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Pathology

Efficacy and Safety of Dapsone Gel 7.5% on the Treatment of Acne Vulgaris: A Study in a Tertiary Care Hospital, Cumilla, Bangladesh

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Abstract **Original Research Article**

A clinical trial was carried out in the Department of Dermatology and Venereology, Cumilla Medical College Hospital; Cumilla, Bangladesh during the period from July 2018 to December 2018. Total sixty (60) patients of clinically diagnosed mild to moderate acne vulgaris was enrolled and thirty (30) of Group I patients were treated by dapsone gel, 7.5% and another thirty of Group II patients were treated by Clyndamycin cream over 28 days in patients with moderate acne vulgaris. Our objectives were to assess the efficacy and safety of dapsone gel, 7.5% on the Treatment of Acne Vulgaris. At baseline mean number of comedones in Group I and Group II was 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 was 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 was 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 Group II 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). 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 good response. It can be concluded dapsone gel 7.5% was found to be more effective than Clyndamycin cream in the treatment of acne vulgaris.

Key words: Efficacy, Safety, Dapsone gel (7.5%), Clyndamycin cream, Acne Vulgaris.

INTRODUCTION

Acne vulgaris is a common dermatological disorder of the pilosebaceous unit presenting usually at puberty [1]. It is characterized by the formation of open and closed comedones (non- inflammatory lesions), papules, pustules, and nodulocystic lesions (inflammatory lesions) generally affecting the face, arms, and back. The pathogenesis is complex and multifactorial which includes abnormal sebum production, follicular hyperkeratinization, bacterial proliferation and inflammation [2-4].The treatment goals are directed to reduce activity of the sebaceous glands, normalize follicular proliferation, reduce bacterial colonization and control inflammation[5,6]. Owing to the use of topical and systemic antibiotics for acne vulgaris, the incidence of antibiotic-resistant Propionibacterium acnes is increasing worldwide. Dapsone is a sulfone antibacterial with anti-inflammatory actions, which are thought to be largely responsible for its efficacy in treating acne vulgaris. The benefits of dapsone 7.5% gel over vehicle were seen as early as week 2 for inflammatory lesion counts, and from week 4 or 8 for other outcomes. Dapsone 7.5% gel was well tolerated, with a low incidence of treatment-related adverse events, with the majority of adverse events being administration-site related and mild or moderate in severity. Thus, dapsone 7.5% gel is an effective and well tolerated option for the topical treatment of acne vulgaris in patients [7]. Acne is a chronic inflammatory skin disease that is estimated to affect approximately 85% of the population at some point in their lives [8]. Generally straightforward to recognize clinically, acne has a variable presentation with a constellation of lesion types including open and closed comedones, papules, pustules, nodules, and cysts [8, 9]. The face is involved in most cases, and the trunk is affected in up to 61% of patients [10-12]. Acne lesions can progress to scars, postinflammatory hyperpigmention (PIH), or both, which can be

bothersome to patients [10-12]. There are different treatment options available for patients with acne vulgaris. All approaches have advantage and disadvantages and none is appropriate for every patient [13]. But dapsone 7.5% gel is well tolerated and most effective than traditional other molecules. The convenient dosage schedule and easy applying feature may make it popular to the patients for the treatment of acne vulgaris.

Objectives

To assess the efficacy and safety of dapsone gel 7.5% on the Treatment of Acne Vulgaris in Bangladesh

To assess the options for better treatment of Acne Vulgaris in Bangladesh

METHOD AND MATERIALS

A clinical trial was conducted in the department of Dermatology and Venereology, Cumilla Medical College Hospital; Cumilla, Bangladesh during the period from July 2018 to December 2018. Patients of acne vulgaris during the study period were enrolled in the study. Complete history, general physical and dermatological examinations were done for all enrolled patients. For women of reproductive age reproductive history, menstrual history, lactation and pregnancy plan were carefully judged. History and physical findings were recorded in a structured questionnaire. Finally 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 gave informed consent to be included in the study, age ≥12 years of both sexes, patients with non-inflammatory (comedones) lesions and inflammatory (papules, pustules) lesions on the face. Data were collected by face to face interview and were recorded in a questionnaire. Information was collected by taking medical history and clinical examination. Baseline laboratory investigations were carried out for purpose of exclusion and monitoring of side effects. Laboratory investigations included complete blood counts, liver function tests, serum creatinine, random blood sugar level, and serum cholesterol and triglyceride level. Total sixty (60) patients of clinically diagnosed mild to moderate acne was enrolled and divided into Group I and Group II. Thirty of Group I patients were treated by dapsone gel 7.5% and thirty of Group II patients were treated by Clyndamycin cream. Patients were clinically assessed monthly for three months. Each time the severity index of the disease was calculated and recorded and clinical photographs were taken. The final clinical assessment was done and the severity index was calculated at the end of the third month. Then the patient was followed up at the second month in the post-treatment period to look for any recurrence. A four point scale is used to measure the level of response to treatment, if >75% clear- Excellent response; if 50-75% clear- good response if 25-50% clear fair response; if <25% clear poor response. Safety and tolerability were assessed through evaluations of local facial tolerability and adverse events. On each follow up, clinical evaluation of the patients were undertaken in order to assess the Efficacy and Safety of dapsone gel 7.5% on the treatment of Acne Vulgaris. Data were analyzed by computer software package and level of significance was measured by using appropriate statistical tests. Statistical significance (p value) was set at 0.05 level and confidence interval at 95% level.

