

A prospective randomised open labelled comparative study of anti inflammatory effects of topical 5% benzoyl peroxide gel vs topical 4% nicotinamide gel for grade I-II acne in a tertiary care hospital

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ABSTRACT

Background: Acne vulgaris is a dermatological disorder characterised by formation of comedones and inflammatory lesions. The treatment of acne basically involves reduction of lesions. Benzoyl peroxide, in concentrations of 5%, 10%, and 20%, has been used effectively in the treatment of acne for more than 20 years. Nicotinamide/ Niacinamide is a newly-approved anti-acne drug with a potent anti-inflammatory effect. The present study assessed the efficacy of 5% Benzoyl peroxide gel in comparison to 4% Nicotinamide gel for topical treatment of mild to moderate acne vulgaris.

Methods: In this study, the patients with mild to moderate acne vulgaris with inflammation were divided into two groups, group I was treated with topical 5% Benzoyl peroxide gel whereas topical Nicotinamide gel was given to the group II. Assessment of efficacy was done by total lesion counting according acne global severity index, the results were compared at the end of 2 weeks and 4 weeks with the baseline values.

Results: At the end of this study, it was found that the reduction of inflammatory and total percentage of decrease in counts of lesions from baseline were highly significant in both the groups ($p < 0.001$), between the groups, differences were statistically significant ($p < 0.001$), therefore 5% Benzoyl peroxide gel has better efficacy than 4% Nicotinamide gel.

Conclusions: Benzoyl peroxide is more efficacious than 4 % Nicotinamide gel in mild to moderate acne.

Keywords: Acne vulgaris, Comedones, Inflammatory

INTRODUCTION

Acne, a chronic inflammatory disease of the pilosebaceous units of the face, neck, chest, and back, is the most common skin disorder occurring universally, with an estimated prevalence of 70-87%.¹

It is a pleomorphic disorder characterized by both noninflammatory (comedones) and inflammatory (papules, pustules, nodules) lesions. Grading of acne is mandatory to determine the appropriate therapeutic

strategy. Effective treatment can dramatically improve a person's quality of life.²

Benzoyl peroxide is frequently used as a first-line therapy for mild to moderate acne. Benzoyl peroxide acts through oxidation and formation of free radicals causing a reduction of P. acnes. This mechanism helps to prevent an induction of resistance in P. acnes often observed during long term acne treatment with antibiotics.³

Niacinamide is a newly-approved anti-acne drug with a potent anti-inflammatory effect. Reduction of inflammation is a major mechanism of anti-acne treatment. More recent studies have noted that topical niacinamide is extremely well tolerated by facial skin that this agent provides several beneficial effects in reducing sebum production.^{4,5}

The present study was done to compare the efficacy of 5% Benzoyl peroxide gel and 4% Nicotinamide gel in mild to moderate acne of inflammatory origin.

METHODS

After obtaining clearance from the Institutional ethical committee and informed consent of all subjects, a prospective randomised open labelled comparative study with topical 5% Benzoyl peroxide vs 4% Nicotinamide gel was conducted in Department of Dermatology, Dr B R Ambedkar medical college and hospital for a period of 6 months from June 2016 to December 2016.

A total of 60 subjects with mild to moderate acne was selected randomly at a ratio of 1:1. Thirty subjects belonging to Group I were treated with topical 5 % Benzoyl peroxide twice daily for 4 weeks, another thirty subjects belonging to Group II were treated with 4% Nicotinamide gel twice daily for 4 weeks.

For each patient at baseline, details of sociodemographic data, history of acne, acne lesion counts and grade of acne was entered in the study proforma. Acne lesions were counted by the dermatologist. Inflammatory acne lesions were included in the study. Thus, total acne lesion count in each patient was considered as 100 % baseline. Baseline clinical grading of acne severity was done according to Acne Global Severity Scale.

Inclusion criteria

Patients aged between 18 to 29 years; grade I-II acne; with written informed consent.

Exclusion criteria

Patients who were already on topical treatment for 2 weeks or systemic treatment with 4 weeks with either isotretinoin, hormones or antibiotics; those who had Nodulocystic acne, with facial dermatosis which interferes with evaluation in the study; patients suffering from immunocompromised states like Diabetes mellitus, AIDS; pregnancy and lactating mothers; those who had already received topical anti acne treatment (Benzoyl peroxide, retinoids, azelaic acid) in the last 1 month, also drugs producing acneiform eruptions either oral or topical drugs like steroids, Vitamin B12, anticonvulsive drugs.

