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Original Research Article

COMPARISON OF ISOTRETINOIN COMBINED WITH DESLORATADINE VERSUS ORAL ISOTRETINOIN ALONE IN THE MANAGEMENT OF ACNE VULGARIS

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ABSTRACT

Background: *Acne vulgaris is a chronic inflammatory skin disorder frequently managed with oral isotretinoin. However, the associated side effects, particularly mucocutaneous and inflammatory reactions, may limit treatment compliance. Antihistamines such as desloratadine have been proposed to mitigate side effects and enhance treatment outcomes.* ***Objective:*** *To compare the therapeutic efficacy and safety profile of oral isotretinoin combined with desloratadine versus isotretinoin alone in patients with acne vulgaris.* ***Study Design****: comparative study* ***Setting:*** *Department of Dermatology, MTI DHQTH/Gomal Medical College, Dera Ismail Khan, Pakistan.* ***Duration of Study:*** *January 2024 to July 2024.* ***Methods:*** *A total of 68 patients diagnosed with moderate-to-severe acne vulgaris were enrolled and divided into two groups (n=34 each). Group A received 20 mg/day of oral isotretinoin plus 5 mg/day of desloratadine, while Group B received 20 mg/day of isotretinoin alone. Treatment was administered for 18 weeks. Efficacy was measured using the Global Acne Grading System (GAGS), with therapeutic success defined as a ≥90% reduction in GAGS score. Side effects were recorded. Statistical analysis was performed using SPSS version 25, with chi-square and independent t-tests applied; $p < 0.05$ was considered significant.* ***Results:*** *The mean age was 22.82 ± 3.64 years in Group A and 22.68 ± 4.13 years in Group B. Group A showed a significantly greater reduction in GAGS scores (1.26 ± 0.75) compared to Group B (3.03 ± 1.26) ($p = 0.0001$). Therapeutic success was achieved in 79.4% of patients in Group A versus 52.9% in Group B ($p = 0.02$). Additionally, Group A reported significantly fewer side effects than Group B ($p = 0.02$).* ***Conclusion:*** *The combination of isotretinoin and desloratadine demonstrated superior efficacy and a more favorable safety profile compared to isotretinoin alone in the management of acne vulgaris. This dual therapy may be a valuable option for improving treatment outcomes and tolerability.*

Keywords: Acne Vulgaris, Isotretinoin, Desloratadine, Combination Therapy, Efficacy, Global Acne Grading System (GAGS), Side Effects, Inflammatory Lesions, Non-Inflammatory Lesions

INTRODUCTION

Acne vulgaris (AV) is a prevalent inflammatory condition of the pilosebaceous unit that exhibits a chronic progression. The condition usually appears with papules and pustules mainly on the face, but it may also involve the upper arms and back. The pathological process of AV encompasses the interplay of various factors that culminate in the development of the main lesion known as "comedo". AV tends to occur in adolescents; nonetheless, it is not limited to this societal and can impact people across different age groups. The severity of this skin disorder varies from mild presentations with few comedones to severe forms designated by disfiguring inflammatory appearances, which may result in hyperpigmentation, scarring, as well as negative psychological effects (1-3). The estimated incidence rates among adolescents are 35% (4). The typical development of this condition may begin between the ages of 7 and 12 and usually resolves by the third decade of life. Acne can last into adulthood for the first time throughout this stage of life. Adolescent acne demonstrates a higher prevalence in males as opposed to females. Conversely, postadolescent acne primarily impacts females. About 20% of those affected encounter severe acne that results in scarring. Evidence indicates that particular ethnic and racial populations may exhibit variances in severity as well as prevalence of AV (5).

Recent studies have focused on the application of various antihistamines in conjunction with retinoids. Antihistamines, as well as anti-inflammatory medications, can act as adjunct therapies for acne treatment (6). Desloratadine is categorised as a second-generation antihistamine due to its outstanding effectiveness as well as acceptable tolerability in the treatment of histamine-related conditions. Isotretinoin targets sebaceous glands as well as is utilised for the treatment of severe acne (7-10). The guidelines implicitly recommend traditional daily administration of isotretinoin to people with severe acne as compared to intermittent dosing. Standard isotretinoin is a viable option (11). The interplay of isotretinoin, antihistamines, as well as retinoic acid receptor beta is situated within the broader structure of retinoic acid signaling networks (12). The combination of this treatment alongside additional first-line medications for acne, including isotretinoin, is right now under investigation (13). Research indicates that antihistamines can decrease inflammation while avoiding the formation of acne scars (14).

AV is a common chronic inflammatory skin condition that significantly impacts the quality of life of affected individuals, particularly adolescents and young adults. Oral isotretinoin remains the most effective treatment for moderate to severe acne. Recent evidence suggests that combining isotretinoin with antihistamines like desloratadine may reduce inflammatory responses and mitigate these side effects, potentially improving treatment tolerability as well as patient compliance. Despite this promising approach, there is a paucity of comparative clinical studies evaluating the efficacy and safety of isotretinoin combined with desloratadine versus isotretinoin alone. This study aims to address this knowledge gap by assessing whether the addition of desloratadine improves clinical outcomes and reduces adverse effects in patients with acne vulgaris undergoing isotretinoin therapy.

