

Comparison of Efficacy and Safety of Combination of Benzoyl Peroxide and Clindamycin with Clindamycin and Benzoyl Peroxide used Separately in Acne Vulgaris

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Abstract: ***Introduction:** Acne vulgaris is a disorder of the pilosebaceous unit. For the treatment of mild to moderate acne vulgaris, various topical drugs have been used either as monotherapy or combined therapy. **AIM:** To compare the efficacy and safety of combination of benzoyl peroxide and clindamycin with clindamycin and benzoyl peroxide used separately in acne vulgaris. **Materials and Method:** Hospital based prospective, comparative and interventional study was conducted in Department of Dermatology in a teaching institute, Pune for 18 months. **Selection of Patients:** A total of 60 patients, newly diagnosed as acne vulgaris (Grade I and II) were divided into 2 groups of 30 patients each. **Group A:** Clindamycin 1% + benzoyl peroxide 2.5% at night, **Group B:** Clindamycin 1% in the morning and Benzoyl peroxide 2.5% at night. **Results:** There was statistically significant reduction between baseline, 4 and 6 weeks values of non-inflammatory lesions and inflammatory lesions in Group A and Group B. The comparison between the groups before and after treatment was comparable. There was no significant difference between the groups. The cases of erythema were significantly more in Group B as compared to Group A ($p < 0.05$). There was no significant difference between the groups for scaling and burning sensation. **Conclusion:** The combination of clindamycin and benzoyl peroxide has an earlier onset of action and better safety but similar efficacy as compared to the two agents when used separately.*

Keywords: Acne, Benzoyl Peroxide, Clindamycin

1. Introduction

Acne vulgaris is a dermatological disorder of the pilosebaceous unit that affects majority of people at sometime during their life. Adolescence is the usual period when people are affected with acne, but it can also persist during adult age.¹ Because of the involvement of face and associated cosmetic problems, acne patients are at increased risk of anxiety and depression which affects their quality of life.² The characteristic lesions in acne are called comedones which are actually the non-inflammatory lesions whereas the inflammatory lesions are papules, pustules and nodules.³ The etiology of acne vulgaris is multifactorial and it is the sum of the factors operating on susceptible individuals that determine the severity of the disease. Certain factors that may precipitate acne include genetic and environmental factors like diet, menstruation, emotional stress and cosmetics. For the treatment of mild and moderate acne vulgaris, there are many topical drugs available like benzoyl peroxide, antibiotics and retinoids, which can be used alone, or in combination.⁴ Benzoyl peroxide is one of the commonly used antimicrobial which is a potent antibacterial, mild anti-inflammatory and comedolytic. It can be utilized as monotherapy, or can be used along with topical antibiotics or topical retinoids in acne treatment.⁵ Clindamycin is a lincosamide antibiotic which inhibits the bacterial protein synthesis by interfering with ribosomal translocation.³ If clindamycin is combined with benzoyl peroxide, it leads to additive effects. The aim of the present study was to compare the efficacy and safety of combination of benzoyl peroxide and clindamycin with clindamycin and benzoyl peroxide used separately in acne vulgaris

2. Material and Methods

This hospital based prospective, comparative and interventional study was conducted in Department of Dermatology in a tertiary health care centre in Pune for a period of 18 months. We included all the patients between 15-40 years of age of both the sexes newly diagnosed as Acne vulgaris (grade I and II) and having lesion count of >15 lesions. Patients using topical or oral anti acne medication in last 30 days, those diagnosed of having hormonal imbalances like PCOD, thyroid disorder, pregnant and lactating women or having any known hypersensitivity to any topical anti-acne medication were excluded.

The present study was carried out with following two groups of 30 patients each:

Group A: Clindamycin 1% + benzoyl peroxide 2.5% at night
Group B: Clindamycin 1% in the morning and Benzoyl peroxide 2.5% at night.

After obtaining informed consent, detailed history was taken which included the onset, duration and progress of condition, past history of similar complaints and history of any other underlying illness. A detailed clinical examination was done which included counting the acne lesions-inflammatory (papules, pustules) and non-inflammatory (comedones) on the face by dividing the face into four quadrants and recorded in the proforma at baseline and at the end of 2nd, 4th, 6th week. Photographs were taken before starting the treatment and at the end of 6 weeks. And any adverse effect like erythema, scaling, burning sensation were noted.

For efficacy assessment of the patients, total lesion counting was done. The change of total lesion, inflammatory and non-

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inflammatory lesions, count from baseline and at 2nd, 4th and 6th week was observed. Investigator's Global Assessment (IGA) score was also done at baseline and at the end of 6 weeks.

