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JATIPHALA LEPA (*MYRISTICA FRAGRANS*) AND ARJUN TWAK LEPA (*TERMINALIA ARJUNA*) WITH HONEY ON THE VYANGA (MELASMA) – A RANDOMISED CONTROLLED CLINICAL TRIAL

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ABSTRACT

Background:
Melasma, also known as *vyanga,* is a prevalent pigmentation disorder that causes dark brown to grey-brown spots on the face, particularly in women of reproductive age. It leads to psychological distress and cosmetic concerns, especially in regions with high levels of sun exposure. Hormonal fluctuations, genetic predisposition, and sun exposure are identified as risk factors. Melasma is often observed in conjunction with hormone replacement therapy, oral contraceptives, and during pregnancy. Conventional treatments generally prove ineffective and may produce adverse effects.

Aim & Objective: This study aims to compare the efficacy of *Jatiphala lepa* (*Myristica fragrans*) and *Arjun twak lepa (Terminalia arjuna)* with honey in managing *vyanga* (melasma).

Materials and Methods: The trial utilised computer-generated randomisation. Participants who met the study's criteria were randomly assigned to one of two groups. Group B received *Arjun twak lepa* with a follow-up on the seventh day, while Group A used Jatiphala lepa for a duration of 14 days. Objective criteria for assessment in-

cluded skin luster score, Varnya scale, lesion size, and number of lesions; subjective criteria were based on *Ayurvedic* parameters.

Results: The findings of the study indicated that while Group A exhibited a significantly greater improvement in Kandu (itching) compared to Group B, Group A's advancement in Daha was also statistically significant. In terms of the Varnya scale, skin luster score, number of lesions, and lesion size, Group A outperformed Group B.

Conclusion: *Jatiphala lepa* demonstrated superior efficacy over *Arjun twak lepa* in the management of v*yanga*, showing significant improvement in the Varnya scale (72%) and other parameters, thereby indicating a remarkable positive effect on the condition.

Keywords: Melasma, *Vyanga, Jatiphala Lepa*, *Arjun Twak Lepa*, Honey, Randomized Controlled Trial.

INTRODUCTION

Human Skin is the largest Organ. Healthy, radiant facial skin improves self-confidence, attractiveness, and beauty, whereas discoloration can cause insecurity, inferiority complex, and reputation. Skin and its appearance remain the priority for every man and woman throughout their lives. Almost skin tone is a manifestation of beauty, any ill physical or mental state would be mirrored in skin.

Vyanga is a common skin disease that falls under *Kshudra roga.* It reduces the glow on the face and affects skin health, affecting beauty and attraction. It is a major cosmetic problem in society.

According to *Ayurveda*, the deterioration of the *Vata* and *Pitta Doshas* is the cause of *vyanga.*

Which is frequently brought on by feelings of grief and anger. *Acharya Vagbhata* attributes *Vyanga* to 'Shoka' and *'Krodha,' but Acharya Sushruta* attributes it to *'Krodha'* and *'Ayasa'. Lohita,* the adhisthan of Vyanga, is one of the seven skin layers mentioned. Its features and causes are explained by *Acharya Sushruta* and *Acharya Vagbhata*.(1) The disease's *lakshanas* In the classical *Ayurvedic* literature, Vyanga is described under the headings of *Kshudra rogas.*

Charaka is considered Vyanga under Rakta Pradoshaja Vikara. The primary sign of Vyanga is a change in skin pigmentation (Vaivarnyata). It is distinguished by the appearance of Shavavarna, *Tanu,* and *Niruja* (painless) *Mandalas* on the face. *Ayurveda* has described *vyanga* as a *Kshudra* Roga, or mild ailment. It has a significant impact on a person's quality of life but is not a major or life-threatening condition. In *Ayurveda, vyanga* is used to describe melasma.

Melasma, known as Vyanga in Ayurvedic terms, is a common hyperpigmentation disorder affecting the skin of the face, resulting in brown or greyish-brown patches on sun-exposed areas. It is associated with hormonal fluctuations (such as those occurring during pregnancy, the use of oral contraceptives, or hormone replacement therapy), UV radiation, and genetic predisposition, particularly in women. This condition can impact psychological well-being due to aesthetic concerns. In India, its prevalence ranges from 1.5% to 33.3%, with a female-to-male ratio of 4:1, indicating that females are significantly more affected.

