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Efficacy of Topical 0.05% Isotretinoin Gel Versus 0.1% Adapalene Gel in The Treatment of Mild to Moderate Acne Vulgaris

Summaya Saleem, Naeem Raza, Nida Saleem*, Saleem Ullah, Ghazala Yasmin, Farrah Yousaf**

Pak Emirates Military Hospital/National University of Medical Science(NUMS) Rawalpindi Pakistan, *Armed Forces Institute of Mental Health/National University of Medical Science(NUMS) Rawalpindi Pakistan, **Quetta Institute of Medical Science, Quetta Pakistan

ABSTRACT

Objective: To compare the efficacy of topical 0.05% Isotretinoin gel versus 0.1% Adapalene gel in treating mild to moderate acne vulgaris.

Study Design: Quasi-Experimental study.

Place and Duration of Study: Department of Dermatology, Pak Emirates Military Hospital (PEMH), Rawalpindi Pakistan, From Feb to Jul 2018.

Methodology: A total of ninety-two patients aged 12 to 25 years with mild to moderate facial acne vulgaris were enrolled and divided into two treatment Groups, Group-A (0.05% Isotretinoin Gel) and Group-B (0.1% Adapalene Gel). Efficacy was measured at 12 weeks post-treatment.

Results: Treatment was found efficacious in 84.8% (n=39/46) of patients in Group-A and 50.0% (n=23/46) of patients in Group-B (p= 0.001). There were similar results when treatment efficacy in both Groups was disease severity. In all cases, efficacy was better in Group-A (p<0.05).

Conclusions: The efficacy of topical 0.05% Isotretinoin gel was better than topical 0.1% Adapalene gel for treating mild to moderate acne vulgaris.

Keywords: Acne vulgaris, Adapalene gel, Efficacy, Isotretinoin gel.

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INTRODUCTION

Acne vulgaris is among the most common and annoying cutaneous disorders seen by dermatologists the world over.[1] It is an inflammatory disease which involves the pilosebaceous glands of the skin and is clinically manifested by papules, pustules, comedones, nodules, and cysts which can progress to scarring, affecting the face, neck, chest, back. Upper extremities.[2] Acne vulgaris can be classified based on the severity of the lesions. The mild form can present as (Papulopustular or comedonal), moderate as (Papulopustular or Nodular), and the severe form as (nodulocystic or conglobate).[3,4]

Topical therapy is the primary choice in mild to moderate acne cases, while systemic agents are usually required in moderate to severe acne.[5] The topical compounds available are benzoyl peroxide, antibiotics and retinoids.[6,7] Retinoids form the mainstay of topical treatment for acne. The current and most frequently prescribed topical retinoids include Isotretinoin and Adapalene.[8,9]

Studies carried out previously to compare the efficacy of Isotretinoin and Adapalene in mild to moderate acne vulgaris mostly employed variable concentrations and formulations of the two drugs, yielding mixed results.[3,10] As the available data comparing the efficacy of these two topical agents in vehicle formulation (gel) in the local population is scant, the rationale of our study was to gauge and compare the effectiveness of two topical drugs, i.e., 0.05% Isotretinoin and 0.1% Adapalene , in mild to moderate acne, specifically in our local population, while both being used in gel formulation.

METHODOLOGY

The quasi-experimental study was carried out at the Dermatology Department of Pak Emirates Military Hospital (PEMH), Rawalpindi Pakistan from February to July 2018 after approval from the Ethics Committee of the Institute (Letter number: A/28/EC/240/2016). The sample size was calculated on the WHO sample size calculator with a 95% confidence level and P1=-80% as the anticipated proportion (efficacy) in Population,[1] and P2=56% as the anticipated proportion (efficacy) in Population.[2,3] Total 92 patients were selected through non-probability consecutive sampling.

Inclusion Criteria: Patients having mild to moderate facial acne vulgaris, aged 12 to 25 years, of either gender were included in the study.

