A Comparative Study of Efficacy of once Daily 0.1% Tazarotene and Adapalene Gel for the Treatment of Facial Acne Vulgaris

Mukunda Ranga Swaroop

Associate Professor, Adichunchanagiri Institute of Medical Sciences, Mandya, Karnataka
Email: mrswaroop79@gmail.com

ABSTRACT

Background: *Acne is a self-limiting chronic inflammatory disorder of pilo- sebaceous follicles seen among young adults with significant psychological and social impact. Tretinoin which was widely used for many years is being replaced gradually by newer generation agents like Tazarotene and Adapalene which unlike Tretinoin are specific for a subset of retinoic acid receptors.*

Objectives: *To compare the efficacy of once daily topical 0.1% Tazarotene and Adapalene gel in the treatment of mild to moderate facial acne vulgaris.*

Method: *A total number of 60 patients with mild to moderate facial acne vulgaris attending out-patient department of Dermatology, Venereology and Leprosy from Oct.2004 – April. 2006 were studied. Patients were allocated alternately to group A and group B. Group A received 0.1% Tazarotene gel and group B patients received 0.1% Adapalene gel and were advised to apply topically once daily in the evening. Patients were followed up on 4th, 8th and 12th week.*

Results: *At the 4thweek of post treatment evaluation, the non-inflammatory lesions (comedones) responded early to Tazarotene 0.1% gel than to Adapalene 0.1% gel. At the end of 12th week treatment period, Tazarotene 0.1% gel had an overall superiority to Adapalene 0.1% gel as an antiacne agent.*

Conclusion: *The results of the study show that Tazarotene 0.1% gel is a better anticomedogenic agent with rapid rate of clinical improvement when compared with Adapalene 0.1% gel.*

Key Words: *Acne vulgaris; Tazarotene 0.1% gel; Adapalene 0.1% gel, once daily, Mild to moderate acne*

INTRODUCTION

Acne is a chronic inflammatory disease of the pilo-sebaceous units. It is characterized by seborrhoea, formation of come dons, erythematous papules and pustules less frequently by nodules, deep pustules, or pseudocysts and in some cases accompanied by scarring.[1] Acne vulgaris is one of the most common skin diseases in adolescence and adults; affecting more than 85% of adolescents.[2] Acne is a self-limiting chronic inflammatory disorder of pilo-sebaceous follicles seen among young adults with significant psychological and social impact. Close to 100% of people between the ages of twelve and seventeen have at least an occasional white head or black head regardless of race or ethnicity. Acne is one of those skin disorders which cause physical trauma, maladjustment between parent and children, feeling of inferiority, insecurity and thus becoming one of the today's teenager's biggest worries especially in females. Hence, management of acne at the earliest period has become a matter of importance.[3]

Retinoids are the key components of antiacne therapy because of their multiple modes of action. They effectively reduce the come dones and inflammatory lesions. Tretinoin which was widely used for many years is being replaced gradually by newer generation agents like Tazarotene and Adapalene, unlike Tretinoin are specific for a subset of retinoic acid receptors exhibiting lower toxicologic risk and producing fewer side-effects.[4]

Since very few clinical trials based on comparative study of efficacy and tolerability of once daily Tazarotene 0.1% gel and Adapalene 0.1% gel have been performed, this study focuses mainly on efficacy of topical Tazarotene and topical Adapalene so as to determine an effective modality of treatment for facial acne vulgaris.

OBJECTIVES OF THE STUDY

1. To study the efficacy of topical Tazorotene 0.1% gel in the treatment of mild to moderate facial acne vulgaris.
2. To study the efficacy of topical Adapalene 0.1% gel in the treatment of mild to moderate facial acne vulgaris.
3. To compare the efficacy of topical 0.1% Tazarotene and Adapalene gel in the treatment of mild to moderate facial acne vulgaris.

MATERIALS AND METHOD

Source of Data:

This study was conducted in the Out-patient Department of Dermatology, Venereology and Leprosy, Father Muller Medical College Hospital, Mangalore during Oct 2004- April 2006. This was a prospective study.

Method of Collection of Data:

Data was collected from 60 patients with mild to moderate facial acne vulgaris (Grade I and II).

The severity of acne was graded as follows:

Grade I: Come dons, occasional papules (Mild)

Grade II: Papules, come dons, few pustules (Moderate)

Grade III: Predominately pustules, nodules, abscesses (Severe)
Grade IV: Mainly cysts, abscesses, widespread scarring (Cystic)

SELETION CRITERIA:

Inclusion Criteria:

a) Age > 12 years
b) Facial acne vulgaris of mild to moderate severity (not > Grade II)
c) Patients willing to undergo treatment and come for follow up.

