Original Article

Comparative Efficacy and Safety of Montelukast versus Doxycycline in the Treatment of Moderate Acne Vulgaris: A Rnadomized Controlled Trial

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Abstract

Background: While clean you do not understand Acne vulgaris as a frequent chronic inflammatory problem of the pilosebaceous unit. Safety issues with the use of antibiotics and resistance issues have led to an interest in other therapies. Leukotriene receptor antagonist Montelukast which is an anti-inflammatory may be a possible non-antibiotic treatment. The aim is to assess the effectivity and safety of montelukast with doxycycline for moderate acne vulgaris. Setting and Design: Conducted randomized controlled trial in settings of Dermatology, Venereology and Leprosy Department, Teerthanker Mahaveer Medical College and Research Centre, Moradabad. **Material and Methods:** The methods and materials consist of 130 patients of moderate Acne Vulgaris, aged between 15 to 40 years were divided into two groups of 65 patients each. Patients were divided into two groups: Group A had oral montelukast 10 mg once a day and topical clindamycin 1%, Group B received oral doxycycline 100 mg once a day and topical clindamycin 1% for 12 weeks. GAGS was used to evaluate acne severity at baseline, and at 4, 8, and 12 weeks. Data were analysed by appropriate statistical tests and $p<0.05$ was used as the limit of significance. **Results:** Dozycyline treatment resulted in a significantly larger decrease in GAGS score than montelukast at week 12 (60.0 vs. 27.1, $p<0.001$). Both treatments were tolerated well. **Conclusion:** Both drugs were effective but doxycycline was more effective. When antibiotic treatment is not appropriate, Montelukast can be considered a safe alternative.

Keywords: Acne vulgaris, Montelukast, Doxycycline, Global Acne Grading System, Randomized controlled trial.

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Introduction

During the current study, the aim was to evaluate the safety and efficacy of montelukast versus doxycycline in moderate acne vulgaris, as it is an anti-inflammatory as well as an antimicrobial drug and may be a safer alternative to doxycycline due to its growing antimicrobial resistance and side effects.

Materials and Methods

This was a prospective, parallel-group, randomized controlled, open label trial carried out in the Department of Dermatology, Venereology and Leprosy at Teerthanker Mahaveer Medical College and Research Centre in Moradabad, Uttar Pradesh, India for 18 months, from June 2024 till November 2025.Participants were randomly allocated in a 1:1 ratio to receive either montelukast or doxycycline. The study was approved by the Institutional Ethics Committee and College Research Committee (Approval No. TMU/IEC/2024-2025/PG/67). The trial was prospectively registered with the Clinical Trials Registry–India (CTRI) (Registration No. CTRI/2024/11/076344). Written informed consent was obtained from all participants prior to enrolment. The study was conducted in accordance with the Declaration of Helsinki (2013) and Good Clinical Practice guidelines.

Patients aged 15–40 years attending the dermatology outpatient department with moderate acne vulgaris, defined by a Global Acne Grading System (GAGS) score of 19–30, were screened for eligibility.

Inclusion Criteria were patients of age 15–40 years, clinically diagnosed moderate acne vulgaris (GAGS score 19–30) and willingness to participate and provide written informed consent.

Exclusion Criteria included use of systemic antibiotics within the preceding 4 weeks, use of oral isotretinoin within the preceding 3 months, use of topical antibiotics, retinoids, or corticosteroids within the preceding 2 weeks, any known hypersensitivity to montelukast, doxycycline, or clindamycin, pregnant or lactating females, patients receiving medications known to interact with study drugs and patients with significant systemic illness or hepatic dysfunction.

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The study was conducted in the outpatient Department of Dermatology, Venereology and Leprosy, Teerthanker Mahaveer Medical College and Research Centre, Moradabad, Uttar Pradesh, India. Participants were assigned to one of the following treatment groups:

Group A (Montelukast Group) patients were administered oral montelukast 10 mg once daily (Montel®, Johnlee Pharmaceuticals Pvt. Ltd., Nagpur, India) with topical clindamycin 1% gel once daily and Group B (Doxycycline Group) patients were administered oral doxycycline 100 mg once daily (Microdox-LBX®, Micro Labs Ltd., Bengaluru, India) with topical Clindamycin 1% gel once daily.

