Self-controlled clinical trial to evaluate the efficacy of *Mukhakantivardhaka Lepa* and *Patoladi Ghanavati* in *Twakvaivarnya* (hypermelanosis)

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Abstract

Background: Beauty is not only a source of joy but also gives confidence to some extent. *Ayurvedic* cosmetology starts from mother's womb and continues with *Dinacharya* (daily routines), *Ratricharya* (diet and regimen for night), *Ritucharya* (seasonal diet and regimen), etc. The symbiosis between cosmetology and *Ayurveda* is the most ancient one. With this research interest, the present study has been undertaken to assess the efficacy of *Mukhakantivardhaka Lepa* and *Patoladi Ghanavati* in *Tvakvaivarnya* (hypermelanosis). **Objectives:** To evaluate the efficacy of *Mukhakantivardhaka Lepa* and *Patoladi Ghanavati* in *Tvakvaivarnya* (hypermelanosis). **Materials and Methods:** This study was a double-armed clinical trial in which 62 patients having signs and symptoms of *Tvakvaivarnya* were selected belonging to the age group of 16–40 years and received *Mukhakantivardhaka Lepa* and *Patoladi Ghanavati* for 60 days with follow-up after every week. For the purpose of perfect diagnosis and assessment of all aspects of the disease, a special research proforma was prepared. **Results:** Both the groups showed 100% improvement in associated symptoms. Regarding the overall effect of therapy in both the groups, moderate improvement was high following marked improvement. No adverse reactions were documented. **Conclusion:** *Mukhakantivardhaka Lepa* and *Patoladi Ghanavati* work excellently on *Tvakvaivarnya* (hypermelanosis) and improve skin complexion.

Keywords: Mukhakantivardhaka Lepa, Patoladi Ghanavati, Tvakvaivarnya, Varnaprasadana

Introduction

Beauty consciousness and the knowledge of application of herb, mineral, and animal products are as old phenomena as the human existence. *Ayurveda* determines beauty by *Prakriti* (body constitution), *Sara* (structural predominance), *Samhanana* (compactness of body), *Tvak* (skin), *Pramana* (measurement), and *Dirghayu Lakshana* (symptom of long life).^[1] Beauty is the desire of every individual to give pleasure to the sense. Melanin pigmentation is a group of disorders characterized by abnormal color of skin that results from increased or decreased melanin production from a normal number of melanocytes in the skin. It includes both hypermelanosis and hypomelanosis. In hypermelanosis, there is formation of flat, distinct, discolored area of skin <1 cm widely known as macules and areas of discoloration that are larger than 1 cm which are referred to as patches particularly on face. Melanin pigmentation disorder can

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be correlated with *Tvakvaivarnya* in *Ayurveda*, but in this study, hypermelanosis has been considered as *Tvakvaivarnya*. According to commentators *Arunadatta* and *Hemadri*, the meaning of *Vaivarnya* is "diversity from normal color or complexion which is not like the normal color of *Tvacha* (skin).^[2,3] Hence, the term *Tvakvaivarnya* means the abnormality in the color of *Tvacha*, i.e., the discoloration of skin. *Ayurveda* considers all skin disorders as a *Kushtha* and some conditions are mentioned under *Kshudra Roga*. In *Ashtanga Hridaya Nidana Sthana* chapter 14, it has been described that the conditions responsible for

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Tvakvaivarnya (hypermelanosis) are considered as a Kushtha.[4] Kushtha runs as a chronic disease which is generally considered as difficult to cure and even if it is cured relapses are common. Though modern medical treatments are cheaper and easily available, they are not useful for complete cure of the disease, whereas surgical treatment requires costly instrument, as well as a high skill. This work was an effort to explore the Ayurvedic line of management of Tvaka Vaivarnva. Hence, in the present study, an attempt has been made to find out some potent and perfect remedy for Tvakvaivarnya (hypermelanosis), which is useful to regain the original beauty of face and to add an esthetic value to the personality. Varnaprasadana,^[5] which has been described as bringing out the clarity of Varna, is thus applicable in Tvakvaivarnya (hypermelanosis). The whole study was designed with the hypothesis of finding out the Varnaprasadana effect of Mukhakantivardhaka Lepa and Patoladi Ghanavati in the disease Tvakvaivarnya (hypermelanosis).

