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EFFICACY AND SAFETY OF TOPICAL LODHRADI FACE PACK FOR TREATMENT OF MODERATE ACNE VULGARIS -A RANDOMIZED CONTROLLED TRIAL

Ayurveda

Sumy Basheer* PG Scholar, Department of Dravyagunavigyana, Government Ayurveda college, Thiruvananthapuram Pin code -695001, Kerala, India*Corresponding Author

Indulekha VC Associate professor, Department of Dravyagunavigyana, Government Ayurveda college, Thiruvananthapuram Pin code -695001, Kerala, India

ABSTRACT

Acne vulgaris (Mukhadushika i) is a chronic inflammatory disease of the pilosebaceous unit, predominantly affecting individuals below 30 years of age and often leads to scarring and psychosocial distress. Current anti-acne therapies are limited by adverse effects and antimicrobial resistance; this highlights the need for safer herbal alternatives. Ayurveda recommends the external use of herbs such as Lodhra and Yashtimadhu for managing acne. **Objectives:** Present study aimed to evaluate the safety and Lodhradi face pack in powder (LC) and paste (LP) formulations in moderate acne. **Materials and Methods:** This randomized comparative clinical trial included Seventy participants (18–35 years) diagnosed with moderate acne (GAGS Score -19–30) randomized into two groups (LC and LP). LC was prepared using Lodhra, Manjishta , Yashtimadhu and Multani mitti, while LP was formulated by combining LC with hydroalcoholic extracts, glycerine, water, and carbopol, following CCRAS standards. Quality control parameters were verified through pharmacognostical and physicochemical evaluation. . Accelerated stability study ,Antioxidant activity and Antimicrobial activities were Estimated Both were applied externally for 10–15 minutes daily, 5 days/week, for 8 weeks. Efficacy and safety were evaluated through GAGS and TEAE Scores. Results and Discussion: Phytochemical analysis revealed the presence of bioactive compounds including flavonoids, tannins, and steroids. HPTLC demonstrated distinct separation profiles. LC and LP exhibited shelf lives of 2 and 1 year, respectively. Antioxidant activity (IC50) was observed at 2177.6 µg/mL (LC) and 3539.6 µg/mL (LP). Both showed antimicrobial activity against Propionibacterium acnes. Clinically Significant reduction in GAGS scores was observed in both groups ($p < 0.01$), with minimal TEAE. **Conclusion:** Lodhradi face pack in powder and paste forms is effective and safe in moderate acne, attributable to its antioxidant, antimicrobial, and anti-inflammatory actions.

KEYWORDS

Acne vulgaris, Mukhadushika, Lodhradi face pack, GAGS, Herbal face-pack

INTRODUCTION

Acne vulgaris is a chronic and multifactorial inflammatory disorder of the pilosebaceous unit, characterized by excess sebum production, follicular hyperkeratinization, Cutibacterium acnes colonization, and inflammation.(1)

It presents clinically as comedones, papules, pustules, and nodules, with a potential for scarring. Acne affects nearly 9.4% of the population globally, and is one of the most prevalent dermatological conditions and Its onset typically occurs during adolescence. Acne may significantly impacts quality of life, being associated with low self-esteem, poor body image, anxiety, and depression.(2)

Conventional management includes topical retinoids, benzoyl peroxide, antibiotics, hormonal therapy, and oral isotretinoin. Being effective, these approaches are limited by adverse effects such as skin irritation, photosensitivity, and teratogenic risks, and chances of antimicrobial resistance.(2) These challenges highlight the need for safer, cost-effective, and sustainable therapeutic alternatives.

Herbal and complementary medicines are becoming promising choices for acne management due to their safety profile, affordability, and holistic benefits.(3) Clinical trials suggest that herbal formulations significantly reduces both inflammatory and non-inflammatory acne lesions and improve acne severity scores. In Ayurveda, acne is described as Mukhadushika or Yuvanapidaka, a condition involving vitiation of Kapha, Vata, and Rakta doshas. Classical texts recommend Shodhana (purification therapies) like vamana, nasya, rakthamokshana and Samana (palliative therapies), with Mukhalepa (herbal face packs) being widely prescribed. (4)These face packs provide cleansing, exfoliating, anti-inflammatory, antimicrobial, and complexion-enhancing effects, aligning with modern therapeutic needs.

Thus, we formulated a combination named Lodhradi face-pack with Lodhra, Manjishta, Yastimadhu and Multani-mitti, selected from Ayurveda textbooks such as Ashtanga- Samgraha, Charaka Samhita (Dasaimani-gana) having Mukhadushikahara, Varnya, kushtagna and Kandugna properties supported by pharmacological evidence of anti-inflammatory, antioxidant, and antimicrobial activities.

Lodhradi face-pack containing Lodhra(Symplocos racemosa Roxb.), Manjishta(Rubia cordifolia Linn.), Yashtimadhu(Glycyrrhiza glabra Linn.) and Multani-mitti; in two dosage forms; Lodhradi face pack powder (LC) in the ratio 1:1:1:1: and Lodhradi face pack paste (LP) by mixing LC, the Hydroalcoholic extracts of these herbs, Glycerin, Distilled water and Carbopol in the ratio. 160:100:125: 125:4.

