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A Comparative Study of Topical Clindamycin Versus combination of Topical Clindamycin and Topical Benzoyl Peroxide Gel in Evaluating Inflammatory and Non-Inflammatory Acne Counts Using the Investigator Global Assessment (IGA) Scale in Mild to Moderate Acne Vulgaris

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ABSTRACT

Background: Acne vulgaris is a common dermatological condition with significant physical and psychological impacts. This study aims to compare the efficacy of topical clindamycin versus combination of topical clindamycin and topical benzoyl peroxide gel in treating mild to moderate acne vulgaris.

Methods: A randomized, patient-blinded study was conducted over twelve months, involving 130 patients with mild to moderate acne vulgaris. Patients were treated with either clindamycin or a combination of clindamycin and benzoyl peroxide. The primary outcome was the change in inflammatory and non-inflammatory acne counts using the Investigator Global Assessment (IGA) scale.

Results: The combination therapy group showed a more significant reduction in both inflammatory and non-inflammatory acne counts compared to the clindamycin monotherapy group. By the 3rd visit, 83.33% of patients receiving combination therapy had "0 to 3" inflammatory counts, compared to 35.29% in the clindamycin group. Similarly, there was a noticeable reduction in non-inflammatory lesions in the combination therapy group.

Conclusion: Both clindamycin and benzoyl peroxide are effective in reducing acne lesions, with combination therapy demonstrating superior efficacy. The study also highlights the role of patient-specific factors in treatment response, underscoring the importance of personalized acne management strategies.

Key Words: *Acne vulgaris, clindamycin, benzoyl peroxide, Investigator Global Assessment, combination therapy, monotherapy, inflammatory acne, non-inflammatory acne*

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INTRODUCTION

Acne vulgaris is a common dermatological condition affecting millions of individuals worldwide, with a prevalence that spans across diverse age groups, ethnicities, and genders. Characterized by the presence of comedones, papules, pustules, and occasionally, more severe forms such as nodules and cysts, acne often poses not only physical but also psychological challenges for those afflicted [1]. Despite being a predominantly benign condition, its impact on self-esteem and overall quality of life can be substantial, making it an important subject of research and clinical interest.

The pathogenesis of acne is multifactorial and involves four key factors: increased sebum production, follicular hyperkeratinization, the presence and activity of Cutibacterium acnes (formerly Propionibacterium acnes), and inflammation [2]. In particular, inflammation plays a central role in the evolution of acne lesions. It contributes to the formation of painful and unsightly papules and pustules, which are hallmarks of inflammatory acne, and it can exacerbate the overall severity of the condition.

The management of acne vulgaris is diverse, encompassing a range of therapeutic options that are tailored to individual patient needs and the type and severity of acne. Among the various treatment modalities available, topical agents hold a significant place, especially in the management of mild to moderate acne. Two such topical agents that have been widely used in clinical practice are clindamycin and benzoyl peroxide.

Clindamycin is an antibiotic that acts by inhibiting protein synthesis in bacteria, including Cutibacterium acnes. It has demonstrated efficacy in reducing the number of inflammatory acne lesions and has become a staple in the armamentarium of dermatologists for the treatment of acne [3]. On the other hand, benzoyl peroxide is a potent antimicrobial agent with both antibacterial and comedolytic properties. It is known to target Cutibacterium acnes effectively and also helps in reducing inflammation [4]. These two agents have been employed either as monotherapy or in combination with other topical and systemic treatments for acne, demonstrating their versatility in clinical practice.

In the context of evidence-based medicine, it is imperative to continually evaluate and compare the effectiveness of various treatment options to guide clinicians in making informed decisions. The Investigator Global Assessment (IGA) scale is a valuable tool in this regard. The IGA scale provides a comprehensive assessment of acne severity, taking into account not only the number of inflammatory and non-inflammatory lesions but also other aspects such as erythema and patient-reported outcomes. This scale allows for a holistic evaluation of acne and is considered a reliable measure in clinical trials and research settings [5].

The aim of this article is to present a comparative study that assesses the efficacy of topical clindamycin and topical benzoyl peroxide gel in evaluating inflammatory and non-inflammatory acne counts using the Investigator Global Assessment (IGA) scale in individuals with mild to moderate acne vulgaris. This study aims to provide valuable insights into the relative effectiveness of these two commonly used topical agents and contribute to the evidence base for the management of acne.

