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Research Article

A CLINICAL STUDY ON THE EFFECT OF SWARNAMRUTHA PRASHANA IN CHILDREN (3 TO 6 YEARS) WITH RECURRENT UPPER RESPIRATORY TRACT INFECTIONS

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Abstract

A very common clinical condition is upper respiratory tract infections which disturbs child daily activities. Upper respiratory tract infections are leading causes of childhood mortality and morbidity. The disease of upper respiratory infections mainly involves fever, cough, sore throat, running nose, tonsillitis etc. Ayurveda is a treasure of many single drugs and formulations which are highlighted as immune promoters. Swarna Prashana is a unique technique of administering gold to the child in order to promote its immunity and intellect so that it can grow healthy without any diseases. It has been further mentioned that if Swarnamrutha Prashana is taken daily for a month, child becomes extremely intelligent and does not suffer from frequent diseases. Thus, present study has been planned for evaluating the effect of Swarnamruthaprashana) on recurrent upper respiratory tract infections in children. To clinically evaluate the effectiveness of swarnamrutha prashana in recurrent upper respiratory tract infections in children between the age group of 3 to 6 years. Open Labeled single arm clinical trial with minimum 30 subjects. 30 Subjects had received a soft gel capsule of Swarnamrutha prashana (equivalent to 2mg of Swarna Bhasma), once a day in the morning in empty stomach with lukewarm water. The administration of drugs was continued for 3 months. Subjects were followed for 3 months after the course of treatment for the occurrence of any upper respiratory tract infection. There was statistically significant improvement in signs and symptoms along with reduction in upper respiratory tract infections which includes kasa swasa, galashotha, jwara and pratishyay. Swarnamrutha Prashana is effective in management of recurrent upper respiratory tract infections in children.

Keywords: Recurrent Upper respiratory tract infections; Swarnamrutha Prashana; Children; Immunity.

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INTRODUCTION

Good health is considered to be the root of the objects of human life. Healthy transformation of a child into an adult is governed by the factors such as nutritious food, age, genetic makeup and non-affliction by diseases.[1] Children are supple and are the victim of physiological handicappedness in many aspects of dhatu (body tissues), sara (qualitative assessment of body tissues), samhanana (compactness of body) and bala (strength) making them susceptible for frequent infections.[2] These diseases hamper the growth and development resulting in morbidity which affects the child throughout their life.

It has been globally estimated that upper respiratory tract infections are responsible for about two million deaths in children. Upper respiratory tract infections are also reasons for school absences in children and visits to physician on a regular basis.[3]

Recurrent Respiratory Tract Infections: Respiratory tract infections can be broadly classified in to upper and lower respiratory tract infections.[4] Most of the children suffer from an upper respiratory tract infection which later may descend down the tract to manifest as the lower respiratory tract infection or a pan-respiratory infection. Upper respiratory tract infection (URI) is a nonspecific term used to describe acute infections involving the nose, paranasal sinuses, pharynx, and larynx.[5] The prototype is the illness known as the common cold.[6] Most URIs occurs more frequently during the cold winter months. When is it called RRTI? There are no standardized criteria laid down in any authentic textbooks of medicine or pathology regarding the number of episodes that are essential to coin the term RRTI. It is well described in various textbooks of Paediatrics that 6-8 episodes of RTIs per year are common in children more than which can be considered as pathological.[7][8][9][10] The frequency reduces as the age progresses. Upper Respiratory Tract Infections are contagious infections caused by a variety of bacteria such as influenza, streptococcus etc. Symptoms usually resolve within two weeks and include a scratchy or sore throat, sneezing, stuffy nose and cough. In the present study patients with occurrence of at least one episode of respiratory infection/allergy/cold /cough every month for the last three months or more were selected for intervention.

Swarnamrutha Prashana (Ayurvedic formulation with gold) is an indigenous preparation which is an adaptation of *swarnaprashana* explained by Acharya kashyapa.[11] It comprises Swarna (Gold), Madhu (Honey), Ghrita (Ghee) and herbal drugs which are well known for nootropic action. Acharya Vagbhatta in Jatmatra Samskara has advised to rub specifies herbal drugs with that of Swarna on stone and to be given to the child with ghee and honey.[11] Acharya Sushruta advises 4 Swarna combinations with few drugs, that is given to children which will enhance children's overall physical and mental health and Vyadhikshamatwa (Immunity).[12] Rasayana (rejuvenation) like Swarnamrutha Prashana exhibit nonspecific but more holistic effects as it boosts the general immunity and host resistance apart from improving overall general health. Rasayana are well known for their Bala Vardhana (increases strength) properties, here in upper respiratory tract infections Bala Vardhana is nothing but the enhancement of immunity thus improving the resistance power of child against various infections. Considering theses all benefits of swarnaprashana, the present study is planned to evaluate the efficacy of daily administration of swarnaprashana for 3 months on recurrent upper respiratory tract infections in children.