A pilot study conducted in five participants having Acne vulgaris and found out that the combination was effective and safe in Acne without causing much irritation on skin. Thus, to determine the efficacy of the LC and LP, a randomized controlled clinical trial was conducted in moderate Acne vulgaris participants, of the age group 18-35 years, and either LC or LP was applied for 10-15 minutes, 5 days per week for a period of 8 weeks and assessed with Global Acne Grading System (GAGS) score. Safety of the LC and LP was assessed by Treatment-Emergent Adverse Event (TEAE)score.

MATERIALS AND METHODS

Procurement and authentication of herbal ingredients

The Bark of Lodhra, root of Manjishta, rhizome of Yashtimadhu and Multani-Miti (Fullers earth) were collected, identified and authenticated as Symplocos racemosa Roxb., Rubia cordifolia Linn. and Glycyrrhiza glabra Linn. by plant taxonomist Voucher specimen was deposited at the herbarium of the institute.

Hydroalcholic extract was prepared. Quantitative and qualitative assessment was done as per ICMR (Indian Council of Medical research) guidelines (5–7) and ensured matching. Plant materials were processed into fine powder (Sieved using mesh -No.85 sieve) and extract form as per the standards mentioned in ICMR guidelines.

Preparation and Standardization of face pack

Lodhradi face pack was developed in two dosage forms as powder and paste. Powder form made by mixing herbal powders with Multani mitti in a ratio of 1:1:1:1. While paste form made by mixing the herbal powders, extracts, glycerine, distilled water and Carbopol in the ratio 160:100:125:125:4 and methyl paraben (0.02%) as preservative blended using an electric stirrer to obtain a smooth paste of uniform consistency and spreadability.

The characterization of face pack done as per pharmaceutical face pack standards by the Bureau of Indian Standards (BIS) under IS 15153:2002.

The powder characteristics (Rheological evaluation) including Angle of repose, Bulk density, tapped density, Carr's index, Hausner's ratio Particle size determination(9) etc,

Powder microscopy, Loss on drying at 105° C / Moisture content, Total ash, Acid - insoluble ash, water soluble extractive, value, alcohol soluble extractive value, total sugar, reducing sugar, pH, HPTLC, inductively coupled plasma mass spectroscopy (ICP- MS) etc were estimated.

Microbial contamination of face pack estimated by analysing Total Bacterial count, Total Fungal count, Presence of Specific pathogens like Escherichia coli, Salmonella spps, Pseudomonas aeruginosa and Staphylococcus aureus.(10)

Rancidity test (Kreis test)(8) and Spreadability test (wooden block method) (11)were conducted in case of paste dosage form as per standard procedureSkin irritancy test (12)was performed in 15 volunteers after taking written consent.

Inductively coupled plasma mass spectroscopy (ICP-MS)(13) was used in the determination of heavy metals .Heavy metals like mercury, cadmium, lead and Arsenic in ppm levels were determined.

HPTLC analysis(14) was conducted on ingredients as well as face pack. Shelf life (15)of both dosage forms were analysed using accelerated stability study

Pharmocological study of LC and LP
Antioxidant assay(16)
Antioxidant assay of both dosage forms were conducted using DPPH assay by following standard protocol and compared with ascorbic acid standard.

Antimicrobial assay(17)
Antimicrobial assay of both dosage forms were conducted by agar well diffusion method by following standard procedure. Antimicrobial activity against Propionibacterium acnes was compared with the standard drug streptomycin. Observed and measured the zones of inhibition (clear zones around the wells) Activity index ,Percentage of inhibition , minimum inhibitory concentration of two dosage forms and Compare it with the values obtained for streptomycin.

Clinical evaluation
Study design
A prospective randomized comparative clinical trial was conducted in the OPD of Govt. Ayurveda college Hospital,Thiruvananthapuram, Kerala, India. The study was from October 2024 to July 2025.

The Trial has been registered with the Clinical Trial Registry-India. under the protocol number CTRI/2024/08/072223 on 09/08/2024. The study was conducted following the Declaration of Helsinki (Brazil) 2013 and the international Council on Harmonization's ER(R2) "Guideline for good Clinical Practice". Institutional Ethics committee Approval was obtained and written informed consent was also collected from all study participants before the initiation of the study. Study population: Participants, irrespective of gender of the age group 18-35 years with Acne vulgaris with Global Acne Grading System (GAGS) score between 19-30 (Moderate Acne vulgaris).

Objectives
To determine the effectiveness of face pack, LP an LC in reducing GAGS, in moderate Acne vulgaris participants, of the age group 18-35 years, for 10-15 minutes, 5 days per week for a period of 8 weeks, attending OPD of Dravyagunavigyan, Government Ayurveda college, Thiruvananthapuram.

