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ISSN: 2663-9491 e-ISSN: 2789-6897

ORIGINAL ARTICLE

Efficacy and Safety of Topical Clascoterone in Mild to Moderate Acne Vulgaris

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Received: 14 October 2026
Accepted: 04 November 2026
Published Online: 15 November 2026

Published by:
Gopalganj Medical College, Gopalganj, Bangladesh

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DOI: 10.5281/zenodo.24238363

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ABSTRACT

Background: *Acne vulgaris is a prevalent chronic inflammatory skin disease that significantly impacts one's quality of life and mental health. The problem with conventional treatments is that they can be irritating to the skin, less effective due to antibiotic resistance, require strict adherence to use, and have deleterious side effects on the whole body. The purpose of this study was to determine the effectiveness and safety of the topical androgen receptor inhibitor, clascoterone 1%, in patients with mild-to-moderate acne vulgaris.* ***Methods & Materials:*** *A prospective interventional study was conducted among 90 patients with mild-to-moderate acne vulgaris at Dhaka Medical College from July 2025 to July 2026. The participants were treated with topical clascoterone 1% for a period of 12 weeks. The patients were examined at baseline, week 4, week 8, and week 12 for lesion count, Investigator Global Assessment (IGA) score, clinical response, adherence to the treatment, and adverse effects. All the data collected were analyzed using Statistical Package for the Social Sciences (SPSS) version 26. The level of significance was set at p<0.05.* ***Results:*** *Among 90 participants, most were aged 21–25 years (40.0%), female (57.8%), and moderate acne vulgaris (56.7%). After 12 weeks, the number of inflammatory, non-inflammatory, and total lesions decreased significantly (all p<0.001), while 77.8% achieved a moderate-to-marked improvement. Acne severity decreased significantly from 3.1±0.6 to 1.5±0.6 (p<0.001). Most participants (65.6%) did not report any adverse events, and baseline severity was not significantly associated with treatment response (p=0.537).* ***Conclusion:*** *Topical clascoterone 1% was effective and well tolerated in patients with mild-to-moderate acne vulgaris, producing significant reductions in lesion counts and acne severity with minimal adverse events.*

Keywords: *Acne vulgaris, Clascoterone, Topical treatment, Androgen receptor inhibitor, Acne severity, Clinical response, Treatment safety.*

(The Insight 2026; 9(3): 937-941)

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INTRODUCTION

Acne vulgaris is one of the most common chronic inflammatory diseases of the pilosebaceous unit, which is manifested by comedones, papules, pustules, and, in severe cases, nodules and scars. This disease is not associated with fatal outcomes but significantly reduces the quality of life and causes psychological discomfort. The main pathophysiological mechanisms include follicular hyperkeratinization and increased sebum production that led to comedone formation, proliferation of cutaneous bacteria, and subsequent inflammation. It is believed that androgen receptor activation and enhanced sebaceous gland activity are integral parts of this process [1,2].

Topical retinoids, benzoyl peroxide, antibiotics, and their combination are commonly used to treat mild-to-moderate acne, but the therapy may be limited by irritability, patient adherence, antibiotic resistance, and insufficient control of androgen-related disease. The systemic use of hormonal therapies such as spironolactone can be effective in females but is limited by systemic effects and the need for appropriate monitoring [2-4]. These limitations have prompted the development of topical treatments that target androgen signaling to minimize systemic drug exposure.

Clascoterone is a novel topical androgen receptor inhibitor developed for the treatment of acne vulgaris. It competitively inhibits androgen receptors in the skin, thereby reducing androgen-mediated effects on sebaceous glands and other acne-related cellular pathways [5-7]. Unlike systemic anti-androgenic therapies, its topical administration results in localized androgen receptor inhibition with limited systemic hormonal activity, making it a potentially useful option for patients with hormonally influenced acne [8,9]. A phase 2b randomized, double-blind, vehicle-controlled study showed clinical efficacy of clascoterone cream in a dose-dependent manner. The 1% formulation demonstrated favorable improvement in facial acne and good tolerability [5].

