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A RANDOMIZED COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF ASHOKA TVAK LEPA AND ARJUNA TVAK LEPA IN THE MANAGEMENT OF DUSHIVISHAJANYA VYANGA WITH SPECIAL REFERENCE TO MELASMA

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Abstract

Background: Vyanga is an Ayurvedic Kshudra Roga characterized by facial discoloration and is clinically comparable with melasma. The present study evaluated two topical Ayurvedic bark preparations in Dushivishajanya Vyanga with special reference to melasma.

Objective: To compare the efficacy of Ashoka Tvak Lepa and Arjuna Tvak Lepa in patients with Dushivishajanya Vyanga.

Materials and Methods: This randomized comparative clinical study was conducted in the outpatient department of Agad Tantra, Institute for Ayurved Studies and Research, Kurukshetra. Fifty-four patients aged 18–50 years meeting the diagnostic criteria were enrolled; 10 withdrew and 44 patients completed the study, with 22 patients in each group. Group A received Ashoka Tvak Lepa and Group B received Arjuna Tvak Lepa, applied locally twice daily for 28 days. Assessment was performed using graded clinical parameters—Shyavata, Mandala, Rukshata and Snigdghata—and the Melasma Area and Severity Index (MASI). Within-group changes were

assessed using the Wilcoxon signed-rank test and between-group differences using the Mann–Whitney U test.

Results: Both groups showed statistically significant improvement in all assessed parameters. Mean MASI decreased from 10.43 to 6.20 in Group A (40.54% improvement; $p < 0.0001$) and from 10.60 to 3.25 in Group B (69.31% improvement; $p < 0.0001$). Between-group comparison showed a significant difference in MASI ($U = 141.5$, $p = 0.0182$), favouring Arjuna Tvak Lepa. Arjuna Tvak Lepa also showed greater improvement in Shyavata and Mandala, whereas between-group differences for Rukshata and Snigdhata were not statistically significant. No adverse effects were reported during the study period.

Conclusion: Both topical interventions improved clinical features of Vyanga; however, Arjuna Tvak Lepa produced greater improvement in overall disease severity as measured by MASI and was superior to Ashoka Tvak Lepa for hyperpigmentation and lesion size in this study.

Keywords: Arjuna, Ashoka, Dushivisha, Melasma, Vyanga

Introduction

Ayurveda describes Vyanga among the Kshudra Rogas and characterizes it by thin, painless, dark facial patches. Classical descriptions implicate Vata and Pitta with Rakta involvement, while Charaka places Vyanga among Raktapradoshaja Vikara. In the present study, Dushivishajanya Vyanga refers to Vyanga interpreted through the Ayurvedic concept of Dushivisha, particularly in the context of chronic exposure to environmental and cosmetic factors.

Melasma is an acquired facial hypermelanosis characterized by symmetrical brown to grey-brown macules, commonly involving sun-exposed facial areas. Its multifactorial nature includes ultraviolet exposure, hormonal influences, genetic susceptibility, inflammation and cosmetic or environmental factors. The Ayurvedic clinical appearance of Vyanga permits a practical correlation with melasma for clinical research.

Topical approaches are frequently used for facial hyperpigmentation, but irritation and other limitations can affect acceptability. Ashoka (*Saraca asoca*) is described in Ayurveda with Varnya and Vishaghna attributes and is included in groups of drugs used for skin-related disorders. Arjuna (*Terminalia arjuna*) has astringent and traditionally described Raktaprasadana/Varnya actions and has also been used as a Lepa for Vyanga in classical literature. Previous Ayurvedic clinical studies have evaluated Arjuna and other Lepa preparations in Vyanga, but the present dissertation identified a gap in comparative clinical evaluation of Ashoka Tvak Lepa versus Arjuna Tvak Lepa specifically in Dushivishajanya Vyanga.

Therefore, the present study was undertaken to compare the efficacy of Ashoka Tvak Lepa and Arjuna Tvak Lepa in Dushivishajanya Vyanga with special reference to melasma.

