evaluate the efficacy of 0.1% Adapalene gel in reducing sebum secretion in patients with mild to moderate acne vulgaris. **Material and Methods:** A total of 50 patients were given topical 0.1% Adapalene gel on an intent-to-elicit its effect on SER in relation to reduction in lesions in mild to moderate acne. Forty of these completed treatment as per protocol (6-weeks period). Facial sebum secretions were measured using a Sebumeter.® Five different facial sites were selected-forehead (mid glabella), nose (the tip), right and left cheek (the most prominent area of both zygomata and chin (the mental prominence). **Results:** Mild acne (Grade I) was seen in 22.5%, moderate acne (Grade II) in 42.5% and moderately severe acne (Grade III) in 27.5%.Of the 40 patients who completed 6 weeks of therapy, 90% showed a global improvement in their acne from baseline. About 19 patients (47.5%) showed excellent and another 15 (37.5%) showed a good improvement. Lesions showed poor response in only 4 patients (3%). Average sebum excretion rate of T- Zone at baseline was 91.34±43.26, whereas after 6-weeks treatment it was 82.68±40.50. **Conclusion:** Treatment with 0.1% Adapalenegel did not show significant decrease in MFSE, even though it significantly reduced acne lesions. This suggestive of other important factors playing vital role in comedogenesis.

Key Word: Acne vulgaris, 0.1% Adapalene gel, mean facial sebum excretion, improvement

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Received Date: 23/07/2018 Revised Date: 08/08/2018 Accepted Date: 10/09/2018
DOI: https://doi.org/10.26611/1021734

Access this article online	
Quick Response Code:	Website: www.medpulse.in
	Accessed Date: 14 September 2018

INTRODUCTION

Acne vulgaris is a chronic, inflammatory disease of the pilosebaceousgland that generally affects seborrhoeic areas like face, back, and chest. The disease is characterized by the formation of open and closed comedones (noninflammatory lesions), papules, pustules, and nodulocystic lesions (inflammatory lesions).[1]In majority of the patients, topical preparations constitute the sole treatment and are a part of therapeutic regimen in almost all patients. Adapalene is a synthetic naphthoic acid derivative with retinoid activity. Adapaleneonce penetrated the stratum corneum, absorbs very slowly in percutaneous layer, and becomes entrapped in the epidermis and hair follicle, which are targeted areas.[2]Adapalene treatment is found to be a good choice for topical treatment of acne vulgaris with less side effects and high efficacy.[3,4] The present study was carried out to evaluate the efficacy of 0.1% Adapalene gel in reducing sebum secretion in patients with mild to moderate acne vulgaris.

How to cite this article: Ajay Govindrao Ovhal, Jerajani H R, Dhurat R S. Efficacy of 0.1% adapalene gel in reducing sebum secretion in patients with mild to moderate acne vulgaris. *MedPulse International Journal of Medicine.* September 2018; 7(3): 81-84. https://www.medpulse.in/Medicine/

MATERIAL AND METHODS

This prospective clinical study was conducted over a period of 6 weeks.A total of 100 individuals 60 patients (Study group) and 40 (Control group) were enrolled. Control group involved the age matched normal healthy subjects. As it is difficult to find individual who never had experienced an acne lesion, we included controls, who never had more than 5 acne lesions, together at any point of time and no visible acne at the time of measurement.

Inclusion Criteria

- Individuals between age group of 13 to 30 years
- Both sexes
- Fresh, untreated patients with acne vulgaris.

Exclusion criteria

- Patients who have received topical acne treatment within previous 2 weeks
- Patients who have received oral antibiotics or systemic or topical anti-inflammatory drugs within the previous 4 weeks, or oral isotretinoin within previous 6 months
- Pregnant, nursing mothers
- Females in reproductive age group not ready to use birth control.
- History of hypersensitivity to topical retinoids.