Materials and Methods

A total of 62 patients irrespective of sex, caste, religion, and socioeconomic status who were diagnosed to have *Tvakvaivarnya* (hypermelanosis) were selected from the outpatient department (OPD) of Basic Principle, IPGT & RA, Jamnagar, Gujarat, India. The study was approved by the IPGT & RA's Institutional Ethics Committee (No–PGT/7/-A/Ethics/2015-16/1470, Dt. 25/08/15). The study has been registered in Clinical Trial Registry, India (No. CTRI/2016/02/006690). An informed consent was obtained from each patient before starting the course of treatment. Fair and lovely color grading scales has been used to assess the color of *Vivarna Mandala* (Discolored patches).

The study was an open-labeled random clinical trial. Sampling technique was simple random sampling by lottery method.

Diagnostic criteria

Patients were diagnosed and assessed thoroughly on the basis of *Ayurvedic* classical signs and symptoms of *Tvakvaivarnya* (hypermelanosis) and were examined on the basis of a specially prepared proforma along with a detailed history. All the patients were subjected to routine hematological examination (hemoglobin%, total white blood cell (WBC), differential leucocyte count (DLC), total red blood cell count (RBC) and blood group and biochemistry investigation [Random Blood sugar (RBS), S.G.P.T., S.G.O.T, Serum bilirubin] to assess the general condition before treatment.

Inclusion criteria

- 1. Patients having Tvakvaivarnya (hypermelanosis) on face
- 2. Patients aged between 16 and 40 years
- 3. Patients were selected without any bar of race, religion, sex etc.

Exclusion criteria

1. Patients having *Tvakvaivarnya* (hypermelanosis) as the symptom of major systemic disease or as a result of side effect of any drugs

- 2. Patients having any allergic condition
- 3. Patients having *Tvakvaivarnya* (hypermelanosis) due to hormonal causes
- 4. Patients having the chronicity of disease for more than 3 years
- 5. Patients having *Tvakvaivarnya* (hypermelanosis) since birth such as nevus of OTA etc.
- 6. Patients aged <16 years and >40 years were excluded from the study.

Drug

Both Mukhakantivardhaka Lepa and Patoladi Ghanavati were prepared in the Pharmacy of Gujarat Ayurved University, Jamnagar. Mukhakantivardhaka Lepa is the formulation mentioned in Sharangadhara Samhita of Sharangadhara, Uttara Khanda, chapter 11, which acts as Vyangaghna and Mukhakantida.^[6] Patoladi Ghanavati is a formulation mentioned in Chakradatta, Visarpa-Visphota Chikitsa. It acts as Pitta-Shleshmahara, Kandunashaka and Tvakdosha Nashaka^[7] [Tables 1 and 2].

Grouping: All the patients were divided into two groups as follows: [Table 3]

- Group A: In this group, 31 patients were treated with *Mukhakantivardhaka Lepa*
- Group B: In this group, 31 patients were treated with *Patoladi Ghanavati*.

Table 1. Ingredients of Mukhakantivardhaka Lena

Content	Latin name	Parts used	Quantity						
Rakta Chandana	Pterocarpus santalinus Linn.f.	Heartwood	1 part						
Manjishtha	Rubia cordifolia Linn.	Root	1 part						
Kushtha	Saussurea lappa C.B.Clerke	Root	1 part						
Lodhra	Symplocos racemosa Roxb.	Bark	1 part						
Priyangu	Callicarpa macrophylla Vahl.	Flower	1 part						
Vata	Ficus benghalensis Linn.	Bud	1 part						
Masura	Lens culinaris Medik.	Seed	1 part						
Madhu	Apis cerana		QS						

Table	2:	Contents	of	Patoladi	Ghanava
lanc	<u> </u>	OUTICITIES	U	<i>i</i> attriaui	ananava

