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Original Article

Efficacy of topical 5% dapsone gel versus 0.1% adapalene gel in the treatment of mild to moderate acne vulgaris

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ABSTRACT

Objective*:* To compare the effectiveness of topical 5% Dapsone gel and Adapalene gel 0.1% in the treatment of mild to moderate acne vulgaris.

Methods*:* Total 60 patients were selected. The diagnosis of acne vulgaris was made by consultant dermatologist. Informed consent was taken from each patient and discretion of the information was ensured. Local and global GAGS score was calculated. Patients were separated into two groups for Dapsone 5% and Adapalene 0.1% and advised to apply their treatment gel twice daily. At fourth visit GAGS score and efficacy of the treatment were documented. All the data was entered in SPSS version 27 and analyzed. Student t-test and chi square test were applied for comparing data, taking $p \leq 0.05$ as significant.

Results*:* In group A, 80% had mild and 20% had moderate acne while in group B, 70% had mild and 30% had moderately severe acne (p=0.371). Treatment was successful in 86.7% of group A and 56.7% of group B patients (p=0.010).

Conclusion: According to this study, there was significant difference between the efficacy of topical 5% Dapsone gel and topical 0.1% Adapalene gel to treat the acne in selected population and dapsone gel can be recommended as a standard treatment for acne vulgaris.

Keywords*:* Acne Vulgaris, Dapsone, Adapalene, Retinoid, Global Acne Grading Scale (GAGS)

1. INTRODUCTION

Acne vulgaris is a very common skin disorder, especially of the young adults, and almost 9.4% of the population is affected by this disorder.[1] There are various economic and psychosocial adverse consequences related to acne vulgaris which led to productivity loss and impaired quality of life.[1-3] Many therapies have been tried for the acne including topical clindamycin, benzoyl peroxide and retinoids as the first line treatment. In case of failure of the initial therapies, further topical preparations containing Dapsone, Adapalene or a combination of different medicines can be started.[4]

As a safer and cheaper alternative to many antibiotics, oral Dapsone was proposed in 1961 for the treatment of acne vulgaris.[5] However, oral Dapsone comes with side effects such as methemoglobinemia, agranulocytosis and hemolytic anemia. Therefore, topical preparations of Dapsone were introduced for acne treatment.[6] Dapsone 5% gel was approved in 2008 for treating acne with twice daily application.[7]

Adapalene is a derivative of synthetic naphthoic acid and is a 3rd generation topical retinoid, which is associated with fewer side effects and better efficacy. Along with having anti-inflammatory effects, Adapalene reverses the abnormal follicular desquamation.[8] In comparison with benzoyl peroxide, Adapalene showed significant improvement as proved in many studies.[9] Adapalene reverses the abnormal follicular desquamation.Thus, even though clinical efficacy shown in literature is comparable for the two topical agents, there is still gap as to which of these topical agents is safer as compared to the other. The purpose of comparing the two drugs is to ascertain the more effective and safer approach to treat acne vulgaris. By conducting this unique study, we shall be able to provide evidence over the better treatment modality for acne vulgaris, which in return helps the clinicians to make better recommendations.

There is no data available in which the topical preparation of Dapsone was compared with Adapalene. However, Kamoji et al.[10] compared 5% Dapsone with clindamycin 1%- Adapalene 0.1% combination for the treatment of acne vulgaris and observed that Adapalene-clindamycin has better outcomes and fewer side effects. Ibrahim SA et al.[11] observed a good response of dapsone 5% gel in 67.5% of the patients. In a study by Mokhtari F et al.[12], 13.3% of the patients favored adapalene 0.1% over other drugs. The current study is planned to compare Dapsone 5% gel with Adapalene 0.1% gel alone for the treatment of acne vulgaris of mild to moderate severity, in our community.

2. METHODOLOGY

This was randomized controlled trial, performed in the Department of Dermatology, Lahore General Hospital, Lahore. from 16-12-2023 to 15-06-2024. Sample size was calculated using OpenEpi software, with efficacy of dapsone 5% as 67.5%[11]; and efficacy of adapalene 0.1% as 13.3%[12], n=30. We selected 60 patients, 30 for each group, using nonprobability consecutive sampling technique.

