

Original Article

Comparative efficacy of different concentrations of topical tazarotene and topical tretinoin in acne vulgaris

Sunidhi Sharma¹, G. P. Thami¹, Jasleen Kaur Sandhu¹, Aashali Kalia¹, Savi Aneja¹, Tanya Jain¹

¹Department of Dermatology, Government Medical College and Hospital, Chandigarh, India.



***Corresponding author:**

Sunidhi Sharma,
Dermatology, Government
Medical College and Hospital,
Chandigarh, India.

sunidhisharma138@gmail.com

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ABSTRACT

Objectives: To compare the clinical efficacy of topical 0.025% and 0.05% tretinoin with topical 0.05% and 0.1% tazarotene in acne vulgaris.

Materials and Methods: It is a randomized prospective trial conducted in a single-center study in a tertiary-level hospital for a duration of 8 weeks. Patients having acne vulgaris (Grade 1 and 2) aged 18 to 50 years were included in the study. Those who were pregnant and lactating, had any systemic illness, or had signs and symptoms of hyperandrogenism were excluded from the study. 108 patients having mild to moderate facial acne vulgaris were selected and divided equally into 4 groups. Daily application of different concentrations of topical tretinoin and topical tazarotene once at bedtime was advised. Patients were followed at 2 weekly intervals up to 8 weeks, and response was graded as per the Indian Acne Alliance system. Any adverse events were also noted.

Results: The mean improvement in total lesion scores was highest for 0.1% tazarotene at 95.4%. This was followed by 0.05% tazarotene at 91.7%, tretinoin 0.05% at 89.4%, and 0.025% tretinoin at 71.5% at 8 weeks.

Conclusion: The tazarotene group was associated with a significantly greater treatment success than the tretinoin group. All the agents were well tolerated, and most of the adverse effects were local and transient. Erythema, burning, and peeling were seen more commonly with higher concentrations.

Keywords: Acne vulgaris, Tazarotene, Tretinoin

INTRODUCTION

Acne vulgaris (AV) is a chronic inflammatory disease of the pilosebaceous units, characterized by non-inflammatory comedones (open and closed) along with inflammatory papules, pustules, and nodules of varying severity.^[1] Pathogenesis of AV is multifactorial, and most of the therapeutic interventions are targeted toward one or more such factors, such as increased sebum production, hypercornification of the pilosebaceous duct, over colonization of *Cutibacterium acnes* (*C. acnes*), and inflammation.^[2] Lately, there has been a decreased response to conventional antibiotics due to an increase in the prevalence of resistant *C. acnes*. Besides the use of antibiotics, retinoids have become the mainstay of treatment of AV in the last few decades. Systemic retinoids such as isotretinoin have, in fact, become the drug of choice for moderate-to-severe (Grade 3 and 4) AV. Similarly, topical retinoids are being widely used as an initial therapy for the management of mild-to-moderate (Grade 1 and 2) AV, as they act on comedones as well as their precursor lesion, microcomedone, which has an anti-inflammatory effect. No head-to-head trials have compared the efficacy of different concentrations of topical retinoids. The present study compared the

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efficacy of topical 0.025% and 0.05% tretinoin with 0.05% and 0.1% tazarotene in mild-to-moderate AV.

MATERIALS AND METHODS

It was a randomized, prospective, open-label, comparative trial conducted in a tertiary care center in North India. The sample size was calculated on the basis of an anticipated response rate of 65% in 0.1% tazarotene cream and 44% in 0.025% tretinoin cream in AV in two groups, as reported in the literature. On the basis of 80% power and 10% level of significance, the calculated sample size was 47 patients in each group. However, to complete the study in a stipulated period, a minimum of 20 patients per group was planned. To account for possible dropouts, 27 patients were enrolled in each group, resulting in a total sample size of 108 participants. The trial was prospectively registered with CTRI, and informed consent was taken from all the patients. Pregnant and lactating mothers, patients with any systemic illness requiring drugs, signs and symptoms of hyperandrogenism, and those who have taken any topical systemic treatment for AV in the past 12 weeks were excluded from the study. Demographic information, including past and present use of topical and systemic medications, smoking history, signs of hyperandrogenism, hirsutism, oligomenorrhea, and irregular menstrual cycles, was recorded for each patient. In each group, grading and scoring of acne were done as per the Indian Acne Alliance guidelines.^[3] All the groups received different treatment regimens as follows:

- Group I – topical tretinoin 0.025%
- Group II – topical tretinoin 0.05%
- Group III – topical tazarotene 0.05%
- Group IV – topical tazarotene 0.1%.