Exclusion Criteria:

a) Age < 12 years
b) Facial acne vulgaris of severe type (Grade 2).
c) History of having taken topical medications for acne in the preceding 14 days, oral antibiotics in the preceding 30 days or oral retiniods in the preceding 1 year.
d) Pregnant women and women who intend to become pregnant.
e) Approval was obtained from the ethical committee.

Treatment Regimen:

Patients were allocated alternately to group A and group B. Group A patients received Tazarotene o.1% gel and group B patients received Adapalene 0.1% gel. Patients were advised to apply the gel once daily in the evening, 15 minutes after wash the face with a gentle non-soap cleanser. Base line assessments included age, gender, overall disease severity, non-inflammatory lesion count (come dons) and inflammatory lesion count (papules and pustules). Response to treatment was evaluated at weeks 4, 8 and 12. The efficacy was assessed by lesion counts at each visit. The response to treatment was assessed on scales 0 to 4.

Scale	**Definition**
0-Completely cleared	100% lesion clearance
1- Marked improvement	> 75% lesion clearance
2- Moderate improvement	50-75% lesion clearance
3- Mild improvement	25-50% lesion clearance
4-Insignificant improvement	<25% lesion clearance

Plan for Data Analysis:

The data is analysed for statistical significance of qualitative variables in both groups by Chi-square test and continuous numerical values by student 't' test.

RESULTS

A comparative study of the efficacy of once daily 0.1% Tazarotene and Adapalene gel for the treatment of mild to moderate facial acne vulgaris was conducted from among 60 patients attending the out-patient department of Dermatology, Venereology and Leprosy. Male to female ratio in our study was 1: 1.9 and mean age of the patients were 21.16 years. At the 4th week of post treatment evaluation of non-inflammatory lesions (come dones), 63.3% (19 patients) on Tazarotene 0.1% gel showed 50-75% lesion clearance (Scale 2) compared to only 23.4% (7 patients) on Adapalene 0.1% gel (p=0.002 which was highly significant). In case of inflammatory lesions (papules and pustules), the response to both the topical agents was similar (p=0.659 which was not significant). At the end of 12 week treatment period, the mean count of non-inflammatory lesions (come dones) for Tazarotene 0.1% gel (2.70) was significantly less than that of Adapalene 0.1% gel (4.43) (p=0.050 which was significant)[Table 1], whereas the difference in the mean lesion count of inflammatory lesions (papules and pustules) was statistically not significant (p=0.734)[Table 2]. At the end of 12 week treatment period, 56.7% (17 patients) on Tazarotene 0.1% gel had 100% lesion clearance (scale 0) of non-inflammatory lesions (come dones) compared to only 30% (9 patients) on Adapalene 0.1% gel which was statistically significant (p=0.044)[Fig. 1]. Both the topical agents were effective in completely clearing the inflammatory lesions (papules and pustules) in almost equal manner (p=0.739 which was not significant)[Fig. 2]. Tazarotene 0.1% gel proved to be superior to adapalene 0.1% gel with respect to mean percentage reduction of both non-inflammatory and inflammatory lesion count (91.60% vs 85.10%) which was statistically significant (p=0.048) at the end of treatment period [Fig. 3]. Though certain side effects were noticed like dryness, burning sensation and peeling in both the cases, they were not significant.

Table 1: Comparison of Mean lesion count of non-inflammatory lesions (come dones) between 0.1% Tazarotene and Adapalene gel at each follow up

	Group	**N**	**Mean**	**Std. Deviation**	**Z**
Week 0	TAZAROTENE	30	18.5333	9.06198	1.161
	ADAPALENE	30	21.3000	9.38873	P=0.253 ns
Week 4	TAZAROTENE	30	10.9000	6.58813	2.136
	ADAPALENE	30	15.7000	8.60293	P=0.033 sig
Week 8	TAZAROTENE	30	6.0333	4.58997	2.068
	ADAPALENE	30	9.1333	5.99847	P=0.039 sig
Week 12	TAZAROTENE	30	2.7000	2.90244	2.003
	ADAPALENE	30	4.4333	3.74795	P=0.050 sig

Table 2: Comparison of Mean lesion count of inflammatory lesions (papules and pustules) between 0.1% Tazarotene and Adapalene gel at each follow up

	Group	N	Mean	Std. Deviation	Z
Week 0	TAZAROTENE ADAPALENE	30 30	9.7000 9.2333	8.06076 7.01075	.09900 P=0.921 ns
Week 4	TAZAROTENE ADAPALENE	30 30	5.3667 5.0000	5.48027 4.44119	.16500 P=0.869 ns
Week 8	TAZAROTENE ADAPALENE	30 30	2.2667 3.0667	3.75025 6.03400	.18400 P=0.854 ns
Week 12	TAZAROTENE ADAPALENE	30 30	.8000 .9667	2.18774 2.31164	.34000 P=0.734 ns

