Research Article

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ROLE OF SWARNAPRASHAN ON RECURRENT ILLNESS IN CHILDREN: A COMPARATIVE CLINICAL STUDY

Kritika Joshi *[1], Mithilesh Verma [2]

[1]Post graduate scholar, P.G. Department of Kaumarabhritya, State Ayurvedic College &Hospital Lucknow, U.P. India

[2]Head of Department, P.G. Department of Kaumarabhritya, State Ayurvedic College &Hospital Lucknow, U.P. India

Received on: 13/03/19 Accepted on: 13/05/19

***Corresponding author**
E-mail: kritikajsh1@gmail.com

DOI: 10.7897/2277-4343.100362

ABSTRACT

Swarnaprashan is a lehan karma in which gold is given in combination with honey, ghrita and various other herbs to the child. It helps in boosting up the intellectual power, physical strength and immunity in the body to fight against diseases. In the present research to assess the recurrence of upper respiratory and gastro intestinal infections, children with recurrent infections falling in age group between 3 to 10 years were registered and divided randomly into two groups. In group A children were given swarna bhasma along with honey and ghee while in group B children were given honey and ghrita only, on daily basis on empty stomach for 30 days and followed for 6 months. After following up it was found that 35% of the children enrolled in group A were relieved while 50% children had moderate improvement. In group B 50% children showed mild to moderate improvement. 50% remained unchanged.

Key words: swarnaprashan, recurrent infections, immunity.

INTRODUCTION

Swarnaprashan is a lehan karma (giving something to lick) which is an unmatched traditional way of immunization in children. In this gold is given in combination with honey, ghrita and various other herbs to the child. It helps in boosting up the intellectual power, physical strength and immunity in the body to fight against diseases.[1]. Various researches on gold have proved its role as immunomodulator, antioxidant etc.[2,3,4] Maximum yogas mentioned in ayurvedic texts as lehana contains gold in them. Other important ingredient of swarnaprashan is honey which is made up of various pollen grains which act as antigen. By its antigenic activity, it stimulates the immune system. The combination of ghee and honey in equal amount act as a virrudh ahara complex[5] (incompatible diet) and regular use of it in smaller amount stimulates the body's immune system. Swarnaprashana given in early stages of life gives good quality of life in future.

Considering all the above facts this study was designed and carried out as per International Conference of Harmonization-Good Clinical Practices Guidelines (ICH-GCP). Before commencement of clinical trial ethical clearance was obtained from Institutional Ethical Committee, State Ayurvedic College, Lucknow, Uttar Pradesh. Written and informed consent was taken from the guardians on the behalf of their children before inclusion in the trial.

Children with recurrent infections between 3 to 10 years of age were registered and were divided randomly into two groups. In Group A 1drop of honey containing 1mg of gold bhasma, was given with 1 drop of ghrita to the children upto 5 years of age and children above five years of age were given 2 drops of honey ,containing 2mg of swarna bhasma, with 2 drops of ghrita once a day on empty stomach for 30 days. In group B honey was given as 1 drop daily to children up to 5 years of age and 2 drops daily to the children more than 5 years of age along with equal amount ghrita once a day on empty stomach for 30 days. Children were followed for 6 months to see the recurrence of disease. After following up it was found that 35% of the children enrolled in group A were relieved (more than 75% relief in their condition) while 50% children had moderate improvement. In group B 50% children showed mild to moderate improvement. 50% remained unchanged.

MATERIAL AND METHODS

The present research study has been planned to conduct with following main objectives-

- To observe the immunomodulatory effect of swarnaprashan in children
- To assess and monitor adverse effect of swarnaprashan, if any during trial.

For purpose of this clinical trial, children of recurrent infection were selected regardless of sex, religion, occupation and socio-economic conditions, with the age group of 3-10 year from O.P.D. & I.P.D. of State Ayurvedic College &Hospital, Lucknow.

Inclusion Criteria

1 Children aged between 3 years to 10 Years of either sex.
2. Children with recurrent respiratory infections
3. Children with recurrent GIT diseases
4. Children with other recurrent infections

Exclusion Criteria-

1. Children below 3 years and above 10 years of age.
2. Children with severe illness
3. Children with any genetic disorder
4. Children with any congenital anomalies.

