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CLINICAL STUDY TO EVALUATE THE EFFICACY OF VARNYA YOGA (MANJISHTHA-YASHTIMADHU-SARIVA) IN THE MANAGEMENT OF VYANGA (MELASMA)

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ABSTRACT

Background: Vyanga is described in Ayurveda as a Kshudra Roga characterized by painless, thin and brownish-black discoloration predominantly affecting the face. Clinically, it may be correlated with melasma, a common acquired disorder of facial hyperpigmentation. Melasma has a multifactorial pathogenesis involving melanogenesis, ultraviolet exposure, oxidative stress, inflammation, hormonal influences and genetic susceptibility. Ayurveda emphasizes the use of Varnya, Raktashodhaka and Pittashamaka drugs for disorders associated with abnormal complexion. Manjishtha, Yashtimadhu and Sariva are traditionally described as having properties relevant to skin health and complexion. **Aim:** To evaluate the efficacy of Manjishtha-Yashtimadhu-Sariva Varnya Yoga in the management of Vyanga (melasma) and compare oral, topical and combined oral-topical administration. **Materials and Methods:** An open-label, comparative, randomized clinical study was conducted in patients clinically diagnosed with Vyanga (melasma). Sixty patients who completed the study were divided into three groups of 20 patients each. Group A received Manjishtha-Yashtimadhu-Sariva Churna orally at a dose of 5 g twice daily after lunch and dinner for 45 days. Group B received the same formulation as Lepa twice daily for 45 days. Group C received both oral Churna and topical Lepa for 45 days. Patients were assessed at baseline and during follow-up. Subjective parameters included Daha and Kandu, while objective parameters included number, size and colour of patches and Melasma Area and Severity Index (MASI). **Results:** All three groups demonstrated improvement in subjective and objective parameters. Overall subjective improvement was 26.35% in Group A, 28.29% in Group B and 43.75% in Group C. Reduction in number of patches was 44.19%, 48.89% and 60.71%; reduction in patch size was 30.00%, 33.33% and 54.17%; and improvement in patch colour was 39.58%, 45.83% and 62.06% in Groups A, B and C, respectively. MASI reduction was 60.60% in Group A, 68.20% in Group B and 74.40% in Group C. Within-group improvements were highly significant, with $p<0.001$ for the principal objective parameters. Between-group comparisons demonstrated significant superiority of Group C over Groups A and B for MASI. **Conclusion:** Manjishtha-Yashtimadhu-Sariva Varnya Yoga was associated with improvement in Vyanga (melasma) in all three treatment groups.

The combined oral and topical regimen produced the greatest improvement, suggesting that simultaneous systemic and local administration may provide greater therapeutic benefit than either route alone. Larger controlled studies with longer follow-up are warranted.

KEYWORDS: Vyanga, Melasma, Varnya Yoga, Manjishtha, Yashtimadhu, Sariva, MASI, Ayurveda, Hyperpigmentation.

INTRODUCTION

Melasma is a common acquired disorder of hyperpigmentation characterized by symmetrical, irregularly bordered brown to grey-brown macules or patches, most frequently involving the face. It is particularly important clinically because facial pigmentation can have considerable cosmetic, psychological and social consequences. Although melasma is not usually associated with serious physical morbidity, its chronic and recurrent nature makes treatment challenging.[1]

The pathogenesis of melasma is complex and multifactorial. Increased melanocyte activity and melanin synthesis are influenced by ultraviolet radiation, oxidative stress, inflammatory mediators, hormonal factors and genetic susceptibility. Melanogenesis involves the conversion of tyrosine into melanin through enzymatic reactions in melanocytes, with tyrosinase representing an important regulatory enzyme.[2,3]

Histopathological and molecular studies have demonstrated that melasma is not simply a disorder of epidermal pigmentation. Alterations involving the dermis, inflammatory mediators, vascular structures, oxidative stress and cellular signalling pathways have also been described. These findings support the concept that several interacting mechanisms contribute to persistence and recurrence of pigmentation.[4,5]

Ultraviolet exposure is an important aggravating factor. Solar radiation can stimulate melanogenesis directly and may increase oxidative stress and inflammatory signalling within the skin. The interaction between ultraviolet radiation, melanocytes, keratinocytes and dermal components contributes to persistent pigmentation.[6]

Modern treatment of melasma includes photoprotection, topical depigmenting agents, chemical peels, laser and light-based therapies, and combination regimens. Hydroquinone and other topical agents have demonstrated efficacy but may be associated with irritation, intolerance or limitations related to prolonged use. Recurrence after discontinuation of treatment remains an important therapeutic challenge.[7-9]