Male as well as female patients of 12-30 years of age, and diagnosed with mild to moderate acne vulgar is were selected for the study. Severity of the acne was labeled as per global GAGS score as follows; (i) mild=1-18, (ii) moderate=19-30, (iii) severe=31-38 and (iv) very severe ≥39. Patients with known hypersensitivity to topical Dapsone and Adapalene, Severe Acne requiring systemic therapy, Pregnant or lactating women and those on any topical medications for the last two months were excluded from the study.

The study was conducted after approval of my synopsis from CPSP. A total of 60 patients fulfilling the inclusion criteria of the study protocol were selected. Acne

vulgaris was diagnosed by the consultant dermatologist after clinical examination. After explaining the objectives of the study, informed consent was taken from each patient before being enrolled in the study. The confidentiality of the information was ensured. The site of the lesions was documented. Local and global GAGS scores were calculated. In order to remove randomization bias, patients were separated into two equal groups using Random Allocation Software 2.0, each for Dapsone 5% and Adapalene 0.1%. Patients were directed to apply their respective prescribed treatment gel twice daily. Patients were called for weekly follow-up. At the fourth visit,the GAGS score and efficacy of the treatment were documented. More than 50% decrease in GAGS score at the 4th visit, as compared to the baseline GAGS score, was labelled as efficacious. Data was collected on a specified form at each follow-up visit.

All the data was entered in SPSS version 27 and analyzed. Continuous data such as age, number of lesions, GAGS local score for areas, initial global GAGS score, and global GAGS score at 4th visits was presented as mean and standard deviation. Nominal data like gender, location of lesions, severity and efficacy was presented as frequency and percentage. Confounding variables were controlled by stratification of data with regard to age, gender, number of lesions, and severity of acne. Post stratification t-test and chi square test were used for comparison of the data between the groups, taking $p \leq 0.05$ as significant.

3. RESULTS

Mean age of the patients of group A was 21.90 ± 5.87 years and of group B was 22.06 ± 4.79 years (p = 0.905). Group A included of 40 % males and 60 % females. Group B comprised of 43.4 % males and 56.7 % females (P = 0.793). Mean number of lesion sites was 3.33 ± 0.71 and 3.30 ± 0.79 in groups A and B, respectively (p = 0.865). Initial GAGS score in group A was 15.63 ± 4.24 and in group B was 16.93 ± 5.16 (p=0.291). In group A, 80% had mild and 20% had moderate acne while in group B, 70% had mild and 30% had moderately severe acne (p = 0.371). Table:I

Table-I: Demographic and baseline data

Variable	Group A (N=30)	Group B (N=30)	P value
Age, years	21.90 ± 5.87	22.06 ± 4.79	0.905
Gender, N (%)			
Male	12 (40.0 %)	13 (43.4 %)	0.793
Female	18 (60.0 %)	17 (56.7 %)	
Total lesion sites	3.33 ± 0.71	3.30 ± 0.79	0.865
Initial GAGS score	15.63 ± 4.24	16.93 ± 5.16	0.291
CI (95%) of difference	[-3.76573, 1.08127]	Cohen's D	-.275
Acne severity, N (%)			
Mild	24 (80.0 %)	21 (70.0 %)	0.371
Moderate	6 (20.0 %)	9 (30.0 %)	

Data is entered as mean ± S.D. unless mentioned otherwise

Table-II :Outcome data

Variable	Group A (N=30)	Group A (N=30)	P value
Initial GAGS score	6.67 ± 1.58	8.43 ± 3.02	0.007
CI (95%) of difference	[-3.01067, -0.59383]	Cohen's D	-.732
Treatment success	26 (86.7 %)	17 (56.7 %)	<0.001

Data is entered as mean ± S.D or number (percentages)

Table-III: Assessment of treatment success after stratification of data

Effect modifier	Subgroup	Group A	Group B	P value
Age, years	12-20	12 (92.3 %)	4 (36.4 %)	0.008
	21-30	14 (82.4 %)	13 (68.4 %)	0.451
Gender	Male	11 (91.7 %)	10 (76.9 %)	0.593
	Female	15 (83.3 %)	7 (41.2 %)	0.015
Severity	Mild	20 (83.3 %)	12 (57.1 %)	0.053
	Moderate	6 (100.0 %)	5 (55.6 %)	0.057
Lesion sites	2	4 (100.0 %)	4 (66.7 %)	0.467
	3	10 (83.3 %)	4 (44.4 %)	0.159
	4	12 (85.7 %)	9 (60.0 %)	0.215

Data is entered as number (percentage)

Table-III explain the treatment success in various patient groups based on age, gender, acne severity and number of lesions.

