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 hyperbilirubinemia. 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 Yoga 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

Kamala 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 Rakhatdhatu is affected mainly that is Rakhatdhatuyanyaya disorder. As well it is also described in Pittaj Namattmajvyadhi 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 Sushrutaasamhita; 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 Koshtashrit 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, ured oxycolic acid etc. hence keeping the fact in mind it was decided to develop a herbal or herbo 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

Thus while going through different Ayurvedic texts Loha Nishadi yog mentioned in Yogaratnakar, which contains Lohabhasma, Haridra (Curcuma Longa), Daruharidra (Berberis Aristata), Haritaki (Terminalia chebula), Bibhitaki (Terminalia bellirica), Amlaki (Emblica officinalis), Kuki (Picrorrhiza Kurroa) is found to fulfil all the above criteria.

Aim & Objectives

1. To evaluate efficacy of LOHA NISHA YOGA in Shakhashrit Kamala.
2. To study the possible mechanism of action of LOHA NISHA YOGA in Shakhashrit Kamala.
3. To compare the efficacy of LOHA NISHA YOGA in Shakhashrit Kamala with established drug Trikatu- saindhav churana.

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 Laghuahara 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 swarasas
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 Shakhashrit 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.

<table>
<thead>
<tr>
<th>Source of Data</th>
<th>Trial Group</th>
<th>Control Group</th>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>O.P.D. and I.P.D. of Kayachikitsa Department</td>
<td>Loha-Nisha Yoga</td>
<td>Nimbuk swarasas</td>
<td>Age -17 to 60yrs.</td>
<td>Pregnancy and Lactating mother.</td>
</tr>
<tr>
<td>M.A. Podar Hospital, Worli, Mumbai-18</td>
<td></td>
<td></td>
<td>Sex- Male and Female.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Patient with signs and symptoms of Shakhashrit Kamala</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Patient having serum bilirubin level above the normal limit</td>
<td></td>
</tr>
</tbody>
</table>
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
2. Serum bilirubin level -Weekly
3. Serum protein, Albumin, Alkaline Phosphate during each follow up.
4. Urine Bile salt and Bile pigment - Weekly
5. USG Abdomen - At the start of the study. (As per needed)
6. Other investigations – (In order to rule out other disease condition)

**Assessment Criteria**
Assessment criteria is done on the basis of following symptoms.
Netra Peetata; Peet Mutrata; ParshvaShool (YakritVrddhi); 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 Dushta Pitta causes prakrut varna of Netra, mutra & Twak. Loha Nisha yoga produces Dosha-Dushyasamayata which leads to Sampraptibhanga of Shakhashrit Kamala.

