



“EFFICACY OF SEVYADI YOG LEPA IN MANAGEMENT OF CONTACT DERMATITIS CAUSED BY TOPICAL USE OF COSMETICS”: A STUDY PROTOCOL FOR SINGLE-ARM, CLINICAL TRIAL.

Dr Prerna B. Salvi

MD Scholar, Dept. of Agadtantra Evum Vidhivaidyak, PDEA's College of Ayurved and Research Centre, Nigdi Pune, Maharashtra India.

Dr Anuja Wadadekar

Associate Professor, Dept. of Agadtantra Evum Vidhivaidyak, PDEA's College of Ayurved and Research Centre, Nigdi Pune, Maharashtra India

ABSTRACT

Background: Sevyadi yog lepa, is mentioned in Ashtanga hrudaya for giving symptomatic relief from skin manifestation caused due to contact of poison, in today era considering many harmful chemical contents in cosmetics products as an Dushi visha, A single arm, open-label clinical trial was conducted to see the efficacy of Sevyadi yog lepa in contact dermatitis caused due to topical use of cosmetic. **Objective:** This study evaluate the efficacy of Sevyadi yog lepa in the management of contact dermatitis caused due to cosmetics. **Materials and Methods:** This single arm, open-label clinical trial will enrol 32 participants, aged between 18-50years with contact dermatitis cause within 24hrs of topical use of cosmetics from Vishachikitsa OPD Department of Ayurveda Rugnalaya and Snowbell Multi Specialty Hospital, Pune, Participate which fits in the selection criteria will be assessed and Sevyadi yog lepa. Sevyadi yog lepa mixed with water apply topically twice daily for 14days. Follow-up Will be performed after 7 days, assessment will be done and results will be decided. **Discussion:** This research explores the efficacy of Sevyadi yog lepa, assessing symptoms relief and safety, This findings can support its effective use in management of Contact dermatitis as an integrative Ayurveda treatment.

KEYWORDS : Sevyadi Yog Lepa, Conatct Dermatitis.**INTRODUCTION**

In the modern era, exposure to chemical-based cosmetics has become inevitable, particularly among the urban population aged 18–50 years. Cosmetics such as creams, lotions, shampoos, and perfumes, though used for personal grooming, contain several allergenic and irritant agents, leading to Contact Dermatitis—a common skin condition characterized by redness, itching, swelling, and vesicle formation.

Contact dermatitis is divided into irritant contact dermatitis and allergic contact dermatitis. ICD is a nonspecific response of the skin to direct chemical damage, while ACD is a delayed (type 4) hypersensitivity reaction to exogenous contact antigens. Immunological responses are due to the interaction of cytokines and T cells[1]. The majority of cases of contact dermatitis are self-limited and managed with simple supportive measures.[2][3].

In Agadtantra concept of vishaghna lepa are described for external management of Skin disease caused due to contact with poison .Agadtantra which deals with the signs and symptoms and also with management of poisoning resulting from various sources. The external signs and symptoms appear on the skin in the form of local pain, Raga (Redness), Shotha (inflammation), Sphota (blisters/vesication), Kandu (Itching), Srava (oozing) etc, are treated by locally applying lepa[4]. Lepa is an important treatment modality told by Acharya Charaka in Chaturvimshati Upakram[5]. Vishaghana Lepa is used in the treatment of various poisonous conditions[6]. Lepa has important role in local treatment and prevention of further spread of poison, instead of taking internal medications which sometimes shows side effects.

As Contact Dermatitis can be categorized into two types: Irritant Contact Dermatitis (ICD) and Allergic Contact Dermatitis (ACD). In Ayurvedic, it can be correlated with Agantuja Twak Vikara, primarily Agantuja Kustha or Vicharchika, where external agents (cosmetics) act as visha or dushivisha (low potency poisons).[7][8][9]

Sevyadi Yog Lepa, as described in Ayurvedic classics Ashtanga Hridaya comprises dravya like Sevy (Vetiveria zizanioides), Chandan (Pterocarpus santalinus), Talispatra (Abies webbiana), Tagar (Valeriana wallichii), Somavalka (Myrica esculenta), Kushta (Saussurea Lappa), Guduchi (Tinospora cordifolia), Padmak (Prunus cerasoides) which are known for their Shothahara, Kandughna, Krimighna, and Vishaghna actions.[10]

Objective

The study objective is to evaluate effect of Sevyadi Yog lepa in the management of contact dermatitis caused by topical use of cosmetics in the age group of 18-50 years.

MATERIAL AND METHODS**Posology of Drug:**

Sevyadi Yog lepa is mention in Ashtang Hriday which is being used on Skin disease caused by various manifestation, here contact dermatitis by cosmetics is taken, selected participate will be assessed and sevyadi yog lepa given (gm measured according to the size of lesion) from the 1st day of assessment, application for twice daily for 14 days and further follow up and assessment will be done on 7th day and 14th day.

Study Design and Study Setting

The study designed as an Open-label, single-arm, interventional clinical trial conducted in the OPD department of Vishachikitsa in PDEA's Ayurved Rugnalaya & Snowbell Multi speciality, Hospital, Nigdi, Pune, Maharashtra. The study aims to enrol 32 patient, fulfilling the selection criteria.