Hypothesis
Null hypothesis Lodhradi Face-pack paste (LP)is not equally effective as Lodhradi Face-pack powder (LC) in moderate severity Acne vulgaris participants in reducing GAGS score Alternate hypothesis Lodhradi Face-pack paste (LP) is equally effective as Lodhradi Face-pack powder in moderate severity Acne vulgaris participants in reducing GAGS score

Inclusion criteria
1. Participants with Global Acne Grading Score (GAGS) between 19-30 of age group 18-35yrs

Exclusion criteria
1. Diagnosed cases of PCOD
2. Pregnant or Lactating women
3. Patients under other medications for Acne vulgaris

Sample size
Sample size is 35 in each group with total of 70.
Therefore 70 Subjects diagnosed with Acne vulgaris in the age group 18-35 years was enrolled and randomly assigned in to two groups as Group 1 and Group 2

Procedure: To recruit trial participants, they underwent a thorough screening process that included a complete medical history, a general physical examination, and systemic examination. The demographic profile of the participants, a detailed history of the disease, and a physical and systemic examination were all recorded in the IEC-approved Case Report Form. At first visit (0th week), the assessment of Acne lesion by inspection and calculation of GAGS score conducted for Subjects.

Eligible participants were provided with either powder or paste which was advised for external application for 10-15 minutes, once in a day, 5 days per week, for a period of 8 weeks. Participants allocation was done at 1:1 ratio using Computer generated random number tables. At second visit (4th week), the first follow -up involved monitoring adverse events, conducting a clinical examination and counting the number of acne lesions and calculated the GAGS Score. At the end of the study (third visit) after 8th week, participant assessed by counting acne lesions and calculating the GAGS score and monitored adverse events.

Outcome measures: The primary end point of this study was the change in GAGS Score from baseline to the end of the study (week 8). Representative patient photographs were taken at baseline and to the end of the study (week 8). Safety was assessed with TEAE score; treatment-emergent adverse event reported by participants. Local and systemic adverse events (AEs) and local skin reactions (LSRs)were evaluated at each study visit. Also assessed LSRs using a 5-point scale (0, none; 1, trace; 2, mild; 3, moderate; 4, severe).

Statistical analysis:
Statistical analysis was done using SSPS software. The homogeneity of initial sociodemographic parameters of the samples in the LC Group and LP Group by Kolomogorov Smirnov and Shapiro wilk tests, Chi Square test and Fischer's test. The normality and homogeneity of variances of the parameters in between group LP and Group LC were tested using Levene's Test for Equality of Variances. The independent samples t-test is used to test the significance of differences in mean scores in between the groups LC and LP. Drop outs were not considered in the statistical part.

RESULT AND ANALYSIS
Standardization of LC and LP
Macroscopic and microscopic characters of ingredients of LC matched with API parameters physicochemical analysis and phytochemical analysis results matches with API parameters and reveals the presence of Alkaloids, Tannins, Flavonoids, Steroids and phenols in qualitative test.

The Inhouse standards of both LP and LC were developed as per standard procedures and the results were given in Table no:1

Table no :1 Standardization of LC and LP

SL NO	PARAMETER	LC	LP
Organoleptic characters			
1.	Appearance	Fine powder	Semi solid mass
2.	Colour	Light brown	Reddish brown
3.	Odour	Characteristic	Characteristic
4.	Taste	Bitter and sweet	Bitter and sweet
5.	Consistency	Smooth	Smooth
Physicochemical evaluation			
6.	Foreign matter	Nil	Nil
7.	Moisture content	7.83%	52.36%
8.	Total ash	27.97%	8.567%
9.	Acid insoluble ash	0.26%	6.185%
10.	Water soluble extractive	19.92%	21.65%
11.	Alcohol soluble extractive	10.26%	19.5%

12.	pH	5.37	4.87%
13.	Total sugar	1.06%	0.13%
14.	Reducing sugar	0.79%	0.12%
	Phytochemical analysis		
15.	Alkaloids	Present	Present
16.	Tannins,	Present	Present
17.	Flavonoids	Present	Present
18.	Steroids	Present	Present
19.	Phenols	Present	Present
	Microbial load analysis		
20.	E. coli	Absent	Absent
21.	Pseudomonas aeruginosa	Absent	Absent
22.	S. aureus	Absent	Absent
23.	Salmonella	Absent	Absent
24.	Total yeast and mould count	≤ 10 cfu/g	≤ 10 cfu/g
25.	Total viable aerobic count	150 cfu/g	200cfu/g
	Heavy metal analysis		
26.	Hg,Cd,Pb,Ar	Within permissible limits	
	HPTLC		
27.	Rf values at 254nm	0.019, 0.240, 0.481	0.021,0.152,0.242, 0.319, 0.447, 0.994
	Rf values at 366nm	0.019,0.065,0.206 ,0.289, 0.481	
28.	Shelf-life study	2 years	1 year

Rheological evaluation

The Rheological parameters such as Bulk density, tapped density, Hausners ratio etc with inference are shown in Table no: 2

Table no:2 The results of rheological evaluation

SL NO	RHEOLOGICAL PARAMETRS	OBSERVATIONS	INFERENCE
1.	Bulk density	0.356 g/ml	Good flowability
2.	Tapped density	0.457 g/ml	Good flowability
3.	Hausner's ratio	1.10	Hausner's ratio between 1-1.11 is considered as good
4.	Carr's index	13.2%	Carr's index between 11-15 is considered as good
5.	Angle of repose	32 degrees	Angle of repose between 31-35 is considered as good
6.	Particle size	55.5 micrometer	Should be less than 100 micrometer

Rancidity, Spreadability and Skin irriatancy

Rancidity test reveals that LP is not rancid. Spreadability of LP was assessed result obtained as 0.34gm.cm/sec. Skin irritancy test for LC and LP reveals that Skin irritation was negligible.

