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TO STUDY THE EFFICACY OF *SANJEEVANI VATI* IN *KRIMIRAGA* WITH SPECIAL REFERENCE TO INTESTINAL HELMINTHIASES.

Mangesh Pawar[1], Naina Vishwakarma[2]

P. G. Scholar[1], Professor[2],
Department of Rognidan Evam Vikriti Vigyan, Late Kedari Redekar Ayurved College Gadhinglaj, Dist- Kolhapur. Maharashtra, India.

*Corresponding Author: Dr. Mangesh Pawar, email: mangeshpawar00005@gmail.com

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ABSTRACT:

Worm infection refers to the worms that live as parasites in the human body and are one of the main cause of disease associated with health and nutrition problems beyond just gastrointestinal track disturbances. The present study was undertaken to evaluate the efficacy of *Sanjeevani Vati* , adapting *Samshaman* as the line of management of *krimiroga* (helminthes) in children. A simple randomized controlled clinical trial was conducted among 60 randomly selected children of 8-12 years age , suffering from *krimiroga* and at least showing the symptom *Udarashoola* (abdominal pain) and presence of ova/cysts/worms of intestinal helminthes on microscopic stool examination. *Sanjeevani Vati* 100mg (trial drug) was administered to 30 such children. Another set of 30 children were administered with Mebendazole 100mg (control drug). All children were subjected to clinical examination for signs and symptoms and parasite positivity, before treatment on 7th day and 14th day after treatment. *Sanjeevani Vati* and Mebendazole have produced almost same level of reduction of signs and symptoms in patents of both groups. The patients of both groups became completely asymptomatic and negative for ova/cysts/worms on 14th day of treatment. The study has proved the efficacy and safety level of the trial drug and has established that *Sanjeevani Vati* is found to be effective safe alternative anthelmintic drug for soil transmitted intestinal helminthiases.

KEY WORDS: *Krimiroga* , Helminthiases ,*Sanjeevani Vati*, Mebendazole, Anthelminthic drug..

INTRODUCTION:

World Health Organization (W.H.O) report that today's scenario of health system is really on a decline state and not meeting the stated demands and changing needs[1]. Paying less attention to the diet and life style has given rise to a good number of aliments challenging the scientific community among which worm infestation s one of the major condition encountered in pediatric practice.

Helminthiasis is infection with one or more intestinal parasitic worms like Round worm (*Ascaris limbricoides*), Whip worms (*Trichuris trichiura*), or Hook worms (*Necator americaus and Ancylostoma duodenale*)[2]

World Health Organization (W.H.O.) considered pre-school and school aged children as high risk population[3] for soil transmitted intestinal helminthes. Hence the agency has recommended for deworming once in every six months for every individual in childhood period . But many anthelminthic drugs used have developed resistance

and have side effect like toxic or allergic reactions. Several herbal and herbo-mineral formulations in *Ayurveda* are described for the treatment of worm infections. But there is no clinical evidence about their efficacy and safety. Therefore Ayurvedic researches n this particular context can aid to achieve the global target [4] of W.H.O to eliminate morbidity due to soil transmitted helminthiases of children by 2020.

Samshamaa[5] (palliation) is one among the line of management of *Krimiroga* according to *Acharya Charaka* which is easier to be administered in children. *Sanjeevani Vati* mentioned in *Bhaisajya Ratnavali*[6] being a Vati preparation, is potent enough for short term administration which is comparable to that of Mebendazole in modern medicine. Moreover, most of the ingredients of this *yoga* namely ,*Vidang*[7],*Pippali*[8],*Haritaki*[9],*Bhibhitaki*[10] ,*Guduchi*[11], *Vacha*[12], *Bhallataka*[13] are said to have *Krimighna* (Antheiminthic) property. Another very unique process used in Ayurveda is the process known as "*Bhavana*" (Impregnation). In this process a drug or mixture of drugs in powdered form is triturted with a liquid till all liquid portions are absorbed completely[14].This unique process exclusively mentioned in Ayurveda mixes completely, breaks the complicated chemical molecules into easily absorbable simpler ones thus augmenting the potency of medicine to many folds. Also *Acharya Charaka* has explained *Krimighana* property of *Mutra*[15].

