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A Randomized, Open Labeled Clinical Survey to Evaluate the Anti-Viral, Anti-Inflammatory and Immune Modulator Role of Polyherbal Combinations in Viral Infections of Respiratory Tract

Dr. Smita Naram [1], Dr. Deepak Mahajan [2], Dr. Hemang Parekh [3]
[1]Department of Research and Development, Ayushakti Ayurveda Pvt Ltd, Bhadran nagar cross road, Malad, Mumbai-64
[2]Research Head, Ayushakti Ayurveda Pvt Ltd, Bhadran nagar cross road, Malad,Mumbai- 64
[3]Medical head, Ayushakti Ayurveda Hospital, Bhadran nagar cross road, Malad,Mumbai-64

ABSTRACT

Cough is the common reflex produced for upper respiratory tract infections (URTI), however, a cough can also be a symptom of other hidden conditions like asthma or other lung diseases. The immune modulation with Ayurvedic formulations as possible therapeutic measures is the need of time. Ancient Indian medicinal system of Ayurveda has a wide scope for treating many diseases by the theory of Rasayana. Rasayana in other terms are called as preparations from plant or herbal sources which have immunomodulatory properties. As this is a Pilot study each participant is supplied with the Swaswin D Vyro (Virofight) 625 mg two tablets twice a day, Swaswin Asthaloc 600 mg two tablets twice a day, Syrup Swaswin Kaphano 5 ml twice a day after food with lukewarm water at each visit.

The results were assessed with a scale developed by Ayushakti Ayurveda Pvt Ltd. The scale is general, and self-administered. It consists of seven symptoms in the respiratory tract. Individual scale symptom responses are assigned a score between 0 (none) to 10 (Extreme). Total assessment of the result was done on the basis of relief from symptoms of the disease.

This combination is helpful for viral infection of healthy individuals as well as in asthma-like chronic conditions of the respiratory tract, including patients with comorbid conditions. This combination acts as an antiviral, anti-inflammatory, antispasmodic, immune modulatory and antitussive.

KEYWORDS: Respiratory system, anti-viral, Cough, Cold.

ARTICLE DETAILS

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BACKGROUND

The common cold can be caused due to many types of viruses. The most common culprit are viruses, it may cause an infection of the nose, throat, larynx and pharynx. Cough is the common reflex produced for upper respiratory tract infections (URTI), however, a cough can also be a symptom of other hidden conditions like asthma or other lung diseases. Maybe it's a productive cough or dry cough. Producing a cough is usually due to more production of phlegm or mucus than normal. Dry cough shows that you are coughing a lot but no mucus comes out.

Cough medicines work differently depending on what the active ingredient is. Some are Antitussive, Expectorants, Antihistamines, and/or Decongestants, some work locally and some work on the central nervous system.

Ayurveda is the most commonly practiced form of complementary and alternative medicine in India. Nowadays Indian patients prefer Ayurveda medicines and herbs for their day to day problems as they aim to integrate and balance the body, mind, and spirit which in turn aids in preventing the disease and promoting wellness. Recently due to new policies and focus by the department of AYUSH under the Ministry of Health and Family Welfare, Ayurveda therapy is becoming more and more noticeable due to dissatisfaction and side effects with modern medicines.

Over the counter medicines for cough and cold are usually widely used by the patients for common cold symptoms, though they have demonstrated a benefit, can be associated

with morbidity and even mortality in both acute overdose and for chronic periods of time even when administered in the correct dose[1].

Viral infections commonly affect both the upper and lower respiratory tract. The respiratory infections are commonly classified clinically according to syndrome like common cold, bronchitis, croup, pneumonia[2]. The viruses mostly act through direct invasion of epithelial cells of the respiratory mucosa. There is an increase in both leukocyte infiltration and nasal secretions, including proteins and immunoglobulin, suggesting cytokines and immune mechanisms may be responsible.

Ancient Indian medicinal system of Ayurveda has a wide scope of treating many diseases by the theory of Rasayana, in other term called as preparations from plant or herbal source including immune modulatory properties 4.The basic concept of immune modulation has been practiced by Ayurvedic practitioners for centuries as it is mentioned in Ayurvedic ancient literature and Samhitas. The goal of immune enhancement is achieved by Ayurvedacharyas by the use of Rasayana concept. The toxic by-product of impaired digestion is called Aama, which clogs the micro channels (Strotas)and is considered the pathogenesis of Inflammation. The herbs which improve the process of digestion, digest the Aama and purify the micro channels are considered anti-inflammatory. There are many such ayurvedic herbs and herbal combinations which are available in ayurvedic literature, which have been used since ancient times to treat many acute and chronic as well as chronic inflammatory diseases. The main focus of this pilot study was to confirm the efficacy of polyherbal combinations for coughs and colds in which modern protocol was unable to give results.

