

Comparison of the Efficacy of 5% Dapsone Gel and 1% Clindamycin Phosphate Gel in the Treatment of Mild to Moderate Acne Vulgaris

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Abstract

Introduction: Acne vulgaris, a chronic dermatological condition, is characterized by hair follicle blockage by dead skin cells and sebum, leading to various manifestations including blackheads, whiteheads, and possible scarring. This study aimed to evaluate dapsone gel's effectiveness and safety in treating acne vulgaris compared to clindamycin gel, offering insights for managing this prevalent skin condition.

Objective: To compare the efficacy of 5% dapsone gel and 1% clindamycin phosphate gel in the treatment of mild to moderate acne vulgaris.

Methods: A randomized clinical trial at Bahawal Victoria Hospital focused on treating mild to moderate acne vulgaris from February to August 2023. 110 patients were recruited, with 55 in Group-I receiving dapsone gel and 55 in Group-II receiving Clindamycin gel. The 3-month treatment aimed at assessing efficacy and safety for moderate acne vulgaris management, offering insights for healthcare professionals.

Results: In group-A (5% Dapsone gel), 43(78.2%) had efficacy, while in group-B (1% Clindamycin gel), 29(52.7%) had efficacy with a p-value 0.005, which is statistically significant.

Conclusion: Dapsone 5% gel monotherapy demonstrated superior efficacy outcomes in comparison to the clindamycin phosphate 1% gel monotherapy following a 12-week treatment period, offering the added benefit of a simplified treatment regimen through its once-daily topical administration.

Keywords: Clindamycin, Dapsone, Acne Vulgaris.

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Introduction

Acne vulgaris is a common skin condition with several types of lesions; comedones, papules, pustules and nodules, as well as cysts and scar formation. Typically starting in adolescence and resolving by the mid-twenties. While mostly benign, severe cases can cause significant psychological distress due to scarring. The primary lesion, a microcomedone, is crucial and involves complex interactions like altered keratinization, sebaceous follicle hyperplasia, Propionibacterium acnes colonization, immune response, and inflammation.¹⁻²

The lesions may start as non-inflammatory comedones and progress to inflamed papules and pustules. Characteristic features in a patient are white and black comedones, papules, pustules, cysts, nodules, abscesses, and scarring. Severity determines classification and treatment options, including systemic and topical therapy. New treatments have evolved with a better understanding of acne pathogenesis. The therapies that are topical are benzoyl peroxide, retinoids, antibiotics, salicylic acid and azelaic acid. The management of the disease involves use of antibiotics, hormonal therapy, and oral isotretinoin.³⁻⁵

Topical clindamycin effectively treats mild-to-moderate acne, either alone or combined with other treatments, such as systemic therapies. Side effects are uncommon but can include pseudo-membranous colitis. Localized skin irritation may occur due to the drug's vehicle. Antibiotic use alone can lead to bacterial resistance, reducing acne treatment efficacy and highlighting the need for new therapeutic options.⁶⁻⁷

Topical dapsone gel was approved in 2005 for the treatment of acne vulgaris for patients that do not suffer from G6PD deficiency. This gel offers anti-inflammatory activity as well as antimicrobial activity with minimal skin penetration. Due to these reasons, it is a candidate of choice for monotherapy in the treatment of acne.⁸⁻⁹

This study was carried out to determine the efficacy of topical dapsone 5% gel in comparison with clindamycin 1% gel for treating mild to moderate acne vulgaris for which no head-to-head local comparison was conducted in our South Punjab especially in Bahawalpur region. The results will assist in identifying the better treatment and enhance the care of acne patients within the community.

Methods

A randomized clinical trial was carried out at the Department of Dermatology, Bahawal Victoria Hospital Bahawalpur, starting from February 2023 to August 2023. The study involved the enrollment of a total of 110 patients diagnosed with clinically mild to moderate acne vulgaris. Individuals between the ages of 12 and 30 of any gender, individuals with mild to moderate acne vulgaris lasting less than 3 months (mild to moderate acne with GAGS score 1-30) and individuals who were willing to receive treatment and attend follow-up appointments were eligible for participation.