HPTLC Analysis

Methonolic extracts of Symplocos racemosa Roxb., Rubia cordifolia Linn., Glycyrrhiza glabra Linn. , LC and LP were used for HPTLC analysis

The optimum separations of constituents were achieved using the solvent system Hexane (7ml): Ethyl acetate (3ml): Formic acid (2 drops) for 4 samples including Rubia cordifolia Linn., Glycyrrhiza glabra Linn, LC and LP. And in case of Symplocos racemosa Roxb.

Solvent system used is Toluene: Ethyl acetate: formic acid: Methanol in the ratio 3:3:0.8:0.2 Rf values at 254 nm and 366 nm are given in Table :1

Shelf life of LC and LP

Shelf life of LC and LP were determined by 6month accelerated stability study and conducted at Ayush Approved Laboratory. Shelf-life parameters such as organoleptic characters, physicochemical parameters like Loss on drying pH, consistency, Spreadability were retained as initial. Total viable Aerobic count, total yeast and mould count were under permissible limit and not changed much. Specific pathogens like E. coli, Pseudomonas aeruginosa, S. aureus, Salmonella spp were absent. Stability parameters of LC and LP was found to be within limits as per the stability protocol. Obtained shelf life as 2 years and 1 year respectively for LC and LP

Observation and results of Antioxidant Activity

The aqueous extracts were subjected to the DPPH assay. The Observation and results of Anti-oxidant assay of LC and LP was shown in Table no: 3 and Concentration vs % inhibition curve of anti-oxidant Activity of LC and LP is shown in Figure no :1

Table no: 3 Observation and result of anti-oxidant assay of LC and LP

Concentration (µg/ml)	Absorbance of LC	% Inhibition of LC	Absorbance of LP	% Inhibition of LP
200	2.662	11.27%	3	0%
400	2.551	14.97%	3	0%
600	2.323	22.57%	3	0%
800	2.313	22.90%	3	0%
1000	2.301	23.30%	2.080	30.67%
1200	1.988	33.73%	2.031	32.30%
1400	1.976	34.13%	1.986	33.80%
1600	1.970	34.33%	1.981	33.97%
1800	1.821	39.30%	1.961	34.63%
2000	1.651	44.97%	1.908	36.40%

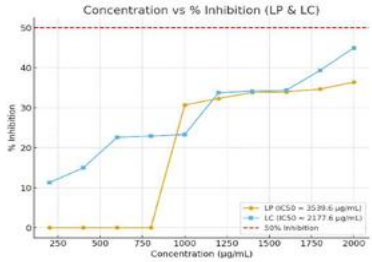

Figure no:1 Anti -oxidant Activity of LC and LP Concentration vs % Inhibition curve

Considering that the extracts were obtained under similar conditions, it is relevant to point out that among them, those from LC showed the highest antioxidant level than LP, with IC50 values of 2177.6 µg/mL and, 3539.6µg/mL respectively while that for the ascorbic acid standard was 11.2 µg/mL.

Observation and results of Antimicrobial Assay

The zones of inhibition for LC, LP and Streptomycin positive control were 17mm, 14mm and 31mm respectively. The Activity index for LC and LP were 0.55 and 0.45 respectively. Also, percentage of inhibition for LC and LP were 55 and 45 respectively. The minimum inhibitory concentration of LC and LP obtained in antimicrobial study was 2.56mg/mL and 2.2mg/mL respectively. The photograph of petri plate is given in Figure no :2

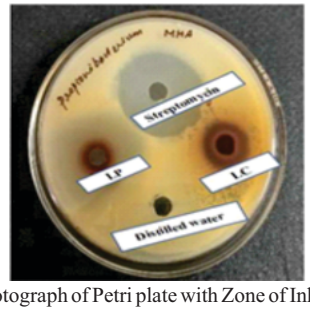

Figure no:2 Photograph of Petri plate with Zone of Inhibition

Clinical study

The study entitled "Efficacy of Lodhradi face pack in Acne Vulgaris (Mukhadushika) was conducted in outpatient department, Government Ayurveda college Thiruvananthapuram.

