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# Clinical evaluation of *Varnya Gana Lepa* in *Vyanga* (melasma)

**Pallavi G., Virupaksha Gupta K. L.[1], Shreevathsa M.[2], Vasudev A. Chate[2], Balakrishna D. L.[3]**

Departments of Basic Principles and [1]Rasa Shastra and Bhaishajya Kalpana, Gaur Brahman Ayurvedic College, Rohtak, Haryana, [2]Departments of Basic Principles and [3]Panchakarma, Government Ayurveda Medical College, Mysore, Karnataka, India

## Abstract

**Background:** *Vyanga* type of *Kshudra Roga*, characterised by *Niruja* (painless), *Shyava Varna Mandalas* (bluish black patches) occurring especially on the face. The clinical features correlate with melasma, which is an acquired chronic hyperpigmentation disorder, usually seen in women of childbearing age. The drugs which constitute the *Varnya Gana Lepa* bestow the normal *Varna* (color) by virtue of their qualities and actions. **Aim:** To determine the efficacy of *Varnya Gana Lepa* in the management of *Vyanga*. **Materials and Methods:** The study was a single armed clinical trial in which total 40 patients of *Vyanga* belonging to the age group of 16–60 years were enrolled. Paste for external application was prepared by mixing the fine powders of 10 drugs (in equal quantity) of *Varnya Gana* with lukewarm water and advised to apply *Lepa* twice daily for 15 days on affected part. The different parameters such as skin color, lesion color, texture-dryness/oiliness, luster, number and size of the lesions, darkness, area and homogeneity of lesion, itching, burning sensation, and melasma area severity index (MASI) score were assessed. **Results:** There was statistically significant improvement in MASI scores, but in overall assessment, 64.5% patients had mild improvement. Clinical improvement was more evident in darkness parameter when compared to other parameters. **Conclusion:** The study concludes that *Varnya Gana Lepa* is a safe and effective formulation in the management of *Vyanga* (melasma).

**Key words:** Melasma, *Varnya, Varnya Gana Lepa, Vyanga*

## Introduction

Acquired hyper-pigmentation disorders of the skin are among the most common complaints in a general dermatology clinic. Among those, melasma is known for causing significant impact on quality of life, including a negative effect on the patient's emotional well-being and social life. Despite the advent of powerful pigment-targeting lasers, the treatment for melasma remains challenging. In the United States alone, approximately 5–6 million individuals are afflicted with melasma of which majority are females (90–95%). In Asia, it is a common diagnosis and can reach an incidence of 0.25–4% of cases seen in any dermatology institution.[1] Melasma should not be dismissed as simply a cosmetic entity because it often evokes emotional distress. In addition, stigma may be associated with melasma, particularly in Asian cultures.

Melasma is a chronic, acquired cutaneous, relapsing hypermelanosis characterized by hyperpigmented patches on sun-exposed areas of the face, neck, and forearms.[2] Exposure to ultraviolet (UV) radiation is believed to be the leading factor in its development. Ayurveda refers this condition as *Vyanga* where in *Vata Pitta Dosha* as well as *Manasika Nidanas* (psychological etiological factors) such as *Krodha* (anger), *Shoka* (sorrow), and *Ayasa* (mental exertion) are the main culprits.[3]

The treatment modalities and other management strategies for hyper-pigmentation are usually unsatisfactory as it shows exacerbation and remission from time to time because of various influencing factors such as frequent exposure to sun rays, pollution, stress, and hormonal variations. *Bahi Parimarjana Chikitsa* (external applications) has a major role to play in the treatment of *Vyanga*. Charaka

**Address for correspondence:** Dr. Pallavi G.,
Lecturer, Dept. of Basic Principles, Gaur Brahman Ayurvedic College, Brahmanwas, Rohtak - 126 101, Haryana, India.
E-mail: drgpallavi@gmail.com



