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Original Research Article

A comparative study of efficacy and safety of topical clindamycin 1% gel versus topical dapsone 5% gel in acne vulgaris over face: a prospective randomized double-blind study

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ABSTRACT

Background: Acne vulgaris is a common chronic condition in both adolescents and adults. While 1% clindamycin gel is a standard topical treatment, increasing antibiotic resistance limits its long-term use. Dapsone 5% gel, with anti-inflammatory and antimicrobial properties, is a potential alternative. This study compared the efficacy and safety of 5% dapsone gel versus 1% clindamycin gel in mild-to-moderate acne.
Methods: This 12-month prospective, randomized, double-blind study was conducted at the dermatology OPD, J.A. Group of Hospital, Gwalior, from November 2023 to October 2024. Eighty patients with facial acne were equally randomized into two groups: group 1 received clindamycin 1% gel; group 2 received dapsone 5% gel. Treatment was applied once daily at night for 12 weeks. Efficacy was assessed at baseline and weeks 4, 8, and 12 using the investigator's global assessment (ISGA) and total lesion count (TLC). Safety and adverse drug reactions (ADRs) were recorded. The Hindi version of the Cardiff acne disability index (CADI) assessed psychosocial impact.
Results: Both groups showed significant improvement by week 12. Final ISGA scores were similar (clindamycin: 1.189±0.397; dapsone: 1.184±0.392; p=0.913). Lesion count reductions were also comparable (p=0.148). Dapsone was more effective for inflammatory lesions- papules (p=0.001) and pustules (p=0.000). Comedone reduction, ADRs (p=0.555), and CADI improvements (p=0.213) were similar.
Conclusions: Dapsone 5% gel showed efficacy comparable to clindamycin 1%, with superior results for inflammatory lesions. Both were well tolerated and improved quality of life, making dapsone a promising alternative.

Keywords: Acne vulgaris, Cardiff acne disability index, Inflammatory lesions, Investigator's static global assessment, Topical clindamycin, Topical dapsone

INTRODUCTION

Acne vulgaris is a common, chronic inflammatory skin disorder affecting the pilosebaceous units, predominantly on the face, chest, and back- areas rich in sebaceous glands.[1] It affects nearly 85% of adolescents, but adult acne, particularly among women, is increasingly prevalent, with women being 12% more likely to experience acne than men.[2] Beyond its physical manifestations, acne can lead to significant psychosocial distress, including anxiety, depression, and social withdrawal.[3]

Treatment options range from topical agents to systemic therapies depending on severity.[1] Topical treatments are preferred due to their ease of use and lower risk of systemic side effects.[4] Common agents include salicylic acid, benzoyl peroxide, retinoids, antibiotics, sulfone drugs, and azelaic acid.[1]

Clindamycin, a lincosamide antibiotic, is widely used topically for mild-to-moderate acne due to its efficacy against *Propionibacterium acnes* and favourable safety profile.[6,7] However, prolonged antibiotic use is associated with bacterial resistance, reducing long-term effectiveness.[8]

Dapsone, a sulfone-class drug with anti-inflammatory and antimicrobial activity, presents a promising alternative. The development of topical formulations, such as 5% and 7.5% dapsone gels, has addressed solubility issues and enabled effective local application with minimal systemic absorption.[9,10]

Given the rising concern of antibiotic resistance and the limitations of systemic therapies, this study aimed to compare the clinical efficacy and safety of 5% dapsone gel with the widely used 1% clindamycin gel in the management of mild-to-moderate acne vulgaris.

METHODS

Study design and ethical approval

This randomized, double-blind, placebo-controlled trial was conducted after receiving approval from the institutional ethics committee (registration number 1206 /IEC-GRMC/ 2023 dated 21.09.2023). The study was registered with the Clinical Trials Registry-India (CTRI) with registration number CTRI/2023/11/059725 dated 09.11.2023. Written informed consent was obtained from all participants before enrolment, and the study adhered to the ethical principles outlined in the Declaration of Helsinki.

Study population

Patients diagnosed with acne vulgaris visiting the dermatology outpatient department (OPD) at J. A. Group of Hospital, Gajra Raja Medical College, Gwalior (MP), were screened for eligibility.