Exclusion criteria encompassed patients who were not utilizing any oral or topical antibiotics or other medications for acne, individuals with facial conditions other than acne vulgaris (e.g., rosacea), a past medical history of active malignancy and G6PD deficiency or drug-induced acne, pregnant and lactating females, as well as individuals with

a documented history of allergy to the investigational medication. Sample size was 110 calculated by using online sample size calculator keeping 95% significance level and 80% power of study and taking expected efficacies of clindamycin 1% gel and dapsone 5% gel to be 63.3% and 40.1%.²⁴

After receiving Institutional Ethical Review Committee permission, the study was carried at the Outpatient Department of Dermatology, Bahawal Victoria Hospital Bahawalpur. Collectively 110 patients of acne vulgaris, clinically diagnosed and fulfilling all the criteria of inclusion were selected. Patients were diagnosed and subtyped by researcher herself under supervision of consultant dermatologist. Patients were randomized into following two equal groups by lottery method: i.e. Group-I: 5% Dapsone gel (n=55) and Group-II: 1% Clindamycin gel (n=55).

Following getting written informed consent from each patient, patients in group-I received 5% Dapsone gel topically at the lesions at night for twelve weeks and patients in the group-II received topical clindamycin 1% gel once daily for twelve weeks. Both the inflammatory as well as non-inflammatory lesions were measured and quantified (with GAGS score 1-30) prior to initiation of the treatment. All the patients were followed up 4-weekly for 12 weeks. At the beginning of the treatment, patients' data such as age, weight using a weight machine, height using stadiometer, duration of acne and past treatment records were collected on a structured proforma. Regarding the acne severity, the global acne grading system score (GAGS) according to the operational definition applied before and during the treatment phase. The GAGS score was used to assess the treatment result and response to therapy at 0 and 12 weeks as definitive assessment in this study.

The Global Acne Grading System Score (GAGS) is determined by adding up individual local scores, and the severity of acne is classified based on the overall score as follows: Mild: Score ranging from 1 to 18, Moderate: Score ranging from 19 to 30, Severe: Score ranging from 31 to 38 and very severe: Score greater than 39. Treatment outcome was categorized as follows: Excellent

when there is a reduction of over 75% in GAGS score, Good when the decrease is between 50-74%, Moderate when the decrease is between 25-50%, and Slight when the decrease is less than 25% in GAGS score. Good to excellent improvement in GAGS score was taken as treatment efficacy.

Inputs to data and analysis were done using Statistical Package for the Social Sciences (SPSS v25.0). The descriptive statistics including mean and standard deviation was also calculated on quantitative variables including age, weight, height, BMI, duration of illness and GAGS score. For nominal data such as gender, the frequencies as well as the percentages were calculated to describe the variables. The comparison of efficacy was performed by Chi-square/Fisher exact test. These include age, gender, and duration of the illness, which confounded and modified the results when applying the Chi-square test with the help of stratification and post-stratification. A p-

value of ≤ 0.05 was considered as the threshold for significance level.

Results

The purpose of presenting research was to know the difference in effectiveness of 5% Dapsone gel and 1% Clindamycin gel for mild to moderate acne vulgaris. There were 16(29.1%) male's patients in group-A (5%Dapsone gel) and 39(70.9%) female's patients. In group-B (1% Clindamycin gel) 13(23.6%) male patients and 42(76.4%) female patients. The descriptive statistics for mean age treated with the different therapies showed that the patients in group-A had an average age 21.75 ± 4 years while in group-B, the mean age was 21.49 ± 4.341 years. Age distribution of the patients showed that 32 patients were in the age group 12-20 and 23 patients in the age group of 21-30 years of group A, while 34 patients were in age group 12-20 and 21 patients in age group of 21-30 of group B.