Patients were instructed to apply the drug once at bedtime over the entire face, sparing periorbital and perioral areas, after washing the face with bath soap and water and letting it dry up naturally for 5–10 min. They were instructed to stay away from applying cosmetics, moisturizers, sunscreens, or other topical treatments on their face. Clinical assessment was done on the 2nd, 4th, 6th, and 8th weeks, respectively. Photographs were taken at baseline, before each session, and at post-treatment follow-up [Supplementary File, Figure S1-S4]. Evaluation and scoring were done before each session and 2 weeks after the last session. Response to the therapy was measured as:

- Nil: 0–25% reduction in lesions
- Mild: 26–50% reduction in lesions
- Moderate: 51–75% reduction in lesions
- Good: 76–100% reduction in lesions.

Patients were informed about the likely adverse effects of topical retinoids, such as dryness, erythema, skin irritation, skin peeling, itching, stinging, and exacerbation of lesions,

and were asked to take note of and report these to the treating physician.

Statistical analysis

Qualitative characteristics were described using proportion/percentage, whereas quantitative parameters were classified in terms of mean along with 95% confidence interval. Response pattern in the four study groups was described and compared using the Kolmogorov–Smirnov test. Means of quantitative parameters were tested for equality using analysis of variance. Pairwise comparison was done using the normal test of proportions. Chi-square test was used for testing the significance of the association between patient characteristics and response rates. Both intentions to treat and as per protocol analysis were presented. Data analysis was carried out using IBM Statistical Package for Social Sciences (version 26.0) software.

RESULTS

A total of 108 patients were recruited in the study [Figure 1]. However, only 81 patients completed the study, and 27 patients were lost to follow-up at different stages of the study. Among the dropouts, 21 patients did not follow up after the 2nd and 3rd scheduled visit, and 6 patients did not qualify for inclusion as one patient developed dermatophytosis over the face, and 5 patients did not follow the study protocol as advised.

The demographic details of the patients are as depicted in Table 1. The majority of the patients were female, with an age range of 18–38 years. The most common type of lesion seen in both groups was the comedone, followed by papule and pustules, respectively.

Efficacy - The baseline mean lesion count within the groups was comparable in all groups. There was a constant decrease in lesion count after each follow-up in all groups. This decrease was statistically significant at the end of 8 weeks from the baseline when compared between the groups (IV>III>II>I), as shown in Table 2 and Figure 2.

On comparing the mean improvement in total lesion scores from the baseline, it was found that there was increased improvement in all the groups, which was more pronounced in Group III and Group IV, with 91.70 and 95.4, respectively. The differences between all the groups were statistically significant at the 4th, 6th, and 8th week [Table 3 and Figure 3].

Tolerability and adverse effects - The study demonstrates the superior tolerability of low concentrations of both topical agents i.e., tretinoin 0.025% and tazarotene 0.05%. While adverse effects were observed in all treatment groups, they were transient and treatment-related, improving with follow-up visits [Table 4].

Table 1: Demographic profile of all the patients.

| Subjects | Groups | | | | Total |
|---------------------------------------|--------------------------------------|--------------------------------------|--|--------------------------------------|-----------|
| | I (Tretinoin 0.025%) <i>n</i> =27 | II (Tretinoin 0.05%) <i>n</i> =27 | III (Tazarotene 0.05%) <i>n</i> =27 | IV (Tazarotene 0.1%) <i>n</i> =27 | |
| Sex (%) | | | | | 108 |
| Female | 18 (66.7) | 20 (74.1) | 21 (77.8) | 20 (74.1) | 79 (73.1) |
| Male | 9 (33.3) | 7 (25.9) | 8 (22.2) | 7 (25.9) | 29 (26.9) |
| Age | | | | | |
| Range | 18–35 | 18–28 | 18–38 | 18–28 | 18–38 |
| Mean | 21.30 | 21.93 | 23.70 | 22.56 | 22.37 |
| Duration of disease (years) | | | | | |
| Mean | 1.48 | 1.29 | 1.54 | 1.83 | 1.53 |
| Previous treatment taken for acne (%) | | | | | |
| Yes | 6 (22.2) | 4 (14.9) | 9 (33.3) | 8 (30) | 27 (25) |
| None | 21 (77.8) | 23 (85.1) | 18 (66.7) | 19 (70) | 81 (75) |