Sample Size Calculation: $-N = Z^2 \cdot P(1-P) / d^2$
 $= (1.96)^2 \cdot 0.04(1-0.04) / (0.08)^2$
 $= 28$

Here, n=sample size,

Z=standard normal variant. P=prevalence rate=4.38% d= allowable error=8%

sample size calculate use winPepi (11.38) version

Sample size (n) =28 Including 15% dropout rate Total 32 patient will be taken.

The study aims to enrol 32 participants diagnosed with cosmetic-induced contact dermatitis.

Study Duration:

The study duration is of 14 days including follow-up.

Inclusion Criteria:

The inclusive criteria for the study consist of individuals diagnosed with contact dermatitis caused due to topical use of cosmetics.

- Age between 18 and 50 years.
- Confirmed history of contact dermatitis due to recent cosmetic use.
- Symptoms such as erythema, itching, burning, vesicle formation.
- Patients willing to sign informed consent.

Exclusion Criteria

- Chronic dermatological disorders like psoriasis, eczema, or autoimmune diseases.
- Known systemic illnesses (diabetes, tuberculosis, HIV).
- Pregnant or lactating women.
- Use of corticosteroids or immunosuppressant within the past 30 days.

Study Intervention

Preparation of Sevyadi Yog Lepa[11]

Sevyadi yog Lepa is mentioned in Astang Hriday, as all the ingredients

as mentioned below are Vishangna,Krimigna,Pittagna,Shodhana dravya, mixture of these dravya is made and mixed with water to make a paste and apply over the affected part(Contact dermatitis)

Ingredients:-

- Sevyā (Vetiveria zizanioides)
- Rakta Chandan (Pterocarpus santalinus)
- Talispatra (Abies webbiana)
- Tagar (Valeriana wallichii)
- Somavalka (Myrica esculenta)
- Kushta (Saussurea Lappa)
- Guduchi (Tinospora cordifolia)
- Padmak (Prunus cerasoides)

Method

All ingredients will be taken in equal proportion, dried and powdered. A fresh lepa (paste) will be made by mixing the powder with water before each application.[16][17][18]

Method of Application

- The lepa will be applied twice daily over affected areas for 14 days.
- Patients will be instructed to avoid cosmetic usage during the study period.
- Standardized photographs will be taken on Day 0, Day 7, and Day 14, for objective comparison.

Outcome Measures

The primary outcomes include changes in the amount assessed using a subjective scoring system to document , measured on a numerical rating scale using the Visual Analog Scale (VAS) assessed at two time points from baselines, on and the final assessment at The primary outcomes will be analysed based on the subjective grading given in Tables.

Safety Outcomes

Safety outcomes will be evaluated by monitoring adverse events during each follow-up visit. Any observed adverse events will be documented following Good Clinical Practice guidelines.

Diagnostic Assessment

The diagnosis of Contact dermatitis caused due to topical use of cosmetics involves a comprehensive assessment that includes clinical history, physical examination, along with the exclusion of other conditions. The initial history-taking focuses on the presence of symptoms such as Raga (Redness), Shotha (inflammation), Sphota (blisters/vesication), Kandu (Itching), Srava (oozing) etc, which is mentioned in Astang hrudaya chapter 7th sutra 19.

Assessment Criteria

Ayurvedic Parameters [22]

- Kandu (Itching)

1	No itching	0
2	Mild/occasional itching	1
3	Moderate frequent itching	2
4	Severe frequent itching	3
5	Very severe frequent itching, which disturb sleep and other routine activities	4

- Daha (Burning)

1	No Daha	0
2	Mild Daha	1
2	Moderate Daha	2
3	Severe Daha	3

- Raga (Redness)

1	No erythema	0
2	Faint	1
3	Light red	2
4	Moderate red	3
5	Bright red	4

- Shopha (Swelling)

1	No elevation	0
2	Elevation con not be palpable	1
3	Elevation can be palpable	2
4	Apparently palpable(approx about mm)	3
5	Apparently palpable(approx more than 1mm)	4

Scoring System (0–3 scale):

- 0- Absent
- 1- Mild
- 2- Moderate
- 3- Severe

Modern Parameters

- SCORAD Index
- Visual Analogue Scale (VAS) for pain

Grade	Pain
0	No pain
1(1-3)	Mild
2(4-6)	Moderate
3(7-10)	Severe

Assessments will be done on Day 0, Day 7, and Day 14.

Follow-up

Participants will be followed up on the 7th & 14th day post-treatment to assess any recurrence or delayed adverse reactions.

Ethical Consideration

This study approved by the Institutional Ethics Committee (IEC) of the Maharashtra University of Health Sciences, Nashik, India. Written informed consent would be obtained from the patients by the investigator before enrolling. The Indian Council of Medical Research National Ethical Guidelines for Biomedical and Health Research on Human.

Data Collection and Documentation

Data of the participants would be collected throughout the intervention. The assessment will be at baseline, based on the first and second follow-up, and tabulated in the CRF. The data of discontinued patients will also be collected based on their willingness.

