

**COMPARATIVE CLINICAL STUDY TO ASSESS THE EFFICACY OF
PATHA (*CISSAMPELOS PAREIRA LINN*) PATRA LEPA AND PATHA
PATRA AVACHURNANA IN THE MANAGEMENT OF DADRU
KUSHTA VIS-A-VIS TINEA CRURIS**

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ABSTRACT

Background and Objectives: Kushta is one among the Asthamahagada explained by Acharya Charaka. In contemporary medicine, Dermatophytosis/tinea/ringworm which is skin fungal infection is correlated to *Dadru Kushta* due to similarities in their signs and symptoms. It causes itchy, red, circular rashes. Fungal infection of groin, perineal, pubic, perianal skin together known as ‘Tinea Cruris’ or Jock itch, predominant in 20–25% of total world populations. The treatment in Modern dermatology is not satisfactory due to more chances of recurrence, long duration of treatment and drug resistance. In ayurveda, the treatment modalities of kushta include Shodhana and Shamana. *Patha*, attributed with Kushtahara-Krimihara karma is extensively used as local application in folklore practices which need to be scientifically validated. **Methodology:** Physicochemical and Phytochemical analysis of the drug was carried out. 40 subjects with lakshanas of Dadru kushta (*Tinea cruris*) fulfilling the inclusion criteria

were selected for the trial under strict randomization. 20 subjects in group A were treated with Patha patra lepa with gomutra and 20 subjects in group B with Patha patra avachurnana for 30 days. **Results:** Phytochemical analysis of the drug showed the presence of Secondary metabolites like Alkaloids, Tannins, Flavanoids, Starch and phenolic compounds. Both the groups showed varied level of significance with good improvement in subjective and objective parameter among which group A showed better results. **Conclusion:** Patha patra churna was found to be effective as bahirparimarjana chikitsa. Both Patha patra lepa and Avachurnana showed similar effect among which former was better than later.

KEYWORDS: Dadru kushta; Tinea cruris; Dermatophytosis; Patha lepa; Avachurnana.

INTRODUCTION

The skin, or integumentary system, is the largest organ of the human body, serving as a dynamic interface between the internal systems and the external environment. In recent years, there has been a considerable increase in incidence of skin problems in the tropical and developing countries like India due to various reasons like poverty, poor sanitation, unhygienic, pollution etc.^[1] One type of insult is free radicals (reactive oxygen species), which cause or contribute to skin problems such as erythema, edema, itching, wrinkling, photoaging, autoimmune reactions, inflammation and hypersensitivity (allergies).^[2] Superficial fungal Infection of the skin is the most common dermatological manifestation affecting up to 15% of world's population in all group.

Dermatophytosis, the highly specialized fungi, may cause a variety of lesions of skin. Moisture and warm conditions are the most suitable factors to a wide distribution of dermatophytosis in tropical countries.^[3] Skin is the most exposed part, patients who suffer from skin disorders face physical, emotional, and socioeconomic stigma in their communities from a cosmetic standpoint. Commonly infection types are named with respect to affected body parts. Fungal infection of groin, perineal, pubic, perianal skin together known as 'Tinea Cruris' or Jock itch, predominant in 20–25% of total world populations.^[4] The treatment in Modern dermatology is not satisfactory due to more chances of recurrence, long duration of treatment and drug resistance.

In Ayurvedic science, skin diseases are classified under broad heading of Kushta. 18 types of Kushta have been mentioned in classics which are classified into Mahakushta and Kshudrakushta.^[5] Dadru is a kaphapittaja variety of kushta^[6], characterised by kandu (severe

itching), raaga (erythema), (burning sensation) and pidaka(discoid lesions), with utssanamandal(elevated borders).^[7] The chikitsa of kushta includes Shodhana and Shamana karma. Many Kushtahara dravyas are mentioned in nighantus among which Patha is one, attributed with Kushtahara, Krimihara, Vishaghna, Rakshoghna, Medhya, Kamyā, Rasayana and Garbhastapana^[8] karmas. Patha is widely used in fungal skin disorders as local application in folklore practices which needs to be evaluated scientifically.