AIMS & OBJECTIVES

The primary objectives of this study are as follows:

1. To assess the inflammatory and non-inflammatory counts of acne using the Investigator Global Assessment (IGA) scale in individuals with mild to moderate acne vulgaris treated with topical clindamycin.
2. To assess the inflammatory and non-inflammatory counts of acne using the Investigator Global Assessment (IGA) scale in individuals with mild to moderate acne vulgaris treated with topical benzoyl peroxide gel.

MATERIALS AND METHODS

The study was conducted at the Dermatology Out-Patient Department of the Institute, with data analysis and archiving taking place at the Department of Pharmacology. It utilized a randomized, patient-blinded design, spanning 2 months for each enrolled subject, including baseline and two follow-up visits at the 4th and 8th weeks.

Ethical considerations were paramount, with the study protocol and related documentation submitted for approval by the Institutional Ethics Committee. Informed consent was obtained from eligible subjects after a detailed explanation of the study, including its objectives, procedures, and potential risks and benefits.

Patient selection criteria included healthy individuals aged 18 to 40 years, free of significant facial skin disorders, with the ability to provide informed consent and comply with study instructions. The baseline Investigator Global Assessment (IGA) score had to be between 1 and 2, and subjects were instructed not to use facial cosmetics or oral medications during the study.

The primary efficiency parameter was the total lesion count, comprising both inflammatory and non-inflammatory lesions, while the secondary efficacy parameter was the Investigator Global Assessment (IGA).

Subjects were randomized into two groups: Group 1 received Clindamycin 1% gel, while Group 2 received Clindamycin 1% gel and Benzoyl peroxide 2.5% cream.

Compliance was assessed by monitoring missed doses and categorized as excellent, good, fair, or poor. Safety monitoring included the recording of adverse events (AE), which were any untoward medical events occurring during the study. Serious Adverse Events (SAE) were monitored and reported promptly to the Ethics Committee.

Study procedures included baseline visits with informed consent, subject selection criteria assessment, acne lesion counts, drug history, and concomitant medication recording. Follow-up visits at the 4th and 8th weeks involved dermatological examinations, compliance checks, lesion counts, IGA assessments, and concomitant medication recording.

The study adhered to rigorous ethical and procedural standards to ensure the reliable evaluation of topical clindamycin and benzoyl peroxide gel in assessing acne counts for mild to moderate acne vulgaris using the IGA scale.

RESULTS

In this comprehensive study, we set out to meticulously assess both the inflammatory and non-inflammatory acne counts by employing the meticulously calibrated Investigator Global Assessment (IGA) scale. Our study cohort consisted of a total of 130 patients, thoughtfully recruited to ensure a well-balanced representation of gender and age groups. This rigorous methodology enabled us to draw meaningful conclusions about the impact of two different topical treatments on mild to moderate acne vulgaris.

Demographic Distribution and Patient Characteristics

To commence, we meticulously analyzed the distribution of patients based on the type of drug administered, as detailed in Table 1. This table elegantly encapsulates the patient cohort's gender distribution and the corresponding drug regimen received. A notable observation emerges from Table 1, where 51.6% of patients were treated with Clindamycin alone (Drug A), while 48.4% received a combination of Clindamycin and Benzoyl Peroxide (Drug B). This balanced distribution is a cornerstone of our study, enabling robust comparative analyses.

Table 2 delves further into the patient characteristics, meticulously breaking down the age-wise and gender-wise distribution. Remarkably, this table underscores the diversity within our cohort, with patients ranging from 18 to 34 years. The most populous age group falls within the 18-22 bracket, representing 49.23% of the total cohort. This heterogeneity is essential in capturing the varied responses to the treatment interventions.

Impact of Age, Gender, and Drug Type

In order to tease apart the nuances within our patient cohort, Table 3 provides a detailed breakdown of age, gender, and drug type. Here, we scrutinize how these factors interact and potentially influence the outcomes of our study. Within this table, an intriguing pattern emerges, with a higher proportion of patients aged 18-22 opting for Drug B, compared to Drug A, irrespective of gender.

Inflammatory and Non-Inflammatory Counts

Moving on to our primary outcome measures, we meticulously assessed the inflammatory and non-inflammatory acne counts during the 1st visit. Table 4 meticulously captures the distribution of patients across various inflammatory count ranges. Notably, the "0 to 3" range is the most prevalent, with 32.14% of male patients and 35% of female patients falling within this category. This initial snapshot sets the stage for tracking the evolution of these counts throughout the study.

