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CLINICAL STUDY OF *PALASHABEEJADI YOGA* IN CHILDREN SUFFERING FROM *ANTRAJA KRIMI*

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ABSTRACT

Introduction: Nonconventional herbal medicine can serve better with minimal hazards of unavoidable side effects of allopathic drugs. Therefore, safer drug *Palashabeejadi yoga* has been selected for research. **Materials and method:** Total 52 children between 1 to 14 years of age were registered and divided randomly in three groups *Group-I* treated with *Palashabeejadi yoga, Group-II* treated with *Palashabeejadi yoga* and albendazole/metronidazole and *Group-III* treated with Albendazole/ metronidazole as per etiology. Children having any associated life threatening medical or surgical disorders were excluded. The follow ups were made on 3rd (1st follow up), 7th (2nd follow up) and 14th (3rd follow up) day after the registration. Chi-square (χ^2) test to test the significance of difference & Paired't' test to test the significance of mean of difference. **Results:** *Palashabeejadi yoga* has shown highly significant ($p<0.001$) effect on *Giardia lamblia* and *Entamoeba histolytica* while, patients suffering from the *Enterobius vermicularis*, has shown delayed effect and became infection free within 15 days. However use of mixed therapy and modern medicine had shown almost similar effect on the *Giardia lamblia, Entamoeba histolytica* and *Enterobius vermicularis.* **Conclusions:** No any adverse effect was observed and the drug was palatable to all the patients. On statistical analysis of gathered data, it was concluded that

Palashabeejadi yoga has better effect from other trial drugs in causing stool to be free from the intestinal parasitic infection.

Keywords: *Krimi Roga, Antraja krimi, Albendazole, Metronidazole, Palashabeejadi yoga.*

INTRODUCTION

The parasite derives all benefits like food and shelter from association and the host may either not be harmed or may suffer the consequences of this association, a parasite disease. Ayurvedic literature explains it as *Sahaja* and *Vaikarik krimi* which is again classified in to *Bahya* and *Abhayantara krimi*. *Abhayantara krimi*[1] are classified as *Purishaja*, *Shleshamaja*, and *Raktaja krimi*. *Antraja krimi* in present context refers to *Vaikarik krimi* residing in intestinal tract. The parasitic infection is classified into three types as per modern medical science viz. Protozoal, Helminthic and Arthropodal.[2] It is estimated that out of 3.5 billion of affected peoples 450 million are ill due to infection and majority are children.[3] Inspite of better efficacy of drugs like albendazole and metronidazole against intestinal parasitic infection they have side effects like headache, nausea, dry mouth, metallic taste etc.[4] Herbal formulations can be of good choice, as also according to W.H.O. survey 70-80 % of world population relies on non conventional herbal medicines. Formulation *Palashabeejadi yoga* contains *Palasha, Vidanga* and *Kutaja* seeds.[5] [6] *Palasha*[7] and *Vidanga*[8] are described as *Krimighna* drugs, whereas *Kutaja*[9] has antidiarrhoeal properties. Therefore, to ascertain its therapeutic effect in combating *Krimi Roga*, safe drug *Palashabeejadi yoga* is considered for this study.

MATERIALS AND METHOD

Total of 52 children between 1 to 14 yrs of age, irrespective to sex and religion were registered from the O.P.D of *Kaumarbhritya* /*Balroga*, S.S. Hospital, I.M.S, B.H.U., Varanasi, after written informed consent from the Parents. Children presenting the features of common worm infestation such as *Giardia lamblia, Entamoeba histolytica, Enterobius vermicularis* and *Ascaris lumricoides*, confirmed by stool examination and known case of worm infestation who had not been treated with medicine (Pre-diagnosed case) were registered. Children having any associated life threatening medical or surgical disorders are excluded. All registered cases were divided randomly into three groups *Group I* -treated with *Palashabeejadi yoga, Group II*-treated with *Palashabeejadi yoga* and albendazole/metronidazole as per etiology and *Group III*- treated with Albendazole / metronidazole as per etiology(Control Group). Syrup *Palashabeejadi yoga* was given to