In Pune, it ranges from 1.5% to 33.3%.(2)

Various *Acharyas* in *Ayurveda* explain several *Chikitsa* for *Vyanga*. These include *Shaman aushadhi, Lepa, Abhyanga, Raktamokshan, Virechan* and *Nasya.* Among these, *lepa* is more effective since it acts directly on the lesion.

Study Objective: To compare the efficacy of *Jatiphala lepa* (*Myristica fragrans*) and *Arjun twak lepa(Terminalia arjuna)*with honey in the management of *vyanga* (melasma).

1. **Clinical Contrive: 1.1 Research Design:** Comparative Open-Label Randomised Clinical Study. **1.2 Ethical Consideration:** DYPCARC/IEC/535/2022 was the approval number assigned by the institution's ethics committee for the trial dated 5th August 2022 and subsequently registered with the Clinical Trial Registry of India (CTRI/2022/12/048415). A comprehensive

case record form was maintained and kept up to date, along with signed consent forms from all the study participants. **1.3 Source of Data**: Clinical trials were conducted on patients screened in the OPD and admitted to the IPD of D.Y. Patil College of Ayurveda and Research Centre. Patients who were eligible and agreed to participate were randomly assigned to two groups.

2.4 Sample size and sampling technique:

A sample size was determined based on the prevalence rate of *Vyanga* (melasma); thus, a total of 60 participants (i.e., 30 in each group). With dropouts taken into account, 68 patients were enrolled in the research study. (Group A had 33 participants, and Group B had 30 participants, as 5 participants of both groups dropped out). To create the allocation sequence, computer-generated randomisation was uti-

lised, and the CONSORT flow chart is provided in Figure 1.

2.5 Drug Source: *Jatiphala lepa* and *Arjun Twak Lepa* were manufactured in the FDA-approved Sudhatatva Pharmacy of College.(4,5,6)

2.6 Implementation: The patients were reviewed by the inclusion and exclusion standards.

2.6.1 Inclusion criteria for the study were participants between the age of 18-60 years who exhibited the clinical features of *vyanga*, which included *kandu* (itching), *daha*(burning sensation), skin lustre, size of lesions (within 0-6), No. of lesions (within 1-6), and *varnya* scale with the range of 1-26.

2.6.2 Exclusion criteria: Individuals including those with *kustharoga*, congenital hyperpigmentation and pregnant & lactating women.

2.7. Intervention (Table 1)

| Group	Drug	Dose	Time	Route of Administration
A	*Jatiphala Lepa*	3 gm – 10 gm (approx.)	Daily locally for 20-30 min	External application on the skin
B	*Arjun Twak Lepa*	3 gm – 10 gm (approx.)	Daily locally for 20-30 min	External application on the skin

Duration of the trial: 14 days study, with follow up on 7th & 14th day.

2.7 Criteria for the evaluation and the scoring pattern: table 2
Subjective Criteria & objective criteria:

Symptoms	0	1	2	3
Kandu (Itching)	No itching	Mild (Itching occasionally but not enough to interfere with daily activities)	Moderate (Regular itching that interferes with daily activities but does not interfere with sleep)	Severe (Regular itching that interferes with sleep and daily activities)
Daha (Burning Sensation)	No Burning sensation	Mild (Burning sensation that occurs occasionally, usually when the patient is exposed to the sun)	Moderate (frequent burning that gets worse when the sufferer is exposed to the sun)	Severe (Constant burning feeling, whether or not exposed to sunlight)
Skin Luster (*Twakvaivarnta*)	Good/Radiant	Moderate	Mild	Poor
Varnya Scale	Scale 1-6	Scale 7-13	Scale 14-20	Scale 21-26
Number of lesions	1-2	3-4	5-6	>6
Size of lesion	0-2	3-4	5-6	>6

Note: The largest lesion's size is taken into account when there are many lesions or patches.

Varnya Scale
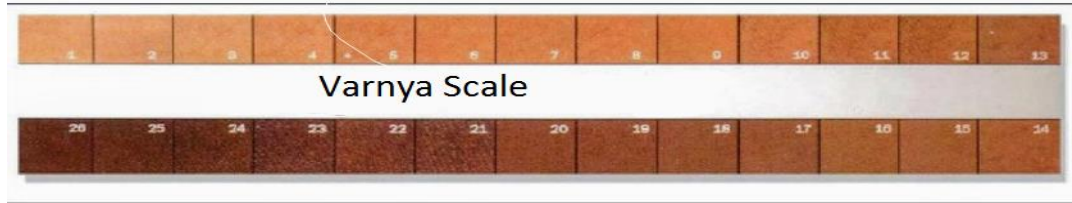
2.9 Statistical Methods: Wilcoxon signed Ranks Test statistical analysis for subjective parameters in Groups A and B.A comparison between Group A and Group B's subjective parameters Statistically, the Mann Whitney U test is utilized. Every test was determined to be statistically significant at a p value of less than 0.05.