Treatment was continued for 12 weeks. Participants were counselled regarding drug compliance and standard acne care measures throughout the study period.

Baseline demographic and clinical characteristics were recorded using a structured case record form. Acne severity was assessed using the Global Acne Grading System (GAGS). Participants were evaluated at baseline and at Weeks 4, 8, and 12 following initiation of therapy.

The primary outcome was the reduction in Global Acne Grading System (GAGS) score from baseline to Week 12. Secondary outcomes included the percentage reduction in GAGS score at Weeks 4, 8, and 12, clinical improvement in acne severity over the study period, the incidence of treatment-related adverse effects, and changes in liver function test parameters during follow-up. Standardized clinical photographs were obtained at baseline and at each follow-up visit for documentation and assessment.

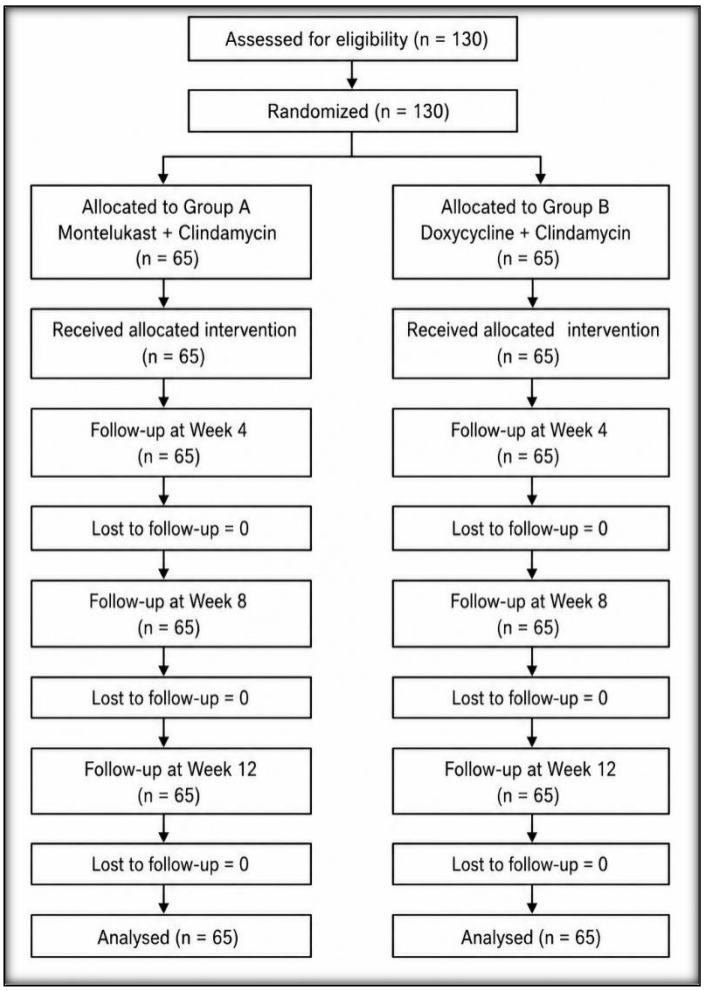
Sample Size Determination- Assuming a confidence level of 95% and a study power of 80%, a minimum sample size of 62 participants was required in each group. Considering an anticipated attrition rate of 5%, 65 participants were enrolled in each group, resulting in a total sample size of 130 participants.

Randomisation- A computer-generated random number table was used to generate the random allocation sequence. Simple randomization with a 1:1 allocation ratio was employed. No blocking, stratification, or other restrictions were used. No allocation concealment mechanism was employed. Following enrolment, participants were assigned to the intervention groups according to the predetermined computer-generated randomization sequence. The random allocation sequence was generated by the principal investigator. Eligible participants were enrolled by the principal investigator and assigned to the intervention groups according to the computer-generated randomization schedule. The study was conducted in an open-label manner. Neither participants, treating physicians, nor outcome assessors were blinded to treatment allocation.

