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Original Article

Comparative study between Isotretinoin Alone versus Isotretinoin Combined with Either Levocetirizine or Desloratadine in The Treatment of Acne Vulgaris

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Abstract

Background: Many studies have proved isotretinoin's effectiveness in the treatment of acne. However, because of the potential for mucocutaneous side effects and acne outbreaks, it should be used and monitored with caution. To avoid undesired side effects, not only different dosing regimens being established, but also new options for decreasing sebum, such as antihistaminic medications.

The aim of the work: This study aims to assess the efficacy and negative impacts of isotretinoin as a single therapy compared to its combination with Levocetirizine or Desloratadine in managing moderate to severe acne.

Patients and methods: This study is a Randomized clinical trial that included 60 moderates to severe acne patients. It was implemented in the dermatology department at Al-Azhar university hospital in Damietta. Patients were randomized into three matched groups; Group A [n=20]; which included patients received isotretinoin alone, Group B [n=20]; which included patients received isotretinoin and levocetirizine. Group C [n=20]; which included patients received isotretinoin and Desloratadine. The primary outcomes of the study were Global Acne Grading System [GAGS], inflammatory, non-inflammatory and total lesion counts.

Results: By comparing the three study groups as regards the GAGS, we found a significant difference between Isotretinoin alone group and the both groups of Isotretinoin-Antihistaminic combination after 3 months of treatment [P <0.05]. As regard to lesions count, we found a statistically significant difference of the mean inflammatory and total acne lesion count between Isotretinoin alone group and the both groups of Isotretinoin-Antihistaminic combination at all 3 the treatment intervals.

Conclusion: The findings of this study show that the combination of oral antihistamines [Desloratadine or Levocetirizine] with oral isotretinoin produces better outcomes and advantages compared to using isotretinoin alone, in terms of both efficacy and tolerability.

Keywords: Isotretinoin; Levocetirizine; Desloratadine; Global Acne Grading System.

INTRODUCTION

Acne vulgaris is a highly common skin disorder that is widespread globally, mostly affecting adolescents, with a prevalence rate of 80.0% [1]. During adolescence, the sebum production is stimulated by androgens because 5-alpha reductase transforms testosterone into the more potent Dihydrotestosterone [DHT], which binds to specific receptors in the sebaceous glands to increase sebum production. It results in excessive proliferation of the follicular epidermis, leading to sebum retention. Inflammation results from the rupture of distended follicles, which releases pro-inflammatory chemicals into the dermis. Malassezia furfur, Staphylococcus epidermis, and C. acnes promote follicular epidermal growth and inflammation [2].

Isotretinoin is considered the most potent medication now on the market among the therapeutic agents. Several studies have shown its efficacy to treat acne as it's the only medication that addresses all acne-causing factors [3]. However, due to unfavorable mucocutaneous side effects and the possibility of acne flare-ups resulting in medication termination at the start, it must be used carefully and be monitored [4].

Not only various regimens for dosage are being introduced to prevent undesirable side effects, but new approaches to decrease sebum production are also being developed. Antihistamines reduce anxiety, hormonal imbalances, inhibit inflammatory mediators, cutibacterium acne-induced irritation, and the generation of less squalene and sebum in sebocytes [5]. By functioning as an inflammatory mediator during the immunological response to inflammatory acne, histamine may play a role in the development of acne. Additionally, Propionibacterium acnes change the pH of the microenvironment around the acne follicle, which is perfect for the synthesis of histamine or histamine-like substances, which causes itching in acne patients [4]. Furthermore, an in vitro study that identified histamine receptors and reduced squalene levels in sebocytes by using an antihistamine illustrated the importance of histamine in the production of sebum. It's demonstrated that oral antihistamines have sebum-regulating activity, mast cell degranulation inhibition, anti-inflammatory effect, and anti-chemotactic properties against various inflammatory cells. Taking everything into consideration, antihistamines have been shown to decrease sebocyte lipogenesis in addition to their potent anti-inflammatory effects [6, 9].

So, the purpose of this research is to compare the efficacy and negative effects of treating moderate to severe acne with isotretinoin alone vs in combination with levocetirizine or desloratadine.

PATIENTS AND METHODS

This study is a randomized clinical trial that included 60 moderates to severe acne patients. It was implemented in the dermatology department at Al-Azhar university hospital in New Damietta from March 2023 to March 2024. We included the patients based on the following criteria.