Hence, the present study entitled “An open labelled randomised comparative clinical study to assess the efficacy of Patha (*cissampelos pareira linn*) patra lepa and Patha patra avachurnana in the management of Dadru kushta vis-a-vis Tinea cruris” was planned.

AIMS OF THE STUDY

To compare the efficacy of Patha patra lepa and avachurnana as a Bahirparimarjana chikitsa in the management of Dadru kushta vis-a-vis Tinea cruris.

OBJECTIVES OF THE STUDY

- To study the preliminary Pharmacognostic and Phytochemical analysis of Patha patra.
- To assess the efficacy of Patha patra lepa in the management of Dadru kushta(Tinea cruris).
- To assess the efficacy of Patha patra avachurnana(dusting) in the management of Dadru kushta(Tinea cruris).
- To compare the effect of Patha patra lepa over Patha patra avachurnana (dusting) in the management of Dadru kushta(Tinea cruris).

MATERIALS AND METHODS

Selection of patients

40 Patients of Dadru kushta(Tinea cruris) were selected from O.P.D. and I.P.D. of Taranath Government Ayurvedic Medical College and Hospital, Ballari by considering inclusion and exclusion criteria.

Study Design: Randomised Prospective Open labelled Comparative Clinical Study.

Estimated enrolment : - 40
Intervention Model : - Comparative
Allocation : - Randomised
Masking : - Open

Primary Purpose : - Treatment

Intervention

A) Group A: n= 20

- Lepa of 10gm of Patha patra churna(sieve no.100) with sufficient quantity of gomutra was applied externally on affected areas.
- Lepa was removed before drying completely.
- Thickness – 1/3rd Angushtha (0.205 inch).
- Applied twice a day(morning and evening, keeping a gap of 12 hours) after washing the affected areas, for 30 days.

B) Group B : n= 20

- Dusting of 10gm of Patha patra churna(sieve no.120) was done on affected areas externally.
- Applied twice a day (morning and evening, keeping a gap of 12 hours) after washing the affected areas, for 30 days.

ETHICAL CLEARANCE

The study was approved by the Institutional Ethics Committee, TGAMC, Ballari(No: TGAMC/SS/02/2019-20).

DIAGNOSTIC CRITERIA

Patients present with classical signs and symptoms of Dadru kushta(Tinea cruris).

Subjective parameters: Subjective parameters were graded and score was given accordingly.

- Kandu(itching)
- Pidaka(eruption)
- Raaga(erythema)
- Daha(burning sensation)
- Udgata mandala(elevated circular lesion)

Objective Parameters

- Size of mandala
- AEC
- KOH Microscopy(Skin scrape test)

INCLUSION CRITERIA

- Subjects aged between 18-60 years were included for study.
- Subjects who have given informed consent.
- Subjects presenting with classical signs and symptoms of dadru kushta.

EXCLUSION CRITERIA

- Subjects having any acute and complex systemic illness.
- Pregnant and lactating women.
- Subjects presenting with any other skin disorder which is associated with dadru kushta.
- Subjects having immune compromising condition or taking immunosuppressive drugs.

ASSESSMENT CRITERIA

- Assessment was done before and after treatment(Day 1 and Day 31).
- The results were compiled and subjected to unpaired “t” test to ascertain statistical significance.

Table No – 1: Showing Grading For Subjective Parameters.

SL NO	SYMPTOM	PARAMETERS	GRADE
1.	Kandu (itching)	No itching	0
		Mild /infrequent itching	1
		Moderate/ frequent itching, compulsive scratching, do not disturb sleep	2
		Severe itching/ very severe itching disturbing sleep and other activities	3
2.	Pidaka (eruption)	No eruption/pidaka	0
		Pidaka in 0-25% affected, 1 to 3 mandal	1
		Pidaka in 25-50% affected, 4 to 6 mandal	2
		Pidaka in 50-75% affected, more than 6 mandal	3
3.	Raaga (erythema)	Normal skin colour	0
		Faint red colour	1
		Red colour	2
		Brownish red colour	3
4.	Daha (burning sensation)	Absent	0
		Mild burning sensation after itching	1
		Moderate burning sensation(No disturbance in sleep)	2
		Severe burning sensation(disrupts sleep)	3

Table No – 2: Showing Grading For Objective Parameters.