Measurement of sebum secretion

Facial sebum secretions were measured using a Sebumeter® (SM 810; C-K Electronics, Cologne, Germany) work on the principle of grease-spot photometry. Five different facial sites were selected- forehead (mid glabella), nose (the tip), right and left cheek (the most prominent area of both zygomata and chin (the mental prominence).

Figure 1

Figure 2

Figure 3

Figure1: Sebumeter with cassett; **Figure2:** Measuring head of cassette with its special tape; **Figure 3:** Collection of sebum by constant pressure for 30s

Sebum was collected from each site on a plastic strip using a constant pressure for 30s (Fig. 3). Participants were asked not to use any cosmetics and not to wash face within two hrs of measurement. Amounts of sebum secretion were recorded and mean facial sebum excretion (MFSE) was calculated. Measurement areas were classified as follows: high sebum secreting zone (T- zone; forehead, nose and chin) and low sebum secreting zone (U- zone; both cheeks). All procedures were performed by same investigator in a room at constant temperature (22-25^{0}C). Out of60 patients with acne, 40 consented for follow up after 6 weeks. Measurements of sebum secretion were performed in them at baseline and after 6 weeks of treatment with 0.1% Adapalene gel. The patient facial skin types were determined using the sebum secretion guidelines supplied with the sebumeter. However, because these guidelines list reference values for individual measurement sites only, they could not be used directly for determining the skin types of the T-Zone, the U- Zone or the whole face (MFSE). Thus, we obtained new sebum secretion reference values for these areas by calculating the mean value for each location (Table 1).

Table 1: Reference values for the evaluation of facial skin types by sebum secretion measured with the Sebumeter® (µg cm^{-2}) (control group)

Skin type	Whole face (MFSE)	T zone	U zone
Dry	<25	<32	<13
Normal	25-82	32-98	13-68
Oily	>82	>98	>68

MFSE = mean facial sebum excretion.

The reference values were calculated by the following equations using regional reference values for sebum secretion suggested by the manufacturers:

1. Whole face = [sum of reference values for the forehead, nose, chin and both cheeks]/5;
2. T-zone = [sum of reference values for the forehead, nose and chin]/3;
3. U-zone = [sum of reference values for both cheeks]/2.

Statistical analysis

Comparisons between patients and controls with respect to amounts of sebum secreted and of acne lesion counts for oily and normal skin types were done using Student's t-test. The strength of the association between sebum secretion and acne lesion number was evaluated using Pearson's correlation coefficients. The effect of 0.1% Adapalene gel on acne and sebum excretion was also done using Student's t-test. P<0.05 was considered to be statistically significant.

RESULTS

Sixty patients with acne (35 males, 25 females) and 39 controls (25 males, 15 females) were enrolled in the study. The mean age of the control group was 20.03 years and that of the acne patient group was 20.34 years, which was statistically similar (P > 0.05). A total of 50 patients were given topical 0.1% Adapalene gel on an intent-to-elicit its effect on SER in relation to reduction in lesions in mild to moderate acne. Forty of these completed treatment as per protocol (6-weeks period). Mild acne (Grade I) was seen in 22.5%, moderate acne (Grade II) in 42.5% and moderately severe acne (Grade III) in 27.5%. Of the 40 patients who completed 6 weeks of therapy, 90% showed a global improvement in their acne (excellent, good, fair improvement) from baseline. About 19 patients (47.5%) showed excellent and another 15 (37.5%) showed a good improvement. There was fair improvement in 2 (5%) patients. Lesions showed poor response in only 4 patients (3%). Average sebum excretion rate of T- Zone at baseline was 91.34±43.26, whereas after 6-weeks treatment it was 82.68±40.50, which was not statistically significant (P>0.05) (Table 1).

