

A CLINICAL TRIAL OF KHADIRARISTA IN THE MANAGEMENT OF KUSTHA

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ABSTRACT

A clinical trial was carried out to evaluate the effect of Khadirarista prepared by sugar and jaggery. As sugar is mentioned in the text Sharangdhara Samhita to prepare Khadirarista, jaggery is widely used instead of sugar and honey for the pharmaceutical benefits. Both were subjected for clinical trial on the patients, having classical symptoms of the disease Kustha. Khadirarista prepared by sugar showed better result on Vataja and Kaphaja symptoms [Rukshata (dryness), Shula (pain), Shyavarunata (cyanosis) and Kandu (itching)] and on the other hand Khadirarista prepared by jaggery exhibited better efficacy on Pitta-Kapha symptoms [Raga (redness), Daha (burning), Utseda (elevation)].

KEY WORDS: Skin diseases, Kandu, Khadira, Devdaru.

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INTRODUCTION

Ayurveda has discussed all skin disease under the umbrella of Kustha (skin diseases)¹. Skin diseases are very common occurrence worldwide and are considered as socio medical hazards. There are not many statistics to prove the exact frequency of skin diseases in the country, but those are included in the primary area of research for the Government of India².

Kustha occurs by vitiation of four Dushya (Twak, Rakta, Mamsa and Ambu) and three Dosha (Vata, Pitta, Kapha)³. Impairment of Dosha creates innumerable type of Kustha. All types of Kustha have their origin from Vata, Pitta, Kapha and microorganism⁴. The disease Kustha has been termed according to the predominant vitiated Dosha. Acharyas have classified the Kustha in three types viz. 7 Mahakustha, 11 Kshudra Kustha and innumerable Kustha⁵. The symptoms like Kandu (itching), Daha (burning), Vaivaryna (discoloration), Pidika (follicle), Utseda (elevation) are almost common in all types of Kustha.

Development in the dosage form is based on some principles i.e., to preserve its quality for a long period, to potentiate the effect of main drug, and to remove the ill effect. Arista is one of the commonly prescribed dosage forms for treatment of Kustha. In the preparations of Asava-Arista, Guda (jaggery) is widely used instead of

Sharkara (sugar) and Madhu (honey). It is needed to assess the therapeutic efficacy of Khadirarista and to support with the clinical data. Here, Khadirarista is selected for the treatment of common symptoms of Kustha. Khadirarista is well known drug for its Kusthahara effect⁶. The main ingredients of Khadirarista are Khadira (Acacia catechu) and Devadaru (Cedrus deodara), both are having Kusthaghna property. Acharya Charaka has mentioned Khadira is the best among the Kusthaghna Dravyas⁷, while Acharya Sushruta opines that during suffering from Kustha one should use Khadira in meals, drinks and also for bath⁸. Khadirarista is mentioned to be prepared by sugar in the original reference⁹, but the modification in the dosage form is mainly made in terms of sweetening agents like, jaggery is used instead of sugar and honey by most of the pharmacies. Though jaggery is used extensively in the pharmacies for the preparation of Khadirarista, but its efficacy must be established in terms of clinical trial on human beings. Drug is effective only when it relieves signs and symptoms of particular disease in human being.

So the present clinical trial was carried out to assess comparative efficacy of Khadirarista prepared by sugar and jaggery on the disease Kustha. In the present study, Kustha has been treated as per involvement of Dosha,

classified into main symptoms of Vata-Pitta-Kapha as per mentioned in the text¹⁰. Vatika symptoms like Rukshata (dryness) Shoola (pain), Shyava Arunata (cyanosis and redness), Paittika symptoms like Daha (burning), Raga (redness), Parisrava (exudation), Paka (suppuration), Avadarana (breaking of skin) and Kaphaja symptoms like Kandu (itching), Utsedya (elevation), Varna Bheda (discolouration), Matsya Saklopam (scaling) has been taken for the present study.

