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Comparison of the Efficacy of Tazarotene 0.1% Cream Versus Clindamycin 1% Gel in the Treatment of Acne Vulgaris

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ABSTRACT

Objective: To compare the efficacy of Tazarotene 0.1% cream versus Clindamycin 1% gel in treating acne vulgaris.
Study Design: Quasi-experimental study.
Place and Duration of the Study: Dermatology Department, Pak Emirates Military Hospital, Rawalpindi Pakistan, from Jan to Jul 2018.
Methodology: One hundred and fifty-four patients of both genders who had moderate acne vulgaris for more than four weeks were divided into two Groups. In both Groups, patients applied one-fourth fingertip unit of Tazarotene 0.1% cream in the evening once daily and Clindamycin 1% gel over the affected area in the morning once daily for 12 weeks. The Global Acne Grading System Score (GAGS score) was used for severity and efficacy assessment.
Results: The majority of the patients belonged to 13-25 years of age, i.e., 61(79.2%) and 54(70.1%) in Group-A (Tazarotene 0.1% cream) and Group-B (Clindamycin 1% gel), respectively. The efficacy of topical Tazarotene cream (0.1%) was better than topical Clindamycin 1% gel, and the difference was statistically significant with a *p*-value less than 0.01. GAGS score <10 was observed in 54.5% and 33.8% of patients in Group-A and Group-B, respectively.
Conclusion: Topical Tazarotene cream (0.1%) was more effective than topical Clindamycin 1% gel in treating acne vulgaris.

Keywords: Acne vulgaris, Clindamycin, Dermatology, GAGS score, Tazarotene.

How to Cite This Article: *Haq AB, Shaikh ZI, Malik S, Ashraf A, Shah SSA, Anwar A. Comparison of the Efficacy of Tazarotene 0.1% Cream Versus Clindamycin 1% Gel in the Treatment of Acne Vulgaris. Pak Armed Forces Med J 2022; 72(5): 1682-1685. DOI: https://doi.org/10.51253/pafmj.v72i5.6764*

INTRODUCTION

Acne vulgaris is one of the most common inflammatory and chronic cutaneous diseases. Although it affects both sexes but is more predominant in women with a median age of 24 years at presentation.[1] Usually, it begins at the age of 12-14 years and continues up to mid-twenties. In up to 40% of individuals, it can persist till their 30s.[2] The severity of acne may vary from patient to patient. There are different scoring systems for grading acne severity; more than 20 grading systems exist for acne severity. The global acne grading system (GAGS) and the global assessment of acne (IGA) are the most popular acne scoring systems. Each of the grading systems has its advantages and disadvantages. IGA is a simpler one, and also FDA approved grading system.[3] IGA score from 0 to 4. A GAG scoring is more elaborate but time-consuming. It takes into account the forehead, cheeks and chest. The score ranges from o to >39. 0 to 18 score is for mild, 19 to 30 is for moderate and more than 30 for severe acne.[4,5] A plethora of over-the-counter (OTC) skin care products is available in hospitals, medical stores and public health centres, increasing with each passing day.[6] Patients not visiting the dermatologist regularly will choose these over-the-counter (OTC) medications, the resulting outcome of which cannot be guaranteed. As a result, there can be post-inflammatory pigmentation and scar formation, attributable to both acne severity and wrong prescription.[7-9]

Clindamycin has been available as a hydroalcoholic solution as a topical antibiotic for about two decades. Hydrophilic gels and lotions are newer formulations designed to reduce skin irritation. The pledget application system, often more convenient than the traditional applicator bottle, gained popularity in the 1990s. These antiacne agents have vastly reduced the inhabitancy of Propionibacterium acnes on our skin and also suppress the chemotaxis of neutrophils due to their anti-inflammatory action.[10] Since no published studies have evaluated the clinical effectiveness of Tazarotene 0.1% cream versus Clindamycin 1% gel in our general population of Pakistan, and there is a paucity of international data on this topic. Therefore, we planned to compare the efficacy of these two drugs in our general population to get the local data. Our study will help us select the right treatment option for acne vulgaris, which is common in our population.

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Received: 24 May 2021; revision received: 28 Aug 2021; accepted: 01 Sep 2021

METHODOLOGY

This quasi-experimental study was conducted at the Department of Dermatology, Pak Emirates Military Hospital, Rawalpindi Pakistan, from January to July 2018. The sample size was calculated through OpenEpi software with a 95% confidence level and alpha=5% with power=80%. By using expected proportion (efficacy) in population-1=60% and expected proportion (efficacy) in population-2=37.52%.[11] Estimated sample size was 77 for each Group, so the total sample size was 154. The study population was divided into Group-A (Tazarotene-Group) and Group-B (Clindamycin-Group), with 77 patients. The sampling technique used was non-probability consecutive sampling.

Inclusion Criteria: Patient of either gender , age 13-35 years, with moderate acne vulgaris (GAGS score 19-30) (acne vulgaris as per operational definition for > 4 weeks), and patients without any medications for acne in the last 30 days were included in the study.

