RESEARCH PAPER

A Randomized Comparative Clinical Study To Evaluate The Efficacy Of Arjuna Lepa And Manjistha Lepa In The Management Of Vyanga

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Abstract

Skin reflects the beauty of healthy individuals. Today, cosmetics have become essential part of our daily routine but natural beauty is getting spoiled because of the harmful chemicals in some cosmetics. Thus, the demand of herbal product is increasing globally in cosmetic field. The concept of Varna dealt in Ayurveda is an innate entity of beauty. Melasma is the skin disease which have high prevalence rate of 1.5% to 33.3%. *Lohita* is the site for *Vyanga* which is one of the *Kshudra Roga,* characterized by *Niruja* (painless), *Shyava Varna Mandala* (bluish black patches) occurring especially on the face. On the basis of clinical features, it is correlated with melasma or facial melanosis, one of the hyperpigmented disorders. In modern medical science, topical steroids have been described in the management of fascial melanosis. However, the topical steroids are not completely free from adverse effects such as irritation, rashes. Hence there is a need to search better methods of management in *Vyanga.*

Key words-*Arjuna, Manjistha, Lepa, Vyanga, Lohita, Twak, Bhrajak Pitta*

How to cite this article: Kumari P, Dubey GK, Singh BP, Thakur B. A randomized comparative clinical study to evaluate the efficacy of Arjuna Lepa and Manjistha Lepa in the management of Vyanga. Int J Drug Deliv Technol. 2026;16(12s): 6-10. DOI: 10.25258/ijddt.16.12s.2

Introduction-

Beauty is one of the most valued aspects in the competitive era. Skin reflects the beauty of healthy individuals. Any impairment can cause cosmetic disfigurement. Today, cosmetics have become essential part of our daily routine but natural beauty is getting spoiled because of the harmful chemicals in some cosmetics. Thus, the demand of herbal product is increasing globally in cosmetic field. The concept of *Varna* dealt in Ayurveda is an innate entity of beauty. *Varna* represents all the parameters for healthy and radiant skin. In this aesthetic era, people are getting more conscious about beauty and the cosmetics. So, it becomes invariably essential to resort to *Varnya Upakramas.*

Vyanga is a disease of skin which is due to anger and exertion that leads to vitiation of *Vata* and combined with *Pitta*. It is characterized as *Mandala* on *Mukha Pradesha* that are *Niruja*, *Tanu* and *Shyavavarnayukta*. *Vyanga* is classified into four types named as *Vataja*, *Pittaja, Kaphaja* and *Raktaja*.[1]

Lohita is the site for *Vyanga* which is one of the *Kshudra Roga,* characterized by *Niruja* (painless), *Shyava Varna Mandala* (bluish black patches) occurring especially on the face. According to *Acharya Charak, Vyanga* is a disease of skin which is due to anger and exertion that leads to vitiation of *Vata* and *Pitta.*[2]

On the basis of clinical features, it is correlated with melasma or facial melanosis, one of the hyperpigmented disorders. Melasma is common pigmentary disorder characterized by bilateral, asymptomatic, light to dark brown macules on face. The etiopathogenesis of melasma includes UV radiation, Birth control pills, some phototoxic topical or Systemic medications, Hormonal disturbances, cosmetics and genetic factors. There are only 3 patterns of melasma, Centro fascial, Malar and Mandibular out of these Centro-fascial is commonest one. Women are more likely than man to develop this condition.[3]

Objectives-

To evaluate the comparative effect of *Arjuna Lepa* with *Manjistha Lepa* in *Vyanga.*

Materials & Methods

Study Design – It was Randomized, Comparative, Prospective and Interventional study Clinical trial was done with a randomized, parallel group

design. The Institutional Ethics Committee had previously approved the study, and C.T.R.I. registration had been completed. Registration no. of CTRI is as follow- CTRI/2022/07/043867

Selection of Subjects

The study will be conducted in patients of *Vyanga* registered in OPD and IPD of N.IA and *SSBH, Jaipur.* F The patients for the clinical study were selected from O.P.D. and I.P.D. of *Kriya Sharir* department, NIA Hospital. Selection was carried out on the basis of relevant history, signs, symptoms and laboratory investigations.