MATERIALS AND METHODS

For the clinical trial, the subject was passed through ethical committee. Detail is as follow, **IEC Dated 23/05/06, No./ PGT / Ethic / 2006-07 / 03**

Patients

Patients attending O.P.D. of Rasa Shastra & Bhaishjya Kalpana Department, Institute for Postgraduate Teaching & Research in Ayurved Hospital, Jamnagar, having classical symptomatology of Kustha (**Table 1**) were included and randomized irrespective of their age, sex, religion, etc.

Inclusion criterion

Patients having classical symptomatology of Kustha Roga as mentioned in the introduction were selected for the present clinical trial. Detailed history was taken along with physical examination incorporating all the signs and symptoms of vitiated Dosha of the general symptoms of disease Kustha (**Table - 1**).

Exclusion criterion

Known patients of other systemic diseases like severe diseases of Liver, heart and kidney, cancer, AIDS, etc.

Criterion for assessment

Efficacy of test drugs was assessed in terms of improvement in cardinal signs and symptoms, before and after treatment. Effect of test drugs was also analyzed on the certain hematological, biochemical and urine parameters before and after treatment, it is also to assess the condition of disease and to exclude any other pathology.

Scoring Pattern

Rukshta (Dryness)

- No dryness 0
- Dryness with rough skin + 1
- Dryness with mild scaling + 2
- Dryness with scaling + 3
- Dryness with cracking + 4

Shoola (Pain)

- No pain 0
- Occasionally pain + 1
- Mild pain on touch + 2
- Mild to moderate pain + 3
- Severe pain + 4

Shyava Arunta (Cyanosis & Redness)

- Normal colour 0
- Not normal but near to normal + 1
- Reddish colouration + 2
- Slight black reddish discolouration + 3
- Deep black reddish discolouration + 4

Daha (Burning sensation)

- No burning 0
- Occasionally + 1
- Mild burning + 2
- Mild to moderate burning + 3
- Severe burning + 4

Raga (Redness)

- Normal colour 0
- Not normal but near to normal + 1
- Slight Reddish colouration + 2
- Reddish discolouration + 3
- Deep reddish discolouration + 4

Parisrava (Discharge)

- No discharge 0
- Occasionally discharge + 1
- Discharge on itching + 2
- Mild to moderate discharge on itching + 3
- Severe discharge + 4

Paka (Suppuration)

- No suppuration 0
- Sometimes suppuration + 1
- Suppuration persists constantly + 2
- Suppuration in half of the affected part + 3
- Suppuration with whole part + 4

Avadarana (Crack)

- No crack 0
- Just superficial crack + 1
- Mild to moderate crack + 2
- 0.5 to 1.0 cm deep crack + 3
- Crack with bleedings + 4

Kandu (Itching)

- No itching 0
- Occasionally itching + 1
- Mild itching + 2
- Mild to moderate itching + 3
- Severe itching + 4

Utseda (Elevation)

- No elevation 0
- Starting of elevation + 1
- Moderately developed elevation + 2
- Spreaded over extremities + 3
- Severely spreaded all over body + 4

Varnabheda (Discolouration)

- Normal colour 0
- Not normal but near to normal + 1
- Starts discolouration + 2
- Slight black reddish discolouration + 3
- Deep black reddish discolouration + 4

Matsya Saklopam (Scaling)

- No scaling 0
- Mild scaling by rubbing or by itching + 1
- Moderate scaling by rubbing or by itching + 2
- Sever scaling by rubbing or by itching + 3
- Scaling without rubbing or itching + 4

Posology

Drug

Khadirarista, (using sugar and honey as a sweetening agent) were prepared in practical laboratory of Department of Rasashastra and Bhaishjya Kalpana, I.P.G.T. &R.A., Gujarat Ayurved University, as per reference mentioned in the Sharangdhar Samhita Madhyam Khanda 10/60-65³. Group B was also prepared using same method described in the reference only change was, made that jaggery was used instead of sugar and honey as a sweetening agent.

Direction

Selected patients were advised to take the Chitrakadi Vati 2g/day twice into divided doses after meal for four days and Eranda Bhrishta Haritaki 3g/day, once at bed time with warm water three days, prior to start the test drugs.

