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A COMPARATIVE STUDY OF EFFICACY OF ONCE DAILY 0.1% TAZAROTENE AND ADAPALENE GEL FOR THE TREATMENT OF FACIAL ACNE VULGARIS

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ABSTRACT

Background: Acne is a chronic inflammatory condition affecting the pilo-sebaceous follicles, primarily observed in young adults, and it carries considerable psychological and social consequences. Tretinoin, which has been extensively utilized over the years, is gradually being supplanted by newer generation treatments such as Tazarotene and Adapalene. Unlike Tretinoin, these newer agents are selective for specific 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 study was conducted involving 60 patients diagnosed with mild to moderate facial acne vulgaris, who visited the outpatient department of Dermatology, Venereology, and Leprosy over a span of two years. The participants were alternately assigned to two groups: Group A and Group B. Group A was treated with 0.1% Tazarotene gel, while Group B received 0.1% Adapalene gel, with instructions to apply the medication topically once daily in the evening. Follow-up assessments were carried out at the 4th, 8th, and 12th weeks. **Results**: During the fourth week of post-treatment assessment, the non-inflammatory lesions (comedones) exhibited a more rapid response to Tazarotene 0.1% gel compared to Adapalene 0.1% gel. By the conclusion of the twelfth week of the treatment period, Tazarotene 0.1% gel demonstrated a clear superiority over Adapalene 0.1% gel in its efficacy as an anti-acne 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 Seborrhea, the development of comedones, and the presence of erythematous papules and pustules, along with less frequent occurrences of nodules, deep pustules, or pseudocysts, may sometimes lead to scarring. Acne vulgaris is among the most prevalent skin conditions affecting both adolescents and adults, impacting over 85% of teenagers.

This chronic inflammatory disorder of the pilo-sebaceous follicles is self-limiting and is commonly observed in young adults, often resulting in significant psychological and social repercussions. Nearly all individuals aged twelve to seventeen experience at least occasional whiteheads or blackheads, irrespective of their racial or ethnic background. Acne can lead to

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physical trauma, strained relationships between parents and children, and feelings of inferiority and insecurity, making it a major concern for many teenagers, particularly females. Consequently, early management of acne has become increasingly important. Retinoids play a crucial role in anti-acne treatment due to their various mechanisms of action. They are effective in diminishing both comedones and inflammatory lesions.

Tretinoin, which has been a standard treatment for many years, is gradually being supplanted by newer agents such as Tazarotene and Adapalene. Unlike Tretinoin, these newer agents are selective for specific retinoic acid receptors, presenting a lower risk of toxicity and fewer side effects. Given the limited number of clinical trials comparing the efficacy and tolerability of once-daily Tazarotene 0.1% gel and Adapalene 0.1% gel, this study primarily aims to evaluate the effectiveness of these topical treatments for facial acne vulgaris.

OBJECTIVES OF THE STUDY

1. To evaluate the effectiveness of topical Tazarotene 0.1% gel in managing mild to moderate facial acne vulgaris.
2. To assess the effectiveness of topical Adapalene 0.1% gel in managing mild to moderate facial acne vulgaris.
3. To compare the effectiveness of topical 0.1% Tazarotene and Adapalene gels in the management 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

Method of Collection of Data:

Data was collected from 60 patients with mild tomoderate 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 forfollow 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 inthe preceding 30 days or oral retiniods in the preceding 1 year.
d) Pregnant women and women who intend tobecome pregnant.
e) Approval was obtained from the ethical committee.

Treatment Regimen

Patients were assigned alternately to either group A or group B. Those in group A received

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Tazarotene 0.1% gel, while patients in group B were administered Adapalene 0.1% gel. Participants were instructed to apply the gel once daily in the evening, specifically 15 minutes after cleansing their face with a gentle non-soap cleanser. Baseline evaluations included age, gender, overall disease severity, the count of non-inflammatory lesions (comedones), and the count of inflammatory lesions (papules and pustules). Treatment response was assessed at weeks 4, 8, and 12, with efficacy determined by lesion counts recorded at each visit. The treatment response was measured using a scale ranging from 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- 4-Insignificant improvement <25% lesion clearance

