Original Research

Assessment of effect of Nadifloxacin and Adapalene in the treatment of acne vulgaris

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ABSTRACT:
Background: Acne vulgaris, commonly referred to as acne, is a skin condition that occurs when hair follicles become clogged with oil and dead skin cells.The present study was conducted to assess effect of Nadifloxacin and Adapalene in the treatment of acne vulgaris. **Materials & Methods:**76 cases of acne vulgarisof both genderswere prescribed 1% nadifloxacin and 0.1% adapalene gel for 8 weeks. The major efficacy variables measured at 2 weeks, 4 weeks, and 8 weeks were reductions in the overall, inflammatory, and non-inflammatory lesion counts from the baseline. **Results:** Out of 76 patients, males were 46 and females were 30. The mean severity score for inflammatory lesions at baseline was 19.2, at 2 weeks was 13.4, at 4 weeks was 10.1 and at 8 weeks was 7.8 and for non- inflammatory lesions was 58.4, 40.6, 32.4, and 19.2 respectively. The difference was significant (P< 0.05). At baseline, 2 weeks, 4 weeks and 8 weeks, mild lesions were8, 12, 14 and 37 respectively. There was reduction in severe lesions from 48 to 35, 28 and 6 from baseline, 2 weeks, 4 weeks and 8 weeks. The difference was significant (P< 0.05). **Conclusion:** For the treatment of mild to severe acne vulgaris, a fixed combination of 1% nadifloxacin and 0.1% adapalene topical gel may be a useful and well-tolerated choice.
Keywords: Acne vulgaris, adapalene, nadifloxacin

INTRODUCTION
Acne vulgaris, commonly referred to as acne, is a skin condition that occurs when hair follicles become clogged with oil and dead skin cells.[1] It is characterized by the presence of pimples, blackheads, whiteheads, cysts, and nodules, primarily on the face, neck, chest, back, and shoulders. Acne is most prevalent during adolescence, but it can also affect adults.[2]

Several factors contribute to the development of acne. The sebaceous glands in the skin produce an oily substance called sebum. Excess sebum production can lead to clogged pores, which provide an ideal environment for acne-causing bacteria to thrive.[3]Normal shedding of dead skin cells can sometimes mix with excess sebum, forming a plug in the hair follicles. This plug can trap bacteria and cause inflammation.Propionibacterium acnes (P. acnes) is a type of bacteria that lives on the skin and can contribute to the development of acne when hair follicles become clogged.Hormonal fluctuations, particularly during adolescence, pregnancy, menstruation, and menopause, can increase sebum production, making individuals more susceptible to acne.[4]

Topical fluoroquinolone nadifloxacin has been shown to have strong antibacterial activity against P. acne, S. epidermidis, and methicillin-resistant Staphylococcus aureus (MRSA), and it does not exhibit cross-resistance with other antibiotics or fluoroquinolones.[5] According to earlier research, topical nadifloxacin cream treatment demonstrated outstanding effectiveness and tolerability while not causing P. acnes strains to develop resistance. Adapalene is a topical retinoid that has anti-inflammatory properties and is known to regulate keratinization.[6]The present study was conducted to assess effect of Nadifloxacin and Adapalene in the treatment of acne vulgaris.

MATERIALS & METHODS
The present study consisted of 76 cases of acne vulgarisof both genders. All gave their written consent to participate in the study.

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Data such as name, age, gender etc. was recorded. All patients were prescribed 1% nadifloxacin and 0.1% adapalene gel for 8 weeks. The major efficacy variables measured at 2 weeks, 4 weeks, and 8 weeks were reductions in the overall, inflammatory, and non-inflammatory lesion counts from the baseline, investigator global assessment (IGA), and reductions in the severity of acne as classified by the combined acne severity categorization.Data thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

RESULTS

Table I Distribution of patients

Total- 76		
Gender	Male	Female
Number	46	30

Table I shows that out of 76 patients, males were 46 and females were 30.

Table II Comparison of mean severity score

Period	Inflammatory	Non- inflammatory
Baseline	19.2	58.4
2 weeks	13.4	40.6
4 weeks	10.1	32.4
8 weeks	7.8	19.2
P value	0.01	0.02

