A CONTROLLED CLINICAL STUDY ON ROLE OF "LOHA NISHA YOGA" IN SHAKHASHRITA KAMALA

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ABSTRACT

Kamala is disease in which yellow pigmentation of skin, cornea, caused by hyperbillurubinenia. Today's lifestyle changes mainly responsible to promote hepatic damage. In modern medicine there is no conventional line of treatment in Hepatitis, So People are choosing *Ayurveda* treatment to cure Hepatitis. **Aim & Objectives–** To evaluate efficacy of *Loha Nisha Yoga* in *Shakhashrita Kamala*. To compare the efficacy of *Loha Nisha Yoga* in *Shakhashrita Kamala* with established drug *Trikatusaindhav Churna* **Methodology-** Prospective open Randomize Controlled study. In this study 60 randomly selected *Shakhashrita Kamala* patients are divided in two equal group. In Trial group of 30 patients treated with *Loha Nisha Yog*a and 30 patients in control group treated with *Trikatusaindhav Churna*. Follow up done weekly until next 21 days. **Statistical Analysis and Discussion-** Statistical Analysis and Discussion about result will be discussed detail in paper. **Result-** The results are encouraging. The therapy shows marked relief from all symptoms at *Kamala* and improvement in Liver Function Test. **Conclusion-** *Loha Nisha Yoga* is significant than *Trikatusaindhav Churna* for reduction of Sign, Symptoms, and Specific biochemical markers in *Shakhashrita Kamala*.

Keywords: *Shakhashrit Kamala, Loha Nisha Yoga, TrikatuSaindhav Churna*

INTRODUCTION

Kamla a disease in which all desires are lost, which can be compared to hepatitis. The main goal of *Ayurveda* is to maintain *Dhatusamya* and *Tridoshsamya*. In *Kamala Raktadhatu* is affected mainly that is *Raktadhatujyanya* disorder. As well it is also described in *Pittaj Nanattmajvyadhi* so that *Pittadushti* is also told which we have to manage. *Kamala* is mentioned in *Ayurvedic* texts mainly in *Brihat-trayi* as:16th chapter of *Charak-samhitachikitsa-sthana*; 44th chapter of *Uttartantra of Sushrutasamhita*; and 13th chapter of *nidansthana* and 16th chapter of *chikitsa-sthana of Ashtang-hridaya.* In all the mentioned above the description of *Kamala* is came along with *Panduroga.*

There are two types of kamala mentioned in *Ayurveda* one in *Koshthashrit Kamala* & Another is *Shakhashrit Kamala*. The present study in dealt with *Shakhashrit Kamala* which can be compared to Viral Hepatitis in Modern Medicine.

The modern treatment modalities mainly comprise of IV fluids, sugar correction, preventive antibiotics, Liver enzymes like L-ornithine, L- aspartate, uredeoxycolic acid etc. hence keeping the fact in mind it was decided to develop a herbal or herbo-minerals formulation with following properties –

1. It is mentioned in classical Ayurvedic text for treatment of *Kamala*.
2. It has Hepato-protective action.
3. It is based on basic principles of treatment of *Shakhashrit Kamala*
4. It possesses Antiviral activity
5. safe, easily available, cost effective
6. Easy methods of preparation, easy & safe route of administration of drug.

Thus while going through different *Ayurvedic* texts *Loha Nishadi yog* mentioned in *Yogratnakar*, which contains *Lohabhasma, Haridra* (Curcuma Longa), *Daruharidra* (Berberis Aristata), *Haritaki* (Terminalia chibula), *Bibhitaki* (Termanaliabelerica), *Amlaki* (Emblica officinalis), *Kutki* Picrorhiza Kurroa) is found to fulfil all the above criteria.

Aim & Objectives

1. To evaluate efficacy of *LOHA NISHA YOGA* in *Shakhashrita Kamala.*
2. To study the possible mechanism of action of *LOHA NISHA YOGA* in *Shakhashrita Kamala.*
3. To compare the efficacy of *LOHA NISHA YOGA* in *Shakashrita Kamala* with established drug *Trikatusaindhav churna.*

Materials & Methods-

Study type - Prospective open Randomize Controlled study.

