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## 1. INTRODUCTION

Ayurveda, the ancient Indian system of medicine, recommends the administration of a specified group of formulations/ herbs known as Rasayana, described in “Charaka Samhita “ (1500 BC), the first treatise on Ayurvedic medicine. The concept has come a long way in terms of scientific understanding in the last few decades. The word “Rasayana” stands for improved circulation of nutrients both at macro and micro levels. Ancient scholars consider that, the use of Rasayana would impart a long, healthy and a disease free life while promoting intelligence, memory and luster. Among Rasayana formulation cited in ‘Charak Samhita’, Chyawanprash is a prominent one. The formulation occurs in a consistency of Jam and contains 45 ingredients including Amla (*Emblica officinalis*) the richest natural source of vitamin C. It is also noteworthy that the use of Amlaki as an independent Rasayana in the same text. Till recent periods the anti-oxidant property were attributed to vitamin C content, however, with recent advances in phyto-chemistry, low molecular weight compounds contained in Amla are now recognized to play a vital role in its anti-oxidant profile. Among all the Rasayanas, Chyawanprash is the best known and most trusted family health tonic in India. Besides its application as Rasayana, Chyawanprash is also recommended for the treatment of recurrent respiratory problems under the heads of *Kasa* and *Svasa*. These specific indication suggest that it could play an important role in respiratory problems in general.

Investigations suggest that, Chyawanprash has an anabolic effect. It was observed to increase the serum protein level and increases the body weight. Chyawanprash is one of the products reported to cause retention of nitrogen (positive nitrogen balance). It also improves steroidal content along with the improvement in health condition.

In a clinical study conducted on pulmonary tuberculosis patients, Chyawanprash showed comparable results with durabolin, multivitamin and protein supplementation with the significant rise in weight without having any toxic effect. These adjuncts to primary anti-tubercular drugs not only help in amelioration of symptoms and signs, but also a relatively quick and effective therapeutic response. This particular study suggests that Chyawanprash contribute positively for promoting quality of life in patients with chronic respiratory ailments.

This study was taken up to assess the adaptogenic properties of Chyawanprash in normal and depressive persons.

## 2. OBJECTIVES OF THE STUDY:

To evaluate the immune status in patients suffering from recurrent cough and cold.

## 3. MATERIALS AND METHODS:

The samples required for the study were provided by Shree Baidyanath Ayurved Bhawan Pvt. Ltd, Kolkata, packed in similar containers with labels, in a codified manner, to blind the investigator, as well as the user.

In the study for Chyawanprash, 45 patients were selected, only 40 patients fulfilled the inclusion criteria laid down for the study and 5 patients has been dropout.

### 3.1 Inclusion Criteria:

- Patients aged between 15-75 years
- Patients having history of allergy and/or other manifestations of allergy
- Patients having history of recurrent viral infection in the throat
- Patients with recurrent bacterial infection were included in the trial

### 3.2 Exclusion Criteria:

- Patients with serious systemic disorders were excluded from the trial.
- Patients suffering from tuberculosis were excluded from the study
- Patients with chronic illness were excluded from the study on ethical grounds
- Patients participating in any other clinical trial were excluded from the study

Patients meeting the enrollment criteria were explained the nature of the study, informed consent was obtained.

### 3.3 Study Design:

Open Clinical Study

### 3.4 Treatment Schedule:

One heaped teaspoon of Chyawanprash was given twice a day to patients enrolled in the study. Observations were made on each case at the (1) start of the study, (2) after 6 weeks and (3) after 12 weeks.

### 3.5 Criteria of Assessment:

Efficacy evaluation was done based on both subjective and objective criteria, at baseline and at the end of the decided treatment duration.

#### 3.5.1 Subjective criteria:

Patients were categorized into following four groups (including the control group) according to the symptoms:

(a) Normal: Apparently no signs and symptoms (control group)

(b) Allergy: Increase of eosinophil cells in the nasal secretions and blood. Increase in IgE in the serum.

(c) Viral: History of viral infection in the throat occurring in many people at a time. Absence of pyogenic bacteria in the throat swab culture.

(d) Bacterial: Sputum culture positive to pathogenic bacterial.

