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Clinical efficacy of *Lakshadi Lepa* on *Dadru Kushtha* w.s.r. to *Dushi Visha*: A Randomized Control Clinical Trial

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ABSTRACT

Dadru is one of the common skin disease mentioned in *ayurveda*. In modern science the clinical manifestation of *dadru* is closely similar to local fungal infection/tinea infection which is affecting upto 15% of population. Excessive severe itching and red patches are the common clinical manifestation which can be diagnosed by *darshana* and *prashanapariksha*. Potassium hydroxide microscopy and fungal culture are the specific tools for diagnosis of fungal infection. *Lepana* and *Shamanachikitsa* will help to cure *Dadru*.

Key Words

Dadru, Shodhana, Shamana Chikitsa, Lepana, KOH

INTRODUCTION

Now a days skin diseases are common at any age of the individual but they are particularly frequent in the elderly. The patients experiences physical, emotional and socio-economic embarrassment in society. Normal 10-15% of the general practitioners work with skin disorders (Roxburgh's common skin Diseases). All the skin diseases in *Ayurveda* have been classified under the broad heading of *Kushtha* which are further categorized in to *Mahakushtha* and *KshudraKushtha*. *Dadru* is considered in both the groups

of *Kushtha* (*kshudra* & *MahaKushtha*) as per *CharakaSamhita* & *SushrutaSamhita*, respectively. In *Ayurveda* classics, any specific aetiology for *Dadru* has not been explained, except the general aetiology of *Kushtha*. Since *Dadru* has been included under *Kushtha*, its aetiology can be constructed on the basis of general aetiology. The main causative factors of *Kushtha* are *Mithya Ahara* and *Mithya Achara*. *Mithya Ahara* means a type of diet which is not proper and not according to the rules. *Vijayaraksita*, the commentator of *Madhava Nidana* defined *Mithya Ahara* as 'a diet opposite to *Ashtha Ahara Vidhi Vishesayatanam*'¹



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Dadru is *Kapha* dominant phenomenon according to *Acharya Sushruta* and *Kaphapittaja* according to *Acharya Charaka*.

Acharya Sushruta added '*Lepana*' therapy or external applications just after formation of the lesion on the skin and continuing it from the very beginning to the 'end curable stage of the disease'. So obviously it should be considered as a best way to treat *Kushtha*, further more *Acharya Charaka* also described '*Lepana Karma*' to apply just after *Raktaavasechana*

AIMS AND OBJECTIVES

Present research work includes following objectives -

1. To evaluate, elaborate and discussion of Ayurvedic aspect of *Dadru kushtha*.
2. To study the clinical efficacy of ***Lakshadi Lepa with Patol-triphaladi kwath Ghan vati*** on *Dadru kushtha*.
3. To evaluate the effect of cutis cream with ***patol-tripladikwathGhanVati***.
4. To compare the clinical efficacy of ***lakshadi Lepa with patol-tripladi kwath Ghan Vati and Cutis Cream*** along with ***Patol-tripladi kwath Ghan vati***.

MATERIALS AND METHODS

(I.E.C no-IEC/ACA/2018/2)

Patients:

For the clinical study, 30 patients were selected from the O.P.D and I.P.D of PG Dept. of *Agad tantra evum Vyavhar Ayurveda*, National Institute

of Ayurveda, Jaipur. Voluntary written informed consent had been taken from each subject before trial starts. Patients fulfilling the criteria for selection were integrated into the study irrespective of caste, religion etc. A detailed history was filled up in dually prepared performance on *Ayurvedic* guidelines.

Method of collection of data :

30 patient's were selected from OPD of National Institute of Ayurveda, Jaipur with complaining of *Kandu* over groin region and other parts of body, *Twak Vaivarnya* with mild discharge and associated symptoms like *Anidra* and incomplete bowel evacuation. They were treated after proper physical examination in OPD and IPD levels. Selected 30 patients were randomly divided in 2 groups.

A. Study group (Group. A) – *Lakshadi Lepa* along with *Patol-triphaladi Kwathghanvati* Was given in 15 patients of *Dadru Kushtha*.

B. Control group (Group. B) - Cutis Cream along with *Patol-triphaladi Kwathghan vati* was given in 15 patients of *Dadru Kushtha*.

Criteria for selection of patients :

Inclusion criteria

1. Patient with the classical sign and symptoms of *Dadru kushtha*.
2. Patient with positive KOH test for Fungal Dermatophytes.
3. Patient between 16 years to 70 years of age were included in this trial.
4. Patients belonging to either gender were included in this trial.



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Exclusion Criteria

1. The patient suffering from systemic disorders (eg. DM, HIV etc) were excluded from this trial.
2. The pregnant women and lactating mother were excluded.

