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ORIGINAL ARTICLE

Efficacy and safety of topical 5% dapsone gel for acne vulgaris.

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ABSTRACT… Objective: To assess the efficacy and safety of topical 5% dapsone gel in treatment of acne vulagris. **Study Design:** Non-Randomised Clinical Trial. **Setting:** Departments of Dermatology, GTTH and SIMS Lahore. **Period:** April, 2022 to July, 2023. **Methods:** A multi-centre study conducted with Topical 5% dapsone gel. Global Acne Assessment Score (GAAS) was calculated at 0,2,4,6,8 and 12 weeks. Efficacy was measured as percentage reduction in the number of lesions as achievement of GAAS 0 or 1 at 12 weeks. Relapse was checked on monthly follow-ups till 24 weeks. **Results:** A total of 90 diagnosed patients of acne vulgaris were enrolled, 12.79% males and 87.21% females; 86 patients aged 13-30 years with mean age 21.31±4.70 years continued treatment. At baseline mean inflammatory, non-inflammatory and total number of lesions were 31.36, 28.21 and 59.57 respectively. At 12 weeks these values decreased to 2.86, 6.90 and 9.58 (p-value <.001). Among 86 patients 47 achieved success and 17 of them later showed relapse. Adverse events were erythema and dryness noted in 9% patients. **Conclusion:** Topical 5% dapsone gel is efficacious and safe for the treatment of acne vulgaris.

Key words: Acne Vulgaris, (GAAS) Score, Topical Dapsone.

INTRODUCTION

Acne vulgaris is a chronic, relapsing and prevalent skin condition, caused by pathological inflammation of pilosebaceous unit.[1] It can remain as an unremitting disease causing prolonged psychiatric, psychosocial and physical consequences.[2] Its multi-factorial pathogenesis includes increased sebum production, follicular plugging, Propionibacterium Acne proliferation and inflammation.[3]

Clinically lesions manifest as non-inflammatory comedones and inflammatory lesions including papules, nodules, pustules and cysts occurring with or without erythema, itching and tenderness on face, chest, shoulders and back.[4] The burden of the disease is more than 85% in adolescents.[5] Topical treatments used for managing adult acne, either alone or in combination with systemic medications include azelaic acid, benzoyl peroxide, retinoids and antibiotics. Topically antibiotics clindamycin and erythromycin resolve acne by eliminating growth of Cutibacterium Acne, but their growing resistance is of great concern.[6,7]

Dapsone (4-4'- diaminodiphenylsulphone) is simplest sulphone structurally, it is antibacterial and anti-inflammatory and is available in oral form is avoided in acne due to its systemic toxicity.[8] It came under scrutiny as an antibiotic in 1937 and was used for treating leprosy in 1945.[9] Its side effects include haemolytic anaemia and methemoglobinemia.[10] The topical form was made for decreasing systemic side effects.[11] Aczone was the first topical preparation of dapsone approved by FDA in 2005.[12] As an anti-inflammatory agent, it inhibits reactive oxygen species, myeloperoxidase enzyme, eosinophilic peroxidase, TNF-α and down regulates interleukin-8 leading to decreased neutrophil mediated inflammation, histamine release and leukotriene formation.[13]

Topical 5% Dapsone gel got approved for treating acne vulgaris on the basis of two studies in US

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that demonstrated the dapsone gel to be effective clinically in treating acne.[14]

Study done by Zoe et al 5% Dapsone gel for treating acne vulgaris demonstrated that at one-month, mean decrease in inflammatory lesion count from baseline was 35%. At 12 weeks, average reduction from baseline was 48%, 32%, and 39% for inflammatory, non-inflammatory, and total lesion counts, respectively ($P<0.001$for inflammatory and total lesion count and $P=0.003$ for non-inflammatory lesion count).Treatment associated mild application-site reactions were present in 38% of the patients other most common adverse events included headache (3.1%) and nasopharyngitis (4.8%). No noteworthy haematological changes were observed even in G6PD deficient patients.

The aim of this study is directed towards reviewing the efficacy as well as safety of 5% dapsone in gel form in patients with acne vulgaris in our population.

METHODS

It was a single arm, non-randomised Clinical trial conducted in out-patient department at Departments of Dermatology, Ghurki Trust Teaching Hospital, Lahore and Services Hospital, Lahore. We enrolled 90 patients selected by non-probability/ consecutive sampling using 90% confidence interval, 8.5% margin of error and mean percentage reduction in total lesion count was taken as 39%.[15] Clinically diagnosed patients of acne from both genders between age range 13-30 years were included. Pregnant and lactating mothers, patients with pure comedonal acne, hypersensitivity to dapsone and known G6PD deficiency were excluded.