## 3.5.2 Objective criteria:

## Hematological and Biochemical parameters

- Blood Hemoglobin
- Serum Albumin
- Serum Protein
- IgE
- IgG

## 4. RESULTS

A total of 40 cases were studied divided into four groups as per the symptoms manifested shown in Table – 1.

Table – 1

Group	No. of cases
Normal	10
Allergic	10
Bacterial	10
Viral	10

The age and sex distribution of the participants is shown in Table – 2. the age range of the participants is 6 – 74 years, average being 35.3 years. Of the 40 patients, 29 are male and remaining 11 are female.

Table – 2

Group	Age (in years)			Sex		Sex Ratio (M/F)
	Min.	Max.	Average	Male	Female	
Normal	20	70	31.6	6	4	1.5 : 1.0
Allergic	10	35	24.5	7	3	2.33 : 1.0
Bacterial	52	74	60.1	7	3	2.33 : 1.0
Viral	6	40	25.1	9	1	9.0 : 1.0

Age: Range = 6 – 74 years, Average = 35.3 years

Sex: Male = 29, Female = 11

Male/ Female ratio = 2.64:1.0

Table – 3 shows sputum culture results in bacterial group.

Table – 3

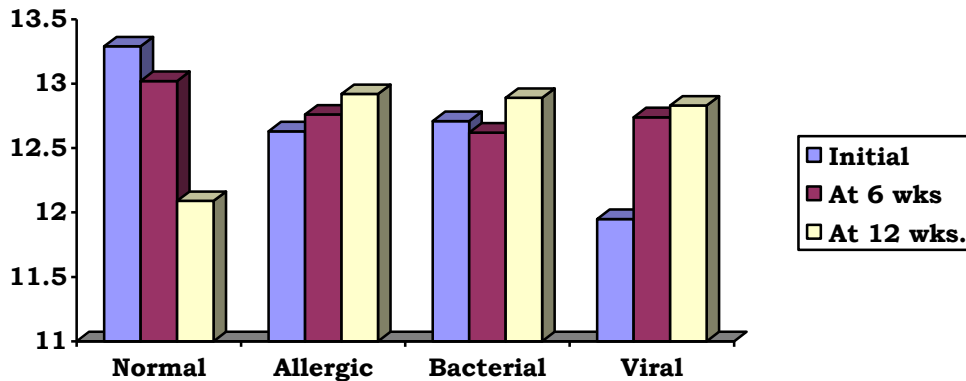
Micro-organisms	No. of patients
Pseudomonas aeruginosa	5
Klebsiella species	2
Staphylococcus aureus	1
Escherichia coli	1
Streptococcus pneumoniae	1
Total	10

As shown in Table – 4, Hemoglobin (Hb) increased in all groups except in the normal subjects. The decrease in normal group was largely due to one person wherein Hb fell considerably.

Table – 4

Group	Initial	At 6 weeks	At 12 weeks	Increased (N=10)	Decreased (N=10)	% change
Normal	13.29	13.02	12.09	4	6	-2.9%
Allergic	12.63	12.76	12.92	6	4	+1.7%
Bacterial	12.71	12.62	12.89	6	4	+0.4%
Viral	11.95	12.74	12.83	7	3	+7.4%
TOTAL				23	17	

Showing levels of Hemoglobin of study population

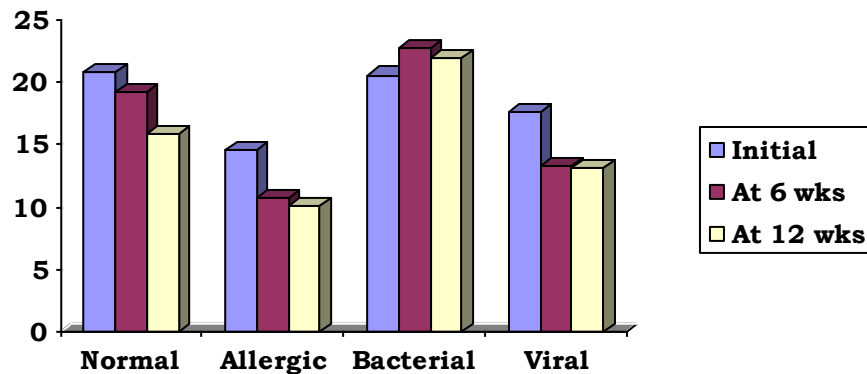


ESR is known to increase during inflammatory process. It was observed that after taking Chyawanprash, ESR fell significantly in Normal, Allergic and Viral groups. EST increased slightly in the Bacterial group as shown in Table – 5.