Source of Data – O.P.D. and I.P.D. of *Kayachikitsa* Department. M.A. Podar Hospital, Worli, Mumbai-18

Trial Group -

Drug Name - *Loha-Nisha Yoga*

Contains -

LohaBhasma…….…… 1/8th part

Daruharidrachurna……1 part

Haridrachurna ……… 1 part

Triphalachurna……..... 1 part

Kutkichurna ………..   1 part

Dose - 5 gm Twice Daily

Anupana - Madhu+ Ghrita in unequal quantity

Time of administration - After meal twice a day

Diet - specified diet *Laghuaahara* as per need *Agni* as per indicated. (*Dugdha-ahar*)

No. of patients - 30 patients

2) Control Group –

Name   -   *Trikatu Saindhav Churna*

Dose   -   5 gm Twice daily

Anupana - Nimbuk swarasa

Time of Administration - Twice daily before meal (*Apankaala*)

No. of Patients -   30 patients

Follow Up - Will be maintained weekly, Follow up for 21 days.

Inclusion Criteria

1. Age -17 to 60yrs.
2. Sex- Male and Female.
3. Patient with signs and symptoms of *Shakhashrita Kamala*
4. Patient having serum bilirubin level above the normal limit.

Exclusion Criteria

1. Patient above 60 years and below 17 years age
2. Pregnancy and Lactating mother.

3. Cases of liver abscess, liver cirrhosis, HBsAg positive and known case HIV Positive.
4. Patients having malignancy.
5. Patients in acute alcohol withdrawal state, intoxication, Hepatic encephalopathy.
6. Serum bilirubin level more than 20mg/dl.
7. Congenital cause, Drug toxicity, AKT

Investigations

1. Liver Function Test –

SGPT (ALT) - Weekly

SGOT (AST) - Weekly

Serum bilirubin level -Weekly

Serum protein, Albumin, Alkaline Phosphate during each follow up.

2. Urine Bile salt and Bile pigment - Weekly

3. USG Abdomen - At the start of the study. (As per needed)

4. Other investigations – (In order to rule out other disease condition)

Haemogram, ESR, RFT, Lipid profile, BSL, HIV, VDRL, HBsAg - at the start of the study.

Assessment Criteria

Assessment criteria is done on the basis of following symptoms.

Netra Peetata; Peet Mutrata; ParshvaShool (YakritVruddhi); Jvara; Daurbalya; Shwas; Twak-Peetata; Vishtambha; Udarshool; Aruchi (Anorexia); Shweta varchus (stool examination); *Mandagni*

Mechanism of Action –

Loha Nisha yoga acted on *Yakrit* which cleared *Margavrodh* of *Kapha. Loha Nisha yoga* shows *Mruduvirechana* action which cause removal of *Pitta* from body. Due to *Raktaprasadak* action; it acted on *Dustha Pitta* causes *prakrut varna* of *Netra, mutra & Twak. Loha Nisha yoga* produces *Dosha-Dushyasamyata* which leads to *Sampraptibhanga* of *Shakhashrit Kamala*.

Observation -

Table 1: Showing significance between symptomatic Relief in trial and control group.

S.N	SYMPTOM	R1	R2	U1	U2	SD	Z	P	
1	*Netra Peetata*	1006	764	299	601	67.63	2.23	0.03	Significant
2	*Peeta Mutrata*	1061	746	304	596	67.63	2.158	0.03	Significant
3	*ParshvaShool*	806	944	479	421	67.63	0.42	0.67	Not significant
4	*Jvara*	815	946	481	419	67.63	0.458	0.65	Not significant
5	*Daurbalya*	819	1010	545	354	67.63	1.41	0.16	Not significant
6	*Shwaas*	888	942	477	423	67.63	0.399	0.69	Not significant
7	*TwakaPeetata*	1039	795	330	569	67.63	1.766	0.08	Not significant
8	*Vishtambha*	816	1013	584	315	67063	1.456	0.15	Not significant
9	*Udarshoola*	882	947	482	417	67.63	0.480	0.03	Not significant
10	*Aruchi*	768	1061	596	303	67.67	2.165	0.03	Significant
11	*Shweta varchus*	851	979	514	386	67.63	0.946	0.34	Not significant
12	*Mandagni*	690	1139	674	225	67.63	3.319	0.008	Significant