Discontinuation Criteria-

1. Any acute or severe illness
2. Parents not willing to continue the treatment.

Method of preparation

On the basis of classical reference adult dose of swarna bhasma as explained in texts is 1/8 to 1/4 ratti [6] i.e 15 to 30 mg/day. Dividing it by average adult body weight (50kg), the calculated pediatric dose is around 0.3 to 0.6 mg / kg body weight. Since this dose is too high to use in pediatric conditions on daily basis for 30 days. The dose of the swarna bhasma was kept near to the dose that has been proved to be safe as per the previous research works; i.e 1mg to 2mg daily.[7] Swarna bhasma is then mixed with honey in such a ratio that 1 drop of honey contains 1 mg of gold bhasma. This combination is then given with equal amount of ghrita to the children. Duration of clinical trial was 30 days. Follow up studies of all registered children was done at fortnight interval for a period of 1 month with trial drug and next 6 months without drug to assess the number of episodes of recurrent infection and to observe any other side effect.

Total 45 children of recurrent infection were registered for the present study. Among these 5 children were drop out.

The enrolled children for the present clinical study were kept into two groups i.e. Group A and Group B.

Group A: 22 children were registered in Group A, out of which 2 were drop out. Children of this group were treated with gold bhasma mixed with honey and ghrita. 1 drop of honey containing 1mg of gold bhasma, was given with 1 drop of ghrita to the children upto 5 years of age and children above five years of age were given 2 drops of honey ,containing 2mg of swarna bhasma, with 2 drops of ghrita once a day on empty stomach for 30 days.

Group B: 23 children were registered in Group B, out of which 3 were drop out. Children of this group were treated with honey and ghrita only. Honey was given as 1 drop daily to children upto 5 years of age and 2 drops daily to the children more than 5 years of age along with equal amount of ghrita.

Grading of Symptoms

All the signs and symptoms were graded 0, 1, 2, 3 on the basis of intensity and severity and confirmed by clinical examination before commencement of trial as shown in the table 1.

The clinical improvement in all parameters, during and after trial has been correlated with previous intensity of the signs and symptoms.

STATISTICAL ANALYSIS

Wilcoxon rank sum test, paired and unpaired t test were used for statistical analysis.

OBSERVATION AND RESULT

The recorded observations were divided into following points:

Demographic observation- It was observed that 56% children were female.64% of total children were hindu. 67% patient had vegetarian diet. Maximum children (78%) belonged to middle class family.87% had complete immunization for age.49% patient were of vata kaphaja prakriti. 76% children had complaints of both pranavaha and annavaha shrotus. In 7% of children cold was the aggravating factor. Maximum 51% had chronicity of 2 years. None had chronicity more than 3 years.

Clinical observation- The clinical features seen in 45 children of recurrent illness showed that maximum patient (80%) had complaint of loss of appetite, 64.4% had complaint of recurrent cough and 53.3% had recurrent pain abdomen, rest of the features like recurrent sneezing, sore throat, nasal congestion, recurrent vomiting and diarrhea were present in less than 50% cases.

Therapeutic observation- To observe the effect of trial regime, the subjective and objective parameters of the children of both groups (Group A-n=20, Group B n= 20) were observed from time to time and rendered to master sheet. Statistical constants were calculated by applying Wilcoxon rank sum test to draw conclusions. Percentage improvement was also computed. The changes were recorded and calculated on 40 children (who completed the study period) and following facts were observed-

Recurrent episodes of sneezing- It was initially found positive in 45% children of group A and 40% children of group B . Baseline mean ± SD was 1.15 ±1.387 in group A while it was 0.75± 1.02 in group B. It gradually decreased during treatment time and remained stable in almost all children. Mean ± S.D after treatment in group A was 0.55± 0.75 and in group B was 0.6 ±0.82

Recurrent sore throat –It was initially found positive in 45% children of group A and group B. Baseline mean ± SD was 0.95 ±1.19 in group A while it was 0.6 ± 0.75 in group B. It gradually decreased during treatment time and remained stable in almost all children. Mean ± S.D after treatment was in group A was 0.25± 0.44 and in group B was 0.55 ±0.68

Recurrent nasal congestion - It was initially found positive 55% children of group A and 50% children of group B. Baseline mean ± SD was 1.0 ±1.02 in group A while it was 0.30± 0.47 in group B. It gradually decreased during treatment time and remained stable in almost all children. Mean ± S.D after treatment was 0.30± 0.47 in group A and in group B it was 0.65 ±0.74