A total of 85 subjects were screened and 75 met inclusion criteria. But, 5 subjects were not willing to take part in the study. The remaining, 74 participants were randomized and received either LC or LP medications. In this study, the first patient was enrolled on October 23, 2024, and the last patient completed the study on July 31, 2025.Two

participants from each group left before the completion of study, as they lost to follow up. Finally, 35 participants in both LC and LP groups completed the interventions and their data was taken for statistical analysis. Consort diagram is shown in Figure no:3

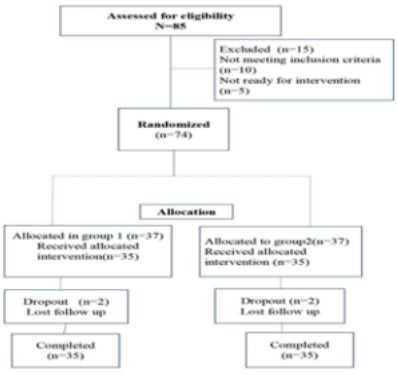

Figure No :3 Consort diagram

Analysis of Socio -Demographic and other Baseline characteristics of participants

The Socio-demographic profiles of the participants are as shown in the Table no :4 Both the Groups are homogeneous with respect to all other parameters.

Table no:4 Socio demographic profile of the Participants

Socio-demographic data	Category	LC Number (%)	LP Number (%)	P VALUE
Age	18-25	27(77.1%)	25 (71.4%)	P= 0.856
	26-30	5 (14.3%)	6 (17.1%)	
	31-35	3 (8.6%)	4 (11.4%)	
Sex	Female	31 (88.6%)	33 (94.3%)	P= 0.673
	Male	4 (11.4%)	2 (5.7%)	
Domicile	Rural	16 (45.7%)	15 (42.9%)	P= =0.347
	Semi Urban	10(28.8%)	6(17.1%)	
	Urban	9(25.7%)	14(40.0%)	
Economic status	Middle	29(82.9%)	32(91.4%)	P value=0.477
	High	6(17.1%)	3(8.6%)	
Education	Intermediate	11(31.4%)	6(17.1%)	p-value=0.375
	Graduate	17(48.6%)	20(57.1%)	
	Post Graduate	7(20.0%)	9(25.7%)	
Built	Lean	10(28.6%)	14(40.0%)	p-value=0.579
	Moderate	21(60.0%)	17(48.6%)	
	Obese	4(11.4%)	4(11.4%)	
Family history	Father			
	No	34(97.1%)	33(94.3%)	p-value=1.0
	Yes	1(2.9%)	2(5.7%)	
	Mother			
	No	27(77.1%)	28(80%)	p-value=0.771
	Yes	8(22.9%)	7(20.0%)	
	Siblings			
	No	29(82.9%)	30(85,7%)	p-value=0.743
	Yes	6(17.1%)	5(14.3%)	

Association of dietary factors and other factors at baseline

Dietary factors and other factors associated with Acne vulgaris at baseline are shown in Table no:5

At baseline, the analysis shows that both the Groups are homogeneous and comparable with respect to all factors minimizing potential confounding.

Table No :5 Dietary factors and other factors associated with Acne vulgaris at baseline

Dietary factors And other Factors	Category	LC Number (%)	LP Number (%)	P VALUE
Diet type	Vegetarian	3(8.6%)	2(5.7%)	p-value=0.643
	Mixed	32(91.4%)	33(94.3%)	
Diet pattern	Regular	25(71.4%)	22(62.9%)	p-value=0.445
	Irregular	10(28.6%)	13(37.1%)	
Oil usage	Mild	8(22.9%)	10(28.65%)	p-value<.01
	Moderate	11(31.45%)	1(2.95%)	
	High	16(45.7%)	24(68.6%)	
Bowel habit	Normal	21(60.0%)	30(85.7%)	p-value<.05
	Constipated	12(34.3%)	5(14.3%)	
	Loose	2(5.7%)	0(0%)	
Dust allergy	Present	18(51.4%)	15(42.9%)	p-value=0.473
	Absent	17(48.6%)	20(57.1%)	
Habit	Excessive intake of coffee or tea			
	Yes	12(34.3%)	13(37.1%)	p-value=0.803
	No	23(65.7%)	22(62.9%)	
	Excessive intake of sweets			
	Yes	4(11.4%)	10(28.6%)	p-value=0.579
	No	31(88.6%)	25(71.4%)	

Analysis of GAGS Score

The pre and post outcome parameters obtained in both the groups were initially subjected to normality test by Kolmogorov -Smirnov test and Shapiro-Wilk test

The results of normality test for LC and LP on GAGS Score as shown in Table no:6

Table no :6 Normality test for LC and LP on GAGS Score

Group		Kolmogorov-Smirnov			Shapiro-Wilk		
		Statistic	Df	p-value	Statistic	df	p-value
LC	GAGS 0th week	.135	35	.053	.896	35	.003
	GAGS 8th Week	.126	35	.174	.971	35	.466
LP	GAGS 0th week	.143	35	.066	.903	35	.005
	GAGS 8th Week	.104	35	.200*	.966	35	.334

Comparison of GAGS score in between LC and LP

The independent samples t-test is used to test the significance of differences in mean scores in between the groups LC and LP. Since the difference in mean scores before the treatment is not statistically significant, t-test is used to compare the mean difference in between LC and LP after the treatment

Comparison of GAGS score in between LC and LP Before (0th week) and After (8th week) is shown in Table no: 7