Content	Latin name	Parts use	Parts
Rakta Chandana	Pterocarpus santalinus Linn.f.	Heartwood	1 part
Patola	Trichosanthes dioica Roxb.	Leaves	1 part
Nimba	Azadirachta indica A. Juss	Bark	1 part
Mustaka	Cyperus rotundus Linn.	Root	1 part
Guduchi	<i>Tinospora cordifolia</i> Miers ex Hook.f. and Thoms.	Stem	1 part
Methika	Trigonella foenum-graecum Linn.	Seed	1 part
Katuki	Picrorhiza kurroa Rovle ex Benth	Root	1 part
Patha	Cissampelos pareira Linn.	Root	1 part
Haridra	Curcuma longa Linn.	Rhizome	1 part
Yavasa	Alhagi camelorum Fisch	Whole plant	1 part
Haritaki	Terminalia chebula Retz.	Fruit	1 part
Bibhitaki	Terminalia bellirica Roxb.	Fruit	1 part
Amalaki	Emblica officinalis Gaertn	Fruit	1 part

General observation

A total of 62 patients were registered in the present study who were divided into two groups, of which 60 patients completed the treatment and 2 patients had withdrawn the treatment against medical advice. A majority of the patients, i.e., 51.31% belonged between 25 and 32 years of age group, 95.1% patients were Hindu, 79.03% patients were female and 41.9% were belonging to upper middle class. Majority of the patients, i.e., 51.6% had completed postgraduation, 78.33% were addicted to tea and 100% were from the Sadharana Desha. A majority, i.e., 80.6% of the patients reported consuming Katu (91.9%) Amla and Lavana (59.6%), Rasa and Ushna (62.9%) and Ruksha Guna-dominant diet (64.5%). Nearly 72.5% of patients had Madhyama Abhyavaharana Shakti (eating capacity), 69.3% had Madhyama Jarana Shakti (digestive capacity), 77.4% had Madhyama Satva, 46.7% of patients had Vishamagni, 29% of patients had Mandagni, 61.29% of patients had chronicity of 1-3 years, 70.9% had progressive disease and 45.1% of patients had exposure to sun rays as an aggravating factor. Tension as an aggravating factor was observed in approximately 54.8% of the patients, 58% of the patients had irregular bowel habits, and 51.61% of the patients had Krura Koshtha. Majority of patients (59.67%)

Table 3: Drug selection and posology

Section	Group A	Group B
Name of drug	Mukhakantivardhaka Lepa	Patolaadi Ghanavati
Dose	Quantity sufficient	2 Vati (BD) with Lukewarm water
Preparation of drug	Lepa (with honey)	Ghanavati
Route of administration	Local application on face (<i>Pralepa</i>)	(Orally) Mukh Dwara
Time of administration	Evening (Sayamkala)	After meal (Bhojanoparanta)
Duration	60 days	60 days

had *Vata-Pittaja Prakriti*, 100% of patients had both *Rasa* and *Rakta Dhatu* vitiation, 29.03% had a positive family history and 64.5% had a positive past history of this disease. Among them, 77.4% of the patients had macule and 25.8% had patch.

The chief complaint of *Vivarnamandala* was seen in all the patients in the present study. As associated symptoms, a majority, i.e., 53.22% of patients had *Daha* (burning sensation), 83.8% had *Rukshata* (dryness), 16.12% had *Snigdhata* and 93.5% had *Kandu* (itching).

Total Effect of therapy:

Steps for calculating overall percentage of improvement of individual patient:

All the BT score before treatment of every symptom of a patient is added.

All the AT scores after treatment of every symptom of that patient is added.

Overall percentage of improvement of each patient was calculated by the formula:

STATISTICAL ANALYSIS:

The obtained data was analyzed statistically and presented as mean \pm SEM (Standard Error of Mean). The change in sign and symptom scores was analyzed by 'Wilcoxon Signed rank test'. The values were considered significant at the levels of *p* <0.05, *p* <0.01 and *p* <0.001.