Exclusion Criteria: Patients using estrogens/birth control pills for the last 12 weeks, cases of pregnant or nursing mothers, and patients with severe acne, e.g. nodulocystic acne, acne conglobata and acne fulminans were excluded from this study.

To check the overall severity of acne among the patients, a scoring system was used, i.e., Global acne grading system score (GAGS score). This score takes into account acne on the forehead, cheeks and chest. The score ranges from 0 to >30. 0 to 18 is for mild acne, 19 to 30 for moderate and more than 30 for severe acne.[4,5]

Acne vulgaris was defined as when the patient presented with eruption on the face with a global acne grading system (GAGS) score of 19-30. *Efficacy* was defined as when the global acne grading system (GAGS) scores <10 after 12 weeks of treatment. We evaluated the response to treatment in both Groups based on GAGS score as good=GAGS score <10, satisfactory GAGS score 10-20, unsatisfactory GAGS score >20.[6]

After taking permission from the hospital ethical and research committee, only those patients registered in the study who fulfilled the study inclusion criteria. A total sample of 154 patients was collected and divided into two Groups comprising 77 each (1:1 ratio). Each patient was coded with a separate number at the study enrollment time according to the drug Group (Tazarotene/Clindamycin). In Group-A, i.e. Tazarotene-Group, patients were instructed to wash their faces before applying 1/4th FTU (fingertip unit) of Tazarotene 0.1% cream once daily in the evening over the affected area regularly for 03 months. While in Group-B, i.e., Clindamycin-Group, patients were advised to apply 1/4th FTU of Clindamycin 1% Gel once daily in the morning for three months. Patients from both Groups were advised to avoid using cosmetics/ moisturizing or other topical or oral anti-acne agents during this period. In addition, patients were advised to avoid exposing themselves to extreme sunlight. Follow-up was carried out every four weeks, and only local examination was done, and patients were asked about compliance. The final evaluation of efficacy (per operational definition) was done after 12 weeks of treatment in both Groups. A specially designed proforma was made by the researchers to look for the efficacy of each drug.

Statistical Package for Social Sciences (SPSS) version 23.0 was used for the data analysis. Quantitative variables were summarized as mean±SD and qualitative variables were summarized as frequency and percentages. The chi-square test was applied to compare the efficacy of both drugs against acne vulgaris. The *p*-value lower than or up to 0.05 was considered as significant.

RESULTS

The ages of patients ranged from 13 to 35 years, with a mean age of 22.06±4.37 years in Group-A and 23.37±4.35 years in Group-B. Most patients aged 13-25 years were in Groups-A and B, i.e., 61(79.2%) and 54(70.1%), respectively. The mean duration of complaints was 12.74±5.14 weeks in Group-A and 9.67±3.63 weeks in Group-B. The mean GAGS score was 23.46 ±2.80 and 23.01±2.31 in Groups-A and B, respectively (Table-I).

Table-I: Age, Duration of Complaints and Baseline Global Acne Grading System (GAGS) Score in both Groups (n=154)

Demographic variables	Group A (Mean±SD) n=77	Group B (Mean±SD) n=77
Age(years)	22.06±4.37	23.37±4.35
Duration of Complaints (weeks)	12.74±5.14	9.67±3.63
Baseline global acne grading system(GAGS) score	23.46±2.80	23.01±2.31

The response to the treatment was graded as good, satisfactory and unsatisfactory with 14(18%), 28(36%) and 35(45.5%) patients, respectively, in each category of Group-A patients. (*p*-value 0.003). In Group-B, 7(9%), 19(24.6%), and 51(66%) patients showed good, satisfactory and unsatisfactory responses,

respectively (*p*-value 0.01), based upon the change in GAGS score after 12 weeks of treatment. Forty-two patients of Group-A showed good or satisfactory responses to Tazarotene, while 26 patients getting treatment with Clindamycin showed either good or satisfactory responses, as shown in Table-II.

Table II: Efficacy grading in both Groups (n=154)

Efficacy Grading Global Acne Grading System (GAGS) Score	Group-A	Group-B	*p*-value
Good (GAGS score <10)	14 (18.0%)	7 (9.0%)	0.009
Satisfactory (GAGS score 11-19)	28 (36.0%)	19 (24.6%)	
Unsatisfactory (GAGS score >20)	35 (45.5%)	51 (66.0%)	
Total	77 (100%)	77 (100%)	

