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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INTRODUCTION

- Acne vulgaris is a chronic inflammatory skin disease, having multifactorial etiology, which makes it challenging to treat[1].
- Antimicrobials should be combined with topical retinoids so as to achieve greater clearing of lesions and to shorten duration of antibiotic use[2].
- The present study was aimed at comparing the efficacy and safety of nadifloxacin and adapalene fixed dose combination (FDC) gel with adapalene monotherapy and nadifloxacin monotherapy.

METHODOLOGY

- It was a randomized, double blind, active-controlled, multicentre, phase III, parallel group study conducted in 6 sites across India.
- In this 8-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 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.
- Study was initiated after approval of Drug Controller General (India) and respective Institutional Ethics Committee as well as registration on CTRI (CTRI/2014/08/004908).Written informed consent obtained from each subject before initiating study activities.

RESULTS

- At the end of treatment, maximum mean reduction in inflammatory lesion counts was comparable in Group A (-11.1) in comparison to Group B (-8.9) and Group C (-8.5). However, the mean reduction in non-inflammatory lesion count at Week 8 was higher in Group A (-13.1) compared to Group B (-12.0); p=0.04 and Group C (-11.5) [P = 0.17].
- Improvement in acne severity was seen in 61.7% of patients in Group A, 54.3% in Group B and 56% in Group C.
- The maximum improvement in quality of life (QOL) score was observed in Group A.
- Adverse events(AES) in the form of mild irritation was observed in 0.5% of the patients.

Figure 1: Patient disposition

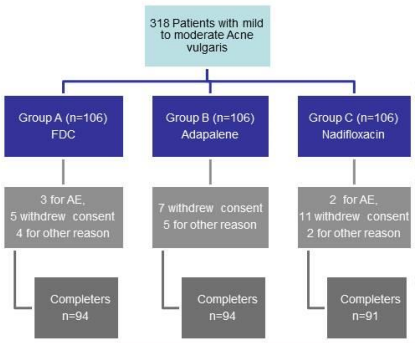


*Figure 2: Change in non-inflammatory lesion count from screening (n=279), (*p=0.0434 for Group A vs Group B)*

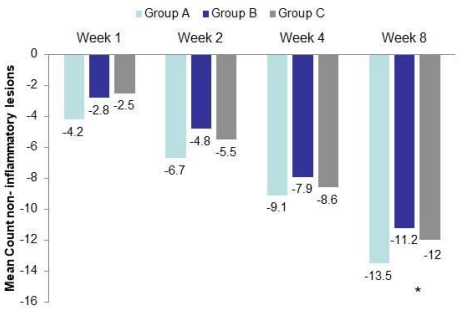
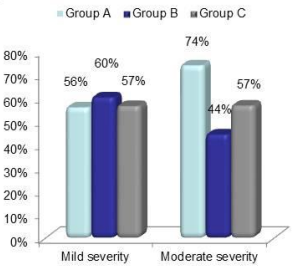


Figure 3: Improvement according to IGA scale at 8 weeks – per protocol population (n=279)



CONCLUSION

Topical fixed dose combination of nadifloxacin 1% and adapalene 0.1% is superior for the treatment of mild to moderate acne with good tolerability.

References: 1) Am J Clin Dermatol. 2012 Dec 1;13(6):357-64. 2) Rao J et al, Medscape Dec 2017

Conflict of Interest:
None of the author has direct commercial interest in either of the three products.

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