Statistical Methods- Data were entered into Microsoft Excel and analysed using IBM SPSS Statistics software version 26.0 (IBM Corp., Armonk, NY, USA). Quantitative variables were expressed as mean ± standard deviation (SD), whereas qualitative variables were expressed as frequencies and percentages.

Between-group comparisons of continuous variables were performed using the independent Student's t-test. Within-group changes over time were analysed using repeated-measures ANOVA. Categorical variables were compared using the Chi-square test or Fisher's exact test, wherever appropriate. A p-value of <0.05 was considered statistically significant.

Results



Participant recruitment was carried out in the Department of Dermatology, Venereology and Leprosy, Teerthanker Mahaveer Medical College and Research Centre, Moradabad. Eligible patients aged 15–40 years with moderate acne vulgaris (GAGS score 19–30) were enrolled after obtaining written informed consent. Each participant was followed prospectively for 12 weeks.

Baseline demographic and clinical characteristics of both groups are presented in [Table 1].

A total of 130 participants were included, with 65 participants in each treatment arm. The majority of participants in both groups belonged to the 15–19-year age group. Females predominated in the Montelukast group (63.1%), whereas males constituted a slight majority in the Doxycycline group (50.8%). Baseline acne severity was comparable between groups, with mean baseline GAGS scores of 24.2 in Group A and 24.6 in Group B, indicating no significant difference before treatment initiation.

All randomized participants were analysed according to their originally assigned treatment groups. No exclusions occurred

after randomization. Thus, efficacy and safety analyses were performed on all 130 participants (65 per group).

As the primary outcome, mean GAGS scores decreased progressively throughout the 12-week follow-up in both treatment groups, from comparable baseline values (24.2 vs 24.6) to 22.1 vs 19.4 at Week 4, 19.6 vs 14.5 at Week 8, and 17.8 vs 10.1 at Week 12 in the Montelukast and Doxycycline groups, respectively, with the Week 12 difference being statistically significant ($p < 0.001$), demonstrating superior efficacy of Doxycycline in reducing acne severity (Figures 1 and 2). The percentage reduction in GAGS score was significantly greater in the Doxycycline group compared with the Montelukast group.

At Week 12, the mean percentage reduction in GAGS score was 27.1% in Group A and 60.0% in Group B, indicating substantially greater clinical improvement among participants receiving Doxycycline ($p < 0.001$) shown in [Table 2].

As a secondary outcome, both treatment groups demonstrated a reduction in inflammatory lesions during follow-up, with papules being the predominant lesion at baseline in 52.3% of participants in Group A and pustules in 58.5% of participants in Group B, while papules and comedones became the predominant residual lesions by Week 12 [Table 3].

Adverse events were generally mild and self-limiting in both treatment groups.

At Week 4, the most common adverse effect in one treatment arm was gastritis while photosensitivity was most common in the other treatment arm. Photosensitivity was the adverse reaction reported most often at Week 8, in 35.4% of Group A participants and 30.8% of Group B participants. No adverse events were noted in either treatment groups by Week 12.

In all subjects, liver function tests were normal throughout the study. No serious adverse events were noted and none of the patients discontinued treatment due to adverse effects.