The Ayurvedic description of Vyanga has considerable clinical similarity with facial hyperpigmentation. Vyanga is included among the Kshudra Rogas and is characterized by Niruja, Tanu and Shyava Mandala occurring on the face. The disease is described in classical Ayurvedic texts with emphasis on Dosha and Rakta involvement and is clinically relevant to disorders of facial complexion.[10,11]

Ayurveda describes several approaches for the management of Vyanga, including Lepa, Abhyanga, Nasya, Raktamokshana and other Dosha-specific measures. External application is particularly relevant because the manifestation is predominantly localized to the skin of the face.[12]

The selection of Manjishtha, Yashtimadhu and Sariva for the present study was based on their traditional Varnya, Raktashodhaka, Pittashamaka and Tvachya properties. Manjishtha (*Rubia cordifolia*) is traditionally regarded as an important drug for Rakta-prasadana and Varnya activity. Yashtimadhu (*Glycyrrhiza glabra*) is described for Varnya, Rasayana and Tvachya actions. Sariva (*Hemidesmus indicus*) is traditionally associated with Rakta-prasadana, Pittashamana and Varnya properties.[13-15]

From a modern pharmacological perspective, the constituents of these plants have been investigated for antioxidant, anti-inflammatory and melanogenesis-related activities. Manjishtha has been reported to contain several bioactive constituents and has been investigated for antioxidant and anti-inflammatory effects.[16] Yashtimadhu contains flavonoids including glabridin, which has been studied for its effects on melanogenesis and tyrosinase activity.[17] Sariva has also been investigated for antioxidant and anti-inflammatory properties.[18]

The clinical rationale for combining these three drugs is therefore based on both Ayurvedic and pharmacological considerations. The formulation may theoretically address pigmentation through Varnya and Rakta-prasadana actions while providing antioxidant and anti-inflammatory effects. However, molecular mechanisms were not directly assessed in the present clinical study.

The present research was undertaken to evaluate the efficacy of Manjishtha-Yashtimadhu-Sariva Varnya Yoga in Vyanga (melasma), with particular emphasis on comparing oral therapy, topical Lepa and combined oral-topical administration.

AIM

To evaluate the efficacy of Manjishtha-Yashtimadhu-Sariva Varnya Yoga in the management of Vyanga (melasma).

OBJECTIVES

1. To evaluate the efficacy of Manjishtha-Yashtimadhu-Sariva Yoga administered orally in Vyanga.

2. To evaluate the efficacy of the same formulation administered externally as Lepa.
3. To evaluate the combined effect of oral administration and external Lepa.
4. To compare the therapeutic efficacy of the three treatment approaches.
5. To observe complications or adverse effects, if any, during the treatment period.

MATERIALS AND METHODS

Study Design

The study was an open-label, comparative, randomized clinical study conducted in the Department of Kayachikitsa, Institute of Post Graduate Ayurvedic Education and Research at Shyamadas Vaidya Shastra Pith and Hospital, Kolkata.

The clinical trial was registered with the Clinical Trials Registry–India under registration number **CTRI/2024/09/073631**.

The study was conducted in accordance with the protocol described in the thesis, following institutional ethical requirements and informed consent procedures.

Study Population

Patients attending the Kayachikitsa outpatient department with clinical features suggestive of Vyanga (melasma) were screened for eligibility.

Although the thesis records 68 patients registering for the clinical study, the final clinical analysis comprised **60 patients who completed the study**, with 20 patients in each treatment group.[19]

Patients of both sexes were considered within the specified age range.

Inclusion Criteria

Patients were included when they fulfilled the clinical features of Vyanga, including painless, thin, brownish or dark facial patches, together with clinical features compatible with melasma.

Patients who were willing to participate and provide informed consent were included.

Exclusion Criteria

Patients below 20 years or above 60 years were excluded. Other exclusion criteria included congenital generalized blackish or reddish-brown pigmentation, Vyanga associated with Kushta, leprosy-associated pigmentation, malignant melanoma and pigmentation caused by endocrine or metabolic disorders such as Addison disease, Nelson syndrome, haemochromatosis and pellagra.

Patients with active acne or inflammatory pigmentation, pregnancy, lactation and relevant oral or depot contraceptive use were excluded. Patients receiving concurrent treatment for melasma were also excluded.

