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COMPARATIVE EVALUATION OF OZENOXACIN AND CLINDAMYCIN IN ACNE MANAGEMENT

Praveen Kumar Rathore[1], Akanksha Singh[2], Harshvardhan Namdeo[3], Pushpendra Singh[4], Akanksha Singh[5]*, Dr. Arpit Singh[6]

[1]Professor & Head, Department of Skin & VD, Rohilkhand Medical College and Hospital, Bareilly International University, Bareilly, Uttar Pradesh, India.
[2]Assistant Professor, Department of Skin & VD, Rohilkhand Medical College and Hospital, Bareilly International University, Bareilly, Uttar Pradesh, India.
[3]Junior Resident (2nd Year), Department of Skin & VD, Rohilkhand Medical College and Hospital, Bareilly International University, Bareilly, Uttar Pradesh, India.
[4]Junior Resident (3rd Year), Department of Skin & VD, Rohilkhand Medical College and Hospital, Bareilly International University, Bareilly, Uttar Pradesh, India.
[5]PhD Scholar, Associate Professor, Department of Periodontics, Institute of Dental Sciences, Bareilly International University, Bareilly, Uttar Pradesh, India.
[6]JR III, Department of Surgery, Shri Ram Murti Medical College, Bareilly, Uttar Pradesh.

***Corresponding Author: Akanksha Singh**
PhD Scholar, Associate Professor, Department of Periodontics, Institute of Dental Sciences, Bareilly International University, Bareilly, Uttar Pradesh, India.

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ABSTRACT

Background: Acne vulgaris is a prevalent dermatological condition, particularly among adolescents and young adults, often leading to both physical and psychosocial challenges. Among available treatment modalities, topical antibiotics continue to play a pivotal role in its management. **Objective:** This study aimed to assess and compare the therapeutic efficacy and tolerability of topical clindamycin 1% and ozenoxacin 2% in individuals presenting with mild to moderate acne vulgaris. **Methods:** A randomized, double-blind pilot study was conducted involving 20 participants diagnosed with mild to moderate acne. Subjects were randomly assigned to two groups: one received clindamycin 1% lotion (Group A), and the other received ozenoxacin 2% lotion (Group B), both applied twice daily over eight weeks. Clinical evaluation included the Global Acne Grading System (GAGS) and the Leeds Revised Acne Grading System to measure inflammatory and non-inflammatory lesion counts. Secondary assessments comprised patient satisfaction and adverse effects. Data were analyzed using SPSS version 23.0, with Student's t-test and chi-square tests applied as appropriate. **Results:** Both treatment groups exhibited significant reductions in lesion counts from baseline. Ozenoxacin demonstrated a slightly superior reduction in inflammatory lesions, while clindamycin showed a marginally better effect on non-inflammatory lesions. Participants in the ozenoxacin group also reported higher satisfaction and fewer side effects. **Conclusion:** Both clindamycin and ozenoxacin were effective in treating mild to moderate acne. Ozenoxacin may provide enhanced anti-inflammatory benefits and better patient tolerance. Further research with larger sample sizes is necessary to substantiate these findings.

KEYWORDS: Acne vulgaris; clindamycin; ozenoxacin; topical antibiotics; comparative efficacy; pilot study.

INTRODUCTION

Acne vulgaris is one of the most prevalent dermatological conditions globally, particularly affecting adolescents and young adults. It is marked by the presence of both inflammatory and non-inflammatory skin lesions, which may cause physical discomfort and psychological distress, including reduced self-esteem and anxiety.[1,2] The development of acne is multifactorial, involving increased sebum production, follicular hyperkeratinization, microbial colonization (particularly *Cutibacterium acnes*), and subsequent inflammation.[2] Topical antibiotics, such as clindamycin, are widely prescribed for treating mild to moderate acne due to their ability to suppress *C. acnes* proliferation and reduce inflammation.[3] However, the increasing emergence of antibiotic-resistant bacterial strains poses a significant challenge to long-term acne management.[4]

Ozenoxacin, a newer-generation topical quinolone, has demonstrated strong antimicrobial properties, especially against Gram-positive organisms, including resistant strains. While it is approved for the treatment of impetigo, its role in acne management remains relatively unexplored in clinical trials.[5,6] Due to its dual antibacterial and anti-inflammatory mechanisms, ozenoxacin could serve as a promising alternative to traditional topical antibiotics like clindamycin.

