

Original Research Article

A Comparative Study on Effectiveness of Adapalene Gel versus Lactosporin 2% Gel in Management of Acne Vulgaris

Dr. Srinivasa Raju Bahatam¹, Dr. Anusha Donapudi², Dr. Monika Patel Kodela³,
Dr. Sekhar Babu Bandar^{4*}

¹post Graduate, Osmania Medical College, Koti, Hyderabad, Telangana.

²assistant Professor, Department Of Anatomy, Government Medical College, Machilipatnam, Andhra Pradesh.

³assistant Professor, Department Of Pharmacology, Kims, Amalapuram, Andhra Pradesh.

^{4*}M.D Pharmacology.

Email: ¹Bahatam6@Gmail.Com, ²Donepudi.Anusha@Gmail.Com,
³monikapatelkodela@gmail.com

Corresponding Email: ^{4*}sekhar51750@gmail.com

Abstract

Introduction: Acne vulgaris is a long-lasting skin disorder characterized by the obstruction and/or inflammation of the pilosebaceous units. The emergence of acne is associated with the interaction of four main factors: excessive sebum secretion, blockage of follicles by sebum and keratinocytes, the colonization of follicles by *Propionibacterium acnes*, and the release of various inflammatory substances. So the present study was undertaken to compare the efficacy of adapalene gel versus lactosporin 2% gel in treatment of acne vulgaris.

Aim and Objectives: To compare the effectiveness of Lactosporin 2% gel vs Adapalene 0.1% gel in the treatment of acne vulgaris.

Materials and Methods: A prospective observational study was done on 50 patients for a duration of 12 months in a tertiary care hospital. Patients with mild to moderate Acne vulgaris of both sexes with age group between 15 years and below 40 years were included in the study. The study population were divided into 2 groups with 25 subjects in each group. Group 1- Adapalene group once a day (at night) (and Group 2-Lactosporin group (be advised to apply twice a day at morning and night).

Results: In our study the mean age of study population in Adapalene group was 22.67 ± 5.21 years and the mean age of Lactosporin group was 23.22 ± 4.57 years. P-value for comparison of gender distribution in between the groups was 0.54 which was statistically in significant. P-value for global acne score in 1st visit was 0.621(>0.05), which is statistically insignificant in between the groups. On comparison of mean global acne grading by paired sample T-test, the paired difference between baseline and 4th week of treatment in Adapalene group was 8.51 ± 1.965 and in Lactosporin group was 5.133 ± 2.209 , P-value is <0.01 which is statistically significant.

Conclusion: Adapalene gel is effective for the treatment of mild to moderate acne vulgaris.

Keywords: Acne Vulgaris, Lactosprin, Adapalene Gel, Pilosebaceous Glands.

1. Introduction

Acne vulgaris is a long-lasting skin disorder characterized by the obstruction and/or inflammation of the pilosebaceous units. The emergence of acne is associated with the interaction of four main factors: excessive sebum secretion, blockage of follicles by sebum and keratinocytes, the colonization of follicles by *Propionibacterium acnes*, and the release of various inflammatory substances (1). This condition is common among all ethnicities around the world, with 90% of individuals experiencing it at some point in their lives. Genetic influences are crucial in determining an individual's vulnerability to acne. Numerous instances of acne in children are observed in those whose parents have experienced similar conditions. Additionally, genetic factors are implicated in racial predisposition and the resemblance of lesions found in monozygotic twins. Appropriate treatment can successfully manage lesions and avert severe complications. There is a growing interest in alternative therapies that carry minimal risks, as well as holistic strategies for managing the condition (2). Adapalene, classified as a third-generation topical retinoid, is primarily utilized for treating mild to moderate acne. It possesses keratolytic and comedolytic effects, yet it may also result in adverse reactions such as photosensitivity, irritation, dryness, and skin peeling. Furthermore, postbiotics, which are extracellular metabolites produced by probiotics, such as Lactosporin, have shown promise in the treatment of mild to moderate acne vulgaris (3). Lactosporin, derived from the fermented broth of *Bacillus coagulans*, exhibits antimicrobial properties in acidic pH environments and can effectively inhibit the growth of *Propionibacterium acnes*. So the present study was undertaken to compare the efficacy of adapalene gel versus lactosporin 2% gel in treatment of acne vulgaris.