Study protocol

Total 31 patients were registered for the clinical trial and divided randomly in 2 groups, containing 17 patients in group-A and 14 patients in group-B.

Group-A were treated with Khadirarista prepared by sugar in 20 ml b.i.d. dose¹¹.

Group-B were treated with Khadirarista prepared by jaggery at same dose.

Khadirarista prepared by both methods was ingested for 28 days. Patients were advised to take the drug after taking meal. All the patients were reviewed after 7 days each.

Diet

Patients were advised to avoid aggravating factors like Viruddha Ahara (milk with sour things, milk with salty things), Amla Ahara (sour things) mentioned in ancient literature.

Statistical analysis

The obtained data were analyzed statistically and presented as Mean ± SEM (standard error of mean). Classical subjective symptoms were graded appropriately to provide objectivity and necessitate proper evaluation.

The observed difference was calculated by adopting student 't' test. P<0.05 was considered as statistically significant and P<0.01 and P<0.001 were considered as statistically highly significant.

RESULTS

Total 31 patients were registered. In group A, 15 patients had completed the treatment schedule and 2 patients left against medical advice. In group B, 10 patients had completed the full course and remaining 4 patients left the course incomplete. So observation of 31 patients and results of 25 patients are highlighted here.

Doshika involvement of symptoms wise distribution of 31 patients has been categorized in **Table 1**. Effect of test drugs has been summarized in **Table 2** according to Doshika involvement.

No changes were observed in the urine parameters. Effect of Khadirarista prepared by sugar (group A) on hematological and biochemical parameters in the 15 patients are shown in **Table 4**. Effect of *Khadirarista* prepared by jaggery (group B) on hematological and biochemical parameters in the 10 patients are shown in **Table 5**.

DISCUSSION

The root cause (condition of Dosha) for the disease Kustha was selected for the present study. In the classics, it is mentioned that the knowledge of Dosha is essential for proper diagnosis of disease and vice versa¹².

In Kustha, mainly Kapha Dosha is involved so medicines were prescribed to take in the Kapha Prakopa Kala i.e. after taking meals it may help in alleviation of Kapha. Before starting the treatment, patients were advised to take Chitrakadi vati (2 g/day) b.i.d. after meal and Eranda Bhrishta Haritaki once at bed time for purification. The therapy was given to remove Ama Dosha and for Srotas Shodhana.

The data of comparative efficacy of test drugs on general symptoms reveals that test drug of group-A i.e., Khadirarista prepared by using sugar as sweetening agent has better activity profile on Rukshata, Shula, Shyavarunata and Kandu, while test drug of group-B i.e., Khadirarista prepared by using jaggery as sweetening agent proved to be better on Raga, Daha, Utseda symptoms. But the difference was not apparent and found to be statistically non-significant (Table 3, Fig.1).

The chief ingredients of Khadirarista are Khadira (*Acacia catechu*), Devadaru (*Cedrus deodara*), Bakuchi (*Psoralea corifolia*), Daruharidra (*Berberis aristata*) and Triphala (fruits of *Terminalia chebula*, *Terminalia bellirica*, *Embellia officinalis*). The action of these drugs may be potentiated and augmented by the self generated alcohol in Khadirarista¹³. So the mode of action of the

drug Khadirarista on the disease Kustha can be explained by the active ingredients of these drugs and alcohol.

Most of the drugs have Tikta, Kashaya Rasa, Laghu, Ruksha Guna, Katu Vipaka and Khadira and Bakuchi have Kusthaghna Prabhava. The vitiated Tridosha (Vata, Pitta, Kapha) deforms the Twak, Rakta, Mamsa and Ambu spreads into body through the Tiryaga Sira reach to the Bahya Marga and produce Kustha. The vitiated Tridosha make the Twak, Rakta, Mamsa and Ambu vulnerable.