Table-1: Comparison of gender distribution, age distribution, BMI & duration of disease between groups

Variable	Category	Group A (5% Dapsone gel) n = 55	Group B(1% Clindamycin gel) n= 55	Total (N=110)
Gender	Male	16 (29.1%)	13 (23.6%)	29 (26.4%)
	Female	39 (70.9%)	42 (76.4%)	81 (73.6%)
Age group	12-20 years	32 (58.2%)	34 (61.8%)	66 (60.0%)
	21-30 years	23 (41.8%)	21 (38.2%)	44 (40.0%)
Body Mass Index (BMI)	Underweight	6 (10.9%)	4 (7.3%)	10 (9.1%)
	Normal	42 (76.4%)	45 (81.8%)	87 (79.1%)
	Overweight	7 (12.7%)	6 (10.9%)	13 (11.8%)
Duration of Disease	≤ 2 months	30 (54.5%)	31 (56.4%)	61 (55.5%)
	≥ 2 months	25 (45.5%)	24 (43.6%)	49 (44.5%)

Table 2 : Comparison of outcome distribution between groups.

Outcome	Groups		Total
	Group-A (5% Dapsone gel)	Group-B (1% Clindamycin gel)	
Excellent (>75%)	29	10	39
	52.7%	18.2%	35.5%
Good (50-74%)	14	19	33
	25.5%	34.5%	30.0%
Moderate (26-49%)	11	9	20
	20.0%	16.4%	18.2%
Slight ($\leq 25\%$)	1	17	18
	1.8%	30.9%	16.4%
Total	55	55	110
	100.0%	100.0%	100.0%

The mean BMI of patients in group-A was 23.4±2.3 kg/m² while in group-B, the mean BMI of patients was 23.6±2.7 kg/m². In group-A, 6(10.9%) were underweight, while 42(76.4%) were normal and 7(12.7%) were overweight. In group-B, 4(7.3%) were underweight, while 45(81.8%) were normal and 6(10.9%) were overweight. The mean duration of disease in group-A was 1.8±1.3 months while in group-B, it was 1.89±1.5 months. In group-A, 30(54.5%) patients had disease for ≤2 months and 25(45.5%) had for >2 months, while in group-B, 31(56.4%) patients had disease for ≤2 months and 24(43.6%) had for >2 months.

In group-A, 29(52.7%) had excellent outcome, 14(25.5%) had good, 11(20.0%) had moderate and 1(1.8%) had slight outcome. In group-B, 10(18.2%) had excellent outcome, 19(34.5%) had good, 9 (16.4%) had moderate and 17(30.9%) had slight outcome. In group-A, 43(78.2%) had efficacy, while in group-B, 29(52.7%) had efficacy with a p-value 0.005, which is statistically significant. Stratification of efficacy of treatment between groups with respect to gender, age and duration of disease was done.

Table 3 : Comparison of efficacy between groups.

Efficacy	Groups		Total	P-value
	Group-A (5% Dapsone gel)	Group-B (1% Clindamycin gel)		
Yes	43 78.2%	29 52.7%	72 65.5%	0.005
No	12 21.8%	26 47.3%	38 34.5%	
Total	55 100.0%	55 100.0%	110 100.0%	

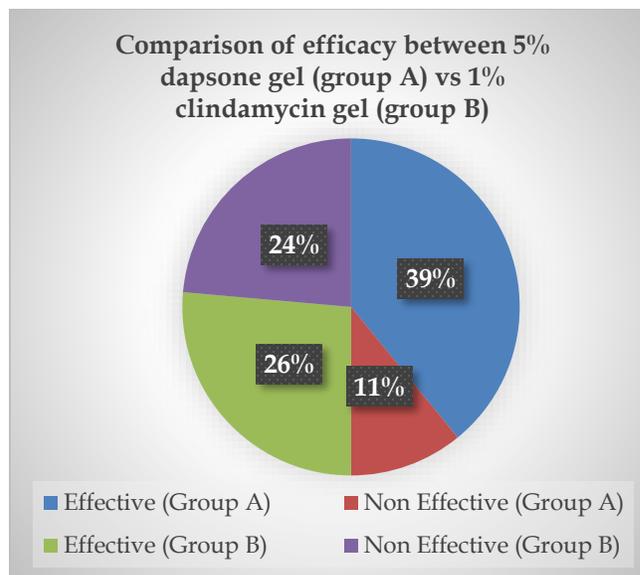


Figure 1: Pie chart demonstrating efficacy between groups.

Table 4: Stratification of efficacy between groups with respect to gender, age & duration of disease.