Recurrent nasal discharge - It was initially found positive in 50 % children of group A and 50% children of group B. Baseline mean ± SD was 1.1 ±1.29 in group A while it was 0.8 ± .95 in group B. It gradually decreased during treatment time and remained stable in almost all children. Mean ± S.D after treatment was in 0.5 ± 0.68 group A was and in group B was 0.7 ±0.80

Recurrent cough - It was initially found positive in 75% children of group A and 50% children of group B. Baseline mean ± SD was 1.75 ±1.20 in group A while it was 0.85 ± 1.04 in group B. It gradually decreased during treatment time and remained stable in almost all children. Mean ± S.D after treatment was 0.85± 0.74 in group A and in group B was 0.10 ±0.95

Recurrent Vomiting –It was initially found positive in 50% children of group A and 50% children of group B . Baseline mean ± SD was0.95 ±1.14 in group A while it was 0.60 ± 0.68 in group B. It gradually decreased during treatment time and remained stable in almost all children. Mean ± S.D after treatment was 0.4± 0.59 in group A and in group B was 0.55 ±0.68

Recurrent Loose Stool –It was initially found positive in 50% children of group A and 45% children of group B. Baseline mean ± SD was 0.95 ±1.09 in group A while it was 0.55 ± 0.68 in group B .It gradually decreased during treatment time and remained stable in almost all children. Mean ± S.D after treatment was 0.35± 0.48 in group A and in group B was 0.50 ±0.68

Recurrent Pain Abdomen –It was initially found positive in 55% children of group A and 60% children of group B. Baseline mean ± SD was 1.15 ±1.18 in group A while it was 1.10 ± 1.026 in group B. It gradually decreased during treatment time and remained stable in almost all children. Mean ± S.D after treatment was.50± 0.68 in group A and in group B was 0.75 ±0.78

Loss of appetite –It was initially found positive in 80 % children of group A and group B . Baseline mean ± SD was in group A 1.00± 0.64 while it was 0.85 ± 0.40 in group B. It gradually decreased during treatment time and remained stable in almost all children. Mean ± S.D after treatment was 0.10 ± 0.30 in group A and in group B was 0.10 ±0.30.
Percentage of improvement in symptoms is shown in table 2.

Laboratory Observation: Laboratory investigations were done in all registered children to observe any significant change in TLC, DLC, hemoglobin, renal function and liver function. There was no significant ($p>0.05$) difference in mean change in all the biochemical parameters between the groups except for TLC and Hb% level which showed significant improvement. Laboratory observation is summarized in table 3.

Result in the present trial drug research work was assessed deeply on the basis of symptomatic improvement and summarized in table 4.

In **Group A** Complete remission was seen in 35% children.50% children showed 'moderate improvement ,10% patient showed mild improvement. 5% of the patient remain unchanged. While in **Group B** no patient had complete remission.10% showed moderate improvement.40% showed mild improvement, 50% of the patient remained unchanged.

TABLE 1: GRADING OF SYMPTOMS

s.no.	Symptoms	Score 0	Score 1	Score 2	Score 3
1.	Recurrent sneezing	No recurrence	Once in 2 months	Once in a month	Twice every month
2.	Recurrent sore throat	No recurrence	Once in 2 months	Once in a month	Twice every month
3.	Recurrent nasal congestion	No recurrence	Once in 2 months	Once in a month	Twice every month
4.	Recurrent nasal discharge	No recurrence	Once in 2 months	Once in a month	Twice every month
5.	Recurrent cough	No recurrence	Once in 2 months	Once in a month	Twice every month
6.	Recurrent vomiting	No recurrence	Once in 2 months	Once in a month	Twice every month
7.	Recurrent loose stool	No recurrence	Once in 2 months	Once in a month	Twice every month
8.	Recurrent pain abdomen	No recurrence	Once in 2 months	Once in a month	Twice every month
9.	Loss of appetite	Eats eagerly	Eats twice or thrice a day but in less quantity as compared to children of same age group	Takes meal once or twice a day but in less quantity as compared to children of same age group	Forcefully takes meal once a day

TABLE 2: THERAPEUTIC OBSERVATION

s.no.	Symptoms	Group A(n=20)		Group B(n=20)	
		Percentage improvement	P value[1]	Percentage improvement	P value [1]
1.	Recurrent sneezing	52.17%	0.0039*	20%	0.25
2.	Recurrent sore throat	73.68%	0.0039	8.33%	0.99
3.	Recurrent nasal congestion	70%	0.0010	7.14%	0.99
4.	Recurrent nasal discharge	54.54%	0.0039	14.2%	0.50
5.	Recurrent cough	51.4%	0.0001	5.88%	0.99
6.	Recurrent vomiting	26.31%	0.0039	8.33%	0.99
7.	Recurrent loose stool	63.15%	0.0020	9.09%	0.99
8.	Recurrent pain abdomen	56.25%	0.0010	25%	0.06
9.	Loss of appetite	90%	<0.0001*	88.23%	<0.0001*