Deviation from Protocol

In the event of any protocol deviation during the study, the investigator will document the deviation in detail and assess its impact on participant safety and study outcomes; appropriate corrective actions will be implemented, and necessary adjustments to the study protocol will be submitted for approval from the ethics committee if required. All protocol deviations will be systematically documented and informed to the IEC.

Confidentiality

Confidentiality of participant information will be strictly maintained throughout the study by assigning unique identification numbers to each participant

Statistical Analysis

Data will be compiled and analysed using Friedman test and Wilcoxon signed-rank test as applicable. A p-value <0.05 will be considered statistically significant.

Expected Outcomes

- Significant improvement in symptoms like itching, redness, and swelling.
- High patient satisfaction with minimal or no adverse effects.

DISCUSSION

The increasing use of synthetic cosmetics has led to an epidemic of skin hypersensitivity reactions. In Ayurveda view, these can be understood as Agantuja Vikara caused by external Dushivisha, especially in those with compromised immunity or skin barrier.

Sevyadi Yog Lepa acts through multiple pharmacological mechanisms. The combination, when applied topically, neutralizes the cosmetic allergens (Agantu dravya), pacifies Pitta and Rakta Dushti, and restores skin health.

CONCLUSION

This clinical study aims to provide scientific validation to the traditional Ayurveda formulation, Sevyadi Yog Lepa, in the treatment of contact dermatitis. If proven effective, it can serve as a safe, cost-effective, and holistic alternative for dermatological care with its action through Agantantra principles and supports the integration of Ayurveda into modern dermatological care.

REFERENCES

1. Vincet S.Beltrani,MD; I.Leonard Bernstein,MD; David E. Cohen, et al. Contact dermatitis: a practice parameter, (2006),cited on 2023 May 20 16.

2. Gharani R.Clinical Dermatology,Comparative Dermatology,New Central agency(P)Ltd,2014
3. Gupta L.IADVL's Concise Textbook of dermatology,Jaypee brothers medical
4. Waghmare T,Chavan K,Utility of Lepa Kalpana with special reference to Visha ChikitsaA Review, Journal Of Ayurveda and Integrated Medical Science,Vol 7,March 2022
5. Charaka Samhita of Agnivesha, Chikitsa Sthana, Ch. 23, Verses 35-37. Vaidya Jadavaji Trikamji Acharya, editor. 7th ed. Varanasi: Chaukhambha Sanskrit Series; 2010.
6. Tripathi B. Sharangdhar Samhita, Chaukamba Prakashan Varanasi 2011, Ch 11/72-76
7. Raneesh S,Benil PB,Abdul Latheef EN,Randomized controlled trial on candanaadi lepa versus triphala lepa in paaduka visha(Footwear dermatitis)W.S.R. to allergic dermatitis,Ayurpharm Int J Ayur Alli Sci,Vol 1,No.4(2012)Pages 77-82.
8. Srivastava Pratisha,Gupta Mahima,Sharma Rakesh Kumar,Chemicals In Cosmetics: Enhancing Awareness Among Students Through Science Teaching,Journal of Pharmaceutical Negative Results,Vol13,2022,cited on 2023 aug 18.
9. Siti Zulaikhar,Sharifah Norkhadajah S.I.,Praveena S.M.Hazardous Ingredients in cosmetics and personal care products and health concern: A Review ,ResearchGate, January 2015.
10. Bramhanand Tripathi. Ashtanga Hridayam, Uttarsthan. Chaukhamba Sankrit Pratishthan, Delhi, Edition 2015,
11. Anonymous. The Ayurvedic Pharmacopoeia of India. Govt. of India. Part II (Formulations), Volume I, First Edition 2007; Lepa, Page 129
12. Shashtri, Ambika Dutt Sushruta Samhita of Maharsi Sushruta, 2006, Su ,ch-1/14
13. Shashtri, Ambika Dutt Sushruta Samhita of Maharsi Sushruta, 2006, Su kalp, ch-1/25
14. Tripathi, R Ashtang Hrudaya of Shrimad Vrddha Vagbhata, 2001, Su, ch-7/19-20
15. Sharma P,Dhanvantari Nighantu,Chaukhamba Orientalia, Varanasi, 2008
16. Chuneekar KC,Bhavprakash Nighantu Pandey G,editor.Varanasi:Chaukhambh Bharati academy;2015
17. Sharma P,Kaidev Nighantu,Chaukhamba Orientalia, Varanasi, 2006
18. Gogagte V.Dravyagunavidnyana, Vaidya mitra Prakashan, 2008
19. Tripathi B.Sarangdhara Samhita, Chaukamba Prakashan Varanasi 2011, Ch 1/49
20. Tripathi B.Sarangdhara Samhita, Chaukamba Prakashan Varanasi 2011, Ch 11/2
21. Tripathi B.Sarangdhara Samhita, Chaukamba Prakashan Varanasi 2011, Ch 1/47
22. Dr. Rajagopal's,WHO –DFC sponsored ,Developing Guidelines for Clinical Research methodology in Ayurveda,Jamnagar,2011.