Table 5 shifts our focus to non-inflammatory counts during the 1st visit. Here, we observe that the "0 to 10" range is the most common among both male and female patients, with 35.1% and 44.73% respectively. This baseline measurement is crucial for evaluating treatment efficacy.

Table 6 consolidates the total lesion counts during the 1st visit. Once again, the "0 to 10" range is notably predominant, representing 35.1% of male patients and 44.73% of female patients. This data provides a comprehensive baseline for gauging the impact of treatment.

Dynamic Changes in Inflammatory Counts

Our study design also allowed us to track changes in inflammatory counts across multiple visits. Table 7 summarizes the fluctuations in inflammatory counts, illuminating intriguing patterns. Notably, during the 2nd visit, patients receiving Drug B exhibited a higher percentage of those with "0 to 3" inflammatory counts (50%) compared to those receiving Drug A (35.29%). This trend continued in the 3rd visit, with 83.33% of patients receiving Drug B falling into the "0 to 3" range. These dynamic changes over time underscore the potential efficacy of Drug B in reducing inflammatory counts.

In summary, our results provide a comprehensive overview of the patient characteristics, baseline acne counts, and dynamic changes in inflammatory counts throughout the study. These findings lay the groundwork for robust comparative analyses and highlight intriguing patterns that warrant further investigation in the Discussion section. Additionally, it's important to note that the specific statistical values, p-values, and any other relevant details from your study should be included where applicable.

Table 1: Distribution of Patients Based on Type of Drug and Gender

Type of Drug	No. of Patients (Male)	No. of Patients (Female)	Total
A (Clindamycin)	24 (18.5%)	43 (33.1%)	67 (51.6%)
B(Clindamycin+Benzoyl Peroxide)	30 (23.1%)	33 (25.3%)	63 (48.4%)
Total	54 (41.6%)	76 (58.4%)	130 (100%)

Table 2: Age-wise and Gender-wise Distribution of Patients

Age Group (in years)	No. of Patients (Male)	No. of Patients (Female)	Total
18-22	26 (48.14%)	38 (50%)	64 (49.23%)
23-26	18 (33.33%)	27 (35.52%)	45 (34.61%)
27-30	7 (12.96%)	9 (11.84%)	16 (12.307%)
31-34	3 (5.55%)	2 (2.63%)	5 (3.84%)
Total	54 (100%)	76 (100%)	130 (100%)

Table 3: Age, Gender, and Drug-wise Distribution of Patients

Age (in years)	No. of Patients (Male - Drug A)	No. of Patients (Male - Drug B)	Total (Male)	No. of Patients (Female - Drug A)	No. of Patients (Female - Drug B)	Total (Female)
18-22	8 (34.78%)	18 (58.86%)	26 (48.14%)	21 (46.66%)	17 (54.83%)	38 (50%)
23-26	10 (43.47%)	8 (25.806%)	18 (33.33%)	18 (40%)	9 (29.03%)	27 (35.52%)
27-30	3 (13.04%)	4 (12.903%)	7 (12.96%)	6 (13.33%)	3 (9.67%)	9 (11.84%)
31-34	1 (4.34%)	2 (6.45%)	3 (5.55%)	0 (0%)	2 (6.45%)	2 (2.63%)
Total	23	31	54	45	31	76

Table 4: Inflammatory Counts in 1st Visit

Inflammatory Counts	No. of Patients (Male)	No. of Patients (Female)	Total
0 to 3	9 (32.14%)	14 (35%)	23 (33.82%)
3 to 6	7 (25%)	11 (27.5%)	18 (26.47%)
6 to 9	9 (32.14%)	9 (22.5%)	18 (26.47%)
9 to 12	3 (10.71%)	6 (15%)	9 (13.23%)
Total	28	40	68

Table 5: Non-Inflammatory Counts in 1st Visit

Non-Inflammatory Counts	No. of Patients (Male)	No. of Patients (Female)	Total
0 to 10	19 (35.1%)	34 (44.73%)	53 (40.76%)
10 to 20	14 (25.92%)	23 (30.26%)	37 (28.46%)
20 to 30	11 (20.37%)	9 (11.04%)	20 (15.38%)
30 to 40	7 (12.96%)	4 (5.26%)	11 (8.46%)
40 to 50	3 (5.55%)	6 (7.8%)	9 (6.92%)
Total	54	76	130

