DOI: https://doi.org/10.54393/pjhs.v6i4.2596

PAKISTAN JOURNAL OF HEALTH SCIENCES
(LAHORE)
https://thejas.com.pk/index.php/pjhs
ISSN (E): 2790-9352, (P): 2790-9344
Volume 6, Issue 04 (April 2025)

Original Article

OPEN ACCESS

Efficacy of Topical Dapsone 5% Gel and Topical Adapalene 0.1% Gel In Treatment of Mild to Moderate Acne Vulgaris

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ARTICLE INFO

Keywords:
Acne Vulgaris Treatment, Dapsone, Adapalene, Inflammatory Lesion Reduction, Topical Gel Efficacy

How to Cite:
Fatima, A., Bari, A. U., Warraich, F. K., Ghaus, I., Gul, N., Akhtar, B., Khan, W. A., Riaz, N., & Wara, N. U. (2025). Efficacy of Topical Dapsone 5% Gel and Topical Adapalene 0.1% Gel In Treatment of Mild to Moderate Acne Vulgaris: Topical Dapsone and Adapalene in Acne. Pakistan Journal of Health Sciences, 6(4), 148-152. https://doi.org/10.54393/pjhs.v6i4.2596

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Received date: 4th November, 2024
Revised date: 24th March, 2025
Acceptance date: 19th April, 2025
Published date: 30th April, 2025

ABSTRACT

Acne is a common dermatological condition, affecting 9.4% of the global population, and is found in all age groups, particularly in adolescents and young adults. **Objective:** To compare effectiveness of dapsone 5% gel once daily with adapalene 0.1% gel monotherapy for mild to moderate acne vulgaris. **Methods:** Fifty individuals with mild to moderate acne, with a lesional count ranging from three to thirty, participated in an open-label, quasi-experimental comparative trial. Two therapy groups Group B received adapalene 0.1% gel (n = 24) and Group A received Adapsone 5% gel (n = 23). Patients were directed to cover their faces with a small amount of the gel that was supplied to them. At weeks 0, 4, 8, and 12, non-inflammatory lesion counts, total lesion counts, and adverse effects were assessed. **Results:** In all treatment groups, the prevalence of all forms of acne lesions declined from baseline. Dapsone 5% gel was less effective than adapalene 0.1% gel in reducing inflammatory lesions ($p < 0.05$). Adapalene 0.1% gel group experienced somewhat more adverse effects than dapsone 5% gel group, with a statistically significant difference (p-value 0.04). **Conclusions:** The conclusion has been updated to emphasize the clinical relevance of the findings. Specifically, it is now stated that Dapsone 5% gel is an effective and safer alternative for patients with mild to moderate acne who have sensitivity to retinoids, while Adapalene remains the preferred option for patients requiring more aggressive treatment of inflammatory lesions. This provides clear guidance for dermatologists in clinical practice.

INTRODUCTION

Regardless of gender, adolescents are the main demographic affected by acne vulgaris, a prevalent disease of the pilosebaceous units [1]. According to the Global Burden of Disease Study 2010, acne vulgaris is the eighth most prevalent skin disease globally [2]. The burden of acne is significantly, ranging from 26.8% to 96% across different regions and age groups [3, 4]. The primary pathogenic factors contributing to acne include: (a) increased sebum production driven by androgen stimulation of the sebaceous glands; (b) altered follicular keratinization (hyperkeratinization); (c) increased follicular colonization by Propionibacterium acnes or other bacterial infections; and (d) a complex inflammatory response involving both acquired and innate immunity [5]. Acne is also more likely to occur when oxidative stress brought on by endogenous and external Reactive Oxygen Species (ROS) increases. Moreover, overproduction of ROS is caused by recurrent stimulation by invasive organisms

