

External Application of *Lodhra* (*Symplocos Racemosa*) Paste with *Mahamanjishthadi Ghana Vati* in *Mukhadushika* (Acne Vulgaris): A Randomised Controlled Clinical Trial

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ABSTRACT

Introduction: *Acne vulgaris*, a common skin disease affecting younger adults, is generally managed by antibiotics, anti-seborrheic agents, hormonal therapy, and topical applications. In ayurveda, this disease is described as *Mukhadushika*, characterised by minute thorn-like eruptions. Its treatment includes both internal administration and external application of blood-purifying drugs.

Aim: To evaluate the effect of external application of *Lodhra* (*Symplocos Racemosa*) paste adjuvant to *Mahamanjishthadi Ghana Vati* (MGV) herbal tablet internally in *acne vulgaris*.

Materials and Methods: An open-label, randomised controlled clinical trial was conducted between March 2023 to June 2024, at Karnataka Lingayat Education (KLE), Ayurveda Hospital, Belagavi, Karnataka, India. A total of 50 patients of either sex, aged between 16-40 years, were assessed using the *Mukhadushika Roopa* (symptom) assessment score and Global Acne Grading Scale (GAGS), and were randomised into two groups. Both group A (control, n=25) and group B (intervention,

n=25) were administered MGV herbal tablet (500 mg) orally, twice daily, for 30 days. Patients in group B were additionally treated with the external application of *Symplocos Racemosa* paste. The Dermatology Life Quality Index (DLQI) of the participants was also assessed. Study outcomes were assessed using *Mukhadushika Roopa* (symptoms) and GAGS on baseline, on 15th and 30th day, whereas DLQI was assessed at baseline and 30th day. Statistical results were evaluated through the Mann-Whitney U test and the Wilcoxon signed-rank test. A p-value of <0.05 was considered statistically significant.

Results: Both groups showed significant improvement in all three parameters after 30 days of intervention (p-value <0.001). On intergroup comparison, *Symplocos Racemosa* paste showed better improvement in symptoms of *acne vulgaris* (p-value <0.001).

Conclusion: External application of *Lodhra* (*Symplocos Racemosa*) paste, as an adjuvant to MGV herbal tablets, appears more beneficial than internal administration of MGV herbal tablets alone in *acne vulgaris*.

Keywords: *Acne vulgaris*, Dermatology life quality index, Global acne grading scale

INTRODUCTION

Skin reflects overall health and is the body's largest organ, protecting against injury and infection. People's self-worth is often tied to their appearance, driving them toward skin care. Despite advanced treatments, factors like diet, lifestyle, and the environment contribute to skin issues such as *acne vulgaris*, which significantly affect both social and emotional well-being. The Global Burden of Disease (GBD) study reports a global prevalence of acne at 9.4%, positioning it as the eighth most prevalent disease worldwide. *Acne vulgaris* affects approximately 85% of individuals aged 12 to 25 years, with incidence rates in this demographic continuing to rise annually [1]. In India, the population affected by acne is projected to reach approximately 23 million by 2026, based on a compound annual growth rate of 0.5% [2].

Pathophysiologically, *acne vulgaris* is characterised by a constellation of mechanisms including hyperseborrhoea, follicular hyperkeratinisation, microbial colonisation (notably *Cutibacterium acnes*), and inflammatory responses. Clinically, lesions range from non inflammatory comedones to inflammatory papules, pustules, and nodulocystic formations [3]. In Ayurvedic literature, *acne vulgaris* is referred to as *Mukhadushika*, with lesions metaphorically described as resembling the thorns of *Salmalica malabarica*. The condition is attributed to the vitiation of *vata* and *kapha* doshas, with *rakta* (blood) serving as the principal *dushya* (affected tissue) [4].

Patients frequently begin management with over-the-counter cosmetics or home remedies, often delaying professional medical consultation. Contemporary therapeutic approaches encompass

antiseborrheic agents, systemic and topical antibiotics, hormonal modulators, and retinoids [3]. However, these interventions are often associated with high costs and adverse effects such as erythema, pruritus, desquamation, and irritation [5]. Consequently, there is a growing impetus to investigate traditional Ayurvedic formulations for their potential efficacy and safety in acne management.

Among such interventions, *Lepa*, a topical application of herbal or herbo-mineral paste, is recognised in Ayurveda as a straightforward and efficacious external modality for dermatological conditions. Applied directly to the affected site, *Lepa* aims to mitigate inflammation, alleviate pain and burning sensations, and address both inflammatory and non inflammatory lesions [6].

