

**CLINICAL TRIAL TO EVALUATE THE EFFICACY OF KRIMI GHATINI VATI ON
PUREESHAJA KRIMI W.S.R TO ENTEROBIUS VERMICULARIS IN CHILDREN****Dr. Amit Kumar Sharma¹, Dr. Prathviraj Puranik^{2*} and Dr. Sharashchandr R.³**¹PG Scholar, Department of PG Studies Kaumarabhritya, Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Udupi, Karnataka, India.²Professor & HOD., Department of PG Studies Kaumarabhritya, Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Udupi, Karnataka, India.³Assistant Professor, Department of PG Studies Kaumarabhritya, Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Udupi, Karnataka, India.***Corresponding Author: Dr. Prathviraj Puranik**

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ABSTRACT

Children are the nation's important resources. Health, education and over all development of every child is important, as progress and welfare of country depends upon them. Helminthiasis is the most common paediatric complaint worldwide and very common in tropical & sub-tropical areas. It is a global health problem which affecting 2 billion people worldwide. The Key factors linked with high prevalence of infection include poor sanitation, socio economic condition, peoples are mostly favour non veg diet, fast food, milk & butter product, sweet product, faulty prepared food or fermented food and all these factors aggregate in outcome of Krimiroga. The branch of Helminthology in Ayurveda is not well established as compared to the allied science. But there are many references available on Krimi and Krimiroga mentioned in Ayurveda classics. These parasites are present in small and large intestine and vary in size from minute to macroscopic and showed similar clinical feature as intestinal worm. In this regard an effective, inexpensive and easily available preparation is required to treat Pureeshaja Krimi in children through Ayurveda. Therefore the present research work intends to study the effect of Krimi Ghatini Vati in the management of Pureeshaja Krimi in children. 30 patients were selected for this clinical trial. The drug was administered for 7 days with a dose of 75m.g BD for the age group of 5years to 5 years 11 months. Patients were evaluated as per the specially designed Proforma. In the study, highly significant results were observed in mitigation of clinical symptoms (Sanjata Krimi lakshana) and significant effect could be claimed for macroscopic stool examination with the administration of Krimi Ghatini Vati.

KEYWORD: Krimi, Enterobius Vermicularis, Krimi Ghatini Vati.**INTRODUCTION**

Worm infestation is the most common paediatric complaint worldwide especially in tropical and sub tropical geographical areas. More than 2 billion persons worldwide are infected with one or more species of intestinal nematodes^[1] either of round worm (Ascariasis), pin worms (Enterobius); tape worms (Taenia Solium). The incidence of worm infestation is about 200 million people in India. Intestinal worm infestations are widely prevalent in tropical and subtropical countries and occur where there is poverty and poor sanitation, use of uncooked food or improper washing of food materials etc, are the important factors for spreading worm infection.

The branch of Helminthology in Ayurveda is not well established as compared to the allied science, but there are many references available on Krimi and Krimiroga mentioned in Ayurveda classics.

Acharya Charaka has beautifully described threefold chikitsa for krimi Roga viz. Apakarshana, Prakritivighata and nidana Parivarjana.^[2] Samshodhana in children is not desirable so keeping this in mind Samshamana treatment is planned with suitable Krimighna drugs, which are described in our classics.

In Ayurveda many Krimighna (Anthelmintic) drugs are mentioned. Commonly single drug therapy is in practice for treatment of krimi. In this regard, an ideal and unique herbo - mineral preparation Krimi Ghathini vati^[3], a combination of 8 best likely Krimighna drugs mentioned in Baishajya Ratnavali was selected, in the reference of Krimichikitsa. Each constituent of Krimi Ghatini Vati has Krimighna properties and chemical constituents of some of these drugs are shown to have anthelmintic properties expecting good efficacy on Enterobius Vermicularis. The compound Krimi Ghathini vati is an anthelmintic drug mentioned in the classical scripts, for

which an attempt is made for the evaluation under clinical studies on selected cases.

Objectives of the study

To evaluate the efficacy of Krimi Ghathini Vati in the management of Pureeshaja Krimi w.s.r.to Enterobius Vermicularis in Children.

MATERIALS AND METHODS

Ingredients of KrimiGhathini Vati

S. N	Ingredients	Botanical name	Parts used	Quantity
1	Bakuchi ^[4]	<i>Psoralea corylifolia</i> linn.	Seed	1 part
2	Haridra ^[5]	<i>Curcuma longa</i> linn.	Rhizome	1 part
3	Pippali ^[6]	<i>Piper longum</i> linn.	Fruit	1 part
4	Kampillaka ^[7]	<i>Mallotus philippensis</i> lam.	Fruit (dried glands covering)	1 part
5	Suddha Gairika ^[8]	Fe ₂ O ₃ [C.F.]		1 part
6	Trivruttha ^[9]	<i>Operculina turpethum</i> (Linn.)	Root	1 part
7	Haritaki ^[10]	<i>Terminalia chebula</i> retz.	Fruit	1 part
8	Palasha ^[11]	<i>Butea monosperma</i> lam.	Seed	1 part

Collection of raw drugs: The raw drugs were procured and made into vati in the SDM Pharmacy of Ayurveda, Udupi, Karnataka, India.