Treatment regimen was under the direction of treating dermatologist. Patients were advised to wash the face and dry it well before application. 1 finger tip unit

(approximately 0.5gram) of each study drug was applied at bed time by dotting it over forehead, cheeks, chin and nose. A thin film was spread evenly over entire face avoiding periorbital, paranasal and perioral areas. Group I was treated with 5% Benzoyl peroxide gel, Group II were treated with 4% Nicotinamide gel. Initially if there was irritation with the drugs they were advised to begin with short contact time of 15-30 minutes then gradually increase over upto 24 hours.

Patients were followed at the end of 2nd week and 4th week for efficacy and safety evaluation. At each follow up compliance was assessed verbally.

Efficacy assessment was done by spot counting of number of inflammatory acne lesions at follow ups with their respective basal counts. If any reduction was noted ,percentage reduction in acne lesion counts were calculated and expressed in terms of improvement in cne and graded.

Safety and tolerability was assessed by noting the local dryness, erythema, pruritus, hyperpigmentation, exfoliation, photosensitivity.

The data are expressed as mean, standard deviation for continuous measurements and number for categorical measurements. To find the significance of study parameters on continuous scale between two groups student's t test was used and for data on categorical scale Chi- square/ Fischer's extract test was used. The level of significance was taken as $p \leq 0.05$ - significant, $p \leq 0.001$ - highly significant and $p \geq 0.05$ - not significant.

RESULTS

Table 1: Demographic and baseline characteristics of acne patients studied in two groups.

Characteristics	Group I	Group II	P value
Age in years			
18-24	70	86.7	0.515
25-29	30	13.3	
Mean±SD	22.30±2.63	21.90±2.07	
Sex (%)			
Female	56.7	63.3	0.598
Male	43.3	36.7	
Number of lesions distribution-Before treatment			
1-5	0	0	
6-10	6.7	3.3	
11-15	50	53.3	
16-20	43.3	43.3	

The study enrolled 60 patients with 30 patients in Group I and 30 patients in Group II. Both the treatment groups were comparable for their demographic characteristics and baseline disease characteristics. Common age group involved in the study was 18-24 years with predominantly females 56.7% in Group I and 63.3% in Group II

respectively. The number of lesions counted were from 1 to 20 among them maximum was found between 11-15 lesions with 50 % and 53.3% in Group I and Group II respectively (Table 1).

Patients were analysed in two grades - Grade 1 with lesions of acne counted from 1-10, Grade II with lesions counted from 11-20. It was noticed that maximum patients presented with lesions from 11-20 belonged to grade II (Table 2).

Table 2: Distribution of patients of acne based on grade of acne.

Grade of Acne	Group I	Group II
Grade I	2 (6.7%)	1 (3.4 %)
Grade II	28 (93.3%)	29 (96.6 %)

Patients aged from 18-29 years were included in the study. Majority of patients were between 18-24 years i.e. 70 % and 86.7 % in Group I and Group II respectively (Figure 1).

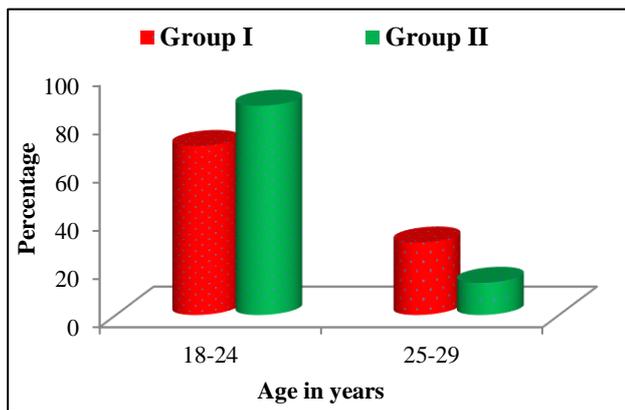


Figure 1: Distribution of acne based on age of the patient.

Both males and females were included in this study among them females were found to have a greater occurrence of acne i.e. 57 % and 63% in Group I and Group II respectively (Figure 2).

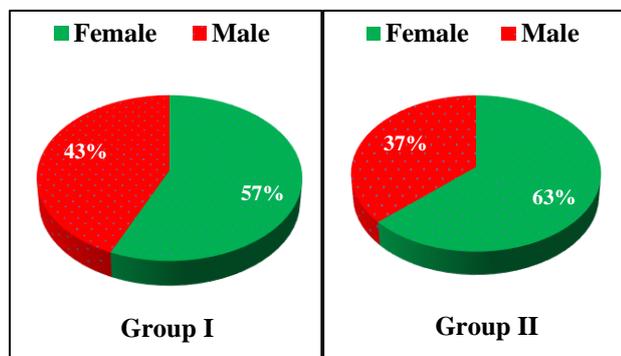


Figure 2: Indicates the gender distribution between the two groups.