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Samhita reveals a major group of drugs that is, *Varnya Gana* (10 drugs) namely *Chandana* (*Santalum album* L.), *Tunga* (*Calophyllum inophyllum* L.), *Padmaka* (*Prunus cerasoides* D. Don), *Usheera* (*Vetiveria zizanioides* L.), *Madhuka* (*Glycyrrhiza glabra* L.), *Manjishtha* (*Rubia cordifolia* L.), *Sariva* (*Hemidesmus indicus* [L.] R.Br.), *Payasya* (*Pueraria tuberosa* [Willd.] DC), and *Sita Lata* (*Cynodon dactylon* [L.] Pers.). *Varnya Gana* is basically meant for the task of restoring the natural color and complexion of the body. It is useful both for *Antah Parimarjana* (purificatory therapies) as well as *Bahi Parimarjana* (external application).[4] The present study was aimed at evaluating the efficacy of an Ayurvedic formulation-*Varnya Gana Lepa* in *Vyanga* (melasma).

## Materials and Methods

Total 40 patients irrespective of sex, caste, religion, and socioeconomic status who were diagnosed to have *Vyanga* were selected from the Outpatient Department and Inpatient Department of Government Ayurveda Medical College (GAMC), Mysore, Karnataka. The study was approved by the GAMC, Mysore, Institutional Ethics Committee (No. GAMC/AS/2010-5; Dt 17/04/2010). The study has been registered retrospectively in Clinical Trial Registry, India (No. CTRI/2012/06/002729). An informed consent from each patient was obtained before starting the course of treatment. The study design was a single group clinical –interventional study of 15 days with a pre, post, and follow-up assessment after 15 days.

### Diagnostic criteria

Patients characterized with *Niruja* (painless), *Shyava* (bluish black), *Tanu Mandalas* (macules) on the face were diagnosed to have *Vyanga*.

### Inclusion criteria

Patients fulfilling the diagnostic criteria, between the age group 16 and 60 years, irrespective of sex, religion, occupation, and chronicity were selected for the study.

### Exclusion criteria

Hyperpigmentation caused due to any systemic diseases such as Addison's disease, Cushing syndrome and systemic lupus erythematosus, hyperpigmentation since birth like nevus and those caused by tumors such as malignant melanoma.

### Posology

*Lepa* (paste) was prepared by using fine powder of 10 *Varnya Gana* drugs and luke warm water as media for mixing. A thick paste was prepared out of it. The patients were advised to wash the face with lukewarm water followed by application of *Lepa* from medial to lateral direction (opposite to the direction of hair follicles) in sufficient quantity, so as to cover the affected areas (moderate thickness) effectively. Patients were advised to apply freshly prepared *Lepa* twice daily (morning and evening), not to apply over the previous *Lepa* and at night time. Patients were advised to wash the face with lukewarm water once the *Lepa* gets dried (after about 15–20 min) and not to expose to sun during the period of treatment.

The raw drugs were procured from the local market of Udupi and Mysore and authenticated at the Department of Dravya Guna, GAMC, Mysore, Karnataka.

### Assessment criteria

The effect of therapy was assessed on the basis of subjective and objective criteria.

#### *Subjective criteria*

It includes itching and burning sensation. A grading system was adopted for assessment:

| Parameters | Grade |
|---|---|
| Itching | |
| No itching | 0 |
| Mild itching (occasional, does not disturb routine) | 1 |
| Moderate itching (frequent itching, disturbs routine activity but not sleep) | 2 |
| Severe itching (disturbs both routine and sleep) | 3 |
| Burning | |
| No burning | 0 |
| Mild burning (occasional, sensation mostly when exposed to sun) | 1 |
| Moderate burning (frequent burning which increases when exposed to sun) | 2 |
| Severe burning (continuous burning without sun exposure) | 3 |

#### *Objective criteria*

It includes skin/lesion color, texture (dry/oily), luster, number of lesions, size of lesions, darkness of the lesion, area of involvement, and homogeneity of the lesion.

