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Outcome of Topical Dapsone 5% Versus Topical Clindamycin 1% in Treatment of Mild to Moderate Acne Vulgaris

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ABSTRACT

Acne vulgaris is a common inflammatory skin disorder, and increasing resistance to conventional topical antibiotics has highlighted the need for alternative therapies such as dispone. **Objective:** To compare the outcome of topical dapsone 5% gel versus topical clindamycin 1% gel in the treatment of mild to moderate acne vulgaris. **Methods:** A Randomized Controlled trial was conducted in the Dermatology Department of Allama Iqbal Memorial Teaching Hospital, Sialkot, from February 2025 to July 2025. A total of 131 patients aged between 18 and 60 years, diagnosed with mild to moderate acne vulgaris based on the Global Acne Grading System (GAGS), were consecutively enrolled. Participants were randomly allocated into two groups (Group A: clindamycin 1% gel twice daily, Group B: dapsone 5% gel once daily). Both regimens were continued for 12 weeks. Mean difference and percentage reduction in GAGS scores, along with adverse events, were noted as outcomes. **Results:** Both groups had similar baseline characteristics without significant differences ($p>0.050$). At 12 weeks, mean GAGS scores were significantly lower in the clindamycin group (9.27 ± 2.95) than in the dapsone group (10.57 ± 4.33; $p=0.047$). Percent reduction in GAGS score was also significantly greater with clindamycin (44.97 ± 14.37) compared to dapsone (38.72 ± 18.52; $p=0.033$). No adverse events occurred in the Clindamycin 1% gel group, while 5 (7.6%) in the Dapsone 5% gel group reported oily skin, pruritus, or irritation. **Conclusions:** Clindamycin 1% gel demonstrated superior efficacy and tolerability compared to Dapsone 5% gel in reducing acne severity over 12 weeks.

INTRODUCTION

Acne vulgaris is a common chronic inflammatory disorder affecting the pilosebaceous unit, arising from a combination of mechanisms such as excessive sebum secretion, obstruction of the follicular canal due to hyperkeratinization, proliferation of Cutibacterium acnes, and the resulting inflammatory cascade [1]. Clinically, it is characterized by recurrent comedones along with inflammatory papules and pustules. These lesions are commonly found on the face, but they can also develop on areas such as the trunk, neck, and Proximal arms [2]. While often considered a self-limiting ailment during adolescence and early adulthood, acne can cause lasting disfigurement in the form of scars and may contribute to considerable psychological morbidity, underscoring the importance of effective treatment strategies [3]. There are various treatment options available for acne, ranging from topical medications to systemic treatments. Topical therapies, typically preferred for managing mild to moderate cases, include combinations of antibiotics and anti-inflammatory agents that offer ease of application and lower risk of systemic side effects [4]. Clindamycin 1% gel is a commonly used topical antibiotic [5]. It has demonstrated efficacy in managing mild to moderate acne [6]. However, the increasing resistance to Clindamycin is now a concern [7], even as a standalone therapy or in combination with systemic treatments [8]. The rise of

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bacterial resistance linked to topical antibiotic use and side effects in a few cases emphasizes the need for alternative therapies [9]. Dapsone, classified as a sulfone, provides both anti-inflammatory and antimicrobial effects [10]. Although historically used as an oral treatment for acne, the risk of systemic toxicity limited its use [11]. Although various treatment modalities exist, there is limited regional evidence comparing topical clindamycin and dapsone, with few studies conducted in South Asia, including Pakistan [12] and neighboring countries [13]. Genetic predisposition, environmental exposures, and lifestyle habits unique to Pakistani patients are likely to influence acne severity and therapeutic response. Locally conducted studies are therefore essential to validate international findings and guide context-specific treatment strategies. Comparing topical dapsone and clindamycin is clinically significant, as increasing antibiotic resistance has reduced the long-term effectiveness of clindamycin, while dapsone offers an alternative with both antimicrobial and anti-inflammatory properties. Furthermore, adherence and cost considerations are critical in resource-constrained settings, underscoring the need for evidence to identify effective, practical, and sustainable treatment options.