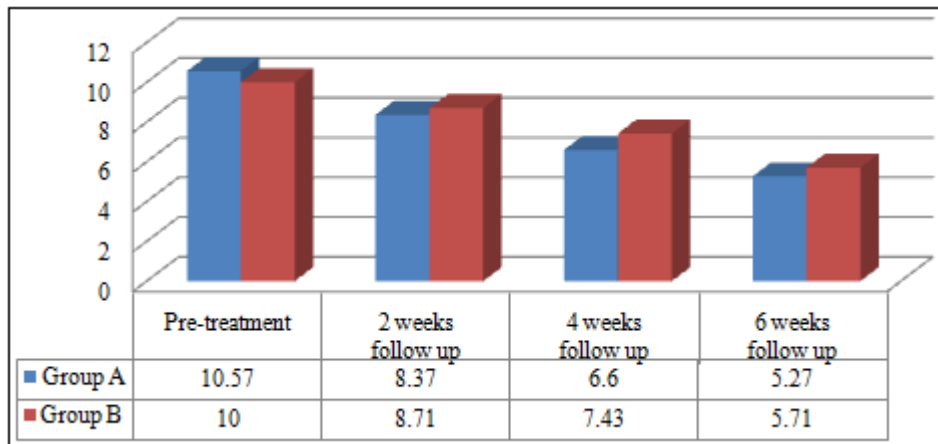
Investigator's global assessment score:

- 1) 0-indicating clearance of inflammatory lesions, some residual hyperpigmentation and erythema may be present.
- 2) 1-almost clear, patients may have a few scattered comedones and fewer than five small papules.
- 3) 2-mild severity, acne is easily recognizable, but less than half the face is involved and there are multiple comedones, papules, and pustules.

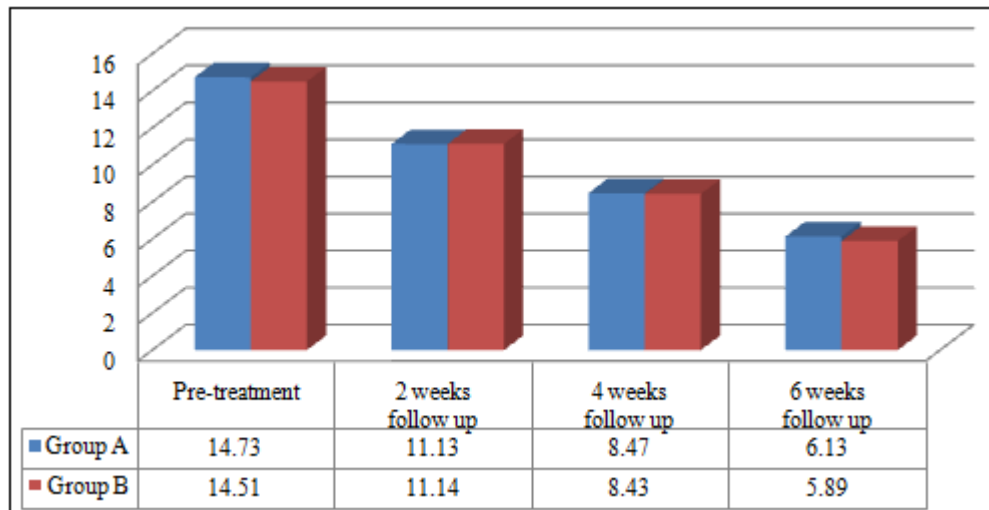
- 4) 3-moderate severity, more than half the face is involved and there are numerous comedones, papules, and pustules.
- 5) 4-severe, the entire face is involved, covered with numerous comedones, papules, pustules, and a few nodules and cysts.
- 6) 5-very severe, patients have high inflammatory acne covering the entire face, with nodules and cysts.

Statistical analysis: For statistical analysis, the following tests were applied, Fischer's test, student 't' test and Chi-Square test using the software SPSS ver. 20.0. $P < 0.05$ was considered significant.

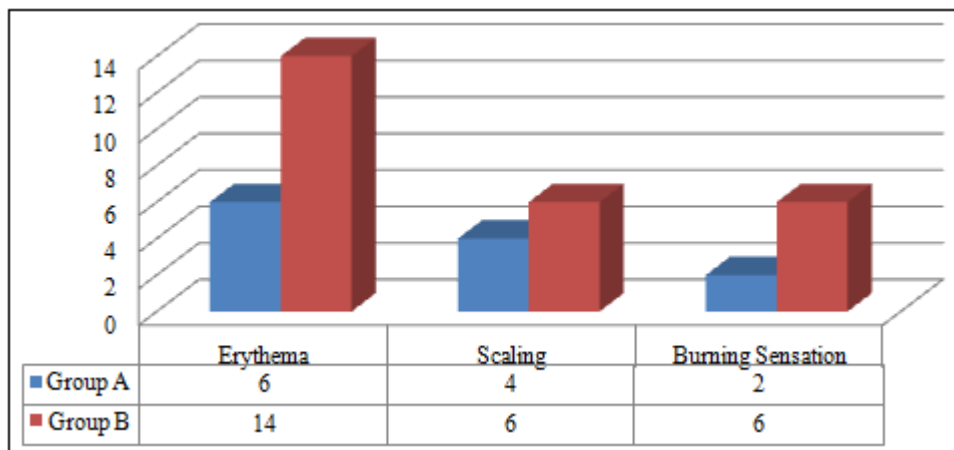
3. Result



Graph 1: Comparison of non-inflammatory lesions between groups before and after treatment