Aim and Objectives:

To compare the effectiveness of Lactosporin 2% gel vs Adapalene 0.1% gel in the treatment of acne vulgaris.

2. Materials and Methods:

A prospective observational study was done on 50 patients for a duration of 12 months in a tertiary care hospital. Patients with mild to moderate Acne vulgaris of both sexes with age group between 15 years and below 40 years were included in the study. Pregnant and lactating mothers, Patients allergic to lactosporin and adapalene and patients who used topical corticosteroids, antibiotics or retinoids within the past two weeks on the face were excluded from the study. The study population were divided into 2 groups with 25 subjects in each group. Group 1-Adapalene group once a day (at night) (and Group 2-Lactosporin group (be advised to apply twice a day at morning and night). Participants from both groups will be instructed to use sunscreen on sun-exposed regions before engaging in outdoor activities during daylight hours. Any adverse reactions, such as erythema, dryness, edema, urticarial, and allergic responses, will be recorded. Follow-up assessments will be conducted for both groups over a four-week period after the treatment has ended to evaluate for any signs of recurrence.

3. Results:

Table1: Mean Age Distribution of the Study Population

Mean age (in years)	Adapalene group (n=25)	Lactosporin group(n=25)
---------------------	------------------------	-------------------------

	22.67 ± 5.21	23.22 ± 4.57
--	--------------	--------------

Table 2: Sex Distribution of the Study Population

GENDER	Adapalene group(n=25)		Lactosporin group (n=25)		Total (n=50)		P value
	No.	Percentage	No.	Percentage	No.	Percentage	
Male	16	64%	14	56%	30	60%	0.54
Female	9	36%	11	44%	20	40%	