Name of herbal combination-

Tablet Swaswin D Vyro (Virofight),
Tablet Swaswin Asthaloc
Swaswin Kaphano syrup.

Manufacturer - Ayushakti Ayurveda Pvt Ltd pharmacy, Plot number 78, Stice, Musalgaon, Sinnar, Nashik- 422112.

2. AIMS AND OBJECTIVES

Primary objective:

- To assess the effectiveness of tablet Swaswin D Vyro (Virofight), tablet Swaswin Asthaloc and Swaswin kaphano syrup as an immunity booster, anti-viral and, anti-inflammatory in the patients suffering from acute and chronic infection of Respiratory tract for more than 2 weeks.
- To assess the effectiveness of tablet Swaswin D Vyro (Virofight), tablet Swaswin Asthaloc and Swaswin kaphano syrup as immunity booster, anti-viral, anti-inflammatory in acute and chronic infection of Respiratory tract for more than 2 weeks in patients with comorbid conditions like HTN and Diabetes.
- To assess the effectiveness of tablet Swaswin D Vyro (Virofight), tablet Swaswin Asthaloc and Swaswin kaphano syrup as immunity booster, anti-viral, anti-inflammatory in acute and chronic viral infection of respiratory tract in patients with chronic conditions like Asthma, Bronchitis, and ILD etc.

3. METHODOLOGY

Informed Consent

Informed written consent will be obtained from each participant in the prescribed format prior to performance of any study related procedures (i.e. physical examination, laboratory screening or any other investigational procedure) and before performing any study related procedure. The process of obtaining written informed consent from the participant will be conducted by the Investigator.

Study Design

Sample size considerations

As this is a Pilot study, with no previous clinical results available, a sample size of 90 participants (30 in each group) has been considered adequate to address the study objectives.

Randomization Criteria

The participants will be allotted to three groups as per the type of cough and cold and other symptoms.

Group I: (30 patients) with acute and chronic history of viral infection received Tablet Swaswin D Vyro (Virofight) orally dose twice daily.

Group II: (30 patients) Acute and chronic history of viral infection with comorbid conditions like diabetes and Hypertension received Swaswin D Vyro (Virofight) tablet Swaswin Asthaloc orally dose twice daily.

Group III: (30 patients) acute and chronic history of viral infection with chronic conditions like Asthma received Swaswin D Vyro (Virofight), tablet Swaswin Asthaloc and Swaswin kaphano syrup orally dose twice daily

Study Population

Inclusion Criteria:

1. Patients with symptoms of acute and chronic viral infection of Respiratory tract.
2. Patients with symptoms of acute and chronic viral infection of Respiratory tract with comorbid conditions.
3. Patients with symptoms of acute and chronic viral infection of Respiratory tract with known conditions like Asthma, Bronchitis, Tonsillitis**,** pharyngitis, laryngitis, sinusitis, otitis media, certain influenza types.
4. Age 16-60 years of age.
5. Ready to abide by trial procedures and to give informed consen**t.**

Exclusion criteria:

1. Acute and chronic Respiratory Distress Syndrome (ARDS)
2. Patients with Tuberculosis.

3. Pregnant women.
4. COPD patients.
5. Age less than 16 years and more than 60 years.
6. Life expectancy less than 1 year due to other co-morbid conditions.

Study drugs

Each participant supplied with the Swaswin D Vyro (Virofight) 625 mg two tablets twice a day, Swaswin Asthaloc 600 mg two tablets twice a day, Syrup Swaswin Kaphano 5 ml twice a day after food with lukewarm water at each visit.

Patients with severe symptoms and breathlessness provided with all the three herbal combination Swaswin D Vyro (Virofight) 625 mg two tablets twice a day, Swaswin Asthaloc 600 mg two tablets twice a day, Syrup Swaswin Kaphano 5 ml twice a day after food with lukewarm water.

Patients with known conditions with asthma, Bronchitis, Tonsillitis**,** pharyngitis, laryngitis, sinusitis, otitis media, certain influenza types were provided with Swaswin D Vyro (Virofight) 625 mg two tablets twice a day, Swaswin Asthaloc 600 mg two tablets twice a day, Syrup Swaswin Kaphano 5 ml twice a day after food with lukewarm water.

