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Safety and efficacy of topical Dapsone 5% gel in the treatment of inflammatory acne vulgaris

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Abstract
Acne vulgaris is a prevalent chronic inflammatory condition of the pilosebaceous unit, commonly affecting adolescents and increasingly adults, particularly women. This study aimed to evaluate the safety and efficacy of topical Dapsone 5% gel in treating inflammatory acne vulgaris. A clinical trial was conducted in the Department of Dermatology & Venereology, Mugda Medical College and Hospital, Dhaka, from April 2023 to April 2024, involving 60 patients diagnosed with acne vulgaris. Participants applied topical Dapsone 5% gel twice daily for 12 weeks and were followed up at 4, 8, and 12 weeks. Data were analyzed using SPSS and Microsoft Excel, with a significance level set at $p<0.05$. The mean age of participants was 23.2±5.7 years, with a majority being female (78.3%). Progressive reductions in acne lesion scores were observed across follow-ups, with the mean total acne score reducing from 14.07±1.81 at the 4th week to 3.87±0.69 at the 12th week. The percent reduction in acne severity from baseline to the final follow-up was 90.3±3.38%, which was statistically significant ($p<0.05$). Investigators' Global Assessment (IGA) scores showed most patients achieved near-clear to clear skin by the end of the study. No severe adverse effects were reported. The results indicate that Dapsone 5% gel is a safe and effective treatment option for inflammatory acne, offering anti-inflammatory and antimicrobial benefits that target key pathogenic mechanisms of acne.

Keywords: Topical Dapsone, acne vulgaris

Introduction
Acne vulgaris is the most common chronic inflammatory disease affecting the pilosebaceous unit, typically involving the face, back, and chest, and characterized by the presence of comedones, papules, pustules, cysts, nodules, and potential scarring. The condition generally begins in adolescence and often resolves by the mid-twenties. Genetic factors play a significant role, as demonstrated by high concordance rates among monozygotic twins with similar sebum excretion rates (SER). Patients with persistent acne often have a strong family history of the same, unlike those with transient adolescent acne. A Bangladeshi epidemiological study reported a mean patient age of 22.1±6.5 years, with females comprising 62.5% of cases. Regarding severity, 29.17% had mild, 41.6% moderate, 16.7% severe, and 12.5% very severe acne based on GAGS classification [1]. Another local study indicated that all patients presented with comedones, with facial acne being universal, and papules, pustules, and nodules present in 78.5%, 17.2%, and 4.3% of patients, respectively. Multiple lesion types were observed in 90.3% of cases. Treatment histories revealed that 28% of patients used topical steroids, 19.6% used retinoids, and 28% used antibiotics [2]. Acne vulgaris is a global burden of disease, triggered by multifactorial processes in the pilosebaceous unit including abnormal keratinocyte desquamation, excess sebum, colonization by *Propionibacterium acnes*, and resultant inflammation. Sebaceous gland hyperactivity and hyperkeratinization of follicular ducts contribute to comedone formation, while severe forms result from follicular rupture and dermal inflammation [3]. Management typically includes topical and systemic therapies targeting microcomedone formation, microbial overgrowth, and inflammation. Mild acne is treated with benzoyl peroxide, retinoids, and/or antibiotics, while moderate acne may require a combination of topical and systemic agents, including oral antibiotics, hormonal therapies, or isotretinoin [4-5].

Delayed or inadequate treatment can result in prolonged disease and psychological sequelae. Inflammation is now recognized as an early and central component of acne pathogenesis, supported by findings of IL-1α expression in subclinical microcomedones and CD4+ T-cell infiltration around lesions, which are also implicated in acne scarring [6-7]. Dapsone, a sulfone with antimicrobial and anti-inflammatory properties, has historically been used systemically for dermatological diseases but carries a risk of dose-related hematologic toxicity, particularly in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency [8]. The development of a topical 5% dapsone gel formulation was aimed at harnessing its therapeutic effects while minimizing systemic absorption. Sulfone compounds like dapsone have long-standing uses in treating leprosy and various chronic dermatoses such as bullous diseases, vasculitis, pustulosis, urticaria, and lupus erythematosus [9-10]. Due to its poor aqueous solubility, earlier topical formulations were challenging, but newer hydrogel formulations have improved bioavailability. Two pivotal 12-week randomized, double-blind, vehicle-controlled studies and a 12-month open-label safety study demonstrated the efficacy of 5% dapsone gel in reducing lesion counts and improving acne severity in adolescents and adults, with minimal adverse events and low systemic absorption [11]. Given the increasing concern over antibiotic resistance, topical dapsone also presents as a viable adjunct or alternative to systemic antibiotics or isotretinoin. In this context, the present study was designed to evaluate the safety and efficacy of 5% topical dapsone gel among patients attending the Department of Dermatology and Venereology at Mugda Medical College and Hospital, Dhaka.