Table 1: Changes in lesions and average SER in T- zone on treatment with 0.1% Adapalene gel

Duration	Total Non Inflammatory lesions	Total Inflammatory lesions	Average sebum excretion rate(T- zone)
Baseline	19.68± 10.27	10.1±7.6	91.34±43.26
6 weeks	8.53±6.2*	1.05±1.5*	82.68±40.50
***P* value**	< 0.05	< 0.05	> 0.05

Similarly, averagesebum excretion rate of U-Zone at baseline was 61.4±49.25 and after 6-weeks of treatment was 54.76±38.11, which is statistically not significant (P>0.05) (Table 2).

Table 2: Changes in lesions and average SER in U- zone on treatment with 0.1% Adapalene gel

Duration	Total Non-Inflammatory lesions	Total Inflammatory lesions	Average sebum excretion rate(U- zone)
Baseline	22.27± 17.98	14.8±10.47	61.4±49.25
6 weeks	11.25±11.24*	1.83±2.64*	54.76±38.11
***P* value**	< 0.05	< 0.05	> 0.05

Significant reduction in inflammatory and non-inflammatory acne lesions was noted with topical therapy. But similar reduction in SER sebum secretion rate was not observed at T and U zone. In the 40 subjects, total of 42 adverse events were reported. The most common ones were post-inflammatory hyperpigmentation (40%), redness (17.5%), itching (17.5%), irritation (12.5%) and dryness (12.5%). All the adverse events were mild to moderate in severity did not interfere with completion of treatment.

DISCUSSION

A correlation between the severity of acne and facial sebum secretion is generally accepted[5,6] but previous studies have failed to consider topographical variations in facial sebum secretion. Facial areas can be categorized as T- and U-zones (high and low sebum secreting areas, respectively) on the basis of sebum secretion levels[7,8] In this study, we measured sebum secretion at five locations on the face to consider regional variations in sebum secretion. In addition, our study involves single observer which reduces the error. However, our study has its limitations. The Sebumeter® was used as a measuring tool, and its measurement area is limited to skin contacting the unit's cassette probe. However, the areas in which lesions were counted were larger than this sebum measuring area, and thus there is a possibility of a disparity between the lesion count area and the sebum measuring area. Our study with 0.1% Adapalene gel did not show significant decrease in MFSE, even though it significantly reduced acne lesions. This study explains the variable results in different regions. We have performed this study in men and women, and is helpful in understanding different sebum secretion patterns in men and women. Thus, there may be a different association between sebum secretion and acne lesion development in men. Also this is the study involving largest sample size and reliable methods involved than previous reported studies. Percy SH[9] found in their study that at the end of therapy, 96.3% of patients showed an improvement in their acne from baseline, with greater than 75% improvement seen in two-thirds of patients. Adverse events were reported in 24% of the patients, none of which were serious. They concluded that Adapalene gel 0.1% is a safe and effective topical agent in the treatment of mild to moderate acne vulgaris in Indian patients. Cunliffe *et al*[10] conducted a meta-analysis of five large studies with more than 900 patients over 12 weeks demonstrated that adapalene 0.1% gel is as effective as tretinoin 0.025% gel. After 12 weeks, both agents were equally effective but adapalene had a faster onset of action and less irritation. Grosshans *et al*[11] compared 0.1% adapalene and 0.025% tretinoin on 105 patients for

3 months and Ellis *et al*[12]compared 0.1% adapalene and 0.025% tretinoin on 297 patients for 3 months. In both of these studies, there was no difference between these drugs in terms of efficacy. In another study, Cunliffe *et al*[3]compared 0.1% adapalene and 0.025% tretinoin on 323 patients for 3 months. They found that adapalene caused more decrease in total and noninflammatory lesions than tretinoin. However, there was no significant difference in terms of inflammatory lesions. Korkut and Piskin[13] demonstrated that adapalane is more effective in noninflammatory lesions than inflammatory lesions. In conclusion, 0.1% Adapalene treatment did not show significant decrease in MFSE, even though it significantly reduced acne lesions. This suggestive of other important factors playing vital role in comedogenesis.

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Source of Support: None Declared
Conflict of Interest: None Declared