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How Well 0.1% Adapalene with 2.5% Benzoyl Peroxide Treats Mild to Moderate Acne Vulgaris in North India Compared to 0.1% Adapalene with 1% Clindamycin

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ABSTRACT

The aim of the present study is to determine how well 0.1% Adapalene with 2.5% Benzoyl Peroxide treats mild to moderate acne vulgaris in North India compared to 0.1% adapalene with 1% Clindamycin? The study protocol was approved by the Institutional Ethics Committee. Subsequently, the study was initiated. This Interventional, Comparative study included subjects aged 12-35 years clinically diagnosed with acne vulgaris in adolescent patients attending the Department of Dermatology at Adesh Medical College and Hospital, Shahabad Mohri, Haryana, India. When the subject was under 18 years of age and below, we obtained special pediatric informed consent from the parent. No significant difference was found between baseline lesions and lesions at the end of 2 weeks ($p>0.05$) in the two groups, but a statistically significant difference was noted in lesions at the end of 4 weeks and 6 weeks ($p<0.05$) in the inflammatory lesions. The difference in visits was statistically significant ($p<0.0001$) in both groups. Statistically, there was a difference in total lesions between the two groups at different visits ($p<0.05$), but no significant difference between the groups at different visits ($p>0.05$). Adapalene exhibits comparable effectiveness and is relatively well tolerated in comparison to the combination of benzoyl peroxide and clindamycin. Therefore, adapalene can be used independently to treat mild to moderate acne vulgaris, similar to the benzoyl peroxide-clindamycin approach. Severe inflammatory lesions of acne can be topically treated with a combination of clindamycin and adapalene, or benzoyl peroxide and clindamycin in conjunction with systemic therapy.

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Key Words
Adapalene, benzoyl peroxide, acne vulgaris, clindamycin, north india

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INTRODUCTION

Acne vulgaris is a common dermatological condition that affects individuals of various age groups. This illness affects approximately 85% of individuals between the ages of 12 and 24 years, with a higher incidence rate of 56% among males and 46% among females aged 14-16 years[1-4]. Acne vulgaris primarily affects the facial region, potentially leading to adverse consequences including negative self-perception, diminished self-worth, depressive symptoms, social anxiety and heightened levels of distress[5]. The management of acne should involve careful consideration and appreciation of the psychological implications associated with this condition[6]. It impacts physical appearance and psychological well-being, necessitating effective and well-tolerated treatment options. Topical formulations combining antibiotics and retinoids have gained prominence in the management of mild-to-moderate acne[7]. Multiple methodologies can be employed to manage acne[8]. Acne vulgaris encompasses various techniques, including topical, systemic, physical and supplementary herbal alternatives and miscellaneous therapies and a set of six guidelines has been formulated for the purpose of treatment. Evidence-based guidelines delineate distinct therapeutic approaches for the mild, moderate and severe manifestations of acne. In instances of severe acne, a combination therapy involving oral antibiotics and topical medications is commonly employed[9]. These may consist of a combination of benzoyl peroxide and antibiotics, retinoids and benzoyl peroxide, or retinoids, benzoyl peroxide and antibiotics. Therefore, oral isotretinoin is a potential treatment option for severe acne[10-13]. This background explored the comparative efficacy and tolerability of two such combinations: 0.1% adapalene with 1% clindamycin versus 0.1% adapalene with 2.5% Benzoyl Peroxide[14].

Efficacy of 0.1% Adapalene with 1% Clindamycin: Clindamycin, a lincosamide antibiotic, exhibits antimicrobial activity against Propionibacterium acnes, which is a key contributor to acne pathogenesis[15]. The combination of 0.1% adapalene and 1% clindamycin was designed to provide a dual-action approach, suppressing bacterial growth and reducing inflammation[16]. The antimicrobial effect of clindamycin targets the underlying cause of acne, whereas its anti-inflammatory properties contribute to the resolution of existing lesions[17-19]. Clinical studies have demonstrated a significant reduction in inflammatory and non-inflammatory lesions with the use of this combination, making it an effective treatment for mild-to-moderate acne vulgaris[20].