An informed consent was taken before the trial. Total 32 patients were registered for the study, but 30 subjects had completed the trial. Selected patients were divided randomly by using the computerized method of randomization into 2 Groups, Namely Group A, Group B. Each group had 15 patients.

Inclusion criteria –

Subjects of either sex between the age group of 18-60 years.

Subjects with classical sign and symptoms of *Vyanga* (Melasma).

Exclusion criteria –

Subjects suffering from any severe systemic or skin diseases.

Withdrawal criteria

During trial, if any serious illness or any adverse effects appears which requires urgent treatment. Subject wants to withdraw from the clinical trial.

Sample Design –

Sampling frame – For this study, apparently healthy subjects were selected from OPD and IPD of NIA and SSBH, Jaipur

Sampling Technique – Randomized control clinical trial (case control study)

Ethical Clearance – Selected research problem was presented in front of Institutional Ethical Committee (IEC) with its aim, objectives and probable outcome. After thorough discussion on ethical aspects related t**d.** present study, it was approved by IEC, National Institute of Ayurveda, Jaipur (letter number IEC/ACA/2021/02-52)

Clinical Examination

The patients who had signed up for the trial were thoroughly assessed according to case report form. It contains information about patients' names, ages, genders, marital status, socioeconomic status, occupation, education, religion, diet, and other general characteristics.

Study interventions

The patients were chosen irrespective of their age, gender, religion, occupation & other factors. The patients were divided into two groups using a computerized random sampling procedure.

Group 1: *Arjuna Churna* + *Madhu* (External application) for 45 days.

Dose – 3-6gm as per area of patches

Thickness- 1/2 Angula Pramana

Duration- *Lepa* should not be removed before it gets dried.

Group 2: *Manjistha Churna* + *Madhu* (External application) for 45 days.

Dose – 3-6gm as per area of patches

Thickness-1/2 *Angula Praman*

Duration- *Lepa* Should not be removed before it gets dried

Method for application of *Arjuna Lepa*:

After carefully cleansing the face, all patients were instructed to use *Arjuna Lepa* with honey over the affected part (in the right quantity according to the size of the lesion). It must be cleaned once it begins to dry. This technique should be performed twice a day.

Method for application of *Manjistha Lepa*:

After carefully cleansing the face, all patients were instructed to use *Manjistha Lepa* with honey over the affected part (in the right quantity according to the size of the lesion). It must be cleaned once it begins to dry. This technique should be performed twice a day.

Duration of study - 45 Days

Follow up- Assessment of the all subject will be done after each 15 days (on 0th day, 15thday& 30th day) during the trial in both groups and post assessment will be done on 45th day on the basis of MASI score.

Criteria for Assessment –

Assessment will be done on the basis of

- 1.MASI Score
- 2.Varna Prasadana (Change in texture, Lusture of skin)

Observation and results-

The demographic data such as age, sex, religion, habitat etc., the *Dashvidha* and *Ashthavidha Pariksha* and the data related to disease were collected. They were presented in tabular form. The results were prepared by using "Graphpad Instat" software and presented in the tabular form as mean, % of relief, SD, SE, P value. Intergroup comparison was done to assess comparative effects of both groups.

Parameters	**Maximum observations in both groups**

	Group A	Frequency	Group B	Frequency
Skin type	Normal	6 (40%)	Oily	6 (40%)
Facial Hygiene	Good	12 (60%)	Good	18 (60%)
Use cosmetics	Yes	10 (66.66 %)	Yes	8 (53.33 %)
Causative factors	Sunlight	7 (46.6%)	Sunlight	9 (60%)
Chronicity	Up to 1 year	9 (60%)	Up to 1 year	7 (46.66 %)
No. of patches	1-2	11 (73.33 %)	1-2	11 (73.33 %)
Site of onset	Malar	7 (46.66 %)	Malar	8 (53.33 %)
Darkness	Moderate	8 (53.33 %)	Moderate	8 (53.33 %)
Distribution of Patches	10-29%	7 (46.66 %)	10-29%	11 (73.33 %)
Homogenity	<1.5 cm	8 (53.33 %)	<1.5 cm	13 (86.66 %)
Texture of patches	Normal	7 (46.66 %)	Normal	6 (40%)
Lusture	Unctuous	8(53.33)	Non-lustrous	7 (46.66 %)