**Skin color**

The method adopted to assess the skin color and lesion color through the color grading scale. Fair and lovely fairness meter was used for this purpose. It comprises 26 grades of color [Figure 1].

| Parameters | Score |
|---|---|
| Skin texture (dryness) | |
| Absent | 0 |
| Mild (not seen but felt) | 1 |
| Moderate (stretching of the skin that a person feels) | 2 |
| Severe (visible dryness chapping of skin-hardness of skin) | 3 |
| Skin texture (oiliness) | |
| Absent | 0 |
| Mild (not seen with naked eye) oiliness felt by touch (no need to wash face frequently, only 1-2 times) | 1 |
| Moderate (visible on skin, need to wash face frequently) | 2 |
| Severe (excessive oiliness, formation of acne) | 3 |
| Skin luster | |
| Poor | 1 |
| Mild | 2 |
| Moderate | 3 |
| Good/radiant | 4 |
| Number of lesion | |

*Contd...*

| Parameters | Score |
|---|---|
| 1-2 | 1 |
| 3-4 | 2 |
| 5-6 | 3 |
| >6 | 4 |
| Size of lesion (in cm) | |
| 0-2 | 1 |
| 3-4 | 2 |
| 5-6 | 3 |
| >6 | 4 |

Note: When lesions or patches are multiple, the size of the largest lesion is taken into consideration

### Melasma area severity index scores

The melasma area severity index (MASI) score[5] is calculated by assessment of three parameters: Area (A), darkness (D), and homogeneity (H) of involvement where in forehead (f) constitutes 30%, right malar region (rm) 30%, left malar region (lm) 30%, and chin (c)-10% [Figure 2]. The MASI score is calculated by adding the sum of the severity ratings for darkness and homogeneity, multiplied by the value of the area of involvement, for each of the four facial areas. The total score range is 0–48. Higher the score, higher is the severity.

The following formula is used for calculation is:
MASI total score = 0.3A (f) [D (f) + H (f)] +0.3A (lm) [D (lm) + H (lm)] +0.3A (rm) [D (rm) + H (rm)] +0.1A (c) [D (c) + H (c)].

### Grading for parameters of melasma area severity index score

| Parameters | Score |
|---|---|
| The area of involvement (%) | |
| No involvement | 0 |
| 0-9 | 1 |
| 10-29 | 2 |
| 30-49 | 3 |
| 50-69 | 4 |
| 70-89 | 5 |
| 90-100 | 6 |
| Darkness | |
| Absent | 0 |
| Slight | 1 |
| Mild | 2 |
| Marked | 3 |
| Maximum | 4 |
| Homogeneity | |
| Absent | 0 |
| Slight | 1 |
| Mild | 2 |
| Marked | 3 |
| Maximum | 4 |


**Figure 1: Color grading scale**

### Overall assessment

Overall assessment was done on the basis of following criteria:

- CD – Clinically deteriorated that is, increase in severity score against initial score
- CS – Clinically stable that is, severity of score remains same as against initial score
- CI-1 – Clinical improvement mild that is, one grade reduction against initial score
- CI-2 – CI moderate that is, two grade reduction against initial score
- CI-3 – CI good that is, three grade reduction against initial score.

### Statistical analysis

The results of the present study were analyzed statistically using descriptive statistics, frequencies and percentages, cross tabulation (contingency table analysis), paired "*t*" test, and repeated measure ANOVA using SPSS for windows (version 16.0 - Manufactured by SPSS Inc, Chicago, USA.).