Acharya Charak opines that drugs of Tikta, Kashaya Rasa having Vata-Kapha-Nashaka properties should be used for Sanshamana therapy of Kustha¹⁴. The chief ingredients of Khadirarista also causes Tikta, Kashaya Rasa, Vata-Kaphanashaka properties and the Arista helps to reach to the active principles of drugs to the target site. The Ushna, Tikshna Guna of Arista also increase the *Agni* and through Urdhvagami Sira it may enter into Hridya, then reaches to the targeted site. After reaching the site of derangement, the drug may pacify the vitiated Dosh and Dushya and bring homeostasis in the body. The Vyavayi and Ashukari properties of Arista may help the drug to reach the site quickly and remove the obstruction of Srotasa and may cure the disease¹⁵.

CONCLUSION

Khadirarista prepared by sugar showed better result on Vataja and Kaphaja symptoms (Rukshata, Shoola, Shyavarunata and Kandu) and on the other hand Khadirarista prepared by jaggery exhibited better efficacy on Pitta-Kapha symptoms (Raga, Daha, Utseda). Subjective parameters showed marked improvement in the disease in both the groups whereas it failed to replicate the same on objective parameters. However no definite conclusions can be drawn. As more improvement were observed in patients of group A i.e. Khadirarista prepared by using sugar as sweetening agent treated group, so it may be inferred that Khadirarista prepared by using sugar as sweetening agent is more effective than Khadirarista prepared by jaggery as sweetening agent, when overall improvement on general symptoms of Kustha are concerned

LIMITATIONS AND FUTURE SCOPE OF STUDY

1. Though, it was the M.D. dissertation, the study had to be completed within stipulated period, so the 'n' was too small to give definite conclusions.
2. More objective parameters should be made for further studies.

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Table-1: Doshika symptoms wise distribution of 31 patients of general symptoms of the disease Kustha

Dosha		No. of Patients		Total	Percentage
		Group A	Group B		
Vata	Rukshata (dryness)	06	08	14	45.16
	Shoola (pain)	08	05	13	41.94
	Shyava Arunata (cyanosis and redness)	09	06	15	48.39
Pitta	Daha (burning)	12	08	20	64.52
	Raga (redness)	08	07	15	48.39
	Parisrava (exudation)	11	03	14	45.16
	Paka (suppuration)	02	02	04	12.90
	Avadarana (breaking of skin)	02	03	05	12.90
Kapha	Kandu (itching)	17	14	31	100
	Utseda (elevation)	10	05	15	48.39
	Varna Bheda (discoloration)	05	00	05	16.13
	Matsya Saklopam (scaling)	04	02	06	19.35

Table-2: Effect of therapy on general symptoms

	Symptoms	Groups	Mean ± SEM			P	
			B.T.	A.T.	%Change		
Vataja	Rukshata	A (n=5)	2.20±0.37	0.80±0.37↓	63.63	<0.01**	
		B (n=6)	2.33±0.21	1.16±0.30↓	49.78	<0.05*	
	Shula	A (n=8)	2.12±0.29	0.75±0.36↓	64.62	<0.05*	
		B (n=3)	1.66±0.33	0.33±0.33↓	80.12	<0.05*	
	Shyavarunta	A (n=9)	3.33±0.28	1.00±0.16↓	69.96	<0.001***	
		B (n=5)	2.60±0.24	1.00±0.31↓	61.53	<0.01**	
Pittaja	Daha	A (n=10)	2.60±0.26	0.60±0.22↓	76.92	<0.001***	
		B (n=6)	2.66±0.21	0.66±0.33↓	75.18	<0.05*	
	Raga	A (n=8)	2.62±0.26	0.87±0.22↓	66.79	<0.001***	
		B (n=6)	2.50±0.22	0.33±0.21↓	86.64	<0.001***	
	Parisrava	A (n=11)	2.09±0.25	0.45±0.15↓	77.99	<0.001***	
		B (n=3)	2.00±0.00	0.33±0.33↓	83.00	<0.05*	
	Paka	A (n=2)	2.00±0.0	0.50 ± 0.50	75.00	>0.10	
		B (n=2)	2.00±0.00	1.00±0.00	50.00	>0.10	
	Avdarana	A (n=2)	3.50±0.50	0.50±0.50↓	85.00	>0.1	
		B (n=2)	3.00±1.00	0.50±0.50↓	83.00	>0.1	
	Kaphaja	Kandu	A (n=15)	3.40±0.19	0.66±0.18↓	80.29	<0.001***
			B (n=10)	3.20±0.29	1.00±0.29↓	69.37	<0.001***
Utseda		A (n=8)	2.25±0.16	0.87±0.22↓	60.08	<0.001***	
		B (n=4)	2.50±0.50	0.75±0.25↓	70.00	<0.05*	
Varnabheda		A (n=4)	3.50±0.28	1.00±0.00↓	71.14	<0.01**	
		B (n=0)	-	-	-	-	

