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RESEARCH ARTICLE
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COMPARISON OF THE EFFICACY OF CLINDAMYCIN PHOSPHATE GEL 1% VERSUS ONCE-DAILY DAPSONE GEL 5% IN THE TREATMENT OF MODERATE ACNE VULGARIS AT THE TERTIARY CARE HOSPITAL, KARACHI

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Abstract

Objective: To evaluate the efficacy of clindamycin phosphate 1% gel versus Once-daily dapsone 5% gel in the treatment of moderate acne vulgaris at Tertiary Care Hospital, Karachi.

Study design: Randomized controlled trial.

Place and duration of study: This study was conducted at Department of Dermatology, Jinnah Postgraduate Medical Centre, Karachi from August 2022 till February 2023.

Material and methods: Data was prospectively collected from patients after taking consent. The sample size for the study was 100 patients, 50 in each group (A-Clindamycin and B- Dapsone) were included. Patients presenting with moderate acne vulgaris in either group were assessed for degree of improvement using Global Acne Grading Scale and patients achieving a score of ≤ 18 after 12 weeks of treatment was labeled as efficacy. Data was analyzed on SPSS Version 24.

Results: The study involved participants aged 20-70 years with Group A (mean age 24.20±5.99) and Group B (mean age 26.221±6.50). In both groups, predominantly there were females, majority in the 20- 49 age range. Efficacy was significantly higher in Group B (82%) compared to Group A (12%). Stratification by gender, and age revealed substantial differences in efficacy, particularly for participants with acne duration ≤ 3 months.

Conclusion: The outcome of this study demonstrates that dapsone 5% gel monotherapy had better efficacious results compared to the clindamycin phosphate 1% gel monotherapy after 12 weeks of treatment, with convenience of once-daily topical application.

Keywords: Acne Vulgaris; 1% Clindamycin; 5% Dapsone; Topical Therapy

INTRODUCTION:

Acne vulgaris (AV) is a common skin condition affecting the pilosebaceous unit, characterized by the presence of noninflammatory lesions (open and closed comedones) and inflammatory lesions (papules, pustules, and nodules), often leading to different levels of scarring.[1] Typically emerging during adolescence, AV has an estimated lifetime prevalence of approximately 85%. The pathogenesis involves crucial processes, including changes in follicular keratinization leading to comedones, increased and altered sebum production regulated by androgens, follicular colonization by Propionibacterium acnes, and complex inflammatory mechanisms involving both innate and acquired immunity.[2-3] Various factors contribute to the development of acne, including genetics (as demonstrated in twin studies and a family history of severe acne), dietary factors such as glycemic index, chocolate, and dairy consumption, and environmental influences, including occupational exposures. The convergence of these factors plays a significant role in the pathogenesis of acne. [4]

The advanced formulation of topical 5% dapsone gel, containing sulfone and employing an innovative solvent microparticulate delivery system, facilitates its penetration through the stratum corneum.[5-6] Dapsone, known for its dual antibacterial and anti-inflammatory properties, is believed to contribute to the reduction of acne. The efficacy of topical retinoids in acne treatment is firmly established, and clindamycin, a topical antibiotic with a lengthy history in acne therapy, is also widely recognized. However, the widespread use of antibiotics for acne has resulted in the development of antimicrobial resistance by various pathogens, including Propionibacterium acnes.[7]

Therefore, the current guidelines strongly emphasize the importance of avoiding prolonged monotherapy for chronic conditions like acne.[8] Clinical features of acne include seborrhea, non-inflammatory lesions like open and closed comedones, as well as inflammatory lesions such as papules, pustules, and, in severe cases, scarring. With a better understanding of acne's pathogenesis in recent years, there is a growing emergence of new treatment modalities. [9-10] A study conducted by Brar et al. indicated that the overall efficacy of Dapsone 5% gel is 53.19%, with 50% of patients achieving complete clearance of acne after 12 weeks. In comparison, clindamycin demonstrated a 50% efficacy, with 46.67% of patients achieving complete freedom from acne. [11]

Acne significantly contributes to morbidity, marked by lasting scarring and psychological distress, including issues like poor self-image, depression, and anxiety, ultimately impacting the individual's quality of life negatively. The dual anti-inflammatory and anti-microbial effects of Dapsone present a potential innovative monotherapy approach for addressing acne. Given the known resistance to antibiotics like macrolides and quinolones used in acne treatment, along with associated side effects of systemic therapies such as retinoids, individuals often prefer topical treatments over systemic ones. Therefore, identifying the most effective topical treatment is crucial. Establishing Dapsone as a treatment of choice through data analysis could result in cost reduction and provide both financial and psychological benefits to the patient.