## Observations

Out of 40 patients, 35 patients completed the study. Observations revealed that 40% of patients were from the age group 31 to 40 years, 88.6% of patients were females, 42.9% of patients had a positive family history, 45.7% patients had exposure to sun as aggravating factor, 62.9% patients had stress and worries as aggravating factor, 14.3% patients had irregular menstrual history, 48.6% patients had *Pitta-Vata Prakriti*, 57.1% patients had malar pattern of melasma, 60% of the patients had dermal lesions, 62.9% of the patients had chronicity of 0–4 years, and 48.6% patients had skin color ranging between 6 and 10. *Kandu* (itching) and *Daha* (burning sensation) were evaluated to find out the prevalence of *Kaphaja* as well as *Raktaja Vyanga* where in *Kaṇḍu* and *Daha* are observed as associated symptoms. Only 20% of patients complained of *Kandu* and 2.8% of patients complained of *Daha*.

## Results

The total mean of the lesion color before treatment was 21.74 and 17.77 after treatment and follow-up [Table 1].

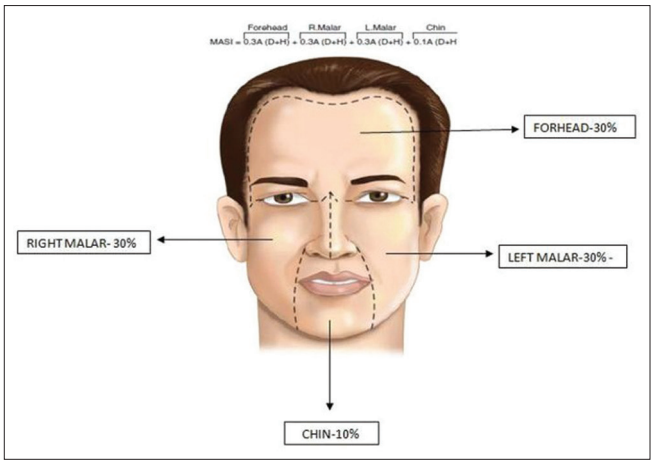


**Figure 2: Melasma area severity index score**

The mean of MASI scores of 35 patients before treatment was 11.69 and after treatment and follow-up, it reduced to 10.35 [Table 2]. Assessment of CI in the parameters is as follows-skin color - 51.4% patients had Grade 1 CI, 42.8% patients had Grade 2 CI, and 5.7% patients had Grade 3 CI. Skin texture (dryness) - 56.5% patients had Grade 1 CI. Skin texture (oiliness) - 66.7% patients had Grade 1 CI. Luster - 2.87% patients had Grade 1 CI. Itching - 60% patients had Grade 1 (CI), 40% patients had Grade 2 CI. Burning sensation and MASI - 100% patients had Grade 1 CI. Area - 0.7% patients had Grade 1 CI. Darkness - 39.3% patients had Grade 1 CI [Table 3]. The overall assessment of the study reveals that 10 (28.9%) patients were said to be clinically stable, 23 (64.34%) patients had mild improvement, and 2 (6.7%) patients had moderate improvement [Table 4]. The clinical improvement in 2 patients of *Vynaga* before and after treatment have been shown in Figure 3 and 4.

## Discussion

Observations revealed that 40% of the patients belonged to the age group 31–40 years which suggests that melasma is more prevalent in childbearing age. About 88.6% of patients were females of different age groups which supports the fact of global incidence of melasma. About 42.9% patients had a family history of melasma which supports the presence of hereditary component in the manifestation of the disease. About 45.7% of patients had exposure to sun rays as a physical aggravating factor which suggests the important role of UV radiation in the causation of melasma. Moreover, 14.3% of the patients had irregular menstruation accounting to the fact that hormonal disturbance is also the causative factors for melasma. 48.6% patients were of *Pitta Prakriti* followed by 31.4% patients were of *Vata Prakriti* suggesting the fact that individuals of *Pitta Prakriti* are more prone to *Vyanga*. Sixty percent of the patients had dermal lesions which suggest the severity of the disease and the depth of involvement. The skin color of 57.2% patients was between 1 and 10 grades suggesting the fair complexion, supporting the fact that those with fair complexion are more prone to melasma. In this study, 62.9% of the patients had stress and worries as aggravating factors which clearly suggests that stress is an important etiological factor in causation of melasma as melanocyte stimulating hormone levels have been shown to be influenced by a rise in adrenocorticotropic hormone levels, which increases with stress[6] correlating to the role of psychological factors such as *Krodha* (anger), *Shoka* (grief), and *Harsha* (happiness) for the manifestation of the disease *Vyanga*.