Study was started after taking permission from institutional ethical committee (Ref. No.LM&DC/5340-44/2022, dated 14.4.2022). A total of 90 patients presenting in out-patient department who fulfilled the inclusion criteria were enrolled in the study. Informed consent was taken along with detailed history and examination including identification and counting of inflammatory and non-inflammatory lesions.

Application of 5% gel in pea sized amount was advised to the patient twice daily topically, on the affected area after washing and dry patting the skin. The treatment was carried out for a period of 3 months. The severity was marked according to GAAS (Global acne assessment score). At base line, the severity of acne was assessed by GAAS criteria and photographic assessment of the lesion before starting treatment. The response assessment was done at 2,4,6,8 and 12 weeks by following the above-mentioned method. Efficacy was measured as percentage reduction in the number of lesions as achievement of 0 (none) or 1(minimal) on GAAS score till 12 weeks. Regular monthly follow ups were done to check for relapse till 24 weeks, which was measured as loss of efficacy. The safety of dapsone gel was assessed by monitoring local reactions including increased oiliness, redness, skin peeling and dryness of face.

Data was collected using standard format with details like age, gender and duration of disease etc. Data was entered and analysed using SPSS version 22.0. Data was presented using descriptive statistics. Frequencies and percentages were used for qualitative variables like gender, patient satisfaction, response to treatment and side effects. Mean & standard deviation were calculated for quantitative variables (duration of disease, age and GAAS Score for inflammatory, non-inflammatory and total lesions). Data stratification for disease duration, age and gender was done and after that paired t-test was used for GAAS score at baseline and primary end point. Chi square test was used to evaluate efficacy with a p-value <0.05 as significant.

RESULTS

Enrolment of 90 patients was done, 86 completed the trial with 12.79% males and 87.21% females with average age 21.31 ± 4.70 years, ranging from 13 to 30 years 82.56% were unmarried while 17.44% were married, 5 had mild, 41 had moderate, and 40 had severe acne.

Variables	N	%	Mean±SD (Range)
Gender			
Male	11	12.79	
Female	75	87.21	
Age (years)			21.31±4.70 (13-30)
Marital Status			
Married	15	17.44	
Unmarried	71	82.56	

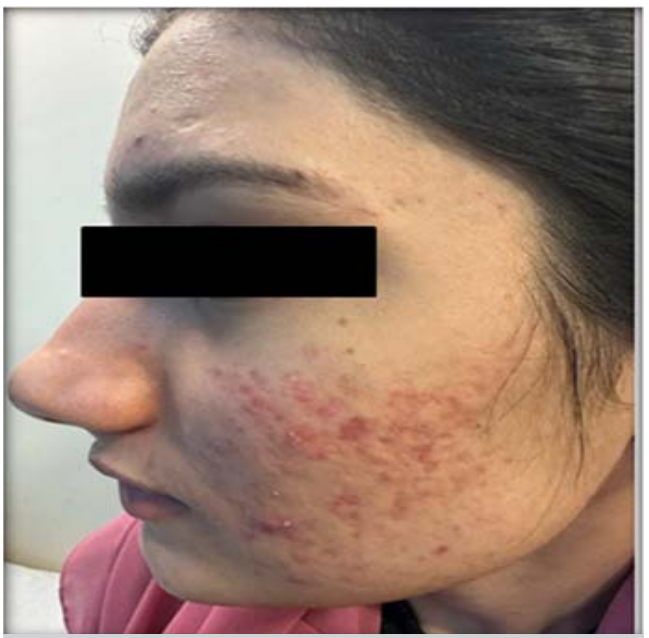
Table-I. Demographic characteristics of dapsone gel for acne vulgaris (n=86)

	Baseline	Week 12	P-Value
Inflammatory Lesion Count	31.36±21.11	2.86±4.92	<.001
Non-inflammatory lesion count	28.21±17.72	6.90±7.70	<.001
Total Lesion Count	59.57±33.08	9.58±10.74	<.001