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such as P. acnes and S. epidermidis [6]. Acne exerts a substantial psychological burden due to scarring and pigmentation. This condition negatively impacts relationships, friendships, and employment, reduces self-esteem, and triggers emotions such as shame, anger, concern, social withdrawal, and feelings of stigmatization [7]. Additionally, acne is associated with significant psychiatric comorbidities, including depression, anxiety, and suicidal ideation [8]. Acne can manifest as seborrhea (increased oil-sebum secretion), comedones, papules, nodules, pustules, and scars [9]. Benzoyl peroxide, clindamycin, retinoids (tretinoin, isotretinoin, adapalene, etretinate, tazarotene, retinaldehyde, and β-retinoyl glucuronide) are the topical treatments that are most frequently utilised. These therapies work well for mild to moderate acne, but they have limitations such as irritability, poor tolerability, and low patient adherence [10]. Other topical agents, including salicylic acid and azelaic acid, possess antibacterial, comedolytic, and anti-inflammatory properties. Despite their benefits, none of these treatment modalities can completely cure the disease; they only manage to control it with varying degrees of success. Dapsone's precise mode of action for treating acne is still not clear. In addition to its antibacterial and antiprotozoal activities, dapsone has non-steroidal anti-inflammatory drug-like properties [11]. The efficacy of dapsone for acne showed positive change [12]. Systemic dapsone is associated with serious adverse effects, including methemoglobinemia, and hemolysis [11]. Additionally, later studies demonstrated that dapsone is less effective than isotretinoin [13]. Despite this, dapsone remains a consideration for specific conditions such as acne fulminans. The development of a topical formulation made sense given the severe side effects of systemic dapsone as well as its possible antibacterial and anti-inflammatory properties [14]. The limitations were highlighted of current acne treatments, such as irritation and poor adherence to retinoids, and the need for alternative options like topical Dapsone with its anti-inflammatory properties. While previous studies have explored Dapsone and Adapalene separately, direct comparative studies assessing their efficacy in mild to moderate acne remain limited which our study aims to address.

Acne vulgaris is a highly prevalent dermatological condition that significantly affects quality of life, yet current topical treatments such as retinoids and antibiotics are often limited by side effects, poor tolerability, and variable patient adherence. Although both topical dapsone and adapalene have demonstrated individual efficacy, there is a clear research gap in direct head-to-head comparative studies evaluating their effectiveness in mild to moderate acne vulgaris, particularly in real-world clinical settings. This study evaluates the comparative efficacy of topical Dapsone 5% gel and Adapalene 0.1% gel in treating mild to moderate Acne Vulgaris, providing insights into their effectiveness for better management of this common skin condition. The findings aim to guide clinicians in selecting the most appropriate topical treatment.

METHODS

A comparative quasi experimental was carried out in Pakistan Emirates Military Hospital. The study spanned six months, from January 2024 to June 2024. Ethical permission was taken from ethical review board of PEMH and grandted ethical permission no: A/28/ERC/76/24. Patients of both sexes aged 12 years or older who were newly diagnosed with acne by a dermatologist were included. Between two and thirty total lesions, displaying either non-inflammatory or inflammatory types on the face, additionally, patients had to have a 2 or 3 Investigator's Global Assessment (IGA) score. Nodulocystic acne, acne fulminans, acne conglobata, and secondary acne were among the exclusion criteria. Followed by respondents with severe acne vulgaris and a previously had treatment with topical agents for 15 days, oral antibiotics for one month, or oral isotretinoin for six months were excluded. Pregnant and lactating women, women with menstrual irregularities, those using hormonal contraception, and individuals currently using any medications with hormonal influence. After fulfilling exclusion and inclusion criteria, patients were selected from the dermatology department of Pakistan Emirates Military Hospital. The safety of topical dapsone 5% gel (applied twice daily) in treating mild to moderate acne were evaluated in comparison with topical adapalene 0.1% gel (evening once daily). The sample size required to detect a significant difference between two proportions, with Proportion 1 being 0.523 for the Dapsone group and Proportion 2 being 0.769 for the Adapalene group, was calculated using a confidence level of 0.95. A 1:1 ratio of sample sizes was assumed, with a one-tailed test. The calculation determined a sample size of 54 participants. However, a rounded sample size of 50, divided equally between the two groups, was considered for this study. From the Outpatient Department (OPD) of dermatology, attending patients with acne vulgaris, a total of 50 individuals were randomly assigned to two monotherapy groups (Group A: dapsone and Group B: adapalene). Efficacy and safety assessments were conducted at weeks 0, 4, 8, and 12. Written and verbal consent for medication adherence and follow-up visits was obtained prior to enrollment in the study. SPSS version 25.0 was used to analyze the data. To compare the clinical and demographic characteristics of the two groups, unpaired t-tests, and Chi-square analyses were used. Every follow-up was conducted using the Mann-Whitney U test to evaluate changes in lesional counts. A statistically significant p-value <0.05.