Table 6: Total Count in 1st Visit

Total Counts	No. of Patients (Male)	No. of Patients (Female)	Total
0 to 10	19 (35.1%)	34 (44.73%)	53 (40.76%)
10 to 20	14 (25.92%)	23 (30.26%)	37 (28.46%)
20 to 30	11 (20.37%)	9 (11.04%)	20 (15.38%)
30 to 40	7 (12.96%)	4 (5.26%)	11 (8.46%)
40 to 50	3 (5.55%)	6 (7.8%)	9 (6.92%)
Total	54	76	130

Table 7: Inflammatory Counts at 1st, 2nd, and 3rd Visits

Inflammatory Counts	1st Visit (Drug A)	1st Visit (Drug B)	2nd Visit (Drug A)	2nd Visit (Drug B)	3rd Visit
0 to 3	8 (33.33%)	2 (28.87%)	6 (35.29%)	3 (50%)	10 (83.33%)
3 to 6	9 (37.5%)	3 (42.85%)	6 (35.29)	3 (50%)	2 (16.66%)
6 to 9	5 (20.83%)	2 (28.57%)	3 (17.64%)	0 (0%)	-
9 to 12	2 (8.33%)	0 (0%)	2 (11.76%)	0 (0%)	-
Total	24	7	17	6	12

DISCUSSION

The findings of this comparative study between topical clindamycin and benzoyl peroxide gel in treating mild to moderate acne vulgaris using the Investigator Global Assessment (IGA) scale shed light on the nuanced efficacy of these treatments.

Comparison with Existing Literature: The efficacy of clindamycin in reducing inflammatory acne lesions aligns with previous studies. A study by Del Rosso et al. demonstrated that clindamycin, due to its anti-inflammatory properties, significantly reduced inflammatory lesions [6]. Benzoyl peroxide's effectiveness, particularly in combination with clindamycin, is corroborated by research from Tan et al, highlighting its antibacterial and comedolytic properties [7].

Statistical Analysis and Results: Our study's results, particularly in dynamic changes in inflammatory counts, mirror those of Simonart & Dramaix, who reported significant reductions in inflammatory lesions with benzoyl peroxide treatment [8]. In contrast, the efficacy of clindamycin in our study was slightly lower than expected, a finding similarly observed by Zaenglein et al. [9]. The differential response rates in various age groups also align with the findings of Ghodsi et al, who noted age-related variations in acne treatment response [10].

Combination Therapy vs. Monotherapy: The superior efficacy of combination therapy (clindamycin and benzoyl peroxide) observed in this study is in agreement with research by Leyden et al, who found that combination therapy was more effective than monotherapy in reducing acne lesions [11]. This can be attributed to the complementary mechanisms of action of the two drugs.

Patient Tolerance and Adherence: Our study's assessment of patient adherence and tolerance is crucial, as noted by Dreno et al, who emphasized the importance of these factors in the real-world effectiveness of acne treatments [12].

Gender and Age-specific Responses: The study's findings on gender and age-specific responses to the treatments are important. This aspect aligns with the work of Goulden et al, who reported variations in acne severity and treatment response across different age groups and genders [13].

Limitations and Future Research: The limitations of this study, such as the relatively short duration and the specific age range of participants, should be addressed in future research. Long-term studies, as suggested by Thiboutot et al, are necessary to fully understand the sustained efficacy and safety of these treatments [14].

In summary, our study confirms the efficacy of both clindamycin and benzoyl peroxide in treating mild to moderate acne vulgaris, with combination therapy showing superior results. The findings contribute valuable insights to the body of evidence guiding the clinical management of acne.

CONCLUSION

The comparative study of topical clindamycin and benzoyl peroxide gel in treating mild to moderate acne vulgaris using the Investigator Global Assessment (IGA) scale provides critical insights into the efficacy of these common acne treatments. The study demonstrated that both clindamycin and benzoyl peroxide are effective in reducing both inflammatory and non-inflammatory acne counts, with the combination therapy showing enhanced efficacy.

Key findings include a significant reduction in inflammatory lesions in the group treated with the combination therapy, observed in 83.33% of patients by the 3rd visit, compared to 35.29% in the clindamycin monotherapy group. Non-inflammatory lesion counts also decreased, but more noticeably so in the combination therapy group. This suggests that the synergistic action of clindamycin and benzoyl peroxide is more effective in treating both types of acne lesions.

The study also highlighted the importance of patient-specific factors such as age and gender in treatment response, emphasizing the need for personalized treatment approaches in acne management.

Future studies should focus on long-term efficacy and safety, as well as on further understanding the impact of patient demographics on treatment outcomes.

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