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Original Article

Efficacy and Safety of Adapalene Gel and Benzoyl Peroxide Gel in the Treatment of Mild to Moderate Acne Vulgaris: A Single Centre, Double Blind, Parallel Arm Randomized Controlled Trial Hospital in Dhaka City of Bangladesh.

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Abstract

Background*:* Acne is a common dermatological disorder of teen age group. There are different modalities of topical and systemic treatments are available to manage this disease. **Objective:** The purpose of the present study was to evaluate the efficacy and safety of Adapalene 0.1% gel in comparison to Benzoyl Peroxide (BPO) 2.5% gel for the treatment of mild to moderate acne vulgaris. **Methodology:** This single centered randomized controlled trial was conducted in the Department of dermatology and venereology Tairunnesa memorial medical college Hospital, Tongi, Gazipur, Bangladesh from October 2023 to April 2024 for a period of six month. A total number of sixty patients of clinically diagnosed acne vulgaris were primarily selected and randomly divided into two equal group (group-A and group-B). Group A was given adapalene 0.1% gel for 12 weeks & Group B was given BPO 2.5% once daily in the evening for same duration. Patients were clinically assessed at baseline and at week 4, 8 and 12. At each visit, the investigator rated, scaling, erythema, dryness, burning, pruritus on a scale ranging from 0 (none) to 3 (severe). Adverse events were evaluated at each visit. **Results:** A total number of 60 patients were recruited after fulfilling the inclusion and exclusion criteria. Among them predominant age group was 20 to 24 years which were 27 (45.0%). Male: female ratio was 1:2.52. 51(85%) patients had oily skin type and 9(15%) had dry skin type. Adapalene 0.1% gel was significantly more effective than BPO 2.5% gel, with significant differences in total lesion counts observed as early as 4 weeks of treatment. Adverse event frequency and cutaneous tolerability profile was significantly favorable for adapalene gel in the treatment of acne vulgaris. **Conclusions:** Once daily Adapalene gel provides significantly greater efficacy and safety for the treatment of mild to moderate acne vulgaris compare to Benzoyl Peroxide gel.

Keywords: Efficacy and Safety; Adapalene Gel; Benzoyl Peroxide Gel; Mild to Moderate Acne Vulgaris
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Introduction

Acne vulgaris is a chronic disease of the pilosebaceous unit. Usually occur at puberty but can also be seen in adult age. A multifactoral pathophysiology including sebaceous gland hyperplasia with seborrhea, altered follicular growth and differentiation, Propionibacterium acnes proliferation, and inflammation[1]. Most cases of acne consist of comedones, papules, pustules, and nodules. Although the course of acne may be self-limiting, but sometime pitted or hypertrophic scar may persist for lifelong[2]. Lesions of acne vulgaris can be divided into four grades – 1, 2, 3, and 4. Grade 1 consists of comedones and occasional papules. Grade 2 consists of papules, comedones and few pustules. Grade 3 consists of predominant pustules, nodules, and abscesses. Grade 4 consists of mainly cysts, abscesses, and widespread scarring[3].

Drugs used for Grades 1 and 2 (mild-to-moderate case) of acne vulgaris are topical comedolytics, antibacterials, and retinoids as monotherapy or combination therapy. Grades 3 and 4 (severe cases) of acne vulgaris require systemic antibacterials along with topical agents[4]. Topical treatments such as adapalene and benzoyl peroxide are popular in mild to moderate acne vulgaris[5]. Among topical treatments, adapalene and benzoyl peroxide (BPO) are widely used for mild to moderate acne. Benzoyl peroxide, a potent topical antibacterial agent, exerts its effects by oxidation and free radical generation, leading to the reduction of C. acnes. In addition to its antibacterial properties, it has comedolytic and mild anti-inflammatory actions. BPO is effective as monotherapy or in combination with other topical agents and is associated with minimal resistance[6]. Adapalene, a third-generation topical retinoid, is a naphthoic acid derivative that selectively targets retinoic acid receptors. It exhibits anti-inflammatory, comedolytic, and anti-comedogenic properties, making it a rational choice for acne treatment.

