



A COMPARATIVE CLINICAL EVALUATION OF KRIMIGHNA KASHAYA (SYRUP) AND MUSTAADI KWATH (SYRUP) IN PUREESHAJA KRIMI W.S.R. TO INTESTINAL WORM INFESTATION IN CHILDREN

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ABSTRACT In modern science treatment protocols for worm infestations, medicines like Mebendazole, Albendazole, and Levamisole are used. In Ayurveda treatment approach is quite unique. The management approach in Ayurveda involves three stages namely Apakarshana (elimination therapy), Prakruti Vighata (to create an unfavorable environment) and Nidana Parivarjana (avoiding the etiology). The present study entitled “A comparative clinical evaluation of Krimighna kashaya (syrup) and Mustaadi kwath (syrup) in Pureeshaja Krimi w.s.r. to intestinal worm infestation in children” was conducted over 40 patients of Pureeshaja Krimi. The selected drugs were Krimighna Kashaya and Mustaadi kwath, both made in syrup form. The clinical research was conducted for a period of 14 days with follow up at 7th day and 14th day after completion of study. The patients were selected from OPD of Kaumarbhritya department, UAU, Gurukul campus, Haridwar, based on inclusion and exclusion criteria after screening (based on classical features of Pureeshaja Krimi and lab parameters). Patients were recruited and administered Group A with Krimighna Kashaya (syrup) and Group B Mustaadi kwath (syrup) to set dosage twice daily for 14 days. The result was concluded by applying appropriate statistical test. Both the trial drugs showed significant result on patients with Pureeshaja Krimi. The percentage relief in all subjective parameters in Group A as follows: Pureeshbheda 71.43%, karshya 0.00%, Gudkandu 60%, udarshoola 66.67%, Agnimandya 62.16%, Panduta 7.69%, balkshaya 68.18%, Average percentage effect of drug was 65.69%. The percentage relief in all subjective parameters in Group B as follows: Pureeshbheda 57.14%, karshya 0.00%, Gudkandu 42.86%, udarshoola 69.23%, Agnimandya 59.46%, Panduta 6.25%, balkshaya 48.15%, Average percentage effect of drug was 55.37%. Difference in the overall effects of Group A and Group B were statistically significant which suggested that Krimighna kashaya syrup (Group A) was better in reducing the subjective and objective parameter than Mustaadi kwath syrup (Group B). These two drugs are wormicidal in nature and they both are attributes of katu, tikta, kashaya, kshara, and ushna as well as the opposite qualities of kapha and pureesh are regarding prakritivighata.

KEYWORDS : Krimighna Kashaya, Mustaadi kwath, Intestinal worm infestation, Pureeshaja Krimi

INTRODUCTION

Worm infestation continues to be a major issue for young children's development. Worm infestations affect all age groups of the population, but they are particularly problematic for young children since they are still learning how to deal with their parasitic foes. The parasite challenge is probably the least known endemic issue. Worldwide more than 3.5 billion people are infested with worms out of which 400 million are children among whom 1.47 billion have roundworm, 1.3 billion have hookworm and 1.05 billion have whipworm infestations. With the highest prevalence recorded from sub-Saharan Africa, China, South America, and Asia, these illnesses afflict the poorest and most deprived communities with insufficient access to clean water, sanitation, and hygiene in tropical and subtropical settings. They are spread via eggs found in human feces, which then pollute the soil in unsanitary locations. In places where these parasites are intensively transmitted, there are about 260 million preschoolers, 654 million school-age kids, 108 million adolescent females, and 138.8 million pregnant and nursing women who need treatment and preventive measures. Worm infestation is the infection of the intestinal tract with any of several species of helminths or parasitic worms, including Ascaris (Roundworm), Enterobius (Pinworm), Trichinella spiralis and various species of Cestodes (Tapeworm). Major worm infections of public health importance include Ascariasis, Trichuriasis, Hookworm, and Enterobiasis, which are transmitted through contaminated soil. *E. histolytica* (6.06%), *G. lamblia* (6.06%), *S. stercoralis* (4.04%), *T. trichiura* (4.04%), *Taenia* sp. (4.04%), *A. lumbricoides* (3.03%), and *H. nana* (1.01%) were the parasites with the highest prevalence.^[4]