This pilot study was designed to compare the clinical efficacy and safety profile of topical ozenoxacin 2% with clindamycin 1% lotion in patients with mild to moderate acne vulgaris, aiming to contribute new evidence toward optimizing topical acne therapy.

AIMS AND OBJECTIVES

- **Primary Aim:** To compare the clinical efficacy of topical clindamycin 1% and topical ozenoxacin 2% lotion in treating mild to moderate acne vulgaris.

- **Objectives**
  - To assess the reduction in inflammatory and non-inflammatory lesion counts using the Global Acne Grading System (GAGS) and the Leeds Revised Acne Grading System.
  - To evaluate patient-reported satisfaction with each treatment.
  - To monitor and compare the adverse effects associated with each treatment.

MATERIALS AND METHODS

Study Design and Setting

This investigation was conducted as a randomized, double-blind, controlled pilot study over an eight-week period. The study aimed to evaluate the clinical efficacy of two topical agents—clindamycin 1% and ozenoxacin 2%—in the treatment of mild to moderate acne vulgaris.

Participant Selection

A total of 20 patients, aged between 12 and 35 years, with a clinical diagnosis of mild to moderate acne were recruited. Individuals with severe acne, known hypersensitivity to the study drugs, or those who had recently used systemic antibiotics or topical acne treatments were excluded.

Randomization and Blinding

Participants were randomly assigned to two groups (n = 10 each) using a computer-generated randomization list. Group A received topical clindamycin 1%, while Group B was treated with ozenoxacin 2%. Both formulations were applied twice daily. Blinding was maintained for both participants and investigators to eliminate bias.

Assessment Parameters

The primary outcomes included the reduction in inflammatory and non-inflammatory lesions, assessed using the Global Acne Grading System (GAGS) and the Leeds Revised Acne Grading System at baseline, week 4, and week 8. Secondary outcomes included patient-reported satisfaction (evaluated via a structured questionnaire) and adverse events.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using SPSS version 23.0. Continuous variables were expressed as mean ± standard deviation (SD), and categorical data as percentages. Between-group comparisons were conducted using Student's t-test, while within-group changes were assessed via paired t-tests. Chi-square tests were used for categorical variables. A p-value less than 0.05 was considered statistically significant.

RESULT

Participant Demographics and Baseline Characteristics

All 20 participants enrolled in the study completed the eight-week trial without any protocol deviations or dropouts. Each group included 10 patients (Group A: clindamycin 1%; Group B: ozenoxacin 2%).

The demographic data and baseline clinical characteristics were statistically comparable between the two groups (Table 1). The average age in Group A was 22.3 ± 4.5 years, while in Group B it was 23.1 ± 3.9 years ($p = 0.56$). Gender distribution was similar, with 60% males in Group A and 50% in Group B ($p = 0.74$). Acne severity at baseline was balanced ($p = 0.68$).

Baseline inflammatory lesion counts were 12.4 ± 3.1 in Group A and 13.1 ± 2.9 in Group B ($p = 0.48$), whereas non-inflammatory lesion counts were 8.2 ± 2.5 and 7.8 ± 2.7, respectively ($p = 0.71$).

Primary Outcomes: Reduction in Lesions

Both groups showed significant clinical improvement over the eight-week period (Table 2). Inflammatory lesions in the ozenoxacin group (Group B) reduced from 13.1 ± 2.9 to 4.3 ± 1.8 ($p = 0.03$), while in the clindamycin group (Group A), the count decreased from 12.4 ± 3.1 to 5.6 ± 2.0 ($p < 0.05$).

For non-inflammatory lesions, Group A showed a reduction from 8.2 ± 2.5 to 3.4 ± 1.5, whereas Group B showed a decrease from 7.8 ± 2.7 to 3.9 ± 1.4 ($p = 0.45$).

Secondary Outcome Measures

Patient satisfaction scores were high in both groups by the end of treatment. Group B (ozenoxacin) had a mean satisfaction score of 8.6 ± 1.1, slightly higher than Group A (clindamycin), which scored 8.1 ± 1.2 ($p = 0.56$). Adverse effects were mild in nature (Table 2). Group A reported two cases (20%) of mild irritation and one case (10%) of moderate irritation. Group B had only one case (10%) of mild irritation. No serious adverse effects occurred ($p = 0.38$).