Inclusion criteria included being above the age of 18 and having moderate to severe acne vulgaris. In addition, female patients who are pregnant, breastfeeding, or planning to become pregnant [due to the potential teratogenic effect of isotretinoin], and patients with other systemic illnesses [such as kidney disease, dyslipidemia, or liver disease], simultaneous use of other acne medications, as well as any patient who did not provide consent or refused to participate in the trial were excluded from the study.

A convenience sample technique was done to assess our research. All attendants who match the inclusion criteria were recruited until the desired sample size was achieved. Patients were randomized using computer-generated tables to allocate treatments in a 1:1:1 ratio into 3 groups: Group A [n=20] received isotretinoin alone at a rate of 0.5-1 mg/kg/day in two divided doses with or after food until the cumulative dose 120-150 mg/Kg over 6 months in severe cases and 0.25-0.5mg/Kg/day for 6 months in moderate cases, Group B [n=20] received isotretinoin [the same dose as group A] and Levocetirizine 5 mg/day just before sleep, and Group C [n=20] received isotretinoin [the same dose as group A] and Desloratadine 5 mg/day just before sleep.

Data Collection:

Patients had baseline, 1-, 3-, and 6-months post-treatment evaluations. Every patient was exposed to the following: full history taking, general and local examination, investigations: CBC, liver function tests [ALT, AST, bilirubin, and albumin], serum Creatinine, and lipid profile.

Digital images were taken at baseline and follow-up visits, and the global acne grading system [GAGS] score was applied to clinically grade the acne lesion. Based on the surface area and distribution/ density of pilosebaceous units, GAGS divides the face, chest, and back into six regions: the forehead, each cheek, nose, chin, chest, and back. Each region is then assigned a factor. A severity level is given to each kind of lesion: no lesions = 0, comedones = 1, papules = 2, pustules = 3, and nodules = 4. The following formula is used to estimate the score [local score] for each region: local score = factor × grade [0–4]. Acne severity was graded using the global score, which is the sum of the local scores. Mild is defined as a score of 1–18, moderate as 19–30, severe as 31–38, and very severe as >39 [6].

The main outcomes were the total number of lesions [inflammatory and non-inflammatory], their site and duration, the Global Acne Grading System [GAGS] score, and the final global score, which ranked the patients' acne from none to very severe [7].

The secondary outcomes were the side effects, which were evaluated at every follow-up visit. These included systemic adverse effects including fatigue, bone/joint pain, muscular cramps, and so on, as well as the frequency and severity of cheilitis, xerosis, xerostomia, dry eyes, epistaxis, and pruritus. Acne flare-up frequency and severity were assessed. A 4-point scale was used to assess the degree of acne flare-ups: none [no new lesion], mild [< 5 nodules], moderate [5–10 nodules], and severe [≥ 10 nodules] [1].

Ethical consideration:

The study design was approved at 13/1/2023 by the Local Ethics Committee of Damietta Faculty of Medicine/ Al-Azhar University [DFM-IRB00012367-23-01005]. Before data collection began, each patient provided informed consent, and the study's purpose and methods were described to the selected individuals. All information gathered is kept private and is solely utilized for research.

Statistical analysis:

The statistical analysis was carried out using SPSS statistical software version 25 [IBM, Chicago, Illinois, USA]. The Kolmogorov-Smirnov test was used to test the normality of data. Quantitative data was presented as mean and standard deviations, median and interquartile range, respectively; qualitative data were represented as numbers and percentages, which were compared using the Chi-square test. To compare the three groups for parametric data, we used One-way ANOVA test while the Kruskal Wallis test was used for nonparametric data. The p-value was considered significant at ≤ 0.05.

RESULTS

Our study included 60 patients. The patients' mean age was 21.1 ± 1.8 years. Forty percentage of patients were male and 60% were female. Thirty-seven patients were from urban areas and 23 patients were from rural areas. All the study groups were relatively similar as regards their demographics [Age, Gender, Residency] and the difference between them was not significant [P > 0.05 for all] **[Table 1].**

In terms of the disease duration, the mean duration was 2.2 ±0.89 years with no significant difference between the three groups [P = 0.4]. According to the family history of acne, 46.7% of the patients had a positive family history **[Table 2].**

In terms of the count of lesions, all three groups had a significant reduction in both inflammatory and non-inflammatory lesions. At all three treatment intervals, we observed a significant difference in the mean number of inflammatory acne lesions between the group receiving isotretinoin alone and the groups receiving isotretinoin-antihistaminic combination **[Table 3].**

The combination group's median GAGS was significantly lower than that of the isotretinoin alone group after three months of therapy [P = 0.003] **[Table 4, Figure 1].**

According to the complications, Cheilitis was the most common side effect after one month, affecting approximately 90% of patients in the 3 groups but there was a significant better improvement over the follow up intervals in the combination groups than the isotretinoin alone group. **[Figure 2]**.