Table 2: Showing difference between two groups with respect to these characters.

s.n	Parameter	Mean diff±sd	SE	T	P	
1	Serum Protein	0.622±2.321	0.4237	1.255	>0.5	Not Significant
2	Serum Albumin	0.2000±1.671	0.2932	0.6805	<0.4	Not significant
3	Serum Alkaline phosphate	2.067± 18.575	3.663	0.5642	<0.5	Not significant
4	SGPT	146.0±340	56.66	2.578	0.01	Significant
5	SGOT	148.70±343.36	56.59	2.628	0.01	Significant
6	Serum Bilirubin	0.6200±2.321	0.4320	1.463	0.1	Not significant
7	Urine Bile salt	0.433±1.251	0.2145	2.020	0.05	Significant
8	Urine Bile Pigment	0.533±1.196	0.1980	2.639	0.01	Significant

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Result of Study-

Table 3: Showing results of study.

	Cured	Markedly improved	Improved	Uncured	Total
Trial group	6(20%)	21 (70%)	3 (10%)	0	30
Control group	2 (6.66%)	18(60%)	10 (33.33%)	0	30
Total	8	39	13	0	60

DISCUSSION

The Prevalence of the disease was more in patients having *Katu, Amla & Lavan Rasa Pradhanaahara* which ultimately gives rise to *Pitta Prakop.* In present study not a single patient suffering from the disease was found having *Samagni* which is a classical indicative of *Agni & Vyadhi* relation mentioned in Ayurvedic classics. Maximum Numbers of patients were of *Krurakoshta* & hence had common complaint of *Malawashtambha* which is a main *hetu* in generating the diseased condition as mentioned by Ayurvedic classics text, thus the occurrence of the diseases in these people is maximum.

Most of patients were having *Vyasana* such as Alcohol, smoking, Tobacco chewing which ultimately indicates association of presence of addiction & Prevalence of disease. Patients of *Vatpittaprakruti* and *Pittkapha Prakriti* were seem to more prone to *Shakhashrita Kamala* due to predominance of *Pitta dosha.* Both the drugs reduced SGPT, SGOT Urine bile salt & pigment level but *Loha Nisha Yoga* reduced SGPT, SGOT, Urine salt & pigment level more effectively. It was observed that *Loha Nisha Yoga* has no significant role over *Trikatusaindhav Churna* on other investigations like Alkaline phosphate, Sr. Protein, Sr. Albumin and Stool colour. Hb % and RBC level probably seemed to be increased in trial group due to presence of *Lohabhasma, Haridra & Daruharidra* in *Loha Nisha Yoga.* As out of 30 patients of trial group 6 patients were cured, 21 markedly improved, 3 patients improved; while out of 30 patients of control group 2 patients were cured, 18 markedly improved, 10 patients improved. Then it clearly indicates that *Loha Nisha Yoga* has significant role in *Shakhashrita Kamala* over *Trikatusaidhav Churna.* With the help of Chi-square test we concluded the result as p was <0.05, hence *Loha Nisha Yoga* was more effective than previously proved single drug *Trikatusaindhav. Loha Nisha Yoga* has significant role in *Shakhashrita Kamala* which is more effective on *Netrapeetata & Peetmutrata* that may be due to *Netryaguna* of *Triphala* & Effect of *Daruharidra* on *Mutravaha Strotasa.*

CONCLUSION

The symptoms wise statistical analysis, it is found that Loha *Nisha Yoga* is significant than *Trikatusaindhav Churna* for reduction of Sign, Symptoms, and Specific biochemical markers like SGPT, SGOT and Serum Bilirubin in *Shakhashrita Kamala*

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