SL NO	SYMPTOM	PARAMETERS	GRADE
1.	Area of lesion	No mandala	0
		< 5 cm	1
		5-10 cm	2
		>10 cm	3
2.	AEC(absolute eosinophil count)	Normal (30-500 cells/ml)	0
		Raised (>500 cells/ml)	1
3.	KOH MICROSCOPY	Negative	0
		Positive	1

OBSERVATION AND RESULTS

The observations of the study was carried out in two phases:

1. Analytical study
2. Clinical study

✧ **Pharmacognostical study**

Table no- 3: Showing Organoleptic characters of Patha patra.

Colour	Green
Taste	Tikta, katu
Odour	No specific odour
Touch	Smooth
Shape	Peltate, cordate at base

Macroscopic study- Peltate cordate at base, green colour leaf, rough surface, bitter taste confirms the identity of drug.

Microscopic study- Powder microscopy showed the presence of lignified xylem vessels, unicellular trichome, wavy epidermis, prismatic calcium oxalate crystals, radial medullary rays which confirms the identity.

✧ **Physicochemical study**

Table no - 4: Showing the observation of Physicochemical tests of Patha.

SR.NO.	TEST	RESULT
1.	Foreign matter	0.5%
2.	Ash value	1.5%
3.	Acid insoluble ash	0.5%
4.	Water soluble ash	0.9%
5.	Alcohol soluble extract	09%
6.	Water soluble extract	12%
7.	Moisture content	8.28%

✧ **Phytochemical study**

Table no- 5: Showing the observations of phytochemical tests of Patha.

SR.NO.	TEST	RESULTS
1.	Carbohydrate	Absent
2.	Protein	Absent
3.	Saponin	Absent
4.	Tannin	Present
5.	Steroid	Absent
6.	Alkaloid	Present
7.	Flavanoids	Present
8.	Triterpenoids	Absent
9.	Starch	Present
10.	Phenolic compounds	Present