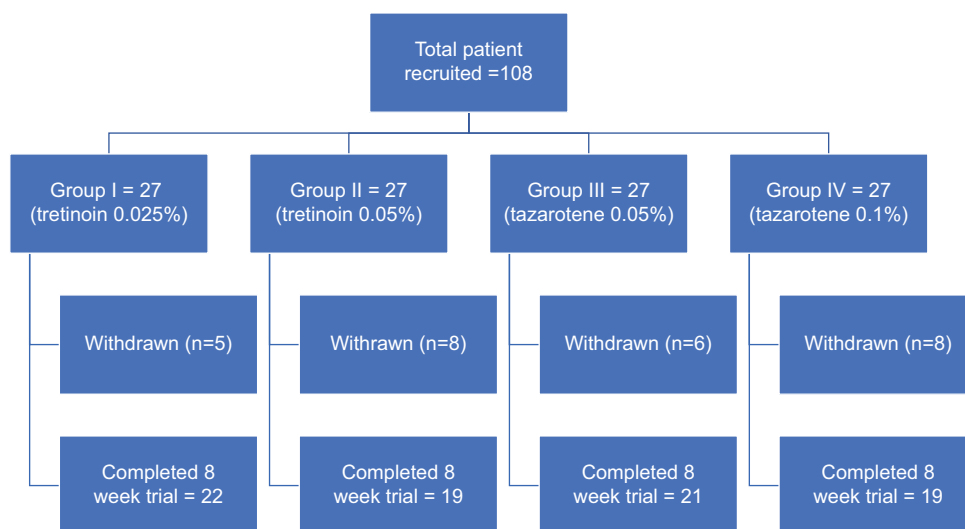


Figure 1: Flow diagram of subjects enrolled in the study.

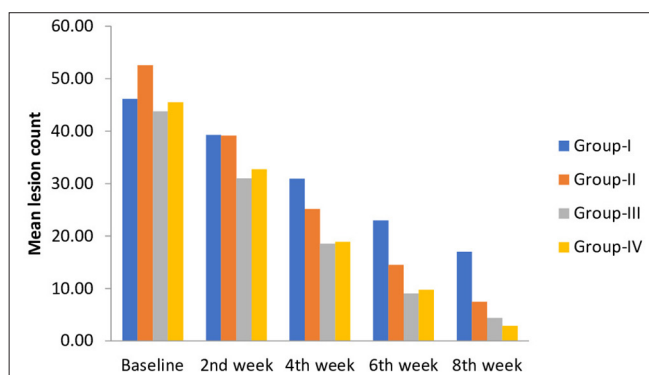


Figure 2: Mean total lesion count.

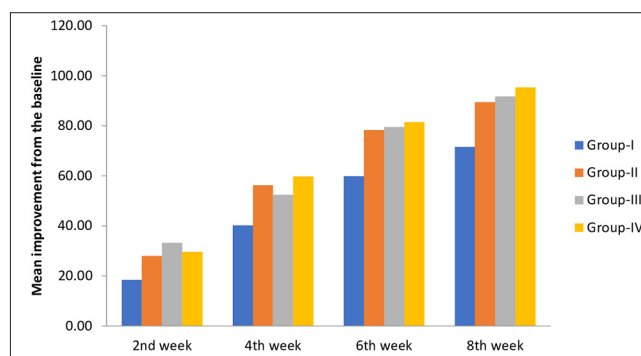


Figure 3: Mean improvement from the baseline among all groups.

DISCUSSION

AV is one of the most common relapsing and remitting dermatologic conditions affecting predominantly teenagers.

Topical retinoids have been used in the treatment of both non-inflammatory and inflammatory AV, both as monotherapy or in combination with other medical therapies.^[4]

Table 2: Comparison of mean total lesion count between the groups.