Mahamanjishthadi Kwath, a polyherbal decoction, is routinely prescribed for a spectrum of skin disorders, including *acne vulgaris* [7]. To enhance its palatability, stability, and ease of administration, it is frequently formulated into tablet form, referred to as *ghana vati* [8-9]. Despite its widespread clinical use in Ayurvedic practice, there is a paucity of published data evaluating *Symplocos racemosa*, either as a monotherapy or as an adjuvant to MGV in the treatment of *acne vulgaris*. Therefore, the present study was undertaken to systematically assess the efficacy of *Symplocos racemosa* paste as an adjunct to MGV tablets in the management of *acne vulgaris*.

MATERIALS AND METHODS

An open-label, randomised controlled clinical trial was conducted between March 2023 to June 2024 at KLE Ayurveda Hospital,

Belagavi, Karnataka, India. The study was initiated after approval from the Institutional Ethics Committee for Research on human subjects (BMK/21/PG/KC/3) and registration in CTRI (Ref. No. CTRI/2022/11/047151).

Inclusion criteria: Patients of either gender, aged 16-40 years with acne were included in the study.

Exclusion criteria: Patients with associated conditions such as Polycystic Ovary Syndrome (PCOS), thyroid disorders, pregnancy or lactating females, and those on oral contraceptive pills, were excluded.

Sample size calculation: A marked improvement in group B of 50% was compared with 13.64% in group A, with an alpha error adjusted at 5% and test power at 80% [10].

$$n = \frac{(z_{1-\frac{\alpha}{2}} + z_{1-\beta})^2 (p_1 q_1 + p_2 q_2)}{(p_1 - p_2)^2}$$

$$n = \frac{(1.96 + 0.84)^2 ((13.64 + 86.36) + (50 \times 50))}{(13.64 - 50)^2}$$

$$n = 21.81, \text{ with } 10\% \text{ attrition rate } n = \frac{21.81}{1 - 0.10} = 24.23 \sim 25 \text{ per group.}$$

The calculated sample size was 21.81. With a 10% attrition rate, this was adjusted to 24.23, rounded to 25 participants per group.

Study Procedure

A computer-generated random number table was used for the randomisation. Participants were allocated to either the control or intervention group in a 1:1 ratio. The randomisation table was securely maintained by the Institutional Medical Research Centre. After baseline assessment, group allocation was disclosed to the principal investigator.

All participants of group A (control) and group B (interventional) received MGV herbal tablet (500 mg) BD orally, before food with lukewarm water for 30 days and participants in group B were treated additionally with external application of *Lodhra* (*Symplocos racemosa*) paste, which is prepared by mixing 5 gm of *Symplocos racemosa* powder with water and applied once daily to the affected area for up to 30 days or until symptoms subsided.

Symplocos racemosa stem bark was procured from Good Manufacturing Practices (GMP)-certified Ayurveda pharmacy, and powdered to mesh size 220. Authentication of the raw material and analysis of the finished product were done at a Government of India-approved Ayurveda, Siddha, and Unani (ASU) drug-testing laboratory of the Institution. MGV herbal tablets were procured from a GMP-certified Ayurvedic pharmacy.

Patients attending the Outpatient Department (OPD) of the Ayurveda hospital and research centre who met the diagnostic criteria, i.e., having pimples on the face, with or without pimples over the neck and upper back and with or without symptoms such as *vedana* (pain), *daha* (burning sensation), *kandu* (itching) and *sotha* (oedema)- were enrolled. Clinical assessment was done thoroughly, and data were systematically documented using the assessment parameters: *Mukhadushika Roopa* (symptoms) assessment score [10], Global Acne Grading Scale (GAGS) [11] and Dermatology Life Quality Index (DLQI) [12].

***Mukhadushika Roopa* (symptoms) assessment score:** This assessment was based on the four clinical symptoms of *Mukhadushika*, selected from a previously published proforma and scoring pattern for acne [10]. Among ten symptoms, four relevant to this study, like *vedana* (pain), *sotha* (oedema), *kandu* (itching) and *daha* (burning) were chosen, and a pre-post assessment was followed. Severity of these was graded from 0-3, where 0 indicated the lowest and 3 as the highest score for symptom severity.

Global Acne Grading Scale (GAGS): GAGS helps in identifying the type and total number of acne lesions. GAGS divides the face (chin, nose, each cheek and forehead), back and chest into six divisions and then the severity in each area is assessed on the scale of 0-4 (0-no lesions, 1-comedones, 2-papules, 3-pustules, 4-nodules). The total score of all six zones is calculated to grade the acne severity as, 1-18 as mild, 19-30 as moderate, 31-38 as severe or >39 as very severe [11].