Method of Krimi Ghathini Vati preparation: The above mentioned drugs are taken and cleaned thoroughly. Then, they are dried and made into fine powders separately. The powder is then processed with quantity sufficient of water to make it into a paste like consistency. Then, the paste when becomes non-sticky while rolled to the fingers; pills of required sized are made by hand. Later, the pills are dried in shade & kept in airtight containers.

Study design: It is an open label clinical trial.

Selection of cases: In this study, 30 children with the complaints of Gudakandu with any two or more symptoms of Sanjata Krimi Lakshana were randomly selected from the Kaumarbharitya O.P.D & I.P.D. of S.D.M. Ayurveda Hospital, Kuthpady, Udupi & referral in and around Udupi.

Inclusion criteria

1. Age group between 5years to 5year 11months irrespective of sex, religion, socio-economic status and food habits.
2. Children with no history of any treatment with any anthelmintic drugs since last 30 Days.
3. Patient with Gudakandu in association with any one or two general signs and symptoms of krimi.

Exclusion criteria

1. Krimi Roga, other than Pureeshaja krimi is excluded.
2. Children suffering from any other systemic disorder along with Enterobius Vermicularis.

Group: Single group minimum of 30 patients.

Plan of intervention

Dosage form: vati

Dose: 75 m.g.

Anupana: water

Times of administration: 12th hourly after food.

Duration of treatment: 7 days

Detail history: The elements in history taking include name, age, sex, socio-economic status, education, chief and associate complains, evaluation of the nature, duration and time, course of symptoms, social history, immunization history, personal history, family history of allergic diseases, and also examined anthropometry, general examination, systemic examination (Inspection, palpation, percussion, auscultation) was performed.

Lab Investigations conducted

1. Hb %
2. Macroscopic stool examination.

Criteria for Assessment

Subjective Parameters

Pandu (Anemia)
 Bhaktadvesha (anorexia)
 Jwara(Fever)
 Vivarnata (Discoloration of the face)
 Shool (Pain in abdomen)
 Atisaar
 Kasa

Objective

1. Hb%
2. Macroscopic stool examination.

Follow-up study: Evaluation for recurrence of the signs & symptoms of krimi general health status & systemic examination were conducted during the follow up period.

Statistical Evaluation: 30 diagnosed children were taken for the study and obtained Observations and results were statistically analyzed.

Statistical analysis was done using Statistical package for social science (SPSS) VER. 20.

All the objective parameter result was analyzed statistically for 'p' value using paired "t" test.

Wilcoxon signed rank test was used for analyzing the significance of Subjective parameters within the group.

The obtained results were interpreted in the statistical terms as

Non-significant: $p > 0.05$

Significant (S): $P < 0.05$

Highly Significant (HS): $P < 0.001$

Ethical clearance: The study has been cleared by institutional Ethical committees; Ref. No. SDMCAU/ACA-49/ECA26/15-16.

OBSERVATION AND RESULTS

Children according to age group	10 children from 5.4 to 5.6 month (33.3%)
Children based on sex incidence	18 children were male (60%)
Children according to geographical area	23 children from semi urban area (76.7%)
Children based on religion	27 children from Hindu Religion (90.0%)
Children based on diet type	21 children had mixed Diet (70.0%)
Children based on dominant rasa in diet	28 children predominant for madhura rasa (93.3%)
Children based on nidra pattern	21 children had disturbed Sleep (70.0%)
Children based on mala pattern	20 children had Sama Mala (66.7%)
Children based on Agnibala	20 children had Avara Agni Bala (66.7%)
Children based on dietary habits	13 children had followed Alpashana (43.3%)
Children based on toilet used	30 children were used defecate in toilet with hygienic environment (100%)
Children based on Abhayavarana Shakti	23 children had Avara Abhayavarana Shakti (76.7%)
Children based on Jaranashakti	21 children had madhyam kosta (70.0%)

