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A RANDOMISED CONTROLLED CLINICAL TRIAL TO STUDY THE EFFICACY OF AN ETHNOMEDICINAL FORMULATION IN DADRU KUSHTA

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ABSTRACT

Dadru is a variety of *Kushta* with *Rasa, Rakta, Mamsadhatu* involvement. Its aetiology includes *Aharaja, Viharaja, Chikithsaapacharaja, Upasargaja* and *Krimija* factors. Tinea infection is analogues to *Dadru* in contemporary science. Being a *Twak vikara*, *Bahirparimarjana chikitsa* like *Alepadi* treatments plays an important role in the treatment of *Dadrukushta*. *Taila* is applied as *Alepa* on the affected part. The present study was conducted on 40 diagnosed subjects of *Dadru kushta* who were randomly allocated with 20 each in two groups. *Tulasyadi taila* was taken for one group which was compared against widely used clinical formulation *Chakramarda taila* taken as standard for local application in another group. The application was done for 14 days, and the data was collected from the subjects at baseline, 7th day (during treatment), 14th day (after treatment) and 21st day (follow-up). The assessment was based on the KASI method of grading and perimeter of the lesion. The results of the study showed that there was no statistically significant difference between the effect of *Tulasyadi taila* and *Chakramarda taila* in *Dadru kushta*.

Keywords: *Dadru*, Tinea, *Tulasyadi taila, Chakramarda taila*

INTRODUCTION

Skin is a protective organ that reflects the health of the individual[1]. It is a target organ for many infections. In general, clinical practices around 10-20% of patients suffer from skin disorders of which, fungal infection constitutes up to 20%[2]. *Dadru* is a variety of *Kushta* with *Rasa, Rakta, Mamsadhatu* involvement[3]. Its aetiology includes *Aharaja, Viharaja, Chikithsaapacharaja, Upasargaja* and *Krimija* factors[4]. It is identified by symptoms such as *Kandu, Deergha pratana, Utsanna Mandala*[5]*, Raaga, Pidaka* with a predominance of *Pitta Kapha dosha*[6]. Tinea is a group name for a highly contagious, segmented mycelia fungus[7]. Tinea infection is analogues to *Dadru* in contemporary science[8]. Being a *Twak vikara, Bahirparimarjana chikitsa*[9] like *Alepadi* treatments plays an important role in the treatment of *Kushta* including *Dadrukushta*. *Taila* is applied as an *Alepa* on the affected part. In this study, *Tulasyadi taila* was taken for one group which was compared against widely used clinical formulation *Chakramarda taila*[10] taken as standard for local application in another group. *Tulasyadi taila* is an indigenous preparation comprised of ingredients like *Tulasi*[11], *Haridra*[12], *Jeeraka*[13], along with Breynia vitis-idaea[14] an ethnobotanical drug that has an Antibacterial and Antioxidant action. *Chakramarda taila* is used as *anubhoota yoga* as a management modality in patients suffering from *Dadru kushta*. Hence an earnest effort was made to compare the effect of this two *taila* in *Dadru Kushta*.

MATERIALS AND METHODS

- **Drug source and Drug Preparation: -** The raw materials for the preparation of medicine were procured from the local area. They were authenticated by experts and medicine was prepared at Dept. of Rasashastra and Bhaishajya Kalpana, Alva's Ayurveda Medical College, Moodbidri.
- **Source of data:**

- **Sample source: -** OPD and IPD of PG studies of *Kayachikitsa*, Alva's Ayurveda Medical College, Moodbidri.

- **Method of data collection:**

a) Selection of subjects: Irrespective of gender, religion, occupation, marital status, socio-economic status and education status.

- **Sample size:** 40 participants
- **Grouping:** 2 arms (A and B)
- **Number:** 20 in each arm
- **Study design:** A Randomized Parallel-Group Comparative Clinical Study
- **Blinding:** Single-blind
- **Method of sampling:** The lottery method

b) Diagnostic criteria:

Based on the following *lakshana* of *Dadru*.