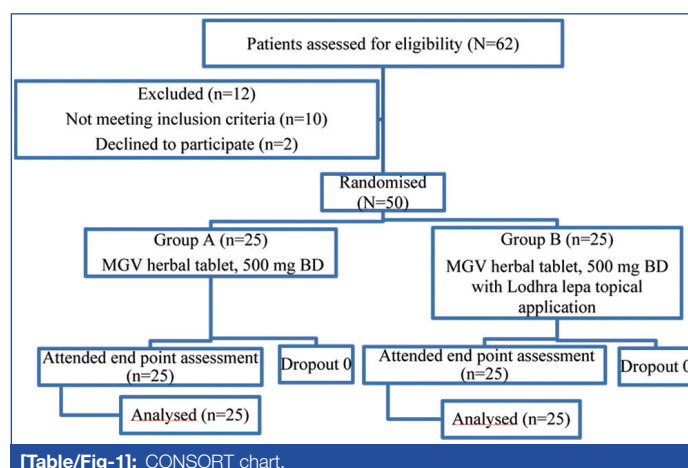
Dermatology Life Quality Index (DLQI): DLQI helps in assessing the dermatology-specific quality of life. It includes 10 questions that concern the patient's perception of the impact of the skin diseases on various aspects of their quality of life, which are health-related over the last week. The total score ranges between 0-30, which is obtained by adding the scoring of each question. The higher the score, the greater the impairment in quality of life. Score more than 10, suggests that the disease has been severely affected the patient's life [12].

STATISTICAL ANALYSIS

Statistical analysis was performed using R software, version 4.3.0. The categorical variables are reported in numbers, and continuous variables are reported in Mean±SD, depending on the distribution of the continuous variable. Categorical variables were compared by the Chi-square test. The continuous variables were compared by the Mann-Whitney U test across groups. The Wilcoxon signed rank test was applied to compare within group differences. The level of significance was considered at 5% throughout the analysis.

RESULTS

A total of 62 patients were screened, and after obtaining written informed consent, 50 among them were enrolled. The details of participant enrollment and follow-up are presented as per the Consolidated Standards of Reporting Trials (CONSORT) statement guidelines [13] [Table/Fig-1].



All the recruited 50 participants have completed the trial without any adverse events or drop-outs. The maximum patients in this study were females aged between 21 to 30 years, and were residing in an urban area, consuming a mixed diet with irregular intake pattern, with a weak state of digestion and metabolism, regular menstrual history, irregular bowel movements with constipation and were majorly affected by stress [Table/Fig-2].

Both groups in this study were effective in reducing the *Mukhadushika Roopa* (symptoms) assessment score, with statistical comparison revealing a significant difference (p-value <0.001). However, on comparison between the two groups, group B was better than group A in improving the *Mukhadushika Roopa* (symptoms) assessment score, with p-value <0.001 as shown in [Table/Fig-3].

The GAGS scores reduced significantly after treatment in both groups (p-value <0.001). However, on comparing the two groups,

Characteristics	Categories	Group A (n=25)	Group B (n=25)	p-value
Age (in years)	16-20	3	2	0.109
	21-30	22	19	
	31-40	0	4	
Gender	Male	9	6	0.354
	Female	16	19	
Habitat	Urban	16	19	0.354
	Rural	9	6	
Diet intake pattern	Regular	9	6	0.354
	Irregular	16	19	
Digestion and metabolism	Regular	4	3	0.570
	Mildly disturbed	8	11	
	Moderately disturbed	13	10	
	Severely disturbed	0	1	
Menstrual history	Regular	16	17	0.181
	Irregular	0	2	
Bowel pattern	Regular	8	6	0.528
	Irregular	17	19	
Bowel	Constipated	15	16	0.771
	Loose	2	3	
	Normal	8	6	
Mental factors	Anger	3	2	0.754
	Stress	17	16	
	Fear	0	0	
	Sorrow	0	0	
	Nil	5	7	

[Table/Fig-2]: Baseline characteristics in both groups.

Chi-square test, p-value <0.05 set as statistically significant

Outcome Measures	Group A (MGV) (n=25)	Group B (MGV+LL) (n=25)	p-value
Mukhadushika Roopa (symptoms)			
Baseline	8.3±0.79	8.6±1.31	0.146
15 th day	6.5±1.15	4.8±0.89	0.0001
30 th day	3.5±1.08	2.0 ±0.97	0.0001
p-value	<0.001*	<0.001*	
GAGS			
Baseline	22.5±8.53	23.8±5.91	0.304
15 th day	18.3±6.11	19.4±6.24	0.510
30 th day	16.0±5.61	12.0±3.48	0.002
p-value	<0.001	<0.001	
DLQI			
Baseline	14.4±2.03	14.9 ±2.34	0.256
30 th day	12.0±2.02	10.0±1.42	0.002
p-value	<0.001	<0.001	

[Table/Fig-3]: Statistical analysis of outcome measures.

Wilcoxon signed rank test, Mann-Whitney U test; p-value <0.05 set as statistically significant

group B showed better results than group A in reducing GAGS score, as the mean difference from pre to post assessment (from 0th day to 30th day) was 6.5 in group A and 11.8 in group B with p-value=0.002, as shown in [Table/Fig-3].