DISCUSSION

Acne vulgaris leads to micro-comedones formation because of obstruction of sebaceous hair follicles. These micro comedones, later on, form the actual acne lesions. Obstruction of the sebaceous follicles leads to the formation of various cutaneous lesions, i.e. visible noninflammatory skin lesions and open and close comedones, due to the continuous production and accumulation of sebum and keratin material. Later, these comedones rupture into the dermis, thus leading to acneiform eruptions over the skin. Many anti-acne agents are available in the market; however, their long-term use is usually limited because of their associated side effects, poor patient compliance, long-term ineffectiveness and cosmetic acceptability. Initially, Tazarotene was used for psoriasis treatment. However, now its usage is also approved for acne vulgaris. It is a synthetic retinoid, which rapidly converts into Tazarotenic acid, its active metabolite. In clinical studies, it was found that 0.1% cream application improves acne vulgaris lesions. However, its usage was associated with post-inflammatory irritation, erythema and burning sensation.[11] In our study, too, we compared the efficacy of Tazarotene with Clindamycin and found the former drug more effective. Tazarotene belongs to thirdgeneration topical retinoids. It has got both anti-inflammatory and anti-proliferative actions. Apart from that, Tazarotene also normalizes keratinocyte differentiation. Primarily it acts on beta and gamma retinoic acid receptors; due to side effects like erythema, burning sensation and tenderness in the lesions are less often seen. Tazarotene 0.1% is the recommended strength for acne treatment.[12]

In our study Tazarotene, 0.1% cream, was more efficacious than Clindamycin, 1% gel. In the study by Schoenberg *et al.* Tazarotene 0.1% cream was effective in 60% of acne patients.[10] In contrast, another study conducted by Paudel *et al.* showed that the efficacy of Clindamycin 1% gel was 37.52%.[13]

Another study showed that combining Clindamycin and Tazarotene greatly reduced the non-inflammatory acne lesions compared to Clindamycin/ Tretinoin (i.e. 71% vs 52% at week 12, $p<0.05$).[14] Efficacy of Tazarotene 0.1% gel and Tretinoin 0.1% microsponge gel was also studied by Leyden *et al.* (2002),[15] they found that reduction in both inflammatory and noninflammatory lesions was found in a greater percentage of patients using once daily Tazarotene gel application for 12 weeks as compared to Tretinoin microsponge gel, i.e. 60% vs 38% ($p=0.02$).

Similarly, Tanghetti *et al.* (2007),[14] also found a greater reduction in noninflammatory acne lesions in patients treated with Tazarotene/Clindamycin compared to those treated with Tretinoin/Clindamycin-Group, i.e., 77% vs 67% at week 12, ($p=0.053$). This observation resembles a study conducted by Tanghetti *et al*. (2007),[14] who observed that >50% global improvement in Tazarotene/Clindamycin Group was much higheras compared to Tretinoin/Clindamycin-Group patients, i.e. 88% vs 75% ($p<0.05$). Leyden *et al*. (2002),[15] also observed that greater than 50% global improvement was much more obvious in Tazarotene/ Clindamycin Group compared to Clindamycin/ Tretinoin-Group, i.e., 67% vs 49%, $p=0.03$. In their study population, Tanghetti *et al*. (2007),[14] also witnessed localized cutaneous adverse effects such as burning sensation of the skin, redness and tenderness were minimally observed and well tolerated by their Study Group. Leyden *et al*. (2002),[15] also observed that only a small percentage of patients observed mild side effects of relatively no clinical significance in both groups. However, two patients from each Group showed poor compliance with the treatment. They ultimately withdrew from the study because of the topical application of these drugs due to erythema and a burning sensation on their skin.

Acne vulgaris greatly affects the individual's quality of life and vastly impacts the patient's psychology and thought process. Individuals can lose confidence in themselves because of their physical appearance.[16] Results obtained from our present study revealed that acne vulgaris greatly affects the individual's QOL(quality of life). However, because of treatments with these medications, a reduction in DLQI was obvious after three months of completion of the-

rapy. Obvious improvement was also noted in QOL of all these patients at the end of treatment.[17,18]

A large number of studies have been carried out on the role of Tazarotene in the treatment of acne vulgaris both in India and USA, and these studies proved that Tazarotene is highly efficacious.[17-19] Moderate to complete clearance of acne lesions was noticed among 93.6% of these patients after completing 12-weeks of the treatment course.[17] During this 12-week study period, both inflammatory and noninflammatory lesions showed an obvious reduction. After these 12 weeks of treatment, inflammatory acne lesions improved by 84.5%, whereas noninflammatory lesions showed improvement by 85.8%.[18] The efficacy and safety of 0.1% and 0.05% Tazarotene gels were evaluated by T Shalita *et al.* After 12 weeks of treatment, 68% and 51% improvement were noted in both Groups respectively.[19,20]

LIMITATIONS OF STUDY

Since this study was performed on a relatively smaller sample group size, one of its main limitations, larger and multicenter trials should be planned to authenticate this study further and choose the most efficacious option among these two treatment options.

CONCLUSION

Our study concluded that applying topical Tazarotene 0.1% cream is a much more preferable option than topical Clindamycin 1% gel in treating acne vulgaris.

Conflict of Interest: None.

Author's Contribution

Following authors have made substantial contributions to the manuscript as under:

ABH: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

ZIS & SM: Data acquisition, data analysis, data interpreta-tion, critical review, approval of the final version to be published.

AA & SSAS: Study design, data analysis, critical review, drafting the manuscript, critical review, approval of the final version to be published.

AA: Critical review, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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