The primary sign of Krimirog is Jwara (fever). Vivarnata (skin discolouration) Painful Sula and heart-related Hridaroga lassitude, sadanam Anorexia, diarrhoea, and vomiting are all symptoms of Bhaktadveso.^[7] The acharya shushrut describes these signs. Apakarsana (removal of visible worm from the body), Prakriti Vighata (to create unfavorable environment by diet and medicine), and Nidana Parivarjana (avoid etiological cause) are the three fundamental ways recommended by Ayurveda for the treatment of Helminthis illness.^[8]

MATERIAL AND METHOD

A Randomized parallel group study was conducted in children suffering from *Pureeshaja Krimi* (Intestinal worm infestation)

INCLUSION CRITERIA-

- Patients between the age group of 3-16 years irrespective of gender.
- Primarily the patients will be selected on the basis of the presence of classical symptomatology of *Pureeshaja Krimi*. (Diarrhea, foul breath, pruritis ani, dark circle under eyes, abdominal pain, constant desire for food, restlessness at night with bad dreams, anemia, headache etc.
- Children with positive stool report for intestinal Helminthes infestation.

(C) EXCLUSION CRITERIA-

- Children below 3 year and above 16 years of age.
- Patients with negative stool report of ova and cyst.
- Patients having *Krimi* other than *Pureeshaja Krimi*
- Children with major congenital disorders and chronic debilitating diseases.
- Known case of Loeffler syndrome, Cholecystitis, cholangitis, pancreatitis & hepatic abscess.
- Intestinal manifestation

(C) DISCONTINUATION CRITERIA-

- Adverse drug reaction
- Patient not willing to continue
- Appearance of any severe complication
- Any other severe acute illness
- Leave against medical advice

SELECTED DRUG: *Krimighna Kashaya* Syrup And *Mustaadi Kwath* Syrup.

COMPOSITION OF MEDICINE-

1. KRIMIGHNA KASHAYA (SYRUP)- *Akshiv, Marich, Gandir, Kebuk, Vidang, Nirgundi, Kinhi, Shwadanshtra, Vrishpharnika and Aakhuparni.*

2. MUSTAADI KWATH (SYRUP) – *Musta, Aakhuparni, Madanphal, Sahijan, Devdaaru, Pippali and Vayavidang.*

FORMULATION OF DRUG: Syrup form

STANDARDIZATION OF TRIAL DRUG

The Trial Drugs Was Manufactured From a GMP No. 13/HHPL/22, Certified Ayurveda Pharmacy (Hans Pharmacy), Sidcul, Haridwar.

ETHICAL CLEARANCE:

This trial has been cleared by Institutional Ethics Committee, Ref- UAU/GC/IEC/2022/3 dated on 04.06.2022

REGISTRATION IN CTRI:

The present clinical trial has been registered in Clinical Trials Registry – India (CTRI). The registration number is CTRI/2022/08/045047 [Registered on:30/08/2022] – Trial Registered Prospectively

METHODOLOGY OF PREPARATION OF KRIMIGHNA KASHAYA SYRUP AND MUSTAADI KWATH SYRUP

The syrup was manufactured in a GMP certified *Ayurveda* pharmacy. The medicine was prepared according to *kwath kalpana* as mentioned in *Ayurvedic* literature. The processing of drugs was started from 10/09/2022.

Doses described by *Acharya Sharangdhar* is ideal, but due to feasibility and variation in *vaya*, *prakriti*, *satwa*, *satmya* etc. of each individual, we have decided the dose of *Krimigana Kashaya* syrup and *Mustaadi kwath* syrup.

Doses Fixed according to Young's rule (Child age / Child age + 12) Adult dose

TABLE 3.1

AGE GROUP	DOSE	DOSE FREQUENCY
3-5 years	5ml	BD
6-9 years	7.5ml	BD
10-16 years	10ml	BD

DURATION OF TREATMENT: 14 days

Follow-ups : The assessment of the patients will be done at the interval of 7th and 14th day.