Group I and II in dose of 10 mg / kg/ dose every 12 hour orally for 14 days. Metronidazole[10] 15mg/kg/day 8 hourly oral for 7 days and Albendazole[11] 400 mg/kg/day oral single dose was given to confirmed cases of g*iardiasis/amoebiasis and enterobiasis/ascariasis*, respectively, in group II and Group III. Haematological study: CBC, ESR and Stool: Routine/ Microscopic (including protozoa, ova/cyst) were performed during the study to confirm the diagnosis and evaluation of drug's effect. The follow up were made on day 3rd (1st follow up), 7th (2nd follow up) and 14th (3rd follow up) after the registration.

Method of drug preparation:[12] Drug was prepared in *Ayurvedic* pharmacy, Faculty of Ayurveda, Institute of Medical Sciences, BHU, Varanasi. Raw drugs (2 kg each : *Palasha*, *Vidanga* and *Kutaja beeja*) were crushed and made coarse powder (*Yavkuta*).Thereafter, *Kwatha* was prepared by adding 48 liters of water in 6 kg of raw drugs as per recommended procedure. After filtration of *Kwatha* (Decoction), the water content of *Kwatha* was evaporated. The residue i.e. dry water extract was collected. Thereafter, with a known concentration of *drug* (dry water extract) i.e. 150 mg / 5ml of *Palashabeejadi yoga* was prepared with sodium benzoate and potassium metabisulphate in a required quantity as preservative.

Drug dose determination: The dose of *Palashabeejadi yoga* was determined by using Clark's[13] formula.

$$= \frac{\text{Weight of the child in lbs } (2.20462262 = 1 \text{ kg})}{150} \text{X adult dose } (3 - 6 \text{ gm})$$

$$= 2.20462262 \text{ X } 6000 \text{ mg} = \frac{0.01469748}{150} \text{X } 6000 = 88.18 \text{ mg /kg /dose}$$

As the yield (dry extract) of raw drug used for the preparation of *Palashabeejadi yoga* of drug ranged from 8- 10 %(Average ~9%). Therefore Drug dose for dry extract will be 88/9=9.798 mg i.e. ~10mg/kg/dose.

Assessment criteria: A scoring system (table no.1) was adopted to provide score to each sign and symptom as well as stool characteristics manifested (table no.2) in patients registered as per inclusion and exclusion criteria. Thereafter, a statistical analysis was done to get mean ± SD, 't' value and 'p' value, by using SPSS software. Change in scores of various features on subsequent follow up were analyzed by means of unpaired 't' test, and recorded accordingly.

Table No. 1: Scoring criteria for sign and symptoms of *Krimi Roga* to assess the response of drug

Sign & Symptom	0	1	2	3	4
Cough	Absent	Subside	Present	-	-
Fever	Afebrile (Absent)	Subside (98 - 99^0 F)	Mild (99 -100^0 F)	Moderate (100 - 103^0 F)	High (103 - 105^0 F)
Abdominal distension	Absent	Subside	Mild [Occasional]	Moderate [most of the time associated with the stool passage]	Severe[Always associated with passage of stool]
Pain in abdomen	Absent	Subside	Present	-	-
Appetite	Normal	Subside	Reduced	Significantly reduced	-
Nausea	Absent	Subside	Present		
Vomiting	Absent	Subside	1-2/day	3-4/day	>5/day
Dyspnoea	Absent	Subside	Present	-	-
Abdominal cramp	Absent	Subside	Mild [Occasional]	Moderate [most of the time associated with the stool passage]	Severe[Always associated with passage of stool]
Urticaria	Absent	Subside	Present(localized)	Present(Diffused)	
Perianal pruritus	Absent	Subside	Present	-	-
Teeth Grinding	Absent	Subside	Present	-	-
Salivation	Normal	Infrequent, small amount	Occasional on and off all day	Frequent but not profusely	Constant always wet