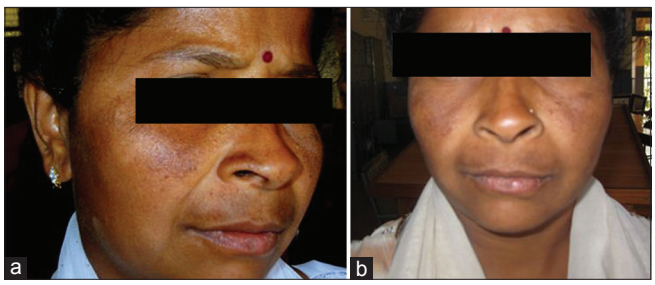


**Figure 3: Patient 1 – (a) Before treatment (b) After treatment**

In this study, 57.1% of the patients had malar type of melasma followed by centrofacial type (42.9%), suggesting the site of involvement and supporting the global incidence as melasma involves only specific sites of the body and not the entire body because melanocytes in the areas affected are more sensitive

**Table 1: Skin colour versus lesion colour**

| Skin colour | *n* | Lesion colour (mean±SD) | | |
|---|---|---|---|---|
| | | Before treatment | After treatment | Follow-up |
| 1-5 | 3 | 22.33±2.08 | 19.67±2.08 | 19.67±2.09 |
| 6-10 | 17 | 20.53±4.37 | 16.71±4.12 | 16.71±4.12 |
| 11-15 | 13 | 22.77±2.20 | 18.31±1.70 | 18.31±1.70 |
| 16-20 | 2 | 24.50±2.12 | 20.50±1.71 | 20.50±1.70 |
| Total | 35 | 21.74±3.57 | 17.77±3.28 | 17.78±3.28 |
| **Colour** | | | ***P*** | |
| Only lesion colour | | | <0.001 | |
| Lesion colour versus skin colour | | | 0.735 | |

SD: Standard deviation

**Table 2: Results of melasma area severity index scores (*n*=35)**

| MASI | Mean±SD | *F* | *P* |
|---|---|---|---|
| Before treatment | 11.69±4.86 | 77.500 | <0.001 |
| After treatment | 10.35±4.58 | | |
| Follow-up | 10.35±4.58 | | |

MASI: Melasma area severity index, SD: Standard deviation

**Table 3: Assessment of clinical improvement in all the parameters**

| Criteria | CS (%) | CI-1 (%) | CI-2 (%) | CI-3 (%) |
|---|---|---|---|---|
| Skin color | - | 51.4 | 42.8 | 5.7 |
| Skin texture (dryness) | 43.47 | 56.5 | - | - |
| Oilyness | 33.3 | 66.7 | - | - |
| Lustre | 97.14 | 2.87 | - | - |
| Number of lesions | 100 | - | - | - |
| Size of lesions | 100 | - | - | - |
| Itching | - | 60 | 40 | - |
| Burning | - | 100 | - | - |
| MASI score | - | 100 | - | - |
| Area | 99.28 | 0.7 | - | - |
| Darkness | 60.7 | 39.3 | - | - |
| Homogenesity | 100 | - | - | - |

CS: Clinically stable, CI: Clinical improvement, MASI: Melasma area severity index

**Table 4: Results of overall assessment**

| Clinical improvement | Number of patients | Percentage |
|---|---|---|
| Clinically deteriorated | 0 | 0 |
| Clinically stable | 10 | 28.9 |
| Mild improvement | 23 | 64.34 |
| Moderate improvement | 2 | 6.7 |
| Good improvement | 0 | 0 |