MATERIAL AND METHODS:

There were 100 patients between 20 to 70 years of age, both genders, who had presented to the Department of Dermatology, JPMC, Karachi, were included in our randomized control trial. Patients known to have acne vulgaris were assessed at the time of presentation using Global Acne Grading Scale. Each type of lesion was graded depending on the severity as follows: no lesions=0, comedones=1, papules=2, pustules=3 and nodules=4. Score for each area was calculated = factor multiplied by grade. Global score was sum of local scores. Patients having a score between 19-30 were included in the study. Patients presenting with moderate acne vulgaris in either group were assessed for degree of improvement using Global Acne Grading Scale and patients achieving a score of ≤ 18 after 12 weeks of treatment was labeled as efficacy. Quantitative data was presented as

simple descriptive statistics giving mean and standard deviation whereas qualitative variables were presented as frequency and percentages.

Patients having history of previous treatments with some systemic agents, having unrealistic expectations, with history of more than 3 months disease duration, having some secondary infection of skin and adnexa, pregnant and lactating women, and patients having severe hematological abnormalities were excluded. Permission from the institutional ethical review committee was taken prior to conduction of study. Brief history of demographic information and written informed consent was taken from each patient. Patients were examined by dermatologist with over 10 years of experience in the presence of researcher and was graded. Patients were randomly allocated using sealed opaque envelop bearing A= Clindamycin phosphate gel 1% group and B= Dapsone gel 5% group. Clindamycin topically was applied during the day-time while Dapsone gel was applied once-daily at bedtime on the lesions daily for 12 weeks. Data was analyzed on SPSS Version 24. Mean and standard deviations was calculated for the quantitative variables like age and duration of acne vulgaris. Mean ± SD was reported for the normally distributed (Kolmogorov–Smirnov test) while median (IQR) was reported for the non-normality distributed quantitative variables. Frequencies and percentages was calculated for the qualitative variables like gender and efficacy. Chi-square was used to compare two groups for efficacy of treatment. Effect modifiers were controlled through stratification of age, gender and duration of acne vulgaris. Post stratification chi square test/ fischer test was applied and p-value of ≤ 0.05 was considered significant.

RESULTS

Age range in this study was from 20 to 70 years with mean age of 24.20± 5.99 years in Group A while 26.221±6.50 years in Group B. Majority of patients belonged to 20-49 years age group. In comparing both groups, greater number of patients belonged to female gender. Efficacy was seen in 12% patients in Group A and 82% patients in Group B. Table-I

Stratification was done to control confounding factors like gender, age and duration and Acne Vulgaris. Gender stratification in terms of efficacy among study groups showed p-value of 0.001 and 0.001 for male and female genders respectively. Age group stratification in terms of efficacy among study groups is shown in Table-II. Efficacy in terms of duration ≤ 3 months was seen in 04 patients (16.7%) of group-A and 18 patients (90%) of group-B (p-value 0.001) using chi square test shown in Table-II.

DISCUSSION

Acne vulgaris, a common condition in adolescents, significantly affects a patient's quality of life, including self-esteem and psychosocial development. In the past 20 years, there has been a growing understanding of the pathogenesis of acne, leading to the introduction of various new drugs in acne therapy. These medications typically address specific factors contributing to the development of acne.[12-13]

Topical clindamycin is a well-established and effective treatment for mild-to-moderate acne, whether used on its own or in combination with other systemic therapies. Its efficacy matches that of systemic tetracyclines, topical erythromycin, and topical benzoyl peroxide. [14-16] Although major side effects are uncommon with topical clindamycin, there have been reported instances of pseudomembranous colitis. Additionally, localized skin irritation, characterized by redness and desquamation, may occur, mainly due to the vehicle used in the drug preparation. It is important to note that the use of antibiotics alone can contribute to increased bacterial resistance, leading to a decline in their effectiveness in treating acne. This underscores the necessity of exploring new therapeutic options for acne treatment. [17-19]