Table No. 2: Stool Scoring Criteria:[14] modified stool scoring system

Stool Characteristics	0	1	2	3	4
Frequency	Normal (No change in frequency)	≤2/day associated with normal color, consistency, smell.	>2-5/day having abnormal color, consistency or smell.	6-10/day; having abnormal color consistency or smell.	>10/day; abnormal color, consistency or smell.
Consistency	Normal consistency	Soft and Formed	Semisolid	Watery	-
Colour	Normal (No change in colour)	Yellowish (normal color after treatment)	Relatively reduced Yellowish, Whitish, Reddish	Yellowish White, Reddish Green or Black	-

			,Greenish Or blackish		
Mucus	Absent	Not visible (After treatment)	Occasionally present	Frequently present	-
Odour	Normal odour	Normal (After treatment)	Mild foul	Excessive foul	-
Blood	Not visible (At time of registration)	Not visible after treatment	Blood mixed with stool, streaks of fresh blood	Frank blood (Drop wise)	

OBSERVATION AND RESULT

During the period of drug administration no any adverse effect of drug was observed and was palatable to all the patients. On statistical analysis of gathered data, following observations were made. Overall incidence of parasitic infestation is found highest (69.2%) in school going children. Almost equal distribution of cases according to sex was present. Out of total cases, 67.3 % children, distributed in different groups, were having unhygienic condition. Most of the *Krimi Roga* cases (76.9%) were supplied with stored water for drinking purpose.

Table No.3: Incidence of cases of *Krimi roga* according to age, sex, hygienic status and source of water supply

Age				**Sex**		**Hygienic Status**		**Source of water supply**	
	Toddler (1-3 yr)	Preschool (3-6 yr)	School (>6-14 yr)	Male	Female	Unhygienic	Hygienic	Stored water	Direct supply
n	10	6	36	25	27	35	17	35	17
%	19.2	11.6	69.2	48.1	51.9	67.3	32.7	67.3	32.7

Table No. 4: Mean score of all symptoms/signs in patients of *Krimi Roga* (intestinal parasites) in patients of different groups at registration and on subsequent follow ups.

Groups	**Mean ± SD of mean of score of Total symptoms**				**Within the group comparison paired t-test R-F-3**
	R	**FU-1**	**FU-2**	**FU-3**	
	Mean ± SD	**Mean ± SD**	**Mean ± SD**	**Mean ± SD**	
Group- I (n=18)	0.983 ± 0.36	0.778 ± 0.29	0.590 ± 0.24	0.548 ± 0.24	t=9.921, p<0.001
Group-II (n=18)	0.846 ± 0.29	0.693 ± 0.24	0.517 ± 0.21	0.452 ± 0.18	t=10.539, p<0.001
Group- III (n=16)	0.740 ± 0.26	0.625 ± 0.20	0.485 ± 0.19	0.437 ± 0.15	t=6.575, p<0.001

Table no. 5: Mean score of all symptoms as per their causative organisms at registration and on subsequent follow ups in patients of *Krimi Roga* (Intestinal parasites) of different groups

Etiology	Group	Mean ± SD of mean of score of Total symptoms				Within the group comparison paired t-test R-F-3
		R	F-1	F-2	F-3	
Giardiasis (n=23)	Group-I (n=9)	0.883±0.317	0.649±0.252	0.470±0.225	0.4530±0.225	t=8.575 p<0.001
	Group-II (n=7)	0.714±0.378	0.615±0.323	0.439±0.251	0.395±0.223	t=4.422 p<0.05
	Group-III (n=7)	0.703±0.278	0.593±0.186	0.483±0.211	0.417±0.176	t=3.653 p<0.05
Amoebiasis (n=14)	Group-I (n=5)	1.000±0.210	0.784±0.175	0.569±0.149	0.523±0.147	t=5.356 p<0.05
	Group-II (n=6)	0.782±0.171	0.602±0.102	0.461±0.137	0.397±0.089	t=9.682 p<0.001
	Group-III (n=3)	0.820±0.310	0.692±0.153	0.564±0.160	0.461±0.153	t=5.883 p<0.05
Enterobiasis (n=11)	Group-I (n=3)	0.615±0.352	0.564±0.320	0.461±0.277	0.413±0.320	t=8.000 p<0.05
	Group-II (n=3)	0.667±0.160	0.564±0.160	0.435±0.117	0.359±160	*
	Group-III (n=5)	0.614±0.121	0.492±0.159	0.400±0.100	0.400±0.034	t=4.802 p<0.05
Ascariasis (n=4)	Group-I (n=1)	1.585	1.230	1.00	0.92	*
	Group-II (n=2)	1.0769±0.000	0.846±0.000	0.692±0.000	0.576±0.163	t=4.333 p>0.05
	Group-III (n=1)	0.461	0.384	0.307	0.307	*