At registration (R)

At 1st day, 7th day and 14th day

TABLE 3.2

Assessment criteria	0	1	2	3
Pureeshbed (Loose motion)	Normal motions	Loose motion 2-3 times a day	Loose motion 5-6 times a day	Loose motion >5
Karshaya (Malnutrition)	Weight for age (%) >80 %	70-80% (mild malnutrition)	70-80% (moderate malnutrition)	51-60% (Severe malnutrition)
Gudkandu (Itching in anal region)	Absent	Itching present at few (1 or 2) times in a day	Itching presents many times in a day	Continuous Itching
Udarashool (Abdominal pain)	Absent	Mild pain	Moderate (pain with grimace)	Severe pain (pain with tenderness)
Agnimandya (Loss of appetite)	Good or Normal	Eating regularly but decreased quantity	Irregular eating due to loss appetite and decreased quantity	Skipping of meal frequently and takes minimum quantity
Panduta (Anemia)	No pallor	Pallor of conjunctiva,	Pallor of conjunctiva, nails, tongue	Pallor of conjunctiva, nails, tongue, skin, palm and soles
Balakshaya (Weakness)	No weakness	Weakness but not hamper daily activity	Weakness hampers daily activity	Severe weakness not able to do any activity

ASSESSMENT CRITERIA:

(a) Subjective Assessment:

Objective parameters: –The objective assessment will be done on the basis of stool examination. – Stool Examination- R and M, Hb%, TLC, DLC

STATISTICAL ANALYSIS:

- To obtain the efficacy of the therapy, proper statistical analysis was carried out of available data by applying following statistical analysis:
- Subjective parameters-Wilcoxon signed -rank test
- Objective parameters – Paired t-test
- On comparison of Subjective criteria : Mann whintney U test
- On comparison of Objective criteria : Unpaired t-test
- The obtained results were interpreted as:

TABLE 3.3

S. NO.	P- value	Significance
1	>0.05	Not Significant
2	≤0.05, <0.01	Significant
3	<0.001	Highly Significant

CRITERIA FOR ASSESSMENT OF OVERALL THERAPY:

The result obtained from individual patient was categorized according to following grades:

Complete improvement	: 100% relief in complaints
Marked improvement	: >75% relief in complaints
Moderate improvement	: >50-75% relief in complaints
Mild Improvement	: 25-50% relief in complaints
Unchanged	: <25% relief in complaints

OBSERVATIONS AND RESULT

- The observations made during the clinical study on various factors are shown in tables and diagrams. In this study, 44 patients were registered irrespective of their age, sex, religion, etc.
- There was a comparative group study with *Krimighna Kashaya* syrup and *Mustaadi kwath* syrup.
- The demographic profile of each patient and following observations were recorded in case record proforma.

TABLE 4.1 NUMBER OF PATIENTS ENROLLED

CATEGORY	NO. OF PATIENT	PERCENTAGE
Registered	44	100%
Completed	40	90%
LAMA	04	10%

Total 44 patients of Krimi were enrolled in this research, out of which 4 patients were left against medical advice and 40 patients completed the trial period of 14 days. Considering the inclusion and exclusion criteria, the whole study was divided under following headings:

A. Demographic profile

B. Clinical profile

A. Demographic profile

The patients were registered ranging between 3-16 years of age. It is evident from the table that out of 44 cases in the series maximum patients 40% were found between the age group of 3-6 years. According to sex wise distribution, out of 44 patients, 45% of patients were female and 54% of them were male and maximum percentage of patients were from rural area 61% and rest were from urban area 39%. The present study reveals that veg dietary habits (56%) were found more than mixed dietary habits (43%). Out of 44 patients, 82.50% patients belonged to hindu community while 17.50% were from Muslim community. Most of the patients i.e., 50% patients belonged to middle class while 30% were from poor class of society and 17% were from upper middle class of society. The result of study showed that maximum number of patients i.e., 94% were full term normal vaginal delivery and 6% were born through LSCS and also showed that maximum no. of patients i.e., 93% were Immunized and 6% were not fully immunized. Most of the patients had loose stool 41%, 25% constipated, Regular 9% and 25% Irregular. It is evident from the study that, maximum number of patients had sound sleep 82% and 18% had disturbed sleep.

B. CLINICAL PROFILE**TABLE 4.12 DISTRIBUTION ACCORDING TO SIGNS AND SYMPTOMS**

Symptoms	Group A	Group B	Total	Percentage
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Pureeshbda (Loose motion)	9	7	16	36%
Karshaya (Malnutrition)	20	22	42	96%
Gudkandu (Itching in anal region)	8	9	17	38%
Udarashool (Abdominal pain)	8	15	23	52%
Agnimandya (Loss of appetite)	22	22	44	100%
Panduta (Anaemia)	15	17	32	72.72%
Balakshaya (Weakness)	19	17	36	81%

All patients TLC and DLC are within range. Out of 44 patients 34 patients (78%) had Hb between 8-10gm/dl, 7 patients (16%) had Hb between 11-12gm/dl and 3 patients (6%) had Hb between 12-14gm/dl. The distribution of 44 patients according to the type of worm infestation in stool examination showed that 96% of patients were diagnosed with *A. lumbricoides* followed by 4% of *T. trichiura*.