Table – 5

Group	Initial	At 6 weeks	At 12 weeks	Increased (N=10)	Decreased (N=10)	% change
Normal	20.9	19.3	15.8	2	8	- 24.4%
Allergic	14.6	10.7	10.1	4	6	- 30.8%
Bacterial	20.6	22.7	21.9	5	5	+ 6.3%
Viral	17.7	13.3	13.1	1	9	- 25.9%
TOTAL				12	28	

Showing levels of ESR study population

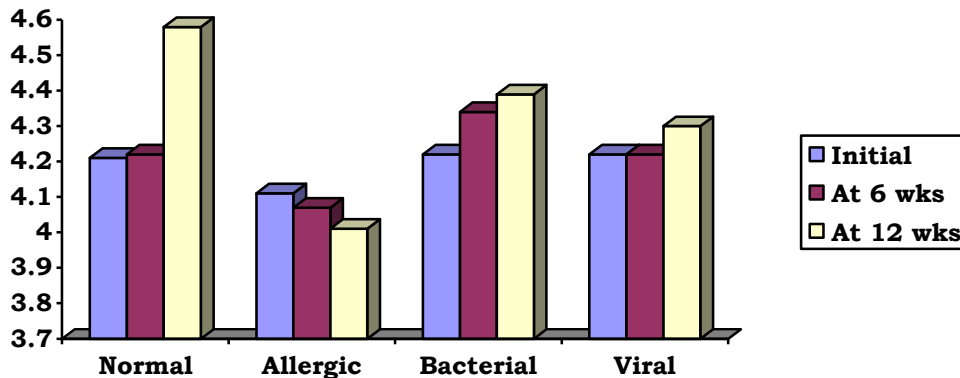


There was marked increase in the protein albumin in normal subjects. Of the 10 subjects in the allergic group, 6 patients showed a fall in serum albumin after 12 weeks. Both the bacterial and viral group showed an increase in the level of albumin as shown in Table – 6.

Table – 6

Group	Initial	At 6 weeks	At 12 weeks	Increased (N=10)	Decreased (N=10)	% change
Normal	4.21	4.22	4.58	5	5	+ 8.8%
Allergic	4.11	4.07	4.01	4	6	- 2.4%
Bacterial	4.22	4.34	4.39	6	4	+ 4.0%
Viral	4.22	4.22	4.30	6	4	+ 1.9%

Showing levels of serum albumin in study population



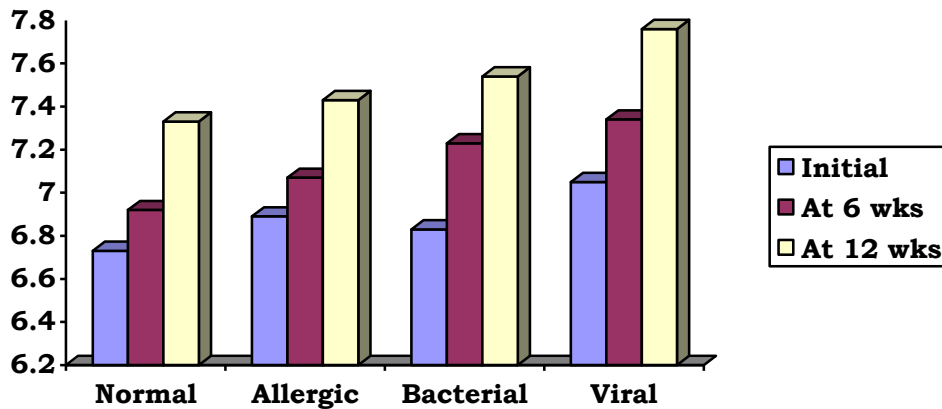
Total serum proteins increased in all groups. Maximum increase occurred in Bacterial group as shown in Table – 7. Minimum increase was noticed in Allergic group. Serum globulins are a heterogenous group of proteins which include alpha and beta globulins as well as serum immunoglobulins (which account for the gamma fractions).