Despite the widespread use of topical clindamycin and dapsone in the management of mild to moderate acne vulgaris, comparative evidence regarding their relative efficacy and safety remains limited in the Pakistani population. Most available studies have been conducted in different geographic and ethnic settings, where variations in microbial resistance patterns, environmental exposures, and treatment adherence may influence therapeutic outcomes. Furthermore, few randomized controlled trials in local settings have evaluated these agents using standardized scoring systems such as GAGS. Therefore, locally generated evidence is needed to guide evidence-based and context-specific acne management strategies. This study aimed to evaluate the efficacy and safety of 5% topical dapsone versus 1% topical clindamycin in mild to moderate acne vulgaris, thereby generating locally relevant data to inform dermatologic practice.

METHODS

This randomized controlled trial was conducted in the Dermatology Unit of Allama Iqbal Memorial Teaching Hospital, Sialkot, from February 2025 to July 2025. Before initiation, the study received ethical approval from the Institutional Review Board of Government Khawaja Muhammad Safdar Medical College, Sialkot (IRB No: 47/REC/KMSMC) and was registered in the Iranian Registry of Clinical Trials (IRCT No: IRCT20250124064503N1). No modification to the study was made after commencement. Patients aged 18 to 60 years of both genders, clinically confirmed as mild to moderate acne vulgaris, were screened for inclusion. Acne was classified into mild to moderate severity using the Global Acne Grading System (GAGS), and patients with scores between 0 and 30 were enrolled. Individuals with severe acne (GAGS ≥ 31), other facial dermatoses such as rosacea, pregnancy, lactation, known hypersensitivity to the study medications, recent systemic antibiotics (within four weeks) or topical antibiotics (within two weeks), and current use of medications that could exacerbate acne (e.g., glucocorticoids, phenytoin, isoniazid, lithium) were excluded. Sample size calculation was performed using Open Epi software, aiming to detect a difference in mean GAGS scores between both groups at the 12th week follow-up. Based on prior data, the anticipated mean GAGS scores were 5.0 ± 2.5 for the clindamycin group and 2.5 ± 4.1 for the dapsone group [14]. With a two-sided alpha of 0.05 and 80% power, 66 participants per group were required, totaling 132. One participant in the dapsone group withdrew, leaving 131 patients for analysis. After obtaining written informed consent, baseline demographic and clinical data were recorded. All eligible patients presenting during the study period were enrolled consecutively and then randomized into the two treatment groups, ensuring equal allocation and minimizing selection bias. Randomization was achieved via a computer-generated sequence, and assignment was performed by a separate staff member not involved in outcome assessment. Participants were allocated to one of two intervention arms using sealed opaque envelopes: Clindamycin 1% gel was prescribed for Group A to be applied twice per day, and dapsone 5% gel was given to Group B for once nightly application over 12 weeks. A CONSORT flow diagram has been provided to depict the screening, randomization, and allocation of participants (Figure 1).

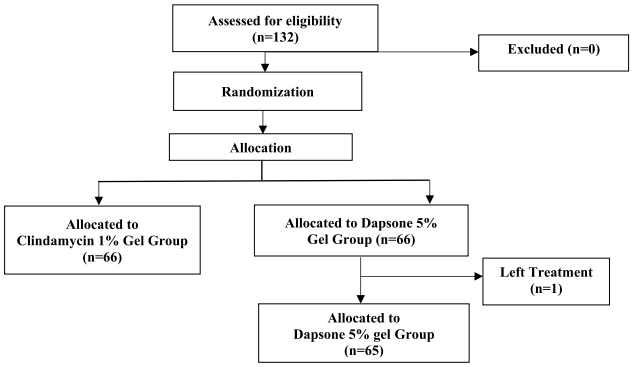

Figure 1: Consort Flow Showing Recruitment of Patients

Although differences in dosage frequency and formulation precluded double blinding, both the outcome assessor and the statistician remained blinded to group allocation. Patients were instructed on proper application techniques