| Lesion count | Treatment group | | | | p-value |
|-----------------------------------|-------------------------------|-------------------------------|---------------------------------|-------------------------------|---------|
| | Group-I (Tretinoin 0.025%) | Group-II (Tretinoin 0.05%) | Group-III (Tazarotene 0.05%) | Group-IV (Tazarotene 0.1%) | |
| Baseline lesion count | | | | | |
| n | 22 | 19 | 21 | 19 | 0.663 |
| Mean | 46.1 | 52.5 | 43.7 | 45.5 | |
| SD | 36.1 | 32.8 | 33.0 | 32.1 | |
| 2 nd week lesion count | | | | | |
| n | 22 | 19 | 21 | 19 | 0.338 |
| Mean | 39.2 | 39.1 | 31.0 | 32.7 | |
| SD | 34.2 | 28.6 | 26.2 | 23.8 | |
| 4 th week lesion count | | | | | |
| n | 22 | 19 | 21 | 19 | 0.342 |
| Mean | 30.9 | 25.1 | 18.5 | 18.8 | |
| SD | 33.5 | 22.5 | 13.0 | 13.6 | |
| 6 th week lesion count | | | | | |
| n | 22 | 19 | 21 | 19 | 0.062 |
| Mean | 22.9 | 14.4 | 9.0 | 9.7 | |
| SD | 30.3 | 18.9 | 9.3 | 10.7 | |
| 8 th week lesion count | | | | | |
| n | 22 | 19 | 21 | 19 | 0.004** |
| Mean | 17.0 | 7.4 | 4.3 | 2.8 | |
| SD | 24.4 | 12.3 | 6.4 | 6.0 | |

SD: Standard deviation, ** = $p < 0.01$ highly statistically significant

Table 3: Improvement in mean lesion count from baseline in groups.

| Improvement | Treatment group | | | | p-value |
|---|-------------------------------|-------------------------------|---------------------------------|-------------------------------|----------|
| | Group-I (Tretinoin 0.025%) | Group-II (Tretinoin 0.05%) | Group-III (Tazarotene 0.05%) | Group-IV (Tazarotene 0.1%) | |
| Improvement from baseline to 2 nd week | | | | | |
| n | 22 | 19 | 21 | 19 | 0.119 |
| Mean | 18.4 | 27.9 | 33.2 | 29.6 | |
| SD | 16.0 | 11.5 | 23.0 | 8.8 | |
| Improvement from baseline to 4 th week | | | | | |
| n | 22 | 19 | 21 | 19 | 0.027* |
| Mean | 40.1 | 56.2 | 52.4 | 59.7 | |
| SD | 20.9 | 16.2 | 17.1 | 15.6 | |
| Improvement from baseline to 6 th week | | | | | |
| n | 22 | 19 | 21 | 19 | 0.002** |
| Mean | 59.8 | 78.3 | 79.5 | 81.4 | |
| SD | 20.9 | 17.0 | 12.8 | 13.6 | |
| Improvement from baseline to 8 th week | | | | | |
| n | 22 | 19 | 21 | 19 | 0.0001** |
| Mean | 71.5 | 89.4 | 91.7 | 95.4 | |
| SD | 25.4 | 12.9 | 9.4 | 8.3 | |

SD: Standard deviation, * = $p < 0.05$ (statistically significant), ** = $p < 0.01$ highly statistically significant

Table 4: Adverse effects seen along with topical retinoids at 8 weeks.

| Adverse effects | Treatment group | | | | | | | | | | p-value |
|------------------|-------------------------------|-------|-------------------------------|-------|---------------------------------|-------|-------------------------------|-------|-------|------|----------|
| | Group-I (Tretinoin 0.025%) | | Group-II (Tretinoin 0.05%) | | Group-III (Tazarotene 0.05%) | | Group-IV (Tazarotene 0.1%) | | Total | | |
| Erythema | | | | | | | | | | | |
| Present | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 5.3 | 1 | 1.2 | 0.347 |
| Absent | 22 | 100.0 | 19 | 100.0 | 21 | 100.0 | 18 | 94.7 | 80 | 98.8 | |
| Burning | | | | | | | | | | | |
| Present | 1 | 4.5 | 5 | 26.3 | 0 | 0.0 | 9 | 47.4 | 15 | 18.5 | 0.0001** |
| Absent | 21 | 95.5 | 14 | 73.7 | 21 | 100.0 | 10 | 52.6 | 66 | 81.5 | |
| Itching | | | | | | | | | | | |
| Present | 1 | 4.5 | 11 | 57.9 | 2 | 9.5 | 13 | 68.4 | 27 | 33.3 | 0.0001** |
| Absent | 21 | 95.5 | 8 | 42.1 | 19 | 90.5 | 6 | 31.6 | 54 | 66.7 | |
| Peeling | | | | | | | | | | | |
| Present | 1 | 4.5 | 8 | 42.1 | 2 | 9.5 | 9 | 47.4 | 20 | 24.7 | 0.001** |
| Absent | 21 | 95.5 | 11 | 57.9 | 19 | 90.5 | 10 | 52.6 | 61 | 75.3 | |
| Exacerbation | | | | | | | | | | | |
| Present | 3 | 13.6 | 1 | 5.3 | 0 | 0.0 | 1 | 5.3 | 5 | 6.2 | 0.314 |
| Absent | 19 | 86.4 | 18 | 94.7 | 21 | 100.0 | 18 | 94.7 | 76 | 93.8 | |
| Photosensitivity | | | | | | | | | | | |
| Present | 0 | 0.0 | 1 | 5.3 | 0 | 0.0 | 0 | 0.0 | 1 | 1.2 | 0.347 |
| Absent | 22 | 100.0 | 18 | 94.7 | 21 | 100.0 | 19 | 100.0 | 80 | 98.8 | |