Table 3: Comparison of effect of intervention within groups before treatment (BT) and after treatment (AT). Descriptive statistics expresed in mean and standard deviation.

Parameter	Group	Meaning Standard Deviation		P value
		BT	AT	
Kandu (Itching)	Group A	0.424242 ±0.70844	0.030303 ± 0.17408	< 0.05
	Group B	0.2667 ± 0.44978	0.0000 ±0.0000	< 0.05
Daha (Burning Sensation)	Group A	0.242424 ± 0.50189	0.030303 ± 0.0000	< 0.05
	Group B	0.23333 ± 0.43018	0.0000 ± 0.0000	< 0.05
Skin Luster (*Twakvaivarnta*)	Group A	1.3636 ± 0.48850	0.6061 ± 0.49620	> 0.05
	Group B	1.2333 ± 0.56832	0.6000 ± 0.62146	> 0.05
Varnya Scale	Group A	1.515151 ± 0.56575	0.424242 ± 0.50189	> 0.05
	Group B	1.5000 ± 0.57235	1.0000 ± 0.58722	> 0.05
Number of lesions	Group A	1.575758 ± 0.11539	0.969697 ±0.08124	> 0.05
	Group B	1.36667 ± 0.61495	0.86667 ±0.50742	> 0.05
Size of lesion	Group A	2.969696 ± 0.72822	1.484848 ±0.83371	> 0.05
	Group B	3.00000 ± 0.94686	1.66667 ± 0.92227	> 0.05

Table 4: Comparison between groups from day 0 to day 14. Expressed in mean rank and percentage effect.

Parameter	Group	Mean Rank	Parentage effect (%)	P value
Kandu (Itching)	Group A	32.91	92.85	> 0.05
	Group B	31.00	100	
Daha (Burning Sensation)	Group A	31.79	100	= 0.05
	Group B	32.23	100	
Skin Luster (*Twakvaivarnta*)	Group A	33.82	55.55	> 0.05
	Group B	30.00	51.35	
Varnya Scale	Group A	35.14	72	< 0.05
	Group B	28.55	57.77	
Number of lesions	Group A	61	38.46	< 0.05
	Group B	60.667	36.58	
Size of lesion	Group A	61	50	< 0.05
	Group B	60.957	44.44	

Table 5: Number of patients with overall percentage effect

Sr. No.	Criteria of Assessment	Grade of Improvement	No. of Patients	
			Group A	Group B
1.	75 - 100 %	Marked	5	3
2.	50 - 74 %	Moderate	18	16
3.	25 - 49 %	Mild	10	9
4.	0 - 24 %	Poor	0	2

Demographic Data:

The age range of the majority of participants (46.62%) was 31–40 years old. Pregnancy or hormonal changes may be the cause of the higher patient incidence in females (77.77%) compared to males. Compared to other occupations, the percentage of housewives (61.90%) is higher due to their demanding daily jobs, unhealthy eating habits, and suppression of natural desires that vitiate *vata* and increase susceptibility to the disease. Of those who are married, 96.82% have a high probability of experiencing *vyanga*. 52.38% of patients with varied eating habits are on the vegetarian diet, making them more susceptible to the illness.

3.Results: Group A and Group B, respectively, experienced mean reductions from 0.424242 to 0.030303 and 0.2667 to 0.000 in *Kandu* (itching), with the B Group achieving a higher performance (100%). With a 100% improvement in both groups, the mean for *Daha* (Burning Sensation) decreased from 0.242424 to 0.030303 in Group A and from 0.23333 to 0.0000 in Group B. Between Group A and Group B (1.2333-0.6000), the skin luster mean decreased from 1.3636 to 0.6061, with Group A achieving a 55.55 percent improvement.In Group A, the mean for **Varnya Scale** decreased from 1.515151 to 0.424242,it's improvement 72% and in Group B, it decreased from (1.5000-0.57235).**Number of lesion**: Group A showed a mean decrease from 1.575758 to 0.969697,having greater improvement i.e 38.46% while Group B improved from 1.36667 to 0.86667. **Size of lesion**: Group A showed a mean decrease from 2.969696 to 1.484848, (50%) while Group B increased from 3.00000 to 1.66667.