Effect Of Therapy on Subjective Parameters
Table showing the intra-group comparison of the effect of *Arjuna Lepa*
Subjective parameters in Group A (Wilcoxon matched paired single ranked test)

GROUP- A									
SYMPTOMS	**N**	**Mean**		**Diff.**	**% of Change**	**SD ±**	**SE ±**	**P**	**R**
		BT	AT						
Area of Patches	15	2.27	1.73	0.53	23.53	0.92	0.24	0.1250	**NS**
Darkness	15	2.2	1.87	0.33	15.15	0.62	0.16	0.1250	**NS**
Homogenity	15	2.47	1.87	0.60	24.32	0.51	0.13	0.0039	**VS**
Texture	15	1.67	1.47	0.20	12	0.49	0.13	0.3750	**NS**
Lusture	15	1.60	1.93	-0.33	20.83	0.49	0.13	0.0625	**NS**
MASI Score	15	6.45	4.36	2.09	32.44	2.06	0.53	0.0020	**VS**

Table Showing the intra-group comparison of effect of *Manjistha Lepa* on Subjective parameters in Group B (Wilcoxon matched paired single ranked test)

GROUP- B									
SYMPTOMS	**N**	**Mean**		**Diff.**	**% of Change**	**SD ±**	**SE ±**	**P**	**R**
		BT	AT						
Area of Patches	15	2.133	1.733	0.40	18.75	0.74	0.19	0.1250	**NS**
Darkness	15	1.93	0.87	1.07	55.17	1.03	0.27	0.0078	**VS**
Homogenity	15	2.87	2.73	0.13	4.65	0.35	0.09	0.5000	**NS**
Texture	15	1.93	1.87	0.07	3.45	0.74	0.19	>0.9999	**NS**
Lusture	15	1.67	1.47	0.20	12	0.49	0.13	0.3750	**NS**
MASI Score	15	6.99	6.43	0.56	8.02	0.83	0.21	0.0312	**S**

InterGroup Comparison of Effect of Therapies
Table Showing the inter Group comparison on subjective parameters (Mann Whitney U test)

Variables	**Mean Diff.**		**SD±**		**SE±**		**U'**	**P**	**R**
	Group A	**Group B**	**Group A**	**Group B**	**Group A**	**Group B**			
Area of Patches	0.5333	0.4000	0.9155	0.7368	0.2364	0.1902	108.5	0.8181	**NS**

Darkness	0.333	1.067	0.6172	1.033	0.1594	0.2667	70.50	0.0440	**S**
Homogenity	0.6000	0.1333	0.5071	0.3519	0.1309	0.0908	60	0.0209	**S**
Textutre	0.333	0.5333	0.4880	0.7432	0.1260	0.1919	100	0.5998	**NS**
Lusture	0.333	0.333	0.4880	0.4880	0.1260	0.1260	112.5	>0.999	**NS**
MASI Score	2.093	0.5600	2.060	0.8322	0.5320	0.2149	63.50	0.0319	**S**

2. **Overall effect-**

When comparing the symptomatic improvement in the two Groups, it was discovered that Group A had the highest average percent of relief (21.37 %), followed by Group B (17%). It indicated that effect of treatment was high in Group A in comparison to Group B.

Result

Manjistha Lepa is effective in treating *Vyanga* as that of Arj*una Lepa* on the parameter of Darkness. Change in normal colour of body is called *Twak Vaivarnya* which is an important symptom of *Vyanga*. The pathology is located in the Lohita layer of the skin and discoloration occurs due to vitiated *Bhrajaka Pitta* and *Udana Vata* along with vitiating *Rakta Dhatu*.[4] According to *Sushruta Varnaprasadana* is one of function of *Rakta Dhatu*.Clinically *Manjistha Lepa* was more effective in patients having oily skin, because it has *Ruksha* in *Guna* & *Ushna Virya*.[5] So, it absorbed the excessive oil from the face and the equilibrium state of the skin is maintained. It has *Rakta sodhak* property and is also mentioned in *Varnya gana*.