DISCUSSION

Acne vulgaris is a chronic inflammatory condition of the pilosebaceous unit, affecting nearly 85% of adolescents and young adults globally.[1,2] It significantly impacts quality of life, leading to psychological stress, reduced self-esteem, and in some cases, depression.[13,14] Effective and well-tolerated topical therapies are therefore essential for managing mild to moderate acne, which constitutes a large subset of clinical cases.

In this pilot study, we compared two topical antibiotics—clindamycin 1% and ozenoxacin 2%—over an eight-week treatment period in patients with mild to moderate acne vulgaris. Both agents resulted in statistically significant reductions in lesion counts, indicating clinical efficacy. However, ozenoxacin was associated with a greater reduction in inflammatory lesions, better patient satisfaction, and fewer adverse events, suggesting it may offer a more favorable therapeutic profile than clindamycin.

Clindamycin remains a commonly prescribed topical antibiotic in acne therapy due to its ability to inhibit Cutibacterium acnes growth and suppress inflammation via reduction of pro-inflammatory cytokines such as IL-1β and TNF-α.[3] Nevertheless, the increasing prevalence of clindamycin-resistant C. acnes strains, particularly due to 23S rRNA gene mutations and erm gene acquisition, has emerged as a major concern.[4,10] Resistance can compromise treatment efficacy, necessitating the development of alternative topical agents with broader antimicrobial action and lower resistance potential.

Ozenoxacin is a novel, non-fluorinated quinolone with broad-spectrum antibacterial activity, including against resistant Gram-positive bacteria such as methicillin-resistant Staphylococcus aureus and resistant C. acnes strains.[5,6,7] Unlike fluoroquinolones, ozenoxacin exhibits low systemic absorption and a better safety profile, making it suitable for topical use.[8] Its dual mechanism—blocking bacterial DNA gyrase and topoisomerase IV—enhances its bactericidal effect while minimizing resistance development.[7,8] Additionally, its anti-inflammatory properties, including inhibition of cytokines such as IL-6 and IL-8, offer therapeutic benefits beyond microbial control.[7]

Our results are consistent with these mechanistic insights. Patients treated with ozenoxacin showed a greater reduction in inflammatory lesions compared to clindamycin, indicating superior anti-inflammatory activity. This could be particularly advantageous in acne cases with prominent papulopustular components. Moreover, patients reported higher satisfaction with ozenoxacin, which likely reflects both clinical improvement and reduced irritation. Previous trials evaluating ozenoxacin in impetigo and other skin infections have also reported excellent tolerability and rapid symptom resolution.[9]

Interestingly, clindamycin demonstrated a slightly better reduction in non-inflammatory (comedonal) lesions in our study. However, the difference was not statistically significant. As comedones are often more responsive to keratolytic agents like retinoids, this result might reflect individual variation or baseline lesion distribution rather than a true pharmacological advantage.[15]

The importance of patient-reported outcomes, such as treatment satisfaction and adverse events, should not be underestimated in acne management. Acne, especially when affecting visible areas such as the face, has been associated with substantial psychosocial morbidity.[13,14] In our study, ozenoxacin was better tolerated than clindamycin, with fewer cases of irritation. This finding aligns with reports that ozenoxacin lacks the phototoxicity and mucosal irritation often associated with older topical antibiotics or retinoid-antibiotic combinations.[8,10]

From a public health and antimicrobial stewardship perspective, the introduction of new agents with low resistance potential is crucial. Current guidelines discourage topical antibiotic monotherapy due to rising resistance rates and instead recommend combination regimens, such as benzoyl peroxide with either clindamycin or adapalene.[3,11] Ozenoxacin, given its potent activity and minimal systemic absorption, may be considered for future combination products, possibly with non-antibiotic agents like niacinamide or azelaic acid to further reduce resistance risk.

Despite promising outcomes, our study has several limitations. The small sample size (n=20) restricts the generalizability of the results. As a pilot study, it was not powered to detect subtle differences between groups or sub-analyze based on age, gender, or lesion type. Second, the eight-week duration, though clinically relevant, may not fully capture long-term efficacy, relapse rates, or post-treatment flare-ups. Third, microbiological analysis (e.g., bacterial culture or PCR for resistance genes) was not performed. Such data would have enriched the interpretation of efficacy, especially regarding ozenoxacin's effect on resistant C. acnes strains. Fourth, quality-of-life tools like the Dermatology Life Quality Index (DLQI) were not used, which could have added valuable insights into psychosocial outcomes. Finally, the lack of a combination therapy arm (e.g., with benzoyl peroxide) limits comparisons with standard-of-care regimens.