Table – 7



Group	Initial	At 6 weeks	At 12 weeks	Increased (N=10)	Decreased (N=10)	% change
Normal	6.73	6.92	7.33	8	2	+ 8.9%
Allergic	6.89	7.07	7.43	6	4	+ 7.8%
Bacterial	6.83	7.23	7.54	8	2	+ 10.4%
Viral	7.05	7.34	7.76	9	1	+ 10.0%
TOTAL				31	9	

Showing levels of total serum proteins in study population

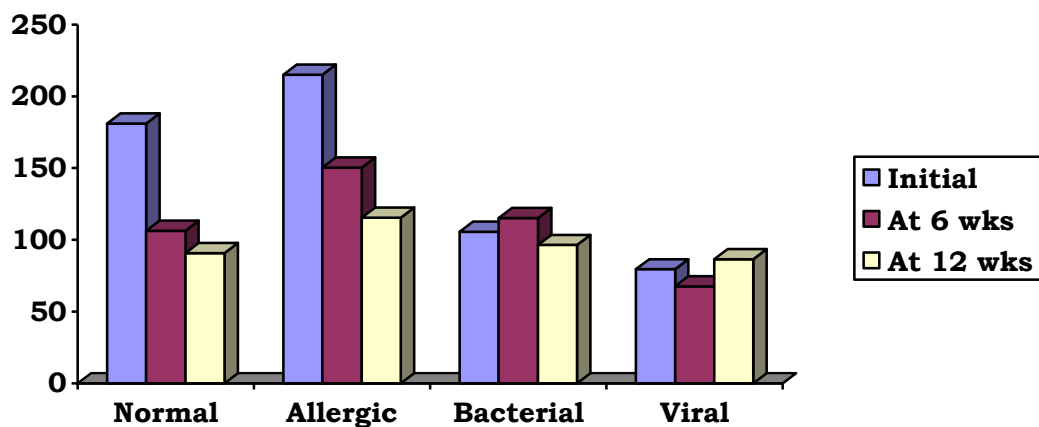


Base-line IgE was maximum in the Allergic group; minimum in the Viral group (Table – 8). In all groups, a definite decrease was noticed after taking Chyawanprash.

Table – 8

Group	Initial	At 6 weeks	At 12 weeks	Increased (N=10)	Decreased (N=10)	% change
Normal	181.1	106.4	90.7	0	10	- 49.9%
Allergic	215.0	150.4	115.5	2	8	- 46.3%
Bacterial	105.7	115.2	96.4	4	6	- 8.8%
Viral	79.5	67.6	86.6	4	6	- 3.0%
TOTAL				10	30	

### Showing IgE levels in study population

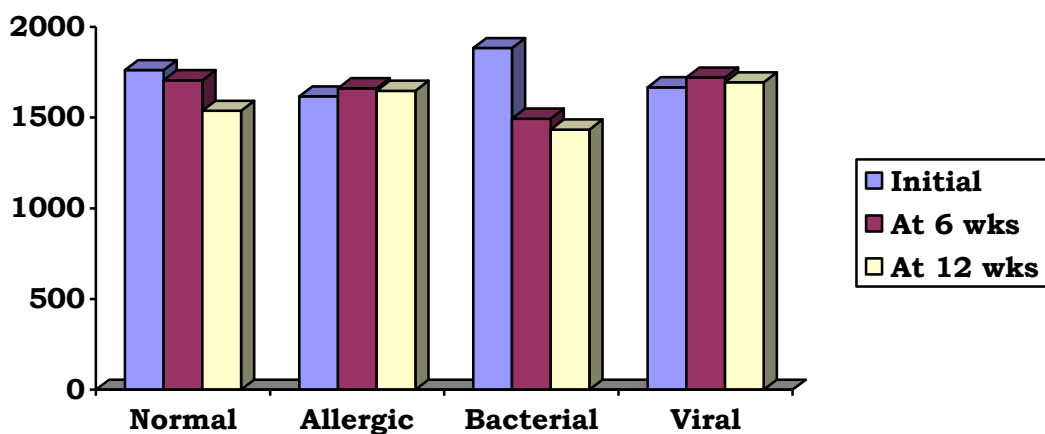


IgG decreased in all groups except the Viral group. Decrease was significant only in the Bacterial group (Table – 9).