International phase 3 trials have established the efficacy and safety of topical clascoterone. Hebert et al. reported higher treatment success and significant reductions in inflammatory and non-inflammatory lesions with clascoterone 1% compared with vehicle, with mostly mild adverse events [1]. A systematic review and meta-analysis of randomized trials also

ISSN: 2663-9491 e-ISSN: 2789-6897

demonstrated improved treatment success and reduced non-inflammatory lesions, with a favorable safety profile [6]. Recent systematic reviews and comparative studies further support clascoterone as an effective option for mild-to-moderate acne and a potential alternative to systemic anti-androgen therapy, while recent narrative reviews and real-world experience have reported good efficacy and tolerability [2,4,9–11].

Despite promising international evidence, published data on topical clascoterone in Bangladesh are lacking. Therefore, this study aimed to evaluate the efficacy and safety of topical clascoterone 1% cream in patients with mild-to-moderate acne vulgaris, focusing on changes in acne severity, lesion counts, clinical response, and treatment-related adverse effects.

METHODS & MATERIALS

Study design and study period: This prospective interventional study was conducted among persons with acne vulgaris attending outpatients of the Department of Dermatology and Venereology, Dhaka Medical College, Dhaka, Bangladesh, for a period of one year (July 2025 to July 2026). Ninety eligible participants were followed for 12 weeks after initiation of topical clascoterone treatment.

Study population: The study population comprised individuals with a clinically diagnosed case of mild to moderate acne vulgaris attending the dermatology outpatient department of the institution during the study period. Individuals fulfilling the eligibility criteria were enrolled consecutively until 90 participants were recruited.

Selection criteria: Participants with clinically diagnosed mild to moderate acne vulgaris who met the study age criteria, consented to 12 weeks of topical clascoterone treatment, and agreed to follow-up were included. Patients with severe/nodulocystic acne, relevant skin disease, clascoterone hypersensitivity, recent systemic anti-acne treatment, concurrent acne-modifying medications, or inability to complete follow-up were excluded.

Data collection procedure: Following the collection of informed consent from the participants, a structured data collection form was used to collect demographic and clinical information. Age, sex, occupation, duration of acne, and baseline acne severity were recorded. The participants were clinically assessed at baseline and subsequently at weeks 4, 8, and 12. At baseline, acne lesions were assessed by counting the number of inflammatory and non-inflammatory lesions. The total lesion count was calculated as the sum of inflammatory and non-inflammatory lesions. The same procedure was repeated at each follow-up visit to assess changes during treatment.

Assessment of acne severity: Baseline acne severity was categorized as mild or moderate based on the clinical severity assessment used in the study. Overall, acne severity was also assessed at baseline and at weeks 4, 8, and 12 using the Investigator's Global Assessment (IGA) scale, if this was the scale used during the clinical assessment. The IGA score was recorded at each assessment to evaluate the change in overall acne severity over the treatment period.

Treatment protocol: The participants received topical clascoterone according to the study treatment protocol for a total duration of 12 weeks. Participants were instructed regarding the proper application of the medication and advised to follow the prescribed treatment regimen throughout the study period. Treatment adherence and any treatment-related complaints were assessed during follow-up visits.

Assessment of treatment response: The participants were classified as per the predefined clinical response criteria after 12 weeks of treatment. They were divided into four groups namely, marked improvement, moderate improvement, mild improvement, and minimal/no improvement. The overall clinical response was assessed at the end of the 12-week treatment period.

Safety assessment: Throughout the treatment period, adverse events were recorded, which were either reported by the participants or observed during clinical examination. Special attention was paid to the incidence of local cutaneous adverse events including dryness, erythema, burning or stinging, itching, and scaling. The frequency and percentage of participants experiencing each adverse event were recorded.

Follow-up: The participants were assessed at baseline and at weeks 4, 8, and 12. At each follow-up visit, the participants' clinical response, inflammatory and non-inflammatory lesion counts, acne severity score, treatment adherence, and adverse events were recorded. Participants who completed the 12-week treatment period were included in the final analysis.

Statistical analysis: The data were entered, cleaned, and analyzed using IBM SPSS Statistics version 26.0. Categorical variables were expressed as frequencies and percentages. Continuous variables were expressed as mean ± standard deviation (SD).