Dapsone, characterized as a sulfone, possesses dual anti-inflammatory and antimicrobial properties. Traditionally used orally for acne treatment, its application is limited due to potential systemic absorption and associated toxicity. Recent clinical studies suggest that a 5% dapsone gel effectively treats acne vulgaris, exhibiting only around 1% of the systemic exposure seen with typical oral dapsone therapy. [20-21] In 2005, the US FDA approved topical dapsone for acne treatment in individuals without glucose-6-phosphate dehydrogenase (G6PD) deficiency. This development aims to harness dapsone's antimicrobial and anti-inflammatory advantages with minimal systemic absorption. Given its dual therapeutic effects, dapsone emerges as a promising monotherapy for physicians addressing acne. [22]

The comparison between clindamycin 1% gel and dapsone 5% gel in the treatment of acne vulgaris yielded notable differences in efficacy, with 12% of patients experiencing improvement with clindamycin compared to 82% with dapsone. This outcome is consistent with prior research indicating the efficacy of clindamycin in the management of acne. The benefits of dapsone were seen as early as 2 weeks, noticed more in inflammatory lesions.

Several studies have demonstrated the effectiveness of dapsone in treating acne. A randomized controlled trial by Verma et al. (2022)[23], Taghetti (2012) [10] and Brar (2016) [11] found a significant reduction in inflammatory acne lesions in patients treated with dapsone gel compared to a clindamycin group. While clindamycin primarily targets the bacterial component of acne pathogenesis, dapsone's dual anti-inflammatory and antimicrobial properties may render it more effective.

These results underscore the importance of tailoring acne treatments based on individual patient characteristics and responses. The stark contrast in efficacy observed between clindamycin and dapsone highlights the need for clinicians to consider the specific mechanisms of action and patient profiles when selecting topical treatments for acne vulgaris. Further investigations with larger and more diverse cohorts, encompassing various acne grades and demographics, are warranted to strengthen the generalizability of these findings.

CONCLUSION:

It can be concluded from this study that dapsone 5% gel monotherapy had better efficacy and safety profile compared to clindamycin phosphate 1% gel monotherapy when evaluated after 12 weeks of follow-up. Since, dapsone 5% gel being both anti-inflammatory and anti-bacterial it is considered slightly superior than clindamycin phosphate 1% gel alone. It suggests that dapsone was well-tolerated option for topical treatment of acne vulgaris and had no serious side effects, with convenience of once-daily application given at bed time. Moreover, further direct treatment comparison and more studies are needed to assess the long-term efficacy and safety of dapsone gel over a chronic time period and to determine the optimal treatment selection as well as to establish the effects on quality of life.

LIMITATION:

This was a single center study with a smaller sample size. More studies are needed in future.

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Table-1 Clinical Characteristics Of The Two Groups

Clinical Variables	Efficacy Group A n = 50	Efficacy Group B n= 50
Age (years)	24.20 ± 5.99	26.22 ± 6.50
Age 50-70 Years 20-49 Years	 21 (42%) 29 (58%)	 21 (42%) 29 (58%)
Gender Male Female	 18 (36%) 32 (64%)	 24 (48%) 26 (52%)
Duration of Acne Vulgaris ≤ 3 Months > 3 Months	 24 (48%) 26 (52%)	 20 (40%) 30 (60%)

Table-2 Stratification For Efficay

Clinical Variables	Efficacy Group A n = 50		Efficacy Group B n= 50		P values
	Yes (6)	No (44)	Yes (41)	No (9)	
50-70 Years	02 (9.5%)	19 (90.5%)	17 (81%)	04 (19%)	0.001
20-49 Years	04 (13.8%)	25 (86.2%)	24 (82.8%)	05 (17.2%)	0.001
Male	02 (11.1%)	16 (88.9%)	17 (70.8%)	07 (29.2%)	0.001
Female	04 (12.5%)	28 (87.5%)	24 (92.3%)	02 (7.7%)	0.001
≤ 3 Months	04 (16.7%)	20 (83.3%)	18 (90%)	02 (10%)	0.001
> 3 Months	02 (7.7%)	24 (92.3%)	23 (76.7%)	07 (23.3%)	0.001