Table II, graph I shows that mean severity score for inflammatory lesions at baseline was 19.2, at 2 weeks was 13.4, at 4 weeks was 10.1 and at 8 weeks was 7.8 and for non- inflammatory lesions was 58.4, 40.6, 32.4, and 19.2 respectively. The difference was significant (P< 0.05).
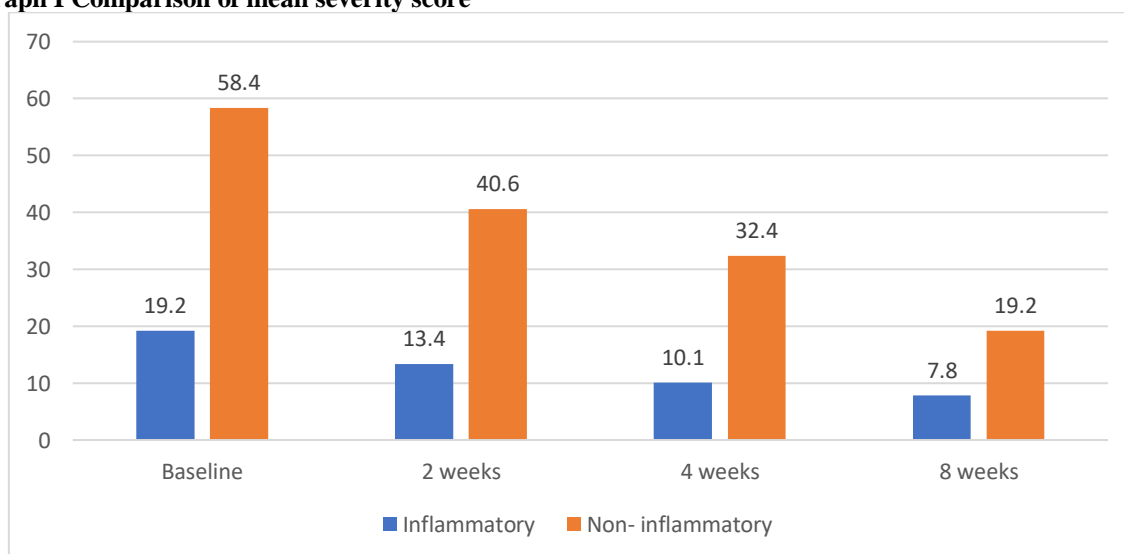
Graph I Comparison of mean severity score

Table III Reduction and lesion count analysis at baseline and at end of week 2, 4 and 8

Response	Baseline	2 weeks	4 weeks	8 weeks	P value
Mild	8	12	14	37	0.05
Moderate	20	29	34	33	0.91
Severe	48	35	28	6	0.04

Table III shows that at baseline, 2 weeks, 4 weeks and 8 weeks, mild lesions were 8, 12, 14 and 37 respectively. There was reduction in severe lesions from 48 to 35, 28 and 6 from baseline, 2 weeks, 4 weeks and 8 weeks. The difference was significant (P< 0.05).

DISCUSSION

A fixed combination of an antimicrobial and retinoid is effective in the management of mild to moderate acne.[7]Nadifloxacin, an antimicrobial and adapalene, a retinoid have frequently been used separately by dermatologists in the management of acne.Nadifloxacin is a topical antibiotic medication that is used in the management of acne vulgaris.[8] It belongs to the class of antibiotics known as fluoroquinolones and works by inhibiting the growth

of acne-causing bacteria on the skin, particularly Propionibacterium acnes (P. acnes).Nadifloxacin exhibits potent antibacterial activity against a wide range of bacteria, including P. acnes, which is a major contributor to the development of acne.[9] By reducing the population of P. acnes on the skin, nadifloxacin helps to decrease inflammation and prevent the formation of acne lesions.In addition to its antibacterial effects, nadifloxacin also possesses anti-inflammatory properties. This can help to reduce redness, swelling, and discomfort associated with acne lesions.[10]

We found that out of 76 patients, males were 46 and females were 30. The mean severity score for inflammatory lesions at baseline was 19.2, at 2 weeks was 13.4, at 4 weeks was 10.1 and at 8 weeks was 7.8 and for non- inflammatory lesions was 58.4, 40.6, 32.4, and 19.2 respectively. Shah et al[11]evaluated the efficacy and tolerability of a topical fixed combination of nadifloxacin (1%) and adapalene (0.1%) in the treatment of mild to moderate acne in Indian patients.Of 119 enrolled patients with mild to moderate acne, 117 patients were evaluated at the end of the study for efficacy parameters. A fixed combination of nadifloxacin (1%) and adapalene (0.1%) topical gel was applied at the affected area once at night for a period of 8 weeks. Reduction in the total, inflammatory and non-inflammatory lesion counts from the baseline, investigator global assessment (IGA) and reduction in the severity of acne as per combined acne severity classification were the primary efficacy variables measured at 2 weeks, 4 weeks, and 8 weeks.Overall, 98.3% patients showed a statistically significant progressive reduction in non-inflammatory lesion counts, inflammatory lesion counts, and total lesion counts over the study duration. By the end of 8 weeks, 75% of the patients had their global assessment scores approaching to normal healthy skin score. The adverse events were mild to moderate in severity.

We found that at baseline, 2 weeks, 4 weeks and 8 weeks, mild lesions were 8, 12, 14 and 37 respectively. There was reduction in severe lesions from 48 to 35, 28 and 6 from baseline, 2 weeks, 4 weeks and 8 weeks. Jung et al[12]evaluated the clinical efficacy and safety of 1% nadifloxacin cream and the histological changes it incurs when used to treat mild to moderate facial acne in patients.At final visits, inflammatory acne lesions were reduced by 70% on nadifloxacin-treated skin and increased by 13.5% on vehicle-treated skin; non-inflammatory acne lesions showed reductions of 48.1 and 10.1%, respectively. A significant difference was observed between the two treatments at four weeks. Histopathological examinations of the acne lesions showed decreased inflammation and interleukin-8 expression but no change in transforming growth factor-β expression in nadifloxacin-treated skin compared with vehicle-treated skin after eight weeks of treatment.

The limitation of the study is the small sample size.

CONCLUSION
Authors found that for the treatment of mild to severe acne vulgaris, a fixed combination of 1% nadifloxacin and 0.1% adapalene topical gel may be a useful and well-tolerated choice.

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