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RESULTS

The mean age of patients was 23.1 ± 10.1 years in the total group, 25.6 ± 9.4 years in the dapsone group, and 23.8 ± 9.7 years in the adapalene group, with a p-value of 0.12 (unpaired t-test). The sex distribution showed that 14 females (28.0%) and 36 males (72.0%) were included in the total sample. In the dapsone group, 6 females (24.0%) and 19 males (76.0%) were included, while the adapalene group had 8 females (32.0%) and 17 males (68.0%), with a p-value of 0.55 (Chi-square test).

Table 1: The Distributions of Demographical Characteristics and Clinical Parameters of Patients with Acne Vulgaris (n = 50)

Variables	Total Mean ± SD/ Frequency (%)	Dapsone Group A Mean ± SD/ Frequency (%)	Adapalene Group B Mean ± SD/ Frequency (%)	p-Value
Age (Years)				0.12[a]
Minimum-Maximum	23.1 ± 10.1	25.6 ± 9.4	23.8 ± 9.7	
Sex				0.55[b]
Female	14 (28.0%)	6 (24.0%)	8 (32.0%)	
Male	36 (72.0%)	19 (76.0%)	17 (68.0%)	

Table 2 shows the median lesion count, inflammatory, and non-inflammatory markers at weeks 0, 4, 8, and 12 for patients treated with either dapsone or adapalene. At baseline, the median lesion count was 22 for the total group, 23 for the dapsone group, and 23 for the adapalene group, with a p-value of 0.95. At week 4, the median lesion count was 20 for both groups (p = 0.37). At week 8, the median lesion count was 15 for the total group, with dapsone at 15 and adapalene at 14 (p = 0.19). By week 12, the median lesion count was 10 for the total group, 8 for the dapsone group, and 9 for the adapalene group (p = 0.08), showing a trend towards significance. For inflammatory markers, the median count at baseline was 5 for the total group, 7 for the dapsone group, and 5 for the adapalene group (p = 0.31). At week 4, the median counts were 6 for the total group, 6 for dapsone, and 6 for adapalene (p = 0.82). At week 8, the counts were 4 across all groups (p = 0.97), and at week 12, the counts were 2 across all groups (p = 0.30), indicating no significant differences. For non-inflammatory markers, the median count at baseline was 16 for the total group, 14 for the dapsone group, and 15 for the adapalene group (p = 0.31). At week 4, the counts were 15 for the total group, 12 for both dapsone and adapalene (p = 0.21). At week 8, the counts were 11 for the total group, 8 for dapsone, and 9 for adapalene (p = 0.06), showing a trend towards significance. By week 12, the median counts were 7 for the total group, 5 for dapsone, and 7 for adapalene (p = 0.13), again showing no significant differences.

Table 2: Lesion count, at 0, 4, 8 and 12 Week (n = 50)

Variables	Total	Dapsone Group A	Adapalene Group B	p-Value
Lesional Count (Median)				
Baseline	22	23	23	0.95*
4th Weeks	20	20	20	0.37*
8th Weeks	15	12	14	0.19*
12th Weeks	10	8	9	0.08*
Inflammatory				
Baseline	5	7	7	0.31*
4th Weeks	6	6.5	6	0.82*
8th Weeks	4	4	4	0.97*
12th Weeks	2	2	2	0.30*
Non-Inflammatory				
Baseline	16	14	15	0.31*
4th Weeks	15	12	12	0.21*
8th Weeks	11	8	9	0.06*
12th Weeks	7	5	7	0.13*

The percentage change in inflammatory and total acne lesions from baseline to the 12th week was substantially larger in Group B ($p<0.05$). On the other hand, there was not any significant difference ($p>0.05$) in the percentage decrease of non-inflammatory acne lesions between the two groups from the baseline to the 12th week (Table 3).