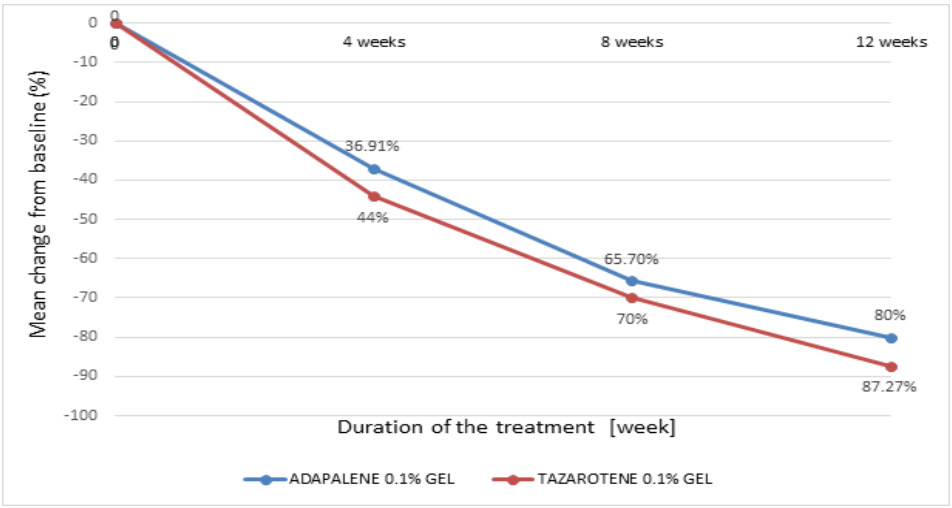

Fig. 1: Mean percentage reduction in non-inflammatory lesion count (come dones) with once daily application of 0.1% Tazarotene and Adapalene gel

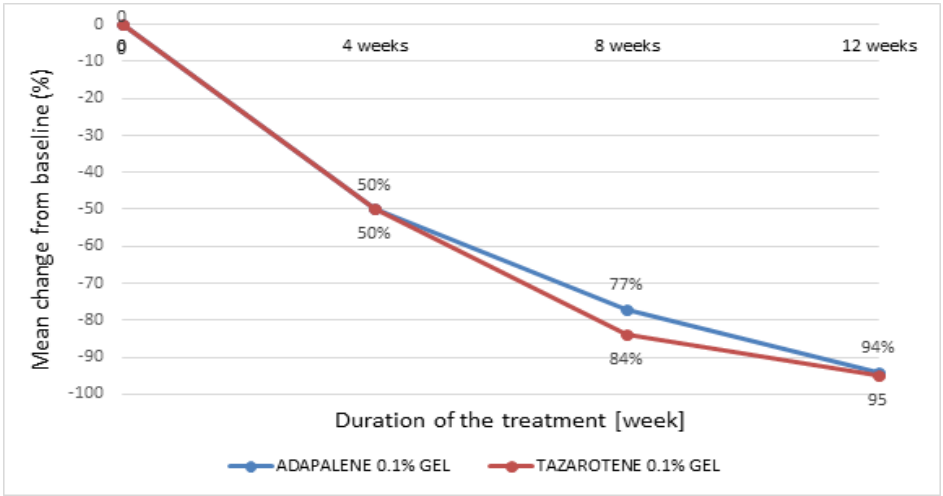

Fig. 2: Mean percentage reduction in inflammatory lesion count (papules and pustules) with once daily application of 0.1% Tazarotene and Adapalene gel

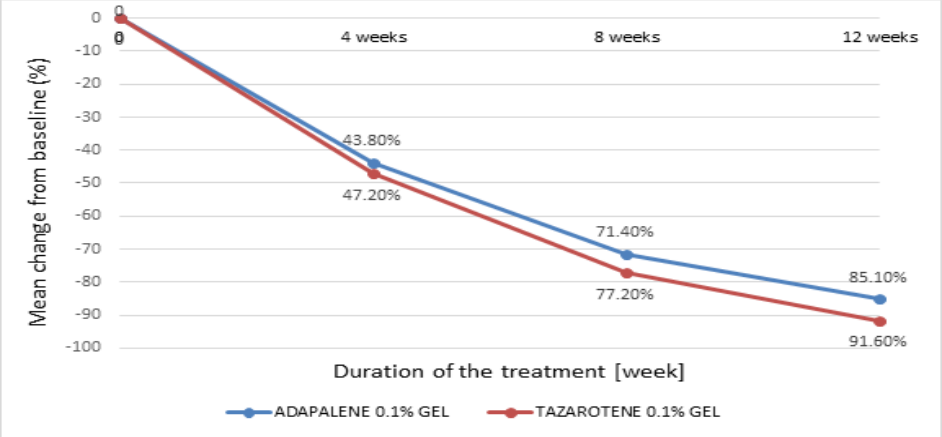

Fig. 3: Mean percentage reduction of both non-inflammatory and inflammatory lesion count with once daily application of 0.1% Tazarotene and Adapalene gel

DISCUSSION

60 patients with mild to moderate facial acne vulgaris attending the Out- patient Department of Dermatology, Venereology and Leprosy, were inducted for the study.