Adapalene demonstrates favorable tolerability and effectiveness, both as a standalone treatment and in combination with antimicrobial agents such as BPO[6,7]. Benzoyl peroxide is a potent topical antibacterial agent, acts through oxidation and formation of free radicals causing a reduction of P. acnes. It also has comedolytic property and mild anti-inflammatory actions. It is usually used alone or in combination with other topical anti-acne medications[3]. Adapalene is a topical retinoid. It is a receptor-selective naphthoic acid derivative with anti-inflammatory, comedolytic, and anti-comedogenic properties[7]. It is recognized as an effective topical retinoid with a favorable tolerability profile and is therefore a rational selection for acne treatment in alone or combination with an antimicrobial agent[8]. Clinical studies comparing adapalene and BPO have focused on their efficacy and tolerability in mild to moderate acne vulgaris. Both agents effectively reduce inflammatory and non-inflammatory lesions; however, adapalene's anti-inflammatory properties offer a potential advantage in minimizing erythema and irritation[9]. BPO, while effective in reducing bacterial proliferation, may cause dryness or peeling, particularly at higher concentrations. Combining the two agents has shown superior efficacy compared to monotherapy, enhancing lesion reduction while mitigating the risk of bacterial resistance[10].

Acne vulgaris treatment requires a tailored approach based on the severity of the condition[8]. For mild to moderate acne, topical therapies such as adapalene and BPO remain cornerstone treatments. Both agents exhibit unique mechanisms of action and are effective individually or in combination[11]. Further studies are warranted to optimize their use, considering efficacy, safety, and patient tolerability. By understanding the comparative benefits of these treatments, clinicians can make informed decisions to improve outcomes for patients with acne vulgaris. This study was planned to compare the efficacy and side effects of topical application of Adapalene alone and BPO alone in the treatment of mild to moderate acne vulgaris.

Methodology

Study Settings & Population: This single centered randomized controlled trial was conducted in the Department of dermatology and venereology Tairunnesa memorial medical college Hospital, Tongi, Gazipur, Bangladesh from October 2023 to April 2024 for a period of six month. Patients between 15 and 30 years of age with mild to moderate facial acne vulgaris, assessed using the Investigator Global Assessment Scale with a minimum of 10 inflammatory lesions, 10 to 100 non-inflammatory lesions, and no more than one nodule or cyst on the face, were included in this study. Patients suffering from nodulo-cystic acne, pregnant women and lactating mother, patient taking any medication for acne, persons having hypersensitivity to adapalene and benzoyl peroxide and patients with other dermatologic conditions interfering with the treatment of acne vulgaris were excluded in this study.

Allocation and Blinding: A total number of sixty patients

of clinically diagnosed acne vulgaris were primarily selected and randomly divided into two equal group (group-A and group-B). Group A was given adapalene 0.1% gel for 12 weeks & Group B was given BPO 2.5% once daily in the evening for same duration.

Follow up and Outcome Measures: Patients were clinically assessed at baseline and at week 4, 8 and 12. The primary efficacy variables were success rate (the percentage of subjects rated "clear" or "almost clear" on the investigator's global assessment scale [IGA] of acne severity) and percentage of lesion reduction from baseline (total, inflammatory, and non-inflammatory). Safety and tolerability were assessed through evaluations of local facial tolerability and adverse events. At each visit, the investigator rated, scaling, erythema, dryness, burning, pruritus on a scale ranging from 0 (none) to 3 (severe). Adverse events were evaluated at each visit.

Statistical Analysis: Computer based statistical analysis were carried out with appropriate techniques and systems. All data were recorded systematically in preformed data collection form (questionnaire) and quantitative data were expressed as mean and standard deviation and qualitative data were expressed as frequency distribution and percentage. Statistical analysis was performed by using window-based computer software devised with Statistical Packages for Social Sciences (SPSS-25) (SPSS Inc, Chicago, IL, USA). A 95% confidence limit was taken. Probability value <0.05 was considered as the level of significance.

Ethical Consideration: All procedures of the present study were carried out in accordance with the principles for human investigations (i.e., Helsinki Declaration) and also with the ethical guidelines of the Institutional research ethics. 3.Formal ethics approval was granted by the IRB of Monno Medical College. Participants in the study were informed about the procedure and purpose of the study and confidentiality of information provided. All participants consented willingly to be a part of the study during the data collection periods. All data were collected anonymously and analysed using the coding system.

Results

A total number of 60 patients were recruited after fulfilling the inclusion and exclusion criteria. Among them predominant age group was 20 to 24 years which were 27 (45.0%) followed by 15 to 19 years which were 21(35.0 %) and 25 to 29 years which were 12(20.0%) (Table 1).

Table: 1. Distribution of Patients According to Age Group

Age Group	Frequency	Percent
15 to 19 Years	21	35.0
20 to 24 Years	27	45.0
25 to 29 Years	12	20.0
Total	60	100.0

Female predominance was observed 43 (71.7%) in comparison to male 17(28.3%). Male: female ratio was 1:2.52 (Table 2).