Other side effects included pruritus, xerosis and a few cases experienced dry eyes, xerostomia, fatigue and only one case in group A had a mild transient epistaxis once. Full details about the complications are in **[Table 5]**

Also, acne flare was reported in 25.0% of patients in group A, 10.0% of patient in group B, and 15.0% of patients in group C and it ranged from mild to moderate in the 3 groups. None of the side effects were different across the 3 groups [p > 0.05] except for pruritus and acne flare which had significant difference with p = 0.03 at 1, 3, 6 months. **[Figure 3, 4]**

Lipid profiles and liver enzyme tests were performed for each patient at baseline and three and six months after their therapy. All patients had normal baseline blood cholesterol and triglyceride levels; throughout treatment follow-up, most patients saw a rise in these levels, but still within normal levels. There were no significant changes in results between the 3 groups **[Table 6].**

Table [1]: Demographic data of the studied patients.

Variables		Total [N=60]	Group A [N=20]	Group B [N=20]	Group C [N=20]	P value
Age [Years]	Mean ± SD	21.1 ± 1.8	21.2 ± 1.6	21.1 ± 1.7	21 ± 2	0.96 [a]
	Range	18 - 25	19 - 24	18 - 25	18 – 24	
Gender [n, %]	Male	24 [40.0%]	9 [45.0%]	7 [35.0%]	8 [40.0%]	0.8
	Female	36 [60.0%]	11 [55.0%]	13 [65.0%]	12 [60.0%]	
Residency [n, %]	Urban	37 [61.7%]	14 [70.0%]	12 [60.0%]	11 [55.0%]	0.6
	Rural	23 [38.3%]	6 [30.0%]	8 [40.0%]	9 [45.0%]	

a: One way ANOVA.

Table [2]: Clinical data of the studied patients

	Variables	Total [N=60]	Group A [N=20]	Group B [N=20]	Group C [N=20]	P value
Disease duration [years]	Mean ±SD	2.2 ±0.89	2 ± 0.8	2.3 ± 0.95	2.4 ±0.94	0.41[a]
	Range	1 – 4	1 – 4	1 – 4	1 – 4	
Weight [Kg]	Mean ±SD	67.5 ± 6	64.7 ± 8.2	66 ± 4.5	68.1 ± 4.6	0.37[a]
	Range	55 – 80	59 – 77	59 – 73	55 – 80	
Family history [n, %]	Positive	28 [46.7%]	8 [40.0%]	10 [50.0%]	10 [50.0%]	0.7
	Negative	32 [53.3%]	12 [60.0%]	10 [50.0%]	10 [50.0%]	

a: One way ANOVA

Table [3]: Comparison between the three studied groups regarding the lesions count over the follow up periods

Group	Lesions count [Mean ± SD]	Baseline	After 1 month	After 3 months	After 6 months	P value [a]
Group A	Inflammatory	46.1 ± 10.4	40.4 ± 5.5	15.6 ± 10.3	2.4 ± 2.1	0.009
	Non-Inflammatory	20.0 ± 14.6	17.2 ± 2.3	5.5 ± 4.6	1.1 ± 1.3	0.9
	Total	66.1 ± 18.2	57.6 ± 5.1	21.1 ± 11.9	3.5 ± 4.2	0.18
Group B	Inflammatory	44.3 ± 10.9	37.3 ± 3.6	12.4 ± 8.3	1.0 ± 1.2	0.009
	Non-Inflammatory	21.6 ± 16.9	16.0 ± 2.7	3.7 ± 5.8	1.2 ± 1.0	0.9
	Total	65.9 ± 19.2	54.3 ± 6.7	16.1 ± 10.9	2.2 ± 1.5	0.18
Group C	Inflammatory	47.0 ± 9.3	35.0 ± 7.8	13.6 ± 9.5	1.1 ± 1.2	0.009
	Non-Inflammatory	20.3 ± 15.7	14.3 ± 4.0	4.2 ± 5.7	1.0 ± 2.0	0.9
	Total	67.3 ± 18.8	49.3 ± 8.3	17.8 ± 11.0	2.1 ± 1.1	0.18

a: One way ANOVA.

