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Dermatology

An Assessment of the Efficacy and Safety of Dapsone Gel: Study in a Local Setting

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| **Abstract** | **Original Research Article** |

Introduction: Acne vulgaris is a long-term skin condition that occurs when dead skin cells and oil from the skin clog hair follicles. Typical features of that condition included blackheads or whiteheads, pimples, oily skin and possible scarring. The aim of the study was to assess the efficacy and safety of dapsone gel in the Treatment of Acne Vulgaris. *Method*: A clinical trial was carried out at Upazilla Health Complex, Fulpur, Mymensingh during the period from January 2018 to December 2018. Total fifty (50) patients of clinically diagnosed mild to moderate acne vulgaris were enrolled and thirty (30) of Group I patients were treated by dapsone gel and another thirty of Group II patients were treated by Clindamycin cream over 28 days in patients with moderate acne vulgaris. *Result:* At baseline mean number of comedones in Group I and Group II were 13.11±3.67 and 12.12±3.61, respectively (p=0.415) and at final follow-up 4.10±4.11 and 4.50±3.10 in each group (p>0.05). At baseline mean number of papules in Group I and Group II were 18.11±9.48 and 19.01±13.44, respectively (p=0.725) and at final follow-up 8.02±7.69 and 8.03±9.68 (p>0.05). At baseline mean number of pustules in Group I and Group II were 0.49±1.43 and 0.50±1.31, respectively (p=0.897) and at final follow-up 0.08±0.36 and 0.00 (p>0.05). At baseline mean of total acne score was 29.96±14.23 and 30.90±17.17 in Group I and B and at final follow-up, it was 11.87±12.04 and 11.20±13.85, respectively in Group I and B (p>0.05). Percent reduction of acne severity from baseline to final follow-up was 69.20±23.41 in Group I and 74.77±23.30 in Group II (p=0.393). At final follow-up, 56.7% of Group I and 63.3% of Group II achieved excellent response and 13.3% of Group I and 16.7% of Group II achieved a good response. *Conclusion:* The study can conclude that dapsone gel was found to be more effective than Clindamycin cream in the treatment of acne vulgaris. This study demonstrated lower systemic exposure with dapsone gel formulations than with Clindamycin cream.
Keywords: Efficacy, Safety, Dapsone gel, Clindamycin cream, Acne Vulgaris.

INTRODUCTION

Acne vulgaris is a long-term skin condition which happens when dead skin cells and oil from the skin clog hair follicles. It is the most `common inflammatory ltrewq1` disease characterized by comedones; papules; pustules; inflamed nodules; superficial pus-filled cysts; and (in extreme cases) canalizing and deep, inflamed, sometimes purulent sacs [1]. Lesions are commonest on the face, but the neck, chest, upper back, and shoulders may additionally be affected. Adolescents and adults with acne have higher rates of tension or anxiety, low self-worth, and depression than those without acne [2]. Also, adults with severe acne have higher unemployment rates than age-matched controls without acne [3]. There are different treatment options available for patients with acne. All approaches have advantages and

disadvantages both and not all approaches are suitable for every patient [4]. The treatment goals are directed to scale back the activity of the sebaceous glands, normalize follicular proliferation, reduce bacterial colonization, and control inflammation [5, 6]. Because of the utilization of topical and systemic antibiotics for acne, the incidence of antibiotic-resistant Propionibacterium acnes is increasing worldwide. Topical benzoyl peroxide (BPO) is used as an alternative to antibiotics for the treatment of acne [7, 8]. Benzoyl peroxide is a powerful antimicrobial agent which destroys both surface and ductal bacterial organisms and yeasts. Its lipophilic properties permit penetration of the pilosebaceous duct and its efficacy is to an excellent extent, against superficial inflammatory lesions. It (BPO) gets decomposed to release free oxygen radicals, which have potent bactericidal activity within the sebaceous follicles and anti-inflammatory

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action. It also has effects on non-inflammatory lesions by reducing follicular hyperkeratosis to a point. They are not related to antimicrobial resistance and are active against fully sensitive and resistant strains of P. acnes [9-11].To treat mild to moderate acne, it can be used alone or in combination with topical antibiotics and topical [12] retinoids.1Clindamycin improves acne by reducing the levels of P. acnes and decreasing inflammation [13,14]. The advantages of this combination therapy are - keratolytic action of BPO is possibly synergistic with the antibacterial activity of clindamycin [15, 16]. This study aims to assess the efficacy and safety of dapsone gel on the Treatment of Acne Vulgaris.