Correspondence: Dr Summaya Saleem, Graded Dermatologist, House No 49, Street No.3 Sector C, Askari 14, Adiala Road, Raw-Pakistan.
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Exclusion Criteria: Patients having severe acne, with concomitant facial dermatoses/eczema, known hypersensitivity to Adapalene and/or Isotretinoin, history of PCOs, history of OCPs use in last three months, history of use of topical treatment for acne in last three months and/or systemic treatment of acne in last six months and female patients who were pregnant or breast-feeding were excluded from the study.

The age, gender, hospital record number and contact address of each patient were noted after obtaining informed written consent. Married female patients were additionally counselled regarding pregnancy risks. Mild acne was defined as having less than 15 inflammatory lesions, or less than 20 comedones, or a total lesion count to be less than 30.[11] Moderate acne was defined as having 15–50 inflammatory lesions, or 20–100 comedones, or a total lesion count ranging from 30–125.[12]

Patients with mild to moderate acne were allocated to Group-A (Isotretinoin gel, n=46) and Group-B (Adapalene gel, n=46) by the lottery method. In both Groups, patients were advised to apply Isotretinoin and Adapalene gel on the affected areas at night. They were also advised not to use any comedogenic lotions & cosmetics. The treatment was deemed efficacious if there was a greater than 60% reduction in the total number of inflammatory and non-inflammatory lesions by the end of 12 weeks. A specially designed proforma was used to record the collected data.

Statistical Package for Social Sciences (SPSS) version 21.0 was used for the data analysis. Mean and standard deviation were calculated for numerical data. Frequencies and percentages were calculated for qualitative data like gender, mild and moderate acne and efficacy. Efficacy among the two Groups was compared by applying the Chi-Square test, and the *p*-value of ≤0.05 was considered statistically significant.

RESULTS

A total of ninety-two (n=92) patients aged 12 to 25 years with mild to moderate facial acne vulgaris were enrolled and divided into two treatment Groups. The patients' mean age in Group-A was 169±3.1 years with,13 (28.3%) males and 33(71.7%) females, respectively. The patients' mean age in Group-B was 17.3±2.8 years with,14 (30.4%) males and 32(69.6%) females, respectively. Acne severity was mild in 60.9% and moderate in 39.1% of cases in the Isotretinoin-Group, while the Adapalene -Group had 63% mild and 37% moderate cases.

Treatment was found efficacious in 84.8% of patients in Group-A (0.05% Isotretinoin Gel) compared to 50.0% in Group-B (0.1% Adapalene Gel) (*p*-value =0.001) (Table-I). There were similar results when treatment efficacy in both Groups was noted for disease severity. Efficacy for disease severity was shown in Table-II.

Table-I: Efficacy of Treatment in both Groups (n=92)

Efficacy	Groups		*p*-value
	0.05% Isotretinoin Gel (n=46)	0.1% Adapalene Gel (n=46)	
Present	39	23	0.001
	(84.8%)	(50.0%)	
Absent	7	23	
	(15.2%)	(50.0%)	

Table-II: Comparison of Efficacy with respect to Acne Severity (n=92)

Acne Severity	Efficacy	Groups		*p*-value
		0.05% Isotretinoin Gel (n=46)	0.1% Adapalene Gel (n=46)	
Mild	Present	22	15	0.034
		(78.6%)	(51.7%)	
	Absent	6	14	
		(21.4%)	(48.3%)	
Moderate	Present	17	8	0.002
		(94.4%)	(47.1%)	
	Absent	1	9	
		(5.6%)	(52.9%)	

DISCUSSION

We planned our study to compare the efficacy of the two topical retinoids, i.e., Adapalene and Isotretinoin gel, in the local population, which revealed Isotretinoin to be superior in the treatment of mild to moderate acne vulgaris as compared to Adapalene. Our results were in concordance with the results already published on the subject. Inayat *et al*,[3] conducted a similar study in 2012 at Mayo hospital Lahore in which the efficacy and tolerability of Isotretinoin gel 0.05% and Adapalene gel 0.1% were compared, in the treatment of mild to moderate acne vulgaris. However, in moderate acne, Isotretinoin was more efficacious than Adapalene (*p*=0.01), whereas, in our study, Isotretinoin was significantly efficacious both in mild (*p*=0.034) and moderate acne (*p*=0.002).