Table [4]: Comparison between the three studied groups regarding the Global Acne Grading System over the follow up periods.

GAGS Median [IQR]	Group A [N=20]	Group B [N=20]	Group C [N=20]	P value [a]
Baseline	31 [24.5–32]	32 [27–34]	31 [24–33]	0.3
After 1 month	23 [20–26.5]	22.5 [18–25]	20.5 [15–23]	0.4
After 3 months	17 [12–19]	12 [10–15.8]	11[9.25–14.9]	0.03
After 6 months	3 [0–5]	1 [0–3]	0 [0–2.5]	0.02

a: Kruskal Wallis test.

Table [5]: Complications of the studied patients.

Complications	Group A [N=20]	Group B [N=20]	Group C [N=20]	P value[a]
Acne Flare	5 [25.0%]	2[10.0%]	3 [15.0%]	0.03
Cheilitis	18 [90.0%]	17 [85.0%]	19 [95.0%]	0.1
Pruritus	15 [75.0%]	4 [20.0%]	2 [10.0%]	0.02
Xerosis	8 [40.0%]	5 [25.0%]	6 [30.0%]	0.5
Dry eyes	3 [15.0%]	0 [0.0%]	1 [5.0%]	0.3
Xerostomia	0 [0.0%]	2 [10.0%]	1 [5.0%]	0.2
Epistaxis	1 [5.0%]	0 [0.0%]	0 [0.0%]	0.6
Fatigue and muscle cramps	2 [10.0%]	3 [15.0%]	2 [10.0%]	0.9

a: One way ANOVA.

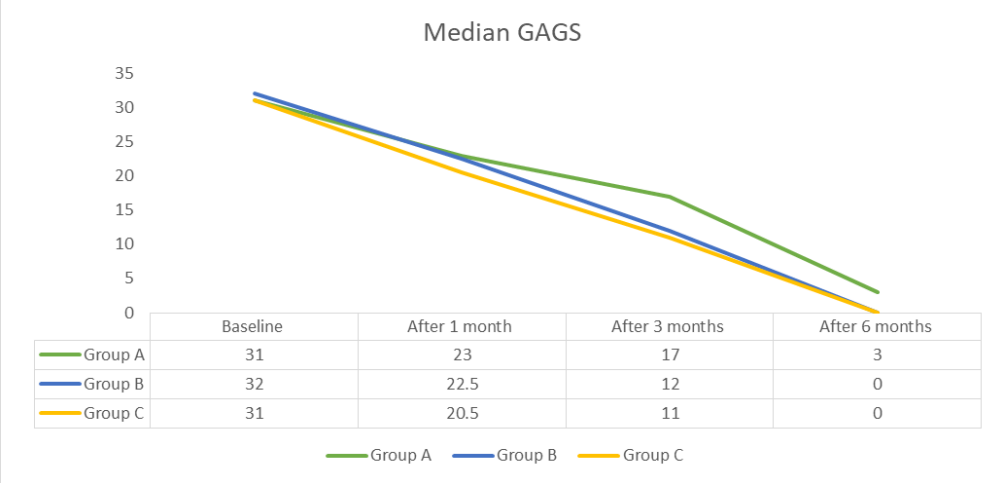

Figure [1]: GAGS of the studied groups all over the follow up periods.

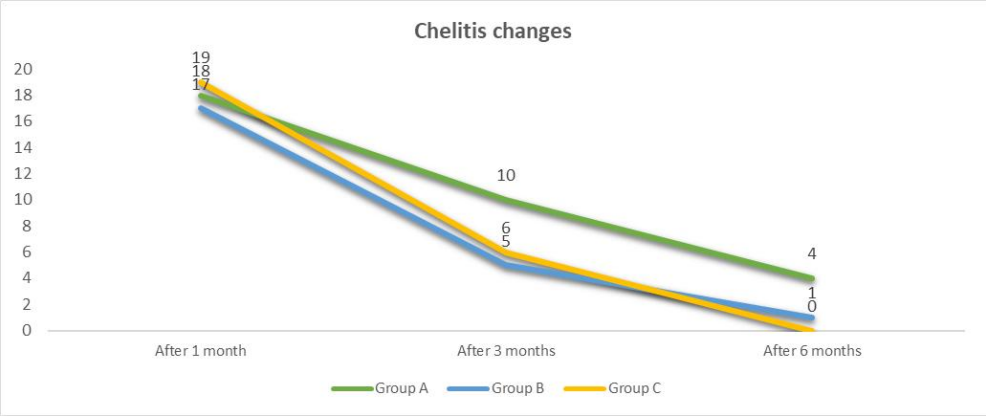

Figure [2]: Cheilitis changes over the 3 follow up intervals.