4.Mode of Action of Drug: **Jatiphala :** *Jatiphala* (Myristica fragrans), commonly known as nutmeg, is a popular herb in Ayurvedic medicine because of its anti-inflammatory, antibacterial, and skin-lightening qualities. It may help reduce the pigmentation associated with *Vyanga* since it is believed to increase circulation and promote the renewal of healthy skin cells.

The skin can receive healthy *Bhrajaka Pitta* right away when *Srodusti, Jatiphala's Katu*, and *Tikta Rasa* are removed. *Tikta Rasa* and *Usna Virya* of *Jatiphala* avoid *Vata Dosha,* which results in a reduction of *Kharatwa* and *Krishnatwa. Jatiphala* contains myristicin, which is known to provide health advantages.Mystric acid helps reduce the skin's melanin secretion and has antioxidant qualities that impact free radicals. By removing harmful skin layers, exfoliation helps in the creation of new, healthy skin.(3)

Arjun Twak: *Arjuna* (Terminalia arjuna) is a plant that has long been used to promote cardiovascular health because of its strong both antioxidant and anti-inflammatory qualities. It is believed to improve the skin's structural integrity, reduce oxidative stress, and speed up wound healing when skin problems occur. By halting water loss, *Arjun* raises the skin's moisture content. Additionally, it enhances blood flow. Its appropriate antioxidant properties prevent skin damage. The astringent (*Kashya*) and cooling (*Sita*) qualities of arjunachaal encourage the production of new skin cells, hydrate the skin, and enhance its suppleness. (4,5) Additionally, because of its ability to relieve inflammation, it lessens tanning and pigmentation.(6,7) The cytoprotective activity of arjunolic acid lowers oxidative stress, making it an excellent antioxidant and free radical destroyer with a variety of therapeutic uses.(8) **Madhu:** The humectant, antimicrobial, antioxidant, and calming characteristics of honey, another component in this study, have made it a staple in many traditional medical systems for mil-

lennia. Honey can be used as a supplement to cure discolouration because it is believed to enhance skin repair, moisturize the skin, and reduce irritation. *Ruksha, Laghu, Pichhla, Yogavahi, Mridu, Sukshma,* and *Vishada* are the *Guna* of *Madhu.* It decreases *Pitta Dosha* by entering the minute channels, according to *Sukshma Guna* and *Yogavahi.Madhu's Tridosha Prasamana* trait influences *Vyanga's* vitiated *Dosha.*The characteristics of *Varnyahar* and *Madhu Prasadan* both brighten skin tone.(6)

Pattern of changes in the colour of mandalas with the treatment in both groups

The images show effect of the treatment in one of the patients

Group A

BT	AT

Group B

BT	AT

CONCLUSION

We can draw the following conclusions regarding the efficacy of *Jatiphala lepa* and *Arjun Twak lepa* on *Vyanga* based on the data analysis and observation of the studies. All signs, symptoms, and the criteria of assessment showed varying degrees of improvement with both drugs, so we can say that both medications worked efficiently to treat *Vyanga*. Based on the data collected, we conclude

that *Arjun Twak lepa* (Group B) had a relatively better impact on Kandu (itching); Groups A and B had an equal impact on Daha (burning sensation); and *Jatiphala lepa* showed better improvement than *Arjun Twak lepa* on specific assessment criteria, namely, size of lesions (50%) and *Varnya* scale (72%).Certain criteria, particularly Kandu (92.85% in Group A and 100% in Group B), Skin Luster Score (55.55% in Group A & 51.35% in Group B), and No. of Lesion (38.46% in Group A & 36.585 in Group B), had nearly identical percentage effects with only slight variations. With no significant variations, *Daha* in particular showed the same percentage effect (100% in Group A and 100% in Group B). Moreover, no negative effects were noted. Therefore, we conclude that *Jatiphala Lepa* surpassed *Arjun Twak Lepa* in the management of *Vyanga* overall. *Jatiphala lepa*, however, demonstrated a significant improvement in one of the disease's primary objective indicators (Varnya Scale: 72%) in addition to apparent improvements in other parameters. Its beneficial effects on *Vyanga* are additionally established.

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