Table:2. Distribution of Patients According to Gender

Gender	Frequency	Percent
Male	17	28.3
Female	43	71.7
Total	60	100.0%
Ratio	1: 2.5	

Among 60 patients, 41 (69.3%) were unmarried and 19 (31.7%) were married (Figure I).

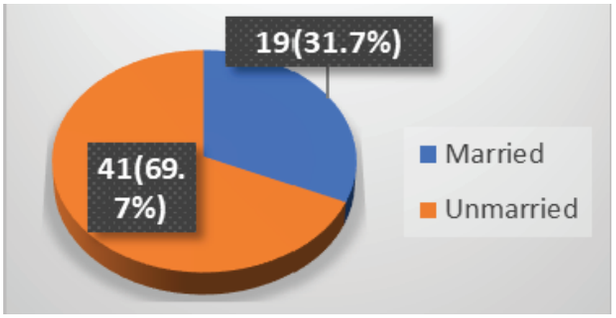

Figure I: Distribution of patients according to marital status

Among 60 patients, 51(85%) patients had oily skin type and 9 (15%) had dry skin type (Figure II).

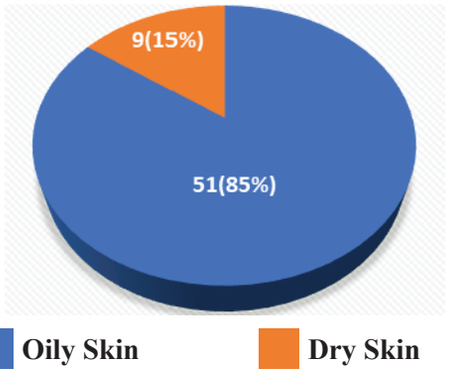

Figure II: Distribution of patients according to skin type

Among 60 patients, face was the common site 56(93.33%) in all the patients, followed by back 34(56.7%) and chest 8(13.33%) (Figure III).

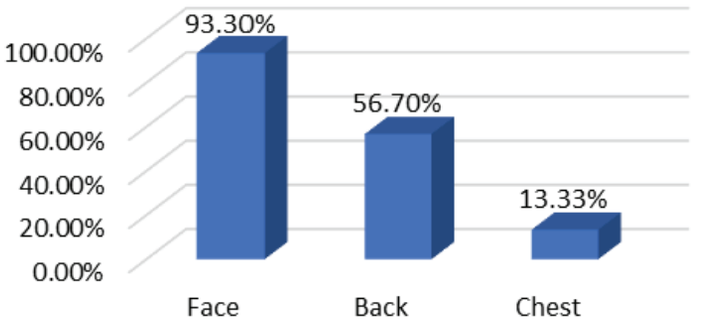

Figure III: Distribution of patients according to site

Mean score for open comedone, closed comedone, papule and pustule was identical between two groups at base line (p>0.05). Significantly better reduction of acne score for open comedone, closed comedone, papule, pustule and total acne score was noticed at 2nd and 3rd follow up (p<0.005) in the group A than the group B. Percent reduction of acne severity from base line to final follow up was 94.76% in group A and 83.42% in group B and it was statistically significant between two group (p=0.001) (table 3).

Table: 3. Efficacy of treatment between two groups

Follow up	**Group A (Adapalen)** (mean lesions count)	**Group B (BPO)** (mean lesions count)	**p-value**
Baseline (0 week)	34.66±6.40	33.66±4.96	0.45
4th week	31.56±3.86	24.0±3.27	0.188
8th week	11.10±2.22	15.26±3.04	<0.001
12th week	2.66±1.17	6.30±1.58	<0.001
Reduction from baseline To 3rd follow up	93.66%	82.32%	<0.001

After 12 week of treatment, in Group-A 6.6% patient had dryness of skin and 3.3% had erythema, whereas in Group -B, who had applied benzoyl peroxide, among them 10% suffered from dryness, 6.6% erythema and 3.3% burning .There was a significant difference of adverse effects between two groups(p>0.05) with favorable to Adapalene (Figure IV).

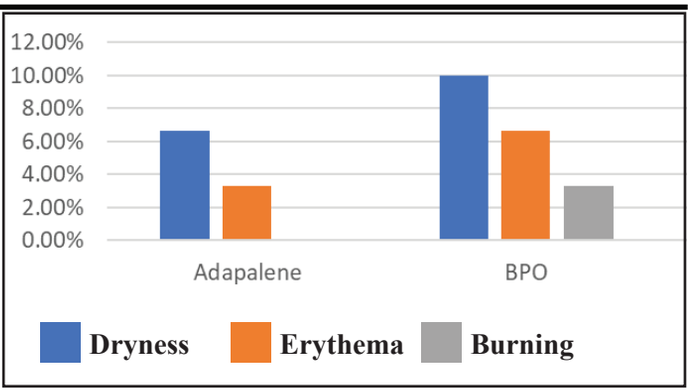

Figure IV: Show Adverse effects at 3rd follow up.