Materials and Methods

This clinical trial was conducted in the Department of Dermatology and Venereology, Mugda Medical College and Hospital, Dhaka, over a period of 12 months from April 2023 to April 2024. A total of 60 patients with acne vulgaris were enrolled using purposive sampling. Patients aged 15-40 years of both sexes, presenting with grade 1-3 acne vulgaris as per the Investigator Global Assessment (IGA) scale, and willing to provide informed consent were included. Exclusion criteria comprised pregnancy, lactation, recent use of topical or systemic acne treatments, severe forms of acne (e.g., cystic acne, acne fulminans), and recent cosmetic procedures. The calculated sample size was 55.49 based on the formula: $n = 2 \times ((Z_{1-}\alpha/2 + Z_{1-}\beta)/\delta_0)^2 \times p \times (1-p)$, where $Z_{1-}\alpha/2 = 1.96$ (95% CI), $Z_{1-}\beta = 1.28$ (90% power), $p = 0.39$, $q = 0.61$, and $\delta_0 = 0.3$. A total of 60 patients were enrolled purposively to account for any dropouts. After taking detailed history, physical and dermatological examinations were performed and recorded using a structured, pretested questionnaire. Each patient was prescribed Dapsone 5% gel to be applied in a thin layer to the affected area of the face twice daily for 12 weeks. Patients were followed up at 4th, 8th, and 12th weeks for efficacy and safety assessments. Efficacy was evaluated using IGA scoring, including achieving a score of 'clear' or 'almost clear' with at least two-grade improvement from baseline at 12 weeks, along with mean percentage reduction in lesion count. Safety was assessed through adverse events, hematological (CBC) and biochemical (ALT, AST) evaluations, and clinical tolerability (burning, dryness, erythema, scaling) rated on a 0-3 scale. Data were analyzed using SPSS version 22. Descriptive statistics were used for baseline characteristics. Categorical variables were analyzed using Chi-square or Fisher's exact test, and continuous variables by Student's t-test. A p-value <0.05 was considered statistically significant. Quality assurance was maintained through a standardized data collection manual, pretesting of the questionnaire, and routine monitoring. Ethical clearance was obtained from the institutional ethics committee. Informed written consent was secured from all participants. Data collection involved a structured workflow: literature review, development and pretesting of data collection tools, patient recruitment, data entry and analysis, and final report preparation.

Results

Table 1: Distribution of the study patients by age (N=60)

Age (In year)	Frequency	Percentage (%)
≤15	10	16.7
16-20	22	36.7
21-25	15	25.0
26-30	9	15.0
>30	4	6.7
Mean ± SD	23.2	±5.7
Range (min-max)	13	-35

Table 2: Distribution of the study patients by gender (n=60)

Gender	Frequency	Percentage (%)
Male	13	21.7
Female	47	78.3
Total	60	100

Table 3: Acne score of open comedones in different follow up (n=60)

Open comedones	Mean ± SD
Baseline	12.32±1.25
1st follow up	9.84±1.65
2nd follow up	2.15±0.36
3rd follow up	1.88±0.28

Table 4: Acne score of papule in different follow up (n=60)

Papule	Mean ± SD
Baseline	9.60±1.18
1st follow up	6.12±1.69
2nd follow up	3.92±1.47
3rd follow up	2.67±0.92

Table 5: Acne score of pustule in different follow up (n=60)

Pustule	Mean ± SD
Baseline	4.01±1.44
1st follow up	3.18±1.88
2nd follow up	2.09±1.09
3rd follow up	1.04±0.50

Table 6: Safety score of Erythema, Burning, Scaling, Dryness and Pruritus in 3rd follow up (n=60)

Safety score	Mean ± SD
Erythema	0.47±0.51
Burning	0.10±0.31
Scaling	2.20±0.76
Dryness	0.63±0.49
Pruritus	0.33±0.48

Table 7: Total Safety score in different follow up (n=60)

Total Safety score	Mean ± SD
1st follow up	11.27±1.01
2nd follow up	7.63±0.96
3rd follow up	3.73±1.01
P value	0.001

Table 8: Evaluation of Investigators Global Assessment (IGA) scale (n=60)

Score	4th week	8th week	12th week
0	3	17	31
1	8	19	17
2	19	9	12
3	30	15	0
4	0	0	0
Mean score	2.32	1.45	0.47