Parameter	Negative ranks			Positive ranks			Ties	Total	Z value	P value	inference
	N	MR	SR	N	MR	SR					
BT-AT	1	1.00	1.00	0	.00	.00	29	30	-1.000	.317	NS
BT-FT	1	1.00	1.00	0	.00	.00	29	30	-1.000	.317	NS
VIVARNATA											
BT-AT	29	15.0	435.0	0	.00	.00	1	30	-5.385	.000	HS
BT-FT	30	15.5	465.0	0	.00	.00	0	30	-4.964	.000	HS
UDARA SHOOLA											
BT-AT	21	11.0	231.0	0	.00	.00	9	30	-4.583	.000	HS
BT-FT	22	11.5	253.0	0	.00	.00	8	30	-4.690	.000	HS
BHAKTA DWESHA											
BT-AT	28	14.5	406.0	0	.00	.00	2	30	-5.209	.000	HS
BT-FT	29	15.0	435.0	0	.00	.00	1	30	-4.875	.000	HS
GUDA KANDU											
BT-AT	28	14.5	406.0	0	.00	.00	2	30	-5.292	.000	HS
BT-FT	28	14.5	406.0	0	.00	.00	2	30	-4.774	.000	HS
ATISAAR											
BT-AT	0	.00	.00	0	.00	.00	30	30	.000	1.000	NS
BT-FT	0	.00	.00	0	.00	.00	30	30	.000	1.000	NS
KASA											
BT-AT	1	1.00	1.00	0	.00	.00	29	30	-1.000	.317	NS
BT-FT	1	1.00	1.00	0	.00	.00	29	30	-1.000	.317	NS
MUCUS IN STOOL											
BT-AT	6	3.50	21	0	.00	.00	24	30	-2.449	.014	S

BT: Before Treatment, AT: After Treatment, FT: Follow up

Effect of Krimi Ghatini Vati on Weight

WEIGHT									
Mean score			Difference in means	Paired "t" Test					
				% of change	S.D.	S.E.M.	"t"	P	Interpretation
BT-AT	17.31	17.47	.158	0.91	.12	.023	6.88	.00	HS
BT-FT	17.31	18.28	.966	5.58	.12	.023	41.73	.00	HS

BT: Before Treatment, AT: After Treatment, FT: Follow up

Effect of Krimi Ghatini Vati on Hb%

Mean score		Difference In means	Paired "t" Test					
BT	AT		% of change	S.D.	S.E.M.	"t"	P	Interpretation
11.66	11.66	.00	.00	.36245	.06617			N.S.

BT: Before Treatment, AT: After Treatment.

Jwara

1. On parameter of Jwara statistical analysis revealed that results were compared Before treatment and After treatment (during the treatment) for variable of Jwara with Wilcoxon Signed ranked test, no significant results were obtained with $Z = -1.000$ to $P = .317$.
2. When results were compared before treatment and Follow up (Overall) for variable Jwara with Wilcoxon Signed ranked test, no significant results were obtained with $Z = -1.000$, $P = .317$.

Vivarnata

1. On parameter of Vivarnata statistical analysis revealed that results were compared Before treatment and After treatment (during the treatment) for variable Vivarnata with Wilcoxon Signed ranked test, Highly significant results were obtained with $Z = -5.385$ to $P = 0.000$.
2. When results were compared before treatment and Follow up (Overall) for variable Vivarnata with Wilcoxon Signed ranked test, Highly-significant results were Obtained with $Z = -4.964$, $P = 0.000$.

Udarashoola

1. On parameter of Udarashoola statistical analysis revealed that results were compared Before treatment and After treatment (during the treatment) for variable Udarashoola with Wilcoxon Signed ranked test, Highly significant results were obtained with $Z = -4.583$, $P = 0.000$.
2. When results were compared before treatment and Follow up (Overall) for variable Vivarnata with Wilcoxon Signed ranked test, Highly-significant results were Obtained with $Z = -4.690$, $P = 0.000$.

Bhaktadwasha

1. On parameter of Bhaktadweshastatistical analysis revealed that results were compared Before treatment and After treatment (during the treatment) for variable Bhaktadwasha with Wilcoxon Signed ranked test, Highly significant results were obtained with $Z = -5.209$, $P = 0.000$.
2. When results were compared before treatment and Follow up (Overall) for variable Bhaktadwasha with Wilcoxon Signed ranked test, Highly-significant results were Obtained with $Z = -4.875$, $P = 0.000$.

Gudakandu

1. On parameter of GudaKandustatistical analysis revealed that results were compared Before treatment and After treatment (during the treatment) for variable GudaKandu with Wilcoxon Signed ranked test, Highly significant results were obtained with $Z = -5.292$, $P = 0.000$.
2. When results were compared before treatment and Follow up (Overall) for variable GudaKandu with Wilcoxon Signed ranked test, Highly-significant results were Obtained with $Z = -4.774$, $P = 0.000$.