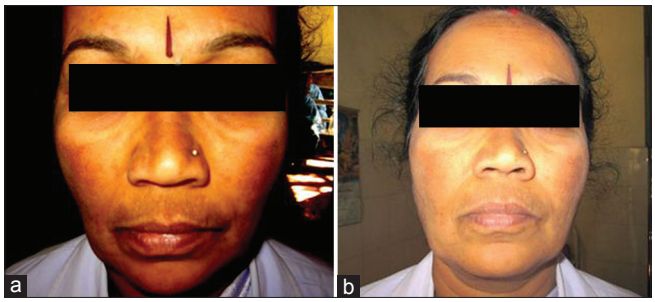


**Figure 4: Patient 2 – (a) Before treatment (b) After treatment**

to hormonal stimulation.[7] and also due to the presence of a greater population of melanocytes in the affected sites.[8]

As per the results, the mean of MASI scores of 35 patients before treatment was 11.69 and after treatment and follow-up, it reduced to 10.35 with high statistical significance ($P < 0.001$). MASI score is influenced by all the three factors that are area, homogeneity, and darkness of the lesion. Since there are no changes in area and homogeneity parameters and only one grade improvement in the darkness of left and right malar regions, the overall score is affected and thus only a mean difference of 0.9 is observed wherein really a difference of at least 15 points is mandatory to assume a good CI. Since the disease is of a stubborn variety and because of the chronicity and influence of hormones which is variable from time to time, all the causative factors cannot be controlled effectively.

The *Rasas* (taste) are said to possess two important *Karmas* that is *Chhedana* and *Upashamana*.[9] The drugs which are administered in the form of *Lepa* mainly are of *Madhura* (sweet), *Tikta* (bitter), *Kaṣhaya* (astringent) *Rasas*. These *Rasas* do the *Chhedana* of *Prakupita* (vitiated) *Vata* and *Pitta* and *Upashamana* which means it does not allow the *Utklesha* of *Doshas* and maintains the equilibrium and thus pacifies *Pitta* which is the main culprit in the causation of *Vyanga*. Out of these 10 drugs, some of the drugs possess *Snigdha* (unctuous) *Guna* (property), and others possess *Laghu* (light), *Ruksha* (dry) *Gunas*. *Snigdha Guna* is responsible for *Mardava* and *Varna Prasadana* whereas *Laghu*, *Ruksha* are the properties of *Agneya Dravya*, which in turn are responsible for *Prabha*, *Prakasa*, and *Varna*.[10] Almost all the drugs selected are of *Shita Virya* (cold potency) and *Shita Virya Dravyas* 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*[11] hence after the entry of the drug by virtue of *Virya*, it enters the circulation. The selected drugs mainly are of *Madhura Vipaka*. *Vipaka* is basically defined as *Karma Nishthaya*, here the term *Nishtha* incorporates *Jatharagni Dhatvagni* and *Bhutagni* irrespective of their order. *Madhura Vipaka* by virtue of its *Snigdha Guna* and *Kapha Vardhana Karma* is responsible for *Varṇa Utkarsha*. By the term *Twachi Vipakva*,[12] it can be said that the drug is absorbed by virtue of *Vipaka* into the circulation.