Figure

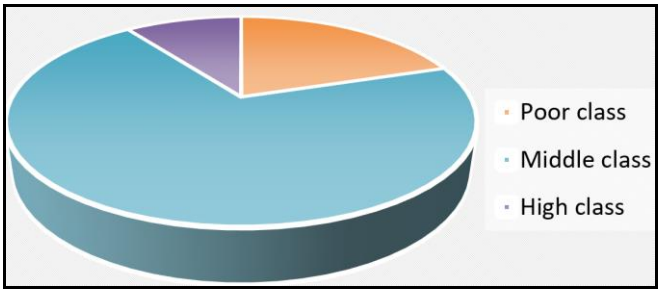

Fig I: Socioeconomic status of the study population (n=60)

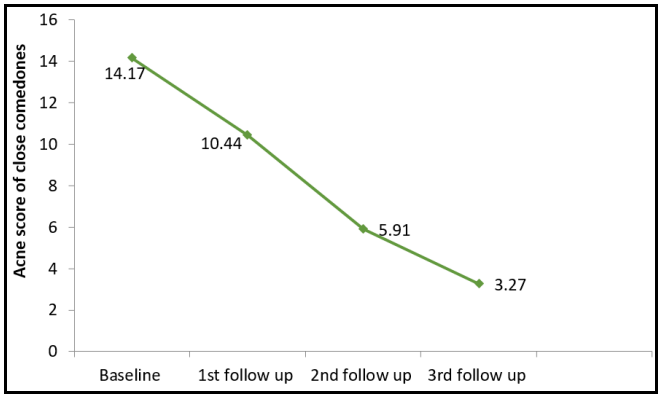

Fig 2: Improvement of acne score of close comedones in different follow up (n=60)

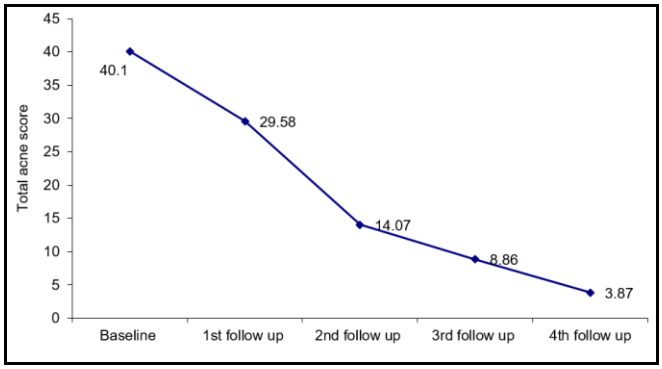

Fig 3: Total acne score in different follow up (n=60)

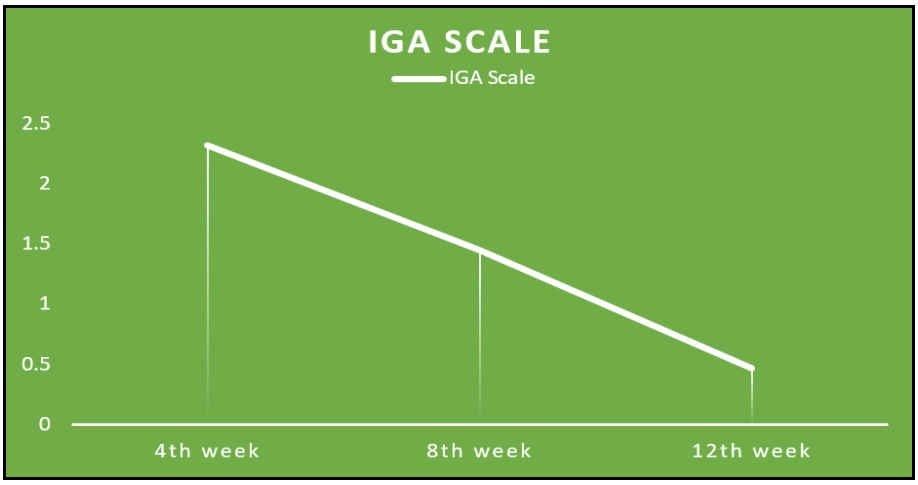

Fig 4: Overall clinical improvement of the respondents (n=60)