MATERIALS AND METHODS

Source of data

Outpatients between the age group of 3 to 6 years visited to OPD of SDM College of

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Ayurveda and Hospital. Hassan. Karnataka, India.

Method of collection of data

Screening

Subjects who fulfilled the diagnostic criteria were screened using screening form and data of patients was collected using specially prepared case report form (CRF).

Research design

An Open Label Single Arm Prospective Clinical Trial IEC No. SDM/IEC/66/2020, CTRI No. REF/2021/02/040929.

Clinical study protocol

Sampling method

A minimum of 30 patients fulfilling the diagnostic and inclusion criteria was selected by convenient sampling method and was considered in a single group.

Drug intervention

- **Trial Drug**: Swarnamrutha Prashana
- **Dosage form**: Opaque gelatinous capsules
- **Dose:** 1 gelatinous capsule of 0.4 ml (Containing 2 mg of swarna bhasma)
- **Time of Administration**: Empty stomach in morning
- **Anupaana**: Boiled water (QS)
- **Duration of therapy**: 90 days
- **Follow up**: Participant's follow-up was be done once in a month for 3-month duration.

Method of preparation of trial drug (Swarnamrutha Prashana)

Swarnamruta prashana is a modified form of classical swarnaprashana. It is a mixer of madhu, ghrita (Amritadi ghrita) and Swarna bhasma.

Amritadi Ghrita was prepared in Madhyam Paka (medium processed oil) as mentioned by in Sharangdhara Samhita using ghee (Karnataka milk federation's Nandini Ghee) and Amrutadi kashayam [using the drugs Amrita (*Tinsopora cordifolia*), Brahmi (*Bacopa monnieri*), Vacha (*Acorus calamus*), Aswagandha (*Withania somnifera*), Yashtimadhu (*Glycyrrhiza glabra*), Shankhapushpi (*Convolvulus pluricaulis*), Jatamansi (*Nardostachys jatamansi*), Pippali (*Piper longum*)] 1 part of Amrita Ghrita mixed with 1 part of honey.

Swarna bhasma is added to this mixture of Madhu and Ghrita. All this mixture is processed through various stages to make homogenous mixture and this mixture is filled in to gelatinous capsules each containing 0.4 ml of mixture and 2mg of Swarna Bhasma in it for the purpose of easy administration and correct dosage of administration daily. (Figure 1 & 2)

Diagnostic Criteria

The children suffering from symptoms of Upper Respiratory Tract infections such as kasa (cough), Pratishaya (Rhinitis), Galashotha (Pharyngitis and Tonsillitis) or Jwara (fever) with recurrence of at least one attack per month for last 3 months.

Inclusion Criteria

1. Children was included in the clinical trial only after remission of acute infections
2. Children with Symptoms mentioned in diagnostic criteria.
3. Patients were selected irrespective of gender, religion and socioeconomic status.
4. Children between age group of 3 to 6 years.

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Figure 1: Swarnamrita soft gelataneous cap

Figure 2: Packed capsule in air tight containers

Exclusion criteria

Known cases of Bronchial asthma, pulmonary tuberculosis, COPD, Bronchitis, tropical eosinophil or with any other systemic were excluded.

Assessment Criteria

The subjects were assessed on 0th day (before treatment), on 30th day, 60th day (during treatment) and on 90th day (after completion of the treatment course). Subjects were followed for 3 months after the course of treatment for the occurrence of upper respiratory tract infections.

Subjective parameters

- Occurrence of upper respiratory tract infections kasa (cough), pratishyaya (allergic rhinitis), galashotha (tonsillitis), jwara (pyrexia).
- Measures of morbidity
- Parenteral feedback on the general health of a child.

Objective parameters

- Laboratory parameter: CBC.
- Assessment of Growth: By Anthropometry

Statistical methods employed for analysis of data

Results were analysed using appropriate statistical test based upon type of data like Friedman's test and post hoc Wilcoxon sign rank test using SPSS version

OBSERVATION AND RESULTS

Table 1 suggests that during BT to 1st visit it was found that 26 subjects had reduction in symptoms, while no subject had aggravation in symptoms. In 4 subjects no Improvement or no further aggravation in their symptoms was found. which was statistically significant with z value = -5.099, p value =0.001, During 1st visit to 2nd and 3rd visit it was found that 16 subjects had reduction in symptoms, while no subject had aggravation in symptoms. In 14 subjects no Improvement or no further aggravation in their symptoms found. which was statistically significant with z value = -3.099, p value =0.001. During AT to follow-up visit it was found that 13 subjects had reduction in symptoms, while 1 subject had aggravation in symptoms.