Efficacy of 0.1% Adapalene with 2.5% Benzoyl Peroxide: Adapalene, a third-generation retinoid, exhibits comedolytic and anti-inflammatory effects by normalizing keratinization and reducing inflammation[21]. Combined with 2.5% Benzoyl Peroxide, which is a potent antimicrobial agent, this formulation targets multiple facets of acne pathogenesis[22]. Adapalene enhances cell turnover and prevents the formation of micro comedones, whereas Benzoyl Peroxide provides antimicrobial activity against P. acnes[23]. Clinical trials have consistently demonstrated a significant reduction in lesion count and an improvement in overall acne severity with the use of 0.1% adapalene and 2.5% Benzoyl Peroxide[24]. Hence the aim of the present study is to determine how well 0.1% Adapalene with 2.5% Benzoyl Peroxide treats mild to moderate acne vulgaris in North India compared to 0.1% adapalene with Clindamycin 1%?.

MATERIALS AND METHODS

The study protocol was approved by the Institutional Ethics Committee (Approval Number: AMCH/ IEC-BHR/2023/03/03A). Subsequently, the study was initiated.

Study Design: This Interventional, Comparative study included subjects aged 12-35 years clinically diagnosed with acne vulgaris in adolescent patients attending the Department of Dermatology at Adesh Medical College and Hospital, Shahabad Mohri, Haryana, India. When the subject was under 18 years of age and below, we obtained special pediatric informed consent from the parent.

Study Period: The duration of the study was one year after approval from the Institutional Ethics Committee.

Inclusion Criteria: Participants were within the age range typically affected by acne vulgaris, typically adolescents and adults between the ages of 12 and 35. Inclusion was restricted to individuals diagnosed with mild to moderate acne vulgaris. Severity was assessed using standardized grading systems such as the Global Acne Grading System (GAGS) or other validated scales. The participants had a confirmed diagnosis of acne vulgaris by a qualified dermatologist or a healthcare professional. Participants were required to have a minimum baseline lesion count, including comedones, papules and pustules, to ensure the presence of mild to moderate acne. Individuals with different skin types prevalent in the North Indian population should be considered, including Fitzpatrick skin types III-V, to account for variations in response to treatments.

Participants should reside in North India to align with the specific geographical focus of the study, considering the potential regional variations in lifestyle, climate and genetic factors. Participants should be in good general health with no known systemic conditions that could interfere with the evaluation of acne or application of topical treatments. Participants currently using topical or systemic acne treatments were excluded to ensure a clear evaluation of the selected interventions. The participants expressed willingness and commitment to comply with the study protocol, including regular follow-up visits and adherence to the prescribed treatment regimen. Informed consent was obtained from the participants or their legal guardians, emphasizing the voluntary nature of participation and the potential risks and benefits associated with the study. Establishing precise inclusion criteria ensures that the study population is relevant to the research question and facilitates the generation of meaningful insights into the comparative efficacy and tolerability of the specified acne treatments in the context of mild to moderate acne vulgaris in North India.

