Research Article

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CLINICAL STUDY TO ASSESS THE EFFECT OF AMALAKI SYRUP AS IMMUNOMODULATER FOR LOWERING DOWN THE MORBIDITY RATE

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ABSTRACT

It has been estimated that about 6 lakhs infant and young children die from RSV annually, and if bacterial co-infections are included then this number may approach 10 lakhs deaths annually. More than 2 million deaths are estimated to result each year in the world as a consequence of diarrheal disease in children of under five years. This statistic shows that children are more vulnerable to infection because their immune system is less or under developed. Therefore, considering these prospects a clinical trial was carried with 156 children (1-7 years of age group) suffering from recurrent diseases like cough, running nose, diarrhoea, fever etc. in three groups. These groups were assigned as Group A with Amalaki syrup, group B with placebo syrup and group C with only observation. This clinical study proves that a simple and cost effective formulation of Amalaki is capable to bring down the morbidity status of children by the mechanism of immune modulation.

Keywords: Children's immunity, morbidity, rural area, Amalaki syrup, immunomodulation.

INTRODUCTION

6.9 million Children under five years of age died in 2011, nearly 19,000/day and 800 every hour. Almost 75 % of all child deaths are attributable to just six conditions: neonatal causes, pneumonia, diarrhoea, malaria, measles, and HIV/AIDS. Respiratory infections and diarrhoeal diseases together contribute to 36 per cent of all deaths in children fewer than five years of age. In India about 1.83 million children die annually before completing their fifth birthday[1]. Recurrent respiratory infection, diarrhoea etc. are the most common causes of morbidity in immune compromised children. Majority of children below the age of 5 years do get 7-8 episodes of cold per year. In developing countries about 15 million children under the age of 5 years die each year. Respiratory infection accounts for 4 million of deaths. In India 15 % of death occurs during infancy and death in 1-5 years of age are due to respiratory infections. More than 2 million deaths are estimated to result each year the world over as a consequence of diarrheal disease in children of fewer than five years. On average 3.3 episodes of diarrhoea are experienced per child per year but in some areas the average exceeds 9 episodes per year[7]. Diarrhoea is a killer disease in children under five and recurrent diarrhoea affect almost 20 % of the population. “It is a tragedy that diarrhoea, which is little more than an inconvenience in the developed world, kills an estimated 1.5 million children each year,” said UNICEF Executive Director Ann M. Veneman. These statistics show that children are more vulnerable to infection because their immune system is less or under developed. Immune system continues to develop as the infant grows. In this period attempt should be prevention of disease and to enhance physical, mental and social well being of children so that each child may achieve the genetic potential with which she/he born. Imagine what will be the status of various disease in 21st century as there are about 200 infectious disease caused by micro organism and how many vaccines will be available to handle such situation. It can be observed that among a group of people exposed to a given disease, only some will be afflicted, while others are left without any effect. This phenomenon itself illustrates two important points -- that the pathogenic factors require some essential favourable conditions to flourish and that the individual is susceptible to the disease. In the absence of such conditions, an individual’s immunity or resistance can evade the disease hence preserving and maintaining a balanced condition. This concept is akin to the principle explained in ancient Vedic literature: Manusmruti, Mahabharata and Panchatantra all explained that the seed sown in non-fertile soil will be destroyed, just as fire thrown in a fuel-less or air-less places subsides. In Ayurvedic texts immunity has been explained by Chakrapani in term of Vyadhikshamatva[2]. According to Ayurveda Ojas is considered as Bala or Prakrita Kapha attributed to immunity. Specific drug called Rasayana in Ayurveda acts to prevent the disease and promote health by improving immunity or Kshamatva. Ojas play an important role in maintaining the resistance power of the body and it is extract of all Dhatus. So the drug Rasayana are responsible to potentiate Ojas or intermediate Dhatus directly or by enhancing Dhatwagnies or by Srotoshodhanam.

Clinical Study
Aims and objectives of study

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

- To decrease the morbidity status.
- To observe the immunomodulatory effect of Amalaki syrup.

Institutional ethics committee clearance

Clinical study was approved by IEC, Order No. F10 (5)/EC/2012/1293-94 Dated 04/05/12.

Selection of cases

The study was conducted on 180 patients; who were randomly selected from villages, from various schools by survey method and O.P.D/I.P.D. National Institute of Ayurveda, Jaipur, Rajasthan, India.

Inclusion criteria

- Children aged between 01 to 07 years of either sex.
- Children with recurrent respiratory infections.
- Children with recurrent G.I.T. diseases.
- Children with other recurrent diseases.