** = $p < 0.01$ (highly statistically significant)

The present study included patients having mild-to-moderate (Grade 1 and 2) AV; comedones (closed) were the most common lesion, followed by papules and pustules. There was a constant and significant decrease in mean lesion count irrespective of the type of lesion at each follow-up as compared to the baseline values, the efficacy being maximum with 0.1% tazarotene, followed by 0.05% tazarotene, 0.05% tretinoin, and 0.025% tretinoin in the decreasing order. Although the difference in efficacy was statistically insignificant during the initial 3 follow-up visits, it became statistically significant at the last follow-up visit. These results are in concordance with those of Shalita *et al.* where total lesion count was reduced more with 0.1% tazarotene followed by 0.05% tazarotene when compared with control vehicle gel at 12 weeks.^[5] Similarly, Webster also noticed that different concentrations of tretinoin were more efficacious than placebo in treating AV.^[6]

All the agents were well tolerated in general by all the patients. Most of the adverse effects were local and transient, which resolved with the course of time. Mild pruritus was observed in all groups at initial follow-ups, to which the subjects developed tolerance with subsequent follow-ups. Erythema, burning, peeling/desquamation were observed more with higher concentrations of both the therapeutic agents, which also subsided in most of the patients with the course of time.

Exacerbation of acne lesions in the form of pustular flare was observed more with tretinoin formulations. The study by Webster stated tretinoin as the cornerstone of topical retinoid therapy. However, its utilization has been restricted due to instances of pustular flaring in a few patients.^[7] Photosensitivity was observed with both 0.025% and 0.05% tretinoin. It was mild and tolerable, which subsided within 5–7 days.

The present study confirms the effectiveness of topical retinoids in the improvement of acne as observed in previous studies.^[7,8] They are effective in reducing both non-inflammatory and inflammatory lesions of acne. Although topical tazarotene appeared to be better than topical tretinoin in improving various lesions of acne, the difference in efficacy was statistically significant between them in the present study when low concentrations of both topical tazarotene and tretinoin were compared. However, no statistically significant difference was found in the efficacy of 0.05% and 0.1% tazarotene in our study.

The present study demonstrates that tazarotene and tretinoin, when used topically, are reasonably good and safe treatment options in mild-to-moderate AV not requiring systemic therapy. Tazarotene outperforms tretinoin in clinical efficacy when compared in an open-label design, as in this study. Among tazarotene, a higher concentration of 0.1% tazarotene

is clinically more effective than 0.05% tazarotene in the management of mild-to-moderate AV. The limitations of our study were a small sample size, a lack of a control group, a short treatment duration, and a shorter follow-up.

Limitations

The present study had certain limitations, including a relatively small sample size and a short follow-up period of 8 weeks. The study was conducted using an open-label design as blinding was not feasible. In addition, the absence of a placebo or control arm may limit the generalizability of the findings.

CONCLUSION

Both topical tretinoin and tazarotene have shown a reduction in lesion count in mild-to-moderate AV. All topical agents can be safely used in the treatment of mild-to-moderate AV as first-line agents. Topical tazarotene has shown to have better efficacy than topical tretinoin in reducing acne lesions. 0.025% topical tretinoin was found to be the least efficacious in treating AV as compared to the other groups.

Ethical approval: The research/study was approved by the Institutional Review Board at Government Medical College, Chandigarh, number GMCH/IEC/829R/2022/259, dated December 26, 2022. CTRI/2023/11/060308 (REGISTERED ON: November 29, 2023).

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest: There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation: The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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