INTERVENTION

The trial formulation consisted of Manjishtha (*Rubia cordifolia* Linn.), Yashtimadhu (*Glycyrrhiza glabra* Linn.) and Sariva (*Hemidesmus indicus* R.Br.).

Group A: Oral Administration

Twenty patients received Manjishtha-Yashtimadhu-Sariva Churna orally at a dose of **5 g twice daily**, after lunch and dinner, with plain water for 45 days.

Group B: External Lepa

Twenty patients received the same formulation as Lepa. The powdered formulation was applied to the affected facial areas twice daily, in the morning and evening, for 45 days.

The Lepa consisted of equal parts of the three drugs. The powder was mixed with water and applied over the affected area after washing the face. It was retained for approximately 20 minutes and subsequently washed off.

Group C: Combined Therapy

Twenty patients received both oral administration of 5 g twice daily and external Lepa twice daily for 45 days.

FOLLOW-UP

Patients were followed during the treatment period and assessed according to the study schedule. Assessment was performed at baseline and subsequent follow-up visits, with the final evaluation at completion of 45 days.

Outcome Measures

Subjective Parameters

The subjective parameters were.

- Daha
- Kandu

Objective Parameters

The objective parameters included

1. Number of patches
2. Size of patches
3. Colour of patches
4. Melasma Area and Severity Index (MASI)

The thesis used graded scoring systems for these parameters.[19]

MASI incorporates the extent of facial involvement, darkness and homogeneity of pigmentation. The reliability and validity of MASI as an assessment tool for melasma have previously been evaluated.[20]

Assessment of Therapeutic Response

The thesis categorized overall response according to percentage relief as follows.

- Complete remission: 100% relief
- Marked improvement: >75% to <100%
- Moderate improvement: >50% to <75%
- Mild improvement: >25% to <50%
- Insignificant improvement: <25%

STATISTICAL ANALYSIS

Data obtained before and after treatment were organized and analyzed using arithmetic mean, percentage, standard deviation, mean difference and appropriate statistical tests. Within-group changes were evaluated statistically, and comparative analysis was performed between treatment groups. A p-value <0.05 was considered statistically significant, while p<0.001 was considered highly significant.

RESULTS

DEMOGRAPHIC CHARACTERISTICS

Among the 60 patients who completed treatment, **86.67% were female and 13.33% were male**.

The age distribution showed 5 patients in the 20–30-year group, 19 in the 30–40-year group, 20 in the 40–50-year group and 16 in the 50–60-year group.

Most participants were from urban areas, with 48 patients classified as urban and 12 as rural.

A sedentary lifestyle was reported in 32 patients (53.33%), while 28 patients (46.67%) had an active lifestyle.

Reduced sleep or Alpa Nidra was reported in 37 patients (61.67%), whereas 23 patients (38.33%) reported Samyaka Nidra.

These observations describe the characteristics of the study population and should not be interpreted as demonstrating causal associations.

EFFECT ON DAHA

All three groups showed improvement in Daha.

The reported percentage relief was.

Group	Percentage relief
Group A – Oral	21.45%
Group B – Lepa	25.00%
Group C – Oral + Lepa	41.67%

The combined group demonstrated the greatest reduction in Daha.

EFFECT ON KANDU

Improvement in Kandu was observed in all three groups.

Group	Percentage relief
Group A – Oral	31.25%
Group B – Lepa	31.58%
Group C – Oral + Lepa	45.83%

The highest improvement was observed in Group C.

The overall subjective improvement obtained by combining the reported Daha and Kandu outcomes was:

- Group A: **26.35%**
- Group B: **28.29%**
- Group C: **43.75%**

EFFECT ON NUMBER OF PATCHES

The number of pigmentation patches decreased in all three groups.

In Group A, the mean score decreased from **2.15 to 1.20**, giving a mean difference of 0.95 and 44.19% relief. The reported t-value was 7.02 with p<0.001.

In Group B, the mean score decreased from **2.25 to 1.15**, giving a mean difference of 1.10 and 48.89% relief. The reported t-value was 11.00 with p<0.001.

In Group C, the mean score decreased from **2.80 to 1.10**, giving a mean difference of 1.70 and 60.71% relief. The reported t-value was 16.19 with p<0.001.

Thus, the reduction in the number of patches was greatest in the combined treatment group.

EFFECT ON SIZE OF PATCHES

Group A showed a reduction in mean patch-size score from **2.20 to 1.55**, with 30.00% relief and a reported t-value of 5.95 (p<0.001).

