

## Original Article

# Topical adapalene cream 0.1% v/s isotretinoin 0.05% in the treatment of acne vulgaris: a randomized open-label clinical trial

Iftikhar Ahmed, Muhammad Sarwar

Department of Biochemistry, Baqai Medical University, Karachi.

**Abstract** *Background* Acne is a common problem in adolescents and young adults. The disease and its associated problems with self-esteem and social inhibition represent a figurative "rite of passage" for as many as 80 percent of adolescents and young adults. Topical retinoids such as tretinoin, isotretinoin or adapalene are effective in many patients with comedonal acne.

*Objective* To compare the efficacy and tolerability of adapalene cream 0.1% and isotretinoin gel 0.05% in the treatment of acne vulgaris of the face.

*Patients and methods* This randomized open-label clinical trial was conducted at Baqai Medical University (BMU) and Skin Cure Centre (SCC), Karachi. 80 subjects were inducted in the study and were divided in two groups comprising of forty each in a group. First group was treated with adapalene cream 0.1% and the second one was treated with isotretinoin gel 0.05% for six weeks.

*Results* Both adapalene and isotretinoin demonstrated comparable efficacy. However, significantly lower skin irritation was noted with adapalene.

*Conclusion* Adapalene is an effective and safe treatment of acne vulgaris. However it causes less irritation than isotretinoin.

### *Key words*

Acne vulgaris, adapalene, isotretinoin.

## Introduction

Acne is a common problem in adolescents and young adults. The disorder is caused by abnormal desquamation of follicular epithelium that results in the obstruction of the pilosebaceous canal. This obstruction leads to the formation of comedones, which can become

inflamed because of overgrowth of *Propionibacterium acnes*.<sup>1,2</sup> Acne and its associated problems with self-esteem and social inhibition represent a figurative "rite of passage" for as many as 80 percent of adolescents and young adults.<sup>3</sup>

Obstruction of the pilosebaceous canal is the primary event in acne and occurs because of a variety of factors. Sebum overproduction stimulated by hypersensitivity of sebaceous glands to androgenic steroids coupled with increased epithelial cell turnover leads to formation of microcomedones, which can

---

### Address for correspondence

Dr. Iftikhar Ahmed,  
Department of Biochemistry,  
Baqai University of Medical Science,  
Karachi.  
Ph# +92 322 2047929  
Email: dr\_iftikharahmed@yahoo.com

progress to open comedones, commonly termed "blackheads," or to closed comedones, often called "whiteheads".<sup>3</sup> This leads to growth of *Propionibacterium acnes*, the principal organism in inflammatory acne lesions. Proliferation of *P. acnes* converts sebum triglycerides to free fatty acids, which are irritating and stimulate the immune response, leading to the development of inflammatory lesions.<sup>2,3</sup>

Acne is usually diagnosed by the patient. The physician needs to determine if the condition is noninflammatory (open and closed comedones), inflammatory (papules or pustules) or a mixture of both (the most common situation). Topical treatment is sufficient in most patients with acne, but systemic therapy is required in patients who have acne nodules and cysts.<sup>4</sup> Topical retinoids such as tretinoin, isotretinoin, or adapalene are effective in many patients with comedonal acne. Patients with inflammatory lesions benefit from treatment with benzyl peroxide, azelaic acid or topical antibiotics.<sup>4</sup> Frequently, the use of comedonal and antibacterial agents is required.

Adapalene is a topical retinoid derived from naphthoic acid with a selective effect on the epidermis. It is indicated for treatment of acne vulgaris, alone or with other antiacneic topicals. It displays comedolytic and anti-inflammatory activities. The only frequent adverse event is a mild skin irritation during the first two weeks of treatment.<sup>4</sup>

The present study was undertaken to compare the efficacy and tolerability of adapalene cream 0.1% and isotretinoin gel 0.05% in the treatment of acne vulgaris of the face.

### Patients and methods

The study was conducted at Baqai Medical

University (BMU) and Skin Cure Centre (SCC), Karachi. After the approval from ethical committee of BMU and SSC, eighty patients of mild to moderate acne irrespective of age, sex and social status were enrolled. Cigarette smokers, alcoholics, pregnant or lactating females and patients having any systemic illness or using any systemic therapy were excluded.

After an informed consent, a detailed history was taken and scrupulous physical examination was performed in each patient. Patients were randomized into two groups A and B. Patients in group A applied adapalene cream 0.1% and group B used isotretinoin gel 0.05% once daily at night for 6 weeks. Quantity of cream or gel remained the same i.e. equivalent to size of half a pea.

All patients were clinically diagnosed. Efficacy variables included noninflammatory and inflammatory lesions and total lesion counts; global grade; and global assessment of improvement in acne severity. Skin tolerability variables included erythema, desquamation (scaling), dryness, pruritus, and stinging/burning.

### Results

Forty patients were treated with adapalene cream 0.1% and 40 patients were treated with isotretinoin gel 0.05%. **Table 1** shows gender distribution and age of the participants. The mean age in group A was 25 years $\pm$ 2.39 years while that in group B was 23 $\pm$ 2.56 years.