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 analysis was conducted to evaluate the effectiveness of once-daily 0.1% Tazarotene and Adapalene gel in treating mild to moderate facial acne vulgaris among 60 patients visiting the outpatient department of Dermatology, Venereology, and Leprosy. The male-to-female ratio in this study was 1:1.9, with a mean patient age of 21.16 years. At the four-week post-treatment assessment of non-inflammatory lesions (comedones), 63.3% (19 patients) using Tazarotene 0.1% gel exhibited a 50-75% reduction in lesions (Scale 2), in contrast to only 23.4% (7 patients) on Adapalene 0.1% gel (p=0.002, indicating high significance). For inflammatory lesions (papules and pustules), the response to both topical treatments was comparable (p=0.659, not significant). By the conclusion of the 12-week treatment period, the mean count of non-inflammatory lesions for Tazarotene 0.1% gel (2.70) was significantly lower than that for Adapalene 0.1% gel (4.43) (p=0.050, significant), while the difference in mean counts of inflammatory lesions was not statistically significant (p=0.734). At the end of the 12 weeks, 56.7% (17 patients) using Tazarotene 0.1% gel achieved complete clearance (Scale 0) of non-inflammatory lesions, compared to 30% (9 patients) on Adapalene 0.1% gel, which was statistically significant (p=0.044). Both topical agents demonstrated similar efficacy in completely clearing inflammatory lesions (p=0.739, not significant). Tazarotene 0.1% gel was found to be superior to Adapalene 0.1% gel regarding the mean percentage reduction of both non-inflammatory and inflammatory lesion counts (91.60% vs. 85.10%), which was statistically significant (p=0.048) at the treatment's conclusion. Although some side effects, such as dryness, burning sensation, and peeling, were observed in both treatments, they were not deemed significant.

Plan for Data Analysis:

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 ADAPALENE	30 30	18.5333 21.3000	9.06198 9.38873	1.161 P=0.253 ns

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Week 4	TAZAROTENE ADAPALENE	30 30	10.9000 15.7000	6.58813 8.60293	2.136 P=0.033 sig
Week 8	TAZAROTENE ADAPALENE	30 30	6.0333 9.1333	4.58997 5.99847	2.068 P=0.039 sig
Week 12	TAZAROTENE ADAPALENE	30 30	2.7000 4.4333	2.90244 3.74795	2.003 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

DISCUSSION

A total of 60 patients diagnosed with mild to moderate facial acne vulgaris were enrolled in the study at the Outpatient Department of Dermatology, Venereology, and Leprosy. Acne predominantly affects young adults, with a nearly equal gender distribution. In a study conducted by Smithard *et al.*, 56% of the participants were male; however, in our research, only 35% were male (M:F ratio of 1:1.9). This higher proportion of females may be attributed to their greater awareness of acne and a tendency to seek treatment sooner than their male counterparts.

The average age of participants in our study was 21.16 years, closely aligning with the age distribution of 19 years reported in the study by Webster *et al.* Numerous comparative studies have examined various topical anti-acne therapies, particularly retinoids such as Tretinoin, Adapalene, and Tazarotene. A review of the literature identified a single study by Webster *et al.* that compared the efficacy of 0.1% Tazarotene and Adapalene gel, which parallels our findings. At the 4th, 8th, and 12th weeks of post-treatment evaluation for non-inflammatory lesions (comedones), the mean lesion count following the application of Tazarotene 0.1% gel was significantly lower than that of Adapalene 0.1% gel, with p-values of 0.033, 0.039, and 0.050, respectively.

This indicates that Tazarotene 0.1% gel is a more effective agent for reducing comedones. These findings are consistent with those of Webster *et al.* In contrast, the difference in mean lesion count for inflammatory lesions (papules and pustules) between the two topical agents was not statistically significant (p = 0.869, 0.854, and 0.734, respectively), although Webster *et al.* reported that Tazarotene 0.1% gel was more effective in clearing inflammatory lesions as well. At the 4th week, 63.3% (19 patients) using Tazarotene 0.1% gel achieved 50-75% lesion

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clearance (scale 2) compared to only 23.4% (7 patients) using Adapalene 0.1% gel for non-inflammatory lesions (comedones). This suggests that Tazarotene 0.1% gel demonstrates a faster action than Adapalene

CONCLUSION

The findings of this research indicate that Tazarotene 0.1% gel serves as a more effective anticomedogenic treatment, demonstrating a quicker rate of clinical improvement in comparison to Adapalene 0.1% gel. The effectiveness of both topical agents appears to be comparable concerning inflammatory lesions, such as papules and pustules. Furthermore, the side effects associated with both retinoids were found to be minimal.

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