- *Kandu*
- *Udgata mandala*
- With or without
- *Raga*
- *Pidaka*
- *Daha*
- *Rookshatha*

c) Inclusion criteria:

- Subjects who gave written consent
- Subjects who fulfilled diagnostic criteria
- Subjects with age group between 16 to 60 years

d) Exclusion criteria:

- Subjects who had lesions with secondary infections
- Subjects with any other systemic disorders

e) Interventions:

Group A- Trial group were given *Tulasyadi taila* for local application

Group B- Standard group were given *Chakramarda taila* for local application

Time of application- 2 times per day

f) Observation period:

Treatment period- 14 days

Days of assessments-

0^{th} day- at baseline

7^{th} day- during treatment

14^{th} day- after treatment

21^{st} day- on follow up

g) Assessment Criteria:

The assessment was based on

- KASI[15] method of grading
- The perimeter of each lesion

h) Statistical Methods:

- Central tendencies and dispersions were measured using Mean, Median, Standard Deviation, Standard Error and Quartiles.
- Tests of significance were done using paired 't' test and the unpaired 't' test.

OBSERVATIONS

It was observed that a maximum number of patients (72.5%) were from the age group of 16-30years. It represents the onset was more in youth and middle-aged. In gender, male predominance (60%) was observed in this study. Based on occupation, 57.5% were student's which indicates the communicable nature of *Dadru* among students, especially residing in hostels & their susceptibility to skin infections due to ignorance and neglect about personal hygiene. A maximum number of patients (82.5%) was from the middle class. In the mode of onset, acute cases were 50% and chronic cases were 50%. According to precipitating and aggravating factors, the present study revealed that about 82.5% of patients had aggravation during excessive sweating. This is due to the moist area on the skin triggers the fungal growth. Based on diet habits, maximum patients (75%) followed the mixed diet. This may be due to continuous intake of *matsya*, or *ksheera* with *matsya* which plays a role in *nidana* of *kushta*. Based on *prakrithi*, most patients i.e. 52.5% are of *vatapitta prakrithi*. 37.5% are of *vatakapha prakrithi*.

RESULTS

The study was carried out in 40 subjects divided into 2 groups. *Tulasyadi taila* was received by Group A and *Chakramarda taila* in Group B. The data was collected from subjects at baseline, 7th day (during treatment), 14th day (after treatment), 21st day (on follow up). In this study, paired and unpaired t-tests were performed to statistically evaluate the effectiveness of the interventions.

There was a statistically significant difference in Assessment parameters in both groups on the 7th, 14th and 21st day when compared to baseline. Table no. 1&2

There is no statistically significant difference in the results between Group A and Group B on the 7th, 14th and 21st day of treatment on KASI score. Table no.3

There is a statistically significant difference in the perimeter of the lesion between Group A and Group B after treatment. Group A subjects showed 68.8% relief and Group B showed 76.7% relief. Group B showed much relief than Group A. Table no.4

In overall effect of treatment, out of 40 subjects, 25% had complete relief, 45% had marked relief and 30% had moderate relief. Table no.5

DISCUSSION

In KASI score, the test showed significant changes in symptoms after treatment with a p-value <0.001 in both groups. In the Perimeter of the lesion, the test showed significant changes in the symptoms after treatment with a p-value <0.001 in both groups.

While comparing the effect of treatment, the KASI score showed an 88.85% reduction in Group A and 92.64% reduction in Group B. The difference in the result obtained was not statistically significant between the two groups. Hence, it is proved that both interventions were equally effective. The perimeter of the lesion shows that the difference between the two groups was statistically significant at the level of p-value =0.013 where Group A showed 68.88% reduction and Group B showed 76.76% reduction.

On the 14th day of assessment, the KASI score between groups showed statistically no significant difference. But perimeter of the lesion showed a significant difference. This is because in Group B even if the perimeter of the lesion reduced after the 14th day, the symptoms like *udgata mandala*, *daha* etc. persisted in that reduced size of the lesion. This may be the reason why the criteria perimeter of the lesion showed statistical significance.

Probable mode of action of *Tulasyadi taila:*

Tulasyadi taila is an indigenous preparation that comprises ingredients like *Tulasi*, *Haridra*, *Jeeraka* & *Breynia vitis-idea* an ethnobotanical drug that has antibacterial and antioxidant action. *Narikela taila* is

used as a base for this preparation which has *kandugha* action and is seen effective in *kota* also. Almost all drugs mentioned here have *kushtagna, kandugna, krimihara* action. *Tulasi* is having *katu, tikta rasa, laghu, rooksha, tikshna guna* with its karma's like *Kushtagna, Kandugna, Krimighna* pacifying *Dadru kushta*. *Haridra* & *Jeeraka* with its *tikta, katu rasa, laghu ruksha guna* nullifies *sneha guna* of *pitta* and *snighda guna* of *kapha*. *Varnya, kandugna, lekhana karma* of *Haridra* acts on *picchila* and *sthirathva* of *kapha.*