Future studies should address these limitations by including larger, multi-center populations, longer follow-up periods, and microbiological assessments. Comparative studies involving combination therapies and patient-centered outcomes such as DLQI will also help position ozenoxacin within current treatment algorithms. Additionally, cost-effectiveness analyses will be critical, especially in resource-constrained settings where clindamycin remains a low-cost staple.

In conclusion, both clindamycin and ozenoxacin are effective topical treatments for mild to moderate acne vulgaris. However, ozenoxacin may offer a better anti-inflammatory response, improved tolerability, and higher patient satisfaction, positioning it as a promising alternative in an era of rising antibiotic resistance.

Highlights

What is current knowledge?

- Topical antibiotics are standard treatment for mild to moderate acne.
- Clindamycin is widely used but resistance rates are increasing.
- Ozenoxacin is a newer quinolone with broad antibacterial activity.

What is new here?

- First direct comparison of ozenoxacin and clindamycin in mild to moderate acne.
- Ozenoxacin showed greater reduction in inflammatory lesions.
- Higher patient satisfaction and fewer side effects were observed with ozenoxacin.

Table 1: Baseline Demographic and Clinical Characteristics of Participants (n = 20).

Characteristic	Group A: Clindamycin 1% (n=10)	Group B: Ozenoxacin 2% (n=10)	p-value
Age (years)	22.3 (4.5)	23.1 (3.9)	0.56
Gender			
Male	6 (60%)	5(50%)	0.74
Female	4 (40%)	5 (50%)	
Acne Severity			
Mild	5(50%)	6(60%)	0.68
Moderate	5 (50%)	4 (40%)	
Lesion Count (GAGS)			
Inflammatory Lesions	12.4 (3.1)	13.1 (2.9)	0.48
Non-inflammatory Lesions	8.2 (2.5)	7.8 (2.7)	0.71
Comorbid Conditions			
None	8 (80%)	9 (90%)	0.62
Other (e.g., eczema)	2 (20%)	1 (10%)	

Notes: Data are presented as mean (standard deviation) or number (percentage). P-values are calculated using t-tests for continuous variables and chi-square tests for categorical variables.

Table 2: Clinical Outcomes, Patient Satisfaction, and Adverse Effects.

Outcome	Group A: Clindamycin 1% (n=10)	Group B: Ozenoxacin 2% (n=10)	p-value
Primary Outcomes			
Reduction in Inflammatory Lesions			
Baseline (mean ± SD)	12.4 ± 3.1	13.1 ± 2.9	0.48
8 Weeks Mean (SD)	5.6 (2.0)	4.3 (1.8)	0.03
Reduction in Non-inflammatory Lesions (GAGS)			
Baseline Mean (SD)	8.2(2.5)	7.8 (2.7)	0.71
8 Weeks Mean (SD)	3.4 (1.5)	3.9 (1.4)	0.45
Secondary Outcomes			
Patient Satisfaction Score			
Baseline Mean (SD)	5.2 (1.0)	5.3 (0.9)	0.82
8 Weeks Mean (SD)	8.1 (1.2)	8.6 (1.1)	0.56
Adverse Effects			
Mild Irritation	2 (20%)	1 (10%)	0.62
Moderate Irritation	1 (10%)	0 (0%)	0.31
No Adverse Effects	7 (70%)	9 (90%)	0.38

Notes: GAGS = Global Acne Grading System.

Values are expressed as mean ± SD or number (percentage).

Statistical comparisons: *Student's t-test* for continuous variables; *Chi-square test* for categoricalvariables.

Bold p-values indicate statistical significance (p < 0.05).

Declaration by Authors

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Authors contribution: PKR: Study conception and design, supervision of clinical work.

AS: Patient recruitment, data collection, and literature review.

HN: Clinical assessments, data recording, and statistical analysis.

PS: Patient follow-up and treatment monitoring.

AS: Manuscript drafting, critical revision, and final approval of the version to be published.

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