Stratification	Efficacy	Group A (5% Dapsone Gel)	Group B (1% Clindamycin gel)	Total	P-Value
Gender					
Male	Yes	11 (68.8%)	4 (30.8%)	15 (51.7%)	0.042
	No	5 (31.3%)	9 (69.2%)	14 (48.3%)	
	Total	16 (100%)	13 (100%)	29 (100%)	
Female	Yes	32 (82.1%)	25 (59.5%)	57 (70.4%)	0.027
	No	7 (17.9%)	17 (40.5%)	24 (29.6%)	
	Total	39 (100%)	42 (100%)	81 (100%)	
Age group 12-20 years	Yes	24 (75.0%)	19 (55.9%)	43 (65.2%)	0.043
	No	8 (25.0%)	15 (44.1%)	23 (34.8%)	
	Total	32(100%)	34(100%)	66(100%)	
21-30 years	Yes	19 (82.6%)	10 (47.6%)	29(65.9%)	0.014
	No	4 (17.4%)	11 (52.4%)	15 (34.1%)	
	Total	23(100%)	21(100%)	44(100%)	
Duration of disease					
≤ 2 months	Yes	21 (70.0%)	16 (51.6%)	37 (60.7%)	0.042
	No	9(30.0%)	15 (48.4%)	24 (39.3)	
	Total	30 (100%)	31(100%)	61(100%)	

≥ 2 months	Yes	22(88%)	13 (54.2%)	35 (71.4%)	0.009
	No	3 (12.0%)	11 (45.8%)	14 (28.6%)	
	Total	25(100%)	24(100%)	49(100%)	

Discussion

In our investigation, 55 patients in Group I underwent treatment with dapsone gel, while 55 patients in Group II received Clindamycin gel. The average age of acne onset was 21.75 ± 4.244 years for Group I and 21.49 ± 4.341 years for Group II. A study by Zaina T. et al, reported a similar mean age of 20.3 years.¹⁰ The duration of the disease was 1.8 ± 1.3 months in Group I and 1.89 ± 1.5 months in Group II, with different findings in a study by Al Sabaa HM et al.¹¹

In a study by Del Rosso JQ et al, the baseline means non-inflammatory lesion count was 25 ± 20 , decreasing to 22 ± 25 at the 4th week, 12 ± 17 at the 10th week, and 12 ± 22 at the 16th week. The baseline mean number of papules in Group I and Group II was 18.11 ± 9.48 and 19.01 ± 13.44 , respectively ($p=0.725$). Similar decreasing trend was observed in subsequent follow-ups, with no significant differences between the two groups ($p>0.05$).¹²

In Group I and Group II at the 1st follow-up, mean number of pustules was 0.30 ± 0.88 and 0.30 ± 0.75 respectively, at the second follow up it was 0.17 ± 0.59 and 0.10 ± 0.31 and at the last follow up, it was 0.08 ± 0.36 and 0.00 , respectively ($p>0.05$). In Del Rosso JQ et al's, study, the mean inflammatory lesion count (both papules and pustules) showed a similar decreasing trend over follow-up intervals.¹²

Initially, the mean total acne score (comprising comedones, papules, and pustules) was 30.90 ± 17.17 in Group I and 29.96 ± 14.23 in Group II at baseline. Subsequent assessments showed comparable scores at 1st follow-up (21.17 ± 16.94 and 20.50 ± 13.64), 2nd follow-up (15.83 ± 15.29 and 16.23 ± 12.74), and final follow-up (11.20 ± 13.85 and 11.87 ± 12.04) for Group I and Group II, respectively ($p>0.05$). Del Rosso JQ et al's, study reported a mean total lesion count of 59 ± 44 at baseline, decreasing to 46 ± 49 at 1st follow-up, 27 ± 35 at 2nd follow-up, and 24 ± 44 at final follow-up.¹²

In group-A (5% Dapsone gel), 29(52.7%) had excellent outcome, 14(25.5%) had good, 11(20.0%) had moderate and 1(1.8%) had slight outcome. In group-B (1% Clindamycin gel), 10(18.2%) had excellent outcome, 19(34.5%) had good, 9(16.4%) had moderate and 17(30.9%) had slight outcome. In group-A, 43(78.2%) had efficacy, while in group-B, 29(52.7%) had efficacy with a p-value 0.005, which is statistically significant.