Materials and Methods

Study design and setting

A randomized comparative clinical study was conducted in the OPD of the Postgraduate Department of Agad Tantra, Institute for Ayurved Studies and Research, Kurukshetra, Haryana. The clinical study was approved by the Institutional Ethics Committee (certificate no. SKAU/Acad/2024/11516-17 dated 25 August 2024) and registered with the Clinical Trials Registry of India (CTRI/2025/03/083301). Written informed consent was obtained from participants before enrolment.

Participants

A total of 54 patients aged 18–50 years with clinical features of Vyanga and a history considered relevant to Dushivisha were enrolled. Ten participants withdrew before completion; 44 participants were included in the final analysis, with 22 in each group. The thesis records the final analysis as based on participants who completed the study; accordingly, the present manuscript describes the analysis as a completer analysis rather than intention-to-treat.

Inclusion criteria were patients with signs and symptoms of Vyanga and a history of cosmetic use such as moisturizer, fairness cream or topical steroid application within the preceding five years; patients with a habit of daytime sleep; and patients aged 18–50 years irrespective of sex, caste or religion. Exclusion criteria included diagnosed systemic/endocrine disorders such as Addison disease or Cushing syndrome, hyperpigmentation due to malignant melanoma or other tumour, and hyperpigmentation present since birth. Participants could be withdrawn for serious illness/adverse drug reaction, irregular follow-up or voluntary discontinuation.

Interventions

Ashoka bark and Arjuna bark were procured from a genuine store in Kurukshetra and authenticated by the Department of Dravyaguna and Research Innovation Department, Institute for Ayurved Studies and Research (Certificate No. IASR/DG/2025/505). The bark powders were prepared by cleaning, coarse grinding, pulverization and sieving through sieve no. 1. The powders were stored in airtight containers.

Group A received Ashoka Tvak Lepa and Group B received Arjuna Tvak Lepa. For each application, the respective powder was mixed with sufficient lukewarm water according to lesion size and applied to the cleansed, dried lesion at approximately 4–5 mm thickness. The

Lepa was applied twice daily for 28 days and allowed to dry; it was then moistened and gently removed with clean cotton. A sensitivity test was performed before application. The dose was based on the surface area of the lesion. Follow-up assessment was performed on day 35.

Outcome measures

Subjective parameters were graded as Shyavata (hyperpigmentation), Mandala (lesion size), Rukshata (dryness) and Snigdhata (unctuousness), each on a four-grade scale from 0 to 3. The objective outcome was the Melasma Area and Severity Index (MASI), ranging from 0 to 48, with higher scores indicating greater severity. Percentage improvement was calculated from the difference between pretreatment and post-treatment scores relative to pretreatment score.

Statistical analysis

Within-group pre- and post-treatment changes were assessed using the Wilcoxon signed-rank test. Between-group comparisons were performed using the Mann–Whitney U test. A p value <0.05 was considered statistically significant.

Results

Among the 44 analyzed participants, 40.90% belonged to the 31–40-year age group, followed by 38.63% aged 21–30 years and 20.45% aged 41–50 years. Females constituted 88.63% of the sample. Most participants were married (81.81%), and 47.72% had Vata-Pitta Prakriti. A history of fairness-cream use was reported by 86.36%, while 52.27% reported topical steroid use. These descriptive findings characterize the study population but were not treated as causal associations.

Within Group A, all four subjective parameters improved significantly: Shyavata ($p < 0.0001$), Mandala ($p < 0.0001$), Rukshata ($p = 0.0015$) and Snigdhata ($p < 0.0001$). Group B also showed significant improvement in Shyavata ($p < 0.0001$), Mandala ($p < 0.0001$), Rukshata ($p = 0.0000024$) and Snigdhata ($p = 0.0003$).

Mean MASI in Group A decreased from 10.4273 ± 5.9266 to 6.2000 ± 5.2943 ($p = 0.000059$), while in Group B it decreased from 10.6045 ± 7.0567 to 3.2545 ± 2.5031 ($p = 0.000040$). The between-group comparison of post-treatment MASI showed a significant difference ($U = 141.5$, $p = 0.01822$), with lower MASI in Group B.