Study Duration

Each participant will be in the study for 1 month. The entire study duration will be around 3 months.

Study Procedures

Potential trial participants were screened at Ayushakti Ayurved Pvt Ltd, Malad, Borivli branches in Mumbai. Following written informed consent, eligible participants enrolled in the study. During the study period, there will be a total of 6 visits including the Screening visit. After reviewing the eligibility of the patient he/she will be randomized to one of the study groups. Ayushakti Ayurveda Medicinal Herbal Formulas were advised.

Assessment criteria

The results were assessed with a scale developed by Ayushakti Ayurveda Pvt Ltd. The scale is general and self-administered. It consists of seven symptoms in the respiratory tract. Individual scale symptom responses are assigned a score between 0 (none) to 10 (Extreme). Total assessment of the result was done on the basis of relief in symptoms of the disease.

RESULTS

Congestion

Patients with viral infection of the respiratory tract showed full recovery in all the three groups, which is highly significant in a symptom of congestion. Still group I patients showed full recovery in 15 days only, group II patients showed 98.51 % recovery in 15 days and 98.51 % in group three.(Table-1)

Table 1. Percentage improvement in Congestion Running Nose

Group-I	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	32.035	43.31	97.75	100	100
	SD	± 2.33	± 1.64	± 0.26	0	0
Group-II	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	26.24	53.47	79.70	98.51	100
	SD	± 3.39	± 2.16	± 1.09	± 0.31	0
Group-III	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	12.014	36.39	56.89	81.27	98.58
	SD	± 0.79	± 0.83	± 1.11	± 0.6	± 0.35

All the three groups showed significant differences in running nose symptoms. Full recovery was observed in Group I in 10 days, 15 days in group II and 100% result in running nose was found in group III in 30 days. (Table-2)

Table 2. Percentage improvement in running nose-Cough-

Group-I	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	27.04	73.58	100	100	100
	SD	±0.66	± 0.51	0	0	0
Group-II	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5

	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	37.5	53.125	73.33	100	100
	SD	± 3.43	± 2.95	± 0.96	0	0
Group-III	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	19.05	46.43	73.81	90.47	100
	SD	±2.16	±1.39	±0.89	±0.51	0

Cough producing or dryness is a major symptom of viral infection in the throat, 99.24% recovery was observed in group I in 10 days, 95.83% changes were observed in group II in 10 days, full recovery observed in group III in 30 days. (Table-3)

Table 3. Percentage improvement in Cough Sneezing-

Group-I	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	40.15	69.69	99.24	100	100
	SD	±1.21	±1.215	±0.25	0	0
Group-II	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	28.125	53.47	75.35	95.83	100
	SD	±1.27	±0.68	±1.54	±0.81	0
Group-III	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	17.12	38.91	57.97	77.43	100
	SD	±0.711	±1.54	±0.49	±0.64	0

Though all three groups showed significant differences, group I showed full recovery in 10 days only, 97.59% recovery observed in group II in 15 days and 100 % in group III patients in 30 days only. (Table-4)

Table 4. Percentage changes in Sneezing Body ache-

Group-I	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	39.20	67.62	100	100	100
	SD	±1.39	±0.62	0	0	0
Group-II	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	25.77	49.83	75.95	97.59	100
	SD	±1.63	±1.68	±2.06	±0.43	0
Group-III	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	19.04	39.68	59.92	76.58	100
	SD	±0.99	±0.58	±0.89	±0.93	0

Viral infection most commonly causes body aches. In this project significant results were observed in all the three group patients. In group I patients showed 80% improvement in 5 days and 100% in 10 days, group II showed 93.87% difference in body ache symptom in 15 days, 100 recovery observed by 30 days in group III. (Table-5)

Table 5. Percentage improvement in Body ache-Sore throat-

Group-I	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	59.58333	80	100	100	100
	SD	±2.11	±1.61	0	0	0
Group-II	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	20.33	53.66	80.08	93.88	100
	SD	±1.68	±1.45	±0.99	±0.3	0
Group-III	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	14.55	38.64	64.09	82.73	100
	SD	±0.91	±1.41	±0.93	±0.94	0

Viral or bacterial, any infection causes an inflammatory process in the throat resulting in symptom soreness. We Observed 98.11 % difference in sore throat symptoms in 10 days only which is highly significant than the other two groups. (Table-6)