This study has evaluated efficacy of *Sanjeevani Vati* in management of *Krimiroga* especially intestinal helmenthiases.

Aims and Objectives

1. To search and re-evaluate *Sanjeevani Vati* in various ayurvedic literatures with references.
2. To study the etiopathology of *Krimi Roga* from *Ayurvedic* and Modern literature.
3. To compare the clinical efficacy of *Sanjeevani Vati* along with Mebendazole.

MATERIAL AND METHODS:

In this clinical study the diagnostic criteria of *Krimiroga* and its treatment modality were assigned with reference to the classical literature from Ayurvedic and Allopathic Medicines. The diagnostic criteria included children having *Udarashoola* (abdominal pain) in association with two o more general features of *Krimi*[16] namely , *Jwara* (fever), *Vivarnata* (discoloration),*Udarashoola*, *Hridroga*, *Sadana* (exhaustion), *Bhrama*, *Bhaktadwesha* (aversion of food), *Atisara*, *Gudakandu* (anal itching) and presence of ova/cyst/worm of *Ascaris lumbrcoides,Trichuris trichura, Necator americanus, Ancylostoma duodenale* or *Enterobius vermicularis* , in microscopic stool examination.

The drug used in study *Sanjeevani Vati* 100mg tablet (trial drug).The trial drug was prepared in the ayurveda pharmacy. The control drug used in this study i.e.100 mg of Mebendazole or (5-benzoyl-1H-Benzimidazole-2-yl) - carbonic acid methyl ester) belongs to the organic compounds benzophenones. It is synthetic broad-spectrum anthelminthic used in the treatment of intestinal helminths[17].This drug required for study was procured from pharmacist's counters.

Study design:

The Simple Randomized Controlled Clinical Trial [18](RCT) was the study design adopted to envisage the present research work. The study population was from among those children who attended the *Kaumarbhritya* outpatient department. A total of 60 children suffering from *Krimiroga* (infested with either Round worm, Whip worm, Hookworm or Pin worm) and fulfilling the inclusion criteria were randomly selected as study subject. They were assigned into 2 groups. Group A (Trial), Group B (Control). Each group with 30 children who were recruited strictly adhering to the guidelines of Indian Council of Medical Research.

Inclusion Criteria:

1. Children of age group between 8-12 years irrespective of sex,religion, socio-economical status and food habits.
2. Children having *Udarashool* in association with two or more symptoms of *Krimi*.
3. Children diagnosed with infestation of *Ascaris lumbrcoides,Trichuris trichura, Necator americanus, Ancylostoma duodenale* or *Enterobius vermicularis* by microscopic stool examination.

Exclusion Criteria:

1. *Ascaris* infestation with complication such as Pancreatitis, Cholecystitis, Pulmonary eosinophilia, intestinal obstruction[19].
2. Microscopic stool examination positive to ova/cysts/larval form of intestinal protozoans ,Tap worm and Filarial worm.

Administration of Dug and observation of patient:

Each child of control group was given 1 tablet of Mebendazole 100mg (twice daily for 3 consecutive days).In the Trial group each child was given 1 tablet of *Sanjeevani Vati* 100mg ((twice daily for 3 consecutive days). Before starting the administration of drug all the children of both the study group were subjected to clinical examination. Subject was further examine for clinical symptoms on 7th day after treatment. Follow up was done on 14th day after drug administration. Both groups all the subjects observed.

Laboratory Investigation:

Stool sample examined before starting treatment add after 7th and 14th day of treatment.

Collection of Recording of Data:

A pre tested proforma was used to record the observations according to assessment criteria. Approximate grading was given for the variables in assessment criteria to correctly evaluate the outcome.

Table1: Grading for the assessment parameters of the study

Parameters	Absent	Present
Jwara	0	1
Vivarnata	0	1
Udarashoola	0	1
Hridroga	0	1
Sadan	0	1
Bhrama	0	1
Bhaktadwesha	0	1
Atisara	0	1
Guda kandu	0	1

OBSERVATION AND RESULTS:

All the 60 children subjected to clinical trial had *Udarashoola* (Abdominal pain) a major sign and symptom of *Krimiroga* (helminthiasis) and all were found positive to ova/ cyst when stool sample were examined prior to drug administration. Other signs and symptoms complained by them.