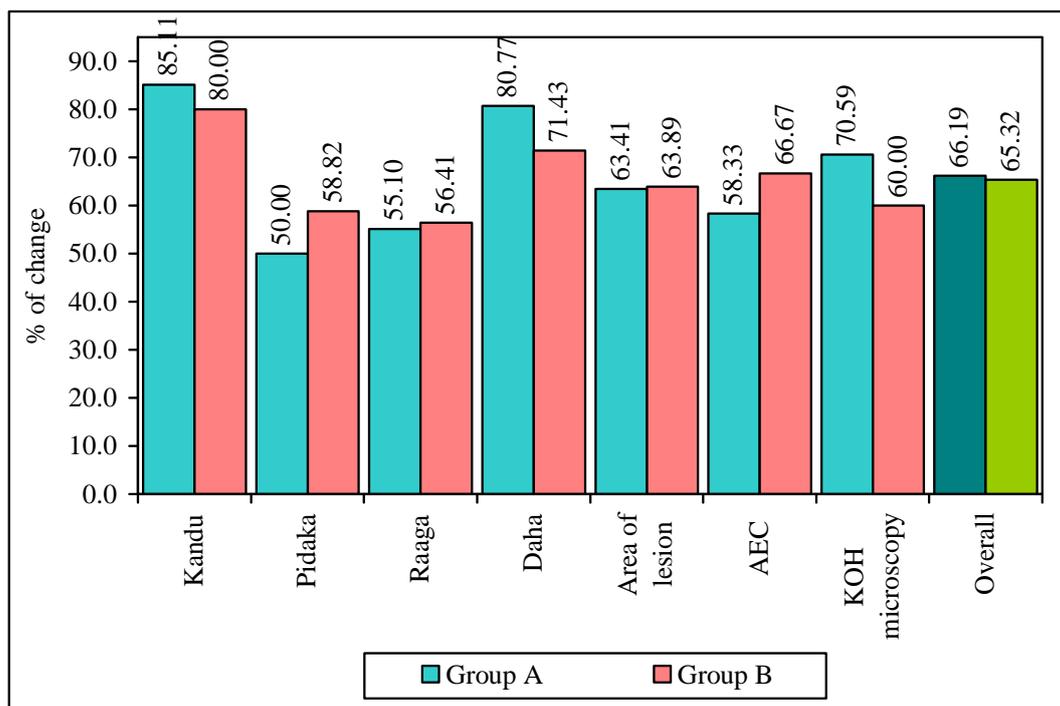
✧ **Chromatographic study**

TLC Extract: Alcohol Mobile phase: Toluene : Ethyl acetate (9:1)	Visible light Rf value: 0.15 0.28 0.45 0.62 0.81 Under 254m Rf Value: 0.15 0.45 0.62 0.81 366m: Rf value: 0.15 0.28 0.45 0.62 0.81
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RESULTS

Table no- 6: Overall changes in each parameter from before treatment to after treatment.

	Parameters	Changes from	Group A	Group B
Subjective parameters	Kandu	Before treatment-After treatment	85.11	80.00
	Pidaka	Before treatment-After treatment	50.00	58.82
	Raaga	Before treatment-After treatment	55.10	56.41
	Daha	Before treatment-After treatment	80.77	71.43
Objective parameters	Area of lesion	Before treatment-After treatment	63.41	63.89
	AEC (Absolute Eosinophil Count)	Before treatment-After treatment	58.33	66.67
	KOH microscopy	Before treatment-After treatment	70.59	60.00
	Overall Assessment:	Before treatment-After treatment	66.19	65.32



Graph no - 1 Overall changes in each parameter from before treatment to after treatment.

- A Significant of 66.19% reduction was seen in Overall assessment parameter from before treatment to after treatment in Group A and 65.32% reduction was seen in Overall assessment parameter from before treatment to after treatment in Group B.
- Thus, the reduction in overall assesment parameter was slightly more in Group A compared to Group B from before treatment to after treatment.

DISCUSSION

1. DISCUSSION ON ANALYTICAL STUDY

Macroscopic and Microscopic analysis

- The organoleptic/Macroscopic studies are on par with the standards which confirms the identity of Patha.
- Powder microscopy of Patha showed presence of lignified xylem vessels, unicellular trichome, wavy epidermis, prismatic calcium oxalate crystals, radial medullary rays which confirms the identity.

Physicochemical analysis

- The foreign matter was 0.5% which is within the standard limits indicating very minimal physical impurities.

- Total ash value (1.5%) was within the standard limits indicating the presence of minimal inorganic compounds.
- Acid insoluble ash values(0.5%) was within standard limits indicating minimal inorganic content.
- The water soluble ash value (0.9%) indicates presence of minimal amount of kshara which may be helpful in healing of skin lesions.
- Water soluble Extractive value (12%) and Alcohol soluble extractive value (8%) values was within the standard limits which indicates the presence of more water soluble components than alcohol soluble components.
- The Moisture content was (8.28%) was indicating minimal contamination by microbes and pests. As standard values are not available for loss on drying it was done in triplicate method.

Phytochemical Analysis

Phytochemical screening of Patha revealed the presence of secondary metabolites like Alkaloids, tannins, flavanoids, terpenoids, starch and phenolic compounds.

- Alkaloids are responsible for anti-inflammatory, antioxidant, antimicrobial and immunomodulatory effects
- Flavonoids possess Anti-inflammatory, Anti-oxidant activities.
- Tannins are anti-oxidant, antimicrobial actions.
- Terpenoids are responsible for anti-inflammatory, anti-microbial and immunomodulatory effects.

Thin layer chromatography

- Under UV 366 nm, alcoholic extract of Patha showed more number of components when compared to that of UV 254 nm.

DISCUSSION OF CLINICAL STUDY

Discussion on data related to drug intervention on subjective and objective parameters

- **Subjective parameters**

i) Discussion on effect of treatment on Kandu

- Statistically highly significant results were observed after the treatment (on 30th day) in both the groups. There was 85.11% and 80% reduction in Kandu in group A and group B respectively.