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Table 1: Effect of Swarnamruta Prashana on duration of Upper Respiratory Tract Infections Evaluation Of Effect Between Before Treatment, After Treatment and during follow-up

Parameter		N	Mean Rank	Sum of ranks	Z value	P value	R
URTI duration BT- 1st visit	Negative rank	26	13.50	351.00	-5.099	0.001	S
	Positive rank	0	0.00	0.00			
	Ties	4	-	-			
	Total	30	-	-			
URTI Duration 1st - 2nd visit	Negative rank	16	8.50	136.00	-3.099	0.001	S
	Positive rank	0	0.00	0.00			
	Ties	14	-	-			
	Total	30	-	-			
URTI duration 2nd - AT	Negative rank	16	8.50	136.00	-3.099	0.001	S
	Positive rank	0	0.00	0.00			
	Ties	14	-	-			
	Total	30	-	-			
URTI duration AT – Follow-up	Negative rank	13	7.00	91.00	-2.668	0.001	S
	Positive rank	1	14.00	14.00			
	Ties	16	-	-			
	Total	30	-	-			

Table 2: Effect of Swarnamrutha Prashana on frequency of Upper Respiratory Tract Infections Evaluation of Effect between before Treatment, After Treatment and during follow-up

Parameter		N	Mean Rank	Sum of Ranks	Z value	P value	R
URTI frequency BT and 1st visit	Negative rank	23	13.00	299.00	-4.200	0.00	S
	Positive rank	2	13.00	26.00			
	Ties	5	-	-			
	Total	30	-	-			
URTI frequency 1st - 2nd visit	Negative rank	20	13.00	260.00	-3.347	0.001	S
	Positive rank	4	10.00	40.00			
	Ties	6	-				
	Total	30	-				
URTI frequency 2nd visit – AT	Negative rank	20	13.00	260.00	-3.347	0.001	S
	Positive rank	4	10.00	40.00			
	Ties	6	-				
	Total	30	-				
URTI frequency AT – Follow-up	Negative rank	17	9.00	153.00	-3.945	0.001	S
	Positive rank	4	10.00	0.00			
	Ties	13	-				
	Total	30	-				

In 16 subjects no Improvement or no further aggravation in their symptoms found. Which was statistically significant with z value = -2.668 p value =0.001

Table 2 shows that during BT to 1st visit it was found that 23 subjects had reduction in symptoms, while 2 subject had aggravation in symptoms. In 5 subjects no Improvement or no further aggravation in their symptoms found. Which was statistically significant with z value = -4.200, p value =0.001. During 1st visit to 3rd visit it was found that 20 subjects had reduction in symptoms, while 4 subject had aggravation in symptoms. In 6 subjects no Improvement or no further aggravation in their symptoms found. which was statistically significant with z value = -3.347, p value, < 0.001. During AT

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to follow-up, it was found that 17 subjects had reduction in symptoms, while 4 subject had aggravation in symptoms. In 13 subjects no Improvement or no further aggravation in their symptoms found. which was statistically significant with z value = -3.945, p value =0.001

Table 3 gives a clear understanding that the mean value of Height before treatment was 116.91 before treatment which increased to 117.95 after treatment with mean difference -1.04 which is statistically significant with t= -7.343, p=<0.001. The mean value of Height was 117.95 after treatment which increased to 119.22 after follow up with mean difference -1.26 which is statistically significant with t= -11.275,p=<0.001. The mean value of Weight was 20.87 before treatment which increased to 21.40 after treatment with mean difference -0.52 which is statistically significant with t= -6.509, p=<0.001. The mean value of Weight was 21.40 after treatment which increased to 22.46 after follow up with mean difference -1.06 which is statistically significant with t= -14.282, p=<0.001.

Table 4 gives us the analysis of hematological parameters and it suggests that the mean value of Haemoglobin was 11.7235 before treatment which increased to 12.0071 with mean difference -0.28353 which is statistically significant with t= - 5.264, p<0.001.