Table – 9

Group	Initial	At 6 weeks	At 12 weeks	Increased (N=10)	Decreased (N=10)	% change
Normal	1761.9	1706.4	1537.3	5	5	- 12.7%
Allergic	1617.6	1662.2	1648.2	5	5	- 1.9%
Bacterial	1884.1	1494.6	1434.2	4	6	- 23.9%
Viral	1667.5	1721.2	1695.4	6	4	+ 1.7%
TOTAL				31	9	

### Showing levels of IgG



## 5. DISCUSSION

All the patients and the normal group were asking for more of Chyawanprash even after the study was over. On questionnaire why they wanted more of it, the answer in the majority of the cases was that it suited them well; their appetite was better; their bowel movements were more satisfactory, and above all, they felt more energetic.

Study of the hemoglobin level showed an increase in its value in all groups of the patients. Enhanced hemoglobin indicated that Chyawanprash provided the ingredients necessary for its formation. Increase in hemoglobin level raises the capacity of the blood to carry more oxygen and this makes the person feel more energetic.

A decrease in ESR in all the groups of patients indicates lessened inflammatory activity in the body, be it in the lungs, nose, throat or anywhere else in the body. Lower ESR, or in other words, lowered inflammatory activity in the body, means lessened expenditure of energy, meaning thereby an increased availability of energy in the body for useful work. So the person taking Chyawanprash would feel more energetic.

Study of the serum proteins showed slight increase in the albumin values except in the Allergic group where it decreased slightly. Serum globulins increased in all the groups of patients as well as the Normal group. The maximum increase in globulins was observed in the Bacterial group of patients. Total serum proteins increased in all groups. Maximum increase occurred in the Bacterial group. Minimum increase was observed in the Allergic group. Serum globulins are a heterogeneous group of proteins which include alpha and beta globulins, as well as serum immunoglobulin which account for gamma fraction.

It has been shown in various studies that increase in the globulin fractions in the absence of liver disease does not hold much diagnostic significance. Similarly a decrease in albumin/ globulin ratio due to an increase in globulin holds no significance.

Very significant observations have come out in the IgE values. It was found that IgE values were the maximum in the Allergic group and minimum in the Viral group. In all groups, a definite decrease was noticed after taking Chyawanprash. Maximum decrease occurred in the Allergic group and the Normal group. Furthermore, it was observed that the decline in IgE was more in children and young adults than in the elderly. It was clearly seen that administration of Chyawanprash was helpful in decreasing the elevated level of IgE in the Allergic group. Decrease in IgE lessens the tendency to develop an allergic reaction. Taking of Chyawanprash thus should be helpful in lessening the tendency to get symptoms of allergy in those who are susceptible to it. As IgE levels in the serum come down even in

the Normal group, it can be surmised that the blood relatives of the allergic patients or normals exposed to lung irritants/ pollutants either because of general air pollution or being in polluting occupations, would become less susceptible to getting symptoms of recurrent cough and cold.

IgG decreased in all groups except the Viral. This was quite appreciable in the Bacterial group. IgG is the predominant antibody in the serum and it carries the major burden of neutralizing the bacterial toxins and binding to microorganisms to enhance their phagocytosis. Significantly lower levels of IgG antibody in the Bacterial group after taking Chyawanprash could be because of lesser bacterial stimulus to the production of IgG antibody. Intake of Chyawanprash probably reduced the number of bacteria which could stimulate IgG production and hence resulted in lower IgG levels. This contention could be further substantiated by subsequent studies on bacterial colony count in sputum cultures after taking Chyawanprash.

In experimental studies conducted on Chyawanprash, its effect on immune status was established. In the study it was observed that Chyawanprash promotes the immune responses. This observation is substantiated in the study going by its effect on IgG levels. On the other hand, the IgE levels were brought down significantly which suggests that Chyawanprash helps to downregulate the negative immune response. Thus the immunomodulatory effect of Chyawanprash is double faceted.

## 6. CONCLUSIONS:

When we combine the observed data in all the groups of cough and cold patients, we find that after taking Chyawanprash.

- Hemoglobin increased in all groups
- Total serum proteins increased in all groups, the increase was more due to the globulins than the albumin
- ESR decreased in all groups except a slight increase in the Bacterial group
- IgE decreased in all groups