Graph 1: Sex Distribution of the Study Population

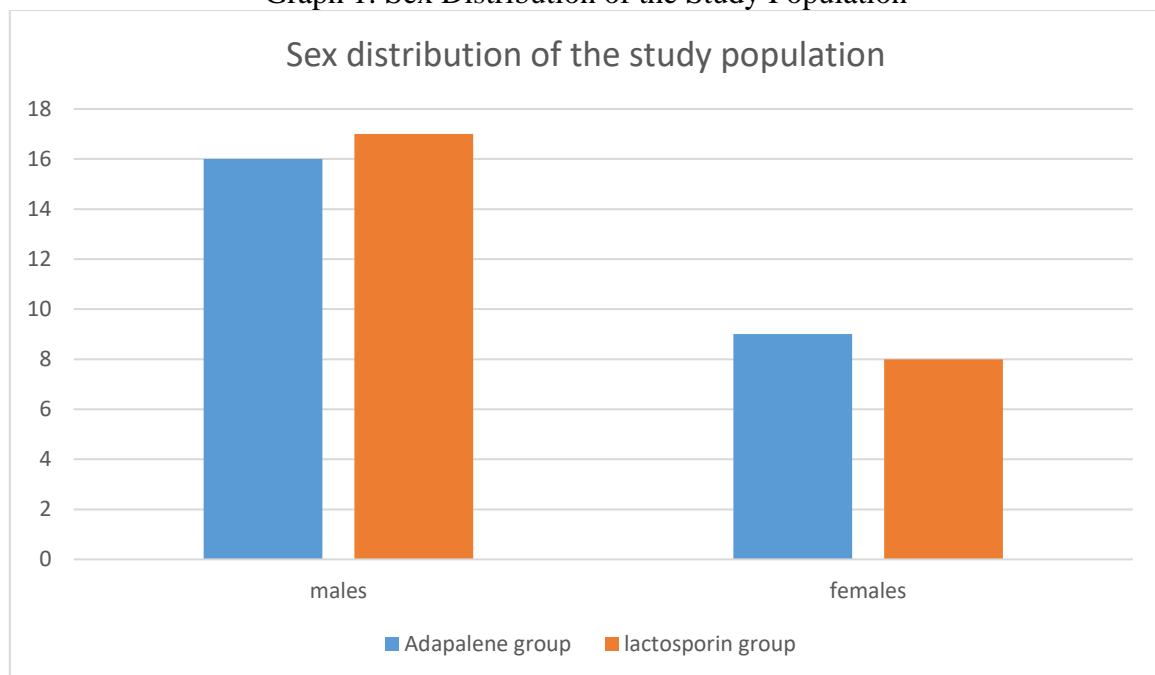


Table 3: Global Acne Grading Score Distribution among the Groups at 1st Visit

GRADING OF SEVERITY	Adapalene group (n=25)		Lactosporin group (n=25)		Total (n=50)		P value
	No.	Percentage	No.	Percentage	No.	Percentage	
Mild Acne (1-18)	19	76%	21	84%	40	80%	0.621
Moderate Acne (19-30)	6	24%	4	16%	10	20%	
Severe Acne (31-38)	0	0.0%	0	0.0%	0	0.0%	

Very severe Acne (≥ 39)	0	0.0%	0	0.0%	0	0.0%	
--------------------------------	---	------	---	------	---	------	--

Table 4: Global Acne Grading Score Distribution among the Groups after 4 Weeks of Treatment

GRADING OF SEVERITY	Adapalene (n=25)		Lactosporin (n=25)		Total (n=50)		P value
	No.	Percentage	No.	Percentage	No.	Percentage	
Mild Acne (1- 18)	24	98%	25	100%	49	98%	0.5
Moderate Acne (19-30)	1	2%	0	0.0%	1	2%	
Severe Acne (31-38)	0	0.0%	0	0.0%	0	0.0%	
Very severe Acne (≥ 39)	0	0.0%	0	0.0%	0	0.0%	

Table 5: Mean Global Acne Grading Score Variation at 1ST Visit and At 4th Week among the Groups

Time period	Mean global acne grading score for Adapalene group	Mean global acne grading score for Lactosporin group	P value	Statistical test used
Baseline (1)	14.74 \pm 5.178	14.63 \pm 5.321	0.978	Independent sample t-test
At 4 th week of treatment (2)	6.23 \pm 3.213	9.36 \pm 4.210	0.003	Independent sample t-test

4. Discussion:

In our study the mean age of study population in Adapalene group was 22.67 \pm 5.21 years and the mean age of Lactosporin group was 23.22 \pm 4.57 years. Our study findings are in correlation with a study done by Muhammed Majeed et al, the mean age of subjects are 24 years as per their study (4). In Adapalene group 16 were males accounting for 64% of the group population and 9 were females accounting for 36% of the group population. In lactosporine group 17 were males accounting for 56% of the study population and 8 were females accounting for 44% of the study population. P-value for comparison of gender distribution in between the groups was 0.54 which was statistically in significant.

On the basis of Global acne grading score distribution among the groups during 1st time visit, the grading of severity in Adapalene group is as follows mild acne (1-18) is observed in 19 patients accounting for 76% of group population, moderate acne (19- 30) is observed in 6

patients accounting for 24% of group population, severe acne (31-38) -0 patients and very severe acne (≥ 39)-0 patients. The grading of severity in lactosporin group is as follows mild acne (1-18) is observed in 21 patients accounting for 84% of group population, moderate acne (19-30) is observed in 4 patients accounting for 16% of group population, severe acne (31-38) -0 patients and very severe acne (≥ 39)-0 patients. P-value is 0.621(>0.05), which is statistically insignificant in between the groups. On the basis of Global acne grading score distribution among the groups after 4 weeks of treatment, the grading of severity in Adapalene group is as follows mild acne (1-18) is observed in 24 patients accounting for 98% of group population, moderate acne (19-30) is observed in 1 patient accounting for 2% of the group population, severe acne (31-38) -0 patients and very severe acne (≥ 39)-0 patients. The grading of severity in lactosporin group is as follows mild acne (1- 18) is observed in 25 patients accounting for 100% of group population, moderate acne (19-30) is observed in 0 patient accounting for 0 of group population, severe acne (31-38) -0 patients and very severe acne (≥ 39)-0 patients. P-value is 0.5(>0.05), which is statistically insignificant in between the groups.

