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AN OPEN LABELED RANDOMIZED STUDY TO ASSESS THE EFFICACY AND SAFETY OF KRIMIHAR YOGA

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ABSTRACT

The prevalence of intestinal helminthes is often recognized as one of the important public health problems in developing countries. Herbal drugs continue to play an essential role in healthcare. It has been estimated by the World Health Organization that 80% of the population of the world rely mainly on traditional medicines for their primary healthcare. The objective of this study was to determine the clinical efficacy and safety of Krimihar Yoga, a poly herbal formulation of herbal ingredients in the management of Krimi of various etiological conditions in open labeled, randomized, prospective study. 20 patients with 5 - 14 years of age, either sex, confirmed as per the sign and symptoms of disease were recruited in the study. Treatment results were assessed on the basis of Investigator’s evaluation. The overall assessment showed that most of the patients were markedly improved after completion of the prescribed treatment.

INTRODUCTION

Prevalence of helminthiasis in developing as well as underdeveloped countries enforcing great threat as it is causing nutritional deficiencies and diseases directly, due to loss of protein, blood and other nutrients as well as indirectly through gastro-intestinal disturbances like anorexia, flatulence, abdominal pain, nausea, vomiting and diarrhea which leads to mal-absorption syndrome and malnutrition. The situation is further aggravated, due to inadequate intake of food and imbalanced diet, ignorance of dietary habits, various socio-economic and environmental factors like lack of proper sanitation, literacy and use of uncooked raw food or improper washing of food materials etc.¹

According to WHO, it is estimated that about ¼ th of the population are infected with one or more of most common type of parasites like Round worms (Ascaris lumbricoides), Hook worms (Necator americanus and Ancylostoma duodenale) and Whip worms (Trichuris trichiura).²

Children are more likely to manifest acute evidence of disease because of low immunity or tolerance and greater opportunity for exposure of parasite infestation; it not only influences the body but rather sometimes leave greater impact on the growth and development of the children.

In Ayurveda, parasitic infection and helminthic infections are included under Krimi Roga. Different varieties of Krimi are described in Ayurvedic literature.³ General symptoms which mark the presence of worms in the system are fever, paleness of complexion, abdominal pain, cardiac troubles, lassitude, vertigo, aversion to food and diarrhea.⁴ Ayurvedic classics explain the treatment as Apakarashna (extraction of worms with the help of Sansodhana therapy- Vaman (therapeutic vomiting or emesis), Virechan (purgation), Vasti (medicated enema), Nasya (elimination of toxins through the nose), Prakriti Vighata (utilising antihelminthic drugs along with dietary regimen non-congenial to proliferation of helminthes) and Nidan-parivarjana (avoidance of all etiological factors of helminthiasis).⁵

In modern medicine Anthelmintic drugs used are Mebendazole, Albendazole, Pyrantel pamoate, Levamisole, Praziquantel etc.⁶ But all these drugs have a long list of adverse effects with them, like diarrhea, nausea, abdominal
pain, allergic reactions, and loss of hairs. Besides that herbal medicine give side benefits instead of side effects. Herbal medicines are cost effective, easily available and safe for long term use. Therefore, the herbal therapeutics has attracted considerable glamour for providing safe and effective remedies.

**Objectives**
1. To study the aetio-pathogenesis of Krimiroga.
2. To assess the efficacy and safety of Krimihar Yoga.

**Test Medicine**
Krimihar Yoga is a poly herbal preparation containing powder of Vidanga (Embelia ribes), Ajwain (Trachyspermum ammi), Ajmoda (Apium graveolens), Khurasani Ajwain (Hyoscyamus niger), Palash Pushpa (Butea monosperma) All the ingredients are safe and individual therapeutic efficacy is also reported in relieving the symptoms of Krimiroga.

**MATERIAL AND METHODS**
The research study entitled “An open labeled randomized study to assess the efficacy and safety of Krimihar Yoga” was an observational clinical trial done with herbal formulations of Krimihar Yoga.

**Research Design**
The study was a single open prospective randomized clinical trial conducted over a period of one week (follow up for 1 months) to evaluate symptomatic and subjective improvement in patients of Krimiroga.

**Inclusion Criteria**
- Either sex ageing between 5-14 years
- Patients having classical symptoms of Krimiroga and presence of Ova/cyst/worms in stool examination

**Exclusion Criteria**
1. Patients having severe illness or complication
2. Patients requiring immediate medical intervention
3. Participating in any other clinical trials.

**Study Population**
Total 20 patients of either sex with confirmed Krimiroga as per the sign and symptoms were enrolled in the study.

**Criteria for Selection of Drug**
Krimihar Yoga consists of certain herbal ingredients presented in the powder form for oral administration. All the ingredients are safe and their individual therapeutic efficacy was also reported in relieving the symptoms of Krimiroga. The raw drugs are easily available and low cost compared to other therapy. Hence Krimihar Yoga was selected for research study.