Mean GAGS Score at 0th week and 8th week of LC and LP shown in Figure no :4

Table no:7 Comparison of GAGS score in between LC and LP Before (0th week) and After (8th week)

Intervention	Before (0th week)	After (8th week)	Mean difference	P value
LC (35)	27.14±2.69	14.17±2.62	12.97	p-value < 0.01
LP (35)	27.00±2.49	13.66±2.67	13.68	p-value < 0.01

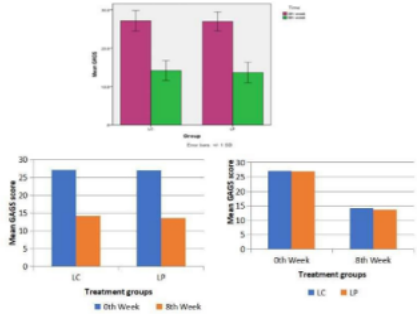

Figure no :4 Mean GAGS Score at 0th week and 8th week of LC and LP

Independent Samples Test

Result of Levene's Test for equality of Variances and t test for equality of means is shown in Table no :8

Table no :8 Result of Levene's Test for equality of Variances and t test for equality of means

Score	Week	Levene's Test for Equality of Variances		t-test for Equality of Means		
		F	Sig	t	Df	P- value
GAGS Score	0^{th} week	.005	.941	.231	68	.818
	8^{th} week	.206	.652	.814	68	.418

The independent sample t-test shows that there are no significant difference mean scores after the treatment in between the groups LC and LP.Thus, even though the reduction in mean value is slightly more in Lodhradi Powder(LC), there is no statistically significant difference in between LC and LP

Effect of treatment on Pain, Itching and Redness

Effect of treatment on pain itching and redness are shown in the Table no: 9

Table no: 9 Effect of treatment on Pain, Itching and Redness

Parameter	Category	LC		LP		
		Before	After	Before	After	P value
Pain	Present	25	11	29	9	p-
	Absent	10 28.6%	24 68.6%	6 17.1%	26 74.3%	p- value<.01
Itching	Present	21 60%	16 45.7%	21 60%	6 17.1%	P value=0.231
	Absent	14 40%	19 54.3%	14 40%	29 82.9%	p- value<.01
Redness	Present	21 60%	8 22.9%	20 57.1%	9 25.7%	p- value<.01
	Absent	14 40%	27 77.1%	15 42.9%	26 74.3%	p- value<.01

Safety of treatment with respect to TEAE Score

Safety of treatment with respect to TEAE score and LSR Score is shown in Table no:10

Table no: 10 Safety of treatment with respect to TEAE Score and LSR score

Category	LC(n=35)	LP(n=35)
Participant experiencing ≥1 TEAE Score	3(8.5%)	2(5.7%)
Participants experiencing LSR Sore by severity		
Mild	2(5.7%) Itching (Score 2)	2(5.7%) stinging (Score 1)
Moderate	1(2.9%) Itching (Score 3)	-
Severe	-	-

DISCUSSION

Acne vulgaris, a common cutaneous inflammatory disorder of the pilosebaceous unit, running a chronic course, typically presenting as papules, pustules, or nodules, not only on affecting the face, but also the upper arms, trunk, and upper back.(18)

The topical therapy is the primary consideration in mild cases of acne, including topical retinoids, topical antibiotics, and benzoyl peroxide etc. When topical retinoids are used to treat acne, some typical adverse effects include dry skin and mucous membranes, irritation, skin flaking, sensitivity to sunlight, myalgia, visual abnormalities, hyperlipidemia, and elevated hepatic transaminase levels.(19)

Lodhradi face pack is a newly formulated drug with the combination of four ingredients mentioned in Caraka-samhitha and Astanga-samgraha. Formulation includes herbal ingredients such as Lodhra (Symplocos racemosa Roxb.), Manjishta (Rubia cordifolia Linn.), Yashtimadhu (Glycyrrhiza glabra Linn.) and Multani-mitti. These drugs have mukhadushika-hara, varnya and kandugna property and is mentioned in specific groups of drugs called Mahakashayas having particular actions like varnya, kushtagna and kandugna properties. All of the individual drugs were having experimentally proven anti-acne potential.

For Standardization of Drugs Ayurveda suggests to adopt a structured quality assurance system called HACCP (Hazard Analysis and Critical control points) guidelines which help to identify, evaluate and control, chemical and physical hazards for herbal raw materials and formulations. HACCP guidelines integrate with GMP (Good manufacturing practices) and GACP (Good Agricultural and collection practices) to assure quality of ayurvedic formulations. These helps to ensure the Safety, efficacy and reproducibility of herbal medicines, thereby strengthening the acceptance of herbal formulation globally.(20)

The standardization of individual drugs of Lodhradi face pack was carried out as per the guidelines mentioned by CCRAS (Central council for research in Ayurvedic sciences for raw plant materials.(8)

Traditional dosage forms including powders (Churnam) are used as face packs in Ayurvedic dermatology. But before being applied, these powders were frequently need to be manually mixed with liquids (such milk, water, rose water, or decoctions), which occasionally results in variations in patient compliance, consistency, and concentration. (21,22) Conversely, a new dosage form, such as a pre-made face pack paste, has a number of benefits, including dosing precision and ease of use.