Criteria For Diagnosis

All the patients were diagnosed and assessed thoroughly on the basis of *Ayurvedic* and modern classical signs and symptoms. Patients examined on the basis of specially prepared proforma as mentioned in below.

Clinical Diagnosis

1. Classical sign and symptoms of *Dadru kushtha* were scored and assessed.

Treatment protocol:

Posology:

Group	Drug	Form	Dose	Route and Time of Administration	Duration
A	<u>LakshadiLepa</u>	Lepa	As per need of the patient (according to affected area)	Route: local application Time: Twice daily Anupan-Takra	1 month
	<u>Patoltripladikwath Ghanvati</u>	Vati	500mg 2 tab twice a day	Route: Oral Time: Twice daily after meal Anupan-Ushnajala	
B	<u>Cutis cream</u>	Lepa	As per need of the patient (according to affected area)	Route: local application Time: Twice daily	1 month
	<u>Patoltripladikwath Ghanvati</u>	Vati	500mg 2 tab twice a day	Route: Oral Time: Twice daily after meal Anupan-ushnajala	

Criteria for assessment

Parameter for the Assessment of Improvement

Classical sign and symptoms of *DadruKustha* would be scored and assessed accordingly. Assessment of effects of therapy was done on the basis of various subjective and objective parameters. For the purpose of

2. Photography

3. KOH Microscopy

Method of research:

The method adopted in present study was open randomized control clinical trial. Ethical clearance was obtained for the study from the Institutional ethics committee. Total 30 patients were registered and categorized into Group A and B.

Informed consent:

The purpose of the study, nature of the study drugs, the procedures to be carried out and the potential risks and benefits were explained to the patients in detail in non-technical terms. Thereafter, their written consent was taken before starting the procedure.

assessment ,a detailed research clinical performa was prepared, which incorporating various parameters like *Dashavidha pariksha*, *Asthavidha pariksha* etc. Assessment was done after every 15 days during the entire study periods. Affected area assessed by photography on 0,15th day and 30th



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day of treatment . Following criteria were adopted for the purpose of assessment.

- (a) Subjective Parameters
- (b) Objective parameters
- (c) Laboratory investigation based parameters

(a) Subjective parameters

On the basis of Ayurvedic classical sign and symptoms of *Dadru Kustha* were considered under subjective parameters and assessment the overall effect of therapies a special scoring method was adopted as follow.

1. Kandu	Score
No itching	0
Mild itching	1
Moderate Itching	2
Severe Itching	3

Mild Itching:- Which comes occasionally, does not disturb routine activity , duration is 2 to 3 min; usually scratching is not required.

Moderate Itching:- Which occurs frequently and disturbs the routine activity but does not disturb sleep.Lasts for longer time, scratching every time is essential , recurs 3 to 4 times in 12 hour.

Severe Itching:- Frequently occurs , disturbs routine activity and sleep , lasts for 20 to 30 min, very essential, recurs 8 to 10 times in 12 hours.

2. Raga	Score
Normal skin colour	0
Mild red colour	1
Mild red colour	2
Dark down colour	3

3. Daha	Score
Absent	0
Mild (occasionally)	1

Moderate (whole day continuous) 2
Severe (Disturbs sleep) 3

4. Rukshata (dryness) score

Absent	0
Mild (Whitening of skin)	1
Moderate (Scaling of skin)	2
Severe (cracking of skin)	3

(b) Objective Parameters

1. No. of Mandal	Score
No Mandal	0
1 to 3 Mandal	1
4 to 6 Mandal	2
More than 6 Mandal	3

2. Size of Mandal	Score
Absent	0
Less than 5 cm	1
5 to 10 cm	2
More than 10 cm	3

When lesions (*Mandal*) are multiple, the size of the largest lesion is taken into consideration.

3. No. of pidika on lesion	Score
No of <i>Pidika</i>	0
1 to 3 <i>pidika</i>	1
4 to 6 <i>Pidika</i>	2
More than 6 <i>Pidika</i>	3

(c) Laboratory investigation based parameters

To find out the other systemic disease routine investigation were carried out before and after treatment.