**Ingredients:** One gram of Krimihar yoga contains –
1. Vidanga (Embelia ribes) – 250 mg
2. Ajwain (Trachyspermum ammi) – 250 mg
3. Ajmoda (Apium graveolens) – 250 mg
4. Khurasani Ajwain (Hyoscyamus niger) – 125 mg
5. Palash Pushpa (Butea monosperma) – 125 mg

Dose of Drug – 1-2 gm BD with Honey/plain water.

**Diagnostic Criteria**
An elaborate case paper incorporating the points of history taking, previous medication, past illness and physical examination was prepared. It mainly emphasized on signs and symptoms of Krimiroga.

Routine laboratory investigation like CBC and Stool examination (Ova/cyst) was made to rule out the conditions.

**Criteria for Assessment**
The assessment was made before and after the treatment on scoring of signs and symptoms of Krimiroga. Scoring pattern was developed according to severity of symptoms. Results were analyzed statistically as per the assessment chart.

**Subjective Parameters**
Symptoms were evaluated on the basis of 0=Normal, 1-Mild, 2-Moderate and 3- Severe.
- Fever
- Paleness of complexion
- Anal itching
- Abdominal pain
- Lassitude
- Anorexia
- Nausea
- Vomiting
- Loose stool

**Objective Parameters**
- Evaluation of Stool examination – Presence of Ova and cyst in microscopic examination was evaluated as: Absent – 0, Present – 1.

**Assessment of total effect:** The total effect of therapy was assessed as;

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete cure</td>
<td>100%</td>
</tr>
<tr>
<td>Marked Relief</td>
<td>&gt; 75 to 99%</td>
</tr>
<tr>
<td>Moderate Response</td>
<td>&gt; 50 to 75%</td>
</tr>
<tr>
<td>Mild Improvement</td>
<td>&gt; 25 to 50%</td>
</tr>
<tr>
<td>No response</td>
<td>0 to 25%</td>
</tr>
</tbody>
</table>

**Observation**
The effect of Krimihar Yoga was studied in 20 patients suffering from Krimiroga, fulfilling the inclusion criteria. On analysis, it was found that maximum number of patients belonged to Hindu community (70%), 80% had educated parents and 60% was belonging to middle class families. 100% of patients were from urban area, had good hygiene 80%, most of the patients 80% were properly immunized to their age whereas 20% were only partially immunized. Majority of patients were weak. Maximum numbers of patients were strict vegetarian’s 70%. Most of the patients 80% were having irregular food habits irrespective of hunger. 60% were having disturbed sleep regularly and 40% were having regular day sleep.
Effect of Therapy

The effect of therapy on all subjective and objective parameters has been documented in tables. The effect of test drug on all cardinal symptoms is showing a highly significant result in anal itching, abdominal pain, lassitude, anorexia and loose stool after completion of one week treatment. Stool examination for ova and cyst showed a highly significant result. In all symptoms the drug showed a remarkably high percentage improvement above 60% except in fever, paleness of complexion, nausea and vomiting. Paleness of complexion showed a significant 59.09% result.

Overall Effect of Therapy

The overall assessment considering all the parameters outlined in the assessment criteria, the final result shows that 65% of patients had marked relief and 15% each had moderate and mild improvement. 5% patient (one patient) was completely cured after treatment.

Table 1 Effect of Krimihar Yoga on symptoms of 20 patients of Krimiroga

<table>
<thead>
<tr>
<th>Symptom</th>
<th>BT</th>
<th>AT</th>
<th>Diff. Mean</th>
<th>% Relief</th>
<th>SD</th>
<th>SE</th>
<th>‘t’ value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fever</td>
<td>0.70</td>
<td>0.30</td>
<td>0.40</td>
<td>57.14</td>
<td>0.50</td>
<td>0.112</td>
<td>1.925</td>
<td>P&gt;0.01</td>
</tr>
<tr>
<td>Paleness of complexion</td>
<td>1.10</td>
<td>0.45</td>
<td>0.65</td>
<td>59.09</td>
<td>0.489</td>
<td>0.109</td>
<td>3.299</td>
<td>P&lt;0.01</td>
</tr>
<tr>
<td>Anal itching</td>
<td>2.25</td>
<td>0.70</td>
<td>1.55</td>
<td>68.88</td>
<td>0.605</td>
<td>0.135</td>
<td>7.566</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>1.80</td>
<td>0.65</td>
<td>1.15</td>
<td>65.88</td>
<td>0.366</td>
<td>0.082</td>
<td>6.046</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td>Lassitude</td>
<td>1.60</td>
<td>0.55</td>
<td>1.05</td>
<td>65.62</td>
<td>0.394</td>
<td>0.088</td>
<td>5.971</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td>Anorexia</td>
<td>1.40</td>
<td>0.50</td>
<td>0.85</td>
<td>60.71</td>
<td>0.365</td>
<td>0.082</td>
<td>4.834</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td>Nausea</td>
<td>1.00</td>
<td>0.60</td>
<td>0.40</td>
<td>40.00</td>
<td>0.503</td>
<td>0.112</td>
<td>2.179</td>
<td>P&lt;0.01</td>
</tr>
<tr>
<td>Vomiting</td>
<td>0.55</td>
<td>0.35</td>
<td>0.20</td>
<td>36.36</td>
<td>0.410</td>
<td>0.092</td>
<td>1.265</td>
<td>P&lt;0.01</td>
</tr>
<tr>
<td>Loose stool</td>
<td>0.75</td>
<td>0.20</td>
<td>0.55</td>
<td>73.33</td>
<td>0.510</td>
<td>0.114</td>
<td>3.584</td>
<td>P&lt;0.001</td>
</tr>
</tbody>
</table>