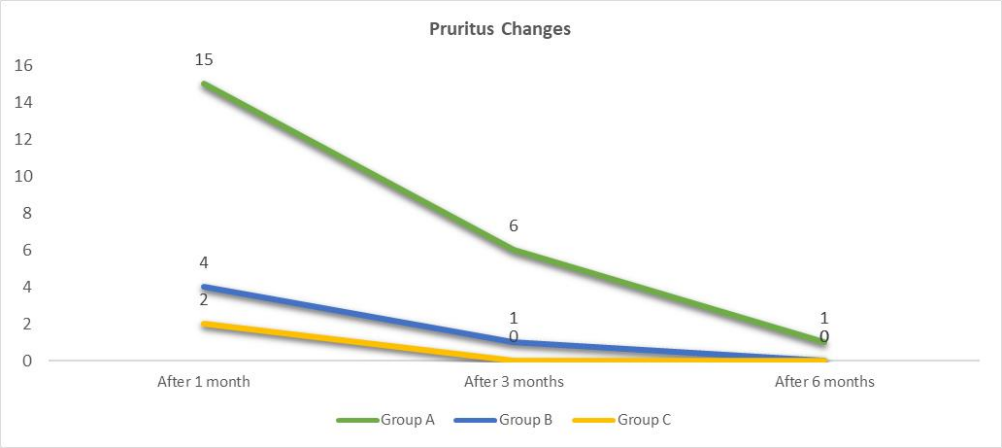

Figure [3]: Pruritus changes over the 3 follow up intervals.

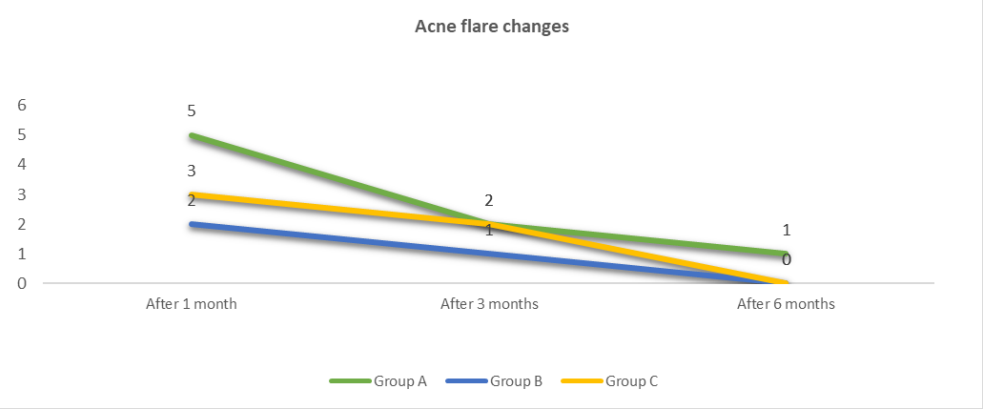

Figure [4]: Acne flare changes over the 3 follow up intervals.

DISCUSSION

Acne vulgaris is a common chronic inflammatory condition affecting the pilosebaceous unit. The disorder most usually presents with papules, pustules, or nodules on the face, it can also affect the upper arms, trunk, and back. Its pathogenesis is characterized by the interaction of various variables that finally lead to the formation of its main lesion, known as "comedo". The severity of this condition ranges, from a mild presentation with a few comedones to more serious forms with disfiguring inflammation that may result in hyperpigmentation, scarring, and negative psychological effects [2].

There is a high prevalence of acne during the teenage years, affecting around 80–90% of adolescents in the Western world. In rural countries, the incidence of acne is estimated to be lower. In most cases, it is brought on by a rise in the levels of androgens such as testosterone, which usually happens throughout puberty in both males and females[4].

Over the last 25 years, a large number of topical and systemic medicines have been produced for acne vulgaris treatment. There are certain patients who are seriously impacted and require additional treatment in addition to acne treatments [8].