**Observation**

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

<table>
<thead>
<tr>
<th>S.N</th>
<th>SYMPTOM</th>
<th>R1</th>
<th>R2</th>
<th>U1</th>
<th>U2</th>
<th>SD</th>
<th>Z</th>
<th>P</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Netra Peetata</td>
<td>1006</td>
<td>764</td>
<td>299</td>
<td>601</td>
<td>67.63</td>
<td>2.23</td>
<td>0.03</td>
<td>Significant</td>
</tr>
<tr>
<td>2</td>
<td>Peet Mutrata</td>
<td>1061</td>
<td>746</td>
<td>304</td>
<td>596</td>
<td>67.63</td>
<td>2.158</td>
<td>0.03</td>
<td>Significant</td>
</tr>
<tr>
<td>3</td>
<td>ParshvaShool</td>
<td>806</td>
<td>944</td>
<td>479</td>
<td>421</td>
<td>67.63</td>
<td>0.42</td>
<td>0.67</td>
<td>Not significant</td>
</tr>
<tr>
<td>4</td>
<td>Jvara</td>
<td>815</td>
<td>946</td>
<td>481</td>
<td>419</td>
<td>67.63</td>
<td>0.458</td>
<td>0.65</td>
<td>Not significant</td>
</tr>
<tr>
<td>5</td>
<td>Daurbalya</td>
<td>819</td>
<td>1010</td>
<td>545</td>
<td>354</td>
<td>67.63</td>
<td>1.41</td>
<td>0.16</td>
<td>Not significant</td>
</tr>
<tr>
<td>6</td>
<td>Shwas</td>
<td>888</td>
<td>942</td>
<td>477</td>
<td>423</td>
<td>67.63</td>
<td>0.399</td>
<td>0.69</td>
<td>Not significant</td>
</tr>
<tr>
<td>7</td>
<td>TwakaPeetata</td>
<td>1039</td>
<td>795</td>
<td>330</td>
<td>569</td>
<td>67.63</td>
<td>1.766</td>
<td>0.08</td>
<td>Not significant</td>
</tr>
<tr>
<td>8</td>
<td>Vishtambha</td>
<td>816</td>
<td>1013</td>
<td>584</td>
<td>315</td>
<td>67063</td>
<td>1.456</td>
<td>0.15</td>
<td>Not significant</td>
</tr>
<tr>
<td>9</td>
<td>Udarshool</td>
<td>882</td>
<td>947</td>
<td>482</td>
<td>417</td>
<td>67.63</td>
<td>0.480</td>
<td>0.03</td>
<td>Not significant</td>
</tr>
<tr>
<td>10</td>
<td>Aruchi</td>
<td>768</td>
<td>1061</td>
<td>596</td>
<td>303</td>
<td>67.67</td>
<td>2.165</td>
<td>0.03</td>
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<tr>
<td>11</td>
<td>Shweta varchus</td>
<td>851</td>
<td>979</td>
<td>514</td>
<td>386</td>
<td>67.63</td>
<td>0.946</td>
<td>0.34</td>
<td>Not significant</td>
</tr>
<tr>
<td>12</td>
<td>Mandagni</td>
<td>690</td>
<td>1139</td>
<td>674</td>
<td>625</td>
<td>67.63</td>
<td>3.319</td>
<td>0.008</td>
<td>Significant</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>S.n</th>
<th>Parameter</th>
<th>Mean diff±sd</th>
<th>SE</th>
<th>T</th>
<th>P</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Serum Protein</td>
<td>0.622±2.321</td>
<td>0.4237</td>
<td>1.255</td>
<td>&gt;0.5</td>
<td>Not Significant</td>
</tr>
<tr>
<td>2</td>
<td>Serum Albumin</td>
<td>0.2000±1.671</td>
<td>0.2932</td>
<td>0.6805</td>
<td>&lt;0.4</td>
<td>Not significant</td>
</tr>
<tr>
<td>3</td>
<td>Serum Alkaline Phosphate</td>
<td>2.067±18.757</td>
<td>3.663</td>
<td>0.5642</td>
<td>&lt;0.5</td>
<td>Not significant</td>
</tr>
<tr>
<td>4</td>
<td>SGPT</td>
<td>146.0±340</td>
<td>56.66</td>
<td>2.578</td>
<td>0.01</td>
<td>Significant</td>
</tr>
<tr>
<td>5</td>
<td>SGOT</td>
<td>148.70±343.36</td>
<td>56.59</td>
<td>2.628</td>
<td>0.01</td>
<td>Significant</td>
</tr>
<tr>
<td>6</td>
<td>Serum Bilirubin</td>
<td>0.6200±2.321</td>
<td>0.4320</td>
<td>1.463</td>
<td>0.1</td>
<td>Not significant</td>
</tr>
<tr>
<td>7</td>
<td>Urine Bile salt</td>
<td>0.433±1.251</td>
<td>0.2145</td>
<td>2.020</td>
<td>0.05</td>
<td>Significant</td>
</tr>
<tr>
<td>8</td>
<td>Urine Bile Pigment</td>
<td>0.533±1.196</td>
<td>0.1980</td>
<td>2.639</td>
<td>0.01</td>
<td>Significant</td>
</tr>
</tbody>
</table>
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 Krrurakoshta & hence had common complaint of Madhavashtambha 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 Vyasanag such as Alcohol, smoking, Tobacco chewing which ultimately indicates association of presence of addiction & Prevalence of disease. Patients of Vatpittapakruti and Pittkapha Prakriti were seem to more prone to Shakhshirita Kamala due to predominance of Pitta dosha. Both the drugs reduced SGPT, SGOT Urine bile salt & pigment level but Loha Nishya 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 Shakhshirita Kamala over Trikatusaindhav Churna.

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 Shakhshirita Kamala which is more effective on Neterapeeta & 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 Shakhshirita Kamala.

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