The changes in the number of inflammatory lesions, the number of non-inflammatory lesions, the total lesion count, and the acne severity score across baseline, week 4, week 8, and week 12 were analyzed using an appropriate repeated-measures statistical test. Post-hoc comparisons with baseline were made where applicable. The association between baseline acne severity and clinical response after 12 weeks was evaluated using the chi-square test or Fisher's exact test, as appropriate, depending on expected cell frequencies. A p-value of <0.05 was considered statistically significant.

Ethical considerations: The study was conducted following approval from the appropriate Institutional Review Board/Ethical Review Committee of Dhaka Medical College. The participants were provided with written informed consent prior to enrollment. The participants were informed of the purpose and procedures of the study, the expected benefits and potential adverse effects of treatment, and their right to withdraw from the study at any time without affecting their usual medical care. Confidentiality of the personal and clinical information of the participants was maintained throughout the study.

RESULTS

Table I below provides the general and clinical characteristics of the 90 study participants. The highest percentage of the patients was in the 21–25 years age bracket (40.0%), followed by 15–20 years (26.7%), 26–30 years (23.3%), and >30 years (10.0%). In this population, females comprised the larger proportion of the participants (57.8%), while males constituted 42.2%. In terms of occupation, the largest group of respondents was students (43.3%), followed by housewives (26.7%), service holders (20.0%), and business professionals (10.0%). In terms of severity, 56.7% of the participants had moderate acne while 43.3% had mild acne. Nearly half of the patients (47.8%) reported a duration of 1–3 years, whereas 27.8% had acne for less than 1 year and 24.4% had acne for more than 3 years.

ISSN: 2663-9491 e-ISSN: 2789-6897

Table I: Sociodemographic and clinical characteristics of the study participants (*n*=90)

Characteristics	Frequency (n)	Percentage (%)
Age (years)		
15–20	24	26.7
21–25	36	40.0
26–30	21	23.3
>30	9	10.0
Sex		
Male	38	42.2
Female	52	57.8
Occupation		
Student	39	43.3
Housewife	24	26.7
Service holder	18	20.0
Business	9	10.0
Acne severity		
Mild	39	43.3
Moderate	51	56.7
Duration of acne		
<1 year	25	27.8
1–3 years	43	47.8
>3 years	22	24.4

Table II below represents the number of pimples observed among patients who received treatment for a span of 12 weeks. The mean number of inflammatory lesions reduced from 18.6±7.4 to 5.6±4.2, whereas the number of non-inflammatory lesions decreased from 24.3±10.2 to 8.0±5.5. Therefore, the total lesion count decreased from 42.9±13.8 to 13.6±7.8 within the period from baseline to week 12. It can be observed that the mean for all three measurements significantly decreased ($p<0.001$).

Table II: Changes in acne lesion counts during treatment (*n*=90)

Assessment	Inflammatory lesions Mean ± SD	Non-inflammatory lesions Mean ± SD	Total lesions Mean ± SD
Baseline	18.6 ± 7.4	24.3 ± 10.2	42.9 ± 13.8
Week 4	12.1 ± 6.0	16.8 ± 8.3	28.9 ± 11.7
Week 8	7.8 ± 5.1	11.2 ± 6.7	19.0 ± 9.6
Week 12	5.6 ± 4.2	8.0 ± 5.5	13.6 ± 7.8
p-value	<0.001	<0.001	<0.001

Table III below contains the overall results of the clinical trial. 38 participants or 42.2% of the sample reported a marked improvement in their condition after the 12-week treatment. An additional 32 participants or 35.6% experienced moderate improvement, while 14 participants or 15.6% noted mild improvement. Finally, 6 participants or 6.7% reported minimal or no improvement. Thus, 77.8% of the participants have reported either moderate or marked clinical improvement after 12 weeks of treatment.