Exclusion Criteria: Individuals with severe nodulocystic acne were excluded to maintain homogeneity in the study population and to focus on mild-to-moderate acne cases. Participants with known hypersensitivity or allergy to any of the active ingredients in the study formulations (Adapalene with Clindamycin or Benzoyl Peroxide) were excluded to prevent adverse reactions. Female participants who were currently pregnant or lactating were excluded because of potential risks associated with certain topical treatments during these periods. Individuals with chronic skin conditions (e.g., psoriasis, eczema) that may interfere with the evaluation of acne or complicate the interpretation of treatment outcomes were excluded. Participants currently using medications contraindicated with the study treatments (e.g., retinoids and certain antibiotics) were excluded to avoid potential interactions and confounding effects. Individuals currently receiving systemic antibiotic therapy for any reason were excluded to prevent interference with the antibacterial effects of topical treatments. Participants using other topical retinoid medications were excluded to avoid potential additive effects and confounding influences on the treatment outcomes. Individuals using other topical or systemic acne treatments (e.g., salicylic acid and isotretinoin) at the time of enrollment were excluded to isolate the effects of the study formulations. Participants with uncontrolled systemic diseases (e.g., diabetes and autoimmune disorders) that may affect skin health or complicate acne assessment were excluded. Individuals who had undergone recent dermatological procedures (e.g., chemical peels and laser therapy) that may affect the skin's response to the study treatments were excluded. Participants with a history of keloid formation were excluded because of the potential risk of hypertrophic scarring in response to treatment. Individuals who were unlikely to comply with the study protocol or attend regular follow-up visits were excluded to ensure data accuracy and to minimize loss to follow-up. A sample size of 172 clinically diagnosed patients with mild to moderate acne vulgaris visiting dept of dermatology OPD was enrolled in the study using the sample size estimation formula- The study population was separated into two groups. Group one was comprised of 86 patients treated with 0.1% adapalene and 1% clindamycin. Group two consisted of 86 patients treated with 0.1% adapalene and 2.5% benzoyl peroxide. By implementing these exclusion criteria, this study aimed to create a focused and well-defined cohort, maximize the internal validity of the research findings and provide a clearer understanding of the comparative efficacy and tolerability of the specified acne treatments in the North Indian population with mild-to-moderate acne vulgaris. After the selection of the study population, the patients were checked and treatments were initiated and evaluated at baseline and at 2-, 4- and 6 weeks' intervals.

Statistical Analysis: Simple tables were used to show the variables obtained. The chi-square test and Fisher's exact test (the latter for n values less than 5) were used to analyze statistically significant difference of variables and the P-value less than 0.05 will be accepted as being statistically significant.

RESULTS AND DISCUSSIONS

A cohort of 172 patients was enrolled in this research endeavor., of these, 86 patients in group B and 86 patients in group A successfully concluded the treatment throughout the duration of the study. Males constituted 40 % and females constituted of about 60% of the total cohort.

Number of Patients of Grad I is 37 and Grade II is 135 (Table 1).

Table 1: Distribution of Patients of Acne Based on Grade of Acne.