Table 1: Baseline demographic and clinical characteristics of study participants

Characteristic	Montelukast Group (n=65)	Doxycycline Group (n=65)	p-value
Age group, n (%)			0.000006
15–19 years	51 (78.5)	48 (73.8)	
20–25 years	12 (18.5)	0 (0)	
>25 years	2 (3.1)	17 (26.2)	
Sex, n (%)			0.112
Male	24 (36.9)	33 (50.8)	
Female	41 (63.1)	32 (49.2)	
Age at onset of acne (10–19 years), n (%)	62 (95.4)	51 (78.5)	0.005
Duration of acne >5 years, n (%)	21 (32.3)	25 (38.5)	0.038
Family history positive, n (%)	14 (21.5)	28 (43.1)	0.009
Combination skin type, n (%)	33 (50.8)	34 (52.3)	0.861
Stress as aggravating factor, n (%)	12 (18.5)	14 (21.5)	0.997
Irregular menstrual cycles, n (%)*	11 (16.9)	9 (13.8)	0.280
BMI, n (%)			0.306
18.5–24.99 kg/m²	33 (51.6)	39 (60.0)	
25–29.99 kg/m²	27 (42.2)	25 (38.5)	
30–34.99 kg/m²	4 (6.2)	1 (1.5)	
Site of involvement, n (%)			0.915
Face only	19 (29.2)	21 (32.3)	
Face + Chest	19 (29.2)	19 (29.2)	
Face + Trunk	27 (41.5)	25 (38.5)	
Grade of acne, n (%)			0.861
Grade II	34 (52.3)	27 (41.5)	
Grade III	31 (47.7)	38 (58.5)	
Baseline GAGS score, mean ± SD	24.2 ± SD	24.6 ± SD	0.528

Abbreviations: BMI, Body Mass Index.
GAGS, Global acne grading system
*Irregular menstrual cycles were assessed among female participants only.
Values are presented as n (%).

Table 2: Global acne grading system scores

Visit	Montelukast Group Mean ± SD	Doxycycline Group Mean ± SD	p-value
Baseline	24.2 ± 3.0	24.6 ± 3.1	0.523
Week 4	22.1 ± 3.7	19.4 ± 3.6	<0.001
Week 8	19.6 ± 3.7	14.5 ± 3.9	<0.001
Week 12	17.8 ± 3.5	10.1 ± 3.2	<0.001
Percentage reduction at Week 12 (%)	27.1	60.0	<0.001

GAGS = Global Acne Grading System.
Values are expressed as mean ± standard deviation.

Table 3: Distribution of predominant acne lesion type during follow-up

Time Point	Group A Predominant Lesion n (%)	Group B Predominant Lesion n (%)
Baseline	Papules 34 (52.3)	Pustules 38 (58.5)
Week 4	Papules 47 (72.3)	Papules 58 (89.2)
Week 8	Papules 61 (93.8)	Comedones 32 (49.2)
Week 12	Papules 54 (83.1)	Comedones 59 (90.8)

Values are presented as n (%). Predominant lesion refers to the lesion type observed in the highest proportion of participants at each assessment time point.

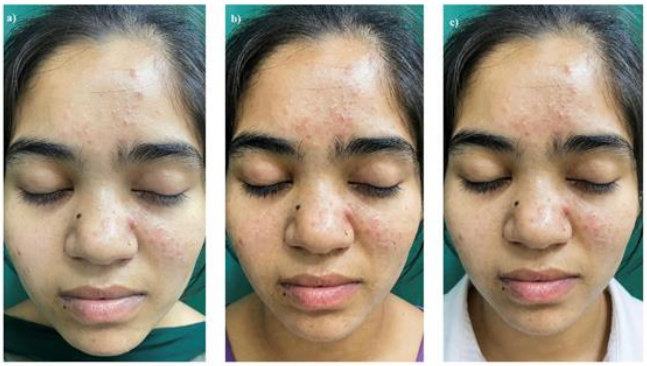


Figure 1: Clinical photographs of the montelukast group at (a) baseline, showing inflammatory papules and pustules; (b) 8 weeks; and (c) 12 weeks, demonstrating mild clinical improvement.

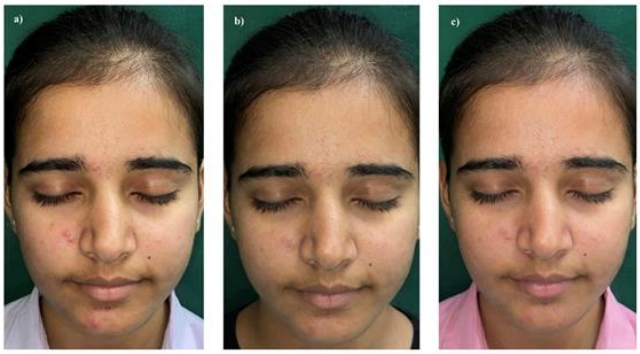


Figure 2: Clinical photographs of the doxycycline group at (a) baseline, showing inflammatory papules and pustules; (b) 8 weeks; and (c) 12 weeks, demonstrating progressive clinical improvement.