Study conducted at Khartoum Teaching Dermatology Hospital Sudan in 2016, Abdalla SF *et al*, [10] compared the efficacy of both Isotretinoin cream to

0.05% and Adapalene cream to 0.1% in 100 patients with facial acne over six weeks. Contrary to our results, they found Adapalene more efficacious than Isotretinoin. In the Adapalene Group, 90% showed a complete cure, and 10% showed improvement, whereas in the Isotretinoin Group, only 8% showed a cure, and 50% showed improvement. Gender distribution in the reference study showed predominantly females (78%) in both Groups, which was almost comparable to our study had an average of 70.7% females in the study population.

A study conducted to compare the efficacy and tolerability of Adapalene cream 0.1% with Isotretinoin gel 0.05% in 80 patients for six weeks revealed that both Isotretinoin and Adapalene gels were remarkably efficacious for facial acne.[13] Another similar conducted to compare both Isotretinoin gel 0·05% and Adapalene gel 0·1% in treating facial acne, showed comparable efficacy, and there were no substantial statistical differences between the two formulations.[14] A previous study compared the efficacy of topical Adapalene gel 0.1% with tretinoin gel 0.025% in 202 patients over six months.[15] Like our study, efficacy was determined at 12 weeks and was deemed excellent if there was a greater than 50% reduction in lesion count at the end of 12 weeks. The treatment response was better in the younger age Group (14-21 years) compared to the older age (22-25 years). We also found a similar trend in our study, where treatment was more efficacious in the younger age Group of 12-18 years (p=0.005). Another study revealed Adapalene gel to be more efficacious (84.2%) compared to tretinoin gel, which showed an overall efficacy of 39.6% (p=.001).[16] Another notable feature was that the resolution of non-inflammatory comedonal lesions was far greater in the Adapalene Group than in the tretinoin Group.[17] This was contrary to our results, but in this study, only patients with mild acne were enrolled, and tretinoin gel was used at a less potent strength .025% compared with Adapalene 0.1%.

Ansar *et al*,[18] in 2018 at Farshchian hospital in Hamadan city, Iran, compared Adapalene gel 0.1% with tretinoin gel 0.05% in 50 patients. Initial evaluation was done at baseline, at four weeks, and then at 12 weeks. In the Adapalene Group, the mean GAGS (Global Acne Grading System) score at baseline was 49.56 (SD=12.24) and 47.76 (SD=11.34) in the tretinoin Group (p=0.592), which reduced to 25.08±9.00 in the Adapalene and 12.12±4.71 in the tretinoin Group (p<0.001) after 12 weeks of treatment. According to these results, Tretinoin gel leads to a greater reduction in acne lesions than Adapalene gel.

Based on an analysis of the literature review, the theme derived is that both preparations have been used and found efficacious in treating patients suffering from acne vulgaris. Upon comparison of different studies in different ethnic populations, the efficacy results are varied. However, our study results prove Isotretinoin gel to be more efficacious than Adapalene gel in treating mild to moderate acne vulgaris in the local population.

CONCLUSION

The efficacy of topical 0.05% Isotretinoin gel was better than topical 0.1% Adapalene gel for treating mild to moderate acne vulgaris in our local population.

Conflict of Interest: None.

Author's Contribution

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

SS & NR: Study design, drafting the manuscript, data interpretation, critical review, approval of the final version to be published.

NS & SU: Data acquisition, data analysis, critical review, approval of the final version to be published.

GY & FY: Critical review, conception, 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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