RESULTS

TABLE 4.21 EFFECT OF KRIMIGHNA KASHAYA SYRUP

Group A	Mean		Median		SD		Wilcoxon W	P-Value	% Effect	Result
	BT	AT	BT	AT	BT	AT				
Pureeshbda	0.35	0.10	0.00	0.00	0.49	0.31	-2.236b	0.0253	71.43	Sig
Karshaya	1.00	1.00	1.00	1.00	0.65	0.65	.000c	1.0000	0.00	NS
Gudkandu	0.25	0.10	0.00	0.00	0.44	0.31	-1.732b	0.0833	60.00	Sig
Udarashool	0.30	0.10	0.00	0.00	0.66	0.31	-2.000b	0.0455	66.67	Sig
Agnimandya	1.85	0.70	2.00	1.00	0.59	0.47	-3.945b	0.0001	62.16	Sig
Panduta	0.65	0.60	1.00	1.00	0.59	0.50	-.378b	0.7055	7.69	NS
Balkshaya	1.10	0.35	1.00	0.00	0.64	0.49	-3.638b	0.0003	68.18	Sig

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy. From above table, we can observe that, P-Value for all parameters is less than 0.05. Hence, we can conclude that, effect observed in subjective parameters is significant.



TABLE 4.22 EFFECT OF MUSTAADI KWATH SYRUP

Group B	Mean		Median		SD		Wilcoxon W	P-Value	% Effect	Result
	BT	AT	BT	AT	BT	AT				
Pureeshbda	0.35	0.15	0.00	0.00	0.49	0.37	-2.000b	0.0455	57.14	Sig
Karshaya	0.80	0.80	1.00	1.00	0.62	0.62	.000c	1.0000	0.00	NS
Gudkandu	0.35	0.20	0.00	0.00	0.75	0.41	-1.732b	0.0833	42.86	Sig
Udarashool	0.65	0.20	1.00	0.00	0.67	0.41	-3.162b	0.0016	69.23	Sig
Agnimandya	1.85	0.75	2.00	1.00	0.67	0.55	-4.025b	0.0001	59.46	Sig
Panduta	0.80	0.75	1.00	1.00	0.52	0.55	-.447b	0.6547	6.25	NS
Balkshaya	1.35	0.70	2.00	1.00	0.88	0.47	-3.000b	0.0027	48.15	Sig

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy. From above table, we can observe that, P-Value for all parameters is less than 0.05. Hence, we can conclude that, effect observed in subjective parameters is significant.

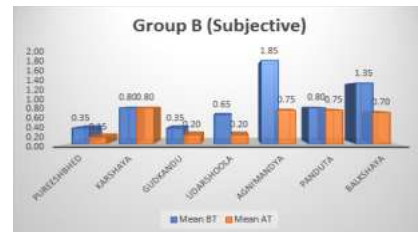


TABLE 4.23 COMPARISON OF BOTH GROUP A AND GROUP B

Variable	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-value
Pureeshbda	Group A	20	21.00	420.00	190.000	0.708
	Group B	20	20.00	400.00		
	Total	40				
Karshaya	Group A	20	20.50	410.00	200.000	1.000
	Group B	20	20.50	410.00		
	Total	40				
Gudkandu	Group A	20	20.50	410.00	200.000	1.000
	Group B	20	20.50	410.00		
	Total	40				
Udarashool	Group A	20	17.50	350.00	140.000	0.050
	Group B	20	23.50	470.00		
	Total	40				
Agnimandya	Group A	20	20.93	418.50	191.500	0.752
	Group B	20	20.08	401.50		
	Total	40				
Panduta	Group A	20	20.53	410.50	199.500	0.987
	Group B	20	20.48	409.50		
	Total	40				
Balkshaya	Group A	20	23.23	464.50	145.500	0.090
	Group B	20	17.78	355.50		
	Total	40				

Mann Whitney U Test is carried out for comparison between Group A and Group B. From above table we can observe that, P-Value is greater than 0.05. Hence, we can conclude that, there is no significant difference between Group A and Group B.