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and dosing schedules. Follow-up assessments were conducted at the baseline and at weeks 4, 8, and 12. Adherence was monitored by checking returned medication tubes and residual content, supplemented by a treatment diary maintained by each participant, recording the date and time of applications. Clinical assessments were performed at baseline and at 12 weeks. The primary outcome was the mean difference in GAGS scores between groups, with greater reductions indicating higher efficacy. Secondary outcomes included the incidence of adverse events, documented through patient self-reports and clinical evaluation. Adverse events, defined in advance to ensure consistency, included skin irritation (stinging, tingling, itching), burning sensation, pruritus, erythema, and increased oiliness. No changes were made to pre-specified outcomes after trial initiation. Data were analyzed using IBM SPSS Statistics version 26.0 on a per-protocol basis, including only participants who completed the study as per the assigned treatment. No imputation methods (e.g., last observation carried forward) were applied for missing data. As attrition was minimal, the risk of attrition bias was considered low. Continuous variables, like age and how long participants had acne, were expressed as mean ± standard deviation (SD) and compared between the two groups using the independent samples t-test. Categorical data, including variables like gender, residential status, and acne severity, were expressed as frequencies and percentages, and analyzed using either the Chi-square test or Fisher's exact test, based on suitability. The Primary outcome, defined as the mean difference in GAGS score from the start of the study to week 12, was analyzed using the independent sample t-test to compare results between the two groups. Changes within each group over time were assessed using the paired samples t-test. The percentage reduction in GAGS scores was also calculated and analyzed between the groups using the independent t-test. All statistical analyses were two-sided, with a p-value<0.050 considered statistically significant. Additionally, 95% confidence intervals (CIs) were calculated for all mean differences.

RESULTS

The study was completed by 131 participants, with 66 receiving clindamycin 1% (Group A) and 65 assigned to the dapsone 5% treatment group (Group B). Study provides a summary of the Pre-treatment demographic and clinical characteristics. There were no significant differences between the two groups in terms of age, gender distribution, acne duration, place of residence, or baseline acne severity (p>0.050 for all), indicating that the two groups were statistically similar at baseline (Table 1).

Table 1: Initial Demographic and Clinical Profiles of Participants in the Clindamycin 1% and Dapsone 5% Treatment Groups

Variables	Total (n=131)	Clindamycin 1% (n=66)	Dapsone 5% (n=65)	p-Value
Age				
Years	21.57 ± 3.87	22.20 ± 4.30	20.94 ± 3.28	0.062α
≤22	88 (67.2%)	41 (46.6%)	47 (53.4%)	0.214β
>22	43 (32.8%)	25 (58.1%)	18 (41.9%)	
Gender				
Male	27 (20.6%)	11 (40.7%)	16 (59.3%)	0.261β
Female	104 (79.4%)	55 (52.9%)	49 (47.1%)	
Duration of Acne				
Years	2.12 ± 1.99	2.11 ± 1.96	2.12 ± 2.04	0.981α
≤2	90 (68.7%)	45 (50.0%)	45 (50.0%)	0.897β
>2	41 (31.3%)	21 (51.2%)	20 (48.8%)	
Residence				
Urban	105 (80.2%)	51 (48.6%)	54 (51.4%)	0.405β
Rural	26 (19.8%)	15 (57.7%)	11 (42.3%)	
Severity of Acne				
Mild	70 (53.4%)	36 (51.4%)	34 (48.6%)	0.797β
Moderate	61 (46.6%)	30 (49.2%)	31 (50.8%)	