RESULTS

Thirty (30) of Group I patients were treated by dapsone gel 7.5% and thirty (30) of Group II patients were treated by Clyndamycin cream. 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), [Table 1]. 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 96.7% of Group I and 100.0% of Group II, neck lesions was 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 Iand Group II was 13.11±3.67 and 12.12±3.61, respectively (p=0.415). At 1st follow-up 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), [Table 3] At baseline mean number of papules in Group I and Group II was 18.11±9.48 and 19.01±13.44 respectively (p=0. 725). At 1st follow-up, 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), [Table 4] 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), [Table 5]. 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 6]. At 1st follow-up, 3.3% of both group got excellent response, 10.0% of Group I and 26.7% Group II got good response, 60.0% of Group I and 40.0% of Group II got fair response and 26.7% of Group I and 30.0% of Group II got poor response (p=0.298). At 2nd follow-up, 13.3% of Group I and 30.0% of Group II got excellent response, 46.7% of Group I and 40.0% of Group II got good response, 30.0% of Group I and 13.3% of Group II got fair response and 10.0% of

Group I and 6.7% of Group II got poor response (p=0.513). At final follow-up, 56.7% of Group I and 63.3% of Group II achieved excellent response, 13.3% of Group I and 16.7% of Group II achieved good response, 23.3% of Group I and 16.7% of Group II achieved fair response and 6.7% of Group I and 3.3% of Group II achieved poor response (p=0.794) [Table 7].

Table-I: Mean and standard deviation of age at first acne appeared (years) and duration of Acne (months). (n=60)

	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-II: Distribution of groups by site of lesion (n=60)

Site	Group		p value*
	Group I	Group II	
Face	29 (96.7)	30 (100.0)	0.276
Neck	2 (6.7)	2 (6.7)	0.888
Nose	1 (3.3)	1 (3.3)	0.888

Table-III: Mean number of comedones at baseline and subsequent follow-ups. (n=60)

Mean number of comedones	Group		p value*
	Group I	Group II	
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

Table-IV: Mean number of papules at baseline and subsequent follow-ups. (n=60)

Mean number of papules	Group		p value*
	Group I	Group II	
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

Table-V: Mean number of pustules at baseline and subsequent follow-ups. (n=60)

Pustules	Group		p value*
	Group II	Group II	
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-VII: Distribution of lesions begin to clear by groups in different follow up (n=60)

Lesions begin to clear	Group		p value*
	Group A	Group II	
1st follow up			
Excellent	1 (3.3)#	1 (3.3)	0.298
Good	3 (10.0)	8 (26.7)	
Fair	18 (60.0)	12 (40.0)	
Poor	8 (26.7)	9 (30.0)	
2nd follow up			
Excellent	4 (13.3)	9 (30.0)	0.513
Good	14 (46.7)	12 (40.0)	
Fair	9 (30.0)	7 (13.3)	
Poor	3 (10.0)	2 (6.7)	
3rd follow up			
Excellent	17 (56.7)	19 (63.3)	0.794
Good	4 (13.3)	5 (16.7)	
Fair	7 (23.3)	5 (16.7)	
Poor	2 (6.7)	1 (3.3)	

DISCUSSION

Thirty (30) of Group I patients were dapsone gel 7.5% and thirty (30) of Group II patients were treated by Clyndamycin cream. 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), [Table 1]. 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 96.7% of Group I and 100.0% of Group II, neck lesions was 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 was 13.11±3.67 and 12.12±3.61, respectively (p=0.415). At 1st follow-up 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 was 18.11±9.48 and 19.01±13.44 respectively (p=0. 725). At 1st follow-up, 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). 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). At 1st follow-up, 3.3% of both group got excellent response, 10.0% of Group I and 26.7% Group II got good response, 60.0% of Group I and 40.0% of Group II got fair response and 26.7% of Group I and 30.0% of Group II got poor response (p=0.298). At 2nd follow-up, 13.3% of Group I and 30.0% of Group II got excellent response, 46.7% of Group I and 40.0% of Group II got good response, 30.0% of Group I and 13.3% of Group II got fair response and 10.0% of Group I and 6.7% of Group II got poor response (p=0.513). At final follow-up, 56.7% of Group I and 63.3% of Group II achieved excellent response, 13.3% of Group I and 16.7% of Group II achieved good response, 23.3% of Group I and 16.7% of Group II achieved fair response and 6.7% of Group I and 3.3% of Group II achieved poor response (p=0.794). In our study, at baseline mean of total acne score was 29.96±14.23 and 30.90±17.17 in Group I and Group II. At 1st follow-up it reduced to 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 (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).

Limitations of the study

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

CONCLUSION

Clyndamycin cream was found to be effective in the treatment of acne vulgaris but dapsone gel 7.5% was found to be superior in efficacy and Safety. Further multicenter, randomized, double-blind study should be conducted with large sample size.

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