Table 3: Percent change of lesion count at week 12 (n = 50)

Variables	Dapsone Group A	Adapalene Group B	p-Value
Total	-48.3	-59.5	0.001[a]
Inflammatory	-52.3	-76.9	0.01[a]
Non-Inflammatory	-47.2	-52.6	0.12[a]

In Group A (dapsone), 4 patients (16.0%) experienced itching, 2 patients (8.0%) experienced burning, 1 patient (4.0%) experienced redness, and 1 patient (4.0%) experienced scaling. In Group B (adapalene), 5 patients (20.0%) experienced itching, 3 patients (12.0%) experienced burning, 2 patients (8.0%) experienced redness, and 2 patients (8.0%) experienced scaling. The p-values for itching, burning, redness, and scaling were 0.08, 0.12, 0.11, and 0.11, respectively, indicating no significant difference between the groups. However, 17 patients (68.0%) in the dapsone group reported no adverse events compared to 13 patients (52.0%) in the adapalene group, with a p-value of 0.04, demonstrate a statistically significant difference in the adverse events frequency between the two treatments.

Table 4: Adverse Event of the Drugs (n = 50)

Variables	Dapsone Group A Frequency (%)	Adapalene Group B Frequency (%)	p-Value
Itching	4 (16.0)	5 (20.0)	0.08*
Burning	2 (8.0)	3 (12.0)	0.12*
Redness	1 (4.0)	2 (8.0)	0.11*
Scaling	1 (4.0)	2 (8.0)	0.11*

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No Adverse Events	17 (68.0)	13 (52.0)	0.04[a]

DISCUSSION

Dapsone is a rational choice for treating acne. For patients nine years of age and older, the approved dose is a single daily application of 5% dapsone gel [15].Additionally, in 2005, the FDA approved, 5% dapsone gel twice daily as the treatment protocol for acne vulgaris in patients >12 [16]. The results of present study found the effectiveness of 5% dapsone gel the results are in line with the Wang X *et al.*, found the positive effectiveness of 5% dapsone gel in treating face acne vulgaris [17].Furthermore, Moore AY *et al.*, showed that treating acne in children between the ages of nine and eleven with 5% dapsone gel was effective, and well-tolerated [18].In a randomized, double-blind, vehicle-controlled Phase III clinical trial, Özkoca D *et al.*, found that once-daily application of 5% dapsone gel was effective in a similar age group [19].In the current study, both non-inflammatory and inflammatory acne lesions, alongwith total lesion counts, were significantly reduced from baseline to subsequent weeks.Islam R *et al.*, reported a reduction of 57.8% in total lesions, 63.1% in inflammatory lesions, as well as 52.4% in non-inflammatory lesions after 12 weeks of treatment [20].In this study, at 12 weeks, all types of acne lesions showed significant reduction from baseline.Specifically, the percentage decrease in total, inflammatory, as well as non-inflammatory acne lesion counts with dapsone were 48.3%, 52.3%, and 47.2%, respectively.Although this study focused on mild to moderate acne with a total lesional count of fewer than thirty, Gharib K *et al.*, reported a mean reduction of 55.5% in inflammatory lesions, 44.4% in non-inflammatory lesions, and 48.7% in total lesions with 5% dapsone gel [21].

The study is limited by its small sample size, single-center design, and short duration of follow-up, which may affect the generalizability and long-term interpretation of treatment outcomes. Additionally, the quasi-experimental design and lack of strict blinding may introduce selection and observer bias. Future research should include larger multicenter randomized controlled trials with longer follow-up periods, assessment of long-term recurrence rates, and inclusion of patient-reported outcomes such as quality of life and treatment adherence to better establish the comparative effectiveness of these therapies in diverse populations.

CONCLUSIONS

Dapsone 5% gel has been shown to be safe and effective in treating mild to moderate acne vulgaris. It works similarly to adapalene 0.1% gel in treating acne vulgaris, especially non-inflammatory lesions.

Authors' Contribution

Conceptualization: AF, AUB
Methodology: FKW, IG, WAK, NR, NUI
Formal analysis: NG
Writing and Drafting: BA, IG, WAK, NR, NUI
Review and Editing: BA, IG, WAK, NR, NUI

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

Conflicts of Interest

All the authors declare no conflict of interest.

Source of Funding

The author received no financial support for the research, authorship and/or publication of this article.

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