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METHODOLOGY

This comparative study was conducted at the Department of Dermatology from January 2024 to July 2024 at MTI DHQTH/Gomal Medical College, Dera Ismail Khan. Sixty-eight patients were enrolled for this study, which was equally distributed to Group A (isotretinoin + desloratadine) and Group B (isotretinoin only).

Inclusion standards required patients to be greater or equal to 18 years old with mild to moderate acne vulgaris, which was assessed by the Global Acne Grading System (GAGS) score. Patients with a history of hypersensitivity to isotretinoin or desloratadine, pregnancy, breastfeeding, or other serious health conditions such as liver or kidney disease were not enrolled.

The treatment regimens involved Group A receiving 20 mg of oral isotretinoin daily combined with 5 mg of desloratadine daily. Group B received 20 mg of oral isotretinoin daily, without any adjunctive medication. Both treatments were administered for a duration of 18 weeks.

Efficacy was primarily evaluated based on changes in the GAGS score, with a >90% reduction in the GAGS score being defined as a notable therapeutic response. Secondary efficacy outcomes included side effects, which were assessed by monitoring the patients throughout the study for Cheilitis/Xerosis and Pruritus. After 18 weeks of treatment, we compared the baseline GAGS score with the post follow-up GAGS score.

All data were analyzed with SPSS 25. We calculated the mean and SD for numerical data, and we evaluated frequencies and percentages for categorical data. The chi-squared test was used for comparing categorical outcomes, while the t-test was used for comparing numerical outcomes. We kept the P value notable at < 0.05.

RESULTS

The mean age in Group A was 22.82±3.64 years and in Group B 22.68±4.13 years. Gender distribution showed that there were 13 (38.2%) males in Group A and 12 (35.3%) in Group B, while females were 21 (61.8%) in Group A and 22 (64.7%) in Group B (Figure 1). The mean no of lesions in both groups can be seen in Table 1.

At baseline, acne severity assessed by GAGS showed no notable difference between groups (p=0.30). After 18 weeks of treatment, Group A demonstrated a markedly greater reduction in GAGS scores, 1.26±0.75 compared to Group B, 3.03±1.26, with the difference being statistically notable (p<0.0001) (Table 2). Efficacy, defined as a >90% reduction in GAGS scores, was achieved by 79.4% patients in Group A, which was potentially higher than the 52.9% observed in Group B (p=0.02) (Table 3).

Regarding safety, Group A reported fewer side effects. Pruritus occurred in 4 (11.8%) patients of Group A versus 10 (29.4%) in Group B (p=0.02). Similarly, cheilitis/xerosis was less frequent in Group A3 (8.8%) compared to Group B8 (23.5%) (Table 4).

These findings suggest that combining isotretinoin with desloratadine enhances therapeutic outcomes, significantly improving acne severity while reducing common adverse effects associated with isotretinoin monotherapy. The results align with prior studies highlighting the anti-inflammatory and sebum-regulating benefits of desloratadine in acne management.

Table 1: Number of lesions in both groups at presentation

Groups		No of lesion
Group A (Combination Therapy (Isotretinoin + Desloratadine)	Mean	54.44
	N	34
	Std. Deviation	7.766
Group B (Isotretinoin alone)	Mean	55.56
	N	34
	Std. Deviation	9.535

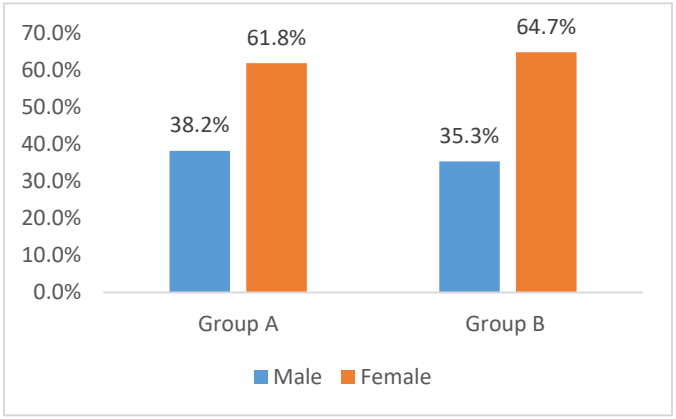

Figure 1: Gender distribution

Table 2: Comparison of GAGS score at baseline and 18 weeks

	Groups	N	Mean	Std. Deviation	P value
GAGS score at baseline	Group A (Combination Therapy (Isotretinoin + Desloratadine)	34	23.53	4.143	0.30
	Group B (Isotretinoin alone)	34	22.53	3.847	
GAGS score after 18 weeks	Group A (Combination Therapy (Isotretinoin + Desloratadine)	34	1.26	.751	0.0001
	Group B (Isotretinoin alone)	34	3.03	1.267	