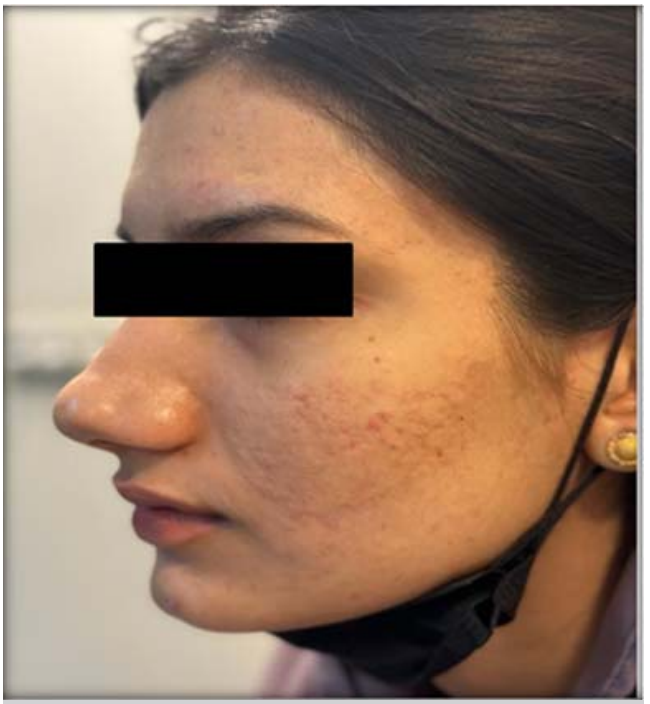
Table-II. Comparison of inflammatory non-inflammatory and total lesions count in dapsone group

Time	GAAS		P-Value
	Success	Failure	
Baseline	-	86	
2 weeks	3	83	<.001
4 weeks	8	78	
6 weeks	22	64	
8 weeks	34	52	
12 weeks	47	39	

Table-III



BEFORE.



AFTER.

At baseline mean mean inflammatory, non-inflammatory and total lesion count was 31.36, 28.21 and 59.57±33.08 and at 12 weeks all decreased to 2.86, 6.90 and 9.58±10.74 (p-value <.001) showing significant decline in non-inflammatory, inflammatory, and total lesion count (Table-II). Results 12 weeks treatment showed 47 out of 86 patients achieved success (defined as GAAS of 0 or 1). Relapse was observed in 17 patients at the end of 24 weeks. During the study period only 9% of the patients had side effects in the initial period of treatment which were erythema and dryness.

DISCUSSION

In our study at 12 weeks, 54.65% patients treated with 5% topical dapsone achieved success on GAAS score. Marked reduction in inflammatory, non-inflammatory and total lesion count at the end of 12 weeks treatment and only 17 patient showed relapse. Similar results were seen in another study by Raimer et al, at week 12, 40.1% of adolescents treated with dapsone gel (232/578) achieved success on GAAS (defined as a GAAS of 0 or 1).

A meta-analysis by Wang et al, done on 7 previous studies regarding dapsone showed that the curative effect of topical dapsone is superior to vehicle gel in the control group, it was completely well tolerated and even safe for G6PD deficient individuals. The local side effects were mild and the skin dryness, redness, and burning sensation were comparable between topical dapsone and vehicle gel treated groups.[16]

A study done by Draelos et al, showed overall side effects between topical dapsone group and control were similar, while patients who dropped treatment due to unfavourable events or efficacy lack, were few. Non-application site treatment related side effects were seen in 1.0% dapsone gel (14/1466) treated patients and 1.3% in vehicle gel (19/1467) treated patients.

Application-site related side effects related to the treatment were also very similar between both groups i.e, (557/1466) 38.0% in dapsone gel group and (555/ 1467) 37.8% of the vehicle gel treated group. The most common adverse events at site of application were dryness and redness.[15]

Similarly, another study conducted by Jawade et al. showed dapsone 5% gel was well-tolerated and effective in treatment of non- inflamed and inflamed acne lesions at 12 weeks.[17]

In our study side effects were observed in few patients (i.e. 9%) and were mild in nature including erythema and dryness in the initial period of treatment which resolved afterwards.

Similarly in a shorter duration study, the average inflammatory and non-inflammatory lesion counts at the end of 8 weeks treatment period ($p<0.001$ both) were markedly reduced. Mild adverse reactions including dryness and burning were observed in 16.9% of the participants during early treatment phase.[18]

Another study done by Verma et al, in 2022 showed statistically significant decrease in comedones, pustules, and papules with dapsone at week 12, average reduction from baseline was 78.9%, 100%, and 50% for non-inflammatory, inflammatory, and total lesion counts, respectively.[19]

A study in which topical 1% clindamycin and topical 5% dapsone gel were compared demonstrated better outcomes with topical dapsone treatment.[20]

CONCLUSION

Dapsone 5% topical is safe and efficacious for treating acne vulgaris. It is more efficacious in treatment of inflammatory lesions than non-inflammatory lesions.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORSHIP AND CONTRIBUTION DECLARATION	
1	**Nabigha Khalid:** Conceptualization, writing, majority of the manuscript, overall project managment.
2	**Saadiya Siddiqui:** Conducted experiment, contributed to data analysis.
3	**Sumera Hanif:** Writing section, critical revision.
4	**Talat Akbar:** Gathered literature, contributed to discussion section.
5	**Faria Asad:** Provided statistical analysis, support for methodology.
6	**Haroon Nabi:** Supervisor and Head, formatting, final proof reading.