Grade of Acne	Number of patients
Grade I	37
Grade II	135

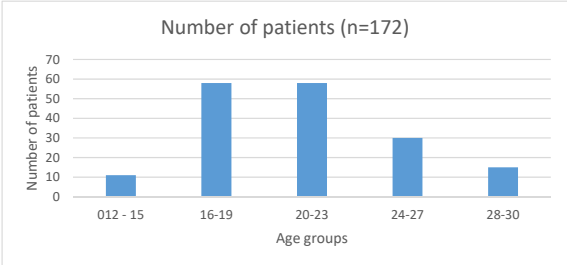

Fig. 1: Distribution of Acne Patients Based on Age of the Patient

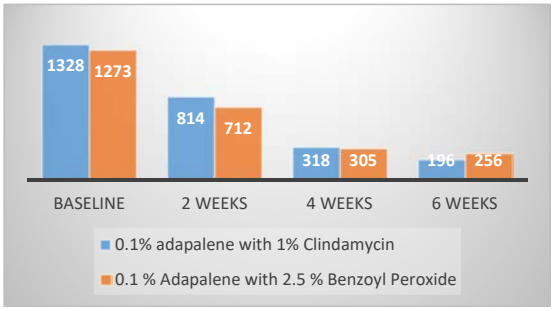

Fig. 2: Prior to and Following Therapy, a Comparison of Non-Inflammatory Lesions

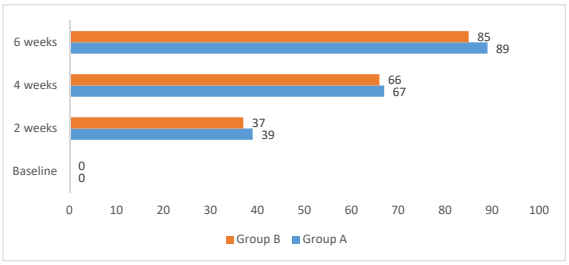

Fig. 3: Decrease of Non-Inflammatory Lesions as a Percentage

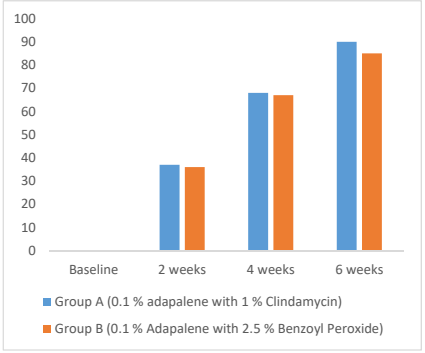

Fig. 4: Reduction in Inflammatory Lesions

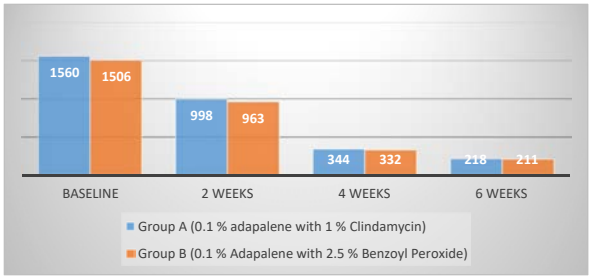

Fig. 5: Total Reduction in Total Lesions

By the end of the first visit (baseline), the mean count of non-inflammatory lesions in group A had decreased from 26.92-17.88, 10.8 and 4.5, respectively. During the first visit, the average number of inflammatory lesions was 17.35., after one, two and three months, it dropped to 11.35, 6.47 and 3 respectively. On the other hand, the average number of total lesions was 29.78; after one, two and three months, it dropped to 19.5, 11.78 and 5.39, respectively. The average number of noninflammatory lesions in group B decreased from 23.54 at the first visit (baseline) to 15.35, 8.71 and 4.12 after one, two and three months, respectively. During the initial visit, the average number of inflammatory lesions was 15.27; after one, two, and three months, it decreased to 11.54, 5.67 and 3.23, respectively. Similarly, the average number of total lesions was 26.43., after one, two and three months, it decreased to 17.38, 9.52 and 4.48, respectively. No significant difference was found between baseline lesions and lesions at the end of 2 weeks ($p>0.05$) in the two groups, but a statistically significant difference was noted in lesions at the end of 4 weeks and 6 weeks ($p<0.05$) in the inflammatory lesions. The difference in visits was statistically significant ($p<0.0001$) in both groups. Statistically, there was a difference in total lesions between the two groups at different visits ($p<0.05$), but no significant difference between the groups at different visits ($p>0.05$). While 3.2% of patients treated with adapalene reported dryness, 3.1% of patients prescribed the benzoyl peroxide-clindamycin combination reported dryness and 3.2% reported itching, indicating that adapalene had a better safety profile in this study. The patients were able to finish their treatment without any complications. Acne vulgaris is a pilosebaceous unit inflammatory disorder caused by inflammation, microbial flora alterations, follicular epidermal hyper proliferation and increased sebum production. Propionibacter acnes infection, androgen influence, certain medications, genetic predispositions and stress are the primary contributors to the development of acne[25]. Acne is distinguished by its characteristic comedones, which are noninflammatory lesions., on the other hand, acne is characterized by its inflammatory papules, pustules and nodules[26]. In

regard to treatment, topical therapy is the prevailing approach for managing acne vulgaris that is classified as mild to moderate[27]. Systemic treatment is recommended for the most severe instances of acne vulgaris[28].