Table III: Overall clinical response after 12 weeks of treatment (*n*=90)

Treatment response	Frequency (n)	Percentage (%)
Marked improvement	38	42.2
Moderate improvement	32	35.6
Mild improvement	14	15.6
Minimal/no improvement	6	6.7
Total	90	100.0

Table IV shows the change over time in the severity of acne. The average severity score decreased from 3.1 ± 0.6 at baseline to 2.4 ± 0.7 at week 4, 1.9 ± 0.7 at week 8, and 1.5 ± 0.6 at week 12. The severity of acne decreased significantly at week 4, 8, and 12 compared with baseline ($p<0.001$ for all comparisons).

Table IV: Changes in acne severity score during treatment (*n*=90)

Time point	Mean ± SD	p-value
Baseline	3.1 ± 0.6	—
Week 4	2.4 ± 0.7	<0.001
Week 8	1.9 ± 0.7	<0.001
Week 12	1.5 ± 0.6	<0.001

ISSN: 2663-9491 e-ISSN: 2789-6897

Figure 1 represent the adverse events that occurred among 90 participants who received treatment. Over half of study participants (59, 65.6%) did not report any adverse events. Dryness was found to be the most common adverse event (10, 11.1%), followed by erythema (7, 7.8%), burning/stinging (5, 5.6%), itching (5, 5.6%), and scaling (4, 4.4%). Thus, it can be stated that adverse events reported by participants were minimal, with dryness being the most prevalent among them.

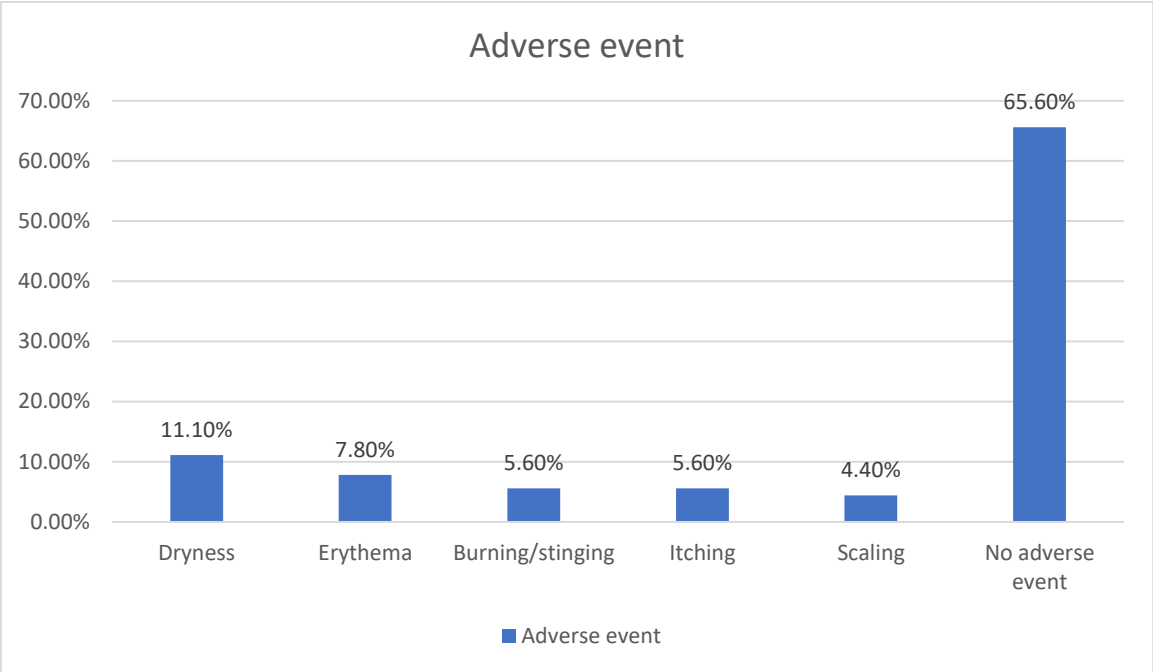


Figure 1: Adverse events reported during treatment (*n*=90)

Table V presents the association between baseline severity of acne and participants' clinical response after 12 weeks of treatment. Among patients with mild acne, 48.7% showed marked improvement, 35.9% – moderate improvement, 10.3% – mild improvement, and 5.1% – minimal/no improvement. For patients with moderate acne, 37.3% showed marked improvement, 35.3% – moderate improvement, 19.6% – mild improvement, and 7.8% – minimal/no improvement. Thus, although the proportion of patients with marked improvement seems to be higher for those with initially diagnosed mild acne, the association between baseline severity and participants' clinical response was not statistically significant (p=0.537).