Results

The score for color of patches was reduced by 61% in Group A, which was statistically highly significant (P < 0.001), while it was reduced by 59.75% in Group B, which was also

Table 4: Total effect of therapy on chief complaints of sixty patients

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Total effect of therapy	п	BT M	AT M	Percentage relief	SD	SE	W	t	Р	Significant
Group A	30	15.1	4.5	69.82	2.8	0.52	-465	-465	< 0.001	HS
Group B	30	15.3	4.7	68.98	2.2	0.41	-465	-465	< 0.001	HS
SD: Standard deviation	SE: Standa	rd error HS	· Highly sig	nificant (BT) M · Mean	(Bafora tr	antmont) (A	$(T) M \cdot M_{eq}$	n (After tre	atment)	

SD: Standard deviation, SE: Standard error, HS: Highly significant, (BT) M : Mean (Before treatment), (AT) M : Mean (After treatment)

Table 5: Total effect of therapy on associated complaints of sixty patients										
Total effect of therapy	п	BT M	AT M	Percentage relief	SD	SE	W	t	Р	Significant
Group A	30	3.6	0	100	1.2	0.22	-465	-465	< 0.001	HS
Group B	30	3.6	0	100	0.84	0.15	-465	-465	< 0.001	HS

SD: Standard deviation, SE: Standard error, HS: Highly significant, (BT) M : Mean (Before treatment), (AT) M : Mean (After treatment)

Table 6: Overall effect on chief & associated complaints of sixty patients										
Total effect of therapy	п	BT M	AT M	Percentage relief	SD	SE	W	t	Р	Significant
Group A	30	15.1	4.5	69.82	2.8	0.52	-465	-465	< 0.001	HS
Group B	30	15.3	4.7	68.98	2.2	0.41	-465	-465	< 0.001	HS
SD: Standard deviation SE: Standard arrow US: Highly significant (BT) M: Maan (Bafara tractment) (AT) M: Maan (After tractment)										

SD: Standard deviation, SE: Standard error, HS: Highly significant, (BT) M : Mean (Before treatment), (AT) M : Mean (After treatment)

Table 7: Overall effect of therapy in both groups								
Effect of therapy	Number of patients							
	Group A (%)	Group B (%)						
Complete remission (100%)	0	0						
Marked improvement (>75%)	6 (20)	5 (16.6)						
Moderate improvement (50%-75%)	23 (76.6)	25 (83.3)						
Mild improvement (25%-50%)	1 (3.3)	0						
Unchanged (<25% or no relief)	0	0						

statistically highly significant (P < 0.001). The score of numbers of the patches was reduced by 58.4% in Group A, which was statistically highly significant (P < 0.001), while in Group B, it was reduced by 58.6%, which was also statistically highly significant (P < 0.001). The affected area was reduced by 55.6% in Group A, which was statistically highly significant (P < 0.001), while in Group B, it was reduced by 57.8%, which was also statistically highly significant (P < 0.001), while in Group B, it was reduced by 57.8%, which was also statistically highly significant (P < 0.001) [Figures 1-8].

Chief complaints

Percentage wise, both the groups showed equal results. Highly significant results were found in both the groups [Table 4].

Associated complaints

Percentage wise, both the groups shows equal results. Highly significant results were found in both the groups [Tables 5-7].