Probable mode of action of *Chakramarda taila:*

Chakramarda taila contains *chakramarda beeja* and *tila taila* as the base. *Chakramarda* possesses *Katu rasa, Laghu, Ruksha guna, Kapha Vatahara, Varnya, Vishagna, Vranaropana* and *Kushtagna* properties. The drug *Chakramarda* is indicated in *Dadru. Tila taila* possesses *madhura, tikta rasa, sookshma, ushna, vyavayi, tikshna guna* and acts as *vata kaphahara, tvachya*. *Tikta rasa, laghu rukshna guna* does *lekhana karma* and alleviates *kapha dosha. Nighantus* like *Adarsha, Kayyadeva* etc says *chakramarda* as *dadrughna* (that alleviates *dadru kushta*).

CONCLUSION

Dadru kushta being a *pitta kapha pradhana vyadhi* and show symptoms like *kandu, udgata mandala, raga, pidaka, daha, rookshata*. It mainly occurs due to *krimija* and *upasargaja nidanas*, so one should maintain hygiene to prevent the spread.

Both *Tulasyadi taila* and *Chakramarda taila* were effective in the treatment of *dadru kushta* with the statistically highly significant result of $p<0.001$. In comparison between 2 groups, there was no statistically significant difference in the effect of treatment in KASI score with $p = 0.737$. There was a statistically significant difference in the effect of treatment in the Perimeter of the lesion with $p=0.013$. Here Group B has shown 76.76% relief in the perimeter of the lesion.

Since the KASI score includes *lakshana* of *Dadru kushta* and it showed no statistically significant difference hence, the conclusion was drawn as there is no statistically significant difference in the effect of *Tulasyadi taila* and *Chakramarda taila* in *Dadru kushta*.

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Table 1: Showing the effect of Group A and Group B on KASI score

Assessment criteria	MEAN SCORE				%	SD	SE	t VALUE	p VALUE
	BT		MEAN AT	BT-AT					
	GROUP A								
KASI SCORE	5.65	7th Day	1.985	3.670	64.89%	2.982	0.667	5.504	<0.001
		14th Day	0.63	5.025	88.85%	3.668	0.820	6.126	<0.001
		21st Day	0.580	5.075	89.74%	3.168	0.809	6.272	<0.001
	GROUP B								
	4.96	7th Day	1.895	3.070	61.83%	3.545	0.793	3.873	<0.001
		14th Day	0.365	4.600	92.64%	4.259	0.952	4.830	<0.001
		21st Day	0.350	4.615	92.95%	4.128	0.923	5.00	<0.001

Table 2: Showing the effect of Group A and Group B on the Perimeter of the lesion

ASSESSMENT CRITERIA	MEAN SCORE			%	SD	SE	t VALUE	p VALUE
	BT	AT (14th ay)	BT-AT					
PERIMETER OF LESION	GROUP A							
	12.375	3.850	8.525	68.88	4.661	1.042	8.180	<0.001
	GROUP B							
	7.100	1.650	5.450	76.76	2.417	0.540	10.086	<0.001

Table 3: Showing the comparative effect of Group A and Group B on KASI score

	MEAN DIFFERENCE			PERCENTAGE RELIEF %		t value	p-value
	GROUP A	GROUP B	A-B	GROUP A	GROUP B		
BT-7th day	3.650	3.070	0.580	64.89	61.83	0.559	= 0.580
BT-14th day	5.025	4.600	0.425	88.85	92.64	0.338	= 0.737
BT-21st day	5.075	4.615	0.460	89.74	92.95	0.375	= 0.710

Table 4: Showing the comparative effect of Group A and Group B on Perimeter of the lesion

	MEAN DIFFERENCE			PERCENTAGE RELIEF %		t value	p-value
	GROUP A	GROUP B	A-B	GROUP A	GROUP B		
BT-14th day	8.525	5.450	3.075	68.88	76.76	2.619	= 0.013

Table 5: Showing Overall Effects of the Treatment in Group A and Group B

Relief	Group A	Group B	Total	%
Complete relief	4	6	10	25%
Marked relief	8	10	18	45%
Moderate relief	8	4	12	30%
Mild relief	0	0	0	0
No relief	0	0	0	0

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