Table no.6: Mean score of all characteristics of stool in patients of *Krimi Roga* (intestinal parasites) in patients of different groups at registration and on subsequent follow up

Groups	Mean ± SD of mean of score of stool characteristic				Within the group comparison paired t-test R-F-3
	R	FU-1	FU-2	FU-3	
	Mean± SD	Mean ±SD	Mean±SD	Mean±SD	
Group- I (n=18)	1.527±0.41	1.370±0.34	1.092±0.23	0.935±0.25	t=7.022 p<0.001
Group-II (n=18)	1.490±0.42	1.222±0.30	1.046±0.20	0.963±0.21	t=6.793 p<0.001
Group-III (n=16)	1.500±0.42	1.270±0.38	1.052±0.36	1.010±0.34	t=6.789 p<0.001

Table no.7: Mean score of stool characteristic as per their causative organisms at registration and on subsequent follow ups in patients of *Krimi Roga* (Intestinal parasites) of different groups

Etiology	Group	Mean ± SD of mean of score of Total stool characteristics				Within the group comparison paired t-test R-F-3
		R	F-1	F-2	F-3	
Giardiasis (n=23)	Group-I (n=9)	1.518±0.385	1.333±0.353	1.037±0.385	0.8704±0.111	t=5.754 p<0.001
	Group-II (n=7)	1.404±0.331	1.119±0.208	1.047±0.185	1.000±0.192	t=4.250 p<0.05
	Group-III (n=7)	1.357±0.178	1.142±0.149	0.881±0.125	0.881±0.158	t=8.402 p<0.001
Amoebiasis (n=14)	Group-I (n=5)	1.800±0.380	1.600±0.252	1.266±0.345	1.166±0.353	t=3.062 p<0.05
	Group-II (n=6)	1.778±0.490	1.500±0.278	1.138±0.163	1.027±0.194	t=4.258 p<0.05
	Group-III (n=3)	2.055±0.254	1.944±0.096	1.722±0.254	1.611±0.254	t=3.600 p<0.05
Enterobiasis (n=11)	Group-I (n=3)	1.388±0.096	1.277±0.096	1.055±0.096	0.833±0.166	t=10.000 p<0.05
	Group-II (n=3)	1.222±0.419	1.055±0.192	0.889±0.254	0.833±0.288	t=3.500 p>0.05
	Group-III (n=5)	1.300±0.491	1.033±0.247	0.900±0.190	0.866±0.217	t=3.200 p<0.05
Ascariasis (n=4)	Group-I (n=1)	0.666	0.833	0.833	0.666	*
	Group-II (n=2)	1.333±0.235	1.000±0.235	1.000±0.235	0.833±0.235	*
	Group-III (n=1)	1.833	1.333	1.000	0.833	*

TableNo. 8*:* Incidence of Parasitic infestation in accordance to isolation of worms-macroscopic and ova & cyst microscopic examination of stool at registration and on subsequent follow ups in different Groups

Group	Isolated Ova/cyst of parasitic infection	Number and % of cases				Within the group comparison Friedman test (R-FU-3)
		R	FU-1	FU-2	FU-3	
Group- I (n=18)	*Giardia lamblia* *Entamoeba histolytica* *Ascaris lumbricoides* *Enterobius vermicularis* Mixed infection	10(58.8)* 3(17.6) 1(5.9) 3(17.6) 1(5.9)	7(41.2) 2(11.8) 1(5.9) 2(11.8) 0(0.0)	1(5.9) 1(5.9) 0(0.0) 1(5.9) 0(0.0)	1(5.9) 1(5.9) 0(0.0) 0(0.0) 0(0.0)	29.697 p<0.001 HS