Discussion

A majority of patients (79.03%) were females, as females have more changes in their hormonal level of concentrations due to monthly cycles and as a result they are more prone to have Tvakvaivarnya (hypermelanosis) in certain age groups and at certain times than males. A majority of patients (53.2%) were belonging to upper middle class. The awareness of esthetic problem initiates them to visit the hospital for consultation. A majority, i.e., 51.6% of the patients had completed their postgraduation. Among all the patients, 78.33% of patients were addicted to tea. By its virtue, causing Vidaha of Rakta, it increases the Ushna-Tikshna Guna of Agni. Further it cause Dhatvagni Dushti which mainly leas to formation of Dushti Rasa and Rakta Dahtu. Leading to Tvaka Vaivarnya. Here in this study maximum number of patients were student (70.9%) working man & women (12.8%). so they all head to stay outside their house for 8-9 hour per day. due to this face was directly exposed to the external environment and got easily affected by the environmental changes. Lepa should not apply at night according to our classics, that's why evening time was choosen for the time of drug application. As Yakrita and Pliha are the root organs of Raktavaha Srotasa, they also have a definite role in vitiation of *Rakta Dhatu*, which is the prime cause of Tvakvaivarnya (hypermelanosis). Moreover, the main sites of patches were cheeks, forehead, perioral area, chin and nose in most of the patients, as they are exposed to sun light directly. A majority of patients reported consuming Katu (Hot), Amla (Sour), Lavana (Salty) Rasa and Ushna (Hot) Guna (Property)-dominant diet. This type of diet aggravates the Pitta Dosha in the body which first vitiates the Rakta Dhatu and may result in Varna Vikriti (Discoloration). A majority of the patients had the habit of Viruddhashana (87%) and Adhyashana (59.6%). It hampers the state of Agni which leads to Dosha Prakopa (vitiation) giving rise to many diseases. In the present study, a majority of the patients (72.5%) reported with Madhvama Abhvavaharana Shakti (eating capacity), but a maximum number of patients (69.3%) were having Madhyama Jarana Shakti (digestive capacity). As a result, Mandagni (loss of appetite) was found in 29% of the patients whereas 46.7% of patients were having Vishamagni (irregular appetite). Acharva Charaka has stated that the wholesome food consumed in appropriate quantity by the respective Agni (digestive enzymes) according to the prescribed method certainly helps the individual in bringing out complexion without disturbing any elements.^[8,9,10] Hence, excess intake by impairing the status of Agni (digestive enzymes) can be considered as a cause of Tvakvaivarnya (hypermelanosis) due to Rasa and Rakta Dushti.[11] About 54.8% of patients had a distressed status of mind. Distressed, as an aggravating factor, was observed in approximately 66.1% of the patients. Moreover, a maximum number of the patients (77.4%) were of Madhyama Sattva. All these highlight the role of mental factor in causing the disease, and hence psychological factor is assigned as a cause of Vaivarnya. Out of 19 married patients, most of the patients had abnormal obstetric history, i.e., either abortion/miscarriage or cesarean. This can induce increased blood level of melanocytes stimulating hormone and stimulation of melanocyte activity. The increase in estrogen and progesterone may also play a role. Among the patients, associated symptoms were present in most of the patients, Daha (53.22%) and Rukshata (83.8%) were observed in majority of the patients, which is probably due to the involvement of Pitta and Vata Dosha in the disease.

Here, Kandu was observed in 93.5% of patients. Though Kandu mainly occurs due to the involvement of Kapha Dosha, vitiation or aggravation of Vata Dosha also leads to extreme dryness in the body and also in the nerves. The irritability in skin and nerves leads to Kandu (itching). This is the reason why a maximum number of patients were complaining of Kandu. In this study, a majority of the patients were using cosmetics such as bleaching cream, foundation cream and compact powder. All these are Tikshna and Ruksha and hence directly cause the Dushti of Bhrajaka Pitta and cause the disease. And also, they aggravate the disease, which was observed in most of the patients (50%). Family history was positive in the majority of patients (29%). Among these patients, family history was observed positive in most of the patients from maternal side. Tvak is mentioned as Matrija Avavava. Moreover, Varna is the entity which comes from the Satmya of mother. It suggests the role of genetic factor and modern science also considers the same thing. Past history was also present in some patients (64.51%). Krura Koshtha was observed in 51.61% of patients, and again a maximum number of patients (56.4%) reported with irregular bowel habits,

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Figure 1: Patient 1 – (a) Before treatment (Macule)[Group -A]



Figure 3: Patient 2 - (a) Before treatment (Patch) [Group -A]



Figure 5: Patient 1 – (a) Before treatment (Macule)[Group -B]

i.e., either constipated or with efforts. This may be due to the *Vata Dosha*, which further leads to the disturbance in *Agni* and hence, it actively participates in causing the disease. Regarding color of the patches, Group A showed better result than Group B.



Figure 2: Patient 1 - (b) After treatment (Macule)[Group -A]



Figure 4: Patient 2 – (b) After treatment (Patch) [Group -A]



Figure 6: Patient 1 – (b) After treatment (Macule)[Group -B]

In reducing the affected area of the patches, Group B showed better result than Group A. Both groups showed approximately equal result in reducing the number of patches.