Table V: Association between baseline acne severity and clinical response after 12 weeks of treatment (*n*=90)

Baseline acne severity	Marked improvement, n (%)	Moderate improvement, n (%)	Mild improvement, n (%)	Minimal/no improvement, n (%)	Total, n (%)	p-value
Mild	19 (48.7)	14 (35.9)	4 (10.3)	2 (5.1)	39 (100.0)	0.537
Moderate	19 (37.3)	18 (35.3)	10 (19.6)	4 (7.8)	51 (100.0)	
Total	38 (42.2)	32 (35.6)	14 (15.6)	6 (6.7)	90 (100.0)	

DISCUSSION

In the present study, most participants were aged 21–25 years, females, and students. The most prevalent forms of acne were moderate one and its duration was 1–3 years. In another study conducted among adolescents in Dhaka, the mean age of respondents was 15.3 years, females comprised 52% and mild-to-moderate acne was the most common [12]. Thus, prevalence of acne among adolescents and young adults can be explained by the fact that during these periods people are more susceptible to hormonal fluctuations and increased sebum production.

In the present study, inflammatory lesions decreased from 18.6±7.4, to 5.6±4.2, non-inflammatory lesions decreased from 24.3±10.2, to 8.0±5.5 and total lesions decreased from 42.9±13.8, to 13.6±7.8 after 12 weeks. This corresponds with recent clinical evidence demonstrating that both inflammatory and non-inflammatory lesions were decreased significantly after clascoterone 1% treatment [13,14]. The decrease was demonstrated to be progressive over time and provides further evidence for the efficacy of topically applied clascoterone in mild-to-moderate acne.

It was found that 42.2% of patients treated demonstrated a significant improvement and another 35.6% showed a moderate improvement in their condition after 12 weeks of treatment leading to an impressive 77.8% of patients with moderate-to-marked responses. A rather small percentage of 6.7% of the participants showed a minimal or no improvement. This result is aligned with the recent clinical evidence on the healing efficiency of clascoterone 1 % after 12 weeks of treatment which demonstrated significant improvement for the majority of patients with mild-to-moderate acne vulgaris [14].

In the current trial, the mean score of acne severity was decreased from 3.1±0.6 at baseline to 1.5±0.6 at week 12, while the mean score significantly improved from baseline at weeks 4, 8, and 12. According to a study, which included a systematic review and meta-analysis, there was a significant improvement in acne after 12 weeks of treatment with clascoterone with comparable efficacy to other new topical treatments for acne [15]. Therefore, it can be concluded that topical clascoterone has an effect on reducing lesion counts over the treatment period.

In the present study, it was found that among participants, 65.6% reported no adverse events, whereas the common events were dryness, followed by erythema, burning/stinging, itching, and scaling. Similarly, a recent real-world pharmacovigilance study reported dry skin and erythema as commonly observed adverse events with clascoterone. In general, clascoterone was well tolerated as a topical agent [16].

In the current research, a slightly higher treatment response was observed for patients with mild acne compared to those with moderate acne, but it was not statistically significant. It means that clascoterone cream was efficient for patients with low and moderate acne severity. The similar results were obtained in other studies that revealed consistent treatment efficacy across severity categories of acne [2,13].

Overall, topical clascoterone 1% was effective and well tolerated in mild-to-moderate acne vulgaris, producing progressive improvement in lesion counts and acne severity with minimal adverse effects.

CONCLUSION

Topically applied clascoterone 1% was effective and well-tolerated in patients with mild-to-moderate acne vulgaris, resulting in significant and progressive reductions in the number of inflammatory and non-inflammatory lesions and overall acne severity over the 12-week treatment period. Most participants experienced moderate-to-marked clinical improvement, and treatment-related adverse events were generally mild and uncommon. These findings suggest that clascoterone could be a valuable treatment option for moderate-to-severe acne vulgaris.

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