Acne involves young adults with almost equal distribution among both the sexes. In a study conducted by smithard et al.[4] 56% were males, but in our study only 35% were males (M: F=1:1.9). This female preponderance is probably due to the fact that they are more conscious about the acne and seek treatment earlier than males.

Mean age of the patients in our study were 21.16 years which is very similar to age distribution (19 years) seen in study done by Webster et al.[6]

There have been several comparative studies with different antiacne topical therapies belonging to retinoids like Tretinoin, Adapalene and Tazarotene. Review of literature showed a single study by Webster et al.[71] wherein efficiency of 0.1% Tazarotene and Adapalene gel have been compared which is similar to our study.

At 4th, 8th and 12th week of post treatment evaluation of non-inflammatory lesions (comedons), the mean lesion count following application of Tazarotene 0.1% gel was less than that of Adapalene 0.1% gel which was statistically significant (p = 0.033, 0.039 and 0.050 respectively) implying that Tazarotene 0.1% gel is a better anticomedogenic agent. These results were in accordance with the study done by Webster et al.[6] The difference in the mean lesion count between the two topical agents was found to be statistically not significant (p = 0.869, 0.854 and 0.734 respectively) in case of inflammatory lesions (papules and pustules), whereas the study done by Webster et al.[6] showed that Tazarotene 0.1% gel was more efficacious in clearance of inflammatory lesions as well.

At 4th week, 63.3% (19 patients) on Tazarotene 0.1% gel had 50-75% lesion clearance (scale 2) compared to only 23.4% (7 patients) on Adapalene 0.1% gel with respect to non- inflammatory lesions (comedons). This shows that Tazarotene 0.1% gel acts faster than 0.1% Adapalene gel as the difference in improvement was statistically highly significant(p=0.002).

Our results were in accordance with studies done by Webster et al.[6] and Leyden et al.[7] wherein the results had proved that Tazarotene 0.1% gel achieves a more rapid rate of clinical improvement than each of the other retinoids including Adapalene. 50-75% lesions clearance (scale 2) of the inflammatory lesions (papules and pustules) was seen in 53.3% and 50% respectively of the group receiving 0.1% Tazarotene and Adapalene gel which was statistically not significant (p=0.659).

At 8th week, 53.30% (16 patients) on Tazarotene 0.1% gel had > 75% lesion clearance (scale 1) as compared to only 26.7% (8 patients) on Adapalene 0.1% gel with respect to non- inflammatory lesions (p=0.038 which was significant). Inflammatory lesions (papules and pustules) responded equally well to both 0.1% Tazarotene and Adapalene gel (p=0.785 which was not significant).

At the end of 12 week treatment period, 56.7% (17 patients) on Tazarotene 0.1% gel had 100% lesion clearance (scale 0) of non- inflammatory lesion (comedons) compared to only 30% (9 patients) on Adapalene 0.1% gel which was statistically significant (p=0.044) implying that Tazarotene 0.1% gel is a better anticomedogenic agent. Both the topical agents were effective in completely clearing the inflammatory lesions (scale 0) in a similar manner, i.e. 83.3% vs 80% respectively (p=0.739 which was not significant). This is in partial agreement with the study done by Webster et al.[6] in Tazarotene 0.1% gel has been found to be superior to Adapalene 0.1% gel with respect to complete clearance of both non-inflammatory and inflammatory lesions.

At the end of 12 week treatment period, Tazarotene 0.1% gel proved to be superior to Adapalene 0.1% gel with respect to mean percentage reduction of both inflammatory and non-inflammatory lesion count (91.60% vs 85.10%, p= 0.048 which was significant). The results of our study correlates with the study done by Webster et al.[6] indicating that tazarotene 0.1% gel is

a better topical agent in the treatment of inflammatory and non-inflammatory lesions when compared to Adapalene 0.1% gel.

In this study, Tazarotene 0.1% gal was associated with slightly increased levels of burning, peeling and erythema at some point of time than Adapalene 0.1% gel. However, the differences were temporary and resolved with continued treatment.

CONCLUSION

The results of this study show that Tazarotene 0.1% gel is a better anticomedogenic agent with rapid rate of clinical improvement when compared to that of Adapalene 0.1% gel. The efficacy of both the topical agents is similar for inflammatory lesions (papules and pustules). The side effects of both the retinoids were not significant.

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