After the analysis of Effectiveness of Lodhradi powder and Lodhradi paste in GAGS score (0th and 8th week), It was found that GAGS Score at 0th week (Before treatment) is 27.14 ±2.69 in Powder Group and 27 ±2.49 in Paste Group. GAGS score at 8th week (After treatment) was 14.7±2.62 in powder group and 13.66±2.67 in paste group. After 8 weeks GAGS scores reduced significantly in both treated groups with mean difference in powder Group as 12.97 ± 3.15 and in paste Group as13.68 ± 2.68 (p-value < 0.01).; but there was no statistical difference between groups. The reduction of GAGS score in participants after treatment may be a direct indicator of clinical improvement in acne severity which reflects the effectiveness of the formulation in reducing both the number and intensity of lesions.

In addition to the reduction in GAGS Score pain itching and redness were also analyzed. In all cases, the Chi square test shows that the reduction of pain, itching and redness is significant at 1% level of significance (p-value<.01) in both groups except in case of effect of treatment on itching in powder group and the Chi square test shows that the reduction is not significant (p-value>.05) As Pain, redness, and itching in acne are mainly due to inflammatory responses, microbial activity, and irritation of the pilosebaceous unit, which reflect the severity of underlying inflammation and contribute to patient discomfort. Reduction in these symptoms suggests a decline in inflammatory mediators, suppression of microbial growth, and soothing of irritated skin. Safety was assessed with TEAE (Treatment-Emergent Adverse Event) Score reported by participants and found out that TEAE Score was insignificant, the Face -pack is safe with less adverse events. This score is relevant in acne treatment as it assesses the safety and tolerability of the formulation by documenting adverse effects arising after therapy. Thereby balancing efficacy with side effects and improves the evaluation of patient compliance. Also Symplocos racemosa Roxb. contains Alkaloids such as Symplocosidine, Loturine, Colloturine which might be responsible for its Anti-microbial and anti-inflammatory activity. (23) While Glycosides & Tannins such as Symplocoside, Ellagic acid, Gallic acid might be responsible for antioxidant and astringent property.(23) Flavanoids such as Quercetin, kaempferol may inhibit inflammatory mediators (IL-1, TNF-α), thereby reduce redness and swelling in Acne.

Similarly, Rubia cordifolia Linn. contains Anthraquinones such as Rubiadin, Purpurin, etc which might be responsible for its antimicrobial and keratolytic activity. Naphthoquinones such as Mollugin may help in anti-inflammatory and antioxidant activity. Glycosides present in Rubia cordifolia Linn. helps in skin healing, and helps in depigmentation(24) . Triterpenoids such as Oleanolic acid, Ursolic acid might acts as Sebostatic (reduce excess sebum) and helps in antibacterial action. (25) Glycyrrhiza glabra Linn.contains Triterpenoid Saponins like Glycyrrhizin,glycyrrhizic acid etc has strong anti-inflammatory activity. (26) Flavonoids such as Liquiritin, isoliquiritigenin, glabridin might exhibit antimicrobial and antioxidant activity.Coumarins such as Herniarin, umbelliferone has antimicrobial and soothing effect.(27) Together, these provide a multifaceted therapeutic effect combining antimicrobial, anti- Lodhradi face pack is found to be effective and safein moderate acne vulgaris

(Mukhadushika) as both dosage forms LC and LP significantly reduced GAGS scores inflammatory, antioxidant, sebum-regulating, and healing activities. They might act synergistically against acne by targeting multiple pathways: reducing bacterial growth, controlling sebum, reducing inflammation, preventing scarring and pigmentation making them highly valuable in holistic acne management

CONCLUSION

Thus, Lodhradi face pack is effective and safe in moderate acne vulgaris (Mukhadushika) as both dosage forms LC and LP significantly and equally reduced GAGS scores and only having insignificant local skin reactions (LSR) and TEAE Score. This may be due to its Anti-oxidant, Anti-inflammatory and Antimicrobial actions.

LIMITATIONS

- SPregnant woman, lactating mother and patients with PCOD were excluded in the study
- Study only included moderate acne participants with GAGS Score between 19-30 and not included mild and severe cases
- Only hospital-based cases with age group 18-35 included in the study, those below 18 years were not included due to ethical issues although adolescent are more prone to acne vulgaris. Also, those above 35 years were not included in present study.