- Itching starts with keratinocyte activation and inflammation, further progressed to Neurotransmitter imbalance and sensory nerve fiber activation leading to release of histamine which manifests as Itching sensation.
- According to Ayurveda, Kandu occurs due to vitiation of kapha dosha and rakta dushti. Kandu is one of the Kapha prakopaka lakshana.
- Patha having tikta, katu rasa and ushna veerya helps in mitigation of pitta and kapha dosha hence relieving symptoms of Kandu. Patha has kanduhara, krimighna and kushtaghna properties. External application of Patha acts as ropana, kushtaghna has helped reducing the itching.

ii) Discussion on effect of treatment on Pidaka

- Statistically highly significant results were observed after the treatment (on 30th day) in both the groups. There was 50% and 58.82% reduction of pidaka in group A and group B respectively.
- The vitiated *Vata Dosha* along with *Prakupita Pitta* and *Rakta* produces *Pidaka* (eruption), which is nothing but the *Roopavastha* of the disease *Dadru*. At this stage exact clinical features of the disease are evident according to the involvement of the *Doshas*.
- *Pidaka* is caused by avarana of rakta by dushita kapha and pitta (Su.Ni 13th/3-4). Application of Patha helps in vrana ropana by its Tikta rasa, kledahara and Vishaghna karma thereby reducing the size of pidaka and further vitiation of doshas.

iii) Discussion on effect of treatment on Raaga

- Statistically highly significant results were observed after the treatment (on 30th day) in both the groups. There was 55.10% and 56.41% reduction of Raaga in group A and group B respectively.
- Erythema in Tinea is due to the skin's inflammatory response to the dermatophyte fungus invading the skin.
- Ayurvedhana, Varnya and Balakaraka^[10] are the Prakruta karmas of agni. As Pitta and Agni share similar properties and the site of Bhrajaka pitta being Twak, vitiation of Agni and Bhrajaka pitta will lead to twak Vaivarnyata. In Kushta samprapti, sthana samshraya of doshas occur in between Twak and Mamsa resulting in Raaga(erythema). Dadru is caused by Kapha- pitta dosha, Raaga(Erythema) here is mainly due to dushita Vata, Bhrajaka Pitta and Rakta.

- As Patha is Kaphapittashamaka and Raktadoshahara, its external application facilitates the drug penetration into the skin thereby regulating Bhrajaka pitta leading to reduction of Raaga in Dadru. Anti-inflammatory and antibacterial actions of Patha helped to reduce the Raaga(erythema) of Dadru.

iv) Discussion of effect of treatment on Daha

- Statistically highly significant results were observed after the treatment (on 30th day) in both the groups. There was 80.76% and 71.42% reduction in Daha in group A and group B respectively.
- Burning sensation particularly in areas of buttocks, groin, perineal region in Tinea infection is due to response to nerve injuries, increase in pro-inflammatory cytokines and neurotransmitters that contribute to the sensation of pain. Daha is due to vitiated pitta dosha, avarana of vata and rakta dushti.
- Tikta rasa of Patha allevates pitta dosha, acts as Raktashodhaka, thereby reducing burning sensation.

Objective Parameters

i) Discussion on Efficacy of Intervention on Area of lesion

- Statistically highly significant results were observed after the treatment (on 30th day) in both the groups. There was 63.41% and 63.88% reduction in size of lesion in group A and group B respectively.
- Size of area depends upon amount of dosha accumulated and Color of the area depends upon the dominant dosha. It was noted that there was no new lesion/no spreading of the skin lesions during and after the treatment.
- Patha patra lepa helps in reduction of accumulated dosha thereby reducing the size of the area maybe due to its vrana ropana.

ii) Discussion on Efficacy of Intervention on AEC

- Statistically significant results were observed after the treatment (on 30th day) in both the groups. There was 58.33% and 66.66% reduction in AEC in group A and group B respectively.
- Elevated eosinophil count leads to white blood cells active in case of allergy, infection, low immune system, kind of infection from virus, bacteria or fungus.