Final GAGS score was 6.67 ± 1.58 and 8.43 ± 3.02 in groups A and B, respectively, with statistically significant difference (p = 0.007). Treatment was successful in 86.7% of group A and 56.7% of group B patients (p = 0.010). Table-II

4. DISCUSSION

Acne vulgaris is a fairly common skin disorder that is frequently encountered by dermatologists in clinical practice. Its clinical manifestations range from comedones, seborrhea, and erythematous papules to pustules, with pseudocysts, nodules, or scarring that occurs less often in some of the cases. The available treatment options are diverse and include the topical therapies such as retinoids and antibiotics, systemic treatments like retinoids, antibiotics, and hormone modulators, as well as surgical procedures, chemical peels, and laser treatments.[13] A recent addition to these options is the topical 5% Dapsone gel.

Due to the limited number of studies comparing the effectiveness of Dapsone gel 5% and other topical treatments, we conducted this study. Topical 5% Dapsone gel targets the Propionibacterium acnes and leukocytes, effectively plummeting bacterial colonization and the inflammation, two key factors in the pathogenesis of acne vulgaris. In the current study, 30 patients were allocated to both groups and treated for 4 weeks. Our statistics showed that both the dapsone group showed statistically significant efficacy as compared to the control group in terms of successful treatment.

Most of the previous studies on topical 5% Dapsone gel have assessed its efficacy as a separate treatment. However, our study aimed to compare it with a commonly prescribed anti-acne medication, i.e., adapalene. Research conducted by Pickert et al. demonstrated that topical Dapsone gel is clinically efficacious as well as well-tolerated by patients of acne vulgaris.[14] Similarly, Lynde CW et al. studied 101 participants of acne vulgaris and found that topical 5% Dapsone gel is a safe as well as effective treatment for facial acne of moderate severity.[15] Tanghetti et al. in their study reported that dapsone gel yielded more promising outcomes in female patients, however, the outcome was not satisfactory among the male patients.[16] On the contrary, in our study, the results were different as the males showed better results after treatment than the females. Our study also showed that the effectiveness of both topical 5% Dapsone gel and topical Adapalene gel is higher in moderate acne than in mild acne. A study conducted by Lucky et al.[17] determined that topical 5% Dapsone is efficacious as well as safe in the long-term management of acne, and also has a fast onset of action in acne patients. As evidenced by the above-mentioned studies, topical 5% Dapsone gel has proven to be a reliable and well-tolerated anti-acne treatment option. Our study further reinforced these findings, reaffirming its efficacy and safety in managing the acne.

Numerous studies support the effectiveness and safety of topical Adapalene as a management option for acne vulgaris. Percy et al.[18] demonstrated in their study the safety and efficacy of adapalene in the treatment of moderate acne in Indian patients. Additionally, topical Adapalene can be used in combination with other topical and oral medications for treating acne. Our study yielded similar findings, confirming the effectiveness and safety of topical Adapalene. This study was conducted as a pilot to compare the two drugs, i.e., dapsone and Adapalene. Despite the relatively small sample size, the dropout rate was not significant. Kamoji et al.[10] compared 5% Dapsone with Adapalene 0.1%-clindamycin 1% combination for treatment of mild to moderate acne and

observed that Adapalene-clindamycin has better outcomes and fewer side effects. Ibrahim SA et al.[11] observed a good response to dapsone 5% gel in 67.5% of the patients. In a study by Mokhtari F et al.[12], 13.3% of the patients preferred adapalene 0.1% over other drugs. These findings correspond to the results of our study establishing the fact that adapalene, although an effective treatment option for acne vulgaris, the best option with significantly more efficacy is dapsone.

The major limitation of current study is the small sample size and thus it is recommended that in future studies must be undertaken with greater sample size so that the results of this study can be validated and therefore a standard choice of topical agent can be established. The significant difference between the two groups does suggest that dapsone is clearly a more effective treatment; however, as the sample size taken for this study is very small, the results can be used to generalized this finding to other populations.

5. CONCLUSION

According to this study, the efficacy of topical 5% Dapsone gel and Adapalene gel 0.1% for acne vulgaris is significantly different in a selected population. Dapsone gel can be recommended as a standard treatment for acne vulgaris.

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