Inclusion criteria

The inclusion criteria were patients with acne vulgaris on the face, patients aged 14-40 years, ISGA score of 1 or more but less than 4 at baseline, willingness to participate in the study with signed informed consent, medically stable patients.

Exclusion criteria

The exclusion criteria included patients not willing to provide informed consent, pregnant or breastfeeding women or those of childbearing age using contraception, patients with nodulocystic lesions (ISGA grade 4 or 5), patients with autoimmune disorders, thyroid conditions, or other dermatological conditions affecting facial skin, patients on systemic treatments (topical or oral) relevant to facial acne within 1-3 months prior to enrolment, use of non-mild cleansers or glycolic acid-based products within the past 2 weeks.

Randomization and group assignment

A total of 80 patients (40 per group) were enrolled in the study. Patients were randomized using a simple randomization method. Each patient drew a chit from a container containing 80 chits (40 for group 1 and 40 for group 2). After drawing, the chit was discarded, and the group number corresponding to the drawn chit was recorded.

Treatment procedure

Patients were assigned to either group 1 or group 2 and provided with coded packets containing the test drug for their respective group.

The patients in group 1 applied topical clindamycin 1% gel (international non-proprietary name: clindamycin) once daily at night.

The patients in group 2 applied topical dapsone 5% gel (international non-proprietary name: dapsone) once daily at night.

Before applying the test drugs, participants were instructed to thoroughly cleanse their faces. They were advised to apply a pea-sized amount of the respective gel over each acne lesion and gently spread it over the affected areas, including the forehead, cheeks, chin, and jawline, avoiding the eyes, lips, and mucous membranes. The gel should not be used as a spot treatment, and only a thin layer should be applied over the entire affected area. After application, participants were instructed to wait 5-10 minutes for the gel to fully absorb, and then to wash their hands thoroughly. They were also advised to use only mild, non-medicated cleansers for their daily face-washing routine to avoid interfering with the effectiveness of the test drugs.

Blinding and coded drug administration

This study was designed as a double-blind trial to ensure unbiased results. The test drugs were packed in identical package by a third party who was not involved in the study. The third party managed the coding and distribution of the packets. Blinding was maintained throughout the study, and the drug codes were revealed only at the end of the trial.

Outcome measures

The primary outcome measures were the investigator's global assessment (ISGA) and total lesion count (TLC), which were used to assess the severity and improvement of acne vulgaris. The ISGA scale was graded from 0 to 4.[1,11] Grade 0: clear skin, grade 1: nearly clear skin with a few lesions, grade 2: mild acne with several non-inflammatory lesions and a few inflammatory ones, grade

3: moderate acne with numerous lesions and a small nodule, grade 4: severe acne with a large number of lesions, including nodules.

The TLC method involved manual counting of both inflammatory and non-inflammatory lesions on the face at baseline and follow-up visits. The percentage reduction in TLC from baseline to 4, 8, and 12 weeks determined the level of improvement.[1,12] Mild improvement: <25% reduction, moderate improvement: 25-50% reduction, significant improvement: 51-75% reduction, excellent improvement: >75% reduction.

Safety evaluation and impact on quality of life

Adverse drug reactions (ADRs) were monitored and recorded throughout the study period.[13] Patients were instructed to report any adverse effects during their monthly visits. The Cardiff acne disability index (CADI) was used to assess the psychosocial impact of acne on participants.[14]

Statistical analysis

Data analysis was performed using SPSS version 25 software. Descriptive statistics were used to summarize quantitative variables (mean and standard deviation), while categorical variables were presented as frequencies and percentages. Intragroup comparisons were performed using the paired t-test, while intergroup comparisons were analyzed using the independent t-test. A p value of less than 0.05 was considered statistically significant.

RESULTS

In the current study, a total of 126 patients of acne vulgaris were interviewed and out of that total 80 patients were selected according to inclusion and exclusion criteria. Five patients left the study because of adverse reactions or non-compliance. Hence, a total of 75 patients completed the study and were further statistically analysed for the final results.

Among the 75 study participants, 37 were assigned to group 1 (clindamycin 1% gel) and 38 to group 2 (dapsone 5% gel). Both groups had a higher proportion of female participants. In group 1, 67.57% were female (25/37) and 32.43% male (12/37), while group 2 had 57.89% females (22/38) and 42.11% males (16/38). Overall, females outnumbered males in both groups, with a more pronounced female predominance in group 1 (Table 1).