For overall therapeutic response based on percentage relief, Group A showed moderate improvement in 40.90%, mild improvement in 45.45% and no improvement in 13.63%; no participant achieved the predefined good-improvement category. Group B showed good improvement in 36.36%, moderate improvement in 59.09% and mild improvement in 4.54%.

with no participant in the no-improvement category. The dissertation reports that no adverse effects occurred during the study period.

Table 1: Percentage relief and between-group comparison

Outcome	Group A: Ashoka	Group B: Arjuna	Between-group p
Shyavata	43.10% relief	56.25% relief	0.0011
Mandala	28.84% relief	65.21% relief	0.00035
Rukshata	55.55% relief	84.00% relief	0.4122
Snigdhata	77.77% relief	93.75% relief	0.1653
MASI	40.54% reduction	69.31% reduction	0.01822

Discussion

The present study demonstrated improvement with both topical bark preparations, while Arjuna Tvak Lepa produced greater improvement in the principal objective outcome. The reduction in MASI was 40.54% with Ashoka Tvak Lepa and 69.31% with Arjuna Tvak Lepa. The statistically significant between-group difference suggests a greater effect of Arjuna Tvak Lepa under the conditions of this study.

From an Ayurvedic perspective, Vyanga is associated with Vata-Pitta and Rakta involvement and presents with facial discoloration. Local Lepa is a classical therapeutic approach for Vyanga. Ashoka is described with Kashaya/Tikta Rasa, Laghu-Ruksha Guna and Sheeta Virya, together with Varnya and Vishaghna actions in the source dissertation. Arjuna is described with Kashaya Rasa and Sheeta Virya and has astringent, Varnya, Raktaprasadana and wound-healing attributes. These properties provide a rationale for topical use, although the proposed mechanisms remain pharmacological interpretations rather than directly measured mechanisms in the present clinical trial.

The greater effect of Arjuna on Shyavata and Mandala is consistent with the observed lower post-treatment MASI. In contrast, Rukshata and Snigdhata did not differ significantly between groups despite numerically greater improvement in Group B. This distinction is important because statistical significance, rather than percentage difference alone, determines whether superiority between interventions can be concluded.

The study has several strengths, including a comparative design, prespecified clinical grading, use of MASI as an objective outcome, authentication of trial drugs, ethics approval and prospective registration. Limitations include the small sample size, single-centre setting, short treatment and follow-up period, absence of a placebo or standard-treatment control, and the loss of 10 of 54 enrolled participants. The source dissertation does not provide sufficient detail about the randomization sequence or allocation concealment; therefore, these procedures are not claimed in this manuscript. Longer, multicentric studies with standardized photographs, blinded outcome assessment, longer follow-up and comparison with established melasma therapy would strengthen the evidence.

Conclusion

Both Ashoka Tvak Lepa and Arjuna Tvak Lepa produced significant improvement in Dushivishajanya Vyanga with special reference to melasma after 28 days of topical treatment. Arjuna Tvak Lepa produced significantly greater improvement in MASI, Shyavata and Mandala than Ashoka Tvak Lepa, whereas the between-group differences in Rukshata and Snigdhata were not statistically significant. Within the limits of this study, Arjuna Tvak Lepa demonstrated superior overall clinical efficacy.

Ethical Approval and Trial Registration

Institutional Ethics Committee approval: SKAU/Acad/2024/11516-17, dated 25 August 2024. Clinical Trials Registry of India: CTRI/2025/03/083301.

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Conflict of Interest

The authors declare no conflict of interest.

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Author Contributions

Dr. Priya Mudhgil: study conception, clinical work, data collection, analysis and manuscript preparation. Dr. Satbir Kumar Chawla: supervision, methodological guidance and critical review.

Prof. (Dr.) Brijendra Singh Tomar: academic supervision and critical review. All authors approved the final manuscript.

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