Values are displayed as mean ± standard deviation for continuous variables and as frequency (percentage) for categorical variables. The p-values are calculated to assess baseline comparability between groups. αIndependent t-test applied. βChi-square/Fisher-Exact test applied. At study initiation, the mean GAGS scores were 17.67 ± 5.80 for the Clindamycin group and 18.18 ± 6.57 for the Dapsone group, with no statistically significant difference (p=0.633). At the end of the 12-week treatment period, both groups demonstrated a noticeable improvement in their GAGS scores. However, the clindamycin group exhibited a significant reduction, with a mean score of 9.27 ± 2.95, compared to 10.57 ± 4.33 in the dapsone group (p=0.047). A greater mean percentage decrease in GAGS scores was also observed in the Clindamycin group (44.97 ± 14.37) compared to the Dapsone group (38.72 ± 18.52), with a difference in means of 6.25 (95% CI: 0.52–11.97, p=0.033) (Table 2).

Table 2: Comparison of Mean GAGS Scores Between Clindamycin 1% and Dapsone 5% Groups at Baseline and After 12 Weeks

Time Point	Group	N	Mean ± SD	Mean Difference	95% CI of Difference	t (df)	p-Value
Baseline	Clindamycin 1%	66	17.67 ± 5.80	-0.52	-2.66 to 1.62	-0.478 (129)	0.633
	Dapsone 5%	65	18.18 ± 6.57				
12 Weeks	Clindamycin 1%	66	9.27 ± 2.95	-1.30	-2.58 to -0.02	-2.007 (129)	0.047*
	Dapsone 5%	65	10.57 ± 4.33				

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Percent Reduction	Clindamycin 1%	65	44.97 ± 14.37	6.25	0.52 to 11.97	2.159 (129)	0.033*
	Dapsone 5%	66	38.72 ± 18.52				

SD = Standard deviation; CI = Confidence interval; df = Degrees of freedom; p < 0.050 considered statistically significant. *Statistically significant difference

No adverse events were reported in the Clindamycin group. In contrast, 5 participants (7.6%) in the Dapsone group reported adverse events. Among these, oily skin and pruritus were the most commonly observed, each occurring in 2 participants (40%), while one participant (20%) experienced skin irritation (Table 3).

Table 3: Frequency and Percentage Distribution of Adverse Effects and Specific Adverse Events among Study Participants

Adverse Effects	Specific Event	Frequency (%)
Any Adverse Effect	Clindamycin 1% gel (n=66)	0 (0%)
	Dapsone 5% gel (n=65)	5 (7.6%)
Type of Adverse Effect in Dapsone 5% Gel (n=5)	Irritation	1 (20.0%)
	Oily skin	2 (40.0%)
	Pruritus	2 (40.0%)