Exclusion criteria

- Children below 01 and above 07 years of age.
- Children with severe diseases.
- Children with chronic diseases.
- Children with any genetic disorder.
- Children having congenital anomalies.

Discontinuation criteria

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

Trial drug

The drugs were prepared in the syrup form in order to enhance its palatability for easy administration in children. They were prepared in the pharmacy of N.I.A., Jaipur, Rajasthan, India.

Dose and duration

The proposed drug Amalaki Syrup was prescribed in doses according to body weight of children (1 ml/kg/day) for 3 months.

Follow-up

All patients were followed on an interval of 15 days i.e. on day 15, day 30, day 45, day 60, day 75, day 90 after recruitment. A window period of +3 days was given to allow for holidays and weekends. One month post follow up was done after trial.

Administration of drug and grouping

Study was conducted in form of double blind randomized controlled group study. Total 180 patients were registered and randomly divided into 3 groups and treated according to following schedules. Each group was of 60 children. Out of 180 patients, 24 patients were dropped out. Rest 156 patients (Group A - 54, Group B - 52, Group C - 50) were continued in the clinical trial.

- Group A - Received Amalaki syrup in children.
- Group B - Received placebo syrup in children.
- Group C - No drug administration.

Flavors were added to proposed syrups in order to get similar appearance and taste. Coding was done by another person not related to study. Information was sealed and kept under safe custody. The envelope was opened after completing the study to decode it for interpretation.

Assessment criteria

The result of the clinical study was assessed based on the observations of clinical features and laboratory findings.

Side effect evaluation criteria

Clinical criteria were adopted to rule out possible side effects of the study drugs. It included the documentation of information related to change in appetite, sleep, abdominal features, drowsiness, irritability etc.

Analytical and statistical method

Observations documented during study were analyzed and findings were evaluated by using 't test' to establish efficacy.

OBSERVATIONS AND RESULTS

Table 1: Demographic observation of the study

S. No.	Finding	Predominance	Percent
1.	Village wise distribution	Sayapura Village	37 %
2.	Sex	Male	51 %
3.	Family type	Joint family	60 %
4.	Religion	Hindu	98 %
5.	Habitat	Rural	100 %
6.	Socio-economic status	Lower class	67 %
7.	Breast feeding initiation	Immediate after birth	70 %
8.	Weaning age	6 - 12 months	60 %
9.	Immunization status	Partially immunized	83 %
10.	Diet pattern	Vegetarian	72 %
11.	Prakriti	Vata - Kapha	49 %
12.	Satva	Madhyam	54 %
13.	Major Sara	Asthi	33 %
14.	Agni	Visham	50 %
15	Disease	Cough	82 %
16.	Age group	1 -5 Years	63 %

Statistical Analysis of Before Treatment and After Treatment

Table 2: Statistical analysis of group A

S. No.	Disease	BT mean ± sd	AT mean ± sd	Mean Diff.	N	T Value	P Value	Rem.
1	Running nose frequency	12.52 ± 3.19	12.26 ± 2.06	0.263	38	0.6378	> 0.1	IN
2	Running nose consistency	12.07 ± 4.20	12.34 ± 2.07	-0.263	38	0.5220	> 0.1	IN
3	Nasal obstruction	9.24 ± 2.80	9.54 ± 2.35	-0.297	37	0.7756	> 0.1	IN
4	Cough frequency	12.24 ± 3.28	11.91 ± 1.98	0.333	45	0.8621	> 0.1	IN
5	Cough character	11.59 ± 3.11	11.80 ± 2.04	-0.20	45	0.4875	> 0.1	IN
6	Sore throat	7.71 ± 2.92	8.14 ± 1.46	-0.428	07	0.4201	> 0.1	IN
7	Enlarge tonsils	8.47 ± 2.39	9.33 ± 1.91	-0.861	36	2.965	< 0.001	IN
8	Dyspnoea	07 ± 1.41	6.5 ± 0.70	0.5	02	1.000	> 0.1	IN
9	Diarrhoea frequency	12.39 ± 3.38	11.28 ± 1.82	1.107	28	2.726	< 0.001	IN
10	Diarrhoea consistency	11.67 ± 3.75	11.14 ± 1.67	0.535	28	1.107	> 0.1	IN
11	Fever character	9.50 ± 2.41	9.92 ± 2.08	-0.42	40	1.288	> 0.1	IN
12	Fever frequency	10.05 ± 2.17	9.95 ± 1.56	0.100	40	0.3229	> 0.1	IN
	Total morbidity	10.88 ± 3.39	10.89 ± 2.28	-0.013	384	0.1044	> 0.1	IN