Currently, isotretinoin is the only medication that targets every pathogenic component linked to acne. However, its use is linked to a number of dose-dependent adverse effects [4].

In response to these worries, a number of papers suggest that patients with acne have found success with low dose or intermittent treatment regimens as opposed to the 0.5–1.0 mg/kg standard daily dosage. Some research looked at the potential use of an antihistamine to reduce sebum in a model system of sebocyte cell culture [5].

Levocetirizine is a second-generation antihistamine that has a higher affinity for H1-receptors, less anticholinergic side effects, and a favorable safety profile. It has the strong capacity to lessen wheal and flare reactions, same as cutaneous histamine-induced itching [4, 5].

Desloratadine is an oral antihistamine of the second generation that is nonsedating. In addition to its sebum-regulating function, it inhibits mast cell degranulation, is anti-inflammatory, and has antichemotactic features against different inflammatory cells. Additional benefits of desloratadine include safety and the lack of a pharmacological interaction with isotretinoin. Acne lesions may be accompanied by itching, which can negatively impact patients' quality of life. Antipruritic medication should prioritize treating acne-related irritation [8, 9]. Therefore, the purpose of this research is to compare the efficacy of isotretinoin alone versus that of isotretinoin combined with either Levocetirizine or desloratadine.

The current study included 60 patients allocated equally into 3 groups; Group A [Isotretinoin alone], Group B [Isotretinoin and Levocetirizine] and Group C [Isotretinoin and Desloratadine]. We reported that there was nonsignificant difference between 3 groups as regard demographic data [age, sex and residency]. Also, as regard to disease duration, weight and family history. **Van *et al.*** investigated how effectively oral isotretinoin worked both by itself and alongside desloratadine to treat moderate cases of acne vulgaris. Van et al.'s findings support ours, showing that there was no apparent difference in weight between the two groups. Additionally, the patient gender, age, average duration of disease, number of lesions, severity of the disease, and isotretinoin dosage were similar between the two groups [1]. In another investigation, **Pandey and Agrawal** aimed to determine if taking isotretinoin alone at week 12 was safer and more effective than taking it with an antihistamine for patients with moderate to severe acne. There were 80 participants in the trial: 39 in the isotretinoin alone group and 41 in the combination group. Both groups were mostly comparable, and there was little variation in age, gender, and family history [4].

An assessment of the efficacy of oral isotretinoin in combination with desloratadine for the treatment of acne vulgaris was conducted in a related study. According to this study, women were more impacted than men; in the study group, women made up 53.3% of the total, while men made up 46.7%. In the control group, the percentages were 63.3 % and 36.7%, respectively [10].

For severe and nodulocystic acne, **Dhaher and Jasim** aimed to assess how well oral desloratadine worked in combination with an azithromycin and isotretinoin regimen. Their study included seventy-six patients who completed the study period [9].

In terms of the lesions count, this study findings revealed that there was a significant difference in the mean number of inflammatory acne lesions between the group receiving isotretinoin alone and the groups receiving isotretinoin-antihistaminic combination at the three treatment intervals [p = 0.009]. This is consistent with the results of Van et al. whose results showed that the number of inflammatory lesions was significantly lower in the combination group than that in the isotretinoin only group [p < 0.025]. Similarly, the results of **Lee *et al.*** revealed a significant difference of the mean non-inflammatory and inflammatory acne lesion count between the two groups after 12 weeks of treatment [p < 0.001] [6].

Our study reported that there was a significant difference [P = 0.003] in median GAGS score between the isotretinoin alone group 17 [12–19] versus the combination groups 12 [10–15.8] & 11[9.25–14.9] after 3 months of treatment. Also, as regard to lesions count, we found a significant difference of the mean count of inflammatory and total acne lesions between Isotretinoin alone group and the both groups of Isotretinoin-Antihistaminic combination at all 3 the follow up intervals.

After 16 weeks, **Van *et al.*** reported that the study group's mean GAGS score was lower than the control group's [3.71 ± 3.81 vs 6.52 ± 4.35], with p = 0.015. This is consistent with our findings [1].

According to **Lee *et al.*** [6], the study group's GAGS scores started to decline in week 2. But the real changes didn't happen until week four.

Yosef's study revealed similar results [5]. Also, in agreement with our results, Pandey and Agrawal found that the mean GAGS score decreased considerably [p=0.005] from 29.52 ± 3.861 to 14.46 ± 5.467 [51.0%] and 17.82 ± 6.07 [38.5%] in the treatment and control groups after 12 weeks [4].