On comparison of mean global acne grading score variation at baseline and at 4th week among the groups, for Adapalene group, the mean global acne score at 1ST visit was 14.74 ± 5.178 and for Lactosporin group is, the mean global acne score at 1st visit was 14.63 ± 5.321 , P-value is 0.978 which is statistically insignificant. At 4th week of treatment for Adapalene group, the mean global acne score is 6.23 ± 3.213 and for lactosporin group, the mean global acne score at 4th week of treatment is 9.36 ± 4.210 , p-value is >0.003 . On comparison of mean global acne grading by paired sample T-test, the paired difference between baseline and 4th week of treatment in Adapalene group was 8.51 ± 1.965 and in Lactosporin group was 5.133 ± 2.209 , P-value is <0.01 which is statistically significant. The use of adapalene carries a theoretical risk of retinoid embryopathy. Nevertheless, the manufacturer indicates that only minimal quantities of adapalene penetrate the skin. In studies conducted on pregnant animals, where doses were administered at levels 120 to 150 times greater than the typical human topical application, no significant increase in adverse outcomes or malformations was observed. To date, there have been no human studies conducted, leaving the risk associated with adapalene use during pregnancy uncertain. However, given that only trace amounts of the medication are absorbed through the skin, it appears improbable that the drug would cause malformations.

5. Conclusion:

Adapalene gel is effective for the treatment of mild to moderate acne vulgaris but Lactosporin demonstrates superior anti-inflammatory effects, as evidenced by users reporting a greater decrease in pain and erythema surrounding the lesion when compared to those utilizing Adapalene.

6. References:

1. Sonsone Bazzano G, Cummings B, Seelar AK, et al. Differences in the lipid constituents of sebum from prepubertal and pubertal subjects. *Br J Dermatol*. 1980; 103:131–137.
2. Pochi PE, Strauss JS. Endocrinological control of the development and activity of the human sebaceous gland. *J Invest Dermatol*. 1974; 62:191–202.
3. Simpson NB, Cunliffe WJ. Disorders of sebaceous glands. In: Burns T, Breathnach S, Cox N, editors. *Rook's Textbook of dermatology*. 7th ed. Oxford: Blackwell Publishing; 2004. p. 43.1–75.
4. Fritsch M, Orfanos CE, Zouboulis CC. Sebocytes are the key regulators of androgen homeostasis in skin. *J Invest Dermatol*. 2001; 116:793–800.

8. Majeed M, Nagabhushanam K, Paulose S, Rajalakshmi HR, MundkurA Randomized Double-Blind, Placebo-Controlled Study to Evaluate the Anti-
9. Skin-Aging Effect of LactoSporin - The Extracellular Metabolite from *Bacillus*
10. *coagulans* (*Weizmannia coagulans*) MTCC 5856 in Healthy Female
11. Volunteers.doi: 10.2147/CCID.S403418. e Collection 2023.
12. Chen W, Thiboutot D, Zouboulis CC. cutaneous androgen metabolism: basic research and clinical perspective. *J Invest Dermatol.* 2002; 119: 992–1007.
13. Pochi PE, Strauss JS. Sebaceous gland suppression with ethinyl oestradiol and diethyl stilboestrol. *Arch Dermatol.* 1973; 108: 210–1.
14. Goolamali SK, Evered D, Shuster S. Thyroid disease and sebaceous function.
15. *Br Med J.* 1976; 1:432–3.
16. Ebling FJ. Antiandrogens in dermatology. In: Mattini L, Molta M, editors.
17. Androgens and antiandrogens. New York: Raven
18. Thiboutot DM, Knaggs H, Gilliland K. Activity of type 1, 5 alpha reductase is greater in the follicular infundibulum compared with the epidermis. *Br J*
19. *Dermatol.* 1997; 136:166–71.
20. Burton JL, Cunliffe WJ, Stafford I, et al. The prevalence of acne vulgaris in adolescence. *Br J Dermatol.* 1971; 85:119–26.
21. Hamilton JB, Terada H, Mestler GE. Greater tendency to acne in white
22. Americans than in Japanese population. *J Clin Endocr Metabol.* 1964; 24:267– 72.