BT: Before Treatment, AT: After Treatment

Table 3: Statistical analysis of group B

S. No.	Disease	BT mean ± sd	AT mean ± sd	Mean Diff.	N	T Value	P Value	Rem.
1	Running Nose frequency	12.81 ± 3.22	16.10 ± 2.42	-3.29	37	7.70	< 0.001	HS
2	Running Nose consistency	11.32 ± 3.21	16.12 ± 2.38	-4.83	37	9.344	< 0.001	HS
3	Nasal obstruction	8.66 ± 2.38	12.78 ± 2.95	-4.12	33	8.188	< 0.001	HS
4	Cough frequency	12.76 ± 2.99	16.07 ± 2.76	-3.31	41	6.743	< 0.001	HS
5	Cough character	12.19 ± 3.26	16.36 ± 2.56	-4.17	41	8.243	< 0.001	HS
6	Sore throat	7.5 ± 2.26	11.25 ± 3.73	-3.75	08	3.57	< 0.001	HS
7	Enlarge tonsils	7.88 ± 1.98	12.88 ± 2.72	-5.00	34	13.159	< 0.001	HS
8	Dyspnoea	12 ± 5.19	13.33 ± 2.30	-1.33	03	0.800	> 0.1	IN
9	Diarrhoea frequency	11.37 ± 2.71	15.25 ± 3.02	-3.88	27	7.54	< 0.001	HS
10	Diarrhoea consistency	10.14 ± 2.69	15.66 ± 3.22	-5.52	27	9.055	< 0.001	HS
11	Fever character	8.88 ± 2.47	13.26 ± 2.59	-4.38	34	10.64	< 0.001	HS
12	Fever frequency	9.14 ± 1.97	13.32 ± 2.54	-4.18	34	13.65	< 0.001	HS
	Total morbidity	10.56 ± 3.26	14.75 ± 3.09	-4.194	356	27.735	< 0.001	HS

BT: Before Treatment, AT: After Treatment

Table 4: Statistical analysis of group C

S. No.	Disease	BT mean ± sd	AT mean ± sd	Mean Diff.	N	T Value	P Value	Rem
1	Running nose frequency	12.22 ± 3.71	16.85 ± 3.69	-4.62	35	8.533	< 0.001	HS
2	Running nose consistency	11 ± 3.46	16.51 ± 3.72	-5.51	35	7.527	< 0.001	HS
3	Nasal obstruction	8.83 ± 2.64	13.69 ± 2.81	-4.86	36	10.654	< 0.001	HS
4	Cough frequency	11.66 ± 3.52	15.19 ± 2.32	-3.52	42	7.68	< 0.001	HS
5	Cough character	11 ± 2.78	14.83 ± 2.73	-3.83	42	7.50	< 0.001	HS
6	Sore throat	8.6 ± 2.98	12.5 ± 3.59	-3.90	10	5.64	< 0.001	HS
7	Enlarge tonsils	7.89 ± 1.74	11.89 ± 3.30	-4.00	37	8.18	< 0.001	HS
8	Dyspnoea	8.25 ± 2.87	13.5 ± 3.31	-5.25	04	5.09	< 0.001	HS
9	Diarrhoea frequency	10.41 ± 2.98	15.31 ± 2.34	-4.89	29	11.29	< 0.001	HS
10	Diarrhoea consistency	10 ± 2.73	15.41 ± 2.84	-5.41	29	10.23	< 0.001	HS
11	Fever character	9.08 ± 2.70	14.25 ± 3.64	-5.17	35	9.80	< 0.001	HS
12	Fever frequency	9.31 ± 2.67	14.05 ± 3.47	-4.74	35	10.915	< 0.001	HS
	Total morbidity	10.10 ± 3.20	14.69 ± 3.39	-4.588	369	28.451	< 0.001	HS