The table also compares the noninflammatory and inflammatory lesions and cutaneous irritations in terms of assessing erythema, scaling and burning with pruritus were assessed before and after the treatment in the two groups.

**Table 1** Demographic and disease characteristics in two groups

	Group A	Group B
Age (years)	25 ± 2.39	23 ± 2.56
Male	13	15
Females	27	25
<i>Before treatment</i>		
Non-inflammatory lesions	22	26
Inflammatory lesions	18	14
Erythema	8	6
Scaling	5	7
Burning	12	8
Pruritus	16	12
<i>After treatment</i>		
Non-inflammatory lesions	7	11
Inflammatory lesions	4	7
Erythema	5	9
Scaling	3	6
Burning	12	19
Pruritus	14	22

In group A, 22 had noninflammatory lesions that were only papular or white and blackheads. 15 showed a significant improvement after treatment with adapalene. Similarly, 18 patients were suffering from inflammatory lesions i.e. pustular and/or nodulocystic acne and improvement occurred in 14 after treatment. In group B, 26 subjects had noninflammatory lesions and 15 of these showed substantive improvement after therapy with isotretinoin. Inflammatory lesions were present in 14 patients and 7 of these improved. The results showed significant improvement in individual groups but the comparative efficacy was similar in both groups.

Comparing the tolerability of treatments, although statistically insignificant, a higher number of patients treated with isotretinoin had erythema, scaling, burning and pruritus as compared to those with adapalene.

## Discussion

The above mentioned results indicate that both adapalene cream 0.1% and isotretinoin gel 0.05% are effective in treating acne of mild to moderate severity. However, adapalene produced less stinging/blazing than isotretinoin. Our results are in accordance with that by previous studies by Ionnides *et al.*<sup>5</sup> (adapalene cream 0.1% vs. isotretinoin gel 0.05%), Thiboutot *et al.*<sup>6</sup> (adapalene cream 0.1% vs. tretinoin microsphere gel 0.1%), Cunliffe *et al.*<sup>7</sup> (adapalene gel 0.1% vs. tretinoin cream 0.05%) and Egan *et al.*<sup>8</sup> (adapalene gel 0.01% vs. tretinoin microsphere gel 0.1%). All these studies demonstrated the efficacy of adapalene cream/gel 0.1% in comparison with other topical retinoids in different formulations, the standard treatment in noninflammatory acne. However, it is suggested that different topical retinoids may differ in their affinity profile for nuclear and cytosolic retinoic acid receptors.

Considering the safety and tolerability, like in all the aforementioned studies,<sup>5-8</sup> this causes less irritation as compared to tretinoin and isotretinoin hence improving patient's compliance, an important factor in treatment success. Adapalene is, therefore, assured of a role in the first-line treatment of acne vulgaris.

Our study also augments the data that adapalene can be used alone in mild acne or in inflammatory acne and has proved efficacious as maintenance treatment.

## Conclusions

Adapalene is an effective addition to the anti-acne armamentarium of dermatologist with relatively high safety and tolerability profile.

## **Acknowledgment**

Thanks to the PharmaHealth Pakistan (Pvt) Ltd. Lahore, Pakistan for their extended cooperation for providing all the required facilities to conduct the study.

## **References**

1. Russell JJ. Topical therapy for acne. *Am Fam Physician* 2000; **61**: 357-66. Toyoda M, Morohashi M. Pathogenesis of acne. *Med Electron Microsc* 2001; **34**: 29-40.
2. Halder RM, Richards GM. Topical agents used in the management of hyperpigmentation. *Skin Therapy Lett* 2004; **9**: 1-3.
3. Haider A, Shaw JC. Treatment of acne vulgaris. *JAMA* 2004; **292**: 726-35.
4. Waugh J, Noble S, Scott LJ. Adapalene: a review of its use in the treatment of acne vulgaris. *Drugs* 2004; **64**: 1465-78.
5. Ioannides D, Rigopoulos D, Katsambas A. Topical adapalene gel 0.1% vs. isotretinoin gel 0.05% in the treatment of acne vulgaris: a randomized open-label clinical trial. *Br J Dermatol* 2002; **147**: 523-7.
6. Thiboutot D, Gold MH, Jarratt MT *et al.* Randomized controlled trial of the tolerability, safety, and efficacy of adapalene gel 0.1% and tretinoin microsphere gel 0.1% for the treatment of acne vulgaris. *Cutis* 2001; **68** (4 Suppl): 10-9.
7. Cunliffe WJ, Danby FW, Dunlap F *et al.* Randomised, controlled trial of the efficacy and safety of adapalene gel 0.1% and tretinoin cream 0.05% in patients with acne vulgaris. *Eur J Dermatol* 2002; **12**: 350-4.
8. Egan N, Loesche MC, Baker MM. Randomized, controlled, bilateral (split face) comparison trial of the tolerability and patient preference of adapalene gel 0.1% and tretinoin microsphere gel 0.1% for the treatment of acne vulgaris. *Cutis* 2001; **68** (4 Suppl): 20-4.

**You can email your manuscripts to [drijazhussain@gmail.com](mailto:drijazhussain@gmail.com)**