Patients were treated with 5 % Benzoyl peroxide for Group I and 4 % Nicotinamide gel for Group II respectively. Percentage of reduction of number of lesions were compared in both the groups which showed percentage reduction of 32.3 % in group I compared to group II of 22.37% at the end of 2 weeks with a p value of 0.001 which was statistically significant. At the end of 4 weeks there was a percentage reduction of 58.03 % in Group I as compared to 36.07 % in group II which showed p value as <0.001 which was statistically significant (Table 3, Figure 3).

Table 3: Percentage of reduction in number of lesions.

Percentage of reduction in number of lesions	Group I	Group II	P value
At 2 weeks	32.3	22.37	0.001
At 4 weeks	58.03	36.07	<0.001
Student t test			

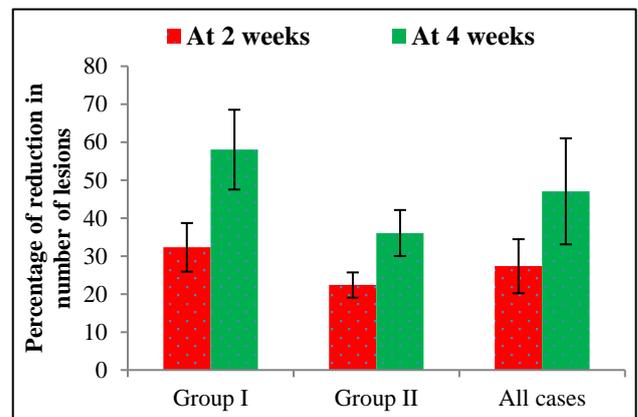


Figure 3: Indicates percentage of reduction in number of lesions at the end of 2 weeks and 4 weeks.

DISCUSSION

Acne vulgaris is an inflammatory disorder of pilosebaceous unit which occurs as a result of follicular epidermal hyperproliferation, increased sebum production, microbial flora changes and inflammation. The influence of androgen, P. acnes infection, some medications, genetic causes and stress are the main factors responsible for acne development.⁶ As far as treatment is concerned, topical therapy is the standard treatment for mild to moderate acne vulgaris.⁷

Benzoyl peroxide and antibiotics are the topical antimicrobials which have efficacy in treating inflammatory acne.⁸

Topical niacinamide has marked anti-inflammatory properties.⁹

This study was undertaken to compare the anti-inflammatory efficacy of 5% benzoyl peroxide gel versus

4% Nicotinamide gel for the topical treatment of mild to moderate acne vulgaris. In this study more acne patients were belonging to 18-24 years (group I -70% and group II -86.7%) with female preponderance 56.7% and 63.3% in group I and group II respectively. Similar age distribution and female preponderance was seen in a study done by Rallis E et al.¹⁰

Group I treated with 5% Benzoyl peroxide were followed up at 2 weeks and 4 weeks which showed 32.3% and 58.03% percentage reduction of number of lesions respectively. This data correlates with the study conducted by Mills OH et al, in 1986, who demonstrated 40.3% and 55.9% percentage of reduction in acne lesions from baseline at the end of 4 weeks and 8 weeks respectively which is in concordance with our study.¹¹

Group II were treated with 4 % Nicotinamide gel and were followed up at 2 weeks and 4 weeks which showed 22.37% and 36.07% percentage of reduction in number of lesions which is similar with the study done by Shalita A et al, who demonstrated 60% reduction in the number of lesions at the end of 4 weeks treated twice daily, whereas in this study we treated the patient once daily at bed time.¹²

In this study, the effects of 5% benzoyl peroxide was compared with 4% nicotinamide gel in the topical treatment of mild to moderate acne vulgaris and it was found that there was a statistical significant difference ($p \leq 0.001$) in efficacy between groups I (5% benzoyl peroxide gel) and group II (nicotinamide gel) which implies benzoyl peroxide has better efficacy as compared with 4% Nicotinamide gel.

Finally to conclude topical 5% Benzoyl peroxide has better efficacy compared to 4% Nicotinamide gel in the treatment of inflammatory mild to moderate acne.

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