The demographic distribution of the study population revealed that the majority (36.7%) of patients were aged between 16-20 years, with a mean age of 23.2±5.7 years, and a predominance of females (78.3%) over males (21.7%), yielding a male-to-female ratio of 1:3.61. Socioeconomically, the majority (70.0%) belonged to the middle class. Clinical assessment showed a progressive and statistically significant reduction in acne severity across follow-up visits. The mean acne scores for open comedones decreased from 2.15±0.36 at the 2nd follow-up to 1.88±0.28 at the 3rd follow-up; closed comedones reduced from 5.91±1.06 to 3.27±0.98; papules from 3.92±1.47 to 2.67±0.92; and pustules from 2.09±1.09 to 1.04±0.5, all with $p<0.05$. Total acne scores showed significant improvement from 14.07±1.81 at the 2nd follow-up to 8.86±0.97 at the 3rd and 3.87±0.69 at the 4th, with an overall percent reduction of 90.3±3.38 ($p<0.05$). Safety evaluations indicated significantly lower scores for erythema, scaling, and burning, though dryness and pruritus were slightly higher; the total safety score improved significantly post-treatment (p=0.001). The Investigators Global Assessment (IGA) scores progressively decreased, with the mean score improving from 2.32 at week 4 to 1.45 at week 8 and 0.47 at week 12, indicating a clear trend of clinical improvement, corroborated by a graphical downhill deceleration of the IGA line chart.

Discussion

The present study was conducted to evaluate the safety and efficacy of topical Dapsone 5% gel in the treatment of

inflammatory acne vulgaris in patients attending the Department of Dermatology & Venereology, Mugda Medical College and Hospital, Dhaka. Among the 60 enrolled patients, the majority (36.7%) were aged between 16-20 years, and the mean age was 23.2±5.7 years. The study population consisted of 21.7% males and 78.3% females, reflecting a male-to-female ratio of 1:8.09. These findings are in agreement with previous research reporting that 83-100% of adolescents experience acne vulgaris during their lifetime, and that acne is one of the most frequently encountered dermatological conditions in both adolescents and adults, including some children as well [12, 13]. In terms of treatment efficacy, this study demonstrated a statistically significant percent reduction ($p<0.05$) in total acne severity score from baseline to final follow-up (90.3±3.38). Notably, open comedones, closed comedones, and total acne scores declined significantly across the follow-up visits. These results are consistent with previous studies that showed a 57.75% mean percent reduction in total lesions, with inflammatory and non-inflammatory lesions reduced by 63.1% and 52.4%, respectively, following 12 weeks of treatment with topical Dapsone 5% gel [14]. The assessment of therapeutic efficacy by patients in prior studies showed a promising response to Dapsone gel, with complete resolution, marked, and moderate improvements observed in varying proportions across grades II, III, and IV of acne vulgaris [14]. The current study also used the Investigators Global Assessment (IGA) scale, which revealed that the majority of patients reached a score of 0 (clear skin) by the 12th week, confirming significant clinical improvement. Previous phase III trials have reported similar reductions in inflammatory and non-inflammatory lesion counts (47.5% and 41.8% respectively) [15], and a study by Lucky *et al* demonstrated comparable mean acne reductions of 58.2%, 19.5%, and 49.0% for inflammatory, non-inflammatory, and total lesions respectively [16]. These results parallel the present study, in which 51% of patients achieved excellent to marked response. Additionally, Dapsone gel has shown similar efficacy and tolerability in long-term treatment protocols. A multicenter, open-label, noncomparative trial using 5% Dapsone topical gel twice daily for up to 12 months confirmed its safety and efficacy, with common but mild adverse events such as headache (20%) and nasopharyngitis (15%). Application-site adverse events were limited and mild, including dryness and rash (3%) and sunburn (2%), with a low discontinuation rate (2.3%) [16]. Importantly, topical Dapsone is not associated with hematologic adverse effects, even in G6PD-deficient patients, as confirmed by earlier studies showing no changes in hemoglobin levels or blood chemistry after long-term use [14, 15]. This highlights its safety profile compared to systemic Dapsone, which is limited by risks such as dose-dependent hemolysis [15, 16]. Dapsone's dual antimicrobial and anti-inflammatory properties, especially targeting *Propionibacterium acnes* and inflammation, position it as a promising alternative topical agent in acne management. Long-term studies have further confirmed sustained lesion reduction over 12 months, particularly for inflammatory lesions, with minimal side effects and no significant systemic toxicity [17]. Therefore, topical Dapsone 5% gel emerges as an effective and safe therapeutic option for managing acne vulgaris, offering an advantageous alternative in cases resistant to conventional therapies and contributing to a better quality of life for affected individuals.

Conclusion

Present study concluded that topical Dapsone 5% gel a consistent and favorable outcome, thereby holding promise as alternative or adjunct to traditional acne treatments. Antimicrobial and anti-inflammatory properties of dapsone gel formulation can be used in treatment of acne vulgaris without risk of serious haematological side effects. Topical dapsone is effective and tolerable option for acne vulgaris patients. Overall improvement or recovery rate was better after treatment of topical Dapsone 5% gel. Therefore, it can be used in treatment of moderate acne vulgaris.

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Conflict of Interest

Not available

Financial Support

Not available

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