Result of the unpaired t-test applied to make a comparison of the effect of treatment between Group A and Group B on 7th day (Table 4) using the mean difference of before treatment and 7th day after treatment showed that the p-values for all criteria's and presence of ova/ cyst/ worm in microscopic examination are >0.01. Hence the difference observed the mean value of all the criteria appear to be statistically not significant while comparing the effects of the two drugs on the 7th day after treatment. Similar result was obtained while unpaired t-test was applied to compare the effect of treatment between Group A and Group B on 14th day (Table 5). The unpaired p-value of the assessment criteria were >0.01

Table 2: Effect of *Sanjeevani Vati* on Assessment Criteria (Group A)

Mean of BT	Mean of		Mean difference	%	Paired t			
					S.D.	S.E.	t – value	P - value
Jwara								
0.600	7th Day	0.100	0.500	83.00%	0.509	0.093	5.385	< 0.001
0.600	14th Day	0.000	0.600	100.00%	0.498	0.091	6.596	< 0.001
Vivarnata								
0.330	7th Day	0.200	0.133	40.00%	0.346	0.063	2.112	0.022
0.330	14th Day	0.130	0.200	60.00%	0.407	0.074	2.693	0.006
Udarashool								
1.000	7th Day	0.400	0.600	60.00%	0.498	0.091	6.596	< 0.001

1.000	14th Day	0.267	0.733	73.33%	0.450	0.082	8.930	< 0.001
Hridroga								
0.000	7th Day	0.000	0.000	-	-	-	-	-
0.000	14th Day	0.000	0.000	-	-	-	-	-
Sadan								
0.500	7th Day	0.333	0.167	33.33%	0.379	0.069	2.408	0.011
0.500	14th Day	0.233	0.267	53.33%	0.450	0.082	3.247	0.001
Bhrama								
0.067	7th Day	0.000	0.000	100.00%	0.254	0.046	1.439	0.080
0.067	14th Day	0.000	0.067	100.00%	0.254	0.046	1.439	0.080
Bhaktadwesh								
0.800	7th Day	0.300	0.500	62.50%	0.509	0.093	5.385	< 0.001
0.800	14th Day	0.133	0.667	83.33%	0.479	0.088	7.616	< 0.001
Atisara								
0.000	7th Day	0.000	0.000	-	-	-	-	-
0.000	14th Day	0.000	0.000	-	-	-	-	-

BT- Before treatment; SD- Standard Deviation; SE- Standard Error

Table 3: Effect of Mebendazole tablet on Assessment Criteria (Group B)

Mean of BT	**Mean of**	**Mean difference**	**%**	**Paired t**			
				S.D.	**S.E.**	**t – value**	**P - value**
Jwara							
0.733	7th Day	0.067	0.667	90.91%	0.479	0.088	7.616	< 0.001
0.733	14th Day	0.000	0.733	100.00%	0.450	0.082	8.930	< 0.001
Vivarnata								
0.500	7th Day	0.167	0.333	66.67%	0.479	0.088	3.808	< 0.001
0.500	14th Day	0.133	0.367	73.33%	0.490	0.089	4.098	< 0.001
Udarashool								
1.000	7th Day	0.400	0.600	60.00%	0.498	0.091	6.596	< 0.001
1.000	14th Day	0.133	0.867	86.67%	0.346	0.063	13.73	< 0.001
Hridroga								
0.000	7th Day	0.000	0.000	-	-	-	-	-
1.000	14th Day	0.000	0.000	-	-	-	-	-
Sadan								
0.400	7th Day	0.167	0.233	58.33%	0.430	0.079	2.971	< 0.001
0.400	14th Day	0.100	0.300	75.00%	0.466	0.085	3.525	< 0.001
Bhrama								
0.133	7th Day	0.000	0.133	100.00%	0.346	0.063	2.112	0.022
0.133	14th Day	0.000	0.133	100.00%	0.346	0.063	2.112	0.022
Bhaktadwesh								
0.767	7th Day	0.267	0.500	65.22%	0.509	0.093	5.385	< 0.001
0.767	14th Day	0.167	0.600	78.26%	0.498	0.091	6.596	< 0.001
Atisara								
0.000	7th Day	0.000	0.000	-	-	-	-	-
0.000	14th Day	0.000	0.000	-	-	-	-	-