The study assessed mean ISGA scores at baseline and at 4, 8, and 12 weeks to evaluate the efficacy of topical clindamycin (group 1) and topical dapsone (group 2). Initially, group 1 had a significantly higher baseline ISGA score than group 2 (p=0.003). However, at all follow-up points (4, 8, and 12 weeks), the differences between groups were not statistically significant (p>0.05), and both groups showed consistent improvement over time. By 12 weeks, ISGA scores were comparable (Table 2).

The efficacy of topical clindamycin (group 1) and topical dapsone (group 2) was assessed by tracking changes in comedones, papules, and pustules over 12 weeks. At baseline, both groups had similar lesion counts with no significant differences. Over time, both treatments significantly reduced comedones, with no difference in effectiveness between the groups at any point, indicating comparable efficacy for non-inflammatory lesions. However, topical dapsone demonstrated significantly greater effectiveness in reducing inflammatory lesions. Group 2 consistently showed a more pronounced reduction in papules from 4 weeks onward, with a notably lower mean count at 12 weeks (p=0.001). Similarly, pustule counts were significantly lower in group 2 at all follow-up points, suggesting superior anti-inflammatory effects (Table 3).

Table 1: Sex-wise distribution of the patients of acne vulgaris.

Gender	Group			
	Group 1: clindamycin 1% gel		Group 2: dapsone 5%	
	Count	Column %	Count	Column %
Female	25	67.57	22	57.89
Male	12	32.43	16	42.11
Total	37	100	38	100

Table 2: ISGA score comparison between both groups.

ISGA score	Group 1 (Top. CLN) (mean±SD)	Group 2 (Top. DAP) (mean±SD)	P value
At baseline	2.81±0.07	2.65±0.48	0.003
At 4 weeks	2.32±0.57	2.50±0.60	0.465
At 8 weeks	1.78±0.67	1.55±0.55	0.683
At 12 weeks	1.189±0.397	1.184±0.392	0.913

Table 3: Mean and standard deviation of comedones, papules and pustules baseline and subsequent follow up with intergroup comparison.

Characteristics	Group		P value
	Group 1	Group 2	
Mean number of comedones			
Baseline	14.32±3.00	14.26±4.95	0.335
1st follow-up (4 weeks)	9.72±1.80	9.15±2.11	0.951
2nd follow-up (8 weeks)	6.40±1.97	5.76±1.34	0.490
Final follow-up (12 weeks)	4.43±1.40	4.07±1.44	0.941
Mean number of papules			
Baseline	27.67±3.11	28.97±6.03	0.559
1st follow-up (4 weeks)	8.45±1.74	10.26±3.11	0.001
2nd follow-up (8 weeks)	5.86±1.78	8.15±3.03	0.015
Final follow-up (12 weeks)	4.97±1.64	0.65±0.93	0.001
Mean number of Pustules			
Baseline	4.56±4.14	3.18±3.31	0.443
1st follow-up (4 weeks)	2.05±1.88	0.52±0.82	0.000
2nd follow-up (8 weeks)	0.20±1.71	0.63±0.99	0.006
Final follow-up (12 weeks)	1.91±1.86	0.65±0.93	0.000

Table 4: Percentage reduction in TLC at the end of 12 weeks.

Percentage reduction at final follow-up	Group 1 (Top. CLN)	Group 2 (Top. DAP)	P value
Mild	0	0	-
Moderate	0	0	-
Significant	21 (56.7%)	12 (31.57%)	0.999
Excellent	16 (43.24%)	26 (68.4%)	

At 12 weeks, participants showed significant to excellent reduction in total lesion count, with no cases of mild or moderate improvement. Both treatments were effective, and with p>0.05, there was no significant difference between them, indicating equal efficacy in reducing overall lesion counts (Table 4). Among 75 patients, ADRs were reported in 40.54% of the clindamycin group and 50% of the dapsone group. Erythema was most common with clindamycin, while dryness and irritation predominated with dapsone. Burning and scaling were less frequent side effects. No pigment changes or photosensitivity occurred in either group. Despite a higher ADR rate in dapsone, the difference was not statistically significant, indicating both treatments are similarly safe. At 12 weeks, both clindamycin and dapsone significantly reduced CADI scores, improving patients' quality of life, with no significant difference between them (p=0.213). Despite improvements, scores remained in the moderate range, indicating some ongoing emotional impact. Acne treatment should address both physical and psychological aspects, with additional support recommended for those with persistent distress.