The mean value of total white blood cells count was 8267.6471 before treatment which reduced to 7891.1765 with mean difference 376.47059 which is statistically significant with t=3.765, p=0. 001.The mean value of neutrophils was 51.3529 before treatment which increased to 56.00with mean difference -4.64706 which statistically significant with t=-8.030, p<0.001.

The mean value of lymphocytes was 43.3529 before treatment which reduced to 41.4118 with mean difference 1.94118 which is statistically significant with t=2.981, p<0.05. The mean value of eosinophil was 3.5294 before treatment which reduced to 1.7059 with mean difference 1.82353 which is statistically significant with t=8.095, p<0.001. The mean value of ESR was 12.5882 before treatment which reduced to 7.5588 with mean difference 5.02941 which is statistically significant with t=7.763, p<0.001.

DISCUSSION

Discussion on Need for the study

Children are supple and are the victim of physiological handicappedness in many aspects of dhatu (body tissues), sara (qualitative assessment of body tissues), samhanana (compactness of body) and bala (strength) making them susceptible for frequent infections. A very common clinical condition is upper respiratory tract infections which disturbs child daily activities. The disease of upper respiratory infections mainly involves fever, cough, sore throat, running nose, tonsillitis etc. hence there is need of therapy which enhances the immunity.

Discussion on the trial drug (Swarnamrita Prashana)

Prashana (first feeding of child) is one of the important practices mentioned under Jatakarma (immediate procedure after delivery) in Ayurvedic classics. Among all authors Kashyapa gave the clearest ideas on Prashana, its vidhi (method), indication contraindications, ingredients, formulations, importance / advantages.

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Table 3: Effect of Swarnamrita Prashana on Anthropometric Parameters: Evaluation Of Effect Between Before Treatment, After Treatment and during follow-up

Parameter	Paired 't' test							
	MeanB.T	Mean A.T	Mean Difference	S.D. (±)	S.E.M. (±)	't' value	p value	Remarks
Height	116.9118	117.9559	-1.04412	.82909	.14219	-7.343	.000	S
Weight	20.8765	21.4056	-.52912	.47401	.08129	-6.509	.000	S

Parameter	Paired 't' test							
	Mean A.T.	MeanF.U.	Mean Difference	S.D. (±)	S.E.M. (±)	't' value	p value	Remarks
Height	117.95	119.22	-1.26471	.65407	.11217	-11.275	.000	S
Weight	21.4056	22.4656	-1.06000	.43276	.07422	-14.282	.000	S

Table 4: Hematological Parameters on 30 patients of recurrent upper respiratory infection.
Evaluation of Effect between before Treatment, after treatment and during follow - up

Parameter	Paired 't' test							
	Mean B.T	Mean A.T	Mean Difference	S.D. (±)	S.E.M. (±)	't' value	p value	Remarks
Haemoglobin	11.7235	12.0071	-.28353	.31409	.05387	- 5.264	.000	S
Total count	8267.64	7891.1765	376.47059	583.1257	173.0083	3.765	.001	S
Neutrophil	51.3529	56.0000	-4.64706	3.37443	-5.82445	-8.030	.000	S
Lymphocyte	43.3529	41.4118	1.94118	3.79746	0.61618	2.981	.005	S
Eosinophil	3.5294	1.7059	1.82353	1.31358	1.36520	8.095	.000	S
ESR	12.5882	7.5588	5.02941	3.77781	3.71127	7.763	.000	S

There are several references of the Svarnaprashana in Ayurvedic literatures mentioning its actions like Balya (strength promoter), Brumhana (nourishing), Rasayana (rejuvenative), Medhya (nootropic), Kantiprada (improves complexion), Tridoshahar, Vyadhidhvamsaka (relieves diseases). Kashyapa explains it as Medhya (intellect promoter),[12] Agnibala Vardhak (improves digestion, strength), Aayushya (provides long life), Mangala (Auspicious), Punya (Virtuous), Vrishya (Aphrodisiac), Varnya (improves complexion), Grahapaham (protects from Graha rogas – psychiatric disorders). It has been further mentioned that if it is taken daily for a month, child becomes extremely intelligent and doesn't suffer with recurrent diseases ("Vyadhibi Na Cha Drushyate") and if taken for 6 months continuously, child is able to retain whatever he hears. As in all the references of Swarnaprashana its mentioned that it increases the Bala which is taken as Vyadhikshmatva (Immunity)[12] in present study and researched.