Table 6. Percentage improvement in Sore throat -Fatigue-

Group-I	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	40.15	71.21	98.11	100	100
	SD	±1.212	±0.82	±0.47	0	0
Group-II	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	20.21	50.17	77.00	97.91	100
	SD	±1.19	±1.006	±1.095	±0.61	0
Group-III	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	21.62	40.93	67.57	90.35	100
	SD	±1.17	±0.85	±0.89	±0.38	0

Fatigue is an overall feeling of tiredness, and it is more common in viral infections and post viral infections. Significant difference was observed in all the three groups. In group I by the 10th day the symptom was 100% better, in group-II 100% result was observed by 15th day, similarly in group III by 30th day. (Table-7)

Table 7. Percentage changes in Fatigue Breathlessness-

Group-I	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	46.7	71.59	95.33	100	100
	SD	±1.69	±1.57	±0.82	0	0
Group-II	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	29.78	56.89	86.67	100	100
	SD	±2.77	±1.77	±0.91	0	0
Group-III	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	12.35	37.85	52.99	79.29	100
	SD	±1.83	±1.42	±2.18	±1.11	0

Breathing difficulty describes discomfort when breathing and feeling as if you can't draw a complete breath. This symptom was less observed in acute and chronic viral infection of the respiratory tract but in other groups that were present may be due to underlying causes. In Group-II 100% significant

difference was observed in 15 days and in 30 days in Group-III. (Table-8)

Table 8. Percentage improvement in Breathlessness

Group-II	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	26.67	47.14	79.05	100	100
	SD	±3.002	±2.29	±1.10	0	0
Group-III	Visits	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
	Day	Day 3	Day 5	Day 10	Day 15	Day 30
	Percentage changes	10.47	27.07	53.068	76.53	100
	SD	±0.78	±0.91	±0.48	±0.38	0

DISCUSSION

Most of the time coughing is due to the common cold which can cause an acute cough. There may be an inflammatory response triggered by a viral upper respiratory infection. Sub-acute or chronic cough can be considered due to irritation of structures of the upper respiratory tract due to infections [5]. Hypersensitivity of the airway sensory nerves may cause chronic cough as cough reflex is determined by interaction of the nervous system with immune system, regular deregulation of one or both of these may lead to chronic cough hypersensitivity [6].

Swaswin Asthaloc tablet helps in reducing bronchial inflammation and is an anti-inflammatory, bronchodilator, and has antihistamine properties. Trikatu powder in Asthaloc tablets has anti-inflammatory, anti-microbial, antioxidant mast cell stabilization, immunomodulatory and anti-histaminic properties. This combination acts as an antiviral, anti-inflammatory and immune modulator [7-13]. All the ingredients may be collectively effective on airflow obstruction, and airway hyper responsiveness by their bronchodilator, anti-inflammatory and antihistaminic properties [14]. Hingu (Ferula foetida) is recommended in the treatment of asthma as it is antispasmodic, expectorant and anti-inflammatory [15]. Swaswin D Vyro (Virofight) (Virofight) tablet is the best effective immunomodulator, as it augments the cell mediated as well as humoral mediated immune response. It is antiviral as it can inhibit replication of several viruses and it is anti-inflammatory by inhibiting various cytokine producing pathways. It has antioxidant and antiulcer properties [16]. Glycerrhiza in tablet D Vyro inhibits the production of RANTES, potent chemotactic cytokine for monocytes, basophils, and T cells, typically detected in nasal secretions of patients with upper respiratory tract infections, involved in epithelial cell-mediated inflammation related to viral infection like influenza virus H1N1[17]. Main ingredient of Swaswin Kaphano syrup is vasa (Adhatoda vasaka), Vasicine is the active ingredient for expelling sputum from the body [18]. The antitussive activity of *Adhatoda vasaka is* similar to that of the non-narcotic antitussive agent Dextromethorph[19].

CONCLUSION

From this pilot study we conclude that Ayushakti's Ayurveda Medicinal Herbal Formula combinations Swaswin D Vyro (Virofight), Swaswin Asthaloc and Swaswin Kaphano syrup can yield significant results in viral infections of the respiratory tract. This combination of three herbal combinations is helpful in viral infection of healthy individuals as well as in asthma-like chronic conditions of respiratory tract even in patients with comorbid conditions as they are antiviral, anti-inflammatory, antispasmodic, immune modulatory and antitussive. These types of combinations are very helpful in the ongoing situation of novel coronavirus. Still more specific designed studies can be done in this regard for better interpretations.

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