Table 2 Effect of Krimihar Yoga on stool examinations of 20 patients of Krimiroga

<table>
<thead>
<tr>
<th>Stool Examination</th>
<th>BT</th>
<th>AT</th>
<th>Diff. Mean</th>
<th>% Relief</th>
<th>SD</th>
<th>SE</th>
<th>‘t’ value</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ova &amp; Cyst</td>
<td>1.00</td>
<td>0.15</td>
<td>0.85</td>
<td>85.00</td>
<td>0.366</td>
<td>0.082</td>
<td>10.376</td>
<td>P&lt;0.001</td>
</tr>
</tbody>
</table>

Table 3 Overall effect of Krimihar Yoga in 20 patients of Krimiroga

<table>
<thead>
<tr>
<th>Result</th>
<th>Number of Patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Response</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Mild Improvement</td>
<td>03</td>
<td>15%</td>
</tr>
<tr>
<td>Marked Relief</td>
<td>13</td>
<td>65%</td>
</tr>
<tr>
<td>Moderate Response</td>
<td>03</td>
<td>15%</td>
</tr>
<tr>
<td>Complete cure</td>
<td>01</td>
<td>5%</td>
</tr>
</tbody>
</table>

DISCUSSION

This study was conducted as ‘An open labeled, randomized prospective study to assess the efficacy and safety of Krimihar Yoga’. The results of this study demonstrate that most of the patients got marked relief after completion of treatment.

Krimihar yoga is a multi-herb powder formulation which contains important herbs in optimum concentrations. One of the important pharmacologically active compounds found in Krimihar Yoga is Vidanga (Embelia ribes), having Katu, Tikta Rasa, Laghu, Ruksha and Tikshna Guna, Ushna Veerya, Katu Vipaka and Anulomana, Deepana, Kriminashana and Vatakaphagna Properties. It acts as ascaridical, anthelmintic, carminative, diuretic, astringent, anti-inflammatory, antibacterial and febrifuge.[7] Anthelmintic activity of Ajwain (Trachyspermum ammi) shows its effect against specific helminthes, e.g. Ascaris lumbricoides in humans and Haemonchus contortus in sheep.[8]

Anthelmintic activity of Trachyspermum ammi exerts by interference with the energy metabolism of parasites through potentiating of ATPase activity and thus loss of energy reserves.[9] The plant has also been reported to possess cholinergic activity with peristaltic movements of the gut, thus helping in expulsion of intestinal parasites which might also be a contributory factor to its anthelmintic activity.[10-13]

Ajmoda (Apium graveolens) is reported as sedative, diuretic and antispasmodic effects which may be due to phthalide constituents (d-limonene, selinene and related phthalides). Essential oil obtained from this plant is reported to have a calming effect on the central nervous system. Some of its constituents showed antispasmodic, sedative and anti-convulsant actions.[12]

The safety and tolerability of study medications was assessed based on adverse events reported by patients or observed by the investigator during evaluation. No clinically significant adverse effect neither reported by the patients nor observed by the researcher during the study.

As revealed by the results, in different subjective and objective parameters remarkable improvement in disease condition was observed, which can be attributed to the test medicine, Krimihar Yoga.

CONCLUSION

Krimihar Yoga provided better result in all the cardinal symptoms of the disease and on the stool examination. The present study has shown positive results on Krimiroga through herbal preparations. These drugs were very much effective in clearing the intestinal parasites, in addition to this; these drugs showed better action on digestion, anorexia, abdominal pain and overall improvement in general health. These drugs are
safe, not having any side or toxic effects and are natural in origin are added advantages.

**References**

2. Park K, Park’s Text Book of Preventive and Social Medicine, Banarasidas Bhanot, Jabalpur, India, 2000. 166.

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**How to cite this article:**