TABLE 4.24 ASSESSMENT OF OBJECTIVE PARAMETRS OF GROUP A

Group A (Objective)		Mean	N	SD	SE	t-Value	P-Value	Result
Hb	BT	10.90	20	0.90	0.20	-1.053	0.306	NS
	AT	11.13	20	0.94	0.21			
Stool Exam	BT	1.00	20	0.00	0.00	10.376	0.000	Sig
	AT	0.15	20	0.37	0.08			

Since observations are quantitative, we have used Paired t-Test to test efficacy. From above table, we can observe that, P-Value for Hb is greater than 0.05 and Stool examination is less than 0.05. Hence, we can conclude that, effect observed in Hb is not significant while significant change observed in stool examination.

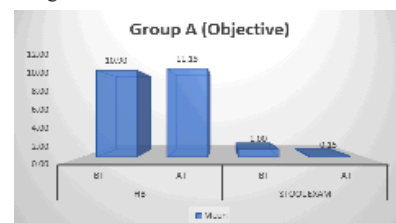


TABLE 4.25 ASSESSMENT OF OBJECTIVE PARAMETRS OF GROUP B

Group B (Objective)		Mean	N	SD	SE	t-Value	P-Value	Result
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Hb	BT	11.04	20	0.75	0.17	0.486	0.632	NS
	AT	10.93	20	0.96	0.21			
Stool Exam	BT	1.00	20	0.00	0.00	5.940	0.000	Sig
	AT							

Since observations are quantitative, we have used Paired t-Test to test efficacy. From above table, we can observe that, P-Value for Hb is greater than 0.05 and Stool examination is less than 0.05. Hence, we can conclude that, effect observed in Hb is not significant while significant change observed in stool examination.

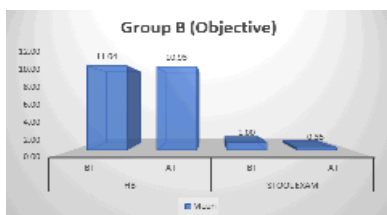


TABLE 4.26 COMPARATIVE RESULT OF OBJECTIVE PARAMETERS

Variable	Group	N	Mean Diff	SD	SE	t-Value	P-Value	Result
Hb	Group A	20	0.23	0.96	0.21	1.086	0.284	NS
	Group B	20	-0.11	0.97	0.22			
Stool Exam	Group A	20	0.85	0.37	0.08	1.463	0.152	NS
	Group B	20	0.65	0.49	0.11			

Unpaired t-test is carried out for comparison between Group A and Group B. From above table we can observe that, P-Value is greater than 0.05. Hence, we can conclude that, there is no significant difference between Group A and Group B.

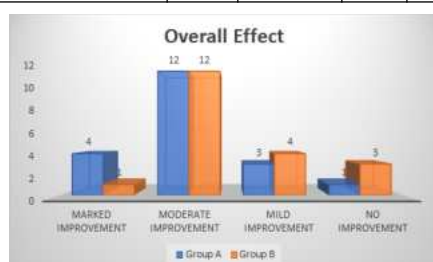
TABLE 4.27 COMPARATIVE PERCENTAGE EFFECT IN SIGNS AND SYMPTOMS

Parameter	% Effect	
	Group A	Group B
Pureeshbhed	71.43	57.14
Karshaya	0.00	0.00
Gudkandu	60.00	42.86
Udarshoola	66.67	69.23
Agnimandya	62.16	59.46
Panduta	7.69	6.25
Balkshaya	68.18	48.15
Average % Effect	65.69	55.37



TABLE 4.28

Overall Effect	Group A		Group B	
	N	%	N	%
Marked Improvement	4	20.00%	1	5.00%
Moderate Improvement	12	60.00%	12	60.00%
Mild Improvement	3	15.00%	4	20.00%
No Improvement	1	5.00%	3	15.00%
TOTAL	20	100.00%	20	100.00%