Table 3: Comparison of efficacy between both groups

Efficacy (>90% reduction in GAGS score)	Groups				P value
	Group A (Combination Therapy (Isotretinoin + Desloratadine)		Group B (Isotretinoin alone)		
	n	%	n	%	
Yes	27	79.4%	18	52.9%	0.02
No	7	20.6%	16	47.1%	

Table 4: Comparison of side effects between both groups

Side effects	Groups				P value
	Group A (Combination Therapy (Isotretinoin + Desloratadine)		Group B (Isotretinoin alone)		
	n	%	n	%	
Pruritus	4	11.8%	10	29.4%	0.02
Cheilitis/Xerosis	3	8.8%	8	23.5%	
No side effects	27	79.4%	16	47.1%	

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DISCUSSION

The population in our study was well-balanced in terms of age and gender, with mean ages of 22.82±3.64 years in the combination group and 22.68±4.13 years in the isotretinoin-alone group. This demographic profile is consistent with Mansoor et al., where the mean age was 21.7±3.2 years in the combination group and 22.5±3.3 years in the monotherapy group (15). The gender distribution, 61.8% females in the combination group and 64.7% in the monotherapy group, also mirrors trends observed in other studies, including Van et al. (2019), where females constituted 20/31 in the combination group and 19/31 in the control group (14). This consistency suggests that acne predominantly affects young adults, particularly females, reinforcing the need for effective and tolerable treatments in this demographic.

The most striking finding was the significant reduction in acne severity (GAGS score) in the combination group (1.26±0.75) compared to isotretinoin alone (3.03±1.26) after 18 weeks ($p<0.0001$). This improvement is consistent with multiple studies. Similarly, Van et al. observed a mean GAGS score of 3.71±3.81 with combination therapy compared to 6.52±4.35 with isotretinoin alone (14). Mansoor et al. reported a final GAGS score of 1.35±1.63 in the combination group versus 4.00±3.40 in the isotretinoin-only group (15). The nearly identical trends across studies suggest a robust synergistic effect between isotretinoin and desloratadine, likely due to the anti-inflammatory and sebum-suppressive properties of antihistamines (16). The efficacy rate (defined as >90% reduction in GAGS score) was considerably higher in the combination group 79.4% than in the isotretinoin-alone group 52.9% ($p=0.02$). This finding is supported by Yosef et al. in who noted that the combination therapy of isotretinoin with antihistamines can result in better efficacy than isotretinoin alone (17). In a mini review, it was stated that isotretinoin in combination with desloratadine provides better efficacy than isotretinoin alone (5). The enhanced efficacy may be attributed to desloratadine's ability to inhibit histamine-mediated inflammation and reduce squalene production in sebocytes (19).

A notable advantage of the combination therapy was its favorable side-effect profile. Pruritus occurred in only 11.8% of patients receiving isotretinoin plus desloratadine compared to 29.4% in the isotretinoin-alone group ($p=0.02$). This aligns with Pandey et al, where they reported that the combination treatment of antihistamine with isotretinoin had notably lower side effects than the alone therapy.20 Similarly, Elsekily et al documented a notably lower rate of pruritus in the combination group when compared with the isotreinoin alone group (21). Cheilitis and xerosis were less frequent in the combination group (8.8%) than in the monotherapy group (23.5%).

Interestingly, 79.4% of patients in the combination group reported no side effects compared to only 47.1% in the isotretinoin-alone group. This is consistent with the aforementioned mini review, where the combination group experienced fewer systemic adverse effects (18). The improved tolerability could enhance treatment adherence, a critical factor in acne management given that isotretinoin's side effects often lead to discontinuation.

Given the enhanced efficacy and reduced side effects observed in our study, isotretinoin-desloratadine combination therapy should be considered a first-line option for moderate to severe acne, particularly in patients prone to isotretinoin-induced dryness or pruritus. Future research should explore optimal dosing strategies and long-term outcomes, including relapse rates and scar prevention.

CONCLUSION

In conclusion, isotretinoin combined with desloratadine exhibited better efficacy in terms of GAGS score and lower incidence of side effects than oral isotretinoin alone in the management of acne vulgaris.

DECLARATIONS

Data Availability Statement
All data generated or analysed during the study are included in the manuscript.

Ethics approval and consent to participate
Approved by the department Concerned.

Consent for publication
Approved

Funding
Not applicable

CONFLICT OF INTEREST

The authors declared an absence of conflict of interest.

AUTHOR CONTRIBUTION

ALSHIFA KHAN AFRIDI *(Postgraduate Resident)*
Conception of Study, Development of Research Methodology Design, Study Design, Review of manuscript, final approval of manuscript.
SAMAN WAHAB *(Postgraduate Resident)*
Manuscript revisions, Critical input, Manuscript drafting, Final Approval of Draft
MANAL LATIF *(MBBS DDERM)*
Study Design, Review of Literature.
MARIA SHAKIR *(Medical Officer)*
Crtical Input, and Literature review
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