On the other hand, **Abuarij and Al Qtwan's** assessment after 16 weeks of treatment revealed that both groups' GAGS scores responded well to therapy, with 86.7% of the study group scoring excellent and 13.3% scoring good, while the control group scored 56.7% excellent and 40% good [10].

As regard to complications; in the current study, cheilitis was the most common side effect after one month, affecting approximately 90% of patients in the 3 groups but there was a significant better improvement over the follow up intervals in the combination groups than the isotretinoin alone group. Other side effects included pruritus, xerosis and a few cases experienced dry eyes, xerostomia, fatigue and only one case in group A had a mild transient epistaxis once. Also, acne flare was reported in 25% of the patients in group A, 10% of patient in group B, and 15% of patients in group C and it ranged from mild to moderate in the 3 groups. There was no difference in side effects between the 3 groups [p > 0.05] except for pruritus and acne flare which had significant difference with p = 0.03 at 1, 3, 6 months.

According to Pandey and Agrawal, cheilitis, skin dryness, facial erythema, nasal dryness, pruritus, eye dryness, and scaling were the most common side effects in both groups. Burning sensation, skin rash, photosensitivity, epistaxis, oiliness, and hair loss were among the other side effects that were recorded. Among these side effects, it was shown that the treated group experienced much less skin dryness and pruritus than the control group. Additional blockage of histamine receptors and inflammatory cytokines in sebocytes may be the cause of this. Furthermore, a flare-up of acne occurred in 14 out of 100 individuals. There was only one patient in the combination group; the other thirteen patients [26%] were in the isotretinoin alone group, with mild to moderate flare-ups. Not any one in either group had a severe flare-up [4]. **Van *et al.*** [1] reported that during the follow-up, both

groups complained of side effects included itching, dry lips, and dry skin. Compared to the control group, the itching rate in the studied group was much lower. Between the two groups, there was no difference in terms of adverse effects such dry lips, dry skin, flaking and blushing. As regard to acne flare, at weeks 2 and 4, the study group had a substantially reduced acne flare rate than the isotretinoin alone group [$p<0.05$]. By the 16th week, neither group experienced any outbreaks.

The most frequent adverse reactions in the treatment and control groups in the **Lee *et al.*** study were cheilitis [75% and 90%], skin dryness [40% and 45%], and pruritus [15% and 45%], respectively [6].

According to **Abuarij and Al Qtwan**, at 16 weeks, 10% of the study group's patients experienced cheilitis and conjunctivitis, while 13.3% of them experienced pruritus [10].

According to **Dhaher and Jasim** [9], the most prevalent adverse effects of both interventions were mucocutaneous and gastrointestinal. Face dryness was frequent in both groups, but GIT problems were less common in the study group compared to the control group [$P < 0.05$].

For the laboratory changes, in current study the baseline serum cholesterol and triglycerides levels were within normal in all patients; during follow up, they increased in most patients. However, for the majority of patients, they were still within normal ranges. There were no significant changes in results between the 3 groups. This is consistent with other studies that reported elevated levels of AST, ALT, serum cholesterol, and triglycerides with oral isotretinoin treatment, with a more noticeable rise in blood triglycerides which may be induced by a reduction in the clearance rate of these lipids from plasma [11–13].

In **Pandey and Agrawal** study, one patient in the combination group had to discontinue therapy because of transaminitis and hypertriglyceridemia. [4]. Other studies have demonstrated an elevation in the LDL-cholesterol fraction and a drop in the HDL fraction, along with an increase in triglycerides in individuals who use isotretinoin for ≥8 weeks. However, these lipid profile changes caused by isotretinoin appear to be transitory, since they recover to baseline levels approximately 8 weeks following the end of therapy [13].

Conclusion: Our study's findings revealed that anti-histamines, when used in combination with isotretinoin as a supplemental therapy for those with moderate to severe acne, have a significant therapeutic advantage because they improve curative effectiveness and minimize side effects such as pruritus which is associated with oral isotretinoin intake. Additionally, they are well tolerated, and the results reveal that antihistamines can reduce acne progress when coupled with isotretinoin, thus offering a new approach to acne treatment. Further To validate the present results and investigate potential future recurrence during long-term follow-up, multicenter, double-blind studies are advised.

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