Discussion on observation

In the present study the children selected are mainly between the age group of 3-6 years because the recurrence of URTI is more prevalent in them because of low immunity, first exposure of infectious agents when they start going to preschools. In this age group the kapha dhatu is predominant and the ahara (food) of these children are also kapha prakopaka (increase kapha) which again are the nidana (cause) for respiratory tract infections. Viharaja nidana (habitual causes) in recurrent URTI are sudden change in the environment,

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pollution, contact with infected person at school were also noted in the present.

Discussion on results

In the present study the children with recurrent upper respiratory tract infections with recurrence of at least one attack per month for last 3 months were included. The trial drug Swarnamrutha prashana in the form of soft gel was administered for a period of 3 months on empty stomach on daily basis. It was found that after taking 1 month of swarnamrutha prashana there was a reduction in duration and frequency of URTI. After the completion of full course of treatment (3 months continuous - 90 days) the children included in the study shown statistically significant in the reduction in the frequency of attacks as well as the duration of the attacks were also reduced. Swarnamrutha prashana has properties like rasayana (rejuvenative) and ojovardhaka (enhances immunity) which has helped in increasing the immunity, by which condition of children got improved. The children after the completion of treatment were followed for a period of 3 months to check for the recurrence. During follow-up period also the statistically significant improvements were noted, which implies the sustained effect of the trial drug. This proves that oral administration of swarnaprashan a for a period of 3 months helps in enhancing humoral immunity in children.

Discussion on objective parameters

In the objective parameters Growth of children was assessed through anthropometric parameters like weight and height. Statistically significant improvement was observed in both weight and height of children which may be because of the reasons like, as the child was not getting recurrence in URTI, child's general health was improving, then appetite was improved. As the appetite were improving, the child's consumption of food was good. Thus, the nutritional status of child was improving. Hence there was considerable statistically significant were observed in weight as well as height of the child.

Discussion on blood parameters

In the blood parameters there was statistically significant improvement in Hb%, reduction in the total counts and ESR were noted, which directly indicates the reduction of infection as well as improvement in the immunity.

Mode of action of trial drugs

Swarnamrithaprashana is a modified form of Swarnaprashana. Swarnaprashana as described in Kashyapa Samhita consists of administration of Swarna with Madhu and Ghritha, whereas in, Swarnamrithaprashana, Amruthadi ghrita is used instead of plain ghrita. Ingredients of Amruthadi ghrita are described earlier in drug review.

Swarna (Gold)

In present formulation of Swarnamrithaprashana gold is used in the form of swarnabhasma. The Pharmacodynamic properties of Swarnabhasma include Madhura rasa (sweet taste conversion after digestion), Madhura vipaka (sweet taste), Sheeta veerya(potency of the drugs), Laghu Snigdha guna (light and slimy properties). Its having functions like Balya (Improves strength), Rasayana (Rejuvenative), Ojovardhaka (Improves immunity), vrushya Varnya (improves complexion).

Madhu

The pharmacodynamics properties include the pharmacodynamics properties include Madhura - Kashaya Rasa (sweet salty taste), Laghu - Rooksha guna (light and rough properties, Sheetha Veerya (potency of the drugs), Madhura Vipaka (sweet processed oil) and Yogavahi (Catalyst). It is hailed for its yogavahi (vehicle which carries drug to the target site by its penetrative action) property.

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It is having functions like deepana (appetiser), varnya (improves complexion), Swarya (improves voice) and prasadana. Thus, honey may have a synergistic role along with Swarna bhasma role in reduction of recurrence of infection in present study

Amritadi Ghritha

Ghritha contains Madhura Rasa (sweet taste), Madhura Vipaka (sweet processed oil), Mrudu – Snigdha - Guru guna (soft, slimy and heavy properties). It has functions like Vata-pittahara (pacifying vata and pitta), Kapha Vardhaka (which helps in increasing cough) (Prakrita kapha), Medhya (promotes intellect), Swarya (improves voice), Deepna (appetiser), Oja-teja-bala (enhances immunity, digestion, strength) and ayushya vridhikara (enhances life span), Vrushya (aphrodisiac), Vayastapana (delays ageing) and Rakshoghna (Protective). Samskarasyanuvarthana (it retain its goodness along with health benefits of whatever it is cooked with) guna of ghrita helps in imbibing properties of other drugs used in the preparation of Amrithprasha ghrita

CONCLUSION

Swarnamrithaprashana was found to be statistically significant in reducing recurrent upper respiratory tract infections in children. Swarnaprashana has helped in enhancing the immunity in children which has reflected by the improvements in assessment parameters. No adverse drug reactions were noted in this study. From the clinical trial, it can be concluded that swarnamaurtha prashana is effective in the management and prevention of recurrent upper respiratory tract infections.

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