Group B showed reduction from **2.25 to 1.50**, with 33.33% relief and a reported t-value of 7.55 (p<0.001).

Group C showed reduction from **2.40 to 1.10**, corresponding to 54.17% relief and a reported t-value of 12.37 (p<0.001).

The combined regimen therefore produced the greatest improvement in patch size.

EFFECT ON COLOUR OF PATCHES

Improvement in colour was also observed in all three groups.

In Group A, the mean colour score decreased from **2.40 to 1.45**, representing 39.58% relief.

In Group B, the score decreased from **2.40 to 1.30**, representing 45.83% relief.

In Group C, the score decreased from **2.90 to 1.10**, representing 62.06% relief.

The reported statistical analysis demonstrated highly significant within-group improvement, with p<0.001.

EFFECT ON MASI

MASI demonstrated substantial reduction following treatment.

Group A showed a **60.60% reduction** in MASI.

Group B demonstrated a **68.20% reduction**.

Group C demonstrated the greatest reduction, with **74.40% improvement**.

In Group C, the mean MASI score decreased from **17.0 ± 2.93 before treatment to 4.4 ± 0.66 after treatment**, giving a mean difference of 12.60. The reported t-value was **16.92**, with **p<0.001**.

Comparison among the three groups showed:

Group C (74.40%) > Group B (68.20%) > Group A (60.60%).

Between-group comparison demonstrated statistically significant differences favouring Group C over Group A and Group B. The thesis reported a t-value of 5.10 for Group A versus Group C and 3.90 for Group B versus Group C, both with p<0.001.

OVERALL OBJECTIVE RESPONSE

The overall objective improvement was.

Parameter	Group A	Group B	Group C
Number of patches	44.19%	48.89%	60.71%
Size of patches	30.00%	33.33%	54.17%
Colour of patches	39.58%	45.83%	62.06%
Overall objective improvement	37.92%	42.68%	58.98%

The combined treatment group consistently demonstrated the greatest improvement.

OVERALL THERAPEUTIC ASSESSMENT

According to the overall therapeutic assessment reported in the thesis, **40 of 60 patients (66.66%) showed mild improvement**, while **20 patients (33.33%) showed moderate improvement**.

No patient was categorized as having complete remission according to the reported overall assessment.

No major local or systemic adverse effects were reported during the treatment period in the thesis.

DISCUSSION

The present study evaluated the efficacy of Manjishtha-Yashtimadhu-Sariva Varnya Yoga in Vyanga (melasma) through three treatment approaches: oral administration, topical Lepa and combined oral-topical administration.

The most important finding was that all three treatment groups demonstrated improvement, while the combined treatment group showed the highest magnitude of response across the majority of parameters.

Melasma is characterized by excessive pigmentation resulting from increased melanogenic activity. The disease is influenced by ultraviolet radiation, oxidative stress, inflammation, hormonal factors and genetic predisposition. The chronicity of melasma and its tendency to recur after treatment make sustained management difficult. The Ayurvedic diagnosis of Vyanga is based on the presence of facial discoloration with characteristic painless and thin patches. Classical Ayurvedic descriptions associate the disease with Dosha and Rakta involvement. The selection of Varnya and Raktashodhaka drugs in the present study is therefore consistent with the traditional therapeutic approach.

Manjishtha is traditionally regarded as an important Raktashodhaka and Varnya drug. Its use in disorders involving altered skin complexion is supported by its classical pharmacological attributes. The thesis describes Manjishtha as possessing Raktashodhaka, Varnya, Kushtaghna and Shothahara actions. Its phytochemical constituents have also been investigated for antioxidant and anti-inflammatory activity.

Yashtimadhu is described as Madhura, Guru and Snigdha with Sheeta Virya and is traditionally used for Pittashamana, Varnya, Rasayana and Tvachya effects. Its principal flavonoid glabridin has been investigated for effects on melanogenesis. These observations provide a possible pharmacological basis for its inclusion in the formulation.

Sariva is traditionally described as Raktashodhaka, Pittashamaka, Dahashamaka and Varnya.[15] Its antioxidant and anti-inflammatory properties may theoretically be relevant to the oxidative and inflammatory components of melasma.

The improvement observed in Group A following oral administration suggests that systemic administration of the formulation may have therapeutic relevance. However, the study did not include biochemical or molecular markers, so the exact mechanism cannot be established from the clinical data alone.

Group B also demonstrated clinically meaningful improvement. The topical route is particularly relevant in Vyanga because the clinical manifestation is localized to the facial skin. Classical Ayurvedic literature describes Lepa or Pralepa among the treatment modalities for facial discoloration.

