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Efficacy and tolerability of fixed dose combination of nadifloxacin and adapalene gel for the treatment of acne vulgaris: A phase III randomized multicenter study in India

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Background: Acne vulgaris is a chronic inflammatory disease. The multifactorial etiology of acne vulgaris makes it challenging to treat. Antimicrobials should be combined with topical retinoids for greater clearing of lesions and shortened duration of antibiotic treatment.

Aim: The present study compared the efficacy and safety of nadifloxacin and adapalene fixed dose combination (FDC) gel with adapalene monotherapy and nadifloxacin monotherapy.

Method: It was a randomized, double blind, controlled, multicentre, phase III, parallel group study conducted in India. In this eight-week study, 318 patients with mild to moderate acne were randomly allocated to either of the three treatment groups; Group A (morning placebo, evening FDC; FDC of nadifloxacin 1% + adapalene 0.1%, n=106), Group B (morning placebo, evening adapalene 0.1%, n=106) and Group C (twice daily nadifloxacin 1% alone, n=106). The outcome variables included lesion counts, acne severity based on investigator global assessment (IGA) scale and quality of life (QOL) assessment. Adverse events (AEs) were recorded at every visit.

Findings: At the end of the treatment, maximum mean reduction in inflammatory lesion counts were comparable in Group A (-11.1) in comparison to Group B (-8.9) and Group C (-8.5); $p>0.05$ for both. However, change from baseline in non-inflammatory lesion count at week eight was higher in Group A (-13.1) compared to Group B (-12.0); $p=0.04$ and Group C (-11.5), $p=0.17$. For acne severity, 61.7% of patients in Group A, 54.3% in Group B and 56% in Group C showed improvement. The maximum improvement in terms of quality of life (QOL) score was observed in Group A; with comparable results for the other group.

Conclusion: Topical fixed dose combination of nadifloxacin 1% and adapalene 0.1% is effective in mild to moderate acne with good tolerability.

Recent Publications:

1. Stein Gold L, Baldwin H E and Lin T (2017) Management of severe acne vulgaris with topical therapy. *Journal of Drugs in Dermatology*: JDD 16(11):1134–8.
2. Kaur J, Sehgal V K, Gupta A K and Singh S P (2015) A comparative study to evaluate the efficacy and safety of combination topical preparations in acne vulgaris. *International Journal of Applied and Basic Medical Research* 5(2):106.
3. Shah B J, Sumathy T K, Dhurat R S, Torsekar R G, Viswanath V, et al. (2014) Efficacy and tolerability of topical fixed combination of nadifloxacin 1% and adapalene 0.1% in the treatment of mild to moderate acne vulgaris in Indian patients: a multicenter, open-labelled, prospective study. *Indian Journal of Dermatology* 59(4):385–9.
4. S Choudhury, S Chatterjee, D K Sarkar and R N Dutta (2011) Efficacy and safety of topical nadifloxacin and benzoyl peroxide versus clindamycin and benzoyl peroxide in acne vulgaris: A randomized controlled trial. *Indian Journal of Pharmacology* 43(6):628.
5. Kobayashi M, Nakagawa T, Fukamachi K, Nakamura M and Tokura Y (2011) Efficacy of combined topical treatment of acne vulgaris with adapalene and nadifloxacin: a randomized study. *The Journal of Dermatology* 38(12):1163–6.

Biography

Bela Shah is an expert Clinical Dermatologist with over 30 years of experience. She is Professor and Head of Dermatology Department at B. J. Medical College and Civil Hospital, Ahmedabad. She has participated in numerous clinical studies and has authored numerous publications in the field of Dermatology. She is a renowned speaker and has made presentations at multiple conferences worldwide. She is one of the Principal Investigators in the presented trial.

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