BT: Before Treatment, AT: After Treatment

Statistical Analysis of Investigations

Table 5: Statistical analysis of investigation in group A

S. No.	Investigation	BT mean ± sd	AT mean ± sd	Mean diff.	T value	P value	Re.
1	IgG g/l	9.26 ± 3.3	11.35 ± 4.3	-2.09	2.137	< 0.01	S
2	Hb g %	12.06 ± 0.96	13.27 ± 0.43	-1.21	7.328	< 0.001	HS
3	TLC	10070 ± 1154.0	8370 ± 499.57	1700 ± 655	6.044	< 0.001	HS
4	Neutrophil	52.10 ± 10.19	51.65 ± 11.17	0.45	0.3800	> 0. 1	IS
5	Lymphocyte	40.30 ± 9.90	40.35 ± 9.06	-0.05	0.0596	> 0. 1	IS
6	Eosinophil	1.80 ± 0.76	1.35 ± 0.81	0.45	2.015	< 0.01	S
7	ESR	11.50 ± 8.03	9.55 ± 6.36	1.95	1.903	< 0.01	S

BT: Before Treatment, AT: After Treatment

Table 6: Statistical analysis of investigation in group B

S. No.	Investigation	BT mean ± sd	AT mean ± sd	M. diff	T value	P value	Re.
1	IgG g/l	8.05 ± 3.12	8.47 ± 3.49	-0.415	0.6300	> 0.1	IS
2	Hb g %	11.96 ± 1.09	12.04 ± 1.01	-0.080	1.633	< 0.01	S
3	TLC	10250 ± 866.03	10170 ± 828.51	80±38	0.2985	> 0.1	IS
4	Neutrophil	54.90 ± 9.44	53.95 ± 10.04	0.950	1.078	> 0.1	IS
5	Lymphocyte	39.90 ± 11.05	40.05 ± 10.98	-0.150	0.1302	> 0.1	IS
6	Eosinophil	1.850 ± 0.98	2.15 ± 0.81	-0.30	1.552	< 0.01	S
7	ESR	10.90 ± 9.30	10.85 ± 7.59	0.050	0.1022	> 0.1	IS

BT: Before Treatment, AT: After Treatment

After Treatment Inter Group Comparison

Table 7: Statistical analysis of inter group comparison after treatment

S. No.	Morbidity	Group	Mean ± sd	Sem	N	Inter group	T value	P value	Rem.
1	Running nose frequency	A	12.26 ± 2.06	0.334	38	A Vs B	7.405	< 0.001	HS
		B	16.10 ± 2.42	0.398	37	A Vs C	6.627	< 0.001	HS
		C	16.85 ± 3.69	0.624	35	B Vs C	1.022	> 0.1	IS
2	Running nose consistency	A	12.34 ± 2.07	0.335	38	A Vs B	7.411	< 0.001	HS
		B	16.16 ± 2.38	0.392	37	A Vs C	5.982	< 0.001	HS
		C	16.51 ± 3.72	0.629	35	B Vs C	0.4806	> 0.1	IS
3	Nasal obstruction	A	9.54 ± 2.35	0.38	37	A Vs B	5.112	< 0.001	HS
		B	12.78 ± 2.95	0.514	33	A Vs C	6.847	< 0.001	HS
		C	13.69 ± 2.81	0.46	36	B Vs C	1.304	< 0.01	S
4	Cough frequency	A	11.91 ± 1.98	0.2961	45	A Vs B	8.07	< 0.001	HS
		B	16.07 ± 2.76	0.4311	41	A Vs C	7.08	< 0.001	HS
		C	15.19 ± 2.32	0.3594	42	B Vs C	1.576	< 0.01	S
5	Cough character	A	11.80 ± 2.04	0.304	45	A Vs B	9.17	< 0.001	S
		B	16.36 ± 2.56	0.400	41	A Vs C	5.894	< 0.001	S
		C	14.83 ± 2.73	0.421	42	B Vs C	2.633	< 0.01	S