Statistically, *Arjuna Lepa* was effective on treating *Vyanga* as that of *Manjistha Lepa* on the parameter of MASI score. MASI score is calculated on the parameters of area of involvement, darkness of patches, distribution pattern (size of patches). If slight change occurs in these parameters, MASI score also shows change.

Discussion

The bark of the *Arjuna* tree is characterized by its taste, which is primarily astringent (*Kashaya Rasa*), and it possesses certain qualities such as being light (*Laghu*) and dry (*Ruksha*). It has a cooling potency (*Sheeta Veerya*) and is known for its ability to primarily balance the *Pitta Dosha* and promote healthy blood (*Rakta*) properties.[6] Its astringent taste (*Kashaya Rasa*) is effective in addressing imbalances related to *Pitta Dosha* and helps restore natural skin color. The cooling nature (*Sheeta Veerya*) of *Arjuna* also combats *Pitta Dosha* and aids in purifying accumulated imbalances in skin pigmentation (*Vyanga*). The blood-purifying and skin-nourishing properties of *Arjuna* contribute to the alleviation of imbalances within the skin. Furthermore, the astringent characteristics of *Arjuna* may have a positive impact on skin toning and firmness, potentially enhancing overall skin appearance. *Arjuna* bark contains antioxidants like flavonoids and tannins, which help neutralize free radicals in the body.[7]

Flavonoids have been extensively used in cosmetics due to their anti-inflammatory properties. These compounds are renowned for their antioxidant properties and their ability to effectively remove free radicals from the skin. The antioxidant properties are closely linked to their calming effects on the skin, and there is increasing evidence to suggest that polyphenolic compounds may be beneficial in sunscreens, as they are capable of absorbing UV light and providing photo stabilization.

Additionally, *Arjuna* bark extract has been found to be beneficial for skin, as it has been shown to reduce Tans Epidermal Water Loss, improve skin moisturization, reduce scaliness, and improve elasticity. Additionally, it has been found to increase blood microflow and sebum content, as well as improve skin thickness in postmenopausal women, and reduce sagging skin. In the case of Darkness, the effect of therapy was more in *Manjistha*. It may be due to its *Varnya ,Raktasodhak, Kapah-pitta* hara property. *Manjistha* contains anthraquinones, including rubiadin, purpurin, and munjistin. These compounds are believed to have skin-brightening properties, helping to reduce skin darkness and improve complexion.[8]

Manjistha chemical constituents include munjistin, flavonoids, puroxanthin, pseudo purpurin, and free alizarin as well as glycoside. these components possess medicinal properties that can be beneficial in the treatment of a variety of skin-related issues, such as discoloration, pigmentation, allergic reactions, eczema, and sunburns. Additionally, *Manjistha* has been found to purify the blood, making it useful in the treatment of blood-related illnesses. Furthermore, it has been reported to improve the complexity of the skin.[9]

Madhu with its *Tridosha Prashamana* property may affect Doshas which are vitiated in *Vyanga (Vata, Pitta*). *Madhu* with its *Yogavahi Guna* it enhances the property of *Arjuna Twak Churna*. [10]The topical application of the medicine aims at providing high concentrations locally. *Madhu* with its *Prasadana* property improves the skin complexion as it has the *Varnyakar* property.

Honey is used in Ayurvedic medicine, a traditional Indian subcontinental medicine, to heal cuts and wounds, eczema, dermatitis, burns, skin illnesses, and Fournier's gangrene. Similarly, Quranic medicine in Pakistan described honey coupled with cinnamon powder as a therapy for pustules, eczema, ringworm, and a range of other skin disorders, and indigenous people in Burkina Faso, Africa, have been known to utilize honey as a skin cleansing agent. [11]

When the average percent of relief in both groups were compared, it was discovered that Group A had a larger average percent (21.37%) of improvement who received *Arjuna Lepa*, followed by Group B (17%) who received *Manjistha Lepa*.

Conclusion

Arjuna Lepa was effective in homogenicity parameter and Manjishtha lepa has effective in darkness of Masi score of *Vyanga.*

Acknowledgments

The authors are thankful to all the study participants for their participation in the study. They also thank all the in-charges and staff of participating centres for providing logistic and technical support during data collection.

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