Preferably utilized topical treatments consist of retinoids and antimicrobial, including benzoyl peroxide and antibiotics. Through their mechanism of action on follicular keratinocytes, topical retinoids inhibit the secretion of inflammatory cytokines and avert excessive cornification and follicular blockage[29]. Inflammatory acne can be effectively treated with topical antimicrobial such as benzoyl peroxide and antibiotics[29]. Adapalene, one of the novel retinoid compounds, has demonstrated efficacy in the topical treatment of acne vulgaris, as supported by several studies[28-30]. It is a naphthoic acid derivative with agonistic activity at retinoid receptors. Keratinization is inhibited and it possesses anti-inflammatory properties[28]. Comparative studies have shown that adapalene is safer for the skin than tretinoin and isotretinoin gel in all of their formulations (gel, ointment and micro sphere gel)[29,30]. Comparing the efficacy and tolerability of adapalene and benzoyl peroxide-clindamycin combinations as topical treatments for mild to moderate acne vulgaris was the purpose of this study. At the conclusion of the three-month period, patients in group A (adapalene) exhibited a mean reduction of 87% in non-inflammatory lesions, 87.6% in inflammatory lesions and 87.9% in total lesion counts. This information is consistent with the findings of a study[29], which revealed that 96% of patients exhibited acne improvement from baseline. In contrast to our research, this study was a non-comparative, multi-center examination of Adapalene gel 0.1% in patients with mild to moderate acne vulgaris[26]. Our study aimed to compare the topical treatment efficacy of benzoyl peroxide-clindamycin and adapalene for mild to moderate acne vulgaris. The results indicated that there was no statistically significant difference ($p>0.05$) in efficacy between groups A (adapalene) and B (benzoyl peroxide-clindamycin). This suggests that adapalene exhibits comparable efficacy to the benzoyl peroxide-clindamycin combination. A comparable investigation was carried out by study[27] wherein they assessed the comparative efficacy of adapalene and azithromycin, both individually and in combination, on non-inflammatory and inflammatory lesions. The findings of this study indicated that adapalene exhibited a greater reduction in noninflammatory lesions than the other two groups. Although there was a correlation between these results and our research, it was not statistically significant. Our study aimed to compare the topical treatment efficacy of benzoyl peroxide-clindamycin and adapalene for mild to moderate acne vulgaris. The results indicated that there was no statistically significant difference ($p>0.05$) in efficacy between groups A (adapalene) and B (benzoyl peroxide-clindamycin). This suggests that adapalene exhibits comparable efficacy to the benzoyl peroxide-clindamycin combination. A comparable investigation was carried out by[28] wherein they assessed the comparative efficacy of adapalene and azithromycin, both individually and in combination, on non-inflammatory and inflammatory lesions. The findings of this study indicated that adapalene exhibited a greater reduction in noninflammatory lesions than the other two groups. Although there was a correlation between these results and our study, no statistically significant distinction was observed in the effectiveness of the three treatment groups with regard to the inflammatory lesions of acne. The study[29] may have incorporated severe inflammatory acne lesions and substituted azithromycin for clindamycin., these factors may account for this disparity. Langner *et al.* concluded in a separate study that both adapalene and the benzoyl peroxide -clindamycin combination are effective treatments for acne, which is consistent with our findings. However, against inflammatory and total lesions, the benzoyl peroxide-clindamycin combination demonstrated a significantly faster onset of action and was significantly more effective[30].

CONCLUSION

Adapalene exhibits comparable effectiveness and is relatively well tolerated in comparison to the combination of benzoyl peroxide and clindamycin. Therefore, adapalene can be used independently to treat mild to moderate acne vulgaris, similar to the benzoyl peroxide-clindamycin approach. Severe inflammatory lesions of acne can be topically treated with a combination of clindamycin and adapalene, or benzoyl peroxide and clindamycin in conjunction with systemic therapy. The findings of this research indicate that both treatment regimens can be effective in reducing acne lesions and improving the overall appearance of the skin. However, it is important to note that individual patient responses may vary and a personalized approach to acne treatment remains essential.

Conflict of Interest: There is no conflict of interest among the present study authors.

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