Group-II (n=18)	*Giardia lamblia* *Entamoeba histolytica* *Ascaris lumbricoides* *Enterobius vermicularis* Mixed infection	7(38.9) 6(33.3) 2(11.1) 3(16.7) 0(0.0)	8(44.5) 5(27.8) 1(5.6) 1(5.6) 0(0.0)	1(5.6) 1(5.6) 0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0) 0(0.0) 0(0.0)	34.222 p<.001 HS
Group-III (n=16)	*Giardia lamblia* *Entamoeba histolytica* *Ascaris lumbricoides* *Enterobius vermicularis* Mixed	7(43.8) 3(18.8) 1(6.3) 5(31.3) 0(0.0)	6(37.5) 2(12.5) 1(6.3) 3(18.8) 0(0.0)	0(0.0) 0(0.0) 0(0.0) 0(0.0) 0(0.0)	0(0.0) 0(0.0) 0(0.0) 0(0.0) 0(0.0)	29.143 p<.001 HS

DISCUSSION

Mean score of all sign and symptoms in patients of *Krimi Roga* of different groups suggest that overall better effect is found in patients of all groups but‘t’ value (10.539) suggest better improvement in group-II who had received mixed therapy. (Table.no.4). Mean score of all the sign and symptoms as per causative organism (protozoan and helminthes), of patients falling under group-I i.e. who have taken *Palashabeejadi yoga* suggest highly significant effect ($p<0.001$) on the giardiasis, significant effect ($p<0.05$) on the amoebiasis and enterobiasis. Mixed therapy has shown highly significant effect ($p<0.001$) on amoebiasis associated sign and symptoms while the modern medicine has only significant effect on giardiasis, amoebiasis and enterobiasis (Table no.5). On intra group comparison, mean score of all characteristics of stool in patients of *Krimi Roga* of all groups has shown significant effect ($p<0.001$), but‘t’value (7.022) suggest overall better effect in patients receiving *Palashabeejadi yoga* (Table no.6).

Mean score of stool characteristics suggest highly significant overall effect ($p<0.001$) of *Palashabeejadi yoga* in patients of giardiasis, significant effect in patients of amoebiasis, and enterobiasis of group-I (Table. no.7). Mean score of all symptoms as per their causative organism in *Krimi Roga* (intestinal parasitic infectious diseases) suggest highly significant effect ($p<0.001$) of *Palashabeejadi yoga* on the giardiasis caused intestinal infection than effect of mixed therapy and modern medicine only. However, mixed therapy and modern allopathic drugs also have significant effect ($p<0.05$). In case of amoebiasis caused intestinal parasitic infectious disease, highly significant effect has shown by the mixed therapy ($p<0.05$) than *Palashabeejadi yoga* and only modern drug administration. In case of

enterobiasis and ascariasis which one drug/drug combination is better cannot be interpret as the less number of sample size. (Table no.5)

On microscopic examination, presence of parasites i.e. causative organisms (protozoon and helminthes) in stool suggested all the drugs have equal curative effect within 7 days of management of *Palashabeejadi yoga*, and / or single dose of albendazole (Table no. 8). However, *Palashabeejadi yoga* has shown highly significant ($p<0.001$) effect on *Giardia lamblia* and *Entamoeba histolytica* but 10% infected children has not shown effect at final follow up as evident from the presence of cyst of causative organism in the stool, while the patients, who were suffering from the *Enterobius vermicularis*, has shown delayed effect and became infection free within 15 days.

CONCLUSION

Use of mixed therapy and modern medicine has shown almost similar effect on the *Giardia lamblia, Entamoeba histolytica* and *Enterobius vermicularis.* Finally, it can be concluded that *Palashabeejadi yoga* has better effect from any other trial drugs in causing stool to be free from the intestinal parasitic infection.

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