BT- Before treatment; SD- Standard Deviation; SE- Standard Error

Table 4: Comparison of effect of Treatments Between Group A and Group B on 7th Day

Assessment Criteria	Mean of B.T. – 7th Day		Mean difference	Standard Deviation		Unpaired t value	P – Value
	Group A	Group B		Group A	Group B		
Jwara	0.500	0.667	0.167	0.509	0.479	- 1.306	0.197
Vivarnata	0.133	0.333	0.200	0.346	0.479	- 1.853	0.069
Udarashool	0.600	0.600	0.000	0.498	0.498	0	1.000
Hridroga	0.000	0.000	0.000	0.000	0.000	-	-
Sadan	0.167	0.233	0.379	0.379	0.430	- 0.637	0.527
Bhrama	0.067	0.133	0.067	0.254	0.346	- 0.851	0.398
Bhaktadwesh	0.500	0.500	0.000	0.508	0.508	0	1.000
Atisara	0.000	0.000	0.000	0.000	0.000	-	-

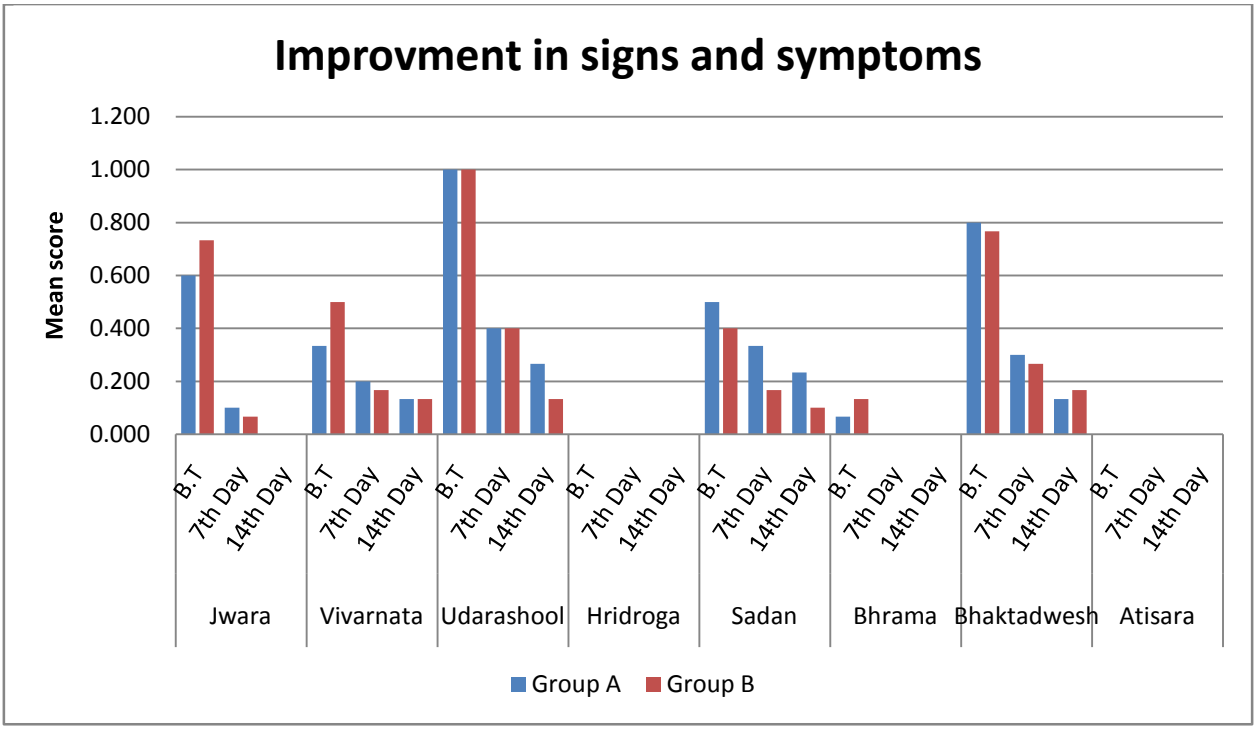
BT- Before treatment; SD- Standard Deviation; SE- Standard Error

Table 5: Comparison of effect of Treatments Between Group A and Group B on 14th Day