Graph 2: Comparison of Inflammatory Lesions between Groups before and after treatment



Graph 3: Comparison of Adverse Events between Groups

4. Discussion

Although the present study compares two groups of treatment, which was previously not done still we can evaluate other studies where one of the combination present in our study is compared with some other combination but of same class.

The study of Thiboutot D et al¹¹³ compared efficacy of 4 groups clindamycin 1.2% plus benzoyl peroxide(BPO) 2.5% gel, clindamycin 1.2% gel, benzoyl peroxide 2.5% gel, vehicle gel for 12 weeks. The mean percent of reduction in inflammatory lesion count and non-inflammatory lesion count was 54.6% and 43.2% respectively for the clindamycin plus benzoyl peroxide group and this group is comparable to group A of our study which showed mean reduction in non-inflammatory lesion by 49.8% and inflammatory lesions by 41.61% at the end of 6 weeks.

The study of Zeichner JA et al¹¹⁴ compared efficacy of clindamycin 1.2% plus benzoyl peroxide 3.5% combination gel versus vehicle gel for 12 weeks. The mean reduction percentage for the non-inflammatory lesions was 60.4% and 68.7% reductions for inflammatory lesions in the clindamycin-benzoyl peroxide group. This is comparable with our study with mean reduction in non-inflammatory lesions being 49.8% and inflammatory lesions being 41.61% at the end of 6 weeks for the group A.

The study of Jain VK et al¹¹⁶ compared efficacy of 2 groups 1% metronidazole in the morning and 5% benzoyl peroxide in the evening and in other group 1% clindamycin phosphate gel in the morning and 5% benzoyl peroxide in the evening for 8 weeks. The mean reduction in group 2 in non-inflammatory lesions is 13.80 from 59.30 (baseline) and inflammatory lesions is 3.35 from 14.20 (baseline). Findings of group 2 of the above mentioned study is in accordance with Group B of our study. The mean reduction in non-inflammatory lesions in our study is 5.71 from 10.00 (baseline) and inflammatory lesions is 5.89 from 14.51 (baseline) at the end of 6 weeks.

Lookingbill DR et al⁴⁹ compared safety of clindamycin 1% plus benzoyl peroxide(BPO) 5% combination gel with clindamycin 1% gel, BPO 5% gel and vehicle gel for 11 weeks. There were no statistically significant differences

between the local irritant effects of the three active preparations versus vehicle. However, treatment with clindamycin plus benzoyl peroxide gel or benzoyl peroxide resulted in a significantly higher frequency of peeling than clindamycin. Erythema was observed more frequently with BPO treatment.

Thiboutot D et al¹¹³ evaluated safety and tolerability of a combination of clindamycin phosphate 1.2% and benzoyl peroxide 2.5% aqueous gel, clindamycin 1.2%, BPO 2.5% and vehicle gel for 12 weeks. The overall incidence of adverse effects related to therapy (erythema, scaling, burning, itching, stinging) was low and was similar among clindamycin-BPO 2.5% gel, active ingredients, and vehicle.

Comparing to the above mentioned studies, it was observed in our study that the cases of erythema was significantly more ($p < 0.05$) in Group B (clindamycin 1% gel in morning and benzoyl peroxide 2.5% gel at night) as compared to Group A (clindamycin 1% plus benzoyl peroxide 2.5% combination). There was no significant difference between the groups for scaling and burning sensation. The combination of benzoyl peroxide and clindamycin demonstrated better safety, but there was no significant difference between the efficacy of the groups.

5. Conclusion

The incidence of acne vulgaris is very common. Various regimens are being used for its management. However most effective and safe therapy is being searched for.

In the present study, the following conclusions were noted:

- 1) The combination of clindamycin and benzoyl peroxide is effective and safe in treatment of acne vulgaris grade 1 and 2 at the end of 6 weeks.
- 2) Clindamycin and benzoyl peroxide when used separately is also effective and safe in treatment of acne vulgaris grade 1 and 2 at the end of 6 weeks.
- 3) The combination of clindamycin and benzoyl peroxide has an earlier onset of action and better safety as compared to the two agents when used separately.
- 4) Due to similar efficacy of both the groups, any modality can be given depending upon patient's requirement to improve patient's compliance.