OBJECTIVES
- To assess the efficacy and safety of dapsone gel in the Treatment of Acne Vulgaris in Bangladesh

METHOD AND MATERIALS
A clinical trial was conducted in Upazilla Health Complex, Fulpur, Mymensingh during the period from January 2018 to December 2018. Acne vulgaris patients during the study period were enrolled in the study. Those patients, who matched the inclusion and exclusion criteria, were selected for the study. Inclusion criteria of patient selection were patients clinically diagnosed as acne vulgaris who given informed written consent to be included in the study, aged ≥12 years of both sexes. Data were collected by face-to-face interviewing and were recorded in a pre-designed questionnaire. Information was taken including a medical history and clinical examination. Baseline laboratory investigations were carried out for purpose of exclusion and monitoring of side effects. Laboratory investigations included with complete blood counts, liver function tests, serum creatinine, random blood sugar level, and serum cholesterol and triglyceride level. Total fifty (50) patients with clinically diagnosed mild to moderate acne were enrolled and divided into Group I and Group II. Twenty-five of Group I patients were treated with dapsone gel and twenty-five of Group II patients were treated with Clindamycin cream. Participants were clinically assessed every month for three months. The severity index of the disease was calculated and clinical photographs were taken in time. Clinical assessment and the severity index were calculated at the end of the last month. Then the patient was followed up second month in the post-treatment period to assess for any recurrence. A four point scale was used to measure the level of response during treatment, if >75% clear-Excellent response; if 50-75% clear- good response if 25-50% clear fair response; if <25% clear poor response. Safety, tolerability and efficacy were assessed through evaluations of local facial tolerability and adverse events. In each follow-up, clinical evaluation of the patients was undertaken to assess the Efficacy and

Safety of dapsone gel in the Treatment of Acne Vulgaris. Data were analyzed by computer software package SPSS and the level of significance was measured. Statistical significance (p-value) was set at <0.05 level and confidence interval at 95% level.

RESULTS
Twenty-five of Group I patients were treated with dapsone gel and twenty-five of Group II patients were treated with Clindamycin cream. Table 1 shows that the Mean ± SD of age of onset of acne was 20.01±3.43 years and 18.02±2.52 years in Group I and Group II, respectively (p=0.345). The mean duration of disease was 17.04±16.77 months and 27.00±39.91 months in Group I and Group II, respectively (p=0.213). Facial lesions were present in 96.0% of Group I and 100.0% of Group II, neck lesions were present in 6.7 % and Nose lesions in 3.3% (p>0.05) in each group (Table-2). At baseline mean number of comedones in Group I and Group II were 13.11±3.67 and 12.12±3.61, respectively (p=0.415). At 1st follow-up the mean number of comedones in Group I and Group II was 7.80±4.11 and 7.77±4.08, respectively, at 2nd follow-up, it was 6.10±4.03 and 5.63±4.16 and at final follow-up 4.17±4.02 and 3.47±4.00 in each group (p>0.05). At baseline mean number of papules in Group I and Group II were 18.11±9.48 and 19.01±13.44 respectively (p=0.725). At 1st follow-up, the mean number of papules in Group I and Group II was 12.40±9.46 and 13.10±12.67, respectively, at 2nd follow-up it was 9.97±8.73 and 10.10±11.17 and at final follow-up 7.63±8.08 and 7.73±9.98, respectively (p>0.05) and Group II was 0.49±1.43 and 0.50±1.31, respectively (p=0.922). At 1st follow-up the mean number of pustules in Group I and Group II was 0.30±0.88 and 0.30±0.75, respectively, at 2nd follow-up, it was 0.17±0.59 and 0.10±0.31 and at final follow up 0.08±0.36 and 0.00, respectively (p>0.05) (Table-3). At baseline mean of total acne score (acne score of comedones, papules, and pustules) was 29.96±14.23 and 30.90±17.17 in Group I and Group II, respectively. At 1st follow-up it was 20.50±13.64 and 21.17±16.94, respectively in Group I and Group II, at 2nd follow-up it was 16.23±12.74 and 15.83±15.29 and at final follow up it was 11.87±12.04 and 11.20±13.85, respectively in Group I and Group II (p>0.05). Percent reduction of acne severity from baseline to final follow-up was 69.20±23.41 in Group I and 74.77±23.30 in Group II (p=0.393), (Table 4). At 1st follow-up, 4.0% of both groups got an excellent response, 8.0% of Group I and 24.0% Group II got a good response, 60.0% of Group I and 40.0% of Group II got a fair response, and 28.0% of Group I and 32.0% of Group II got a poor response (p=0.298). At 2nd follow-up, 12.0% of Group I and 32.0% of Group II got an excellent response, 48.0% of Group I and 40.0% of Group II got a good response, 32.0% of Group I and 20% of Group II got a fair response and 8.0% of Group I and 8.0% of Group II got a poor response (p=0.513). At final follow-up, 56.0% of Group I and 64.0% of