Figure 7: Patient 2 – (a) Before treatment(Patch)[Group -B]

Probable mode of action of Mukhakantivardhaka lepa

When Dravya, that is, Mukhakantivardhak Lepa having Madhura (Sweet), Kashaya (Astringent) and Tikta (Bitter) is applied on Tvaka (Skin), by the process of Nipata, these Rasas act on Bhrajaka Pitta. The Rasas (taste) are said to possess two important Karmas that is Chhedana (Piercing) and Upashamana (alleviation).^[12] These Rasas do the Chhedana of Prakupita (vitiated), Vata and Pitta and Upashamana, which means that they do not allow the Utklesha of Doshas and maintain the equilibrium and thus pacify Pitta which is the main culprit in the causation of Tvakvaivarnya. Out of these seven drugs of Lepa, some of the drugs possess Snigdha (unctuous) Guna (property) and others possess Laghu (light) and Ruksha (dry) Gunas. Snigdha Guna is responsible for Mardava and Varnaprasadana, whereas Laghu and Ruksha are the properties of Agneva Dravya, which in turn are responsible for Prabha, Prakasa and Varna.^[13] Almost all the drugs selected are of Shita Virya and Shita Virya Dravyas which are endowed with Rakta Prasadana Karma. While explaining the direction for application of Lepa, it is said that the active principles of the drug enter through the Sira Mukha,^[14] hence after the entry of the drug by virtue of Virya, it enters the circulation. The selected drugs mainly are of Katu Vipaka. Vipaka is basically defined as Karma Nishthava, here the term Nishtha incorporates Jatharagni Dhatvagni and Bhutagni irrespective of their order. By virtue of Katu Vipak, Lepa clears the unwanted metabolites (Kledahara) and Meda lekhan^[15] and causes Prakrit Agni Karma. Then, continuous application of Lepa Dravya causes normalization of Bhrajakagni that results in Samyaka Paka of Lepa Dravya. On the other hand, Katu Vipaka leads to Srotoshuddhi and Samyaka Rasa vahana, and ultimately gives Varnaprasadana Karma.

Probable mode of action of Patoladi Ghanavati

Patoladi Ghanavati possesses Madhur, Tikta and Kashaya Rasas with dominancy of Guru, Snigdha Guna and a combination of Ushna and Shita Virya drugs exhibiting Tridoshshamaka property, thereby exerting curative action on Daha, Vrana and acts as Kushthaghna. Madhura Rasa



Figure 8: Patient 2 – (b) After treatment (Patch)[Group -B]

has properties of Prasadan and Balavarnakara. Hence, it improves fairness of the skin and bestows ideal skin texture. Due to Prinana property, possibly scar or Vranavastu gets healed which could be understood as providing nutrition to epidermal layer, maintaining its health. Kashaya Rasa brings about Rukshata and Laghuta, and reduces Sharira Kleda, which is primarily essential to achieve cure of the disease. Tikta and Katu Rasas have the properties of Dipan and Pachan, so they potentiate Jathragni and Dhatvagni. Further, they reduce the formation of Ama. With these properties, the drug causes Pitta Shamana and Kapha Chhedana, which leads to Prakrit Agni Karma and further causes Samyak Ahara Rasa Nirmana. Due to the predominance of Ushna Virya in the composition of Patoladi Ghanavati, it brings about pacification of Vata Dosha and also improves Dhatvagni. Due to Katu Vipaka, it causes Srotoshuddhi and Uttarottar Dhatu Nirmana which leads to the formation of normal Rasa, Rakta Dhatu and further leads to Varnaprasadana. And on the other hand, normal Mamsa Dhatu leads to the formation of normal Upadhatu, i.e., Tvacha.

Conclusion

From this study, it can be concluded that *Mukhakantivardhaka Lepa* and *Patoladi Ghanavati* provide highly significant results in improving the color of patches and diminishing the intensity of the darkness and number of the patches. By the virtue of the *Varnaprasadana* drug, function of *Bhrajaka Pitta* is improved, disease can be controlled and the normal color of the skin can be regained. During the therapy, no untoward side effect was reported by any patient. Hence, *Mukhakantivardhaka Lepa* and *Patoladi Ghanavati* are safe and effective formulations which can be prescribed in *Tvakvaivarnya*.

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Conflicts of interest

There are no conflicts of interest.

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