A prior investigation demonstrated that the utilization of Dapsone gel, 5%, proves to be efficacious, secure, and easily tolerated in the management of acne vulgaris, showcasing a swift commencement of therapeutic effects. This finding underscores the notable benefits of incorporating Dapsone gel, 5%, into the treatment regimen for individuals with acne vulgaris.¹³

A study conducted by Verma et al, presented a comparative split-face analysis that indicated a mean decrease in the total number of lesions following a 12-week treatment with dapsone 5% was 5.4 ± 5.05 (50.0%), whereas the reduction achieved with clindamycin 1% gel was 5.0 ± 2.76 (50.5%). The findings from this research demonstrate the efficacy of these two treatments in managing skin lesions, providing valuable insights for dermatological practice.¹⁴

In a comparative trial conducted by Balvinder et al, it was revealed that the overall efficacy of Dapsone 5% gel was determined to be 53.19%, demonstrating a notable effectiveness in treating acne. Specifically, the study found that 50% of the patients who used the Dapsone gel were completely free of acne after the 12-week treatment period, indicating a promising outcome for this particular treatment option. Conversely, the efficacy of clindamycin was reported to be 50%, with 46.67% of patients achieving complete clearance of acne, highlighting the slightly lower success rate compared to Dapsone in the trial.¹⁵

A recent comparative research analysis has demonstrated that a majority of 56.7% individuals

who underwent treatment with dapsone gel experienced a notable improvement, while a slightly higher percentage of 63.3% of patients who received clindamycin gel also showed excellent response to the treatment. Moreover, a smaller percentage of 13.3% participants in the dapsone group and 16.7% in the clindamycin group exhibited a good response to the respective treatments, as indicated by the study findings.¹⁶

Several research investigations have provided evidence regarding the efficacy of dapsone in the management of acne. Verma, Taghetti, and Brar conducted randomized controlled trials which revealed a noteworthy decrease in inflammatory acne lesions among individuals who received treatment with dapsone gel in comparison to those in a clindamycin cohort. While clindamycin principally aims at the bacterial element of acne pathogenesis, the dual anti-inflammatory and antimicrobial characteristics of dapsone might contribute to its superior effectiveness in addressing this dermatological condition.¹⁷⁻¹⁹

One study showed, dapsone treatment resulted in a complete improvement (100%) in inflammatory lesions, whereas clindamycin was more effective at reducing non-inflammatory lesions, such as comedones.²⁰ In another study, success rate of 5% dapsone gel monotherapy was 40.1-69.4%.²¹ In a study, conducted at hospital of Karachi, Efficacy was observed in 12% of patients treated by clindamycin gel, while 82% of patients treated with dapsone gel.²² Contrary to this, Clindamycin 1% gel has shown effective results in treating acne vulgaris, often surpassing Dapsone 5% gel.²³

These findings highlight the need to personally tailor the acne management to the patient's characteristics as well as their therapeutic outcomes. Due to the great disparity in its efficiency with clindamycin, the necessity of seriously considering differences in therapeutic mechanisms and patients' characteristics when prescribing topical agents for acne vulgaris can be underscored. However, it is important to draw more participants for subsequent studies that will help increase the generality of these findings in terms

of acne intensity and participants' demographic characteristics. Such investigations are required to improve the validity and generality of the findings obtained from this study.

Conclusion

Dapsone 5% gel monotherapy demonstrated superior efficacy outcomes in comparison to clindamycin phosphate 1% gel monotherapy following a 12-week treatment period, offering the added advantage of a once-daily application for enhanced convenience.

Conflict of Interest: There was no conflict of interest to be declared by any author.

Ethical Approval: The Institutional Review Board, Quaid-e-Azam Medical College, Bahawalpur approved this study vide letter No. 1943/DME/QAMC/Bahawalpur.

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Author's Contribution

AI: Acquisition of data, analysis & interpretation of data, Conception & design, drafting of article.

NL: Drafting of article, critical revision for important intellectual content, final approval.

SM: Acquisition of data, analysis & interpretation of data.

MT: Acquisition of data, analysis & interpretation of data.

HK: Acquisition of data, drafting of article.

KN: Analysis & interpretation of data.

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