Group II achieved an excellent response, 12.0% of Group I and 16.0% of Group II achieved a good response, 24.0% of Group I and 16.0% of Group II achieved fair response and 8.0% of Group I and 4.0% of Group II achieved poor response (p=0.794), (Table 5).

Table-1: Mean and standard deviation of age at first acne appeared (yrs.) and duration of Acne (months). (n=50)

Characteristics	Group		p-value
	Group I	Group II	
Age at first acne appeared (yrs.)	20.01±3.43	18.02±2.52	0.345
Duration of acne (months)	17.04±16.77	27.00±39.91	0.213

Table-2: Distribution of groups by the site of lesion (n=50)

Site	Group		p-value
	Group I	Group II	
Face	24 (96.0%)	25 (100.0%)	0.276
Neck	2 (6.7%)	2 (6.7%)	0.888
Nose	1 (3.3%)	1 (3.3%)	0.888

Table-3: Mean and standard deviation of comedones papules and pustules baseline and subsequent follow up (n=50)

Characteristics	Group		p-value
	Group I	Group II	
Mean number of comedones			
Baseline	13.11±3.67	12.12±3.61	0.415
1st follow-up	7.80±4.11	7.77±4.08	0.879
2nd follow-up	6.10±4.03	5.63±4.16	0.714
Final follow-up	4.10±4.11	4.50±3.10	0.498
Mean number of papules			
Baseline	18.11±9.48	19.01±13.44	0.725
1st follow-up	12.40±9.46	13.10±12.67	0.713
2nd follow-up	9.97±8.73	10.10±11.17	0.878
Final follow-up	8.02±7.69	8.03±9.68	0.934
Pustules			
Baseline	0.49±1.43	0.50±1.31	0.897
1st follow-up	0.30±0.88	0.30±0.75	0.888
2nd follow-up	0.17±0.59	0.10±0.31	0.614
Final follow-up	0.08±0.36	0	0.387

Table-4: Mean of total acne score at different follow-up visits. (n=50

Mean of total acne score	Groups		p-value
	Group I	Group II	
Baseline	29.96±14.23	30.90±17.17	0.756
1st follow-up	20.50±13.64	21.17±16.94	0.798
2nd follow-up	16.23±12.74	15.83±15.29	0.782
Final follow-up	11.87±12.04	11.20±13.85	0.7124
Percent of reduction from baseline to final follow-up	69.20±23.41	74.77±23.30	0.393

Table-5: Distribution of lesions begin to clear by groups in different follow up (n=50)

Lesions begin to clear	Group		p-value
	Group A	Group II	
1st follow up			
Excellent	1 (4.0%)	1 (4.0%)	0.298
Good	2 (8.0%)	6 (24.0%)	
Fair	15 (60.0%)	10 (40.0%)	
Poor	7 (28.0%)	8 (32.0%)	
2nd follow up			
Excellent	3 (12.0%)	8 (32.0%)	0.513
Good	12 (48.0%)	10 (40.0%)	
Fair	8 (32.0%)	5 (20.0%)	
Poor	2 (8.0%)	2 (8.0%)	
3rd follow up			
Excellent	14 (56%)	16 (64.0%)	0.794
Good	3 (12.0%)	4 (16.0%)	
Fair	6 (24.0%)	4 (16.0%)	
Poor	2 (8.0%)	1 (4.0%)	