1Wilcoxon rank sum test, *significant

TABLE 3: LABORATORY OBSERVATION

Parameters	Group A(n=20)		Group B(n=20)	
	Mean change (BT-AT) ± SD	P value[1]	Mean change (BT-AT) ± SD	P value [1]
HB	-0.53 ± 0.99	0.026 *	-0.17±0.78	0.30
TLC	-755±1022.6	0.0038*	-55±206.4	0.2481
NEUTROPHIL	-2.25 ± 6.15	0.11	1.50±9.10	0.47
LYMPHOCYTE	-3.55 ± 9.0	0.095	-3.0 ± 3.54	0.70
EOSINOPHIL	0.65 ± 1.72	0.10	0.35± 2.58	0.55
BASOPHIL	0.05 ± 0.22	0.32	0.10± 0.44	0.32
MONOCYTES	-0.100± 0.71	0.54	0.15 ± 0.48	0.18
ESR	2.2±7.91	0.22	0.80 ± 5.04	0.24
SR. BILIRUBIN	0.05±0.15	0.126	0.02± 0.01	0.14
ALP	-1.8± 7.20	0.27	2.1± 4.57,	0.05
SGPT	-4.1 ±10.81	0.10	7.0 ±15.678	.060
SGOT	-3.95 ± 10.34,	0.1041	5.65± 15.48,	0.11
SR. CREATININE	0.02± 0.10	0.3092	0.03± 0.12,	0.28
UREA	0.15± 1.38	0.61	0.56 ± 1.40	0.09

1.Unpaired t test 2. Paired t test *significant

TABLE 4: RESULT

Group	Relieved >75%		Improved				Unchanged <25%	
			Moderate Improved 50-74%		Mild Improved 49-25%			
GROUP A N=20	**No. of patient**	**%**	**No. of patient**	**%**	**No. of patient**	**%**	**No. of patient**	**%**
	7	35%	10	50%	2	10%	1	5%
GROUP B N=20	0	0%	2	10%	8	40%	10	50%

DISCUSSION AND CONCLUSION

The present trial showed that most of the children (60%) had average and poor hygiene. This could be the most probable reason for the recurrent infections of Upper respiratory and Gastrointestinal tract in these children. This may result in recurrent URT problems as madhura rasa is kapha prakopaka which may lead to shrotorodha. Most of the children enrolled for the trial were completely vaccinated as per the schedule but still they were suffering from recurrent infections of respiratory and gastrointestinal tract. Maximum number of children had mandagni. Mandagni results in production of incompetent dhatus. Since oja is the essence of all the dhatus. Incompetent dhatus results in diminished oja and hence decreases vyadhishamatva (immunity). Maximum number of children had complaint of decreased appetite (80%) followed by the complaints of recurrent cough (64.4%) and recurrent pain abdomen (53.3%). There was significant change in symptoms like recurrent sneezing, nasal discharge, loose stool, vomiting etc, in group A, where children were given swarnaprasahan as compared to group B, where children were given madhu and ghrita only. Frequency of getting infection depends upon the status of immunity and allergic conditions. Improvement in the children of group A is more as compared to children in group B. It is probably because of Synergistic action of all ingredients of swarnaprashan, which are tridoshkshaman, agnideepan, immunomodulation, analgesic, antioxidant, antiinflammatory, antidiarrhoeal and nootropic effect. There is significant improvement in appetite in group B also, where only honey and ghrita were given. Ghrita also helps in increasing digestive fire. This could be a possible reason behind improvement in appetite in both the groups.

The research showed that the regimen was well tolerated by the children and did not show any side effects. Thus it can be concluded that swarnaprashan is effective in decreasing recurrence of illness in children when given on daily basis for 30 days and it should be tested on large scale.

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Cite this article as:

Kritika Joshi and Mithilesh Verma. Role of swarnaprashan on recurrent illness in children: A comparative clinical study. Int. J. Res. Ayurveda Pharm. 2019;10(3):55-58 http://dx.doi.org/10.7897/2277-4343.100362

Source of support: Nil, Conflict of interest: None Declared