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CONFLICTS OF INTEREST

Authors have not any conflicts of interest

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REFERENCES

1. Hebert A, Thiboutot D, Gold LS, Cartwright M, Gerloni M, Fragasso E, et al. Efficacy and safety of topical clascoterone cream, 1%, for treatment in patients with facial acne: two phase 3 randomized clinical trials. JAMA Dermatol. 2020;156(6):621–30.
2. Vos T, Flaxman AD, Naghavi M, Lozano R, Michaud C, Ezzati M, et al. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990–2010: a systematic analysis for the Global Burden of Disease Study 2010. The lancet. 2012;380(9859):2163–96.
3. Proenca AC, Luis A, Duarte AP. The role of herbal medicine in the treatment of acne vulgaris: a systematic review of clinical trials. Evidence-Based Complement Altern Med. 2022;2022(1):2011945.
4. Vagbhata, AshtangaHridaya, Translated by Prof. K.R.Srikantha Mutrhy, ChowkhambaKrishnadas Academy, Varanasi, 9th edition 2013, Sutrasthana12/1, p-166.
5. Gupta AK, Tandon N, Sharma M, editors. QUALITY STANDARDS OF INDIAN MEDICINAL PLANTS Volume 4. New Delhi: Indian Council of Medical Research; 2006.
6. Gupta AK, Tandon N, Sharma M, editors. QUALITY STANDARDS OF INDIAN MEDICINAL PLANTS Volume 3. New Delhi: Indian Council of Medical Research; 2005.
7. Gupta AK, Tandon N, Sharma M, editors. Quality standards of Indian medicinal plants. Volume 9. New Delhi: Indian Council of Medical Research; 2011.
8. Central Council for Research in Ayurvedic Sciences. Guidelines for development of Ayurvedic formulations. Volume 1. New Delhi: Ministry of AYUSH, Government of India; 2018.
9. Sriwastava, N. K., Shreedhara, C. S. & Ram, H. A. Standardization of Ajmodadi churna, a polyherbal formulation. Pharmacogn. Res. 2, 98 (2010).
10. World Health Organization (WHO). Quality Control Methods for Medicinal Plant Materials. Geneva: WHO; 1998. Chapter: Microbial Contamination Tests.
11. Singla, V., Saini, S., Joshi, B. & Rana, A. C. Emulgel: A new platform for topical drug delivery. Int. J. Pharma Bio Sci. 3, 485–498 (2012).
12. Aglawe, S. B., Gayke, A. U., Mindhe, S. A. & Rane, V. G. Formulation and evaluation of herbal face pack. Int J Pharm Biol Sci 8, 49–52 (2018).
13. Wilschefski, S. C. & Baxter, M. R. Inductively coupled plasma mass spectrometry: introduction to analytical aspects. Clin. Biochem. Rev. 40, 115 (2019).
14. Jain, V. et al. HPTLC method development and quantification of marker compound eugenol in ayurvedic polyherbal formulations: Avipattikar churna. Tradit. Med. Mod. Med. 6, 9–16 (2023).
15. World Health Organization. Stability testing of active pharmaceutical ingredients and finished pharmaceutical products. WHO Technical Report Series No. 1010. Annex 10. Geneva: WHO; 2018.
16. Oktay, M., Gülçin, İ. & Küfrevioğlu, Ö. İ. Determination of in vitro antioxidant activity of fennel (Foeniculum vulgare) seed extracts. LWT-Food Sci. Technol. 36, 263–271 (2003).
17. Tortora GJ, Funke BR, Case CL. Microbiology: An Introduction. 9th Ed. Boston (MA): Benjamin Cummings; Chapter 20; 2007.
18. Tan AU, Schlosser BJ, Paller AS. A review of diagnosis and treatment of acne in adult female patients. Int J Womens Dermatol. 2018;4(2):56–71.
19. Sutaria AH, Masood S, Saleh HM, et al. Acne Vulgaris. [Updated 2023 Aug 17]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan.
20. Govindaraghavan, S. & Sucher, N. J. Quality assessment of medicinal herbs and their extracts: Criteria and prerequisites for consistent safety and efficacy of herbal medicines. Epilepsy Behav. 52, 363–371 (2015).
21. Sindhu RK, Suryamani. Formulation Development and Standardization of Herbal Face Pack. Saudi Journal of Medical and Pharmaceutical Sciences. 2018;4(11):1343-49. Scholars Middle East Publishers.
22. Pawar S, Gosavi T, Jain BV, Shaikh T, Baviskar KD, Usman MR. Formulation and Evaluation of Herbal Face Pack Powder for Enhanced Skin Care Applications. African Journal of Biomedical Research. 2024;27(3):3072-78).
23. Sc Sunil. In vitro and in vivo antioxidant activity of Symplocos racemosa Roxb. (Authors: Sunil C, et al.) Life Sciences. 2011;88(23-24):111-17.).
24. Chandrasekhar, G. et al. Characterization and antimicrobial evaluation of anthraquinones and triterpenes from Rubia cordifolia. J. Asian Nat. Prod. Res. 25, 1110–1116 (2023).
25. Humbare, R. B. et al. Phytochemical characterization, antioxidant and anti-proliferative properties of Rubia cordifolia L. extracts prepared with improved extraction conditions. Antioxidants 11, 1006 (2022).
26. Wahab, S. et al. Glycyrrhiza glabra (Licorice): A comprehensive review on its phytochemistry, biological activities, clinical evidence and toxicology. Plants 10, 2751 (2021).
27. Zhou Y, Ho WS. Combination of liquiritigenin and glabridin exhibits enhanced antibacterial effect against methicillin-resistant Staphylococcus aureus. Molecules. 2019;24(19):3567. doi:10.3390/molecules24193567.