Assessment Criteria	Mean of B.T. – 14th Day		Mean difference	Standard Deviation		Unpaired t value	P – Value
	Group A	Group B		Group A	Group B		
Jwara	0.600	0.733	- 0.133	0.498	0.450	- 1.088	0.281
Vivarnata	0.200	0.367	- 0.167	0.407	0.490	- 1.433	0.157
Udarashool	0.733	0.867	- 0.133	0.450	0.346	- 1.287	0.203
Hridroga	0.000	0.000	0.000	-	-	-	-
Sadan	0.267	0.300	0.033	0.450	0.466	- 0.282	0.779
Bhrama	0.067	0.133	0.067	0.254	0.346	- 0.851	0.398
Bhaktadwesh	0.667	0.600	0.067	0.479	0.498	0.528	0.599
Atisara	0.000	0.000	0.000	-	-	-	-

BT- Before treatment; SD- Standard Deviation; SE- Standard Error

Figure 1: Improvement in signs and symptoms Between Group A and Group B



DISCUSION:

In this clinical study the most common parasitosis of patients was due to *Enterobius vermicularis* (Pin worm) followed by *Ascarisand Hookworms.* Though the life span of pinworms is brief, longstanding infections occur due to continuous reinfection[20]. In addition to the presence of abdominal pain, other major clinical symptoms like aversion to food, discoloration and exhaustion and were observed in majority of the children. These clinical findings also get support from *Samprapti* (pathogenesis) proposed for *Krimiroga*[21].

The present study revealed that the signs and symptoms due to worm infestation among the children were significantly reduced by the effects of treatment with trial drug (*Sanjeevani Vati*) and control drug (Mebendazole). Both these drugs were found to be equally effective in decreasing the symptoms *Udarashool,Jwara,Bhaktadwesha* and *Sadan*. Due to *Krimighna* property of *Vidang, Pippali, Haritaki, Bibhitaki, Guduchi, Vacha, Bhallataka* , worms are made immobile and dead later, which are gradually eliminated thereby reducing pain. All the contents are helpful in increasing digestive power by improving *Agni* and also creating a hostile environment inside the gastro intestinal tract (GIT), later removing the parasites and reducing the symptoms of *Krimirago* by *Deepan* and *Pachan* property.

Due to *Jwaraghna* property of *Vatsanabh, Pippali, Shunthi Haritaki, Aamalaki, Bibhitaki, Guduchi* and *Vacha* reduces *Jwara* gradually. *Anulomana* property of *Vidang, Pippali, Shunthi, Haritaki, Amalaki, Bibhitaki, Guduchi* and *Vacha* helps to expel worms from the body.

Last but not least *Gomutra* used for *Bhavana* in this formulation has *Deepan, Swedan, Vat-Kapha Shamak, and Krimighna* as well as *Vishaghna* properties[22]. Thus it also enhances the desirable properties of *Sanjeevani Vati* to many folds.

Embeline is responsible for anthelminthic activity exhibited that the principle mode of action for Mebendazole[23] is by its inhibitory effect on tubulin polymerization, which results in decreased production of adenosine triphosphate (ATP). Due to diminished energy reduction, the parasites are immobilized and eventually die. In the light if these modes of action of both the drugs, it is also understood that the effect of trial drug and control drug were almost similar in reducing clinical symptoms and decreasing parasitic load on stool samples of treated patients.

CONCLUSION:

Findings established that *Samshamana* (palliative) method is also effective in treating *Krimiroga,* which has been described by *Acharya Charaka* along with *Apakarshana* (extraction), *Prakriti Vighata* (disruption of pathogenesis), *Nidan Parivarjana* (avoiding causative factors) and *Samshodhana* (evacuation of doshas). Treatment with *Sanjeevani Vati* produced effects on all the clinical symptoms assessed in study especially *Jwara, Udarashoola, Bhaktadwesha, and Guda Kandu.* The trial drug also proved beneficial in eliminating the ova/cysts/worms of helminthes which was evident in microscopic stool examination. The trial drug is also found to be absolutely free from any sort of side effects or adverse reaction in its therapeutic dose and duration. Thus the present clinical study proves that *Sanjeevani Vati* can be used as a safe and effective alternative anthelminthic drug for soil transmitted intestinal helminthiases.

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