Discussion

Acne vulgaris is a chronic inflammatory condition of the pilosebaceous unit which predominantly affects adolescents and young adults and substantially affects Quality of Life. The present RCTs were conducted to evaluate and compare the efficacy and safety of montelukast against doxycycline in moderate acne vulgaris.

The demographic and clinical data for both treatment groups were overall similar. The subjects were most commonly aged from 15–19 years, and acne had onset most commonly during the adolescent age. The predominant lesions were papules and pustules while involvement of face and trunk was common. The results are similar to those found in recent studies of moderate acne vulgaris.[1]

The main outcome measure was a change in GAGS scores. The GAGS scores for both groups were comparable at enrolment, showing similar disease severity. The trend toward lower GAGS scores was seen over the duration of the study for both of the treatment groups, indicating that both montelukast and doxycycline was effective in lowering acne severity levels. But that was much more pronounced in the doxycycline group. The mean GAGS score for the doxycycline group was 10.1, while the mean GAGS score for the montelukast group was 17.8; this represents a percentage change of 60.0% and 27.1%, respectively. The results of this study indicated that doxycycline is more effective at improving moderate acne vulgaris.

Montelukast may have an anti-inflammatory effect, which could account for its beneficial effects. Pathways involved in pathogenesis of acne include those involving leukotrienes, and blocking these pathways may help to decrease the formation of inflammatory lesions. However, Doxycycline has anti-inflammatory activity as well as antimicrobial activity and can affect various mechanisms of pathogenicity that contribute to the development of acne, which can account for its larger therapeutic value observed in the current study.[1,2]

The results from the present study concur with prior studies. In moderate acne vulgaris, Haghighi et al. showed that montelukast was significantly effective in relieving acne severity. In the same way, Rokni et al. have noted a good efficacy and safety of montelukast when used for acne. Aslam et al. concluded that oral doxycycline was more effective than oral Montelukast and its results were similar to the present study. Moreover, Kumar et al. found that doxycycline was most effective of the systemic treatments available for moderate acne vulgaris. As far as sensitivity is concerned, both treatment methods were tolerated. Adverse effects were reported the most commonly were photosensitivity and gastritis, but hepatic abnormalities were not detected clinically over the follow-up period. There were no serious adverse events reported and liver function tests were normal throughout the study. The results of this investigation provide further evidence of the good safety profile of montelukast and the high tolerability of doxycycline from recent studies.[3-5]

There are certain limitations to this study, such as it was carried out at a single tertiary care centre and the sample size was relatively small, which may restrict external validity. No assessment of long term efficacy, relapse or recurrence or maintenance of remission could be done during a follow-up period limited to 12 weeks. Furthermore, the study was open label and non-blinded, which could have resulted in observer bias. Although randomized, a significant difference at baseline ($p<0.001$) was seen in age distribution between treatment groups. Although baseline acne severity was comparable, this demographic imbalance may have acted as a potential confounding factor and should be considered while interpreting the results.

Conclusion

Despite these limitations, the randomized design, comparable baseline disease severity, and prospective follow-up strengthen the validity of the findings. The results suggest that doxycycline remains the preferred first-line systemic therapy for moderate inflammatory acne vulgaris. However, montelukast demonstrated meaningful clinical improvement with a favourable safety profile and may serve as a useful non-antibiotic alternative in patients who are unable to tolerate antibiotics, have contraindications to tetracyclines, or require antibiotic-sparing treatment strategies. Larger multicentric studies with longer follow-up periods are warranted to further define the role of montelukast in acne management.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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