Atisaar

1. On parameter of Atisaar statistical analysis revealed that results were compared Before treatment and After treatment (during the treatment) for variable Atisaar with Wilcoxon Signed ranked test, no significant results were obtained with $Z = .000$ to $P = 1.000$.
2. When results were compared before treatment and Follow up (Overall) for variable Atisaar with Wilcoxon Signed ranked test, no significant results were obtained with $Z = .000$, $P = 1.000$.

Kasa

1. On parameter of Kasa statistical analysis revealed that results were compared Before treatment and After treatment (during the treatment) for variable Kasa with Wilcoxon Signed ranked test, no significant results were obtained with $Z = -1.000$ to $P = .317$.
2. When results were compared before treatment and Follow up (Overall) for variable Kasa with Wilcoxon Signed ranked test, no significant results were obtained with $Z = -1.000$, $P = .317$.

Mucus in Stool

On parameter of mucus in stool statistical analysis revealed that results were compared Before treatment and After treatment (during the treatment) for variable mucus in stool with Wilcoxon Signed ranked test, significant results were obtained with $Z = -2.449$ to $P = .014$.

Weight

On parameter of weight statistical analysis revealed that slight improvement in weight from mean value 17.31 BT to mean value 17.47 AT, showing highly significant P-

value of 0.00 with a relief rate of 0.9127% at 7th day assessment. When results were compared before treatment and Follow up (Overall) shows improvement in weight from mean value 17.31 BT to mean value 18.28 AT, showing highly significant P-value of .00 with a relief rate of 5.5805% at 30th day assessment. Drug was found to be highly significant in improving weight.

HB%

On parameter of Hb% statistical analysis revealed that standard error of the difference is 0.

Analysis shows given drug is no significant in improving Hb% of children.

DISCUSSION

Krimi Roga hampers the growth and development of the child decrease immunity and creates many allergic phenomena and cause recurrent cough and cold and other systematic disease. Thus worm infestation causes many complications which attract the children towards pediatrician. The incidence of Krimiroga is very high due to the unhygienic condition, illiteracy, child's dependant age. Hence, present clinically study was designed, Krimi Ghathini vati shown statistically significant results in reducing symptoms of krimi (*Enterobius Vermicularis*) such as Gudakandu (Perianal itching), Vivarnata, Bhakta Dwesha, Abdominal pain.

Whereas Krimi Ghatini Vati did not show statistically significant result in symptoms Jwara, Kasa, and Atisaar. The reason behind this could be probably there was not sufficient number of children exhibiting with these symptoms. All the symptoms were seen to reduce effectively within the first week in most of the children. But whoever persisted with those symptoms were completely reduced by the fourth week.

Mode of action of Krimi Ghathini vati

Krimi Ghathini Vati is a compound drug with Katu, Tikta, Kashaya rasa predominance; all these are antagonistic to Kapha along with the action of Krimighna. Ushna virya and Katu Vipaka acts as Kapha Vatahara. Gunas like Laghu, Ruksha, and Tikshana also subside the Dushta Kapha. The presence of Katu Rasa and Vipaka helps in Deepana and Pachana (Ama Pachana) property and also in Stroto Shodhana. Thus in total, the drug possesses Deepana, Pachana, Kaphaghna, Stroto Srodhahara, Krimighna properties which are required for the drug to be used in Krimi Roga. Thus with all these properties this drug may help in subsiding the symptoms of Krimi Roga.

CONCLUSION

Krimi is a major public health problem as it adversely affects the nutritional status of a child but neglected due to poor socio - economic status. It affects the children more frequently than adult. Krimi hampers the growth and development of a child which shows its effect on the school performance of the child.

According to the habitat, *Enterobius Vermicularis* is one of the type of Pureeshaja Krimi.

Enterobiasis is the most prevalent worms found in children worldwide with an estimated in 61% population of India. Enterobiasis may remain asymptomatic or cause Perianal pruritus, insomnia, restlessness, irritability and rarely impetigo of scratched skin, vulvovaginitis, or enuresis. According to the Samprapti, Agnimandya and Ama Utpatti are the main causes of Krimi Utpatti. The Pathya, Apathya and personal hygiene should be explained to the patient and their family, which plays an important role to prevent and avoid its recurrence.

The present study revealed that the ingredients Kampillaka, Pippali, Palasha, Bakuchi, Gairika, Haritaki, Trivruttha and Haridra have the action of Deepana, Pachana, Rechaka, Kanduhara, Krimighna, Kushthaghna, Udara Rogahara etc, which was observed during the clinical study.

From the clinical study it was observed that the trial drug Krimi Ghatini Vati is absolutely free from any sort of adverse effects in its therapeutic dose and therefore, it is found to be a safe remedy for Pureeshaja krimi.

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