The rationality of the mode of action can be analyzed in three steps. Step 1 - *Lepa* comes in contact with the *Roma* and *Romakupa* which in turn are connected to the *Tiryak Gata Dhamanis*,[12] which perform the function of *Sweda Vahana* that is the active drug enters the sweat ducts and hair follicles. Hair follicles represent a reservoir that may store topically applied substance. Differences in the follicular penetration are observed in different ethnic groups. Hair follicles appear to present an important pathway for percutaneous absorption in nondiseased skin. Even solid particles may enter deep into the follicular orifice, a phenomenon that lends itself to the concept of follicular targeting of drugs. It was found that nanoparticles were stored 10 times longer in the hair follicles than in the stratum corneum; it should be noted that when topically applied substances penetrate into the hair follicles, they do not necessarily penetrate through the skin barrier into the living tissue because hair follicles also have barrier properties.[13] Step 2 - After the contact of the drug, there is *Paka* (metabolism) of *Dravya* (external application) in *Twacha* (skin). *Paka* refers to the action of *Bhrajaka Agni* and *Rasa Dhatwagni*. It occurs by virtue of *Ushna Guna* (warmth) of *Bhrajaka Pitta*, i.e. it takes up and metabolizes the *Kriya Dravya* (externally applied drug). This *Ushma* (warmth) present in *Lasika*, *Rasa*, *Rakta*, *Twacha*, maintains the *Dravatva* in *Rasa* and *Rakta*, which in turn are responsible for *Varna Utkarsha* (improvement in *Varna*).[14] These two steps correspond to the pathway across stratum corneum and viable tissue. Step 3 - These steps finally lead to *Rasa Tarpana* (nourishment of the *Rasa Dhatu*) which is mainly achieved by *Udana*[15] and *Vyana Vata* that supplies *Anna Rasa* (nutrition) to the concerned *Shareera Ghataka* or *Avayava* (tissues of the body) and *Varna Utkarsha* (improvement in *Varna*) is thus achieved. Hence, it is quoted that *Varnasampannah Rasapurnatvat*.[16] It corresponds to the process of metabolism in skin. Metabolism in skin compartments plays a significant role in determining the fate of a topically applied active compound. Metabolic activity is found in the skin surface, appendages, the stratum corneum, and viable epidermis. The level of many enzymes is highest in the epidermis. The relatively large size of the dermal component may result in a significant role in the metabolism of topically applied substances.

It is recommended that the same study can be carried out for extended intervention period, with different media (according to the *Doshic* predominance) for mixing the drugs for better accuracy in results and the same formulation can be tried in other skin diseases to evaluate its effect on the parameters such as skin hydration, skin pigmentation, skin sensitivity, and skin wrinkling.

## Conclusion

*Varnya Gana Lepa* is an effective formulation in *Vyanga* (melasma) and shows statistically highly significant improvement in the MASI scores by reducing the darkness parameter along with subjective parameters such as itching and burning sensation. Hence, *Varnya Gana Lepa* is a safe and effective formulation which can be prescribed in *Vyanga*.

### Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

**Conflicts of interest**
There are no conflicts of interest.

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# हिन्दी सारांश

## वर्ण्य गण लेप का व्यङ्ग में चिकित्सीय मूल्यांकन

पल्लवी जी., विरुपाक्ष गुप्ता के.एल., श्रीवत्स एम., वासुदेव ए. चाटे, बालकृष्ण डी.एल.

**व्यङ्ग एक क्षुद्र चर्म रोग है, जिसमे चेहरे पर श्याव, कुष्ण अथवा नील वर्ण के दर्द रहित चकते पड़ जाते हैं। यह खास तौर पर महिलाओं में पाया जाता है। आयुर्वेदानुसार व्यङ्ग व्याधि में बहिर्परिमार्जन चिकित्सा का प्रमुख रूप में वर्णन किया गया है। इस अध्ययन का मुख्य उद्देश्य वर्ण्य गण लेप का व्यङ्ग में चिकित्सीय मूल्यांकन करना था। इस अध्ययन में एक वर्ग में ३५ मरिजों को पंजीकृत किया गया और वर्ण्य गण चूर्ण का गुनगुने पानी के साथ मुखलेप बनाकर १५ दिन तक दिन में दो बार मरीजों को लगाने के लिए दिया गया। मूल्यांकन मानदण्डों के आधार पर वर्ण्य लेप का असर निर्धारण किया गया। चिकित्सीय अध्ययन में मुख लेप से अच्छे परिणाम प्राप्त हुए।**