↓ = decrease; * = Significant; ** = Highly significant; *** = Highly significant

Table-3: Comparative effect of test drugs on improvement of symptoms in 25 patients of Kustha

Symptoms	Group	'n'	Change Mean ± SEM	P
Rukshata	A	05	1.40 ± 0.24	>0.10
	B	06	1.16 ± 0.30	-
Shoola	A	08	1.37 ± 0.49	>0.10
	B	03	1.33 ± 0.33	-
Shyavarunata	A	09	2.33 ± 0.23	>0.05
	B	05	1.60 ± 0.24	-
Daha	A	10	2.00 ± 0.25	-
	B	06	2.00 ± 0.36	-
Raga	A	08	1.75 ± 0.31	-
	B	06	2.16 ± 0.30	>0.10
Kandu	A	15	2.73 ± 0.23	>0.10
	B	10	2.22 ± 0.29	-
Utseda	A	08	1.37 ± 0.18	-
	B	04	1.75 ± 0.47	>0.10

Table-4: Effect of Khadirarista prepared by sugar (group A) on hematological and biochemical parameters in the 15 patients of general symptoms of Kustha

Parameter	Mean ± SEM			Relief (%)	P
	B.T.	A.T.	Change		
Hb gm%	11.38±0.30	11.41±0.31	0.12±0.14↑	1.00	>0.10
TLC	6672±297.07	6513.33 ± 324.60	280.00±270.83↓	4.19	>0.10
Neutrophil	61.60±01.45	58.40±01.42	03.20±01.62↓	5.19	>0.05
Lymphocyte	32.80±01.55	32.86±01.29	0.60±1.52↑	1.82	>0.10
Eosinophil	2.86±0.23	3.33±0.38	0.46±0.30↑	16.08	>0.10
Monocyte	2.73±0.15	2.80±0.10	0.06±0.15↑	2.19	>0.10
ESR	23.46±4.20	19.81±2.27	3.72±3.25↓	15.85	>0.10
FBS	90.60±3.30	91.73±2.24	0.20±3.51 ↑	0.22	>0.10
S. cholesterol	178.46±7.83	164.60±6.22	13.86±4.42↓	7.76	<0.01**
S. triglyceride	100.73±8.90	98.73±6.09	2.13± 1.15↓	2.11	>0.10
HDL cholesterol	41.20±1.85	44.80±2.26	3.60±2.76↑	8.73	>0.10
Alkaline phosphatase	68.06±3.40	77.66±3.28	9.60±4.08↑	14.10	<0.05*
SGOT	21.60±1.48	20.20±01.20	0.20±1.44↓	0.92	>0.10
SGPT	22.66±3.18	19.60±1.61	2.40±2.02↓	10.59	>0.10

↓ = decrease; * = Significant; **= Highly significant; *** = Highly significant

Table-5: Effect of Khadirarista prepared by jaggery (group B) on hematological and biochemical parameters in the 10 patients of general symptoms of Kustha