DISCUSSION

In our study, twenty-five of Group I patients were treated with dapsone gel and thirty of Group II patients were treated with Clindamycin cream. The Mean ± SD of age of onset of acne was 20.01±3.43 years and 18.02±2.52 years in Group I and Group II, respectively. Similar results were found in another study by Zaina T. et al.[17] where the mean age was 20.3 years. The mean duration of disease was 17.04±16.77 months and 27.00±39.91 months in Group I and Group II, respectively (p=0. 213). Similar results were found in another study by Al Sabaa HM et al. [18], where the duration of acne ranged from half to 4 years with a mean duration of 1.53 ± 0.92. Facial lesions were present in 96.0% of Group I and 100.0% of Group II, neck lesions were present in 6.7 %, and Nose lesions in 3.3% (p>0.05) in each group. At baseline mean number of comedones in Group I and Group II were 13.11±3.67 and 12.12±3.61, respectively (p=0.415). At 1st follow-up the mean number of comedones in Group I and Group II was 7.80±4.11 and 7.77±4.08, respectively, at 2nd follow-up, it was 6.10±4.03 and 5.63±4.16 and at final follow-up 4.17±4.02 and 3.47±4.00 in each group (p>0.05). In another study of Del Rosso JQ et al.[19], among 20 study people mean non-inflammatory lesion at baseline was 25±20, in the follow-up time at 4th week mean non-inflammatory lesion was 22±25, in the follow-up time at 10th week mean non-inflammatory lesion was 12±17 and in the final follow up time at 16th week mean non-inflammatory lesion was 12±22. At baseline mean number of papules in Group I and Group II were 18.11±9.48 and 19.01±13.44 respectively (p=0. 725). At 1st follow-up, the mean number of papules in Group I and Group II was 12.40±9.46 and 13.10±12.67, respectively, at 2nd follow-up it was 9.97±8.73 and 10.10±11.17 and at final follow-up 7.63±8.08 and 7.73±9.98, respectively (p>0.05) and Group II was 0.49±1.43 and 0.50±1.31, respectively (p=0. 922). At 1st follow-up mean number of pustules in Group I and

Group II was 0.30±0.88 and 0.30±0.75, respectively, at 2nd follow-up, it was 0.17±0.59 and 0.10±0.31, and at final follow up 0.08±0.36 and 0.00, respectively (p>0.05). In the study of Del Rosso JQ et al.[19], mean inflammatory lesion count (both papules and pustules) at baseline was 34±26, mean inflammatory lesion count at 1st follow up was 24±25, mean inflammatory lesion count at 2nd follow up was 14±19, mean inflammatory lesion count at final follow up was 12±23.

At baseline mean of total acne score (acne score of comedones, papules, and pustules) was 29.96±14.23 and 30.90±17.17 in Group I and Group II, respectively. At 1st follow-up it was 20.50±13.64 and 21.17±16.94, respectively in Group I and Group II, at 2nd follow-up it was 16.23±12.74 and 15.83±15.29 and at final follow up it was 11.87±12.04 and 11.20±13.85, respectively in Group I and Group II (p>0.05). In the study of Del Rosso JQ et al. [19], mean total lesion count at baseline was 59±44, mean total lesion count at 1st follow up was 46±49, mean total lesion count at 2nd follow up was 27±35, and mean total lesion count at final follow up was 24±44. Percent reduction of acne severity from baseline to final follow-up was 69.20±23.41 in Group I and 74.77±23.30 in Group II (p=0.393). At 1st follow-up, 4.0% of both groups got an excellent response, 8.0% of Group I and 24.0% Group II got a good response, 60.0% of Group I and 40.0% of Group II got a fair response, and 28.0% of Group I and 32.0% of Group II got a poor response (p=0.298). At 2nd follow-up, 12.0% of Group I and 32.0% of Group II got an excellent response, 48.0% of Group I and 40.0% of Group II got a good response, 32.0% of Group I and 20% of Group II got a fair response and 8.0% of Group I and 8.0% of Group II got a poor response (p=0.513). At final follow-up, 56.0% of Group I and 64.0% of Group II achieved an excellent response, 12.0% of Group I and 16.0% of Group II achieved a good response, 24.0% of Group I and 16.0% of Group II

achieved fair response and 8.0% of Group I and 4.0% of Group II achieved a poor response.

Limitations of the study

This was a single-center study with small sample size. So, the study results might not be reflected in the whole country.

CONCLUSION AND RECOMMENDATIONS

Study found that clindamycin cream was to be effective in the treatment of acne vulgaris but dapsone gel was found to be superior in efficacy, tolerability and Safety. We suggest multicenter, randomized, double-blind study with a large sample size.

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