1. Hb%
2. E.S.R
3. R.B.S
4. KOH SCRAPPING TEST



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To access the efficacy of two therapies intergroup comparison was done. As the variables are nonparametric we used **Mann-Whitney Test** for statistically analysis. The results are as follows.(Table 1)

RESULTS

A. Intergroup comparison of Subjective Parameters

Table 1 Intergroup comparison of therapy's on subjective parameters Score

Variables	Mean Diff.		SD±		SE±		P	Result
	Group A	Group B	Group A	Group B	Group A	Group B		
<i>Kandu</i>	1.933	1.733	0.5936	0.5936	0.1533	0.1533	0.1841	N.S
<i>Daha</i>	0.6000	0.6000	0.7368	0.5071	0.1902	0.1309	0.3992	N.S
<i>Raga</i>	1.067	0.9333	0.5936	0.2582	0.1533	0.06667	0.2198	N.S
Number of Mandal	0.9333	1.333	0.7037	0.4880	0.1817	0.1260	0.0508	N.Q.S
<i>Size of Mandal</i>	1.467	1.067	0.5164	0.4577	0.1333	0.1182	0.0194	S
<i>Piḍika</i>	0.8000	1.067	0.6761	0.7037	0.1746	0.1817	0.1517	N.S
<i>Rukshata</i>	0.7333	0.6000	0.5936	0.5071	0.1533	0.1309	0.2891	N.S

Table 2 Intergroup comparison of therapy's Effect on Laboratory Investigation Score-

Variable	Mean Diff.		SD±		SD±		T	P	Result
	Group A	Group B	Group A	Group B	Group A	Group B			
Hb %	0.3800	0.3867	0.5158	0.6632	0.1332	0.1712	0.03073	0.4879	N.S
ESR	3.400	1.867	3.112	1.356	0.8036	0.3501	1.749	0.0456	S
RBS	1.587	1.547	2.286	2.283	0.5902	0.5896	0.04795	0.4810	N.S
KOH scrapping	0.6000	0.7333	0.5071	0.4577	0.1309	0.1182	0.7559	0.2280	N.S

Table 3 Percentage relief in both the groups in subjective parameters

Subjective parameters	% Relief in Group A	% Relief in Group B
<i>Kandu</i>	72.96%	66.6%
<i>Daha</i>	59.277%	75%
<i>Raga</i>	44.7%	66.66%
Number of Mandal	36.84%	49.98%
<i>Size of Mandal</i>	61.1%	51.62%
<i>Piḍika</i>	57.14%	59.27%
<i>Rukshata</i>	84.60%	79.99%

Table 4 Percentage relief in both the groups in Objective parameters

Objective parameters	% relief in Group A	%relief in Group B
Hb %	2.75%	1.58%
ESR	22.46%	16.37%
RBS	0.99%	0.19%
KOH scrapping	75.00%	79.99%

Table 5 SammuchaLakshana (Overall symptoms)

Groups	N	Mean B.T.	Mean A.T.	Mean Diff.	Mean %	S.D.	S.E.	p
Group A	15	1.742	0.685	1.057	60.6%	0.625829	0.161586	0.00406
Group B	15	1.71	0.676	1.038	60.70%	0.503529	0.13001	0.00248



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For evaluating the effect of therapy within group before and after treatment for the subjective parameters Wilcoxon matched-pairs signed-ranks test is used separately on both study and control groups.

➤ In case of *Kandu*, the study group showed 72.96% extremely significant results and control group showed 66.6% extremely significant results. (Table no 3)

➤ The clinical effect of study group on *Daha* had showed 59.27% significant results and control group showed 75% very significant results. (Table no 3)

➤ The clinical effect of study group on *Raga* had showed 44.7% extremely significant results and control group showed 66.66% extremely significant result. (Table no 3)

➤ In case of number of *Mandala*, the study group showed 36.84% extremely significant result and control group showed 49.98% extremely significant result. (Table no 3)

➤ The clinical effect of study group on *pidika* has showed 57.14% very significant result and control group showed 59.27% extremely significant result. (Table no 3)

➤ In case of size of *Mandala*, the study group showed 61.1% extremely significant result and control group showed 51.62% E.S significant result. (Table no 3)

➤ In case of *Rukshata* study group showed 84.60% very significant result and control group showed 79.9 % very significant result. (Table no 3)

➤ Group A and group B shows extremely significant reduction in ESR which is supposed to be an inflammatory mediator proves potent Anti inflammatory action of *Ayurvedic* Trial drug and Control drug. (Table no 4)

➤ Group A drug shows significant result in increase of Hb% before and after treatment. and also shows significant results in KOH microscopy, group B shows not significant improvement in Hb after and before treatment and very significant in KOH microscopy. (Table no 4)

The analysis of the relief percentage of the *Sammuchya Lakshnas* (overall symptoms) showed that the percentage relief for Group A patients was 60.6% and the relief was maximum for Group B is 60.7%. The statistical analysis of the both groups shows that the improvements in both Groups were highly significant. In overall assessment of therapy also better results were observed by both groups. (Table no 5).