DISCUSSION

Acne treatment varies from topical to systemic therapies, often using combinations tailored to severity, age, lifestyle, and other factors.[15] Topical treatments are preferred for their ease and fewer side effects, but long treatment durations and psychological impacts can affect patient compliance. Cutibacterium acnes is a key factor in acne, making antibiotics a core part of treatment.[16] However, long-term use raises concerns about antibiotic resistance, complicating management.

In our study, patients with acne vulgaris ranged from 14 to 40 years, with a mean age of 27. The majority were between 14-25 years, highlighting its prevalence in adolescents- a group particularly vulnerable to psychological impacts. This aligns with findings by Shah et al, where most participants were aged 14-25, and the mean age was 22.1±5 years. Few participants were from the 36-40 age group. These results reflect the consistent trend of acne being most common in younger individuals. 63% were females and 37% were males, with a male-to-female ratio of 0.6:1, showing female predominance in both treatment groups. These findings align with Shah et al, who also reported a higher female representation (61%).[17] In contrast, Verma et al found male predominance (60%), highlighting regional variations.[18] Our study reflects a higher prevalence among females in the Gwalior, Madhya Pradesh region.

At baseline, group 1 had a significantly higher ISGA score than group 2, but by week 4 onward, both groups showed comparable reductions, with no significant differences through week 12. Both treatments effectively reduced acne severity over time, as reflected in the shift from higher ISGA scores at baseline to lower scores (0-1) by the final follow-up. This indicates equal efficacy of topical clindamycin and dapsone. Similar trends were reported in studies by Hayashi et al using ISGA, and by Shah et al using the comparable GAGS score. both treatments significantly reduced total lesion count (TLC) over 12 weeks.[17,19] Baseline TLCs were comparable (46.51±5.49 versus 46.32±5.67; p=0.844), with similar reductions at week 4 (20.32±3.09 versus 19.94±3.00; p=0.712), week 8 (14.40±2.62 versus 14.55±2.86; p=0.546), and week 12 (14.39±2.63 versus 11.63±2.05; p=0.148). Comedone reduction was also similar at week 12 (4.43±1.40 versus 4.07±1.44; p=0.941). Dapsone showed significantly greater reduction in papules at weeks 4 (p=0.001), 8 (p=0.015), and 12 (0.65±0.93 versus 4.97±1.64; p=0.001), and pustules at weeks 4 (p=0.000), 8 (p=0.006), and 12 (1.91±1.86 versus 0.65±0.93; p=0.000). These results suggest both treatments are effective, but dapsone is superior for inflammatory lesions. Findings are supported by studies from Verma et al, Islam et al, Wang et al, and Tan et al.[18,20-22]

Clindamycin has long been used in acne treatment for its antimicrobial effects, but rising antibiotic resistance has highlighted the need for alternatives.[23] Dapsone, recently approved (May 2024, Zydus Lifesciences) in India, offers a unique anti-inflammatory action and shows promise, particularly for inflammatory lesions and sensitive skin types.[24] Unlike clindamycin, which often requires combination with benzoyl peroxide to prevent resistance, dapsone can be effective as monotherapy.[25] This study aimed to fill the research gap by comparing the efficacy of both drugs, focusing on inflammatory lesion reduction. In light of antibiotic stewardship efforts, these findings support dapsone as a sustainable alternative in acne management.[26,27]

The study's 12-week duration limits insights into long-term outcomes and resistance development. A modest sample size restricts generalizability, necessitating larger, multicentric trials. Combination therapies were not explored, which could further enhance treatment efficacy.

CONCLUSION

This study concludes that 5% topical dapsone is as effective as 1% topical clindamycin in treating acne vulgaris. Both treatments reduced non-inflammatory lesions, but dapsone showed superior efficacy in managing inflammatory lesions. Its dual antimicrobial and anti-inflammatory actions make it a strong alternative to clindamycin, especially in the context of rising antibiotic resistance. Dapsone also offers better tolerability, particularly for sensitive skin. Future studies should explore its long-term effects and potential in combination therapies.

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