Parameter	Mean ± SEM			Relief (%)	P
	B.T.	A.T.	Change		
Hb gm%	12.78±0.40	13.24± 0.49	0.46± 0.26↑	3.59	>0.10
TLC	6340± 300.81	5900±401.38	440±287.98↑	06.94	>0.10
Neutrophil	59.80 ± 1.74	59.20 ± 02.60	00.60±02.26↓	01.00	>0.10
Lymphocyte	33.90 ± 01.66	34.50 ± 02.44	0.70±02.08↑	2.06	>0.10
Eosinophil	3.40 ± 0.22	3.00 ± 0.14	0.40±0.30↓	11.76	>0.10
Monocyte	2.90 ± 0.10	3.00 ± 0.25	0.10±0.27↑	03.44	>0.10
ESR	14.40 ± 04.31	15.70 ± 06.95	1.30±03.89↑	9.02	>0.10
FBS	95.70 ± 08.80	93.20 ± 05.41	03.50±08.80↓	03.65	>0.10
S. cholesterol	180.50 ± 13.16	177.30±09.74	07.77±04.89↓	4.30	>0.10
S. triglyceride	101.60 ± 19.62	101.50±16.18	0.10±18.71↓	0.09	>0.10
HDL cholesterol	44.30 ± 02.01	46.00 ± 02.56	04.70±03.10↑	10.60	>0.10
Alkaline phosphate	57.10 ± 5.82	62.90 ± 04.65	05.20±05.45↑	09.10	>0.10
SGOT	22.60 ± 01.26	23.10 ± 01.27	0.40±01.73↑	1.76	>0.10
SGPT	19.20 ± 7.30	21.0 ± 6.64	1.90±1.94↑	9.89	>0.10

↓ = decrease; * = Significant; **= Highly significant; *** = Highly significant

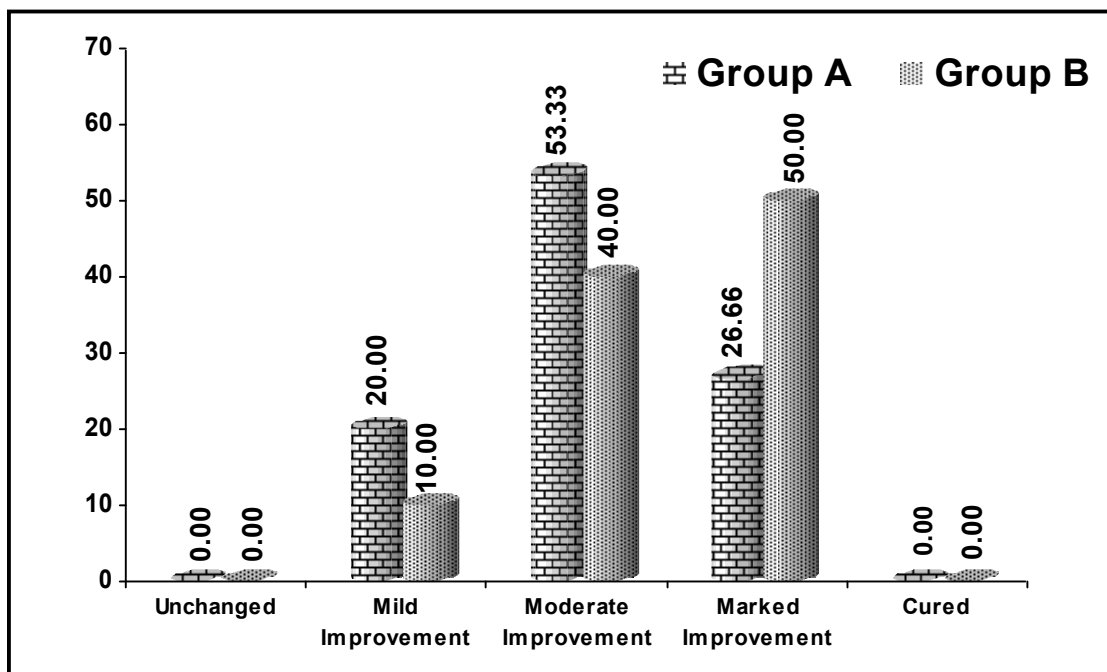


Fig. 1: Overall effect of therapy

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