DISCUSSION

Pureeshaja Krimi and its ailment can be associated with Intestinal worm infestation as they have many similarities. Pakvashaya is considered as Sthana for Pureeshaja Krimi. Pakwashaya is considered as a part of intestine between Ileocecal junction and sigmoid colon. According to the modern parasitology, organisms like Ascaris lumbricoides (round worms), hook worm etc also dwell in the same locality. Pureeshaja Krimi are found in different types of shape such as Sookshma (minute), Vritha (round), Deerga (long), Sthoola (big), Prithavapucksa (flat tail) and Tanu (thin). On the other hand Intestinal worms like Ascaris lumbricoides has also been identified to be a round, elongated worm measuring from 15-30cm in males and 20-40cm in females with curved proximities and the tail end being elongated and flat. Pureeshaja Krimi has been reported to be coloured Shweta (white), Shyava (grey), Neela (blue), Harita (green), and Peeta (yellow). Like pureeshaja Krimi, intestinal worms like ascaris worms also be pinkish white or even yellowish in appearance.

PROBABLE MODE OF ACTION OF KRIMIGHNA KASHAYA

- Treatment guiding principle of krimi is Apakarshana (Expulsion of poisonous substances by shodhan chikitsa), Prakriti vighata (countermeasures/modalities), and nidanaparivarjan and the three aspects of Krimi.
- The substance is employed because it has the attributes of katu, tikta, kashaya, kshara, and ushna as well as the opposite qualities of kapha and purish as regarding prakritivighata.
- Except for Swadanstra, all the dravyas that belong to the krimighna mahakasaya have ushna virya (which is kapha shamaka), laghu, ruksha, kasaya rasa, tikshana guna, katu, tikta, and kasaya rasa. Gokshur has sheeta virya, guru, snigdha guna, madhura rasa and vipaka, and these qualities contradict the idea of prakriti vighata. However, it may cause the krimighna action through Apakarshan since every feature it possesses makes it easier to expell the krimi through virechana, or it may act because of its Prabhava and particular characteristics.
- All ten of these medications have antibacterial, anthelmintic, and antiprotozoal activity. Vidanga (Embelia ribes L.), one of these 10 medications, is regarded as the excellent Krimighna Dravya. (विडङ्ग क्रिमिघ्नानि)
- All the drugs of mahakashaya contain phytochemical constituents like Alkaloids, tannin, flavonoids, essential oils etc. to which antimicrobial action can be attributed.

PROBABLE MODE OF ACTION OF MUSTAADI KWATH

- Drugs like Vidang, Aakhuparni and Sahijan are potent wormicidal described in ayurveda.
- In mustaadi kwath drugs (Musta, Pippali, Devdaaru) have katu, tikat, kashay ras and Ushna virya which are opposite quality of kaph and purish so that they helps in prakritivighat of Krimi.
- Deepan- pachan properties of drugs (Musta and Devdaaru) give symptomatic relief in agnimadhy.
- Essential oil of Musta exhibited anthelmintic activity and methanol extract was found to significantly suppress the frequency of the diarrheal episodes
- Madanphal is best vama in nature. It has ethanolic extract which larvicidal in nature.
- Pippali contains piperin which act larvicidal activity.
- All drugs are wormicidal and larvicidal in nature, and have antibacterial, anthelmintic property.
- On comparing the effect of therapy on sign and symptoms of pureeshaja krimi in both group A and group B, there is no significant difference between Group A and Group B as p value is >0.05
- On comparing the overall percentage relief as per standard criteria on subjective and objective parameters Marked improvement 20% seen in Group A and 5% in Group B. Moderate improvement 60% in both groups, mild improvement 15% in Group A and 20% in

Group B. no improvement 5% in Group A and 15% in Group B .

- Difference in the overall effects of Group A and Group B were statistically significant($p<0.01$) which suggested that Krimighna kashaya syrup (Group A) was better in reducing the subjective and objectives parameter than Mustaadi kwath syrup (Group B)

CONCLUSION –

- As per discussion on disease review, we can say Pureeshaja Krimi is very similar to Intestinal worm infestation o the basis of similar symptoms.
- In this study both the groups show statistically significant results on comparison of subjective parameters, in which Group A showed better result based on percentage relief and mean rank.
- The over all effect of Group A was better than Group B in relieving all the symptoms .
- No side effect were observed in patients during and after the course of treatment. So it can be concluded that the patients of Pureeshaja Krimi (Intestinal worms) can be managed effectively through Ayurveda without fear of side effect as seen in other medical science drugs.

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