6	Sore throat	A	8.14 ± 1.46	0.553	7	A Vs B	2.061	< 0.01	S
		B	11.25 ± 3.73	1.319	8	A Vs C	3.011	< 0.001	HS
		C	12.50 ± 3.59	1.138	10	B Vs C	0.7206	> 0.1	IS
7	Enlarge tonsils	A	9.33 ± 1.91	0.318	36	A Vs B	6.332	< 0.001	HS
		B	12.88 ± 2.72	0.467	34	A Vs C	4.032	< 0.001	HS
		C	11.89 ± 3.30	0.543	37	B Vs C	1.370	< 0.01	S
8	Dyspnoea	A	6.50 ± 0.707	0.50	2	A Vs B	3.880	< 0.01	S
		B	13.33 ± 2.30	1.33	3	A Vs C	2.793	< 0.01	S
		C	13.5 ± 3.31	1.65	4	B Vs C	0.0738	> 0.1	IS
9	Diarrhoea frequency	A	11.28 ± 1.82	0.344	28	A Vs B	5.932	< 0.001	HS
		B	15.25 ± 3.02	0.581	27	A Vs C	7.213	< 0.001	HS
		C	15.31 ± 2.34	0.4358	29	B Vs C	0.070	> 0.1	IS
10	Diarrhoea consistency	A	11.14 ± 1.67	0.315	28	A Vs B	6.570	< 0.001	HS
		B	15.66 ± 3.22	0.620	27	A Vs C	6.874	< 0.001	HS
		C	15.41 ± 2.84	0.528	29	B Vs C	0.3117	> 0.1	IS
11	Fever character	A	9.925 ± 2.08	0.328	40	A Vs B	6.141	< 0.001	HS
		B	13.26 ± 2.59	0.4454	34	A Vs C	6.415	< 0.001	HS
		C	14.25 ± 3.64	0.616	35	B Vs C	1.298	< 0.01	S
12	Fever frequency	A	9.95 ± 1.56	0.247	40	A Vs B	6.97	< 0.001	HS
		B	13.32 ± 2.54	0.436	34	A Vs C	6.741	< 0.001	HS
		C	14.05 ± 3.47	0.5869	35	B Vs C	0.9988	> 0.1	IS
13	Total morbidity	A	10.89 ± 2.28	0.116	384	A Vs B	19.377	< 0.001	HS
		B	14.75 ± 3.09	0.164	356	A Vs C	18.073	< 0.001	HS
		C	14.69 ± 3.39	0.176	369	B Vs C	0.2447	> 0.1	IS

HS – Highly Significant, S – Significant, IS – Intermittently Significant

DISCUSSION

Village wise distribution

It was observed that maximum numbers of patients enrolled in the study were belonging to Saypura village (37 %) because according to census 2001 maximum children were residing in Sayapura village (total 349, male-187 and female-162).

Sex

Out of 156 patients 80 (51 %) patients were male child. It shows that there is no relation between sex and immunological status of the children.

Family type

Most of the patients (60 %) enrolled in the study were belonging to joint families because area chosen for this study was rural and it was observed that in rural area maximum people lives in joint families.

Religion

It was evident that, majority of patients i.e. 153 (98 %) were Hindu by religion due to Hindu predominance in study area. No study shows that Hindu are more vulnerable to infectious diseases.

Socio-economic status

It was observed that Maximum (67 %) patients were found in lower class. This type of distribution was found because in rural area maximum family's economy is based on farming. In Rajasthan there is uncertainty of farmer's economy because of low water supply, below average rain, low water level of field etc.

Immunization status

It was observed that majority of patients i.e. 83 % were partially immunized as per the above given schedule (BCG, OPV, DPT, Hep-B, MEASLES, MMR, Other). It may be due to unawareness, less advertising and some myth regarding vaccination in rural areas. Statistics shows that lack of immunization or partial immunization increases morbidity rate as compare to fully immunization.

Prakriti

Majority of patients enrolled in the study were having Vata-Kapha Prakriti (49 %). There is predominance of Kapha in Balyavastha so chances of Kapha Sthan (Uraha) Gata Vyadhi (URTI) is more in children and low immunity may be due to:
Srotavarodha ⟶ Aparipakva Dhatu ⟶ Alpa Ojas.
In other reference Vata Prakriti children also have Alpa Bala[3], so may be Vata-Kapha Prakriti is more vulnerable for higher morbidity.

Diseases

It was observed that maximum 128 (82 %) patients were suffering from recurrent episodes of cough, followed by 111 (72 %) with recurrent running nose. WHO data also reveals that upper respiratory tract infection is a most common cause of morbidity in children. Recurrent cough, running nose, cough and nasal blockage are major features of URTI.

Age group

In age group of 1-5 years, there were 98 (63 %) patients. WHO data also suggests that those 1 to 5 years of age group are most vulnerable for diseases or we can say

maximum morbidity rate was found in this age group because of low immunity in 1-5 years of children.

Effect on morbidity features

Overall, it has been observed that Amalaki syrup is highly effective in lowering the morbidity rate. There was highly significant increase in morbidity rate in non treated group, whereas Amalaki treated group shown insignificant changes. It shows that in group A there was insignificant change; group B and C had shown highly significant change in almost all morbidity features (Table 2, 3, 4). It may be due to the effect of season (heavy rain) in Jaipur, India during trial period; because morbidity increases in rainy season due to suitable atmosphere for bacteria and viruses. Group A wherein Amalaki Syrup was given shown minimal change in morbidity, on other hand group B (placebo group) and group C (observational group) shown increasing morbidity rates. This result shows that Amalaki syrup modulates the immunity of child by which he/she can fight with diseases.