Discussion

To evaluate the on efficacy and safety of Adapalene gel and Benzoyl peroxide gel in the treatment of mild to moderate Acne Vulgaris 60 patient has been selected according to inclusion and exclusion criteria. Among them predominant age group was 20 to 24 years. Despite its spontaneous regression in most patients, acne persists in 10.% of those patients over the age of 25 years[11]. Female predominance was observed. Male: female ratio was 1:2.52. Among 60 patients, 51(85%) patients had oily skin type and face was the common site 56(93.33%) in all the patients, followed by back 34(56.7%) and chest 8(13.33%). Additionally, a significant number of patients reported similar findings which is consistent to other study.

For mild to moderate acne vulgaris, topical therapy is the standard treatment[12]. The retinoids and benzoyl peroxide are frequently used drugs for the topical treatment. Benzoyl peroxide is a bactericidal agent that has moderate comedolytic and anti-inflammatory action[9]. Topical retinoids reduce the abnormal growth and development of keratinocytes within pilosebaceous duct[13]. Adapalene, which is a topical retinoid, binds to specific retinoic acid nuclear receptors, and modulates the cellular differentiation, keratinization and inflammatory processes[14]. Despite the fact that there are a lot of studies with benzoyl peroxide, or adapalene alone, there are only a few studies which compare these two drugs[7]. In our study, reduction of non-inflammatory lesion, inflammatory lesion and total lesion counts from baseline values were highly significant in both the groups (p<0.001) and between the groups also, there was a statistically significant difference present in different visits (p<0.05).

These findings conclude the better efficacy of adapalene as compared to benzoyl peroxide for the treatment of mild to moderate acne vulgaris. This data correlates with the study conducted by another study, they found adapalene to be

significantly more superior to benzoyl peroxide in reducing the lesions of mild acne vulgaris[15]. But they found a faster onset of action of benzoyl peroxide (at month 1) against inflammatory lesions, which they concluded to be due to its more rapid and superficial antibacterial and anti-inflammatory functions. Like our study, this study was also a single centre, randomized study comparing efficacy and safety of adapalene 0.1% gel and benzoyl peroxide 2.5% gel for a study period of 3 mont16. A similar comparative clinical study of efficacy and safety of adapalene 0.1% gel versus benzoyl peroxide 2.5% gel for the treatment of acne vulgaris. They found that a better efficacy and safety of adapalene than benzoyl peroxide in the treatment of mild to moderate acne vulgaris[17].

In a similar study, it has also compared the efficacy and safety of adapalene 0.1% gel and benzoyl peroxide, but the concentration of benzoyl peroxide was different, they used 4% benzoyl peroxide, and unlike our study, they found benzoyl peroxide to be more efficacious than adapalene on non-inflammatory and inflammatory lesions at 2 weeks and 5 weeks18. Compared these two drug monotherapies with their combination, and concluded that the combination therapy has no superior efficacy over adapalene or benzoyl peroxide monotherapy. This was also an open-label, prospective study but unlike our study, they used 5% benzoyl peroxide lotion[19]. The adverse events are also major determinants in selecting a topical medication for acne patients. In our study, we found lesser side effects with adapalene group than those with benzoyl peroxide. The patients treated with adapalene suffered from 6.6% dryness, 3.3% erythema whereas those treated with benzoyl peroxide had 10% dryness, 6.6% erythema and 3.3% burning. The adverse events did not interfere with the completion of the treatment. Similarly, a study conducted by Babaeinejad and Fouladi20, mild and transient side effects were found in both adapalene and benzoyl peroxide groups. It has been justified that benzoyl peroxide 2.5% is as effective as higher concentrations (5% and 10%) in treating acne vulgaris while causing fewer side effects[21-23].

In the study conducted both adapalene and benzoyl peroxide were found to be safe drugs although they used 4% benzoyl peroxide. In another study concluded that there were no significant differences between the 3 groups (adapalene, benzoyl peroxide and adapalene-benzoyl peroxide combination) with regard to erythema, dryness or burning. All the side effects diminished with the continuation of the treatment[22].

Conclusion

Adapalene has better efficacy and safety than benzoyl peroxide, thus adapalene monotherapy can be used for the treatment of mild to moderate acne vulgaris, whereas severe inflammatory lesions of acne should be treated with combining adapalene with other drugs, along with the systemic therapy as suggested by previous studies.

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