DISCUSSION

This randomized controlled trial demonstrated that topical 1% clindamycin gel led to significantly greater improvement in acne severity compared to topical 5% dapsone gel, as measured by mean GAGS score reduction and percent reduction after 12 weeks, with both agents showing a favorable safety profile. Our findings differ from those of a clinical trial conducted in Bangladesh, which compared topical dapsone gel with clindamycin cream applied over a 4-week period in patients with mild to moderate acne vulgaris [15]. That study found no statistically significant variation between both groups in terms of comedone, papule, pustule counts, or total acne score at final follow-up. Though similar to the current study finding, percent reduction in acne severity was numerically higher for clindamycin (74.77%) than dapsone (69.20%), but this difference was not statistically significant [15]. Notably, the treatment period in that trial was shorter (4 weeks) compared to our 12-week intervention, which may partly explain why our study detected statistically significant differences favoring clindamycin. Additionally, the Bangladesh study used clindamycin cream rather than gel, which can have different skin penetration characteristics. Similarly, Iftikhar et al. (2025), in a Lahore-based study reported that dapsone 5% gel monotherapy significantly reduced total lesion counts after 12 weeks [16]. Another important point of notice is that in the current study Clindamycin 1% gel was given twice a day whereas Dapsone 5% gel once daily. This deviates from most studies which use once daily dose for both. The reason behind using Clindamycin 1% gel twice a day in the current study is because of its short half-life while Dapsone 1% gel longer half-life allows once daily dosing. Our results are partially aligned with those of Iqra et al. in Pakistan, who compared topical dapsone 5% gel and clindamycin 1% gel in mild to moderate acne vulgaris and reported clindamycin 1% gel as effective [17]. In contrast, earlier Indian studies, such as those reported by Verma et al. have found no significant difference between the two agents when used as monotherapy [18]. This variation may be explained by differences in treatment protocols, particularly our twice-daily clindamycin application versus once-daily dapsone and regional differences in Cutibacterium acnes resistance profiles. Several South Asian studies have evaluated only dapsone 5% gel or with other regimens, such as Fatima et al. who compared it to adapalene 0.1% gel [19]. Similar findings were reported by Darjani et al. from Iran who reported dapsone 5% gel as effective compared to benzoyl peroxide 5% in combination with doxycycline [20]. These trials demonstrated significant reductions in inflammatory and non-inflammatory lesions with dapsone, highlighting its safety and tolerability. With respect to safety, the low incidence of mild adverse effects in our trial (3.8%) is in line with prior reports, including the Bangladesh study [15] and trials by Iqra et al. [17]. Lastly, a previous study from Pakistan reported significant associations between acne occurrence and factors such as skin type, physical activity, menstrual cycle, and use of skincare products like toners. These population-specific and potentially modifiable factors warrant further exploration in relation to treatment response [21]. Most adverse events were mild and self-limiting, and no participant discontinued treatment due to side effects, reinforcing the tolerability of both agents. The study had several strengths, including an adequately calculated sample size, use of standardized and validated outcome measures (GAGS), and active compliance monitoring. The results of this study have important clinical and public health implications. Clinically, the superior efficacy of clindamycin 1% gel in reducing acne severity, combined with its favorable safety profile, supports its use as a first-line topical therapy for mild to moderate acne vulgaris. These findings provide evidence to guide dermatologists in selecting treatments that optimize patient outcomes, enhance adherence, and minimize adverse effects. From a public health perspective, acne represents a common chronic condition that can substantially affect psychosocial well-being and quality of life. Demonstrating effective and well-tolerated topical interventions, such as clindamycin, can contribute to reducing the overall burden of disease, improving patient satisfaction, and informing

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treatment guidelines in local clinical settings. Collectively, these results underscore the importance of evidence-based, context-specific approaches to acne management that address both individual patient care and broader public health priorities. Future research should focus on multi-center trials across Pakistan and neighboring countries to address regional variability in treatment response and resistance patterns. Studies comparing combination regimens such as clindamycin with benzoyl peroxide versus dapsone monotherapy could provide more practical clinical guidance. Extended follow-up studies are necessary to evaluate relapse rates and the long-term effectiveness beyond the 12 weeks.

This study has certain limitations, including its single-center design and relatively short follow-up duration of 12 weeks, which precludes assessment of long-term relapse rates and sustained efficacy. The difference in dosing frequency between the two treatment groups may also have influenced comparative outcomes. Additionally, microbiological assessment of antibiotic resistance patterns was not performed. Future multicenter trials with longer follow-up periods, standardized dosing regimens, and evaluation of combination therapies and resistance profiling are recommended to optimize acne treatment strategies in regional populations.

CONCLUSIONS

This randomized controlled trial compared the efficacy and safety of topical clindamycin 1% gel and topical dapsone 5% gel in patients with mild to moderate acne vulgaris. Clindamycin demonstrated superior reduction in GAGS scores over 12 weeks, while both treatments were well tolerated with minimal adverse events.

Authors' Contribution

Conceptualization: MBI
Methodology: MBL, ZS
Formal analysis: MBI
Writing and Drafting: BB
Review and Editing: BB, MBI, MBL, ZS

All authors approved the final manuscript and take responsibility for the integrity of the work

Conflicts of Interest

The authors declare no conflict of interest.

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