- Mutation in high AEC disrupts skin barrier integrity and hair follicle biology. In chronic cases, the persistent presence of fungus stimulates the immune system, leading to an increased production and circulation of eosinophils to fight the infection at affected skin site.
- Vishaghna karma of Patha may be helpful in AEC. Patha acts as immunomodulatory, antioxidant, antifungal, antihelminthic, antimicrobial and also as disinfectant which helps in reduction of high level of AEC.

iii) Discussion on Efficacy of Intervention on KOH microscopy

- Statistically significant results were observed after the treatment (on 30th day) in both the groups. There was 70.58% and 60% improvement in group A and group B respectively.
- A potassium hydroxide mount of a skinscraping is a common procedure performed to demonstrate the evidence of fungal infection in skin, hair and nails. Presence of hyphae and spores confirms fungal infection. It is fast, easy and cost effective method for initial diagnosis.
- Patha due to its krimighna, and vishaghna karma helps to reduce fungal growth. Anti-inflammatory and antimicrobial activity of Patha helps in healing and stops further microbial growth.

Discussion on Comparative results of Group A and Group B

- Comparative analysis of the overall effect of the treatments in both the groups was done statistically with unpaired t test. The test shows that the treatment is significant in Group A when compared to Group B. Group A overall result is 66.19% and Group B overall result is 65.32%.
- Both Patha patra lepa and avachurnana exhibit similar results in reducing the lakshanas of Dadru kushta. A slightly enhanced result of lepa may be due to addition of gomutra.

MODE OF ACTION OF PATHA PATRA

Patha Patra

- Patha patra has Tikta-katu rasa, Laghu and tikshna guna, Ushna veerya, Katu vipaka, also Tridosha hara in action which helps in pacifying pitta and kapha dosha predominantly. Tikta rasa^[9] has Vishaghna, krimighna, dahaprashamana, kandughna and kushtaghna actions.

- Laghu and tikshna guna may help in faster penetration of the drug into the affected part and relieve kapha avarana.
- Due to its usna virya and Laghu, tikshna guna, Patha is lekhana and ropana in action, enhances antioxidant defences. Usna virya accounts for the majority of the elements, and its vatakaphashamaka and ashupaka actions enable it to act quickly on srotas.
- Katu vipaka assists in srotoshodhana. It has anti-inflammatory, antifungal, antimicrobial properties commonly used traditional medicine in south india for eczema, fungal infections.

❖ Mode of action of Gomutra

Gomutra is selected as adjuvant therapy for the medicine because it acts as a binder. Cow urine is projected as Bio-enhancer for various drugs. Bio-enhancers^[10] is such a material which increases the activity of drug when mixed with the main drug. This activity might be due to laghu and tikshna guna of gomutra. Gomutra having katu, tikta, kashaya, kinchit madhura rasa, tikshna, usna, laghu guna, possessing usna virya, katu vipaka. Gomutra does shodhana and is vatakapha shamaka in action.

CONCLUSION

- Physicochemical analysis of the drug *Cissampelos pariera* Linn. are in accordance with the standards mentioned in the API, which confirms the genuinity of the drug. Phytochemical analysis of Patha(*Cissampelos pariera* Linn.) showed the presence of common secondary metabolites such as alkaloids, flavanoids, triterpenoids and tannins having anti-inflammatory, anti-oxidant actions which contributes to antifungal activity.
- In present clinical study Group A and Group B given lepa with *Patha patra churna and gomutra* and *Patha patra avachurnana* respectively for a period of 30 days. Patha has shown statistically significant results ($P < 0.05$) in all the parameters of Dadru kushta. Both Patha patra lepa and avachurnana exhibit similar results in reducing the lakshanas of Dadru kushta. A slightly enhanced result of lepa may be due to addition of gomutra.
- Patha patra lepa with gomutra is suitable in Tinea infection of chronic stage associated with hyperkeratosis, hyperpigmentation and erythema whereas Patha patra avachurnana is better in Tinea infection of Acute stage associated with erythema, maceration of skin with moist exudative rash.

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Conflicts of interest

There are no conflicts of interest.

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