DISCUSSION

The case's selected in this study depend on *Nidana (Dushi Visha)* and *lakshana (Kandu, Raga, Pidika)*, number and size of *Mandala, rukshata, Daha* on body were diagnosed as *Dadru*.

Dadru is Kapha dominant phenomenon. In the explanation of the *chikitsa* for *Dadru Kushtha*, *Bahiparimarjana Chikitsa* type of treatment is mentioned. So, *Lakshadi Lepa* is selected for the present study. As a house on fire is brought to normalcy by sprinkling water like wise the *Lepa* applied brings down the concerned *Vikara*¹. This



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simile by *Acharya Sushruta* imparts the importance of *Lepa* which is one among the *bahiparimarjanachikitsa*.

Dadru and concept of Dushivisha

This is a most important and unique concept of *Ayurveda* which plays an important role in skin disorders. *Acharya Sushruta* has described *Dushivisha* in *Su.Ka. 2/25-26*. According to *Sushruta* when a person is afflicted by artificial or natural toxins, he is treated with antitoxic treatments. As a result, a complete elimination of these toxins from within the body is not possible. They may remain in a passive state for quiet long period. *Acharya Charaka* similar meaning can be elucidated from *Ch. Chi. 23/7,31*. He has opined that intake of toxic drugs which are less potent (*Heena Veerya*) remains in a inactive state within the body for many years together, without causing any harm to the body. It remains in the latent stage due to covering (*Avaran*) of *Kapha*.

On *Dhatu Dushti Chakrapani* has commented upon this statement of *Acharya Charaka*, that "*Dushivisha*" vitiates the *Dhatu*s after the lapse of a long time on obtaining a favourable condition.

Explaining further *Acharya Sushruta (su. Ka. 2/33)* has mentioned that "when causative factors like *Desha* (place), *Kala* (time), *Anna* (diet) and *Divaswapna* (day sleep) are favorable conditions for *Dushivisha*, it will become more potent vitiating *Dhatu*s leading to the manifestation of a disease."

Probable Mode of Action of *Lepa*

LEPA APPLICATION



RELEASE ACTIVE PRINCIPLES OF INGREDIENTS



ABSORBED THROUGH SVEDAVAHISROTASA AND SIRAMUKHA



PACHANA BY BHRAJAKAGNI



NEW METABOLITES FORMATION



PACIFICATION OF DOSHA



BREAKING OF PATHOGENESIS

In *Ayurveda*, the action of a drug is understood by the properties of its basic physico-chemical factors. Maximum Contents of *Lakshadi Lepa* are *Kapha-Vataghna* and *tikta and Katu* in *rasa*. Maximum compounds are *Ushna Virya* and *Madhura Katu Vipaka*; which subsides *Kapha-Vatadosha*. Because of *Katu-Tikta Rasa* of drugs. compound act as *Rochana, Deepan, Pachana* and stimulates both *Jathagni* and *Dhatvagni*. This compound act as *aAmapachaka* and prevents further formation of *ama* and *Dushivisha*. *Ushanavirya* helps in *Srotodshodhana* by *Lekhana karma*. *Chakramarda (Casiatora)* is well known *Kushthaghna*. *Haridra (Curcuma longa Linn)* breaks the pathogenesis of *Dadru* due to its *vishaghna and Kushthaghna* property. All these drugs possess *Kushthaghna* property. *Vishaghna*,
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Kushthana and *Krimighna karma* of *Marich,shunthi,Laksha,Chakramard* and *Pippali* and *RaktaSodhaka Karma* of *Haridra* and *Kushtha* help in purification of blood and work as anti-fungal, antiseptic and help in check in infection. Due to *Snigdha* and *LaghuGuna* of drugs acts as a *Vatashamaka*. Due to *Tikshna* and *Laghuguna* of drugs act as a *Kaphashamaka*. Due to *LaghuGuna* the drug causes *Deepana, Kaphashamana, Vatanulomana, Srotoshodhana, Vranaropana* and decreases the *Mala*. So all drugs have *Deepana, Pachana, Anulomana, Raktashodhaka, Vishaghana,kushthaghana, RaktapittaShamaka*, relieves the sign and symptoms of *Dadrukushtha*.

CONCLUSION

The results suggested that (*LakshadiLepa* along with *Patol-TriphaladiKwathGhanVati* and *Cutis cream* along with *Patol-TriphaladiKwathGhanVati*) in intergroup comparison showed that there is no major difference in efficacy of *Ayurvedic* trial drug & control drug. There was statistical difference in the clinical manifestation of *Dadruw.s.r.* to *Dushivisha* in both groups, but before and after treatment most of the clinical manifestation was controlled/ cured in both groups. Though there was no significant difference statistically in study and control groups but clinical relief in patient belonging to control group were found better than study group.



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