The greatest response was observed in Group C, which received both oral and topical treatment. The combined group demonstrated 60.71% improvement in number of patches, 54.17% improvement in patch size and 62.06% improvement in patch colour. Overall objective improvement reached 58.98%.

The same pattern was observed with MASI. The reduction was 60.60% in Group A, 68.20% in Group B and 74.40% in Group C.

The greater efficacy of the combined regimen may be interpreted as the result of complementary systemic and local treatment. Oral administration may act through the Ayurvedic concept of correction of Dosha and Rakta-related abnormalities, whereas topical Lepa provides direct local application to the affected skin. However, this interpretation is a therapeutic hypothesis rather than a mechanistically proven finding. The high statistical significance observed in all groups indicates that the observed pre-treatment to post-treatment changes were statistically significant within the studied population. Nevertheless, statistical significance does not by itself establish superiority over conventional treatment.

The use of MASI strengthens the clinical assessment because it provides a composite measure incorporating the extent and intensity of pigmentation. MASI is a widely used clinical outcome measure in melasma

research, although it contains observer-dependent components.

The demographic findings showed a predominance of female patients, consistent with the established epidemiological pattern of melasma. A high proportion of participants also reported sedentary lifestyle and reduced sleep. Although these observations are interesting from an Ayurvedic and lifestyle perspective, the present study was not designed to establish whether these factors are independent risk factors for melasma. The absence of major reported adverse effects during 45 days of treatment provides preliminary evidence of short-term tolerability. However, the sample size was small and follow-up was short. Therefore, these findings should not be interpreted as establishing long-term safety. The study also has limitations related to study design. It was open-label and did not include a placebo group or conventional active comparator. Consequently, observer bias, participant expectation, natural variation and other nonspecific influences cannot be completely excluded. The findings are nevertheless clinically relevant because the study directly compared three administration strategies using the same formulation. The consistent superiority of the combined treatment across several outcome measures supports further investigation of combined internal and external Ayurvedic therapy for Vyanga.

Future studies should include a larger sample size, concealed allocation, blinded assessment, standardized digital photography, objective colorimetric assessment, quality-of-life instruments, longer treatment duration and long-term recurrence monitoring. Comparison with established conventional therapies would also help determine the relative clinical effectiveness of the intervention.

LIMITATIONS

The principal limitations of the study were the relatively small sample size, short 45-day treatment duration and absence of long-term recurrence follow-up.

The open-label design may have introduced participant and investigator bias. There was no placebo or conventional active-control group, and therefore comparative efficacy against standard melasma treatment cannot be determined.

The study primarily relied on clinical scoring parameters. Instrument-based assessment of pigmentation, biochemical markers of melanogenesis and molecular biomarkers of oxidative stress or inflammation were not reported.

The reported safety assessment was based on the treatment period and did not establish long-term safety.

CONCLUSION

The present randomized comparative clinical study demonstrated significant improvement in the clinical features of *Vyanga* (melasma) following treatment with *Manjishtha-Yashtimadhu-Sariva Varnya Yoga*. All three treatment groups showed improvement in both subjective and objective parameters; however, the combined oral and topical regimen demonstrated the greatest overall therapeutic response. The combined regimen produced 43.75% overall subjective improvement, with a 60.71% reduction in the number of patches, 54.17% improvement in patch size, and 62.06% improvement in patch colour. Overall objective improvement was 58.98%, accompanied by a 74.40% reduction in MASI score. The improvement within the treatment groups was statistically highly significant, while the combined regimen demonstrated superior efficacy compared with oral or topical therapy alone, particularly with respect to MASI.

These findings suggest that combined internal and external administration of *Manjishtha-Yashtimadhu-Sariva Varnya Yoga* may be a promising Ayurvedic therapeutic approach for *Vyanga* (melasma). Nevertheless, the findings should be interpreted cautiously because of the study limitations. Larger, adequately powered, rigorously controlled clinical trials incorporating standardized objective pigmentation measurements, longer follow-up, and assessment of recurrence are warranted to establish the efficacy, durability, and clinical applicability of this therapeutic approach.

DECLARATIONS

Ethical approval: The study was conducted according to the institutional ethical requirements described in the thesis.

Clinical trial registration: CTRI/2024/09/073631.

Informed consent: Written informed consent was obtained from participants according to the study documents.

Funding: No external funding was reported in the thesis.

Conflict of interest: No conflict of interest was reported in the thesis.

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