Effect on laboratorial parameters
Haemoglobin

Laboratorial data shows that in group A there was highly significant and in group B significant changes were found. In group A reasons may be due to Amalaki as it provides better medium to iron absorption by its acidic nature and higher concentration of Vit. C[11] other property of Amalaki also helps in increasing Hb[9]. In group B reason may be due citrate (flavouring agents) which also increases the acid nature of compound or may be some dietary changes. In Ayurvedic text books Amalaki with cane juice and honey is used in Panduroga[4].

TLC

Data reveals that TLC reduction was highly significant (p value - < 0.001) in Group A and in group B insignificant changes were found (p value- > 0.1). It shows the increased immunity level in group A.

Neutrophil and lymphocyte count

Insignificant changes were found in both group A and group B. It means that Amalaki does not show any effect on neutrophil as well as lymphocyte count. But there is a paucity of studies on the immunomodulatory properties of fruit extracts of Amla in immuno-compromised states, with the emphasis on lymphocytes.[8]

Eosinophils

Data shows that both groups shown significant results (p value - < 0.01) but in group A there was decrease and in group B there was increase in the number of eosinophils. It means Amalaki is very effective in allergic conditions wherein eosinophil counts increases due to hyper responsiveness of immune system.

ESR

Observation shows that in group A there was significant (p value - < 0.01) decrease in ESR. It reveals that Amalaki has anti infective properties.

IgG

Data shows that in group A (Amalaki treated) there was significantly increase in IgG level. It means Amalaki increases the IgG level which is main component for immunity boosting.

Probable mode of action of drug

Pharmacodynamic properties of herbal drug Amalaki shows that it has all five Rasas except Lavana Rasa (Pancharasa alavana), Laghu, Ruksha, Sheeta Gunas, Sheeta Veerya, Madhur Vipaka, Tridoshahara, Pitta Shamaka Dosha Karma. In upper respiratory tract infection the Pranavaha Srotas is basically involved (Pratishyaya and Kasa Roga). In this disorder the Dosha involved are Kapha Vatapradhan and Alpa Pitta. Dushya involved is Rasa and Rakta Dhatu and Srotas affected are Pranavaha, Annavaha and Udakavaha Srotas. Considering above factors, the drug chosen besides having a Tridoshahara activity should have strong affinity to act on Pranavaha Srotas (Kasa-Shwas Hara). Drug possesses Laghu Guna and also Kasa-Shwas Hara properties. Its Sheet Guna doesn't hamper other Khaphaghana properties. Due to its Laghu, Sheeta and Tridosh Hara Guna it is very effective in Fever (Jwara). It also has Vishamjwaraghana and Jwarahara properties. Amalaki fruit powder with Shunthi, sugar and Ghrita is recommended in Jawara[5]. In the condition of recurrent diarrhea Amalaki had shown very good results, this may be due to its Ruksha, Laghu Guna and Sheeta Veerya properties or may be due to destroying the Ama production in the body. *In vitro* studies using rodent jejunum and ileum as well as in live mice shows the anti diarrheal and spasmolytic effects on castor oil-induced diarrhoea, possibly due to muscarinic action and calcium channel blockade.[10] The fresh juice of the fruit mixed with Ghrita is used as Rasayana and has a beneficial activity upon the intestinal flora[6]. Specific drug called Rasayana in Ayurveda acts to prevent the disease and promote health by improving immunity or Kshamatva. Ojas play an important role in maintaining the resistance power of the body and it is extract of all Dhatus. So the drug Rasayana are responsible to potentiate Ojas or intermediate Dhatus directly or by enhancing Dhatwagnies or by Srotoshodhanam. Amalaki is a drug that plays a very good role in immunomodulation.

CONCLUSION

1-5 years of age group is more prone to recurrent diseases, in which recurrent cough and running nose are main component. Children with Vata-Kapha predominant Sharirika Prakriti are more prone to high morbidity rate. Ayurveda can augment the recovery of children suffering from high morbidity features with its Rasayana therapy.

In the present study, the trial drug Amalaki syrup increased haemoglobin concentration, decreased TLC, increased IgG level in Children at a statistical significant level suggesting the effectiveness of the drug. This clinical study proves that a simple and cost effective formulation of Amalaki is capable to bring down the morbidity status of children by the mechanism of immunomodulation.

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