Quality of life also improved significantly in both groups, with p-value <0.001. However, on comparison between the two groups, group B was better than group A in improving quality of life as the mean difference from pre to post assessment (from 0th day to 30th day) was 2.4 in group A and 4.9 in group B with p-value=0.002, as shown in [Table/Fig-3].

External application of herbs and herbo-mineral preparations, alongside oral medicines, is generally prescribed for better outcomes in various skin disorders.

The present clinical trial indicates that the addition of single herb *Symplocos racemosa* as topical therapy, adjuvant to MGV oral herbal medication, significantly enhances the clinical outcomes in patients with *acne vulgaris* in an outpatient setting. Notably, there was significant improvement in GAGS and DLQI in group B, additionally treated with external application of *Symplocos racemosa*, suggesting that the topical application of a single herbal medicine in the form of paste provides added therapeutic benefit over oral treatment alone.

MGV herbal tablet is a commonly prescribed medicine for various skin ailments, including *acne vulgaris*. It is a solidified dosage form of *Mahamanjishthadi Kwatha*, a herbal decoction comprising 44 drugs like *Manjishtha* (*Rubia cordifolia*), *Kutaja* (*Holarrhena antidysenterica*), *Musta* (*Cyperus rotundus*), *Kushta* (*Saussurea lappa*) etc [14]. These ingredients possess the kapha and pitta-alleviating, complexion-enhancing, blood purifying, anti-inflammatory, wound healing, and antipruritic properties [15].

Phytochemicals such as flavonoids, phenols, glycosides, tannins, terpenoids, saponins, alkaloids, etc. and phytoconstituents like gallic acid, lupeol and ellagic acid, etc. present in the MGV herbal tablet contribute to the effectiveness in treating skin conditions [16]. Proliferation of *P. acne* is inhibited by the methanol extract of *Manjishtha* (*Rubia cordifolia*) [15].

Previously published Ayurvedic studies on topical applications of *Salmalyadi* (*Salmalica malabarica*, etc.) [10], *Arjuna tvak* (*Terminalia arjuna*) paste [17,18], have evaluated the effect of herbal lepa in the management of *acne vulgaris*.

Symplocos racemosa, used as an ingredient in different formulations, was proved to be effective in relieving many skin complaints, but as a single drug it has not yet been explored in *acne vulgaris*. It is a herb with *kashaya* (astringent), *tikta* (bitter) taste, and *sheeta veerya* (cold potency) acts on *kapha* and *pitta dosha*, indicated in the treatment of *kushta* (various skin disorders), *vrana* (wounds) and boils etc [9]. Thus, in present study, *Symplocos racemosa* powder was mixed with water, and the paste was applied over the acne lesions. Active principles of the applied drugs are absorbed into the deeper skin layers through minute hair follicles [19], act on the targeted pathology and help in treating the condition.

The anti-inflammatory properties of *Symplocos racemosa* are derived from phytochemicals such as flavonoids and tannins, which help reduce local inflammation associated with acne lesions [20]. Flavonoids present in *Symplocos racemosa* exhibit antioxidant activity by neutralising the reactive oxygen species, which are produced during inflammation. Thus, by protecting the skin cells from oxidative damage, *Symplocos racemosa* may support for faster resolution of acne lesions [21]. By inhibiting the growth of *Cutibacterium acne*, alkaloids and saponins present in the *Symplocos racemosa* yield the antimicrobial activity, thus help to reduce the bacterial colonisation and subsequent inflammation in the acne lesions [22]. Blood purifying action of *Symplocos racemosa* improves the local blood circulation and aids in cell regeneration, which may accelerate the healing process of acne lesions [23].

As acne is one of the cosmetic problems leading to challenges in social behaviour, a reduction of lesions would definitely reduce phobias and improve life quality by enhancing self-confidence. It can be supported by the antistress property of *Manjishtha* (*Rubia cordifolia*) [24] and the antioxidant properties [25] of the MGV herbal tablet and *Symplocos racemosa* together.

Limitation(s)

One limitation of the study was that it did not include *Shodhana* (purificatory therapies), which might have offered better and more

sustained outcomes in the management of *acne vulgaris*. Secondly, lack of control over participants' diet and lifestyle habits may have contributed to the variations in the results.

CONCLUSION(S)

External application of *Lodhra* (*Symplocos racemosa*) paste for thirty days, as an adjuvant to internal MGTV herbal tablets, produced better outcomes than the internal treatment alone when assessed by symptom severity, Global Acne Grading Scale and Dermatology-related quality of life. Further studies with a larger sample size are required to establish efficacy of *Lodhra* (*Symplocos racemosa*) in *acne vulgaris*.

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